

Viedoc User Guide for Monitors

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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.

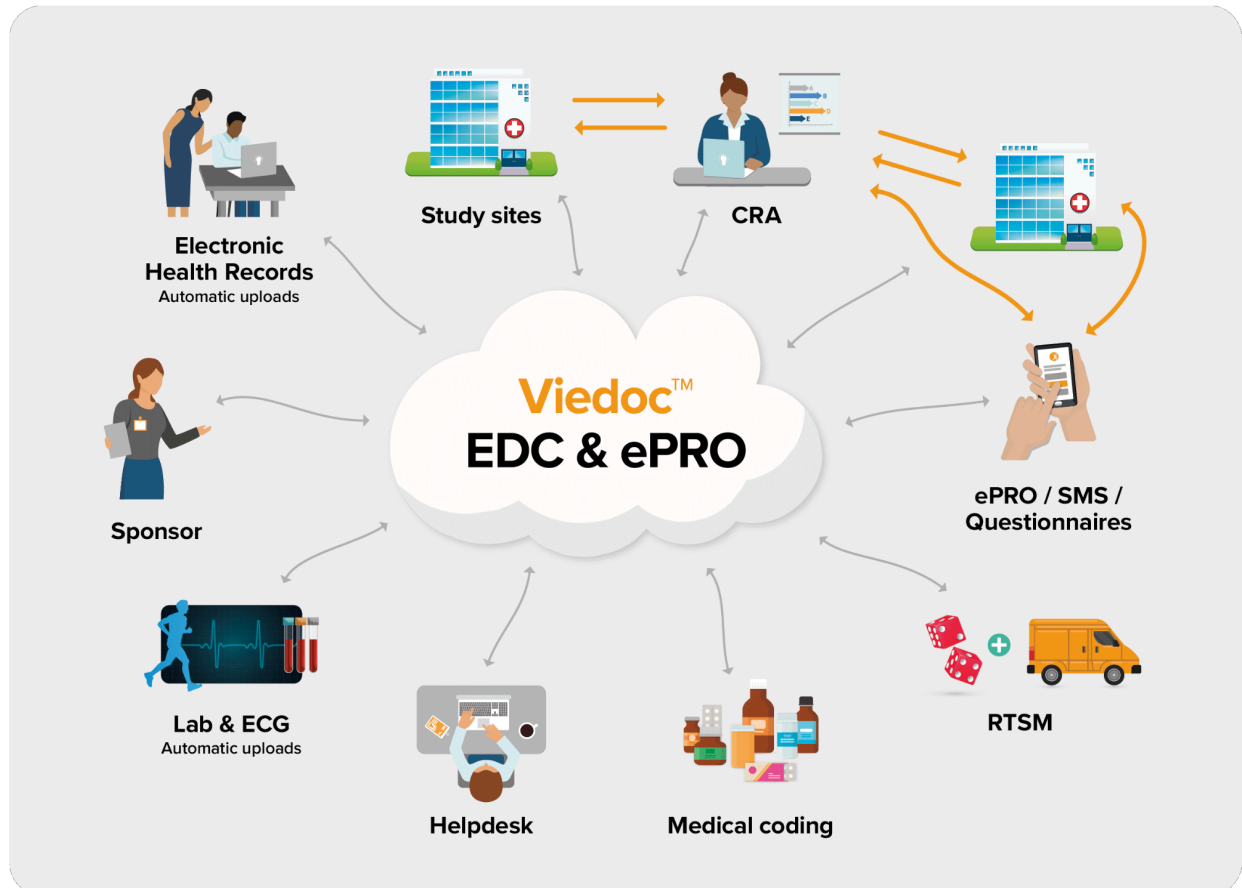
Viedoc is a study centric system, that is, all the functionalities are more or less related to a specific study. Usually a study in Viedoc corresponds to a clinical trial or other types of projects where data collection is applicable.

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

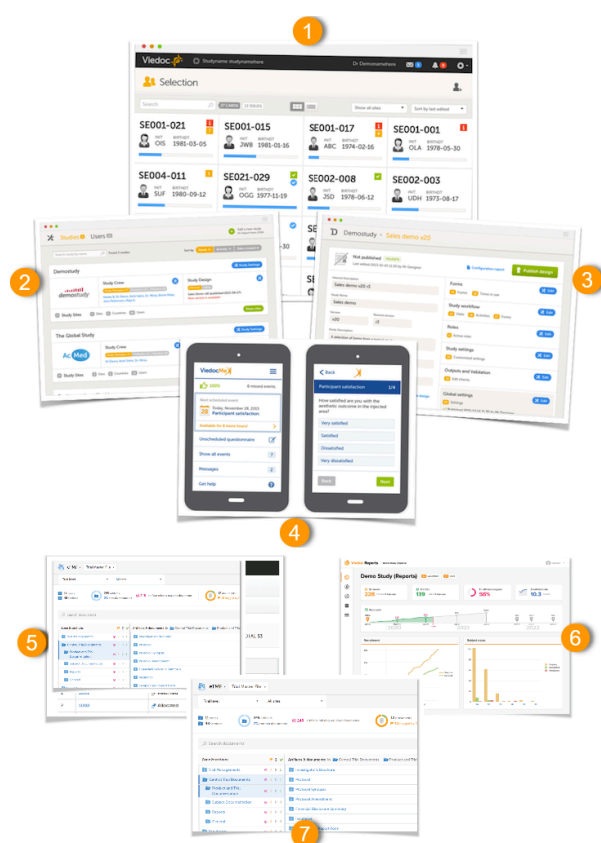
During a study, there are typically a number of questions to be answered and completed with data about the subject. A group of questions that belong together are captured in a form. Forms can be **event-dependent** or **event-independent** (log forms / common events). **Event-dependent** forms are linked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

Curriculum	English	Chinese	Japanese	URL
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.

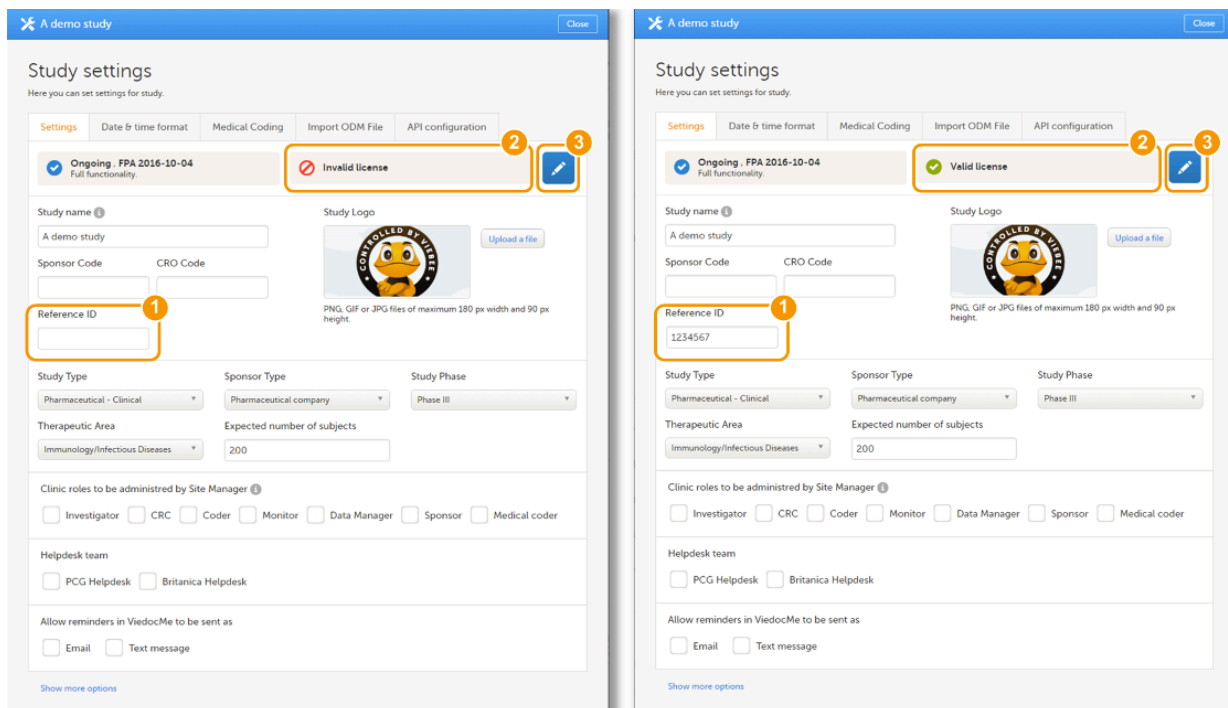
Contact your organization administrator to get access to the respective area.

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.

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?](#)



System requirements

System requirements

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[1.1 Browser 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

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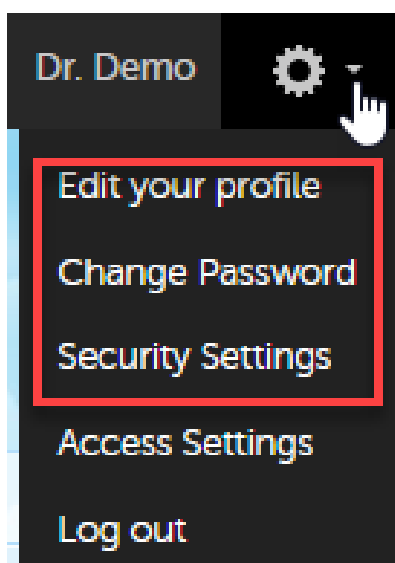
[5.11 Postponing the approval/rejection of a study invitation](#)

[6. Logging out](#)

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:

The screenshot shows the Viedoc user settings interface. On the left is a sidebar with a 'viedoc learning' button highlighted. The main area is titled 'User Settings' and includes a warning about phone number verification. The form contains fields for user name, first and last names, and a display name.

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.

User Settings

▲ Ownership of [redacted]@viedoc.com has not been verified!

13

▲ Ownership of [redacted] 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.

Select language

Primary email address

DoctorDemo@viedoc.com

Secondary email addresses

Emails from Viedoc will also be sent to these addresses

[redacted]@viedoc.com

Set as primary

Delete

[redacted]@viedoc.com

Verify email address

Delete

+ 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

Street address

City

City

Postal code

Postal code

Country

Select country

State

State

Cancel

Save changes

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

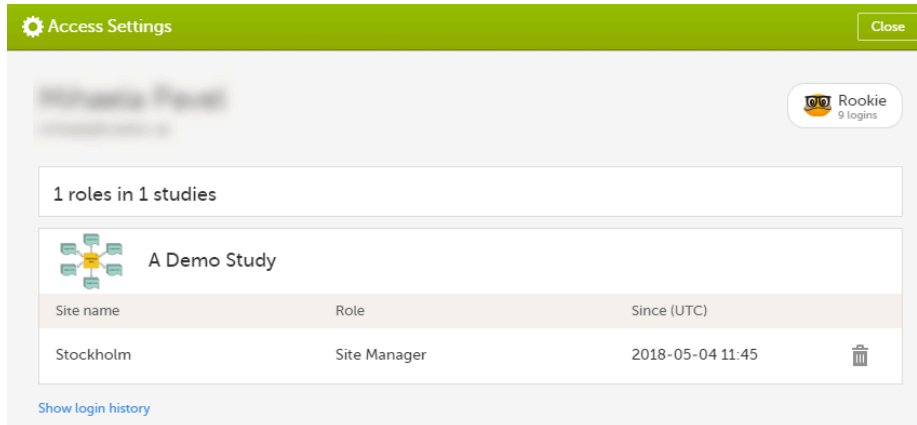
From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.



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](#))

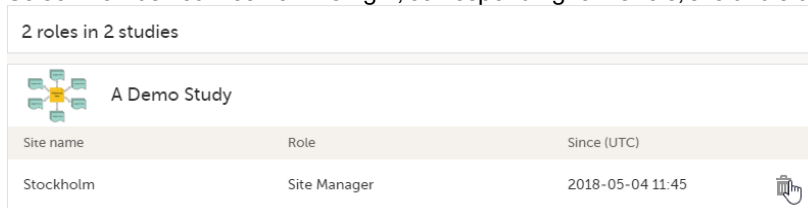
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

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

4.2 Deleting study access

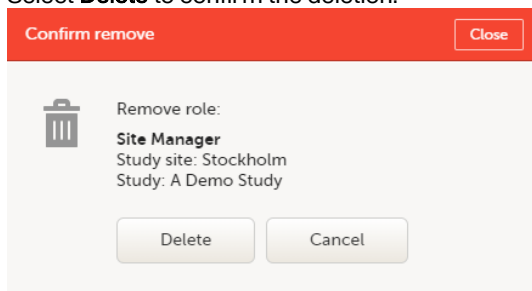
To remove yourself from a certain role within a study:

- 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:



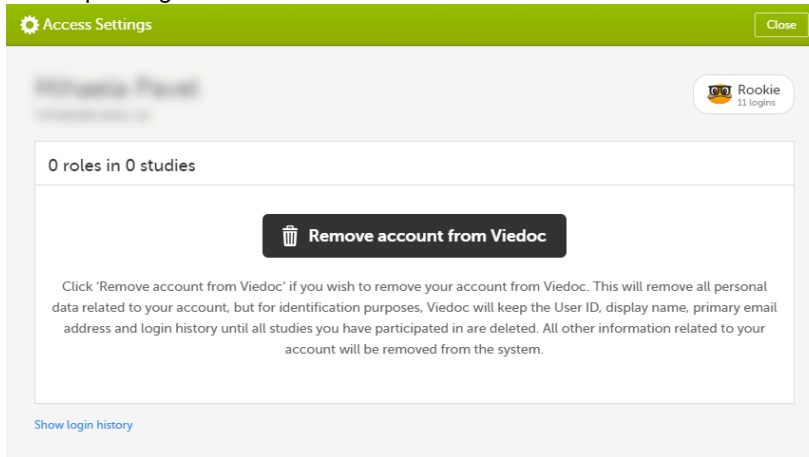
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

4.3 Deleting your Viedoc account

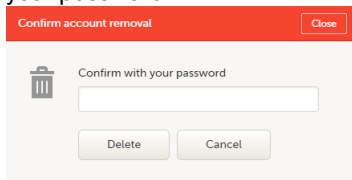
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

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:



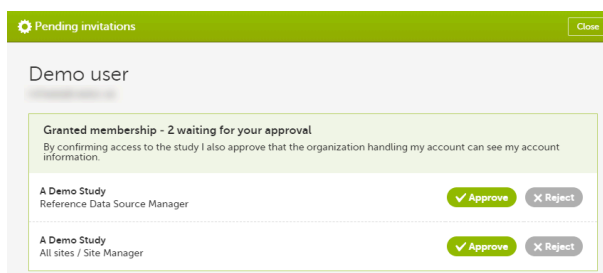
Thank you and goodbye!

Your account is now removed from Viedoc.

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

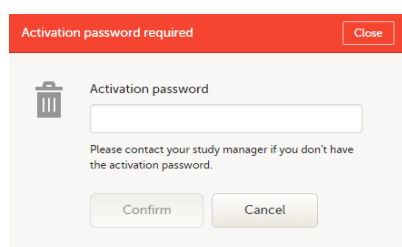
5 Pending invitations

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

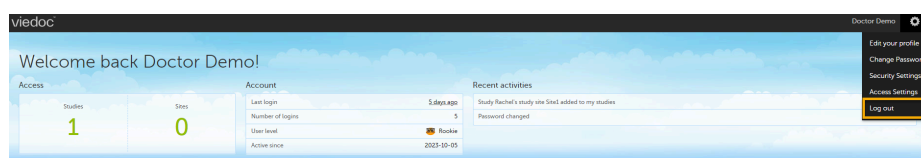
To postpone the approval or rejection of study invitations, select **Close** in the top right corner of the **Pending invitations** dialog box and postpone providing an answer to the study invitation.

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.

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**.

User Settings

- Change Password
- Security Settings
- Authentication Log

viDoc learning

User Settings

Ownership of +4612345678 has not been verified

User name

This is used to log in to ViDoc

doctor.demog@viDoc.com

First name

Doctor

Last name

Demo

Display name

This is your ViDoc user name

Doctor Demo

System language

The language will be used when available

English

Primary email address

doctor.demog@viDoc.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

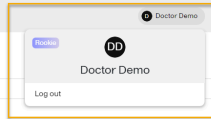
Country

Select country

State

Cancel

Save changes



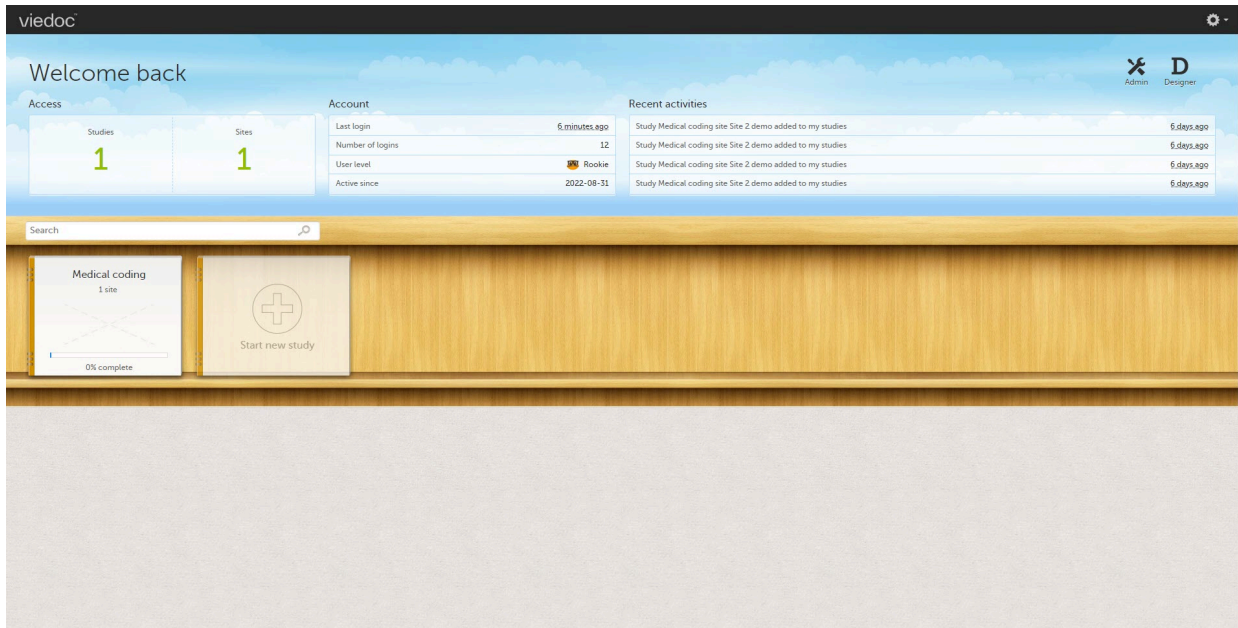


Overview of the landing page

Overview of the landing page




Published by Viedoc System 2024-10-10


This lesson describes the landing page, which is displayed directly after a successful log in:



The landing page provides the following summary information:

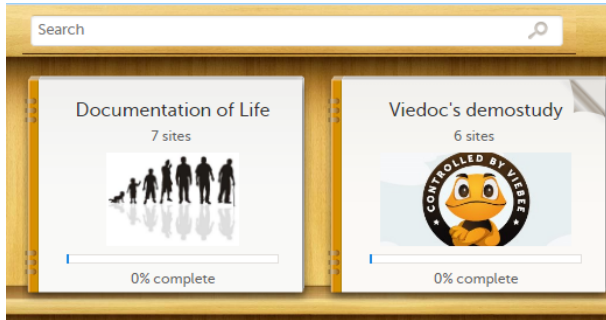
- **Access**
 - **Studies** - the total number of studies you have access to
 - **Sites** - the total number of production sites you have access to
- **Account**
 - **Last login** - the time passed since the last time you have logged in to Viedoc
 - **Number of logins** - the total numbers of logins to Viedoc since you activated your account
 - **User level** - the number of logins by a user, giving an indication of how experienced the user is in using Viedoc

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

Skill level	Icon	Description
Legend		> 1000 logins

- **Active since** - the date when you activated your Viedoc account
- **Recent activities** - a short summary of the most recent four activities, such as last password change and being assigned a role within a new site

The study slider shows the studies you have access to - each study is represented by a study logo. If you have access to many studies, you can easily find a specific study by entering the study name in the search field. All studies containing characters of the search string appear in the search results.



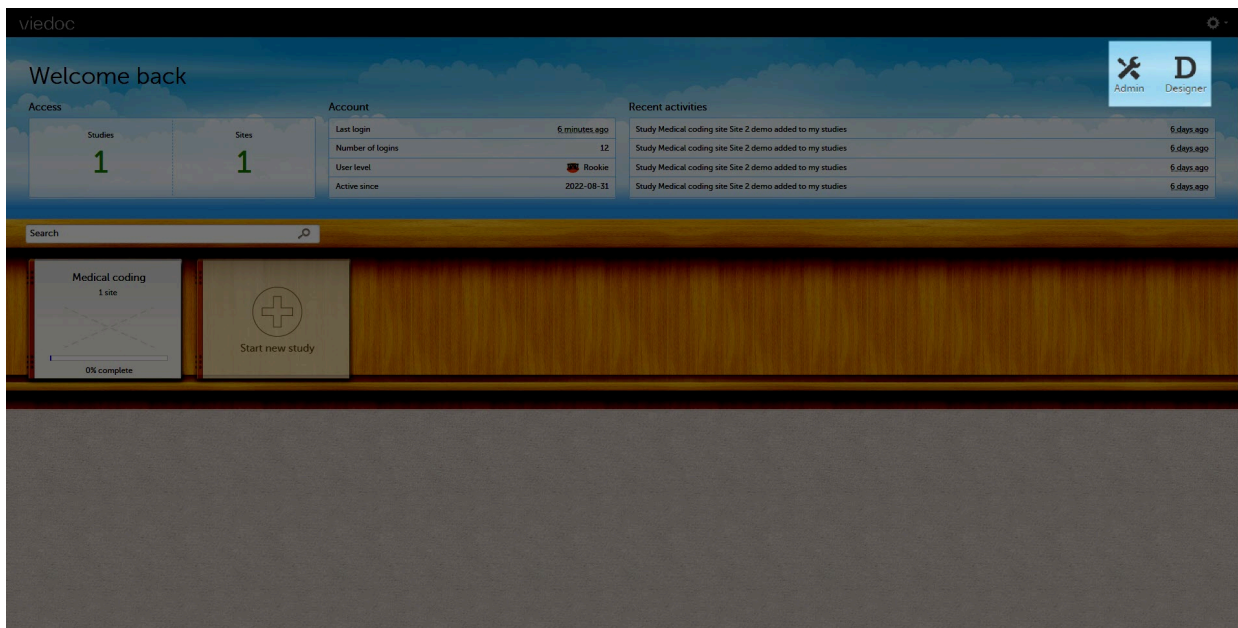
A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

Note!

- Only production sites are included in the calculation.
- Deleted subjects are not included in the calculation.
- If the expected number of subjects is not set in Viedoc Admin > Study Settings, then 0% will be displayed.

Click on a study logo to select a study to work with. The study start page is loaded on the bottom-half of the screen, see [Study start page](#).

If you are an Administrator and/or Designer you will also have access to Viedoc Admin and Viedoc Designer. Click the respective icon at the top right corner of the landing page:





Study start page

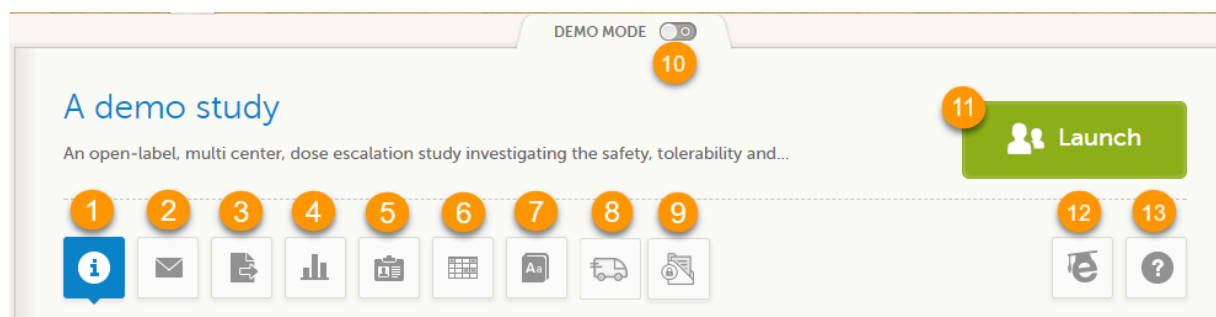
Study start page

Published by Viedoc System 2024-12-03

- [1. Introduction](#)
- [2. Study status](#)
- [3. Messages](#)
 - [3.1 Alert messages](#)
- [4. Data export](#)
- [5. Metrics and Viedoc Reports](#)
- [6. Roles](#)
 - [6.2 My roles](#)
 - [6.3 All roles and users for my site\(s\)](#)
 - [6.3.1 User logs](#)
 - [6.3.1.1 Log of users and roles in PDF format](#)
 - [6.3.1.2 User administration log in Excel format](#)
- [7. Reference data](#)
- [8. Medical coding](#)
- [9. Viedoc Logistics](#)
- [10. Viedoc eTMF](#)
- [11. Demo mode](#)
- [12. Launch](#)
- [13. eLearning / Documentation & Training](#)
- [14. Support](#)

1 Introduction

When you select the study logo in the landing page, the study start page loads, which contains the following icons that give access to different features, or enable you to view information about the study:



- [1. Study status](#)
- [2. Messages](#)
- [3. Data Export](#)
- [4. Metrics and Viedoc Reports](#)
- [5. Roles](#)
- [6. Reference data](#)
- [7. Medical coding](#)
- [8. Viedoc Logistics](#)
- [9. Viedoc eTMF](#)
- [10. Demo mode](#)
- [11. Launch](#)
- [12. eLearning / Documentation & Training](#)
- [13. Support](#)

Notes!

- The export, metrics and medical coding icons, the demo mode switch, and the launch button are only visible if you have access to the respective features. Whether you have access to these features, depends on the role assigned to you, and on the permissions that are included in your role.
- Roles and permissions are set up in the study design. The latest effective design for each site will be used to define the permissions that will apply to each role.

The first page displayed when you select a study is, depending on the status of the mandatory documentation and training materials, as below:

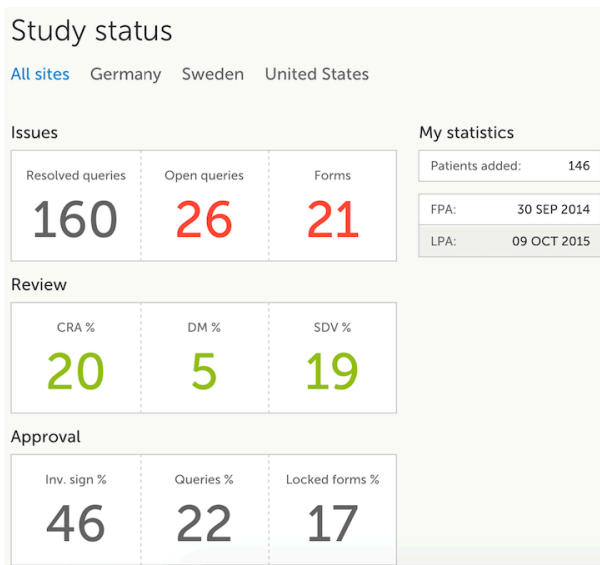
- If you have mandatory documentation pending to be read and signed, then the first page that opens is the [Documentation & Training](#).

Important! All the mandatory materials must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

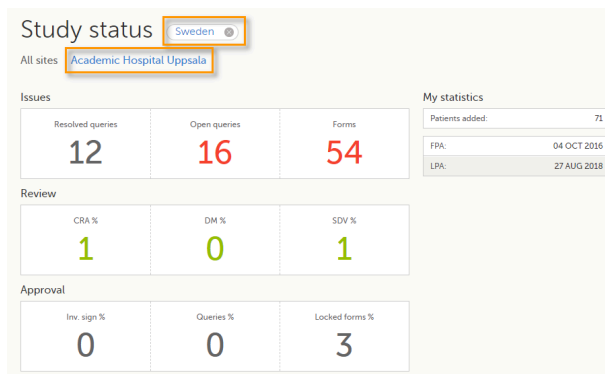
- If you do not have any mandatory documentation pending signing, then the first page that opens is the Study status page.

2 Study status

The Study status page is the first page that is shown when accessing a study, if you do not have any mandatory documentation and training material that needs to be signed. This page gives you an overview of the progress of the study - on study, country and/or site level (depending on which sites you have access to):



You can filter the displayed data for country or site by selecting the name of the country or site:



The following statistical information is provided, for the selected site(s):

- Issues
 - **Resolved queries** - total number of resolved queries
 - **Open queries** - total number of open queries
 - **Forms** - total number of forms with issues

Note! For resolved and open queries, this includes only manual and validation queries, not missing data queries. For resolved queries, the following statuses are included: **Resolved**, **Rejected**, **Approved**, and **Closed**.

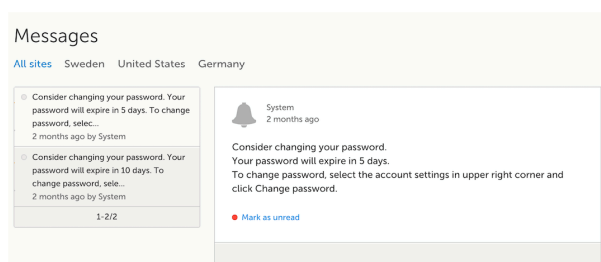
- Review
 - **CRA %** - percentage of forms that were marked as Clinical Research Associate ([CRA](#)) reviewed out of total number of forms that can be CRA reviewed within the study
 - **DM %** - percentage of forms that were marked as DM reviewed out of total number of forms that can be DM reviewed within the study
 - **SDV %** - percentage of forms that were marked as Source Data Verification ([SDV](#)) reviewed out of total number of forms that can be SDV reviewed within the study
- Approval
 - **Inv. sign %** - percentage of the forms signed by investigator out of total number of forms
 - **Queries %** - percentage of approved queries out of total number of queries that await approval. For details about query states and process, see [Queries Overview](#).
 - **Locked forms %** - percentage of the locked forms out of total number of filled in forms
- My statistics
 - **Patients added** - the total number of patients added to the study
 - **FPA** - date when the First Patient was Added
 - **LPA** - date when the Last Patient was Added

Note! All the numbers reflect the data entered in the selected operation mode (demo or production), that is, if demo mode is selected, then the numbers reflect only the data entered in demo mode.

3 Messages

A message can either be a [system message](#) (such as notifications on password expiration), a [study message](#) (such as eCRF changes - for more information, see [Approving eCRF changes](#), or other notifications according to the study configuration).

An indicator in the top bar of the application indicates whether you have unread messages.



3.1 Alert messages

According to the study configuration, you can receive alert notifications about important occurrences in the data. (For example, in case of a Serious Adverse Event). Alert notifications can be received in the Messages page and as an email.

Depending on the configuration/study setup, the email might have the PDF of the form that triggered that alert as an attachment.

If the option to enable password protection for the alert email attachments has been selected for your study, you should receive a password to enter to open the attachments. The password is provided by your Study Manager.

When you receive an email copy of the alert message with a password-protected attachment, when you open the file you will see the dialog box below where you can enter your password:

Password required

This document is password protected. Please enter a password.

Submit

4 Data export

The Data export page enables you to review and download study data in the following formats:

- Excel
- PDF
- Comma-Separated Values ([CSV](#))
- Statistical Analysis System ([SAS](#))
- Operational Data Model ([ODM](#))

Note! Data export might not be available to all users.

For more information about data export and preview, see [Exporting data](#).

5 Metrics and Viedoc Reports

The Metrics page gives an overview of the quality of data in terms of open queries and missing data.

Note! Metrics might not be available to all users.

For a detailed description, see [Metrics](#).

If Viedoc Reports is included in the study license and enabled, it is accessed from the Metrics feature. For more information, see [Launching Viedoc Reports](#).

6 Roles

Note! The Roles page is only available for users with special permission to view roles, as per the study design.

The Roles page provides information on:

- The roles that are assigned to you, see [My roles](#)
- All the roles for the sites you have access to, see [All roles and users for my site\(s\)](#)

6.1 My roles

Under My roles you can see the roles that you have in the respective study:

Roles

All sites Sweden

My roles

Investigator
Save, sign, reset, delete and export data, resolve queries
Stockholm, Uppsala





The following information is displayed (with *examples*):

- The role name (*Investigator*)
- The list of the permissions (*Save, sign, reset, delete and export data, resolve queries*)
- The site(s) you have access to (*Stockholm, Uppsala*)

By selecting the green arrow button to the right, you will be directed to the [Selection page](#). This is equivalent to selecting the **Launch** button.

6.2 All roles and users for my site(s)

Here you can see a list of all the roles and the respective user(s) for the site(s) you have access to:

All roles and users for the sites I have access to			
	2	Investigator(s)	Hide log ▼
User/Site	Access granted	Access revoked	Data edits/Sessions
Mihaela Pavel (362), [redacted] Group: All sites	2018-04-05 12:22 UTC Doctor Demo	-	0 0
Doctor Demo (317), [redacted] Multiple sites	2017-08-11 12:37 UTC Doctor Demo	-	143 77
	1	Monitor(s)	Show log ▼
	1	Data Manager(s)	Show log ▼
 Download log of users and roles as a PDF file			

To see user details of each role, select **Show log**. The log displays:

- **User/Site** - the name of the user, email address and site
- **Access granted** - when* and by whom (user name) access was granted
- **Access revoked** - when* and by whom (user name) access was revoked (if applicable)
- **Data edits/Sessions** - the number of times the user edited any data, and the total number of login sessions by the user (defined as the number of times the user has accessed the study)

*date and time in Coordinated Universal Time ([UTC](#)) time zone

6.2.1 User logs

For each study, you can download user logs with information about all users and roles for the sites you have access to. The generated file reflects the country/site selection in the language you have currently set in Viedoc. The following logs can be downloaded:

- [Log of users and roles in PDF format](#)
- [User administration log in Excel format](#)

If it's the first time the log is generated for the country/site selection in the language you have currently set in Viedoc, you can generate it by selecting the **Generate a PDF file / Generate an Excel file** link at the bottom of the page:



After the user log was generated you can choose to:

- Download the latest generated log 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, or
- Select **Regenerate** - if you need a more recent version than the one available for download.



6.2.1.1 Log of users and roles in PDF format

The Log of users and roles PDF contains the following chapters:

- **Summary** - the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.
- **Roles** - a list of the permissions associated with each role and corresponding history, grouped in one section per site.
- **User log per site** - a list of all users who ever had access to data, including user activity, grouped in one section per site.
- **User account logs** - a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the user ID).

6.2.1.2 User administration log in Excel format

The User administration log contains the following sheets:

- **Report Info** - general information about when and by whom the log was generated, and some information about the study status.
- **User Access Log** - a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:
 - **Site Group** - indicates when a user is granted access to the site through a site group invitation. Possible values are Training sites, Countries, and All sites.
 - **2FA** - indicates what level of two-factor authentication the user has. Possible values are Study level, Account level, or No two-factor authentication enabled.
- **Certification Log** - a list of certifications per user. Certifications performed before release 4.65 lack information about what roles the certification applies to. That is, the cells in column "Certified With Roles" are empty.
- **Summary** - a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
- **Account Settings Log** - a list with all user accounts setting changes with user id, change log, user name, and date/time.

7 Reference data

When you select the reference data icon, the list of available reference data source-scope combinations is displayed. From here you can open the reference data editor. For details see [Working with reference data](#).

Note! Reference data might not be available to all users.

8 Medical coding

The medical coding feature allows you to code reported events like Adverse Events, Medical History and Concomitant Medications. When you select the medical coding icon, the page displays metrics regarding medical coding. There is one set of metrics for each medical coding scope available.

Note! Medical coding might not be available to all users.

For more information about medical coding, see [Medical coding](#).

9 Viedoc Logistics

Viedoc Logistics is the interface for managing the supply of your study. A valid license is required to use Viedoc Logistics.

For more information about Viedoc Logistics, see [Viedoc Logistics User Guide](#).

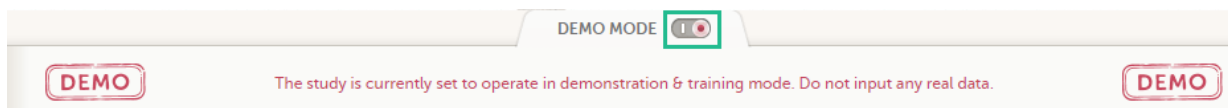
10 Viedoc eTMF

Viedoc eTMF is a digital repository for capturing, managing, sharing, and storing essential documents.

For more information about Viedoc eTMF, see [Viedoc eTMF User Guide](#).

11 Demo mode

If enabled, a study can operate in demo mode. You can easily switch between demo mode and production mode using the **DEMO MODE** switch:



The **DEMO MODE** switch is only visible when you have access to both production and demo mode.

The demo mode is clearly indicated with demo icons. Make sure you do not enter any real data in demo mode!

See also the video tutorial [Activate demo mode](#).

12 Launch

Select the **Launch** button to access the patient data and electronic Case Report Forms ([eCRFs](#)). The button is only visible when you have access to the study in Viedoc Clinic.

If multiple roles are assigned to you in this study, you are first prompted to select the role you would like to use to access the study.

13 eLearning / Documentation & Training

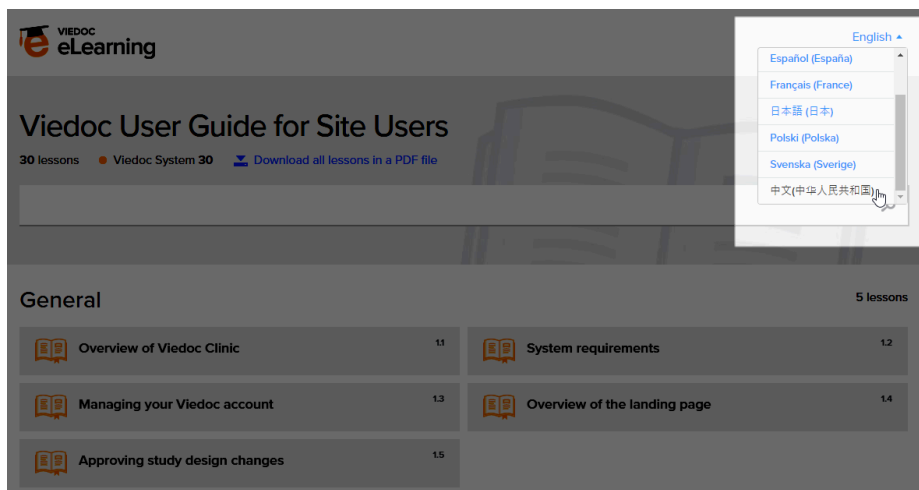
If you have mandatory documentation pending to be read and signed, this is the first page that is displayed when you access the study.

Under this section, you have access to several eLearning programs and various documentation, depending on the roles that have been assigned to you. For details about the user documentation and certificates, see [Documentation & Training](#).

The Viedoc Clinic User Guides are available in the following languages:

- English
- Chinese
- Japanese

To change the language of the Viedoc User Guide, once opened, select the language from the upper right corner, as illustrated below:



Tip! The various lessons in the Viedoc eLearning can easily be compiled into a PDF and printed if you need to store them in the investigator binder.

14 Support

Select the support icon to open a pop-up with contact details to the users that can help you in case you need support. Normally you will find the contact details of the Monitor here, as the Monitor typically is the first point of contact to the site.

