










## Viedoc Admin User Guide

55 Lessons ■ 55 from Viedoc System





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Overview of Viedoc

# Overview of Viedoc

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## 1 Introduction

Viedoc is a service over the internet system for managing Case Report Form ([CRF](#)) data in clinical studies and patient registries.

Viedoc is an Electronic Data Capture ([EDC](#)) system that enables easy data capture, management, validation and presentation of clinical trial data. Viedoc is a Software-as-a-Service ([SaaS](#)) accessed directly through a web browser and requires no installation. It is intuitive and user-friendly and enables efficient sharing of information.

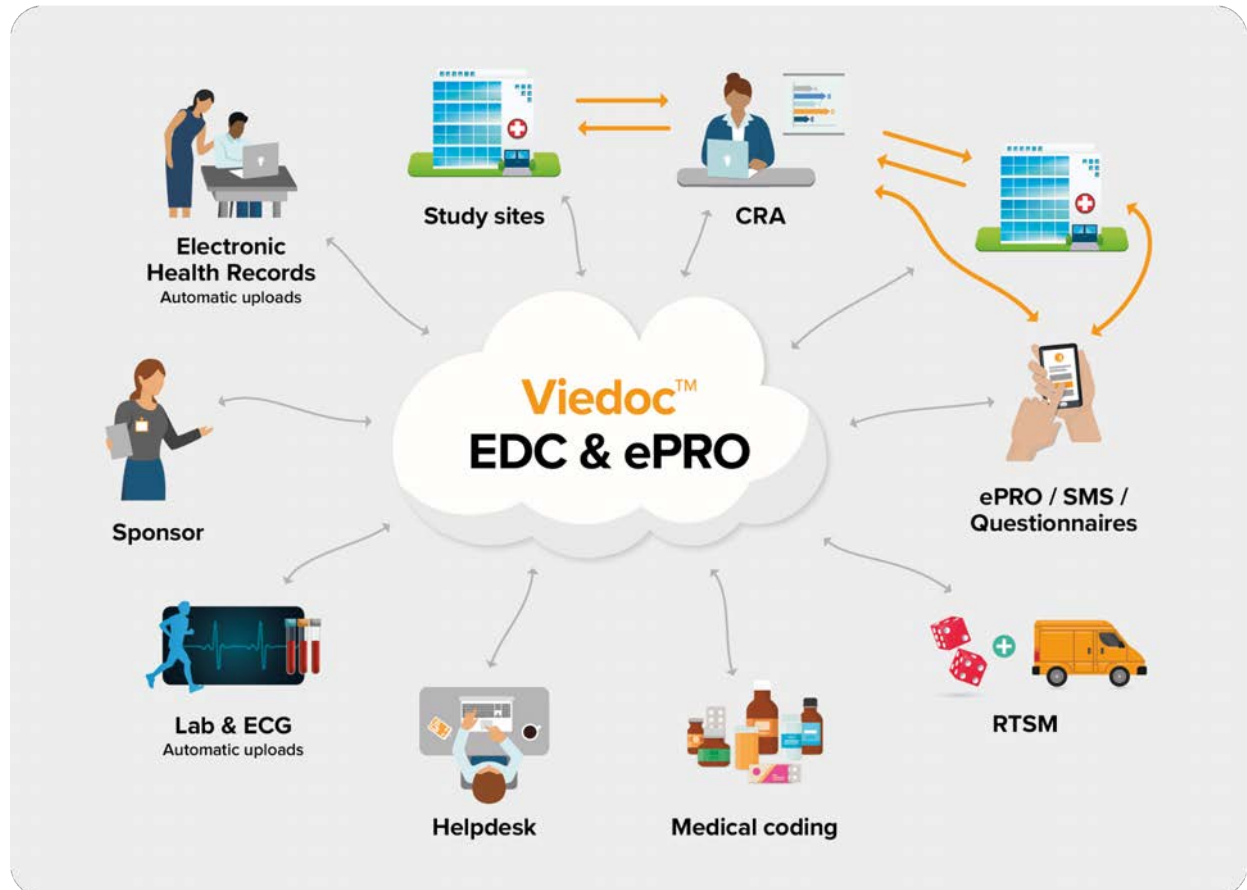
Viedoc is a study centric system, that is, all the functionalities are more or less related to a specific study. Usually a study in Viedoc corresponds to a clinical trial or other types of projects where data collection is applicable.

The main functionalities provided by Viedoc are:

- Data handling:
  - Subject screening
  - Online data entry (eSource compliant)
  - Automatic data transfer
  - Data signing
  - Commenting
  - Medical coding
  - File uploads
- Randomization and Trial Supply Management ([RTSM](#))
  - Randomization and advanced allocation
  - Viedoc Logistics
- Output:
  - Export to the following formats:
    - Microsoft Excel - Office Open Extensible Markup Language ([XML](#))
    - Comma-Separated Values ([CSV](#))
    - PDF - PDF Archive ([PDF/A](#))
    - Clinical Data Interchange Standards Consortium ([CDISC](#)) Operational Data Model ([ODM](#)) - Extensible Markup Language ([XML](#))
  - Automatic creation of empty and annotated CRFs
  - Audit trail
  - Data Quality Metrics
  - Study statistics

- Data review/Monitoring:
  - Source-Data Verification ([SDV](#))
  - Clinical/Data Review & Lock
  - Pre-query & Query Handling
- Other:
  - Single point of login
  - 24/7 technical support

The following diagram is an overview of the main Viedoc interactions and functionalities:



Viedoc is compliant with all relevant guidelines, standards and regulations in Europe, North America and Japan, including:

- Food and Drug Administration ([FDA](#)) 21 Code of Federal Regulations ([CFR](#)) part 11
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ([ICH](#)) - Good Clinical Practice ([GCP](#))
- Clinical Data Interchange Standards Consortium ([CDISC](#))
- Computerized Systems Used In Clinical Investigations ([CSUCI](#))
- Health Insurance Portability and Accountability Act ([HIPAA](#))
- Developed according to Good Automated Manufacturing Practice ([GAMP](#)) 5
- General Data Protection Regulation ([GDPR](#))

## 2 A study in Viedoc

### 2.1 Study sites

Every study has at least one study site, which corresponds to a clinic. A Viedoc user can have access to one or several studies in Viedoc and for one study the user can have access to one, several or all study sites. A Viedoc user is linked to a study site using a user role. A single user can have one or several roles for a study site and can also have different roles for different sites.

## 2.2 Events and forms

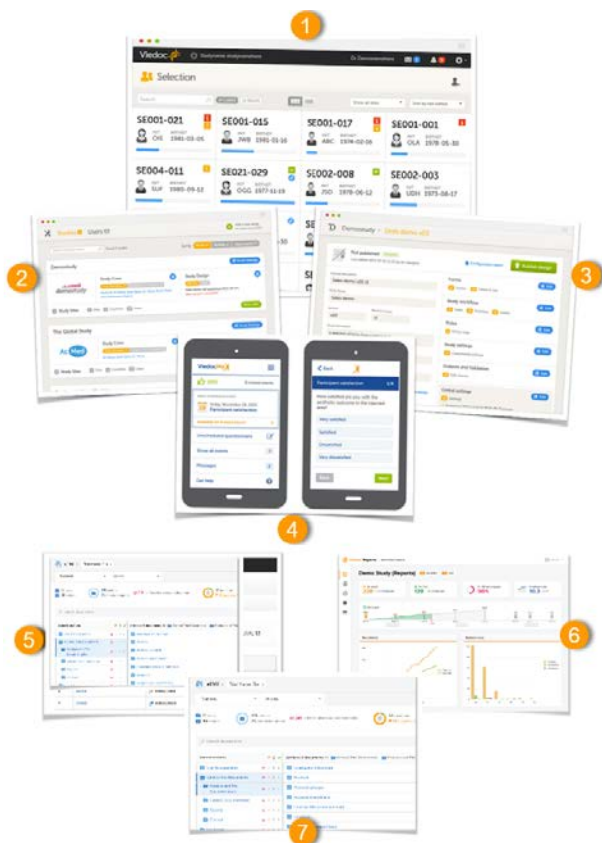
During a study, there are typically a number of questions to be answered and completed with data about the subject. A group of questions that belong together are captured in a form. Forms can be **event-dependent** or **event-independent** (log forms / common events). **Event-dependent** forms are linked to a specific **event** and the data belonging to these forms is registered during or in relation to a study **event**. **Event-independent** forms can be used to report data or events that happen before, between, or after **events**. Medical history events, concomitant medications, or adverse events are examples of forms that can be captured in **event-independent** forms.

## 2.3 Subjects

All study subjects are identified using a unique subject key. In addition to the subject key, a subject can be identified using background information such as gender, initials, or date of birth. The subject's background information is usually entered when adding the subject in the system and will most likely not change during the course of a study.

# 3 System architecture

## 3.1 The Viedoc platform



The Viedoc platform consists of seven different applications:

1. Viedoc **Clinic** - for site staff and project team members that need to have access to CRF data.
2. Viedoc **Admin** - for parts of the study team to handle users, sites and updates in study designs. Viedoc Admin is the interface where you initiate a new study, manage the study while it is running and finally close the study.
3. Viedoc **Designer** - for the study developer to design the study. Viedoc Designer is the tech part where you design forms, set the study workflow, add roles, prepare the randomization, add edit checks and much more.
4. Viedoc **Me** - the subject diary, or electronic Patient Reported Outcome ([ePRO](#)). All subject questionnaires are easily completed and submitted by the subject through this application.
5. Viedoc **Logistics** - for supply managers who handle the Investigational Products ([IPs](#)) of your study.
6. Viedoc **Reports** - for viewing and analyzing study progress and performance.
7. Viedoc **eTMF** - for capturing, managing, sharing, and storing essential documents for your study in a digital repository.

## 3.2 System languages

Viedoc **Clinic** and Viedoc **Logistics** are available in the following languages:

- Chinese (Simplified)
- Chinese (Traditional)
- English
- French
- German
- Japanese
- Polish (not available in **Logistics**)
- Portuguese
- Spanish
- Swedish

Viedoc **Admin** and Viedoc **Designer** are available in the following languages:

- Chinese (Simplified)
- English
- German
- Japanese
- Swedish

Viedoc **Me** is available in the following languages:

- Afrikaans
- Arabic
- Bulgarian
- Chinese (Simplified)
- Chinese (Traditional, Hong Kong S.A.R.)
- Chinese (Traditional, Taiwan)
- Chinese (Traditional)
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- French (Belgium)
- Georgian
- German
- Greek
- Hebrew
- Hebrew(Israel)
- Hungarian
- Italian
- Japanese
- Kazakh
- Korean
- Latvian
- Lithuanian
- Malay
- Norwegian (Bokmål)
- Norwegian (Nynorsk)
- Polish
- Portuguese
- Romanian
- Russian
- Serbian (Cyrillic)
- Serbian (Latin)
- Setswana
- Slovak
- Slovenian
- Southern Sotho
- Spanish
- Swedish
- Thai
- Turkish
- Ukrainian
- Vietnamese
- Xhosa
- Zulu



Viedoc **Reports** is available in the following languages:

- Chinese (Simplified)
- Chinese (Traditional)
- English
- Japanese
- Swedish

Viedoc **TMF** is available in the following languages:

- Chinese (Simplified)
- English
- Japanese
- Swedish

To change the language, see [Manage your Viedoc account](#).

If you require any additional language that is not listed above, please contact your Viedoc representative.

**Note!** Viedoc does not allow users to use a default browser translation within the system. This prevents individual users from overriding the chosen system language and agreed upon terminology and formulations.

### 3.3 eLearning

The following table shows the current eLearning curriculums and the language versions.

The **green** curriculums are the main user guides for the different applications.

The **orange** curriculums are role-specific ones, meaning they are tailor-made for our different users.

Curriculum	English	Chinese	Japanese	URL
<b>Viedoc Clinic User Guide</b>	x	x	x	<a href="https://help.viedoc.net/c/47e0ad">https://help.viedoc.net/c/47e0ad</a>
<b>Viedoc User Guide for Monitors</b>	x	x	x	<a href="https://help.viedoc.net/c/c63e06">https://help.viedoc.net/c/c63e06</a>
<b>Viedoc User Guide for Site Users</b>	x	x	x	<a href="https://help.viedoc.net/c/94d6f0">https://help.viedoc.net/c/94d6f0</a>
<b>Viedoc User Guide for Data Managers</b>	x	x	x	<a href="https://help.viedoc.net/c/1994d8">https://help.viedoc.net/c/1994d8</a>
<b>Viedoc User Guide for Project Managers</b>	x	x	x	<a href="https://help.viedoc.net/c/04361f">https://help.viedoc.net/c/04361f</a>
<b>Viedoc User Guide for Medical Coders</b>	x	x	x	<a href="https://help.viedoc.net/c/3108de">https://help.viedoc.net/c/3108de</a>
<b>Viedoc Admin User Guide</b>	x	x	x	<a href="https://help.viedoc.net/c/331b7a">https://help.viedoc.net/c/331b7a</a>
<b>Viedoc Designer User Guide</b>	x	x	x	<a href="https://help.viedoc.net/c/e311e6">https://help.viedoc.net/c/e311e6</a>
<b>Viedoc Logistics User Guide</b>	x	x	x	<a href="https://help.viedoc.net/c/4a40d5">https://help.viedoc.net/c/4a40d5</a>
<b>Viedoc Reports User Guide</b>	x	x	x	<a href="https://help.viedoc.net/c/8a3600">https://help.viedoc.net/c/8a3600</a>
<b>Viedoc eTMF User Guide</b>	x		x	<a href="https://help.viedoc.net/c/88fc29">https://help.viedoc.net/c/88fc29</a>
<b>Viedoc User Guide for eTMF Managers</b>	x		x	<a href="https://help.viedoc.net/c/fd74dc">https://help.viedoc.net/c/fd74dc</a>
<b>Viedoc PMS User Guide for Clinic Side Users</b>	x		x	<a href="https://help.viedoc.net/c/91715f">https://help.viedoc.net/c/91715f</a>
<b>Viedoc PMS User Guide for Sponsor Side Users</b>	x		x	<a href="https://help.viedoc.net/c/590df1">https://help.viedoc.net/c/590df1</a>
<b>Viedoc PMS Designer User Guide</b>	x			<a href="https://help.viedoc.net/c/ed5d47">https://help.viedoc.net/c/ed5d47</a>

Curriculum	English	Chinese	Japanese	URL
Viedoc User Account Management Guide	x			<a href="https://help.viedoc.net/c/508fda">https://help.viedoc.net/c/508fda</a>

### 3.4 Organizations

Studies are grouped in Viedoc under organization(s); that is, each client has its own organization where all studies belonging to that organization are stored. By default, one organization administrator is appointed to each organization. This person has been trained by a Viedoc Product Specialist and is responsible for providing access to users within the organization and for adding new studies to the platform.

**Important!** It is the responsibility of the organization administrator to make sure that all users within the organization have received appropriate training for their respective tasks.

### 3.5 System environment

As a Viedoc client, you will be provided with access to two separate environments/instances: one for test/development studies and one for production studies. The purpose of the test/development environment is to allow the evaluation and use of Viedoc without the need of a contract for a specific ongoing study.

Any study that is to be taken in production is normally initiated on the test/development environment and later moved to the production environment once it is “ready” to be shared with the Sponsor or other external party. Please observe that a study in the production environment can be set to operate in demo mode by adding a site of the type “training” to it.

**Note!** The demo mode of a production study should not be confused with a study in the test/development environment. The purpose of the demo mode is to allow site staff access to specific training site(s) in order to gain sufficient knowledge of the system before accessing production data. When a study has sites with both production and training types added, a switch will be available in Viedoc Clinic. This offers a choice of which mode the data will be entered to - demo or production.

Studies and study designs can be easily transferred from one environment to the other via the ODM export and import feature.

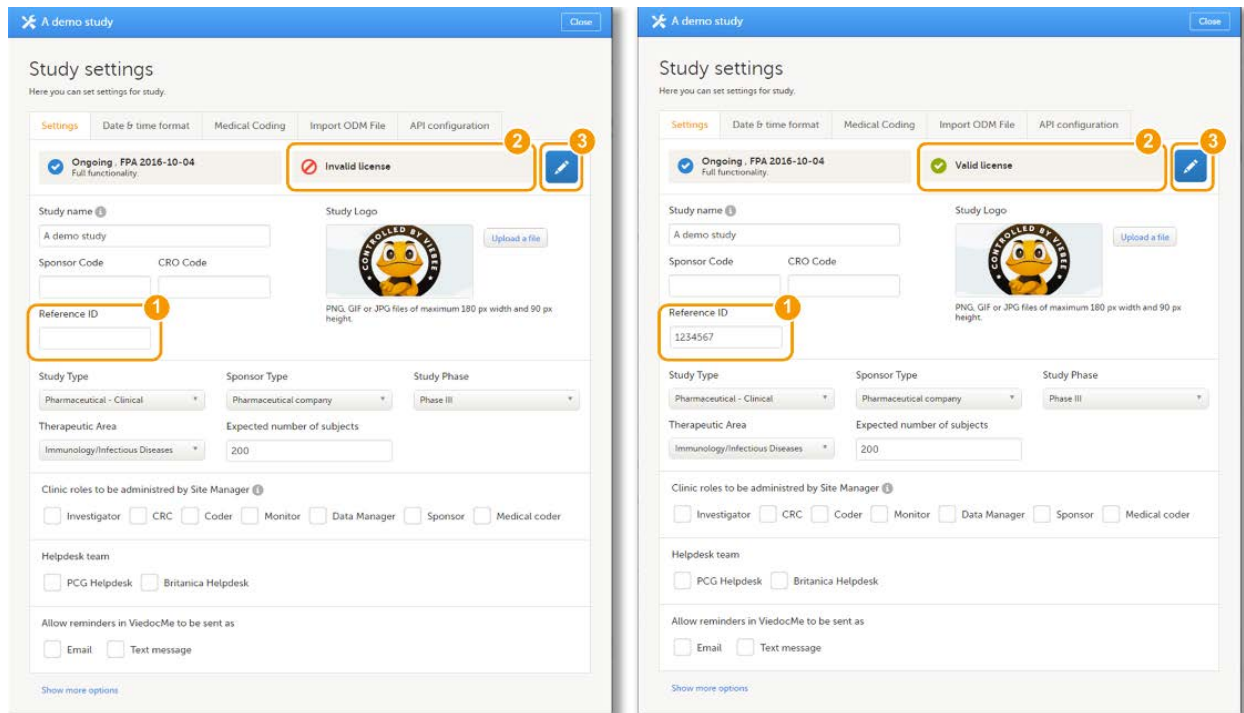
Contact your organization administrator to get access to the respective area.

**Note!** There is no guarantee that studies running on the test/development environment are completely and continuously backed-up. This environment should therefore never be used for any production studies.

### 3.6 Licensing

All production studies need to have a valid license before they can be taken into production. The license is provided by a Viedoc representative. The license fee for the study is based on several factors such as duration, number of sites and patients, among others. The license fee is charged starting with the **first patient added** and for the duration of the study; which means, until the study is locked in Viedoc. If the study is not deleted from the database within 2 months, a post-study access fee may apply.

Every license is connected to a reference ID. The reference ID can be found on the signed study work order and should be entered in the field **Reference ID** in the Study settings in Viedoc Admin (nr. 1 in the image):



Upon entry of the reference ID, the reference ID is verified. If the reference ID is valid, the text **Valid license key** will be indicated at the following places:

- Study settings in Viedoc Admin (nr. 2 in the image)
- Studies list in Viedoc Admin
- Study status in Viedoc Admin (nr. 3 in the image)

Once the reference ID has been verified, the study can be taken into production. A study is in the production mode once **Production** is selected as a site type. As soon as at least one site of production type is added, the Reference ID is locked and there is no way to unlock it afterwards.

For more information regarding license fee and reference ID, please contact your Viedoc representative.

## 4 Keep yourself updated!

Viedoc is being developed at a rapid pace. To make sure you are using the platform correctly and to its full potential, use this guide as a refresher after every new release.

Brief information about new and updated functionality after every release can be found in:

- the **Release notes**, which are sent out before every release, and can be downloaded from the Viedoc website, click:
  - [here](#) for the international website
  - [here](#) for the Japanese website
  - [here](#) for the Chinese website
- the **eLearning**, in [What's new in the latest release?](#)



Overview of Viedoc Admin

# Overview of Viedoc Admin

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## [1. Introduction](#)

## [2. Organization overview](#)

## [3. Study overview](#)

### [3.1 Study status](#)

### [3.2 Used data storage](#)

### [3.3 Open a study](#)

## [4. The study details page](#)

This section provides an overview of Viedoc Admin. It summarizes the main settings that can be configured in Viedoc Admin.

## 1 Introduction

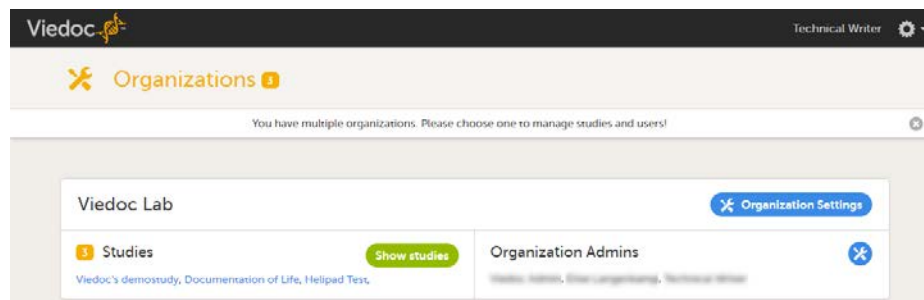
Viedoc Admin is the starting point for every new Viedoc project. Viedoc Admin is the application where you can manage the administrative aspects of a study. The following actions can be performed in Viedoc Admin:

- Add a new study
- Manage user accounts
- Invite users to system roles and clinical roles
- Add study sites
- Assign designs to study sites
- Manage general study settings and fill out study details
- Manage randomization lists
- Upload coding dictionaries and create coding instances
- Manage reference data sources
- Configure the Application Programming Interface ([API](#))

Access to Viedoc Admin is granted by either the Organization Administrator or the Study Manager.

## 2 Organization overview

For the Organization Administrator, the organization overview is the first page that is shown upon accessing Viedoc Admin.



On the organization overview, you can:

- Edit the **Organization Settings**, for example update the contact details for the organization and configure single sign-on.

- View or access all studies within the organization. Click **Show studies** to view a detailed list of all studies, or click on the name of a study to directly access the study.
- View a list of all Organization Administrators, and invite users to the role of Organization Administrator. Click the toolbox icon to open the organization administrators dialog. For more information about how to assign organization administrators, see [Managing users \(Org Admin\)](#).

## 3 Study overview

For all users that are not Organization Administrator, the study overview is the first page that is shown upon accessing Viedoc Admin. This page lists all studies in which the user has a system role.

For each study, the following information is displayed:

1. The logo of the study
2. The name of the study
3. Some study details are:
  - The total number of production and training sites
  - The study Status
  - The date of first patient added ([FPA](#)) (only for production sites)
  - The status of the study license number, if a valid license exists
  - Used data storage

### 3.1 Study status

This section explains Study Status.

A study can have these statuses:

- Not commenced
- Ongoing
- Locked by (*the name of the user who locked the study*)
- Study delete requested by (*the name of the user who requested the study delete*)
- Study delete confirmed by (*the name of the user who confirmed the study deletion*) - this is only visible for the Organization Administrator. For other users, the study disappears from the **Studies overview** once the study deletion is confirmed by the Organization Administrator.

**Note!** The study status will change from *Not commenced* to *Ongoing* when the first production site is added. A [study license](#) is required to make that change.

### 3.2 Used data storage

Your used data storage keeps track of the amount of data used by the documents added in Admin, as well as the files uploaded in [eCRF](#).

### 3.3 Open a study

To open a study and access the study details page, click the study. You can search for a study by entering the study name in the search field. You can sort the studies by study name or by the date when the study was created.

**Note!** A study needs to have a valid license to be taken into production. For more information about the study license, see the chapter about licensing in [Overview of Viedoc](#). For more information about how to take a study live, see [Adding a new study](#).

## 4 The study details page

The study details page is the first page that is shown upon accessing a study. On the study details page, you can interact with the settings in the following ways (see image):

The screenshot shows the 'Viedoc Me study' details page. At the top, there are three status indicators: 'Ongoing, FPA 2022-03-31' (1), 'Valid license: 5892332' (2), and 'Used data storage: 134.9 kB' (3). A 'Study settings' button (4) is in the top right. Below are several settings cards: 'RTSM. Check for available slots, append existing or add new lists.' (5), 'Medical coding. Create and edit instances, upload files.' (6), 'eTMF. Manage your eTMF application here' (7), 'Reference data source(s). Manage contact information, design scopes and link them to applicable sites.' (8), and 'API configuration. Add and edit API clients, view data history.' (9). The 'Study crew' section (10) shows 'Study Managers (2)', 'Designers (2)', and 'Helpdesk team (0)'. The 'Study design' section (11) shows 'Effective' and 'Latest' tabs, and 'Design 2022 1.0 (effective on 2022-07-19 00:00)'. The 'Study Sites' section (12) has filters for '6 Sites', '3 Countries', and '3 Site users', and a 'Show all sites' button. A table lists five sites with columns for '#', 'Site name', 'Code', 'Country', 'Effective Design', 'Production', and 'Users'. Each row has an edit icon (12). At the bottom, there is a '+ Add a site to this study' button (13).

#	Site name	Code	Country	Effective Design	Production	Users
1	Karolinska Institute Stockholm	KI	SE	Design 2022 1.0	✓	2 / 3
2	Uppsala University Hospital	UU	SE	Design 2022 1.0	✓	2 / 3
3	Helsinki University Hospital	HU	FI	Design 2022 1.0	✓	2 / 3
4	Franklin Memorial Hospital	FR	SE	Design 2022 1.0	⊘	1 / 2
5	Martin Luther Hospital	BR	SE	Design 2022 1.0	✓	1 / 2

1. [FPA](#)
2. [License status](#)
3. [Data storage](#)
4. Edit the general study settings, see [General study settings](#).
5. Manage the reference data sources, see [Managing reference data sources](#).
6. Upload and manage medical coding dictionaries, see [Managing medical coding dictionaries](#).
7. Manage the eTMF, see [Quick guide for setting up Viedoc TMF](#)
8. Manage the reference data sources, see [Managing reference data sources](#).
9. Configure the API, see [Viedoc WCF API](#), [API configuration](#), and [Viedoc Data Import Application](#).
10. Manage the study crew, see [Managing users \(Org Admin\)](#) and [Managing users \(STM and SIM\)](#).
11. Apply study design versions and revisions, see [Assigning a study design](#).

12. Edit the study site settings and invite users to the study site, see [Managing study sites](#) and [Managing users \(STM and SIM\)](#).
13. Add study sites, see [Managing study sites](#).



System requirements

# System requirements

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[1.1 Browser requirements](#)

[1.2 Screen resolution](#)

[1.3 Internet connection](#)

[1.4 Firewall policy](#)

## [2. Security](#)

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## 1 Customer computer requirements

Customer computer requirements are defined as capabilities required by the customer computer to use all features of Viedoc with the intended graphical presentation and within guaranteed response times of Viedoc.

### 1.1 Browser requirements

Viedoc supports the following browsers:

- Chrome, the latest 10 major releases (6-week browser release interval)
- Firefox, the latest 15 major releases (4-week browser release interval)
- Edge (Chromium edition), the latest 10 major releases (6-week browser release interval)
- Safari (MacOS/iOS only), the latest 2 major releases (1-year browser release interval)

For non-compliant browsers you will receive a message on the login page that your browser is not supported.

For Viedoc Designer:

- Chrome is recommended
- Allow pop-ups must be enabled

Viedoc does not support the use of private mode browsing in Safari.

The following are required for Viedoc to run in the compatible web browsers:

- JavaScript
- Session cookies
- Local web storage (only required by the main portal of Viedoc 4)

No data is permanently stored on the customer computer. All data stored in session cookies or local web storage is deleted when the browser session is terminated. The only exception to this is the optional persistent cookie used in the main portal of Viedoc 4 to remember if a user chooses to issue a 2FA trust for the browser for 30 days, and thus avoid further second-factor authentication during this period.

Viedoc 3 has no automatic checks enforcing the above requirements. Viedoc 4 checks for, and enforces, browser type and version, and support for JavaScript, local web storage, and session cookies.

### 1.2 Screen resolution

The following screen resolutions are required:

- Viedoc 3: at least 800×600
- Viedoc 4: at least 1024×768



### 1.3 Internet connection

Viedoc requires an internet connection of at least 384 kbit/s.

### 1.4 Firewall policy

Viedoc requires an outbound firewall policy allowing encrypted HTTP to be established and communicated to a remote server on port 443 (HTTPS) using Transport Layer Security ([TLS](#)) version 1.2 or higher.

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## 2 Security

There are several layers of security built into the platform. Below are some examples:

- **Login attempts** - after three failed attempts to enter a correct password, your account is locked. Use the "Forgot your password?" link on the login page to unlock and reset your password. The reset password link must be used within 3 hours from a request. There are restrictions on how many times you can submit a request in 24 hours.
- **Inactivity** - if you are inactive for more than 20 minutes, the system automatically logs you out. Inactivity means no activity whatsoever in the application.
- **Two-factor authentication** - two-factor authentication is an extra security measure that requires an extra confirmation step at login, in addition to user name and password.
- **Password expiration** - the password expiration time depends on the settings for your study. However, the default setting is 90 days. In addition to this, a history of the latest 10 passwords are kept to prevent reusing old passwords.



Managing your Viedoc account

# Managing your Viedoc account

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## [4. Pending invitations](#)

### [4.1 Approving a study invitation](#)

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## [5. Logging out](#)

# 1 Introduction

All information related to managing your Viedoc account can be found in the following user guide: [Viedoc User Account Management](#)

From the settings button (wheel) you can perform all actions related to managing your Viedoc account by selecting any of the following: **Edit your profile**, **Change Password**, **Security Settings**.

Selecting any of these options opens a new page, in the example below, the User Settings page. Select the Viedoc learning link to open the Viedoc User Account Management Guide:

viedoc

- User Settings
- Change Password
- Security Settings
- Authentication Log
- viedoc learning

### User Settings

▲ Ownership of +4812345678 has not been verified!

**User name**  
This is used to log in to Viedoc

doctordemo@viedoc.com

**First name**      **Last name**

Doctor      Demo

**Display name**  
This is your Viedoc user name

Doctor Demo

# 2 Study access management

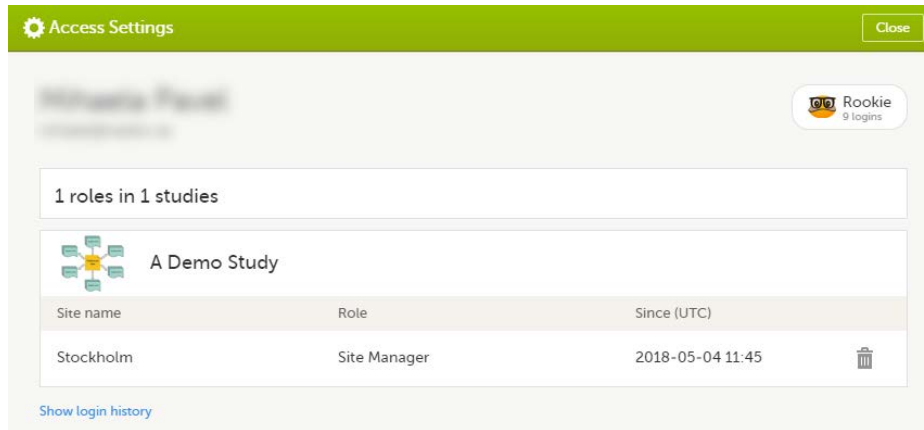
From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.



### 3 Access settings

Select the settings button (wheel) in the top right corner of the window, and select **Access settings**.

#### 3.1 Study membership



The following information is provided, grouped by study:

- **Site name**
- **Role**
- **Since (UTC)** - the date and time when the membership was approved, in Coordinated Universal Time ([UTC](#))

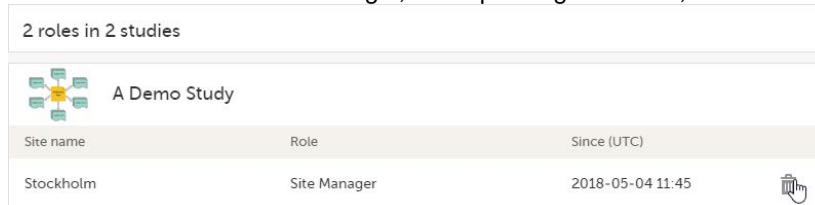
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

- **Organization name**
- **Role**
- **Since (UTC)** - the date and time when the membership was approved, in [UTC](#)

#### 3.2 Deleting study access

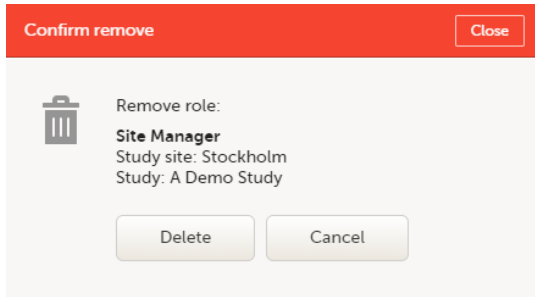
To remove yourself from a certain role within a study:

- 1 Select the trash can icon on the right, corresponding to the role, site and study to be removed from:



A confirmation dialog is displayed.

2 Select **Delete** to confirm the deletion:



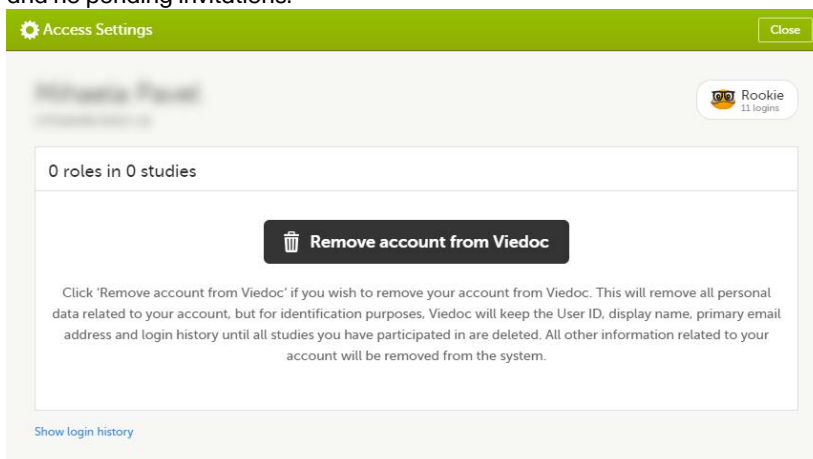
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

### 3.3 Deleting your Viedoc account

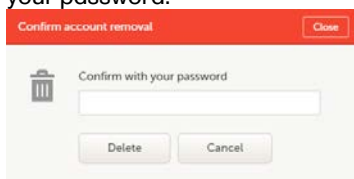
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

1 Go to **Access Settings**. To be able to remove your account, you should have no roles left in any study and no pending invitations:



2 Select **Remove account from Viedoc**. You will be prompted to confirm the account removal by entering your password:



3 Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



**Thank you and goodbye!**

Your account is now removed from Viedoc.

For identification purposes, Viedoc will keep: the user ID, display name, primary email address, and login history. They are kept until all the studies you have participated in are deleted. All other information related to your account will be removed from Viedoc.

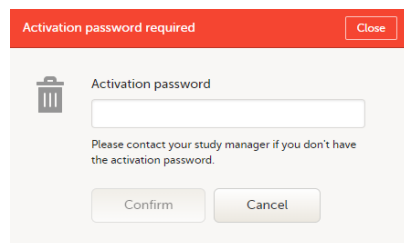
## 4 Pending invitations

In case you have study invitations that you have not accepted or rejected yet, the **Pending invitations** window displays a list of all your pending study invitations:



### 4.1 Approving a study invitation

To accept a study invitation, select **Approve** next to the respective study role. If this is the first role you have in the respective study, and if the study requires an activation password, you will be prompted to enter it:



**Note!** All the pending role invitations for a user are automatically approved when the Application Programming Interface (API) method `GetToken / Token` is used.

### 4.2 Rejecting a study invitation

To reject a study invitation, select **Reject** next to the respective study role. The invitation will be removed from the Pending invitations list.

### 4.3 Postponing the approval/rejection of a study invitation

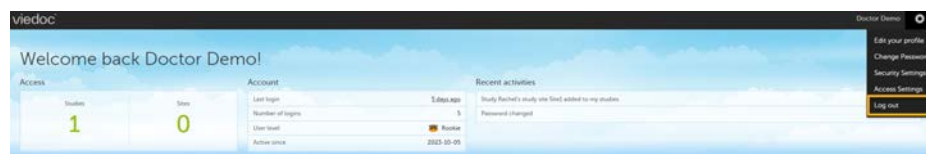
To postpone the approval or rejection of study invitations, select **Close** in the top right corner of the **Pending invitations** dialog box and postpone providing an answer to the study invitation.

To access the pending invitations again, the **Pending invitations** dialog box is shown:

- Automatically, after logging in.
- By selecting **Pending invitations** on top of the landing page.

## 5 Logging out

From Viedoc you can log out from different locations:



- To log out from settings, select the settings button (wheel) in the top right corner of the window, and select **Log out**. Use this link every time you leave the application from this location.

**Note!** If you exit the system without logging out, any subject you are currently working with will be locked for other users. After 5 minutes, the subject will be automatically unlocked.

- To log out from **User Settings**, **Security Settings**, **Change password** or **Authentication Log**: select your avatar on the top right hand side and select **Log out**.

The screenshot shows the Vedio user settings interface. On the top right, a user profile dropdown menu is highlighted with a yellow box. The menu contains a 'Vedio' logo, a circular avatar with the initials 'DD', the name 'Doctor Demo', and a 'Log out' button. The main settings page includes sections for 'User name', 'First name' (Doctor) and 'Last name' (Demo), 'Display name' (Doctor Demo), 'System language' (English), 'Primary email address' (doctordemo@vedio.com), 'Phone number' (+402345678), and 'Contact information' (Street address, City, Postal code, Country, State).



Viedoc study configuration management

# Viedoc study configuration management

Published by Viedoc System 2023-10-09

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## 1 Introduction

The configuration of a study in Viedoc consists of two types of settings:

- **Non version-controlled settings** - settings that are configured by the Study Manager in the Viedoc Admin application and that are effective immediately. These settings are common to the study at any given point in time. They are described in detail in the lesson [General study settings](#).
- **Version-controlled settings** - settings that are configured by the Designer in Viedoc Designer, but not effective until assigned to site(s) by the Study Manager in Viedoc Admin.

This lesson focuses on the configuration type that holds most of the study configuration, that is **version-controlled settings**.

---

## 2 Configuration overview

### 2.1 Study design version numbers

Version-controlled settings are contained in a "design" and are identified by a version number. Study design version numbers are unique within a study. If there exist five study design versions, all originating from the same design, and a new design is created from scratch within the same study, it will have version 6.

Study design version numbers are accompanied with a revision number. For example, "1.0" means that this is version 1 and that it has not been revised, since the revision part of the version is 0. Revisions are explained in [Revision of study design version](#).

## 2.2 Assignment of study design to site(s)

Study designs are assigned on site level. Work on a site cannot start before a study design is assigned to that site, as there is no study configuration associated with that site.

When the Designer has finished setting up a study design in Viedoc Designer, he/she has to publish the study design, so that it becomes available to the Study Manager in Viedoc Admin.

The Study Manager then chooses to assign the study design to one or several study sites. This step is accompanied with selecting an effective starting time for the study design on the selected study sites.

There can be more than one design version assigned to a site.

## 2.3 Version "burn-in"

Versions are burnt in at event level, based on the date of first data entry.

The applicable design version for an event is determined by comparing the event date to the effectiveness period of the study design version(s) assigned to the site. When an instance of an event is started, the study design version is burnt into it, indefinitely. All forms belonging to this event will then inherit that same study design version.

When the version has been burnt-in, the forms within the event always get their settings, structure and lay-out read from that same study design version, even if the event date, or design effectiveness periods, have changed so that a different study design version is available.

## 2.4 Event dates

In Viedoc, there are four different types of events, and the study design version is burnt in as follows:

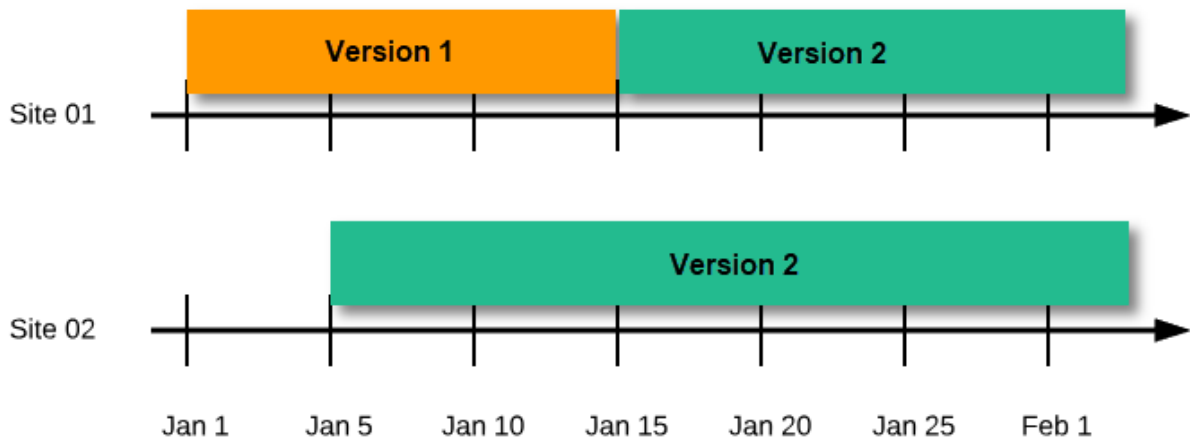
- **Study start** event - typically one simple form containing patient identification data. The study start event has no manual event date entry. Thus, even if it only contains one form and this form contains something called a "start date", it will not be used as event date. The event date of this type of event is always the time of event initialization, that is, when the event instance is entered for the first time.
- **Scheduled events** - visits scheduled according to the protocol. These require a date to be input when they are started/initiated. For these events this is the event date, and the study design version will burn in when the event is first started/initiated. If the event date is changed there will be no new burn-in. However, until the first form of the event is entered, the event can be stopped/uninitiated and this is then treated as a reset of the event and a new burn-in will occur when the event is again started/initiated.
- **Unscheduled events** - additional, on-demand visits. These require a date to be input when they are started/initiated. For these events this is the event date, and the study design version will burn in when the event is first started/initiated. If the date is changed there will be no new burn-in. However, until the first form of the event is entered, the event can be stopped/uninitiated. This is then treated as a reset of the event and a new burn-in will occur when the event is again started/initiated.
- **Common events** - events occurring separately or parallel to the workflow, for example concomitant medication, adverse events, dose adjustments, daily compliance reporting. These have no manual date entry. Thus, even if they only contain one form and this form contains something called a "start date", it will not be used as event date. The event date of these types of events are always the time of event initialization, that is, when the event instance is entered for the first time.

**Note!** The above applies even for the events that are using the "automatic event date" functionality, that is, if the event is configured to use an event date based either on the date of first data entry or on a date item. For details on the automatic event date settings, see the [Study workflow](#) lesson.

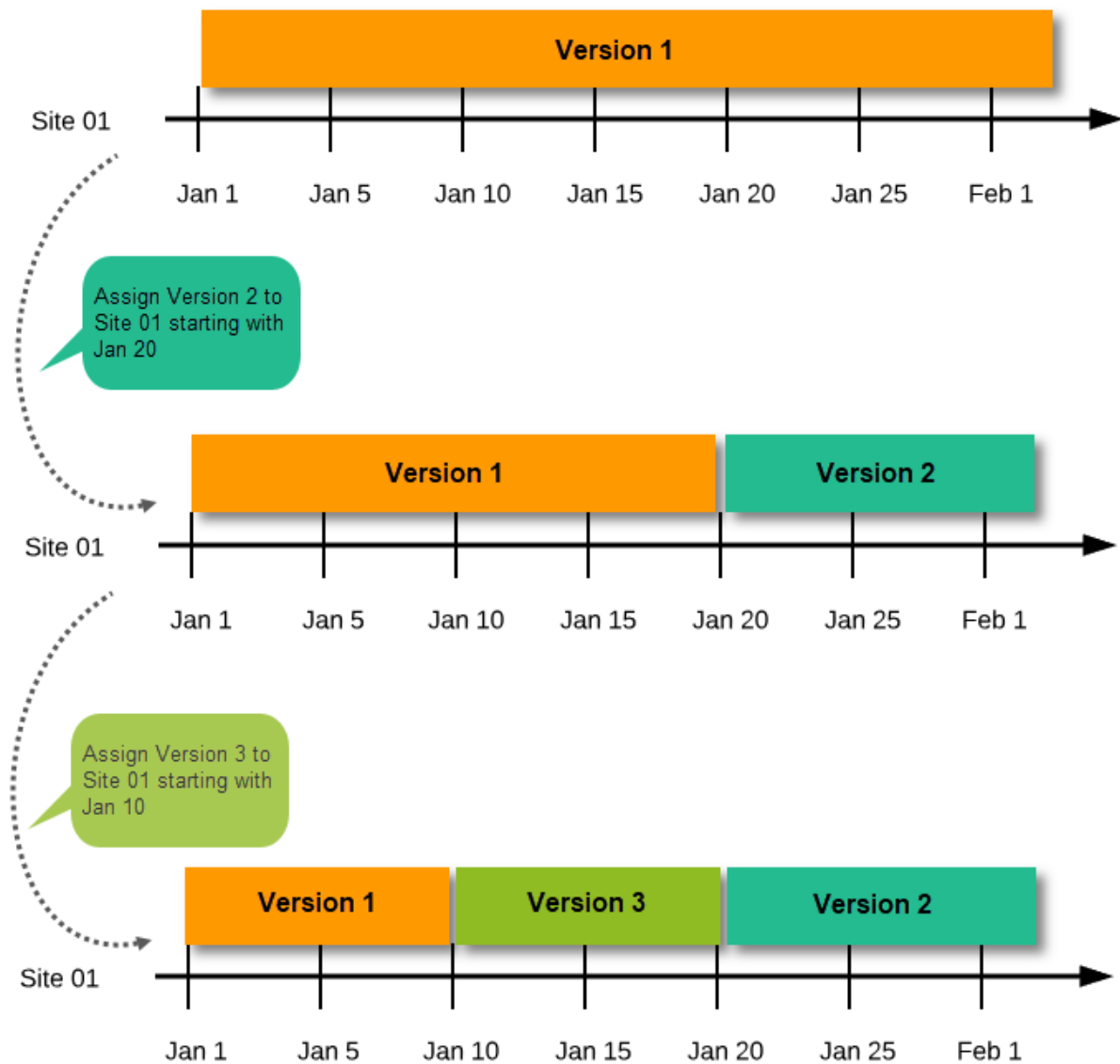
## 2.5 Multiple versions over time

During the course of a study, multiple versions of the study design can be assigned to a site, with different periods of effectiveness. For example, Site 01 could have Version 1 as the effective study design version during January 1st – January 15th and Version 2 as effective study design version after January 15th, whereas Site 02 has Version 2 as the only effective study design version starting January 5th, as illustrated in the image:





There is no end date for the effectiveness periods of study design versions. If a design is applied on January 1<sup>st</sup>, this is the effective version until a new version with a later start date is encountered, independently of when it was assigned.



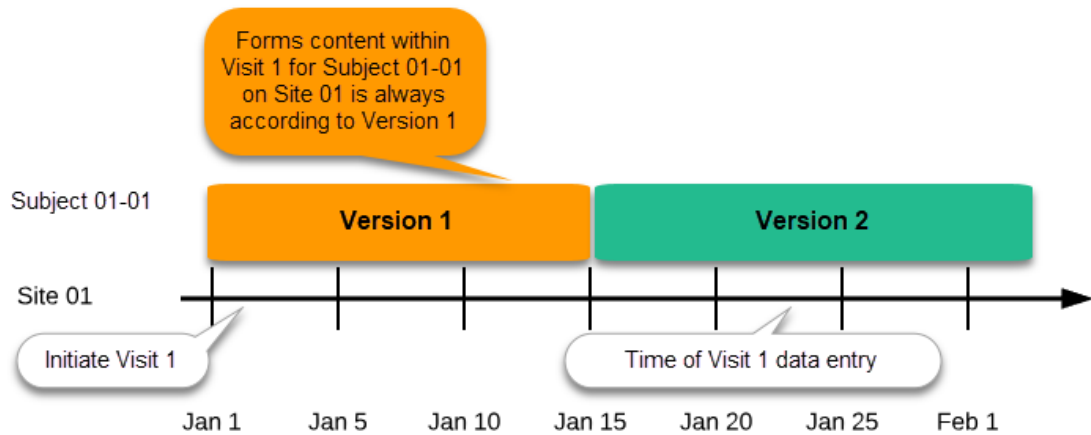
**Important!** The periods of effectiveness of a study design version are connected to the event timing of the first data entry and not to the current time at system usage. For example, in the below image, if:

- Version 1 is effective between January 1<sup>st</sup> - January 15<sup>th</sup> for Site 01.

- Version 2 is effective starting with January 16<sup>th</sup> for Site 01.
- Event 1 is initiated on January 2<sup>nd</sup> for Subject 01-01 on Site 01.

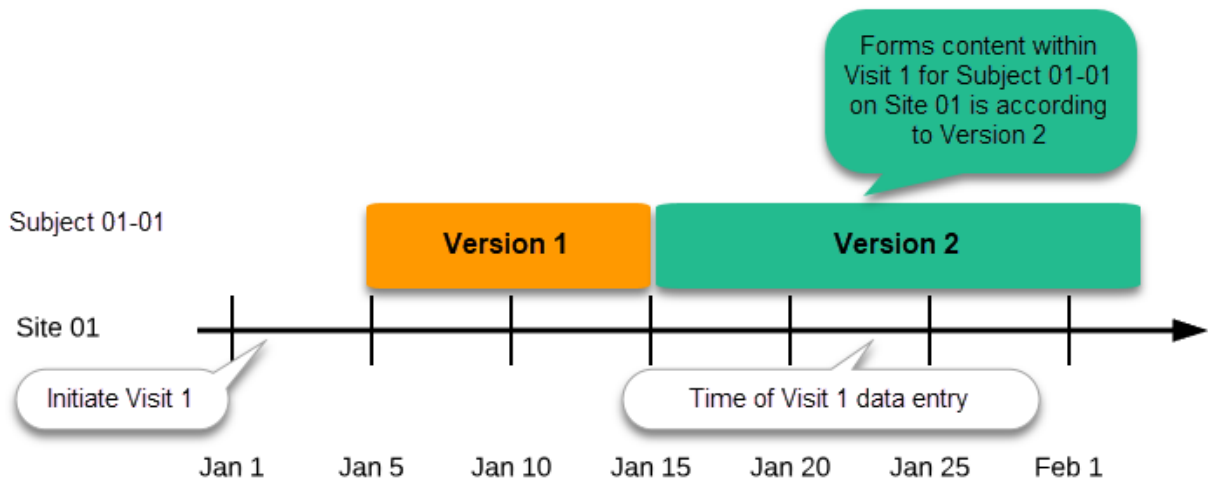
...then:

- Form content of Event 1 for Subject 01-01 on Site 01 will always be according to Version 1 (because Event 1 was initiated within the validity period of Version 1), regardless of the time of data entry:



### 2.5.1 Event created before starting point of any version

If an event is initiated with a date when no design version is in effect, the version effective at current time of system usage will be used:



### 2.5.2 New version with same timing as current version

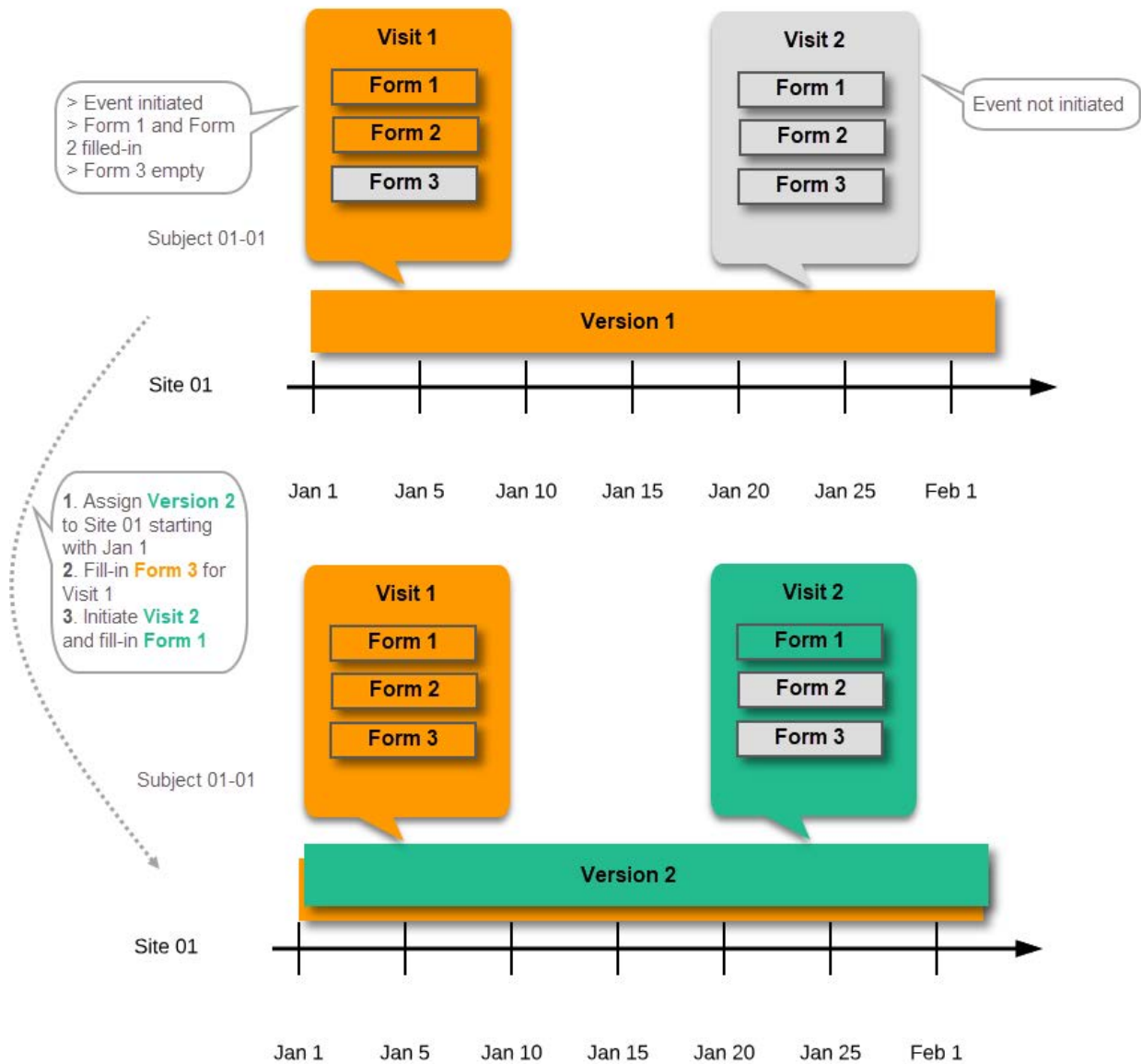
A new version can be assigned with the same timing as the currently assigned version and will then replace the currently assigned version, except for already entered data (due to the version “burn-in”, as described in [Version burn-in](#)).

For example, if we have Version 1 assigned to Site 01 starting at Jan 1, and we have the following events:

- Event 1 - initiated and containing 3 forms:
  - Form 1 and Form 2 filled in
  - Form 3 empty
- Event 2 - not initiated

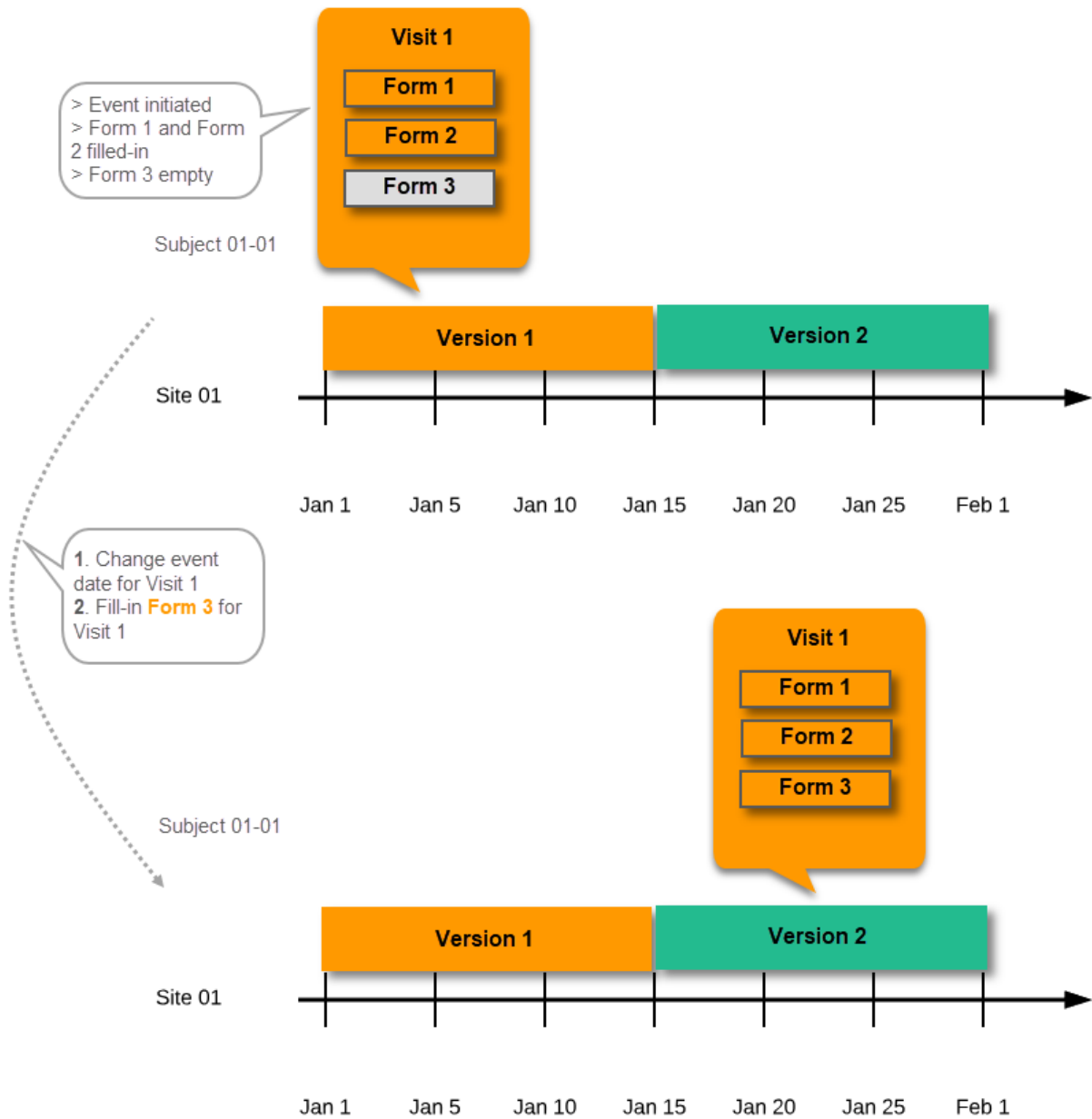
...and we assign Version 2 to Site 01 starting at Jan 1, and then:

- fill in Form 3 for Event 1 - this will have also Version 1, as this was burnt-in at the time when Event 1 was initiated.
- initiate Event 2 and fill in Form 1, this will have Version 2 (as well as all the other forms within Event 2)



### 2.5.3 Event date changed after it was initiated

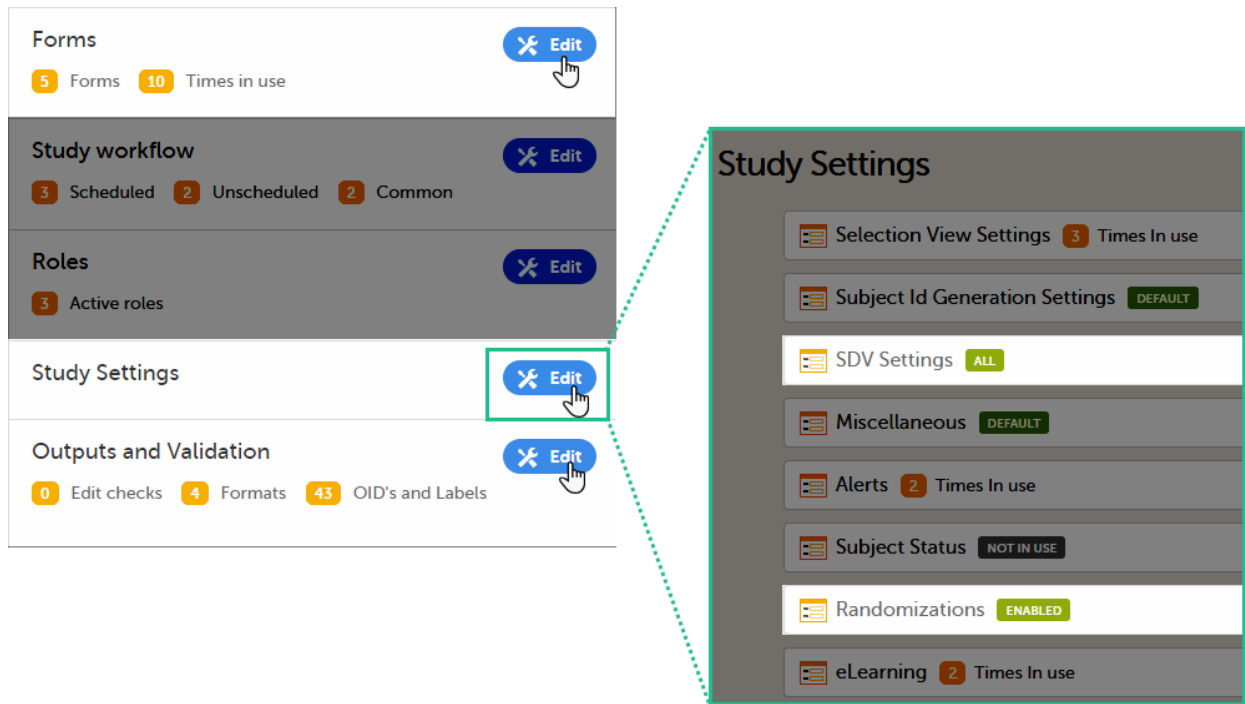
In case the event date is changed after it was initiated, to a date when another version is applicable, the version for that event does not change, as it was burnt-in at the date when the event was initiated (see [Version burn-in](#)):



## 2.6 Settings read from the study design version burnt-into the event

The following settings are always read from the study design version that is burnt-into the event:

- Forms
- Study settings
  - Source Data Verification ([SDV](#)) settings
  - Randomizations
- Output and Validation
  - Automatic data validation ("Edit checks")
  - Output formats
  - Output ID:s and labels

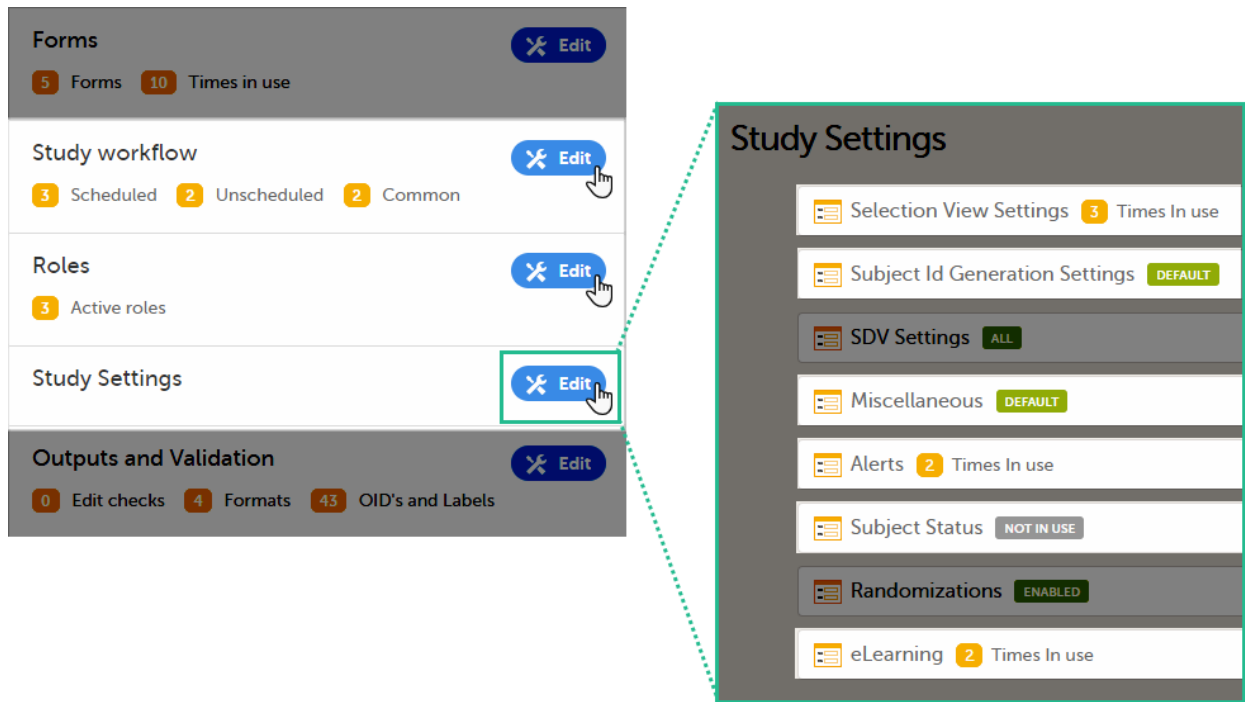


## 2.7 Settings read from current effective design

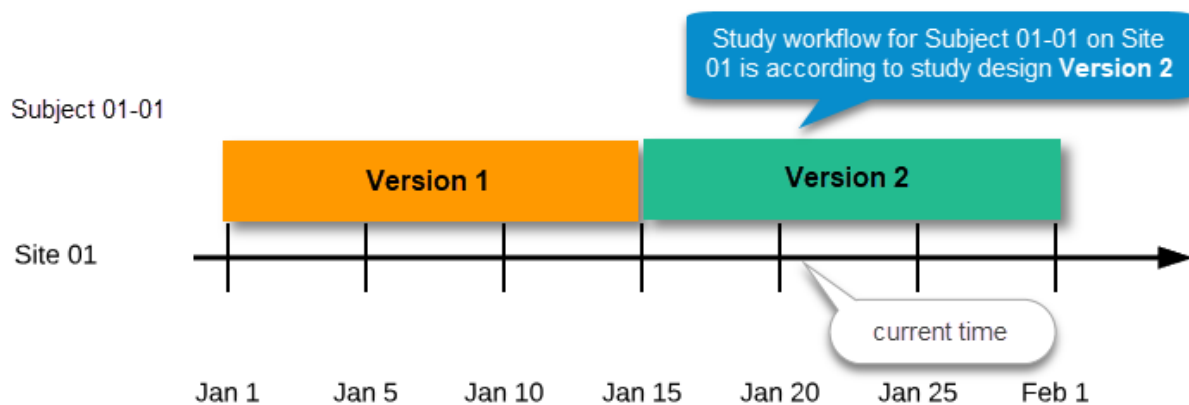
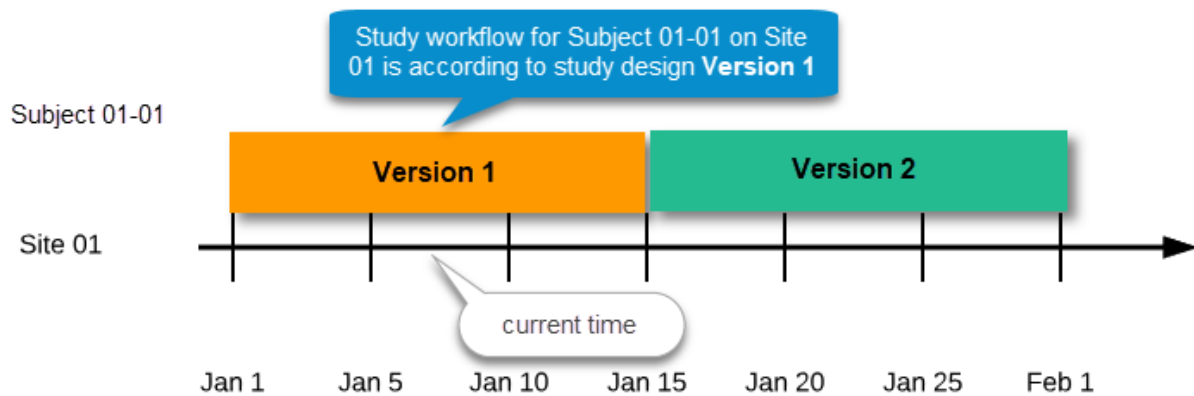
We call "current effective design" the study design version that is effective at the current time of system usage.

Settings that are not directly related to data collection structure, as well as settings that are common on the site level, are read from the study design version that is effective at the time of system usage (that is, "time right now"). These settings are:

- Study workflow
  - Study start event
  - Scheduled events
  - Unscheduled events
  - Common events
- Roles
- Study settings
  - Layout of subject card and subject selection page
  - Subject Id format
  - Miscellaneous
  - Alerts
  - Subject status
  - eLearning



This means that the study workflow for a subject can change as time passes and a new design version becomes effective for the site the subject belongs to:



## 2.8 Revisions of study design version

If there is a need to correct something in a study design version that is already assigned, and in particular if it has already been used to enter data (as that version is then burnt in and cannot be replaced by assigning a new version with the same time frame of validity), the study design version has to be revised.

The following settings can be revised as part of a revision of a study design version:

- Forms \*
- Study workflow \*
- Roles
- Output and Validation

The latest effective design for each site will be used to define the permissions that will apply to each role.

\* **Note!** The study design IDs (Event IDs, Activity IDs, Form IDs, Item group IDs and Item IDs), item dictionary (“choice”) codes and any items involved in randomization cannot be changed. An exception is that if an item needs to be moved to another item group, the ID can and must be changed as this will be treated as deleting an item and adding it again.

Once a study design version is revised, the revision part of the version number (initially 0) is incremented. For example, if study design version 1.0 is revised, it will receive the version number 1.1. When a revision of a study design version is published, it replaces its predecessor in terms of site assignment. For example, if a Study Manager wants to assign version 1 to a site, and this version now has a revision, version 1.1 will be available for assignment and not 1.0.

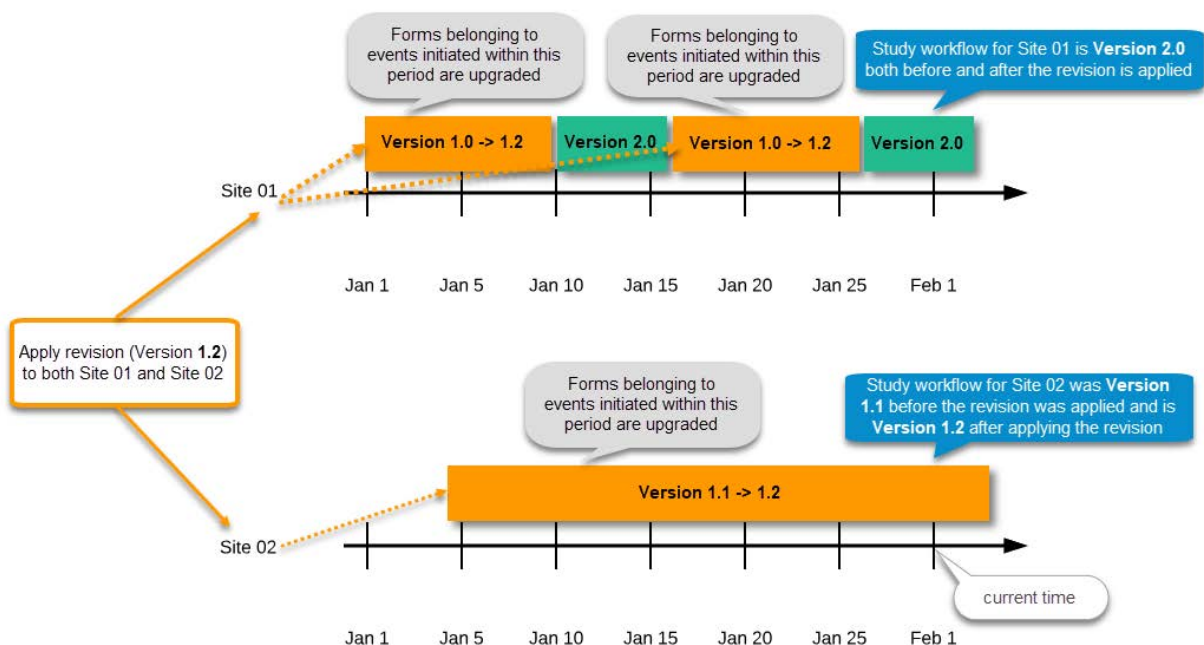
Additionally, only the latest revision of each study design version can be used as starting point for additional revision. For example, if we want to revise study design version 1, that has already been revised to version 1.1, we can only select 1.1 as starting point of the revision and not 1.0.

If forms that were previously part of an event in the workflow are now removed, already initiated forms are not touched. From a study workflow point-of-view they are now orphan forms, but from a user point-of-view there is no real difference to the appearance, as they stay as is on the event that they were previously part of.

## 2.9 Applying a revised study design version to a site

Application of a revised study design version is used to upgrade forms that are already burnt-in, with a predecessor of the study design version in terms of revisions, to the latest revision of the study design. Applying a revision is different from assigning study design versions, as assigning study design versions only affects forms belonging to events that have not been initiated yet.

When a revised version of a study design version is applied to a site, that revision will (eventually, after necessary site confirmations, see [Changes in a revision that affect data integrity](#) below) replace the version it is revising, including the base version and all previous revisions made to the version (as illustrated in the example in the image below, where 1.2 replaces both 1.0 and 1.1). Thus, effective period is not changed.



There are two parallel tracks being followed when a revised study design is applied, depending on whether the data integrity is affected by the changes in a revision or not, as described in the following subsections.

### 2.9.1 Changes in a revision that do not affect data integrity

A revision with changes that do not affect data integrity is applied without confirmation by the site staff. For all form instances in which form data is not affected by the revision, the revision is processed immediately.

Changes within a revision that do not affect data integrity:

- Forms – updated settings on:
  - Required/optional
  - Data checks
  - Min and max length
  - Number of decimal digits and/or number of decimals for numeric data type
  - Output IDs and labels
- Study workflow – actual workflow changes
 

**Note!** If these are the only changes made, this will be the same as assigning the study design to the site, as workflow is always read from the version effective at time of system usage as pointed out in [Settings read from current effective design](#).

  - Addition/deletion of events
  - Addition/deletion of activities/forms on existing event
- Roles
- Output and Validation

Any discrepancies no longer valid are closed and any new discrepancies will be flagged.

The forms that are locked (by Monitor, Data Manager, or any user who has data lock permission) will be upgraded, as no data will be touched by these types of changes.

Form signature and review status will not be affected by these kind of updates.

### 2.9.2 Changes in a revision that affect data integrity

Applying a revision with changes that potentially do affect data integrity requires confirmation by the site staff. Before the Study Manager can apply a revised study design, a mandatory information text has to be entered that will be used to notify the site staff about the changes (see the complete workflow below in [Workflow - Revision of an existing version](#)).

Changes that potentially do affect data integrity:

- Forms – addition/deletion of items and changes to:
  - Name of form
  - Item labels, including static text items
  - Item and item group position and input field size
  - Measurement units
  - Dictionary ("choice") labels
  - Instruction texts
  - Visibility conditions
 

**Note!** Changes of the role visibility conditions do not require site approval.
  - Function and default value expressions
- Study Workflow
  - Visibility conditions affecting form contents
  - Event date settings
 

**Note!** Changes of the event date(s) as a result of changing the "automatic event date" settings do not require site approval. For details on the automatic event date settings, see the [Study workflow](#) lesson.

A flag will be put on the form instance indicating that there is an upgrade pending. Until the upgrade is confirmed by site personnel (see [Site confirmation of version upgrade](#)), the form will remain in its original version.

#### 2.9.2.1 Site confirmation of version upgrade to revised version

When a revised study design is applied to a site, all forms pending an upgrade (where data integrity is potentially affected) are marked by a red flag, and a notification for the site is displayed on the Messages pane on the study start page.

The notification is accompanied with a standard text informing the site about the upgrade action and confirmation prompt that has to be electronically signed. This action can be performed by anyone at the site with data edit permission. See also the lesson in Viedoc Clinic User Guide - [Approving eCRF changes](#).

When signed, all forms pending upgrade (listed in [Changes in a revision that affect data integrity](#)) will be upgraded to the revised version of the study design. This is a background activity that can take some time if there are considerable amounts of forms to be upgraded.

For the subjects that are being edited by clinic users during the upgrade process, the upgrade will stay pending until the respective subjects are released.

Optionally, forms can be upgraded manually, one-by-one, by the site. This is performed by navigating to the forms affected, opening them for editing and re-saving them. When the form is opened for editing, it will be shown using the new upgraded design with all data filled in.



A recommendation to the site could be to manually upgrade a few forms to fully understand the potential impact of the upgrade and then upgrade the rest using the batch approval feature.

**Important!** The upgrade is not performed for:

- locked forms (locked by Monitor, Data Manager, or any user who has data lock permission).
- forms for which the approving user does not have view/edit permission.

If performing batch approval and forms affected by the upgrade are skipped, as a result of one of the above mentioned scenarios, a new message will be displayed on the Message page. The changes can then be approved after a user with permission unlocks the locked forms.

Forms upgraded to a new design revision lose any existing signature and review flags (clinical review, data review). The SDV flag is lost on item level.

If a particular item, that did not require SDV, is affected by the upgrade (that is, edited in the design, see [Changes in a revision that affect data integrity](#)), the form-level SDV flag will be kept. That means an upgrade of a form can lead to losing existing signature and review flags (clinical review, data review), but keeping the SDV flag.

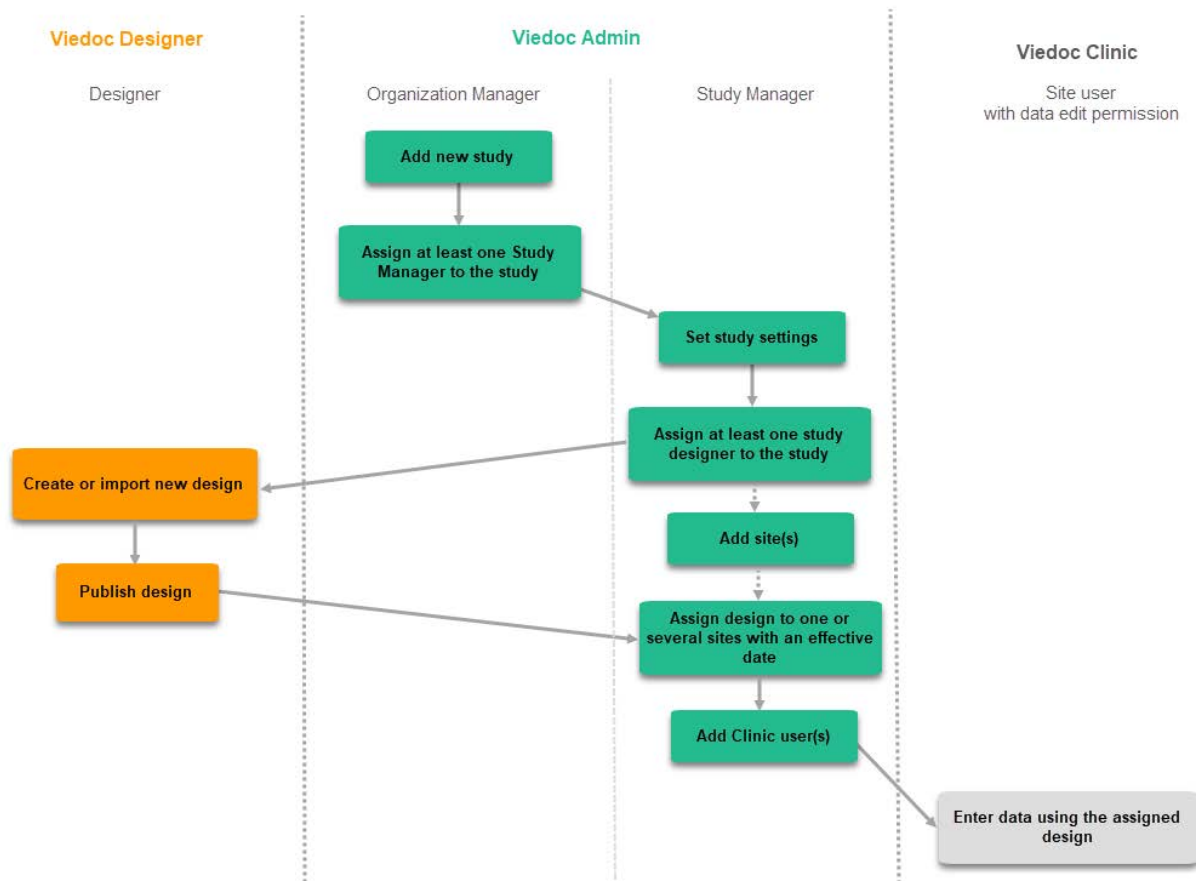
If a particular item, that was previously source data verified, is affected by the upgrade (that is, edited in the design, see [Changes in a revision that affect data integrity](#)), it is no longer flagged as having been source-data verified. The form-level SDV flag is lost if any item in the form lost its SDV flag. The form-level SDV flag is also lost if an item is removed from a form as part of the upgrade.

## 3 Configuration workflow

### 3.1 New study - first study design version

The following steps have to be performed in Viedoc when creating and configuring the study for the first time:

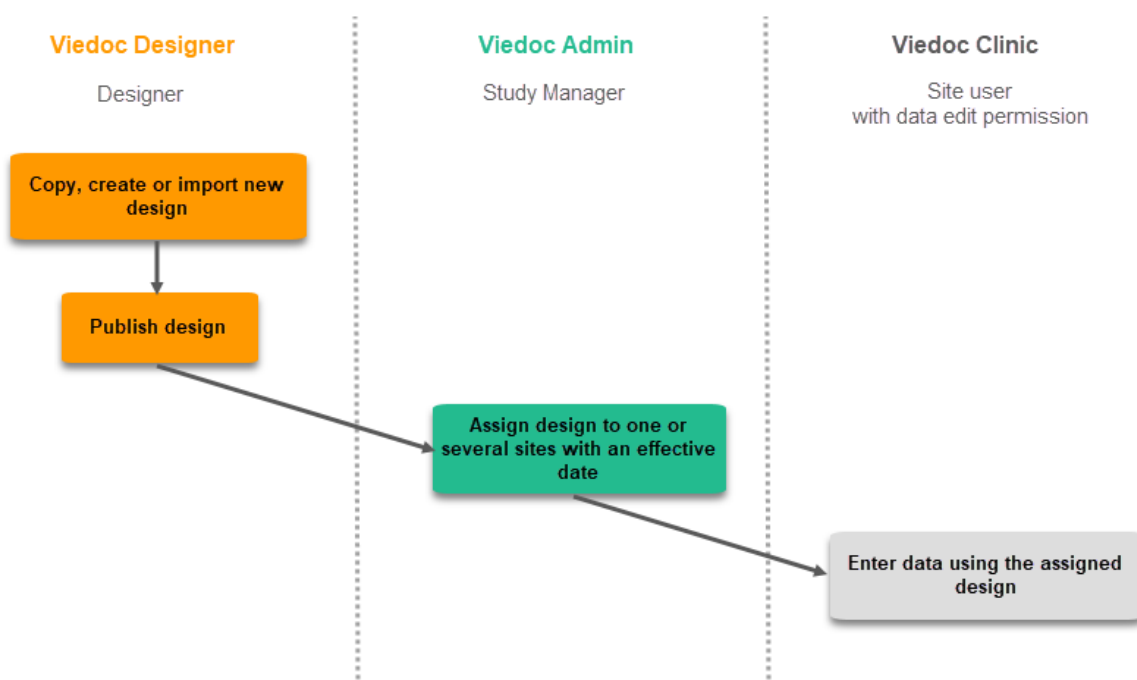
1. In Viedoc Admin, the Organization Manager creates the new study and appoints a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non version-controlled common settings and appoints a Designer.
3. In Viedoc Designer, the Designer creates the first version of the version-controlled settings and makes it available to the Study Manager by publishing the design to Viedoc Admin.
4. In Viedoc Admin, the Study Manager creates site(s) and assigns the first version to the site(s)
5. The site user can start entering data in Viedoc Clinic, using the assigned design.



### 3.2 Subsequent versions

The workflow for creating a new design version starting from an existing version of the study design, to implement a protocol amendment and assign it to one or several sites, is the following:

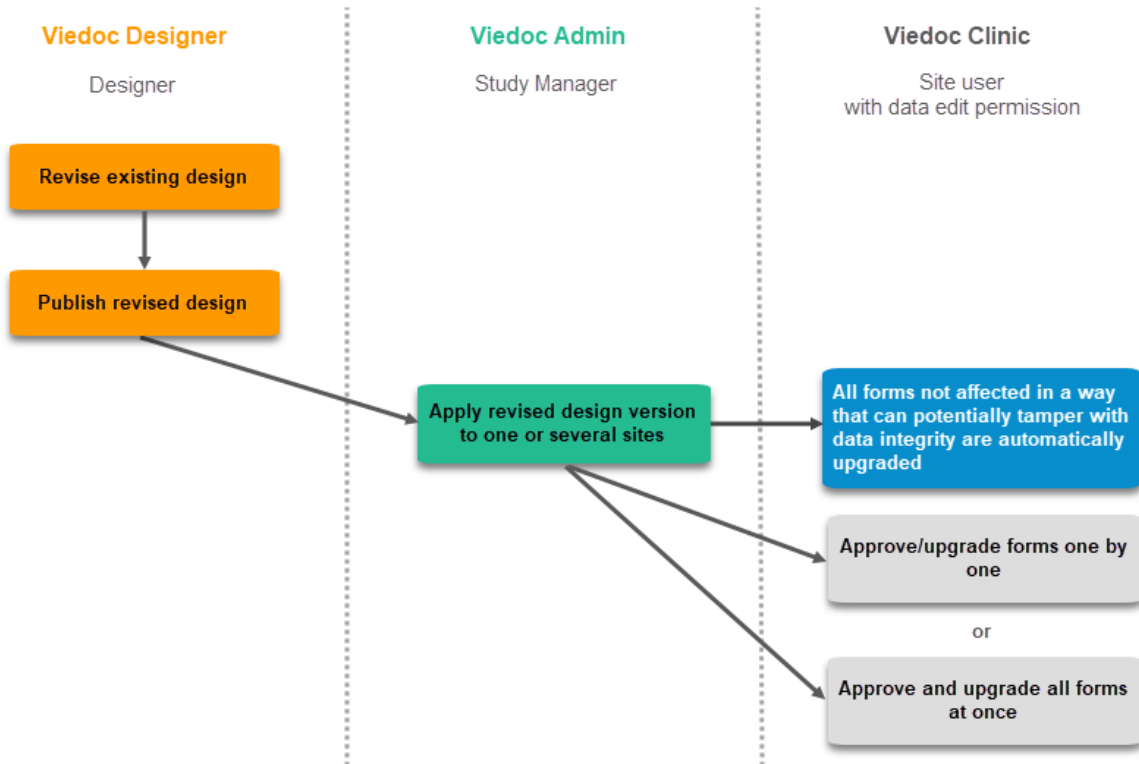
1. In Viedoc Designer, the Designer makes a full copy of the existing version of the study design.
2. In Viedoc Designer, the Designer makes the additional settings required by the protocol amendment and then publishes the design, which then becomes available in Viedoc Admin.
3. In Viedoc Admin, the Study Manager assigns the new version to one or several sites that should have the amendment. For instructions see [Assigning a study design](#).



### 3.3 Revision of existing version

The workflow for revising an existing study design version and applying it to one particular site is as following:

1. In Viedoc Designer, the Designer makes a revision of an existing version.
2. In Viedoc Designer, the Designer makes the additional settings and then publishes the design that becomes available in Viedoc Admin.
3. In Viedoc Admin, the Study Manager applies the revised version to one or several sites that should have the revision. For instructions see [Assigning a study design](#).



**Important!** If a new revision is applied before previous one(s) are approved by a site user, then the approval will upgrade affected forms to the latest revision, regardless of which of the upgrades the site user approves. For information on site approval see [Approving eCRF changes](#) in Viedoc Clinic User Guide.

**Note!** An upgrade message is displayed for the site under the Messages pane on the study start page, even for the revisions with changes that do not affect data integrity, that is, when the forms are automatically upgraded.

## 4 Configuration management

If an iterative approach is used during development of a configuration, there will be many versions created as part of the workflow: [ setup -> test -> correct -> test -> setup -> test -> correct -> test -> ... ]. It is still advisable to revise existing versions (instead of creating new versions) whenever possible to keep the number of versions to a minimum, as this will make the study design repository less cluttered and more easy to manage.

### 4.1 In Viedoc Designer

In Viedoc Designer, the following actions related to the study design can be performed, as described in the respective lessons:

- [Initiating a study design](#) - describes how to initiate a design, either by adding a new empty version or by importing one.
- [Validating a study design](#)
- [Publishing a study design](#) - describes how to publish and unpublish a design.
- [Duplicating a design](#) - describes how to either create a new version by copying an existing version, or revise an existing version.
- [Exporting/Locking/Deleting a study design](#)

## 4.2 In Viedoc Admin

In Viedoc Admin, you can see the current effective design for each site, assign a study design version to one or several sites, and apply a revised version of a study design to one or several sites. All these are described in detail in [Assigning a study design](#).



What's new in the latest release?

# What's new in the latest release?

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## 1 What's new in the latest release?

The following changes are released in version 4.78. They will be available to users according to the release schedule here: <https://www.viedoc.com/support/release-notes/release-notes-viedoc-4.78/>

Viedoc 4.78 introduces the following new and updated functionality:

- This release is dedicated to introducing a new identity provider for authentication of Viedoc users, offering better support for enhanced security and centralized user management. The migration of user accounts will occur seamlessly and will have the same functionality as before. Users will not see any changes unless they are logged in and access their user profile.
- From the landing page, users are directed to a new page for managing their user account when selecting the following links: Edit your profile, Change Password, Security Settings, Show login history from Access Settings. On the new page, which also has an updated UI, users can access the User Settings, the Security Settings, the Authentication Log (previously the Login history), and Change Password.
- For password recovery/resetting a password, the security question has been removed. Instead, an authentication code must be provided instead of answering the security question. The authentication code is sent to one of the following: a phone number set to receive text messages or to a secondary email address (even if not verified).  
If these options are unavailable, the reset password link must be provided by the Study Manager, and the user will receive the reset password link and will be able to reset the password without providing the authentication code.
- The Login History has been renamed to the Authentication Log, which provides detailed information on the actions performed by the user and the result of those actions, for the latest login sessions, both for the users themselves as well as in Viedoc Admin > User Settings.
- Please note that the list of trusted devices - the list of devices the user has designated as trusted at login time, is not migrated. If the trusted devices option is selected, users will need to confirm their trusted devices at the next login.

### 1.1 Viedoc Reports

- We have added new lessons to the eLearning that describe the sub-reports in greater detail.

This release also consists of a set of bug fixes.

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## 2 What's planned for the next releases?

### 2.1 Planned changes for the upcoming release, Viedoc 4.79 (available in 2024)

- **Document sharing – Viedoc eTMF**  
Support for sharing links to documents with other users.
- **Document signing – Viedoc eTMF**  
Support for document signatures in the eTMF compatible with 21 CFR Part 11.
- **Study Design management – Viedoc Designer, Viedoc Admin**  
Support for improved design change management

## 2.2 Planned for future releases

- **Coding application** – [Viedoc Coder](#)  
Support for a new Viedoc Coder application added to the Viedoc eClinical suite.
- **UI optimization** – [Viedoc eTMF](#)  
A complete upgrade of the user experience.
- **Role-based queries** – [Viedoc Clinic](#)  
Added support for query management for the individual roles that work with queries.
- **Output formats** – [Viedoc Report](#)  
Additional output formats will be added (XML, JSON).
- **Risk-based monitoring** – [Viedoc Clinic](#)  
Support for risk-based approach to site monitoring activities.

*For more information on future releases, please contact your Viedoc representative.*



Known limitations

# Known limitations

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# 1 Viedoc Clinic

## 1.1 CSV export

- The export to CSV fails if the same OID was used in Viedoc Designer in different design versions with different casing (for example, an OID defined as AE in design version 1 and AE in design version 2).
- Labels are truncated to 200 characters when CSV data is imported to SAS using the CSV2SAS macro.
- The Excel/CSV export does not include items set to "Hide Always" in visibility conditions when a single form is selected for export.

## 1.2 Data export

- The export preview with graph pages results in a JavaScript error on Internet Explorer 8 on some instances.
- The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.

### 1.3 Data review

- Queries of the type “Required value missing” responded with “Confirmed as missing” and cannot be rejected by the sponsor side.
- A field that is required for SDV but is hidden on a form (due to, for example, visibility conditions) can normally not be marked as having been verified by SDV. Yet, if the entire form is marked as having been verified by SDV, then even hidden fields are included and marked as having been verified by SDV.

### 1.4 Edit/enter data

- For scheduled and unscheduled events, when the event date form (\$EVENT) is excluded when you use automatic event dates, it still counts. In the signing console the counter (number of forms) for a event includes the \$EVENT form. It cannot be selected to be signed but can be signed if you select sign all (for subject or event). If you sign forms on an event individually you will not be able to sign the \$EVENT form. This in turn makes it so that the sign symbol that appears on the event when everything is signed does not appear, even though it looks like everything is signed.
- When populating numeric fields using functions and reference data, they automatically receive the number of decimals configured in the design.
- It is not possible to delete unscheduled events if automatic event dates are enabled.

### 1.5 File upload

- For security reasons, uploading executable files is not allowed. The complete list of unsupported file types can be found in the Viedoc 4.34 Release Notes.
- The upload of password-protected zip files is not supported, as Viedoc is not able to scan these files for viruses.

### 1.6 Issues and task

- The Issue list will not be visible for sites that have more than 1000 subjects.

### 1.7 Medical coding

- The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OS X.

### 1.8 Metrics

- The number of open queries differs between the Queries page and the Performance page. The Performance page also includes queries with the state “Removed”.

### 1.9 PDF export

- Visit date form history will not be included in PDF export if no forms were filled in, or if forms were initiated from Viedoc Me.
- When using Windows 7, file names added to the zip archive during PDF export get scrambled when they contain Unicode characters. The extracted file content is not affected by this. There is a Hotfix for Windows 7 available at: <https://support.microsoft.com/en-us/kb/2704299> that addresses this issue.
- PDFs generated upon form save in Viedoc versions prior to 4.51 were generated and stored based on the role visibility conditions applied to the user that last saved the form. Items that were hidden to the user due to role visibility conditions are not shown/included in such generated PDFs.
- Fully PDF/A compliant archives are only supported if all the included form PDFs and study event PDFs were generated on, or, after 2017-03-10 (Viedoc 4.33). It is still possible to generate PDF/A compliant archives that contain form and study event PDFs generated before this date, but you might receive warning messages related to PDF transparency issues.
- In the PDF/A export output, the header, footer, and the text on the respective Contents page are missing for the deleted forms/events/subjects.

### 1.10 Selection page

- The descending sorting in the subject list view is not working properly.
- When clicking to sort a column containing dates in the subject list view, Viedoc sorts all dates using a numeric variant of US date representation (for example, 1977-NOV-16 comes before 1967-DEC-16 because the first is sorted like 11/16/1977 and the latter is sorted like 12/16/1967).
- The event overview page is not working with Safari running on Windows OS or older Safari versions running on Mac OS X.



## 1.11 Documentation and training

- When downloading a PDF of the Viedoc User Training Certificate, the generated PDF is limited to two pages. This means that when there are more training sections completed than can fit onto two pages, the PDF will not generate a third page and some of the training sections will be missing.
- 

# 2 Viedoc Admin

## 2.1 Apply revision

- The affected forms count shown in Viedoc Admin while applying a study design revision is implemented only for production sites. Demo/Training site forms are not included in this count.

## 2.2 Data import

- It is only possible to import values (choice numbers), not strings (choice labels), when importing data into data fields where multiple checkboxes can be checked.

## 2.3 ODM import/export

- It is not possible to import an ODM file that was exported from Viedoc including the Event Dates into Viedoc Admin. The following error message is displayed: "An item with the same key has already been added".
- Only one (selected) design can be imported from each CDISC ODM file.
- ODM export fails when subject data contains large, uploaded files.

## 2.4 User management

- Any of the Organization Administrator, Organization Designer, and Site Manager roles that were removed from a user are not listed in Viedoc Admin, under User Settings > Studies and Roles.
- When sorting studies by group and generating a "User and Roles" or "User Administration Log" report, the Download link is not exposed for the newly generated file until the page is refreshed.

## 2.5 Study settings

- The Logs tab for generating the Admin audit trail report does not appear on the Study Settings page if the system language is German or Swedish.
  - The Documentation tab for the documentation and training feature, do not appear on the Study Settings page if the system language is German.
- 

# 3 Viedoc Designer

## 3.1 Alerts

- If the condition for an alert is set within a form for which the option to auto-update functions is enabled, and the alert is triggered, the alert message will be sent twice.

## 3.2 Edit checks

- Edit checks are not triggered on dates when the event date is used as default value, and the calendar picker is used to choose the date.
- Using \$THIS inside a form to refer to an item within a different instance of the same form, does not work, as it always refers to the same form instance. This is true when referring to an item in the same form within another activity, or when referring to another form instance within the same activity (applicable for repeating forms).
- If two scheduled events have the same event date, and both events contain a form with a function or data check that uses the \$PREV function, the \$PREV functions in these two events refer to each other as the previous event, and not to the event that occurred earlier in the study workflow. This creates a circular reference and makes it impossible to refer to earlier event(s).

### 3.3 Form and workflow PDF

- If, in the Study Workflow, there are more activities with the same activity name within the same event, then the forms in these activities are incorrectly displayed in the Bookmarks list in the study workflow PDF. Please note that only the Bookmarks list is affected, the events/activities/forms are correctly displayed within the document.
- The PDFs generated as Empty CRFs will not display all code list items for radio buttons, drop-down lists and checkboxes if these have been configured with many code list items in a vertical layout.

### 3.4 Item settings

- For the code list items (checkboxes, radio buttons, dropdown), it is possible to set the same code list values for multiple choices within the same item. This is not recommended. Unique code list values should be used for each of the choices within the same item.

### 3.5 JavaScript

- The setMonth function with negative values is not supported. The date is not saved into the system correctly when the function is run on the server-side.

### 3.6 Roles and permissions

- If the role that has the permission for Emergency unblinding also has a role visibility condition that makes the blinded outcome hidden for this role, the outcome gets hidden for all roles after unblinding, and not just for the role specified in Viedoc Designer.

### 3.7 Study workflow

- When the Event ID for the Study Start event contains the word "START", including combinations with other words and punctuation, and scheduling other events based on the Study Start event, this results in an error. The workaround is to use a different ID for the Study Start event, one that doesn't contain the word "START".

### 3.8 Validation of study design

- Validation of alerts, selection view settings, event visibility, subject status condition, common event summary format and subject ID generation settings for deleted items is not performed.

### 3.9 Visibility conditions

- When creating forms for Viedoc Me, visibility conditions can only include variables that have already been introduced, and that are in the same form and on the same page. This behavior differs from the one in forms for Viedoc Clinic.

### 3.10 Design configuration report

- When using Chinese or Japanese characters to label sites in Designer, the name of the design configuration file report will display an incorrect string of text.

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## 4 Viedoc API

- The API method SubmitData allows submitting data into a form that exists in the effective design but does not exist within the respective event according to the study workflow. In such a case, a new form is created and added to the event.
- When using the WCF API to push data into forms, if there are items that have functions setup to calculate data from other items, or item groups, those calculations will not be automatically updated. However, if an item that relies on a function is added to the same item group it relies on, it will perform the calculation.

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## 5 Viedoc Me

- In the UI-optimized version of Viedoc Me, when a simple visibility condition has been set to make a form item show depending on the selection of a radio button, and a subject selects the radio button, an error message is displayed.

- If additional languages are imported (to be used in Viedoc Me) and after that code lists are combined via “Formats” (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
  - For Viedoc Me translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated Viedoc Me form).
  - The drawing pad item is not working on IE 11. For Safari it only works on Safari 12+ versions.
  - Viedoc Me does not support forms with form link items.
  - The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.
  - Long option labels for radio buttons and check boxes do not have line breaks.
- 

## 6 Viedoc Logistics

- In the exported stock list, the audit trail shows one row for the create action for older kits. For more recently uploaded kits, the audit trail shows two rows for the create action.
- 

## 7 Viedoc Reports

- There are some graphical limitations of the interface on mobile devices.
  - Variables/fields that have an output field ID defined will be identified with this ID in the Data Browser and Reports pages, whereas they will be identified with field ID in the Dashboard, Demographics, and AE pages.
  - The Overdue Events Report does not include any Viedoc Me events. Events without a proposed date are not included in this report. Events that have been planned or initiated are not included in this report, even if the planned/initiated event is outside of the event window.
- 

## 8 Viedoc eTMF

- Viedoc eTMF is only running in Production mode.
- For security reasons, the document preview in the Trial Master File view does not support ActiveX components.
- The search for document content is disabled on the training server.
- Viedoc eTMF does not work on Safari 16.3 and later.
- Viedoc eTMF does not work on production or training servers in China.



## Glossary

# Glossary

Published by Viedoc System 2023-10-23

This glossary contains common terms and acronyms found in the eLearning. They are sorted in alphabetical order by the full term (not by abbreviation).

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

Term	Abbreviation	Definition
<b>A</b>		
Active Pharmaceutical Ingredient	API	The ingredient in a pharmaceutical drug or pesticide that is biologically active.
Adverse Event	AE	Any unwanted effect caused by the administration of drugs. The onset of an adverse event may be sudden or develop over time.
Anatomic Therapeutic Chemical classification system	ATC	A drug classification system that classifies the active ingredient of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.
Application Programming Interface	API	A set of routines, protocols, and tools for building software applications that specifies how software components should interact.
Attributable, Legible, Contemporaneous, Original, Accurate	ALCOA+	The principles of data integrity. The plus sign denotes the four additions: Complete, Consistent, Enduring, and Available.
Audit trail		An audit trail (or audit log) is a security-relevant chronological record, set of records, or destination and source of records that provide documentary evidence of the sequence of activities that have affected at any time a specific operation, procedure, or event. The records are of importance for the clinical study, as specified by applicable international standards (from the FDA and EMEA).
<b>B</b>		
<b>C</b>		
Case Report Form	CRF	A printed, optical, or electronic document designed to record all protocol-required information on each study subject.
The China Personal Information Protection Law	PIPL	The data privacy law in China, targeted at personal information protection.
Clinical Data Acquisition Standards Harmonization	CDASH	A standard developed by CDISC that provides guidance to develop the CRF.

Term	Abbreviation	Definition
Clinical Data Interchange Standards Consortium	CDISC	A global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata.
Clinical Data Interchange Standards Consortium Define Extensible Markup Language	CDISC Define-XML	A metadata format defined by CDISC that is sent with every study in each submission, which tells the regulatory authorities what datasets, variables, controlled terms, and other specified metadata were used.
Clinic role		User roles in Viedoc that give access to Viedoc Clinic, such as Investigators, Monitors, and Data Managers. The clinic roles are study-specific. These roles, and the rights that belong to these roles, can be defined in Viedoc Designer. Each study can have an unlimited number of clinic roles.
Clinical data manager		Responsible for the management of the data in the clinical trial. Assists in protocol development and database selection and configuration.
Clinical Research Associate	CRA	A person employed by the sponsor, or by a CRO, acting on a sponsor's behalf, who handles most of the administrative responsibilities of a clinical trial, acts as a liaison between investigative site and sponsor, monitors the progress of the investigator's sites participating in a clinical study, and reviews all data and records before a monitor's visit.
Clinical Review	CR	A clinical review gives the Monitor the possibility to mark forms as reviewed.
Clinical Trial Management System	CTMS	A Clinical Trial Management System is a software system used by biotechnology and pharmaceutical industries to manage clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.
Code of Federal Regulations	CFR	The codification of the general and permanent rules and regulations by the executive departments and agencies of the U.S. federal government.
Comma-Separated Values	CSV	A set of database rows and columns stored in a text file such that the rows are separated by a new line while the columns are separated by a semicolon or a comma.
Common event		An event that occurs separately or parallel to the workflow, for example concomitant medication, adverse event, medical history, dose adjustments, and daily compliance reporting.
Computerized Systems Used In Clinical Investigations	CSUCI	A guidance document established by the FDA intended to assist in ensuring confidence in the reliability, quality, and integrity of electronic source data and source documentation (that is, electronic records).
Concomitant Medication	CM	Drugs given to a patient at the same time, or almost at the same time, as the drug under study.
Contract Research Organization	CRO	A company that contracts with the sponsor to perform one or more of the sponsor's duties in a trial.
Coordinated Universal Time	UTC	The primary time standard by which the world regulates clocks and time. Viedoc stores all timestamps in UTC. In the cases when a time zone can be established (for example a specific site scope is selected), the timestamp is displayed with the time zone applied.

Term	Abbreviation	Definition
<b>D</b>		
Data Manager	DM	A user role in Viedoc with permission to lock and export data into different formats, view reports and metrics, and add pre-queries.
Demo mode		A mode in Viedoc specifically used for demonstrations and training new Viedoc users. No real data should ever be entered in Demo mode.
Designer		A user role in Viedoc that can create the setup (design) of the study in Viedoc Designer.
Dictionary Manager		A user role in Viedoc with permission to upload medical coding dictionaries.
Drug Information Association	DIA	A global forum for those involved in healthcare product development and lifecycle management to exchange knowledge and collaborate.
<b>E</b>		
Edit checks		A check of the data that verifies whether the data entered into the form are within a certain range that is specified in Viedoc Designer. If the entered data are outside the specified range, the system will automatically display a message that is defined under Query Message.
Electronic Case Report Form	eCRF	An electronic document designed to record all protocol-required information on each study subject.
Electronic Common Technical Document	eCTD	A standard format for submitting applications, amendments, supplements, and reports to the FDA.
Electronic Data Capture	EDC	The use of computerized systems to collect clinical trial data in electronic form as opposed to paper form.
Electronic Investigator Site File	eISF	The digital version of the minimum list of essential documents that a study site needs to maintain throughout a clinical trial. Included documents could be: Clinical Study Protocol, Investigator Brochure, Informed Consent, CVs etc.
Electronic Patient Reported Outcome	ePRO	A patient-reported outcome that is collected by electronic methods. Viedoc Me is the ePRO solution of Viedoc.
Electronic Trial Master File	eTMF	A type of content management system with a collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated.
eTMF Manager		A user role in Viedoc that has permission to manage the eTMF application in Viedoc Admin. The eTMF Manager maps Viedoc Clinic roles to eTMF roles. The eTMF Manager also has permission to manage the eTMF structure in Viedoc eTMF.
Event		A moment when the patient visits or contacts the clinic, or initiates an event through the Viedoc ePRO application Viedoc Me, and data are recorded.
European Medicines Agency	EMA	A decentralised agency of the European Union (EU) that is responsible for the scientific evaluation, supervision, and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.

Term	Abbreviation	Definition
European Medicines Agency Good Clinical Practice Inspectors Working Group	EMA GCP IWG	The EMA GCP Inspectors Working Group focuses on harmonisation and co-ordination of GCP related activities at Community level. It is involved in the preparation of new and revised guidance on GCP and community procedures relating to inspection.
Exchange Mechanism Standard	EMS	The exchange mechanism standard is a model for transferring eTMF data between sponsors, CROs, other stakeholders, and vendor systems.
Extensible Markup Language	XML	A markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.
<b><u>F</u></b>		
Food and Drug Administration	FDA	An agency of the U.S. federal government's Department of Health and Human Services that ensures the safety of foods, pharmaceuticals and other products.
<b><u>G</u></b>		
General Data Protection Regulation	GDPR	A regulation in the European Union (EU) law on data protection and privacy in the EU and the European Economic Area (EEA). Primarily aimed to give control to individuals over their personal data and to simplify the regulatory environment for international business by unifying the regulation within the EU.
Good Automated Manufacturing Practice	GAMP	A subcommittee of, and a series of good practice guides on drug manufacturing published by, the International Society for Pharmaceutical Engineering.
	GAMP5	The last major revision of the GAMP Guide for Validation of Automated Systems in Pharmaceutical Manufacture, released in February 2008.
Good Clinical Practice	GCP	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible, accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Good Manufacturing Practice	GMP	The manufacturing guidelines recommended by the relevant agencies.
Globally Unique Identifier	GUID	A unique key containing numbers and letters that identifies the study.
<b><u>H</u></b>		
Health Insurance Portability and Accountability Act	HIPAA	A Privacy Rule that is the first comprehensive Federal protection for the privacy of personal health information. Research organizations and researchers may or may not be covered by the HIPAA Privacy Rule.
Hyper Text Markup Language	HTML	The standard markup language for documents designed to be displayed in a web browser.
<b><u>I</u></b>		
Identity Provider	IdP	A system entity that creates, maintains, and manages identity information.

Term	Abbreviation	Definition
Independent Ethics Committee	IEC	An institutional review board (IRB).
Input factors		When used in randomization: Prognostic factors that might influence the effect of treatment on the subjects.
Institutional Review Board	IRB	Committee(s) made up of experts and community representatives who review and approve clinical trials to make certain that they fulfill stringent ethical standards to protect subjects' rights as participants in an experiment.
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	ICH	An initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration.
International Organization for Standardization	ISO	An organization promoting worldwide proprietary, industrial, and commercial standards.
Investigational Medicinal Product	IMP	A medicine for research.
Investigational Product	IP	A preventative (vaccine), a therapeutic (drug or biologic), device, diagnostic, or palliative used in a clinical trial. Also abbreviated IMP (Investigational Medicinal Product) and IMD (Investigational Medical Device).
Investigator Site File	ISF	The minimum list of essential documents that a study site needs to maintain throughout a clinical trial. Included documents could be Clinical Study Protocol, Investigator Brochure, Informed Consent, CVs etc.
Iyakuhinmei Data File	IDF	A medical coding dictionary used for coding clinical and drug safety data and for reporting safety data to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).
<a href="#">J</a>		
Japanese Pharmaceuticals and Medical Devices Agency	PMDA	PMDA (Pharmaceuticals and Medical Devices Agency) is a Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare. Their obligation is to protect the public health by assuring safety, efficacy and quality of pharmaceuticals and medical devices.
JavaScript	JS	A scripting language, primarily used on the web. It is used to enhance HTML pages and is commonly found embedded in HTML code. Viedoc is using JS to define advanced edit checks, expressions, and comparisons.
<a href="#">K</a>		
Key Risk Indicator	KRI	In Viedoc Reports, the Key Risk Indicators are the measurement of unfavorable events that can adversely impact a study, and are measured by site.
<a href="#">L</a>		
Linking form		A linking form is a form that contains a link to refer to another form. There can be one or more instances of the linked form.
Linked form		A linked form is a form that is linked to from another form (a linking form).
<a href="#">M</a>		



Term	Abbreviation	Definition
Medical coding		The process of translating reported events like Adverse Events, Medical History and Concomitant Medications in a universal code according to a medical coding dictionary.
Medical Dictionary for Regulatory Activities	MedDRA	A medical coding dictionary developed by the Maintenance and Support Services Organization (MSSO). MedDRA is supported by ICH.
<b><u>N</u></b>		
National Medical Products Administration	NMPA	The Chinese agency for regulating drugs and medical devices.
<b><u>O</u></b>		
Object Identifier	OID	An identifier mechanism for naming any object, concept, or "thing" with a globally unambiguous persistent name.
Operational Data Model	ODM	A standard for electronic clinical data as defined by CDISC. The highlights of ODM include audit trail, utilization of XML technology, and machine-readable and human-readable data. All information is independent of databases, and storage of ODM is independent of hardware and software.
Output factors		When used in randomization: the result after a patient has been randomized, that is, the treatment group or kit number (in case of a blinded output) that the patient is assigned to.
<b><u>P</u></b>		
Patient Reported Outcome	PRO	A health outcome directly reported by the patient who experienced it.
Portable Document Format Archive	PDF/A	An ISO-standardized version of the PDF specialized for use in the archiving and long-term preservation of electronic documents.
Post Marketing Surveillance	PMS	The practice of monitoring the safety of a pharmaceutical drug or device after it has been released on the market and an important part of the science of pharmacovigilance. Viedoc PMS is Viedoc's electronic data capture solution developed especially for post-marketing surveillance studies.
<b><u>Q</u></b>		
Quality Control	QC	The operational technique and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial are met.
<b><u>R</u></b>		
Randomization		A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the difference among groups by equally distributing people with particular characteristics among all the trial arms.
Randomization and Trial Supply Management	RTSM	A system that unifies the randomization, allocation, and supply management in a clinical trial.
Representational State Transfer	REST	A REST API (also known as RESTful API) is an application programming interface (API or web API) that conforms to the constraints of REST architectural style and allows for interaction with RESTful web services.

Term	Abbreviation	Definition
<b>S</b>		
Scheduled event		Events to the clinic by the patient that are defined in the study protocol. The events can also be subject-initiated through Viedoc Me, the ePRO application.
Study Data Tabulation Module	SDTM	A CDISC standard for how to structure raw data for a submission.
Security Assertion Markup Language	SAML	An open XML-based standard for exchanging authentication and authorization identities between security domains.
Security Token Service	STS	An open standard web service for issuing, validating, renewing, and cancelling security tokens for use with, for example, an API.
Single Sign-On	SSO	An authentication process that allows a user to access multiple applications with one set of login credentials.
Site		A clinic or other medical institute visited by subjects and where their data are recorded.
Site Manager	SIM	A user role in Viedoc Admin that can edit the details of their respective sites and invite site users to their sites.
Software As A Service	SaaS	Also known as web-based software, on-demand software, cloud software, and hosted software. Typically accessed by users via a web browser.
Standard Operating Procedure	SOP	Detailed, written instructions to achieve uniformity of the performance of a specific function.
Source Data		The original data when first recorded.
Source Data Verification	SDV	The process by which data within the CRF is compared to the original source of information (and vice versa).
Source Documentation		All original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in the source documents.
Sponsor		Any organization that provides the institutional base for clinical trial researchers. This includes commercial groups: pharmaceutical companies, non-profit organizations, universities, and medical centers.
Statistical Analysis System	SAS	A format used for statistical analysis in the SAS software suite.
Study crew		Viedoc users and all staff involved in the clinical trial. In most cases, these terms refer to users of Viedoc Clinic (see also Clinic role).
Study design		The design of the study that covers all the details about how the study is supposed to be performed, such as treatment details, medical examinations and other data to be collected, the workflow, and the Viedoc permissions of the different clinic roles that contribute to the study. The study design is set up in accordance with the clinical trial protocol.

Term	Abbreviation	Definition
Study Manager	STM	A user role in Viedoc that has permission to manage the administration of the study in Viedoc Admin. The study manager invites the study crew, adds sites, and applies study designs to sites. This user role is usually assigned to the project manager of the clinical trial.
Subject		A person participating in the clinical trial. Also referred to as patient.
System roles		User roles in Viedoc that are defined by the system and give access to Viedoc Admin and/or Viedoc Designer. Examples are: Study Manager, Site Manager, Designer, Dictionary Manager, Unblinded Statistician.
<u>T</u>		
Transport Layer Security	TLS	Protocols designed to provide communications security over a computer network.
Trial Master File	TMF	A type of content management system for the pharmaceutical industry, providing a formalized means of organizing and storing documents, images, and other digital content for clinical trials that may be required for compliance with government regulatory agencies.
<u>U</u>		
Unblinded statistician		A user role in Viedoc that manages the randomization and kit allocation lists in Viedoc Admin.
Unscheduled event		Additional events to the clinic by the patient that are not pre-defined in the study protocol.
<u>V</u>		
Viedoc Inspection Readiness Packet	VIRP	A file that can be downloaded in Viedoc, containing all the information needed to fulfill regulatory expectations.
<u>W</u>		
World Health Organization Drug Dictionary	WHO DD	A dictionary maintained and updated by Uppsala Monitoring Centre.
<u>X</u>		
<u>Y</u>		
<u>Z</u>		



How to prepare for a regulatory inspection

# How to prepare for a regulatory inspection

Published by Viedoc System 2023-04-25

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## 1 Introduction

It is important to be fully prepared for an inspection of relevant documentation about the EDC system used in a clinical trial. If the correct documentation is available for review by the regulatory authorities and certain validations have been performed, inspectors can then assess the systems used when collecting subject data in clinical trials.

There are also specific expectations that sponsors must comply with, depending on the regulatory body, EMA GCP Inspectors Working Group, ([EMA GCP IWG](#)) Food and Drug Administration ([FDA](#)) and the Japanese Pharmaceuticals and Medical Devices Agency ([PMDA](#)) even though these are similar in that they all expect the sponsor to have a complete understanding of the system. They also expect that the sponsor (or Contract Research Organization ([CRO](#)), if delegated) fully understands the functionality of the EDC system being used and can demonstrate this understanding and explain how the system has been validated.

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## 2 Viedoc Inspection Readiness Packet

To assist in preparing for inspections, Viedoc has developed the Viedoc Inspection Readiness Packet ([VIRP](#)) which provides you with the information you need in order to fulfil regulatory expectations and requirements.

The VIRP is available for every release of Viedoc. The VIRP introduction describes the contents of VIRP in more detail, and also talks about additional documentation you should provide. The VIRP introduction is included in VIRP.

### 2.1 Documents included in VIRP:

- User Requirements Specification describing the epics<sup>1</sup> and features<sup>1</sup> and listing the user stories<sup>1</sup> included in the release.
- Traceability Matrix detailing the testing performed for every requirement in the URS.
- Validation Summary Report describing the validation activities performed for this release, and their result.
- Release Notes describing the additions to Viedoc in the release.

- Release Certificate verifying that we have followed our documented procedures during the implementation and associated activities for the release.
- EDC Management Sheet for submissions to the PMDA.
- Acknowledgement Form describing what you need to review and containing space for your signature as evidence that you have completed your review. You can use this form with every new release of Viedoc to document that you do not need to revalidate the study setup. That is, that nothing in the new release affected your study setup. The signed form should be stored as part of the study record in the sponsor (e)TMF and can be shown to the inspector, and it minimizes the risk of a finding in the audit.
- Table of Contents of applicable SOPs used by Viedoc Technologies in the production of this release.
- An introduction, describing the contents of the Viedoc Inspection Readiness Packet (VIRP)

## 2.2 Other resources

- eLearning: Viedoc also provides an eLearning lesson - [Inspection Readiness when Working in Viedoc](#), which describes in detail the information needed step-by-step, as well as having additional information about potential pitfalls, what happens when new functionality is introduced in a release, about backward compatibility and more.
- The Viedoc Release Binder. We also store a snapshot of the information in our development environment for each release. This information is included in the Release Binder for that release which is stored in SharePoint and can be shared with inspectors either in a webinar or onsite.

