viedoc learning™

Viedoc Clinic User Guide

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Overview of Viedoc Clinic

Overview of Viedoc Clinic

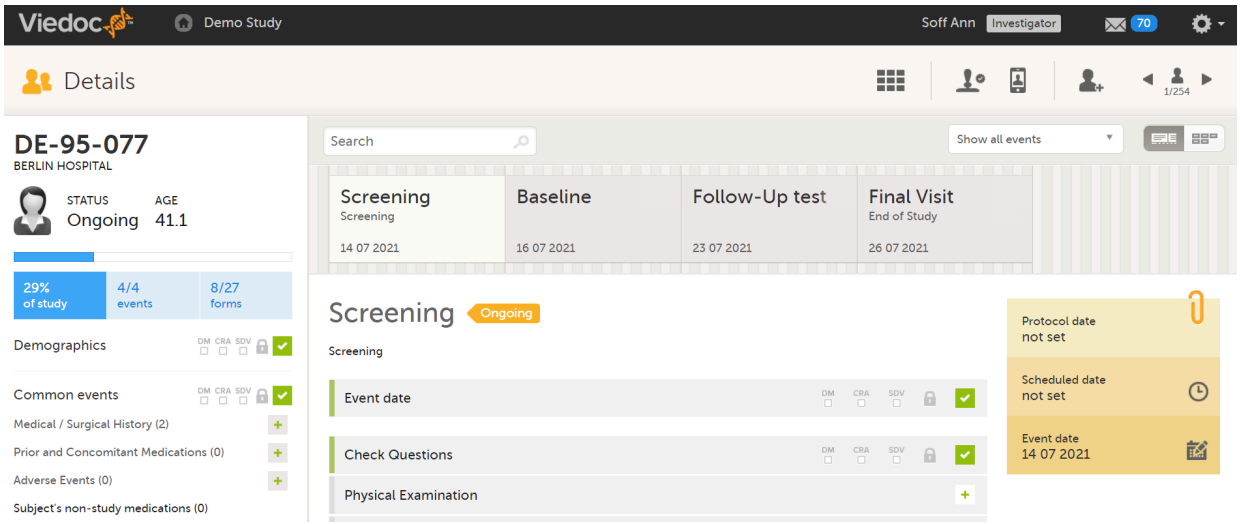
Published by Viedoc System 2024-10-10

1. Introduction
2. Languages

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:

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

System requirements

System requirements

Published by Viedoc System 2022-06-16

1. Customer computer requirements
    1.1 Browser requirements
    1.2 Screen resolution
    1.3 Internet connection
    1.4 Firewall policy
2. Security

1 Customer computer requirements

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

1.1 Browser requirements

Viedoc supports the following browsers:

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

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

For Viedoc Designer:

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

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

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

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

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

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

1.2 Screen resolution

The following screen resolutions are required:

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

1.3 Internet connection

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

1.4 Firewall policy

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

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2 Security

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

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

Managing your Viedoc account

Managing your Viedoc account

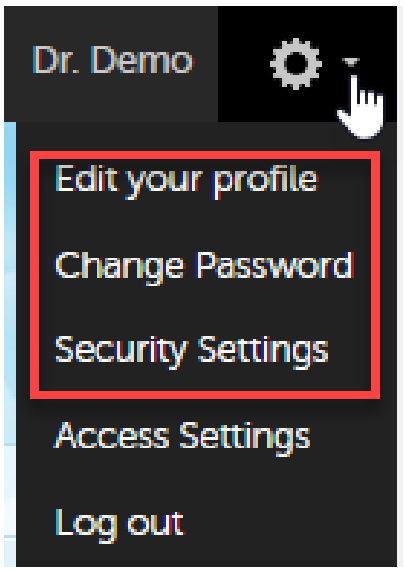
Published by Viedoc System 2024-10-10

1. Viedoc user account management
2. User settings
    2.1 Adding a secondary email address
    2.2 Verifying a secondary email address
    2.3 Changing the primary email address
    2.4 Editing your phone number
    2.5 Verifying your phone number
3. Study access management
4. Access settings
    4.6 Study membership
    4.7 Deleting study access
    4.8 Deleting your Viedoc account
5. Pending invitations
    5.9 Approving a study invitation
    5.10 Rejecting a study invitation
    5.11 Postponing the approval/rejection of a study invitation
6. Logging out

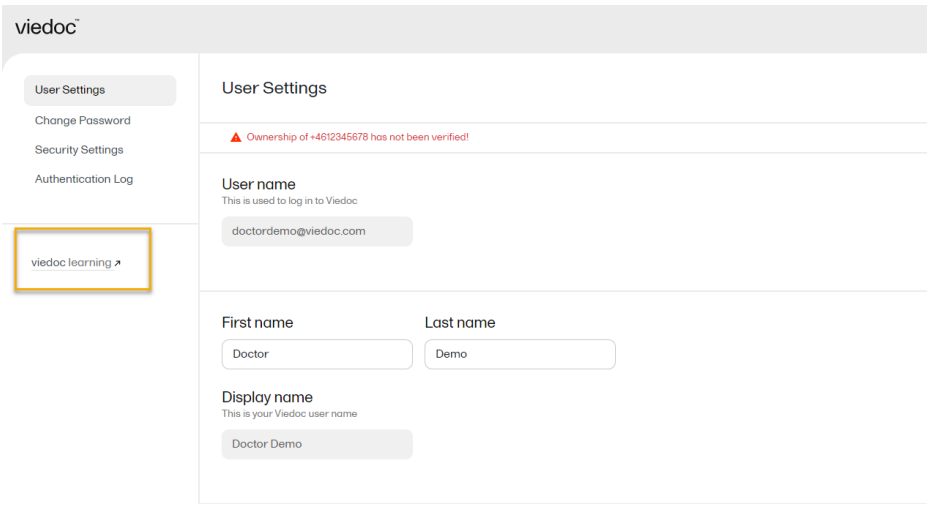
1 Viedoc user account management

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

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



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



2 User settings

Once logged in, you can edit your profile.

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

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

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

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

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

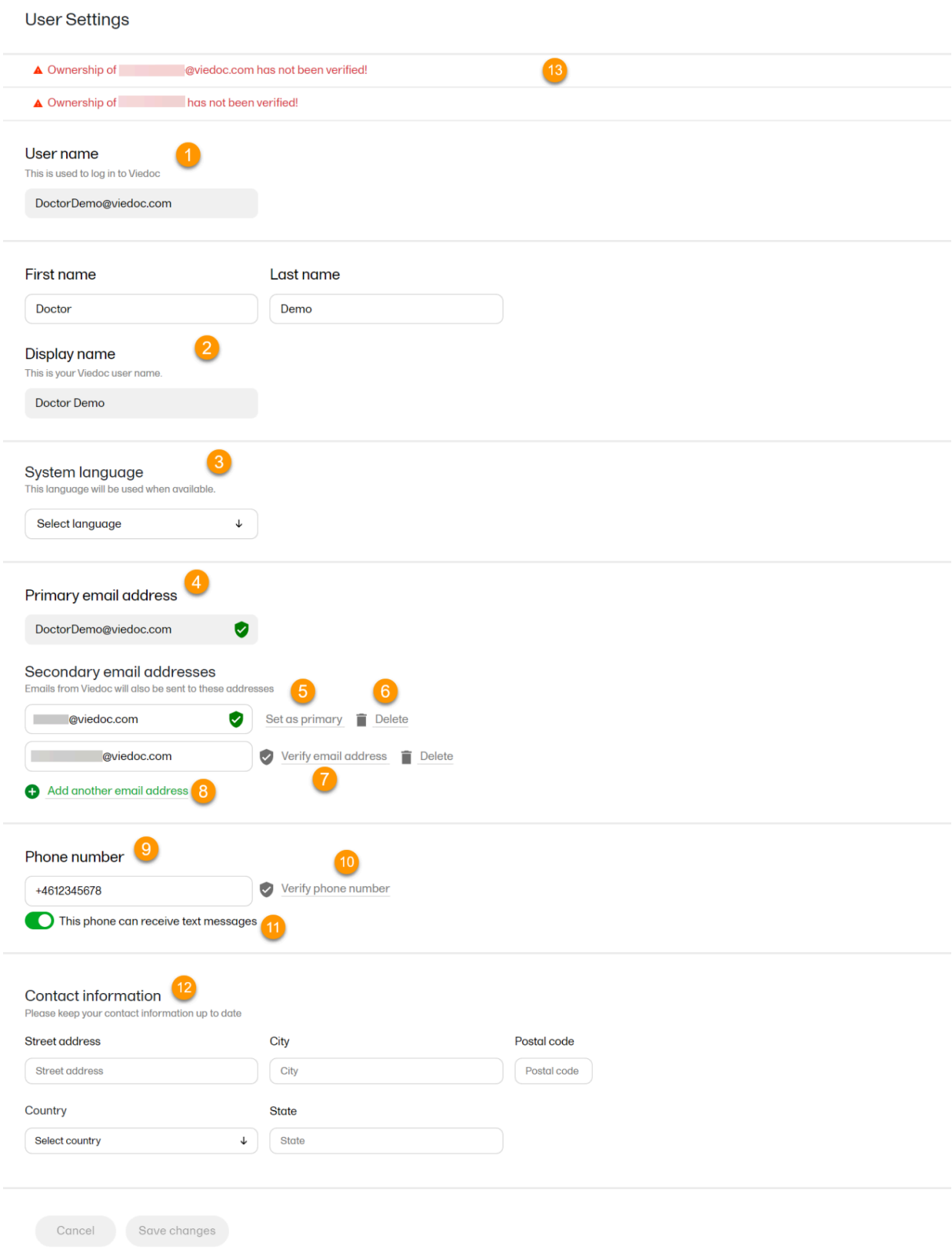
5, 6, 7, 8. **Secondary email addresses** - you can add up to 3 additional email addresses that will be used by Viedoc to send notifications on alerts and trackers as configured in Viedoc Designer. Viedoc alert emails will be sent to all the primary and verified secondary email addresses set up for your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

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

Important!

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

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



2.1 Adding a secondary email address

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

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

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

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

2.2 Verifying a secondary email address

To verify a secondary email address:

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

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

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

2.3 Changing the primary email address

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

1. Select **Set as primary** (5) next to the secondary email address that is to be set as the primary email address.

2. Select **Save changes**. A notification email will be sent to both email addresses to inform you about the change. You will use the new primary email address the next time you log in to Viedoc.

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

2.4 Editing your phone number

To edit your phone number:

1. Enter the number in the **Phone number** field in the format +[CountryCodePhoneNumber] (for example: +46123456789).

2. Select **Save changes**. A notification email will be sent to your primary email address to inform you about the change.

2.5 Verifying your phone number

To verify your phone number:

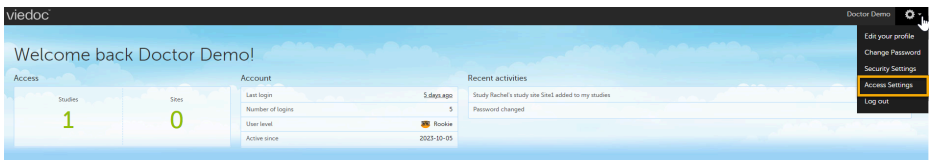
1. Make sure that the phone number is correctly entered and that the **Phone can receive text messages** option is selected.

2. Select the **Verify phone number** link. A six-digit code will be sent as a text message to your phone and a **Verify ownership** dialog box is displayed. It will ask you to provide the code in order to verify the phone number.

3. Enter the code and select **Confirm**. The phone number is now verified.

3 Study access management

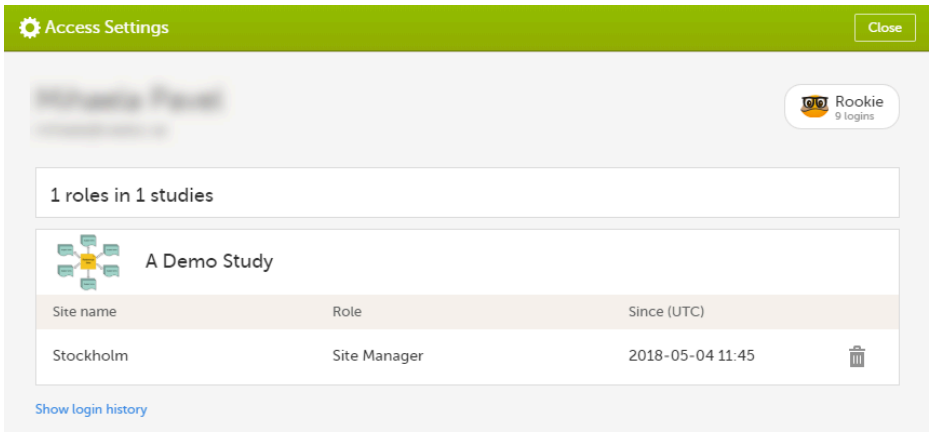
From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.



4 Access settings

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

4.1 Study membership



The following information is provided, grouped by study:

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

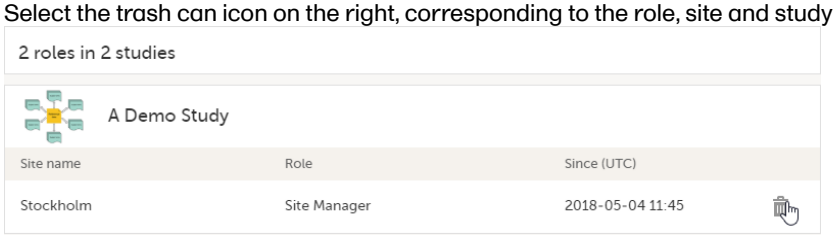
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

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

4.2 Deleting study access

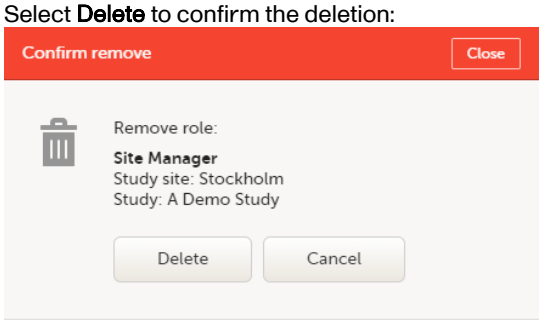
To remove yourself from a certain role within a study:

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



A confirmation dialog is displayed.