[Back to top of page](#)



Documentation and Training

Documentation & Training

Published by Viedoc System 2020-06-04

- [1. Introduction](#)
- [2. Becoming a certified user](#)
- [3. Downloading your user certificate](#)

1 Introduction

Depending on the study settings and on the role(s) you have within a study, you might have access to various user documentation. This lesson describes the scenario when, under the eLearning section, you get access to the Documentation & Training page, with mandatory and/or optional documentation section(s), as illustrated in the following image:

The available documentation and training materials are split in two main categories:

1. Mandatory sections - contains all the materials that are mandatory for you to read, understand and sign before starting to work.

If you have mandatory documentation pending to be read and signed, then the first page that opens when you access the study is the Documentation and Training.

Important! All the materials under Mandatory sections must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

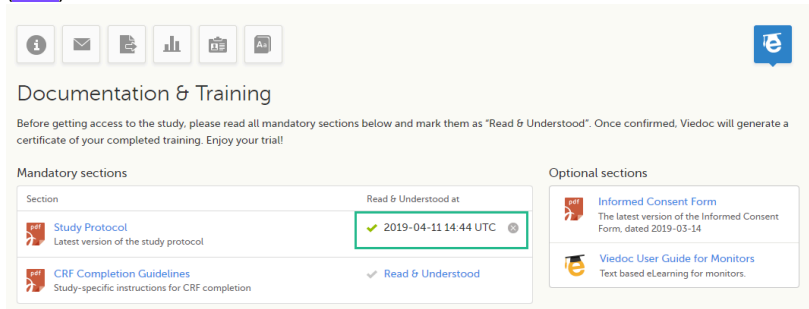
2. Optional sections - contains additional educational and reference materials that you have access to. Simply click on the link to open each of the available documents/links.

2 Becoming a certified user

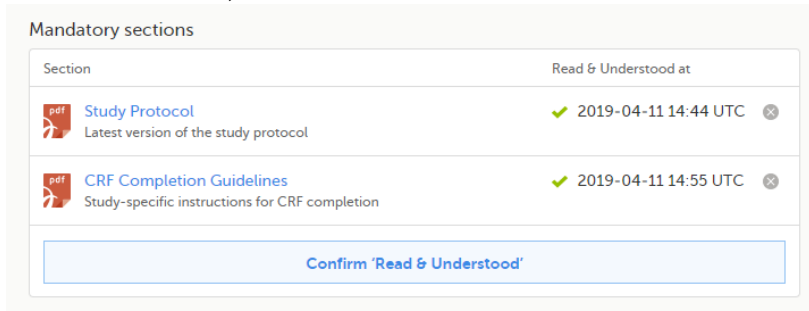
To work within a study for which mandatory training sections were assigned, you need to read, understand and sign all the sections listed as mandatory.

To obtain the user certificate:

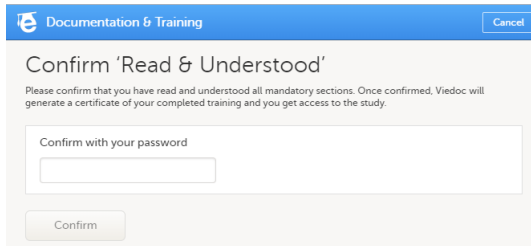
- 1 Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:



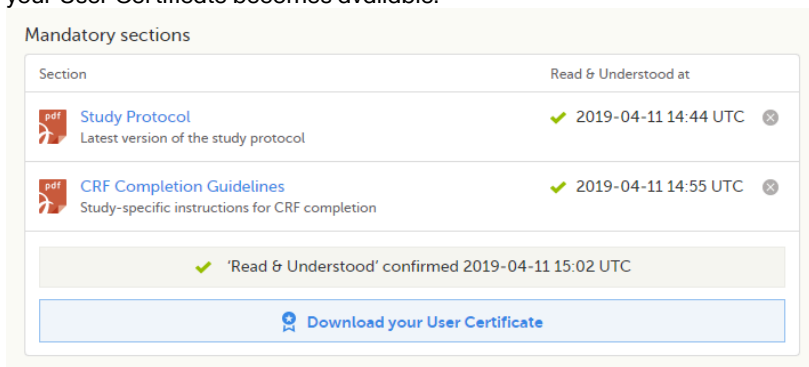
- 2 Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:



- 3 Click **Confirm 'Read & Understood'**. A confirmation pop-up opens:



- 4 Enter your Viedoc account password and click **Confirm**. A confirmation message together with the date and time stamp (UTC) is displayed at the bottom of **Mandatory sections**. Also, a link to Download your User Certificate becomes available:



- 5 Now you got your certification and are able to access the study. The Launch button is now available.

You can also **Download your User Certificate**. For details, see [Downloading your user certificate](#).

The mandatory sections are still available for your further reference, you can at any time go back and open any of those by clicking the section link.

3 Downloading your user certificate

After you have completed all your mandatory readings and have signed and confirmed, as described in the previous section, you can download your user certificate in PDF format by clicking **Download your User Certificate** in the bottom of **Mandatory sections**.

The following information is provided on the certificate:

- User name (user ID is available on the page footer)
- User role(s) for which the certificate was obtained
- Date and time ([UTC](#)) when the certification was obtained (confirmed with password)
- Mandatory sections that were confirmed as "Read & Understood"



Selection page

Selection page

Published by Viedoc System 2023-10-09

1. Introduction

[1.1 Sorting and filtering](#)

[1.2 Searching](#)

[1.3 Icons](#)

2. Views of the Selection page

[2.4 The Cards view](#)

[2.4.1 The subject card overview](#)

[2.5 The issues view](#)

[2.6 The Viedoc Me view](#)

[2.7 The Events view](#)

3. Adding a new subject

1 Introduction

The Selection page displays all the subjects from all the sites you have access to:

Subject ID	Hospital	Status	Age
SE-KI-004	KAROLINSKA INSTITUTE STOCKHOLM	Screened	51.2
SE-KI-003	KAROLINSKA INSTITUTE STOCKHOLM	Screened	27.9
FI-HU-005	HELSINKI UNIVERSITY HOSPITAL	Screened	26.9
SE-UU-002	UPPSALA UNIVERSITY HOSPITAL	Screened	58.2
FI-HU-004	HELSINKI UNIVERSITY HOSPITAL	Screened	37.1
FI-HU-003	HELSINKI UNIVERSITY HOSPITAL	Screened	29.1
FI-HU-002	HELSINKI UNIVERSITY HOSPITAL	Screened	30.6
SE-UU-001	UPPSALA UNIVERSITY HOSPITAL	Screened	38.8
FI-HU-001	HELSINKI UNIVERSITY HOSPITAL	Screened	35.0
SE-KI-002	KAROLINSKA INSTITUTE STOCKHOLM	Screened	50.9
SE-KI-001	KAROLINSKA INSTITUTE STOCKHOLM	Screened	36.7

In the default view, each subject is represented by a card. Depending on your study setup, the Selection page can be displayed in several ways. See [Views of the Selection page](#).

1.1 Sorting and filtering

In the top right corner of the Selection page, you have dropdown menus to sort and filter the view. The options depend on the selected view. The selected sorting will be kept throughout your session.

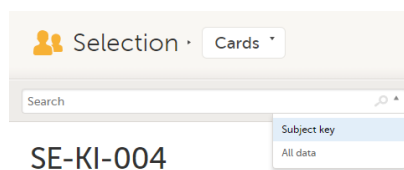
Show all sites ▼ Sort by added date ▼

In the table view of the Selection page, you can also sort by column in descending or ascending order by selecting a column header with the arrow symbol. Lit-up arrows indicate the selected sorting in orange:

Gender	ID	Status	Age
	SE-KI-004	Screened	51.2
	SE-KI-003	Screened	27.9
	FI-HU-005	Screened	26.9
	SE-UU-002	Screened	58.2
	FI-HU-004	Screened	37.1
	FI-HU-003	Screened	29.1
	FI-HU-002	Screened	30.6
	SE-UU-001	Screened	38.8
	FI-HU-001		35.0
	SE-KI-002	Screened	50.9
	SE-KI-001	Screened	36.7

1.2 Searching

To search for a specific subject or any other information collected for a subject, you can type the text you are looking for in the search field:



The system will return the subjects with the information sought that has been entered in the Case Report Form (CRF).

Subject key and **All data** are two filters that can be applied to the search.

- **Subject key** will return results where the search term is part of the subject ID.
- **All data** will return results where the search term is mentioned.
- **All data** also requires specificity when you commit a search for visit name and form name. It does not return partial results in these instances.





Note! For faster searches, we recommend that you select the **Subject key** filter.

Important! If your search returns nothing, it could indicate a problem with your study design. Please contact your Professional Services representative to assist you.

1.3 Icons

The Selection page displays a number of icons explained in the following table:

Icon	Description
	Issue - at least one open query and/or missing data
	Task - there are tasks to be completed, the number indicates the number of tasks
	Complete - all initiated events have been completely filled in

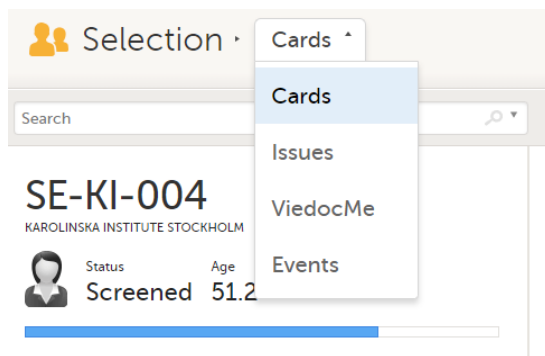
Icon	Description
	Signed - all data that is possible to sign has been signed
	Read-only - the card is being open for edit by another user. Note that the subject card can still be accessed for review or SDV by a user without edit permissions, for example a monitor or a data manager.
	In progress - the event is initiated but not completed This icon is only shown when none of the other status icons apply
	Locked - the data in all forms of the event is locked

Note! The icons showing depend on your user role permissions.

2 Views of the Selection page

Depending on the study setup, the Selection page looks a bit different.

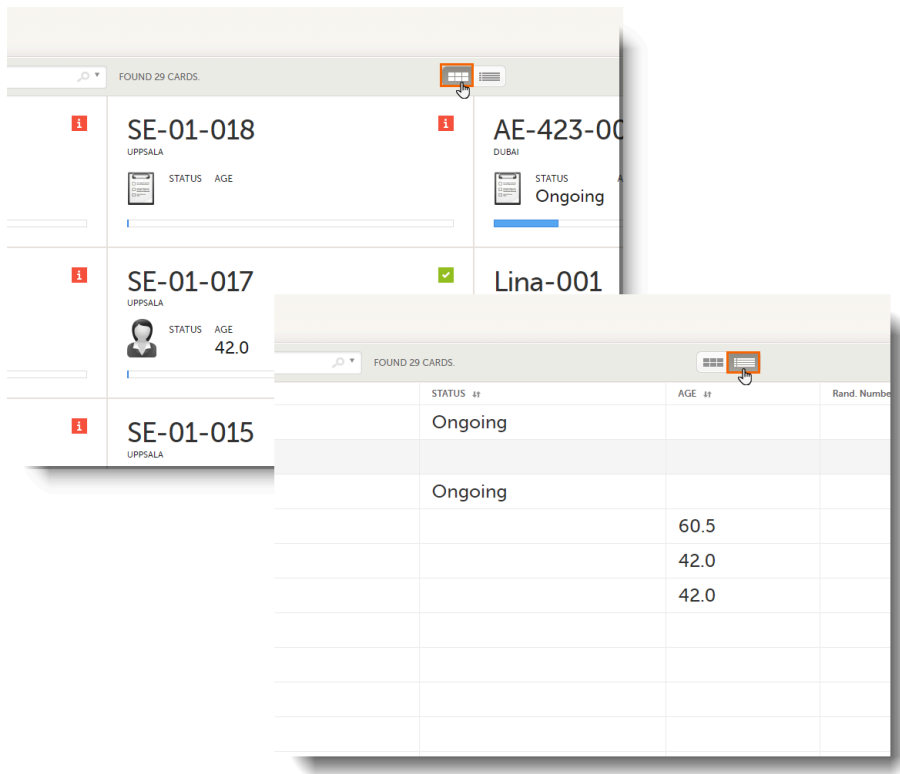
- If the study is configured with extended selection pages, you can select a view at the top of the page. Select **Cards**, **Issues**, **Viedoc Me** or **Events** from the dropdown menu to open the view. The Viedoc Me view is only available to select if the Viedoc Me feature is included in your study.



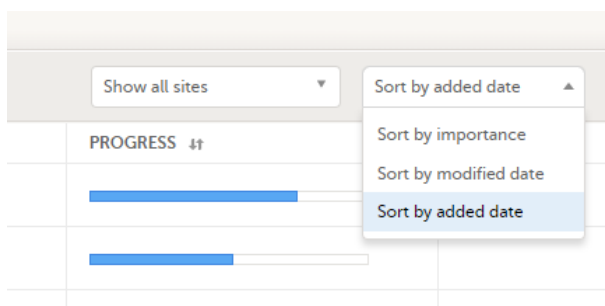
- If the study is not configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

2.1 The Cards view

In the **Cards** view, you can see all the subjects from all the sites you have access to. Select to display the subject cards side-by-side (default) or in a table:

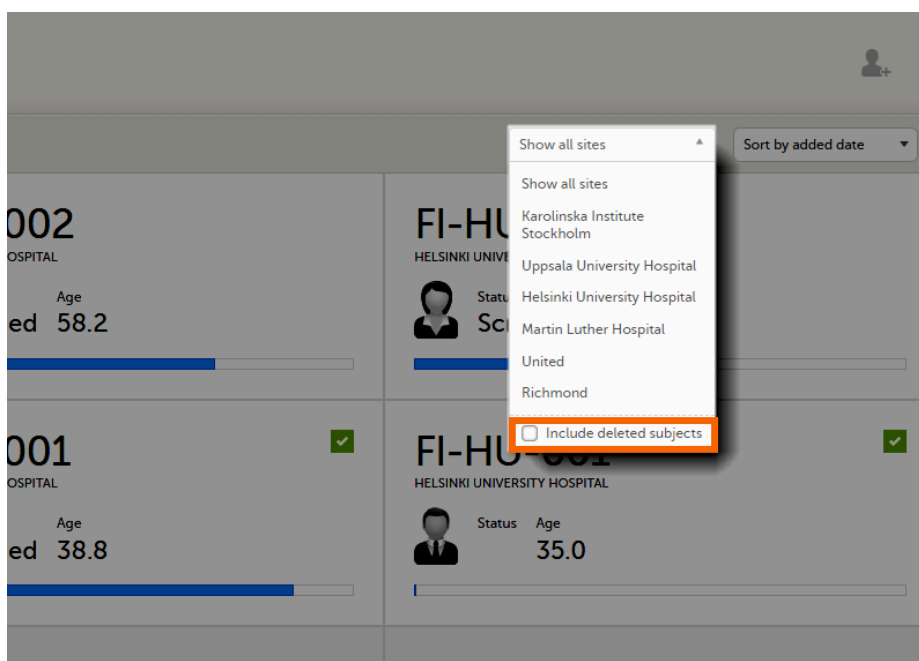


The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:



- **Sort by importance** - sort on forms with issues in descending order
- **Sort by modified date** - sort on modified forms in descending order
- **Sort by added date** - sort on added forms in descending order

To display only the subjects for a particular site, select the site from the dropdown list. Click **Include deleted subjects** at the bottom of the dropdown menu to display deleted subjects:

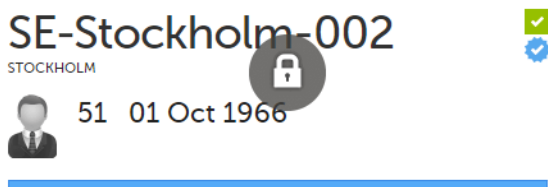


2.1 The subject card overview

Each card provides subject information as per the respective study design:

- Subject ID
- Site name
- Gender indicated by an avatar
- Some [CRF](#) data
- Subject status indicated by the icon in the top right corner

If all the forms were locked (typically by the Monitor), this is shown with a padlock icon on the respective subject card:



- Progress bar indicating the completion status (in blue)

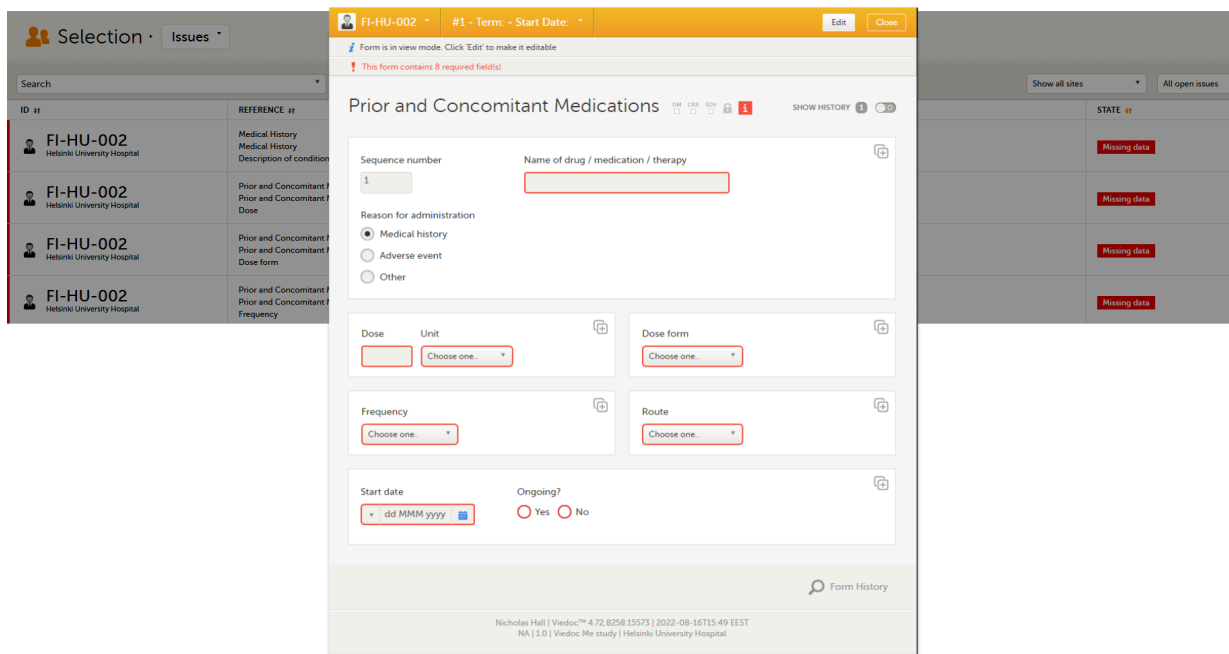
Note! The Selection page does not consider the role visibility except for task count; therefore, the subject status reflects the general status of the subject in the study, regardless of the user who has work to be performed. The subject details view reflects the subject status considering the role visibility. This could result in a subject status where a subject could have a green check mark or be locked, while in the Selection page it is not (due to some other user role having unfinished work or forms to complete on the respective subject). See [Entering and Editing data](#) for more information on the subject details view.

2.2 The issues view

In the **Issues** view, you can see the existing issues listed in a table:

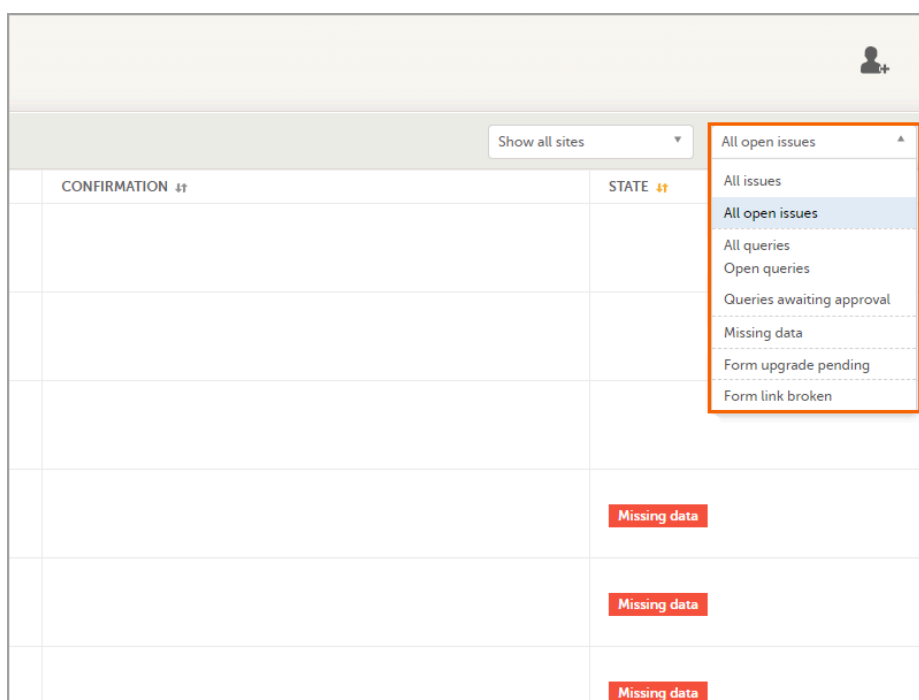
ID #	REFERENCE #	ISSUE DETAIL #	CONFIRMATION #	STATE #
FI-HU-002 Helsinki University Hospital	Medical History Medical History Description of condition / event / surgery	! Missing data		Missing data
FI-HU-002 Helsinki University Hospital	Prior and Concomitant Medications Prior and Concomitant Medications Dose	! Missing data		Missing data
FI-HU-002 Helsinki University Hospital	Prior and Concomitant Medications Prior and Concomitant Medications Dose form	! Missing data		Missing data
FI-HU-002 Helsinki University Hospital	Prior and Concomitant Medications Prior and Concomitant Medications Frequency	! Missing data		Missing data

Click any row to open the form where the issue was raised:



Close the form to go back to the **Issues** list.

You can filter the **Issues** list using the dropdown lists in the upper right corner of the page:



- By site - view data from a specific site or from all sites
 - Include deleted subjects
- By issue type/status:
 - **All issues:**
 - a. Missing data
 - b. All queries, regardless of status
 - c. Form upgrade pending
 - d. Pending reference data upgrade
 - **All open issues:**
 - a. Missing data
 - b. Queries with the status "Awaits answer"
 - c. Form upgrade pending
 - d. Pending reference data upgrade
 - **All queries**
 - **Open queries**
 - **Queries awaiting approval**
 - **Missing data**

- Form upgrade pending
- Form link broken

2.3 The Viedoc Me view

In the **Viedoc Me** account view, you can monitor and follow up on the subjects' expected Viedoc Me event submissions.

ID #	# LOGINS (LAST LOGIN) #	COMPLIANCE #	# MISSED EVENTS (LAST MISSED) #	STUDY COMPLETION #	NEXT SCHEDULED #	ACCOUNT STATUS #
SE-KI-004 Karolinska Institute Stockholm	2 2022-06-16 08:31 CEST	50%	1/2 (2022-06-11 00:00 CEST)	100%	-	Open
SE-KI-003 Karolinska Institute Stockholm	1 2022-06-02 11:59 CEST	0%	2/2 (2022-06-02 00:00 CEST)	100%	-	Open
FI-HU-005 Helsinki University Hospital	1 2022-06-01 11:39 EEST	-	-	0%	-	Open
SE-UU-002 Uppsala University Hospital	0	-	-	0%	-	Initiated
FI-HU-004 Helsinki University Hospital	14 2022-06-21 21:15 EEST	100%	0/2 -	100%	-	Open
FI-HU-003 Helsinki University Hospital	0	-	-	0%	-	Initiated
FI-HU-002 Helsinki University Hospital	19 2022-06-16 09:29 EEST	-	-	-	-	Open
SE-UU-001 Uppsala University Hospital	1 2022-05-13 17:18 CEST	-	-	-	-	Open
FI-HU-001 Helsinki University Hospital	14 2022-05-23 19:15 EEST	-	-	-	-	Open
SE-KI-002	10	-	1/2	-	-	-

For each subject, the following information is listed:

- **ID** - the subject ID, avatar, and site
- **# LOGINS (LAST LOGIN)** - the total number of logins with the last login shown in parentheses
- **COMPLIANCE** - how well the subject is submitting events, counted on scheduled Viedoc Me events
- **# MISSED EVENTS (LAST MISSED)** - the total number of missed Viedoc Me events, with the last missed event shown in parentheses
- **STUDY COMPLETION** - how far into the study the subject is, counted on scheduled Viedoc Me events
- **NEXT SCHEDULED** - the date and time of the next Viedoc Me event
- **ACCOUNT STATUS** - the current status of the subject account, which can be filtered in the upper right corner:
 - **All accounts** - all created Viedoc Me accounts: Initiated/Open/Locked
 - **Initiated** - accounts that are created but the subjects have never logged in to their accounts
 - **Open** - accounts that the subjects have logged in to (at least once)
 - **Locked** - accounts that are locked
 - **Not created** - accounts that are not yet created

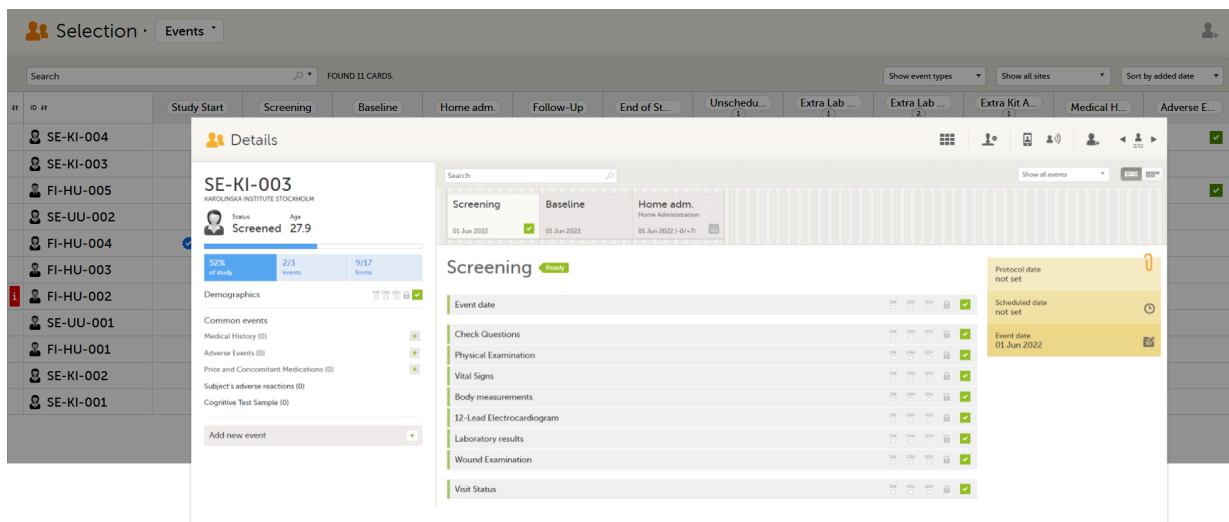
2.4 The Events view

In the **Events** view, you can see the status of each event for each subject listed in a table.

#	ID #	Study Start	Screening	Baseline	Home adm.	Follow-Up	End of St...	Unschedu... 1	Extra Lab... 1	Extra Lab ... 2	Extra Kit A... 1	Medical H...	Adverse E...
	SE-KI-004	✓	✓	⌘	⌘			⌘				✓	✓
	SE-KI-003	✓	✓	⌘									
	FI-HU-005	✓	⌘									✓	✓
	SE-UU-002	✓	⌘										
	FI-HU-004	ⓘ	✓	⌘	🔒	✓		ⓘ					
	FI-HU-003	✓	⌘										
!	FI-HU-002	✓	⌘						⌘	⌘			!
	SE-UU-001	✓	✓										
	FI-HU-001	✓											
	SE-KI-002	✓	✓	⌘	⌘								
	SE-KI-001	✓	⌘	⌘		⌘							

The first column indicates if there are issues/tasks in any of the subjects' events. If there are both issues and tasks for a subject, then issues [i] are shown in the column.

Select any cell to go to the event in the Details page:



Click back in the browser to return to the Events view.

Select an empty cell to view the subject's latest event.

The list of subjects can be filtered using the dropdown lists in the upper right corner of the page:

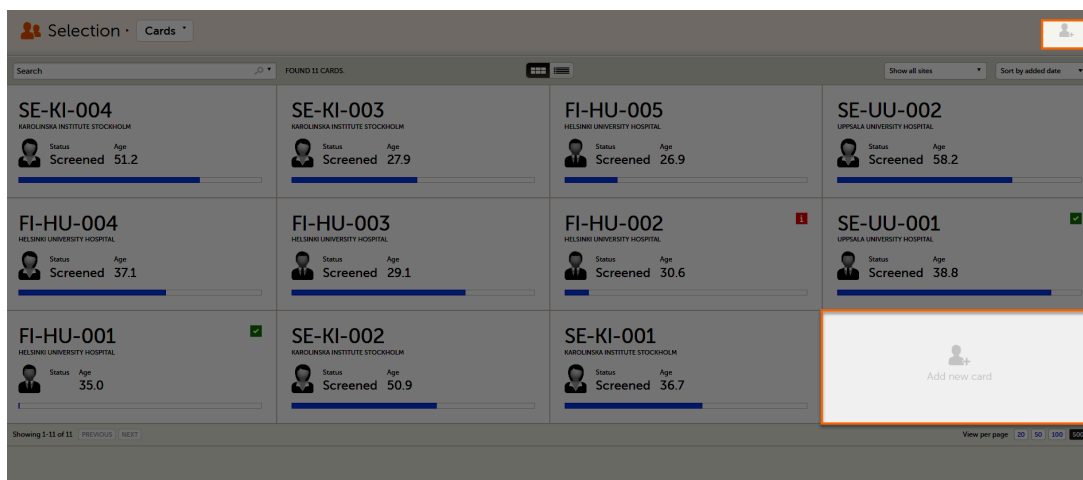
- By event type
 - **Scheduled events**
 - **Unscheduled events**
 - **Common events**
 - **Subject-initiated events**
- By site - select to view data from a specific site or from all sites
 - Select to **Include deleted subjects**

Note! On the selection page, in the **Events** view, the event name (as set in the Study event settings in the study design) is displayed. If there is a recurring event, a counter is shown under the event name, for example: Follow up 1, Follow up 2.

3 Adding a new subject

To add a new subject:

- 1 Make sure that you have selected a site (center) from the sites dropdown list. Click **Add new card** on the last card or select the icon in the top right corner of the page:



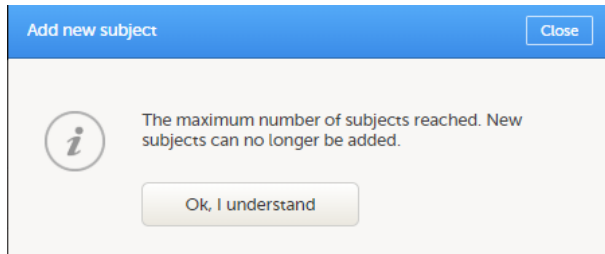
The first form in the study is displayed.

- 2 Complete the form and select **Save changes** on the top right side of the page. A new subject is now added.

Note! Only user roles with editing permissions for the study start event form can add a new subject. If you do not have editing permissions, you cannot select **Add new card** and no icon is visible in the top right side of the page.

See also the video tutorial [Add and select subjects](#).

If you receive the following message, the maximum number of subjects that is configured for your site has been reached, and you cannot add new subjects. If you need to add a new subject anyway, contact your Study Manager.





Metrics

Metrics

Published by Viedoc System 2022-02-10

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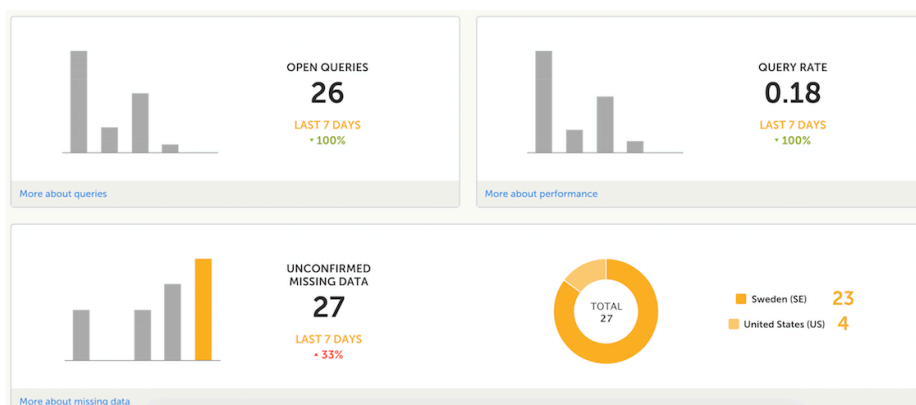
[4.21 Subjects with unconfirmed missing data](#)

[4.22 Save and export](#)

1 Metrics overview

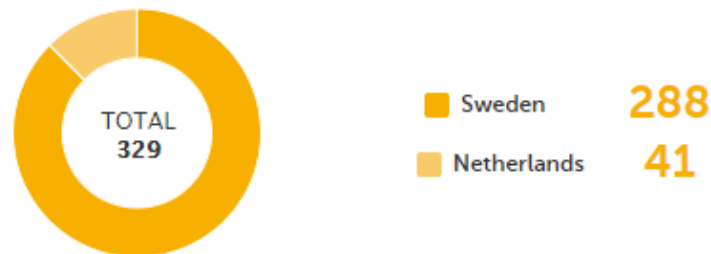
Note! As a Viedoc Clinic user, you need a special permission to view the metrics.

The metrics feature gives an overview of the quality of data in terms of open queries, missing data and overall site performance. You can filter the displayed data by country and site.

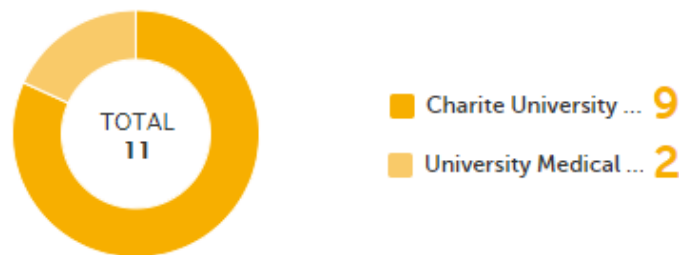


The metrics graphs depict:

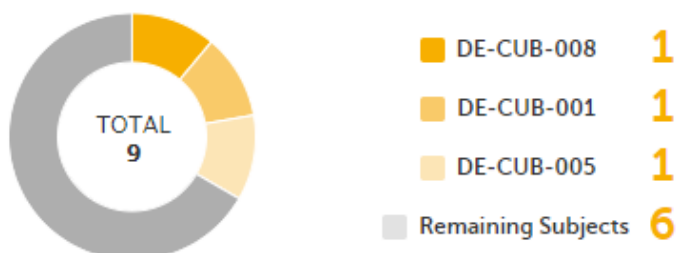
- Open queries** - the number of currently open (not resolved) queries.
 A column graph shows five bars indicating the progress of posted queries during the last five weeks, where each bar indicates a seven day period.
 The latest seven days including today are shown in orange and the previous weeks are gray.
 A percentage indicator is also displayed to indicate the trend between the current week and the previous week. For example, +10% means that in the recent seven days, 10% more queries were in the state 'raised' as compared to the previous 7-day-period.
- Query rate** - the current query rate, counted as the total number of queries / number of subjects (according to the selection).
 A column graph shows five bars indicating changes to the query rate during the last five weeks, where each bar indicates a seven day period.
 The latest seven days including today are shown in orange and the previous weeks are gray.
 A percentage indicator is also displayed to indicate the trend between the current week and the previous week.
- Unconfirmed missing data items** - the amount of unconfirmed missing data items.
 A column graph shows five bars indicating the changes to the missing data rate during the last five weeks, where each bar indicates a seven day period.
 The latest seven days including today are shown in orange, other weeks are gray.
 A percentage indicator is displayed to indicate the trend between the current week and the previous week.
 A ring graph shows the distribution of missing data over those countries / sites / subjects with the most unconfirmed missing data, according to the selection made at the top of the page, as follows:
 - All sites** (default) - distribution over those countries with most unconfirmed missing data:



- Country** - distribution over those sites within the selected country, with most unconfirmed missing data:



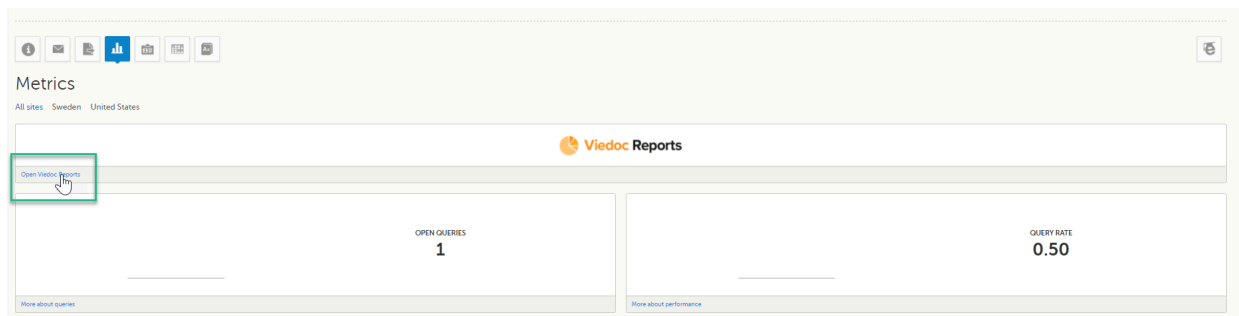
- Site** - distribution over those subjects with most unconfirmed missing data (in orange) out of the total number of subjects with unconfirmed missing data within the selected site (in gray):



Click **More about [...]** to open a page with detailed metrics about [queries](#), [performance](#) or [missing data](#). All detailed metrics pages include filtering possibilities and a bar to show the review status.

1.1 Viedoc Reports

If you have access to Viedoc Reports, you can open it from the Metrics feature.



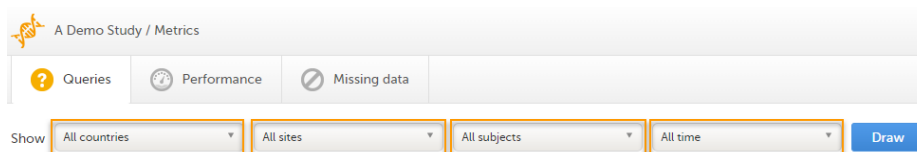
2 Queries

The Queries page includes filtering possibilities and a bar to show the review status for the entire study.

For detailed information about the query process in Viedoc, see [Queries overview](#).

