viedoc learning™

Viedoc User Guide for Project Managers

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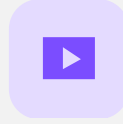
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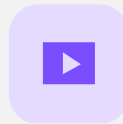
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Overview of Viedoc Clinic

Overview of Viedoc Clinic

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This lesson provides an overview of Viedoc Clinic. It describes the user interface and summarizes the main settings that can be configured in Viedoc Clinic.

1 Introduction

Viedoc Clinic 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) and keeps track of all the activities performed by the site.

The access to Viedoc Clinic 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 main actions can be performed in Viedoc Clinic:

- Data entry - covered by the following lessons:
    - Selection page
    - Entering/Editing data
    - Resetting and deleting data
    - Signing data
    - Working with reference data

- Raise and resolve queries - described in Resolving queries
- Data export - described in Exporting data
- Medical coding - described in Medical coding
- View study metrics - described in Metrics and Viedoc Reports

2 Languages

Viedoc Clinic is available in the following languages:

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

System requirements

System requirements

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1   Customer computer requirements

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

1.1   Browser requirements

Viedoc supports the following browsers:

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

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

For Viedoc Designer:

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

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

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

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

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

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

1.2   Screen resolution

The following screen resolutions are required:

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

1.3 Internet connection

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

1.4 Firewall policy

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

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2 Security

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

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

Managing your Viedoc account

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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
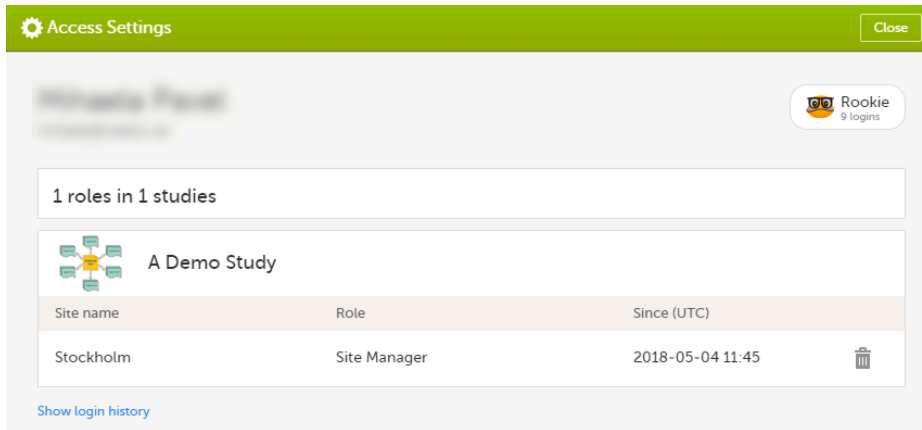
The following information is provided, grouped by study:

- **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:
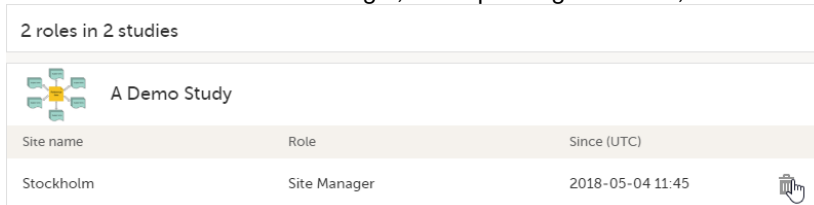
A confirmation dialog is displayed.

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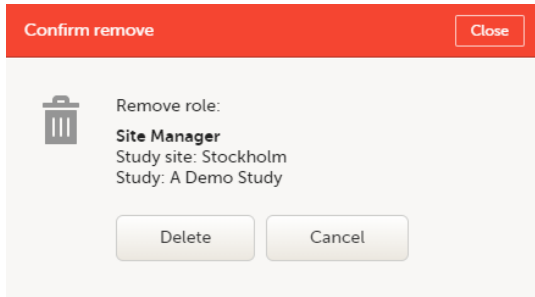
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

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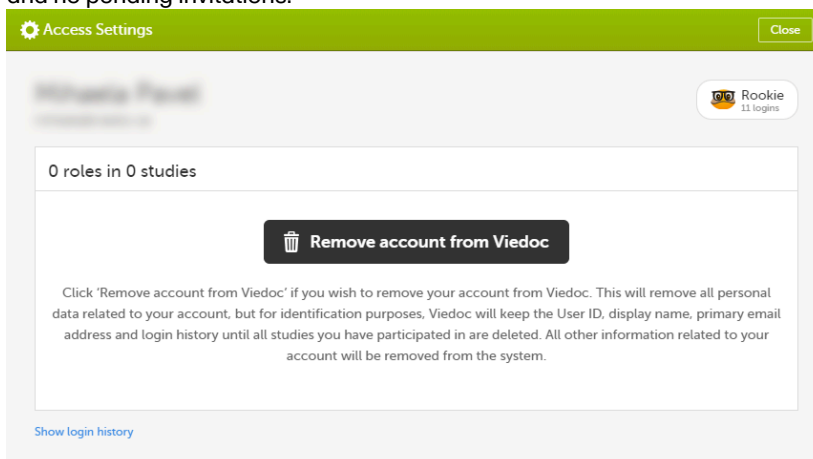
2   Select **Remove account from Viedoc**. You will be prompted to confirm the account removal by entering your password:
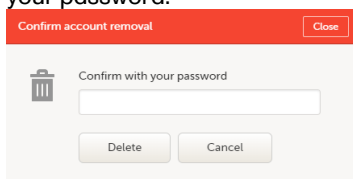
3   Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:

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:
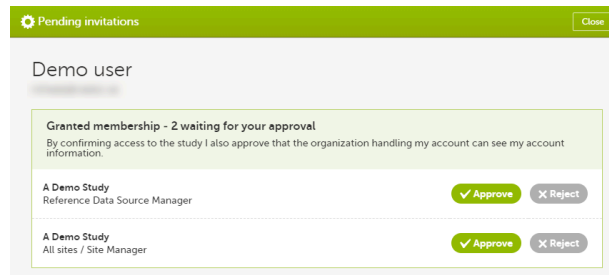
4.1   Approving a study invitation

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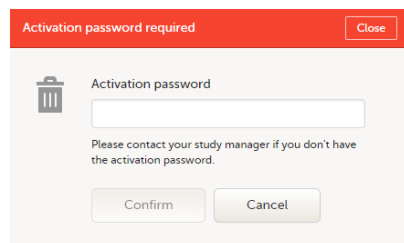
Note! All the pending role invitations for a user are automatically approved when the Application Programming Interface (API) method `GetToken / Token` is used.

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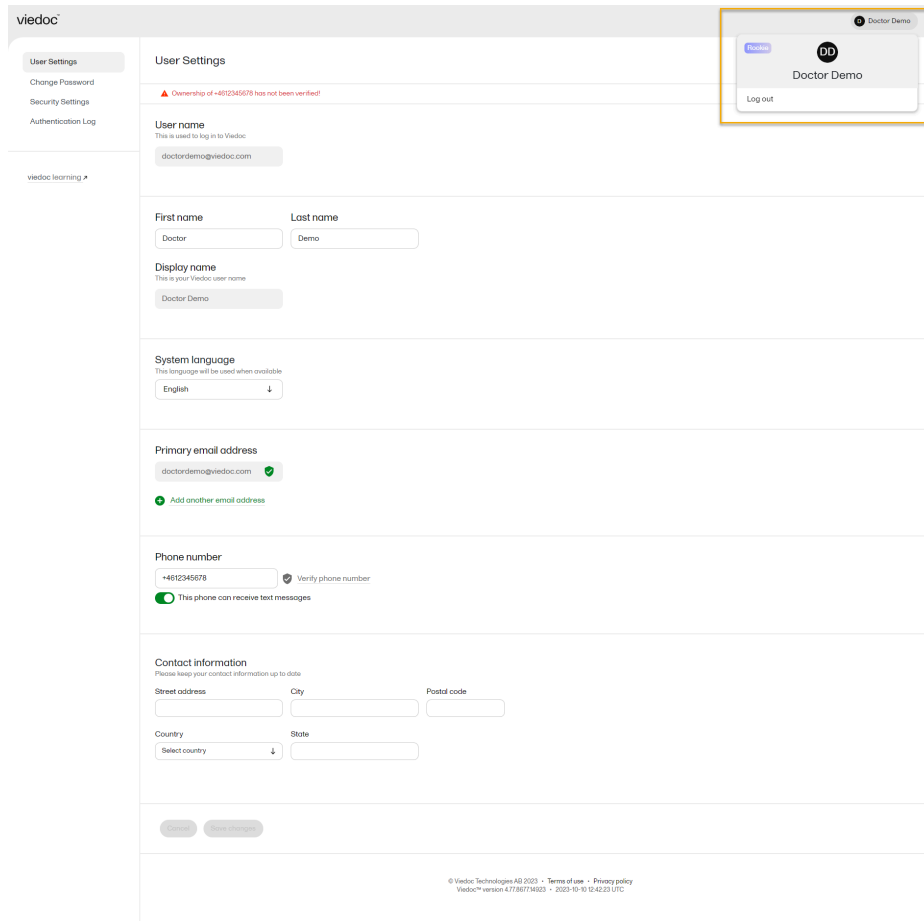
From Viedoc you can log out from different locations:
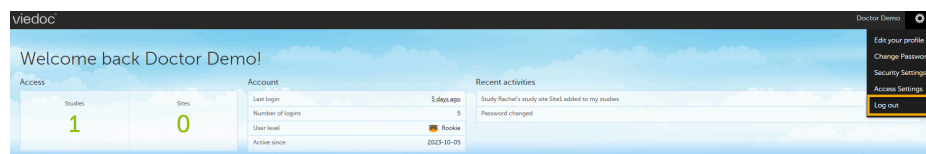
- To log out from settings, select the settings button (wheel) in the top right corner of the window, and select **Log out**. Use this link every time you leave the application from this location.

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

Published by Viedoc System 2022-10-18

This lesson describes the landing page, which is displayed directly after a successful log in:
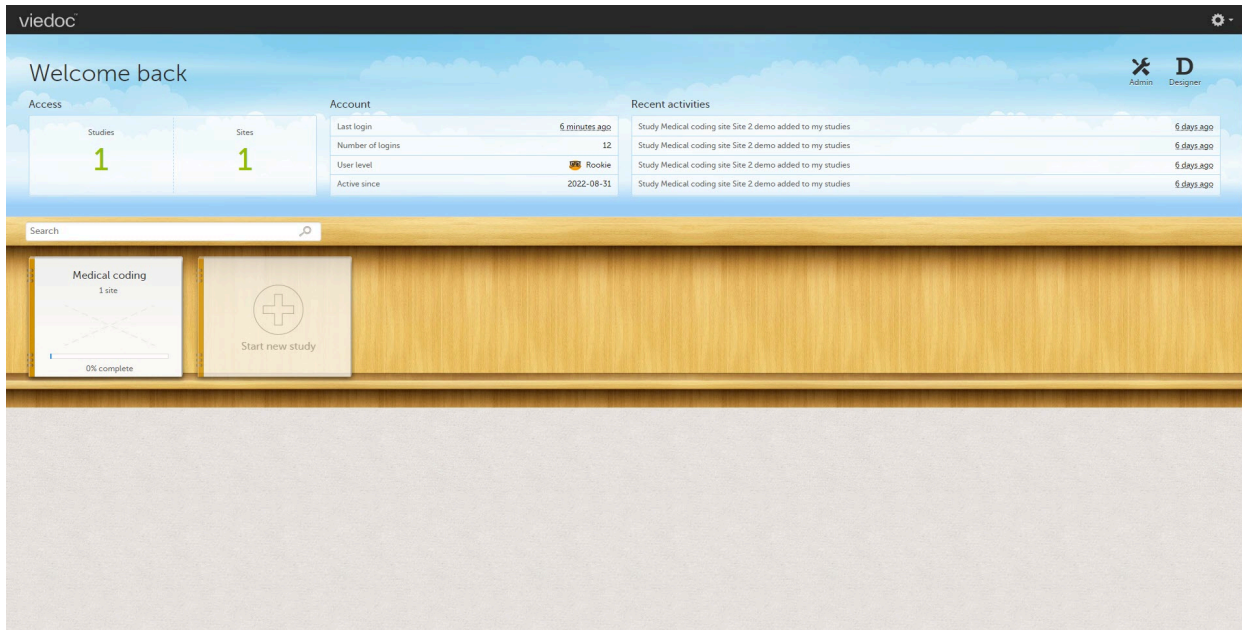
The landing page provides the following summary information:

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

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

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

Skill level	Icon	Description
Legend		> 1000 logins

- **Active since** - the date when you activated your Viedoc account

- **Recent activities** - a short summary of the most recent four activities, such as last password change and being assigned a role within a new site

The study slider shows the studies you have access to - each study is represented by a study logo. If you have access to many studies, you can easily find a specific study by entering the study name in the search field. All studies containing characters of the search string appear in the search results.
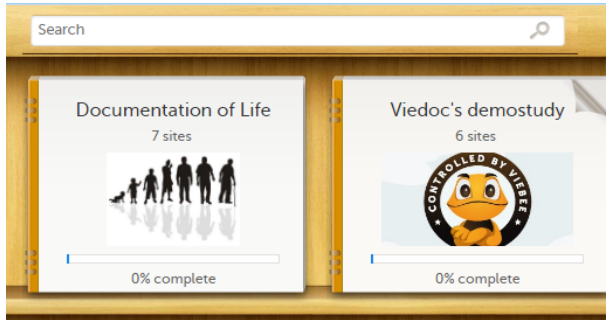
A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

Note!

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

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

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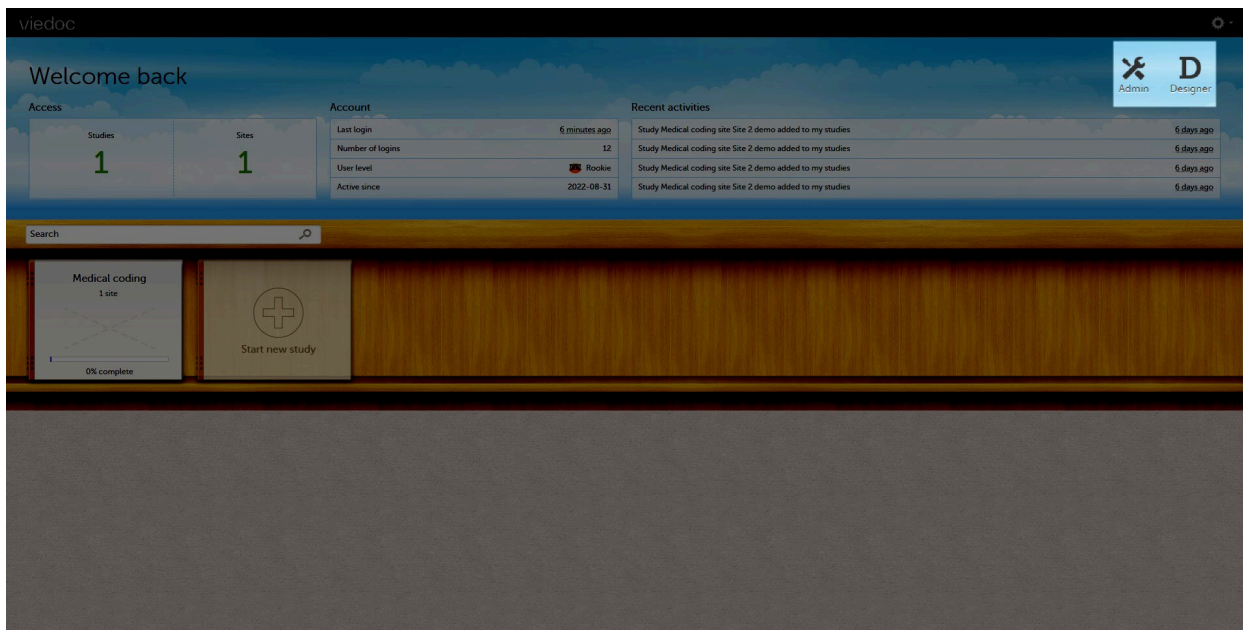
Study start page

Study start page

Published by Viedoc System 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:
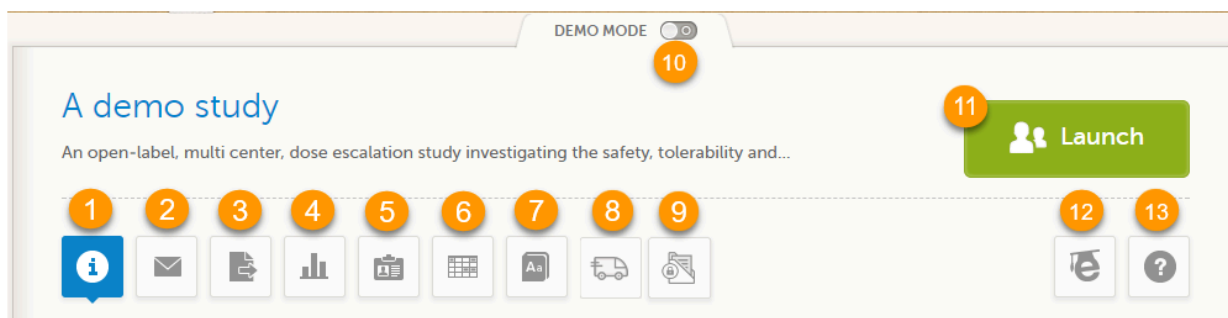
1. Study status
2. Messages
3. Data Export
4. Metrics and Viedoc Reports
5. Roles
6. Reference data
7. Medical coding
8. Viedoc Logistics
9. Viedoc eTMF
10. Demo mode
11. Launch
12. eLearning / Documentation & Training
13. Support

- 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.

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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):
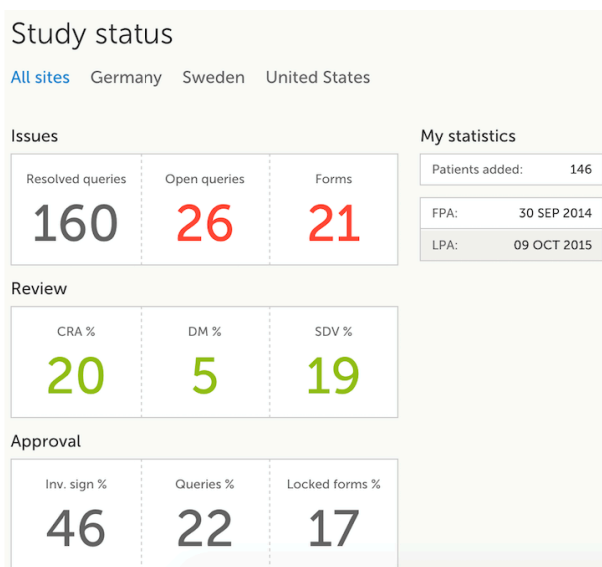
You can filter the displayed data for country or site by selecting the name of the country or site:
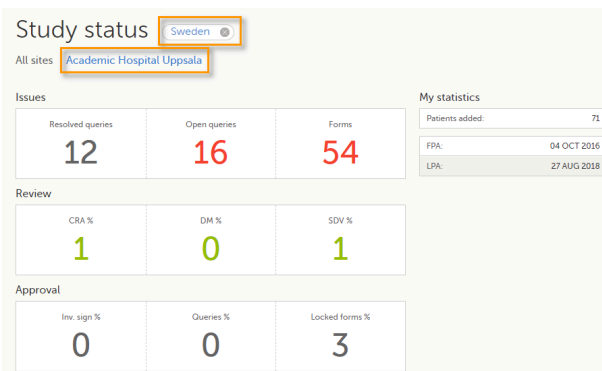
The following statistical information is provided, for the selected site(s):

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

3 Messages

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

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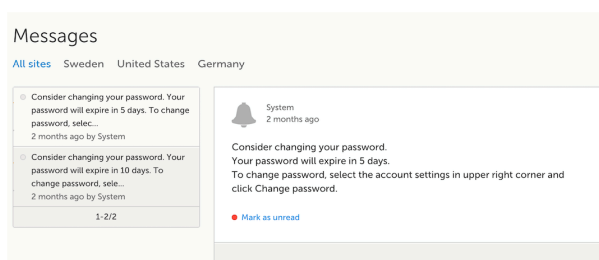
3.1 Alert messages

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

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

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

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

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.

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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.