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



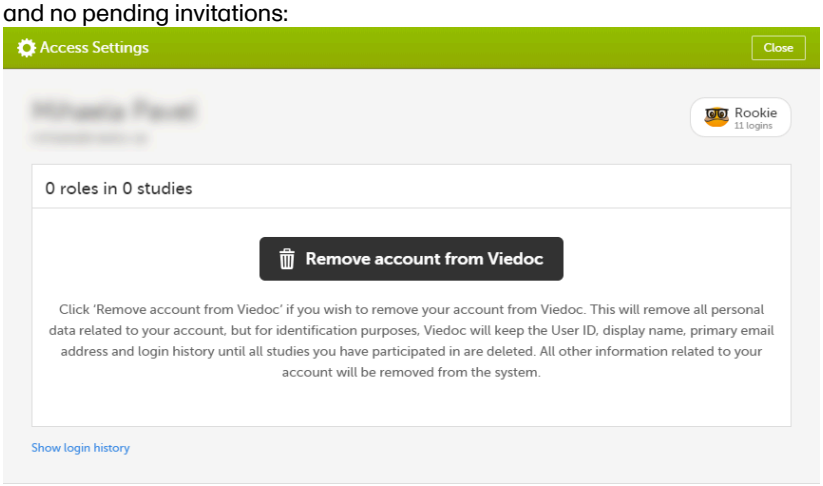
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

4.3 Deleting your Viedoc account

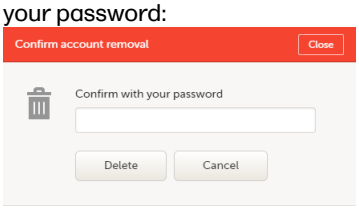
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

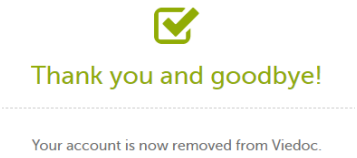
1 Go to **Access Settings**. To be able to remove your account, you should have no roles left in any study and no pending invitations:



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



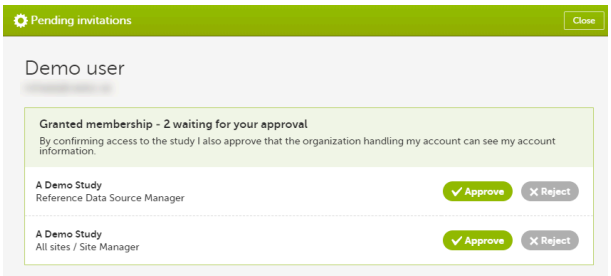
3 Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



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

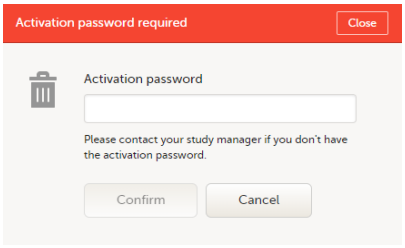
5 Pending invitations

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



5.1 Approving a study invitation

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



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

5.2 Rejecting a study invitation

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

5.3 Postponing the approval/rejection of a study invitation

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

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

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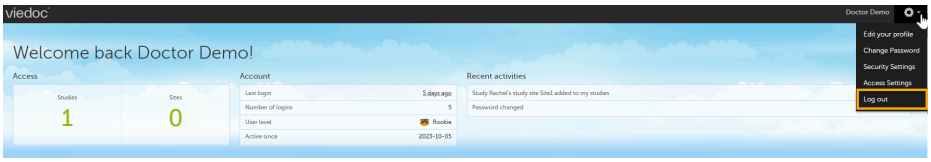
6 Logging out

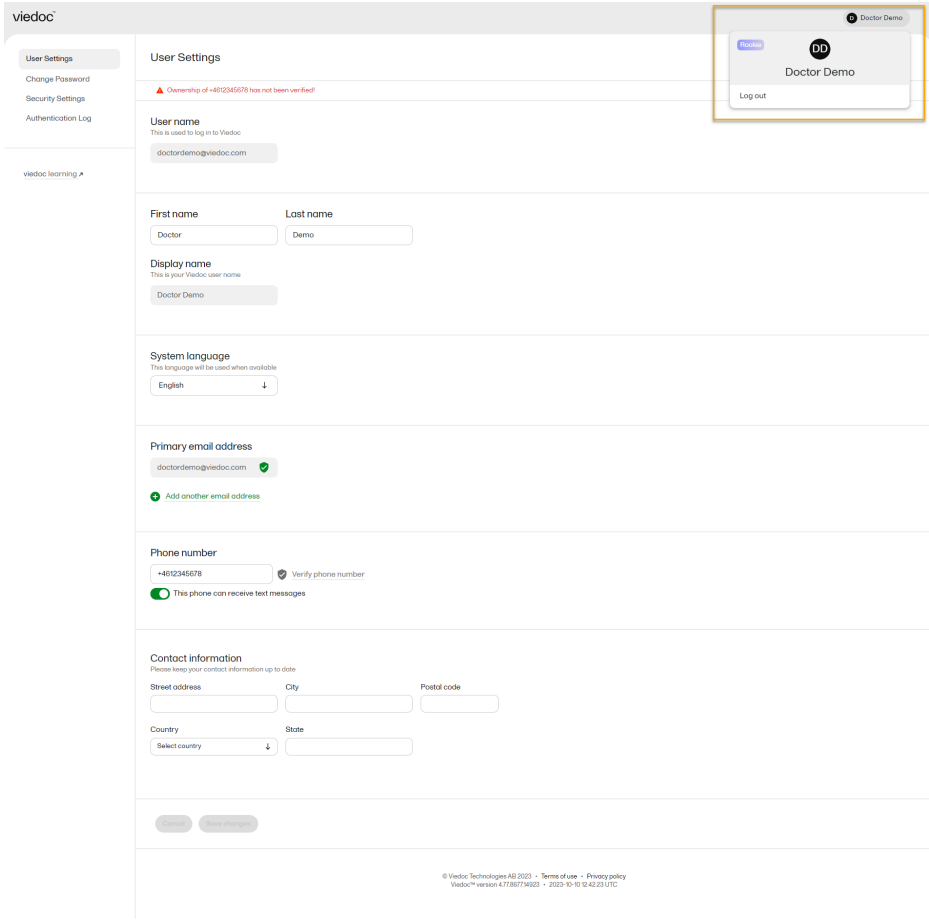
From Viedoc you can log out from different locations:



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

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

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


viedoc
Doctor Demo
User Settings
Change Password
Security Settings
Authentication Log
viedoc learning
User Settings
Ownership of +4612345678 has not been verified!
Rookie
DD
Doctor Demo
Log out
User name
This is used to log in to Viedoc
doctordemo@viedoc.com
First name
Doctor
Last name
Demo
Display name
This is your Viedoc user name
Doctor Demo
System language
This language will be used when available
English
Primary email address
doctordemo@viedoc.com
Add another email address
Phone number
+4612345678
Verify phone number
This phone can receive text messages
Contact information
Please keep your contact information up to date
Street address
City
Postal code
Country
Select country
State
Cancel
Save changes
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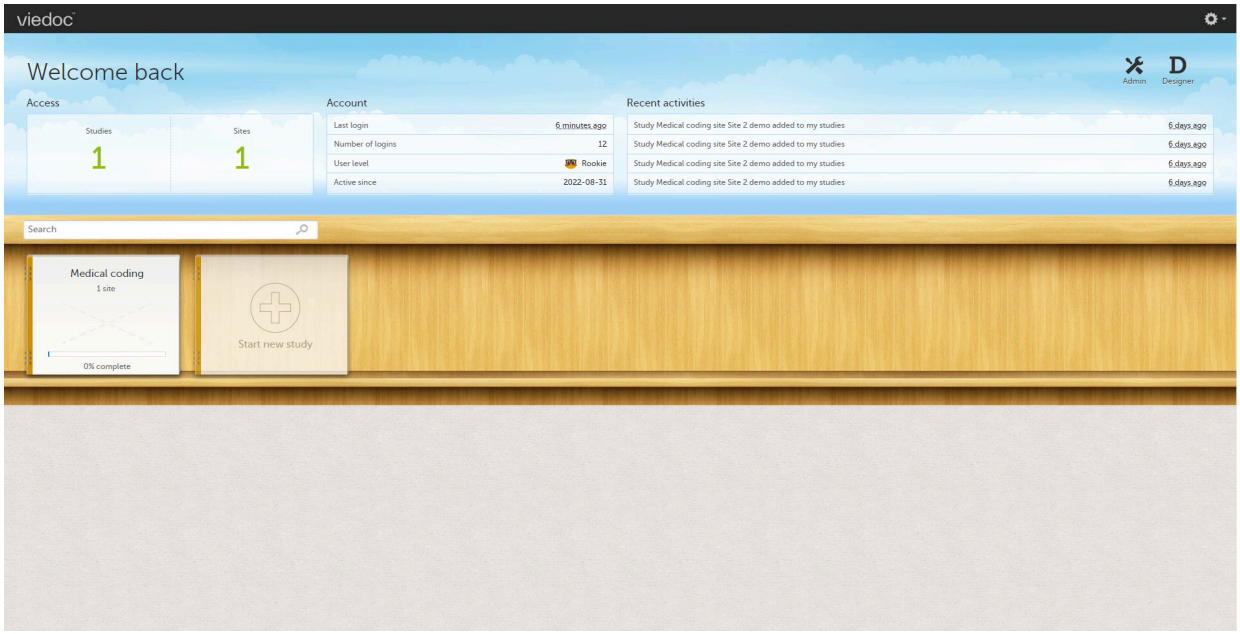
Viedoc™ version 4.77.867714923 • 2023-10-10 12:42:23 UTC

Overview of the landing page

Overview of the landing page

Published by Viedoc System 2024-10-10

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



The landing page provides the following summary information:

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

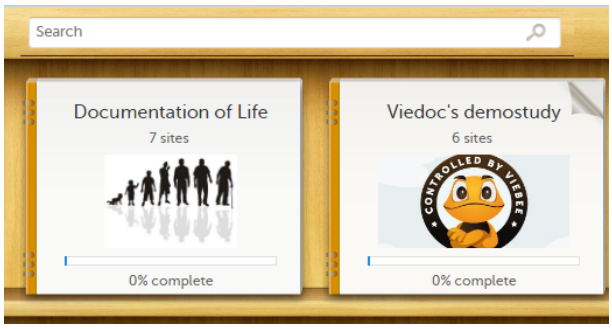
Skill level	Icon	Description
Rookie		≤ 20 logins
Semi-pro		21-100 logins
Pro		101-1000 logins

Skill level	Icon	Description
Legend		> 1000 logins

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

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

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



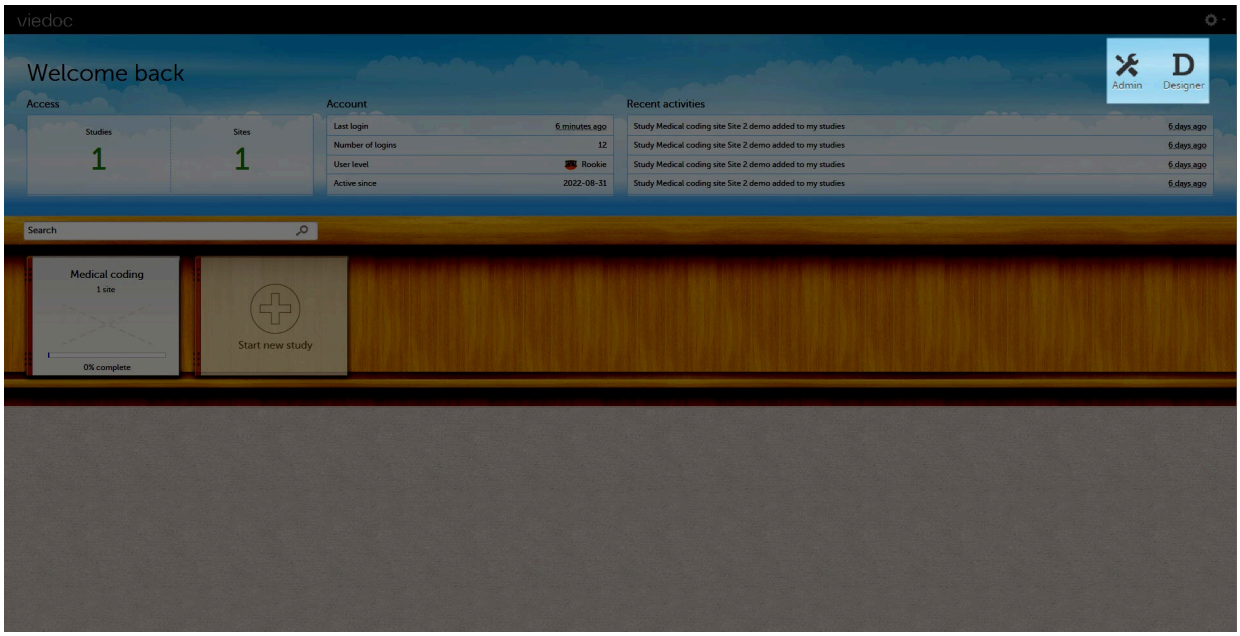
A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

Note!

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

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

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



Approving eCRF changes

Published by Viedoc System 2021-11-24

1. Introduction
2. How a change is flagged and how to approve
3. What happens if I don't do anything?
4. Who can approve?

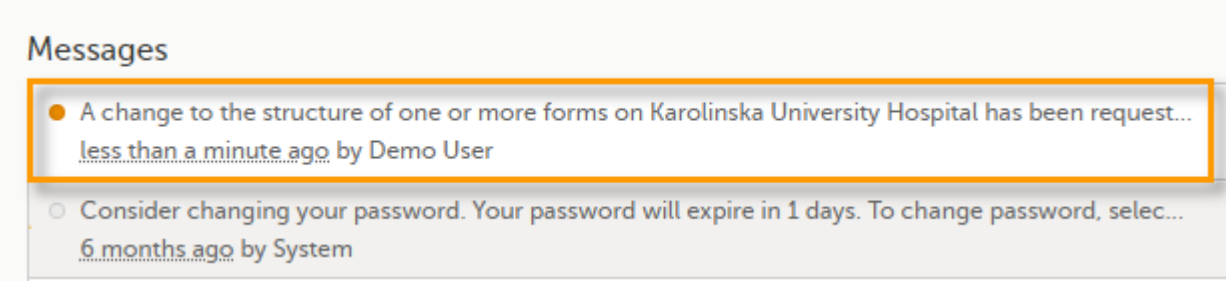
1 Introduction

Changes to the electronic Case Report Form (eCRF) can occur during the course of a study. Normally this is due to an amendment. The definition of an amendment is that it is a change in the protocol from a specific time-point. This means that already saved forms and events should not be affected by the amendment.

Sometimes there is however a need to change the structure/content of already saved forms and events, for example when there is an error in the configuration (a missed question, a spelling error, and so on). For these changes to be applied on already saved data, a confirmation is needed from the site staff.

2 How a change is flagged and how to approve

Whenever there is a change to the structure of the form(s), a message will appear on the study start page, in the Messages pane on the right side, for the site to acknowledge:

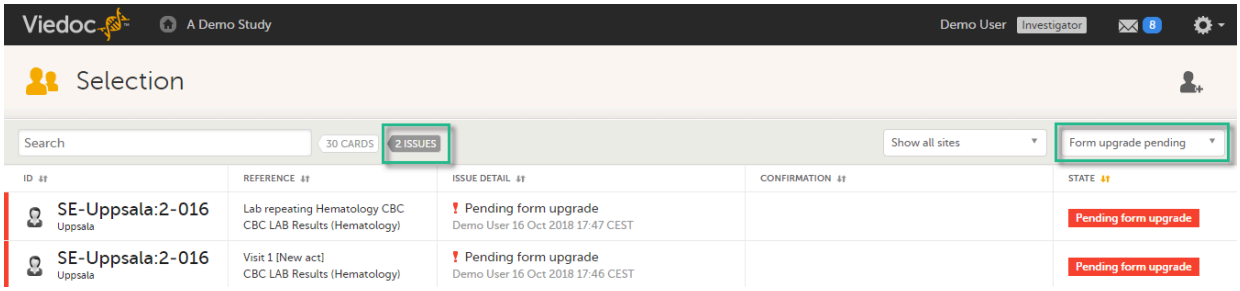


By clicking on the message, a detailed text is shown, that summarizes the changes to the eCRF as entered by the Study Manager.

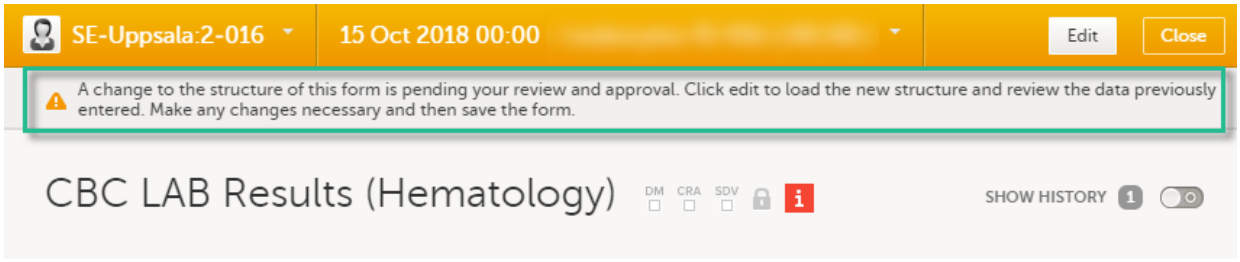
An approval is needed before the saved forms will be upgraded to the new version, for those types of changes that potentially affect data integrity, such as form names, field labels, instructions text, and so on.