2.1 Queries - filter

You can filter the data by selecting from the drop-down lists in the top of the page:



- Country
- Site
- Subject
- Time period - choose between:
 - All time
 - Last 24 hours
 - Last 3 days
 - Last week
 - Last 3 weeks

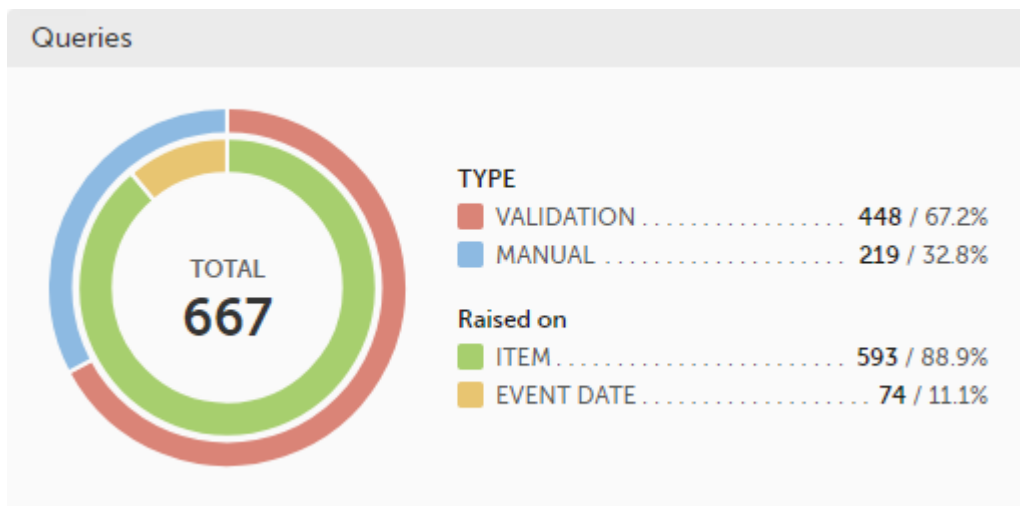
Based on the selected filter, the following information is provided:

- [Queries](#)
- [Query state](#)
- [Top 5 events](#)
- [Top 5 forms](#)
- [Top 5 items](#)
- [Top 5 OIDs](#)
- [Top 5 subjects \(raised queries\)](#)
- [Save and export](#)

2.2 Queries

Queries - a diagram that shows the graphical distribution, the total number as well as the percentage of:

- The distribution of the type of queries that have been raised (**VALIDATION, MANUAL**)
- The number of queries that were raised on item or event date, respectively (**ITEM, EVENT DATE**)



The number in the center of the circle shows the total number of queries.

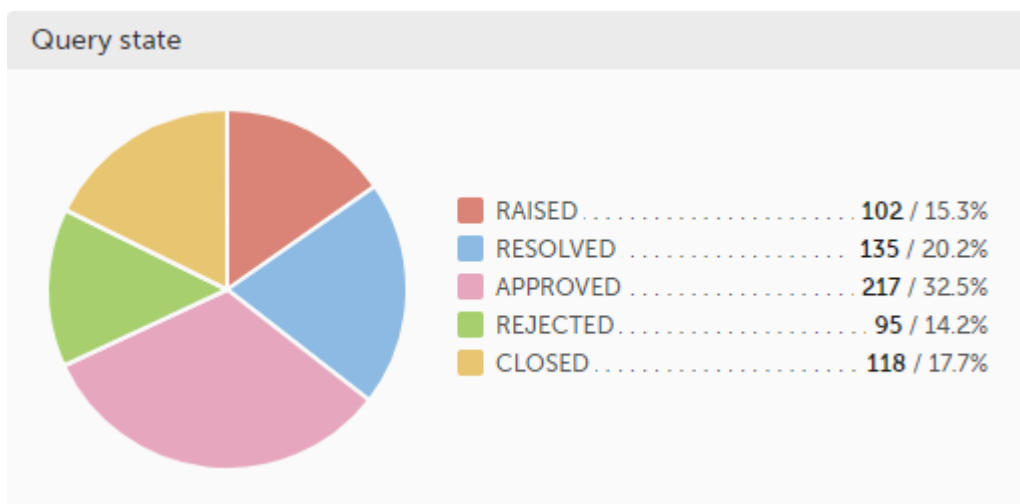
Note!

- All queries are included, regardless of the query state.
- Missing data is not regarded as queries, and therefore not included in the count.

For detailed information about query states and pro, see [Queries overview](#).

2.3 Query state

Query state - a pie chart shows the queries distribution based on the query state:

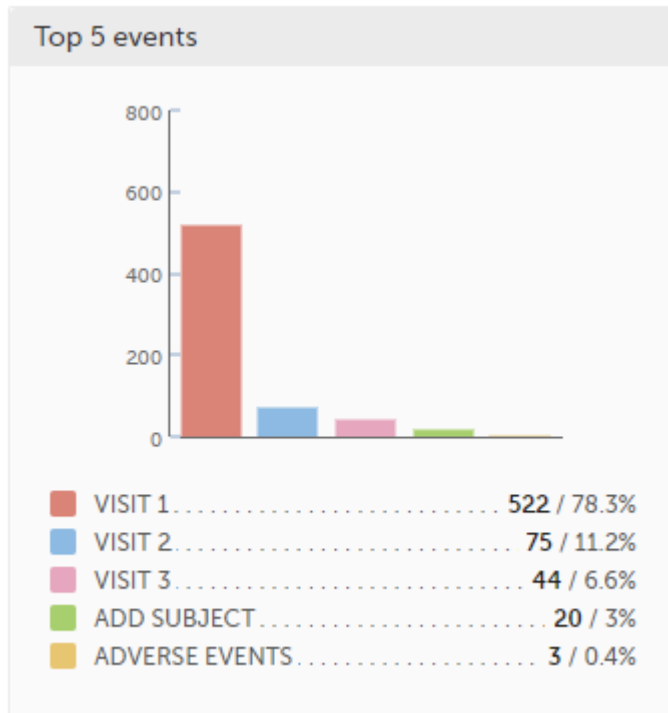


- **RAISED** - number of raised queries / percentage of raised queries out of total number of queries
- **RESOLVED** - number of resolved queries / percentage of resolved queries out of total number of queries
- **APPROVED** - number of approved queries / percentage of approved queries out of total number of queries
- **REJECTED** - number of rejected queries / percentage of rejected queries out of total number of queries
- **CLOSED** - number of closed queries / percentage of closed queries out of total number of queries

For detailed information about query states and process, see [Queries overview](#).

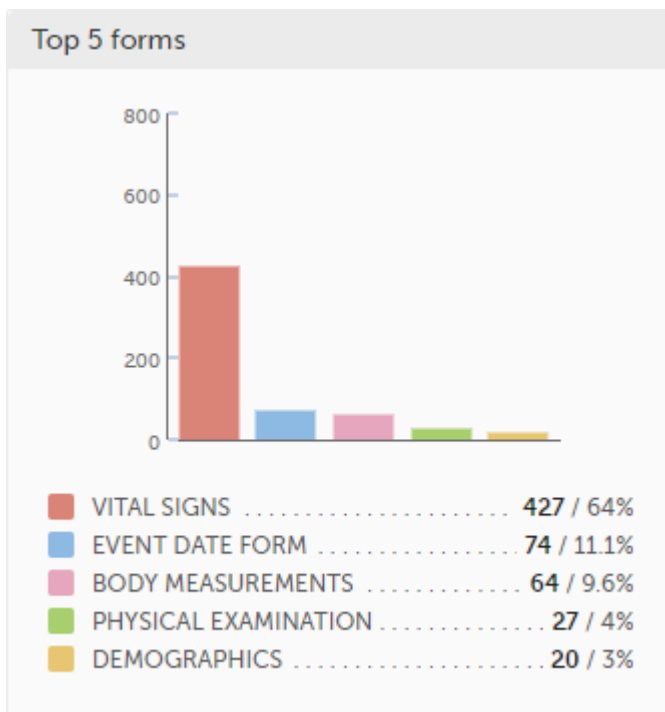
2.4 Top 5 events

Top 5 events - a column bar shows the top five events with the highest number of raised queries (numeric and percentage). The legend of the graph displays the event name.



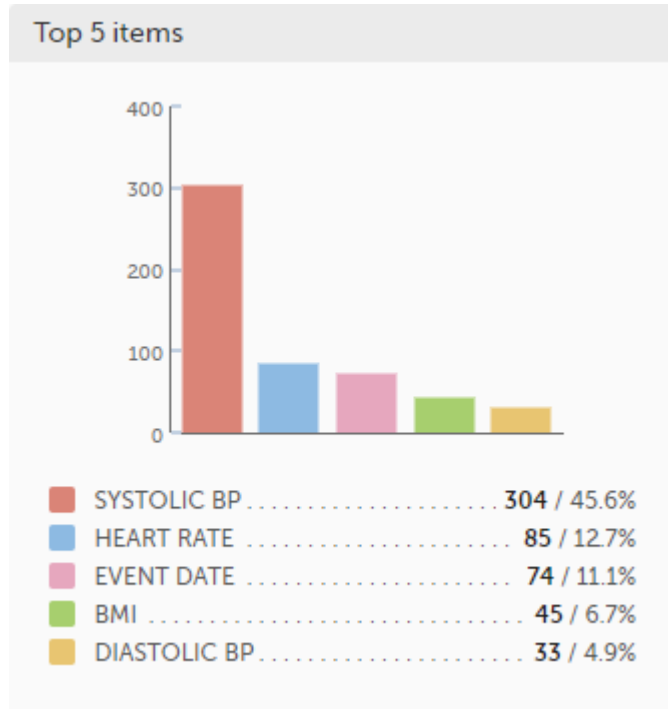
2.5 Top 5 forms

Top 5 forms - a column bar shows the top five forms with the highest number of raised queries (numeric and percentage). The legend of the graph displays the form name.



2.6 Top 5 items

Top 5 items - a column bar shows the top five items with the highest number of raised queries (numeric and percentage). The legend of the graph displays the item name.



2.7 Top 5 check OIDs

Top 5 check OIDs - top five most triggered edit checks are displayed in a table including the actual number, percentage, Object Identifier (OID), form name as well as the query message. The last row of the table shows the total number of queries.

Top 5 check OIDs

n	%	FORM NAME	ITEM NAME	QUERY MESSAGE	OID
244	54.5	Vital Signs	Systolic BP	Value is outside of normal range. Please verify.	RC_VSSYS_0_0_1
65	14.5	Event Date form	Event Date	Visit date is not within the protocol visit window	
44	9.8	Body measurem...	BMI	BMI is outside of normal range. Please verify.	RC_BMBMI_5_0_1
24	5.4	Vital Signs	Diastolic BP	Value is outside of normal range. Please verify.	RC_VSDIA_0_0_1
20	4.5	Vital Signs	Heart rate	Value is outside of normal range. Please verify.	RC_VSPULSE_0_0_1
448	100	In total			

2.8 Top 5 subjects (raised queries)

Top 5 subjects (raised queries) - top five subjects that have the highest number of queries with current status *raised* are displayed in a table including the actual number, percentage, subject ID, study progress, site name as well as date of when the latest query was raised, name of who raised the query as well as the actual query message. The last row of the table shows the total number of subjects.

Top 5 subjects (raised queries)

n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST QUERY (date, by, message)
5	4.9	SE-01-045	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Karolinska U...	28 Feb 2018 09:46, Richard Schломann, Test Query.
5	4.9	SE-01-119	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Karolinska U...	20 May 2016 08:24, Mr Demo, Correct?.
4	3.9	SE-01-118	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Karolinska U...	07 Sep 2016 11:51, System, Value is outside of normal range. Plea...
3	2.9	SE-01-219	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Karolinska U...	07 Jun 2017 17:06, Lyle Wiemerslage, r?.
2	2	SE-01-348	<div style="width: 100%;"><div style="width: 100%;"></div></div>	Karolinska U...	28 Mar 2018 12:44, System, Visit date is not within the protocol vi...
102	100	In total			

For detailed information about query states and process, see [Queries overview](#).

2.9 Save and export

In the bottom of the Queries details page you have the options to:

- **Save as a PDF file** all the metrics data as displayed on the screen.
- **Send by email** to your primary email address, a PDF file with all the metrics data as displayed on the screen.

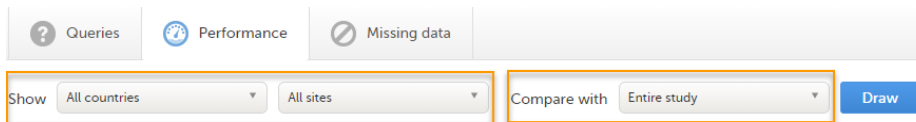
3 Performance

The Performance page allows you to compare data from:

- Selected country (individual country or All countries)
- Selected site(s) in the previously selected country (individual site or All sites)

With data in one of the following:

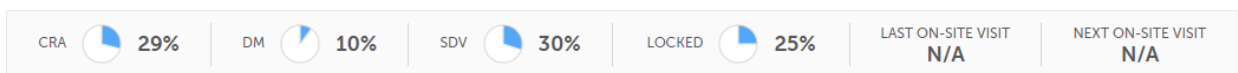
- Entire study (default)
- All sites in selected country
- A particular site in the selected country



Based on the comparison selection the graphs will show statistics about:

- [Review status](#)
- [Subjects](#)
- [Queries](#)
- [Missing data](#)
- [Other](#)
- [Save and export](#)

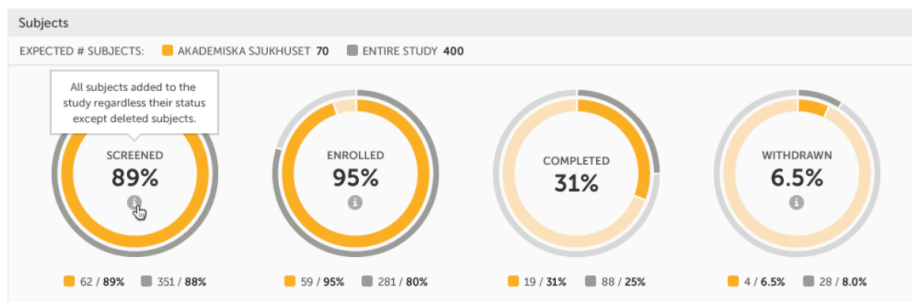
3.1 Review status



- **CRA** - percentage of Clinical Research Associate ([CRA](#)) reviewed data
- **DM** - percentage of Data Manager ([DM](#)) reviewed data
- **SDV** - percentage of Source Data Verification ([SDV](#)) reviewed data
- **Locked** - percentage of locked data

3.2 Subjects

Subjects - detailed data on the subjects on the selected site(s) (in orange) and compared site(s) (in gray):



The conditions for the following subject statuses are defined in the study design (in Viedoc Designer under *Study Settings > Subject status*):

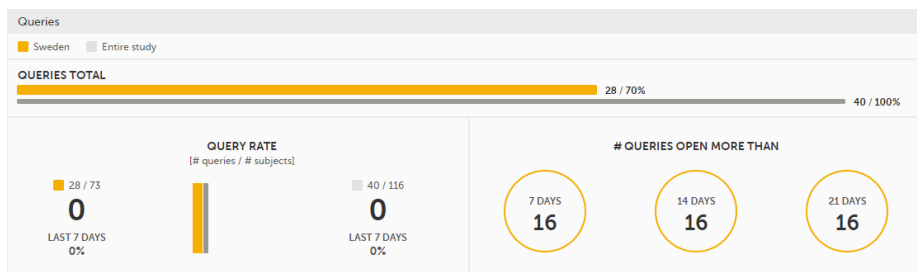
- **Screened** - the number of subjects screened:
 - at selected site(s) - in orange
 - at site(s) to compare to - in gray

- percentage of screened subjects at selected site(s) out of total number of expected subjects - in the center (number of expected subjects for a study/site, is defined in Study/Site Settings in Viedoc Admin)
- Enrolled** - the number of subjects enrolled:
 - at selected site(s) - in orange
 - at site(s) to compare to - in gray
 - percentage of enrolled subjects at selected site(s) out of total number of screened subjects - in the center
- Completed** - the number of subjects completed:
 - at selected site(s) - in orange
 - at site(s) to compare to - in gray
 - percentage of completed subjects at selected site(s) out of total number of screened subjects - in the center
- Withdrawn** - the number of subjects withdrawn:
 - at selected site(s) - in orange
 - at site(s) to compare to - in gray
 - percentage of withdrawn subjects at selected site(s) out of total number of screened subjects - in the center

Tip! If there is an **i** symbol inside of a ring graph, you can hover over it to see a description of the status.

3.3 Queries

Queries - detailed data on queries on the selected site(s) (in orange) and compared site(s) (in gray):

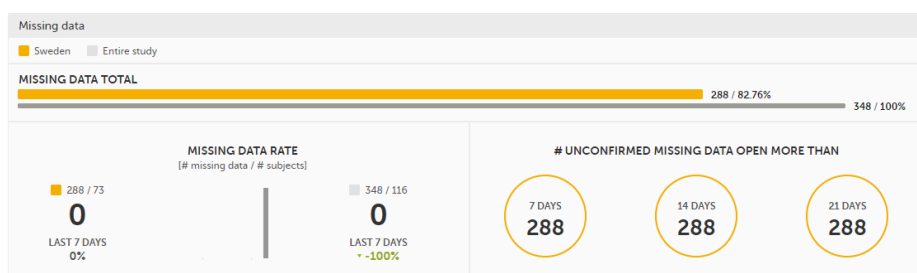


- Queries total** - the total number of queries on selected site(s) (in orange) and compared site(s) (in gray) are shown both in % and in actual numbers.
- Query rate** - total number of raised queries out of total number of subjects. The column graph consists of 5 bars indicating the progress of the query rate the last 5 weeks period, where each bar indicates a 7 days period. Columns for selected sites are displayed in orange and columns for compared site(s) in gray. A percentage indicator shows the trend of the number of queries compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):
 - down - green
 - up - red
 - equal - black
- Queries open more than** - three circles display the number of queries currently in a Raised state, that have been open for more than, 7, 14 and 21 days on the selected site(s), which give a good indication of the pace queries are processed within different sites.

For detailed information about query states and process, see [Queries overview](#).

3.4 Missing data

Missing data - detailed information on missing data (both confirmed and unconfirmed data) on the selected site(s) (in orange) and compared site(s) (in gray):

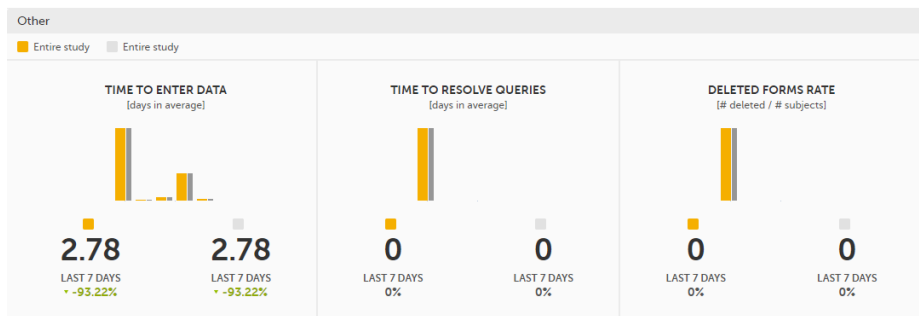


- Missing data total** - Total number of missing data on selected site(s) (in orange) and compared site(s) (in gray) both numeric and percentage out of all missing data in the entire study. Hidden forms/items are not included in the count.

- Missing data rate** - current missing data rate calculated as total number of missing data per total number of subjects.
 The column graph consists of 5 bars indicating the progress of the missing data rate the last 5 weeks period where each bar indicates a 7 days period.
 Columns for selected sites are displayed in orange and columns for compared site(s) in gray.
 A percentage indicator shows the trend of the missing data compared to the previous 7 day period for selected (to the left) and compared site(s) (to the right):
 - down - green
 - up - red
 - equal - black
- Unconfirmed missing data open more than** - three circles display the number of currently unconfirmed missing data items that has been missing for more than, 7, 14 and 21 days (counted from the date the form was edited with unconfirmed missing data until current date) on the selected site(s).

3.5 Other

Other - miscellaneous detailed data on the selected site(s) (in orange) and compared site(s) (in gray):



- Time to enter data** - the average time (in days) it takes to enter data for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as a difference between the event date and the date the item data was entered, per form.
 The column graph consists of 5 bars indicating the average time to enter data over the last 5 weeks period where each bar indicates a 7 days period.
 Columns for selected sites are displayed in orange and columns for compared site(s) in gray.
 A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):
 - down - green
 - up - red
 - equal - black
- Time to resolve queries** - the average time to resolve a query (in days) for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as the difference in days from the date the query was Raised until the date the query was Resolved. The queries that are automatically closed by the system (see [Queries overview](#) for details on when a query is automatically closed) are also included in the count.
Note! The queries that were removed or automatically resolved are not included in the count.
 For detailed information about query states and process, see [Queries overview](#).
 The column graph consists of 5 bars indicating the average time to resolve queries over the last 5 weeks period where each bar indicates a 7 days period.
 Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray.
 A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):
 - down - green
 - up - red
 - equal - black
- Deleted forms rate** - the rate of deleted forms, calculated as the number of deleted forms per number of subjects, for selected site(s) (in orange) and compared site(s) (in gray).
 The column graph consists of 5 bars indicating the deleted forms rate over the last 5 weeks period where each bar indicates a 7 days period.
 Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray.
 A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):
 - down - green
 - up - red
 - equal - black

3.6 Save and export

In the bottom of the **Performance** details page you have the options to:

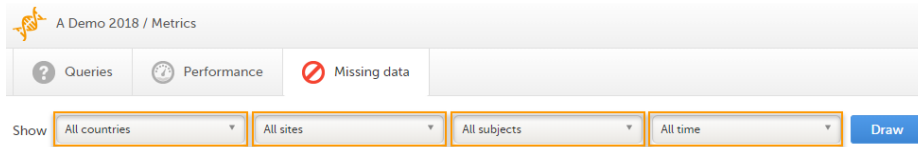
- Save as a PDF file** all the metrics data as displayed on the screen.

- **Send by email** to your primary email address, a PDF file with all the metrics data as displayed on the screen.

4 Missing data

The **Missing data** page includes filtering possibilities and a bar to show the review status for the entire study.

You can filter the data by selecting from the drop-down lists in the top of the page:



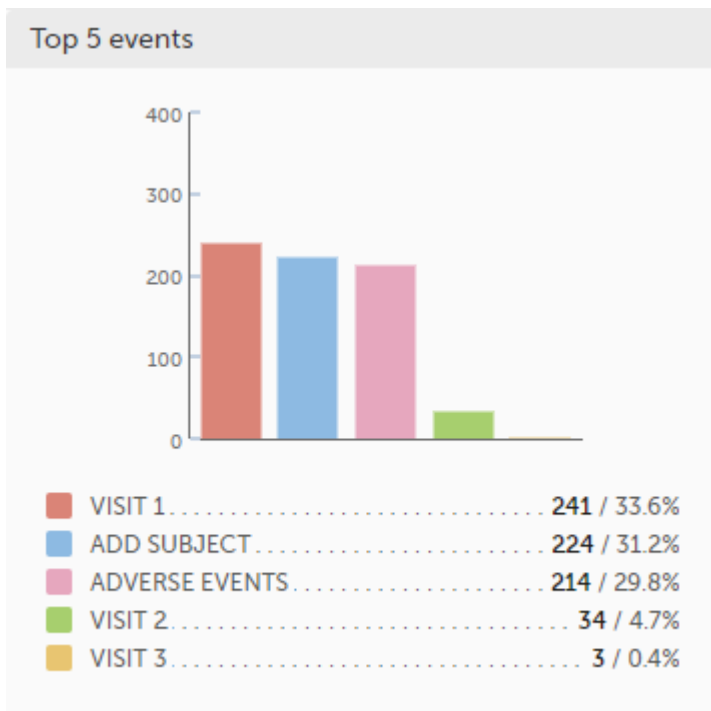
- Country
- Site
- Subject
- Time period - choose between:
 - All time
 - Last 24 hours
 - Last 3 days
 - Last week
 - Last 3 weeks

Based on the selected filter the graphs will show statistics about:

- [Top 5 events](#)
- [Top 5 forms](#)
- [Top 5 items](#)
- [Subjects with confirmed missing data](#)
- [Subjects with unconfirmed missing data](#)
- [Save and export](#)

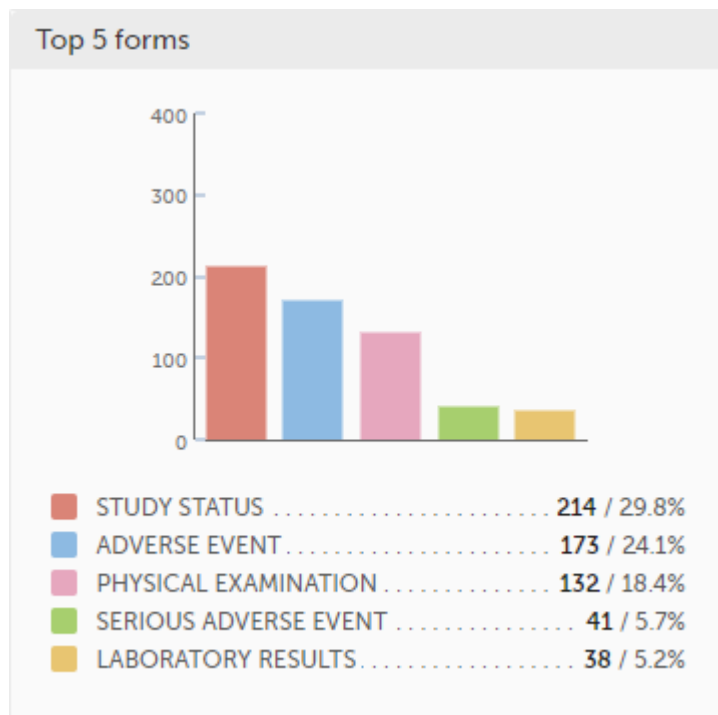
4.1 Top 5 events

Top 5 events - a column bar shows the top five events with the highest number of items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the event name.



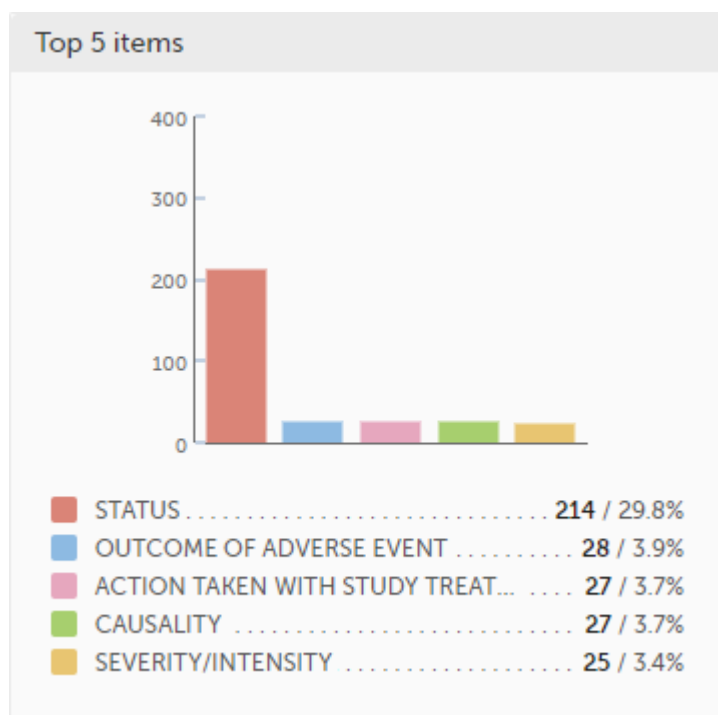
4.2 Top 5 forms

Top 5 forms - a column bar shows the top five forms with the highest number of items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the form name.



4.3 Top 5 items

Top 5 items - a column bar shows the top five items with missing data (confirmed and unconfirmed), both numeric and percentage. The legend of the graph displays the item name.



4.4 Subjects with confirmed missing data

The top 5 subjects that have the highest level of confirmed missing data are displayed in a table including:

- The actual number
- Percentage
- Subject ID
- Study progress

- Site name
- Date, visit, form and item (item output label if defined, otherwise the field label of the item) taken from the visit where the missing data occurs

The last row of the table shows the total number of subjects with confirmed missing data.

Subjects with confirmed missing data						
	n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
	2	4.1	SE-01-332	<div style="width: 4.1%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	12 Mar 2018 15:33, [Link] , Visit 1, Body measurements, Wei...
	2	4.1	SE-01-284	<div style="width: 4.1%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	25 Jan 2018 08:43, Lyle W, Visit 1, Safety Laboratory Parameters, Pleas...
	2	4.1	SE-01-316	<div style="width: 4.1%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	24 Jan 2018 10:53, [Link] , Visit 1, 12-Lead ECG, Performed.
	2	4.1	SE-01-166	<div style="width: 4.1%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	07 Feb 2017 14:05, [Link] , Visit 1, Physical Examination, Lymph ...
	2	4.1	SE-01-110	<div style="width: 4.1%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	30 Mar 2016 11:58, [Link] , Visit 1, Body measurements, Hei...
	48	100	In total			

4.5 Subjects with unconfirmed missing data

The top 5 subjects that have the highest level of unconfirmed missing data are displayed in a table including:

- The actual number
- Percentage
- Subject ID
- Study progress
- Site name
- Date, visit, form and item (item output label if defined, otherwise the field label of the item) taken from the visit where the missing data occurs

The last row of the table shows the total number of subjects with unconfirmed missing data.

Subjects with unconfirmed missing data						
	n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
	42	6.2	SE-01-320	<div style="width: 6.2%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	12 Feb 2018 10:59, [Link] , Adverse Events, Serious Ad...
	24	3.5	SE-01-344	<div style="width: 3.5%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	19 Mar 2018 11:05, [Link] , Adverse Events, Serious Adverse E...
	22	3.2	SE-01-331	<div style="width: 3.2%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	08 Mar 2018 16:35, [Link] , Adverse Events, Adverse Event, ...
	19	2.8	SE-01-249	<div style="width: 2.8%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	18 Aug 2017 09:52, [Link] , Adverse Events, Adverse Event, ...
	16	2.3	SE-01-281	<div style="width: 2.3%;"><div style="background-color: #007bff; height: 10px;"></div></div>	Karolinska Uni...	28 Sep 2017 09:07, [Link] , Visit 1, Laboratory results, Crea...
669	100	In total				

4.6 Save and export

In the bottom of the Missing data details page you have the options to:

- **Save as a PDF file** all the metrics data as displayed on the screen.
- **Send by email** to your primary email address, a PDF file with all the metrics data as displayed on the screen.



Issues and tasks

Issues and tasks

Published by Viedoc System 2024-10-10

[1. Introduction](#)

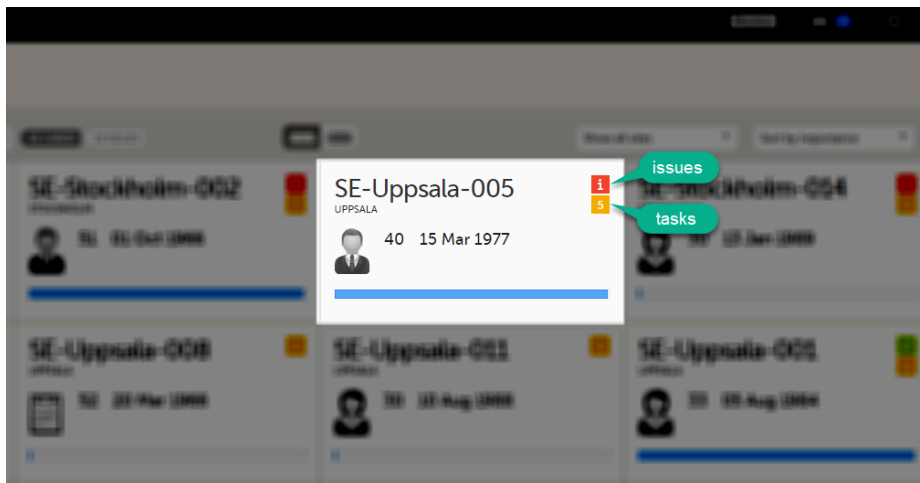
[2. Issues](#)

[3. Tasks](#)

1 Introduction

The [Selection page](#) displays all subjects from all sites you have access to. Each subject is represented by a subject card.

In the top right corner of each subject card, orange and red icons are displayed when there are issues (such as queries) and tasks to be solved/completed for that subject. These icons help you identify where actions are needed.

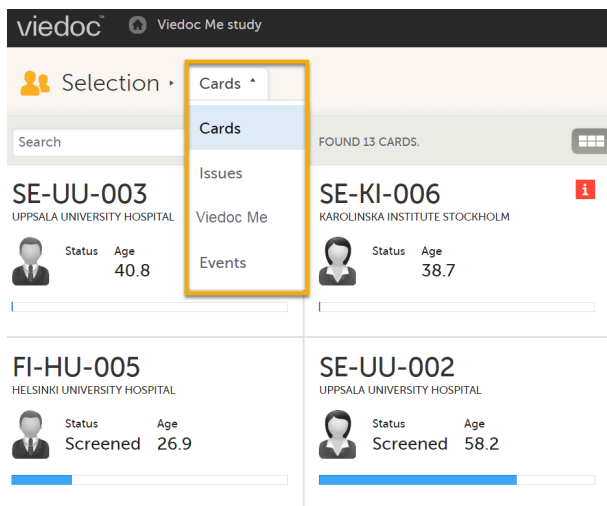


- **Red icon: Issues** - indicating that the subject has open queries and/or unconfirmed missing data. Both open queries and unconfirmed missing data should be handled and resolved by the site but, as a Monitor or Data Manager, it is important for you to be aware of these issues as well. For more details, see [Queries overview](#).
- **Orange icon: Task** - indicating the number of tasks to be completed for this subject, such as approving query answers, perform reviews, and so on.

All issues and tasks should eventually disappear but while being present they help you identify where action is needed.

2 Issues

It is possible to switch between the views showing Cards/Issues/Viedoc Me/Events by selecting the dropdown list next to **Selection**.



The **ISSUES** view displays the list of existing issues.

ID #	REFERENCE #	ISSUE DETAIL #	CONFIRMATION #	STATE #
SE-02-006 Uppsala	Visit 1 Lab	! Missing data Demo User 07 Jul 2017 14:56 CEST		Missing data
SE-02-007 Uppsala	Visit 1 Lab Collection Date and Time	! Missing data Demo User 17 Aug 2017 14:26 CEST		Missing data
SE-02-006 Uppsala	Visit 1 Lab Collection Date and Time	? Is the date correct? Please verify! Demo User 01 Oct 2018 09:54 CEST		Awaits answer
SE-02-007 Uppsala	Visit 1 Lab Leukocytes	! Missing data Demo User 17 Aug 2017 14:26 CEST		Missing data
SE-02-007 Uppsala	Visit 1 Lab Leukocytes	! Missing data Demo User 17 Aug 2017 14:26 CEST		Missing data

Select any row to open the form where the issue is raised. If you close the form, you will return to this issue list again.

The list of issues can be filtered by using the drop-down lists on the top right side of the page. You can filter the issues:

- By site - select to view data from a specific site or from all sites.
- By issue type/status:
 - **All issues** - all the issues regardless of the status, except for pre-queries
 - **All open issues** (default if role-based queries is not enabled for your study) - all the issues with an open status:
 - Missing data
 - Pending form upgrade
 - Pending reference data upgrade
 - Open queries (with status *Awaits answer*)
 - **All queries** - all queries regardless of the status
 - **Open queries** - only queries with status *Awaits answer*
 - **Queries awaiting approval** - only queries with status *Awaits approval*
 - **My queries** -

Note! The following applies only if role-based queries is not enabled for your study:(default for users with permissions to Add/change queries, Add pre-queries, Promote pre-queries):

 - For user with permissions to Add pre-queries - all pre-queries that were raised by the user, regardless of the status
 - For user with permissions to Promote pre-queries - all pre-queries promoted by the user and all pre-queries raised regardless by whom they were raised
 - For user with permissions to Add/change queries - all queries raised or updated by the user, all queries awaiting approval regardless by whom they were raised, show all pre-queries promoted regardless by whom they were promoted
 - **Pre-queries** - all pre-queries regardless of status
 - **My role's queries** -

Note! When role-based queries is enabled for a study, for user roles with permission to Add/change queries, such as Monitors and Data Managers, this filter is applied by default when opening the **ISSUES** list. My role's queries lists all the open manually raised queries that were raised by the same role with the status *Awaits approval* or *Awaits answer*.

 - **Missing data** - all unconfirmed missing data

- **Form upgrade pending** - forms pending upgrade as a result of applying a revision of the study design

3 Tasks

As soon as data has been entered, the orange task icon appears, indicating that there is data ready for review, or queries answers to be approved (see [Raising/Approving/Rejecting Queries](#)). The number of tasks is displayed. If there are more than nine tasks to be performed on a booklet or form, +9 will be displayed in the icon. Tasks should be handled continuously throughout the study to make sure data at all times is as clean and accurate as possible.

Tasks are tracked on three levels:

- Subject
- Event
- Form

The screenshot displays a user interface for a clinical trial. At the top left, there is a 'Details' header with a person icon. Below it, the study ID 'SE-20-003' and 'UPPSALA UNIVERSITY HOSPITAL' are shown. The subject's status is 'Withdrawn' and their age is '70.1'. A progress bar indicates '0% of study' completion, with '1/1 events' and '0/5 forms' completed. A 'tasks pending' counter shows '8' tasks. Below this, there are sections for 'Common events' (Medical / Surgical History (3) and Prior and Concomitant Medications (0)). The main area shows a 'Screening' event with a date of '30 07 2020' and a status of 'Ongoing'. A search bar and 'Show all events' dropdown are at the top right. On the right side, there are three yellow sticky notes: 'Protocol date not set', 'Scheduled date not set', and 'Event date 30 07 2020'. An orange task icon with the number '2' is visible in the top right corner of the main content area, and another '2' is visible in the bottom right corner of the 'Screening' event details.

As soon as a task is completed, it will disappear from the views.

Note! If Role based queries is enabled for your study, the task counter includes only the queries raised by the same role, that is, the ones that the active user role can take action on.



Clinical review, SDV, and Lock

Clinical review, SDV, and Lock

Published by Viedoc System 2023-10-09

[1. Introduction](#)

[2. Clinical review](#)

[3. SDV](#)

[3.1 SDV on item level](#)

[4. Lock](#)

[4.2 Locking a form](#)

[4.3 Unlocking a form](#)

[4.4 Locking/unlocking a subject-submitted \(Viedoc Me\) form](#)

[5. Data review console](#)

[6. Study status and metrics](#)

1 Introduction

The requirements on data review and Source Data Verification ([SDV](#)) vary between studies. This lesson describes what is possible in Viedoc.

In this example, clinical review and SDV are tasks to be completed. The number of tasks to be completed is displayed in the orange task icon:

The screenshot shows a 'Patient Info' form. At the top, there is a header with 'Patient Info' and a status bar containing icons for DM, CRA, SDV, a lock, and a checkmark. A 'SHOW HISTORY' button with a '1' indicator is on the right. Below the header, the form contains fields for 'Gender' (with radio buttons for Male, Female, Transgender), 'Date of Birth' (with a date picker showing '05 Aug 1984'), and 'Age' (with a text input showing '33'). At the bottom of the form, there are three checkboxes: 'Clinical review', 'SDV', and 'Lock'. A green callout bubble with the text '2 tasks' points to an orange square icon with the number '2' inside, which is positioned above the 'Clinical review' and 'SDV' checkboxes. The 'Clinical review' and 'SDV' checkboxes are currently unchecked, while the 'Lock' checkbox is checked. There are also 'Form History' and 'Add note' buttons at the bottom right.

The orange task icon disappears when the checkboxes for clinical review and SDV are selected and the tasks are completed.

The screenshot shows the 'Patient Info' form. At the top left, there are three status indicators: 'DM' (unchecked), 'CRA' (checked), and 'SDV' (checked). To the right is a 'SHOW HISTORY' button with a notification icon and a toggle switch. The main form area contains fields for 'Gender' (radio buttons for Male, Female, Transgender), 'Date of Birth' (calendar icon, dropdown showing '05 Aug 1984'), and 'Age' (input field showing '33'). At the bottom of the form, there are three checkboxes: 'Clinical review' (checked), 'SDV' (checked), and 'Lock' (unchecked). To the right of these are 'Form History' and 'Add note' buttons.

