viedoc learning™

Viedoc Admin User Guide

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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.

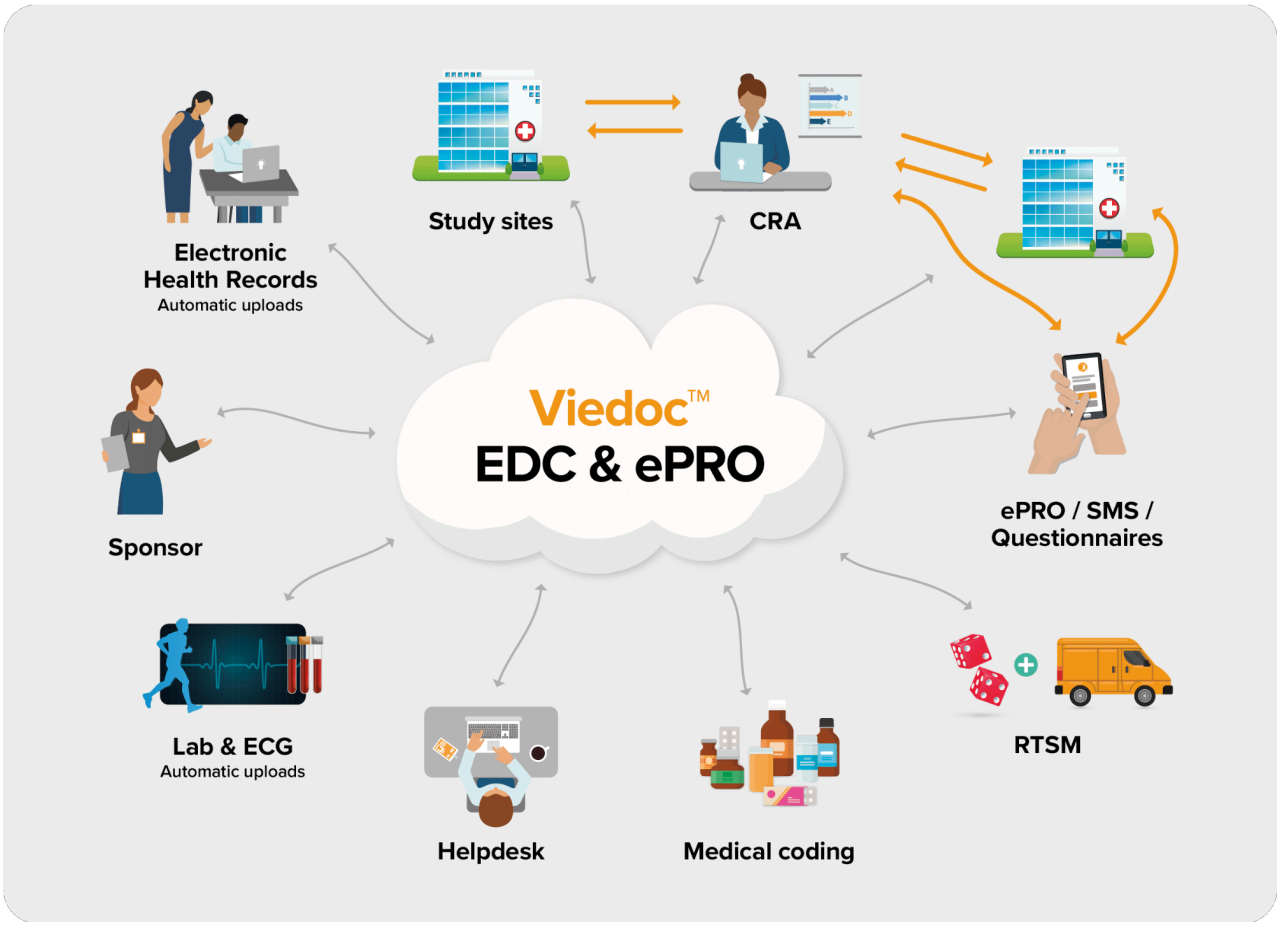
Viedoc is an Electronic Data Capture (EDC) system that enables easy data capture, management, validation and presentation of clinical trial data. Viedoc is a Software-as-a-Service (SaaS) accessed directly through a web browser and requires no installation. It is intuitive and user-friendly and enables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

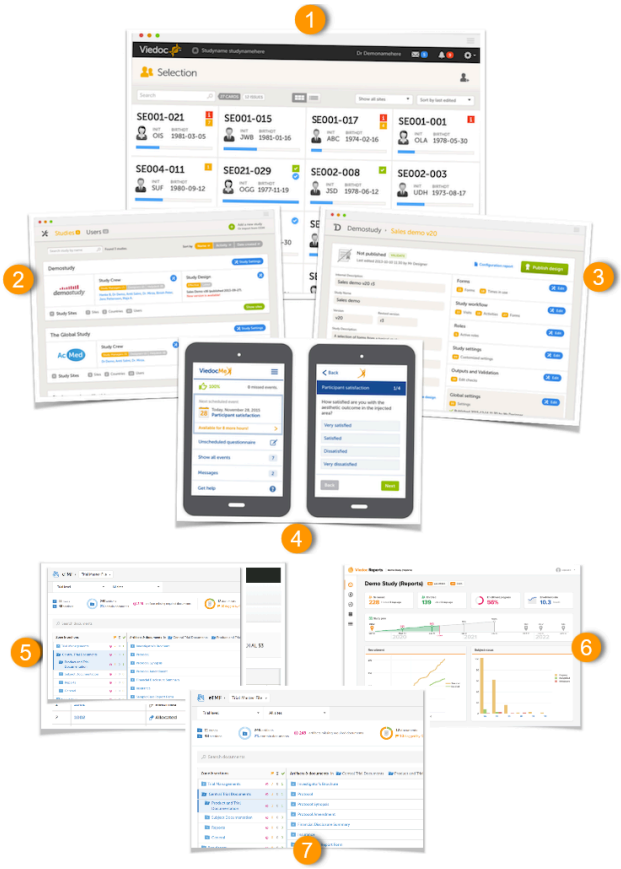
During a study, there are typically a number of questions to be answered and completed with data about the subject. A group of questions that belong together are captured in a form. Forms can be event-dependent or event-independent (log forms / common events). Event-dependent forms are linked to a specific 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.
8. Viedoc Coder - for doing medical coding.

3.2 System languages

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

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

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

- Chinese (Simplified)
- Chinese (Traditional)
- English
- French
- German
- Japanese
- Spanish
- Swedish

Viedoc **Me** and Viedoc **Share** are 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
Viedoc Clinic User Guide	x	x	x	https://help.viedoc.net/c/47e0ad
Viedoc User Guide for Monitors	x	x	x	https://help.viedoc.net/c/c63e06
Viedoc User Guide for Site Users	x	x	x	https://help.viedoc.net/c/94d6f0
Viedoc User Guide for Data Managers	x	x	x	https://help.viedoc.net/c/1994d8

Curriculum	English	Chinese	Japanese	URL
Viedoc User Guide for Project Managers	x	x	x	https://help.viedoc.net/c/04361f
Viedoc User Guide for Medical Coders	x	x	x	https://help.viedoc.net/c/3108de
Viedoc Admin User Guide	x	x	x	https://help.viedoc.net/c/331b7a
Viedoc Designer User Guide	x	x	x	https://help.viedoc.net/c/e311e6
Viedoc Logistics User Guide	x	x	x	https://help.viedoc.net/c/4a40d5
Viedoc Reports User Guide	x	x	x	https://help.viedoc.net/c/8a3600
Viedoc eTMF User Guide	x		x	https://help.viedoc.net/c/88fc29
Viedoc User Guide for eTMF Managers	x		x	https://help.viedoc.net/c/fd74dc
Viedoc PMS User Guide for Clinic Side Users	x		x	https://help.viedoc.net/c/91715f
Viedoc PMS User Guide for Sponsor Side Users	x		x	https://help.viedoc.net/c/590df1
Viedoc PMS Designer User Guide	x			https://help.viedoc.net/c/ed5d47
Viedoc User Account Management Guide	x			https://help.viedoc.net/c/508fda

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.

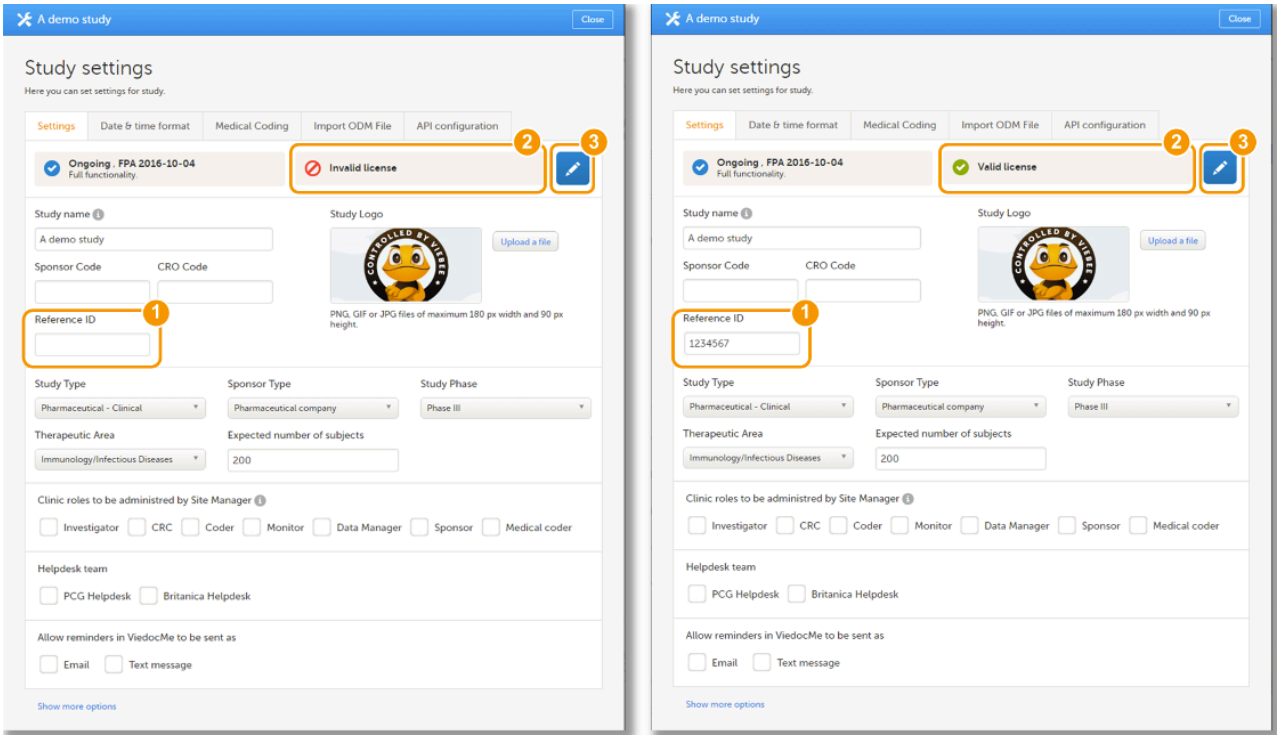
Contact your organization administrator to get access to the respective area.

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.

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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

Published by Viedoc System 2022-10-18

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

1 Introduction

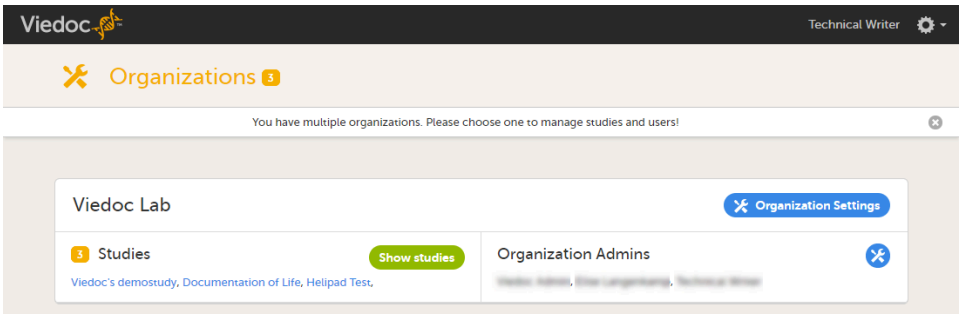
Viedoc Admin is the starting point for every new Viedoc project. Viedoc Admin is the application where you can manage the administrative aspects of a study. The following actions can be performed in Viedoc Admin:

- 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.

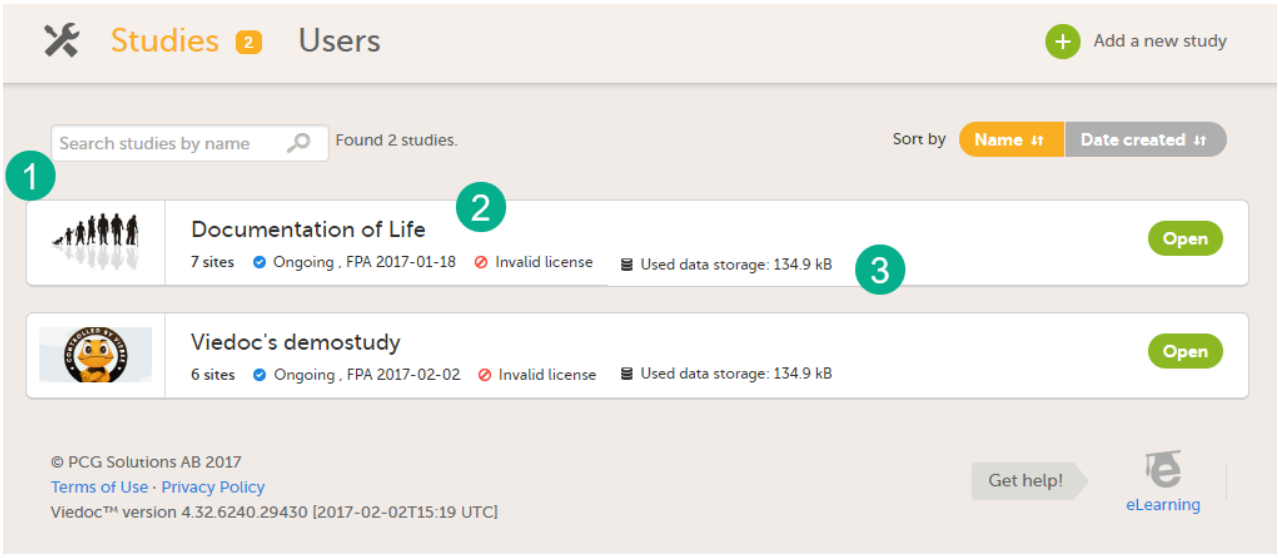


On the organization overview, you can:

- 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.

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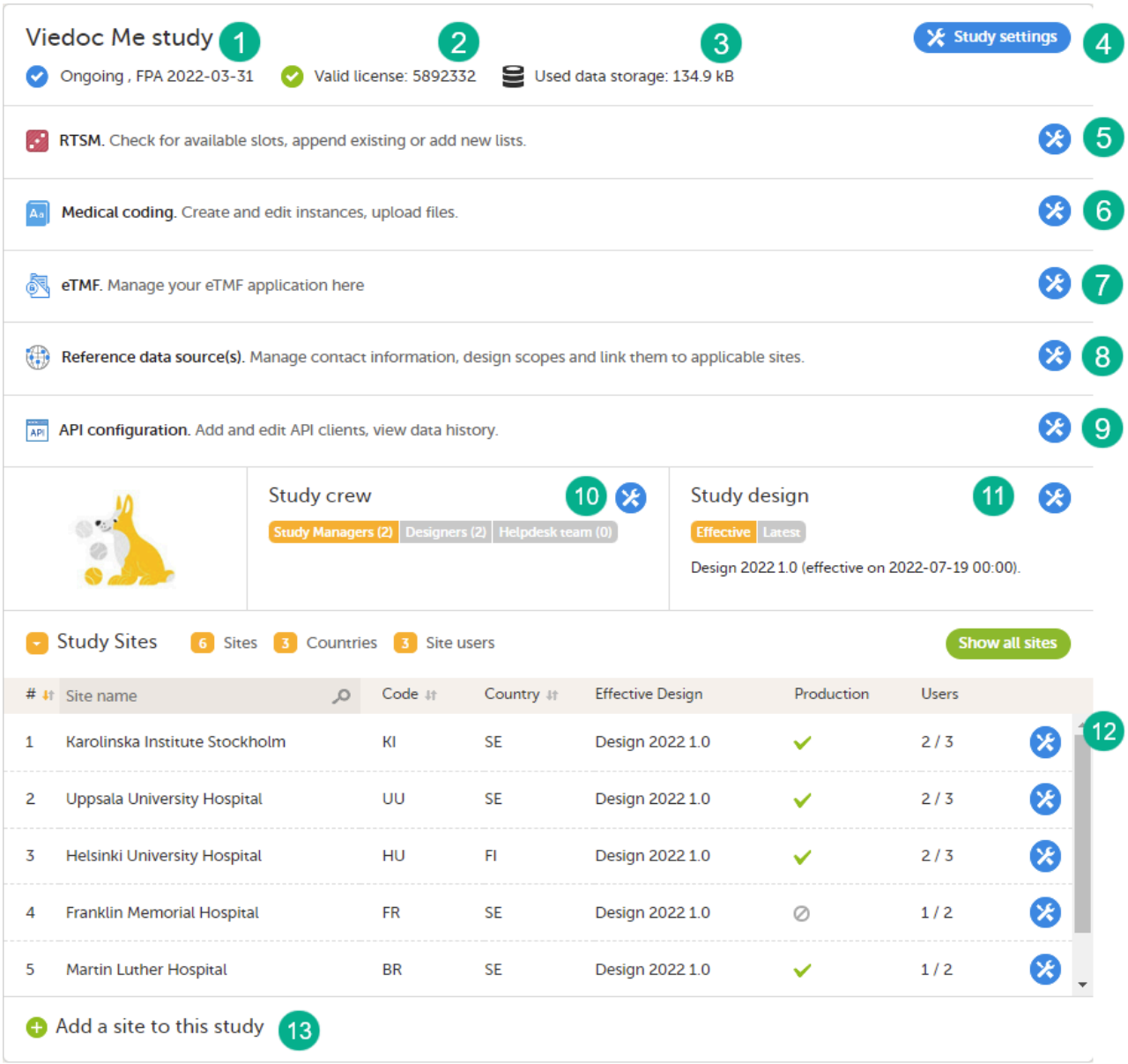
4 The study details page

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):



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 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.

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

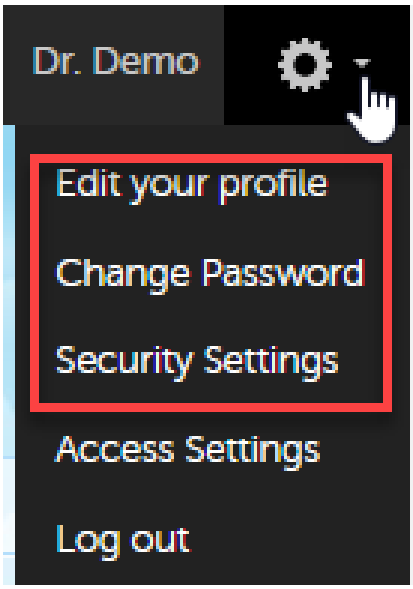
Managing your Viedoc account

Published by Viedoc System 2024-10-10

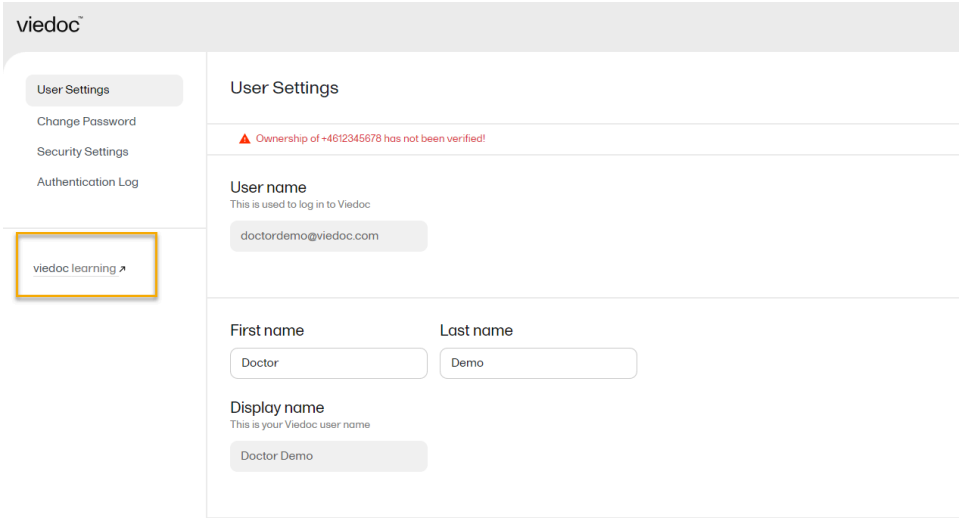
1 Viedoc user account management

> Important! 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:



2 User settings

Once logged in, you can edit your profile.

To view or edit your user settings, select the settings button (wheel) in the top right corner of the landing page, and select **Edit your profile**. The **User Settings** page opens, where you can configure the following:

1. **User name** - this is your primary email address used for your Viedoc account. This is the user name you use to log in to Viedoc. See below information on primary email address.

2. **First name** and **Last name** - fill in these fields that will be used to compose the **Display name** which will be used in Viedoc to identify your user.

3. **System language** - select the language of your choice from the drop-down menu.

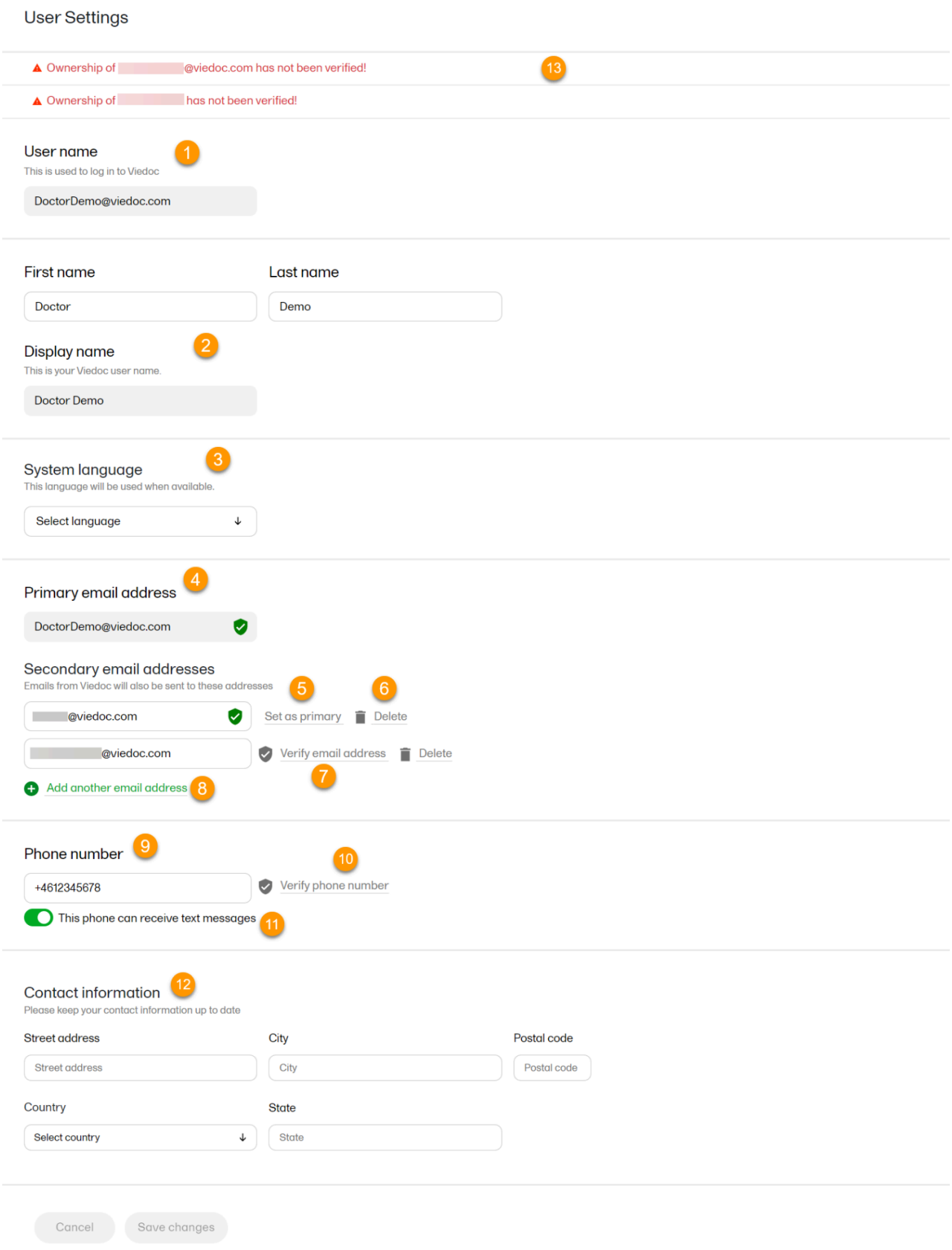
4. **Primary email address** - this is the same as the **User name** described above. It is the email address used in Viedoc to log in, as well as for Viedoc user account-related operations (account setup, password recovery, study invitations).
By default, this is set to the email address used to initiate the Viedoc user account.
The primary email address must be unique and is mandatory. Therefore, it is not possible to delete the primary email address.
See Changing the primary email address.

5, 6, 7, 8. **Secondary email addresses** - you can add up to 3 additional email addresses that will be used by Viedoc to send notifications on alerts and trackers as configured in Viedoc Designer. Viedoc alert emails will be sent to all the primary and verified secondary email addresses set up for your account.
See Adding a secondary email address and Verifying a secondary email address.

9, 10, 11. **Phone number** - enter your phone number in format +[CountryCodePhoneNumber] (for example +46123456789) and if you want to receive text messages, select **This phone can receive text messages**.
See Editing your phone number and Verifying your phone number.

> **Important!**
> - You must either select one of the options **This phone can receive text messages**, or configure a secondary email address to be able to recover your password yourself. If neither of these options are selected, you will need to contact your Study Manager to receive a link to reset your password.
> - One of the above options is needed in order to send the authentication code you will need to provide for resetting your password. The phone number or secondary email address provided will be used to send the authentication code even if these are not verified.

12. **Contact information** - fill in the following fields: your street address, city, state, postal code and country.



2.1 Adding a secondary email address

To add a new (secondary) email address to your account:

1 Select **Add another email address** link (8) next to the current primary email address.

2 Enter the email address in the new field under **Secondary email addresses**.

3 Select **Save changes**. A notification email is sent to both the primary email address and to the newly added email address to inform you about the change. At the top of the **Edit your profile** dialog box, you will see a warning message saying that the newly entered email address is not verified (13).

2.2 Verifying a secondary email address

To verify a secondary email address:

1. Select the **Verify email** (7) link next to the newly added email address. A six-digit code will be sent to your new email address and a **Verify ownership** dialog box is displayed asking you to provide the code in order to verify the new email address.

   Note! The verification link for the secondary email address is shown only after having saved the changes you may have performed on the other fields on the same page.

2. Enter the received code and select **Confirm**. The newly added secondary email address is now verified.

2.3 Changing the primary email address

To change the primary address to one of the existing secondary email addresses:

1. Select **Set as primary** (5) next to the secondary email address that is to be set as the primary email address.
2. Select **Save changes**. A notification email will be sent to both email addresses to inform you about the change. You will use the new primary email address the next time you log in to Viedoc.

Note! For a secondary email address to be able to be set as primary, it has to be verified first.

2.4 Editing your phone number

To edit your phone number:

1. Enter the number in the **Phone number** field in the format +[CountryCodePhoneNumber] (for example: +46123456789).
2. Select **Save changes**. A notification email will be sent to your primary email address to inform you about the change.

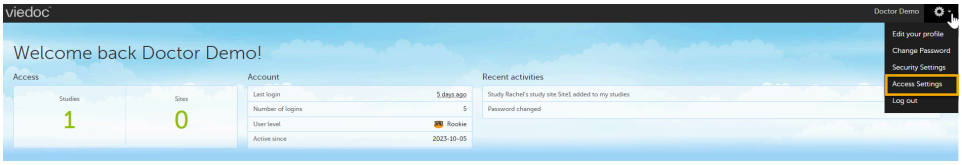
2.5 Verifying your phone number

To verify your phone number:

1. Make sure that the phone number is correctly entered and that the **Phone can receive text messages** option is selected.
2. Select the **Verify phone number** link. A six-digit code will be sent as a text message to your phone and a **Verify ownership** dialog box is displayed. It will ask you to provide the code in order to verify the phone number.
3. Enter the code and select **Confirm**. The phone number is now verified.

3 Study access management

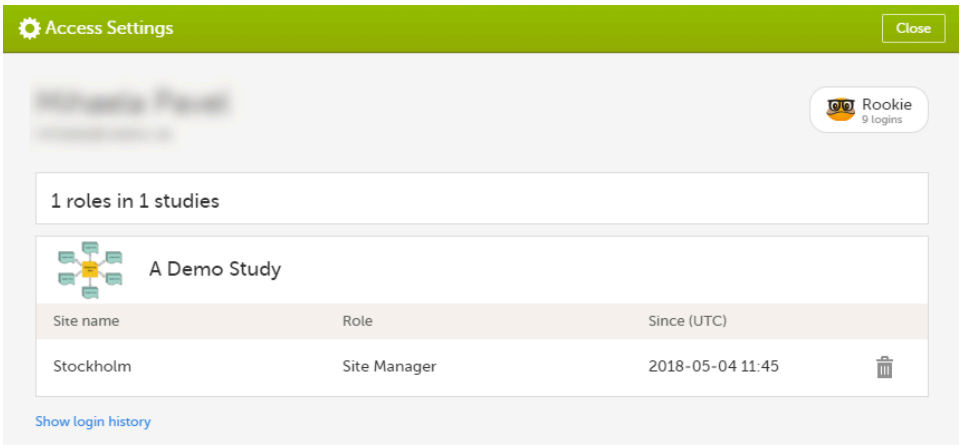
From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.



4 Access settings

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

4.1 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)

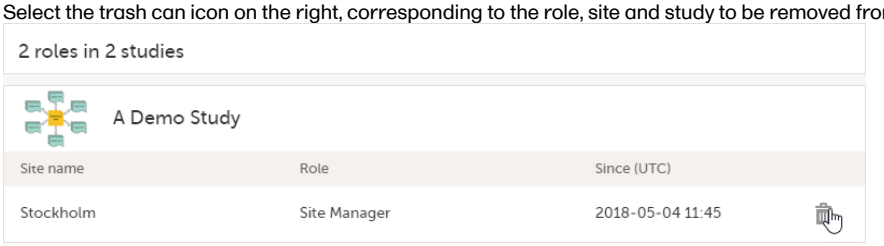
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

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

4.2 Deleting study access

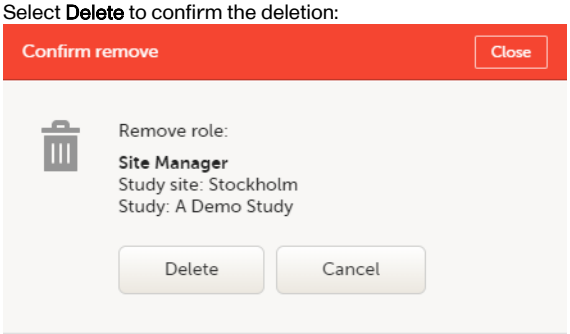
To remove yourself from a certain role within a study:

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:



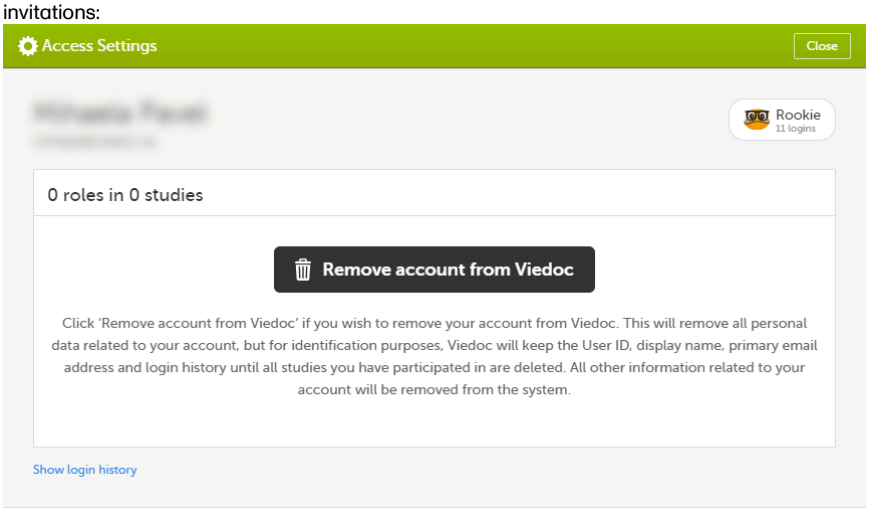
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

4.3 Deleting your Viedoc account

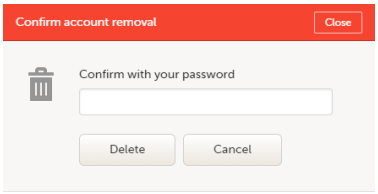
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

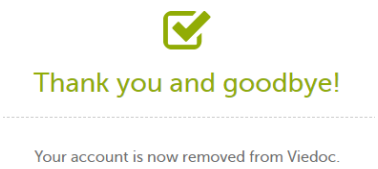
1 Go to **Access Settings**. To be able to remove your account, you should have no roles left in any study and no pending invitations:



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



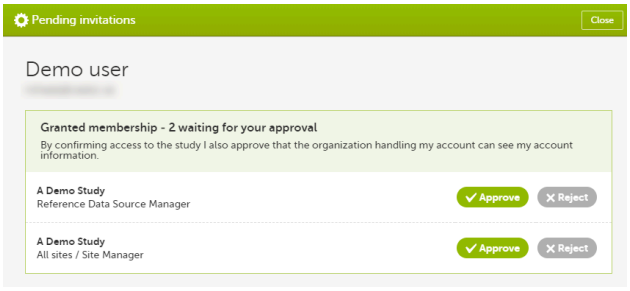
3 Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



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.

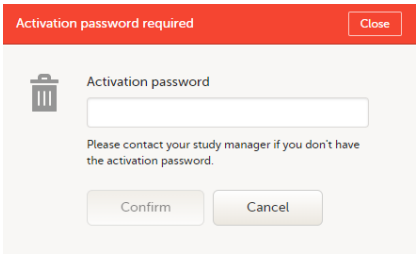
5 Pending invitations

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:



5.1 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.

5.2 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.

5.3 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.

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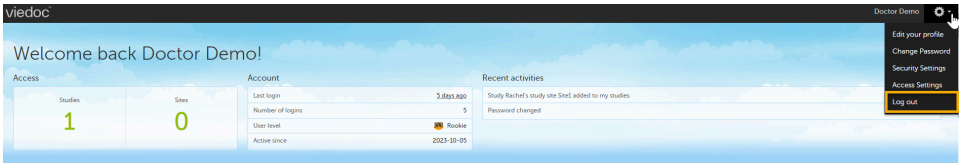
6 Logging out

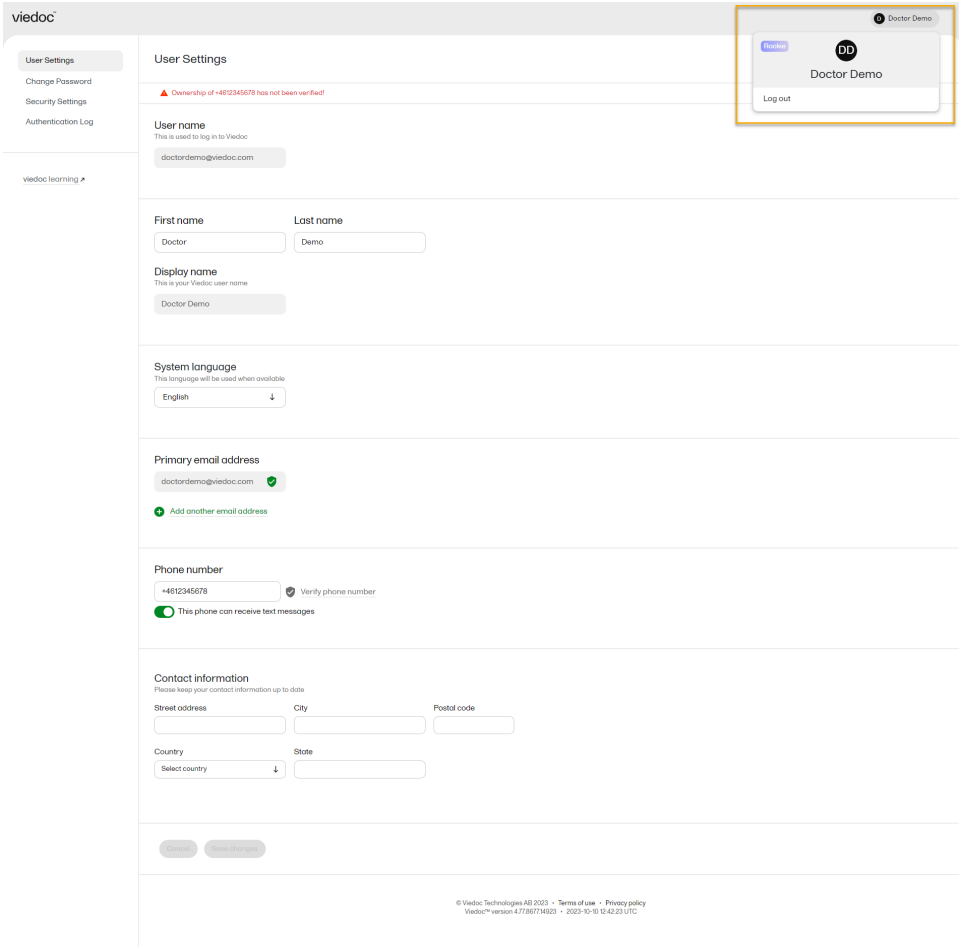
From Viedoc you can log out from different locations:



- 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**.


viedoc
Doctor Demo
Rookie
DD
Doctor Demo
Log out
User Settings
Change Password
Security Settings
Authentication Log
viedoc learning ↗
User Settings
Ownership of +4612345678 has not been verified!
User name
This is used to log in to Viedoc
doctordemo@viedoc.com
First name
Doctor
Last name
Demo
Display name
This is your Viedoc user name
Doctor Demo
System language
This language will be used when available
English
Primary email address
doctordemo@viedoc.com
Add another email address
Phone number
+4612345678
Verify phone number
This phone can receive text messages
Contact information
Please keep your contact information up to date
Street address
City
Postal code
Country
Select country
State
Cancel
Save changes
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Viedoc™ version 4.77.8671.14923 · 2023-10-10 12:42:23 UTC

Viedoc study configuration management

Viedoc study configuration management

Published by Viedoc System 2024-12-03

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.

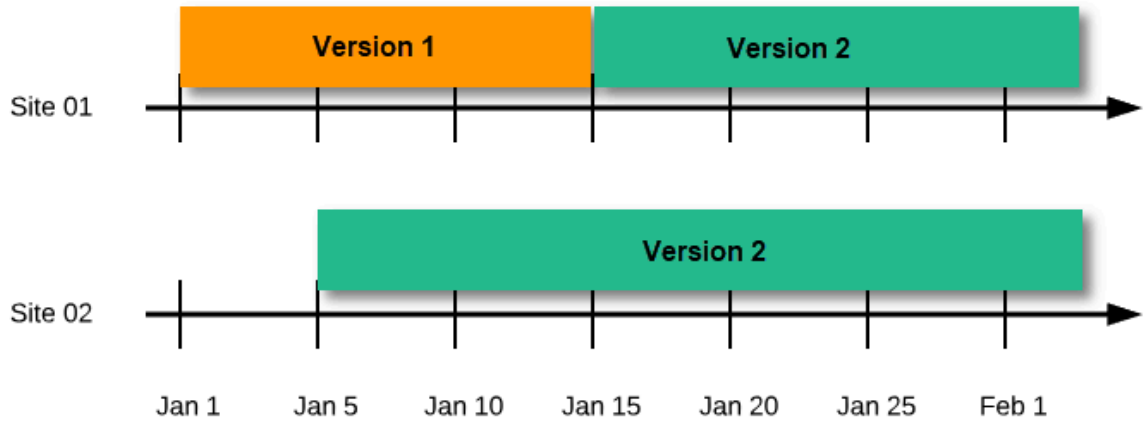
Notes!

- 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.
- Events that are added using the automatic event date functionaility will burn-in the current effective design.

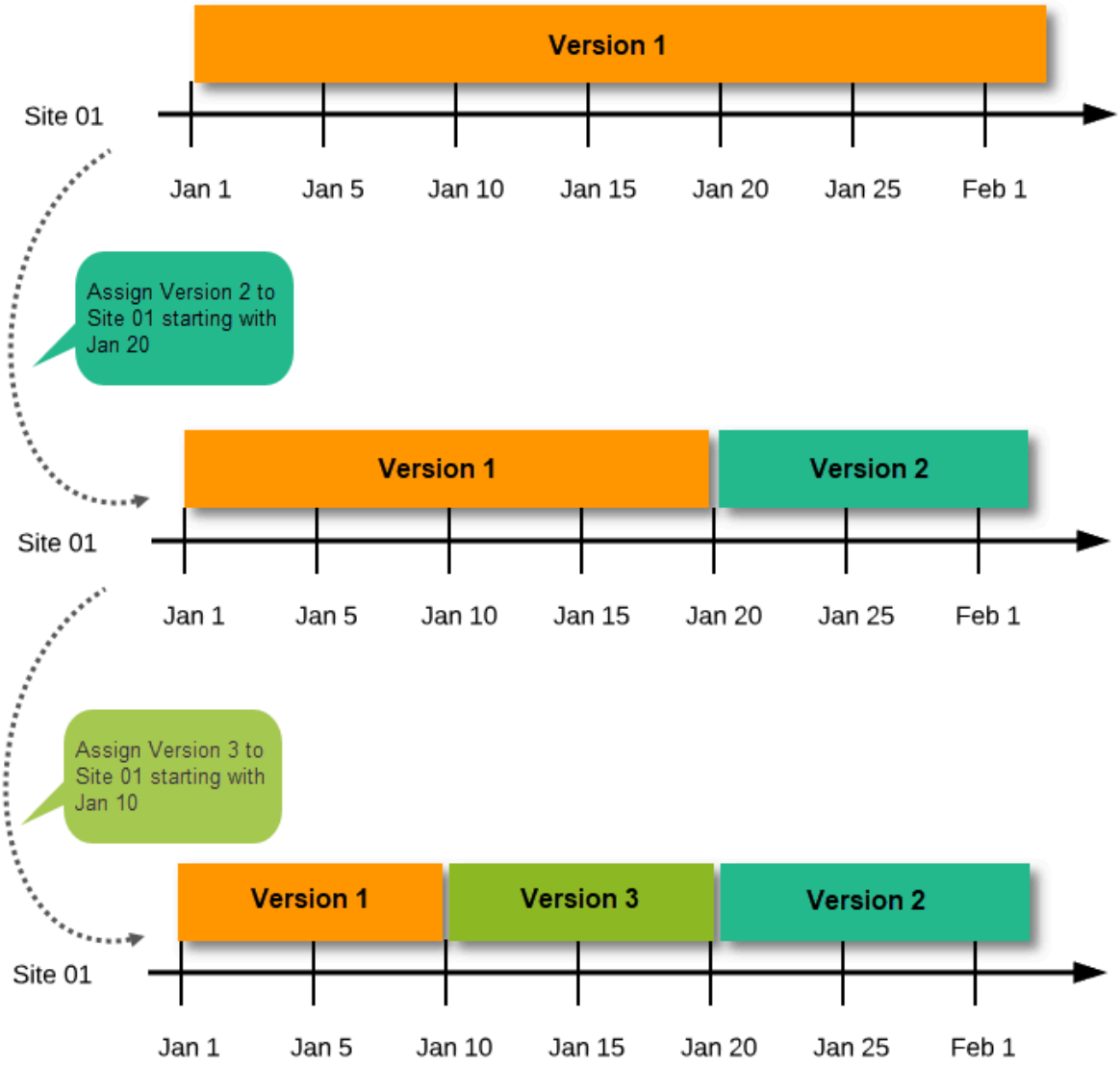
For more details on the automatic event date settings, see the Study workflow lesson.

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 1st, this is the effective version until a new version with a later start date is encountered, independently of when it was assigned.

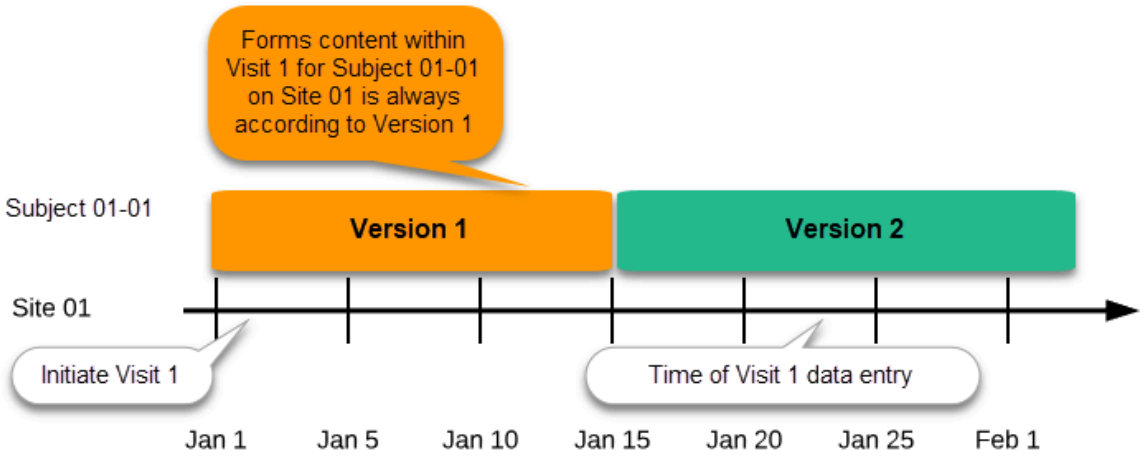


Important! The periods of effectiveness of a study design version are connected to the event timing of the first data entry and not to the current time at system usage.
For example, in the below image, if:

- Version 1 is effective between January 1st - January 15th for Site 01.
- Version 2 is effective starting with January 16th for Site 01.
- Event 1 is initiated on January 2nd for Subject 01-01 on Site 01.

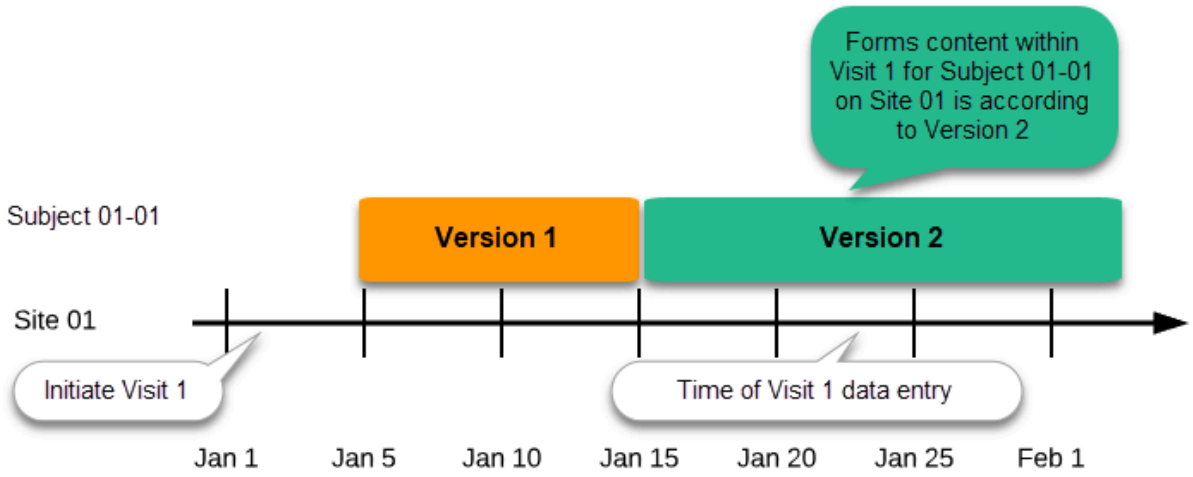
...then:

- 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

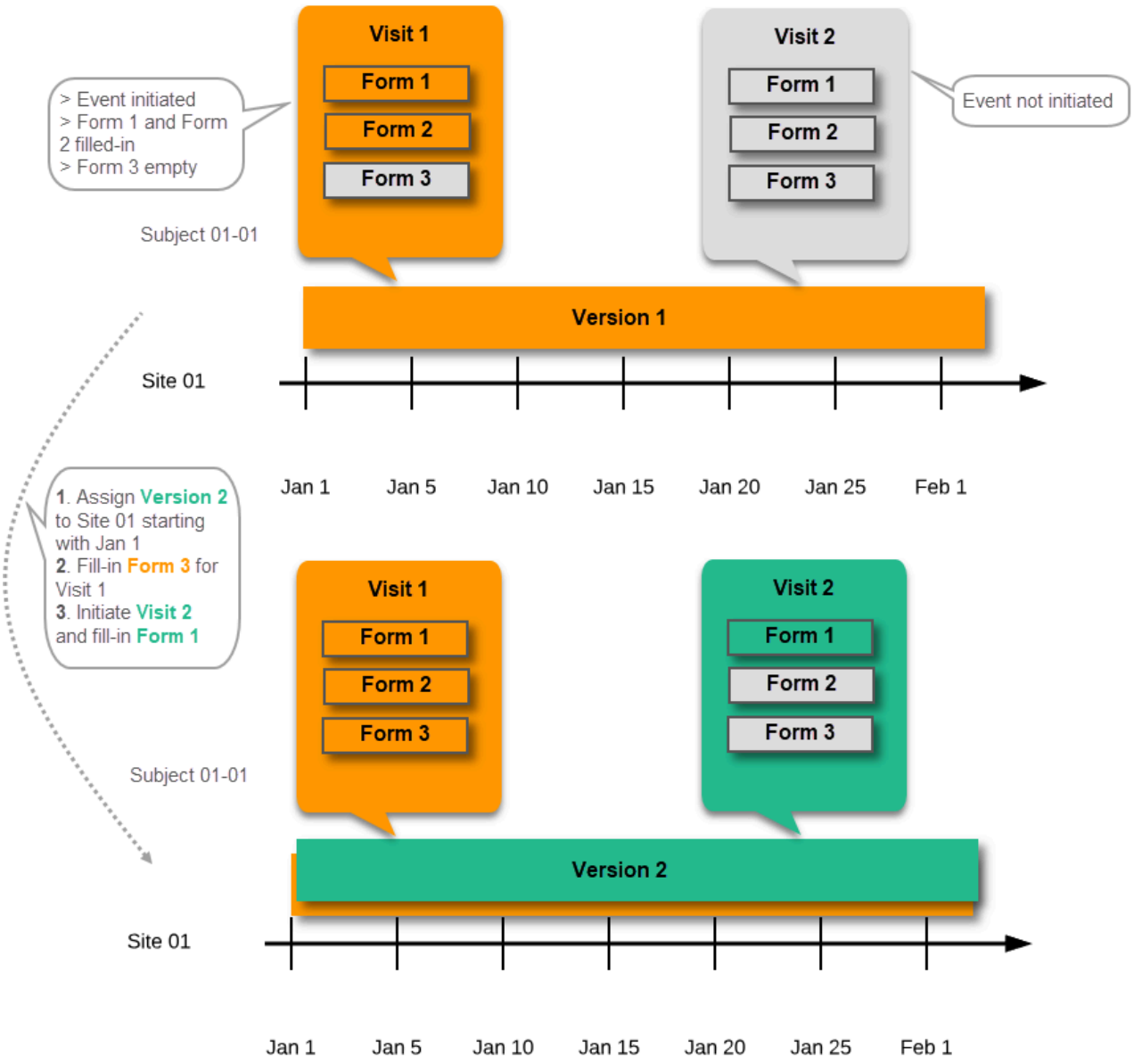
A new version can be assigned with the same timing as the currently assigned version and will then replace the currently assigned version, except for already entered data (due to the version "burn-in", as described in Version burn-in).

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

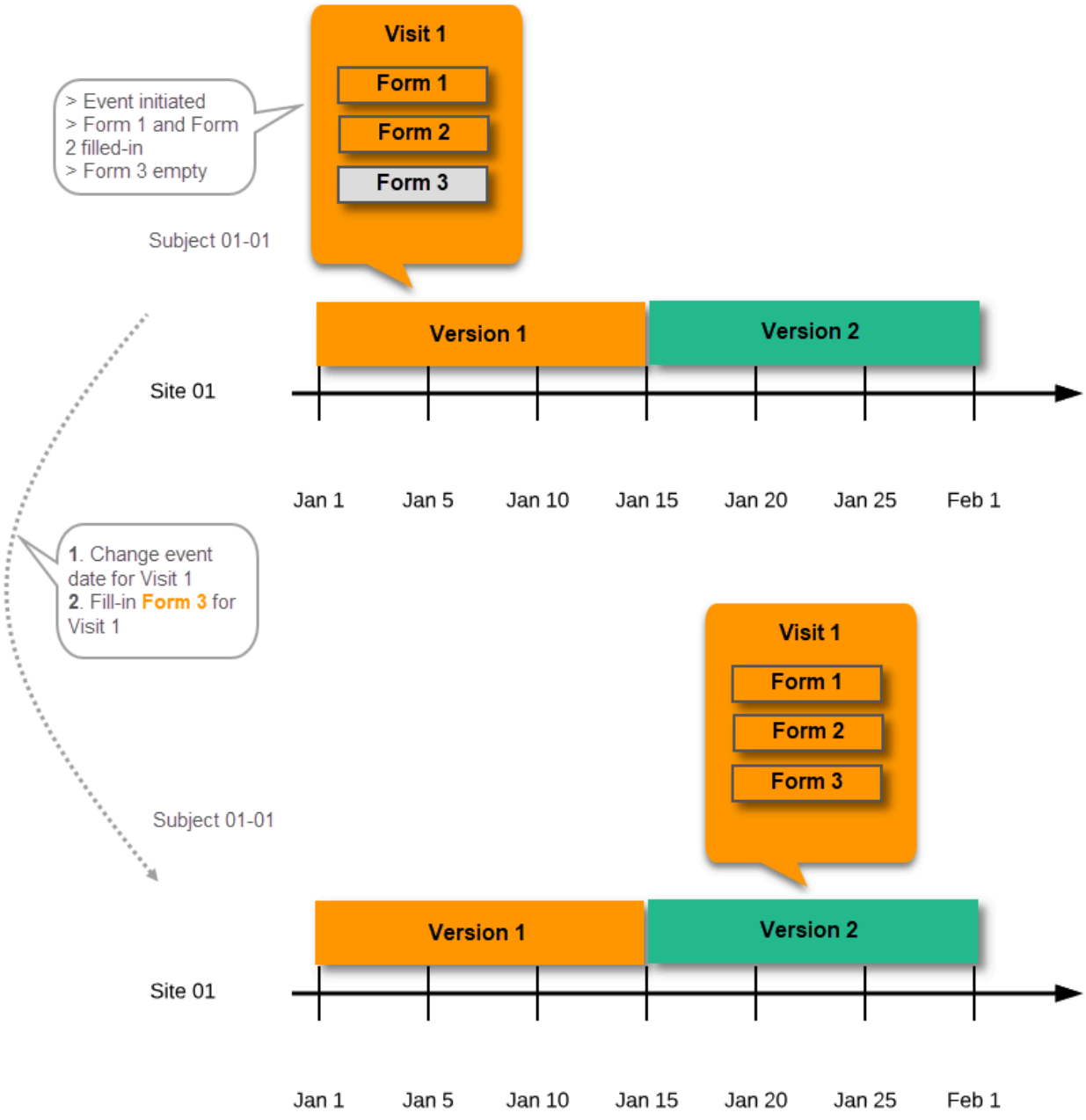
...and we assign Version 2 to Site 01 starting at Jan 1, and then:

- 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

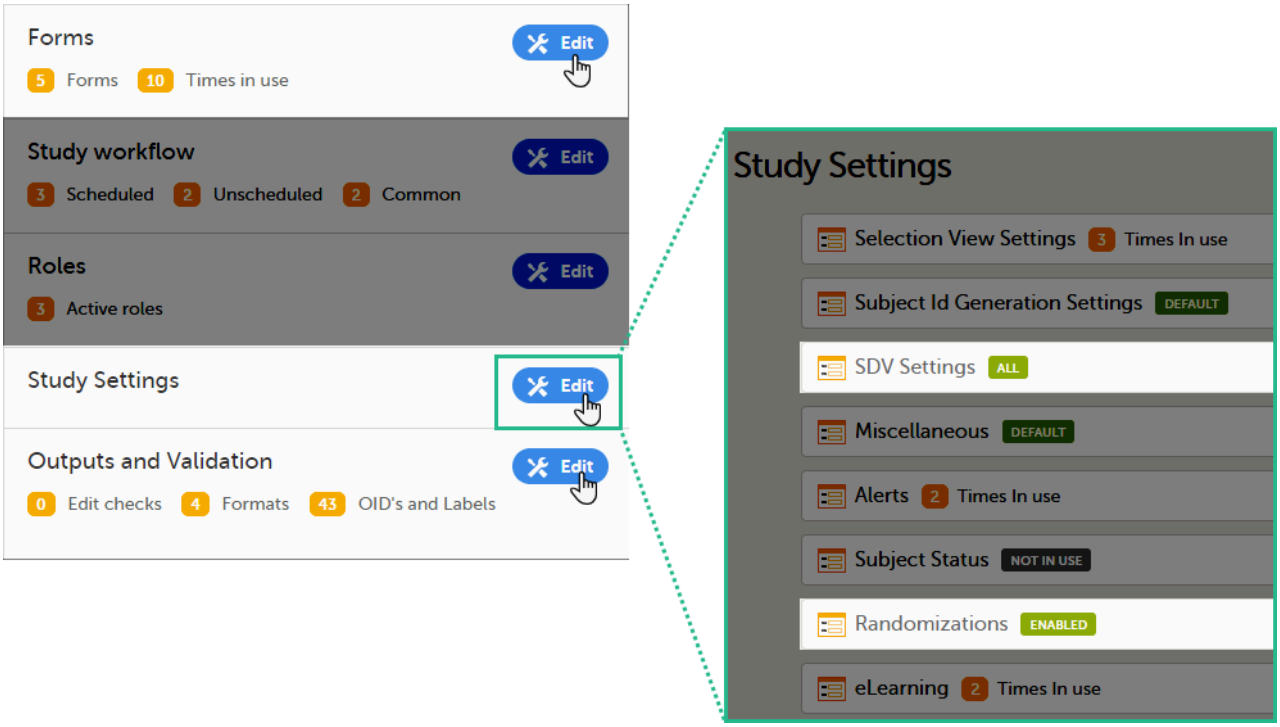
In case the event date is changed after it was initiated, to a date when another version is applicable, the version for that event does not change, as it was burnt-in at the date when the event was initiated (see Version burn-in):



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

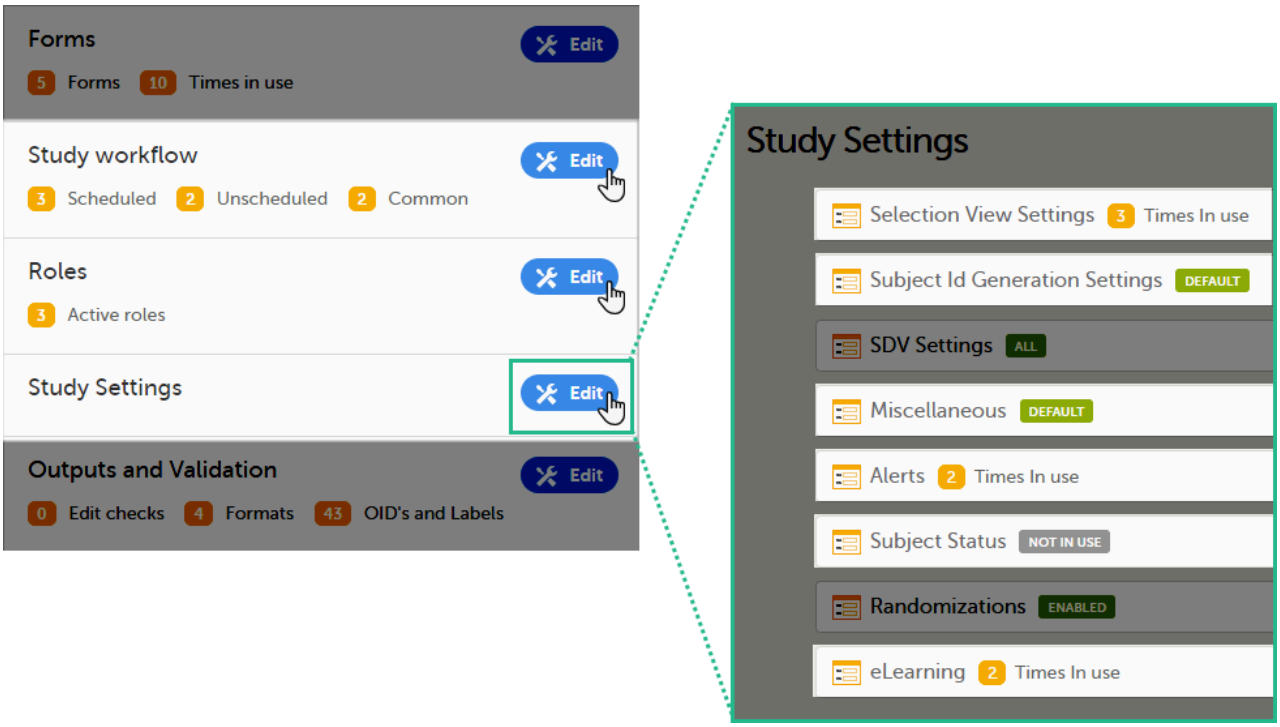


2.7 Settings read from current effective design

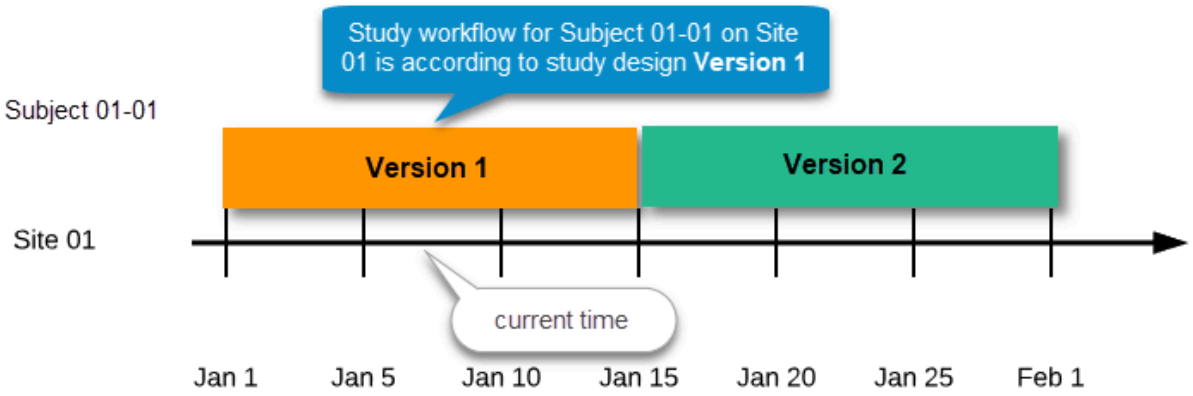
We call "current effective design" the study design version that is effective at the current time of system usage.

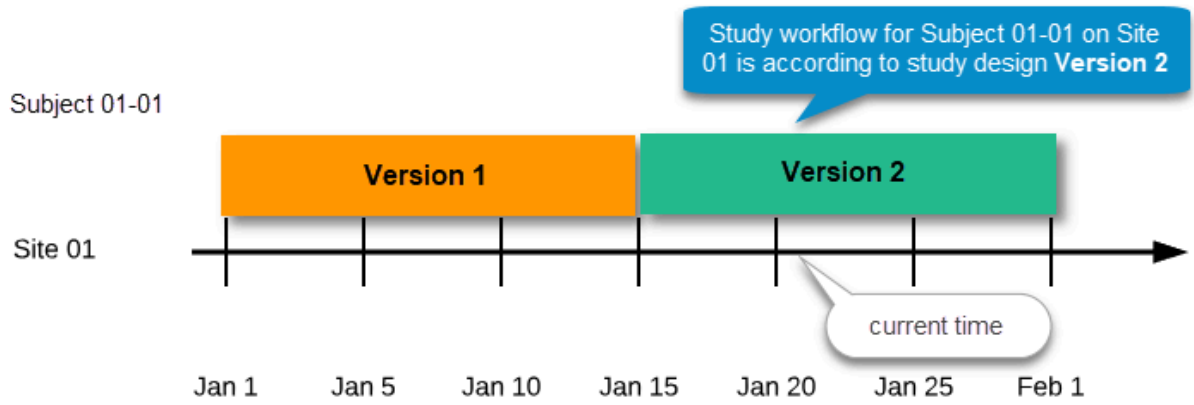
Settings that are not directly related to data collection structure, as well as settings that are common on the site level, are read from the study design version that is effective at the time of system usage (that is, “time right now”). These settings are:

- 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.

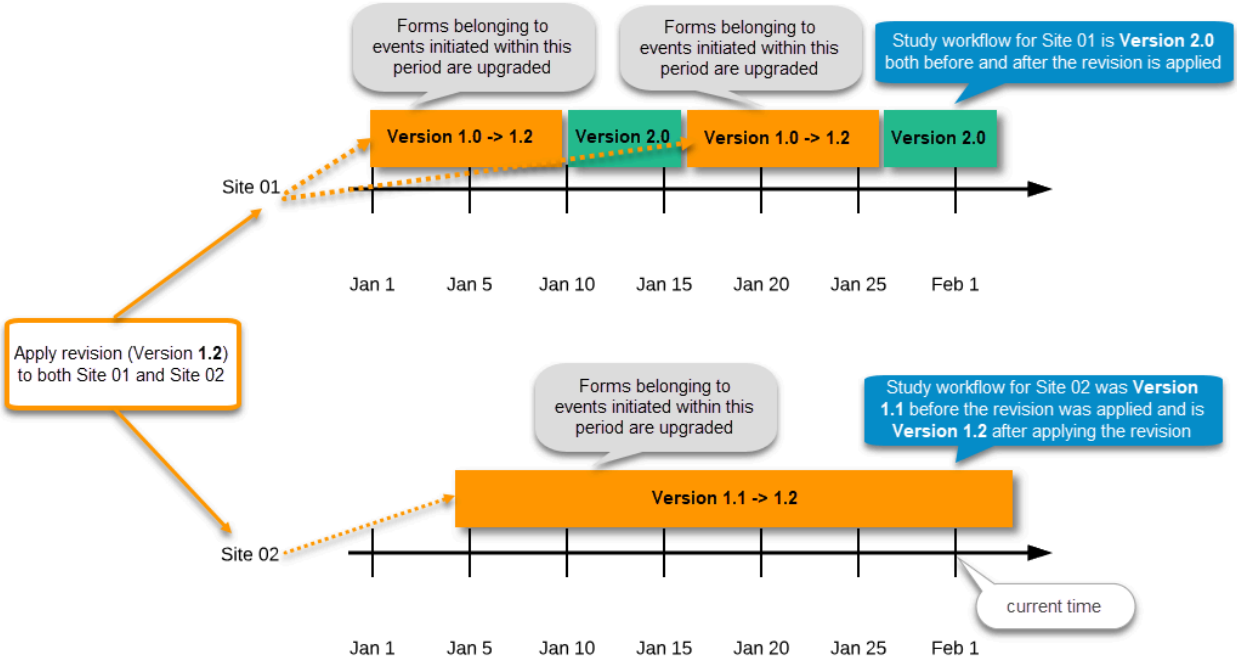
Additionally, only the latest revision of each study design version can be used as starting point for additional revision. For example, if we want to revise study design version 1, that has already been revised to version 1.1, we can only select 1.1 as starting point of the revision and not 1.0.

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.

Note! It is recommended that you use the design revision impact analysis before you apply any revision. For more information, see Design revision impact analysis.

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.

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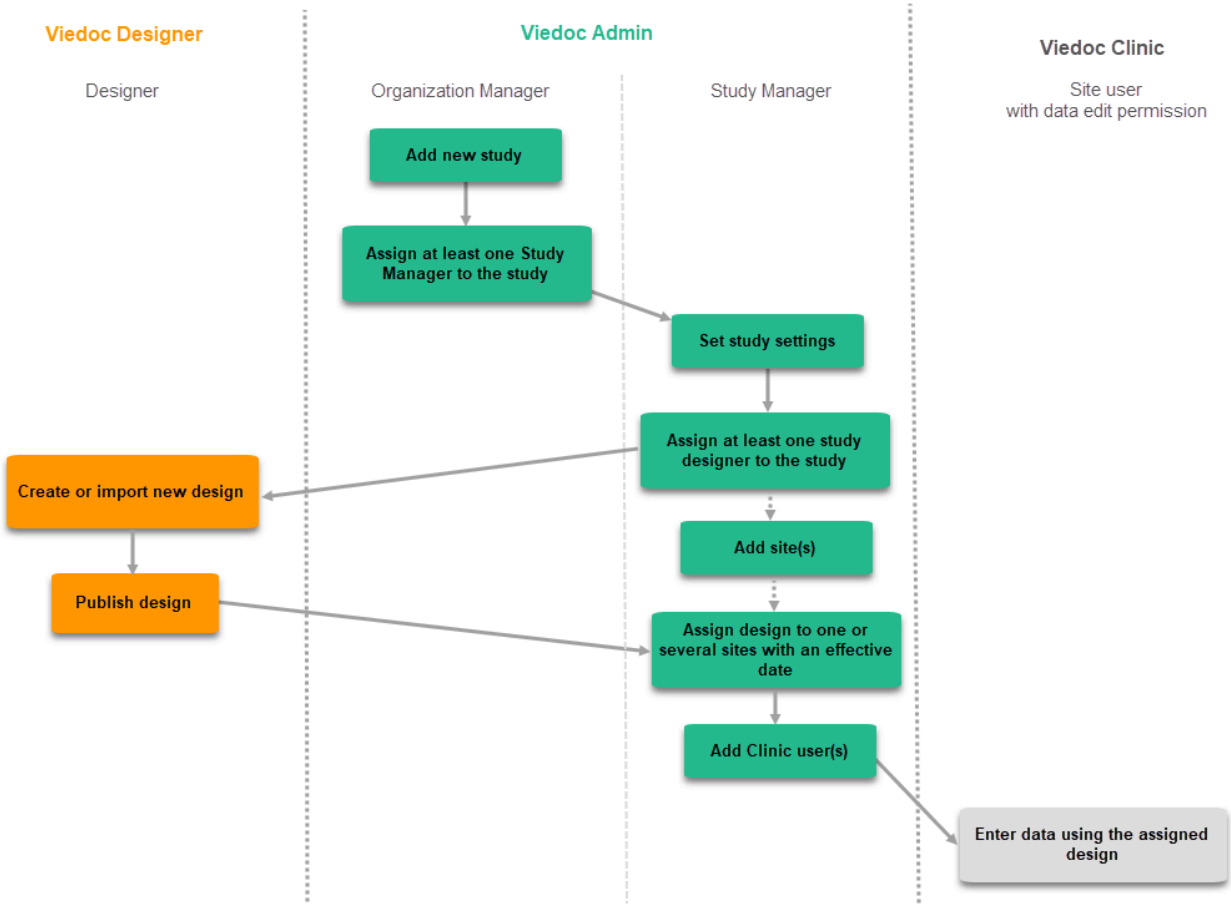
3 Configuration workflow

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:

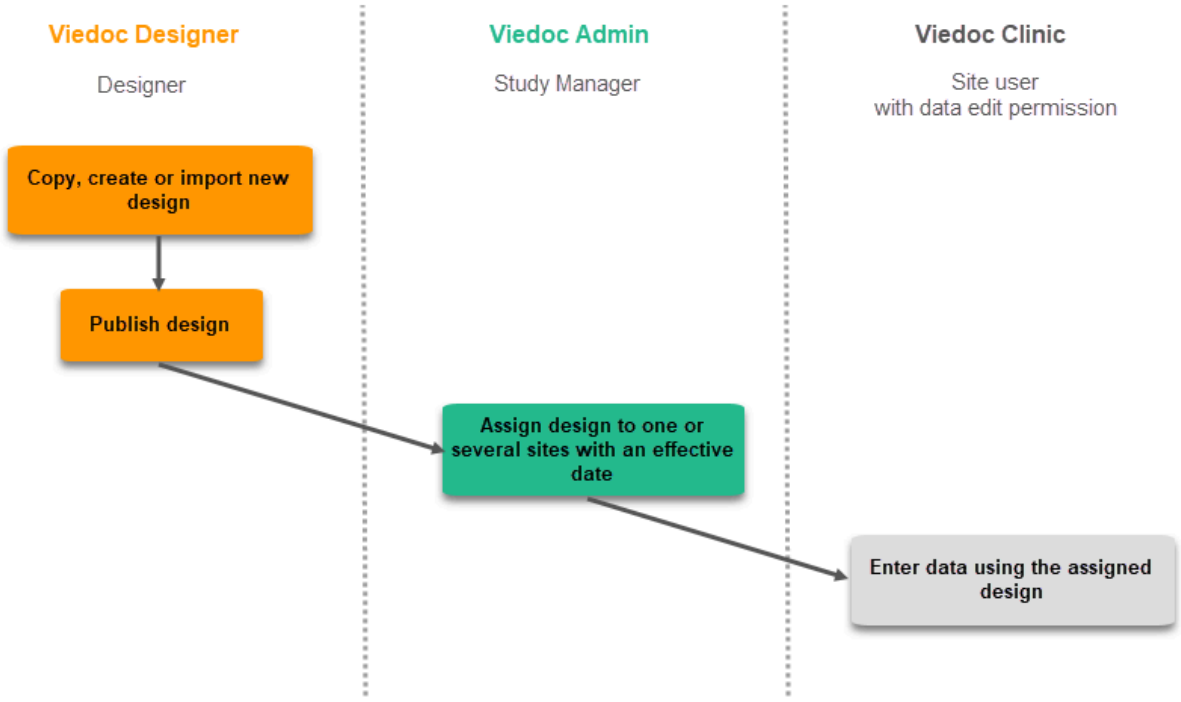
1. In Viedoc Admin, the Organization Manager creates the new study and appoints a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non version-controlled common settings and appoints a Designer.
3. In Viedoc Designer, the Designer creates the first version of the version-controlled settings 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:

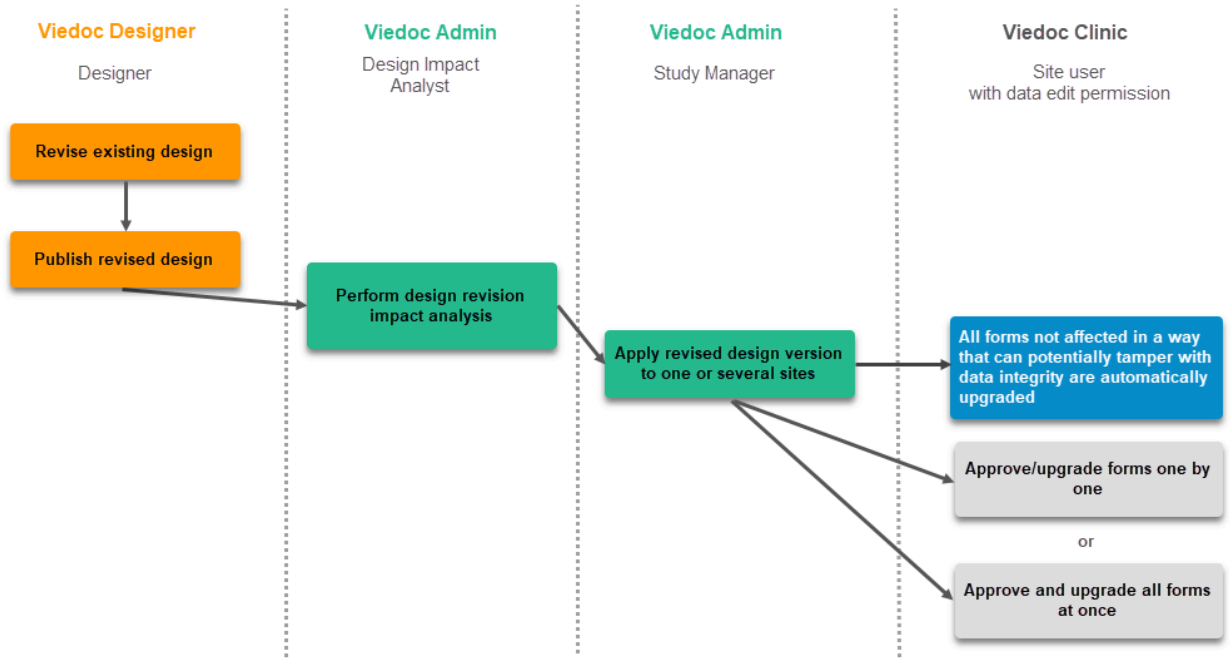
1. In Viedoc Designer, the Designer makes a full copy of the existing version of the study design.
2. In Viedoc Designer, the Designer makes the additional settings required by the protocol amendment and then publishes the design, which then becomes available in Viedoc Admin.
3. In Viedoc Admin, the 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 Design Impact Analyst performs the revision impact analysis. For more information, see Design revision impact analysis.
4. 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.

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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?

Published by Viedoc System 2024-12-03

1 What's new in the latest release?

Detailed information on changes in the current release, the release schedule and notes from previous releases can be found in the release notes on the Viedoc website here:

https://www.viedoc.com/support/release-notes/

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

Known limitations

Known limitations

Published by Viedoc System 2024-12-04

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 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.
- The MedDRA Chinese translation version 26.0 and onwards has the term 牙开. This term will be displayed as 牙开 in the Viedoc system, as the last character is not supported.

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 forWindows 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.
- In the PDF export output, each event should have a Contents section. The Contents list can in some scenarios be truncated and not show everything for the event.

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 OSX.

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2 Viedoc Admin

We no longer support SMS notifications in the following countries:

- +7 Russia
- +92 Pakistan
- +994 Azerbaijan
- +967 Yemen

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 fi le 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.

- API configuration: After creating new and editing existing Web API clients, it is not possible to save the setup unless the user system language is set to English or 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 datacheck 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 workfl ow. 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.

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.

5 Viedoc Me

- 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).
- 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.
- Sharing the Viedoc Me access details via text message does not work for studies that are running on the Viedoc China instance.

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 TMF

- Viedoc TMF 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 TMF does not work on Safari 16.3 and later versions.

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
A		
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		
C		
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.
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.

Term	Abbreviation	Definition
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.
D		
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.
E		
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.

Term	Abbreviation	Definition
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.
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.
F		
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.
G		
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.
H		
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.
I		
Identity Provider	IdP	A system entity that creates, maintains, and manages identity information.
Independent Ethics Committee	IEC	An institutional review board (IRB).

Term	Abbreviation	Definition
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).
J		
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.
K		
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.
L		
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).
M		
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.
N		
National Medical Products Administration	NMPA	The Chinese agency for regulating drugs and medical devices.
O		
Object Identifier	OID	An identifier mechanism for naming any object, concept, or "thing" with a globally unambiguous persistent name.

Term	Abbreviation	Definition
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.
P		
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.
Q		
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.
R		
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.
S		
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).

Term	Abbreviation	Definition
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.
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.
T		
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		
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.
V		
Viedoc Inspection Readiness Packet	VIRP	A file that can be downloaded in Viedoc, containing all the information needed to fulfill regulatory expectations.
W		
World Health Organization Drug Dictionary	WHO DD	A dictionary maintained and updated by Uppsala Monitoring Centre.
X		
Y		
Z		

How to prepare for a regulatory inspection

How to prepare for a regulatory inspection

Published by Viedoc System 2024-10-10

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, European Medicines Agency (EMA) 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.

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 and features, and listing the user stories 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
- Clinical Trial Cloud System Checklist
- Viedoc Impact Assessment documenting at a feature level the risks and potential consequences arising from the release of new and updated features in the release
- Acknowledgement Form describing what you need to review, and containing room for your signature as evidence that you have completed your review
- 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.

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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[1] level, and where necessary, individual features[1].

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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.

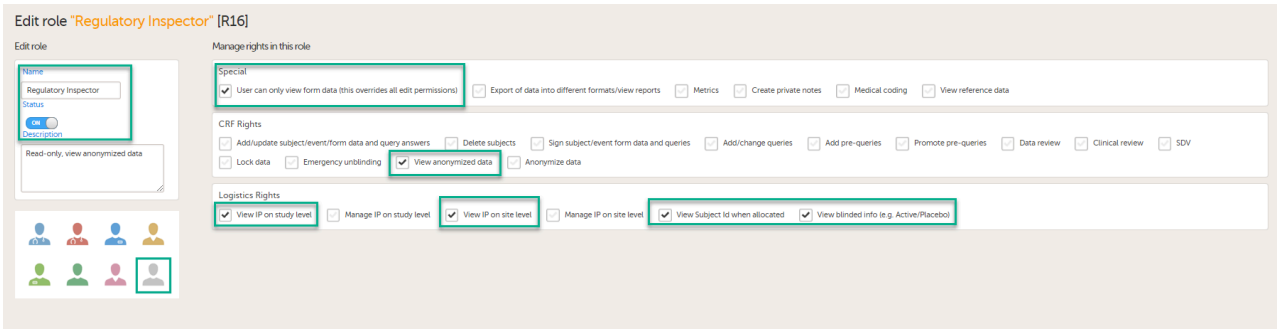
To allow the Regulatory Inspector access to study data, their role must be configured with Read-only for form data and View anonymized data and blinded data permissions on the **Roles** page.

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.

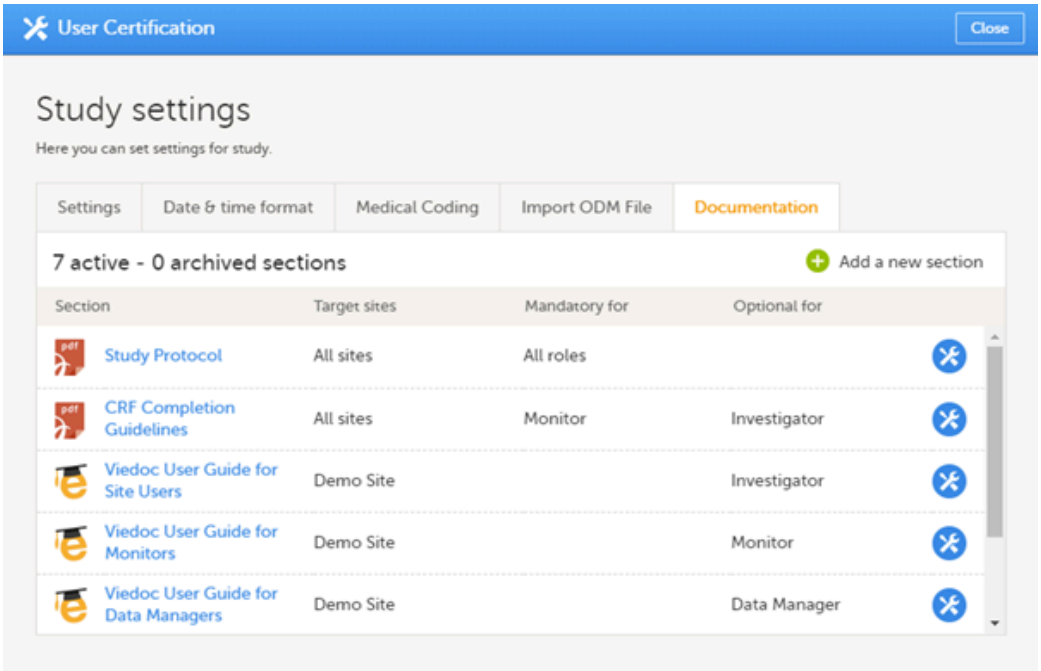
In Viedoc Admin, the study manager invites the Regulatory Inspector to the study for all sites. See Managing users.

- 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.

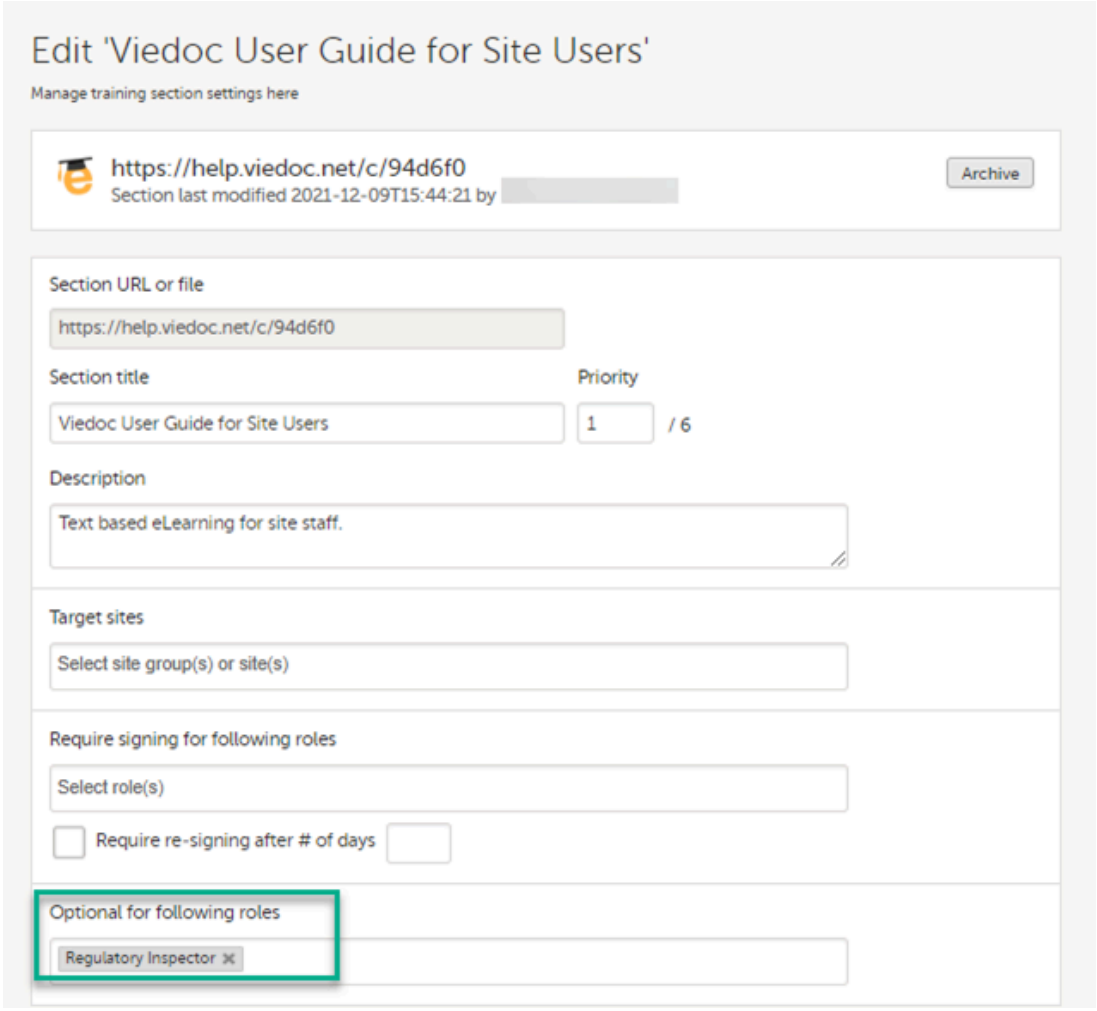
Note! This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.

- 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.



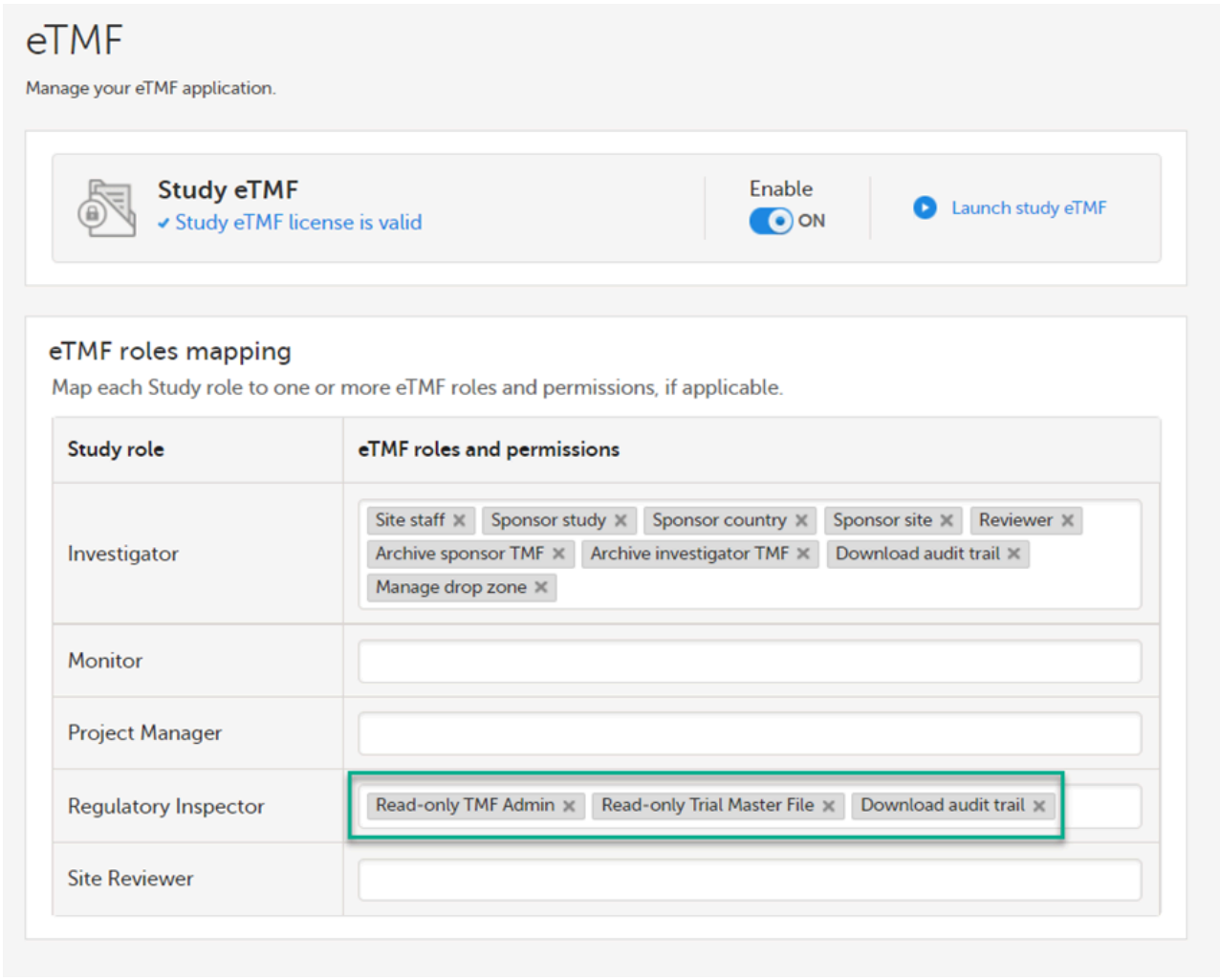
The Regulatory Inspector role should be granted access to the relevant eLearning documentation on the Study settings page.



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.



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

[1] 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.

Guide to Viedoc server instances (for Admin & Designer)

Guide to Viedoc server instances

Published by Viedoc System 2024-12-03

This lesson is intended as a guide for which production instance to use. We recommend using your training instance in the same region as the production instance you plan to use.

1 Technical Overview

Viedoc maintains server instances in Europe, Japan, China and the US. Each region has a primary server as well as a redundancy. They are served out of two Microsoft Azure regions as follows: The US instances are in US West and US East. The European instances use France Central and France South, the Japanese instances use Japan East and Japan West , and the mainland China instances use China North and China South. These locations are chosen for connectivity and privacy regulation purposes.

1.1 Region capabilities

Each region has a training and a production instance for your studies.

When a production study is added in Viedoc, it is added within an organisation in one of the four production instances. We recommend that the entire study should use the chosen production instance, but this is not an absolute must. It is possible to run different studies on different instances.

Certain regions have alternate capabilities which use different sub-processors. You can find out more here: Service Status.

Note! Viedoc Connect is disabled on the Chinese instances.

For a more in-depth technical description, please see Viedoc Technical Description.

2 Available Viedoc Instances

Note! Sometimes there may be a need to work on several servers for reasons such as the following:

- To maintain multiple Viedoc accounts
- Due to connectivity issues in China
- Due to a study design in multiple languages, such as Japanese or Chinese
- Due to concerns about mainatianing GDPR compliance

See also Navigating GDPR for Clinical Trials for more information about GDPR for clinical trials.

A short summary of the available Viedoc instances is listed below.

- US Instances
    - Recommended for: The US instance is always recommended when a US sponsor runs trials using US sites. It can also be used for sponsors and sites located outside of the US, for example: Australia or South America.
    - Response times are very short for the entire western world. Users accessing the US instance from within China might experience a lag time, and this lag could be considerable from time to time.
    - Production: https://clinic.us.viedoc.com
    - Training: https://clinictraining.us.viedoc.com
- EU Instances
    - The EU instance is always recommended when European sponsors run trials using European sites. It can also be used when sponsors and sites involved are neither from US, Europe, China or Japan (e.g. for studies run in Australia or the Middle East).

- Response times are very short for the entire western world. Users accessing the EU instance from China might experience a lag time, and this lag could be considerable periodically.
- Production: https://v4.viedoc.net
- Training: https://v4training.viedoc.net

Note! The EU instance is recommended for customers that must maintain GDPR compliance.

- JP Instances
  - The JP instance is always recommended when Japanese sponsors are running studies using Japanese sites. It can also be used when sponsors and sites involved are neither from US, Europe, China or Japan (e.g. for studies run in Australia or South East Asia).
  - Response times are very short for the entire western world. Users accessing the EU instance from China might experience a lag time, but it would be barely noticeable for the user.
  - Production: https://v4jp.viedoc.net
  - Training: https://v4trainingjp.viedoc.net

Note! This instance is recommended for customers that must maintain APPI compliance.

- CN instance
  - The CN instance is always recommended when Chinese sponsors are running studies using Chinese sites.
  - Response times are very short from within China. However, at times there will be a noticeable lag for users outside of China due to reasons beyond Viedoc's control.
  - Production: https://clinic.viedoc.cn
  - Training: https://clinictraining.viedoc.cn

Note! This instance is recommended for customers that must maintain compliance with HGR and PIPL.

More information on managing studies in China can be found here: Managing studies in China.

2.1 Viedoc WCF API

For connecting your development environment or any other system to the Viedoc public web service using the Windows Communication Foundation (WCF) standards, use the following:

For the EU:

https://v4api.viedoc.net/HelipadService.svc?wsdl
https://v4apitraining.viedoc.net/HelipadService.svc?wsdl

For Japan:

https://v4apijp.viedoc.net/HelipadService.svc?wsdl
https://v4apitrainingjp.viedoc.net/HelipadService.svc?wsdl
https://v4apistagejp.viedoc.net/HelipadService.svc?wsdl

For China:

https://api.viedoc.cn/HelipadService.svc?wsdl
https://apitraining.viedoc.cn/HelipadService.svc?wsdl

For the USA:

https://api.us.viedoc.com/HelipadService.svc?wsdl
https://apitraining.us.viedoc.com/HelipadService.svc?wsdl

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3 Data Protection Impact Assessment

It is important to know that when transferring data from one region to another you will need to comply with the local data privacy legislation, for example:

- Transferring data from the EU to another region, GDPR must be considered.
- Transferring data from JP to another region, APPI must be considered.
- Transferring data from CN to another region, HGR and PIPL must be considered.
- More information can be found here: Data Protection Impact Assessment.

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4 Choosing your instance

- Grouping your studies
  - For some studies, it will be clear which instance to use while other situations might present more challenges. When you encounter a challenging situation, we recommend grouping your studies to the extent it is possible to do so. For example, if most of your studies run on the EU instance, we recommend that you run new studies on the EU instances, as well. If you are planning your first Viedoc study, then we recommend using an instance where you expect you'll conduct most of your future studies.
  - If a study involves sites from multiple regions, we recommend that you choose an instance based on where the majority of the sites are located

4.1 Using several instances for the same study

It is not possible to share a study between instances, but it is possible to run a separate study on an alternate instance. Doing so present some things to be considered:

- Settings in Admin and the global design settings in Viedoc designer will need to be remade for the alternate study.
- User management and user account setup will be separate for the alternate study
- You will not be able to combine data from both studies in Viedoc Suite applications like: Reports or export.
- When reviewing data for the entire trial (on all instances) you will need to export data from both studies and merge the data offline (e.g. in SAS) or in another system. This process can be made easier by using the same CRF design version where all IDs are identical for the studies.
- It is possible to use different languages on item labels in the two studies, so if the item IDs are identical you can have item labels in Chinese on Chinese instances and English labels on US instances.

4.2 Recommendations from Viedoc

Below we have listed a few scenarios advising on which instances we would recommend using.

- US sponsor - EU sites
  - Use the EU instance because all sites are in the EU.
- EU sponsor - US sites
  - Use the US instance because all sites are in the US.
- JP sponsor - US sites
  - Use the US instance because all sites are in the US.
- SA sponsor - AU sites
  - Use the EU, US, or Japanese instances as all are a suitable fit.
- CN sponsor - US and EU sites
  - Use the EU or US instance, or whichever has the majority of the sites.
- EU sponsor - EU and US sites
  - Use the EU instance
- US sponsor - EU, US, CN, and JP sites
  - Use EU, US, JP, or CN instances

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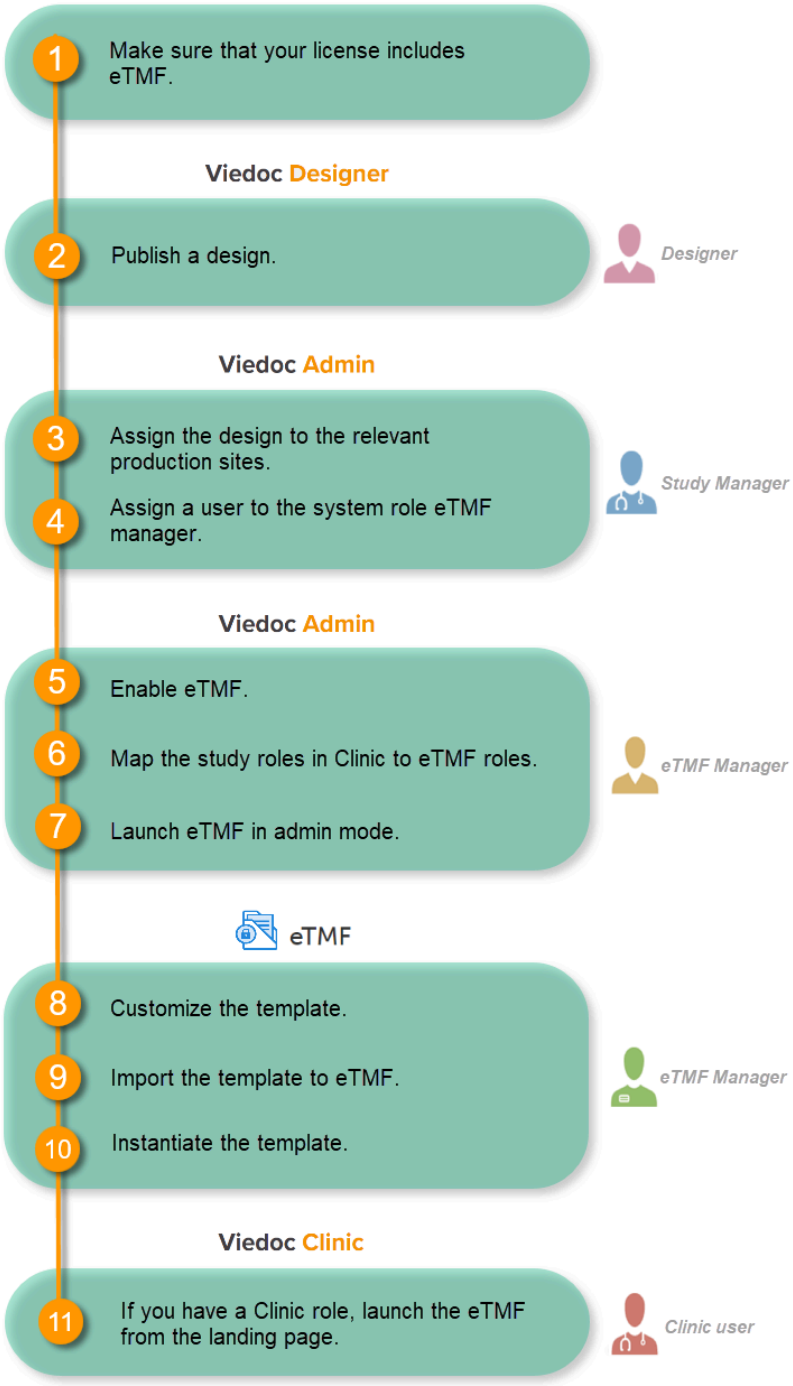
5 FAQ

- If a study has been initiated on one instance, can it be moved to another instance later?
  - It is not possible to move studies across instances. The study remains on the instance that it started on until it is either locked or purged.
- As a customer, am I allowed to use different instances for different studies?
  - Yes! During the WI stage, you will specify which instance you want to run your study on. If a sponsor is running some of their studies in the US and some in China, we recommend using the instance that is most suitable for each study.

Quick guide for setting up Viedoc eTMF

Published by Viedoc System 2023-04-25



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.

Notel 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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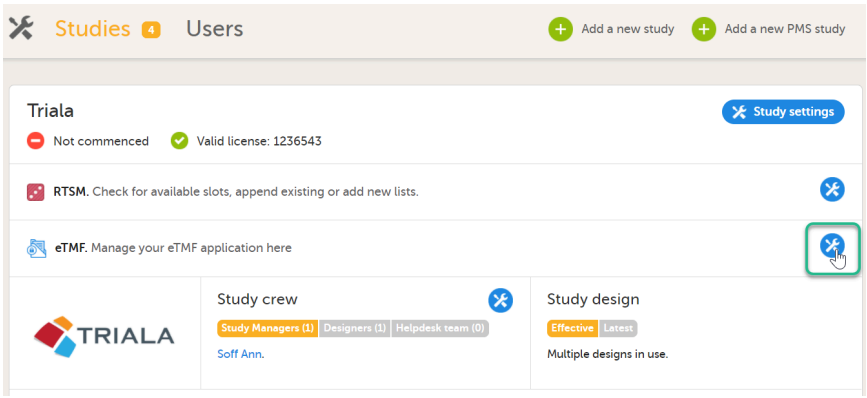
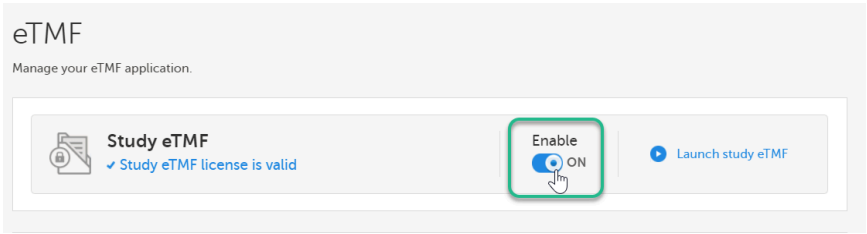
5 Enable eTMF

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:



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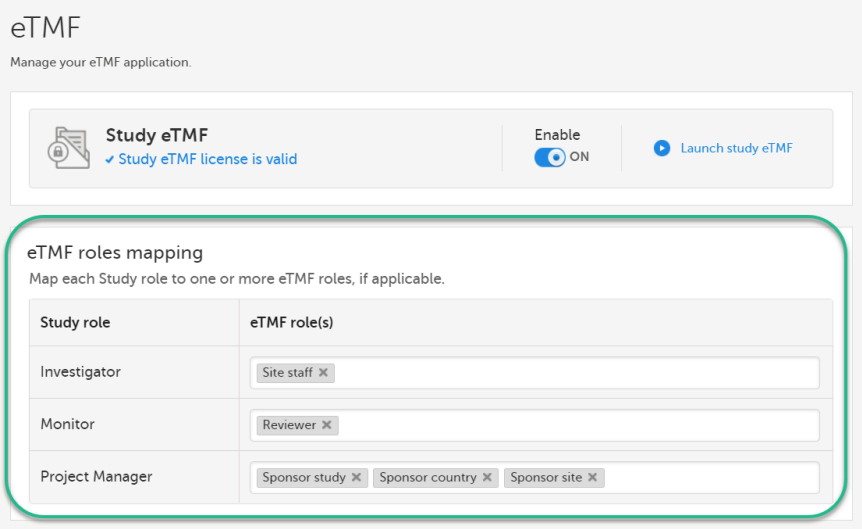
6 Map study roles to eTMF roles and permissions

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:

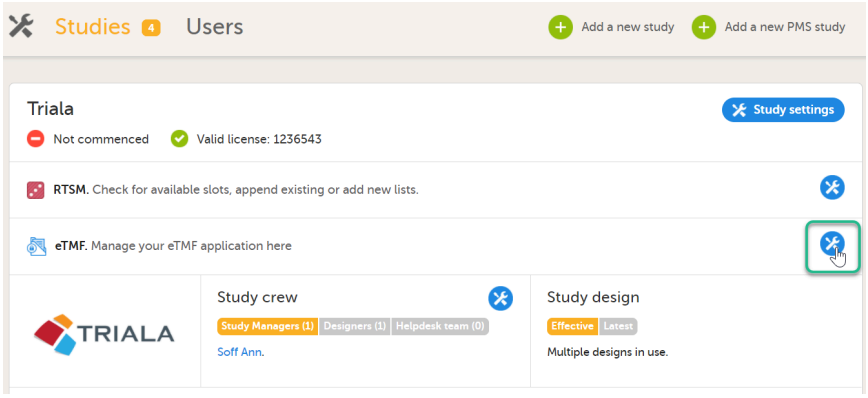


2 Select **Save changes**.

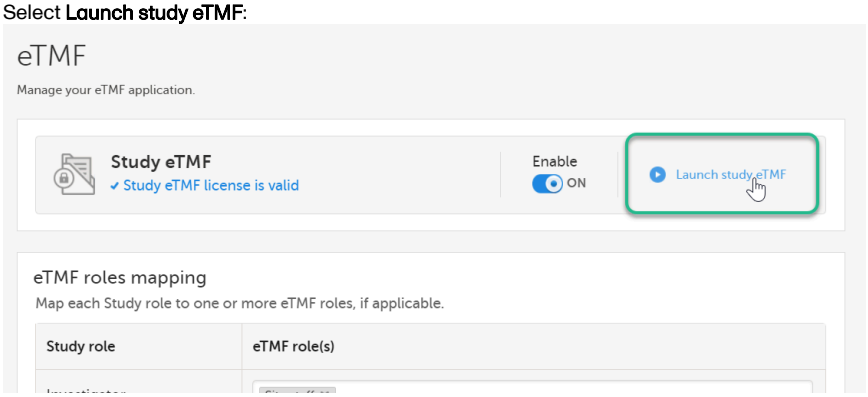
7 Launch eTMF in admin mode

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.

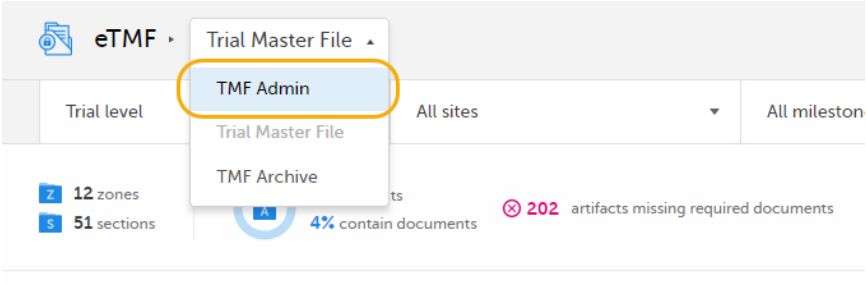
Once customized, import the template to eTMF, see Import the template.