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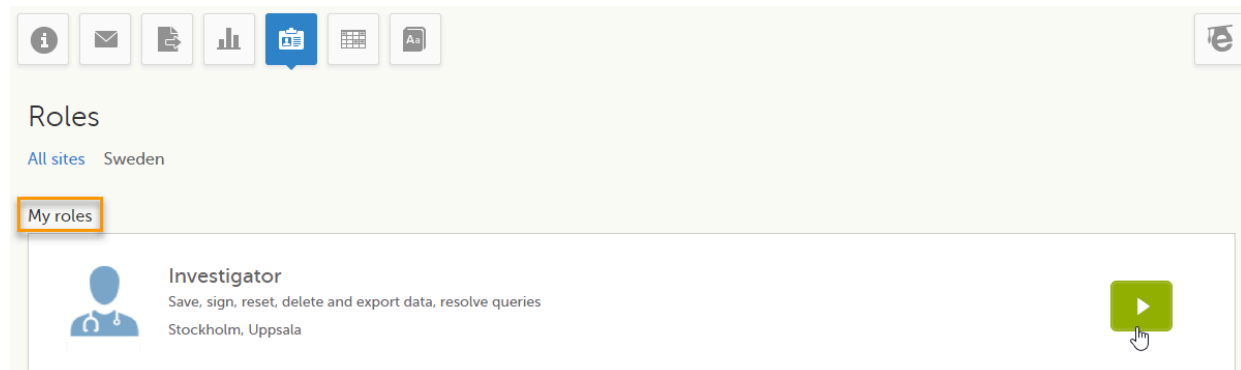
Note! The Roles page is only available for users with special permission to view roles, as per the study design.

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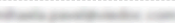
The following information is displayed (with *examples*):

- 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).

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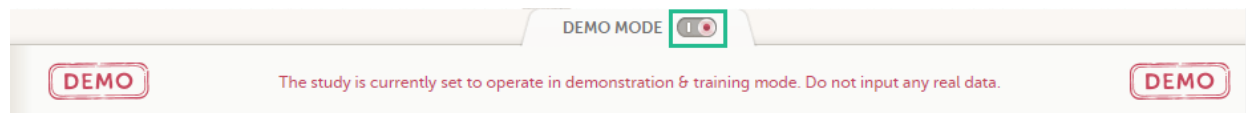
The **DEMO MODE** switch is only visible when you have access to both production and demo mode.

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](#).

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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.

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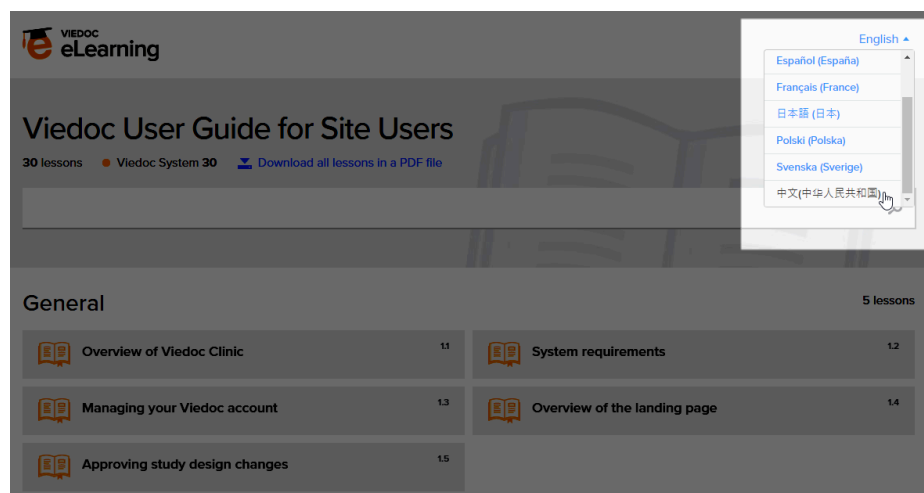
Tip! The various lessons in the Viedoc eLearning can easily be compiled into a PDF and printed if you need to store them in the investigator binder.

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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.

Documentation and Training

Documentation & Training

Published by Viedoc System 2020-06-04

1 Introduction

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

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

1. **Mandatory sections** - contains all the materials that are mandatory for you to read, understand and sign before starting to work.
If you have mandatory documentation pending to be read and signed, then the first page that opens when you access the study is the Documentation and Training.

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

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

2 Becoming a certified user

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

To obtain the user certificate:

1   Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:
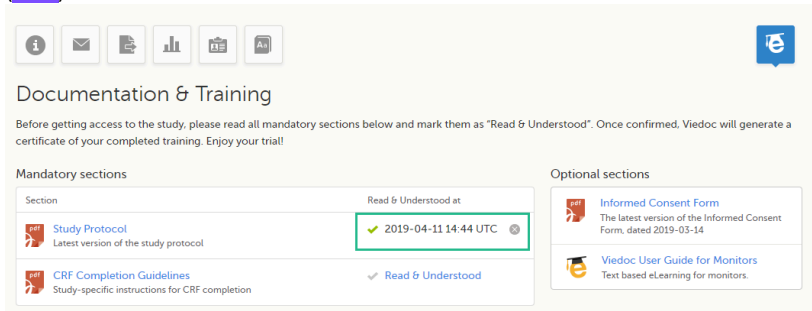
2   Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:
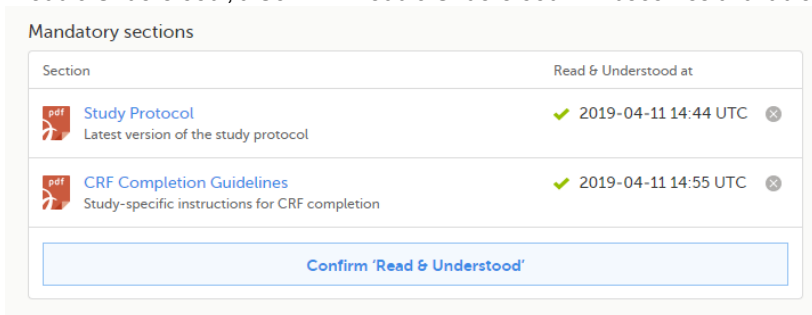
3   Click **Confirm 'Read & Understood'**. A confirmation pop-up opens:
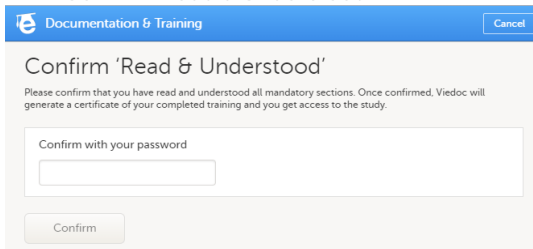
4   Enter your Viedoc account password and click **Confirm**. A confirmation message together with the date and time stamp (UTC) is displayed at the bottom of **Mandatory sections**. Also, a link to Download your User Certificate becomes available:
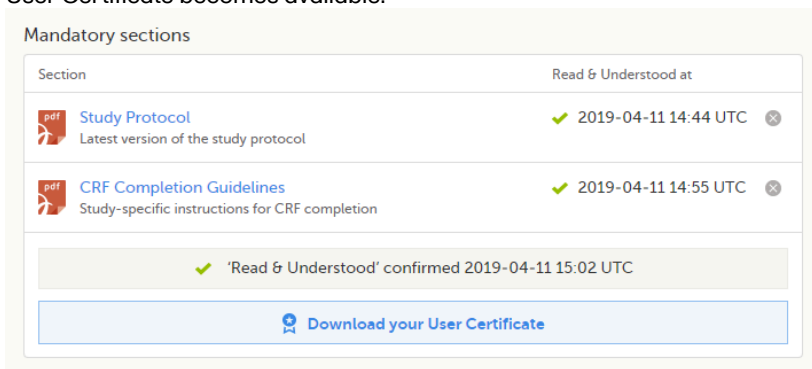
5   Now you got your certification and are able to access the study. The Launch button is now available.

           You can also **Download your User Certificate**. For details, see Downloading your user certificate.

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

3 Downloading your user certificate

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

The following information is provided on the certificate:

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

Selection page

Selection page

Published by Viedoc System 2023-10-09

1   Introduction

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:
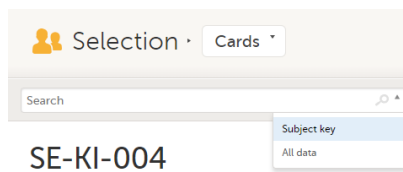
The system will return the subjects with the information sought that has been entered in the Case Report Form (CRF).
Subject key and **All data** are two filters that can be applied to the search.

- **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.

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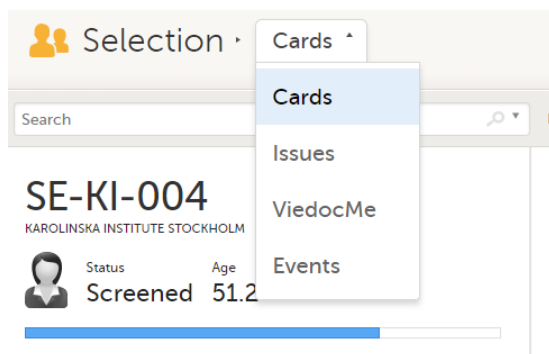
- If the study is <u>not</u> configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

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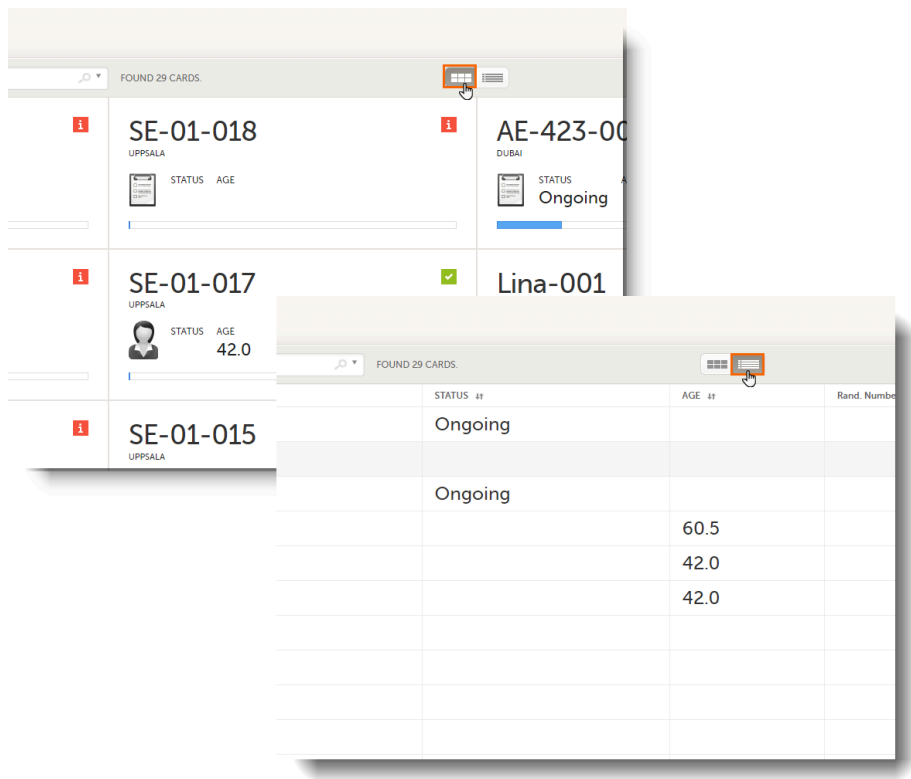
The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:
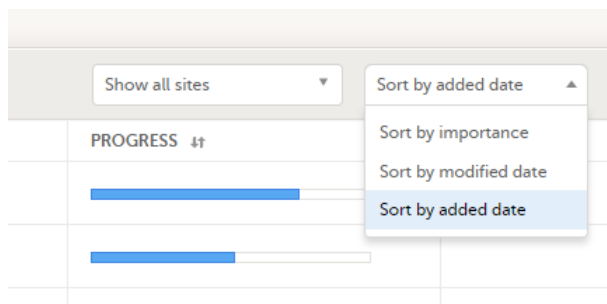
- **Sort by importance** - sort on forms with issues in descending order
- **Sort by modified date** - sort on modified forms in descending order
- **Sort by added date** - sort on added forms in descending order

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:
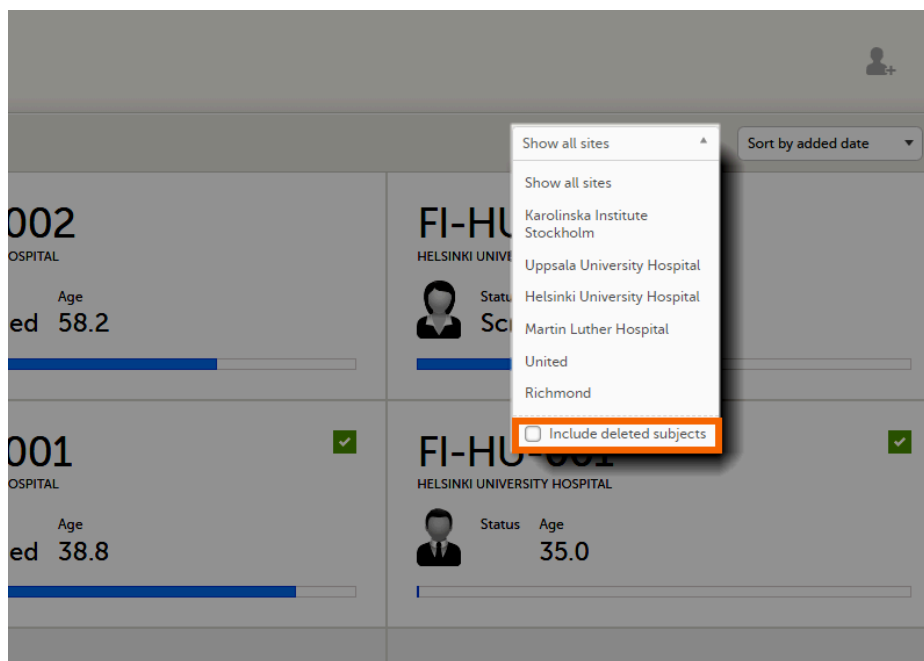
The subject card overview

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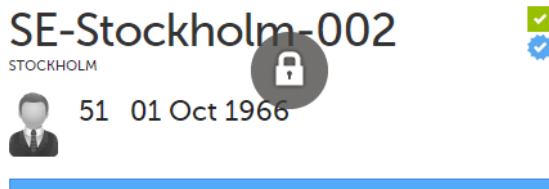
- Progress bar indicating the completion status (in blue)

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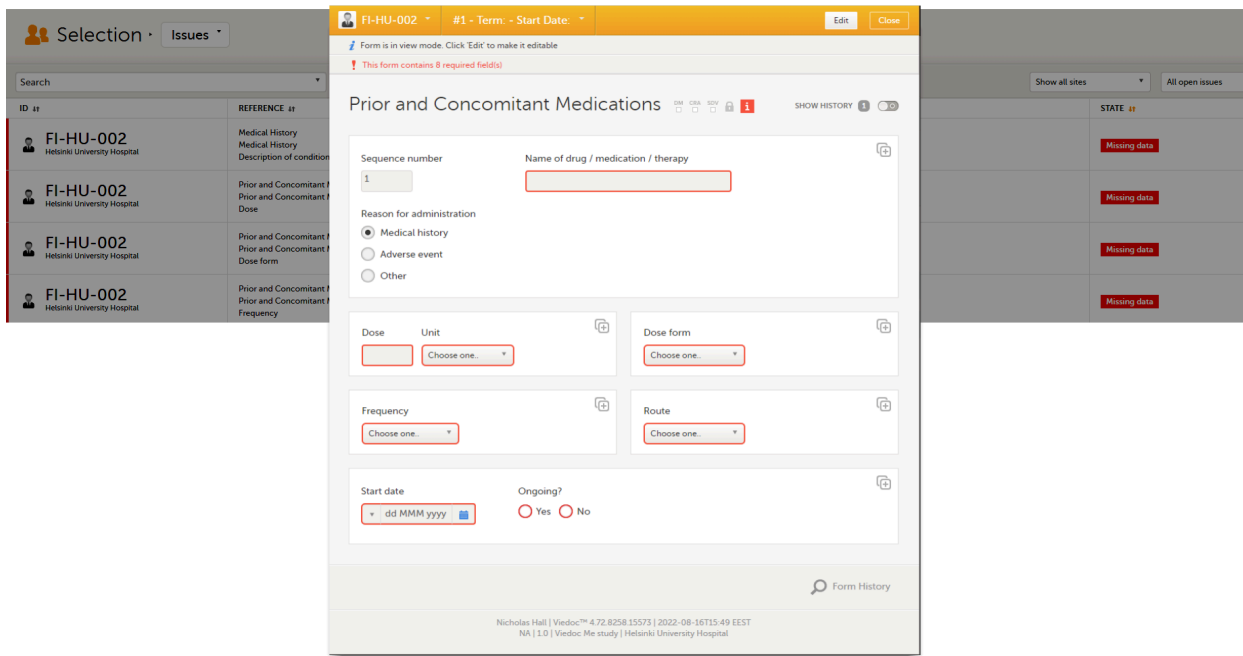
Close the form to go back to the **Issues** list.

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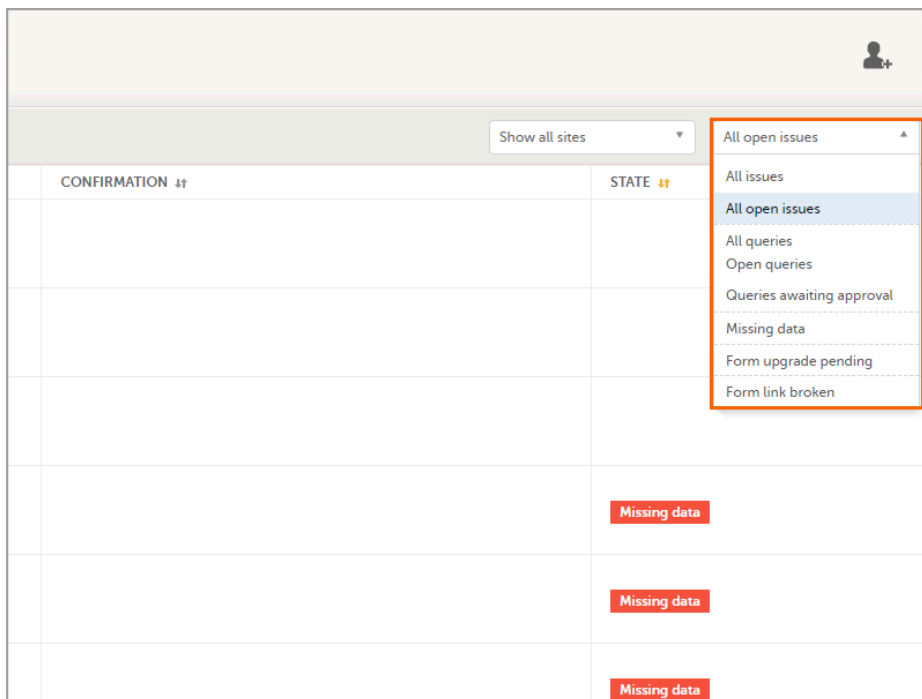
- By site - view data from a specific site or from all sites
  - Include deleted subjects

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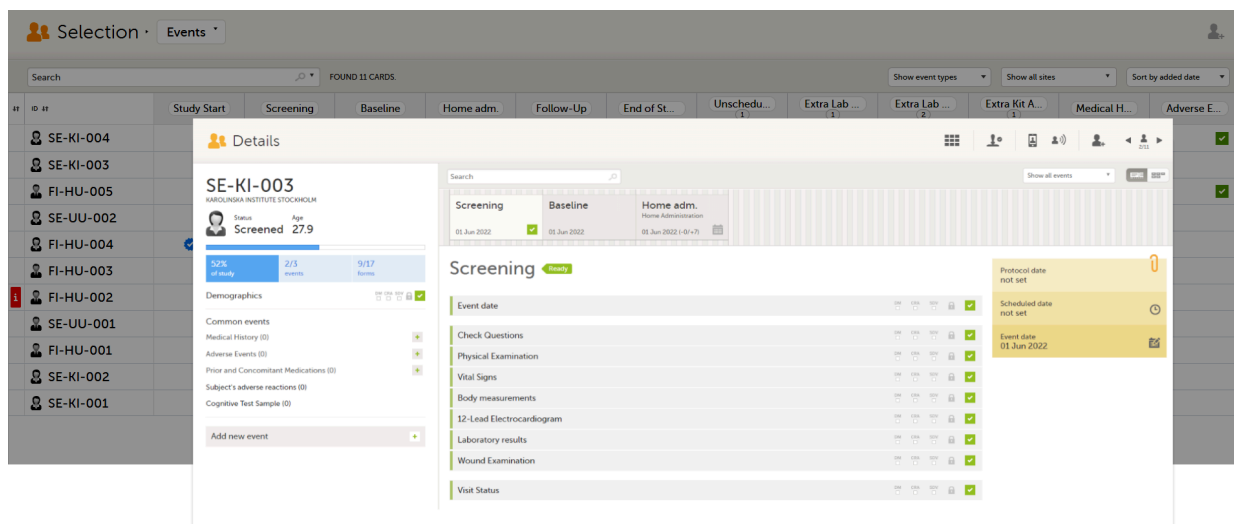
Click back in the browser to return to the Events view.