Note! If a user with edit permission is editing the subject card, you can still perform the clinical review and the SDV. And vice versa, the clinical review and SDV will not lock the subject for users who need to edit it.

2 Clinical review

The purpose of clinical review is to give the Monitor the possibility to mark forms as reviewed.

Marking a form as clinical reviewed can be performed in one of the following ways:

- At the bottom of each form, by checking the **Clinical review** checkbox.
- Batch-wise through the review console. Read more about the [review console](#) below.

Marking a form as reviewed does not mean that you are on-site having access to source data. It means that you have done a clinical review off-site of the content in the forms, and that you are prepared for your upcoming monitoring visit.

Note! If a form is edited after you have marked it as clinical reviewed, the review status breaks and the form must be reviewed again. The review task appears again in the orange task box icon.

3 SDV

Source data verification is normally the most time-consuming activity for the Clinical Research Associate ([CRA](#)), as it requires access to source notes. All forms that require [SDV](#) are highlighted with task(s).

SDV can be performed in one of the following ways:

- On item level, by clicking on the SDV flag for the item in the form.
- On form level, by selecting **SDV** at the bottom of the form.
 - Note!** If there are items in the form that require SDV and are hidden due to data visibility conditions in the study design, you will not be able to apply SDV on form level.
- Batch-wise through the review console. Read more about the [review console](#) below.

Note! If a form is edited after you have marked it as SDV, the SDV status is reset, and the form has to be SDV'ed again. The SDV task appears again in the orange task box icon. However, only the fields that were changed on the form are required to be SDV'ed again. These fields are clearly indicated with the red SDV icon.

3.1 SDV on item level

If the study has the setting for item-level SDV enabled, SDV can be performed for individual items in a form.

If the study design specifies that an item requires SDV, there will be an SDV icon next to the item in the form. The red icon indicates that SDV has not been performed. To perform SDV, simply click on the red icon. The icon then turns into a green SDV icon.

DE-95-093 Add subject [07 Jul 2023] Close

Form is in read-only mode.

Demographics

DM CRA SDV SHOW HISTORY 2

SDV Date of Informed Consent

SDV Sex Female Male

SDV Date of birth

SDV Age years

SDV Race American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White

SDV Ethnicity Hispanic or Latino Not Hispanic or Latino

Clinical review SDV Lock

Viedoc™ 4.77.8648.13864 | 2023-09-06T16:34 CEST
1 | 56.0 | 2022 - Demo Study | Berlin Hospital

When all visible items that require SDV have been SDV'ed, the **SDV** checkbox at the bottom of the form will be automatically selected. And vice versa, if you select the **SDV** checkbox at the bottom of the form, all visible items that require SDV will be indicated with a green SDV icon.

Notes!

- If the form contains items that require SDV but are not visible to you, you will not be able to change the SDV status for the entire form.
- If an item is edited after the SDV has been performed, the SDV status is reset, and the item has to be SDV'ed again.
- When a study event form is SDV'ed, the event date form is automatically SDV'ed.

4 Lock

4.1 Locking a form

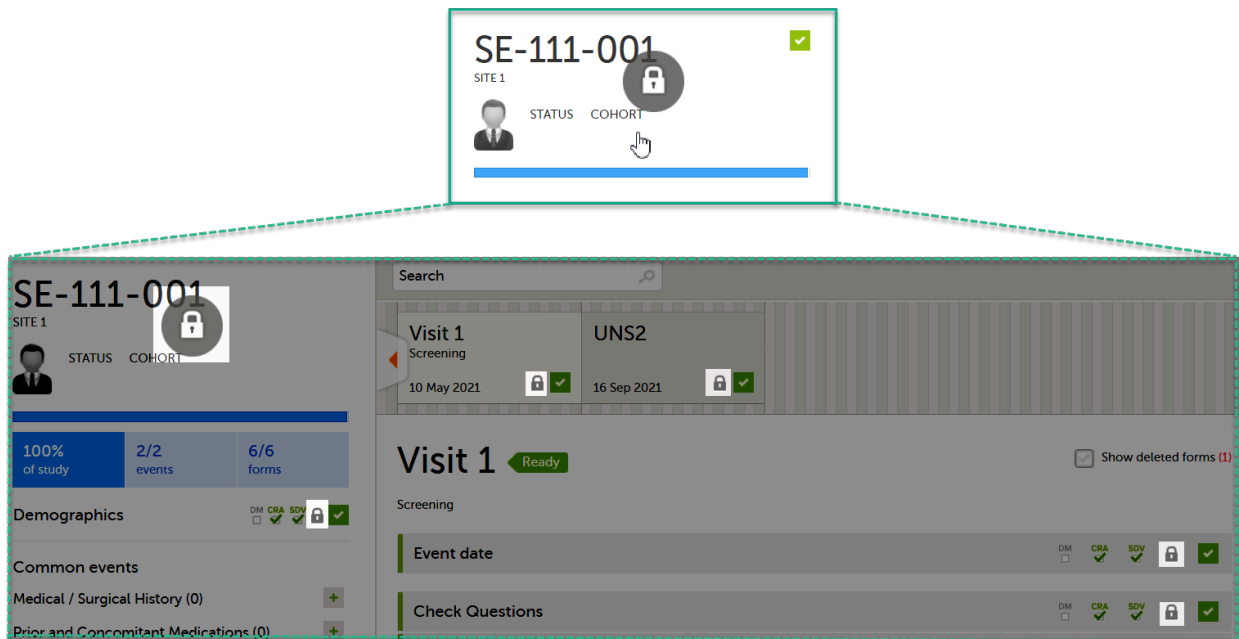
Locking data in a form can be performed in one of the following ways:

- At the bottom of every form, by selecting **Lock**.
- Batch-wise using the review console. Read more about the [review console](#) below.

Locking a form should only be performed if there are no more expected changes to that form, that is, if the data is clean.

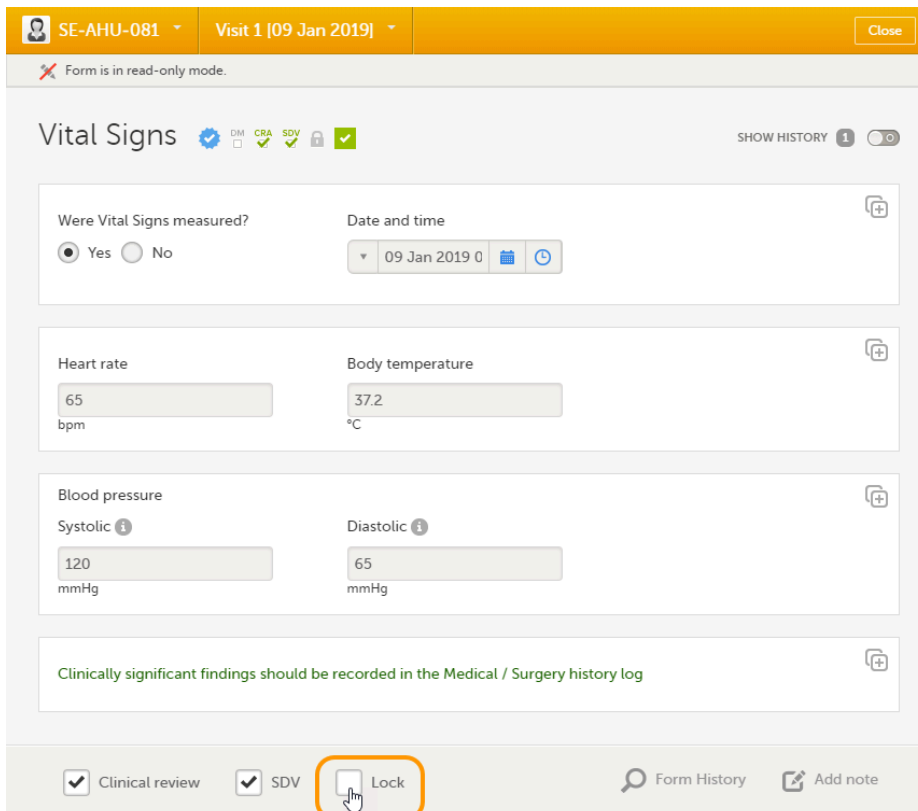
Important! Updates to the electronic Case Report Form (eCRF) are not applied to locked forms. If you are aware of any upcoming changes to the eCRF that potentially affect already saved and locked forms, make sure that these are unlocked before the new design version is published to the site.

If all forms in all events for a subject have been locked, the subject card on the [Selection page](#) will be displayed with a lock icon, indicating all data is locked:



4.2 Unlocking a form

Regular clinic forms can be unlocked by clearing the **Lock** checkbox at the bottom of a form. Unlocking a form opens it up for editing by users with edit data permission (for example the Investigator).



4.3 Locking/unlocking a subject-submitted (Viedoc Me) form

Subject-submitted (Viedoc Me) forms that are filled in by the subject are locked by default.

You may have the possibility to unlock a subject-submitted form if this option is activated for your study. In this case, the **Lock** checkbox appears at the bottom of the subject-submitted form. The form can be locked or unlocked by selecting or clearing the checkbox respectively. Unlocking a form opens it up for editing by users with edit data permission (for example the Investigator).

SE-AHU-081 Home Admin 1 23 Jan 2019 Close

Form is in read-only mode.

Home administration

SHOW HISTORY 1

Did you take the dose? Yes No

When did you take the dose? 23 Jan 2019 15:39

How many tablets did you take? 1

Click on the scale below to indicate how severe your pain is. 49

Have you experienced any adverse reactions? Yes No

Have you taken any other medication apart from the study medication? Yes No

Clinical review Lock

Form History Add note

5 Data review console

You can perform clinical review, [SDV](#), and/or lock of the forms batch-wise, by using the data review console. To open the data review console, click the icon in the top right corner of the **Details** page.

Details

SE-111-002 SITE 1

STATUS COHORT 1

Search Show all events

Visit	Count	Date	Status
Visit 1 Screening	9+	16 Sep 2021	Reviewed (Green eye icon)
Visit 2	8	17 Sep 2021	Not reviewed (Grey eye icon)

Data review

The data review console displays an overview of all forms of a subject that require data review, SDV, or lock. It shows which forms have been reviewed, SDV'ed, or locked. The green and grey eye icons help you identifying forms that you have not previously visited: the green eye icon marks the forms that you have already visited, the grey eye icon marks the forms that you have not visited yet.

To review and/or lock the forms:

- 1 Select the form(s) to be reviewed in one of the following ways:
 - Select all forms by clicking the *n forms* link on the top of the page:

- Select all forms within an event, by clicking the *n forms* link to the right of the respective event:

- Individually, check the review and/or lock icon for each individual form. Step 2 is not applicable in this case.

2 In the dialog that opens, select **Clinical review, SDV, Lock** as needed, and click **Ready**:

A dialog box titled "All forms, Visit 1" with a close button in the top right. It contains three sections, each with a title, a radio button selection, and a count of forms:

- Verify SDV**: All forms (2), Only visited forms (2)
- Verify CRA**: All forms (2), Only visited forms (2)
- Lock**: All forms (2), Only visited forms (2)

At the bottom are "Ready" and "Cancel" buttons.

The status of the selected forms is updated according to the selected actions.

A screenshot of a web interface showing a list of forms. At the top, there is a "Show all forms" dropdown and a "3 forms" indicator with a copy icon. Below this are sections for "Add Patient" (1 form) and "Visit 1" (2 forms). Each form row includes a "DM" checkbox, "CRA" and "SDV" status indicators (green checkmarks), a lock icon, a green checkmark, a green eye icon, and a gear icon. An orange box highlights the "CRA", "SDV", and lock icons for the "Event date: 10 May 2021" form.

If any of the marked forms have not been visited by you before, you will be asked whether you want to continue with the action or not. If you choose to continue, the forms will be marked according to your selections, that is, the system will not prevent you from marking unvisited forms as reviewed, [SDV](#)'ed, or locked.

Note! If the study has the setting for item-level SDV enabled, and a form contains items that require SDV but are not visible to you, you will not be able to change the SDV status for the entire form.

6 Study status and metrics

The current workload can be checked on the [Study status](#) or the [Metrics](#) pages.



Queries overview

Queries overview

Published by Viedoc System 2024-10-10

[1. Introduction](#)

[2. Role-based queries](#)

[3. Manually raised queries](#)

[3.1 Pre-queries](#)

[3.1.1 Pre-query states](#)

[3.2 Queries](#)

[4. Validation queries](#)

[5. Query states](#)

[6. Queries in export output](#)

[6.3 Queries in ODM export](#)

[6.4 Queries in Excel export](#)

[7. Related topics](#)

1 Introduction

A query is a question about data. In Viedoc, queries can be raised:

- Manually, by a user that has permissions for raising queries/pre-queries, after the form has been saved.
- Automatically (validation queries), by the system during data entry, for example when entered data are outside specified limits and an edit check fires.

Note! All the related queries are automatically closed, when:

- A form field becomes hidden.
- A form is reset.
- An event is deleted.
- A study event date is cleared (only queries raised on the study event date are closed).

In case of a validation query, when this is resolved by data edit, it is automatically closed. See [Validation queries](#).

Resolving a query always breaks the form signature, even if there are no data changes involved.

A summary of the number of queries is displayed on the study start page, as illustrated below.

Note! This is a summary of the whole study and it does not take into consideration the role visibility conditions.

A demo study

An open-label, multi center, dose escalation study investigating the safety, tolerability and ...

Study status


All sites Sweden Finland Germany Netherlands Austria Belgium Italy United Kingdom Switzerland

Issues		
Resolved queries	Open queries	Forms
13	21	71

My statistics	
Patients added:	113
FPA:	04 OCT 2016
LPA:	13 AUG 2018

Review		
CRA %	DM %	SDV %
3	1	4

Approval		
Inv. sign %	Queries %	Locked forms %
0	0	3

A query is raised in a form field. After a query is raised, the respective form is marked with the red issue icon  :

Details

SE-111-002
SITE 1

STATUS COHORT
1 1

66% of study 2/2 events 8/12 forms

Demographics 2 DM CRA SDV

1 forms with issue(s)
9+ tasks pending

Common events
1 queries to be resolved

Visit 1 Screening 16 Sep 2021
Visit 2 17 Sep 2021

Visit 2 Ongoing

Event date
Enrolment
Eligibility

Visit 2 2 DM CRA SDV

Protocol date 16 Sep 2021- 30 Sep 2021 23 Sep 2021(-7/+7)

Event date 17 Sep 2021

Event date Is this the correct visit date? | Sophia Stonestream (826) 17 Sep 2021 11:04 Awaits answer

2 Role-based queries

Important! For all new studies started after release 4.80, the default setting **Enable role-based queries** is selected.
For studies started before release xxx, the default setting **Enable role-based queries** is cleared. For studies started before Viedoc release 4.80, all query actions will still work as usual until role-based queries is enabled.

When the role-based queries option is enabled for your study, it restricts, at study level, the approval of the query resolution to the same user role who raised the query.

Notes!

- Enabling role-based queries applies to manually raised queries and pre-queries only.
- This does not apply to validation queries or to data confirmed as missing. All user roles with permission to add/change queries are still able to approve/reject/edit validation queries.

For more information, see the eLearning lesson on [Role-based queries](#).

3 Manually raised queries

Viedoc Clinic users with permission to raise queries/pre-queries, can manually add a query to any field value.

Manually raised queries can be:

- [Pre-query](#) - needs to be promoted and released before it is visible to the site as a normal query.
- [Query](#) - visible to the site as soon as either a query was manually raised or a pre-query was released.

3.1 Pre-queries

Viedoc offers support for query review, that is, to review a query before it is released to the site. This is done through pre-queries.

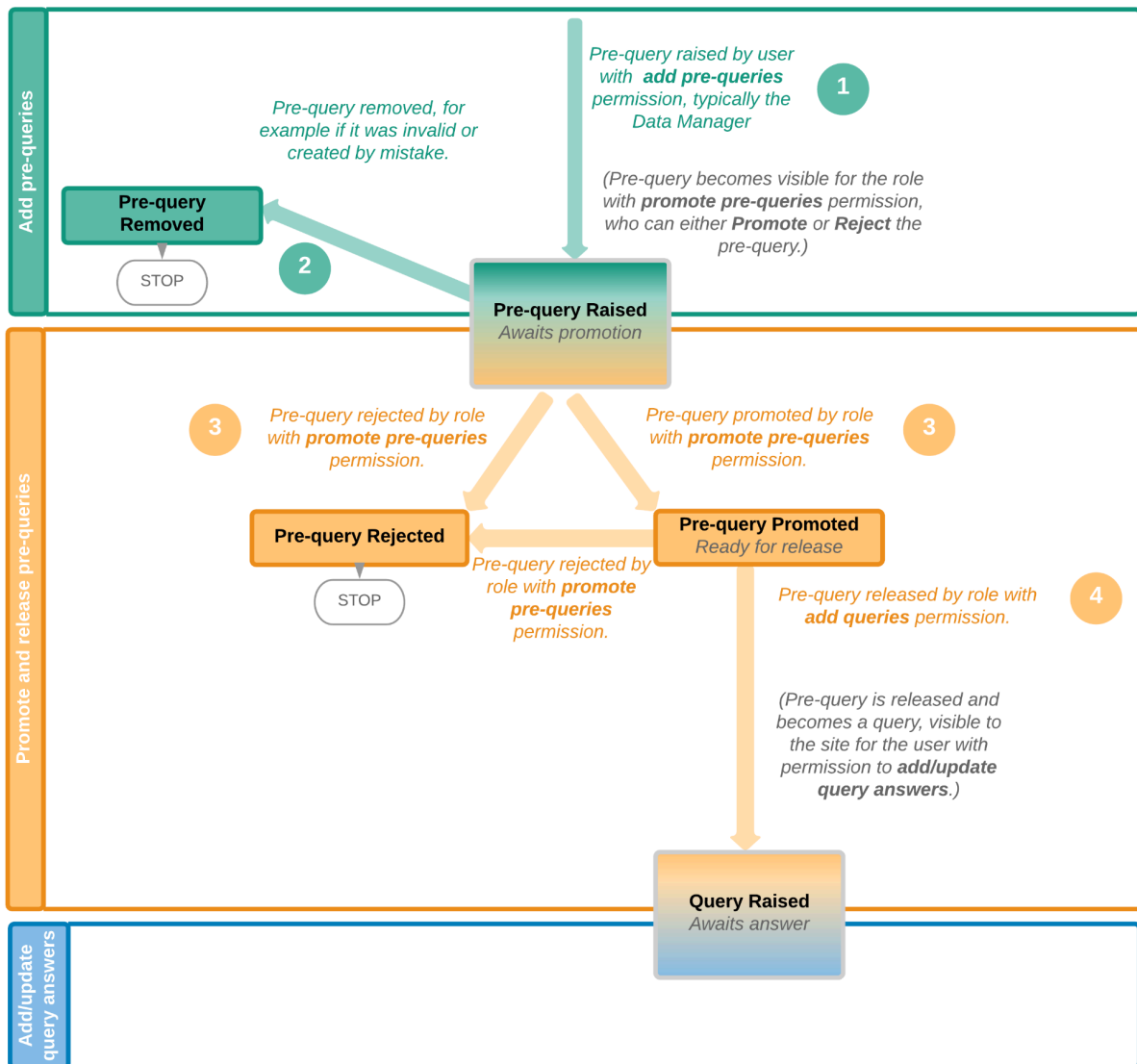
The pre-query process can involve either two or three roles, as follows:

- Two roles: one role with permission to [add pre-queries](#), typically the **Data Manager**, and one role with permission to [promote pre-queries and add queries](#), typically the **Monitor**.
- Three roles: one role with permission to [add pre-queries](#), for example the **Data Manager**, one role with permission to [promote](#) the pre-query, for example the **Sponsor**, and one role with permission to [add queries](#), for example the **Monitor**.

An unlimited number of pre-queries can be added on the same field at the same time.

The following image illustrates the main actions that can be performed on a pre-query and all the states the pre-query goes through before it is released as a query:

1. The pre-query is added by the user with permission to [add pre-queries](#), typically the **Data Manager**. As a result, a pre-query is raised, becoming visible for the Viedoc Clinic user with permission to [promote pre-queries](#), typically the **Monitor**.
2. The raised pre-query can be removed, for example if it is invalid or added by mistake.
3. The raised pre-query is promoted or rejected by the Viedoc Clinic user with permission to [promote pre-queries](#), typically the **Monitor**.
4. The promoted pre-query is released by the Viedoc Clinic user with permission to [add queries](#) (typically the **Monitor**), becoming a raised query that is visible for the Viedoc Clinic user with permission to [add/update query answers](#) (typically the **Investigator**), who will be responsible for resolving the query, as described in [Queries](#).



3.1.1 Pre-query states

The table below summarizes the different states of a pre-query in Viedoc Clinic, in the export output (Excel/Operational Data Model (ODM)), as well as the possible actions that can be performed on a pre-query and the state this will transition to.

In Viedoc Clinic	In export output	through...	becomes...
Awaits promotion	PrequeryRaised	Promote pre-query (by Monitor)	PrequeryPromoted (Ready for release)
		Reject pre-query (by Monitor)	PrequeryRejected (Rejected)
Ready for release	PrequeryPromoted	Release pre-query (by Monitor)	QueryRaised (Awaits answer)
		Reject pre-query (by Monitor)	PrequeryRejected (Rejected)
Rejected	PrequeryRejected	N/A. No action can be performed on a rejected pre-query.	N/A. Final state
Removed	PrequeryRemoved	N/A. No action can be performed on a removed pre-query.	N/A. Final state

3.2 Queries

The query process involves two different roles with different permissions in handling queries:

- One role with permissions to raise and approve queries, typically the **Monitor**.
- One role with permission to resolve queries, typically the **Investigator**.

A query is raised in Viedoc either when a query is manually added or when a pre-query is released.

An unlimited number of queries can be added on the same item at the same time.

The following image illustrates the main actions that can be performed on a query and all the states it goes through:

1. A query is raised through one of the following:

- Manually added query by a user with **add/change queries** permission
- When a pre-query is released. See [pre-queries](#) section above.
- When a validation query was resolved by confirming data as correct, and then rejected. See [Validation queries](#) section later on.

2. A raised query can be removed, for example if it is invalid or added by mistake.

3.a. The user with permission to **add/update subject/event/form data and query answers**, typically the **Investigator**, resolves the query by one of the following:

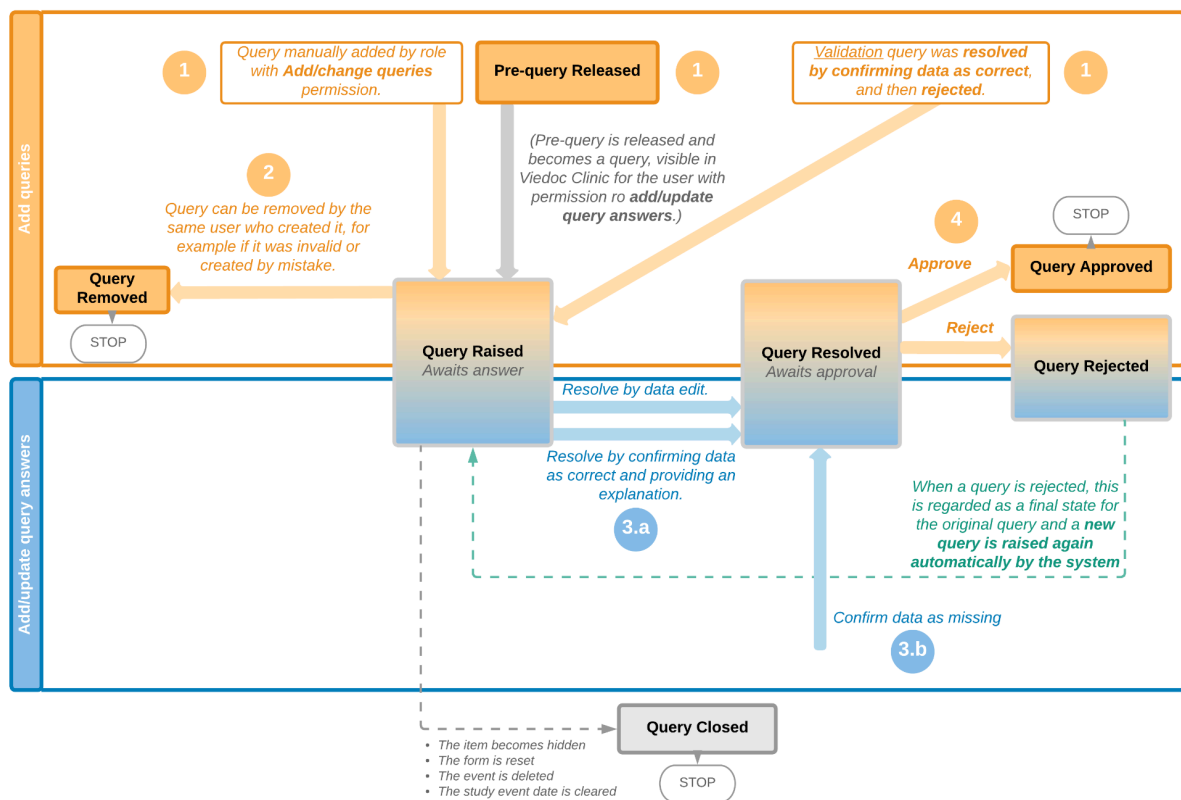
- Editing the data
- Confirming the data is correct and providing an explanation

3.b. When confirming data as missing, typically by the **Investigator**, this becomes a resolved query that awaits approval. This type of query can only be approved at step 4 below.

4. The user with permission to **add/change queries** can:

- **Approve** the resolved query.
 - **Reject** the resolved query. The old query becomes **Rejected** and a new query is raised.
- Note!** An exception is a query raised as a result of confirming data as missing by the site user (see 3.b. above). This type of query can only be approved.

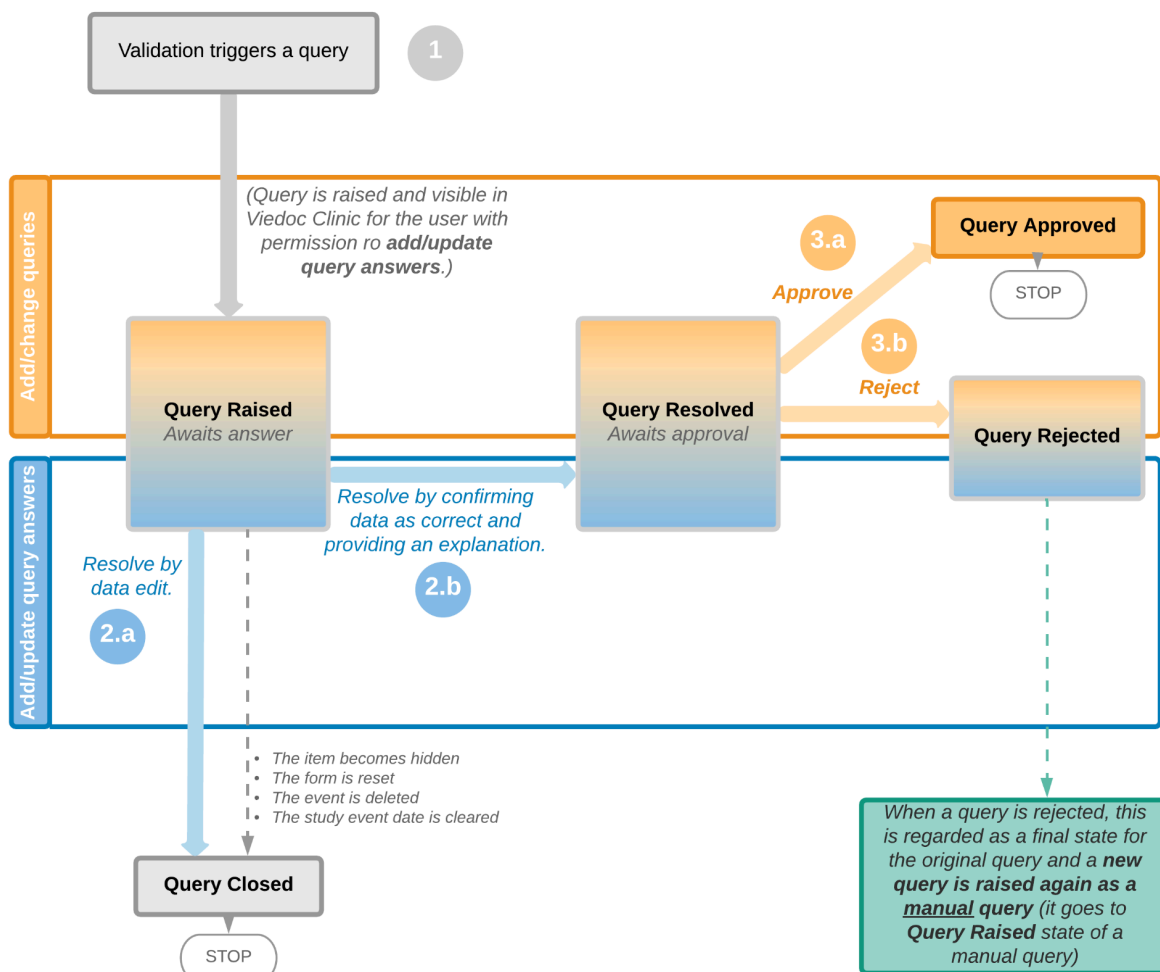
See also [Query states](#).



The following image illustrates the main actions that can be performed on a validation query and all the states it goes through:

1. A query is raised as a result of a validation performed by the system.
2. The user with permission to **add/update subject/event/form data and query answers**, typically the **Investigator**, resolves the query by one of the following:
 - a. Editing the data. As a result, the query is closed.
 - b. Confirming the data is correct and providing an explanation. The query is now resolved and waiting for approval.
3. The user with permission to **add/change queries** can:
 - a. **Approve** the resolved query.
 - b. **Reject** the resolved query. The old query becomes **Rejected** and a new query is raised and becomes a **manual** query. So from here it will follow the path of a manual query from the **Query Raised** state, as described earlier in [Manual queries > Queries](#).

See also [Query states](#).



5 Query states

The table below summarizes the different states of a query in Viedoc Clinic, in the export output (Excel/[ODM](#), as well as the possible actions that can be performed on a query and the state this will transition to.

Note! All the related queries are automatically closed, when:

- The item becomes hidden

- The form is reset
- The event is deleted
- The study event date is cleared (only queries raised on the study event date are closed)

In Viedoc Clinic	In export output	Through...	Becomes...
Awaits answer	QueryRaised	Remove query (by Monitor)	QueryRemoved (Removed)
		Edit query (by Monitor)	QueryRaised (Awaits answer)
		Resolve query (by Investigator)	QueryResolved (Awaits approval)
Awaits approval	QueryResolved	Approve query (by Monitor)	QueryApproved (Approved)
		Reject query (by Monitor)	QueryRejected (Rejected)
Rejected	QueryRejected	N/A. No action can be performed on a rejected query. Note! When a query is rejected, this is regarded as a final state for the original query and a new query is raised again automatically by the system.	N/A. Final state
Approved	QueryApproved	N/A. No action can be performed on an approved query.	N/A. Final state
Closed	QueryClosed	N/A. No action can be performed on a closed query.	N/A. Final state
Removed	QueryRemoved	N/A. No action can be performed on a removed query.	N/A. Final state

6 Queries in export output

In order to include the query information in the exported file, you need to select **Queries** under the **Type of data** in the Data export page. When selecting to include Queries, the **Query history** option becomes available.

The queries can be exported to the following export output formats:

- Microsoft Excel - Office Open Extensible Markup Language ([XML](#))
- Comma-Separated Values ([CSV](#))
- Operational Data Model ([ODM](#)) - in this case, the **Query history** is not optional, but will be included regardless. For this reason it is not displayed as an option.

Data Export

All sites Sweden

Subjects to include (21) +
All subjects ⊙

Events and time period +
All events ⊙

Forms and items +
All forms ⊙

Type of data -

Signed data ⊙ Not Signed data ⊙ SDV performed or NA ⊙ SDV pending ⊙ Queries ⊙ Query history ⊙

<input checked="" type="checkbox"/> Signed data	<input checked="" type="checkbox"/> Not Signed data
<input checked="" type="checkbox"/> SDV performed or NA	<input checked="" type="checkbox"/> SDV pending

In addition to data, also include the following in the export (will not be included in Preview data)

<input checked="" type="checkbox"/> Queries	<input checked="" type="checkbox"/> Query history
<input type="checkbox"/> Review status	<input type="checkbox"/> Medical coding
<input type="checkbox"/> Event dates	<input type="checkbox"/> Edit status
<input type="checkbox"/> Uploaded files	

For more details and instructions on how to perform an export, see [Exporting data](#).

6.1 Queries in ODM export

For details on how queries look in the [ODM](#) export see [Queries in ODM export](#).

6.2 Queries in Excel export

For details on how queries look in the Excel/[CSV](#) exported file see [Queries in Excel export](#).

7 Related topics

- [Role-based queries](#)
- [Raising and promoting pre-queries](#)
- [Raising/Approving/Rejecting queries](#)
- [Queries in ODM export](#)
- [Queries in Excel export](#)
- [Role-based queries](#)
- [Metrics](#)
- Video tutorial [Issues: Resolve a query](#)



Raising and promoting pre-queries

Raising and promoting pre-queries

Published by Viedoc System 2024-10-10

[1. Raising a pre-query](#)

[2. Promoting/Rejecting a pre-query](#)

[3. Releasing/Rejecting a pre-query](#)

For an overview of the entire query process see [Queries overview](#).

1 Raising a pre-query

To be able to raise a pre-query you must have the permission to **add pre-queries**, typically the Data Manager ([DM](#)).

To add a pre-query:

- 1 Open the form that contains the field the pre-query will be raised on.
- 2 Click the **+** icon in the top-right corner of the group that contains the respective field. The **Add new action** pop-up is displayed:
 - Select the field the pre-query will be added to from the drop down list.
 - Choose the type of action - **Add a pre-query**.
 - Enter the pre-query text.

- 3 Click **Ready**. The pre-query is created and needs to be promoted and released by the user with permission to promote pre-queries (typically the Monitor), in order to be visible as a query for the site staff.

The pre-query can be edited or removed (if invalid or created by mistake) by clicking the **Edit** or **Remove** links:

A **Removed** state is a final state for a pre-query.

A pre-query is always marked by this icon:



Once a pre-query has been promoted and released, it becomes a query and it is marked by this icon:



2 Promoting/Rejecting a pre-query


To be able to promote/reject a pre-query you must have the permission to **promote pre-queries**, typically the Monitor.

If there are any pre-queries that await promotion, these are marked as tasks. For details about tasks, see [Issues and tasks](#).

To promote a pre-query:

- 1 Browse to the task and open the respective pre-query that is marked with state **Awaits promotion**. A pop-up is displayed where you can either **Promote** or **Reject** the pre-query:

Result

 Is this the correct result? (pre-query)
By Demo User (317) 13 Aug 2018 15:29 CEST

Awaits promotion

Promote Reject

Close

- 2
 - To promote the pre-query, select **Promote** and click **Save query**. The pre-query will enter the **Ready for release** state.
 - To reject the pre-query, select **Reject** and click **Save query**. The pre-query state will be **Rejected**. This is a final state for a pre-query.

3 Releasing/Rejecting a pre-query

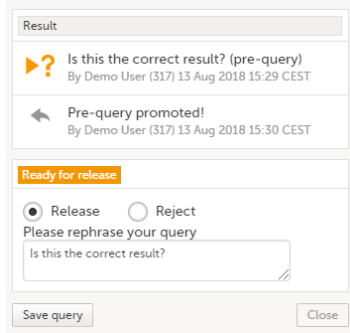
A pre-query can be released after it has been promoted, that is, a pre-query in **Ready for release** state.

A pre-query waiting to be released is marked as a task. For details about tasks, see [Issues and tasks](#).

After releasing a pre-query, this will become a raised query visible to the site staff. This is why, releasing a pre-query can be performed by a user with permission to add queries.

To release a pre-query:

- 1 Browse to the task and open the pre-query that is **Ready for release**. A pop-up is displayed where you can either **Release** or **Reject** the pre-query:



The screenshot shows a pop-up window with a 'Result' header. It contains two entries: 'Is this the correct result? (pre-query)' and 'Pre-query promoted!'. Below these is a section titled 'Ready for release' with radio buttons for 'Release' (selected) and 'Reject'. A text input field contains 'Is this the correct result?'. At the bottom are 'Save query' and 'Close' buttons.

- 2
- To release the pre-query, select **Release**, rephrase the query text if needed and click **Save query**. The pre-query will be released as a query to the site, with state **Awaits answer**.
 - To reject the pre-query, select **Reject** and click **Save query**. The pre-query state will be **Rejected**. This is a final state for a pre-query.

Note! When role-based queries is enabled for your study, when a pre-query is released, (typically by the Monitor):

- The new query visible for the site staff is considered as being raised by the same role that released the pre-query.
- Only that same role will be able to approve/reject the query resolution, for more information, see [Role-based queries](#).

For more information on pre-queries, see [Queries overview](#).



Raising/Approving/Rejecting queries

Raising/Approving/Rejecting queries

Published by Viedoc System 2024-10-10

[1. Adding a query](#)

[2. Editing a query](#)

[3. Removing a query](#)

[4. Approving/Rejecting a query](#)

[4.1 Approving a query](#)

[4.2 Rejecting a query](#)

For an overview of the entire query process see [Queries overview](#).

A query can be added/edited/removed/approved by the user with permission to add/change queries.

Note! When the role-based queries option is enabled for your study, all of the above actions are restricted to the same role as the role who raised the query. For more information, see [Role-based queries](#).

1 Adding a query

To raise a query:

- 1 Open the form that contains the field the query will be raised on.
- 2 Click the + icon in the top-right corner of the group that contains the respective field. The **Add new action** pop-up is displayed.
 - Select the field the query will be added to from the drop down list.
 - Choose the type of action - **Add query**.
 - Enter the query text.

Add new action

Choose type of action

Add a query ?

Add query text here

Is the event date correct?

Ready Cancel

- 3 Click **Ready**. The query was raised and it is now visible for the site and ready to be resolved, with state **Awaits answer**:

The screenshot shows a web interface for a clinical trial form. At the top, there is a blue header with 'SE-88-011', 'Home adm. [20 Jun 2022]', and a 'Close' button. Below the header, a message states 'Form is in read-only mode.' The main content area is titled 'Home adm.' and includes a 'SHOW HISTORY' button. The form contains two date fields: 'Protocol date' (12 Jun 2022- 19 Jun 2022) and 'Event date' (20 Jun 2022). A query is highlighted with a green box, showing a question mark icon, the text 'Event date Correct date?', a timestamp '(199) 27 May 2024 14:38 CEST', and a status 'Awaits answer'. At the bottom, there are checkboxes for 'Clinical review' and 'Lock', and a 'Form History' button.

After the query has been raised it can be:

- Resolved by the site (Investigator).
- Edited by any user with permission to add/change queries.
- Removed by any user with permission to add/change queries (in case the query was invalid or added by mistake).

2 Editing a query

The text of a raised query can be edited as long as the query was not resolved (**Awaits answer**).

