viedoc learning™

Viedoc PMS User Guide for Sponsor Side Users

17 Lessons   ■ **17** from Viedoc System

General
4 lessons

Overview of Viedoc PMS — 1.1

System requirements — 1.2

Updated Managing your Viedoc account — 1.3

Overview of the landing page for Viedoc PMS — 1.4

Handling booklets and AE reports
3 lessons

Overview of the submit-receive-return function — 2.1

Booklet overview — 2.2

Handling booklets, AE reports and forms — 2.3

Data entry
4 lessons

Study start page — 3.1

Selection page — 3.2

Metrics — 3.3

Working with reference data — 3.4

Data review
2 lessons

Issues and tasks in a PMS study — 4.1

Data review in a PMS study — 4.2

Queries

Queries overview — 5.1

Raising and promoting pre-queries — 5.2

Raising/Approving/Rejecting queries — 5.3

Data export

Updated Exporting data — 6.1

Overview of Viedoc PMS

Overview of Viedoc PMS

Published by Viedoc System 2022-12-14

## 1 Introduction to Viedoc PMS

Viedoc PMS is the product on the Viedoc platform that can be used for Japanese Post Marketing Surveillance ([PMS](#)) studies. It fulfills all requirements of a PMS study, supports collection of data in booklets, and supports the process of sharing data between site (clinic) and sponsor via the submit-receive-return *Kaifu* function.

1.1 Clinic side versus sponsor side

In Viedoc [PMS](#), the database is shared by two different sides, a clinic side and a sponsor side. The database contains two versions of each data set, one version that is displayed to the clinic side users and one version that is displayed to the sponsor side users. On the clinic side, typically the Investigator enters subject data, while on the sponsor side the Data Manager typically reviews the data and archives (freezes) the data.
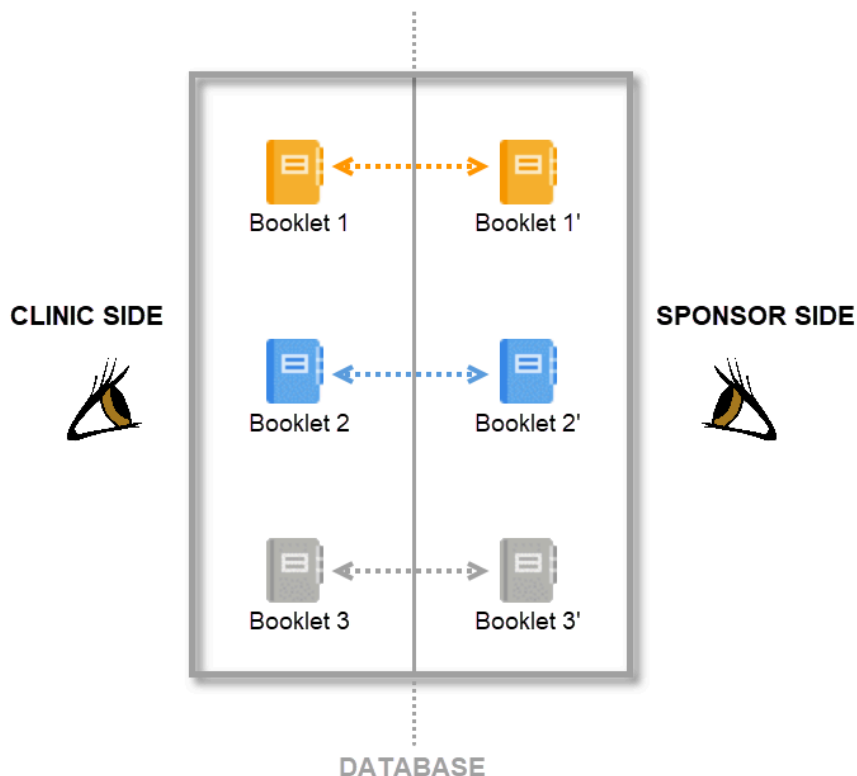
Synchronization of data between the clinic side and the sponsor side is not performed automatically and continuously, but is controlled by the clinic side users and sponsor side users via the send-receive-return process. This means that data are only transferred from the clinic side to the sponsor side when the clinic user actively

performs a submit action and the sponsor side user actively performs a receive action. Similarly, queries raised by the sponsor side user are only displayed to the clinic side user after a return action is performed by the sponsor side user. The send-receive-return process is described in more detail below.

1.2 Booklets

By mirroring the data collection and review process via booklets, Viedoc matches the workflow of a Japanese PMS study. A booklet can be seen as a compilation of data being collected during a specific period of time rather than during a specific event date, which is more typical in clinical trials.

1. Subject details
2. Overview of booklets
3. Content of selected booklet
4. Details of selected booklet

1.3 The send/receive/return process for handling booklets (Kaifu)

Sending and receiving data on request is a fundamental requirement for a Japanese PMS study. Viedoc PMS offers support for sending and receiving booklets back and forth between site and sponsor, a process referred to as *Kaifu*. In the *Kaifu* process, the clinic user chooses when to share data with the sponsor and the sponsor side user chooses when to receive the data. One of the important characteristics of this process is that the sponsor side user does not have access to any data entered in a booklet, until the booklet has been shared by the clinic through the submit function, and a receive action has been actively performed by the user at the sponsor side.

For more information, see Overview of the submit-receive-return process.

2 Working with Viedoc PMS

Viedoc PMS is the interface for the end user, and is primarily used by site and study staff (Investigators, Study Coordinators, Monitors, Data Managers, and so on).

The access to Viedoc PMS is by invitation only and provided by either the Study Manager or Site Manager. If invited, you will find the invitation in your email inbox (from *no-reply@viedoc.net*). In some cases the email can be caught by your email spam filter and in that case you will find it in the email spam folder. For detailed instructions on account activation, see Managing your Viedoc account.

The following actions can be performed in Viedoc PMS:

- Data entry - described in the following lessons:
  - Selection page
  - Entering and editing data in a PMS study
  - Resetting and deleting data in a PMS study

- Reference data
- Review data, and raise and resolve queries - described in the following lessons:
  - Data review in a PMS study
  - Raising and promoting pre-queries
  - Raising/Approving/Rejecting queries
  - Resolving queries.

- Handle booklets - described in the following lessons:
  - From the clinic side: Sending and recalling booklets
  - From the sponsor side: Receiving and returning booklets, and Freezing booklets

- Data export - described in the lesson Exporting data
- Medical coding - described in the lesson Medical coding in Viedoc Clinic
- View study metrics - described in the lesson Metrics

---

3 Languages

Viedoc PMS is available in the following languages:

- English
- Japanese

System requirements

System requirements

Published by Viedoc System 2022-06-16

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 2024-03-18

1 Introduction

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

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

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

2 Study access management

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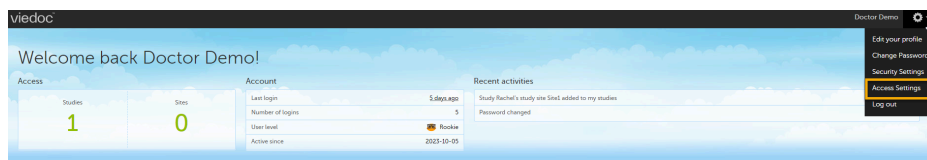
3   Access settings

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

3.1   Study membership
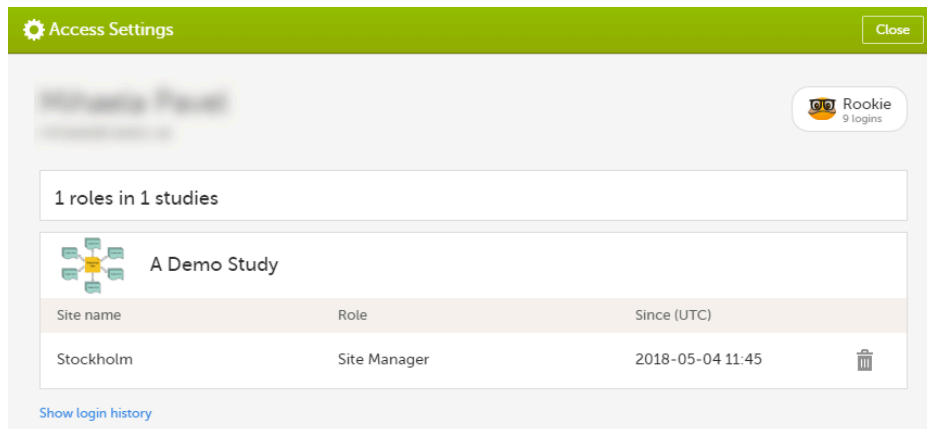
The following information is provided, grouped by study:

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

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

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

3.2   Deleting study access

To remove yourself from a certain role within a study:

1   Select the trash can icon on the right, corresponding to the role, site and study to be removed from:
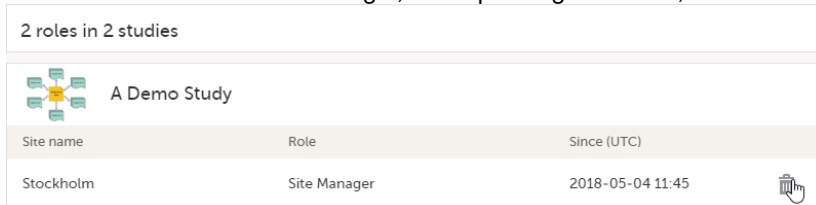
A confirmation dialog is displayed.

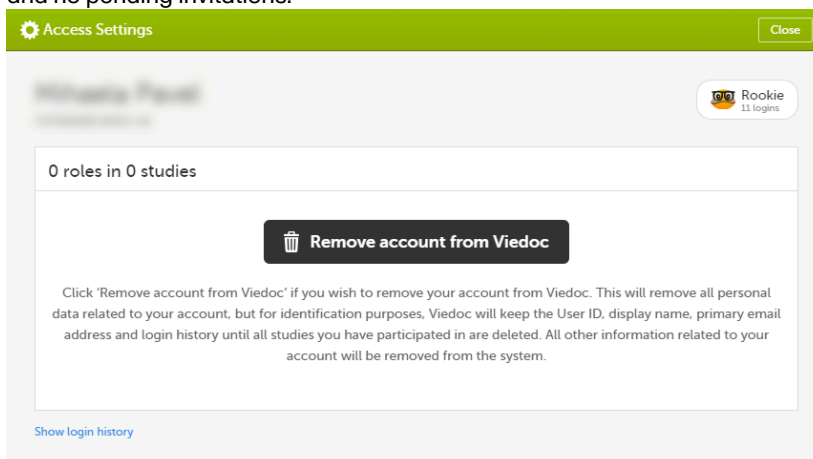**2**   Select **Delete** to confirm the deletion:
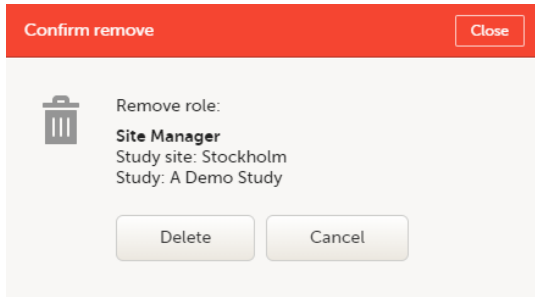
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

## 3.3   Deleting your Viedoc account

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

To delete your Viedoc account:

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

2   Select **Remove account from Viedoc**. You will be prompted to confirm the account removal by entering your password:
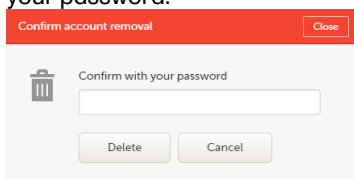
3   Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:

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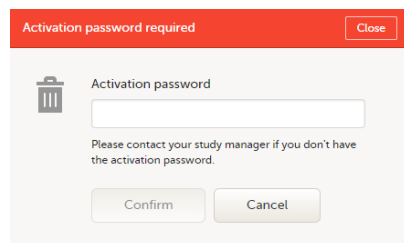
4   Pending invitations

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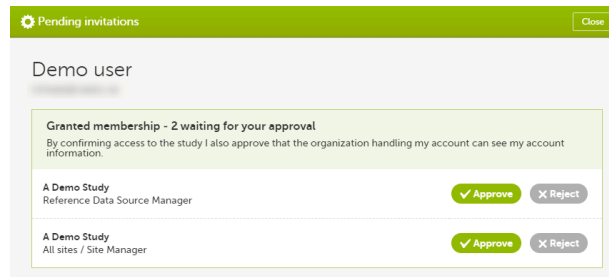
4.1   Approving a study invitation

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

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

4.2   Rejecting a study invitation

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

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

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

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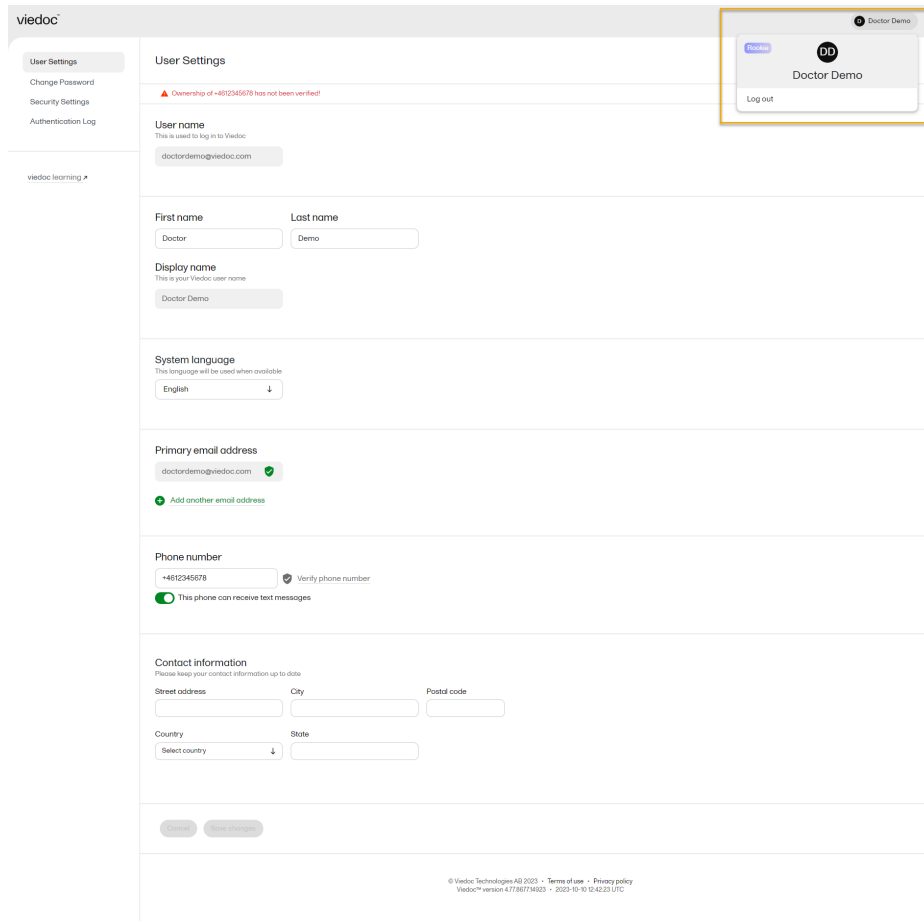
5   Logging out

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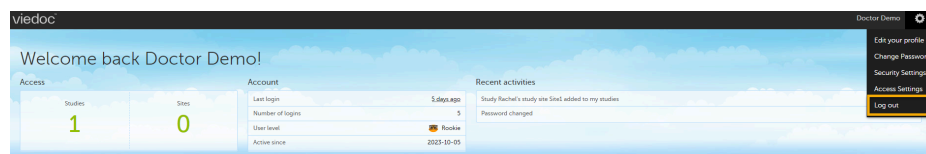
- To log out from settings, select the settings button (wheel) in the top right corner of the window, and select **Log out**. Use this link every time you leave the application from this location.

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

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

Overview of the landing page for Viedoc PMS

Published by Viedoc System 2023-06-21

1   The landing page

This lesson describes the landing page. The landing page is displayed when you log in to Viedoc.

The landing page provides the following summary information:

- *Access*:
    - Studies - the total number of studies you have access to.
    - Sites - the total number of 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 - 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

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

- Active since - the date when you have 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 an icon for each study you have access to. For those users having access to regular clinical studies as well as PMS studies, the PMS studies are marked with a **PMS** icon.

---

2 Entering a study

To enter a study, select a study icon in the bookshelf. The study start page is loaded on the bottom-half of the screen. For more information, see Study start page.

If you have access to both the clinic side and the sponsor side of the same study, the following launch box opens when you select the study icon in the bookshelf:

Select data side

i

Japanese PMS 1

You have access to data both on Clinic and Sponsor sides. Please select which kind of data you wish to work with.

Clinic side data

Sponsor side data

Select **Clinic side** to enter the clinic side of the study, and add subjects, enter data, answer queries and submit booklets and Adverse Event (AE) reports. Select **Sponsor side** data to enter the sponsor side of the study to review data, raise queries, and return or freeze booklets and AE reports.

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

Welcome back Technical Writer!

2

13

Overview of the submit-receive-return function

1   Introduction

Viedoc PMS offers support for collecting data in booklets, allowing data to be collected during a specific time period rather than a specific event date, and support for sending and receiving booklets back and forth between site and sponsor. This process of handling booklets in a Japanese post-marketing surveillance study is known as the *Kaifu* process. In the *Kaifu* process, the clinic user chooses when to share data with the sponsor and the sponsor-side user chooses when to receive the data. One of the important characteristics of this process is that the sponsor-side user does not have access to any data entered in a booklet, until the booklet has been submitted by the clinic, and a receive action has been actively performed by the user at the sponsor side.

Booklets can only be submitted to the sponsor when all events and forms in the booklet are completed.

There is an exception to this rule, which depends on your study configuration. It is possible that some forms, (for example, but not limited to, Adverse Events) can be managed, that is, submitted/received/returned/reviewed/reported individually. When these forms are saved, a warning message is displayed and a **Manage** link is available. For more information, see Submitting and recalling booklets, AE reports and forms and Handling booklets, AE reports and forms for more information.

This lesson provides a description and a schematic overview of the submit-receive-return process of handling booklets and adverse events.

2   Handling booklets

2.1   Schematic overview of the *Kaifu* process

The below image provides a schematic overview of the submit-receive-return process of handling booklets.

CLINIC SIDE   **SPONSOR SIDE**

Booklet open for data entry — *Submit*

Booklet submitted — *Recall*

Resolve queries

Booklet received — *Receive* / *Return*

Booklet returned — *Recall return*

Booklet frozen — *Unfreeze* / *Freeze*

Legend:

= booklet is not open for edit, and does not contain data

= booklet is open for edit/review/queries

= booklet is not open for edit, data can be viewed but is not synchronized between sides

2.2 Description of the workflow during the *Kaifu* process

A booklet, a compilation of data being collected during a specific period of time, is initiated on the clinic side and data are entered. Once a booklet is completed and all required items are filled in, the booklet can be submitted. The clinic user has to confirm submission of the booklet by entering his/her password. By giving the password, the user at the same time signs the data in the booklet. Submission of a booklet does not immediately result in the booklet appearing at the sponsor side, instead, the sponsor side user has to actively receive the submitted booklets. A submitted booklet can be recalled at any time up until the moment that the sponsor side has received the booklet. A recalled booklet can then be edited before submitting it again to the sponsor side.

On the sponsor side, the booklet receive action has to be confirmed by clicking **Confirm**. Only once a booklet is received at the sponsor side, is the data in the booklet displayed to the user at the sponsor side. The sponsor side user can review the data and raise queries, while at the clinic, the booklet is in read-only state and no data changes can be made. The sponsor user has the possibility to either return the booklet to the clinic, in case queries are raised for example, or freeze the booklet if all data are reviewed, all possible queries are closed, and the booklet is ready to be shelved. It is possible for the sponsor side user to unfreeze a booklet that has been frozen. This opens up the booklet for raising queries and returning it to the clinic.

All submit, recall, receive, and return actions are recorded in the audit trail.

2.3 The actions during the *Kaifu* process

The actions in the submit-receive-return process are summarized in the table below.

Action	Executed on which side?	When?	State of the data in the booklet	
			Clinic side	Sponsor side
Initiate booklet/data entry	Clinic side	When adding a subject, and when the time period for a booklet has passed.	Open for data edit	No data can be viewed*
Submit to sponsor side	Clinic side	When all required items are filled in.	Read-only	No data can be viewed until *Receive*.
Recall to clinic side	Clinic side	When the booklet is submitted, but not yet received on the sponsor side*	Open for data edit	No data can be viewed*
Receive	Sponsor side	When the booklet is submitted, and not recalled to the clinic side.	Read-only	Read-only, but open for data review and raising queries

Action	Executed on which side?	When?	State of the data in the booklet	
			Clinic side	Sponsor side
Return to clinic side	Sponsor side	When the booklet is received.	Open for data edit**	Read-only, no actions
Recall return to sponsor side	Sponsor side	When the booklet is returned but not handled by the clinic side.	Read-only	Read-only, but open for data review and raising queries
Freeze	Sponsor side	When the booklet is received, all data are reviewed and all queries are closed.	Read-only	Read-only, no actions
Unfreeze	Sponsor side	When the booklet is frozen.	Read-only	Read-only, but open for data review and raising queries

*The subject is not displayed at the sponsor side until the first booklet of this patient has been submitted and received by a sponsor side user. From that moment on, the submitted booklet with its data, and the structure of the remaining booklets (yet without data) are displayed at the sponsor side. The events and forms inside any not-submitted booklet can be viewed, but the forms cannot be opened.

**The booklet needs to be submitted by the clinic side user again to continue in the workflow.

3 Handling adverse events

3.1 AE reports

AE forms can be submitted, recalled, received, and returned in two ways:

- As part of a complete booklet submission/recall/receive/return.
- As an individual AE report.

When an AE is registered before the booklet is ready to be submitted, it is possible to submit the AE separately, that is, without having to submit the entire booklet. Similarly, the sponsor can return only the AE form instead of returning the complete booklet, even if the complete booklet has been submitted and received. A separately submitted or returned AE is called an AE report. AE reports follow the same Kaifu process for submit, recall, receive, and return as booklets.

Similarly to handling booklets, the clinic user has to confirm submission of the AE report by entering his/her password, and by which he/she at the same time signs the data. A submitted AE report can be recalled until the AE report has been received by the sponsor. Only once the AE report is received, the data is displayed at the sponsor side. The sponsor user has the possibility to return the AE report if necessary. All submit, recall, receive, and return actions are recorded in the audit trail.

3.2 Schematic overview of the submit-receive-return process for adverse events

The following workflows are possible.

1. The user on the clinic side submits only the AE report. The user on the sponsor side receives, and if necessary returns, only the AE report. This can be done for example when an adverse event has occurred before the time period of a booklet is finished and the booklet is not ready for submission, or when the user on the sponsor side returns only an AE report and not the complete booklet (as described in workflow 2).