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:
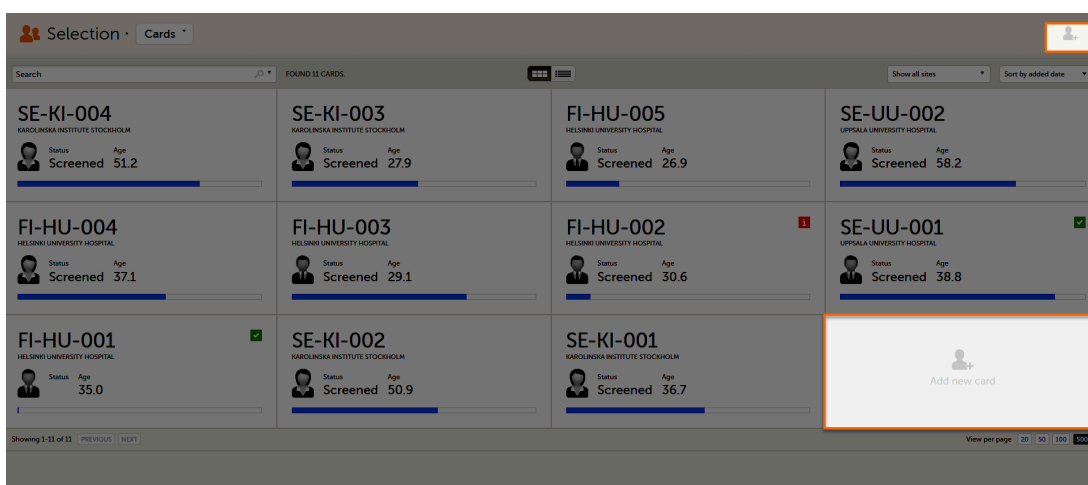
The first form in the study is displayed.

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

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.
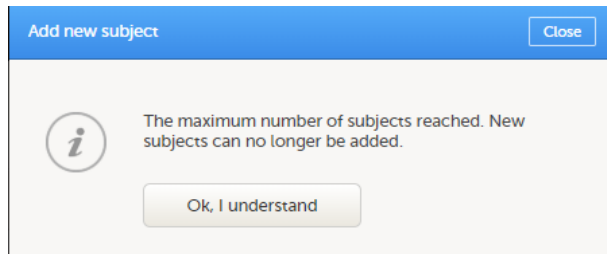
Metrics

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.
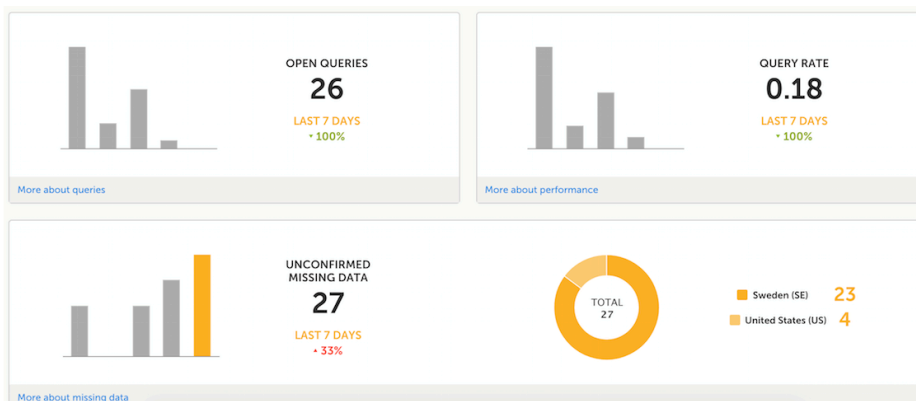
The metrics graphs depict:

- **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:

TOTAL 329

- Sweden **288**
- Netherlands **41**
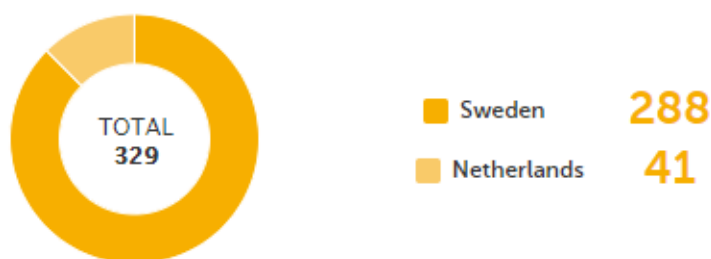
  - **Country** - distribution over those sites within the selected country, with most unconfirmed missing data:

TOTAL 11

- Charite University … **9**
- University Medical … **2**
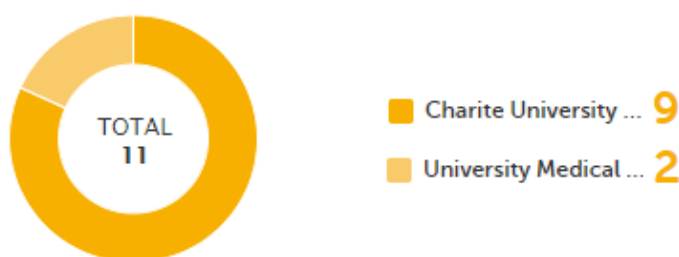
  - **Site** - distribution over those subjects with most unconfirmed missing data (in orange) out of the total number of subjects with unconfirmed missing data within the selected site (in gray):

TOTAL 9

- DE-CUB-008 **1**
- DE-CUB-001 **1**
- DE-CUB-005 **1**
- Remaining Subjects **6**
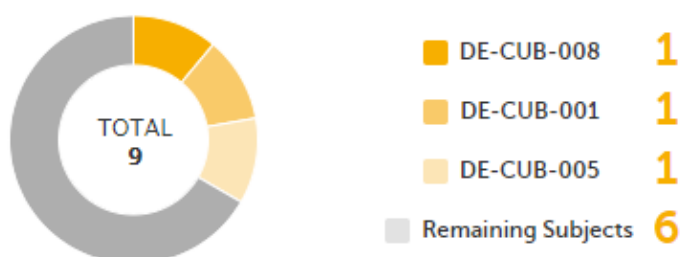
Click **More about [...]** to open a page with detailed metrics about queries, performance or missing data. All detailed metrics pages include filtering possibilities and a bar to show the review status.

1.1   Viedoc Reports

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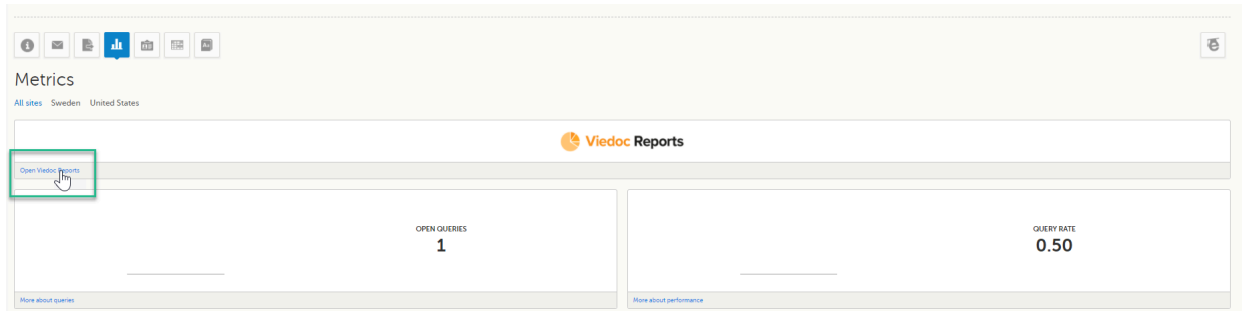
2   Queries

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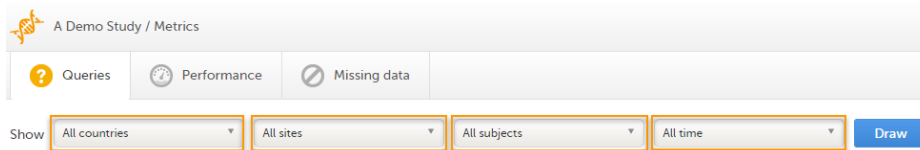
- Country
- Site
- Subject
- Time period - choose between:
  - All time
  - Last 24 hours
  - Last 3 days
  - Last week
  - Last 3 weeks

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

TYPE
- VALIDATION . . . . 448 / 67.2%
- MANUAL . . . . 219 / 32.8%

Raised on
- ITEM . . . . 593 / 88.9%
- EVENT DATE . . . . 74 / 11.1%
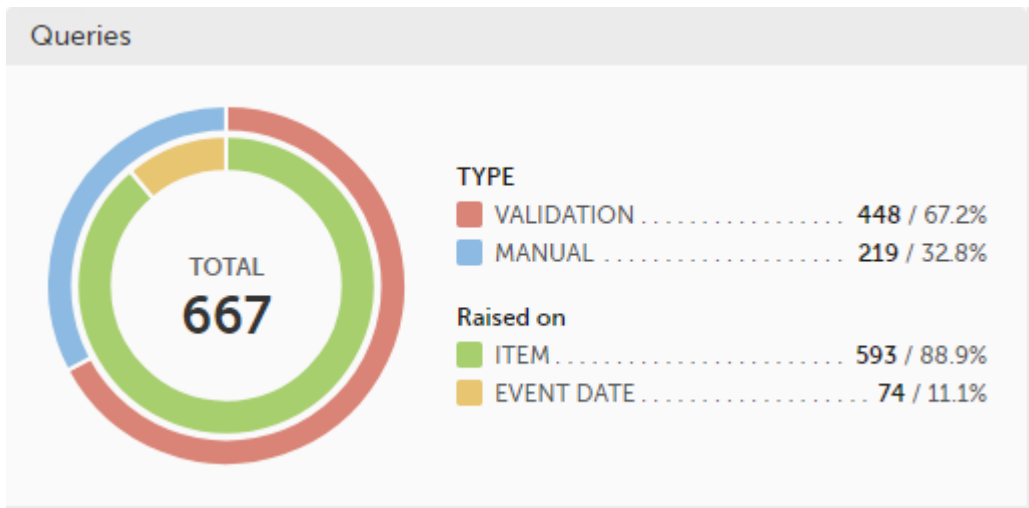
The number in the center of the circle shows the total number of queries.

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:

Query state

- RAISED . . . . 102 / 15.3%
- RESOLVED . . . . 135 / 20.2%
- APPROVED . . . . 217 / 32.5%
- REJECTED . . . . 95 / 14.2%
- CLOSED . . . . 118 / 17.7%
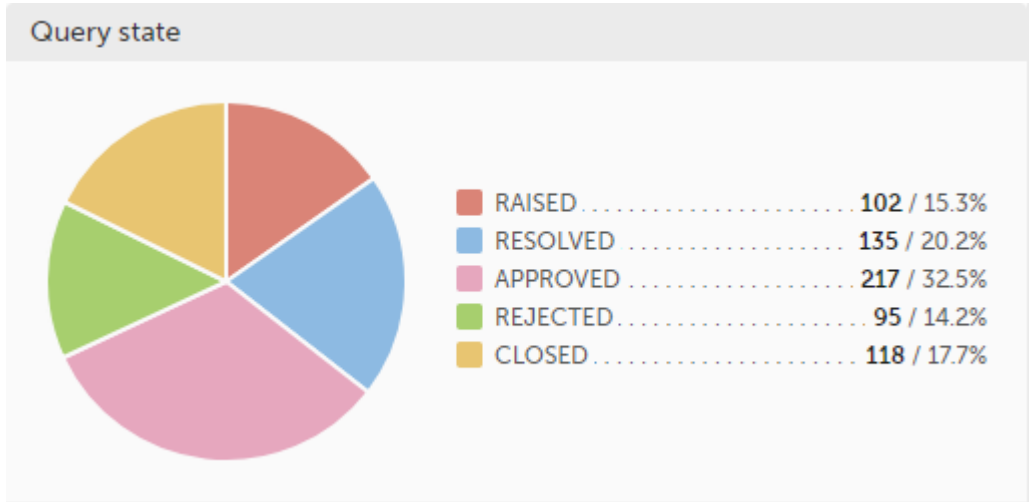
- **RAISED** - number of raised queries / percentage of raised queries out of total number of queries
- **RESOLVED** - number of resolved queries / percentage of resolved queries out of total number of queries
- **APPROVED** - number of approved queries / percentage of approved queries out of total number 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.

Top 5 events

■ VISIT 1	....	522 / 78.3%
■ VISIT 2	....	75 / 11.2%
■ VISIT 3	....	44 / 6.6%
■ ADD SUBJECT	....	20 / 3%
■ ADVERSE EVENTS	....	3 / 0.4%

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.

Top 5 forms

■ VITAL SIGNS	....	427 / 64%
■ EVENT DATE FORM	....	74 / 11.1%
■ BODY MEASUREMENTS	....	64 / 9.6%
■ PHYSICAL EXAMINATION	....	27 / 4%
■ DEMOGRAPHICS	....	20 / 3%
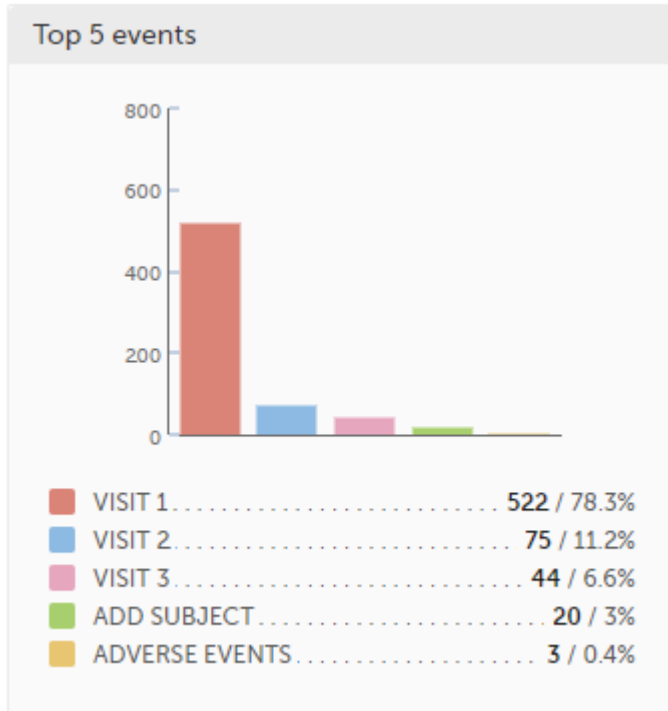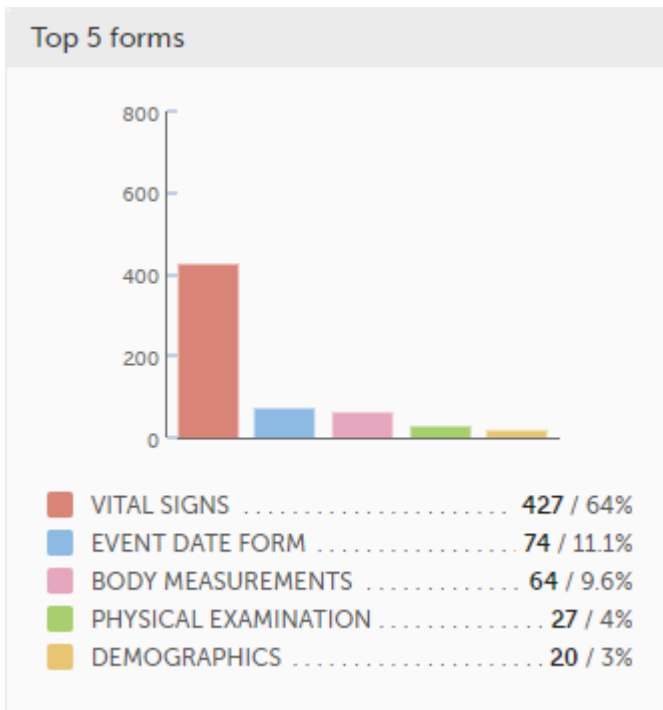
2.6   Top 5 items

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.
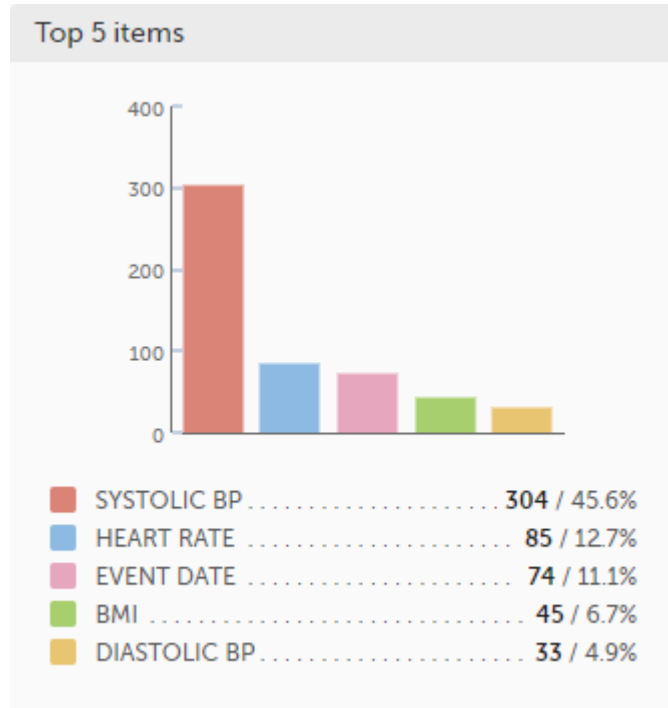
2.7   Top 5 check OIDs

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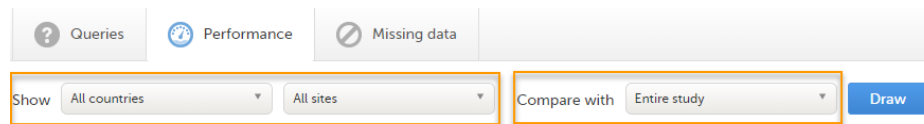
Based on the comparison selection the graphs will show statistics about:

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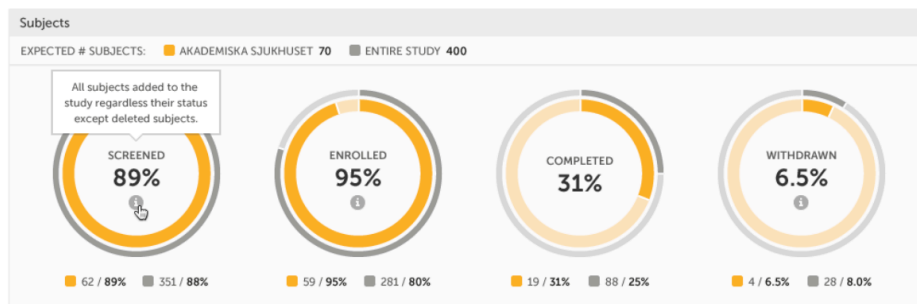
The conditions for the following subject statuses are defined in the study design (in Viedoc Designer under *Study Settings > Subject status*):

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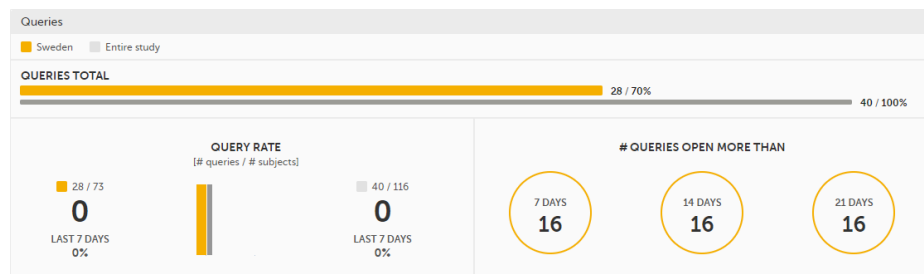
- **Queries total** - the total number of queries on selected site(s) (in orange) and compared site(s) (in gray) are shown both in % and in actual numbers.
- **Query rate** - total number of raised queries out of total number of subjects. The column graph consists of 5 bars indicating the progress of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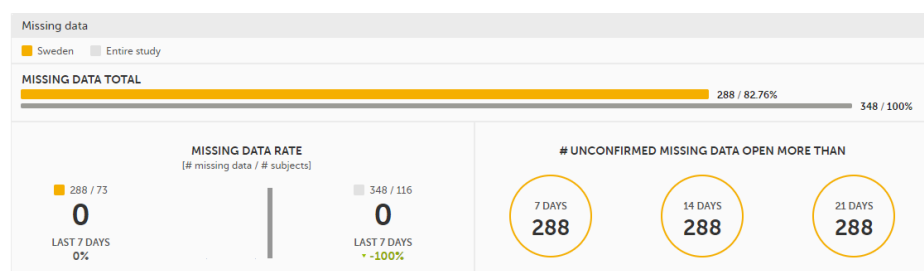
- **Missing data total -** Total number of missing data on selected site(s) (in orange) and compared site(s) (in gray) both numeric and percentage out of all missing data in the entire study. Hidden forms/items are not included in the count.