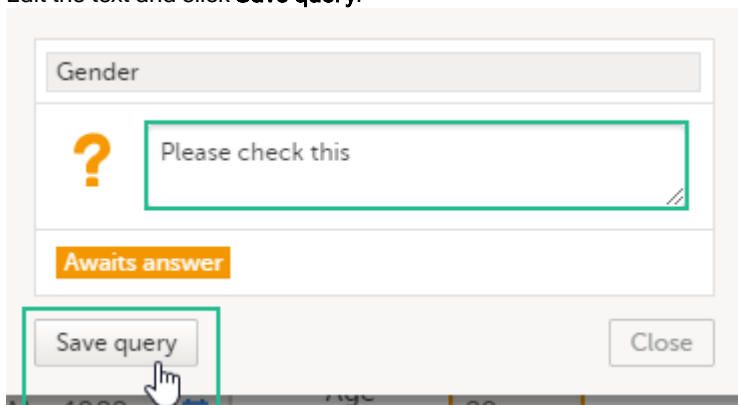
To edit a query:

- 1 Open the query (from the respective form) and click **Edit**:

The screenshot shows a query dialog box. At the top, there is a text input field containing 'Event date'. Below it, a question mark icon is followed by the text 'Is this date correct?'. The text 'By' is followed by a blurred name and the timestamp '(199) 27 May 2024 15:12 CEST'. Below this, there is a user icon and the name 'Monitor'. At the bottom of the dialog, there are two buttons: 'Edit' and 'Remove'. A status bar at the bottom of the dialog shows 'Awaits answer' in an orange box. A 'Close' button is located at the bottom right of the dialog.

Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see [Role-based queries](#).

- 2 Edit the text and click **Save query**:



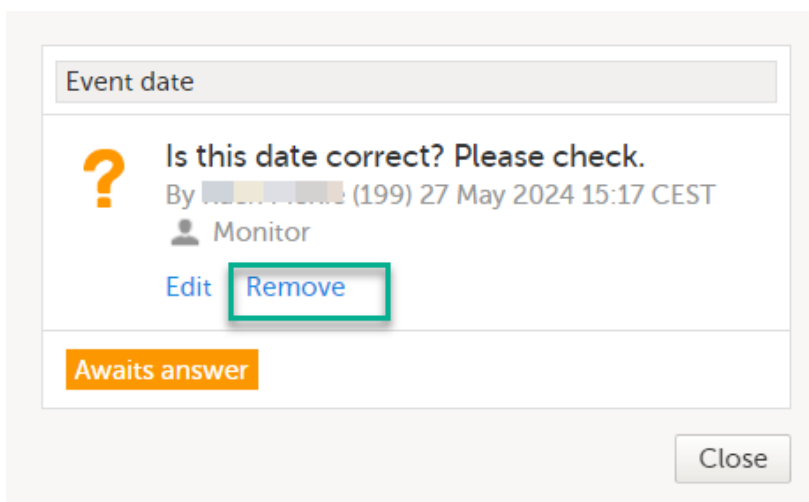
The query text is now updated.

3 Removing a query

A query can be removed, for example if invalid or added by mistake, as long as the query was not resolved (**Awaits answer**).

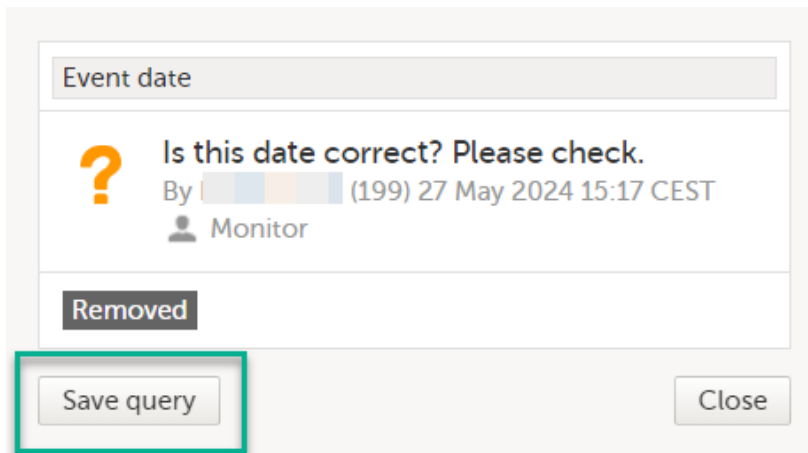
To remove a query:

- 1 Open the query (from the respective form) and click **Remove**:



Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see [Role-based queries](#).

2 Click **Save query** to confirm:

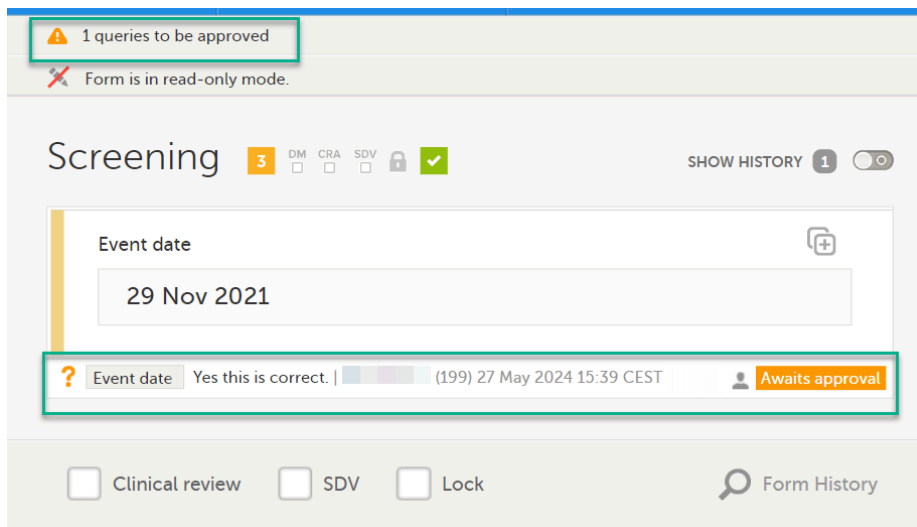


The query state is **Removed**. This is a final state for a query.

4 Approving/Rejecting a query

After the query was resolved by the site (typically the Investigator), it is marked as a task, it is in **Awaits approval** state and can be either approved or rejected.

Note! An exception is a query raised as a result of confirming data as missing by the site user. This type of query can only be approved.



4.1 Approving a query

To approve a query:

- 1 Open the query. The query pop-up opens displaying the list of the query history:

The screenshot shows a query pop-up window with the following content:

- Event date
- Is the event date correct?
By [redacted] 17 Sep 2021 11:11 CEST
- Data confirmed as correct!
Yes, the event date is correct.
By [redacted] 17 Sep 2021 13:05 CEST
- Awaits approval
- Approve Reject
- Close

- 2 Select **Approve** and click **Save query**:

The screenshot shows the same query pop-up window as above, but with the following changes:

- The **Approve** radio button is selected.
- The **Reject** radio button is unselected.
- A mouse cursor is pointing at the **Save query** button.
- The **Close** button is still present.

The query is now **Approved**. This is a final state for a query:

The screenshot shows the query pop-up window in its final state:

- Event date
- Is the event date correct?
By [redacted] 17 Sep 2021 11:11 CEST
- Data confirmed as correct!
Yes, the event date is correct.
By [redacted] 17 Sep 2021 13:05 CEST
- Answer approved!
By [redacted] 17 Sep 2021 13:19 CEST
- Approved
- Close

4.2 Rejecting a query

To reject a query:

- 1 Open the query. The query pop-up opens displaying the list of the query history:

Event date

Is this date correct? Please check.
By [Avatar] (199) 27 May 2024 15:17 CEST
Monitor

Data confirmed as correct!
Yes this is correct.
By [Avatar] (199) 27 May 2024 15:39 CEST

Awaits approval

Approve Reject

Close

Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see [Role-based queries](#).

- 2 Select **Reject**, optionally rephrase the query and click **Save query**:

Event date

Is this date correct? Please check.
By [Avatar] (199) 27 May 2024 15:17 CEST
Monitor

Data confirmed as correct!
Yes this is correct.
By [Avatar] (199) 27 May 2024 15:39 CEST

Awaits approval

Approve Reject
Please rephrase your query
Is this date correct? Please check.

Save query Close

The old query is closed with state **Rejected** and a new query is raised that **Awaits answer**:

Final Visit DM CRA SDV SHOW HISTORY

Protocol date
18 07 2021- 01 08 2021 25 07 2021(-7/+7)

Event date
21 07 2021

Event date 21 07 2021 Event initiated | By [Avatar] 22 Jul 2021 15:41 CEST

Event date Please check once more! | [Avatar] 17 Sep 2021 13:30 CEST **Awaits answer**

Event date Yes, the event date is correct. | [Avatar] 17 Sep 2021 13:28 CEST **Rejected**



Exporting data

Exporting data

Published by Viedoc System 2025-02-18

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[2.3 Events and time period](#)

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[2.3.2 Selecting a time period](#)

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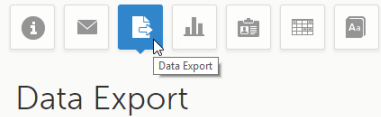
[8.19 Latest exports](#)

[9. Exporting Data FAQ](#)

1 Introduction

The Data Export page can be accessed by clicking the **Data Export** icon in the study start page:

A Demo Study



The Data Export page enables you to preview and download study data:

- **Preview** - Using the preview feature, you can review the data directly on the screen, and generate different types of graphs from the data. It is also possible to directly access the underlying electronic Case Report Form ([eCRF](#)) pages.
- **Export** - You can export the data to an external file for further analysis or archiving. Viedoc supports export of data to the following formats:
 - Excel
 - PDF
 - Comma-Separated Values ([CSV](#))
 - Statistical Analysis System ([SAS](#))
 - Operational Data Model ([ODM](#))

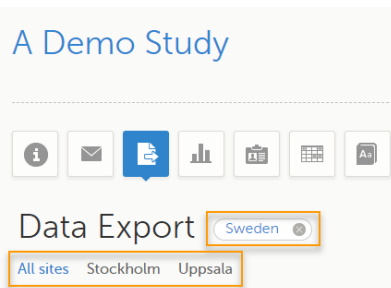
2 Filtering the data to be previewed/exported

You can filter the data that you want to preview/export, as described in the following sections.

2.1 Filtering data by country and site

If you have access to multiple sites, you can filter the data for a specific country or site.

To filter data for a specific country, click on the name of the country. The selected country appears in blue letters besides the **Data Export** header, while the site(s) for the selected country are listed below:



For a specific country, you can choose to export the data for:

- **All sites** (default)
- A specific site that you select. The current selection is highlighted in blue text.
Note! Only one site can be selected at a time.

To undo the selection of the site, click **All sites**.

To undo the selection of a country, click the cross **x** icon beside the name of that country.

While filtering for country or site, the number of subjects depicted in between brackets in the **Subjects to include** field is updated accordingly.

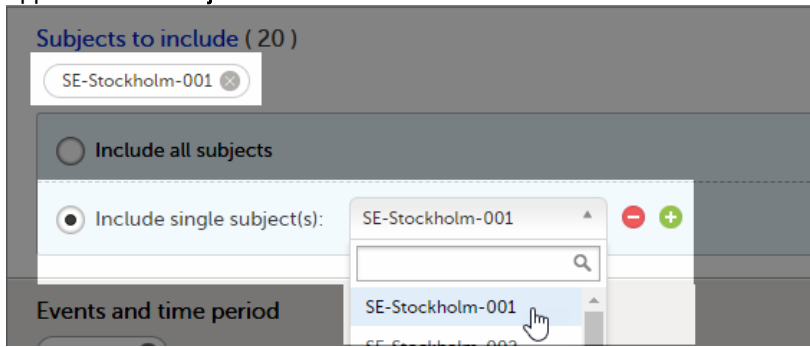
2.2 Including subjects

You can choose to include all subjects in the data preview or export, or include a selection of subjects.

To select which subjects to include:

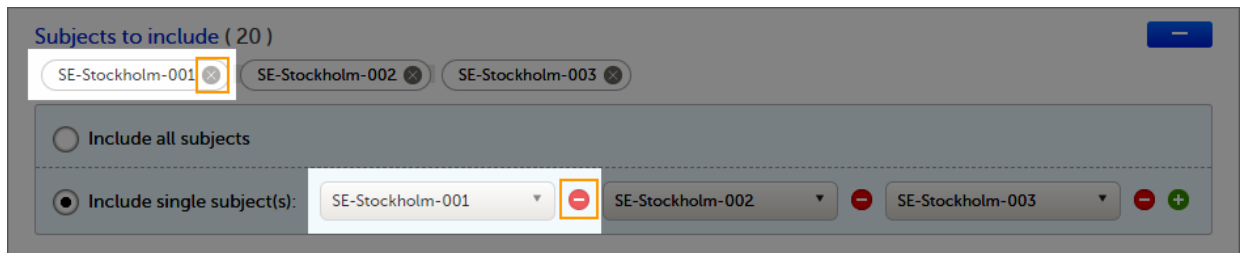
- 1 Select **Include single subject(s)**.

- 2 Click the + icon and select from the drop-down list the subject you want to add. The selected subject appears in the **Subjects to include** field:



Repeat this step for each subject you want to include in the data preview/export.

To undo the selection of certain subjects, click the - icon, or click the cross x icon next to the subject ID:



2.3 Events and time period

You can choose to include all the data or only for certain events. You can also filter the data added or edited during a certain time period.

Note! The available events are the ones existing in the latest design version applied on the first of the selected sites to be included in the export. If there are multiple design versions running for different of the selected sites, you have to select one site at a time in order to get the available events for the respective site.

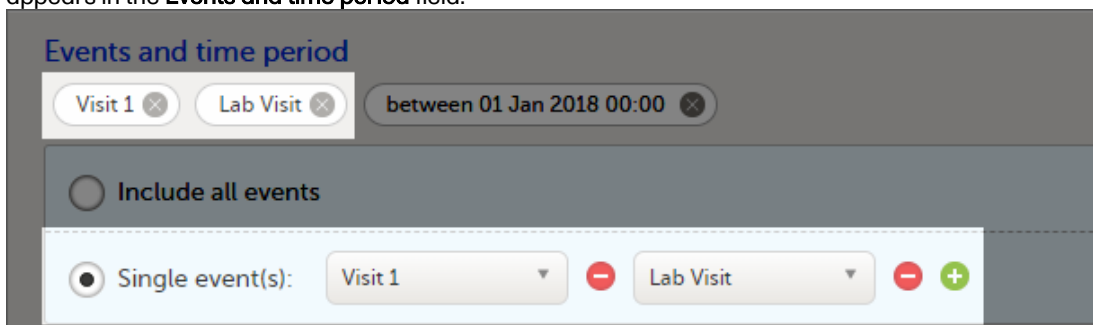
2.3.1 Selecting events

You can choose to:

- **Include all events** (default)
- Include **Single events**. See below the instructions for selecting single events.

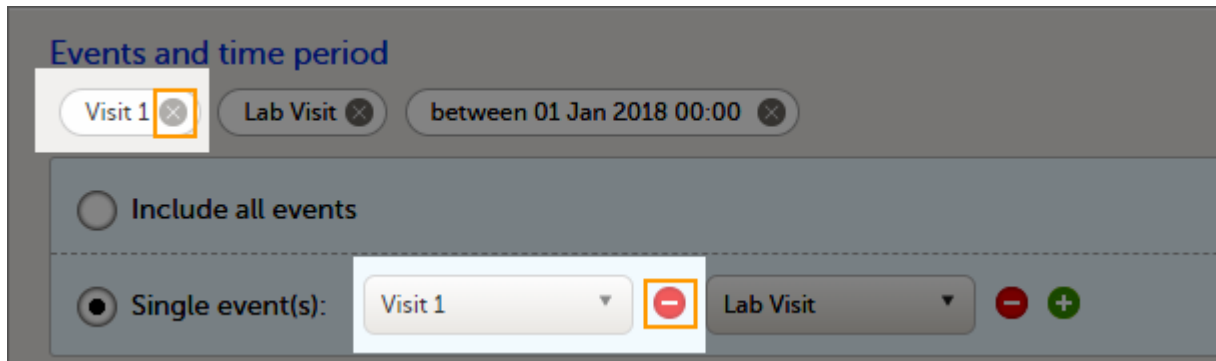
To select which events to include:

- 1 Select **Single event(s)**.
- 2 Click the + icon and select from the drop-down list the event you want to add. The selected event appears in the **Events and time period** field:



Repeat this step for each event you want to include in the data preview/export.

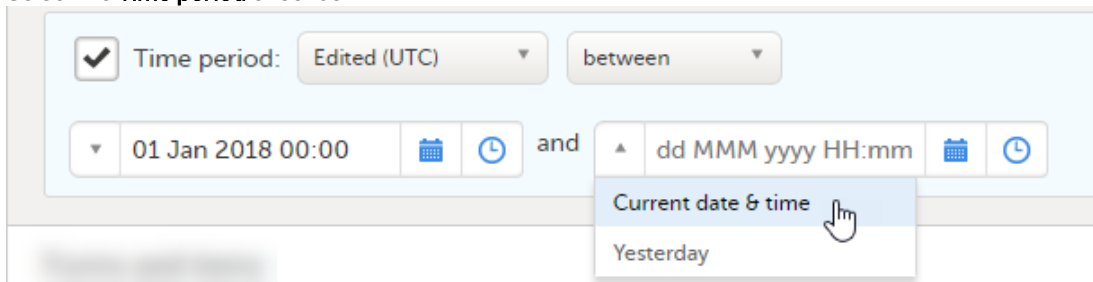
To undo the selection of certain events, click the  icon, or click the cross  icon next to the event:



2.3.2 Selecting a time period


To include data from a specific time period:

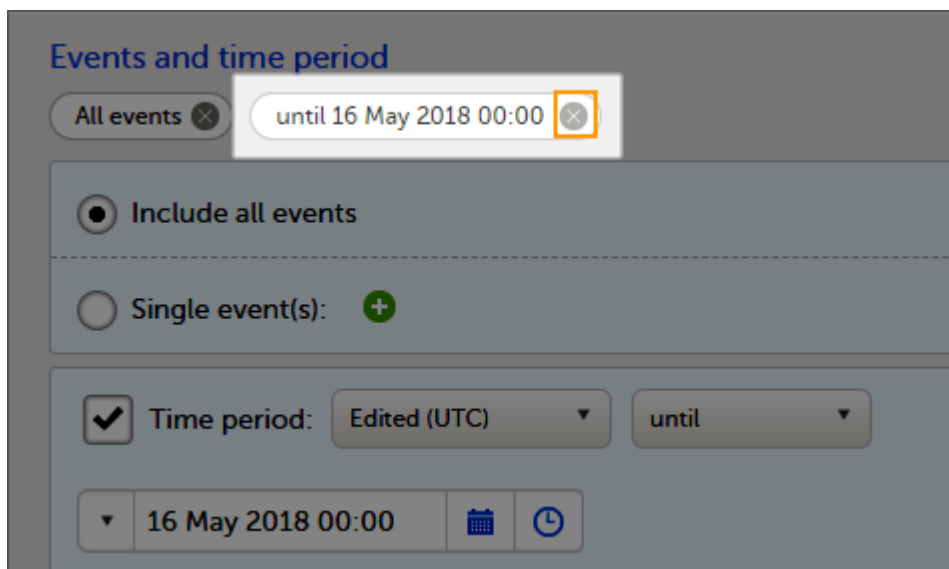
- 1 Select the **Time period** checkbox:



- 2 Select one of the following options from the first drop-down list:
 - **Edited (UTC)** - to include data based on the date they were added or last edited.
Note! This feature includes data based on Coordinated Universal Time (**UTC**), not on the local time a user has added or edited data. Note that also the time period should be specified in UTC.
 - **Event date** - to include data based on the event date.
- 3 Select whether to define the time period **until** a certain date, **from** a certain date, or **between** two dates.
- 4 Select the date(s).

Tip! Filtering for data that were added or edited since a specific date is especially useful if you want to see all new and changed data since for example your last monitoring visit.

To undo the selection of a certain time period, click the cross  icon next to it:



2.4 Forms and items

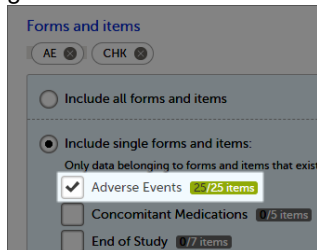
You can choose which forms and items to be included in the export output:

- **Include all forms and items** (default)
- **Include single forms and items** - see the instructions below on how to select forms and items.

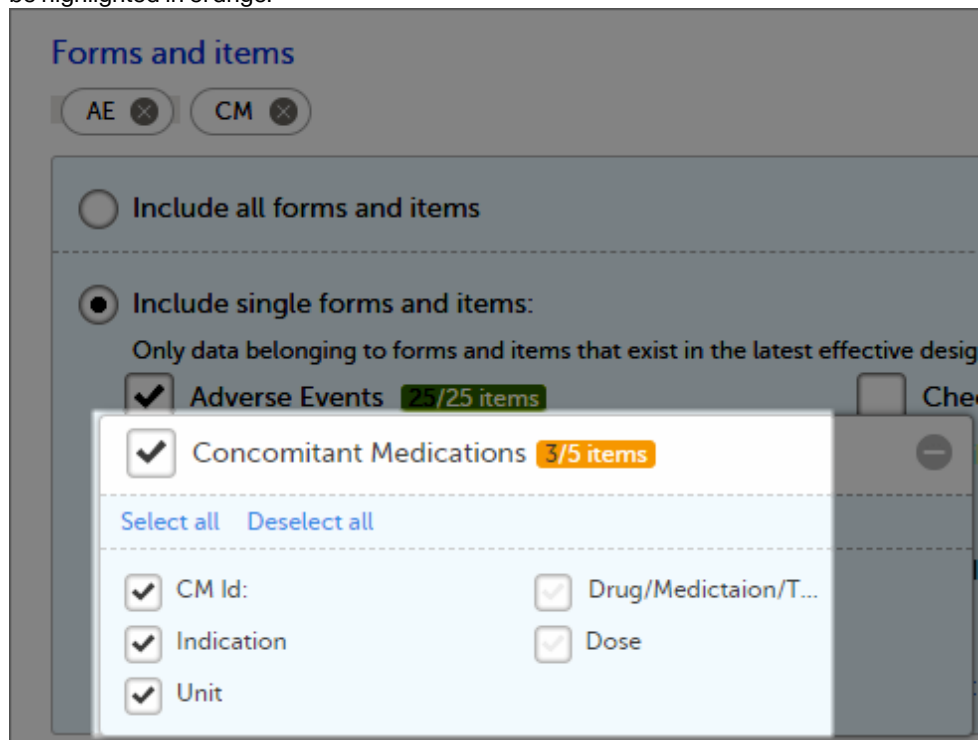
Note! Only data belonging to forms and items that exist in the latest effective design applied to the first of the selected sites will be included in the export. Also note that the forms and fields available to choose from are determined by the visibility settings for your user role.

To include data from specific form(s):

- 1 Select **Include single forms and items**.
- 2 Select the forms and items to be included, in one of the following ways:
 - Select the checkbox corresponding to a form in the list displayed, to include the respective form with all the items contained. The selected/total number of items will be highlighted in green:



- Click the field **[.]/[.] items** next to the form name, and select/deselect specific items. You can also use **Select all / Deselect all** for selecting/deselecting all the items in the form at once. If selecting only some of the items in the form, the selected/total number of items will be highlighted in orange:



To undo the selection of a certain form, click the cross **x** icon next to it:

2.5 Type of data

2.5.1 Filter data by review status

You can filter the data to be included in the export by the review status, as follows:

- **Signed data** (selected by default) - data that has been signed in Viedoc Clinic (typically by the Investigator). For information on how data is signed see [Signing data](#).
- **Not signed data** (selected by default) - unsigned data.
- **SDV performed or N/A** (selected by default) - data on which the Source Data Verification ([SDV](#)) was performed (marked by the SDV flag in Viedoc Clinic) and data that does not require SDV.
- **SDV pending** (selected by default) - data that requires SDV that was not performed (not yet marked by the SDV flag in Viedoc Clinic).

2.5.2 Additional information

You can select to include additional information, depending on the [export output format](#), as described in the following sections.

2.5.2.1 Booklet status

For PMS studies, there is an option to include booklet status and booklet status history in the export.

When selecting to include **Booklet status**, the **Booklet status history** option becomes available.

Depending on if the booklet status is included in the export or not, the export contains the following information:

- Without **Booklet history** - there is one row for each booklet, providing information about the current status of the booklet.
- With **Booklet history** - there is one row for each change in the booklet status, that is, there can be many rows for one and the same booklet.

Booklets in submitted status are not included in exports triggered by users on the sponsor side. The booklets are included to those users when they are received.

Note! Clinic actions to submit/recall back and forth are not available on the sponsor side. Only the latest submit of the booklet that was received by the sponsor is included.

If the **Booklet Status** is selected and the following options: **Require Responsible Investigator** for booklet submission, and **Require Contract** for booklet submission, are enabled for the study, two columns are added to the export.

- Contract number - of the selected contract for the specific booklet.
- Responsible Investigator - user name (internal ID) of the user selected as Responsible Investigator for the specific booklet.

If **Booklet history** is selected at export, the historically selected Contract and Responsible Investigator are included in the respective booklet status. The most recent contract information shall be shown, regardless of the booklet status.

Note! If the contract linked to a booklet is edited, the contract information is updated in the existing row for that booklet in the export performed *after the information was updated*.

The booklet status can be exported to the following export output formats:

- Microsoft Excel - Office Open [XML](#)
- [CSV](#)
- [ODM](#) - in this case, the Booklet history is not available.

When selecting to include **Booklet status** in the Excel export, a separate **Booklet status** sheet is created that lists all the forms with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Booklet sequence number	A counter that identifies the booklet within the sequence of booklets for the same subject
Booklet Id	The booklet ID, as set in the study design (in Viedoc Designer)
Booklet name	The booklet name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Booklet status	One of Not initiated, Initiated, Submitted, Received, Returned, or Frozen
Booklet activity	Initiated, Submitted, Recalled, Received, Frozen, Unfrozen, or Returned
Date & time (UTC)	The date and time of the status change
User name (ID)	The name (ID) of the user who changed the booklet status
Contract number	The number of the selected contract for the specific booklet. Note! This column is present in the export only if the option to link the booklet to a contract is enabled for the study.
Responsible Investigator	User name (internal userID) of the user selected as Responsible Investigator for the specific booklet. Note! This column is present in the export only if the option to link the booklet to a contract is enabled for the study.

2.5.2.2 Queries and Query history

When selecting to include **Queries**, the **Query history** option becomes available.

The Queries can be exported to the following export output formats:

- Microsoft Excel - Office Open Extensible Markup Language ([XML](#))
- [CSV](#)
- Operational Data Model [ODM](#) - in this case, the **Query history** is not optional, but will be included regardless. For this reason it is not displayed as an option.

See also:

- [Queries in ODM export](#)
- [Queries in Excel export](#)

2.5.2.3 Review status

The review status can be exported to the following export output formats:

- Microsoft Excel - Office Open [XML](#) - when selecting **one row per item** as **Layout**, the review status is not included in the export.
- [CSV](#) - when selecting **one row per item** as **Layout**, the review status is not included in the export.
- PDF - PDF Archive ([PDF/A](#)) - only the signature information is included (not SDV, lock status, or CRA review status).
[ODM](#)

See also:

- [Review status in ODM export](#)
- [Review status in Excel export](#)

2.5.2.4 Event dates

The event dates can be exported to the following export output formats:

- Microsoft Excel - Office Open [XML](#)
- [CSV](#)
- [ODM](#)

When selecting to include **Event dates** in the Excel export, a separate **Event dates** sheet is created that lists all the events with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event Id	The event ID, as set in the study design (in Viedoc Designer)
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Event status	The current status of the event. It can be one of the following: <ul style="list-style-type: none"> ▪ <i>Initiated</i> ▪ <i>Proposed</i> ▪ <i>Not Initiated</i> ▪ <i>Planned</i>
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Planned date	The event planned date, as set in Viedoc Clinic when the event is planned
Proposed date	The proposed date for the event, if set in the study design
Window start date	The event time window start date, if set in the study design.
Window end date	The event time window end date, if set in the study design
Initiated by	The name and ID of the user who initiated the event
Initiated date (UTC)	The date and time (UTC) when the event was initiated
Last edited by	The name and ID of the user who last edited the event
Last edited date (UTC)	The date and time (UTC) when the event was last edited

Column name	Description
Design version	The design version/revision that is active for the event

2.5.2.5 Uploaded files

When selecting the **Uploaded files** option, the uploaded file together with the thumbnail (if it exists) are part of the Excel, CSV and PDF export output:

- **Excel** - the export file (.xls) together with all the referenced file uploads are included in a zip file.
- **CSV, PDF** - A folder with all the referenced file uploads is included in the export zip file.
- When you select **Include history** (available only for **one row per item**), the current version of the uploaded file will be included as usual, and the previous versions of the files will be stored in subfolders named as the *Edit sequence number*.

The export output (Excel, PDF, [CSV](#), [ODM](#)) as well as the **Data preview** provides the following information about uploaded files:

- File Name
- File Size (in bytes)
- File Hash
- Path to where the actual file is located in the exported zip file

The following information on the uploaded file is available in the full history:

- Who has uploaded the file
- Upload date
- Initial/Updated (first file uploaded/update of an existing file)
- File Name
- File Size (in bytes)
- File Hash (MD5)
- Link to file

2.5.2.6 Pending forms

The pending forms can be exported to the following export output formats:

- Microsoft Excel - Office Open [XML](#)
- [CSV](#)

Forms are considered pending when they are uninitiated in initiated events. This applies to all types of events, including subject-initiated events. For repeating forms, if the first instance of the form is uninitiated, the form is considered pending. Resetting a form results in that form being pending.

When selecting to include **Pending forms** in the Excel export, a separate **Pending forms** sheet is created that lists all the forms with the following information:

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	A counter that identifies the event within the sequence of events for the same subject
Event Id	The event ID, as set in the study design (in Viedoc Designer)

Column name	Description
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer)
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Form Id	The form ID, as set in the study design (in Viedoc Designer)
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Pending since	The date and time since when the form has been pending This is not always the date when the event was initiated. For a form that has been hidden due to a visibility condition, the pending since date is the date when the form is made available.

2.5.2.7 Medical coding

The medical coding can be exported to the following export output formats:

- Microsoft Excel - Office Open [XML](#). For details, see [Medical coding in Excel export](#).
- [CSV](#) - similar output information as in Excel.
- [ODM](#) - for details, see [Medical coding in ODM export](#).

2.5.2.8 Edit status

The edit status can be exported to the following export output formats:

- Microsoft Excel - Office Open [XML](#)
- [CSV](#)
- PDF - [PDF/A](#)
- [ODM](#)

2.5.2.9 Subject status

The subject status can be exported to the following export output formats:

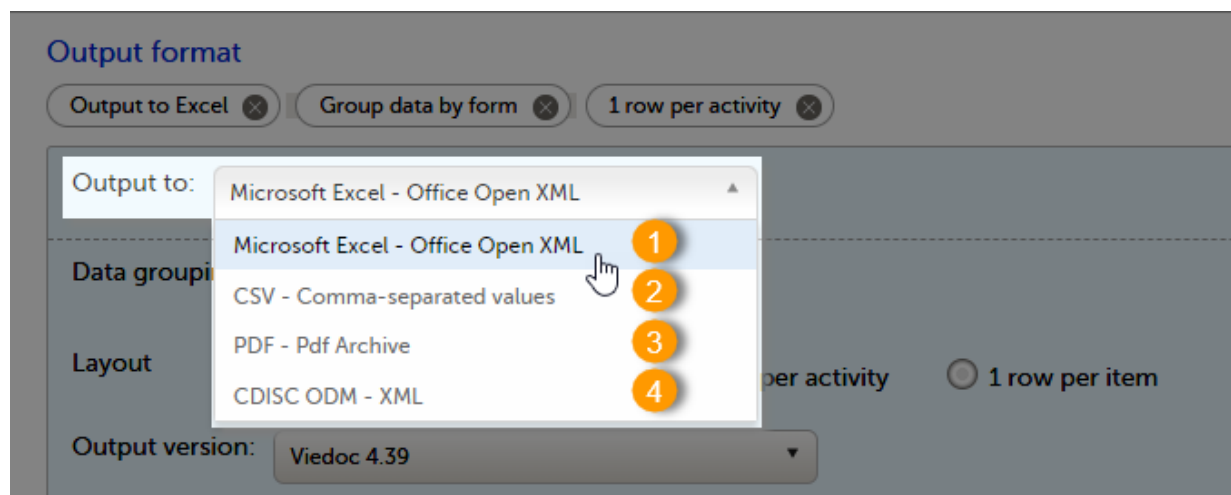
- Microsoft Excel - Office Open [XML](#)
- [CSV](#)
- [ODM](#)

The sheet **Calculated subject status** contains the following columns:

- Site sequence number
- Site name
- Site code
- Subject sequence number
- Subject Id
- Screened state
- Screened on date/datetime (site local)
- Enrolled state
- Enrolled on date/datetime (site local)
- Completed state
- Completed on date/datetime (site local)
- Withdrawn state
- Withdrawn on date/datetime (site local)

3 Export output formats

Select the export output format of the data under **Output format** > **Output to**:



You can export the data to one of the following formats:

1. Microsoft Excel - Office Open [XML](#)
2. [CSV](#)
3. PDF - [PDF/A](#)
4. [ODM](#)

3.1 Microsoft Excel / CSV

Viedoc uses Microsoft Excel Open [XML](#) format which is compatible with Excel version 2007 and later.

For details about the Excel export options and the format/structure of the output file, see [Excel export](#).

3.2 CSV

The output of the [CSV](#) export is similar to the Excel export output. The CSV export output consists of a zip archive containing one CSV file that corresponds to each sheet from the Excel export. For details about the Excel export options and the format/structure of the output file, see [Excel export](#).

For the CSV export and **one row per activity** selected layout, there is also the option to **Include corresponding SAS script**. For details, see [Exporting for SAS](#).

3.3 PDF

For details about the PDF export and the format/structure of the output file, see [PDF export output](#).

3.4 CDISC ODM

The Clinical Data Interchange Standards Consortium ([CDISC](#)) Operational Data Model ([ODM](#)) is a vendor neutral, platform independent format for interchange and archive of clinical trials data. The format includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long-term retention as part of an archive is included in the model.

This is used for exporting the data to an [ODM](#) file, with or without Viedoc extensions. To include the Viedoc extensions in the exported file, select the **Include extensions** checkbox. Viedoc extensions are Viedoc-specific settings that cannot be described as part of the CDISC standards. If the exported file is to be imported to Viedoc at a future time, the checkbox should be selected.

Select **SAS compliant XML** to automatically populate the SAS field name and the SAS dataset name.

The ODM export file is built up as follows:

- The `Study` tag contains the information on the study settings, study design, workflow.
- The `AdminData` contains data about the user and site settings.
- The `ClinicalData` tag contains the data that was filled in in Viedoc Clinic.
- The `Association` tag contains information about the performed actions such as [SDV](#), raising and approving queries, medical coding, lock, [CRA](#) and [DM](#) reviews.

See also:

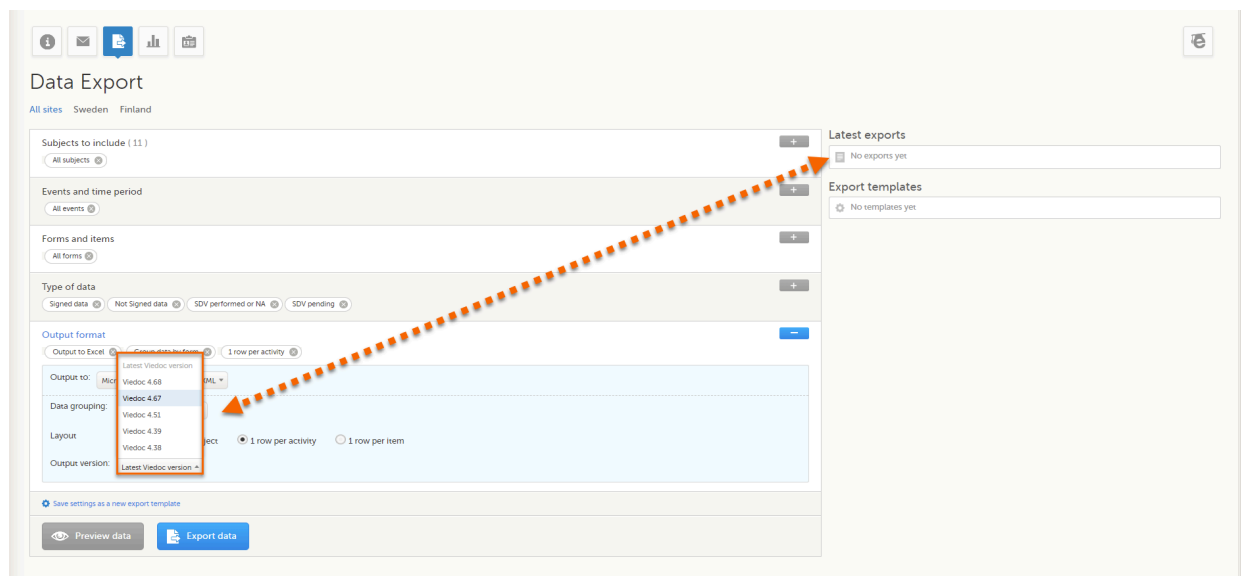
- [Queries in ODM export](#)
- [Medical coding in ODM export](#)
- [Review status in ODM export](#)
- [Excel export](#) (See for more information on how to export Audit trail history.)

4 Export compatibility with previous Viedoc versions

It is possible to select the Viedoc version that the exported file should be compatible with. This option enables you to export files that have the same format as files exported from previous Viedoc versions.

Note! This functionality is optional and set in the study settings in Viedoc Admin. It might not be activated for your study.

If activated for your study, you can select the Viedoc version that you wish the exported file to be compatible with under **Output format and export**, from the **Output version** drop-down menu. If you wish to create an export file according to the latest Viedoc version, select **Latest Viedoc version**:



The Viedoc version used for data export is listed in the **Latest exports** area on the right side of the export page.

The exported file contains information about which Viedoc version was used to create it. You can find information about the Viedoc version in the following places:

- For Excel, the Viedoc version used is displayed in the *README* sheet.
- For [CSV](#), the Viedoc version used is displayed in the *README* text file.
- For PDF, the Viedoc version used is displayed on every page in the footer or side bar.
- For [ODM](#), the Viedoc version used is displayed in the *Export version* extension.

4.1 Output versions

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

As of Viedoc release 4.79, the following output versions are available:

Output version	Changes in data structure
Latest Viedoc version	When choosing Latest Viedoc version , the exported data will automatically follow the structure of the latest Viedoc release in which changes to the data structure were introduced.
Viedoc 4.79	Introduction of a number of changes to the ODM data export. See the table below for details.
Viedoc 4.77	For studies where item-level SDV is enabled, when exporting review status, the SDV sheet in the CSV and Excel data exports will include only the items that require SDV and are visible to the user. On the Review status sheet, items that do not require SDV are indicated with N/A.
Viedoc 4.68	Introduction of pdf archive export system check which splits the archive into one pdf file per subject and stores resultant PDF in a zip file.
Viedoc 4.67	Introduction of two new columns for approving medical coding: "approved by" and "approved on date".
Viedoc 4.51	Introduction of three new form repeat keys and the table of contents in the PDF export, see the table below for details
Viedoc 4.39	Introduction of repeating forms and recurring events, see the table below for details.
Viedoc 4.38	Original output format (Viedoc versions 4.38 or older).