STATE | CLINIC SIDE | SPONSOR SIDE

Not submitted (open for data entry/edit)
Submitted
Received
Returned

Resolve queries
Submit
Recall
Submit
Recall
Receive
Return
Recall return

Legend:
= AE report is open for edit/review/queries
= AE report is not open for edit, data can be viewed but is not synchronized between sides
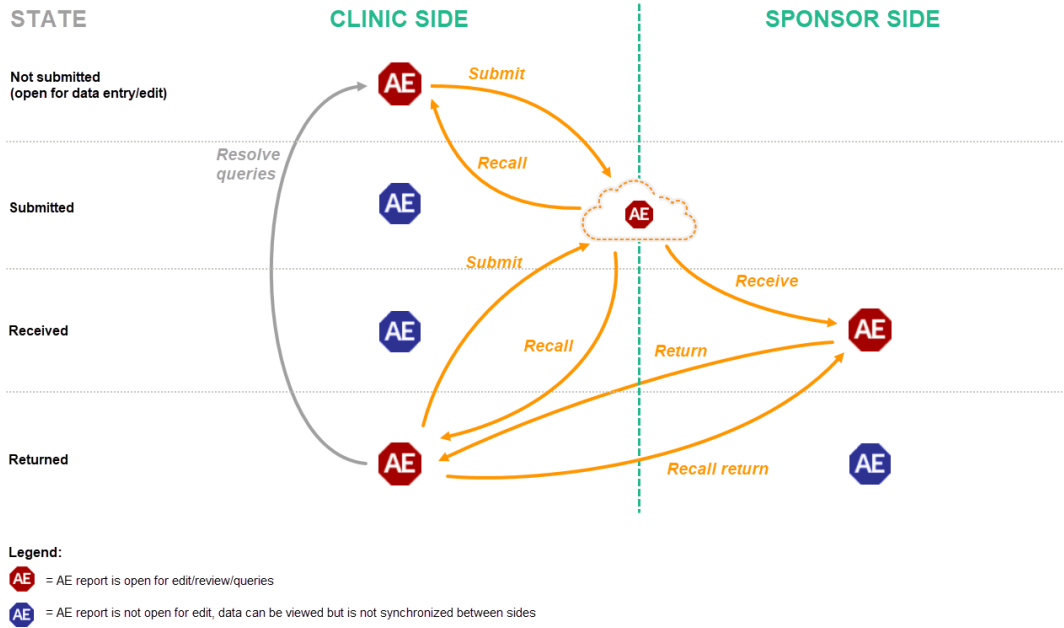
2. The user on the clinic side submits the complete booklet. The user on the sponsor side receives the complete booklet, but returns only the AE report. After any possible queries are resolved, the user on the clinic side then has to submit the AE report separately (see the image in workflow 3).

STATE | CLINIC SIDE | SPONSOR SIDE

Not submitted (open for data entry/edit)
Submitted
Received
Returned
Frozen (only for booklets)

Resolve queries
Submit
Recall
Submit
Recall
Receive
Return
Recall return
Unfreeze
Freeze

Legend:
= booklet is not open for edit, and does not contain data
= booklet is open for edit/review/queries
= AE report is open for edit/review/queries
= booklet is not open for edit, data can be viewed but is not synchronized between sides
= AE report is not open for edit, data can be viewed but is not synchronized between sides

3. The user on the clinic side submits the complete booklet, containing the AE. The user on the sponsor side receives the complete booklet, and returns the complete booklet. This workflow is exactly the same as described in Handling booklets.

CLINIC SIDE | **SPONSOR SIDE**

Not submitted (open for data entry/edit)

Submitted

Received

Returned

Frozen (only for booklets)

Submit — *Recall* — *Resolve queries* — *Submit* — *Recall* — *Receive* — *Return* — *Recall return* — *Unfreeze* — *Freeze*

Legend:

= booklet is not open for edit, and does not contain data

= booklet is open for edit/review/queries

= booklet is not open for edit, data can be viewed but is not synchronized between sides

= AE report is open for edit/review/queries

= AE report is not open for edit, data can be viewed but is not synchronized between sides

The actions that can be performed with AE reports are similar to the actions that can be performed with booklets, see The actions during the *Kaifu* process.

Notes!

- Only booklets can be frozen. It is not possible to separately freeze an AE report.
- If the user on the clinic side submits a booklet, he/she can recall the complete booklet, but cannot recall the AE report only. AE reports can only be recalled if submitted separately.

Booklet overview

Published by Viedoc System 2023-06-21

1   Booklet overview on the study start page

When you select the study icon on the landing page, the study start page loads. The booklet overview page is displayed by default.
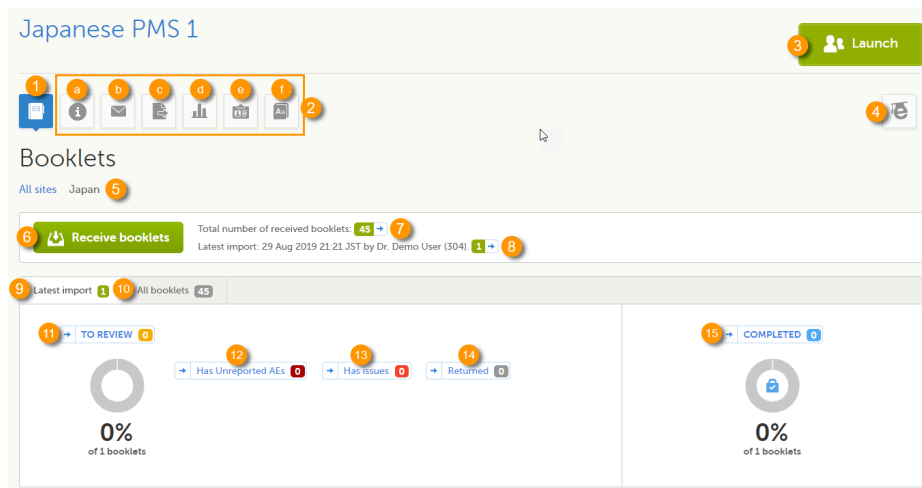
1. Booklet overview icon
2. Icons giving access to other Viedoc functionality, these are described in [Study start page](#). Note that these icons are displayed based on your rights and permissions, so you might not see all of these, or you might even see other icons.
a. Study status
b. Messages
c. Data export
d. Metrics
e. Roles
f. Medical coding
3. Launch button to enter the study
4. eLearning/Documentation & Training
5. Filter the displayed booklet information for country, or select **All sites** to display booklet information regarding all sites in the study.
6. **Receive** button. Select to receive all booklets that were submitted since the last time a receive action was performed.
7. Total number of received booklets. Select to enter the Selection page displaying all received booklets. See [Booklet overview on the Selection page](#) below.
8. The date of latest import and the number of booklets imported. Select to enter the Selection page displaying only the booklets received during the last import. See [Booklet overview on the Selection page](#) below.
9. **Latest import** tab, displays booklet information (see 11-14) of all booklets imported during the latest import.
10. **All booklets** tab, displays booklet information (see 11-14) of all booklets in the study.
11-14 display booklet information of booklets among the latest import or among the total number of received booklets, depending on the tab that has been selected (see 9 and 10). These links also serve as shortcuts to enter the Selection page displaying the respective booklets:
11. Number and percentage of booklets to review. Select to enter the Selection page displaying the booklets that contain data to be reviewed.

12. Number of booklets that contain unreported Adverse Events (AE). Select to enter the Selection page displaying the booklets with unreported AEs.

13. Number of booklets that contain issues. Select to enter the Selection page displaying the booklets that contain issues.

14. Number of booklets that are returned. Select to enter the Selection page displaying the booklets that are returned from the sponsor side to the clinic side.

15. Number and percentage of booklets that are completed (frozen). Select to enter the Selection page displaying the booklets that have the status *frozen*.

---

2   Booklet overview on the Selection page

On the booklet overview of the Selection page, booklets are displayed in a table. The main purpose of this table is to give the sponsor side user a quick overview of the booklets that require action: AE reports and booklets containing AEs and issues are therefore listed first. Each row in the table represents one booklet, the columns provide the following information:

1. Avatar representing a subject and displaying the subject's sex
2. Subject ID
3. Name of the booklet
4. State of the booklet (*Not submitted*, *Received*, *Returned*, *Frozen*)
5. Latest activity: describing the latest action performed with the booklet (*Received*, *Partly received*, *Returned*, *Partly returned*, *Frozen*)
6. Latest date: date of latest activity
7. Latest user: name of the user that executed the latest activity
8. The symbols in the last column indicate if there are actions to be taken. They summarize the status of the booklet (*Submitted*, *Returned*, *Frozen*), or indicate if the booklet contains any issues or AEs. See below for more information.

On the selection page, you can perform or view the following:

1. Search through subjects and booklets by entering any string in the search field
2. Switch to the card view (see below)
3. Switch to the issue list (see below)
4. Switch to the booklet overview (if you are on the card view or issue list)
5. Filter the displayed booklets for booklet name by selecting **All booklets** or the booklet name from the drop-down list
6. Filter the displayed booklets for booklet status by selecting one of the following options from the drop-down list:

   - All statuses
   - Has AE
   - Has issues
   - Not reviewed
   - Returned
   - Frozen

7. Switch to the previous or next page of the booklet overview.
8. Select how many booklets should be displayed per page.
9. The color band displayed in front of the subject avatar means the following:

- orange: booklet has been received and is under review by a sponsor side user
- blue: booklet is frozen
- red: booklet contains issues that need to be solved
- grey: booklet has been returned to the clinic side and is no longer under control of the sponsor side

From the Selection page, you can also enter the card view and issue view by selecting the **Cards** and **Issues** tabs as follows:
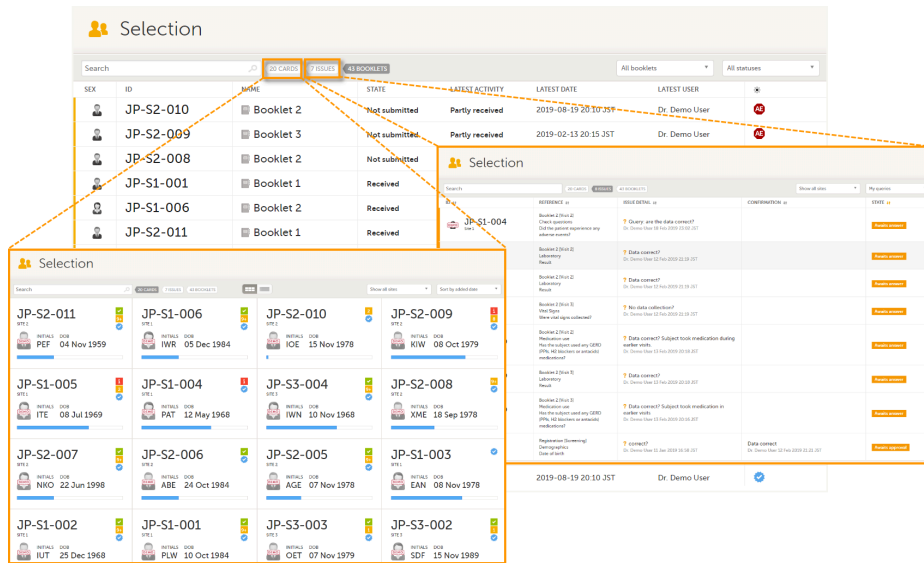
The icons in the last column of the Selection page have the following meaning:

Symbol	Definition
	Received - the complete booklet has been signed and submitted by the clinic, and received on the sponsor side.
	Issue - at least one open query and/or missing data
	Frozen - the booklet has been frozen on the sponsor side, and is locked for data edit
	Returned - the booklet has been returned from the sponsor side to the clinic side
	Adverse Event - this form contains an adverse event
	Adverse Event reported - the adverse event in this form has been reported to the authorities

By default, booklets are sorted in the following order:

- First sorted by state:

    1. Booklets that are not reviewed and contain AEs or issues.

    2. Booklets that are not reviewed and do not contain AEs or issues.

    3. Booklets that are reviewed booklets and contain issues.

    4. Booklets that are reviewed and do not contain issues.

5. Returned booklets

6. Frozen booklets.
- ...then sorted by date, most recently changed booklets first.

- ...then sorted by subject ID.

- ...then sorted by booklet name.

Handling booklets, AE reports and forms

Published by Viedoc System 2023-06-21

1 Introduction

Viedoc [PMS](#) offers support for sending and receiving booklets back and forth between site and sponsor. For an overview of this process, see [Overview of the submit-receive-return process](#).

In the submit-receive-return (*Kaifu*) process, the clinic user chooses when to share data with the sponsor and the sponsor-side user chooses when to receive the data. One of the important characteristics of this process is that the sponsor-side user does not have access to any data entered in a booklet, until the booklet has been submitted by the clinic, and a receive action has been actively performed by the user at the sponsor side.

Booklets can only be submitted to the sponsor when all events and forms in the booklet are completed.

There is an exception to this rule, which depends on your study configuration. It is possible that some forms (for example, but not limited to, Adverse Events) can be managed, that is, submitted/received/returned/reviewed/reported individually. When these forms are saved, a warning message is displayed and a **Manage** link is available. For more information, see [Receiving booklets, AE reports and individual forms](#).

Note! As soon as an AE has been added, the system displays a warning message at the top of the booklet to facilitate the timely submission of AEs.

The status of the booklet is displayed on the subject **Details** page. You can select to display the complete history of submitting-receiving-returning the booklet by selecting **Show history**. You can select to display only the current status of the booklet by selecting **Hide history**.

1. Select a booklet to work with
2. Current status of the selected booklet
3. History of the selected booklet
4. Show/hide history

2 Receiving booklets, AE reports, individual forms and linked forms

2.1 Overview

Forms can be received from the clinic side individually, depending on how your study is configured, you can:

- Receive only Adverse Events (AE) reports individually.
- Receive some of the other forms contained in a booklet individually, as well as AE forms, providing the AE form has been actively defined as an AE in the study design.
- Receive forms linked to another form in order to view complementary data added to a submitted form.

Note! Forms that are linked to other forms can be received individually or as part of a booklet submit. When a linking form (for example an AE) is linked to another form, (for example the Prior and Concomitant Medications form), and the AE form is submitted individually, a read-only copy of the linked form (Prior and Concomitant Medications) is received, if not already available on the sponsor side.

This applies even if the booklet is not yet completed.

There are different icons, warning messages and dialogs shown, depending on the your study configuration.

2.2 Icons and warning messages

The icons displayed on the form are as described below:

The forms marked as Adverse Events in your study are flagged with this icon.	**AE**
The forms that are NOT marked as Adverse Events in your study, but which can be managed individually are marked with this icon.	**!**

The warning messages are as shown below:

Once receiving a form that was submitted individually, a warning message is shown. The warning message differs depending on the study configuration.

This applies even if the booklet has the status *frozen*.

- If there is a <u>new effective study design</u> assigned to a site, and <u>new forms have been selected to be submitted individually</u> in that design version:
- Warning messages will <u>only</u> appear for received forms that are connected to the new forms added in the study design if the booklet <u>does not</u> have the status frozen.

2.3 Receiving booklets, AEs, other forms, and linked forms

To receive booklets, AE reports, and other forms that have been submitted from the clinic side:

1   Select **Receive booklets**.
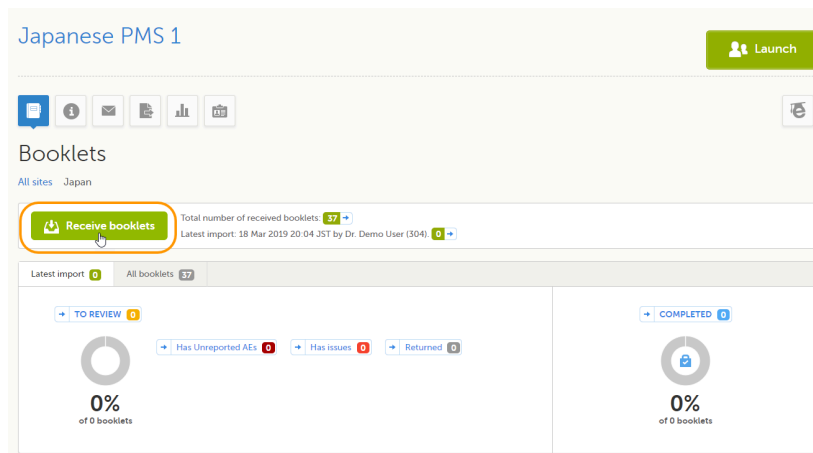
2   A window appears that asks you to confirm the receive action.
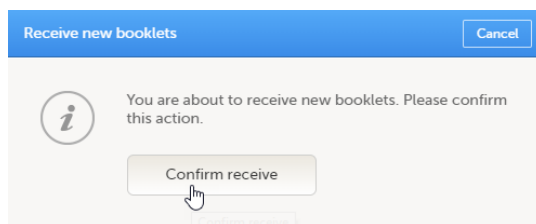
3   After the booklet/AE report/form is confirmed as received, a **Manage** link is shown:
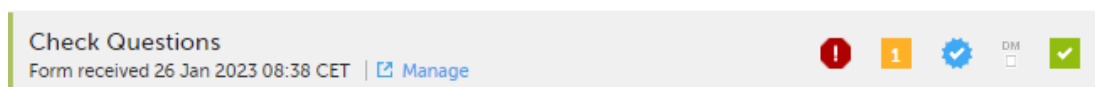
On the relevant form, select **Manage**.

4   A text appears. Depending on the study configuration and the received form, the text is as shown below:

Manage Form

In History, the complete history of the form's submit-receive-return actions is shown.

The information on the **Latest import** tab is updated with the booklet counts of the latest import.

Notes!

- The receive action takes site access into account. Thus, only the booklets submitted at sites to which the user has access will be received.
- You can always launch the study and enter the booklet overview without receiving booklets by selecting **Launch**, or by selecting one of the shortcuts to the booklet overview described in Booklet overview.

2.4   Viewing linked forms

You can view a linked form from the linking form by selecting any link item to open and read that form. In the example shown below, the Prior and Concomitant Medications form is the linked form. Closing the form returns you to the original (linking) form, in this example, the Adverse Event form.

Note! If the linked form is not under control of the sponsor, that is, it is under clinic control, the linked form is available for the sponsor only as a read-only copy, and no *Kaifu* actions can be taken on the form (such as reviewing a form, returning a form, marking a form as reported, or adding queries, etc). When forms marked as AEs are received as linked form copies, they are not included in the AE forms count.
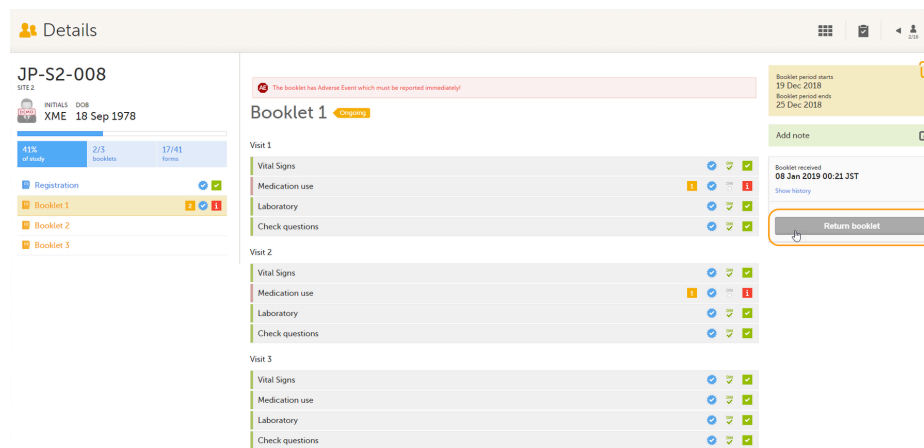
For a linked form that has been received as a read-only copy when a linking form was submitted individually, depending on the received linked form, the the complete history of the form's submit-receive-return actions is shown as below:

3 Handling booklets
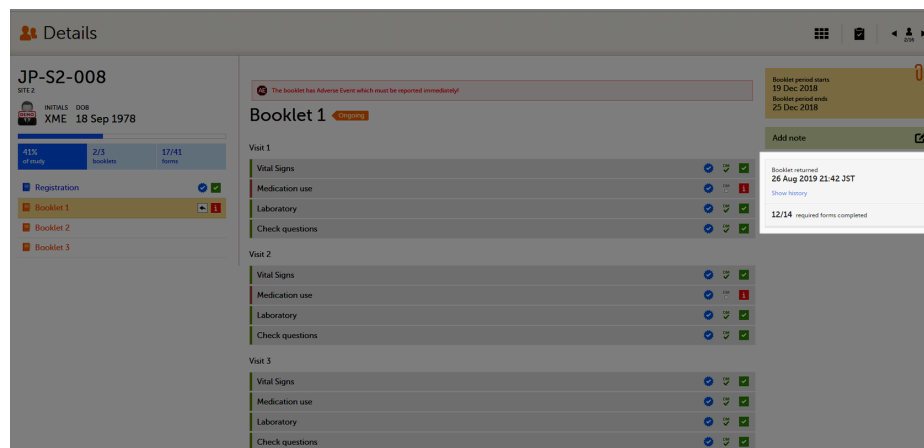
3.1 Returning a booklet

To return a booklet, select **Return booklet**.

The booklet status changes into *returned*, and the date and time of the *return* action are displayed.

On the booklet overview, the booklet receives the following icon, indicating that the booklet has been returned.

3.2 Recalling a returned booklet

The recall function is available for users with the return booklet permission. The function is available when a booklet was returned to the Investigator but has not yet been changed/edited by the Investigator. After a sponsor performs a Recall return action, the booklet is brought back in control of the sponsor and it is no longer possible to edit the booklet on the clinic side.

To recall a booklet, select **Recall returned booklet**.

Note! If any data in the booklet is changed or added, or, if the booklet has already been recalled, the action is rejected.

After recalling a booklet, the following happens:

- The booklet status is changed to *received*.
- The action is tracked in an audit trail record telling who, when, and what was done. The audit trail record is visible on the booklet details page and is included in the booklet status export.
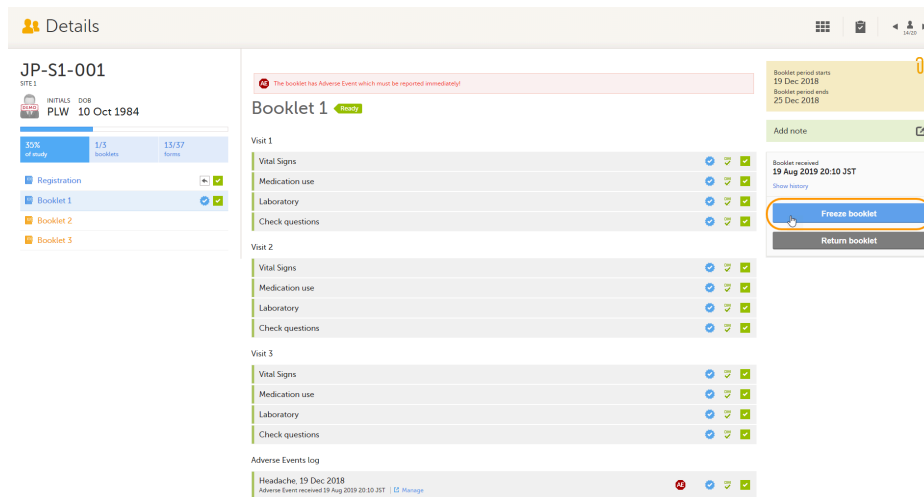
...which means that:

- All forms in a received booklet are locked for editing by the Investigator.
- Revision updates are queued instead of applied.
- The booklet is from now on visible and in control for the users who can receive booklets and for the users who can review booklets in the **Details** page.
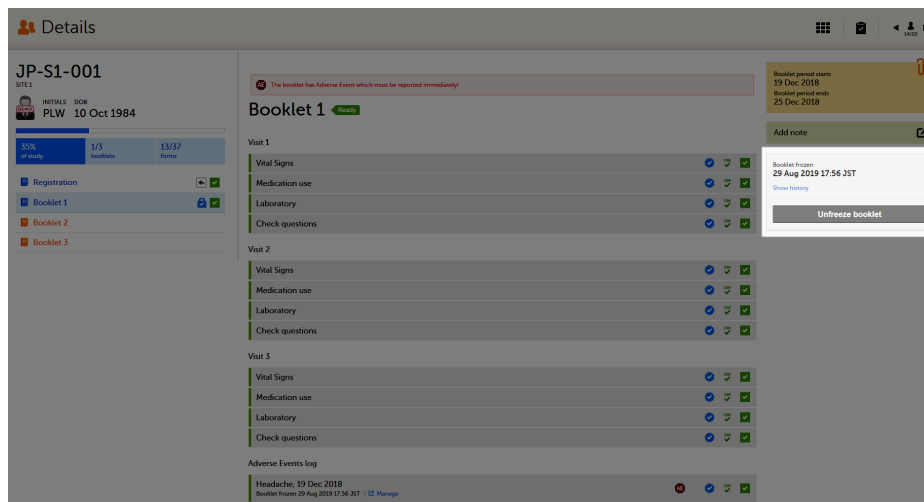
3.3 Freezing a booklet

To freeze a booklet, select **Freeze booklet**.

Note! Booklets can only be frozen when all data in the booklet is completed, all data is reviewed and there are no open queries or other issues.

The booklet status changes into *frozen*, and the date and time of the freeze action are displayed.

On the booklet overview, the booklet receives the following icon, indicating that the booklet has been frozen.

4 Handling AE reports and individual forms

4.1 Returning an AE report or an individually submitted form

Depending on your study configuration, AEs can be submitted separately as an AE report. Other individual forms and linked forms can be submitted separately, even if the booklet is not yet completed.