8.2 Existing templates

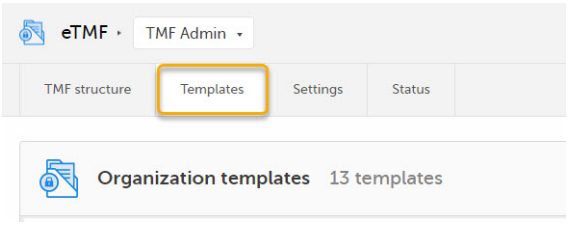
Imported templates can be customized to fit your study needs.

To export a template for customization:

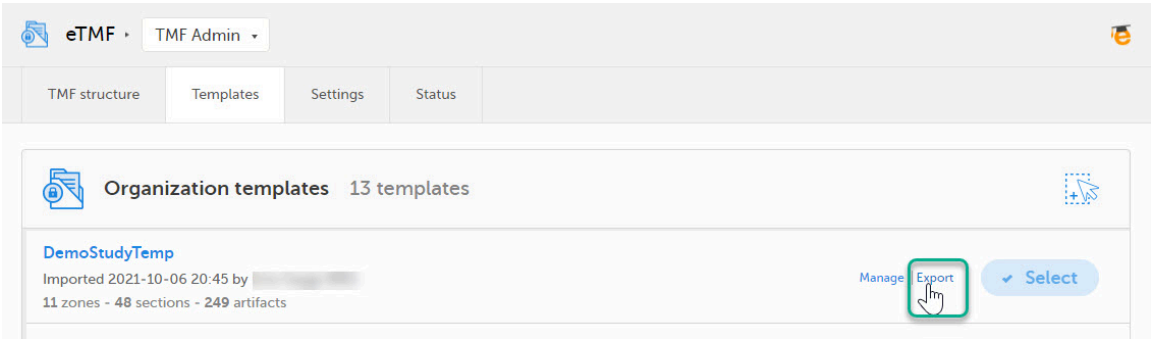
1 In Viedoc eTMF, select the **TMF Admin** view:



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.

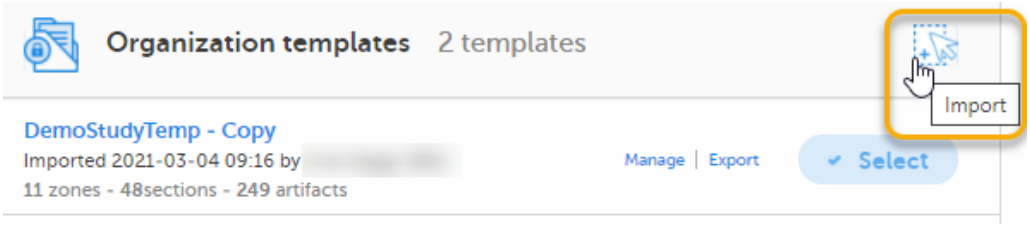
See also Customizing a template.

---

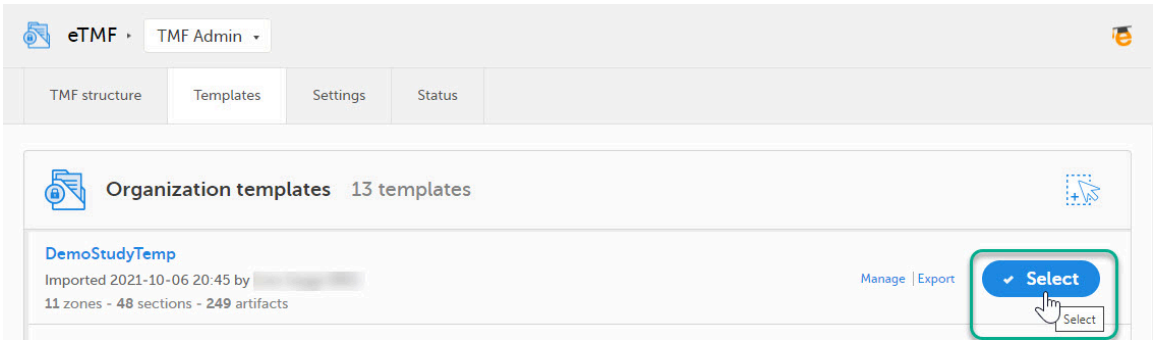
9 Import the template

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.

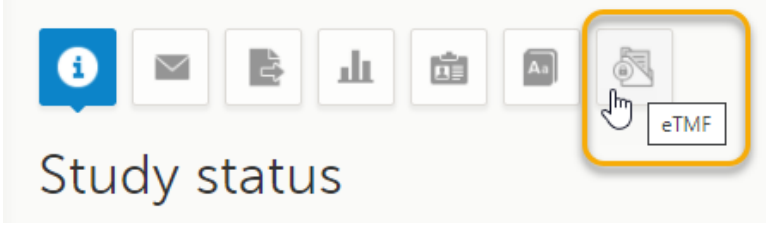
On the **TMF structure** tab, select the **Instantiate** button for the template.

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:

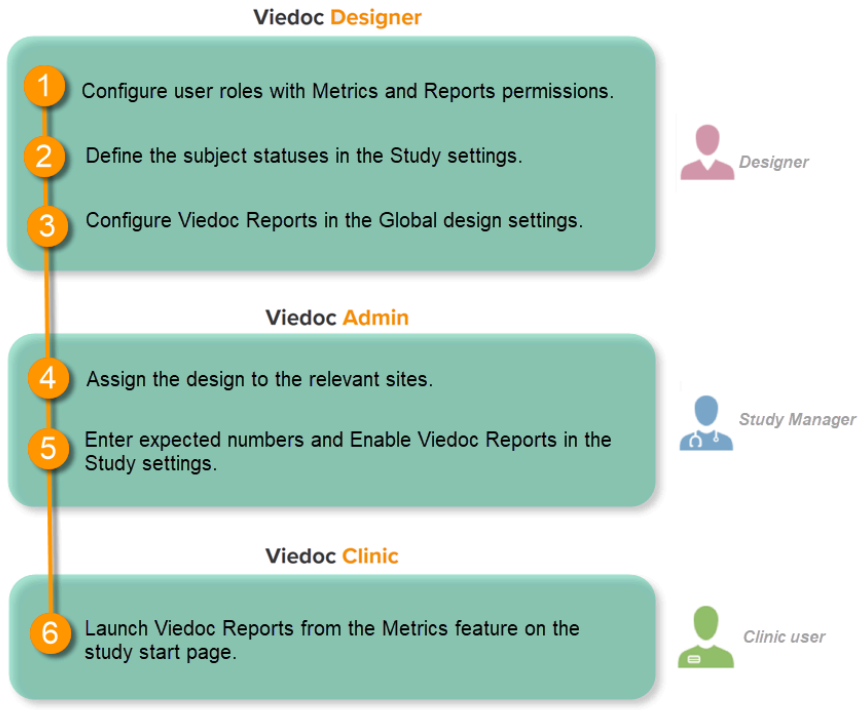


The eTMF application opens.

Quick guide for setting up Viedoc Reports

Quick guide for setting up Viedoc Reports

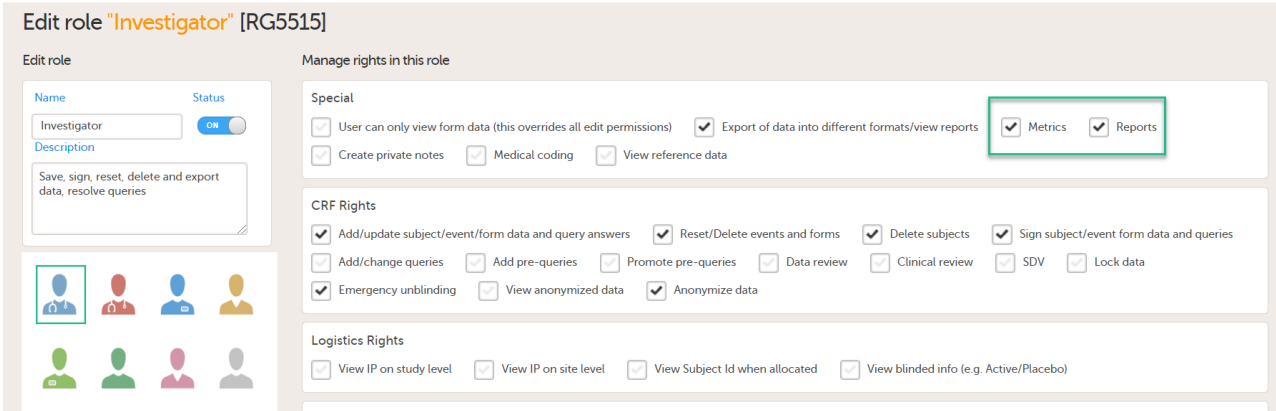
Published by Viedoc System 2023-04-25



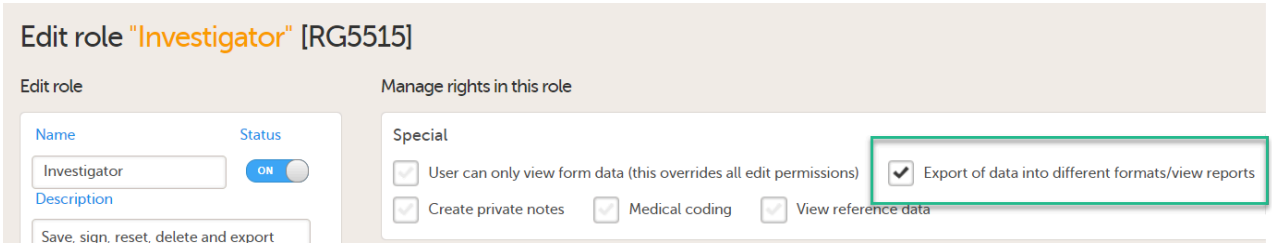
1 Configure the roles

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.



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



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.

---

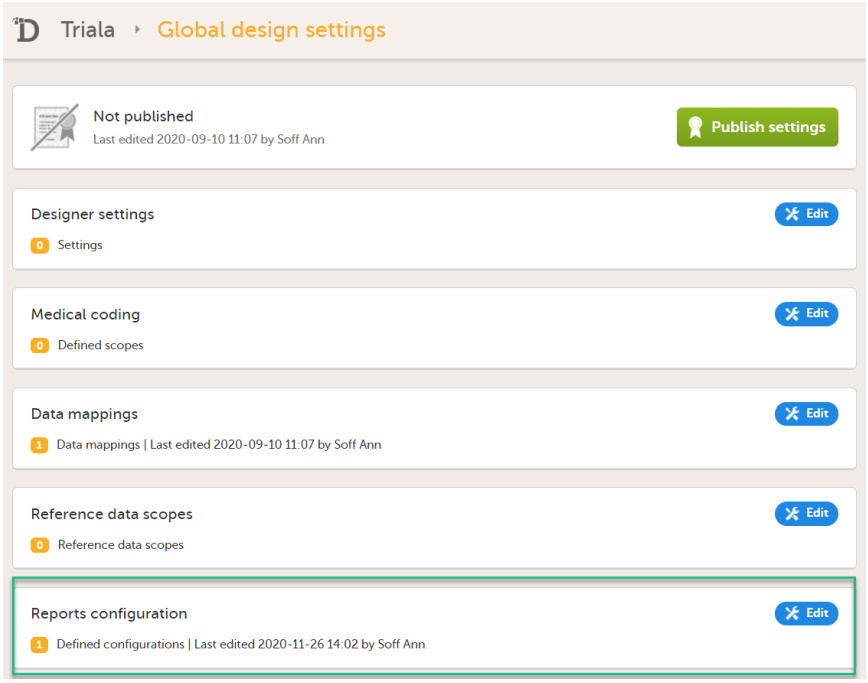
3 Configure Viedoc Reports

This step is performed by the Designer.

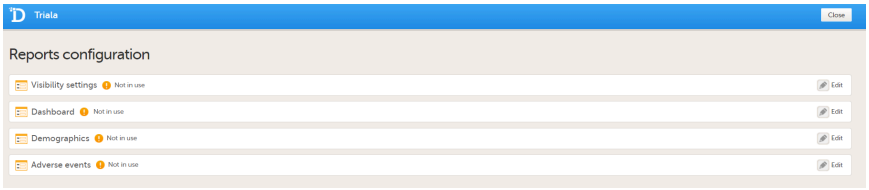
1 In Viedoc Designer, select the study for which you would like to configure Viedoc Reports.

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

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

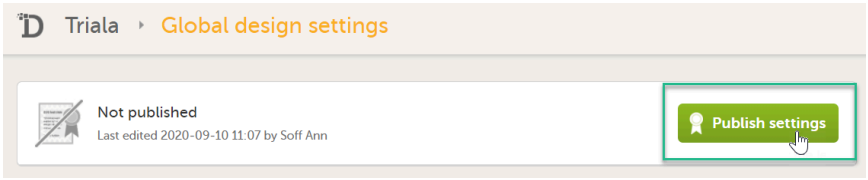


4 You can now configure the settings by clicking **Edit** in one of the fields: Visibility settings, Dashboard, Demographics, Adverse events, and Custom reports. See Configuring Viedoc Reports for details.



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.

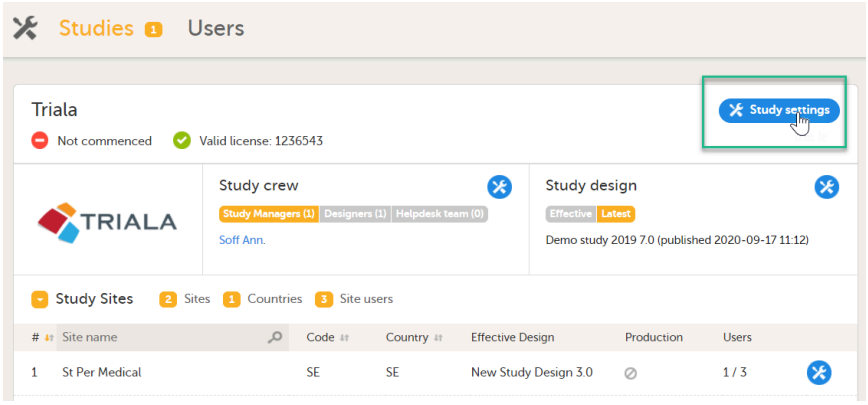
See Assigning a study design.

---

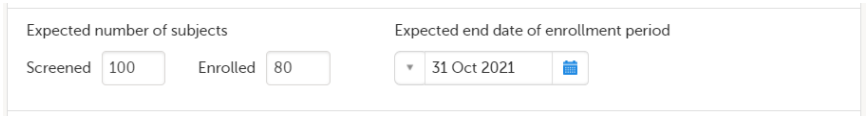
5 Enter the expected numbers and enable Viedoc Reports

This step is performed by the Study Manager.

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

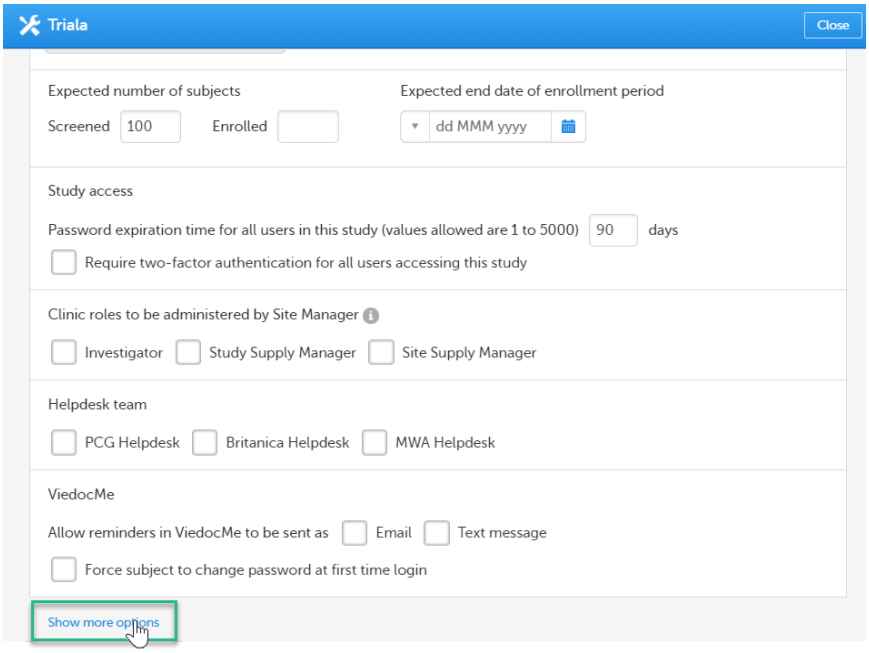


2 In the **Study settings** pop-up window, enter the total number of expected screened and enrolled subjects and the expected end date of the enrollment period.

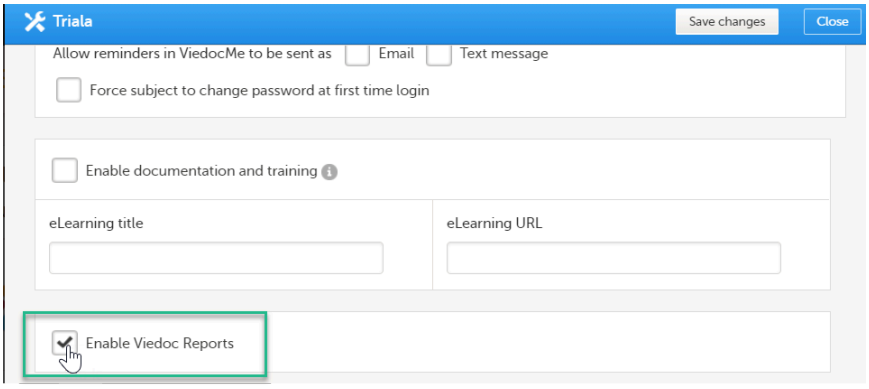


Note! This data must be entered on both study level and for each individual site.

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



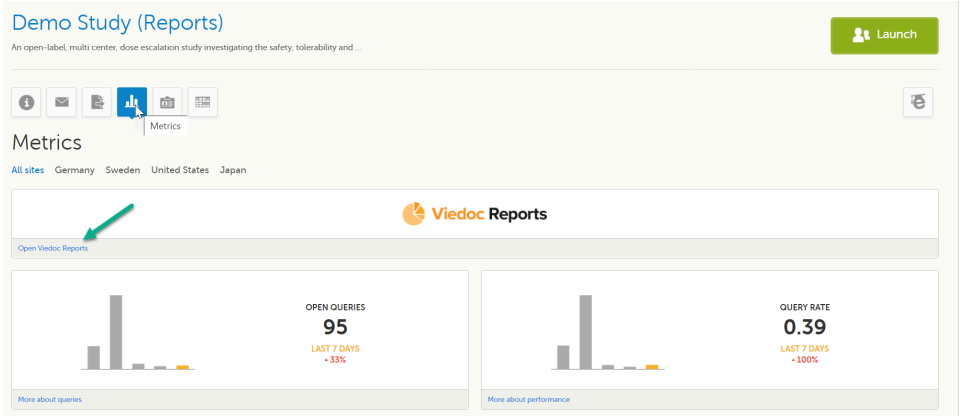
4 Select **Enable Viedoc Reports** and click **Save changes**.



6 Launch Viedoc Reports

This step is performed by the Clinic user.

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



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

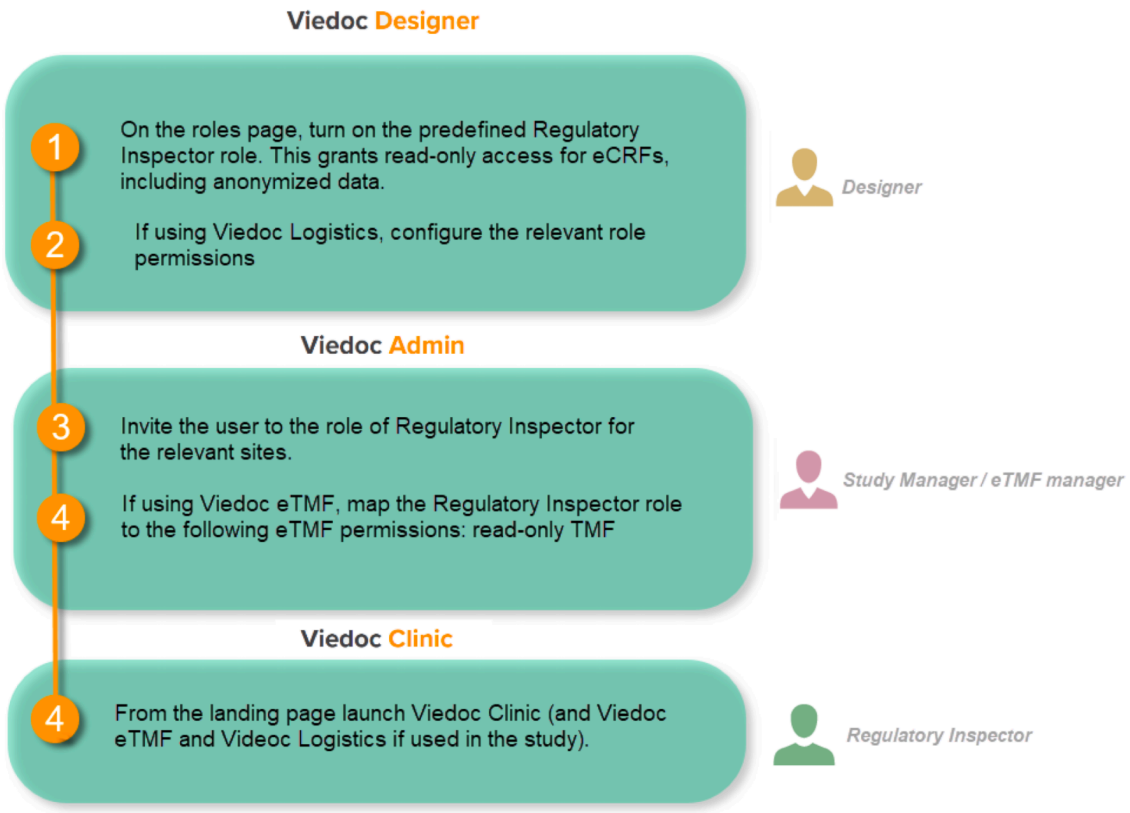
Thorough preparation for inspection of the EDC system used in a clinical trial is of great importance. The regulatory authorities see the EDC system used for a clinical trial as an important computerized system with regards to both patient safety and data integrity.

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!

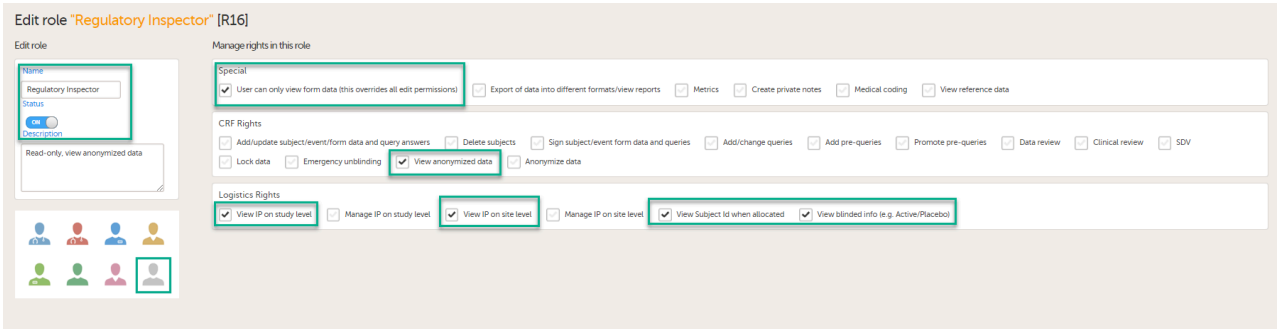
- The role of Regulatory Inspector must be turned on in Designer.
- By default, a set of predefined roles is set up by the system, and can be modified for your study. Permissions for the role of Regulatory Inspector should be set to READ-ONLY access to all parts of the system, including the eTMF (if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



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

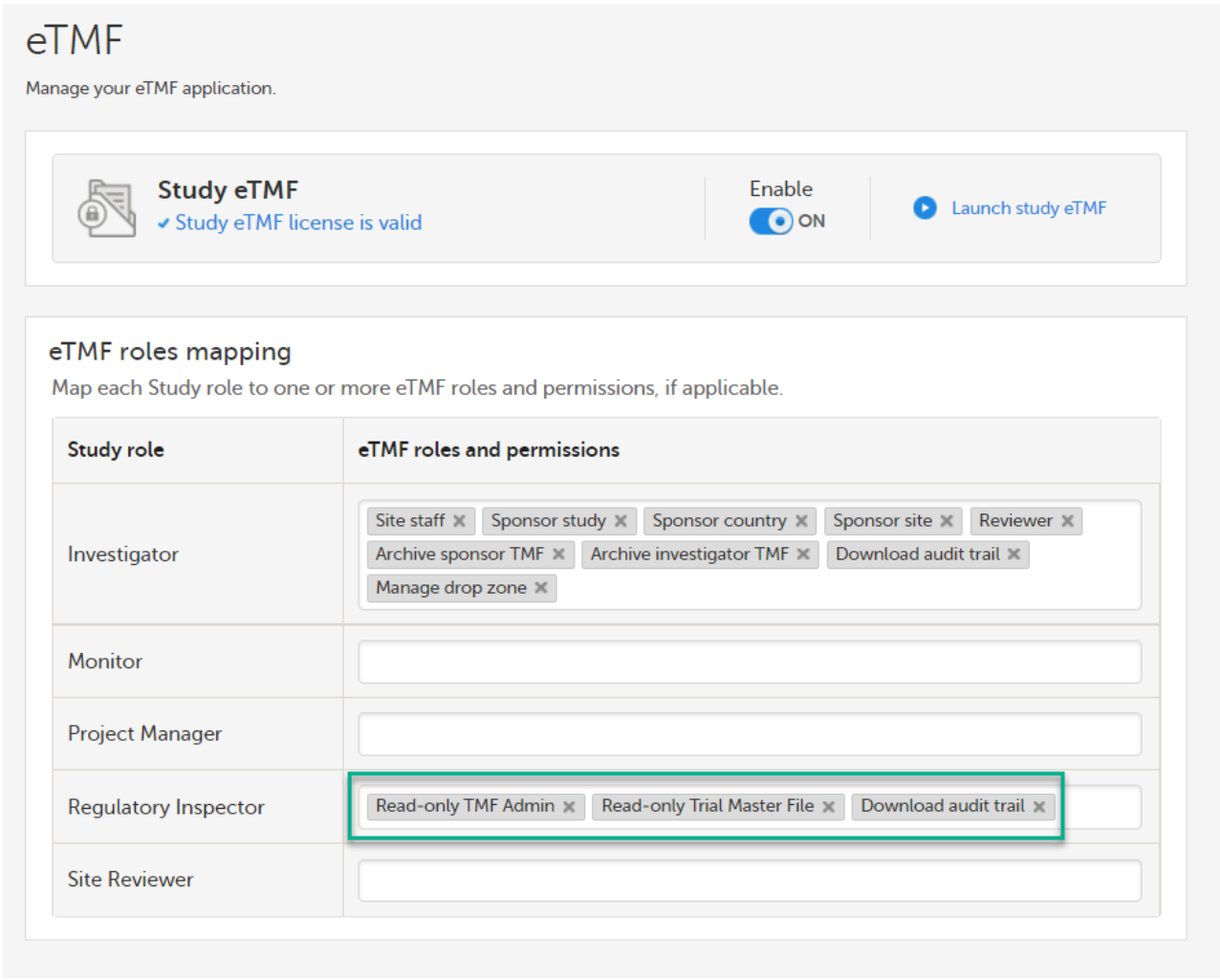
This step is performed by the Study Manager.

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.



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.

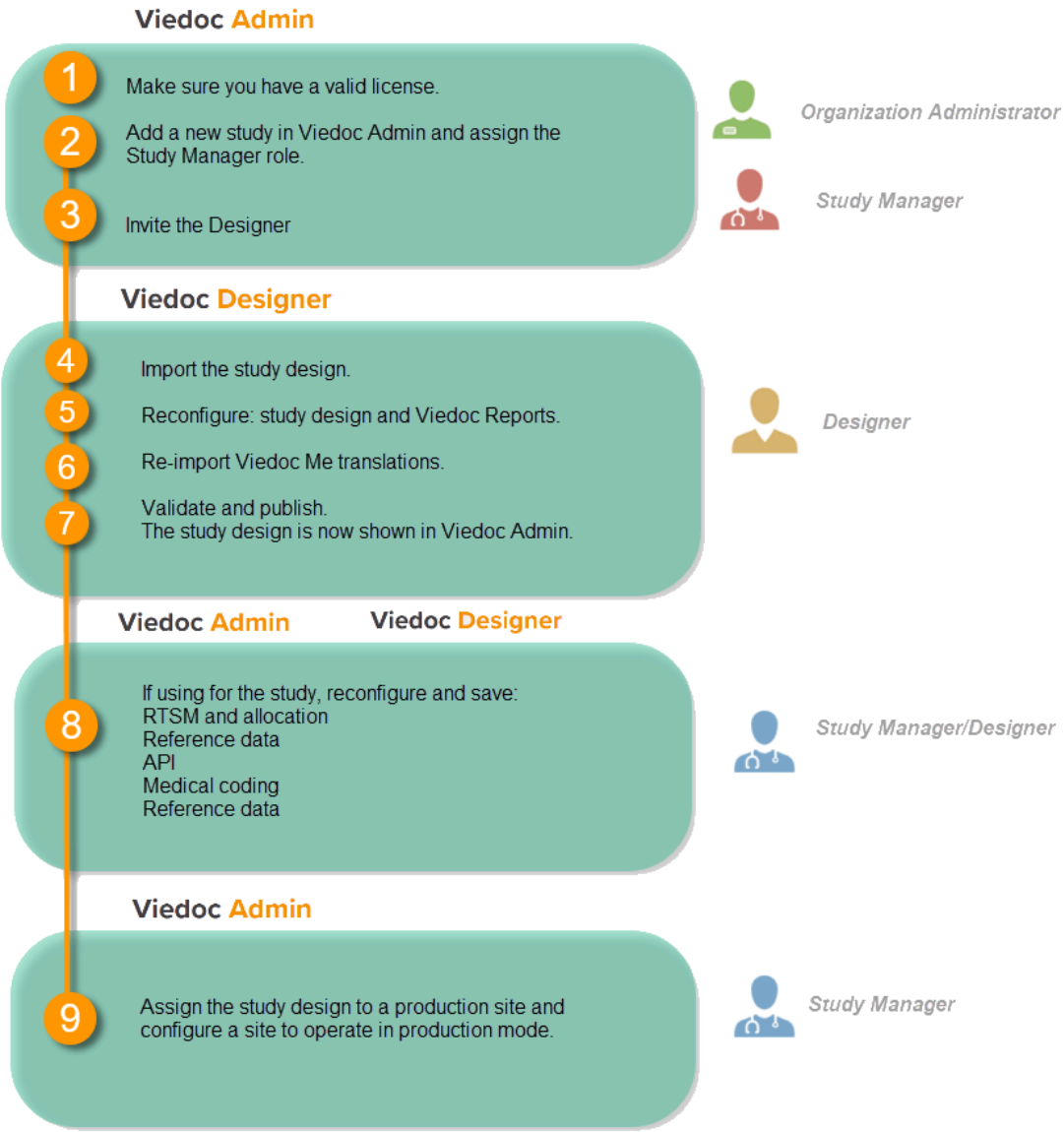
Quick Guide for going live

Quick guide for going live

Published by Viedoc System 2023-04-25

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.

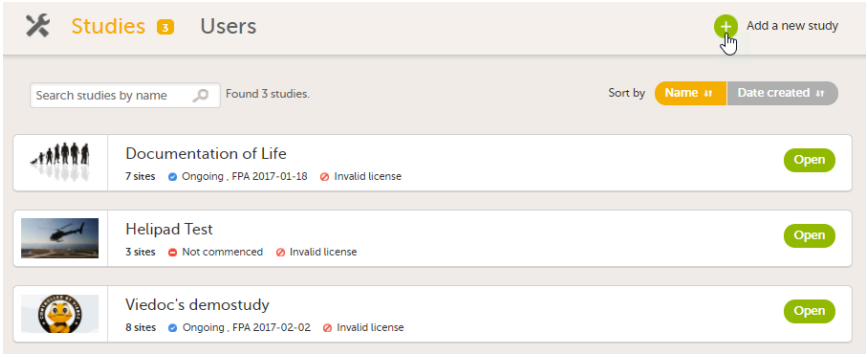
- Make sure you have a valid license: All production studies must have a valid license before they can be taken into production. The license is provided by a Viedoc representative. Every license is connected to a reference ID. The reference ID can be found on the signed study work order. For more information, 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.

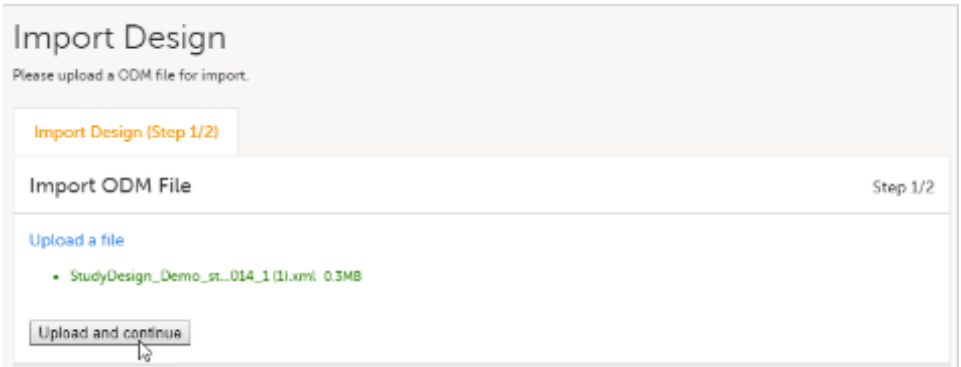
Invite a user to the Designer role. For more information, see Managing users (for Org Admin).

---

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).



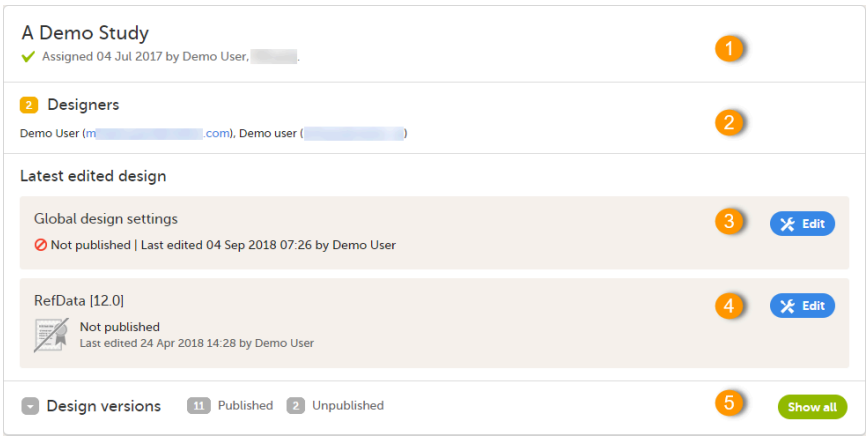
For further instructions, see Importing a new design version.

---

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

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 2024-06-28

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.

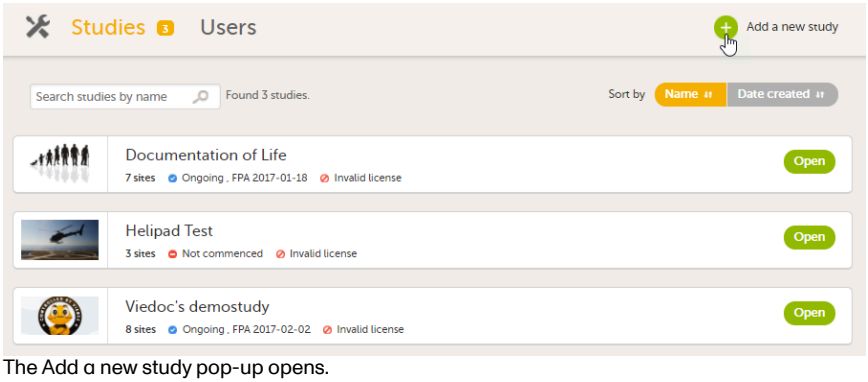
Note! For all production studies, make sure a contract with Viedoc Technologies exists before proceeding. See Overview of Viedoc for information about licensing.

2 Adding a study

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

To add a new study:

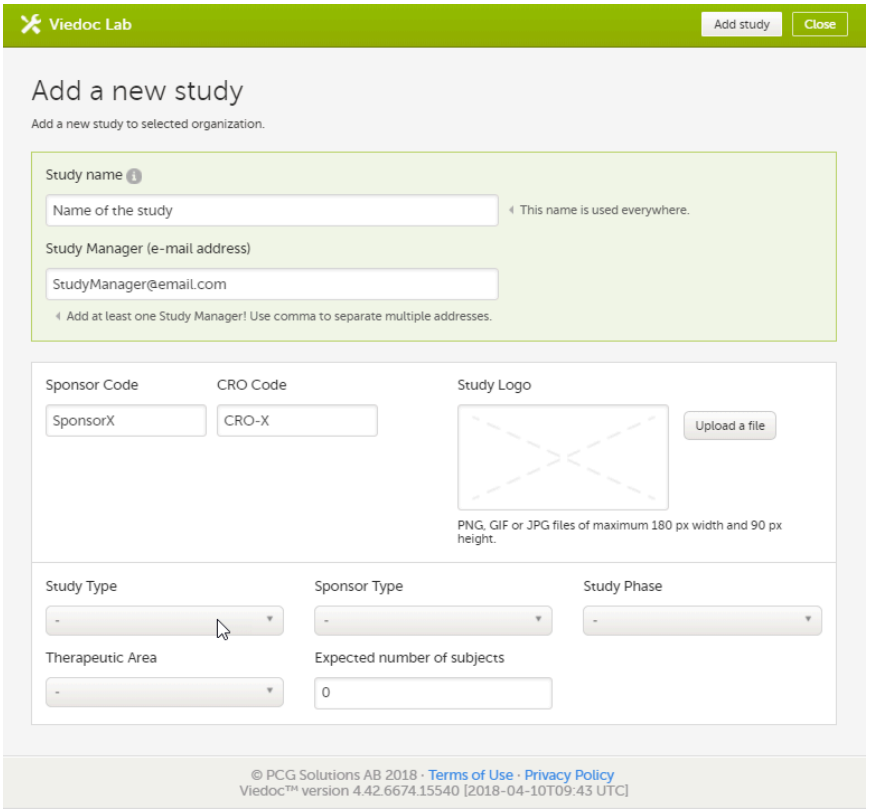
1. Open Viedoc Admin and click **Show studies** in the organization you would like to add a study to. The study overview page opens.
2. Click **Add a new study**.



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.

Important! The name of the study in the **Study name** field must not exceed 100 characters. Entering a Study name of more than 100 characters results in an error message.



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)

Published by Viedoc System 2024-10-10

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

Can not output single-source

1.2 About roles in Viedoc

Can not output single-source

1.3 About the study users

Can not output single-source

1.4 User settings in Viedoc Admin

Can not output single-source

1.5 About the user report

Can not output single-source

1.6 About system site groups

Can not output single-source

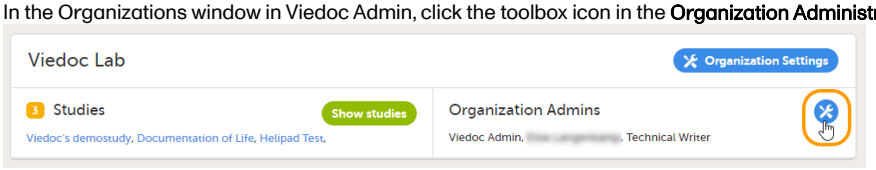
2 Step-by-step guides for the Org Admin

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.

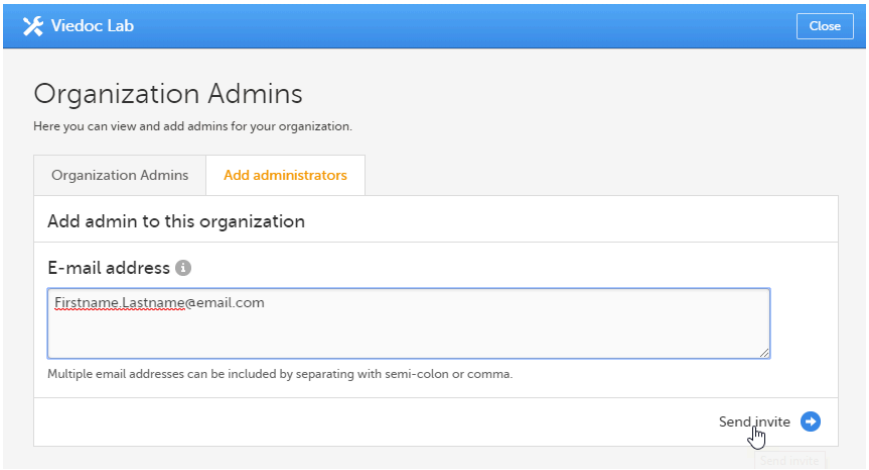
To add an Organization Administrator:

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 email address of the user you would like to invite to the role Organization Administrator.

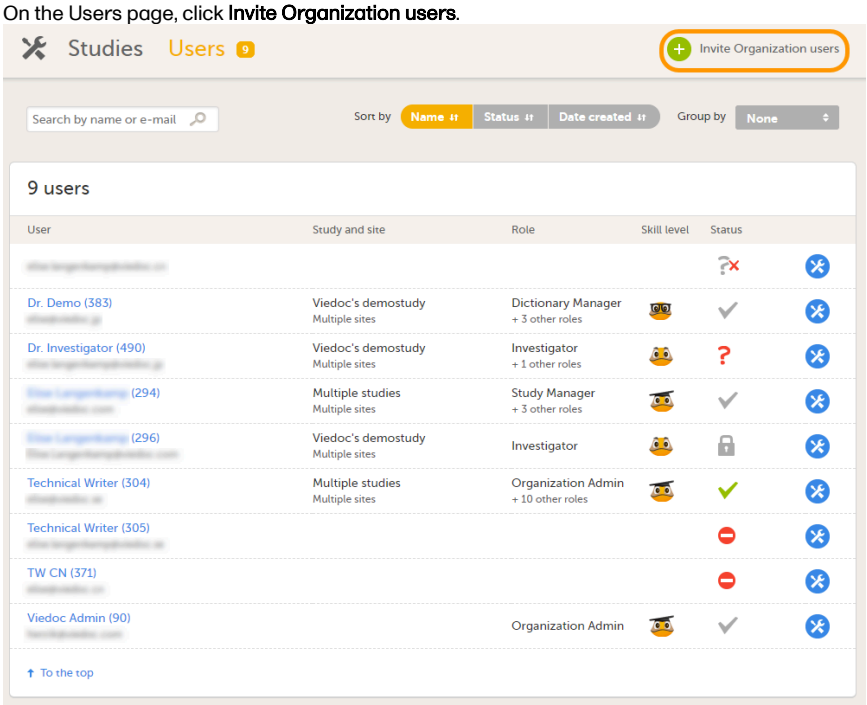


Tip! You can invite multiple users at once by adding multiple email addresses in the field. Separate the email addresses with a semi-colon or comma.

3 Click **Send invite**.
An invitation email is sent to the email address you specified.

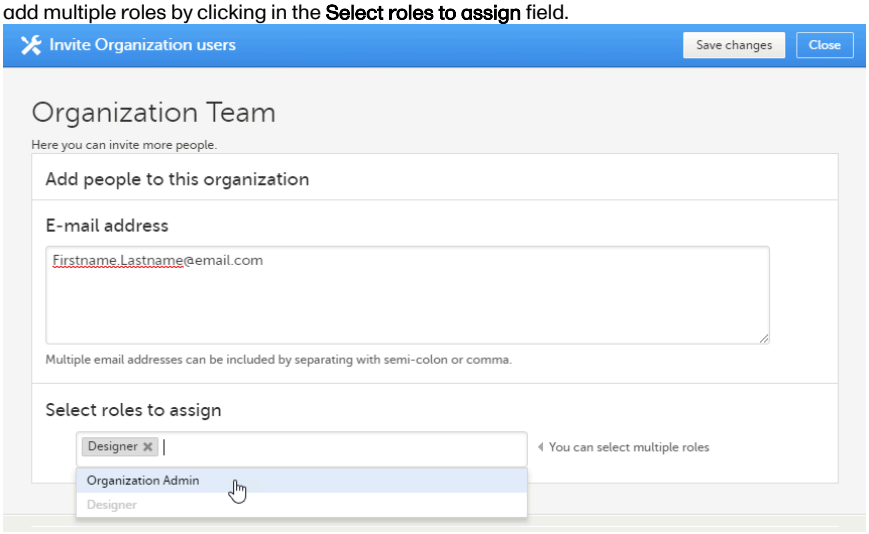
You can also assign users to organization roles (Organization Administrator, eLearning Administrator, and Designer at organization level) via the Users page:

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



The Organization team pop-up opens.

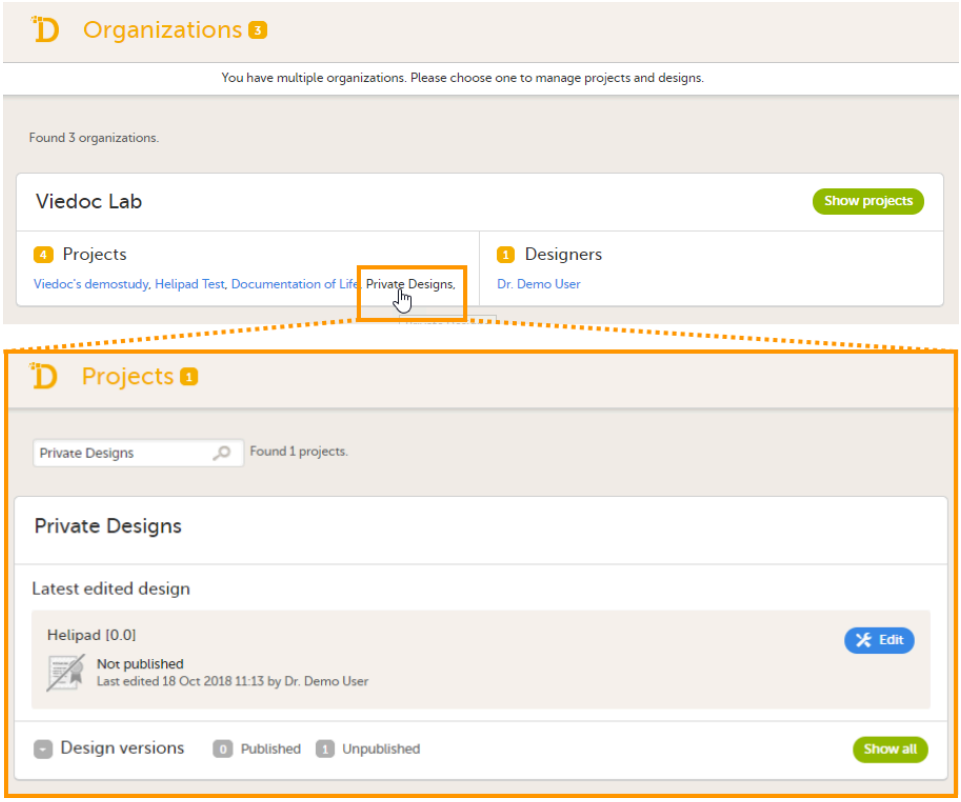
2 Enter the email address of the user you would like to invite, and select the role to which you would like to invite the user. You can add multiple roles by clicking in the **Select roles to assign** field.



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

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

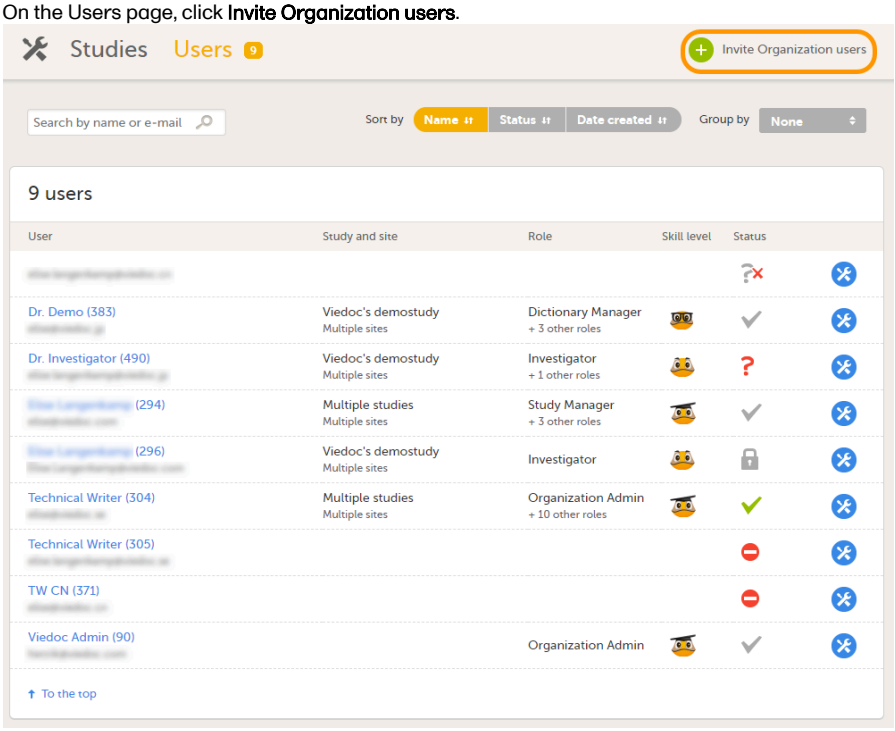
A Designer at organization level receives access to Viedoc Designer for all studies within the organization, and receives access to the Private Designs section, see image below.



2.2 Assigning an eLearning Administrator

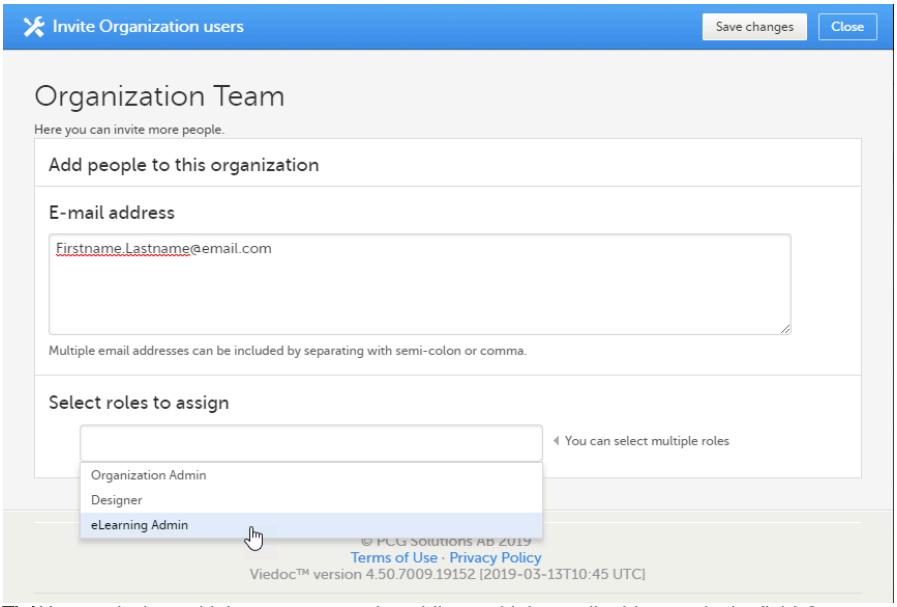
To assign an eLearning Administrator via the Users page:

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



The Organization team pop-up opens.

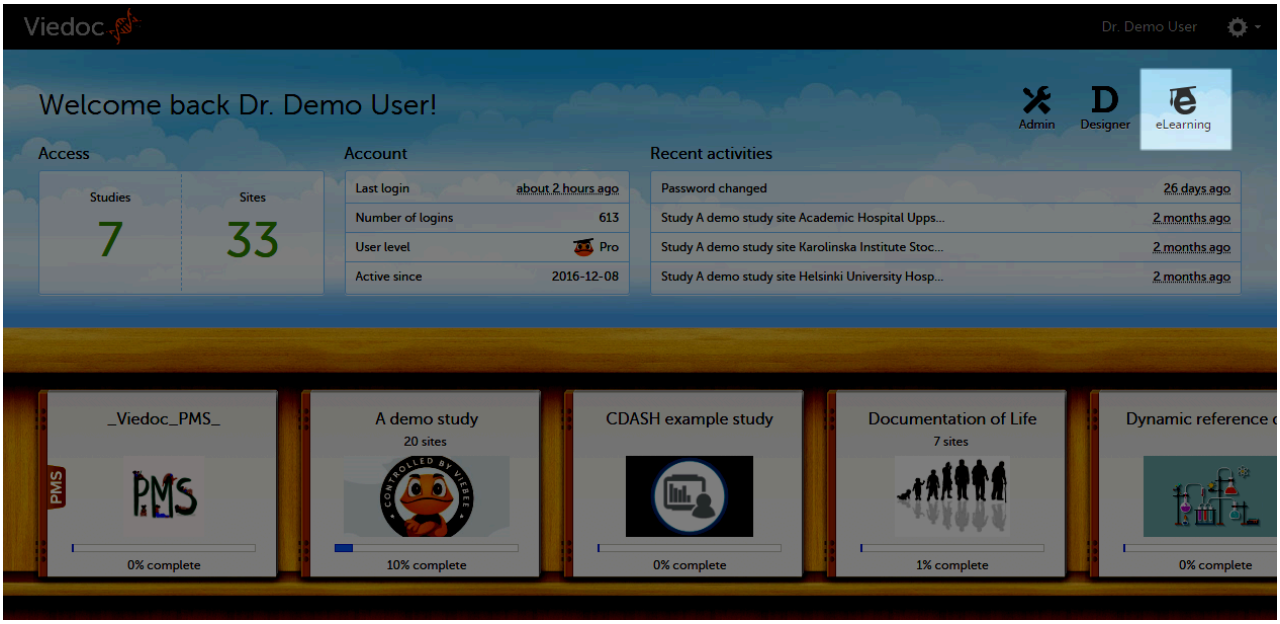
2 Enter the email address of the user you would like to invite, and select the role to which you would like to invite the user. You can add multiple roles by clicking in the **Select roles to assign** field.



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

3 Click **Save changes**.
An invitation email is sent to the email 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

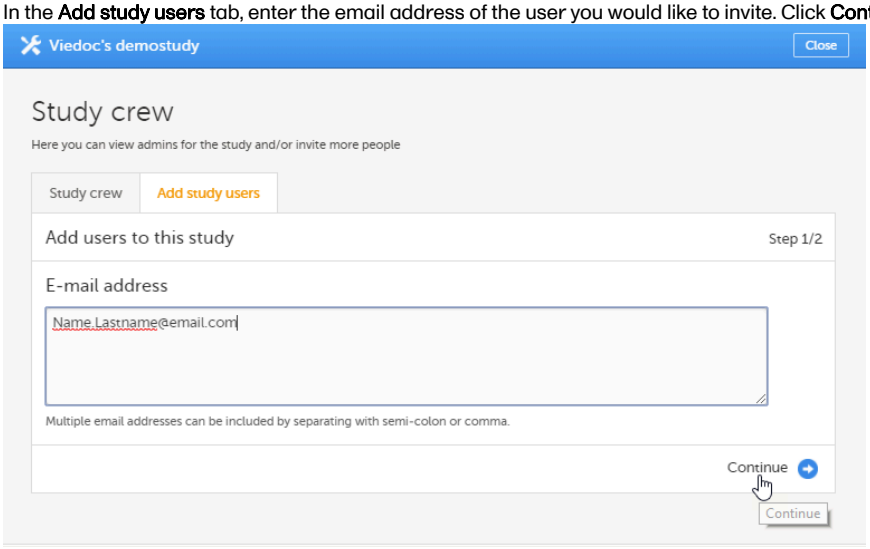
Note! Study Managers can only be added by the Organization Administrator.

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 email address of the user you would like to invite. Click **Continue**.



Tip! You can invite multiple users at once by adding multiple email addresses in the field. Separate the email 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 email is sent to the email address(es) you specified.

2.4 Removing a user from the organization

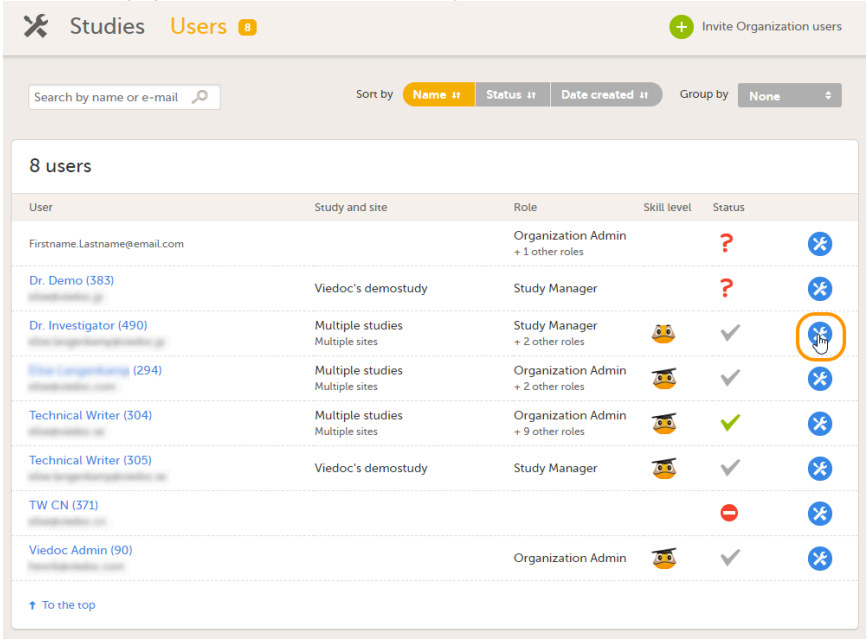
Viedoc offers the possibility to remove all roles from a user in all studies within the organization at once. Only users that have active roles can be removed from the organization, if the user has any pending invitations, it is not possible to remove the user from the organization.

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.

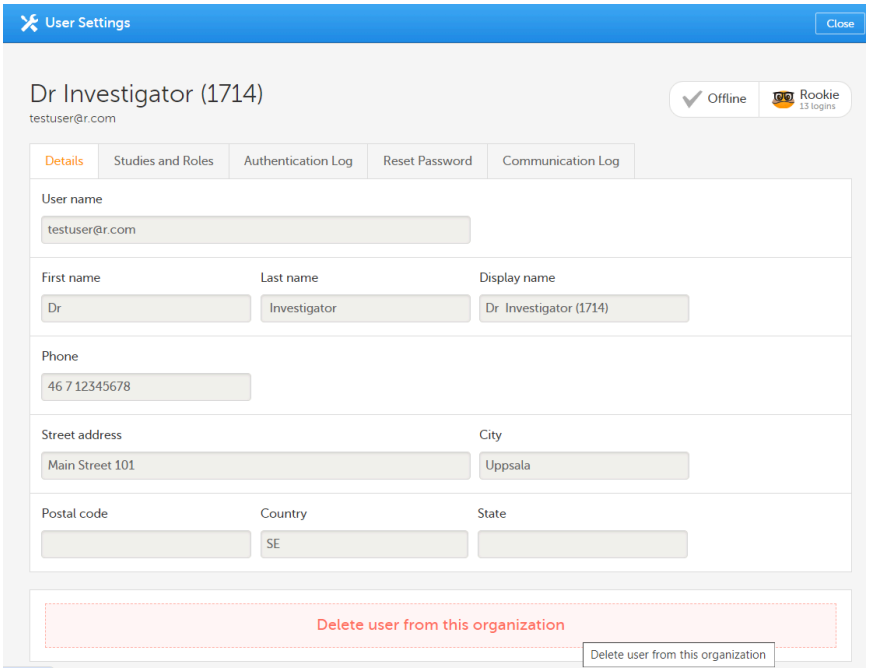
To remove all roles from a user at once:

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**.

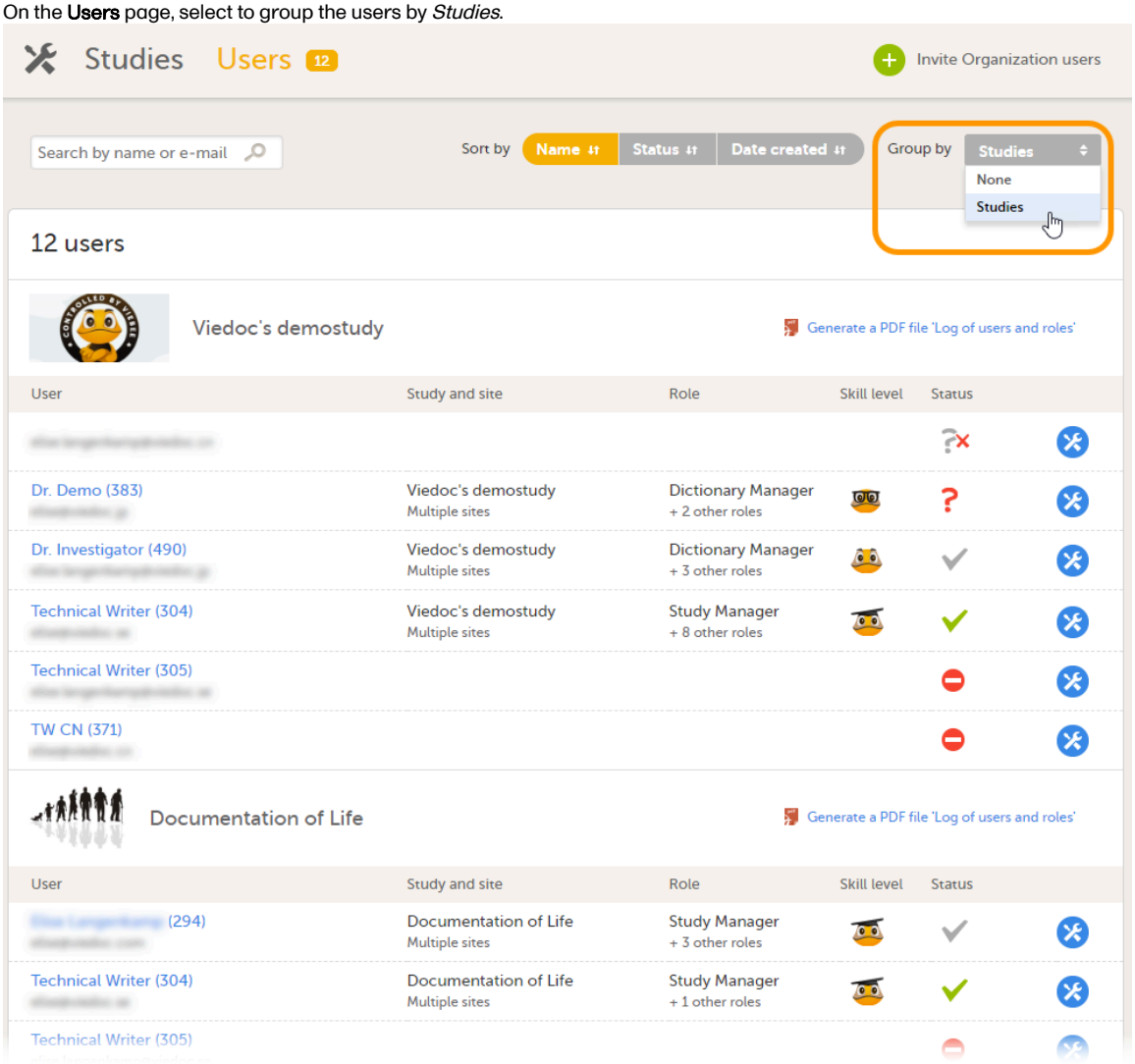


3 Click **Delete** to confirm that the roles should be removed.
All roles to which the user had access will be removed and the user's status will appear as *Removed* on the Users page.

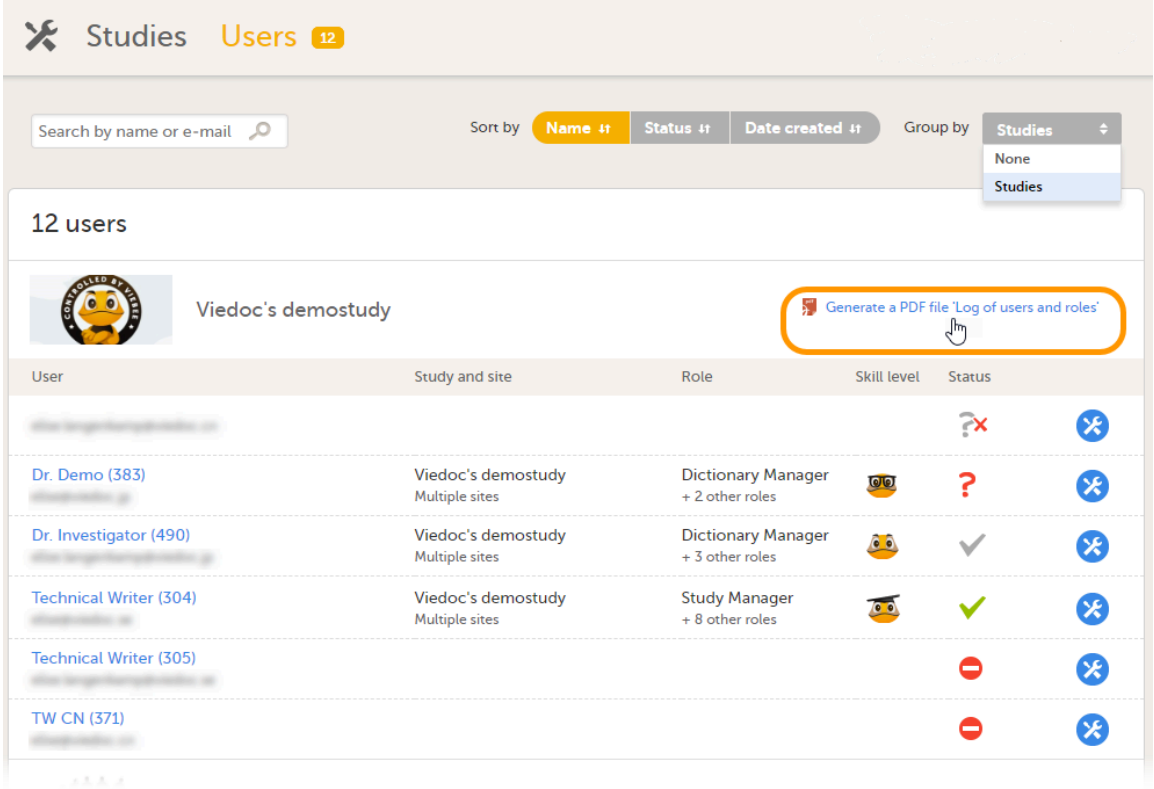
2.5 Downloading the user roles report

To download the user roles report:

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



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:



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:

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

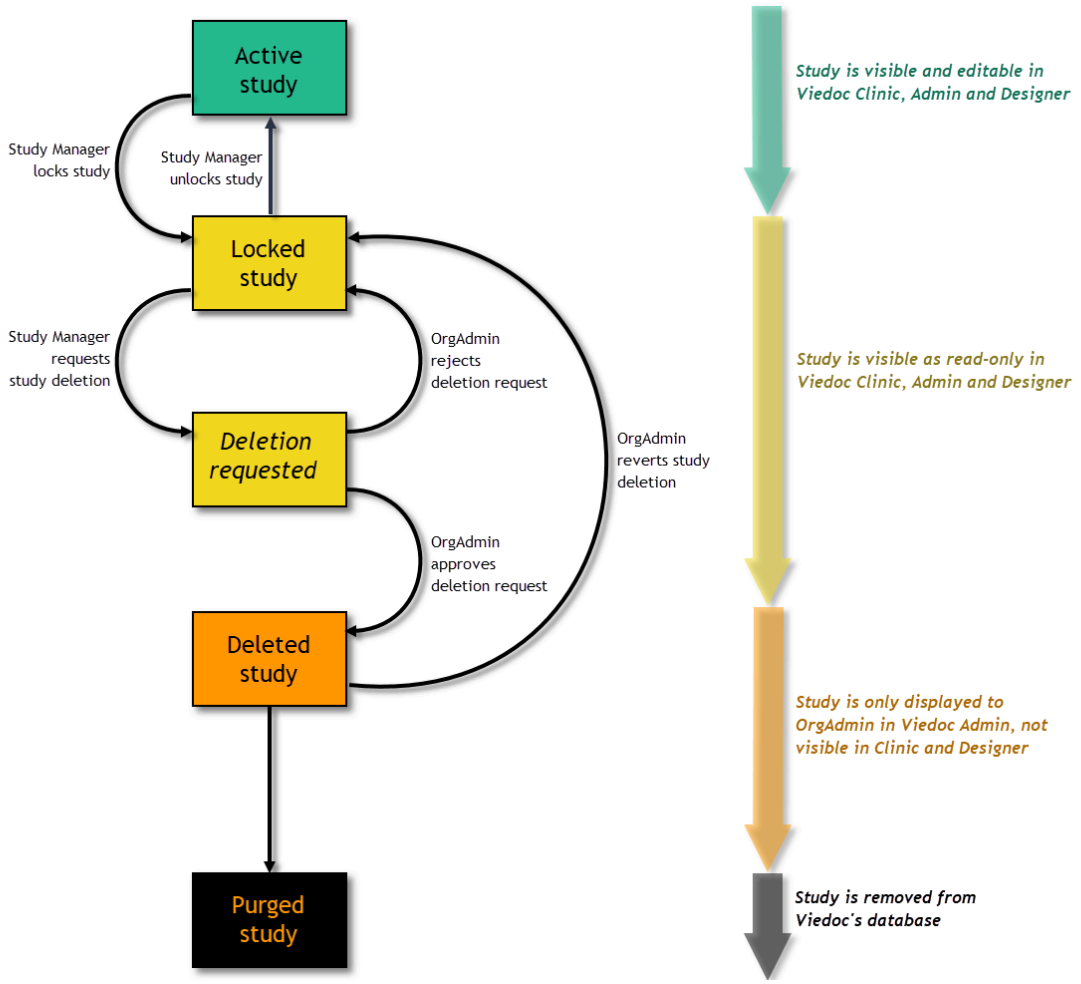
This lesson describes how a study is deleted. The instructions are intended for the Organization Administrator.

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).

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2 Step-by-step guides for the Org Admin

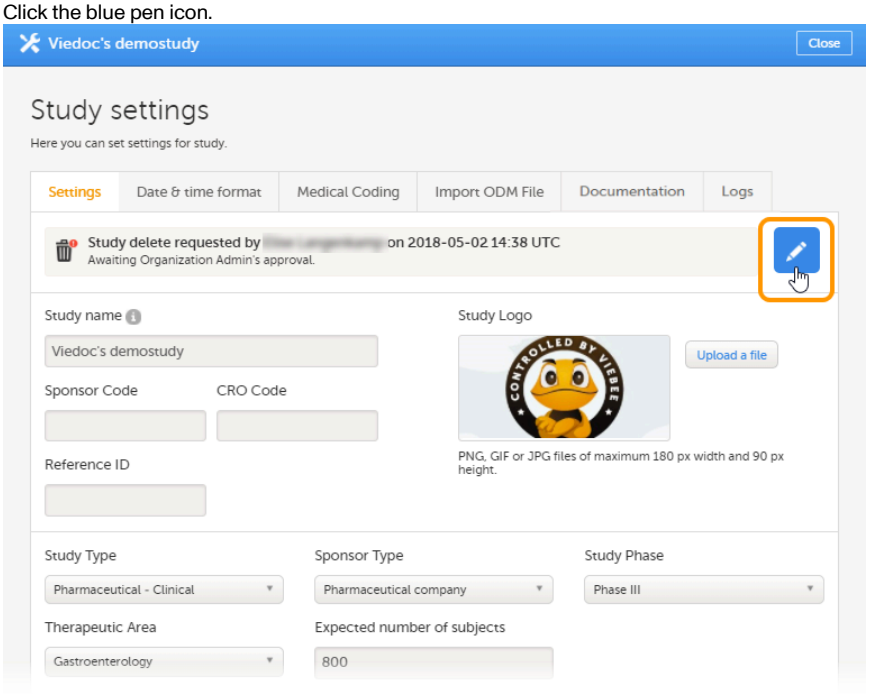
2.1 Approving a study delete request

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:

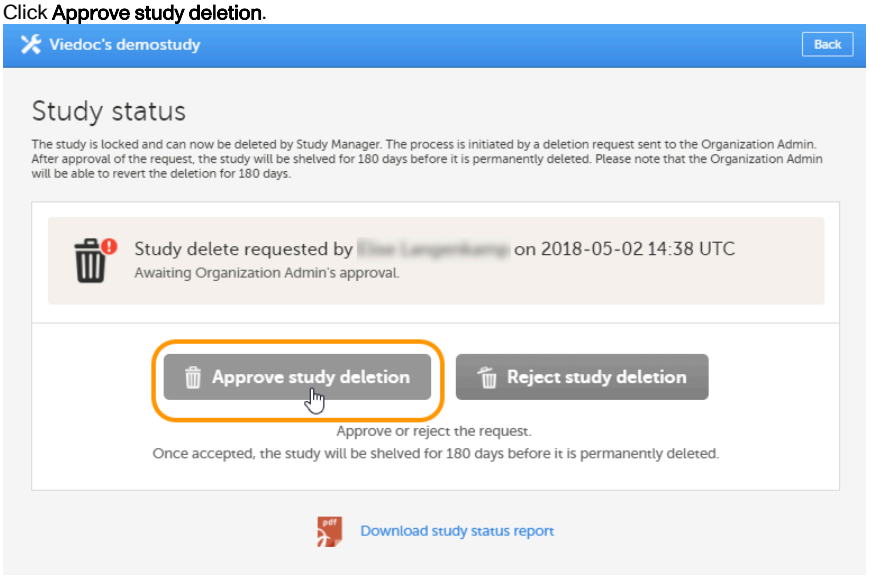
1 Open the study in Viedoc Admin and click **Study settings**.
The **Study settings** dialog opens.

2 Click the blue pen icon.



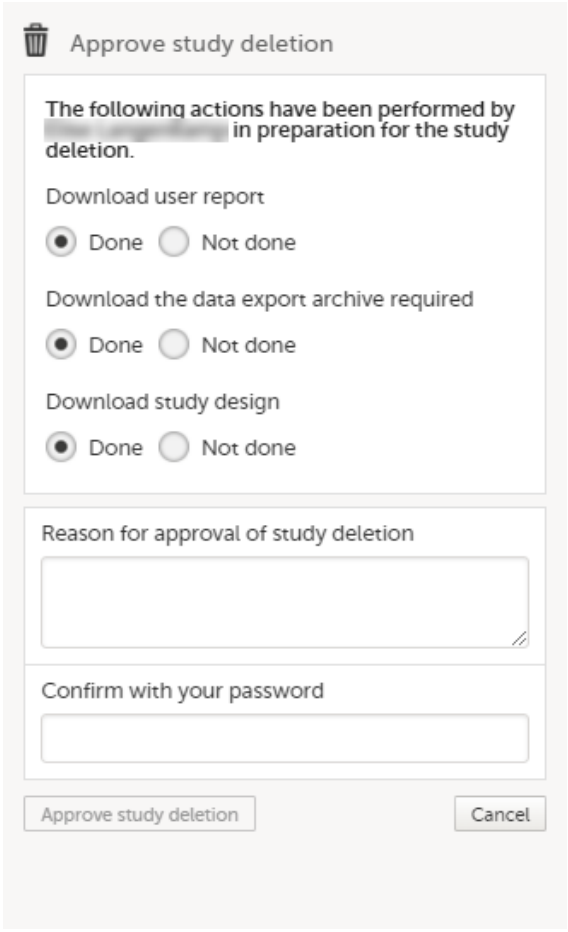
The study status dialog opens.

3 Click **Approve study deletion**.



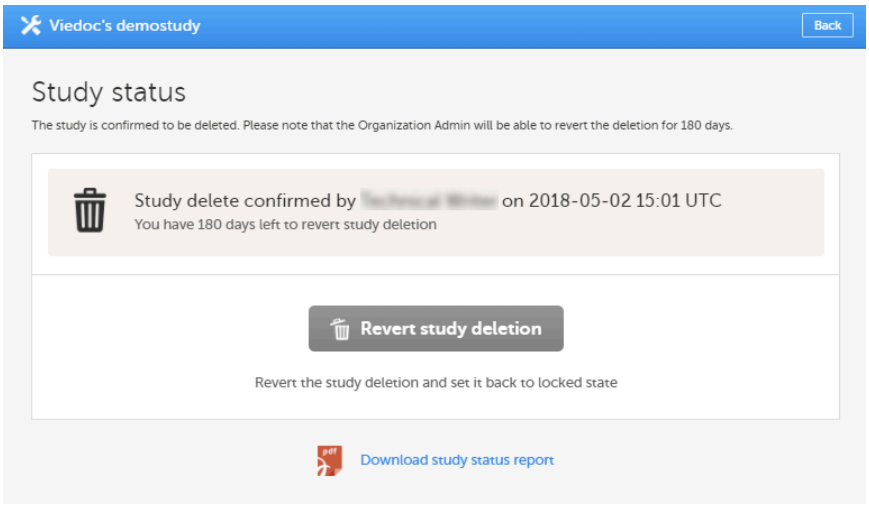
A pop-up opens, listing whether the following actions are done or not done by the study manager:

- 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.



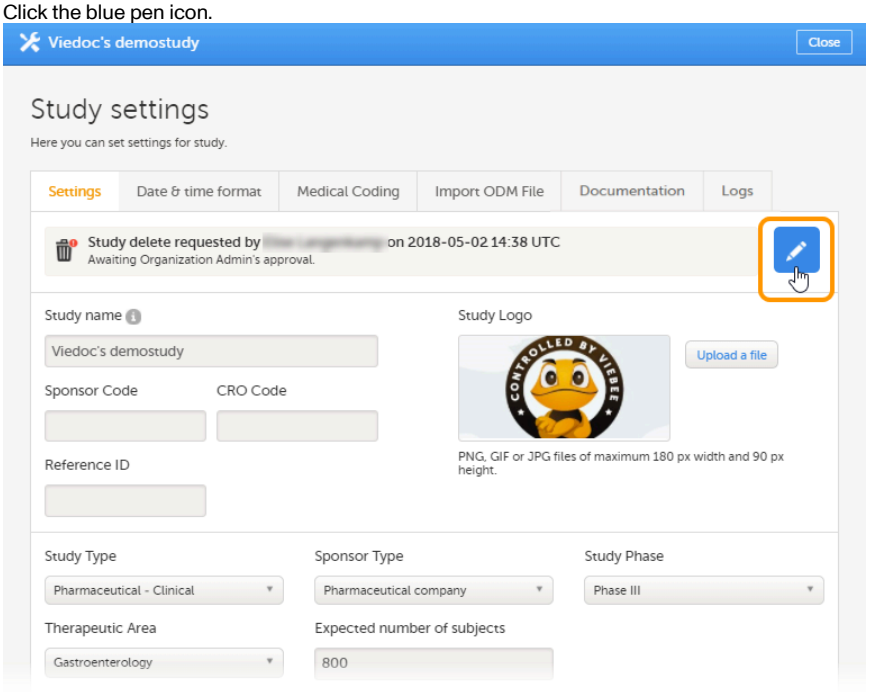
When study deletion is approved, the study will not be visible anymore in Viedoc Clinic or Viedoc Designer, and all user roles will be inactivated. The study will only be displayed to the Organization Administrator on the study overview page.

2.2 Rejecting a study delete request

To reject a request for study deletion:

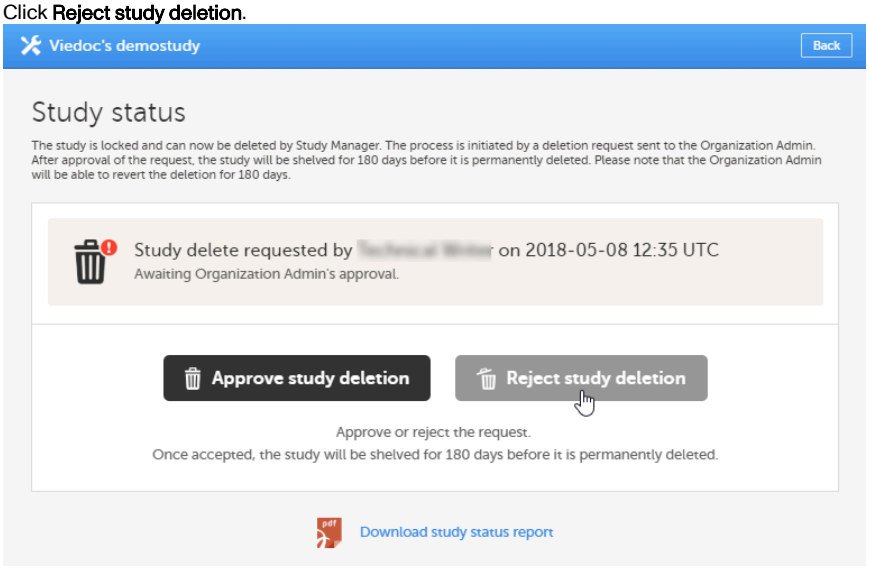
1 Open the study in Viedoc Admin and click **Study settings**.
The **Study settings** dialog opens.

2 Click the blue pen icon.



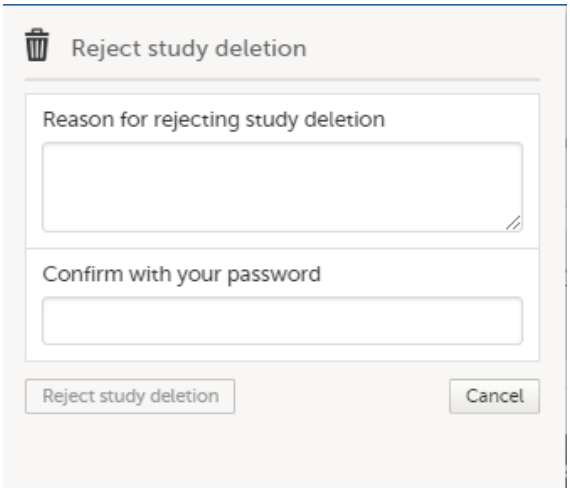
The study status dialog opens.

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**.

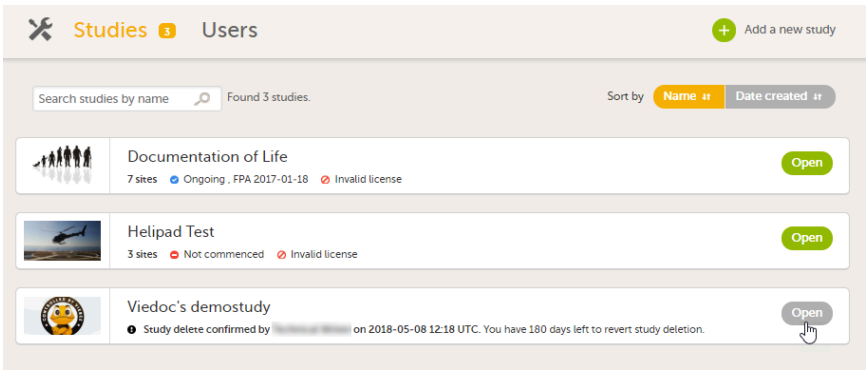
All Study Managers and Organization Administrators will be notified of the rejection by email.

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.

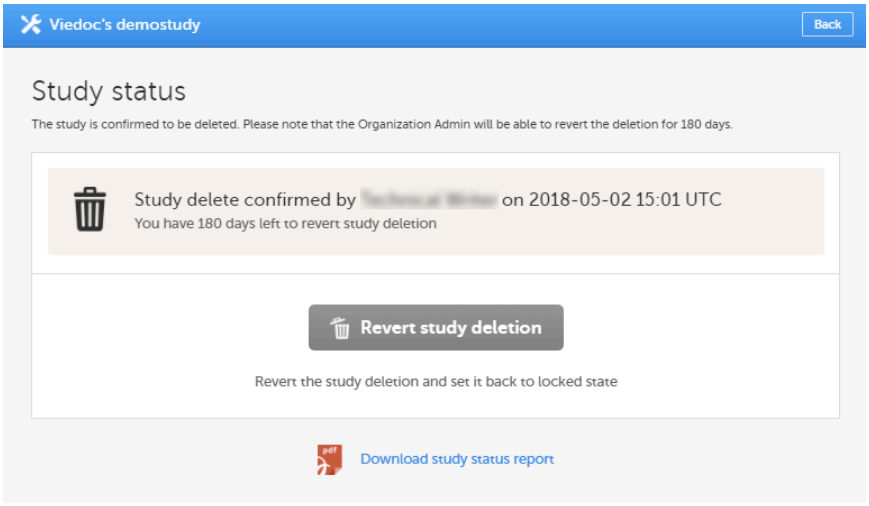
To revert the study deletion:

1 Open the study in Viedoc Admin.



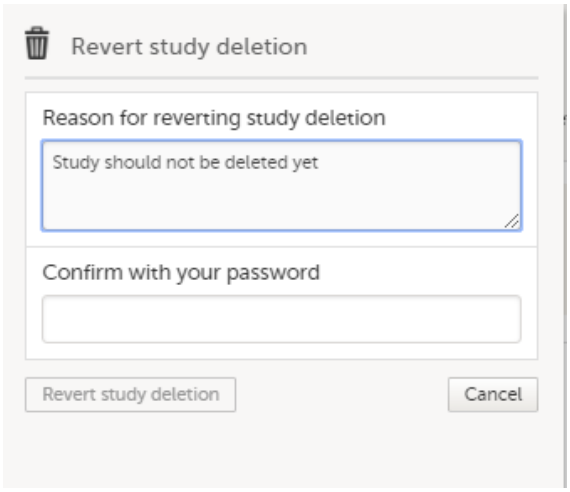
The study status dialog opens.

2 Click **Revert study deletion**.



A pop-up opens

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



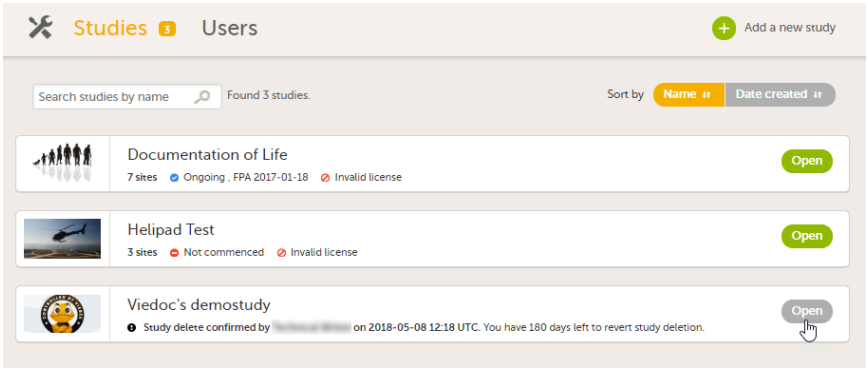
4 Click **Revert study deletion**.

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

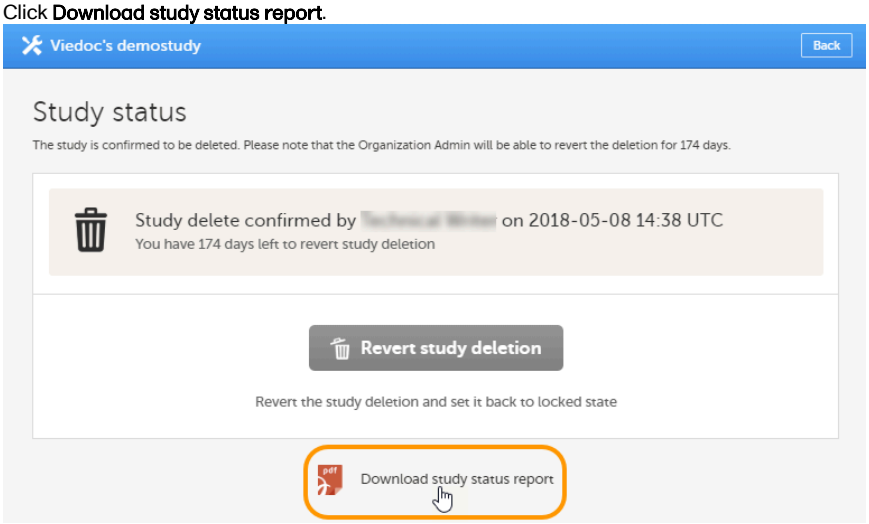
To download the study status report:

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

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:

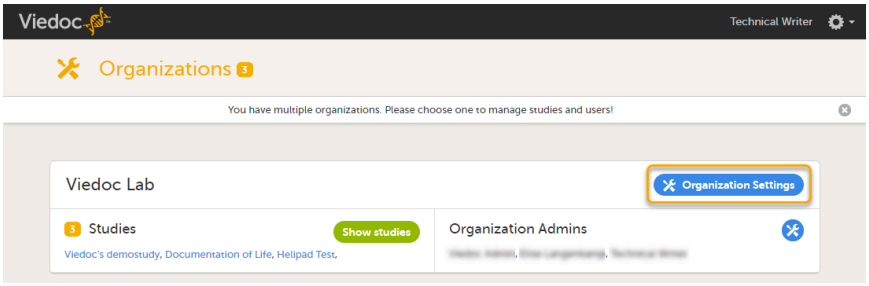
1. **Add domain**
2. **Verify domain**
3. **Validate setup**
4. **Activate SSO**

The steps are described in more detail below.

2.1 Add domain

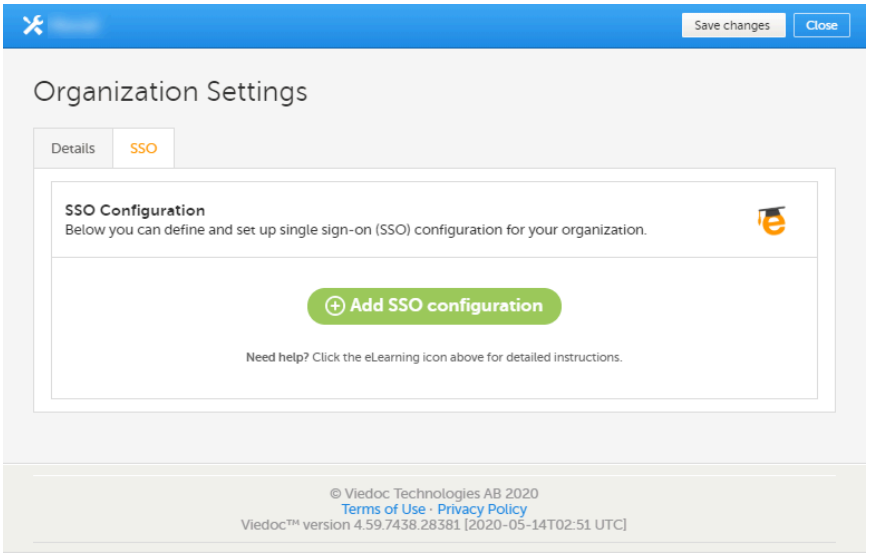
To add a domain:

1 Click **Organization Settings**.

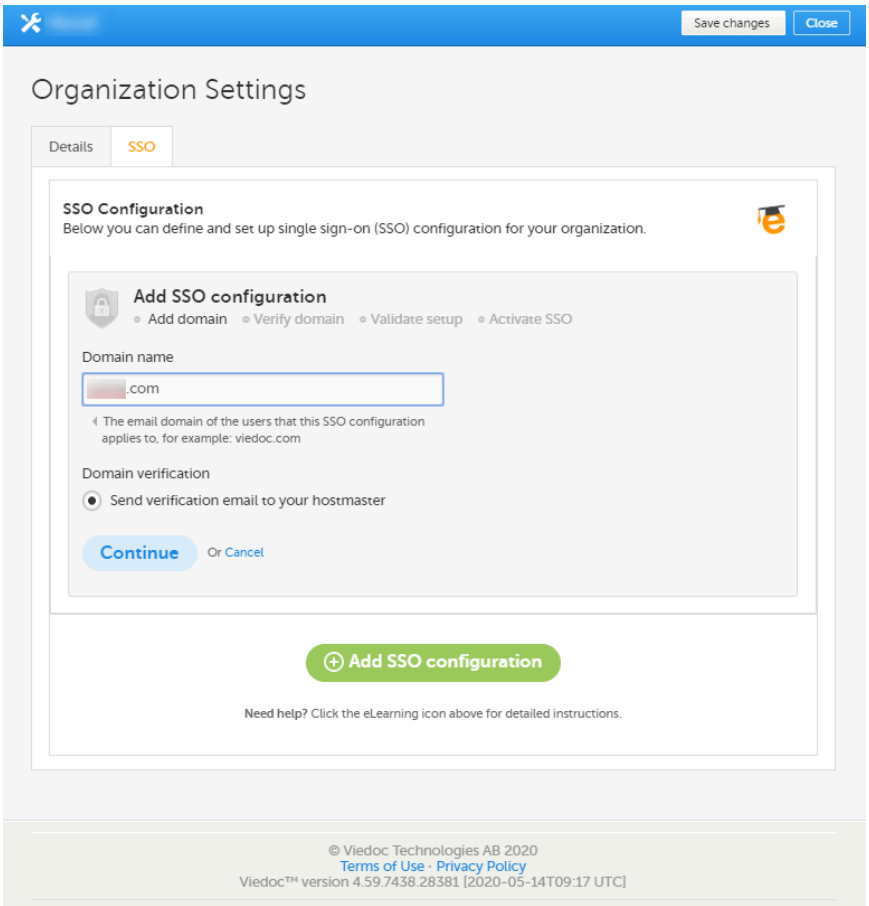


2 Click the **SSO** tab.

3 Click **Add SSO configuration**.



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

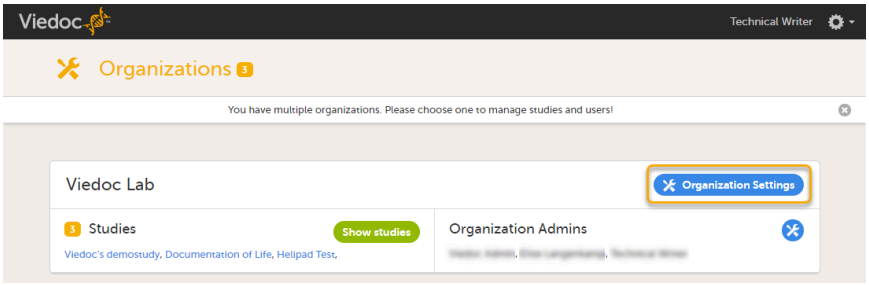


An email is sent to the hostmaster of that domain. The email contains a verification key that you will need in the next step.

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:

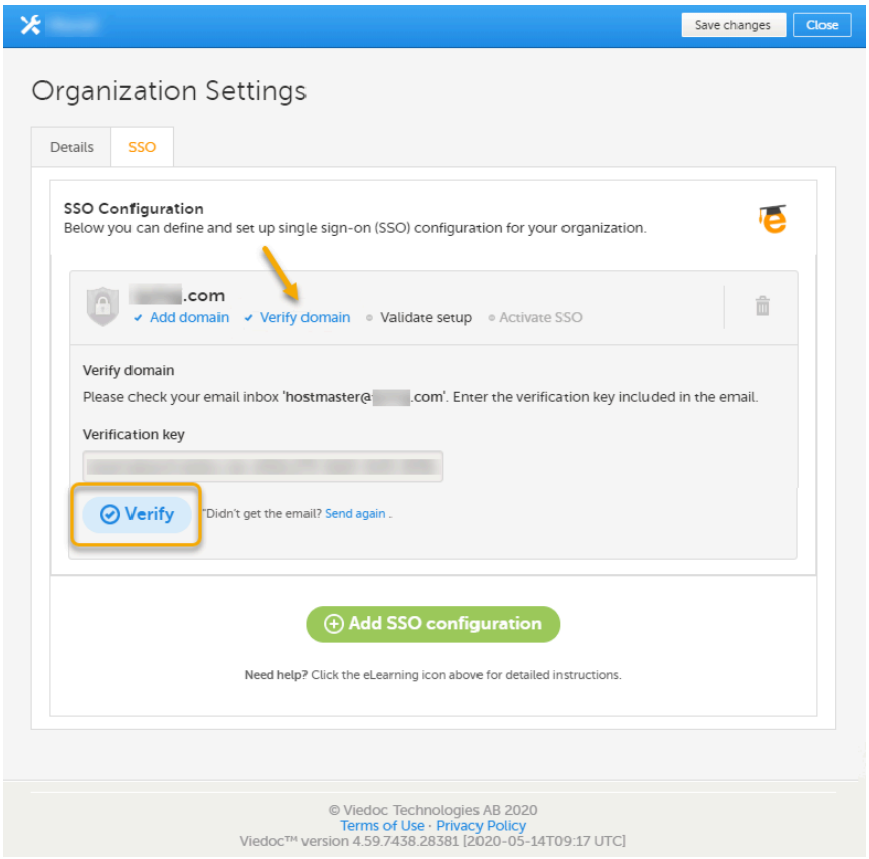
1 Click **Organization Settings**.



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**.



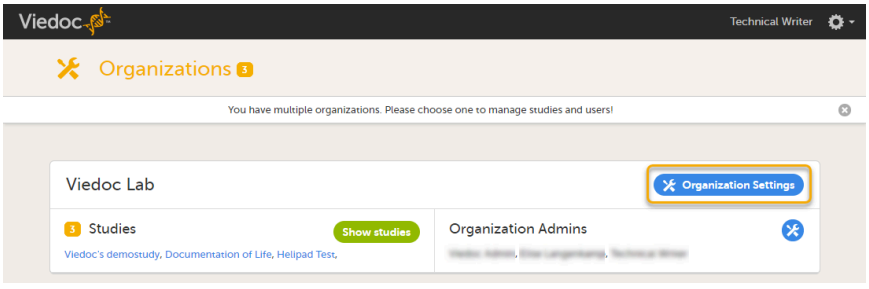
4 When the verification is successfully performed, Viedoc automatically redirects you to the **Validate setup** step.

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.

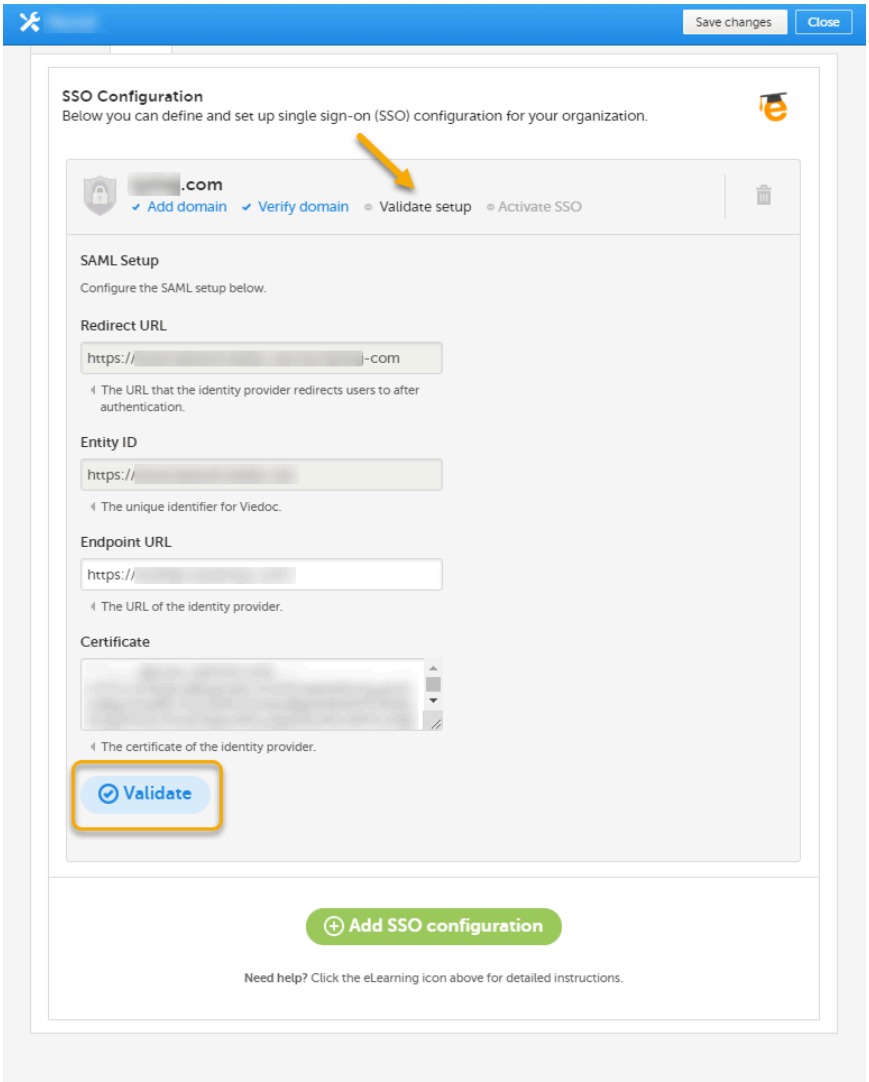
3 If you are not automatically directed to the **Validate setup** step, click the corresponding link.

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):

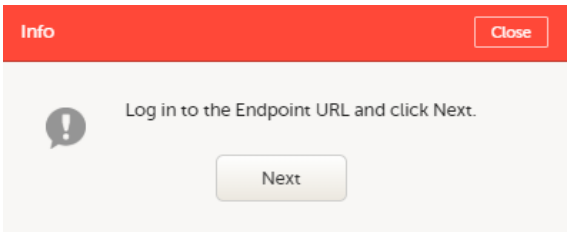
- **Endpoint URL**: This is the URL to the IDP.
- **Certificate**: This is the Base64 certificate of the IDP server.

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.

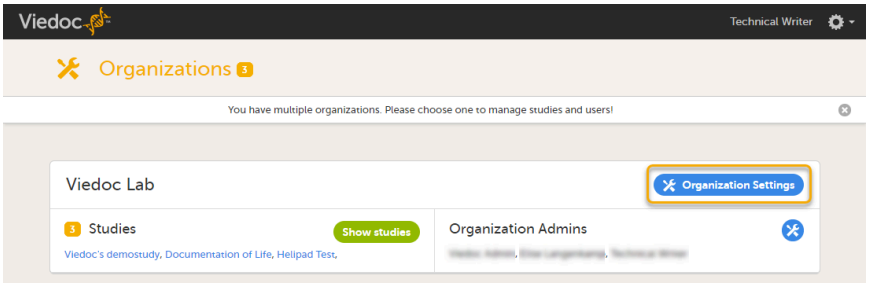
If the validation was successful, you are now ready to continue with the **Activate SSO** step.

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:

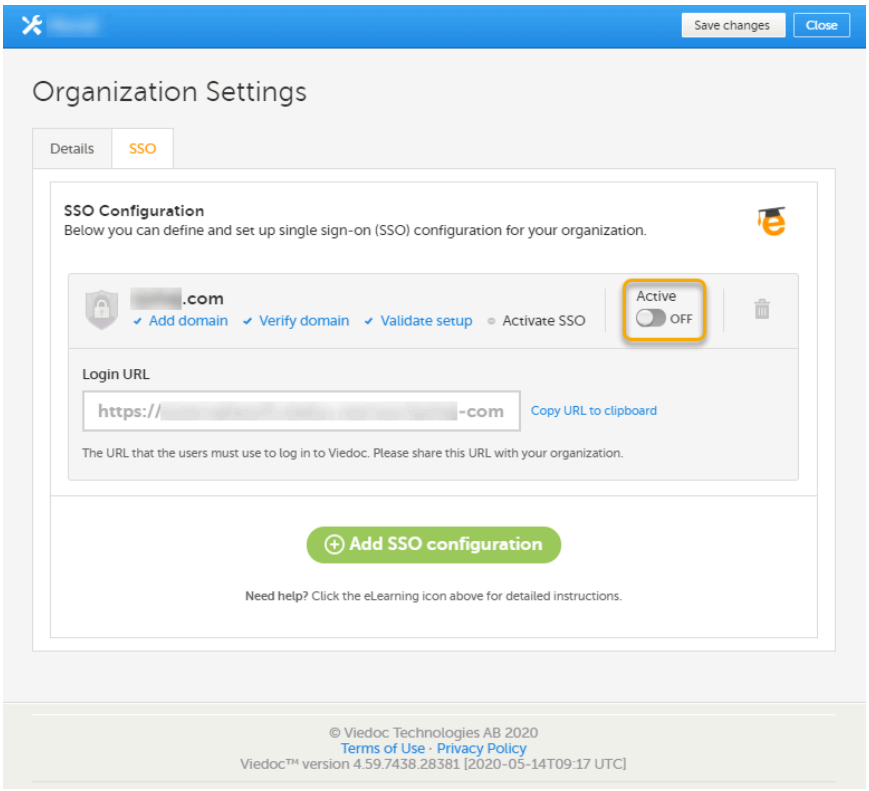
1 Click **Organization Settings**.



2 Click the **SSO** tab.

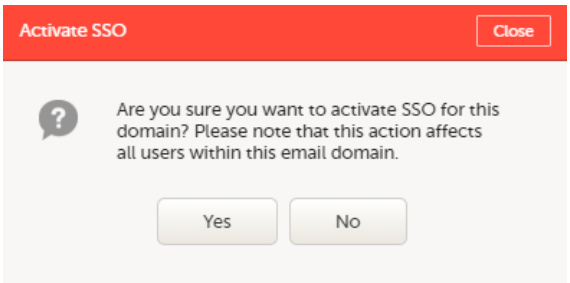
3 If you are not automatically directed to the **Activate SSO** step, click the corresponding link.

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.

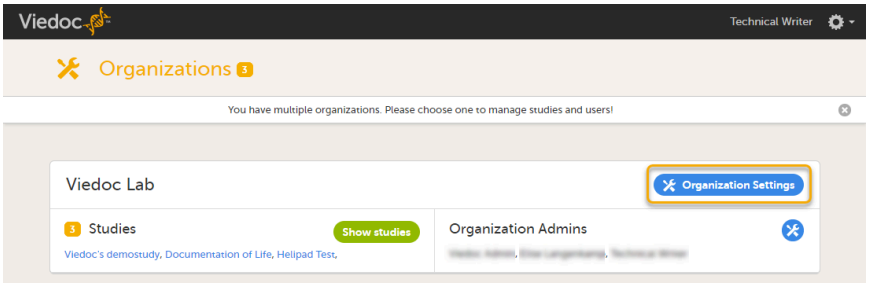
5 If all your SSO settings are correct and if your organization has been informed of the new login routine, click **Yes**.



3 Deactivating SSO for your organization

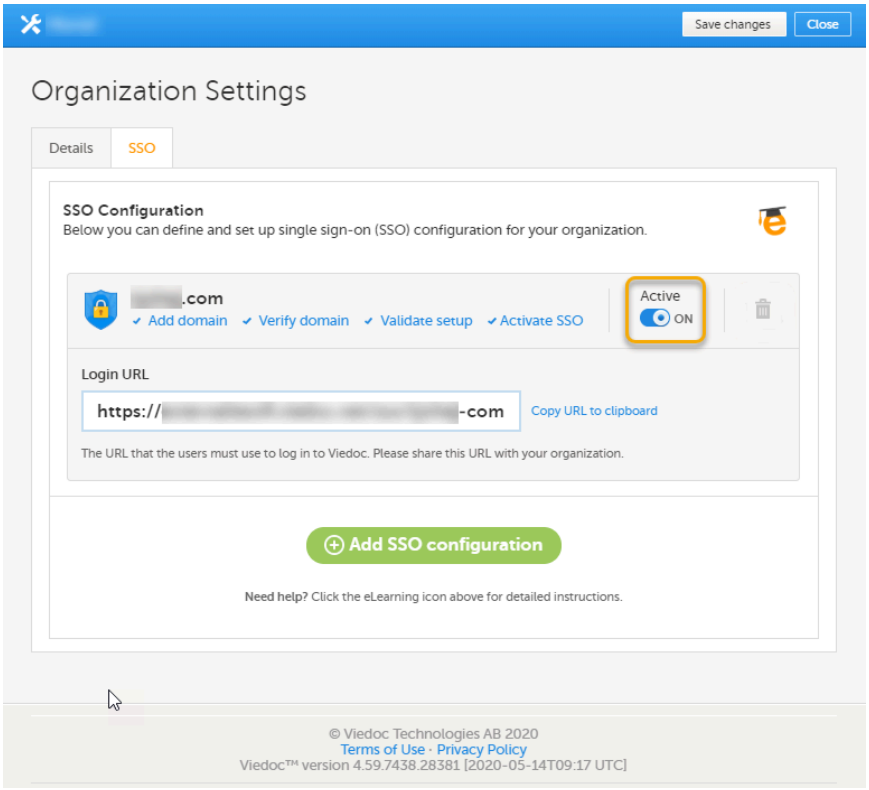
To deactivate SSO:

1 Click **Organization Settings**.

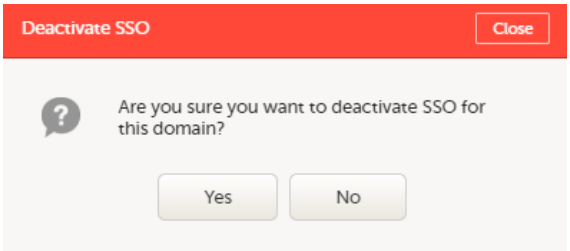


2 Click the **SSO** tab.

3 Click the **Active** switch to turn it off.



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

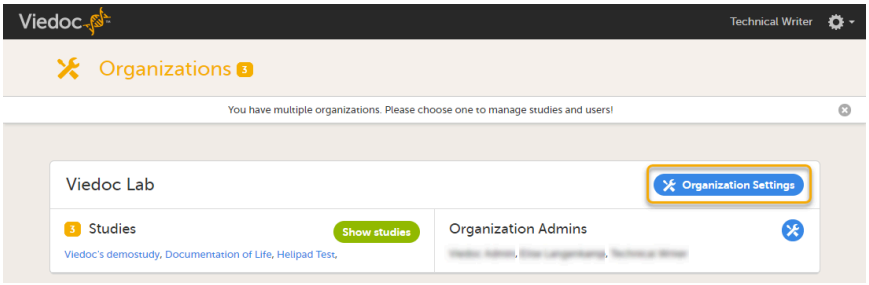


Note! Deactivating an SSO configuration does not delete the configuration information from Viedoc.