The changes that do not affect data integrity, such as field length, number of decimals, and so on, are automatically applied and the confirmation from the site staff is not required.

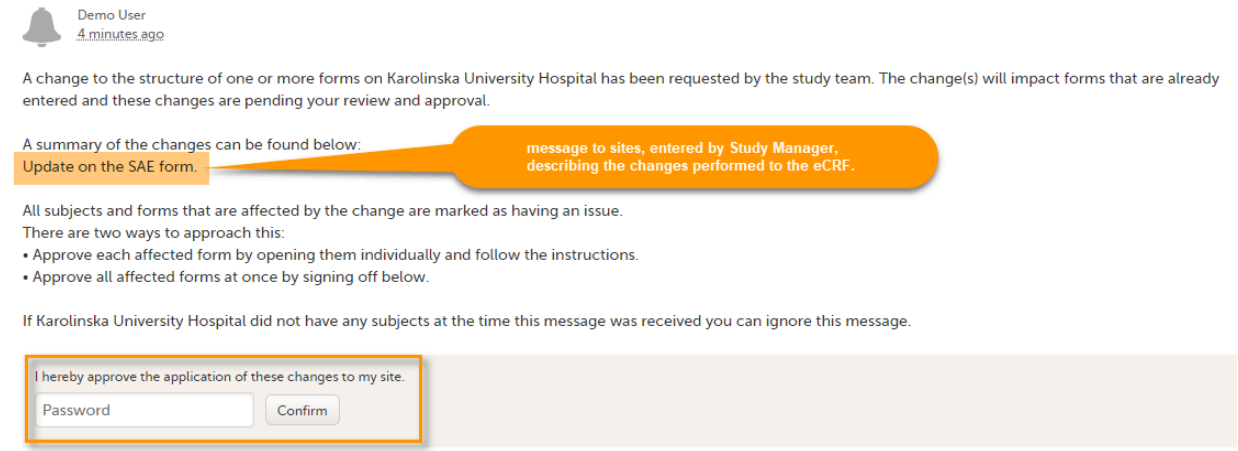
The forms affected by the upgrade are marked with an issue flag (the red **[i]** icon). A summary of the affected forms can be viewed in the Selection page, by selecting the **ISSUES** view and filtering from the drop-down list in the upper right corner by **Form upgrade pending**:



By clicking on each of the forms in the list, the respective form is open, highlighting that a change to the structure of the form was performed and you need to edit the form to load the new structure and review the data:



It is also possible to batch approve all affected forms at once by typing in your password and clicking **Confirm** in the upgrade message pane:



A recommended approach is to manually upgrade a few forms to fully understand the potential impact of the upgrade and then upgrade the rest using the batch approval feature.

> Important! If a change is applied before previous one(s) being approved, then the approval will upgrade affected forms to the latest applied version, regardless which of the upgrades the site user approves, and regardless of the approval method (described above) used.

3 What happens if I don't do anything?

If no confirmation is given:

- The forms will keep the old version, if the changes potentially affect data integrity such as form names, field labels, instructions text, and so on. There will however still be an issue flag indicating that there is a pending upgrade to the form.
- The forms will be automatically updated, if the changes do not affect data integrity such as field length, number of decimals, and so on. No approval from the site staff is required.

4 Who can approve?

Any site user with data edit permission can approve the changes. Once confirmed, the date and name of the user who approved will be displayed in the message.

Important! The upgrade is not being performed for:

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

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

What's new in the latest release?

Published by Viedoc System 2024-12-03

1. What's new in the latest release?

1 What's new in the latest release?

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

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

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

Known limitations

Known limitations

Published by Viedoc System 2025-02-18

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1 Viedoc Clinic

1.1 CSV export

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

1.2 Data export

- The export preview is not working with Safari running on Windows OS or older Safari versions running on Mac OSX.

1.3 Data review

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

verified by SDV, then even hidden fields are included and marked as having been verified by SDV.

1.4 Edit/enter data

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

1.5 File upload

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

1.6 Issues and task

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

1.7 Medical coding

- The Medical coding console is not working with Safari running on Windows OS or older Safari versions running on Mac OS X.
- The MedDRA Chinese translation version 26.0 and onwards has the term 牙开. This term will be displayed as 牙开 in the Viedoc system, as the last character is not supported.

1.8 Metrics

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

1.9 PDF export

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

1.10 Selection page

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

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2 Viedoc Admin

We no longer support SMS notifications in the following countries:

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

2.1 Apply revision

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

2.2 Data import

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

2.3 ODM import/export

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

2.4 User management

- Any of the Organization Administrator, Organization Designer, and Site Manager roles that were removed from a user are not listed in Viedoc Admin, under User Settings > Studies and Roles.
- When sorting studies by group and generating a “User and Roles” or “User Administration Log” report, the Download link is not exposed for the newly generated file until the page is refreshed.
- API configuration: After creating new and editing existing Web API clients, it is not possible to save the setup unless the user system language is set to English or German.

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3 Viedoc Designer

3.1 Alerts

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

3.2 Edit checks

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

3.3 Form and workflow PDF

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

3.4 Item settings

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

should be used for each of the choices within the same item.

3.5 JavaScript

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

3.6 Roles and permissions

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

3.7 Study workflow

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

3.8 Validation of study design

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

3.9 Visibility conditions

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

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4 Viedoc API

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

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5 Viedoc Me

- If additional languages are imported (to be used in Viedoc Me) and after that code lists are combined via “Formats” (for example for SAS export) then the imported languages are lost. The workaround is to import the languages again after the code lists have been combined.
- For Viedoc Me translations, if any of the translated values in the file to be imported is a number, the file import fails without prompting any feedback to the end user. The workaround is to remove the numbers from the columns in the translated file that correspond to the translated content before importing the file in Viedoc Designer (the numeric values will be kept in the original English version and will be displayed as such in the translated Viedoc Me form).
- Viedoc Me does not support forms with form link items.
- The PDF export containing form PDFs submitted from the new Viedoc Me application in Japanese Kanji will not be generated correctly if embedded fonts are included.
- Long option labels for radio buttons and check boxes do not have line breaks.
- Sharing the Viedoc Me access details via text message does not work for studies that are running on the Viedoc China instance.
- In Viedoc Clinic, when activating a Viedoc Me account, there is the option of sharing the access details via a PDF file. This PDF file is translated to the supported system languages only, and not to all supported Viedoc Me languages. This is also applicable to the test email and test text message that are used solely to verify the subject's contact information, and not to verify the selected Viedoc Me language.

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6 Viedoc Logistics

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

7 Viedoc Reports

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

8 Viedoc TMF

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

Glossary

Glossary

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

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

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

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

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

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

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

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

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

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

How to prepare for a regulatory inspection

Published by Viedoc System 2024-10-10

1. Introduction
2. Viedoc Inspection Readiness Packet
    2.1 Documents included in VIRP:
    2.2 Other resources
3. Areas of responsibility
    3.3 Viedoc responsibility
    3.4 Sponsor/CRO responsibility
4. What to do on the day of inspection
    4.5 Viedoc Designer
    4.6 Viedoc Logistics
    4.7 Viedoc Admin
    4.8 Viedoc eTMF
    4.9 Viedoc Clinic
5. Footnotes

1 Introduction

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

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

2 Viedoc Inspection Readiness Packet

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

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

2.1 Documents included in VIRP:

- User Requirements Specification describing the epics and features, and listing the user stories included in the release
- Traceability Matrix detailing the testing performed for every requirement in the URS
- Validation summary report describing the validation activities performed for this release, and their result
- Release Notes describing the additions to Viedoc in the release
- Release Certificate verifying that we have followed our documented procedures during the implementation and associated activities for the release
- EDC Management Sheet for submissions to the PMDA
- Clinical Trial Cloud System Checklist

- Viedoc Impact Assessment documenting at a feature level the risks and potential consequences arising from the release of new and updated features in the release
- Acknowledgement Form describing what you need to review, and containing room for your signature as evidence that you have completed your review
- Table of Contents of applicable SOPs used by Viedoc Technologies in the production of this release
- An introduction describing the contents of the Viedoc Inspection Readiness Packet (VIRP)

2.2 Other resources

- eLearning: Viedoc also provides an eLearning lesson - Inspection Readiness when Working in Viedoc, which describes in detail the information needed step-by-step, as well as having additional information about potential pitfalls, what happens when new functionality is introduced in a release, about backward compatibility and more.

- The Viedoc Release Binder. We also store a snapshot of the information in our development environment for each release. This information is included in the Release Binder for that release which is stored in SharePoint and can be shared with inspectors either in a webinar or onsite.

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3 Areas of responsibility

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

3.1 Viedoc responsibility

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

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

- The new release must be 100% backward compatible.

- Any new functionality in the release shall be disabled for ongoing studies by default.

3.2 Sponsor/CRO responsibility

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

- It is a Sponsor/CRO responsibility to validate the study configuration and confirm that the study has been set up in accordance with the study protocol. This validation should be documented.

- The different versions of systems used during the study and a synopsis of the differences between the versions should be stored as part of the study record in the sponsor (e)TMF.

- A risk-based assessment documenting the decision to rely on VIRP should be carried out.

- A checklist of the required functions (such as randomization module, patient ePRO module, coding module) for your trial on our epic[1] level, and where necessary, individual features[1].

---

4 What to do on the day of inspection

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

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

4.1 Viedoc Designer

This step is performed by the Designer.

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

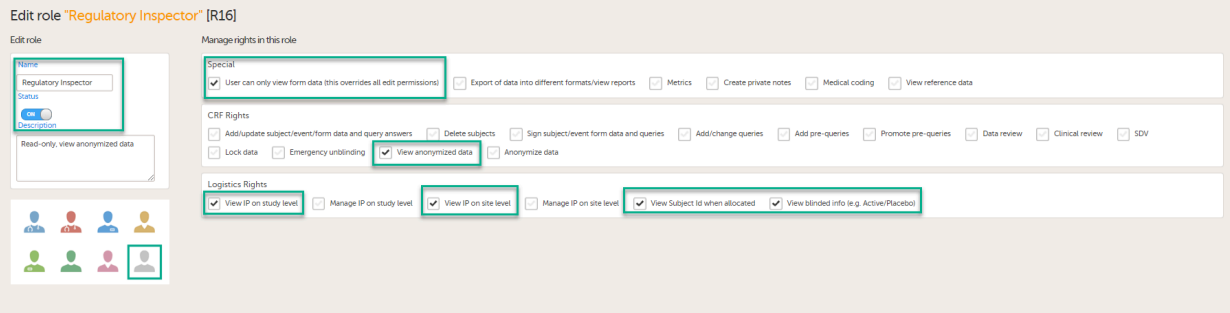
To allow the Regulatory Inspector access to study data, their role must be configured with Read-only for form data and View anonymized data and blinded data permissions on the **Roles** page.

4.2 Viedoc Logistics

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

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

See the image below and Configuring roles.



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

4.3 Viedoc Admin

These steps are performed by the Study manager.

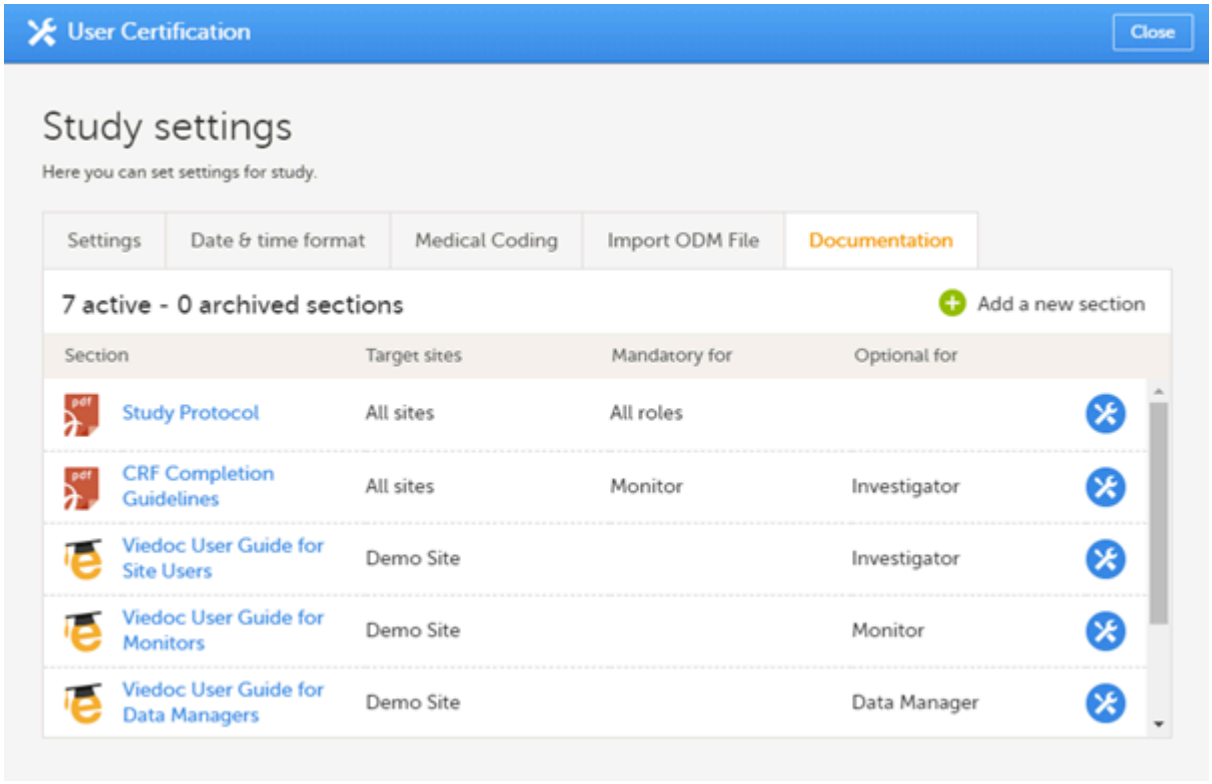
In Viedoc Admin, the study manager invites the Regulatory Inspector to the study for all sites. See Managing users.