- **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):
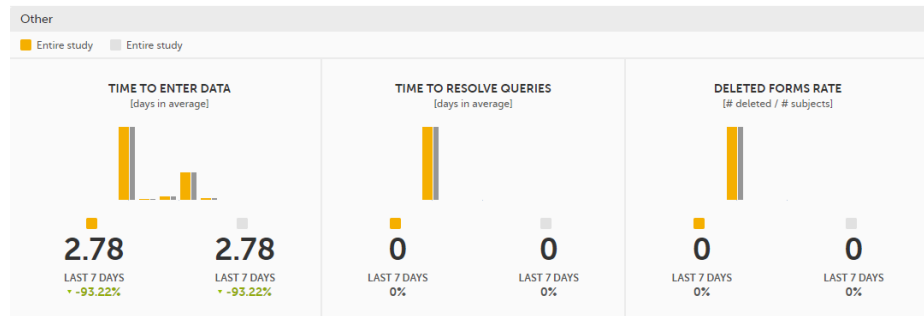
- **Time to enter data** - the average time (in days) it takes to enter data for selected site(s) (in orange) and compared site(s) (in gray). This is calculated as a difference between the event date and the date the item data was entered, per form.
  The column graph consists of 5 bars indicating the 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 <u>Raised</u> until the date the query was <u>Resolved</u>. The queries that are automatically closed by the system (see <u>Queries overview</u> 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 <u>Queries overview</u>.
  The column graph consists of 5 bars indicating the average time to resolve queries over the last 5 weeks period where each bar indicates a 7 days period.
  Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray.
  A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):
    - down - green
    - up - red
    - equal - black

- **Deleted forms rate** - the rate of deleted forms, calculated as the number of deleted forms per number of subjects, for selected site(s) (in orange) and compared site(s) (in gray).
  The column graph consists of 5 bars indicating the deleted forms rate over the last 5 weeks period where each bar indicates a 7 days period.
  Columns for selected site(s) are displayed in orange and columns for compared site(s) in gray.
  A percentage indicator shows the trend compared to the previous 7 days period for selected (to the left) and compared site(s) (to the right):
    - down - green
    - up - red
    - equal - black

3.6 Save and export

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

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

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

4 Missing data

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

You can filter the data by selecting from the drop-down lists in the top of the page:
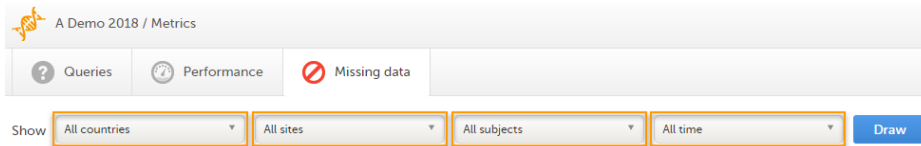
- Country
- Site
- Subject
- Time period - choose between:
  - All time
  - Last 24 hours
  - Last 3 days
  - Last week
  - Last 3 weeks

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

- Top 5 events
- Top 5 forms
- Top 5 items
- Subjects with confirmed missing data
- Subjects with unconfirmed missing data
- Save and export

4.1 Top 5 events

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

4.2 Top 5 forms

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

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%
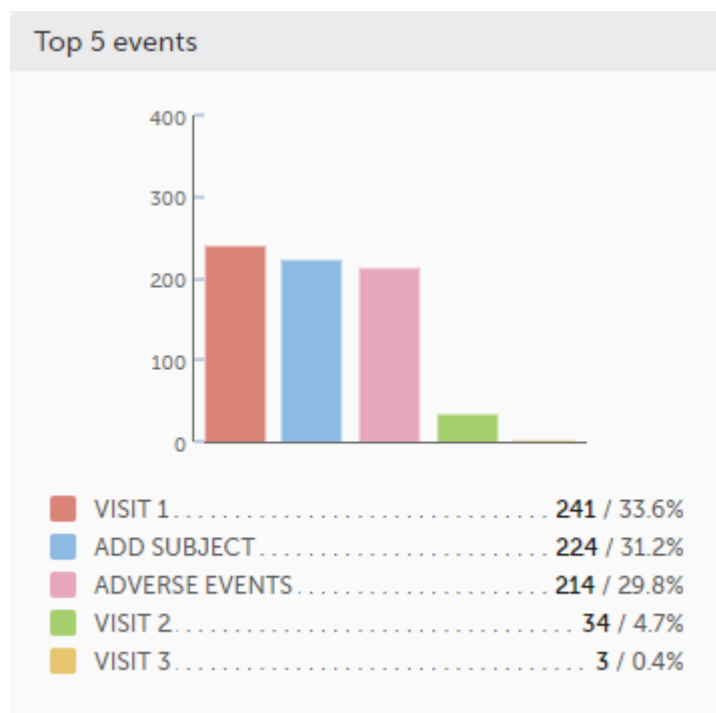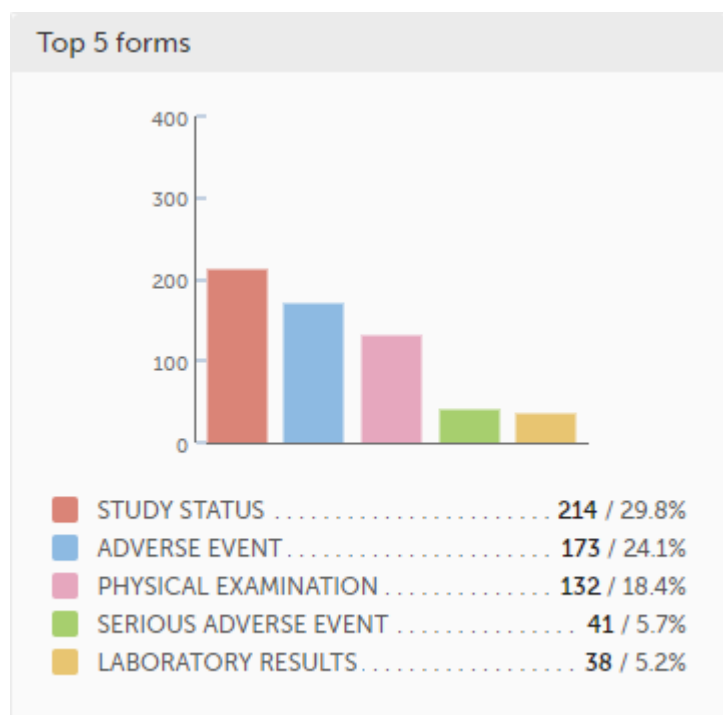
4.3 Top 5 items

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%
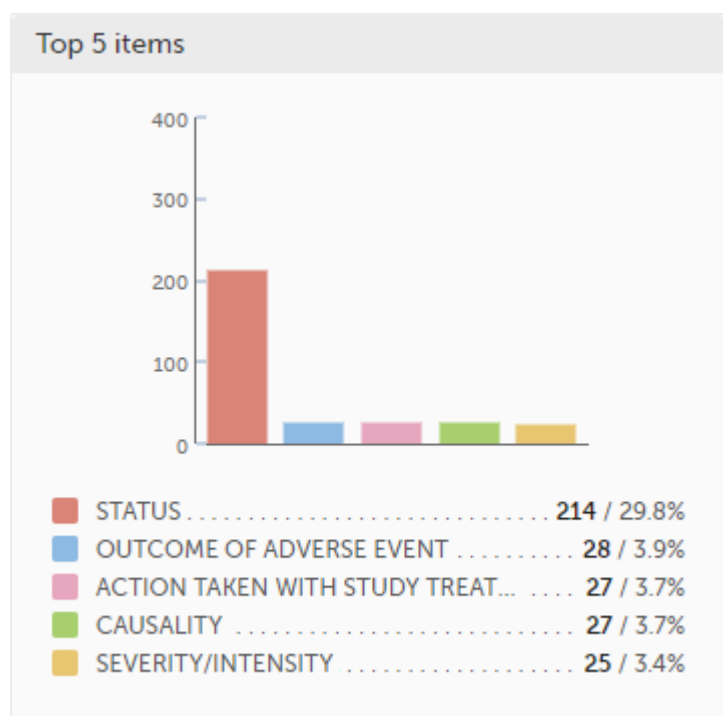
4.4 Subjects with confirmed missing data

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.

	n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
	2	4.1	SE-01-332		Karolinska Uni...	12 Mar 2018 15:33, ▓▓▓, Visit 1, Body measurements, Wei...
	2	4.1	SE-01-284		Karolinska Uni...	25 Jan 2018 08:43, Lyle W, Visit 1, Safety Laboratory Parameters, Pleas...
	2	4.1	SE-01-316		Karolinska Uni...	24 Jan 2018 10:53, ▓▓▓, Visit 1, 12-Lead ECG, Performed.
	2	4.1	SE-01-166		Karolinska Uni...	07 Feb 2017 14:05, ▓▓▓, Visit 1, Physical Examination, Lymph ...
	2	4.1	SE-01-110		Karolinska Uni...	30 Mar 2016 11:58, ▓▓▓, Visit 1, Body measurements, Hei...
	48	100	In total			

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.

	n	%	SUBJECT ID	PROGRESS	SITE NAME	LATEST MISSING ITEM (date, visit, form, item)
	42	6.2	SE-01-320		Karolinska Uni...	12 Feb 2018 10:59, ▓▓▓, Adverse Events, Serious Ad...
	24	3.5	SE-01-344		Karolinska Uni...	19 Mar 2018 11:05, ▓▓▓, Adverse Events, Serious Adverse E...
	22	3.2	SE-01-331		Karolinska Uni...	08 Mar 2018 16:35, ▓▓▓, Adverse Events, Adverse Event, ...
	19	2.8	SE-01-249		Karolinska Uni...	18 Aug 2017 09:52, ▓▓▓, Adverse Events, Adverse Event, ...
	16	2.3	SE-01-281		Karolinska Uni...	28 Sep 2017 09:07, ▓▓▓, Visit 1, Laboratory results, Crea...
	669	100	In total			

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.

Exporting data

Exporting data

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1   Introduction

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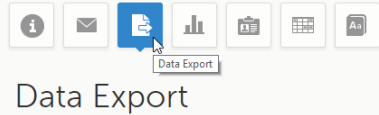
The Data Export page enables you to preview and download study data:

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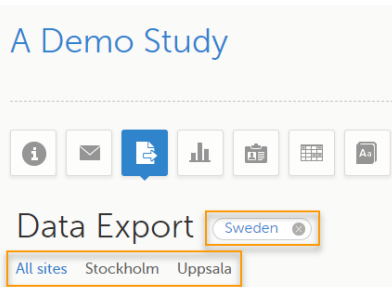
For a specific country, you can choose to export the data for:

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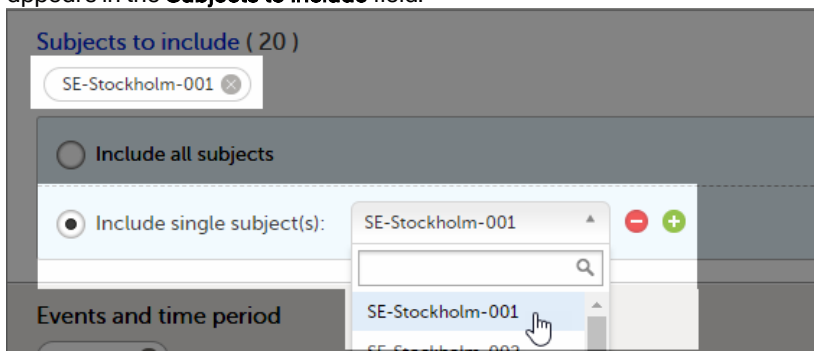
Repeat this step for each subject you want to include in the data preview/export.

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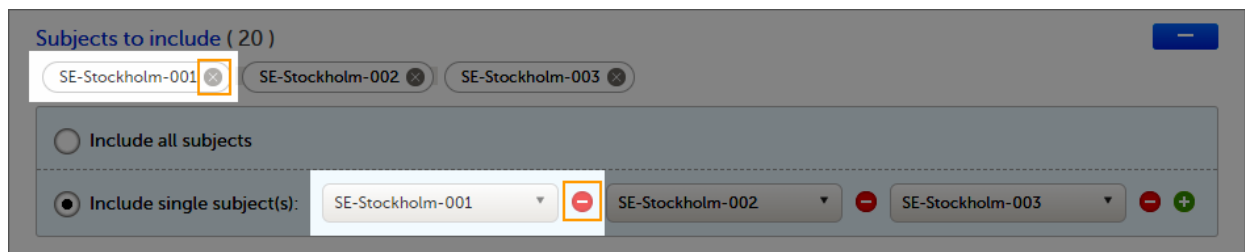
2.3   Events and time period

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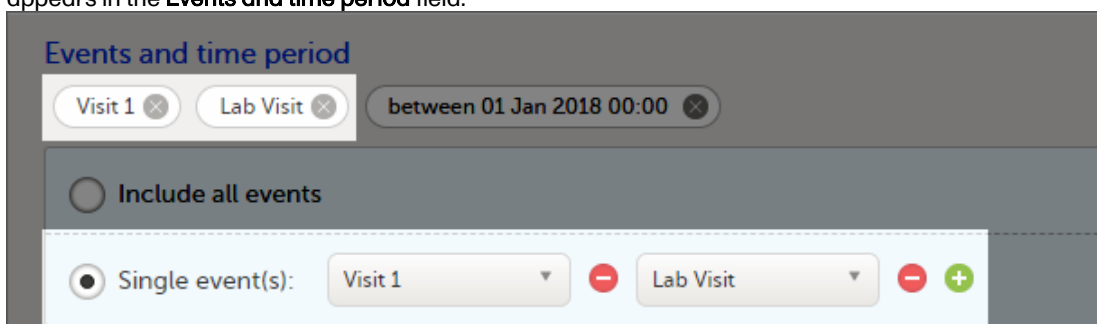
Repeat this step for each event you want to include in the data preview/export.

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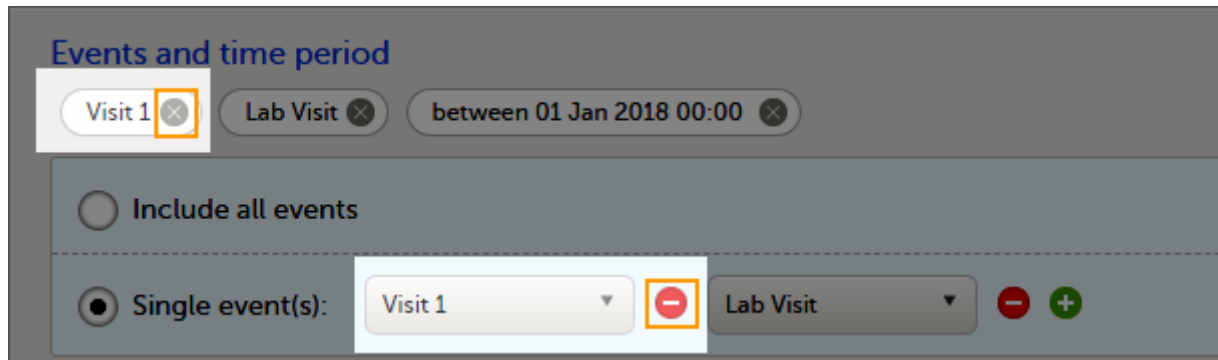
Selecting a time period

To include data from a specific time period:

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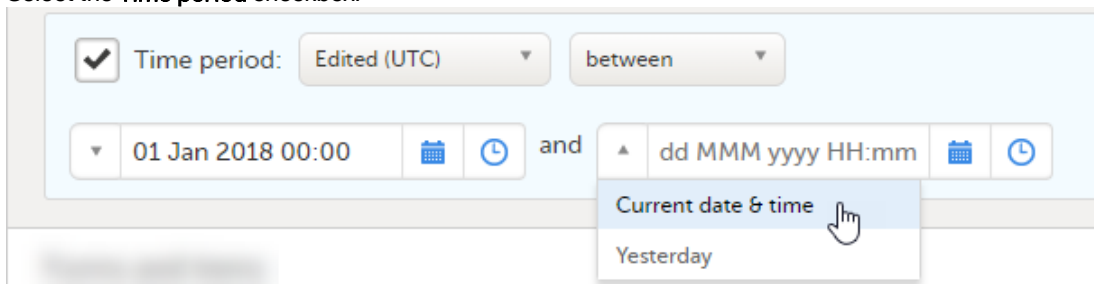
2   Select one of the following options from the first drop-down list:
   - **Edited (UTC)** - to include data based on the date they were added or last edited.
     Note! This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note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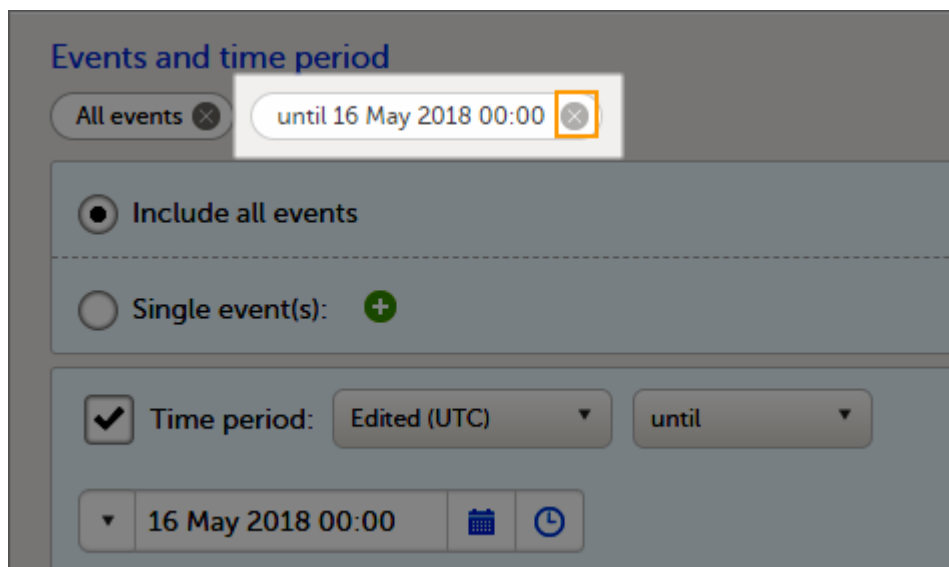
2.4 Forms and items

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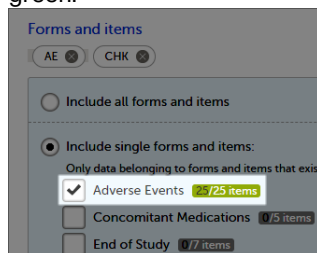
- Click the field **[..]/[..] items** next to the form name, and select/deselect specific items. You can also use **Select all / Deselect all** for selecting/deselecting all the items in the form at once. If selecting only some of the items in the form, the selected/total number of items will be highlighted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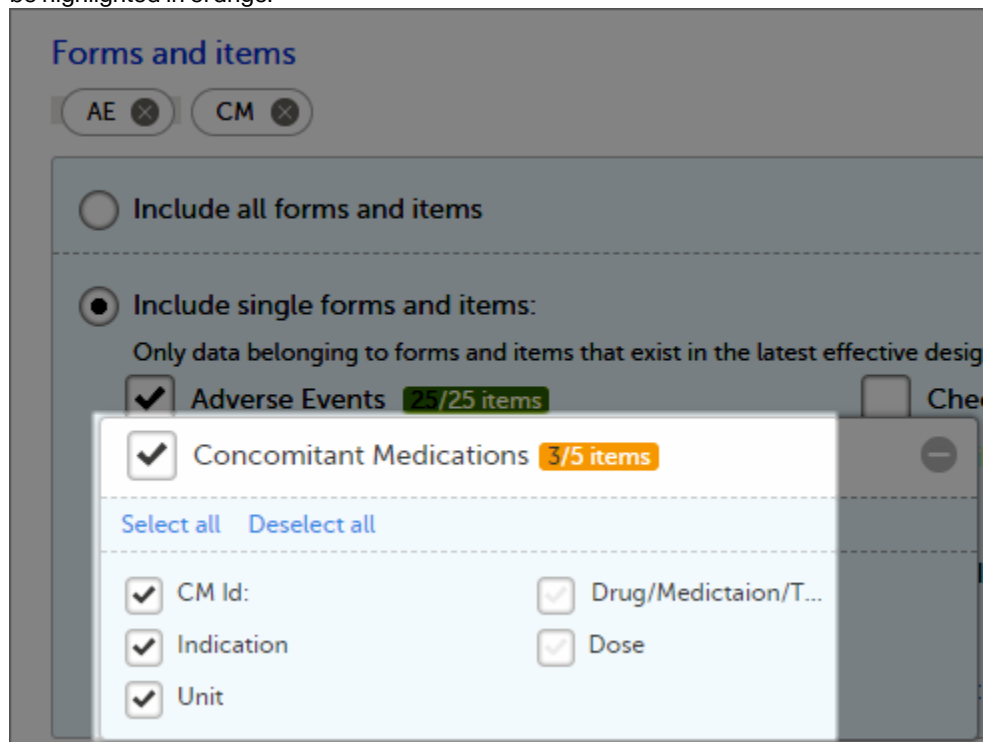
To undo the selection of a certain form, click the cross x icon next to it:

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

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

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

- Microsoft Excel - Office Open XML
- CSV
- ODM - in this case, the Booklet history is not available.