# 3 Areas of responsibility

When it comes to preparing for regulatory inspections, there are different areas of responsibility for the Sponsor/CRO and Viedoc.

## 3.1 Viedoc responsibility

The Sponsor/CRO should be able to rely on Viedoc standard qualification documentation as there are no sponsor or study-specific software modifications made to the standard product. The configuration of Viedoc for use in a study is done using only functionality that has been validated before being released to the study.

Each new Viedoc version is fully validated before release - which takes place every 6-8 weeks. These releases are installed on all production servers at the same time, meaning all customers and all studies are updated at the same time. Furthermore, we ensure that ongoing studies are not affected by fulfilling the following two requirements:

- The new release must be 100% backward compatible.
- Any new functionality in the release shall be disabled for ongoing studies by default.

## 3.2 Sponsor/CRO responsibility

Some areas and activities, however, remain the responsibility of the sponsor/CRO and should be documented:

- It is a Sponsor/CRO responsibility to validate the study configuration and confirm that the study has been set up in accordance with the study protocol. This validation should be documented.
- The different versions of systems used during the study and a synopsis of the differences between the versions should be stored as part of the study record in the sponsor (e)TMF.
- A risk-based assessment documenting the decision to rely on VIRP should be carried out.
- A checklist of the required functions (such as randomization module, patient ePRO module, coding module) for your trial on our epic<sup>1</sup> level, and where necessary, individual features<sup>1</sup>.

# 4 What to do on the day of inspection

When the inspector visits, they must have access to Viedoc. Regulatory inspectors have the legal right to view all data in the study – even patient data and hidden (anonymized) items in the audit trail. The study manager should invite the inspector to the Viedoc user role Regulatory Inspector when they arrive.

Follow these steps to ensure that the inspector has all the correct access permissions in Viedoc:

## 4.1 Viedoc Designer

This step is performed by the **Designer**.

In Viedoc Designer, on the **Roles** page, configure the Regulatory Inspector user role and make sure it is turned on.

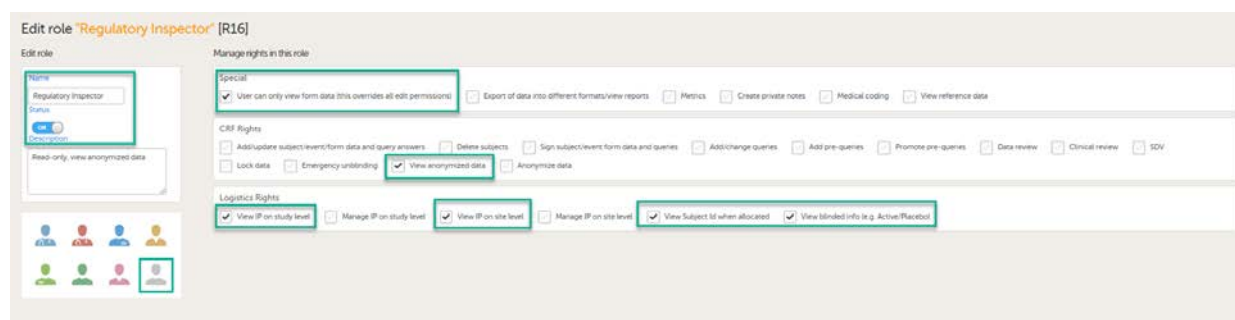
To allow the Regulatory Inspector access to study data, their role must be configured with Read-only for form data and View anonymized data and blinded data permissions on the **Roles** page.

## 4.2 Viedoc Logistics

If the study uses Viedoc Logistics, the following role permissions in Logistics Rights for the Regulatory Inspector role must be configured on the **Roles** page:

- View IP ([Investigational Product](#)) on study level,
- View IP on site level
- View subject ID when allocated
- View blinded info (e.g. Active/Placebo).

See the image below and [Configuring roles](#).



**Note!** Should the inspector also require access to Viedoc Admin or Viedoc Designer, and the study is managed by a Viedoc representative, you are always welcome to contact your Viedoc representative if you need assistance.

## 4.3 Viedoc Admin

These steps are performed by the **Study manager**.

In Viedoc Admin, the study manager invites the Regulatory Inspector to the study for all sites. See [Managing users](#).

- The inspector should also be invited to the study with the role of Unblinded Statistician, in order to have access to the randomization lists and be able to download them in Viedoc Admin.











**Note!** This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.

- The inspector should also be able to access the eLearning. There is a requirement for customers to be able to present to regulatory inspectors, on request, the version of the eLearning used to train staff during the course of the study.

The Documentation tab under Study settings provides a list of all documentation and training sections.

## Study settings


Here you can set settings for study.

Settings	Date & time format	Medical Coding	Import ODM File	Documentation
<b>7 active - 0 archived sections</b>				+ Add a new section
Section	Target sites	Mandatory for	Optional for	
 Study Protocol	All sites	All roles		
 CRF Completion Guidelines	All sites	Monitor	Investigator	
 Viedoc User Guide for Site Users	Demo Site		Investigator	
 Viedoc User Guide for Monitors	Demo Site		Monitor	
 Viedoc User Guide for Data Managers	Demo Site		Data Manager	

The Regulatory Inspector role should be granted access to the relevant eLearning documentation on the Study settings page.

## Edit 'Viedoc User Guide for Site Users'

Manage training section settings here

 <https://help.viedoc.net/c/94d6f0>  
Section last modified 2021-12-09T15:44:21 by

Archive

Section URL or file

Section title

Priority

/ 6

Description

Target sites

Require signing for following roles

Require re-signing after # of days

Optional for following roles

See the Viedoc Admin User Guide [Setting up user documentation and training](#)

## 4.4 Viedoc eTMF

If the study uses Viedoc eTMF, the study manager/eTMF manager should map the Regulatory Inspector study role to an eTMF role with at least the following permissions: Read-only TMF Admin, Read-only Trial Master File and Download audit trail.

**eTMF**  
Manage your eTMF application.

**Study eTMF**  
✓ Study eTMF license is valid

Enable **ON**

Launch study eTMF

**eTMF roles mapping**  
Map each Study role to one or more eTMF roles and permissions, if applicable.

Study role	eTMF roles and permissions
Investigator	Site staff x Sponsor study x Sponsor country x Sponsor site x Reviewer x Archive sponsor TMF x Archive investigator TMF x Download audit trail x Manage drop zone x
Monitor	
Project Manager	
Regulatory Inspector	Read-only TMF Admin x Read-only Trial Master File x Download audit trail x
Site Reviewer	

See Viedoc User Guide for eTMF Managers - [Managing Viedoc eTMF](#) - Mapping user roles.

## 4.5 Viedoc Clinic

These steps are performed by the Regulatory Inspector.

The regulatory inspector accepts the invitation and activates their account - see [Viedoc User Guide for Site Users: Managing your Viedoc account](#)

The inspector can now launch Viedoc Clinic and the Viedoc eTMF from the [landing page](#).

## 5 Footnotes

<sup>1</sup>At Viedoc, we publish our User Requirements Specification in an easy-to-understand format made up of epics, features, and user stories.

- Epics describe an overall module within Viedoc, such as audit trail, ePRO, and medical coding.
- Features describe a given functionality in more detail, such as Viedoc Connect, form link items, and email alerts.
- User stories are the detailed, broken-down requirements used by the system developers when designing, implementing, and validating Viedoc.





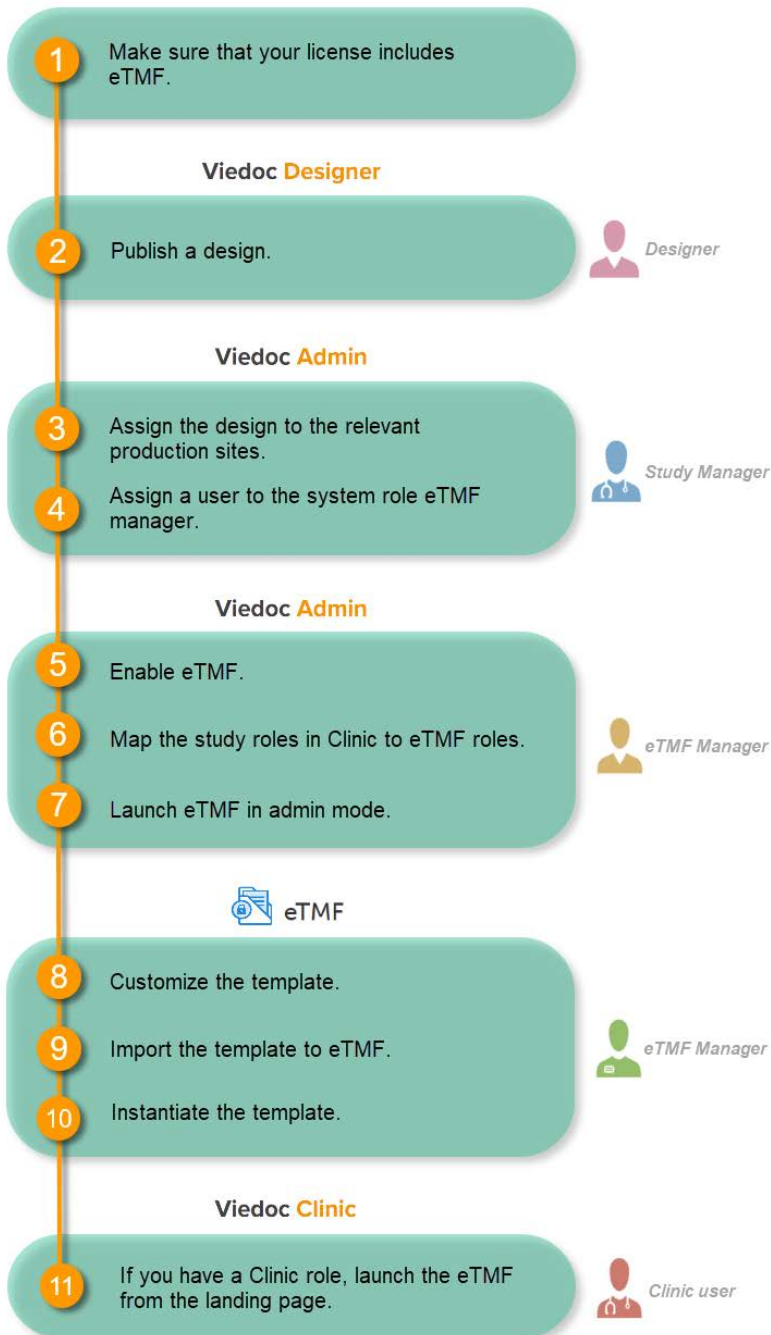
Quick guide for setting up Viedoc eTMF

# Quick guide for setting up Viedoc eTMF

Published by Viedoc System 2023-04-25

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- [1. Get a license](#)
- [2. Publish a design](#)
- [3. Assign the design to production sites](#)
- [4. Invite an eTMF Manager](#)
- [5. Enable eTMF](#)
- [6. Map study roles to eTMF roles and permissions](#)
- [7. Launch eTMF in admin mode](#)
- [8. Customize the template](#)
  - [8.1 Baseline template](#)
  - [8.2 Existing templates](#)
- [9. Import the template](#)
- [10. Instantiate the template](#)
- [11. Launch eTMF in production mode](#)



## 1 Get a license

Make sure you have a valid license for using Viedoc eTMF.

## 2 Publish a design

This step is performed by the **Designer**.

**Note!** To publish the CRF design, you only need to have the roles configured and enabled, and a form added to the start event in your workflow (the form can be without any items at this stage). The actual CRF design can be added in subsequent versions.

See [Publishing a study design](#).

### 3 Assign the design to production sites

This step is performed by the **Study Manager**.

See [Assigning a study design](#).

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### 4 Invite an eTMF Manager

This step is performed by the **Study Manager**.

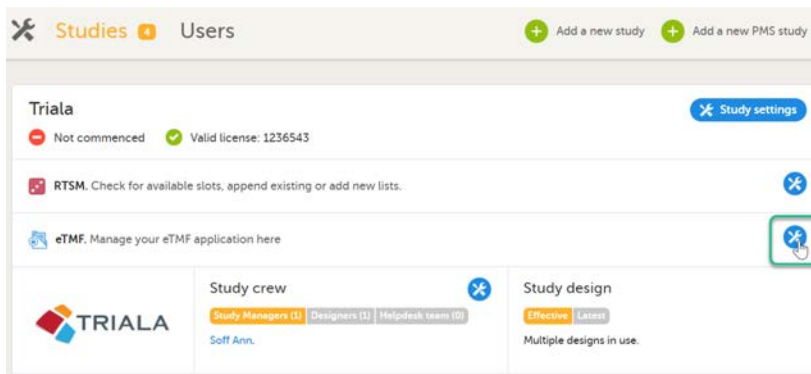
See [Managing users](#).

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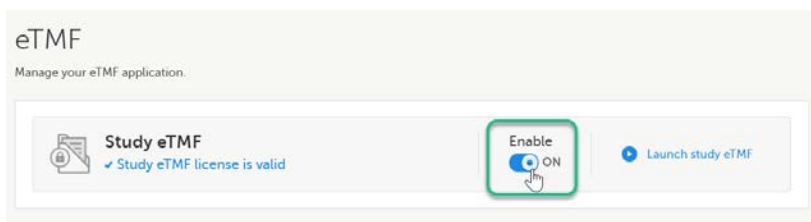
### 5 Enable eTMF

This step is performed by the **eTMF Manager**.

- 1 In the study details page, click the tools symbol in the **eTMF** area:



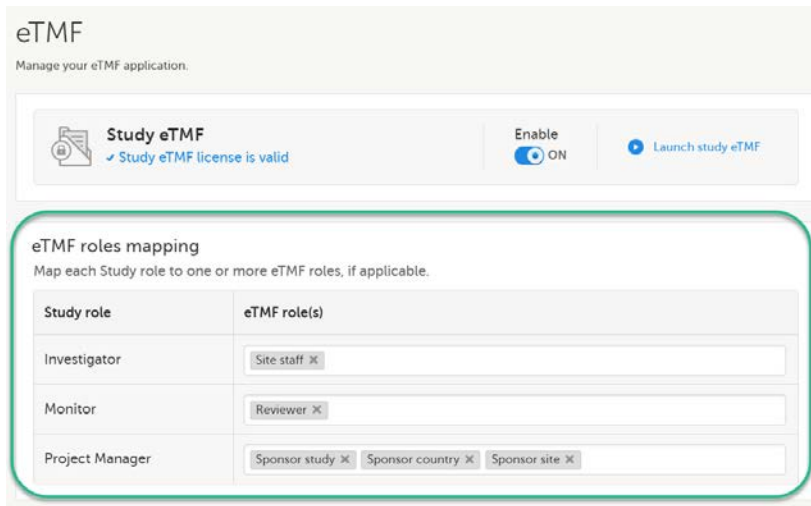
- 2 Toggle the **Enable** switch to **ON** in the eTMF settings dialog:



### 6 Map study roles to eTMF roles and permissions

This step is performed by the **eTMF Manager**.

- 1 In the **eTMF roles mapping** area, select the eTMF roles and permissions that you want to map to the Viedoc study roles:

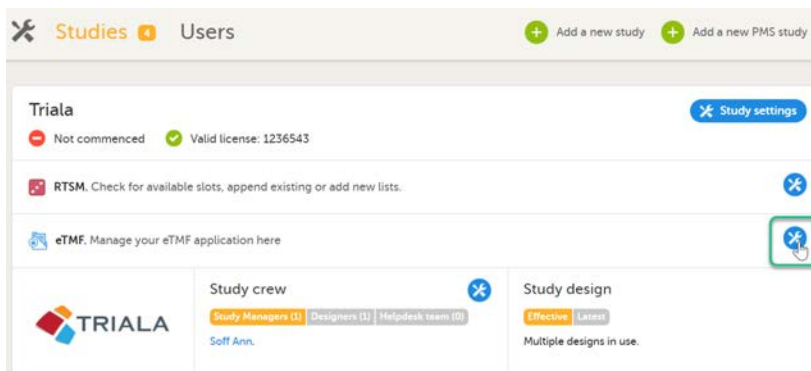


- 2 Select **Save changes**.

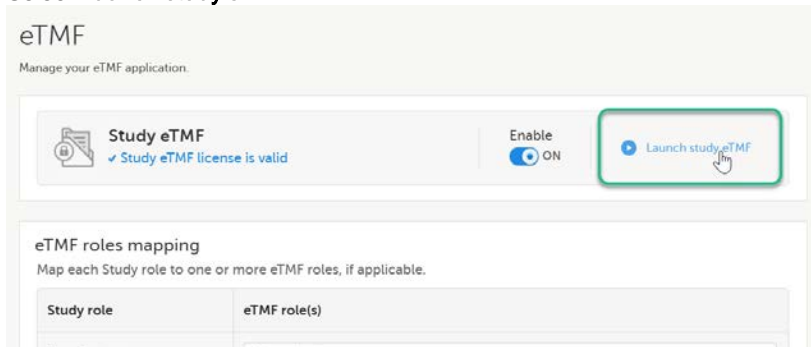
## 7 Launch eTMF in admin mode

This step is performed by the **eTMF Manager**.

- 1 On the study details page, select the tools symbol in the **eTMF** area:



- 2 Select **Launch study eTMF**:



## 8 Customize the template

This step is performed by the **eTMF Manager**.

## 8.1 Baseline template

The first time you set up your eTMF application, you begin with a baseline template provided by Viedoc. This template is not intended to be used as it is, but to be adapted to the needs of your organization. See [Viedoc-provided templates](#) to download the template.

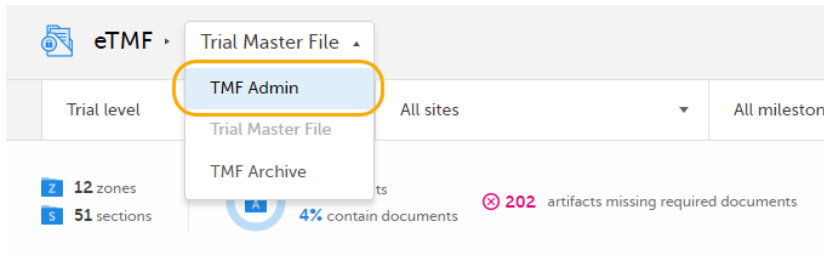
Once customized, import the template to eTMF, see [Import the template](#).

## 8.2 Existing templates

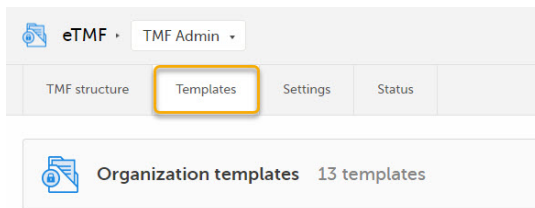
Imported templates can be customized to fit your study needs.

To export a template for customization:

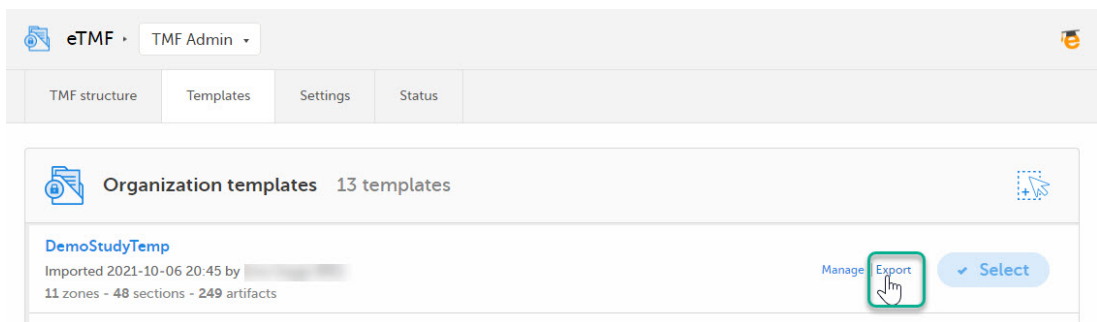
- 1 In Viedoc eTMF, select the **TMF Admin** view:



- 2 Select the **Templates** tab:



- 3 Select **Export** for the template you want to customize. The template is downloaded in Excel format.



There are two types of templates:

- **Organization template** - available for all studies within your organization
- **Study template** - available only for the specific study

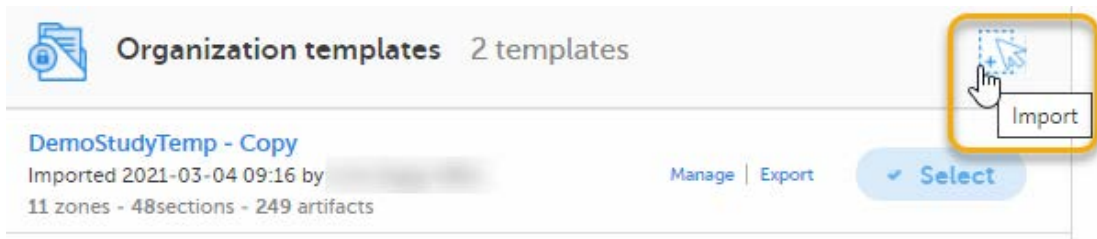
It is recommended that you adapt the eTMF template to your specific documentation landscape. For example, you can customize, add, or delete zones, sections, and artifacts.

See also [Customizing a template](#).

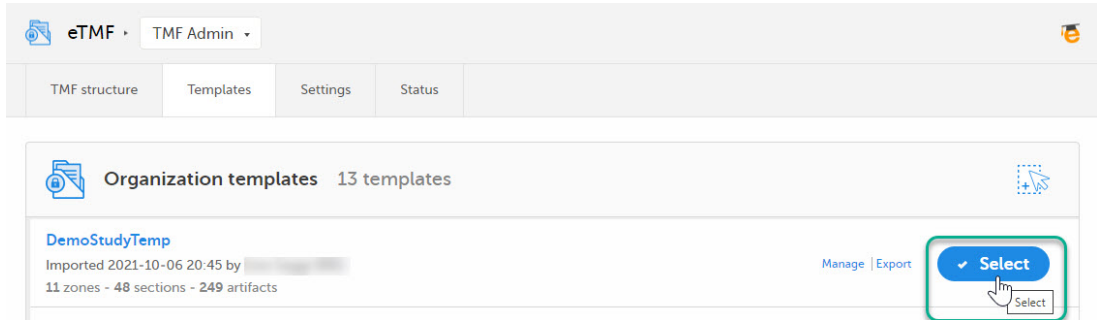
## 9 Import the template

This step is performed by the **eTMF Manager**.

- 1 Select **Import** in Organization templates or Study templates, depending on what type of template you're importing.



- 2 Once imported, select your template to make it available in the **TMF structure**.



## 10 Instantiate the template

This step is performed by the **eTMF Manager**.

On the **TMF structure** tab, select the **Instantiate** button for the template.

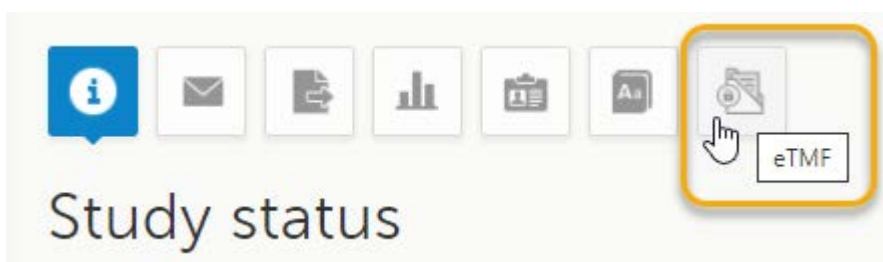


The template is now applied to the trial and the eTMF structure is available for end users to work with.

## 11 Launch eTMF in production mode

This step is performed by a **Clinic user** with a mapped eTMF role.

Select the **eTMF** icon on the Viedoc landing page:



The eTMF application opens.

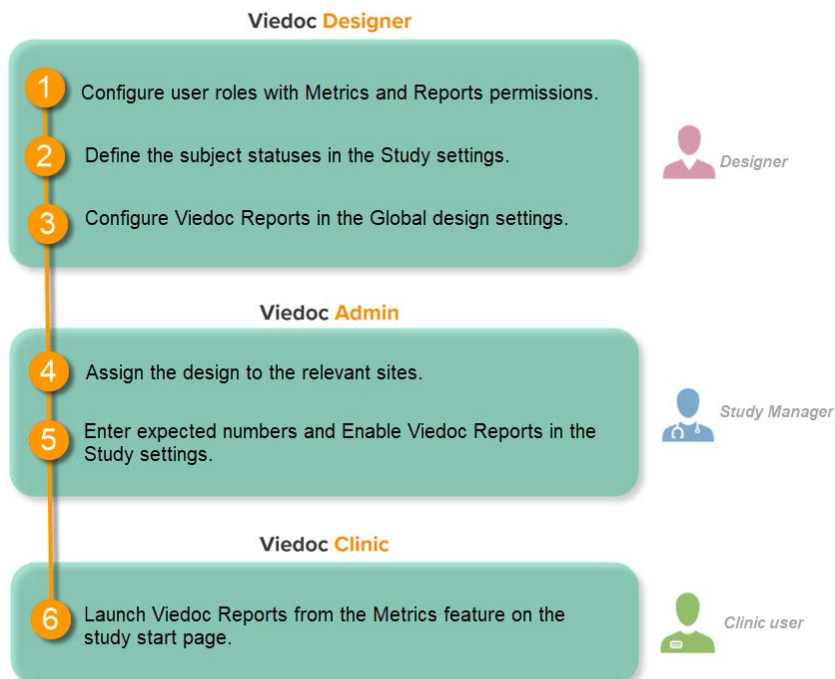


Quick guide for setting up Viedoc Reports

# Quick guide for setting up Viedoc Reports

Published by Viedoc System 2023-04-25

- [1. Configure the roles](#)
- [2. Define the subject statuses](#)
- [3. Configure Viedoc Reports](#)
- [4. Assign the design to sites](#)
- [5. Enter the expected numbers and enable Viedoc Reports](#)
- [6. Launch Viedoc Reports](#)



## 1 Configure the roles

This step is performed by the **Designer**.

To let Clinic users use Viedoc Reports, their roles must be configured with Metrics and Reports permissions in the Roles page. The Reports option becomes visible when selecting Metrics.

**Edit role "Investigator" [RG5515]**

**Edit role**

Name: Investigator Status: ON

Description: Save, sign, reset, delete and export data, resolve queries

**Manage rights in this role**

**Special**

User can only view form data (this overrides all edit permissions)  Export of data into different formats/view reports  Metrics  Reports

Create private notes  Medical coding  View reference data

**CRF Rights**

Add/update subject/event/form data and query answers  Reset/Delete events and forms  Delete subjects  Sign subject/event form data and queries

Add/change queries  Add pre-queries  Promote pre-queries  Data review  Clinical review  SDV  Lock data

Emergency unblinding  View anonymized data  Anonymize data

**Logistics Rights**

View IP on study level  View IP on site level  View Subject Id when allocated  View blinded info (e.g. Active/Placebo)

To be able to download report files, the user also needs the permission **Export of data into different formats/view reports**.

**Edit role "Investigator" [RG5515]**

**Edit role**

Name: Investigator Status: ON

Description: Save, sign, reset, delete and export

**Manage rights in this role**

**Special**

User can only view form data (this overrides all edit permissions)  Export of data into different formats/view reports

Create private notes  Medical coding  View reference data

**Note!** The export is allowed only if the export permission is applicable to all the assigned sites.

See [Configuring roles](#).

## 2 Define the subject statuses

This step is performed by the **Designer**.

Set an expression for how and when a subject is considered both screened and enrolled in the study.

See [Subject status](#).

## 3 Configure Viedoc Reports

This step is performed by the **Designer**.

1 In Viedoc Designer, select the study for which you would like to configure Viedoc Reports.

2 In the Global design settings field, click **Edit**.

**Viedoc's demostudy**  
 ✓ Assigned 03 Feb 2017 by Technical Writer, Viedoc Lab.

**1 Designers**  
 Technical Writer [email@viedoc.com]

**Latest edited design**

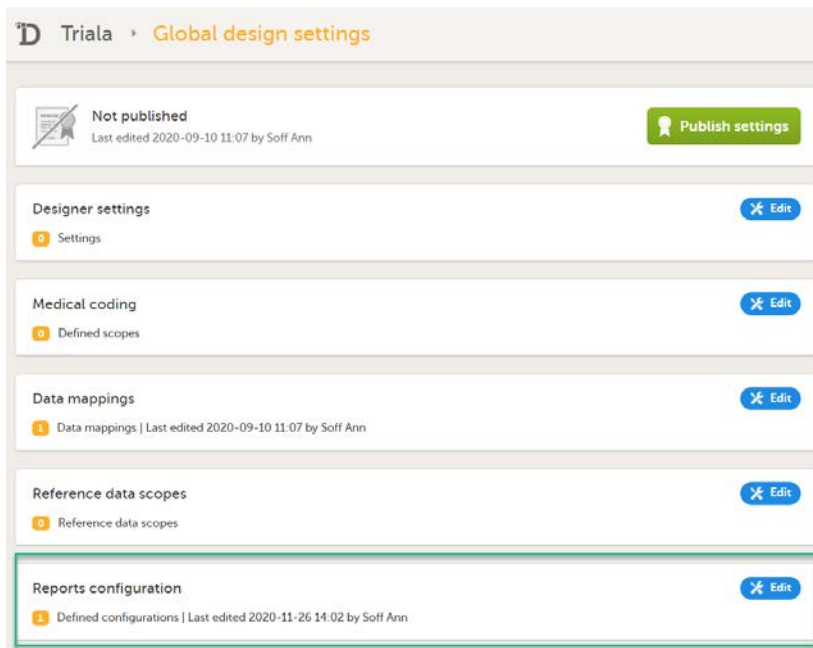
Global design settings  
 ✓ Published 12 Feb 2018 13:02 by Technical Writer | ✓ Effective **Edit**

DemoStudyDesign [3.0]  
 Published **View**  
 Last edited 23 Jan 2018 13:58 by Technical Writer

Design versions 2 Published 1 Unpublished **Show all**



- 3 In the Reports configuration field, click **Edit**.

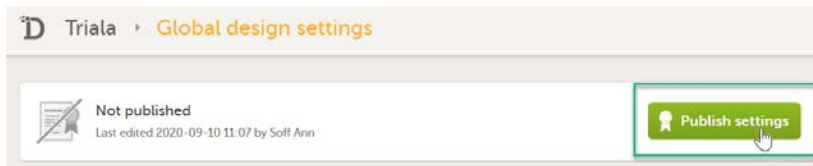


- 4 You can now configure the settings by clicking **Edit** in one of the fields: Visibility settings, Dashboard, Demographics, Adverse events, and Custom reports. See [Configuring Viedoc Reports](#) for details.



After editing and saving any changes, the **Not in use** status changes to **In use**.

- 5 Publish your global design settings.



- 6 Publish your design. See [Publishing a study design](#).

## 4 Assign the design to sites

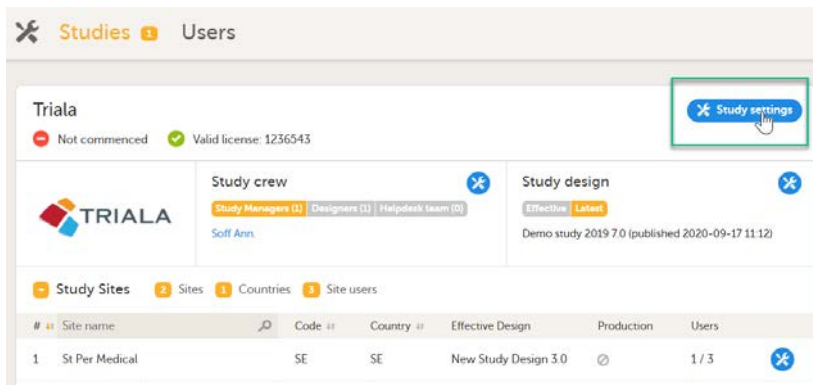
This step is performed by the **Study Manager**.

See [Assigning a study design](#).

## 5 Enter the expected numbers and enable Viedoc Reports

This step is performed by the **Study Manager**.

- 1 Click **Study settings** for the study in which you want to set up Viedoc Reports.



- 2 In the **Study settings** pop-up window, enter the total number of expected **screened** and **enrolled** subjects and the expected **end date** of the enrollment period.

The screenshot shows a form with two main sections. The first section is 'Expected number of subjects', with 'Screened' set to 100 and 'Enrolled' set to 80. The second section is 'Expected end date of enrollment period', with a date picker set to 31 Oct 2021.

**Note!** This data must be entered on both study level and for each individual site.

- 3 Scroll down to and click **Show more options**.

The screenshot shows the 'Study settings' pop-up window. The 'Show more options' button at the bottom is highlighted with a red box. The window contains several sections: 'Expected number of subjects' (Screened: 100, Enrolled: empty), 'Expected end date of enrollment period' (dd MMM yyyy), 'Study access' (Password expiration time: 90 days, Require two-factor authentication: unchecked), 'Clinic roles to be administered by Site Manager' (Investigator, Study Supply Manager, Site Supply Manager: all unchecked), 'Helpdesk team' (PCG Helpdesk, Britanica Helpdesk, MWA Helpdesk: all unchecked), and 'ViedocMe' (Allow reminders: Email, Text message; Force subject to change password: unchecked).

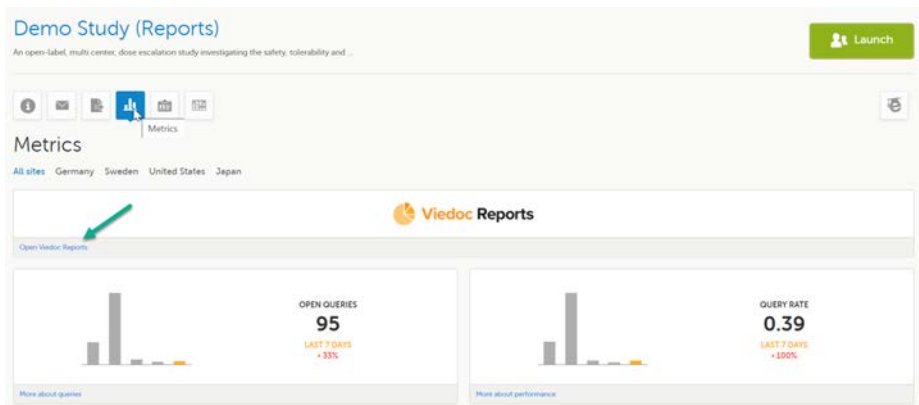
- 4 Select **Enable Viedoc Reports** and click **Save changes**.

The screenshot shows the 'Study settings' pop-up window. The 'Enable Viedoc Reports' checkbox at the bottom is checked and highlighted with a red box. The 'Save changes' button is visible at the top right. The window also shows the 'eLearning' section with fields for 'eLearning title' and 'eLearning URL'.

## 6 Launch Viedoc Reports

This step is performed by the **Clinic user**.

Launch Viedoc Reports from the Metrics feature on the study start page.



The screenshot displays the 'Demo Study (Reports)' interface. At the top, there is a 'Launch' button. Below it, a navigation bar includes 'Metrics' and a sub-menu. The 'Metrics' section shows a list of sites: 'All sites', 'Germany', 'Sweden', 'United States', and 'Japan'. A green arrow points to the 'Open Viedoc Reports' link. The main content area features two performance metrics: 'OPEN QUERIES' with a value of 95 (LAST 7 DAYS +33%) and 'QUERY RATE' with a value of 0.39 (LAST 7 DAYS +100%).

See [Launching Viedoc Reports](#).



Quick guide for preparing for regulatory inspections

# Quick guide for preparing for regulatory inspections

Published by Viedoc System 2023-04-25

- [1. Configure the role](#)
- [2. Configure Logistics permissions if used](#)
- [3. Invite a Regulatory Inspector](#)
- [4. Map eTMF permissions if used](#)
- [5. Launch Viedoc](#)

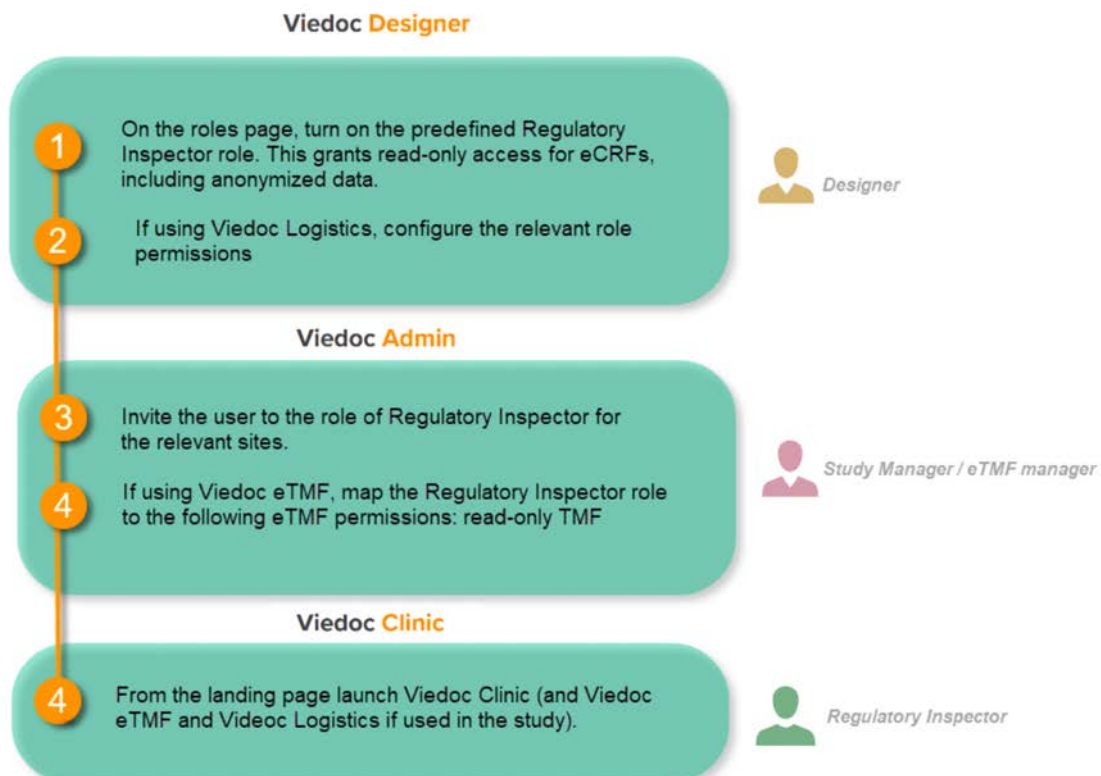
Thorough preparation for inspection of the EDC system used in a clinical trial is of great importance. The regulatory authorities see the EDC system used for a clinical trial as an important computerized system with regards to both patient safety and data integrity.

To assist in this process, Viedoc has developed the Viedoc Inspection Readiness Packet ([VIRP](#)) which provides you with the information you need to prepare for a regulatory inspection and to fulfil regulatory expectations and requirements. The VIRP introduction describes the contents of VIRP in more detail, and also talks about additional documentation you should provide. The VIRP introduction is included in VIRP.

If you decide to use VIRP we provide an eLearning lesson which describes the information needed step-by-step in order to fulfil inspector expectations: [Inspection Readiness When Working in Viedoc](#)

You can read about how to download the Viedoc Inspection Readiness Packet here: [VIRP](#)

You will need to give full read-only access and invite the inspector to the Regulatory Inspector role in the Viedoc system as described below.



## 1 Configure the role

This step is performed by the **Designer**.

To allow the Regulatory Inspector viewing access to study data, their role must be configured with read-only and view anonymized and blinded data permissions on the **Roles** page.

### Note!

- The role of Regulatory Inspector must be turned on in Designer.
- By default, a set of predefined roles is set up by the system, and can be modified for your study. Permissions for the role of Regulatory Inspector should be set to **READ-ONLY** access to all parts of the system, including the eTMF (if it is used) and the eLearning.

## 2 Configure Logistics permissions if used

If the study uses Viedoc Logistics, the following role permissions in Logistics Rights for the Regulatory Inspector role must be configured on the **Roles** page:

- View IP ([Investigational Product](#)) on study level,
- View IP on site level
- View subject ID when allocated
- View blinded info (e.g. Active/Placebo).

See [Configuring roles](#).

Edit role "Regulatory Inspector" [R16]

Edit role

Regulatory Inspector

Status

Read-only, view anonymized data

Manage rights in this role

Special

User can only view form data (this overrides all edit permissions)  Export of data into different formats/view reports  Metrics  Create private notes  Medical coding  View reference data

CRF Rights

Add/update subject/event/form data and query answers  Delete subjects  Sign subject/event form data and queries  Add/change queries  Add pre-queries  Promote pre-queries  Data review  Clinical review  SDV

Lock data  Emergency unblinding  View anonymized data  Anonymize data

Logistics Rights

View IP on study level  Manage IP on study level  View IP on site level  Manage IP on site level  View Subject ID when allocated  View blinded info (e.g. Active/Placebo)

**Note!** Should the inspector also require access to Viedoc Admin or Viedoc Designer, you are always welcome to contact your Viedoc representative if you need assistance.

## 3 Invite a Regulatory Inspector

This step is performed by the **Study Manager**.

**Note!** For randomized studies, the inspector should also be invited to the study with the role of Unblinded Statistician, in order to have access to the randomization lists and be able to download them in Viedoc Admin.

See [Managing users](#).

## 4 Map eTMF permissions if used

If the study is using the eTMF, map the Regulatory Inspector study role to an eTMF role with the permissions read-only, **TMF Admin**, read-only, **Trial Master File** and **Download audit trail**.

# eTMF

Manage your eTMF application.



## Study eTMF

✓ Study eTMF license is valid

Enable



Launch study eTMF

## eTMF roles mapping

Map each Study role to one or more eTMF roles and permissions, if applicable.

Study role	eTMF roles and permissions
Investigator	Site staff x Sponsor study x Sponsor country x Sponsor site x Reviewer x Archive sponsor TMF x Archive investigator TMF x Download audit trail x Manage drop zone x
Monitor	
Project Manager	
Regulatory Inspector	Read-only TMF Admin x Read-only Trial Master File x Download audit trail x
Site Reviewer	

This step is performed by the **Study Manager/eTMF Manager**.

## 5 Launch Viedoc

Launch Viedoc Clinic and Viedoc eTMF and Viedoc Logistics (if used in the study) from the [landing page](#).

This step is performed by the **Regulatory Inspector**.



Quick Guide for going live

## Quick guide for going live

Published by Viedoc System 2023-04-25

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- [1. Check your license](#)
- [2. Add a study to the production server](#)
- [3. Invite the Designer](#)
- [4. Import the study design](#)
- [5. Reconfigure design settings](#)
- [6. Re-import translations](#)
- [7. Validate and publish](#)
- [8. Reconfigure features](#)
- [9. Assign the study design](#)

When building a study in Viedoc, you are first given access to a training server, (for example, v4training.viedoc.net). This is so that you can use and evaluate Viedoc without the need for a contract or license. Studies that are to be taken into production are then migrated from the training server to the production server. For more information, see [Migrating a study design from training to production](#).

A study can be considered as **live** when there is a validated study design on a production site. The schematic below shows the steps that are needed, and which roles have permission to perform these steps.



## 1 Check your license

This step is performed by the **Organization Administrator**.

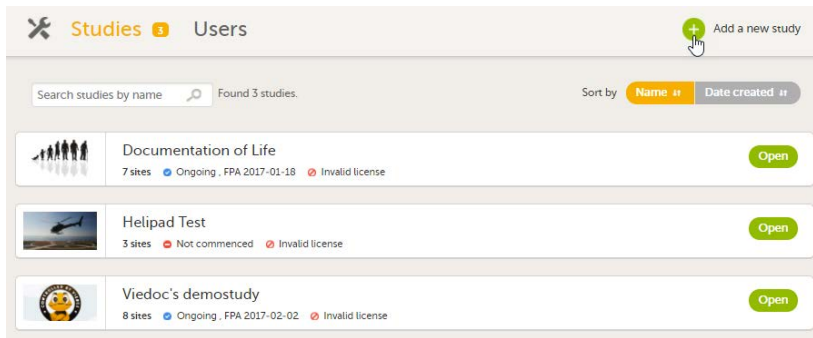
- Make sure you have a valid license: All production studies must have a valid license before they can be taken into production. The license is provided by a Viedoc representative. Every license is connected to a reference ID. The reference ID can be found on the signed study work order. For more information, see the section on licensing in [Overview of Viedoc](#)
- Make sure the license includes all of the features required for your study. These are listed in Viedoc Admin after the reference ID is entered.

## 2 Add a study to the production server

This step is performed by the **Organization Administrator**, after the study has been built and tested on the training server and the study design is exported.



- 1 On the production server, add a new study in Viedoc Admin. For more information, see [Adding a new study](#).



- 2 Assign the Study Manager role to yourself or anyone from the team. For more information, see [Managing users \(for Org Admin\)](#).

### 3 Invite the Designer

This step is performed by the **Study Manager**.

Invite a user to the Designer role. For more information, see [Managing users \(for Org Admin\)](#).

### 4 Import the study design

This step is performed by the **Designer**.

Import the study design [ODM](#) file (which was previously exported from the training server).

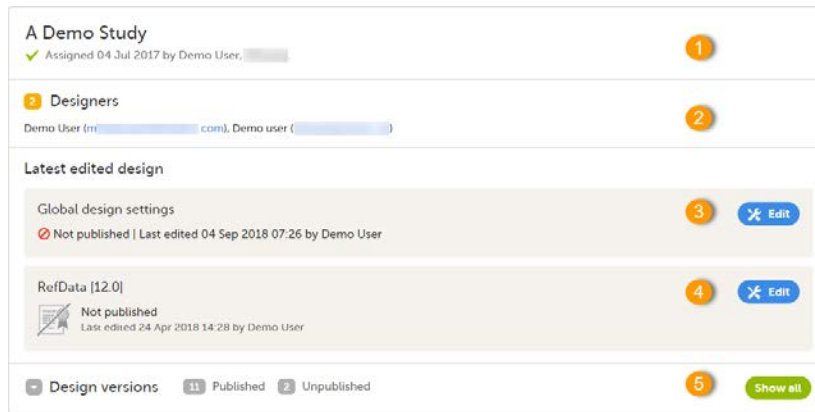


For further instructions, see [Importing a new design version](#).

### 5 Reconfigure design settings

This step is performed by the **Designer**.

- 1 Reconfigure, validate, and publish the global design settings (as these are not in the ODM file) in the same way as on the test environment. For more information, see [Overview of Viedoc Designer](#).



- 2 If used for the study, reconfigure Viedoc Reports. For more information, see [Quick Guide for setting up Viedoc Reports](#).

## 6 Re-import translations

If used for the study, import the Viedoc Me translations. For instructions, see [Managing translations for subject-initiated events](#).

## 7 Validate and publish

Validate and publish the design. For more information, see [Validating a study design](#).

**Note!** The study design becomes available to the Study Manager in Viedoc Admin when it has been published.

## 8 Reconfigure features

These steps are performed by the **Study Manager** and the **Study Designer**.

If the features listed below are used for the study, the Study Manager will need to manually reconfigure and save these features in Viedoc Admin:

- Randomization and Trial Supply Management ([RTSM](#)) and [global allocation list](#)
- Application Programming Interface ([API](#)) configuration.

If the features listed below are used for the study, the Study Designer will need to manually reconfigure and save these features in Viedoc Designer:

- Medical coding - for more information, see [Configuring medical coding scopes](#).
- Reference data - for more information, see [Configuring reference data scopes](#).

**Note!** To perform these reconfigurations, the user must be assigned to the relevant user roles. For example, Unblinded Statistician for the RTSM and global allocation list, Reference Source Data Manager for the reference data, Dictionary Manager to manage the medical coding dictionaries, and API Manager for the API configuration.

## 9 Assign the study design

This step is performed by the **Study Manager**.

Assign the study design to at least one or several *production sites* in the study, and select an effective starting time for that design to be applied to the site.

Once a study is on the **production server** it is possible to configure the *sites* to operate in one of the following modes:

- **training (demo) mode** only: does not require a license, and the data is saved on the demo/training instance only. This is to be used for the test sites only.
- **production mode** only: used for the *production site(s)*, that is, real sites where real data will be entered, not for testing purposes.
- both **training (demo)** and **production modes** (this is **not** recommended, see [Training\(Demo\) vs Production mode](#)).

Your study is now in production, and you can start work on the site.

**Important!** This process cannot be used for revising an existing design version on production, as importing the design will always result in a totally new version.  
For more information about new versions and revisions see: [handling eCRF updates after going live](#).



Organization Administrator introduction

# Organization Administrator introduction

Published by Viedoc System 2023-06-21

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[1. The hierarchy of Organization Administrator and Study Manager](#)

[2. Org Admin responsibilities](#)

[3. Customers and the Org Admin role](#)

[3.1 Control of organization](#)

[3.2 Limit data access](#)

[4. Org Admin appointment](#)

[4.1 High-level overview](#)

[4.2 Managing Org Admins](#)

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## 1 The hierarchy of Organization Administrator and Study Manager

Studies are grouped in Viedoc under organizations; that is, each client has its own organization where all studies belonging to that organization are stored. The System Administrator at Viedoc Technologies can add a new organization, and then also assign at least one **Organization Administrator** (Org Admin) to that organization. The Org Admin can then create studies and invite **Study Managers** to those studies within that organization.

---

## 2 Org Admin responsibilities

For the Org Admins, the organization overview is the first page that is shown upon accessing Viedoc Admin. As an Org Admin, you can:

- Add new studies - see eLearning lesson [here](#)
- Invite Study Managers - see eLearning lesson [here](#)
- Confirm deletion of studies - see eLearning lesson [here](#)
- Invite additional Org Admins - see eLearning lesson [here](#)
- Enable SSO (Single Sign-On) for your organization - see eLearning lesson [here](#)
- Access the Viedoc Inspection Readiness Packet (VIRP) - see eLearning lesson [here](#)

More information about Viedoc Admin can be found here: [Overview of Viedoc Admin](#)

It is the responsibility of the Org Admin to make sure that all users within the organization have received appropriate training for their respective tasks. More information about managing users for Org Admins can be found [here](#).

---

## 3 Customers and the Org Admin role

### 3.1 Control of organization

As the Org Admin has the authority (directly and indirectly) to manage access to studies in their organization, Viedoc recognizes the importance for the customer to be in sole control of their organization and data. No Viedoc employee will have Org Admin access to a customer's organization when there are live studies in the organization.

## 3.2 Limit data access

Users with access as Org Admin have the permission to invite themselves or other users as Study Manager to the studies within their organization. The Study Manager has the permission to invite users with different roles to the given study. Thus, the Org Admin has the authority (directly and indirectly) to manage access to studies in their organization. So by granting Org Admin access only to one or a few trusted users, you can limit the number of users and vendors that have access (directly or indirectly) to your data.

---

# 4 Org Admin appointment

## 4.1 High-level overview

Users with Org Admin access should preferably have a high-level overview within the company or organization, since the Org Admin can directly or indirectly access all studies within the organization as well as create new studies. This should be a user that is trusted and authorized to perform the activities as described in section 2.1. The role of this user might differ for different companies, but it could be the CEO, Director of Data Management, Lead Data Manager, Manager of Clinical Operations etc.

## 4.2 Managing Org Admins

Org Admins can delegate the responsibility by inviting additional Org Admins. By doing this, each organization can manage their own organization after having it set up by the Viedoc System Administrator and having the first Org Admin invited. Giving too many user Org Admin access is a security risk and we recommend that you try to have 2-4 Org Admins in your organization to have sufficient backup.

The System Administrator at Viedoc will only be allowed to invite customer users as Org Admins once this has been confirmed in writing by the legal representative (the person signing the Master Service Agreement).



Adding a new study

# Adding a new study

Published by Viedoc System 2020-06-04

- [1. Introduction](#)
- [2. Adding a study](#)
- [3. Continue setting up the study](#)
- [4. More information](#)

## 1 Introduction

This lesson provides instructions on how to add a new study. Adding a new study is done in Viedoc Admin. Only the Organization Administrator can add studies.

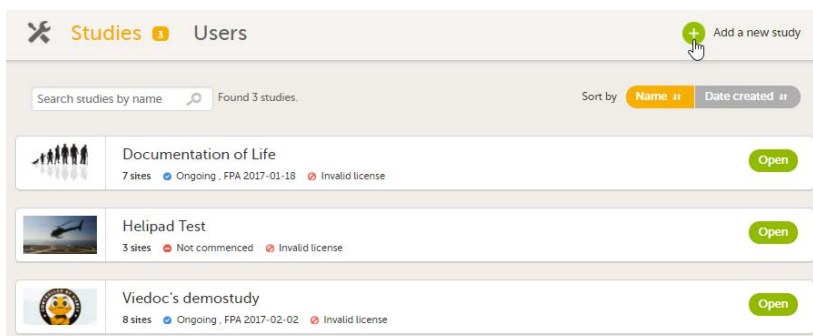
**Note!** For all production studies, make sure a contract with Viedoc Technologies exists before proceeding. See [Overview of Viedoc](#) for information about licensing.

## 2 Adding a study

**Note!** Adding a new study can only be done by the Organization Administrator.

To add a new study:

- 1 Open Viedoc Admin and click **Show studies** in the organization you would like to add a study to. The study overview page opens.
- 2 Click **Add a new study**.



The Add a new study pop-up opens.

- 3 Enter a name for the study, and the e-mail address to the person that will be appointed as Study Manager.

The screenshot shows the 'Add a new study' form in Viedoc Lab. The form is titled 'Add a new study' and includes a green header with 'Viedoc Lab' and 'Add study' and 'Close' buttons. The form is divided into several sections: 'Study name' with a text input field and a note 'This name is used everywhere.'; 'Study Manager (e-mail address)' with a text input field and a note 'Add at least one Study Manager! Use comma to separate multiple addresses.'; 'Sponsor Code' and 'CRO Code' with text input fields; 'Study Logo' with a placeholder image and an 'Upload a file' button; 'Study Type', 'Sponsor Type', and 'Study Phase' with dropdown menus; and 'Therapeutic Area' with a dropdown menu and 'Expected number of subjects' with a text input field. At the bottom, there is a footer with copyright information: '© PCG Solutions AB 2018 · Terms of Use · Privacy Policy Viedoc™ version 4.42.6674.15540 [2018-04-10T09:43 UTC]'.

The information in the green area is required. Optionally, you can enter details about the sponsor and the study, but these fields can also be filled in at a later stage by the appointed Study Manager under **Study settings**.

- 4 Click **Add study**.  
The study will appear in the list of studies on the study overview page. An e-mail is sent to the Study Manager with an invitation to the newly created study.

### 3 Continue setting up the study

To complete setting up the study, the following steps need to be performed by the Study Manager:

1. Invite a Designer that will build the study design in Viedoc Designer.
2. Add study site(s).
3. Enter the study details under **Study settings**: sponsor code, Contract Research Organization ([CRO](#)) code, reference ID, study type, sponsor type, study phase, therapeutic area, expected number of subjects, and so on.
4. Assign a study design to the sites in the study, once the Designer has published a study design.
5. Invite users to the different system roles and clinic roles.
6. Open the study in Viedoc Clinic and test the study.

These steps are described in more detail in the eLearning lessons under [Study Management](#).

### 4 More information

For an overview of the configuration workflow for initiating a study, see [Initiating a design](#).

For a video tutorial that demonstrates how to add a new study in Viedoc Admin, create a simple study design in Viedoc Designer, manage users in Viedoc Admin and enter data as a site user in Viedoc Clinic, see [How to set up a study](#).



Managing users (for Org Admin)

# Managing users (for Org Admin)

Published by Viedoc System 2024-03-27

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## 1. Introduction

- [1.1 Important information about signatures](#)
  - [1.2 About roles in Viedoc](#)
    - [1.2.1 Two types of roles](#)
    - [1.2.2 System roles](#)
    - [1.2.3 Clinic roles](#)
  - [1.3 About the study users](#)
    - [1.3.1 Overview of users in the organization/study/site](#)
    - [1.3.2 Users](#)
    - [1.3.3 Study crew](#)
    - [1.3.4 Site users](#)
    - [1.3.5 Viedoc skill level](#)
    - [1.3.6 User status](#)
  - [1.4 User settings in Viedoc Admin](#)
  - [1.5 About the user report](#)
    - [1.5.1 Log of users and roles in PDF](#)
    - [1.5.2 User administration log in Excel](#)
    - [1.5.3 Communication log in Excel](#)
      - [1.5.3.1 User-specific information](#)
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  - [1.6 About system site groups](#)
- ## 2. Step-by-step guides for the Org Admin
- [2.1 Assigning an Organization Administrator](#)
  - [2.2 Assigning an eLearning Administrator](#)
  - [2.3 Assigning a Study Manager](#)
  - [2.4 Removing a user from the organization](#)
  - [2.5 Downloading the user roles report](#)

This lesson describes the types of roles that are supported by Viedoc, how to assign roles to users and where to view the users that have access to a study, and the user details. The instructions are intended for the Organization Administrator (Org Admin).

---

## 1 Introduction

### 1.1 Important information about signatures

The Study Manager should, in cooperation with the Site Manager(s), ensure that all users of Viedoc are informed, and certify that all electronic signatures created in the system are intended to be the legally binding equivalent of a traditional handwritten signature.

In Viedoc, the purpose/meaning of a signature is always “responsibility” as used in Sec. 11.50 of Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11. The signer is thereby acknowledging his/her responsibility for the entered data. Viedoc keeps account of what was signed, who signed it, and when the signature was performed.

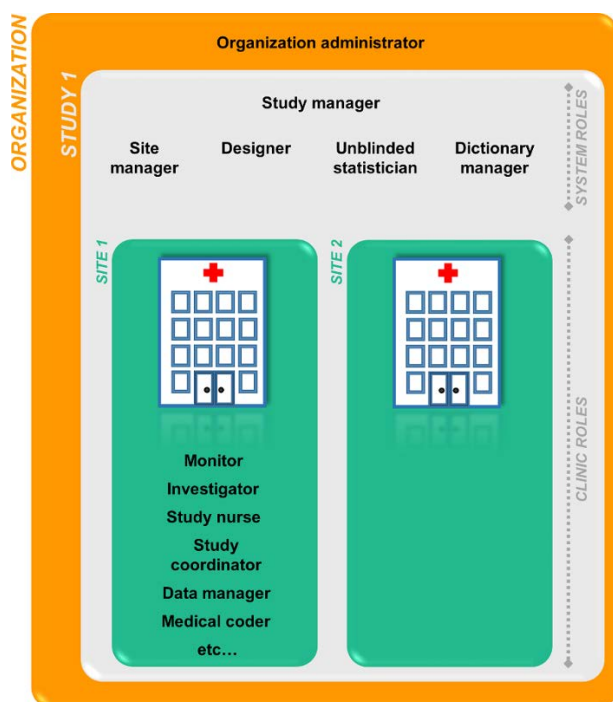
### 1.2 About roles in Viedoc

#### 1.2.1 Two types of roles

Viedoc supports two different types of roles.



1. **System roles** are roles that are predefined in the system and give access to Viedoc Admin or Viedoc Designer, see [System roles](#).
2. **Clinic roles** are roles that are study-specific and give access to Viedoc Clinic, see [Clinic roles](#).



The Organization Administrator invites the Study Manager. The Study Manager can assign users to system roles and clinic roles. The Study Manager can also delegate the management of clinic roles to the Site Manager.

### 1.2.2 System roles

The system roles are predefined in Viedoc, they cannot be adjusted for your study. The system roles give access to various features in Viedoc Admin or Viedoc Designer.

The following system roles are available.

Role	Description
Organization Administrator	The Organization Administrator is responsible for all projects within the organization. The Organization Administrator initiates projects, and assigns Study Managers to every project in Viedoc Admin.
Study Manager	The Study Manager assigns roles to users, adds sites to the study and applies study designs to the sites in Viedoc Admin. For a typical clinical trial, the role of Study Manager in Viedoc is assigned to the project manager.
Designer	The Designer builds the study in Viedoc Designer.
Site Manager	The Site Managers are appointed by the Study Manager and use Viedoc Admin to assign clinic roles to site users. For a typical clinical trial, the role of Site Manager in Viedoc is assigned to the Clinical Research Associate ( <a href="#">CRA</a> ).
Unblinded Statistician	The Unblinded Statistician manages the randomization lists in Viedoc Admin. This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.
Dictionary Manager	The Dictionary Manager uploads medical coding dictionaries.
Reference Data Source Manager	The Reference Data Source Manager manages the reference data sources at study level. The Reference Data Source Manager can also delegate the management of data sources at site level to the Site manager.
API Manager	The Application Programming Interface ( <a href="#">API</a> ) Manager has access to the API settings and performs the API configurations. Complete instructions on how to configure the API are provided in <a href="#">Viedoc API</a> .

Role	Description
eTMF Manager	The eTMF Manager manages the <a href="#">eTMF</a> application in Viedoc Admin. The eTMF Manager maps Viedoc Clinic roles to eTMF roles. The eTMF Manager also has permission to manage the eTMF structure in Viedoc eTMF.

One organization can have more than one Organization Administrator. One study can have more than one Study Manager, Designer, Unblinded Statistician, Dictionary Manager, Reference Data Source Manager and API Manager. One site can have more than one Site Manager.

### 1.2.3 Clinic roles

The clinic roles, and the rights that belong to these roles, can be set up in the study design in Viedoc Designer. They are study-specific and give access to Viedoc Clinic. Clinic roles are assigned to site users by the Study Manager or the Site Manager. Each study can have an unlimited number of clinic roles.

Examples of clinic roles are:

- Investigator
- Study Nurse
- Study Coordinator
- Data Manager
- Medical Coder

## 1.3 About the study users

### 1.3.1 Overview of users in the organization/study/site

A list of users can be viewed at the following three places:

The screenshot shows the Viedoc interface for a study named 'Viedoc's demostudy'. The top navigation bar has 'Studies' and 'Users' (highlighted with a '1'). Below the navigation bar, there are several settings cards: 'Randomization is on', 'Medical coding', 'Reference data source(s)', 'API configuration', 'Study crew' (highlighted with a '2'), and 'Study design'. At the bottom, there is a 'Study Sites' section with a table of sites and their users. The 'Site users' tab is highlighted with a '3'.

#	Site name	Code	Country	Effective Design	Production	Users
1	Karolinska Institute Stockholm	KI	SE	DemoStudyDesign 4.0	✓	1 / 6
2	Uppsala University Hospital	UU	SE	DemoStudyDesign 7.0	✓	1 / 6
3	Helsinki University Hospital	HU	FI	DemoStudyDesign 4.0	✓	1 / 5
4	University College Hospital London	CL	GB	DemoStudyDesign 6.0	✓	1 / 5
5	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign 3.0	✓	1 / 6

1. On the **Users** page. This page displays a list of users assigned to any role in any study within the **organization**.
2. In the **Study crew** window. This window displays a list of all users assigned to a system role in the **study**.
3. On the **Site users** tab of the site settings window. This tab displays a list of all users assigned to a clinic role within that specific **site**.

**Note!** All three user lists only display the users and roles you have permission to manage (invite or remove). If you are a Study Manager, you can also see the Organization Administrator. If you are a Site Manager, you can also see the Study Manager. However, in both cases you cannot invite users to these roles or remove these roles from users.

### 1.3.2 Users

User	Study and site	Role	Skill level	Status
[Redacted]				?
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	👨‍🎓	✓
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Investigator + 1 other roles	👨‍🎓	?
[Redacted] (294)	Multiple studies Multiple sites	Study Manager + 3 other roles	👨‍🎓	✓
[Redacted] (296)	Viedoc's demostudy Multiple sites	Investigator	👨‍🎓	🔒
Technical Writer (304)	Multiple studies Multiple sites	Organization Admin + 10 other roles	👨‍🎓	✓
Technical Writer (305)				✖
TW CN (371)				✖
Viedoc Admin (90)		Organization Admin	👨‍🎓	✓

The Users page lists all users within the organization, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Study/studies and site(s) the user has access to
- Role(s) assigned to the user
- Viedoc skill level of the user (see [Viedoc skill level](#))
- Status of the user (see [User status](#))

If a user has no approved roles, because the invitation is still pending or rejected, or because the roles have been removed, only the user's e-mail address is displayed and all the other fields remain empty.

On this page, you can (see image):

1. Search for a specific user among all users within the organization by entering the user's name or e-mail address in the search field
2. Sort the list of users by name, status or date of creation
3. Group the list of users by study by selecting **Studies** in the **Group by** field
4. Invite organization users (only available for the Organization Administrator)

### 1.3.3 Study crew

User	Role	Since	Skill level	Status
Technical Writer (304)	Study Manager Designer	2018-04-10 08:49		✓
Dr. Demo (383)	Dictionary Manager	2018-04-27 08:04		✓
Site Investigator (294)	Study Manager Reference Data Source Manager	2018-05-02 14:36		✓
	Dictionary Manager	2018-05-15 08:32		?
				✗

The Study crew window lists all users in the study that are assigned to a system role, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Role(s) assigned to the user
- Date and time the user has been invited to that role (if the invitation is still pending) or has access to that role (if the invitation has been accepted)\*
- Viedoc skill level of the user (see [Viedoc skill level](#))
- Status of the user (see [User status](#))

\*If the user has multiple roles, the date and time of invitation or acceptance of the first role that gives access to that site is displayed.

You can sort the users by name, role, date of (accepted) invitation and status. To sort the users, click on the column headers, or click on the arrows to the right of the column header. You can sort the users in ascending and descending order.

### 1.3.4 Site users

User	Role	Since (UTC)	Skill level	Status
Technical Writer (304)	Site Manager + 1 other roles	2018-05-15 09:18 UTC		✓
Dr. Demo (383)	Data Manager	2018-05-15 09:23 UTC		?
Site Investigator (294)	Medical Coder	2018-05-15 09:21 UTC		✓
Dr. Investigator (490)	Investigator + 1 other roles	2018-05-15 09:21 UTC		✓

The Site users tab in the Site settings window lists all users with clinic roles that have access to that site, and displays the following information:





- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Role(s) assigned to the user
- Date and time the user has been invited to that role (if the invitation is still pending) or has access to that role (if the invitation has been accepted)\*
- Viedoc skill level of the user (see [Viedoc skill level](#))
- Status of the user (see [User status](#))

\*If the user has multiple roles, the date and time of invitation or acceptance of the first role that gives access to that site is displayed.

You can sort the users by name, role, date of (accepted) invitation and status. To sort the users, click on the column headers, or click on the arrows to the right of the column header. You can sort the users in ascending and descending order.








### 1.3.5 Viedoc skill level

The Viedoc skill level gives an indication of how experienced the user is in using Viedoc. It is based on the number of logins by that user.

Skill level	Icon	Description
Rookie		≤ 20 logins
Semi-pro		21-100 logins
Pro		101-1000 logins
Legend		> 1000 logins

### 1.3.6 User status

The status of the users is displayed in the status column:

Status	Icon	Description
Online		The user is currently logged in to Viedoc, and has no pending invitations.
Offline		The user is currently not logged in to Viedoc, and had no pending invitations.
Pending		The user has at least one pending invitation to a role. The question mark is displayed even if the user has accepted invitations to other roles.
Pending certification		The user has mandatory documentation assigned that was not confirmed as read & understood.
Rejected		The user has rejected all invitations to roles. The user has never had access to the study.
Locked out		The user is locked out from Viedoc (the user has entered the wrong password three times in a row).
Removed		The user has had roles in the study before, but has currently no roles left.

For the **Users** page (see [Users](#)), the following applies:

If the users are not grouped by study, the user's status symbol will reflect the overall status in all studies you have access to. That means, if the user has one pending invitation in one of the studies, the status will be *pending* and a

red question mark will appear. If the users are grouped by study, the status symbol will reflect the status per study. That means that a user's status can be *pending* in one study, and *logged in* in another study.

## 1.4 User settings in Viedoc Admin

To view the details of a specific user, click the toolbox icon behind the name of that user in any of the previously described user lists. The User Settings window opens:

The screenshot shows the 'User Settings' window for a user named 'Dr Investigator (1714)'. The window has a blue header with a close button. Below the header, the user's name and ID are displayed, along with status (Offline) and skill level (Rookie, 13 logins). There are five numbered tabs: 1. Details, 2. Studies and Roles, 3. Authentication Log, 4. Reset Password, and 5. Communication Log. The Details tab is active, showing fields for User name (testuser@tr.com), First name (Dr), Last name (Investigator), Display name (Dr Investigator (1714)), Phone (46 7 12345678), Street address (Main Street 101), City (Uppsala), Postal code, Country (SE), and State. A red dashed box at the bottom contains the text 'Delete user from this organization'.

The **User Settings** window displays the name and email address of the user, the user ID (in parentheses), the status and the skill level. You can perform the following actions:

1. On the **Details** tab, you can view the user's name and contact details.
2. On the **Studies and Roles** tab, you can view a list of all roles and sites the user has access to, including the date and time of invitation/acceptance of that role. The roles are grouped per study. You can delete roles by clicking the trash can icon next to the role.
3. On the **Authentication log** tab, you can view a list of logins by the user, including date and time, the IP address, and the browser that was used. The number of displayed entries is limited to the latest 100 logins.
4. On the **Reset Password** tab, you can reset the password for that user, if the user has forgotten their password and does not have the phone number that can receive a text message or a secondary email address. Viedoc will send a notification to the user with a link to create a new password.

**Note!** The authentication code will be required if the user wants to reset their password using the **Forgot your password?** link on the login page. The authentication code is sent to the phone number the user set to receive text messages or to the user's secondary email address. If neither of these options are selected, the user needs to contact their Study Manager to receive a link to reset their password.

5. On the **Communication Log** tab, you can view the latest 20 communication logs for a user and download an Excel file with the complete user-specific **Communication Log** containing information about email and SMS communication to study users. All users with access permissions (Study/Site Managers) to the User settings in Viedoc Admin can access the Communication Log.

**Note!** Email and SMS communication logs before the Viedoc 4.70 release are available, however these do not have the same level of detail.

## 1.5 About the user report

For each study, you can download user logs in PDF and Excel format with information about all users and roles for the sites you have access to. See [Downloading the user logs](#) for instructions.

**Note!** Only production sites and roles/users for production sites are included in the logs.

The content of the logs depends on the system role that you have, as follows:

If you are a...	... then the logs contain:
Organization Administrator	The system roles Application Programming Interface (API) Manager, Dictionary Manager, Unblinded Statistician, Reference Data Source Manager, and eTMF Manager.
Study Manager	The system roles API Manager, Dictionary Manager, Unblinded Statistician and Reference Data Source Manager, eTMF Manager, and all sites and site users in the study.
Site Manager	The system roles API Manager, Dictionary Manager, Unblinded Statistician and Reference Data Source Manager, eTMF Manager, and all sites you have access to, together with their site users.

### 1.5.1 Log of users and roles in PDF

The Log of users and roles PDF contains information about all users and roles for the sites you have access to, grouped in the following chapters:

- Summary** - the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.
  - An **Active role** is the current distinct role all active users have for a site.
  - An **Inactive role** is a role that was previously assigned but currently lacks any active user.
  - An **Active user** is a user with at least one active role.
  - An **Inactive user** is a user who had at least one role at a site, but all roles for the site have been revoked.
- Roles** - a list of the permissions associated with each role and corresponding history, grouped in one section per site.
- User log per site** - a list of all users who ever had access to data, including user activity, grouped in one section per site.
- User account logs** - a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the User ID).

### 1.5.2 User administration log in Excel

The User administration log contains information about all users and roles for the sites you have access to, with the following sheets:

- Report Info** - general information about when and by whom the log was generated, and some information about the study status.
- User Access Log** - a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:
  - Site Group** - indicates when a user is granted access to the site through a site group invitation. Possible values are *Training sites*, *Countries*, and *All sites*.
  - 2FA** - indicates what level of two-factor authentication the user has. Possible values are *Study level*, *Account level*, or *No two-factor authentication enabled*.
  - Certified** - indicates if the user is certified for the role. Possible values are *Yes*, *No*, or an empty cell for roles that don't have mandatory training sections to read.
- Certification Log** - a list of certifications per user. Certifications performed before the release of 4.65 lack information about what roles the certification applies to. That is, the cells in column **Certified With Roles** are empty.
- Summary** - a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
- Account Settings Log** - a list with all user accounts setting changes with user ID, change log, user name, and date/time.

### 1.5.3 Communication log in Excel

There are two different Communication logs. One contains user-specific and one contains study-specific communication information.

#### Note!

- This Communication log does not include any subject-related communication (Viedoc Me).
- Email and SMS communication logs before the Viedoc 4.70 release are available, however these do not have the same level of detail.

### 1.5.3.1 User-specific information

The user-specific Communication log contains information about email and SMS communication to the study users.

All users with access permissions (study/site managers) for the User Settings in Viedoc Admin can view the Communication Log for a specific user. The **Communication Log** tab has the following columns:

- Date & Time
- Message type
- Status - **Note!** The status labels are **Success** or **Failed**, where **Success** means that the message was successfully sent from Viedoc, and **Failed** means that the message failed to send from Viedoc. Further, if the status was **Success** but the recipient did not receive a message, then the problem lies outside of Viedoc. Please contact your PS representative if this should occur, or if your status returns **Failed**.

Date and Time	Message type	Status
2022-03-21 09:41:50 (UTC)	Two factor authentication	Success
2022-03-21 09:25:18 (UTC)	Two factor authentication	Success
2022-03-21 04:41:07 (UTC)	Two factor authentication	Success
2022-03-21 04:39:28 (UTC)	Recover account request	Success
2022-03-19 07:09:22 (UTC)	Two factor authentication	Success
2022-03-18 09:59:30 (UTC)	Two factor authentication	Success
2022-03-18 09:50:58 (UTC)	Two factor authentication	Success
2022-03-18 06:16:34 (UTC)	Two factor authentication	Success
2022-03-18 05:40:42 (UTC)	Verify phone number	Success
2022-03-18 05:40:39 (UTC)	Change phone number	Success

The Excel file contains a sheet named **User Communication Logs** and includes all email and text message (SMS) communications to the study user on the same Excel sheet.

**Note!** Users must have activated the Viedoc account and accepted at least one invitation in order to have their communication included in the Communication Log tab in the **User Settings** window.

The **User Communication Logs** sheet in the Excel file contains information about user-specific communication – this is the user activity in Viedoc that is unrelated to a specific study:

- Reset password
- Verification & notifications (changing telephone number/email address)
- 2FA (email/SMS)

The file name format is: UserCommunicationLog-UserID-YYYYMMDDhhmmss. (Using UTC)

All the logs are included in the same Excel sheet. The excel sheet has the following columns:



<b>Column</b>	<b>Description</b>
<b>Message ID</b>	GUID: A unique identifier for the message
<b>Type of Communication</b>	SMS/email
<b>Datetime (UTC)</b>	Date and time for the communication
<b>Message Type</b>	The action that the communication is related to: <ul style="list-style-type: none"> <li>▪ <i>Reset password</i> - for messages related to password reset</li> <li>▪ <i>2FA login</i> - for messages related to the 2 factor authentication</li> </ul>
<b>To</b>	The email address the message is sent to. For SMS messages, this column is empty.
<b>Status</b>	<i>Success/Failed</i>
<b>Provider</b>	Provider name - the provider that was used to send the message to the recipient

Communication logs						
Message Id	Type of Communication	Datetime (UTC)	Message Type	To	Status	Provider
9970d495-aa67-4bed-b246-cc3f8b1c8d47	Email	2022-03-01 07:46:25	Two Factor Authentication	user1@viedoc.com	Success	Primary-Primary
a96f1beb-c63c-4376-9ae0-e9dcabcb8d4	Email	2022-03-01 07:44:29	Recover Account Request	user2@gmail.com	Success	Secondary-Secondary
00520b3e-f26a-4077-9dec-edc9458cc30a	Sms	2022-03-01 06:16:22	Verify Phone Number		Success	Primary-Primary
e01f2d59-8af4-48ba-81b7-fb4045d18767	Email	2022-03-01 06:16:20	Verify Email Address	123@mail.com	Success	Primary-Primary
9ad92c51-7582-4bce-b243-d63737bb079d	Sms	2022-03-01 06:11:07	Verify Phone Number		Success	Primary-Primary
44807068-faea-4dc3-b07a-a892457eb358	Email	2022-03-01 06:11:00	Verify Email Address	999@gmail.com	Success	Primary-Primary
14e6048b-a1a9-48bb-85e2-94ab6ec14f42	Sms	2022-03-01 04:44:05	Verify Phone Number		Failed	Secondary
399a561a-4299-4ceb-a0ac-a87825cdfbaa	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
8aec881c-78ab-45c9-95e4-5123e09ce129	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
f8ef8347-de0e-422b-be2a-d8bba0a7d650	Email	2022-03-01 04:42:41	Verify Email Address	789@gmail.com	Failed	Secondary
16c884e2-3cf3-4063-8f47-a8cf0c02233a	Email	2022-03-01 04:39:43	Verify Email Address	abcd@gmail.com	Failed	Secondary
9c813fce-6633-4dee-b0ba-3666ee14cf5f	Sms	2022-03-01 04:39:38	Verify Phone Number		Success	Secondary-Primary
fc98775c-01f2-4b4d-aad7-	Email	2022-03-01 04:39:29	Verify Email Address	123@mail.com	Failed	Secondary

### 1.5.3.2 Study-specific information

In Admin, under **Users** - Group by Studies, in the User Logs dropdown list, a separate file called User communication log is available containing the information listed below.

The screenshot shows the Admin interface for 'Users'. The 'Group by' dropdown is set to 'Studies'. A dropdown menu is open for 'User logs', showing options like 'Log of users and roles', 'User administration log', and 'User communication log'. The 'User communication log' option is highlighted with a green box, and its sub-menu shows 'Download (2022-03-02 09:25)' and 'Regenerate'.

This log contains information about study-specific communication and emails only, related to:

- Alerts
- Invitations to a specific role within a study
- Notifications (study access deletion, etc.)

The Excel file contains a sheet named **Study Communication Logs**.

The file name format is: UserCommunicationLog-YYYYMMDDhhmmss. (Using UTC)

The Excel sheet has the following columns:

Column	Description
Message ID	GUID: A unique identifier for the message
Communication Type	Email
Date time (UTC)	Date and time for the communication
Message Type	The action that the communication is related to: <ul style="list-style-type: none"> <li>▪ <i>Invite user</i></li> <li>▪ <i>Event Reminder</i></li> <li>▪ <i>Remove User Access Notification</i></li> <li>▪ <i>Subject Account Lock Notification</i></li> <li>▪ <i>Study Unlock Notification</i></li> <li>▪ <i>Export Chart</i></li> <li>▪ <i>Export Metric</i></li> <li>▪ <i>Reject User Invitation</i></li> </ul>
Site Type	Training/Production (For the message types Invitation and Invitation rejected, this column is empty.)
To	Email address(es) (For SMS messages, this column is empty.)
CC	The email address(es) of the recipients of a copy
BCC	The email address(es) of the recipients of a blind copy
Status	<i>Success/Failed</i>
Provider	Provider name - The provider that was used to send the email to the recipient

Communication Logs										
Message Id	Communication Type	Datetime (UTC)	Message Type	Site Type	To	CC	BCC	Status	Provider	
f76002c-8d5-4f3-4932-870ae99b8bd4	Email	2022-03-03 06:52:07	Form Alert True Action	Production	rb@doc.com	rb@doc.com	#f53@mail.com, user11.pghyam@gmail.com	Success	Secondary/Secondary	
87916f21-00c0-4770-9094-e00ffec0e64	Email	2022-03-03 06:52:05	Event Reminder	Production	rb@doc.com	user1@mail.com	gjuu7d7@mail.com, user78.hjstf@gmail.com	Success	Secondary/Secondary	
a2e09907-1890-4945-9d17-ff0254602a	Email	2022-03-03 06:52:08	Study Unlock Notification	Production	user1@mail.com	user3@gmail.com	faf0n3@gmail.com, user56.vinof@gmail.com	Success	Secondary/Secondary	
9757c6d5-60c1-435a-8d97-81f677c0b022	Email	2022-03-03 06:52:01	Invite User	Production	user2@se.com	user@vc.com	fmnk378@gmail.com, user8971.uhfm@gmail.com	Success	Secondary/Secondary	
85e58411-4529-40b3-979e-0e9c0b83902	Email	2022-03-03 06:43:53	Remove User Access Notification	Production	thu.nustf@mail.com	mot.hbdb@mail.com	#f866@gmail.com, f05ourf0.r1@mail.com	Success	Secondary/Secondary	

### Note!

- This log does not include user-specific information related to Reset Password, 2FA, etc.
- This log file is available in Viedoc Admin only.

## 1.6 About system site groups

The Study Manager can give users access to individual sites, or to a groups of sites at once. These groups of sites are called system site groups and are automatically created by the system when sites are added to the study. The following systems site groups are created by the system:

- All sites, containing all sites in the study.
- All production sites, containing all production sites in the study, including the sites that are in both production and training mode.
- Country-specific, for example 'Sweden', containing all production sites (including the sites that are in both production and training mode) in that specific country in the study.

When you invite users to a system site group, the users will *automatically receive instant access* to all sites in that group, including all future sites that will be added to that group at a later time. For example, if you invite a user to the country 'Hungary', that user will receive access to all sites in Hungary. Similarly, users that were invited to a system site group will automatically lose access to a site if that site is removed from the group. For more information about system site groups, see [Managing study sites](#).

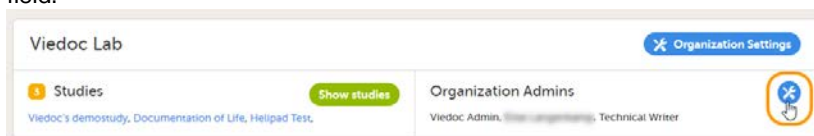
## 2 Step-by-step guides for the Org Admin

### 2.1 Assigning an Organization Administrator

By default, every organization has at least one Organization Administrator, added by the system administrator at Viedoc Technologies. Additional Organization Administrators can only be added by the Organization Administrator.

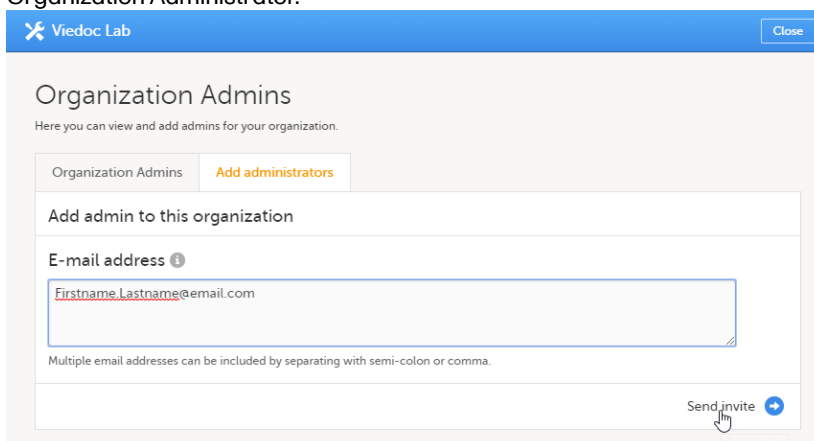
To add an Organization Administrator:

- 1 In the Organizations window in Viedoc Admin, click the toolbox icon in the **Organization Administrators** field.



The Organization Admins pop-up opens.

- 2 On the **Add administrators** tab, enter the e-mail address of the user you would like to invite to the role Organization Administrator.

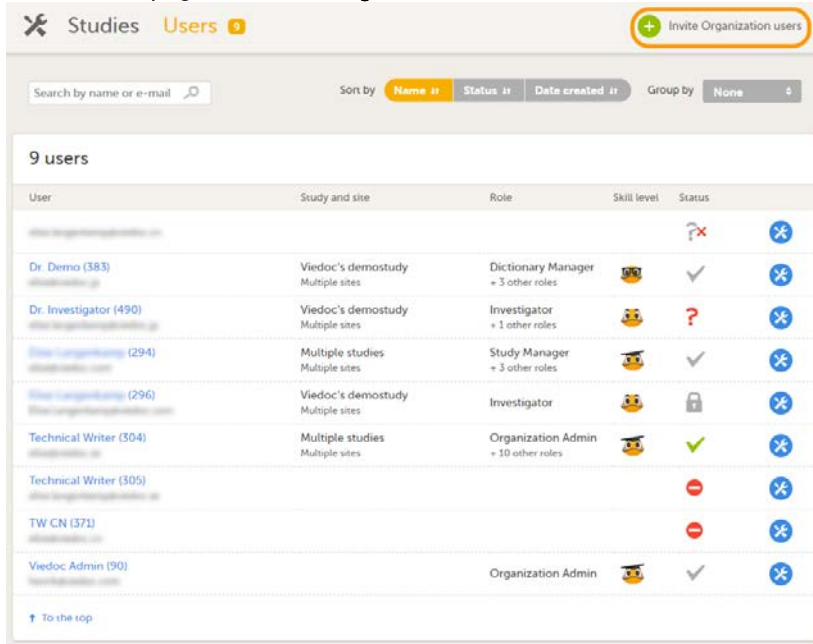


**Tip!** You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

- 3 Click **Send invite**.  
An invitation e-mail is sent to the e-mail address you specified.

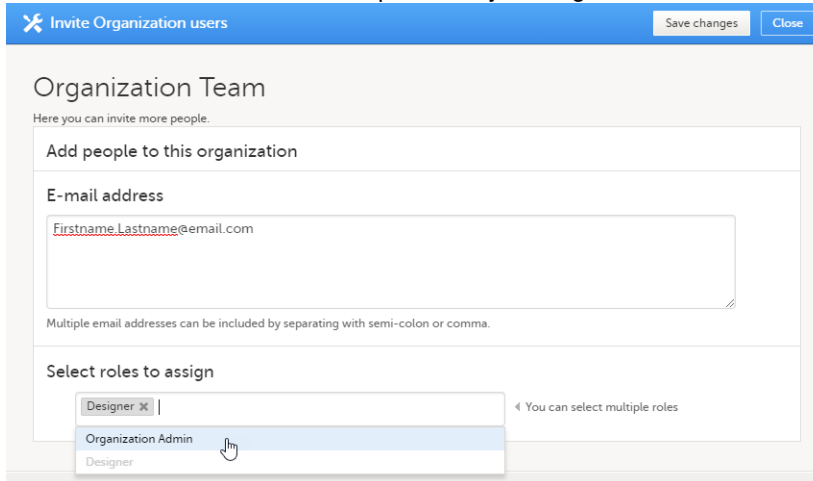
You can also assign users to organization roles (Organization Administrator, eLearning Administrator, and Designer at organization level) via the Users page:

1 On the Users page, click **Invite Organization users**.



The Organization team pop-up opens.

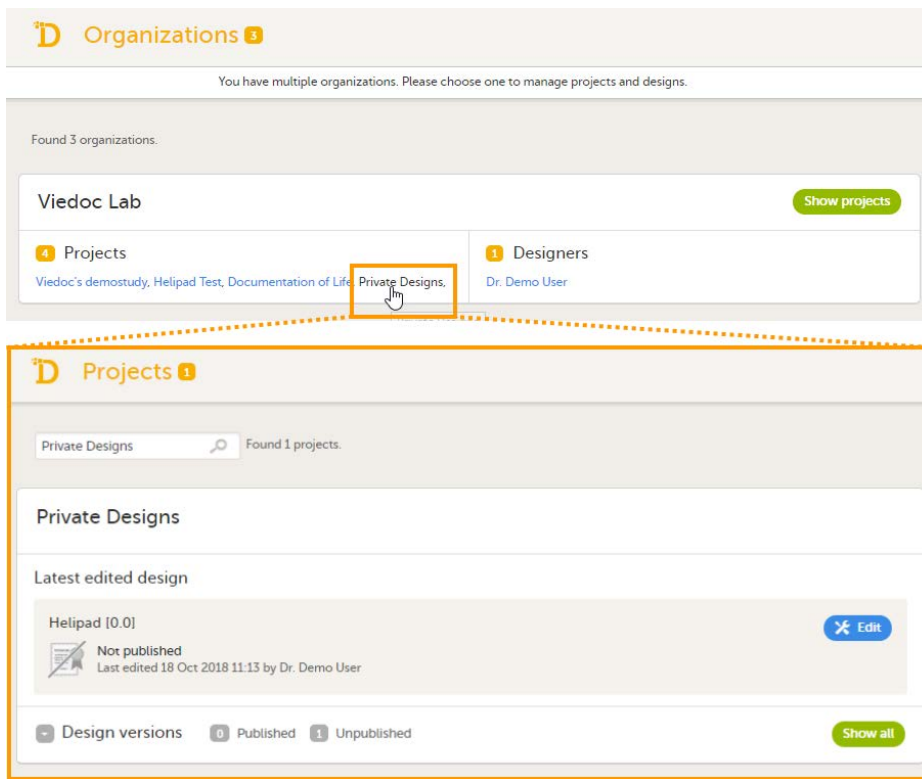
2 Enter the e-mail address of the user you would like to invite, and select the role to which you would like to invite the user. You can add multiple roles by clicking in the **Select roles to assign** field.



**Tip!** You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma. All entered users will be assigned to all selected roles.

3 Click **Save changes**.  
An invitation e-mail is sent to the e-mail address(es) you specified.

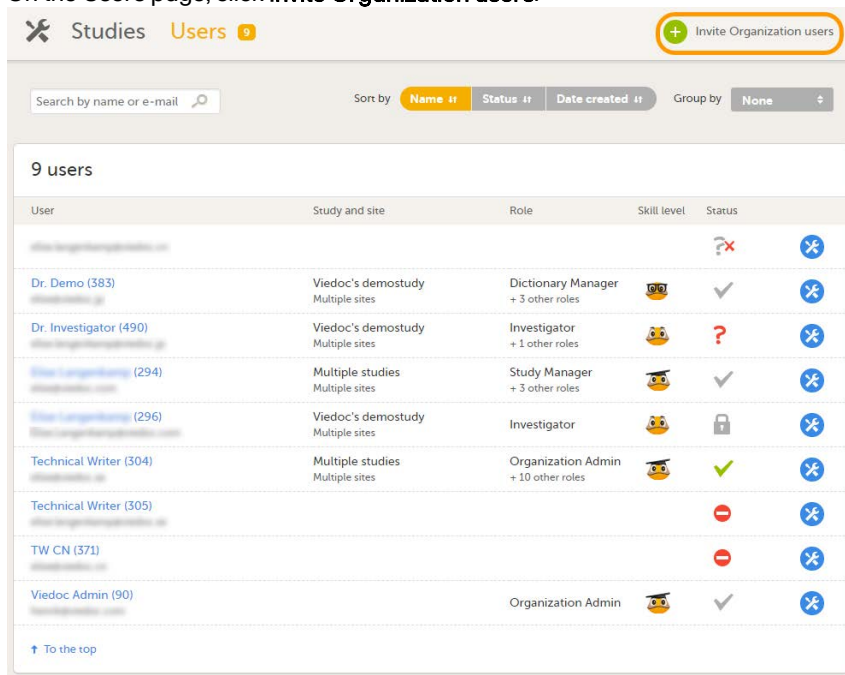
A Designer at organization level receives access to Viedoc Designer for all studies within the organization, and receives access to the Private Designs section, see image below.



## 2.2 Assigning an eLearning Administrator

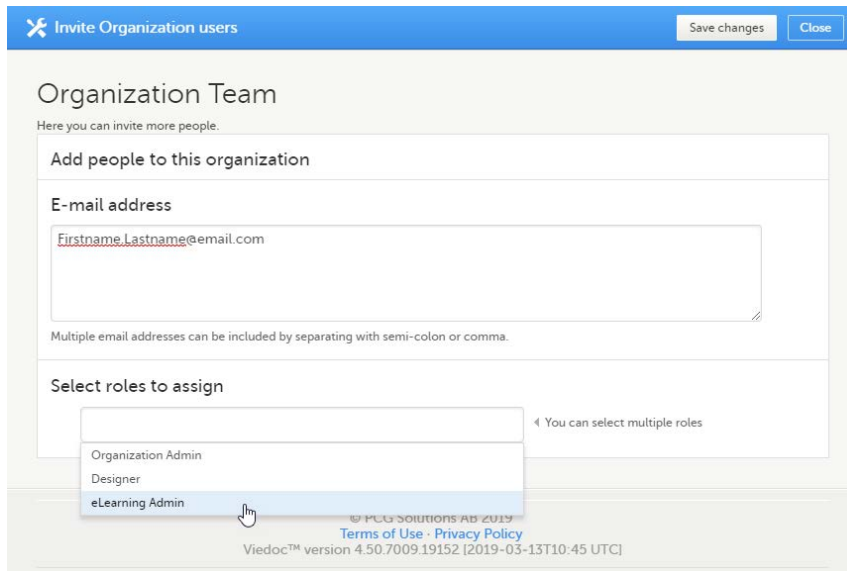
To assign an eLearning Administrator via the Users page:

- 1 On the Users page, click **Invite Organization users**.



The Organization team pop-up opens.

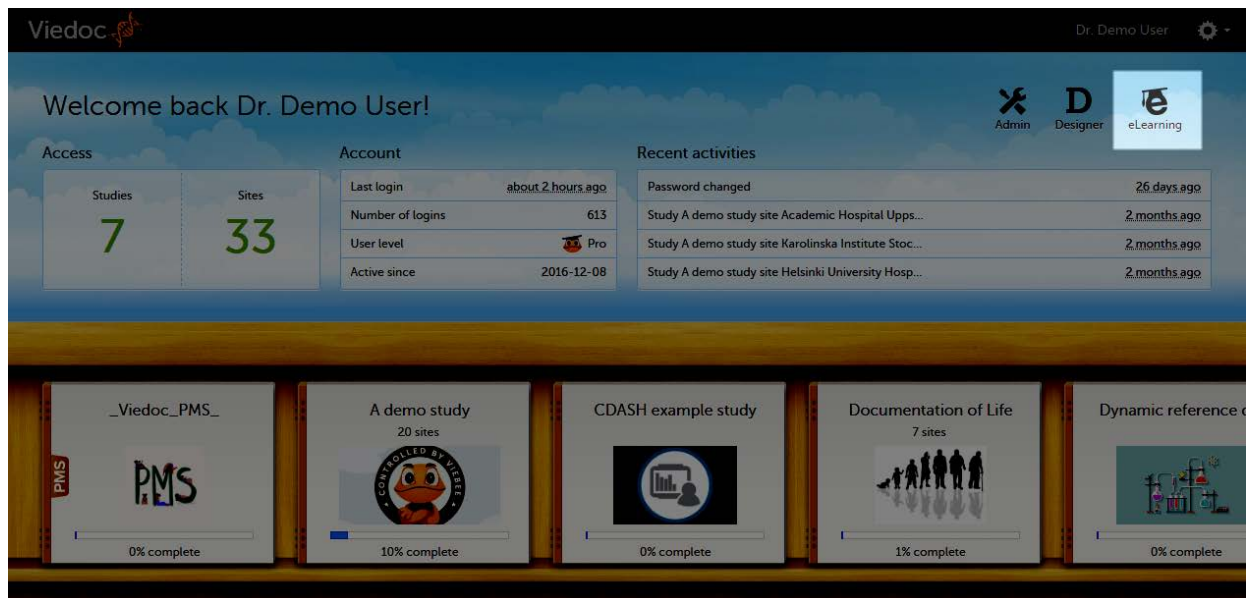
- 2 Enter the e-mail address of the user you would like to invite, and select the role to which you would like to invite the user. You can add multiple roles by clicking in the **Select roles to assign** field.



**Tip!** You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma. All entered users will be assigned to all selected roles.

- 3 Click **Save changes**.  
An invitation e-mail is sent to the e-mail address(es) you specified.

Once a user has been assigned to the role eLearning Administrator, the user can access the Viedoc eLearning platform and create customized user documentation for your organization. For users with eLearning Administrator permissions, the following icon appears on the landing page in Viedoc Clinic, which gives access to the Viedoc eLearning platform.



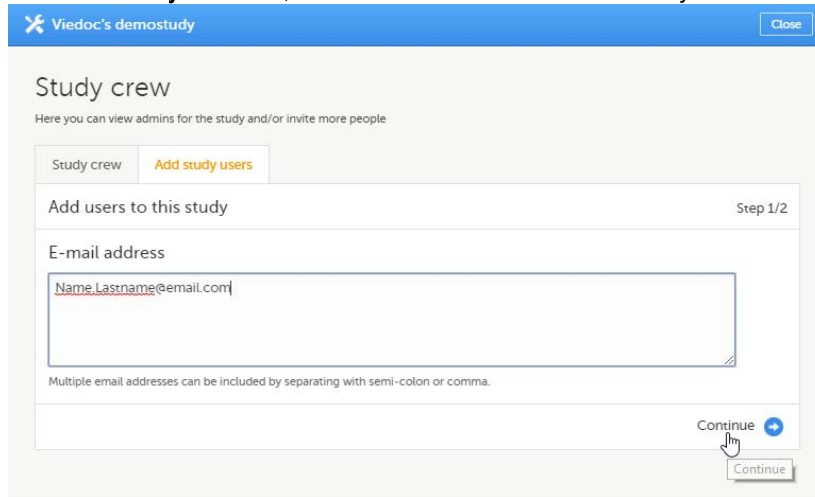
## 2.3 Assigning a Study Manager

**Note!** Study Managers can only be added by the Organization Administrator.

To add a Study Manager:

- 1 In Viedoc Admin, open the study to which you would like to invite users.
- 2 Click the toolbox icon in the **Study crew** field.  
The Study crew pop-up opens.

- 3 In the **Add study users** tab, enter the e-mail address of the user you would like to invite. Click **Continue**.



**Tip!** You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

- 4 Select the role to which you would like to invite the user.  
You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.
- 5 Click **Send invite**.  
An invitation e-mail is sent to the e-mail address(es) you specified.

## 2.4 Removing a user from the organization

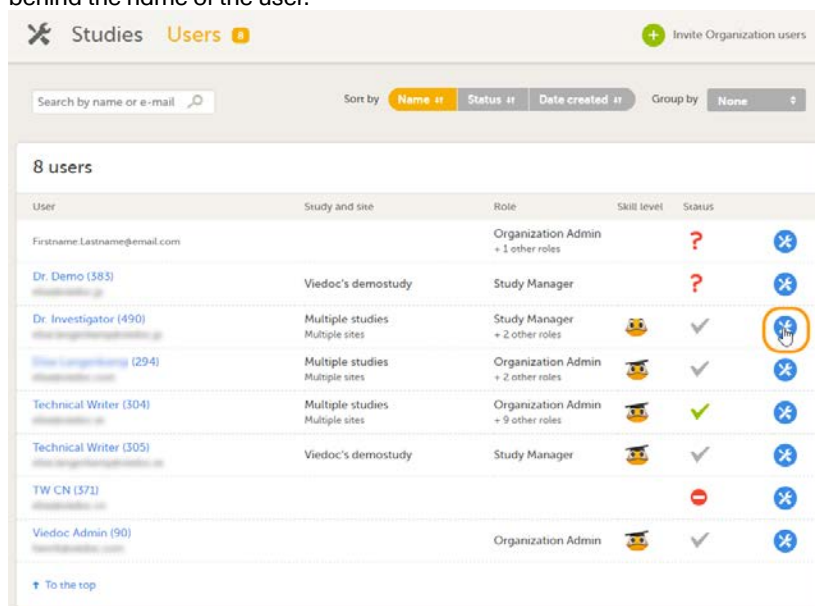
Viedoc offers the possibility to remove all roles from a user in all studies within the organization at once. Only users that have active roles can be removed from the organization, if the user has any pending invitations, it is not possible to remove the user from the organization.

Only the Organization Administrator can remove a user from the organization.

**Note!** This feature does not remove the user account, it only removes all roles and permissions within the organization. The user can still log in and log out, but not view any studies within that organization.

To remove all roles from a user at once:

- 1 On the **Users** page, scroll to the user whose roles you would like to remove. Click the toolbox icon behind the name of the user.



The User Settings pop-up opens.

2 Click **Delete user from this organization**.

The screenshot shows the 'User Settings' interface for a user named 'Dr Investigator (1714)' with email 'testuser@r.com'. The user is currently 'Offline' and has a 'Rookie' status with 13 logins. The 'Details' tab is active, showing fields for User name, First name (Dr), Last name (Investigator), Display name (Dr Investigator (1714)), Phone (46 7 12345678), Street address (Main Street 101), City (Uppsala), Postal code, Country (SE), and State. A large red button labeled 'Delete user from this organization' is visible at the bottom of the form.

3 Click **Delete** to confirm that the roles should be removed. All roles to which the user had access will be removed and the user's status will appear as *Removed* on the Users page.

## 2.5 Downloading the user roles report

To download the user roles report:



1 On the **Users** page, select to group the users by *Studies*.

Studies Users 12

Invite Organization users

Search by name or e-mail

Sort by Name Status Date created

Group by Studies

None

Studies

12 users

Viedoc's demostudy [Generate a PDF file 'Log of users and roles'](#)

User	Study and site	Role	Skill level	Status
<a href="#">[Redacted]</a>				
<a href="#">Dr. Demo (383)</a> <a href="#">[Redacted]</a>	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles		
<a href="#">Dr. Investigator (490)</a> <a href="#">[Redacted]</a>	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles		
<a href="#">Technical Writer (304)</a> <a href="#">[Redacted]</a>	Viedoc's demostudy Multiple sites	Study Manager + 8 other roles		
<a href="#">Technical Writer (305)</a> <a href="#">[Redacted]</a>				
<a href="#">TW CN (371)</a> <a href="#">[Redacted]</a>				

Documentation of Life [Generate a PDF file 'Log of users and roles'](#)

User	Study and site	Role	Skill level	Status
<a href="#">[Redacted]</a> (294) <a href="#">[Redacted]</a>	Documentation of Life Multiple sites	Study Manager + 3 other roles		
<a href="#">Technical Writer (304)</a> <a href="#">[Redacted]</a>	Documentation of Life Multiple sites	Study Manager + 1 other roles		
<a href="#">Technical Writer (305)</a> <a href="#">[Redacted]</a>				

2

Scroll to the study from which you would like to download the user report, and, if the **Log of users and roles** PDF has not been previously generated for the study, you can generate it by clicking the **Generate a PDF file 'Log of users and roles'** link:

12 users

Viedoc's demostudy

Generate a PDF file 'Log of users and roles'

User	Study and site	Role	Skill level	Status
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles	🧐	?
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	🧐	✓
Technical Writer (304)	Viedoc's demostudy Multiple sites	Study Manager + 8 other roles	🧐	✓
Technical Writer (305)				✖
TW CN (371)				✖

As a result, the PDF file that contains a full history of all roles and users, permissions, user logs sorted per site, and all user account logs sorted per user is generated and available for download:

Download 'Log of users and roles' 2019-03-01 08:42 | [Generate a new PDF file](#)

After the PDF file was generated for the study, you can choose to:

- Download the latest generated PDF for the country/site selection - the most recent version generated has a date and time stamp and is stored on the server, making it possible to directly download the file instead of generating a new one, which would be more time consuming,  
or
- **Generate a new PDF file** - if you need a more recent version than the one available for download.



Deleting a study (for Org Admin)

# Deleting a study (for Org Admin)

Published by Viedoc System 2022-10-18

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## [1. Introduction](#)

## [2. Step-by-step guides for the Org Admin](#)

[2.1 Approving a study delete request](#)

[2.2 Rejecting a study delete request](#)

[2.3 Reverting study deletion](#)

[2.4 Downloading the study status report](#)

This lesson describes how a study is deleted. The instructions are intended for the **Organization Administrator**.

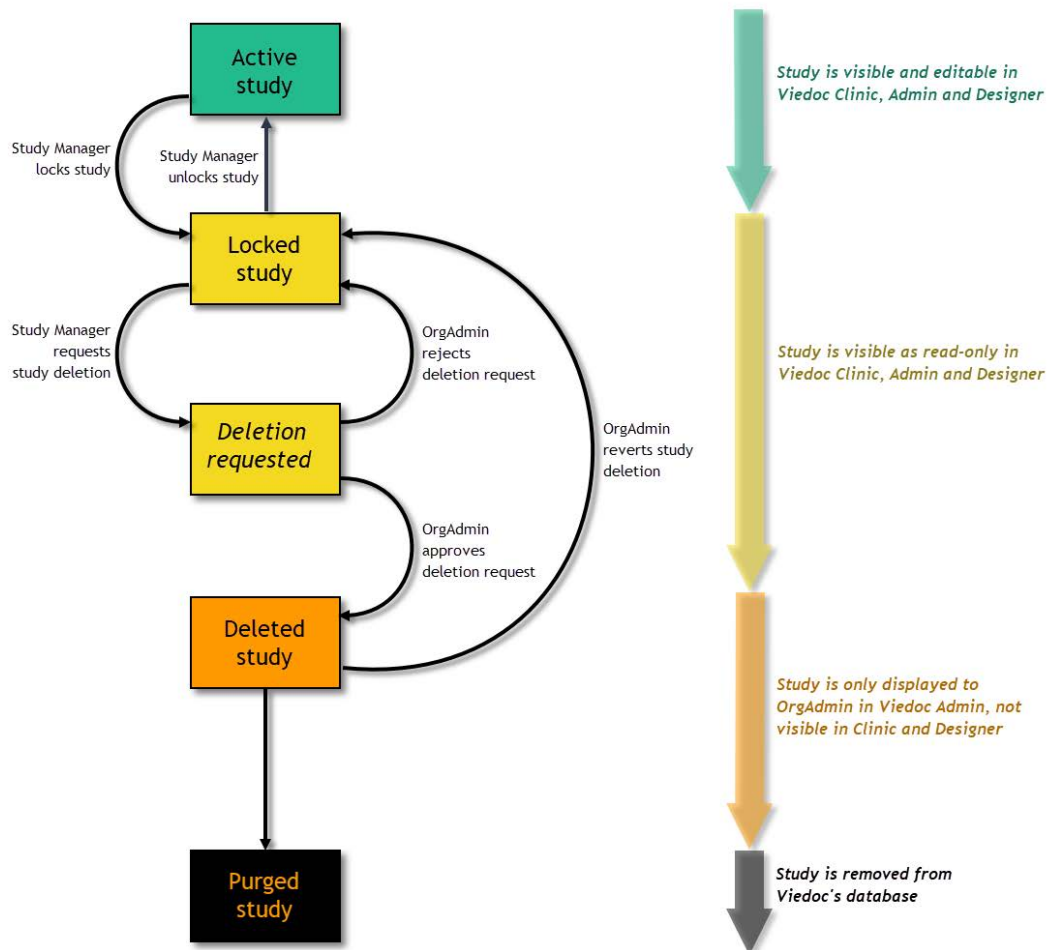
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## 1 Introduction

A study can be permanently deleted from Viedoc when the study is locked. Deletion is initiated by the **Study Manager**, who can submit a request to delete the study from Viedoc to the **Organization Administrator**. The **Organization Administrator** can then approve or reject a request for study deletion.

After study deletion is requested by the Study Manager and approved by the Organization Administrator, the study is shelved on Viedoc's database. A deleted study is not visible in Viedoc Clinic or Viedoc Designer, the study is only displayed in the study overview page of the Organization Administrator in Viedoc Admin.

The Organization Administrator is able to revert the deletion of a study within 180 days after the deletion request has been approved. After this period, the study will be permanently purged from Viedoc's database, and all study details and data will be permanently removed. It will not be possible to find any traces of the study and the subjects included.



For traceability, all study delete actions are audit trailed. You can download a report that provides a full history of all requests for study deletion, approvals of study deletion, and reversions of study deletion that are performed in the study, including who performed the actions and when (date and time in Coordinated Universal Time ([UTC](#))), and the reason that was given for deleting the study or reverting study delete.

**Note!** This section is intended for the Organization Administrator. For instructions for the Study Manager, see [Deleting a study \(STM\)](#).

## 2 Step-by-step guides for the Org Admin

### 2.1 Approving a study delete request

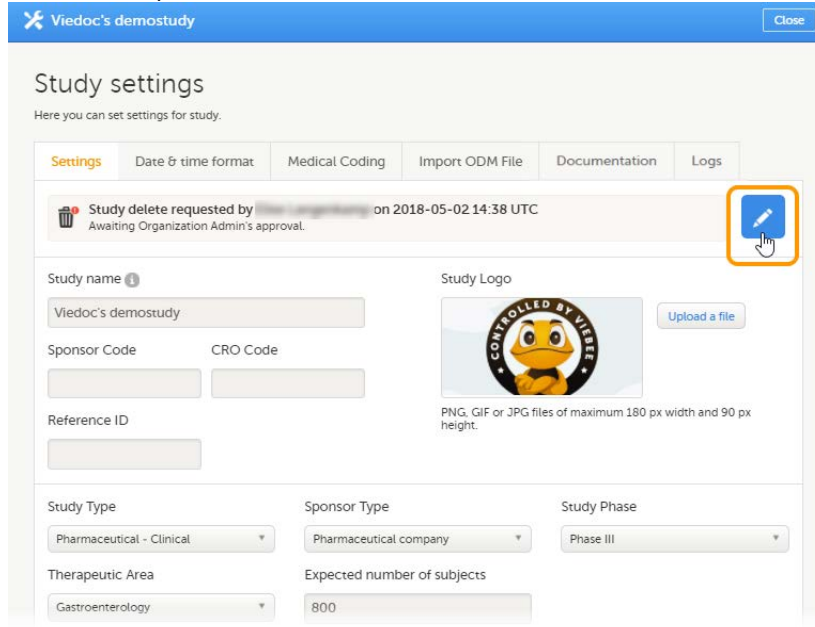
**Note!** Before approving the deletion of a study, make sure that the necessary user reports, data export archive and study design are downloaded.

To approve a request for study deletion:

- 1 Open the study in Viedoc Admin and click **Study settings**. The **Study settings** dialog opens.

2

Click the blue pen icon.





Viedoc's demostudy Close

### Study settings

Here you can set settings for study.


**Settings** | Date & time format | Medical Coding | Import ODM File | Documentation | Logs

 Study delete requested by [redacted] on 2018-05-02 14:38 UTC  
Awaiting Organization Admin's approval. 

Study name ⓘ  
Viedoc's demostudy

Sponsor Code CRO Code

Reference ID

Study Logo  
 Upload a file  
PNG, GIF or JPG files of maximum 180 px width and 90 px height.

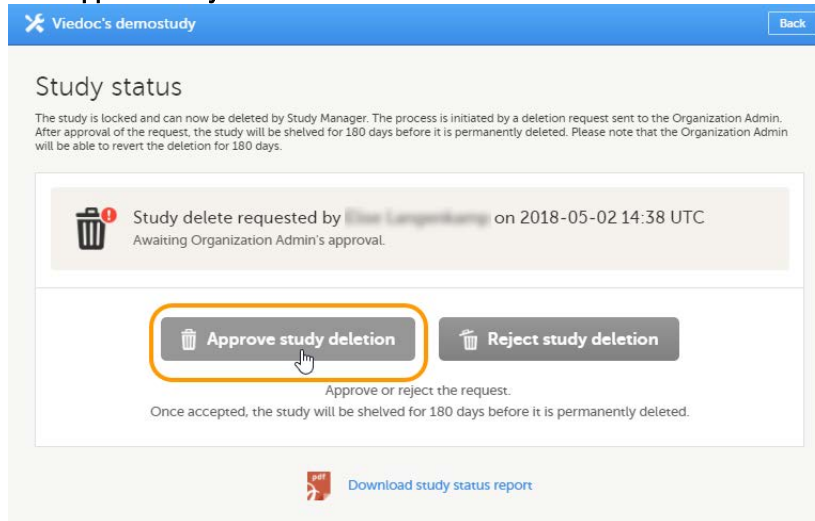
Study Type: Pharmaceutical - Clinical | Sponsor Type: Pharmaceutical company | Study Phase: Phase III

Therapeutic Area: Gastroenterology | Expected number of subjects: 800

The study status dialog opens.

3

Click **Approve study deletion**.



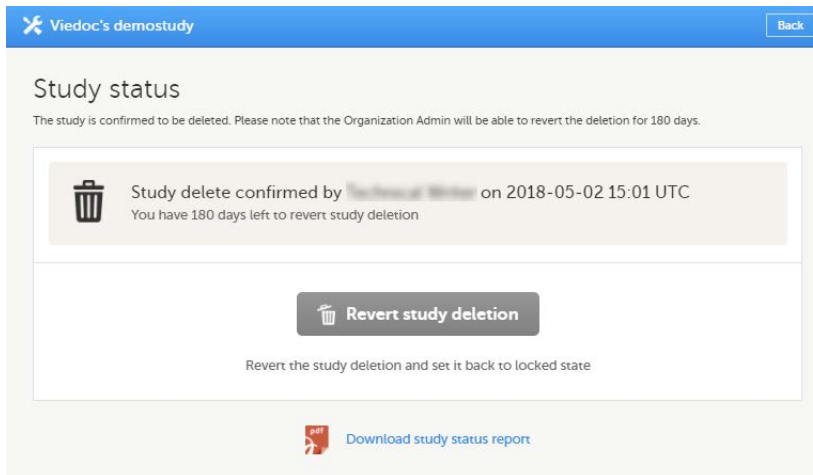
A pop-up opens, listing whether the following actions are done or not done by the study manager:

- Download user report
- Download the data export archive required
- Download study design

4

If you agree that all necessary actions are completed, enter a reason for approval of study deletion, and enter your password.

- 5 Click **Approve study deletion**.  
The study status pop-up displays that the study deletion request is confirmed, by whom, and when (date and time in [UTC](#)). All Study Managers and Organization Administrators will be notified of the approval by email.

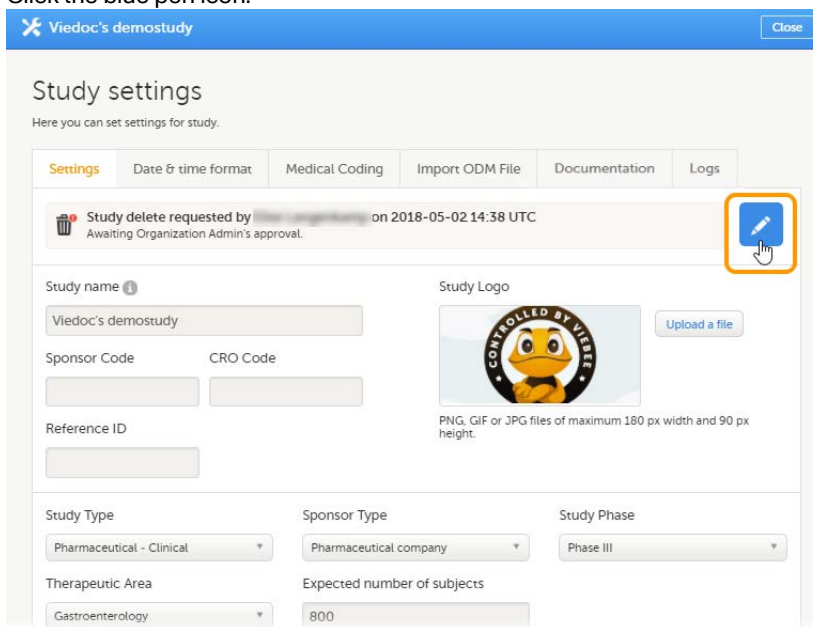


When study deletion is approved, the study will not be visible anymore in Viedoc Clinic or Viedoc Designer, and all user roles will be inactivated. The study will only be displayed to the Organization Administrator on the study overview page.

## 2.2 Rejecting a study delete request

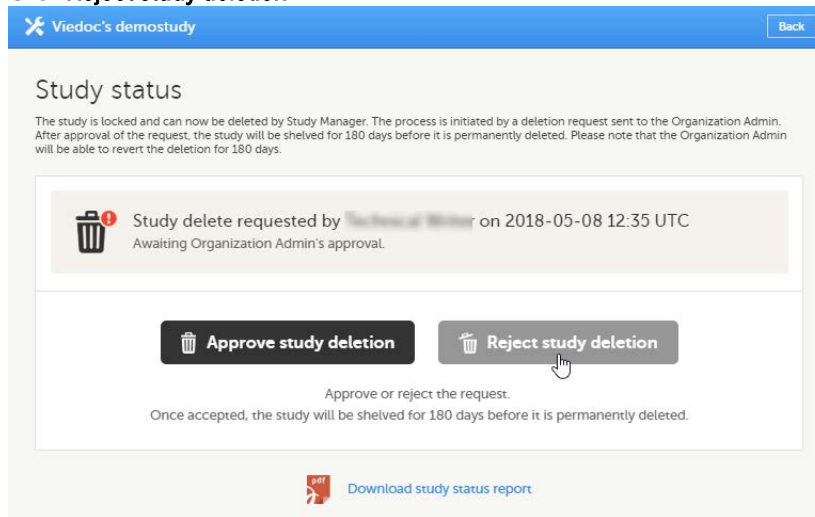
To reject a request for study deletion:

- 1 Open the study in Viedoc Admin and click **Study settings**.  
The **Study settings** dialog opens.
- 2 Click the blue pen icon.



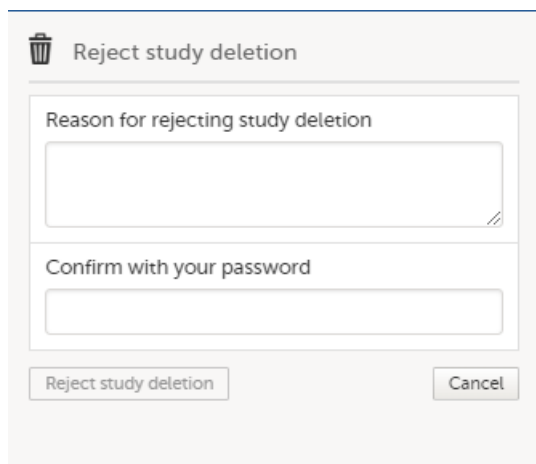
The study status dialog opens.

3 Click **Reject study deletion**.



A dialog opens.

4 Enter a reason for rejecting the study deletion and enter your password.



5 Click **Reject study deletion**.

All Study Managers and Organization Administrators will be notified of the rejection by email.

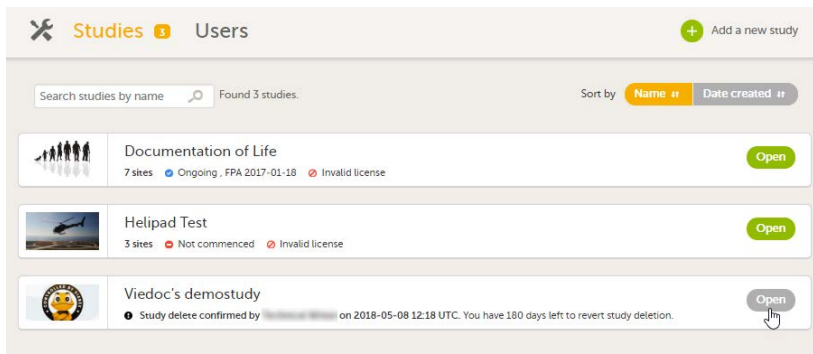
## 2.3 Reverting study deletion

**Note!** Deletion of a study can be reverted within 180 days after study deletion was approved. The study will then be set back to locked state.