When an AE is registered, a warning message appears at the top of the booklet stating that *The booklet has Adverse Event which must be reported immediately!* The adverse event has the status *Not reported*, and a red AE icon appears on the form.

When another individual form is registered, a warning message appears at the top of the booklet stating that *The booklet has one or more forms to be reported,* and a red exclamation mark icon appears on the form.

Note!

- If the linking form has previously been received on the Sponsor side, a copy of the linked form will also be available on the Sponsor side.
- If the linking form is returned and deleted, and the booklet is then submitted, the form will be marked as deleted on the Sponsor side upon booklet receive and the linked copy will retain the same status.

To return an AE/individual form:

1 On the relevant form, in this example the Adverse Event form, select **Manage**.
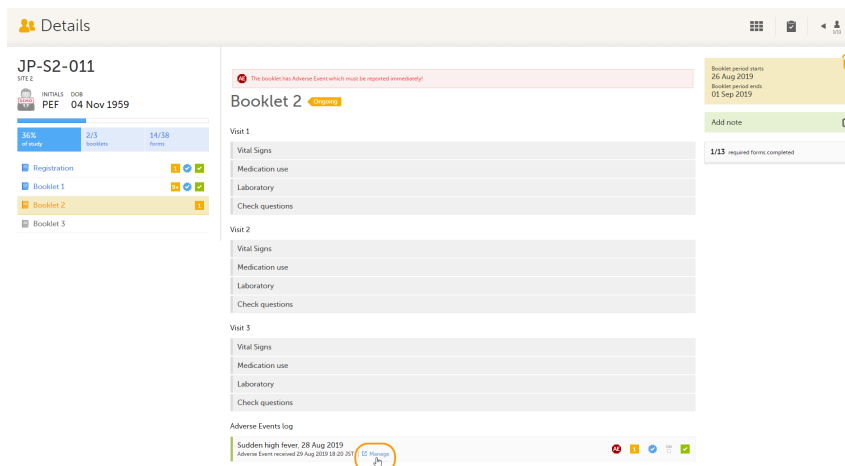
A window appears.

2 Select **Return Adverse Event**.
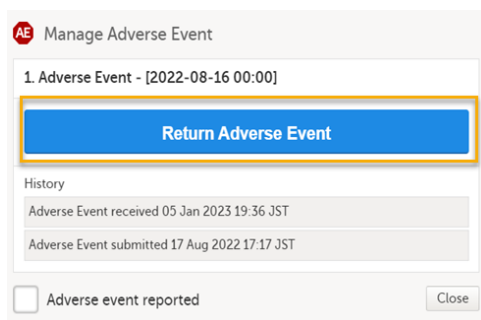
To return a form that was submitted individually, select **Return Form**.
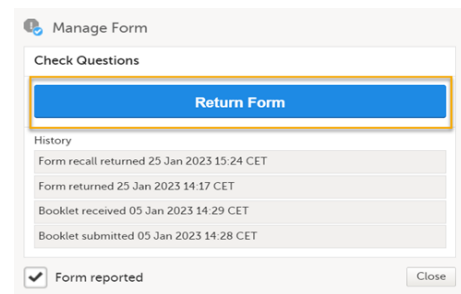
| **3** | The status of the adverse event changes from *Adverse Event received* to *Adverse Event returned + date of submission*. | The status of the form changes from *Form received* to *Form returned + date of submission*. |

Adverse Events log
Sudden high fever, 28 Aug 2019
Adverse Event returned 29 Aug 2019 20:46 JST | ⧉ Manage

The complete history of AE submission/recall/receive is shown in the history in the **Manage Adverse Event** window that appears upon selecting **Manage**.

Check Questions
Form returned 26 Jan 2023 08:58 CET | ⧉ Manage
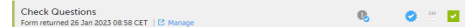
Note! Forms that are received as part of a booklet submit can only be returned if the form has been configured to be submitted individually in the effective study design.

4.2   Recalling a returned AE report or an individual form.

The recall function is available for users with the return booklet permission. The function is available when an AE or an individually submitted form was returned to the Investigator but has not yet been changed/edited by the Investigator. After a sponsor return recall, the booklet is brought back in control of the sponsor and it is no longer possible to edit the booklet on the Clinic side.

To recall an AE or an individual form, select **Recall returned adverse event/Recall return Form**.
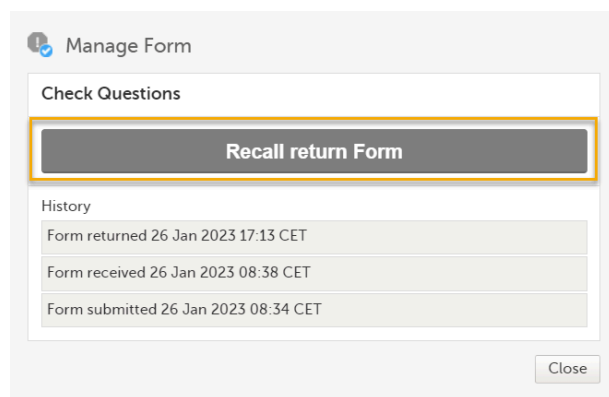
Note! If any data in the AE/individually submitted is changed or added, or, if the AE/individual form has already been recalled, the action is rejected.

After recalling an AE/individual, the following happens:

- The AE/other form is set back to *received*.
- The action is tracked in an audit trail record telling who, when, and what was done. The audit trail record is visible in the **AE/Manage Form** window.

...which means that:

- All forms in a received AE/individual form are locked for editing by the Investigator.
- Revision updates are queued instead of applied.
- The booklet/individual form is from now on visible and in control for the users who can receive booklets and for the users who can review booklets in the **Details** page.

4.3   Marking an AE/individual form as reported to authorities

Note! Forms that have been received on the sponsor side and do not have the status *frozen* can still be marked as reported to the authorities.

To mark an AE/individual form as reported:

1   Select **Manage** on the relevant form you want to report.

The example below is an Adverse Event form.
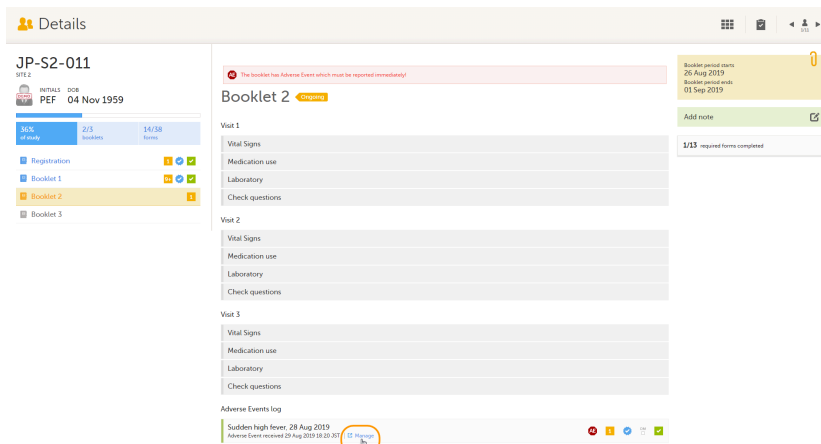
A window opens.

2   Select the **Adverse event reported** and select **Close**.
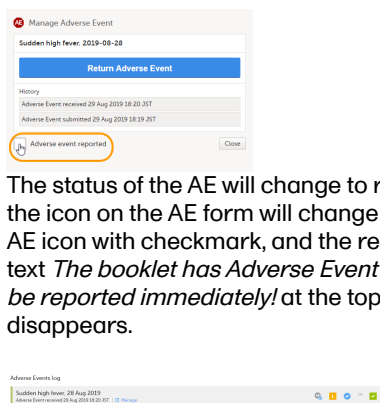
The status of the AE will change to reported, the icon on the AE form will change into a grey AE icon with checkmark, and the red warning text *The booklet has Adverse Event which must be reported immediately!* at the top of the page disappears.

For other forms, select **Form reported** and select **Close**.
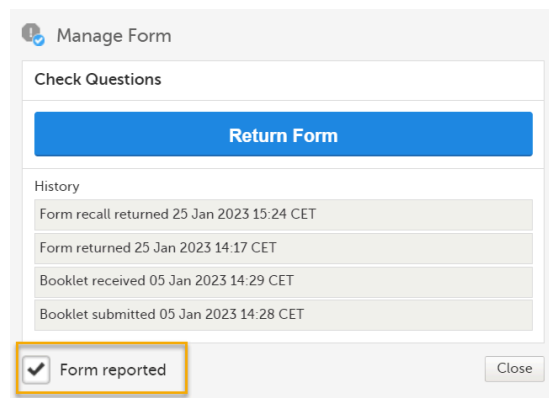
The status of the individually submitted form will change to reported, the icon on the Check Questions form will change into a grey exclamation mark with checkmark, and the red warning text *The booklet has one or more forms to be reported* at the top of the page disappears.

Note! The text in the warning text may differ, depending on the study design.
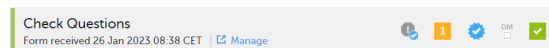
5   Handling deleted subjects

5.1   Receiving a deleted subject

Deleted subjects are included in the receive action. Once data is received at the sponsor side, deleted subjects are displayed in the following places:

- Cards Selection page
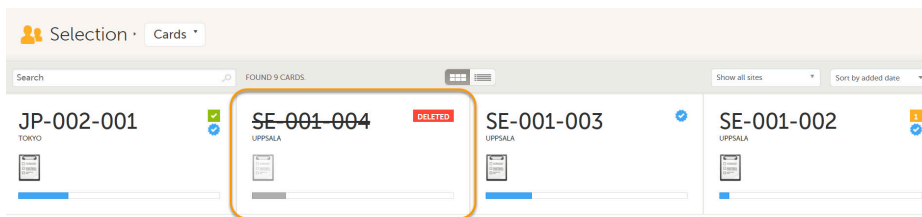
- Booklet Selection page
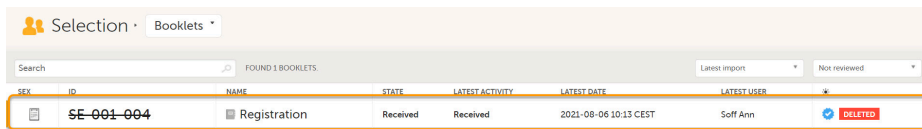
- Subject Details page
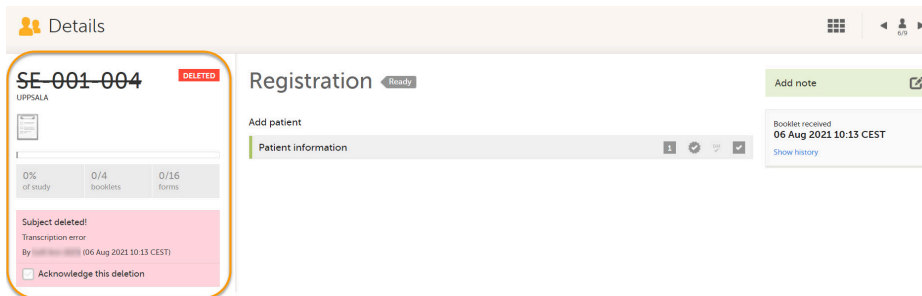
Deleted subjects also appear in the Issues selection page if the deleted subjects had issues.

5.2 Acknowledging a deleted subject

When deleted subjects have been received, they can be acknowledged by selecting **Acknowledge this deletion** on the subject Details page.
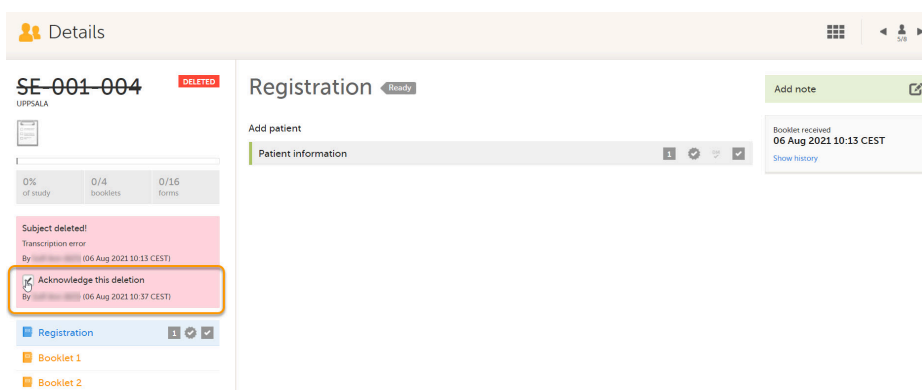
This action is recorded below the checkbox with information about who and when the deleted subject was acknowledged. The acknowledgment causes the deleted subjects to become hidden from the main views. To view acknowledged subjects, select **Include acknowledged deleted subjects**.
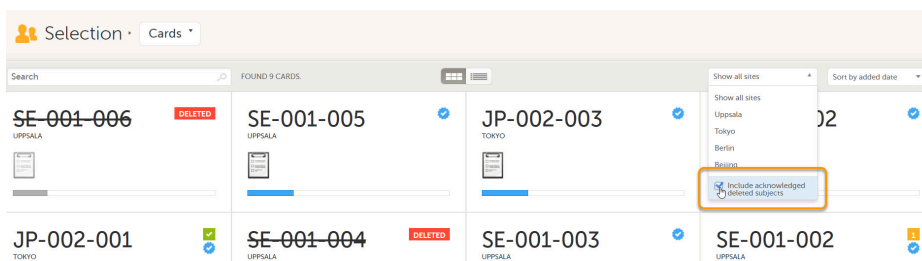
5.3 Updates to study design

If the study design is updated and configured so that forms can no longer be submitted individually, or if a new study design version is applied to a site, the following rules apply to the actions and messages for existing individually submitted forms:

- The existing individuallly submitted forms on the sponsor side are still visible on the **Details** page.
- Sponsor-side users can no longer perform *Kaifu* actions.

- Sponsor-side users can no longer select/deselect the form as reported/unreported in the **Form reported** checkbox in the **Manage Form** window.
- The **Manage** link is still available and can still be selected to show the complete history of the form's submit-receive-return actions.
  Note! This only applies to individually submitted forms and not if the form was part of a booklet submission.

There are no warning messages displayed on the subject details page for that form.

5.4   Unreported Adverse Events

Forms that have been configured to be individually submitted and also are selected as AEs are included in the counters for **Has unreported AEs** on the sponsor side shown on the booklet overview page. See Booklet overview for more information.

NOTE! The **Has unreported AEs** counter is NOT updated when a form is received as a copy.
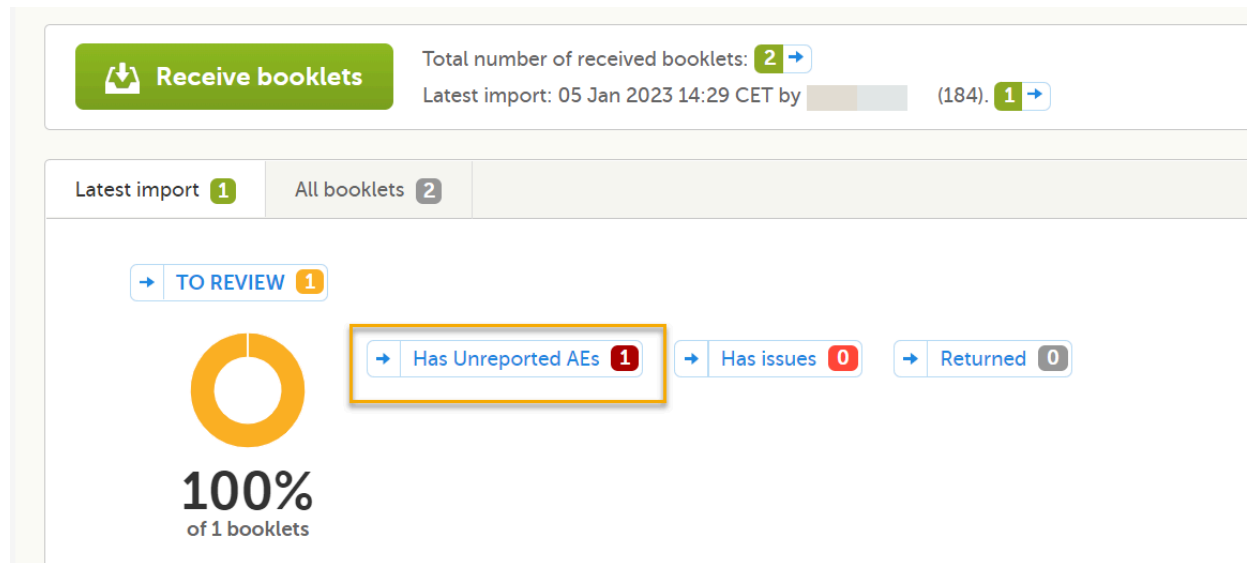
Unreported AE forms for studies where submitting individual forms is configured are counted when the following conditions apply:

- **Select as Adverse Event** has been selected for the form in the study design.
- The form on the sponsor side is not marked as reported.
- The Booklets selection page status is filtered by **Has AE**.

Study start page

Study start page

Published by Viedoc System 2023-10-09

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:
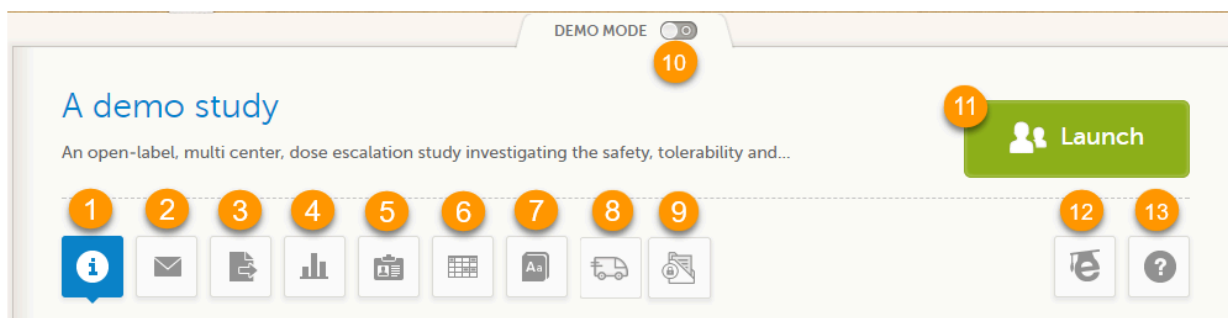
- The export, metrics and medical coding icons, the demo mode switch, and the launch button are only visible if you have access to the respective features. Whether you have access to these features, depends on the role assigned to you, and on the permissions that are included in your role.
- Roles and 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, <u>if you do not have any mandatory documentation and training material that needs to be signed</u>. 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):
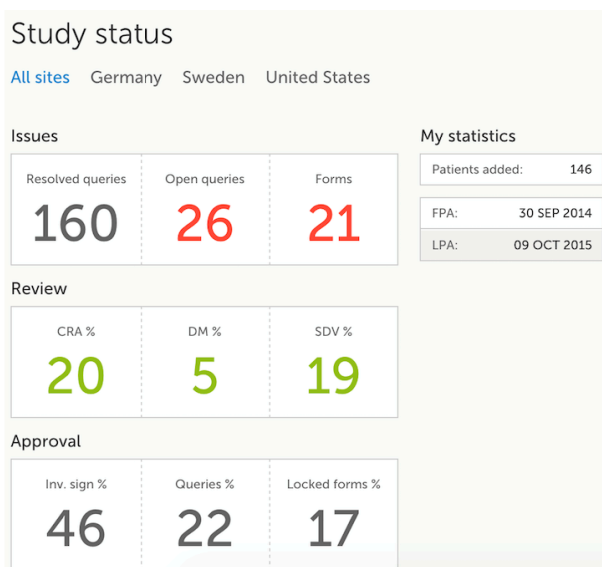
You can filter the displayed data for country or site by selecting the name of the country or site:
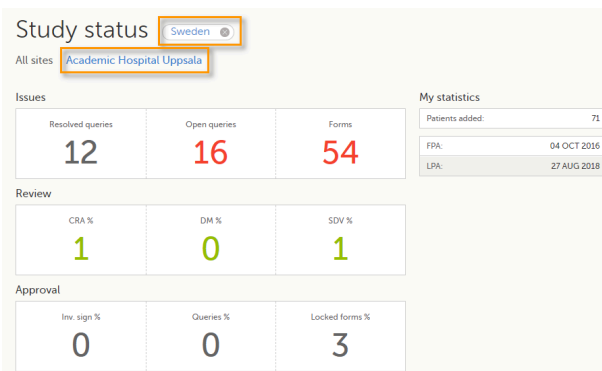
The following statistical information is provided, for the selected site(s):

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

- 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, <u>if demo mode is selected</u>, then the numbers reflect <u>only the data entered in demo mode</u>.

3 Messages

A message can either be a <u>system message</u> (such as notifications on password expiration), a <u>study message</u> (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.
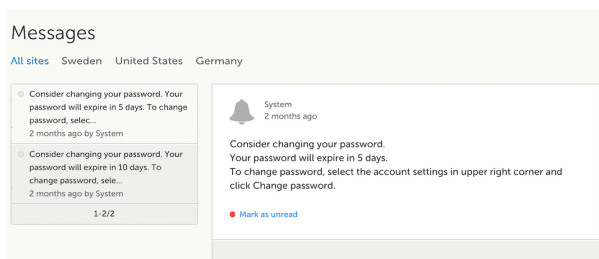
3.1 Alert messages

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:

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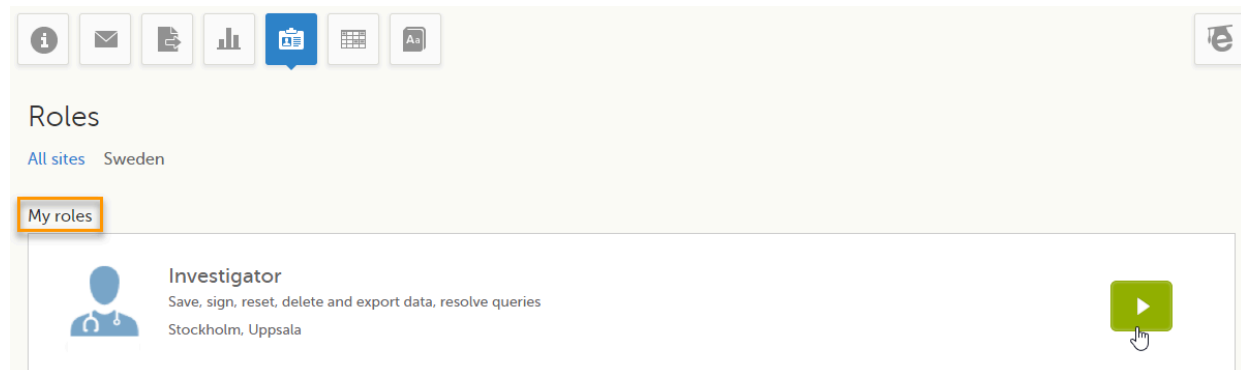
Note! The Roles page is only available for users with special permission to view roles, as per the study design.

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:

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:

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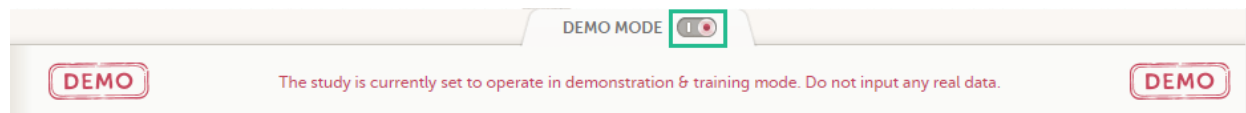
The **DEMO MODE** switch is only visible when you have access to both production and demo mode.