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

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

2.5.2.2 Queries and Query history

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

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

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

See also:

- Queries in ODM export
- Queries in Excel export

2.5.2.3 Review status

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

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

See also:

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

2.5.2.4 **Event dates**

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

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

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

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event Id	The event ID, as set in the study design (in Viedoc Designer)
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Event status	The current status of the event. It can be one of the following: - *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**:
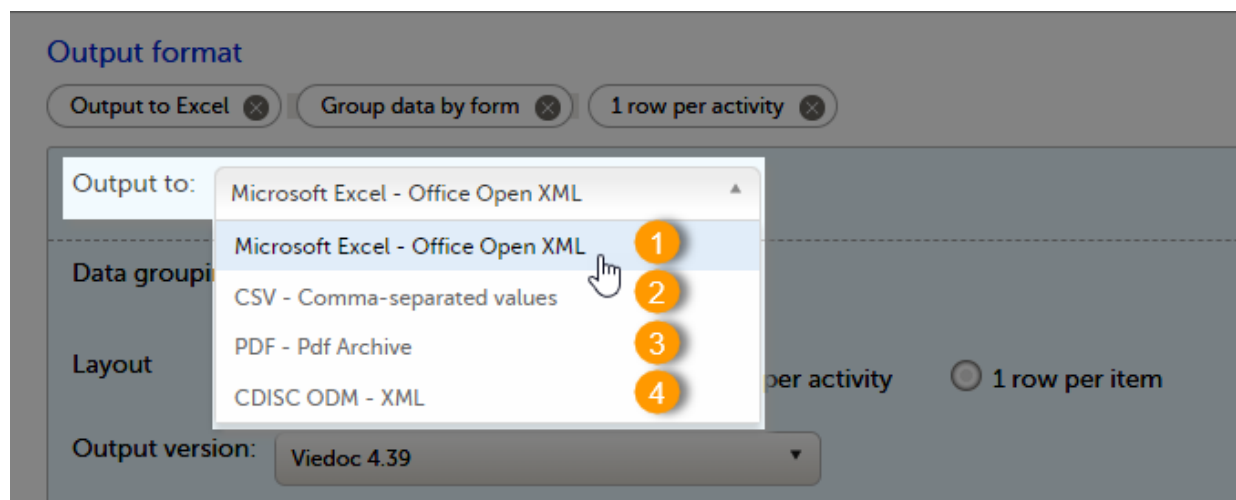
You can export the data to one of the following formats:

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.

See also:

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

4   Export compatibility with previous Viedoc versions

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

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

If activated for your study, you can select the Viedoc version that you wish the exported file to be compatible with under **Output format and export**, from the **Output version** drop-down menu. If you wish to create an export file according to the latest Viedoc version, select **Latest Viedoc version**:
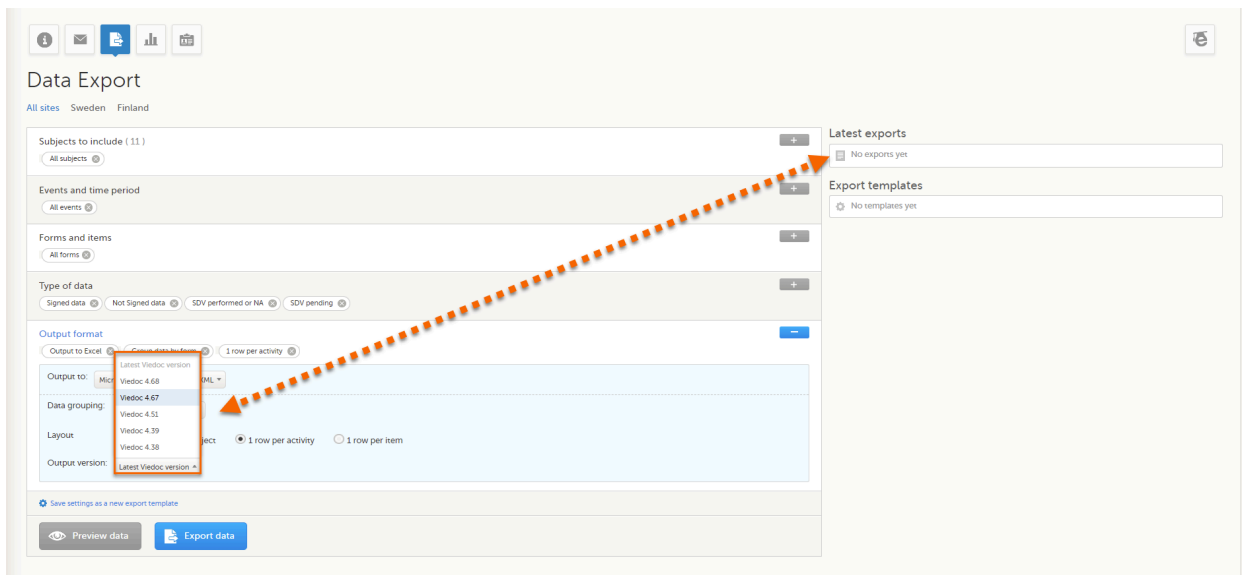
The Viedoc version used for data export is listed in the **Latest exports** area on the right side of the export page.

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

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

4.1   Output versions

The Viedoc versions available in the **Output version** dropdown menu are <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
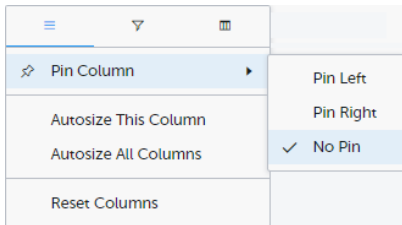
Pin Left/Right makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select **No Pin** to unpin the column.

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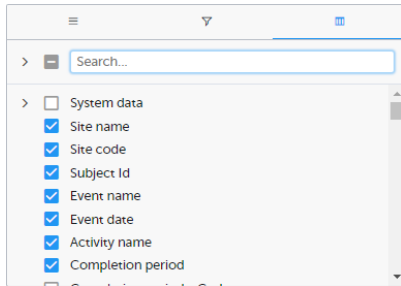
Use the **Search** field to search for columns.

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.

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.

Pie chart

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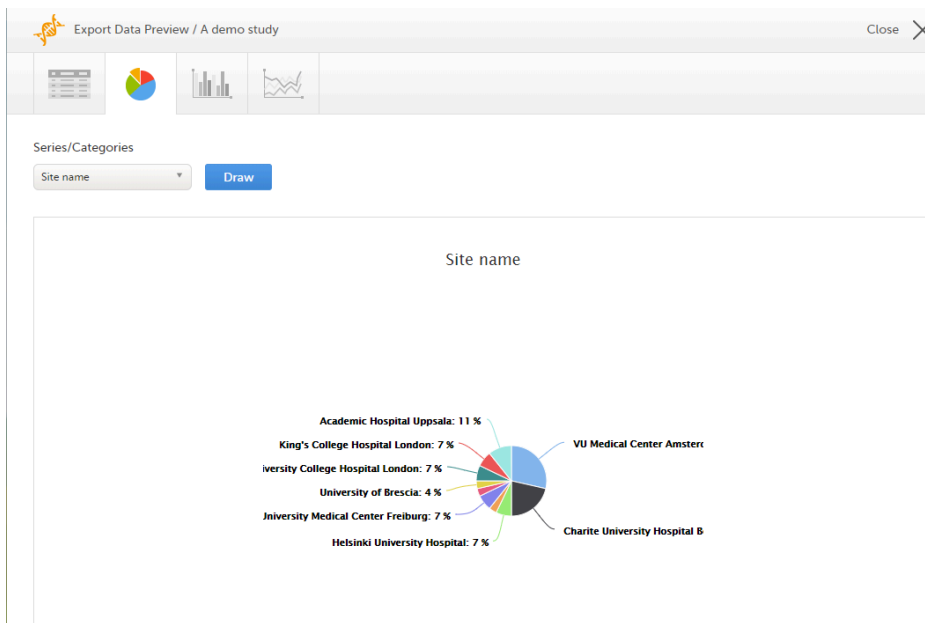
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

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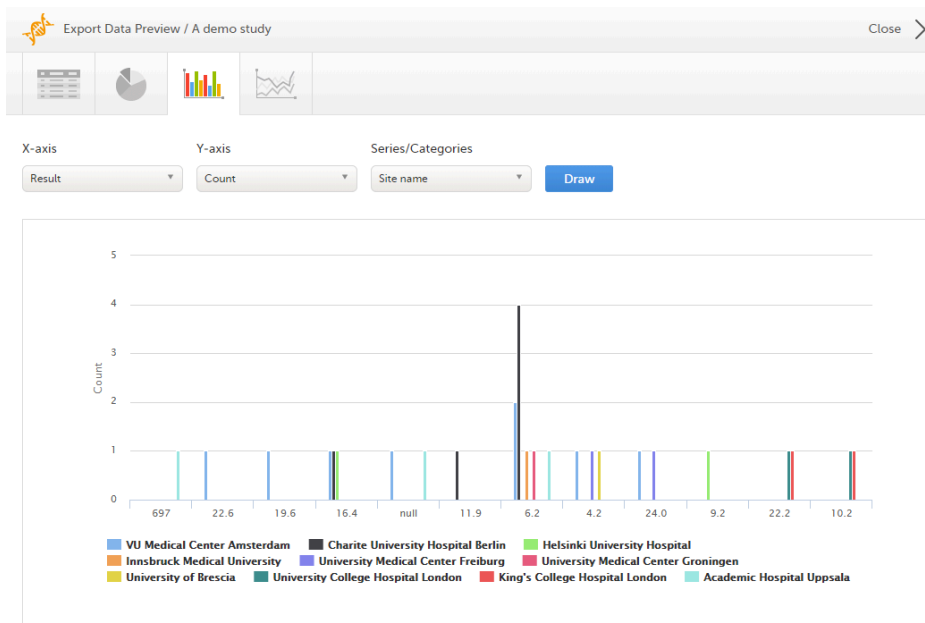
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

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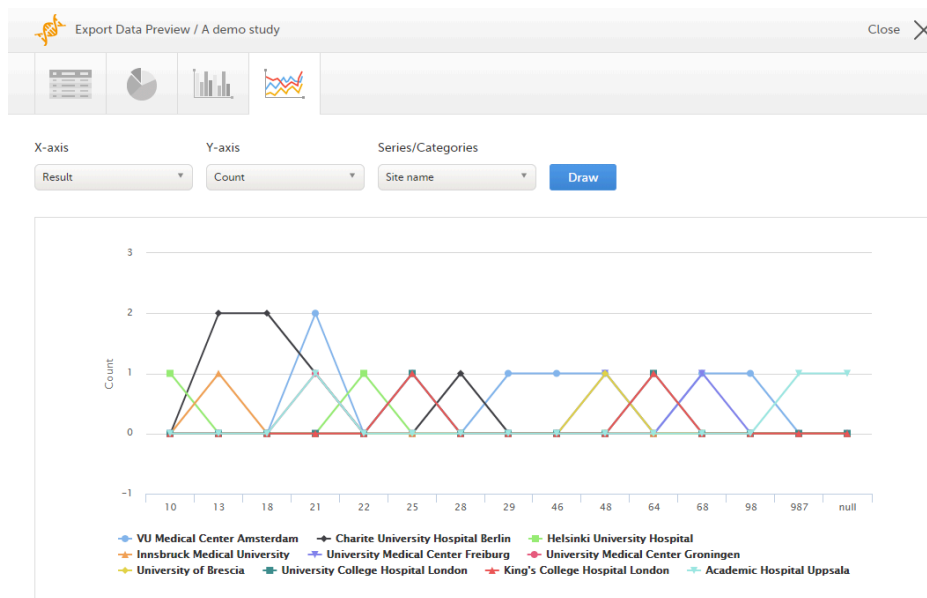
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

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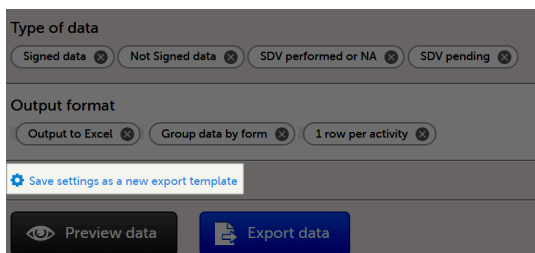
2   In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

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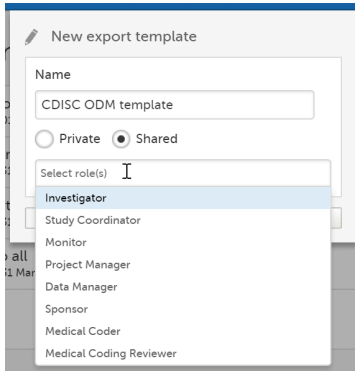
3   Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:
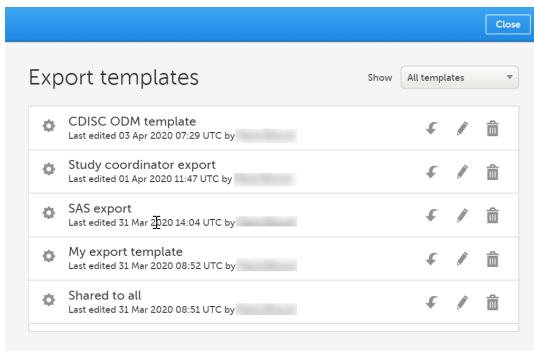
6.2 Applying a data export template

To apply a data export template:

1   Click **View all templates** in the **Export templates** area of the **Data export** page.
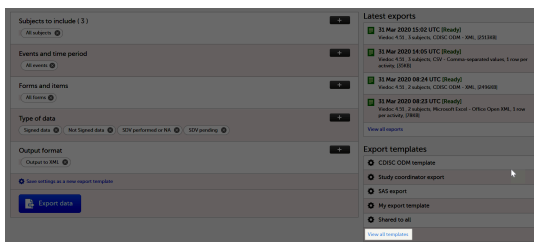
2   Click the apply icon for the template that you want to apply.
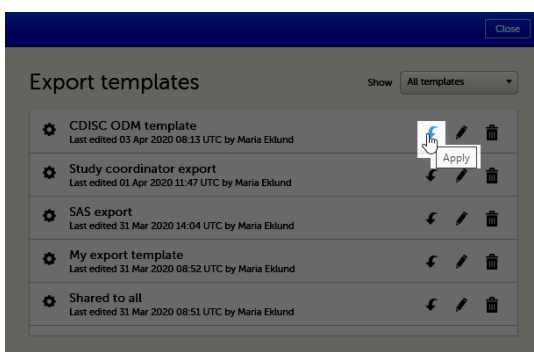
3   Click **Export data** to perform an export with the settings in the template.

Tip! Alternatively, you can use the quick access apply, available in the **Export templates** area:
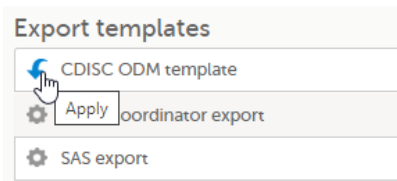
6.3   Editing a data export template

To edit a data export template:

1   Click **View all templates** in the **Export templates** area of the **Data export** page.
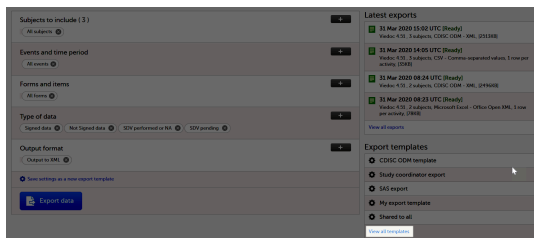
2   The **Export templates** list is displayed. Click the edit icon for the template that you want to edit.
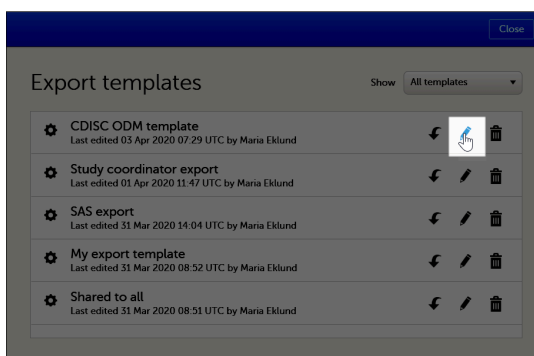
3   In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

        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.
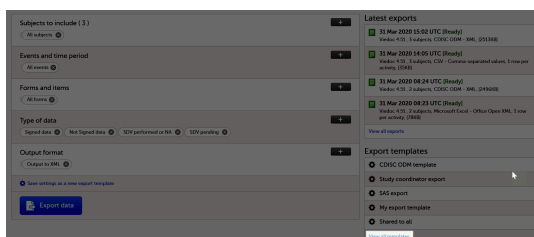
2   The **Export templates** list is displayed. Click the trash can icon for the template that you want to delete.
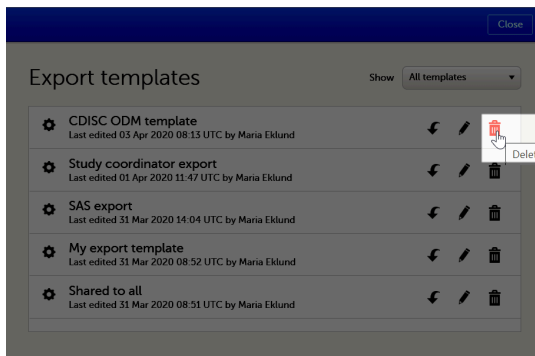
3   In the pop-up that is displayed, click **Delete**.
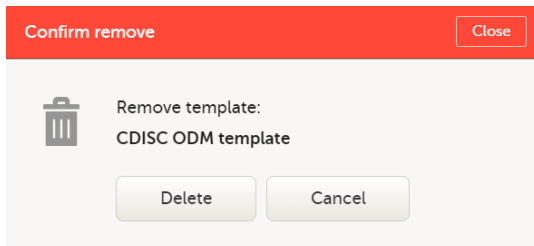
Note: You can only delete a data export template that you created yourself.