To revert the study deletion:

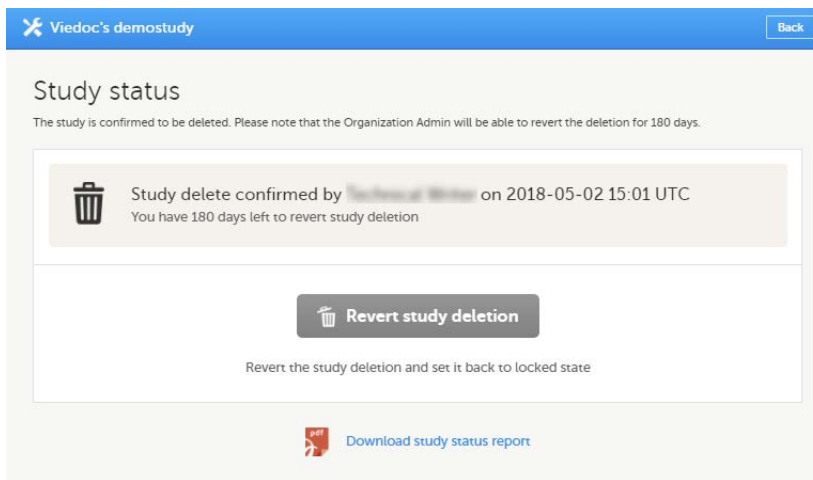


1 Open the study in Viedoc Admin.



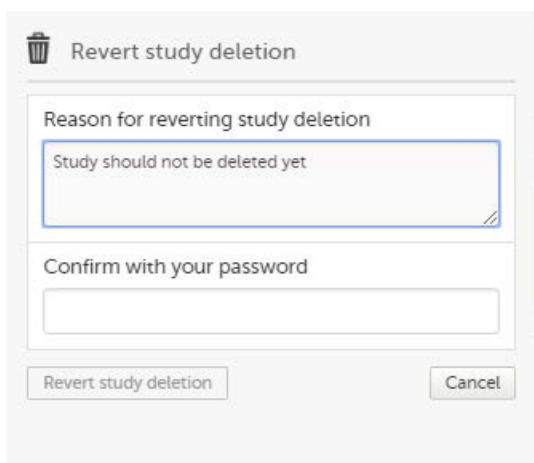
The study status dialog opens.

2 Click **Revert study deletion**.



A pop-up opens

3 Enter a reason for reverting the study deletion and enter your password.



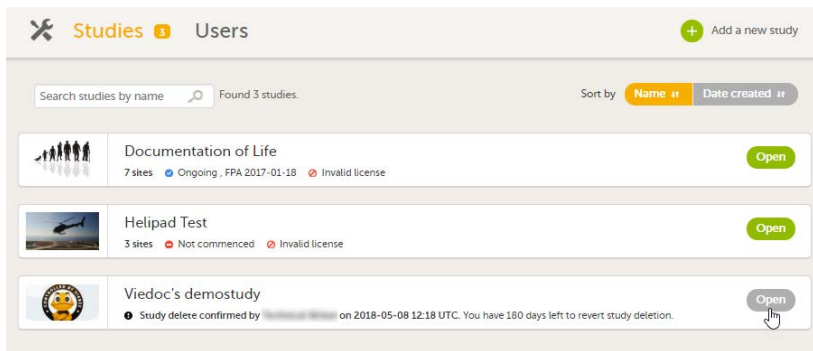
4 Click **Revert study deletion**.

All Study Managers and Organization Administrators will be notified of the reversion of study deletion by email. The study will be set back to locked state and be visible again in Viedoc Clinic and Viedoc Designer.

## 2.4 Downloading the study status report

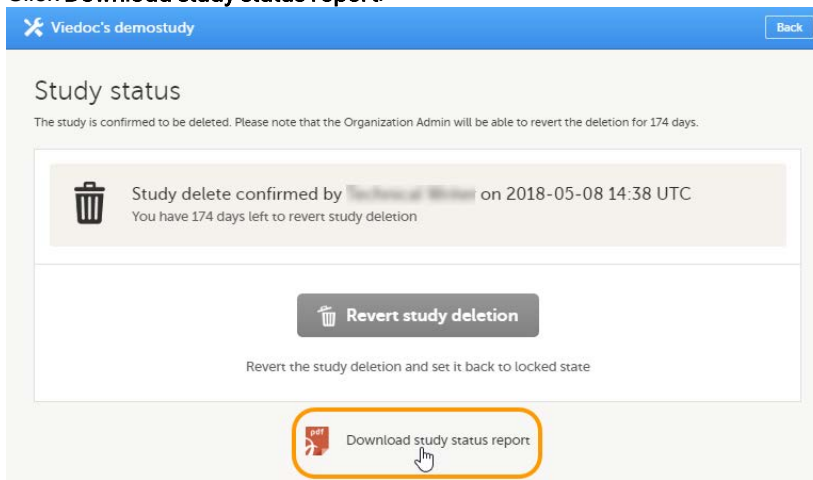
To download the study status report:

1 Open the study in Viedoc Admin.



The Study status dialog opens.

2 Click **Download study status report**.



A PDF is downloaded that lists all database lock and delete actions, including when and by whom the study was locked/deleted, and the reason that was given for locking/deleting the study.



Single sign-on

# Single sign-on

Published by Viedoc System 2020-07-10

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## [1. Introduction](#)

## [2. Configuring single sign-on for your organization](#)

### [2.1 Add domain](#)

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### [2.3 Validate setup](#)

### [2.4 Activate SSO](#)

## [3. Deactivating SSO for your organization](#)

## [4. Deleting an SSO configuration](#)

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## 1 Introduction

Single sign-on ([SSO](#)) is a user verification method that lets you access multiple, independent software systems by using only one set of login credentials (username and password).

Once you have set up and activated SSO for your organization in Viedoc, all users with the same email domain will be authenticated via the external Identity Provider ([IDP](#)) that you specify.

The Viedoc SSO solution uses Security Assertion Markup Language ([SAML](#)) 2.0. It is an open Extensible Markup Language ([XML](#))-based standard for exchanging authentication and authorization identities between security domains.

**Note!** If a user account is set up for SSO, Application Programming Interface ([API](#)) access to Viedoc is not allowed.

## 2 Configuring single sign-on for your organization

Configuring single sign-on in Viedoc is a four-step procedure:

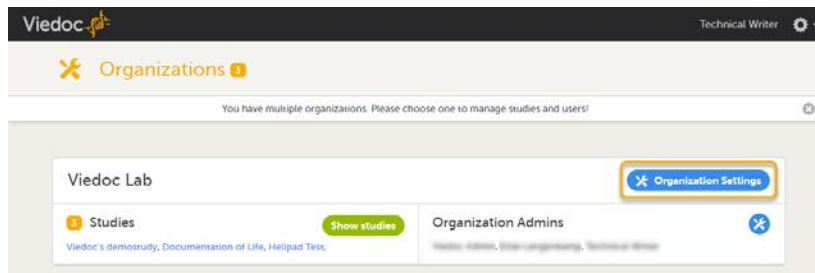
1. **Add domain**
2. **Verify domain**
3. **Validate setup**
4. **Activate SSO**

The steps are described in more detail below.

### 2.1 Add domain

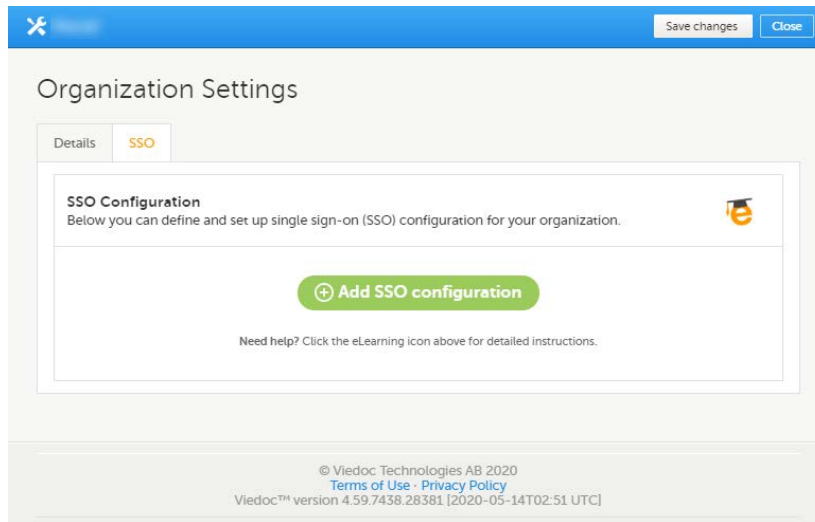
To add a domain:

- 1 Click **Organization Settings**.

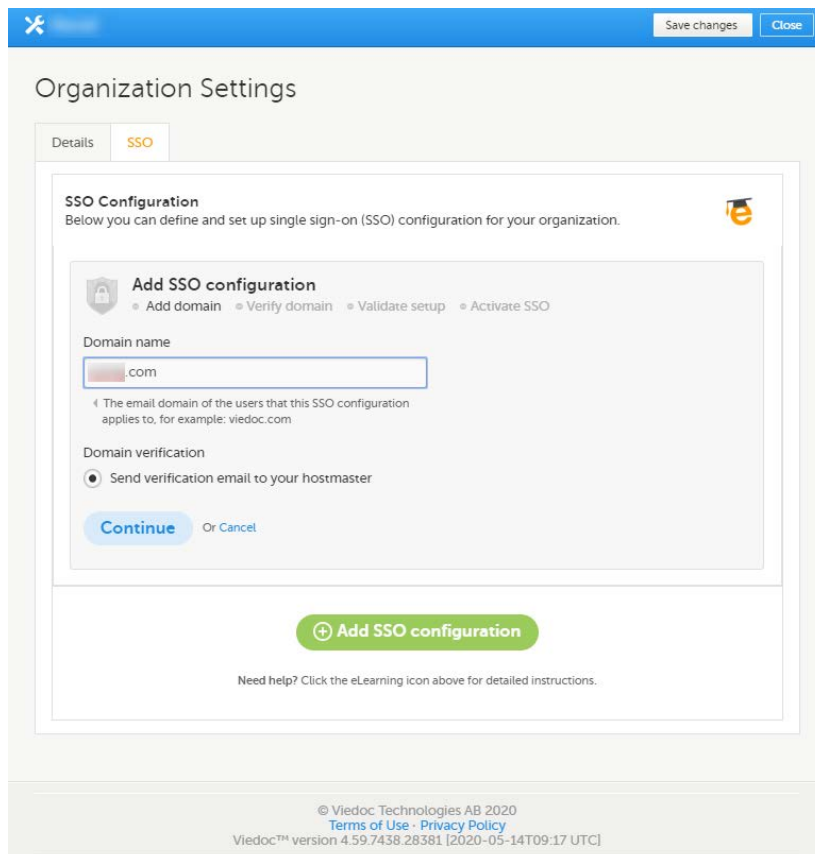


- 2 Click the **SSO** tab.

- 3 Click **Add SSO configuration**.



- 4 Enter the name of the domain that you want the **SSO** configuration to apply to and click **Continue**.

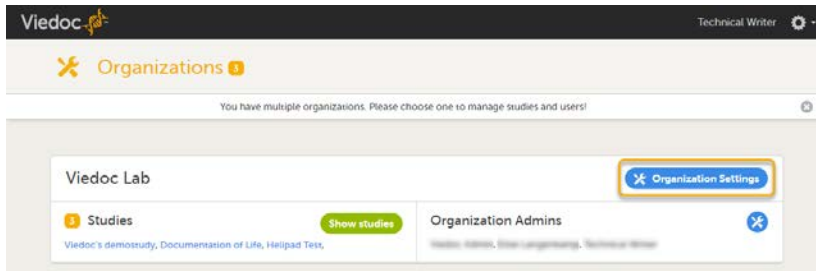


An email is sent to the hostmaster of that domain. The email contains a verification key that you will need in the next step.

## 2.2 Verify domain

To make sure that you are authorized to set up single sign-on for a specific domain, you need to verify ownership of the domain. To do so, follow the steps below:

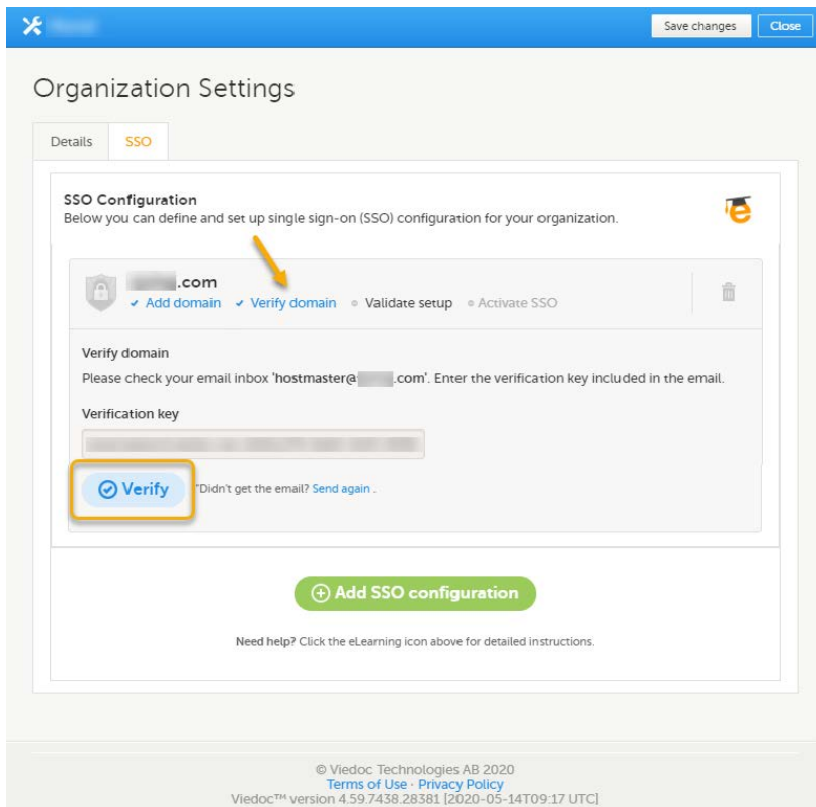
- 1 Click **Organization Settings**.



- 2 Click the **SSO** tab.

- 3 If you are not automatically directed to the **Verify domain** step, click the corresponding link.

Enter the verification key from the email that was sent to the domain hostmaster and click **Verify**.



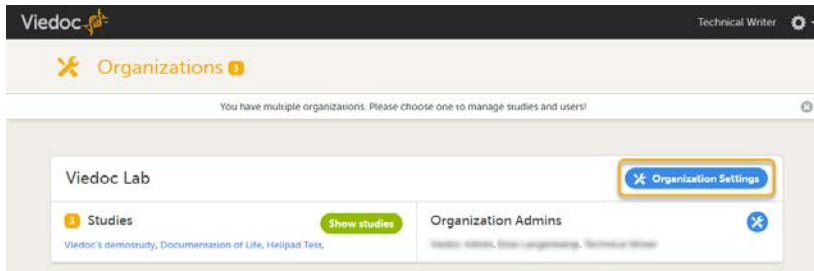
- 4 When the verification is successfully performed, Viedoc automatically redirects you to the **Validate setup** step.

## 2.3 Validate setup

This step specifies the information that is needed for the [SAML](#) setup.

To validate the setup:

1 Click **Organization Settings**.



2 Click the **SSO** tab.

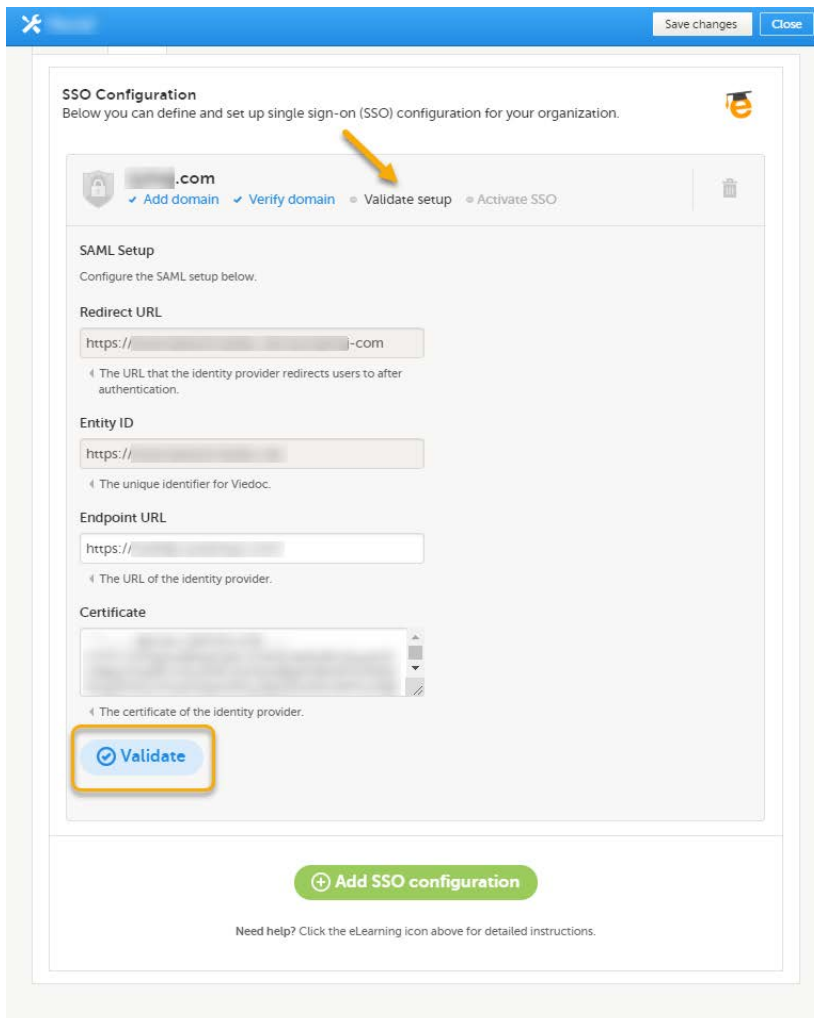
3 If you are not automatically directed to the **Validate setup** step, click the corresponding link.

The fields **Redirect URL** and **Entity ID** are automatically filled in with information retrieved from the previous step. They are not editable in this step. If you need to edit this information, click **Verify domain** to go back one step.

Enter the following information (which you typically can obtain from your IT department):

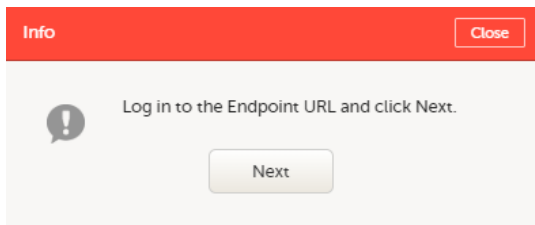
- **Endpoint URL:** This is the URL to the [IDP](#).
- **Certificate:** This is the Base64 certificate of the IDP server.

Click **Validate** to start a trial login sequence. This opens a new browser tab where you are prompted to log in to the specified IDP at the Endpoint URL.



**Note!** For underlying technical reasons, the **Redirect URL** field displays a hyphen ( - ) instead of a period ( . ). This has no effect on the actual URL that the users will be redirected to.

- 4 After logging in to the IDP, return to the Viedoc tab of your browser and click **Next**.



If the validation was **not** successful, please check your settings and try again.

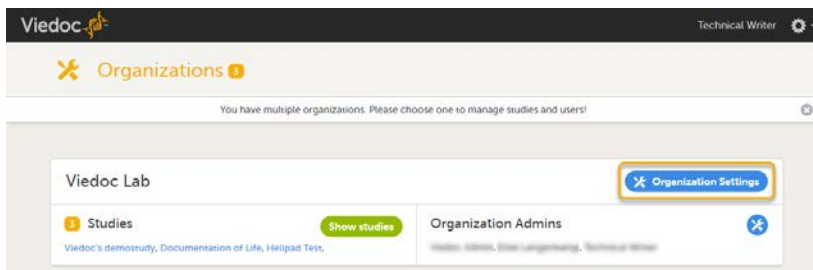
If the validation was successful, you are now ready to continue with the **Activate SSO** step.

## 2.4 Activate SSO

When the steps **Add domain**, **Verify domain**, and **Validate setup** have been successfully completed, you can activate the [SSO](#) configuration.

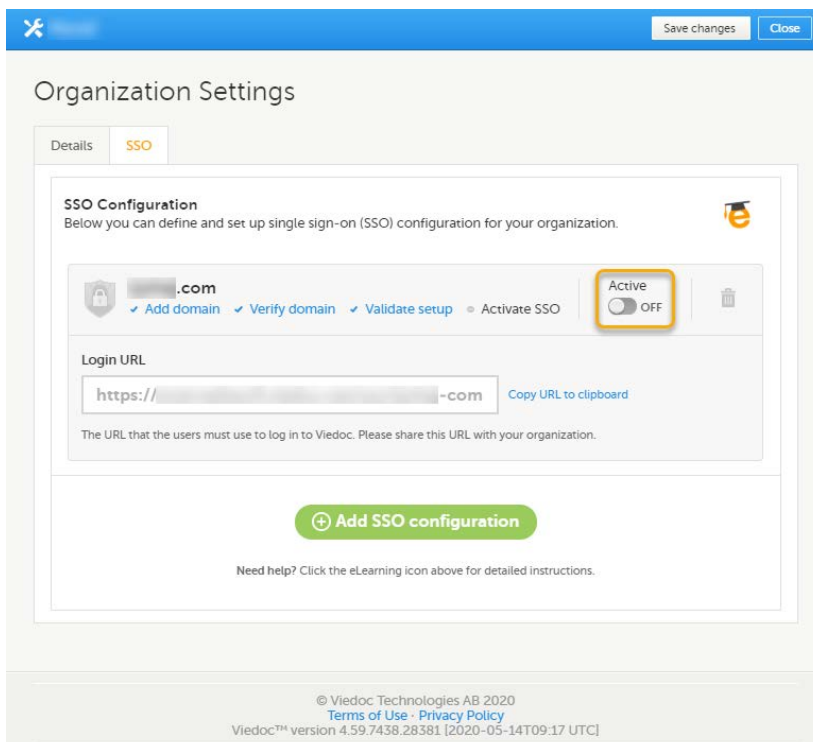
To activate the SSO configuration:

- 1 Click **Organization Settings**.

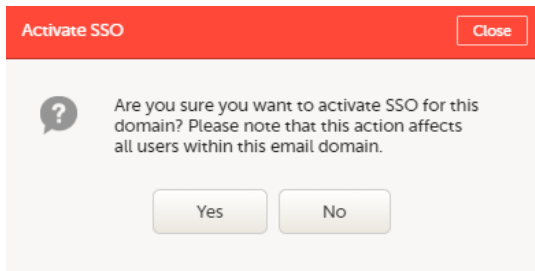


- 2 Click the **SSO** tab.
- 3 If you are not automatically directed to the **Activate SSO** step, click the corresponding link.

Click the **Active** switch to turn it on.



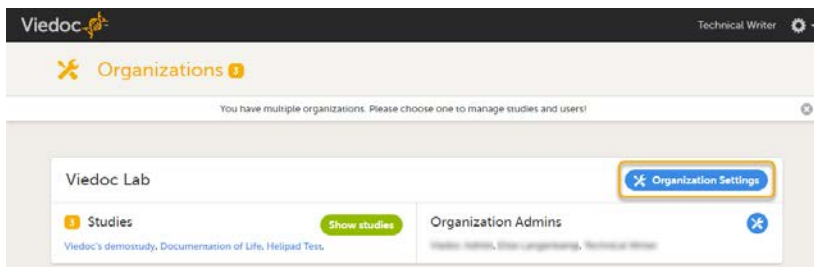
- 4 Copy the login URL and share it with the users in your organization. When you activate the SSO configuration, this is the URL that they must use to log in to Viedoc.
- 5 If all your SSO settings are correct and if your organization has been informed of the new login routine, click **Yes**.



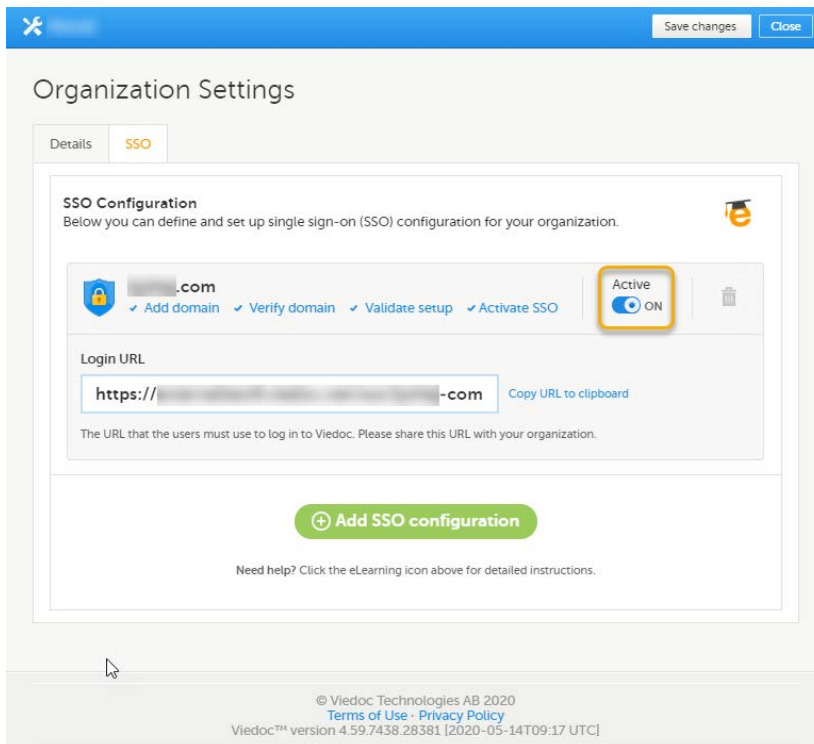
### 3 Deactivating SSO for your organization

To deactivate [SSO](#):

- 1 Click **Organization Settings**.

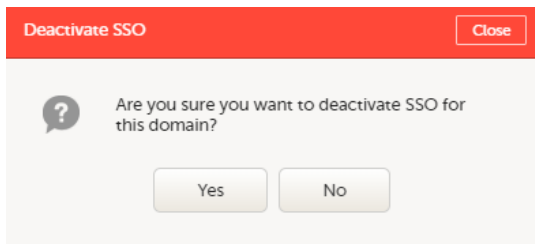


- 2 Click the **SSO** tab.
- 3 Click the **Active** switch to turn it off.





- 4 In the dialog box that is displayed, click **Yes**.

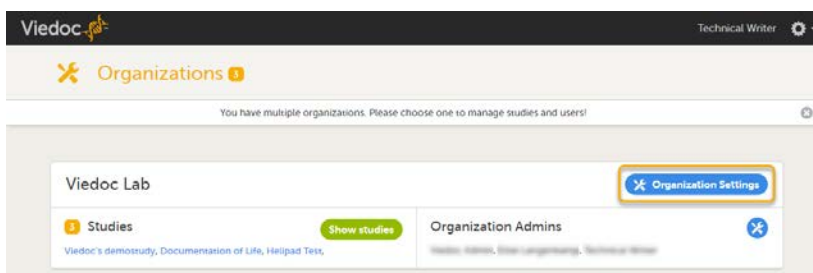


**Note!** Deactivating an SSO configuration does not delete the configuration information from Viedoc.

## 4 Deleting an SSO configuration

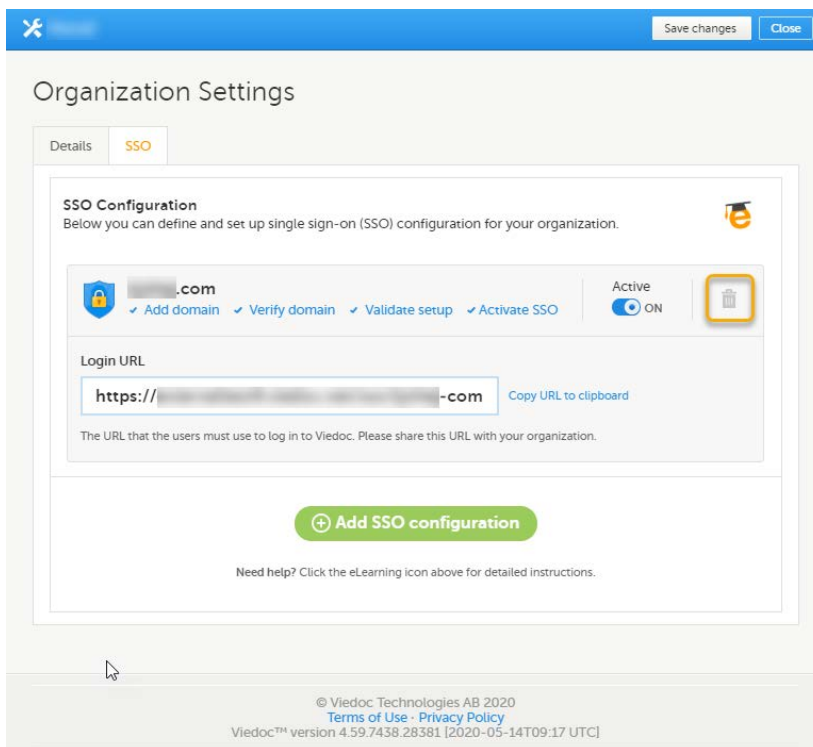
To delete an [SSO](#) configuration:

- 1 Click **Organization Settings**.

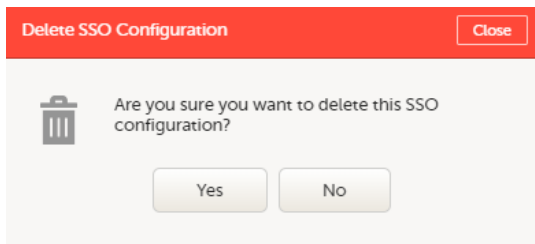


- 2 Click the **SSO** tab.

- 3 Click the trash can icon.



4 In the dialog box that is displayed, click **Yes**.



**Note:** Deleting an SSO configuration affects all Viedoc organizations that use the same SSO configuration.



Downloading VIRP

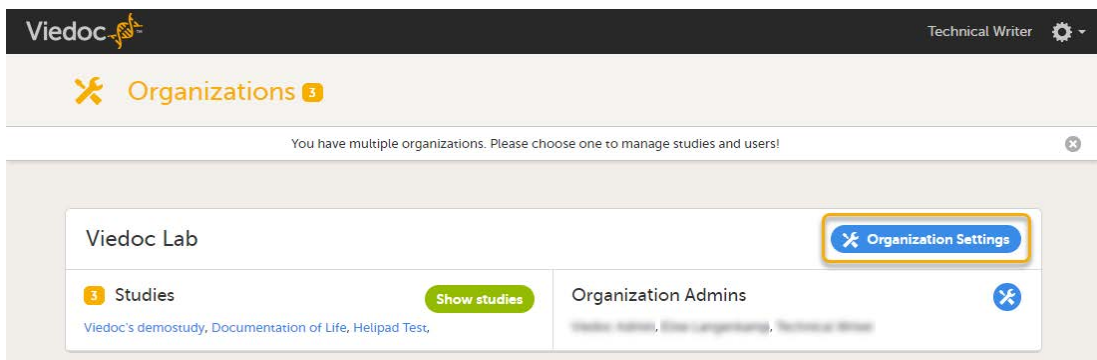
# Downloading VIRP

Published by Viedoc System 2020-08-21

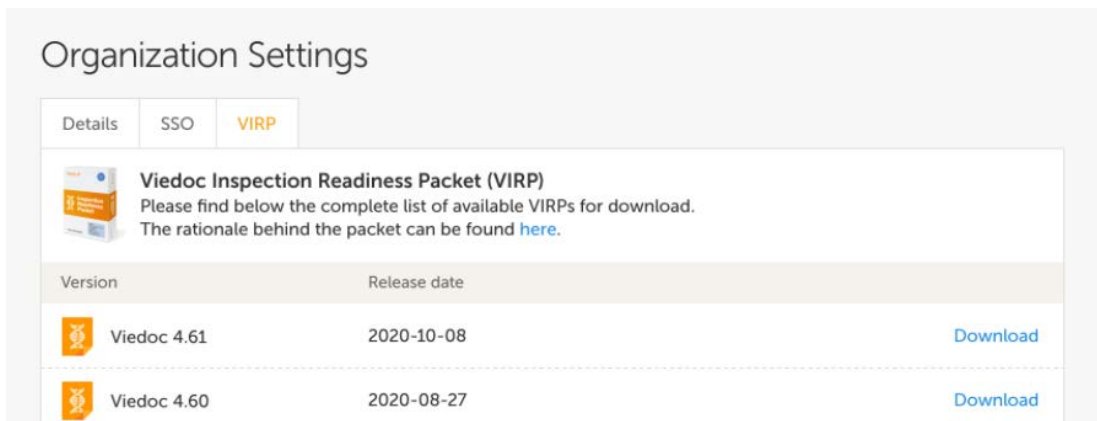
Organization Administrators can download Viedoc Inspection Readiness Packet ([VIRP](#)), which contains all the information you need to fulfill inspector expectations. When using Viedoc, you only need to validate that your study configuration is in compliance with your study protocol, the rest is included in VIRP. You can read more about VIRP [here](#).

To download VIRP:

- 1 Open Viedoc Admin and click **Organization Settings**.



- 2 Click the **VIRP** tab.



- 3 Click **Download** on the packet you wish to download.  
**Note!** All previous Viedoc versions (from 4.0 and onward) are always included in each packet.



General study settings

# General study settings

Published by Viedoc System 2023-10-09

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## [2. The Study settings dialog](#)

## [3. The Settings tab](#)

### [3.1 PMS studies](#)

### [3.2 Adding an additional eLearning curriculum](#)

### [3.3 Study access settings](#)

#### [3.3.1 Password expiration time](#)

#### [3.3.2 Two-factor authentication](#)

### [3.4 Data export compatibility with previous Viedoc versions](#)

#### [3.4.1 Setting the Viedoc version to be used for data export](#)

#### [3.4.2 Available Viedoc versions](#)

## [4. The Date & time format tab](#)

## [5. The Medical Coding tab](#)

## [6. The Import ODM file tab](#)

## [7. The Documentation tab](#)

## [8. The Logs tab](#)

This lesson describes the settings that can be made in **Study settings**.

## 1 Introduction

In **Study settings**, you can configure the general settings of the study such as details about the study, access to the study, and manage the helpdesk. You can also adjust the date and time formats used throughout the whole study, manage the medical coding dictionaries, import Operational Data Model ([ODM](#)) files, and access the Admin audit trail report.

## 2 The Study settings dialog

To open the settings, click **Study settings** on the study details page:

The screenshot shows the Viedoc interface for a study named "2022 - Demo Study". The top navigation bar includes "Studies 197" and "Users". The study details section shows "Ongoing", "FPA 2020-07-10", "Valid license", and "Used data storage: 33.2 MB". A "Study settings" button is visible in the top right. Below this, there are two main sections: "Study crew" and "Study design". The "Study crew" section shows "Study Managers (22)", "Designers (23)", and "Helpdesk team (0)". The "Study design" section shows "Effective" and "Latest" tabs, and a note "Multiple designs in use.". At the bottom, there is a "Study Sites" section with "12 Sites", "4 Countries", and "36 Site users", and a "Show all sites" button. A table below shows the list of sites:

#	Site name	Code	Country	Effective Design	Production	Users
4	University Medical Center Freiburg	96	DE	2020 - Demo Study 54.0	✓	1 / 36


In the **Study settings** dialog, the following tabs are available:

- [Settings](#)
  - [Date & time format](#)
  - [Medical Coding](#)
  - [Import ODM file](#)
  - [Documentation](#)
  - [Logs](#)
- 

## 3 The Settings tab

## Study settings

Here you can set settings for study.

Settings	Date & time format	Medical Coding	Import ODM File	Documentation	Logs
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid #ccc; padding: 5px; border-radius: 5px;"> <p><b>1</b> <span style="color: green;">✔</span> Ongoing , FPA 2020-07-10 Full functionality.</p> <p><b>Included features:</b></p> <div style="display: flex; gap: 5px;"> <span>ViedocMe</span> <span>Logistics</span> <span>Medical coding</span> <span>eTMF</span> <span>Connect</span> </div> </div> <div style="border: 1px solid #ccc; padding: 5px; border-radius: 5px;"> <p><span style="color: green;">✔</span> Valid license <span style="float: right;">✎</span></p> </div> </div>					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>2</b> Study name <span style="font-size: small;">?</span></p> <input type="text" value="2022 - Demo Study"/> <p>Sponsor Code <input type="text"/></p> <p>CRO Code <input type="text"/></p> <p>Reference ID <span style="font-size: small;">?</span></p> <input type="text"/> </div> <div style="width: 45%;"> <p>Study Logo</p> <div style="border: 1px solid #ccc; padding: 5px; text-align: center;">  </div> <p style="font-size: x-small;">PNG, GIF or JPG files of maximum 100 px width and 90 px height.</p> <p style="text-align: center; border: 1px solid #ccc; padding: 2px;">Upload a file</p> </div> </div>					
<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p><b>3</b> Study Type</p> <input type="text" value="Pharmaceutical - Clinical"/> </div> <div style="width: 30%;"> <p>Sponsor Type</p> <input type="text" value="Pharmaceutical company"/> </div> <div style="width: 30%;"> <p>Study Phase</p> <input type="text" value="Phase I/II"/> </div> </div> <p>Therapeutic Area</p> <input type="text" value="Cardiology/Vascular"/>					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>4</b> Expected number of subjects</p> <p>Screened <input type="text" value="200"/> Enrolled <input type="text" value="100"/></p> </div> <div style="width: 45%;"> <p>Expected end date of enrollment period</p> <p><input type="text" value="08 Feb 2023"/> <span style="font-size: x-small;">📅</span></p> </div> </div>					
<p><b>5</b> Study access</p> <p>Password expiration time for all users in this study (values allowed are 1 to 5000) <input type="text" value="90"/> days</p> <p><input type="checkbox"/> Require two-factor authentication for all users accessing this study</p>					
<p><b>6</b> Clinic roles to be administered by Site Manager <span style="font-size: small;">?</span></p> <p> <input type="checkbox"/> Investigator         <input type="checkbox"/> CRC         <input type="checkbox"/> Medical Coder         <input type="checkbox"/> Monitor         <input type="checkbox"/> Data Manager         <input type="checkbox"/> Sponsor         <input type="checkbox"/> Ref Data Manager         <input type="checkbox"/> Report Scheduler       </p>					
<p><b>7</b> Helpdesk team</p>					
<p><b>8</b> ViedocMe</p> <p>Allow reminders in ViedocMe to be sent as <input type="checkbox"/> Email <input type="checkbox"/> Text message</p> <p> <input type="checkbox"/> Force subject to change password at first time login  <input checked="" type="checkbox"/> Use the new application design for training sites  <input type="checkbox"/> Use the new application design for production sites       </p>					

On the **Settings** tab, you can:

1. Click the pen icon to open the **Study status** page, see [Locking a study](#) for more information. Here you can view the study status, the study license status, and the features included in the license. You can also see the production and demo study Globally Unique Identifier ([GUID](#)), which is used for identification of your study when contacting Viedoc support. If you would like to add a feature, please contact your Viedoc representative.
2. Enter details of the study: study name, sponsor code, study logo, and the reference ID (for information

about the reference ID, see the section *Licensing* in [Overview of Viedoc](#)).

3. Enter a description of the study.

4. Set the number of expected screened and enrolled subjects, and the expected end date of the enrollment period. These settings are used by the Metrics and Viedoc Reports applications.

5. Select whether a study will require two-factor authentication and when the password expiry should take place. Please see [Study access settings](#) for more information.

6. Select the clinic roles that are to be administered by the Site Manager instead of the Study Manager, see [Managing users](#).

7. Manage the helpdesk settings, see [Assigning a helpdesk](#).

8. Select the options for Viedoc Me:

- If reminders should be sent to the subjects, as email and/or text messages. For reminders to be sent, at least one of the options must be selected. For more information on how reminders are configured, see the section *Setting Viedoc Me reminders* in [Study workflow](#) in Viedoc Designer User Guide.
- If subjects themselves should be allowed to change their contact information and reminder settings in Viedoc Me. This option appears only if enabling reminders, by selecting the option(s) **Email/Text message**.
- If subjects should be forced to change their PIN code when they log in to Viedoc Me for the first time, and after the clinic staff reset their PIN code.
- If the new application design should be used for production and training sites.

#### Study-specific considerations for text message reminders in China

When studies are run with Viedoc Me in China and text message reminders are used, we need to have the message contents approved by the underlying text message gateway providers, in order to comply with the Cyber Security Law of the Peoples Republic of China, so that the text messages are allowed and come through to the trial subjects. After you have finalized the message contents, you will need to contact your Viedoc representative and provide some details of the study so that we can get the approval. Please plan for one week for your request to process. All system functionality works in the same way and if you're not looking at the URL, you won't notice the difference between the Chinese and European instances.

When you click **Show more options**, the following options appear:

9  Enable documentation and training ⓘ  
 Prevent access to Demo sites until mandatory documentation and training sections are confirmed.

10  Enable Viedoc Reports

11 Activation Password ⓘ

12 File protection password ⓘ

13  Allow single sites to be in both modes (production and training mode) ⓘ

14  Allow roles with Lock data permission to unlock forms submitted from Viedoc Me

15  Allow Clinic users to change an automatically assigned event date

16  Enable navigation to extended selection pages

17  Enable subject edit lock only for users with edit permissions ⓘ

18  Enable item-level SDV ⓘ

19  Allow user to override default output version in Data Export  
 Default output version

### 9. Enable documentation and training

- The option **Enable documentation and training** is **selected** by default for studies starting after the release of Viedoc 4.51 (May 2019).

Enable documentation and training ⓘ  
 Prevent access to Demo sites until mandatory documentation and training sections are confirmed.

When this option is selected, then:

- All documentation is set up in Viedoc Admin.
- The user can upload study specific documentation, set up eLearning guides and make them available to different user roles, as well as set up mandatory documentation for user certification. This is described in detail in [Setting up user documentation and training](#).
- The eLearning settings are not available in Viedoc Designer. Instead, all the eLearning curriculums and additional documentation is setup in Viedoc Admin.
- The option **Prevent access to Demo sites until mandatory documentation and training sections are confirmed** becomes available. If selected, clinic users that are assigned mandatory documentation will not be able to launch the study at all, not even in demo mode, until all mandatory documentation is read and signed. If deselected, clinic users can launch the study only in demo mode until the mandatory documentation is read and signed. For more details, see [Setting up user documentation and training](#).



- The option **Enable documentation and training** is **deselected** by default for studies that started **before** the release of Viedoc 4.51.

The screenshot shows a settings form with the following elements:

- A checkbox labeled "Enable documentation and training" with an information icon, which is currently unchecked.
- Two input fields below the checkbox: "eLearning title" and "eLearning URL".

When this option is deselected, then:

- All documentation is set up in Viedoc Designer. See [eLearning settings](#) for more information.
- The fields **eLearning title** and **eLearning URL** can be used for adding an additional curriculum to the eLearning curriculums that have been set up for the study in Viedoc Designer, see [Adding an additional eLearning curriculum](#) for more information.

**10. Enable Viedoc Reports.** When this option is selected, users with Reports permission are able to launch Viedoc Reports from the Metrics feature.

**11. Activation password.** If a password is set, all study users (clinic roles and system roles) are required to enter that password to access the study. This password is required only once, when the user accepts a role invitation and accesses the study for the first time.

**12. File protection password.** If **Attach form PDF** is selected for an email copy of alert messages, there is an option to enable password protection for the attached files. If a file protection password is set here, the attached form PDFs sent with the alert emails will be password protected and the user receiving the email needs the password in order to open the file. Only study users with edit rights for study settings, (the Organization Administrator and the Study Manager) can edit and save a password. Study users with view permission (the Site Manager) can view the file protection password. The file protection password option is also available for Japanese PMS studies.

**Note!** If the option to enable file protection password is not set (the field is not filled in), the attached files will not be password protected.

**13. Allow single sites to be in both modes (production and training mode).** If this option is selected, a site can operate as either a production environment, a demo (training) environment, or both (that is, you can select between the two). This is used to invite users to a training site before they go live. After the training, the site can be activated (that is, set to production).

**14. Allow roles with Lock data permission to unlock forms submitted from Viedoc Me.** When this option is selected, users with lock permission can unlock forms submitted by subjects through Viedoc Me, so that the forms are open for data edit by for example the Investigator. This option is automatically selected for all studies starting after the Viedoc release 4.48 in February 2019. For studies that started earlier, this option is by default set to inactive, and can be selected manually.

**15. Allow Clinic users to change an automatically assigned event date.** If this option is selected, it is possible for the clinic users to change automatically set event dates in the Event date form, if the date is based on the first data entry. The event date is **not** editable if it is based on a form item. For more information, see [Study workflow](#) in Viedoc Designer User Guide.

**16. Enable navigation to extended selection pages.** When this option is selected, users can navigate between all the selection pages that they have access to in Viedoc Clinic.

**17. Enable subject edit lock only for users with edit permission.** When this option is selected, multiple users without edit permissions (for example, monitors and data managers) can, in Viedoc Clinic, work on the same subject that is being edited by a user with edit permission (for example, an investigator or a study coordinator).

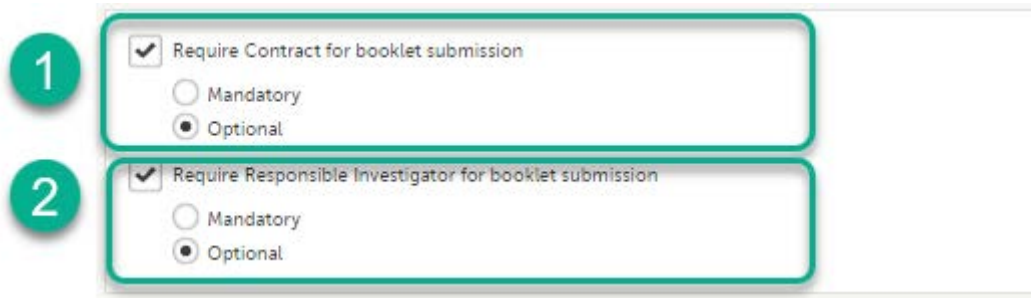
**18. Enable item-level SDV.** If this option is selected, users with SDV permission can apply SDV to individual items in a form. This option is **deselected** by default for studies that started **before** the release of Viedoc 4.77. The option is **selected** by default for studies that start **after** the release of Viedoc 4.77.

**19. Allow user to override default option version in Data Export,** see [Data export compatibility with previous Viedoc versions](#) below for more information.

### 3.1 PMS studies

**Note!** In addition to the options described in the previous section, there are two settings available under **Show more options** for Japanese PMS Studies.

- 1. Require Contract for booklet submission.** This option is cleared by default. When this option is selected, there is the option to link a booklet to one of the available *contracts* for that site in Viedoc Clinic at the time of submitting the booklet. You can choose to make this option **Mandatory** or **Optional** - The default is **Optional**.
- 2. Require Responsible Investigator for booklet submission.** This option is cleared by default. When selected, there is the option to link the booklet to a *Responsible Investigator* at the time of submitting the booklet. You can choose to make this option **Mandatory** or **Optional** - The default is **Optional**.



### 3.2 Adding an additional eLearning curriculum

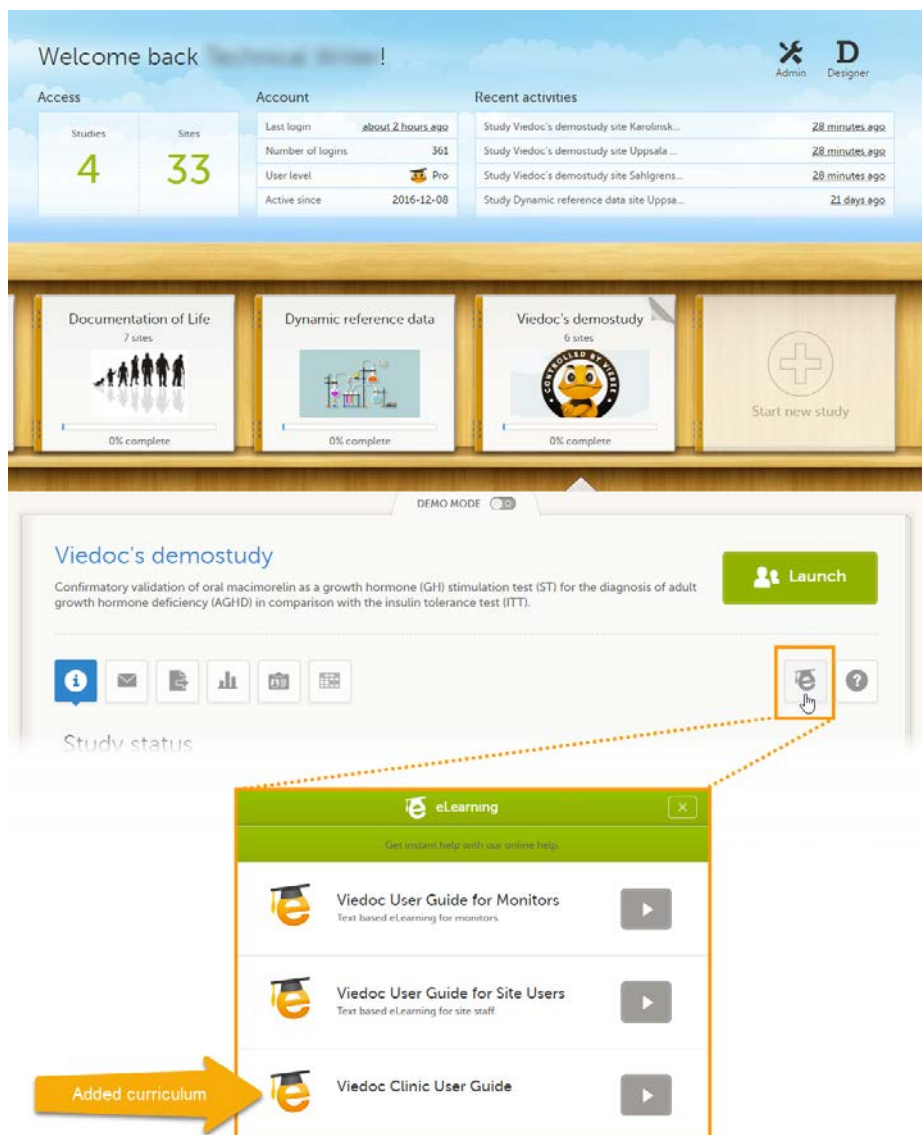
On the **Settings** tab, if **Enable documentation and training** is **deselected**, the eLearning curriculums that clinic users have access to from Viedoc Clinic are configured in Viedoc Designer. For details, see [eLearning settings](#) and [Configuring roles](#) in Viedoc Designer User Guide.

If **Enable documentation and training** is **selected**, it is possible to add an additional curriculum from Viedoc Admin that clinic users can access when launching the eLearning from Viedoc Clinic.

To add an additional curriculum:

- 1 In Viedoc Admin, click **Study settings**.  
The **Study settings** dialog opens.
- 2 On the **Settings** tab, scroll down to the bottom of the dialog and click **Show more options**.
- 3 Enter the name of the curriculum you would like to add in the **eLearning title** field. Enter the URL to that curriculum in the **eLearning URL** field.
- 4 Click **Save changes**.  
The dialog closes.

If a clinic user launches the eLearning from the landing page in Viedoc Clinic, a dialog appears in which the clinic user can select which eLearning curriculum he/she would like to view. The newly added curriculum is included in the dialog.



### 3.3 Study access settings

On the **Settings** tab, in the **Study access** field, you can configure the password expiration time and activate two-factor authentication for all users in the study.

#### 3.3.1 Password expiration time

If a user has access to more than one study, the password settings for all studies are checked upon login. If the password expiration settings for any of these studies dictate that the password is expired, the user is redirected to the **Change password** dialog and is forced to change his/her password. An internal message displayed on the Messages page in Viedoc Clinic will notify the user about the password expiration time ten days in advance.

The password expiration time can be set to any value between 1 day and 5000 days.

#### 3.3.2 Two-factor authentication

The use of two-factor authentication provides an extra security measure at login. After entering the user name and password, the user is required to enter an authentication code that he/she received via text message or email to be able to login.

### 3.4 Data export compatibility with previous Viedoc versions

When exporting data, Viedoc offers the possibility to create a data export file that is compatible with files exported from previous versions of Viedoc. The default Viedoc version that is used when exporting data can be set in Viedoc Admin.

#### 3.4.1 Setting the Viedoc version to be used for data export

To set the Viedoc version to be used for data export:

- 1 In Viedoc Admin, select **Study settings** to open the study settings dialog.
- 2 On the **Settings** tab, select **Show more options**.

- 3 Select the default export output version from the **Default output version** dropdown list.

- 4 If you would like to allow clinic users to be able to override the default output version and select the output version themselves, select **Allow user to override default output version in Data Export**. When this option is selected, clinic users can select the export output version themselves. If this option is left deselected, clinic users can only export data in the output version selected here.
- 5 Click **Close** to save the changes.

### 3.4.2 Available Viedoc versions

The Viedoc versions available in the **Output version** dropdown menu are only those versions in which changes to the data structure were introduced.

As of Viedoc release 4.77, the following output versions are available:

Output version	Changes in data structure
Latest Viedoc version	When choosing <b>Latest Viedoc version</b> , the exported data will automatically follow the structure of the latest Viedoc release in which changes to the data structure were introduced.
Viedoc 4.77	For studies where item-level SDV is enabled, when exporting review status, the SDV sheet in the CSV and Excel data exports will include only the items that require SDV and are visible to the user. On the Review status sheet, items that do not require SDV are indicated with N/A.
Viedoc 4.68	Introduction of pdf archive export system check which splits the archive into one pdf file per subject and stores resultant PDF in a zip file.
Viedoc 4.67	Introduction of two new columns for approving medical coding: "approved by" and "approved on date".
Viedoc 4.51	Introduction of three new form repeat keys and the table of contents in the PDF export, see the table below for details
Viedoc 4.39	Introduction of repeating forms and recurring events, see the table below for details.
Viedoc 4.38	Original output format (Viedoc versions 4.38 or older).

In **Viedoc 4.51**, the following changes to the export output were introduced:

File type	Changes in the export output format
Excel	<p>Addition of three columns for the new form sequence numbers introduced:</p> <ul style="list-style-type: none"> <li>▪ <code>SubjectFormSeqNo</code> – Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and is incremented each time a new instance of the form is created for that subject.</li> <li>▪ <code>OriginSubjectFormSeqNo</code> – For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the <code>SubjectFormSeqNo</code>.</li> <li>▪ <code>SourceSubjectFormSeqNo</code> – For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the <code>SubjectFormSeqNo</code> from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty.</li> </ul>
ODM	Three new form sequence numbers were introduced, as Viedoc extensions: <code>v4:SubjectFormSeqNo</code> , <code>v4:OriginSubjectFormSeqNo</code> and <code>v4:SourceSubjectFormSeqNo</code> , within the <code>FormData</code> , right after the <code>FormRepeatKey</code> .
PDF	A table of contents was added to the PDF archive, starting on page 2 of the file.

In **Viedoc 4.39**, the following changes to the export output were introduced:

File type	Changes in the export output format
Excel	Addition of a column for Form sequence number ( <code>FormSeq</code> ) that contains the <code>FormRepeatKey</code> .
ODM	The <code>FormRepeatKey</code> now contains the activity ID as well, in the following format: <code>FormRepeatKey\$ActivityId</code> . The <code>ExportVersion</code> attribute has been added to the ODM.
PDF	The summary formats are used to display the event and form names.

## 4 The Date & time format tab

On the **Date & time format** tab, you can edit the format of date and time used in all fields displaying a date or a time in Viedoc.

Study settings

Here you can set settings for study.

Settings **Date & time format** Medical Coding Import ODM File

Date culture  
User selected language

Date pattern ⓘ  
dd MMM yyyy 16 Apr 2018

Unknown day pattern ⓘ  
MMM yyyy 1 Apr 2018

Unknown month pattern ⓘ  
yyyy 2018

Date & time pattern ⓘ  
dd MMM yyyy HH:mm 16 Apr 2018 10:59

Time pattern ⓘ  
HH:mm 10:59

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Viedoc™ version 4.42.6680.18569 [2018-04-16T08:59 UTC]

You can edit the date and time format in two different ways:

- By selecting a language from the **Date culture** dropdown list on the **Date and time format** tab. Dates and times will then be displayed in the format that is used in the selected language.
- By directly entering a pattern in one or more fields on the **Date and time format** tab.

You can choose one of the following formats:

Date/time format	Description	Example
dd	Two-digit day of the month	01
d	One-digit day of the month	1
MMMM	Name of the month fully spelled	February
MMM	Abbreviated name of the month (three letters)	Feb
MM	Two-digit number of the month	02
yyyy	Four-digit year	2010
yy	Two-digit year	10
HH	Two-digit 24-hour time	08:15
H	One-digit 24-hour time	8:15
hh	Two-digit 12-hour time (use in conjunction with tt)	08:15 am

Date/time format	Description	Example
h	One-digit 12-hour time (use in conjunction with tt)	8:15 am
mm	Two-digit minutes	15
ss	Two-digit seconds	30
tt	am or pm	am

You can configure the following date and time fields:

Date field	Description
Date pattern*	Format for dates, in cases where day, month and year to be entered are known
Unknown day pattern	Format for dates, in cases where only the month and year to be entered are known
Unknown month pattern	Format for dates, in cases where only the year to be entered is known
Date & time pattern*	Format for dates, in cases where both date and time are to be entered
Time pattern*	Format for times

\*For studies that use the Viedoc eTMF application, the patterns set in Viedoc Admin will be inherited by the eTMF application.

After you have edited the date and time format, click **Save changes** to save the settings and close the dialog.

## 5 The Medical Coding tab

On the **Medical Coding** tab, you can attach medical coding dictionary instances to medical coding scopes. For more information about managing the medical coding dictionaries, see [Managing medical coding dictionaries](#).

## 6 The Import ODM file tab

On the **Import ODM file** tab, you can upload and import [ODM](#) files. For more information on how to upload an ODM file, see [Importing data from ODM file](#).

## 7 The Documentation tab

On the **Documentation** tab, you can manage the documentation and training sections. For detailed information about the documentation and training, see [Setting up user documentation and training](#).

**Note!** This tab is visible only if the option **Enable documentation and training** is selected in **Study settings**.

## 8 The Logs tab

On the **Logs** tab, you can generate and download an Admin audit trail report in Excel format.

The Admin audit trail report contains information about all settings and changes of study settings that have been made by authorized users in Viedoc Admin.


If the report has already been generated, you can download the latest generated report or regenerate it.

2022 - Demo Study Close

### Study settings

Here you can set settings for study.

Settings	Date & time format	Medical Coding	Import ODM File	Documentation	Logs
----------	--------------------	----------------	-----------------	---------------	------

 **Admin audit trail report**  
[Download 2022-08-09 08:41:35](#) | [Regenerate](#)

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Viedoc™ version 4.72.8258.11291 [2022-08-11T08:40 UTC]

For more information about the report, see [Admin audit trail report](#).





Setting up user documentation and training

# Setting up user documentation and training

Published by Viedoc System 2020-01-30

## 1. Introduction

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- [1.2 For new studies starting after Viedoc release 4.51](#)
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## 2. Managing training sections

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- [2.3 Archiving/Restoring a section](#)
- [2.4 Deleting a section](#)

## 3. How it looks in Viedoc Clinic

## 4. Users not certified

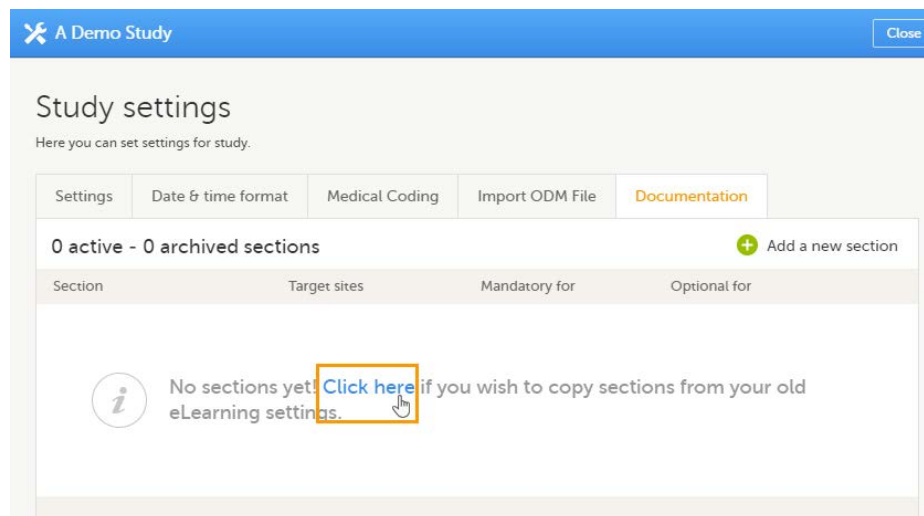
# 1 Introduction

If the **Enable documentation and training** option is checked under Study Settings (see [General study settings](#)), a separate **Documentation** section is available in Viedoc Admin under Study Settings, that allows to:

- Make the Viedoc eLearning curriculums available for clinic users.
- Enable site user certification, by setting up mandatory documentation to be read and signed by the users.
- Add new URL(s) or upload file(s) and make them available to clinic users.

## 1.1 For ongoing studies started before Viedoc release 4.51

If the **Enable documentation and training** option is checked under Study Settings in Viedoc Admin for ongoing studies (started before Viedoc release 4.51), any already configured eLearning sections in Viedoc Designer will not be available anymore. Instead, these can be copied and transferred from Viedoc Designer to Viedoc Admin, by clicking the link that is available when accessing the **Documentation** page, as illustrated below:



**Note!** This operation can be performed only:

- if there were existing eLearning sections defined in Viedoc Designer before selecting the **Enable documentation and training** option under Study Settings in Viedoc Admin, and
- before any new sections are added in Viedoc Admin under **Documentation**.

As a result, the existing eLearning sections from Viedoc Designer are copied and listed under the **Documentation** tab and can be further configured (that is, assigned to specific roles/sites), as described later in this lesson.

## 1.2 For new studies starting after Viedoc release 4.51

For new studies, starting after Viedoc release 4.51 in May 2019, the following 5 role-based Viedoc eLearning curriculums for site staff are provided by default as training sections:

Viedoc eLearning curriculum	Section URL
Viedoc User Guide for Site Users	https://help.viedoc.net/c/94d6f0
Viedoc User Guide for Monitors	https://help.viedoc.net/c/c63e06
Viedoc User Guide for Data Managers	https://help.viedoc.net/c/1994d8
Viedoc User Guide for Project Managers	https://help.viedoc.net/c/04361f
Viedoc User Guide for Medical Coders	https://help.viedoc.net/c/3108de
Viedoc User Guide for Supply Managers (for Logistics)	https://help.viedoc.net/c/4a40d5/
Viedoc PMS User Guide for Clinic Side Users	https://help.viedoc.net/c/91715f
Viedoc PMS User Guide for Sponsor Side Users	https://help.viedoc.net/c/590df1

In order to make these curriculums available for the different clinic roles, you need to edit each of the training sections, as described in section [Editing a training section](#) below.

## 1.3 Overview of Documentation page

The **Documentation** tab under **Study Settings** provides a list of all the existing sections, as illustrated in the following image.

A training section is a piece of documentation (either a file or an URL) that can be made available (as optional or mandatory) for specific user roles within specific sites, as instructed in [Managing training sections](#) below.

The screenshot shows the 'Study settings' interface with the 'Documentation' tab selected. It displays a table of active sections:

Section	Target sites	Mandatory for	Optional for
Study Protocol	All sites	All roles	
CRF Completion Guidelines	All sites	Monitor	Investigator
Viedoc User Guide for Site Users	Demo Site		Investigator
Viedoc User Guide for Monitors	Demo Site		Monitor
Viedoc User Guide for Data Managers	Demo Site		Data Manager

On the top bar you can see:








- to the left - a summary of the total number of sections as well the number of archived sections.
- to the right - the plus-icon for adding a new section. See [Adding a new section](#) below.

For each section in the list the following information is provided:

- Section - the icon illustrating the section type, as listed in the table below, followed by the section name as set when adding or editing the section (see [Editing a section](#) below). By clicking the section name link you

- can open the respective file/URL.
- Target sites - the site(s) the section is set for.
- Mandatory for - the roles for which the section is set as mandatory.
- Optional for - the roles for which the section is set as optional.
- Edit section - the tools icon link that allows you to open the section page where you can edit/archive/delete the section. See [Editing a section](#) below.

The section icons for various types of files/URLs used are listed in the table below:

Icon	Description
	URL to Viedoc eLearning system
	URL (other than Viedoc eLearning, mentioned above)
	PDF file
	Word document
	Excel file
	Power Point file
	Other file type than the ones mentioned above

## 2 Managing training sections

### 2.1 Adding a new section

To add a new section, follow the steps below.

1

Click **Add a new section** link on the top right of the Documentation page. The **Add a new training section** page is displayed.

The screenshot shows the 'Add a new training section' form. At the top, there is a blue header with the text 'User Certification' and two buttons: 'Add section' and 'Close'. Below the header, the main title is 'Add a new training section' and the subtitle is 'Manage training section settings here'. The form is divided into several sections: 1. 'Section URL or file': A text input field with an 'Upload a file' link to its right. 2. 'Section title': A text input field. 3. 'Priority': A numeric input field with the value '8' and a maximum of '8'. 4. 'Description': A large text area for entering the section's description. 5. 'Target sites': A dropdown menu with the placeholder text 'Select site group(s) or site(s)'. 6. 'Require signing for following roles': A dropdown menu with the placeholder text 'Select role(s)'. Below this is a checkbox labeled 'Require re-signing after # of days' with a numeric input field set to '365'. 7. 'Optional for following roles': A dropdown menu with the placeholder text 'Select role(s)'.

Here you can set the following:

- **Section URL or file** - mandatory
  - if you want to add a link, just type in the URL
  - if you want to add a file, click **Upload a file** to the right, browse for the file and add it.
- **Notes!**
  - The restricted file formats are listed in **Blacklisted file formats** chapter in [this lesson](#).
  - The maximum file size is 100MB. The size of the uploaded files is counted in the total amount of data used by a study, that can be monitored in Viedoc Admin on the Studies overview page and on the Study page - **Used data storage**.
- **Section title** - type in the section title that will be displayed both in the Documentation page in Viedoc Admin under Study Settings, as well as in Viedoc Clinic. This field is mandatory.
- **Priority** - the number that defines the position of the section in the list displayed under the Documentation page, from 1 (first position in the list) to  $n$  (last position in the list), where  $n$  is the total number of sections. By default, this is set to the last position ( $n$ ). This field is mandatory.
- **Description** - additional descriptive text for the section, that will be displayed in Viedoc Clinic under Documentation & training, as illustrated in section [How it looks in Viedoc Clinic](#). This field is optional.
- **Target sites** - click and select the site(s) or site group(s) that the clinic user shall have access to in order to see the section in Viedoc Clinic. If a site group is selected (including *All sites*), the site(s) added to the group in the future will also get access. If empty, the section will not be displayed in Viedoc Clinic under Documentation & training, as illustrated in section [How it looks in Viedoc Clinic](#). This field is optional.
- **Require signing for following roles** - click and select the clinic roles that will have the section as mandatory reading in Viedoc Clinic. If you select *All roles*, the clinic roles added in the future will also get the section as mandatory reading. If empty, the section will not be displayed in Viedoc Clinic under Documentation & training > Mandatory section. This field is optional.
  - **Important!** Users to whom mandatory documentation is assigned will not be able to launch the study (except for demo mode, depending on the study settings, see [General study settings](#)) until the user has read and signed all the mandatory documentation.
- **Require re-signing after # of days** - if checked, a new signature is required in Viedoc Clinic after the specified number of days (default is 365) from the previous signing date. If the checkbox is selected, the number of days is mandatory. This field is optional and unchecked by default.
- **Optional for following roles** - here you can add reference documentation for your study that will be available for clinic users. Click and select the clinic roles that will have the section as

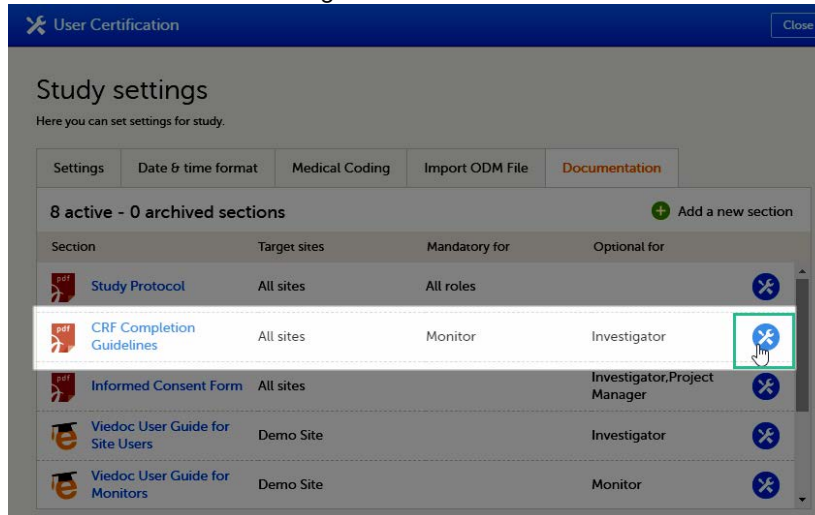
optional reading in Viedoc Clinic. If you select *All roles*, the clinic roles added in the future will also get the section as optional reading. If empty, the section will not be displayed in Viedoc Clinic under Documentation and training > Optional sections. This field is optional.

- 2 Click **Add section** on the top right of the page. The section will be added to the list under the **Documentation** page.

## 2.2 Editing an existing section

To edit an existing section, follow the steps below.

- 1 Click the toolbox icon to the right of the section in the list:



The edit section page opens.

- 2 Perform the changes you need and click **Save changes** in the the top right of the page. You can edit all the fields, except for the Section URL/file. For a detailed description of the fields, see [Adding a new section](#).

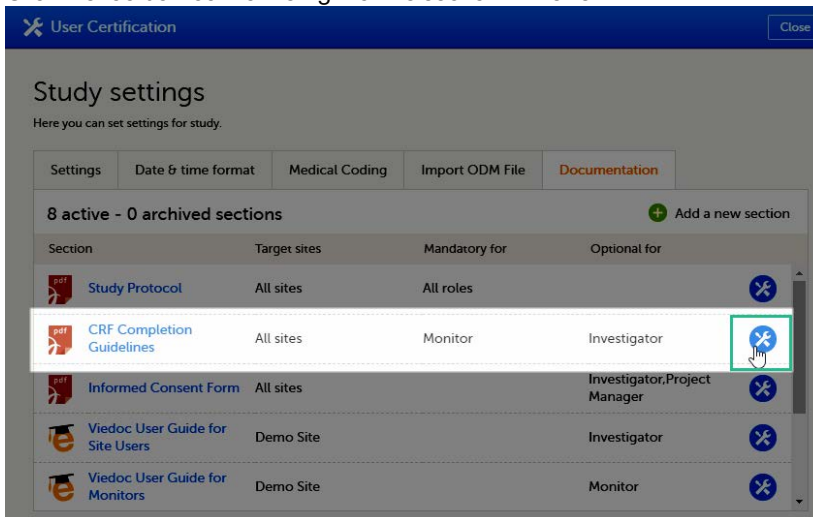
## 2.3 Archiving/Restoring a section

It is possible to archive an existing section, for versioning purposes. For example, if we have an existing section with the study protocol file (version 1), and, at some point, we get an updated version of the file (version 2) that we want to make accessible for clinic users. In this case, we would archive the section that contains the version 1 of the file and would add a new section where we upload the version 2 of the study protocol.

An archived section will no longer be accessible in Viedoc Clinic under Documentation & training (as illustrated in section [How it looks in Viedoc Clinic](#)). An archived section can be restored at any time, becoming accessible again in Viedoc Clinic, according to the settings made for the section.

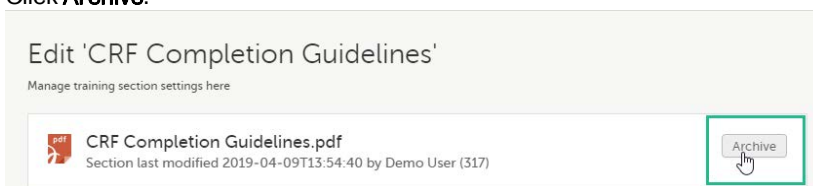
To archive an existing section, follow the steps below.

1 Click the toolbox icon to the right of the section in the list:

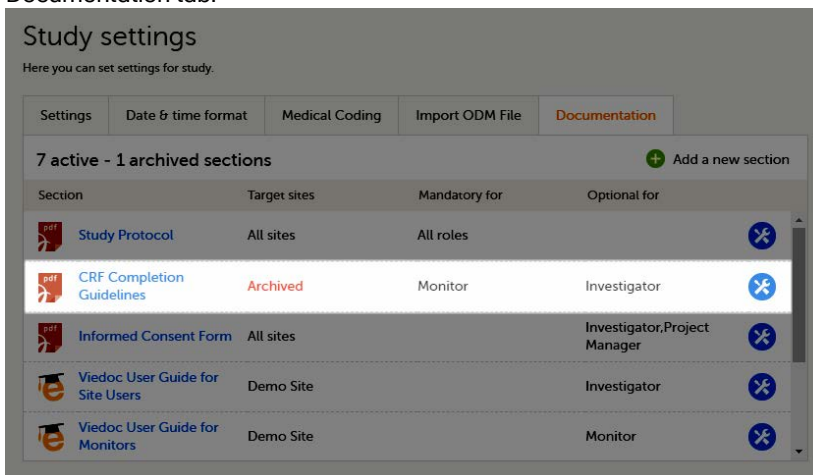


The edit section page opens.

2 Click **Archive**:



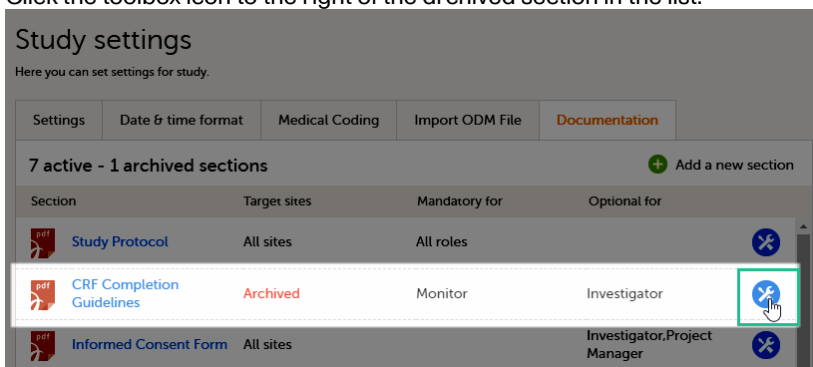
The edit section page closes and the section is displayed as **Archived** in the list under the Documentation tab:



An archived section will no longer be accessible in Viedoc Clinic. An archived section can be restored at any time, becoming accessible again in Viedoc Clinic, according to the settings made for the section.

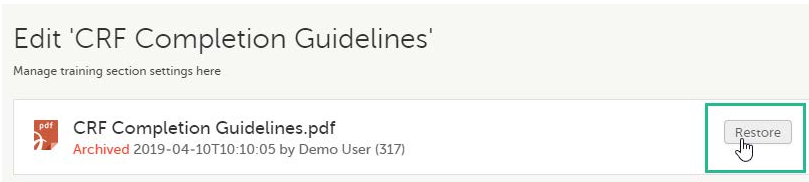
To restore an archived section, follow the steps below:

1 Click the toolbox icon to the right of the archived section in the list:



The edit section page opens.

2 Click **Restore**:



The section will be restored and become accessible again in Viedoc Clinic, according to the section settings.

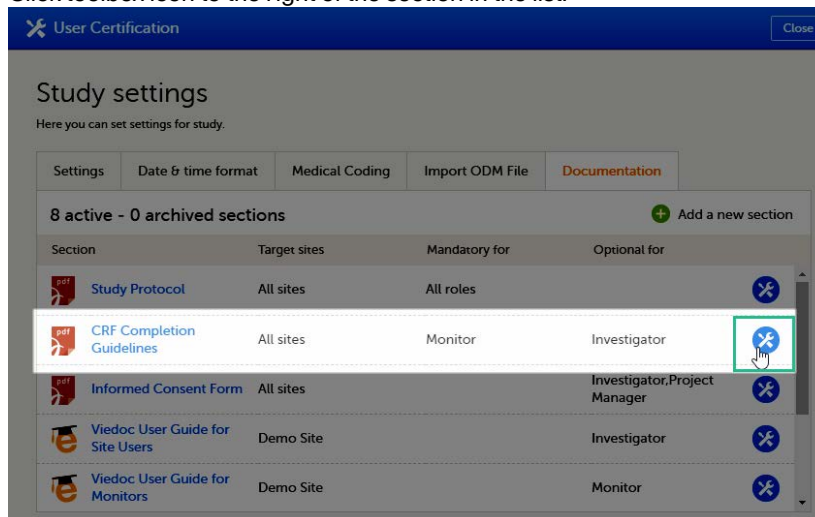
## 2.4 Deleting a section

It is possible to delete an existing section. Deleting a section cannot be undone, so if you need to re-use the section, you might want to archive it instead (see [Archiving/Restoring a section](#) above). An archived section can be restored afterwards, while a deleted section will be completely removed. Therefore, if you like to keep a history over the documentation versions that have been available for reading throughout the study it is recommended to archive instead of deleting.

A deleted section will no longer be visible in Viedoc Clinic.

To delete an existing section follow the steps below:

1 Click toolbox icon to the right of the section in the list:



The edit section page opens.

2 Click **Delete this section** in the bottom of the page:

Manage training section settings here

CRF Completion Guidelines.pdf  
Section last modified 2019-04-10T10:46:07 by Demo User (317) Archive

Section URL or file  
CRF Completion Guidelines.pdf

Section title: CRF Completion Guidelines      Priority: 2 / 8

Description  
Study-specific instructions for CRF completion

Target sites  
All sites x

Require signing for following roles  
Monitor x  
 Require re-signing after # of days: 365

Optional for following roles  
Investigator x

Delete this section

A confirmation pop-up is displayed.

3 Click **Confirm** to delete the section, or **Cancel** to return to the edit section page without deleting.

Delete section Cancel

*i* The delete action cannot be undone, while archived section can be restored. Are you sure you want to continue deleting this section?

Confirm

### 3 How it looks in Viedoc Clinic

For example, if we have the following sections defined in Viedoc Admin under **Study Settings > Documentation**:

User Certification Close

Study settings  
Here you can set settings for study.

Settings   Date & time format   Medical Coding   Import ODM File   **Documentation**

4 active - 0 archived sections + Add a new section

Section	Target sites	Mandatory for	Optional for	
Study Protocol	All sites	All roles		
CRF Completion Guidelines	All sites	Monitor		
Informed Consent Form	All sites		Investigator, Project Manager, Monitor	
Viedoc User Guide for Monitors	Demo Site		Monitor	



The user having the Monitor role for the Demo Site, will see in Viedoc Clinic, on the Study Start page, under **Documentation and training**, the following:

**Documentation & Training**

Before getting access to the study, please read all mandatory sections below and mark them as "Read & Understood". Once confirmed, Viedoc will generate a certificate of your completed training. Enjoy your trial!

Section	Read & Understood at
<b>Study Protocol</b> Latest version of the study protocol	✓ <a href="#">Read &amp; Understood</a>
<b>CRF Completion Guidelines</b> Study-specific instructions for CRF completion	✓ <a href="#">Read &amp; Understood</a>

**Optional sections**

- Informed Consent Form**  
The latest version of the Informed Consent Form, dated 2019-03-14
- Viedoc User Guide for Monitors**  
Text based eLearning for monitors.

For more details about the **Documentation and training** section in Viedoc Clinic, see [Documentation and Training](#).

## 4 Users not certified

The clinic users having mandatory documentation assigned who have not read and signed all the mandatory documentation yet, are displayed in the user listings in Viedoc Admin with the status **Not certified**. For details about user status see [Managing users](#).

Information on which users have been certified, for which roles and which sections, is also included in the 'Log of users and roles' PDF report that can be downloaded from Viedoc Admin, as described in [Managing users](#).



Managing users

# Managing users

Published by Viedoc System 2024-03-27

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This lesson describes the types of roles that are supported by Viedoc, how to assign roles to users and where to view the users that have access to a study, and their user details. The instructions are intended for **Study Managers (STM)** and **Site Managers (SIM)**.

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## 1 Introduction

### 1.1 Important information about signatures

The Study Manager should, in cooperation with the Site Manager(s), ensure that all users of Viedoc are informed, and certify that all electronic signatures created in the system are intended to be the legally binding equivalent of a traditional handwritten signature.

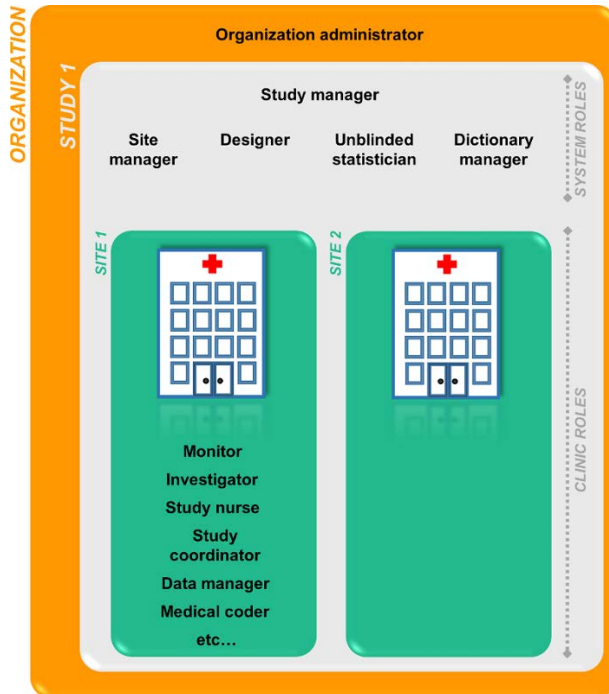
In Viedoc, the purpose/meaning of a signature is always “responsibility” as used in Sec. 11.50 of Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11. The signer is thereby acknowledging his/her responsibility for the entered data. Viedoc keeps account of what was signed, who signed it, and when the signature was performed.

## 1.2 About roles in Viedoc

### 1.2.1 Two types of roles

Viedoc supports two different types of roles.

1. **System roles** are roles that are predefined in the system and give access to Viedoc Admin or Viedoc Designer, see [System roles](#).
2. **Clinic roles** are roles that are study-specific and give access to Viedoc Clinic, see [Clinic roles](#).



The Organization Administrator invites the Study Manager. The Study Manager can assign users to system roles and clinic roles. The Study Manager can also delegate the management of clinic roles to the Site Manager.

### 1.2.2 System roles

The system roles are predefined in Viedoc, they cannot be adjusted for your study. The system roles give access to various features in Viedoc Admin or Viedoc Designer.

The following system roles are available.

Role	Description
Organization Administrator	The Organization Administrator is responsible for all projects within the organization. The Organization Administrator initiates projects, and assigns Study Managers to every project in Viedoc Admin.
Study Manager	The Study Manager assigns roles to users, adds sites to the study and applies study designs to the sites in Viedoc Admin. For a typical clinical trial, the role of Study Manager in Viedoc is assigned to the project manager.
Designer	The Designer builds the study in Viedoc Designer.
Site Manager	The Site Managers are appointed by the Study Manager and use Viedoc Admin to assign clinic roles to site users. For a typical clinical trial, the role of Site Manager in Viedoc is assigned to the Clinical Research Associate ( <a href="#">CRA</a> ).
Unblinded Statistician	The Unblinded Statistician manages the randomization lists in Viedoc Admin. This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.
Dictionary Manager	The Dictionary Manager uploads medical coding dictionaries.

Role	Description
Reference Data Source Manager	The Reference Data Source Manager manages the reference data sources at study level. The Reference Data Source Manager can also delegate the management of data sources at site level to the Site manager.
API Manager	The Application Programming Interface (API) Manager has access to the API settings and performs the API configurations. Complete instructions on how to configure the API are provided in <a href="#">Viedoc API</a> .
eTMF Manager	The eTMF Manager manages the <a href="#">eTMF</a> application in Viedoc Admin. The eTMF Manager maps Viedoc Clinic roles to eTMF roles. The eTMF Manager also has permission to manage the eTMF structure in Viedoc eTMF.

One organization can have more than one Organization Administrator. One study can have more than one Study Manager, Designer, Unblinded Statistician, Dictionary Manager, Reference Data Source Manager and API Manager. One site can have more than one Site Manager.

### 1.2.3 Clinic roles

The clinic roles, and the rights that belong to these roles, can be set up in the study design in Viedoc Designer. They are study-specific and give access to Viedoc Clinic. Clinic roles are assigned to site users by the Study Manager or the Site Manager. Each study can have an unlimited number of clinic roles.

Examples of clinic roles are:

- Investigator
- Study Nurse
- Study Coordinator
- Data Manager
- Medical Coder

## 1.3 About the study users

### 1.3.1 Overview of users in the organization/study/site

A list of users can be viewed at the following three places:

The screenshot shows the Viedoc interface for a study named 'Viedoc's demostudy'. The top navigation bar includes 'Studies' and 'Users' (highlighted with a red circle and '1'). Below the navigation bar, there are several sections: 'Viedoc's demostudy' with a 'Study settings' button; a list of study settings like 'Randomization is on', 'Medical coding', 'Reference data source(s)', and 'API configuration'; a 'Study crew' section with 'Study Managers (2)', 'Designers (1)', and 'Helpdesk team (0)'; and a 'Study design' section. At the bottom, there is a table of 'Study Sites' with columns for '#', 'Site name', 'Code', 'Country', 'Effective Design', 'Production', and 'Users'. The table lists five sites, and the 'Users' column shows the number of users per site. A red circle and '3' highlight the 'Users' column in the table. A red circle and '2' highlight the 'Study crew' section.

#	Site name	Code	Country	Effective Design	Production	Users
1	Karolinska Institute Stockholm	KI	SE	DemoStudyDesign 4.0	✓	1 / 6
2	Uppsala University Hospital	UU	SE	DemoStudyDesign 7.0	✓	1 / 6
3	Helsinki University Hospital	HU	FI	DemoStudyDesign 4.0	✓	1 / 5
4	University College Hospital London	CL	GB	DemoStudyDesign 6.0	✓	1 / 5
5	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign 3.0	✓	1 / 6

1. On the **Users** page. This page displays a list of users assigned to any role in any study within the **organization**.
2. In the **Study crew** window. This window displays a list of all users assigned to a **system role** in the **study**.
3. On the **Site users** tab of the site settings window. This tab displays a list of all users assigned to a **clinic role** within that specific **site**.

**Note!** All three user lists only display the users and roles you have permission to manage (invite or remove). If you are a Study Manager, you can also see the Organization Administrator. If you are a Site Manager, you can also see the Study Manager. However, in both cases you cannot invite users to these roles or remove these roles from users.

### 1.3.2 Users

User	Study and site	Role	Skill level	Status
[Redacted]				?x
Dr. Demo (383)	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles	👤	✓
Dr. Investigator (490)	Viedoc's demostudy Multiple sites	Investigator + 1 other roles	👤	?
[Redacted] (294)	Multiple studies Multiple sites	Study Manager + 3 other roles	👤	✓
[Redacted] (296)	Viedoc's demostudy Multiple sites	Investigator	👤	🔒
Technical Writer (304)	Multiple studies Multiple sites	Organization Admin + 10 other roles	👤	✓
Technical Writer (305)				⊖
TW CN (371)				⊖
Viedoc Admin (90)		Organization Admin	👤	✓

The Users page lists all users within the organization, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Study/studies and site(s) the user has access to
- Role(s) assigned to the user
- Viedoc skill level of the user (see [Viedoc skill level](#))
- Status of the user (see [User status](#))

If a user has no approved roles, because the invitation is still pending or rejected, or because the roles have been removed, only the user's e-mail address is displayed and all the other fields remain empty.

On this page, you can (see image):

1. Search for a specific user among all users within the organization by entering the user's name or e-mail address in the search field
2. Sort the list of users by name, status or date of creation
3. Group the list of users by study by selecting **Studies** in the **Group by** field
4. Invite organization users (only available for the Organization Administrator)

### 1.3.3 Study crew

User #†	Role #†	Since #†	Skill level	Status #†
Technical Writer (304) [email address]	Study Manager Designer	2018-04-10 08:49	🎓	✓
Dr. Demo (383) [email address]	Dictionary Manager	2018-04-27 08:04	🎓	✓
[email address] (294) [email address]	Study Manager Reference Data Source Manager	2018-05-02 14:36	🎓	✓
[email address]	Dictionary Manager	2018-05-15 08:32		?
[email address]			?	✗

The Study crew window lists all users in the study that are assigned to a system role, and displays the following information:

- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Role(s) assigned to the user
- Date and time the user has been invited to that role (if the invitation is still pending) or has access to that role (if the invitation has been accepted)\*
- Viedoc skill level of the user (see [Viedoc skill level](#))
- Status of the user (see [User status](#))

\*If the user has multiple roles, the date and time of invitation or acceptance of the first role that gives access to that site is displayed.

You can sort the users by name, role, date of (accepted) invitation and status. To sort the users, click on the column headers, or click on the arrows to the right of the column header. You can sort the users in ascending and descending order.

### 1.3.4 Site users

User #†	Role #†	Since (UTC) #†	Skill level	Status #†
Technical Writer (304) [email address]	Site Manager + 1 other roles	2018-05-15 09:18 UTC	🎓	✓
Dr. Demo (383) [email address]	Data Manager	2018-05-15 09:23 UTC		?
[email address] (294) [email address]	Medical Coder	2018-05-15 09:21 UTC	🎓	✓
Dr. Investigator (490) [email address]	Investigator + 1 other roles	2018-05-15 09:21 UTC	🎓	✓

The Site users tab in the Site settings window lists all users with clinic roles that have access to that site, and displays the following information:





- Name of the user
- User ID (in parentheses behind the user's name)
- E-mail address
- Role(s) assigned to the user
- Date and time the user has been invited to that role (if the invitation is still pending) or has access to that role (if the invitation has been accepted)\*
- Viedoc skill level of the user (see [Viedoc skill level](#))
- Status of the user (see [User status](#))

\*If the user has multiple roles, the date and time of invitation or acceptance of the first role that gives access to that site is displayed.

You can sort the users by name, role, date of (accepted) invitation and status. To sort the users, click on the column headers, or click on the arrows to the right of the column header. You can sort the users in ascending and descending order.








### 1.3.5 Viedoc skill level

The Viedoc skill level gives an indication of how experienced the user is in using Viedoc. It is based on the number of logins by that user.

Skill level	Icon	Description
Rookie		≤ 20 logins
Semi-pro		21-100 logins
Pro		101-1000 logins
Legend		> 1000 logins

### 1.3.6 User status

The status of the users is displayed in the status column:

Status	Icon	Description
Online		The user is currently logged in to Viedoc, and has no pending invitations.
Offline		The user is currently not logged in to Viedoc, and had no pending invitations.
Pending		The user has at least one pending invitation to a role. The question mark is displayed even if the user has accepted invitations to other roles.
Pending certification		The user has mandatory documentation assigned that was not confirmed as read & understood.
Rejected		The user has rejected all invitations to roles. The user has never had access to the study.
Locked out		The user is locked out from Viedoc (the user has entered the wrong password three times in a row).
Removed		The user has had roles in the study before, but has currently no roles left.

For the **Users** page (see [Users](#)), the following applies:

If the users are not grouped by study, the user's status symbol will reflect the overall status in all studies you have access to. That means, if the user has one pending invitation in one of the studies, the status will be *pending* and a

red question mark will appear. If the users are grouped by study, the status symbol will reflect the status per study. That means that a user's status can be *pending* in one study, and *logged in* in another study.

## 1.4 User settings

To view the details of a specific user, click the toolbox icon behind the name of that user in any of the previously described user lists. The User Settings window opens:

The screenshot shows the 'User Settings' window for a user named 'Dr Investigator (1714)'. The window has a blue header with the title 'User Settings' and a 'Close' button. Below the header, the user's name 'Dr Investigator (1714)' is displayed, along with a status indicator 'Offline' and a skill level 'Rookie 13 logins'. There are five numbered tabs: 1. Details, 2. Studies and Roles, 3. Authentication Log, 4. Reset Password, and 5. Communication Log. The 'Details' tab is active, showing a form with fields for: User name (testuser@r.com), First name (Dr), Last name (Investigator), Display name (Dr Investigator (1714)), Phone (46 7 12345678), Street address (Main Street 101), City (Uppsala), Postal code, Country (SE), and State. At the bottom, there is a red button labeled 'Delete user from this organization'.

The **User Settings** window displays the name and email address of the user, the user ID (in parentheses), the status and the skill level. You can perform the following actions:

1. On the **Details** tab, you can view the user's name and contact details.
2. On the **Studies and Roles** tab, you can view a list of all roles and sites the user has access to, including the date and time of invitation/acceptance of that role. The roles are grouped per study. You can delete roles by clicking the trash can icon next to the role.
3. On the **Authentication log** tab, you can view a list of logins by the user, including date and time, the IP address, and the browser that was used. The number of displayed entries is limited to the latest 100 logins.
4. On the **Reset Password** tab, you can reset the password for that user, if the user has forgotten their password and does not have the phone number that can receive a text message or a secondary email address. Viedoc will send a notification to the user with a link to create a new password.

**Note!** The authentication code will be required if the user wants to reset their password using the **Forgot your password?** link on the login page. The authentication code is sent to the phone number the user set to receive text messages or to the user's secondary email address. If neither of these options are selected, the user needs to contact their Study Manager to receive a link to reset their password.

5. On the **Communication Log** tab, you can view the latest 20 communication logs for a user and download an Excel file with the complete user-specific **Communication Log** containing information about email and SMS communication to study users. All users with access permissions (Study/Site Managers) to the User settings in Viedoc Admin can access the Communication Log.

**Note!** Email and SMS communication logs before the Viedoc 4.70 release are available, however these do not have the same level of detail.

## 1.5 User report

For each study, you can download user logs in PDF and Excel format with information about all users and roles for the sites you have access to. See [Downloading the user logs](#) for instructions.

**Note!** Only production sites and roles/users for production sites are included in the logs.

The content of the logs depends on the system role that you have, as follows:



If you are a...	... then the logs contain:
Organization Administrator	The system roles Application Programming Interface (API) Manager, Dictionary Manager, Unblinded Statistician, Reference Data Source Manager, and eTMF Manager.
Study Manager	The system roles API Manager, Dictionary Manager, Unblinded Statistician and Reference Data Source Manager, eTMF Manager, and all sites and site users in the study.
Site Manager	The system roles API Manager, Dictionary Manager, Unblinded Statistician and Reference Data Source Manager, eTMF Manager, and all sites you have access to, together with their site users.

### 1.5.1 Log of users and roles in PDF

The Log of users and roles PDF contains information about all users and roles for the sites you have access to, grouped in the following chapters:

1. **Summary** - the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.
  - An **Active role** is the current distinct role all active users have for a site.
  - An **Inactive role** is a role that was previously assigned but currently lacks any active user.
  - An **Active user** is a user with at least one active role.
  - An **Inactive user** is a user who had at least one role at a site, but all roles for the site have been revoked.
2. **Roles** - a list of the permissions associated with each role and corresponding history, grouped in one section per site.
3. **User log per site** - a list of all users who ever had access to data, including user activity, grouped in one section per site.
4. **User account logs** - a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the User ID).

### 1.5.2 User administration log in Excel

The User administration log contains information about all users and roles for the sites you have access to, with the following sheets:

1. **Report Info** - general information about when and by whom the log was generated, and some information about the study status.
2. **User Access Log** - a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:
  - **Site Group** - indicates when a user is granted access to the site through a site group invitation. Possible values are *Training sites*, *Countries*, and *All sites*.
  - **2FA** - indicates what level of two-factor authentication the user has. Possible values are *Study level*, *Account level*, or *No two-factor authentication enabled*.
  - **Certified** - indicates if the user is certified for the role. Possible values are *Yes*, *No*, or an empty cell for roles that don't have mandatory training sections to read.
3. **Certification Log** - a list of certifications per user. Certifications performed before the release of 4.65 lack information about what roles the certification applies to. That is, the cells in column **Certified With Roles** are empty.
4. **Summary** - a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
5. **Account Settings Log** - a list with all user accounts setting changes with user ID, change log, user name, and date/time.

### 1.5.3 Communication log in Excel

There are two different Communication logs. One contains user-specific and one contains study-specific communication information.

#### Note!

- This Communication log does not include any subject-related communication (Viedoc Me).
- Email and SMS communication logs before the Viedoc 4.70 release are available, however these do not have the same level of detail.

### 1.5.3.1 User-specific information

The user-specific Communication log contains information about email and SMS communication to the study users.

All users with access permissions (study/site managers) for the User Settings in Viedoc Admin can view the Communication Log for a specific user. The **Communication Log** tab has the following columns:

- Date & Time
- Message type
- Status - **Note!** The status labels are **Success** or **Failed**, where **Success** means that the message was successfully sent from Viedoc, and **Failed** means that the message failed to send from Viedoc. Further, if the status was **Success** but the recipient did not receive a message, then the problem lies outside of Viedoc. Please contact your PS representative if this should occur, or if your status returns **Failed**.

Date and Time	Message type	Status
2022-03-21 09:41:50 (UTC)	Two factor authentication	Success
2022-03-21 09:25:18 (UTC)	Two factor authentication	Success
2022-03-21 04:41:07 (UTC)	Two factor authentication	Success
2022-03-21 04:39:28 (UTC)	Recover account request	Success
2022-03-19 07:09:22 (UTC)	Two factor authentication	Success
2022-03-18 09:59:30 (UTC)	Two factor authentication	Success
2022-03-18 09:50:58 (UTC)	Two factor authentication	Success
2022-03-18 06:16:34 (UTC)	Two factor authentication	Success
2022-03-18 05:40:42 (UTC)	Verify phone number	Success
2022-03-18 05:40:39 (UTC)	Change phone number	Success

The Excel file contains a sheet named **User Communication Logs** and includes all email and text message (SMS) communications to the study user on the same Excel sheet.

**Note!** Users must have activated the Viedoc account and accepted at least one invitation in order to have their communication included in the Communication Log tab in the **User Settings** window.

The **User Communication Logs** sheet in the Excel file contains information about user-specific communication – this is the user activity in Viedoc that is unrelated to a specific study:

- Reset password
- Verification & notifications (changing telephone number/email address)
- 2FA (email/SMS)

The file name format is: UserCommunicationLog-UserID-YYYYMMDDhhmmss. (Using UTC)

All the logs are included in the same Excel sheet. The excel sheet has the following columns:

Column	Description
Message ID	GUID: A unique identifier for the message
Type of Communication	SMS/email
Datetime (UTC)	Date and time for the communication
Message Type	The action that the communication is related to: <ul style="list-style-type: none"> <li>Reset password - for messages related to password reset</li> <li>2FA login - for messages related to the 2 factor authentication</li> </ul>
To	The email address the message is sent to. For SMS messages, this column is empty.
Status	Success/Failed
Provider	Provider name - the provider that was used to send the message to the recipient

Communication logs						
Message Id	Type of Communication	Datetime (UTC)	Message Type	To	Status	Provider
9970d495-aa67-4bed-b246-cc3f8b1c8d47	Email	2022-03-01 07:46:25	Two Factor Authentication	user1@viedoc.com	Success	Primary-Primary
a96f1beb-c63c-4376-9ae0-e9cdabcb8d4	Email	2022-03-01 07:44:29	Recover Account Request	user2@gmail.com	Success	Secondary-Secondary
00520b3e-f26a-4077-9dec-edc9458cc30a	Sms	2022-03-01 06:16:22	Verify Phone Number		Success	Primary-Primary
e01f2d59-8af4-48ba-81b7-fb4045d18767	Email	2022-03-01 06:16:20	Verify Email Address	123@mail.com	Success	Primary-Primary
9ad92c51-7582-4bce-b243-d63737bb079d	Sms	2022-03-01 06:11:07	Verify Phone Number		Success	Primary-Primary
44807068-faea-4dc3-b07a-a892457eb358	Email	2022-03-01 06:11:00	Verify Email Address	999@gmail.com	Success	Primary-Primary
14e6048b-a1a9-48bb-85e2-94ab6ec14f42	Sms	2022-03-01 04:44:05	Verify Phone Number		Failed	Secondary
399a561a-4299-4ceb-a0ac-a87825cdfbaa	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
8aec881c-78ab-45c9-95e4-5123e09ce129	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
f8ef8347-de0e-422b-be2a-d8bba0a7d650	Email	2022-03-01 04:42:41	Verify Email Address	789@gmail.com	Failed	Secondary
16c884e2-3cf3-4063-8f47-a8cf0c02233a	Email	2022-03-01 04:39:43	Verify Email Address	abcd@gmail.com	Failed	Secondary
9c813fce-6633-4dee-b0ba-3666ee14cf5f	Sms	2022-03-01 04:39:38	Verify Phone Number		Success	Secondary-Primary
fc98775c-01f2-4b4d-aad7-	Email	2022-03-01 04:39:29	Verify Email Address	123@mail.com	Failed	Secondary

### 1.5.3.2 Study-specific information

In Admin, under **Users** - Group by Studies, in the User Logs dropdown list, a separate file called User communication log is available containing the information listed below.

The screenshot shows the Admin interface for 'Users'. The 'Group by' dropdown is set to 'Studies'. A dropdown menu is open for 'User logs', showing options like 'Log of users and roles', 'User administration log', and 'User communication log'. The 'User communication log' option is highlighted with a green box, and its sub-menu is visible, showing 'Download (2022-03-02 09:25)' and 'Regenerate'.

This log contains information about study-specific communication and emails only, related to:

- Alerts
- Invitations to a specific role within a study
- Notifications (study access deletion, etc.)

The Excel file contains a sheet named **Study Communication Logs**.

The file name format is: UserCommunicationLog-YYYYMMDDhhmmss. (Using UTC)

The Excel sheet has the following columns:

Column	Description
Message ID	GUID: A unique identifier for the message
Communication Type	Email
Date time (UTC)	Date and time for the communication
Message Type	The action that the communication is related to: <ul style="list-style-type: none"> <li>▪ <i>Invite user</i></li> <li>▪ <i>Event Reminder</i></li> <li>▪ <i>Remove User Access Notification</i></li> <li>▪ <i>Subject Account Lock Notification</i></li> <li>▪ <i>Study Unlock Notification</i></li> <li>▪ <i>Export Chart</i></li> <li>▪ <i>Export Metric</i></li> <li>▪ <i>Reject User Invitation</i></li> </ul>
Site Type	Training/Production (For the message types Invitation and Invitation rejected, this column is empty.)
To	Email address(es) (For SMS messages, this column is empty.)
CC	The email address(es) of the recipients of a copy
BCC	The email address(es) of the recipients of a blind copy
Status	<i>Success/Failed</i>
Provider	Provider name - The provider that was used to send the email to the recipient

Communication Logs										
Message Id	Communication Type	Datetime (UTC)	Message Type	Site Type	To	CC	BCC	Status	Provider	
f76020c-8d5-4f3-4932-870ae99b8bd4	Email	2022-03-03 06:52:07	Form Alert True Action	Production	rb@doc.com	rb@doc.com	#f53@mail.com, user11.pghyam@gmail.com	Success	Secondary/Secondary	
8739af21-000b-4776-9094-ed0ffec0e64	Email	2022-03-03 06:52:05	Event Reminder	Production	rb@doc.com	user1@mail.com	qjuu7at@gmail.com, user78.hjstf@gmail.com	Success	Secondary/Secondary	
a2e09907-1890-4945-9d17-ff6254602a	Email	2022-03-03 06:52:08	Study Unlock Notification	Production	user1@mail.com	user3@gmail.com	fafdn3@gmail.com, user56.vinof@gmail.com	Success	Secondary/Secondary	
9737c6d5-60c1-435a-9d97-81f677c0b022	Email	2022-03-03 06:52:01	Invite User	Production	user2@se.com	user@vc.com	fmnk378@gmail.com, user8971.uhfm@gmail.com	Success	Secondary/Secondary	
85e34411-4529-40b3-979e-0e9c0b83902	Email	2022-03-03 06:43:53	Remove User Access Notification	Production	thu.nustf@mail.com	mot.hbdb@mail.com	#f866@gmail.com, f65ourf6.rk@gmail.com	Success	Secondary/Secondary	

**Note!**

- This log does not include user-specific information related to Reset Password, 2FA, etc.
- This log file is available in Viedoc Admin only.

## 1.6 System site groups

The Study Manager can give users access to individual sites, or to a groups of sites at once. These groups of sites are called system site groups and are automatically created by the system when sites are added to the study. The following systems site groups are created by the system:

- All sites, containing all sites in the study.
- All production sites, containing all production sites in the study, including the sites that are in both production and training mode.
- Country-specific, for example 'Sweden', containing all production sites (including the sites that are in both production and training mode) in that specific country in the study.

When you invite users to a system site group, the users will *automatically receive instant access* to all sites in that group, including all future sites that will be added to that group at a later time. For example, if you invite a user to the country 'Hungary', that user will receive access to all sites in Hungary. Similarly, users that were invited to a system site group will automatically lose access to a site if that site is removed from the group. For more information about system site groups, see [Managing study sites](#).

## 2 Step-by-step guides for the **Study Manager**

### 2.1 Assigning users to system roles and/or clinic roles

Only the **Study Manager** can invite users to system roles. The Study Manager can also invite users to clinic roles, or he/she can delegate the management of (some of the) clinic roles to the Site Manager, see [Delegating user management to the Site Manager](#) for instructions. Once the management of clinic roles is delegated to the Site Manager, the Study Manager cannot invite users to these roles anymore.

If a user should receive access to multiple sites, the quickest way to invite the user is through the study crew window (described in this section). If a user should receive access to only one site, you can also invite the user through the site settings window of that site (see [Assigning users to clinic roles](#) for instructions).

To invite users:

- 1 In Viedoc Admin, open the study to which you would like to invite users.
- 2 Click the toolbox icon in the **Study crew** field. The Study crew pop-up opens.
- 3 On the **Add study users** tab, enter the e-mail address of the user you would like to invite. Click **Continue**.

Viedoc's demostudy [Close]

### Study crew

Here you can view admins for the study and/or invite more people

Study crew [Add study users]

Add users to this study Step 1/2

E-mail address

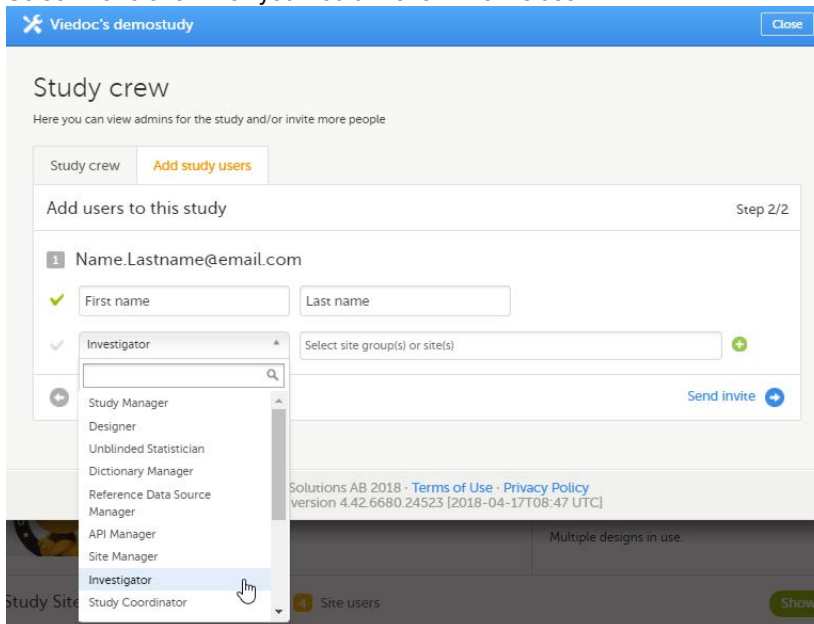
Name.Lastname@email.com

Multiple email addresses can be included by separating with semi-colon or comma.

[Continue +] [Continue]

**Tip!** You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

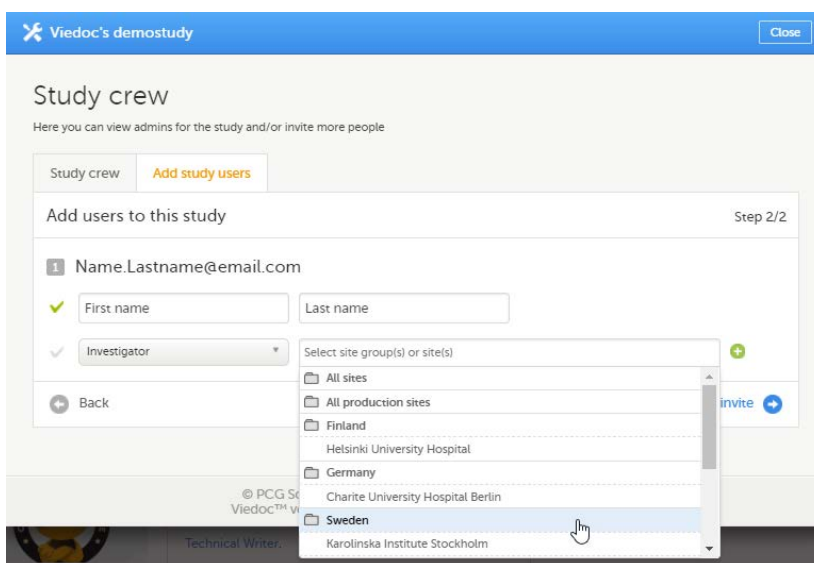
4 Select the role to which you would like to invite the user.



You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.

**Note!** If any of the clinic roles are delegated to the Site Manager (see [Delegating user management to the Site Managers](#)), the delegated roles do not appear in the dropdown list.

5 If you selected the role Site Manager or a clinic role, select the system site group or the individual sites to which the user should get access. To select a system site group, click on the name of the group (displayed in bold). To select an individual site, click on the name of the site.



**Note!**

- Sites that do not belong to a system site group (for example training sites) are listed under a separate header (for example "Training sites") at the bottom of the list of site groups and sites. This header lacks the folder icon, and does not represent a system site group (see image).
- For Demo sites to work with Viedoc Reports, a user must be invited with direct site access (not through All sites site group). For Production sites, Viedoc Reports is available for all site groups (All sites and the country-specific groups).

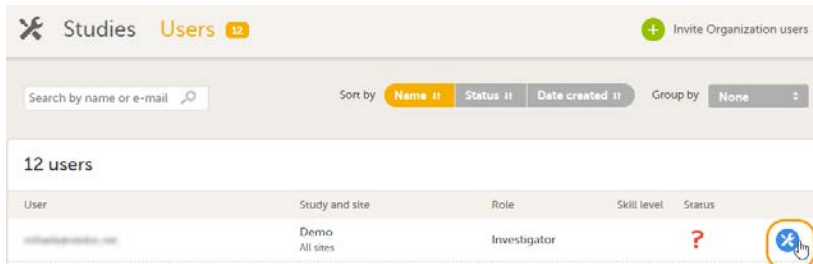
6 Click **Send invite**.  
An invitation e-mail will be sent to the e-mail address(es) you specified.

## 2.2 Resending the invitation to a user

It is possible to re-invite a user to those roles that are in state pending, i.e. to resend the invitation email to the user for that role.

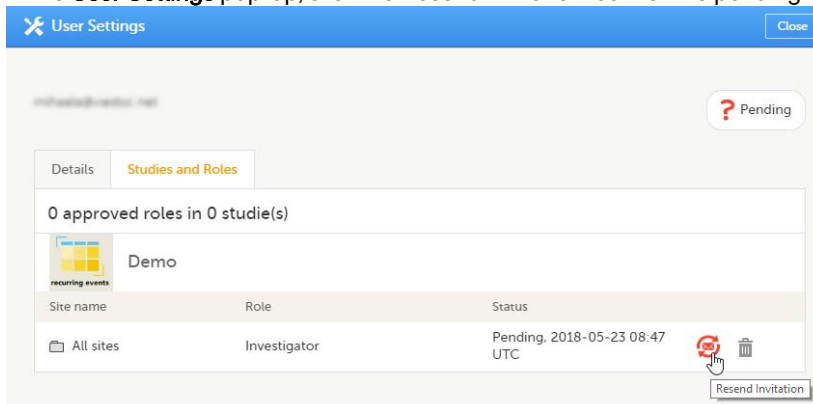
To resend an invitation:

- 1 On the **Users** page, scroll to the user whom you would like to re-invite. Click the toolbox icon behind the name of the user:



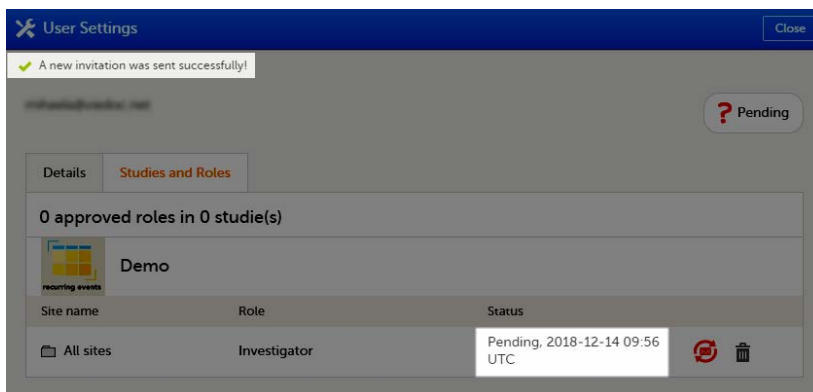
The **User Settings** pop-up opens.

- 2 In the **User Settings** pop-up, click the Resend invitation icon for the pending role:



A new invitation email is sent and:

- a notification message is displayed on the top of the pop-up
- the date displayed in the **Status** column is updated to the date of the last invitation



## 2.3 Removing access to a role

It is possible to remove a user's access to a role. This can only be done by the Study Manager. If the Study Manager has delegated the management of clinic roles to the Site Managers, only the Site Managers can remove access to these roles and sites.

To remove the access from users:

1

On the **Users** page, scroll to the user whose access you would like to remove. Click the toolbox icon behind the name of the user.

Search by name or e-mail  Sort by **Name**  **Status**  **Date created**  Group by **None**

10 users

User	Study and site	Role	Skill level	Status
<a href="#">testuser@br.com</a>				
Firstname.Lastname@email.com		Organization Admin + 1 other roles		
<b>Dr. Demo (383)</b> <a href="#">testuser@br.com</a>	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles		
<b>Dr. Investigator (490)</b> <a href="#">testuser@br.com</a>	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles		
<b>Steve Longenbong (294)</b> <a href="#">testuser@br.com</a>	Multiple studies Multiple sites	Study Manager + 5 other roles		
<b>Steve Longenbong (296)</b> <a href="#">testuser@br.com</a>	Viedoc's demostudy Multiple sites	Investigator		
<b>Technical Writer (304)</b> <a href="#">testuser@br.com</a>	Multiple studies Multiple sites	Organization Admin + 10 other roles		
<b>TW CN (371)</b> <a href="#">testuser@br.com</a>				
<b>Viedoc Admin (90)</b> <a href="#">testuser@br.com</a>		Organization Admin		

[↑ To the top](#)

The User Settings pop-up opens.

**User Settings**

**Dr Investigator (1714)**  
testuser@br.com  Offline 1.5 logins

**Details** | Studies and Roles | Authentication Log | Reset Password | Communication Log

User name

First name  Last name  Display name

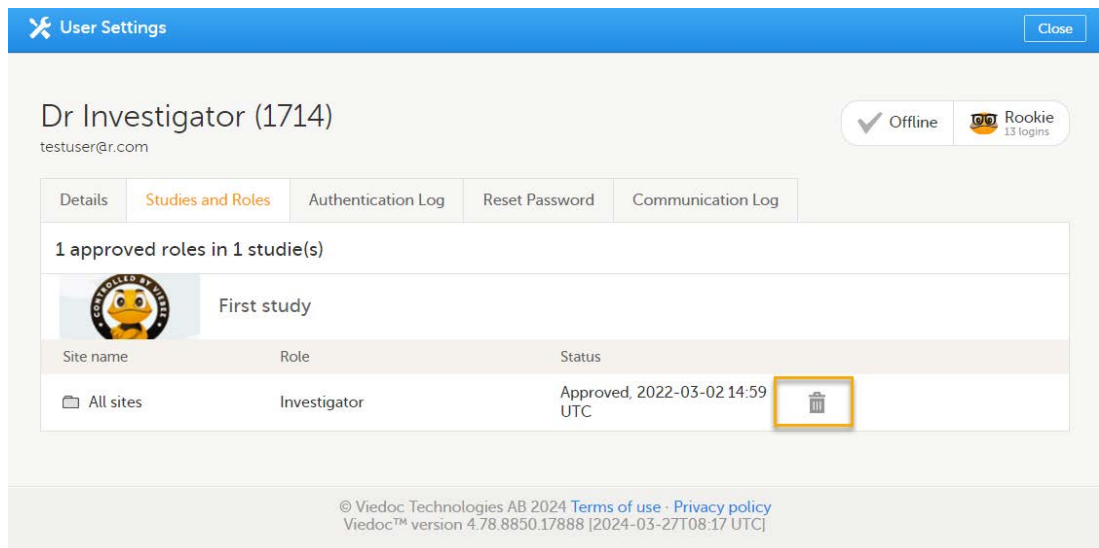
Phone

Street address  City

Postal code  Country  State



- 2 On the **Studies and Roles** tab, scroll to the study, site and role for which the access should be removed. Click the trash can icon.



A pop up appears.

- 3 Click **Delete** to confirm that the access should be removed, or click **Cancel** to cancel. The role for which you removed the access, will be removed from the **Studies and Roles** list. If all roles for that user have been removed, the user's status will appear as *Removed* on the Users page.

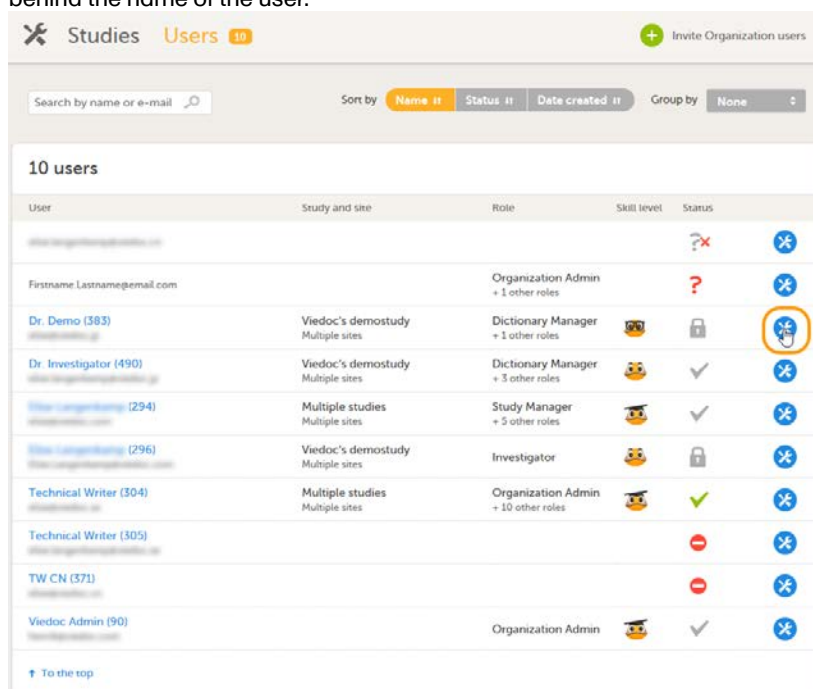
Any records generated by the user are stored in the audit trail even when the user has been removed.