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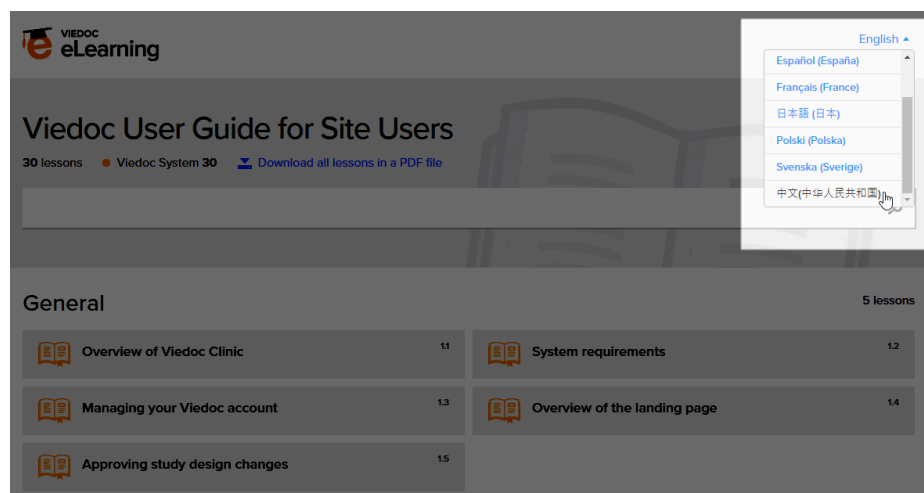
Tip! The various lessons in the Viedoc eLearning can easily be compiled into a PDF and printed if you need to store them in the investigator binder.

---

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.

Selection page

Selection page

Published by Viedoc System 2023-10-09

1 Introduction

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

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.

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
i	**Issue** - at least one open query and/or missing data
7	**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.
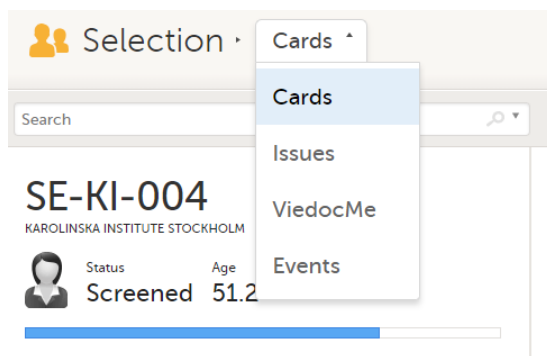
- If the study is **not** configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

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:
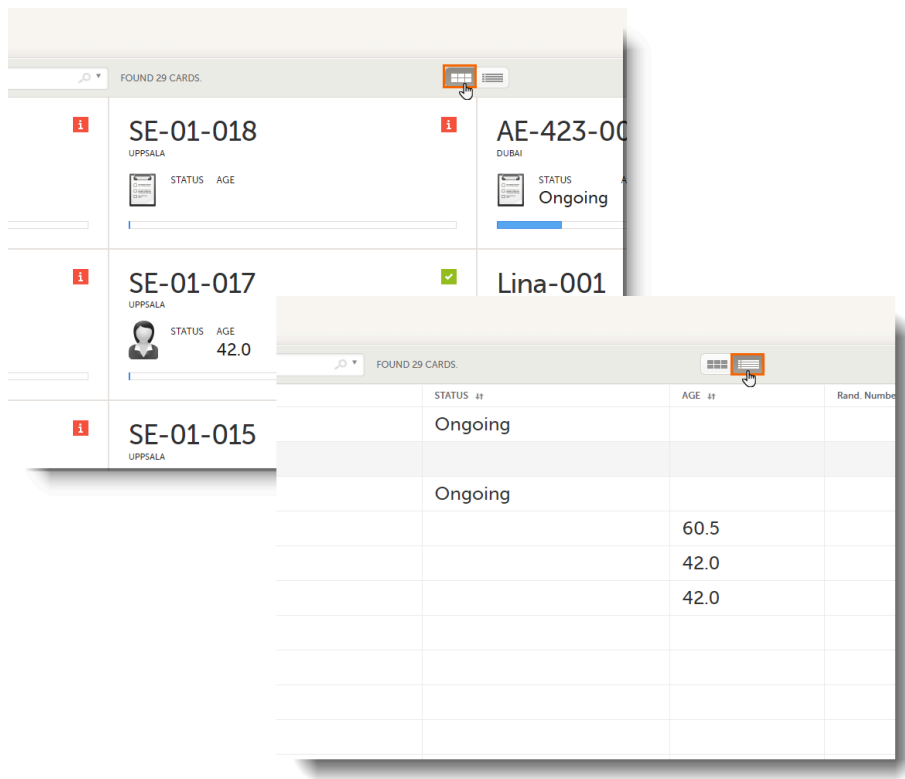
The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:
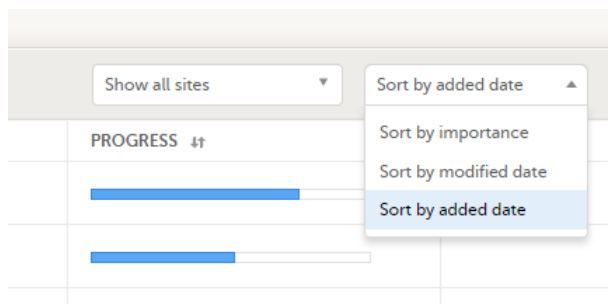
- **Sort by importance** - sort on forms with issues in descending order
- **Sort by modified date** - sort on modified forms in descending order
- **Sort by added date** - sort on added forms in descending order

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:
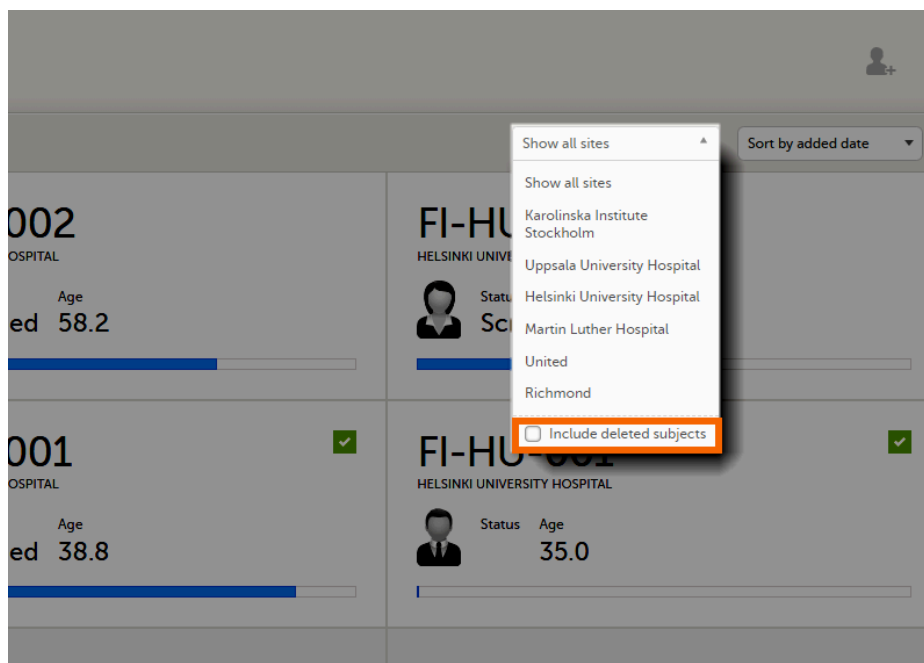
The subject card overview

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:
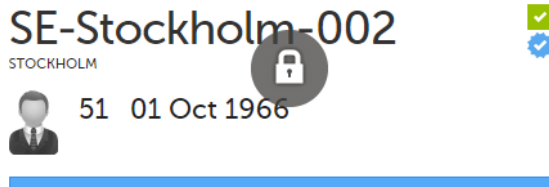
- Progress bar indicating the completion status (in blue)

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:

Click any row to open the form where the issue was raised:
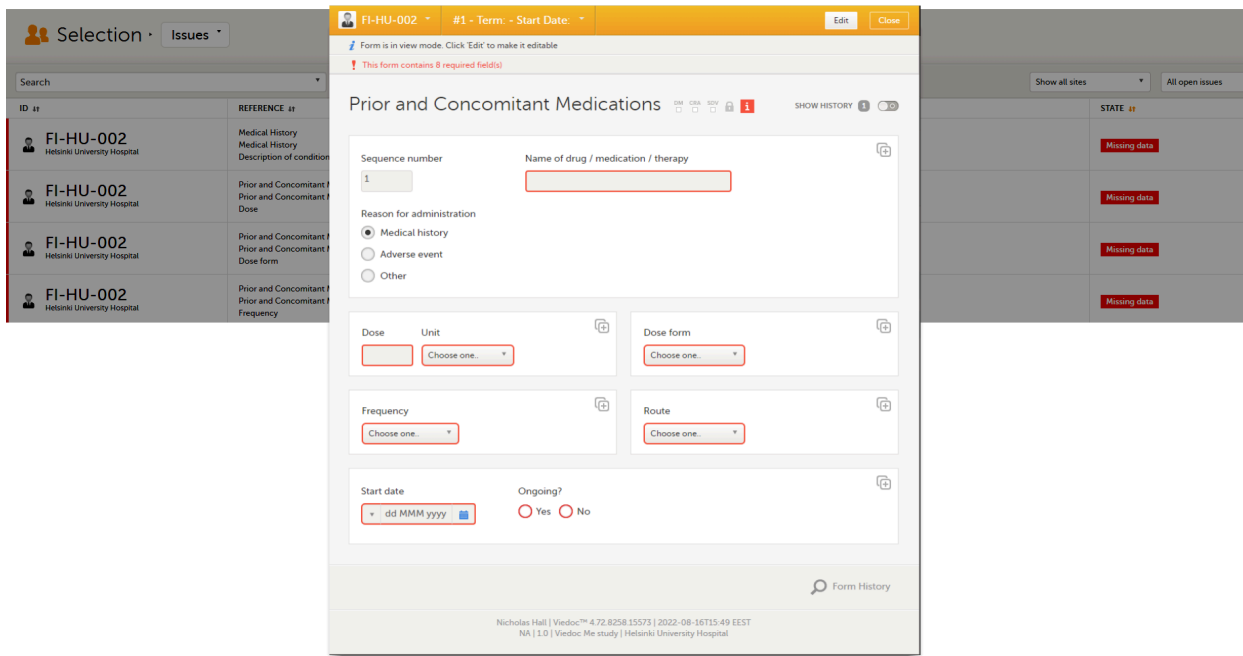
Close the form to go back to the **Issues** list.

You can filter the **Issues** list using the dropdown lists in the upper right corner of the page:
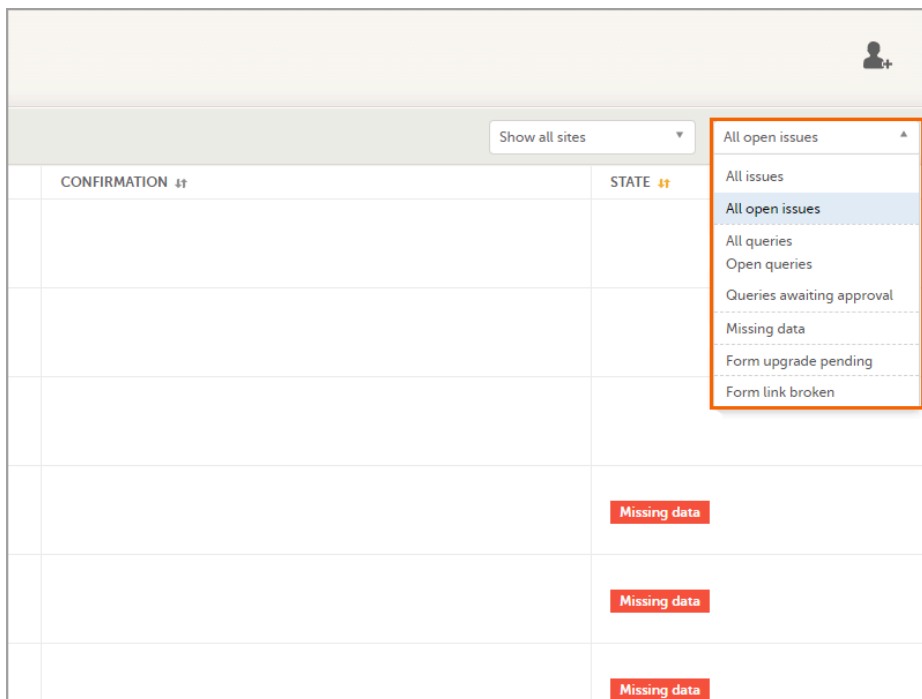
- By site - view data from a specific site or from all sites
    - Include deleted subjects

- 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.

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.

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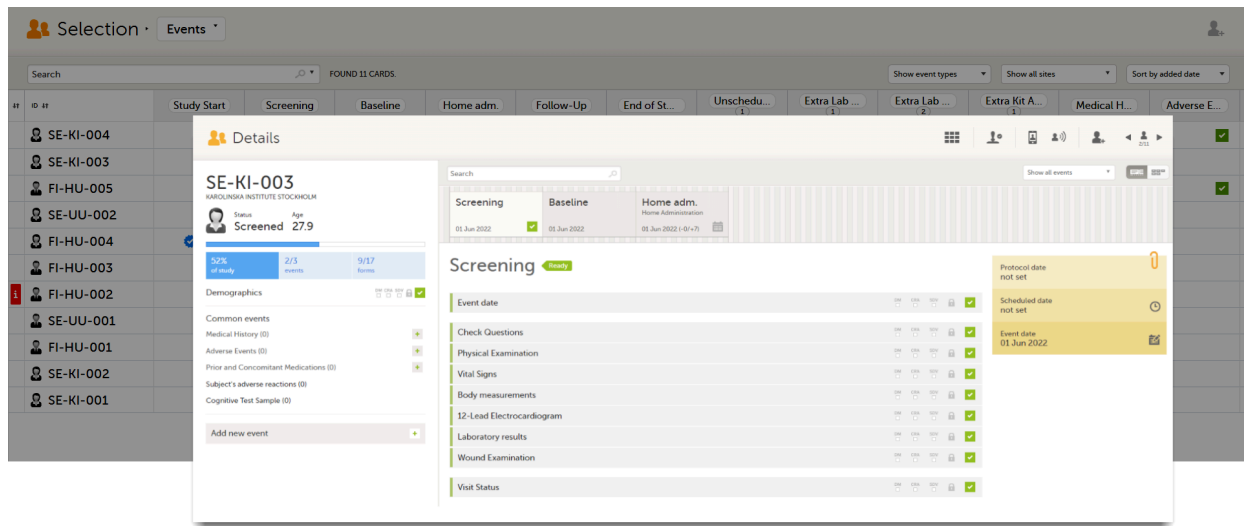
Click back in the browser to return to the Events view.

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 <u>event name</u> (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:
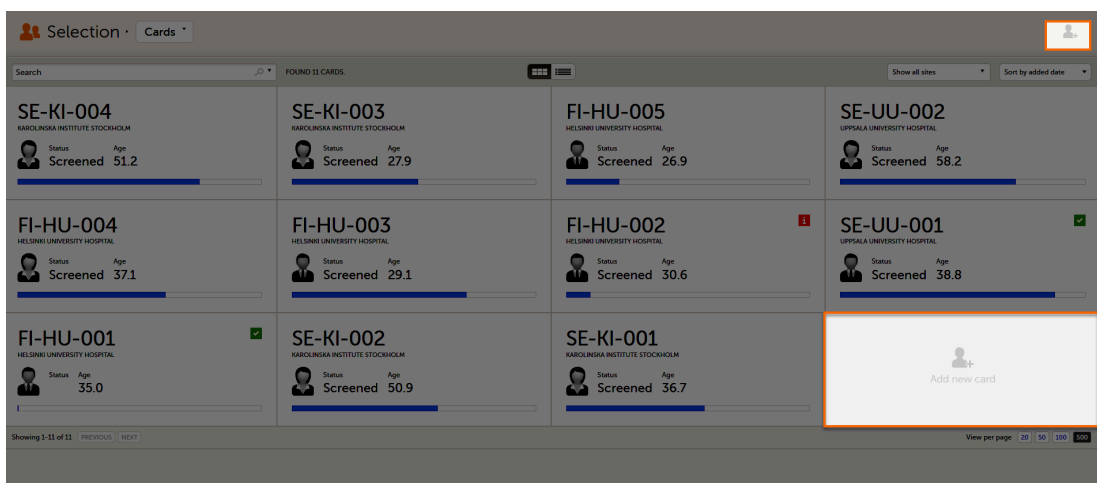
The first form in the study is displayed.

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 <u>study start event</u> 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 <u>Add and select subjects</u>.

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.
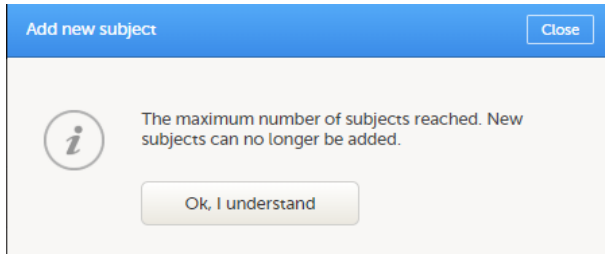
Metrics

Metrics

Published by Viedoc System 2022-02-10

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.
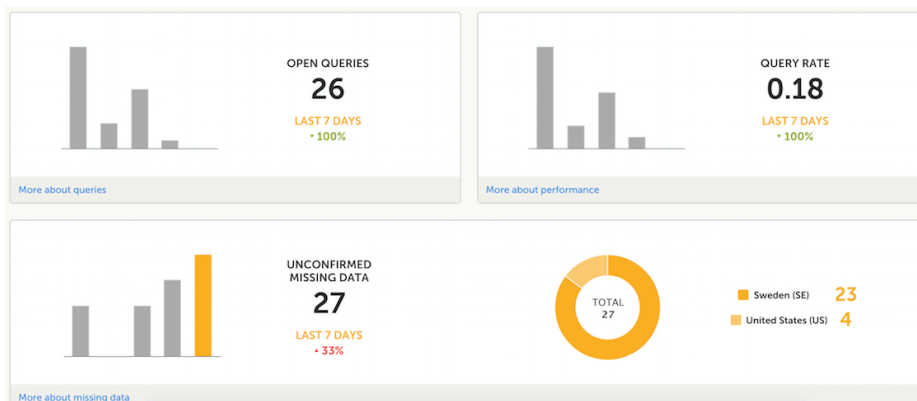
The metrics graphs depict:

- **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:
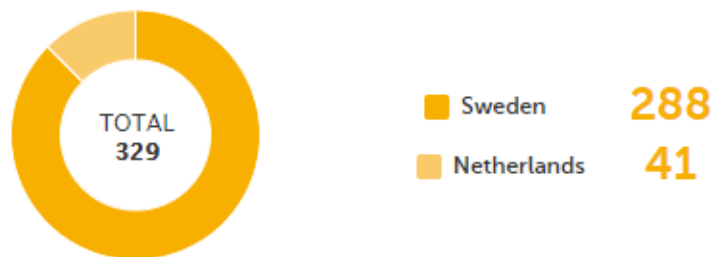
  - **Country** - distribution over those sites within the selected country, with most unconfirmed missing data:
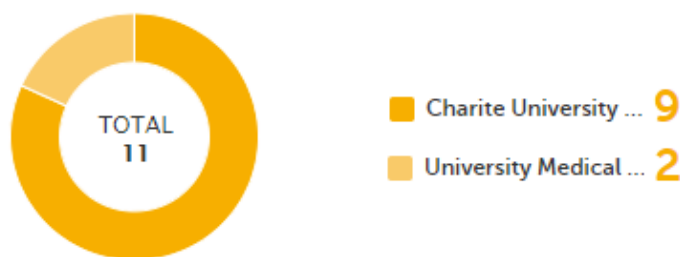
  - **Site** - distribution over those subjects with most unconfirmed missing data (in orange) out of the total number of subjects with unconfirmed missing data within the selected site (in gray):
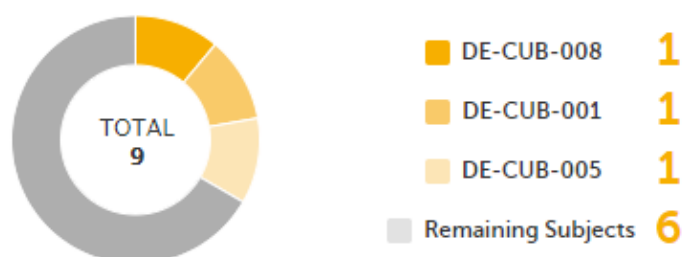
Click **More about [...]** to open a page with detailed metrics about queries, performance or missing data. All detailed metrics pages include filtering possibilities and a bar to show the review status.

1.1 Viedoc Reports

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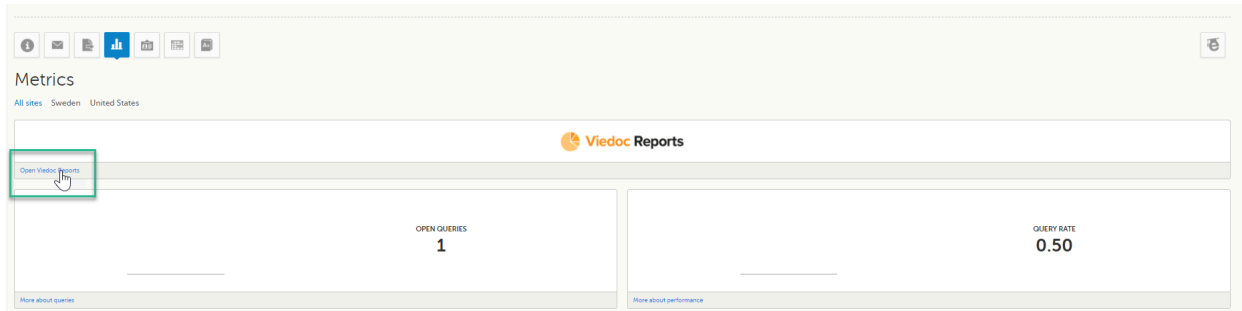
2 Queries

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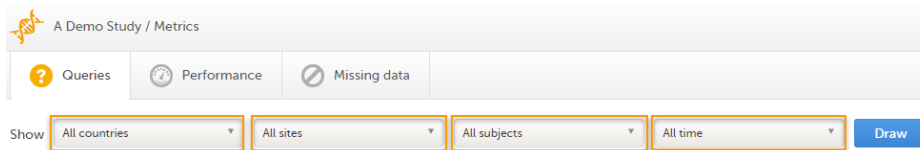
- Country
- Site
- Subject
- Time period - choose between:
    - All time
    - Last 24 hours
    - Last 3 days
    - Last week
    - Last 3 weeks

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**)
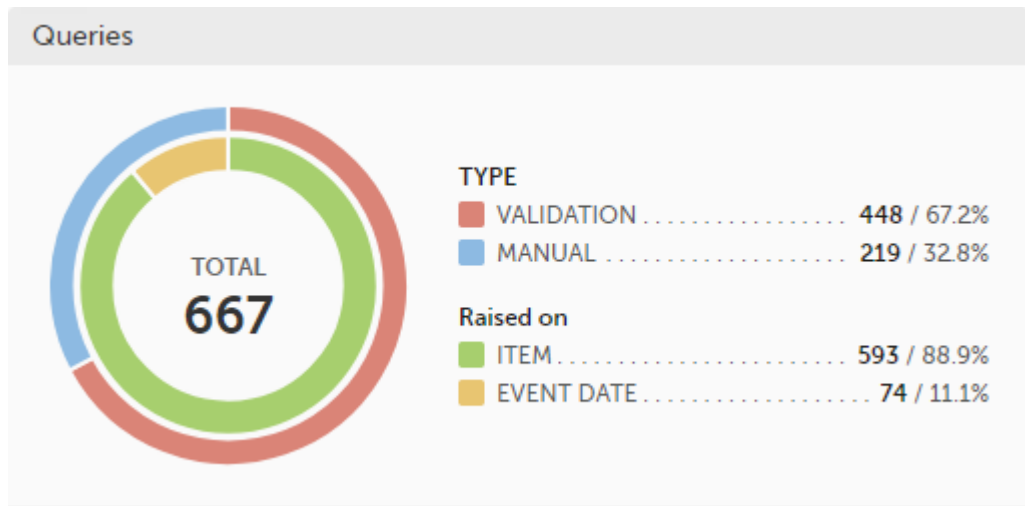
Queries