7 Exporting data

To perform a data export:

1   Filter the data to be exported. See [Filtering the data to be exported](#).

2   Select the [Output format](#).

3   Optionally, select the [Output version](#).

4   Optionally, [preview the data](#) to be exported.

5   Click **Export data**. The status of the export is displayed in the **Latest exports** area, on the top of the list. When the export is completed, you can download the exported file:
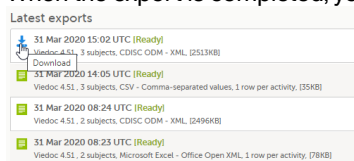
The exported file is downloaded locally. The filename is generated as follows: *SponsorCode_CountryCode_SiteCode_Date_Time*, where:

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

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

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.
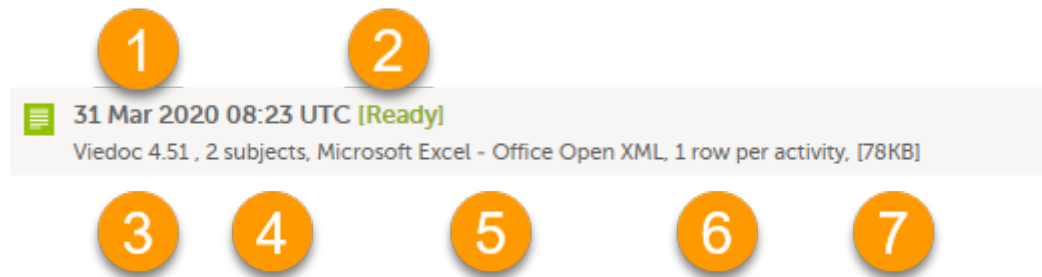
Each log entry provides the following information:

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.
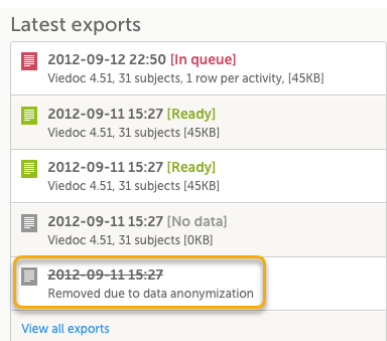
Excel export

Excel export

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1   Introduction

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

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

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

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

2   File structure

The Excel export contains the following sheets:

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

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

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

	Group data by form	Do not group data
one row per subject	- *README* - one separate sheet for each form - *Items* - *CodeLists*	- *README* - *Data* - *Items* - *CodeLists*
one row per activity	- *README* - one separate sheet for each form - *Items* - *CodeLists*	- *README* - *Data* - *Items* - *CodeLists*
one row per item	- *README* - one separate sheet for each form	- *README* - *Data*

2.1 Header rows

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

1. Human-readable format

2. Machine-readable format

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

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

Race__2	Race__2 - Code
DMRACE__2	DMRACE__2CD
Native Hawaiian	4
Native Hawaiian	4
Black	1

3   Data filtering - Type of data

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

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

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

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

4   Data grouping

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

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

4.1   Group data by form

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

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

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

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

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

4.2 Do not group data

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

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

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

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

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

5 Layout

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

- one row per subject
- one row per activity (default)
- one row per item

5.1 One row per subject

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

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

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

The first columns provide information on the site and subject:

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

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

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

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

5.2 One row per activity

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

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

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

5.3 One row per item

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

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

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

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

5.3.1 Include history

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

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

- **Edit sequence number** - a counter for each change per item.
- **Edit reason** - reason for change (initial or given reason at data edit).
- **Edit by** - the user who performed the changes (user name and user id in parentheses).
- **Edit date/time (UTC)** - edit date/time (Coordinated Universal Time (UTC)).

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

5.3.2 Checkboxes

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

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

6 Form link items in the export output

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

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

6.1   One row per activity

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

In the example below:

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

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

There are also two header **rows** in the output:

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

6.2   One row per item

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

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

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

6.3 One row per subject

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

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

There are also two header rows in the output:

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

7   Recurring events in the export output

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

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

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

8   Repeating forms in the export output

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

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

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

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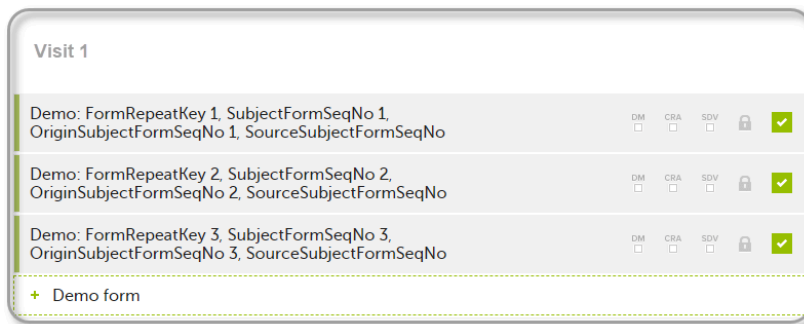
The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

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

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

We perform the following actions in Viedoc Clinic:
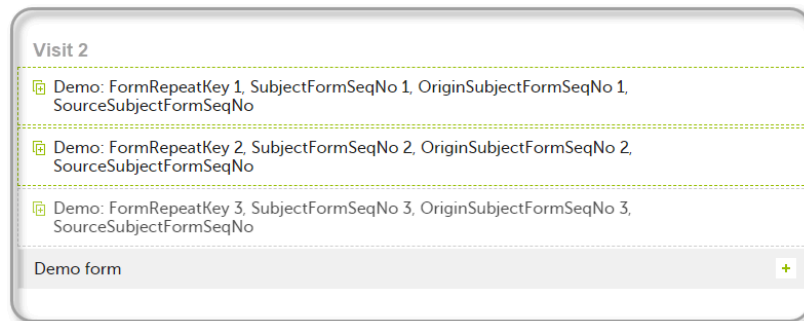
1   Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:

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

3   Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:
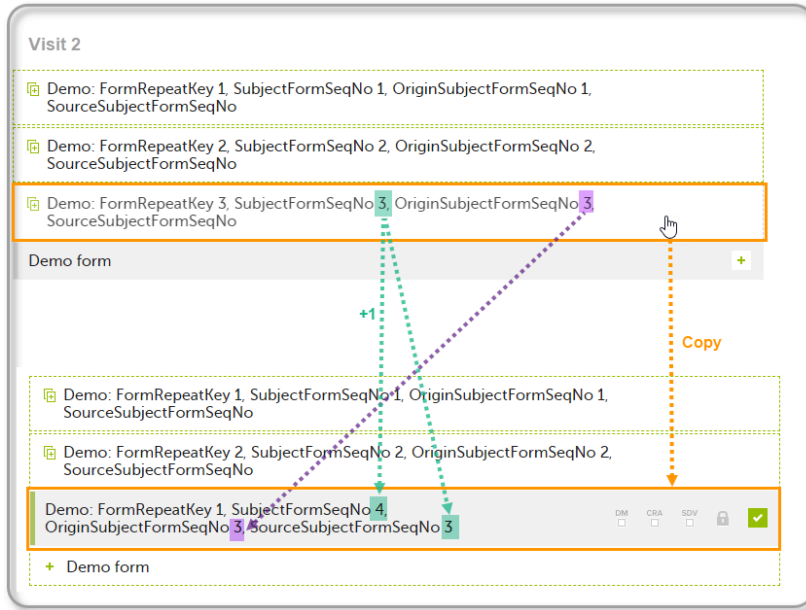
4   Initiate Visit 3. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1 and Visit 2, as below:
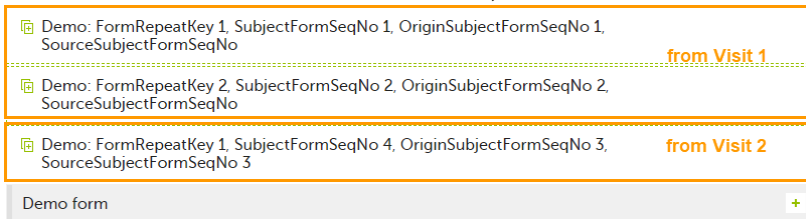
5   Create an instance of Demo form within Visit 3 by copying the data from the form filled in within Visit 2. This will result in the new form instance getting the sequence numbers as illustrated below:
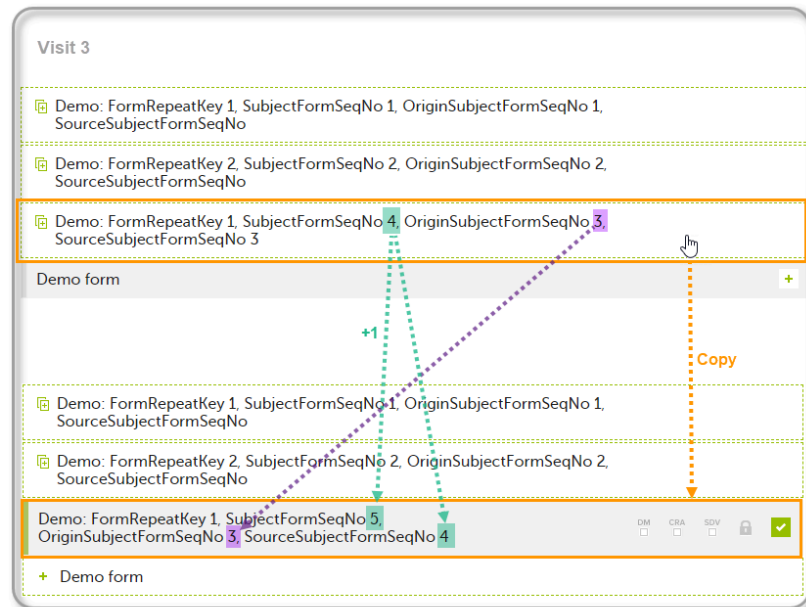
These sequence numbers are available to be used within expressions only to get the value of the sequence number for a specific form instance, that is, by using {SubjectFormSeqNo}, {OriginFormSeqNo}, {SourceFormSeqNo}.

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

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

Notes!

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

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

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

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

PDF export output

PDF export output

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1   Introduction

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

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

2   Output file(s)

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

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

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

3 PDF file structure/content

This section describes the structure of the exported PDF file.
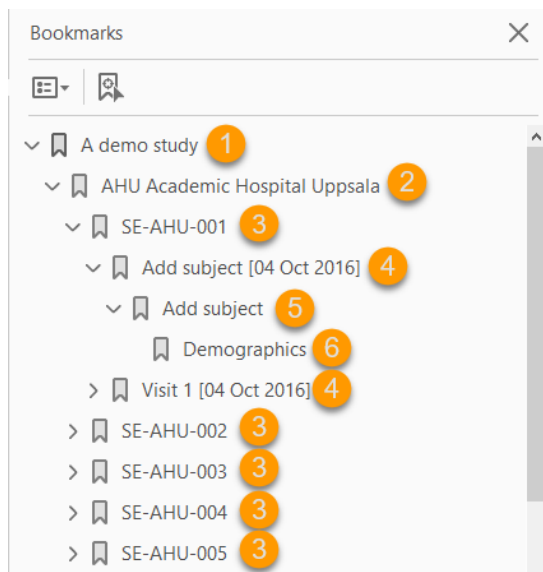
The file is structured as follows:

1. A study summary on the first page.

2. A site summary page.

3. One separate sub-section for each subject in the respective site.

4. For each subject, one sub-section for each event.

5. For each event, one sub-section for each activity.

6. For each activity, one sub-section for each form. The latest version of the form PDFs are included here. See also **Audit trail and Form History** section in Entering/editing data.

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

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

3.1   First page

The first page provides a short summary, as illustrated in the image and explained below:
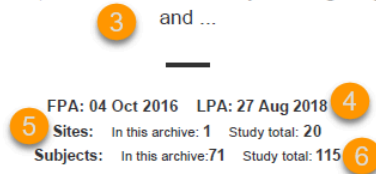
1. The study logo image, if any, as set in Viedoc Admin, under Study Settings.

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

3. Study description, as set in Viedoc Designer.

4. The dates for:

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

5. The number of **sites**:

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

6. The number of **subjects**:

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

3.2   Site summary page

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

A demo study 1

Academic Hospital Uppsala 2

Site code		Country	
3	AHU	Sweden	4

Time zone	
5	(UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

FPA		LPA	
6	04 Oct 2016	27 Aug 2018	7

Subjects (in this archive/total)	
8	71/71

1. The study name, as set in Viedoc Admin.

2. The site name, as set in Viedoc Admin.

3. The site code, as set in Viedoc Admin.

4. The country for the respective site, as set in Viedoc Admin.

5. The site time zone, as set in Viedoc Admin.

6. Date of First Patient Added (FPA) to the site, in the site timezone.

7. Date of Last Patient Added (LPA) to the site, in the site timezone.

8. Number of subjects from the site included in the export / total number of subjects in the site (this number will exclude deleted subjects if *Exclude deleted subjects/events/forms* is checked).

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

3.3   Subject summary page

The subject summary page provides the following information:

A demo study / Academic Hospital Uppsala 1

SE-AHU-023 2

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

5 **Contents**

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

1. The study name and site name, as set in Viedoc Admin.

2. Subject ID in the format set in Viedoc Designer.

3. The date and time the subject was added.

4. The number of **Forms** filled in / the total number of forms for that subject.

5. A table of **Contents** with a list of all the events that contain data for the respective subject, the event status and the page numbers where the data related to the respective event can be found.

3.4   Event summary page

The event summary page provides the following information:

1. The study name and site name, as set in Viedoc Admin.

2. Subject ID in the format set in Viedoc Designer and the event name together with the date when it was initiated.

3. A table of **Contents** with a list of all the forms within the respective event for Scheduled and Unscheduled events, providing the following information:

- Form name (**4**)
- Status (**5**) - one of the following, depending on if the form was signed by the site:
    - *Awaits signing*
    - *Signed*, followed by the name of the user who has signed and the timestamp (in site timezone).
- Page numbers (**6**) where the respective form can be found.

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

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

3.4.1   The sort order of the forms

The forms in the PDF are sorted by these characteristics:

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

The following example illustrates the sort order.

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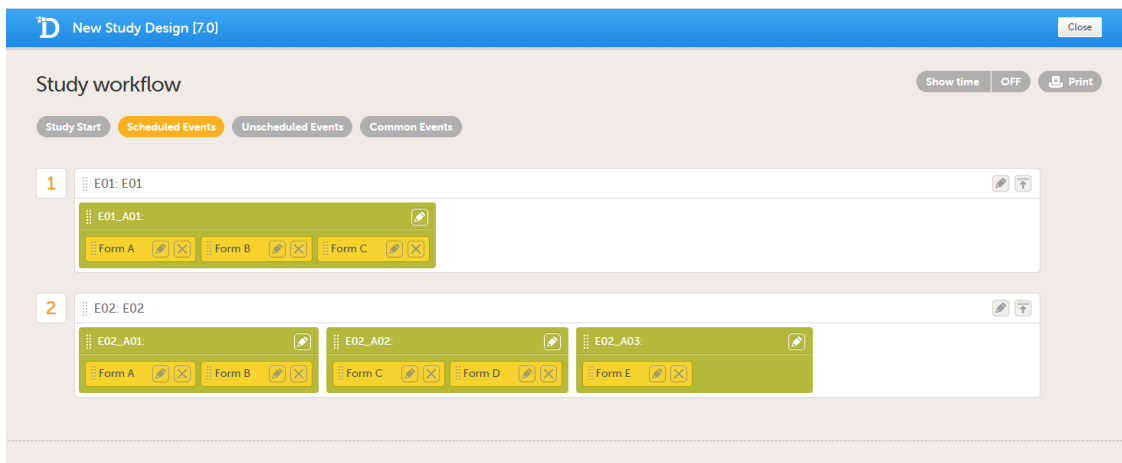
For the event E01, all forms belong to the same activity. This means that the order of the forms in the PDF will always be like this:

- Form A
- Form B
- Form C

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

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

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

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

Queries in Excel export

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

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

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

Data Export

All sites   Sweden

Subjects to include (21)   [+]
All subjects ⊗

Events and time period   [+]
All events ⊗

Forms and items   [+]
All forms ⊗

Type of data   [−]
Signed data ⊗   Not Signed data ⊗   SDV performed or NA ⊗   SDV pending ⊗   Queries ⊗   Query history ⊗

☑ Signed data   ☑ Not Signed data

☑ SDV performed or NA   ☑ SDV pending

In addition to data, also include the following in the export (will not be included in Preview data)
☑ Queries   ☑ Query history
☐ Review status   ☐ Medical coding
☐ Event dates   ☐ Edit status
☐ Uploaded files

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

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

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

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

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

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

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

Sheet tabs: ... | CC | LAB | MH | HA | CM | AE | ExampleForm | Items | CodeLists | **Queries**

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

Column name	Description
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Query specific information	
Query item sequence number	Counter that identifies the query within a sequence of queries for the same item.

Raised on	Specifies if the query was raised on an item or on the event date:
	
	  • *Item*
	  • *Event date*

Query type	Specifies the query type, depending on how it was raised:
	
	  • *Validation* - for automatically raised queries, as a result of validation.
	  • *Manual* - for manually raised queries.
	  • *Unconfirmed missing data*

Range check OID	Only for automatically raised item queries (i.e. **Query type** = *Validation* and **Raised on** = *Item*). The unique Object Identifier ([OID](#)) of the edit check that generated the query, as set in Viedoc Designer.
Query text	The text of the query.

Query state	Can be one of the following (see also [Query overview](#)):
	
	  • *Query Raised*
	  • *Query Resolved*
	  • *Query Approved*
	  • *Query Rejected*
	  • *Query Closed*
	  • *Query Removed*
	
	Note! The queries that were automatically closed due to form reset/delete (with status *Query Closed*) are not included in the export.

Query resolution	The resolution text entered when resolving (answering) the query. Not applicable for those changes performed by the system (i.e. **User name** = *System (0)*)
User name	The name of the user who performed the changes, followed by the user ID in parentheses. Note! For those changes performed by the system (such as validation queries, that are automatically raised by the system) the **User name** = *System (0).*
Date & time (UTC)	The date and time when the change was performed.

Medical coding in Excel export

Medical coding in Excel export

1   Introduction

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

To include the medical coding information in the exported file, you need to select **Medical coding** under **Type of data** in the Data Export page:

For general details about data export, see Exporting data.

2   Medical coding information in Excel

For medical coding, in the Excel export output file, there is one sheet for each dictionary. Only values that have been coded will be present in the export:

Form Id	Form name	Form sequence number	Item Id	Item name	Term	Dictionary instance	Coding scope description	Coding scope leve
FormId	FormName	FormSeq	ItemId	ItemName	Term	DictInstance	CodingScopeDesc	CodingScopeLevel
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Cinnarizine	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Cinnarizine	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Montelukast	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Humalog insulin	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Paracetamol	WHODrug, Version 180829	Concomitant medication	Item
CM	Prior and Concomitant Medications	1	CMDRUG	Drug	Aspirin	WHODrug, Version 180829	Concomitant medication	Item

◄ ► ... | HA | CM | AE | ExampleForm | Items | CodeLists | **MedDRA** | **WHODrug** | ⊕ ⋮ ◄

The columns provide information on the item that was coded, followed by the medical coding specific information, as listed in the following table:

Column name	Description
Columns that identify the item	
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 date	The event date, as set in Viedoc Clinic when the event is initiated
Activity Id	The activity ID, as set in the study design (in Viedoc Designer)
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Form Id	The form ID, as set in the study design (in Viedoc Designer)
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms. For non-repeating forms, this is **1**. If a form is reset and then saved again the new form has sequence number **2**, and so on. Form sequence number increases one step every time reset/initiate occurs.
Item Id	The item ID, as set in the study design (in Viedoc Designer)
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic

Column name	Description
Subject form sequence number	Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and it is incremented each time a new instance of the form is created for that subject.
Origin Subject form sequence number	For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the `SubjectFormSeqNo`.
Source Subject form sequence number	For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the `SubjectFormSeqNo` from which the form instance was copied. For the first instance of the form (not copied) it is empty (null).
Medical coding-specific information	
Term	The coded term
Dictionary instance	The description of the dictionary instance, as set in Viedoc Admin when uploading the dictionary
Coding scope description	The coding scope description, as defined in Viedoc Designer
Coding scope level	The coding scope level, as defined in Viedoc Designer, can be one of the following: • Event • Activity • Form • Item group • Item
Code sequence number	A counter that identifies the code for those values with more than one code
Approved by user	The name and ID of the user who approved the items
Approved on date (UTC)	The date and time (UTC) when the item was approved
Dictionary-specific information	

WHODrug:	MedDRA:	ATC without DDD:	IDF:
• DrugCode • DrugName • NameSpecifier • OldForm • Ingredients • ATCCodes • CountryCode • CountryName • MAH (MAH) • PharmForm • Strength • MedProdId • Generic	• soc_code • soc_name • soc_abbrev • hlgt_code • hlgt_name • hlt_code • hlt_name • pt_code • pt_name • pt_soc_code	• L1code • L1name • L2code • L2name • L3code • L3name • L4code • L4name	• L1 薬剤コード • L1 薬剤名 • L1 薬剤名カナ • L2 薬剤コード • L2 薬剤名 • L2 薬剤名カナ • L3 薬剤コード

Column name	Description
Interpretation	The medical coder's interpretation of the applied coding value
Coded by user	The name of the user who performed the coding, followed by the user ID in parentheses
Coded on date (UTC)	The date and time when the coding was performed

Column name	Description
Version	The dictionary version
Dictionary-specific information	

Column name	Description		

WHODrug:
 	
    ■ PreferredCode
    ■ PreferredName
	MedDRA:
	
	    ■ llt_code
	    ■ llt_name
	    ■ llt_currency
		ATC without DDD:
		
		    ■ L5Code
		    ■ L5Name
			IDF:
			
			    ■ L3 薬剤名
			    ■ L3 薬剤名カナ
			    ■ L4 薬剤コード
			    ■ L4 薬剤名
			    ■ L4 薬剤名カナ
			    ■ L5 薬剤コード
			    ■ L5 薬剤名
			    ■ L5 薬剤名カナ
			    ■ L5 一般名
			    ■ L5 一般名カナ
			    ■ L5 使用区分1
			    ■ L5 使用区分2
			    ■ L5 基準名コード
			    ■ L5 メーカーコード
			    ■ L5 メーカーの略称
			    ■ L5 剤形コード
			    ■ L5 薬剤コード区分1
			    ■ L5 メンテ年月
			    ■ L6 薬剤コード
			    ■ L6 薬剤名
			    ■ L6 薬剤名カナ
			    ■ L6 一般名
			    ■ L6 一般名カナ
			    ■ L6 使用区分1
			    ■ L6 使用区分2
			    ■ L6 基準名コード

Column name	Description		
			- L6 メーカーコード - L6 メーカーの略称 - L6 剤形コード - L6 薬剤コード区分1 - L6 メンテ年月

3   An example - WHODrug in Excel exported file

This section illustrates an example of how the data coded using the World Health Organization Drug Dictionary (WHO DD) dictionary looks in the Excel export output.