## 2.4 Unlocking a user account

If a user has typed in the wrong password more than three times, and forgotten the answer to the challenge question – and therefore cannot use the **Forgot your password** link – the account will be locked. The Study Manager or Site Manager can unlock a locked account.

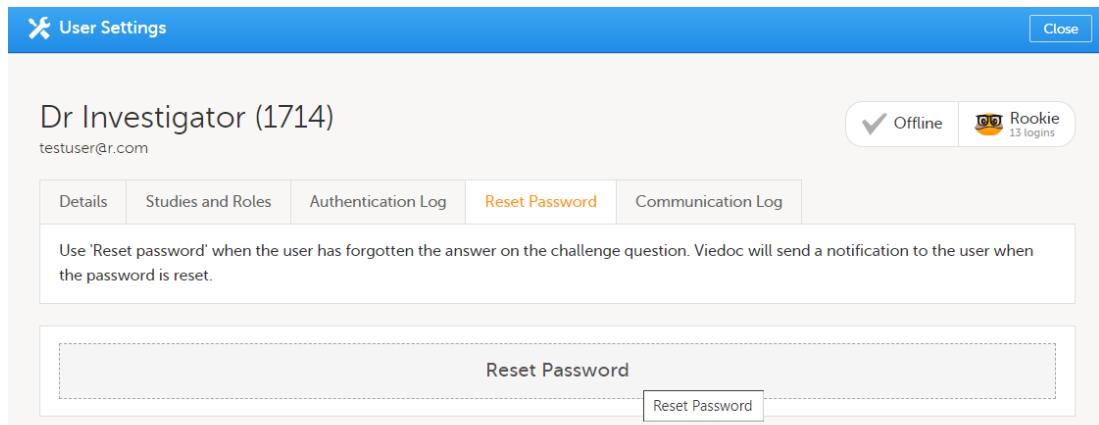
To unlock a user account:

- 1 On the **Users** page, scroll to the user whose account you would like to unlock. Click the toolbox icon behind the name of the user.



The User Settings pop-up opens.

- 2 On the **Reset Password** tab, click **Reset Password**.



The user will receive an e-mail with a link to reset the password. The user can then reset their password without having to provide an authentication code.

**Note** The authentication code will be required if the user wants to reset their password using the **Forgot your password?** link on the login page. The authentication code is sent to the phone number the user set to receive text messages or to the user's secondary email address. If neither of these options are selected, the user needs to contact their Study Manager to receive a link to reset their password.

**Note** The email with the link to reset the password is only valid for twelve hours. If the user has not reset the password within twelve hours, a new e-mail needs to be sent.

## 2.5 Delegating user management to the Site Managers

The Study Manager can delegate the management of clinic roles to the Site Manager.

To select the roles that should be managed by the Site Manager:

- 1 In Viedoc Admin, click **Study settings**.  
The study settings window opens.

- 2 On the **Settings** tab, in the field **Clinic roles to be administered by Site Manager**, select which roles should be assigned by the site manager.

Viedoc's demostudy Save changes Close

### Study settings

Here you can set settings for study.

Settings ! Date & time format Medical Coding Import ODM File

Ongoing, FPA 2017-02-02 Full functionality.  Invalid license

Study name  Study Logo CRO Code

Reference ID

Study Type  Sponsor Type  Study Phase

Therapeutic Area  Expected number of subjects

Study access

Password expiration time for all users in this study (values allowed are 1 to 5000)  days

Require two-factor authentication for all users accessing this study

**Clinic roles to be administered by Site Manager**

Investigator  Study Coordinator  Monitor  Project Manager  Data Manager

Sponsor  DRC Coordinator  Trial Manager  Medical Coder  Lab Import

Helpdesk team

PCG Helpdesk  Britanica Helpdesk

Allow reminders in ViedocMe to be sent as

Email  Text message

[Show more options](#)

The roles that can be selected here are the clinic roles that are defined in the study design.

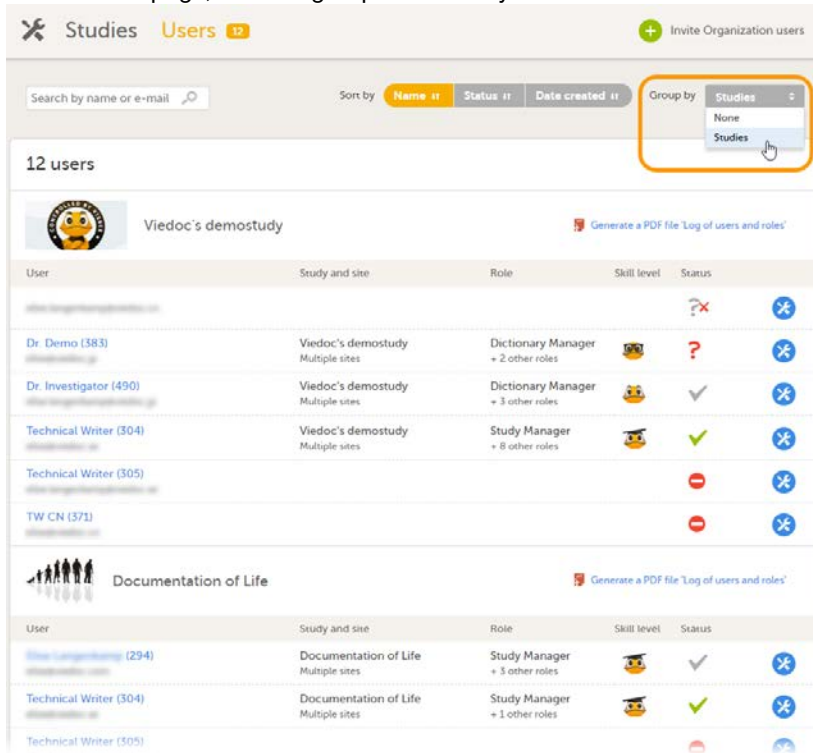
- 3 Click **Save changes**, and click **Close**.

**Note!** These settings apply to all sites and all Site Managers involved in the study. When the assignment of (some of the) clinic roles is delegated to the Site Manager, these clinic roles can no longer be managed by the Study Manager.

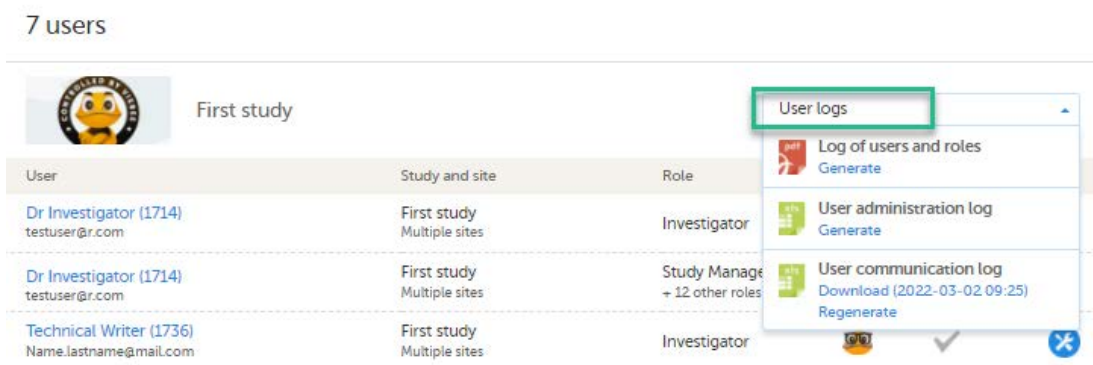
## 2.6 Downloading the user logs

To download the user logs:

1 On the **Users** page, select to group the users by **Studies**.



2 Scroll to the study from which you would like to download the user log and click **User logs** to open the dropdown menu.



If the log was not previously generated, click **Generate a PDF file** or **Generate an Excel file**. If the log was previously generated, the most recent version is stored on the server, shown with a date and time stamp. You can download it by clicking the link, or, generate an updated version by clicking **Regenerate**.

**Note!** The user logs are generated in the language set by the user who is generating the log. Therefore, the previously generated file is available for download only if it was generated in the language you have currently set in Viedoc.

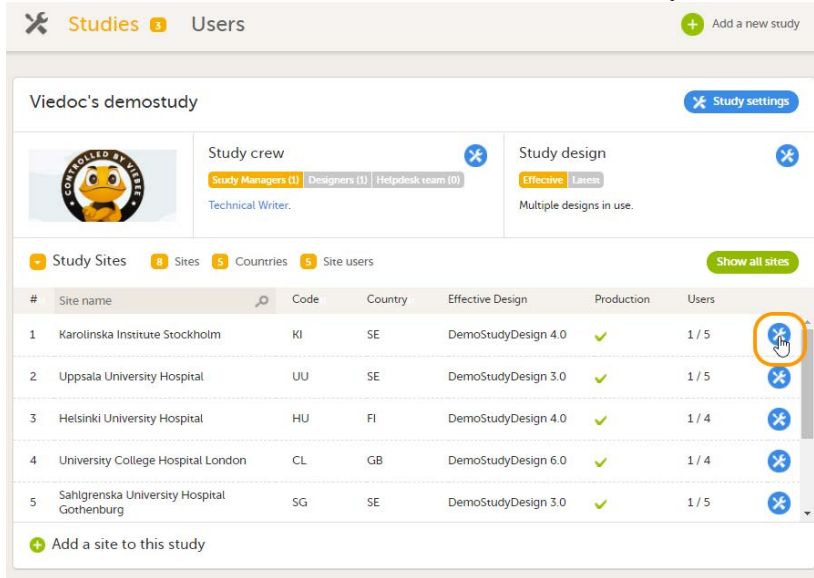
## 3 Step-by-step guides for the **Site Manager**

### 3.1 Assigning users to clinic roles

The **Site Manager** can invite users to (some of the) clinic roles, if the study manager has delegated the management of these clinic roles to the site manager.

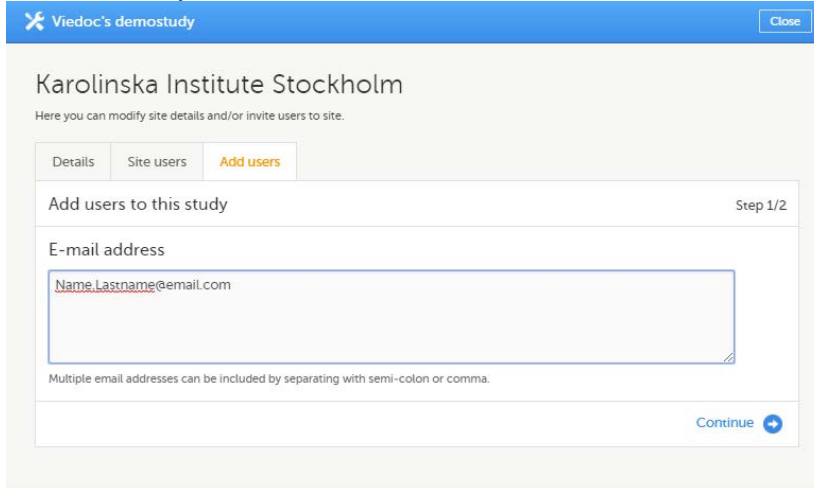
To invite users to a specific site:

1 In Viedoc Admin, click the toolbox icon behind the site to which you would like to invite users.



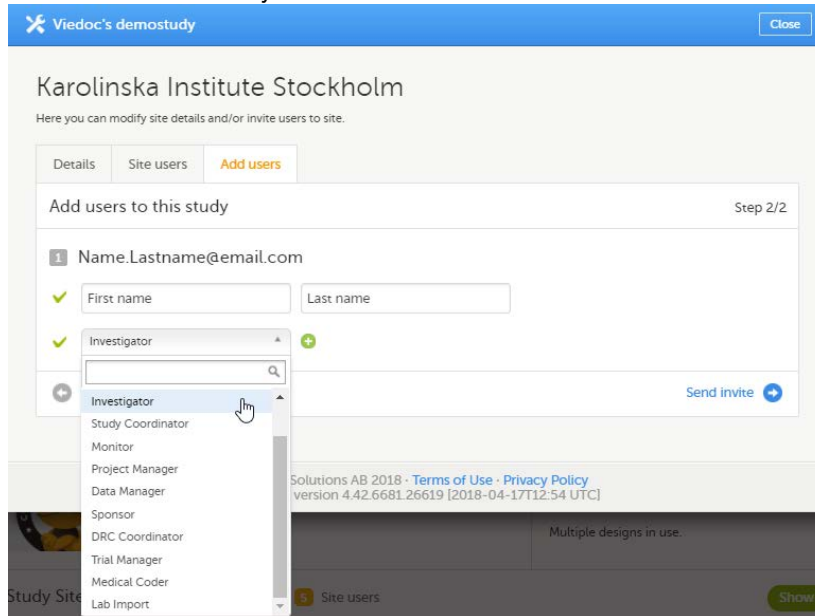
The site settings pop-up opens.

2 On the **Add study users** tab, enter the e-mail address of the user you would like to invite. Click **Continue**.



**Tip!** You can invite multiple users at once by adding multiple e-mail addresses in the field. Separate the e-mail addresses with a semi-colon or comma.

**3** Select the role to which you would like to invite the user.



You can add multiple roles by clicking the + icon. Newly added roles can be removed by clicking the - icon.

**4** Click **Send invite**.  
An invitation e-mail will be sent to the e-mail address or e-mail addresses you specified.

### 3.2 Removing a user

Click [here](#) for instructions on how to remove a user.

### 3.3 Unlocking a user account

Click [here](#) for instructions on how to unlock a user account.



Managing study sites

# Managing study sites

Published by Viedoc System 2021-02-04

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## [1. Introduction](#)

[1.1 About the study site list](#)

[1.2 About system site groups](#)

[1.2.1 What are system site groups?](#)

[1.2.2 How do system site groups work?](#)

[1.3 About the management of study sites](#)

[1.3.1 Maximum number of subjects per site](#)

## [2. Step-by-step guides](#)

[2.1 Adding a study site](#)

[2.2 Editing a study site](#)

[2.3 Removing a study site](#)

This lesson provides instructions on how to manage the study sites in your study. It also provides a description of system site groups.

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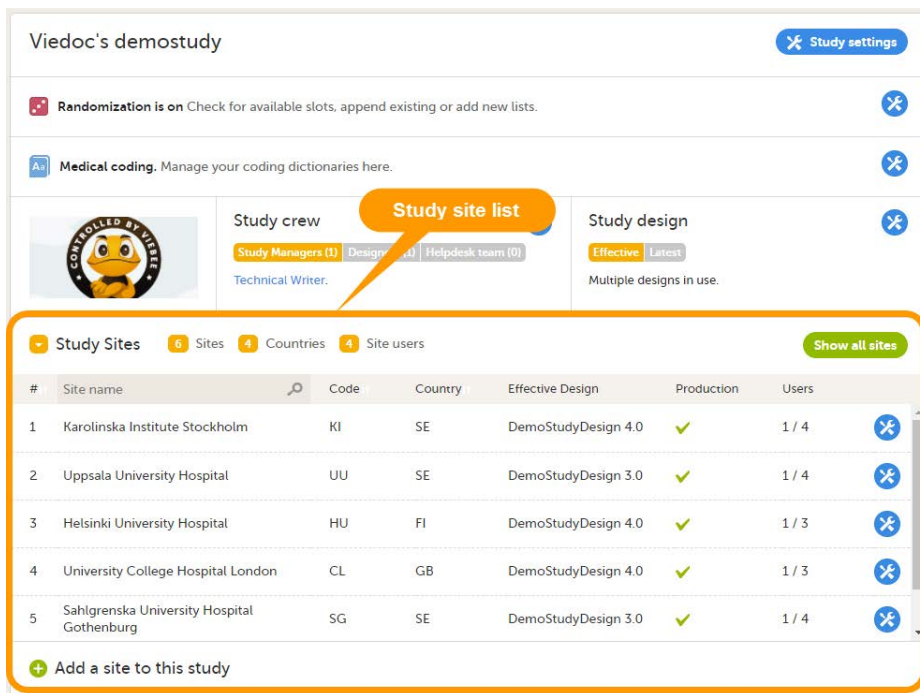
## 1 Introduction

### 1.1 About the study site list

The study site list displays all sites that are included in the study. For each site, the study site list also displays the site code, country, which study design version is used, and whether the site is a production site or not. The column **Users** indicates how many users the site has, and the amount of users that are currently logged in. For example, 1/4 means that the site has 4 users of which 1 is currently logged in.

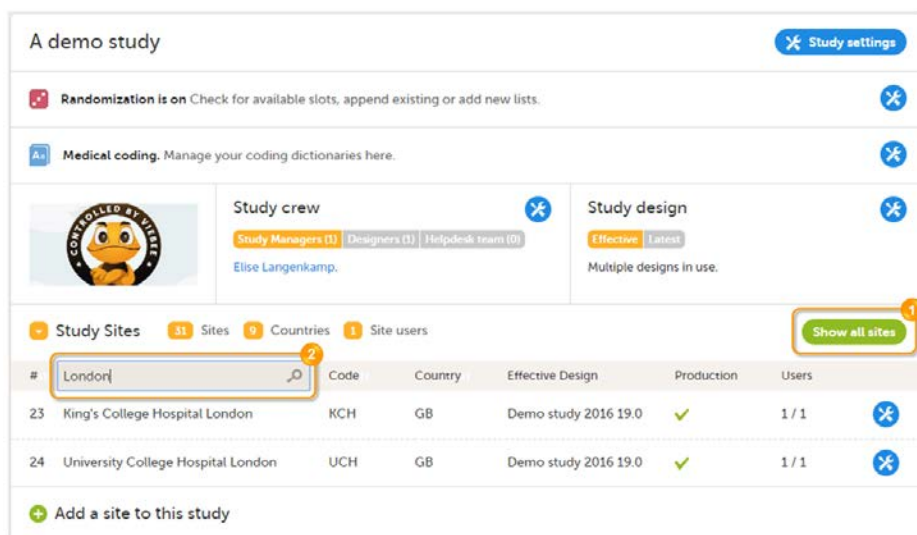
The header of the study site list summarizes the total number of sites, the total number of countries and the total number of site users.

The sites are numbered in the order they are added. You can sort the sites in the study site list by number, site code and country by clicking on the respective column header of the study site list.



If you have added many sites to your study, a scrollbar appears to the right of the study site list that enables you to scroll through the study sites. To view a list of all sites, click the **Show all sites** button (see no. 1 in the image below). To return to the default view with the scrollbar, click the **Show less** button.

**Tip!** You can search for a site by entering (part of) its name in the search field (see no. 2 in the image below).



## 1.2 About system site groups

### 1.2.1 What are system site groups?

The system automatically creates groups of the sites that are added. This enables the Study Manager to assign site staff to all sites within a group at once. Site staff can also be assigned to individual sites.

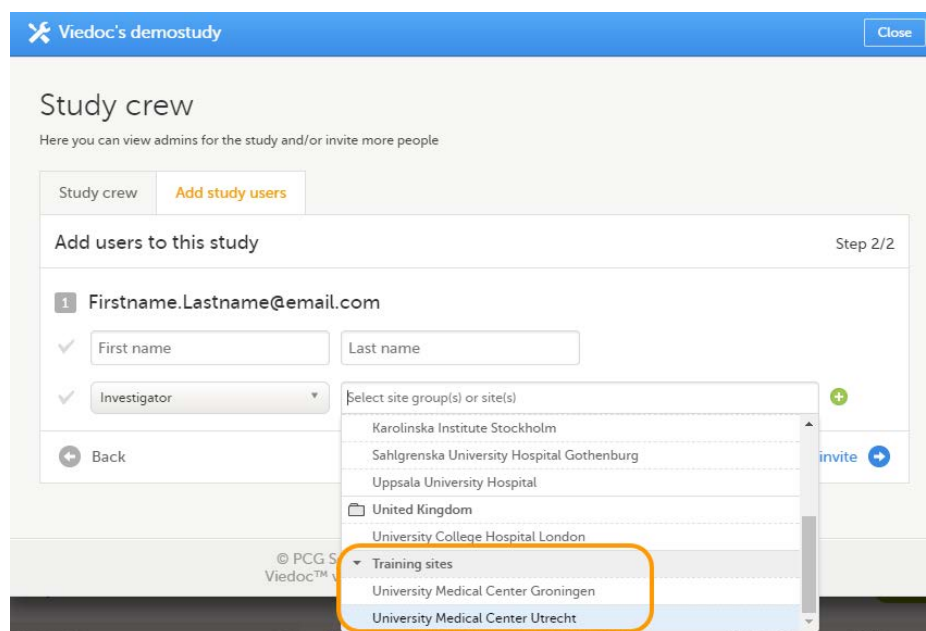
The system site groups are visible when adding site staff to the study crew, as displayed in the image. See also the eLearning section [Managing users](#).

The following system site groups are automatically created by the system:

- **All sites**, containing all sites in the study. This group is created once the first site is added to the study.
- **All production sites**, containing all production sites in the study, including the sites that are in both production and training mode. This group is created once the first production site is added to the study.
- **Country-specific**, for example *Austria*, containing all **production** sites (including the sites that are in both production and training mode) in that specific country in the study. This group is created once the first production site of that country is added.



Note that sites that do not belong to a system site group (such as training sites) are listed under a separate header (for example *Training sites*) at the bottom of the list of site groups and sites when assigning staff. This header lacks the folder icon, and does not represent a system site group.



### 1.2.2 How do system site groups work?

When you add a new site to the study, the site will automatically be added to the applicable system site groups. The site staff assigned to those system site groups will automatically receive instant access to the newly added site.

When a site is removed from the study, the site will automatically be removed from the applicable system site groups. The site staff assigned to those system site groups will not have access to that site anymore.

When you change the country settings of a site from country A to country B, that site will automatically be removed from the **country A** group and added to the **country B** group. Similarly, when you edit the production/training mode settings of a site, that site will automatically be added to or removed from the **All production sites** group.

## 1.3 About the management of study sites

Adding sites to the study can only be done by the Study Manager.

The role of a Site Manager is to invite site users to a site. Yet, before a Site Manager can invite site users to a site, the Study Manager must select to which roles the Site Manager can invite users. These are normally roles like Investigator, Study Nurse, or Study Coordinator. For more information, see the eLearning section [Managing users](#).

Only the Study Manager can edit the site settings. The Site Manager can view the site settings as read-only.

### 1.3.1 Maximum number of subjects per site

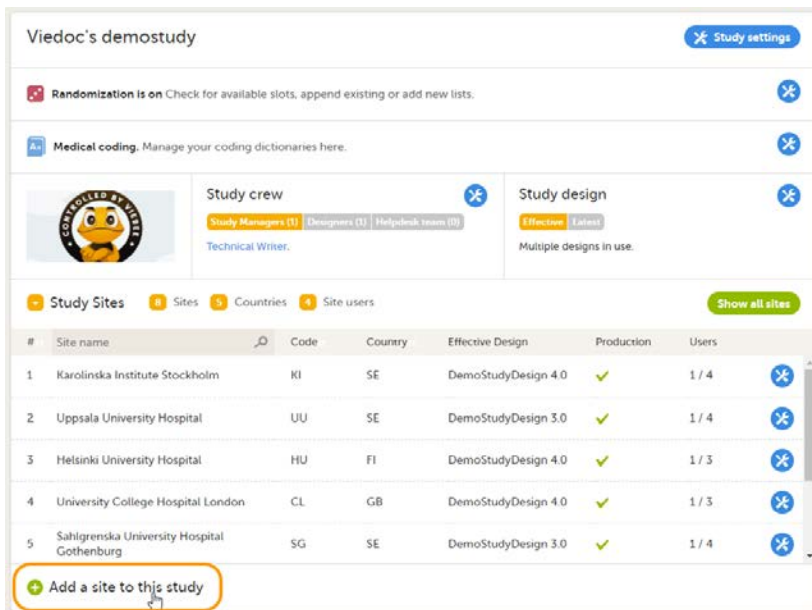
It is possible to limit the number of subjects for a site by setting a maximum number of subjects in the site settings. Once this limit is reached, it is not longer possible to add a new subject to the site, nor in Viedoc Clinic, neither through the import of data via the Application Programming Interface ([API](#)). Deleted subjects are not included in this limit.

## 2 Step-by-step guides

### 2.1 Adding a study site

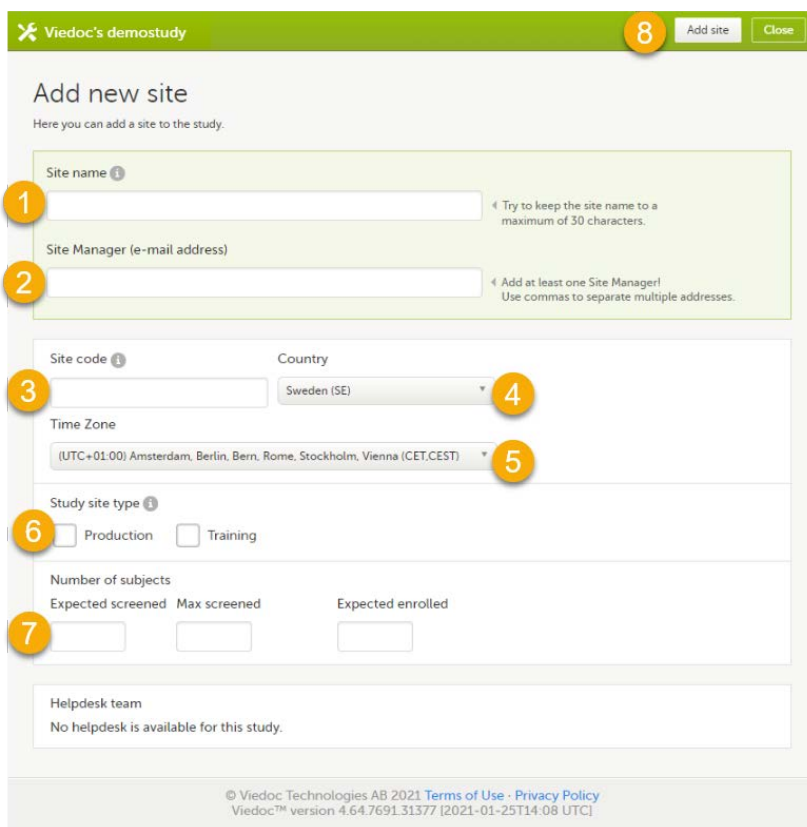
To add a site/clinic to the study:

1 In Viedoc Admin, on the study overview page, click **Add a site to this study**.



A pop-up window opens.

2 Enter the name of the site (1), and enter the e-mail address of the Site Manager (2). The role of the Site Manager is to invite site staff to the site.



3 Enter a code for the site (3). The site code can be used as part of the patient ID and will be indicated on the card.

4 Select the country in which the site is located (4), and select the time zone in which the site is located (5).

5 In the **Study site type** field (6), select whether the site should be available in production mode or training mode.

- Optionally, in the **Number of subjects** field (7), enter the expected number of screened subjects, the maximum number of screened subjects, and the expected number of enrolled subjects for the site.

The expected numbers of subjects are used for Metrics in Viedoc Clinic (see [Metrics](#)). The maximum is used to limit the number of subjects for this site, see [Maximum number of subjects per site](#) above.

- Click **Add site** (8).  
The pop-up closes and the site is added to the list of study sites.

## 2.2 Editing a study site

To edit the settings for a study site:

- Click the toolbox icon behind the name of the site in the study site list.

The screenshot shows the 'Viedoc's demostudy' interface. At the top, there are sections for 'Randomization is on', 'Medical coding', 'Study crew', and 'Study design'. Below these is the 'Study Sites' section, which contains a table with the following data:

#	Site name	Code	Country	Effective Design	Production	Users	
1	Karolinska Institute Stockholm	KI	SE	DemoStudyDesign 4.0	✓	1 / 4	✕
2	Uppsala University Hospital	UU	SE	DemoStudyDesign 3.0	✓	1 / 4	✕
3	Helsinki University Hospital	HU	FI	DemoStudyDesign 4.0	✓	1 / 3	✕
4	University College Hospital London	CL	GB	DemoStudyDesign 4.0	✓	1 / 3	✕
5	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign 3.0	✓	1 / 4	✕

At the bottom of the table, there is a '+ Add a site to this study' button. A hand cursor is shown clicking the '✕' icon in the rightmost column of the first row.

A pop-up opens.

2 Edit the settings you would like to change.

Viedoc's demostudy Close

### Karolinska Institute Stockholm

Here you can modify site details and/or invite users to site.

**Details** | Site users | Add users

Site name ⓘ  
Karolinska Institute Stockholm Site name is displayed to users

Site code ⓘ Country  
KI Sweden (SE)

Time Zone  
(UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna (CET,CEST)

Study site type ⓘ  
 Production  Training

Number of subjects  
Expected screened Max screened Expected enrolled  
10

Helpdesk team  
No helpdesk is available for this study.

Helpdesk users

<input type="checkbox"/> Site administrator	<input type="checkbox"/> Phone	<input type="checkbox"/> Email
<input type="checkbox"/> Dr. Investigator	<input type="checkbox"/> Phone	<input type="checkbox"/> Email
<input type="checkbox"/> Dr. Demo User	<input type="checkbox"/> Phone	<input type="checkbox"/> Email

### 2.3 Removing a study site

It is not possible to remove a study site in production mode from the study.



Assigning a study design

# Assigning a study design

Published by Viedoc System 2020-06-04

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- [1. Introduction](#)
- [2. Versions and revisions](#)
- [3. Viewing the effective study designs](#)
- [4. Assigning a study design](#)
- [5. Assigning a new design version](#)
- [6. Applying a design revision](#)
- [7. Viewing the audit trail of study designs](#)

This section explains how to assign a design to a the sites in a study. It is necessary to assign a study design to the sites in the study to start work on the site.

---

## 1 Introduction

Study designs are assigned to a study on a site level. The work on a site can only start when a study design version or revision has been assigned to that site. Without a design, there is no study configuration associated with the site.

When the Study Designer has finished setting up a study design in Viedoc Design, and has published the study design, it becomes available in Viedoc Admin. The Study Manager can then assign the study design to one or several sites in the study, and select an effective starting time for that design to be applied to the site.

At least one site should have been added to the study, before a study design can be assigned. A design can be assigned to all sites at once, or to individual sites in the study. It is thus possible to assign different study design versions or revisions to different sites in the study. Since study design versions or revisions are assigned to sites with a certain starting date, one site can have a certain study design version or revision assigned to it during a certain period of time, and another version or revision during another period of time.

The Study design field in the Study details pages displays the active designs in the study, and whether there are any new design versions or revisions available.

**Study design**

Effective Latest

Multiple designs in use.

#	Site name	Code	Country	Effective Design	Production	Users
1	Karolinska Institute Stockholm	KI	SE	DemoStudyDesign 4.0	✓	1 / 4
2	Uppsala University Hospital	UU	SE	DemoStudyDesign 3.0	✓	1 / 4
3	Helsinki University Hospital	HU	FI	DemoStudyDesign 4.0	✓	1 / 3
4	University College Hospital London	CL	GB	DemoStudyDesign 4.0	✓	1 / 3
5	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign 3.0	✓	1 / 4

To see the study design or designs that are in use, click **Effective**.

**Study design**

Effective Latest

Multiple designs in use.

To see whether there is a new design version or revision available, click **Latest**.

**Study design**

Effective Latest

DemoStudyDesign 6.0 (published 2018-04-16 14:28)

**Note!** The study design needs to be published in Viedoc Designer, before it is available in Viedoc Admin.

## 2 Versions and revisions

The settings in the study design are version-controlled and identified by the version number. Study design version numbers are unique within a study. If there are five study design versions in the study, and a new one is created, the new version will have version number 6. Study design version numbers are accompanied with a revision number. For example, version "1.6" means revision 6 of version 1.

The main reason to assign a new study design version to a site after study start is that protocol amendments require changes to be made to the study design, for example changes to the study that apply from a specific point in time during the course of the study.

If there is a need to correct errors in a study design version that has already been assigned and used for entering data, the study design version has to be revised and the revision has to be applied to the applicable sites.

For more detailed information, see [Viedoc study configuration management](#).

### 3 Viewing the effective study designs

To view a list of effective designs for all sites, click the toolbox icon in the **Study design** field on the study details page. The Design settings pop-up opens:

Site	Design	Effective on (UTC)	Scheduling (UTC)
Karolinska Institute Stockholm	DemoStudyDesign 4.0	2018-02-13 09:44	-
Karolinska Institute Stockholm	DemoStudyDesign 7.0	-	🕒 2018-05-16 00:00
Uppsala University Hospital	DemoStudyDesign 3.0	2018-02-13 09:43	-
Helsinki University Hospital	DemoStudyDesign 4.0	2018-02-13 09:44	-
University College Hospital London	DemoStudyDesign 6.0	2018-04-16 14:43	-
Sahlgrenska University Hospital Gothenburg	DemoStudyDesign 3.0	2018-02-13 09:43	-
Charite University Hospital Berlin	DemoStudyDesign 3.0	2018-02-13 09:43	-

In the **Effective design per site** list, the current effective designs (design effective on this date) and the designs scheduled to become effective are listed per site. The list also includes information about when that design became effective on the site, and/or when the design is scheduled to become effective on the site. Time is displayed in Coordinated Universal Time ([UTC](#)).

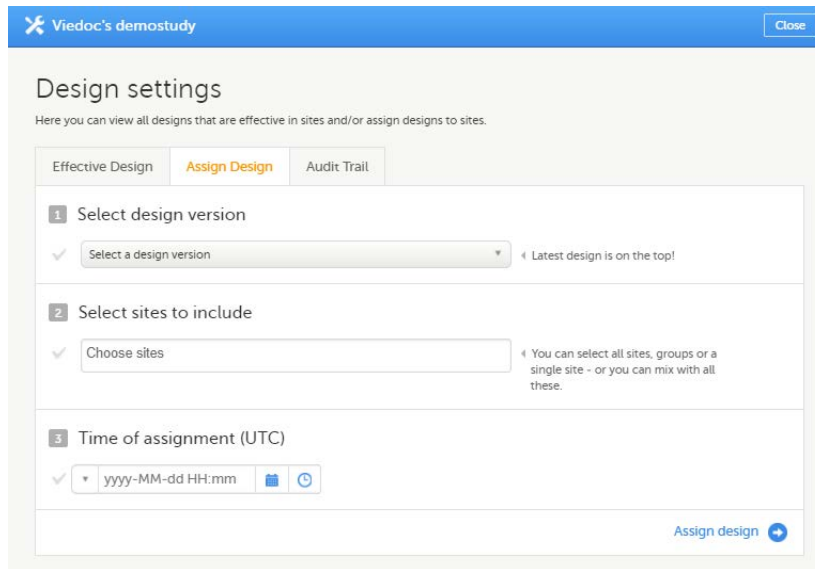
### 4 Assigning a study design

To assign a design to sites in a study, follow the steps below.

- 1 Click the toolbox icon in the **Study design** field on the study details page. The Design settings pop-up opens.

2 On the **Assign Design** tab:

1. Select the design version from the drop-down list.
2. Select the sites to include. It is possible to select 'All sites', or individual sites.
3. Select the time of assignment. This can be done in various ways:
  - Click the arrow to the left of the date field and select 'Now' or 'Tomorrow', or
  - Click the calendar icon and select a date.



3 Click **Assign design**.

The design is applied to the site and a confirmation message is briefly shown.

## 5 Assigning a new design version

Assigning a new design version is done in exactly the same way as assigning a study design. See [Assigning a study design](#) for instructions.

## 6 Applying a design revision

Application of a revised study design is used to upgrade forms that are already saved. When a revision of a study design is applied to a site, that revision will (after confirmation by the site) replace the version it is revising.

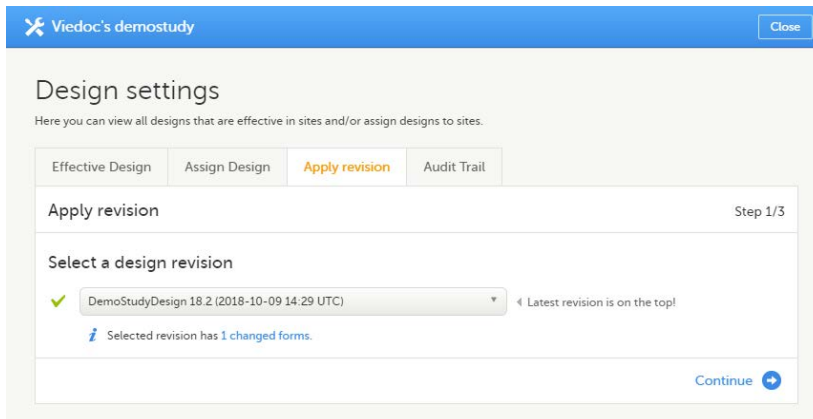
**Note!** A revision of a version only replaces the version it is revising. If you need to change something that is present in more than one version effective in your study, you need to revise all those versions applicable to the change. See [Duplicate a design - versions and revisions](#).

To apply a design revision to sites in a study, follow the steps below.

- 1 Click the toolbox icon in the **Study design** field on the study details page. The Design settings pop-up opens.

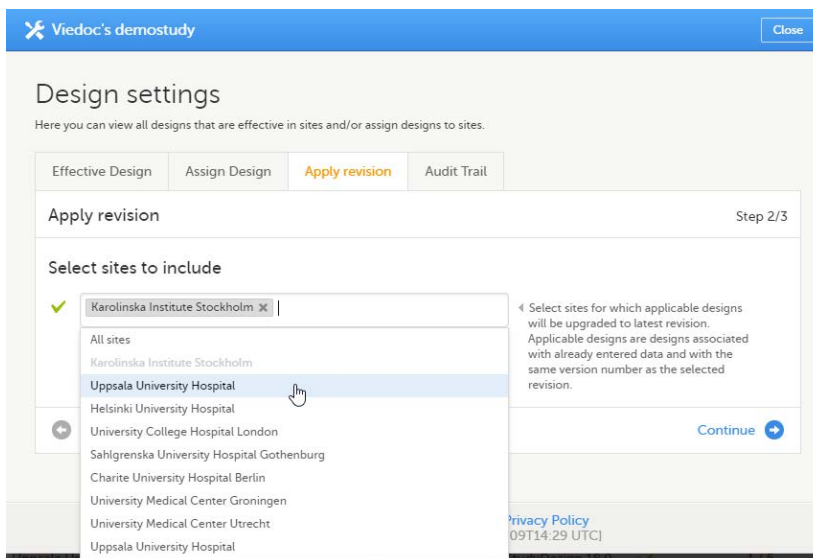


- 2 On the **Apply Revision** tab, select the design revision from the drop-down list and click **Continue** (Step 1/3).



The system provides information about the impact of the revision by showing how many forms have been changed in blue text.

- 3 Select the sites the revision should be applied to. It is possible to select 'All sites', or individual sites. Click **Continue** (Step 2/3).



- 4 Type a message to the Clinic user in the Upgrade message field. This message could be a summary of the changes in the revision. It is displayed in Viedoc Clinic on the Messages page.

Click **Apply revision** (Step 3/3).  
The pop-up closes and the revision is applied.

After a revision has been applied, the clinic user (with permission to enter data) needs to approve the application in Viedoc Clinic. On the Messages page in Viedoc Clinic, the following message is displayed.

Application of the revision can be done in two ways:

1. Approve the changes to all affected forms at once by entering the password and clicking **Confirm** below the displayed message (batch approval).
2. Approve each affected form by opening them individually and follow the instructions. Affected forms are indicated by the red issue icon.

Forms upgraded to a new design revision by the site will lose any existing signature and review flags (clinical review, data review). The Source Data Verification (**SDV**) flag is lost on item level. If a particular item, that was previously source data verified, is affected by the upgrade, it will no longer be flagged as having been source-data verified. The form-level SDV flag will be lost if any item in the form lost its SDV flag. The form-level SDV flag will also be lost if an item is removed from a form as part of the upgrade.

## 7 Viewing the audit trail of study designs

To view a list of effective designs for all sites, click the toolbox icon in the **Study design** field on the study details page. In the Design settings pop-up, open the **Audit Trail** tab.

## Design settings

Here you can view all designs that are effective in sites and/or assign designs to sites.

Effective Design   Assign Design   **Audit Trail**

### Study site audit trail

Site	Design	Effective on (UTC)	Applied by	Applied on (UTC)
Uppsala University Hospital	DemoStudyDesign 7.0	2018-04-24 09:35	Technical Writer	2018-04-24 09:38
Karolinska Institute Stockholm	DemoStudyDesign 7.0	2018-05-16 00:00	Technical Writer	2018-04-24 09:31
University College Hospital London	DemoStudyDesign 6.0	2018-04-16 14:43	Technical Writer	2018-04-16 14:56
Karolinska Institute Stockholm	DemoStudyDesign 4.0	2018-02-13 09:44	Technical Writer	2018-02-13 09:44
Helsinki University Hospital	DemoStudyDesign 4.0	2018-02-13 09:44	Technical Writer	2018-02-13 09:44
University College Hospital London	DemoStudyDesign 4.0	2018-02-13 09:44	Technical Writer	2018-02-13 09:44
Uppsala University Hospital	DemoStudyDesign 3.0	2018-02-13 09:43	Technical Writer	2018-02-13 09:43

The audit trail lists the sites to which designs are assigned, which design is assigned, on what date that design is effective. It also lists who assigned the design to that site and on what date.



Assigning helpdesk users

# Assigning helpdesk users

Published by Viedoc System 2019-04-05

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[1. Introduction](#)

[2. Adding helpdesk users](#)

This lesson describes how to configure the helpdesk information for a study.

---

## 1 Introduction

A helpdesk user is a user that can act as support for the individual site. When a user is selected to be a helpdesk user, his/her contact information (name, phone and/or email) becomes available to the site staff, and the site staff can contact him/her with questions about the study. A helpdesk user can be any user that has access to the study, and that has a role that is not delegated to the Site Manager.

For information about delegating roles to the Site Manager, see the eLearning section about [Managing users \(STM and SIM\)](#).

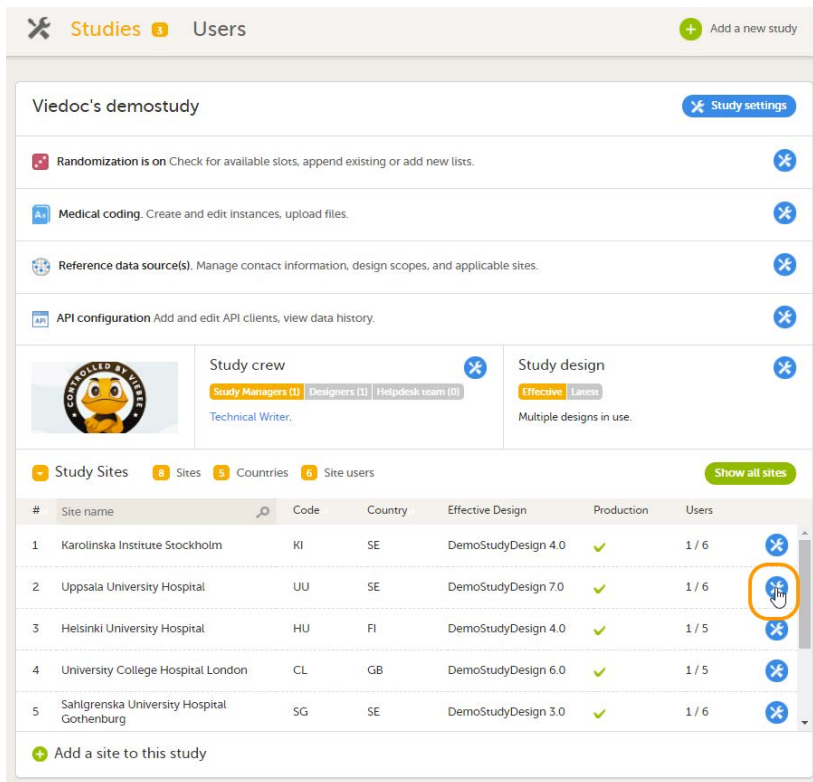
Helpdesk users are assigned on site level.

---

## 2 Adding helpdesk users

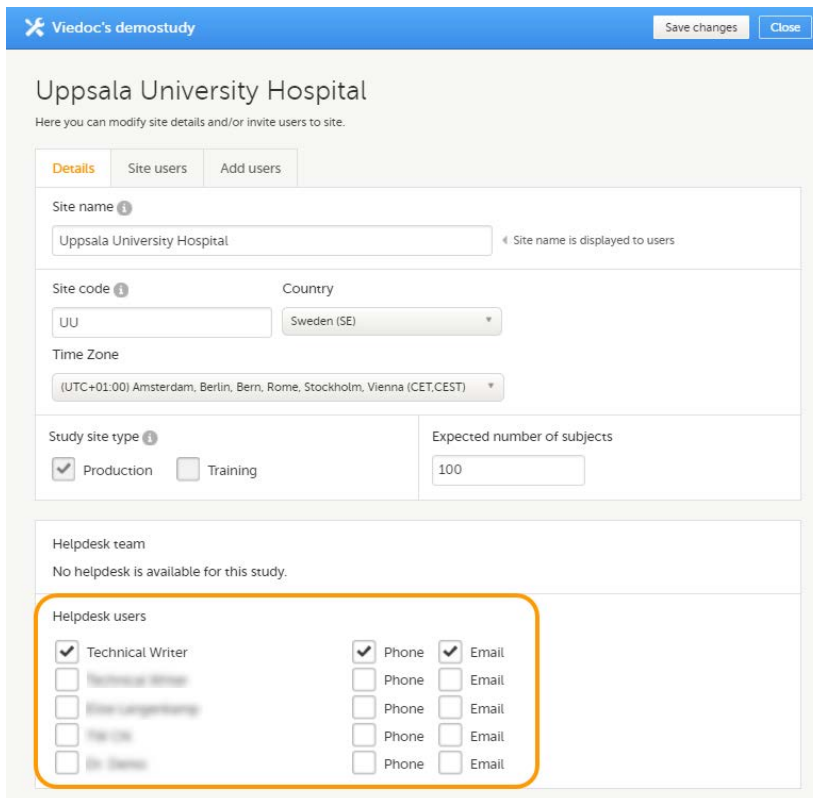
To add a helpdesk user, follow the steps below.

- 1 Click the toolbox icon behind the name of the site in the study site list to open the site settings pop-up.



- 2 In the field **Helpdesk users**, select the users that should be available as helpdesk users. The users listed in this field are all clinic users that are assigned to that specific site, and that have a role that is not administered by the Site Manager. Select the way the helpdesk user can be contacted: phone and/or e-mail.

**Note!** The user roles administered by the Site Manager are defined in the **Study Settings** (see [General study settings](#)).

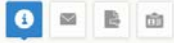




The users selected as helpdesk users will be displayed in Viedoc Clinic. Click the help icon on the landing page to view a list of helpdesk users that can be contacted by the site staff in case they need support.

## Viedoc's demostudy


Confirmatory validation of oral macimorelin as a growth hormone (GH) stimulation test (ST) for the diagnosis of adult growth hormone deficiency (AGHD) in comparison with the insulin tolerance test (ITT) - (only for site Italy)


 Launch



 Contact us if you need any help 


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Locking a study

# Locking a study

Published by Viedoc System 2021-11-24

## [1. Introduction](#)

### [2. Step-by-step guides](#)

#### [2.1 Locking a study](#)

#### [2.2 Unlocking a study](#)

#### [2.3 Downloading the study status report](#)

## 1 Introduction

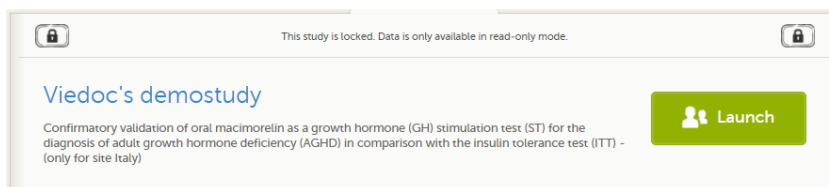
A study can be locked in Viedoc when the study is completed, that is, when all events have been completed, reviewed and approved/signed, and no more data will be added to the study. When the study is locked in Viedoc, it is still possible to view and export data, but it is NOT possible to add or edit any data. It is also NOT possible to change the study settings or add new sites. However, it is still possible to invite new users to existing sites. These users will then receive access as read-only.

When the study is locked, a lock icon is displayed in Viedoc Clinic:

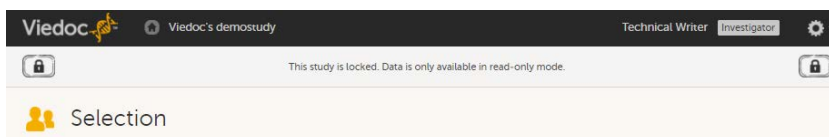
- On the study card on the landing page...



- ...above the study name when entering the study from the landing page...



- ...and on the Selection page within the study.



**Note!** The study license is based on the study state and will be invoiced until the study is locked. After the study is locked, a post study access fee will be charged if the study is not deleted within three months.

**Note!** It is possible to unlock a locked study, and lock it again.

When the study is locked, a request for deletion of the study from Viedoc can be submitted, see [Deleting a study \(STM\)](#) for more information.

For traceability, all lock and unlock actions are audit trailed. You can download a report that provides a full history of the lock and unlock actions, including who performed the actions and when (date and time in Coordinated Universal Time (UTC)), and the reason that was given for locking/unlocking the study. The report also contains the full history of all requests for study deletion, approvals of study deletion, and reversions of study deletion that are performed in the study.

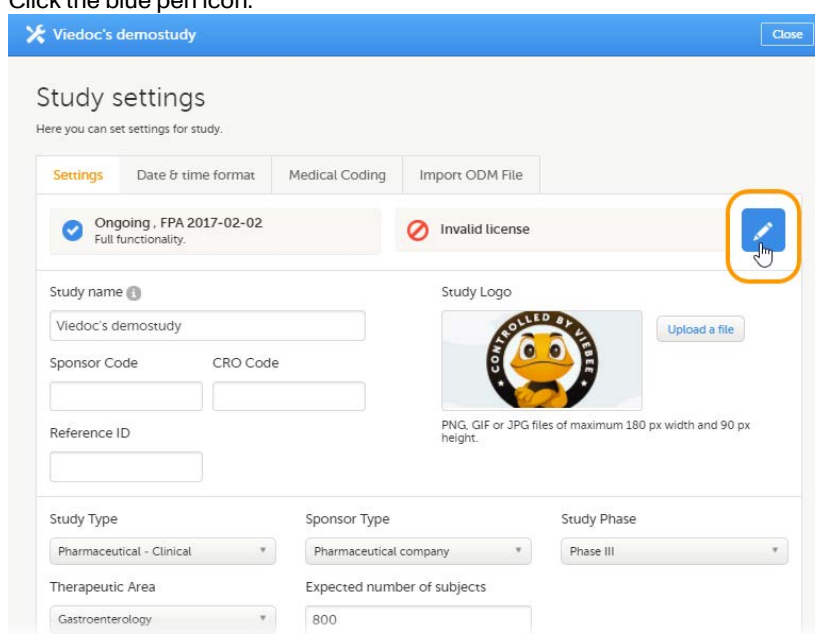
## 2 Step-by-step guides

### 2.1 Locking a study

**Note!** A study can only be locked by the **Study Manager**.

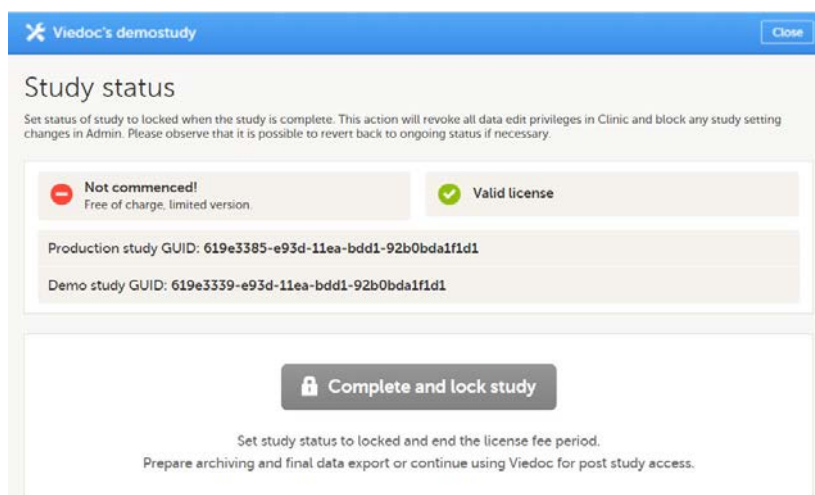
To lock a study, follow the steps below.

- 1 Open the study in Viedoc Admin and click **Study settings**.  
The Study settings window opens.
- 2 Click the blue pen icon.



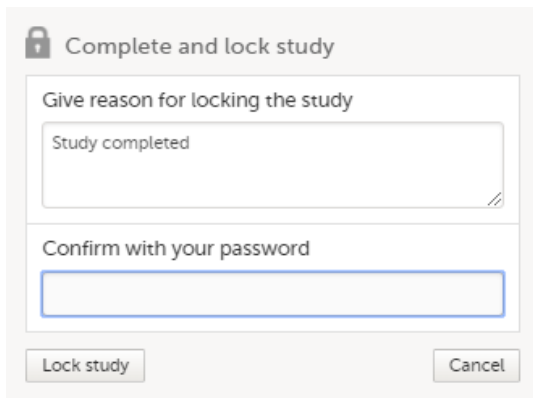
The Study status pop-up opens.

- 3 Click **Complete and lock study**.



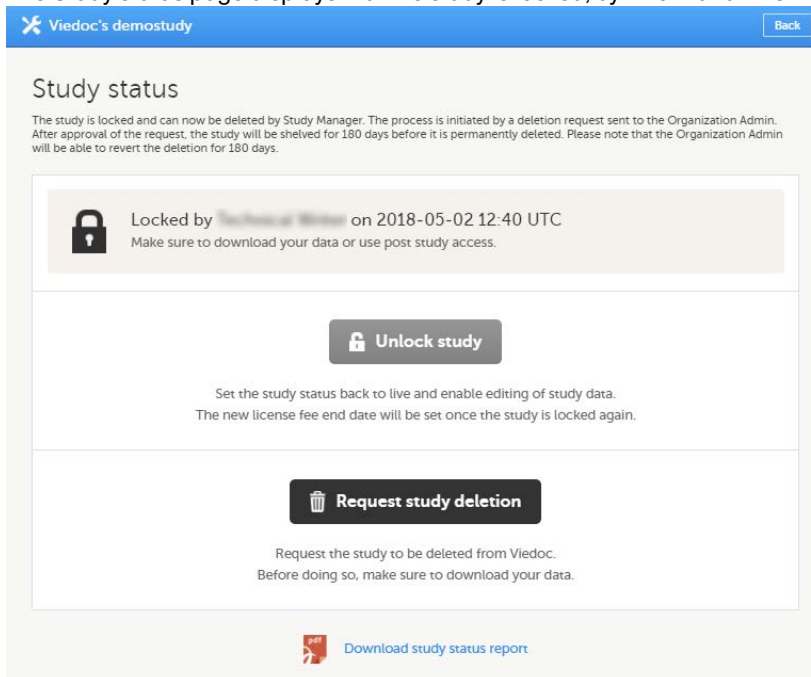


- 4 A pop-up opens. Enter a reason for locking the study, and enter your password.



The dialog box is titled "Complete and lock study" and contains two text input fields. The first field is labeled "Give reason for locking the study" and contains the text "Study completed". The second field is labeled "Confirm with your password" and is currently empty. At the bottom of the dialog, there are two buttons: "Lock study" on the left and "Cancel" on the right.

- 5 Click **Lock study**.  
The Study status page displays that the study is locked, by whom and when.



The screenshot shows the "Study status" page for "Viedoc's demostudy". At the top, there is a blue header with the study name and a "Back" button. Below the header, the page title "Study status" is followed by a paragraph explaining that the study is locked and can be deleted by the Study Manager. A central notification box states: "Locked by Technical Writer on 2018-05-02 12:40 UTC. Make sure to download your data or use post study access." Below this, there are three main action buttons: "Unlock study" (with a lock icon), "Request study deletion" (with a trash icon), and "Download study status report" (with a PDF icon). The "Unlock study" button includes a sub-note: "Set the study status back to live and enable editing of study data. The new license fee end date will be set once the study is locked again."

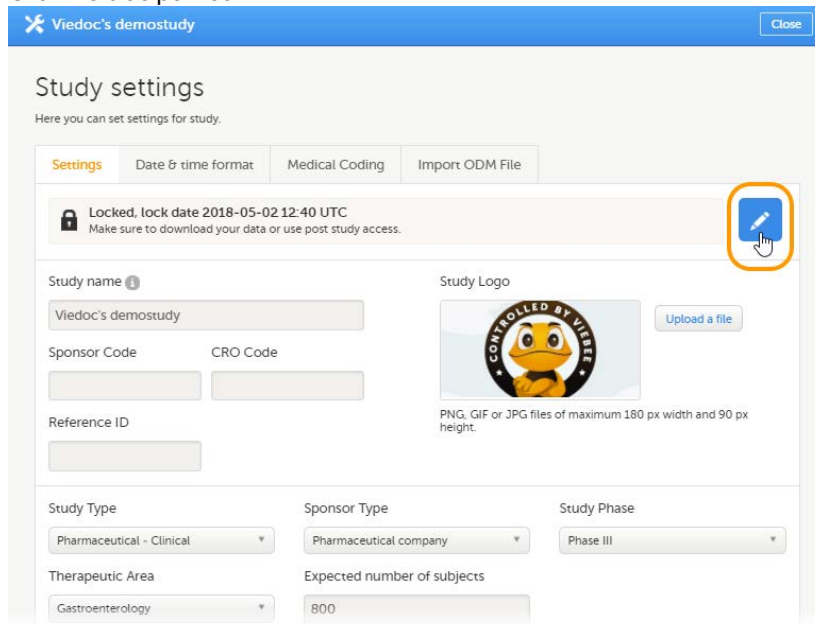
## 2.2 Unlocking a study

**Note!** A study can only be unlocked by the **Study Manager**.

To unlock a study, follow the steps below.

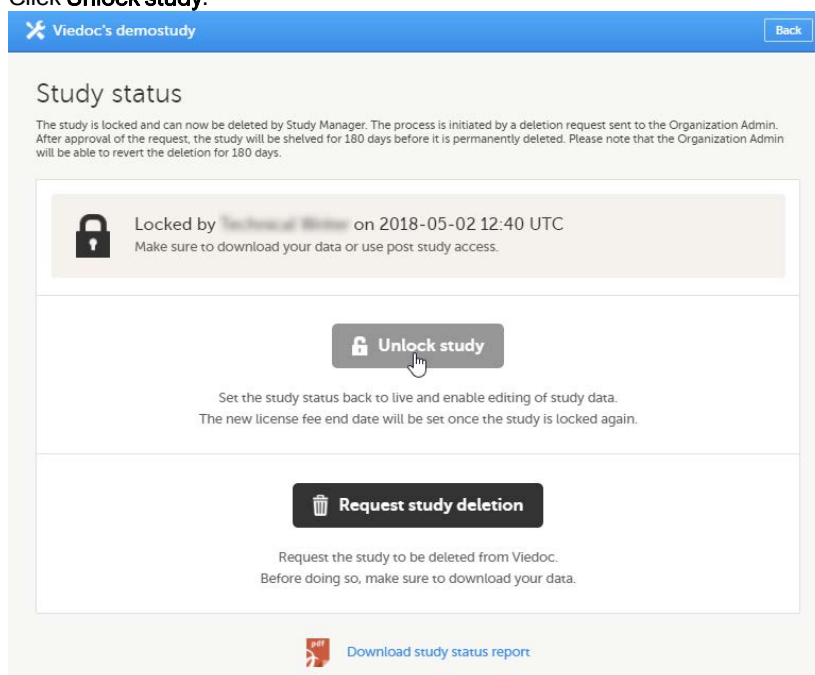
- 1 Open the study in Viedoc Admin and click **Study settings**.  
The Study settings window opens.

2 Click the blue pen icon.



The Study status pop-up opens.

3 Click **Unlock study**.



Enter a reason for unlocking the study, and enter your password.

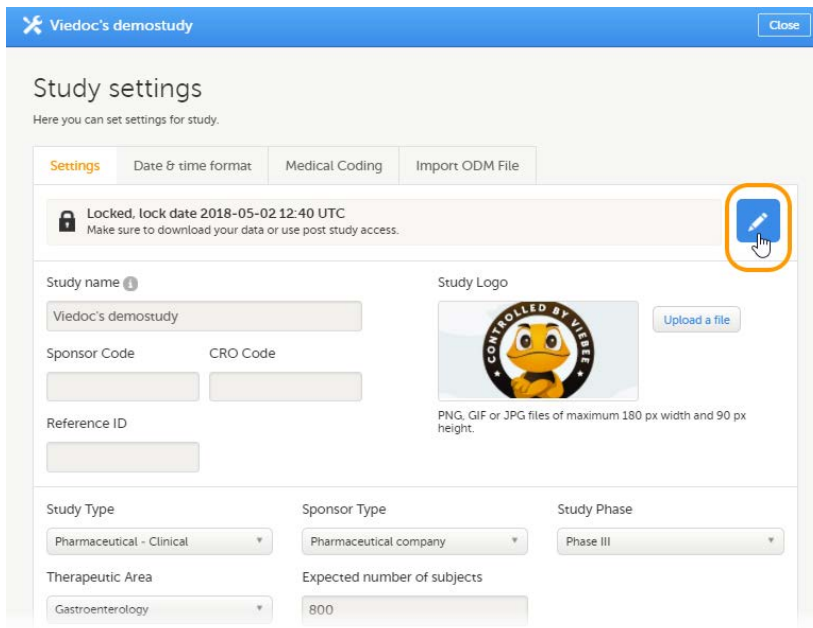
4 Click **Unlock study**.

## 2.3 Downloading the study status report

To download the study status report, follow the steps below.

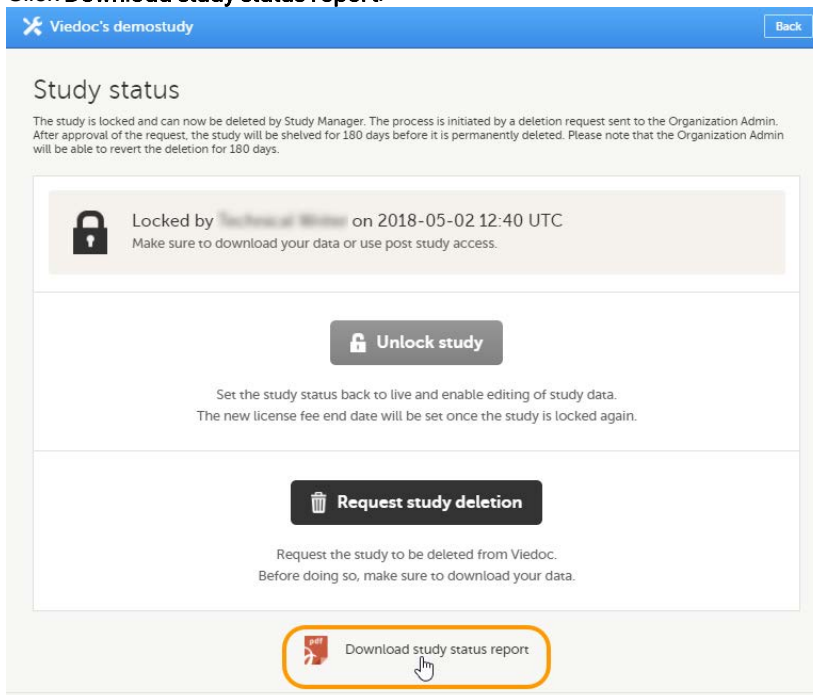
1 Open the study in Viedoc Admin and click **Study settings**. The Study settings window opens.

2 Click the blue pen icon.



The Study status pop-up opens.

3 Click **Download study status report**.



A PDF is downloaded that lists all database lock and delete actions, including when and by whom the study was locked/deleted, and the reason that was given for locking/deleting the study.



Archiving a study

# Archiving a study

Published by Viedoc System 2023-03-08

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[1. Lock study](#)

[2. Export data](#)

[2.1 Export study data](#)

[2.2 Export study design](#)

[3. Download user logs](#)

[4. Delete a study](#)

This is a description of the main steps in the process of archiving a clinical study. The detailed instructions for each step are described in the linked lessons.

Archiving a clinical study is the responsibility of the sponsor (study Trial Master File ([TMF](#))) and the investigators (site TMFs). The study archive should include all study data and metadata, including the study design.

When a study is complete, you typically need to go through the steps below.

---

## 1 Lock study

As a Study Manager, you can lock a study when all events have been completed, reviewed, approved/signed, and no more data will be added to the study.

When a study is locked, it is still possible to view and export data. It is not possible to add or edit any data. It is also not possible to change the study settings or add new sites. However, it is still possible to invite new users to existing sites. These users will then receive read-only access.

For more information, see [Locking a study](#).

---

## 2 Export data

### 2.1 Export study data

You can export **study data** if your Viedoc Clinic user role is set up with the rights for it. For more information, see the *Data export* section in [Viedoc Clinic User Guide](#).

Make sure to filter the data export to include the following:

- Audit trail
- Query history
- Medical coding
- Review status

The data export in Viedoc supports all file formats that are required for archiving and regulatory purposes, including these formats:

- Portable Document Format Archive ([PDF/A](#)) - an International Organization for Standardization ([ISO](#))-standardized version of the PDF format, specialized for archiving and long-term preservation of electronic documents
- Office Open Extensible Markup Language ([XML](#)) - a zipped, XML-based file format for spreadsheets (for example Excel), charts, presentations, and word processing documents
- Statistical Analysis System ([SAS](#)) - a format used for statistical analysis in the SAS software suite

- Operational Data Model (ODM) - a vendor-neutral, platform-independent format for exchanging and archiving clinical research data, along with their associated metadata, administrative data, reference data, and audit information

## 2.2 Export study design

As part of the TMF structure, the sponsor should define the exact details of:

- What data should be exported from Viedoc for archiving
- When data should be exported
- How data will be archived

You can export the **study design** from Viedoc Designer. For more information, see [Exporting/Locking/Deleting a study design](#). If a study has more than one version of the study design, remember to export all versions.

## 3 Download user logs

On the **Users** page, select to group the users by *Studies*.

The screenshot shows the Viedoc Users interface. At the top, there are tabs for 'Studies' and 'Users' (with a '12' badge). A search bar is on the left, and sorting options (Name, Status, Date created) are in the center. A 'Group by' dropdown menu is open, showing 'Studies' selected. Below the menu, there are two study sections: 'Viedoc's demostudy' and 'Documentation of Life'. Each section has a table of users with columns for User, Study and site, Role, Skill level, and Status. The 'Viedoc's demostudy' table lists users like 'Dr. Demo (383)', 'Dr. Investigator (490)', and 'Technical Writer (304)'. The 'Documentation of Life' table lists users like 'Blair Langenberg (294)' and 'Technical Writer (304)'. Each user row has a 'Generate a PDF file 'Log of users and roles'' button.

Scroll to the study from which you would like to download the user log and select **User logs** to open the dropdown menu.

7 users

The screenshot shows a user management interface for a study named "First study". A table lists three users: "Dr Investigator (1714)", "Dr Investigator (1714)", and "Technical Writer (1736)". A dropdown menu titled "User logs" is open, showing options for "Log of users and roles", "User administration log", and "User communication log". Each option has a "Generate" button. The "User communication log" option also includes a "Download (2022-03-02 09:25)" link and a "Regenerate" button. The table columns are "User", "Study and site", and "Role".

User	Study and site	Role
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Investigator
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Study Manager + 12 other roles
Technical Writer (1736) Name.lastname@mail.com	First study Multiple sites	Investigator

If the log was not previously generated, click **Generate a PDF file** or **Generate an Excel file**. If the log was previously generated, the most recent version is stored on the server, shown with a date and time stamp. You can download it by selecting the link, or generate an updated version by clicking **Regenerate**.

**Note!** The user logs are generated in the language set by the user who is generating the log. Therefore, the previously generated file is available for download only if it was generated in the language you have currently set in Viedoc.

## 4 Delete a study

A study can be permanently deleted from Viedoc when the study is locked. Deletion is initiated by the Study Manager, who can submit a request to delete the study to the Organization Administrator. The Organization Administrator can then approve or reject the request.

After study deletion is approved by the Organization Administrator, the study is shelved in Viedoc's database. A deleted study is not visible in Viedoc Clinic or Viedoc Designer, the study is only displayed in the study overview page of the Organization Administrator in Viedoc Admin.

The Organization Administrator can revert the deletion of a study within 180 days after the deletion request has been approved. After this period, the study, including all study details and data, will be permanently deleted from the Viedoc database. It will not be possible to find any traces of the study and the subjects included.

For more information, see:

- [Deleting a study \(for the Study Manager\)](#)
- [Deleting a study \(for the Organization Administrator\)](#)



Deleting a study (for Study Manager)

# Deleting a study (for Study Manager)

Published by Viedoc System 2020-06-04

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## [1. Introduction](#)

## [2. Step-by-step guides - for the Study Manager](#)

### [2.1 Requesting study deletion](#)

### [2.2 Downloading the study status report](#)

This lesson describes how a study is deleted. The instructions are intended for the **Study Manager (STM)**.

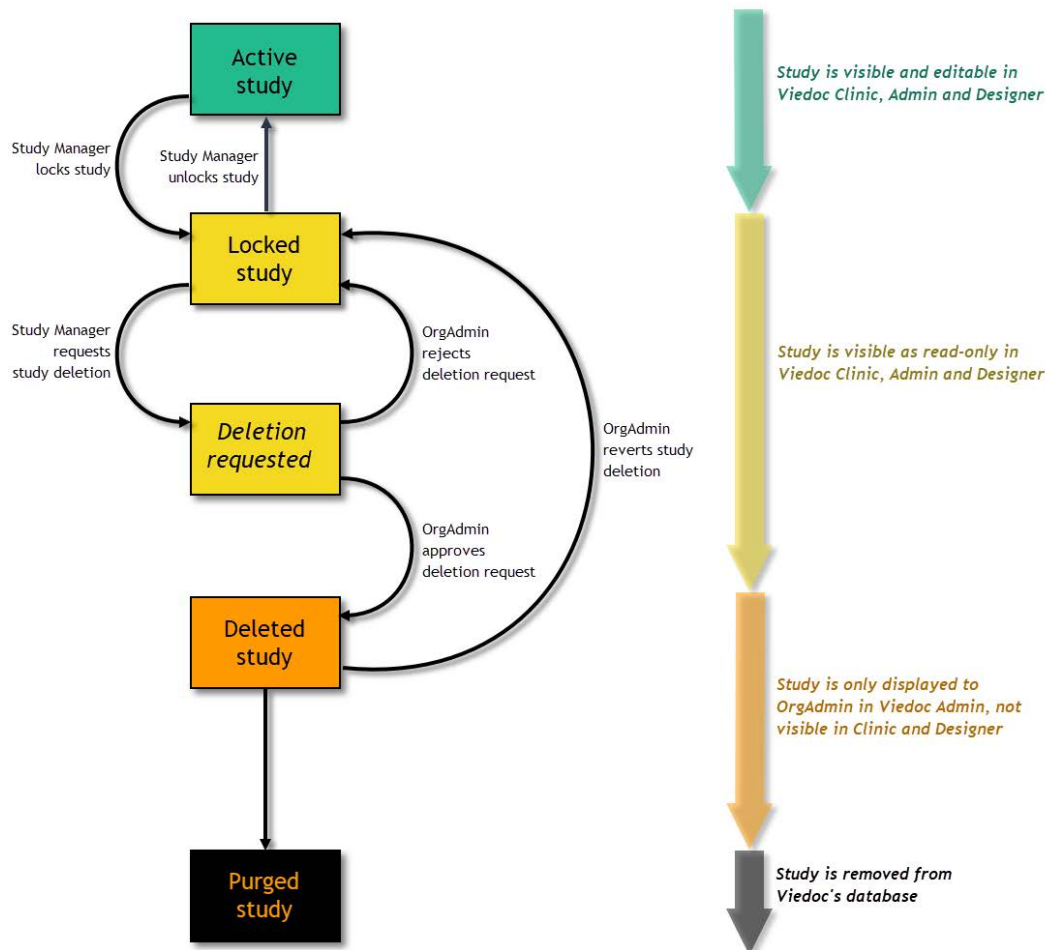
---

## 1 Introduction

A study can be permanently deleted from Viedoc when the study is **locked**. Deletion is initiated by the **Study Manager**, who can submit a request to delete the study from Viedoc to the **Organization Administrator**. The **Organization Administrator** can then approve or reject a request for study deletion.

After study deletion is requested by the Study Manager and approved by the Organization Administrator, the study is shelved on Viedoc's database. A deleted study is not visible in Viedoc Clinic or Viedoc Designer, the study is only displayed in the study overview page of the Organization Administrator in Viedoc Admin.

The Organization Administrator is able to revert the deletion of a study within 180 days after the deletion request has been approved. After this period, the study will be permanently purged from Viedoc's database, and all study details and data will be permanently **removed**. It will not be possible to find any traces of the study and the subjects included.



For traceability, all study delete actions are audit trailed. You can download a report that provides a full history of all requests for study deletion, approvals of study deletion, and reversions of study deletion that are performed in the study, including who performed the actions and when (date and time in [UTC](#)), and the reason that was given for deleting the study or reverting study delete. The report also contains the full history of all lock and unlock actions.

**Note!** This section is intended for the Study Manager. For instructions for the Organization Manager, see [Deleting a study \(Org Admin\)](#).

## 2 Step-by-step guides - for the Study Manager

### 2.1 Requesting study deletion

A request for study deletion can only be submitted by the Study Manager. A study can only be deleted after the study is locked. For information on how to lock a study, see [Locking a study](#).

**Note!** Before deleting the study, make sure that you have downloaded the user report, the data export archive and the study design. Download and archive the study data in the formats necessary, available formats are Excel, Comma-Separated Values ([CSV](#)), Operational Data Model ([ODM](#)) and PDF. For instructions, see:

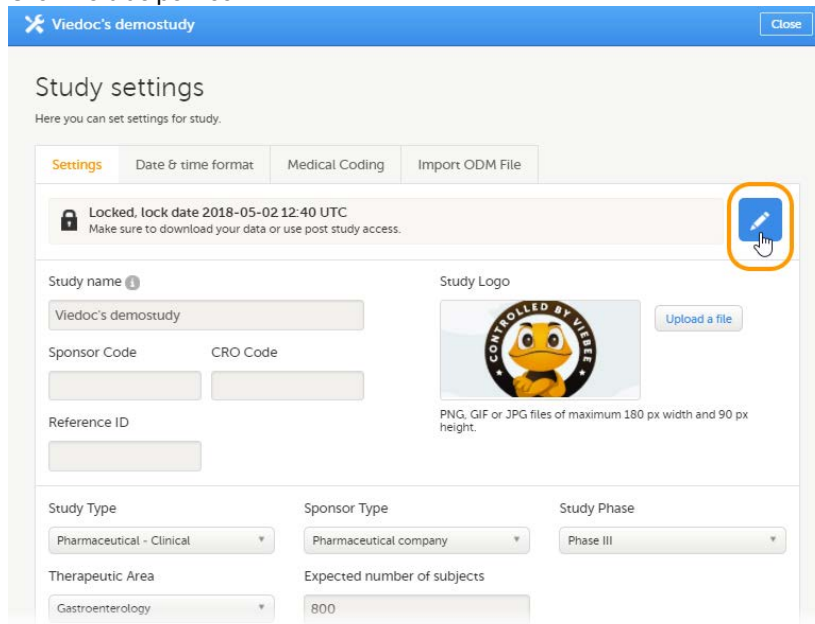
1. [Downloading the user report in Managing Users \(STM and SIM\)](#) (Viedoc Admin),
2. [Exporting data](#) (Viedoc Clinic),
3. [Exporting/Locking/Deleting a study design](#) (Viedoc Designer).

To submit a request for study deletion:

1. Open the study in Viedoc Admin and click **Study settings**. The Study settings dialog opens.

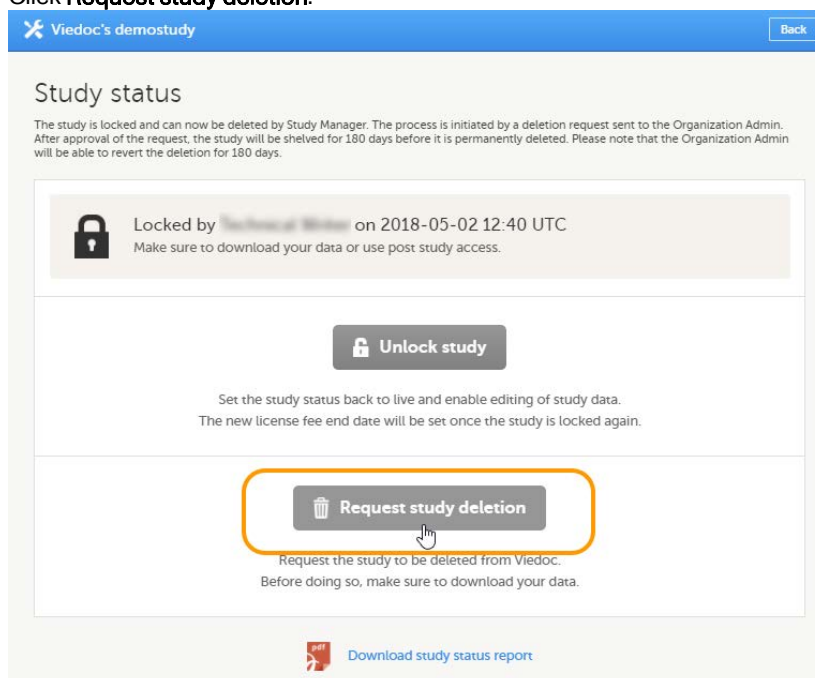


2 Click the blue pen icon.



The study status pop-up opens.

3 Click **Request study deletion**.



The request study delete pop-up opens.

4 Select whether the following actions are done or not done:

- Download user report
- Download the data export archive required
- Download study design

Enter a reason for deleting the study, and enter your password.

**Request study deletion**

Before deleting the study, I understand that I am responsible for the following actions:

Download user report  
 Done  Not done

Download the data export archive required  
 Done  Not done

Download study design  
 Done  Not done

Reason for study delete  
Study completed and ready for deletion

Confirm with your password

Request study deletion Cancel

5 Click **Request study deletion**.

The Study status page displays that deletion of the study is requested, by whom and when (date and time in Coordinated Universal Time (UTC)), and the study delete request will be sent to the Organization Administrator. All Study Managers and Organization Administrators will be notified of the request by email.

Viedoc's demostudy Back

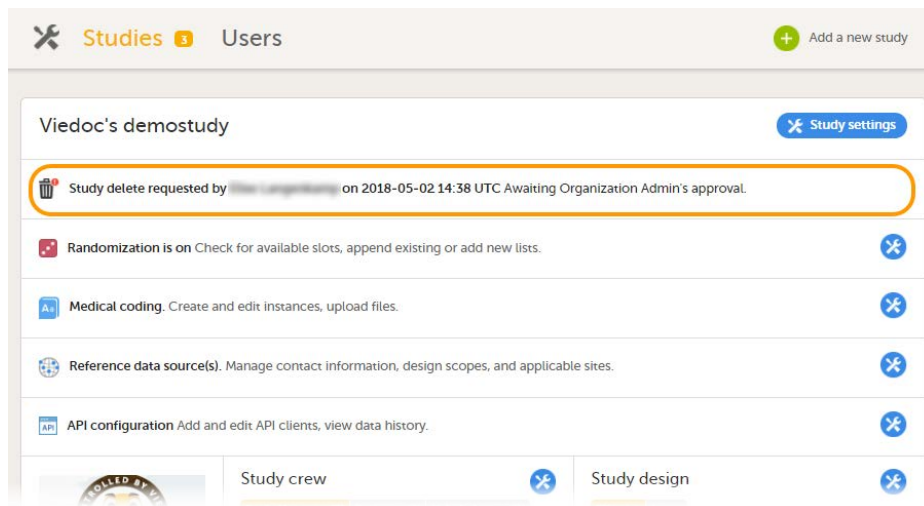
### Study status

The study is locked and can now be deleted by Study Manager. The process is initiated by a deletion request sent to the Organization Admin. After approval of the request, the study will be shelved for 180 days before it is permanently deleted. Please note that the Organization Admin will be able to revert the deletion for 180 days.

Study delete requested by [User Name] on 2018-05-02 14:38 UTC  
Awaiting Organization Admin's approval.

Download study status report

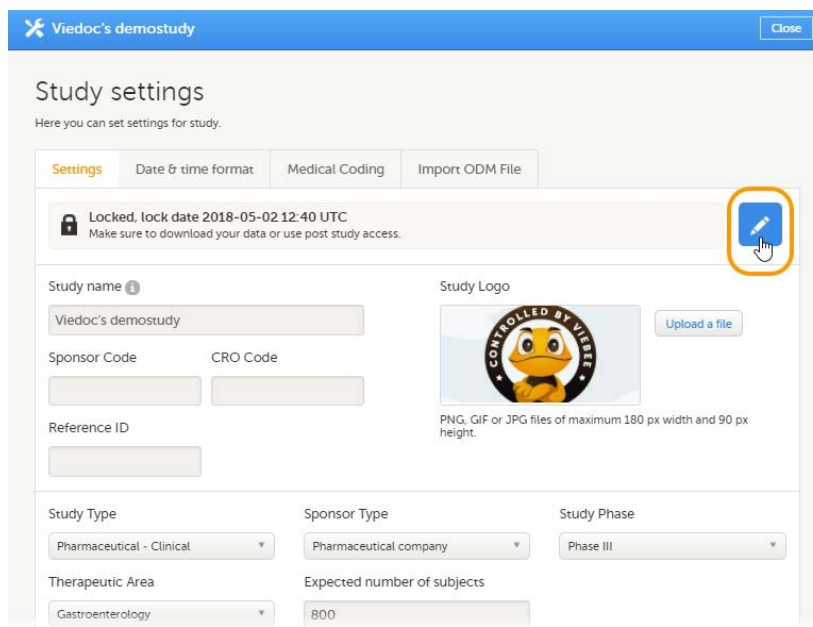
When study deletion has been requested, the study page will display the status "Study delete requested by ... on ..."  
Until the request has been approved, the study will be in locked state and visible in Viedoc Clinic and Viedoc Designer.



## 2.2 Downloading the study status report

To download the study status report:

- 1 Open the study in Viedoc Admin and click **Study settings**. The Study settings dialog opens.
- 2 Click the blue pen icon.



The Study status pop-up opens.

3

Click **Download study status report**.

Viedoc's demostudy Back

### Study status

The study is locked and can now be deleted by Study Manager. The process is initiated by a deletion request sent to the Organization Admin. After approval of the request, the study will be shelved for 180 days before it is permanently deleted. Please note that the Organization Admin will be able to revert the deletion for 180 days.

Locked by **Technical Admin** on 2018-05-02 12:40 UTC  
Make sure to download your data or use post study access.

**Unlock study**

Set the study status back to live and enable editing of study data.  
The new license fee end date will be set once the study is locked again.

**Request study deletion**

Request the study to be deleted from Viedoc.  
Before doing so, make sure to download your data.

**Download study status report**

A PDF is downloaded that lists all database lock and delete actions, including when and by whom the study was locked/deleted, and the reason that was given for locking/deleting the study.



Admin audit trail report

# Admin audit trail report

Published by Viedoc System 2023-10-09

[1. Downloading the Admin audit trail report](#)

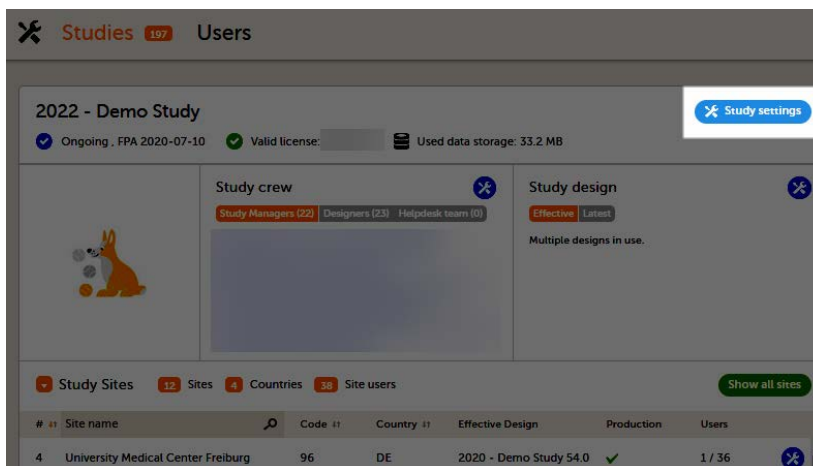
[2. The contents of the Excel file](#)

The Admin audit trail report contains information about all settings and changes of study settings that have been made by authorized users in Viedoc Admin.

## 1 Downloading the Admin audit trail report

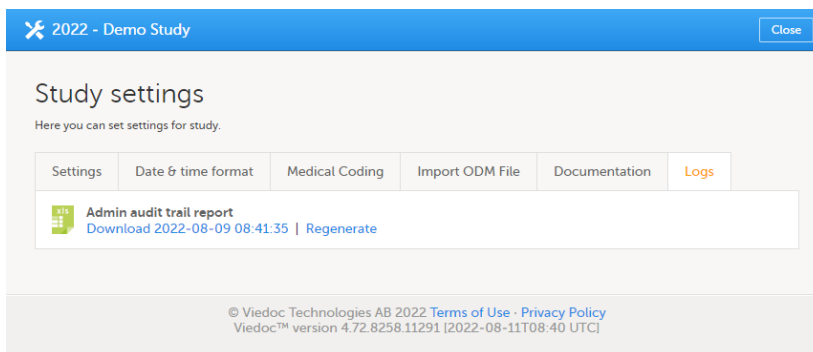
To download the Admin audit trail report:

- 1 In Viedoc Admin, open the study settings from the study details page.

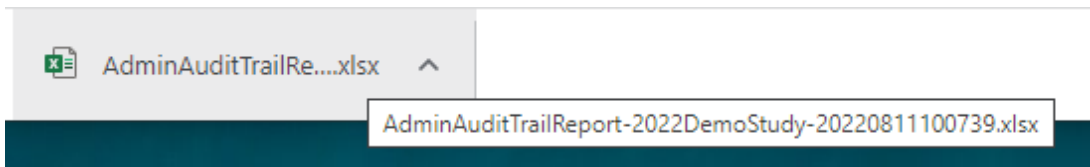


- 2 On the **Logs** tab, you can generate and download the Admin audit trail report.

If the report was already generated, you can regenerate it to get a report with all the latest information.



3 When you select **Download**, an Excel file is available in your browser.



## 2 The contents of the Excel file

The Excel file contains the following sheets:

- **Report Info** - general information about when and by whom the report was generated and some information about the study status
- **Action Logs** - a list with detailed information about each action regarding the study in Viedoc Admin. The columns in this sheet are:
  - Area - one of the following values: eTMF, Medical Coding, Reference Data Sources, RTSM, Site Settings, Study Design, Study Settings, User Invitations, User Logs, WCF API client configuration, and Web API client configuration
  - Action - see the table below.
  - Identifier - see the table below.
  - Old Values - list of edited properties with their old values. If making a setting for the first time, the Old Values field is empty.
  - New Values - list of set or edited properties with their new values
  - Reason - if available, a user-entered reason for setting or changing a property. Otherwise, the reason is the same as the action. See also the table below.
  - Date/time - date and time of the action in the format YYYY-MM-DD HH:MM:SS
  - User - display name of the user who performed the action

The following table lists the actions, identifiers, and reasons that are associated with the areas:

Area	Action	Identifier	Reason
eTMF	<ul style="list-style-type: none"> <li>▪ Enable</li> <li>▪ Map roles</li> </ul>	<i>empty</i>	<p>For the Enable action: If switched on, <b>Enable eTMF</b>, if switched off, <b>Disable eTMF</b></p> <p>For the Map roles action: <b>Configure access to eTMF</b></p>
Medical Coding	<ul style="list-style-type: none"> <li>▪ Create a new medical coding instance</li> <li>▪ Edit medical coding</li> </ul>	<p>For the edit medical coding instance action: The sequence and name</p>	User-entered reason if available, otherwise the same as the action
Reference Data Sources	<ul style="list-style-type: none"> <li>▪ Edit settings</li> <li>▪ Add reference data source</li> <li>▪ Edit</li> <li>▪ Delete</li> </ul>	<p>Unique identifier if available</p> <p>For the Add, Edit, and Delete actions: The sequence of the reference data source</p>	<p>For the Edit settings action: <b>Edit reference data sources settings</b></p> <p>For the Add action: <b>Add reference data source</b></p> <p>For the Edit action: <b>Edit reference data source</b></p> <p>For the Delete action: <b>Delete reference data source</b></p>

Area	Action	Identifier	Reason
RTSM	<ul style="list-style-type: none"> <li>▪ Approve settings</li> <li>▪ Uploaded randomization list</li> <li>▪ Add to randomization list</li> <li>▪ Upload individual allocation list</li> <li>▪ Add to individual allocation list</li> <li>▪ Restart</li> </ul> <p>(For dynamic randomizations only): Create configuration, Edit configuration</p> <ul style="list-style-type: none"> <li>▪ Approve global allocation list settings</li> <li>▪ Mapping for global allocation list</li> <li>▪ Upload global allocation list</li> <li>▪ Add global allocation list</li> </ul>	<p>RTSM name or allocation name if available.</p> <p>For the actions on global allocation, the identifier is <b>Global allocation</b>.</p>	<p>The same as the action if not specified below.</p> <p>For all the actions that are performed on a specific Production or Demo mode, this is added to the reason, for example, <b>Upload randomization list - Production</b></p> <p>For the Approve settings action: <b>Approve RTSM settings</b></p> <p>For the Upload randomization list action: <b>Upload randomization list</b></p> <p>For the Upload individual allocation list action: <b>Upload allocation list</b></p> <p>For the Add to randomization list action: <b>Add to randomization list</b></p> <p>For the Add to individual allocation list action: <b>Add to individual allocation list</b></p> <p>For the Restart action: <b>Restart RTSM</b></p> <p>For the Edit configuration action: <b>Edit RTSM configuration</b></p> <p>For the Create configuration action: <b>Create RTSM configuration</b></p>
Site Settings	<ul style="list-style-type: none"> <li>▪ Add new site</li> <li>▪ Edit site</li> </ul>	The site number	The same as the action
Study Design	<ul style="list-style-type: none"> <li>▪ Assign design</li> <li>▪ Apply revision</li> </ul>	Design or revision name and version	The same as the action

Area	Action	Identifier	Reason
Study Settings	<ul style="list-style-type: none"> <li>▪ Add Study</li> <li>▪ Edit study settings</li> <li>▪ Edit date &amp; time format</li> <li>▪ Edit medical coding</li> <li>▪ Import ODM file to Demo</li> <li>▪ Import ODM file to Production</li> <li>▪ Edit documentation</li> <li>▪ Archive documentation</li> <li>▪ Restore documentation</li> <li>▪ Delete documentation</li> <li>▪ Lock study</li> <li>▪ Unlock study</li> <li>▪ Request study deletion</li> <li>▪ Approve study deletion</li> <li>▪ Reject study deletion</li> <li>▪ Revert study deletion</li> <li>▪ Enable item level SDV</li> </ul>	<p>For the edit medical coding action: the coding scope</p> <p>For the documentation actions: the section name</p>	<p>For the Add study action: <b>Create study</b></p> <p>For the other actions: User-entered reason if available. Otherwise, the reason is the same as the action.</p>
User Invitations	<ul style="list-style-type: none"> <li>▪ Invite user</li> <li>▪ Delete invitation</li> <li>▪ Reset password</li> <li>▪ Resend invitation</li> <li>▪ Remove user role from study</li> </ul>	<p>Unique identifier if available.</p> <p>For the reset password action:</p> <ul style="list-style-type: none"> <li>▪ User = user display name</li> <li>▪ Email = user email address</li> </ul>	<p>The same as the action</p>
User Logs	<ul style="list-style-type: none"> <li>▪ Generate log of users and roles</li> <li>▪ Generate user administration log</li> <li>▪ Generate user communication log</li> </ul>	<p><i>empty</i></p>	<p>The same as the action</p>
WCF API client configuration	<ul style="list-style-type: none"> <li>▪ Add</li> <li>▪ Edit</li> <li>▪ Delete</li> </ul>	<p>Client ID (GUID)</p>	<p>For the Add action: <b>Add API client</b></p> <p>For the Edit action: <b>Edit API client</b></p> <p>For the Delete action: <b>Delete API client</b></p>



Area	Action	Identifier	Reason
Web API client configuration	<ul style="list-style-type: none"><li>▪ Add</li><li>▪ Edit</li><li>▪ Delete</li></ul>	Client ID (GUID)	For the Add action: <b>Add API client</b>  For the Edit action: <b>Edit API client</b>  For the Delete action: <b>Delete API client</b>

**Note!** Some data might not be available for the actions performed before the release of Viedoc 4.72.



Viedoc study configuration management

# Viedoc study configuration management

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## 1 Introduction

The configuration of a study in Viedoc consists of two types of settings:

- **Non version-controlled settings** - settings that are configured by the Study Manager in the Viedoc Admin application and that are effective immediately. These settings are common to the study at any given point in time. They are described in detail in the lesson [General study settings](#).
- **Version-controlled settings** - settings that are configured by the Designer in Viedoc Designer, but not effective until assigned to site(s) by the Study Manager in Viedoc Admin.

This lesson focuses on the configuration type that holds most of the study configuration, that is **version-controlled settings**.

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## 2 Configuration overview

### 2.1 Study design version numbers

Version-controlled settings are contained in a "design" and are identified by a version number. Study design version numbers are unique within a study. If there exist five study design versions, all originating from the same design, and a new design is created from scratch within the same study, it will have version 6.

Study design version numbers are accompanied with a revision number. For example, "1.0" means that this is version 1 and that it has not been revised, since the revision part of the version is 0. Revisions are explained in [Revision of study design version](#).

## 2.2 Assignment of study design to site(s)

Study designs are assigned on site level. Work on a site cannot start before a study design is assigned to that site, as there is no study configuration associated with that site.

When the Designer has finished setting up a study design in Viedoc Designer, he/she has to publish the study design, so that it becomes available to the Study Manager in Viedoc Admin.

The Study Manager then chooses to assign the study design to one or several study sites. This step is accompanied with selecting an effective starting time for the study design on the selected study sites.

There can be more than one design version assigned to a site.

## 2.3 Version "burn-in"

Versions are burnt in at event level, based on the date of first data entry.

The applicable design version for an event is determined by comparing the event date to the effectiveness period of the study design version(s) assigned to the site. When an instance of an event is started, the study design version is burnt into it, indefinitely. All forms belonging to this event will then inherit that same study design version.

When the version has been burnt-in, the forms within the event always get their settings, structure and lay-out read from that same study design version, even if the event date, or design effectiveness periods, have changed so that a different study design version is available.

## 2.4 Event dates

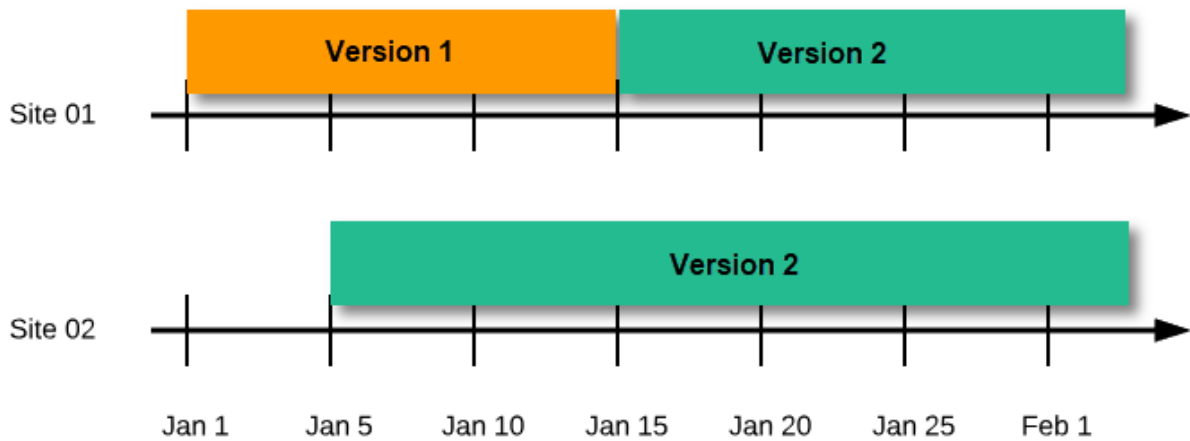
In Viedoc, there are four different types of events, and the study design version is burnt in as follows:

- **Study start** event - typically one simple form containing patient identification data. The study start event has no manual event date entry. Thus, even if it only contains one form and this form contains something called a "start date", it will not be used as event date. The event date of this type of event is always the time of event initialization, that is, when the event instance is entered for the first time.
- **Scheduled events** - visits scheduled according to the protocol. These require a date to be input when they are started/initiated. For these events this is the event date, and the study design version will burn in when the event is first started/initiated. If the event date is changed there will be no new burn-in. However, until the first form of the event is entered, the event can be stopped/uninitiated and this is then treated as a reset of the event and a new burn-in will occur when the event is again started/initiated.
- **Unscheduled events** - additional, on-demand visits. These require a date to be input when they are started/initiated. For these events this is the event date, and the study design version will burn in when the event is first started/initiated. If the date is changed there will be no new burn-in. However, until the first form of the event is entered, the event can be stopped/uninitiated. This is then treated as a reset of the event and a new burn-in will occur when the event is again started/initiated.
- **Common events** - events occurring separately or parallel to the workflow, for example concomitant medication, adverse events, dose adjustments, daily compliance reporting. These have no manual date entry. Thus, even if they only contain one form and this form contains something called a "start date", it will not be used as event date. The event date of these types of events are always the time of event initialization, that is, when the event instance is entered for the first time.

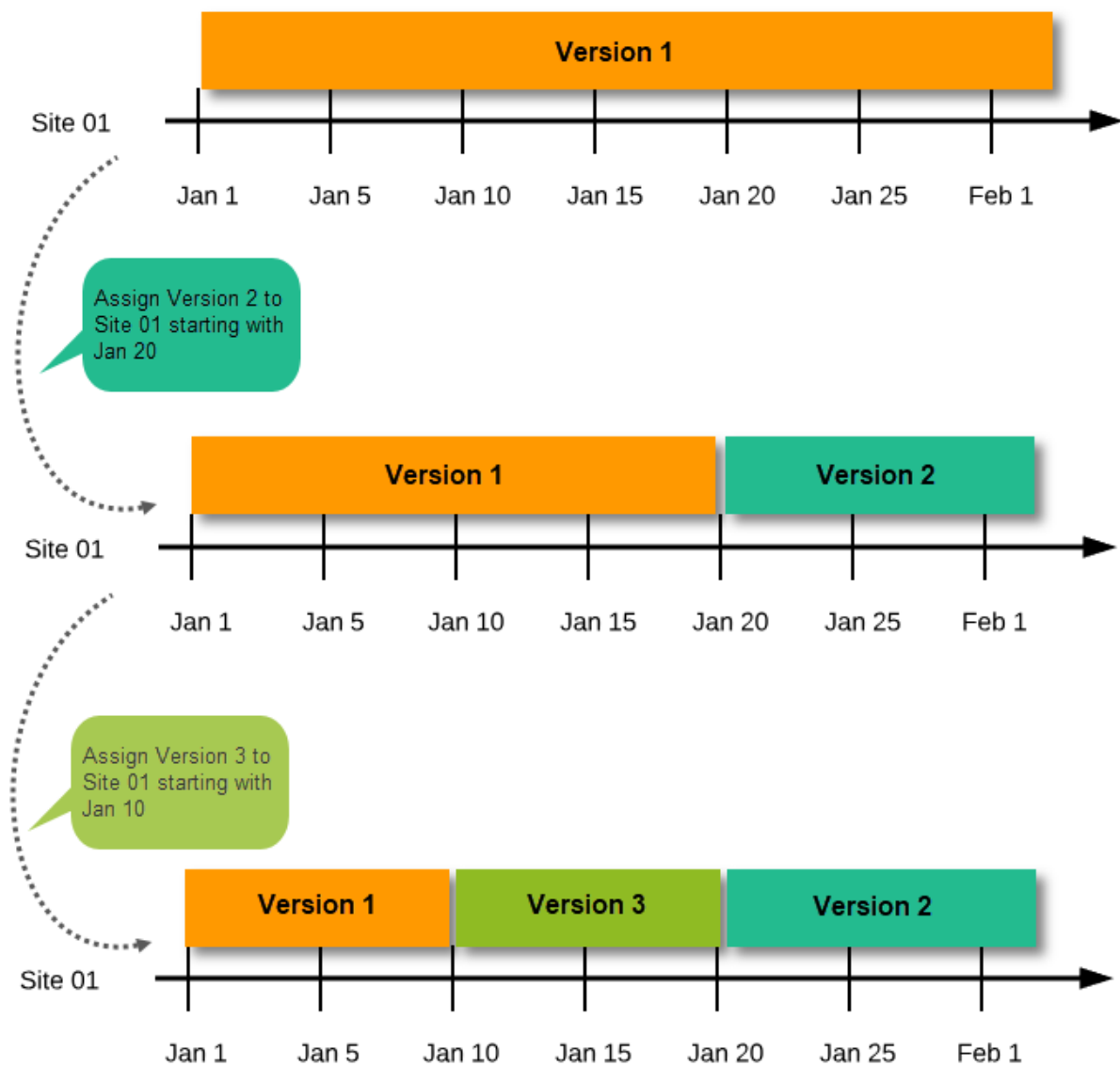
**Note!** The above applies even for the events that are using the "automatic event date" functionality, that is, if the event is configured to use an event date based either on the date of first data entry or on a date item. For details on the automatic event date settings, see the [Study workflow](#) lesson.

## 2.5 Multiple versions over time

During the course of a study, multiple versions of the study design can be assigned to a site, with different periods of effectiveness. For example, Site 01 could have Version 1 as the effective study design version during January 1st – January 15th and Version 2 as effective study design version after January 15th, whereas Site 02 has Version 2 as the only effective study design version starting January 5th, as illustrated in the image:



There is no end date for the effectiveness periods of study design versions. If a design is applied on January 1<sup>st</sup>, this is the effective version until a new version with a later start date is encountered, independently of when it was assigned.



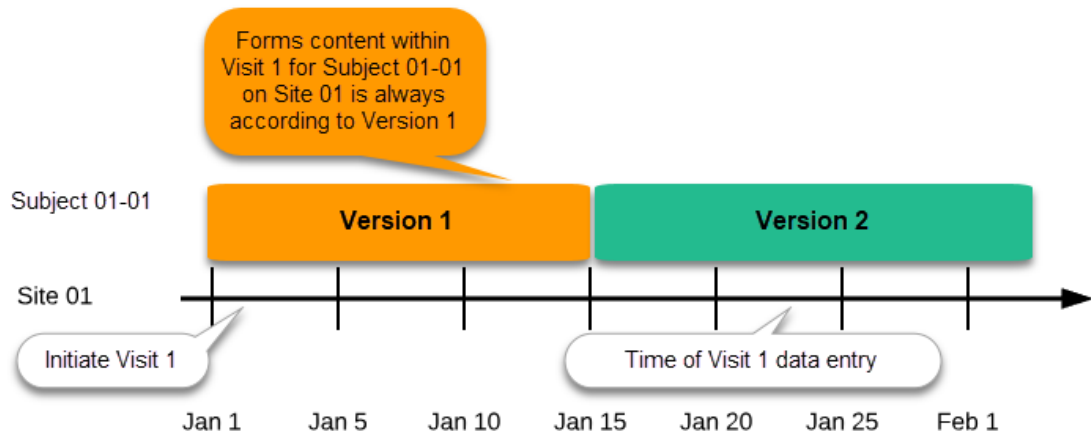
**Important!** The periods of effectiveness of a study design version are connected to the event timing of the first data entry and not to the current time at system usage. For example, in the below image, if:

- Version 1 is effective between January 1<sup>st</sup> - January 15<sup>th</sup> for Site 01.

- Version 2 is effective starting with January 16<sup>th</sup> for Site 01.
- Event 1 is initiated on January 2<sup>nd</sup> for Subject 01-01 on Site 01.

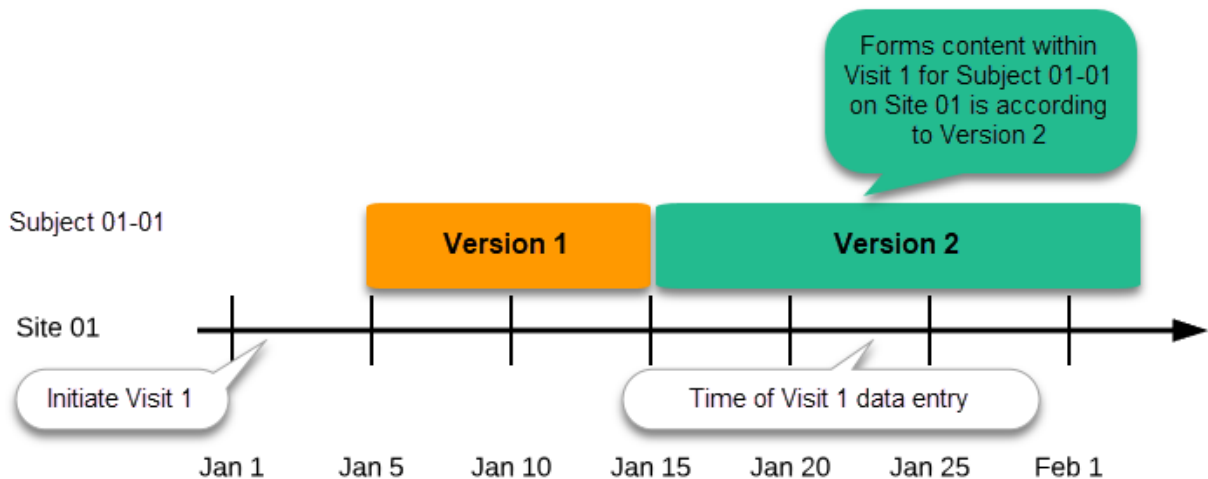
...then:

- Form content of Event 1 for Subject 01-01 on Site 01 will always be according to Version 1 (because Event 1 was initiated within the validity period of Version 1), regardless of the time of data entry:



### 2.5.1 Event created before starting point of any version

If an event is initiated with a date when no design version is in effect, the version effective at current time of system usage will be used:



### 2.5.2 New version with same timing as current version

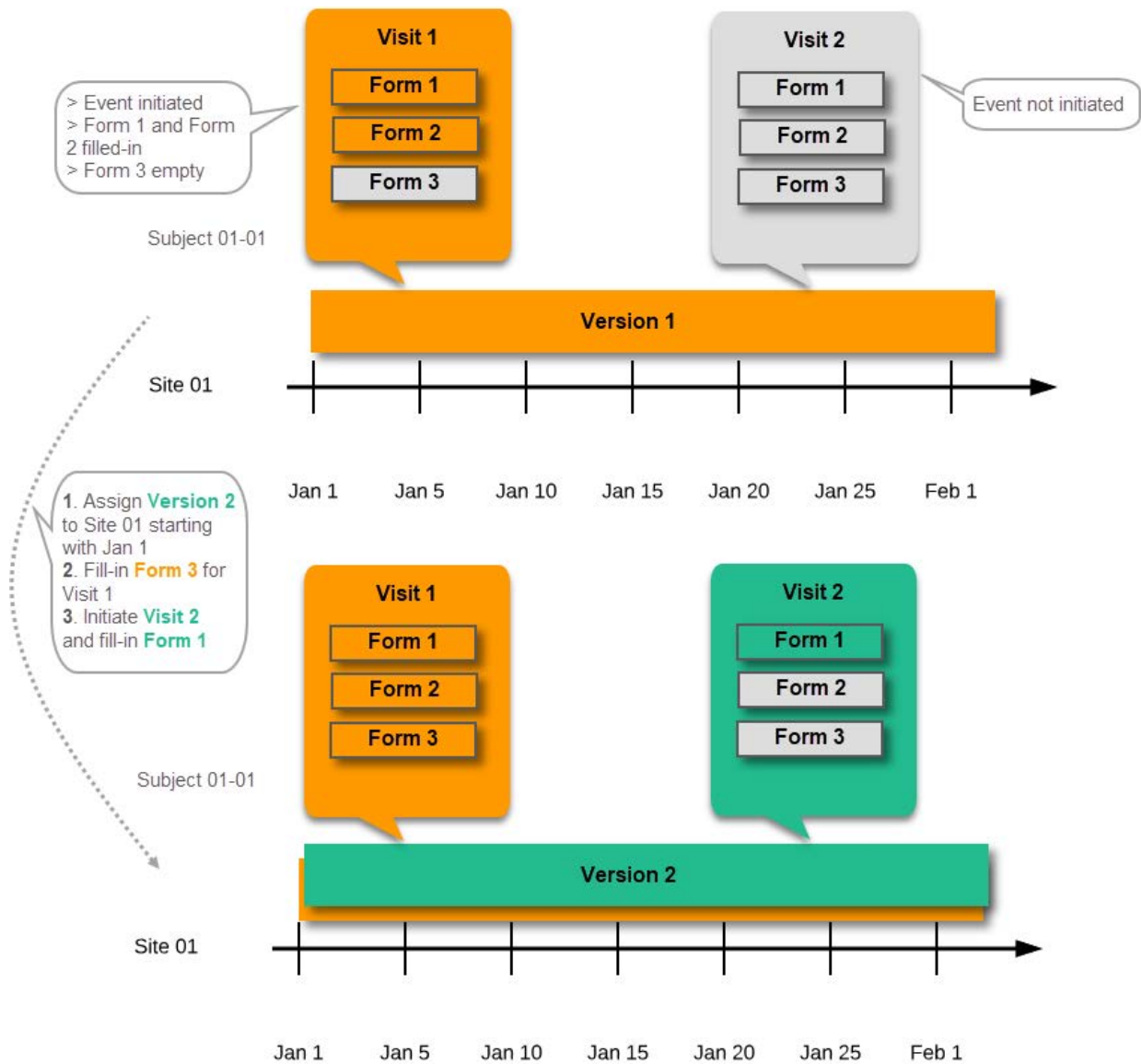
A new version can be assigned with the same timing as the currently assigned version and will then replace the currently assigned version, except for already entered data (due to the version “burn-in”, as described in [Version burn-in](#)).

For example, if we have Version 1 assigned to Site 01 starting at Jan 1, and we have the following events:

- Event 1 - initiated and containing 3 forms:
  - Form 1 and Form 2 filled in
  - Form 3 empty
- Event 2 - not initiated

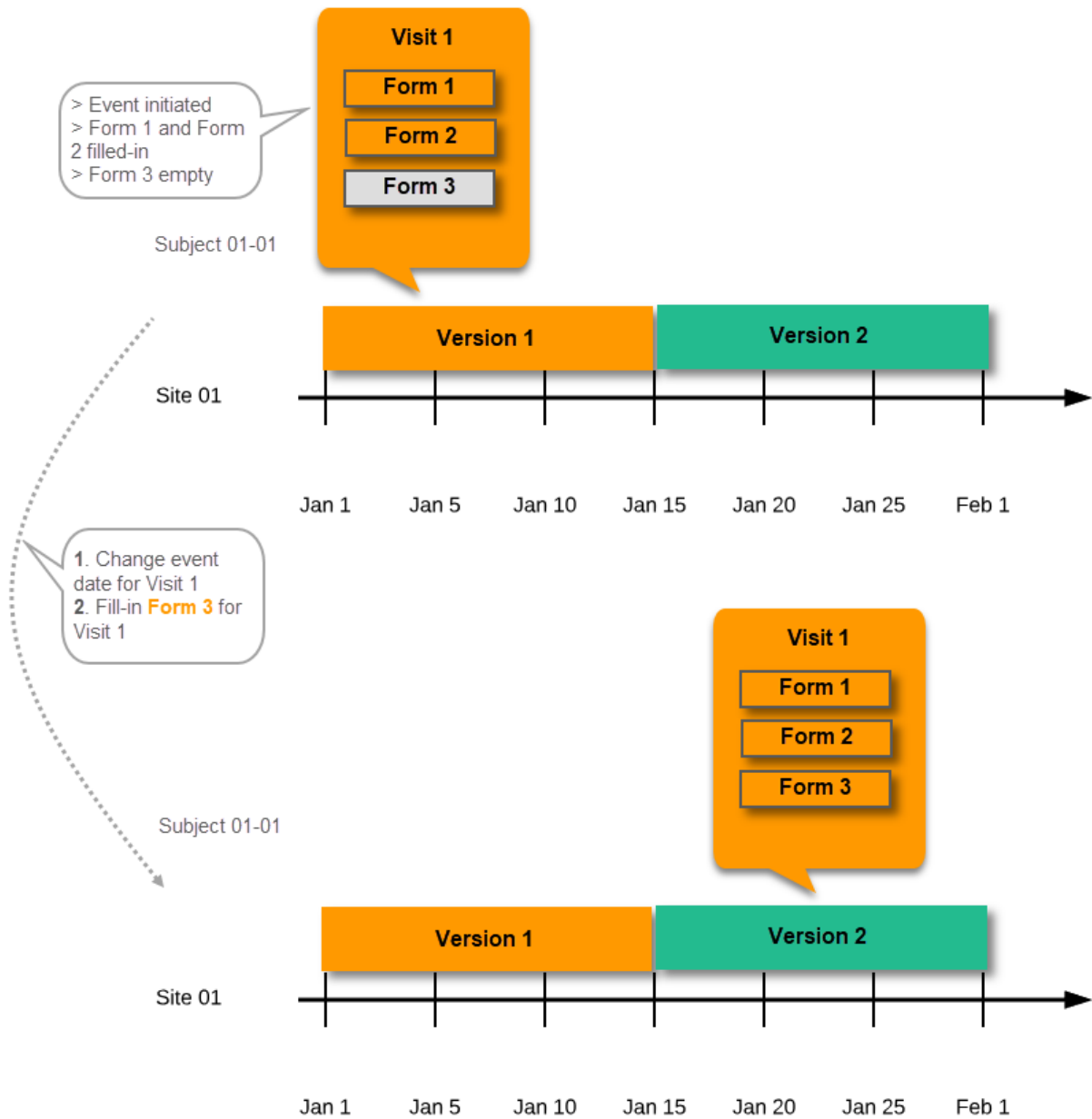
...and we assign Version 2 to Site 01 starting at Jan 1, and then:

- fill in Form 3 for Event 1 - this will have also Version 1, as this was burnt-in at the time when Event 1 was initiated.
- initiate Event 2 and fill in Form 1, this will have Version 2 (as well as all the other forms within Event 2)



### 2.5.3 Event date changed after it was initiated

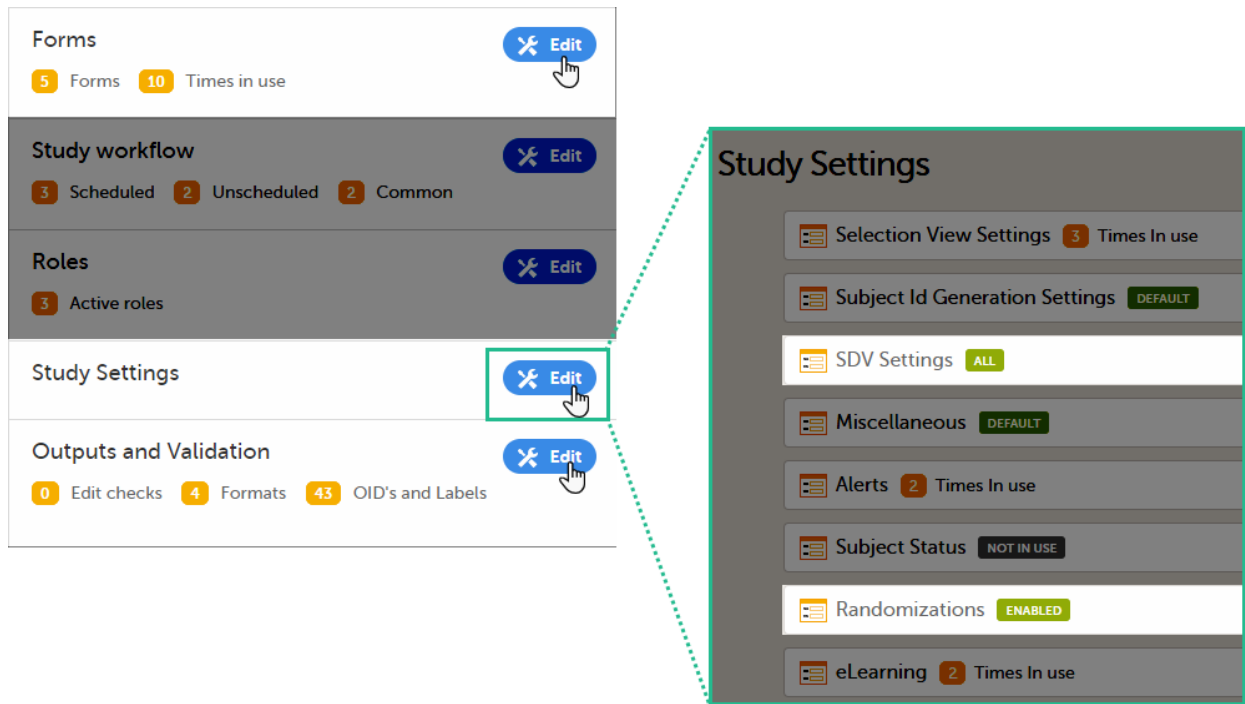
In case the event date is changed after it was initiated, to a date when another version is applicable, the version for that event does not change, as it was burnt-in at the date when the event was initiated (see [Version burn-in](#)):



## 2.6 Settings read from the study design version burnt-into the event

The following settings are always read from the study design version that is burnt-into the event:

- Forms
- Study settings
  - Source Data Verification ([SDV](#)) settings
  - Randomizations
- Output and Validation
  - Automatic data validation (“Edit checks”)
  - Output formats
  - Output ID:s and labels



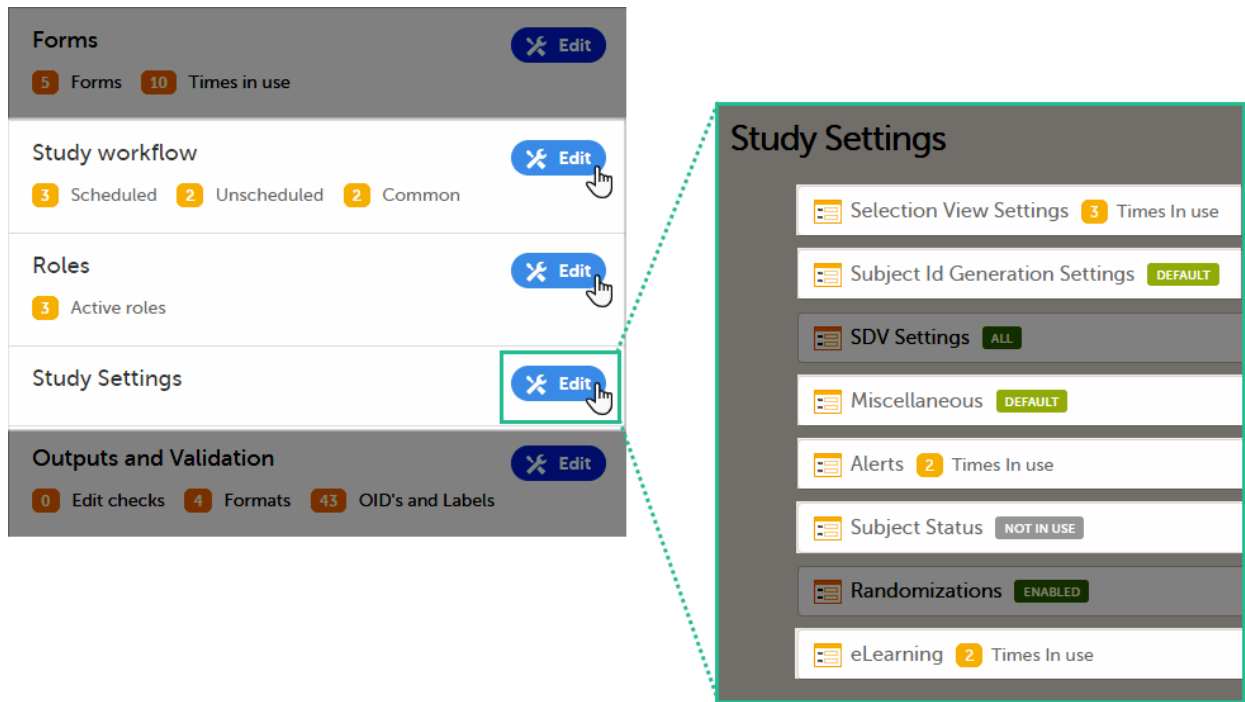
## 2.7 Settings read from current effective design

We call "current effective design" the study design version that is effective at the current time of system usage.