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

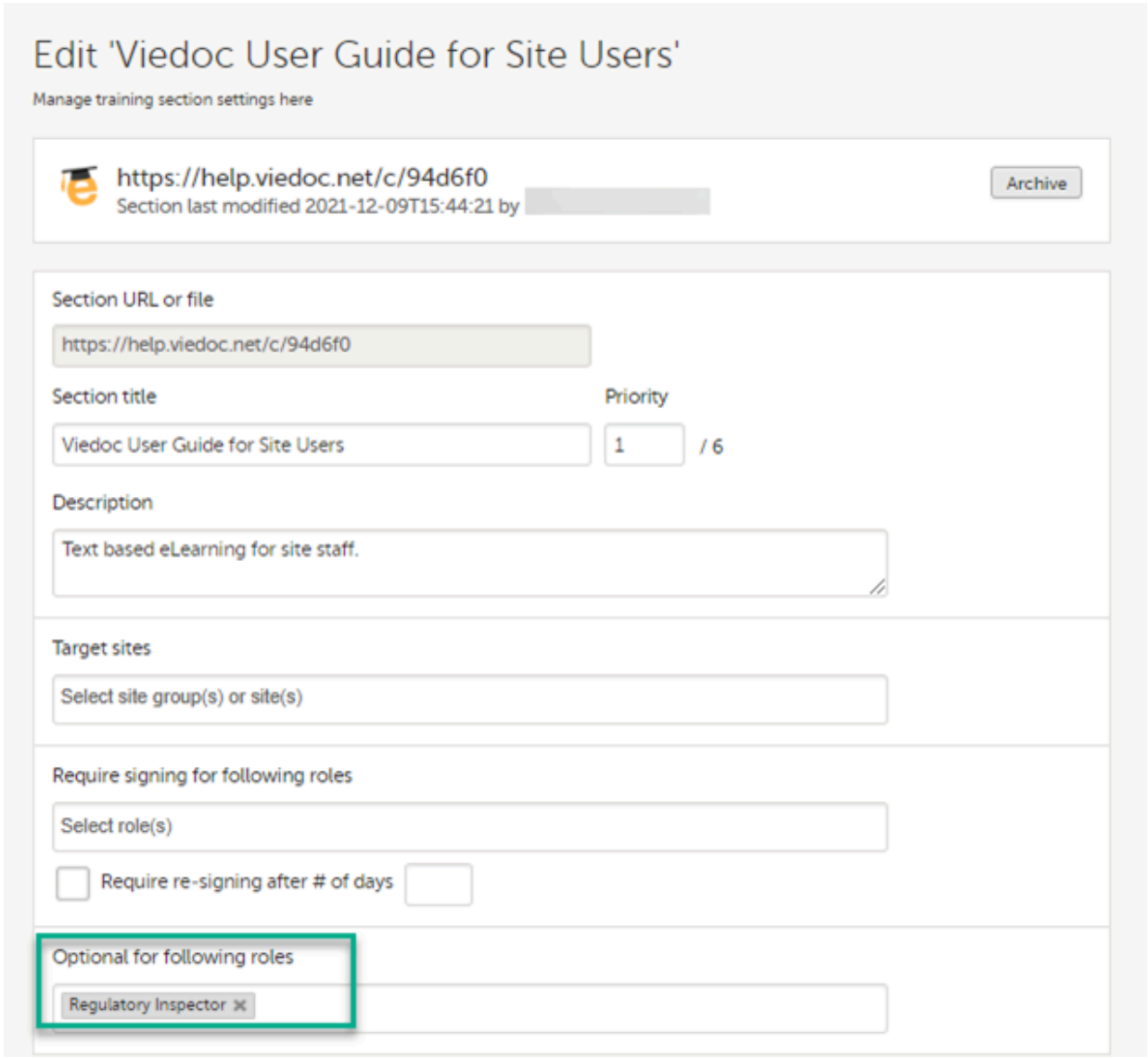
Note! This role is only used for randomized studies, when it is necessary to have control over who has access to and can manage the randomization lists.

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

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



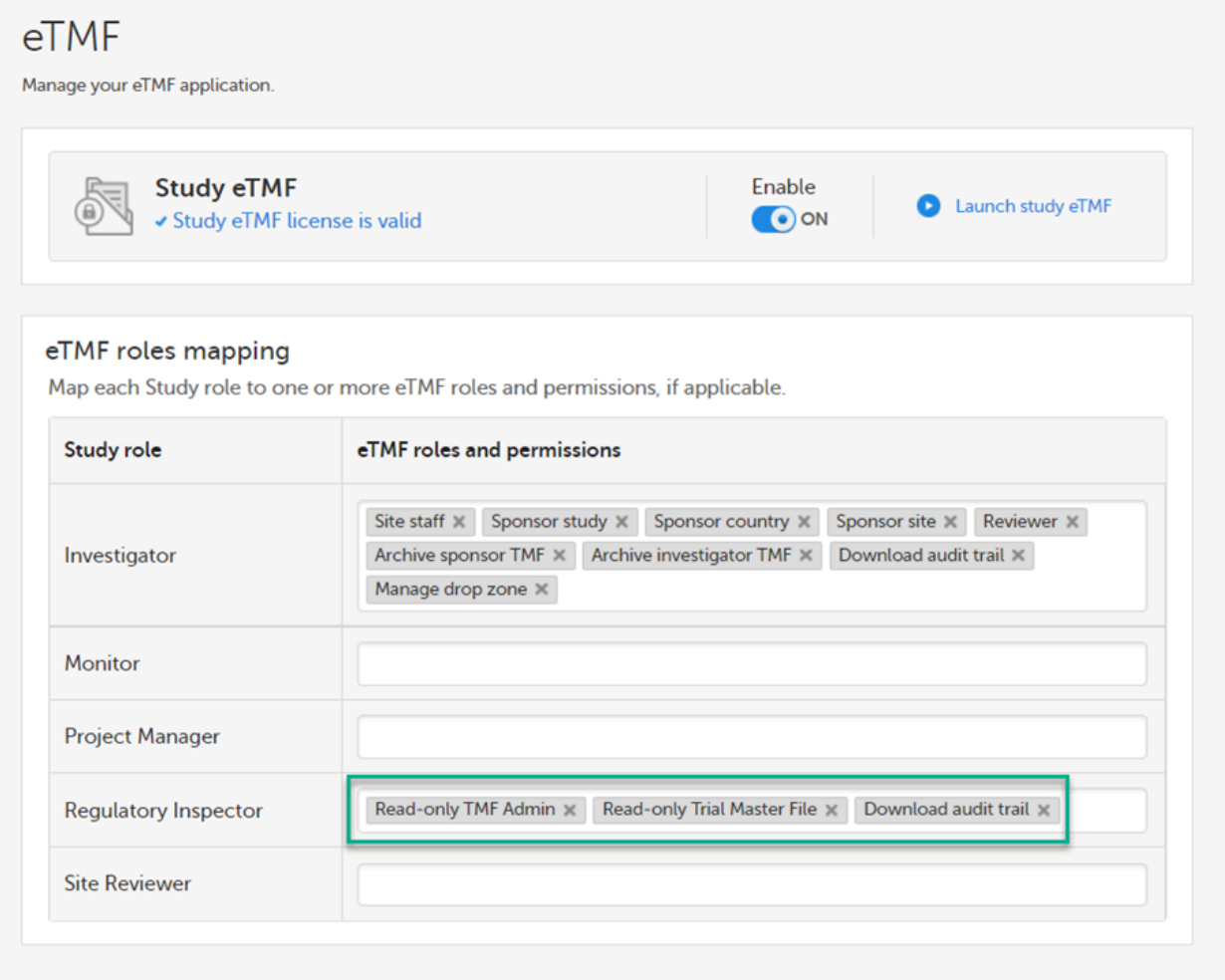
The Regulatory Inspector role should be granted access to the relevant eLearning documentation on the Study settings page.



See the Viedoc Admin User Guide Setting up user documentation and training

4.4 Viedoc eTMF

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



See Viedoc User Guide for eTMF Managers - Managing Viedoc eTMF - Mapping user roles.

4.5 Viedoc Clinic

These steps are performed by the Regulatory Inspector.

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

The inspector can now launch Viedoc Clinic and the Viedoc eTMF from the landing page.

5 Footnotes

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

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

Quick guide for preparing for regulatory inspections

Quick guide for preparing for regulatory inspections

Published by Viedoc System 2023-04-25

1. Configure the role
2. Configure Logistics permissions if used
3. Invite a Regulatory Inspector
4. Map eTMF permissions if used
5. Launch Viedoc

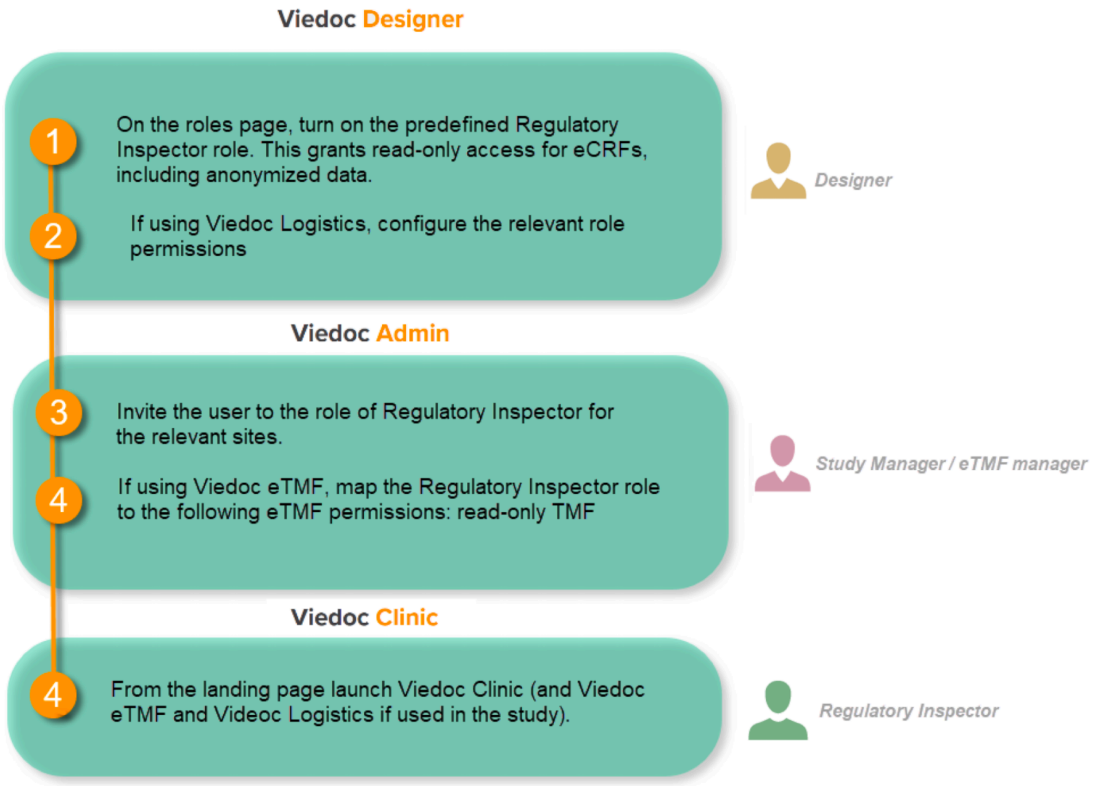
Thorough preparation for inspection of the EDC system used in a clinical trial is of great importance. The regulatory authorities see the EDC system used for a clinical trial as an important computerized system with regards to both patient safety and data integrity.

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

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

You can read about how to download the Viedoc Inspection Readiness Packet here: VIRP

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



1 Configure the role

This step is performed by the Designer.

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

Note!

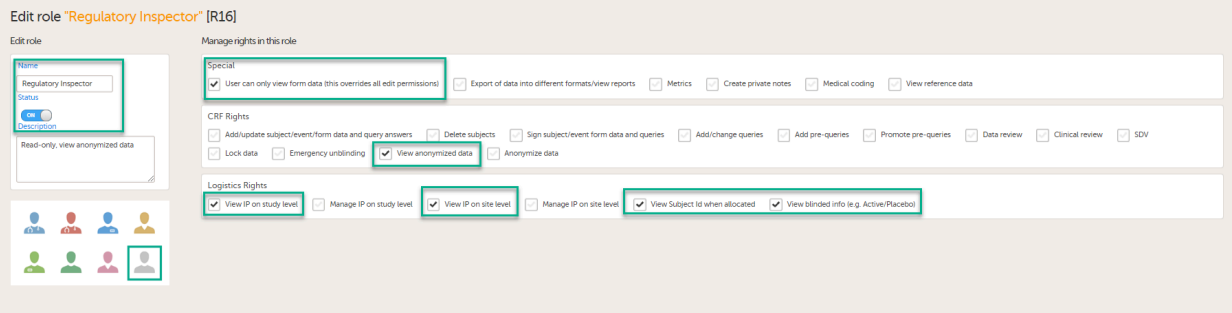
- The role of Regulatory Inspector must be turned on in Designer.
- By default, a set of predefined roles is set up by the system, and can be modified for your study. Permissions for the role of Regulatory Inspector should be set to READ-ONLY access to all parts of the system, including the eTMF (if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

2 Configure Logistics permissions if used

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

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

See Configuring roles.



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

3 Invite a Regulatory Inspector

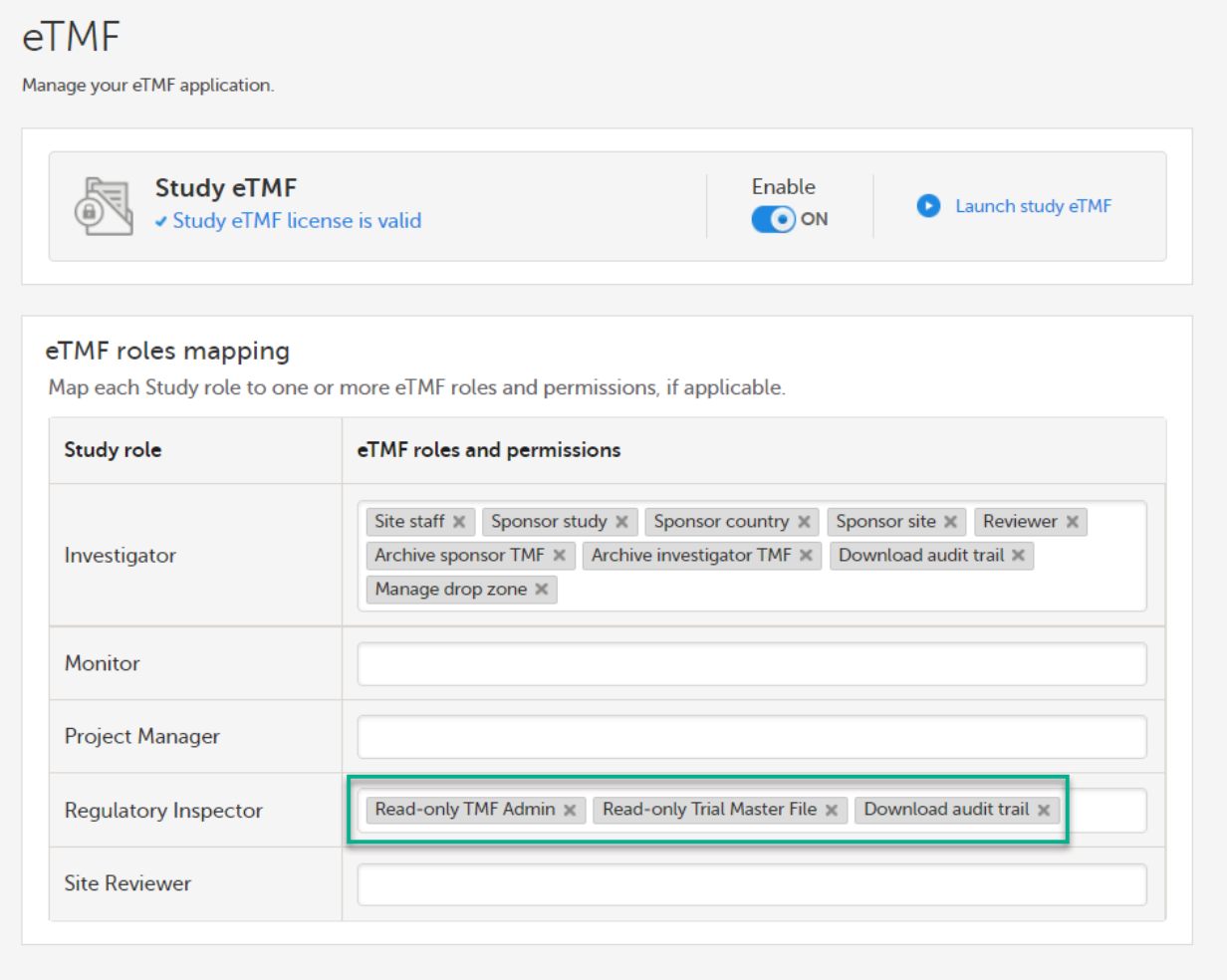
This step is performed by the Study Manager.