4 Deleting an SSO configuration

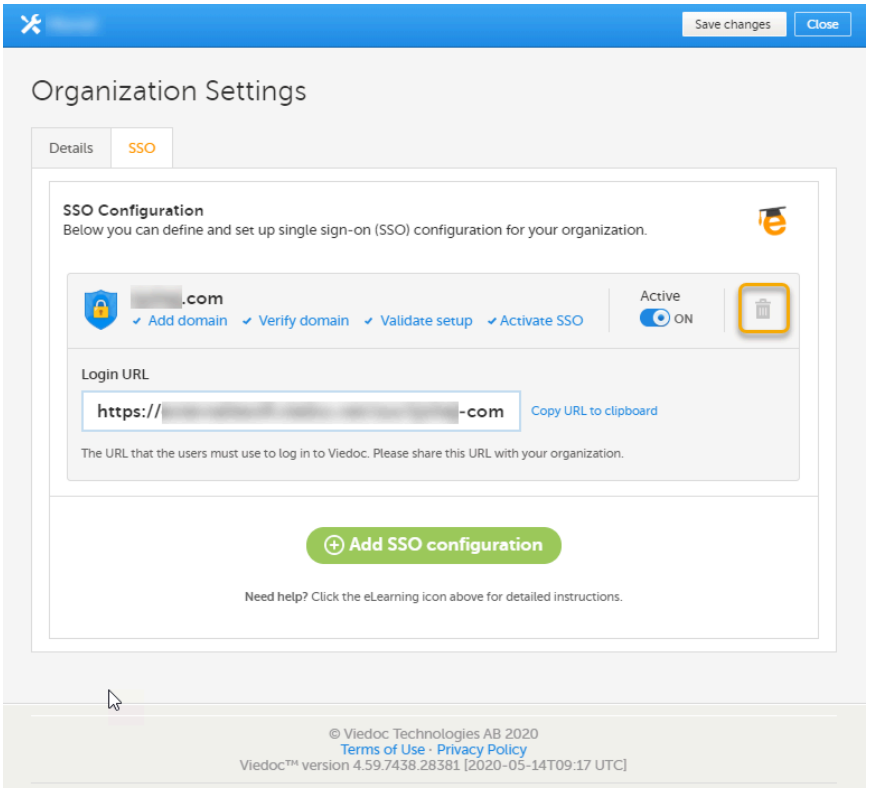
To delete an SSO configuration:

1 Click **Organization Settings**.

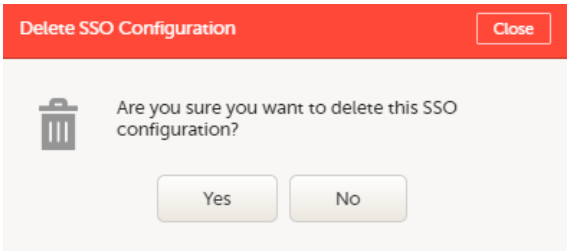


2 Click the **SSO** tab.

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

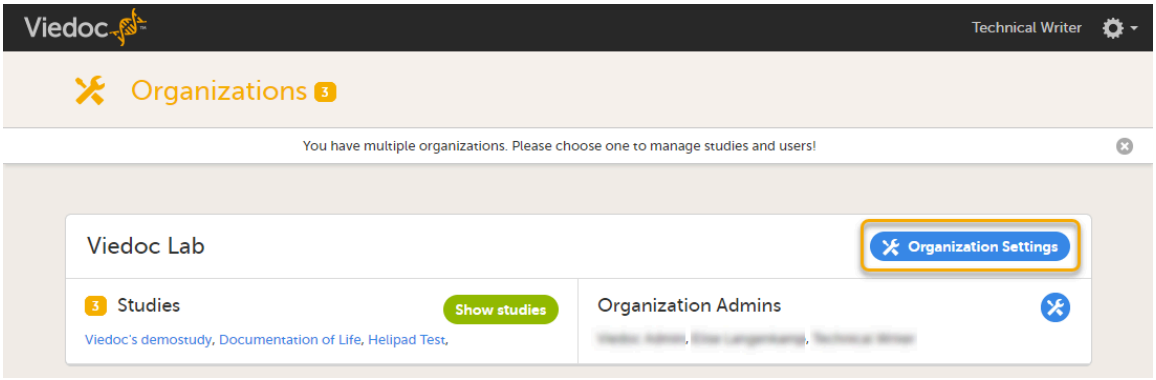
Downloading VIRP

Published by Viedoc System 2020-08-21

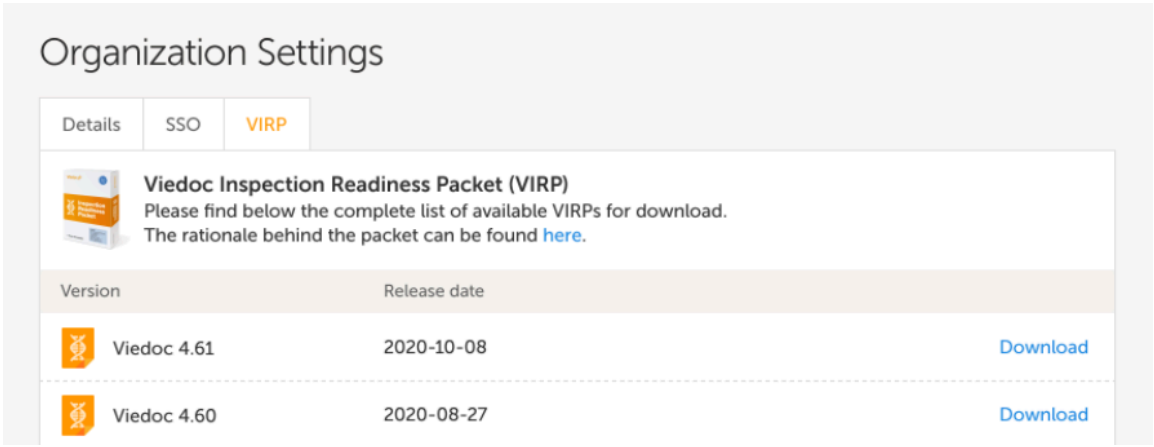
Organization Administrators can download Viedoc Inspection Readiness Packet (VIRP), which contains all the information you need to fulfill inspector expectations. When using Viedoc, you only need to validate that your study configuration is in compliance with your study protocol, the rest is included 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 2024-12-03

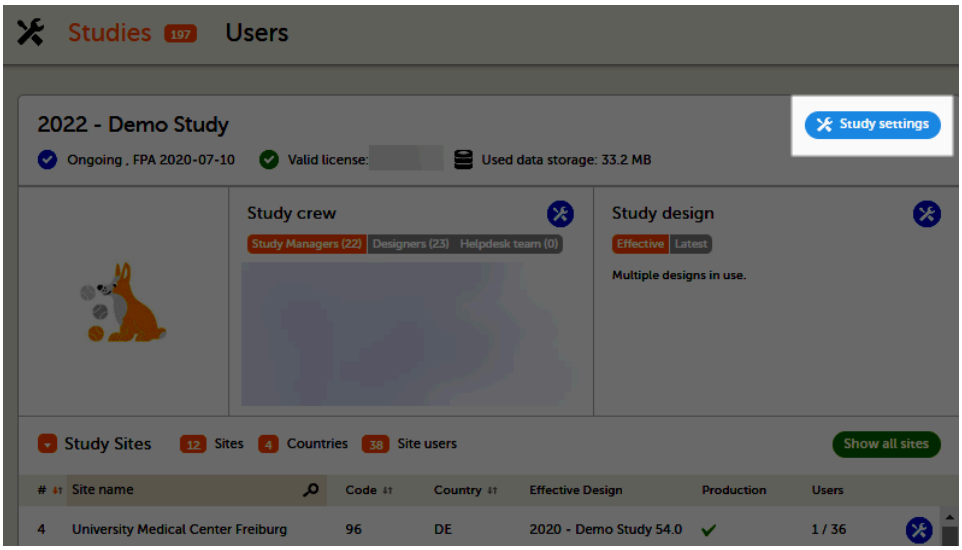
This lesson describes the settings that can be made in **Study settings**.

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:

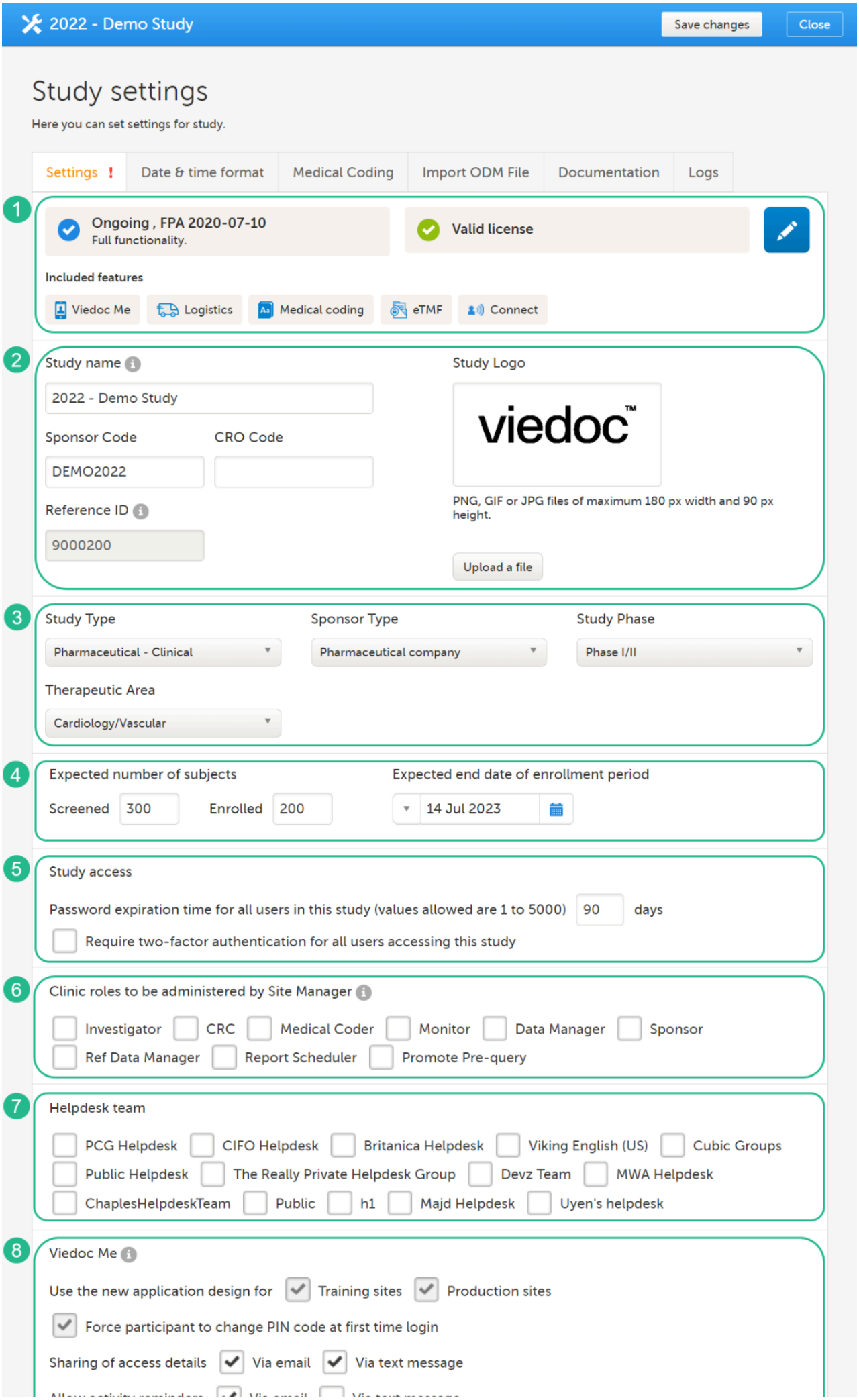


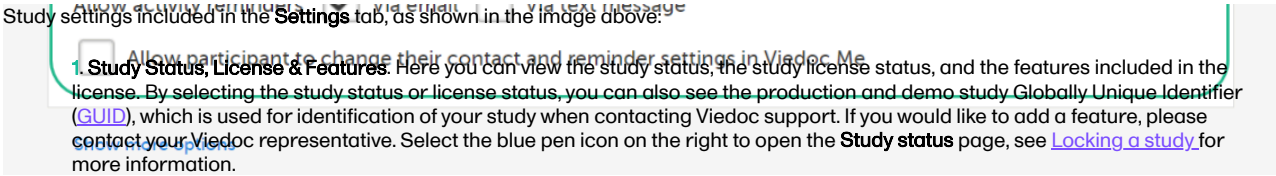
In the **Study settings** dialog, the following tabs are available:

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

3 The Settings tab

On the **Settings** tab, you can set various settings for the study:


2022 - Demo Study
Save changes
Close
Study settings
Here you can set settings for study.
Settings !
Date & time format
Medical Coding
Import ODM File
Documentation
Logs
1
Ongoing , FPA 2020-07-10
Full functionality.
Valid license
Included features
Viedoc Me
Logistics
Medical coding
eTMF
Connect
2
Study name
2022 - Demo Study
Sponsor Code
DEMO2022
CRO Code
Reference ID
9000200
Study Logo
viedoc™
PNG, GIF or JPG files of maximum 180 px width and 90 px height.
Upload a file
3
Study Type
Pharmaceutical - Clinical
Sponsor Type
Pharmaceutical company
Study Phase
Phase I/II
Therapeutic Area
Cardiology/Vascular
4
Expected number of subjects
Screened 300
Enrolled 200
Expected end date of enrollment period
14 Jul 2023
5
Study access
Password expiration time for all users in this study (values allowed are 1 to 5000) 90 days
Require two-factor authentication for all users accessing this study
6
Clinic roles to be administered by Site Manager
Investigator
CRC
Medical Coder
Monitor
Data Manager
Sponsor
Ref Data Manager
Report Scheduler
Promote Pre-query
7
Helpdesk team
PCG Helpdesk
CIFO Helpdesk
Britanica Helpdesk
Viking English (US)
Cubic Groups
Public Helpdesk
The Really Private Helpdesk Group
Devz Team
MWA Helpdesk
ChaplesHelpdeskTeam
Public
h1
Majd Helpdesk
Uyen's helpdesk
8
Viedoc Me
Use the new application design for
Training sites
Production sites
Force participant to change PIN code at first time login
Sharing of access details
Via email
Via text message



Study settings included in the **Settings** tab, as shown in the image above:

1. **Study Status, License & Features**. Here you can view the study status, the study license status, and the features included in the license. By selecting the study status or license status, 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. Select the blue pen icon on the right to open the **Study status** page, see Locking a study for more information.
2. **Study Details**. Enter details of the study: study name, sponsor code, CRO code, study logo, and the reference ID (for information about the reference ID, see the section *Licensing* in Overview of Viedoc).
3. **Study Description**. Select the information relevant to the study, including the study type, sponsor type, study phase, and therapeutic area. The following options are available in the dropdown lists:

Study Type	Sponsor Type	Study Phase	Therapeutic Area
Pharmaceutical - Clinical	Pharmaceutical company	Preclinical	Cardiology/Vascular
Pharmaceutical - Post-approval	Biotechnology company	Phase 0	Dental Implant
Medical Device	Government agency	Phase I	Dermatology/Plastic Surgery
Veterinary	Academic research	Phase I/II	Endocrinology
Uncategorized/Other	Other	Phase II	Epidemiology
	Uncategorized/Other	Phase IIA	Gastroenterology
		Phase IIB	Hematology
		Phase III	Immunology/Infectious Diseases
		Phase IV - PMS	Musculoskeletal/Sports Medicine
		Phase IV - Japanese PMS	Nephrology/Urology
		Phase V	Neurology
		Patient registry	Obstetrics/Gynecology
		Uncategorized/Other	Oncology
			Ophthalmology
			Otolaryngology
			Pediatrics/Neonatology
			Pharmacology/Toxicology
			Psychiatry/Psychology
			Pulmonary/Respiratory Diseases
			Rheumatology
			Trauma/Emergency Medicine
			Uncategorized/Other

4. **Expected Subjects & Enrollment Period**. Set the number of expected screened and enrolled subjects, and the expected end date of the enrollment period. These settings are used by the Viedoc Reports applications.
5. **Study Access**. Select when the password expiry should take place and whether a study will require two-factor authentication. Please see Study access settings for more information.
6. **Clinic roles to be administered by the Site Manager**. Select the roles that are to be administered by the Site Manager instead of the Study Manager, see Managing users for more information.
7. **Helpdesk Team**. Manage the Helpdesk settings, see Assigning a helpdesk for more information.
8. **Viedoc Me**. Select the options for Viedoc Me:

- Select whether the new application design should be used for training and/or production sites.
- Select whether 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.

  Note! Changing a PIN code is required when sharing access details via email or text message. To turn off this option, you must uncheck both share access options, and instead share the access details via paper/PDF)

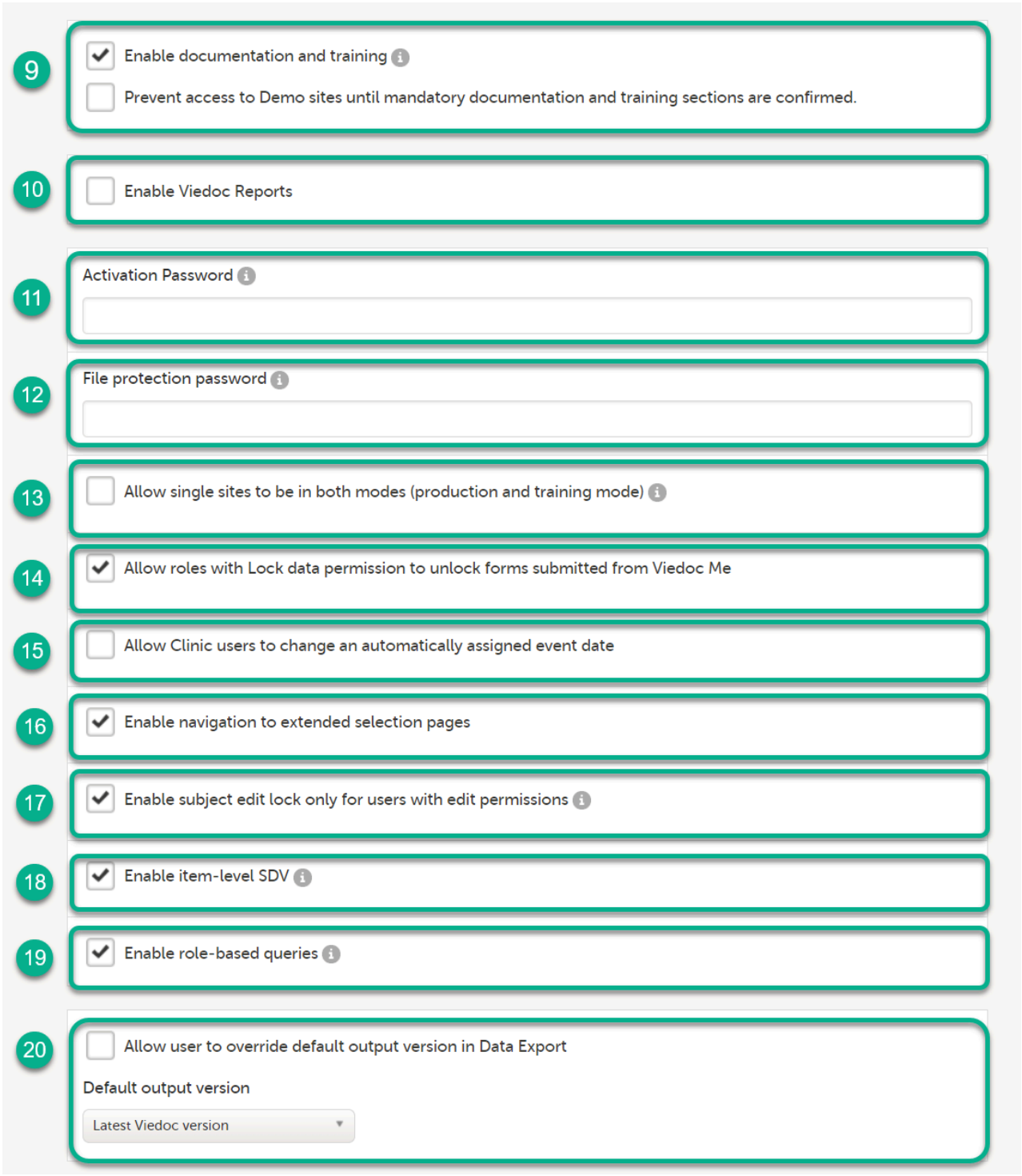
- Select whether access details (login info) should be sent to the subjects as email and/or text messages. If neither email or text message is selected, the login info can only be shared to the participant via a PDF. Detailed information on how to share login info with participants can be found in the Managing Viedoc Me lesson for clinic staff.

- Select whether 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.
- Select whether subjects should be allowed to change their contact information and reminder settings in Viedoc Me themselves. Note: this option appears only if email and/or text reminders are enabled.

Note! When changes have been made on this tab, a red exclamation sign will appear at the top of the settings tab. If you select the **Save Changes** button at the top right of the window, the exclamation sign will disappear.

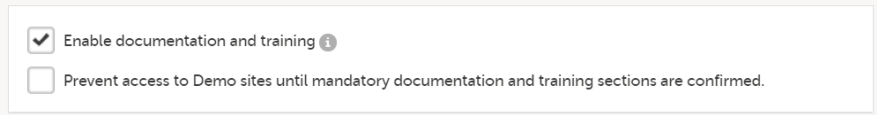
Study-specific considerations for text message reminders in China
When studies are run with Viedoc Me in China and text message reminders are used, we need to have the message contents approved by the underlying text message gateway providers, in order to comply with the Cyber Security Law of the Peoples 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**

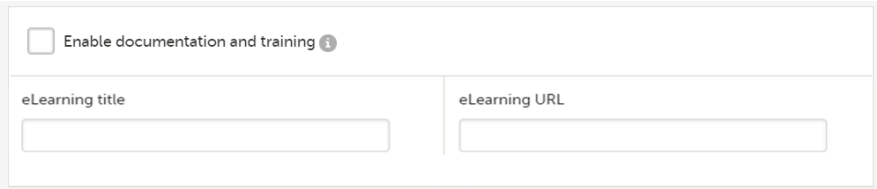
- The option **Enable documentation and training** is selected by default for studies starting after the release of Viedoc 4.51 (May 2019).



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.



When this option is deselected, then:

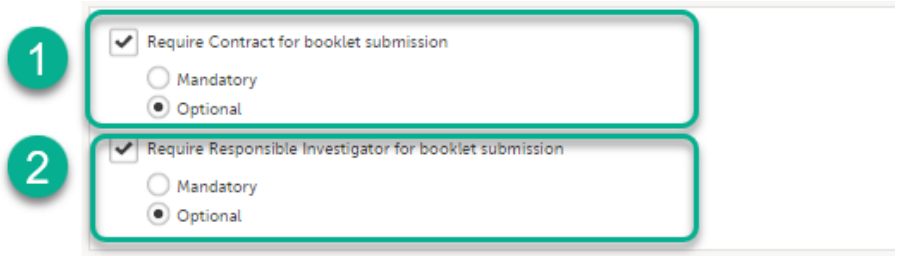
- All documentation is set up in Viedoc Designer. See eLearning settings for more information.
- The fields **eLearning title** and **eLearning URL** can be used for adding an additional curriculum to the eLearning curriculums that have been set up for the study in Viedoc Designer, see Adding an additional 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. **Enable role-based queries**. If this option is selected, it restricts, at study level, the approval of the query resolution to the same user role who raised the query. This option is deselected by default for studies that started before the release of Viedoc 4.80. The option is selected by default for studies that started after the release of Viedoc 4.80.
20. **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

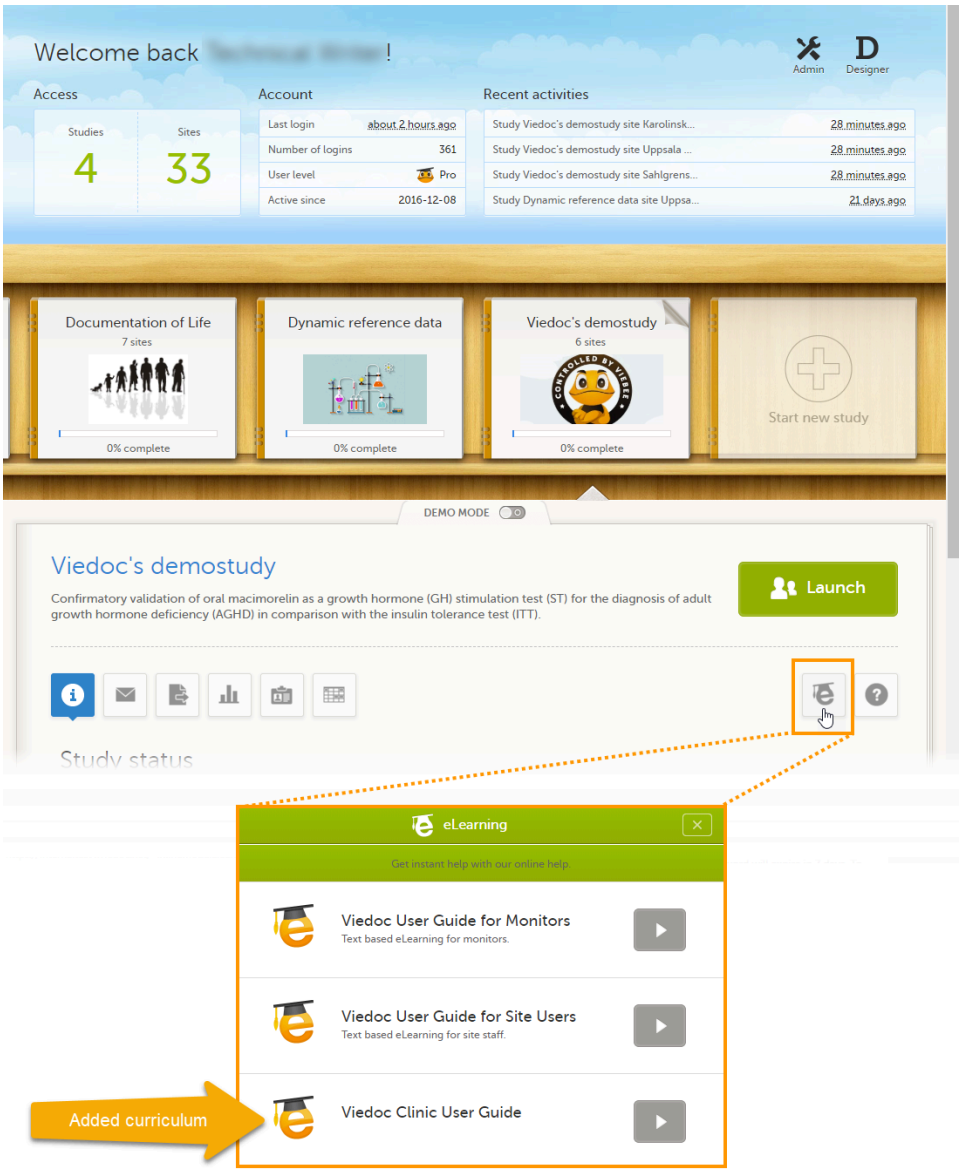
On the **Settings** tab, if **Enable documentation and training** is deselected, the eLearning curriculums that clinic users have access to from Viedoc Clinic are configured in Viedoc Designer. For details, see eLearning settings and Configuring roles in Viedoc Designer User Guide.

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

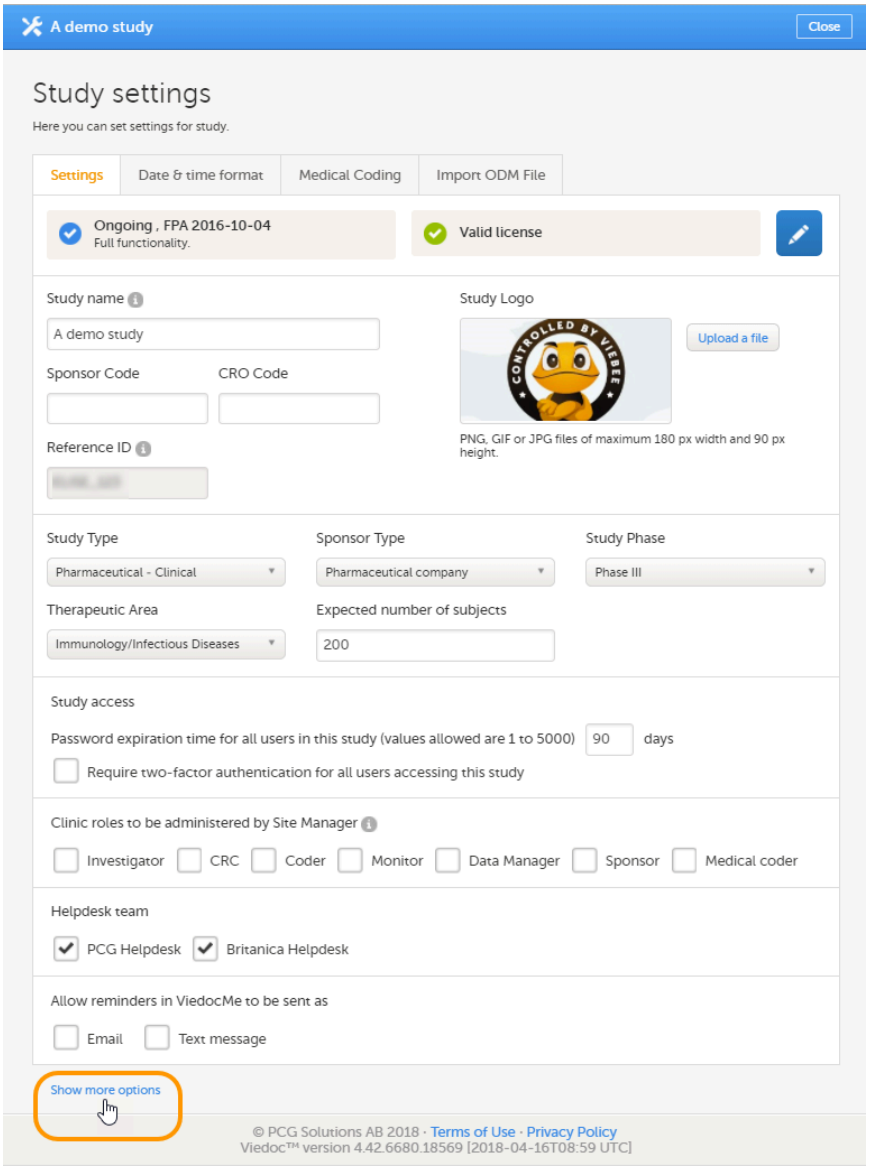
When exporting data, Viedoc offers the possibility to create a data export file that is compatible with files exported from previous versions of Viedoc. The default Viedoc version that is used when exporting data can be set in Viedoc Admin.

3.4.1 Setting the Viedoc version to be used for data export

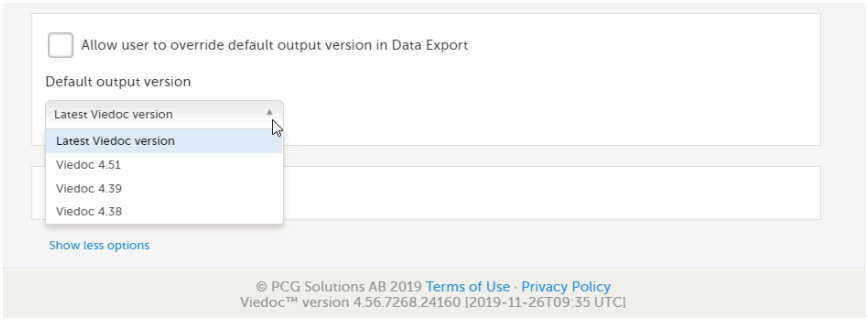
To set the Viedoc version to be used for data export:

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.

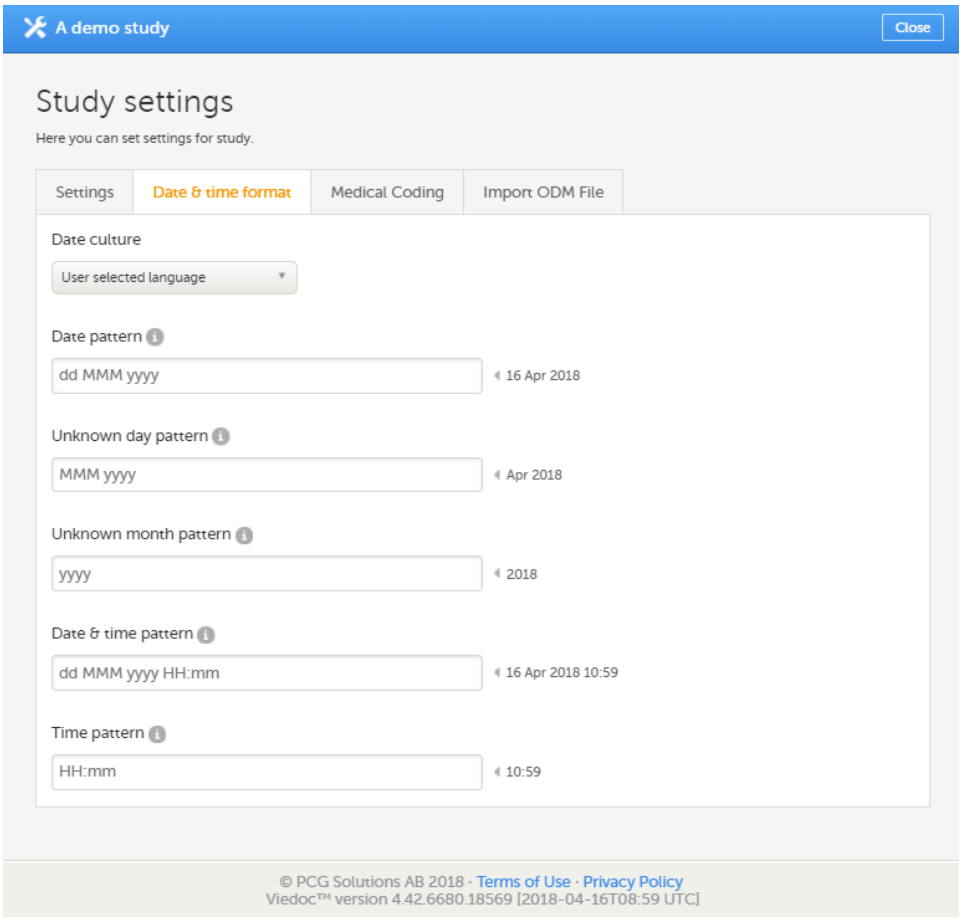
3.4.2 Available Viedoc versions

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

Can not output single-source

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.



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
h	One-digit 12-hour time (use in conjunction with tt)	8:15 am
mm	Two-digit minutes	15
ss	Two-digit seconds	30

Date/time format	Description	Example
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. There is also an option for enabling or disabling auto coding. For more information about the medical coding settings, 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.

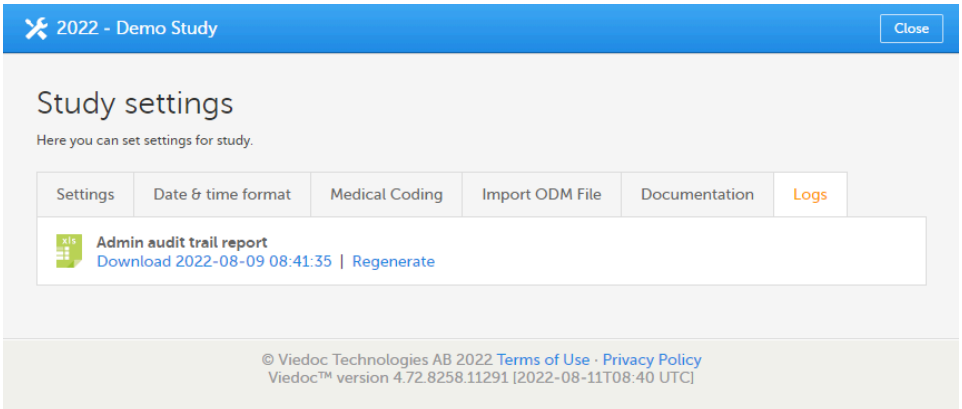
Note! This tab is visible only if the option **Enable documentation and training** is selected in **Study settings**.

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.



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

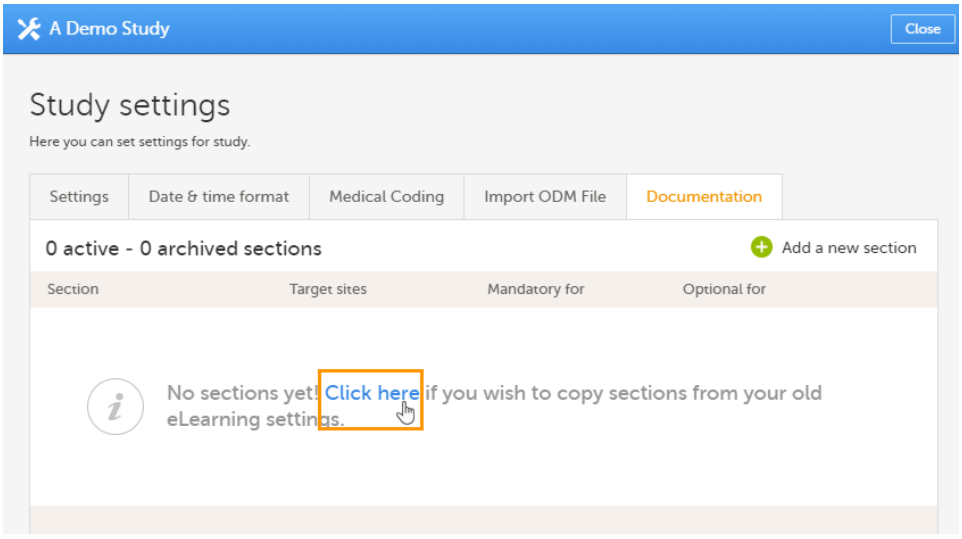
1 Introduction

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:

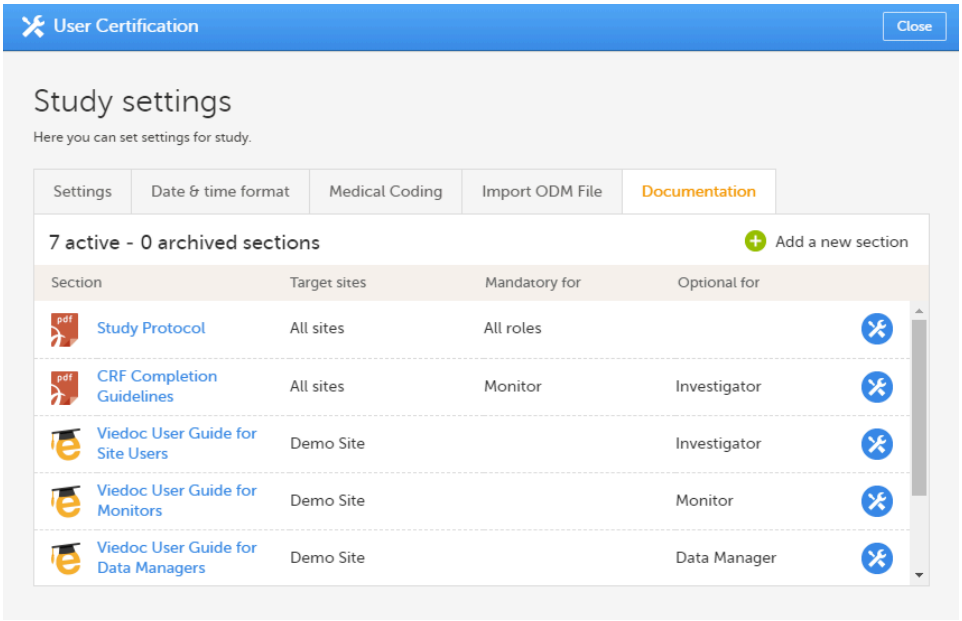
Viedoc eLearning curriculum	Section URL
Viedoc User Guide for Site Users	https://help.viedoc.net/c/94d6f0
Viedoc User Guide for Monitors	https://help.viedoc.net/c/c63e06
Viedoc User Guide for Data Managers	https://help.viedoc.net/c/1994d8
Viedoc User Guide for Project Managers	https://help.viedoc.net/c/04361f
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.



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)

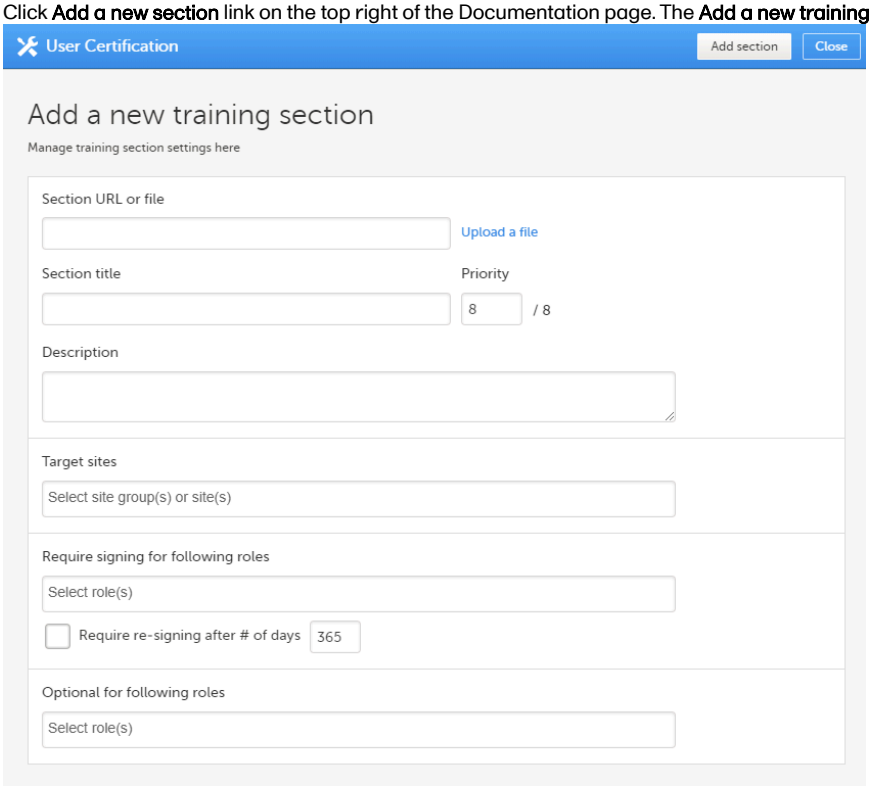
Icon	Description
	PDF file
	Word document
	Excel file
	Power Point file
	Other file type than the ones mentioned above

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.



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.

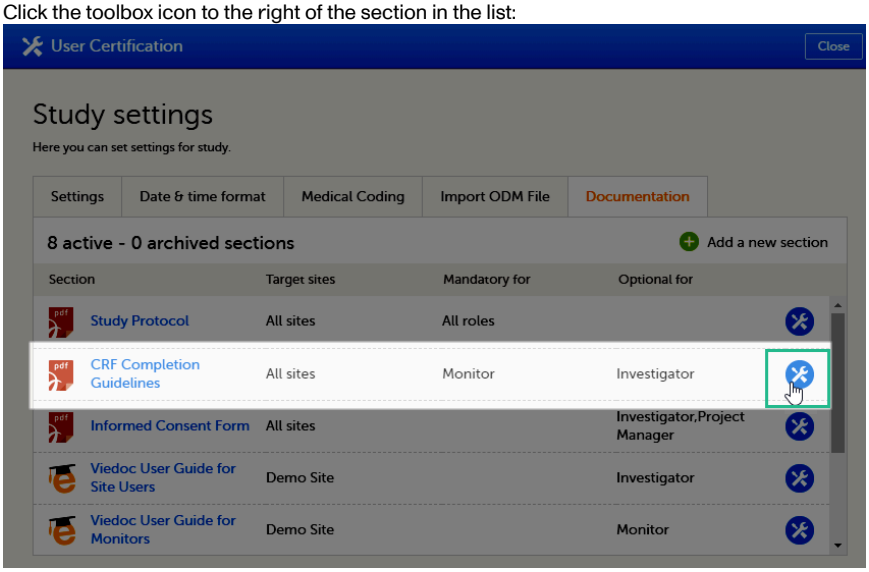
- **Require re-signing after # of days** - if checked, a new signature is required in Viedoc Clinic after the specified number of days (default is 365) from the previous signing date. If the checkbox is selected, the number of days is mandatory. This field is optional and unchecked by default.
- **Optional 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.

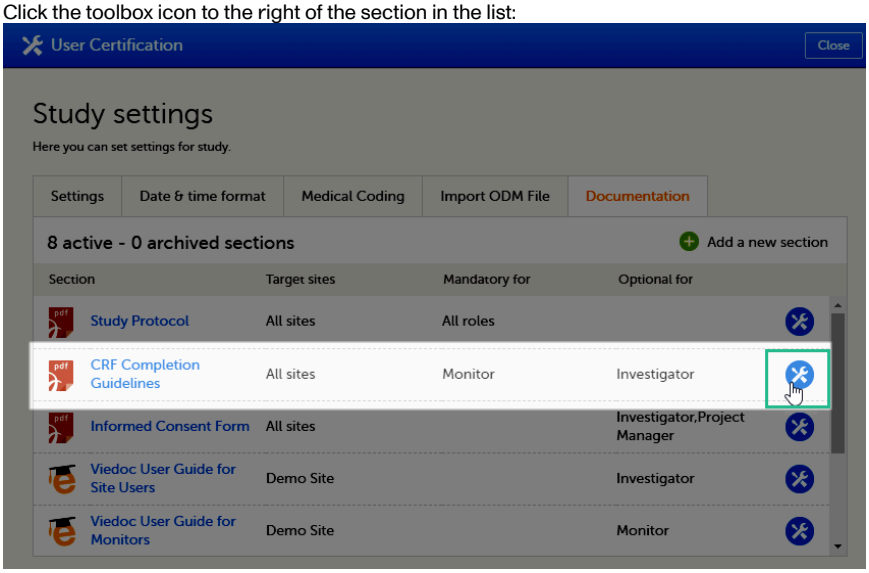
2.3 Archiving/Restoring a section

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.

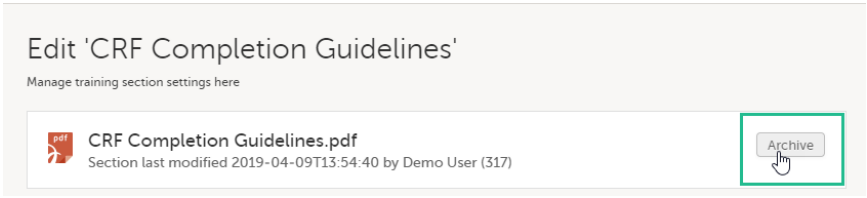
To archive an existing section, follow the steps below.

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

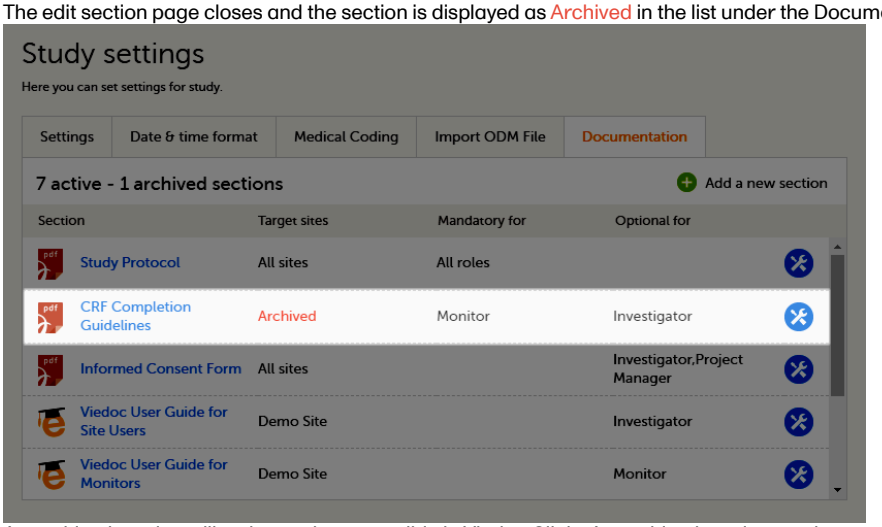


The edit section page opens.

2 Click **Archive**:



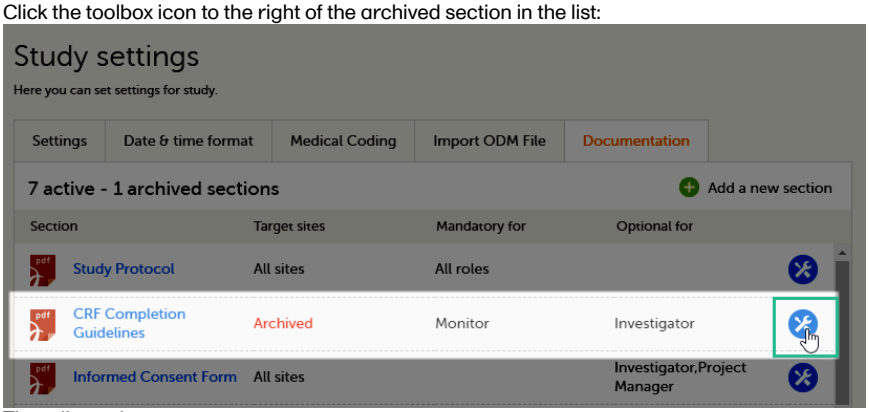
The edit section page closes and the section is displayed as Archived in the list under the Documentation tab:



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.

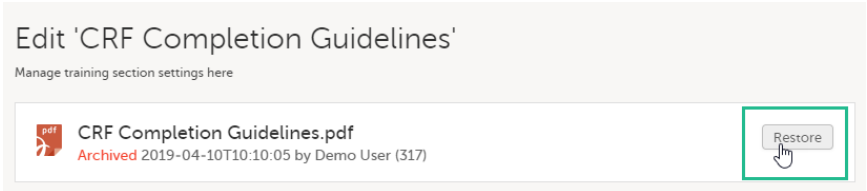
To restore an archived section, follow the steps below:

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.

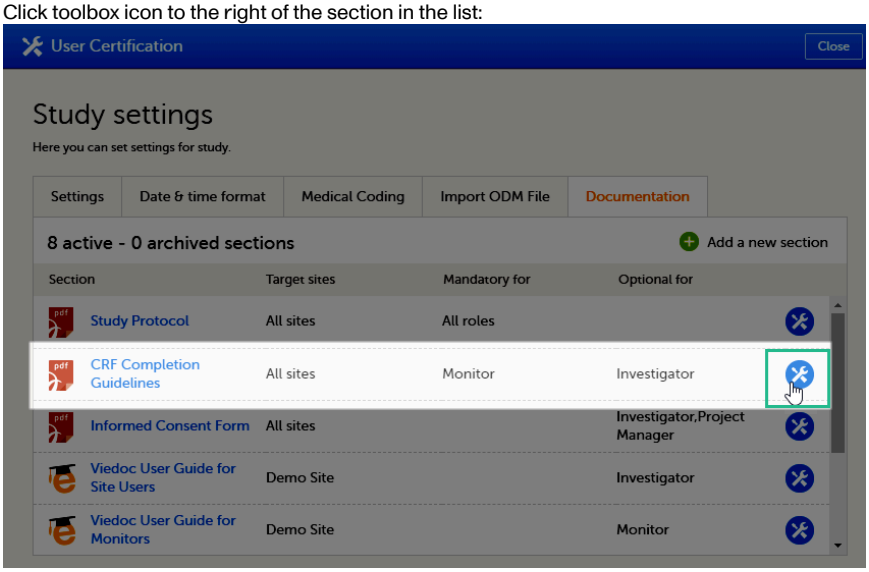
2.4 Deleting a section

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.

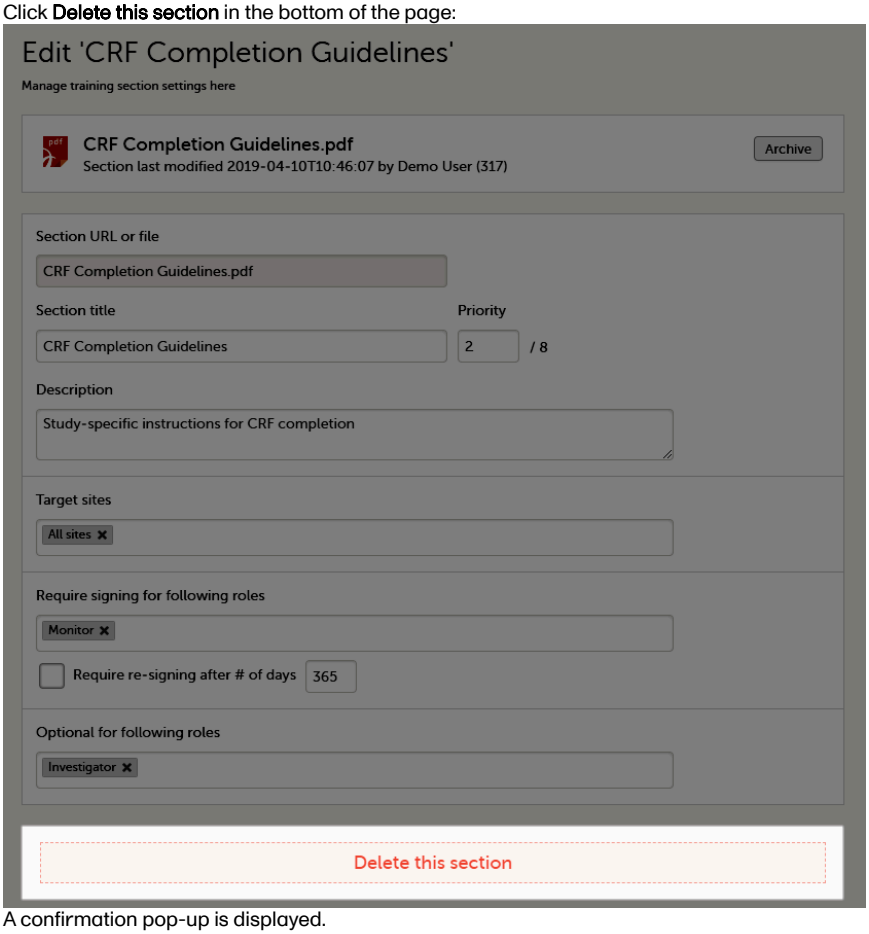
To delete an existing section follow the steps below:

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



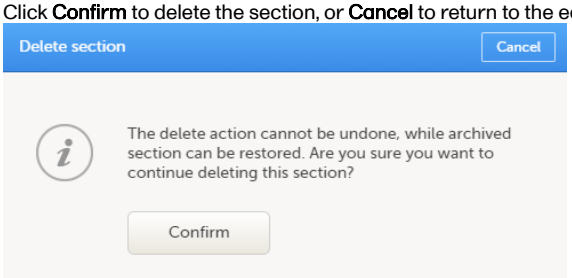
The edit section page opens.

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



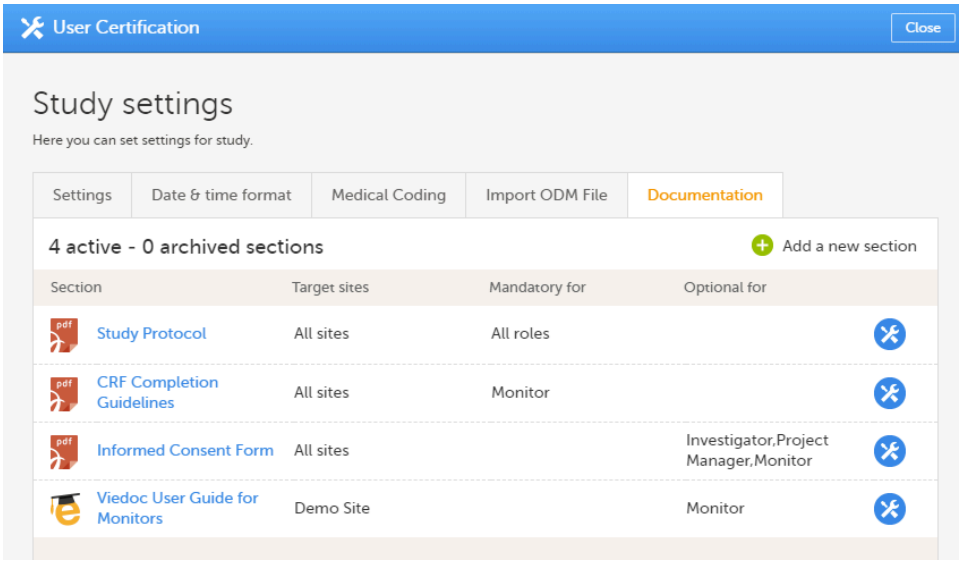
A confirmation pop-up is displayed.

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

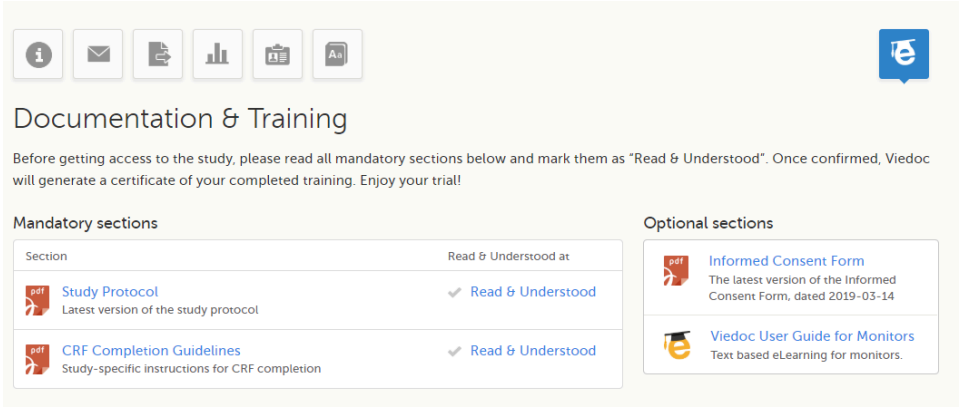


3 How it looks in Viedoc Clinic

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



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:



For more details about the **Documentation and training** section in Viedoc Clinic, see Documentation and Training.

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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 2024-10-10

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).

1 Introduction

1.1 Important information about signatures

Can not output single-source

1.2 About roles in Viedoc

Can not output single-source

1.3 About the study users

Can not output single-source

1.4 User settings

Can not output single-source

1.5 User report

Can not output single-source

1.6 System site groups

Can not output single-source

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.

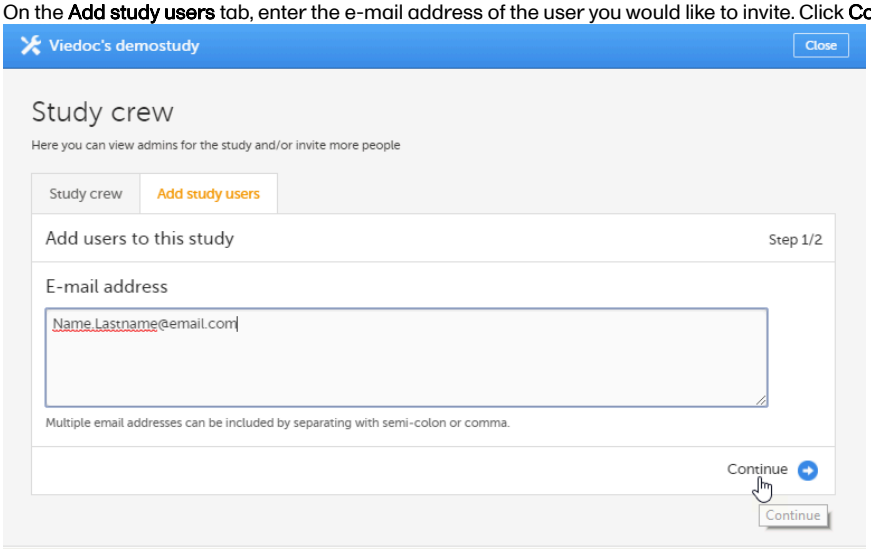
If a user should receive access to multiple sites, the quickest way to invite the user is through the study crew window (described in this section). If a user should receive access to only one site, you can also invite the user through the site settings window of that site (see Assigning users to clinic roles for instructions).

To invite users:

1 In Viedoc Admin, open the study to which you would like to invite users.

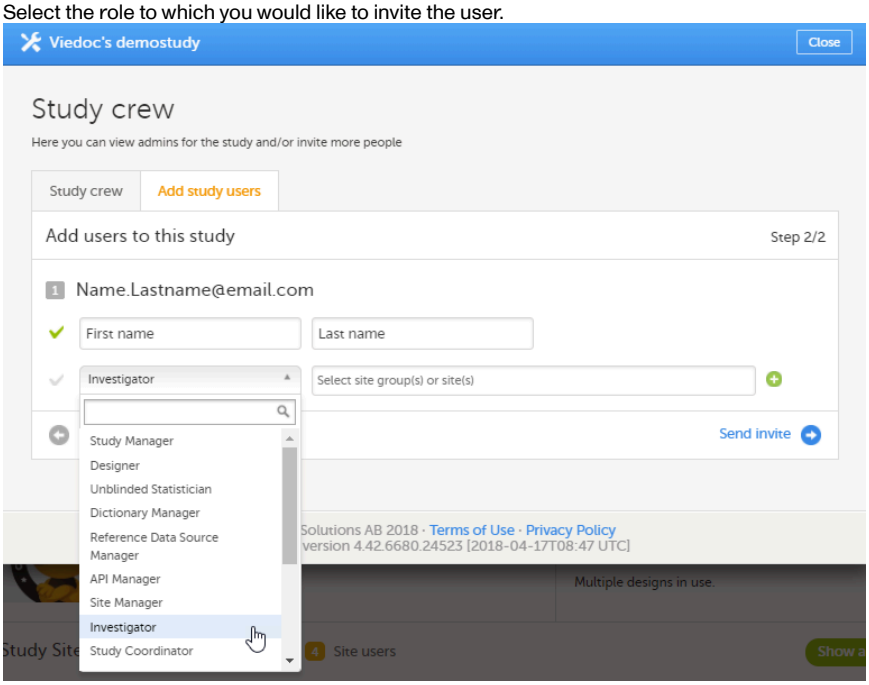
2 Click the toolbox icon in the **Study crew** field.
The Study crew pop-up opens.

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



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.

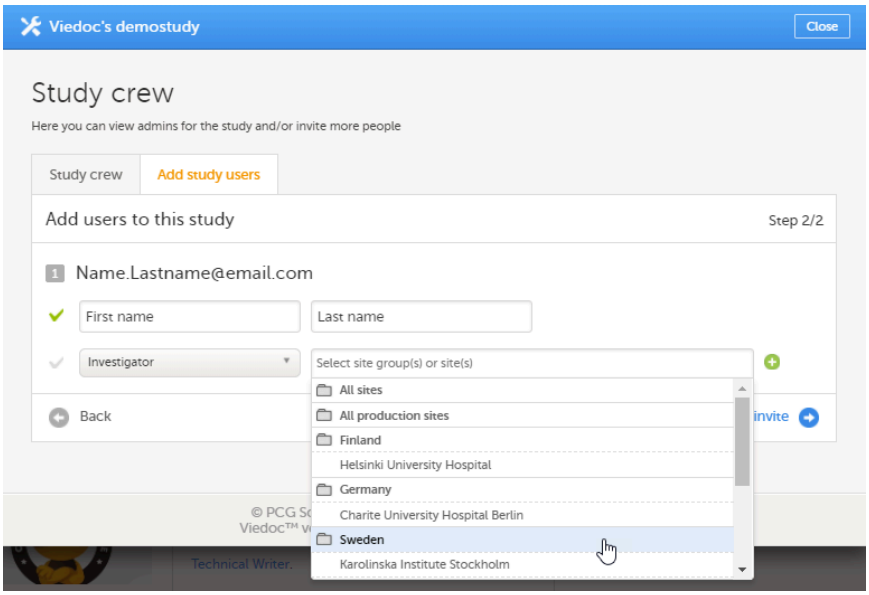
4 Select the role to which you would like to invite the user.



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).

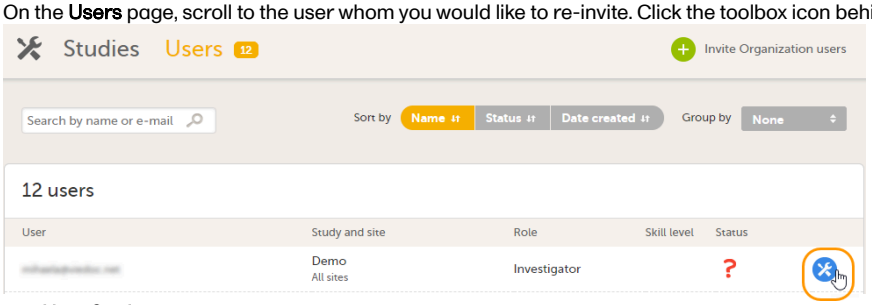
6 Click **Send invite**.
An invitation e-mail will be sent to the e-mail address(es) you specified.

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.

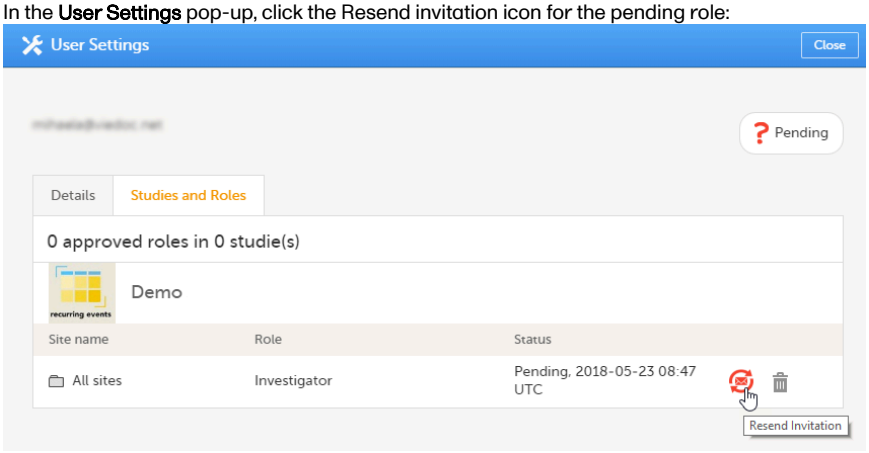
To resend an invitation:

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:



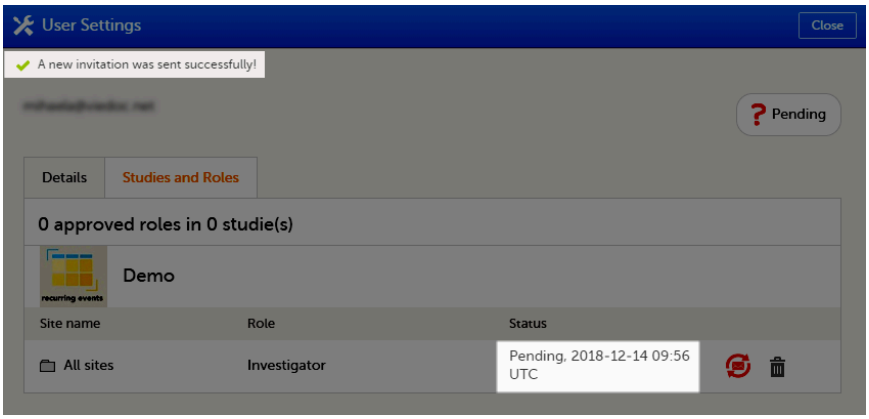
The **User Settings** pop-up opens.

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

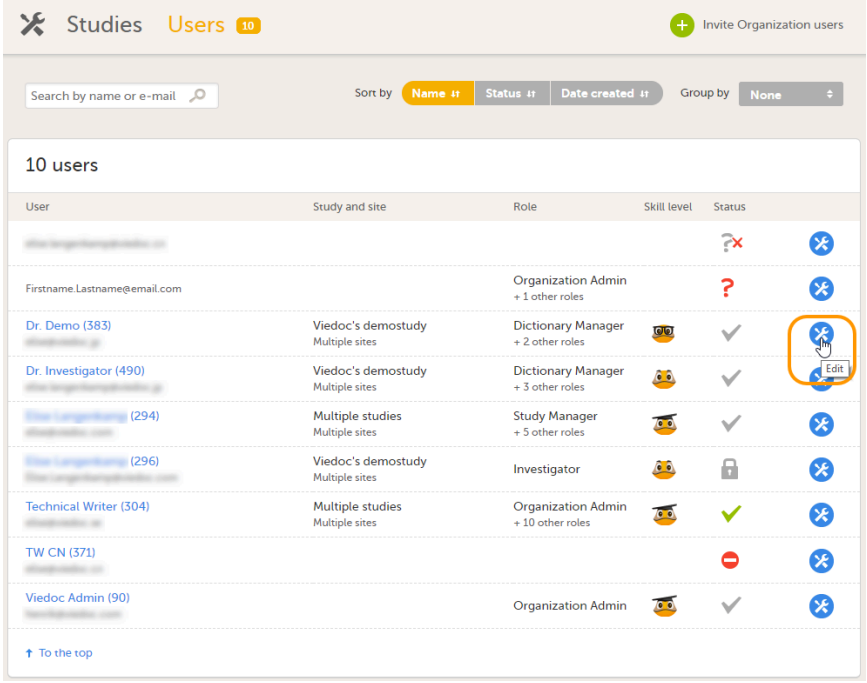


2.3 Removing access to a role

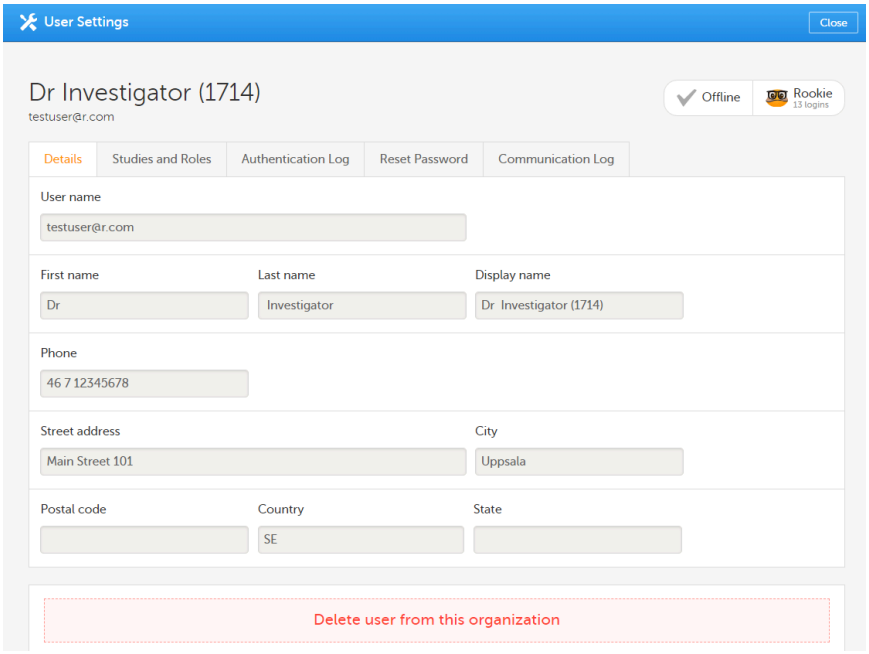
It is possible to remove a user's access to a role. This can only be done by the Study Manager. If the Study Manager has delegated the management of clinic roles to the Site Managers, only the Site Managers can remove access to these roles and sites.

To remove the access from users:

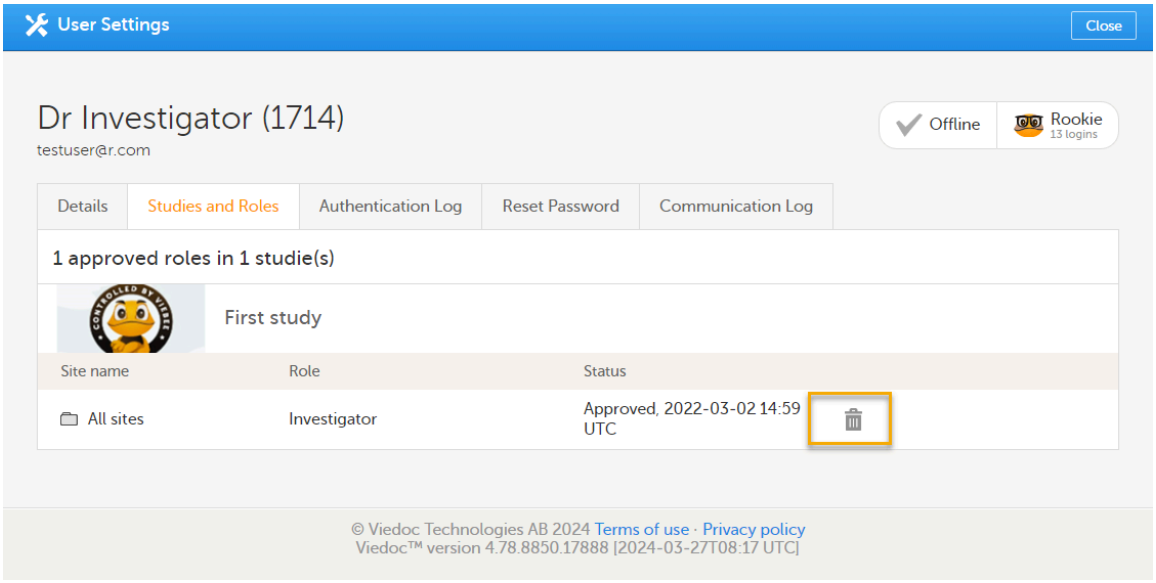
1 On the **Users** page, scroll to the user whose access you would like to remove. Click the toolbox icon behind the name of the user.



The User Settings pop-up opens.



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.

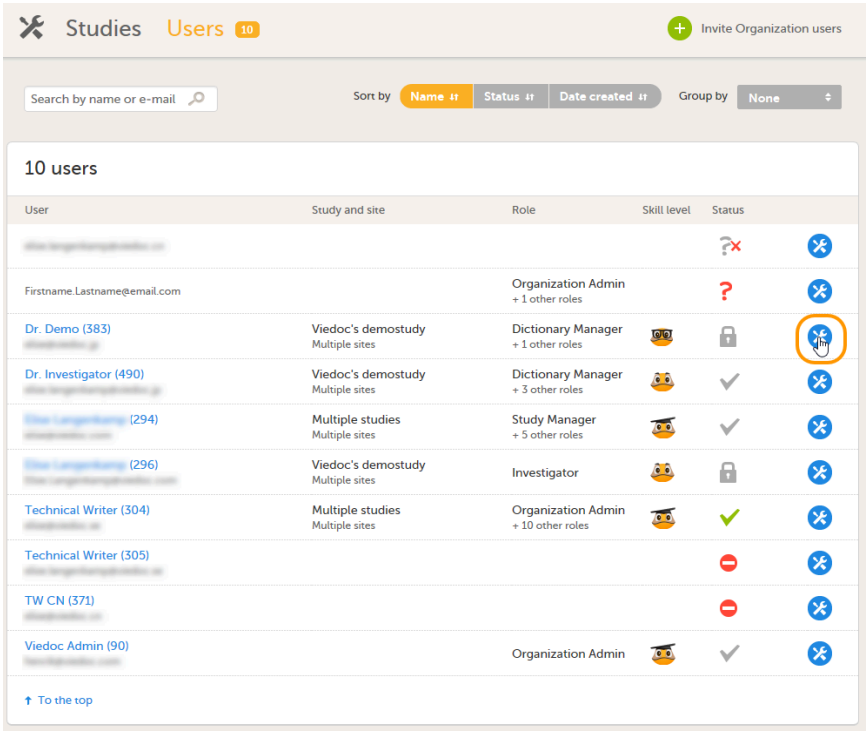
Any records generated by the user are stored in the audit trail even when the user has been removed.

2.4 Unlocking a user account

If a user has typed in the wrong password more than three times, and do not have a secondary email address or phone number with text messaging enabled – 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 so the user can reset their password without having to provide an authentication code.

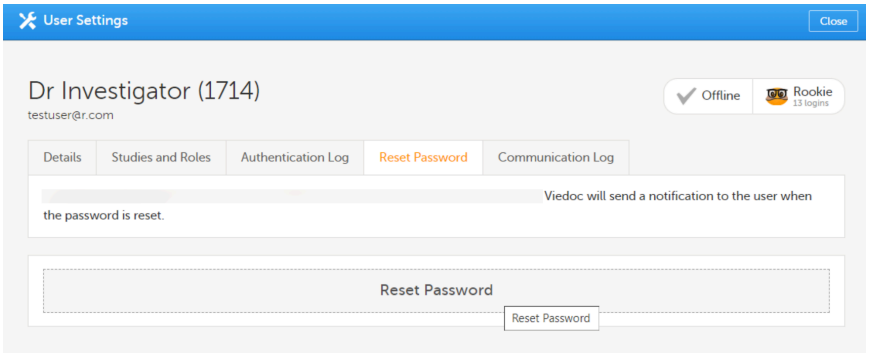
To unlock a user account:

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.

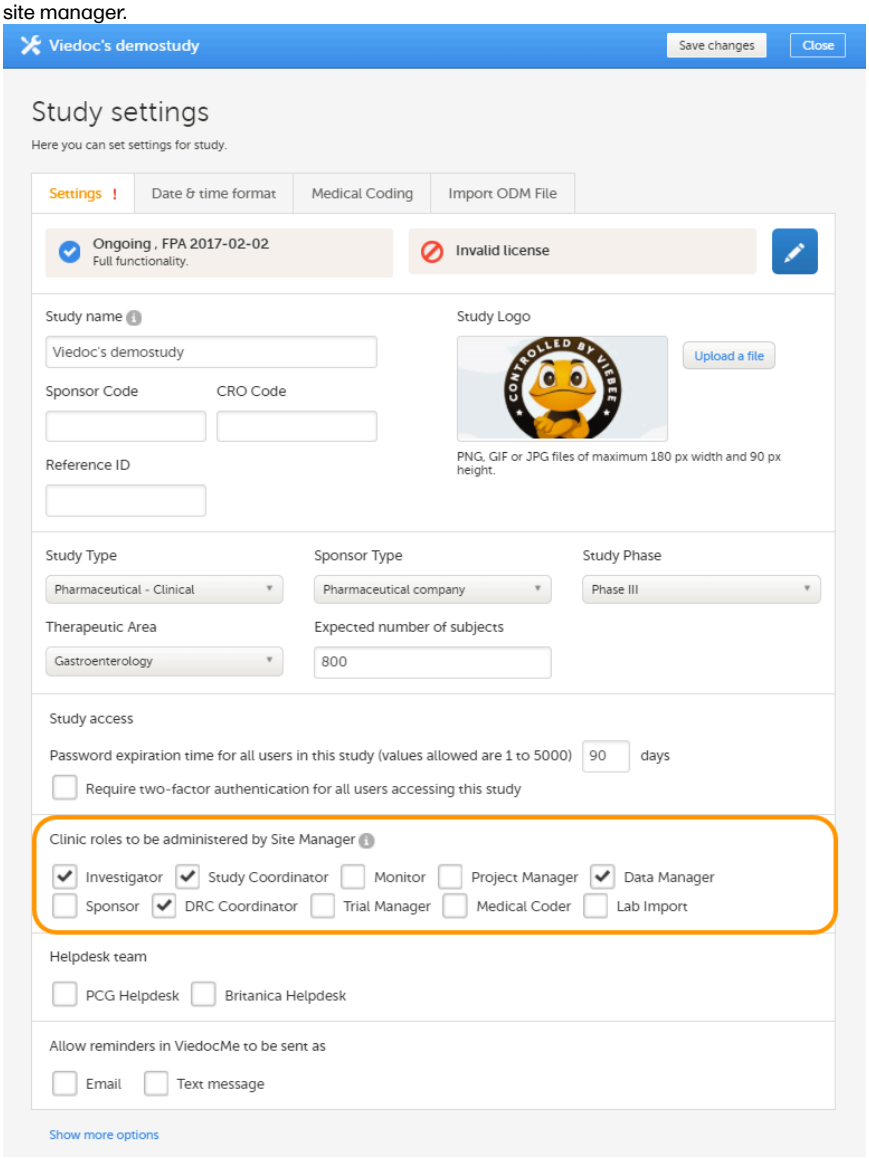
2.5 Delegating user management to the Site Managers

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.



The roles that can be selected here are the clinic roles that are defined in the study design.

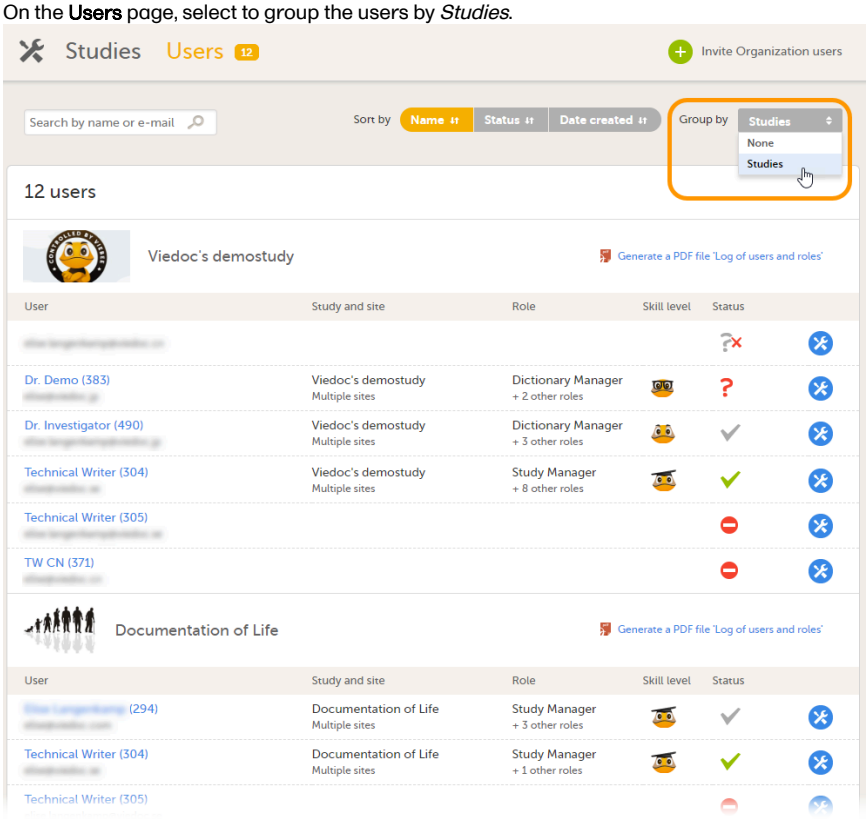
3 Click **Save changes**, and click **Close**.

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.

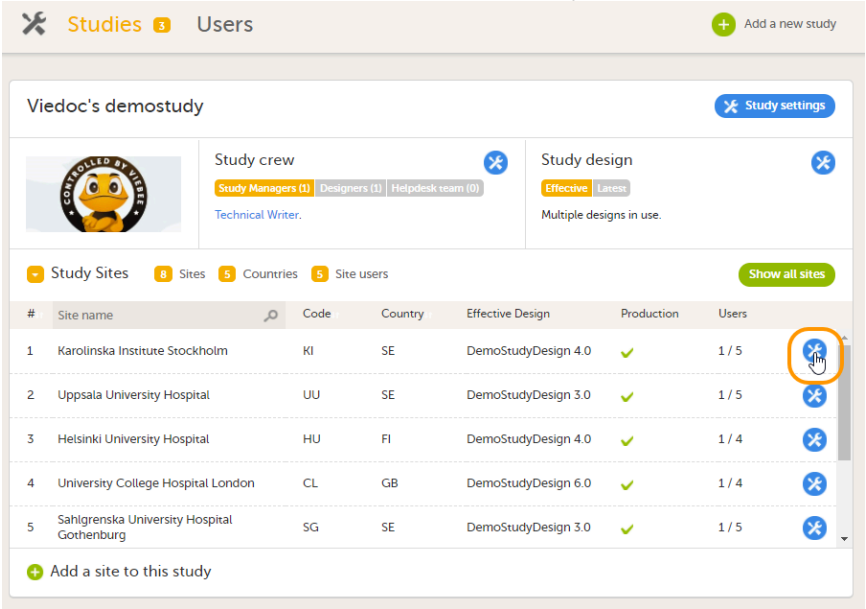
3 Step-by-step guides for the Site Manager

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.

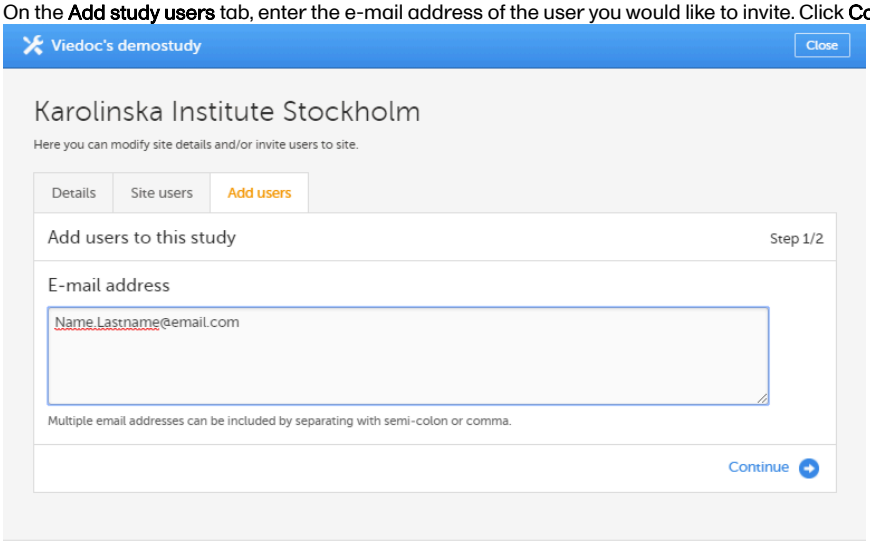
To invite users to a specific site:

1 In Viedoc Admin, click the toolbox icon behind the site to which you would like to invite users.



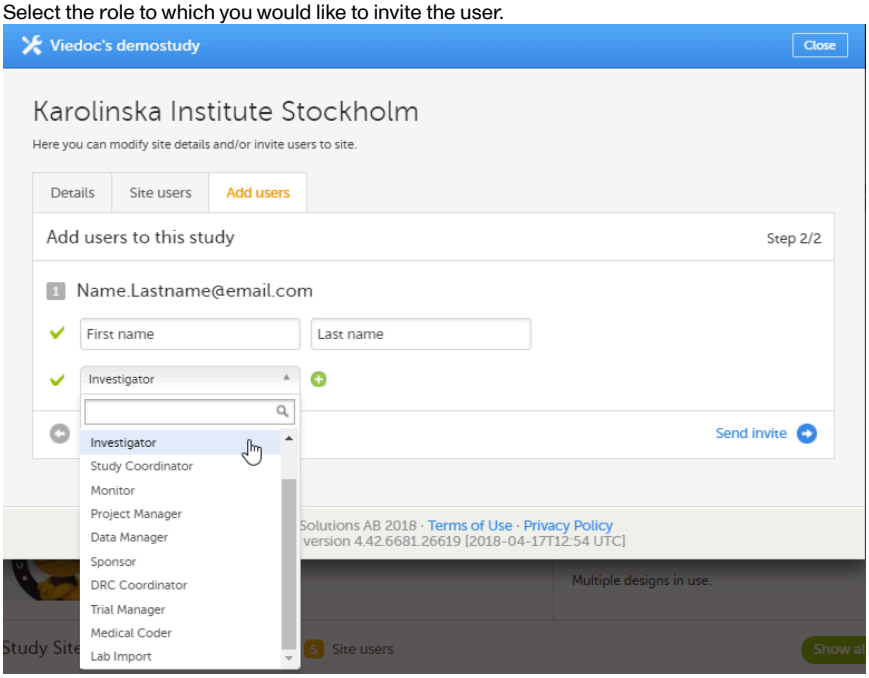
The site settings pop-up opens.

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

This lesson provides instructions on how to manage the study sites in your study. It also provides a description of system site groups.

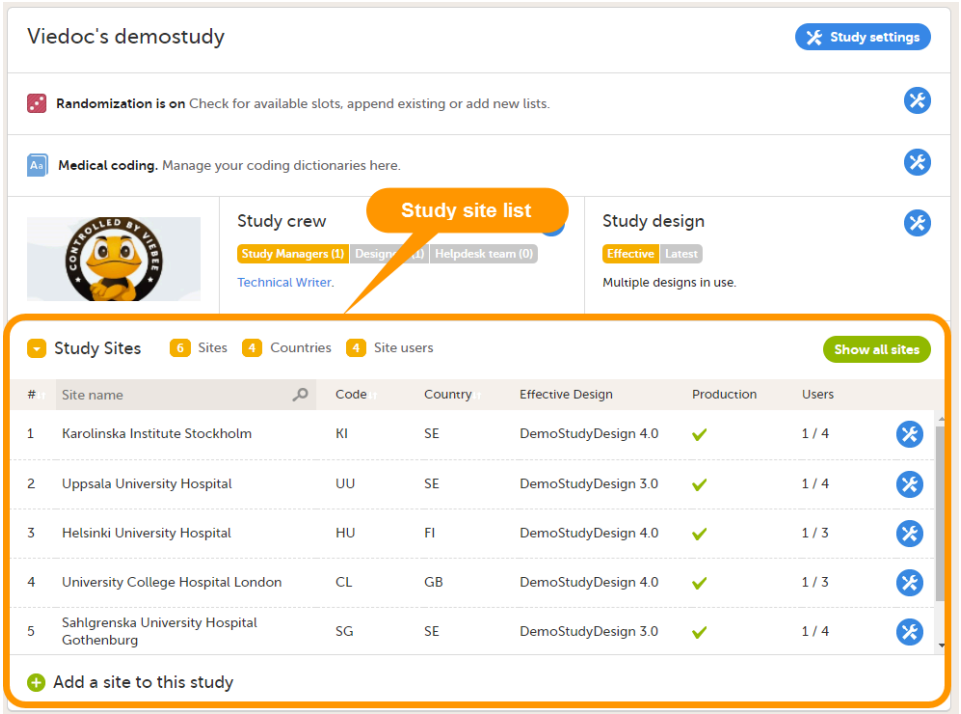
1 Introduction

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.

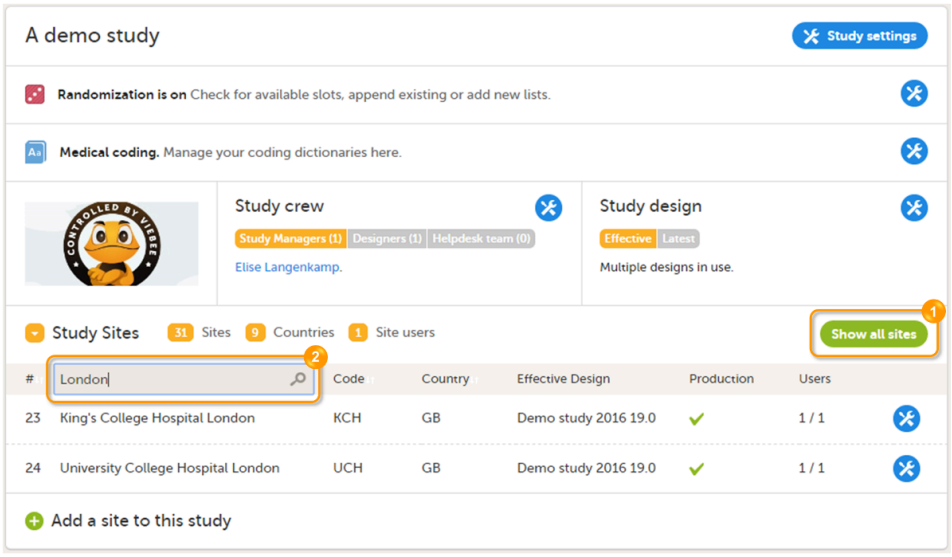
The header of the study site list summarizes the total number of sites, the total number of countries and the total number of site users.

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?

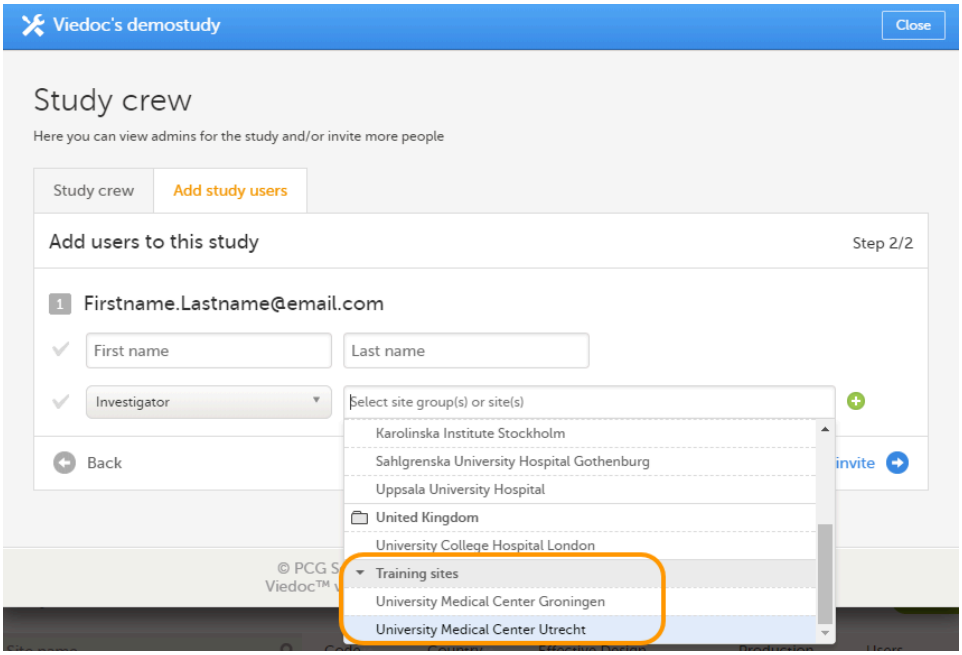
The system automatically creates groups of the sites that are added. This enables the Study Manager to assign site staff to all sites within a group at once. Site staff can also be assigned to individual sites.

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.

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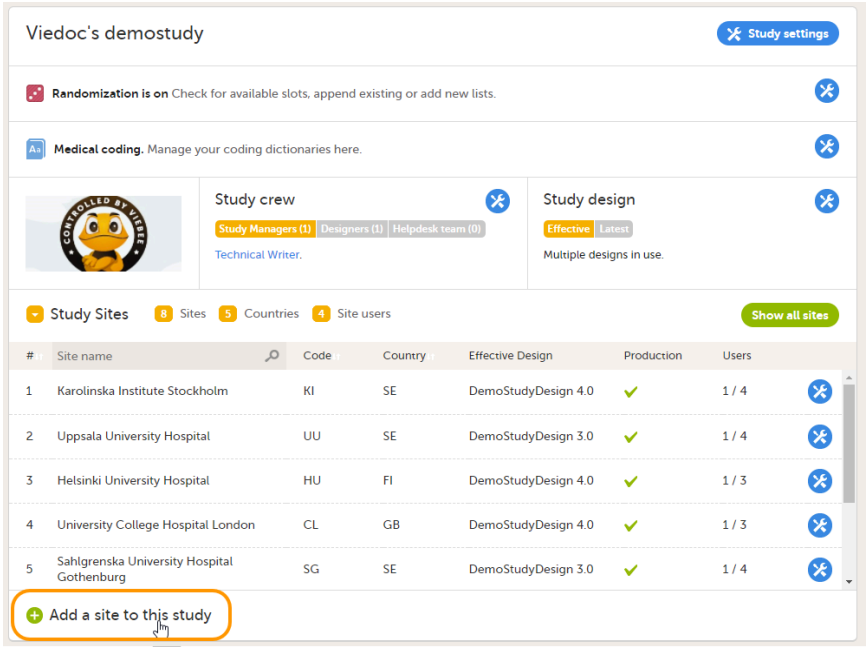
2 Step-by-step guides

2.1 Adding a study site

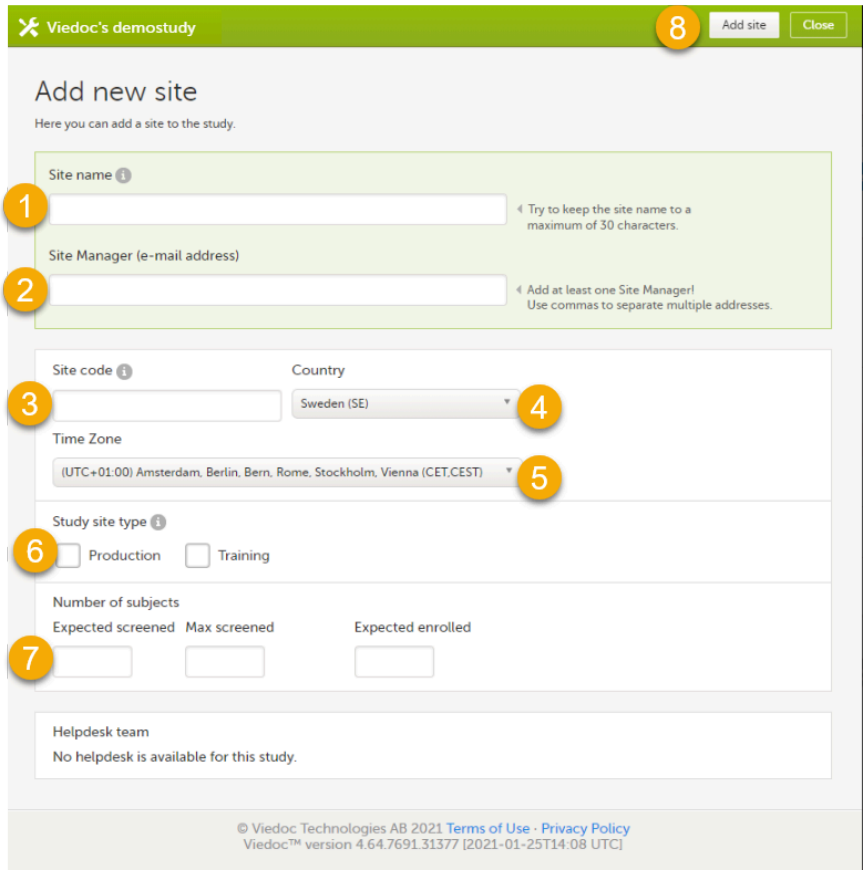
To add a site/clinic to the study:

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.

6 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.

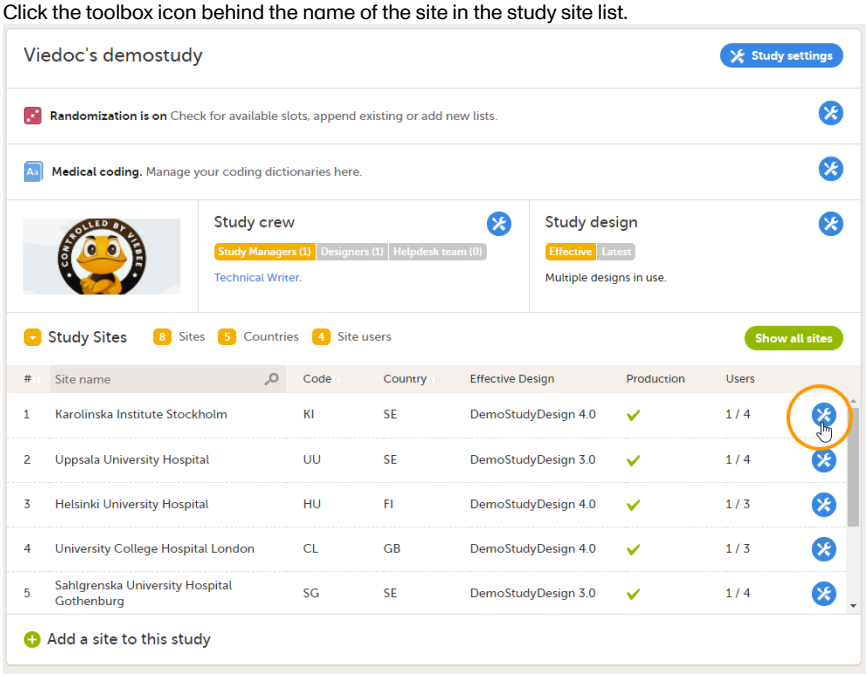
The expected numbers of subjects are used for Metrics in Viedoc Clinic (see Metrics). The maximum is used to limit the number of subjects for this site, see Maximum number of subjects per site above.

7 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

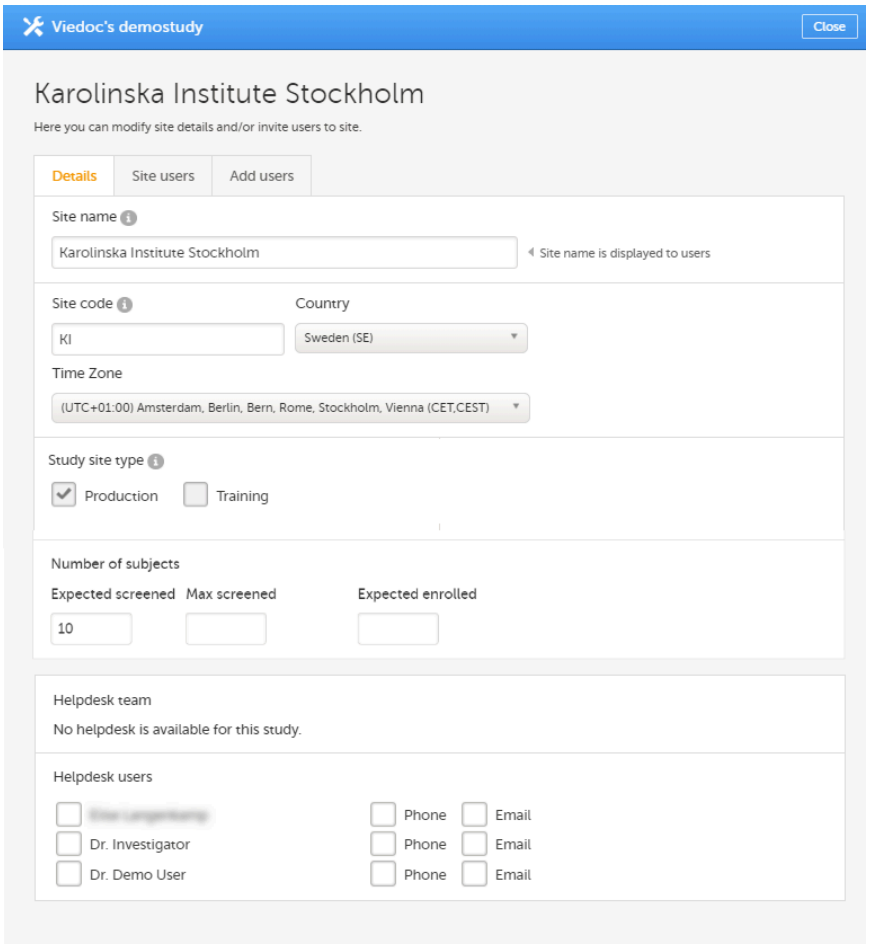
To edit the settings for a study site:

1 Click the toolbox icon behind the name of the site in the study site list.



A pop-up opens.

2 Edit the settings you would like to change.



2.3 Removing a study site

It is not possible to remove a study site in production mode from the study.

Managing the study design

Published by Viedoc System 2024-12-03

This section explains how to assign a design to sites in a study. It is necessary to assign a study design to the sites in the study to start work on the site.

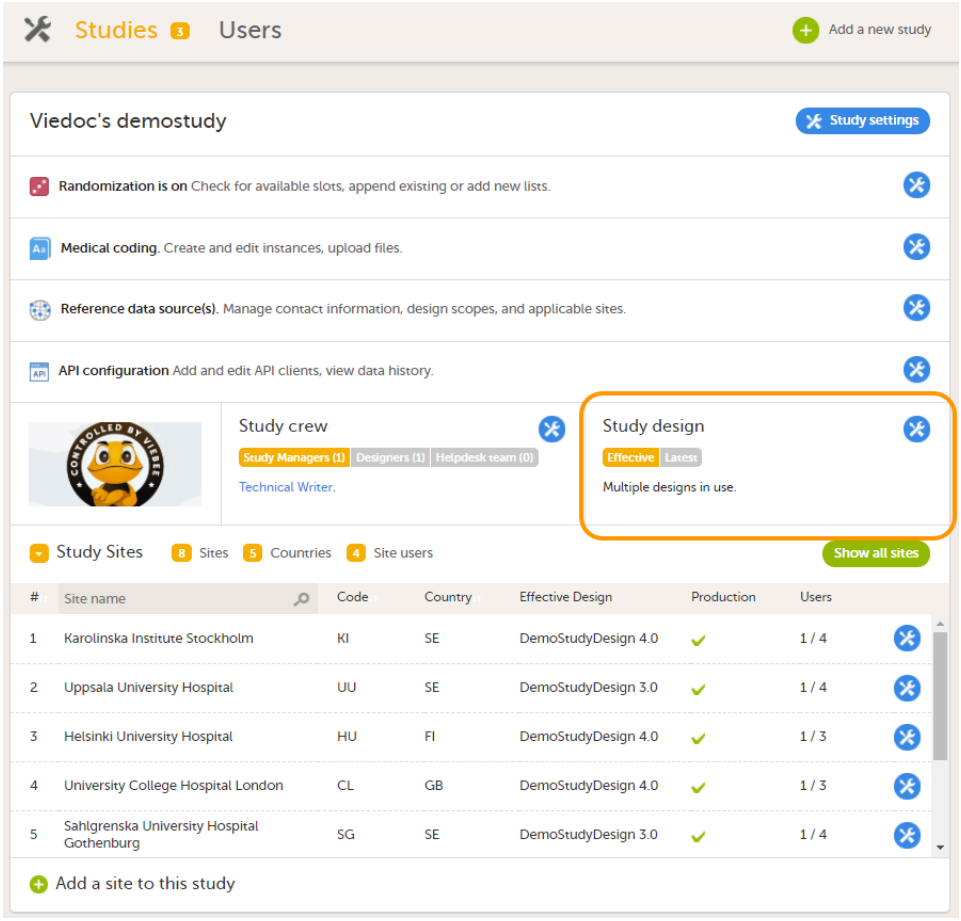
1 Introduction

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.

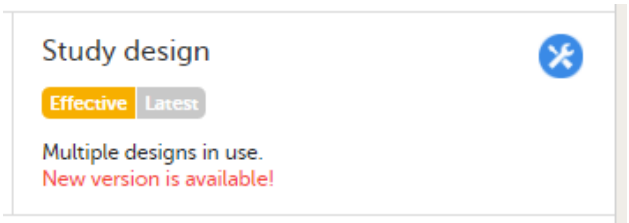
When the Study Designer has finished setting up a study design in Viedoc Designer, and has published the study design, it becomes available in Viedoc Admin. At least one site should have been added to the study before a study design can be assigned. The Study Manager can then assign the study design to one or several sites in the study, and select an effective starting time for that design to be applied to the site.