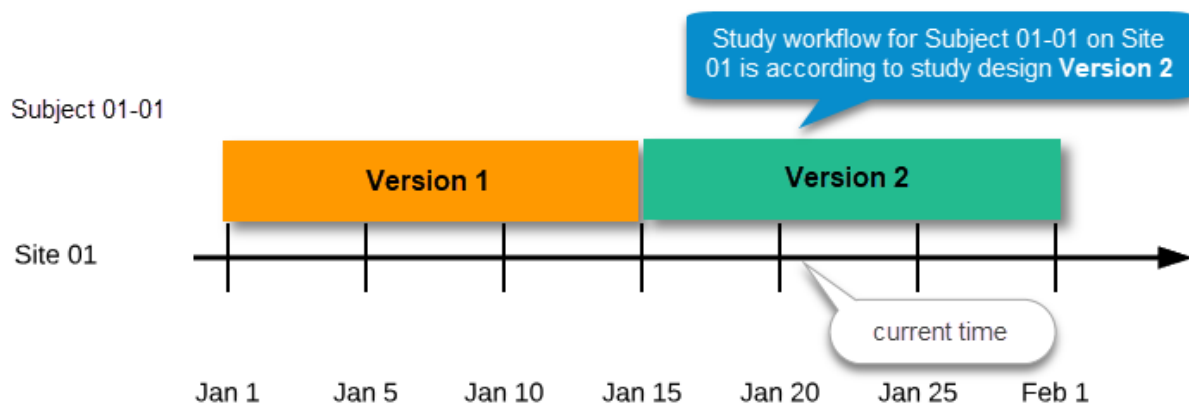
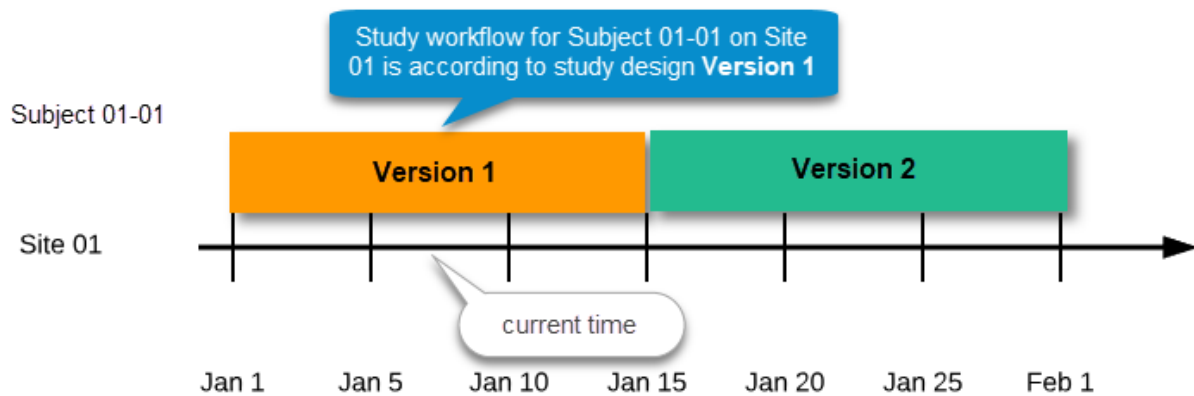
Settings that are not directly related to data collection structure, as well as settings that are common on the site level, are read from the study design version that is effective at the time of system usage (that is, "time right now"). These settings are:

- Study workflow
  - Study start event
  - Scheduled events
  - Unscheduled events
  - Common events
- Roles
- Study settings
  - Layout of subject card and subject selection page
  - Subject Id format
  - Miscellaneous
  - Alerts
  - Subject status
  - eLearning





This means that the study workflow for a subject can change as time passes and a new design version becomes effective for the site the subject belongs to:



## 2.8 Revisions of study design version

If there is a need to correct something in a study design version that is already assigned, and in particular if it has already been used to enter data (as that version is then burnt in and cannot be replaced by assigning a new version with the same time frame of validity), the study design version has to be revised.

The following settings can be revised as part of a revision of a study design version:

- Forms \*
- Study workflow \*
- Roles
- Output and Validation

The latest effective design for each site will be used to define the permissions that will apply to each role.

\* **Note!** The study design IDs (Event IDs, Activity IDs, Form IDs, Item group IDs and Item IDs), item dictionary (“choice”) codes and any items involved in randomization cannot be changed. An exception is that if an item needs to be moved to another item group, the ID can and must be changed as this will be treated as deleting an item and adding it again.

Once a study design version is revised, the revision part of the version number (initially 0) is incremented. For example, if study design version 1.0 is revised, it will receive the version number 1.1. When a revision of a study design version is published, it replaces its predecessor in terms of site assignment. For example, if a Study Manager wants to assign version 1 to a site, and this version now has a revision, version 1.1 will be available for assignment and not 1.0.

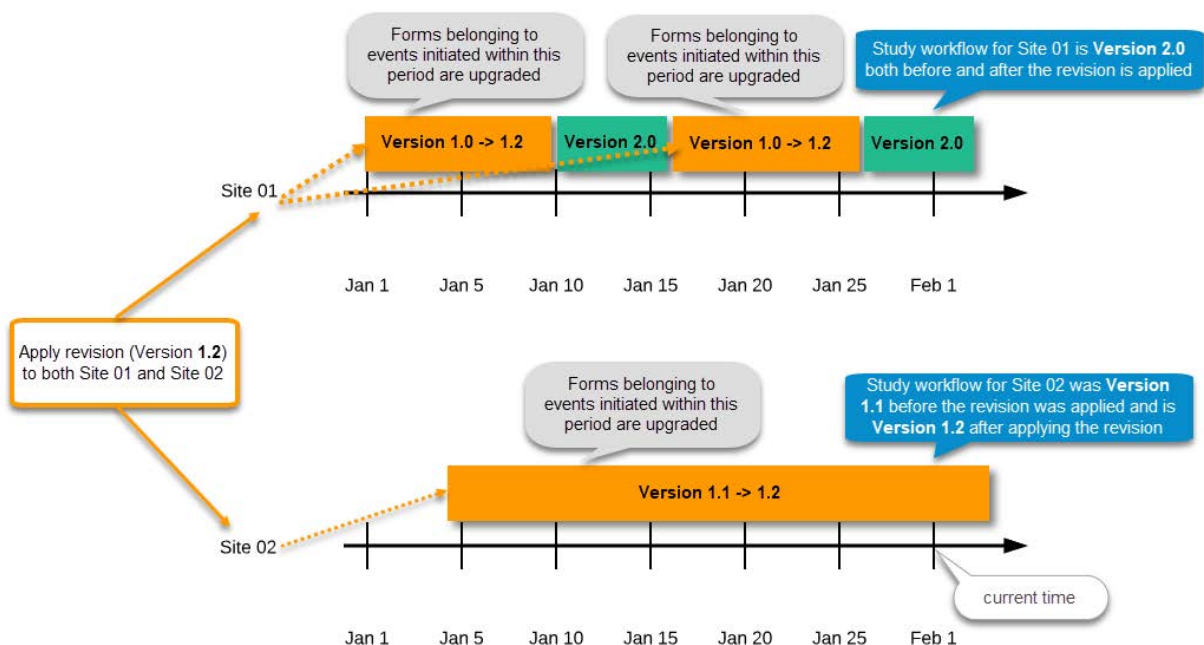
Additionally, only the latest revision of each study design version can be used as starting point for additional revision. For example, if we want to revise study design version 1, that has already been revised to version 1.1, we can only select 1.1 as starting point of the revision and not 1.0.

If forms that were previously part of an event in the workflow are now removed, already initiated forms are not touched. From a study workflow point-of-view they are now orphan forms, but from a user point-of-view there is no real difference to the appearance, as they stay as is on the event that they were previously part of.

## 2.9 Applying a revised study design version to a site

Application of a revised study design version is used to upgrade forms that are already burnt-in, with a predecessor of the study design version in terms of revisions, to the latest revision of the study design. Applying a revision is different from assigning study design versions, as assigning study design versions only affects forms belonging to events that have not been initiated yet.

When a revised version of a study design version is applied to a site, that revision will (eventually, after necessary site confirmations, see [Changes in a revision that affect data integrity](#) below) replace the version it is revising, including the base version and all previous revisions made to the version (as illustrated in the example in the image below, where 1.2 replaces both 1.0 and 1.1). Thus, effective period is not changed.



There are two parallel tracks being followed when a revised study design is applied, depending on whether the data integrity is affected by the changes in a revision or not, as described in the following subsections.

### 2.9.1 Changes in a revision that do not affect data integrity

A revision with changes that do not affect data integrity is applied without confirmation by the site staff. For all form instances in which form data is not affected by the revision, the revision is processed immediately.

Changes within a revision that do not affect data integrity:

- Forms – updated settings on:
  - Required/optional
  - Data checks
  - Min and max length
  - Number of decimal digits and/or number of decimals for numeric data type
  - Output IDs and labels
- Study workflow – actual workflow changes
 

**Note!** If these are the only changes made, this will be the same as assigning the study design to the site, as workflow is always read from the version effective at time of system usage as pointed out in [Settings read from current effective design](#).

  - Addition/deletion of events
  - Addition/deletion of activities/forms on existing event
- Roles
- Output and Validation

Any discrepancies no longer valid are closed and any new discrepancies will be flagged.

The forms that are locked (by Monitor, Data Manager, or any user who has data lock permission) will be upgraded, as no data will be touched by these types of changes.

Form signature and review status will not be affected by these kind of updates.

### 2.9.2 Changes in a revision that affect data integrity

Applying a revision with changes that potentially do affect data integrity, requires confirmation by the site staff. Before the Study Manager can apply a revised study design, a mandatory information text has to be entered that will be used to notify the site staff about the changes (see the complete workflow below in [Workflow - Revision of an existing version](#)).

Changes that potentially do affect data integrity:

- Forms – addition/deletion of items and changes to:
  - Name of form
  - Item labels, including static text items
  - Item and item group position and input field size
  - Measurement units
  - Dictionary ("choice") labels
  - Instruction texts
  - Visibility conditions
 

**Note!** Changes of the role visibility conditions do not require site approval.
  - Function and default value expressions
- Study Workflow
  - Visibility conditions affecting form contents
  - Event date settings
 

**Note!** Changes of the event date(s) as a result of changing the "automatic event date" settings do not require site approval. For details on the automatic event date settings, see the [Study workflow](#) lesson.

A flag will be put on the form instance indicating that there is an upgrade pending. Until the upgrade is confirmed by site personnel (see [Site confirmation of version upgrade](#)), the form will remain in its original version.

#### 2.9.2.1 Site confirmation of version upgrade to revised version

When a revised study design is applied to a site, all forms pending an upgrade (where data integrity is potentially affected) are marked by a red flag, and a notification for the site is displayed on the Messages pane on the study start page.

The notification is accompanied with a standard text informing the site about the upgrade action and confirmation prompt that has to be electronically signed. This action can be performed by anyone at the site with data edit permission. See also the lesson in Viedoc Clinic User Guide - [Approving eCRF changes](#).

When signed, all forms pending upgrade (listed in [Changes in a revision that affect data integrity](#)) will be upgraded to the revised version of the study design. This is a background activity that can take some time if there are considerable amounts of forms to be upgraded.

For the subjects that are being edited by clinic users during the upgrade process, the upgrade will stay pending until the respective subjects are released.

Optionally, forms can be upgraded manually, one-by-one, by the site. This is performed by navigating to the forms affected, opening them for editing and re-saving them. When the form is opened for editing, it will be shown using the new upgraded design with all data filled in.

A recommendation to the site could be to manually upgrade a few forms to fully understand the potential impact of the upgrade and then upgrade the rest using the batch approval feature.

**Important!** The upgrade is not performed for:

- locked forms (locked by Monitor, Data Manager, or any user who has data lock permission).
- forms for which the approving user does not have view/edit permission.

If performing batch approval and forms affected by the upgrade are skipped, as a result of one of the above mentioned scenarios, a new message will be displayed on the Message page. The changes can then be approved after a user with permission unlocks the locked forms.

Forms upgraded to a new design revision lose any existing signature and review flags (clinical review, data review). The SDV flag is lost on item level.

If a particular item, that did not require SDV, is affected by the upgrade (that is, edited in the design, see [Changes in a revision that affect data integrity](#)), the form-level SDV flag will be kept. That means an upgrade of a form can lead to losing existing signature and review flags (clinical review, data review), but keeping the SDV flag.

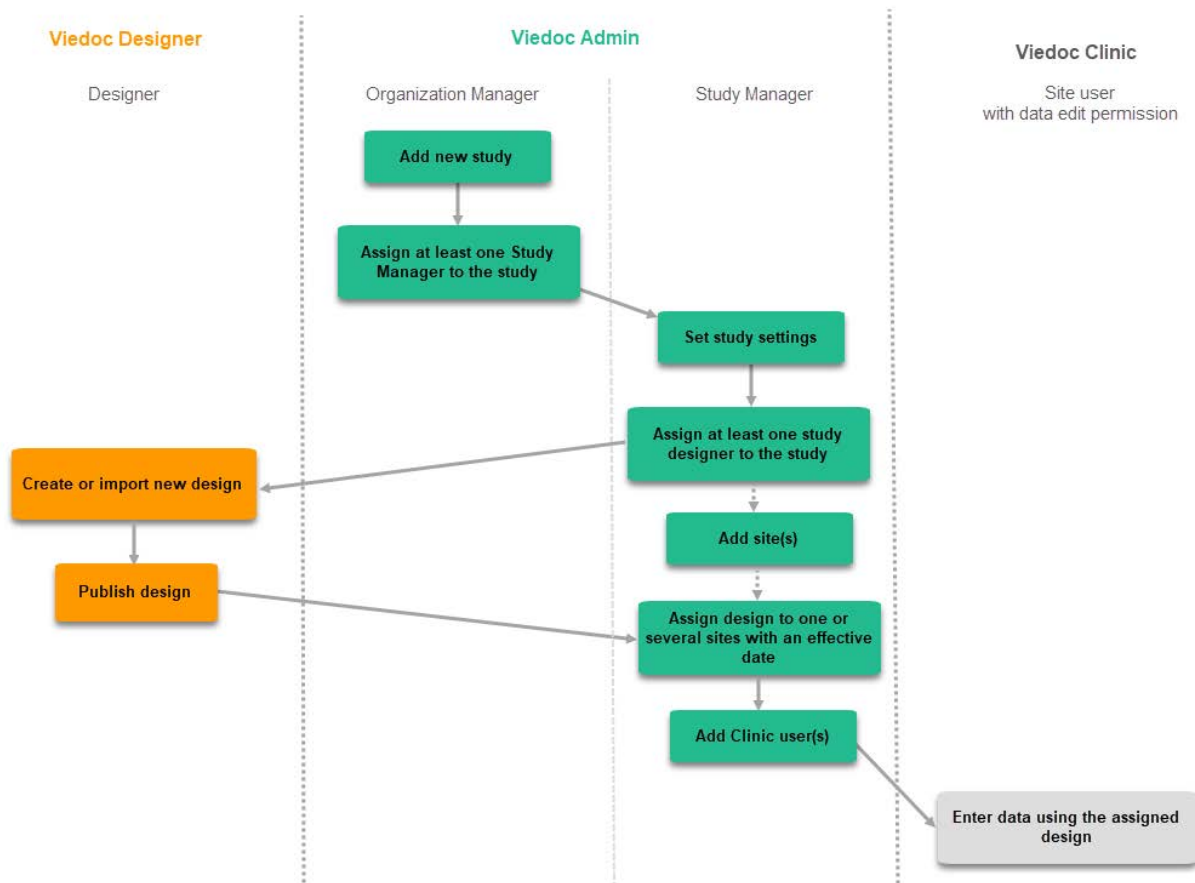
If a particular item, that was previously source data verified, is affected by the upgrade (that is, edited in the design, see [Changes in a revision that affect data integrity](#)), it is no longer flagged as having been source-data verified. The form-level SDV flag is lost if any item in the form lost its SDV flag. The form-level SDV flag is also lost if an item is removed from a form as part of the upgrade.

## 3 Configuration workflow

### 3.1 New study - first study design version

The following steps have to be performed in Viedoc when creating and configuring the study for the first time:

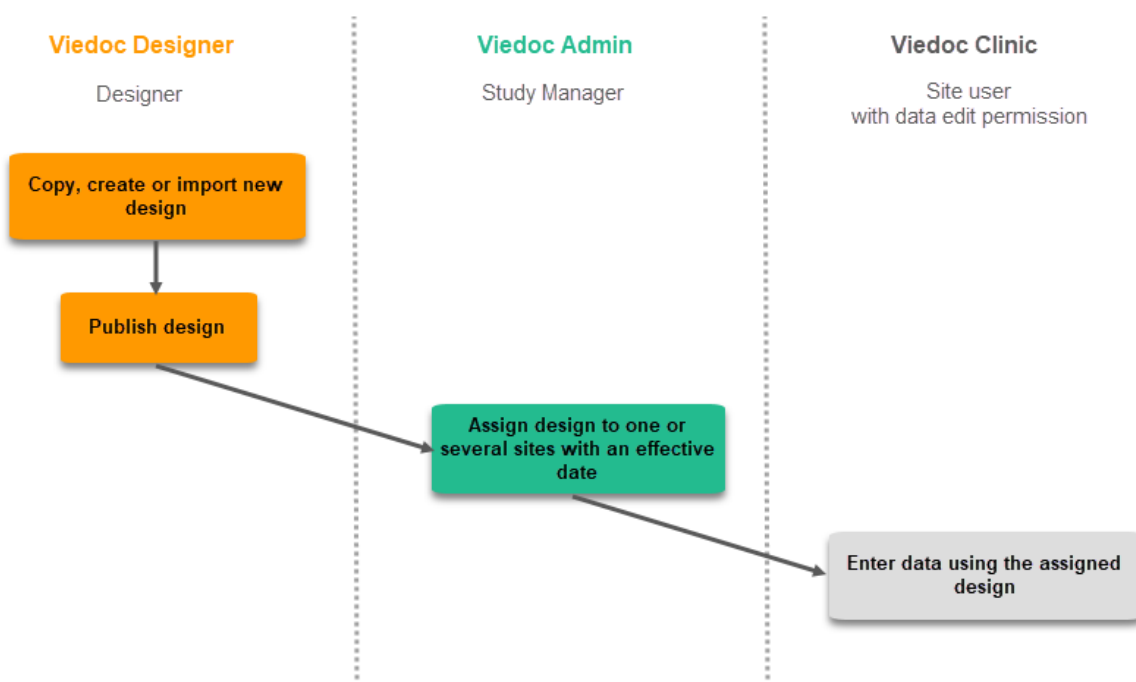
1. In Viedoc Admin, the Organization Manager creates the new study and appoints a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non version-controlled common settings and appoints a Designer.
3. In Viedoc Designer, the Designer creates the first version of the version-controlled settings and makes it available to the Study Manager by publishing the design to Viedoc Admin.
4. In Viedoc Admin, the Study Manager creates site(s) and assigns the first version to the site(s)
5. The site user can start entering data in Viedoc Clinic, using the assigned design.



### 3.2 Subsequent versions

The workflow for creating a new design version starting from an existing version of the study design, to implement a protocol amendment and assign it to one or several sites, is the following:

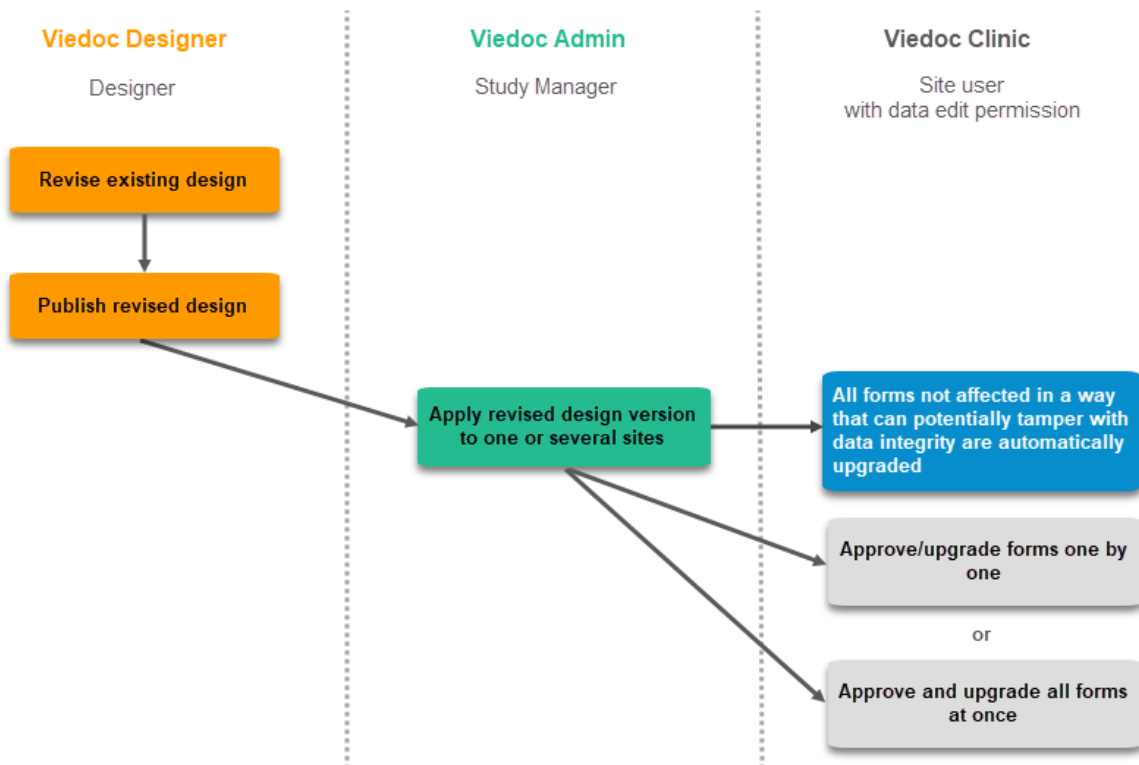
1. In Viedoc Designer, the Designer makes a full copy of the existing version of the study design.
2. In Viedoc Designer, the Designer makes the additional settings required by the protocol amendment and then publishes the design, which then becomes available in Viedoc Admin.
3. In Viedoc Admin, the Study Manager assigns the new version to one or several sites that should have the amendment. For instructions see [Assigning a study design](#).



### 3.3 Revision of existing version

The workflow for revising an existing study design version and applying it to one particular site is as following:

1. In Viedoc Designer, the Designer makes a revision of an existing version.
2. In Viedoc Designer, the Designer makes the additional settings and then publishes the design that becomes available in Viedoc Admin.
3. In Viedoc Admin, the Study Manager applies the revised version to one or several sites that should have the revision. For instructions see [Assigning a study design](#).



**Important!** If a new revision is applied before previous one(s) are approved by a site user, then the approval will upgrade affected forms to the latest revision, regardless of which of the upgrades the site user approves. For information on site approval see [Approving eCRF changes](#) in Viedoc Clinic User Guide.

**Note!** An upgrade message is displayed for the site under the Messages pane on the study start page, even for the revisions with changes that do not affect data integrity, that is, when the forms are automatically upgraded.

## 4 Configuration management

If an iterative approach is used during development of a configuration, there will be many versions created as part of the workflow: [ setup -> test -> correct -> test -> setup -> test -> correct -> test -> ... ]. It is still advisable to revise existing versions (instead of creating new versions) whenever possible to keep the number of versions to a minimum, as this will make the study design repository less cluttered and more easy to manage.

### 4.1 In Viedoc Designer

In Viedoc Designer, the following actions related to the study design can be performed, as described in the respective lessons:

- [Initiating a study design](#) - describes how to initiate a design, either by adding a new empty version or by importing one.
- [Validating a study design](#)
- [Publishing a study design](#) - describes how to publish and unpublish a design.
- [Duplicating a design](#) - describes how to either create a new version by copying an existing version, or revise an existing version.
- [Exporting/Locking/Deleting a study design](#)

## 4.2 In Viedoc Admin

In Viedoc Admin, you can see the current effective design for each site, assign a study design version to one or several sites, and apply a revised version of a study design to one or several sites. All these are described in detail in [Assigning a study design](#).



Assigning a study design

# Assigning a study design

Published by Viedoc System 2020-06-04

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- [1. Introduction](#)
- [2. Versions and revisions](#)
- [3. Viewing the effective study designs](#)
- [4. Assigning a study design](#)
- [5. Assigning a new design version](#)
- [6. Applying a design revision](#)
- [7. Viewing the audit trail of study designs](#)

This section explains how to assign a design to a the sites in a study. It is necessary to assign a study design to the sites in the study to start work on the site.

---

## 1 Introduction

Study designs are assigned to a study on a site level. The work on a site can only start when a study design version or revision has been assigned to that site. Without a design, there is no study configuration associated with the site.

When the Study Designer has finished setting up a study design in Viedoc Design, and has published the study design, it becomes available in Viedoc Admin. The Study Manager can then assign the study design to one or several sites in the study, and select an effective starting time for that design to be applied to the site.

At least one site should have been added to the study, before a study design can be assigned. A design can be assigned to all sites at once, or to individual sites in the study. It is thus possible to assign different study design versions or revisions to different sites in the study. Since study design versions or revisions are assigned to sites with a certain starting date, one site can have a certain study design version or revision assigned to it during a certain period of time, and another version or revision during another period of time.

The Study design field in the Study details pages displays the active designs in the study, and whether there are any new design versions or revisions available.



**Study design**

Effective Latest

Multiple designs in use.

#	Site name	Code	Country	Effective Design	Production	Users
1	Karolinska Institute Stockholm	KI	SE	DemoStudyDesign 4.0	✓	1 / 4
2	Uppsala University Hospital	UU	SE	DemoStudyDesign 3.0	✓	1 / 4
3	Helsinki University Hospital	HU	FI	DemoStudyDesign 4.0	✓	1 / 3
4	University College Hospital London	CL	GB	DemoStudyDesign 4.0	✓	1 / 3
5	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign 3.0	✓	1 / 4

To see the study design or designs that are in use, click **Effective**.

**Study design**

Effective Latest

Multiple designs in use.

To see whether there is a new design version or revision available, click **Latest**.

**Study design**

Effective Latest

DemoStudyDesign 6.0 (published 2018-04-16 14:28)

**Note!** The study design needs to be published in Viedoc Designer, before it is available in Viedoc Admin.

## 2 Versions and revisions

The settings in the study design are version-controlled and identified by the version number. Study design version numbers are unique within a study. If there are five study design versions in the study, and a new one is created, the new version will have version number 6. Study design version numbers are accompanied with a revision number. For example, version "1.6" means revision 6 of version 1.

The main reason to assign a new study design version to a site after study start is that protocol amendments require changes to be made to the study design, for example changes to the study that apply from a specific point in time during the course of the study.

If there is a need to correct errors in a study design version that has already been assigned and used for entering data, the study design version has to be revised and the revision has to be applied to the applicable sites.

For more detailed information, see [Viedoc study configuration management](#).

### 3 Viewing the effective study designs

To view a list of effective designs for all sites, click the toolbox icon in the **Study design** field on the study details page. The Design settings pop-up opens:

Site	Design	Effective on (UTC)	Scheduling (UTC)
Karolinska Institute Stockholm	DemoStudyDesign 4.0	2018-02-13 09:44	-
Karolinska Institute Stockholm	DemoStudyDesign 7.0	-	🕒 2018-05-16 00:00
Uppsala University Hospital	DemoStudyDesign 3.0	2018-02-13 09:43	-
Helsinki University Hospital	DemoStudyDesign 4.0	2018-02-13 09:44	-
University College Hospital London	DemoStudyDesign 6.0	2018-04-16 14:43	-
Sahlgrenska University Hospital Gothenburg	DemoStudyDesign 3.0	2018-02-13 09:43	-
Charite University Hospital Berlin	DemoStudyDesign 3.0	2018-02-13 09:43	-

In the **Effective design per site** list, the current effective designs (design effective on this date) and the designs scheduled to become effective are listed per site. The list also includes information about when that design became effective on the site, and/or when the design is scheduled to become effective on the site. Time is displayed in Coordinated Universal Time ([UTC](#)).

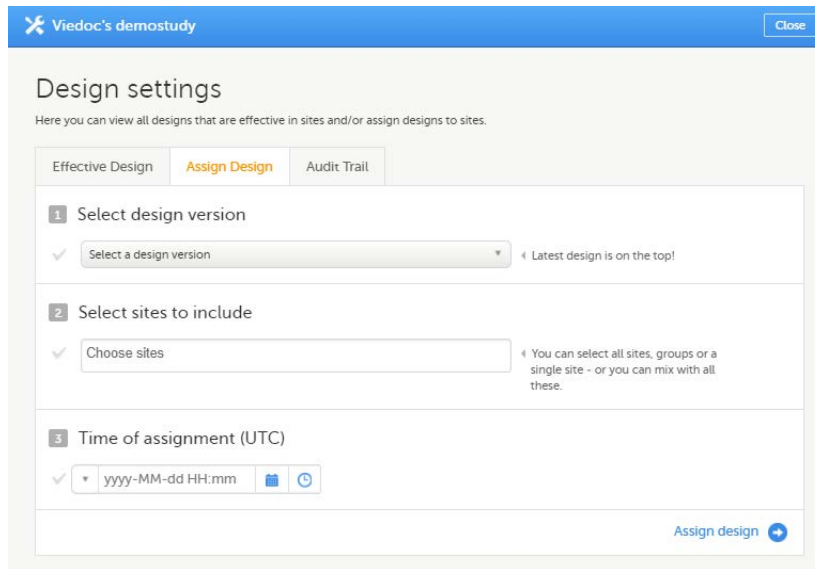
### 4 Assigning a study design

To assign a design to sites in a study, follow the steps below.

- 1 Click the toolbox icon in the **Study design** field on the study details page. The Design settings pop-up opens.

2 On the **Assign Design** tab:

1. Select the design version from the drop-down list.
2. Select the sites to include. It is possible to select 'All sites', or individual sites.
3. Select the time of assignment. This can be done in various ways:
  - Click the arrow to the left of the date field and select 'Now' or 'Tomorrow', or
  - Click the calendar icon and select a date.



3 Click **Assign design**.

The design is applied to the site and a confirmation message is briefly shown.

## 5 Assigning a new design version

Assigning a new design version is done in exactly the same way as assigning a study design. See [Assigning a study design](#) for instructions.

## 6 Applying a design revision

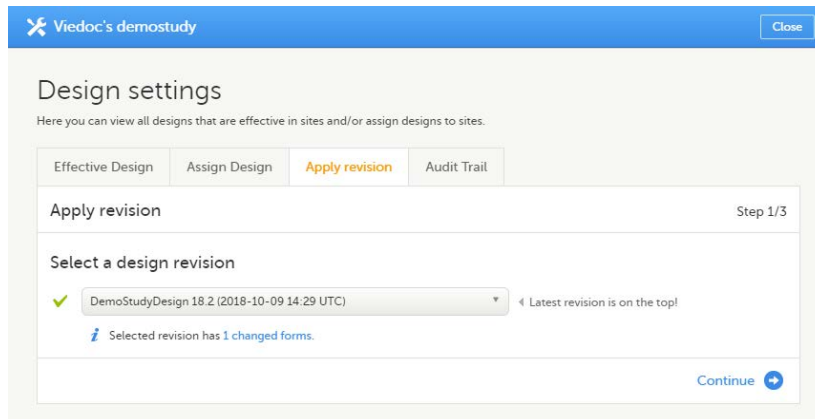
Application of a revised study design is used to upgrade forms that are already saved. When a revision of a study design is applied to a site, that revision will (after confirmation by the site) replace the version it is revising.

**Note!** A revision of a version only replaces the version it is revising. If you need to change something that is present in more than one version effective in your study, you need to revise all those versions applicable to the change. See [Duplicate a design - versions and revisions](#).

To apply a design revision to sites in a study, follow the steps below.

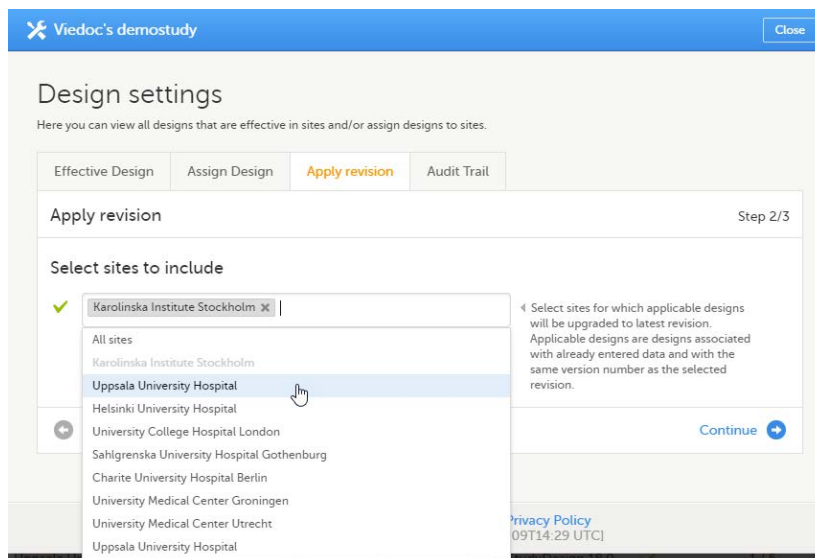
- 1 Click the toolbox icon in the **Study design** field on the study details page. The Design settings pop-up opens.

- 2 On the **Apply Revision** tab, select the design revision from the drop-down list and click **Continue** (Step 1/3).

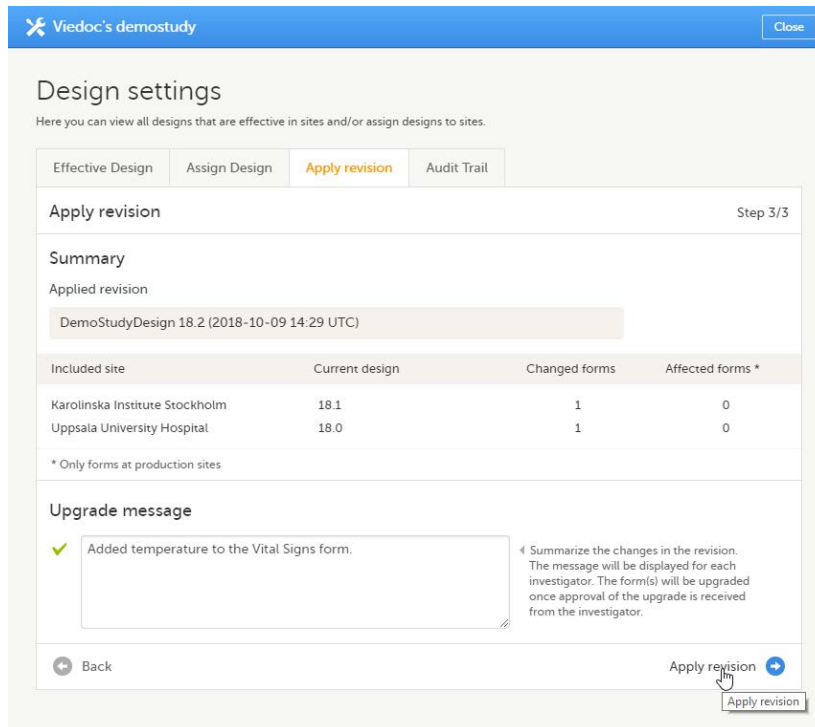


The system provides information about the impact of the revision by showing how many forms have been changed in blue text.

- 3 Select the sites the revision should be applied to. It is possible to select 'All sites', or individual sites. Click **Continue** (Step 2/3).

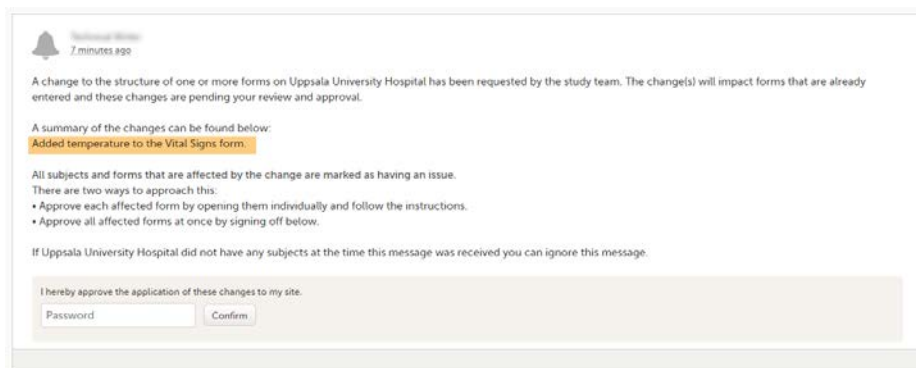


- 4 Type a message to the Clinic user in the Upgrade message field. This message could be a summary of the changes in the revision. It is displayed in Viedoc Clinic on the Messages page.



Click **Apply revision** (Step 3/3).  
The pop-up closes and the revision is applied.

After a revision has been applied, the clinic user (with permission to enter data) needs to approve the application in Viedoc Clinic. On the Messages page in Viedoc Clinic, the following message is displayed.



Application of the revision can be done in two ways:

1. Approve the changes to all affected forms at once by entering the password and clicking **Confirm** below the displayed message (batch approval).
2. Approve each affected form by opening them individually and follow the instructions. Affected forms are indicated by the red issue icon.

Forms upgraded to a new design revision by the site will lose any existing signature and review flags (clinical review, data review). The Source Data Verification (SDV) flag is lost on item level. If a particular item, that was previously source data verified, is affected by the upgrade, it will no longer be flagged as having been source-data verified. The form-level SDV flag will be lost if any item in the form lost its SDV flag. The form-level SDV flag will also be lost if an item is removed from a form as part of the upgrade.

## 7 Viewing the audit trail of study designs

To view a list of effective designs for all sites, click the toolbox icon in the **Study design** field on the study details page. In the Design settings pop-up, open the **Audit Trail** tab.

## Design settings

Here you can view all designs that are effective in sites and/or assign designs to sites.

Effective Design   Assign Design   **Audit Trail**

### Study site audit trail

Site	Design	Effective on (UTC)	Applied by	Applied on (UTC)
Uppsala University Hospital	DemoStudyDesign 7.0	2018-04-24 09:35	Technical Writer	2018-04-24 09:38
Karolinska Institute Stockholm	DemoStudyDesign 7.0	2018-05-16 00:00	Technical Writer	2018-04-24 09:31
University College Hospital London	DemoStudyDesign 6.0	2018-04-16 14:43	Technical Writer	2018-04-16 14:56
Karolinska Institute Stockholm	DemoStudyDesign 4.0	2018-02-13 09:44	Technical Writer	2018-02-13 09:44
Helsinki University Hospital	DemoStudyDesign 4.0	2018-02-13 09:44	Technical Writer	2018-02-13 09:44
University College Hospital London	DemoStudyDesign 4.0	2018-02-13 09:44	Technical Writer	2018-02-13 09:44
Uppsala University Hospital	DemoStudyDesign 3.0	2018-02-13 09:43	Technical Writer	2018-02-13 09:43

The audit trail lists the sites to which designs are assigned, which design is assigned, on what date that design is effective. It also lists who assigned the design to that site and on what date.



Handling eCRF updates after going live

# Handling eCRF updates after going live

Published by Viedoc System 2023-10-10

## [1. When to do a new version versus a revision](#)

### [2. Best practices for handling eCRF updates](#)

#### [2.1 General](#)

#### [2.2 Items and IDs](#)

#### [2.3 New versions](#)



#### [2.4 Revisions](#)

### [3. Doing a revision](#)

**Prerequisite:** Please read the following lesson to understand the difference between a revision and a new version: [Viedoc study configuration management](#)

## 1 When to do a new version versus a revision

The way of handling protocol amendments and updates/corrections to the eCRF depends on the situation each time. The following table gives a general guideline on when to do a new version versus a revision:

 <p>New version</p>	<p>In a new version, all changes to the study design are allowed. However, just because something can be changed does not mean it is a good idea to do so. It is safest to stick to the original structure and design as far as possible. For example, when making changes in the Study Workflow, be mindful of how these changes will affect the dependencies of previous versions. In terms of scheduling and visibility conditions, all events will behave as per the current effective design.</p> <p><b>Note!</b> The final order of the events as seen in PDF records depends on the dates entered by the user and not on what was programmed in the Study Workflow.</p> <p>A new version is required when:</p> <ul style="list-style-type: none"><li>▪ Only future events are to be affected (to not break SDV or signature on previous forms).</li><li>▪ There are changes to randomization forms (using the built-in randomization feature). These forms are locked and cannot be unlocked.</li><li>▪ Viedoc Me forms are locked upon receipt. These forms must be unlocked before a revision can be applied. Therefore, it is best to change Viedoc Me forms in a new version. Remember to also update translations if necessary.</li></ul>
 <p>Revision</p>	<p>In a revision, the types of changes that can be made to the design are limited:</p> <p><b>a.</b> It is not possible to add items with the same ID, and a deleted item cannot be brought back. <b>b.</b> Item types cannot be changed—a number cannot be converted to a string, and a radio button cannot be converted to a checkbox. In general, these changes must be done in a new version. Ask support for the best advice if the solution isn't obvious.</p> <p>A revision is required when:</p> <ul style="list-style-type: none"><li>▪ Forms have been saved with subject data and the forms require an update.</li></ul>



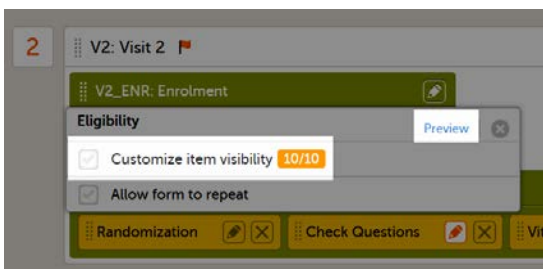
Both

Sometimes an update to the eCRF will require both a new version and one or more revisions.

## 2 Best practices for handling eCRF updates

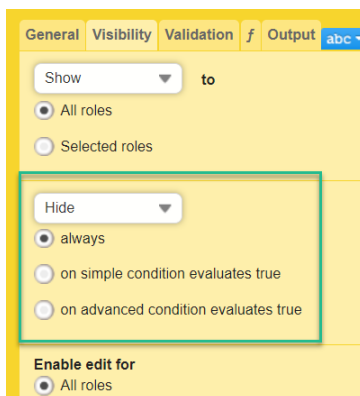
### 2.1 General

- Click the **Validate** button often. The design should not be published with errors.
- Use the Study Workflow to control visibility. The point-and-click visibility settings are much easier than writing the equivalent JavaScript code.
- Preview the form in Study Workflow to see how it will look for a specific event/activity.

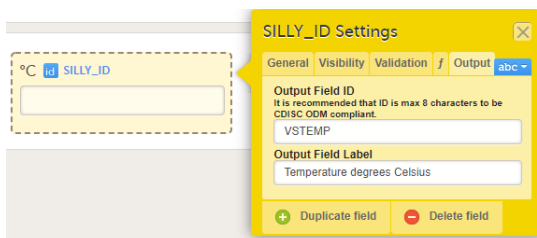


### 2.2 Items and IDs

- Consider hiding items instead of deleting them. If an item is deleted it can never be brought back in that same version. Instead, change the item's visibility to **Hide always**. If the item needs to be brought back, then the visibility can easily be changed back to **Show always**.



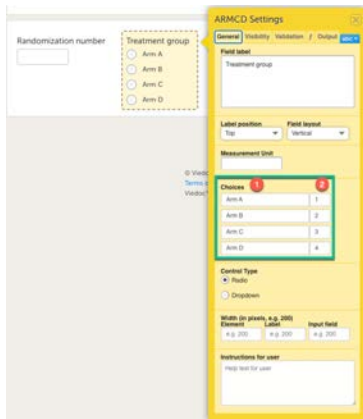
- If an ID needs to be changed, consider changing the output ID instead:



For items with code lists—radio buttons, dropdown lists, and checkboxes—each code list option consists of two parts:

1. The **label**
  2. The **code**
- For example:





- Adding an entirely new option in a new/ revised design version is okay. However, when it comes to changing the existing labels or codes, keep the following in mind:
- **Labels** - Editing an existing label while keeping the same code value will cause a data split in the export. This will be indicated by ItemID\_n where "n" is the number of versions there are of the code list. If there are different labels for the same code value, this may cause errors in your design.

**Code values** - The codes of the existing options should not be changed. Codes should be unique. Thus, make sure not to add a code list that existed previously or was later removed.

- Be mindful of items that will require updates. For example, a dropdown lists labelled *Patient consented under protocol version*:—if such an item was placed on the starting form, then SDV and signatures would break every time this item was updated.

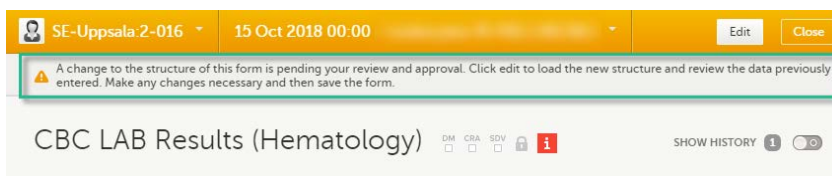
## 2.3 New versions

- Try to keep the number of new versions to a minimum. For example, if there are 10 versions of the eCRF, and all require a revision, then you'll need to perform 10 revisions (one per version).
- In Admin, when assigning a new version, the suggested practice is to always assign the version on the same date as the last one. Check the audit trail of when the previous versions were assigned. For example, if version 1.0 was assigned on 2020 JAN 01, then version 2.0 should also be assigned on 2020 JAN 01. This ensures that version 2.0 is used regardless of the event date. Please see the lesson [Viedoc study configuration management](#) for examples and consequences of version management and dates.

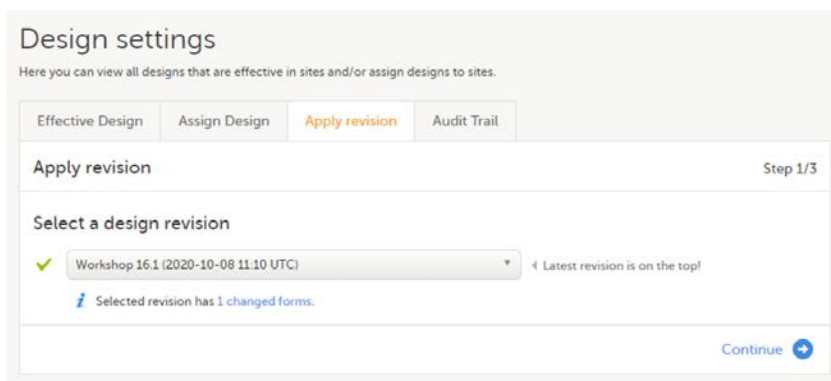
Site	Design	Effective on (UTC)	App
St Per Medical	New Study Design 3.0	2020-02-20 00:00	Soft
Jewel Clinic	New Study Design 3.0	2020-02-20 00:00	Soft
St Per Medical	New Study Design 1.0	2020-02-20 00:00	Soft
Jewel Clinic	New Study Design 1.0	2020-02-20 00:00	Soft

## 2.4 Revisions

- Be aware that if a revision affects data integrity in any way—even grammar corrections or adding an option in a dropdown menu—SDV, signatures, and review flags will break.



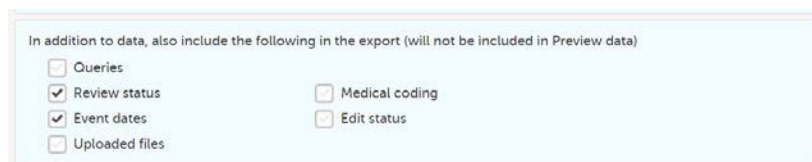
- During a revision, if form updates are approved in a batch but fail to apply to all forms, then the approval message will appear again. The updates could have failed either due to forms being locked, or the user not having view/edit permissions for the revised items.
- If a form is locked, then the updates applied in a revision will not take effect. The form must be unlocked by a user with lock permissions.
- If an item is removed in a revision—either by deletion or by changes to its visibility conditions—and data have been stored for this item, the removal will show in the audit trail.
- In Admin, make sure that revisions aren't accidentally assigned as versions! You do not enter a date of assignment for a revision; it uses the previously set date. It is important to understand the difference between "assigning a new version" and "applying a revision".



### 3 Doing a revision

**Note!** All steps below are performed on the production server. After going live, the training server should only be used to test a proof of concept.

- 1 Do an Excel export of all forms that will be affected by the update. Select the **Event dates** and **Review status** options.

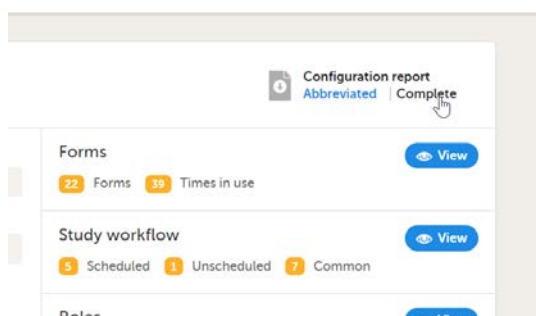


- The Review status option is to check for impact to signatures and SDV, as well as check if forms are locked.
- The Event dates options is to check if events have been initialized under a design or not.

- 2 The effective design version can be found in the export for each form under the column **Design version**. Use this information to see which versions will need to be revised.

Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Subject form sequence number	Origin form sequence number	Source form sequence number	Design version
EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	SubjectForm	OriginSubj	SourceSubj	DesignVersion
001	1	AP	Add patient 2020-01-07	SS	SS1	1	1	1		1.0
002	1	AP	Add patient 2020-01-27	SS	SS1	1	1	1		1.0
003	1	AP	Add patient 2020-01-28	SS	SS1	1	1	1		1.0

- 3 Go to Designer and download a complete configuration report for each version that needs revision.



- 4 In each configuration report, check for items that will be affected (do a Ctrl+F search of the item's ID). Check for dependencies on visibility conditions, functions, and edit checks. For more information, see [Configuration report](#).

- 5 Make changes as appropriate in each version.



Managing reference data sources

# Managing reference data sources

Published by Viedoc System 2018-11-09

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## [1. Introduction](#)

[1.1 About reference data](#)

[1.2 Terminology](#)

[1.3 Workflow](#)

## [2. Reference data sources in Viedoc Admin](#)

[2.1 About reference data sources](#)

[2.2 Who can configure reference data sources?](#)

[2.3 Description of the Reference Data Sources window](#)

## [3. Step-by-step guides](#)

[3.1 Adding a reference data source](#)

[3.2 Editing a reference data source](#)

[3.3 Deleting a reference data source](#)

This lesson describes how to manage reference data sources in **Viedoc Admin**.

---

## 1 Introduction

### 1.1 About reference data

Viedoc offers support for adding reference data that will be automatically populated to specific forms. When reference data are configured for your study, it is not necessary to fill in reference values for each subject in each form separately.

It is possible to configure different sets of reference data that will be populated to the form based on:

- factors that can affect the reference data, such as age or gender
- reference data source, such as a lab
- site
- date

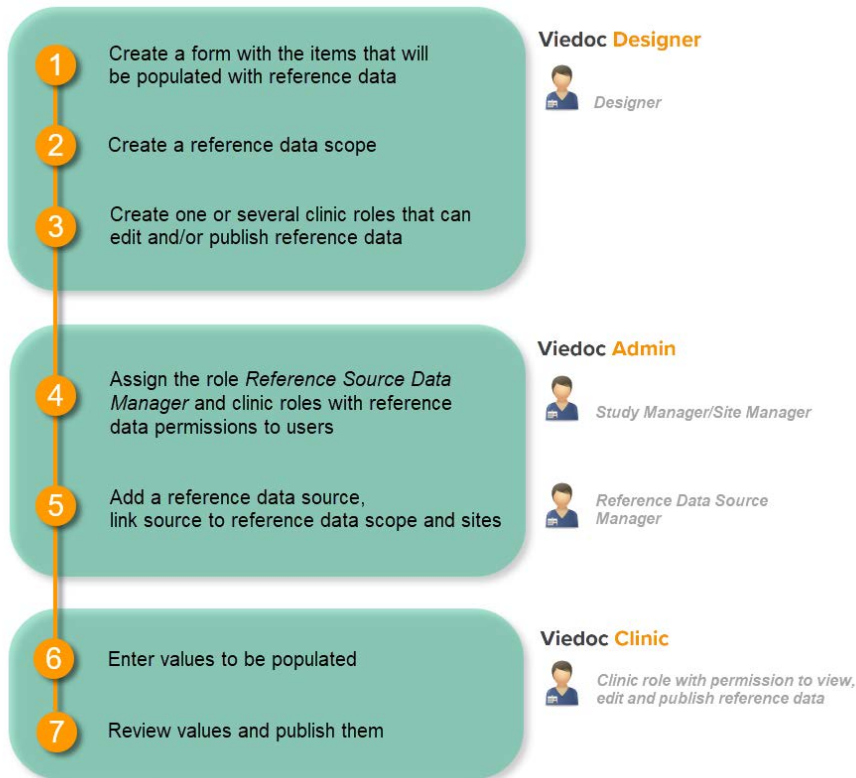
### 1.2 Terminology

Term	Definition
Reference data source	An institute that provides reference data, for example a lab.
Reference data scope	A mapping of the items that should be automatically populated with reference values, and the factors that they should depend on. One or more reference data scopes can be configured in Viedoc Designer > Global Settings, as set(s) of variables and factors (see definitions below).
Factor	A parameter that affects the reference data, for example a subject's sex. Factors may affect the normal range for a test result.
Variable	A specific measurement to be carried out.
Date factor	The date the sample was collected or the measurement carried out. This field determines on which date the reference data to be populated are based, for example when the event date is not the same as the collection or measurement date.

Term	Definition
Target type	An item of a certain type of information that a reference data source can provide for a specific variable (such as range, unit, low/high values, etc.). Any number of target types can be defined by the user.

## 1.3 Workflow

Reference data are configured in Viedoc Designer, Viedoc Admin and Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps.



For more detailed instructions regarding these steps, see:

- [Configuring reference data scopes](#) in Viedoc Designer
- [Managing reference data sources](#) in Viedoc Admin (**this lesson!**)
- [Working with reference data](#) in Viedoc Clinic

For a detailed example of how to work with reference data, see:

- [A use case for working with reference data](#)

For a video tutorial on how to work with reference data, see

- [Reference data video tutorial](#)

## 2 Reference data sources in Viedoc Admin

### 2.1 About reference data sources

The reference data sources are configured in Viedoc Admin. A reference data source is an institute that provides reference values, for example a laboratory. It is possible to add multiple reference data sources. Each reference data source is linked to one or more reference data scopes that define the following:

- which measurements the reference data source carries out,

- which factors might affect the results,
- what are the ranges/units that are used for these parameters.

The reference data source is also linked to one or more sites in the study.

## 2.2 Who can configure reference data sources?

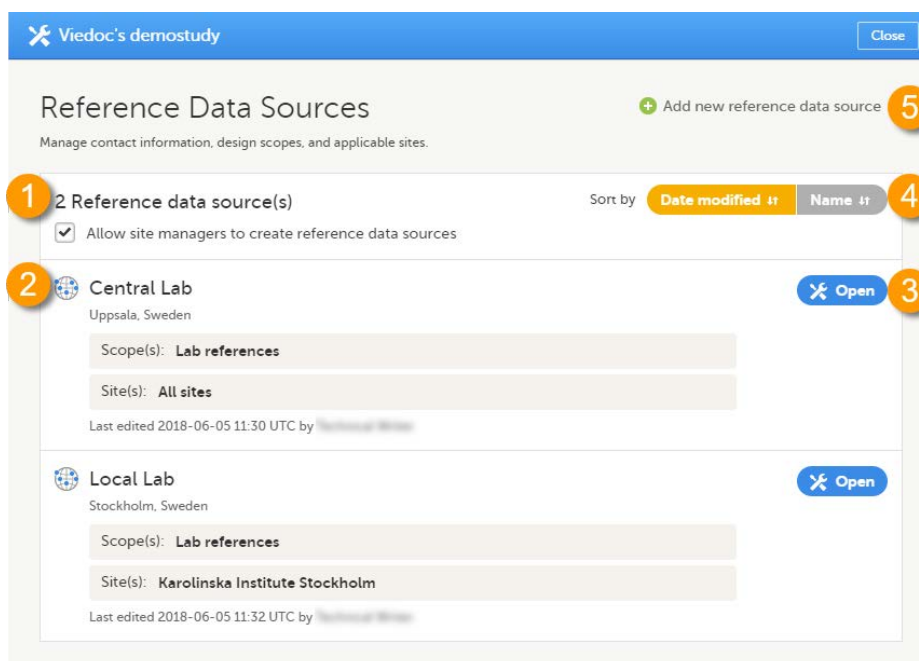
The user roles that give permission to manage the reference data sources in Viedoc Admin are:

- **Reference data source manager** - can manage the reference data sources at study level. A user who has this role can delegate the management of data sources at site level to the **Site manager**.
- **Site manager** - can manage the reference data sources at site level (for the managed site), if the **Reference data source manager** has delegated this task.

**Note!** The site-specific reference data sources that were added by the site manager are not editable by the reference data source manager, they can only be viewed as read-only by the reference data source manager.

See [Managing users \(STM and SIM\)](#) for more information about the different user roles and the management of these roles.

## 2.3 Description of the Reference Data Sources window



On the Reference Data Sources window, you can:

1. view a list of all reference data sources. If the **Allow site managers to create reference data sources** option is checked, then the site managers are allowed to manage the data sources assigned to the study site(s) they are managing.
2. view the details of a reference data source:
  - Name and location of the reference data source.
  - **Scope(s)**: which reference data scopes are mapped to the data source.
  - **Site(s)**: which sites are mapped to the data source.
  - Information about when and by whom the data source was last edited.
3. open and edit the details of a reference data source.
4. sort the list of the reference data sources by:
  - **Date modified** in ascending or descending order.
  - **Name** in ascending or descending alphabetical order.

The option that is currently used for sorting is highlighted in orange.

5. add a new reference data source.

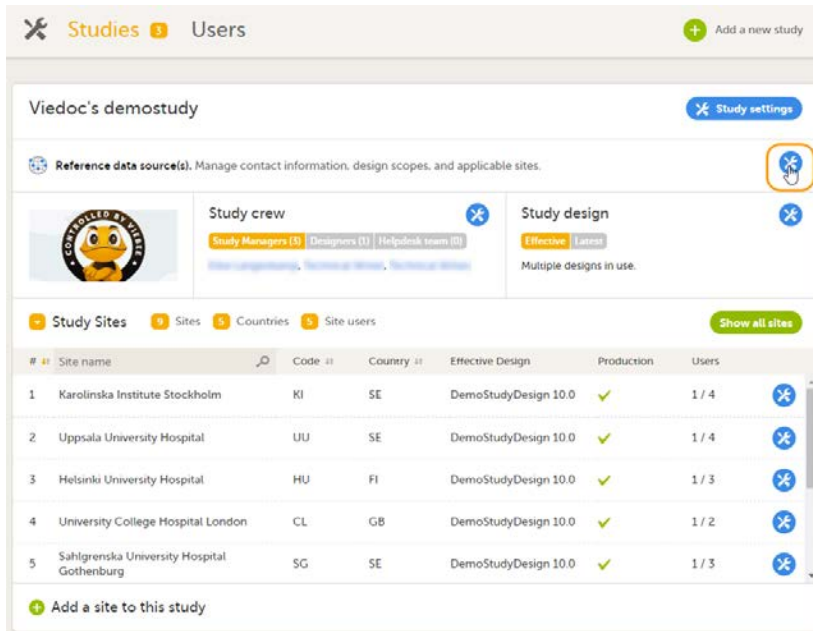
## 3 Step-by-step guides

### 3.1 Adding a reference data source

**Note!** Adding a reference data source can only be done by the **Reference Data Source Manager**.

To add a new reference data source, follow the steps below.

- 1 Click the toolbox icon in the **Reference data source(s)** field.

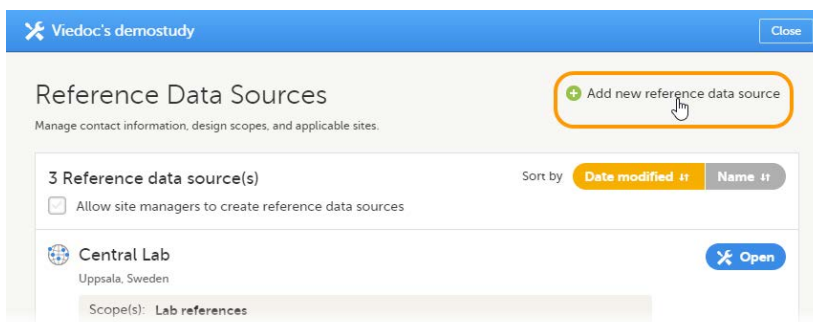


The screenshot shows the 'Viedoc's demostudy' interface. At the top, there are tabs for 'Studies' and 'Users', and a '+ Add a new study' button. Below the study name, there is a 'Study settings' button. The main area is divided into sections: 'Reference data source(s)' (with a toolbox icon highlighted), 'Study crew' (with 'Study Managers (5)', 'Designers (1)', and 'Helpdesk team (0)' listed), and 'Study design' (with 'Effective' and 'Latest' tabs and 'Multiple designs in use.'). Below these is a 'Study Sites' section with a 'Show all sites' button. A table lists five sites with columns for '#', 'Site name', 'Code', 'Country', 'Effective Design', 'Production', and 'Users'. Each row has a toolbox icon in the 'Users' column.

#	Site name	Code	Country	Effective Design	Production	Users
1	Karolinska Institute Stockholm	KI	SE	DemoStudyDesign 10.0	✓	1 / 4
2	Uppsala University Hospital	UU	SE	DemoStudyDesign 10.0	✓	1 / 4
3	Helsinki University Hospital	HU	FI	DemoStudyDesign 10.0	✓	1 / 3
4	University College Hospital London	CL	GB	DemoStudyDesign 10.0	✓	1 / 2
5	Sahlgrenska University Hospital Gothenburg	SG	SE	DemoStudyDesign 10.0	✓	1 / 3

The Reference Data Sources window opens.

- 2 Click **Add new reference data source**.



The screenshot shows the 'Reference Data Sources' window for 'Viedoc's demostudy'. It has a 'Close' button in the top right. The main title is 'Reference Data Sources' with a subtitle 'Manage contact information, design scopes, and applicable sites.' Below this is a '+ Add new reference data source' button, which is highlighted with an orange box and a mouse cursor. Underneath, there is a section for '3 Reference data source(s)' with a 'Sort by' dropdown set to 'Date modified' and a 'Name' dropdown. A checkbox 'Allow site managers to create reference data sources' is present. Below this is a list of reference data sources, starting with 'Central Lab' (Uppsala, Sweden) and an 'Open' button. A 'Scope(s): Lab references' field is also visible.

3 Enter the following details about the reference data source:

- Name (mandatory to enter)
- Country
- City
- Contact person
- E-mail address
- Phone number
- Description

In the **Link to following reference data scopes** field, select the reference data scopes to which the source should be linked.

In the **Available for use in the following sites** field, select the study sites to which the source should be linked. You can select individual sites, or a complete study site group at once (for more information about study site groups, see *About system site groups* in [Managing study sites](#)). You can add multiple sites or study site groups.

The screenshot shows a form titled "Central Lab" with the following fields and values:

- Name: Central Lab
- Country: Sweden
- City: Uppsala
- Contact person: Mr. Lab
- E-mail address: Central@ViedocLabs.com
- Phone number: 0123456789
- Description: A central lab for all sites in the study

The "Link to following reference data scopes" field contains "Lab references".

The "Available for use in following sites" field has a dropdown menu open, showing the following options:

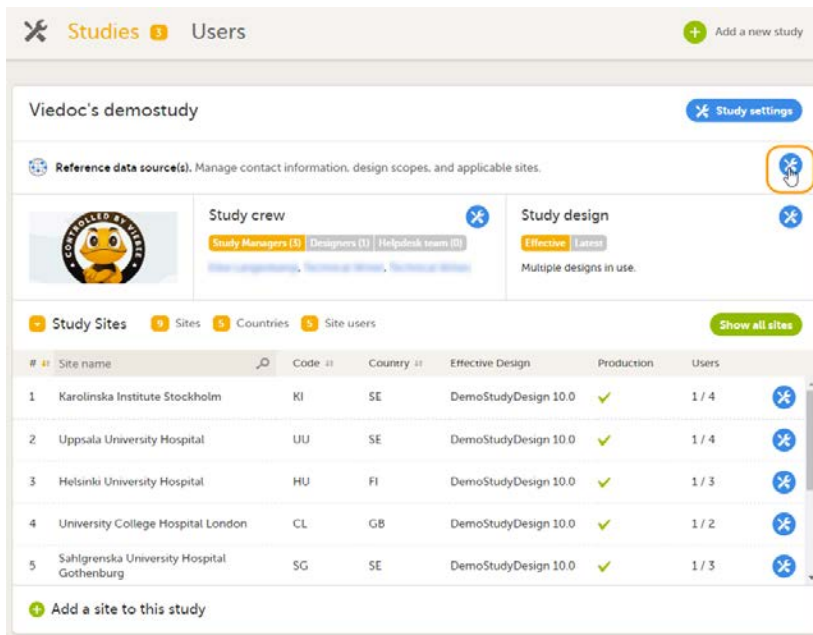
- All sites (highlighted)
- All production sites
- Finland
  - Helsinki University Hospital
- Germany
  - Charite University Hospital Berlin
- Sweden
  - Karolinska Institute Stockholm

4 Click **Save**. The new reference data source is added to the list of reference data sources.

## 3.2 Editing a reference data source

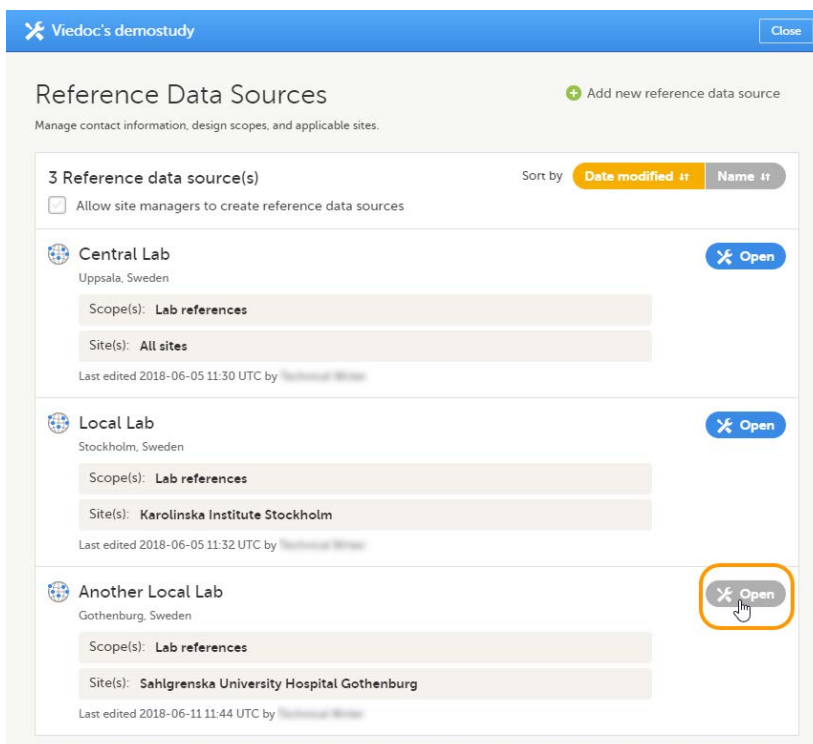
To edit the details of a reference data source, follow the steps below.

- 1 Click the toolbox icon in the **Reference data source(s)** field.



The Reference Data Sources window opens

- 2 Click **Open** to open the reference data source you would like to edit.



- 3 Edit the details and click **Save** to save the changes you made.

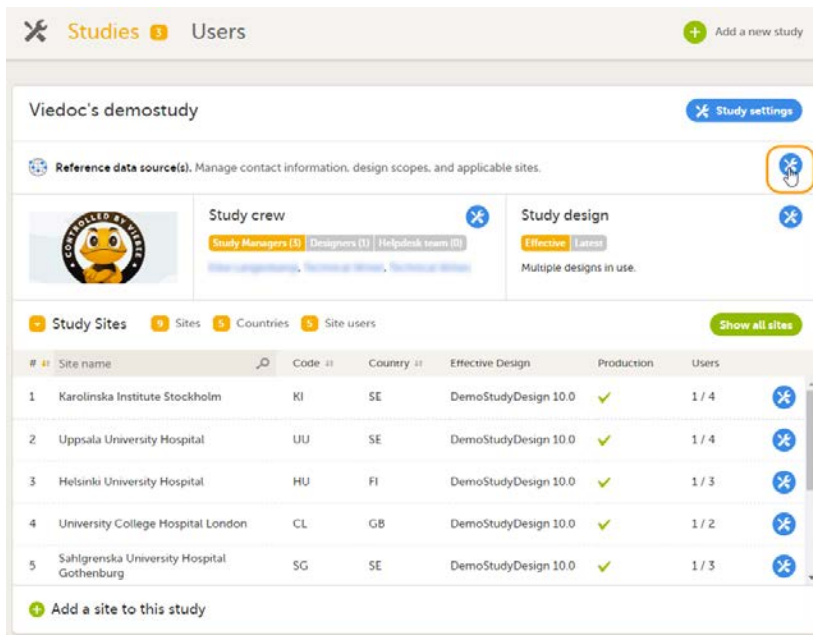
### 3.3 Deleting a reference data source

To delete a reference data source, follow the steps below.

**Note!** A reference data source cannot be deleted if at least one site in production mode was assigned to that source and if reference data has been published in Viedoc Clinic for that data source (in combination with a reference data scope).

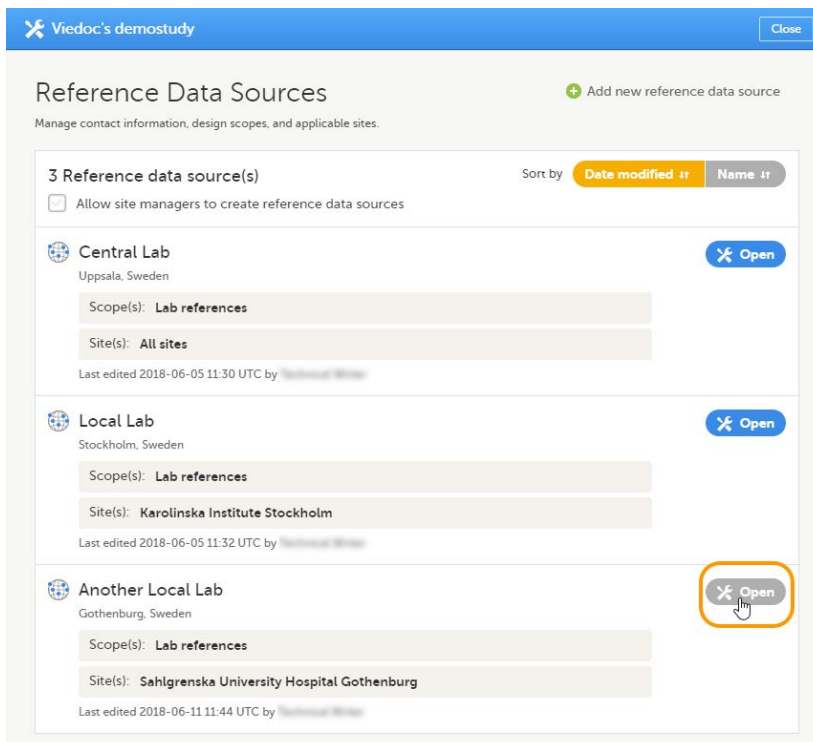


1 Click the toolbox icon in the **Reference data source(s)** field.



The Reference Data Sources window opens.

2 Click **Open** to open the reference data source you would like to delete.



3 Click **Delete this reference data source**.

The screenshot shows a web form titled "Another Local Lab" with a close icon (X) in the top left corner. The form contains several input fields and sections:

- Name:** "Another Local Lab"
- Country:** "Sweden" (dropdown menu)
- City:** "Gothenburg"
- Contact person:** (empty text box)
- E-mail address:** (empty text box)
- Phone number:** (empty text box)
- Description:** (empty text area)
- Link to following reference data scopes:** "Lab references X" (text box)
- Available for use in following sites:** "Sahlgrenska University Hospital Gothenburg X" (text box)

At the bottom of the form, there is a red dashed rectangular box containing the text "Delete this reference data source". A mouse cursor is pointing at this text. Below this box, there is a faint, disabled version of the same text and a "Cancel" button.

The reference data source is deleted.



A use case for reference data

# A use case for working with reference data

Published by Viedoc System 2023-04-25

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## 1. Introduction

- [1.1 About reference data](#)
- [1.2 Terminology](#)
- [1.3 Workflow](#)
- [1.4 Objective of this lesson](#)

## 2. Working with reference data - an example

- [2.1 Configuring a reference data scope in Viedoc Designer](#)
- [2.2 Adding a reference data source in Viedoc Admin](#)
- [2.3 Entering reference values in Viedoc Clinic](#)
- [2.4 Auto-population of reference data to the subject forms](#)

This lesson provides a use case for working with reference data in **Viedoc Designer**, **Viedoc Admin**, and **Viedoc Clinic**.

---

## 1 Introduction

### 1.1 About reference data

Viedoc offers support for adding reference data that will be automatically populated to specific forms. When reference data are configured for your study, it is not necessary to fill in reference values for each subject in each form separately.

It is possible to configure different sets of reference data that will be populated to the form based on:

- factors that can affect the reference data, such as age or gender
- reference data source, such as a lab
- site
- date

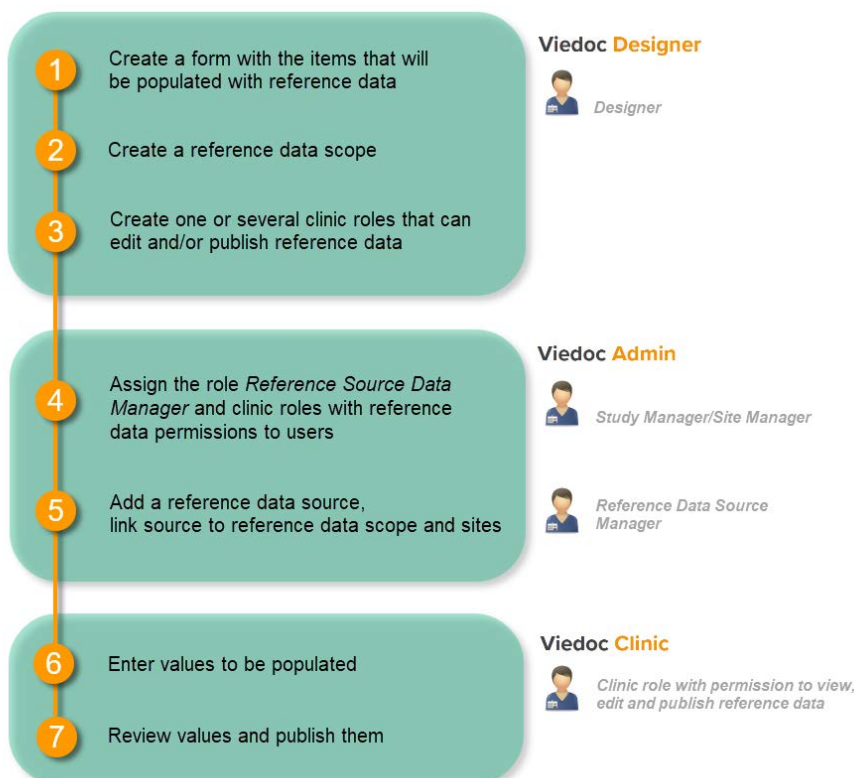
### 1.2 Terminology

Term	Definition
Reference data source	An institute that provides reference data, for example a lab.
Reference data scope	A mapping of the items that should be automatically populated with reference values, and the factors that they should depend on. One or more reference data scopes can be configured in Viedoc Designer > Global Settings, as set(s) of variables and factors (see definitions below).
Factor	A parameter that affects the reference data, for example a subject's sex. Factors may affect the normal range for a test result.
Variable	A specific measurement to be carried out.
Date factor	The date the sample was collected or the measurement carried out. This field determines on which date the reference data to be populated are based, for example when the event date is not the same as the collection or measurement date.

Term	Definition
Target type	An item of a certain type of information that a reference data source can provide for a specific variable (such as range, unit, low/high values, etc.). Any number of target types can be defined by the user.

## 1.3 Workflow

Reference data are configured in Viedoc Designer, Viedoc Admin and Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps.



For more detailed instructions regarding these steps, see:

- [Configuring reference data scopes](#) in Viedoc Designer
- [Managing reference data sources](#) in Viedoc Admin
- [Working with reference data](#) in Viedoc Clinic

For a video tutorial on how to work with reference data, see

- [Reference data video tutorial](#)

## 1.4 Objective of this lesson

This lesson illustrates an example of configuring reference data in Viedoc Designer, Viedoc Admin, and Viedoc Clinic. It also shows how reference data are populated to the subject forms in Viedoc Clinic.

# 2 Working with reference data - an example

## 2.1 Configuring a reference data scope in Viedoc Designer

1. In Viedoc Designer, create the form that will be auto-populated with reference values. In the example in the image, this form is the *Lab* form, and the items that will be populated with reference values are *Low Normal*, *High Normal* and *Range*.

- Set up a **Reference data scope**. The reference data scope defines a set of measurements that a reference data source (e.g., a lab) carries out, and the factors that might affect these data. In this example, the reference data scope *Hematology CBC* was set up, with:
  - Sex and Age as Factors** - because these are the factors that the respective reference values might depend on.
  - Leukocytes, Lymphocytes and Neutrophils as Variables** - because these are the parameters that are going to be measured. For each variable, we set the **date factor** (the date on which the reference values to be populated are based) to the *LAB\_DATE* item in the *Lab* form. We also set up two **target types** that correspond to the *Low Normal* and *High Normal* items in the *Lab* form.

The screenshot shows the Viedoc Designer interface. On the left, there are two panels: 'Forms / Demographics' and 'Forms / Lab'. The 'Forms / Demographics' panel shows fields for 'Date of Informed Consent', 'Gender', 'Date of birth', and 'Age'. The 'Forms / Lab' panel shows 'Collection Date and Time' and 'Hematology - CBC' results for WBC, NEUT, and LYM, each with 'Result', 'Low Normal', and 'High Normal' fields. The 'Hematology - CBC2' panel shows 'Mono' and 'Baso' results with 'Range' fields.

On the right, the 'Reference data scopes' panel shows a list of scopes: 'Hematology CBC Factors: 2, Variables: 3' and 'Hematology CBC2 Factors: 2, Variables: 2'. Below this, the 'Reference data scope | Hematology CBC' configuration is shown. It includes a 'Scope name' field set to 'Hematology CBC'. The 'Factors' section contains a table:

#	Factor label	Factor expression	Factor options
1	Sex	\$FIRST DM.DMSEX	Male, Female
2	Age	\$FIRST DM.DMAGE	TEC

The 'Variables' section contains a table:

#	Form	Name	Date factor	Target types
1	Lab (LAB)	Leukocytes	LAB_DATE	Low Normal (LAB_WBC_LOW), High Normal (LAB_WBC_HIGH)
2	Lab (LAB)	Neutrophils	LAB_DATE	Low Normal (LAB_NEUT_LOW), High Normal (LAB_NEUT_HIGH)
3	Lab (LAB)	Lymphocytes	LAB_DATE	Low Normal (LAB_LYM_LOW), High Normal (LAB_LYM_HIGH)

Dotted orange lines connect the 'Date of birth' and 'Age' fields in the 'Forms / Demographics' panel to the 'Sex' and 'Age' factors in the 'Reference data scope | Hematology CBC' configuration. Similarly, dotted orange lines connect the 'Collection Date and Time' field in the 'Forms / Lab' panel to the 'Date factor' column in the 'Variables' table. Other dotted orange lines connect the 'Result', 'Low Normal', and 'High Normal' fields in the 'Hematology - CBC' section to the corresponding 'Target types' in the 'Variables' table.

- Publish the **Global design settings**, so that the defined reference data scope will become available in Viedoc Admin and Viedoc Clinic.
- Create one or more clinic roles that have permission to perform one or more of the following actions:
  - View reference data** - allows the user to see the existing reference data in read only mode in Viedoc Clinic. When enabling this option the following two options become available:
  - Edit reference data** - allows the user to edit and save reference data.
  - Publish reference data** - allows the user to publish the reference data values, so that the values will become available for the forms in Viedoc Clinic.

**Note!** You need to have at least one clinic role with permission to edit reference data and one clinic role with permission to publish reference data. This does not have to be the same role.

**Roles**  
Compare and manage user roles ?

Viedoc Designer  
Designer

	Save	Sign	Review	Output	Read-only
<b>Investigator</b> Role ID: RG5515	Yes	No	No	Yes	No
<b>Monitor</b> Role ID: RG5518	No	No	Yes	Yes	No
<b>Data Manager</b> Role ID: RG5519	No	No	Limited	Yes	No
<b>Sponsor</b>	No	No	No	Yes	Yes

**Edit role "Data Manager" [RG5519]**

**Edit role**

Name: Data Manager Status: ON

Description:

Avatar:

**Manage rights in this role**

**Special**

- User can only view form data (this overrides all edit permissions)
- Export of data into different formats/view reports
- Medical coding
- Metrics
- Create private notes
- View reference data
- Edit reference data
- Publish reference data

**CRF Rights**

- Add/update subject/event/form data and query answers
- Sign subject/event form data and queries
- Promote pre-queries
- Delete subjects
- Add/change queries
- Data review
- Clinical review
- Add pre-queries
- SDV
- Lock data

**eLearning**

- Site User Training (SUTV4)
- Monitoring Training (MTPV4)

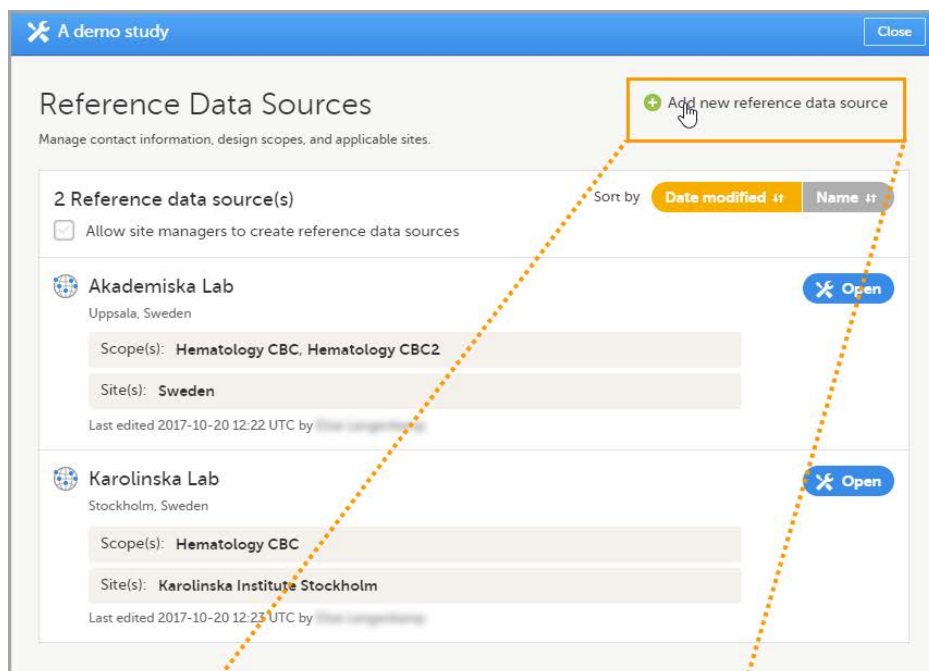
For more detailed instruction, see [Configuring reference data scopes](#), and [Configuring roles](#) in Viedoc Designer.

## 2.2 Adding a reference data source in Viedoc Admin

In Viedoc Admin, open the **Reference data source(s)** window and add the reference data sources (the labs or institutes that will provide the reference data). Link the reference data source to the reference data scopes and to the sites for which they should be used.

For more detailed instruction, see [Managing reference data sources](#) in Viedoc Admin.

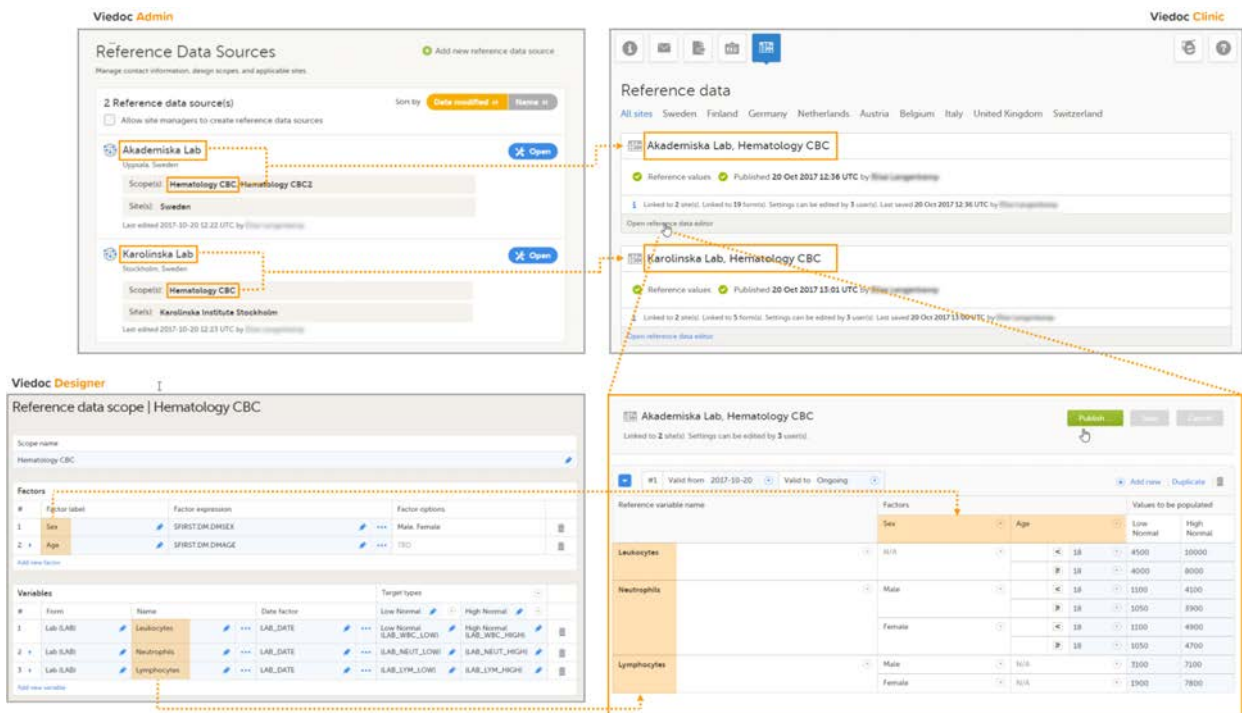
In this example, we have defined two reference data sources: *Akademiska Lab* and *Karolinska Lab*. The *Akademiska Lab* is linked to two scopes: *Hematology CBC* and *Hematology CBC2*. It is also linked to the system site group *Sweden* (all production sites in Sweden). The *Karolinska Lab* is only linked to the scope *Hematology CBC*, and to the site *Karolinska Institute Stockholm*.



For each of the defined reference data source-scope combinations, reference data value sets will become available in Viedoc Clinic.

## 2.3 Entering reference values in Viedoc Clinic

1. In Viedoc Clinic, on the landing page, click the reference data icon. A list of all reference data source-scope combinations is displayed.
2. Click **Open reference data editor** to open the reference data editor. In this example, we enter the values for the *Akademiska Lab, Hematology U* source-scope combination.
  - Select the time period the values are valid.
  - Select the factors to include. In this example, both *Age* and *Sex* are included, yet not used for all three variables. We set sex to *N/A* (not applicable) for the variable *Leukocytes*, and age to *N/A* for the variable *Lymphocytes*.
  - Select the factor options to include, and/or define the range. In this example, we include *Male* and *Female* as factor options for the factor *Sex*, and we specify *<18* and *≥18* as ranges for the factor *Age*.
  - Enter the reference values.
3. Click **Save** to save the reference values.
4. Click **Publish** to publish the reference values. Publishing will make the reference values available for autopopulation to the subject forms.



For more detailed instruction, see [Working with reference data](#) in Viedoc Clinic.

## 2.4 Auto-population of reference data to the subject forms

1. Open the form to which the reference data will be populated, in this example *Lab*. Viedoc automatically identifies forms that have items that belong to reference data scopes, and displays a section in which the source for the reference data can be selected: *Link the scope with the reference data source that provided the test results*.
2. For each scope, select the reference data source that provided the reference data from the drop-down list. In this example we select *Akademiska Lab* for the scope *Hematology CBC*.
3. Set the **Collection date and time**.



**Akademiska Lab, Hematology CBC**  
Linked to 2 site(s). Settings can be edited by 3 user(s).

Reference variable name	Factors	Values to be populated		
	Sex	Age	Low Normal	High Normal
Leukocytes	N/A	< 18	4500	10000
		≥ 18	4000	8000
Neutrophils	Male	< 18	1100	4100
		≥ 18	1050	3900
Lymphocytes	Female	< 18	1100	4900
		≥ 18	1050	4700
	Male	N/A	3100	7100
	Female	N/A	1900	7800

**Demographics**

Date of Informed Consent: 13 Aug 2018

Gender:  Male  Female

Date of Birth: 10 Jul 1979

Age: 39.1 years

**Lab**

Link the scope with the reference data source that provided the test results

Hematology CBC: Akademiska Lab

Hematology CBC2: Akademiska Lab

Collection Date and Time: 13 Aug 2018 10:04

**Hematology - CBC**

WBC	Result	Low Normal	High Normal
Leukocytes		4000	8000
NEUT		1050	3900
LYM		3100	7100

**Hematology - CBC2**

Mono	Result	Range
Baso		- -

In the reference data scope, the date factor is set to *LAB\_DATE*, which is this item in the form.

If there is no reference data scope defined for these variables, or if no reference values have been published for this source-scope combination, no reference values are populated. These items are editable, so they can be filled in manually.

The system verifies:

- which date factor has been defined in the reference data scope (so on which date the reference values should be based), and whether this date lies within the time period that the reference values are valid. In this example, the date factor is set to the item *LAB\_DATE*, which has the value *13 Aug 2018 10:04*. This date lies within the time period *#1* that the reference values of the source-scope combination *Hematology CBC-Akademiska Lab* is valid.
- what the factors are, in this example the gender (male) and the age (39, thus  $\geq 18$ ) of the subject. This information is taken from the *Demographics* form.

If the date matches the validity of the reference values, the system auto-populates the relevant reference values to the subject form, based on the defined factors.

If you do not select a reference data source, no values will be automatically populated. The items are editable so that they can be filled in manually. Similarly, if no scope is defined (as for the *Mono* and *Baso* items in the form), or if no reference values are entered for that specific source-scope combination or for that specific date, the items remain empty and can be filled in manually.

For more detailed instruction, see [Working with reference data](#) in Viedoc Clinic.



Viedoc Data Import Application

# Viedoc Data Import Application

Published by Viedoc System 2024-03-19

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## 1 Introduction

Viedoc offers the possibility to import data, for example laboratory data, into your study in Viedoc using the Viedoc Data Import Application. When importing data, the Viedoc Data Import application does the following:

1. It converts the provided data into Operational Data Model ([ODM](#)) format using a data mapping file, and
2. It pushes the data into Viedoc through the Viedoc Application Programming Interface ([API](#)).

This document describes how to import data into Viedoc using the Viedoc Data Import Application. It describes the data import procedure in general, and provides instructions for the following steps:

1. Downloading the data mapping file in Clinical Data Interchange Standards Consortium Define Extensible Markup Language ([CDISC Define-XML](#)) format from Viedoc Designer.
2. Creating a Viedoc API client ID in Viedoc Admin. For information, see [API configuration](#).
3. Creating a configuration file.
4. Preparing the work folder.
5. Downloading the Viedoc Data Import Application.
6. Dropping data into the work folder.
7. Running the Viedoc Data Import Application.

### 1.1 More information

This document does not describe how to create the data mapping file in [CDISC Define-XML](#) format. Instructions on how to create a data mapping file can be found in [Creating a data mapping for import of data](#).

More information on importing data into Viedoc can be found in our [video tutorial](#).

---

## 2 About importing data into Viedoc

### 2.1 The Viedoc Data Import Application

Viedoc offers the possibility to import data into forms, for example laboratory data, via the Viedoc Data Import Application.

To import data into Viedoc, the Viedoc Data Import Application first converts the supplied data into [ODM](#) clinical data format. To do this, the application needs:

- A data mapping file, which will be used to translate the supplied data into ODM format,
- A configuration file,
- The data file containing the data to be imported into Viedoc. The data file should be a delimited file. Comma-Separated Values ([CSV](#)) files are supported as default; any other file delimiter can be used by specifying the delimiter of choice in the configuration file.

Then, the Viedoc Data Import Application pushes the ODM clinical data into Viedoc through the Viedoc [API](#). To do this, the application needs:

- A Viedoc user name and password with access to role appropriate permissions.
- A study-specific Viedoc API client key.

You can download the latest version of the Viedoc Data Import Application from the Data mappings window in Global design settings in Viedoc Designer. For instructions, see section [3.6 Downloading the Viedoc Data Import Application](#).

### 2.2 The data mapping file

The data mapping file defines how the external data are mapped into form items in Viedoc. It describes each column of the data file to be imported, and the destination of the data in Viedoc.

The data mapping file is created in Global design settings in Viedoc Designer. Internally, the data mapping is stored in [CDISC Define-XML](#) format. For each type of data file to be imported, a separate data mapping file should be created.

For instructions on how to create a data mapping file, see [Creating a data mapping for import of data](#).

### 2.3 The configuration file

The configuration file defines the following:

- which Viedoc studies the data should be imported into,
- where to find the data mapping file,
- where to find the data file containing the data that should be imported,
- which [API](#) instance the data should be imported into (v4, v4training, v4jp and so on),
- the login credentials that should be used when importing the data.

The above information is mandatory to define in the configuration file. Optionally, you can use the configuration file to define the following:

- whether you would like new subjects to be created automatically during the data import, when the imported data contain data for a subject that has not been added to the study yet,
- whether you would like events to be initiated during the data import, when the imported data contain data for events that have not been initiated yet,
- which character encoding should be used, when the imported file is read, and
- which file delimiter should be used, when the imported file is parsed.

The configuration file is an [XML](#) file that can be created in any text editor. One configuration file can contain the import configurations for multiple import projects and studies.

For instructions on how to create a configuration file, see section [3.5 Creating a configuration file and prepare the work folder](#).

## 3 Importing data into Viedoc using the Viedoc Data Import Application

### 3.1 Introduction

This section provides instructions for importing data into Viedoc using the Viedoc Data Import Application.

### 3.2 Creating a data mapping file

#	Column name	Description	Link to	IM	Destination (Viedoc expression)	CL
1	PatientID	Subject ID			{SubjectKey}	
-1		Subject ID			{CountryCode}-{SiteCode}-{SiteSubjectSeqNo}	
-2		Site Code Subject ID			{StudyEventDerID}	
2	VISITID		Name		{EventDate}	
3	VISITDAT	Visit Date			{StudyEventRepeatKey}	
-1		Visit Date				
-2		Study Event Repeat Key				
4	PARAMETER		Name			
CL1	ALAT					
CL2	ALKP					
CL3	ASAT					
5	Result		PARAMETER			
-1	-- ALAT	Alanine aminotransferase - Result			{STHS.CC.RES_ALAT}	
-2	-- ALKP	Alkaline phosphatase - Result			{STHS.CC.RES_ALKP}	
-3	-- ASAT	Aspartate aminotransferase - Result			{STHS.CC.RES_ASAT}	
6	Unit		PARAMETER			
-1	-- ALAT	ALAT			{STHS.CC.UNIT_ALAT}	
-2	-- ALKP	ALKP			{STHS.CC.UNIT_ALKP}	
-3	-- ASAT	ASAT			{STHS.CC.UNIT_ASAT}	

Create a data mapping file in Viedoc Designer according to the instructions in [Creating a data mapping for import of data](#). In the data mapping file, every column of the data file should be mapped to the corresponding form item in Viedoc. You need one data mapping file for each type of data file that you wish to import.

When all the columns in the data file are mapped, save the data mapping, and publish the changes in the Global design settings window.

### 3.3 Downloading the data mapping file

Download the data mapping file as follows (see also the instructions in [Data mapping for import of data in the eLearning](#)):

- 1 In the **Data mappings** field, click **Edit** to open the data mappings overview.
- 2 Click the **Download** icon behind the data mapping that you just created. An [XML](#) file will be downloaded that contains the data mapping.

### 3.4 Creating a Viedoc API client ID

See [API configuration](#).

### 3.5 Creating a configuration file and preparing the work folder

#### 3.5.1 Creating a folder structure on your computer

To create a folder structure to store the configuration file, the data mapping file, and the data to be imported:

1. Create a work folder on your computer.  
In the example used for this document, a work folder called "helipad" is directly created on the C-drive,

see also section [3.5.3 An example of a correct folder structure](#).

2. Within the work folder, create one subfolder (project folder) for each import project, for example "ProjectFolder1".
3. Save the data mapping file in the respective project folder within the work folder.

### 3.5.2 Creating the configuration file

To create the configuration file:

- 1 In a text editor of choice, create an [XML](#) file according to the following example (copy and paste the text if necessary):

```
<?xml version="1.0" encoding="utf-8"?>
<ViedocImportConfiguration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
<BasePath>C:\helipad</BasePath>
<ImportConfiguration>
<FolderName>ProjectFolder1</FolderName>
<DefineXmlFileName>DemoStudy-Datamapping.xml</DefineXmlFileName>
<ApiUrl>https://v4api.viedoc.net/HelipadService.svc</ApiUrl>
<ClientGuid>5091c8d8-dbe8-4119-9caa-0b5cbc747759</ClientGuid>
<UserName>majd@viedoc.net</UserName>
<Password>YourP@ssw0rd</Password>
<AllowCreatingSubjects>>true</AllowCreatingSubjects>
<AllowInitiatingStudyEvents>>true</AllowInitiatingStudyEvents>
<FileDelimiter>,</FileDelimiter>
<FileEncoding>utf-8</FileEncoding>
</ImportConfiguration>
</ViedocImportConfiguration>
```

2 Edit the XML tags and specify the following information.

**Note!** All XML tags are case sensitive!

The <BasePath> is the path to the work folder that contains the configuration file and the different project folders.

In the <ImportConfiguration> section, specify the following information:

- a) <FolderName> : The name of the project folder where the data mapping file and the data file to be imported are saved. This folder should be a subfolder within your work folder.
- b) <DefineXmlFileName> : The name of the data mapping file.
- c) <ApiUrl> : The URL to the Viedoc [API](#) instance that the data should be imported into. The URL is named as follows: Application + Instance + Country (no country name is used for instances in Stockholm).

For all countries except Japan, the URL is:

- <https://v4api.viedoc.net/HelipadService.svc>
- <https://v4apitraining.viedoc.net/HelipadService.svc>
- <https://v4apistage.viedoc.net/HelipadService.svc>

For Japan, the URL is:

- <https://v4apijp.viedoc.net/HelipadService.svc>
- <https://v4apitrainingjp.viedoc.net/HelipadService.svc>
- <https://v4apistagejp.viedoc.net/HelipadService.svc>

- d) <ClientGuid> : The Viedoc API client ID.
- e) <UserName> : The username of the Viedoc user that should be used to log in.
- f) <Password> : The password of the user. After running the application for the first time, the password is replaced with an encrypted password.
- g) <AllowCreatingSubjects> : When set to true, new subjects are automatically created during the import, if the data file contains data for subjects that have not been added to the study yet. Default is true
- h) <AllowInitiatingStudyEvents> : When set to true, events are automatically initiated during the import, if the data file contains data for events that have not been initiated yet. Default is true.
- i) <FileDelimiter> : Sets the delimiter that is used when parsing the imported file. Default is “,” (comma). All possible symbols and the tab are supported as file delimiters.
- j) <FileEncoding> : Specifies the type of character encoding that is used when parsing the imported file, see table 2 for a list of all supported encoding. Default is utf-8 .

Note that the <ClientGuid> , <UserName> and <Password> must all belong to the Viedoc API instance specified by the <ApiUrl> tag.

The <AllowCreatingSubjects> , <AllowInitiatingStudyEvents> , <FileDelimiter> ,and <FileEncoding> tags are optional to specify. If nothing is specified, the application will take the default.

3 If you would like to import multiple types of data files, add a new <ImportConfiguration> section for each type of data file, and edit the XML tags as described in step 2.

4 Save the configuration file in the work folder.

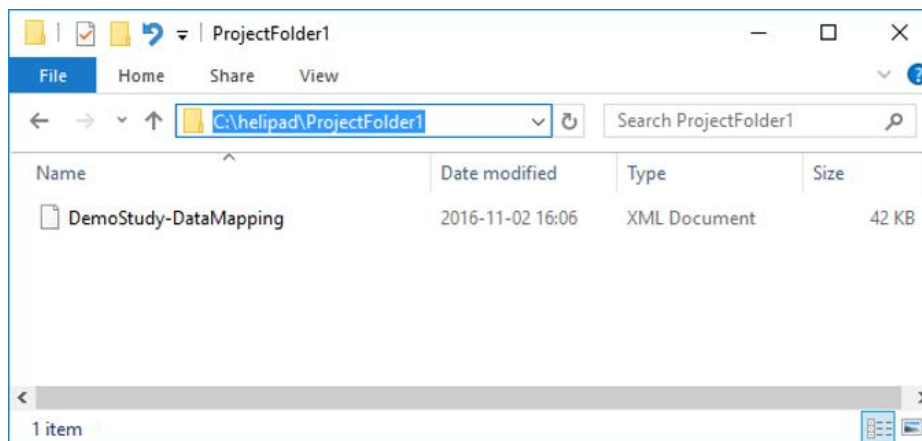
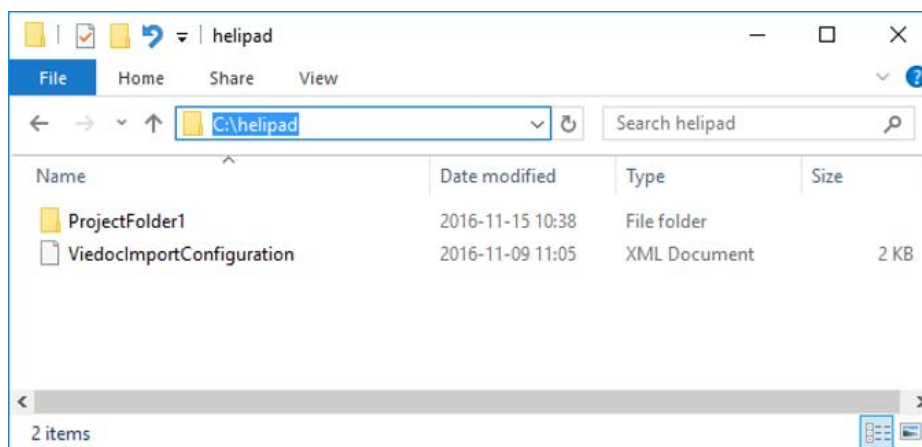
Name	Type of encoding
gb2312	Chinese Simplified (GB2312)

Name	Type of encoding
utf-16	Unicode
unicodeFFFE	Unicode (Big endian)
Windows-1252	Western European (Windows)
x-mac-korean	Korean (Mac)
x-mac-chinesesimp	Chinese Simplified (Mac)
utf-32	Unicode (UTF-32)
utf-32BE	Unicode (UTF-32 Big endian)
us-ascii	US-ASCII
x-cp20936	Chinese Simplified (GB2312-80)
x-cp20949	Korean Wansung
iso-8859-1	Western European (ISO)
iso-8859-8	Hebrew (ISO-Visual)
iso-8859-8-1	Hebrew (ISO-Logical)
iso-2022-jp	Japanese (JIS)
csISO2022JP	Japanese (JIS-Allow 1 byte Kana)
iso-2022-jp	Japanese (JIS-Allow 1 byte Kana - SO/SI)
iso-2022-kr	Korean (ISO)
x-cp50227	Chinese Simplified (ISO-2022)
euc-jp	Japanese (EUC)
EUC-CN	Chinese Simplified (EUC)
euc-kr	Korean (EUC)
hz-gb-2312	Chinese Simplified (HZ)
GB18030	Chinese Simplified (GB18030)
x-iscii-de	ISCII Devanagari
x-iscii-be	ISCII Bengali
x-iscii-ta	ISCII Tamil
x-iscii-te	ISCII Telugu
x-iscii-as	ISCII Assamese
x-iscii-or	ISCII Oriya
x-iscii-ka	ISCII Kannada

Name	Type of encoding
x-iscii-ma	ISCII Malayalam
x-iscii-gu	ISCII Gujarati
x-iscii-pa	ISCII Punjabi
utf-7	Unicode (UTF-7)
utf-8	Unicode (UTF-8)

### 3.5.3 An example of a correct folder structure

In the configuration file of the example above, the work folder is *C:\helipad*. The work folder contains the project folder *ProjectFolder1* and the configuration file *ViedocImportConfiguration.xml*.



The data file(s) containing the data to be imported should also be saved in the project folder.

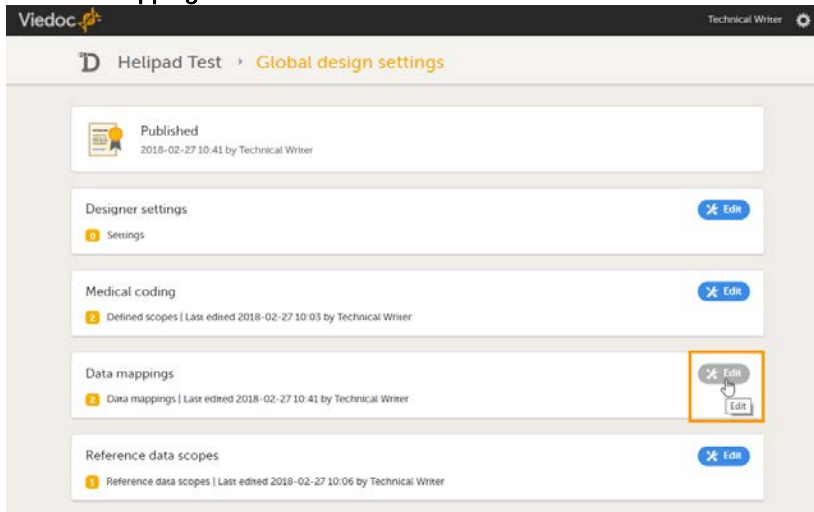
## 3.6 Downloading the Viedoc Data Import Application

**Note!** The Data Import Application only works for Windows OS and not Linux or Mac.

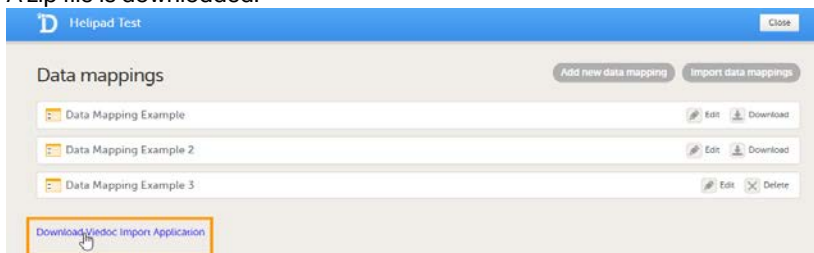
To download and install the Viedoc Data Import Application:



- 1 In the Global design settings in Viedoc Designer, click the **Edit** icon in the **Data mappings** field to open the **Data mappings** window.



- 2 Click **Download Viedoc Import Application** to download the installation file. A zip file is downloaded.



- 3 Save the zip file on any location on your computer and extract the contents.

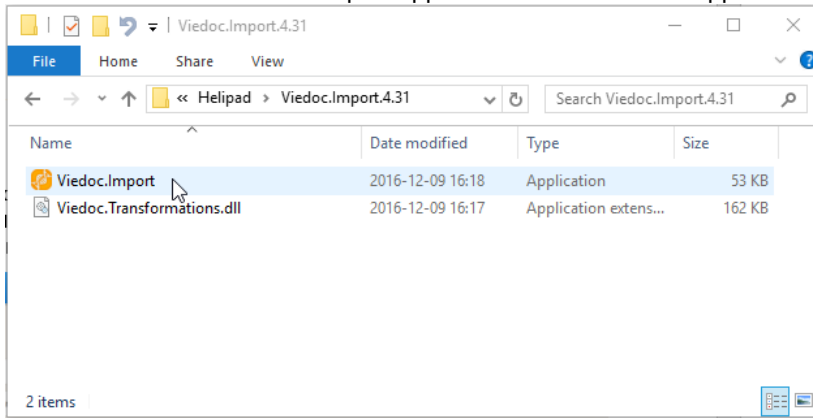
### 3.7 Dropping data into the project folder

Save the data file containing the data to be imported in the project folder.

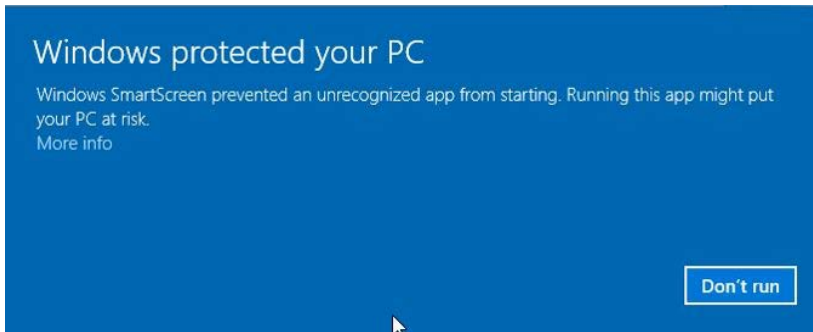
### 3.8 Running the Viedoc Data Import Application

To run the application and import the data:

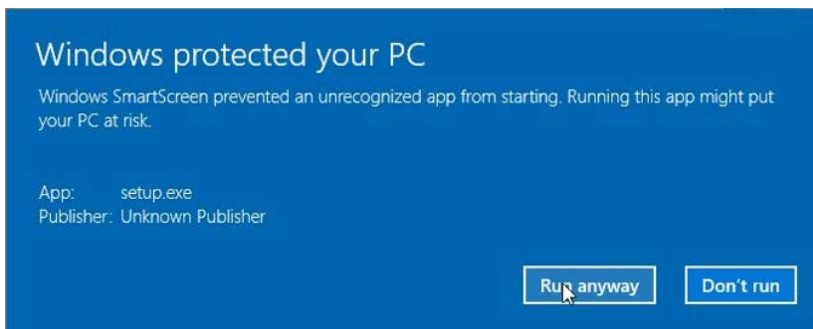
1 Double-click the Viedoc Data Import Application icon to start the application.



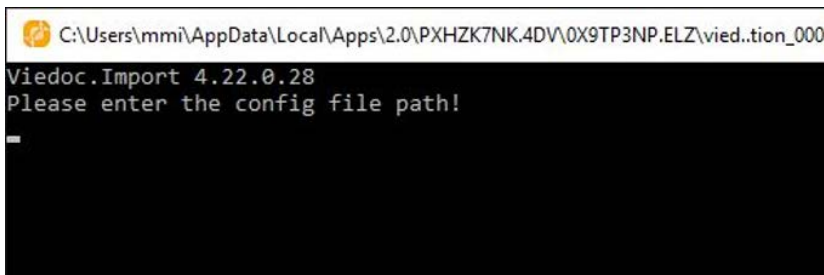
When starting the application for the first time, the following window appears:



2 Click **More info**, and then click **Run anyway**.



The following window appears:



3 Enter the path to the configuration file, for example: *C:\helipad\ViedocImportConfiguration.xml*, and press Enter. The application imports the data in the data file into Viedoc, and moves the data file into an archive folder within the project folder (the systems creates the archive folder automatically, if it has not created one yet).

When the application is run, it goes through all the project folders that are specified in the configuration file, and imports the data of all the data files found in these project folders. If no data files are found in a specific project folder, that project is skipped.

After the import, the application closes automatically.

You can monitor the status of the import in Viedoc Admin. To do this, click the **Edit** icon in the **API configuration** field in Viedoc Admin to open the [API](#) configuration window. The Submit data History list displays which client ID is used for the import, the date and time of the import, and the status. The contents of the data import and a log file can be downloaded.

**Note** The file path that the application references can be updated by changing the reference in a settings file. This settings file can be located via `C:\Users\USERNAMEHERE\AppData\Local\Viedoc`. Also note that the AppData folder may be hidden by default.

### 3.9 Importing more data

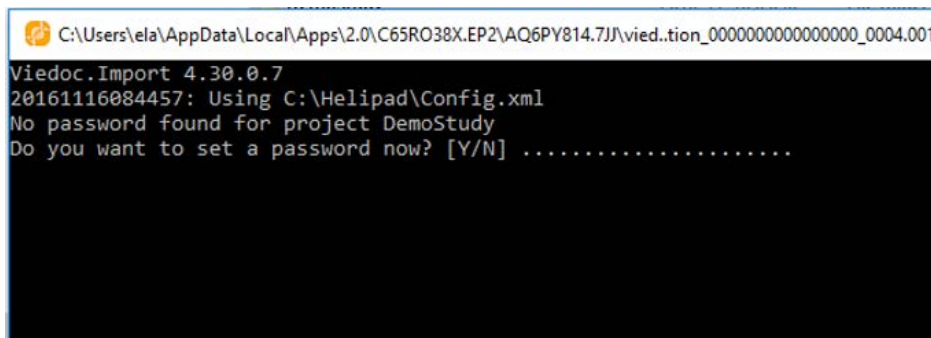
Whenever you have new data to import, save the data file in the respective project folder and run the application again by double-clicking the Viedoc Data Import Application icon. There is no need to specify the path to the configuration file because the application has stored that information when it was run for the first time.

You can edit the configuration file at any time to add, edit, or remove import projects.

### 3.10 About the password

If you have specified a password in the configuration file, the Viedoc Data Import Application replaces this password with an encrypted password when running the application for the first time. The encrypted password is saved in the configuration file.

If you have not specified a password in the configuration file, the application asks you for a password upon start-up.



```
C:\Users\rela\AppData\Local\Apps\2.0\C65RO38X.EP2\AQ6PY814.7JJ\vied..tion_0000000000000000_0004.001
Viedoc.Import 4.30.0.7
20161116084457: Using C:\Helipad\Config.xml
No password found for project DemoStudy
Do you want to set a password now? [Y/N] .....
```

To enter a password, press Y (yes), type your password and press Enter. Type your password again and press Enter. The system will save your password as an encrypted password in the configuration file.

If you press N (no), or do not press anything for 15 seconds, or enter the wrong password, the application cannot login and does not import any data. The application displays `Error logging in: Invalid userName or password`.

If you have changed your Viedoc password, replace the old password in the configuration file with the new password and save the configuration file. The next time the Viedoc Data Import Application is run, the new password will be used to login and import the data.

---

## 4 Automating import through the Task Scheduler

Please see this [link](#) for instructions on how to automate imports through the Task Scheduler.



Viedoc WCF API

# Viedoc WCF API

Published by Viedoc System 2023-10-09

---

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## 1 Introduction

This document contains information on connecting your development environment or any other system to the Viedoc public web service using the Windows Communication Foundation (WCF) standards.

The Viedoc public Application Programming Interface ([API](#)) is a Simple Object Access Protocol (SOAP) over a Hypertext Transfer Protocol (HTTP) service. The API can be reached at: [https://\[VIEDOC\\_HOST\]/HelipadService.svc](https://[VIEDOC_HOST]/HelipadService.svc)

A wsdl metadata file can be downloaded from: [https://\[VIEDOC\\_HOST\]/HelipadService.svc?wsdl](https://[VIEDOC_HOST]/HelipadService.svc?wsdl)  
For example:

<https://v4api.viedoc.net/HelipadService.svc?wsdl>  
<https://v4apitraining.viedoc.net/HelipadService.svc?wsdl>

Contact Viedoc Technologies for information about which host to connect to.

---

## 2 Methods

### 2.1 Token

#### 2.1.1 Description

The `Token` method is used for authenticating the client. This method must be called to receive a token for authenticating all subsequent requests.

To authenticate the client, the following must be provided:

- An active Client ID, a client ID (GUID) linked to a specific study in Viedoc. The client ID is linked to either the demo or the production study.
- A Viedoc user name and password. To submit data into Viedoc, you need access to the study in Viedoc and to the study site with a role that allows data entry.

**Note!** You can only access the API configuration window and create an API client ID if you are assigned the role API Manager. All the pending role invitations for a user are automatically approved when the `Token / GetToken` method is used.

For information about how to obtain a client ID, see [API configuration](#).

#### 2.1.2 C# Syntax

```
ApiTokenModel tokenModel = Token(ApiAuthenticationModel loginModel);
```

### 2.1.3 Parameters

The `Token` method has the following parameters:

Parameter	Data type	Description
<code>loginModel</code>	<code>ApiAuthenticationModel</code>	A collection of authentication information. See section <a href="#">3.1 ApiAuthenticationModel</a> for a description.