In **Viedoc 4.79**, the following changes to the export output were introduced:

File type	Changes in the export output format
ODM	<p>Introduction of support for partial datetime, date, and time. This is now the default type when exporting designs and data in ODM format. Partial dates as per the ISO 6801 standard are written up to the most detailed value available.</p> <p>This makes the export compliant with CDISC ODM.</p>
ODM	<p>When exporting a design to ODM, multi-selection code lists are handled as follows:</p> <p>Checkbox item definitions are split by code list items.</p> <ul style="list-style-type: none"> ▪ During metadata export, checkbox ItemDef is replaced with one for each code list item. ▪ For clinical data export, the comma-separated values are replaced for the checkbox with ItemData for each respective value. <p>For example, when splitting a checkbox ItemDef with OID="CHK" and code list IDs "Yes" and "No", the split checkbox ItemDefs will have the OIDs "__CHK__Yes" and "__CHK__No", respectively. That is, the original OIDs and the code list IDs are prefixed with two underscore characters and separated by two underscore characters.</p> <p>In Viedoc Designer, checkbox items are exported as multiple ItemDefs - one for each selection value. In Viedoc Clinic and the Viedoc API: In the latest export version, checkboxes are exported as separate items for metadata and clinical data. In previous export versions, checkboxes are exported as one item.</p> <p>This has been introduced to be compliant with CDISC ODM.</p>

File type	Changes in the export output format
ODM	<p>Bug fix: In the ODM data export, the content of the Question element for study event items and booklet forms was not complete. According to the CDISC standard, the element should include one of the TranslatedText attributes. This is now solved, and the Question element is populated with a string related to the corresponding OID.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the MeasurementUnit.Name contained HTML code, making it non-compliant with the CDISC standard. This is now solved, and the HTML code is removed from the name.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the translated text was missing for meta.Protocol.Description.TranslatedText. This is now solved, and the body is populated with the protocol name, as visible on the design overview page.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the Length attribute was incorrect, making it non-compliant with the CDISC standard. This is now solved, and Length is populated as per the ItemDef data type.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, there was a mismatch between the item data type and the code list data type for checkboxes. This is now solved, and the checkbox data is split into different items, in the same way as for CSV and Excel exports.</p> <p>This is implemented in a new export version, version 4.79.</p>
ODM	<p>Bug fix: In the ODM data export, the study OID and ClinicalData didn't respect the Production/Demo mode for sites. This is now solved, and the study OID and ClinicalData are populated based on the Production/Demo mode of the exported study.</p> <p>This is applied without a new export version.</p>
ODM	<p>Bug fix: In the ODM data export, non-repeating forms included a repeat key, making the ODM data export non-compliant with the CDISC standard. This is now solved.</p> <p>This is implemented in a new export version, version 4.79.</p>
ODM	<p>Bug fix: In the ODM data export, the KeySet elements had an unregistered value for the ItemOID attribute, making the ODM data export non-compliant with the CDISC standard. This is now solved, and the KeySet elements reference items within the same MetadataVersion.</p> <p>This is implemented in a new export version, version 4.79.</p>
ODM	<p>Bug fix: In the ODM data export, the attribute OrderNumber of the element StudyEventRef was not valid with respect to its type, integer. This is now solved, and StudyEventRef elements have unique and non-empty consecutive order numbers.</p> <p>This is applied to all export versions.</p>

File type	Changes in the export output format
ODM	<p>Bug fix: In the ODM data export, there was a data type mismatch between CodeList and ItemDef, making the ODM data export non-compliant with the CDISC standard. This is now solved by always having a matching data type between ItemDef and CodeList.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the element MeasurementUnitRef had an unregistered value for the MeasurementUnitOID attribute, making the ODM data export non-compliant with the CDISC standard. This is now solved, and measurement units not referenced in any MetaDataVersion are not included in the ODM data export.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the Alias names were not correctly populated. This is now solved, and any code list item aliases with empty names are removed at import and export - and the Alias names are populated with the context values.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the SAS field name and the SAS dataset name were not populated. This is now solved, and the SAS field name is populated based on the ItemDef OID, and the SAS dataset name is populated based on the FormDefOID, which means that the OIDs are SAS-compliant. There is an option for this in the data export.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, revisions linked to study events and revisions linked to forms requiring approval of the new design revision were not included. This is now solved.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, alerts had repeating order numbers. This is now solved, and the order numbers for all study settings alerts in Viedoc Designer are removed.</p> <p>This is applied to all export versions.</p>
ODM	<p>Bug fix: In the ODM data export, the item group containing the reference data items was not added to the MetaDataVersion. This is now solved.</p> <p>This is applied to all export versions.</p>

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

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

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

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

5 How study design impacts data export

When exporting data from Viedoc, the system determines the available events, forms, and data points based on the **study design version** applied to the **first selected site**. Understanding how this works is important when a study includes sites with different study designs or multiple design versions.

What happens when study designs differ?

If a study contains multiple study designs or different versions across sites, the exported data is structured based on the design of the first selected site. This means:

- The **available events** in the export are those that exist in the latest design version applied to the **first site selected**.
- The **forms and items** included in the export are those that exist in the latest effective design applied to the **first selected site**.
- The **columns (data points)** in CSV/Excel exports reflect the latest effective design used by the **first selected site**.

What does "first selected site" mean?

The first selected site is the **first site in the study** that is chosen for export. The exact determination depends on:

- The order in which sites appear in the selection list.
- The default site selected when multiple sites are chosen.
- The system logic (which may use the site with the lowest ID or first site in a country, if applicable).

Example: If a study has sites in **Germany, Sweden, United States, and Japan**, and Germany is the first selected site, the export will be based on the latest design version applied to the first site in Germany.

Selecting multiple sites with different study designs

If multiple sites are selected and they have **different design versions**, users must:

- Select **one site at a time** to get events and forms applicable to that site's specific design.
- Be aware that selecting multiple sites with different designs may result in missing or misaligned data.
- Verify design versions with an **Admin** if unsure which design applies to a site.

Best practices to ensure accurate exports:

- Check in Viedoc Admin if all sites have the same current effect design version before exporting data.
- If all sites are on the **same design version**, then it is fine to export all sites at the same time.
- If sites have **different design versions**, perform individual exports for each design version.
- Review exported data against the annotated CRF (link) or complete configuration report (link) of the design version to ensure completeness and consistency.

Note! User visibility settings affect data exports. If an item is missing, check that your user role has the necessary permissions, and that the item exists in the latest design version applied to the first selected site.

Example scenario: How study design affects data export

Scenario: A study has Site A using **Design Version 1.0**, and Site B using **Design Version 2.0**. When exporting data:

- If Site A is selected first, the export includes only forms and events from **Design 1.0**.
- If Site B is selected first, the export includes only forms and events from **Design 2.0**.
- If both sites are selected together, the system may only include data compatible with the first selected site's design.

6 Previewing data

The **Preview data** button is only available when you have selected **Excel** or **CSV** as output format for the export.

The preview is not available when you have selected **1 row per item**.

6.1 Data table

On the data tab, you can preview the data in table format:

The screenshot shows the 'Export Data Preview / AutoRecurring' window. At the top, there are icons for different views and a 'Close' button. Below the icons, there are three callouts: 1 points to the 'Included forms' dropdown menu (set to 'Screening Diary / SCRD'), 2 points to the 'Filter' search box, and 3 points to a view toggle button. The main area is a table with columns: Site name, Site code, Subject Id, Event name, Event date, Activity name, and Completion period. Each column has a dropdown arrow. Callout 4 points to the 'Event date' column, 5 to the 'Activity name' column, and 6 to the 'Subject Id' column. The table contains 15 rows of data for 'AutoRecur1' at site 'AR1', with 'Screening - Visit 1a' events from 2018-01-15 to 2018-01-17. Callout 7 points to the 'Completion period' column. At the bottom left, there is a 'Cross-check' checkbox and callout 8 points to it. The bottom right shows 'Rows: 1,009'.

Site name	Site code	Subject Id	Event name	Event date	Activity name	Completion period
AutoRecur1	AR1	AR1-50001	Screening - Visit 1a	2018-01-15		Prior to or during the BPS
AutoRecur1	AR1	AR1-50002	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50003	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50004	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50005	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50006	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50008	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50009	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50010	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50013	Screening - Visit 1a	2018-01-17		Prior to or during the BPS
AutoRecur1	AR1	AR1-50014	Screening - Visit 1a	2018-01-17		After the BPS
AutoRecur1	AR1	AR1-50015	Screening - Visit 1a	2018-01-17		Prior to or during the BPS

1. If you have selected **Group data by form**, you can select the form for which you want to display data.

2. Use the **Filter** text box to filter the preview data by any text in any field. The preview is filtered on all words in this field.

3. Toggle between spacious view and compact view.

4. Click a column header to sort the data in ascending order. Click again to sort in descending order. A third click removes the column sort order. To rearrange the order of the columns in the table, simply click on a column header and drag the column sideways.

5. Click to open the column menu. For more information, see [Column menu](#).




6. Click to access the column filter. For more information, see [Column filter](#).

7. Click any hyperlink data point in the table to view the underlying form in read-only mode.

8. Select **Cross-check** to display a second data table. This lets you cross-check data between the two tables. Form selection and the filtering and sorting of data in the second table are independent of the settings in the first table.

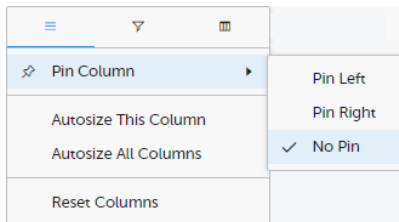
6.1.1 Column menu

The column menu contains:

- column display options 
- column filter 
- column selection options 

For more information, see the following sub-sections.

6.1.1.1 Column display options



Pin Left/Right makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select **No Pin** to unpin the column.

Autosize adjusts the column width to the width of the text in the column.

Reset Columns resets the pinning, sizing, and order of columns to the initial state.

6.1.1.2 Column filter

Use the column filters to narrow down the selection of preview data.

1. Depending on the type of item in the column, you can specify one of these types of filters:

- **Text filter** with the following filter operators:
 - Contains
 - Not contains
 - Equals
 - Not equal
 - Starts with
 - Ends with

Form items that are radio buttons, drop-down menus, checkboxes, dates, or date/time items are treated as text.

Note! The text filters are case-insensitive.

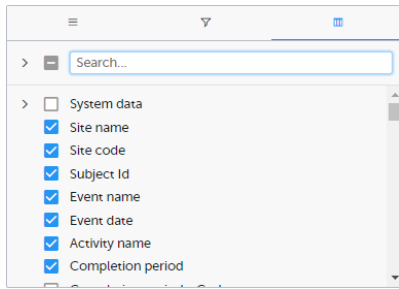
- **Number filter** with the following filter operators:
 - Equals
 - Not equal
 - Less than
 - Less than or equals
 - Greater than
 - Greater than or equals
 - In range

2. Once you have specified a filter, you can specify another one for the same column, either as an **AND** filter or an **OR** filter.

3. Predefined filter options based on the data available in the column.

6.1.1.3 Column selection options

Select the columns to be displayed in the preview table.



Use the **Search** field to search for columns.

By default, system data is excluded from the table. To include system data, select the column(s) to include from the **System data** category. Note that some system data columns are only available when you have selected 1 row per activity. For more information, see [Excel export](#).

6.1.2 Data table context menu

When you right-click in a cell in the data table, this context menu is displayed:



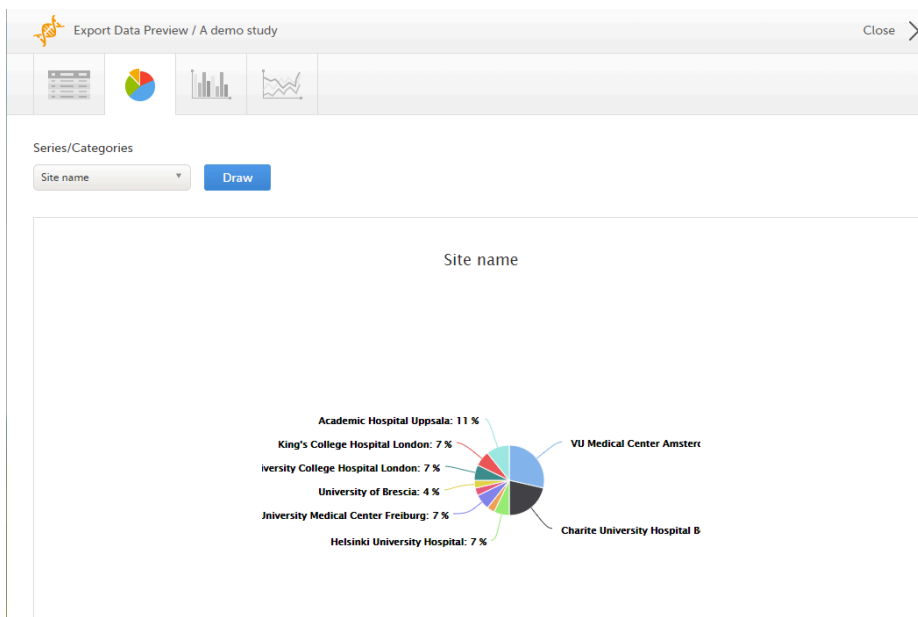
Copy: Copies the cell value to your clipboard.

Copy with Headers: Copies the cell value and its column header to your clipboard.

Excel Export: Exports the preview data on the data tab. The resulting Excel file will have the same sorting and filtering of data and order of columns as the preview.

6.2 Pie chart

Select the data set you wish to plot in a chart, and click **Draw**:



If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any data point to view its details.

Note! The pie chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the pie chart.

6.3 Column chart

Select which data you would like to plot on the X-axis and Y-axis, which series should be created, and click **Draw**:



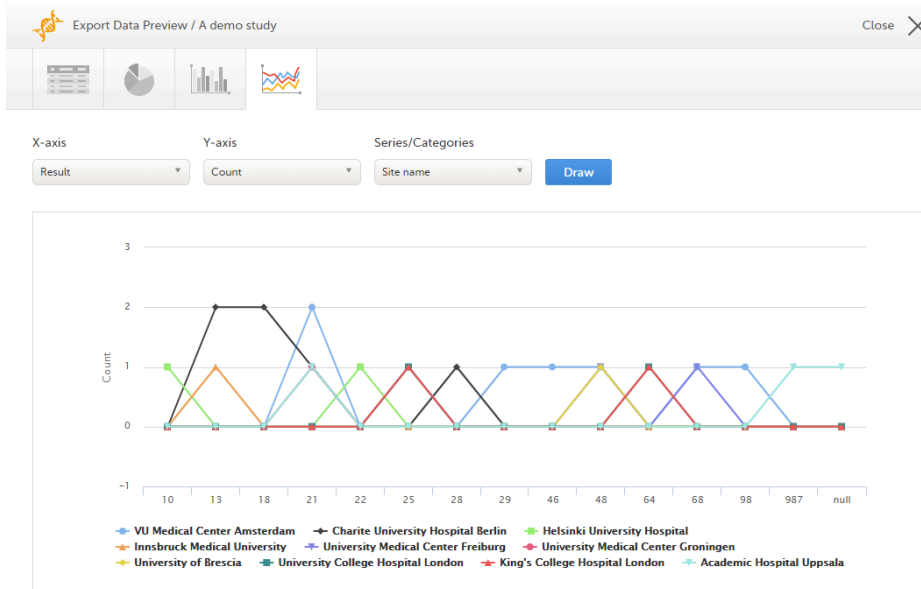
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any column to view details of the data.

Note! The column chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the column chart.

6.4 Line chart

Select which data you would like to plot on the X-axis and Y-axis, which series should be created, and click **Draw**:



If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Note! The line chart has access to the same data as the data tab. That means that if you applied filters on the data tab, only the filtered data will be available in the line chart.

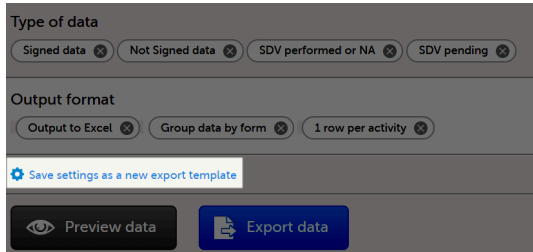
7 Data export templates

When you have made settings for an export, you can save them as a template. Then you, and optionally others, can use the template to easily make new exports with the same settings.

7.1 Saving export settings as a template

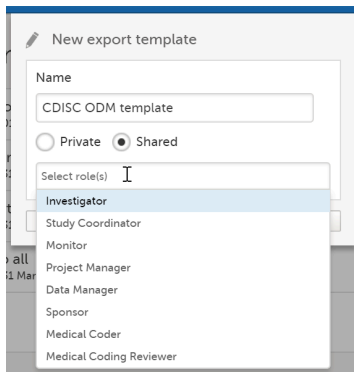
To save your settings as a template:

- 1 Click **Save settings as a new export template**.

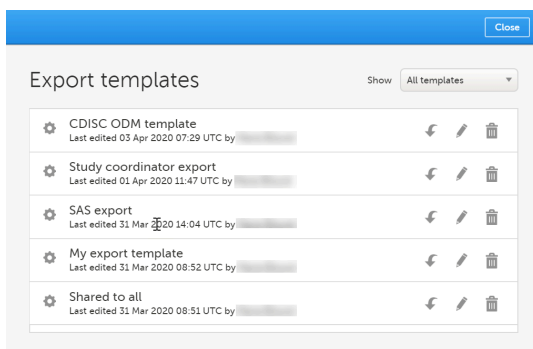


- 2 In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

If you select **Shared**, you are prompted to also select the roles that will be able to use the template. The roles available in the drop-down list are the ones with export permissions for the latest effective design of the study in question.



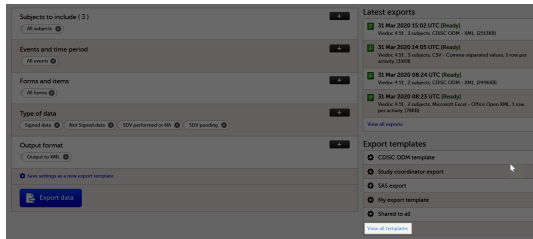
- 3 Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:



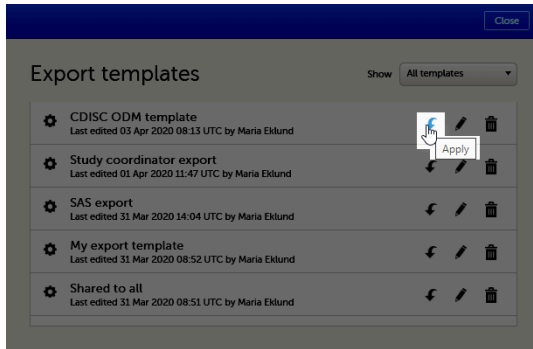
7.2 Applying a data export template

To apply a data export template:

- 1 Click **View all templates** in the **Export templates** area of the **Data export** page.

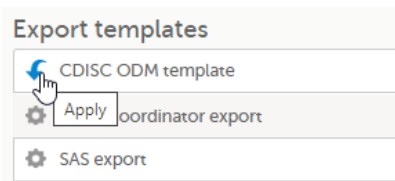


- 2 Click the apply icon for the template that you want to apply.



- 3 Click **Export data** to perform an export with the settings in the template.

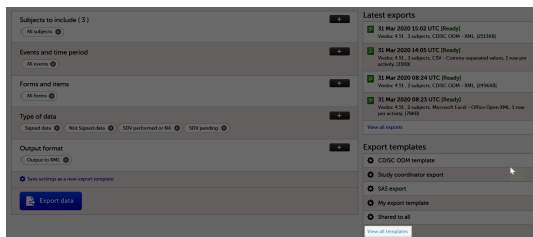
Tip! Alternatively, you can use the quick access apply, available in the **Export templates** area:



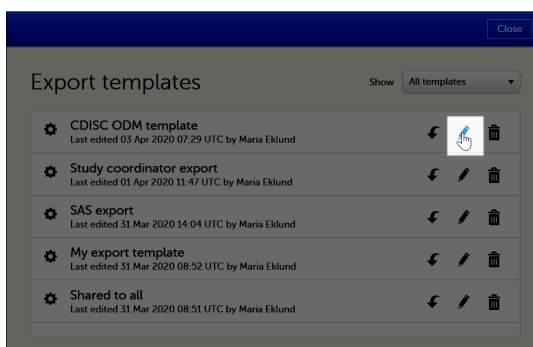
7.3 Editing a data export template

To edit a data export template:

- 1 Click **View all templates** in the **Export templates** area of the **Data export** page.



- 2 The **Export templates** list is displayed. Click the edit icon for the template that you want to edit.



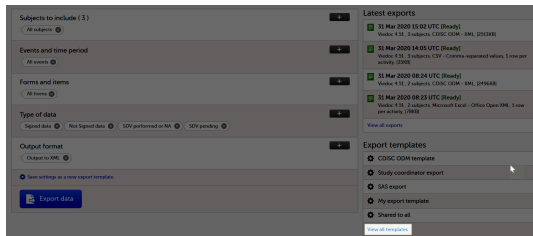
- 3 In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

Note! You can only edit a template that you created yourself.

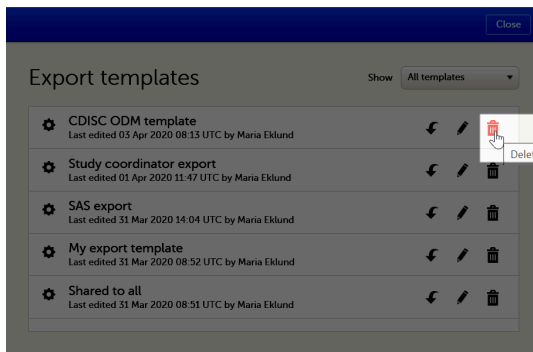
7.4 Deleting a data export template

To delete a data export template:

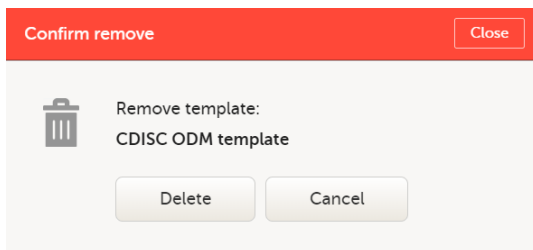
- 1 Click **View all templates** in the **Export templates** area of the **Data export** page.



- 2 The **Export templates** list is displayed. Click the trash can icon for the template that you want to delete.



- 3 In the pop-up that is displayed, click **Delete**.



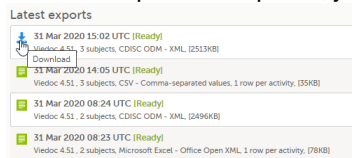
Note: You can only delete a data export template that you created yourself.

8 Exporting data

To perform a data export:

- 1 Filter the data to be exported. See [Filtering the data to be exported](#).
- 2 Select the [Output format](#).
- 3 Optionally, select the [Output version](#).
- 4 Optionally, [preview the data](#) to be exported.

- 5 Click **Export data**. The status of the export is displayed in the **Latest exports** area, on the top of the list. When the export is completed, you can download the exported file:



The exported file is downloaded locally. The filename is generated as follows: *SponsorCode_CountryCode_SiteCode_Date_Time*, where:

- *SponsorCode* - the sponsor code, as set in Viedoc Admin, under Study Settings.
- *CountryCode* - the code of the country selected in Viedoc Admin, under Site Settings.
- *SiteCode* - the site code, as set in Viedoc Admin, under Study Settings.
- *Date* - the date when the export was requested, in format *yyyymmdd*.
- *Time* - the time ([UTC](#)) when the export was requested, in format *hhmmss*.

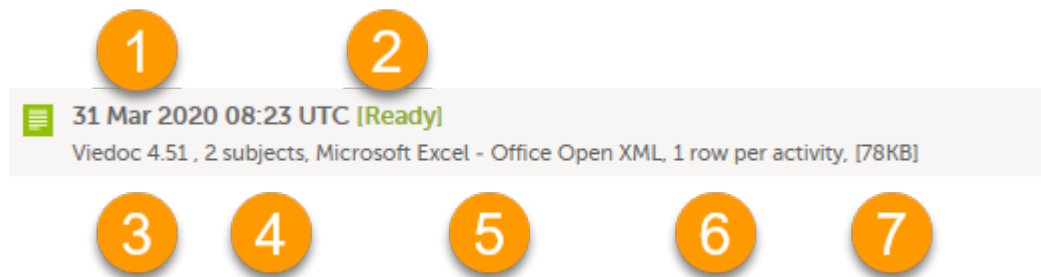
Note! If any of the characters that are invalid for a filename in Windows are used within any of the *SponsorCode* or *SiteCode*, these characters will be automatically replaced with - within the exported filename.

8.1 Latest exports

You can see a log of the requested exports in the **Latest exports** area, where you can download the exported files or delete the logs.

Note! The list of the latest exports is user-specific, that is, you can only see the exports made by yourself.

The latest five exports are shown in the list. To get the complete list of the initiated exports, click the **View all exports** link at the bottom of the list.








Each log entry provides the following information:

1. The date and time when the export was initiated.
2. The export status:
 - **In Queue** - the export request is in queue, waiting to be processed.
 - **In Progress** - the exported started and is in progress.
 - **Ready** - the file was successfully exported and is ready for download.
 - **Error** - an error was encountered and the export was not performed.
3. Viedoc output version - see [Output versions](#).
4. The number of exported subjects.
5. The format of the output file.
6. The selected layout, if applicable.
7. File size

Note! If data has been masked after an export was made, it is not possible to download that export because it could include the data that was later masked.

Latest exports

 2012-09-12 22:50 [In queue] Viedoc 4.51, 31 subjects, 1 row per activity, [45KB]
 2012-09-11 15:27 [Ready] Viedoc 4.51, 31 subjects [45KB]
 2012-09-11 15:27 [Ready] Viedoc 4.51, 31 subjects [45KB]
 2012-09-11 15:27 [No data] Viedoc 4.51, 31 subjects [0KB]
 2012-09-11-15:27 Removed due to data anonymization

[View all exports](#)

9 Exporting Data FAQ

The following are some frequently asked questions and answers about exporting data in Viedoc:

Q: How do I export the audit trail (history)?

A: Any PDF data export will include the audit trail (history) by default. You can also get an Excel or CSV version by changing the layout to one row per item and including the history. See the [Include history](#) section in the Excel Export lesson for more information.

Q: Is there a size limit to exports?

A: No, there are no size limits to exports.

Q: Can I schedule exports automatically?

A: Yes, you can configure customized automatic exports using Viedoc's web API. Please see the [Exporting data via Viedoc's web API](#) for more information.

Q: How is missing data handled?

A: Viedoc's approach to missing data is to leave it blank. The system does not use "N/A" or "missing." Both unconfirmed and confirmed missing data are included when [exporting queries and query history](#).

Q: Why does the export seem stuck at a certain percent?

A: Sometimes exports (especially PDF exports of large studies) can take a longer time to complete and appear "stuck". If you log out, the export will continue in the background. Please do not make multiple requests for the same export. If the export fails with an error message, please contact Viedoc for assistance.



Excel export

Excel export

Published by Viedoc System 2024-12-03

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1 Introduction

Viedoc uses Microsoft Excel Open Extensible Markup Language ([XML](#)) format which is compatible with Excel version 2007 and later.

When selecting Microsoft Excel as **Output format** in the Data export page, you have different options for grouping data and for the layout, as described in the following sections.

For general information about data export in Viedoc, see [Exporting data](#).

Note! Since the maximum number of rows supported for Excel is 1048576, in case data in a sheet exceeds this number, data will be split into multiple sheets.

2 File structure

The Excel export contains the following sheets:

- **README** - always the first sheet in the Excel export output, with general information about:
 - the Viedoc output version (for details see [Exporting data](#))
 - the time zones used for date/time fields
 - the meaning of the signature, only if the **Review status** was selected to be included in the export
- Depending on the selected **Data grouping**:
 - If **Group data by form** is selected, there is one separate sheet for each form, as described below in [Group data by form](#).
 - If **Do not group data** is selected, there is one sheet called **Data** that contains all exported data. See [Do not group data](#).

- **Items** - after the data sheet(s), there is the **Items** sheet, that lists all the existing items in the exported data with the following information (columns):
 - **Note!** This sheet is not included when selecting the **one row per item** layout.
 - **ID** - the item ID, as set in the study design
 - **Label** - the field label, as set in the study design
 - **Data type** - the type of data, as set for the respective item in the study design. Can be one of the following:
 - integer
 - double
 - text
 - string
 - date
 - datetime
 - base64Binary (for *File upload* items)
 - **Mandatory:**
 - True - if the item was set as mandatory in the study design
 - False - if the item was not set as mandatory in the study design
 - **Decimals** - the number of allowed decimals in the data content.
 - **Min Length** - the minimum required length for the respective field, if set in Viedoc Designer. For checkbox items, this is the minimum number of checkboxes required to be set, a set in Viedoc Designer.
 - **Max Length** - the maximum number of characters that can be entered, if set on item level in Viedoc Designer.
 - **Format Name** - the format name, if set in Viedoc Designer (under *Outputs and Validation > Formats*). For the codes of the checkbox or radio button items, a default value is generated even if no format name is set in Viedoc Designer.
 - **Content Length** - the maximum number of characters of the data content. That is, this is set by the length of the content
- **CodeLists** - the last sheet in the export, containing all the code list items in the exported data with the following information:
 - **Note!** This sheet is not included when selecting the **one row per item** layout.
 - **Format Name**
 - **Data Type**
 - **Code Value**
 - **Code Text**

Note! If the Output IDs (OID) and Output labels have been defined in the study design, these are shown in the Excel/CSV/SAS export. If the Output IDs (OID) and Output labels are left undefined (blank) in the study design, then the configured Item ID and label is used. For more information about the item settings in the study design, see [Outputs and Validation](#).

The table below lists which sheets are included in the Excel file, depending on the selected **Grouping** and **Layout**:

	Group data by form	Do not group data
one row per subject	<ul style="list-style-type: none"> ▪ <i>README</i> ▪ one separate sheet for each form ▪ <i>Items</i> ▪ <i>CodeLists</i> 	<ul style="list-style-type: none"> ▪ <i>README</i> ▪ <i>Data</i> ▪ <i>Items</i> ▪ <i>CodeLists</i>
one row per activity	<ul style="list-style-type: none"> ▪ <i>README</i> ▪ one separate sheet for each form ▪ <i>Items</i> ▪ <i>CodeLists</i> 	<ul style="list-style-type: none"> ▪ <i>README</i> ▪ <i>Data</i> ▪ <i>Items</i> ▪ <i>CodeLists</i>
one row per item	<ul style="list-style-type: none"> ▪ <i>README</i> ▪ one separate sheet for each form 	<ul style="list-style-type: none"> ▪ <i>README</i> ▪ <i>Data</i>

2.1 Header rows

The headers are always represented by the first two rows in a sheet, as illustrated in the following image:

1. Human-readable format
2. Machine-readable format

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate
1	Karolinska	01	1	SE-01-001	1	SCR	Add subject	2014-10-02
1	Karolinska	01	3	SE-01-003	1	SCR	Add subject	2014-11-14
1	Karolinska	01	4	SE-01-004	1	SCR	Add subject	2014-11-25
1	Karolinska	01	5	SE-01-005	1	SCR	Add subject	2014-12-05

An item that was changed within a new/revised study design version will have a "_n" suffix added, where n is incremented for each study design version where the respective item was changed:

Race_2	Race_2 - Code
DMRACE_2	DMRACE_2CD
Native Hawaiian	4
Native Hawaiian	4
Black	1

3 Data filtering - Type of data

Under **Type of data**, you can filter the data to be exported. If you filter data for **Signed data**, **Not signed data**, **SDV performed or NA**, or **SDV pending**, certain cells in the data sheets in the exported Excel file may appear empty. The data rows that contain empty cells due to the filtering are marked by an "X" in the last column of the data sheets that is named **Empty cells on row may be due to export filter**.

For example, let's say that we have an *Add Patient* event, and the *Date of Birth* is one of the data entered during this event. For a particular subject, this data was entered, signed by the Investigator, and afterwards modified, but not signed after the change. We perform an export that includes only the signed data, as illustrated in the image below:

Type of data

Signed data
 SDV performed or NA
 SDV pending

Signed data
 Not Signed data

SDV performed or NA
 SDV pending

The value of the *Date of birth* field that was recently changed and not signed is not included in the export (the cell appears empty). The data row containing the empty cell is marked by a "X" the **Empty cells on row may be due to export filter**, as shown below:

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity Name	Form sequence number	Design version	Gender	Gender - Code	Date of Birth	Age	Number	Empty cells on row may be due to export filter
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVer	GENDER	GENDERCD	DOB	AGE	PI2	HAS_FILTERED_VALUES
1	Stockholm	D8	2	EH-D8-002	1	AP	Add Patien	2017-08-11	APA		1	2.0	Male	M	1966-10-01	51		
2	Uppsala	Uppsala:2	2	SE-Uppsala1	1	AP	Add Patien	2017-08-11	APA		1	2.0	Female	F	1959-09-21	58		
2	Uppsala	Uppsala:2	5	SE-Uppsala1	1	AP	Add Patien	2017-08-11	APA		1	2.0	Male	M	1977-03-15	40		
2	Uppsala	Uppsala:2	15	SE-Uppsala1	1	AP	Add Patien	2018-10-12	APA		1	14.2	Female	F	1965-02-22	54		
2	Uppsala	Uppsala:2	17	SEUppsala1	1	AP	Add Patien	2018-11-12	APA		1	19.0	Male	M	1989-11-24	29		
2	Uppsala	Uppsala:2	19	SEUppsala1	1	AP	Add Patien	2018-11-30	APA		1	20.2	Male	M	1954-02-10	65		
2	Uppsala	Uppsala:2	20	SEUppsala1	1	AP	Add Patten	2018-11-30	APA		1	20.2	Female	F	1968-04-29	51		
2	Uppsala	Uppsala:2	24	SEUppsala1	1	AP	Add Patien	2019-01-16	APA		1	20.2	Male	M		63	X	

4 Data grouping

You can select whether the data should be grouped by form or not, from the **Data grouping** dropdown list.

Note! The data grouping is available only for the Excel/Comma-Separated Values (CSV) output.

4.1 Group data by form

When grouping the data by form, a separate sheet is created for each form. The sheet name is the Form ID, as set in the study design (in Viedoc Designer).

In each form sheet, the first columns (to the left) are the same for all the forms and provide information about the site, subject, event, activity and design version:

Column	Description
Site Sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms. For non-repeating forms, this is "1". If a form is reset and then saved again the new form has sequence number "2", and so on. Form sequence number increases one step every time reset/initiate occurs.
Subject form sequence number	Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject.
Origin Subject form sequence number	For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the SubjectFormSeqNo .
Source Subject form sequence number	For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the SubjectFormSeqNo from which the form instance was copied. For the first instance of the form (not copied) it is empty (null).
Design version	The design version used at the time of data edit for the respective form.

The example in the image below shows an export with the default settings for the **Layout**, that is, **1 row per activity**.

The following columns are specific to each form, one column for each item in the respective form. Each column has the *<Item name>*, as set in the study design (in Viedoc Designer) as column header.

4.2 Do not group data

If you choose not to group the data, then all data from all forms will be exported in the same sheet (**Data**) of the output file.

The example in the image below shows an export with the default settings for the **Layout**, that is, **1 row per activity**.

In the **Data** sheet, the first columns (to the left, marked in **green**) are the common for all the forms and provide information about the site, subject, event and activity.

The following columns (to the right, marked in **orange**) contain form-specific information for all the forms within the event. For each of the forms, the following columns are added:

- *<FormName>_Design Version* - the form name, as set in the study design (in Viedoc Designer) and displayed in Clinic. In the example in the image, the form name is *Demographics*.
- *<FormName>(<Form Repeat Key>)_<ItemName>* - for each item in the respective form. The form name and item name, as set in the study design (in Viedoc Designer) and displayed in Clinic. The *Form Repeat Key* identifies the instance of the form (for repeating forms). For non-repeating forms, the *Form Repeat Key* is always 1.

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	
Site Sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Demographic Design version	Demographics(1) Date/Time of Informed Consent	Demographic(1) Gender	Demographic(1) Gender - Code	Demographic(1) Date/Time of Birth	Demographic(1) Age	Demographic(1) CHB Result	Demographic(1) CHB Code	Demographic(1) Reason for No CHR	Demographic(1) Reason for No CHR	Demographic(1) Race - Code	Demographic(1) Race - Code	
1	Academic I AHU	1	SE-AHU-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-07-04	Male	1	1964-06-11	52.1							White	5	
4	Academic I AHU	1	SE-AHU-001	1	V1	Visit 1	2016-10-04	V1															
5	Academic I AHU	2	SE-AHU-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1					Asian	3	
6	Academic I AHU	2	SE-AHU-001	1	V1	Visit 1	2016-10-04	V1															
7	Academic I AHU	3	SE-AHU-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-09-04	Male	1	1968-08-04	48.1							White	5	
8	Academic I AHU	3	SE-AHU-001	1	V1	Visit 1	2016-10-02	V1															
9	Academic I AHU	4	SE-AHU-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-06-05	Male	1	1952-10-01	63.7							Black	1	
10	Academic I AHU	5	SE-AHU-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmenop	1			White	5	
11	Academic I AHU	5	SE-AHU-001	1	V1	Visit 1	2016-10-02	V1															
12	Charite Uni CUB	1	DE-CUB-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-08-07	Male	1	1980-02-22	36.5							White	5	
13	Charite Uni CUB	1	DE-CUB-001	1	V1	Visit 1	2016-10-02	V1															
14	Charite Uni CUB	2	DE-CUB-001	1	SCR	Add subject	2016-10-04	SCR	Add subject 3.0	2016-03-02	Male	1	1960-11-02	55.3							White	5	
15	Charite Uni CUB	2	DE-CUB-001	1	V1	Visit 1	2016-10-04	V1															

5 Layout

In the **Layout** section, you can select whether the data should be organized in the output file as:

- [one row per subject](#)
- [one row per activity](#) (default)
- [one row per item](#)

5.1 One row per subject

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per subject**.

1	Site name	Site code	Subject sequence number	Subject Id	Add subject(1)-Add subject(1)-Design version	Add subject(1)-Add subject(1)-Date/Time of Consent	Add subject(1)-Add subject(1)-Gender	Add subject(1)-Add subject(1)-Code	Add subject(1)-Add subject(1)-Date/Time of Birth	Add subject(1)-Add subject(1)-CHB	Add subject(1)-Add subject(1)-Result	Add subject(1)-Add subject(1)-Reason for No CHB	Add subject(1)-Add subject(1)-CHB Code	Add subject(1)-Add subject(1)-Race Code	Add subject(1)-Add subject(1)-Race Code
2	Academic f AHU	1	SE-AHU-001	3.0	2016-07-04	Male	1	1964-06-11	52.1					White	5
3	Academic f AHU	2	SE-AHU-002	3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1			Asian	5
4	Academic f AHU	3	SE-AHU-003	3.0	2016-09-04	Male	1	1968-08-04	48.1					White	5
5	Academic f AHU	4	SE-AHU-004	3.0	2016-06-05	Male	1	1952-10-01	63.7					Black	1
6	Academic f AHU	5	SE-AHU-005	3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmenop	1	White	5
7	Charite Uni CUB	1	DE-CUB-001	3.0	2016-08-07	Male	1	1980-02-22	36.5					White	5
8	Charite Uni CUB	2	DE-CUB-002	3.0	2016-03-02	Male	1	1960-11-02	55.3					White	5
9	VU Medica VUA	1	NL-VUA-001	3.0	2016-10-02	Male	1	1961-07-31	55.2					White	5
10	VU Medica VUA	2	NL-VUA-002	3.0	2016-08-07	Male	1	1973-12-21	42.6					White	5
11	VU Medica VUA	6	SE-AHU-006	12.0	2016-10-02	Female	2	1976-02-01	40.7	Yes	1			White	5

There is one sheet for each form, as the default setting is to **Group data by form**.