There are two different use cases, depending on the which level of granularity is selected when applying the code in Viedoc Clinic:

1. **Drug** (default)

2. **Pref**erred name

3.1   When selecting Drug

The image below illustrates how the coded data looks in the export output, if the **Drug** is selected when applying the code in Viedoc Clinic.

When **Drug** is selected, the **Preferred code** and **Preferred name** come out in the export as well, in the last columns, as illustrated in the image.

Applied code in Excel export output

	V	W	X	Y	Z	AA
1	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients	ATCCodes
2	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients	ATCCodes
3	12818602012	A. c. with codeine		N	Acetylsalicylic acid;Caffeine;Codeine phosphate	N02AJ Opioids in combination with non-opioid analgesics
4						
5						
6						
7						
8						
9						
10						
11						

README | PI | LAB | PainLevel | LABR | Items | CodeLists | **WHODrug** | ⊕

AM	AN
Preferred Code	Preferred Name
PreferredCode	PreferredName
12818602001	Acetylsalicylic acid;Caffeine;Codeine phosphate

3.2 When selecting Preferred name

The image below illustrates how the coded data looks in the export output, if the **Preferred name** is selected when applying the code in Viedoc Clinic.

After the **Preferred name** is selected and the code is applied, for the respective coded item, the value of the **Preferred name** ends up in both **Drug** and **Pref** fields, in both Viedoc Clinic, as well as in the exported output.

Find and apply code

WHODrug

Search options ▼

codeine 🔍

Pref	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate	⦿
Drug	12818602012 A. c. with codeine	○
Spec		
INGR	Acetylsalicylic acid;Caffeine;Codeine phosphate	
ATC	N02AJ Opioids in combination with non-opioid analgesics ✖	

Select Pref and apply code

Find and apply code

WHODrug

Search options ▼

Search 🔍

Pref	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate	⦿
Drug	12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate	○
Spec		
INGR	Acetylsalicylic acid;Caffeine;Codeine phosphate	
ATC	N02AJ Opioids in combination with non-opioid analgesics ✖	

Find and apply code

WHODrug

Search options ▼

Search 🔍

Pref `12818602001` Acetylsalicylic acid;Caffeine;Codeine phosphate ⦿

Drug `12818602001` Acetylsalicylic acid;Caffeine;Codeine phosphate ○

Spec

INGR Acetylsalicylic acid;Caffeine;Codeine phosphate

ATC N02AJ Opioids in combination with non-opioid analgesics ✕

Applied code in Excel export output

	V	W	X	Y	Z	AA
1	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients	ATCCodes
2	DrugCode	DrugName	NameSpecifier	OldForm	Ingredients	ATCCodes
3	12818602001	Acetylsalicylic acid;Caffeine;Codeine phosphate		N	Acetylsalicylic acid;Caffeine;Codeine phosphate	N02AJ Opioids in combination with non-opioid analgesics
4						

	AM	AN
	Preferred Code	Preferred Name
	PreferredCode	PreferredName
	12818602001	Acetylsalicylic acid;Caffeine;Codeine phosphate

Review status in Excel export

Review status in Excel export

Published by Viedoc System 2023-10-09

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

For general details about data export, see Exporting data.

1 Review status

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

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

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

◄ ► ... PI LAB PainLevel LABR Items CodeLists **Review status** SDV ⊕

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

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

Column name	Description
Event Id	The event ID, as set in the study design (in Viedoc Designer).
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Event date	The event date, as set in Viedoc Clinic when the event is initiated.
Activity Id	The activity ID, as set in the study design (in Viedoc Designer).
Activity name	The activity name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form Id	The form ID, as set in the study design (in Viedoc Designer).
Form name	The form name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms. For non-repeating forms, this is **1**. If a form is reset and then saved again the new form has sequence number **2**, and so on. Form sequence number increases one step every time reset/initiate occurs.
Review status information	
Reviewed item	Can be one of the following: • *Event date* - if the review action was performed on the event date. • *Form* - if the review action was performed at form level.
Clinical review by	User name and user ID of the user that performed the clinical review.
Clinical review date (UTC)	The date and time in Coordinated Universal Time (UTC) when the clinical review was performed
Data review by	User name and user ID of the user that performed the data review (marked by the DM review flag).
Data review date (UTC)	The date and time (UTC) when the data review was performed.
SDV by	User name and user ID of the user that performed the Source Data Verification (SDV) (marked by the SDV review flag). For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed. For studies where SDV is performed on item level, this column will contain N/A for items that do not require SDV.
Signed by	User name and user ID of the user that signed the form.
Signed date (UTC)	The date and time (UTC) when the form was signed by investigator.
Lock by	User name and user ID of the user that locked the form.
Lock date (UTC)	The date and time (UTC) when the form was locked.

2 SDV

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

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

| ◀ | ▶ | ... | PI | LAB | PainLevel | LABR | Items | CodeLists | Review status | **SDV** | ⊕ | ⋮ | ◀ |

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

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

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

Column name	Description
Form sequence number	Counter that identifies the instance of the respective form within the respective activity. This is mostly used for repeating forms. For non-repeating forms, this is **1**. If a form is reset and then saved again the new form has sequence number **2**, and so on. Form sequence number increases one step every time reset/initiate occurs.
Item ID	The item ID, as set in the study design (in Viedoc Designer)
Item name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic.
SDV information	

Reviewed item	Can be one of the following:
	
	    ▪ *Event date* - if the review action was performed on the event date.
	    ▪ *Form* - if the review action was performed at form level.

SDV by	User name and user ID of the user that performed the SDV.
SDV date (UTC)	The date and time (UTC) when the SDV was performed.

Managing users

Published by Viedoc System 2023-10-09

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

1   Introduction

1.1   Important information about signatures

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

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

1.2 About roles in Viedoc

1.2.1 Two types of roles

Viedoc supports two different types of roles.

1. **System roles** are roles that are predefined in the system and give access to Viedoc Admin or Viedoc Designer, see System roles.
2. **Clinic roles** are roles that are study-specific and give access to Viedoc Clinic, see Clinic roles.
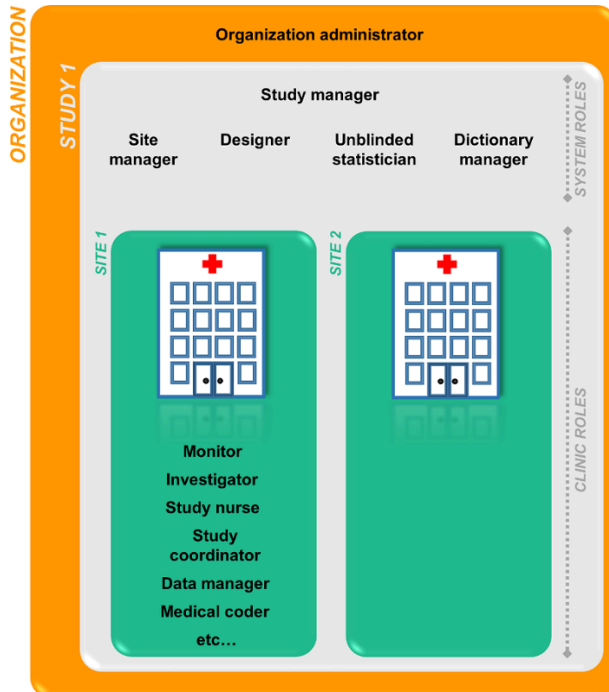
The Organization Administrator invites the Study Manager. The Study Manager can assign users to system roles and clinic roles. The Study Manager can also delegate the management of clinic roles to the Site Manager.

1.2.2 System roles

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

The following system roles are available.

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

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

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

1.2.3 Clinic roles

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

Examples of clinic roles are:

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

1.3 About the study users

1.3.1 Overview of users in the organization/study/site

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

1. On the **Users** page. This page displays a list of users assigned to any role in any study within the organization.

2. In the **Study crew** window. This window displays a list of all users assigned to a system role in the study.

3. On the **Site users** tab of the site settings window. This tab displays a list of all users assigned to a clinic role within that specific site.

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

1.3.2   Users

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

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

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

On this page, you can (see image):

1. Search for a specific user among all users within the organization by entering the user's name or e-mail address in the search field

2. Sort the list of users by name, status or date of creation

3. Group the list of users by study by selecting **Studies** in the **Group by** field

4. Invite organization users (only available for the Organization Administrator)

1.3.3 Study crew

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

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

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

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

1.3.4 Site users

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

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

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

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

1.3.5   Viedoc skill level

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

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

1.3.6   User status

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

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

For the **Users** page (see [Users](#)), the following applies:
If the users are not grouped by study, the user's status symbol will reflect the overall status in all studies you have access to. That means, if the user has one pending invitation in one of the studies, the status will be *pending* and a

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

1.4 User settings

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

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

1. On the **Details** tab, you can view the user's name and contact details.

2. On the **Studies and Roles** tab, you can view a list of all roles and sites the user has access to, including the date and time of invitation/acceptance of that role. The roles are grouped per study. You can delete roles by clicking the trash can icon next to the role.

3. On the **Login History** tab, you can view a list of logins by the user, including date and time, the IP address, and the browser that was used. The number of displayed entries is limited to the latest 100 logins.

4. On the **Reset Password** tab, you can reset the password for that user, if the user has forgotten his/her password <u>and</u> the answer to his/her challenge question. Viedoc will send a notification to the user with a link to create a new password.

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

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

1.5 User report

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

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

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

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

1.5.1 Log of users and roles in PDF

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

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

1.5.2 User administration log in Excel

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

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

Communication log in Excel

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

Note!

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

1.5.3.1   User-specific information

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

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

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

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

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

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

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

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

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

Column	Description
Message ID	GUID: A unique identifier for the message
Type of Communication	SMS/email
Datetime (UTC)	Date and time for the communication

Message Type	The action that the communication is related to:
	
	    ▪ *Reset password* - for messages related to password reset
	    ▪ *2FA login* - for messages related to the 2 factor authentication

To	The email address the message is sent to. For SMS messages, this column is empty.
Status	*Success/Failed*
Provider	Provider name - the provider that was used to send the message to the recipient

	Message Id	Type of Communication	Datetime (UTC)	Message Type	To	Status	Provider
				Communication logs			
3	9970d495-aa67-4bed-b246-cc3f8b1c8d47	Email	2022-03-01 07:46:25	Two Factor Authentication	user1@viedoc.com	Success	Primary-Primary
4	a96f1beb-c63c-4376-9ae0-e9dcdabcb8d4	Email	2022-03-01 07:44:29	Recover Account Request	user2@gmail.com	Success	Secondary-Secondary
5	00520b3e-f26a-4077-9dac-edc9458cc30a	Sms	2022-03-01 06:16:22	Verify Phone Number		Success	Primary-Primary
6	e01f2d59-8af4-48ba-81b7-fb4045d18767	Email	2022-03-01 06:16:20	Verify Email Address	123@mail.com	Success	Primary-Primary
7	9ad92c51-7582-4bce-b243-d63737bb079d	Sms	2022-03-01 06:11:07	Verify Phone Number		Success	Primary-Primary
8	448b70b8-faea-4dc3-b07a-a892457eb358	Email	2022-03-01 06:11:00	Verify Email Address	999@gml.com	Success	Primary-Primary
9	1de6048b-a1a9-48bb-85e2-94ab6ecf4f42	Sms	2022-03-01 04:44:05	Verify Phone Number		Failed	Secondary
10	399a561a-4299-4ceb-a0ac-a87825cdfbaa	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
11	8aec881c-78ab-45c9-95e4-5123e09ce129	Sms	2022-03-01 04:42:42	Verify Phone Number		Failed	Secondary
12	f8ef8347-de0e-422b-be2a-d8bba0a7d650	Email	2022-03-01 04:42:41	Verify Email Address	789@gmil.com	Failed	Secondary
13	16c884e2-3cf3-4063-8f47-a8cf0c02233a	Email	2022-03-01 04:39:43	Verify Email Address	abcd@gmil.com	Failed	Secondary
14	9c813fce-6633-4dee-b0ba-3666ee14cf5f	Sms	2022-03-01 04:39:38	Verify Phone Number		Success	Secondary-Primary
	fc98775c-01f2-4b4d-aad7-	Email	2022-03-01 04:39:29	Verify Email Address	123@mgil.com	Failed	Secondary

User Communication Logs

Study-specific information

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

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

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

The Excel file contains a sheet named Study Communication Logs.

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

The Excel sheet has the following columns:

Column	Description
Message ID	GUID: A unique identifier for the message
Communication Type	Email
Date time (UTC)	Date and time for the communication
Message Type	The action that the communication is related to: - *Invite user* - *Event Reminder* - *Remove User Access Notification* - *Subject Account Lock Notification* - *Study Unlock Notification* - *Export Chart* - *Export Metric* - *Reject User Invitation*
Site Type	Training/Production (For the message types Invitation and Invitation rejected, this column is empty.)
To	Email address(es) (For SMS messages, this column is empty.)
CC	The email address(es) of the recipients of a copy
BCC	The email address(es) of the recipients of a blind copy
Status	*Success/Failed*
Provider	Provider name - The provider that was used to send the email to the recipient

Message Id	Communication Type	Datetime (UTC)	Message Type	Site Type	To	CC	BCC	Status	Provider
f76302cc-8c85-4f33-a992-87bde89b8bd2	Email	2022-03-03 06:52:07	Form Alert True Action	Production	rb@doc.com	rb@doc.com	gf53@mail.com, user11.pghryam@amail.com	Success	Secondary-Secondary
673fef21-bceb-477d-9b94-ad0ffe080e64	Email	2022-03-03 06:52:05	Event Reminder	Production	rb@doc.com	user1@mail.com	dyuhftst7@dmail.com, user78.hjystfg@amail.com	Success	Secondary-Secondary
d2e09907-1b90-4945-9d17-fffb594a0b2a	Email	2022-03-03 06:52:03	Study Unlock Notification	Production	user1@mail.com	user3@amail.com	fdfdtr3@dmail.com, user56.klofd@amail.com	Success	Secondary-Secondary
9757c6d5-60c1-435a-8d97-81f677cdb022	Email	2022-03-03 06:52:01	Invite User	Production	user2@se.com	user@vc.com	fnmkj378@amail.com, user8971.uhafm@amail.com	Success	Secondary-Secondary
85e5a421-d529-40b3-979e-de4acb183902	Email	2022-03-03 06:43:53	Remove User Access Notification	Production	ghu.nustf@mail.com	mol.hbdb@mail.com	gfdgs65@amail.com, fsfsuifs.fklj@mail.com	Success	Secondary-Secondary

Study Communication Logs

Note!

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

1.6 System site groups

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

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

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

2 Step-by-step guides for the Study Manager

2.1 Assigning users to system roles and/or clinic roles

Only the Study Manager can invite users to system roles. The Study Manager can also invite users to clinic roles, or he/she can delegate the management of (some of the) clinic roles to the Site Manager, see Delegating user management to the Site Manager for instructions. Once the management of clinic roles is delegated to the Site Manager, the Study Manager cannot invite users to these roles anymore.

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

To invite users:

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

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

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

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

4   Select the role to which you would like to invite the user.
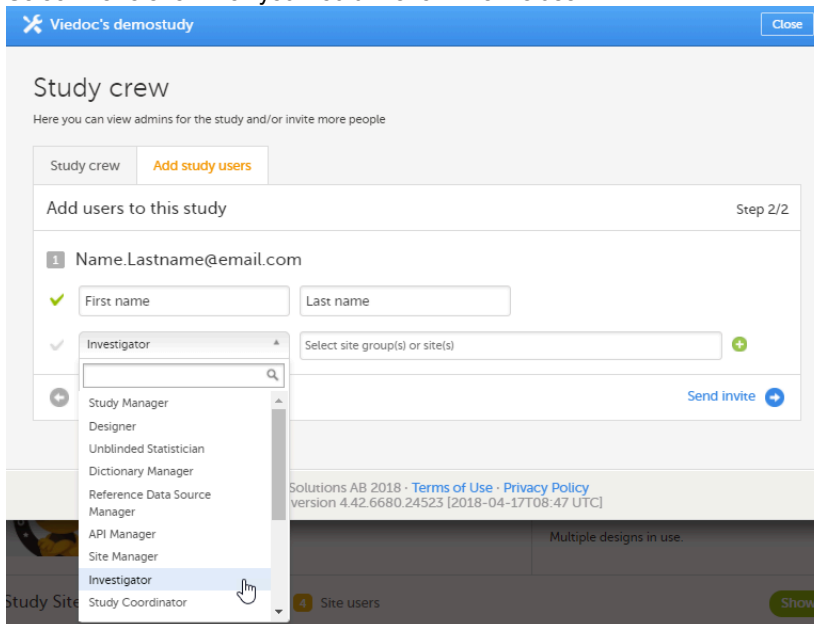
You can add multiple roles by clicking the **+** icon. Newly added roles can be removed by clicking the **-** icon.

Note! If any of the clinic roles are delegated to the Site Manager (see Delegating user management to the Site Managers), the delegated roles do not appear in the dropdown list.

5   If you selected the role Site Manager or a clinic role, select the system site group or the individual sites to which the user should get access. To select a system site group, click on the name of the group (displayed in bold). To select an individual site, click on the name of the site.
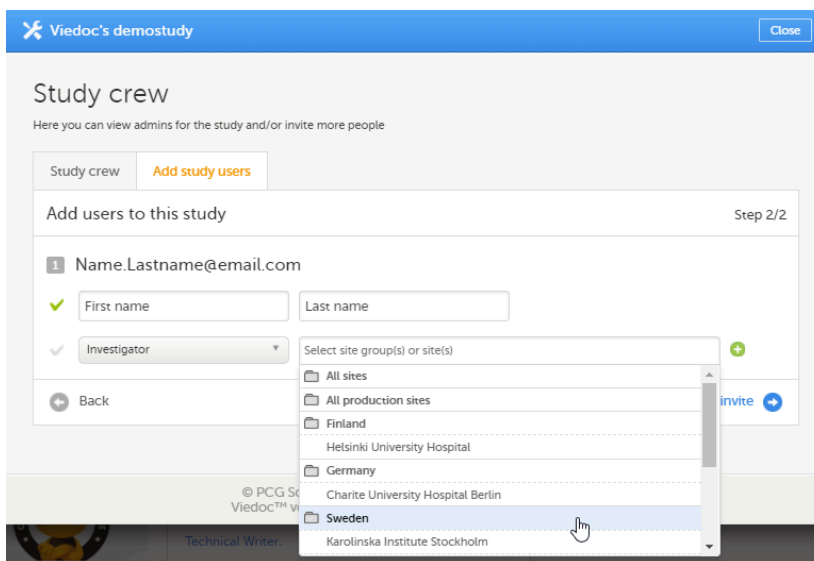
Note!

- Sites that do not belong to a system site group (for example training sites) are listed under a separate header (for example "Training sites") at the bottom of the list of site groups and sites. This header lacks the folder icon, and does not represent a system site group (see image).
- For Demo sites to work with Viedoc Reports, a user must be invited with direct site access (not through All sites site group). For Production sites, Viedoc Reports is available for all site groups (All sites and the country-specific groups).

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

2.2   Resending the invitation to a user

It is possible to re-invite a user to those roles that are in state <u>pending</u>, i.e. to resend the invitation email to the user for that role.

To resend an invitation:

1   On the **Users** page, scroll to the user whom you would like to re-invite. Click the toolbox icon behind the name of the user:
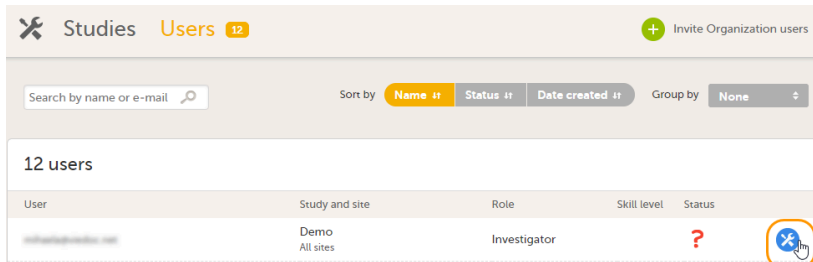
The **User Settings** pop-up opens.