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:
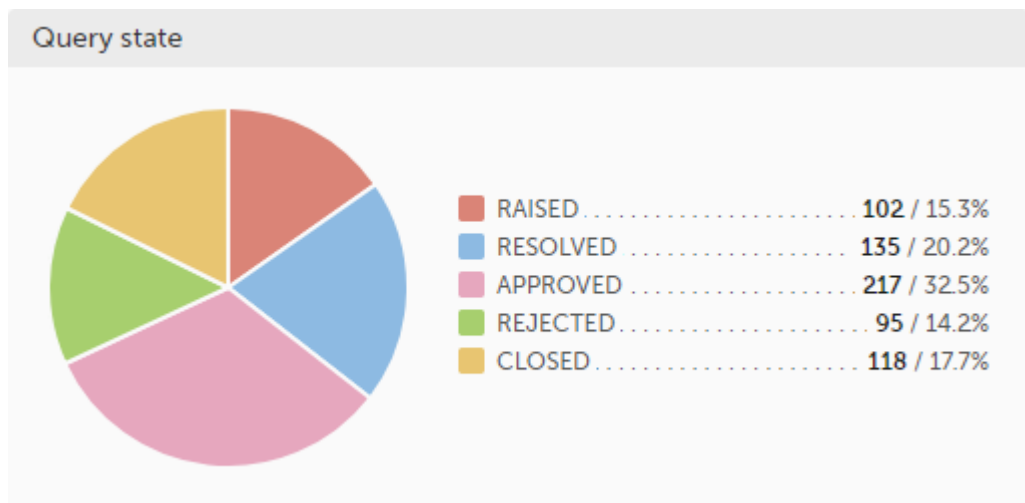
- **RAISED** - number of raised queries / percentage of raised queries out of total number of queries
- **RESOLVED** - number of resolved queries / percentage of resolved queries out of total number of queries
- **APPROVED** - number of approved queries / percentage of approved queries out of total number 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.
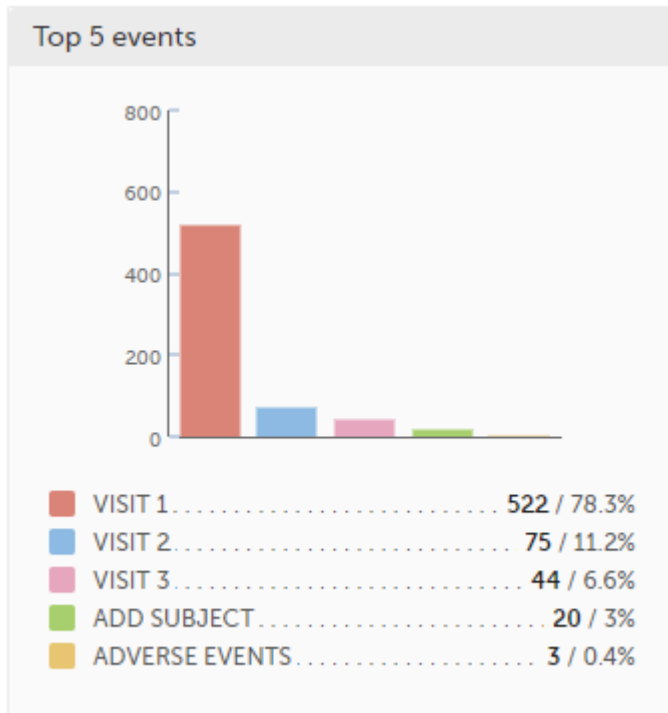
2.5   Top 5 forms

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.
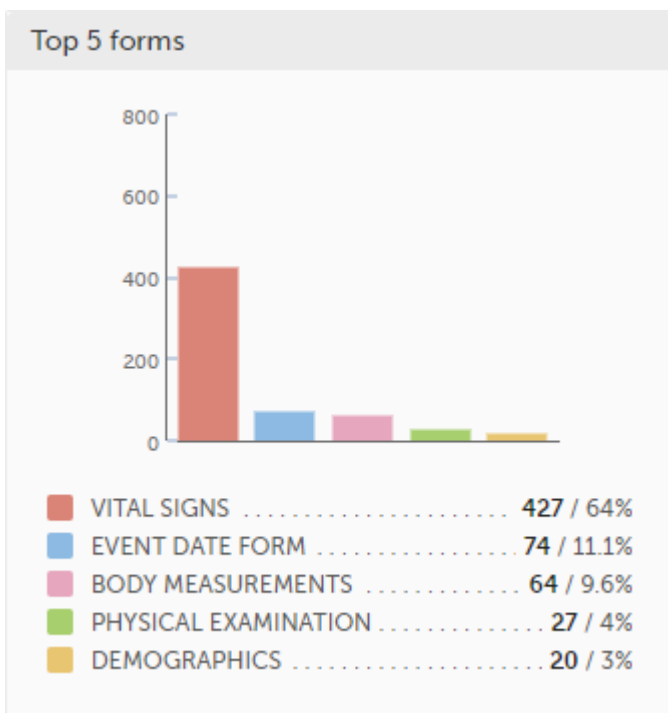
2.6　Top 5 items

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.
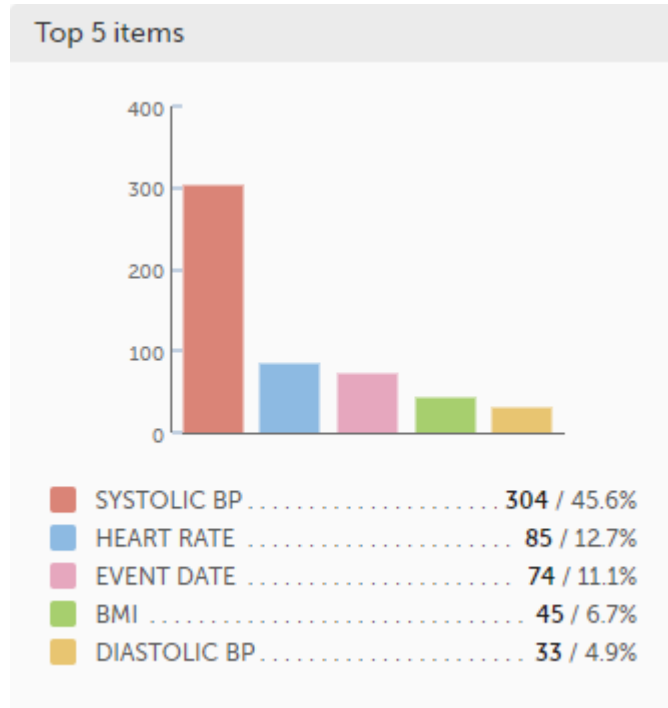
2.7　Top 5 check OIDs

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.

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.

n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST QUERY (date, by, message)
5	4.9	SE-01-045		Karolinska U...	28 Feb 2018 09:46, Richard Schlomann, Test Query.
5	4.9	SE-01-119		Karolinska U...	20 May 2016 08:24, Mr Demo, Correct?.
4	3.9	SE-01-118		Karolinska U...	07 Sep 2016 11:51, System, Value is outside of normal range. Plea...
3	2.9	SE-01-219		Karolinska U...	07 Jun 2017 17:06, Lyle Wiemerslage, r?.
2	2	SE-01-348		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
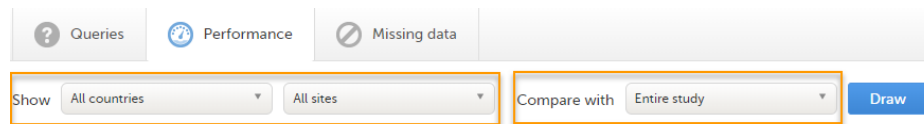
Based on the comparison selection the graphs will show statistics about:

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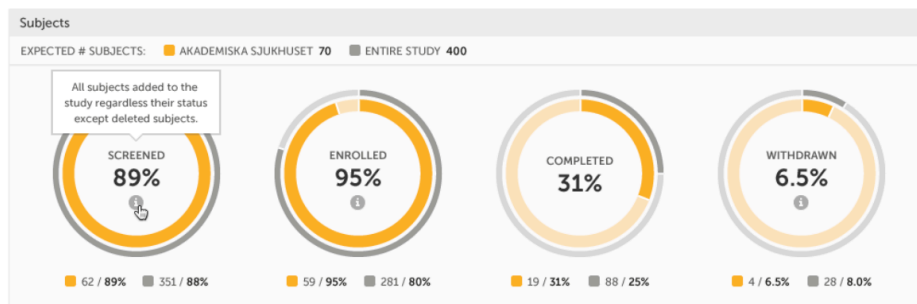
The conditions for the following subject statuses are defined in the study design (in Viedoc Designer under *Study Settings > Subject status*):

- **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):
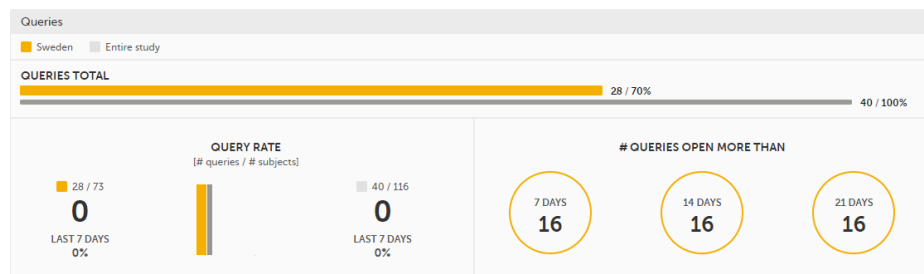
- **Queries total** - the total number of queries on selected site(s) (in orange) and compared site(s) (in gray) are shown both in % and in actual numbers.
- **Query rate** - total number of raised queries out of total number of subjects. The column graph consists of 5 bars indicating the progress of 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):
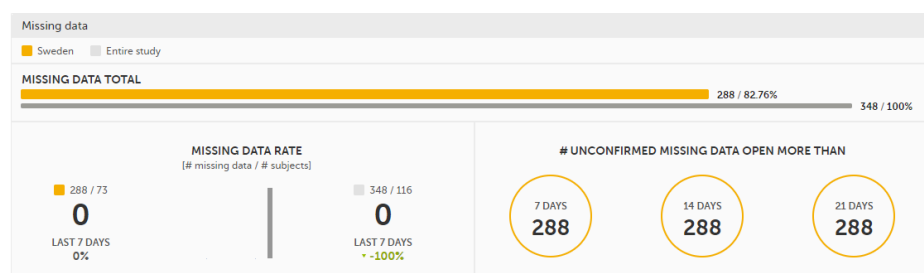
- **Missing data total -** Total number of missing data on selected site(s) (in orange) and compared site(s) (in gray) both numeric and percentage out of all missing data in the entire study. Hidden forms/items are not included in the count.

- **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):
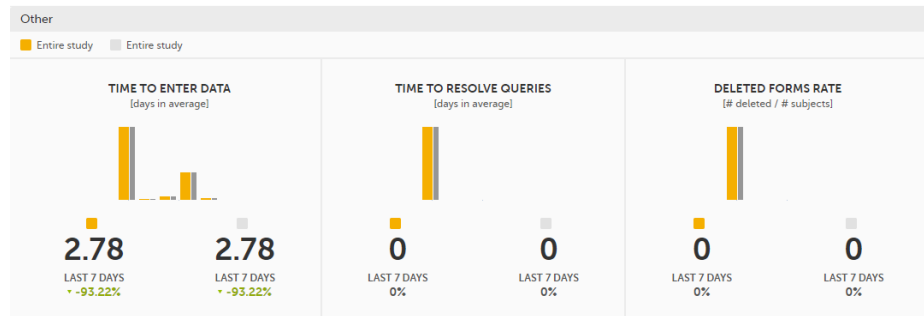
- **Time to enter data** - the average time (in days) it takes to enter data for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as a difference between the event date and the date the item data was entered, per form.
  The column graph consists of 5 bars indicating the 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 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

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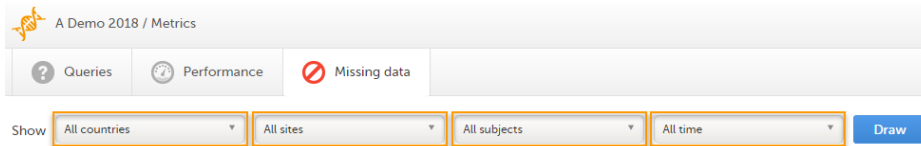
- Country
- Site
- Subject
- Time period - choose between:
  - All time
  - Last 24 hours
  - Last 3 days
  - Last week
  - Last 3 weeks

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.

Top 5 forms

- STUDY STATUS .... 214 / 29.8%
- ADVERSE EVENT .... 173 / 24.1%
- PHYSICAL EXAMINATION .... 132 / 18.4%
- SERIOUS ADVERSE EVENT .... 41 / 5.7%
- LABORATORY RESULTS.................. 38 / 5.2%
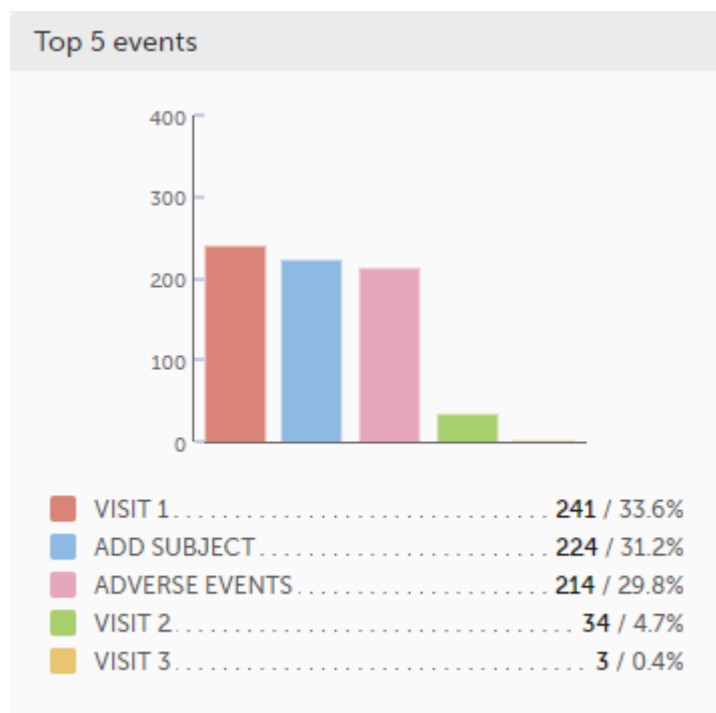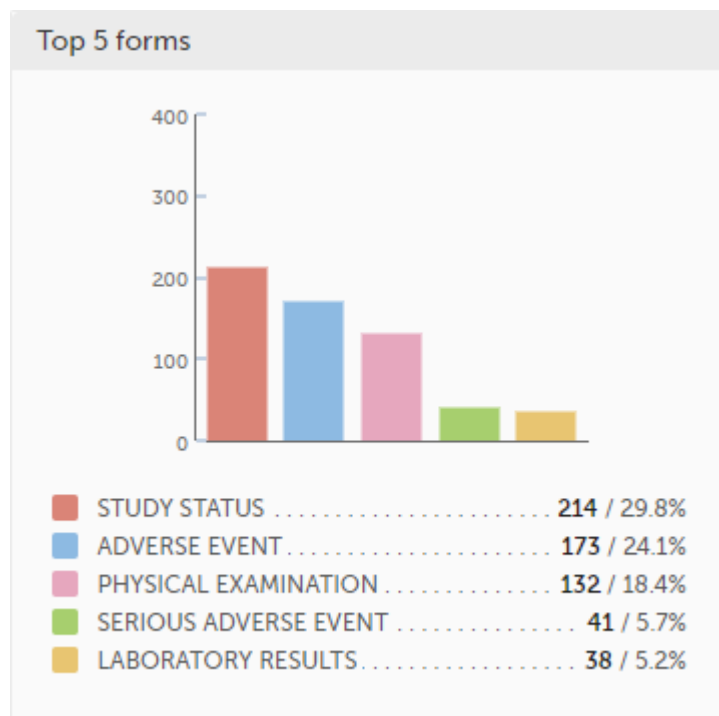
4.3 Top 5 items

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.

Top 5 items

- STATUS .... 214 / 29.8%
- OUTCOME OF ADVERSE EVENT .... 28 / 3.9%
- ACTION TAKEN WITH STUDY TREAT... .... 27 / 3.7%
- CAUSALITY .... 27 / 3.7%
- SEVERITY/INTENSITY .... 25 / 3.4%
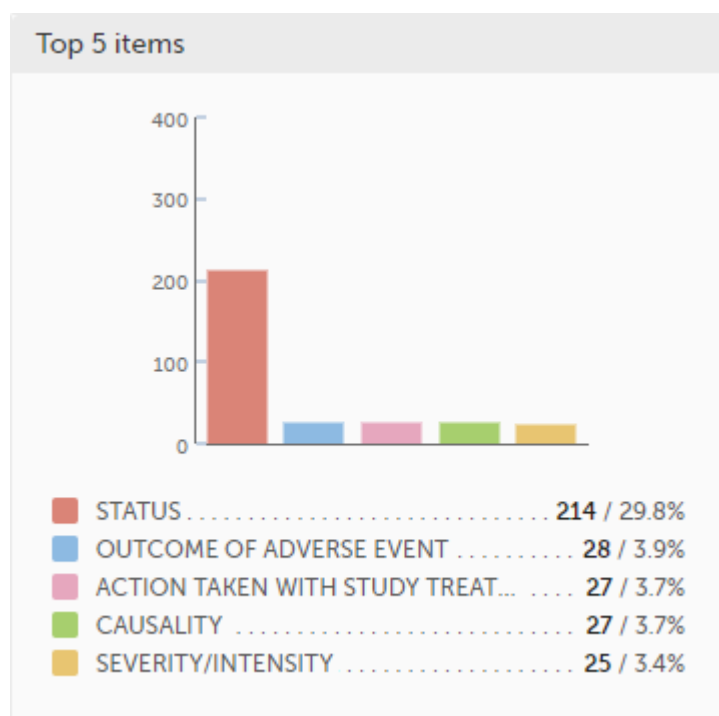
4.4 Subjects with confirmed missing data

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.

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.

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.

Working with reference data

Published by Viedoc System 2021-11-24

1   Introduction

1.1   About reference data

Viedoc offers support for adding centralized reference data to the study, which will be automatically populated to the subject forms. When centralized reference data are added to the study, it is not necessary to fill in the reference values for each subject in each form separately.

It is possible to configure different sets of reference data that will be populated to the form based on:

- Factors that can affect the reference data, such as age or gender
- Reference data source, such as a lab
- Site
- Date of measurement

1.2   Terminology

Term	Definition
Reference data source	A source that provides reference data (for example a lab).
Reference data scope	A set of measurements that a reference data source carries out, and the parameters that might affect these data. The data in one reference data scope are going to be populated to one lab data form. One or more reference data scopes can be configured in Viedoc Designer > Global Settings, as set(s) of variables and factors (see definitions below).
Factor	A parameter that affects the reference data, for example a subject's gender. Factors may affect the normal range for a test result.
Variable	A specific measurement to be carried out.
Target type	Item of a certain type of information that a reference data source can provide (such as range, unit, low/high values) for a specific measurement (defined by a variable). Any number of target types can be defined by the user.

1.3 Workflow

Reference data sources are configured in Viedoc Admin. Each reference data source is linked to one or more reference data scopes that define the following:

- Which measurements the reference data source carries out
- Which factors might affect the results
- What ranges/units are used

For each reference data source-scope combination, the reference values that should be auto-populated to the forms should be entered in the reference data editor in Viedoc Clinic. This can be done by clinic users that have permission to edit and save reference data.

To make the reference values available for auto-population to the subject forms, the reference values should be published. This can be done by clinic users that have permission to publish the reference data values.

See also the video tutorial demonstrating how to work with reference data in Enter reference data.

---

2 Reference data overview

2.1 Overview of reference data on the landing page

Note! You only have access to reference data on the landing page, and to the reference data editor, if you have a role with permission to view, edit and/or publish reference data.

On the landing page, you can view or do the following:

1. Click the **Reference data** icon to display all the reference data source-scope combinations that are linked to the sites you have access to.

For each reference data source-scope combination, the following information is provided:

2. Status indicator that indicates whether **reference values** have been entered (green) or whether the fields are still empty (grey).

3. Status indicator that indicates whether the reference values have been **Published** (including date, time and user who published them) or whether the reference values are **Not published** yet.

4. The number of sites that the reference data source is linked to. This gives an indication of how many sites are impacted in case the reference values are edited.

5. The number of forms that the reference values have been populated to. This gives an indication of how many forms are impacted in case the reference values are edited.

6. The number of users that have permission to edit the reference values.

7. Name of the user who performed the last changes to the reference values, including date and time.

8. Warning message if the latest saved version was not published.

9. Click **Open reference data editor** to view or edit the reference data, see The reference data editor.

2.2 The reference data editor

2.2.1 How to use the reference data editor

When you click **Open reference data editor** on the reference data section of the landing page, the reference data editor opens for that specific reference data source-scope combination. Depending on the user rights that are connected to your role, you can view as read-only, edit and/or publish the reference data.

On the reference data editor, you can view or do the following:

1. Click the arrow to expand the reference data table for that specific time period.The newest time period is expanded by default and shown on the top of the list.

2. The number of the reference data set for a given time period. This number is given by default, based on the order in which the reference data sets have been created.

3. The period the reference data set is valid.

- **Valid from** (1) - the beginning of the time period. By default this is set to the current date. To change this, click the arrow to the right of the date and select the date.
- **Valid to** (2) - the end of the time period. By default this is set to "ongoing". To change this, click the arrow to the right of the date and select the date.

4. Click **Add new** to create a new reference data set for a new time period.

5. Click **Duplicate** to create a new reference data set for a new time period based on a previously created set.

6. Click the trash can icon to remove an existing reference data set time period.

7. Reference variable name - the variable that are defined for that reference data scope. A variable is a specific measurement to be carried out. See Variables for more information.

8. Factors - the factors that are defined in the scope. Factors are parameters that affect the reference data. See Factors for more information.

9. Values to be populated - the reference data values provided by the reference data source. The values entered here will automatically be populated to the subject forms.

10. Click **Cancel** to discard all the changes performed and revert to the latest published reference data.

11. Click **Save** to save the changes performed.

Note! Only users with clinic roles that have permission to edit reference data can edit and save the reference data.

Upon save, the reference data set becomes available for publishing.

12. Click **Publish** to publish the reference data. A dialog appears asking you to enter a message. This message appears in the **Messages** section on the landing page.

Publishing makes the data available for auto-population into the subject forms.

Note! Only users with clinic roles that have permission to publish reference data can publish the reference data.

2.2.2 Variables

The column **Reference variable name** displays the variables that were configured for the reference data scope. By clicking the arrow to the right of the variable name, you can:

- **Reset** the existing reference values for that variable in the *Values to be populated*. This action is only available for a variable that is included in the reference data list, such as **1** and **2** in the image.
- Select **Not available** to exclude the variable from the reference data. The variable then appears as *Not included*. This action is only available for a variable that is included in the reference data list, such as **1** and **2** in the image.

When the variable is not included, such as **3** in the image, you can:

- Select **Include** to add the variable to the reference data set again.

Note! If you do not want automatic population of reference data for a certain variable, the variable should be set to *Not included*. This way, it is possible to manually add reference data for that variable to a form.

2.2.3 Factors

The column **Factors** displays the factors that were configured for the reference data scope. In this column, you can:

1. Click the arrow to the right of **Factors**, and select a factor from the drop-down list to add that factor to the table. If no arrow is displayed, all factors predefined in the reference data scope are already added (as in the image).

2. Click the arrow to the right of the factor label and click **Remove** to remove that factor from the table.

By default, a newly added factor is populated with *N/A* (not applicable) in the table. You can edit this by clicking the arrow to the right of *N/A* and select one of the options from the drop-down list. The drop-down list displayed varies depending on whether the factor has predefined factor options or not.

3. For a factor that has predefined options, such as *Sex* in the example:

- **A**: Select one of the options in the list to set the current row to that option, or
- **B**: Select one of the options with a + in front of it to add a new row to the column populated with the selected option, or
- Select **Delete row** to remove the current row from the table

4. For a numeric range (no predefined options), such as *Age* in the example:

- Select one of the options that define the range: inclusive in between, less than, less than or equal to, greater than, greater than or equal to, equal, and fill in the number(s); or,
- Select **N/A** (not applicable), or
- Select **Add new row** to add a new row to the table, or
- Select **Delete row** to delete the row from the table

Note! If you would like to add the factor option *N/A* to a factor that also has other options, the option *N/A* should be the last entry for that variable in the table. The reason for this is that, while populating a form with reference data, the system is matching the factor options starting from the top of the table. If a match is found, the corresponding data

are populated to the form. The option *N/A* is always a match. So if N/A is listed at the top of the table, the search will stop and the form will be populated with the data corresponding to *N/A*. If you want the system to match the other factor options first, these should be listed <u>before</u> N/A in the table.