There is one row per subject, that is, one row for each SubjectID (that uniquely identifies the subject).

The first columns provide information on the site and subject:

Column	Description
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.

The following columns are the item-specific values, one set as described below for each item in the exported data. The order of the items is by event, as set in the study workflow.

- In case **Do not group data** is selected under *Data grouping* (see [Do not group data](#)):
 - `<Event name><Event Repeat Key> - <Activity name> <Form name> <Item name> <Code list value>`, where:
 - `<Event name>` - the event name, as set in the study design and displayed in Clinic.
 - `<Event Repeat Key>` - the event repeat key, applicable only for the unscheduled/common events.
 - `<Activity name>` - the activity name, as set in the study design
 - `<Form name>` - the form name, as set in the study design and displayed in Clinic.
 - `<Item name>` - the item label, as set in the study design and displayed in Clinic.
 - `<Code list value>` - applicable only for the checkbox items. This is the code list value set in Viedoc Designer for each choice of the respective checkbox item
 - In case **Group data by form** was selected under *Data grouping* (see [Group data by form](#)), the columns are named similar as for the not grouped data above, without the `<Form name>`, as the form is identified by the sheet name.

Note! The columns Event sequence number, Event Id, Activity Id, Form sequence number, Subject form sequence number, Origin Subject form sequence number, and Source Subject form sequence number are not included when you have selected **1 row per subject**.

5.2 One row per activity

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per activity**.

There is one sheet for each form, as the default setting is to **Group data by form**.

The data is grouped so that, for each subject (1), there is one row for each activity (2).

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Physical Examination performed	Physical Examination performed - Code
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVer	PEYN	PEYNCD
1	Academic H AHU	11	SE-AHU-011		1	V1	Visit 1	2017-10-20	V1		1	32.0	Yes	1
4	Academic H AHU	14	SE-AHU-014		1	V1	Visit 1	2017-11-10	V1		1	33.0	No	0
5	Academic H AHU	14	SE-AHU-014		1	UNS_1	Unscheduled	2017-11-13	UNS_1		1	34.0	Yes	1
6	Academic H AHU	18	SE-AHU-018		1	V1	Visit 1	2017-11-14	V1		1	36.0	Yes	1
7	Academic H AHU	22	SE-AHU-022		1	V1	Visit 1	2017-11-14	V1		1	39.0	Yes	1
8	Academic H AHU	23	SE-AHU-023		1	V1	Visit 1	2017-10-16	V1		1	27.0	Yes	1
9	Academic H AHU	23	SE-AHU-023		1	V3	Visit 3	2017-10-27	V4		1	33.0	Yes	1
10	Academic H AHU	24	SE-AHU-024	1	1	V1	Visit 1	2017-11-01	V1	2	1	33.0	Yes	1
11	Academic H AHU	24	SE-AHU-024		1	V3	Visit 3	2017-11-14	V4		1	39.0	Yes	1
12	Academic H AHU	32	SE-AHU-032		1	V1	Visit 1	2017-11-21	V1		1	44.0	Yes	1
13	Academic H AHU	34	SE-AHU-034		1	V1	Visit 1	2017-11-21	V1		1	46.0	Yes	1
14	Academic H AHU	36	SE-AHU-036		1	V1	Visit 1	2017-11-20	V1		1	44.0	Yes	1
15	Academic H AHU	43	SE-AHU-043		1	V1	Visit 1	2018-01-01	V1		1	51.0	Yes	1
16	Academic H AHU	44	SE-AHU-044		1	V1	Visit 1	2018-01-02	V1		1	51.0	Yes	1
17	Academic H AHU	50	SE-AHU-050		1	V1	Visit 1	2018-01-06	V1		1	55.0	Yes	1
18	Academic H AHU	73	SE-AHU-073		1	V1	Visit 1	2018-03-20	V1		1	57.0	Yes	1
19	Academic H AHU	75	SE-AHU-075		1	V1	Visit 1	2018-08-13	V1		1	59.0	Yes	1

5.3 One row per item

The output in this case will look as shown in the below image. The example shows an export performed with all the default settings except for the **Layout** which is set to **1 row per item**.

There is one sheet for each form, as the default setting is to **Group data by form**.

The data is grouped so that there is one row for each item (3) within an activity (2) for a subject (1).

Subject Id	Event sequence	Event Id	Event name	Event date	Activity Id	Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequence	Item Id	Item export label
SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId	ItemExportLabel
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG_10217_1	1	PEDT	Date/Time of Examination
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG7	1	PECARES	Cardiovascular - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG8	1	PEABRES	Abdomen - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG9	1	PELYRES	Lymph nodes - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG10	1	PEEXRES	Extremities - result
SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG11	1	PEOTHRES	Other - result
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PENDREA	Examination not performed reason
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEYN	Physical Examination performed
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG_10217_1	1	PEDT	Date/Time of Examination
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result

The data is sorted by: site, subject, event date, event repeat key, form repeat key, form ID, item group ID, item ID. If the **Include history** option is selected (see following section), the data is ordered from the oldest to the current item data (that is, by the **Edit sequence number**).

5.3.1 Include history

When selecting **1 row per item**, the option to **Include history** becomes available. If selected, the edit history information (audit trail) will be included in the exported output (that is, the information shown in Viedoc Clinic on form level when selecting **Show history**).

The following information (columns) is added for each entry in the output file:

- **Edit sequence number** - a counter for each change per item.
- **Edit reason** - reason for change (initial or given reason at data edit). The edit reasons are the following:
 - Initial data entry
 - Function execution
 - Transcription error
 - Confirmed as missing!
 - Automatically updated due to dependency change
 - Removed due to data dependency
 - Revision applied
 - Query resolution
 - Form reset: Transcription error
 - Form reset: Query resolution
 - Import
 - Other (the text the user enters as the reason)

- **Edit by** - the user who performed the changes (user name and user id in parentheses).
- **Edit date/time (UTC)** - edit date/time (Coordinated Universal Time ([UTC](#))).

The items belonging to a reset or deleted form/event/subject are included as well in the export, together with a full history that gives the reason for resetting or deleting the form/event/subject.

5.3.2 Checkboxes

Checkbox items are output as one row per code list item. All code list items are listed, regardless if they contain data or not. Each row is labeled, in the **Item Id** column, with the item Object Identifier ([OID](#)) and an 1-based index, as illustrated in the following image:

Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequence	Item Id	Item export label	Edit sequence
ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId	ItemExportLabel	EditSeqNo
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes1	Check boxes - 1	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes2	Check boxes - 2	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes3	Check boxes - 3	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes4	Check boxes - 4	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes5	Check boxes - 5	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes6	Check boxes - 6	1
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes1	Check boxes - 1	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes2	Check boxes - 2	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes3	Check boxes - 3	2
Eligibility	IE	Eligibility	1	IEG10	1	checkboxes4	Check boxes - 4	2

If the option to **Include history** is selected, then the code list items are ordered by the time of data entry (that is, by the **Edit sequence number**).

Checkbox items generate two columns per code of the item, one for the code and another one for the code description.

The items that have a code list assigned are output to an additional row with the ID suffixed with “CD”, for the code.

5.3.3 Reference ranges

When reference ranges are used for a laboratory form, The laboratory name and the laboratory code are included and the following two columns are added: **SCOPE_XXX** and **SCOPE_XXXCD** (where XXX is the numeric value)

6 Form link items in the export output

Form link items can be organized in the Output format as:

- One row per **activity** (default)
- One row per **item**
- One row per **subject**

6.1 One row per activity

Selecting **1 row per activity** generates the output as shown in the image below. The exported file contains two columns per linked form instance, the Data column and the Identifier column, (the header is labelled Identifier).

In the example below:

- Each linked form instance shows its display value (as displayed in Clinic) and the Identifier.
- The medication Paracetamol in this example is linked to two different entries in the Adverse Event log.
- The format for the identifier: EventId-EventSeq-ActivityId-FormId-FormSeq.

Name of drug / medication / therapy	Reason for administration	Adverse event link 1	Adverse event link 1 - Identifier	Adverse event link 2	Adverse event link 2 - Identifier
CMTRT	CMINDC	CM31	CM31CD	CM32	CM32CD
Paracetamol	Adverse event	1 - Headache - 14 Mar 2022	COMMON_AE-1-LOG_AE-AE-1	2 - Migraine - 13 Mar 2022	COMMON_AE-2-LOG_AE-AE-1

There are also two header rows in the output:

Header rows, one row per activity	
Row 1: Data column	Item Label, Counter of the selected link starting at one
Row 1: Identifier column	Item Label, Counter of the selected link starting at one, Identifier
Row 2: Data column	Item ID, Counter of the selected link starting at one
Row 2: Identifier column	Item ID, Counter of the selected link starting at one, ID

6.2 One row per item

Selecting **1 row per item** generates the output as shown in the image below. The exported file contains two additional columns with the headers Item value and Item code, and one row per linked form instance.

Item value	Item code
ItemValue	ItemCode
3	
Alvedon	
Adverse event	2
16 Dec 2021 - Headache	COMMON_AE-1-LOG_AE-AE-1
250	
Milligram	2
Capsule	2
Twice daily	2
Oral	1
2021-12-16	
01:20	
No	0
2021-12-16	
01:25	
4	
Alvedon	
Adverse event	2
16 Dec 2021 - Headache	COMMON_AE-1-LOG_AE-AE-1
500	
Milligram	2
Tablet	1
Once daily	1
Oral	1
2021-12-16	
09:00	
No	0
2021-12-16	
End time not available	99

Note! In the export preview the form identifier column is excluded by default. The order the form link item was added (time of data entry) is followed in the export.

6.3 One row per subject

Selecting **1 row per subject** generates the output as shown in the image below. The exported file adds two columns per linked form instance to the exported file, the Data column and the Identifier column:

Prior and Concomitant Medications(1)- (1)Medical history link(s) 1	Prior and Concomitant Medications(1)- (1)Medical history link(s) 1 - Identifier
COMMON_CM[1].LOG_CM[1].CM41	COMMON_CM[1].LOG_CM[1].CM41ID
Headache - 07 Jan 2022	COMMON_MH-1-LOG_MH-MH-1

There are also two header rows in the output:

Header rows, one row per subject	
Row 1: Data column	Event Label (event counter), Activity label (activity counter), Item label (counter of the selected link.)
Row 1: Identifier column	Event Label (event counter), Activity label (activity counter), Item label (counter of the selected link), Identifier
Row 2: Data column	Event ID (event counter), Activity ID (activity counter), Item ID (counter of the selected link.)
Row 2: Identifier column	Event ID (event counter), Activity ID (activity counter), Item ID, (counter of the selected link), ID

7 Recurring events in the export output

Recurring events are identified in the export output by the `StudyEventRepeatKey`.

The image illustrates the form *Vital Signs* in the Excel export output. The form is used in three events (Visit 1, Visit 2 and Visit 3), of which Visit 3 is a recurring event. The four instances of Visit 3 are identified by the `StudyEventRepeatKey` that is listed in the **Event sequence number (EventSeq)** column:

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Vital Signs done?	Vital Signs Code	Date/Time	Not measured reason	Heart rate	Body temperature	Systolic BP	Diastolic BP
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V1	Visit 1	2018-01-01	V1		1	55.0	Yes	1	2018-01-01 00:00		61	37.0	120	65
4	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V2	Visit 2	2018-01-05	V2		1	55.0	Yes	1	2018-01-05 00:00		62	37.1	125	70
5	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V3	Visit 3	2018-01-06	ACT_2		1	55.0	Yes	1	2018-01-06 00:00		62	37.2	130	65
6	Academic Hospital Uppsala	AHU	48	SE-AHU-048	2	V3	Visit 3	2018-01-07	ACT_2		1	55.0	Yes	1	2018-01-07 00:00		64	37.4	125	70
7	Academic Hospital Uppsala	AHU	48	SE-AHU-048	3	V3	Visit 3	2018-01-08	ACT_2		1	55.0	Yes	1	2018-01-08 00:00		65	37.5	125	75
8	Academic Hospital Uppsala	AHU	48	SE-AHU-048	4	V3	Visit 3	2018-01-09	ACT_2		1	55.0	Yes	1	2018-01-09 00:00		66	37.6	125	70

Note! Support for recurring events has been added in Viedoc release 4.39. That means that if you would like to export recurring events, you should select Viedoc version 4.39 or later in the **Output version** dropdown menu under **Output format**.

8 Repeating forms in the export output

Repeating forms are identified in the export output by the `FormRepeatKey`.

The image illustrates the repeating form *Lab* in the export to Excel. The instances of the form are identified by the `FormRepeatKey` that is listed in the **Form sequence number (FormSeq)** column:

Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Collection Date and Time	Result	Low Normal	High Normal
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		1	51.0	2018-01-08 00:00	4589	4000	8000
4	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		2	51.0	2018-01-09 13:26	6987	5500	11000
5	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		3	51.0	2018-01-08 00:00	5877	5500	11000

Note! Support for repeating forms has been added in Viedoc release 4.39. That means that if you would like to export repeating forms, you should select Viedoc version 4.39 or later in the **Output version** dropdown menu under **Output format**.

9 Forms initiated by copying data from previous event

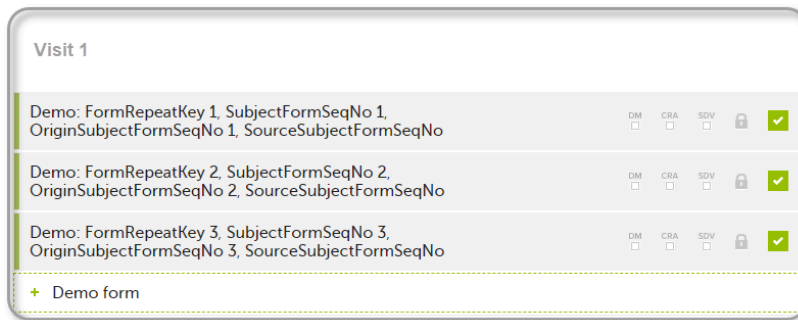
The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

- **FormRepeatKey** - Counter that identifies the specific instance of a repeating form within a specific activity. This is available in the export output for Viedoc output version 4.39 and onwards.
- **SubjectFormSeqNo** – Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject. This is available in the export output for Viedoc output version 4.51 and onwards.
- **OriginSubjectFormSeqNo** – For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the **SubjectFormSeqNo** . This is available in the export output for Viedoc output version 4.51 and onwards.
- **SourceSubjectFormSeqNo** – For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the **SubjectFormSeqNo** from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty, that is, null. This is available in the export output for Viedoc output version 4.51 and onwards.

The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

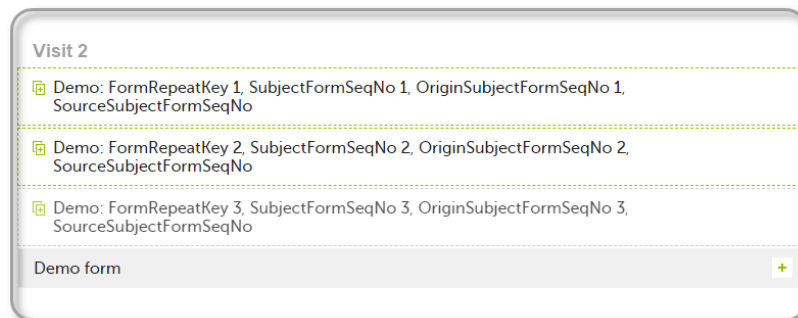
We perform the following actions in Viedoc Clinic:

- 1 Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:



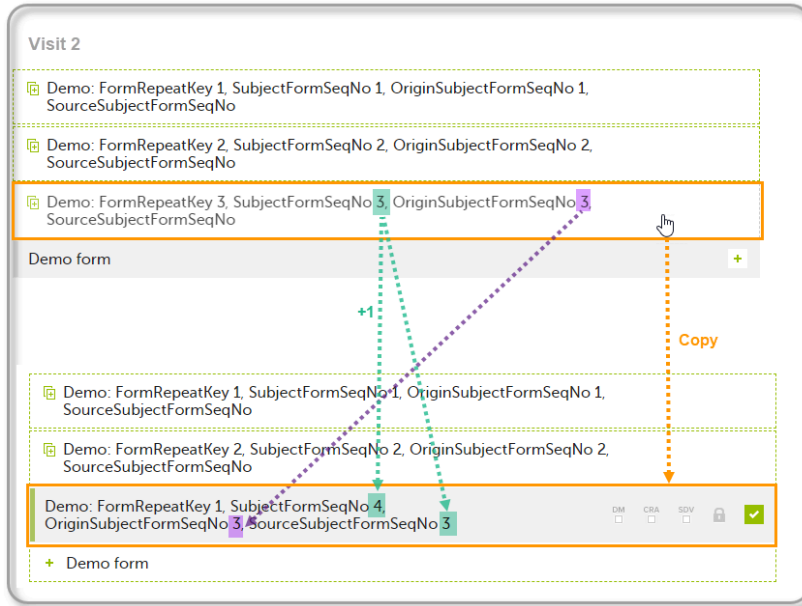
The screenshot shows the 'Visit 1' interface. It contains three rows of form data, each with a green checkmark in the top right corner. The first row is: 'Demo: FormRepeatKey 1, SubjectFormSeqNo 1, OriginSubjectFormSeqNo 1, SourceSubjectFormSeqNo'. The second row is: 'Demo: FormRepeatKey 2, SubjectFormSeqNo 2, OriginSubjectFormSeqNo 2, SourceSubjectFormSeqNo'. The third row is: 'Demo: FormRepeatKey 3, SubjectFormSeqNo 3, OriginSubjectFormSeqNo 3, SourceSubjectFormSeqNo'. Below these rows is a dashed box containing a '+ Demo form' button. To the right of each row are icons for 'DM', 'CRA', 'SDV', a lock icon, and a green checkmark.

- 2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:

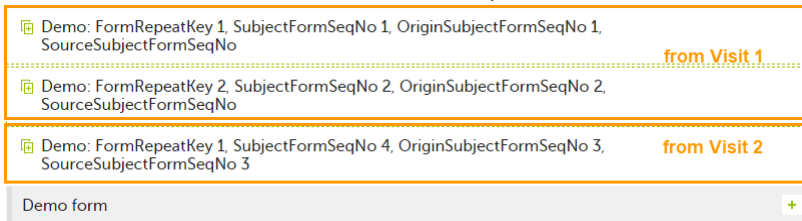


The screenshot shows the 'Visit 2' interface. It contains three rows of form data, each with a ghost icon (a square with a diagonal line) in the top left corner. The first row is: 'Demo: FormRepeatKey 1, SubjectFormSeqNo 1, OriginSubjectFormSeqNo 1, SourceSubjectFormSeqNo'. The second row is: 'Demo: FormRepeatKey 2, SubjectFormSeqNo 2, OriginSubjectFormSeqNo 2, SourceSubjectFormSeqNo'. The third row is: 'Demo: FormRepeatKey 3, SubjectFormSeqNo 3, OriginSubjectFormSeqNo 3, SourceSubjectFormSeqNo'. Below these rows is a dashed box containing a '+ Demo form' button.

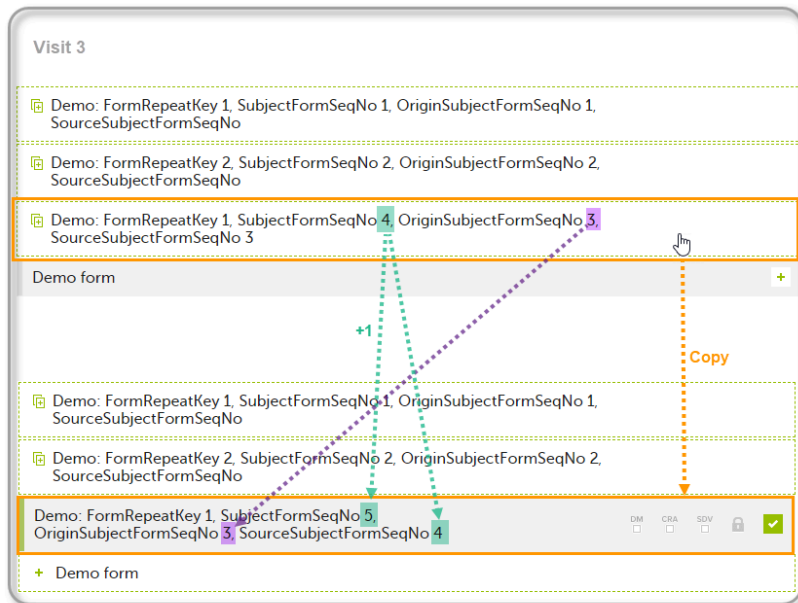
- 3 Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



- 4 Initiate Visit 3. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1 and Visit 2, as below:



- 5 Create an instance of Demo form within Visit 3 by copying the data from the form filled in within Visit 2. This will result in the new form instance getting the sequence numbers as illustrated below:



These sequence numbers are available to be used within expressions only to get the value of the sequence number for a specific form instance, that is, by using {SubjectFormSeqNo}, {OriginFormSeqNo}, {SourceFormSeqNo}.

In the above example, the form Summary format was configured by using these sequence numbers as below:

Form Repeat Key {FormRepeatKey}, SubjectFormSeqNo {SubjectFormSeqNo}, OriginFormSeqNo {OriginFormSeqNo}, SourceFormSeqNo {SourceFormSeqNo}

Notes!

- Only the FormRepeatKey is used to identify a specific instance of the form in data mapping for data import, as well as in the item identifier used in JavaScript (for example `EventID.FormID$ActivityID[FormRepeatKey].ItemID`).
- When resetting a form, the sequence numbers are still allocated to it, and the next available ones are used for the new instances.

In the excel export output, these form sequence numbers allow to track, for the form instances that were initiated by copying data from previous events, where the data originates from, as below:

Form sequence number	Subject form sequence number	Origin Subject form sequence number	Source Subject form sequence number	Design version
FormSeq	SubjectFor	OriginSubj	SourceSubj	DesignVers
1	1	1		2.1
2	2	2		2.1
3	3	3		2.1
1	4	3	3	2.1
1	5	3	4	2.1

Analyzing the values of the form sequence numbers, only the form instances that were initiated by copying the data from previous visits have values populated in the *Source Subject form sequence number* column, that is, the last two rows in the example. The data was copied from the form instance having the same *Subject form sequence number* value, highlighted in green in the above image. The form instance that the data was copied for the first time is identified by the value of the *Origin Subject form sequence number*, that is, "3" in our example.



PDF export output

PDF export output

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[2. Output file\(s\)](#)

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[3.4 Event summary page](#)

[3.4.1 The sort order of the forms](#)

1 Introduction

When choosing **PDF** as output format, you have the following options:

- **Exclude deleted subjects / events / forms** - if checked, the deleted subjects, events and forms will be excluded from the PDF export.
 - **Create PDF/A compliant archive** - if checked, the PDF export output will be in a Portable Document Format Archive ([PDF/A](#)) compliant format. The PDF/A is a standardized format specialized for long-term preservation of electronic documents.
 - **Embed complete fonts (no subsets)** - if checked, this will force embedding the complete fonts (not only subsets) into an archive and all the font subsets embedded in the PDF file will be replaced with fully embedded fonts.
Note! Please note that this will lead to significantly larger file sizes.
 - **FDA submission format (eCTD)** - if checked, the PDF export output will be structured according to the electronic Common Technical Document ([eCTD](#)) format specified by the Food and Drug Administration ([FDA](#)). The eCTD format provides a structure where the Case Report Forms ([CRFs](#)) are listed twice, ordered by event/workflow and ordered by domain.
 - **Note!** For *non-production* data, the number of subjects in the PDF archive are limited to improve performance. The most recently added subjects are included according to the date the subject card was created.
An information message is displayed: **For this mode the PDF Archive is limited to a sample of [X] subjects.**
-

2 Output file(s)

One .zip file is downloaded for each PDF export performed.

- One separate PDF file is generated for each site and all the PDFs are archived in a .zip file. The PDF file names reflect the site code and site name, as set in Viedoc Admin, under site settings.

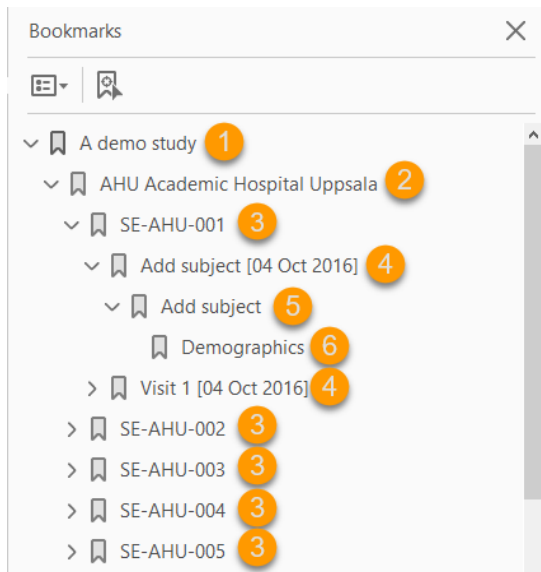
Name	Type
AHU Academic Hospital Uppsala	Adobe Acrobat Document
CUB Charite University Hospital Berlin	Adobe Acrobat Document
HUH Helsinki University Hospital	Adobe Acrobat Document
IMU Innsbruck Medical University	Adobe Acrobat Document
KCH King's College Hospital London	Adobe Acrobat Document
KIS Karolinska Institute Stockholm	Adobe Acrobat Document
UBR University of Brescia	Adobe Acrobat Document
UCH University College Hospital London	Adobe Acrobat Document
UMF University Medical Center Freiburg	Adobe Acrobat Document
UMG University Medical Center Groningen	Adobe Acrobat Document
VUA VU Medical Center Amsterdam	Adobe Acrobat Document

- For the **FDA submission format (eCTD)**, there is one folder for each site, and each folder contains one separate PDF file for each subject (file name is the same as the subject ID):

Name	Type	Compressed size
SE-AHU-001	Adobe Acrobat Document	98 KB
SE-AHU-002	Adobe Acrobat Document	100 KB
SE-AHU-003	Adobe Acrobat Document	98 KB
SE-AHU-004	Adobe Acrobat Document	86 KB
SE-AHU-005	Adobe Acrobat Document	100 KB
SE-AHU-006	Adobe Acrobat Document	115 KB
SE-AHU-007	Adobe Acrobat Document	97 KB
SE-AHU-008	Adobe Acrobat Document	100 KB
SE-AHU-009	Adobe Acrobat Document	85 KB
SE-AHU-010	Adobe Acrobat Document	108 KB
SE-AHU-011	Adobe Acrobat Document	198 KB
SE-AHU-012	Adobe Acrobat Document	84 KB
SE-AHU-013	Adobe Acrobat Document	112 KB

3 PDF file structure/content

This section describes the structure of the exported PDF file.



The file is structured as follows:

- A study summary on the [first page](#).
- A [site summary page](#).
- One separate sub-section for each [subject](#) in the respective site.
- For each subject, one sub-section for each event.
- For each event, one sub-section for each activity.
- For each activity, one sub-section for each form. The latest version of the form PDFs are included here. See also **Audit trail and Form History** section in [Entering/editing data](#).

The meaning of the signature in Viedoc is included on the last page.

Note! If the number of forms for a site exceeds 1000, the system splits the archive into one PDF file per subject and stores them in a zip file.

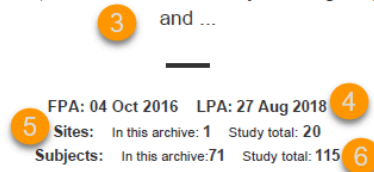
3.1 First page

The first page provides a short summary, as illustrated in the image and explained below:



2 A demo study

An open-label, multi center, dose escalation study investigating the safety, tolerability and ...



1. The study logo image, if any, as set in Viedoc Admin, under Study Settings.

2. Study name, as set in Viedoc Admin, under Study Settings.

3. Study description, as set in Viedoc Designer.

4. The dates for:

- First Patient Added (FPA) in the study
- Last Patient Added (LPA) in the study

5. The number of **sites**:

- In this archive - the number of sites selected to be included in the export.
- Study total - the total number of sites in the study.

6. The number of **subjects**:

- In this archive - the number of subjects selected to be included in the export.
- Study total - the total number of subjects in the study.

3.2 Site summary page

The site summary page provides a summary of the site, as illustrated in the image and explained below:

A demo study **1** Academic Hospital Uppsala **2**

3 Site code	AHU	Country	Sweden 4
5 Time zone	(UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna		
6 FPA	04 Oct 2016	LPA	27 Aug 2018 7
8 Subjects (in this archive/total)	71/71		

1. The study name, as set in Viedoc Admin.
2. The site name, as set in Viedoc Admin.
3. The site code, as set in Viedoc Admin.
4. The country for the respective site, as set in Viedoc Admin.
5. The site time zone, as set in Viedoc Admin.
6. Date of First Patient Added (FPA) to the site, in the site timezone.
7. Date of Last Patient Added (LPA) to the site, in the site timezone.
8. Number of subjects from the site included in the export / total number of subjects in the site (this number will exclude deleted subjects if *Exclude deleted subjects/events/forms* is checked).

Following the site summary page, comes a Contents list of the subjects included in the export for the respective site, with the Subject ID and corresponding pages. After that, comes one sub-section for each subject, described in the next topic.

3.3 Subject summary page

The subject summary page provides the following information:

A demo study / Academic Hospital Uppsala **1**
SE-AHU-023 **2**

3 Subject added	17 Nov 2017 11:11 CET	4 Forms (in this archive/total)	23/24
------------------------	-----------------------	--	-------

5 Contents

Add subject [17 Nov 2017]		Initiated	5 - 6
Visit 1 [16 Oct 2017]		Initiated	7 - 19
Visit 2 [23 Oct 2017]		Initiated	20 - 28
Visit 3		Initiated	29 - 39

1. The study name and site name, as set in Viedoc Admin.
2. Subject ID in the format set in Viedoc Designer.

3. The date and time the subject was added.
4. The number of **Forms** filled in / the total number of forms for that subject.
5. A table of **Contents** with a list of all the events that contain data for the respective subject, the event status and the page numbers where the data related to the respective event can be found.

3.4 Event summary page

The event summary page provides the following information:

A demo study / Academic Hospital Uppsala **1**

SE-AHU-023 / Visit 1 [16 Oct 2017] **2**

<p>Contents 3</p> <p>4</p> <p>Visit 1 [16 Oct 2017]</p> <p>Check Questions</p> <p>Physical Examination</p> <p>Vital Signs</p> <p>12-Lead ECG</p> <p>Body measurements</p> <p>Safety Laboratory Parameters</p> <p>Eligibility</p> <p>Visit status</p> <p>Clinical chemistry</p>	<p>5</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p> <p>Awaits signing</p>	<p>6</p> <p>8</p> <p>9</p> <p>10 - 11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18 - 19</p>
---	---	---

1. The study name and site name, as set in Viedoc Admin.
2. Subject ID in the format set in Viedoc Designer and the event name together with the date when it was initiated.
3. A table of **Contents** with a list of all the forms within the respective event for Scheduled and Unscheduled events, providing the following information:
 - Form name (**4**)
 - Status (**5**) - one of the following, depending on if the form was signed by the site:
 - *Awaits signing*
 - *Signed*, followed by the name of the user who has signed and the timestamp (in site timezone).
 - Page numbers (**6**) where the respective form can be found.

For Common Events, each entry will have its own Event summary page.

For each form, the form PDF is included, in the same format as for the form history pdf file. For details, see **Form history PDF** in [Entering/editing data](#).

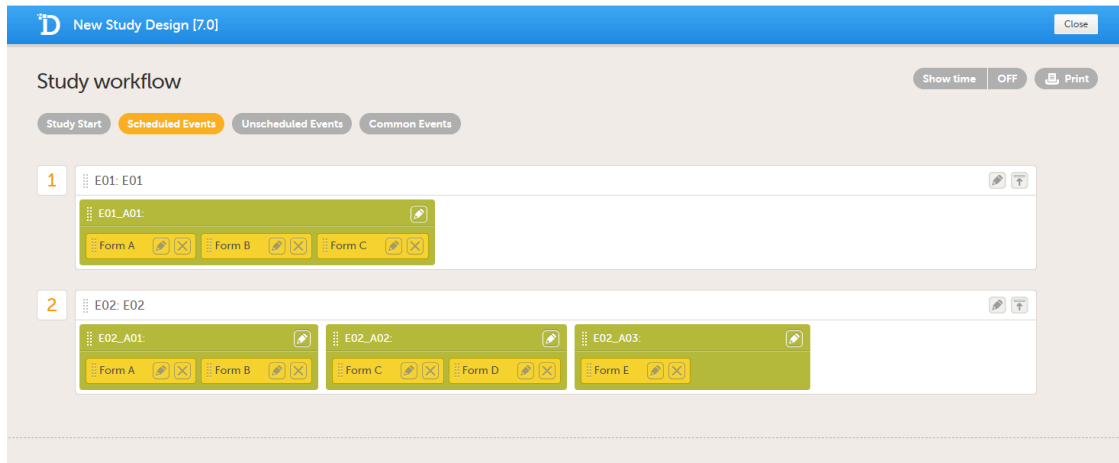
3.4.1 The sort order of the forms

The forms in the PDF are sorted by these characteristics:

1. Subject key, in ascending order
2. Event type (scheduled, unscheduled, common)
3. Date - the date of the first form save of the activity
4. The order of the forms according to the study design

The following example illustrates the sort order.

Suppose the study design looks like this:



For the event E01, all forms belong to the same activity. This means that the order of the forms in the PDF will always be like this:

- Form A
- Form B
- Form C

For the event E02, there are three activities. This means that if any form from A02 gets saved first, then any form from A01 gets saved second, and then any form from A03 gets saved third, the order of the forms will be:

1. All forms from A02 according to the design
2. All forms from A01 according to the design
3. All forms from A03 according to the design

In other words, the order of forms for event E02 for this specific example will be like this:

- Form C
- Form D
- Form A
- Form B
- Form E



Queries in Excel export

Queries in Excel export

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The Queries can be exported to the following export output formats:

- Microsoft Excel - Office Open Extensible Markup Language ([XML](#))
- Comma-separated values ([CSV](#))
- Operational Data Model ([ODM](#))

To include the query information in the exported file, you need to select **Queries** under **Type of data** in the Data export page. When selecting to include **Queries**, the **Query history** option becomes available.

The screenshot shows the 'Data Export' configuration interface. It includes sections for 'Subjects to include (21)', 'Events and time period', and 'Forms and items', each with a dropdown menu set to 'All'. The 'Type of data' section has a row of buttons for 'Signed data', 'Not Signed data', 'SDV performed or NA', 'SDV pending', 'Queries', and 'Query history'. Below this, there are two rows of checkboxes: the first row has 'Signed data' and 'Not Signed data'; the second row has 'SDV performed or NA' and 'SDV pending'. A third section, titled 'In addition to data, also include the following in the export (will not be included in Preview data)', contains a grid of checkboxes: 'Queries' and 'Query history' are checked and highlighted with an orange box; other options include 'Review status', 'Event dates', 'Uploaded files', 'Medical coding', and 'Edit status'.

Depending on if the **Query history** is included in the export or not, the information in the export output file is grouped as follows:

- Without **Query history** - there is one row for each query, providing information on the current state of the query.
- With **Query history** - there is one row for each change in a query state, that is, there can be many rows for one and the same query.

In the Excel export output, considering as an example the default settings under **Output format**:

- Output to Excel
- Group data by form
- 1 row per activity

...the query information is grouped in a separate sheet of the excel file, called **Queries**.

The columns provide information on the item that the query was raised on, followed by the query specific information, as illustrated in the image (the image shows the query-specific information only) and listed in the following table:

	R	S	T	U	V	W	X
1	Query item sequence number	Raised on	Query type	Range check OID	Query text	Query state	Query resolution
2	QueryItemSeqNo	RaisedOn	QueryType	RangeCheckOID	QueryText	QueryState	QueryResolution
402	1	Item	Validation	RC_DMAGE_1_0_1	Age is not within the expected range (19-65), defined per	Query Raised	
403	1	Item	Validation	RC_DMAGE_1_0_1	Age is not within the expected range (19-65), defined per	Query Closed	Closed due to data edit
404	2	Event date	Manual		Visit date is not within the protocol visit window	Query Raised	
405	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
406	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
407	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
408	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
409	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
410	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
411	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
412	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Resolved	Correct
413	1	Item	Validation	RC_VSSYS_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
414	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
415	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	
416	1	Event date	Validation		Visit date is not within the protocol visit window	Query Raised	
417	1	Event date	Validation		Visit date is not within the protocol visit window	Query Raised	
418	1	Item	Manual		Is data correct?	Query Raised	
419	1	Item	Manual		Is data correct?	Query Resolved	Data correct
420	1	Item	Validation	RC_VSPULSE_0_0_1	Value is outside of normal range. Please verify.	Query Raised	

Column name	Description
Query study sequence number	Counter that identifies the query globally within the whole study. This field is empty for the <i>Unconfirmed missing data</i> .
Columns that identify the item	
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is used for the repeating forms. For non-repeating forms, this is always "1".
Item Id	The item ID, as set in the study design (in Viedoc Designer).

Column name	Description
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Query specific information	
Query item sequence number	Counter that identifies the query within a sequence of queries for the same item.
Raised on	Specifies if the query was raised on an item or on the event date: <ul style="list-style-type: none"> ▪ <i>Item</i> ▪ <i>Event date</i>
Query type	Specifies the query type, depending on how it was raised: <ul style="list-style-type: none"> ▪ <i>Manual</i> - for manually raised queries. ▪ <i>Missing data</i> - data confirmed as missing ▪ <i>Pending form upgrade</i> - forms pending upgrade as a result of applying a revision of the study design ▪ <i>Unconfirmed missing data</i> ▪ <i>Validation</i> - for automatically raised queries, as a result of validation.
Range check OID	Only for automatically raised item queries (i.e. Query type = <i>Validation</i> and Raised on = <i>Item</i>). The unique Object Identifier (OID) of the edit check that generated the query, as set in Viedoc Designer.
Query text	The text of the query.
Query state	Can be one of the following (see also Query overview): <ul style="list-style-type: none"> ▪ <i>Query Raised</i> ▪ <i>Query Resolved</i> ▪ <i>Query Approved</i> ▪ <i>Query Rejected</i> ▪ <i>Query Closed</i> ▪ <i>Query Removed</i> <p>Note! The queries that were automatically closed due to form reset/delete (with status <i>Query Closed</i>) are not included in the export.</p>
Query resolution	The resolution text entered when resolving (answering) the query. Not applicable for those changes performed by the system (i.e. User name = <i>System (0)</i>)
User name	The name of the user who performed the changes, followed by the user ID in parentheses. Note! For those changes performed by the system (such as validation queries, that are automatically raised by the system) the User name = <i>System (0)</i> .
Date & time (UTC)	The date and time when the change was performed.
User role	The role of the user who <u>performed the action on the query</u> .
Query raised by role	The role of the user who <u>raised the query</u> .



Review status in Excel export

Review status in Excel export

Published by Viedoc System 2023-10-09

[1. Review status](#)

[2. SDV](#)

This lesson describes how the review status information is structured within an Excel file exported from Viedoc.

For general details about data export, see [Exporting data](#).

1 Review status

Note! When selecting **one row per item** as **Layout**, the review status is not included in the export.