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

See Managing users.

4 Map eTMF permissions if used

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



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

5 Launch Viedoc

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

This step is performed by the Regulatory Inspector.

Study start page

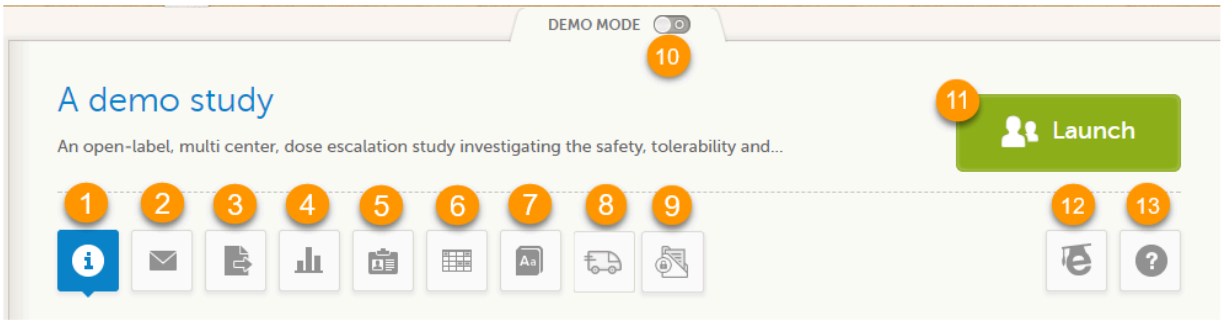
Study start page

Published by Viedoc System 2024-12-03

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

1 Introduction

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



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

Notes!

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

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

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

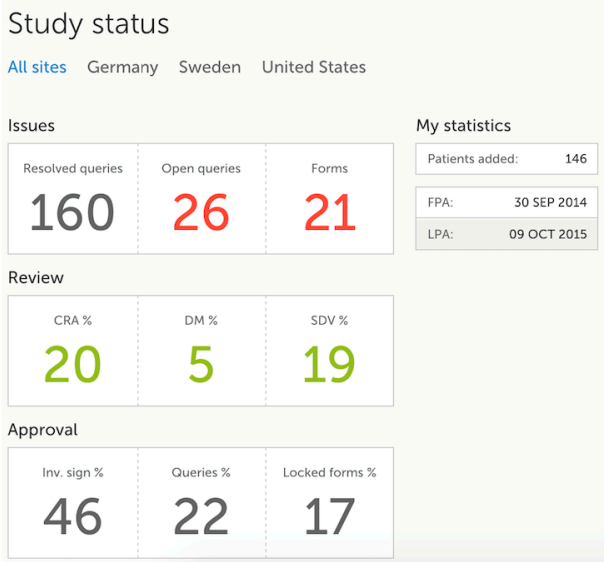
  > Important! All the mandatory materials must be "Read & Understood" and signed before you can launch the study. You might be able to launch the study in demo mode, depending on the study settings performed by the Study Manager.

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

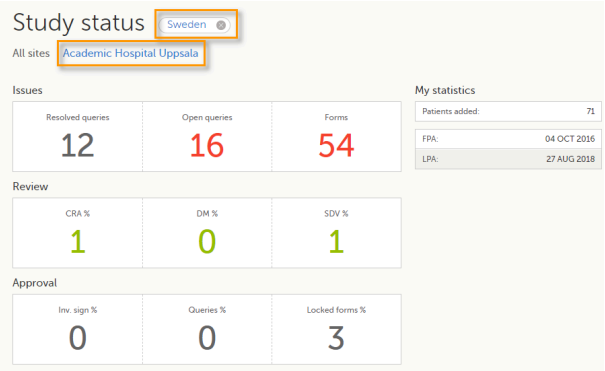
---

2 Study status

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



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



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

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

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

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

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

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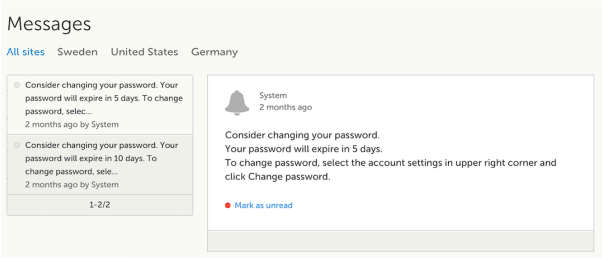
3 Messages

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.



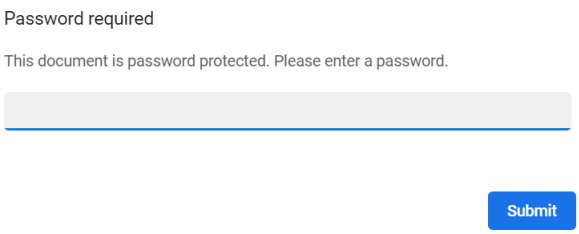
3.1 Alert messages

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

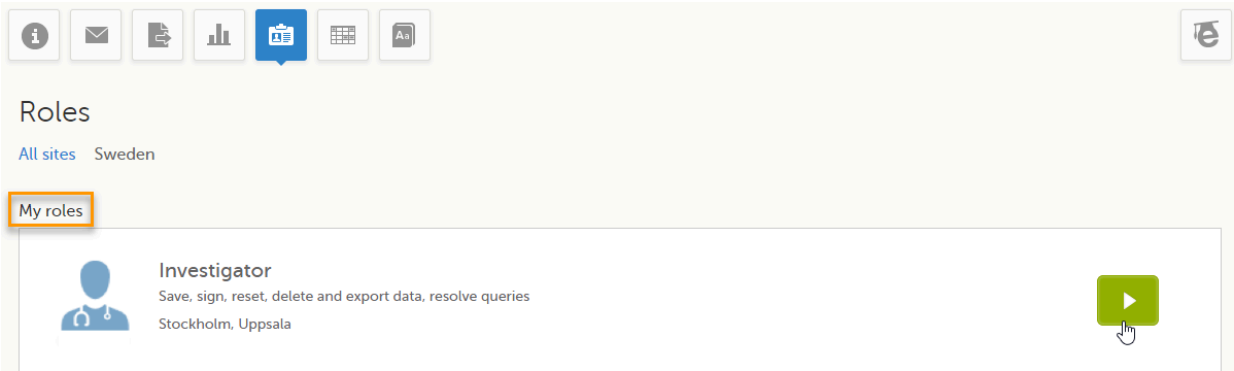
Note! The Roles page is only available for users with special permission to view roles, as per the study design.

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:



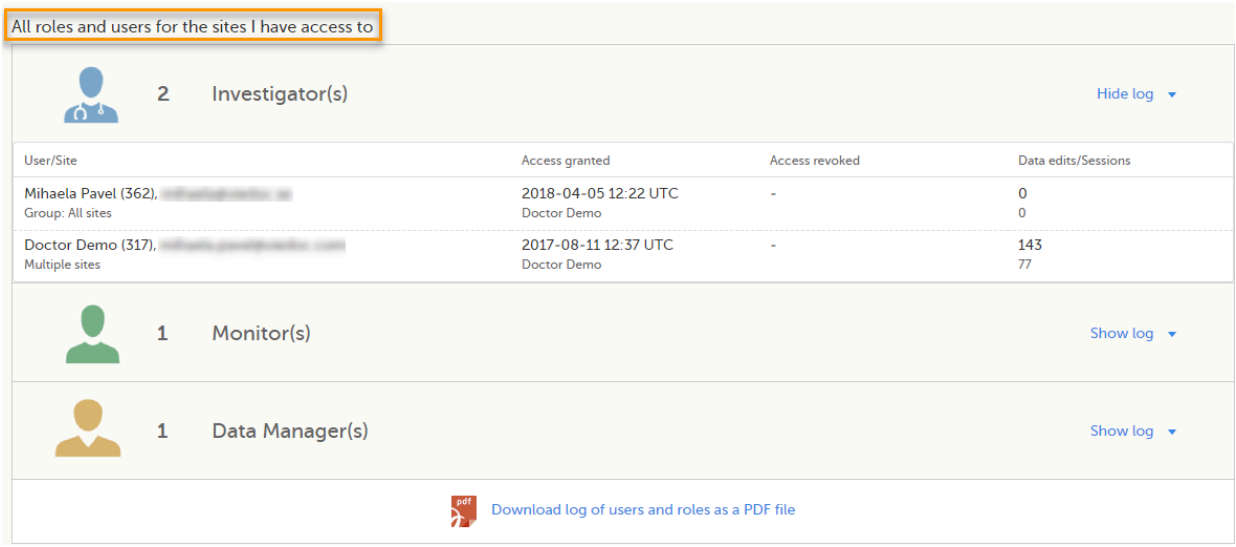
The following information is displayed (with *examples*):

- 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).

6.2.1.2 User administration log in Excel format

The User administration log contains the following sheets:

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

---

7 Reference data

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

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

---

8 Medical coding

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

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

For more information about medical coding, see Medical coding.

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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.

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10 Viedoc eTMF

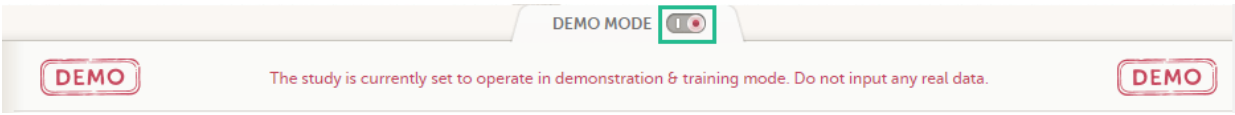
Viedoc eTMF is a digital repository for capturing, managing, sharing, and storing essential documents.

For more information about Viedoc eTMF, see Viedoc eTMF User Guide.

---

11 Demo mode

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



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

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

See also the video tutorial Activate demo mode.

---

12 Launch

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

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

---

13 eLearning / Documentation & Training

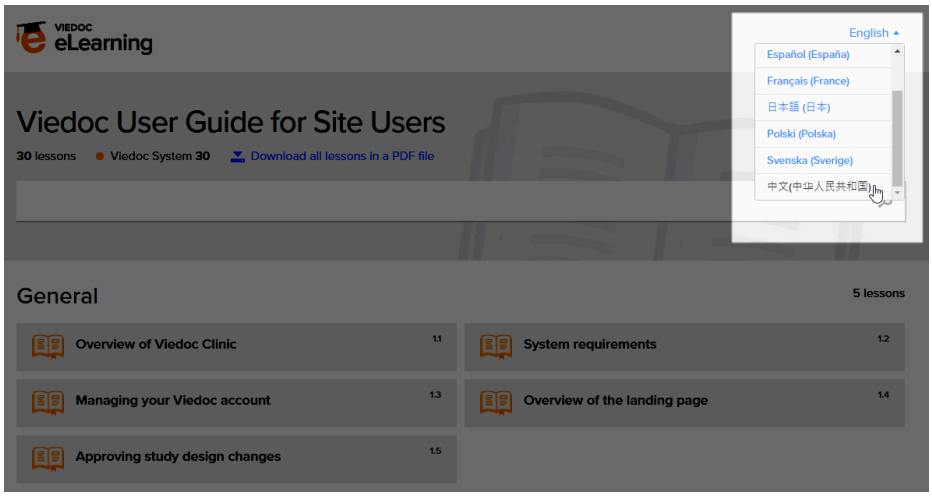
If you have mandatory documentation pending to be read and signed, this is the first page that is displayed when you access the study.

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

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

- English
- Chinese
- Japanese

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



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

---

14 Support

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

Back to top of page

Documentation and Training

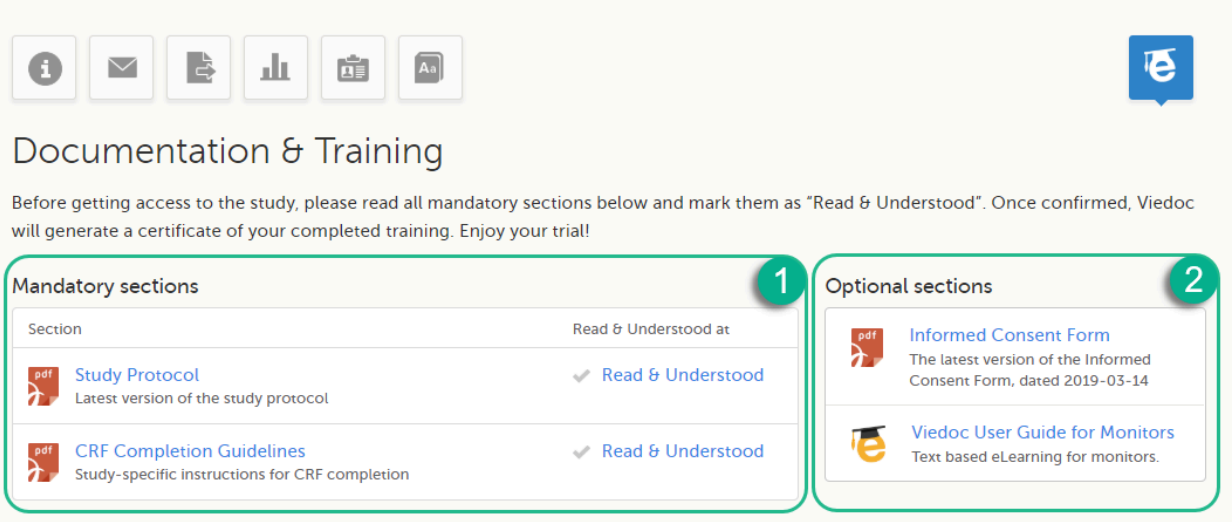
Documentation & Training

Published by Viedoc System 2020-06-04

1. Introduction
2. Becoming a certified user
3. Downloading your user certificate

1 Introduction

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



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

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

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

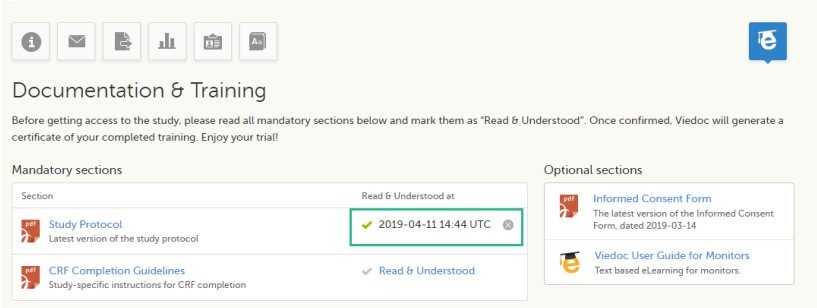
2. **Optional sections** - contains additional educational and reference materials that you have access to. Simply click on the link to open each of the available documents/links.

2 Becoming a certified user

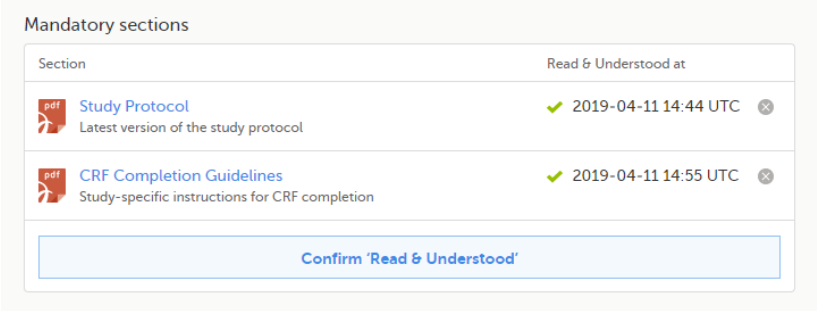
To work within a study for which mandatory training sections were assigned, you need to read, understand and sign all the sections listed as mandatory.