2.3   How the *reference data* feature works within the forms

When the reference data are published, they become available for auto population to the forms they are intended to be used in.

To populate a form with reference data, the Investigator/Study Nurse/site staff selects:

- For each scope in the form, the reference data source that provided the results, from the drop-down list
- The date and time of collection

It is also possible that the event date is used instead of date and time of collection. In that case, the reference data populate after the source is selected.

Tip! If you do not want any reference data to be populated automatically, do not select a reference data source, but leave the drop-down list to *Select a source*. No automatic population of data will take place and you can fill in the fields manually.

Note! No reference data can be populated, if...

- The items used as factors are left empty for a specific subject.
- The selected **Date and time of collection** does not fall within the time frame the reference value set is valid.
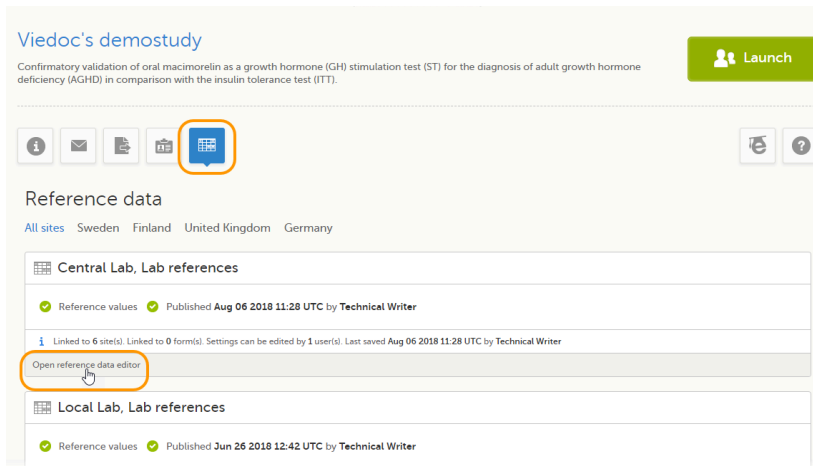
3   Entering and publishing reference data values

Note! You can only enter reference values when your role has permission to edit reference data.

To enter a new set of reference values:

1   On the Viedoc landing page, click the **Reference data** icon.

2   Click **Open reference data editor** for the reference data source-scope combination you would like to enter values into.


The reference data editor opens and displays the variables and the target types to be populated, as defined in the reference data scope. If you would like to exclude some of the variables, click the arrow to the right of the variable name and select **Not available**. See also Variables for more information.

3   Select the date from which, and to which, this set of reference values is valid in the **Valid to** and **Valid from** fields.
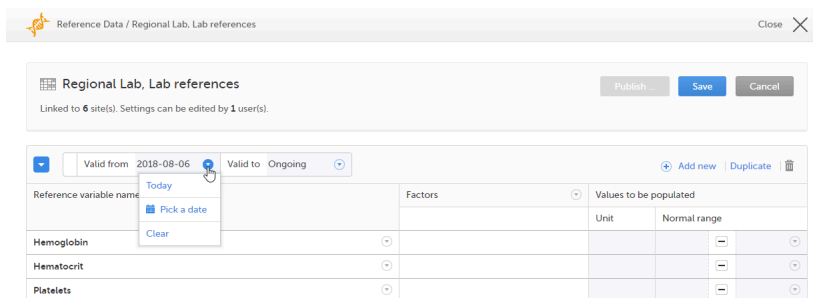
4   Click the arrow to the right of **Factors** and select the factors that should be included.
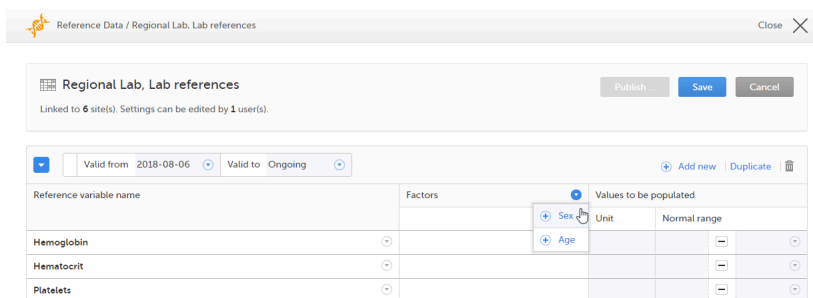
5   For every variable, and for every factor, click the arrow to the right of *N/A* and select the factor options that should be included.

If the factor is a numeric range, select **Set a value**. By default, the *inclusive in between* option appears.

If you would like to change the type of the range, click the arrow again and select the type of range you would like to include. If necessary, click **Add new row** to add rows. Manually enter the values of the range in the blue fields.

See also Factors for more information.

6   For every variable, and for every factor, enter the reference values that should be automatically populated to the forms.

7   Click **Save** to save the reference data.
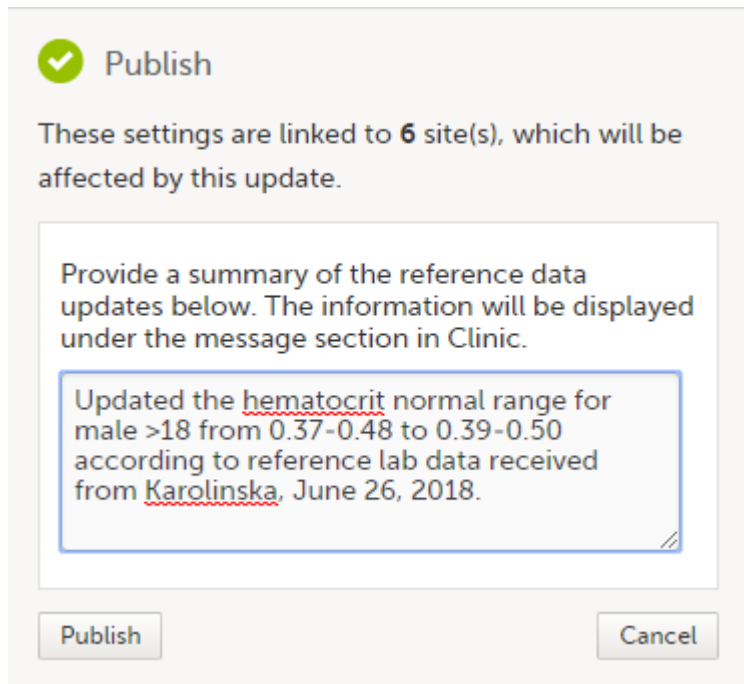
To publish reference data:

Note! You can only publish reference data when your role has permission to publish reference data.

**1**   Click **Publish**.

A dialog opens.

2   Enter a summary of the reference data updates in the field.

Click **Publish**.
The reference values are published and available for auto-population to the forms.

If the reference data scope is changed and published in Viedoc Designer <u>after</u> the reference values have been published in Viedoc Clinic, the following message will appear on the Reference data page.
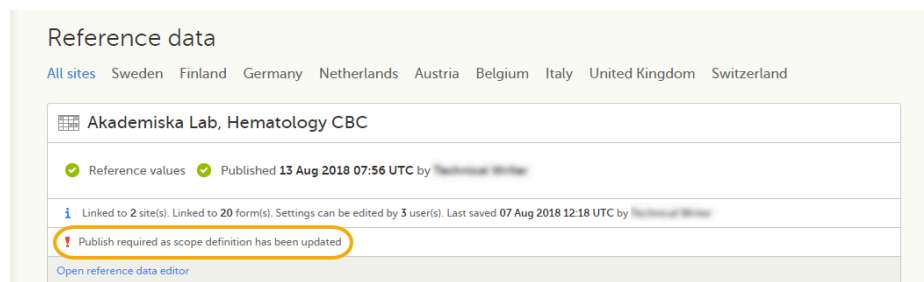
The reference date source-scope combination needs to be updated and <u>published again</u> in Viedoc Clinic, for the reference values to become available for auto-population to the subject forms.

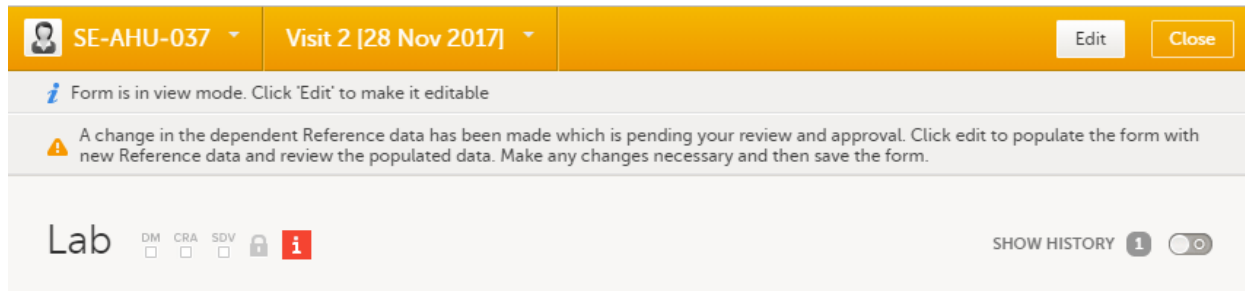If the reference values change for already populated data, the affected forms will be marked with a red issue icon **[i]**.

4   Editing reference data values

Note! You can only edit data when your role has permission to edit reference data.

To edit a set of reference values:

1   On the Viedoc landing page, click the **Reference data** icon.

2   Click **Open reference data editor** for the reference data source-reference data scope combination you would like to enter values into.

3   Edit the variables (see <u>Variables</u>), factors (see <u>Factors</u>), or the reference values.

4   Click **Save** to save the reference data.

If the reference values change for already populated data, the affected forms will be marked with a red issue icon [i], and a message is displayed on the top of the form as illustrated below:

The affected forms are also listed in the Selection page, under the **ISSUES** view, being marked as **Pending Reference data upgrade**. For more details, see Selection page.

Issues and tasks in a PMS study

1 Introduction

The Selection page (see 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.
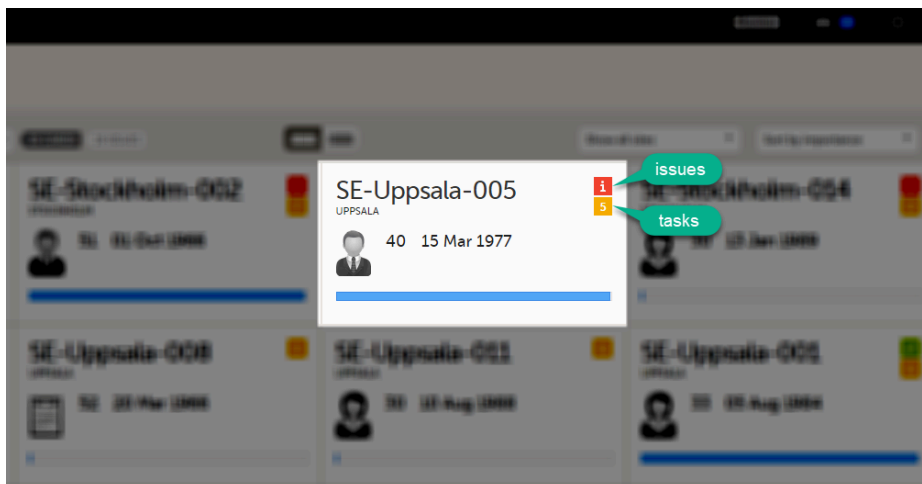

- **Red** icon: **Issues** - indicating that the subject has open queries and/or unconfirmed missing data. Both open queries and unconfirmed missing data should be handled and resolved by the site but, as a Monitor or Data Manager, it is important for you to be aware of these issues as well. For more 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. The orange icons are only displayed on the sponsor side.

2 Issues

It is possible to switch between the *Cards* view and *Issues* view by clicking the **Cards** icon or **Issues** icon next to the search field.

The **Issues** view displays only the list of existing issues.

Click 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 open issues
    - All queries
    - Open queries
    - Queries awaiting approval
    - My queries (default)
    - Pre-queries
    - Missing data
    - Form upgrade pending

3 Tasks

Note! Task icons are only displayed on the sponsor side.

When a booklet or Adverse Event (AE) report has been received, the orange task icon appears indicating that there is data ready for review, or query answers to be approved. The number of tasks is displayed. If there are more than 9 tasks to be performed on a booklet or form, *+9* is 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 (as displayed on the subject card on the Selection page)
- Booklet (see image below)
- Form (see image below)

DEMO   The study is currently set to operate in demonstration & training mode. Do not input any real data.   DEMO

👥 **Details**   ⊞ ☑   ◀ 👤 ▶
                                                         1/1

JP-S2-009
SITE 2

INITIALS   DOB
KIW   08 Oct 1979

| 70%
of study | 3/3
booklets | 28/40
forms |

📄 Registration   ✅ ✔
📄 Booklet 1   🔒 ✔
📄 Booklet 2   7 ✅ 1
📄 Booklet 3   1

⚠ AE The booklet has Adverse Event which must be reported immediately!

Booklet 2 Ongoing

Visit 1
Vital Signs		✅ DM ✔
Medication use		✅ DM ✔
Laboratory		✅ DM ✔
Check questions		✅ DM ✔

Visit 2
Vital Signs		✅ DM ✔
Medication use	1	✅ DM i
Laboratory	1	✅ DM ✔
Check questions		✅ DM ✔

Visit 3
Vital Signs	1	✅ DM ✔
Medication use	1	✅ DM i
Laboratory	1	✅ DM i
Check questions	1	✅ DM ✔

Adverse Events log
| Headache, 16 Jan 2019
Adverse Event received 17 Jan 2019 19:27 JST ⧉ Manage | AE | ✅ DM ✔ |
| Headache, 17 Jan 2019
Booklet received 13 Feb 2019 20:15 JST ⧉ Manage | AE 1 | ✅ DM ✔ |

Booklet period starts
15 Jan 2019
Booklet period ends
21 Jan 2019

Add note ✎

Booklet received
13 Feb 2019 20:15 JST
Show history

Return booklet

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

Data review in a PMS study

Published by Viedoc System 2021-08-09

1   Data review

This section describes how data review is performed in a Post Marketing Surveillance (PMS) study. The purpose of data review is to give the Data Manager the possibility to mark forms as reviewed.

Data review is a task to be completed. The number of tasks to be completed is displayed in the orange task icon:

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

- at the bottom of each form, by checking the **Data review** checkbox, see the image below.
- batch-wise using the review console, see Data review console below.

The orange task icon disappears when the **Data review** checkbox is selected and the task is completed.

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

2   Data review console

2.1   Description of the data review console

You can perform **Data review** of multiple forms at once, batch-wise, by using the **Data review** console.

To open the Data review console, click the Data review icon in the top right corner of the subject **Details** page.

The data review console displays an overview of all forms that require data review for one subject, and shows which forms have been reviewed.
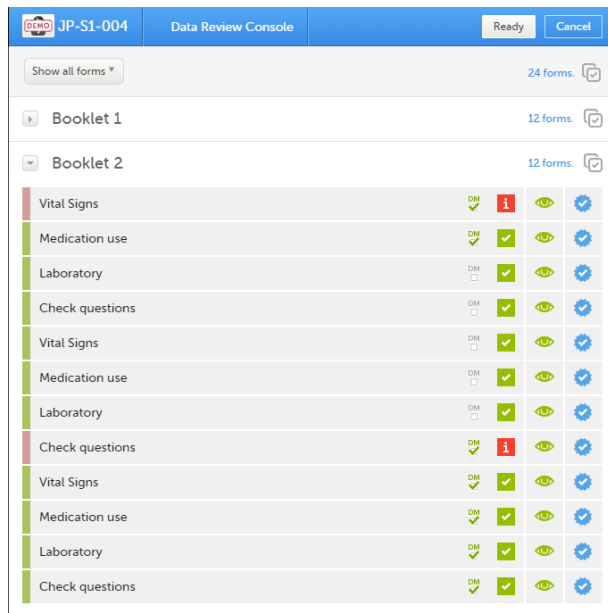
The icons in the data review console have the following meaning:

Icon	Description
DM ✓	Data are reviewed
DM ☐	Data are not reviewed
✓	All data in the form is completed and the form contains no issues
i	The form contains issues, for example, open queries
👁	You have visited the latest version of the form
👁	You have not visited the latest version of the form
✓	Data are signed by the Investigator

2.2 Marking forms as reviewed using the data console

To mark the forms as reviewed:

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.
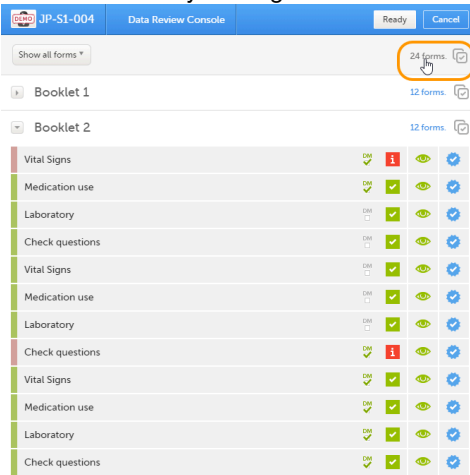
- Select all forms within one booklet, by clicking the *n forms* link to the right of the booklet name.
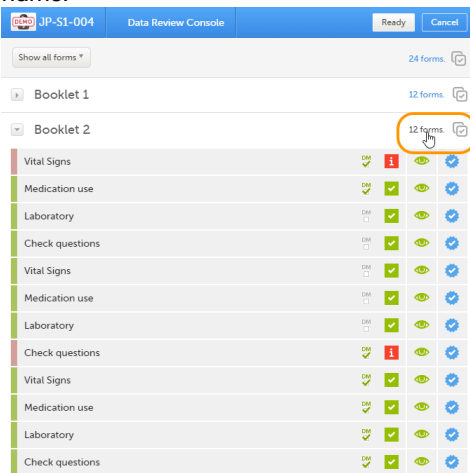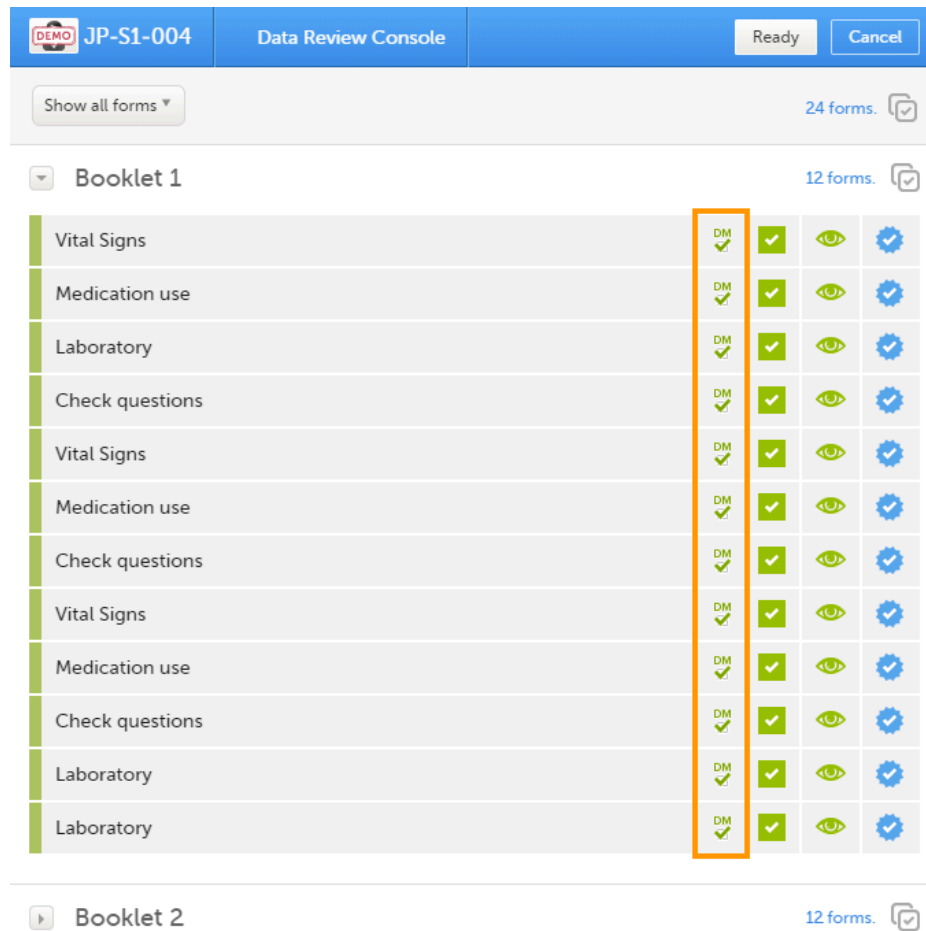
- Select individual forms by clicking the DM icon of the form. Step 2 is not applicable in this case.
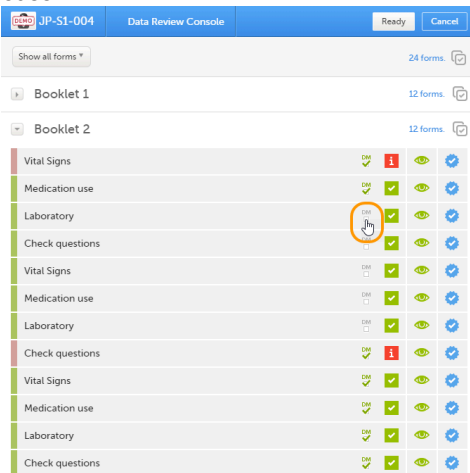
2   In the pop-up that opens, select *All forms* or *Only visited forms*, and click **Ready**.
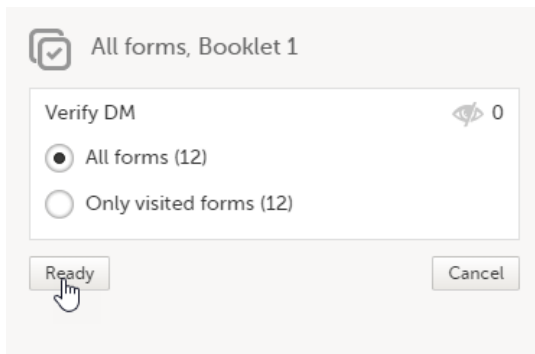
The status of the selected forms is updated according to the performed actions.

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 as reviewed according to your selections. Thus, the system will not prevent you from marking unvisited forms as reviewed.

3   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 2021-11-24

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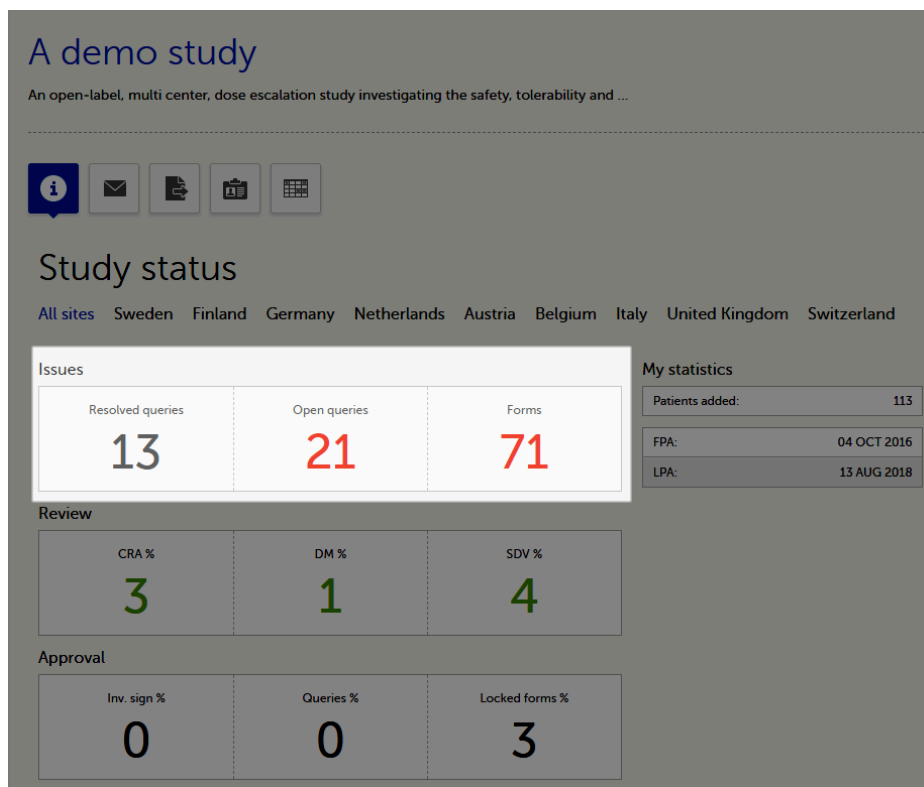
A query is raised in a form field. After a query is raised, the respective form is marked with the red issue icon `i`:

2   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.