A design can be assigned to all sites at once, or to individual sites in the study. It is therefore 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.



To see the study design or designs that are in use, click **Effective**.



To see whether there is a new design version or revision available, click **Latest**.

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.

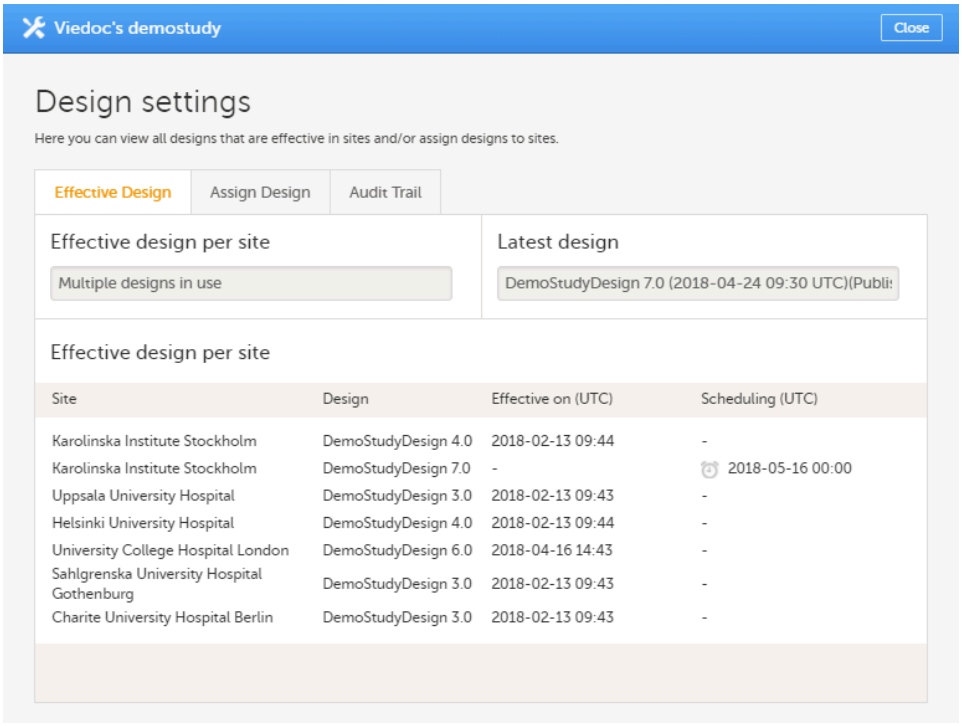
The main reason to assign a new study design version to a site after study start is that protocol amendments require changes to be made to the study design, for example changes to the study that apply from a specific point in time during the course of the study.

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:



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).

---

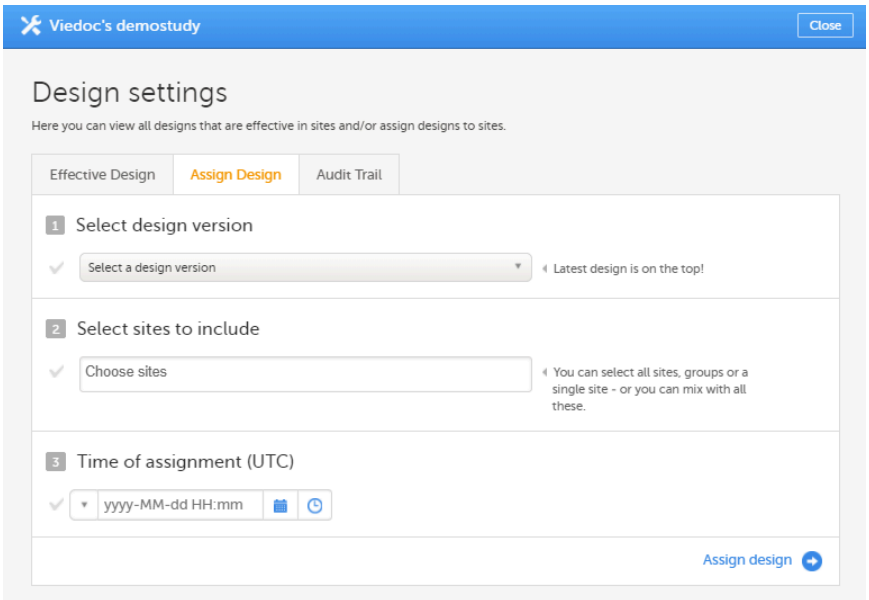
4 Assigning a study design

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.

Note! It is a good idea to keep all production sites on the same design version. For more information about the consequences to exports when the design versions do not match, please see https://help.viedoc.net/c/47e0ad/01d540/en/.

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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.

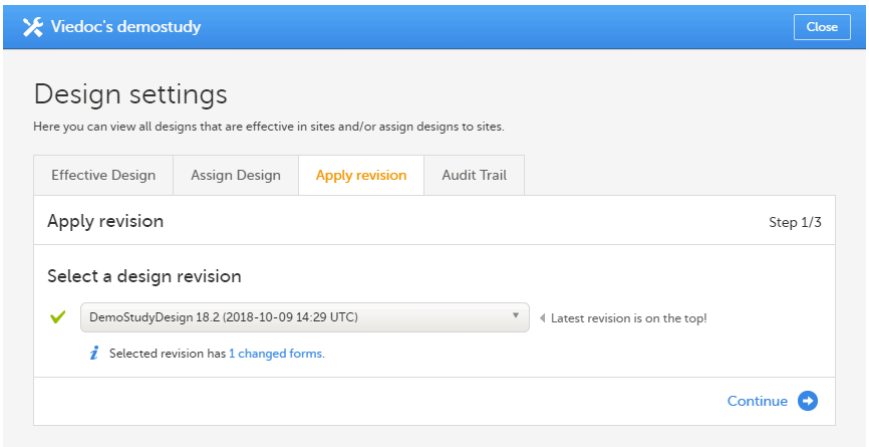
Note! It is recommended that you use the revision impact analysis before applying any revision. For more information, see Design revision impact analysis.

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.

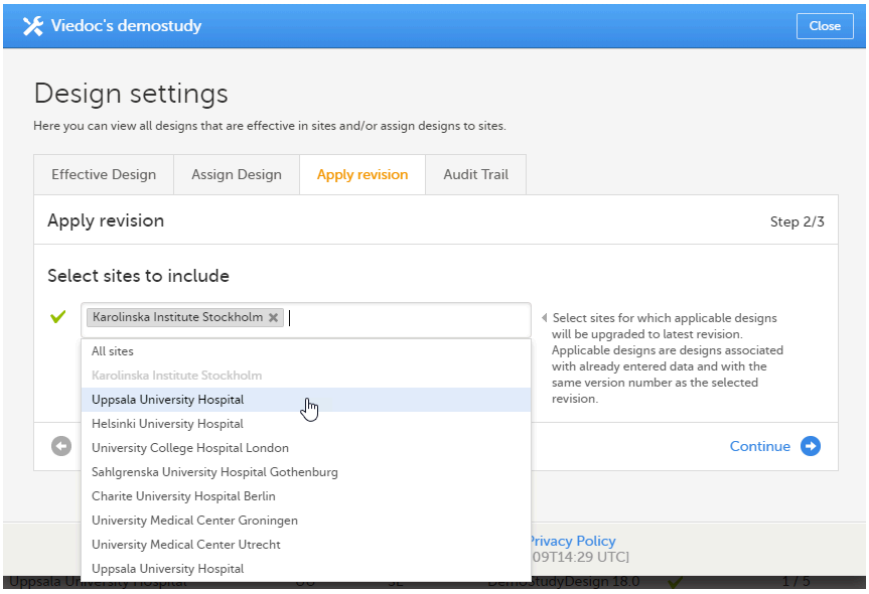
1 Click the toolbox icon in the **Study design** field on the study details page.
The Design settings pop-up opens.

2 On the **Apply Revision** tab, select the design revision from the drop-down list and click **Continue** (Step 1/3).

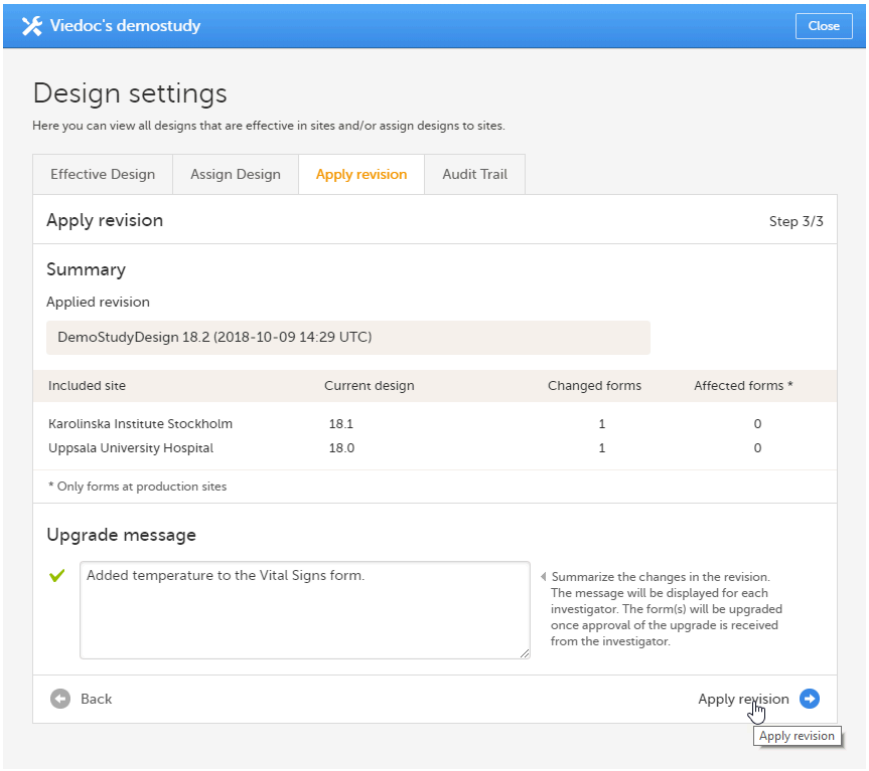


The system provides information about the impact of the revision by showing how many forms have been changed in blue text.

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).

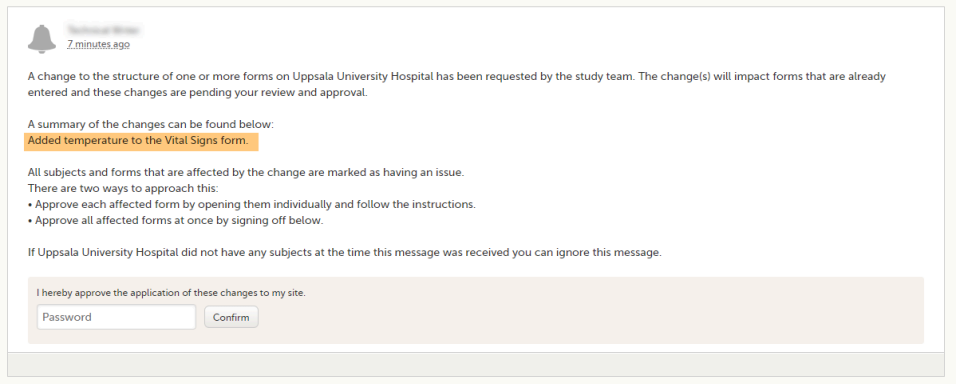


4 Type a message to the Clinic user in the Upgrade message field. This message could be a summary of the changes in the revision. It is displayed in Viedoc Clinic on the Messages page.



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 en 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.

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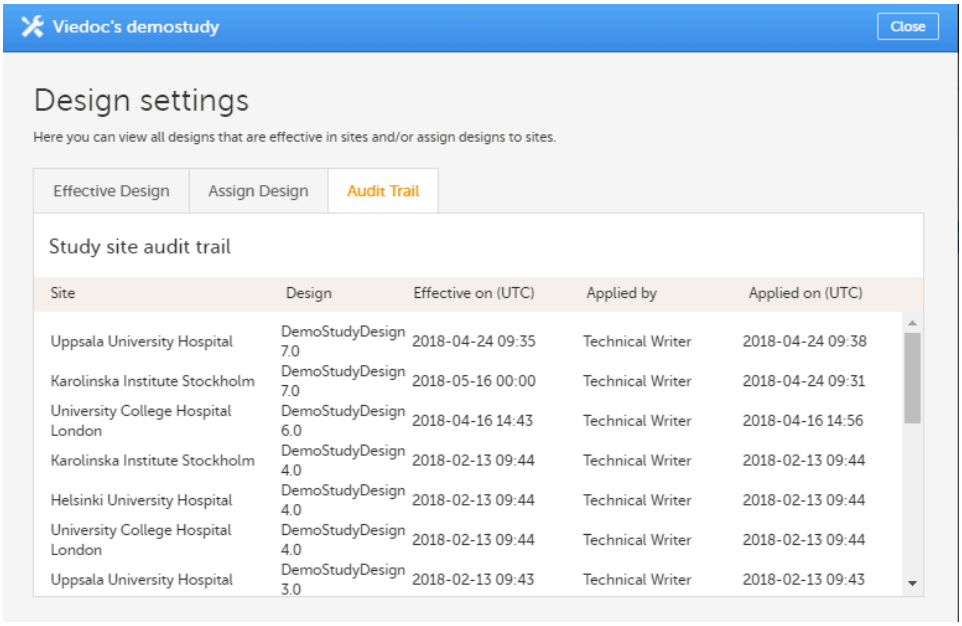
7 Viewing the audit trail of study designs

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.



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 assign, 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

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.

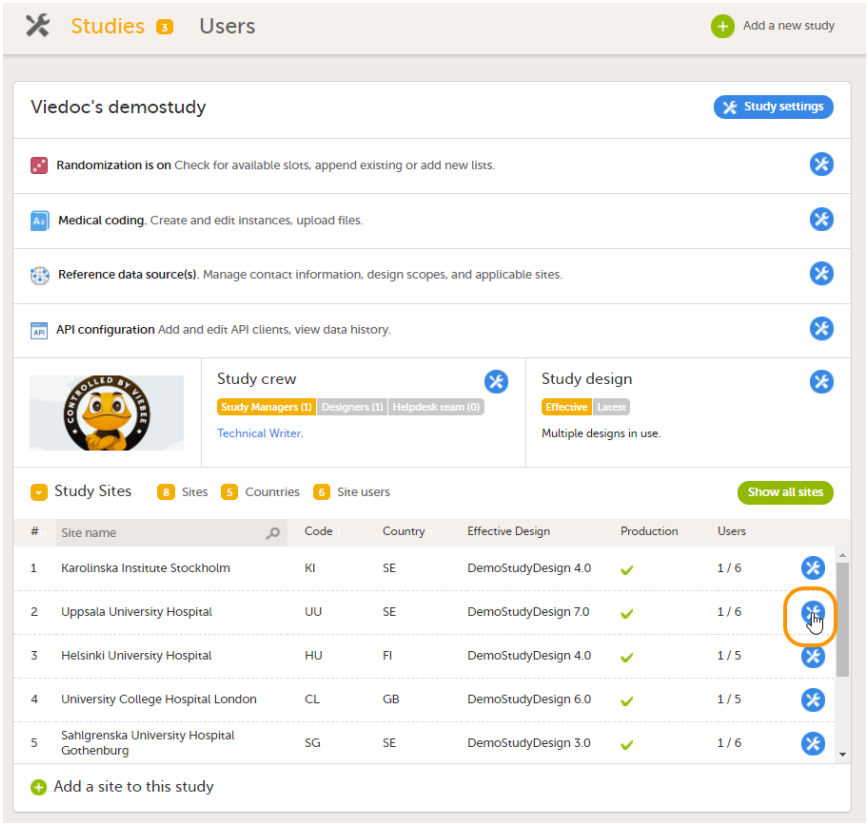
For information about delegating roles to the Site Manager, see the eLearning section about Managing users (STM and SIM).

Helpdesk users are assigned on site level.

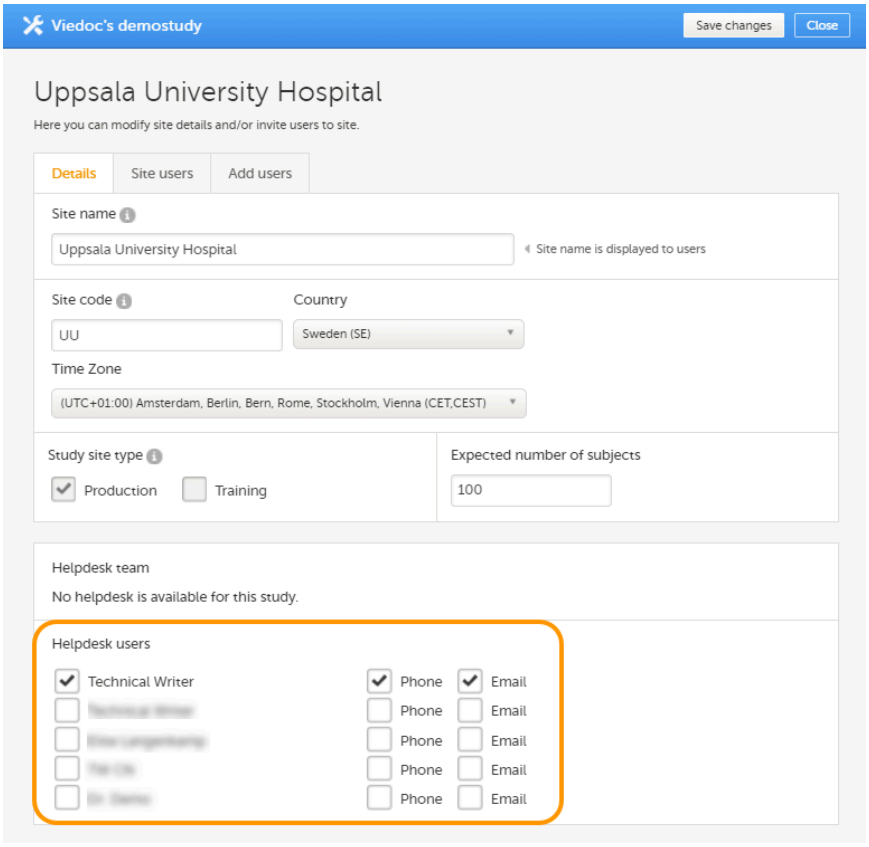
2 Adding helpdesk users

To add a helpdesk user, follow the steps below.

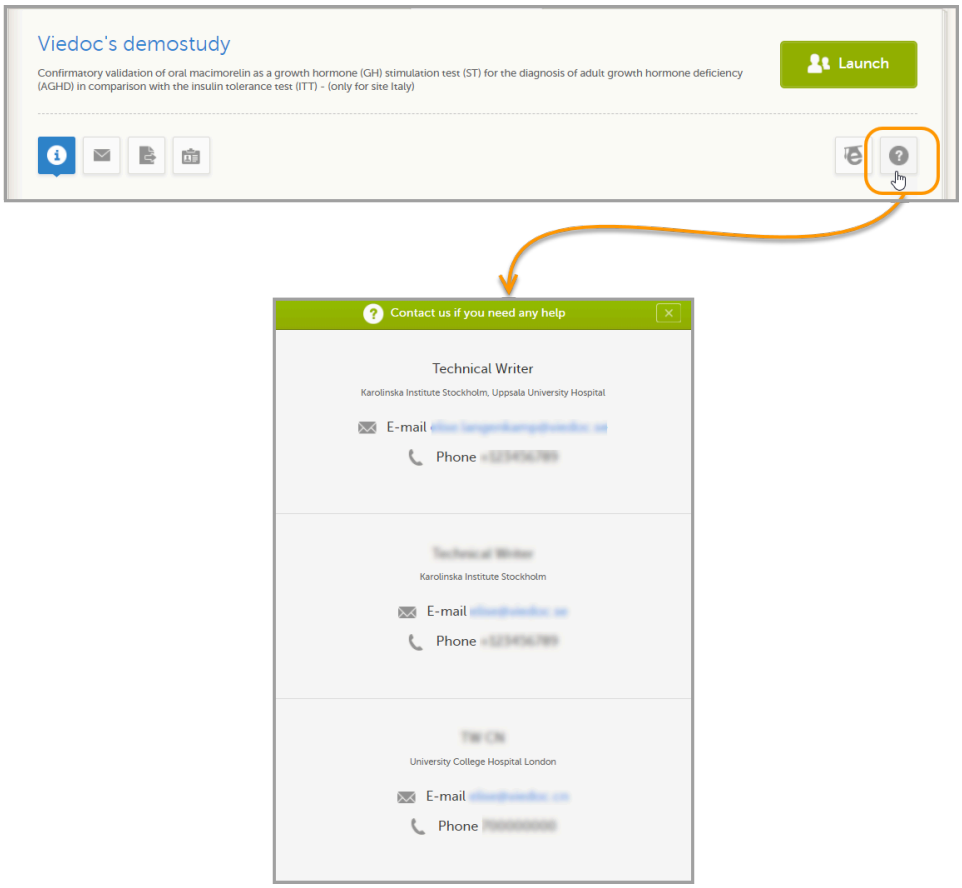
1 Click the toolbox icon behind the name of the site in the study site list to open the site settings pop-up.



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.



Locking a study

Locking a study

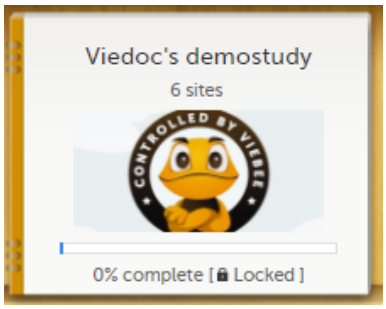
Published by Viedoc System 2021-11-24

1 Introduction

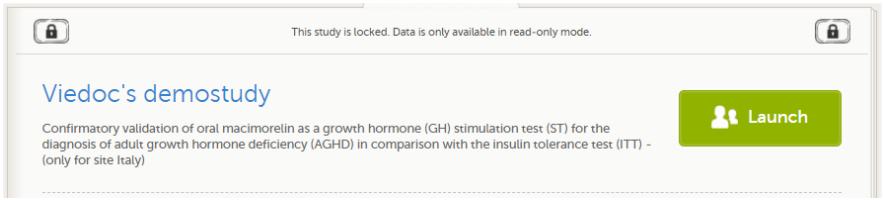
A study can be locked in Viedoc when the study is completed, that is, when all events have been completed, reviewed and approved/signed, and no more data will be added to the study. When the study is locked in Viedoc, it is still possible to view and export data, but it is NOT possible to add or edit 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:

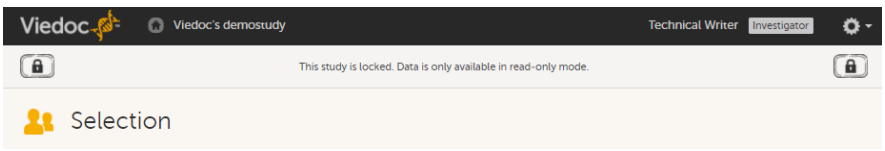
- On the study card on the landing page...



- ...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 a 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

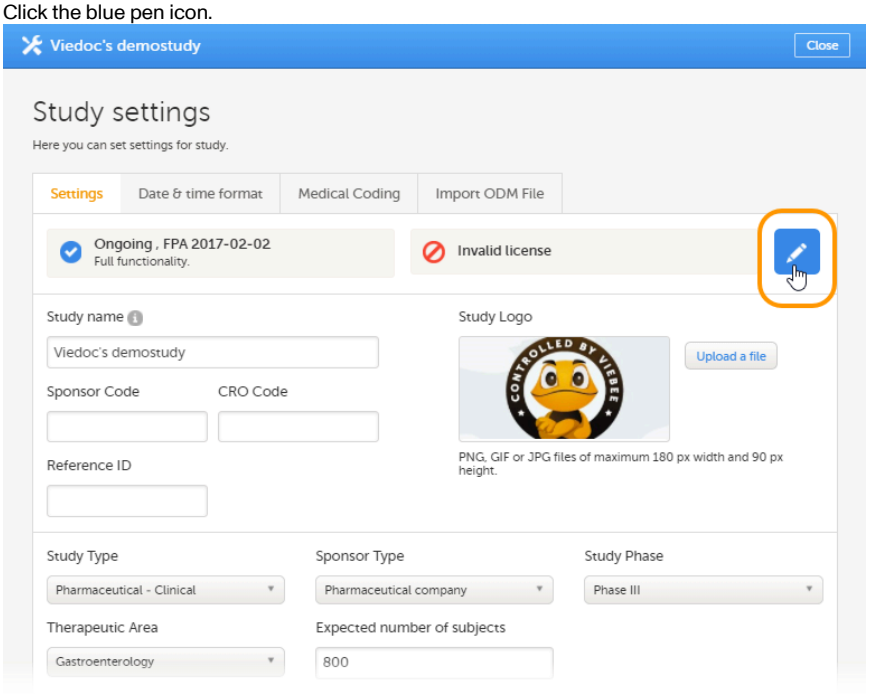
2.1 Locking a study

Note! A study can only be locked by the Study Manager.

To lock a study, follow the steps below.

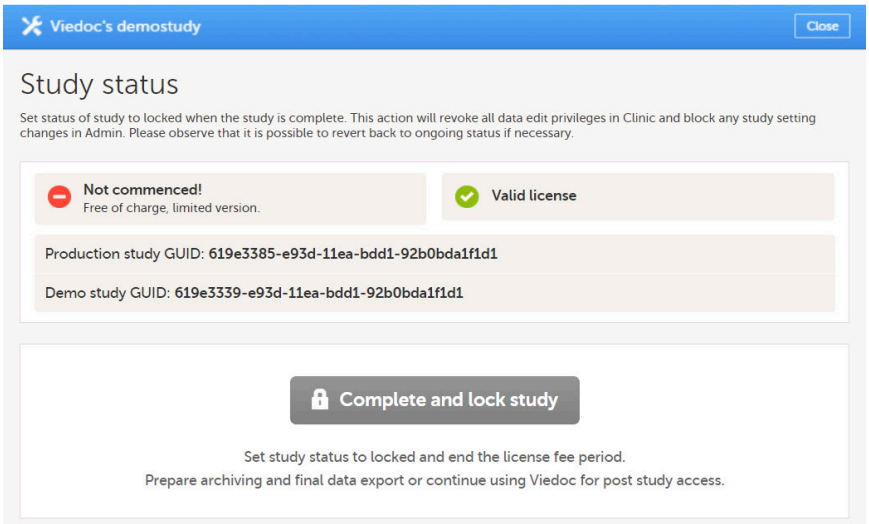
1 Open the study in Viedoc Admin and click **Study settings**.
The Study settings window opens.

2 Click the blue pen icon.

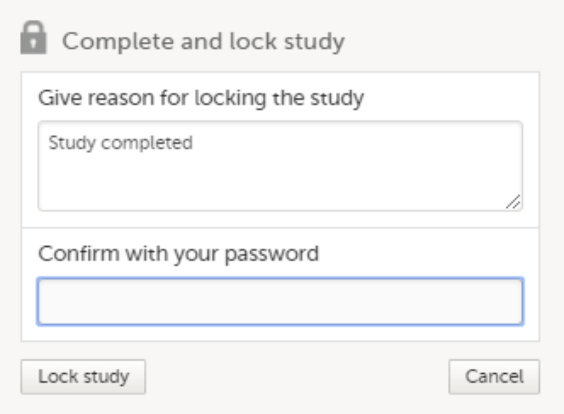


The Study status pop-up opens.

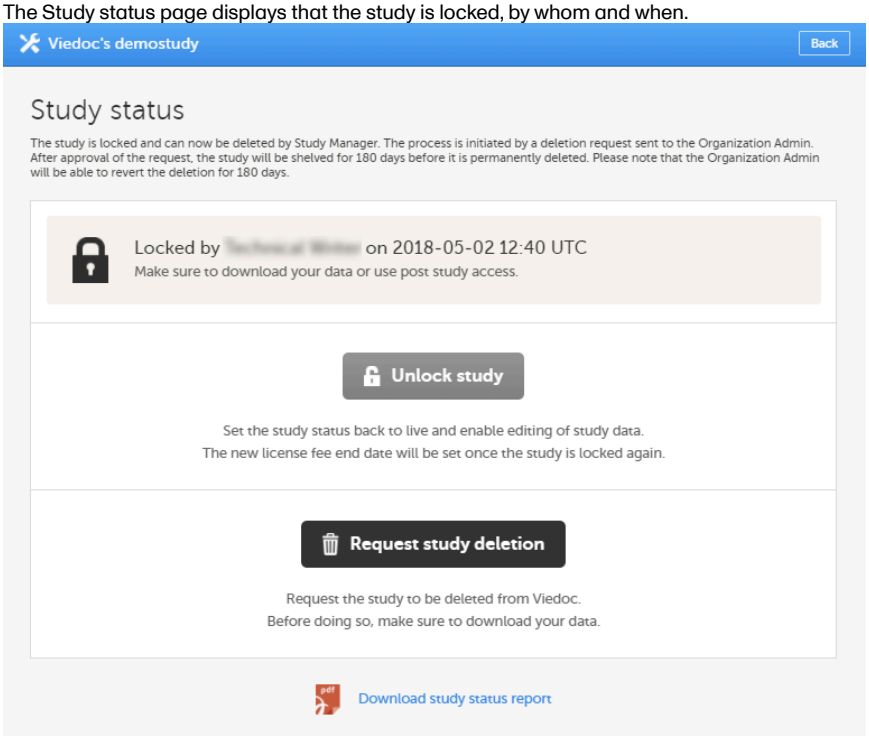
3 Click **Complete and lock study**.



4 A pop-up opens. Enter a reason for locking the study, and enter your password.



5 Click **Lock study**.
The Study status page displays that the study is locked, by whom and when.



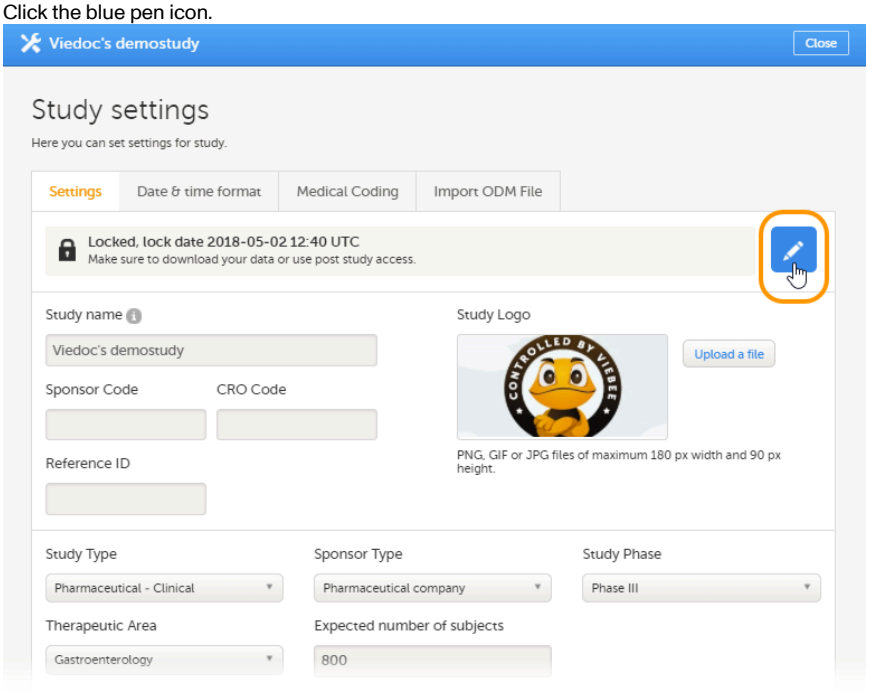
2.2 Unlocking a study

Note! A study can only be unlocked by the Study Manager.

To unlock a study, follow the steps below.

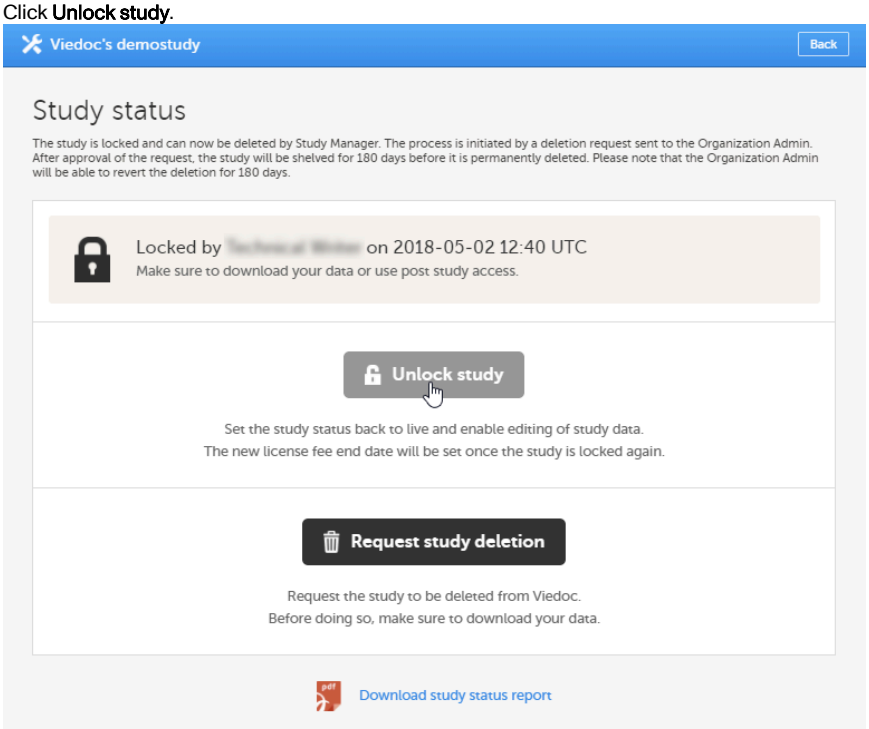
1 Open the study in Viedoc Admin and click **Study settings**.
The Study settings window opens.

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.

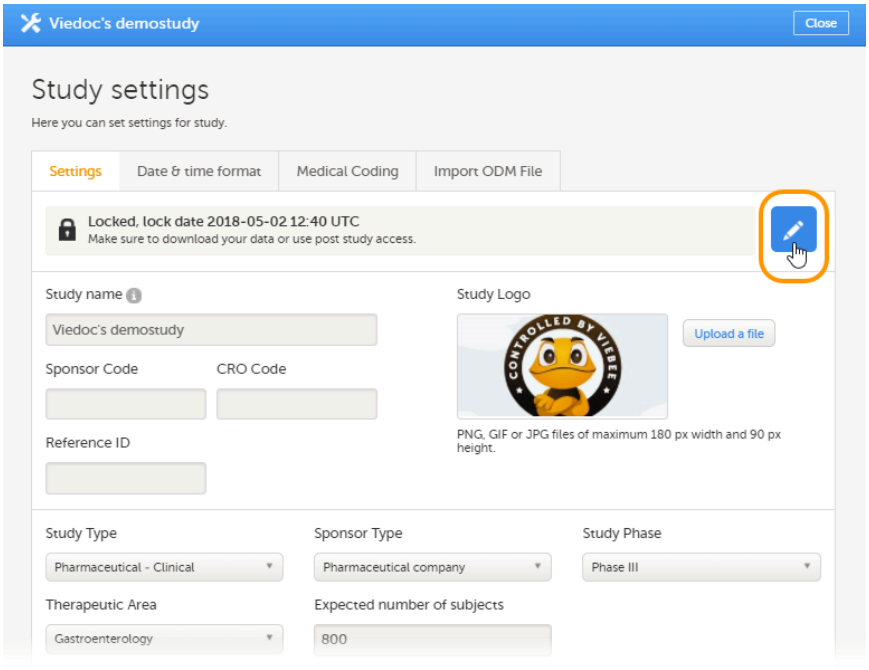
4 Click **Unlock study**.

2.3 Downloading the study status report

To download the study status report, follow the steps below.

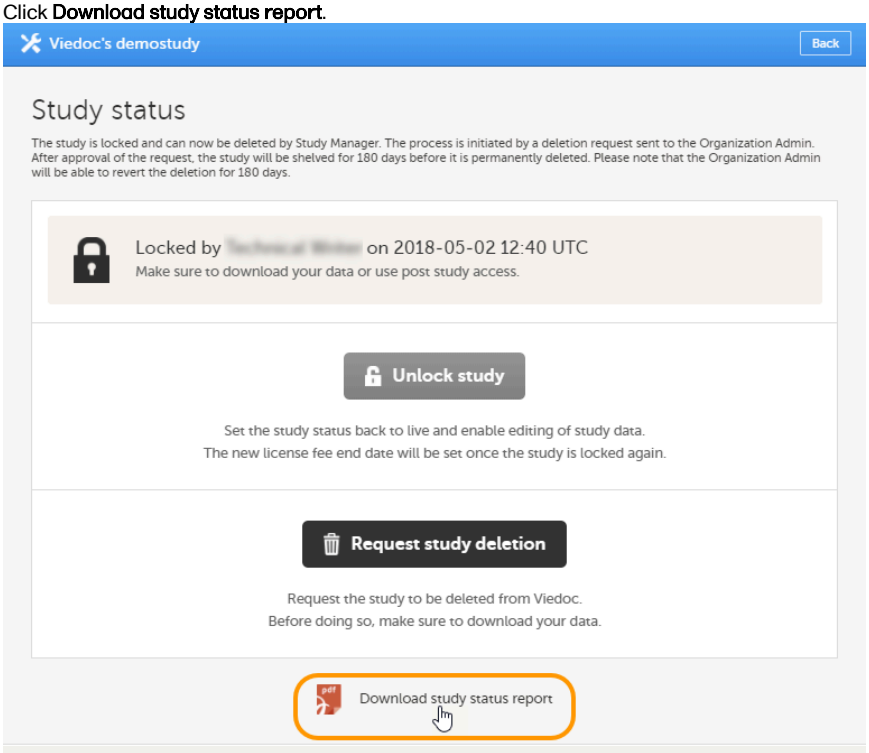
1 Open the study in Viedoc Admin and click **Study settings**.
The Study settings window opens.

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

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

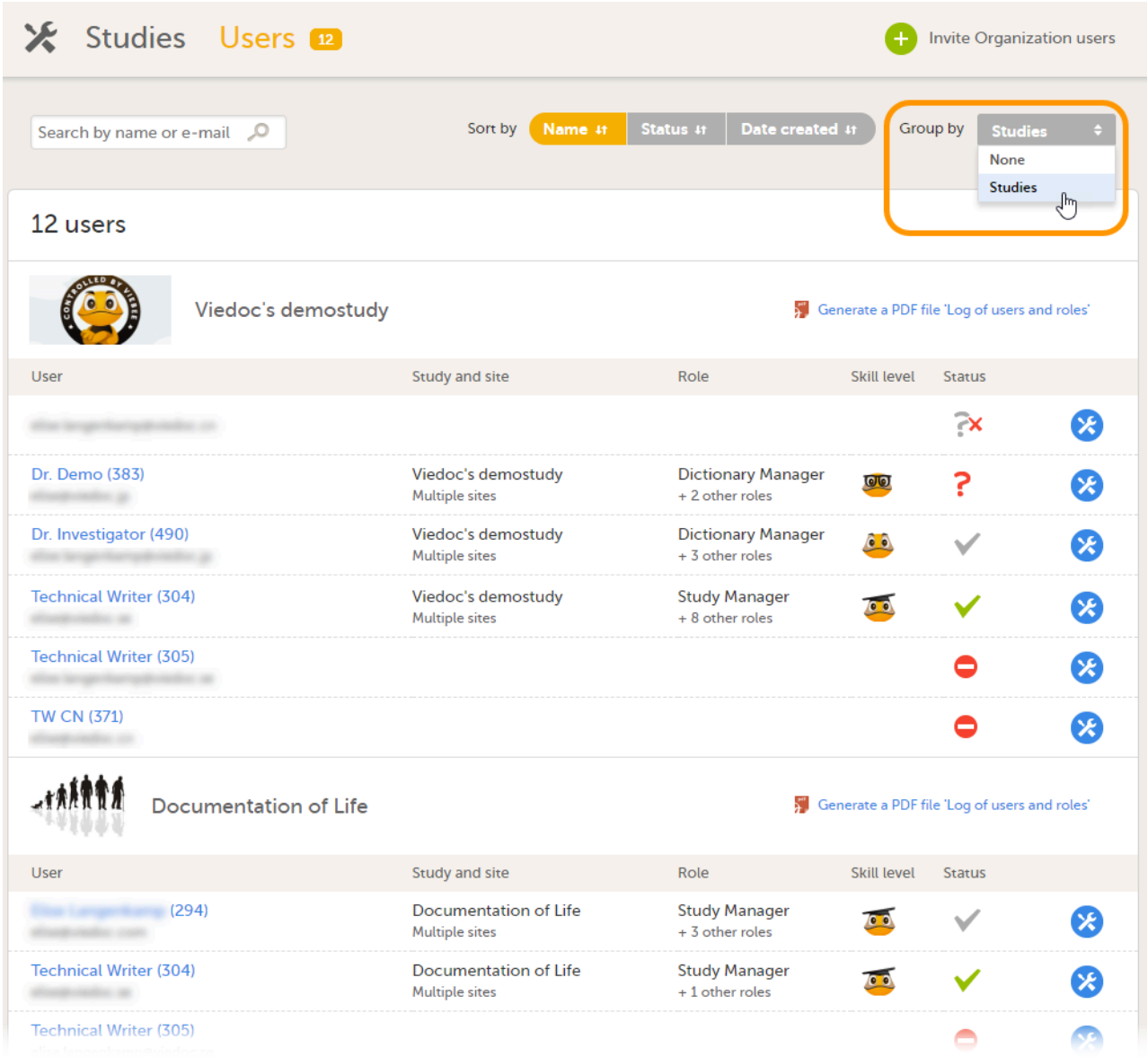
As part of the TMF structure, the sponsor should define the exact details of:

- 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*.



Scroll to the study from which you would like to download the user log and select **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 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

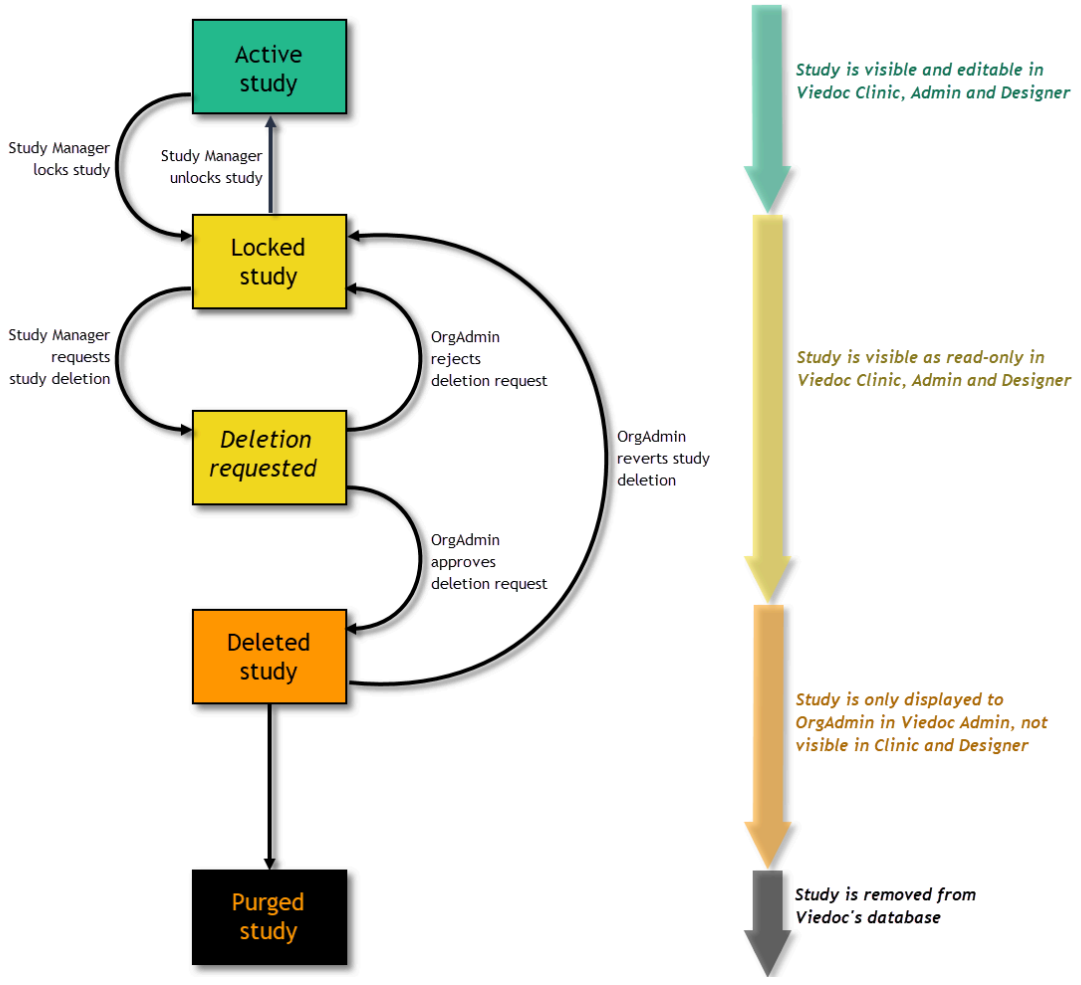
This lesson describes how a study is deleted. The instructions are intended for the Study Manager (STM).

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).

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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.

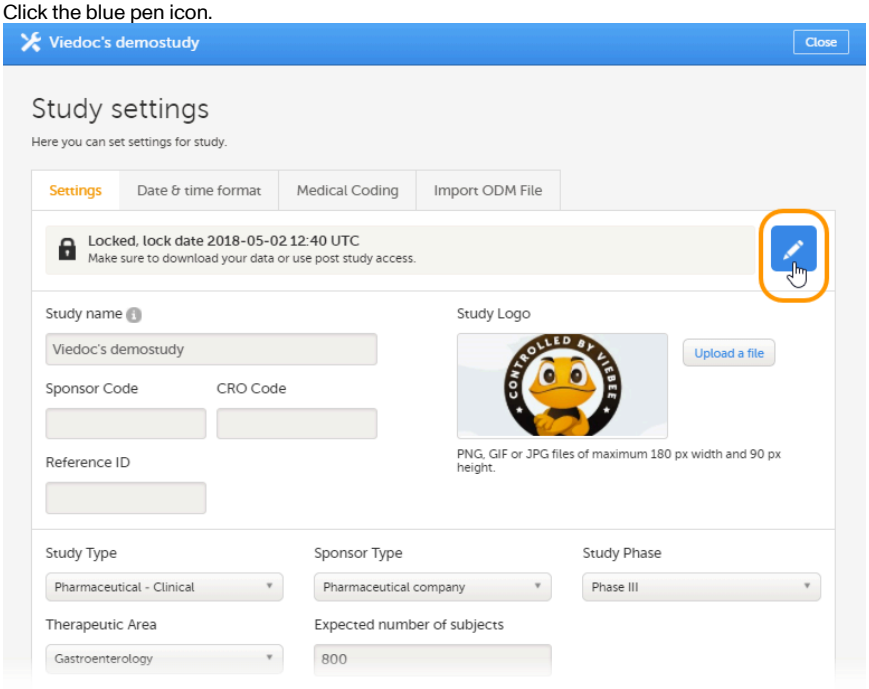
Note! Before deleting the study, make sure that you have downloaded the user report, the data export archive and the study design. Download and archive the study data in the formats necessary, available formats are Excel, Comma-Separated Values (CSV), Operational Data Model (ODM) and PDF. For instructions, 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:

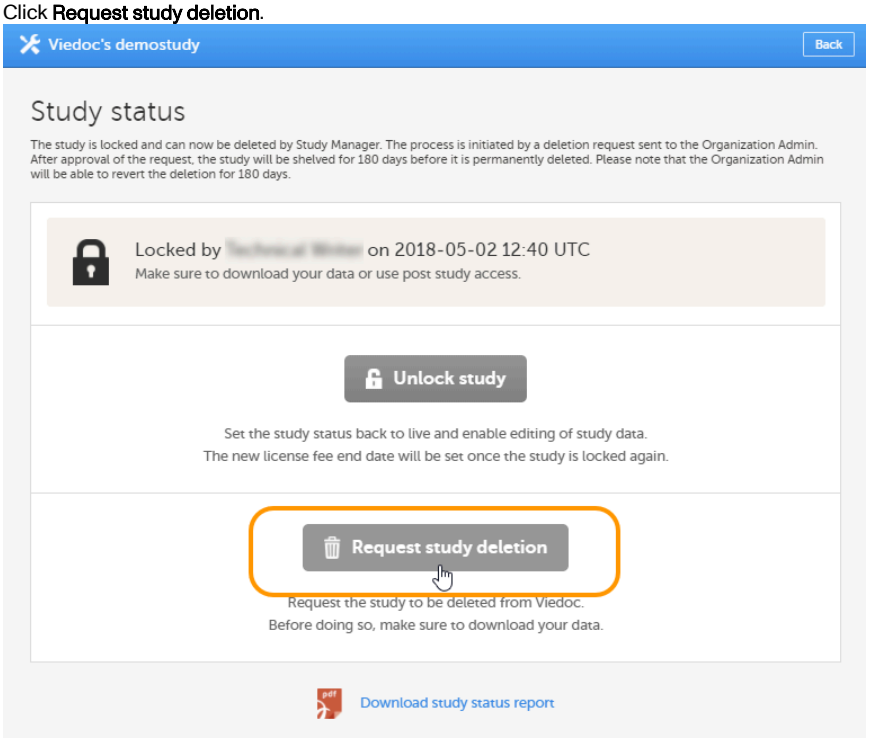
1 Open the study in Viedoc Admin and click **Study settings**.
The Study settings dialog opens.

2 Click the blue pen icon.



The study status pop-up opens.

3 Click **Request study deletion**.

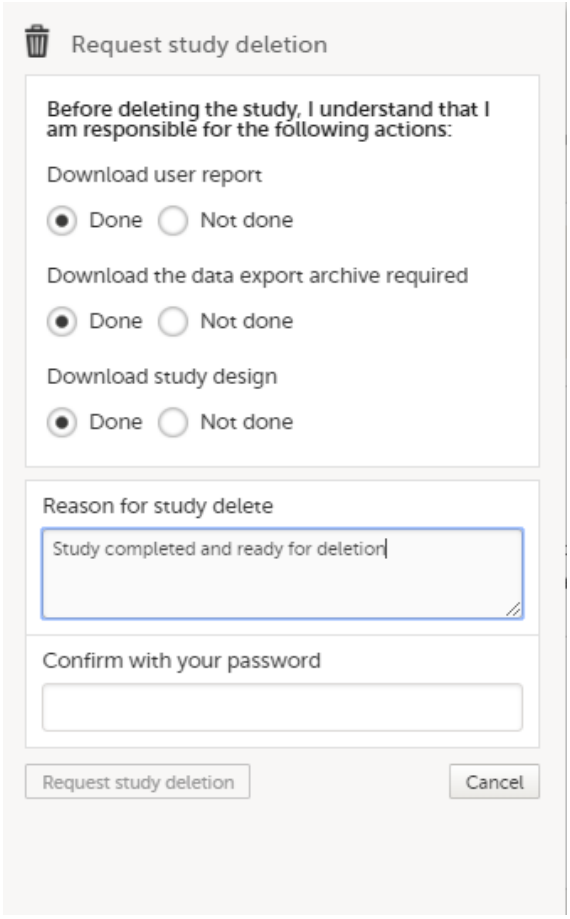


The request study delete pop-up opens.

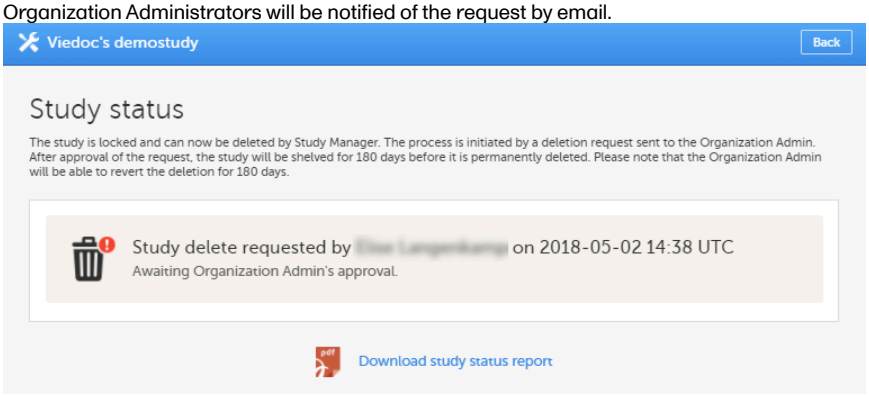
4 Select whether the following actions are done or not done:

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

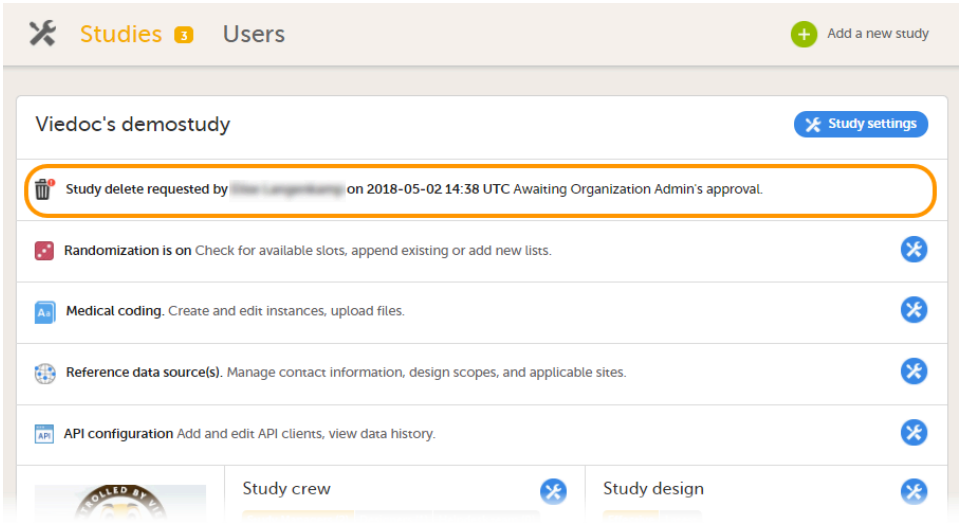
Enter a reason for deleting the study, and enter your password.



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.



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.

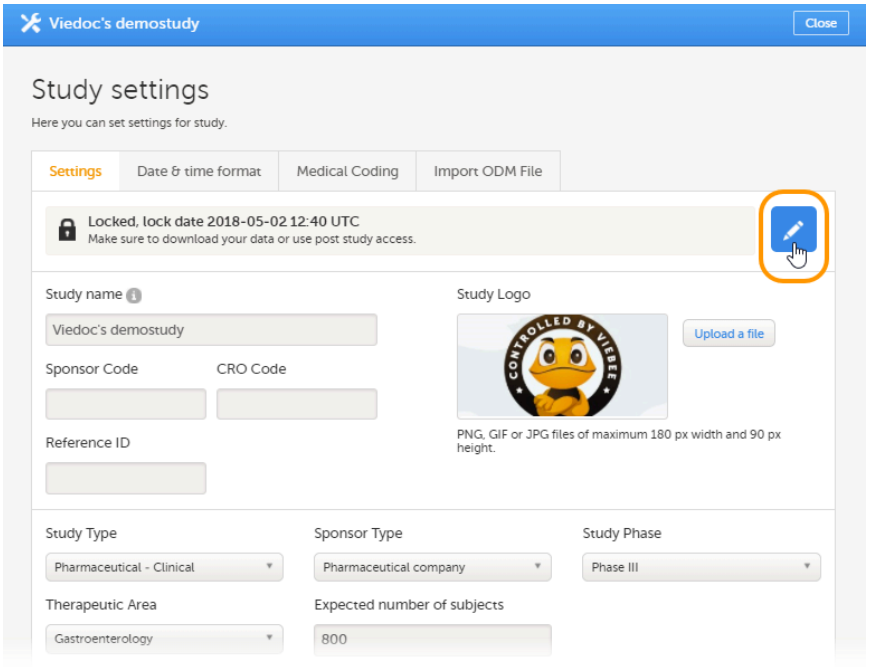


2.2 Downloading the study status report

To download the study status report:

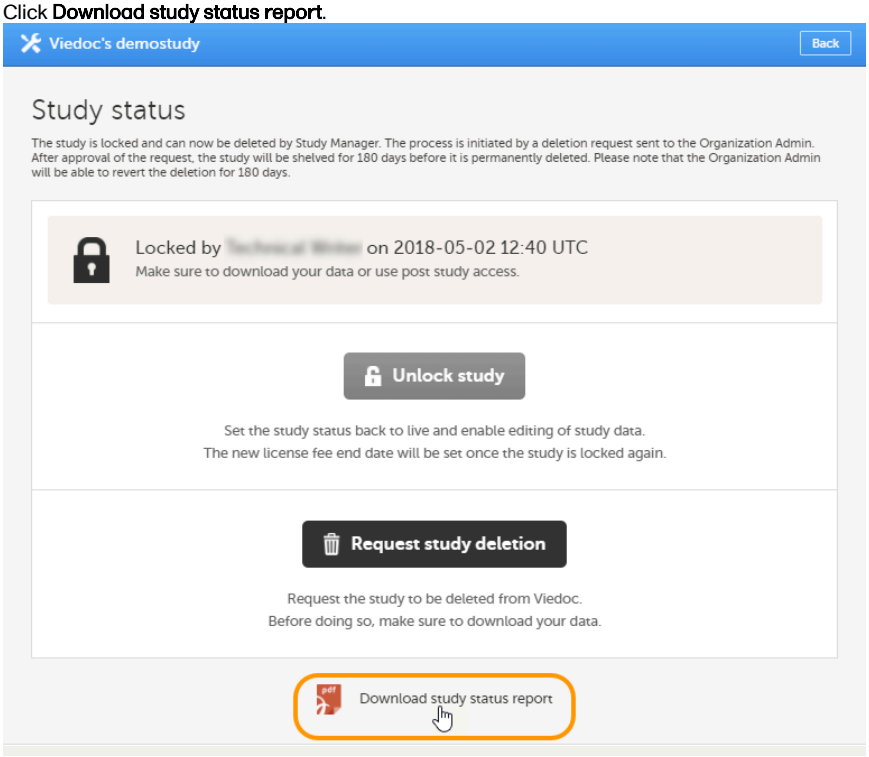
1 Open the study in Viedoc Admin and click **Study settings**.
The Study settings dialog opens.

2 Click the blue pen icon.



The Study status pop-up opens.

3 Click **Download study status report**.



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

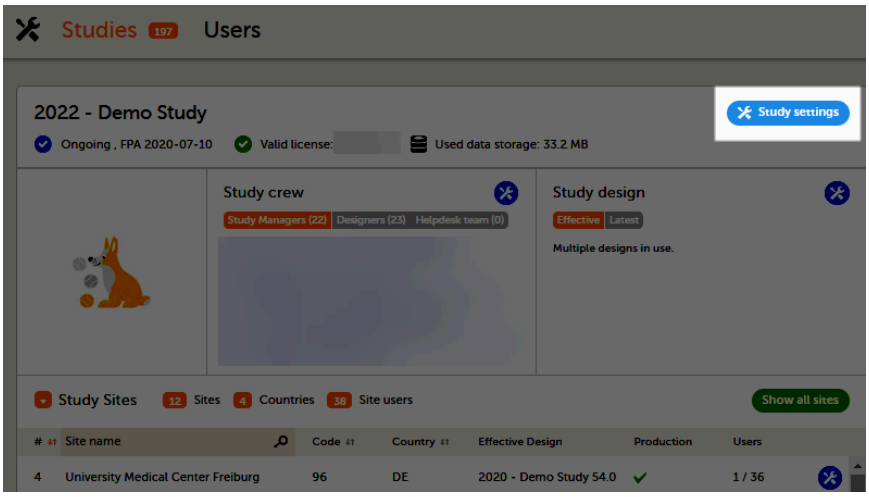
Published by Viedoc System 2024-10-10

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

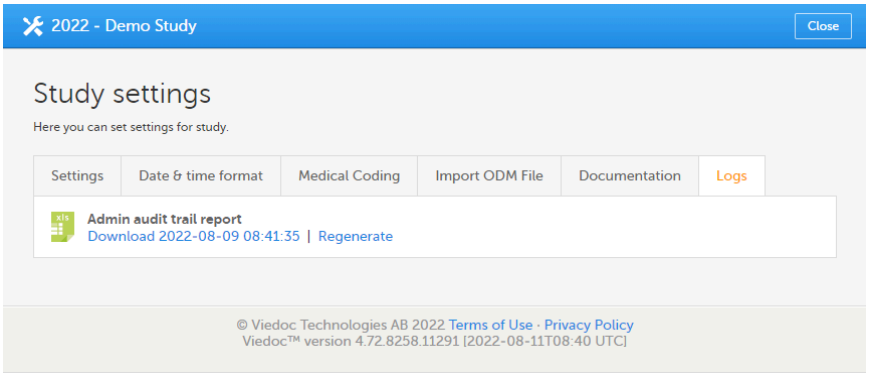
To download the Admin audit trail report:

1 In Viedoc Admin, open the study settings from the study details page.

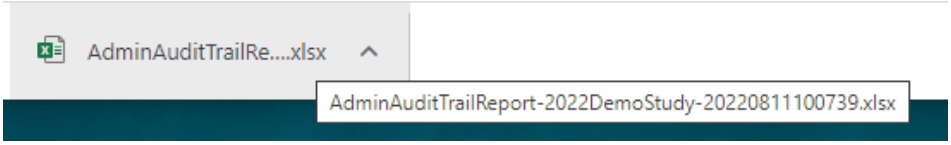


2 On the **Logs** tab, you can generate and download the Admin audit trail report.

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	• Enable • Map roles	*empty*	For the Enable action: If switched on, **Enable eTMF**, if switched off, **Disable eTMF** For the Map roles action: **Configure access to eTMF**
Medical Coding	• Create a new medical coding instance • Edit medical coding	For the edit medical coding instance action: The sequence and name	User-entered reason if available, otherwise the same as the action
Reference Data Sources	• Edit settings • Add reference data source • Edit • Delete	Unique identifier if available For the Add, Edit, and Delete actions: The sequence of the reference data source	For the Edit settings action: **Edit reference data sources settings** For the Add action: **Add reference data source** For the Edit action: **Edit reference data source** For the Delete action: **Delete reference data source**

Area	Action	Identifier	Reason
RTSM	▪ Approve settings ▪ Uploaded randomization list ▪ Add to randomization list ▪ Upload individual allocation list ▪ Add to individual allocation list ▪ Restart (For dynamic randomizations only): Create configuration, Edit configuration ▪ Approve global allocation list settings ▪ Mapping for global allocation list ▪ Upload global allocation list ▪ Add global allocation list	RTSM name or allocation name if available. For the actions on global allocation, the identifier is **Global allocation**.	The same as the action if not specified below. For all the actions that are performed on a specific Production or Demo mode, this is added to the reason, for example, **Upload randomization list - Production** For the Approve settings action: **Approve RTSM settings** For the Upload randomization list action: **Upload randomization list** For the Upload individual allocation list action: **Upload allocation list** For the Add to randomization list action: **Add to randomization list** For the Add to individual allocation list action: **Add to individual allocation list** For the Restart action: **Restart RTSM** For the Edit configuration action: **Edit RTSM configuration** For the Create configuation action: **Create RTSM configuration**
Site Settings	▪ Add new site ▪ Edit site	The site number	The same as the action
Study Design	▪ Assign design ▪ Apply revision	Design or revision name and version	The same as the action
Study Settings	▪ Add Study ▪ Edit study settings ▪ Edit date & time format ▪ Edit medical coding ▪ Import ODM file to Demo ▪ Import ODM file to Production ▪ Edit documentation ▪ Archive documentation ▪ Restore documentation ▪ Delete documentation ▪ Lock study ▪ Unlock study ▪ Request study deletion ▪ Approve study deletion ▪ Reject study deletion ▪ Revert study deletion ▪ Enable item level SDV ▪ Enable role-based queries	For the edit medical coding action: the coding scope For the documentation actions: the section name	For the Add study action: **Create study** For the other actions: User-entered reason if available. Otherwise, the reason is the same as the action.
User Invitations	▪ Invite user ▪ Delete invitation ▪ Reset password ▪ Resend invitation ▪ Remove user role from study	Unique identifier if available. For the reset password action: ▪ User = user display name ▪ Email = user email address	The same as the action
User Logs	▪ Generate log of users and roles ▪ Generate user administration log ▪ Generate user communication log	*empty*	The same as the action

Area	Action	Identifier	Reason
WCF API client configuration	▪ Add ▪ Edit ▪ Delete	Client ID (GUID)	For the Add action: **Add API client** For the Edit action: **Edit API client** For the Delete action: **Delete API client**
Web API client configuration	▪ Add ▪ Edit ▪ Delete	Client ID (GUID)	For the Add action: **Add API client** For the Edit action: **Edit API client** For the Delete action: **Delete API client**

Note! Some data might not be available for the actions performed before the release of Viedoc 4.72.

Design revision impact analysis

Design revision impact analysis

Published by Viedoc System 2024-06-27

Before applying a new design revision, Admin users with the system role Design Impact Analyst can use the design revision impact analysis tool to perform an impact analysis. The analysis shows the number of existing form instances per site that will require confirmation by site staff, regardless of who created the revision.

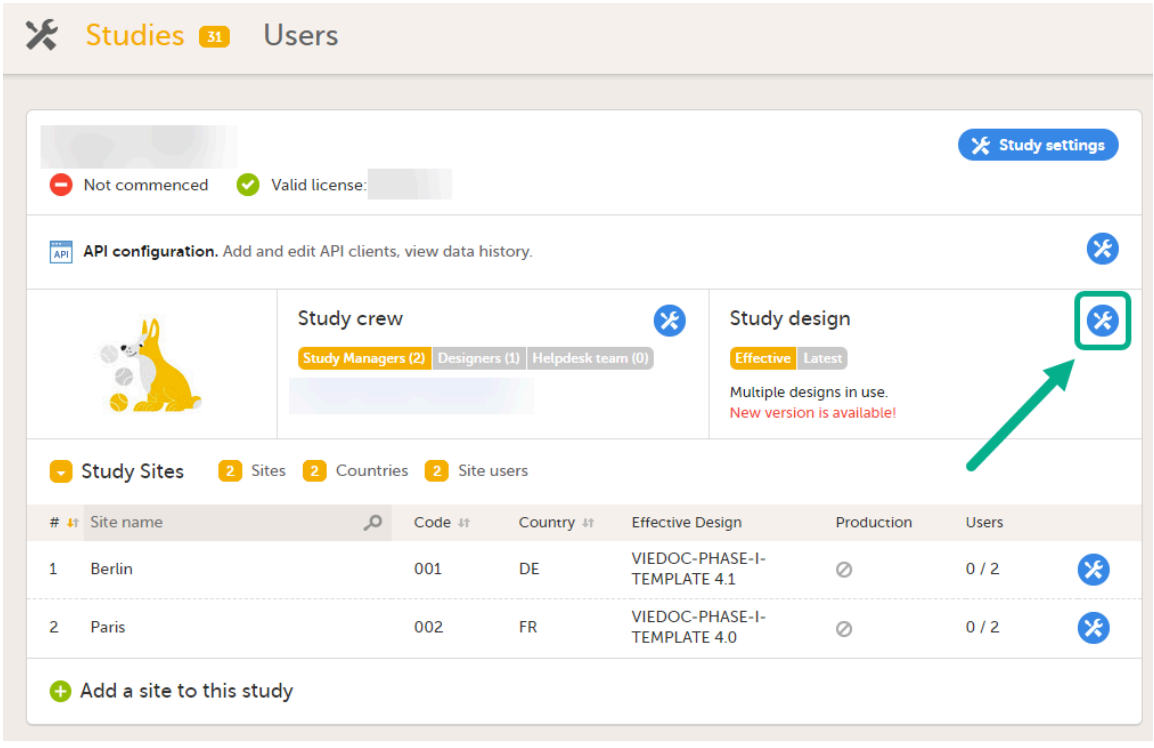
Important! It is recommended that this revision impact analysis is used before applying any revision.

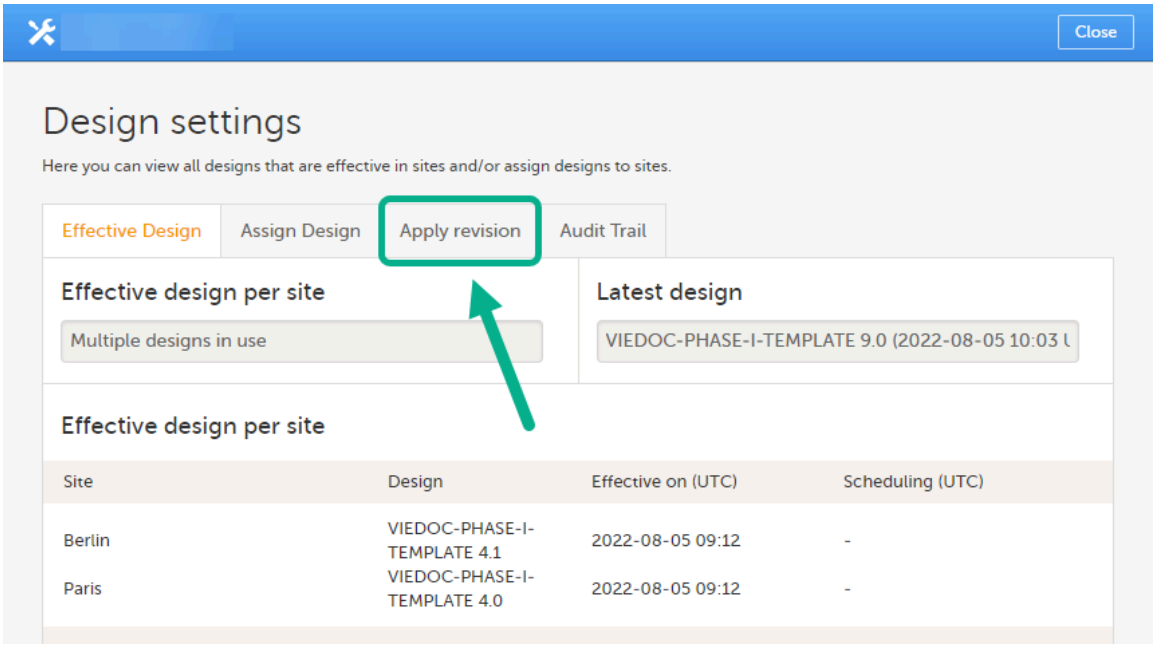
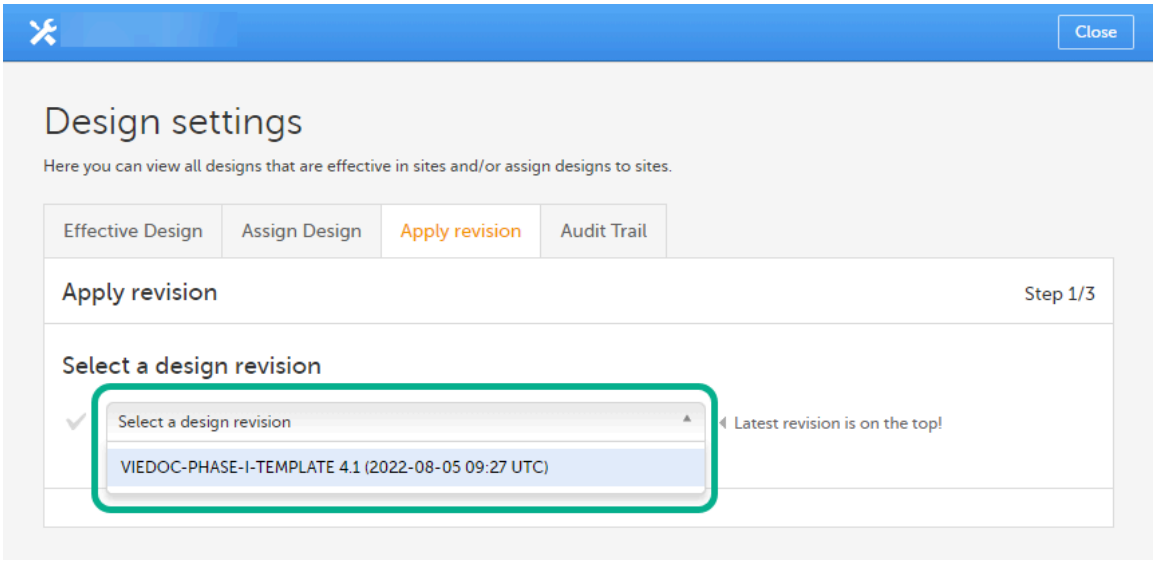
1 The design revision impact analysis report

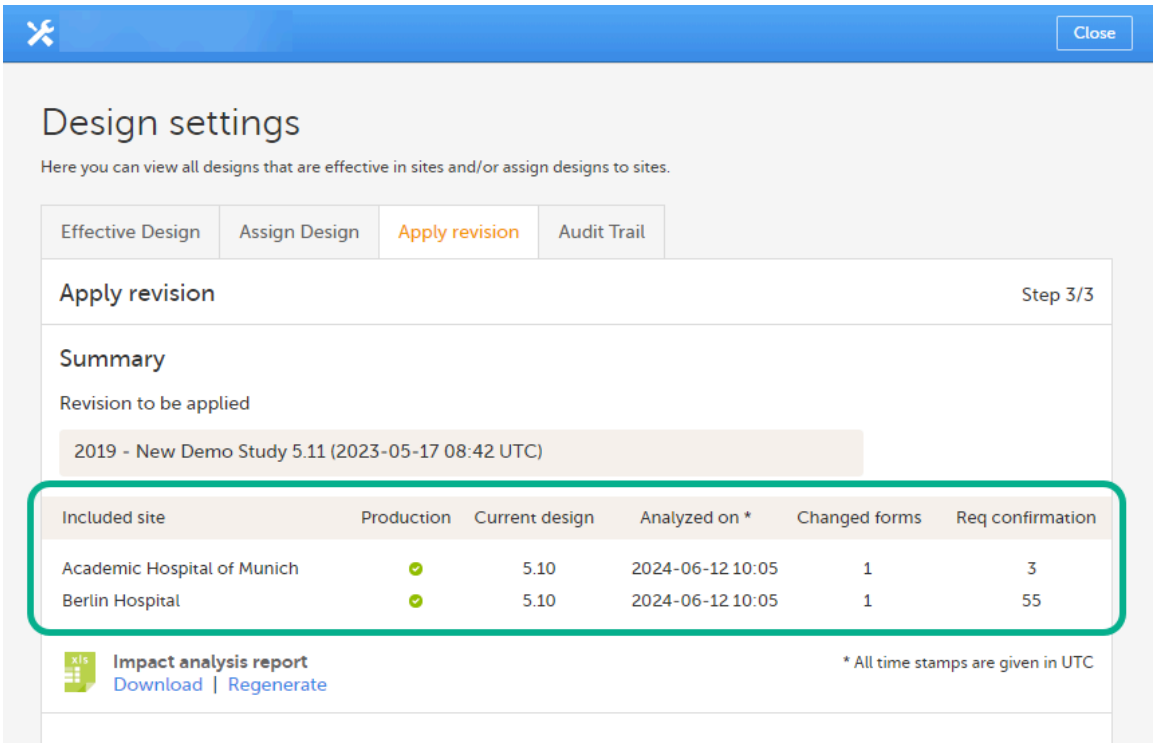
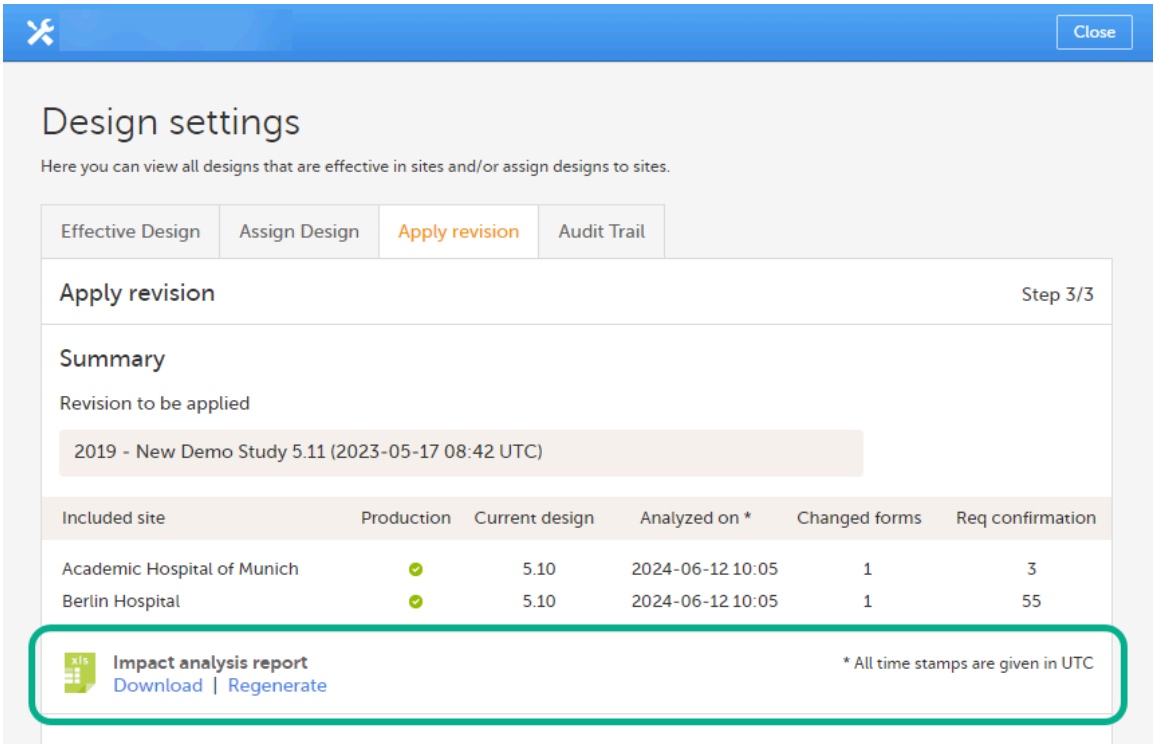
The Design Impact Analyst can generate, regenerate, and download the Excel report.

1.1 Generating the Excel report

To generate the Excel report:

1	In Viedoc Admin, select your study.
2	Select **Edit** in the **Study design** section. 

3	In the **Design settings** window, open the tab **Apply revision**. 
4	On the tab **Apply revision**, select a design revision in the dropdown menu. 
5	Select **Continue** to go to the next step.
6	Select the sites where the revision will be applied.
7	Select **Continue** to go to the next step.

8	In step 3, you'll see a summary of the revision. The table includes a column called **Req confirmation**, which is the number of existing form instances that will require confirmation from site staff. The time of the latest performed impact analysis per site is shown in the table. 
9	If this is the first impact analysis, you can select to **Generate** the report. Then select **Download**. For subsequent sessions, you can select **Download** or **Regenerate**. 

1.2 The contents of the Excel report

The Excel report contains these sheets:

- **Summary** - general information about the report
- **Production** - the forms for subjects at the analyzed production sites
- **Training** - the forms for subjects at the analyzed training sites

The **Summary** sheet shows the number of forms that will potentially lose their status regarding these parameters:

- Signature

- SDV
- Clinical Review
- Data Review

Note! By default, the contents of the Excel sheets **Production** and **Training** are filtered to show only the rows that have the value **Yes** in the column **Req confirmation**.

The **Production** and **Training** sheets contain these columns:

Column	Description
Site Code	The site code, as defined for the study
Site Name	The site name, as defined for the study
Current Design	The version and revision number of the currently used design for the site
Revision being analyzed	The version and revision number of the design revision that is being analyzed
Subject Key	The subject key
StudyEventDefId	The ID of the study event
StudyEventRepeatKey	The number of repeats of the study event
FormDefId	The form ID
FormRepeatKey	The number of repeats of the form
ActivityDefId	The activity ID
FormEditStateLocked	**Yes** - if the form was locked for edit when the report was generated **No** - if the form was NOT locked for edit when the report was generated
Req confirmation	**Yes** - if the form instance will require a confirmation by site staff after the revision has been applied **No** - if the form instance will NOT require a confirmation by site staff after the revision has been applied
Signed	**Yes** - if the form instance is signed **No** - if the form instance is NOT signed
SDV	**Yes** - if the form instance has been SDVd **No** - if the form instance has NOT been SDVd
ClinicalReview	**Yes** - if the form instance has undergone a clinical review **No** - if the form instance has NOT undergone a clinical review
DataReview	**Yes** - if the form instance has undergone a data review **No** - if the form instance has NOT undergone a data review
PMS side	Note! This column is only available for PMS studies. **Clinic** - if the form belongs to the Clinic side of the PMS study. Forms that are submitted but not yet received belong to the Clinic side. **Sponsor** - if the form belongs to the Sponsor side of the PMS study

2 Unblinding

It is important to understand that the revision impact analysis provides a lot of details about the upcoming revision, and it might even be unblinding in certain circumstances.

If a study design uses role-based visibility for items that could reveal the subject's treatment, **and the mere presence of the item** is unblinding, the revision impact analysis could reveal which treatment the subject is on.

For this reason, the permission to view and generate the revision impact analysis is isolated to a dedicated user role, and we recommend caution before you invite a user with this role.

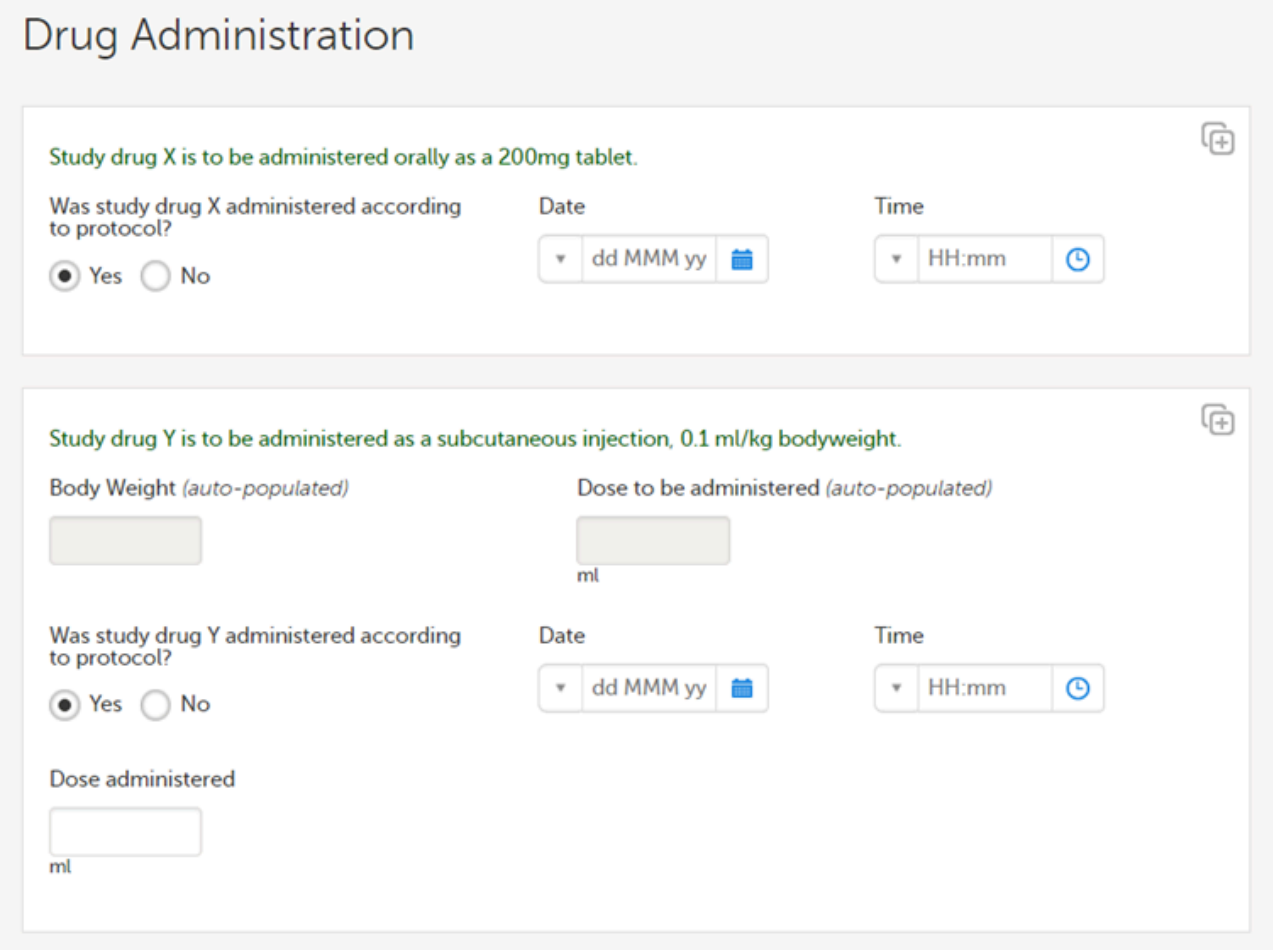
2.1 Example 1

A CRF design uses a role called treating investigator and another called evaluating investigator. The treatment is blinded to all users in the study except for the treating investigator.

The RTSM settings for the design uses a non-blinded outcome to display the treatment, but this is only visible to the treating investigator.

Subjects are assigned to treatment X or treatment Y.

Based on the assigned treatment, in the randomization form, the form **Drug Administration** is triggered. This form is filled in by the treating investigator and hidden to all other users because this is also revealing the treatment of the subject.



The first item group is only displayed to subjects assigned to treatment X, and the second item group is only displayed when the subject is assigned to treatment Y.

Let's assume that there are complaints on this CRF design, and the second item group is changed in a revision by changing the label of the final item from **Dose administered** to **Actual dose administered** for clarity. The revision impact analysis will then show which forms, and for which subjects, forms are requiring a manual upgrade - this would be all subjects that have been assigned to treatment Y. This is where the revision impact analysis would be unblinding.

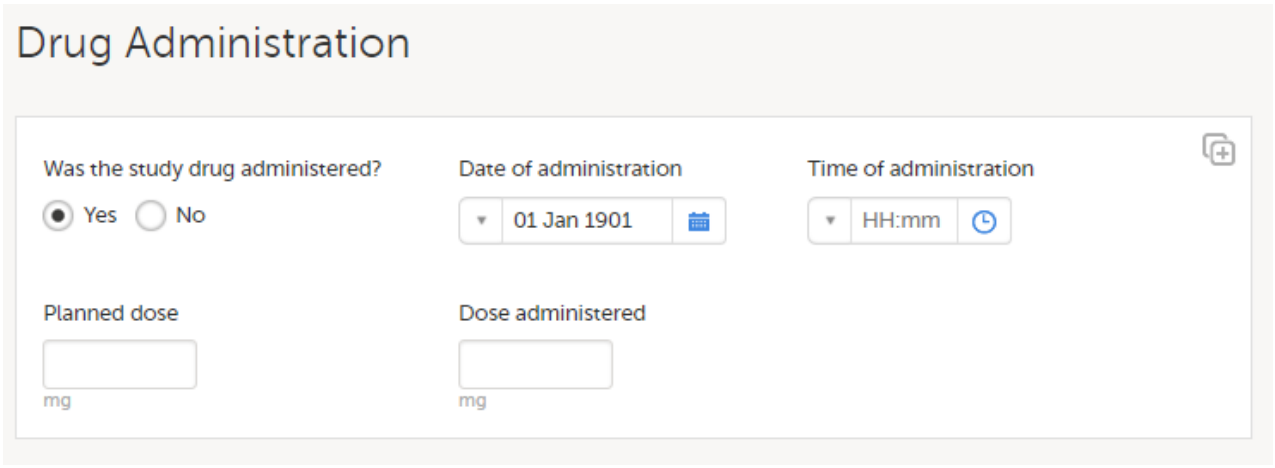
In a scenario like this, we recommend that an unblinded user in the study team is invited with the Design Impact Analyst role to avoid unblinding to other members of the study team.

Note! If a designer has access as a Design Impact Analyst, this user could theoretically identify the treatment of each subject by creating a revision with changes to sensitive items (as described above), with the sole purpose to see the impact in the impact analysis report, and afterwards deleting the revision. For this reason, we recommend that the Design Impact Analyst role is not given to a designer when the CRF is designed according to the example above.

2.2 Example 2

A similar study is using the same approach with the roles treating investigator and evaluating investigator. The difference is that, in this CRF design, dosing details for treatment X and treatment Y are captured in the same form, using the same item. The difference between subjects assigned to the different treatments will be the values in the items rather than the presence of certain items.

If a change to a label is done in a revision, the revision impact analysis will NOT be unblinding, because all randomized subjects are expected to have the same items.



In a scenario like this, any user of the study team could be invited with the Design Impact Analyst role, as this will not risk unblinding other members of the study team. The recommendation is to invite users that would be responsible for applying the revision to this role so they can see the impact before they apply a revision.

Thus, if a study design uses role-based visibility for items that could reveal the subject's treatment, **and the mere presence of the item** is unblinding, the revision impact analysis could reveal which treatment the subject is on.

Viedoc study configuration management

Viedoc study configuration management

Published by Viedoc System 2024-12-03

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.

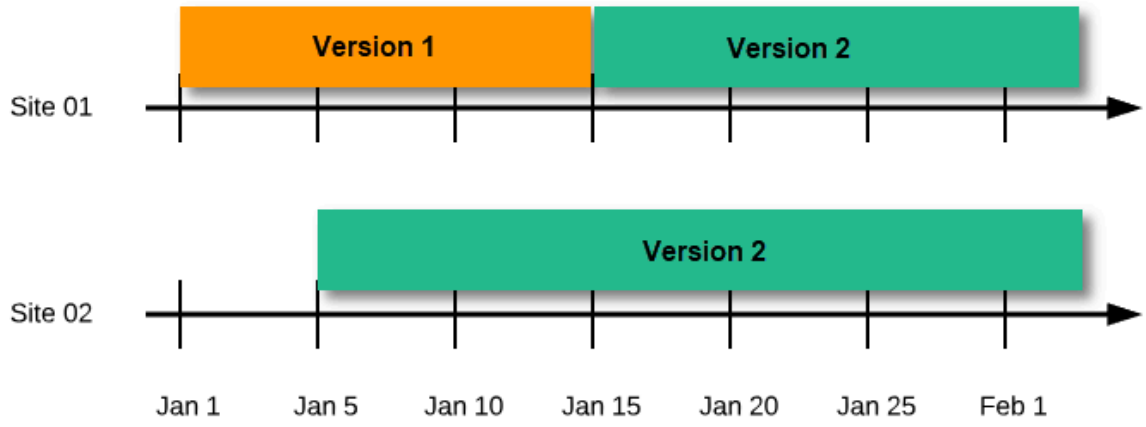
Notes!

- 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.
- Events that are added using the automatic event date functionaility will burn-in the current effective design.

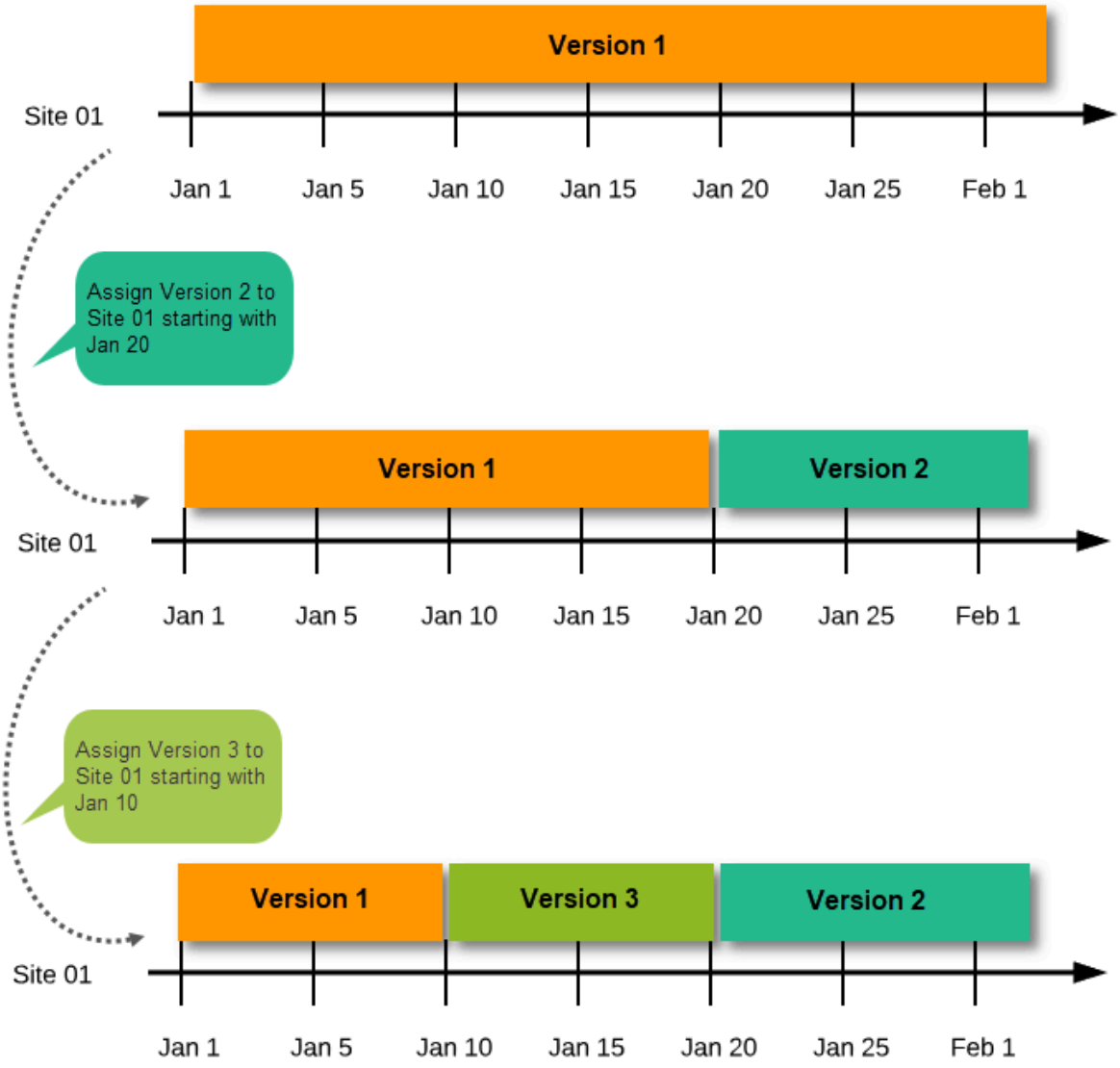
For more details on the automatic event date settings, see the Study workflow lesson.

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 1st, this is the effective version until a new version with a later start date is encountered, independently of when it was assigned.

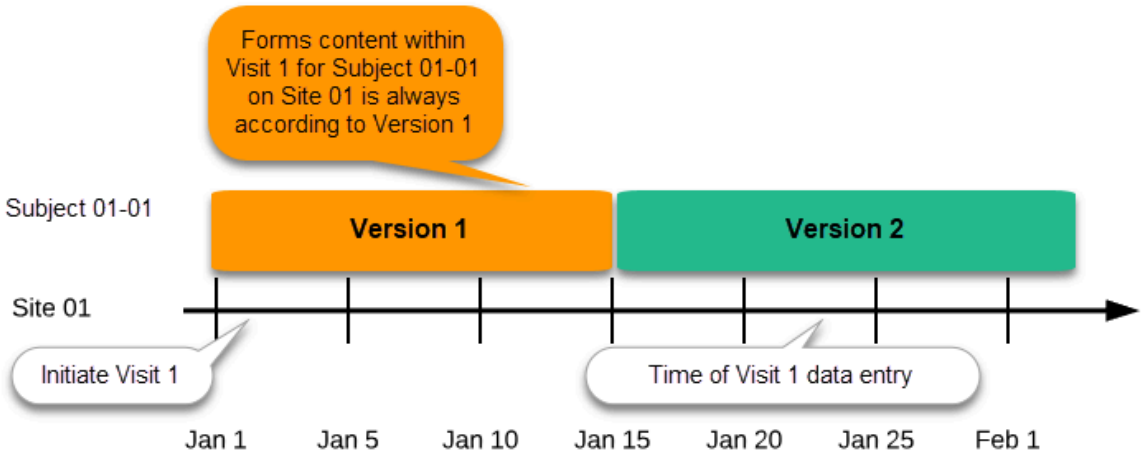


Important! The periods of effectiveness of a study design version are connected to the event timing of the first data entry and not to the current time at system usage.
For example, in the below image, if:

- Version 1 is effective between January 1st - January 15th for Site 01.
- Version 2 is effective starting with January 16th for Site 01.
- Event 1 is initiated on January 2nd for Subject 01-01 on Site 01.

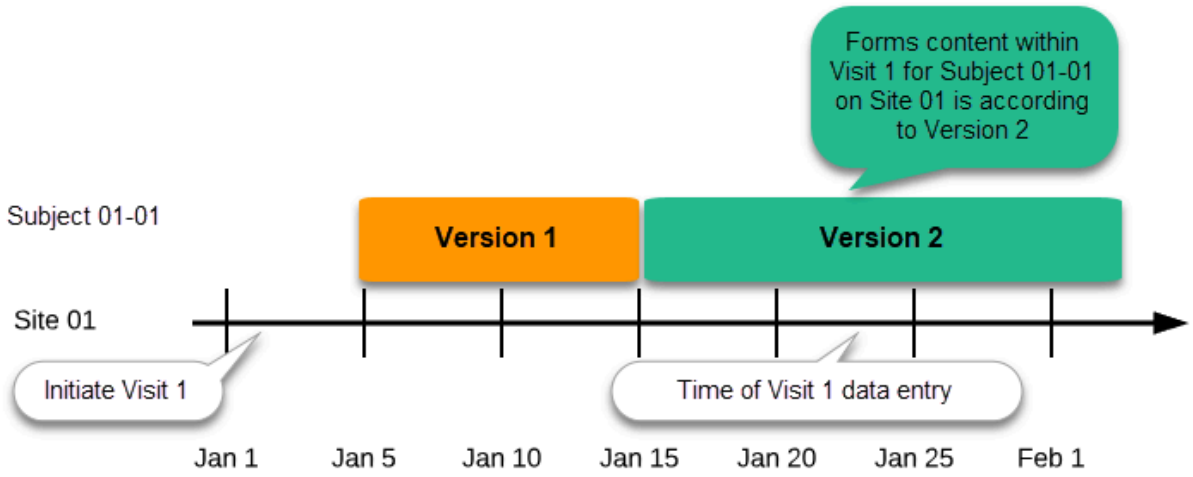
...then:

- 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

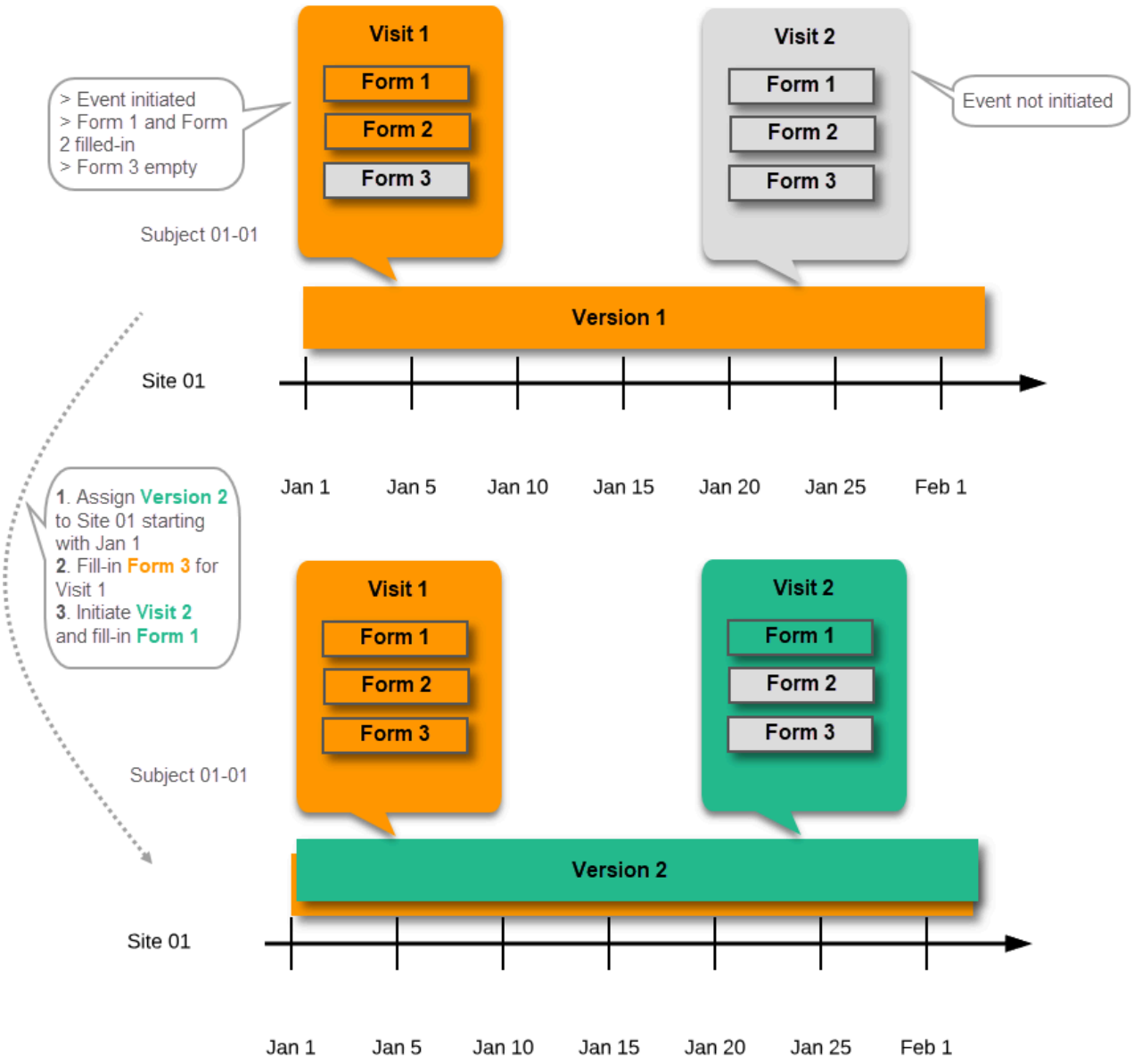
A new version can be assigned with the same timing as the currently assigned version and will then replace the currently assigned version, except for already entered data (due to the version "burn-in", as described in Version burn-in).