To obtain the user certificate:

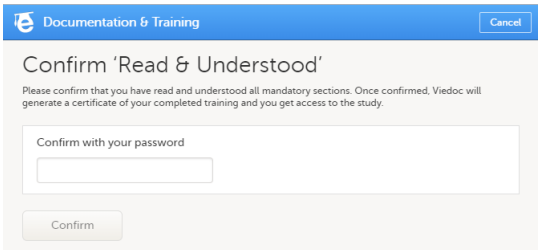
1 Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:



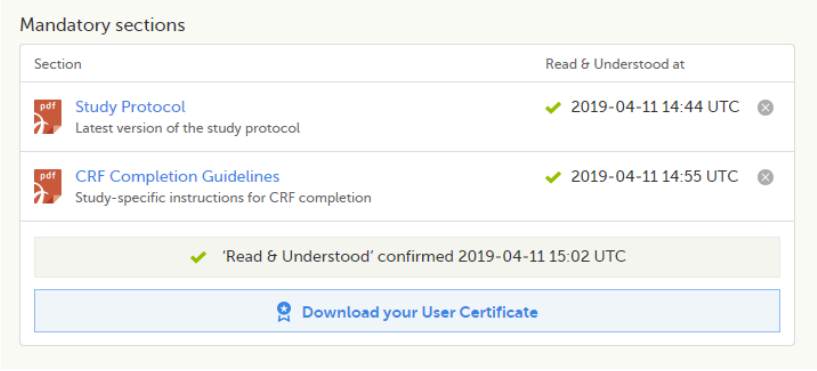
2 Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:



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



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



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

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

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

3 Downloading your user certificate

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

The following information is provided on the certificate:

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

Metrics

Metrics

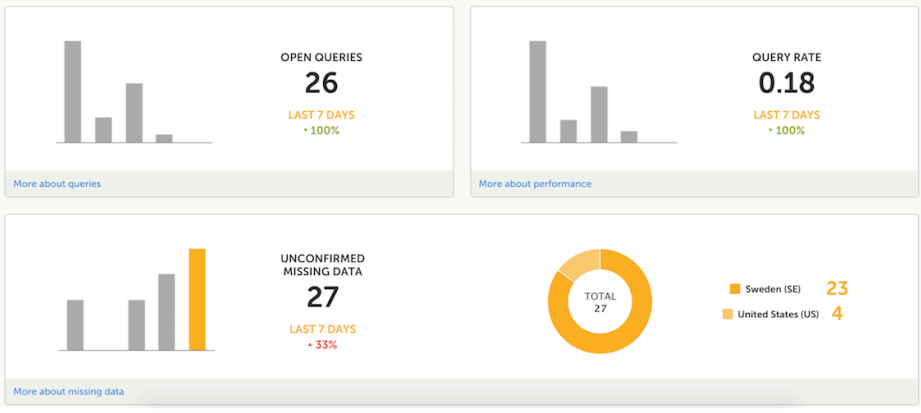
Published by Viedoc System 2022-02-10

1. Metrics overview
    1.1 Viedoc Reports
2. Queries
    2.2 Queries - filter
    2.3 Queries
    2.4 Query state
    2.5 Top 5 events
    2.6 Top 5 forms
    2.7 Top 5 items
    2.8 Top 5 check OIDs
    2.9 Top 5 subjects (raised queries)
    2.10 Save and export
3. Performance
    3.11 Review status
    3.12 Subjects
    3.13 Queries
    3.14 Missing data
    3.15 Other
    3.16 Save and export
4. Missing data
    4.17 Top 5 events
    4.18 Top 5 forms
    4.19 Top 5 items
    4.20 Subjects with confirmed missing data
    4.21 Subjects with unconfirmed missing data
    4.22 Save and export

1 Metrics overview

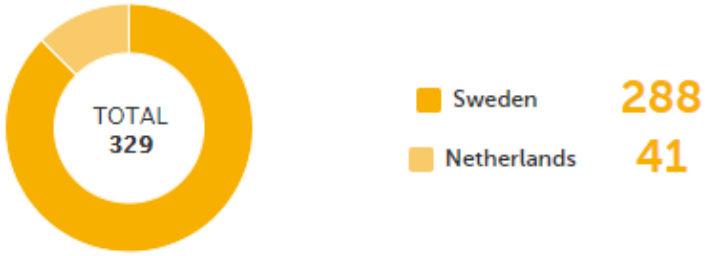
Note! As a Viedoc Clinic user, you need a special permission to view the metrics.

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

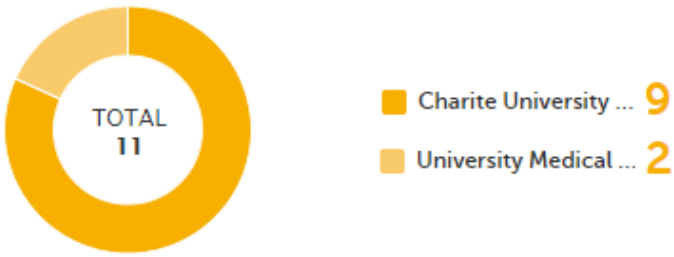


The metrics graphs depict:

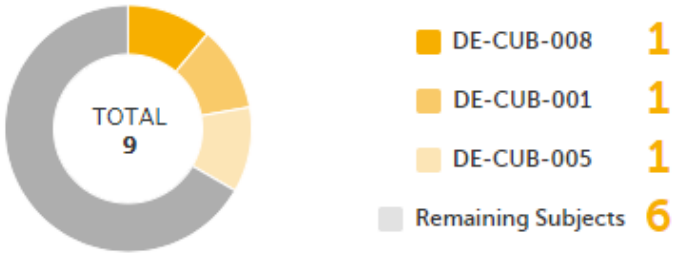
- **Open queries** - the number of currently open (not resolved) queries.
  A column graph shows five bars indicating the progress of posted queries during the last five weeks, where each bar indicates a seven day period.
  The latest seven days including today are shown in orange and the previous weeks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



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



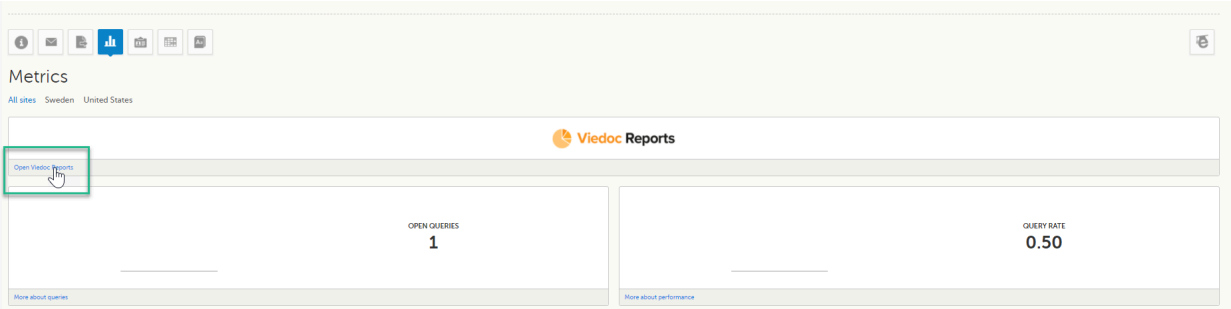
  - **Site** - distribution over those subjects with most unconfirmed missing data (in orange) out of the total number of subjects with unconfirmed missing data within the selected site (in gray):



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

1.1 Viedoc Reports

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



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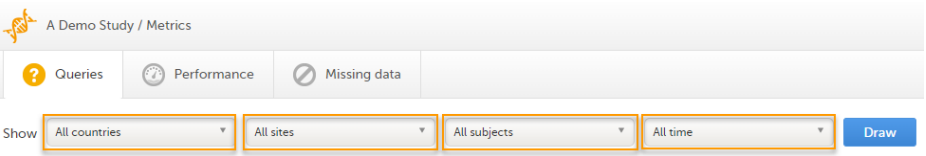
2 Queries

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

For detailed information about the query process in Viedoc, see Queries overview.

2.1 Queries - filter

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



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

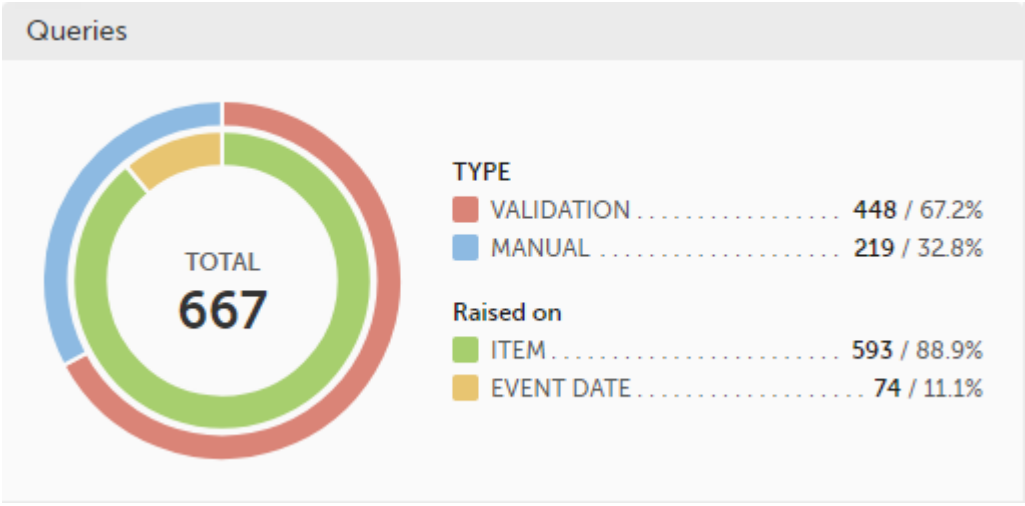
Based on the selected filter, the following information is provided:

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

2.2 Queries

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

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



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

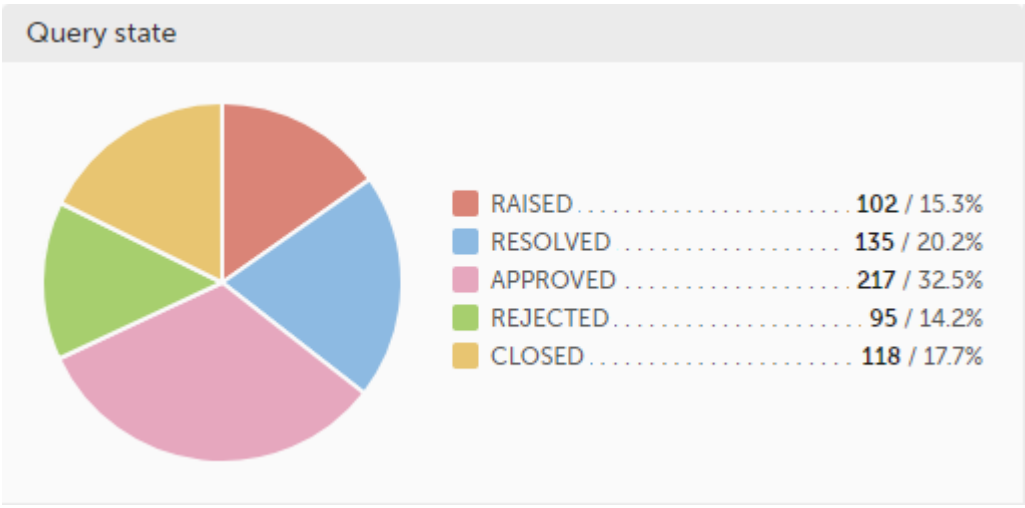
Notel

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

For detailed information about query states and pro, see Queries overview.

2.3 Query state

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

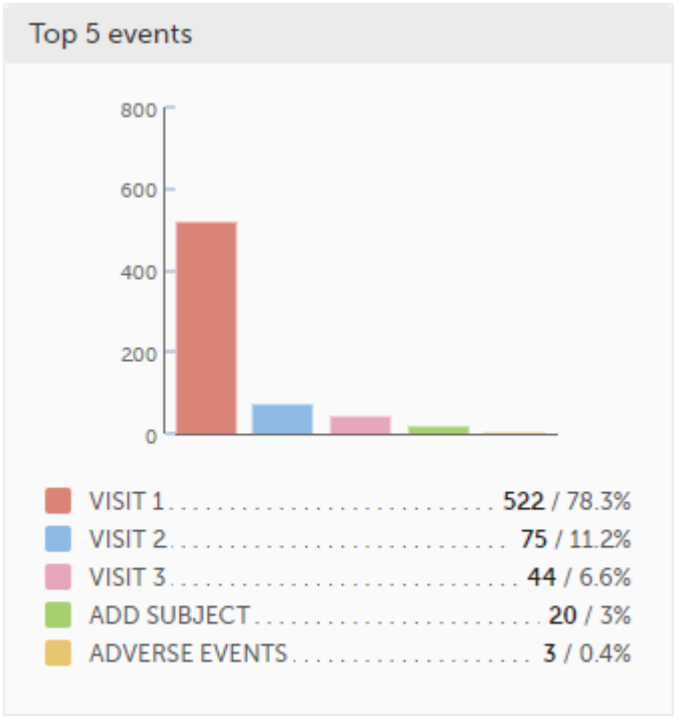


- **RAISED** - number of raised queries / percentage of raised queries out of total number of queries
- **RESOLVED** - number of resolved queries / percentage of resolved queries out of total number of queries
- **APPROVED** - number of approved queries / percentage of approved queries out of total number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

For detailed information about query states and process, see Queries overview.