### 2.1.4 Returns

The `Token` method returns an `ApiTokenModel` object that has the following properties:

Property	Data type	Description
<code>Token</code>	<code>string</code>	A new authentication token that can be used for authentication in subsequent requests
<code>Result</code>	<code>ApiResultType</code>	Defines the type and status of the result returned from method invocation. See section <a href="#">3.2 ApiResultType</a> for details
<code>ErrorCode</code>	<code>int</code>	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
<code>ErrorMessage</code>	<code>string</code>	In case of an error result: human readable description of the error
<code>ExpiryDateTime</code>	<code>DateTime</code>	Token expiration date and time

### 2.1.5 Example HTTP call

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API"
xmlns:vied1="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public">
  <soapenv:Header/>
  <soapenv:Body>
    <vied:Token>
      <vied:loginModel>
        <vied1:ClientGuid>f4680c73-f936-48be-bf5e-560f05af640c</vied1:ClientGuid>
        <vied1:UserName>[USERNAME]</vied1:UserName>
        <vied1>Password>[PASSWORD]</vied1>Password>
        <vied1:TimeSpanInSeconds>180</vied1:TimeSpanInSeconds>
      </vied:loginModel>
    </vied:Token>
  </soapenv:Body>
</soapenv:Envelope>
```

### 2.1.6 Example HTTP response

```

<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <TokenResponse xmlns="Viedoc.API">
      <TokenResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>C8AD03E3C4...4A23A01E59</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:ExpiryDateTime>2017-01-17T15:50:14.6564955+00:00</a:ExpiryDateTime>
      </TokenResult>
    </TokenResponse>
  </s:Body>
</s:Envelope>

```

## 2.2 GetToken

### 2.2.1 Description

For a description of the `GetToken` method, see the description of the `Token` method in section [2.1 Token](#).

### 2.2.2 C# Syntax

```

ApiTokenModel GetToken(Guid ClientGuid, string UserName, string password,
int timeSpanInSeconds);

```

### 2.2.3 Parameters

The `GetToken` method has the following parameters:

Parameter	Data type	Description
ClientGuid	ApiAuthenticationModel	Client ID linked to a specific study in Viedoc. Can be obtained from Viedoc Admin. Required.
UserName	string	Viedoc login username. Required.
Password	string	Matching Viedoc login password. Required.
TimeSpanInSeconds	int	Time (in seconds) that the authentication token will be valid for. Optional. Default is 300 seconds (5 min). Maximum is 1800 seconds (30 min).

### 2.2.4 Returns

For a list of the returns of the `GetToken` method, see the returns of the `Token` method as described in section [2.1.4 Returns](#).

## 2.3 SubmitData

### 2.3.1 Description

The `SubmitData` method can be used for submitting data into Viedoc.

### 2.3.2 C# Syntax

```
ApiSubmitResultModel SubmitData(string token, string odmXml,  
    ApiSubmitDataOptions options = null);
```

### 2.3.3 Parameters

The `SubmitData` method has the following parameters:

Parameter	Data type	Description
<code>token</code>	<code>string</code>	Authentication token. Can be obtained by invoking the <code>Token</code> method with client ID, username, and password.
<code>odmXml</code>	<code>string</code>	The data to be uploaded in <a href="#">ODM</a> format
<code>options</code>	<code>ApiSubmitDataOptions</code>	Submit data options. Optional. See section <a href="#">3.3 ApiSubmitDataOptions</a> .

### 2.3.4 Returns

The `SubmitData` method returns an `ApiSubmitResultModel` object that has the following properties:

Property	Data type	Description
<code>Token</code>	<code>string</code>	A new authentication token that can be used for authentication in subsequent requests
<code>Result</code>	<code>ApiResultType</code>	Defines the type and status of the result returned from method invocation. See the section <a href="#">3.2 ApiResultType</a> for details.
<code>ErrorCode</code>	<code>int</code>	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
<code>ErrorMessage</code>	<code>string</code>	In case of an error result: human readable description of the error
<code>TransactionGuid</code>	<code>GUID</code>	A GUID assigned to the transaction that can be used to identify the transaction in future requests, for example when invoking <code>TransactionStatus</code> or <code>TransactionData</code> . Every single call to the <code>SubmitData</code> method will be assigned one transaction GUID, irrespective of how many subjects or data points are uploaded.



### 2.3.5 Example call

```

<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API"
xmlns:vied1="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public">
  <soapenv:Header/>
  <soapenv:Body>
    <vied:SubmitData>
      <vied:token>71DD872555...BAD895B819</vied:token>
      <vied:odmXml><![CDATA[
<ODM>
  <ClinicalData MetadataVersionOID="12.0">
    <SubjectData SubjectKey="SE-AHU-006">
      <SiteRef LocationOID="AHU" />
      <StudyEventData StudyEventOID="V1">
        <FormData FormOID="$EVENT">
          <ItemGroupData ItemGroupOID="EventDateGroup">
            <ItemDataDate ItemOID="EventDate">2016-10-02</ItemDataDate>
          </ItemGroupData>
        </FormData>
        <FormData FormOID="VS" FormRepeatKey="V1">
          <ItemGroupData ItemGroupOID="VSG1">
            <ItemDataDatetime ItemOID="VSDT">2017-01-03T00:00</ItemDataDatetime>
            <ItemDataInteger ItemOID="VSYN">1</ItemDataInteger>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="VSG6">
            <ItemDataDouble ItemOID="VSDIA">75</ItemDataDouble>
            <ItemDataDouble ItemOID="VSSYS">120</ItemDataDouble>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="VSG9">
            <ItemDataDouble ItemOID="VSPULSE">80</ItemDataDouble>
          </ItemGroupData>
        </FormData>
      </StudyEventData>
    </SubjectData>
    <AuditRecords />
  </ClinicalData>
</ODM >
]]> </vied:odmXml>
      <vied:options>
        <vied:AllowCreatingSubjects>True</vied:AllowCreatingSubjects>
        <vied:AllowInitiatingStudyEvents>True</vied:AllowInitiatingStudyEvents>
      </vied:options>
    </vied:SubmitData>
  </soapenv:Body>
</soapenv:Envelope>

```

**Note!** To access the example call as a text that you can copy into your tool, click [here](#).

Number	Item	Description
1	MetadataVersionOID	[ Version ] . [ Revision ] of the metadata that will be used for the imported data
2	SubjectKey	Subject key in Viedoc for the subject that the data will be imported to
3	LocationOID	Study site ID, can be obtained from Viedoc Admin
4	StudyEventOID FormOID ItemOID	Event, form, or item Object Identifiers (OIDs), can be obtained from an exported metadata version or from Viedoc Designer  <b>Note!</b> If the StudyEvent repeats, a StudyEventRepeatKey should be given. For example: <StudyEventData StudyEventOID="AE" StudyEventRepeatKey="1">
5	ItemDataInteger	Allowed data value types are: <ul style="list-style-type: none"> <li>▪ ItemDataString</li> <li>▪ ItemDataInteger</li> <li>▪ ItemDataDouble</li> <li>▪ ItemDataDateTime *</li> <li>▪ ItemDataDate</li> <li>▪ ItemDataTime</li> </ul>

\* CRF variables that collect time data have no container for time zone in Viedoc. Data in such variables is typically regarded to represent time in the same time zone as where the study site is located. Thus, it is recommended to submit time data without the time zone information, for example 2020-01-29T08:34:00. If time zone is of interest, for example if a blood sample was analyzed in a lab located in a different time zone, an additional CRF variable can be

used to collect that information. When time zone information is submitted to Viedoc through the API (or the import application) as part of a data value, it will be factored into the data value. This is due to the fact that Viedoc has no place to store it. For example, 2000-01-01T00:00:00+01:00 (1 hour offset) will be converted to 1999-12-31T23:00:00Z (no offset) and will be visible in the CRF as 1999-12-31 23:00. For this reason, it is advisable to take care of any conversions required to get rid of time zone information before you submit time data to Viedoc.

### 2.3.6 Example response

```
<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <SubmitDataResponse xmlns="Viedoc.API">
      <SubmitDataResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>77D5F18B4D...81066FCCB3</a:Token>
        <a:Result>Pending</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:TransactionGuid>b9d315b1-adb7-4eb2-93d7-f43c682aec9a</a:TransactionGuid>
      </SubmitDataResult>
    </SubmitDataResponse>
  </s:Body>
</s:Envelope>
```

## 2.4 TransactionStatus

### 2.4.1 Description

The `TransactionStatus` method can be used to check the import status of previously submitted data.

### 2.4.2 C# Syntax

```
ApiResponseModel resultModel = TransactionStatus(string token, GUID transactionGUID);
```

### 2.4.3 Parameters

The `TransactionStatus` method has the following parameters:

Parameter	Data type	Description
token	string	Authentication token
transactionGUID	GUID	The transaction GUID obtained when invoking the <code>SubmitData</code> method

### 2.4.4 Returns

The `TransactionStatus` method returns an `ApiResponseModel` object that has the following properties:

Property	Data type	Description
Token	string	A new authentication token that can be used for authentication in subsequent requests
Result	ApiResponseType	Defines the type and status of the result returned from method invocation. See section <a href="#">3.2 ApiResponseType</a> for details.
ErrorCode	int	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
ErrorMessage	string	In case of an error result: human readable description of the error

#### 2.4.5 Example call

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API">
  <soapenv:Header/>
  <soapenv:Body>
    <vied:TransactionStatus>
      <vied:token>0D8D295A92...F019C59CE1</vied:token>
      <vied:transactionGuid>b9d315b1-adb7-4eb2-93d7-
f43c682aec9a</vied:transactionGuid>
    </vied:TransactionStatus>
  </soapenv:Body>
</soapenv:Envelope>
```

#### 2.4.6 Example response

```
<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <TransactionStatusResponse xmlns="Viedoc.API">
      <TransactionStatusResult
xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>910F3E7984...8F25E0B4C1C</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
      </TransactionStatusResult>
    </TransactionStatusResponse>
  </s:Body>
</s:Envelope>
```

## 2.5 TransactionData

### 2.5.1 Description

The `TransactionData` method can be used to obtain previously submitted data.

### 2.5.2 C# Syntax

```
ApiTransactionDataModel dataModel = TransactionData(string token, GUID transactionGUID);
```

### 2.5.3 Parameters

The `TransactionData` method has the following parameters:

Parameter	Data type	Description
token	string	Authentication token
transactionGUID	GUID	GUID obtained when invoking the <code>SubmitData</code> method

### 2.5.4 Returns

The `TransactionData` method returns an `ApiTransactionDataModel` object that has the following properties:

Property	Data type	Description
Token	string	A new authentication token that can be used for authentication in subsequent requests
Result	ApiResponseType	Defines the type and status of the result returned from method invocation. See section <a href="#">3.2 ApiResponseType</a> for details.
ErrorCode	int	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
ErrorMessage	string	In case of an error result: human readable description of the error
OdmXml	string	The uploaded data in <a href="#">ODM</a> format

### 2.5.5 Example call

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API">

  <soapenv:Header/>

  <soapenv:Body>

    <vied:TransactionData>

      <vied:token>0D8D295A92...F019C59CE1</vied:token>

      <vied:transactionGuid>b9d315b1-adb7-4eb2-93d7-
f43c682aec9a</vied:transactionGuid>

    </vied:TransactionData>

  </soapenv:Body>

</soapenv:Envelope>
```



```

<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <TransactionDataResponse xmlns="Viedoc.API">
      <TransactionDataResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>78EE476F86...C8235F79326</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:OdmXml><![CDATA[<ODM>
<ClinicalData MetaDataVersionOID="12.0">
<SubjectData SubjectKey="SE-AHU-006">
  <SiteRef LocationOID="AHU" />
  <StudyEventData StudyEventOID="V1">
    <FormData FormOID="$EVENT">
      <ItemGroupData ItemGroupOID="EventDateGroup">
        <ItemDataDate ItemOID="EventDate">2016-10-02</ItemDataDate>
      </ItemGroupData>
    </FormData>
    <FormData FormOID="VS" FormRepeatKey="V1">
      <ItemGroupData ItemGroupOID="VSG1">
        <ItemDataDateTime ItemOID="VSDT">2017-01-03T00:00</ItemDataDateTime>
        <ItemDataInteger ItemOID="VSYN">1</ItemDataInteger>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="VSG6">
        <ItemDataDouble ItemOID="VSDIA">75</ItemDataDouble>
        <ItemDataDouble ItemOID="VSSYS">120</ItemDataDouble>
      </ItemGroupData>
      <ItemGroupData ItemGroupOID="VSG9">
        <ItemDataDouble ItemOID="VSPULSE">80</ItemDataDouble>
      </ItemGroupData>
    </FormData>
  </StudyEventData>
</SubjectData>
<AuditRecords />

```

```

</ClinicalData> </ODM >]]></a:OdmXml>

    </TransactionDataResult>

</TransactionDataResponse>

</s:Body>

</s:Envelope>

```

## 2.6 GetMetaData

### 2.6.1 Description

The `GetMetaData` method can be used to get any study metadata version in [ODM](#) format.

### 2.6.2 C# Syntax

```

ApiGetMetaDataResultModel metaDataResultModel =
GetMetaData(string token, string metaDataOid, bool includeSdm, bool includeViedocExtensions)
;

```

### 2.6.3 Parameters

The `GetMetaData` method has the following parameters:

Parameter	Data type	Description
token	string	Authentication token
metaDataOid	string	Metadata <a href="#">OID</a> in the format: [Version].[Revision]. For example, 1.1 means version 1 and revision 1. The metadata OID can be obtained from Viedoc Admin or Designer.
includeSdm	bool	Defines whether Study Design Model (SDM) properties should be included in the exported metadata <a href="#">ODM</a> file. Can be set to true or false , default is set to false .
includeViedocExtensions	bool	Defines whether Viedoc-specific extension properties should be included in the exported metadata ODM file. Can be set to true or false , default is set to false .

### 2.6.4 Returns

The `GetMetaData` method returns an `ApiGetMetaDataResultModel` object that has the following properties:

Property	Data type	Description
Token	string	A new authentication token that can be used for authentication in subsequent requests
Result	ApiResponseType	Defines the type and status of the result returned from method invocation. See section <a href="#">3.2 ApiResponseType</a> for details.
ErrorCode	int	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
ErrorMessage	string	In case of an error result: human readable description of the error
OdmXml	string	<a href="#">ODM</a> including the requested metadata version in the study

## 2.6.5 Example call

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API">

  <soapenv:Header/>

  <soapenv:Body>

    <vied:GetMetaData>

      <vied:token>3C5C012B4A...4AA6982B94</vied:token>

      <vied:metaData0id>12.0</vied:metaData0id>

      <vied:includeSdm>true</vied:includeSdm>

      <vied:includeViedocExtensions>true</vied:includeViedocExtensions>

    </vied:GetMetaData>

  </soapenv:Body>

</soapenv:Envelope>
```

## 2.6.6 Example response



```

<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <GetMetaDataResponse xmlns="Viedoc.API">
      <GetMetaDataResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>65E6DF0A0B...26FDB77A85</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:OdmXml><![CDATA[<?xml version="1.0"?>
          <ODM xmlns:sdm="http://www.cdisc.org/ns/studydesign/v1.0"
            xmlns:v4="http://www.viedoc.net/ns/v4" SourceSystemVersion="4.32.6226.25712"
            SourceSystem="VIEDOC" Originator="PCG Solutions AB" ODMVersion="1.3" AsOfDateTime="2017-
            01-18T12:49:44.503Z" FileOID="" Granularity="Metadata" FileType="Snapshot"
            Description="Demo study 2016" CreationDateTime="2016-10-05T08:48:41"
            v4:ModifiedSystemVersion="4.32" xmlns="http://www.cdisc.org/ns/odm/v1.3">
            <Study OID="369cbf09-3322-43cc-b0ef-895be23bead0">
              <GlobalVariables>
                <StudyName>Demo study 2016</StudyName>
                <StudyDescription>An open-label, multi center, dose escalation study investigating
                the...</StudyDescription>
                ...
              </GlobalVariables>
              <BasicDefinitions>
                ...
              </BasicDefinitions>
              <MetaDataVersion OID="12.0" Name="1" Description="Demo study 2016">
                ...
              </MetaDataVersion>
            </Study>
          </ODM>]]>/a:OdmXml>
        </GetMetaDataResult>
      </GetMetaDataResponse>
    </s:Body>
  </s:Envelope>

```

## 2.7.1 Description

The `GetMetaDataVersionForKeySets` method can be used to get the study design version(s) (metadata version) for a set of data point(s).

## 2.7.2 C# Syntax

```
ApiGetMetaDataVersionsResultModel GetMetaDataVersionsForKeySets(string token,
List<ViedocKeySet> keySets)
```

## 2.7.3 Parameters

The `GetMetaDataVersionForKeySets` method has the following parameters:

Parameter	Data type	Description
token	string	Authentication token
keySets	List<ViedocKeySet>	Contains a list of keysets for which study design (metadata) version should be fetched. All the individual keys in a keyset are optional and the returned study design version will be based on all the keys specified. See section <a href="#">3.4 ViedocKeySet</a> .

## 2.7.4 Returns

The `GetMetaDataVersionForKeySets` method returns an `ApiGetMetaDataVersionsResultModel` object that has the following properties:

Property	Data type	Description
Token	string	A new authentication token that can be used for authentication in subsequent requests
Result	ApiResponseType	Defines the type and status of the result returned from method invocation. See section <a href="#">3.2 ApiResponseType</a> for details.
ErrorCode	int	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
ErrorMessage	string	In case of an error result: human readable description of the error
KeySets	List<ViedocKeySet>	<a href="#">ODM</a> including the requested metadata version in the study

## 2.7.5 Example HTTP call

```

<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API"
xmlns:vied1="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public">

  <soapenv:Header/>

  <soapenv:Body>

    <vied:GetMetaDataVersionsForKeySets>

      <vied:token>D188460837...6A04F67878</vied:token>

      <vied:keySets>

        <!--Zero or more repetitions:-->

        <vied1:ViedocKeySet>

          <vied1:uniqueId>1234</vied1:UniqueId>

          <vied1:SubjectKey>SE-AHU-006</vied1:SubjectKey>

          <vied1:CountryCode>SE</vied1:CountryCode>

          <vied1:SiteCode>AHU</vied1:SiteCode>

          <vied1:SiteNo>1</vied1:SiteNo>

          <vied1:StudySubjectSeqNo>006</vied1:StudySubjectSeqNo>

          <vied1:SiteSubjectSeqNo>006</vied1:SiteSubjectSeqNo>

          <vied1:StudyEventDefId>V1</vied1:StudyEventDefId>

          <vied1:FormDefId>VS</vied1:FormDefId>

          <vied1:ItemDefId></vied1:ItemDefId>

          <vied1:MetaDataVersionOID></vied1:MetaDataVersionOID>

        </vied1:ViedocKeySet>

      </vied:keySets>

    </vied:GetMetaDataVersionsForKeySets>

  </soapenv:Body>

</soapenv:Envelope>

```

## 2.7.6 Example response

```

<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <GetMetaDataVersionsForKeySetsResponse xmlns="Viedoc.API">
      <GetMetaDataVersionsForKeySetsResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>4E06BC9189...756CF1EA42</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:KeySet>
          <a:ViedocKeySet>
            <a:UniqueId>1234</a:UniqueId>
            <a:SubjectKey>SE-AHU-006</a:SubjectKey>
            <a:StudySiteId>13845</a:StudySiteId>
            <a:CountryCode>SE</a:CountryCode>
            <a:SiteCode>AHU</a:SiteCode>
            <a:SiteNo>1</a:SiteNo>
            <a:StudySubjectSeqNo>6</a:StudySubjectSeqNo>
            <a:SiteSubjectSeqNo>6</a:SiteSubjectSeqNo>
            <a:StudyEventDefId>V1</a:StudyEventDefId>
            <a:StudyEventRepeatKey i:nil="true"/>
            <a:EventDate>0001-01-01T00:00:00</a:EventDate>
            <a:FormDefId>VS</a:FormDefId>
            <a:FormRepeatKey i:nil="true"/>
            <a:ItemDefId i:nil="true"/>
            <a:MetaDataVersionOID>12.0</a:MetaDataVersionOID>
          </a:ViedocKeySet>
        </a:KeySet>
      </GetMetaDataVersionsForKeySetsResult>
    </GetMetaDataVersionsForKeySetsResponse>
  </s:Body>
</s:Envelope>

```

### 2.8.1 Description

The `GetClinicalStudySites` method returns information about the sites that a user has access to in Viedoc Clinic.

### 2.8.2 C# Syntax

```
ApiGetClinicalStudySitesResultModel GetClinicalStudySites(string token);
```

### 2.8.3 Parameters

The `GetClinicalStudySites` method has the following parameters:

Parameter	Data type	Description
token	string	Authentication token.

### 2.8.4 Returns

The `GetClinicalStudySites` method returns an `ApiStudySiteModel` object that has the following properties:

Property	Data type	Description
Country	string	The country name
CountryCode	string	Two-letter country code
ExpectedNumberOfSubjectsEnrolled	int	The expected number of enrolled subjects on site
ExpectedNumberOfSubjectsScreened	int	The expected number of screened subjects on site
MaximumNumberOfSubjectsScreened	int	The maximum number of screened subjects on site
Guid	string	Unique ID of the site
SiteCode	string	Site code as set in Admin
SiteName	string	Site name as set in Admin
SiteNumber	int	Site number
SiteType	string	Site type: Training or Production
TimeZone	string	The Windows time zone ID
TzOffset	int	The offset (in minutes) from UTC

### 2.8.5 Example HTTP call

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API">

  <soapenv:Header/>

  <soapenv:Body>

    <vied:GetClinicalStudySites>

      <vied:token>7C57A5F819...633211A5A2</vied:token>

    </vied:GetClinicalStudySites>

  </soapenv:Body>

</soapenv:Envelope>
```

#### 2.8.6 Example HTTP response

```
<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <Get ClinicalStudySitesResponse xmlns="Viedoc.API">
      <GetClinicalStudySitesResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>BDE...930</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:StudySites>
          <a:ApiStudySiteModel>
            <a:Country>United States</a:Country>
            <a:CountryCode>US</a:CountryCode>
            <a:ExpectedNumberOfSubjectsEnrolled>75</a:ExpectedNumberOfSubjectsEnrolled>
            <a:ExpectedNumberOfSubjectsScreened>100</a:ExpectedNumberOfSubjectsScreened>
            <a:Guid>c57ffd6c-c279-11e9-b974-78c880284afa</a:Guid>
            <a:MaximumNumberOfSubjectsScreened>120</a:MaximumNumberOfSubjectsScreened>
            <a:SiteCode>01</a:SiteCode>
            <a:SiteName>The Mayo Clinic</a:SiteName>
            <a:SiteNumber>1</a:SiteNumber>
            <a:SiteType>Training</a:SiteType>
            <a:TimeZone>Eastern Standard Time</a:TimeZone>
            <a:TzOffset>300</a:TzOffset>
          </a:ApiStudySiteModel>
          <a:ApiStudySiteModel>
            <a:Country>Singapore</a:Country>
            <a:CountryCode>SG</a:CountryCode>
            <a:ExpectedNumberOfSubjectsEnrolled>40</a:ExpectedNumberOfSubjectsEnrolled>
            <a:ExpectedNumberOfSubjectsScreened>50</a:ExpectedNumberOfSubjectsScreened>
            <a:Guid>c5800324-c279-11e9-b974-78c880284afa</a:Guid>
            <a:MaximumNumberOfSubjectsScreened>60</a:MaximumNumberOfSubjectsScreened>
            <a:SiteCode>02</a:SiteCode>
            <a:SiteName>Singapore General Hospital</a:SiteName>
            <a:SiteNumber>2</a:SiteNumber>
            <a:SiteType>Training</a:SiteType>
          </a:ApiStudySiteModel>
        </a:StudySites>
      </GetClinicalStudySitesResult>
    </Get ClinicalStudySitesResponse>
  </s:Body>
</s:Envelope>
```

```

        <a:TimeZone>Singapore Standard Time</a:TimeZone>

        <a:TzOffset>480</a:TzOffset>

    </a:ApiStudySiteModel>

</a:StudySites>

</GetClinicalStudySitesResult>

</GetClinicalStudySitesResponse>

</s:Body>

</s:Envelope>

```

## 2.9 GetClinicalData

### 2.9.1 Description

The `GetClinicalData` method can be used for exporting clinical data in [ODM](#) format.

### 2.9.2 C# Syntax

```

ApiGetClinicalDataResultModel GetClinicalData(string token, ApiGetClinicalDataRequestModel options);

```

### 2.9.3 Parameters

The `GetClinicalData` method has the following parameters:

Parameter	Data type	Description
token	string	Authentication token
options	ApiGetClinicalDataRequestModel	Options and filters for clinical data export. See section <a href="#">3.5 ApiGetClinicalDataRequestModel</a> .

### 2.9.4 Returns

The `GetClinicalData` method returns an `ApiGetClinicalDataResultModel` object that has the following properties:

Property	Data type	Description
Token	string	A new authentication token that can be used for authentication in subsequent requests
Result	ApiResponseType	Defines the type and status of the result returned from method invocation. An <code>ApiResponseType</code> enum with the value <code>Success</code> or <code>Error</code> is used.
ErrorCode	int	In case of an error result: contains an integer specifying the type of error. See section <a href="#">4 Error codes</a> for details.
ErrorMessage	string	In case of an error result: human readable description of the error
OdmXml	string	The exported data in <a href="#">ODM</a> format



## 2.9.5 Example HTTP call

**Note!** The order of the clauses is crucial. It is important to follow the order in the example code below.

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:vied="Viedoc.API"
xmlns:vied1="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public">

  <soapenv:Header/>

  <soapenv:Body>

    <vied:GetClinicalData>

      <vied:token>2BB747D2E2...B46846DE34</vied:token>

      <vied:options>

        <vied1:SiteCode>AHU</vied1:SiteCode>

        <vied1:SubjectFilter></vied1:SubjectFilter>

        <vied1:SubjectKey>SE-AHU-006</vied1:SubjectKey>

        <vied1:StudyEventOID>V1</vied1:StudyEventOID>

        <vied1:FormOID>VS</vied1:FormOID>

        <vied1:ItemOID>VSSYS</vied1:ItemOID>

        <vied1:ExcludeExtensions>>false</vied1:ExcludeExtensions>

        <vied1:IncludeAdminData>>true</vied1:IncludeAdminData>

        <vied1:IncludeVisitDates>>true</vied1:IncludeVisitDates>

        <vied1:IncludeQueries>>true</vied1:IncludeQueries>

        <vied1:IncludeReviewStatus>>true</vied1:IncludeReviewStatus>

        <vied1:IncludeSignatures>>true</vied1:IncludeSignatures>

        <vied1:IncludeMedicalCoding>>true</vied1:IncludeMedicalCoding>

        <vied1:IncludeSubjectStatus>>true</vied1:IncludeSubjectStatus>

      </vied:options>

    </vied:GetClinicalData>

  </soapenv:Body>

</soapenv:Envelope>
```

## 2.9.6 Example HTTP response

```
<s:Envelope xmlns:s="http://schemas.xmlsoap.org/soap/envelope/">
  <s:Body>
    <GetClinicalDataResponse xmlns="Viedoc.API">
      <GetClinicalDataResult
        xmlns:a="http://schemas.datacontract.org/2004/07/Viedoc.Services.Public"
        xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
        <a:Token>A53447308F...B9F6DB81BE</a:Token>
        <a:Result>Success</a:Result>
        <a:ErrorCode>0</a:ErrorCode>
        <a:ErrorMessage i:nil="true"/>
        <a:OdmXml><![CDATA[<?xml version="1.0"?>
          <ODM xmlns:sdm="http://www.cdisc.org/ns/studydesign/v1.0"
            xmlns:v4="http://www.viedoc.net/ns/v4" FileType="Snapshot" v4:ModifiedSystemVersion="4.32"
            xmlns="http://www.cdisc.org/ns/odm/v1.3">
            <Study OID="369cbf09-3322-43cc-b0ef-895be23bead0">
            ...
            </Study>
            <AdminData StudyOID="369cbf09-3322-43cc-b0ef-895be23bead0">
            ...
            </AdminData>
            <ClinicalData StudyOID="369cbf09-3322-43cc-b0ef-895be23bead0"
              MetaDataVersionOID="21.0">
              <SubjectData SubjectKey="SE-AHU-006" v4:StudySubjectSeqNo="10"
                v4:SiteSubjectSeqNo="6">
              ...
              </SubjectData>
              <AuditRecords>
              ...
              </AuditRecords>
            </ClinicalData>
          </ODM>]]></a:OdmXml>
        </GetClinicalDataResult>
      </GetClinicalDataResponse>
    </s:Body>
  </s:Envelope>
```

**Note!** GetClinicalData does not support StudyEventRepeatKey.

## 3 Complex Data Types

### 3.1 ApiAuthenticationModel

The `ApiAuthenticationModel` data type contains the following elements:

Property	Data type	Description
ClientGUID	GUID	Client ID linked to a specific study in Viedoc. Can be obtained from Viedoc Admin. Required.
UserName	string	Viedoc login username. Required.
Password	string	Matching Viedoc login password. Required.
TimeSpanInSeconds	int	Time (in seconds) that the authentication token will be valid for. Optional. Default is 300 seconds (5 min). Maximum is 1800 seconds (30 min).

### 3.2 ApiResultType

`ApiResultType` is an `enum` data type with one of the following values\*:

Pending	The request is being processed and no result yet.
Success	The request has completed successfully.
Error	The request terminated with an error. See error code and message for a description of the error that occurred.
InProgress	Data import has started and data is currently being processed.
PartialComplete	Data import has started but is in an idle state waiting for remaining subjects to be unlocked so that data import can resume.  Data import has started but a subject is not found due to invalid ID. The subject is not imported and the system continues to identify the next subject.

\*For `GetClinicalData`, only an `ApiResultType` `enum` data type with the value `Success` or `Error` is used.

### 3.3 ApiSubmitDataOptions

Property	Data type	Description
AllowCreatingSubjects	bool	Defines whether new subjects will be created during the data import when unmatched subjects are found. Can be set to <code>true</code> or <code>false</code> , default is set to <code>true</code> .
AllowInitiatingStudyEvents	bool	Defines whether uninitiated events will be initiated during the data import. Can be set to <code>true</code> or <code>false</code> , default is <code>true</code> .

### 3.4 ViedocKeySet

The `ViedocKeySet` data type contains the following properties:

Property	Data type	Description
Uniqueld	string	For internal use only. The value of this property will be ignored if populated in a request.
SubjectKey	string	Subject key of a subject in Viedoc
StudySiteId	int	Database ID of the study site
CountryCode	string	Two letter country code
SiteCode	string	Site code as set in Admin. Required.
SiteNo	int	Site number
StudySubjectSeqNo	int	Sequence number of a subject on a study level
SiteSubjectSeqNo	int	Sequence number of a subject on a site level
StudyEventDefId	string	Study event <a href="#">OID</a> as set in the study design
StudyEventRepeatKey	string	Study event repeat key
EventDate	DateTime	Event date in ISO8601 format
FormDefId	string	Form OID as set in the study design
FormRepeatKey	string	Form repeat key
ItemDefId	string	Item OID as set in the study design
MetaDataVersionOID	string	Study design OID (version) in the form [ VERSION ] . [ REVISION ]. Will be populated in the response based on the submitted values of all the previous keys.

### 3.5 ApiGetClinicalDataRequestModel

The `ApiGetClinicalDataRequestModel` data type contains the following properties:

Property	Data type	Description
SiteCode	string	Site code as set in Admin. Required.
SubjectFilter	string	Subject filter using any string. Optional.
SubjectKey	string	Subject key of a subject in Viedoc. Optional.
StudyEventOID	string	Study event <a href="#">OID</a> as set in the study design. Optional.
FormOID	string	Form OID as set in the study design. Optional.
ItemOID	string	Item OID as set in the study design. Optional.
TimePeriodDateType	ApiTimePeriodDateType	SystemDate EventDate. Optional.
TimePeriodOption	ApiTimePeriodOption	Until From Between. Optional.
FromDate	DateTime	Used to match data by entered or event date. Optional.

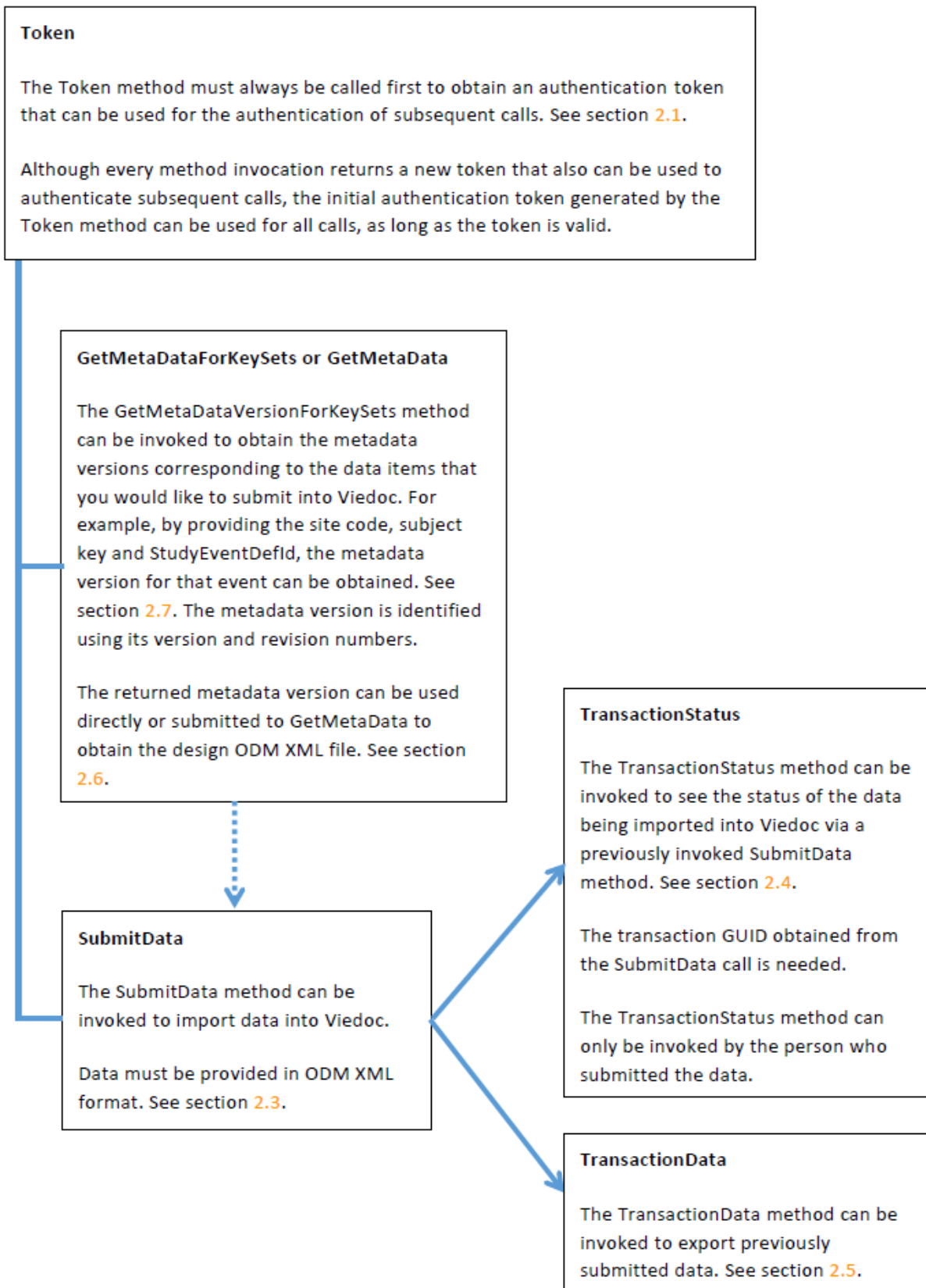
Property	Data type	Description
ToDate	DateTime	Used to match data by entered or event date. Optional.
ExcludeExtensions	bool	Defines whether to exclude the Study Design Model (SDM), Viedoc and audit trails. Can be set to true or false , default is set to false .
IncludeAdminData	bool	Defines whether to include user and study site data in the export. Can be set to true or false , default is set to false .
IncludeVisitDates	bool	Defines whether the event date form will be included in the export. The event date form includes the event date, planned date and the event window. Can be set to true or false , default is set to false .
IncludeQueries	bool	Defines whether queries will be included in the export. Can be set to true or false , default is set to false .
IncludeReviewStatus	bool	Defines whether review status will be included in the export. Can be set to true or false , default is set to false .
IncludeSignatures	bool	Defines whether signatures will be included in the export. Can be set to true or false , default is set to false .
IncludeMedicalCoding	bool	Defines whether medical coding will be included in the export. Can be set to true or false , default is set to false .
IncludeSubjectStatus	bool	Defines whether to include the subject status in the export. Can be set to true or false , default is set to false .
ViedocVersion	string	Defines which data structure version is used for the export. As of Viedoc release 4.39, the data structure version can be set to 4.38, 4.39 or Latest Viedoc Version. If nothing is specified, the Viedoc version set in the <a href="#">API</a> configuration settings in Viedoc Admin is used.

## 4 Error codes

The following table displays a list of error codes and their description.

Code	Message	Description
100	Invalid username or password	The provided username or password is invalid.
101	Invalid Client GUID	The provided client ID is invalid.
102	Invalid token	The token is invalid.
103	NOT USED	
104	Xml data is required	No <a href="#">ODM XML</a> data was included in the request.
105	NOT USED	
106	Invalid Client GUID/User	The provided token represents an invalid client GUID or an invalid user. This is very unlikely to occur when the token is generated from the system.
107	NOT USED	
108	NOT USED	
109	Unauthorized access, only user who submitted data can get transaction information	TransactionData and TransactionStatus can only be invoked by the user who submitted the data.
110		
111	Permission denied	The user does not have access to the specified resource.
112	Metadata version not found	The requested metadata version could not be found in the study.
114	User is SSO user	The domain is set up for single sign-on, and API login is not supported.
121	Invalid study site	
122	User does not have export permission to site	

## 5 A workflow example



## 6 An example of how to submit data into Viedoc

### 6.1 Introduction

This chapter serves as an example of how to submit data into Viedoc. It provides instructions on where in Viedoc you can obtain the following information:

- A client ID
- Study site ID and design version
- Element OIDs

- Item data types
- Subject ID

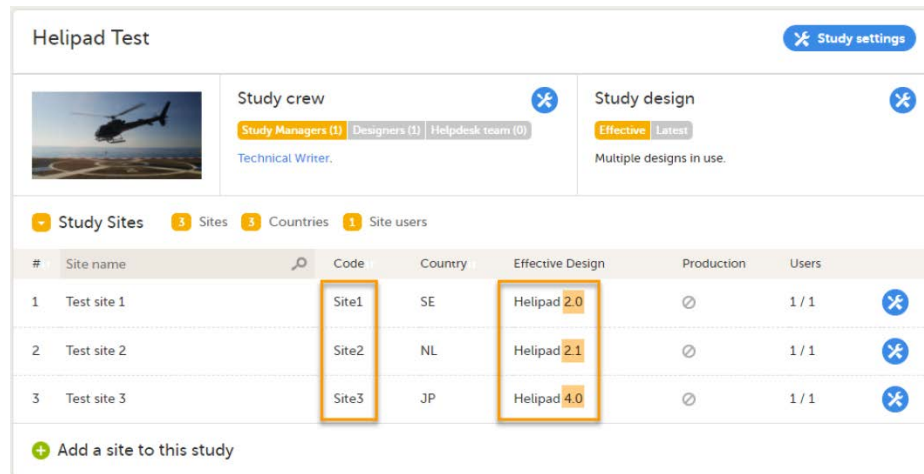
This chapter also provides instructions to construct the clinical data file using the obtained information.

## 6.2 Obtaining the client ID

See [API configuration](#).

## 6.3 Obtaining the study site code and design version

Note down the study site code and effective design version for the site or sites that data will be imported into. The study site code and effective design are displayed in the study sites list in Viedoc Admin. The effective design version is displayed in the form of [ VERSION ] . [ REVISION ] for each site separately.



#	Site name	Code	Country	Effective Design	Production	Users
1	Test site 1	Site1	SE	Helipad 2.0	⊗	1 / 1
2	Test site 2	Site2	NL	Helipad 2.1	⊗	1 / 1
3	Test site 3	Site3	JP	Helipad 4.0	⊗	1 / 1

## 6.4 Obtaining the element OIDs

Obtain the following [OIDs](#):

1. StudyEventOID
2. FormOID
3. ItemGroupOID
4. ItemOID

These OIDs can either be obtained from the study design in Viedoc Designer or by downloading the metadata version by invoking the `GetMetaData` [API](#) method.

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:tem="http://tempuri.org/">
  <soapenv:Header>
  <soapenv:Body>
    <tem:GetMetaData>
      <tem:token>FE4...171</tem:token>
      <tem:metaDataOid>8.0</tem:metaDataOid>
      <tem:includeSdm>true</tem:includeSdm>
      <tem:includeViedocExtensions>true</tem:includeViedocExtensions>
    </tem:GetMetaData>
  </soapenv:Body>
</soapenv:Envelope>
```



If you choose to download the metadata version by invoking the `GetMetaData` API method, search the returned [ODM](#) file for the following elements, and note down the OIDs:

- `StudyEventDef` (to obtain the `StudyEventOID` )

```
<StudyEventDef OID="VISIT1" Name="Visit 1" Repeating="No" Type="Scheduled">
  <Description>
    <TranslatedText xml:lang="en">The visit 1</TranslatedText>
  </Description>
  <FormRef FormOID="DM" Mandatory="No" />
  <FormRef FormOID="ALL" Mandatory="No" />
  <sdm:ActivityRef ActivityOID="ACT_VISIT1_START" />
  <sdm:ActivityRef ActivityOID="ACT_1" />
</StudyEventDef>
```

- `FormDef` (to obtain the `FormOID` )

```
<FormDef OID="DM" Name="Demographics" Repeating="No" Hidden="No" AutoUpdate="No"
Created="2014-11-14T09:10:57.5897684Z" LastModified="2014-12-15T14:53:52.0558249Z"
v411:Sdv="Required">
  <Description>
    <TranslatedText xml:lang="en" />
  </Description>
  <ItemGroupRef ItemGroupOID="DMG1" Mandatory="No" Role="" RoleHideShow="show">
    <v40:Layout Width="full" Spacing="wide" />
  </ItemGroupRef>
  <ItemGroupRef ItemGroupOID="DMG2" Mandatory="No" Role="" RoleHideShow="show">
    <v40:Layout Width="full" Spacing="wide" />
  </ItemGroupRef>
  <ItemGroupRef ItemGroupOID="DMG3" Mandatory="No" />
</FormDef>
```

- `ItemGroupDef` (to obtain the `ItemGroupOID` ) and `ItemRef` (to obtain the `ItemOID` )

```
<ItemGroupDef OID="DMG1" Repeating="No" Role="">
  <Description>
    <TranslatedText xml:lang="en" />
  </Description>
  <ItemRef ItemOID="SBP" Role="" Mandatory="Yes" RoleHideShow="show">
    <v40:Layout Orientation="horizontal" LabelPosition="top" />
  </ItemRef>
  <ItemRef ItemOID="DBP" Role="" Mandatory="Yes" RoleHideShow="show">
    <v40:Layout Orientation="horizontal" LabelPosition="top" />
  </ItemRef>
  <v40:Layout Width="full" Spacing="wide" />
</ItemGroupDef>
<ItemGroupDef OID="DMG2" Repeating="No" Role="">
  <Description>
    <TranslatedText xml:lang="en" />
  </Description>
  <ItemRef ItemOID="WEIGHTYN" Role="" Mandatory="Yes" RoleHideShow="show">
    <v40:Layout Orientation="horizontal" LabelPosition="top" />
  </ItemRef>
  <ItemRef ItemOID="WEIGHT" Role="" Mandatory="Yes"
CollectionExceptionConditionOID="COND_WEIGHT_DM" RoleHideShow="show">
    <v40:Layout Width="408" InputWidth="115" Orientation="horizontal"
LabelPosition="top" />
  </ItemRef>
  <v40:Layout Width="full" Spacing="wide" />
</ItemGroupDef>
<ItemGroupDef OID="DMG3" Repeating="No">
  <Description>
    <TranslatedText xml:lang="en" />
  </Description>
  <ItemRef ItemOID="EXPLAIN" Role="" Mandatory="Yes"
CollectionExceptionConditionOID="COND_EXPLAIN_DM" RoleHideShow="show">
    <v40:Layout Orientation="horizontal" LabelPosition="top" />
  </ItemRef>
</ItemGroupDef>
```

## 6.5 Obtaining the item data types

Obtain the item data types. The item data types can be obtained from Viedoc Designer or found in the `DataType` attribute of the `ItemDef` element in [ODM](#).

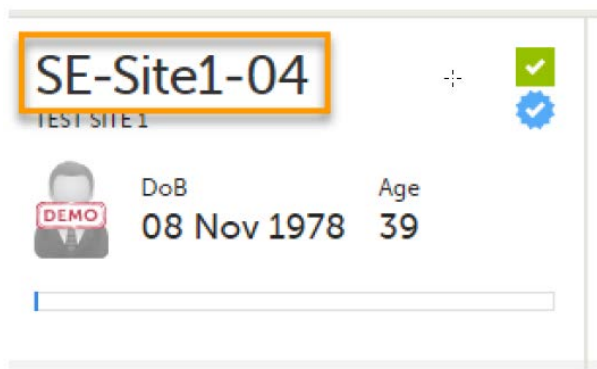
```
<ItemDef MinLength="1" DataType="text" Length="100" Name="" OID="EXPLAIN"
v411:Sdv="Undefined">
  <Description>
    <TranslatedText xml:lang="en" />
  </Description>
  <Question>
    <TranslatedText xml:lang="en">Diff is tooo big, explain</TranslatedText>
  </Question>
</ItemDef>
```

When constructing the `ClinicalData` elements, use the data element corresponding to the item data type.

ItemDef Data type	ItemData Data type
String	ItemDataString
Text	ItemDataString
Integer	ItemDataInteger
Double	ItemDataDouble
DateTime	ItemDataDateTime
Date	ItemDataDate
Time	ItemDataTime

## 6.6 Obtaining the subject key

The subject key is obtained from Viedoc Clinic.



It is also possible to match subjects using the `StudySubjectSeqNo` or the `StudySiteSubjectSeqNo`. These are the sequence number of the subject in a study and study site respectively.

When trying to match data for an imported subject with a subject in Viedoc, the `StudySubjectSeqNo` and `StudySiteSubjectSeqNo` are used first. They can both be specified as extension attributes on the `SubjectData` element in the [ODM](#) clinical data. If no matching subject is found using the `StudySubjectSeqNo` or `StudySiteSubjectSeqNo`, the subject key is used to find a matching subject.

If no matching subject could be found using either method, the following applies:

- If `AllowCreateSubjects` is set to `true`, a new subject is created.
- If `AllowCreateSubjects` is set to `false`, the subject is skipped.  
The `DataImportLog` is indicated as `PartialComplete` and shows which subject that does not exist.

When creating a new subject in Viedoc, the subject will receive the next available `StudySubjectSeqNo` and `StudySiteSubjectSeqNo`. These sequence numbers can be overridden in two different ways:

- By explicitly providing the subject sequence numbers as attributes.
- By including the subject sequence numbers in the subject key format, so that the subject sequence numbers can be extracted from the subject key. This requires the site code and site subject sequence number to be as specified in the Subject ID Generation Settings in the study design in Viedoc Designer.

## 6.7 Constructing the ODM XML ClinicalData file

```
<ODM FileOID="123" FileType="Snapshot">
  <ClinicalData MetaDataVersionOID="8.0">
    <SubjectData SubjectKey="SE-01-043">
      <SiteRef LocationOID="1"></SiteRef>
      <StudyEventData StudyEventOID="VISIT1">
        <FormData FormOID="DM" FormRepeatKey="">
          <ItemGroupData ItemGroupOID="DMG1">
            <ItemDataInteger ItemOID="SBP">160</ItemDataInteger>
            <ItemDataInteger ItemOID="DBP">100</ItemDataInteger>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="DMG2">
            <ItemDataInteger ItemOID="WEIGHTYN">2</ItemDataInteger>
            <ItemDataInteger ItemOID="WEIGHT">99</ItemDataInteger>
          </ItemGroupData>
          <ItemGroupData ItemGroupOID="DMG3">
            <ItemDataInteger ItemOID="EXPLAIN">This is just a
test</ItemDataInteger>
          </ItemGroupData>
        </FormData>
      </StudyEventData>
    </SubjectData>
  </ClinicalData>
</ODM>
```

**Note** To access the example ODM XML ClinicalData file as a text that you can copy into your tool, click [here](#).

All text highlighted in yellow should be replaced with the MetaData version [OID](#), Studysite OID, and Item OIDs obtained as previously described.

All text highlighted in green should be replaced with the values for the respective items.

The ClinicalData ODM can then be submitted using the `SubmitData` method as described earlier, see section [2.3 SubmitData](#).



Importing data from ODM file

# Importing data from ODM file

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## 1. Introduction

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## 2. Importing an ODM file

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---

# 1 Introduction

## 1.1 About ODM import to Viedoc

Viedoc supports the import of data using the Clinical Data Interchange Standards Consortium ([CDISC](#)) Operational Data Model ([ODM](#)) Extensible Markup Language ([XML](#)) standard format, making it possible to migrate data from other Electronic Data Capture ([EDC](#)) systems to Viedoc.

ODM is a vendor-neutral, platform-independent format for exchanging and archiving clinical study data. ODM includes all information (clinical data, along with its associated metadata, administrative data, reference data, and audit information) necessary to share data among different software systems during study setup, operation, analysis, and submission. ODM also includes all information for long-term retention as part of an archive to facilitate the regulatory-compliant acquisition, archival and exchange of metadata and data. For more information see <https://www.cdisc.org/standards/data-exchange/odm>.

In Viedoc Admin, you can import data from another EDC system (including Viedoc 3) using the ODM standard format to Viedoc by uploading an ODM XML file. Viedoc supports data import:

- As per standard CDISC ODM format, or
- Using an ODM file that contains Viedoc extensions (for example, previously exported from Viedoc, see [Exporting data](#)). The Viedoc extensions are always prefixed with " **v4:** ".

## 1.2 Good to know before starting an import

### Important!

- Please note that functions are re-executed after the import, which can cause issues when functions use current date/time, that is, existing event date(s) might change as a result of re-executing the functions based on current date/time.
- Forms that utilize the Viedoc randomization service are not recommended to be imported.

## 1.3 Limitations of the ODM import

The following data is not included in the [ODM](#) import:

- Medical coding
- Queries
- Review status
- Clinical data history (only snapshot is supported)

## 1.4 How are data mapped during the import of an ODM file?

### 1.4.1 Import of study sites

The system performs an automatic mapping based on site Name (not case-sensitive). If the Code extension is present (for example if the [ODM](#) file originates from Viedoc), this is mapped as well. If this is empty, only the Name is used.

```
<Location OID="LOC.163" Name="Karolinska University Hospital" LocationType="Site" v4:TimeZone="W. Europe Standard Time" v4:Code="01" v4:StudySiteSeqNo="1">
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="2.0" EffectiveDate="2014-03-01" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="26.0" EffectiveDate="2016-01-01" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="8.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="3.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="4.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="11.0" EffectiveDate="2014-12-01" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1fd5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="5.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
</Location>
```

If `v4:TimeZone` is present in the ODM file, this will be used during the import. If this is not present, the UTC time zone will be used.

If `v4:StudySiteSeqNo` is present in the ODM file, this will be used during the import. If this is not present, it will be assigned the following value: the maximum `v4:StudySiteSeqNo` + 1.

If `<v4:Address>` and `<Country>` are present in the ODM file, these will be used during the import, otherwise the default will be "SE" (Sweden).

### 1.4.2 Import of users

The users are imported by full name and email address.

**Note!** The users are not active immediately after the import is performed. They are only imported to the system. You have to send invitations to these users using the imported email addresses in order for them to get login access to Viedoc.

```
<User OID="USR.294">
  <LoginName>john.johansson@gmail.com</LoginName>
  <DisplayName>John Johansson</DisplayName>
  <FullName>John Johansson</FullName>
  <Email>john.johansson@gmail.com</Email>
  <LocationRef LocationOID="LOC.6956">
    <v4:RolesRef RoleOID="RG5515" IsDeleted="false" AssignedDateTime="2016-10-04T09:11:56Z" />
    <v4:RolesRef RoleOID="RG5516" IsDeleted="false" AssignedDateTime="2016-10-04T09:11:56Z" />
    <v4:RolesRef RoleOID="RG5518" IsDeleted="false" AssignedDateTime="2016-10-04T09:11:56Z" />
    <v4:RolesRef RoleOID="RG5519" IsDeleted="false" AssignedDateTime="2016-10-04T09:11:57Z" />
    <v4:RolesRef RoleOID="R8" IsDeleted="true" AssignedDateTime="2016-11-17T12:57:51Z" DeletedDateTime="2016-11-23T13:11:24Z" />
    <v4:RolesRef RoleOID="R8" IsDeleted="true" AssignedDateTime="2016-11-17T12:57:51Z" DeletedDateTime="2016-11-23T13:11:24Z" />
    <v4:RolesRef RoleOID="RG5515" IsDeleted="false" AssignedDateTime="2016-11-23T13:41:20Z" />
    <v4:RolesRef RoleOID="RG5518" IsDeleted="false" AssignedDateTime="2016-11-24T10:00:23Z" />
    <v4:RolesRef RoleOID="R8" IsDeleted="false" AssignedDateTime="2016-12-02T10:02:16Z" />
  </LocationRef>
  <LocationRef LocationOID="LOC.6957">
</User>
```

The element `LocationRef` allows specifying which sites a user is invited to.

The element `v4:RolesRef` is a Viedoc extension that allows specifying which roles the respective user has for a specific site, as well as the date when the role was assigned/deleted.

### 1.4.3 Import of subjects

When importing an [ODM](#) file to an existing study with existing data, the first step is to assign the subject to a site. This is done by using the subject's `SiteRef` information in the ODM file:

```
<SubjectData SubjectKey="DE-CUB-001" v4:StudySubjectSeqNo="6" v4:SiteSubjectSeqNo="1">
  <AuditRecord>
    <SiteRef LocationOID="LOC.6959" />
    <StudyEventData StudyEventOID="SCR" v4:EventDate="2016-10-04T15:05:52">
  </SubjectData>
```

All the sites in the ODM file to be imported ( LocationOID s) are mapped to existing site(s) or new one(s), as described at [Step 2/5](#), prior to the subjects mapping.

A subject is identified in the ODM file by the SubjectKey attribute, which is a standard ODM parameter (string) and it corresponds in Viedoc to the Subject ID that is generated in Viedoc according to the [Subject Id Generation Settings](#).

```
<SubjectData SubjectKey="SE-AHU-001">
```

#### 1.4.3.1 Mapping to existing subjects by SubjectKey

The subject mapping is performed using the SubjectKey .

1. The system checks if any of the existing subjects in Viedoc, within the specified site, has the Subject ID identical with the provided SubjectKey , and:
  - If a match is found, then the data is imported to the existing subject.
  - If no match is found then a new subject is created within the specified site and the data is imported to it.
2. After the data is imported, the Subject ID is generated according to the [Subject Id Generation Settings](#) and using the newly imported data.

When a new subject is created in Viedoc, there are two behind-the-scenes system items created for it:

```
<SubjectData SubjectKey="SE-01-001" v4:StudySubjectSeqNo="2" v4:SiteSubjectSeqNo="1">
```

- v4:StudySubjectSeqNo is a sequence number of subjects on study level. If a subject is the second subject in the study, this item is 2.
- v4:SiteSubjectSeqNo is a sequence number of subjects on site level. So if the same subject is the first subject on the site, this item is 1.

These two system items (Viedoc extensions) are used for various purposes, of which the Subject ID is the most important, see [Subject Id Generation Settings](#). For a newly created subject, these sequence numbers can be:

- either parsed from the provided SubjectKey , if they are being used in the [Subject Id Generation Settings](#) for the study the data is imported to, or otherwise
- allocated the next available sequence numbers within the study ( v4:StudySubjectSeqNo ) and site ( v4:SiteSubjectSeqNo ) respectively.

#### Notes!

- If the [ODM](#) file to be imported originates from Viedoc and it was exported including the Viedoc extensions, these sequence numbers are included in the ODM file.
- If any of the v4:StudySubjectSeqNo or v4:SiteSubjectSeqNo is either provided in the ODM file to be imported or mapped during the import process (at [Step 3/5](#) described later on), these are used to perform the subject mapping, see [Mapping to existing subjects by StudySubjectSeqNo and/or SiteSubjectSeqNo](#) below.

#### 1.4.3.2 Mapping to existing subjects by v4:StudySubjectSeqNo and/or v4:SiteSubjectSeqNo

These two system items (Viedoc extensions) are used for various purposes, of which the Subject ID is the most important, see [Subject Id Generation Settings](#).

If any of these sequence numbers is provided in the [ODM](#) file as Viedoc extension, or if they are mapped during the import process (see [Step 3/5](#) below), the subject mapping is performed as follows:

- If any of the sequence numbers is provided, these are used to perform the matching, first by the v4:SiteSubjectSeqNo and then by v4:StudySubjectSeqNo .
- If the sequence numbers are provided, but no match is found, then the SubjectKey is used for mapping, as described above in [Mapping to existing subjects by SubjectKey](#).

**Note!** If the sequence numbers for these items are present in the ODM file, but they are also mapped during the import process (see [Step 3/5](#) below), then the mapping takes precedence.

## 1.5 Workflow

Before you start importing the [ODM](#) file, you have to make sure that you already have a study in Viedoc that has a study design that matches the data structure in the ODM file to be imported. The metadata version(s) in the ODM file to be imported must contain all the events, forms, item groups, items and code list values that are referenced by *ClinicalData*. The import process performs the matching only by using [OIDs](#).

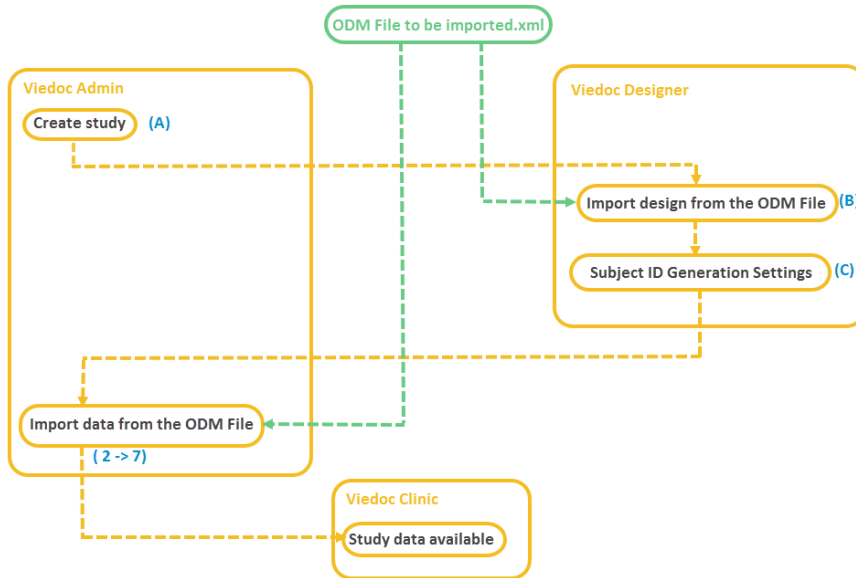
In case you do not have such a study yet, you can create a study and perform the ODM import as described below:

A. Create a study in Viedoc Admin (for instructions see [Adding new study](#)) and invite a user as Study Designer. This user will get access to Viedoc Designer.

B. In Viedoc Designer, import the design from the ODM file to the study you have just created in Viedoc Admin (for instructions see [Initiating a design](#)).

C. In Viedoc Designer, open the study with the newly imported study design, go to **Study Settings** and configure the **Subject ID Generation Settings** (for instructions see [Subject Id Generation Settings](#)). This will impact the selection you have to make later on during the import in [Step 3/5](#).

**Note!** Step C does not have to be performed if the ODM file has been exported from Viedoc 4 including extensions.



## 2 Importing an ODM file

This section provides a step by step guide for importing an [ODM](#) file.

### 2.1 Step 1/5 - uploading the ODM file

In Viedoc Admin, go to the study into which the data should be imported. Click **Study Settings**. The Study settings pop-up opens.

Study settings  
Here you can set settings for study.

Settings | Date & time format | Medical Coding | **Import ODM File** | API configuration

Import ODM File Step 1/5

[Upload a file](#)

- DEMO\_123\_20170503\_090338.xml 0.3MB

Import to demo

[Upload and continue](#)

History

File Name	Date and Time	User Name	Status	Log
-----------	---------------	-----------	--------	-----

On the **Import ODM File** tab, click **Upload a file**, and browse to the [ODM](#) file you would like to import. The file name and size will appear right under the **Upload a file** button.

If you would like to import the ODM file to a demo version of the study, select the **Import to demo** checkbox.

In case you receive an error message saying that the file cannot be uploaded due to missing content (according to the [CDISC ODM standard](#)), you have to go back to your ODM file, fix the error and upload the file again.

Click **Upload and continue**. This takes you to step 2/5.

## 2.2 Step 2/5 - mapping the study sites

In the **Metadata version to study design version mappings** field, two columns are displayed. **Metadata version OID (from xml)** lists all the versions found in the [ODM](#) file you have uploaded. In the **Study design version** select the study design version in Viedoc that the data should be imported into. The design has to match exactly your ODM data to be imported.

In the **Study site mappings** field, three columns are displayed. Column **1** and **2** (see image) represent all the sites found in the ODM file you have uploaded. Column **3** represents the sites available in the study you have selected to import into. The system performs an automatic mapping based on site name (not case sensitive). If the *code* extension is present (if the ODM file originates from Viedoc), this is mapped as well. If the *code* extension is empty, only the name is mapped. If no match is found, the system will map to "Create new site" as a default.

Study settings  
Here you can set settings for study.

Settings Date & time format Medical Coding **Import ODM File** API configuration

Import ODM File Step 2/5

DEMO\_123\_20170503\_090338.xml - Source system: VIEDOC 4.34.6310.23264 - Subjects: 4

Metadata version to study design version mappings

Metadata version OID (from xml) Study design version

1.0 Demo study 2014 2.0

Study site mappings

1 LOC.2815 2 Uppsala 3 Uppsala (01)

E-mail address to be used for invented audit records

test@uppsala.com

Continue ➔

Check whether the automatic mapping performed by the system is correct. If necessary, manually perform the mapping by selecting a site from the drop-down list.

**Note!** If a match is found but you anyway select **Create new site** from the drop-down list, a duplicate site will be created. This is not recommended!

**Note!** Make sure that every *Location* in the ODM file to be imported has at least one *MetaDataTypeRef* defined, otherwise no design version will be assigned to the respective site.

In the **Email address to be used for invented audit records** field, enter an email address that can be used when the import needs to create audit records.

Click **Continue**. This takes you to step 3/5.

## 2.3 Step 3/5 - mapping the study event dates

Under **Study event dates**, select what date items you want to be matched to your events. If no selection is made and a form and item combination within the event called *\$EVENT.EventDate* is found (the way Viedoc stores event dates), this will be used. If the [ODM](#) file originates from Viedoc 4, and has been exported including extensions, you will find this form/item combination in the drop-down list.



## Study settings

Here you can set settings for study.

The settings to be performed under **Populate** depend on whether the ODM file to be imported originates from Viedoc and thus has the *SiteSubjectSeqNo* and/or *StudySubjectSeqNo* extensions, or not. See also [Import of subjects](#).

- If the ODM file has the *SiteSubjectSeqNo* and/or *StudySubjectSeqNo* extensions, then no settings are required at this step. These items will be imported automatically. You can continue to Step 4/5.
- If the ODM file does not have the *SiteSubjectSeqNo* and/or *StudySubjectSeqNo* extensions, the settings to be made depend on how the **Subject ID Generation Settings** are configured in Designer (see [Workflow](#)).
  - If you have used one of the *SiteSubjectSeqNo* or *StudySubjectSeqNo* items, select this item from the first **Populate** drop-down list (1 in the image), and then select the form this item will be picked from in the **(Form/Item)** drop-down list (3 in the image). If the item you selected occurs multiple times for a single subject, you can select whether the first or last occurrence should be used in the second **Populate** drop-down list (2 in the image, default is *First*).
  - If you have used a different variable than the *SiteSubjectSeqNo* and *StudySubjectSeqNo*, then you don't need to make any selection in the **Populate** fields.

**Note!** Once you have selected an option from the drop-down list, it is not possible to clear the selection and return to the default (--- or no selection). It is only possible to select another option from the drop-down list.

Click **Continue**. This takes you to step 4/5.

### 2.4 Step 4/5 - selecting events and forms to be excluded

In the **Select events to be excluded** field, click and select from the drop-down list the events that you do not want to be included in the imported study. If you want to exclude multiple events, click and select again.

In the **Select forms to be excluded** field, click and select from the drop-down list the forms that you do not want to be included in the imported study. If you want to exclude multiple forms, click and select again.

**Important!** When importing an [ODM](#) file that was exported from Viedoc 4, you must exclude the *\$EVENT* form.

## Study settings

Here you can set settings for study.

Settings   Date & time format   Medical Coding   **Import ODM File**   API configuration

**Import ODM File** Step 4/5

DEMO\_123\_20170503\_090338.xml - Source system: VIEDOC 4.34.6310.23264 - Subjects: 4

Select events to be excluded

Select forms to be excluded

- Physical Examination(PE)
- Vital Signs(VS)
- Study status(SS)
- Visit status(STAT)
- Demographics(DM)
- Home administration(HA)
- Check Questions(CQ)**
- Eligibility(IE)
- Safety Laboratory Parameters(LB)

Continue +

Click **Continue**. This takes you to step 5/5.

## 2.5 Step 5/5 - confirming the import

In the **Users** field, a list of the imported users identified by email address and full name is displayed. In the **Confirm import with your password** field, enter your password to confirm the list of users to be added to your study, and click **Import**.

**Note!** The users are not active immediately after the import is performed. They are only imported to the system. You have to send invitations to these users using the imported email addresses in order for them to get login access to Viedoc. For instructions see [Managing users](#).

## Study settings

Here you can set settings for study.

Settings   Date & time format   Medical Coding   **Import ODM File**   API configuration

**Import ODM File** Step 5/5

DEMO\_123\_20170503\_090338.xml - Source system: VIEDOC 4.34.6310.23264 - Subjects: 4

**Users**

E-mail address	Full name
id@viedoc.com	Michael Pease
id@viedoc.com	Spencer

Confirm import with your password

..... Import

Back

## 2.6 After the import

Once you have imported the file and invited the users, your study is available in Viedoc and accessible for the users you have invited.

The PDFs with form history are not immediately available after the import. They will be generated and become available in Viedoc after you have performed an export to PDF in Viedoc Clinic. For instructions, see [Exporting data](#).

All the functions are re-executed after the import.



API configuration

# API configuration

Published by Viedoc System 2023-10-09

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[1. Accessing the API configuration feature](#)

[2. The API client ID](#)

[3. Adding a Viedoc WCF API client and obtaining the API client ID](#)

[4. Adding a Viedoc Web API client and obtaining the API client ID](#)

[5. About the data structure version of the API client ID](#)

## 1 Accessing the API configuration feature

To access the API configuration feature and to manage API clients for a study in Viedoc Admin, you need to have the user role API Manager for the study.

## 2 The API client ID

An API client ID is needed when using the API to connect to and interact with any API endpoint related to your Viedoc study.

The client ID is used as follows:

- For the Viedoc WCF API, the client ID is used together with the Viedoc user name and the password for authorizing the user.
- For the Viedoc Web API, the client ID and the client secret are used for authorization. No user context is needed.

To ensure backward compatibility with previous Viedoc versions, you can select which data structure version should be used when creating an API client ID.

## 3 Adding a Viedoc WCF API client and obtaining the API client ID

To add an API client and to obtain a client ID:

- 1 On the Viedoc landing page, click on the **Admin** icon to open Viedoc Admin.

- 2 Open the study that you would like to work with and click the **Edit** button in the API configuration field to open the **API configuration** dialog.

The screenshot shows the Viedoc Admin interface. At the top, there's a navigation bar with 'Viedoc Admin' and a settings icon. Below it, there are tabs for 'Studies' and 'Users'. The main content area displays study details for 'Ongoing, FPA 2020-08-19'. It includes a 'Study settings' button, 'Medical coding', 'eTMF', and 'API configuration' sections. The 'API configuration' section is highlighted with a yellow box, showing an 'Edit' button. Below this, there are sections for 'Study crew' and 'Study design'. At the bottom, there's a 'Study Sites' section with a table of sites.

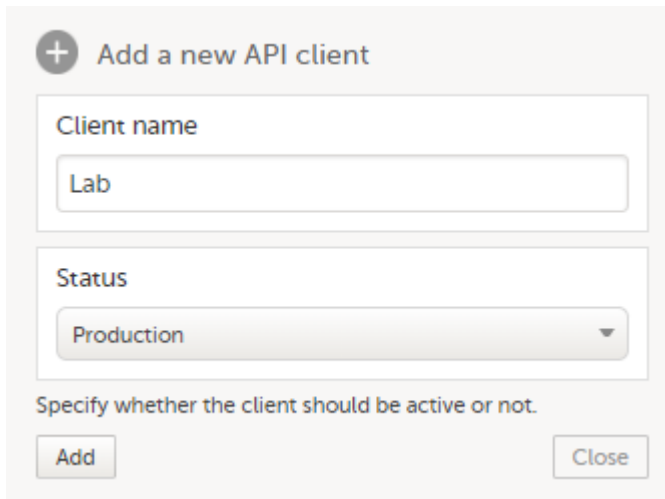
#	Site name	Code	Country	Effective Design	Production	Users
1	newsite1	s1	NO	Anonymous 4.0	✓	1 / 2
2	newsite2	s2	NO	Anonymous 4.0	✓	1 / 2

**Note!** You must have the API Manager user role to see the **API configuration** field.

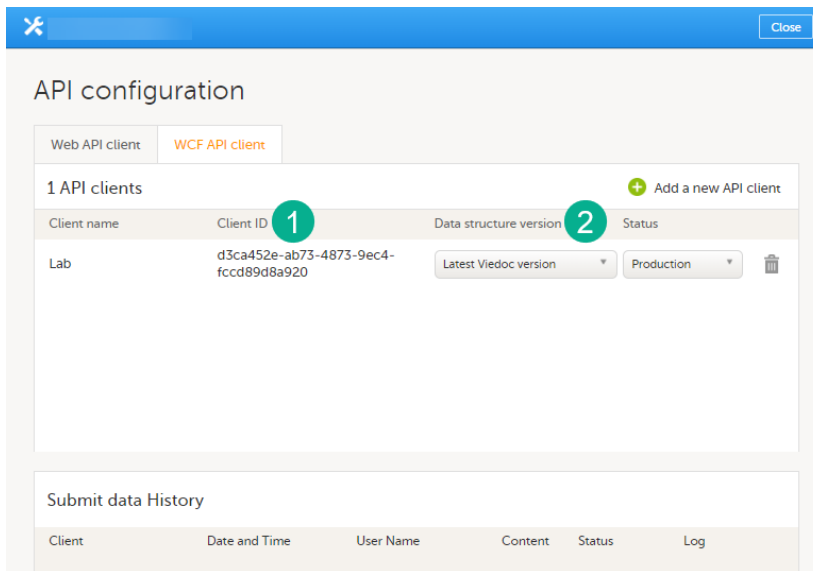
- 3 On the tab **WCF API client**, click on **Add a new API client**.

The screenshot shows the 'API configuration' dialog box. It has a title bar 'Helipad Test' and a 'Close' button. The main content area is titled 'API configuration' and has two tabs: 'Web API client' and 'WCF API client'. The 'WCF API client' tab is selected. Below the tabs, it says '0 API clients' and has an 'Add a new API client' button highlighted with a yellow box. Below this is a table with columns: 'Client name', 'Client ID', 'Data structure version', and 'Status'. At the bottom, there's a 'Submit data History' section with a table with columns: 'Client', 'Date and Time', 'User Name', 'Content', 'Status', and 'Log'.

- 4 Enter a name for the API client and select whether the client should be linked to a production or demo study in the **Status** dropdown menu. Click **Add**.



- 5 A client ID is generated and appears in the list of WCF API clients (1).



- 6 Select which data structure version you want the data structure to be compatible with from the **Data structure version** dropdown menu (2). You can edit the status of a client at any time by selecting a new status (**Production**, **Inactive**, or **Demo**) from the **Status** dropdown menu.

For more information about the versions, see [About the data structure version of API client ID](#).

- 7 Note down the client ID to be used later.

---

## 4 Adding a Viedoc Web API client and obtaining the API client ID

To add a Viedoc Web API client and to obtain the API client ID:

- 1 On the Viedoc landing page, click on the **Admin** icon to open Viedoc Admin.

- 2 Open the study that you would like to work with and click the **Edit** button in the API configuration field to open the **API configuration** dialog.

The screenshot shows the Viedoc Admin interface. At the top, there is a navigation bar with 'Viedoc Admin' and a settings icon. Below it, there are tabs for 'Studies' and 'Users'. The main content area displays various study settings and configurations. A yellow box highlights the 'API configuration' field, which includes an 'Edit' button (represented by a blue 'X' icon). Other visible fields include 'Study settings', 'Medical coding', 'eTMF', 'Study crew', and 'Study design'. At the bottom, there is a table for 'Study Sites' with columns for '#', 'Site name', 'Code', 'Country', 'Effective Design', 'Production', and 'Users'. The table contains two rows of data for 'newsite1' and 'newsite2'.

#	Site name	Code	Country	Effective Design	Production	Users
1	newsite1	s1	NO	Anonymous 4.0	✓	1 / 2
2	newsite2	s2	NO	Anonymous 4.0	✓	1 / 2

**Note!** You must have the API Manager user role to see the **API configuration** field.

- 3 On the tab **Web API client**, click on **Add a new Web API client**.

The screenshot shows the 'API configuration' dialog. At the top, there is a blue header bar with a close button and a 'Close' button. Below it, there are two tabs: 'Web API client' (selected) and 'WCF API client'. The main content area displays '0 Web API client(s)' and a yellow box highlights the '+ Add a new Web API client' button. Below this, there is a table with columns for 'Client name', 'Client ID', 'Data structure version', and 'Status'. The table is currently empty.

4 Enter a name for the API client.

The screenshot shows a web form titled "Add Web API client". It contains the following fields and controls:

- Client name:** A text input field containing "abc".
- Data structure version:** A dropdown menu with "Latest Viedoc version" selected.
- Status:** A dropdown menu with "Production" selected.
- Scopes:** A list of seven scopes, each with a folder icon and a close button (X):
  - Export
  - Create/update site
  - Get site information
  - Invite Clinic user
  - Invite Admin user
  - Get User information
  - Manage contract
- IP address(es):** A text input field containing "123.456.789; 123.456.987".
- Client secret expiry date (UTC):** A date picker showing "28 Oct 2023".
- Buttons:** "Add API client" and "Close" are located at the bottom of the form.

5 Select which data structure version you want the data structure to be compatible with.

6 Select whether the client should be linked to a production or a demo study in the **Status** dropdown menu. You can edit the status of a client at any time by selecting a new status (**Production**, **Inactive**, or **Demo**) from the **Status** dropdown menu.

**Note!** If you are configuring your API for a PMS study, you can select the **Data controller** dropdown to choose **Sponsor side** or **Clinic side** to narrow the scope.

7 Select the applicable scopes for a user. The available scopes are:

- **Export**
- **Create/update site**
- **Get site information**
- **Invite Clinic user** - requires the client **Status** to be **Production**
- **Invite Admin user** - requires the client **Status** to be **Production**
- **Manage contract**
- **Get User information**

8 Optionally, enter the IP addresses from which requests to the Web API endpoints are permitted. You can add a semi-colon separated list of multiple IP addresses.


9 The client secret expiry date is set to one year ahead by default. If needed, you can set another date, but it cannot be more than one year after the current date.

10 Click on **Add API client**.

11 When the API client has been added, the following fields are displayed:

- **Client secret** - **Tip!** Make sure you copy it, because it is shown only once. If needed, you can regenerate it.
- **Client ID**
- **Token URL**
- **Grant type**
- **API URL**



 Edit Web API client


Client name

Data structure version



Status

Scopes

IP address(es)

Client secret  
 

*Make sure you copy the client secret. It is shown only once. If needed, you can regenerate it.*

Client secret expiry date (UTC)   
 

Client ID

Token URL

grant\_type

API URL

**Delete client**

- 12 Note down the client ID to be used later.
- 13 If needed, you can change the settings for the scopes, the status, and the data structure version.
- 14 Click on **Save changes**.

## 5 About the data structure version of the API client ID

When creating an [API](#) client ID, you need to select which data structure version you would like to use. The Viedoc versions you can select are only those versions in which changes to the data structure were introduced.

As of Viedoc 4.77, the following data structure versions are available:

Data structure version	Changes in data structure
Latest Viedoc version	When selecting Latest Viedoc version, the data structure through which the Viedoc API communicates will automatically follow the structure of the latest Viedoc release in which changes to the data structure were introduced.
Viedoc 4.77	For studies where item-level SDV is enabled, when exporting review status, the SDV sheet in the CSV and Excel data exports will include only the items that require SDV and are visible to the user. On the Review status sheet, items that do not require SDV are indicated with N/A.
Viedoc 4.68	Introduction of PDF archive export system check which splits the archive into one PDF file per subject and stores the resultant PDF in a zip file.
Viedoc 4.67	Introduction of two new columns for approving medical coding: "approved by" and "approved on date".
Viedoc 4.51	Introduction of three new form repeat keys and the table of contents in the pdf export, see the table below for details.
Viedoc 4.39	Introduction of repeating forms and recurring events. See the table below for details.
Viedoc 4.38	Original output format (Viedoc versions 4.38 or older).

In [Viedoc 4.51](#), the following changes to the export output were introduced:

File type	Changes in the export output format
Excel	Addition of three columns for the new form sequence numbers introduced: <ul style="list-style-type: none"><li>▪ <code>SubjectFormSeqNo</code> - Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and is incremented each time a new instance of the form is created for that subject.</li><li>▪ <code>OriginSubjectFormSeqNo</code> - For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the <code>SubjectFormSeqNo</code>.</li><li>▪ <code>SourceSubjectFormSeqNo</code> - For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the <code>SubjectFormSeqNo</code> from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty.</li></ul>
ODM	Three new form sequence numbers were introduced, as Viedoc extensions: <code>v4:SubjectFormSeqNo</code> , <code>v4:OriginSubjectFormSeqNo</code> , and <code>v4:SourceSubjectFormSeqNo</code> , within the <code>FormData</code> , right after the <code>FormRepeatKey</code> .
PDF	A table of contents was added to the PDF archive, starting on page 2 of the file.

In [Viedoc 4.39](#), the following changes to the export output format were introduced:

File type	Changes in the export output format
Excel	Addition of a column for Form sequence number (FormSeq) that contains the FormRepeatKey .
ODM	The FormRepeatKey now contains the activity ID as well, in the following format: FormRepeatKey\$ActivityId . The ExportVersion attribute has been added to the ODM.
PDF	The summary formats are used to display the event and form names.



Viedoc Web API

# Viedoc Web API

Published by Viedoc System 2023-03-07

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## 1 Introduction

The Viedoc Security Token Service ([STS](#)) is a centralized service for issuing and validating access tokens for use with APIs in the Viedoc eClinical suite. In other words, the Viedoc STS is an Identity Provider ([IdP](#)) that provides authentication services for so-called principals (or security principals). Principals can be computers, services, computational entities such as processes and threads, or any group of such things.

The Viedoc STS is separate from the Viedoc REST API.

**Note!** Viedoc STS is not used for the [Viedoc WCF API](#).

The Viedoc STS consists of a web service with endpoints for getting and validating tokens. The Viedoc STS also exposes metadata (as JSON documents). This metadata is used by clients and APIs for self-configuration when communicating with the service.

The Viedoc STS follows the OAuth 2.0 standard, which is the industry standard for authentication and authorization for web applications and mobile applications. For more information, see [The OAuth 2.0 Authorization Framework](#).

The Viedoc STS is publicly accessible.

## 2 Authorization in Viedoc REST API

The Viedoc REST API requires authentication and authorization on every request. To achieve this, an access token must be included in the request as an HTTP authorization header. The token should be supplied with the **Bearer authentication HTTP scheme**.

The Viedoc REST API only accepts tokens issued by the Viedoc STS.

## 3 Receiving tokens from Viedoc STS

## 3.1 Grant types

Viedoc STS uses a non-interactive grant type called **Client Credentials**. This grant type is easy to use and is specifically made for scenarios where there is no user ID. In other words, this grant type lets you retrieve tokens for machine-to-machine communication only.

## 3.2 Credentials

In a token issue request to the Viedoc STS, you need to supply a set of credentials, that is, keys and values, as form data in an HTTP POST request. These are examples of such credentials:

Key	Value	Description
client_id	viedoc-web	The client ID to issue a token for.
client_secret	viedoc-secret	The client secret (=password) for the given client ID.
grant_type	client_credentials	The type of authentication.

**Note!** For information about the Web API client (how to obtain the client id and client secret), see [API Configuration](#).

## 3.3 Approach 1: Plain HTTP client

To retrieve an access token, make a POST request to the "token endpoint" of the Viedoc STS, located at `http://<base-url>/connect/token`, with the keys and values (described in the section [Credentials](#)) above the POST request body.

## 3.4 Approach 2: Identity Model library

When using the Identity Model in .NET Framework or .NET Core, you can use extension methods on `HttpClient`. The following example shows a suitable method for working with the Client Credentials grant type:

```
var client = new HttpClient();

var response = await client.RequestClientCredentialsTokenAsync(new
ClientCredentialsTokenRequest
{
    Address = "http://<base-url>/connect/token",
    ClientId = "viedoc-web",
    ClientSecret = "viedoc-secret",
});
```

Running the code above will generate a strongly typed response containing either an error or, if successful, an access token to use in requests to the Viedoc API.

For more information, see the [documentation](#) of the .NET integration library `IdentityModel`.

# 4 Validating tokens

Tokens must be validated on several parameters for your application to trust that the tokens have not been tampered with. The main validation criteria are:

- the audience claim
- the scope claims
- the issuer claim
- the cryptographic signature

You can validate tokens with one of these two methods:

- **Offline** - by the receiving application/API. This method is strongly preferred for performance reasons.
- **Online** - by sending the token back to the STS for verification, so called **introspection**. This method should only be used when no other options are available.

The validation can be done automatically with the use of convenience libraries. See examples for .NET and JavaScript below.

## 4.1 Offline validation with IdentityModel in .NET

When building a Web API based on ASP.NET Core, token validation can be done via extensions to the request pipeline. The request pipeline automatically works with the built-in authorization system, that is "principals", in ASP.NET Core. When you set up the pipeline in your `Startup.cs` file, you can add JWT Bearer authorization as in the following example.

The first step in the example adds the NuGet package `Microsoft.AspNetCore.Authentication.JwtBearer`.

```
public void ConfigureServices(IServiceCollection services)
{
    services.AddAuthentication("Bearer")
        .AddJwtBearer("Bearer", options =>
        {
            options.Authority = "http://<base-url>";
            options.TokenValidationParameters = new TokenValidationParameters
            {
                ValidateAudience = true
                //More validation options here
            };
        });

    services.AddAuthorization(options =>
    {
        //Adding a policy to validate the scope claim of the incoming token
        options.AddPolicy("ApiScope", policy =>
        {
            policy.RequireAuthenticatedUser();
            policy.RequireClaim("scope", "<your required scope name here>");
        });
    });
}

public void Configure(IApplicationBuilder app)
{
    app.UseAuthentication();
    app.UseAuthorization();
}
```

For more information, see [Overview of ASP.NET Core Authentication | Microsoft Docs](#).

## 4.2 Offline validation with JavaScript

You can use the `oidc-client` JavaScript library to:

- download metadata from the STS
- validate tokens
- extract claims

The library is available as an [NPM package](#), and it is primarily intended for use in JavaScript clients. For more information, see the `oidc-client` [documentation](#).

## 4.3 Web validation

The web site <https://jwt.io> offers the possibility to validate tokens. Simply paste your token into the field **Encoded** and then the field **Decoded** will display information about your token.

## 4.4 Online validation (introspection) with the STS

Sending the token back to the STS for validation should be seen as a last resort, in cases where, for some reason, it is impossible or infeasible to validate the token with an offline method.

For more information, see [Introspection Endpoint](#).

## 5 Viedoc Web API documentation

The Viedoc Web API is documented on the Viedoc API swagger page. The Viedoc API swagger page is accessible at: <API URL>/swagger, where the API URL depends on the environment. For example, see the following link:

<https://v4apitraining.viedoc.net/swagger/>

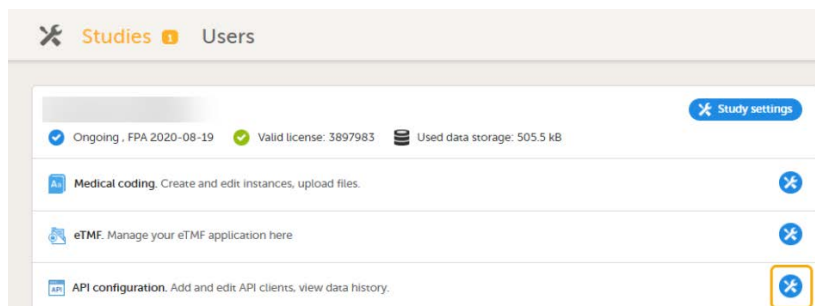
For more information, see the instructions below on how to access the API URL for your environment.

To view the Viedoc Web API swagger page, you need the **API URL** in Viedoc Admin.

**Note!** You must have the API Manager user role to see the **API configuration** field.

To view the **API URL** in Viedoc Admin:

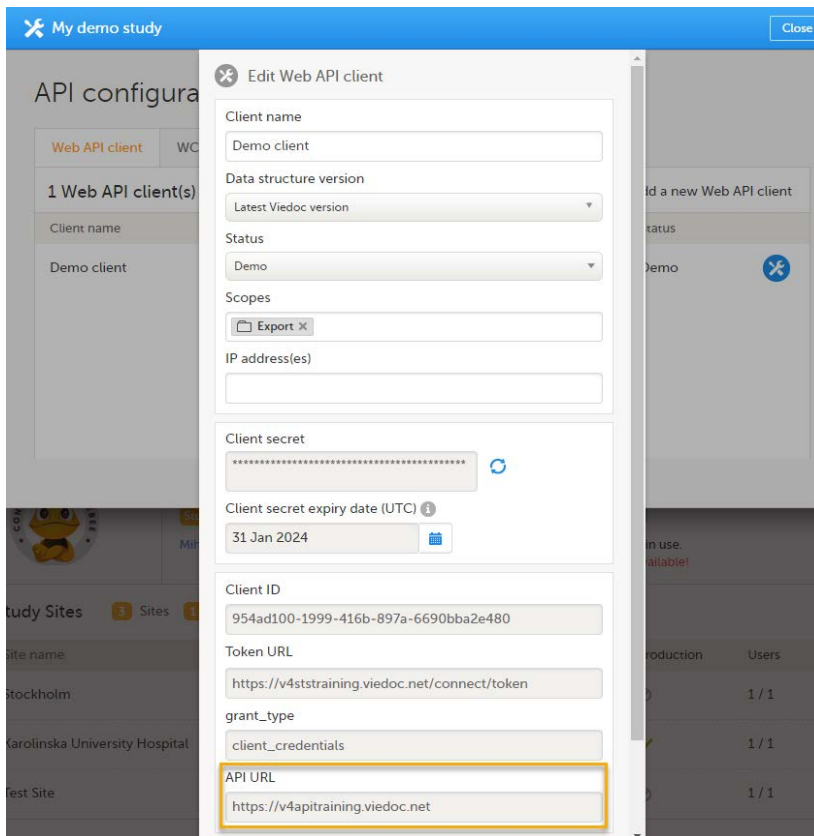
- 1 On the Viedoc landing page, select the **Admin** icon to open Viedoc Admin.
- 2 Open the study that you would like to work with and select the **Edit** button in the API configuration field to open the **API configuration** dialog.



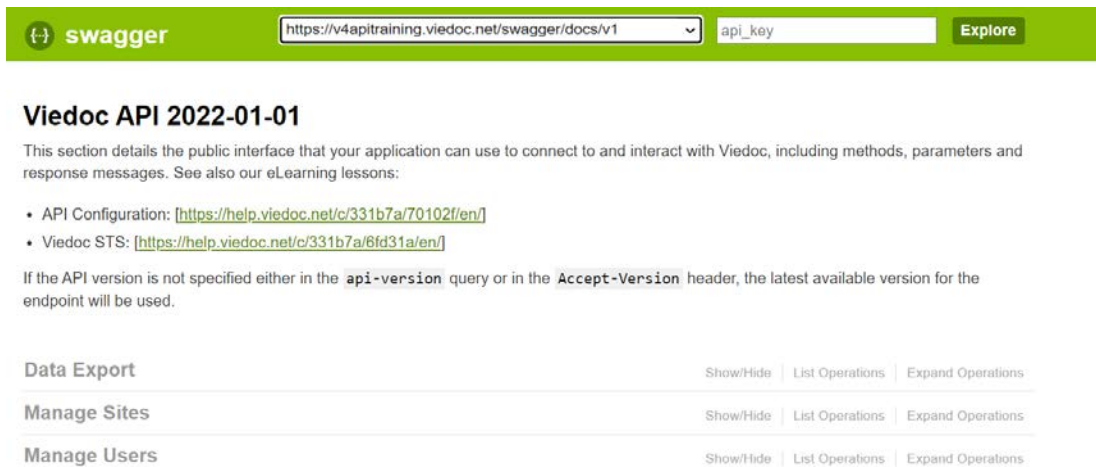
- 3 On the Web API client tab, select **Edit** for the API Client you want to access.



4 The Edit Web API client dialog opens:



Using the example above, add /swagger to the API URL: <https://v4apitraining.viedoc.net/swagger> to open the swagger page:



## 5.1 Viedoc Web API version

The Viedoc Web API swagger page contains information about how to connect to and interact with Viedoc using the Viedoc Web API, including methods, parameters and response messages.

Updates to the Viedoc Web API considered as breaking changes will always be introduced in a new API version. To ensure backward compatibility is maintained, you need to specify the API version to be used.

**Important!** If the API version is not specified either in the `api-version` query or in the `Accept-Version` header, the latest available version for the endpoint will be used. Different versions will also be available for different endpoints.

In the `api-version` query field or in the `Accept-Version` header field you can specify which API version should be used to connect to and interact with Viedoc.

To specify the API version, enter the date of the version required into the `api-version` query field or into the `Accept-Version` header field as shown in the example below for the `dataexport/start` endpoint.



**POST** /clinic/dataexport/start Starts an export process in the background. Use /clinic/dataexport/status to check the progress.

**Implementation Notes**

Required scopes in access token

- viedoc.api.clinic.export (Export)

**Response Class (Status 200)**  
OK

Model Example Value

```
{
  "exportId": "b2dfd70f-2e0c-4614-a63f-c17b157e9cdd"
}
```

Response Content Type

**Parameters**

Parameter	Value	Description	Parameter Type	Data Type
<b>requestModel</b>	(required)	Request model	body	Model Example Value
	<input type="text" value="application/json"/>			<pre>{   "roleId": "R1",   "siteIds": [     "a9aa5e91-4cb7-4c00-8602-0e73ff4366c6"   ],   "eventDefIds": [     "V1"   ],   "formDefIds": [     "AE"   ], }</pre>
<b>Accept-Version</b>	<input type="text" value="2022-01-01"/>	The requested API version	header	string
<b>api-version</b>	<input type="text" value="2022-01-01"/>	The requested API version	query	string

### Available versions

Viedoc Web API version  
Changes from previous version: N/A- first version.

2022-01-01

## 6 Further reading

- The IdentityServer [documentation](#)
- The IdentityModel [documentation](#)



Managing medical coding dictionaries

# Managing medical coding dictionaries

Published by Viedoc System 2022-10-18

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## **1. Introduction**

[1.1 About medical coding](#)

[1.2 Workflow](#)

## **2. About the dictionary instances in Viedoc Admin**

[2.1 Workflow for creating dictionary instances in Viedoc Admin](#)

[2.2 Where to find dictionary instances in Viedoc Admin](#)

## **3. Step-by-step guides**

[3.1 Creating a dictionary instance](#)

[3.1.1 WHODrug files](#)

[3.2 Linking coding scopes to a dictionary instance](#)

[3.3 Updating a dictionary version](#)

This lesson describes how to manage medical coding dictionaries in Viedoc Admin.

# 1 Introduction

## 1.1 About medical coding

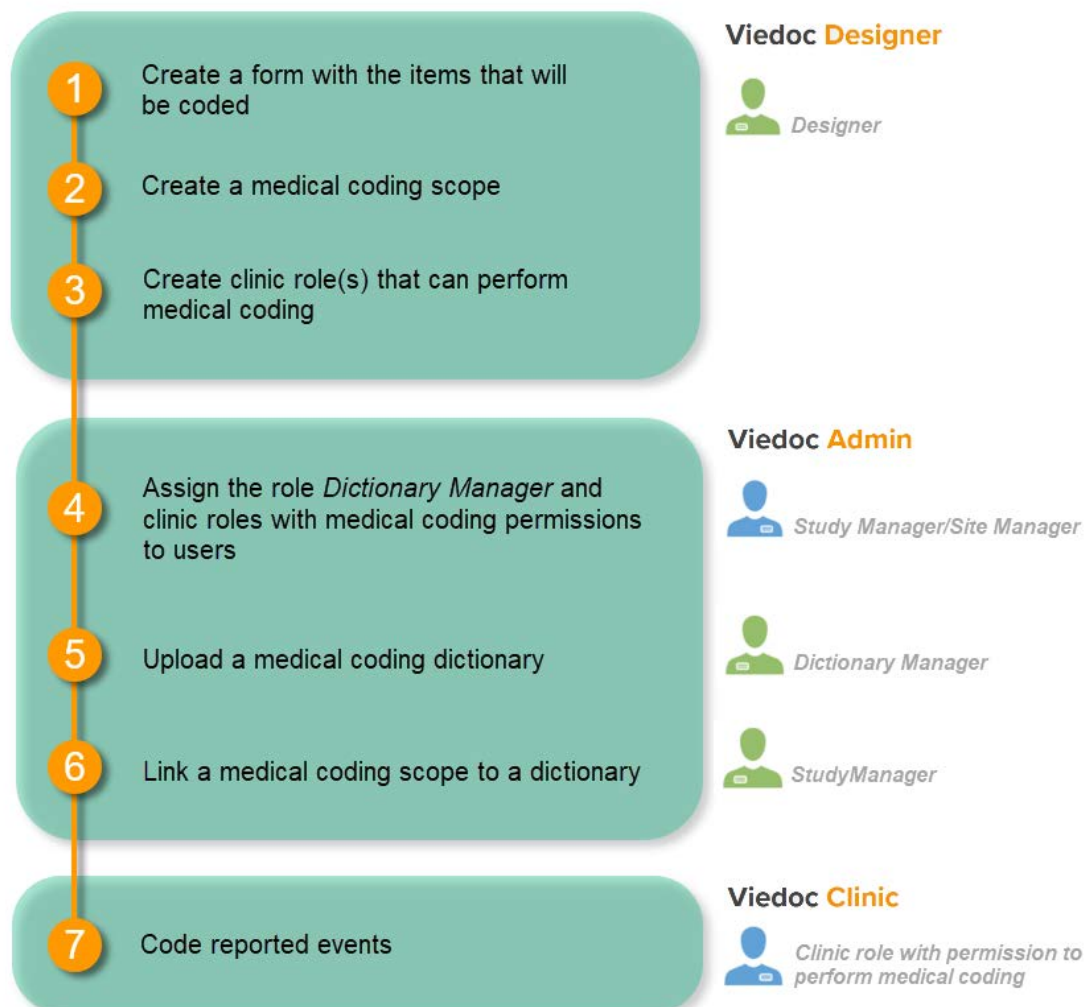
Viedoc offers support for medical coding. The medical coding feature allows you to code data, such as Adverse Events, Medical History and Concomitant Medications, in a standardized way.

Viedoc supports the following types of dictionaries:

- Medical Dictionary for Regulatory Activities ([MedDRA](#)) (including Chinese version)
- MedDRA/J (Japan)
- Anatomic Therapeutic Chemical Classification System ([ATC](#)) without Defined Daily Dose (DDD)
- Iyakuhinmei Data File ([IDF](#))
- World Health Organization Drug Dictionary ([WHO DD](#)) WHODrug - C and C3 formats (including Chinese version)

## 1.2 Workflow

Medical coding is configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps.



For more detailed instructions regarding these steps, see:

- [Configuring medical coding scopes](#) in Viedoc Designer
- [Managing medical coding dictionaries](#) in Viedoc Admin ([this lesson!](#))
- [Medical coding](#) in Viedoc Clinic

## 2 About the dictionary instances in Viedoc Admin

### 2.1 Workflow for creating dictionary instances in Viedoc Admin

In Viedoc Admin, creating a dictionary instance is done according to the following procedure:

1. The Study Manager invites a user to the system role Dictionary Manager.
2. The Dictionary Manager uploads the medical coding dictionary to create a dictionary instance. This makes the dictionary available for the study.
3. The Study Manager links the medical coding scopes that have been defined in the study design to the uploaded medical coding dictionaries.

For detailed instructions, see the [Step-by-step guides](#) below.

**Note!** Licenses for medical coding dictionaries are not supplied by Viedoc. It is the user's own responsibility to purchase a license for the dictionary to be used, and to update the uploaded dictionaries.

### 2.2 Where to find dictionary instances in Viedoc Admin

To enter the Medical coding page in Viedoc Admin, and to view uploaded dictionary instances or create a new instance, click the toolbox icon in the **Medical coding** field on the study start page. The Medical coding page opens.

**Note!** The Medical coding page is only visible for users with the system role **Dictionary Manager**.

The screenshot shows the 'A demo study' overview page. In the 'Medical coding' section, a toolbox icon is highlighted with a blue box and a hand cursor. A dotted line connects this icon to the 'Medical coding' page below. The 'Medical coding' page has a blue header with 'A demo study' and a 'Close' button. Below the header, it says 'Medical coding' and 'Create and edit instances, upload files.' There are '4 dictionary instances.' listed in a table:

1 Name	2 Version	3 Description	4 Created	5 In use	6
MedDRA		Version 161107	2016-11-07 13:32 by [user]	✓	✕
WHODrug	WHO DDE C3 September 1, 2017	Version 180829	2018-08-29 09:41 by [user]	✓	✕
IDF		Version 180913	2018-09-13 10:51 by [user]	—	✕
ATC without DDD		Version 180913	2018-09-13 10:52 by [user]	—	✕



At the bottom, there is a button '7 + Create a new instance'.

On this page, the following information is displayed:

1. **Name** - the type of dictionary
2. **Version** - the version of the dictionary, if applicable
3. **Description** - a custom description of the dictionary, added by the Dictionary Manager when uploading the dictionary

4. **Created** - the date when the dictionary has been uploaded, and by whom

5. **In use** - shows whether the dictionary is linked to a coding scope, as follows:

Icon	Description
	The dictionary instance is linked to a coding scope.
	The dictionary instance is not linked to a coding scope.

On this page, you can perform the following actions:

6. Click the toolbox icon to edit the dictionary instance. You can only edit the description of the dictionary instance.

7. Click **Create a new instance** to upload a new dictionary, see [Creating a new dictionary instance](#).

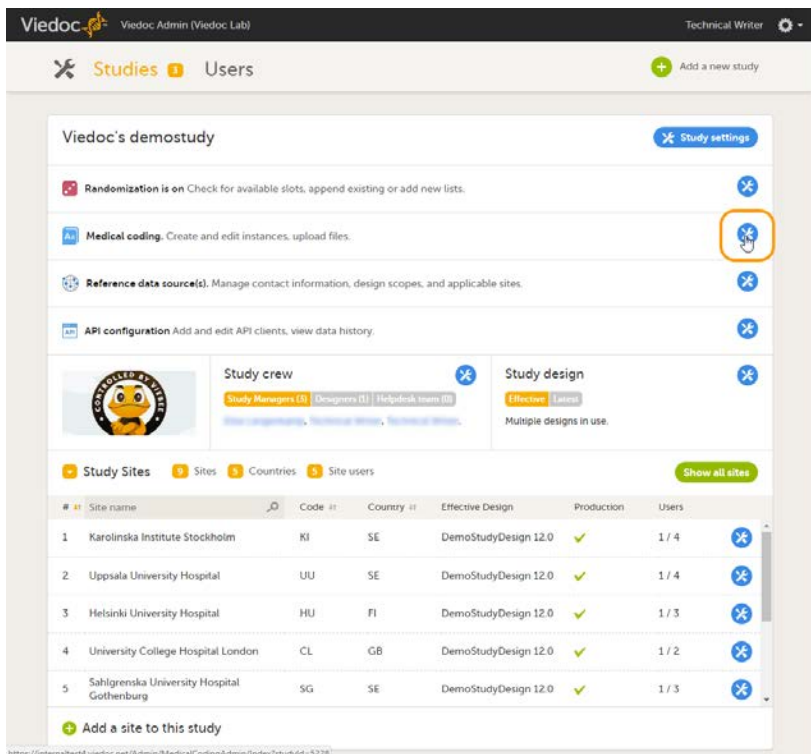
## 3 Step-by-step guides

### 3.1 Creating a dictionary instance






**Note!** Creating a dictionary instance (uploading a dictionary) can only be done by the **Dictionary Manager**.

To create a dictionary instance, follow the steps below.

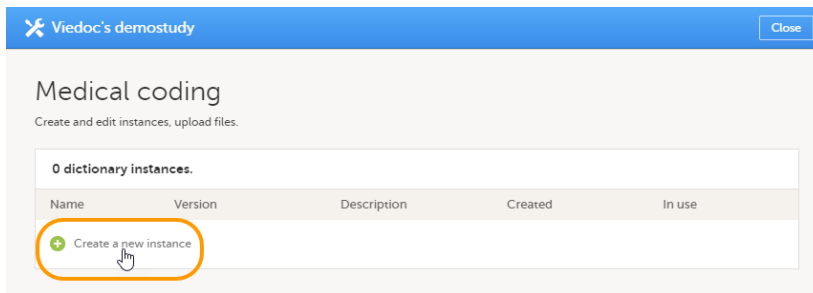
- 1 On the study page in Viedoc Admin, click the toolbox icon in the **Medical coding** field to open the Medical coding window.



The screenshot shows the Viedoc Admin interface for a study named 'Viedoc's demostudy'. The 'Medical coding' field is highlighted with a red box, and a red circle highlights the toolbox icon (a blue square with a white wrench and screwdriver) next to it. The interface includes a navigation bar with 'Studies' and 'Users' tabs, and a 'Study settings' button. Below the 'Medical coding' field, there are sections for 'Reference data source(s)', 'API configuration', 'Study crew', and 'Study design'. At the bottom, there is a table of 'Study Sites' with columns for Site name, ID, Code, Country, Effective Design, Production, and Users.

#	Site name	ID	Code	Country	Effective Design	Production	Users	
1	Karolinska Institute Stockholm	KI	SE	SE	DemoStudyDesign 12.0	✓	1 / 4	
2	Uppsala University Hospital	UU	SE	SE	DemoStudyDesign 12.0	✓	1 / 4	
3	Helsinki University Hospital	HU	FI	FI	DemoStudyDesign 12.0	✓	1 / 3	
4	University College Hospital London	CL	GB	GB	DemoStudyDesign 12.0	✓	1 / 2	
5	Sahlgrenska University Hospital Gothenburg	SG	SE	SE	DemoStudyDesign 12.0	✓	1 / 3	

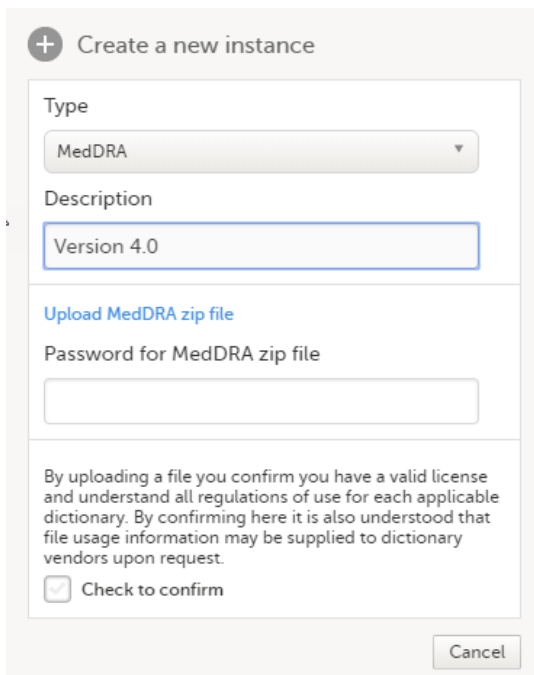
2 Click **Create a new instance**.



A dialog opens.

3 In the **Create a new instance** dialog:

1. Select the type of dictionary.
2. Type a version description, for example 'Version 4.0' or 'October 2016 HD'.
3. Click **Upload...file** and select the dictionary file that should be uploaded. For World Health Organization Drug Dictionary ([WHO DD](#)) WHODrug files, see [WHODrug files](#) below.
4. If the uploaded dictionary file is protected by a password, enter the password.
5. Read the legal text and select the **Check to confirm** checkbox.
6. Click **Create**.



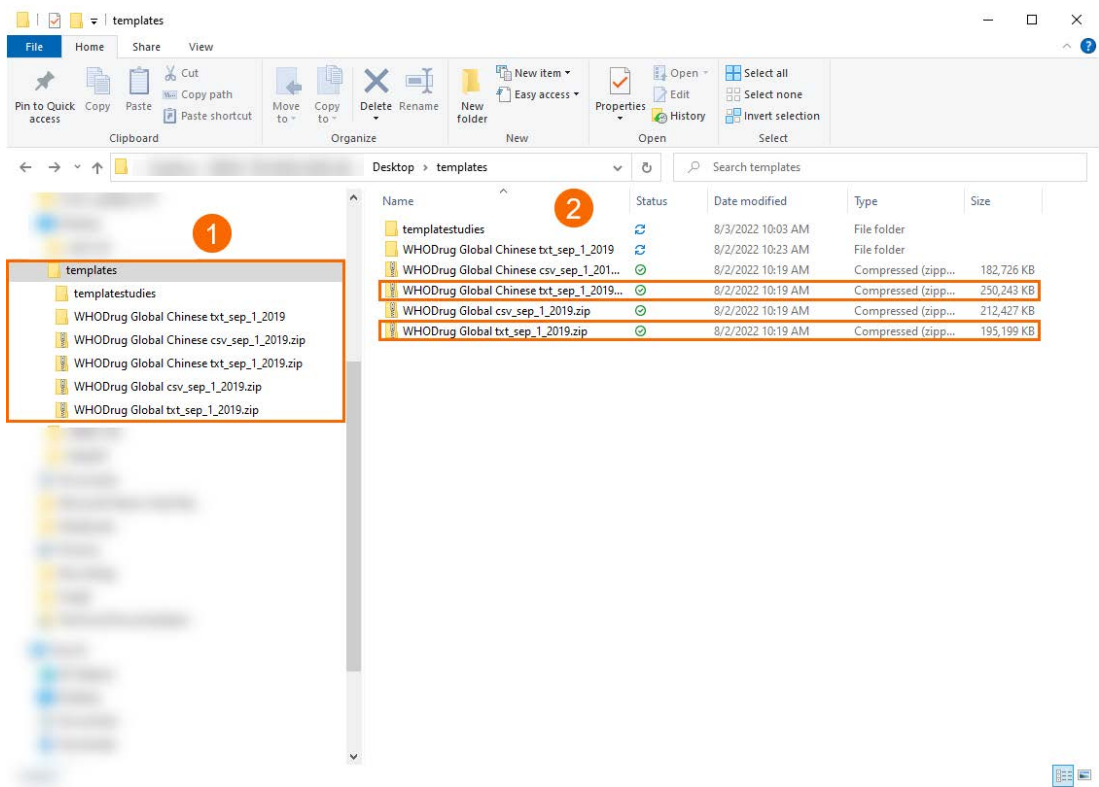
It may take up to several minutes to upload the file and create the dictionary instance. When the dictionary instance has been created, the **Create a new instance** pop-up closes automatically.

4 Click **Close** to close the Medical coding window.

### 3.1.1 WHODrug files

When you have downloaded the WHODrug Global files, you should locate them in your system. Below is a view of how it will possibly appear once you've located them:

1



1. This is an example of a file tree that displays a file path for the documents.

2. These are the the relevant folders that you need to select to extract or unzip.

**Note!** You want to select the files that are labeled as **txt**, not CSV.

2

Once you've selected the relevant file folder, you must extract (unzip) its contents. Then you will select the next folder which is the one labeled **c3**, as shown below:

Name	Type	Compressed size	Password ...	Size	Ratio	Date modified
additional_features_whodrug_glob...	Compressed (zipped) Fol...	4,643 KB	No	4,922 KB	6%	8/14/2019 3:46 PM
additional_features_whodrug_glob...	Compressed (zipped) Fol...	4,031 KB	No	4,053 KB	1%	8/14/2019 3:46 PM
WHODrug Standardised Drug Grou...	Compressed (zipped) Fol...	24,208 KB	No	26,038 KB	8%	8/14/2019 3:46 PM
whodrug_global_b3_sep_1_2019.zip	Compressed (zipped) Fol...	12,833 KB	No	15,295 KB	17%	8/14/2019 3:45 PM
whodrug_global_c3_sep_1_2019.zip	Compressed (zipped) Fol...	149,484 KB	No	182,913 KB	19%	8/14/2019 3:45 PM

3

Upload this zipped folder to Viedoc and Viedoc will complete the final extraction for you placing the WHODrug files in your study.

### 3.2 Linking coding scopes to a dictionary instance

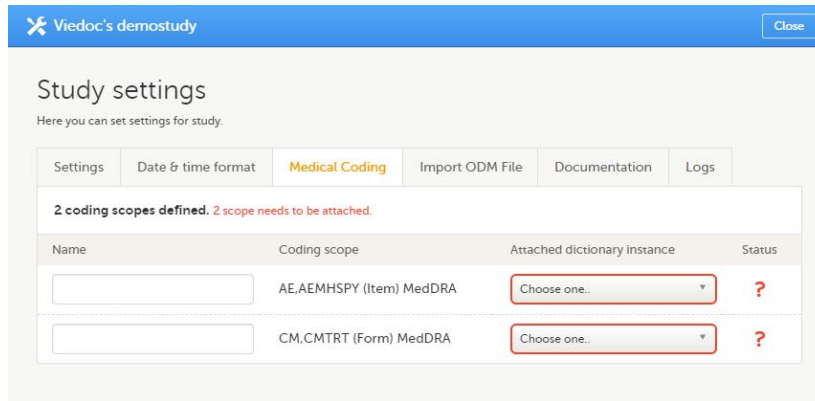
**Note!** Linking the coding scopes to the uploaded medical coding dictionaries can only be done by the **Study Manager**.

To link the coding scopes to a dictionary instance:

1

On the study details page in Viedoc Admin, click **Study settings** to open the study settings dialog.

- 2 Select the **Medical Coding** tab.  
The coding scopes that have been defined in the study design are displayed. The coding scopes that have not been linked to a dictionary are marked with a red question mark in the **Status** column.

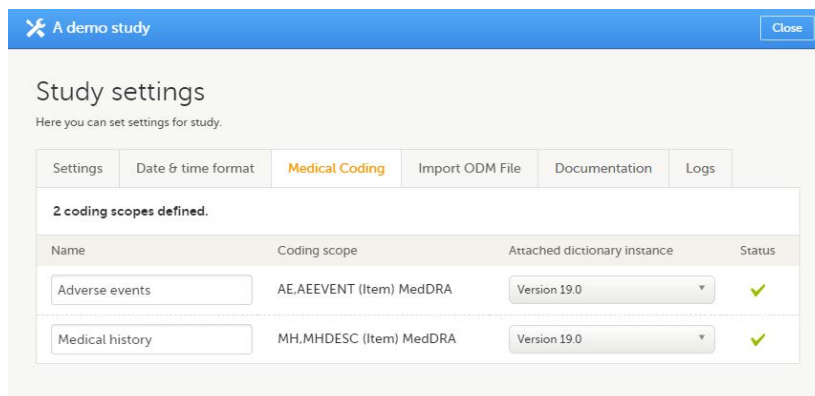


If no scopes are listed, contact the Designer of the study.

- 3 Type a name for each coding scope in the **Name** field. This name is displayed in the medical coding console in Viedoc Clinic.

- 4 Select which dictionary and which version should be applied to each coding scope. You can only select an instance applicable for the coding scope. For example, you can only link a Medical Dictionary for Regulatory Activities ([MedDRA](#)) dictionary instance to a MedDRA scope.

When you have selected a dictionary instance, the **Status** icon for that coding scope will change from a red question mark into a green check mark.



- 5 Click **Save changes** to save the changes.  
The study settings dialog closes.

### 3.3 Updating a dictionary version

You can replace an old version of the medical coding dictionary with a new version, and continue coding on the same scopes. Replacing an old medical coding dictionary version with a new version involves the following steps:

1. The Dictionary Manager creates a new dictionary instance by uploading the latest dictionary version, see [Creating a dictionary instance](#) for instructions.
2. The Study Manager links the medical coding scopes to the new dictionary instance, see [Linking the dictionary instance to coding scopes](#) for instructions.

**Note!** It is not necessary to create new coding scopes in the study design.

From the moment the new medical coding dictionary version has been uploaded and linked to the medical coding scope, the medical coding console in Viedoc Clinic will use the new version for coding the terms in that scope. Terms that have been coded before updating the dictionary version will keep their codes from the previous dictionary version. The dictionary version that is used for coding each term is displayed when the medical coding is exported.

It is not possible to delete a dictionary instance.





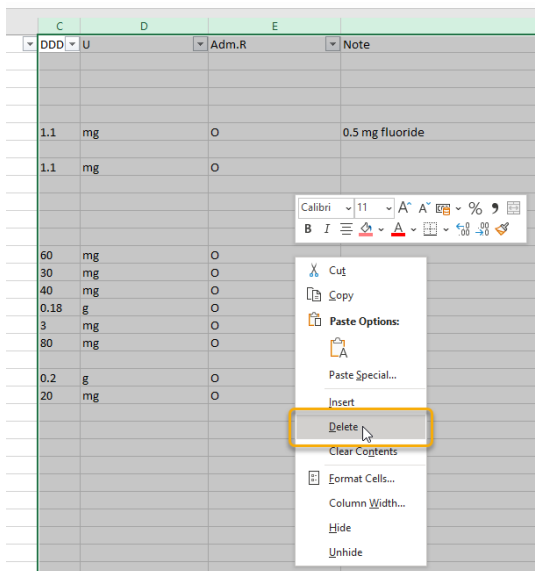
Converting an ATC dictionary from Excel format to ASCII format

# Converting an ATC dictionary from Excel format to ASCII format

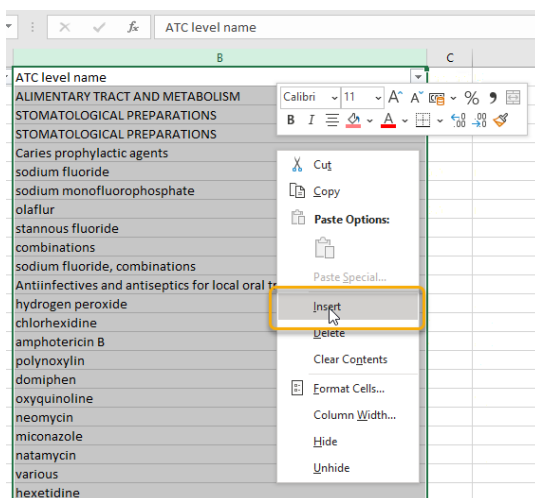
Published by Viedoc System 2022-02-10

To convert an Anatomic Therapeutic Chemical classification system ([ATC](#)) dictionary:

- 1 Open the `xlsx` file in Microsoft Excel.
- 2 If Defined Daily Dose (DDD) is included in the file (columns C, D, E, and F), delete these columns, as well as the note column if there is one.



- 3 Insert a new column B.



- 4 In cell B2, write a formula. To add a formula, start by typing an equal sign ( = ). Then Excel interprets the text in that cell as a formula (unless otherwise specified).

The formula will look different depending on the language of your Excel installation. These are some examples:

- English: =CONCAT(LEFT(CONCAT(A2;REPT(" ";5));4);" ";MID(CONCAT(A2;REPT(" ";20));5;6);C2)
- French: =CONCAT(GAUCHE(CONCAT(A2;REPT(" ";5));4);" ";STXT(CONCAT(A2;REPT(" ";20));5;6);C2)
- Spanish: =CONCAT(IZQUIERDA(CONCAT(A2;REPETIR(" ";5));4);" ";EXTRAE(CONCAT(A2;REPETIR(" ";20));5;6);C2)
- German: =TEXTKETTE(LINKS(TEXTKETTE(A2;WIEDERHOLEN(" ";5));4);" ";TEIL(TEXTKETTE(A2;WIEDERHOLEN(" ";20));5;6);C2)
- Swedish: =SAMMAN(VÄNSTER(SAMMAN(A2;REP(" ";5));4);" ";EXTTEXT(SAMMAN(A2;REP(" ";20));5;6);C2)

**Notel** Depending on the regional settings in your operating system, you might need to replace the semicolons with commas.

	A	B	C
1	ATC code	Column1	ATC level name
2	A	A ALIMENTARY TRACT AND	ALIMENTARY TRACT AND METABOLISM
3	A01	A01 STOMATOLOGICA	STOMATOLOGICAL PREPARATIONS
4	A01A	A01A STOMATOLOGIC	STOMATOLOGICAL PREPARATIONS
5	A01AA	A01A A Caries prophyla	Caries prophylactic agents

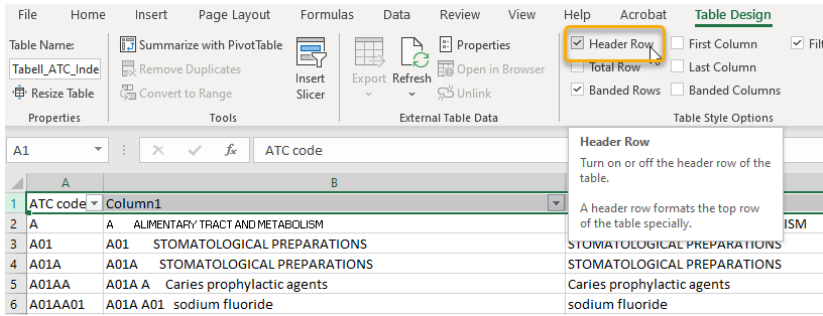
The formula does the following:

1. It takes the first four characters from column A (padded right with spaces unless the text is four characters long).
2. It adds one space character.
3. It adds characters 5, 6, and 7 from column A (padded right with spaces unless the text is seven characters long).
4. It adds three space characters.
5. It adds all of column C.

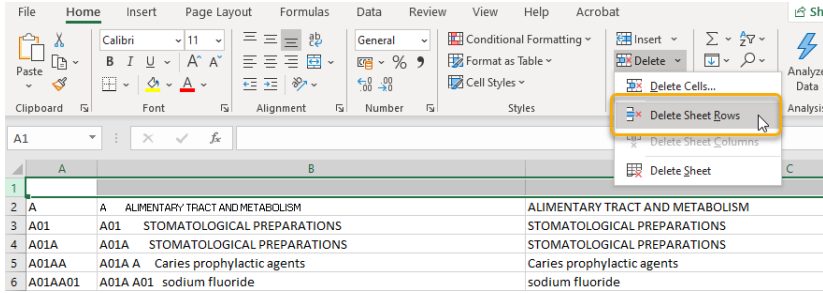
- 5 Fill all cells in the B column with the same formula, for example by dragging the small plus sign ( + ) downwards to cover the entire column.

	A	B	
1	ATC code	Column1	ATC
2	A	A ALIMENTARY TRACT AND METABOLISM	ALI
3	A01	A01 STOMATOLOGICAL PREPARATIONS	STO
4	A01A	A01A STOMATOLOGICAL PREPARATIONS	STO
5	A01AA	A01A A Caries prophylactic agents	Cari
6	A01AA01	A01A A01 sodium fluoride	sodi

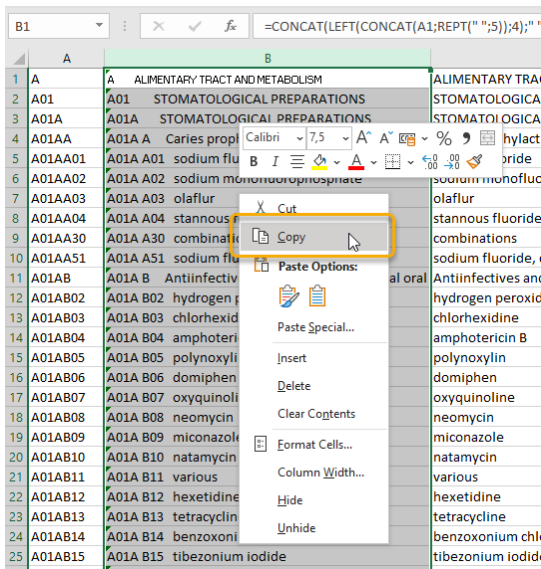
- 6 Remove row 1 (the header row). Do to this, you might first need to turn off the header row on the **Table Design** page.



Then you can delete the sheet row from the **Home** page.

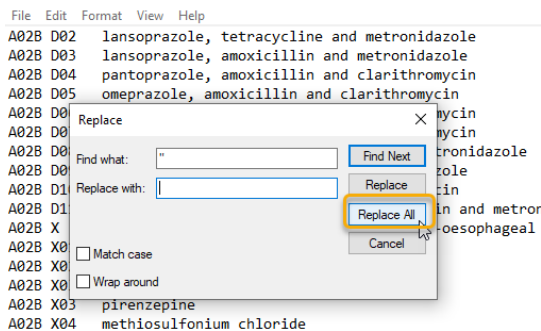


- 7 Select column B and copy it.



- 8 Paste the copied column into a raw text editor such as Windows Notepad. It is important to use an editor that does not add any formatting.

- 9 In the raw text editor, search for the quotation mark character ( " ) and remove any such occurrences.



10 If there are empty lines at the end of the file, remove them.