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

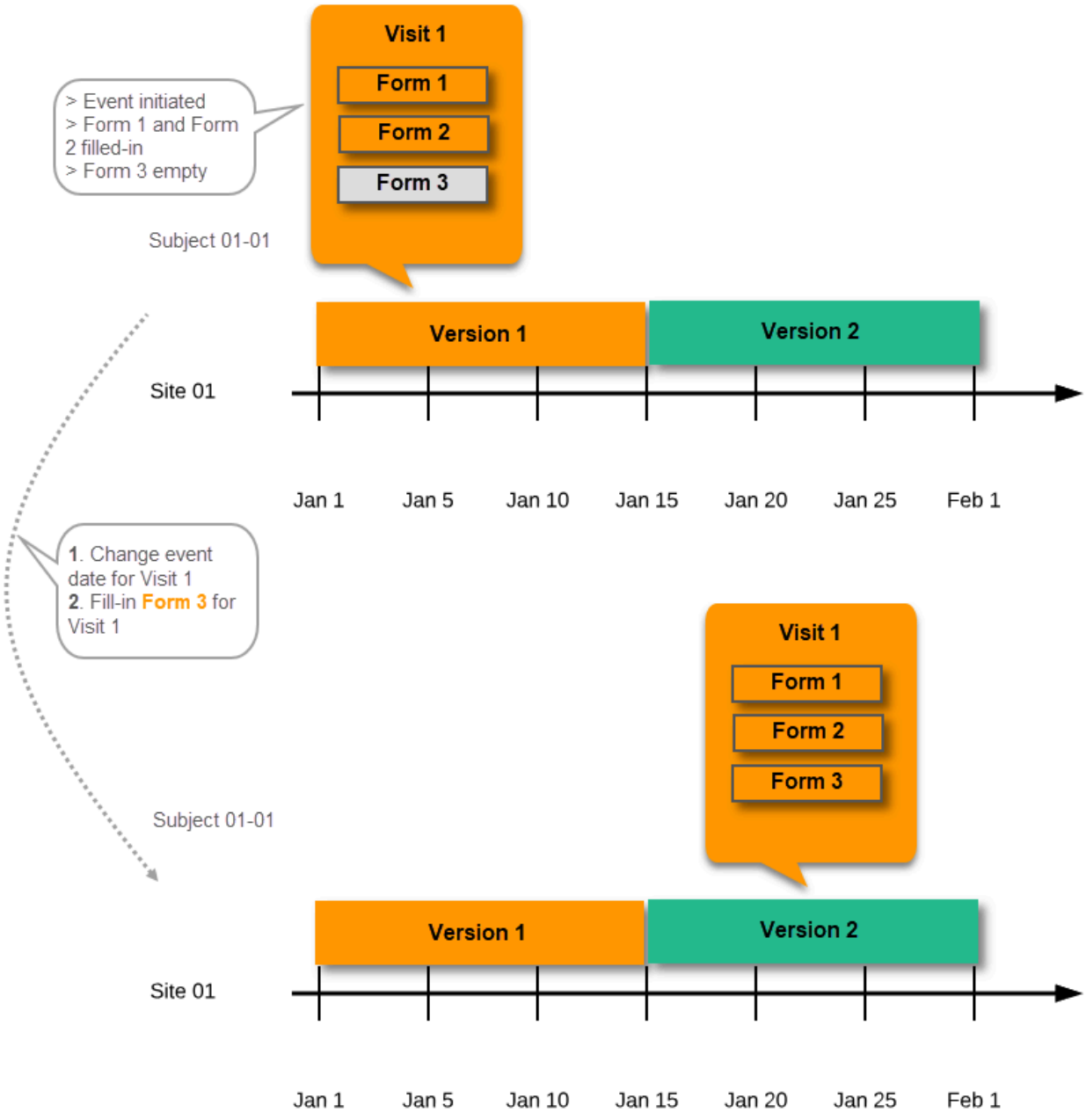
...and we assign Version 2 to Site 01 starting at Jan 1, and then:

- 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

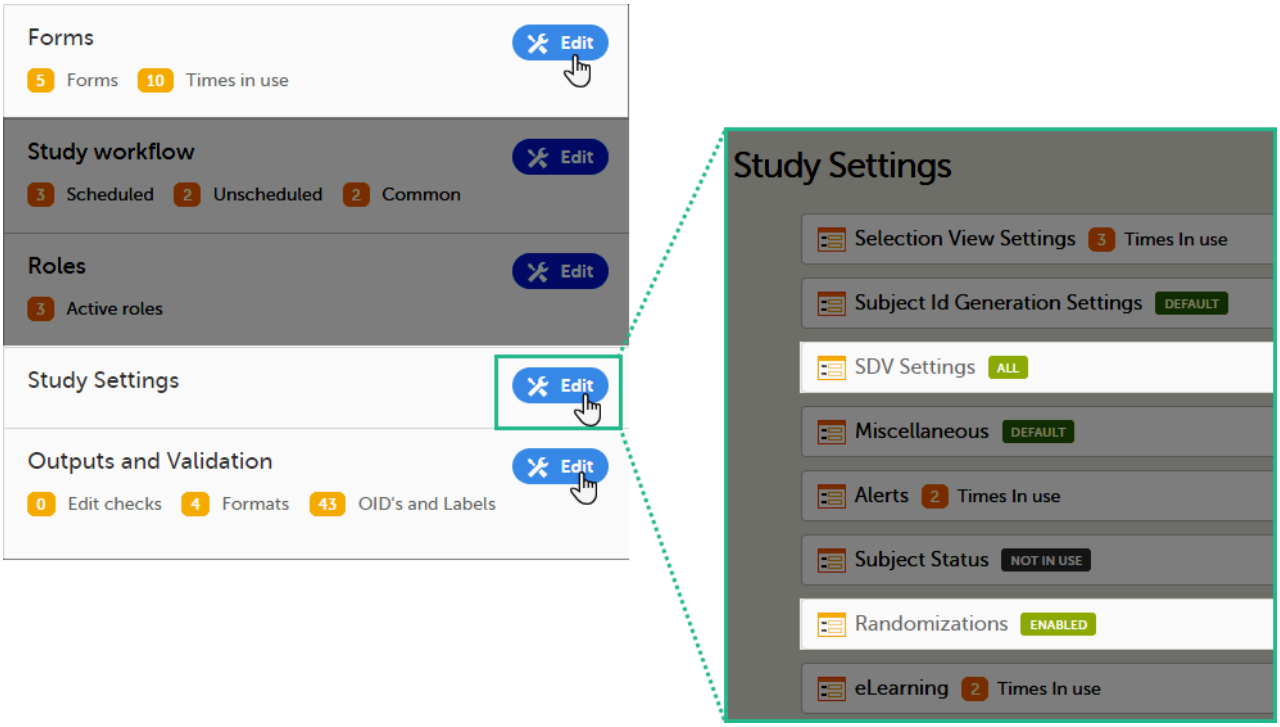
In case the event date is changed after it was initiated, to a date when another version is applicable, the version for that event does not change, as it was burnt-in at the date when the event was initiated (see Version burn-in):



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

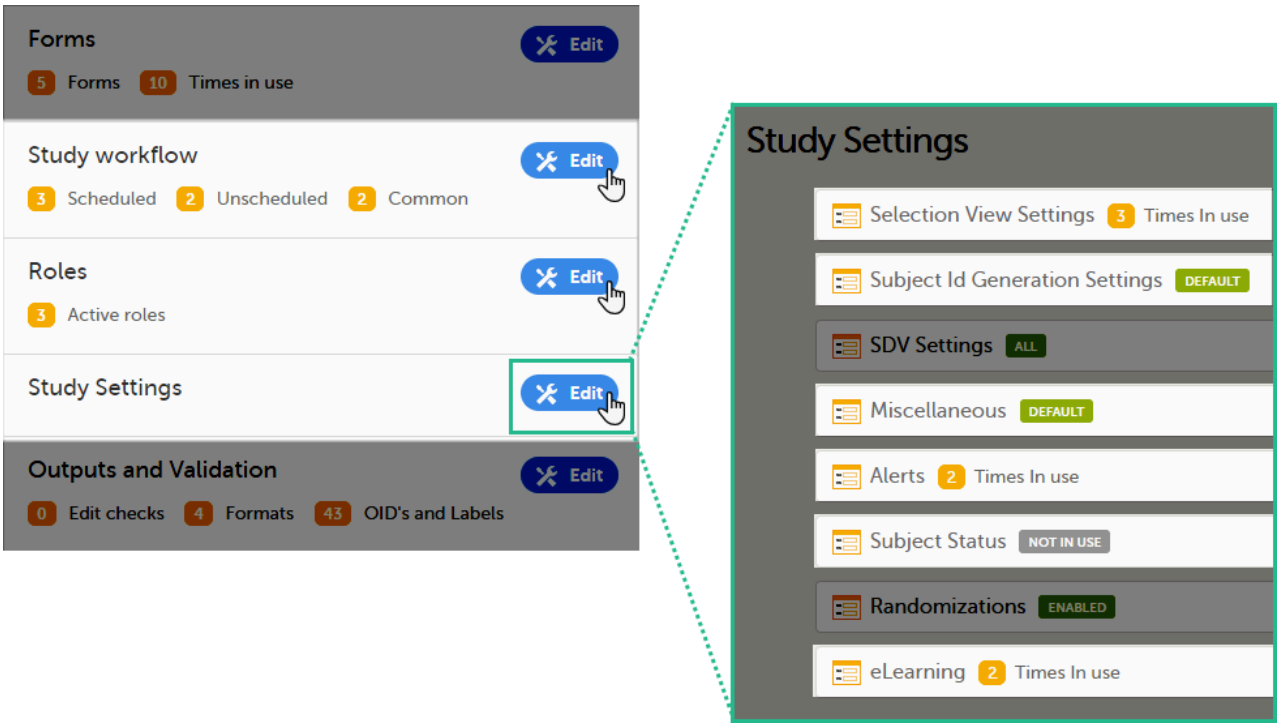


2.7 Settings read from current effective design

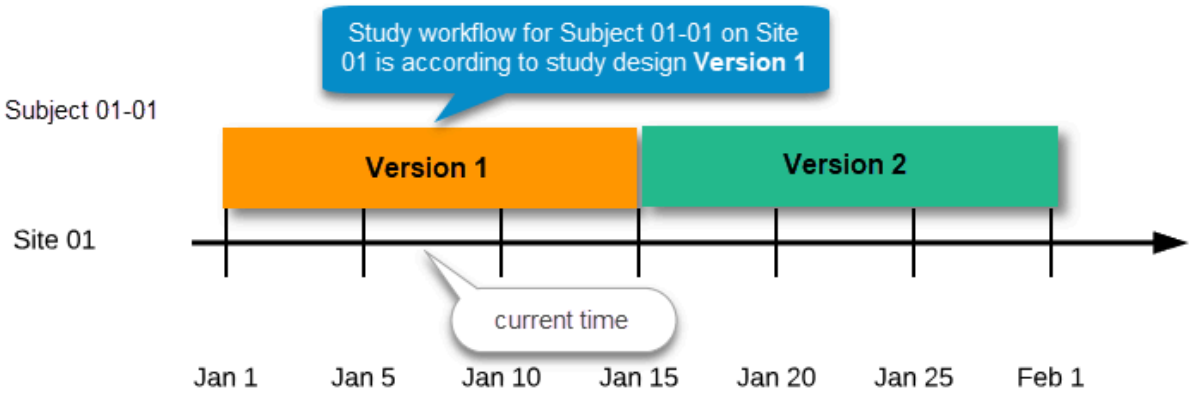
We call "current effective design" the study design version that is effective at the current time of system usage.

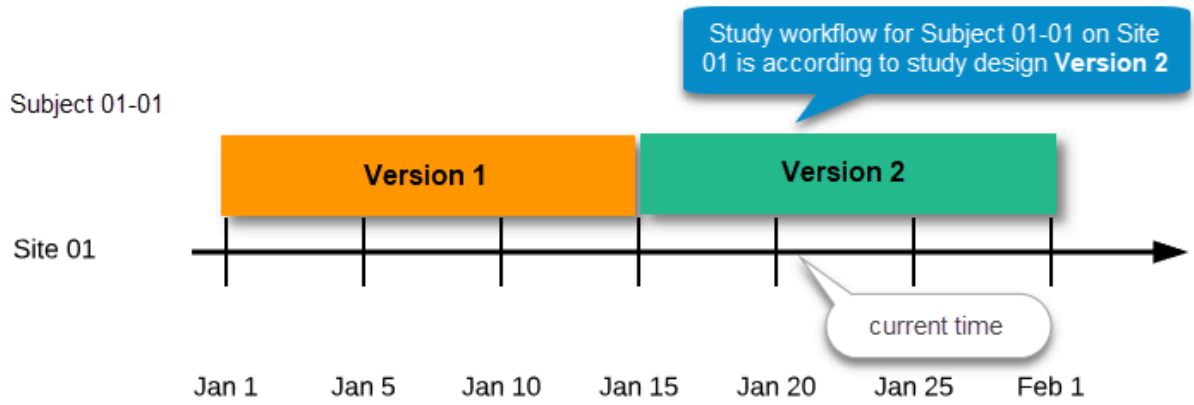
Settings that are not directly related to data collection structure, as well as settings that are common on the site level, are read from the study design version that is effective at the time of system usage (that is, “time right now”). These settings are:

- 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.

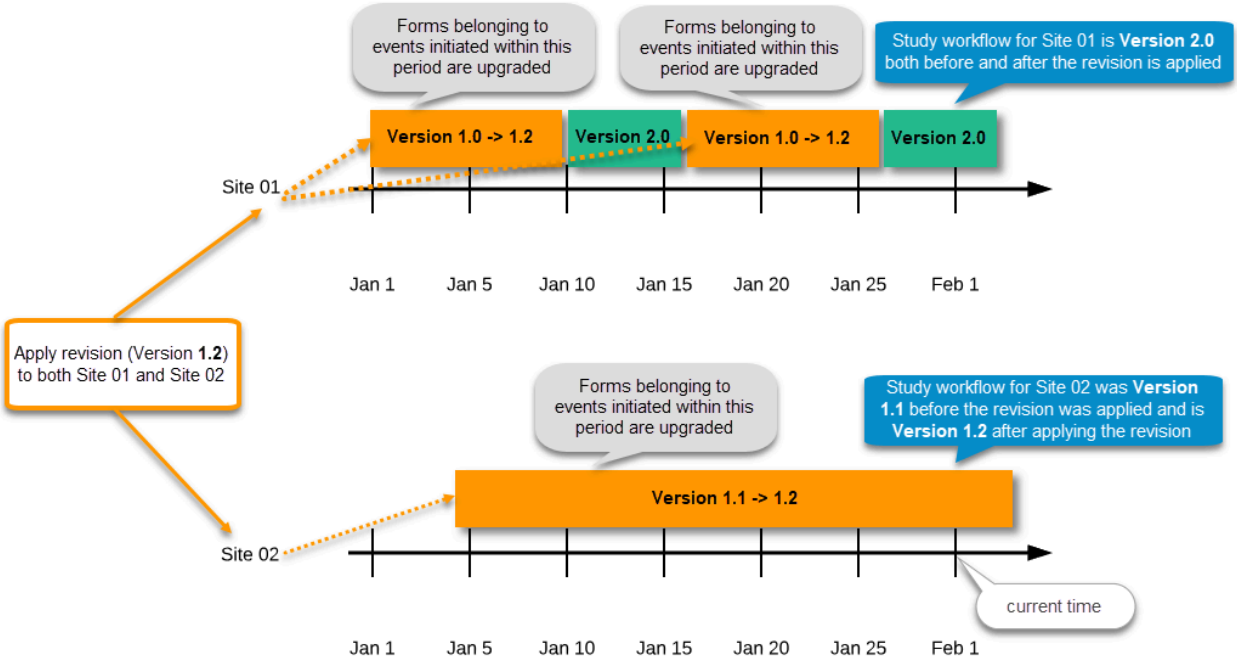
Additionally, only the latest revision of each study design version can be used as starting point for additional revision. For example, if we want to revise study design version 1, that has already been revised to version 1.1, we can only select 1.1 as starting point of the revision and not 1.0.

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.

Note! It is recommended that you use the design revision impact analysis before you apply any revision. For more information, see Design revision impact analysis.

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.

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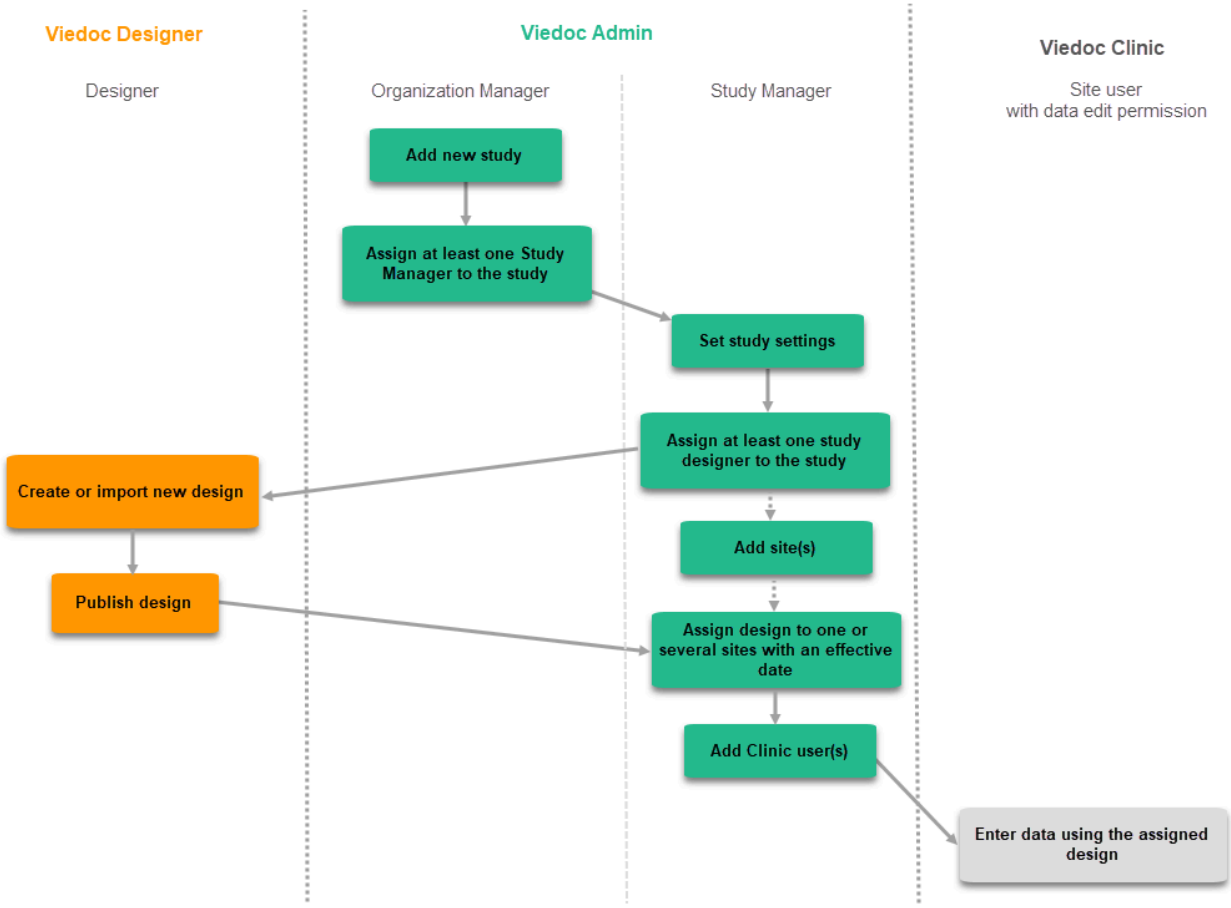
3 Configuration workflow

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:

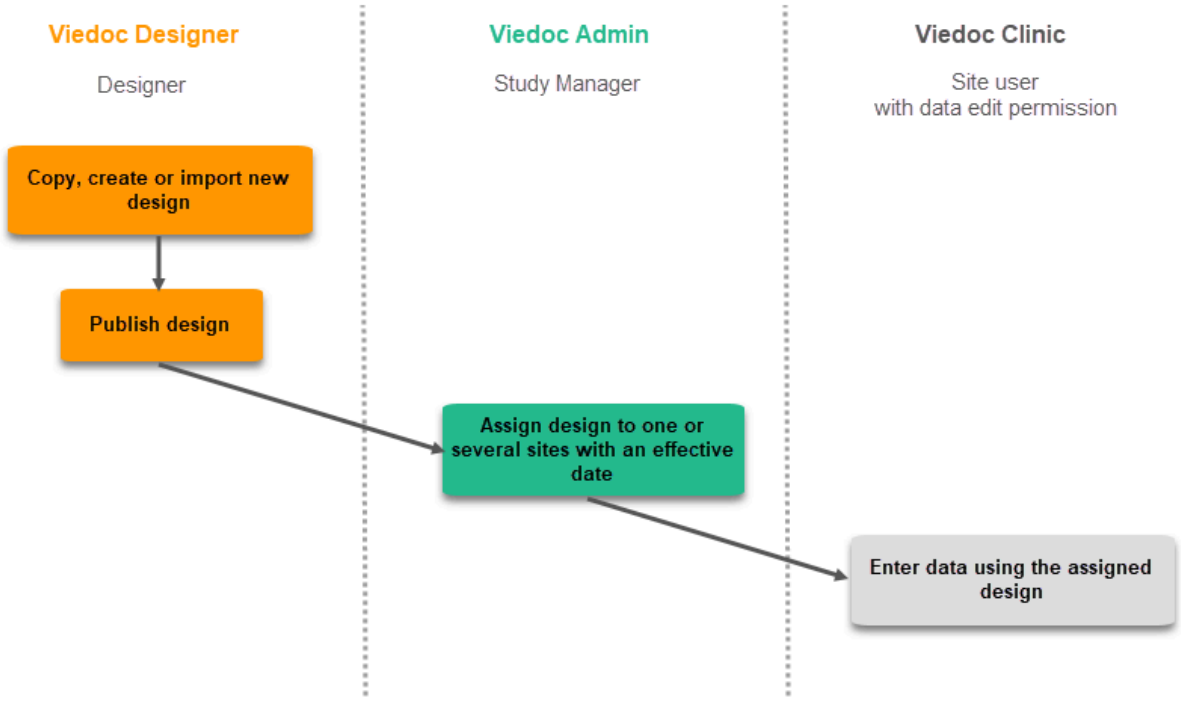
1. In Viedoc Admin, the Organization Manager creates the new study and appoints a Study Manager.
2. In Viedoc Admin, the Study Manager sets the non version-controlled common settings and appoints a Designer.
3. In Viedoc Designer, the Designer creates the first version of the version-controlled settings 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:

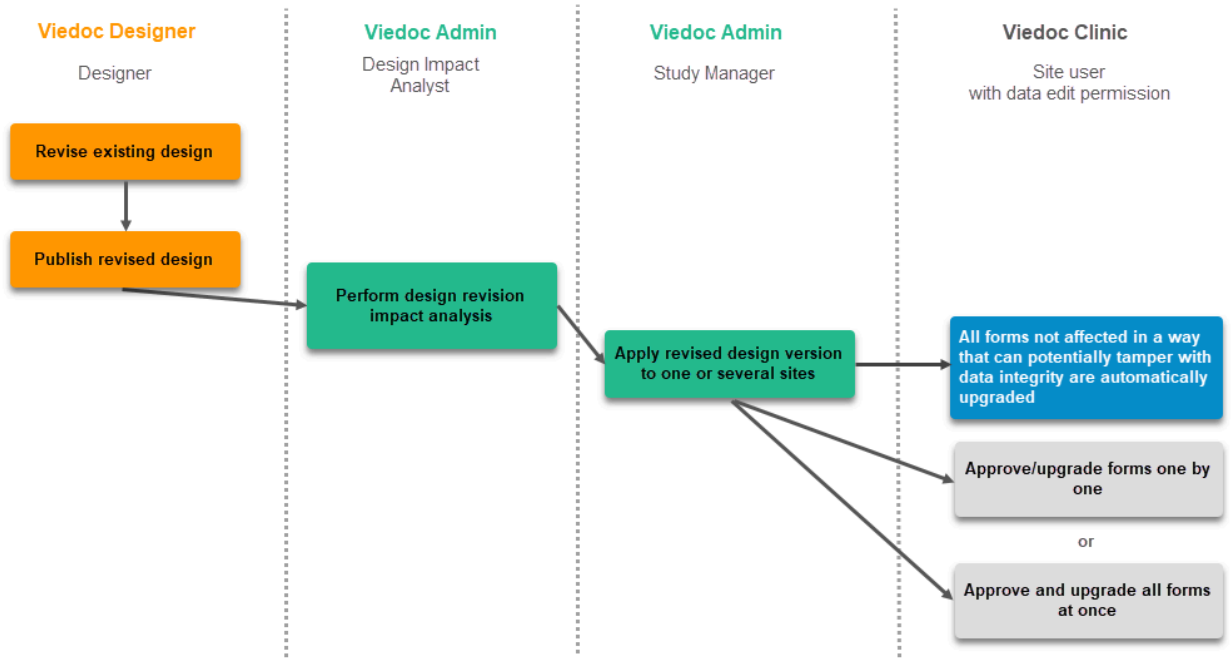
1. In Viedoc Designer, the Designer makes a full copy of the existing version of the study design.
2. In Viedoc Designer, the Designer makes the additional settings required by the protocol amendment and then publishes the design, which then becomes available in Viedoc Admin.
3. In Viedoc Admin, the 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 Design Impact Analyst performs the revision impact analysis. For more information, see Design revision impact analysis.
4. 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.

Managing the study design

Published by Viedoc System 2024-12-03

This section explains how to assign a design to sites in a study. It is necessary to assign a study design to the sites in the study to start work on the site.

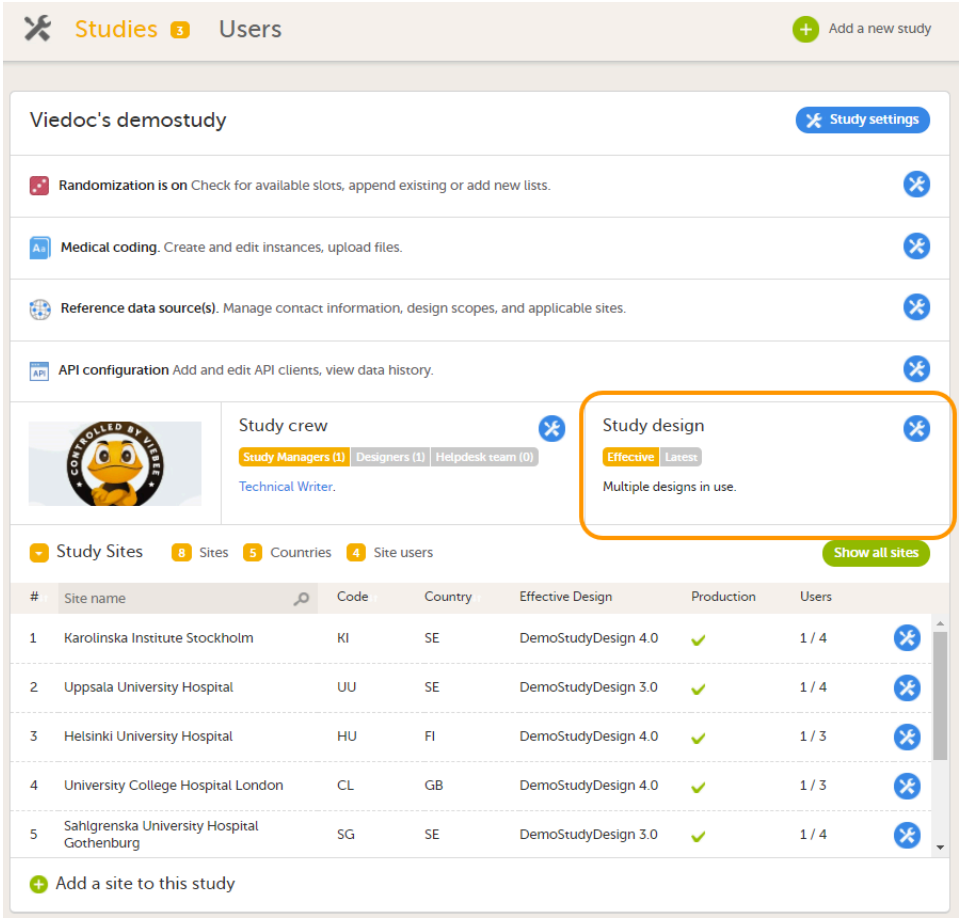
1 Introduction

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.

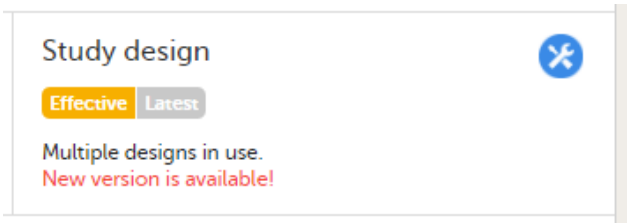
When the Study Designer has finished setting up a study design in Viedoc Designer, and has published the study design, it becomes available in Viedoc Admin. At least one site should have been added to the study before a study design can be assigned. The Study Manager can then assign the study design to one or several sites in the study, and select an effective starting time for that design to be applied to the site.

A design can be assigned to all sites at once, or to individual sites in the study. It is therefore 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.



To see the study design or designs that are in use, click **Effective**.



To see whether there is a new design version or revision available, click **Latest**.

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.

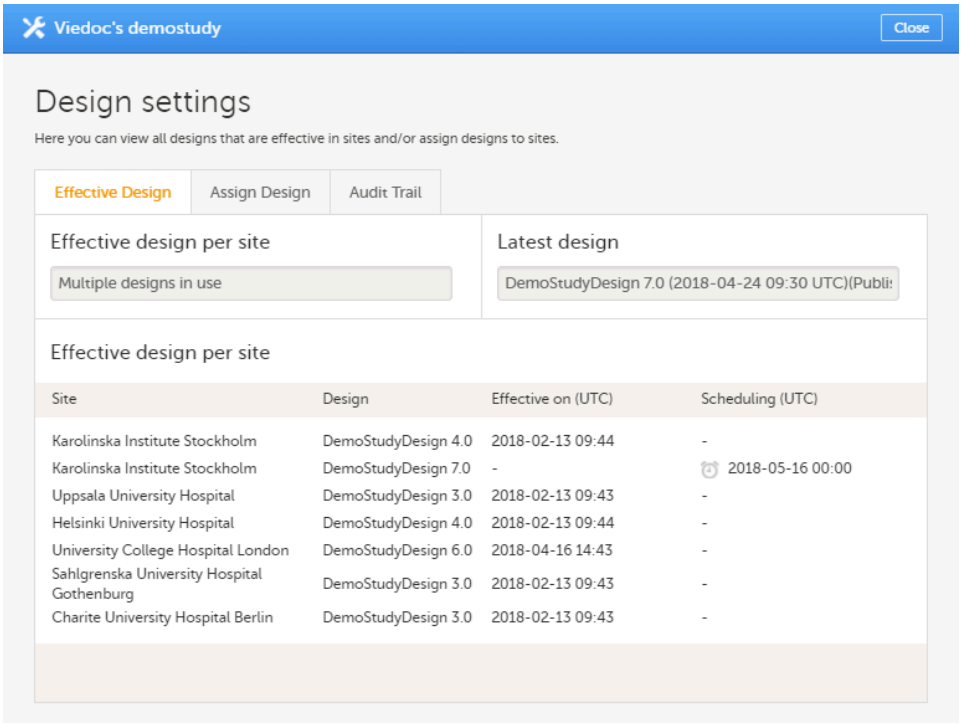
The main reason to assign a new study design version to a site after study start is that protocol amendments require changes to be made to the study design, for example changes to the study that apply from a specific point in time during the course of the study.

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:



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).

---

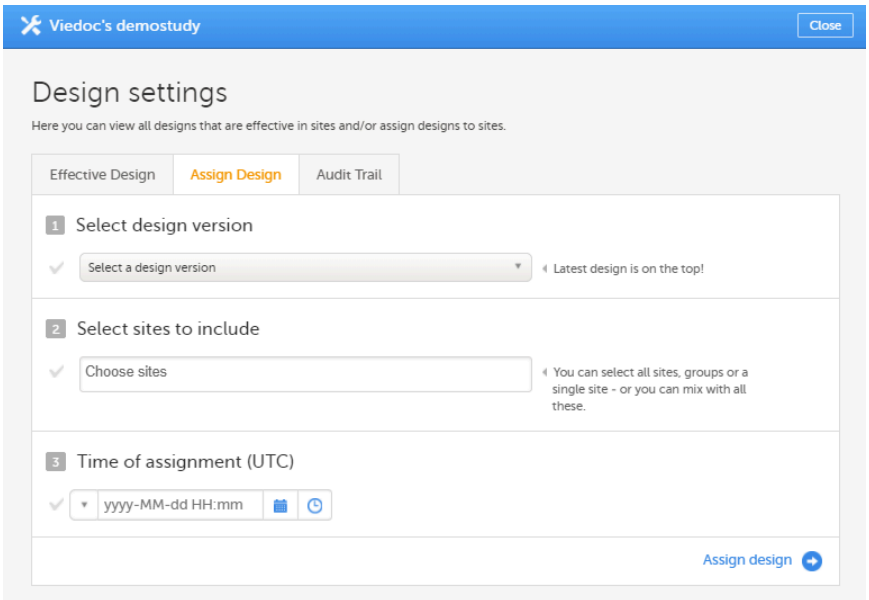
4 Assigning a study design

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.

Note! It is a good idea to keep all production sites on the same design version. For more information about the consequences to exports when the design versions do not match, please see https://help.viedoc.net/c/47e0ad/01d540/en/.

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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.

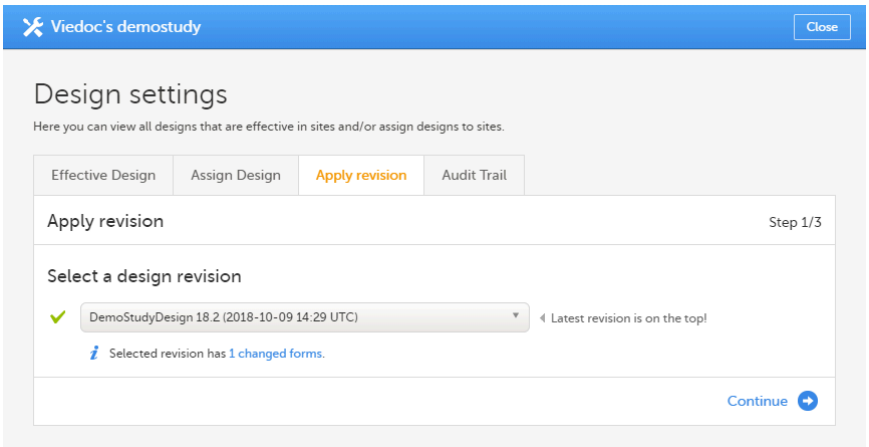
Note! It is recommended that you use the revision impact analysis before applying any revision. For more information, see Design revision impact analysis.

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.

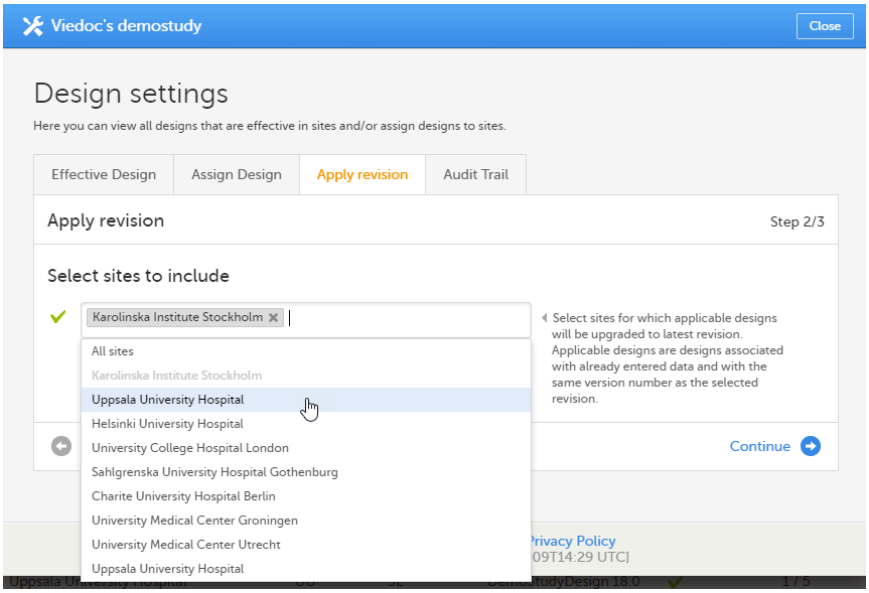
1 Click the toolbox icon in the **Study design** field on the study details page.
The Design settings pop-up opens.

2 On the **Apply Revision** tab, select the design revision from the drop-down list and click **Continue** (Step 1/3).

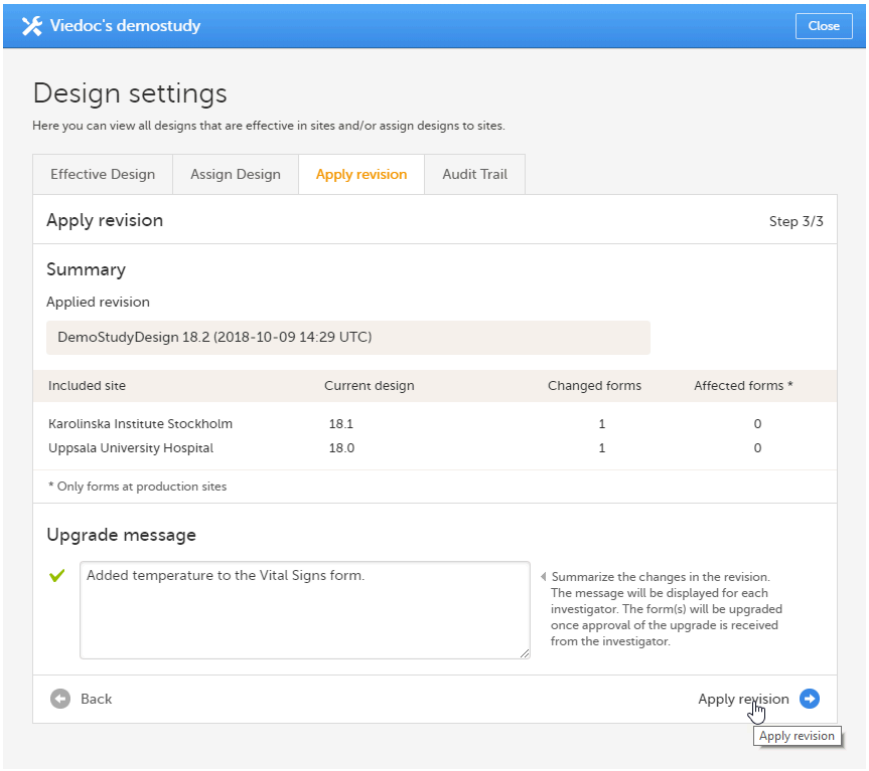


The system provides information about the impact of the revision by showing how many forms have been changed in blue text.

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).

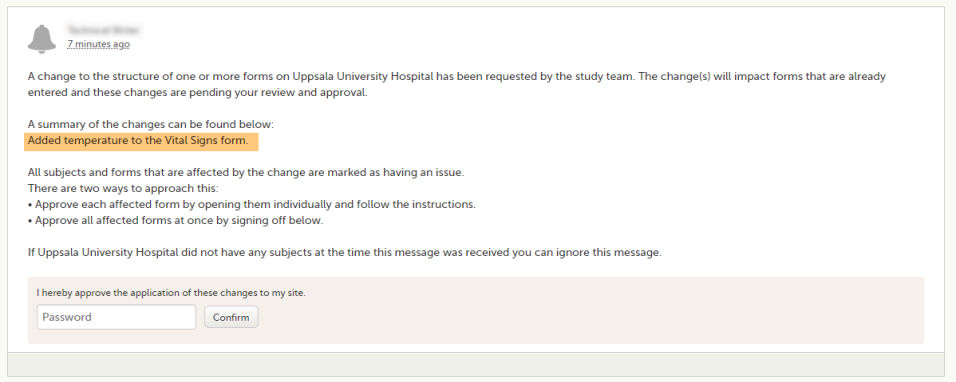


4 Type a message to the Clinic user in the Upgrade message field. This message could be a summary of the changes in the revision. It is displayed in Viedoc Clinic on the Messages page.



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 en 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.

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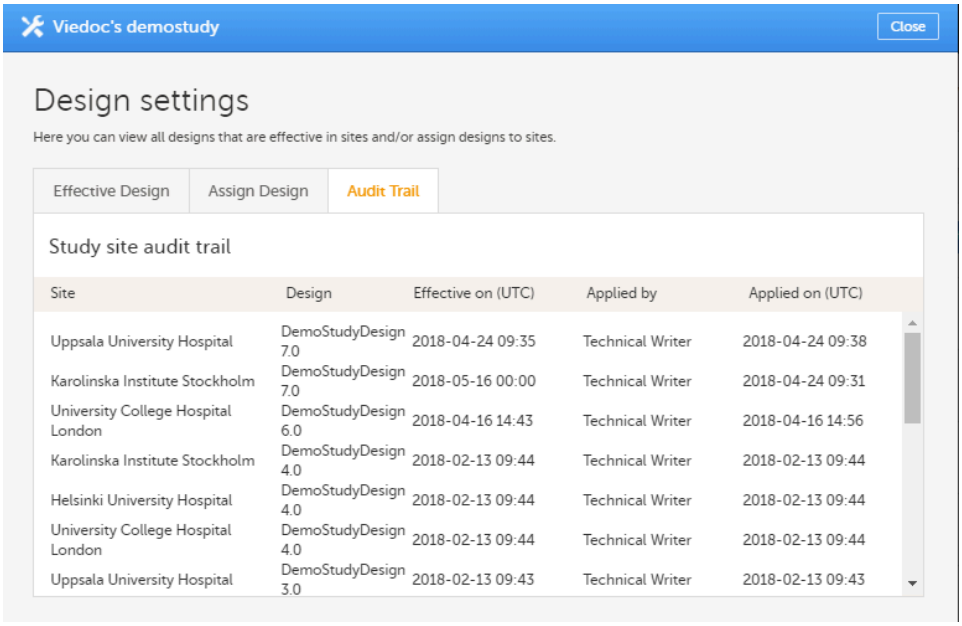
7 Viewing the audit trail of study designs

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.



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 assign, 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

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

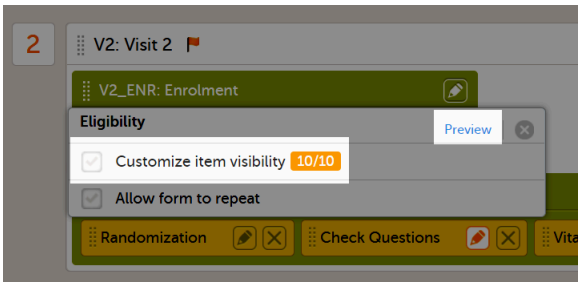
The way of handling protocol amendments and updates/corrections to the eCRF depends on the situation each time. The following table gives a general guideline on when to do a new version versus a revision:

 New version	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. Note! 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. A new version is required when: ▪ Only future events are to be affected (to not break SDV or signature on previous forms). ▪ There are changes to randomization forms (using the built-in randomization feature). These forms are locked and cannot be unlocked. ▪ 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.
 Revision	In a revision, the types of changes that can be made to the design are limited: **a.** It is not possible to add items with the same ID, and a deleted item cannot be brought back. **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. A revision is required when: ▪ Forms have been saved with subject data and the forms require an update.
 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

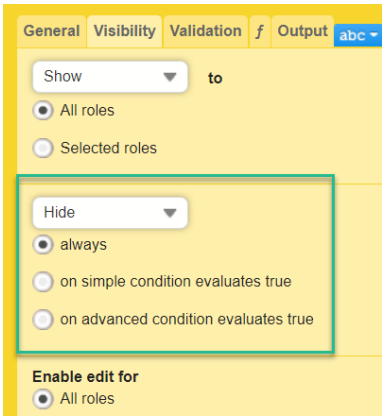
2.1 General

- 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.

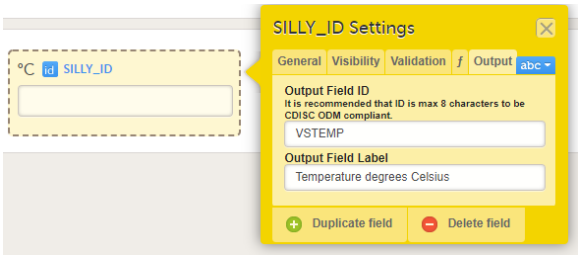


2.2 Items and IDs

- 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**.



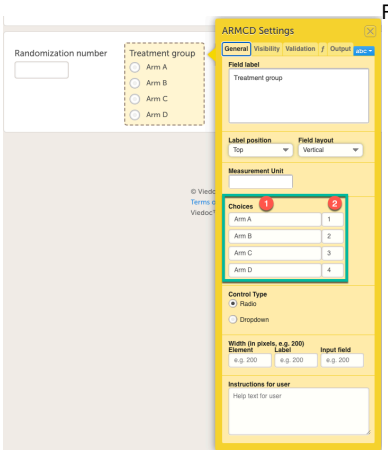
- If an ID needs to be changed, consider changing the output ID instead:



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:



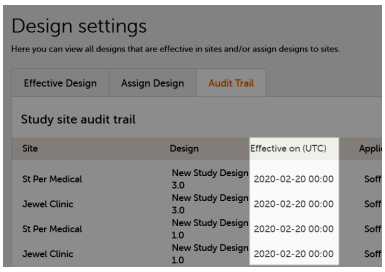
- Adding an entirely new option in a new/revised design version is okay. However, when it comes to changing the existing labels or codes, keep the following in mind:
- **Labels** - Editing an existing label while keeping the same code value will cause a data split in the export. This will be indicated 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.

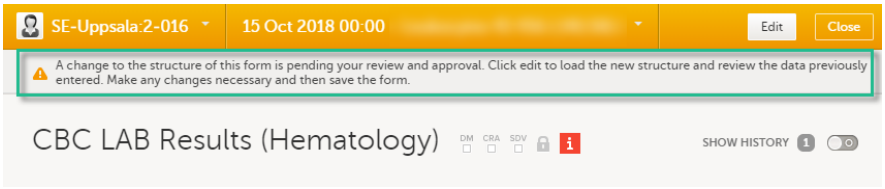
2.3 New versions

- 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.

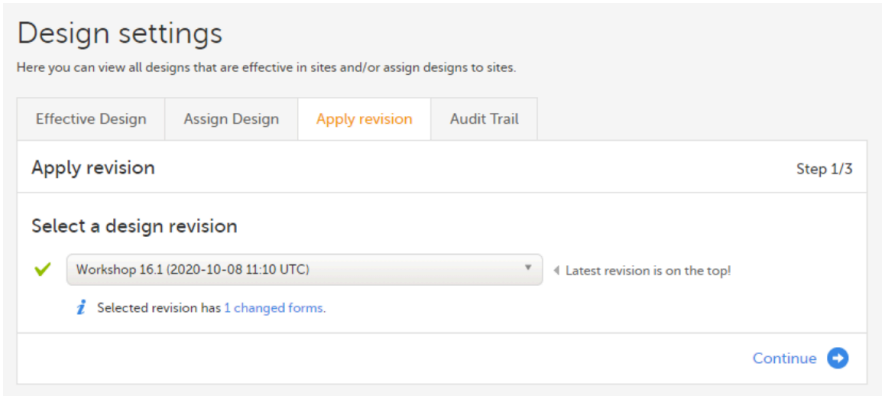


2.4 Revisions

- 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".



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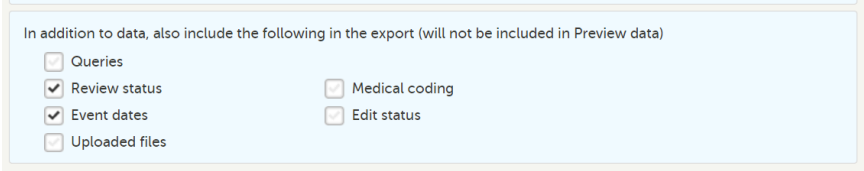
3 Doing a revision

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.

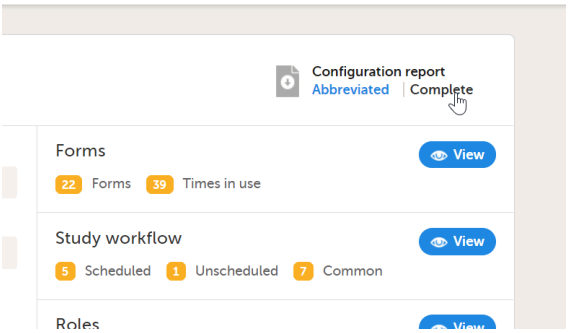


- The Review status option is to check for impact to signatures and SDV, as well as check if forms are locked.
- The Event dates options is to check if events have been initialized under a design or not.

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.

ect Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Subject form sequence number	Origin Subject form sequence number	Source Subject form sequence number	Design version
ectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityNam	FormSeq	SubjectForn	OriginSubje	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

This lesson describes how to manage reference data sources in Viedoc Admin.

1 Introduction

Can not output single-source

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?

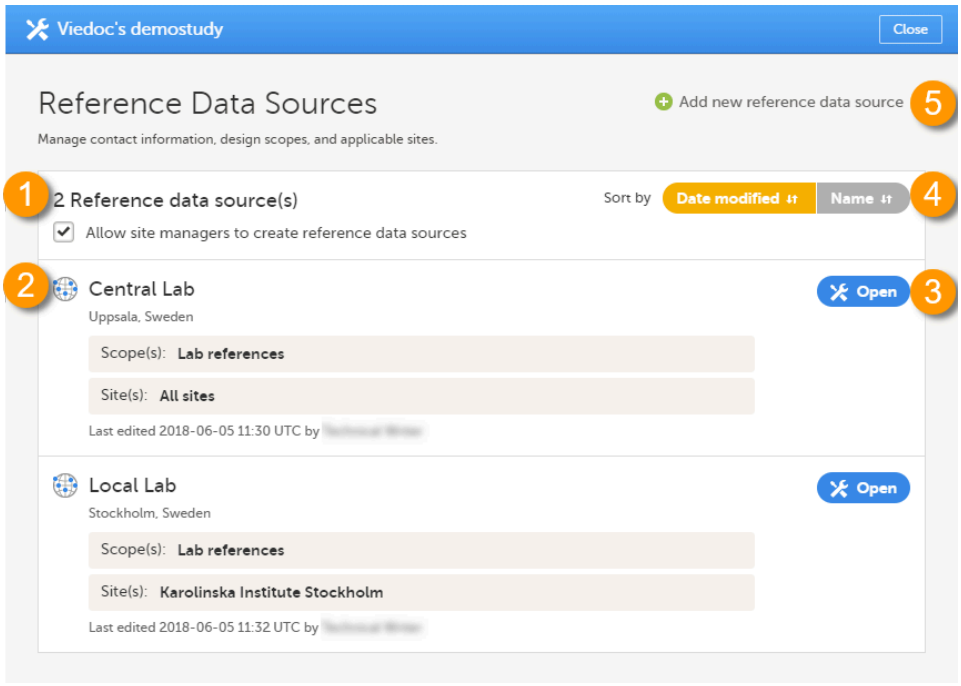
The user roles that give permission to manage the reference data sources in Viedoc Admin are:

- 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.

---

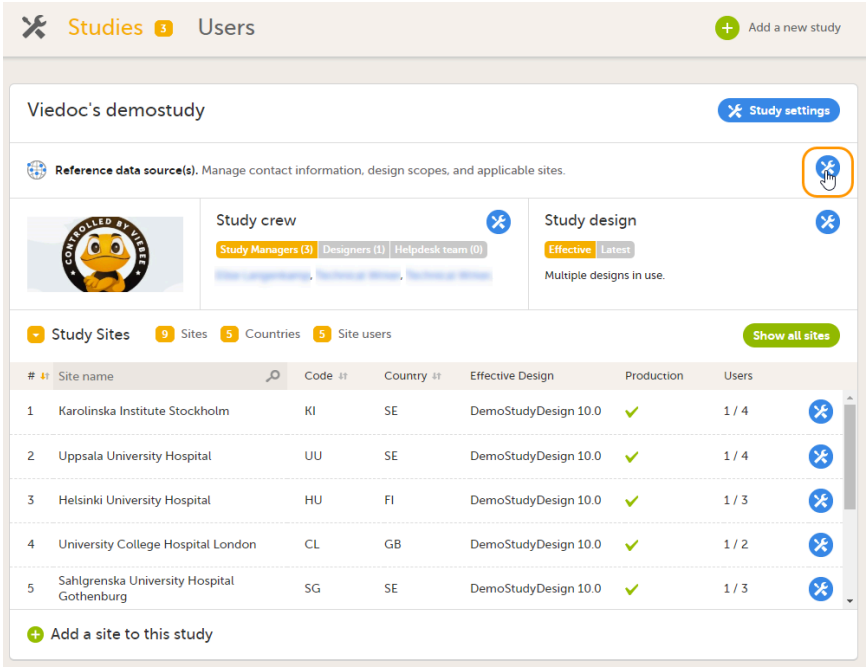
3 Step-by-step guides

3.1 Adding a reference data source

Note! Adding a reference data source can only be done by the Reference Data Source Manager.

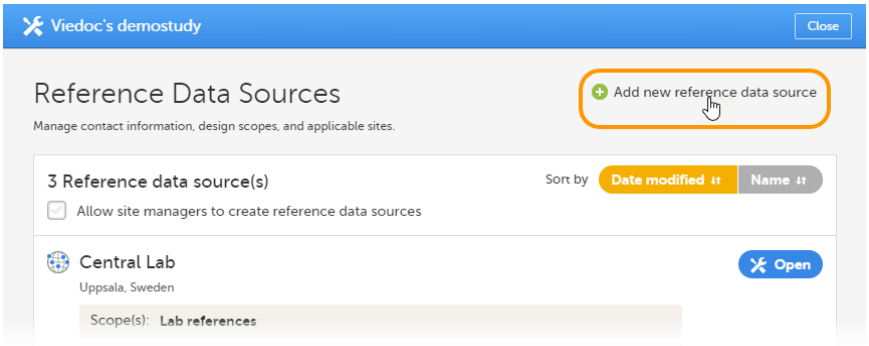
To add a new reference data source, follow the steps below.

1 Click the toolbox icon in the **Reference data source(s)** field.



The Reference Data Sources window opens.

2 Click **Add new reference data source**.

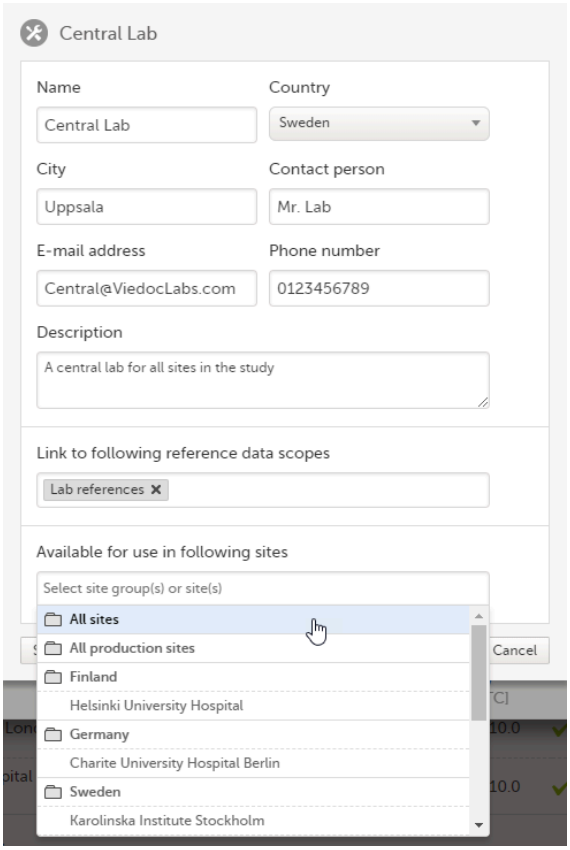


3 Enter the following details about the reference data source:

- 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.

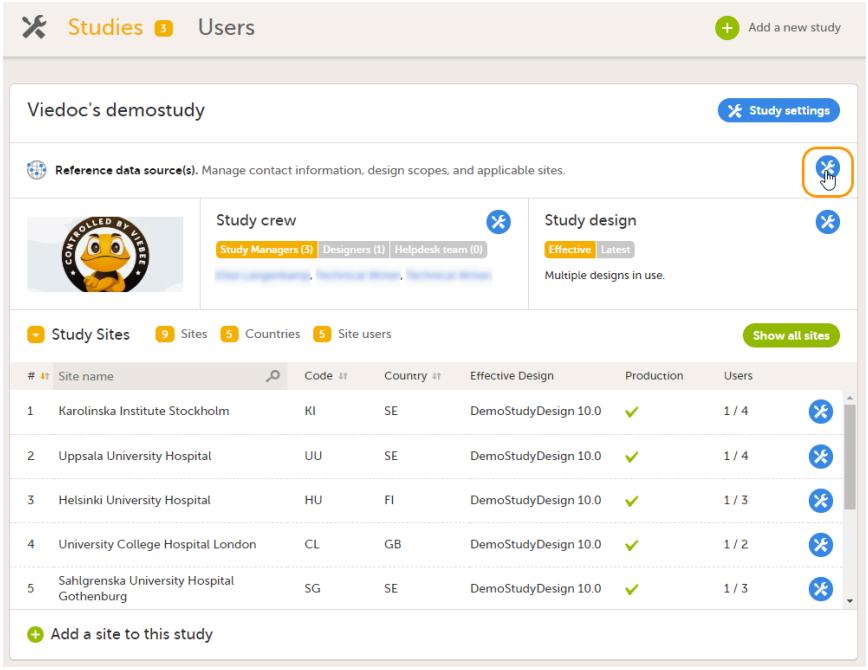


4 Click **Save**. The new reference data source is added to the list of reference data sources.

3.2 Editing a reference data source

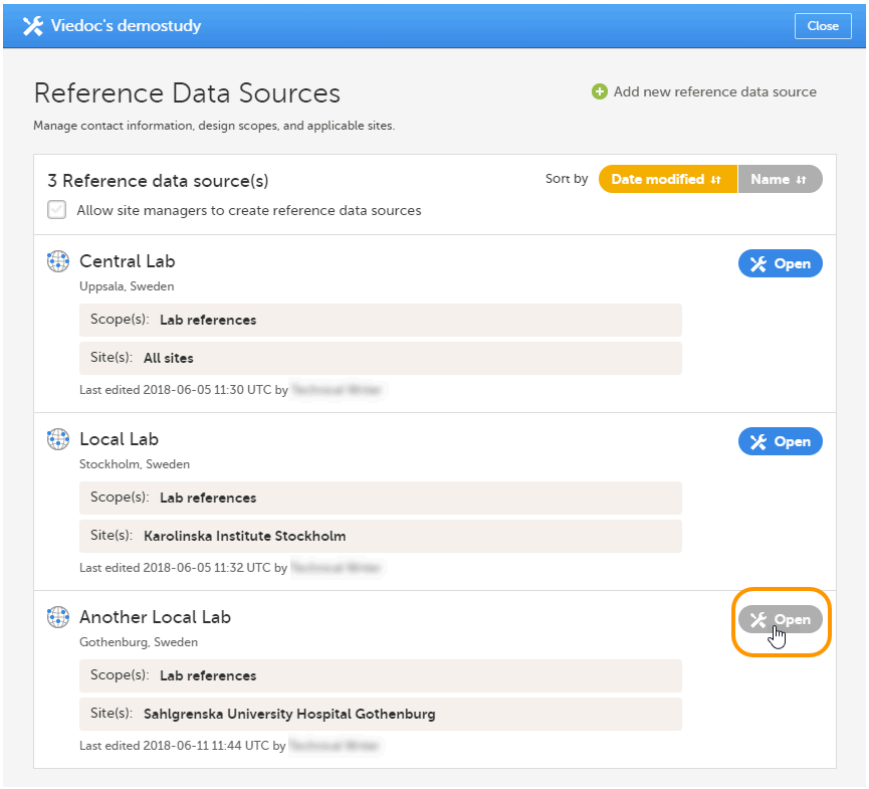
To edit the details of a reference data source, follow the steps below.

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.



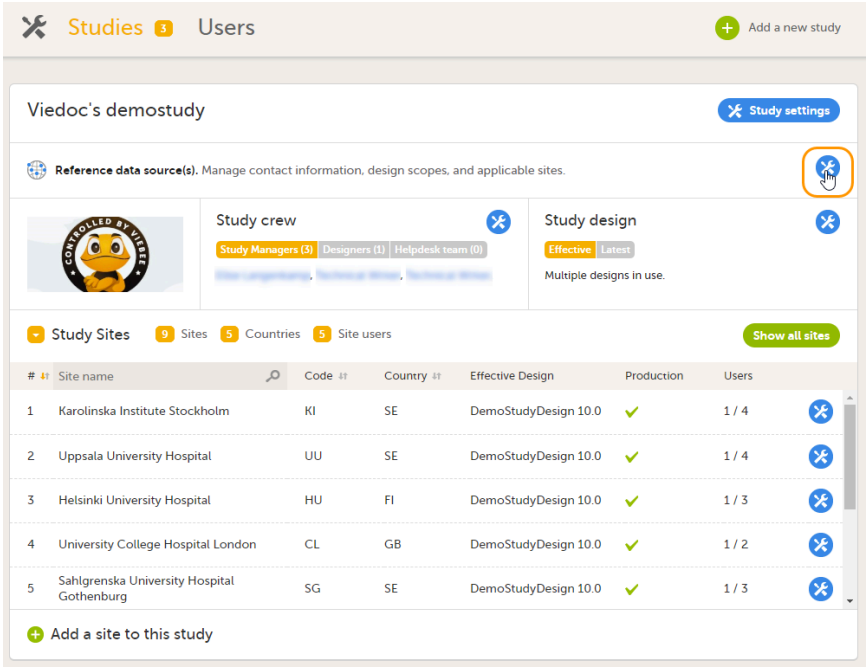
3 Edit the details and click **Save** to save the changes you made.

3.3 Deleting a reference data source

To delete a reference data source, follow the steps below.

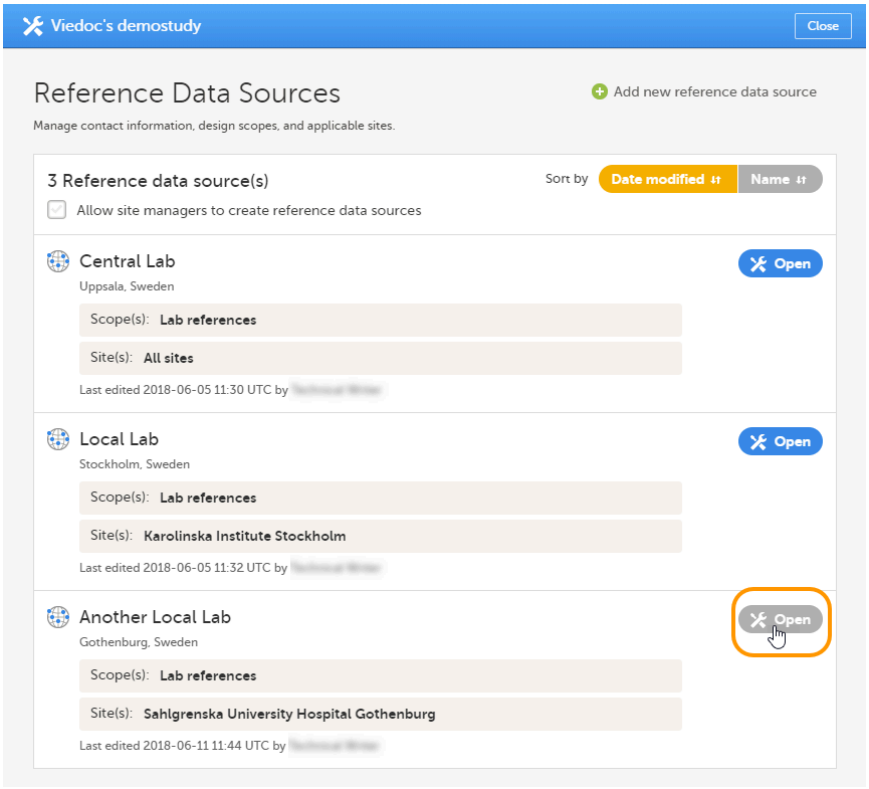
Note! A reference data source cannot be deleted if at least one site in production mode was assigned to that source and if reference data has been published in Viedoc Clinic for that data source (in combination with a reference data scope).

1 Click the toolbox icon in the **Reference data source(s)** field.

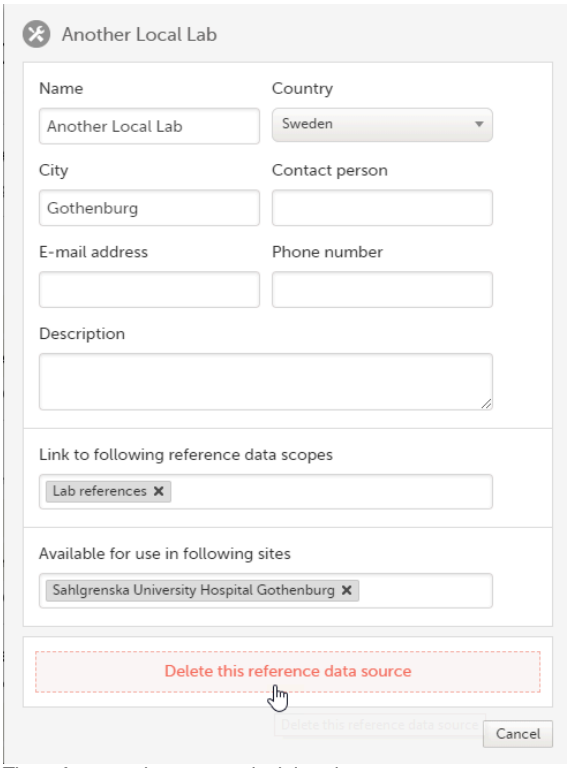


The Reference Data Sources window opens.

2 Click **Open** to open the reference data source you would like to delete.



3 Click **Delete this reference data source**.



The 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

This lesson provides a use case for working with reference data in Viedoc Designer, Viedoc Admin, and Viedoc Clinic.

1 Introduction

Can not output single-source

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

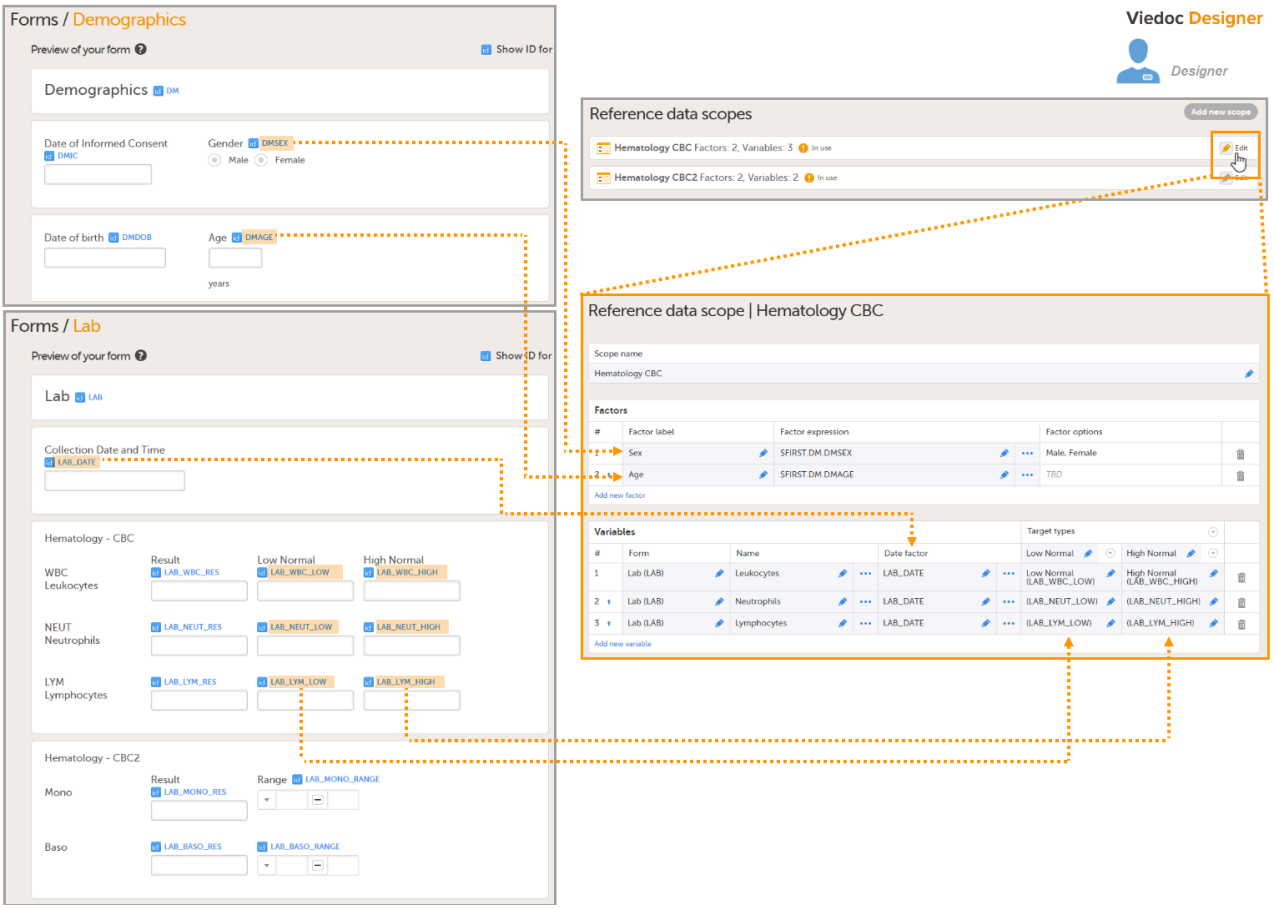
1.1 Objective of this lesson

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

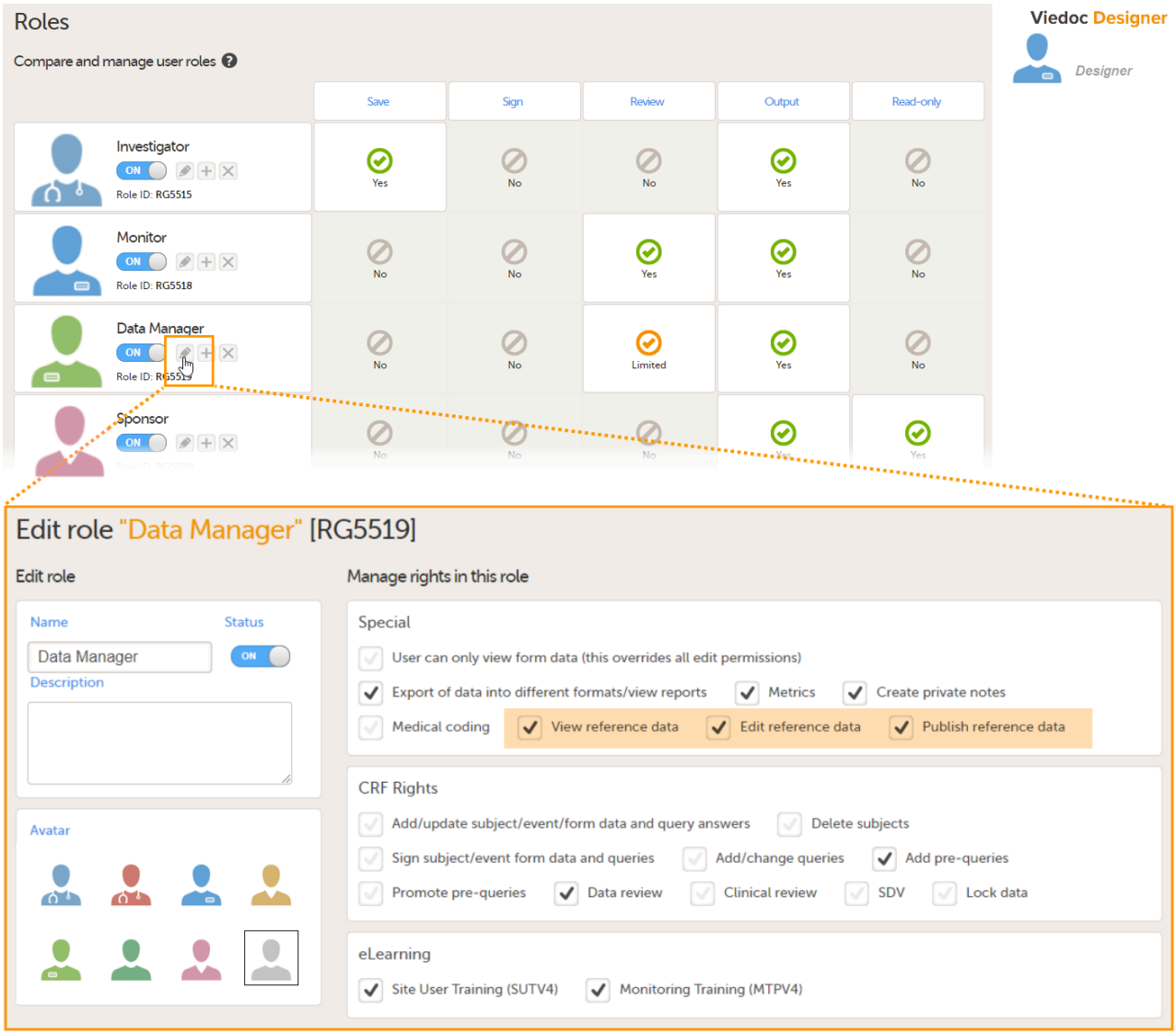
2.1 Configuring a reference data scope in Viedoc Designer

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*.
2. 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.



3. Publish the **Global design settings**, so that the defined reference data scope will become available in Viedoc Admin and Viedoc Clinic.
4. 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.



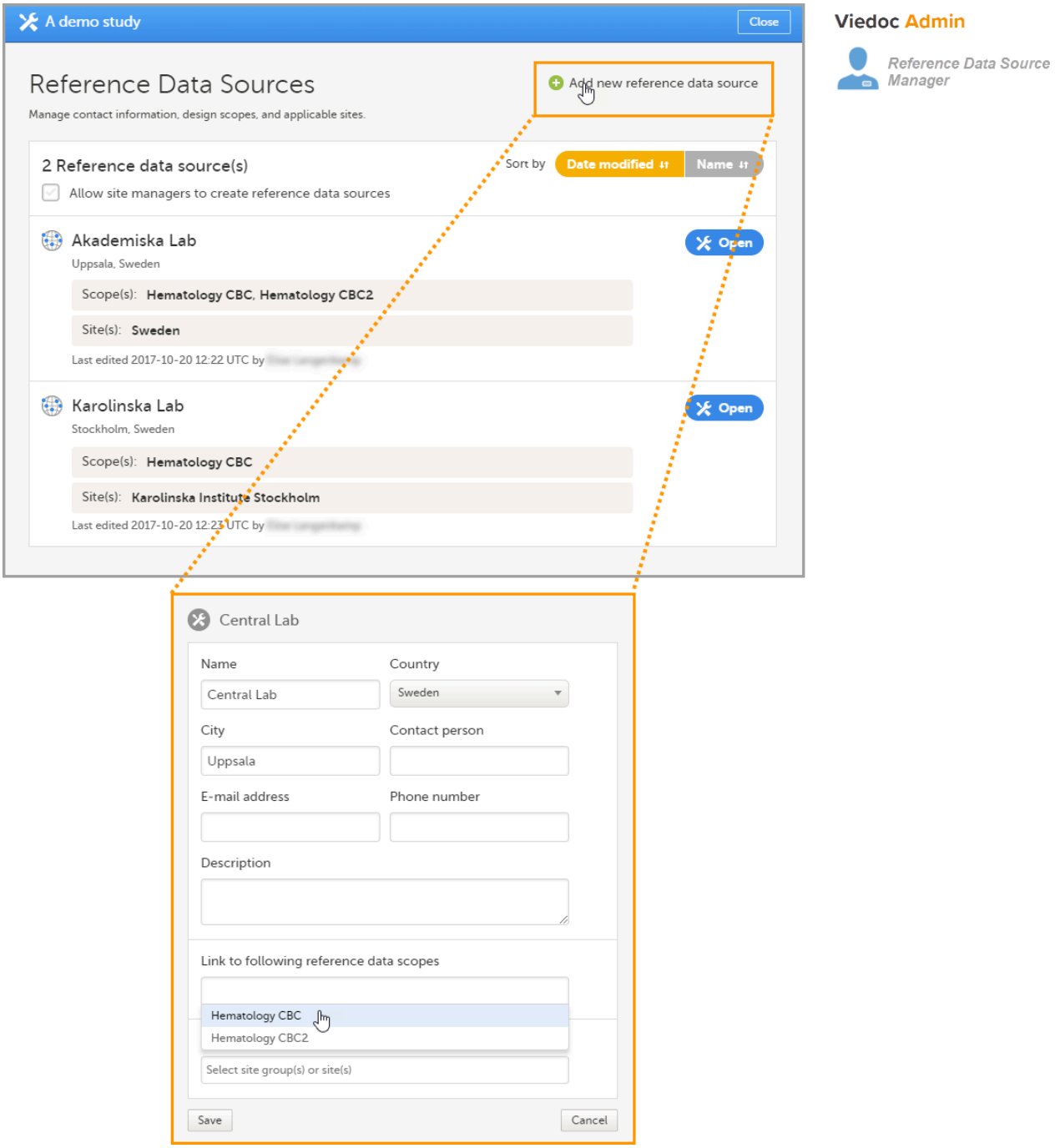
For more detailed instruction, see Configuring reference data scopes, and Configuring roles in Viedoc Designer.

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.

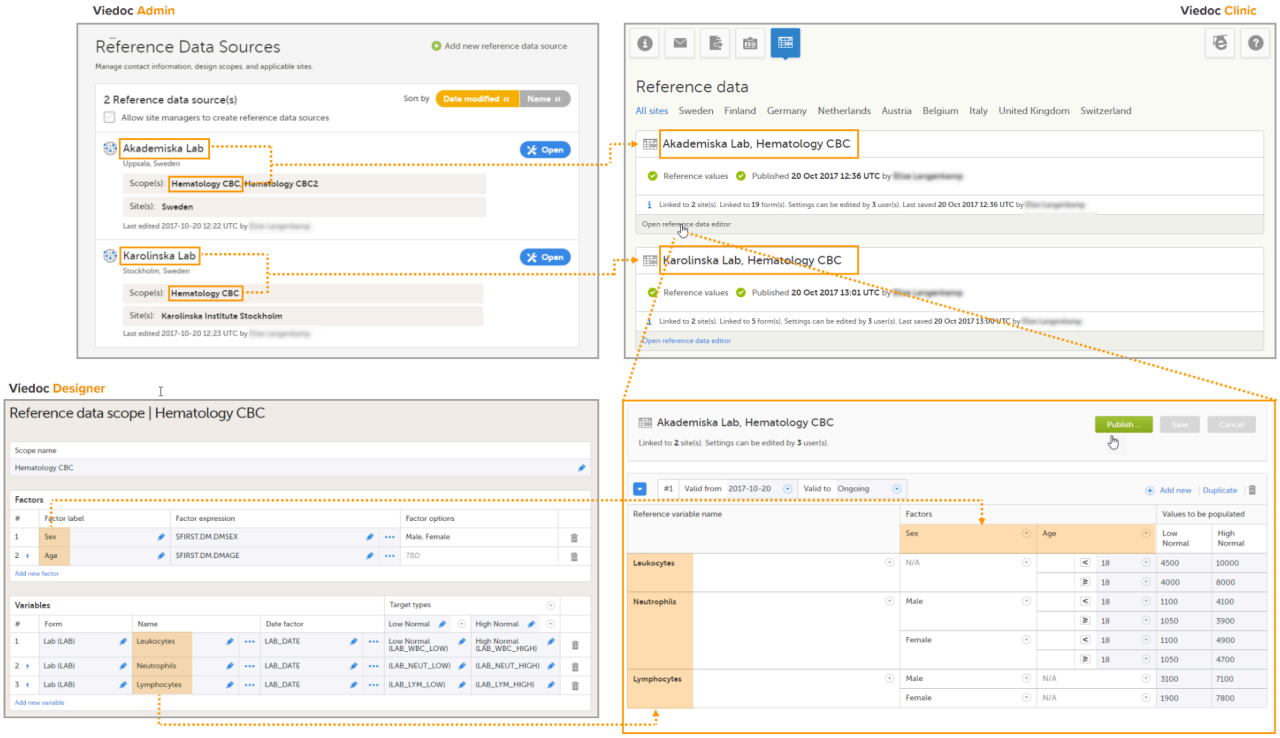
In this example, we have defined two reference data sources: *Akademiska Lab* and *Karolinska Lab*. The *Akademiska Lab* is linked to two scopes: *Hematology CBC* and *Hematology CBC2*. It is also linked to the system site group *Sweden* (all production sites in Sweden). The *Karolinska Lab* is only 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

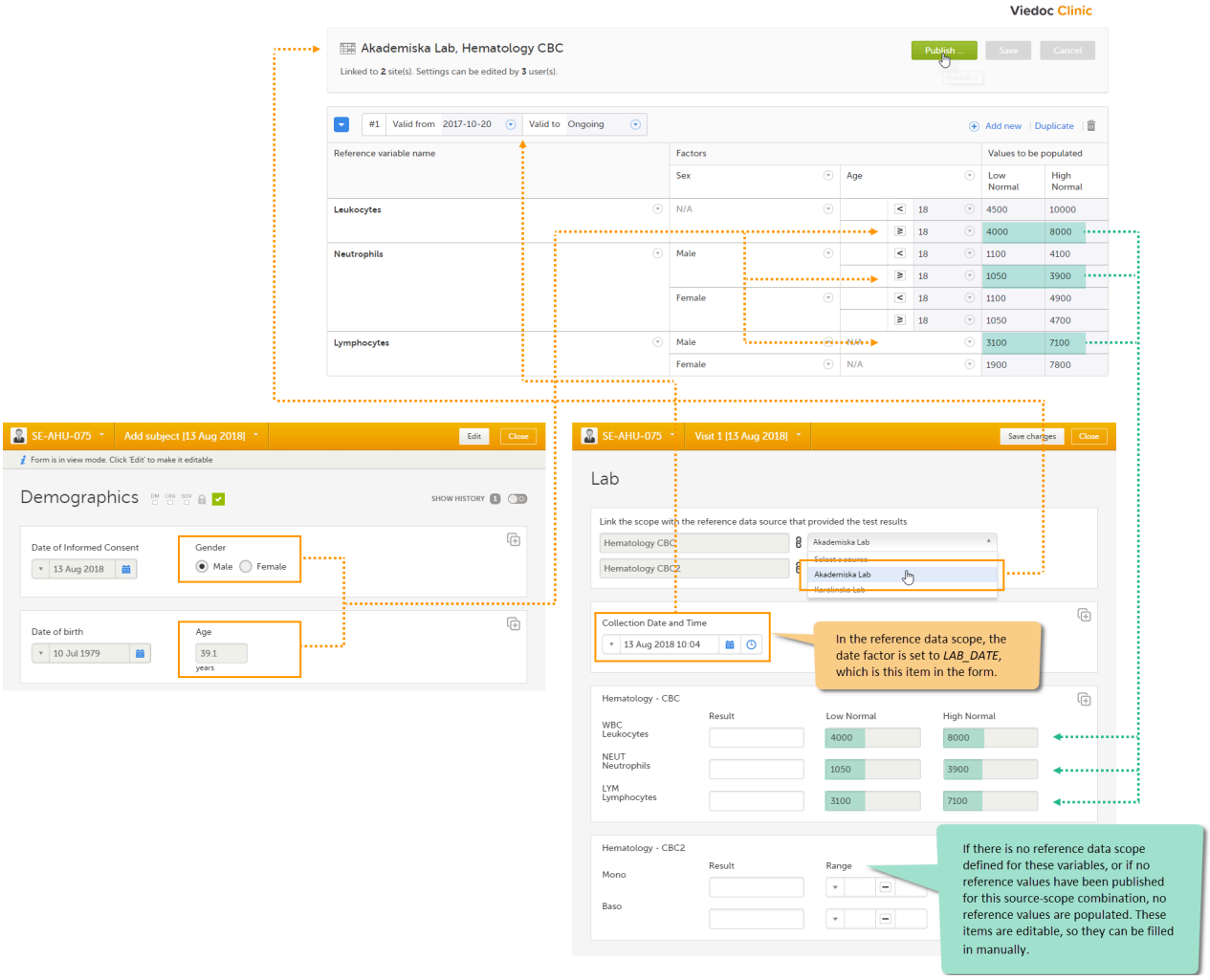
1. In Viedoc Clinic, on the landing page, click the reference data icon. A list of all reference data source-scope combinations is displayed.
2. Click **Open reference data editor** to open the reference data editor. In this example, we enter the values for the *Akademiska Lab, Hematology U* source-scope 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**.



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 ≥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 2024-10-11

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.

More information about server instances can be found in Guide to Viedoc server instances

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.

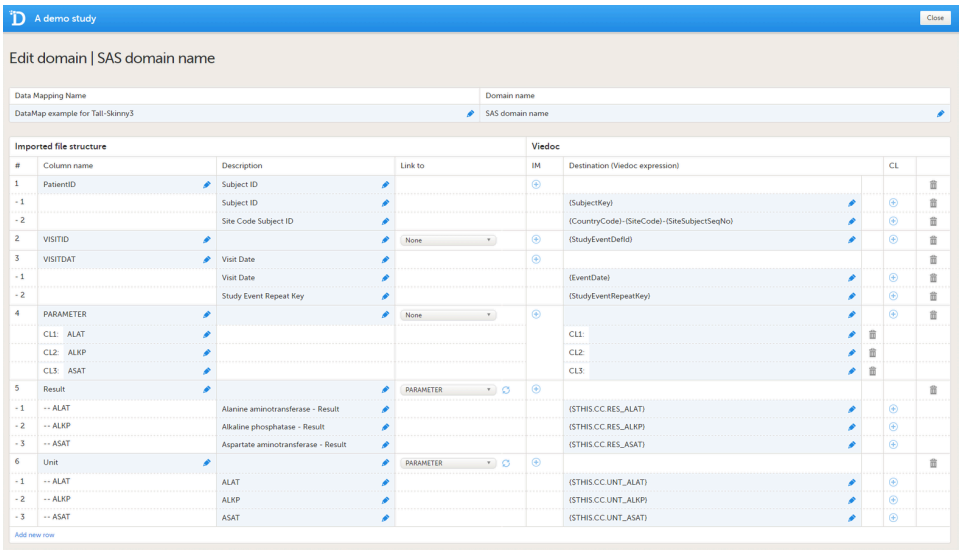
---

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



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 the EU, the URL is:

- `https://v4api.viedoc.net/HelipadService.svc?wsdl`
- `https://v4apitraining.viedoc.net/HelipadService.svc?wsdl`

For Japan, the URL is:

- `https://v4apijp.viedoc.net/HelipadService.svc?wsdl`
- `https://v4apitrainingjp.viedoc.net/HelipadService.svc?wsdl`

For China, the URL is:

- `https://api.viedoc.cn/HelipadService.svc?wsdl`
- `https://apitraining.viedoc.cn/HelipadService.svc?wsdl`

For the USA, the URL is:

- `https://api.us.viedoc.com/HelipadService.svc?wsdl`
- `https://apitraining.us.viedoc.com/HelipadService.svc?wsdl`

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.

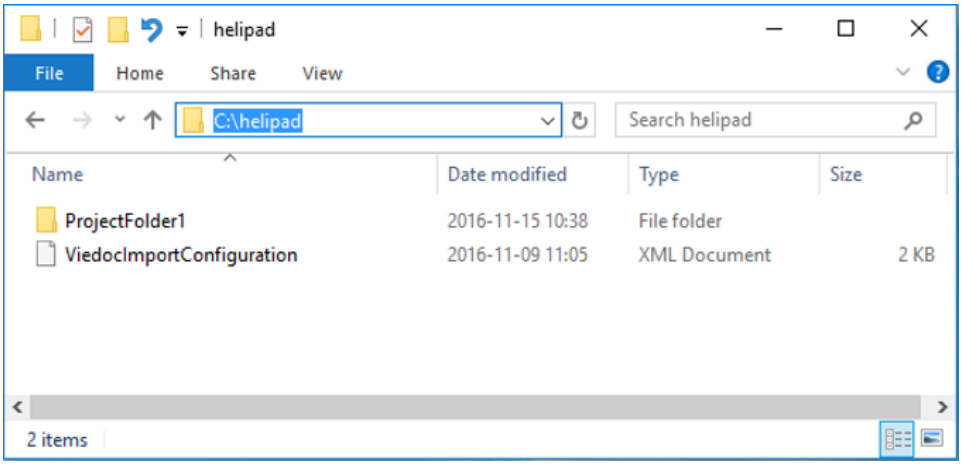
4 Save the configuration file in the work folder.

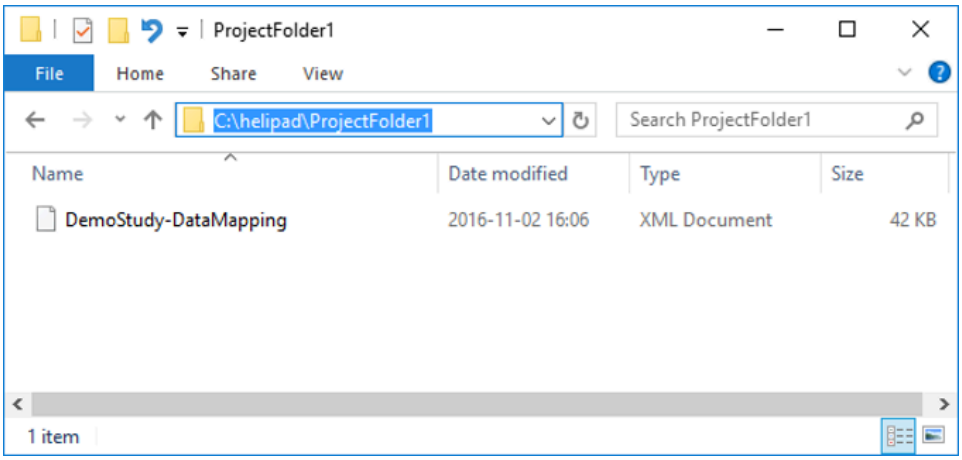
Name	Type of encoding
gb2312	Chinese SImplified (GB2312)
utf-16	Unicode
unicodeFFFE	Unicode (Big endian)
Winodws-1252	Western European (Windows)
x-mac-korean	Korean (Mac)
x-mac-chinesesimp	Chinese Simplified (Mac)
utf-32	Unicode (UTF-32)
utf-32BE	Unicode (UTF-32 Big endian)
us-ascii	US-ASCII
x-cp20936	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
x-iscii-ma	ISCII Malayalam

Name	Type of encoding
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*.





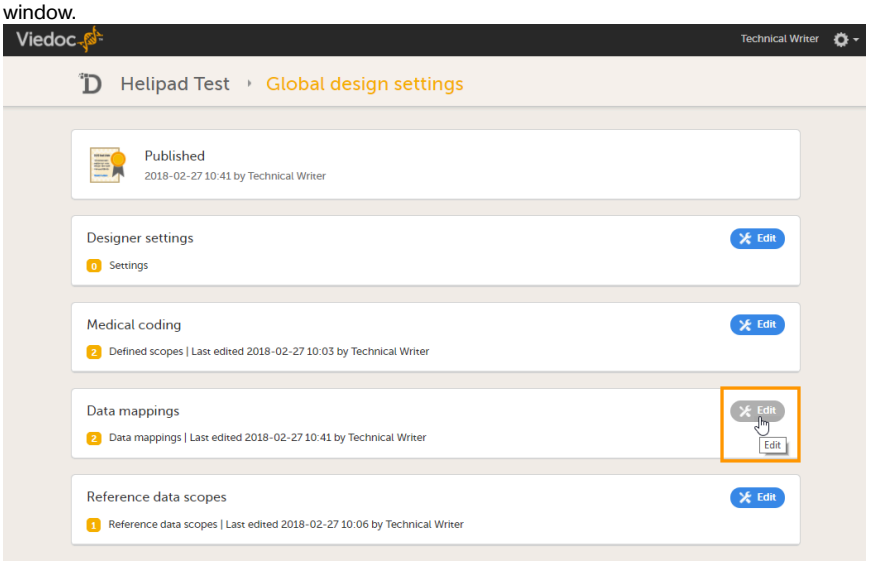
The data file(s) containing the data to be imported should also be saved in the project folder.

3.6 Downloading the Viedoc Data Import Application

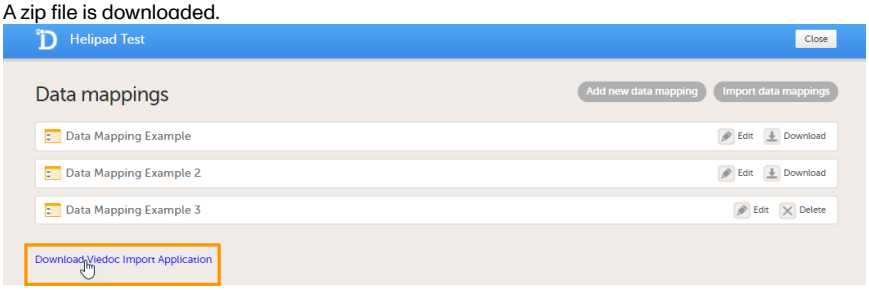
Note! The Data Import Application only works for Windows OS and not Linux or Mac.

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.

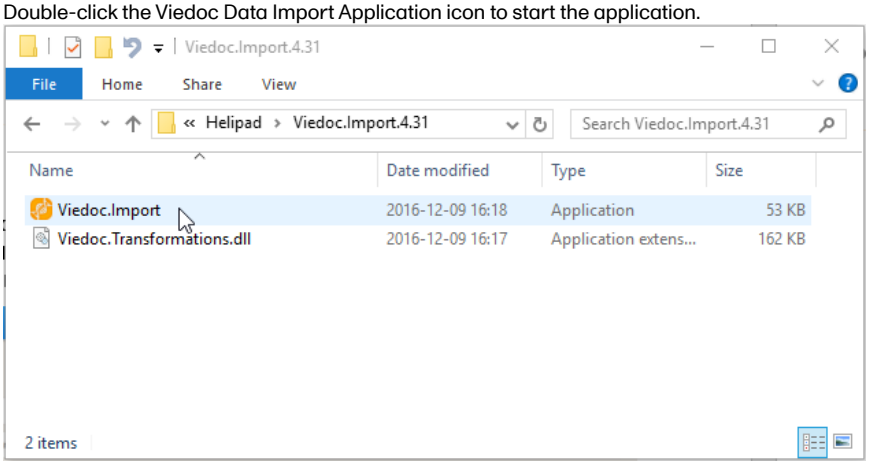
3.7 Dropping data into the project folder

Save the data file containing the data to be imported in the project folder.

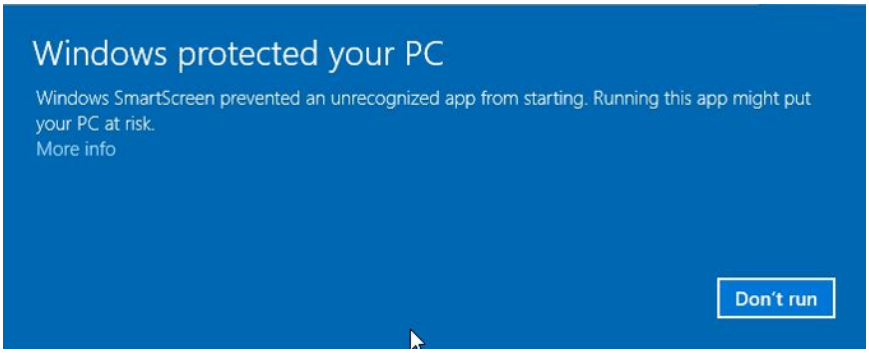
3.8 Running the Viedoc Data Import Application

To run the application and import the data:

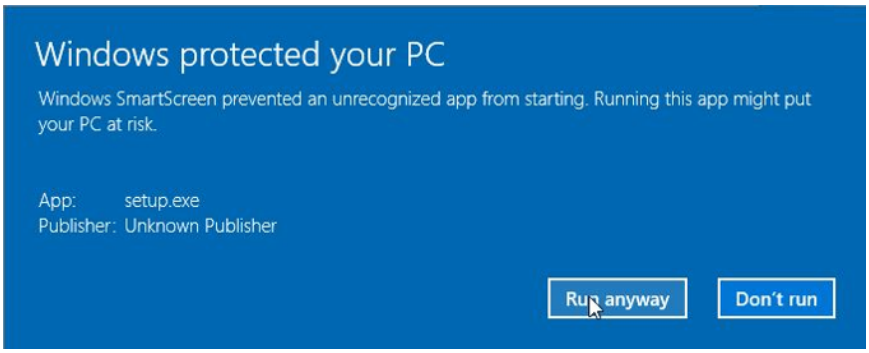
1 Double-click the Viedoc Data Import Application icon to start the application.



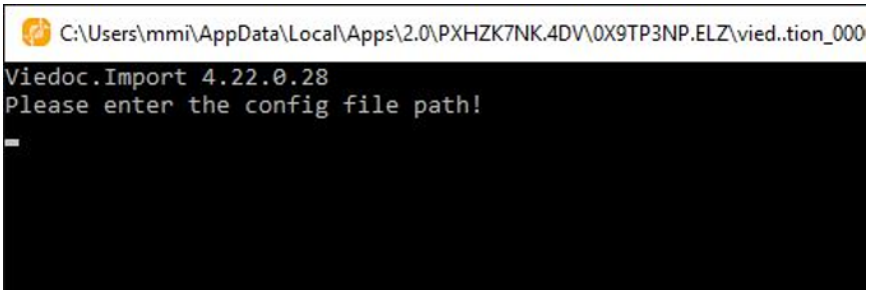
When starting the application for the first time, the following window appears:



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.

3.9 Importing more data

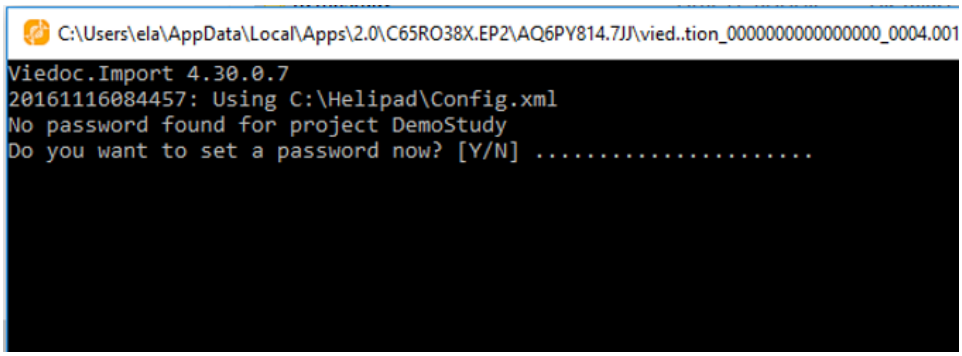
Whenever you have new data to import, save the data file in the respective project folder and run the application again by double-clicking the Viedoc Data Import Application icon.

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.



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.

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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 2024-12-03

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

A wsdl metadata file can be downloaded from: https://[VIEDOC_HOST]/HelipadService.svc?wsdl

For the EU:

https://v4api.viedoc.net/HelipadService.svc?wsdl
https://v4apitraining.viedoc.net/HelipadService.svc?wsdl

For Japan:

https://v4apijp.viedoc.net/HelipadService.svc?wsdl
https://v4apitrainingjp.viedoc.net/HelipadService.svc?wsdl
https://v4apistagejp.viedoc.net/HelipadService.svc?wsdl

For China:

https://api.viedoc.cn/HelipadService.svc?wsdl
https://apitraining.viedoc.cn/HelipadService.svc?wsdl

For the USA:

https://api.us.viedoc.com/HelipadService.svc?wsdl
https://apitraining.us.viedoc.com/HelipadService.svc?wsdl

Contact Viedoc Technologies for information about which host to connect to.

See Guide to Viedoc server instances for more information.

---

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
`loginModel`	`ApiAuthenticationModel`	A collection of authentication information. See section 3.1 ApiAuthenticationModel for a description.

2.1.4 Returns

The `Token` method returns an `ApiTokenModel` 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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. See section 3.2 ApiResultType for details
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes for details.
`ErrorMessage`	`string`	In case of an error result: human readable description of the error
`ExpiryDateTime`	`DateTime`	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
`token`	`string`	Authentication token. Can be obtained by invoking the `Token` method with client ID, username, and password.
`odmXml`	`string`	The data to be uploaded in ODM format
`options`	`ApiSubmitDataOptions`	Submit data options. Optional. See section 3.3 ApiSubmitDataOptions.

2.3.4 Returns

The `SubmitData` method returns an `ApiSubmitResultModel` 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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. See the section 3.2 ApiResultType for details.
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes for details.
`ErrorMessage`	`string`	In case of an error result: human readable description of the error
`TransactionGuid`	`GUID`	A GUID assigned to the transaction that can be used to identify the transaction in future requests, for example when invoking `TransactionStatus` or `TransactionData`. Every single call to the `SubmitData` 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 Vledoc Admin

4	`StudyEventOID`
	
	`FormOID`
	
	`ItemOID`
		Event, form, or item Object Identifiers (OIDs), can be obtained from an exported metadata version or from Viedoc Designer
		
		Note! If the StudyEvent repeats, a StudyEventRepeatKey should be given. For example:
		`<StudyEventData StudyEventOID="AE" StudyEventRepeatKey="1">`

5	`ItemDataInteger`	Allowed data value types are: ▪ `ItemDataString` ▪ `ItemDataInteger` ▪ `ItemDataDouble` ▪ `ItemDataDateTime` * ▪ `ItemDataDate` ▪ `ItemDataTime`

* 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

```
ApiResultModel 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 `SubmitData` method

2.4.4 Returns

The `TransactionStatus` method returns an `ApiResultModel` 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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. See section 3.2 ApiResultType for details.
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes 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 `SubmitData` 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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. See section 3.2 ApiResultType for details.
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes for details.
`ErrorMessage`	`string`	In case of an error result: human readable description of the error
`OdmXml`	`string`	The uploaded data in ODM 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>
```

2.5.6 Example response

<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 OID 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 ODM 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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. See section 3.2 ApiResultType for details.
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes for details.
`ErrorMessage`	`string`	In case of an error result: human readable description of the error
`OdmXml`	`string`	ODM 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:metaDataOid>12.0</vied:metaDataOid>
         <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 GetMetaDataVersionForKeySets

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 3.4 ViedocKeySet.

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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. See section 3.2 ApiResultType for details.
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes for details.
`ErrorMessage`	`string`	In case of an error result: human readable description of the error
`KeySets`	`List<ViedocKeySet>`	ODM 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:StudySubjectSqeNo>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 GetClinicalStudySites

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>SingaporeGeneral Hospital</a:SiteName>

                  <a:SiteNumber>2</a:SiteNumber>

                  <a:SiteType>Training</a:SiteType>

                  <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 3.5 ApiGetClinicalDataRequestModel.

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`	`ApiResultType`	Defines the type and status of the result returned from method invocation. An `ApiResultType` `enum` with the value `Success` or `Error` is used.
`ErrorCode`	`int`	In case of an error result: contains an integer specifying the type of error. See section 4 Error codes for details.
`ErrorMessage`	`string`	In case of an error result: human readable description of the error
`OdmXml`	`string`	The exported data in ODM 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 date 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 `true` or `false`, default is set to `true`.
`AllowInitiatingStudyEvents`	`bool`	Defines whether uninitiated events will be initiated during the data import. Can be set to `true` or `false`, default is `true`.

3.4 ViedocKeySet

The `ViedocKeySet` data type contains the following properties:

Property	Data type	Description
`UniqueId`	`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
`StudySujbectSeqNo`	`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 OID as set in the study design
`StudyEventRepeatKey`	`string`	Study event repeat key

Property	Data type	Description
`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 OID 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.
`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` .

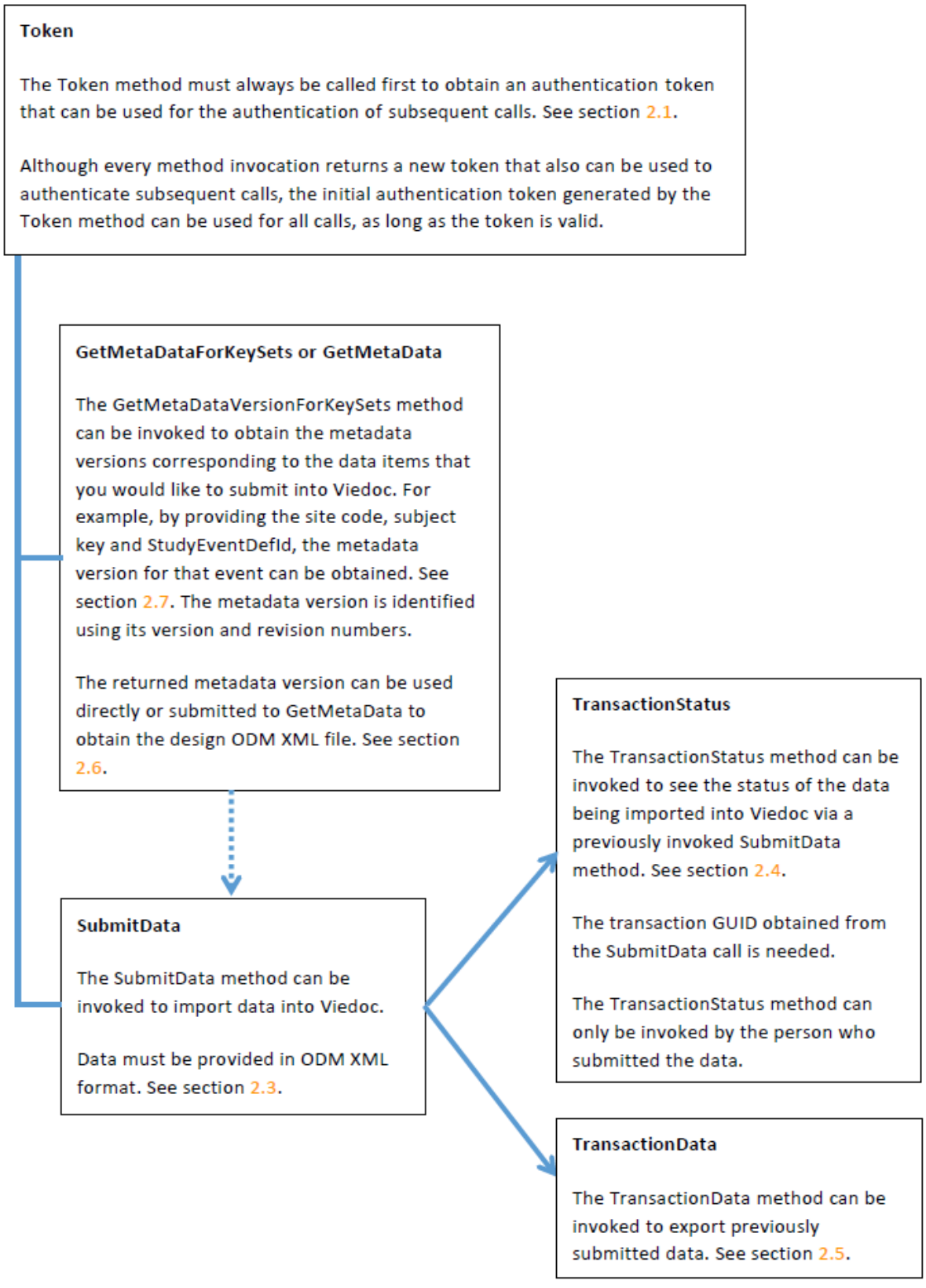
Property	Data type	Description
`ViedocVersion`	`string`	Defines which data structure version is used for the export. As of Viedoc release 4.39, the data structure version can be set to 4.38, 4.39 or Latest Viedoc Version. If nothing is specified, the Viedoc version set in the API configuration settings 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 ODM XML 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

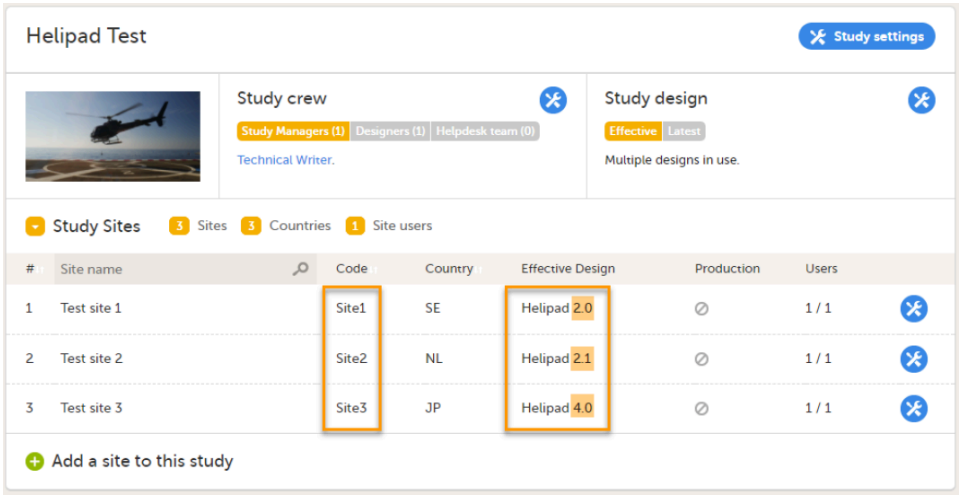
This chapter also provides instructions to construct the clinical data file using the obtained information.

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.



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:vied="Viedoc.API"
   <soapenv:Header>
   <soapenv:Body>
      <vied:GetMetaData>
         <vied:token>FE4...171</tem:token>
         <vied:metaDataOid>8.0</tem:metaDataOid>
         <vied:includeSdm>true</tem:includeSdm>
         <vied:includeViedocExtensions>true</tem:includeViedocExtensions>
      </vied: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`

ItemDef Data type	ItemData Data type
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.

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Importing data from ODM file

Importing data from 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.
- Viedoc does not recommend importing data to forms that have randomization configured. That is, the data that is to be imported may have used randomization, but the study design that it is being imported into should not have randomization configured.

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="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="2.0" EffectiveDate="2014-03-01" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="26.0" EffectiveDate="2016-01-01" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="8.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="3.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="4.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="11.0" EffectiveDate="2014-12-01" v4:EffectiveTime="T00:00Z" />
  <MetaDataVersionRef StudyOID="4dd1f1d5-86a4-11e4-a8f0-005056a353c3" MetaDataVersionOID="5.0" EffectiveDate="2014-03-02" v4:EffectiveTime="T00:00Z" />
```

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">
```

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

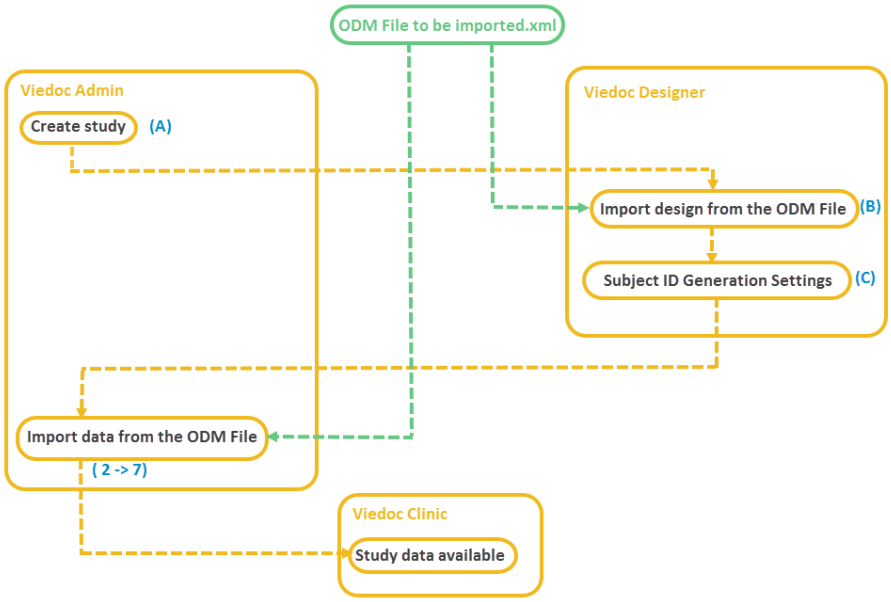
Before you start importing the ODM file, you have to make sure that you already have a study in Viedoc that has a study design that matches the data structure in the ODM file to be imported. The metadata version(s) in the ODM file to be imported must contain all the events, forms, item groups, items 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.

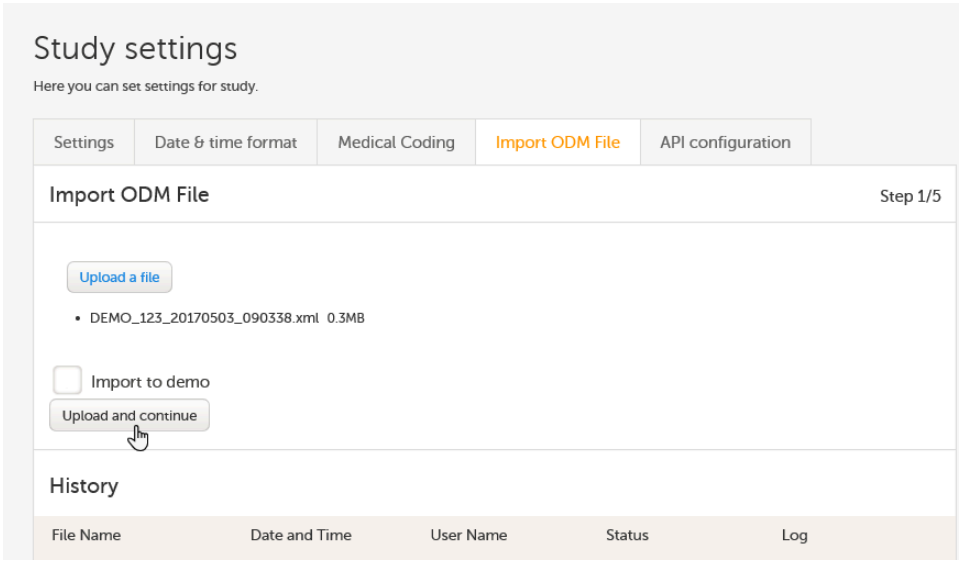


2 Importing an ODM file

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.