2.1 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 <u>add pre-queries</u>, typically the Data Manager, and one role with permission to <u>promote pre-queries and add queries</u>, typically the Monitor.
- Three roles: one role with permission to <u>add pre-queries</u>, for example the Data Manager, one role with permission to <u>promote</u> the pre-query, for example the **Sponsor**, and one role with permission to <u>add queries</u>, 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.
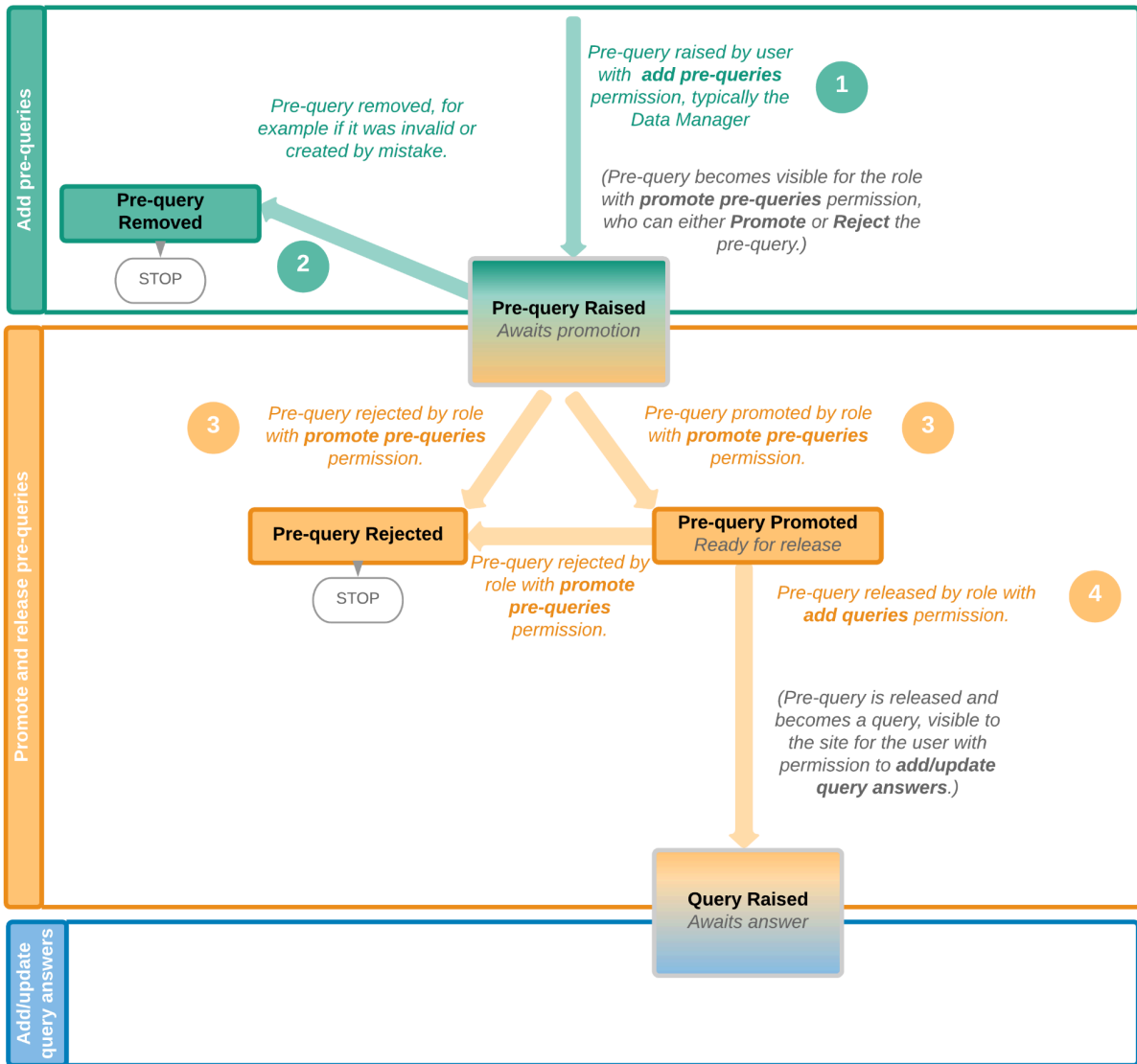
Pre-query states

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

2.2 Queries

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

- One role with permissions to <u>raise and approve queries</u>, typically the **Monitor**.
- One role with permission to <u>resolve queries</u>, 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:

    a. Manually added query by a user with **add/change queries** permission
    b. When a pre-query is released. See <u>pre-queries</u> section above.
    c. When a validation query was resolved by confirming data as correct, and then rejected. See <u>Validation queries</u> 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 <u>approved</u> 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 <u>approved</u>.

See also <u>Query states</u>.

---

3   Validation queries

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:

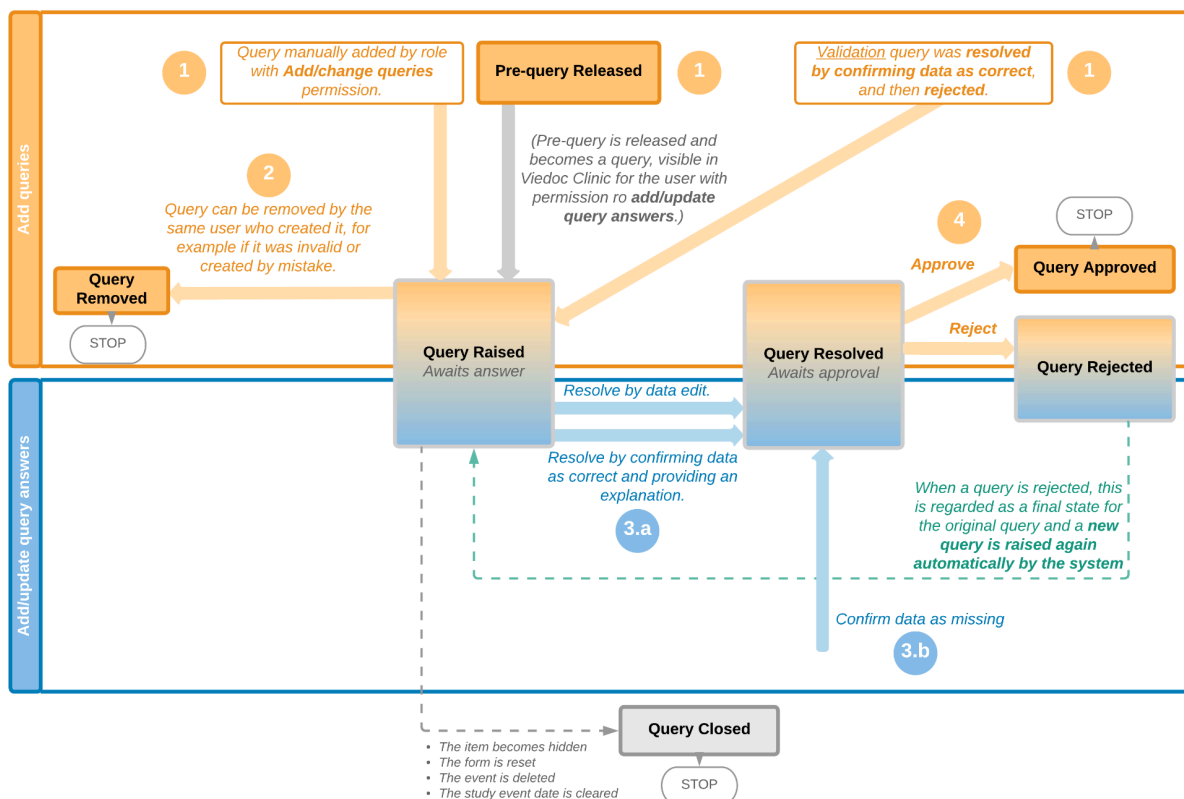   a. Editing the data. As a result, the query is closed.
   b. Confirming the data is correct and providing an explanation. The query is now resolved and waiting for approval.

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.
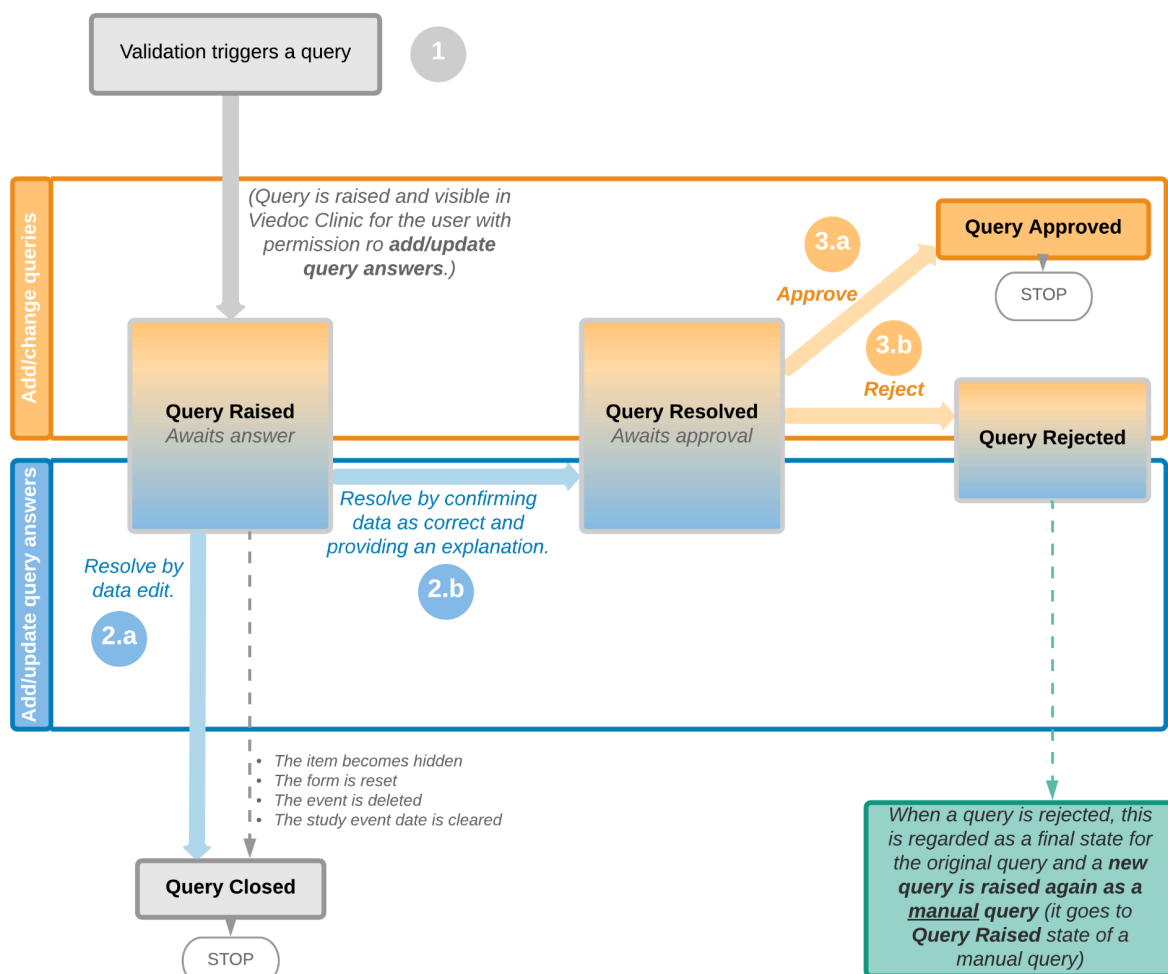
4 Query states

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

5   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.

For more details and instructions on how to perform an export, see Exporting data.

5.1 Queries in ODM export

For details on how queries look in the ODM export see Queries in ODM export.

5.2 Queries in Excel export

For details on how queries look in the Excel/CSV exported file see Queries in Excel export.

---

6 Related topics

- Raising and promoting pre-queries
- Raising/Approving/Rejecting queries
- Queries in ODM export
- Queries in Excel export
- Metrics
- Video tutorial Issues: Resolve a query

Raising and promoting pre-queries

Published by Viedoc System 2020-04-27

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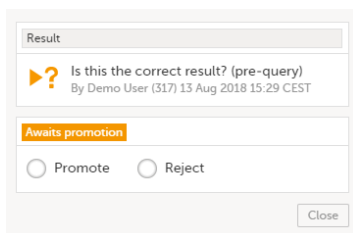
2   ▪ To promote the pre-query, select **Promote** and click **Save query**. The pre-query will enter the Ready for release state.
▪ To reject the pre-query, select **Reject** and click **Save query**. The pre-query state will be **Rejected**. This is a final state for a pre-query.

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:

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 <u>query</u> 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.

Raising/Approving/Rejecting queries

Published by Viedoc System 2021-11-24

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.

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.

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

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**:

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**:

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.
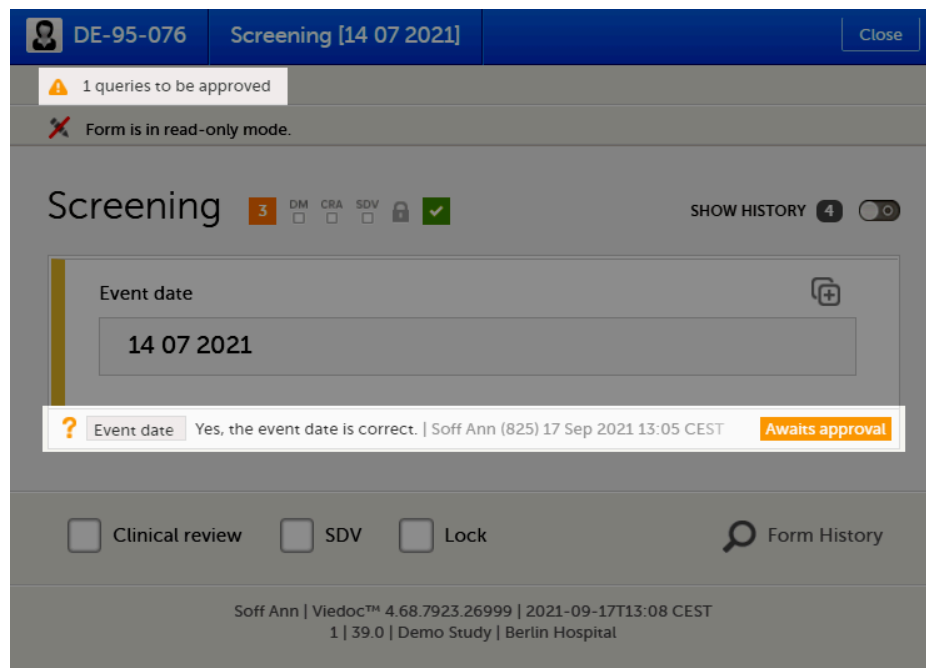
4.1 Approving a query

To approve a query:

1   Open the query. The query pop-up opens displaying the list of the query history:
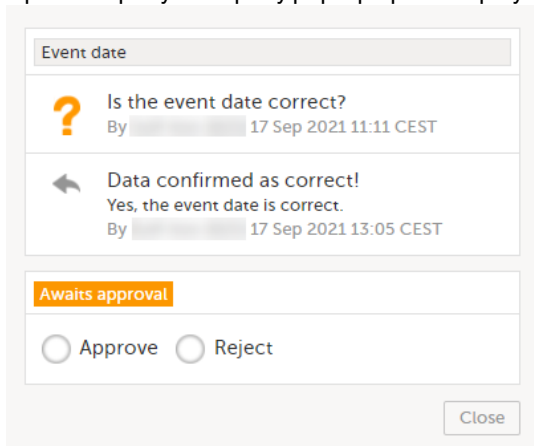
2   Select **Approve** and click **Save query**:

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

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:

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

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

Exporting data

Exporting data

Published by Viedoc System 2024-03-19

1   Introduction

The Data Export page can be accessed by clicking the **Data Export** icon in the study start page:
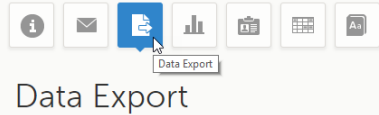
The Data Export page enables you to preview and download study data:

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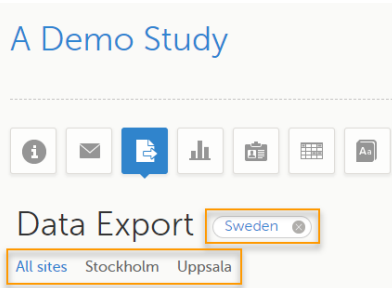
For a specific country, you can choose to export the data for:

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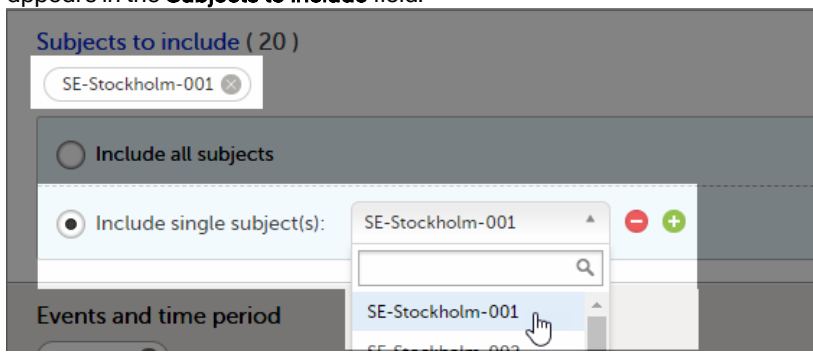
Repeat this step for each subject you want to include in the data preview/export.

To undo the selection of certain subjects, click the - icon, or click the cross x icon next to the subject ID:
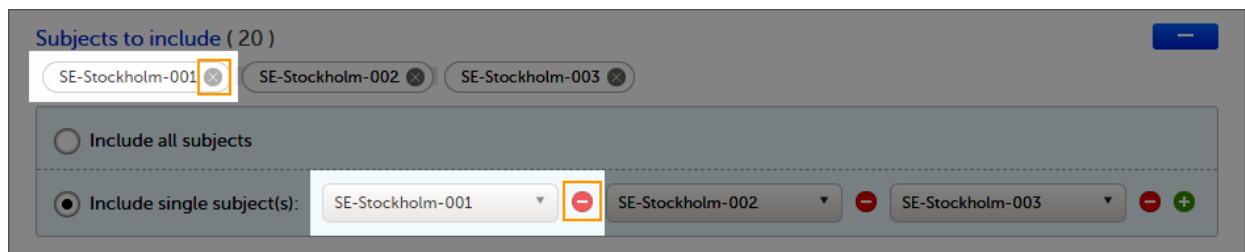
2.3   Events and time period

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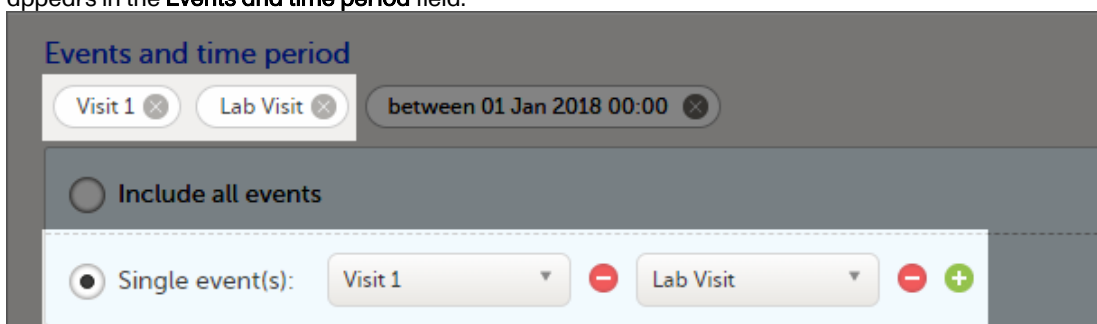
Repeat this step for each event you want to include in the data preview/export.

To undo the selection of certain events, click the - icon, or click the cross x icon next to the event:
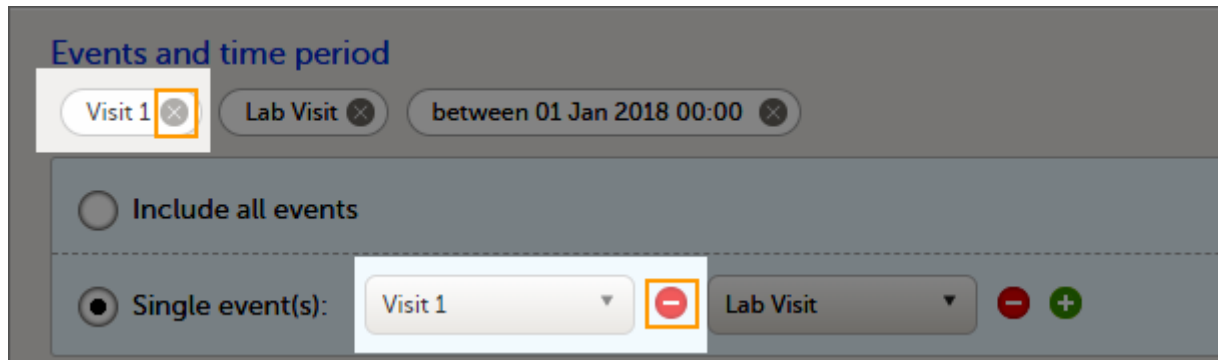
2.3.2   Selecting a time period

To include data from a specific time period:

1   Select the **Time period** checkbox:
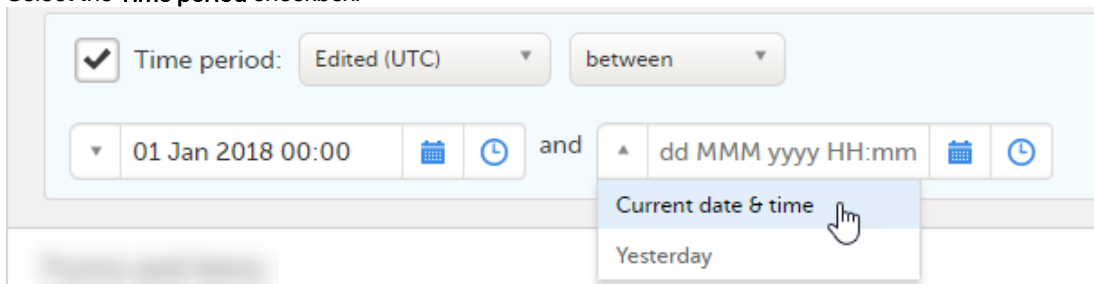
2   Select one of the following options from the first drop-down list:
- **Edited (UTC)** - to include data based on the date they were added or last edited.
  Note! This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note that 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 x icon next to it:
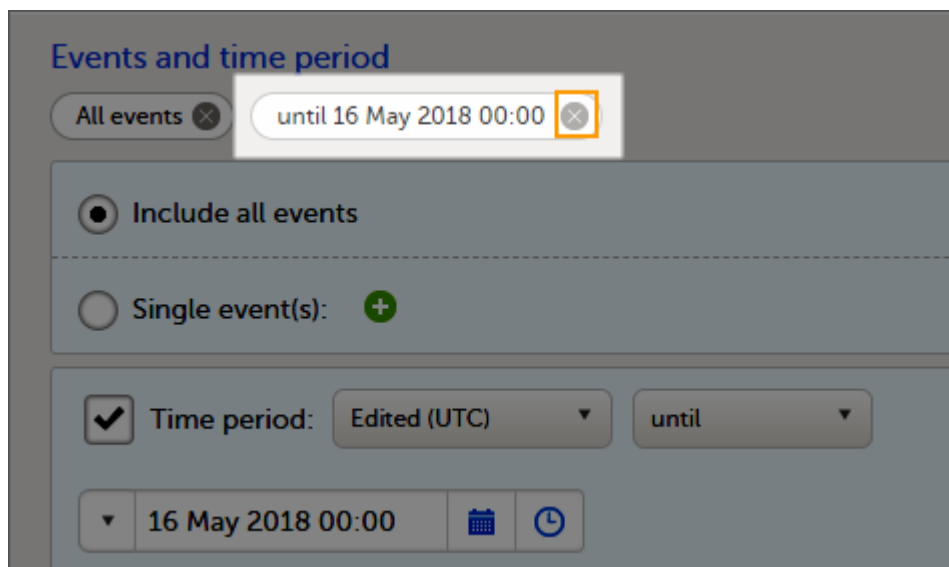
2.4   Forms and items