```
V10X X03 radium (223Ra) dichloride
V10X X04 lutetium (177Lu) oxodotreotide
V20      SURGICAL DRESSINGS
```



11 Save your file with an appropriate filename that reflects the [ATC](#) version and with the filename extension `.asc`.

12 Upload the file to Viedoc according to these instructions: [Creating a dictionary instance](#).



Configuring a static randomization

# Configuring a static randomization

Published by Viedoc System 2023-10-09

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## [1. Introduction](#)

- [1.1 About the randomization service](#)
- [1.2 Terminology](#)
- [1.3 Workflow](#)

## [2. Study license and randomization](#)

### [3. Static randomization in Viedoc Admin](#)

- [3.1 What is static randomization?](#)
- [3.2 Description of the randomization page](#)
- [3.3 The randomization list](#)
- [3.4 The allocation list](#)

## [4. Step-by-step guides](#)

- [4.1 Configuring a static randomization](#)
- [4.2 Configuring a randomization list for static randomization](#)
  - [4.2.1 Downloading a template randomization list](#)
  - [4.2.2 Uploading a randomization list](#)
  - [4.2.3 Viewing a randomization list](#)
  - [4.2.4 Editing a randomization list](#)
- [4.3 Configuring the allocation list](#)
  - [4.3.1 Individual allocation list](#)
    - [4.3.1.1 Downloading a template allocation list](#)
    - [4.3.1.2 Uploading an allocation list](#)
    - [4.3.1.3 Viewing an allocation list](#)
    - [4.3.1.4 Editing an allocation list](#)

This lesson describes how to configure a static randomization in **Viedoc Admin**.

---

## 1 Introduction

### 1.1 About the randomization service

Viedoc offers support for randomization. Subjects can be randomized using:

- **static randomization**: randomization based on a randomized list,
- **dynamic randomization** (Pocock and Simon): randomization based on an algorithm.

Dynamic randomization ensures a more even distribution of subjects across the treatment groups, with regard to prognostic factors that might influence the effect of treatment on the subjects.

The randomization in Viedoc is configured in a similar way for static and dynamic randomization. The main difference is that for static randomization, a list with outcomes (randomization numbers, treatment groups, and so on) - the randomization list - is created and uploaded by the user, while for dynamic randomization, an algorithm is used to assign subjects to a treatment group and the randomization list is created by the system.

It is possible to upload a separate allocation list that allocates an Investigational Product (IP) to the subject. When the subject is randomized, Viedoc informs the clinic user which IP should be given to the subject. The allocation list is most commonly used in double-blind studies. Uploading of the allocation list is done in a similar way for static and dynamic randomization.

## 1.2 Terminology

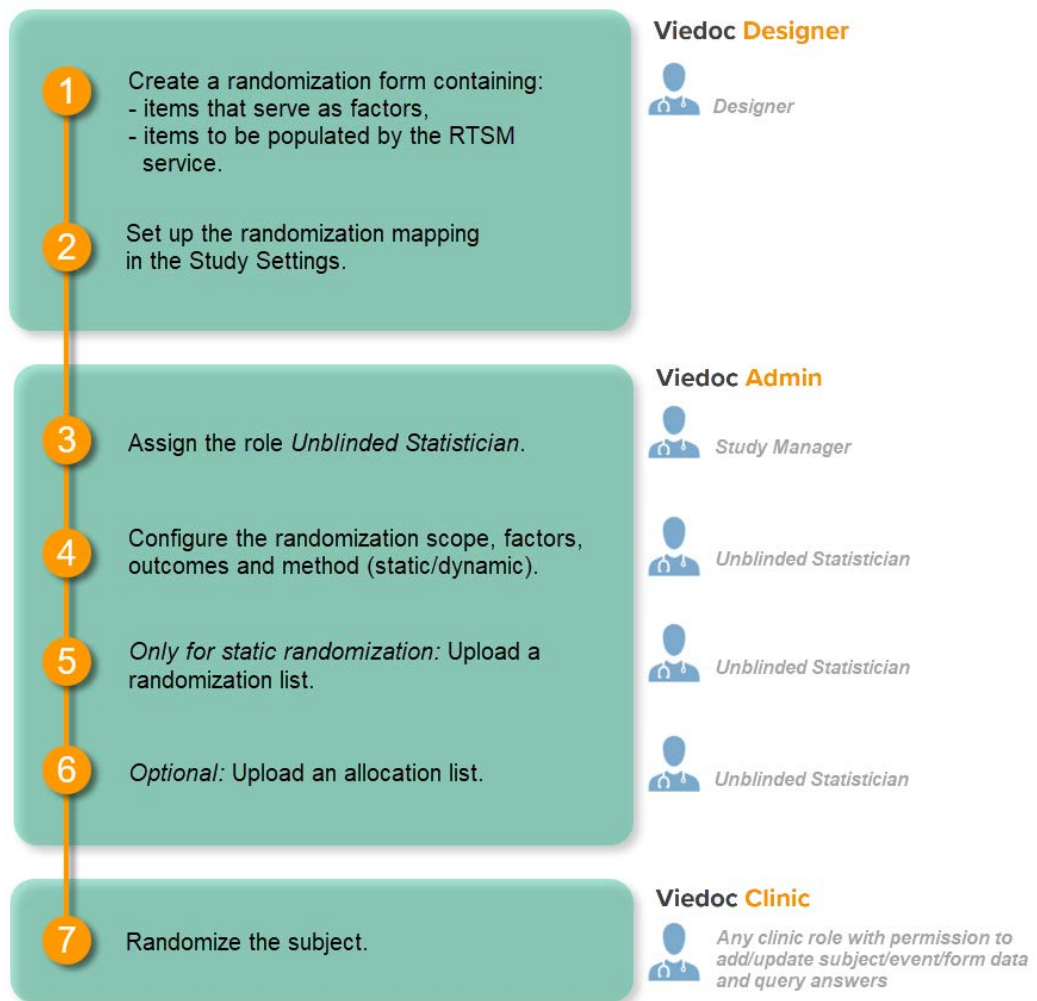
Term	Definition
RTSM	Randomization and Trial Supply Management.
Blinded role	A role that does not know which treatment the subject is receiving. Most roles in a clinical trial should be blinded.
Unblinded Statistician	<p>A system role that can configure the randomization in Viedoc Admin.</p> <p>The Unblinded Statistician sees which subjects are assigned to which treatments, and should therefore not have any role in the study where he/she should not know this information. An Unblinded Statistician can never again work in a blinded role within that study.</p>
Randomization list	A list for allocating subjects to treatments or groups. The randomization list shows all available slots in the randomization. When randomization has started (that is, when the first subject has been randomized), the randomization list also shows which subjects have been assigned to which treatment or group.
Allocation list	<p>A list for allocating <a href="#">IP</a> to subjects. The allocation list shows all available IPs. When randomization has started, the allocation list also shows which IPs have been assigned to which subjects. Advanced allocation can be set up and for this there are two options for the allocation list(s):</p> <ul style="list-style-type: none"><li>▪ Use individual allocation list for each randomization.</li><li>▪ Use one global allocation list for all your randomizations.</li></ul> <p><b>Note!</b> To be able to use <b>Logistics</b>, a Global allocation list must be used.</p>
Scope	<p>Defines the scope from which a randomization slot or an IP should be selected. One of the following scopes can be chosen:</p> <ul style="list-style-type: none"><li>▪ Study</li><li>▪ Country</li><li>▪ Site</li></ul>
Factor (Prognostic factor)	Items that might influence the effect of treatment on the subjects, and that are to be used as input when randomizing the subject. For example sex or age. Viedoc supports the use of drop-down lists, radio buttons, integer and free text data types as input items.
Outcome	Items to be populated by the randomization service, for example treatment group.
Blinded outcome	Items to be populated by the randomization service, that should remain blinded until after the subject has been unblinded or emergency unblinded for a specific subject. These items will not be visible for any user in the system, except for the Unblinded Statistician who can see them in Viedoc Admin, or until an emergency unblinding was performed (for details on how the emergency unblinding is performed in Viedoc Clinic, see <a href="#">Randomization, allocation and emergency unblinding</a> ).

## 1.3 Workflow

Randomizations are configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps, depending on the allocation configuration type as described below:

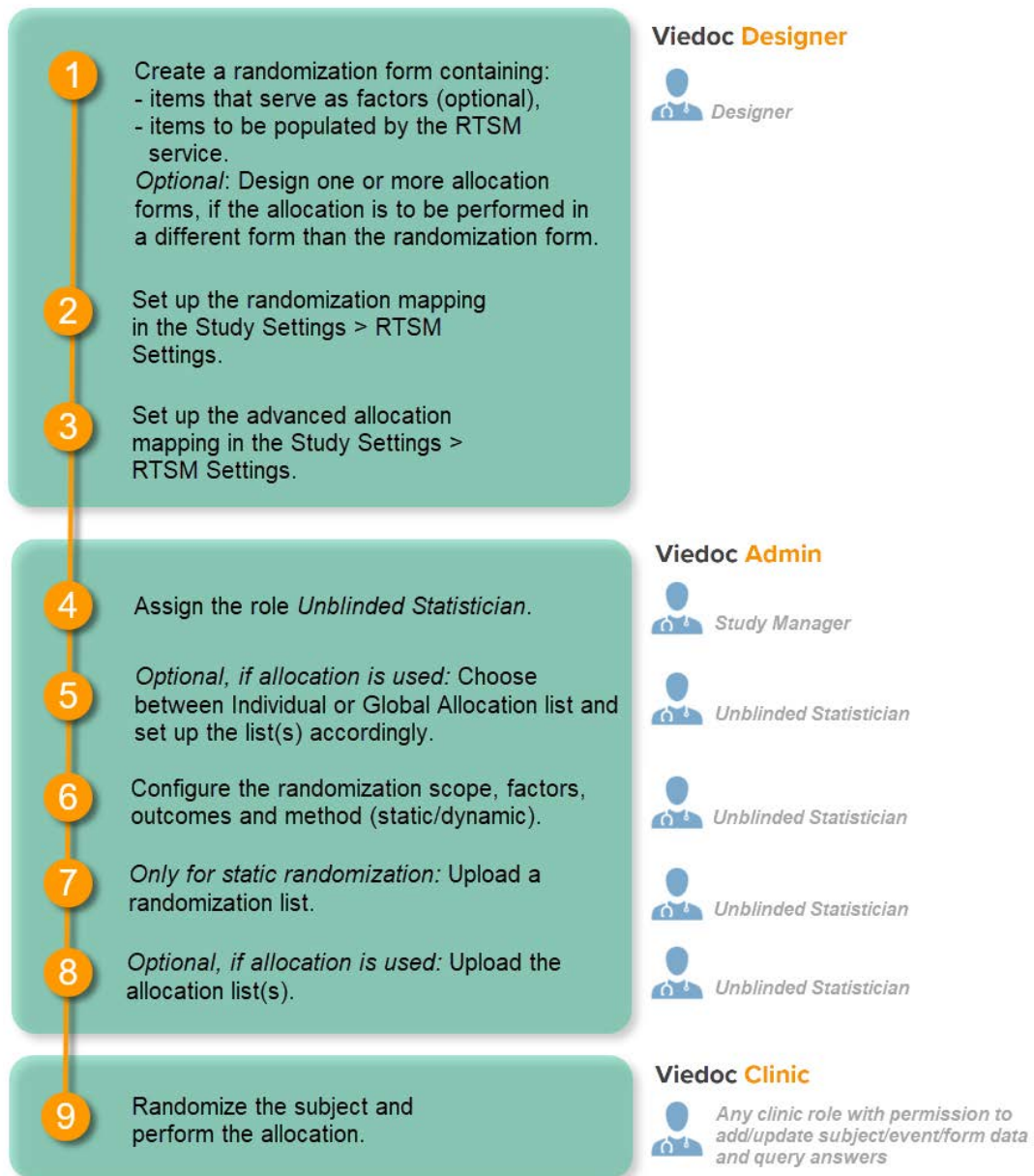
- Randomization, optionally together with allocation performed at the same time as the randomization within the same form. In this case the form is locked (and therefore not possible to be edited) after the randomization is performed in Viedoc Clinic.

The configuration workflow in this case looks as illustrated in the following image:



- Randomization, optionally together with **advanced allocation** allows you to set up the allocation in a more flexible way, including:
  - Configuring individual forms for randomization and allocation, to keep the two steps separated in the study workflow
  - The possibility to perform multiple allocations at different visits during the study
  - The possibility to replace an already performed allocation with a new allocation
  - The possibility to undo an already performed allocation

The configuration workflow in this case looks as illustrated in the following image:



Detailed instructions regarding these steps are described in:

- [Setting up the randomization](#) in Viedoc Designer
- [Configuring a static randomizations](#) in Viedoc Admin (**this lesson!**)
- [Configuring a dynamic randomization](#) in Viedoc Admin

An example of how to configure a dynamic randomization is described in detail in the following lesson:

- [A use case for dynamic randomization](#)

For a video tutorial on how to configure a static list randomization and a dynamic randomization, see:

- [Randomization video tutorial](#)

## 2 Study license and randomization

**Important!** The randomization feature must be included in your study license in order for the randomization configuration to be available in production mode. You can still configure a randomization in demo mode without a license.



On the [randomization page](#), under the **Demo mode tab**, you can perform all the configuration actions, select the link to download the template (Excel file) for the randomization list, and upload a file with a randomization list or an allocation list.

If your study license has the randomization feature included, it will be shown on the **Study settings** page on the **Settings tab** under **Included features**:

The screenshot shows the 'Study settings' page in the RandStudy2 application. The 'Included features' section is highlighted, showing 'Randomization' as an active feature. The 'Study name' is 'RandStudy2', 'Sponsor Code' is 'RS2', 'CRO Code' is 'RFT', and 'Reference ID' is '2376890'. The 'Study Type' is 'Pharmaceutical - Post-approval', 'Sponsor Type' is 'Government agency', and 'Study Phase' is 'Phase 0'. The 'Therapeutic Area' is 'Dermatology/Plastic Surgery'. The 'Expected number of subjects' section has 'Screened' and 'Enrolled' input fields. The 'Expected end date of enrollment period' is set to 'dd MMM yyyy'. The 'Study access' section has 'Password expiration time for all users in this study (values allowed are 1 to 5000)' set to '90 days' and 'Require two-factor authentication for all users accessing this study' unchecked. The 'Clinic roles to be administered by Site Manager' section has 'Investigator', 'Monitor', 'Data Manager', 'Study IP Manager', and 'Site IP Manager' all unchecked. The 'Helpdesk team' section is empty. The 'ViedocMe' section has 'Allow reminders in ViedocMe to be sent as' with 'Email' and 'Text message' unchecked, 'Force subject to change password at first time login' unchecked, 'Use the new application design for training sites' checked, and 'Use the new application design for production sites' checked.

If your study does not have a license key (Reference ID), or has a license key that does not include the randomization feature, on the [randomization page](#), under the **Production tab**:

- A message is shown informing you that the randomization feature is not included in the license:

- The link to download the template (Excel file) for the randomization list is not available.
- It is not possible to upload a file with a randomization list or an allocation list.

For more information about licensing, see [Overview of Viedoc](#)

## 3 Static randomization in Viedoc Admin

### 3.1 What is static randomization?

Static randomizations are based on randomized lists that are uploaded by the user. These lists should be generated by the user in advance to ensure that the allocation of subjects to treatments, and of Investigational Products (IP) to subjects, is random. When a subject is randomized, Viedoc assigns that subject to the next free slot in the list, which then decides the treatment the subject is to receive.

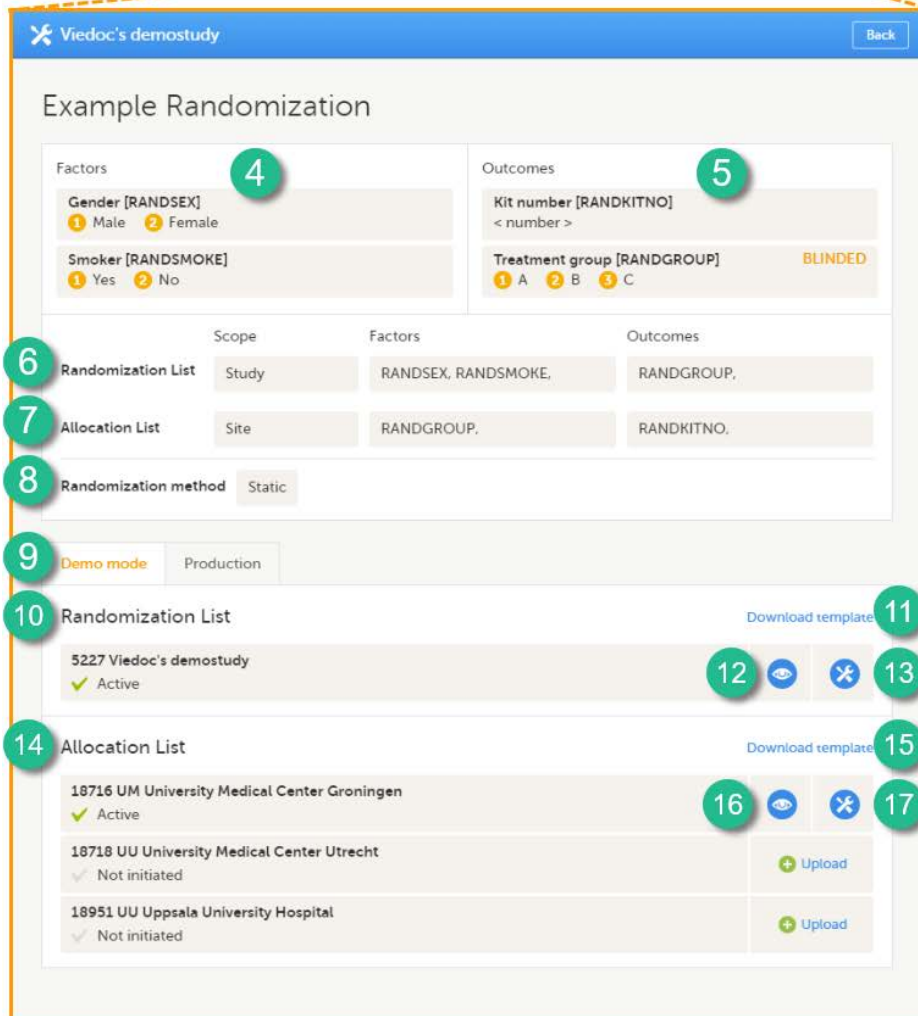
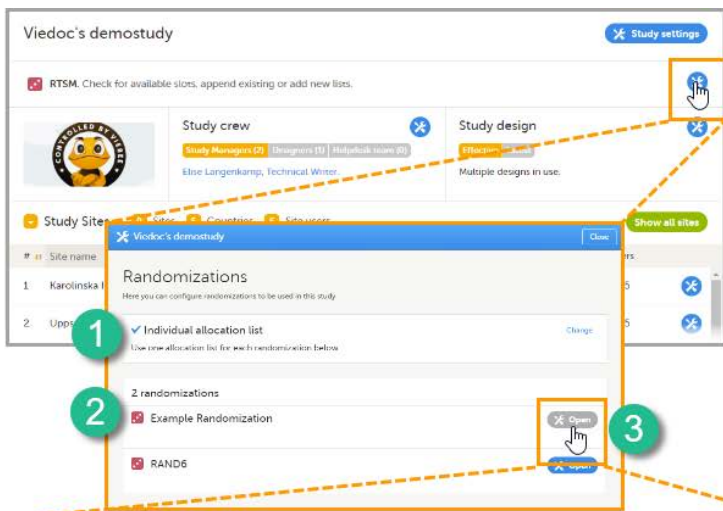
### 3.2 Description of the randomization page

**Note!** The randomization page is only visible for users with the role **Unblinded Statistician**.

Once the randomization mapping has been set up in Viedoc Designer, the **RTSM** field appears for users with the role Unblinded Statistician. When you click the toolbox icon in the **RTSM** field, the Randomizations pop-up opens. Here you can do the following:

1. Choose the type of the allocation list to be used:
  - Individual allocation list - separate allocation lists for each of the randomizations in your study.
  - Global allocation list - one global allocation list for all the randomizations in your study.

**Note!** To be able to use **Logistics**, a Global allocation list must be used.
2. View a list of randomizations that have been added to your study.
3. Open the Randomization page to configure the randomization or view the randomization details.



On the Randomization page, you can view or do the following:

4. View the items, and their code lists, that have been mapped as input factors.
5. View the items, and their code lists, that have been mapped as outcome and blinded outcome.
6. Set up the randomization list by defining:
  - The scope of the randomization list. You can select one of the following options:
    - Study
    - Country
    - Site

**Note!** If you set the scope to *Country* or *Study site*, a separate randomization list for each country or site will be created. In that case, you cannot use *Country* or *Site* respectively as input factor(s).
  - The factors - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the factors are automatically populated from the settings in Viedoc Designer.

- The outcome - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the outcomes are automatically populated from the settings in Viedoc Designer.

7. Optional: set up the allocation list by defining:

- The scope of the allocation list. You can select one of the following options:
  - Study
  - Country
  - Study site

**Note!** If you set the scope to *Country* or *Study site*, a separate allocation list for each country or site has to be uploaded.
- The factors - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the factors are automatically populated from the settings in Viedoc Designer.
- The outcomes - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the outcomes are automatically populated from the settings in Viedoc Designer.

8. Select the randomization method.

9-17. You can test the randomization in demo mode by uploading dummy randomization lists and dummy allocation lists to make sure everything works as expected before randomizing patients in production mode. Click the tab (9) to switch between demo mode and production mode.

10. View the details of the randomization list for the different scopes: the scope (in this example the study) and the status (**Active**, **Inactive** or **Not initiated**). In this field, you can upload the randomization list by clicking **Upload** (not visible in the image). Once a randomization list has been uploaded, icon 11 and 12 appear.

11. Download a template (Excel file) for the randomization list.

12. View the randomization list. An Excel file is downloaded. For a description of the randomization list, see [The randomization list](#).

13. Edit the randomization list. You can select one of the two following options:

- **Add to list** - to upload a randomization list (Excel file) that adds slots to the existing randomization list.
- **Upload a new list** - to upload a randomization list (Excel file) that replaces the existing randomization list. The current list will then be inactivated. This will not affect already randomized subjects.

14. View the details of the allocation lists for the different scopes: the scope (in this example the sites, for each scope a different allocation list needs to be uploaded) and the status (**Active**, **Inactive** or **Not initiated**). In this field, you can upload the randomization list by clicking **Upload**. Once a randomization list has been uploaded, icon 15 and 16 appear.

15. Download a template (Excel file) for the allocation list.

16. View the allocation list. An Excel file is downloaded. For a description of the allocation list, see [The allocation list](#).

17. Edit the allocation list here, if you selected to use **Individual allocation list**. You can select one of the two following options:

- **Add to list** - to upload an allocation list (Excel file) that adds slots to the existing allocation list.
- **Upload a new list** - to upload an allocation list (Excel file) that replaces the existing allocation list. The current list will then be inactivated. This will not affect already randomized subjects.

The numbers in front of the study name and site names in the Randomization List and Allocation List fields (5227, 18716, 18718, and 18951 in the image) are the study identification number and site identification numbers that are generated by the system and used for internal identification of study and sites.

### 3.3 The randomization list

A template randomization list customized for your randomization configuration can be downloaded by clicking **Download template** in the **Randomization List** field (see nr 11 in the image above). For the example shown in the image above, the template randomization list looks as follows:

	A	B	C	D	E	F	G	H	I
1	RANDSEX	RANDSMOKE	RANDGROUP						
2	1	1	1						
3	1	1	2						
4	1	1	3						
5	1	2	1						
6	1	2	2						
7	1	2	3						
8	2	1	1						
9	2	1	2						
10	2	1	3						
11	2	2	1						
12	2	2	2						
13	2	2	3						
14									
29									
30									
31									

Item ID

Code lists

The list shows the factors and outcomes. The Item IDs are displayed as column names, their code lists are displayed in the rows below. Every possible combination of factor(s) and outcome(s) is shown here. The randomization list that you should upload, should contain exactly these Item IDs as column names. It also should contain exactly these combinations of factor(s) and outcome(s), in a randomized manner. Each row represents a slot, the total number of rows in the randomization list equals the total number of slots.

Once the randomization is started, it is possible to view the active randomization list by clicking **View** in the **Randomization List** field (see nr 12 in the image above). An Excel file is downloaded that has the following sheets:

- **Configuration** - summarizes the factors and outcomes and their code lists configured for the randomization.
- **Current distribution** - displays the distribution of randomized subjects over the different factors and treatments.
- **Slots** - lists all the slots, the factors and outcomes, and whether the slot is still available. If the slot has been taken, the subject details, user details (e-mail address) of the clinic user who randomized the subject, and date and time of randomization are also displayed, see the image below.

#	Gender	Gender - Code	Smoker	Smoker - Code	Treatment group	Treatment group - Code	Available	Subject Id	Subject key	User reference	Date and time
RANDSEX	RANDSEXCD	RANDSMOKE	RANDSMOKECD	RANDGROUP	RANDGROUPCD	Available	SubjectId	SubjectKey	UserRef	Datetime	
1	Male	1	Yes	1	A	1	FALSE	215402	KI-05		2018-09-21 02:45:15
2	Male	1	Yes	1	B	2	TRUE				
3	Male	1	Yes	1	C	3	TRUE				
4	Male	1	No	2	A	1	TRUE				
5	Male	1	No	2	B	2	TRUE				
6	Male	1	No	2	C	3	TRUE				
7	Female	2	Yes	1	A	1	TRUE				
8	Female	2	Yes	1	B	2	TRUE				
9	Female	2	Yes	1	C	3	TRUE				
10	Female	2	No	2	A	1	TRUE				
11	Female	2	No	2	B	2	TRUE				
12	Female	2	No	2	C	3	TRUE				

Slot Nr

Factors

Outcomes

Patient and randomization details

### 3.4 The allocation list

If allocation is activated, a file with available slots (kit numbers) should be uploaded for each reference scope (study, country or site), before the first allocation is performed.

A template allocation list customized for your randomization configuration can be downloaded by clicking **Download template** in the **Allocation List** field (see nr 15 in the image above). For the example shown in the image above, the template allocation list looks as follows:



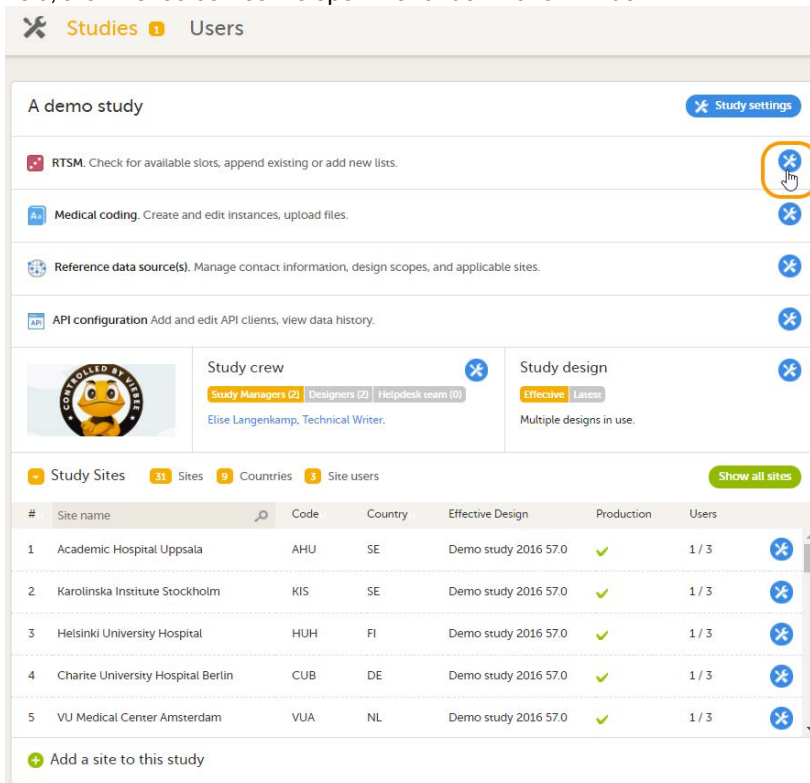
## 4 Step-by-step guides

### 4.1 Configuring a static randomization

**Note!** The randomization can only be configured by users that are assigned the system role **Unblinded Statistician**.

To configure the randomization, follow the steps below.

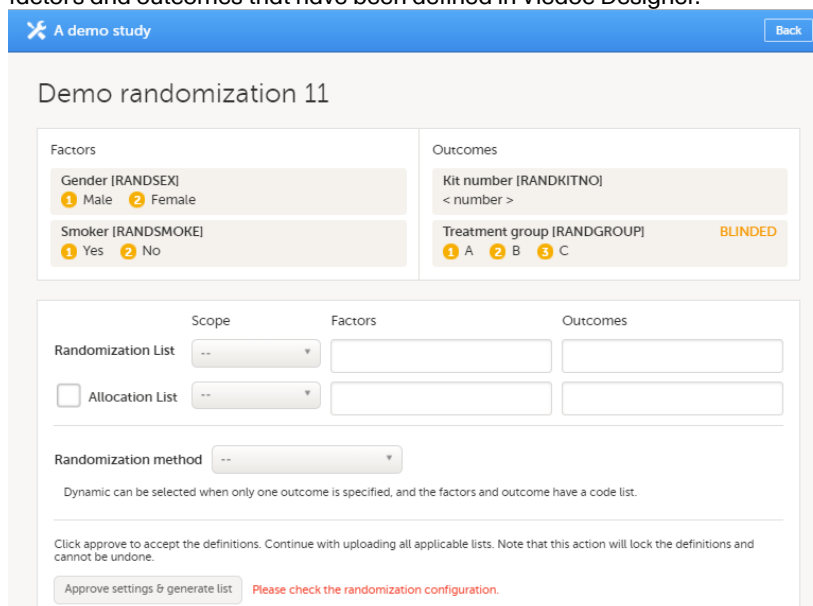
- 1 In Viedoc Admin, go to the study for which you would like to configure the randomization. In the **RTSM** field, click the toolbox icon to open the randomization window.



The screenshot shows the 'A demo study' page in Viedoc Admin. The page has a header with 'Studies' and 'Users' tabs. Below the header, there are several sections: 'Study settings', 'RTSM' (with a toolbox icon circled in red), 'Medical coding', 'Reference data source(s)', 'API configuration', 'Study crew', and 'Study design'. At the bottom, there is a 'Study Sites' table with columns for '#', 'Site name', 'Code', 'Country', 'Effective Design', 'Production', and 'Users'. The table lists five sites: Academic Hospital Uppsala, Karolinska Institute Stockholm, Helsinki University Hospital, Charite University Hospital Berlin, and VU Medical Center Amsterdam.

- 2 Click **Open** to select the randomization you would like to configure.

The Randomization configuration window opens as a pop up. This window also displays the prognostic factors and outcomes that have been defined in Viedoc Designer.



The screenshot shows the 'Demo randomization 11' configuration window. The window has a blue header with 'A demo study' and a 'Back' button. Below the header, there are two main sections: 'Factors' and 'Outcomes'. The 'Factors' section includes 'Gender [RANDSEX]' with options '1 Male' and '2 Female', and 'Smoker [RANDSMOKE]' with options '1 Yes' and '2 No'. The 'Outcomes' section includes 'Kit number [RANDKITNO]' with a '< number >' field, and 'Treatment group [RANDGROUP]' with options '1 A', '2 B', and '3 C', and a 'BLINDED' label. Below these sections, there are three columns: 'Scope', 'Factors', and 'Outcomes'. The 'Randomization List' field has a dropdown menu with '--'. The 'Allocation List' field has a dropdown menu with '--' and a checkbox. The 'Randomization method' field has a dropdown menu with '--'. Below these fields, there is a note: 'Dynamic can be selected when only one outcome is specified, and the factors and outcome have a code list.' At the bottom, there is a 'Click approve to accept the definitions. Continue with uploading all applicable lists. Note that this action will lock the definitions and cannot be undone.' and a 'Approve settings & generate list' button with a red warning: 'Please check the randomization configuration.'

3 In the **Randomization List** field, select:

1. the scope of the randomization list  
and, only if **advanced allocation is not enabled** in Viedoc Designer:
2. the factors that should be balanced for in the randomization,
3. the outcome.

A demo study Back

### Demo randomization 11

Factors	Outcomes
Gender [RANDSEX] 1 Male 2 Female	Kit number [RANDKITNO] < number >
Smoker [RANDSMOKE] 1 Yes 2 No	Treatment group [RANDGROUP] <b>BLINDED</b> 1 A 2 B 3 C

Scope	Factors	Outcomes
Randomization List: Study	Gender x Smoker x	Kit number Treatment group
<input type="checkbox"/> Allocation List: --		

Randomization method: --

Dynamic can be selected when only one outcome is specified, and the factors and outcome have a code list.

Click approve to accept the definitions. Continue with uploading all applicable lists. Note that this action will lock the definitions and cannot be undone.

Approve settings & generate list Please check the randomization configuration.

4 If you want to use allocation, select the **Allocation list** checkbox, select the scope of the allocation list, and, only if **advanced allocation is NOT enabled** in Viedoc Designer, the input factors, and the desired outcome (for example, kit number). Based on the allocated treatment, a kit number will then be assigned to the subject.

A demo study Back

### Demo randomization 11

Factors	Outcomes
Gender [RANDSEX] 1 Male 2 Female	Kit number [RANDKITNO] < number >
Smoker [RANDSMOKE] 1 Yes 2 No	Treatment group [RANDGROUP] <b>BLINDED</b> 1 A 2 B 3 C

Scope	Factors	Outcomes
Randomization List: Study	Gender x Smoker x	Treatment group x
<input checked="" type="checkbox"/> Allocation List: Study site	Treatment group x	Kit number x

Randomization method: --

Dynamic can be selected when only one outcome is specified, and the factors and outcome have a code list.

Click approve to accept the definitions. Continue with uploading all applicable lists. Note that this action will lock the definitions and cannot be undone.

Approve settings & generate list Please check the randomization configuration.

5 From the **Randomization method** drop-down list, select **Static randomization**.

6 Click **Approve settings & generate list**.  
The randomization page reloads and the randomization lists and allocations lists can be uploaded.

## 4.2 Configuring a randomization list for static randomization

The randomization list initially indicates status **Not initiated**. A randomization list with the available slots for randomization should be uploaded to enable randomization.



#### 4.2.1 Downloading a template randomization list

You can download a template slot list in Excel from Viedoc Admin, or you can create one yourself. To download the template slot list from Viedoc, click **Download template**.

The screenshot displays the Viedoc Admin interface for a demo study. At the top, there is a blue header with 'A demo study' and a 'Back' button. The main content area is titled 'Demo randomization 8'. It is divided into two columns: 'Factors' and 'Outcomes'. The 'Factors' column includes 'Gender [RANDSEX]' with options 1 Male and 2 Female, and 'Smoker [RANDSMOKE]' with options 1 Yes and 2 No. The 'Outcomes' column includes 'Kit number [RANDKITNO]' with a placeholder '< number >' and 'Group [RANDGROUP]' with options 1 A, 2 B, and 3 C, and a 'BLINDED' status. Below these are two rows of configuration: 'Randomization List' with 'Scope' set to 'Study', 'Factors' set to 'RANDSEX, RANDSMOKE,', and 'Outcomes' set to 'RANDGROUP,'; and 'Allocation List' with 'Scope' set to 'Site', 'Factors' set to 'RANDGROUP,', and 'Outcomes' set to 'RANDKITNO,'. A 'Randomization method' is set to 'Static'. At the bottom, there are two tabs: 'Demo mode' (selected) and 'Production'. Under 'Demo mode', there are two sections: 'Randomization List' and 'Allocation List'. The 'Randomization List' section shows one entry: '5179 A demo study' with a checkmark and 'Not initiated' status, and a '+ Upload' button. A 'Download template' button is circled in orange. The 'Allocation List' section shows three entries for different hospitals: '17999 SUH Sahlgrenska University Hospital Gothenburg', '18001 LIH Linköping University Hospital', and '18003 OUH Örebro University Hospital', each with a checkmark, 'Not initiated' status, and a '+ Upload' button. A 'Download template' button is also present for this section.

#### 4.2.2 Uploading a randomization list

To upload a randomization list, follow the steps below.

1

Click **Upload**.

A demo study Back

### Demo randomization 8

Factors		Outcomes	
Gender [RANDSEX]	1 Male 2 Female	Kit number [RANDKITNO]	< number >
Smoker [RANDSMOKE]	1 Yes 2 No	Group [RANDGROUP]	1 A 2 B 3 C <b>BLINDED</b>

	Scope	Factors	Outcomes
Randomization List	Study	RANDSEX, RANDSMOKE,	RANDGROUP,
Allocation List	Site	RANDGROUP,	RANDKITNO,

Randomization method Static

**Demo mode** Production

#### Randomization List Download template

5179 A demo study	Not initiated	<b>Upload</b>
-------------------	---------------	---------------

#### Allocation List Download template

17999 SUH Sahlgrenska University Hospital Gothenburg	Not initiated	<b>Upload</b>
18001 LIH Linköping University Hospital	Not initiated	<b>Upload</b>
18003 OUH Örebro University Hospital	Not initiated	<b>Upload</b>

2

Select the file containing the slot list and click **Open**. The file will be uploaded.

#### 4.2.3 Viewing a randomization list

Once the randomization list has been uploaded, the status of the randomization will turn into **Active**. From that moment, the randomization list (displaying which slots are taken) can be downloaded in Excel format by clicking **View**.

A demo study Back

## Demo randomization 8

**Factors**

Gender [RANDSEX]  
1 Male 2 Female

Smoker [RANDSMOKE]  
1 Yes 2 No

**Outcomes**

Kit number [RANDKITNO]  
< number >

Group [RANDGROUP] **BLINDED**  
1 A 2 B 3 C



Scope: Study    Factors: RANDSEX, RANDSMOKE,    Outcomes: RANDGROUP,

Allocation List: Site    RANDGROUP,    RANDKITNO,






Randomization method: Static

Demo mode: **Production**

**Randomization List** Download template

5180 A demo study ✓ Active		
-------------------------------	---	---

**Allocation List** Download template

13845 AHU Academic Hospital Uppsala ✓ Active		
13847 KIS Karolinska Institute Stockholm ✓ Active		
13849 HUH Helsinki University Hospital ✓ Not initiated	 Upload	

### 4.2.4 Editing a randomization list

To edit an active randomization list, follow the steps below.

- 1 Click the toolbox icon.

A demo study Back

## Demo randomization 8

**Factors**

Gender [RANDSEX]  
1 Male 2 Female

Smoker [RANDSMOKE]  
1 Yes 2 No

**Outcomes**

Kit number [RANDKITNO]  
< number >

Group [RANDGROUP] **BLINDED**  
1 A 2 B 3 C



Scope: Study    Factors: RANDSEX, RANDSMOKE,    Outcomes: RANDGROUP,

Allocation List: Site    RANDGROUP,    RANDKITNO,






Randomization method: Static

Demo mode: **Production**

**Randomization List** Download template

5180 A demo study ✓ Active		
-------------------------------	--	---

**Allocation List** Download template

13845 AHU Academic Hospital Uppsala ✓ Active		
13847 KIS Karolinska Institute Stockholm ✓ Active		
13849 HUH Helsinki University Hospital ✓ Not initiated	 Upload	

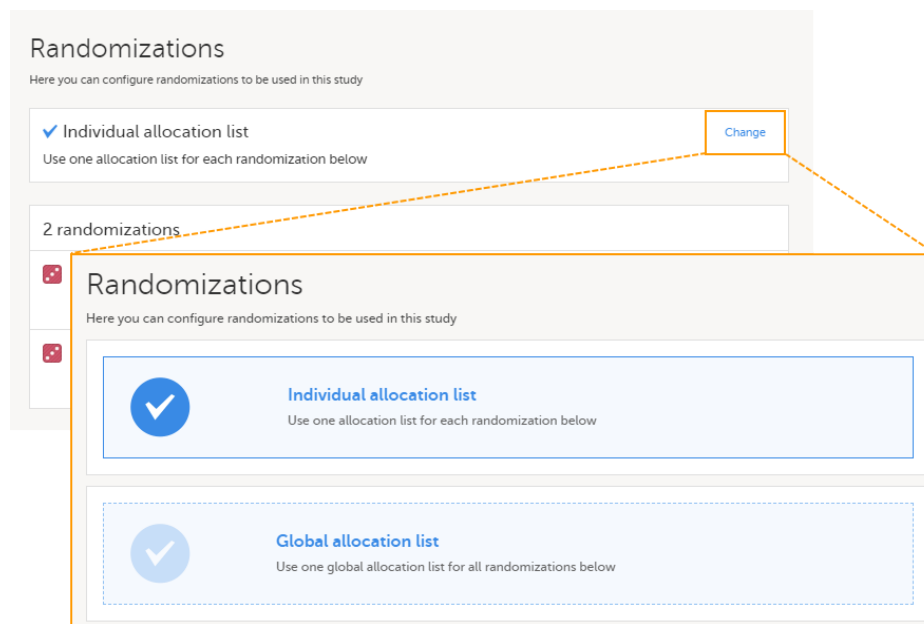
- 2 Select: **Add to list** or **Upload new list**.
  - **Add to list** - adds new slots to the existing slot list. Empty spots in the existing slot list will still be allocated.
  - **Upload new list** - discards the existing slot list and replaces it with the new slot list.
- 3 Select the file containing the slot list and click **Open**.  
The file will be uploaded.

## 4.3 Configuring the allocation list

There are two different options for the allocation list, as follows:

- [Individual allocation list](#) - separate allocation lists are used for each defined randomization. If the allocation list is not uploaded, the subject can be randomized in Viedoc Clinic, but no kit is allocated.
- [Global allocation list](#) - one global allocation list is used for all the defined randomizations. This is available only if **advanced allocation** is enabled in Viedoc Designer (for details on advanced allocation settings in Viedoc Designer, see [Setting up the randomization](#) lesson).  
To be able to use **Logistics**, a Global allocation list must be used.  
If the allocation list is not uploaded, or, in case of using Logistics, if no kits are available at the current defined scope (*Study / Country / Study Site*), when trying to perform the allocation in Viedoc Clinic, the system will respond with *No slots found for allocation*.  
Setting up a Global allocation list is described in [Configuring the Global allocation list](#).

This is set up under the **RTSM** settings in Viedoc Admin, as illustrated in the image below:



### 4.3.1 Individual allocation list

If individual allocation list(s) are used for each randomization, the allocation list will be uploaded separately for each defined randomization, as described below.

#### 4.3.1.1 Downloading a template allocation list

You can download a template slot list in Excel from Viedoc Admin, or you can create one yourself. To download the template allocation list from Viedoc, click **Download template**.

## Demo randomization 8

Factors		Outcomes	
Gender [RANDSEX] 1 Male 2 Female		Kit number [RANDKITNO] < number >	
Smoker [RANDSMOKE] 1 Yes 2 No		Group [RANDGROUP] <b>BLINDED</b> 1 A 2 B 3 C	
Randomization List	Scope Study	Factors RANDSEX, RANDSMOKE,	Outcomes RANDGROUP,
Allocation List	Site	RANDGROUP,	RANDKITNO,
Randomization method	Static		

Demo mode **Production**

## Randomization List

Download template

5180 A demo study  
✓ Active

## Allocation List

Download template

13845 AHU Academic Hospital Uppsala  
✓ Active13847 KIS Karolinska Institute Stockholm  
✓ Active13849 HUH Helsinki University Hospital  
✓ Not initiated

+ Upload

13851 CUB Charite University Hospital Berlin  
✓ Not initiated

+ Upload

**4.3.12** Uploading an allocation list

For an example of the allocation list to be uploaded, see [The allocation list](#).

To upload an allocation list, follow the steps below.

1

Click **Upload**.

A demo study Back

### Demo randomization 8

**Factors**

Gender [RANDSEX]  
1 Male 2 Female

Smoker [RANDSMOKE]  
1 Yes 2 No

**Outcomes**

Kit number [RANDKITNO]  
< number >

Group [RANDGROUP] **BLINDED**  
1 A 2 B 3 C

**Randomization List** Scope: Study Factors: RANDSEX, RANDSMOKE, Outcomes: RANDGROUP,

**Allocation List** Site: RANDGROUP, RANDKITNO,

Randomization method: Static

Demo mode: **Production**

**Randomization List** Download template

5180 A demo study ✓ Active		
-------------------------------	--	--

**Allocation List** Download template

13845 AHU Academic Hospital Uppsala ✓ Active		
13847 KIS Karolinska Institute Stockholm ✓ Active		
13849 HUH Helsinki University Hospital ✓ Not initiated		
13851 CUB Charite University Hospital Berlin ✓ Not initiated		
13853 VUA VU Medical Center Amsterdam ✓ Not initiated		

2

Select the file containing the slot list and click **Open**. The file will be uploaded.

#### 4.3.1.3 Viewing an allocation list

The allocation list can be viewed in a similar way as the randomization list, see [Viewing a randomization list](#).

#### 4.3.1.4 Editing an allocation list

The allocation list can be edited in a similar way as the randomization list, see [Editing a randomization list](#).



Configuring a dynamic randomization

# Configuring a dynamic randomization

Published by Viedoc System 2023-10-09

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This lesson describes how to configure a dynamic randomization in **Viedoc Admin**.

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## 1 Introduction to randomizations

### 1.1 About the randomization service

Viedoc offers support for randomization. Subjects can be randomized using:

- **static randomization**: randomization based on a randomized list,
- **dynamic randomization** (Pocock and Simon): randomization based on an algorithm.

Dynamic randomization ensures a more even distribution of subjects across the treatment groups, with regard to prognostic factors that might influence the effect of treatment on the subjects.

The randomization in Viedoc is configured in a similar way for static and dynamic randomization. The main difference is that for static randomization, a list with outcomes (randomization numbers, treatment groups, and so on) - the randomization list - is created and uploaded by the user, while for dynamic randomization, an algorithm is used to assign subjects to a treatment group and the randomization list is created by the system.

It is possible to upload a separate allocation list that allocates an Investigational Product (IP) to the subject. When the subject is randomized, Viedoc informs the clinic user which IP should be given to the subject. The allocation list is most commonly used in double-blind studies. Uploading of the allocation list is done in a similar way for static and dynamic randomization.

## 1.2 Terminology

Term	Definition
RTSM	Randomization and Trial Supply Management.
Blinded role	A role that does not know which treatment the subject is receiving. Most roles in a clinical trial should be blinded.
Unblinded Statistician	<p>A system role that can configure the randomization in Viedoc Admin.</p> <p>The Unblinded Statistician sees which subjects are assigned to which treatments, and should therefore not have any role in the study where he/she should not know this information. An Unblinded Statistician can never again work in a blinded role within that study.</p>
Randomization list	A list for allocating subjects to treatments or groups. The randomization list shows all available slots in the randomization. When randomization has started (that is, when the first subject has been randomized), the randomization list also shows which subjects have been assigned to which treatment or group.
Allocation list	<p>A list for allocating <a href="#">IP</a> to subjects. The allocation list shows all available IPs. When randomization has started, the allocation list also shows which IPs have been assigned to which subjects. Advanced allocation can be set up and for this there are two options for the allocation list(s):</p> <ul style="list-style-type: none"><li>▪ Use individual allocation list for each randomization.</li><li>▪ Use one global allocation list for all your randomizations.</li></ul> <p><b>Note!</b> To be able to use <b>Logistics</b>, a Global allocation list must be used.</p>
Scope	<p>Defines the scope from which a randomization slot or an IP should be selected. One of the following scopes can be chosen:</p> <ul style="list-style-type: none"><li>▪ Study</li><li>▪ Country</li><li>▪ Site</li></ul>
Factor (Prognostic factor)	Items that might influence the effect of treatment on the subjects, and that are to be used as input when randomizing the subject. For example sex or age. Viedoc supports the use of drop-down lists, radio buttons, integer and free text data types as input items.
Outcome	Items to be populated by the randomization service, for example treatment group.
Blinded outcome	Items to be populated by the randomization service, that should remain blinded until after the subject has been unblinded or emergency unblinded for a specific subject. These items will not be visible for any user in the system, except for the Unblinded Statistician who can see them in Viedoc Admin, or until an emergency unblinding was performed (for details on how the emergency unblinding is performed in Viedoc Clinic, see <a href="#">Randomization, allocation and emergency unblinding</a> ).

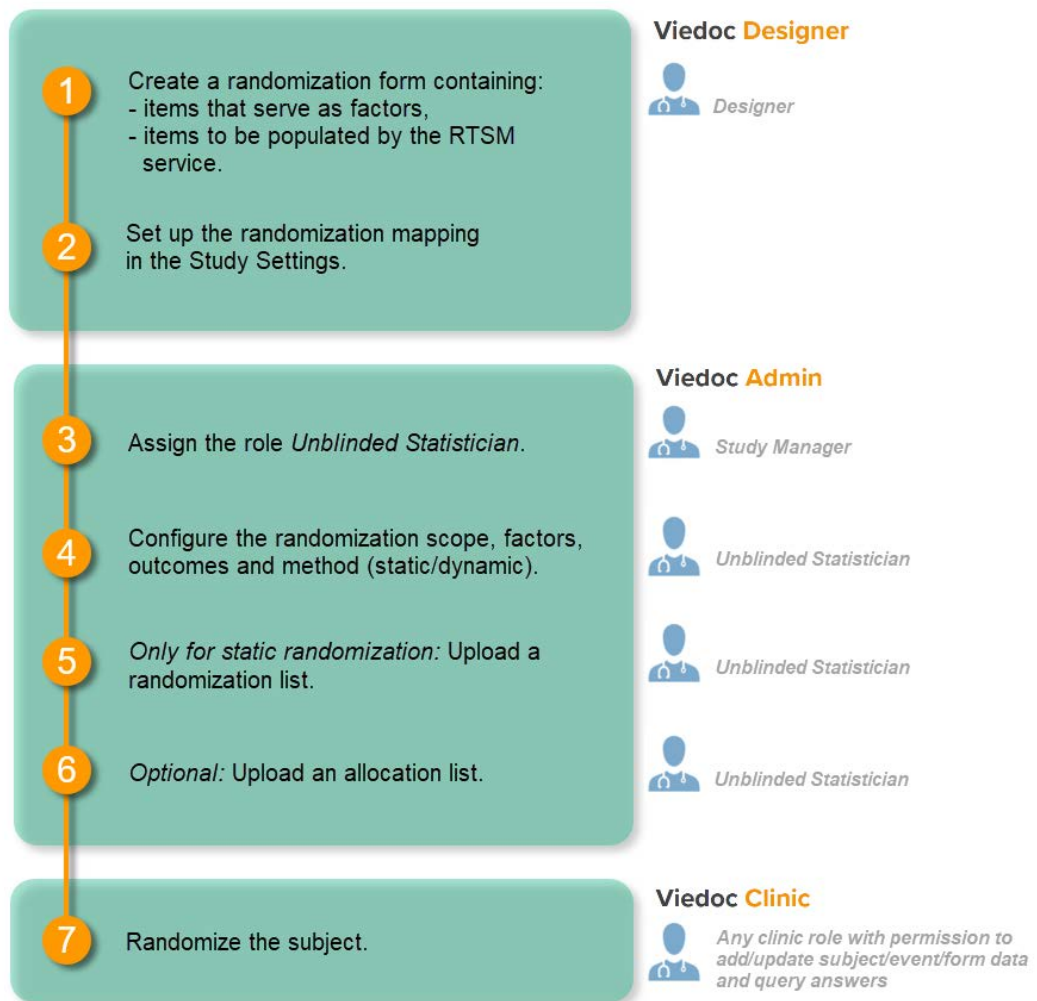
## 1.3 Workflow

Randomizations are configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps, depending on the allocation configuration type as described below:

- Randomization, optionally together with allocation performed at the same time as the randomization within the same form. In this case the form is locked (and therefore not possible to be edited) after the randomization is performed in Viedoc Clinic.

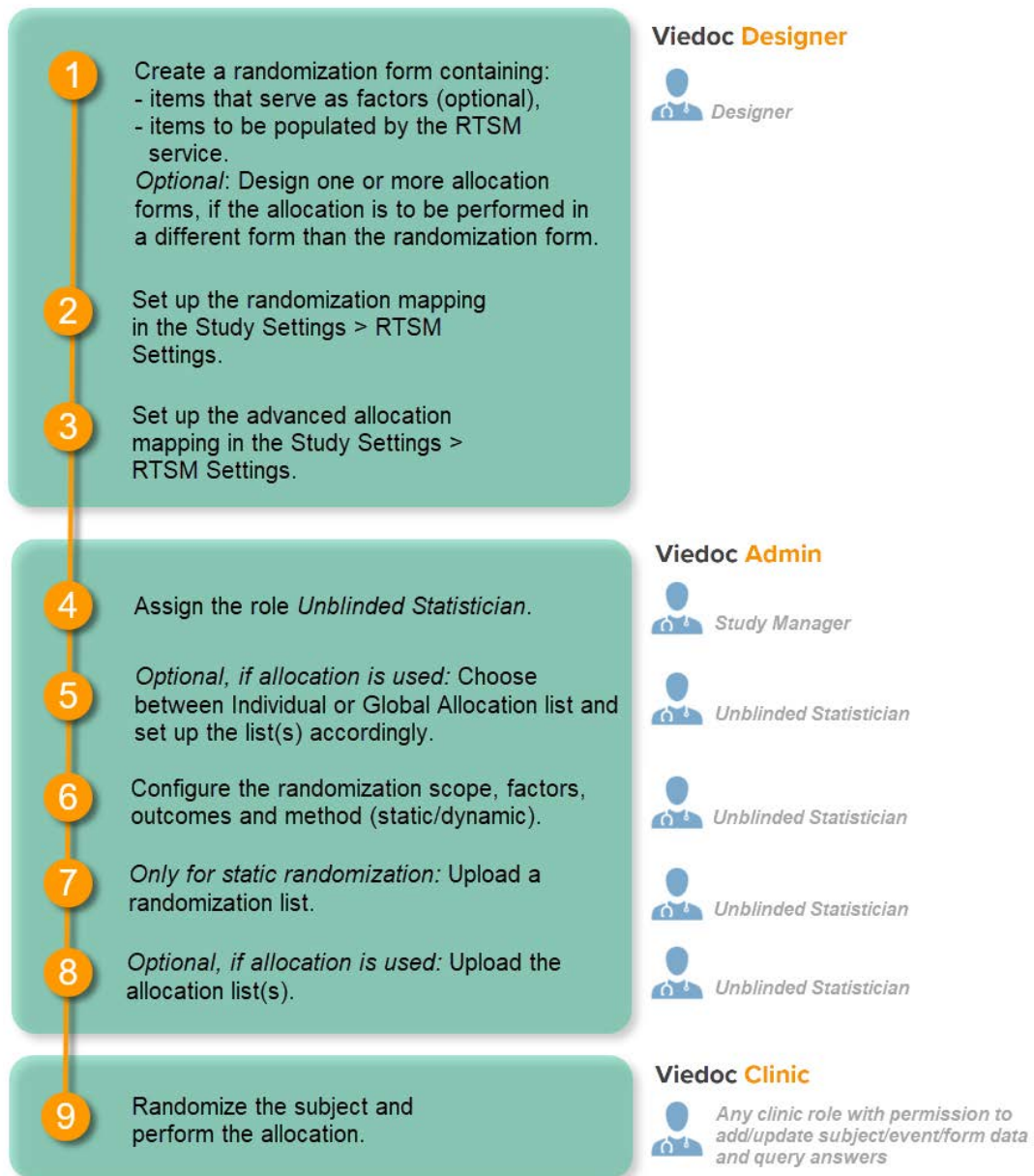


The configuration workflow in this case looks as illustrated in the following image:



- Randomization, optionally together with **advanced allocation** allows you to set up the allocation in a more flexible way, including:
  - Configuring individual forms for randomization and allocation, to keep the two steps separated in the study workflow
  - The possibility to perform multiple allocations at different visits during the study
  - The possibility to replace an already performed allocation with a new allocation
  - The possibility to undo an already performed allocation

The configuration workflow in this case looks as illustrated in the following image:



Detailed instructions regarding these steps are described in:

- [Setting up the randomization](#) in Viedoc Designer
- [Configuring a static randomizations](#) in Viedoc Admin
- [Configuring a dynamic randomization](#) in Viedoc Admin (**this lesson!**)

An example of how to configure a dynamic randomization is described in detail in the following lesson:

- [A use case for dynamic randomization](#)

For a video tutorial on how to configure a static list randomization and a dynamic randomization, see:

- [Randomization video tutorial](#)

## 2 Study license and randomization

**Important!** The randomization feature must be included in your study license in order for the randomization configuration to be available in production mode. You can still configure a randomization in demo mode without a license.

On the [randomization page](#), under the **Demo tab**, you can create the configuration and perform all the configuration actions for the dynamic randomization, and select the **Edit settings and generate new list** link.

If your study license has the randomization feature included, it will be shown on the **Study settings** page under **Included features** on the **Settings** tab:

The screenshot shows the 'Study settings' page for 'RandStudy2'. At the top, there is a blue header with the 'RandStudy2' logo and a 'Close' button. Below the header, the page title 'Study settings' is followed by the subtitle 'Here you can set settings for study.' A navigation bar contains tabs for 'Settings', 'Date & time format', 'Medical Coding', 'Import ODM File', 'Documentation', and 'Logs'. The 'Settings' tab is active. The main content area is divided into several sections: 1. 'Ongoing, FPA 2023-04-25 Full functionality.' and 'Valid license' status indicators. 2. 'Included features' section with icons for 'ViedocMe', 'Logistics', 'Connect', and 'Randomization'. The 'Randomization' icon is highlighted with an orange box. 3. 'Study name' (RandStudy2), 'Sponsor Code' (RS2), 'CRO Code' (RFT), and 'Reference ID' (2376890) fields. 4. 'Study Logo' upload area with a note: 'PNG, GIF or JPG files of maximum 180 px width and 90 px height.' and an 'Upload a file' button. 5. 'Study Type' (Pharmaceutical - Post-approval), 'Sponsor Type' (Government agency), and 'Study Phase' (Phase 0) dropdown menus. 6. 'Therapeutic Area' (Dermatology/Plastic Surgery) dropdown menu. 7. 'Expected number of subjects' (Screened and Enrolled) and 'Expected end date of enrollment period' (dd MMM yyyy) fields. 8. 'Study access' section with 'Password expiration time' (90 days) and a checkbox for 'Require two-factor authentication'. 9. 'Clinic roles to be administered by Site Manager' with checkboxes for Investigator, Monitor, Data Manager, Study IP Manager, and Site IP Manager. 10. 'Helpdesk team' section. 11. 'ViedocMe' section with checkboxes for 'Allow reminders in ViedocMe to be sent as Email/Text message', 'Force subject to change password at first time login', 'Use the new application design for training sites', and 'Use the new application design for production sites'. A 'Show more options' link is at the bottom left.

If your study either does not have a license key (Reference ID), or has a license key that does not include the randomization feature, on the [randomization page](#), under the **Production** tab:

- A message is shown informing you that the randomization feature is not included in the license:

Factors

Sex [SEX3]  
 1 Male 2 Female

Outcomes

Treatment [TREAT2] **BLINDED**  
 1 Placebo 2 Allocation

Randomization List

Scope	Factors	Outcomes
Study	SEX3,	TREAT2,
Country	ITEM,	KITNO, EXPIRYDATE,

Randomization method: Dynamic (Pocock/Simon)

Demo mode | **Production**

Note! The Randomization feature is not included in this study license

Randomization List

RandStudy1 (Production)  
 ✓ Not initiated

Allocation List

Sweden (Production)  
 ✓ Not initiated

- The **Create configuration** and **Edit configuration** links are not available.

For more information on licensing, see [Overview of Viedoc](#)

## 3 Dynamic randomization

### 3.1 What is dynamic randomization?

For dynamic randomization, the randomization service in Viedoc allocates a treatment to the subject based on previously given information. That means that the probability of a subject getting assigned to a treatment will change depending on previous assignments. This way, dynamic randomization ensures a more even distribution of the subjects across factors and treatments for each site.

For dynamic randomization, you do not need to upload a randomization list in the beginning of the study. Instead, you need to configure an algorithm for how the probability of assignments will be calculated. The randomization service in Viedoc then creates a randomization list while assigning subjects to treatments.

Viedoc offers the Pocock and Simon method for dynamic randomization. The Pocock and Simon method aims to minimize imbalance in the distribution of subjects across the treatment groups, with regard to prognostic factors that might influence the effect of treatment on the subjects. It does so by hypothetically assigning a new subject to each of the treatment groups and calculating the amount of imbalance for each assignment. The method then assigns the subject to the treatment group with the smallest imbalance.

When configuring a Pocock and Simon randomization, it is possible to set the relative importance of the factors, and the desired division of treatments to be allocated. Two different variation methods can be chosen: Range and Range squared, see [Concepts and terminology for dynamic randomizations](#) for more information.

The original statement of the Pocock and Simon method was deterministic, random number values were only used in tie-breaking situations. The randomization service in Viedoc is based on a modified Pocock and Simon method in which every randomization decision depends on a random number. For this, Donald E. Knuth's subtractive random number generator algorithm is used, see [References](#).

### 3.2 References

The underlying theory for the dynamic randomization method that is implemented in Viedoc is described in the following articles:

- Pocock S.J. and Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics* 1975;31:103-115.
- Miller E. Probability sharing in a modified Pocock-Simon method. 12th Int. Conf. of S.C.M.A Jun 22, 2005.

The Donald E. Knuth's subtractive random number generator algorithm that is used in the modified Pocock and Simon method implemented in Viedoc is described in the following article:

- Donald. E. Knuth. *The Art of Computer Programming, volume 2: Seminumerical Algorithms*. Addison-Wesley, Reading, MA, second edition, 1981.

### 3.3 Concepts and terminology for dynamic randomizations

In Viedoc, the same annotations as in the above mentioned articles are used.

Term	Description
Factor weight	<p>The relative importance of a factor when calculating imbalance, set as an integer value greater than zero.</p> <p>For example, if it is more important to achieve balance in the factor <i>Gender</i> than in the factor <i>Age</i>, then a factor weight of 2 could be set on <i>Gender</i> and a factor weight of 1 set on <i>Age</i>.</p>
Outcome weight	<p><b>Allocation ratio.</b> The desired division of treatments to be allocated.</p> <p>For example, if we have three treatments, A, B and C, and we would like treatment A to be allocated 50% of the time, and treatment B and C 25% of the time respectively, we would set the allocation ratio as follows: Treatment A: 2, Treatment B: 1, and Treatment C: 1.</p>
D	<p>The amount of variation in the set of values for a factor, that is, the imbalance for one factor.</p> <p>The amount of variation can be calculated as:</p> <ul style="list-style-type: none"> <li>▪ Range - the difference between the highest and the lowest values in the set.</li> <li>▪ Range Squared - the square of the range.</li> </ul> <p><b>Tip!</b> Range square increases the spread of the distribution and may be useful if you have many factors.</p> <p><b>Note!</b> When calculating D, the allocation ratio is taken into account. A treatment that should be allocated more often (that is, has a higher outcome weight) has its D reduced so as to favour the treatment.</p>
G	<p>The total amount of imbalance across all factors.</p> <p>G is calculated by multiplying D for each factor with its factor weight, and then summing this up for all factors. In other words, G is calculated as the weighted sum of <math>\{d_{ik}\}</math>, where <math>d_{ik}</math> is the lack of balance among treatment assignments. The weighted sum is used when some prognostic factors are considered more important than others.</p> <p>If it is more important to obtain balance across a certain factor, this factor will get a higher factor weight. Thus its imbalance will have a larger impact on the G, which will make the treatment assignment leading to that specific G more unfavourable.</p> <p>If D is calculated as range square, the range is squared before any factor weight is applied.</p>

Term	Description
P (p)	<p>The probability with which the treatment that minimizes imbalance is assigned. The probability determines the extent to which one wishes to favour the treatment group that would lead to the smallest imbalance.</p> <p>During the randomization, the probability P for each treatment assignment is calculated, based on a probability cut-off. This probability cut-off (referred to as p below) is a static decimal between 0 and 1 that is provided by a statistician. In Viedoc, the probability cut-off has to be entered as x/1000. So for a p of 0.8 (80%), the number 800 should be entered.</p> <p>During randomization, P for each treatment will be distributed as follows: (N = number of treatments, p = probability cut-off)</p> <ul style="list-style-type: none"> <li>▪ If the Gs are the same for all treatment assignments, then the probability will be the same for each treatment: <math>P=p/N</math>.</li> <li>▪ If one treatment has the lowest G, then it will have its probability P as p. The remaining treatments will split the remaining probability: <math>P=(1 - p)/(N - 1)</math></li> <li>▪ If one or more treatments share the lowest G value, then Viedoc first calculates what the remaining non-favoured treatments will get and then splits the remainder between the favoured treatments.</li> </ul>
Random	A random number between 0 and 1, generated using Donald E. Knuth's subtractive random number generator algorithm.
seed	A value that is used to initialize the random number generator and that is based on the number of ticks to represent the current date.

### 3.4 Calculations behind the scenes

In the section [A use case for dynamic randomization](#), a detailed example of how to configure a dynamic randomization is provided. This use case example also describes the algorithm, and the calculations that are executed by Viedoc in order to assign a subject to a treatment group.

## 4 Working with randomizations in Viedoc Admin

### 4.1 Description of the randomization page

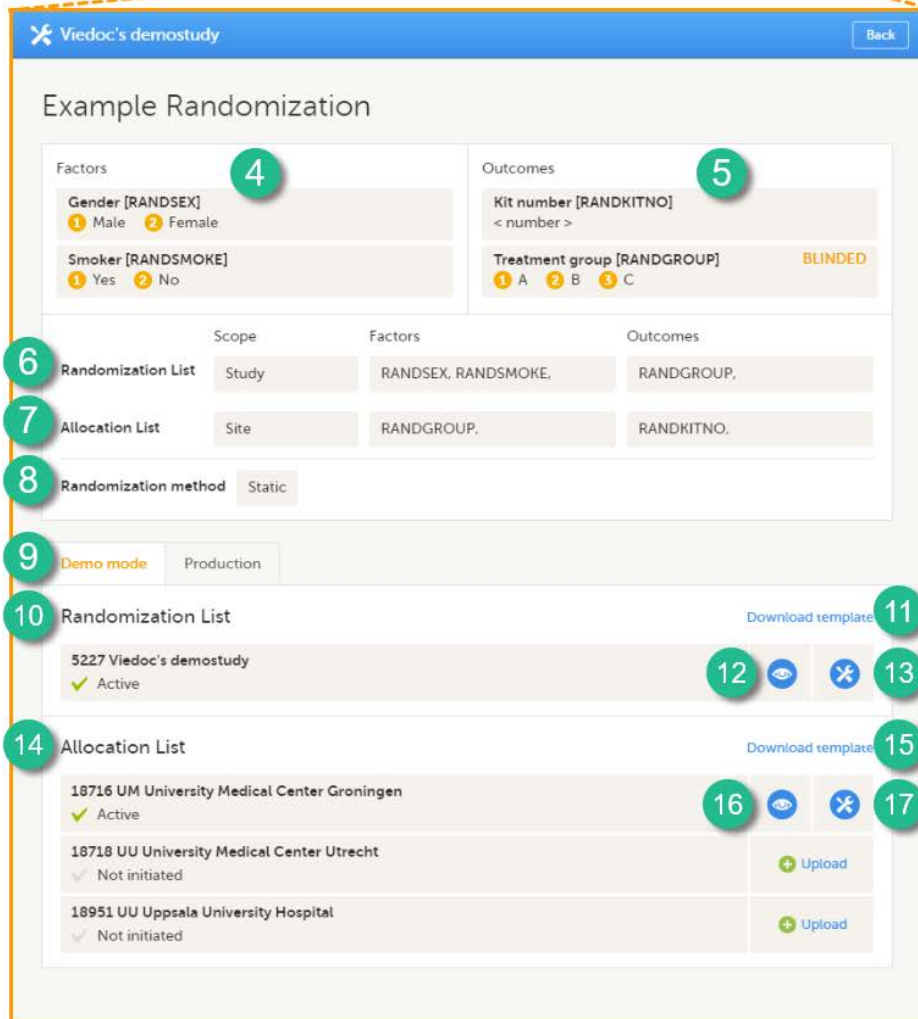
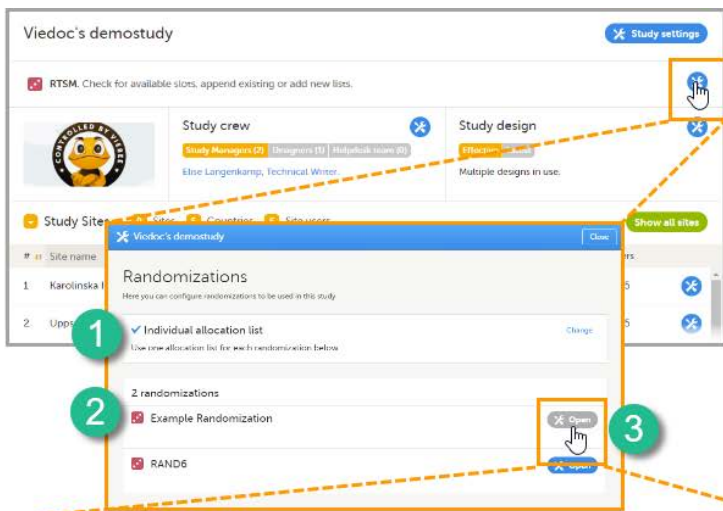
**Note!** The randomization page is only visible for users with the role **Unblinded Statistician**.

Once the randomization mapping has been set up in Viedoc Designer, the **RTSM** field appears for users with the role Unblinded Statistician. When you click the toolbox icon in the **RTSM** field, the Randomizations pop-up opens. Here you can do the following:

1. Choose the type of the allocation list to be used:
  - Individual allocation list - separate allocation lists for each of the randomizations in your study.
  - Global allocation list - one global allocation list for all the randomizations in your study.

**Note!** the upcoming Drug logistics feature will require a Global allocation list to be used.
2. View a list of randomizations that have been added to your study.
3. Open the Randomization page to configure the randomization or view the randomization details.

**Note!** If no randomization configuration is created, it is not possible to randomize a patient in Viedoc Clinic.



On the Randomization page, you can view or do the following:

4. View the items, and their code lists, that have been mapped as input factors.
5. View the items, and their code lists, that have been mapped as outcome and blinded outcome.
6. Set up the randomization list by defining:
  - The scope of the randomization list. You can select one of the following options:
    - Study
    - Country
    - Site

**Note!** If you set the scope to *Country* or *Study site*, a separate randomization list for each country or site will be created. In that case, you cannot use *Country* or *Site* respectively as input factor(s).
  - The factors - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the factors are automatically populated from the settings in Viedoc Designer.

- The outcome - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the outcomes are automatically populated from the settings in Viedoc Designer.

7. Optional: set up the allocation list by defining:

- The scope of the allocation list. You can select one of the following options:
  - Study
  - Country
  - Study site

**Note!** If you set the scope to *Country* or *Study site*, a separate allocation list for each country or site has to be uploaded.
- The factors - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the factors are automatically populated from the settings in Viedoc Designer.
- The outcomes - only if the advanced allocation is not enabled in Viedoc Designer (see [Setting up the randomization](#) lesson in the Viedoc Designer User Guide for details on advanced allocation). If advanced allocation is enabled, then the outcomes are automatically populated from the settings in Viedoc Designer.

8. Select the randomization method.

9-17. You can test the randomization in demo mode by uploading dummy randomization lists and dummy allocation lists to make sure everything works as expected before randomizing patients in production mode. Click the tab (8) to switch between demo mode and production mode.

10. View the details of the randomization list for the different scopes: the scope (in this example the study) and the status (**Active**, **Inactive** or **Not initiated**). In this field, you can upload the randomization list by clicking **Upload** (not visible in the image). Once a randomization list has been uploaded, icon 11 and 12 appear.

11. Download a template (Excel file) for the randomization list.

12. View the randomization list. An Excel file is downloaded. For a description of the randomization list, see [The randomization list](#).

13. Edit the randomization list. You can select one of the two following options:

- **Add to list** - to upload a randomization list (Excel file) that adds slots to the existing randomization list.
- **Upload a new list** - to upload a randomization list (Excel file) that replaces the existing randomization list. The current list will then be inactivated. This will not affect already randomized subjects.

14. View the details of the allocation lists for the different scopes: the scope (in this example the sites, for each scope a different allocation list needs to be uploaded) and the status (**Active**, **Inactive** or **Not initiated**). In this field, you can upload the randomization list by clicking **Upload**. Once a randomization list has been uploaded, icon 15 and 16 appear.

15. Download a template (Excel file) for the allocation list.

16. View the allocation list. An Excel file is downloaded. For a description of the allocation list, see [The allocation list](#).

17. Edit the allocation list here, if you selected to use **Individual allocation list**. You can select one of the two following options:

- **Add to list** - to upload an allocation list (Excel file) that adds slots to the existing allocation list.
- **Upload a new list** - to upload an allocation list (Excel file) that replaces the existing allocation list. The current list will then be inactivated. This will not affect already randomized subjects.

The numbers in front of the study name and site names in the Randomization List and Allocation List fields (5228, 18213, 18215, and 18217 in the image) are the study identification number and site identification numbers that are generated by the system and used for internal identification of study and sites.

## 4.2 The randomization list

Once the randomization is started, it is possible to view the randomization list by clicking **View** in the **Randomization List** field (see nr 12 in the image above). An Excel file is downloaded that has the following sheets:

- **Configuration** - summarizes the factors and outcomes and their code lists configured for the randomization, and the randomization details (randomization method, variation method, probability, maximum number of slots per list, factor weights and allocation ratio).
- **Current distribution** - displays the distribution of randomized subjects over the different factors and treatments.
- **Slots** - one row for each randomized subject, listing:



- the details of the randomization: factors and outcomes, subject details, user details (e-mail address) of the clinic user who randomized the subject, and date and time of randomization,
- the details of the applied algorithm: variation method, probability P, factor weights, allocation ratio, maximum number of slots per list, Gs (the total amount of imbalance for each possible assignment), Ps (the probability P for each possible assignment), Random (a random number between 0 and 1, generated using Donald E. Knuth's subtractive random number generator algorithm) and Seed (a value used to initialize the random number generator, based on the number of ticks to represent the current date). See the image below.

The screenshot shows a spreadsheet with multiple tabs. The 'Slots' tab is active, displaying a table with columns A through L. The table contains patient information such as Gender, Smoker status, and Treatment group. Below this, there are callouts for 'Slot nr.', 'Factors', 'Outcomes', and 'Patient and randomization details'. Another section shows 'Dynamic randomization algorithm details' with columns M through U, detailing parameters like Variation method, P, Factor weights, Allocation ratio, Max slots, Gs, Ps, Random, and Seed.

### 4.3 The allocation list

If allocation is activated, a file with available slots (kit numbers) should be uploaded for each scope (study, country or site), before the first subject can be randomized.

A template allocation list customized for your randomization configuration can be downloaded by clicking **Download template** in the **Allocation List** field (see nr 15 in the image above). For the example shown in the image above, the template allocation list looks as follows:

The screenshot shows a spreadsheet with columns A through I. Column A is labeled 'RANDGROUP' and column B is labeled 'RANDKITNO'. The first three rows show Item IDs 1, 2, and 3, with corresponding code lists in column B. Callouts point to 'Item ID' and 'Code lists'. The spreadsheet is titled 'Slots' at the bottom.

The list shows the factors and outcomes. The Item IDs are displayed as column names, their code lists are displayed in the rows below. Every possible combination for the factors and outcomes is shown here. The item *RANDKITNO* (kit numbers) was configured to be an open text field, so the allocation list says `<string>`. A list of kit numbers has to be added to the file, before the template can be uploaded as allocation list, as in the example below:

The screenshot shows a spreadsheet with columns A through I. Column A is labeled 'RANDGROUP' and column B is labeled 'RANDKITNO'. The first three rows show Item IDs 1, 2, and 3, with corresponding kit numbers in column B. Callouts point to 'Item ID', 'Three treatment options, that are copied to generate more slots', and 'Generated a list of kit numbers'. The spreadsheet is titled 'Slots' at the bottom.

Once the randomization is started, it is possible to view the allocation list by clicking the view button in the **Allocation List** field (see nr 16 in the image above). An Excel file is downloaded that has the following sheets:

- **Configuration** - summarizes the factors and outcomes and their code lists configured for the randomization.
- **Current distribution** - displays the distribution of randomized subjects over the different factors and groups.
- **Slots** - lists all the slots, the factors and outcomes (kit number in this case), and whether the slot is still available. If the slot has been taken, subject details, user details (e-mail address) of the clinic user who randomized the subject, and date and time are also displayed, see the image below.

#	Treatment group	Treatment group - Code	Kit number	Kit number - Code	Available	Subject id	Subject key	User reference	Date and time
#	RANDGROUP	RANDGROUPCD	RANDKITNO	RANDKITNOCD	Available	SubjectId	SubjectKey	UserRef	Datetime
3	1 A	1	101	101	FALSE	215406	KI-06		2018-09-24 11:35:22
4	2 B	2	102	102	FALSE	215408	KI-08		2018-09-24 11:37:15
5	3 C	3	103	103	FALSE	215407	KI-07		2018-09-24 11:36:22
6	4 A	1	104	104	FALSE	215409	KI-09		2018-09-24 11:38:17
7	5 B	2	105	105	FALSE	215410	KI-10		2018-09-24 11:39:13
8	6 C	3	106	106	TRUE				
9	7 A	1	107	107	TRUE				
10	8 B	2	108	108	TRUE				
11	9 C	3	109	109	TRUE				
12	10 A	1	110	110	TRUE				
13	11 B	2	111	111	TRUE				
14	12 C	3	112	112	TRUE				
15	13 A	1	113	113	TRUE				
16	14 B	2	114	114	TRUE				
17	15 C	3	115	115	TRUE				

Annotations below the table:

- Slot nr. (points to column 1)
- Factors (points to columns 2-3)
- Outcomes (points to columns 4-5)
- Patient and randomization details (points to columns 6-10)

## 5 Step-by-step guides

### 5.1 Configuring a dynamic randomization

**Note!** The randomization can only be configured by users that are assigned the system role **Unblinded Statistician**.

To configure the randomization, follow the steps below.

- 1 In Viedoc Admin, go to the study for which you would like to configure the randomization. In the **RTSM** field, click the toolbox icon to open the randomization window.

The screenshot shows the 'Studies' section in Viedoc Admin. Under 'A demo study', there are several configuration options, each with a toolbox icon (a square with an 'X') to its right:

- RTSM**: Check for available slots, append existing or add new lists. (This icon is circled in red in the image)
- Medical coding**: Create and edit instances, upload files.
- Reference data source(s)**: Manage contact information, design scopes, and applicable sites.
- API configuration**: Add and edit API clients, view data history.
- Study crew**: Includes roles like Study Managers (2), Designers (2), and Helpdesk team (0). A specific user, Elise Langenkamp, is listed as Technical Writer.
- Study design**: Shows 'Effective' and 'Latest' designs, with a note 'Multiple designs in use.'

Below these options, there is a 'Study Sites' section with a 'Show all sites' button. A table lists the sites:

#	Site name	Code	Country	Effective Design	Production	Users
1	Academic Hospital Uppsala	AHU	SE	Demo study 2016 57.0	✓	1 / 3
2	Karolinska Institute Stockholm	KIS	SE	Demo study 2016 57.0	✓	1 / 3
3	Helsinki University Hospital	HUH	FI	Demo study 2016 57.0	✓	1 / 3
4	Charite University Hospital Berlin	CUB	DE	Demo study 2016 57.0	✓	1 / 3
5	VU Medical Center Amsterdam	VUA	NL	Demo study 2016 57.0	✓	1 / 3

At the bottom, there is a '+ Add a site to this study' button.

2 Click **Open** to select the randomization you would like to configure.

The Randomization configuration window opens as a pop up. This window also displays the prognostic factors and outcomes that have been defined in Viedoc Designer.

3 In the **Randomization List** field, select:

1. the scope of the randomization list  
and, only if advanced allocation is not enabled in Viedoc Designer:
2. the factors that should be balanced for in the randomization,
3. the outcome.

**Note!** To be able to perform a dynamic randomization, you need to specify only one outcome for the randomization list, and you need to make sure that the items used as factors and outcome have a code list. It is not possible to use free text items in the randomization list for dynamic randomization.

**Note!** You can also select *Country* or *Study Site* as factors. Yet, if you have set the scope to *Country* or *Study site*, you cannot use *Country* or *Site* respectively as input factor(s).

- 4 If you want to use allocation, select the **Allocation list** checkbox, select the scope of the allocation list, and, only if advanced allocation is not enabled in Viedoc Designer, the input factors, and the desired outcome (for example, kit number). Based on the allocated treatment, a kit number will then be assigned to the subject.

From the **Randomization method** dropdown list, select **Dynamic (Pocock and Simon)**.

- 5 Select **Approve settings & generate list**. The **Create configuration** link is displayed.