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.

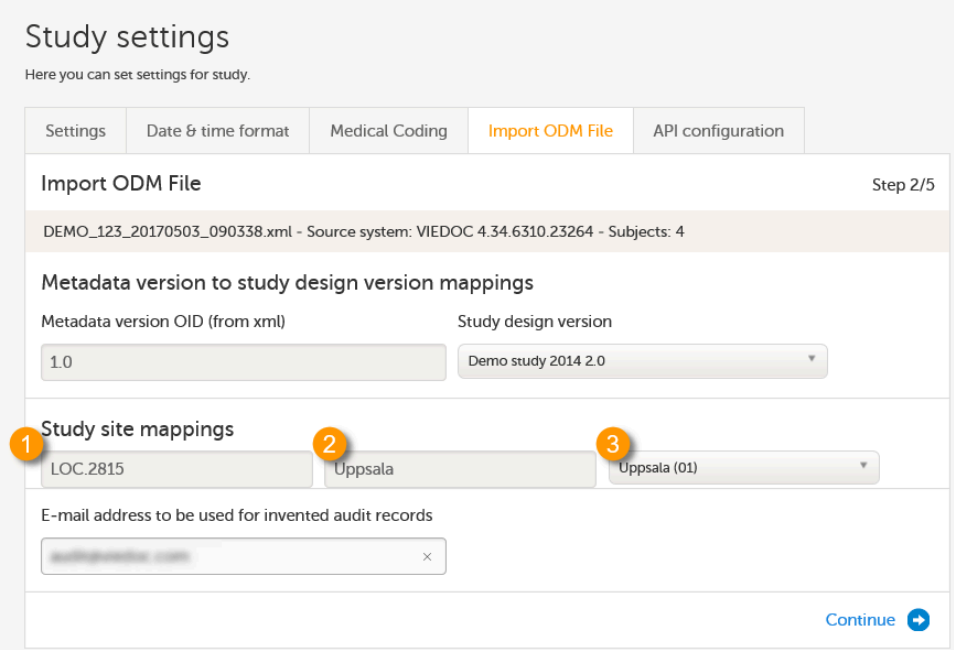
In case you receive an error message saying that the file cannot be uploaded due to missing content (according to the CDISC ODM standard), you have to go back to your ODM file, fix the error and upload the file again.

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.



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!

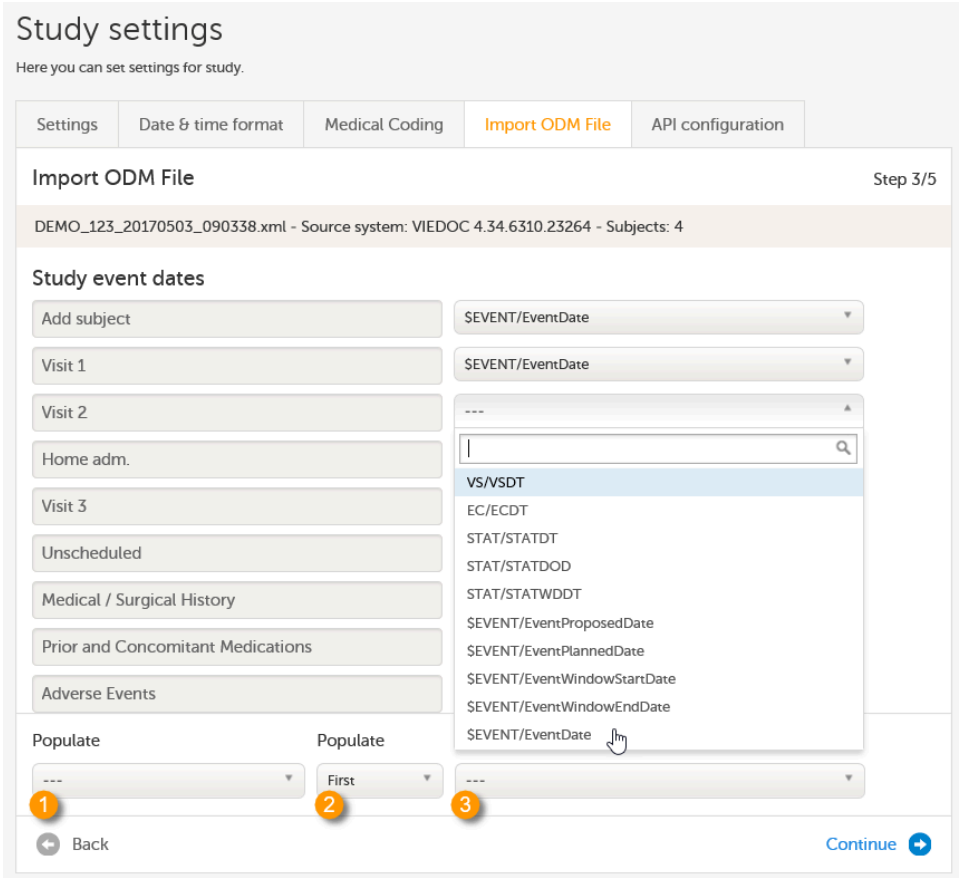
Note! Make sure that every *Location* in the ODM file to be imported has at least one *MetaDataVersionRef* defined, otherwise no design version will be assigned to the respective site.

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.



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.

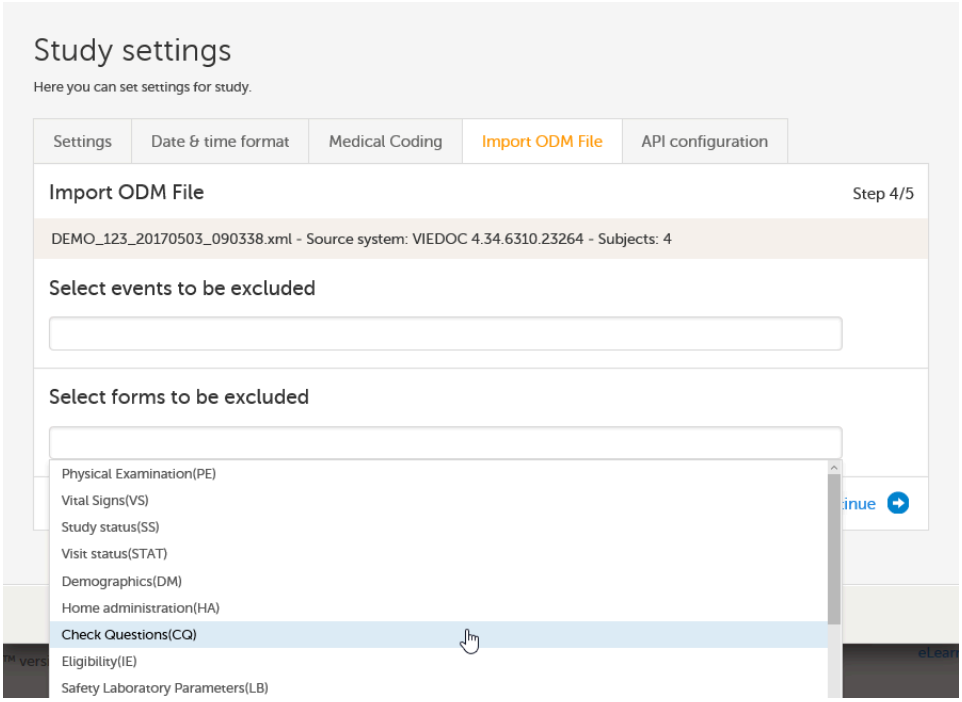
Click **Continue**. This takes you to step 4/5.

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.

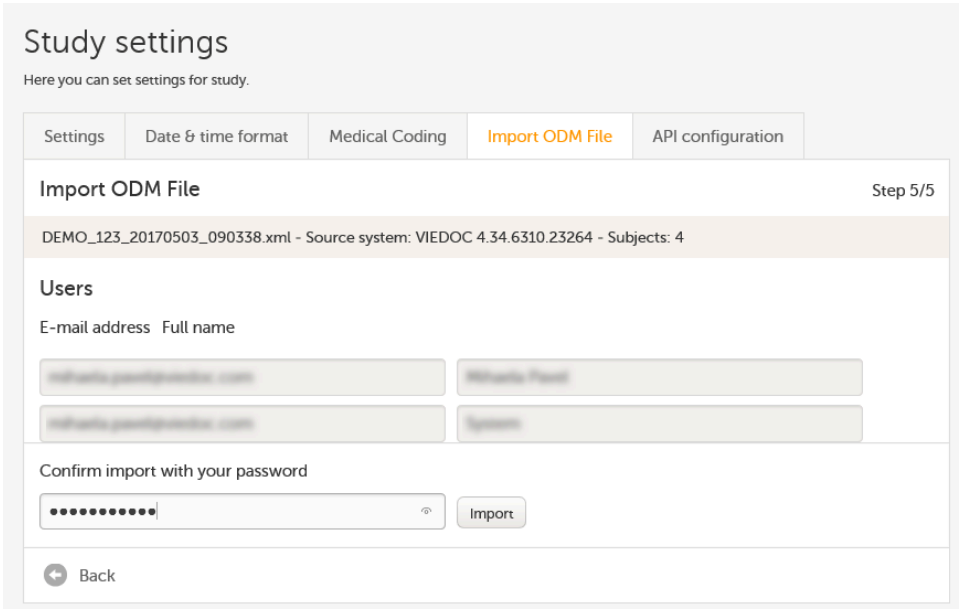


Click **Continue**. This takes you to step 5/5.

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.



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 2025-01-14

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.

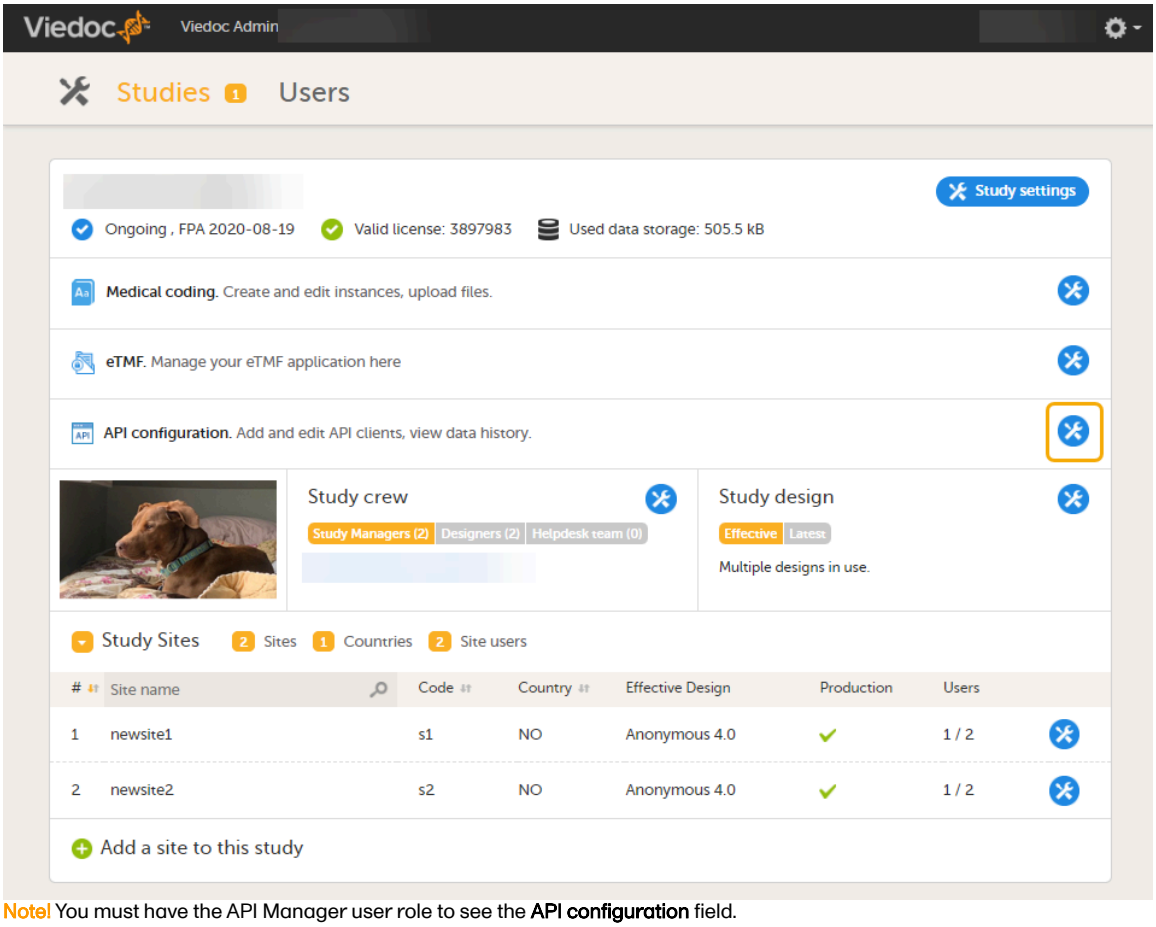
To ensure backward compatibility with previous Viedoc versions, you can select which data structure version should be used when creating an API client ID.

3 Adding a Viedoc WCF API client and obtaining the API client ID

To add an API client and to obtain a client ID:

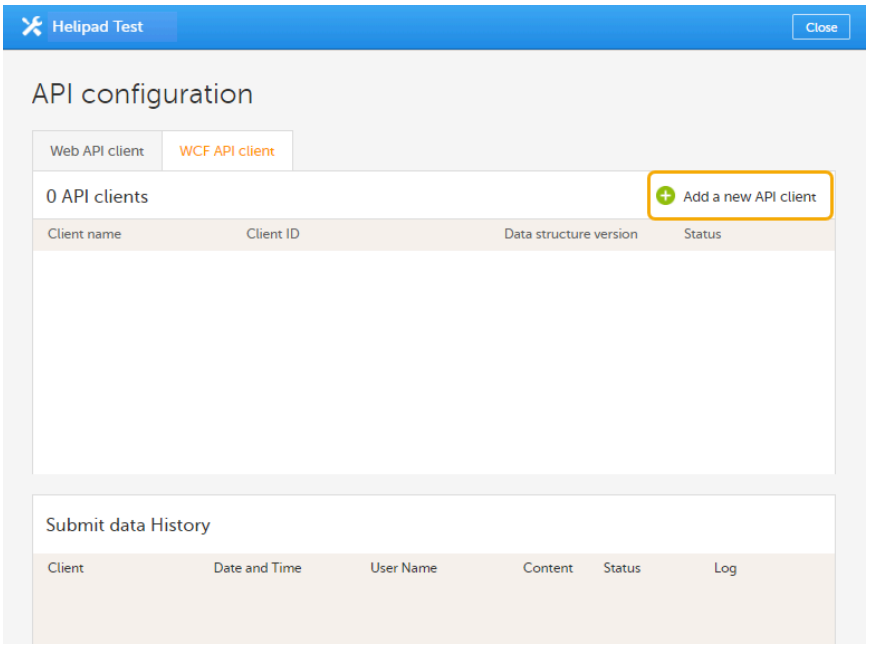
1 On the Viedoc landing page, click on the **Admin** icon to open Viedoc Admin.

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.

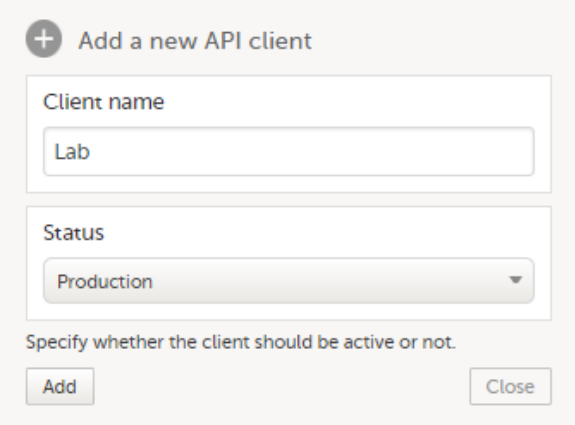


Note! You must have the API Manager user role to see the **API configuration** field.

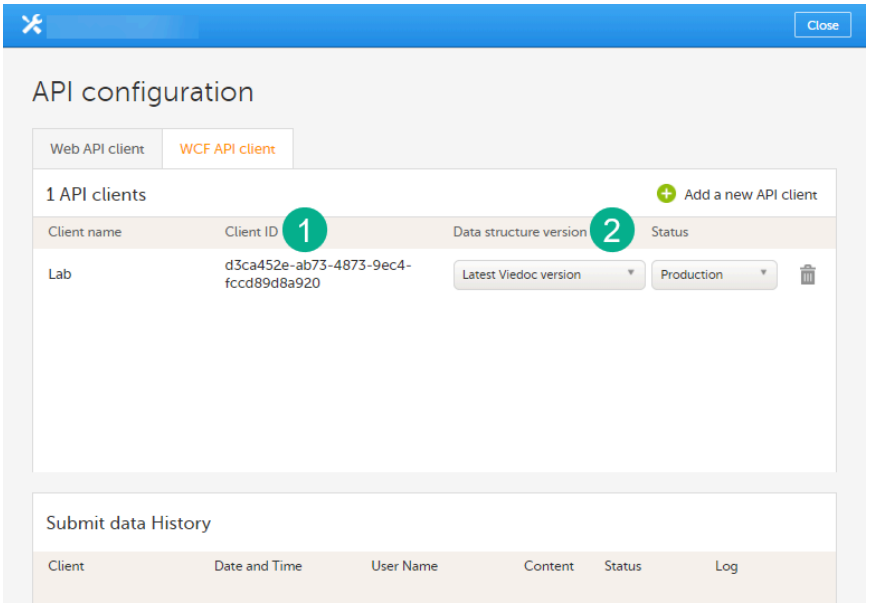
3 On the tab **WCF API client**, click on **Add a new API client**.



4 Enter a name for the API client. 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.

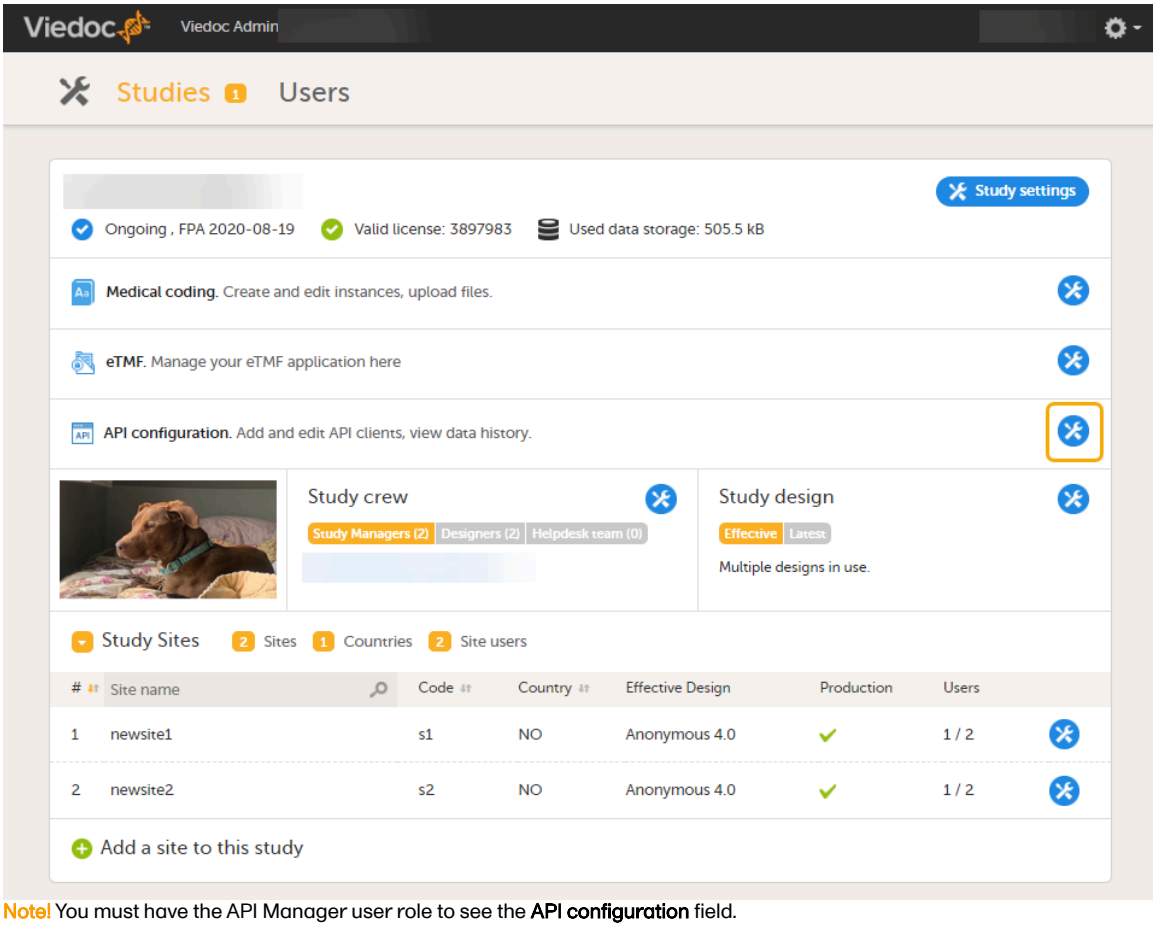
7 Note down the client ID to be used later.

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:

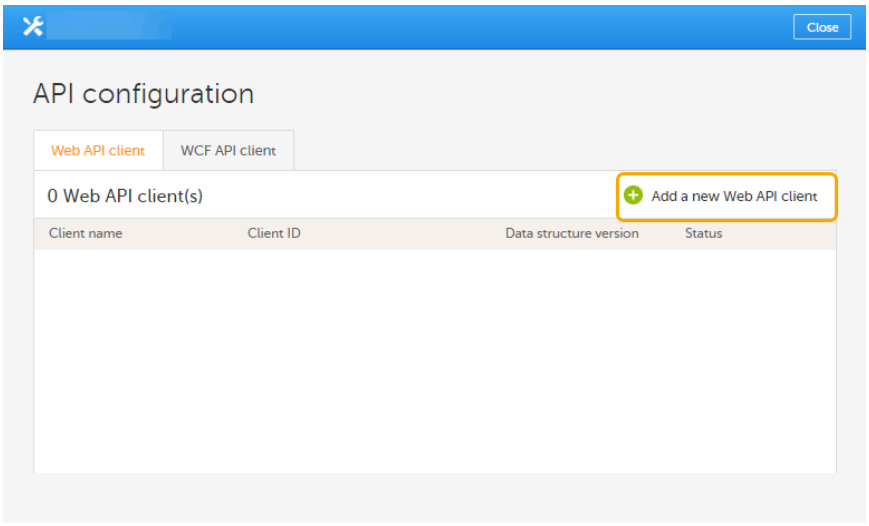
1 On the Viedoc landing page, select the **Admin** icon to open Viedoc Admin.

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 box.

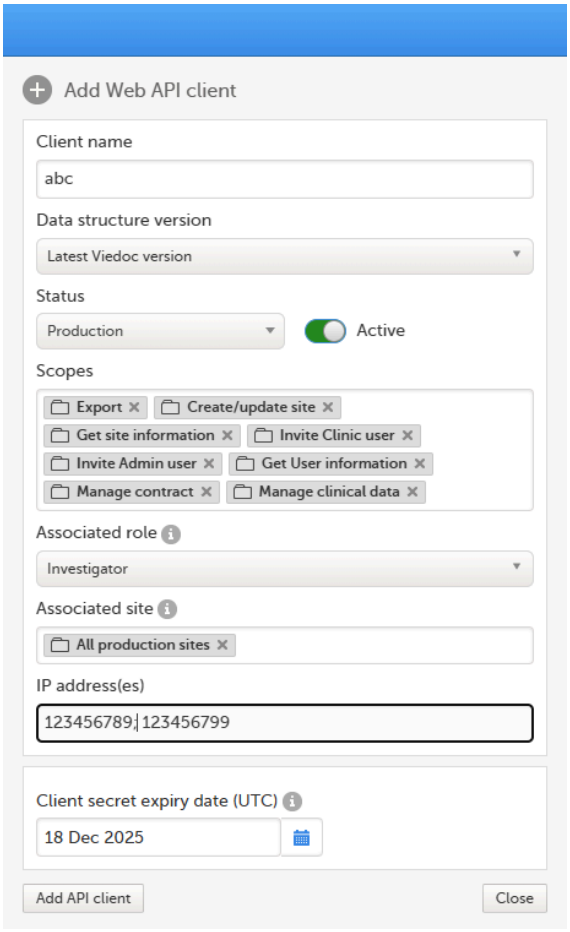


Note! You must have the API Manager user role to see the **API configuration** field.

3 On the tab **Web API client**, click on **Add a new Web API client**.



4 Enter a name for the API client.



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**, or **Demo**) from the **Status** dropdown menu.
You can also select the **Active/Inactive** button to switch the study status. This is a fast way to inactivate the Web API Client. Using an inactive client in an API call will be rejected.

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**
- **Manage clinical data** - for use with future Web API endpoints

Note! See below for more information about how to define the Export scope.

8 Optionally, enter the IP addresses from which requests to the Web API endpoints are permitted.

Note!

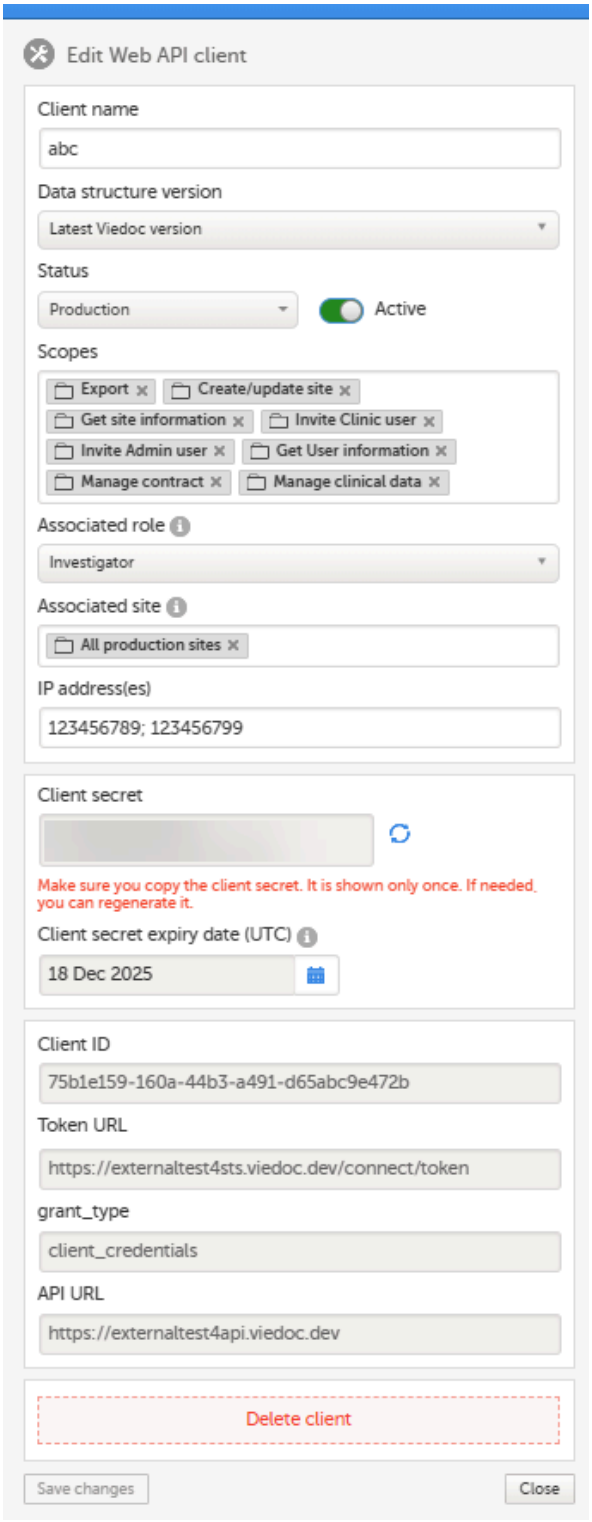
- You can add a semi-colon separated list of multiple IP addresses.
- If calls from any IP address are allowed, the IP address(es) field can be left blank.

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**



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.

Can not output single-source

6 Defining the export scope for the Web API client

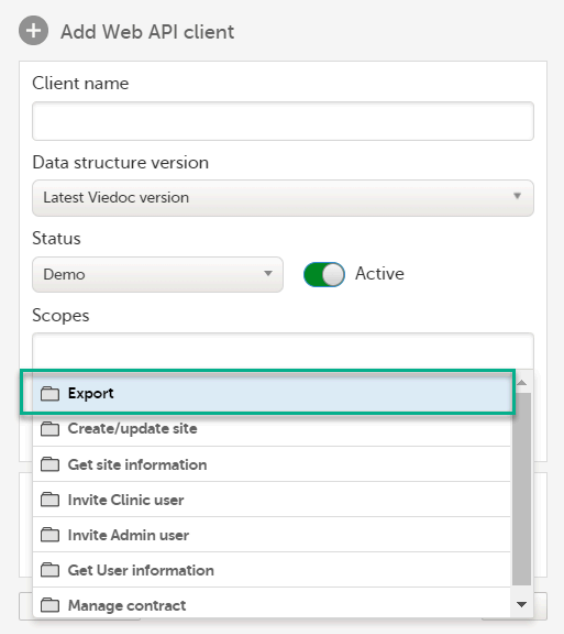
As an API Manager, in order to restrict what data is available to export through the Web API, when configuring a Web API Client you need to define the export scope. This is done by associating a role and site(s) to the Web API Client.
Only data that is available for the associated role under one of the associated sites will be included in the exported data.

The API export endpoint will then be accessible to a specific associated user role and site(s) only.

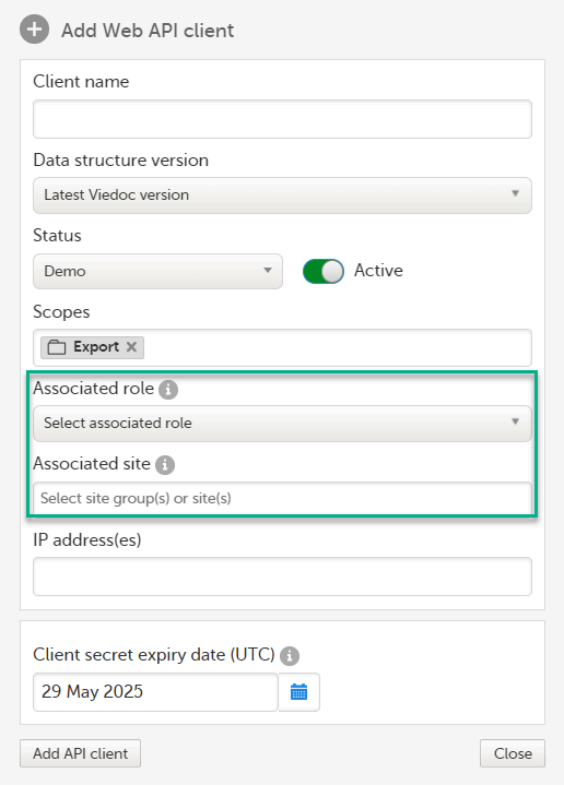
Note! You can select only one **Associated role** per Web API client.

To define the Export scope:

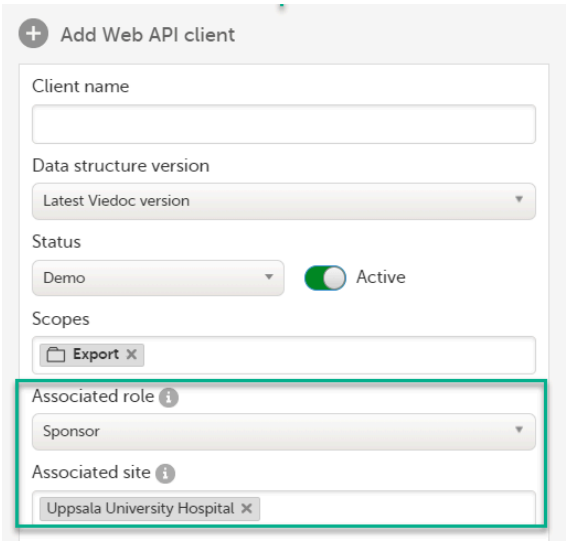
1 In the **Add Web API client**, in the **Scopes** field, select **Export**:



The **Associated role** and **Associated site** dropdown menus are displayed:



2 Select the **Associated role** and **Associated site**:



The associated roles available for selection are the Clinic user roles which have data export permission.

The available sites are the sites with an assigned study design together with their corresponding site groups.

Note! Web API requests will return an error code if a role and/or site is specified that does not comply with the configuration of the Web API client.

For example, if the configuration of the Web API Client is as follows:

- If the Web API Client Role is configured for the associated role "Role 1", and the associated site(s) as All production sites, if the request specifies "Role 1" and the site is not specified, the data that is accessible (and thus returned) for the role and site is the data for "Role 1" and for all production sites.
- If the Web API Client associated site is configured for a country and for the associated role "Role 1", a request for a specific site, but no associated role, will return data for "Role 1" and that site only - as long as the site is in the same country group.
- If the Web API Client Role is configured for the associated role "Role 1", and the associated site as a specific site, If the request instead is for "Role 2" and the same site, this will result in an error code.
- Requesting a different site to the configured associated site in the Web API Client results in an error code even if the associated role is requested is the same.
- If the Web API Client site(s) is configured for a country and the Web API Client Role is configured for the associated role "Role 1", a request for a site in a different country with no associated role specified will result in an error code.
- If the Web API Client site is configured for a country and the associated role "Role 1", if the request specifies "Role 1", and the request is for one site in the specified country and also another site not in the same country, this will result in an error code.

Notes!

- If a study has an existing Web API client with the export scope, when the API Manager selects **Edit**, the **Associated Role** and **Associated site** dropdown menus are highlighted with a red border. The Web API client edits cannot be saved until a valid Associated role and Associated site are selected.
- The role information (Name/ RoleID) and all changes to the Associated role of a Web API Client is included in the Admin Audit Trail Report.

Viedoc Web API

Viedoc Web API

Published by Viedoc System 2024-10-10

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.

Key	Value	Description
`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.

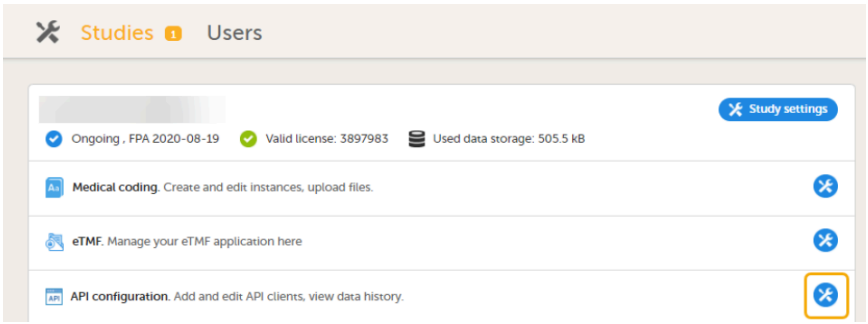
To view the Viedoc Web API swagger page, you need the **API URL** in Viedoc Admin.

Note! You must have the API Manager user role to see the **API configuration** field.

To view the **API URL** in Viedoc Admin:

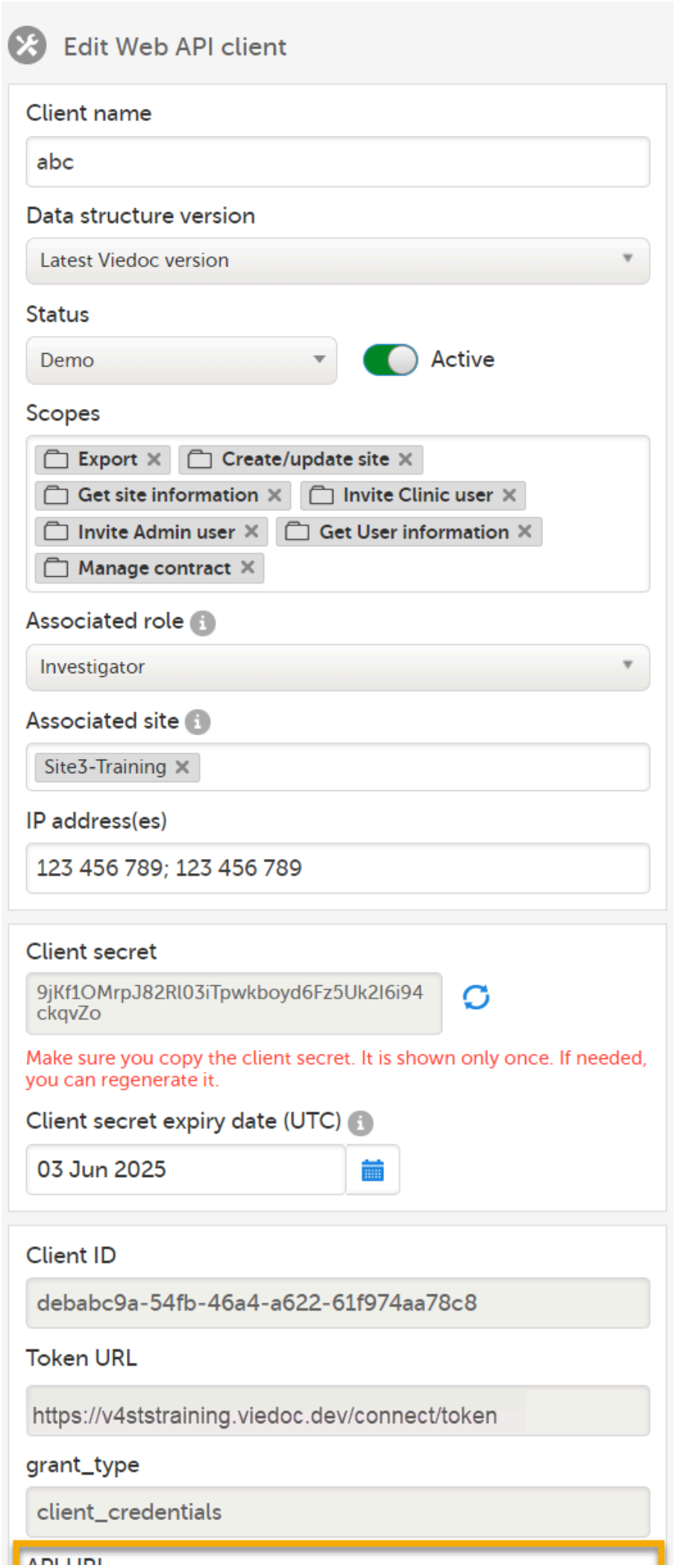
1. On the Viedoc landing page, select the **Admin** icon to open Viedoc Admin.

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.

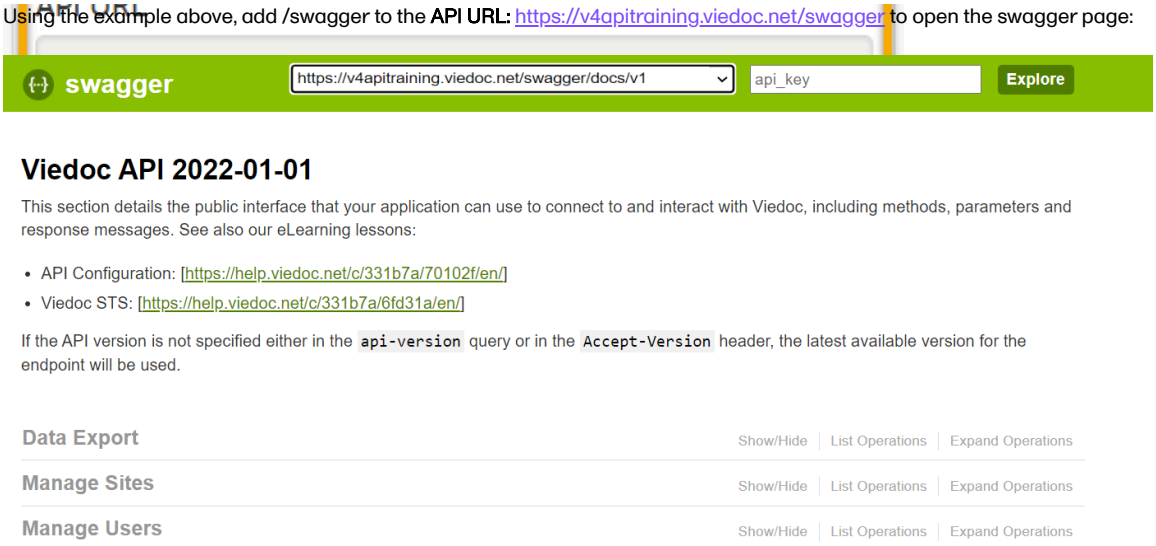


3 On the Web API client tab, select **Edit** for the API Client you want to access.

4 The **Edit Web API client** dialog opens:


Edit Web API client
Client name
abc
Data structure version
Latest Viedoc version
Status
Demo
Active
Scopes
Export
Create/update site
Get site information
Invite Clinic user
Invite Admin user
Get User information
Manage contract
Associated role
Investigator
Associated site
Site3-Training
IP address(es)
123 456 789; 123 456 789
Client secret
9jKf1OMrpJ82Rl03iTpwkboyd6Fz5Uk2l6i94ckqvZo
Make sure you copy the client secret. It is shown only once. If needed, you can regenerate it.
Client secret expiry date (UTC)
03 Jun 2025
Client ID
debabc9a-54fb-46a4-a622-61f974aa78c8
Token URL
https://v4ststraining.viedoc.dev/connect/token
grant_type
client_credentials

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

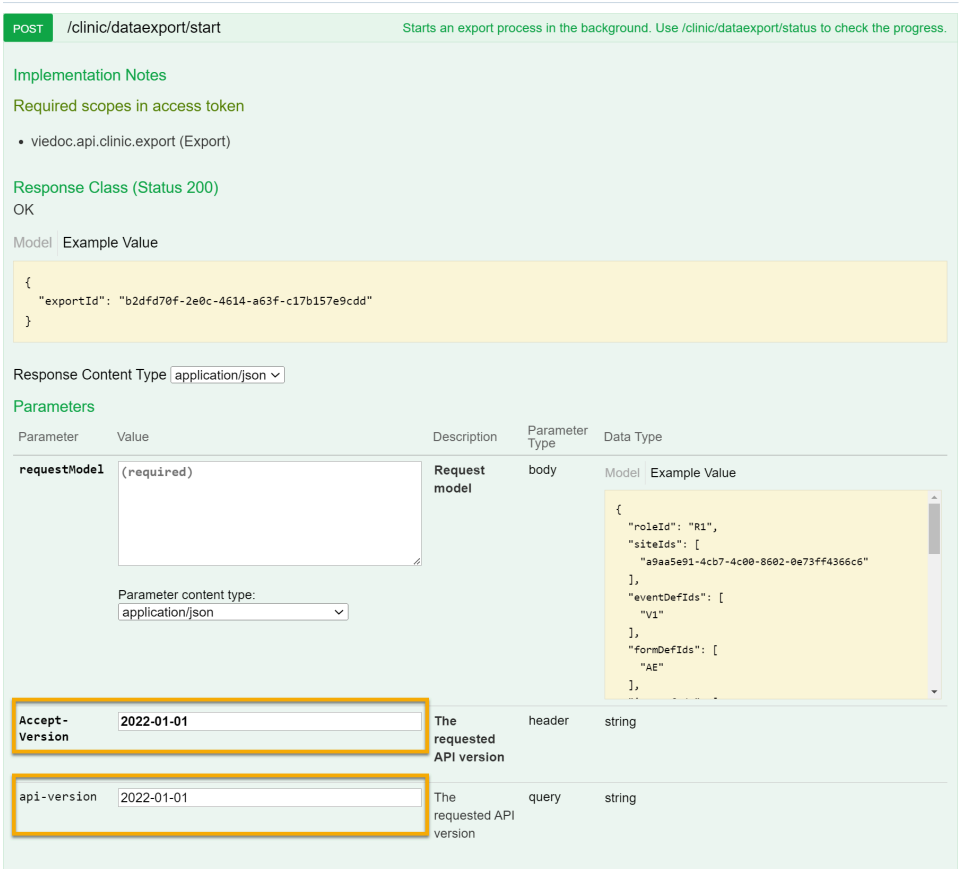
The Viedoc Web API swagger page contains information about how to connect to and interact with Viedoc using the Viedoc Web API, including methods, parameters and response messages.

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.



> **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

Exporting data via Viedoc's Web API

Exporting data via Viedoc's web API

Published by Viedoc System 2025-01-14

This lesson explains how to export data via Viedoc's web API. You will be shown three examples: Windows command prompt, Python, and R.

Note! You must have the API Manager role in order to see the API configuration field.

1 Configuring the API client

Important! To export data, enable the **Export scope** and to select the correct **Status** while configuring the API client. We have two modes: **demo** and **production**.

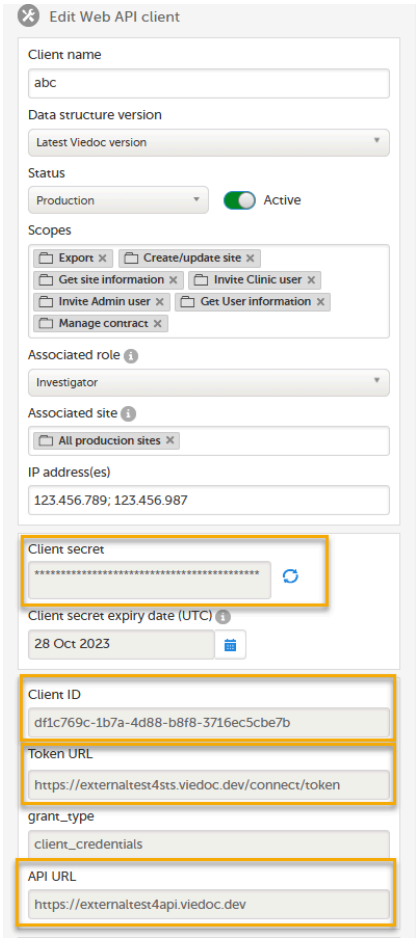
Demo – Used to access sites that operate in Demo/Training mode
Production – Used to access sites that operate in Production mode

After creating the API client, take note of the following information, as it is needed in subsequent steps:

Client secret – Needed to obtain the token. Tip! Make sure you copy it, because it is shown only once. If needed, you can regenerate it.
Client ID – Needed to obtain the token.
Token URL – Used for obtaining the token, which is needed to authorize all subsequent API calls.
API URL – All other API calls are made to this base URL with varying endpoints.

Notes!

- An Associated role and an Associated site must be selected for the Export scope.
- The roleID can be optionally selected when exporting via the API. If a roleID is selected, it must match the role selected when configuring the export scope for the Web API client.



For more information on how to configure the API client, select this link: API configuration.

2 Examples

2.1 Windows command prompt

This section describes the steps to export the data using the Windows command prompt.

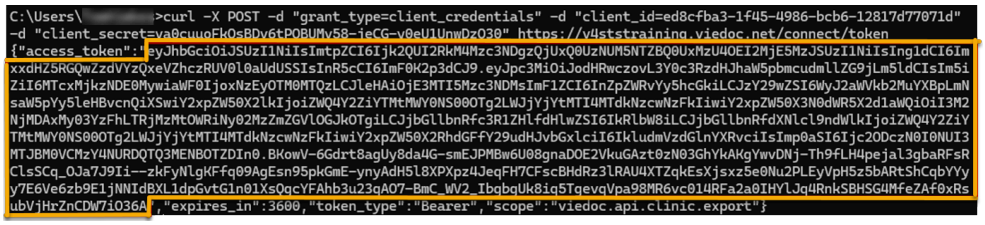
1 Obtain the token

To obtain the token, use the following code:

```
curl -X POST -d "grant_type=client_credentials" -d "client_id=xxxx" -d "client_secret=yyyy" TokenURL
```

Note! Replace "xxxx" with your Client ID and "yyyy" with your Client Secret. The TokenURL is obtained from Viedoc Admin.

This is an example of template including the output:



2 Start the export process

To start the export process, you can use the following code as a template:

```
 curl -X POST -H "Authorization: Bearer xxxx --json "yyyy"
APIURL/clinic/dataexport/start
```

Note! Replace `xxxx` with the token generated in the above step. The `yyyy` should specify the desired JSON export format. The `APIURL` should contain the URL obtained from Viedoc Admin.

This is an example of the template including the output:

```
C:\Users\        >curl -X POST -H "Authorization: Bearer eyJhbGciOiJSUzI1NiIsImtpZCI6Ijk2QUI2RkM4Mzc3NDgzQjUxQ0UzNUM5NT
ZBQ0UxMzU4OEI2MjE5MzJSUzI1NiIsIng1dCI6ImxxdHZ5RGQwZzdVYzQxeVZhczRUV0l0aUdUSSIsInR5cCI6ImF0K2p3dCJ9.eyJpc3MiOiJodHRwczovL
3Y0c3RzdHJhaW5pbmcudmllZG9jLm5ldCIsIm5iZiI6MTcxMjEzNjAwMiwiaWF0IjoxNzEyMTM2MDAyLCJleHAiOjE3MTIxMzk2MDIsImF1ZCI6InZpZWRvY
y5hcGkiLCJzY29wZSI6WyJ2aWVkb2MuYXBpLmNsaW5pYy5leHBvcnQiXSwiY2xpZW50X2lkIjoiMDhmZTI4ZDUtMzNjZi00Yz01LWEyNzUtMjg2MmI4NTViM
zNlIiwiY2xpZW50X3N0dWR5X2d1aWQiOiI4MjlkNTBjNi0yNzEwLTRkZTQtODUyMi1hNjAzOWFkNmQzMGEiLCJjbGllbnRfc3R1ZHlfdHlwZSI6IkRlbW8iLC
JjbGllbnRfdXNlcl9ndWlkIjoiMDhmZTI4ZDUtMzNjZi00Yz01LWEyNzUtMjg2MmI4NTViMzNlIiwiY2xpZW50X2RhdGFfY29udHJvbGxlciI6IkludmVzd
GlnYXRvciIsImp0aSI6Ijg4NjFBNTMxMTMwQjVCMjE1QzY3QUIxN0ZFNkEwREFBIn0.ME5tsyuNRgklKEUec90xvkgDxL-BDRrkq1swtay4smSYKOXG1fFO-
W5YAQYJKcq2q6D_Q7JK8lvgFOamBDE9fwW8gBhYUgmWX-iRwA180WjoeYVpBbHpf2ZPyCR0DtT36g35NI0Db-BX9fp5p7ynye_Kx8kw9gmZooC7FmGvpzw2C
04jNdm2p23VYzG7dEZ2GBsq9_8XAW3uQCa-H7oKxslYsQs3MpB8adaKremo1YOAfpNPdGUcrNajogNEOjfD3KlkWK45uYBMp-0WR9XHNXBjVqrSHBHfls_zW
XEnMzTefVbDjYnA0PPEYXxgCby4ZFs0Dxazl_yFHgxLRRe2Dg" --json "{'roleId':'R1','formDefIds':['DM'],'includeSubjectStatus':tru
e,'outputFormat':'Excel'}" https://v4apitraining.viedoc.net/clinic/dataexport/start
{"exportId":"4fc72017-e872-46a7-9da0-a0b598ad76de"}
```

Note! You must specify the export with a JSON format. Below is a template which shows all the available export properties. The applied properties are optional. See our Swagger page for more information on export settings.

```
 {'roleId':'','siteIds':[],'eventDefIds':[],'formDefIds':[],'itemDefIds':[],'includeVisitDates':true,
'includeNotSigned':true,'includeSignedOnly':false,'includeSDVPerformedOrNA':true,
'includeSDVPending':true,'includeEditStatus':true,'grouping':'GroupByForm','rowLayout':'RowPerActivity',
'outputFormat':'CSV','timePeriodDateType':'EventDate','timePeriodOption':'Between','includeHistory':true,
'includeMedicalCoding':true,'includeSignatures':true,'includeReviewStatus':true,'includeSdv':false,
'includeQueries':true,'includeQueryHistory':false,'includeViedocExtensions':true,'fromDate':'','toDate':'',
'exportVersion':'','includeSubjectStatus':true,'includeBookletStatus':false,'includeBookletStatusHistory':false,
'includeSasScript':false,'includePendingForms':true}
```

3 Check the export process

To check the export process, you can use the following code as a template:

```
 curl -X GET -H "Authorization: Bearer xxxx"
APIURL/clinic/dataexport/status?exportId=yyyy
```

Note! Replace `xxxx` with the token and the `APIURL` with the API URL obtained from Viedoc Admin. Replace `yyyy` with the export ID obtained in the previous step.

This is an example of the output:

```
C:\Users\        >curl -X GET -H "Authorization: Bearer eyJhbGciOiJSUzI1NiIsImtpZCI6Ijk2QUI2RkM4Mzc3NDgzQjUxQ0UzNUM5NTZ
BQ0UxMzU4OEI2MjE5MzJSUzI1NiIsIng1dCI6ImxxdHZ5RGQwZzdVYzQxeVZhczRUV0l0aUdUSSIsInR5cCI6ImF0K2p3dCJ9.eyJpc3MiOiJodHRwczovL3
Y0c3RzdHJhaW5pbmcudmllZG9jLm5ldCIsIm5iZiI6MTcxMjEzNjAwMiwiaWF0IjoxNzEyMTM2MDAyLCJleHAiOjE3MTIxMzk2MDIsImF1ZCI6InZpZWRvVy
5hcGkiLCJzY29wZSI6WyJ2aWVkb2MuYXBpLmNsaW5pYy5leHBvcnQiXSwiY2xpZW50X2lkIjoiMDhmZTI4ZDUtMzNjZi00Yz01LWEyNzUtMjg2MmI4NTViMz
NlIiwiY2xpZW50X3N0dWR5X2d1aWQiOiI4MjlkNTBjNi0yNzEwLTRkZTQtODUyMi1hNjAzOWFkNmQzMGEiLCJjbGllbnRfc3R1ZHlfdHlwZSI6IkRlbW8iLC
JjbGllbnRfdXNlcl9ndWlkIjoiMDhmZTI4ZDUtMzNjZi00Yz01LWEyNzUtMjg2MmI4NTViMzNlIiwiY2xpZW50X2RhdGFfY29udHJvbGxlciI6IkludmVzdG
lnYXRvciIsImp0aSI6Ijg4NjFBNTMxMTMwQjVCMjE1QzY3QUIxN0ZFNkEwREFBIn0.ME5tsyuNRgklKEUec90xvkgDxL-BDRrkq1swtay4smSYKOXG1fFO-W
5YAQYJKcq2q6D_Q7JK8lvgFOamBDE9fwW8gBhYUgmWX-iRwA180WjoeYVpBbHpf2ZPyCR0DtT36g35NI0Db-BX9fp5p7ynye_Kx8kw9gmZooC7FmGvpzw2C0
4jNdm2p23VYzG7dEZ2GBsq9_8XAW3uQCa-H7oKxslYsQs3MpB8adaKremo1YOAfpNPdGUcrNajogNEOjfD3KlkWK45uYBMp-0WR9XHNXBjVqrSHBHfls_zWX
EnMzTefVbDjYnA0PPEYXxgCby4ZFs0Dxazl_yFHgxLRRe2Dg" https://v4apitraining.viedoc.net/clinic/dataexport/status?exportId=4fc
72017-e872-46a7-9da0-a0b598ad76de
{"exportStatus":"Ready","progressPercent":100}
```

When the export status shows as `Ready`, you can continue to the next step.

4 Download the export

To download the export, you can use the following code as a template:

```
curl -X GET -H "Authorization: Bearer xxxx"
APIURL/clinic/dataexport/download?exportId=yyyy --output
path\where\to\save\file.zip
```

Note! Replace `xxxx` with the token and the `APIURL` with the API URL obtained in Viedoc Admin. Replace `yyyy` with the export ID. Finally, the path where the file will be saved needs to be specified along with the name and file extension (.zip for CSV exports, .xlsx for Excel, and .xml for XML).
This is an example of the template including the output:

```
C:\Users\        >curl -X GET -H "Authorization: Bearer eyJhbGciOiJSUzI1NiIsImtpZCI6Ijk2QUI2RkM4Mzc3NDgzQjUxQ0UzNUM5NTZ
BQ0UxMzU4QEI2MjE5MzJSUzI1NiIsIng1dCI6ImxxdHZ5RGQwZzdVYzQxeVZhczRUV0l0aUdUSSIsInR5cCI6ImF0K2p3dCJ9.eyJpc3MiOiJodHRwczovL3
Y0c3RzdHJhaW5pbmcudmllZG9jLm5ldCIsIm5iZiI6MTcxMjEzNjAwMiwiaWF0IjoxNzEyMTM2MDAyLCJleHAiOjE3MTIxMzk2MDIsImF1ZCI6InZpZWRvVy
5hcGkiLCJzY29wZSI6WyJ2aWVkb2MuYXBpLmNsaW5pYy5leHBvcnQiXSwiY2xpZW50X2lkIjoiMDhmZTI4ZDUtMzNjZi00YzM1LWEyNzUtMjg2MmI4NTViMz
NlIiwiY2xpZW50X3N0dWR5X2d1aWQiOiI4MjlkNTBjNi0yNzEwLTRkZTQtODUyMi1hNjAzOWFkNmQzMGEiLCJjbGllbnRfc3R1ZHlfdHlwZSI6IkRlbW8iLC
JjbGllbnRfdXNlcl9ndWlkIjoiMDhmZTI4ZDUtMzNjZi00YzM1LWEyNzUtMjg2MmI4NTViMzNlIiwiY2xpZW50X2RhdGFfY29udHJvbGxlciI6IkludmVzdG
lnYXRvciIsImp0aSI6Ijg4NjFBNTMxMTMwQjVCMjE1QzY3QUIxN0ZFNkEwREFBIn0.ME5tsyuNRgklKEUec90xvkgDxL-BDRrkq1swtay4smSYKOXG1fFO-W
5YAQYJKcq2q6D_Q7JK8lvgFOamBDE9fwW8gBhYUgmWX-iRwA180WjoeYVpBbHpf2ZPyCR0DtT36g35NI0Db-BX9fp5p7ynye_Kx8kw9gmZooC7FmGvpzw2C0
4jNdm2p23VYzG7dEZ2GBsq9_8XAW3uQCa-H7oKxslYsQs3MpB8adaKremo1YOAfpNPdGUcrNajogNEOjfD3KlkWK45uYBMp-0WR9XHNXBjVqrSHBHfls_zWX
EnMzTefVbDjYnA0PPEYXxgCby4ZFs0Dxazl_yFHgxLRRe2Dg" https://v4apitraining.viedoc.net/clinic/dataexport/download?exportId=4
fc72017-e872-46a7-9da0-a0b598ad76de --output C:\Users\        \Downloads\DataExport.xlsx
  % Total    % Received % Xferd  Average Speed   Time    Time     Time  Current
                                 Dload  Upload   Total   Spent    Left  Speed
100 37789  100 37789    0     0   100k      0 --:--:-- --:--:-- --:--:--  101k
```

2.2 Python

This section will take you through the steps to export data using Python.

Note! This example uses the *requests* package for Python. Ensure that you have it installed before running the code below. To install the requests package open command prompt or terminal and type `pip install requests`.

1 Obtain the token

To obtain the token, you can use the following code as a template:

```
import requests
clientId = "xxxx"
clientSecret = "xxxx"
tokenURL = "xxxx"
apiURL = "xxxx"
params = {"grant_type": "client_credentials", "client_id": clientId, "client_secret": clientSecret}
response = requests.post(tokenURL, data = params)
token = response.json() .get("access_token")
```

Note! Replace `xxxx` with the information you obtained from setting up the API in Viedoc Admin.

This is an example of how to structure the request for a token in Python:

```
## Obtaining the token
import requests
clientId = "08fe28d5-33cf-4c35-a275-2862b855b33e"
clientSecret = "pnmC6UBEbaIvmVQLlzR8sVTkqijLzxSR4Fw2jsrLTyI"
tokenURL = "https://v4ststraining.viedoc.net/connect/token"
apiURL = "https://v4apitraining.viedoc.net"
params = {"grant_type": "client_credentials", "client_id": clientId, "client_secret": clientSecret}
response = requests.post(tokenURL,data=params)
token = response.json().get("access_token")
```

2 Start the export

To start the export process, you can use the following code as a template:

```
 header = {"Accept": "application/json", "Authorization": "Bearer " + token}
params = {

 "roleId":"",
"siteIds":[],
"eventDefIds":[],
"formDefIds":[],
"itemDefIds":[],
"includeVisitDates":"True",
"includeNotSigned":"True",
"includeSignedOnly":"False",
"includeSDVPerformedOrNA":"True",
"includeSDVPending":"True",
"includeEditStatus":"True",
"grouping":"GroupByForm",
"rowLayout":"RowPerActivity",
"outputFormat":"CSV",
"timePeriodDateType":"EventDate",
"timePeriodOption":"Between",
"includeHistory":"True",
"includeMedicalCoding":"True",
"includeSignatures":"True",
"includeReviewStatus":"True",
"includeSdv":"False",
"includeQueries":"True",
"includeQueryHistory":"False",
"includeViedocExtensions":"True",
"fromDate":"",
"toDate":"",
"exportVersion":"",
"includeSubjectStatus":"True",
"includeBookletStatus":"False",
"includeBookletStatusHistory":"False",
"includeSasScript":"False",
"includePendingForms":"True"}
response = requests.post("apiURL/clinic/dataexport/start", json=params,headers=header)
exportId = response.json().get("exportId")
```

Note! The `params` dictionary specifies the export settings. Key value pairs are optional. See our Swagger page for more information about the export settings.

This is an example of the start of the export process:

```
## Starting the export process
header = {"Accept":"application/json", "Content-Type":"application/json", "Authorization":"Bearer " + token}
params = {
"eventDefIds":["SCR"],
"formDefIds":["DM","VS"],
"includeVisitDates":"True",
"outputFormat":"Excel",
"grouping":"None",
"rowLayout":"RowPerValue"
}
response = requests.post(apiURL + "/clinic/dataexport/start",json=params,headers=header)
exportId = response.json().get("exportId")
```

3 Check the export status

To check the export status, you can use the following code as a template:

```
 from time import sleep
while(response.json().get("progressPercent") != 100 and response.json().get("exportStatus") !=
"Error"):
sleep(3)
response = requests.get(apiURL + "/clinic/dataexport/status?exportId="
+ exportId,headers=header)
```

Note! The above code checks for the completion of the export process every 3 seconds.

This is an example of the export process check:

```
## Waiting for export to finish
from time import sleep
while(response.json().get("progressPercent") != 100 and response.json().get("exportStatus") != "Error"):
    sleep(3)
    response = requests.get(apiURL + "/clinic/dataexport/status?exportId=" + exportId,headers=header)
```

4 Download the export

To download the export, you can use the following code as a template:

```
if response.json().get("exportStatus") == "Error":

     print("Export failed!")

elif response.json().get("exportStatus") == "Ready":

     print("Downloading and saving the export.\\n")

     response = requests.get(apiURL + "/clinic/dataexport/download?exportId=" + exportId,
    headers=header)

     if params["outputFormat"] == "CSV":

          extension = ".zip"

     elif params["outputFormat"] == "Excel":

          extension = ".xlsx"

     with open("path/where/to/save/file" + extension, "wb") as output:

               output.write(response.content)

     print("Output saved: " + "path/where/to/save/file" + extension)
```

Note! You need to specify the file path where you will save the file, as well as the file name.

This is an example of the export download:

```
## Downloading the export
if response.json().get("exportStatus") == "Error":
    print("Export failed!")
elif response.json().get("exportStatus") == "Ready":
    print("Downloading and saving the export.\n")
    response = requests.get(apiURL + "/clinic/dataexport/download?exportId=" + exportId,headers=header)

    ## Saving the download
    if params["outputFormat"] == "CSV":
        extension = ".zip"
    elif params["outputFormat"] == "Excel":
        extension = ".xlsx"
    with open("C:/Users/TomKimkes/Downloads/DataExport" + extension, "wb") as output:
            output.write(response.content)
    print("Output saved: C:/Users/TomKimkes/Downloads/DataExport" + extension)
```

2.3 R

This section will take you through how to export data using R.

Note! This example uses the httr and jsonlite packages for R. You need to install them before running the code in this example. To do so, type `(install.packages(c("httr", "jsonlite"))` into your R console. You only need to do this once.

1 Obtain the token

To obtain the token, you can use the following code as a template:

```
 library(httr)
library(jsonlite)
clientId <- "xxxx"
clientSecret <- "xxxx"
tokenURL <- "xxxx"
apiURL <- "xxxx"
params <- list("grant_type" = "client_credentials", "client_id" = clientId, "client_secret" =
clientSecret)
response <- POST(url = tokenURL, body = params, encode = "form")
response <- fromJSON(content(response, "text"))
token <- response$access_token
```

Note! Replace the `xxxx` fields with the information you obtained from Viedoc Admin.

This is an example of how to structure a token request:

```
library(httr)
library(jsonlite)

## Get token
params <- list("grant_type"= "client_credentials",
               "client_id"= "08fe28d5-33cf-4c35-a275-2862b855b33e",
               "client_secret"= "pnmC6UBEbaIvmVQLlzR8sVTkqijLzxSR4Fw2jsrLTyI")
tokenURL <- "https://v4ststraining.viedoc.net/connect/token"
apiURL <- "https://v4apitraining.viedoc.net"
response <- POST(
  url = tokenURL,
  body = params,
  encode = "form")
response <- fromJSON(content(response, "text"))
token <- response$access_token
```

2 Start the export process

To start the export process, you can use the following code as a template:

```
 params <- list(
"roleId"="",
"siteIds"=list(),
"eventDefIds"=list(),
"formDefIds"=list(),
"itemDefIds"=list(),
"includeVisitDates"="True",
"includeNotSigned"="True",
"includeSignedOnly"="False",
"includeSDVPerformedOrNA"="True",
"includeSDVPending"="True",
"includeEditStatus"="True",
"grouping"="GroupByForm",
"rowLayout"="RowPerActivity",
"outputFormat"="Excel",
"timePeriodDateType"="EventDate",
"timePeriodOption"="Between",
"includeHistory"="True",
"includeMedicalCoding"="True",
"includeSignatures"="True",
"includeReviewStatus"="True",
"includeSdv"="False",
"includeQueries"="True",
"includeQueryHistory"="False",
"includeViedocExtensions"="True",
"fromDate"="",
"toDate"="",
"exportVersion"="",
"includeSubjectStatus"="True",
"includeBookletStatus"="False",
"includeBookletStatusHistory"="False",
"includeSasScript"="False",
"includePendingForms"="True")
response <- POST(
url = paste(apiURL, "/clinic/dataexport/start", sep = ""),
accept_json(),
add_headers(Authorization = paste("Bearer", token, sep = " ")),
body= params,
encode = "json")
response <- fromJSON(content(response, "text"))
exportID <- response$exportId
```

Note! The `params` list specifies the export settings. You do not need to provide all of the options. See our Swagger page for more information on the export settings.

This is an example of the start of the data export process:

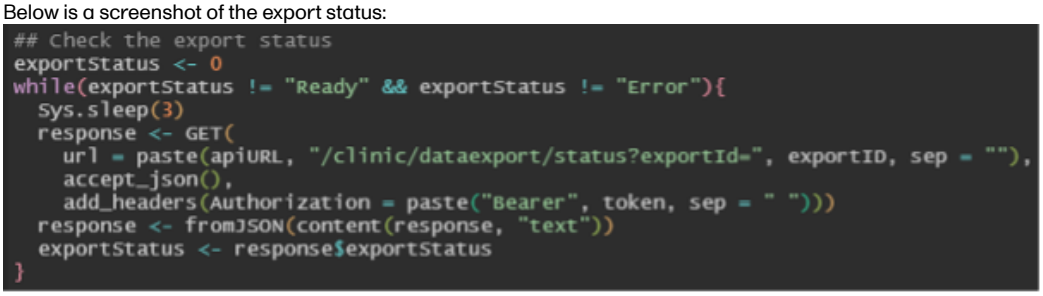
```
## Start data export process
params <- list(
  "roleId"="RS",
  "formDefIds"=list("AE","CM","MH"),
  "includeMedicalCoding"="True",
  "outputFormat"="CSV")
response <- POST(
  url = paste(apiURL, "/clinic/dataexport/start", sep = ""),
  accept_json(),
  add_headers(Authorization = paste("Bearer", token, sep = " ")),
  body = params,
  encode = "json")
response <- fromJSON(content(response, 'text'))
exportID <- response$exportId
```

3 Check the export status

To check the export status, you can use the following code as a template:

```
 exportStatus <- 0
while(exportStatus != "Ready" && exportStatus != "Error"){
Sys.sleep(3)
response <- GET(
url = paste(apiURL, "/clinic/dataexport/status?exportId=", exportID, sep = ""),
accept_json(),
add_headers(Authorization = paste("Bearer", token, sep = " "))
response <- fromJSON(content(response, "text"))
exportStatus <- response$exportStatus
```

Below is a screenshot of the export status:



```
## Check the export status
exportStatus <- 0
while(exportStatus != "Ready" && exportStatus != "Error"){
  Sys.sleep(3)
  response <- GET(
    url = paste(apiURL, "/clinic/dataexport/status?exportId=", exportID, sep = ""),
    accept_json(),
    add_headers(Authorization = paste("Bearer", token, sep = " ")))
  response <- fromJSON(content(response, "text"))
  exportStatus <- response$exportStatus
}
```

Note! The above code checks for the completion of the export process every 4 seconds.

4 Download the export

To download the data export, you can use the following code as a template:

```
 if(exportStatus == "Ready"){
response <- GET(
url= paste(apiURL, "/clinic/dataexport/download?exportId=", exportID,
sep = ""),
accept_json(),
add_headers(Authorization = paste("Bearer", token, sep = " "))
)
writeBin(response$content, "path/where/to/save/file.extension")
}
```

Note! You need to specify the file path where you will save the file, as well as the file name.

Below is a screenshot of the export download:

```
## Download the export
if(exportStatus == "Ready"){
  response <- GET(
    url = paste(apiURL, "/clinic/dataexport/download?exportId=", exportID, sep = ""),
    accept_json(),
    add_headers(Authorization = paste("Bearer", token, sep = " ")))
  writeBin(response$content, "dataExport.zip")
  paste("Output saved: ", getwd(), "/dataExport.zip", sep = "")
}
```

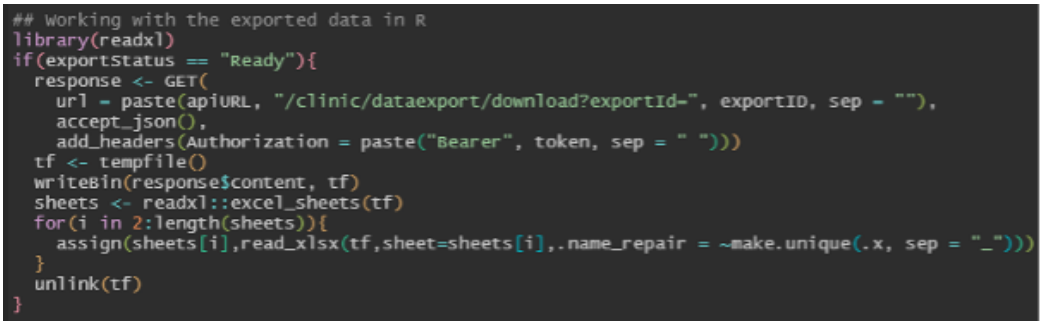
5 Analysis

If you want to analyze the data in R, you can use the following code as a template:

```
 library(readxl)
if(exportStatus == "Ready"){
response <- GET(
url = paste(apiURL, "/clinic/dataexport/download?exportId=", exportID, sep = ""),
accept_json(),
add_headers(Authorization = paste("Bearer", token, sep = " ")))
tf <- tempfile()
writeBin(response$content, tf)
sheets <- readxl::excel_sheets(tf)
for(i in 2:length(sheets)){
assign(sheets[i],read_xlsx(tf,sheet=sheets[i],.name_repair = ~make.unique(.x, sep = "_")))
}
unlink(tf)
}
```

Note! To analyze the data in Excel, you need to set the `outputFormat` from step 2 to `Excel`.

This is a screenshot of the exported data for analysis:



Medical coding settings

Medical coding settings

Published by Viedoc System 2024-12-03

This lesson describes how to manage medical coding dictionaries in Viedoc Admin.

1 Introduction

Can not output single-source

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.

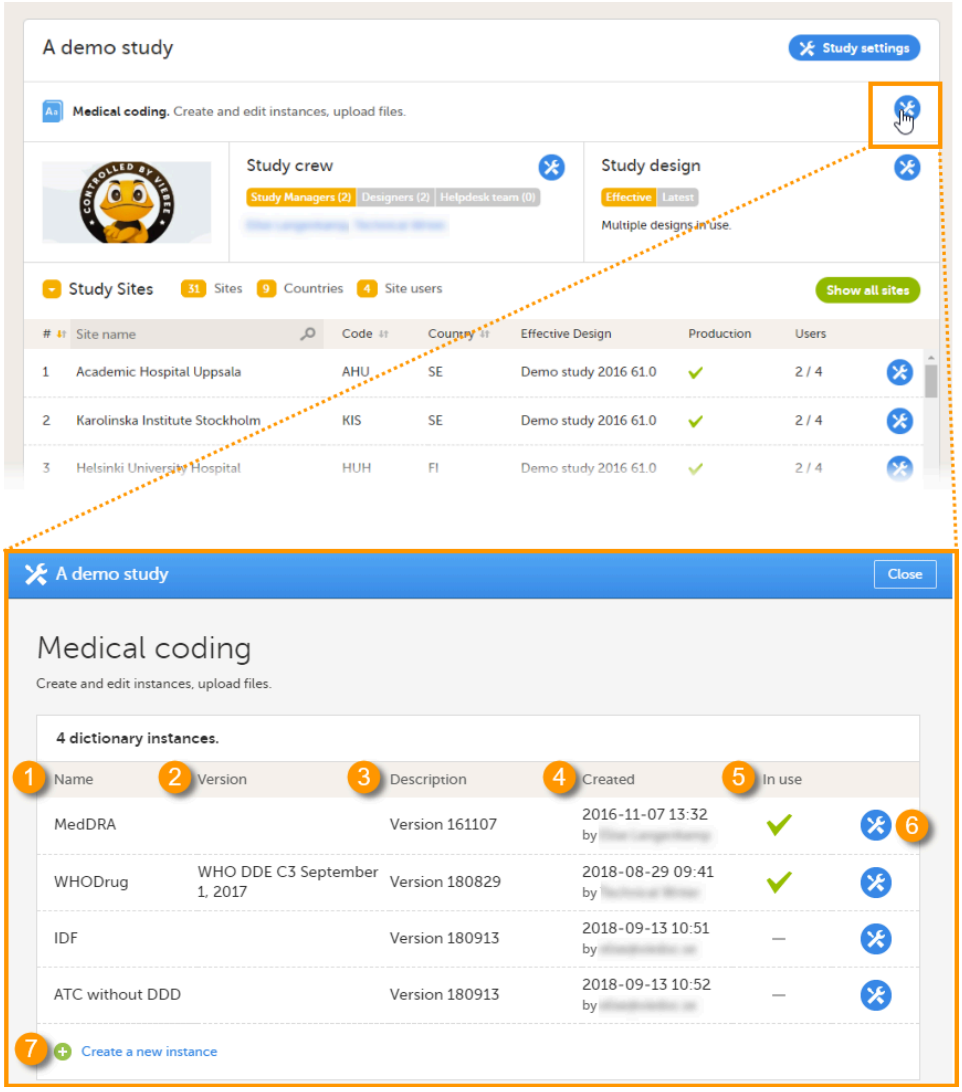
For detailed instructions, see the Step-by-step guides below.

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.



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.

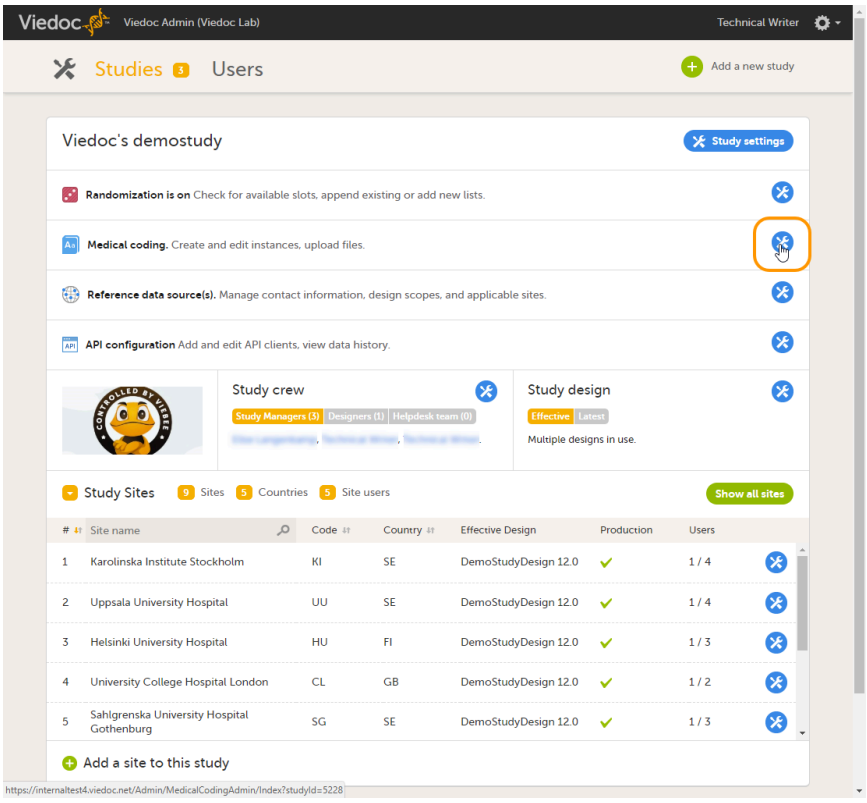
3 Step-by-step guides

3.1 Creating a dictionary instance

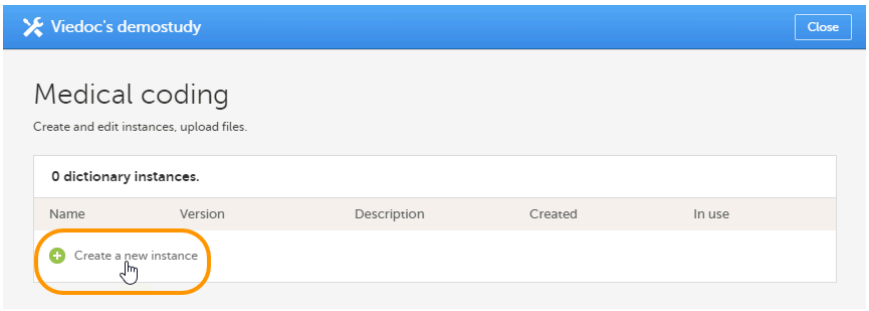
Note! Creating a dictionary instance (uploading a dictionary) can only be done by the Dictionary Manager.

To create a dictionary instance, follow the steps below.

1 On the study page in Viedoc Admin, select the toolbox icon in the **Medical coding** field to open the Medical coding window.



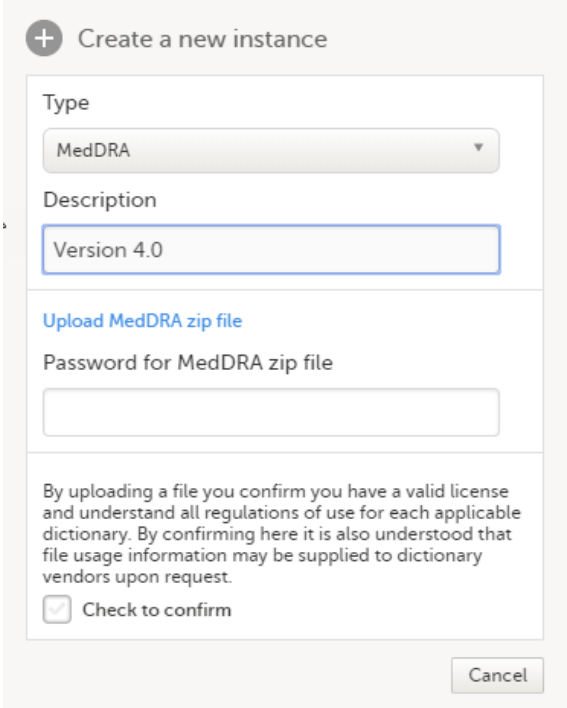
2 Select **Create a new instance**.



A dialog box opens.

3 In the **Create a new instance** dialog box:

1. Select the type of dictionary.
2. Type a version description, for example 'Version 4.0' or 'October 2016 HD'.
3. Select **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 **Check to confirm**.
6. Select **Create**.



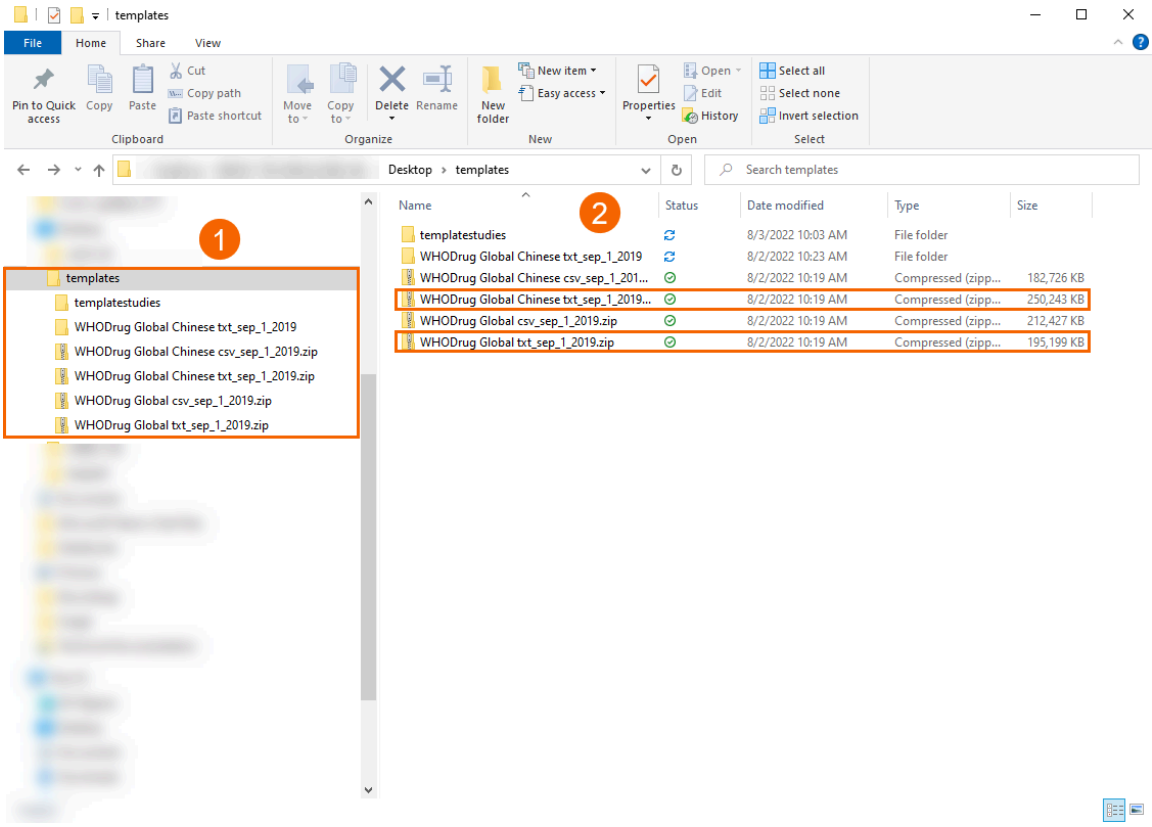
It may take up to several minutes to upload the file and create the dictionary instance. When the dictionary instance has been created, the **Create a new instance** dialog box closes automatically.

4 Select **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

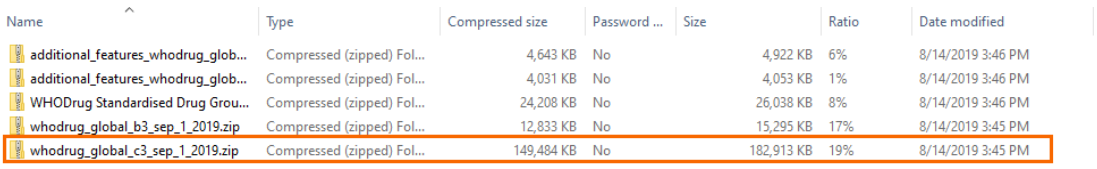


1. This is an example of a file tree that displays a file path for the documents.

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:



3 Upload this zipped folder to Viedoc and Viedoc will complete the final extraction for you, placing the WHODrug files in your study.

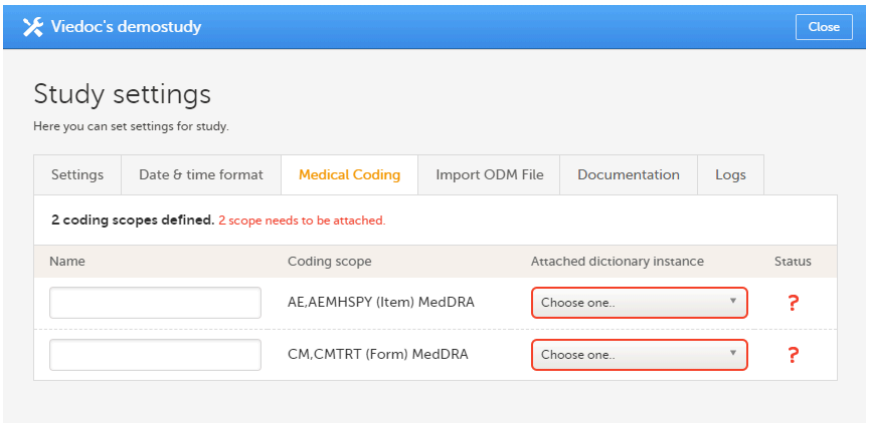
3.2 Linking coding scopes to a dictionary instance and enabling auto coding

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 and to enable auto coding:

1 On the study details page in Viedoc Admin, select **Study settings** to open the study settings dialog box.

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.

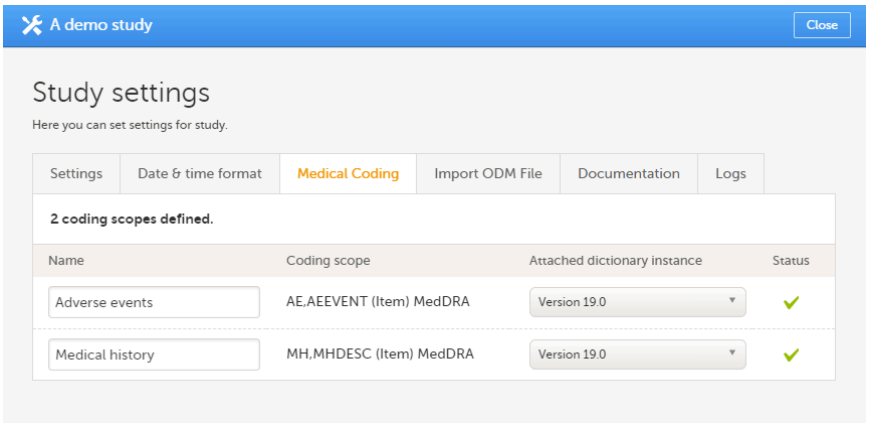


If no scopes are listed, contact the Designer of the study.

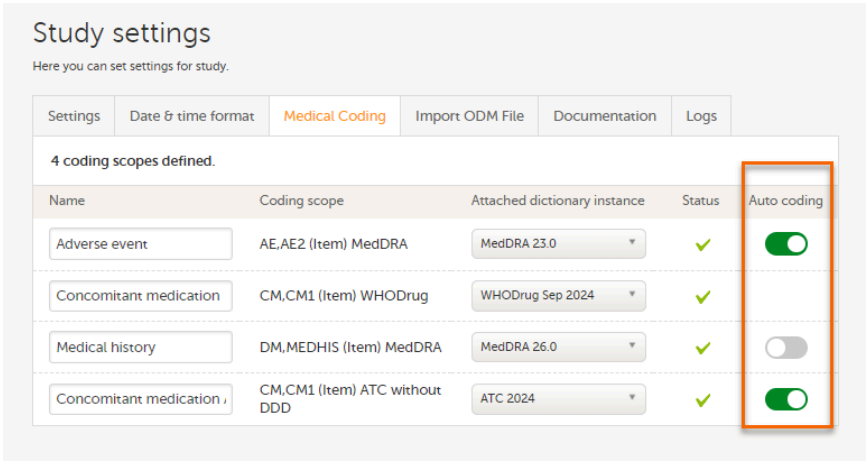
3 Type a name for each coding scope in the **Name** field. This name is displayed in the medical coding console in Viedoc Clinic.

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 Select the button to enable or disable auto coding for the respective scope.



6 Select **Save changes** to save the changes.
The study settings dialog box 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.

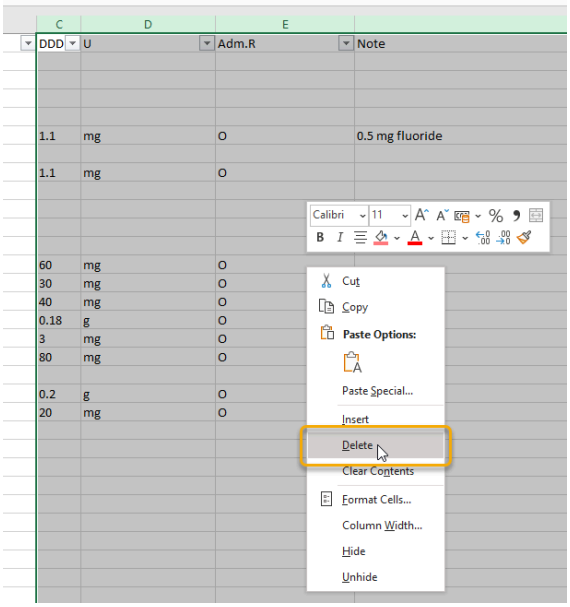
Converting an ATC dictionary from Excel format to ASCII format

Published by Viedoc System 2022-02-10

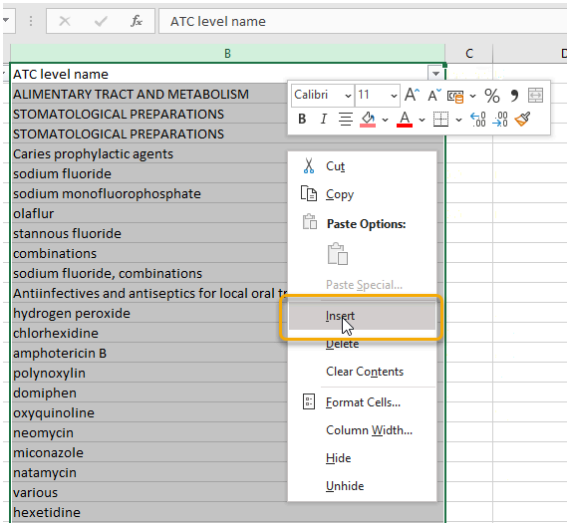
To convert an Anatomic Therapeutic Chemical classification system (ATC) dictionary:

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.

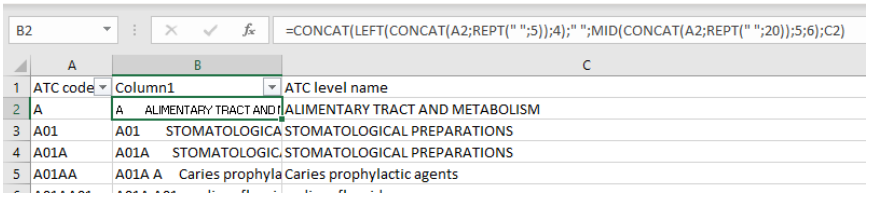


4 In cell B2, write a formula. To add a formula, start by typing an equal sign (=). Then Excel interprets the text in that cell as a formula (unless otherwise specified).

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);" ";EXTEXT(SAMMAN(A2;REP(" ";20));5;6);C2)

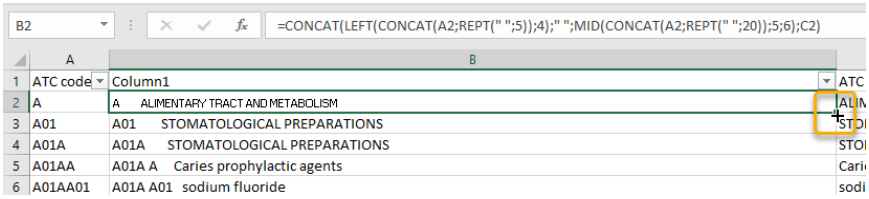
Note! Depending on the regional settings in your operating system, you might need to replace the semicolons with commas.



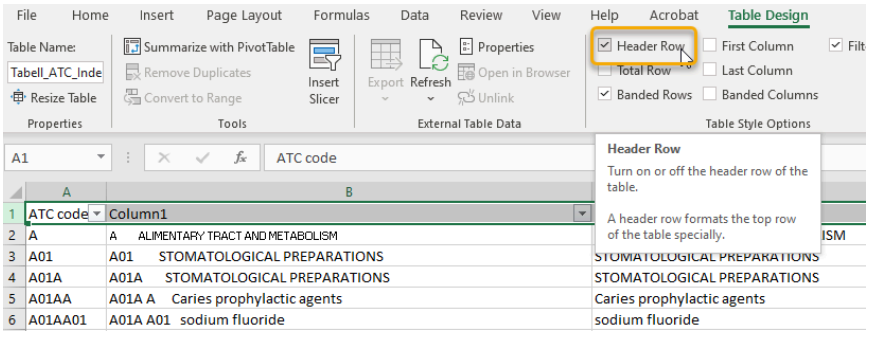
The formula does the following:

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.

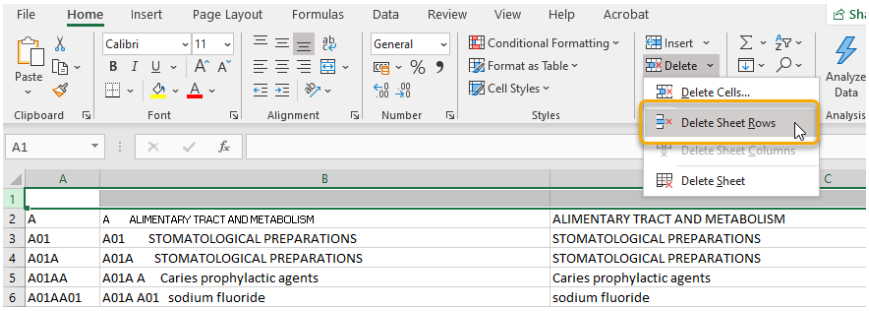
5 Fill all cells in the B column with the same formula, for example by dragging the small plus sign (+) downwards to cover the entire column.



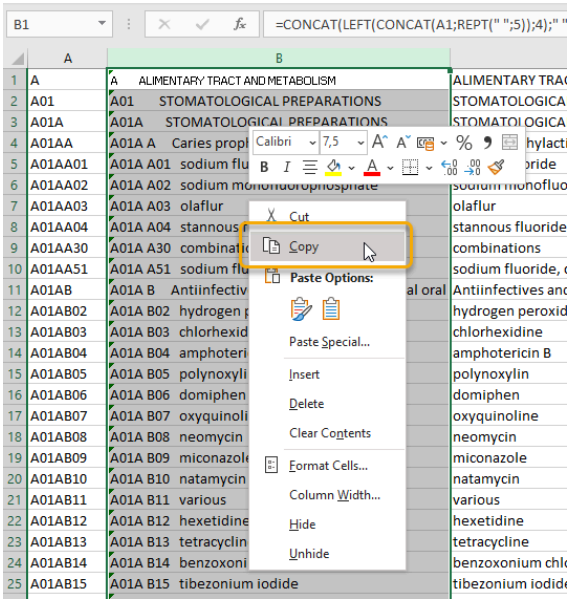
6 Remove row 1 (the header row). Do to this, you might first need to turn off the header row on the **Table Design** page.



Then you can delete the sheet row from the **Home** page.

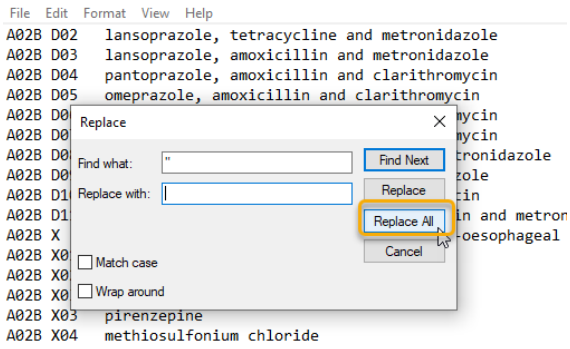


7 Select column B and copy it.

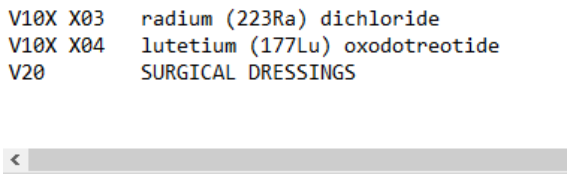


8 Paste the copied column into a raw text editor such as Windows Notepad. It is important to use an editor that does not add any formatting.

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.



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

Published by Viedoc System 2023-10-09

This lesson describes how to configure a static randomization in Viedoc Admin.

1 Introduction

Can not output single-source

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:

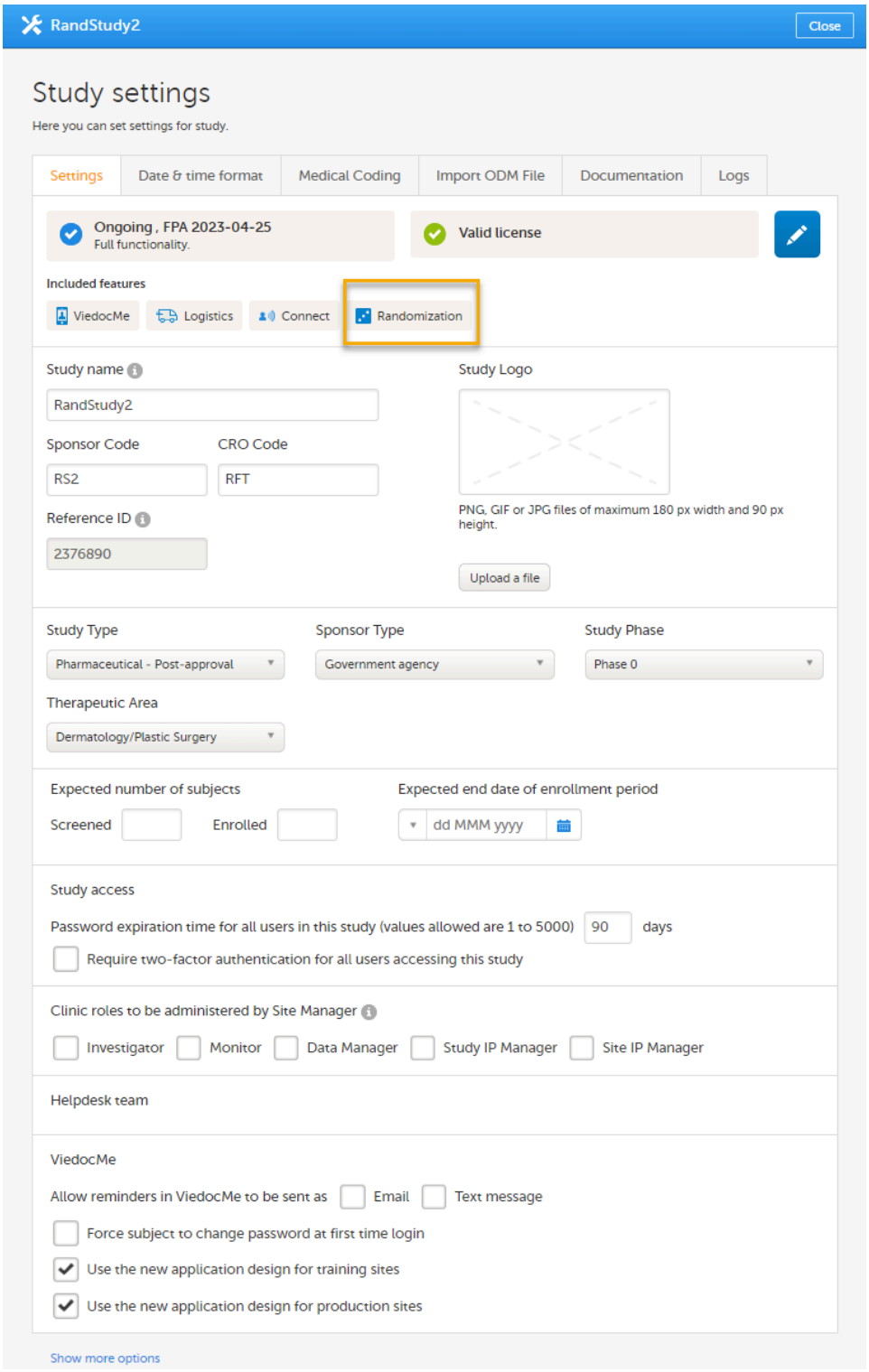
- Randomization video tutorial

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.

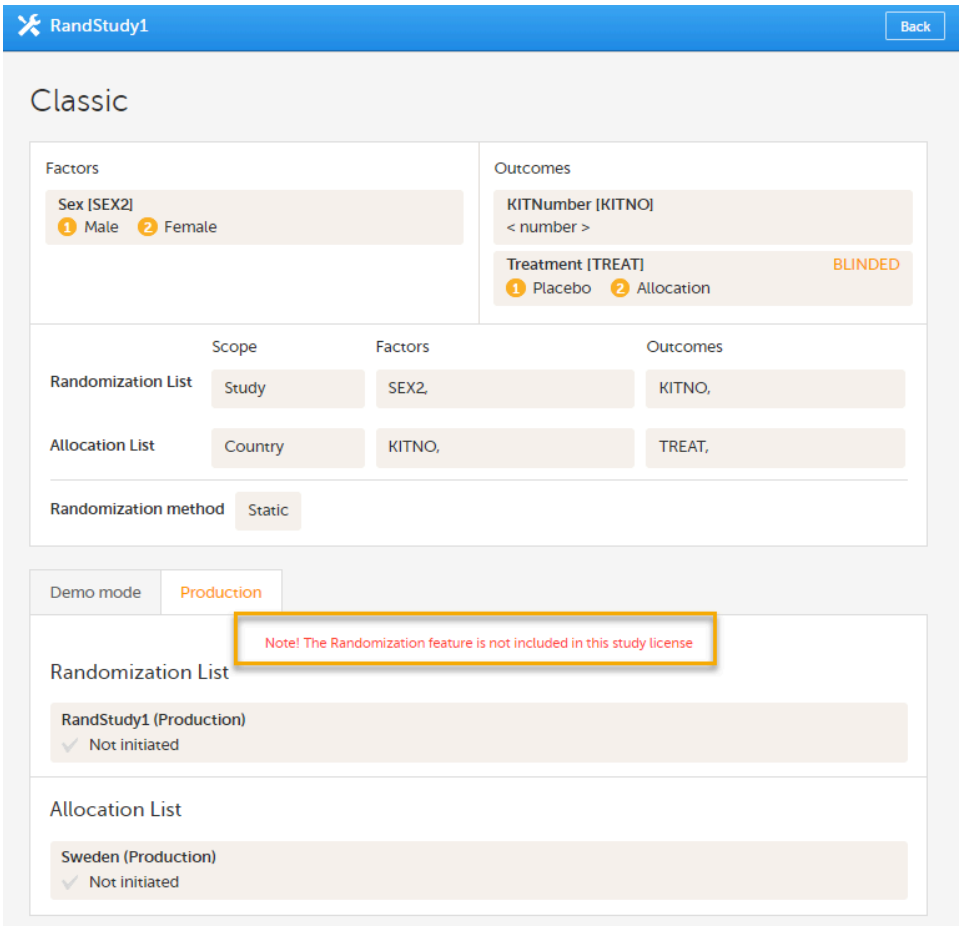
On the randomization page, under the **Demo mode tab**, you can perform all the configuration actions, select the link to download the template (Excel file) for the randomization list, and upload a file with a randomization list or an allocation list.

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**:



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 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.

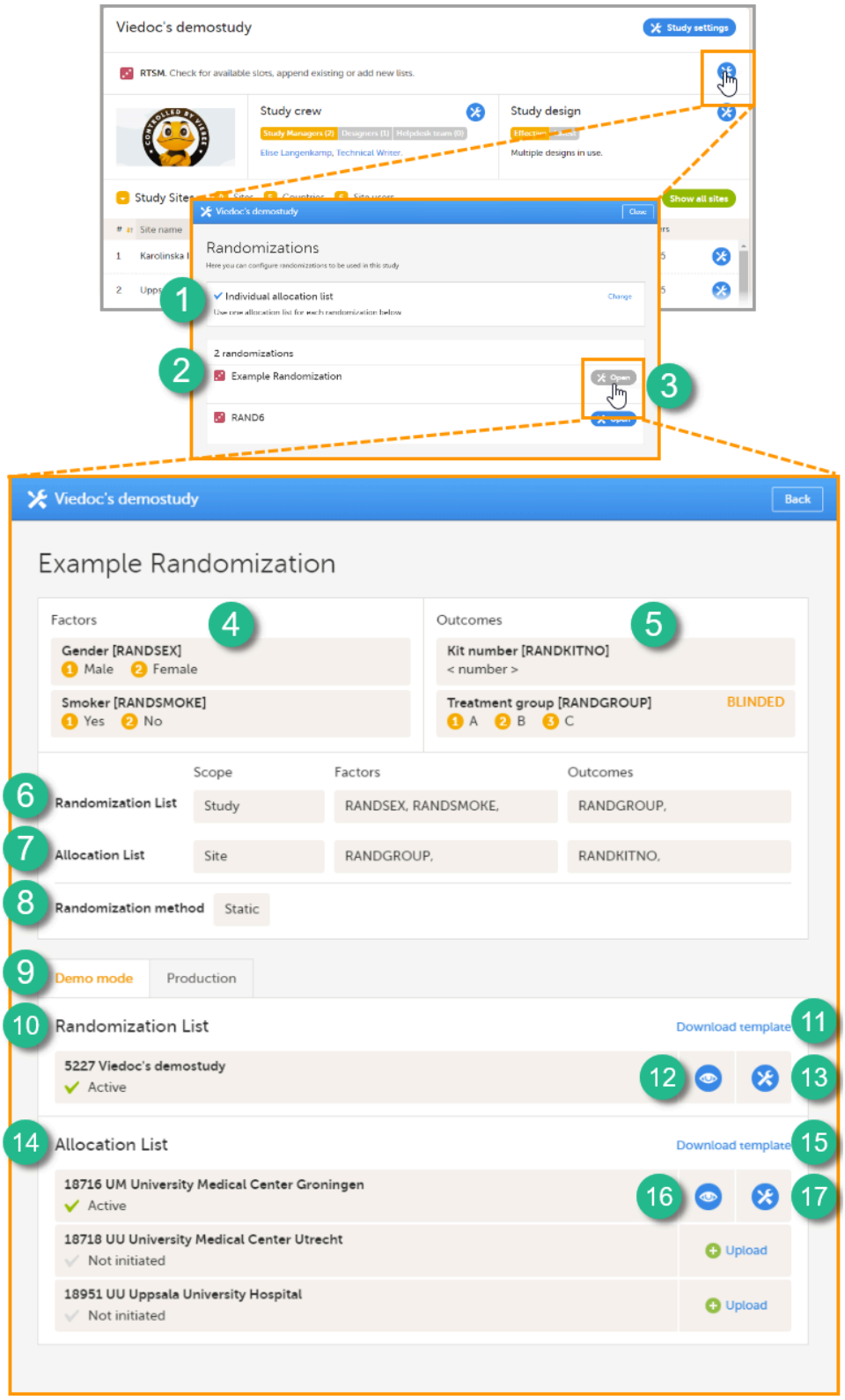
Once the randomization mapping has been set up in Viedoc Designer, the **RTSM** field appears for users with the role Unblinded Statistician. When you click the toolbox icon in the **RTSM** field, the Randomizations pop-up opens. Here you can do the following:

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.