2   In the **User Settings** pop-up, click the Resend invitation icon for the pending role:
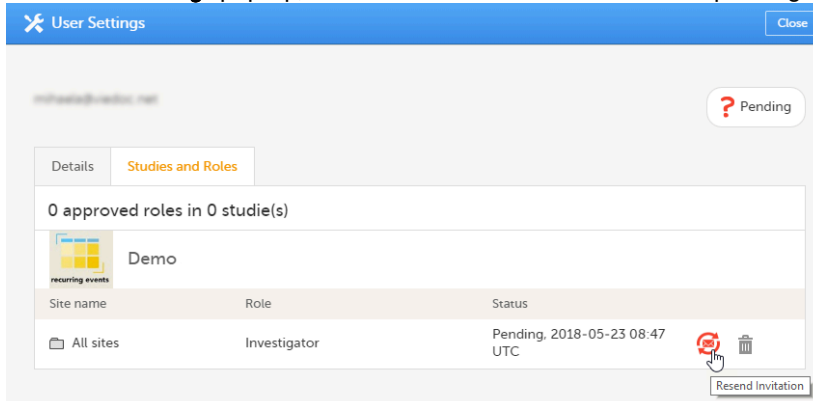
A new invitation email is sent and:

   ▪ a notification message is displayed on the top of the pop-up
   ▪ the date displayed in the **Status** column is updated to the date of the last invitation
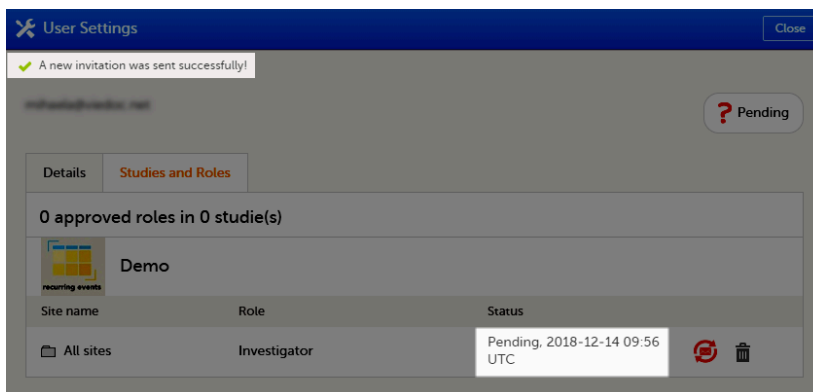
2.3   Removing access to a role

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

To remove the access from users:

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

The User Settings pop-up opens.

2   On the **Studies and Roles** tab, scroll to the study, site and role for which the access should be removed. Click the trash can icon.
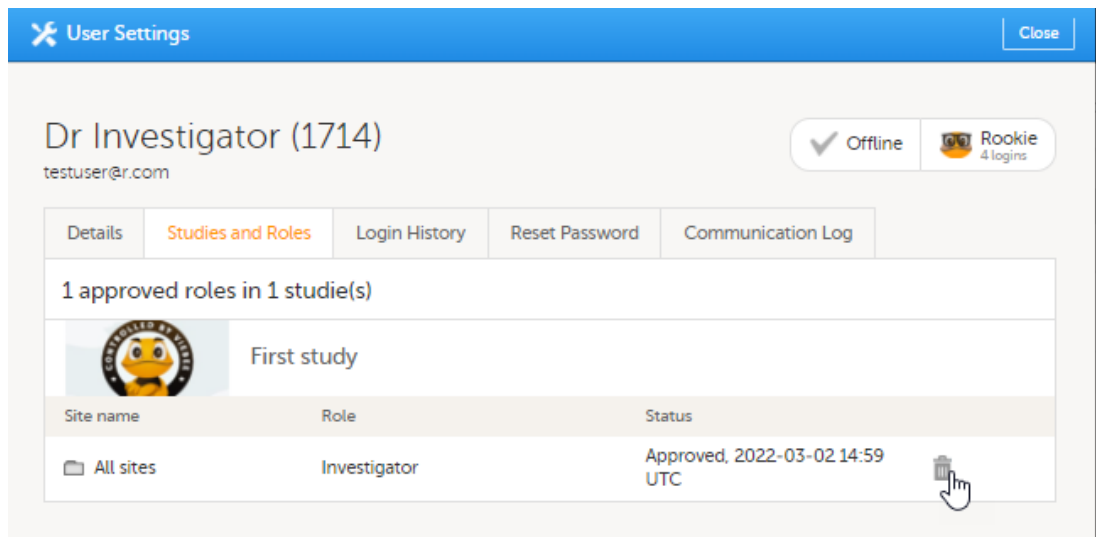
A pop up appears.

3   Click **Delete** to confirm that the access should be removed, or click **Cancel** to cancel.
The role for which you removed the access, will be removed from the **Studies and Roles** list. If all roles for that user have been removed, the user's status will appear as *Removed* on the Users page.

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

2.4   Unlocking a user account

If a user has typed in the wrong password more than three times, and forgotten the answer to the challenge question – and therefore cannot use the *Forgot your password* link – the account will be locked. The Study Manager or Site Manager can unlock a locked account.

To unlock a user account:

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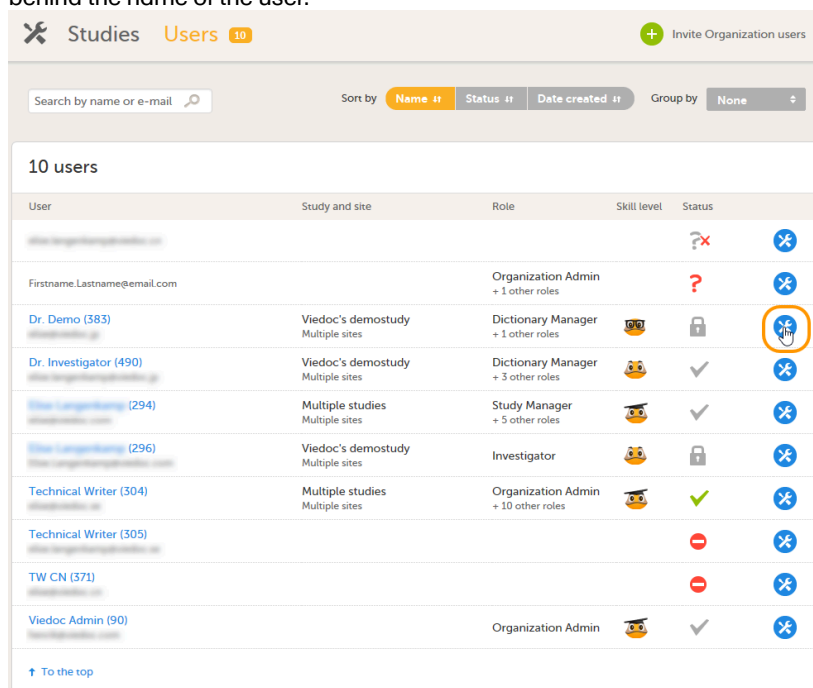

The User Settings pop-up opens.

2   On the **Reset Password** tab, click **Reset Password**.
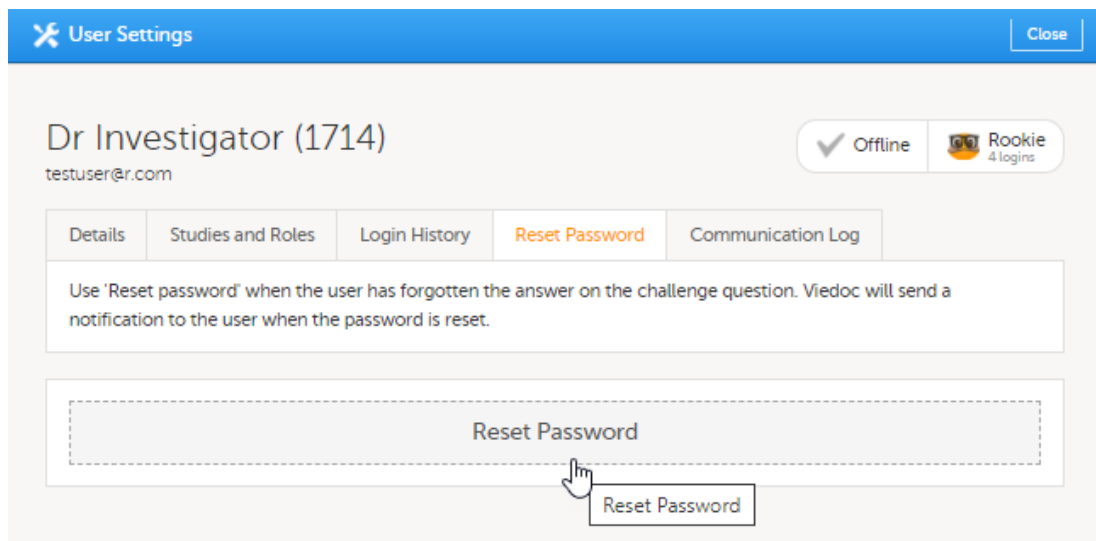
The user will receive an e-mail with a link to reset the password.

The link directs the user to a window where the user is asked to set an answer to the challenge question, and to create a new password. The challenge question is the same as previously chosen by the user, but any answer is accepted for resetting the password.
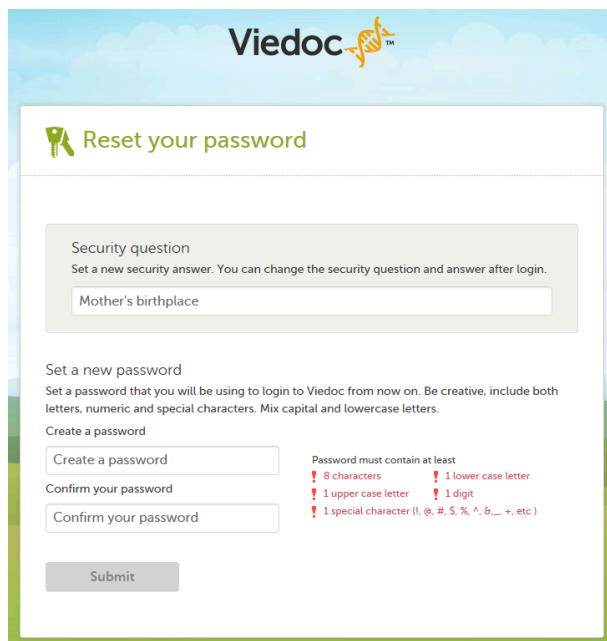
Once the password has been reset, the user can login and select a new challenge question in the security settings.

Note! The email with the link to reset the password is only valid for twelve hours. If the user has not reset the password within twelve hours, a new e-mail needs to be sent.

2.5 Delegating user management to the Site Managers

The Study Manager can delegate the management of clinic roles to the Site Manager.

To select the roles that should be managed by the Site Manager:

1   In Viedoc Admin, click **Study settings**.
        The study settings window opens.

2   On the **Settings** tab, in the field **Clinic roles to be administered by Site Manager**, select which roles
      should be assigned by the site manager.

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

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

Note! These settings apply to all sites and all Site Managers involved in the study. When the assignment of (some of
the) clinic roles is delegated to the Site Manager, these clinic roles can no longer be managed by the Study Manager.
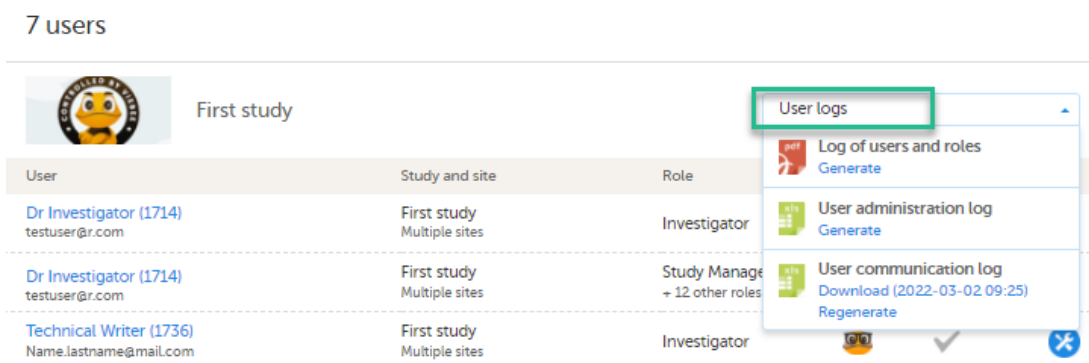
2.6   Downloading the user logs

To download the user logs:

1   On the **Users** page, select to group the users by *Studies*.
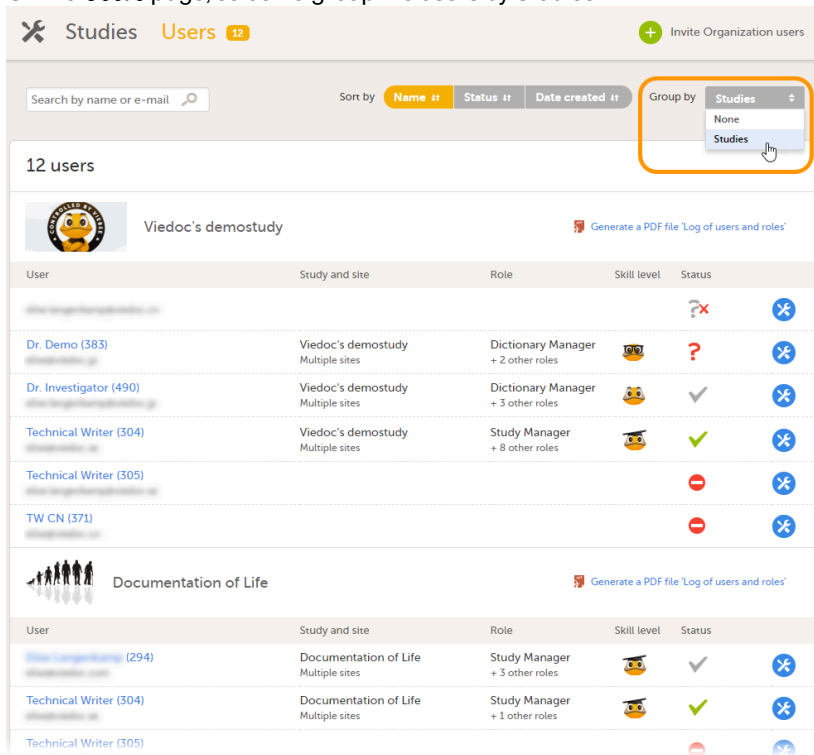
2   Scroll to the study from which you would like to download the user log and click **User logs** to open the dropdown menu.

If the log was not previously generated, click **Generate a PDF file** or **Generate an Excel file.** If the log was previously generated, the most recent version is stored on the server, shown with a date and time stamp. You can download it by clicking the link, or, generate an updated version by clicking **Regenerate.**

Note! The user logs are generated in the language set by the user who is generating the log. Therefore, the previously generated file is available for download only if it was generated in the language you have currently set in Viedoc.
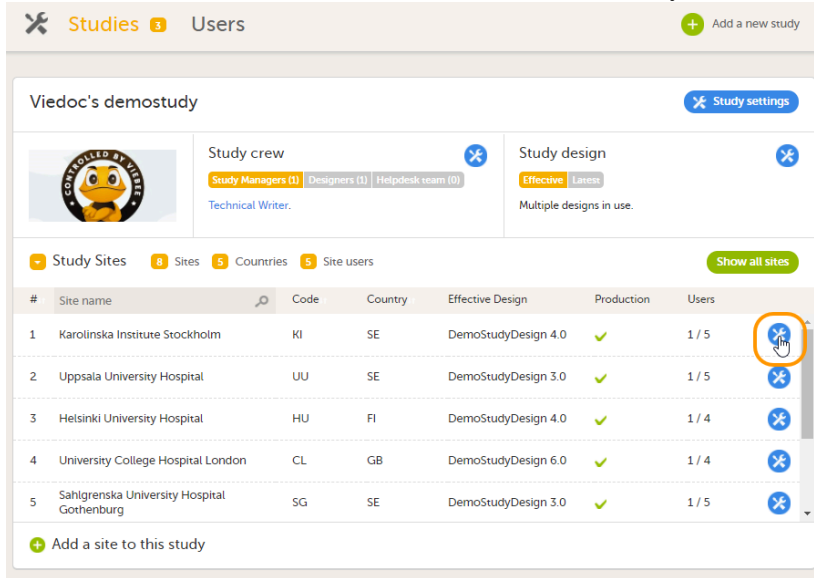
3   Step-by-step guides for the Site Manager

3.1   Assigning users to clinic roles

The Site Manager can invite users to (some of the) clinic roles, if the study manager has delegated the management of these clinic roles to the site manager.
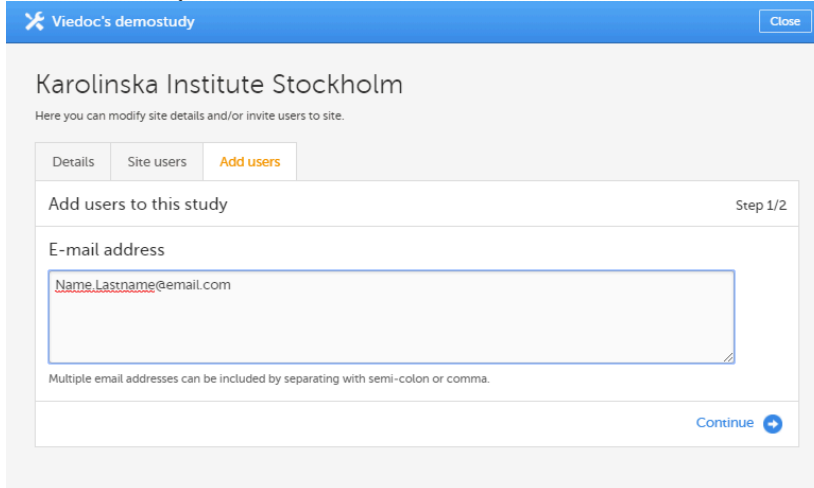
To invite users to a specific site:

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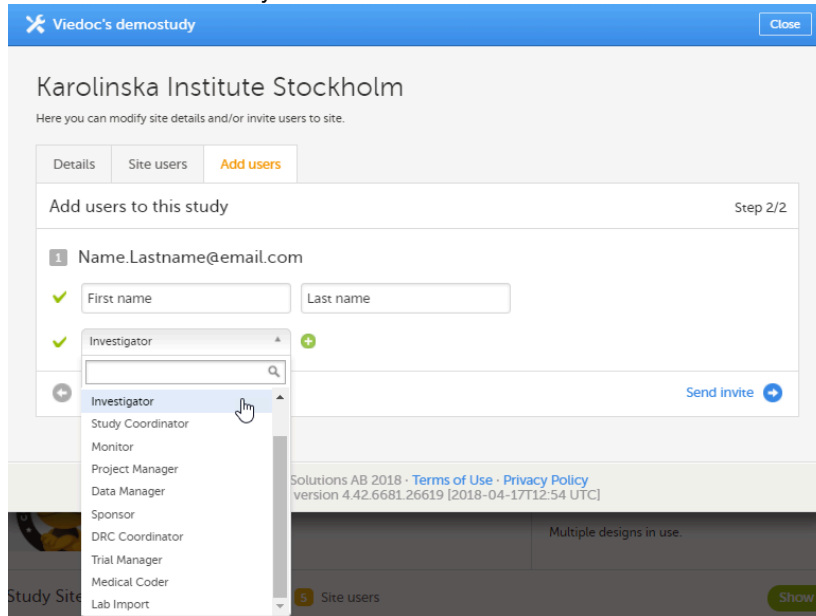

The site settings pop-up opens.

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

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

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

You can add multiple roles by clicking the **+** icon. Newly added roles can be removed by clicking the **-** icon.

4   Click **Send invite**.
An invitation e-mail will be sent to the e-mail address or e-mail addresses you specified.

3.2   Removing a user

Click here for instructions on how to remove a user.

3.3   Unlocking a user account

Click here for instructions on how to unlock a user account.

▶

Create a user account

Create a user account

Published by Viedoc System 2018-11-12

This video walks you through the process of creating a Viedoc user account.

If you have difficulties in viewing this video click here.

Log in/Log out and reset password

Log in/Log out and reset password

Published by Viedoc System 2019-11-14

This video shows how to log in/log out to/from Viedoc and how to reset your password.

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

Landing page

Landing page

Published by Viedoc System 2018-11-07

This video provides a quick overview of the landing page as well as of the study start page.

If you have difficulties in viewing this video, click here.

Activate demo mode

Published by Viedoc System 2018-11-07

This video demonstrates how to switch between demo and production mode within a study.

If you have difficulties in viewing this video, click here.

User Management

Published by Viedoc System 2018-12-12

This video demonstrates how to manage users in Viedoc Admin.

If you encounter difficulties in viewing this video click here.