In the Excel export output file, there is one separate sheet for the **Review status**:

Reviewed Item	Clinical review by	Clinical review date (UTC)	Data review by	Data review date (UTC)	SDV by	SDV date (UTC)	Signed by	Signed date (UTC)	Lock by	Lock date (UTC)
ReviewedItem	CrBy	CrDate	DmBy	DmDate	SdvBy	SdvDate	SignBy	SignDate	LockBy	LockDate
Event date	Demo User (317)	2018-09-10 08:01			Demo User (317)	2018-09-10 08:01				
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00				
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00
Event date										
Event date										
Event date										
Event date					Demo User (317)	2018-07-31 11:45				
Event date										
Event date										
Event date										
Event date	Demo User (317)	2018-09-07 11:44			Demo User (317)	2018-09-07 11:44			Demo User (317)	2018-09-07 11:45
Event date	Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00			Demo User (317)	2018-09-10 08:00

The first columns provide information for identifying the form that was reviewed, followed by the review information, as listed in the following table:

Column name	Description
Columns that identify the form	
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.

Column name	Description
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	<p>Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.</p> <p>For non-repeating forms, this is 1. If a form is reset and then saved again the new form has sequence number 2, and so on.</p> <p>Form sequence number increases one step every time reset/initiate occurs.</p>
Review status information	
Reviewed item	<p>Can be one of the following:</p> <ul style="list-style-type: none"> ▪ <i>Event date</i> - if the review action was performed on the event date. ▪ <i>Form</i> - if the review action was performed at form level.
Clinical review by	User name and user ID of the user that performed the clinical review.
Clinical review date (UTC)	The date and time in Coordinated Universal Time (UTC) when the clinical review was performed
Data review by	User name and user ID of the user that performed the data review (marked by the DM review flag).
Data review date (UTC)	The date and time (UTC) when the data review was performed.
SDV by	User name and user ID of the user that performed the Source Data Verification (SDV) (marked by the SDV review flag). For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed. For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
Signed by	User name and user ID of the user that signed the form.
Signed date (UTC)	The date and time (UTC) when the form was signed by investigator.
Lock by	User name and user ID of the user that locked the form.
Lock date (UTC)	The date and time (UTC) when the form was locked.

2 SDV

If, on the Data Export page, it was selected to include the [SDV](#) information, there is one separate sheet for the **SDV** information in the Excel export output file:

Activity name	Form Id	Form name	Form sequence number	Item Id	Item name	Reviewed item	SDV by	SDV date (UTC)
ActivityName	FormId	FormName	FormSeq	ItemId	ItemName	ReviewedItem	SdvBy	SdvDate
PI	Patient Info	Patient Info	1	AGE	Age	Item	Demo User (317)	2017-11-17 12:26
PI	Patient Info	Patient Info	1	DOB	Date of Birth	Item	Demo User (317)	2017-11-17 12:26
PI	Patient Info	Patient Info	1	GENDER	Gender	Item	Demo User (317)	2017-11-17 12:26
LABR	CBC LAB Results (Hematology)	CBC LAB Results (Hematology)	1	LABR_RANGE	Normal Range	Item	Demo User (317)	2018-09-10 08:01
LABR	CBC LAB Results (Hematology)	CBC LAB Results (Hematology)	1	LABR_RESULT	Result	Item	Demo User (317)	2018-09-10 08:01
LABR	CBC LAB Results (Hematology)	CBC LAB Results (Hematology)	1	LABR_TYPE	Lab results type	Item	Demo User (317)	2018-09-10 08:01
LABR	CBC LAB Results (Hematology)	CBC LAB Results (Hematology)	1	LABR_UNIT	Unit	Item	Demo User (317)	2018-09-10 08:01
LABR	CBC LAB Results (Hematology)	CBC LAB Results (Hematology)	1	LABR_DATE	SampleDate	Item	Demo User (317)	2018-09-10 08:01
PI	Patient Info	Patient Info	1	AGE	Age	Item	Demo User (317)	2018-09-10 08:00
PI	Patient Info	Patient Info	1	DOB	Date of Birth	Item	Demo User (317)	2018-09-10 08:00
PI	Patient Info	Patient Info	1	GENDER	Gender	Item	Demo User (317)	2018-09-10 08:00

Note! For studies where SDV is performed on item level, this sheet will include only the items that require SDV and are visible to the user.

The first columns provide information for identifying the item that was SDV-ed, followed by the review information, as listed in the following table:

Column name	Description
Columns that identify the item	
Site sequence number	Counter that identifies the site globally within the study.
Site name	The site name, as set in Viedoc Admin.
Site code	The site code, as set in Viedoc Admin.
Subject sequence number	Counter that identifies the subject within the site.
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event sequence number	Counter that identifies the event within the sequence of events for the same subject.
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.

Column name	Description
Form sequence number	<p>Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms.</p> <p>For non-repeating forms, this is 1. If a form is reset and then saved again the new form has sequence number 2, and so on.</p> <p>Form sequence number increases one step every time reset/initiate occurs.</p>
Item ID	The item ID, as set in the study design (in Viedoc Designer)
Item name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
SDV information	
Reviewed item	<p>Can be one of the following:</p> <ul style="list-style-type: none"> ▪ <i>Event date</i> - if the review action was performed on the event date. ▪ <i>Form</i> - if the review action was performed at form level.
SDV by	User name and user ID of the user that performed the SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed.



Managing users

Managing users

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

1 Introduction

1.1 Important information about signatures

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

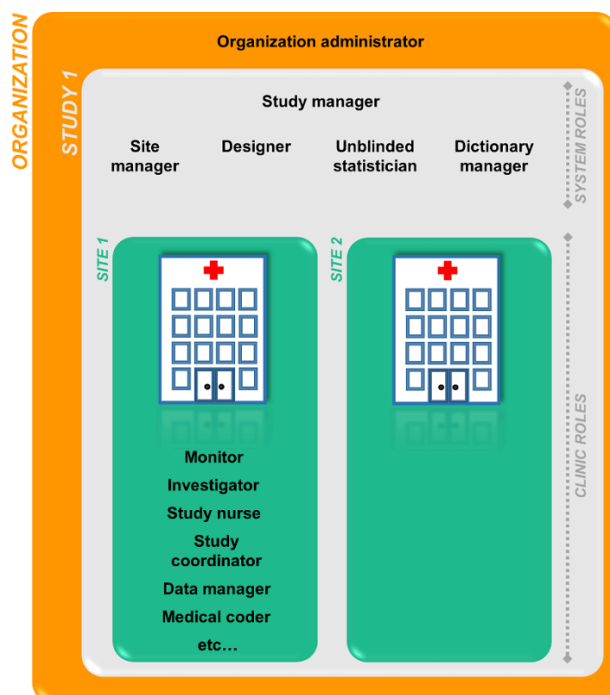
In Viedoc, the purpose/meaning of a signature is always “responsibility” as used in Sec. 11.50 of Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11. The signer is thereby acknowledging his/her responsibility for the entered data. Viedoc keeps account of what was signed,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

1.2 About roles in Viedoc

1.2.1 Two types of roles

Viedoc supports two different types of roles.

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



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

1.2.2 System roles

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

The following system roles are available.

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

Role	Description
Reference Data Source Manager	The Reference Data Source Manager manages the reference data sources at study level. The Reference Data Source Manager can also delegate the management of data sources at site level to the Site manager.
API Manager	The Application Programming Interface (API) Manager has access to the API settings and performs the API configurations. Complete instructions on how to configure the API are provided in Viedoc API .
eTMF Manager	The eTMF Manager manages 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.
Design Impact Analyst	The Design Impact Analyst can run an impact analysis in Viedoc Admin. A user with the role can see what impact a new design revision will have on existing form instances before applying the revision. Note! Before you invite a user with this role, read Design revision impact analysis to understand in which scenarios the design revision impact analysis report might reveal blinded information.

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

1.2.3 Clinic roles

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

Examples of clinic roles are:

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

1.3 About the study users

1.3.1 Overview of users in the organization/study/site

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

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

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

1.3.2 Users

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

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

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

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

On this page, you can (see image):

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

1.3.3 Study crew

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

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

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

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

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

1.3.4 Site users

Viedoc's demostudy Close

Uppsala University Hospital

Here you can modify site details and/or invite users to site.

Details **Site users** Add users

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

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

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

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

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








1.3.5 Viedoc skill level

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

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

1.3.6 User status

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

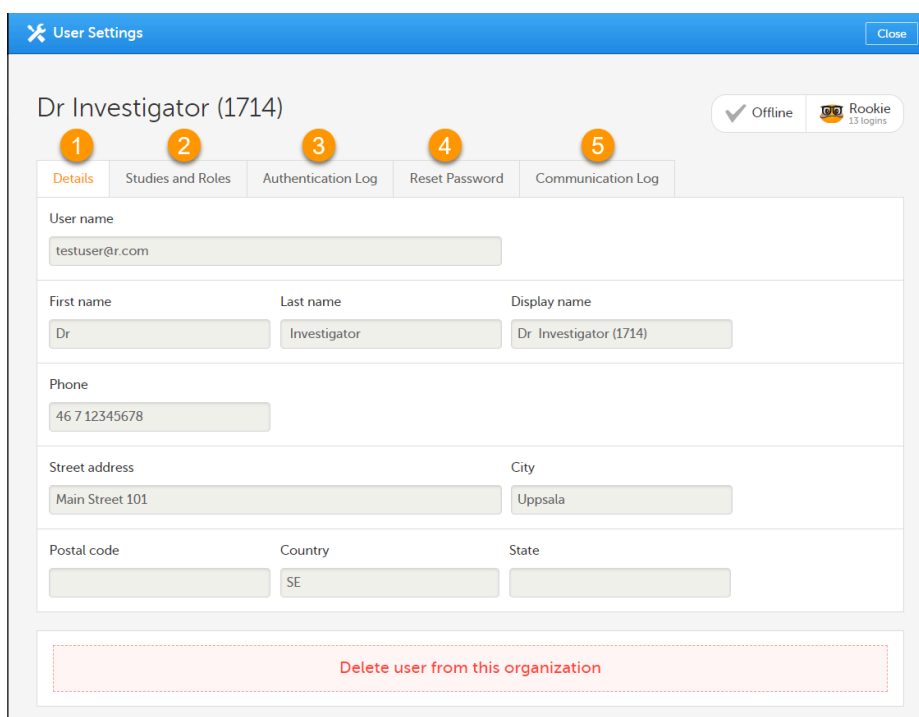
Status	Icon	Description
Online		The user is currently logged in to Viedoc, and has no pending invitations.
Offline		The user is currently not logged in to Viedoc, and had no pending invitations.
Pending		The user has at least one pending invitation to a role. The question mark is displayed even if the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

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

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

1.4 User settings

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



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

1. On the **Details** tab, you can view the user's name and contact details.

2. On the **Studies and Roles** tab, you can view a list of all roles and sites the user has access to, including the date and time of invitation/acceptance of that role. The roles are grouped per study. You can delete roles by clicking the trash can icon next to the role.

3. On the **Authentication log** tab, you can view a list of logins by the user, including date and time, the IP address, and the browser that was used. The number of displayed entries is limited to the latest 100 logins.

4. On the **Reset Password** tab, you can reset the password for that user, if the user has forgotten their password and does not have the phone number that can receive a text message or a secondary email address. Viedoc will send a notification to the user with a link to create a new password.

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

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

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

1.5 User report

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

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

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

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

1.5.1 Log of users and roles in PDF

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

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

1.5.2 User administration log in Excel

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

1. **Report Info** - general information about when and by whom the log was generated, and some information about the study status. The following more detailed information is contained:

- The Organization name
- The Study name
- Production study GUID
- Demo study GUID
- For PMS studies: Sponsor side Production study GUID
- For PMS studies: Sponsor side Demo study GUID

2. **User Access Log** - a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles. Some columns in this sheet are further explained here:

- **Site Group** - indicates when a user is granted access to the site through a site group invitation. Possible values are *Training sites*, *Countries*, and *All sites*.
 - **2FA** - indicates what level of two-factor authentication the user has. Possible values are *Study level*, *Account level*, or *No two-factor authentication enabled*.
 - **Latest system login date/time** - information about the latest login of each user.
 - **Certified** - indicates if the user is certified for the role. Possible values are *Yes*, *No*, or an empty cell for roles that don't have mandatory training sections to read.
 - If the user has signed the certification associated to their role, the column will display: Certified:Yes.
 - If the user has selected Read & Understood but not signed the associated certification, the column will display: Certified: No.
 - **User type** - indicates the type of user. Possible values are *End User or API Client*, to indicate if the user is an end user that can log in to the system or a Web API Client that can access the API with a role.
 - **Latest system login date/time** - information about the latest login of each user for end users only, not API client users.
3. **Certification Log** - a list of certifications per user. Certifications performed before the release of 4.65 lack information about what roles the certification applies to. That is, the cells in column **Certified With Roles** are empty.
4. **Summary** - a summary of users per site with information about country, side code, site name, number of active/inactive users, and date/time of last access change.
5. **Account Settings Log** - a list with all user accounts setting changes with user ID, change log, user name, and date/time.

1.5.3 Communication log in Excel

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

Note!

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

1.5.3.1 User-specific information

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

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

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

User Settings
Close

User One (1234)

user.one@mail.com

✔ Online

 Pro
369 logins

Details	Studies and Roles	Login History	Reset Password	Communication Log
---------	-------------------	---------------	----------------	-------------------

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

Communication log

Download (2022-03-18 05:22)
Regenerate

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

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

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

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

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

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

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

Communication logs						
Message id	Type of Communication	Datetime (UTC)	Message Type	To	Status	Provider
99704495-aa67-4bed-b246-cc3f8b1c8d47	Email	2022-03-01 07:46:25	Two Factor Authentication	user1@viedoc.com	Success	Primary-Primary
a96f1beb-c63c-4376-9ae0-e9dcda1cb8d4	Email	2022-03-01 07:44:29	Recover Account Request	user2@gmail.com	Success	Secondary-Secondary
00520b3e-f26a-4077-9dac-edc9458cc30a	Sms	2022-03-01 06:16:22	Verify Phone Number		Success	Primary-Primary
e01f2d59-8af4-48ba-81b7-fb4045d18767	Email	2022-03-01 06:16:20	Verify Email Address	123@mail.com	Success	Primary-Primary
9ad92c51-7582-4bce-b243-d63737bb079d	Sms	2022-03-01 06:11:07	Verify Phone Number		Success	Primary-Primary
448b70b8-faea-4dc3-b07a-a892457eb358	Email	2022-03-01 06:11:00	Verify Email Address	999@gmail.com	Success	Primary-Primary
1de6048b-a1a9-48bb-85e2-94ab6ec4f42	Sms	2022-03-01 04:44:05	Verify Phone Number		Failed	Secondary
399a561a-4299-4ceb-a0ac-a87825cdfbaa	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
8ee881c-78ab-45c9-95e4-5123e09cc129	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
f8ef8347-de0e-422b-be2a-d8bba0a7d650	Email	2022-03-01 04:42:41	Verify Email Address	789@gmail.com	Failed	Secondary
1fc884e2-3cf3-4063-8f47-a8cfc02233a	Email	2022-03-01 04:39:43	Verify Email Address	abcd@gmail.com	Failed	Secondary
9c813fce-6633-4dee-b0ba-3666ee14cf5f	Sms	2022-03-01 04:39:38	Verify Phone Number		Success	Secondary-Primary
fc98775c-01f2-4b4d-aad7-	Email	2022-03-01 04:39:29	Verify Email Address	123@mail.com	Failed	Secondary

1.5.3.2 Study-specific information

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

The screenshot shows the Admin interface for 'Studies' and 'Users'. The 'Users' section is active, showing a list of 7 users for 'First study'. The users are listed with their names, email addresses, and roles. A dropdown menu is open over the 'User logs' column, showing options for generating logs. The 'User communication log' option is highlighted, and the 'Download (2022-03-02 09:25)' button is visible.

User	Study and site	Role
Dr Investigator (1714) testuser@r.com	First study Multiple sites	Investigator
Rachel McKie (1680) rachel@viedoc.com	First study Multiple sites	Study Manager + 12 other roles
Technical Writer (1736) Name.lastname@mail.com	First study Multiple sites	Investigator

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

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

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

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

The Excel sheet has the following columns:

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

Message ID	Communication Type	Datetime (UTC)	Message Type	Site Type	To	CC	BCC	Status	Provider
176502c-8c85-4753-8952-8750e0e18b0c7	Email	2022-03-03 06:52:07	Form Alert True Action	Production	rb@doc.com	rb@doc.com	#f53@mail.com, user51.eghrvm@gmail.com	Success	Secondary-Secondary
6734e721-bceb-477d-9e94-8d07f0e0e0e4	Email	2022-03-03 06:52:05	Event Reminder	Production	rb@doc.com	user1@mail.com	dyuHtst7@gmail.com, user78.hystff@gmail.com	Success	Secondary-Secondary
42d0907-1569-4945-9d17-ff6584e0e2a	Email	2022-03-03 06:52:03	Study Unlock Notification	Production	user1@mail.com	user3@gmail.com	ff0f05@gmail.com, user56.kiofd@gmail.com	Success	Secondary-Secondary
9797c6d5-60c1-435a-8d97-81677c0b022	Email	2022-03-03 06:52:01	Invite User	Production	user2@sse.com	user@vc.com	hmki378@gmail.com, user6972.uhvm@gmail.com	Success	Secondary-Secondary
85e5a421-d529-40b3-979e-de4ac183902	Email	2022-03-03 06:45:53	Remove User Access Notification	Production	ghu.nustf@mail.com	mol.hbdb@mail.com	ffgds65@gmail.com, ffsuifs.fk@gmail.com	Success	Secondary-Secondary

Note!

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

1.6 System site groups

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

- All sites, containing all sites in the study.

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

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

2 Step-by-step guides for the **Study Manager**

2.1 Assigning users to system roles and/or clinic roles

Only the **Study Manager** can invite users to system roles. The Study Manager can also invite users to clinic roles, or he/she can delegate the management of (some of the) clinic roles to the Site Manager, see [Delegating user management to the Site Manager](#) for instructions. Once the management of clinic roles is delegated to the Site Manager, the Study Manager cannot invite users to these roles anymore.

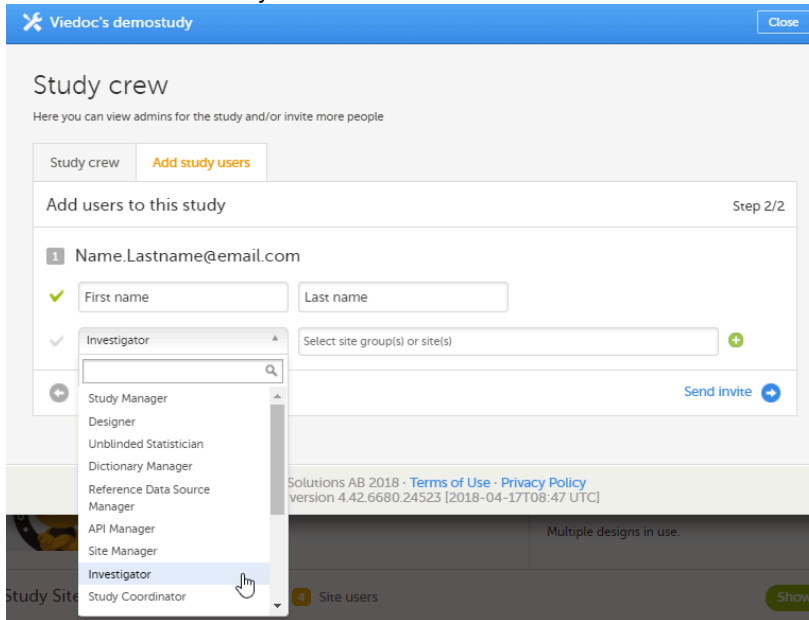
If a user should receive access to multiple sites, the quickest way to invite the user is through the study crew window (described in this section). If a user should receive access to only one site, you can also invite the user through the site settings window of that site (see [Assigning users to clinic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

To invite users:

- 1 In Viedoc Admin, open the study to which you would like to invite users.
- 2 Click the toolbox icon in the **Study crew** field. The Study crew pop-up opens.
- 3 On the **Add study users** tab, enter the e-mail address of the user you would like to invite. Click **Continue**.

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.

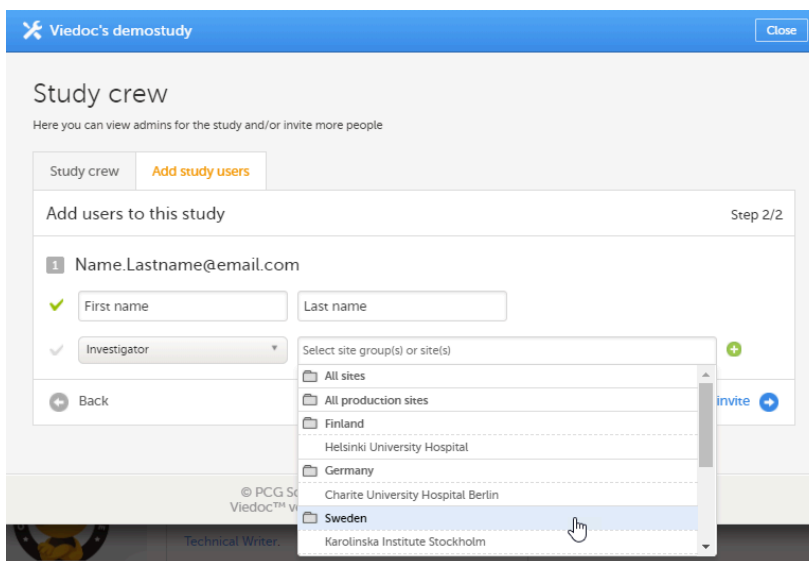
4 Select the role to which you would like to invite the user.



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**.

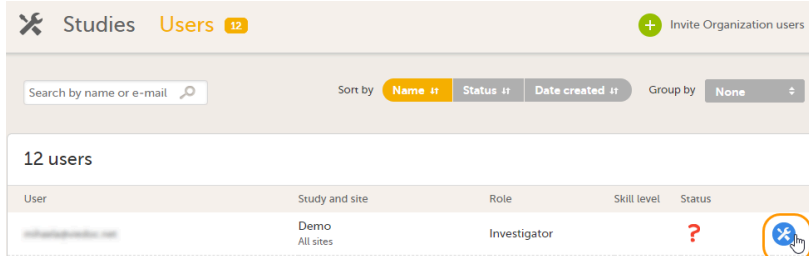
An invitation e-mail will be sent to the e-mail address(es) you specified.

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.

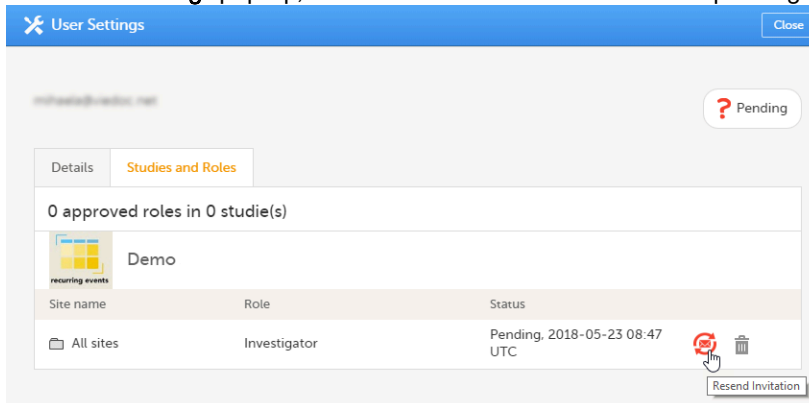
To resend an invitation:

- 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:



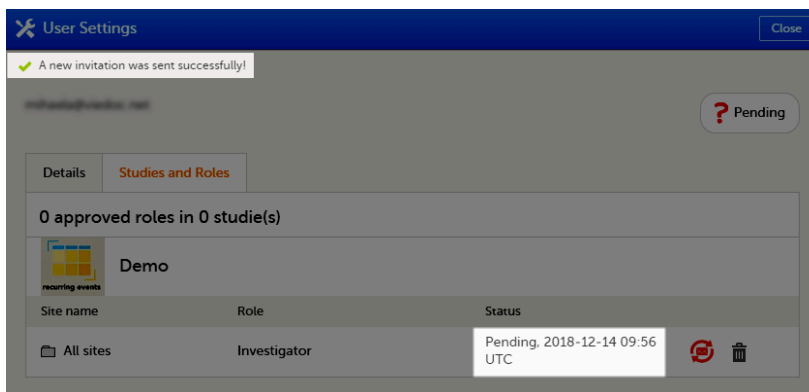
The **User Settings** pop-up opens.

- 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.

Studies Users 10 Invite Organization users

Search by name or e-mail Sort by Name # Status # Date created # Group by None #

10 users

User	Study and site	Role	Skill level	Status
[Redacted]				
Firstname.Lastname@email.com		Organization Admin + 1 other roles		
Dr. Demo (383) [Redacted]	Viedoc's demostudy Multiple sites	Dictionary Manager + 2 other roles		
Dr. Investigator (490) [Redacted]	Viedoc's demostudy Multiple sites	Dictionary Manager + 3 other roles		
[Redacted] (294) [Redacted]	Multiple studies Multiple sites	Study Manager + 5 other roles		
[Redacted] (296) [Redacted]	Viedoc's demostudy Multiple sites	Investigator		
Technical Writer (304) [Redacted]	Multiple studies Multiple sites	Organization Admin + 10 other roles		
TW CN (371) [Redacted]				
Viedoc Admin (90) [Redacted]		Organization Admin		

[↑ To the top](#)

The User Settings pop-up opens.

User Settings Close

Dr Investigator (1714)
testuser@r.com Offline Rookie 2.3 logins

Details Studies and Roles Authentication Log Reset Password Communication Log

User name
testuser@r.com

First name Last name Display name

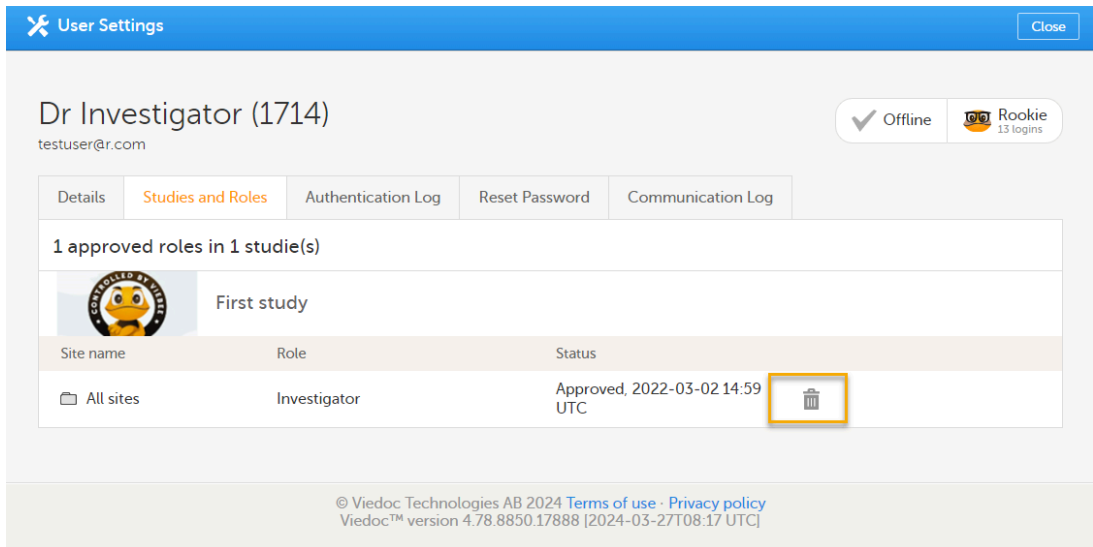
Phone

Street address City

Postal code Country State

[Delete user from this organization](#)

- 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.



The screenshot shows the 'User Settings' interface for a user named 'Dr Investigator (1714)'. The user's email is 'testuser@r.com'. The 'Studies and Roles' tab is selected, showing a table of roles. The table has columns for 'Site name', 'Role', and 'Status'. One role is listed: 'Investigator' for 'All sites' in the 'First study'. A trash can icon is highlighted in the table row. The user's status is 'Offline' and they are a 'Rookie' with 13 logins. The footer contains copyright information for Viedoc Technologies AB 2024.

Site name	Role	Status
All sites	Investigator	Approved, 2022-03-02 14:59 UTC

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.

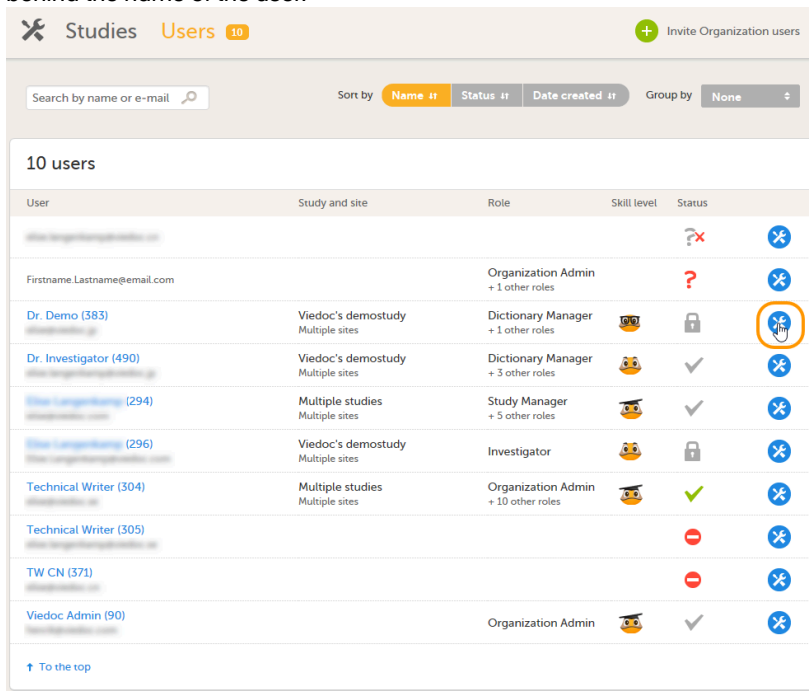
Any records generated by the user are stored in the audit trail even when the user has been removed.

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.

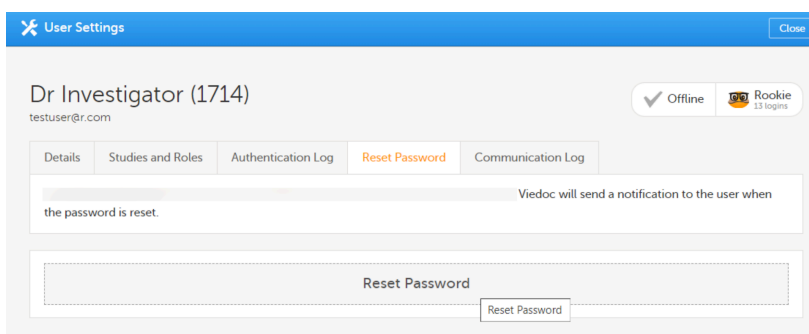
To unlock a user account:

- 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.

Viedoc's demostudy Save changes Close

Study settings

Here you can set settings for study.

Settings ! Date & time format Medical Coding Import ODM File

Ongoing, FPA 2017-02-02 Full functionality. Invalid license

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

Sponsor Code CRO Code

Reference ID

Study Type Sponsor Type Study Phase

Therapeutic Area Expected number of subjects

Study access

Password expiration time for all users in this study (values allowed are 1 to 5000) days

Require two-factor authentication for all users accessing this study

Clinic roles to be administered by Site Manager

Investigator Study Coordinator Monitor Project Manager Data Manager

Sponsor DRC Coordinator Trial Manager Medical Coder Lab Import

Helpdesk team

PCG Helpdesk Britanica Helpdesk

Allow reminders in ViedocMe to be sent as

Email Text message

[Show more options](#)

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

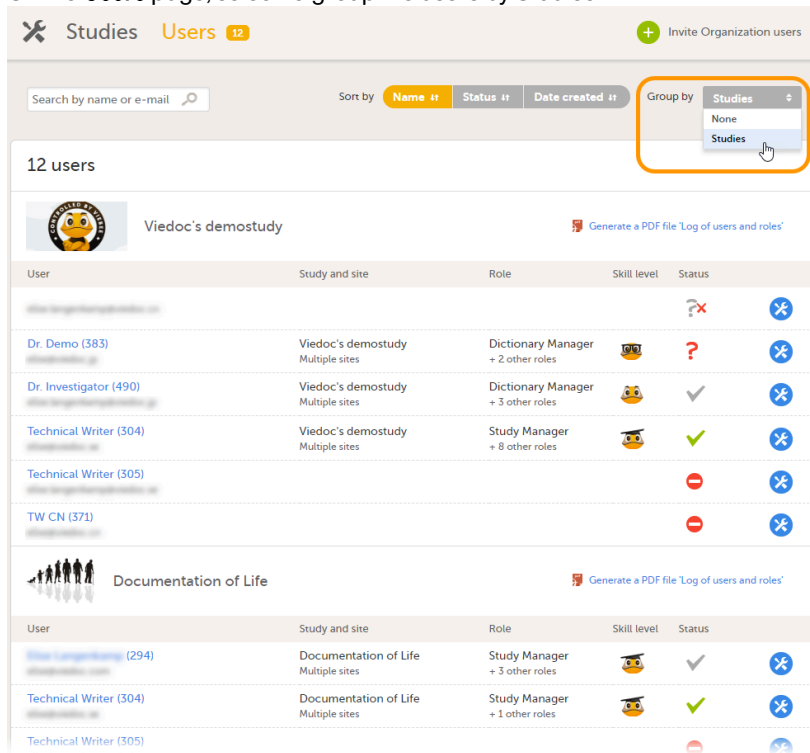
- 3 Click **Save changes**, and click **Close**.

Note! These settings apply to all sites and all Site Managers involved in the study. When the assignment of (some of the) clinic roles is delegated to the Site Manager, these clinic roles can no longer be managed by the Study Manager.

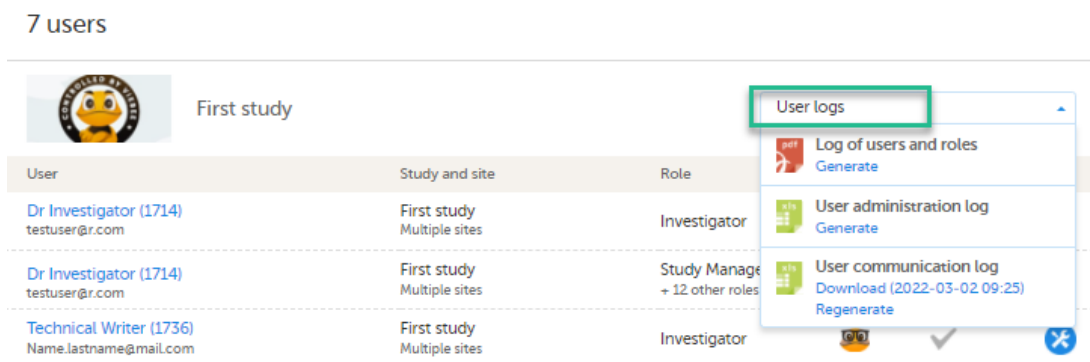
2.6 Downloading the user logs

To download the user logs:

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



2 Scroll to the study from which you would like to download the user log and click **User logs** to open the dropdown menu.



If the log was not previously generated, click **Generate a PDF file** or **Generate an Excel file**. If the log was previously generated, the most recent version is stored on the server, shown with a date and time stamp. You can download it by clicking the link, or, generate an updated version by clicking **Regenerate**.

Note! The user logs are generated in the language set by the user who is generating the log. Therefore, the previously generated file is available for download only if it was generated in the language you have currently set in Viedoc.

3 Step-by-step guides for the **Site Manager**

3.1 Assigning users to clinic roles

The **Site Manager** can invite users to (some of the) clinic roles, if the study manager has delegated the management of these clinic roles to the site manager.

To invite users to a specific site:

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

The screenshot shows the 'Viedoc's demostudy' interface. At the top, there are tabs for 'Studies' and 'Users'. Below this, there are sections for 'Study crew' and 'Study design'. The main part of the interface is a table titled 'Study Sites' with columns: '#', 'Site name', 'Code', 'Country', 'Effective Design', 'Production', and 'Users'. The first row is highlighted, and a red circle is drawn around the toolbox icon in the 'Users' column for the first site, 'Karolinska Institute Stockholm'. Below the table, there is a '+ Add a site to this study' button.

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

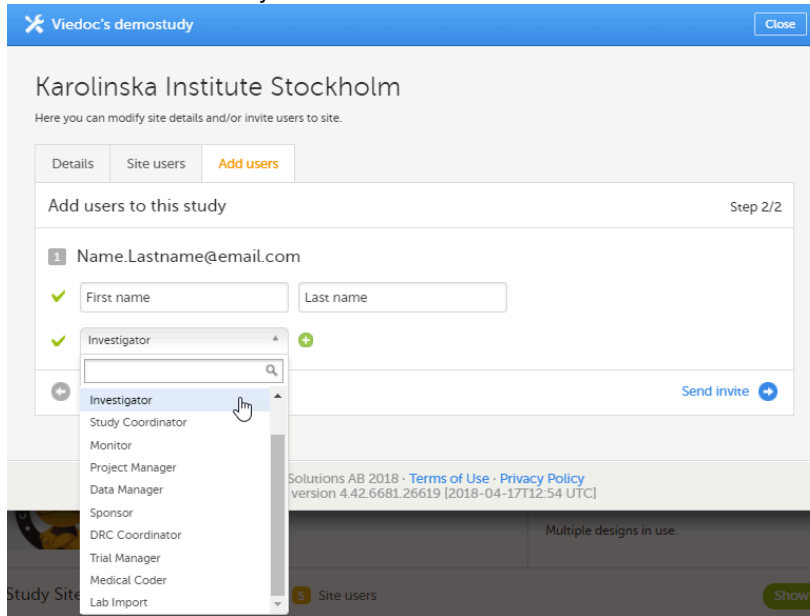
The site settings pop-up opens.

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

The screenshot shows the 'Add study users' pop-up for 'Karolinska Institute Stockholm'. The interface has a blue header with the study name and a 'Close' button. Below the header, there are tabs for 'Details', 'Site users', and 'Add users'. The 'Add users' tab is selected. The main content area is titled 'Add users to this study' and 'Step 1/2'. It contains an 'E-mail address' field with a placeholder text 'Name.Lastname@email.com'. Below the field, there is a note: 'Multiple email addresses can be included by separating with semi-colon or comma.' At the bottom right, there is a 'Continue' button with a right arrow.

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.



Create a user account

Create a user account

Published by Viedoc System 2018-11-12

This video walks you through the process of creating a Viedoc user account.

If you have difficulties in viewing this video click [here](#).



Log in/Log out and reset password

Log in/Log out and reset password

Published by Viedoc System 2019-11-14

This video shows how to log in/log out to/from Viedoc and how to reset your password.

If you have difficulties in viewing the video, click [here](#).



Landing page

Landing page

Published by Viedoc System 2018-11-07

This video provides a quick overview of the landing page as well as of the study start page.

If you have difficulties in viewing this video, click [here](#).



Activate demo mode

Activate demo mode

Published by Viedoc System 2018-11-07

This video demonstrates how to switch between demo and production mode within a study.

If you have difficulties in viewing this video, click [here](#).



Monitor training video

Monitor training video

Published by Viedoc System 2021-05-05

This is a Viedoc introductory video for monitors.

If you encounter difficulties in viewing this video click [here](#).



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](#).

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