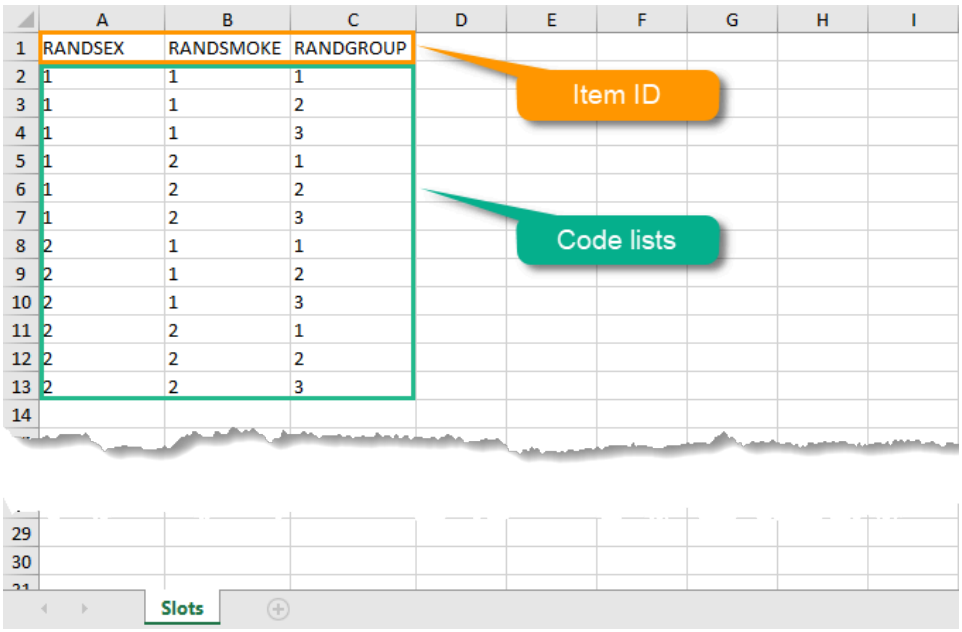
17. Edit the allocation list here, if you selected to use **Individual allocation list**. You can select one of the two following options:

- **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

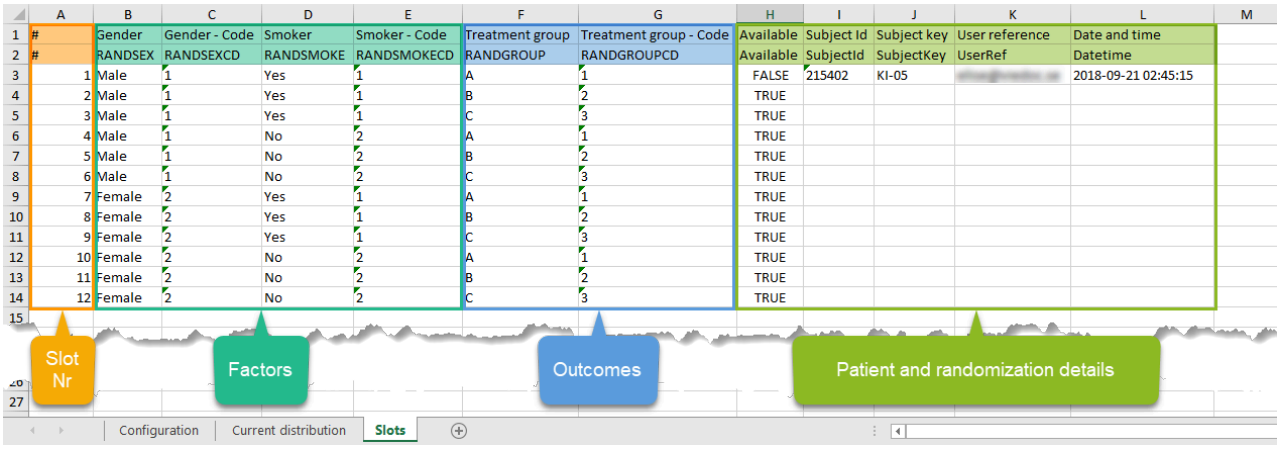
A template randomization list customized for your randomization configuration can be downloaded by clicking **Download template** in the **Randomization List** field (see nr 11 in the image above). For the example shown in the image above, the template randomization list looks as follows:



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:

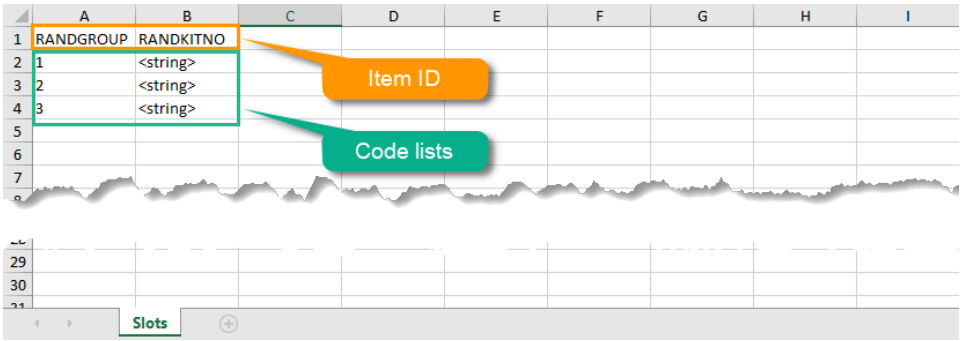
- **Configuration** - summarizes the factors and outcomes and their code lists configured for the randomization.
- **Current distribution** - displays the distribution of randomized subjects over the different factors and treatments.
- **Slots** - lists all the slots, the factors and outcomes, and whether 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.



3.4 The allocation list

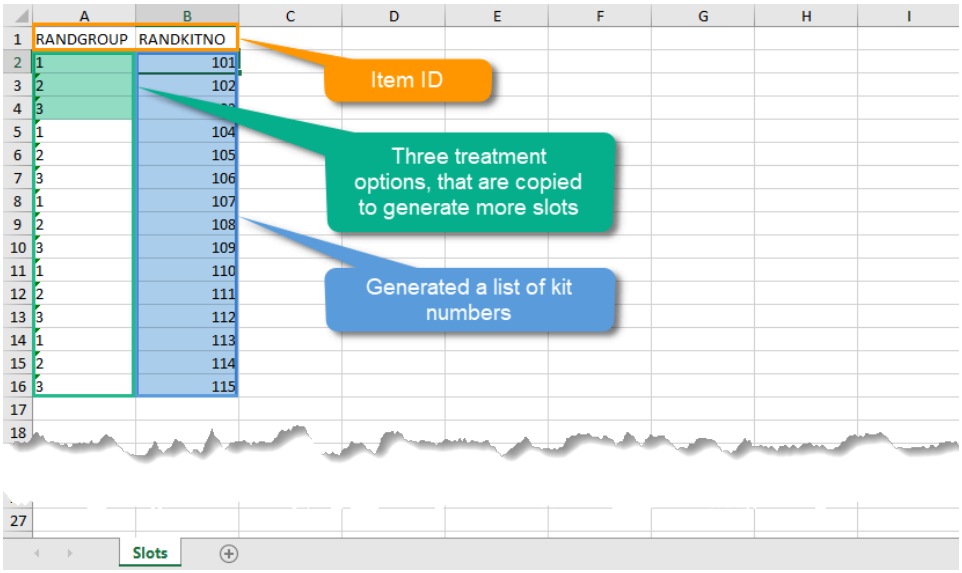
If allocation is activated, a file with available slots (kit numbers) should be uploaded for each scope (study, country or site), before the first allocation is performed.

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:



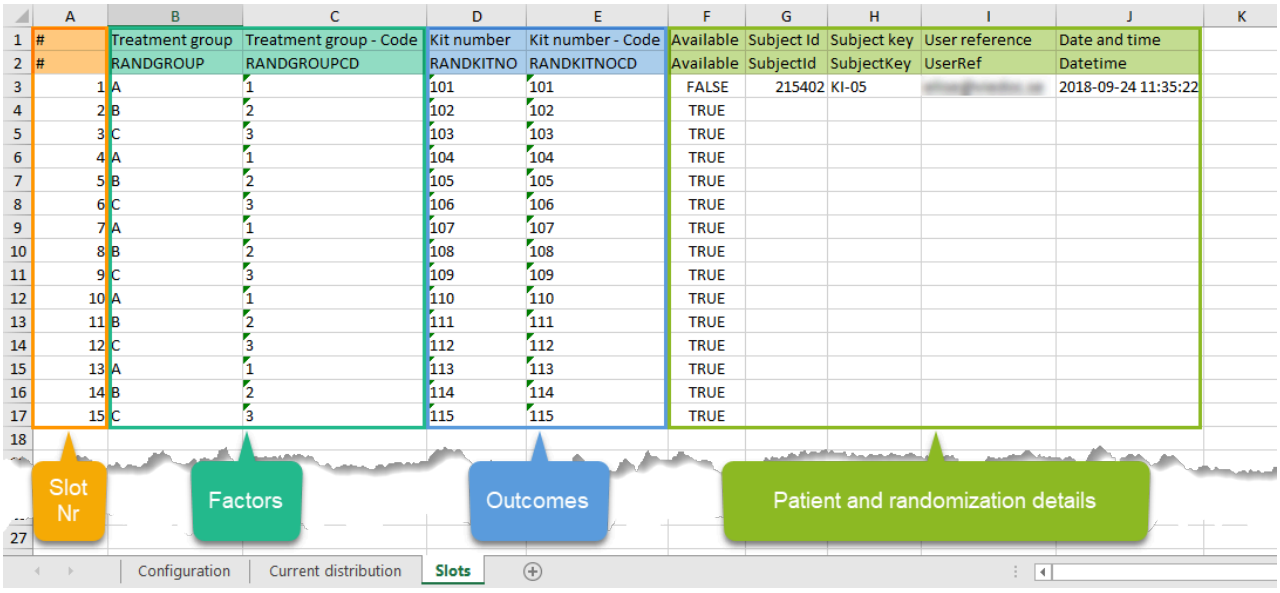
The list shows the factors and outcomes. The Item IDs are displayed as column names, their code lists are dispayed in the rows below. Every possible combination for the factors and outcomes is shown here. The item *RANDKITNO* (kit numbers) was configured to be a free text field, so the allocation list 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:



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 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 (e-mail address) of the clinic user who randomized the subject, and date and time of randomization are also displayed, see the image below.



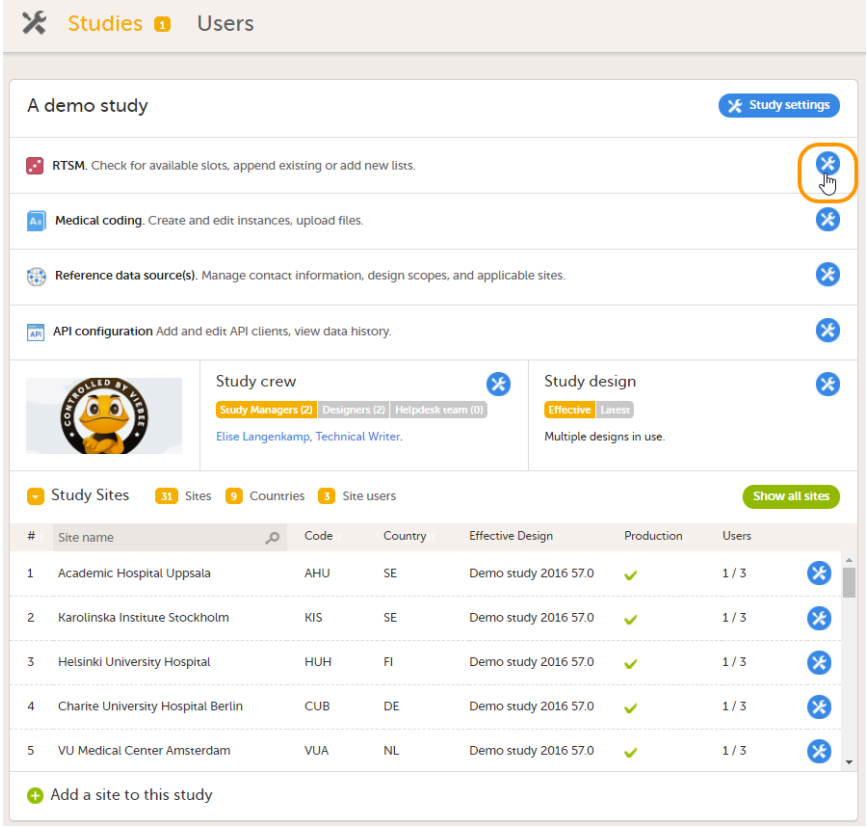
4 Step-by-step guides

4.1 Configuring a static randomization

Note! The randomization can only be configured by users that are assigned the system role Unblinded Statistician.

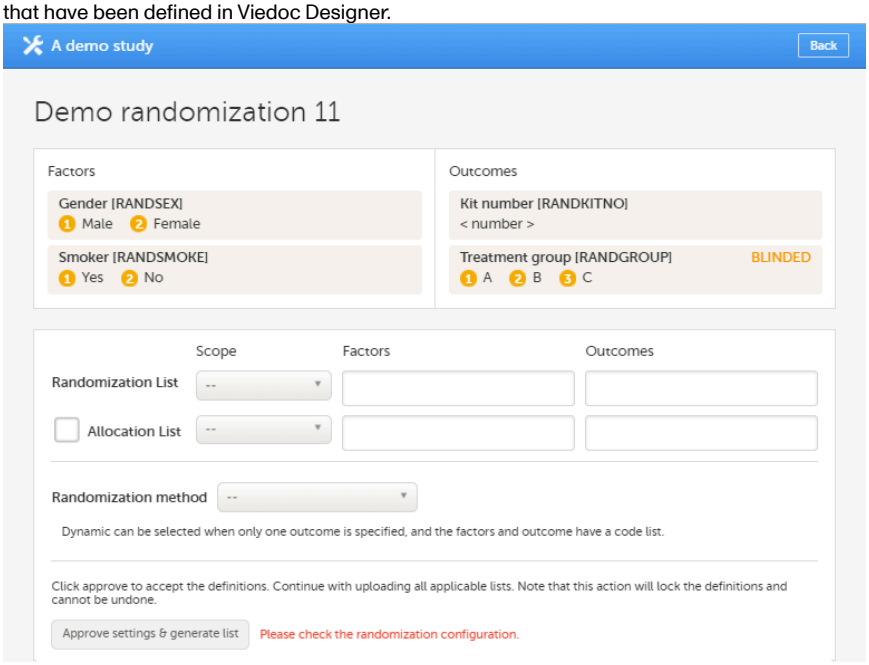
To configure the randomization, follow the steps below.

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.



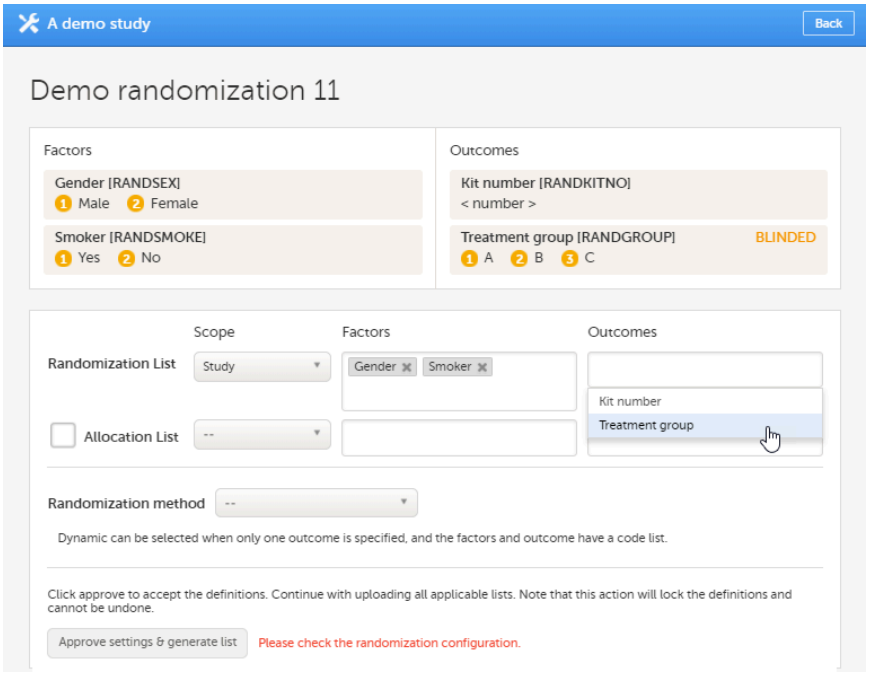
2 Click **Open** to select the randomization you would like to configure.

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.

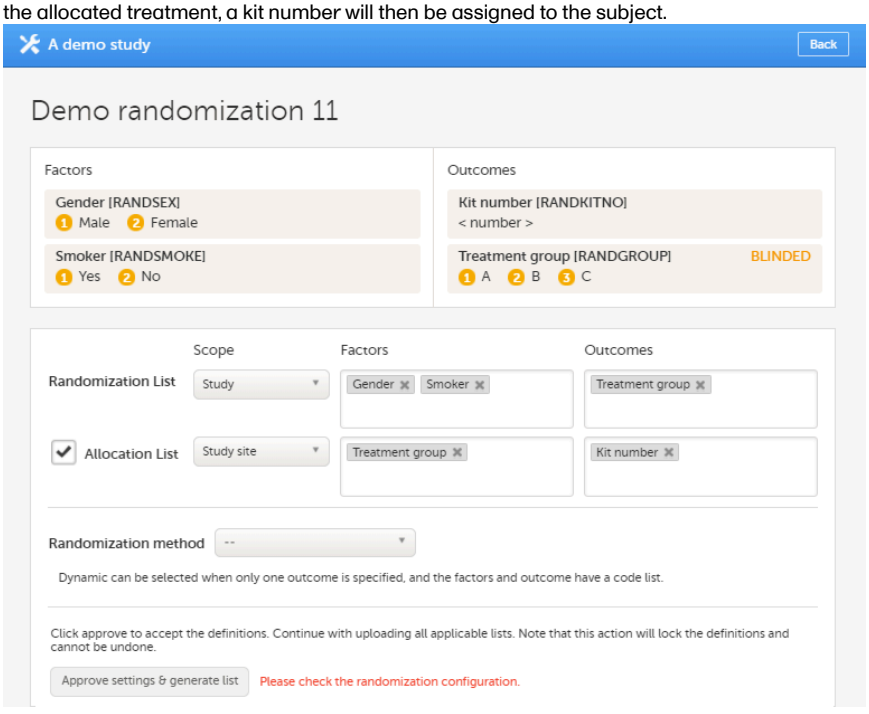


3 In the **Randomization List** field, select:

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.



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.



5 From the **Randomization method** drop-down list, select **Static randomization**.

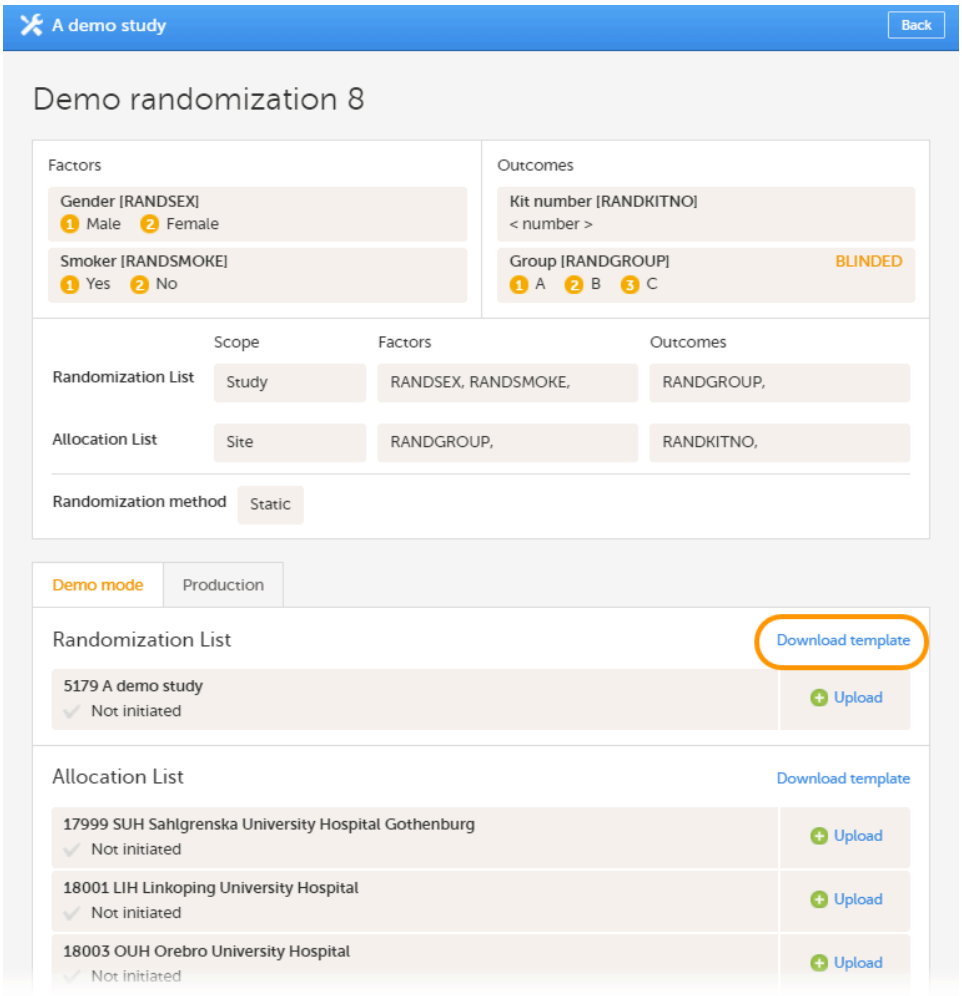
6 Click **Approve settings & generate list**.
The randomization page reloads and the randomization lists and allocations lists can be uploaded.

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

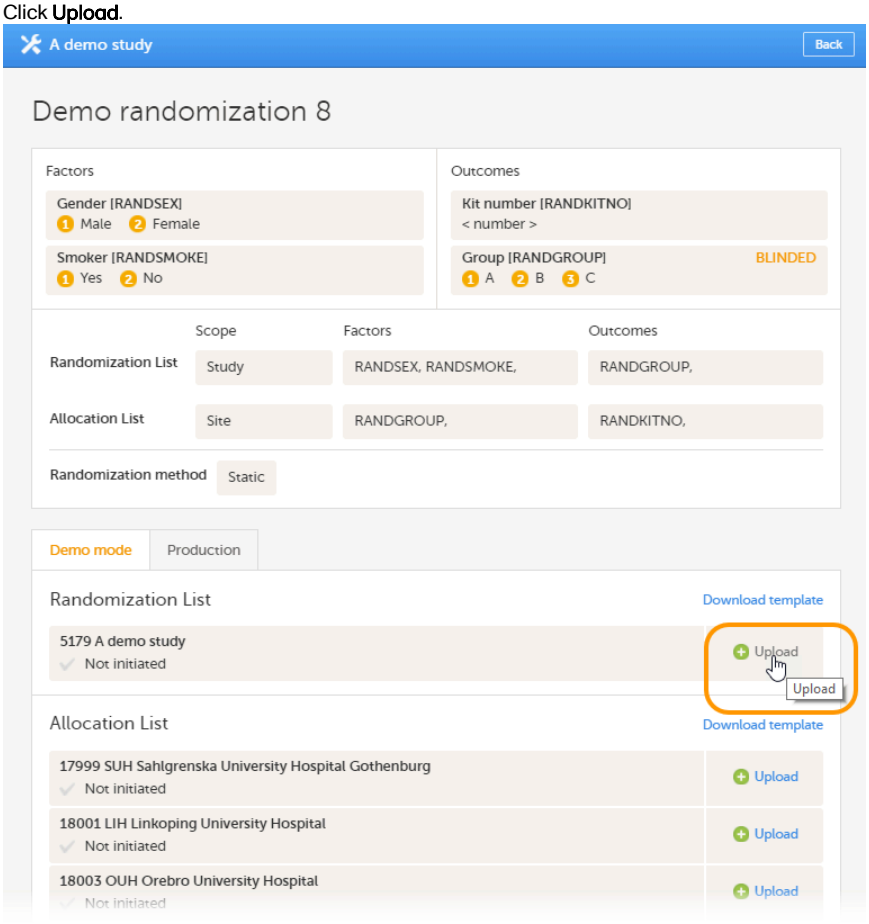
You can download a template slot list in Excel from Viedoc Admin, or you can create one yourself. To download the template slot list from Viedoc, click **Download template**.



4.2.2 Uploading a randomization list

To upload a randomization list, follow the steps below.

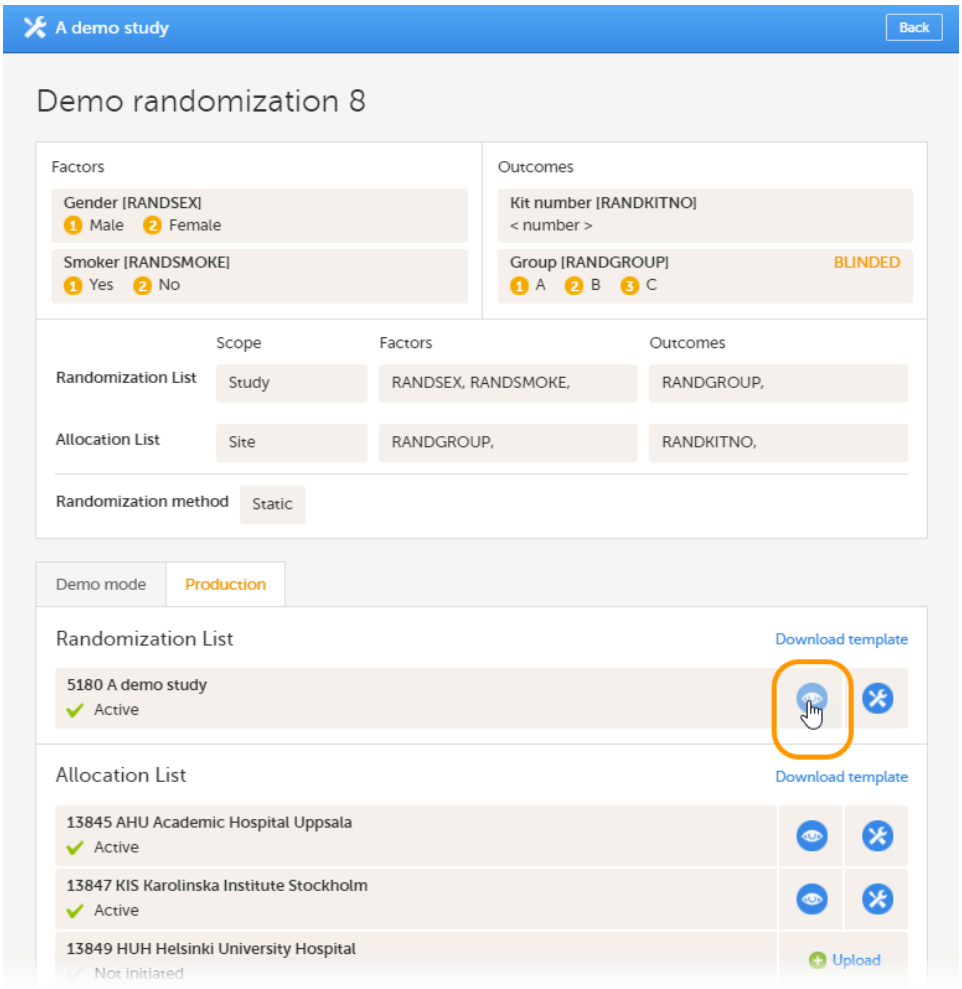
1 Click **Upload**.



2 Select the file containing the slot list and click **Open**. The file will be uploaded.

4.2.3 Viewing a randomization list

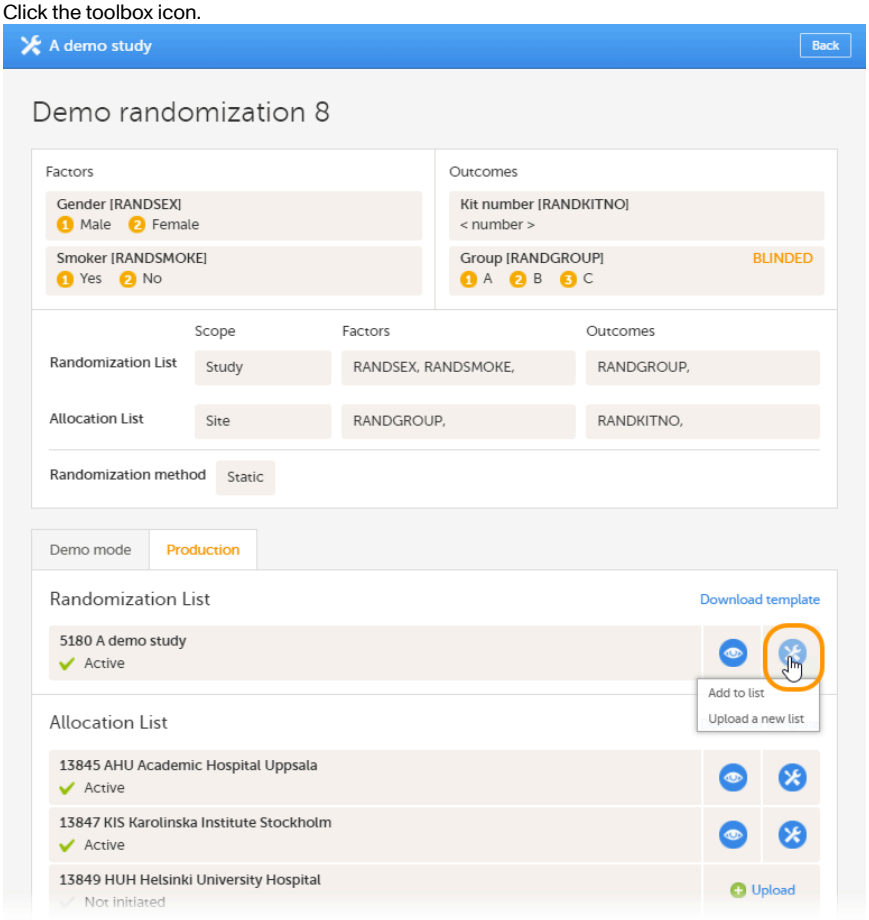
Once the randomization list has been uploaded, the status of the randomization will turn into **Active**. From that moment, the randomization list (displaying which slots are taken) can be downloaded in Excel format by clicking **View**.



4.2.4 Editing a randomization list

To edit an active randomization list, follow the steps below.

1 Click the toolbox icon.



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.

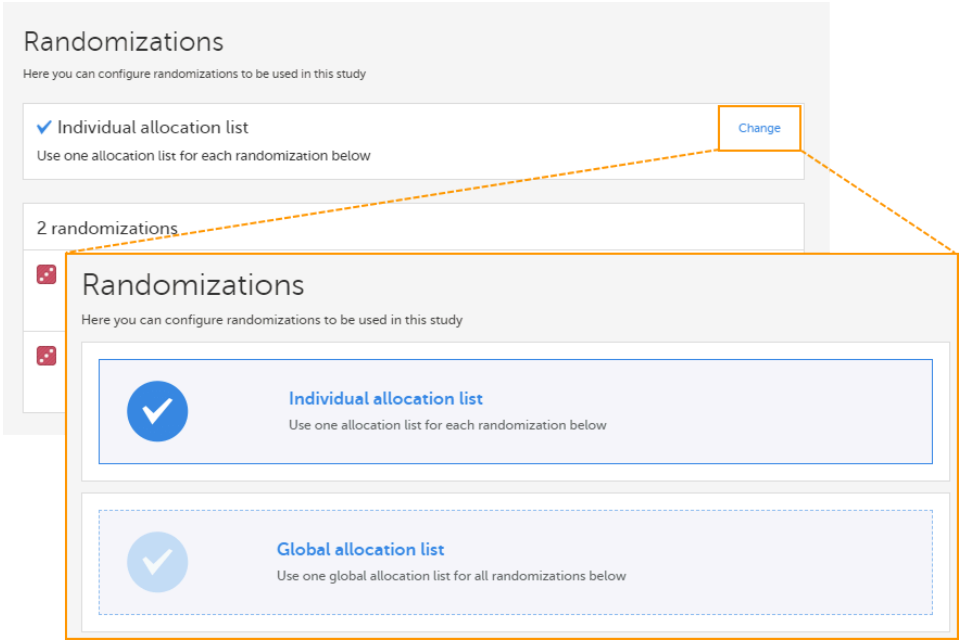
3 Select the file containing the slot list and click **Open**.
The file will be uploaded.

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:

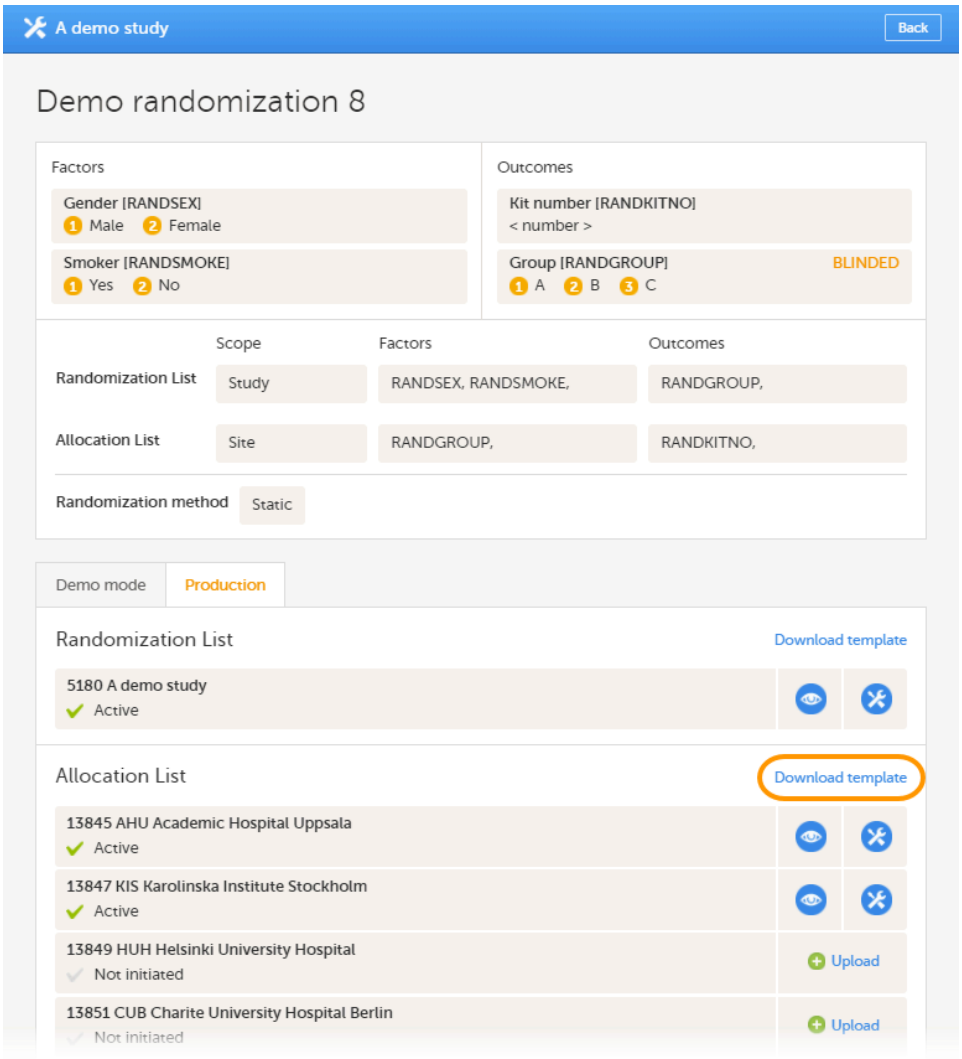


4.3.1 Individual allocation list

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**.

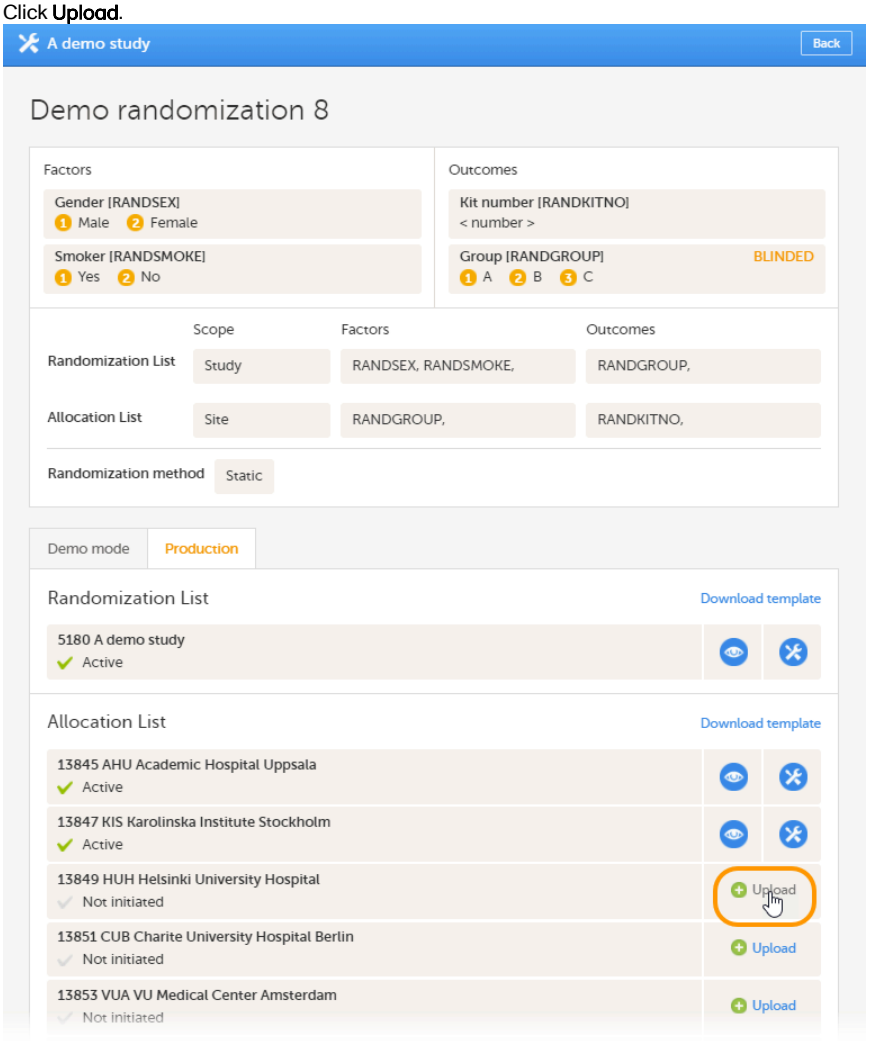


4.3.1.2 Uploading an allocation list

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**.



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

This lesson describes how to configure a dynamic randomization in Viedoc Admin.

1 Introduction to randomizations

Can not output single-source

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:

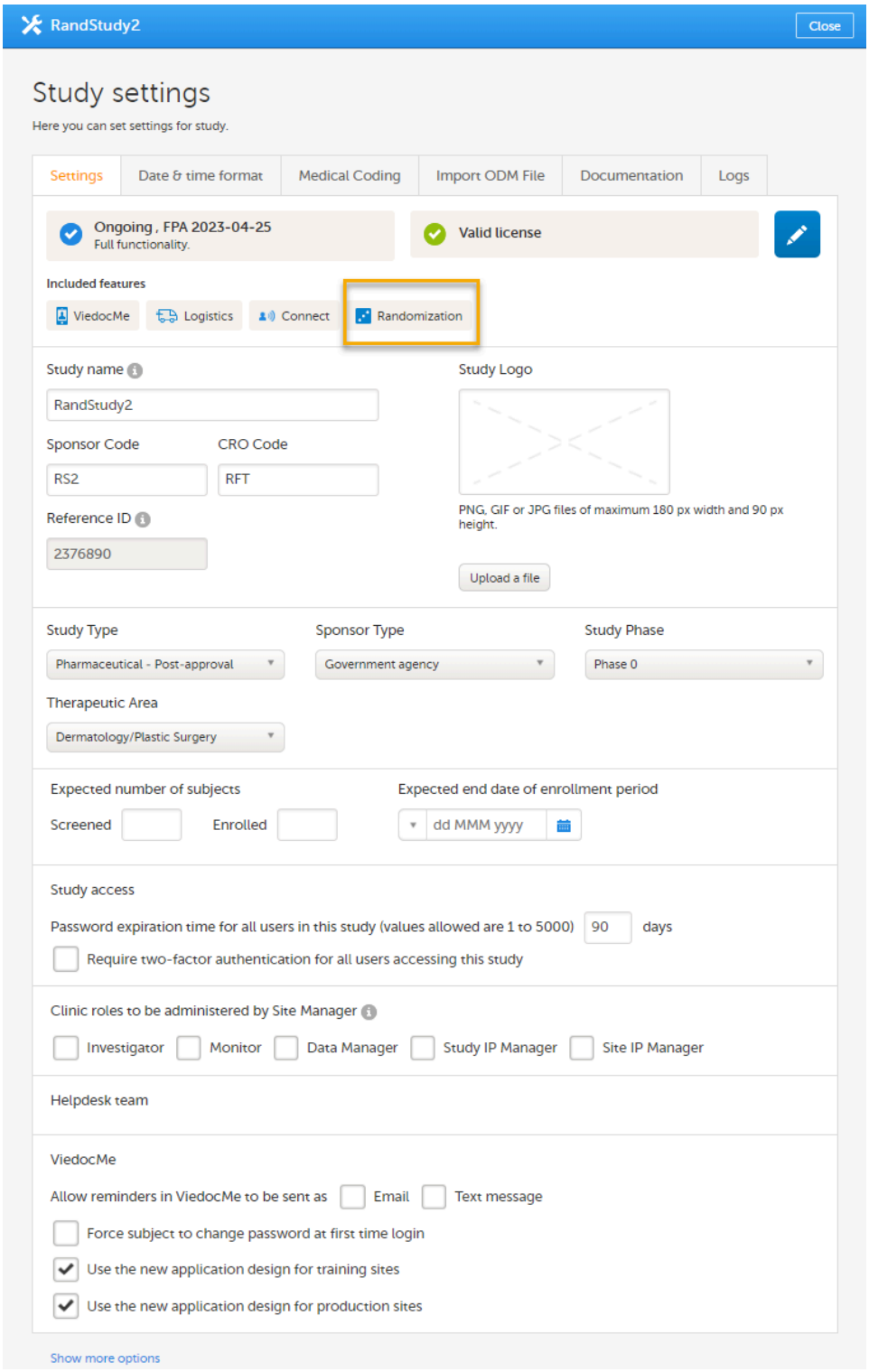
- Randomization video tutorial

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.

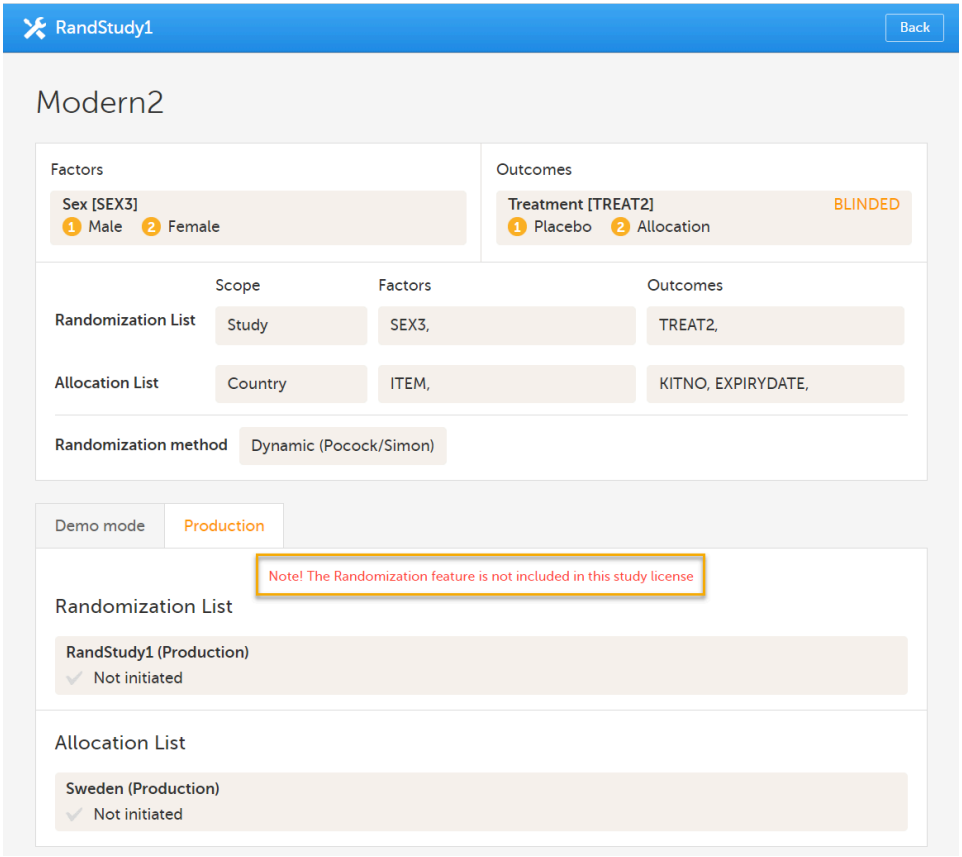
On the randomization page, under the **Demo tab**, you can create the configuration and perform all the configuration actions for the dynamic randomization, and select the **Edit settings and generate new list** link.

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:



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:



- The **Create configuration** and **Edit configuration** links are not available.

For more information on licensing, see Overview of Viedoc

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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 randomizatons 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	The relative importance of a factor when calculating imbalance, set as an integer value greater than zero. For example, if it is more important to achieve balance in the factor *Gender* than in the factor *Age*, then a factor weight of 2 could be set on *Gender* and a factor weight of 1 set on *Age*.
Outcome weight	**Allocation ratio.** The desired division of treatments to be allocated. 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.
D	The amount of variation in the set of values for a factor, that is, the imbalance for one factor. The amount of variation can be calculated as: ▪ Range - the difference between the highest and the lowest values in the set. ▪ Range Squared - the square of the range. Tip! Range square increases the spread of the distribution and may be useful if you have many factors. Note! 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.
G	The total amount of imbalance across all factors. 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 $\{d_{ik}\}$, where d_{ik} is the lack of balance among treatment assignments. The weighted sum is used when some prognostic factors are considered more important than others. 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. If D is calculated as range square, the range is squared before any factor weight is applied.
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. 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. During randomization, P for each treatment will be distributed as follows: (N = number of treatments, p = probability cut-off) ▪ If the Gs are the same for all treatment assignments, then the probability will be the same for each treatment: P=p/N. ▪ If one treatment has the lowest G, then it will have its probability P as p. The remaining treatments will split the remaining probability: P=(1 - p)/(N - 1) ▪ 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.
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:

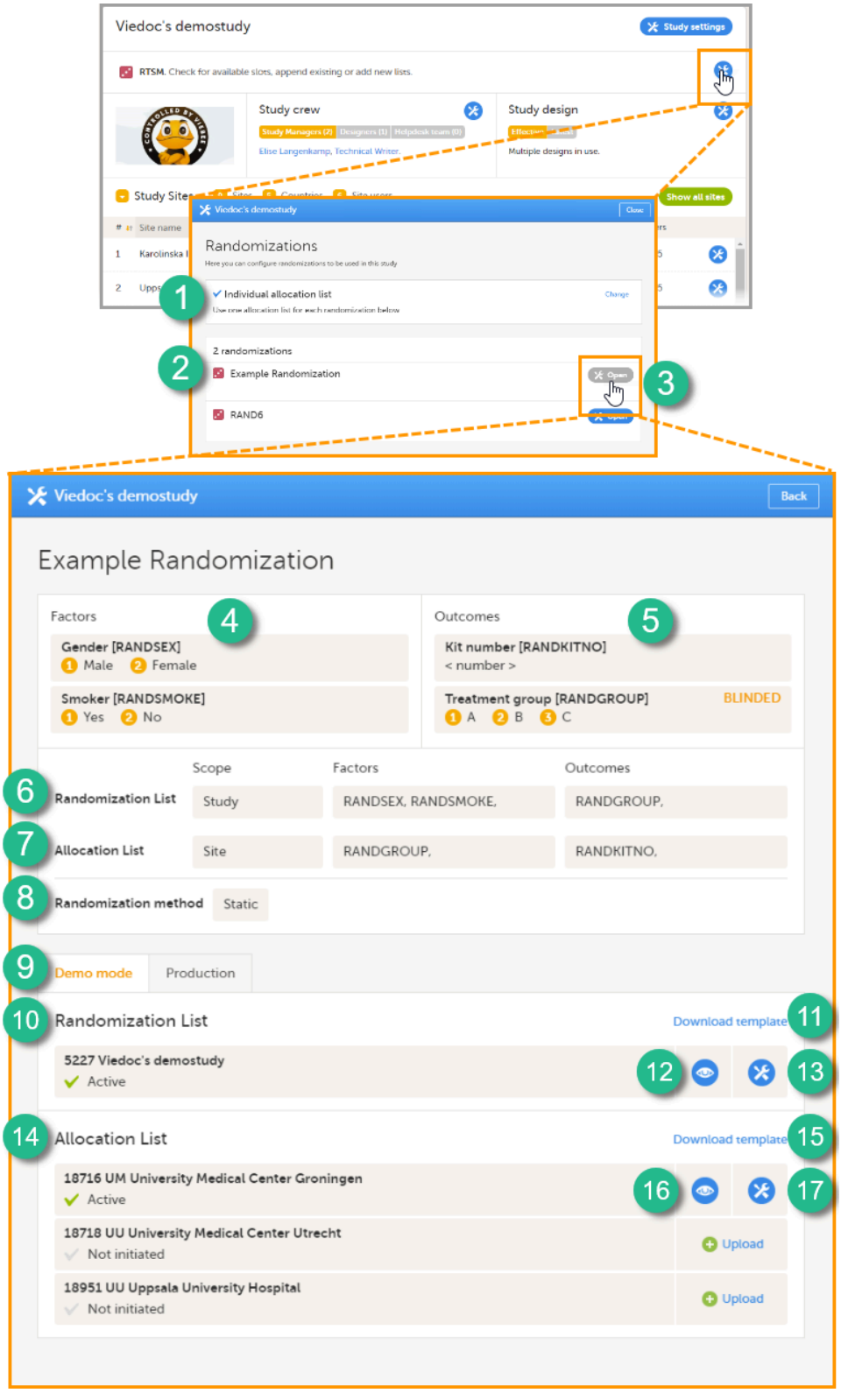
1. Choose the type of the allocation list to be used:

   - 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.

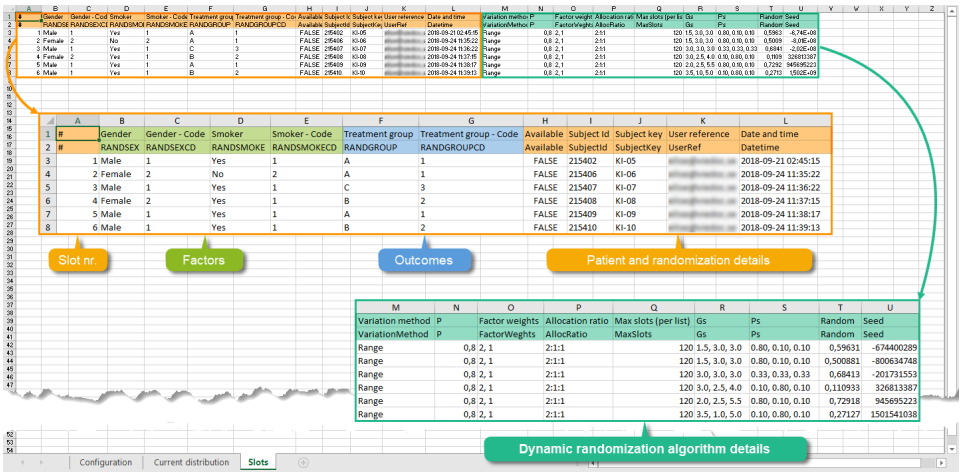
The numbers in front of the study name and site names in the Randomization List and Allocation List fields (5228, 18213, 18215, and 18217 in the image) are the study identification number and site identification numbers that are generated by the system and used for internal identification of study and 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:

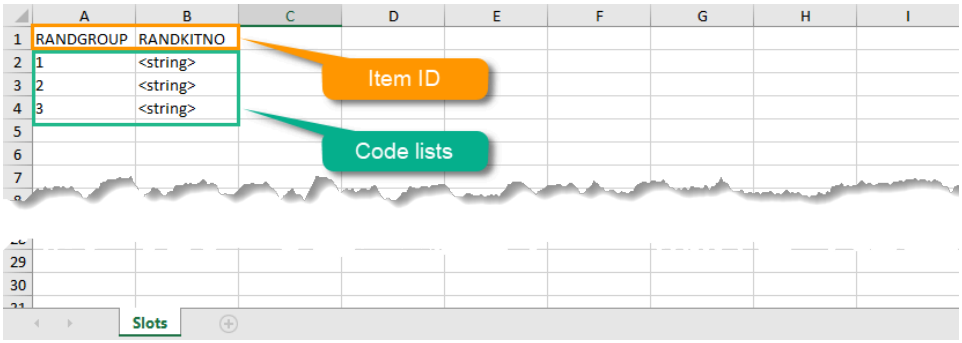
- the details of the randomization: factors and outcomes, subject details, user details (e-mail address) of the clinic user who randomized the subject, and date and time of randomization,
- the details of the applied algorithm: variation method, probability P, factor weights, allocation ratio, maximum 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.



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:

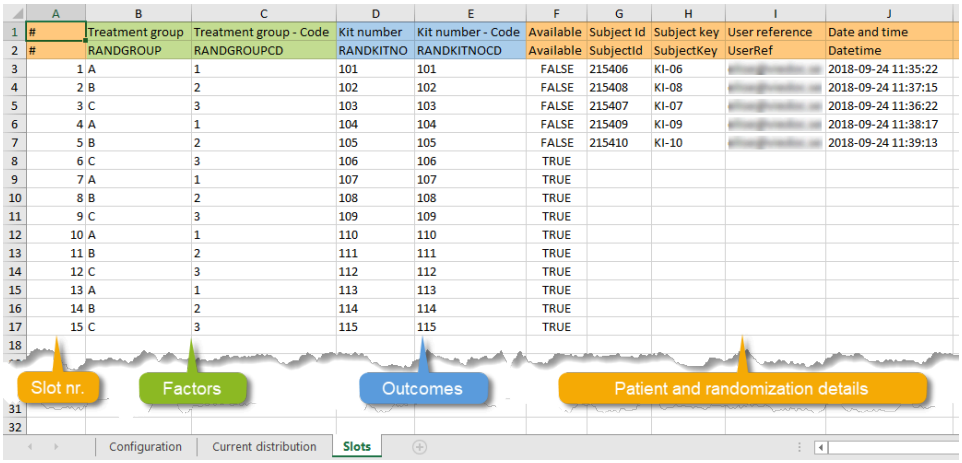


The list shows the factors and outcomes. The Item IDs are displayed as column names, their code lists are dispayed in the rows below. Every possible combination for the factors and outcomes is shown here. The item *RANDKITNO* (kit numbers) was configured to be an open text field, so the allocation list 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:

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.



	A	B	C	D	E	F	G	H	I	J
1	#	Treatment group	Treatment group - Code	Kit number	Kit number - Code	Available	Subject Id	Subject key	User reference	Date and time
2	#	RANDGROUP	RANDGROUPCD	RANDKITNO	RANDKITNOCD	Available	SubjectId	SubjectKey	UserRef	Datetime
3	1	A	1	101	101	FALSE	215406	KI-06	[redacted]	2018-09-24 11:35:22
4	2	B	2	102	102	FALSE	215408	KI-08	[redacted]	2018-09-24 11:37:15
5	3	C	3	103	103	FALSE	215407	KI-07	[redacted]	2018-09-24 11:36:22
6	4	A	1	104	104	FALSE	215409	KI-09	[redacted]	2018-09-24 11:38:17
7	5	B	2	105	105	FALSE	215410	KI-10	[redacted]	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				
18										
31										
32										

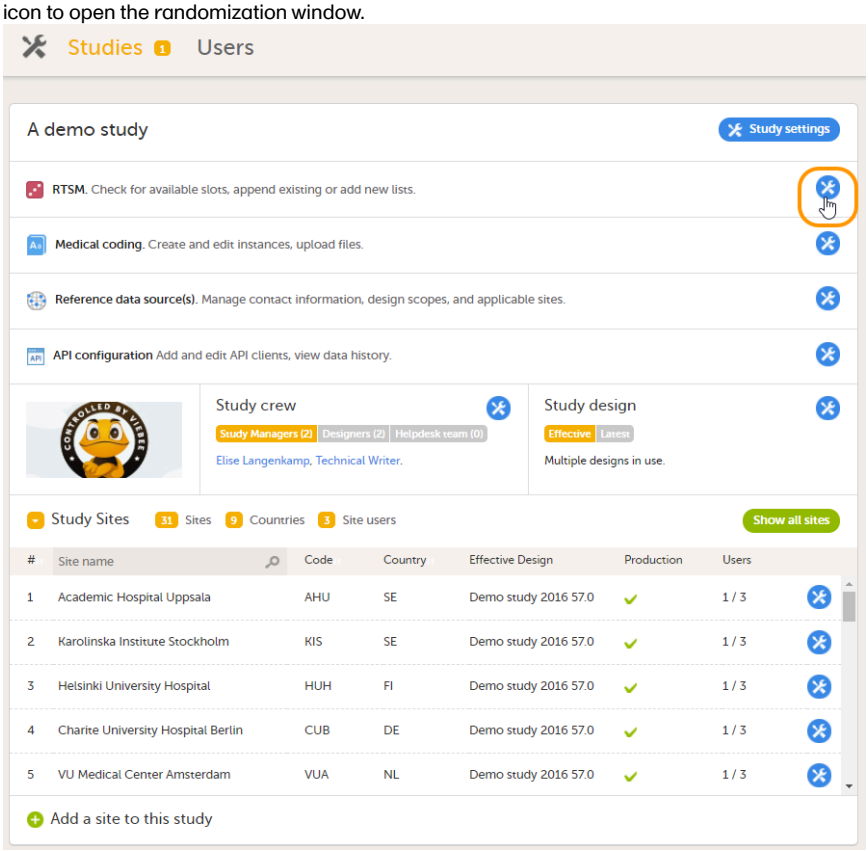
5 Step-by-step guides

5.1 Configuring a dynamic randomization

Note! The randomization can only be configured by users that are assigned the system role Unblinded Statistician.

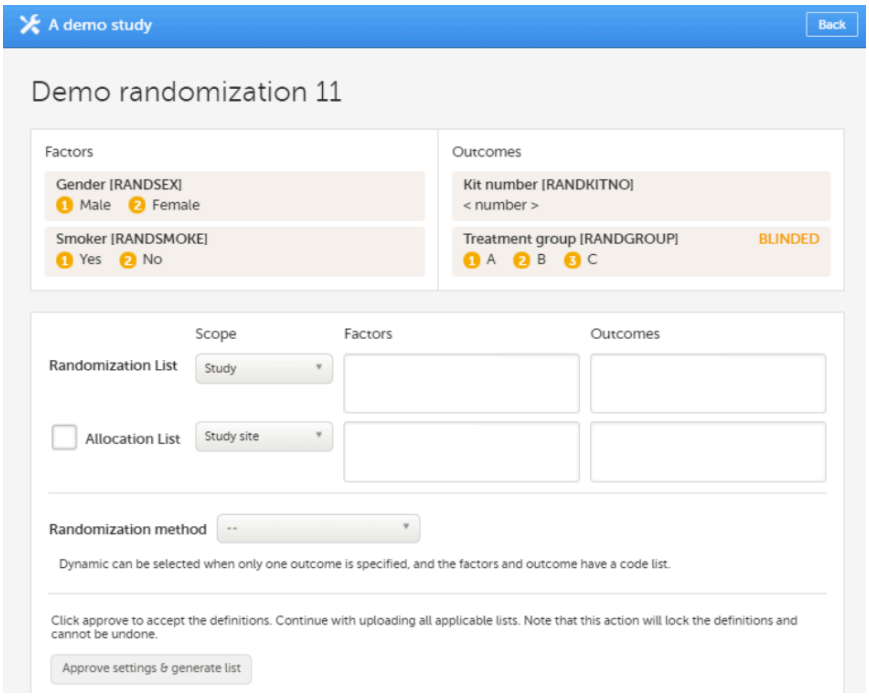
To configure the randomization, follow the steps below.

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.



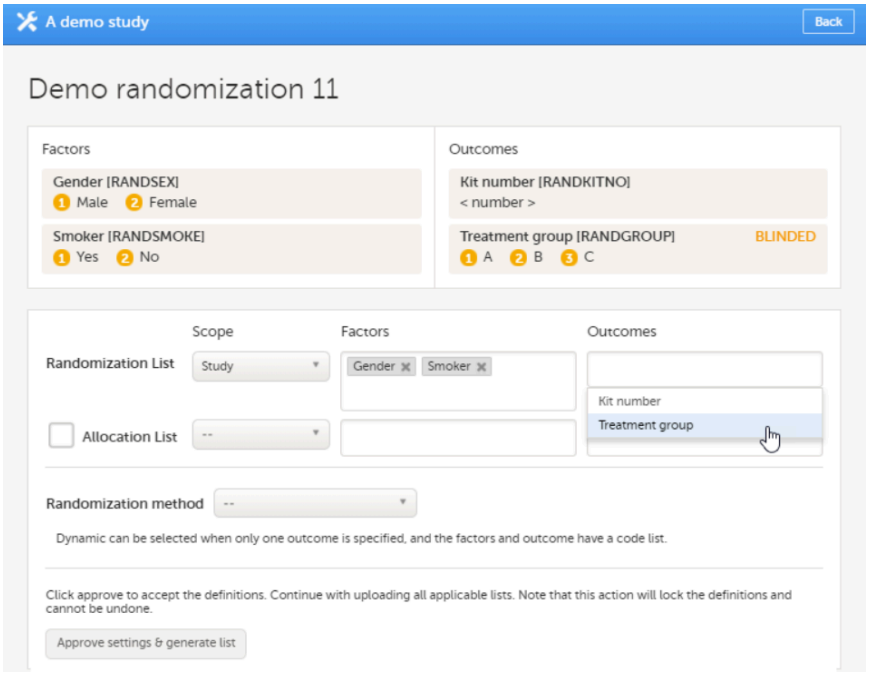
2 Click **Open** to select the randomization you would like to configure.

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:

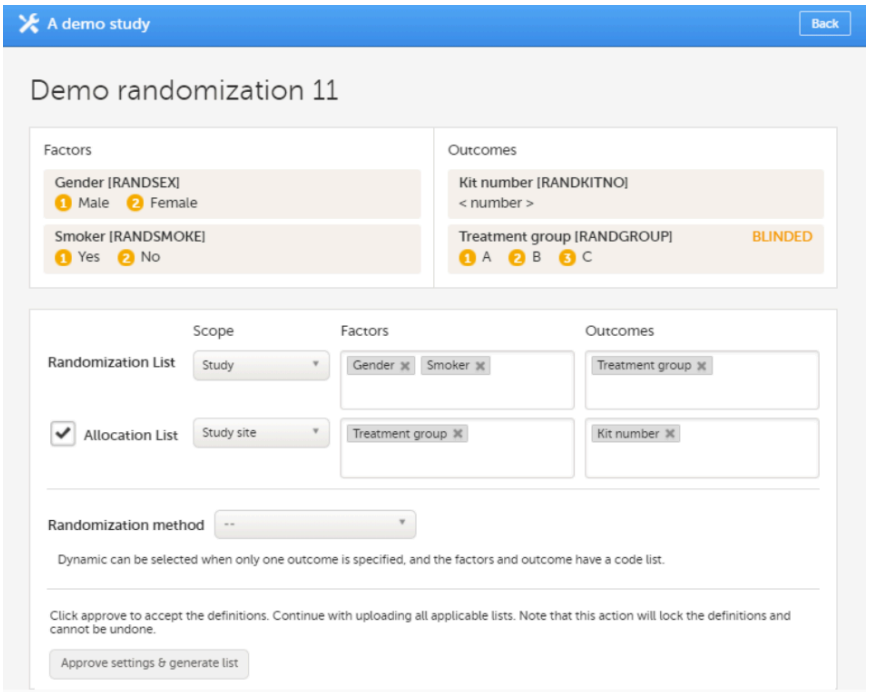
1. the scope of the randomization list
   and, only if advanced allocation is not enabled in Viedoc Designer:
2. the factors that should be balanced for in the randomization,
3. the outcome.



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).

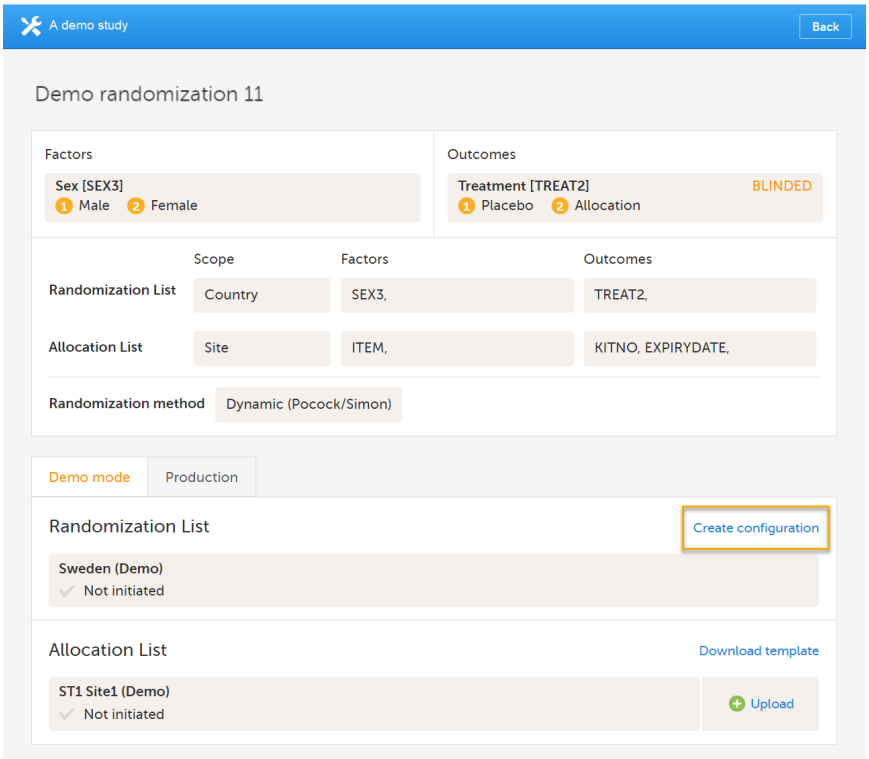
4 If you want to use allocation, select the **Allocation list** checkbox, select the scope of the allocation list, and, only if advanced allocation is not enabled in Viedoc Designer, the input factors, and the desired outcome (for example, kit number). Based on the allocated treatment, a kit number will 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.

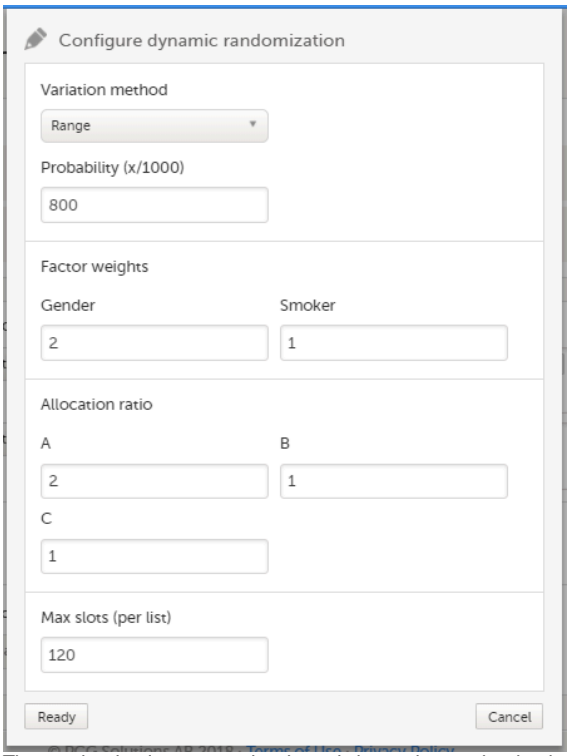
Select **Create configuration** to configure the dynamic randomization:



Note! You will need to create the dynamic randomization configuration individually for demo mode and production mode after creating the dynamic randomization settings.

6 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**).

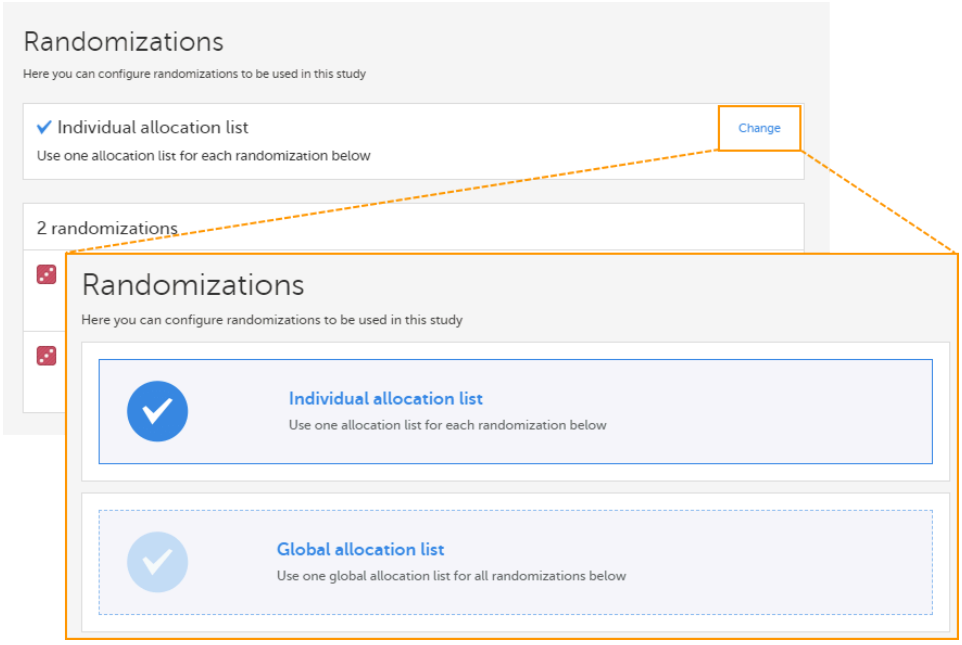
When the maximum number of slots is reached during randomization, no additional subjects can be randomized. You can edit the maximum number of slots in the randomization configuration at any time, see Editing the configuration of a dynamic randomization.

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.

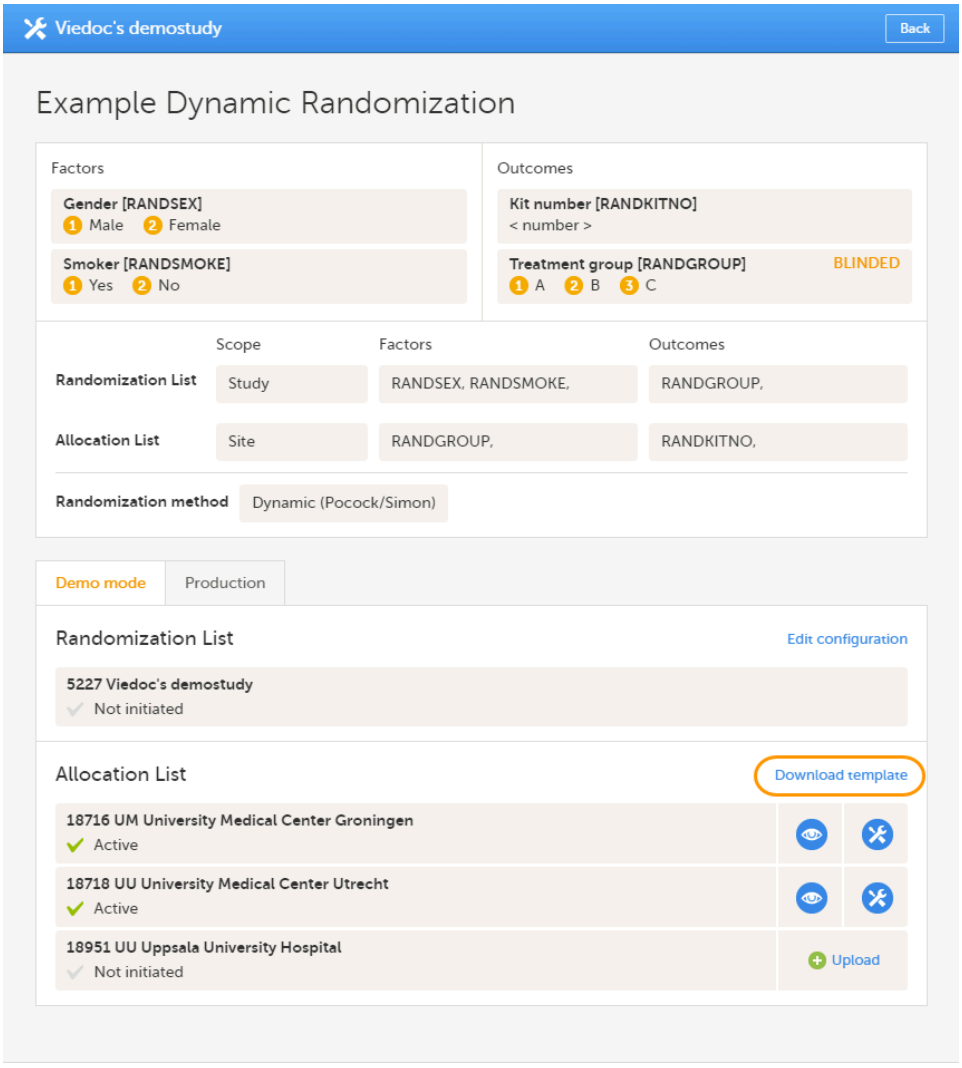
This is set up under the **RTSM** settings in Viedoc Admin, as illustrated in the image below:



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.

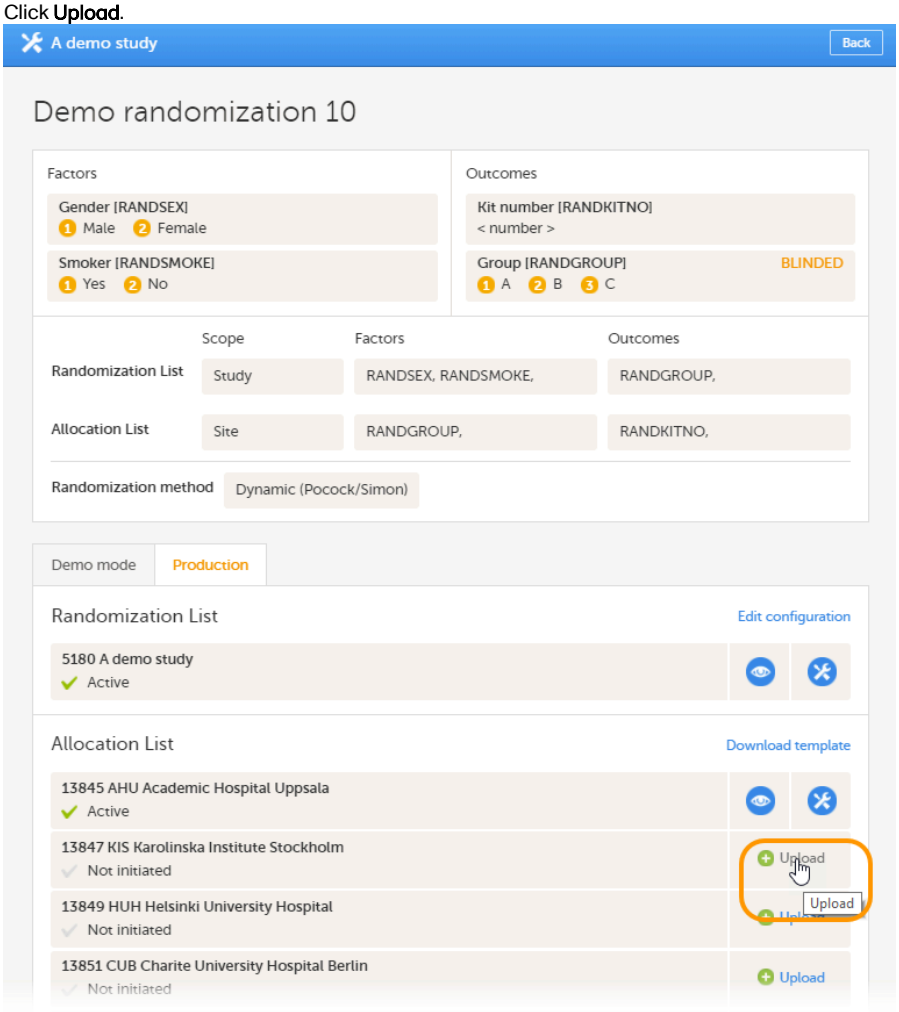
5.2.1.1 Downloading a template allocation list



5.2.1.2 Uploading an allocation list

To upload an allocation list, follow the steps below.

1 Click **Upload**.



2 Select the file containing the slot list and click **Open**. The file will be uploaded.

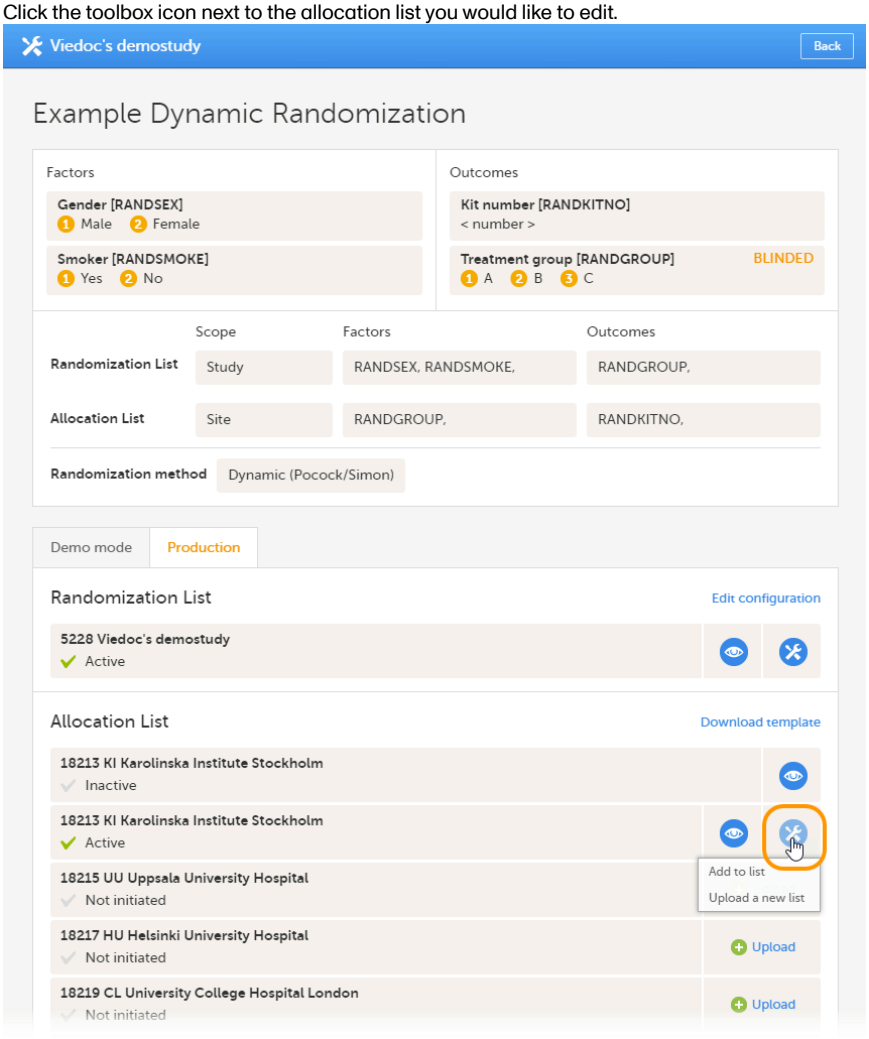
5.2.2 Viewing an allocation list

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.



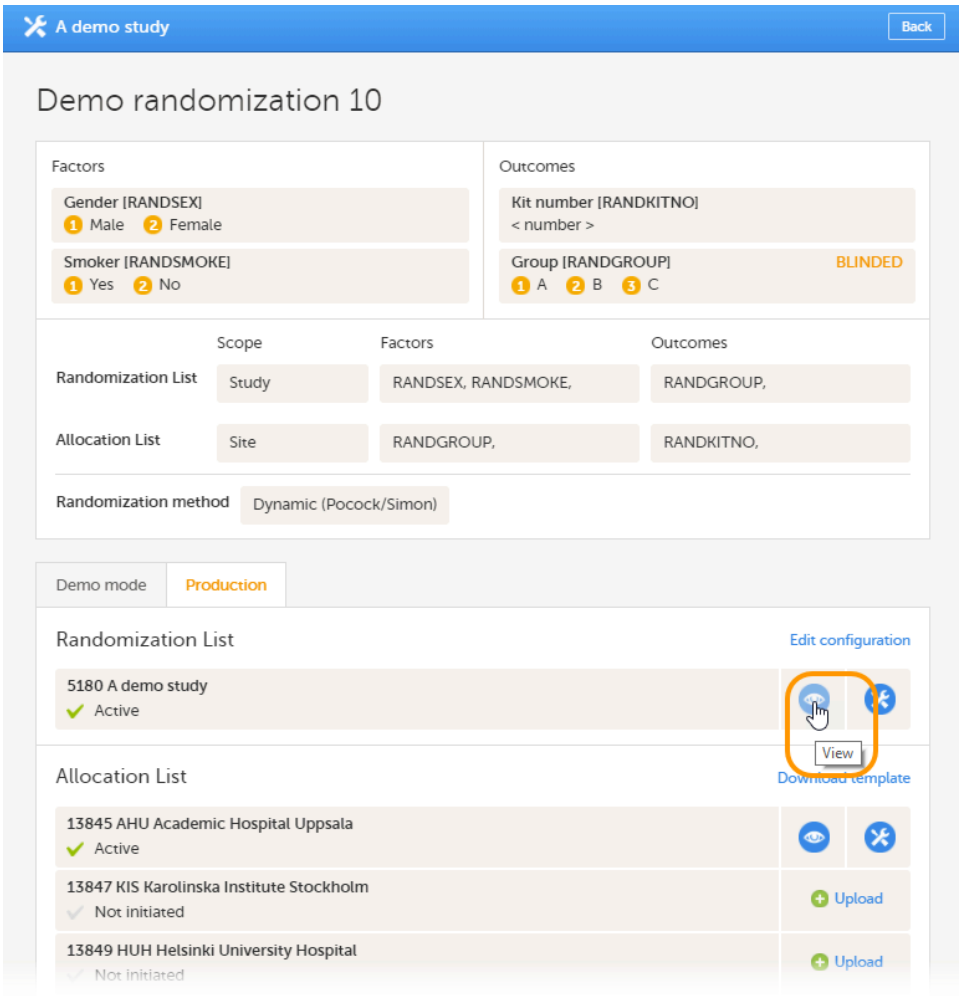
2 Select: **Add to list** or **Upload new list**.
- **Add to list** - adds new slots to the existing slot list. Empty spots in the existing slot list will still be allocated.
- **Upload new list** - discards the existing slot list and replaces it with the new slot list.

3 Select the file containing the slot list and click **Open**.
The file will be uploaded.

5.3 Viewing the randomization list

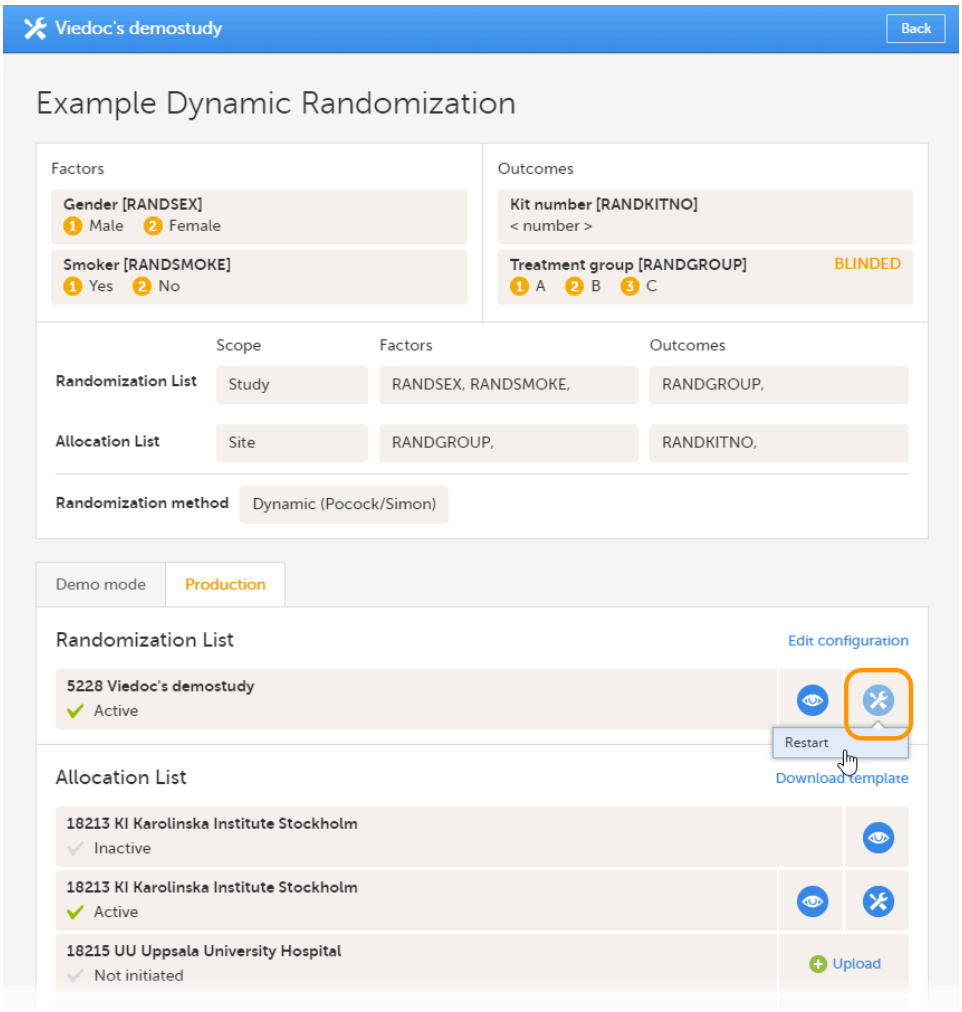
The randomization list initially indicates status **Not initiated** and turns to status **Active** once the first subject has been randomized.

From that moment, the distribution list can be downloaded in Excel format by clicking **View**.



5.4 Restarting a dynamic randomization

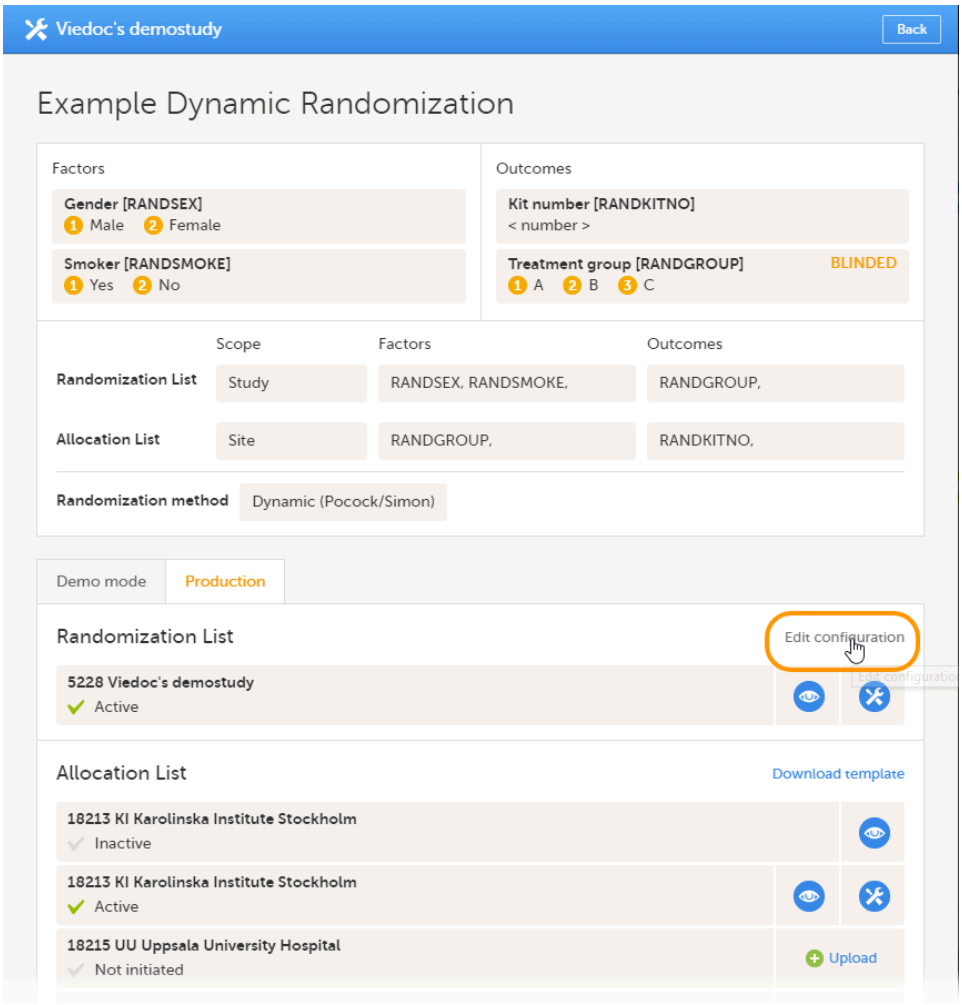
If you would like to restart a dynamic randomization, click the toolbox icon in the **Randomization List** field and select **Restart**.



Restarting the randomization will reset the slot list. Newly added subjects will be randomized independently of the subjects that were randomized before the restart.

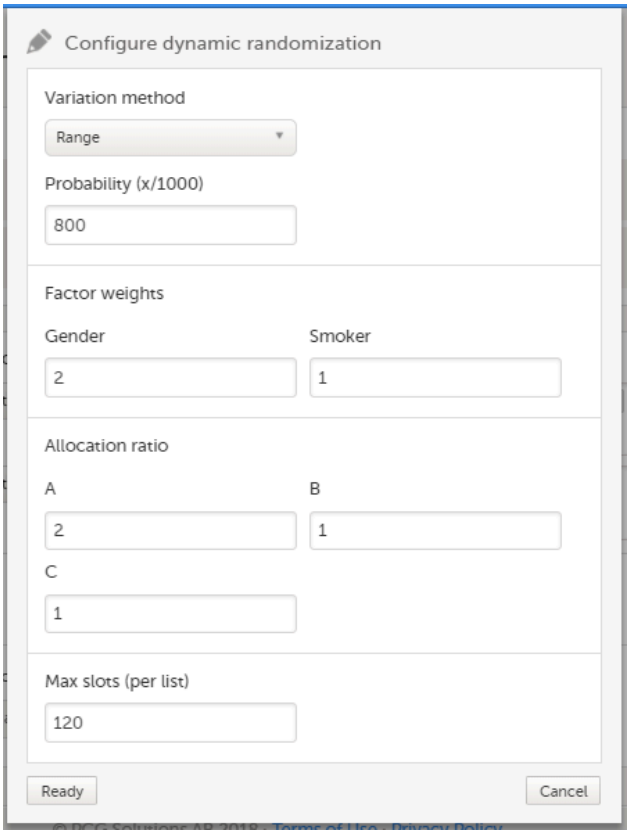
5.5 Editing the configuration of a dynamic randomization

If you would like to edit the configuration of an ongoing Pocock and Simon dynamic randomization, click **Edit configuration**.



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.



Configuring the global allocation list

Published by Viedoc System 2023-10-09

1 Introduction

The allocation list setup can be performed only by users assigned to the Unblinded Statistician role.

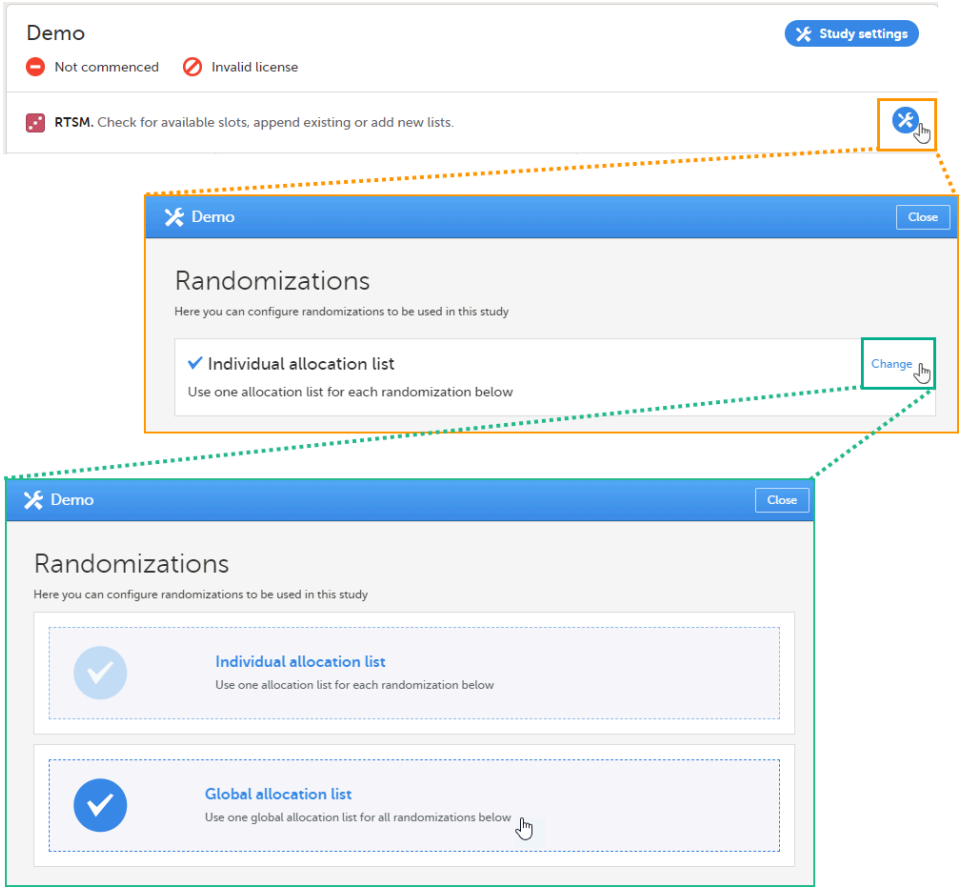
When randomization is used within a study (see Configuring a static randomization / Configuring a dynamic randomization), the allocation list can be defined in two different ways:

> 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.

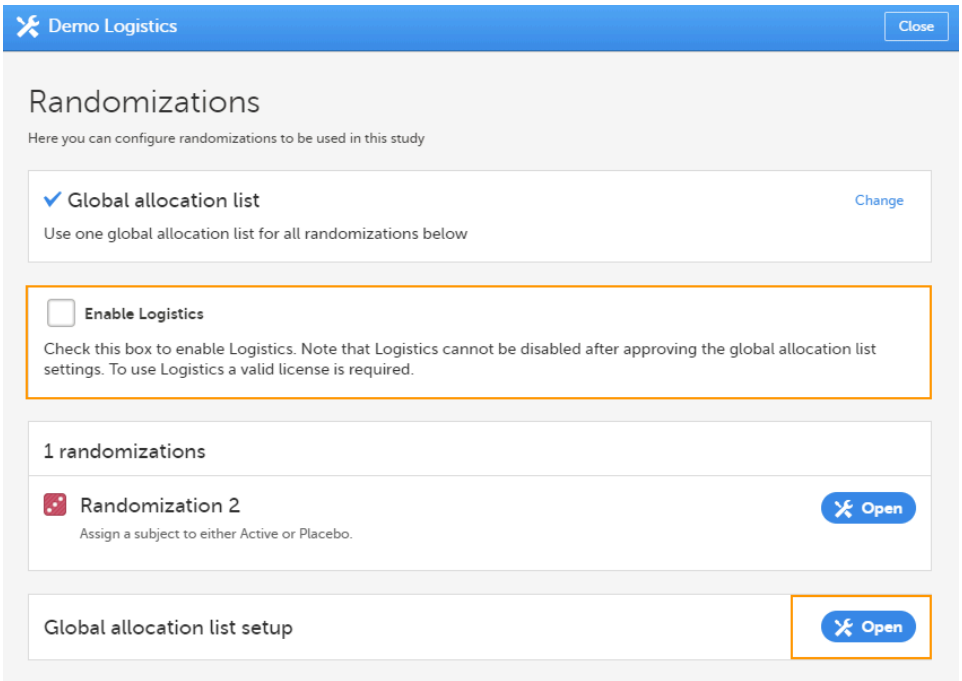
- **Individual allocation list** - separate allocation lists are used for each defined randomization. In this case, the allocation list is configured and uploaded in the randomization settings page in Viedoc Admin as described in Configuring a static randomization / Configuring a dynamic randomization.
- **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.

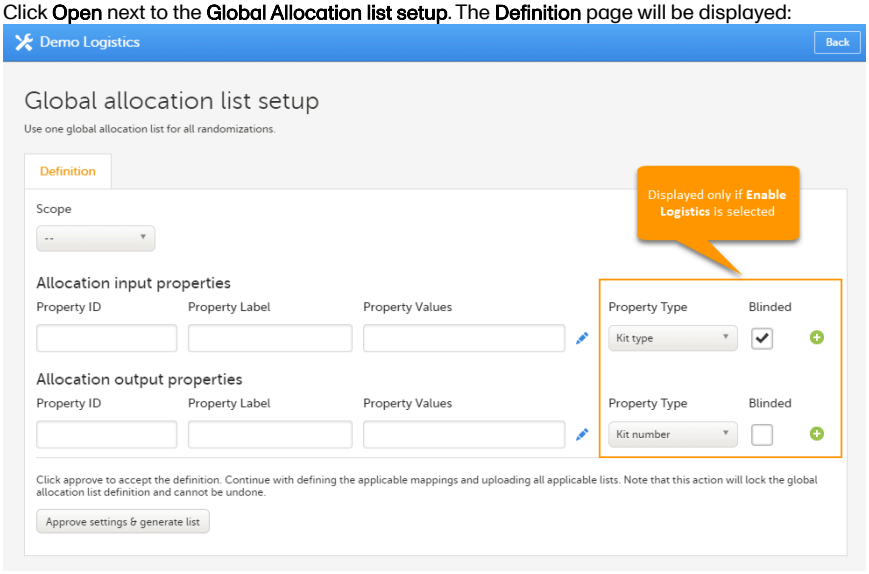
Important!

- 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:

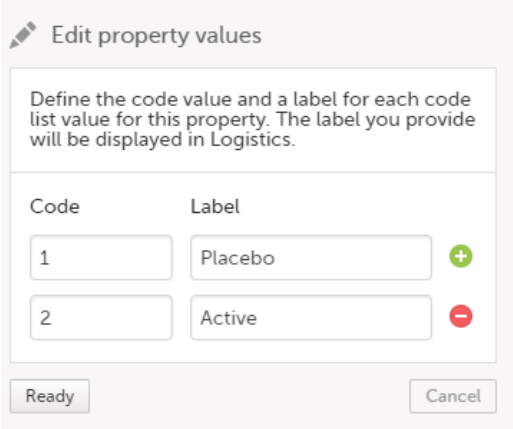


2 Under the **Definition** tab, set the following:

- 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:

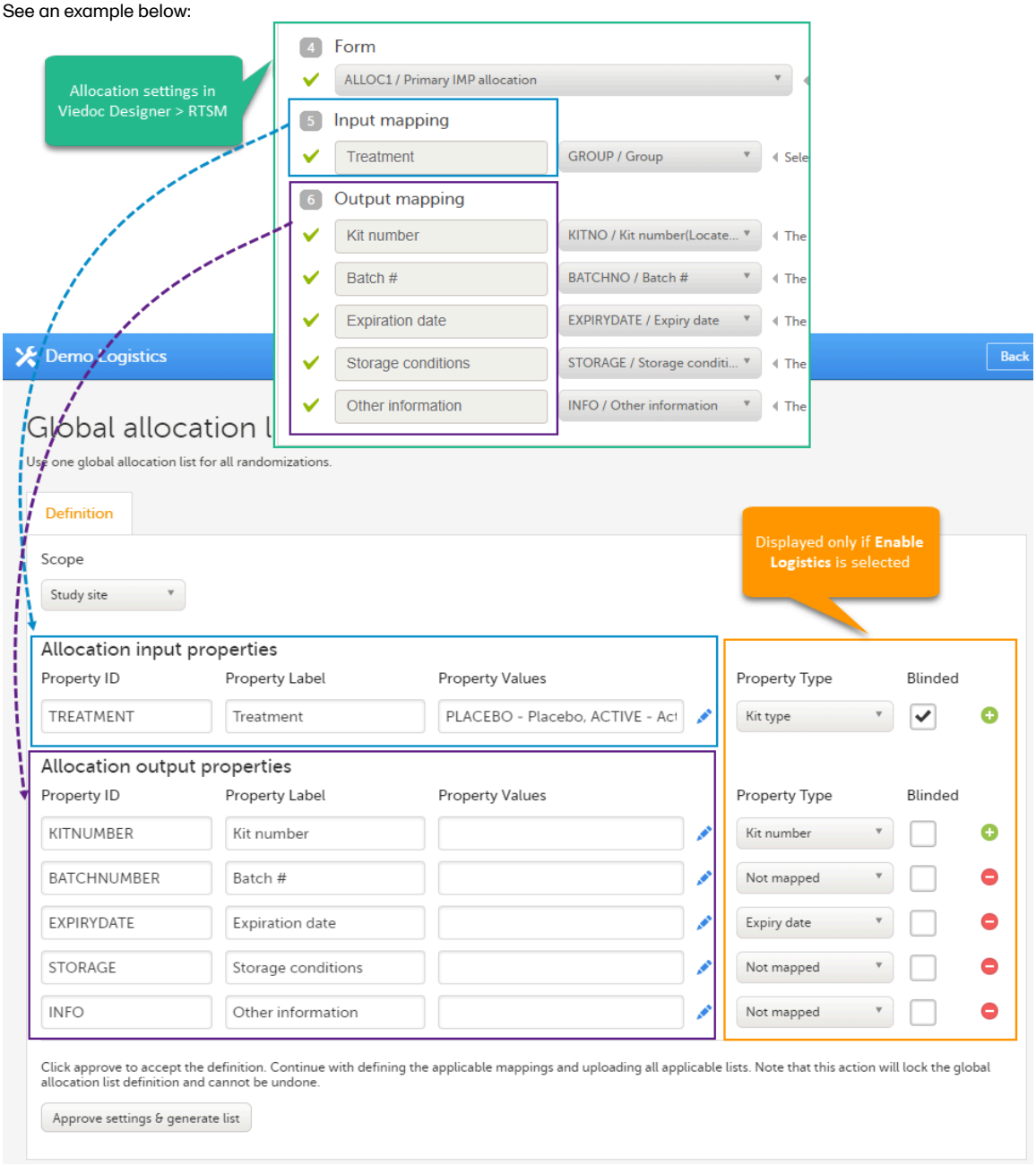


Note! The codes must be defined for all the code list items to be able to upload the allocation list. If any codes that were not defined here with **Code** and **Label** are included in the allocation list, this will not be uploaded. You must use the same codes as defined in the study design.
If the **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:



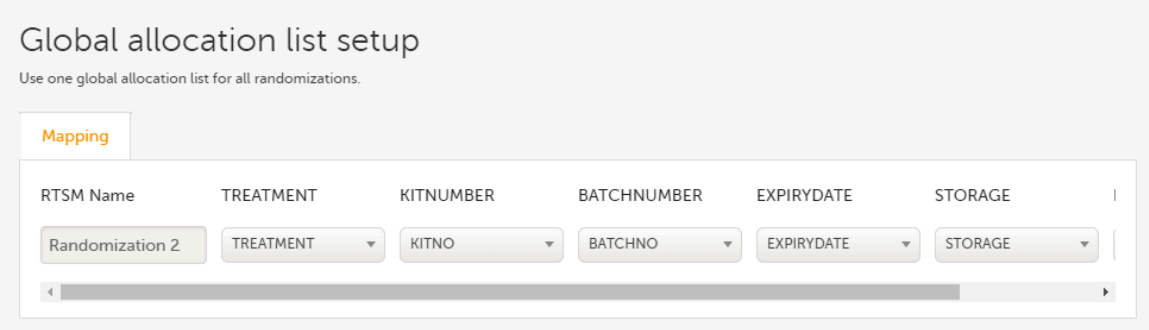
3

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.

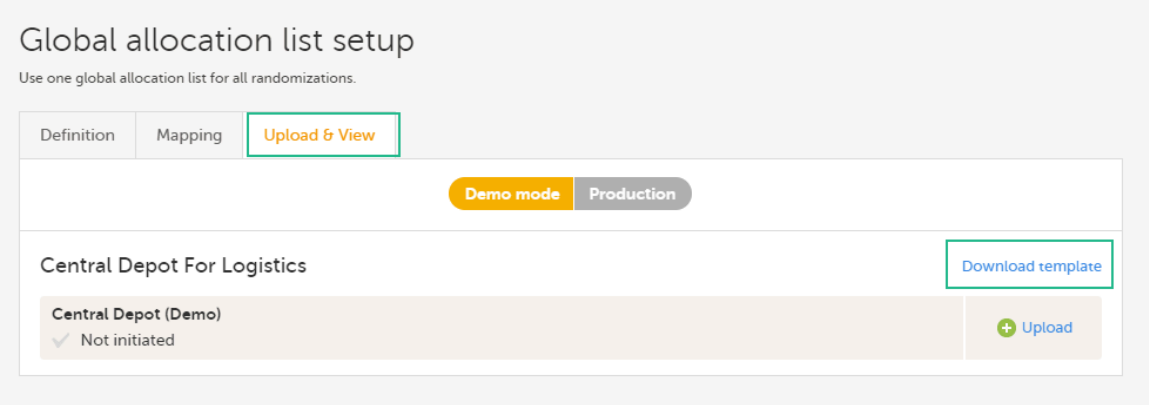
Note that enabling/disabling **Logistics** will not be possible after approving the settings.

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**.