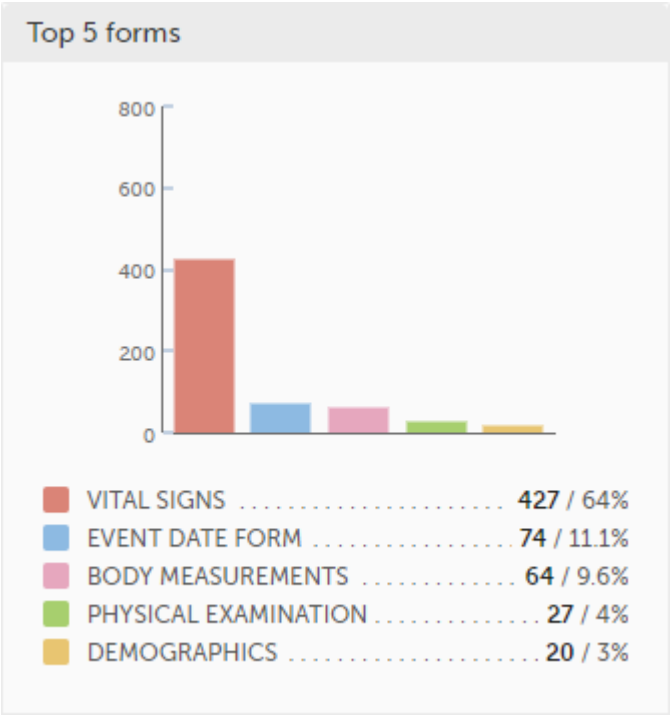
2.4 Top 5 events

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



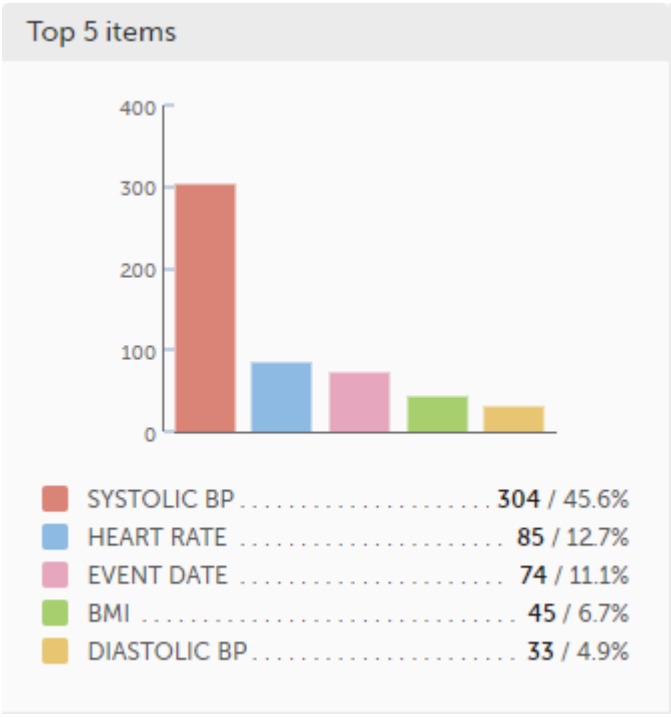
2.5 Top 5 forms

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



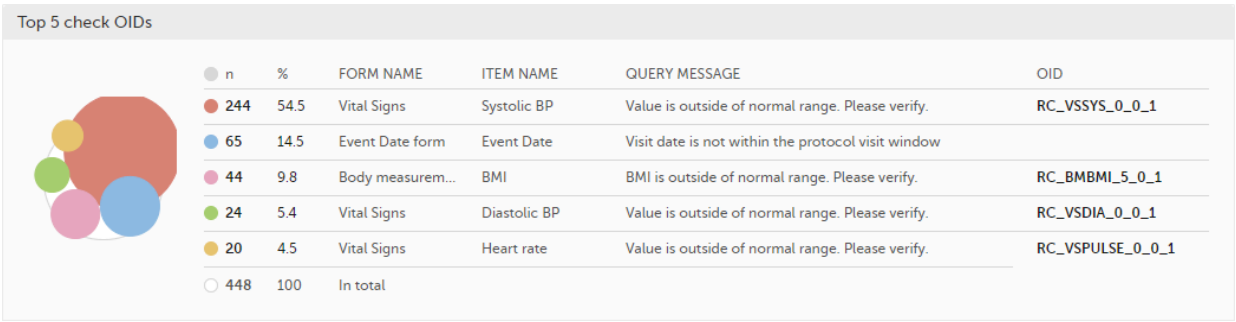
2.6 Top 5 items

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



2.7 Top 5 check OIDs

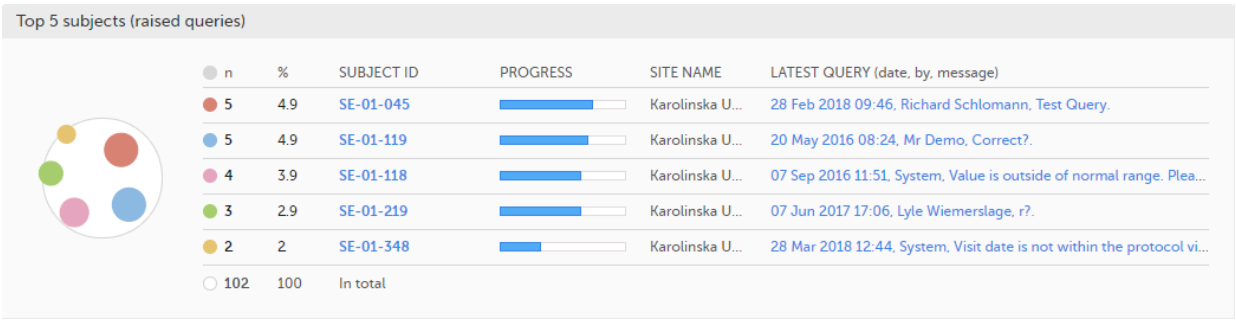
Top 5 check OIDs - top five most triggered edit checks are displayed in a table including the actual number, percentage, Object Identifier (OID), form name as well as the query message.
The last row of the table shows the total number of queries.


Top 5 check OIDs

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

2.8 Top 5 subjects (raised queries)

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


Top 5 subjects (raised queries)

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

For detailed information about query states and process, see Queries overview.

2.9 Save and export

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

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

---

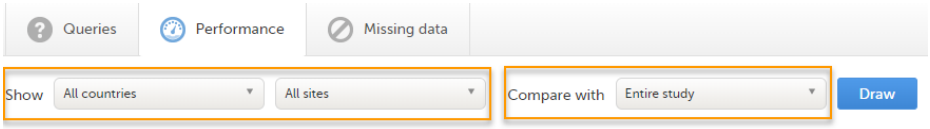
3 Performance

The Performance page allows you to compare data from:

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

With data in one of the following:

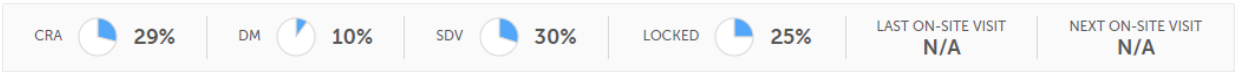
- Entire study (default)
- All sites in selected country
- A particular site in the selected country



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

- Review status
- Subjects
- Queries
- Missing data
- Other
- Save and export

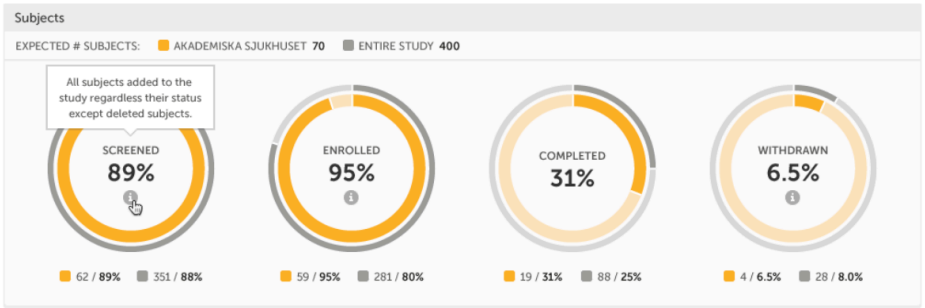
3.1 Review status



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

3.2 Subjects

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



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

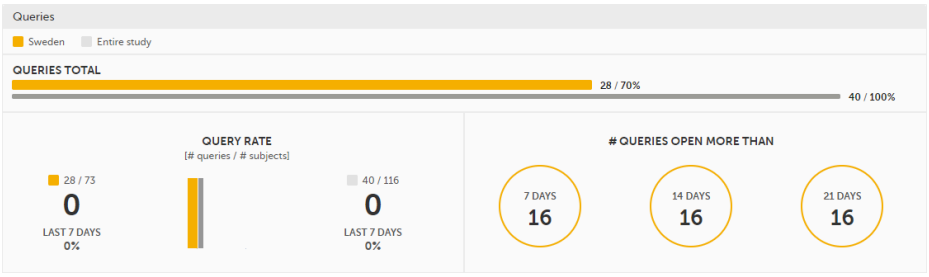
- **Screened** - the number of subjects screened:
  - at selected site(s) - in orange
  - at site(s) to compare to - in gray

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

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

3.3 Queries

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

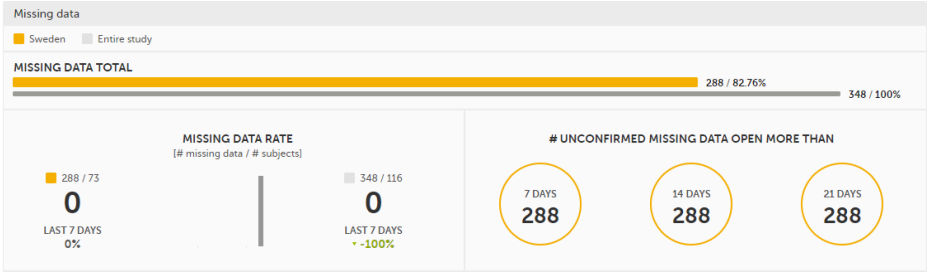


- **Queries total** - the total number of queries on selected site(s) (in orange) and compared site(s) (in gray) are shown both in % and in actual numbers.
- **Query rate** - total number of raised queries out of total number of subjects. The column graph consists of 5 bars indicating the progress of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

For detailed information about query states and process, see Queries overview.

3.4 Missing data

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

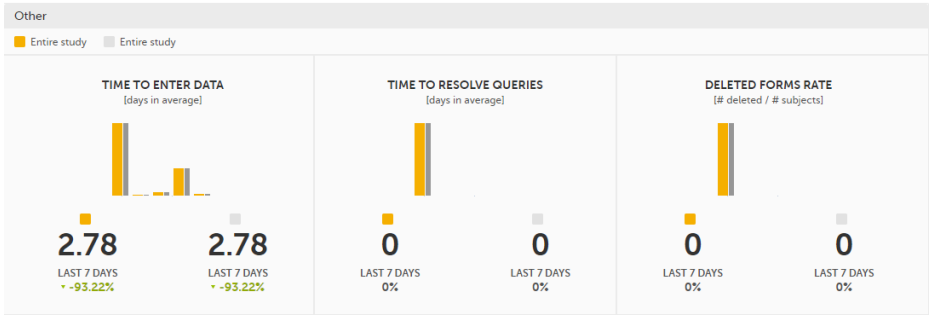


- **Missing data total -** Total number of missing data on selected site(s) (in orange) and compared site(s) (in gray) both numeric and percentage out of all missing data in the entire study. Hidden forms/items are not included in the count.

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

3.5 Other

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



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

3.6 Save and export

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

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

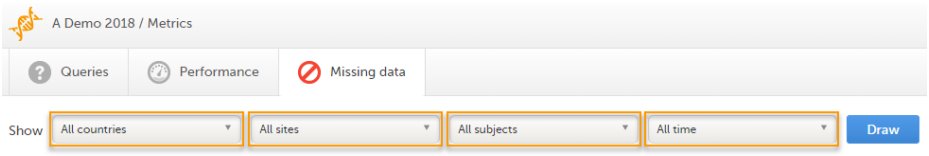
- **Send by email** to your primary email address, a PDF file with all the metrics data as displayed on the screen.

---

4 Missing data

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

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



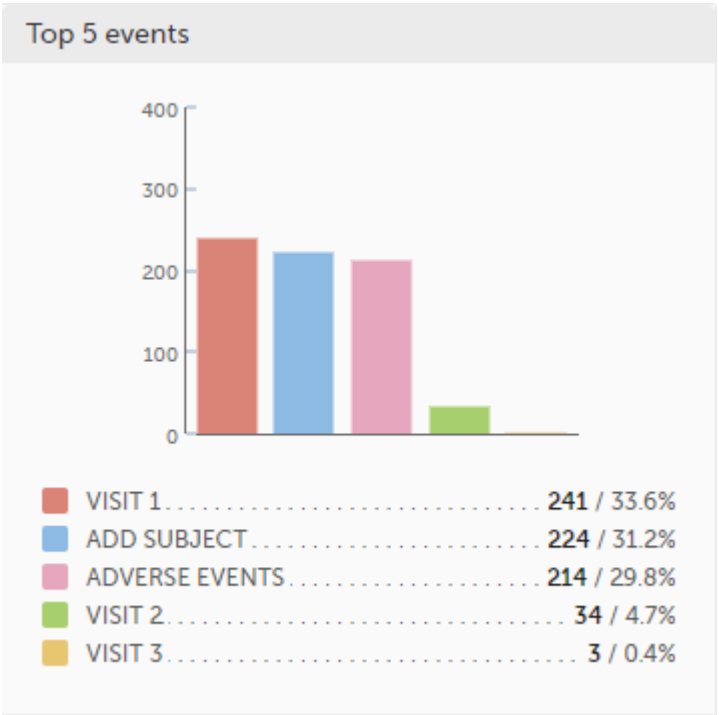
- Country
- Site
- Subject
- Time period - choose between:
    - All time
    - Last 24 hours
    - Last 3 days
    - Last week
    - Last 3 weeks

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

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

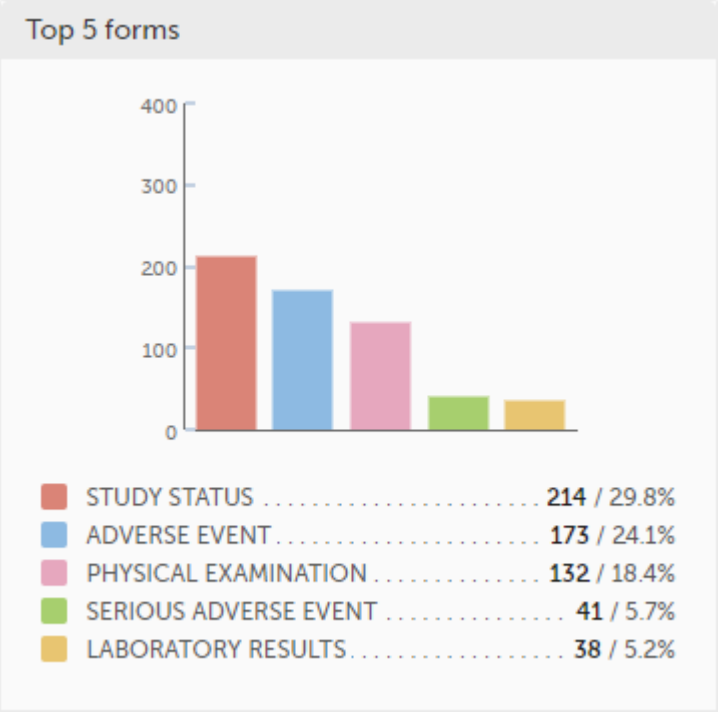
4.1 Top 5 events

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



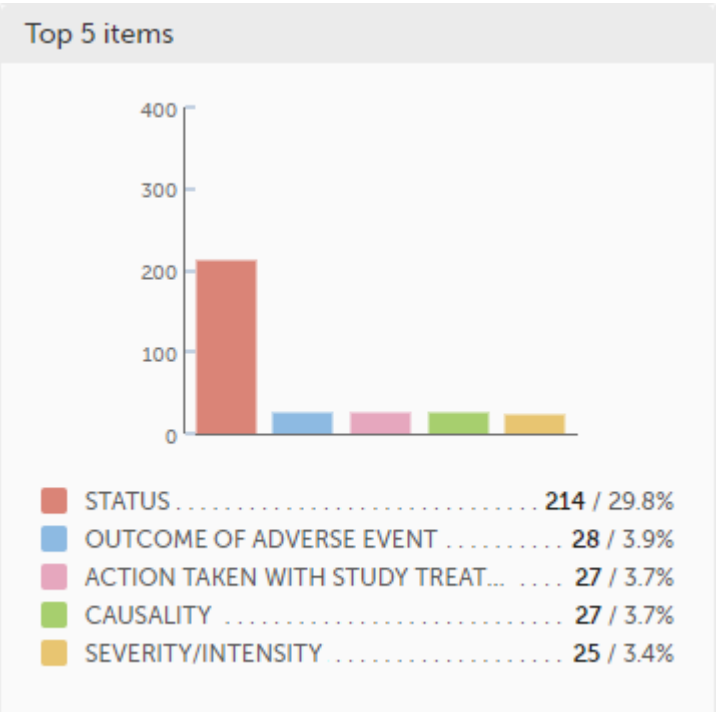
4.2 Top 5 forms

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



4.3 Top 5 items

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



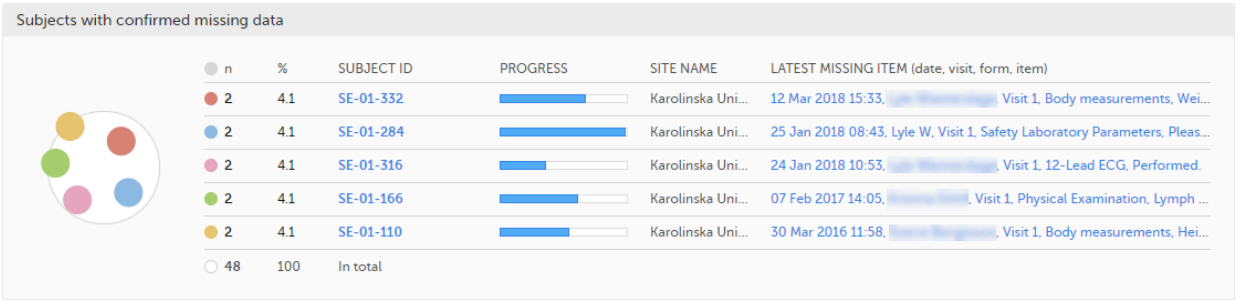
4.4 Subjects with confirmed missing data