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 <u>the first</u> 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:
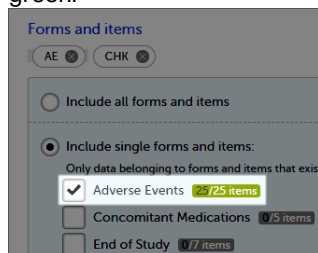
- Click the field **[..]/[..] items** next to the form name, and select/deselect specific items. You can also use **Select all / Deselect all** for selecting/deselecting all the items in the form at once. If selecting only some of the items in the form, the selected/total number of items will be highlighted in orange:
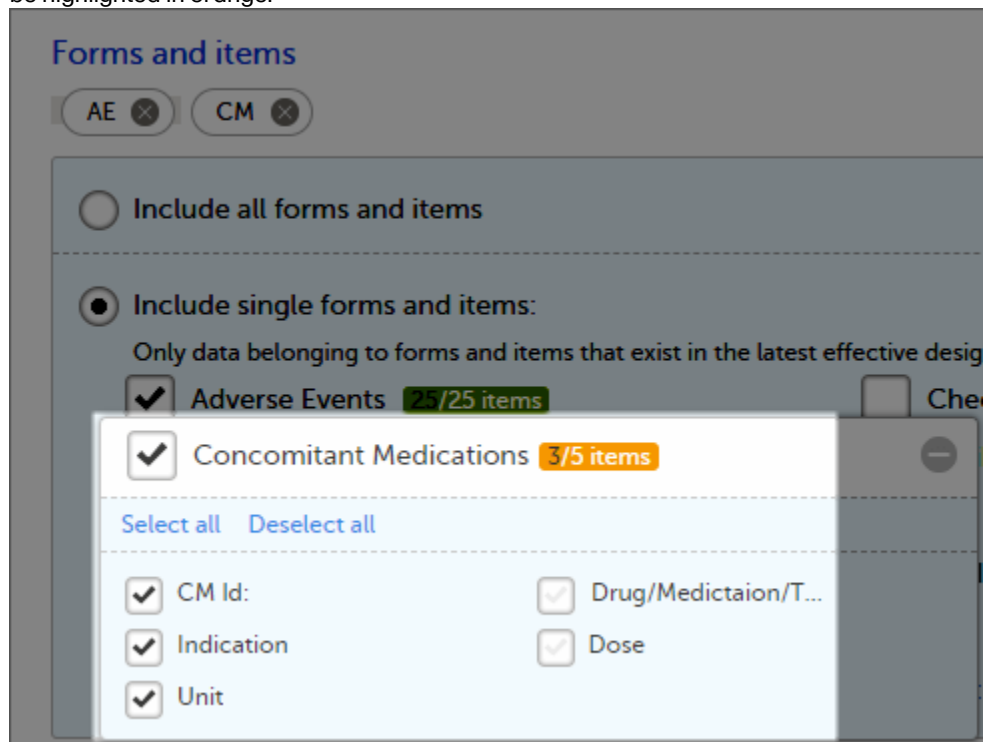
To undo the selection of a certain form, click the cross   x   icon next to it:

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 histor**y 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: - *Initiated* - *Proposed* - *Not Initiated* - *Planned*
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
Design version	The design version/revision that is active for the event

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)
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.

Column name	Description
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:
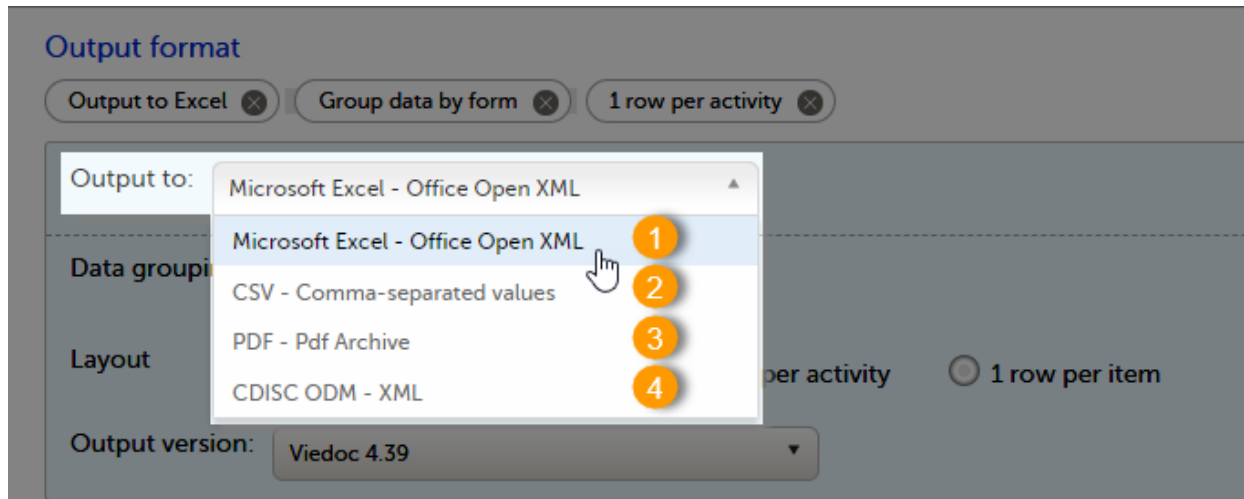
- Microsoft Excel - Office Open XML
- CSV
- ODM

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 to export 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 checked.

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.

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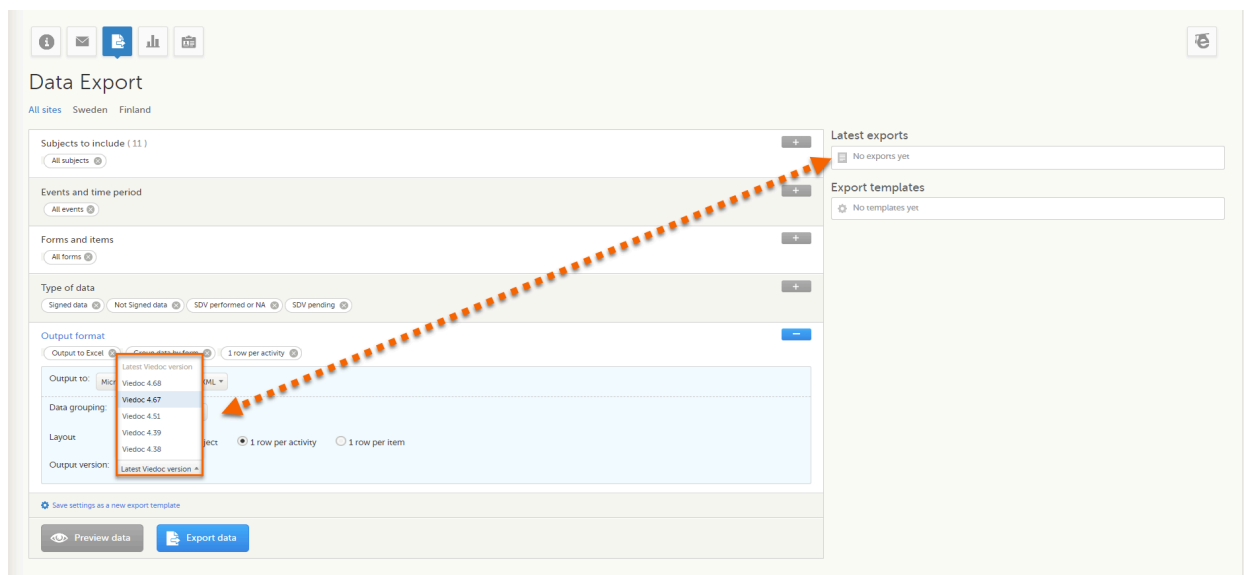
The Viedoc version used for data export is listed in the **Latest exports** area on the right side of the export page.

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 <u>only</u> those versions in which changes to the data structure were introduced.

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

Output version	Changes in data structure
Latest Viedoc version	When choosing **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.

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

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

File type	Changes in the export output format
Excel	Addition of three columns for the new form sequence numbers introduced: - `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: `v4:SubjectFormSeqNo`, `v4:OriginSubjectFormSeqNo` and `v4:SourceSubjectFormSeqNo`, within the `FormData`, right after the `FormRepeatKey`.
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 (`FormSeq`) that contains the `FormRepeatKey`.
ODM	The `FormRepeatKey` now contains the activity ID as well, in the following format: `FormRepeatKey$ActivityId`. The ExportVersion attribute has been added to the ODM.
PDF	The summary formats are used to display the event and form names.

5 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**.

5.1   Data table

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

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.
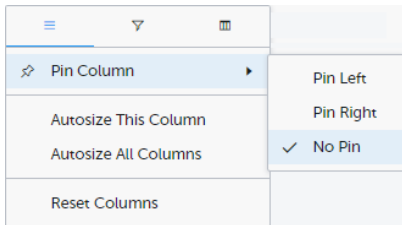
5.1.1   Column menu

The column menu contains:

- column display options

- column filter

- column selection options

For more information, see the following sub-sections.

5.1.1.1   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.

5.1.1.2 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.

Column selection options

Select the columns to be displayed in the preview table.
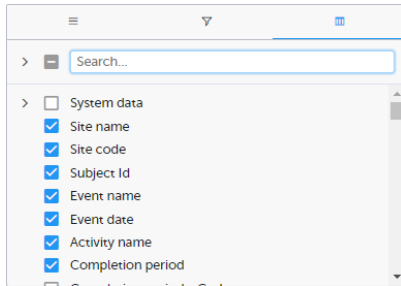
Use the **Search** field to search for columns.

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](#).

5.1.2 **Data table context menu**

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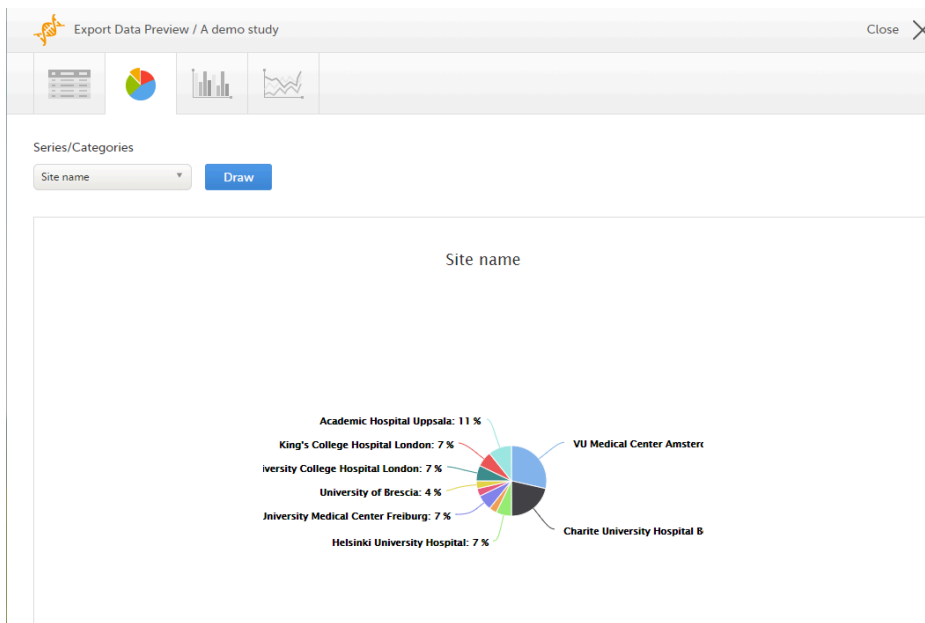

Copy: Copies the cell value to your clipboard.

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.

5.2 **Pie chart**

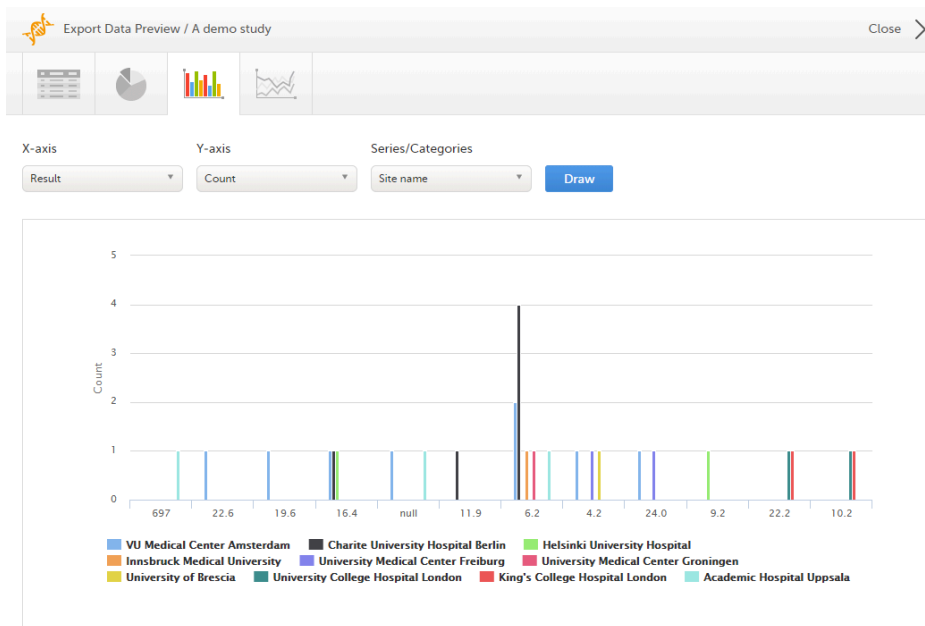Select the data set you wish to plot in a chart, and click **Draw**:
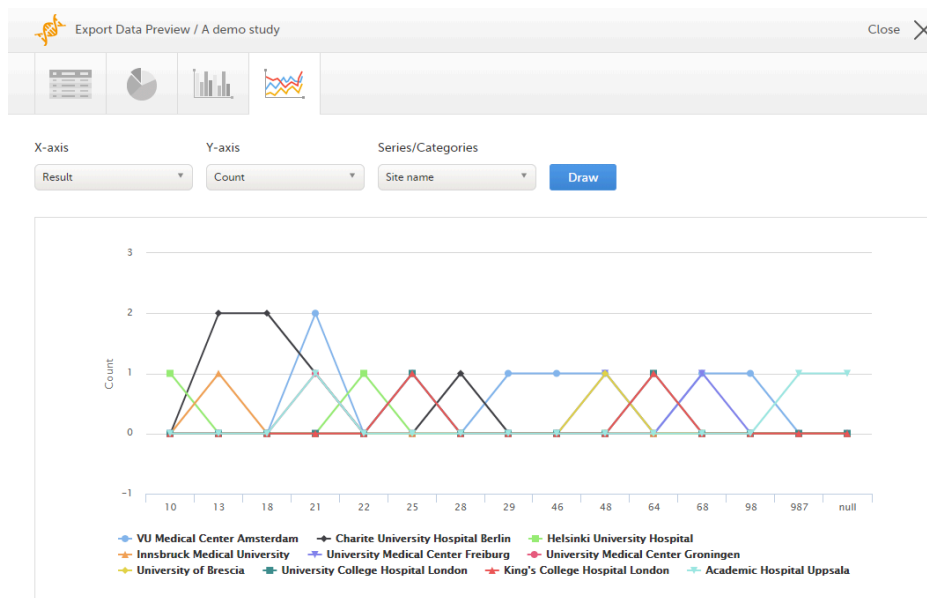
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

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.

5.3 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.

5.4 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.
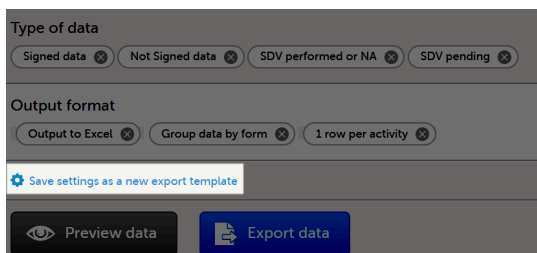
6   Data export templates

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.

6.1   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.
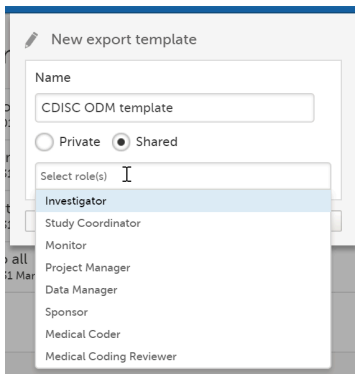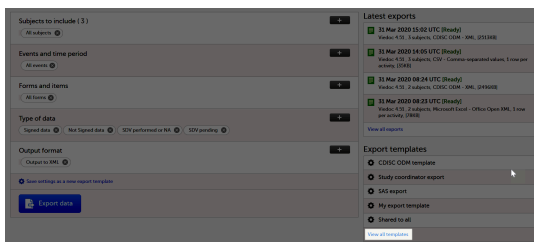

3   Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:
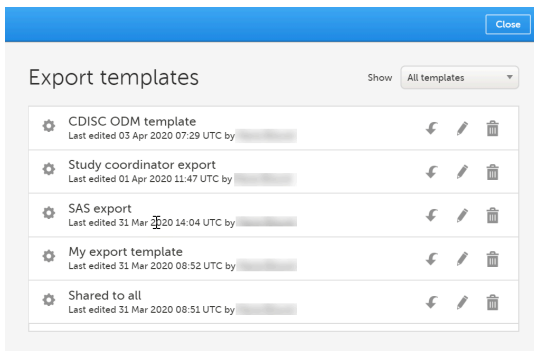
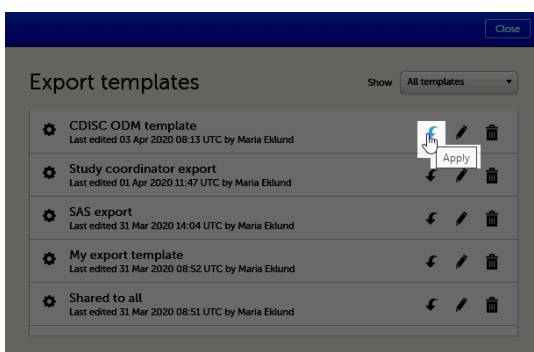## 6.2   Applying a data export template

To apply a data export template:

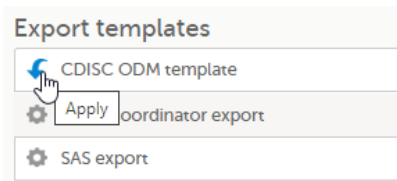1   Click **View all templates** in the **Export templates** area of the **Data export** page.

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

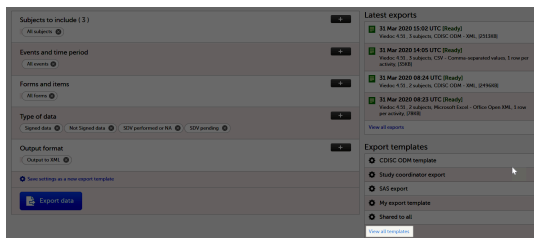**3**   Click **Export data** to perform an export with the settings in the template.

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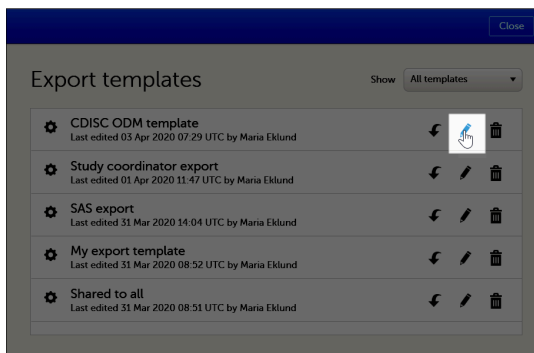

6.3   Editing a data export template

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.
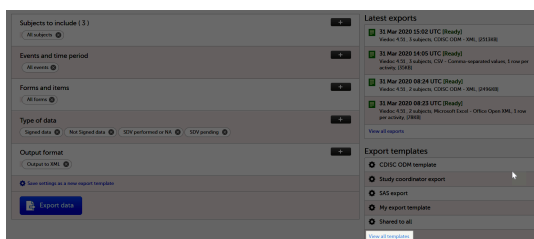

3   In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

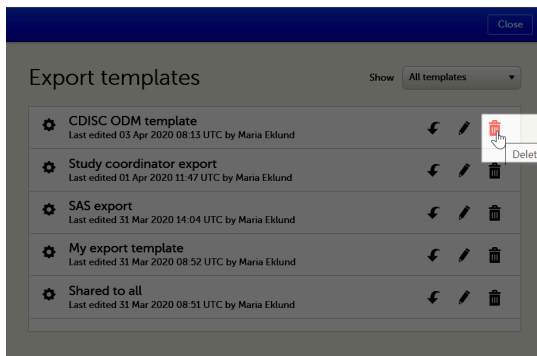   **Note!** You can only edit a template that you created yourself.

6.4   Deleting a data export template
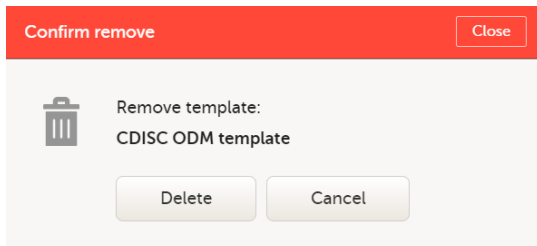
To delete a data export template:

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.

7 Exporting data

To perform a data export:

1 Filter the data to be exported. See <u>Filtering the data to be exported</u>.

2 Select the <u>Output format</u>.

3 Optionally, select the <u>Output version</u>.

4 Optionally, <u>preview the data</u> 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:
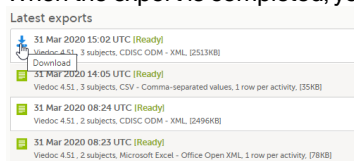
The exported file is downloaded locally. The filename is generated as follows: *SponsorCode_CountryCode_SiteCode_Date_Time*, where:

- *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 (<u>UTC</u>) 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.

7.1 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.
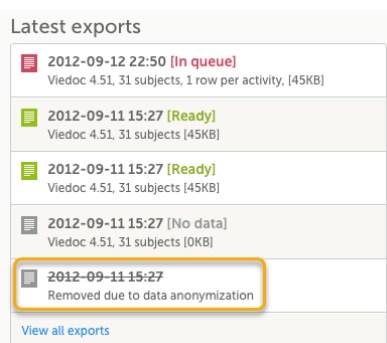
The latest five exports are shown in the list. To get the complete list of the initiated exports, click the **View all exports** link at the bottom of the list.
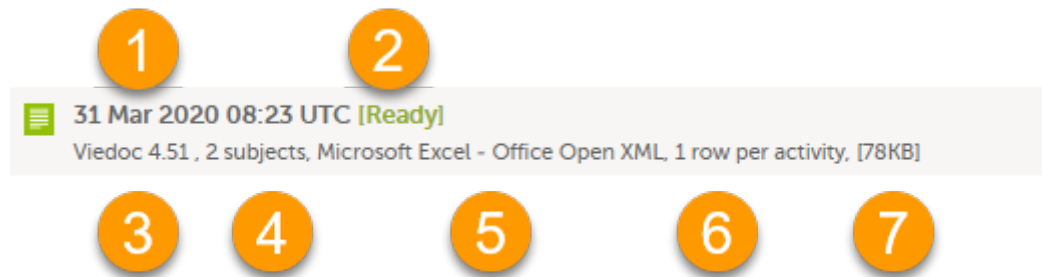
Each log entry provides the following information:

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.