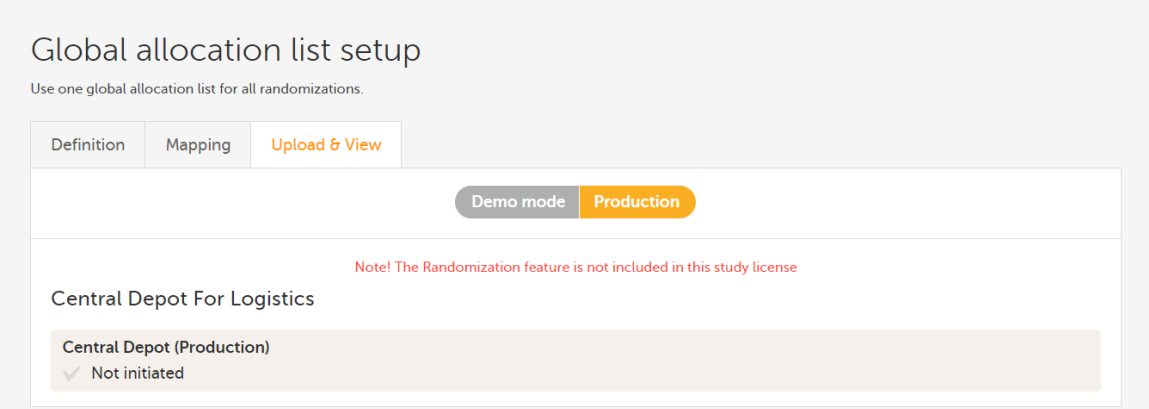


5 Under the **Upload & View** tab, download the template of the allocation list:



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:

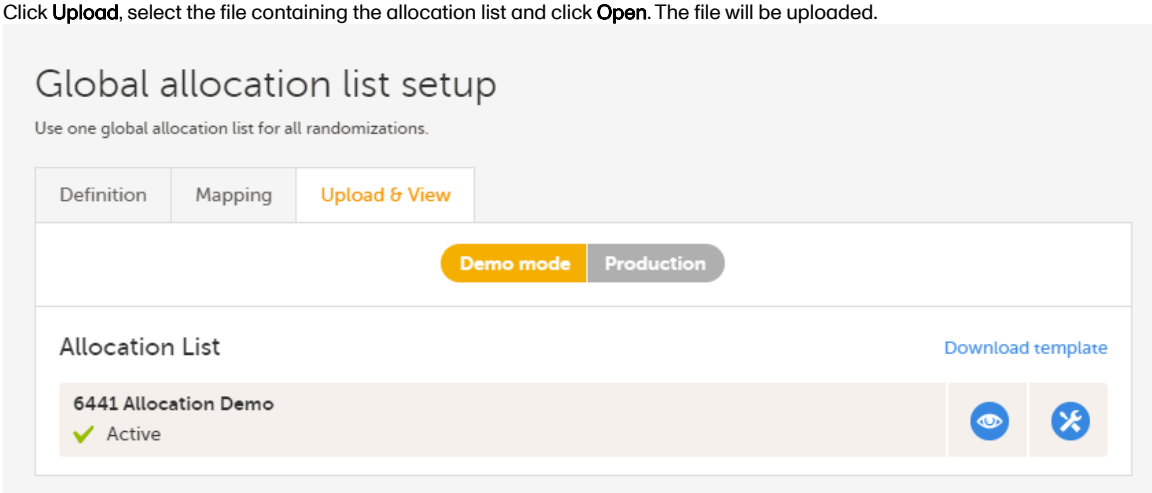
	A	B	C	D	E	F
1	TREATMENT	KITNUMBER	BATCHNUMBER	EXPIRYDATE	STORAGE	INFO
2	PLACEBO	<string>	<string>	<string>	<string>	<string>
3	ACTIVE	<string>	<string>	<string>	<string>	<string>
4						
5						
6						

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

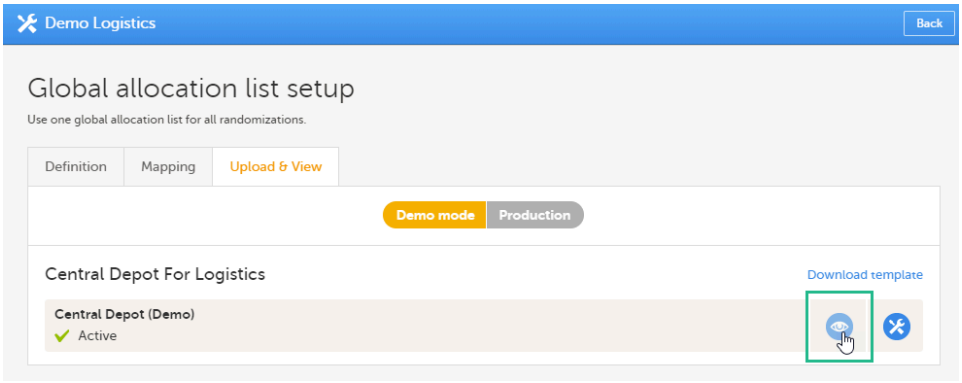
Note! The cell format for the dates (for example EXPIRYDATE) must be set to Text. Make sure that Excel does not format this to Date. If the format of the dates is not set to text, the upload of the allocation list will fail and an error message will be displayed.

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:

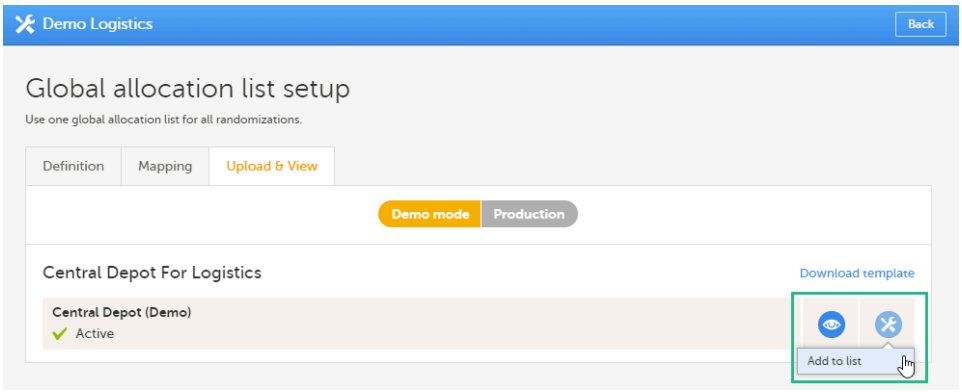
- **Configuration** - summarizes the factors and outcomes and their code lists configured for the allocation.
- **Current distribution** - displays the distribution of randomized patients over the different factors and groups.
- **Slots** - lists all the slots, the factors and outcomes (kit number in 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

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

Can not output single-source

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 (<= 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 (<= 30 or > 30)
- Factor weights: 2 for sex, 1 for age.

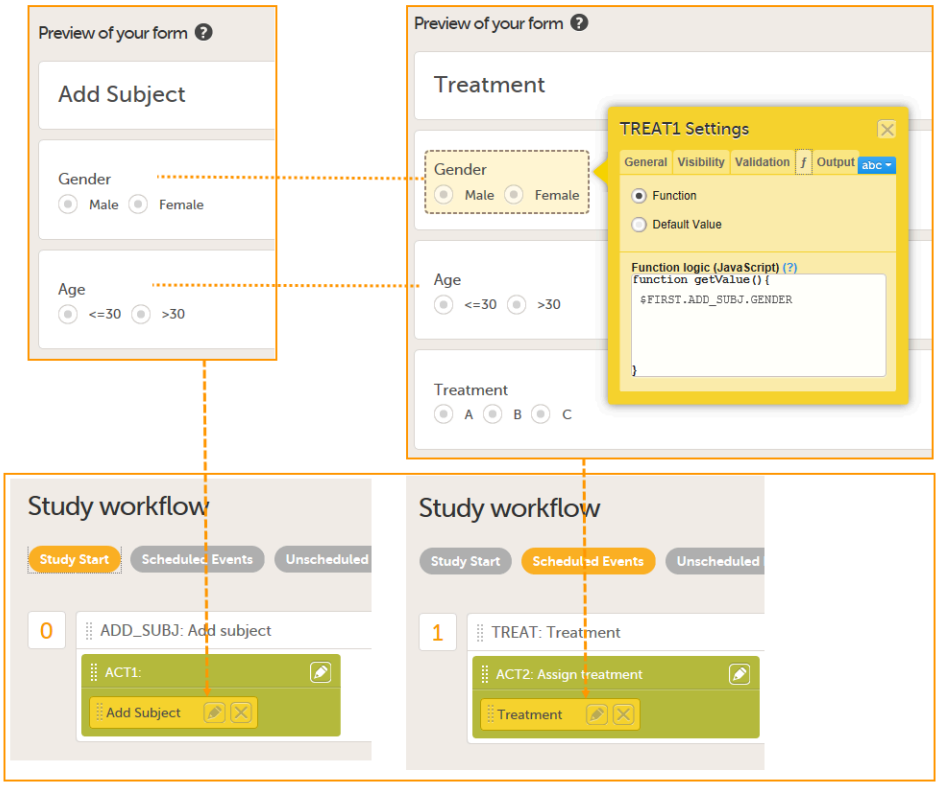
3 The procedure

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.

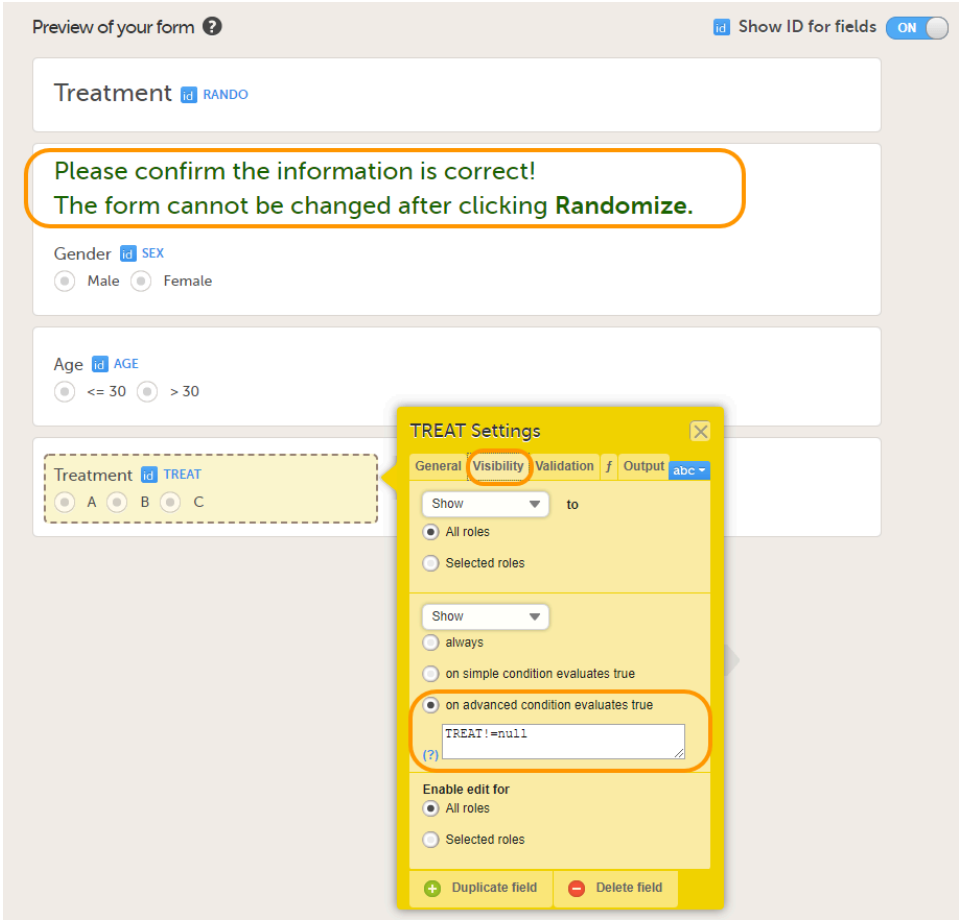


The form *Add Subject* is added to the activity *ACT1* in the *Add_SUBJ* Study Start event. The form *Treatment* is added to the activity *ACT2: Assign treatment* in the *Treatment event,* which is the first scheduled event.

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 *TREAT!=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.



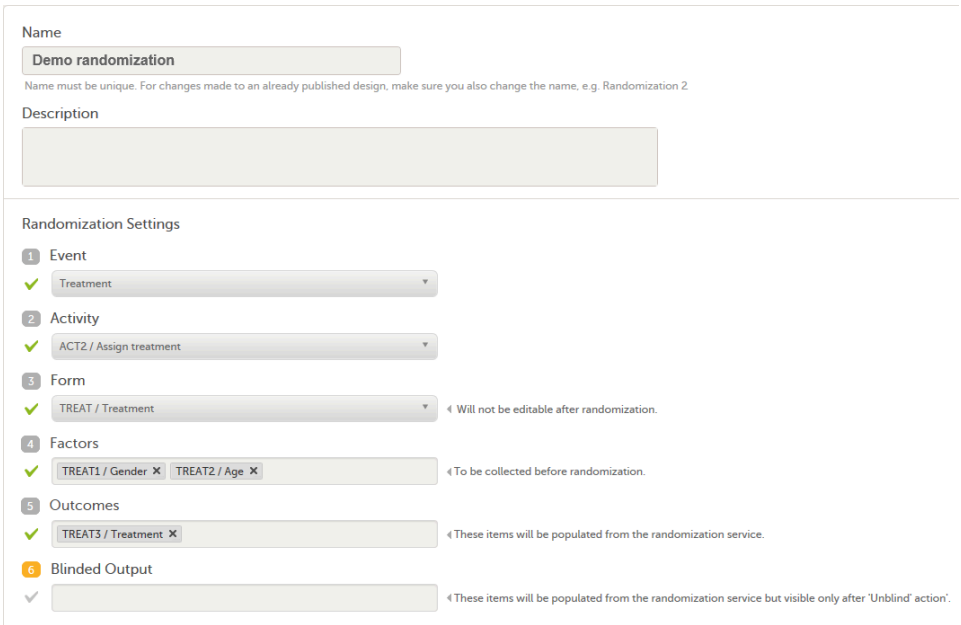
In this example, the randomization outcome (treatment) is not blinded. If you decide to set up a blinded outcome, this item has to be included in the randomization form as well. The blinded outcome will never be shown to the clinic user, it is not available in the export, and you cannot program visibility 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*

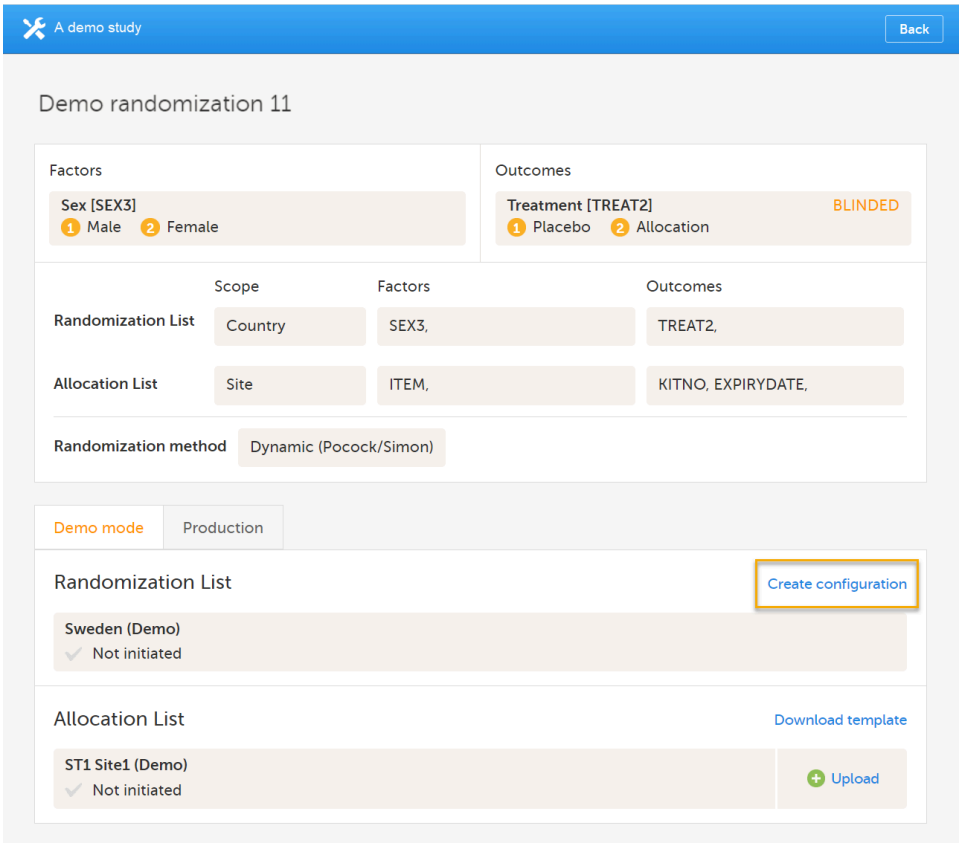
From the **Randomization method** dropdown list, we select *Dynamic (Pocock/Simon)*.

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.

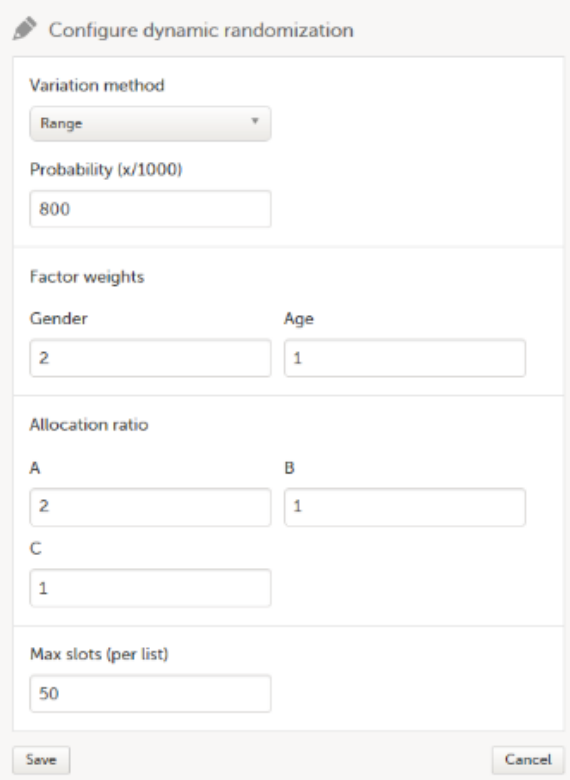
Select **Approve settings & generate list**. The **Create configuration** link is displayed:



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.

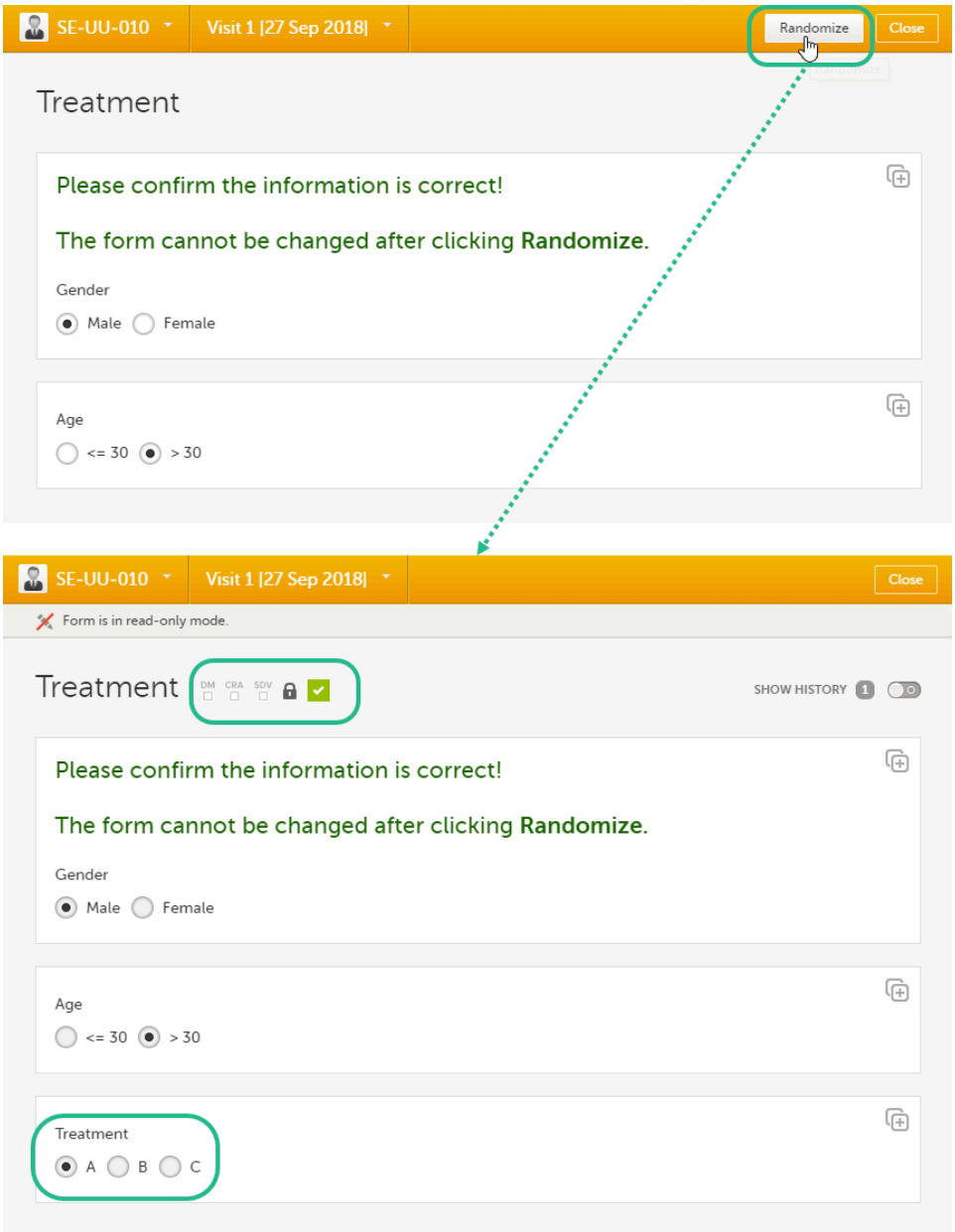


For step by step instructions on how to set up the randomization in Viedoc Admin, see Configuring a dynamic randomization.

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

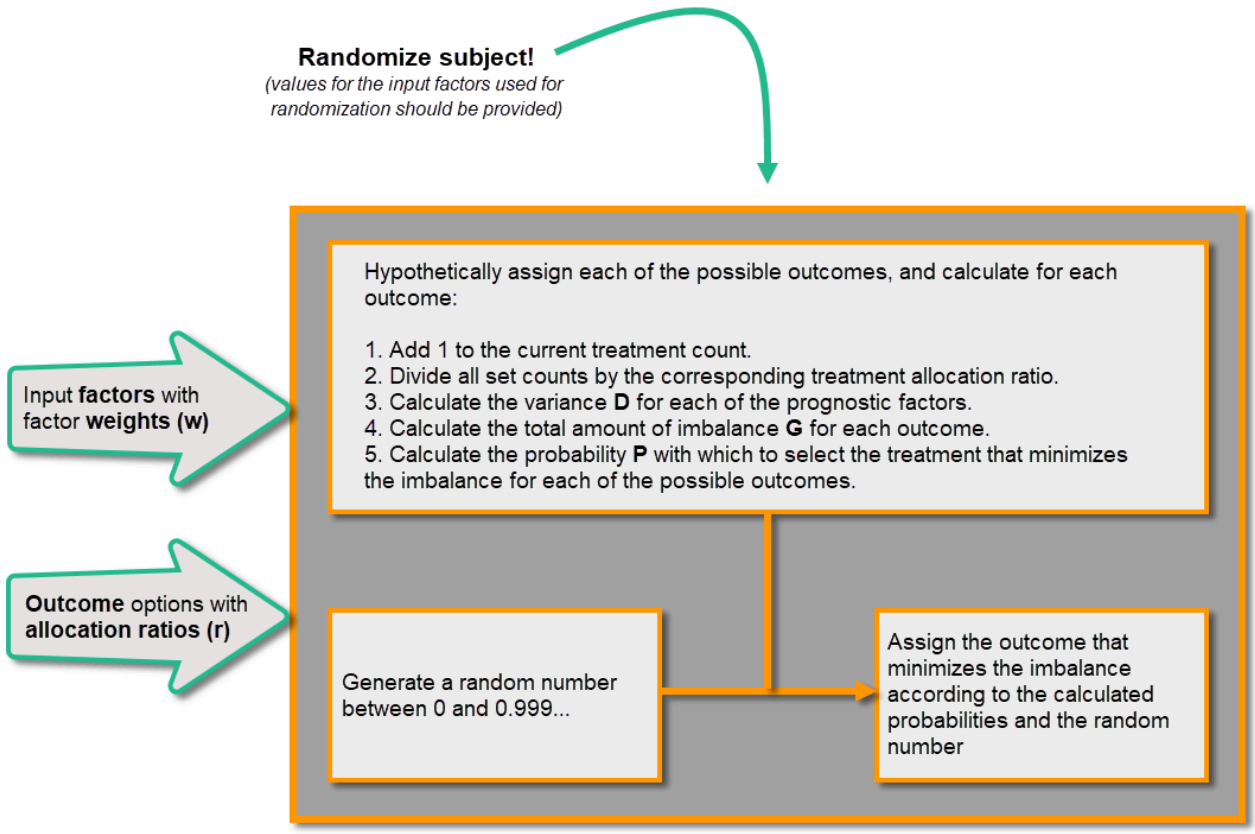
The following table lists the terms that the algorithm used for dynamic randomization according to the Pocock and Simon method is based on.

Term	Description	Calculated as
D	The amount of variation in the set of values for a factor	▪ Range - the difference between the highest and the lowest values in the set, or ▪ Range Squared - the square of the range.
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	The probability determines the extent to which one wishes to favour the treatment group that would lead to the smallest imbalance. 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. During randomization, P for each treatment will be distributed as follows: (N = number of treatments, p = probability cut-off) ▪ If the Gs are the same for all treatment assignments, then the probability will be the same for each treatment: P=p/N. ▪ If one treatment has the lowest G, then it will have its probability P as p. The remaining treatments will split the remaining probability: P=(1 - p)/(N - 1) ▪ 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.
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

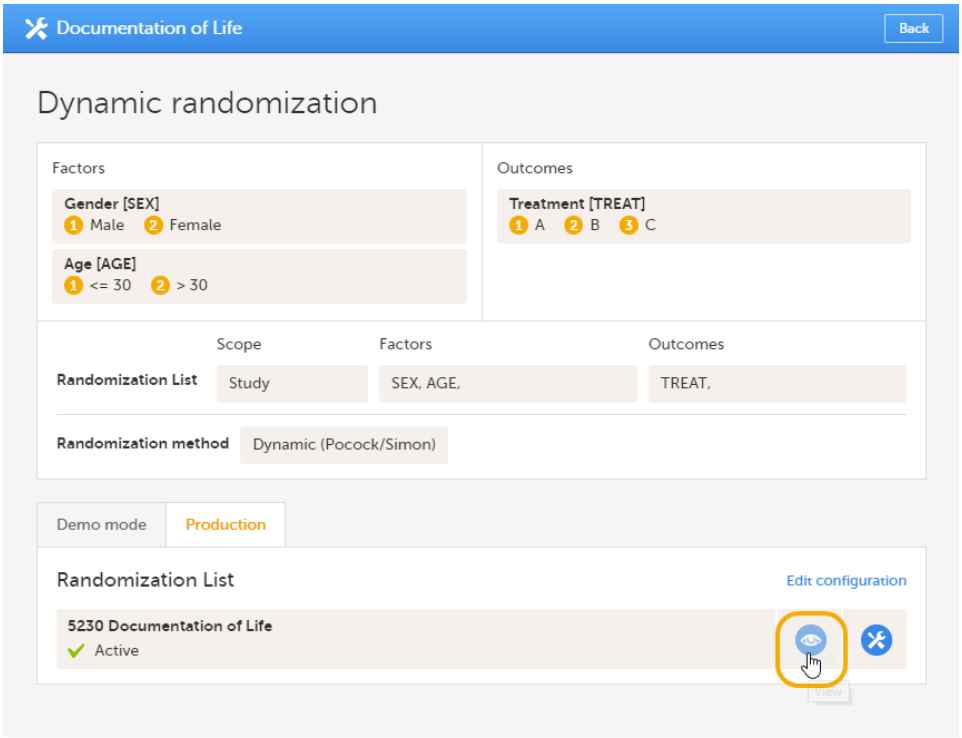
Using the above algorithms, a frequency table is calculated for each new subject to be randomized. A random number greater than or equal to 0 and less than 1 is generated using a seed value based on the number of ticks to represent the current date. Using the Ps and this random number, a treatment index 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:



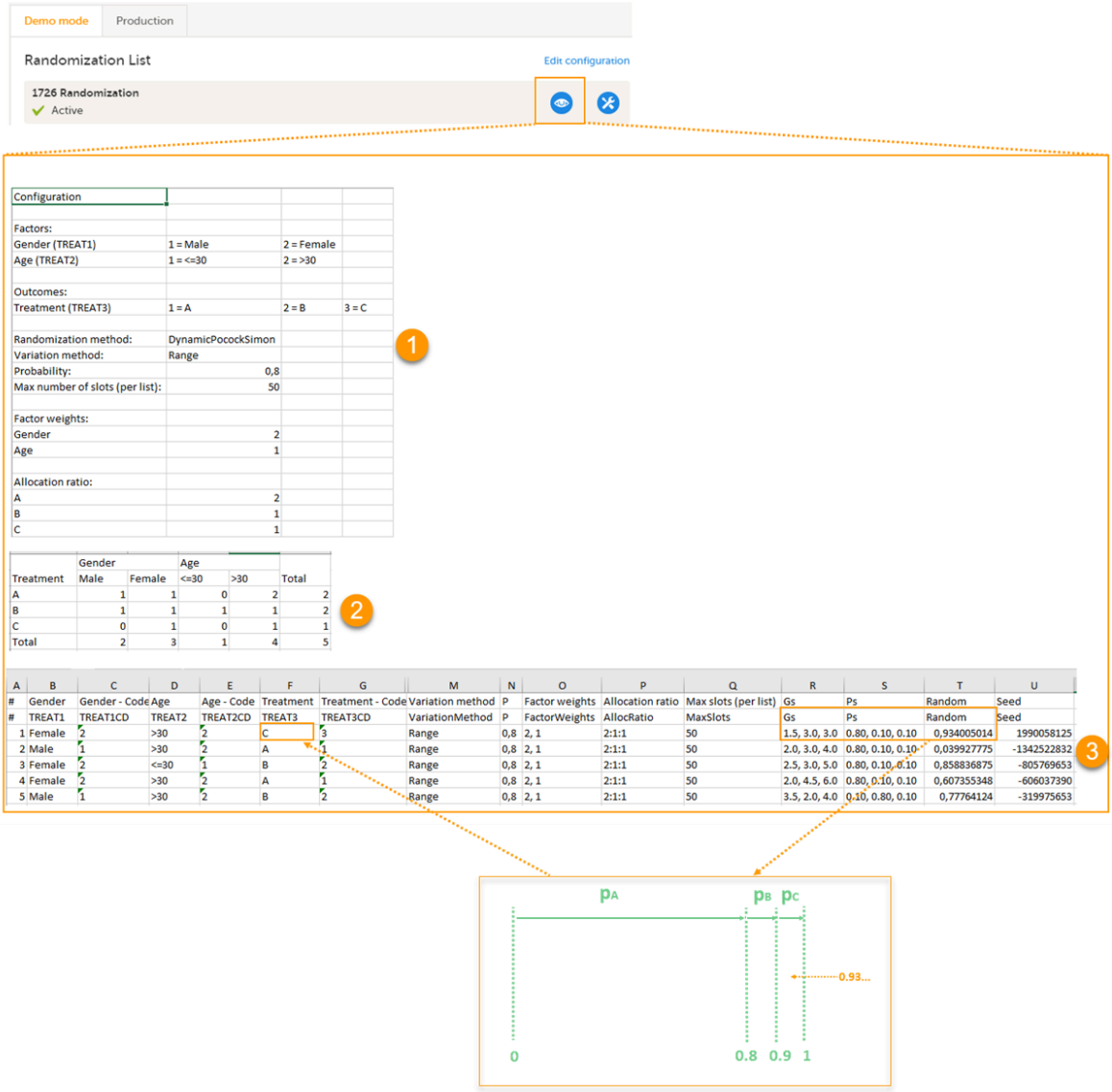
4.4 Calculations

Once the first subject is randomized, it is possible to download the randomization list from Viedoc Admin.



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.



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		

	Gender		Age		
Treatment	Male	Female	<=30	>30	Total
A	1	1	0	2	2
B	1	1	1	1	2
C	0	1	0	1	1
Total	2	3	1	4	5

#	Gender	Gender - Code	Age	Age - Code	Treatment	Treatment - Code	Variation method	P	Factor weights	Allocation ratio	Max slots (per list)	Gs	Ps	Random	Seed
#	TREAT1	TREAT1CD	TREAT2	TREAT2CD	TREAT3	TREAT3CD	VariationMethod	P	FactorWeights	AllocRatio	MaxSlots	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 -> $1/r_A$ = 1/2 = 0.5 d_{AF} = max (0.5, 0, 0) – min (0.5, 0, 0) = 0.5 – 0 = 0.5	0	0 -> +1 -> $1/r_A$ = 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 <= 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 treamment 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

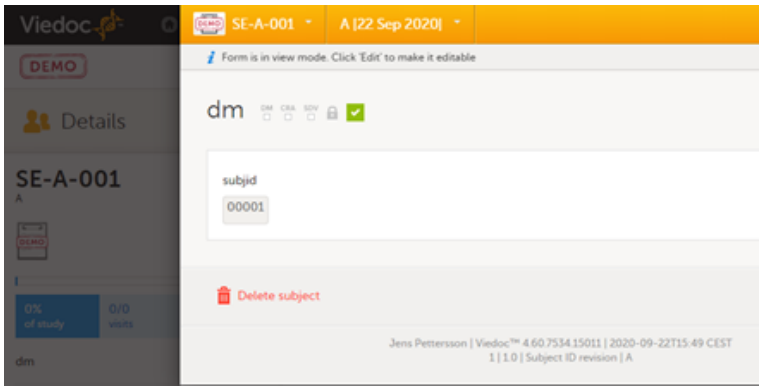
This use case shows how to change from an autogenerated to a manually entered subject ID, to avoid a mix of patterns in the study.

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:

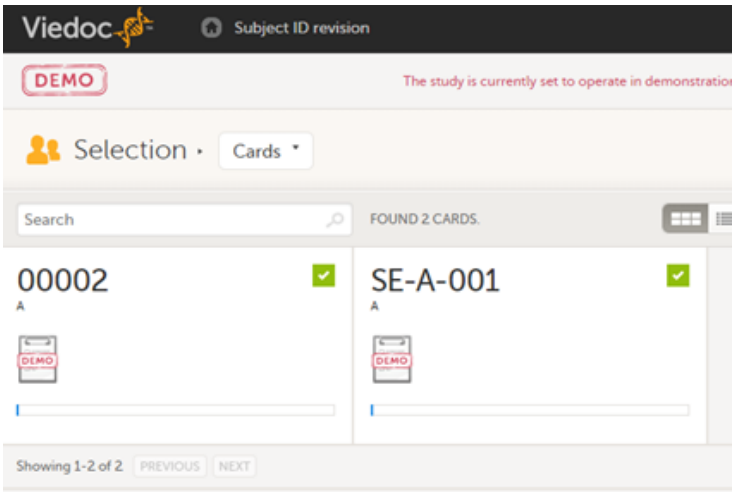
- In version 2 of the design, the subject IDs are taken from the field **subjid** in the Study start event, thus the pattern:

  ```
  subjid
  ```

  This is assigned to all sites and subjects get subject IDs looking like this:

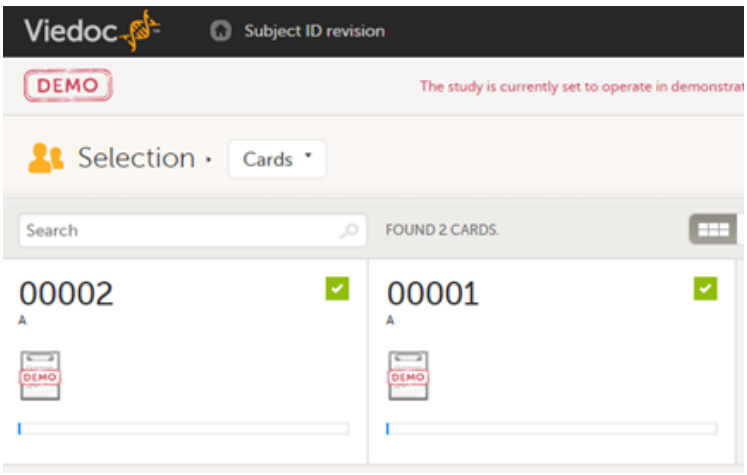
- In Viedoc Clinic, you can now see a mix of patterns for the subject IDs:



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

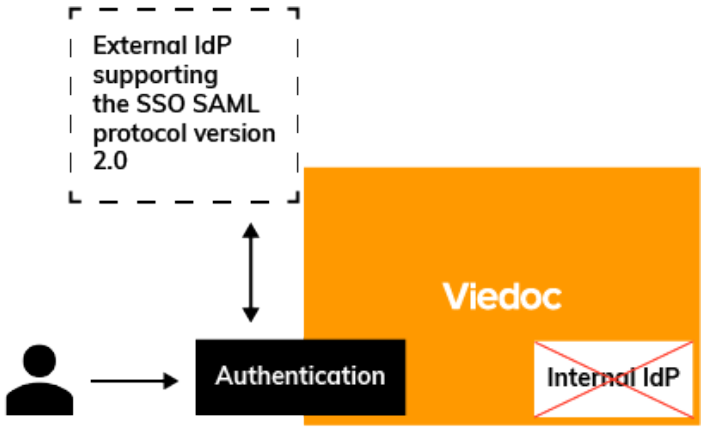
1 Introduction

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

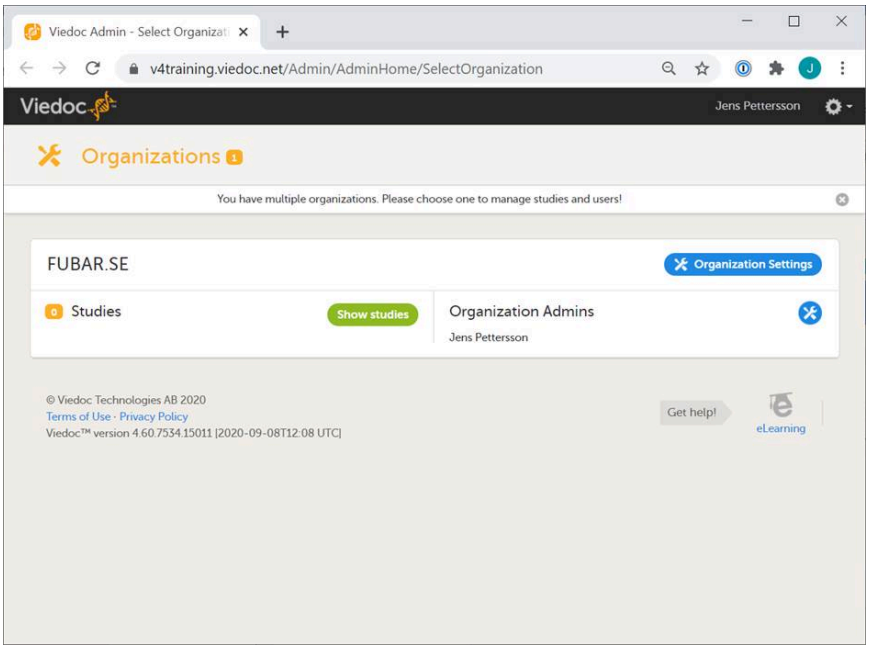
- The domain name for which you want to configure SSO must have an email address like this: hostmaster@your.domain.name, and you must be able to get hold of a key sent to that address.
- You must have Organization Administrator access to Viedoc.

- You must have Administrator access to Google Workspace.

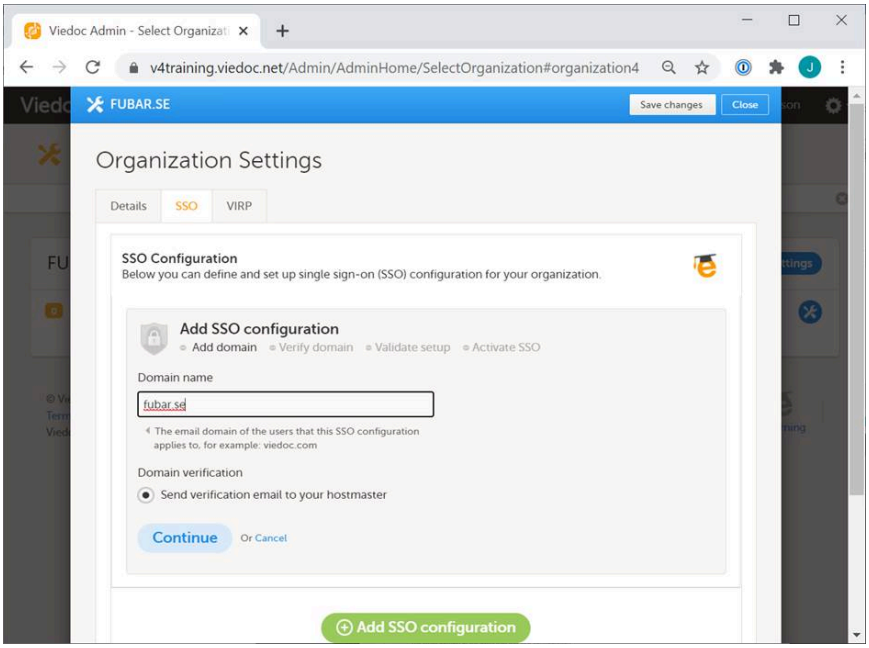
2.2 Step-by-step guide

In this guide we use the domain name **fubar.se** and the European Viedoc training instance.

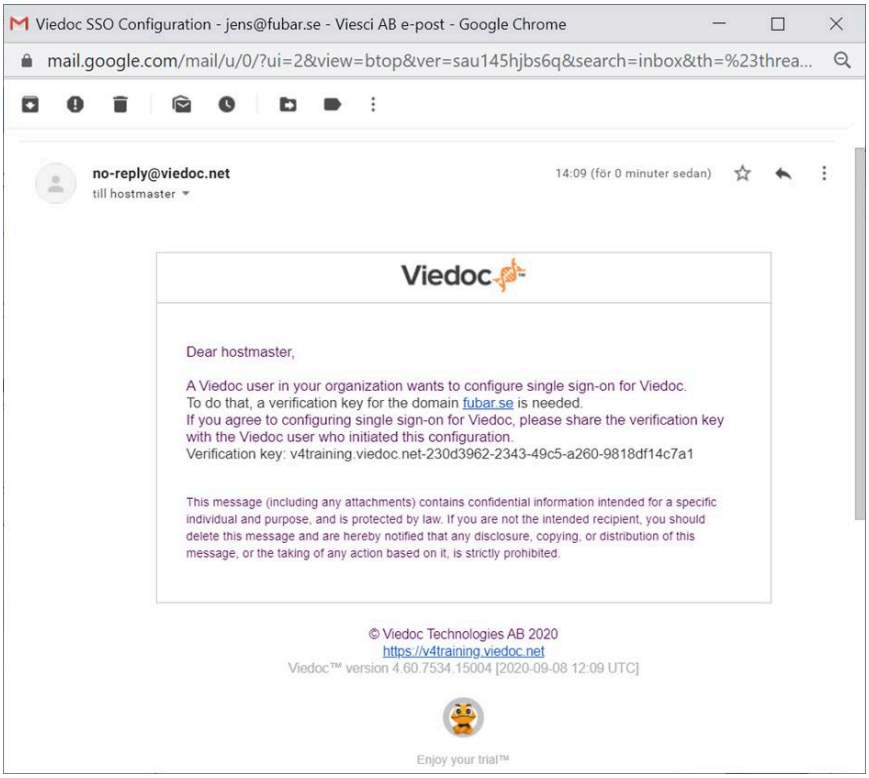
1 As Organization Administrator, go to Admin and click **Organization Settings**:



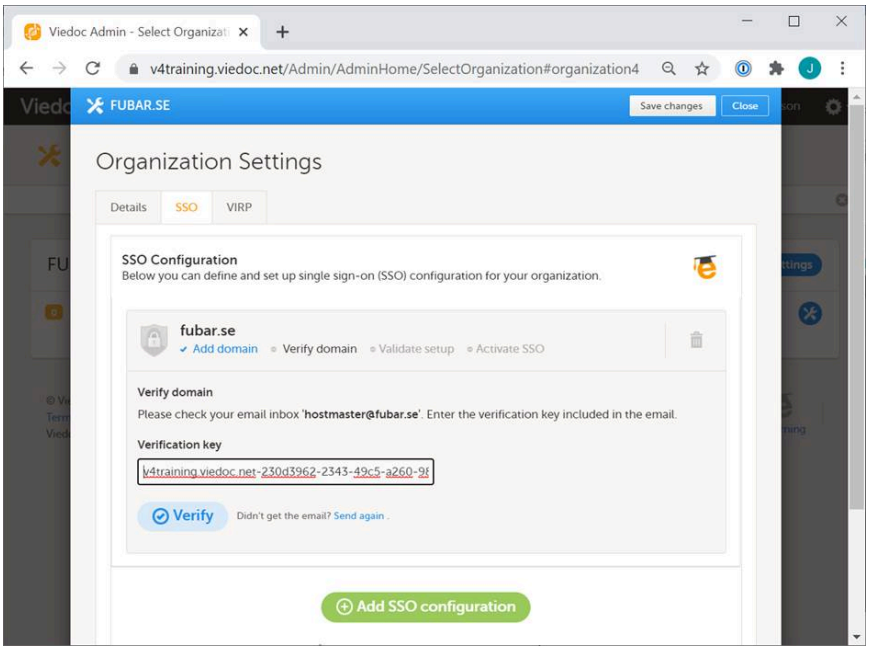
2 Click the tab **SSO** > **Add SSO configuration**, enter the **Domain name** and click **Continue**.



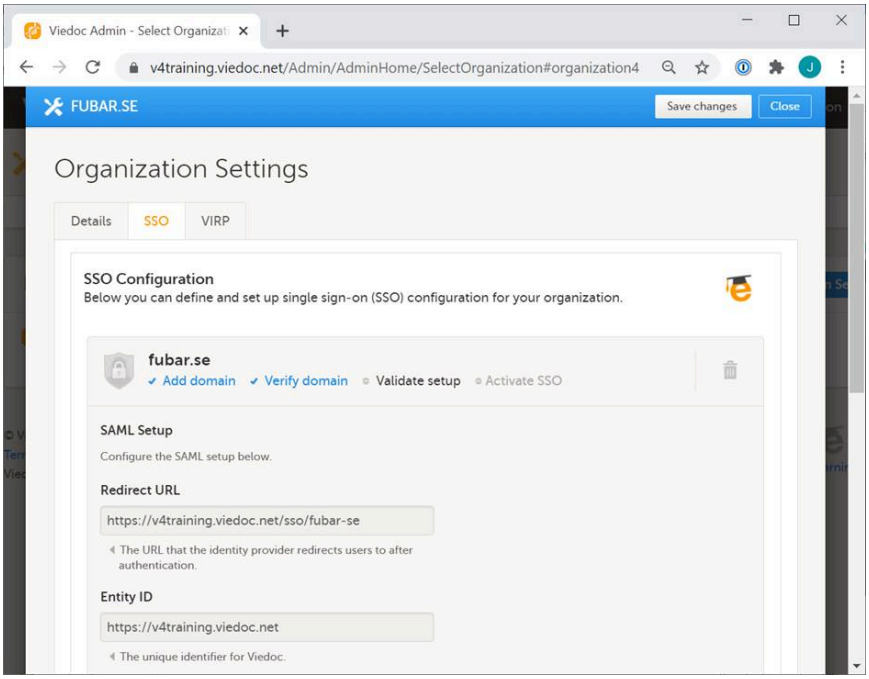
3 Contact the person in your organization with access to the hostmaster@your.domain.name email inbox, to retrieve the verification key that proves that you own the domain.



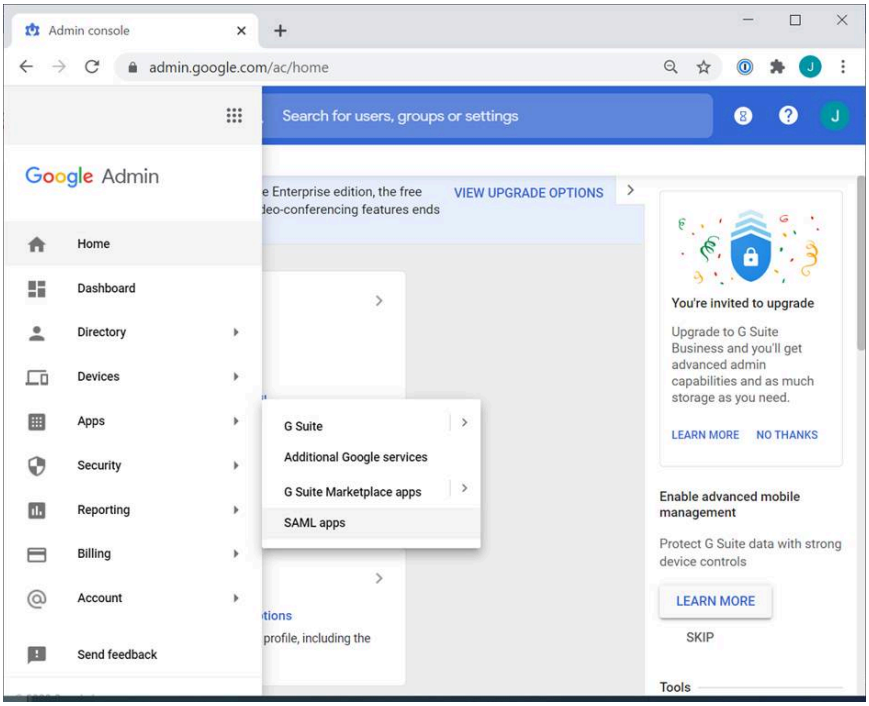
4 Enter the verification key in Viedoc and click **Verify**.



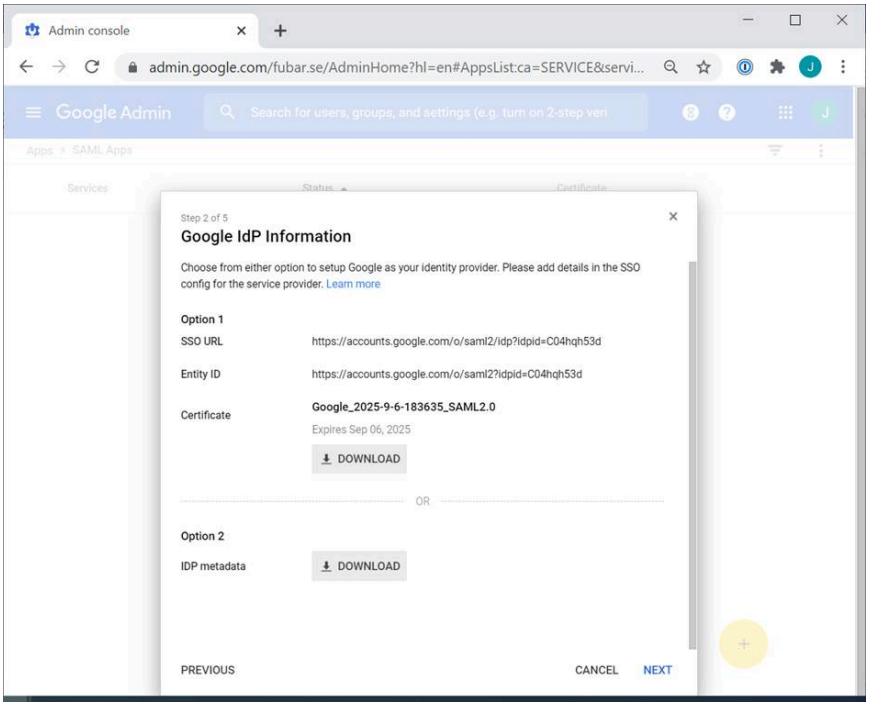
5 Make a note of the **Redirect URL** and the **Entity ID**.



6 In a separate tab, log in to Google Workspace Admin Console, go to **Apps** > **SAML apps**.



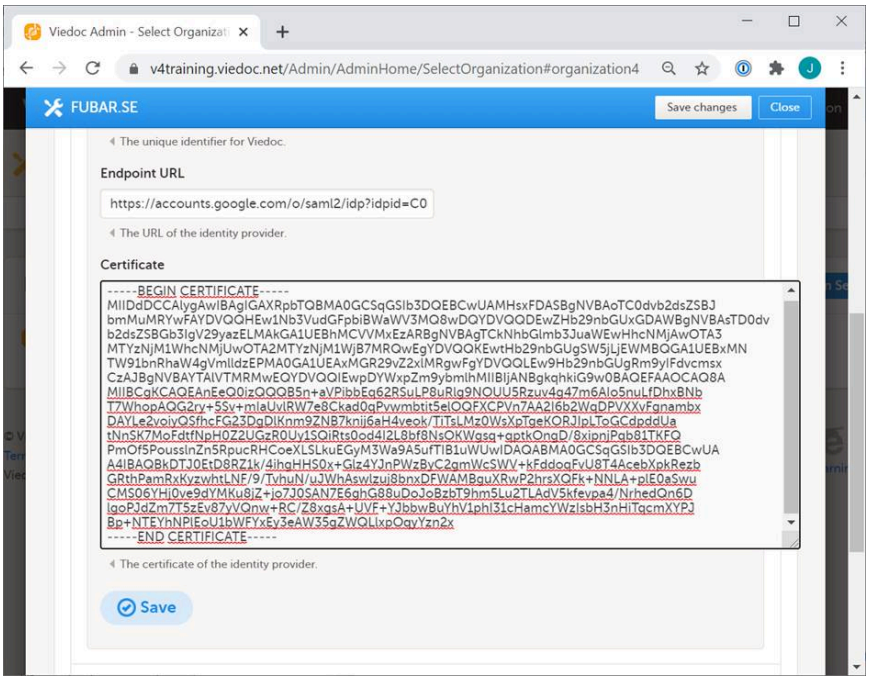
7 Click to **Add service** and click to **SETUP MY OWN CUSTOM APP**:



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**.

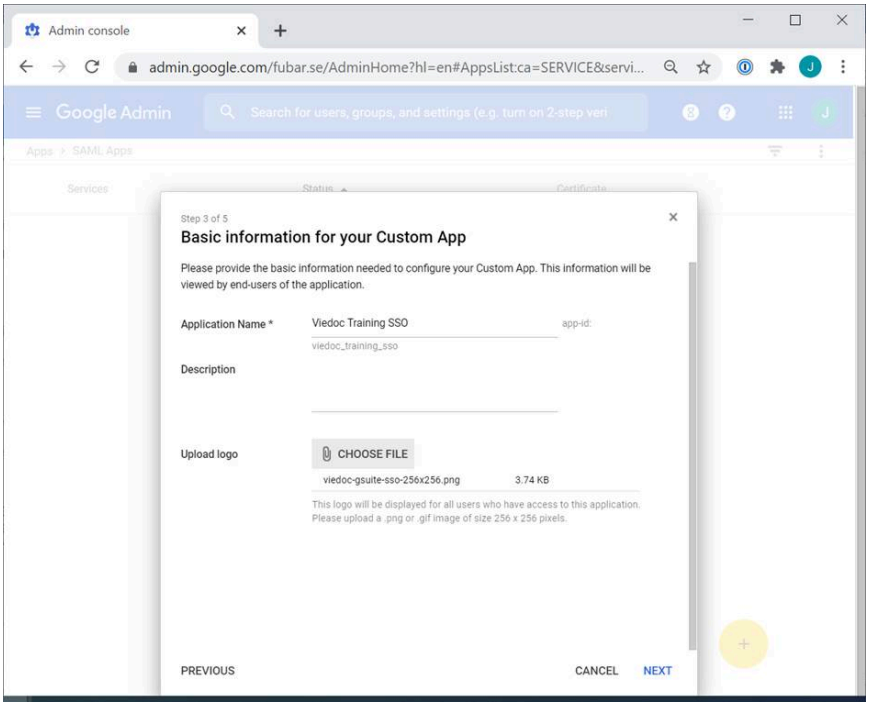


9 In Viedoc, copy the redirect URL and go back to the Google Workspace tab and click **Next**.

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-sso-256×256.png and upload it in the Google Workspace dialog box.

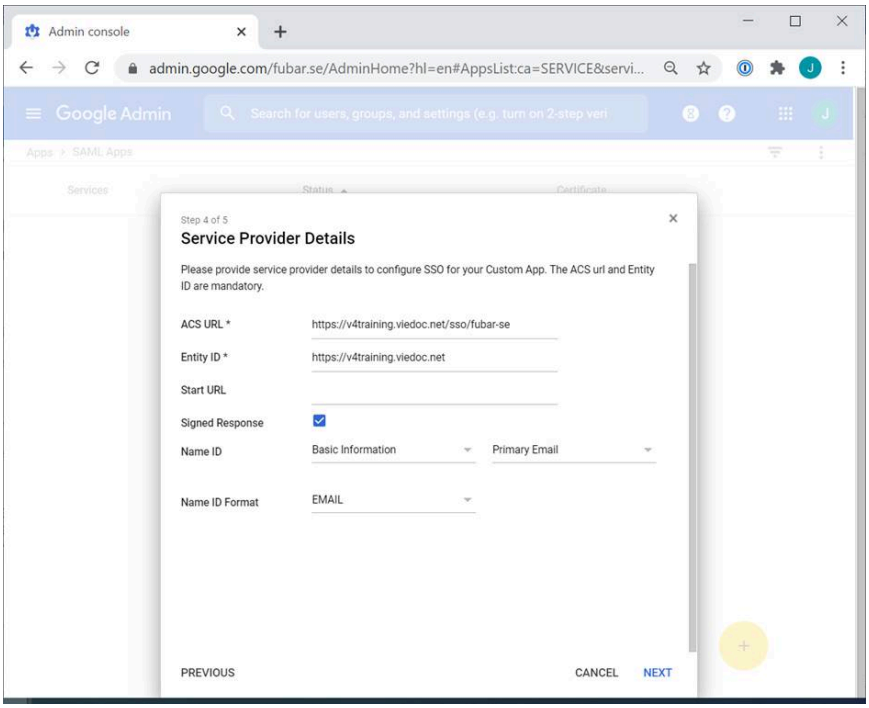
Click **Next**.



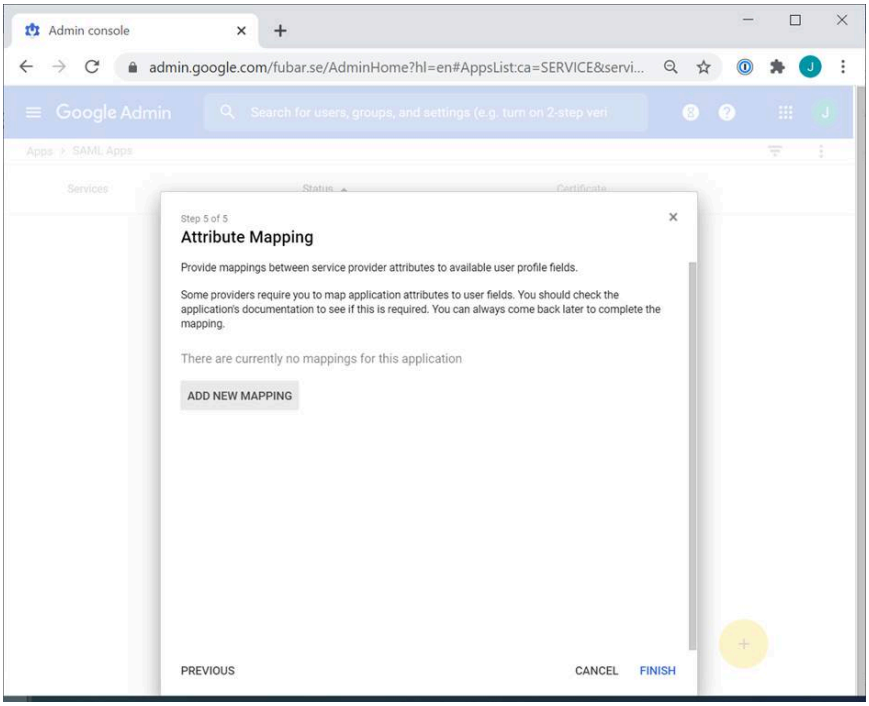
11 In the **Service Provider Details** window:

- 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**.

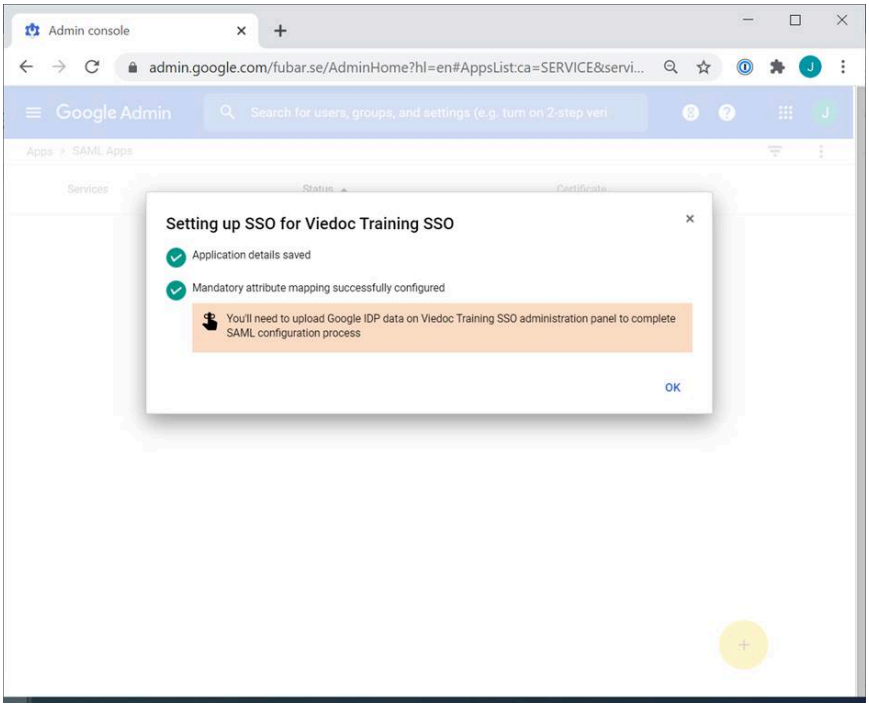
Click **Next**.



12 In the **Attribute Mapping** window, click **Finish**.

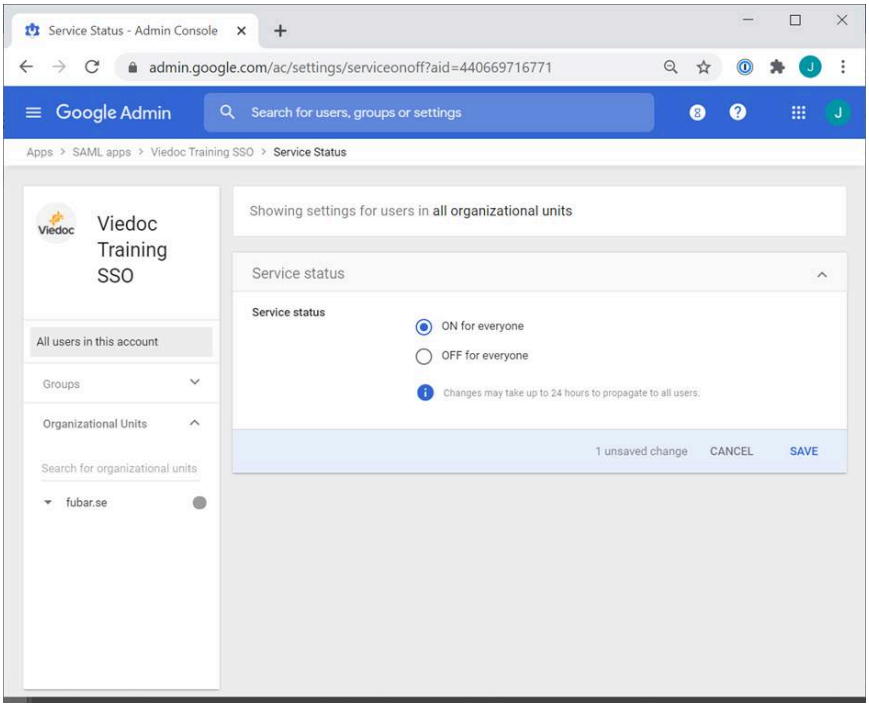


13 Click **OK**.



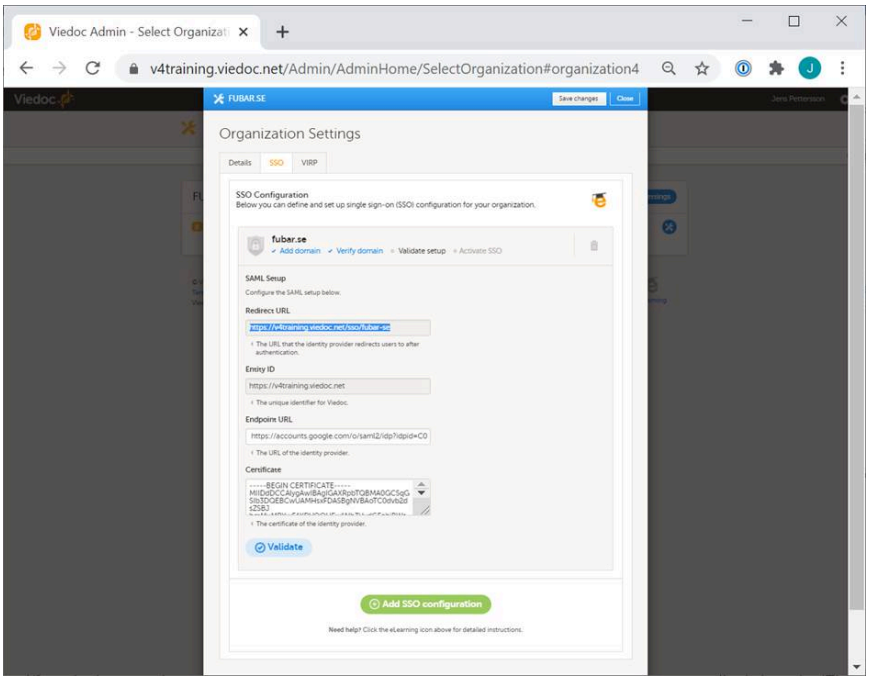
14 Click the down arrow of the **User access** section of the newly configured SAML App.

Select **ON for everyone** and click **Save**.

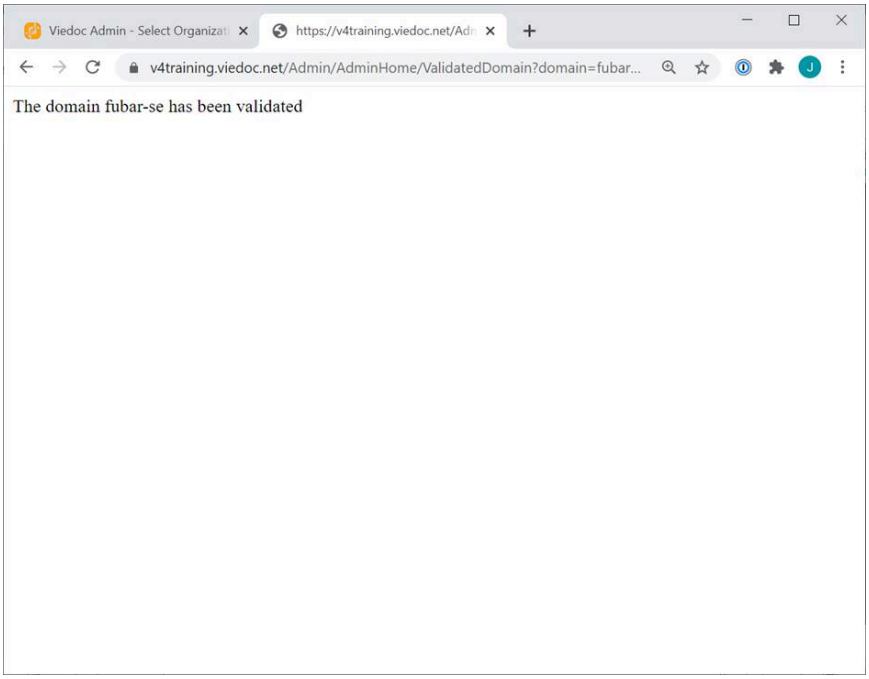


15 Go back to the Viedoc tab and click **Validate**.

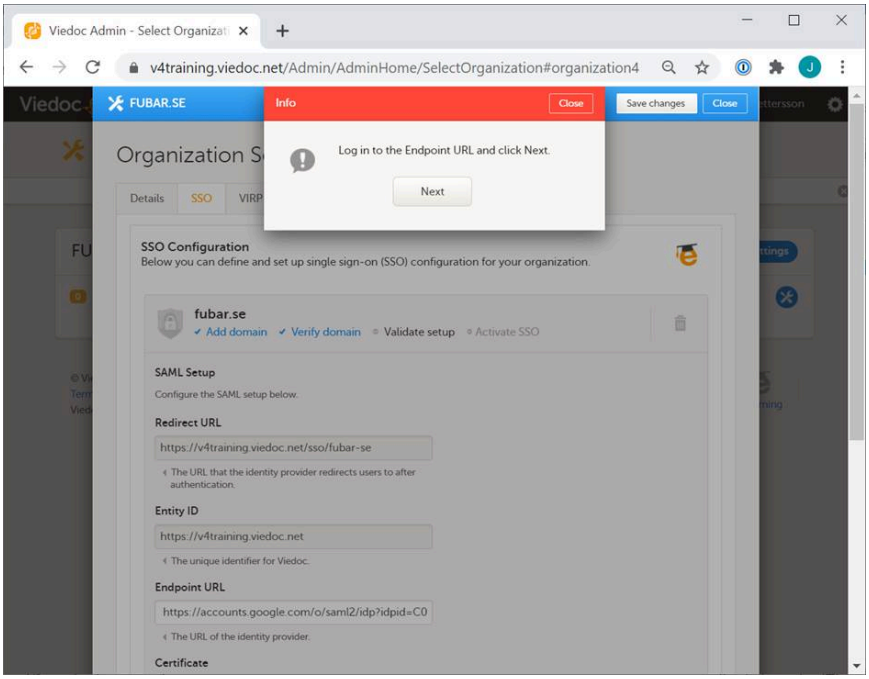
Note! You might be promted to enter your email address and password in order to authenticate with your IdP if not already logged in. Upon successful authentication you will automatically be redirected to the domain verification page.



16 Verify that the domain is validated and then close the tab.

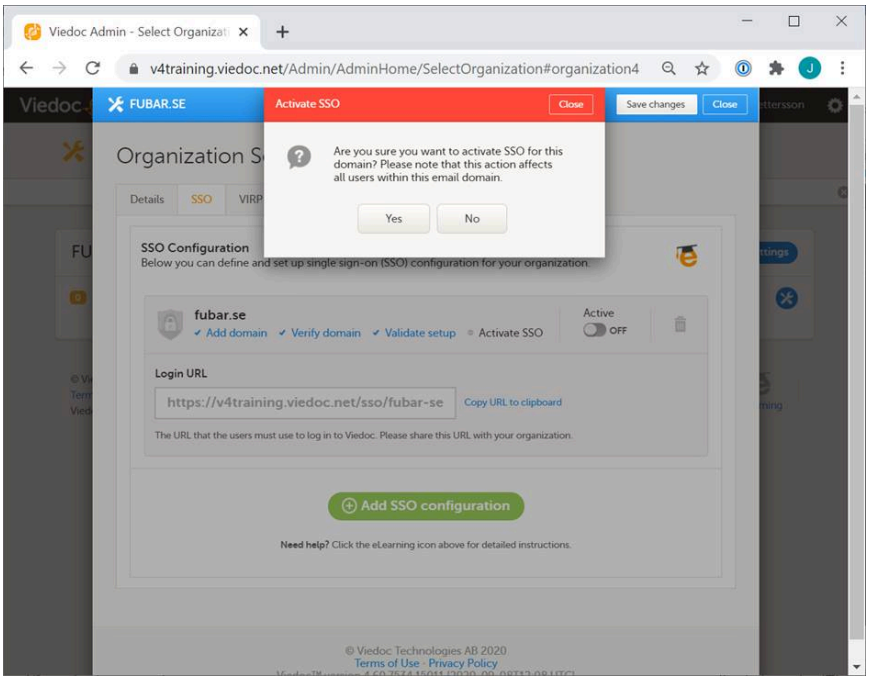


17 Click **Next**.



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

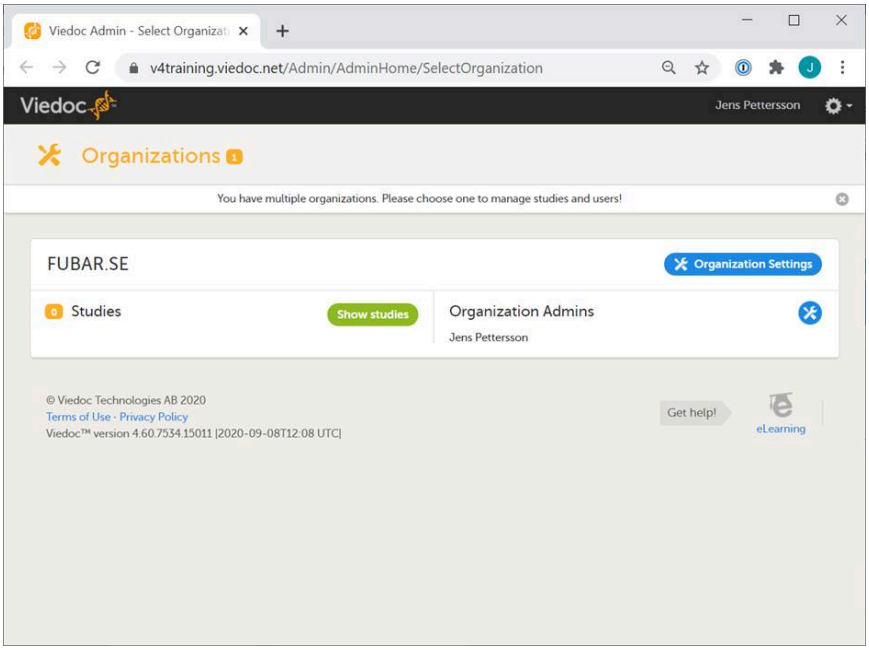
3.1 Pre-requisites:

- 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).

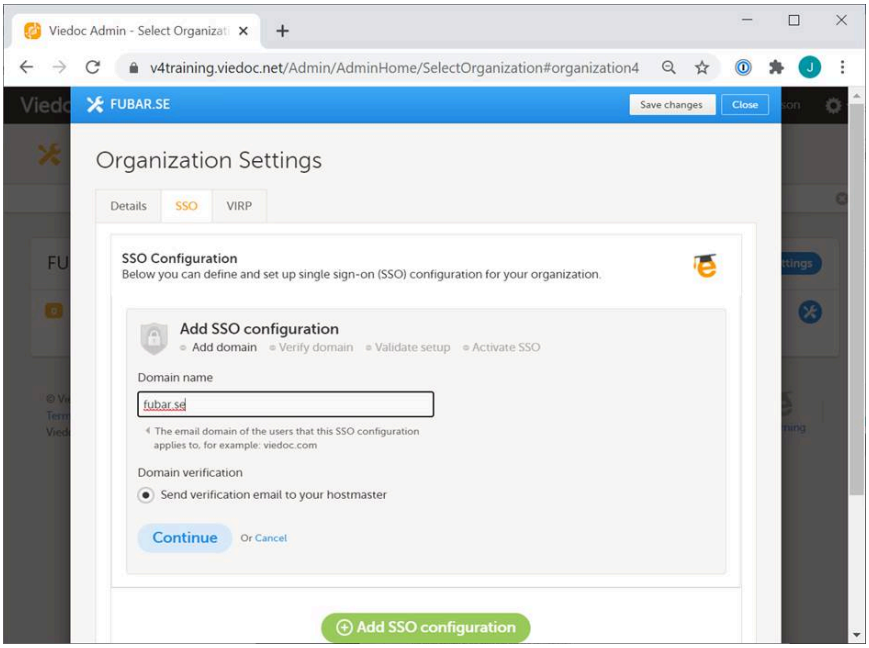
3.2 Step-by-step guide

In this guide we use the domain name **pcg-solutions.com** and the European Viedoc training instance.

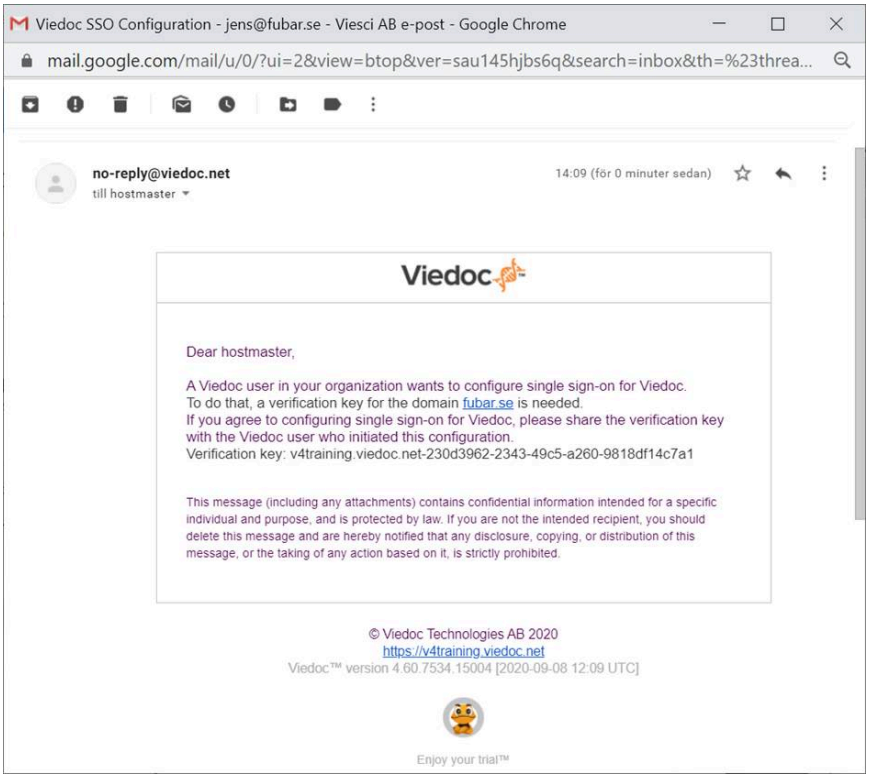
1 As Organization Administrator, go to Admin and click **Organization Settings**:



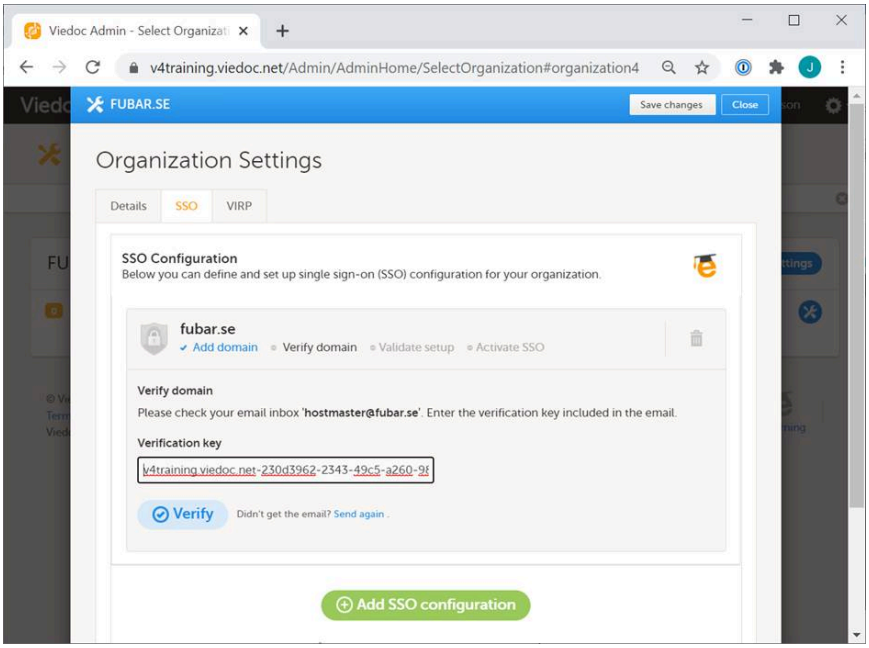
2 Click the tab **SSO** > **Add SSO configuration**, enter the **Domain name** and click **Continue**.



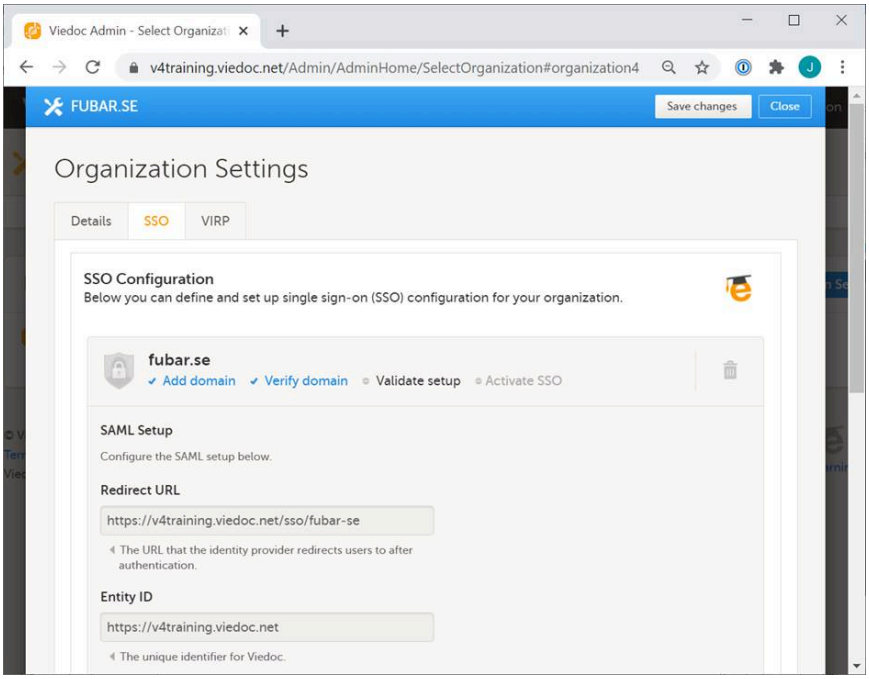
3 Contact the person in your organization with access to the hostmaster@your.domain.name email inbox to retrieve the verification key that proves that you own the domain.



4 Enter the verification key in Viedoc and click **Verify**.

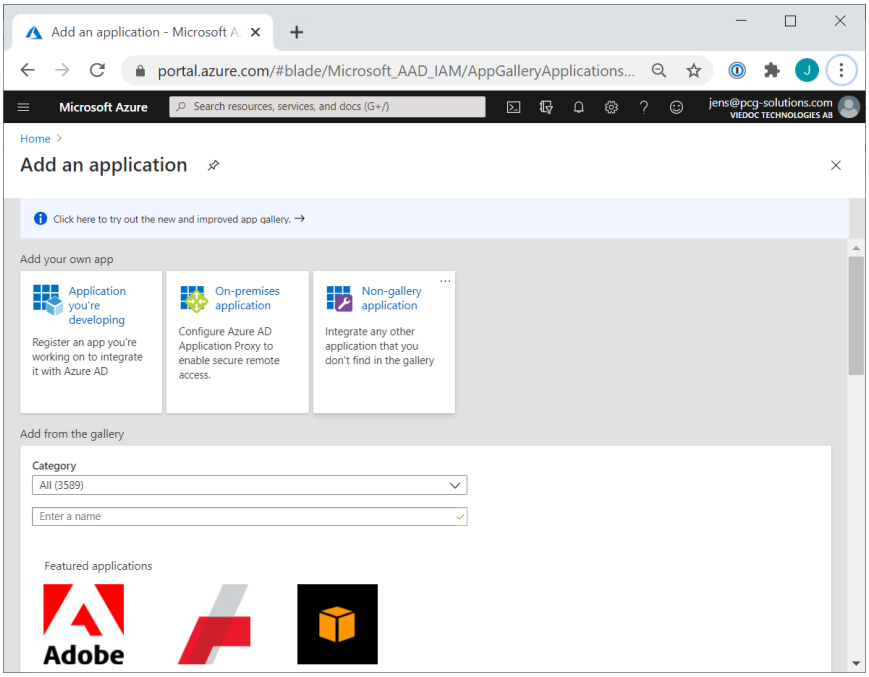


5 Make a note of the **Redirect URL** and the **Entity ID**.



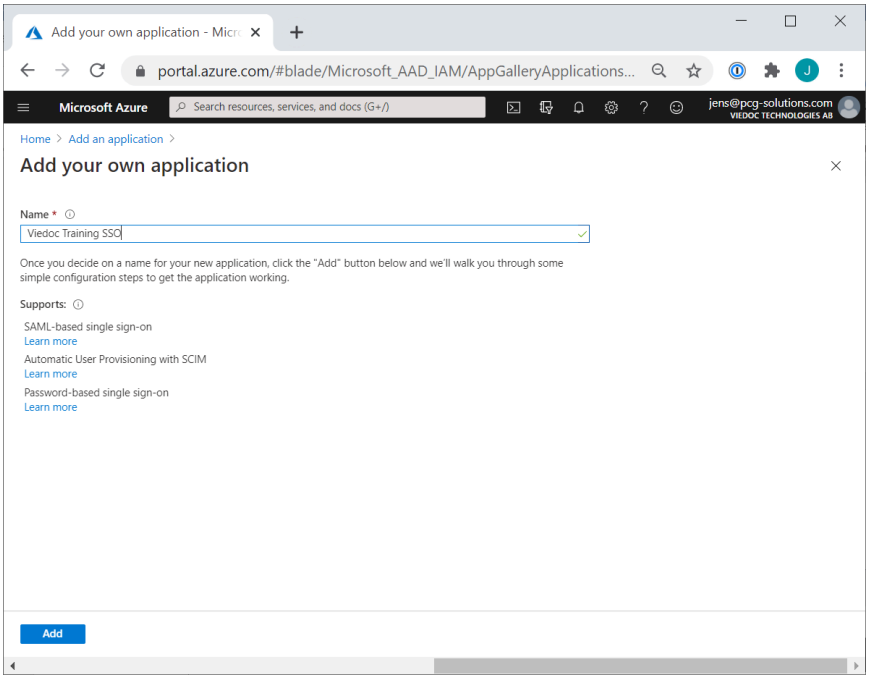
6 In a separate tab, log in to the Microsoft Azure portal and go to **Azure Active Directory**.

Click **Enterprise Applications** > **New application** and select **Non-gallery application**.

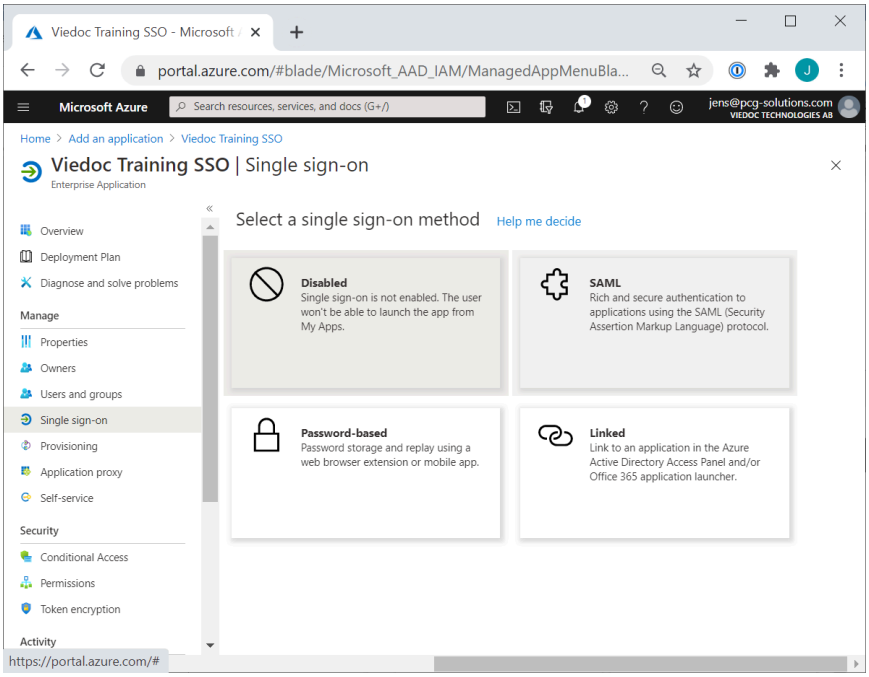


7 Enter an appropriate **Name** describing the Viedoc instance, for example “Viedoc Training SSO”.

Click **Add**.



8 Click **Single Sign-On** > **SAML**.

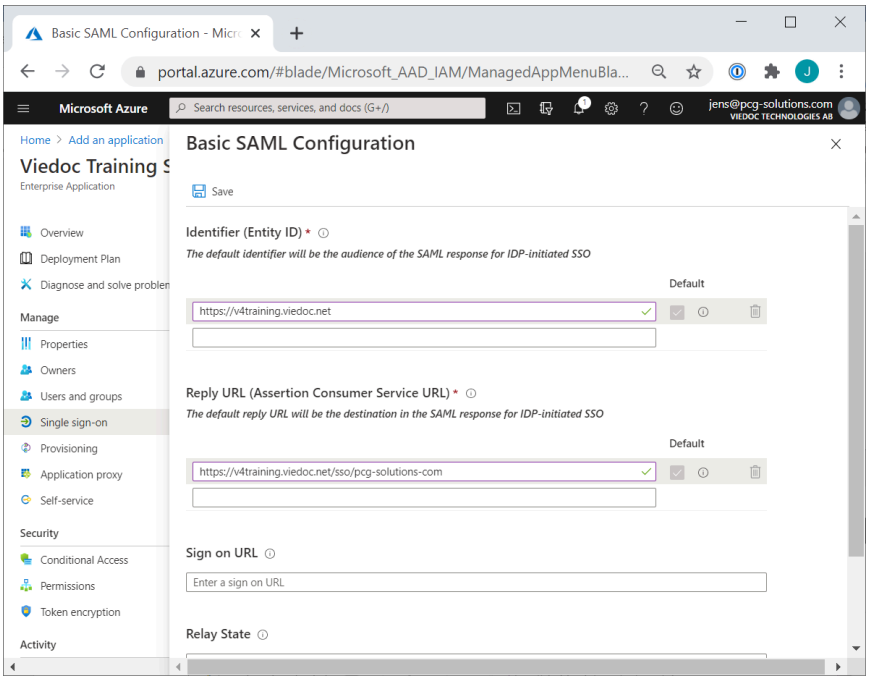


9 Click **Edit the Basic SAML Configuration**.

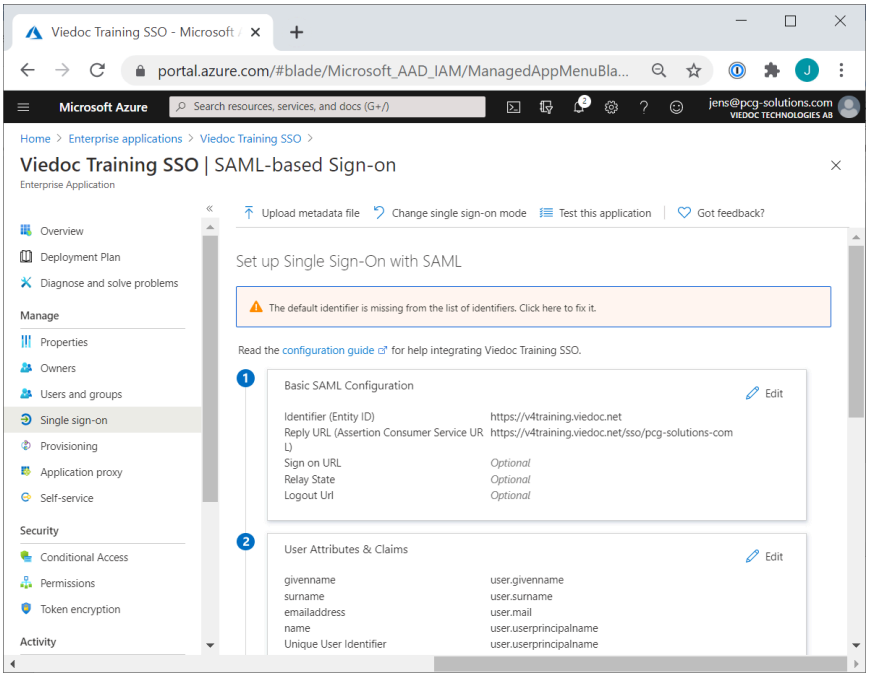
From the Viedoc tab, copy and paste:

- The Entity ID into the **Identifier (Entity ID)** field.
- The Redirect URL into the **Reply URL (Assertion Consumer Service URL)** field.

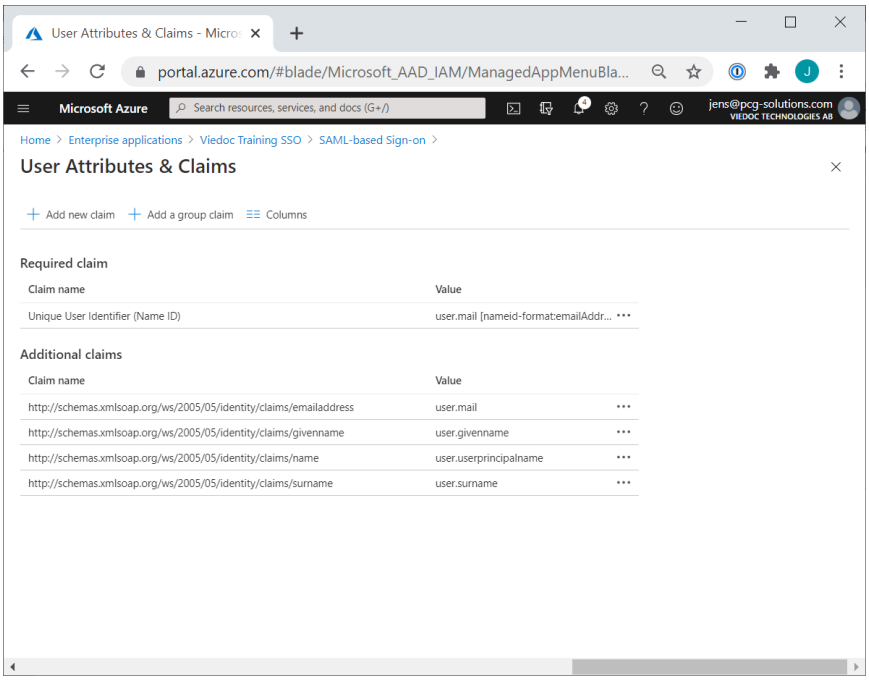
Click **Save** and close the dialog box.



10 Click to **Edit** the **User Attributes & Claims**.



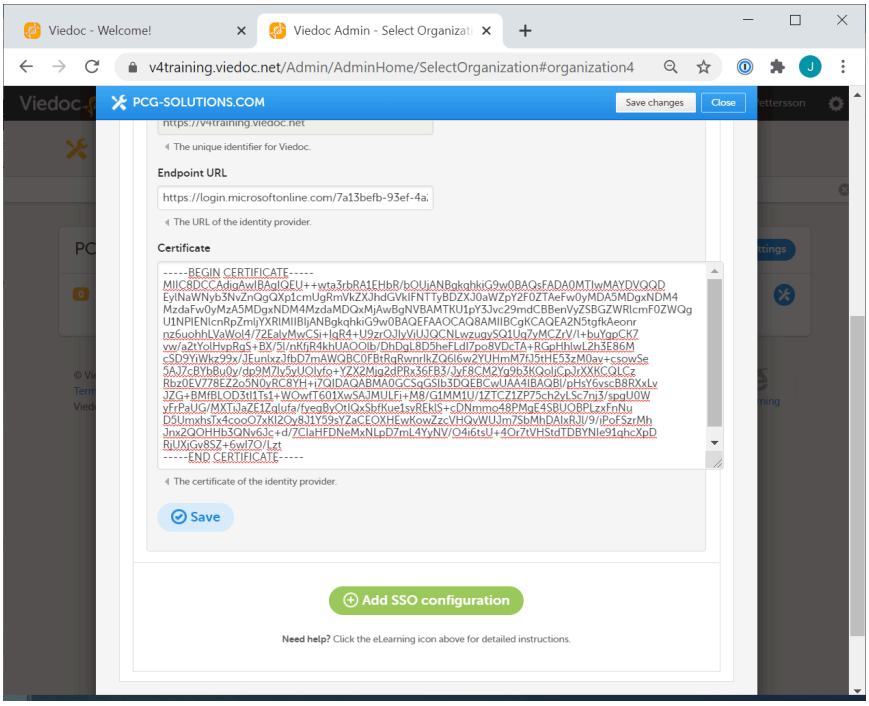
11 Map the **Unique User Identifier (Name ID)** to the attribute that best matches the email address that users authenticate with in Viedoc, typically [user.userprincipalname] or [user.mail].



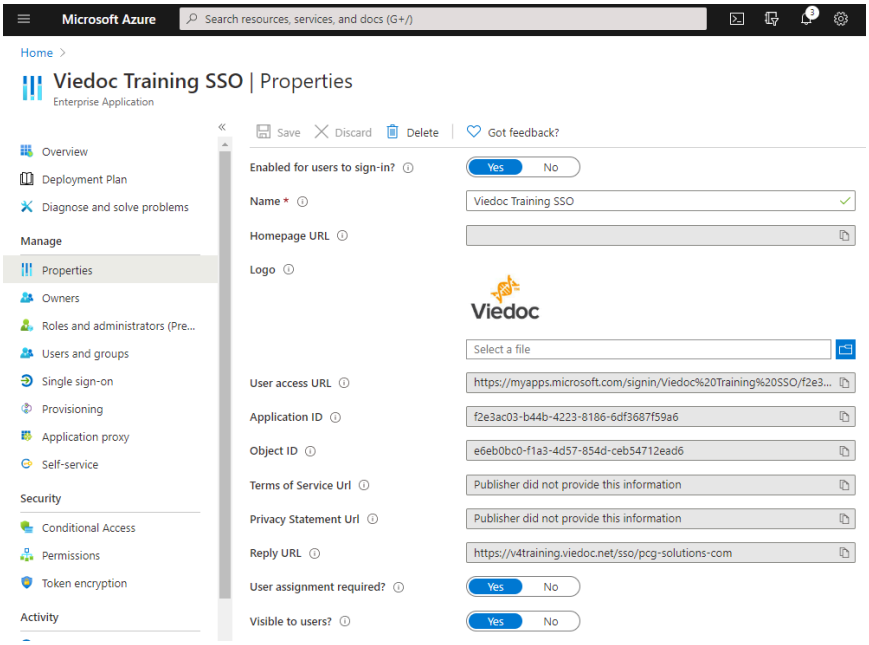
12 From the Azure AD window:

- 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.

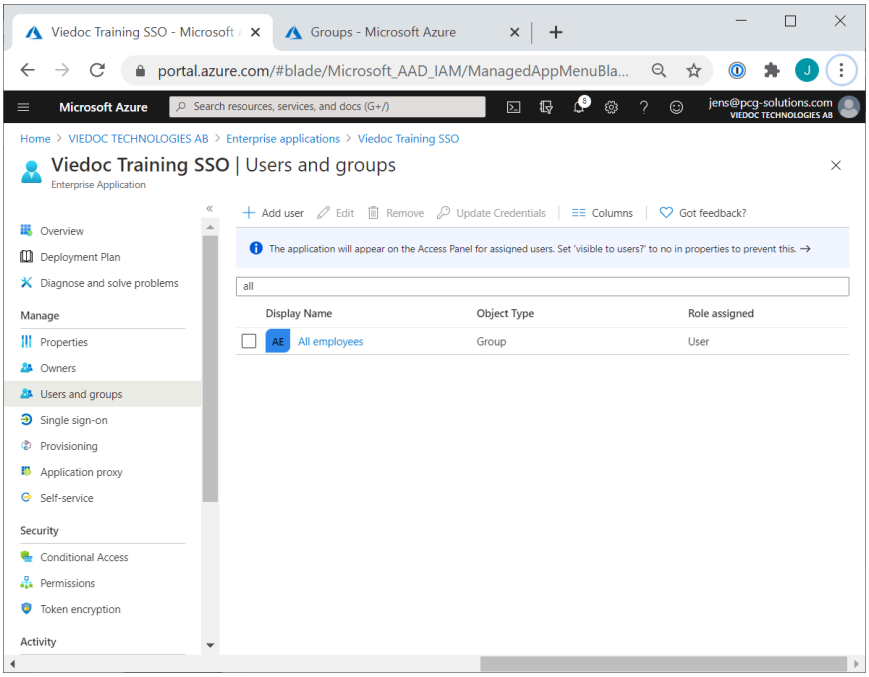
Click **Save**.



13 Download the Viedoc logo from the following URL https://www.viedoc.com/viedoc-msaad-sso-256×256.png and upload it to the **Properties** section in the Azure AD tab.

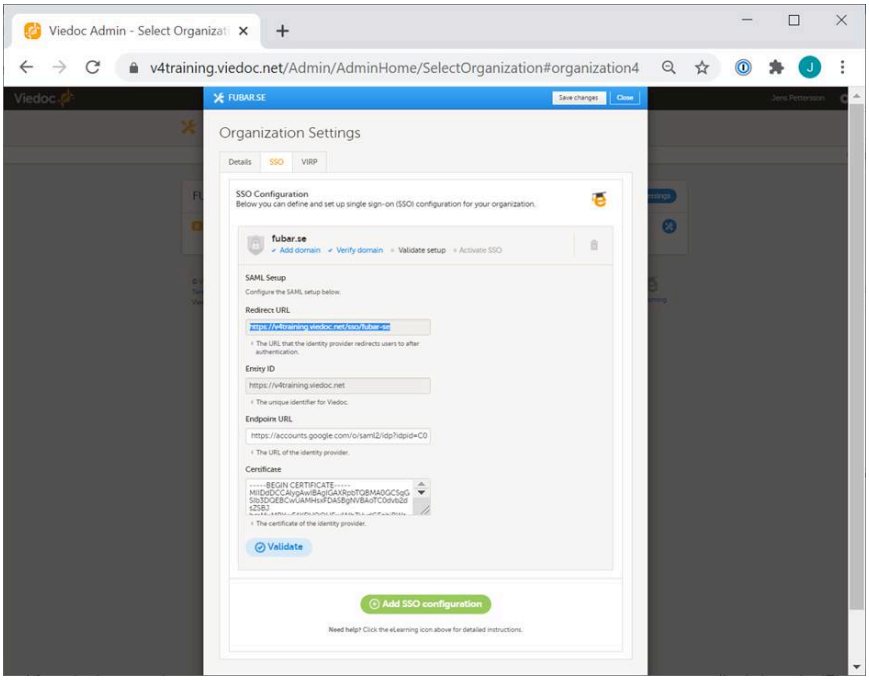


14 Under **Users and groups**, add all users or security groups that shall be able to log in to Viedoc using SSO.

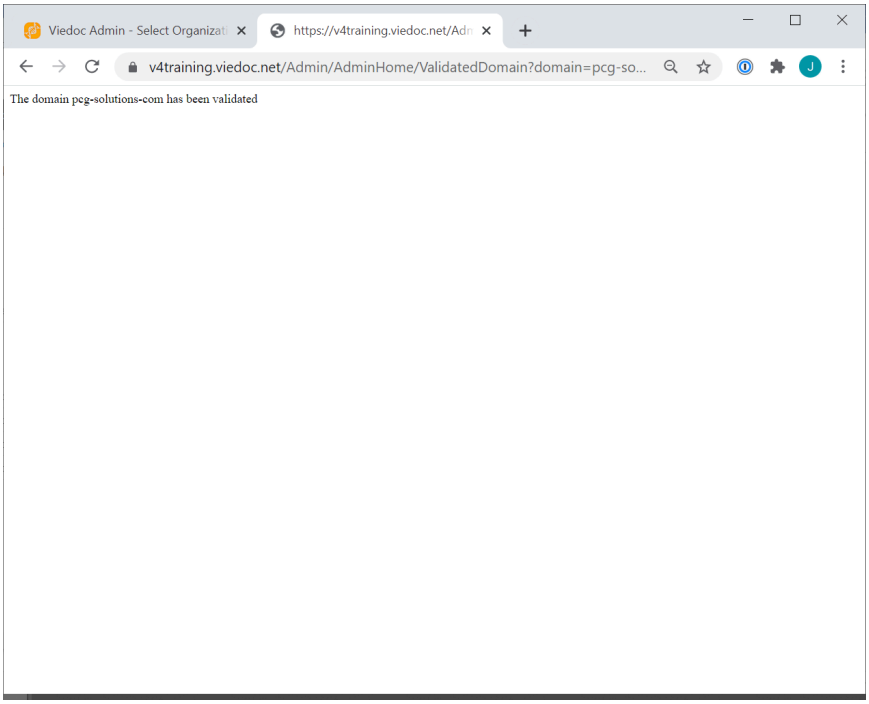


15 Go back to the Viedoc tab and click **Validate**.

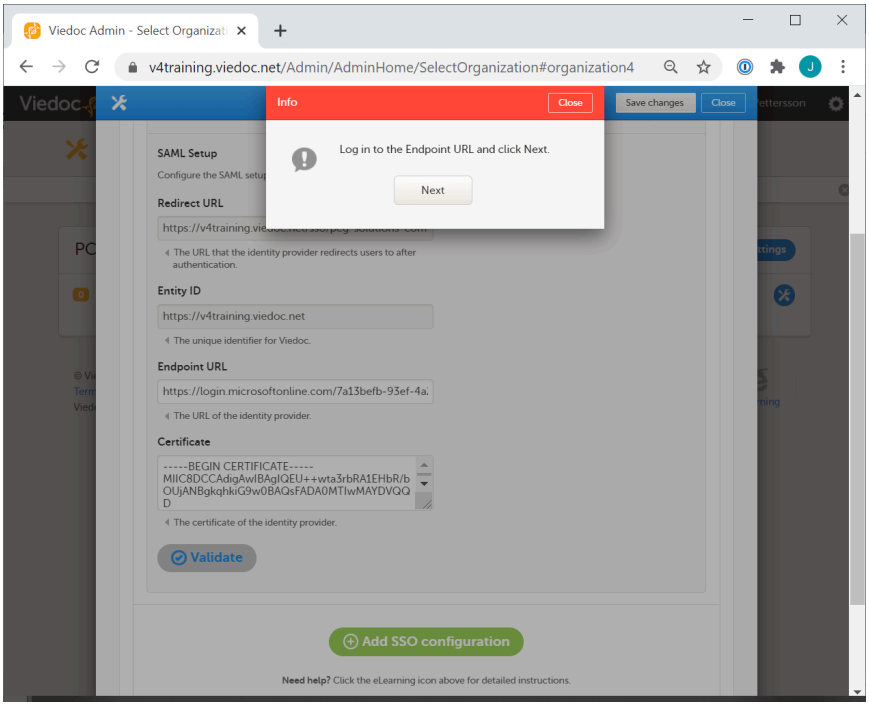
Note! You might be promted to enter your email address and password in order to authenticate with your IdP if not already logged in. Upon successful authentication you will automatically be redirected to the domain verification page.



16 Verify that the domain is validated and then close the tab.

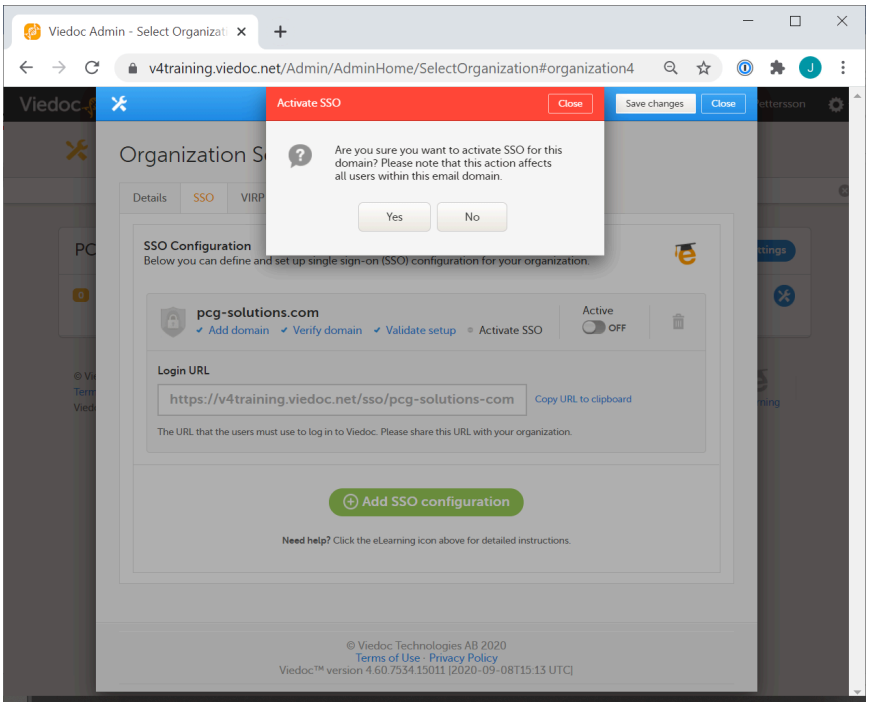


17 Click **Next**.



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

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

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

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

This video demonstrates how to configure a static list randomization and a dynamic randomization in Viedoc.

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User Management

User Management

Published by Viedoc System 2018-12-12

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

This video demonstrates how to set up Viedoc Me in Admin and Designer.

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How to set up Viedoc Logistics

Published by Viedoc System 2021-03-24

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

This video demonstrates how to use R with Viedoc Reports.

If you have difficulties viewing the video, please click here.

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