Select **Create configuration** to configure the dynamic randomization:

**Note!** You will need to create the dynamic randomization configuration individually for demo mode and production mode after creating the dynamic randomization settings.

Configure the dynamic randomization (see also [Concepts and terminology for dynamic randomization](#)):

1. Select the variation method from the **Variation method** drop down menu.
2. Enter the desired value for probability.  
The probability (p) determines the extent to which one wishes to favour the treatment group that would lead to the smallest imbalance. P should be between 1/(number of groups) and 1. To achieve this, enter a value (x) between 1000/(number of groups) and 1000.
3. In **Factor Weights**, enter the relative importance of the prognostic factors by typing their weights.  
For example, if it is more important to achieve balance in Factor A (*Gender* in the image below) than Factor B (*Smoker* in the image below), then a weight of 2 could be set on Factor A and a weight of 1 set on Factor B.
4. In **Allocation ratios**, enter the desired division of treatments to be allocated.  
For example, say we have three treatments A, B and C. If we would like treatment A to be allocated 50% of the time, and treatments B and C 25% of the time respectively, we would set the outcome weights as follows: Treatment A: 2, Treatment B: 1, Treatment C: 1.
5. Type the maximum number of slots per list in the **Max slots per lists** field.
6. Click **Ready**. The pop-up closes.
7. Click **Approve settings & generate list**.

The randomization page reloads and shows the randomization list with status **Inactive**, and the Allocation lists that are to be uploaded (status **Not initiated**).

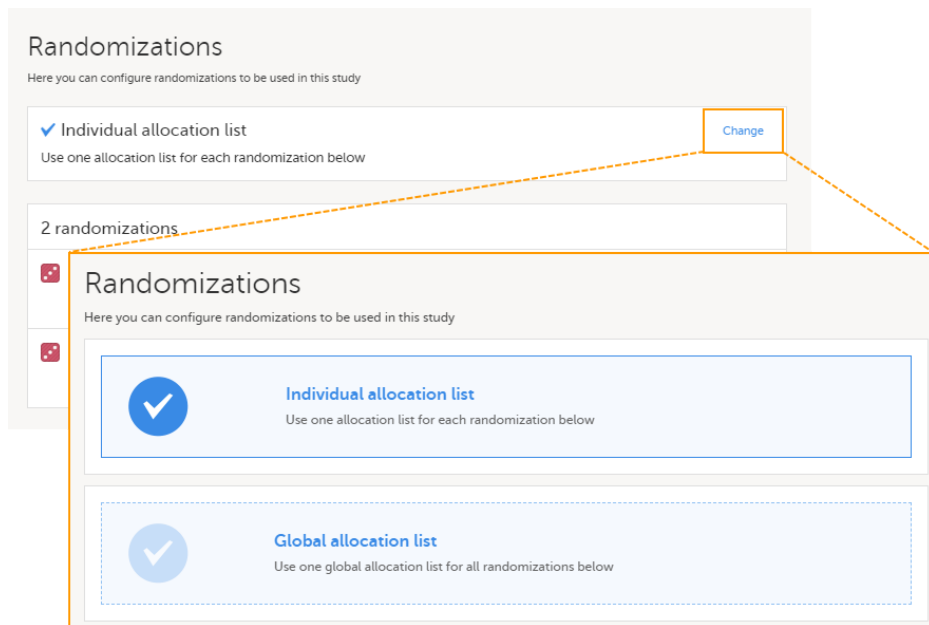
When the maximum number of slots is reached during randomization, no additional subjects can be randomized. You can edit the maximum number of slots in the randomization configuration at any time, see [Editing the configuration of a dynamic randomization](#).

## 5.2 Configuring the allocation list

There are two different options for the allocation lists, as follows:

- [Individual allocation list](#) - separate allocation lists are used for each defined randomization. If the allocation list is not uploaded, the subject can be randomized in Viedoc Clinic, but no kit is allocated.
- [Global allocation list](#) - one global allocation list is used for all the defined randomizations. This is available only if **advanced allocation** is enabled in Viedoc Designer (for details on advanced allocation settings in Viedoc Designer, see [Setting up the randomization](#) lesson).  
To be able to use **Logistics**, a Global allocation list must be used.  
If the allocation list is not uploaded, or, in case of using Logistics, if no kits are available at the current defined scope (*Study / Country / Study Site*), when trying to perform the allocation in Viedoc Clinic, the system will respond with *No slots found for allocation*.  
Setting up a Global allocation list is described in [Configuring the Global allocation list](#).

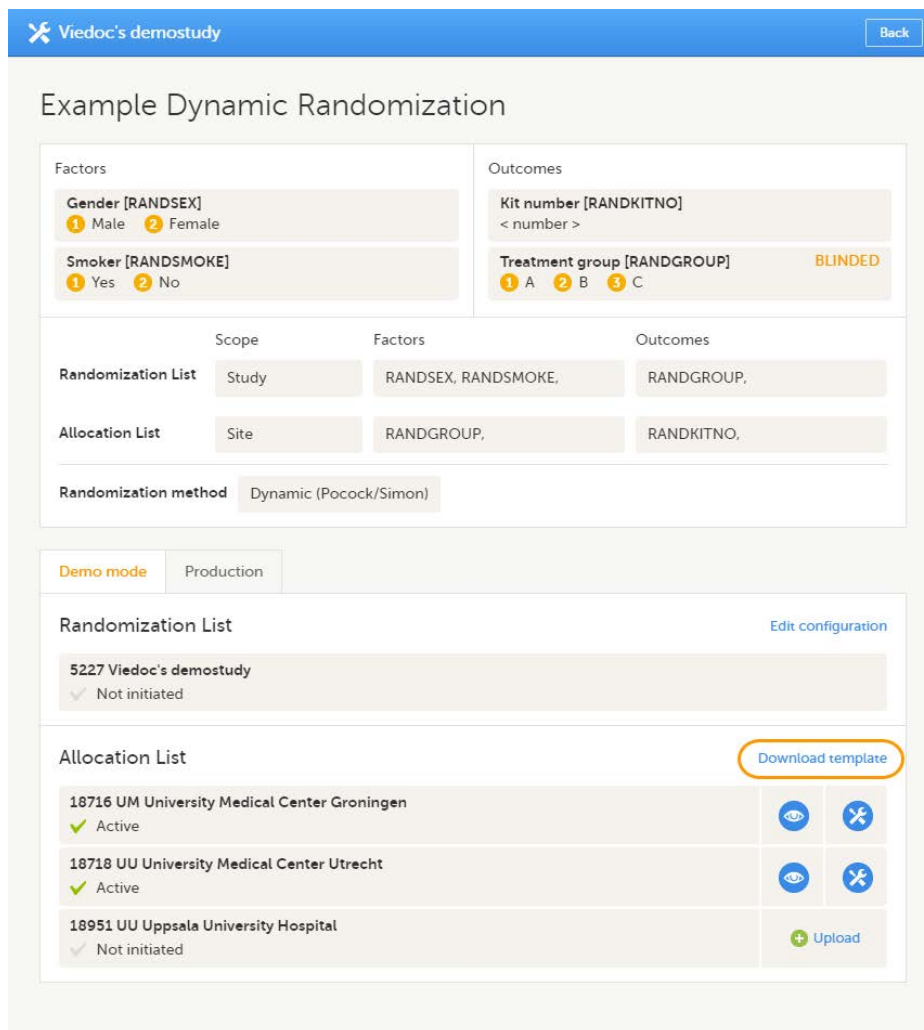
This is set up under the **RTSM** settings in Viedoc Admin, as illustrated in the image below:



### 5.2.1 Individual allocation list

If individual allocation list(s) are used for each randomization, the allocation list will be uploaded separately for each defined randomization, as described below.

#### 5.2.1.1 Downloading a template allocation list



### 5.2.1.2 Uploading an allocation list

To upload an allocation list, follow the steps below.

## 1 Click Upload.

The screenshot shows the 'Demo randomization 10' configuration interface. At the top, there's a blue header with 'A demo study' and a 'Back' button. The main content is divided into several sections:

- Factors:** Gender [RANDSEX] with options 1 Male, 2 Female; Smoker [RANDSMOKE] with options 1 Yes, 2 No.
- Outcomes:** Kit number [RANDKITNO] < number >; Group [RANDGROUP] with options 1 A, 2 B, 3 C, and a 'BLINDED' label.
- Randomization List:** Scope: Study; Factors: RANDSEX, RANDSMOKE; Outcomes: RANDGROUP.
- Allocation List:** Site: RANDGROUP; Outcomes: RANDKITNO.
- Randomization method:** Dynamic (Pocock/Simon).
- Demo mode:** Production.
- Randomization List Table:** One row: 5180 A demo study, Active, with Edit configuration, Eye, and X icons.
- Allocation List Table:** Four rows with site names and status. The '13847 KIS Karolinska Institute Stockholm' row has an 'Upload' button highlighted with a red circle.

## 2 Select the file containing the slot list and click **Open**. The file will be uploaded.

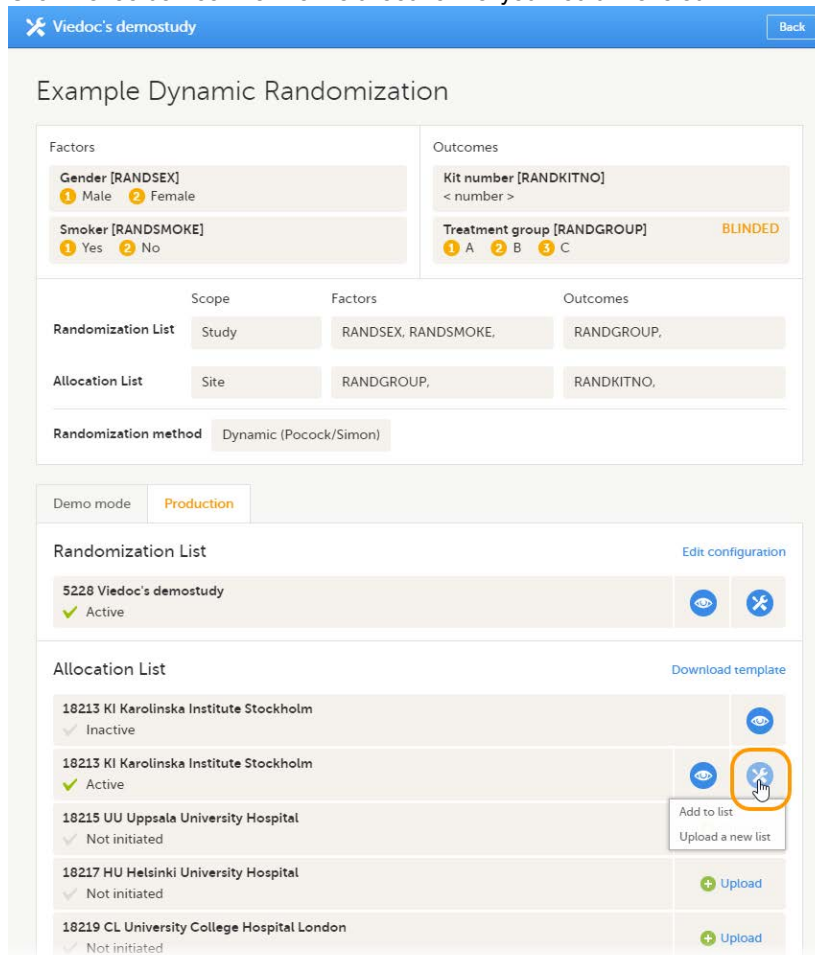
### 5.2.2 Viewing an allocation list

The allocation list can be viewed in a similar way as the randomization list, see [Viewing the randomization list](#).

### 5.2.3 Editing an allocation list

To edit an active allocation list, follow the steps below.

1 Click the toolbox icon next to the allocation list you would like to edit.



- 2 Select: **Add to list** or **Upload new list**.
- **Add to list** - adds new slots to the existing slot list. Empty spots in the existing slot list will still be allocated.
  - **Upload new list** - discards the existing slot list and replaces it with the new slot list.
- 3 Select the file containing the slot list and click **Open**.  
The file will be uploaded.

### 5.3 Viewing the randomization list

The randomization list initially indicates status **Not initiated** and turns to status **Active** once the first subject has been randomized.

From that moment, the distribution list can be downloaded in Excel format by clicking **View**.



## Demo randomization 10

<b>Factors</b>		<b>Outcomes</b>	
Gender [RANDSEX] 1 Male 2 Female		Kit number [RANDKITNO] < number >	
Smoker [RANDSMOKE] 1 Yes 2 No		Group [RANDGROUP] <b>BLINDED</b> 1 A 2 B 3 C	
<b>Randomization List</b>	Scope Study	Factors RANDSEX, RANDSMOKE,	Outcomes RANDGROUP,
<b>Allocation List</b>	Site	RANDGROUP,	RANDKITNO,
Randomization method Dynamic (Pocock/Simon)			

Demo mode **Production**

## Randomization List

[Edit configuration](#)5180 A demo study  
✓ Active

## Allocation List

[Download template](#)13845 AHU Academic Hospital Uppsala  
✓ Active13847 KIS Karolinska Institute Stockholm  
✓ Not initiated13849 HUH Helsinki University Hospital  
✓ Not initiated

## 5.4 Restarting a dynamic randomization

If you would like to restart a dynamic randomization, click the toolbox icon in the **Randomization List** field and select **Restart**.

## Example Dynamic Randomization

<b>Factors</b>	<b>Outcomes</b>
<b>Gender [RANDSEX]</b> 1 Male 2 Female	<b>Kit number [RANDKITNO]</b> < number >
<b>Smoker [RANDSMOKE]</b> 1 Yes 2 No	<b>Treatment group [RANDGROUP]</b> <b>BLINDED</b> 1 A 2 B 3 C

	Scope	Factors	Outcomes
<b>Randomization List</b>	Study	RANDSEX, RANDSMOKE,	RANDGROUP,
<b>Allocation List</b>	Site	RANDGROUP,	RANDKITNO,





**Randomization method** Dynamic (Pocock/Simon)

Demo mode **Production**

### Randomization List

5228 Viedoc's demostudy  
✓ Active[Edit configuration](#)  
Restart  
[Download template](#)

### Allocation List

18213 KI Karolinska Institute Stockholm  
∨ Inactive18213 KI Karolinska Institute Stockholm  
✓ Active18215 UU Uppsala University Hospital  
∨ Not initiated  
  
  
 Upload

Restarting the randomization will reset the slot list. Newly added subjects will be randomized independently of the subjects that were randomized before the restart.

## 5.5 Editing the configuration of a dynamic randomization

If you would like to edit the configuration of an ongoing Pocock and Simon dynamic randomization, click **Edit configuration**.

Viedoc's demostudy Back

## Example Dynamic Randomization

**Factors**

**Gender [RANDSEX]**  
1 Male 2 Female

**Smoker [RANDSMOKE]**  
1 Yes 2 No

**Outcomes**

**Kit number [RANDKITNO]**  
< number >

**Treatment group [RANDGROUP]** BLINDED  
1 A 2 B 3 C

	Scope	Factors	Outcomes
<b>Randomization List</b>	Study	RANDEX, RANDSMOKE,	RANDGROUP,
<b>Allocation List</b>	Site	RANDGROUP,	RANDKITNO,

**Randomization method** Dynamic (Pocock/Simon)

---

Demo mode Production

**Randomization List** Edit configuration

5228 Viedoc's demostudy  
✓ Active 👁️ ⚙️

**Allocation List** Download template

18213 KI Karolinska Institute Stockholm  
✗ Inactive 👁️

18213 KI Karolinska Institute Stockholm  
✓ Active 👁️ ⚙️

18215 UU Uppsala University Hospital  
✗ Not initiated + Upload

A pop-up opens where you can edit the settings for variation method, probability, factor weights, allocation ratio and maximum number of slots per list. For a more detailed explanation, see [step 6 in Configuring a dynamic randomization](#).

You can edit the randomization configuration at any time during randomization.

**Configure dynamic randomization**

---

**Variation method**  
Range ▾

**Probability (x/1000)**

---

**Factor weights**

Gender <input type="text" value="2"/>	Smoker <input type="text" value="1"/>
--	--

---

**Allocation ratio**

A <input type="text" value="2"/>	B <input type="text" value="1"/>	C <input type="text" value="1"/>
-------------------------------------	-------------------------------------	-------------------------------------

---

**Max slots (per list)**

Ready
Cancel



Configuring the global allocation list

# Configuring the global allocation list

Published by Viedoc System 2023-10-09

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## [1. Introduction](#)

### [2. Configuring the global allocation list](#)

#### [2.1 Configuring the global allocation list](#)

#### [2.2 Viewing an allocation list](#)

#### [2.3 Editing an allocation list](#)

## 1 Introduction

The allocation list setup can be performed only by users assigned to the **Unblinded Statistician** role.

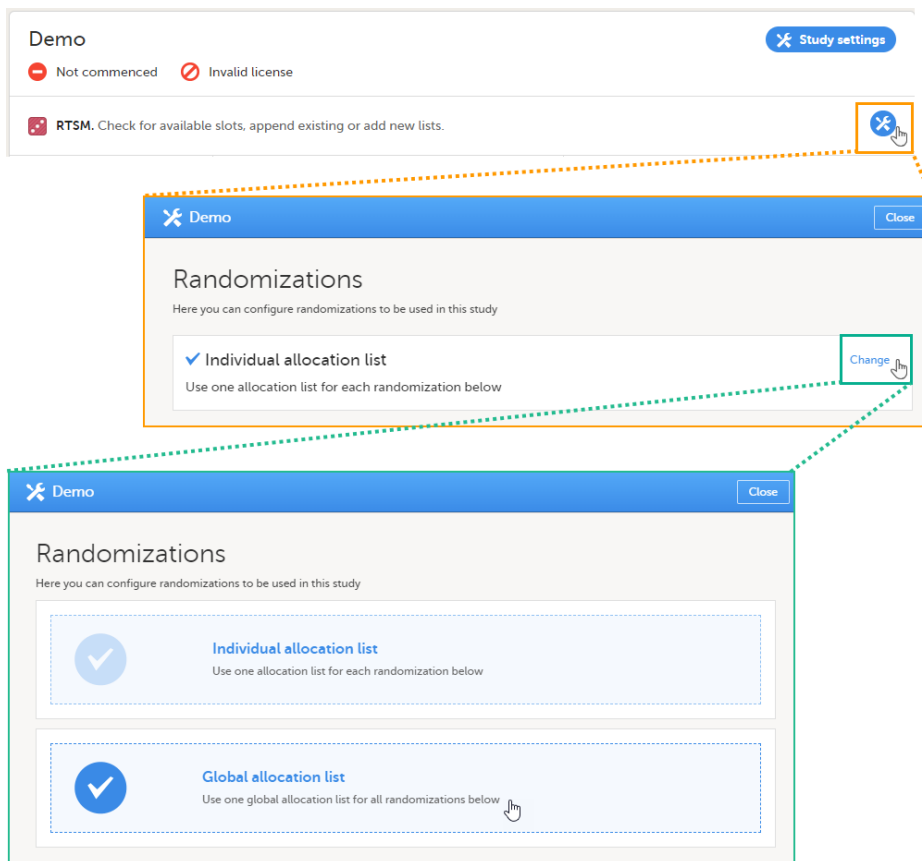
When randomization is used within a study (see [Configuring a static randomization](#) / [Configuring a dynamic randomization](#)), the allocation list can be defined in two different ways:

**Important!** The randomization feature must be included in your study license in order for the randomization configuration and the global allocation list to be available in production mode. You can still configure a randomization in demo mode without a license.

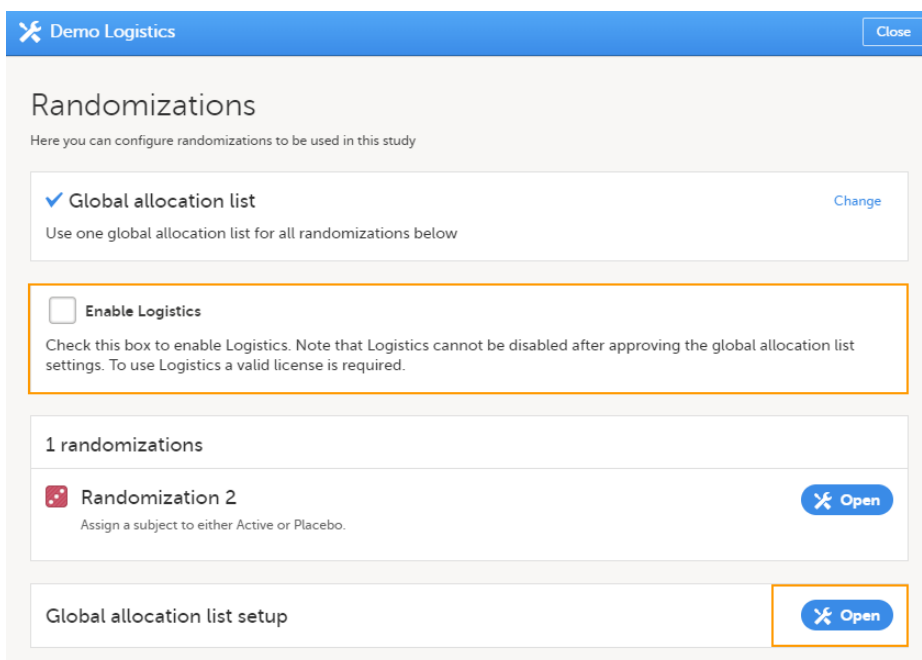
- **Individual allocation list** - separate allocation lists are used for each defined randomization. In this case, the allocation list is configured and uploaded in the randomization settings page in Viedoc Admin as described in [Configuring a static randomization](#) / [Configuring a dynamic randomization](#).
- **Global allocation list** - one global allocation list is used for all the defined randomizations. This is available only if **advanced allocation** is enabled in Viedoc Designer (for details on advanced allocation settings in Viedoc Designer, see [Setting up the randomization](#) lesson)..
- To be able to use Logistics, a global allocation list must be used. If the allocation list is not uploaded, or, in case of using Logistics, if no kits are available at the current defined scope (*Study / Country / Study Site*), when trying to perform the allocation in Viedoc Clinic, the system will respond with "No slots found for allocation."

## 2 Configuring the global allocation list

The global allocation list is set up under the **RTSM** settings in Viedoc Admin:



If the global allocation list is selected to be used for all the randomizations defined in the study, the **Global allocation list setup** is displayed at the bottom of the **Randomizations** pop-up, as well as the option to **Enable logistics**, as below:



**Enable Logistics** - if checked, this allows you to use the Logistics functionality in Viedoc. For more information about the logistics functionality see [Overview of Viedoc Logistics](#).

### Important!

- The **Enable Logistics** option cannot be selected/deselected after the global allocation list settings have been approved.
- A valid license that includes the Logistics feature is required to be able to run Logistics in production. You can however still run Logistics in demo mode without a license.

## 2.1 Configuring the global allocation list

To configure the global allocation list:

- 1 Click **Open** next to the **Global Allocation list setup**. The **Definition** page will be displayed:

**Global allocation list setup**  
Use one global allocation list for all randomizations.

**Definition**

Scope: --

Property ID	Property Label	Property Values	Property Type	Blinded
			Kit type	<input checked="" type="checkbox"/>

Property ID	Property Label	Property Values	Property Type	Blinded
			Kit number	<input type="checkbox"/>

Click approve to accept the definition. Continue with defining the applicable mappings and uploading all applicable lists. Note that this action will lock the global allocation list definition and cannot be undone.

Approve settings & generate list.

2 Under the **Definition** tab, set the following:

- the **Scope** of the allocation - defines the scope from which an Investigational Product (IP) (kit) should be allocated. One of the following scopes can be chosen:
  - *Study*
  - *Country*
  - *Study Site*

If **Logistics** is enabled, this impacts the way the kits can be managed, as described in [Managing kits](#).

- **Allocation input properties** - make sure to add the input properties for all IPs that need to be allocated for all randomizations defined in the study. Enter the **Property ID**, and the **Property label**.

For the code list items (for example radio buttons), add the **Property values** to define the codes and the matching labels:

Code	Label
1	Placebo
2	Active

**Note!** The codes must be defined for all the code list items to be able to upload the allocation list. If any codes that were not defined here with **Code** and **Label** are included in the allocation list, this will not be uploaded. You must use the same codes as defined in the study design. If the **Property values** are not set for code list items, only the codes will be displayed in Logistics.

- **Allocation output properties** - make sure to add the output properties for all IPs that need to be allocated for all randomizations defined in the study. Enter the **Property ID**, **Property label** and, for the code list items, add the **Property values** to define the codes and the labels.
- If Logistics is enabled, set the following for all the input and output properties defined:
  - **Property type** - this defines which column in the allocation list contains the *Kit type*, *Kit number* and *Expiry date*.
  - **Blinded** - select this option if the item should be blinded to the users accessing the Logistics in Viedoc Clinic.

**Important!**

This setting will only affect the display of blinded properties in Logistics. Whether the property is visible or not in Clinic (the forms) is configured separately in Designer by specifying the item either as output or blinded output.

Even if the item is set as blinded output in the randomization settings, this will be visible on the Logistics page(s) if it is not set as blinded here.

See an example below:

Allocation settings in Viedoc Designer > RTSM

4 Form  
ALLOC1 / Primary IMP allocation

5 Input mapping  
Treatment

6 Output mapping  
Kit number  
Batch #  
Expiration date  
Storage conditions  
Other information

GROUP / Group  
KITNO / Kit number(Locate...  
BATCHNO / Batch #  
EXPIRYDATE / Expiry date  
STORAGE / Storage conditi...  
INFO / Other information

Demo Logistics

Global allocation list

Use one global allocation list for all randomizations.

Definition

Scope  
Study site

Allocation input properties

Property ID	Property Label	Property Values
TREATMENT	Treatment	PLACEBO - Placebo, ACTIVE - Act

Allocation output properties

Property ID	Property Label	Property Values
KITNUMBER	Kit number	
BATCHNUMBER	Batch #	
EXPIRYDATE	Expiration date	
STORAGE	Storage conditions	
INFO	Other information	

Property Type Blinded

Property Type	Blinded
Kit type	<input checked="" type="checkbox"/>
Kit number	<input type="checkbox"/>
Not mapped	<input type="checkbox"/>
Expiry date	<input type="checkbox"/>
Not mapped	<input type="checkbox"/>
Not mapped	<input type="checkbox"/>

Click approve to accept the definition. Continue with defining the applicable mappings and uploading all applicable lists. Note that this action will lock the global allocation list definition and cannot be undone.

Approve settings & generate list

Displayed only if Enable Logistics is selected

3

**Important!**

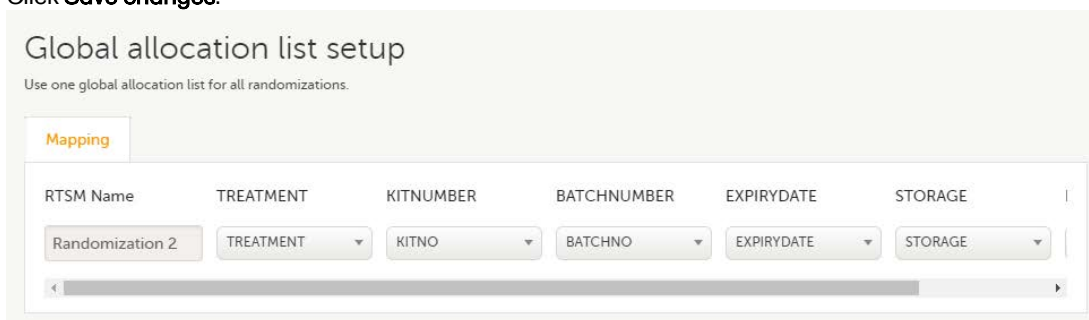
Make sure that all the needed input and output properties are defined, as it will not be possible to add or change these after approving the settings.

Note that enabling/disabling **Logistics** will not be possible after approving the settings.

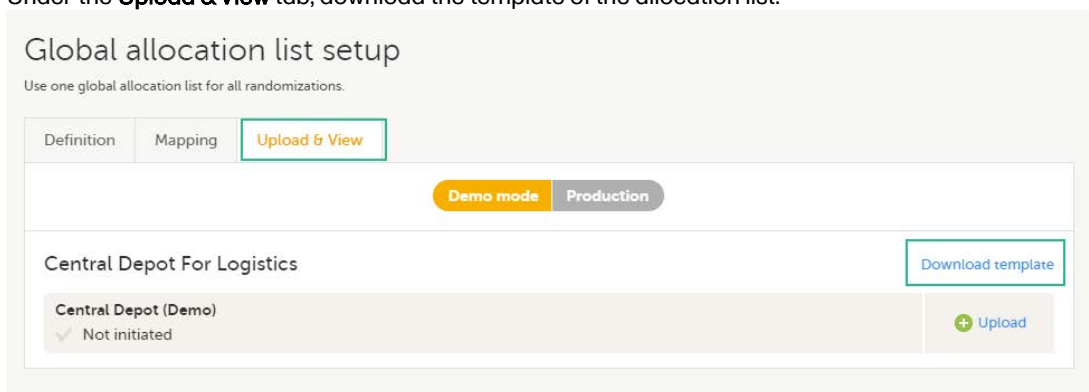
Click **Approve settings & generate list**. The **Mapping** tab becomes available.



- 4 Under the **Mapping** tab, map each input and output properties defined in step 1 to the respective input and output properties defined for each advanced allocation in the study design. For the properties that do not apply to one or more of the randomizations in the list, select **Not mapped**. Note that multiple rows and thus multiple mappings will only be needed when different definitions has been used. Click **Save changes**.

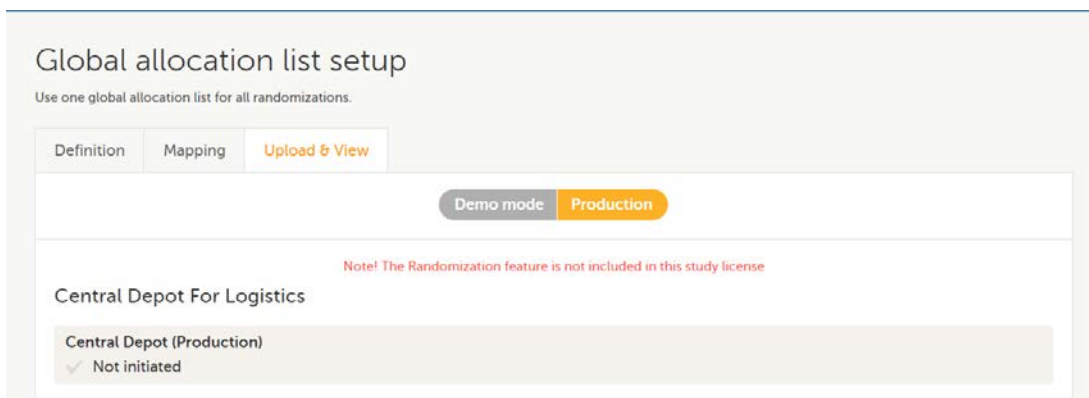


- 5 Under the **Upload & View** tab, download the template of the allocation list:



**Note!** If your study does not have a license key (Reference ID), or has a license key that does not include the randomization feature, on the Global allocation list setup, under the **Upload and view** tab:

- A message is shown informing you that the randomization feature is not included in the license:



- The **Download template** and **Upload** links are not available.

A template excel file is downloaded:

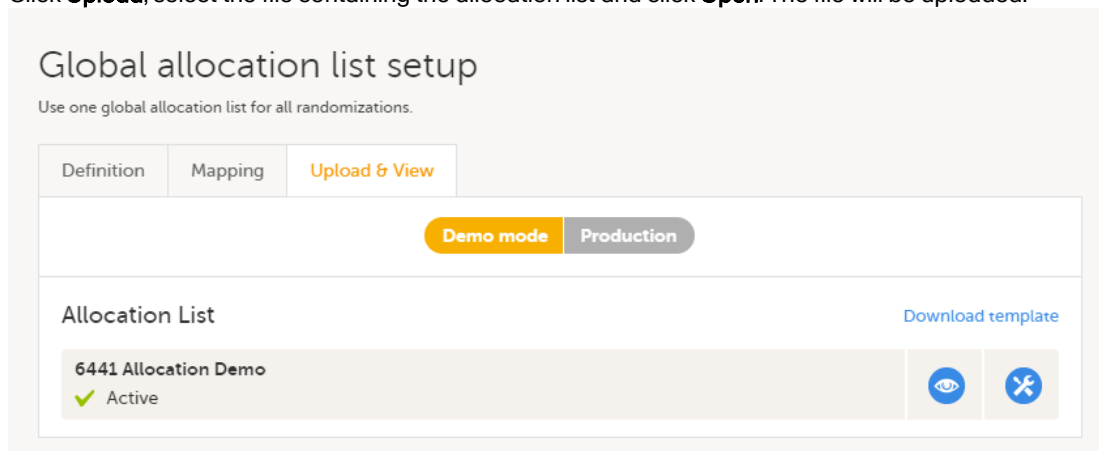
	A	B	C	D	E	F
1	TREATMENT	KITNUMBER	BATCHNUMBER	EXPIRYDATE	STORAGE	INFO
2	PLACEBO	<string>	<string>	<string>	<string>	<string>
3	ACTIVE	<string>	<string>	<string>	<string>	<string>
4						
5						
6						

6 Use the downloaded template file to fill in the allocation list and save the file:

	A	B	C	D	E	F
1	TREATMENT	KITNUMBER	BATCHNUMBER	EXPIRYDATE	STORAGE	INFO
2	PLACEBO	IMP0015	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
3	ACTIVE	IMP0016	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
4	PLACEBO	IMP0017	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
5	ACTIVE	IMP0018	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
6	PLACEBO	IMP0019	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
7	ACTIVE	IMP0020	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
8	PLACEBO	IMP0030	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
9	ACTIVE	IMP0033	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
10	PLACEBO	IMP0034	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
11	ACTIVE	IMP0035	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is
12	PLACEBO	IMP0036	BATCH0001	2021-01-01	Room temperature	Lorem Ipsum is

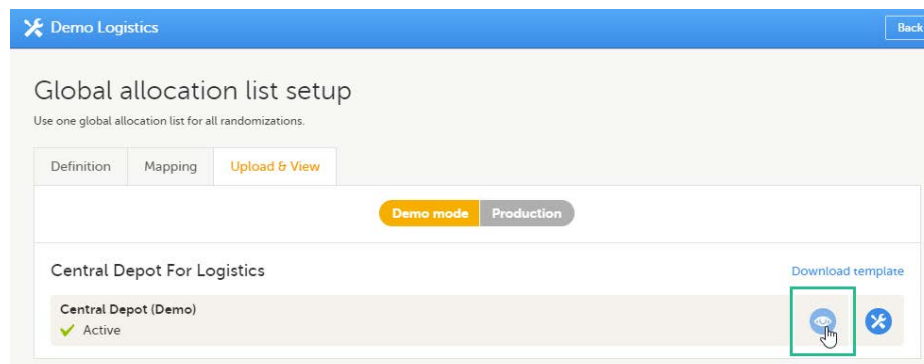
**Note!** The cell format for the dates (for example EXPIRYDATE) must be set to Text. Make sure that Excel does not format this to Date. If the format of the dates is not set to text, the upload of the allocation list will fail and an error message will be displayed.

7 Click **Upload**, select the file containing the allocation list and click **Open**. The file will be uploaded.



## 2.2 Viewing an allocation list

To view the allocation list, under **Upload & View** tab, click the view icon:



An Excel file is downloaded that has the following sheets:

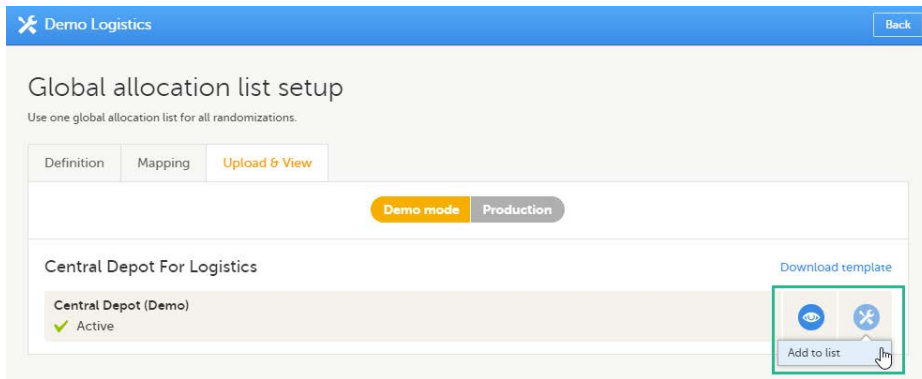
- **Configuration** - summarizes the factors and outcomes and their code lists configured for the allocation.
- **Current distribution** - displays the distribution of randomized patients over the different factors and groups.
- **Slots** - lists all the slots, the factors and outcomes (kit number in this case), and whether the slot is still available. If the slot has been taken, the subject details, the user details (email address) of the clinic user who allocated the subject, and date and time of allocation are also displayed.

**Note!** The above Excel file reflects the kit status according to the randomization and allocation forms in Viedoc Clinic. All changes to kit status made in the Logistics interface can be seen in the Logistics stock list Excel file ([see Stock list and Kit details view](#)).

If the Logistics functionality is enabled, the **Slots** and **Current distribution** always reflects only the list of kits currently at Central depot. The kits that are on site are not included in the list, these can be tracked only from the Logistics interface (see [Viedoc Logistics User Guide](#)).

## 2.3 Editing an allocation list

To add new kits to the allocation list, click the tools icon and select **Add to list**:



Upload the Excel file with the new kits. This has to be in the same format as the originally uploaded list, see **step 6** in [Configuring the global allocation list](#) above.



A use case for dynamic randomization

# A use case for dynamic randomization

Published by Viedoc System 2023-10-09

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- [1.2 Terminology](#)
- [1.3 Workflow](#)

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  - [3.1.1 Set up forms in Viedoc Designer](#)
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  - [3.2.1 Inviting a user to the role Unblinded Statistician](#)
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- [4.4 Calculations](#)

This lesson provides a use case for configuring a dynamic randomization in **Viedoc Designer**, **Viedoc Admin**, and **Viedoc Clinic**. It also explains the algorithm that is used for assigning subjects to treatments, and how the calculations are executed.

**Important!** The Randomization feature must be included in your study license in order for the randomization configuration to be available in production mode. You can still configure a randomization in demo mode without a license.

## 1 Introduction

### 1.1 About the randomization service

Viedoc offers support for randomization. Subjects can be randomized using:

- **static randomization**: randomization based on a randomized list,
- **dynamic randomization** (Pocock and Simon): randomization based on an algorithm.

Dynamic randomization ensures a more even distribution of subjects across the treatment groups, with regard to prognostic factors that might influence the effect of treatment on the subjects.

The randomization in Viedoc is configured in a similar way for static and dynamic randomization. The main difference is that for static randomization, a list with outcomes (randomization numbers, treatment groups, and so on) - the randomization list - is created and uploaded by the user, while for dynamic randomization, an algorithm is used to assign subjects to a treatment group and the randomization list is created by the system.

It is possible to upload a separate allocation list that allocates an Investigational Product (IP) to the subject. When the subject is randomized, Viedoc informs the clinic user which IP should be given to the subject. The allocation list is most commonly used in double-blind studies. Uploading of the allocation list is done in a similar way for static and dynamic randomization.

## 1.2 Terminology

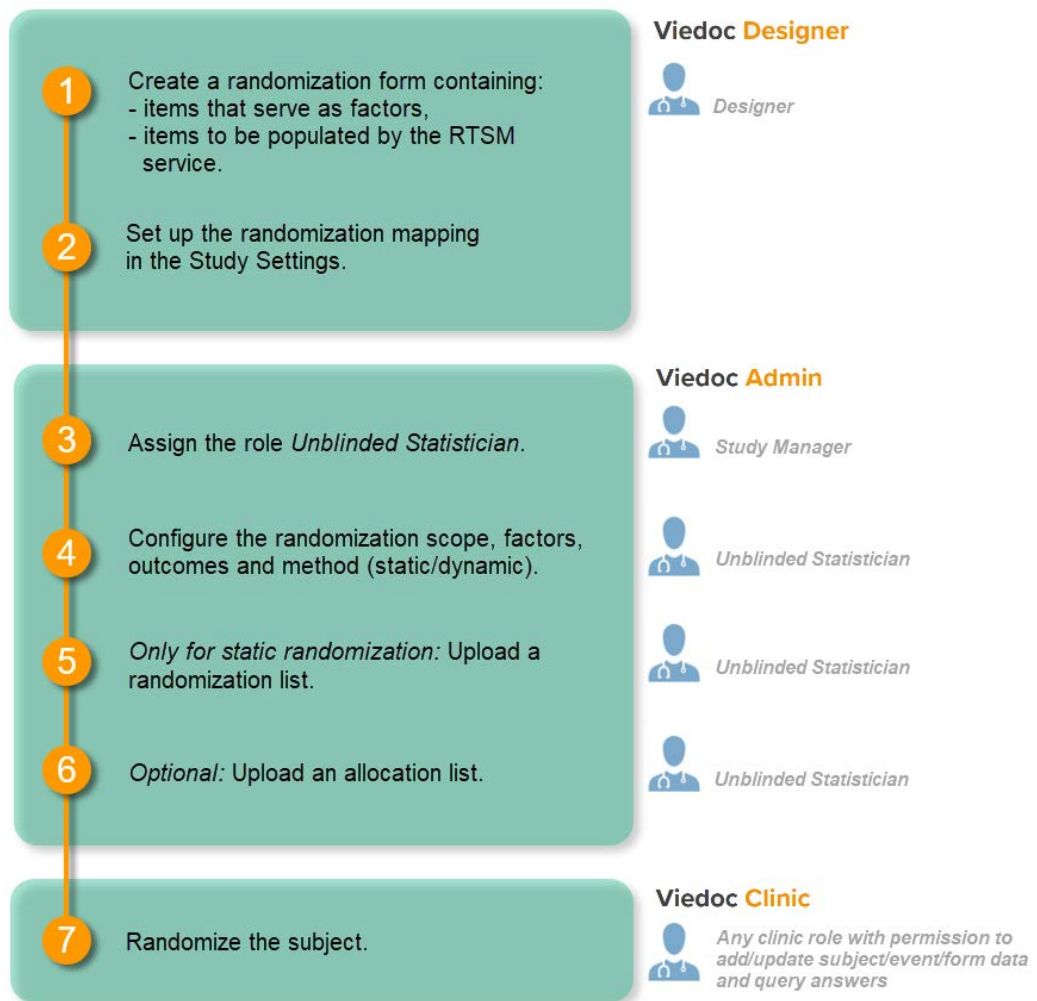
Term	Definition
RTSM	Randomization and Trial Supply Management.
Blinded role	A role that does not know which treatment the subject is receiving. Most roles in a clinical trial should be blinded.
Unblinded Statistician	<p>A system role that can configure the randomization in Viedoc Admin.</p> <p>The Unblinded Statistician sees which subjects are assigned to which treatments, and should therefore not have any role in the study where he/she should not know this information. An Unblinded Statistician can never again work in a blinded role within that study.</p>
Randomization list	A list for allocating subjects to treatments or groups. The randomization list shows all available slots in the randomization. When randomization has started (that is, when the first subject has been randomized), the randomization list also shows which subjects have been assigned to which treatment or group.
Allocation list	<p>A list for allocating <a href="#">IP</a> to subjects. The allocation list shows all available IPs. When randomization has started, the allocation list also shows which IPs have been assigned to which subjects. Advanced allocation can be set up and for this there are two options for the allocation list(s):</p> <ul style="list-style-type: none"><li>▪ Use individual allocation list for each randomization.</li><li>▪ Use one global allocation list for all your randomizations.</li></ul> <p><b>Note!</b> To be able to use <b>Logistics</b>, a Global allocation list must be used.</p>
Scope	<p>Defines the scope from which a randomization slot or an IP should be selected. One of the following scopes can be chosen:</p> <ul style="list-style-type: none"><li>▪ Study</li><li>▪ Country</li><li>▪ Site</li></ul>
Factor (Prognostic factor)	Items that might influence the effect of treatment on the subjects, and that are to be used as input when randomizing the subject. For example sex or age. Viedoc supports the use of drop-down lists, radio buttons, integer and free text data types as input items.
Outcome	Items to be populated by the randomization service, for example treatment group.
Blinded outcome	Items to be populated by the randomization service, that should remain blinded until after the subject has been unblinded or emergency unblinded for a specific subject. These items will not be visible for any user in the system, except for the Unblinded Statistician who can see them in Viedoc Admin, or until an emergency unblinding was performed (for details on how the emergency unblinding is performed in Viedoc Clinic, see <a href="#">Randomization, allocation and emergency unblinding</a> ).

## 1.3 Workflow

Randomizations are configured in Viedoc Designer and Viedoc Admin, and executed in Viedoc Clinic. The schematic below depicts what different steps need to be taken, and which roles have permission to perform these steps, depending on the allocation configuration type as described below:

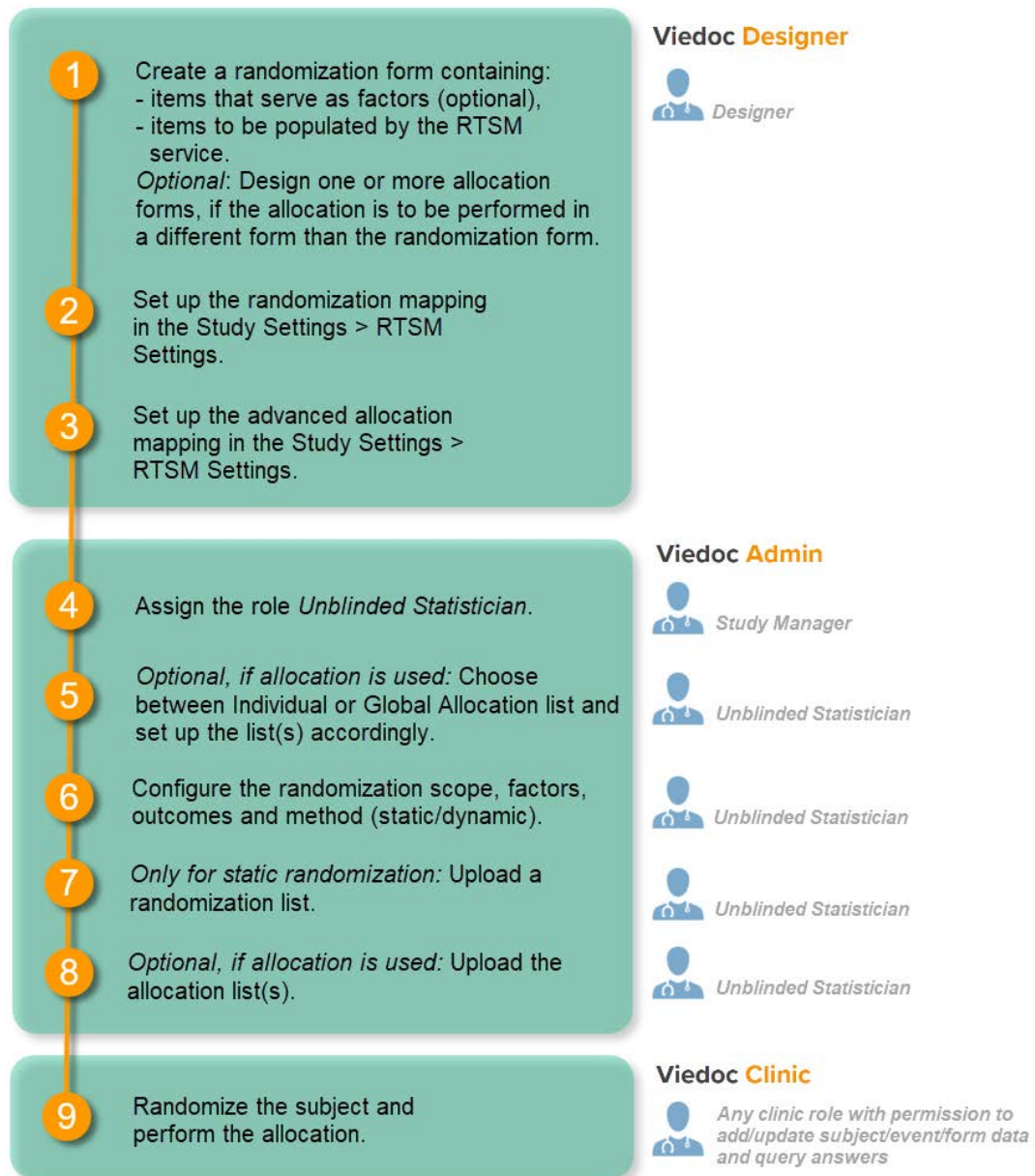
- Randomization, optionally together with allocation performed at the same time as the randomization within the same form. In this case the form is locked (and therefore not possible to be edited) after the randomization is performed in Viedoc Clinic.

The configuration workflow in this case looks as illustrated in the following image:



- Randomization, optionally together with **advanced allocation** allows you to set up the allocation in a more flexible way, including:
  - Configuring individual forms for randomization and allocation, to keep the two steps separated in the study workflow
  - The possibility to perform multiple allocations at different visits during the study
  - The possibility to replace an already performed allocation with a new allocation
  - The possibility to undo an already performed allocation

The configuration workflow in this case looks as illustrated in the following image:



Detailed instructions regarding these steps are described in:

- [Setting up the randomization](#) in Viedoc Designer
- [Configuring a static randomizations](#) in Viedoc Admin
- [Configuring a dynamic randomization](#) in Viedoc Admin

For a video tutorial on how to configure a static list randomization and a dynamic randomization, see:

- [Randomization video tutorial](#)

## 2 Description of the use case

Let's consider the following scenario: We conduct a trial in which we compare three treatments: A, B and C. We want to randomly assign patients to these treatments, and we want treatment A to be allocated 50% of the time, and treatments B and C 25% of the time respectively. The prognostic factors that might influence the effect of the treatment on the subject, and that we would like to balance for in the randomization, are the subject's sex (male or female) and the subject's age ( $\leq 30$  or  $> 30$ ). We consider it more important to balance for the subject's sex than for the subject's age, so we set a higher factor weight on the factor sex.

In summary:

- Three treatment groups: A, B and C.
- Allocation ratio for A:B:C = 2:1:1

- Two factors: sex (male or female) and age ( $\leq 30$  or  $> 30$ )
- Factor weights: 2 for sex, 1 for age.

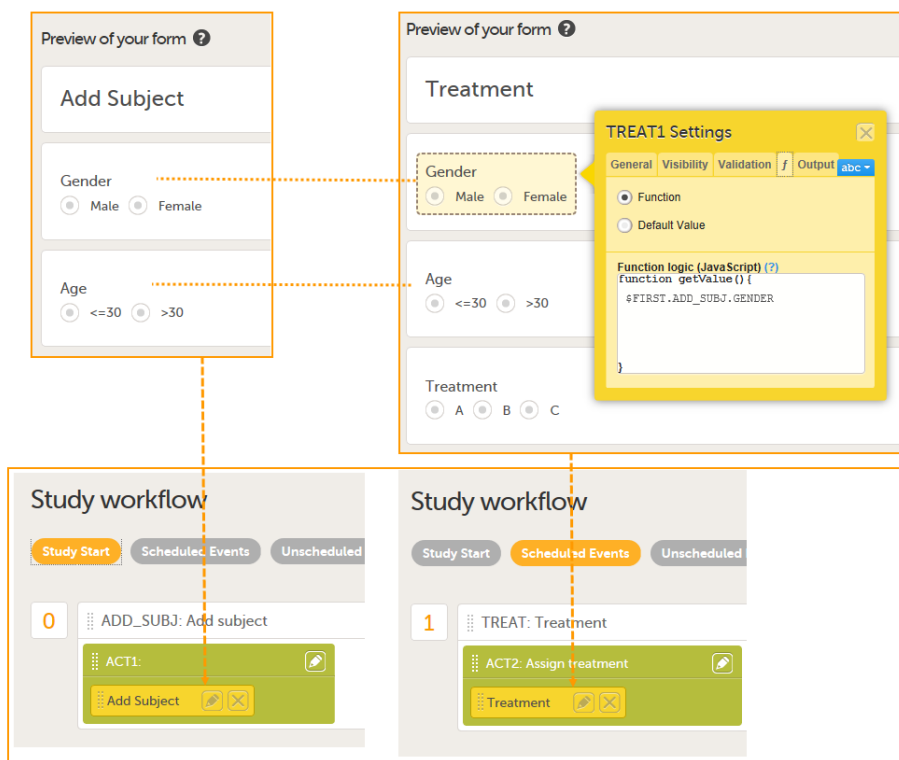
## 3 The procedure

### 3.1 Actions to be performed in Viedoc Designer

#### 3.1.1 Set up forms in Viedoc Designer

In this randomization example, we use two forms:

1. **Add Subject** form - containing two items:
  - *Gender*
  - *Age*
2. **Treatment** form (**the randomization form**) - containing three items:
  - *Gender* - returns the value for *Gender* in the *Add Subject* form.
  - *Age* - returns the value for *Age* in the *Add Subject* form.
  - *Treatment* - containing a code list with three choices: A, B, and C. This item will be populated by the randomization service.



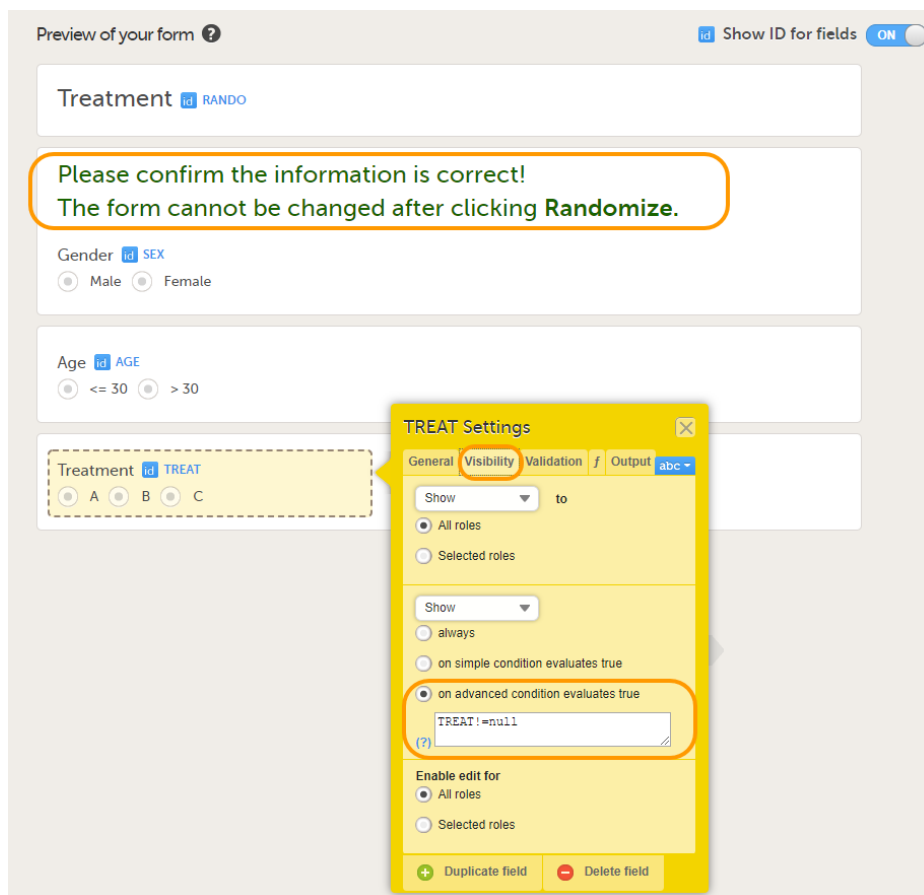
The form *Add Subject* is added to the activity *ACT1* in the *Add\_SUBJ* Study Start event. The form *Treatment* is added to the activity *ACT2: Assign treatment* in the *Treatment* event, which is the first scheduled event.

**Note!** The randomization form (here called *Treatment*) must contain all of the input factors and outcomes you intend to use for making assignments.

**Tip!** Once saved in Viedoc Clinic, the randomization form cannot be edited anymore. Add a message to the form asking the clinic user to make sure that the data are correct before randomizing the patient (see image below).

**Tip!** Because the *Treatment* item in the *Treatment* form is the item that will be populated by the randomization service, and should not be filled in by the clinic user, it may be a good idea to make it invisible to the clinic user as long as the patient is not randomized. In order to achieve this, you can set the visibility conditions **On advanced conditions evaluates true** for this item to  $TREAT1=null$  (show item when it is not null). Then, the clinic user cannot see the item when opening the form. But once the clinic user clicks **Randomize**, the randomization service allocates the subject to a treatment, the item is not equal to null anymore and appears in the form.





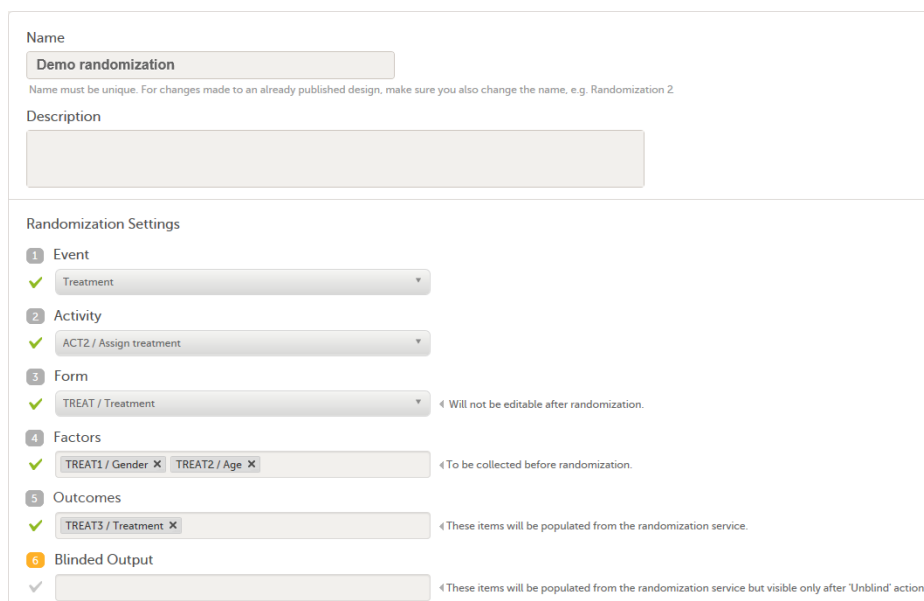
In this example, the randomization outcome (treatment) is not blinded. If you decide to set up a blinded outcome, this item has to be included in the randomization form as well. The blinded outcome will never be shown to the clinic user, it is not available in the export, and you cannot program visibility conditions or edit checks based on the blinded outcome.

### 3.1.2 Setting up the randomization in Viedoc Designer

The randomization mapping is set up under **Study Settings** in the study design in Viedoc Designer. The randomization mapping tells Viedoc where the randomization form is and how to use the variables on that form.

We set up the randomization as follows:

- We select the **Event, Activity** and **Form** for our *Treatment* form.
- As **Factors**, we select the *Gender* and *Age* items in the *Treatment* form.
- As **Outcome**, we select the *Treatment* item in the *Treatment* form. This item is going to be populated by the randomization service.



For step by step instructions on how to set up the randomization mapping in Viedoc Designer, see [Setting up the randomization](#).

After the randomization mapping has been set up, the study design needs to be published for the randomization to become active.

## 3.2 Actions to be performed in **Viedoc Admin**

### 3.2.1 Inviting a user to the role Unblinded Statistician

The Study Manager needs to invite a user to the role **Unblinded Statistician**. The role Unblinded Statistician should only be given to users that are supposed to be unblinded and that do not participate in study evaluation procedures, otherwise the blind will break. An Unblinded Statistician can never work in a blinded role within that study.

For step by step instructions on how to assign roles to users, see [Managing users \(STM and SIM\)](#).

### 3.2.2 Configuring the dynamic randomization in Viedoc Admin

**Note!** The randomization can only be configured by users that are assigned the system role **Unblinded Statistician**.

To enter the Randomizations page, select the toolbox icon in the **Randomization is on** field in Viedoc Admin.

In this example, we do not use allocation, so we only set up a Randomization list, as follows:

- We set the **Scope** of the Randomization list to *Study*.
- As **Factors**, we select *Gender* and *Age*.
- As **Outcome**, we select *Treatment*

From the **Randomization method** dropdown list, we select *Dynamic (Pocock/Simon)*.

**Note!** The dynamic randomization method can only be chosen if the following criteria are met:

- Only one outcome is selected
- The selected input factors, as well as the outcome, have a code list (no free text fields can be used).

**Note!** You will need to create the dynamic randomization configuration individually for demo mode and production mode after creating the dynamic randomization settings.

Select **Approve settings & generate list**. The **Create configuration** link is displayed:

The screenshot shows the Viedoc Admin interface for configuring a dynamic randomization. The interface is titled "Demo randomization 11" and includes a "Back" button in the top right corner. The main content area is divided into several sections:

- Factors:** Sex [SEX3] with options 1 Male and 2 Female.
- Outcomes:** Treatment [TREAT2] with options 1 Placebo and 2 Allocation, and a BLINDED status.
- Randomization List:** Scope: Country; Factors: SEX3; Outcomes: TREAT2.
- Allocation List:** Site; ITEM; KITNO, EXPIRYDATE.
- Randomization method:** Dynamic (Pocock/Simon).

Below these settings, there are two tabs: "Demo mode" (selected) and "Production". Under "Demo mode", there are two sections:

- Randomization List:** A table with one entry: "Sweden (Demo)" with a status of "Not initiated". A "Create configuration" button is highlighted in a yellow box.
- Allocation List:** A table with one entry: "ST1 Site1 (Demo)" with a status of "Not initiated". There is a "Download template" button and an "Upload" button.

Select **Create configuration** to configure the dynamic randomization.

We configure the dynamic randomization as follows:

- As **Variation method**, we select *Range* (this is the difference between the highest and the lowest value in the set).
- We set the **Probability** to 800 (the equivalent of 80%).
- In our example, it is more important to achieve balance in the factor *Gender* than in the factor *Age*, so we set the **Factor weights** to 2 for *Gender* and 1 for *Age*.
- Because we want treatment A to be allocated 50% of the time, and treatments B and C 25% of the time respectively, we set the **Allocation ratio** to 2 for treatment A, and to 1 for treatment B and C.
- As **Max slots (per list)** we enter a maximum of 50 slots.

The screenshot shows a web form titled "Configure dynamic randomization". It contains the following fields and values:

- Variation method:** A dropdown menu with "Range" selected.
- Probability (x/1000):** A text input field containing the number "800".
- Factor weights:** Two text input fields. "Gender" contains "2" and "Age" contains "1".
- Allocation ratio:** Three text input fields. "A" contains "2", "B" contains "1", and "C" contains "1".
- Max slots (per list):** A text input field containing the number "50".

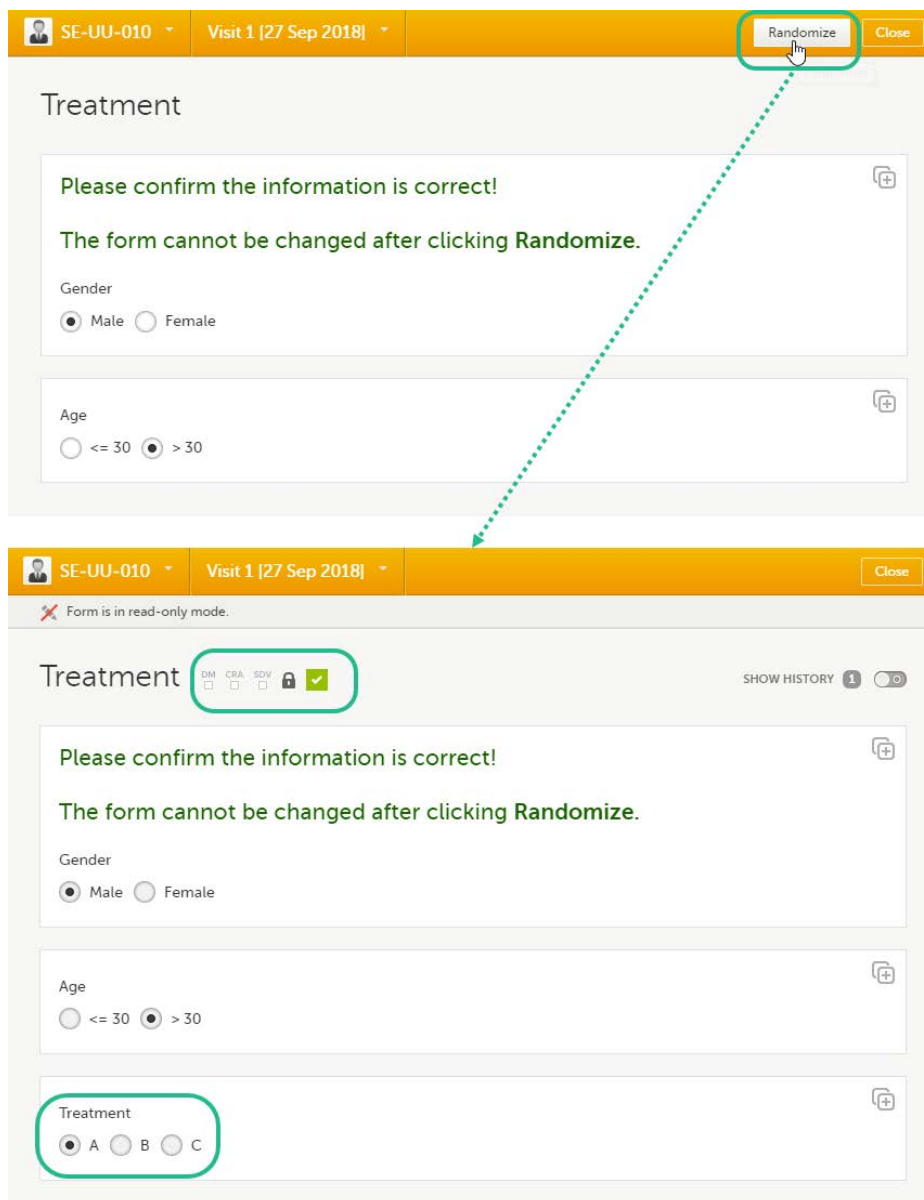
At the bottom of the form are two buttons: "Save" and "Cancel".

For step by step instructions on how to set up the randomization in Viedoc Admin, see [Configuring a dynamic randomization](#).

### 3.3 Actions to be performed in **Viedoc Clinic**

#### 3.3.1 Randomize a patient in Viedoc Clinic

When the clinic user has added a subject in Viedoc Clinic (*i.e.*, filled in the *Add Subject* form), and opens the *Treatment* form, the values for *Gender* and *Age* are automatically populated from the *Add subject* form. Upon clicking **Randomize**, the subject will be assigned to one of the treatment groups. The *Treatment* item will appear in the form, populated by the randomization service.



**Note!** Upon randomizing the subject, the randomization form (*Treatment* form) becomes read-only. This means that no item in the *Treatment* form will be editable, not even if the value for *Gender* or *Age* changes in the original *Add subject* form.

## 4 Calculations behind the scenes

This section explains how the calculations are made for assigning one of the three treatments (A, B or C) each time a new subject is randomized.

### 4.1 References

The underlying theory for the dynamic randomization method that is implemented in Viedoc is described in the following articles:

- Pocock S.J. and Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics* 1975;31:103-115.
- Miller E. Probability sharing in a modified Pocock-Simon method. 12th Int. Conf. of S.C.M.A Jun 22, 2005.

The Donald E. Knuth's subtractive random number generator algorithm that is used in the modified Pocock and Simon method implemented in Viedoc is described in the following article:

- Donald. E. Knuth. *The Art of Computer Programming, volume 2: Seminumerical Algorithms*. Addison-Wesley, Reading, MA, second edition, 1981.

## 4.2 Concepts and terminology for dynamic randomization

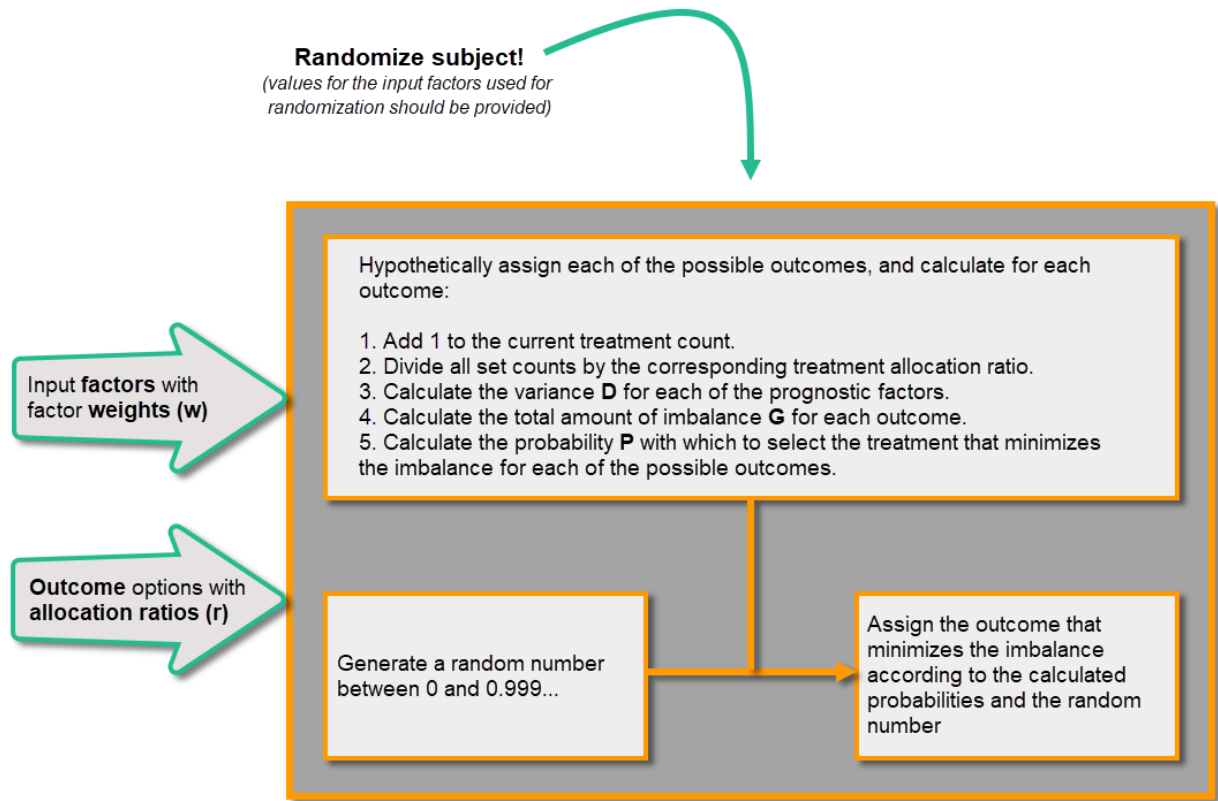
The following table lists the terms that the algorithm used for dynamic randomization according to the Pocock and Simon method is based on.

Term	Description	Calculated as
D	The amount of variation in the set of values for a factor	<ul style="list-style-type: none"> <li>▪ Range - the difference between the highest and the lowest values in the set, or</li> <li>▪ Range Squared - the square of the range.</li> </ul>
G	The total amount of imbalance across all factors	Sum of weighted D (D multiplied by factor weight) for all factors.
P (p)	The probability with which the treatment that minimizes imbalance is assigned	<p>The probability determines the extent to which one wishes to favour the treatment group that would lead to the smallest imbalance.</p> <p>During the randomization, the probability P for each treatment assignment is calculated, based on a probability cut-off. This probability cut-off (referred to as p below) is a static decimal between 0 and 1 that is provided by a statistician. In Viedoc, the probability cut-off has to be entered as x/1000. So for a p of 0.8 (80%), the number 800 should be entered.</p> <p>During randomization, P for each treatment will be distributed as follows: (N = number of treatments, p = probability cut-off)</p> <ul style="list-style-type: none"> <li>▪ If the Gs are the same for all treatment assignments, then the probability will be the same for each treatment: <math>P=p/N</math>.</li> <li>▪ If one treatment has the lowest G, then it will have its probability P as p. The remaining treatments will split the remaining probability: <math>P=(1 - p)/(N - 1)</math></li> <li>▪ If one or more treatments share the lowest G value, then Viedoc first calculates what the remaining non-favoured treatments will get and then splits the remainder between the favoured treatments.</li> </ul>
Random	A random number between 0 and 1	Generated using Donald E. Knuth's subtractive random number generator algorithm
seed	A value used to initialize the random number generator	Based on the number of ticks to represent the current date

## 4.3 Procedure

Using the above algorithms, a frequency table is calculated for each new subject to be randomized. A random number greater than or equal to 0 and less than 1 is generated using a seed value based on the number of ticks to represent the current date. Using the Ps and this random number, a treatment index is chosen and the patient is thereby assigned this treatment.

When a new subject is added and should be randomly assigned a treatment, the following calculations are performed:



#### 4.4 Calculations

Once the first subject is randomized, it is possible to download the randomization list from Viedoc Admin.

Documentation of Life Back

### Dynamic randomization

Factors

Gender [SEX]  
1 Male 2 Female

Age [AGE]  
1 <= 30 2 > 30

Outcomes

Treatment [TREAT]  
1 A 2 B 3 C

Scope: Study Factors: SEX, AGE Outcomes: TREAT

Randomization List

Randomization method: Dynamic (Pocock/Simon)

Demo mode: Production

Randomization List Edit configuration

5230 Documentation of Life	Active
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Download (Excel icon)

An Excel file is downloaded, which has the following three sheets:

- **Configuration (1)** - a summary of the factors and outcomes and their code lists, and the randomization details (randomization method, variation method, probability, maximum number of slots per list, factor weights and allocation ratio).
- **Current distribution (2)** - a summary of the number of entries sorted by the factors and the outcome. In our example, we can see how many subjects are assigned to each treatment, how many of them are males/females and how many are aged <=30 and >30.
- **Slots (3)** - one row for each randomized subject, listing:
  - the details of the randomization: factors and outcomes, subject details, user details (e-mail address) of the clinic user who randomized the subject, and date and time of randomization,

- the details of the applied algorithm: variation method, probability P, factor weights, allocation ratio, maximum number of slots per list, Gs, Ps, Random and Seed.

Demo mode Production

Randomization List Edit configuration

1726 Randomization Active

Configuration

Factors:  
 Gender (TREAT1) 1 = Male 2 = Female  
 Age (TREAT2) 1 = <=30 2 = >30

Outcomes:  
 Treatment (TREAT3) 1 = A 2 = B 3 = C

Randomization method: DynamicPocockSimon  
 Variation method: Range

Probability: 0,8  
 Max number of slots (per list): 50

Factor weights:  
 Gender 2  
 Age 1

Allocation ratio:  
 A 2  
 B 1  
 C 1

Treatment	Gender	Age	Total
	Male	Female	
A	1	1	2
B	1	1	2
C	0	1	1
Total	2	3	5

A	B	C	D	E	F	G	M	N	O	P	Q	R	S	T	U
#	Gender	Gender - Code	Age	Age - Code	Treatment	Treatment - Code	Variation method	P	Factor weights	Allocation ratio	Max slots (per list)	Gs	Ps	Random	Seed
1	Female	2	>30	2	C	3	Range	0,8	2, 1	2:1:1	50	1,5, 3,0, 3,0	0,80, 0,10, 0,10	0,934005014	1990058125
2	Male	1	>30	2	A	1	Range	0,8	2, 1	2:1:1	50	2,0, 3,0, 4,0	0,80, 0,10, 0,10	0,039927775	-1342522832
3	Female	2	<=30	1	B	2	Range	0,8	2, 1	2:1:1	50	2,5, 3,0, 5,0	0,80, 0,10, 0,10	0,858836875	-805769653
4	Female	2	>30	2	A	1	Range	0,8	2, 1	2:1:1	50	2,0, 4,5, 6,0	0,80, 0,10, 0,10	0,607355348	-606037390
5	Male	1	>30	2	B	2	Range	0,8	2, 1	2:1:1	50	3,5, 2,0, 4,0	0,10, 0,80, 0,10	0,77764124	-319975653

calculating the variances (d) and imbalance (G) when the first added subject is Female with age > 30, assuming that treatment A would be assigned

		$w_G=2$ (factor weight for Gender)		$w_A=1$ (factor weight for Age)		
		Male	Female	<=30	>30	
$r_A = 2$	A	0	0 -> $+1 \rightarrow 1/r_A = 1/2 = 0.5$ $d_{AF} = \max(0.5, 0, 0) - \min(0.5, 0, 0) = 0.5 - 0 = 0.5$	0	0 -> $+1 \rightarrow 1/r_A = 1/2 = 0.5$ $d_{A(>30)} = \max(0.5, 0, 0) - \min(0.5, 0, 0) = 0.5 - 0 = 0.5$	$G_A = d_{AF} * w_G + d_{A(>30)} * w_A = 0.5 * 2 + 0.5 * 1 = 1.5$
$r_B = 1$	B	0	0 -> $0/r_B = 0/1 = 0$	0	0 -> $0/r_B = 0/1 = 0$	
$r_C = 1$	C	0	0 -> $0/r_C = 0/1 = 0$	0	0 -> $0/r_C = 0/1 = 0$	

Let's consider the first added subject and take a look at how the first set of calculations is performed in order to assign a randomized treatment.

All the values in the distribution table (illustrated by 2 in the image) are equal to 0 at start point. We are adding a first subject with *Gender = Female* and *Age > 30*. For this, we follow the workflow for calculating D, G and P for each of the three possible outcomes (treatments).

We are going to use the following notations:

- Factor weights
  - $w_G$  - factor weight for gender = 2
  - $w_A$  - factor weight for age = 1
- Allocation ratios
  - $r_A$  - allocation ratio for treatment A = 2
  - $r_B$  - allocation ratio for treatment B = 1
  - $r_C$  - allocation ratio for treatment C = 1

- Variance
  - $d_{AM}$  - variance for treatment = A, and gender = male
  - $d_{AF}$  - variance for treatment = A, and gender = female
  - $d_{A(<=30)}$  - variance for treatment = A, and age  $\leq 30$
  - $d_{A(>30)}$  - variance for treatment = A, and age  $> 30$
  - $d_{BM}$ ,  $d_{BF}$ ,  $d_{B(<=30)}$ ,  $d_{B(>30)}$ ,  $d_{CM}$ ,  $d_{CF}$ ,  $d_{C(<=30)}$ ,  $d_{C(>30)}$  - variances for treatment B, respective C, in the same manner as described above for treatment A.

We start by hypothetically assigning each of the three treatments and calculating the variances for each assignment. Because the subject to be added is a female with age  $> 30$ , we only have to calculate the variances for those factor values.

- Assuming that treatment A would be assigned, we add 1 to the distribution table, in the row for *Treatment A*, in the *Female* column and in the *Age > 30* column. The variances for each factor are calculated as below and illustrated by the last table in the image:
  - $d_{AF} = 1/r_A - 0 = 1/2 = 0.5$  (one female subject was added, which makes the highest value in the distribution table corresponding to the *Female* column = 1 and the lowest = 0)
  - $d_{A(>30)} = 1/r_A - 0 = 1/2 = 0.5$  (one subject was added with age  $> 30$ , which makes the highest value in the distribution table corresponding to the *Age > 30* column = 1 and the lowest = 0)
- Assuming that treatment B would be assigned, we add 1 to the distribution table, in the row for *Treatment B*, in the *Female* column and in the *Age > 30* column. The variances for each factor:
  - $d_{BF} = 1/r_B - 0 = 1$  (one female subject was added, which makes the highest value in the distribution table corresponding to the *Female* column = 1 and the lowest = 0)
  - $d_{B(>30)} = 1/r_B - 0 = 1$  (one subject was added with age  $> 30$ , which makes the highest value in the distribution table corresponding to the *Age > 30* column = 1 and the lowest = 0)
- Assuming that treatment C would be assigned, we add 1 to the distribution table, in the row for *Treatment C*, in the *Female* column and in the *Age > 30* column. The variances for each factor:
  - $d_{CF} = 1/r_C - 0 = 1$  (one female subject was added, which makes the highest value in the distribution table corresponding to the *Female* column = 1 and the lowest = 0)
  - $d_{C(>30)} = 1/r_C - 0 = 1$  (one subject was added with age  $> 30$ , which makes the highest value in the distribution table corresponding to the *Age > 30* column = 1 and the lowest = 0)

Then we calculate the total amount of imbalance for each of the three possible treatment assignments. These are the values displayed in the table in the Slots sheet (3 in the image), for the first entry, in the  $G_s$  column:

- $G_A = d_{AF}W_G + d_{A(>30)}W_A = 0.5*2 + 0.5*1 = 1.5$
- $G_B = d_{BF}W_G + d_{B(>30)}W_A = 1*2 + 1*1 = 3$
- $G_C = d_{CF}W_G + d_{C(>30)}W_A = 1*2 + 1*1 = 3$

Then we calculate the probability (P) for each of the three possible treatment assignments. We have set the probability (p) to 0.8 in our example. The treatment with the lowest G (in our case A) will receive the Probability (P) as p (in our case 0.8). The remaining treatment assignments will split the remaining probability. These are the values displayed in the table in the Slots sheet (3 in the image), for the first entry, in the  $P_s$  column:

- $P_A = 0.8$  (thus covering all values greater than or equal to 0 and less than 0.8)
- $P_B = 0.1$  (thus covering all values greater than or equal to 0.8 and less than 0.9)
- $P_C = 0.1$  (thus covering all values greater than or equal to 0.9 and less than 1)

Then we generate a random number between 0 and 1 using Donald E. Knuth's subtractive random number generator algorithm and a seed value based on the number of ticks to represent the current date. The number is displayed in the table in the Slots sheet (3 in the image), for the first entry, in the Random column, in our example Random = 0.934...Considering the probabilities for each treatment assignment, and the random number, treatment C will be assigned to the first subject, as illustrated in the image.





Forcing change in subject ID pattern

# Forcing change in subject ID pattern

Published by Viedoc System 2020-10-12

## [1. Introduction](#)

## [2. Scenario](#)

## [3. Solution](#)

[3.1 Apply a new version and make a small change](#)

[3.2 Change the country.](#)

## 1 Introduction

This use case shows how to change from an autogenerated to a manually entered subject ID, to avoid a mix of patterns in the study.

## 2 Scenario

- In version 1 of the design, the subject IDs are auto-generated according to the pattern:

{CountryCode}-{SiteCode}-{SiteSubjectSeqNo:000}

Subjects get subject IDs looking like this:

The screenshot shows the Viedoc system interface. The top bar displays 'SE-A-001' and 'A [22 Sep 2020]'. The main content area shows a form in view mode with the subject ID '00001' entered in the 'subjid' field. The sidebar on the left shows 'Details' and 'SE-A-001'. At the bottom, there is a 'Delete subject' button and a footer with the text 'Jens Pettersson | Viedoc™ 4.60.7534.15011 | 2020-09-22T15:49 CEST 1 | 1.0 | Subject ID revision | A'.

- In version 2 of the design, the subject IDs are taken from the field **subjid** in the Study start event, thus the pattern:

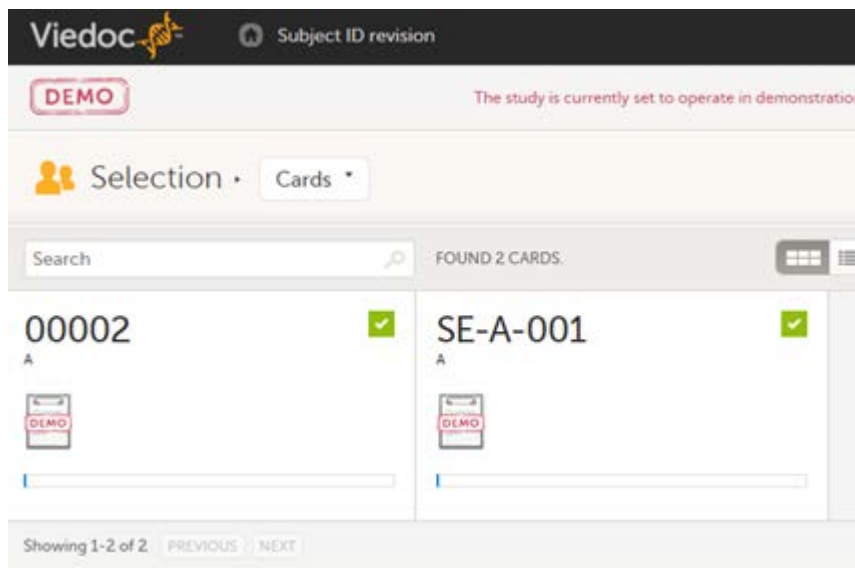
subjid

This is assigned to all sites and subjects get subject IDs looking like this:



The screenshot shows a Viedoc form in view mode. The header includes the Viedoc logo, a study ID of 00002, and a date of 22 Sep 2020. The form content includes a 'dm' field, a 'subjid' field containing '00002', and a 'Delete subject' button. A footer note reads: 'Jens Pettersson | Viedoc™ 4.60.7534.15011 | 2020-09-22T15:55 CEST | 1 | 2.0 | Subject ID revision | A'.

- In Viedoc Clinic, you can now see a mix of patterns for the subject IDs:

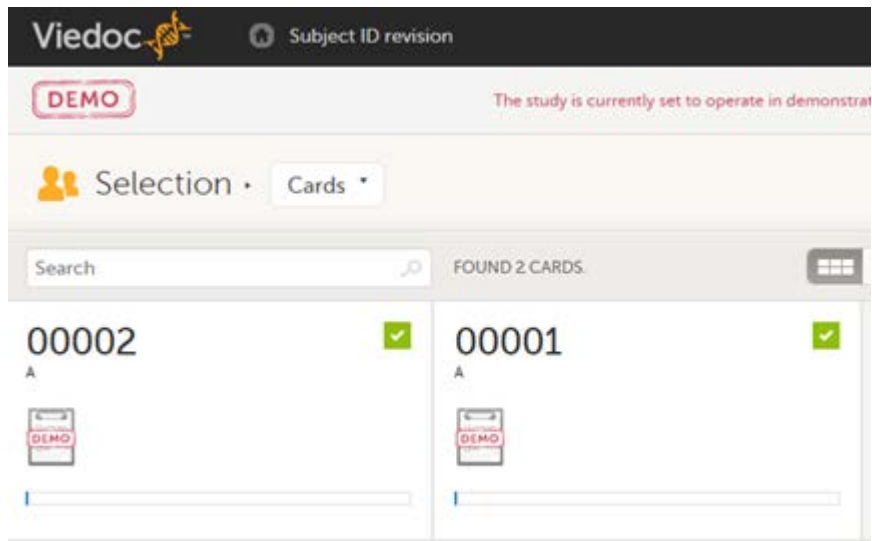


The screenshot shows the Viedoc Clinic interface for 'Subject ID revision'. It features a search bar with the text '00002' and a result count of 'FOUND 2 CARDS.'. Below the search bar, two subject ID cards are displayed: '00002' and 'SE-A-001'. Each card has a 'DEMO' label and a green checkmark. The bottom of the interface shows 'Showing 1-2 of 2' and navigation buttons for 'PREVIOUS' and 'NEXT'.

### 3 Solution

#### 3.1 Apply a new version and make a small change

One way of solving the mix of patterns is to make a revision of the Study start event form in version 1 and apply it to the study. The revision will not change the subject ID pattern, as this is not possible in revisions, instead we make an insignificant change to trigger an update of the subject ID. The recommended change is an insignificant text change to one of the items in the Study start event form. The Investigator then has to approve this change, and the subject IDs are updated:



### 3.2 Change the country

Another way of doing it is to trigger an update of all subject IDs by changing the country of all sites, and then immediately change it back again.



Activating SSO

# Activating SSO

Published by Viedoc System 2020-12-10

## [1. Introduction](#)

## [2. Using Google Workspace as IdP](#)

### [2.1 Pre-requisites](#)

### [2.2 Step-by-step guide](#)

## [3. Using Microsoft Azure AD as IdP](#)

### [3.1 Pre-requisites:](#)

### [3.2 Step-by-step guide](#)

## 1 Introduction

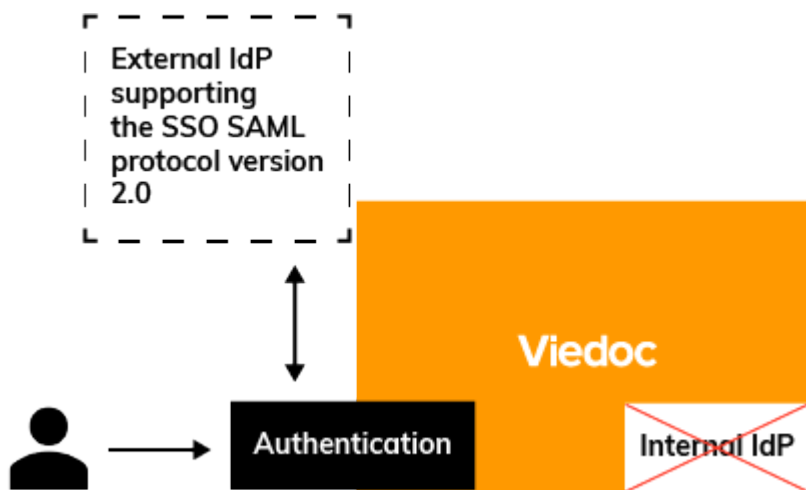
This use case shows how users can authenticate themselves in Viedoc using an external identity provider (IdP) instead of the built-in identity provider, and thus being able to log in using single sign-on (SSO).

The users identify themselves with an email address containing a domain name—below referred to as `hostmaster@your.domain.name`—that the user owns or that you as the Organization Administrator is in control of.

We go from this:



...to this:



## 2 Using Google Workspace as IdP

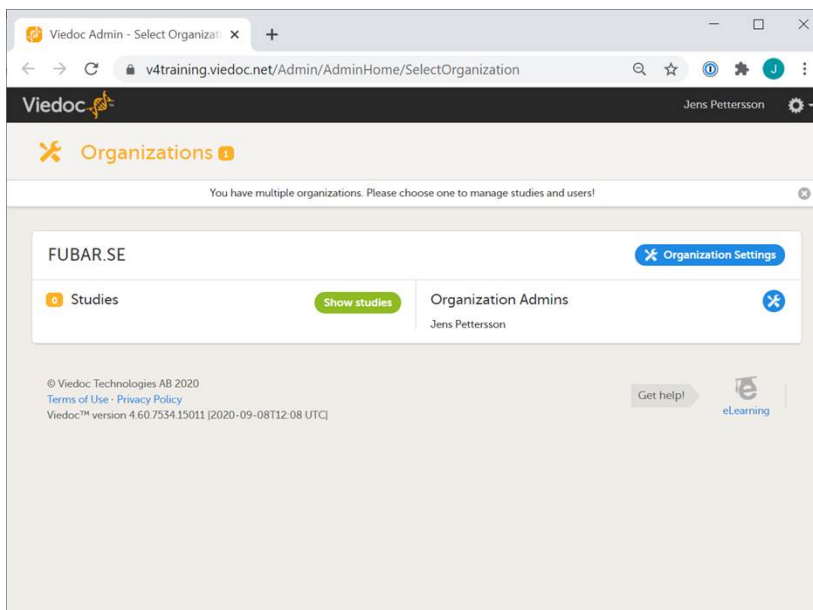
### 2.1 Pre-requisites

- The domain name for which you want to configure [SSO](#) must have an email address like this: `hostmaster@your.domain.name`, and you must be able to get hold of a key sent to that address.
- You must have Organization Administrator access to Viedoc.
- You must have Administrator access to Google Workspace.

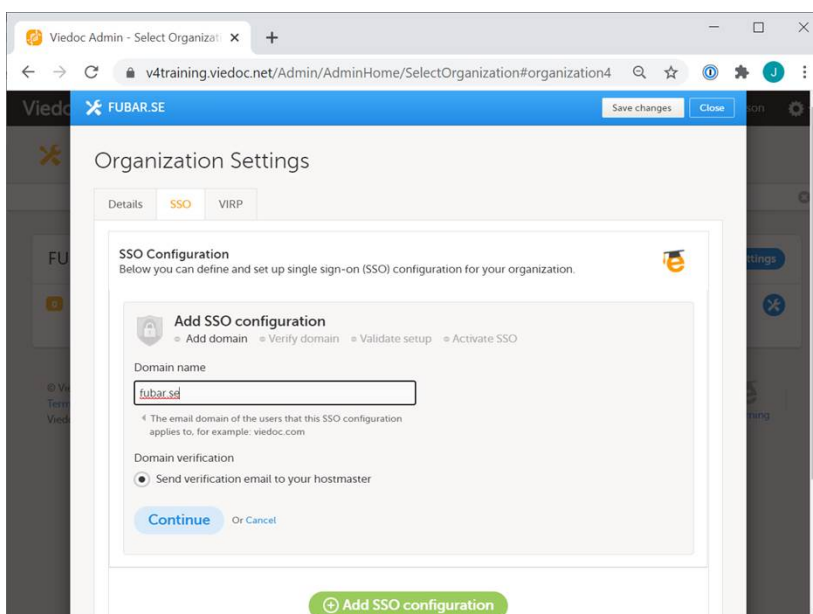
### 2.2 Step-by-step guide

In this guide we use the domain name **fubar.se** and the European Viedoc training instance.

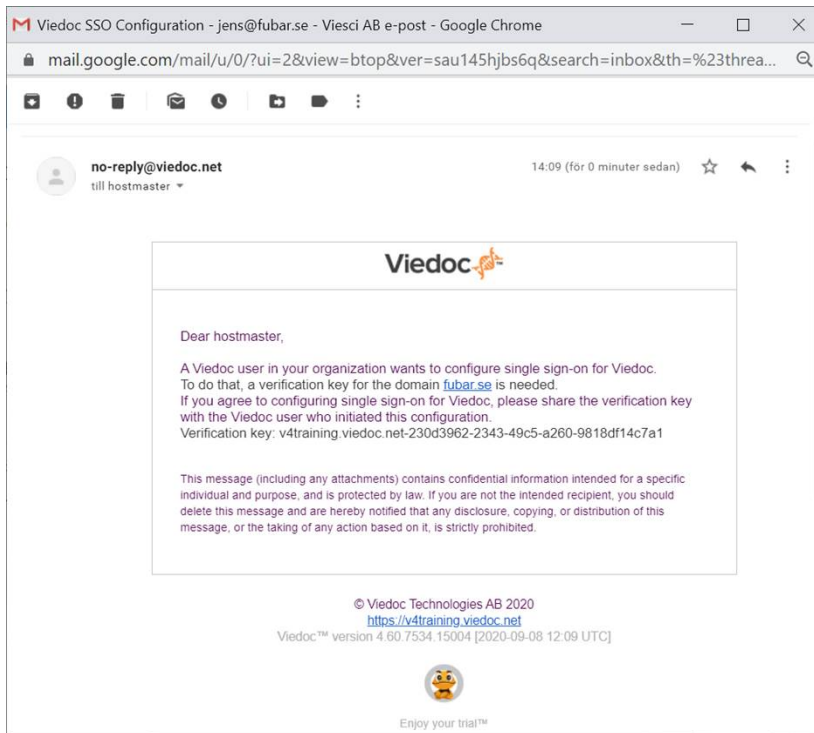
- 1 As Organization Administrator, go to Admin and click **Organization Settings**:



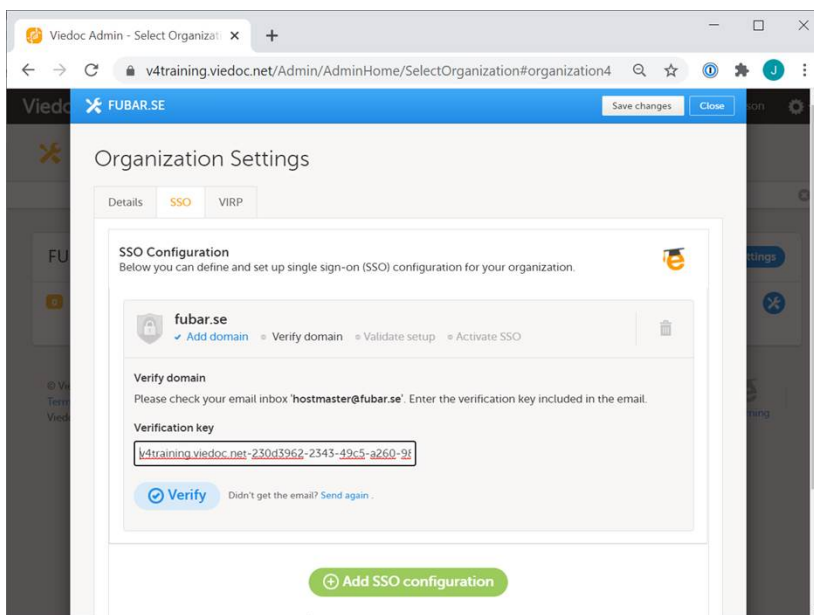
- 2 Click the tab **SSO > Add SSO configuration**, enter the **Domain name** and click **Continue**.



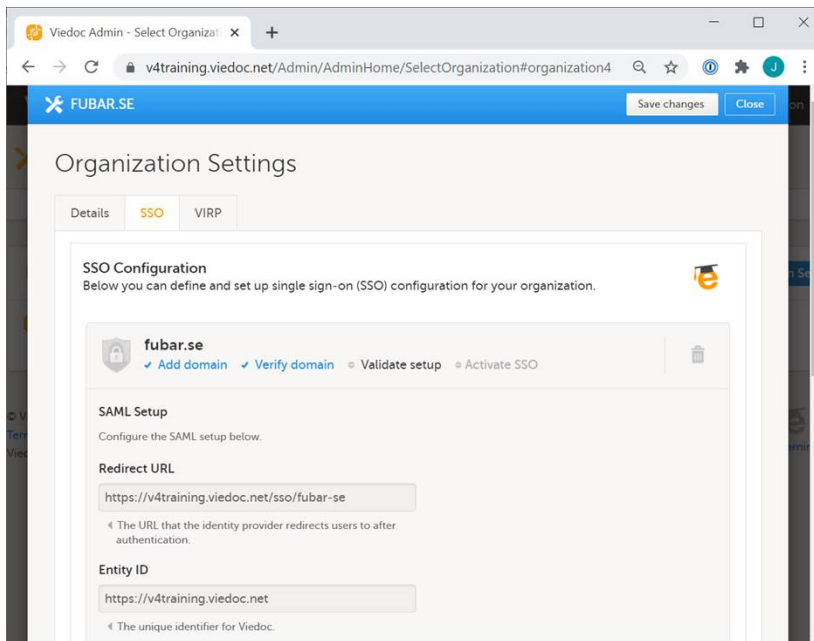
- 3 Contact the person in your organization with access to the `hostmaster@your.domain.name` email inbox, to retrieve the verification key that proves that you own the domain.



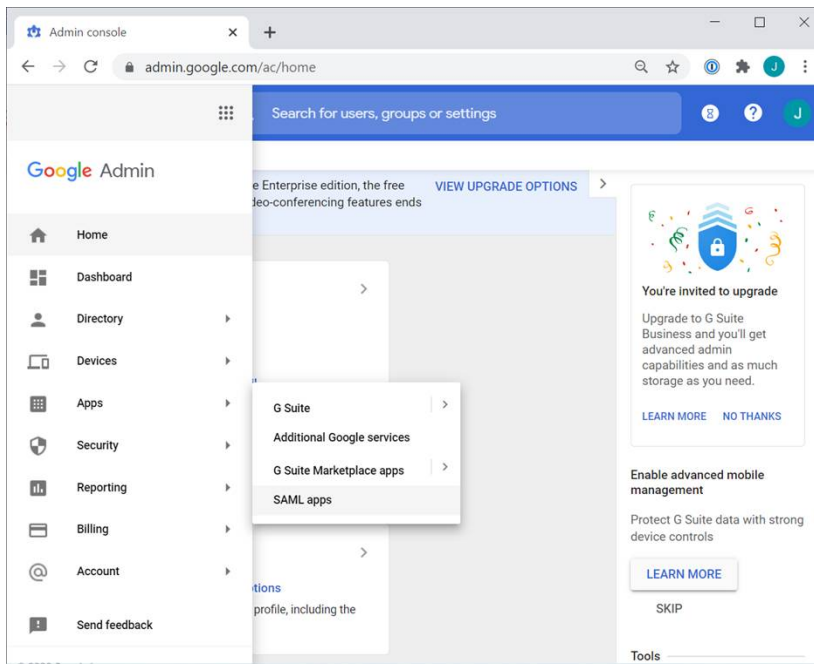
- 4 Enter the verification key in Viedoc and click **Verify**.



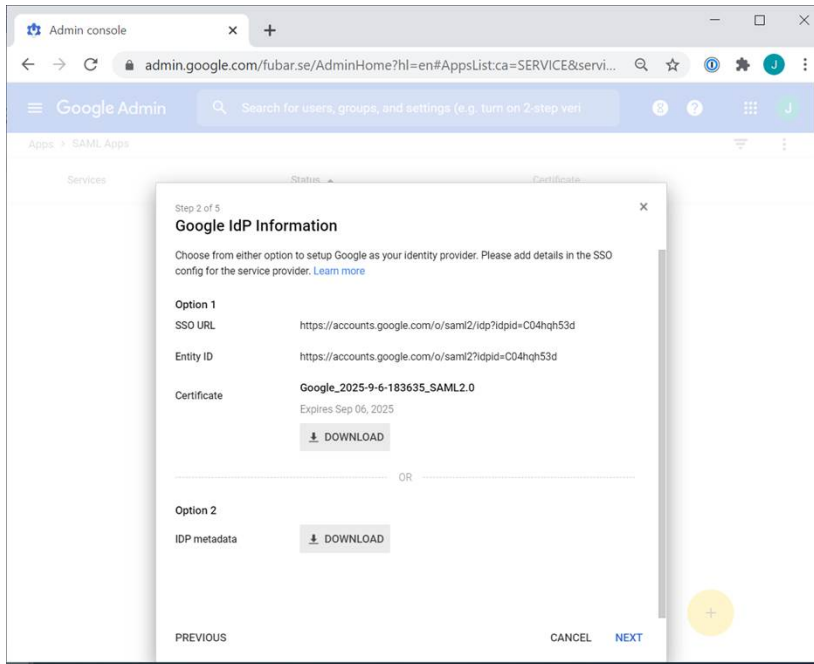
5 Make a note of the **Redirect URL** and the **Entity ID**.



6 In a separate tab, log in to Google Workspace Admin Console, go to **Apps > SAML apps**.



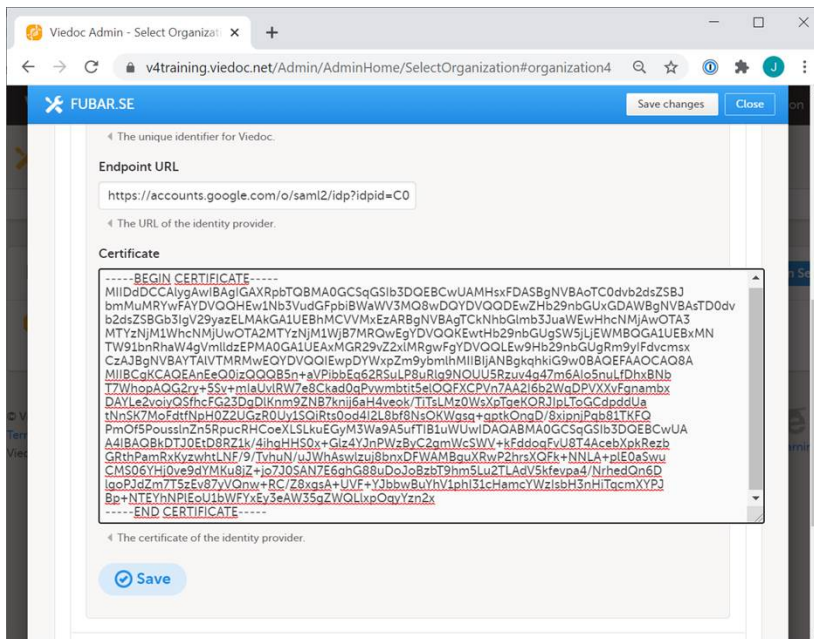
7 Click to **Add service** and click to **SETUP MY OWN CUSTOM APP**:



8 From the Google IdP Information window:

- Copy the [SSO URL](#) and paste it into the Viedoc field titled **Endpoint URL**.
- Download the certificate and open it in a text editor, for example Notepad. Copy and paste it into the Viedoc field **Certificate**.

Click **Save**.



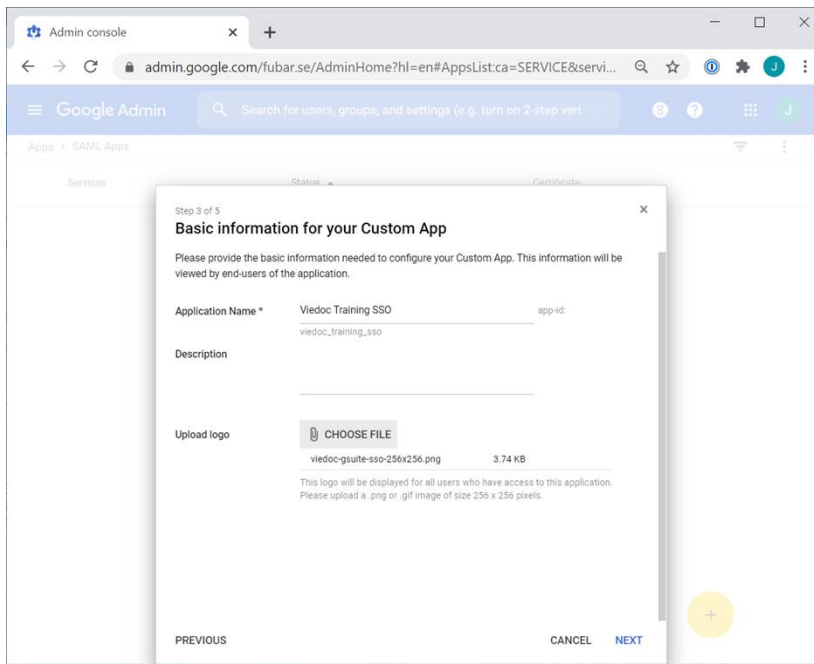
9 In Viedoc, copy the redirect URL and go back to the Google Workspace tab and click **Next**.



10 In the **Basic information for your Custom App** window:

- Enter an appropriate **Application Name** describing the Viedoc instance, for example “Viedoc Training SSO”.
- Download the Viedoc logo from the following URL <https://www.viedoc.com/viedoc-gsuite-ss0-256x256.png> and upload it in the Google Workspace dialog box.

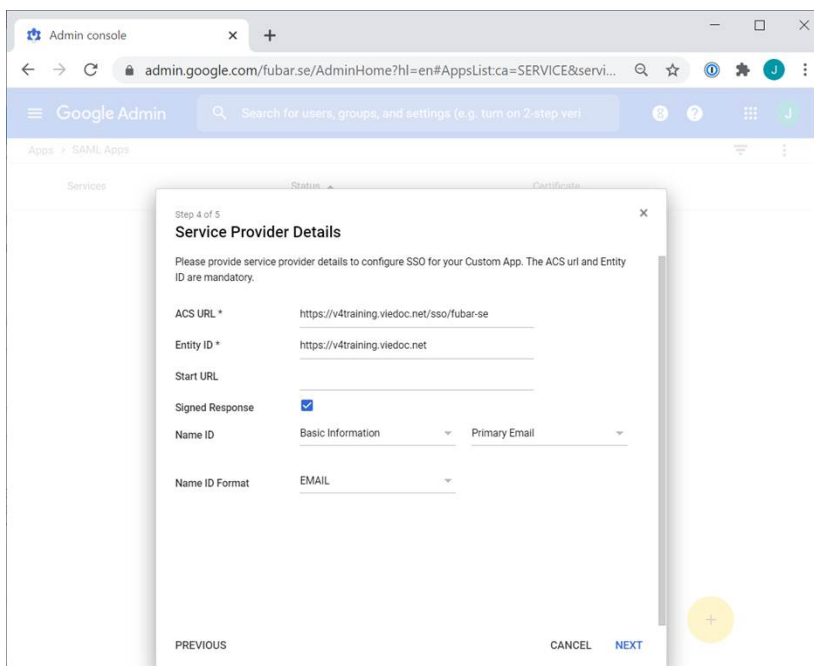
Click **Next**.



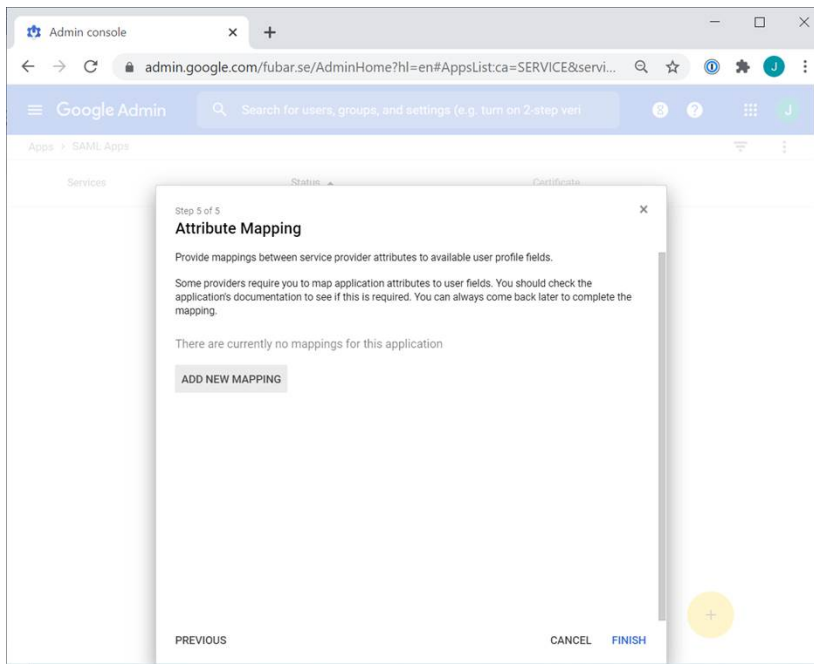
11 In the **Service Provider Details** window:

- Paste the redirect URL into the **ACS URL** field.
- Copy the Entity ID from the Viedoc tab into the **Entity ID** field in the Google Workspace tab.
- Select **Signed Response**.
- Set the Name ID to **Basic Information** and **Primary Email**.
- Set the Name ID format to **EMAIL**.

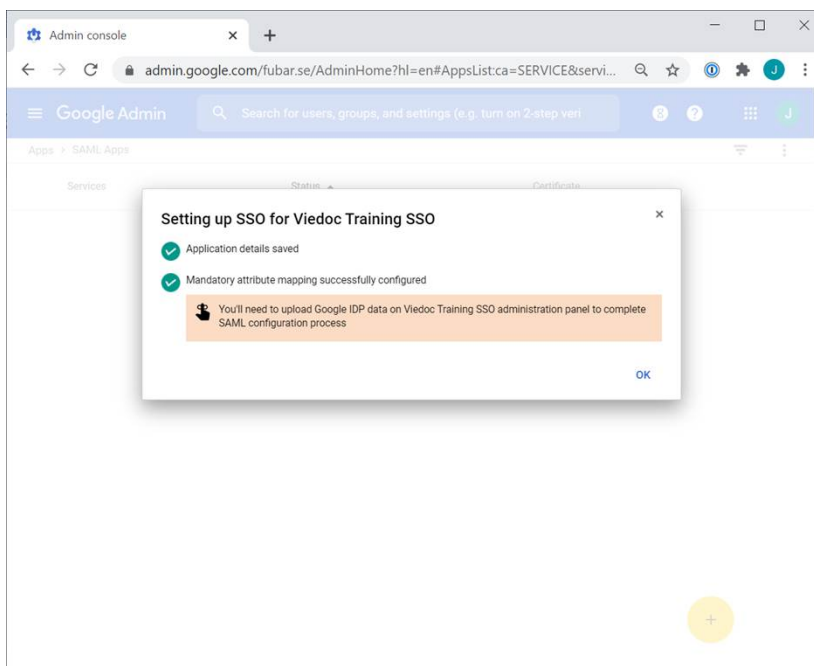
Click **Next**.



12 In the **Attribute Mapping** window, click **Finish**.

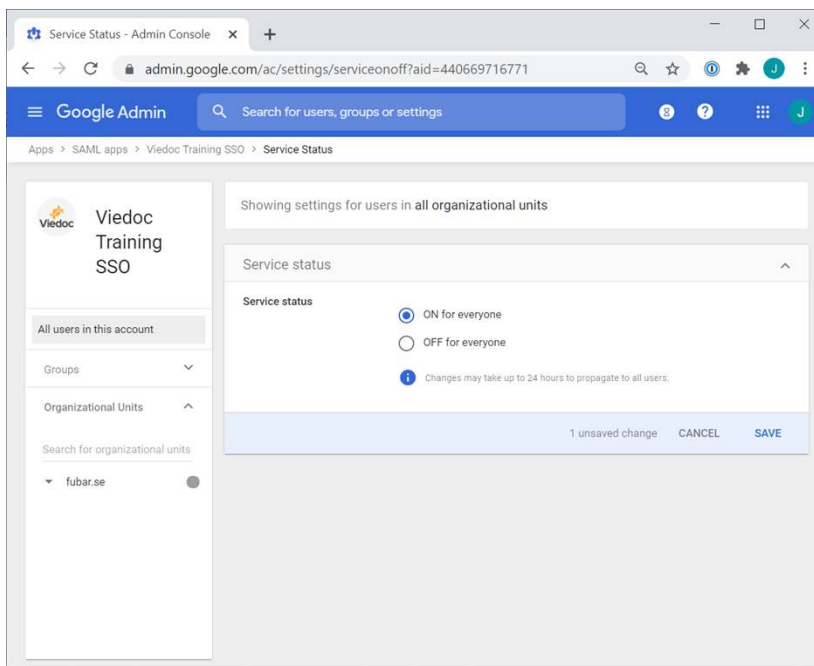


13 Click **OK**.



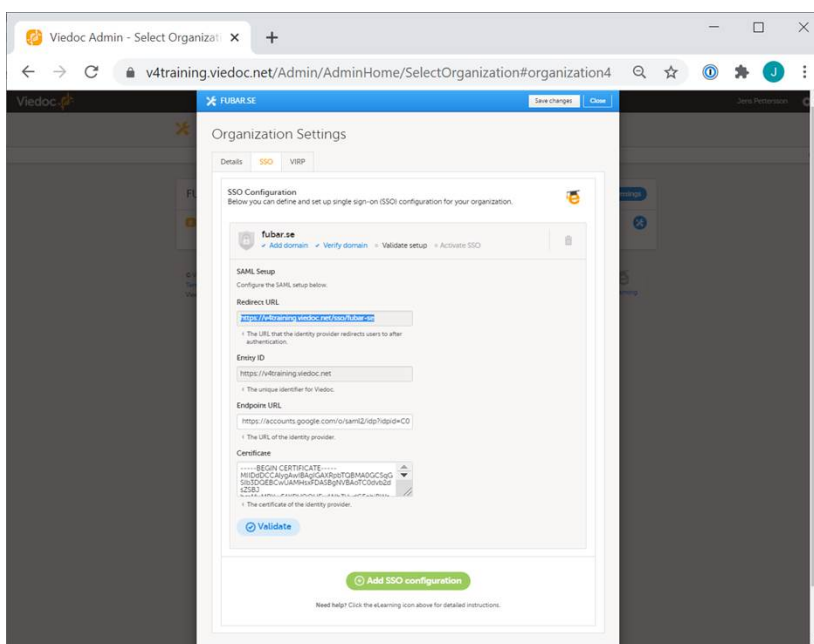
14 Click the down arrow of the **User access** section of the newly configured SAML App.

Select **ON for everyone** and click **Save**.

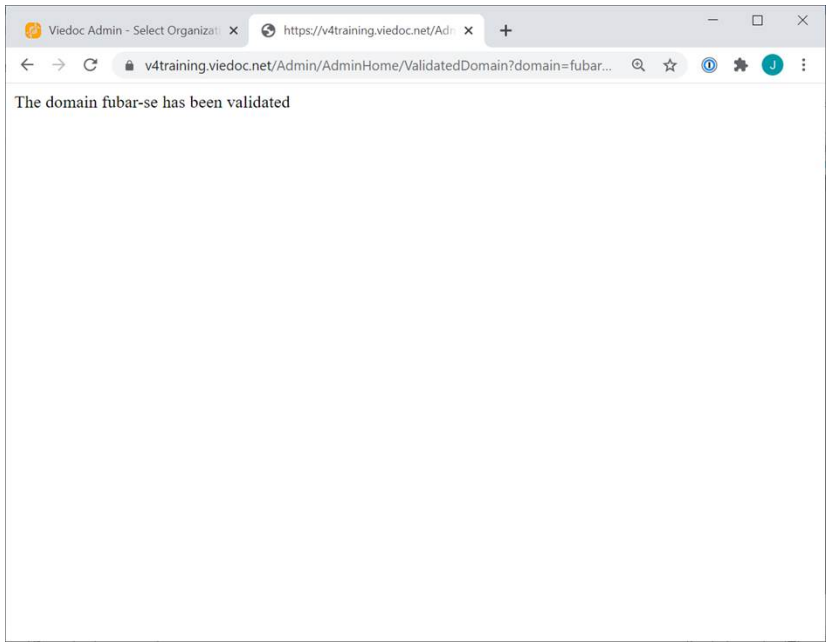


15 Go back to the Viedoc tab and click **Validate**.

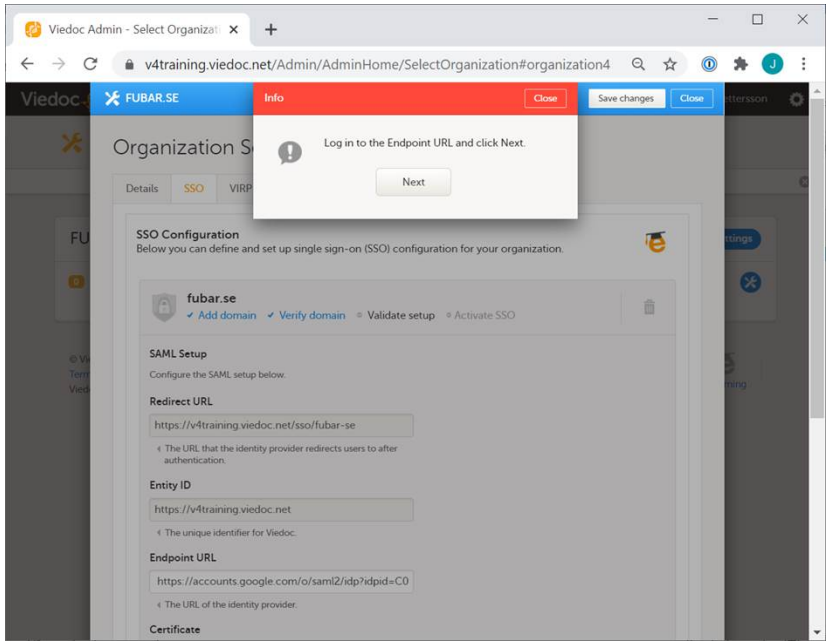
**Note!** You might be prompted to enter your email address and password in order to authenticate with your IdP if not already logged in. Upon successful authentication you will automatically be redirected to the domain verification page.



16 Verify that the domain is validated and then close the tab.

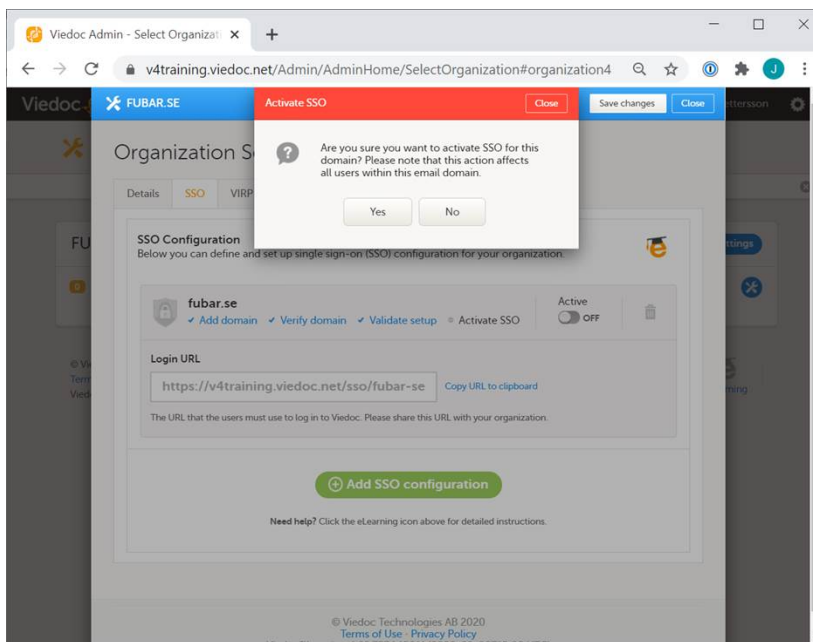


17 Click **Next**.



18 The SSO configuration is now completed.

When all users are informed about the new login URL—with the configured domain as their login name (the primary email address is used for authentication in both the IdP and in Viedoc)—click **Activate** > **Yes**.



## 3 Using Microsoft Azure AD as IdP

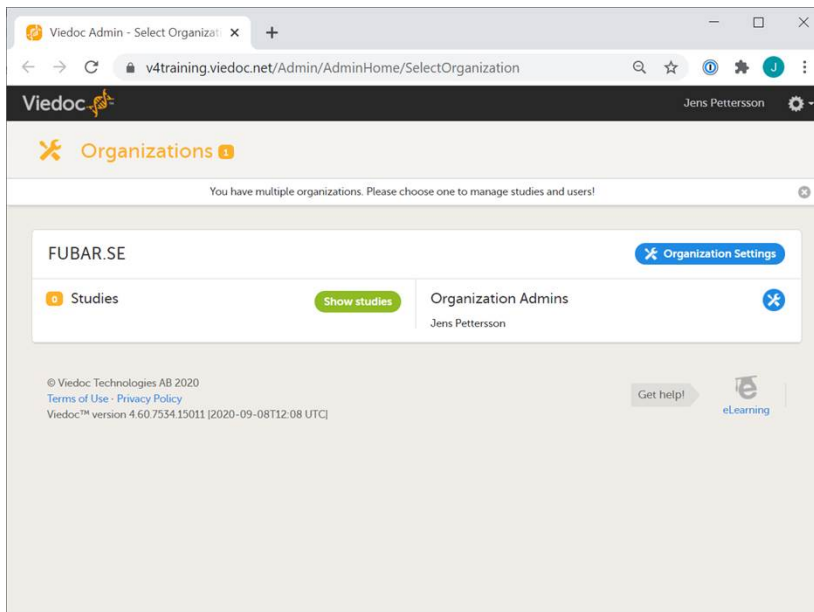
### 3.1 Pre-requisites:

- The domain name for which you want to configure [SSO](#) must have an email address like this: `hostmaster@your.domain.name`, and you must be able to get hold of a key sent to that address.
- You must have Organization Administrator access to Viedoc.
- You must have Administrator access, or higher, in Microsoft Azure Active Directory (AD).

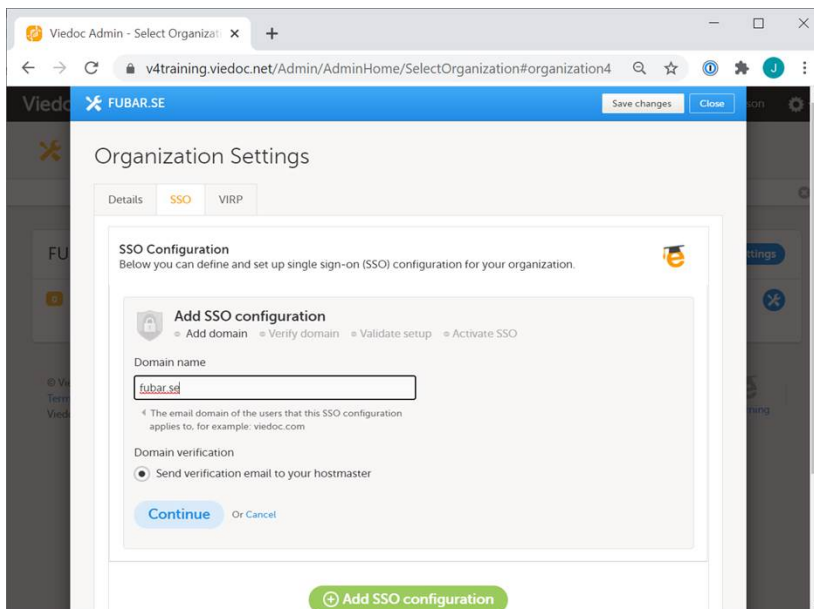
### 3.2 Step-by-step guide

In this guide we use the domain name **pcg-solutions.com** and the European Viedoc training instance.

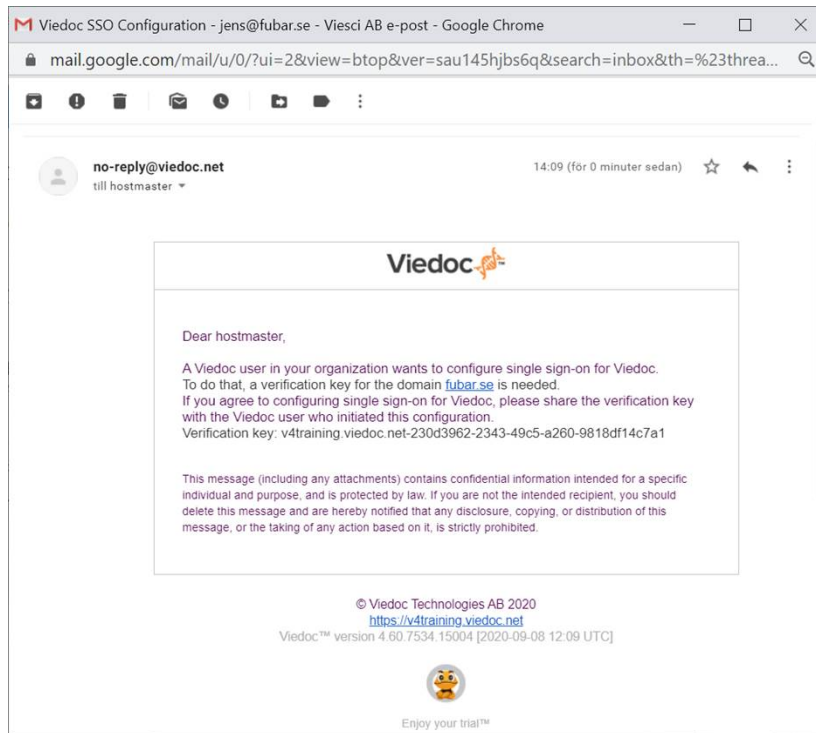
1 As Organization Administrator, go to Admin and click **Organization Settings**:



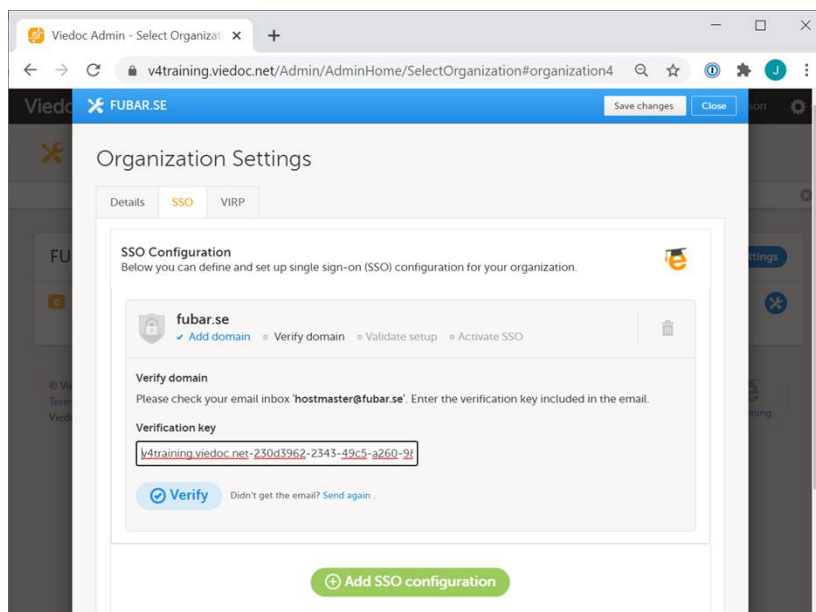
2 Click the tab **SSO > Add SSO configuration**, enter the **Domain name** and click **Continue**.



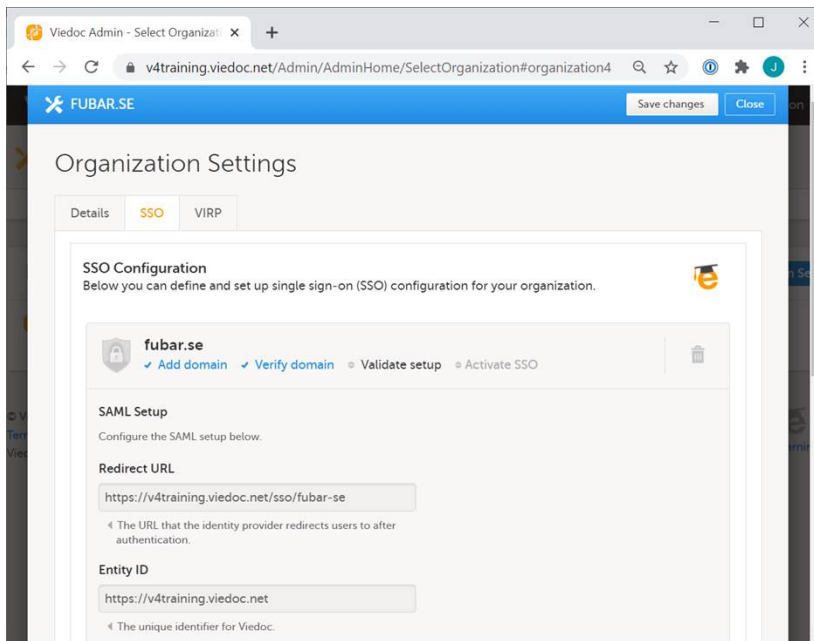
- 3 Contact the person in your organization with access to the `hostmaster@your.domain.name` email inbox to retrieve the verification key that proves that you own the domain.



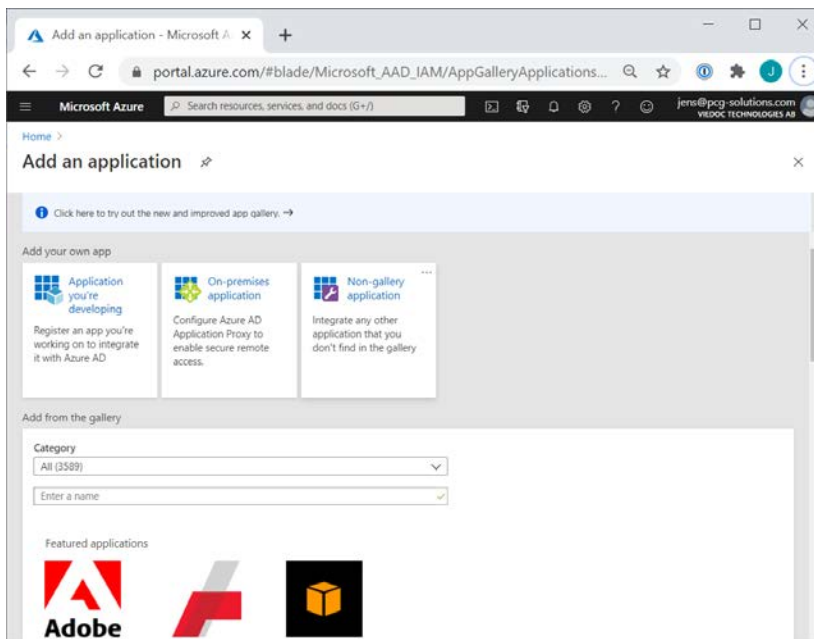
- 4 Enter the verification key in Viedoc and click **Verify**.



5 Make a note of the **Redirect URL** and the **Entity ID**.



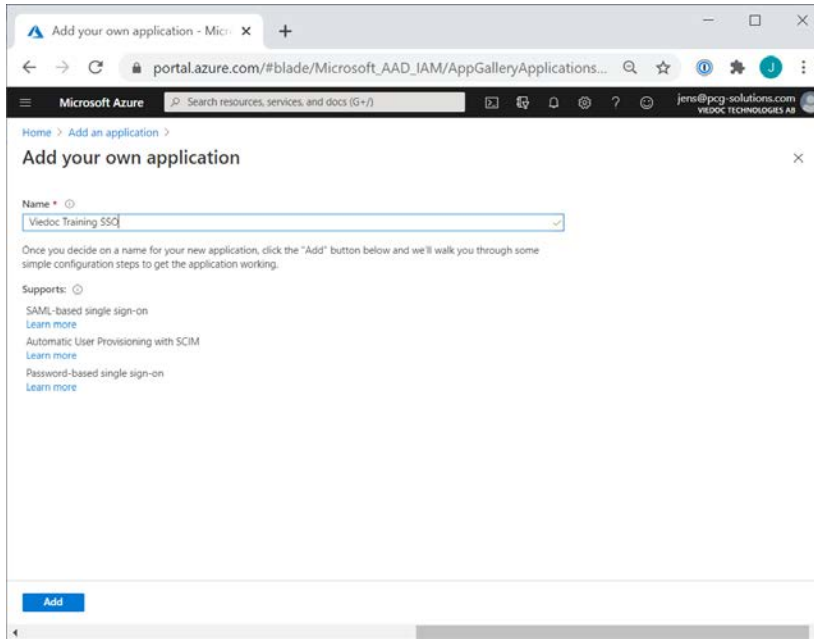
6 In a separate tab, log in to the Microsoft Azure portal and go to **Azure Active Directory**.  
Click **Enterprise Applications** > **New application** and select **Non-gallery application**.



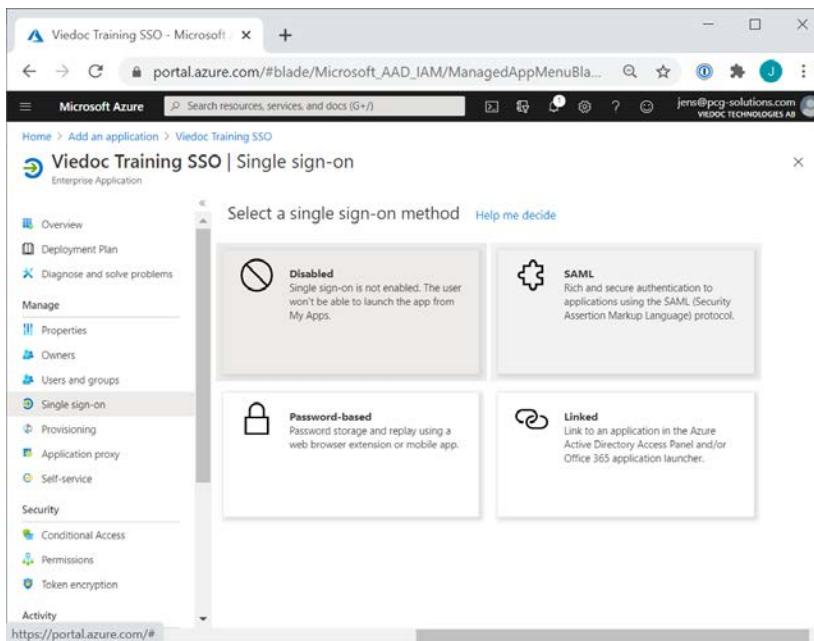


7 Enter an appropriate **Name** describing the Viedoc instance, for example “Viedoc Training SSO”.

Click **Add**.



8 Click **Single Sign-On > SAML**.

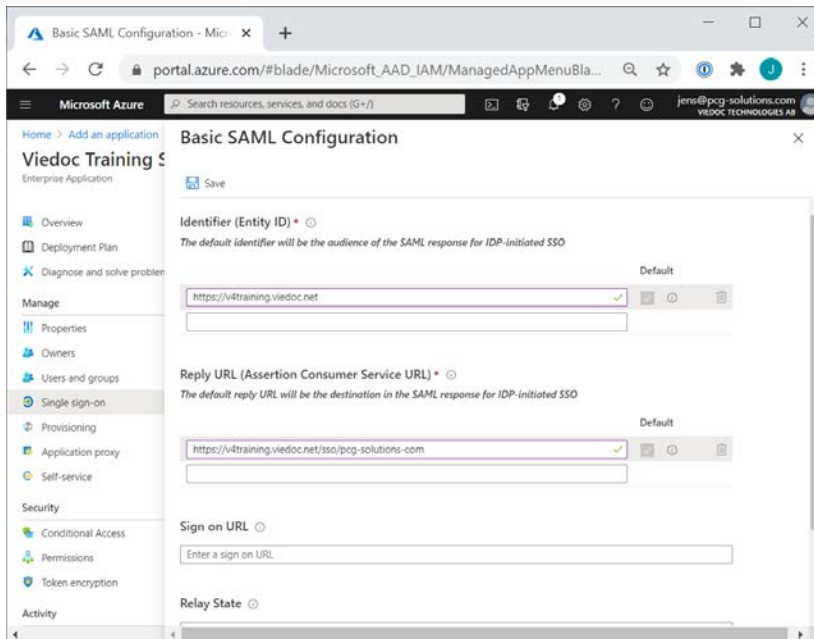


9 Click **Edit the Basic SAML Configuration**.

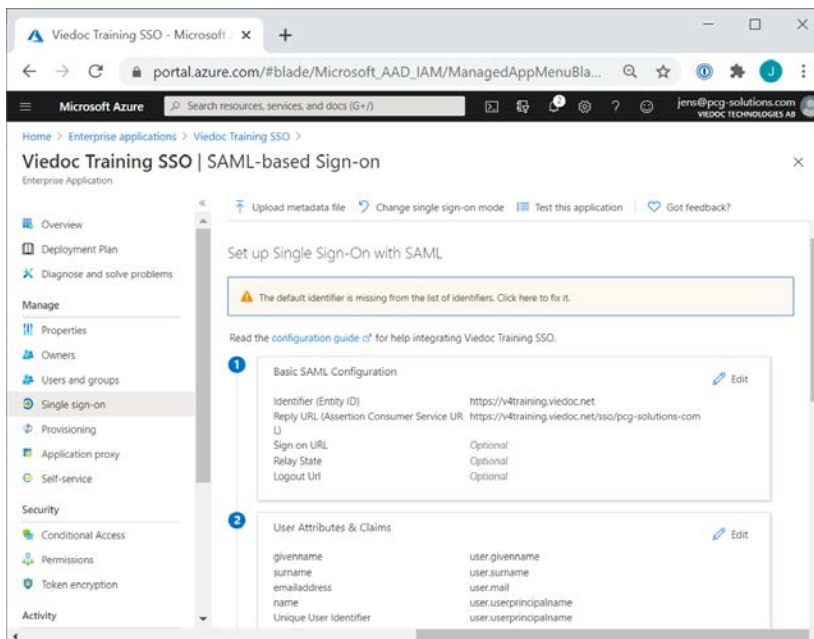
From the Viedoc tab, copy and paste:

- The Entity ID into the **Identifier (Entity ID)** field.
- The Redirect URL into the **Reply URL (Assertion Consumer Service URL)** field.

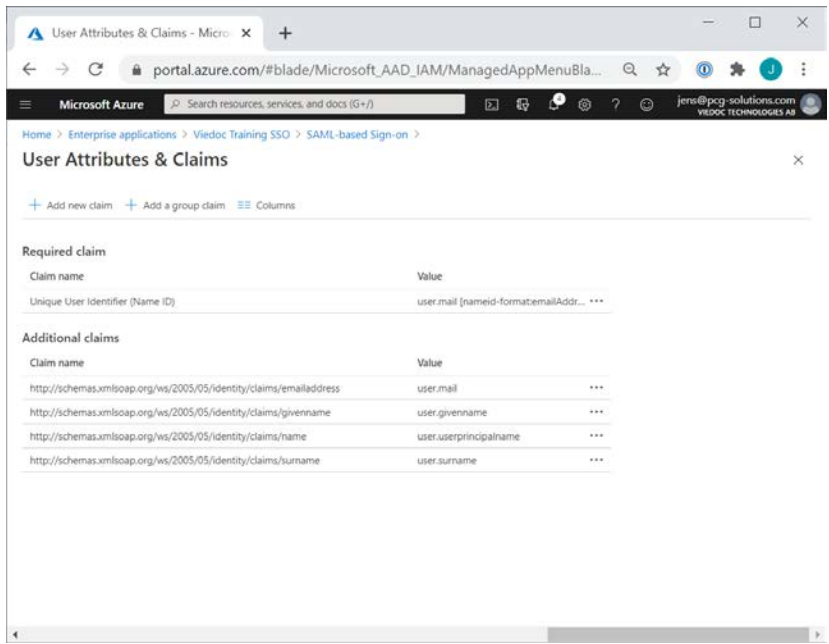
Click **Save** and close the dialog box.



10 Click to **Edit the User Attributes & Claims**.



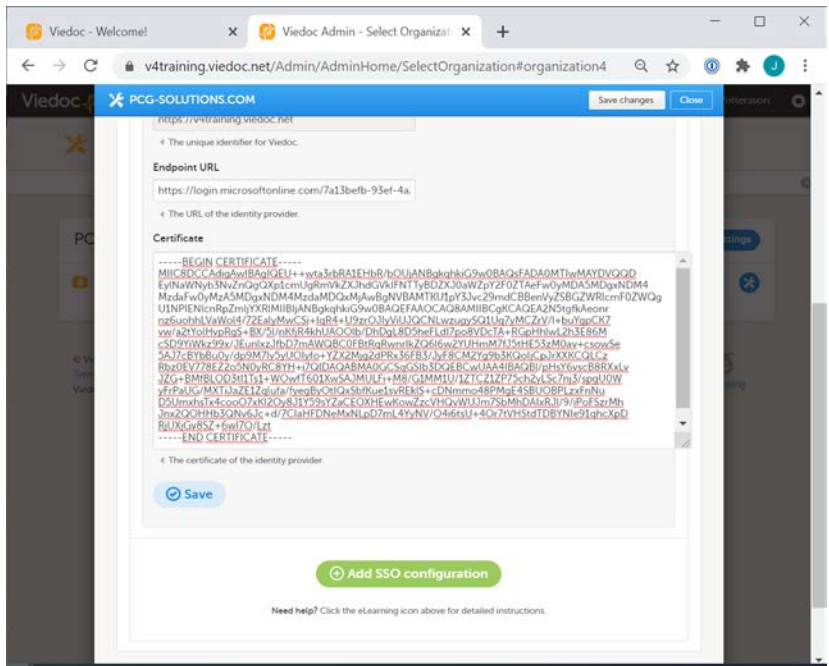
11 Map the **Unique User Identifier (Name ID)** to the attribute that best matches the email address that users authenticate with in Viedoc, typically [user:userprincipalname] or [user.mail].



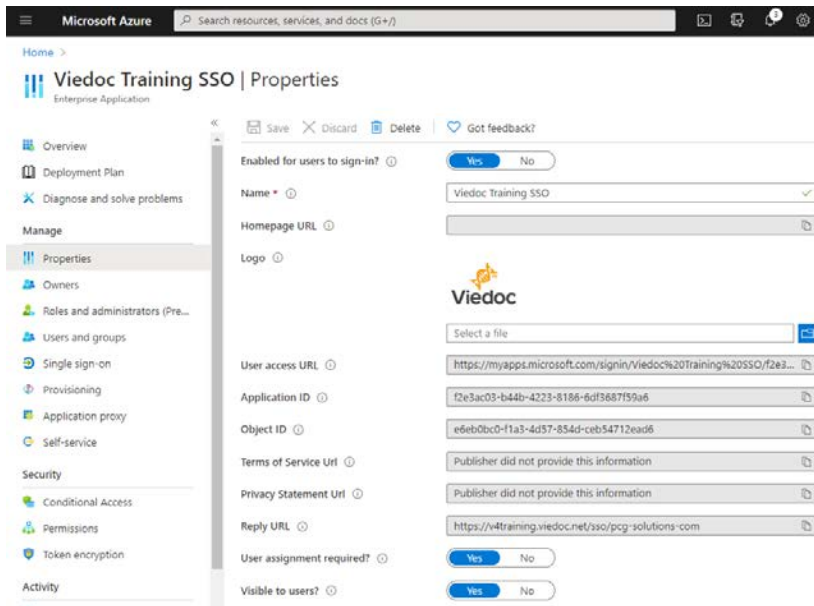
12 From the Azure AD window:

- Download the certificate in base64 format and open it in a text editor, for example Notepad. Copy and paste it into the Viedoc field titled **Certificate**.
- Click to copy the login URL and paste it in the **Endpoint URL** field in the Viedoc tab.

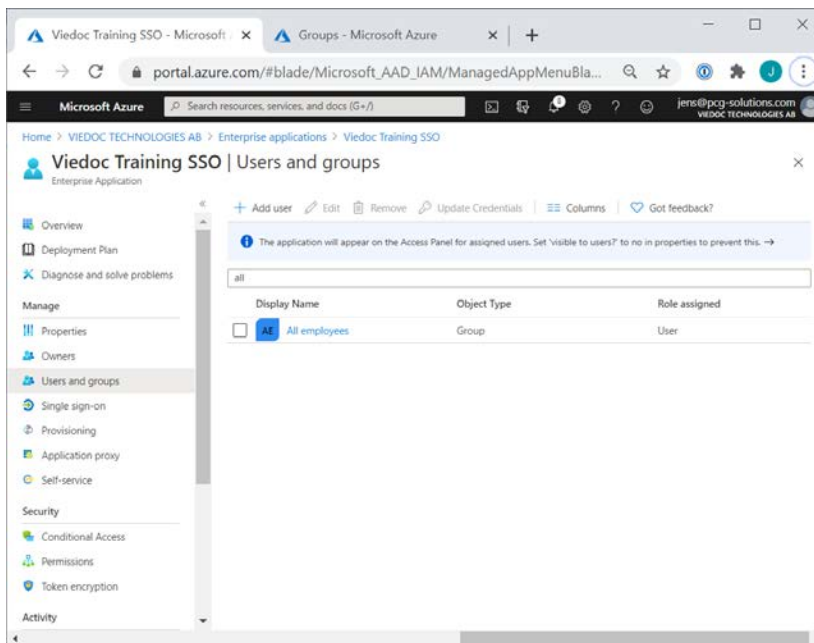
Click **Save**.



- 13 Download the Viedoc logo from the following URL <https://www.viedoc.com/viedoc-msaad-ss0-256x256.png> and upload it to the **Properties** section in the Azure AD tab.

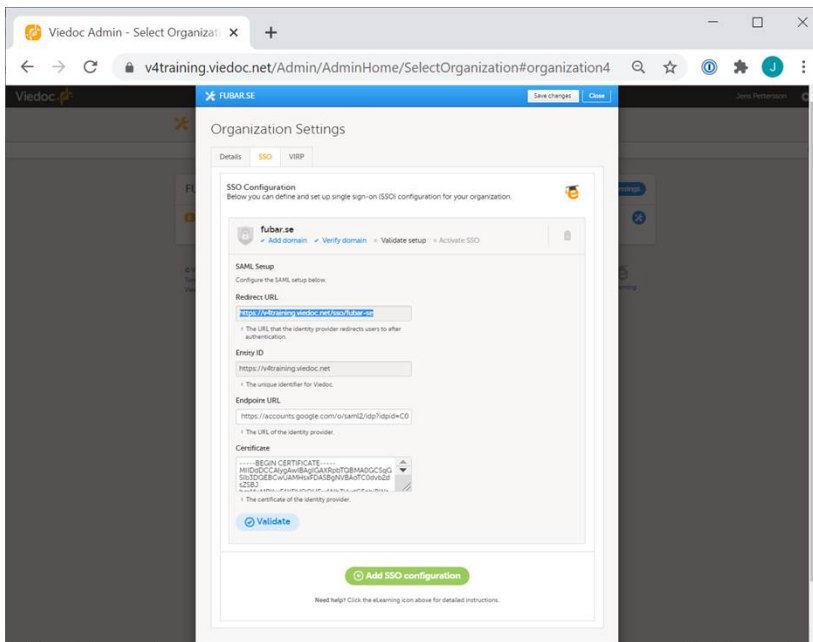


- 14 Under **Users and groups**, add all users or security groups that shall be able to log in to Viedoc using SSO.

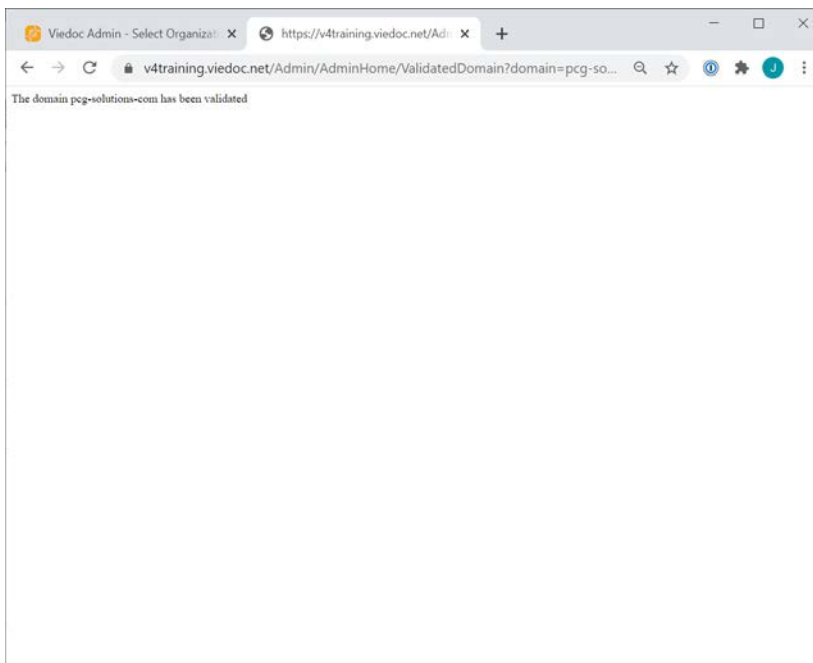


15 Go back to the Viedoc tab and click **Validate**.

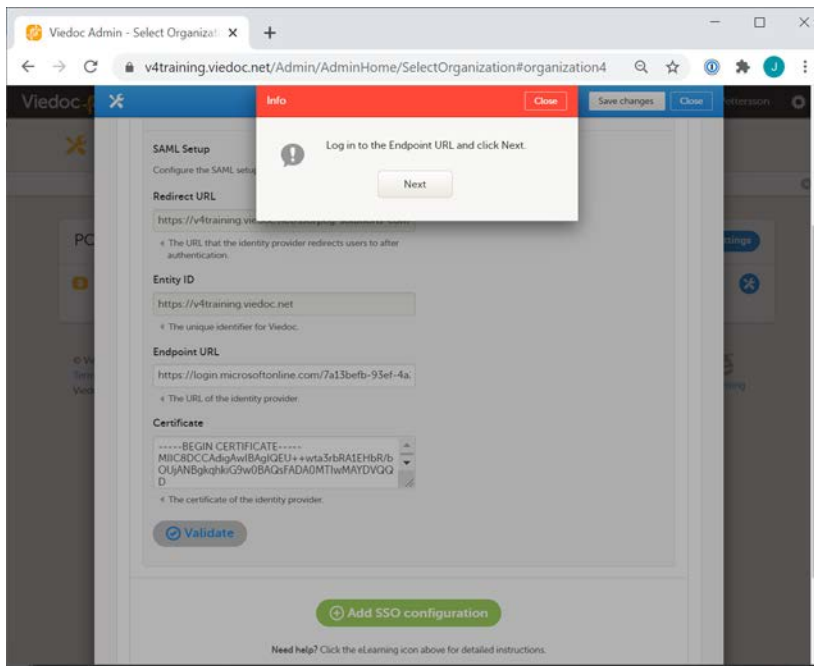
**Note!** You might be prompted to enter your email address and password in order to authenticate with your IdP if not already logged in. Upon successful authentication you will automatically be redirected to the domain verification page.



16 Verify that the domain is validated and then close the tab.

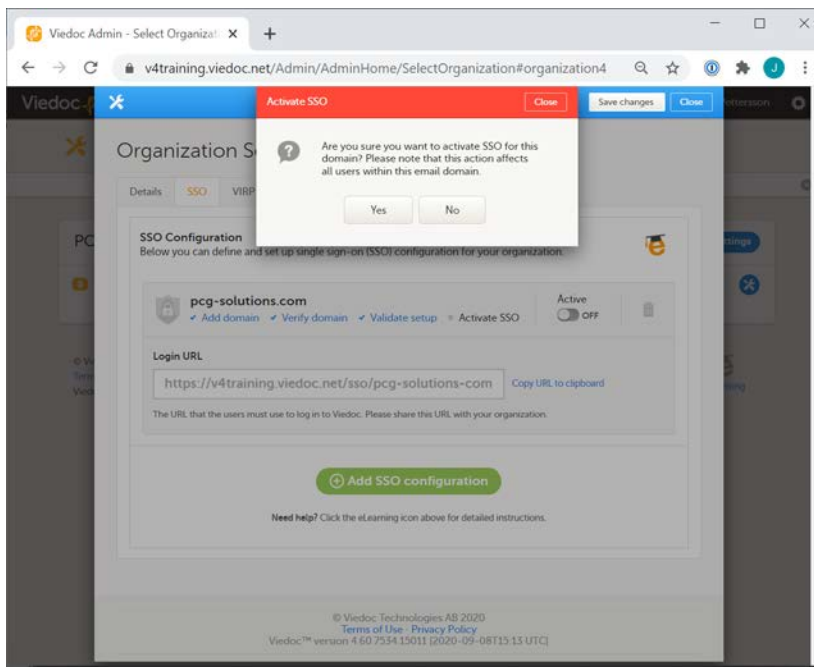


17 Click **Next**.



18 The SSO configuration is now completed.

When all users are informed about the new login URL—with the configured domain as their login name (the primary email address is used for authentication in both the IdP and in Viedoc)—click **Activate** > **Yes**.



19 Log out and log in using the new login URL. You will now be authenticated and redirected to the newly configured external IdP.



How to set up a study

## How to set up a study

Published by Viedoc System 2018-11-13

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This video demonstrates how to add a new study in Viedoc Admin, create a simple study design in Viedoc Designer, manage users in Viedoc Admin and enter data as a site user in Viedoc Clinic.

If you have difficulties in viewing the video, click [here](#).



How to import data using the Viedoc Data Import application

## How to import data using the Viedoc Data Import application

Published by Viedoc System 2019-11-14

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This video demonstrates how to import data into Viedoc using the Viedoc Data Import Application.

If you have difficulties in viewing the video, click [here](#).

For more information, see [Viedoc Data Import Application](#).





How to configure reference data

## How to configure reference data

Published by Viedoc System 2018-10-12

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This video demonstrates how to work with reference data in Viedoc.

If you have difficulties in viewing the video, click [here](#).



How to configure a randomization

## How to configure a randomization

Published by Viedoc System 2018-10-12

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This video demonstrates how to configure a static list randomization and a dynamic randomization in Viedoc.

If you have difficulties in viewing the video, click [here](#).



User Management

# User Management

Published by Viedoc System 2018-12-12

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This video demonstrates how to manage users in Viedoc Admin.

If you encounter difficulties in viewing this video click [here](#).



How to set up Viedoc Me

## How to set up Viedoc Me

Published by Viedoc System 2023-06-21

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This video demonstrates how to set up Viedoc Me in Admin and Designer.

If you have difficulties in viewing the video, click [here](#).



How to set up Viedoc Logistics

## How to set up Viedoc Logistics

Published by Viedoc System 2021-03-24

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This video gives an overview of how to set up Viedoc Logistics to ship your investigational product between sites and depots and how to allocate kits to patients.

If you have difficulties in viewing this video, click [here](#).



How to work with R

## How to work with R

Published by Viedoc System 2022-06-20

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This video demonstrates how to use R with Viedoc Reports.

If you have difficulties viewing the video, please click [here](#).

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