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

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

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

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

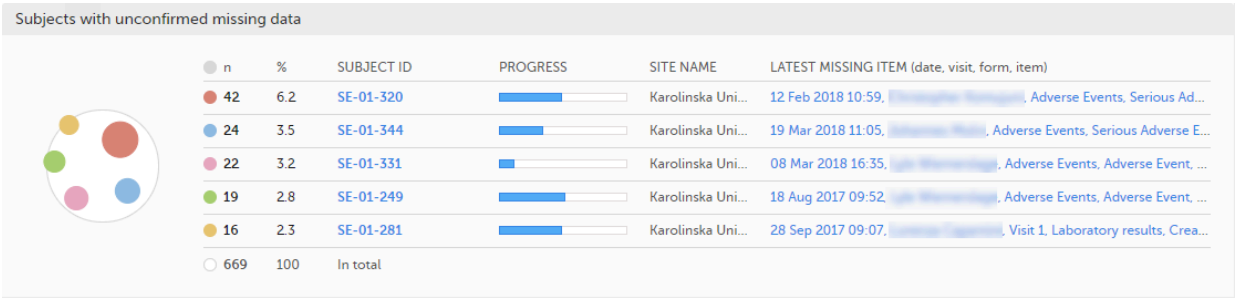


4.5 Subjects with unconfirmed missing data

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

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

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



4.6 Save and export

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

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

Selection page

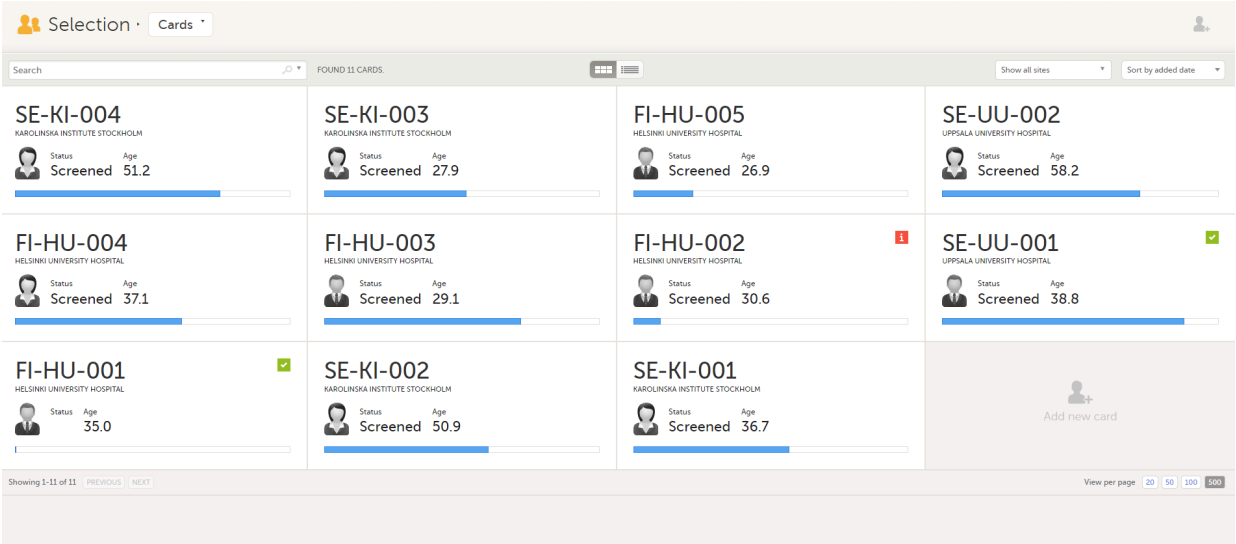
Selection page

Published by Viedoc System 2023-10-09

1. Introduction
    1.1 Sorting and filtering
    1.2 Searching
    1.3 Icons
2. Views of the Selection page
    2.4 The Cards view
        2.4.1 The subject card overview
    2.5 The issues view
    2.6 The Viedoc Me view
    2.7 The Events view
3. Adding a new subject

1 Introduction

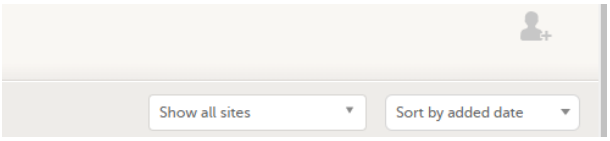
The Selection page displays all the subjects from all the sites you have access to:



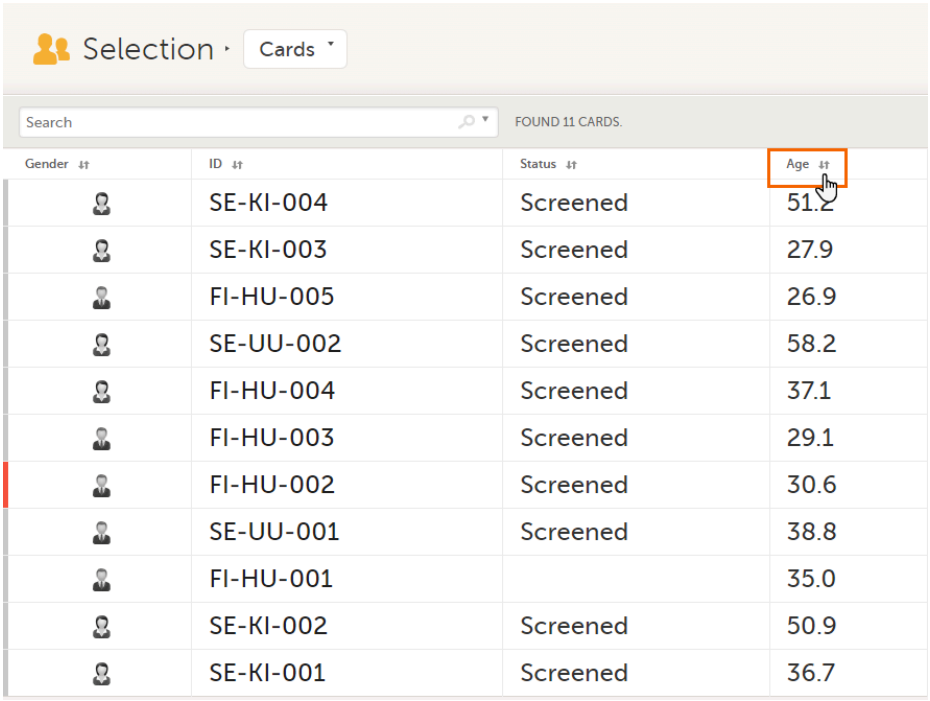
In the default view, each subject is represented by a card. Depending on your study setup, the Selection page can be displayed in several ways. See Views of the Selection page.

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.

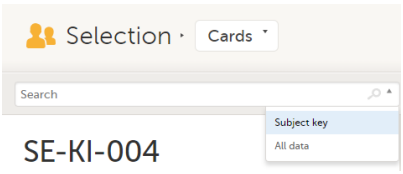


In the table view of the Selection page, you can also sort by column in descending or ascending order by selecting a column header with the arrow symbol. Lit-up arrows indicate the selected sorting in orange:



1.2 Searching

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



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

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

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

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

1.3 Icons

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

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

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

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

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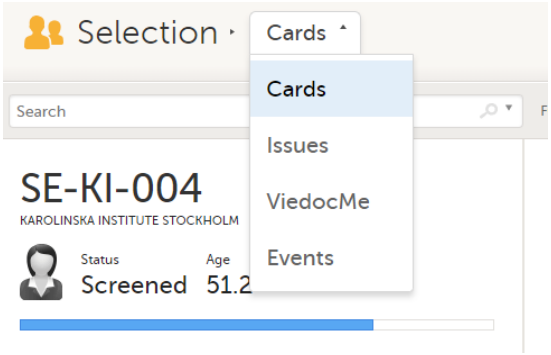
2 Views of the Selection page

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

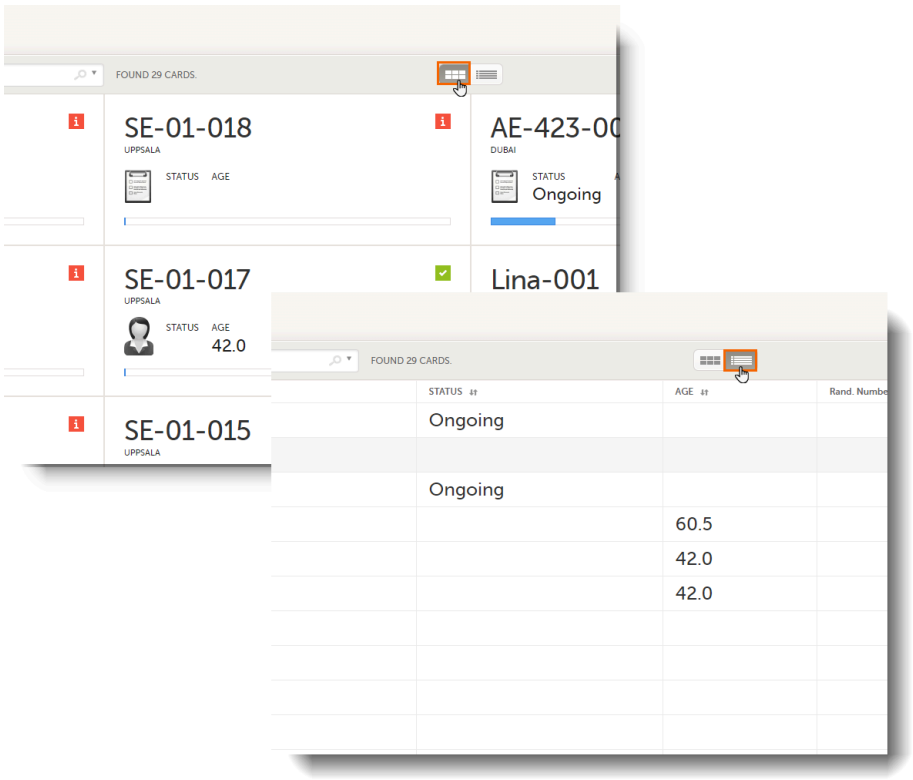
- If the study is configured with extended selection pages, you can select a view at the top of the page. Select **Cards**, **Issues**, **Viedoc Me** or **Events** from the dropdown menu to open the view. The Viedoc Me view is only available to select if the Viedoc Me feature is included in your study.



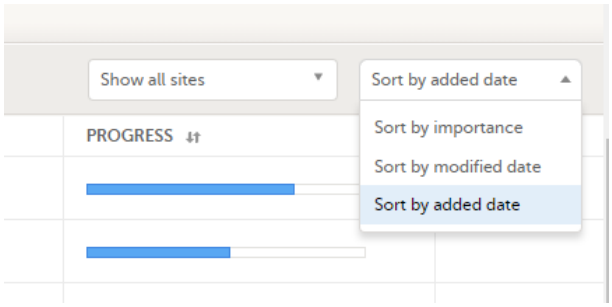
- If the study is not configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

2.1 The Cards view

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

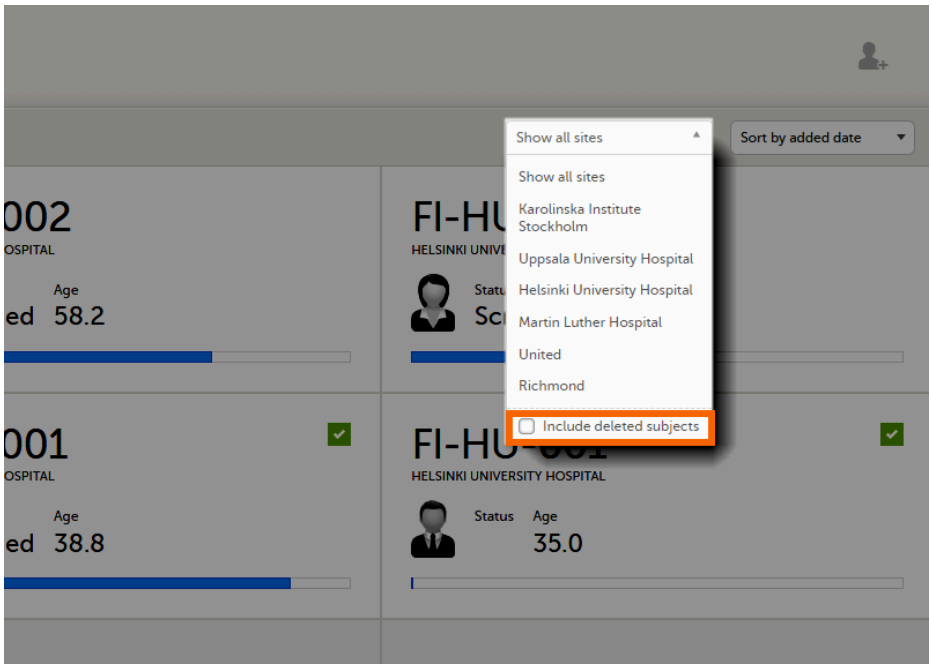


The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:



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

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

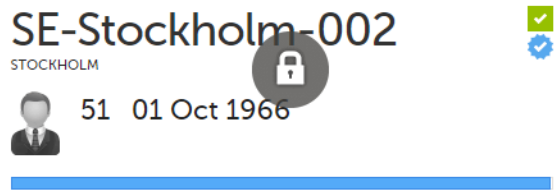


2.1.1 The subject card overview

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

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

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

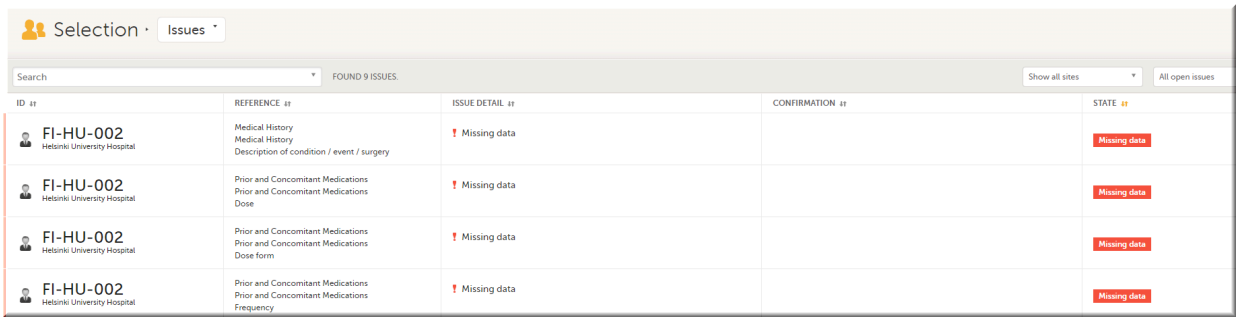


- Progress bar indicating the completion status (in blue)

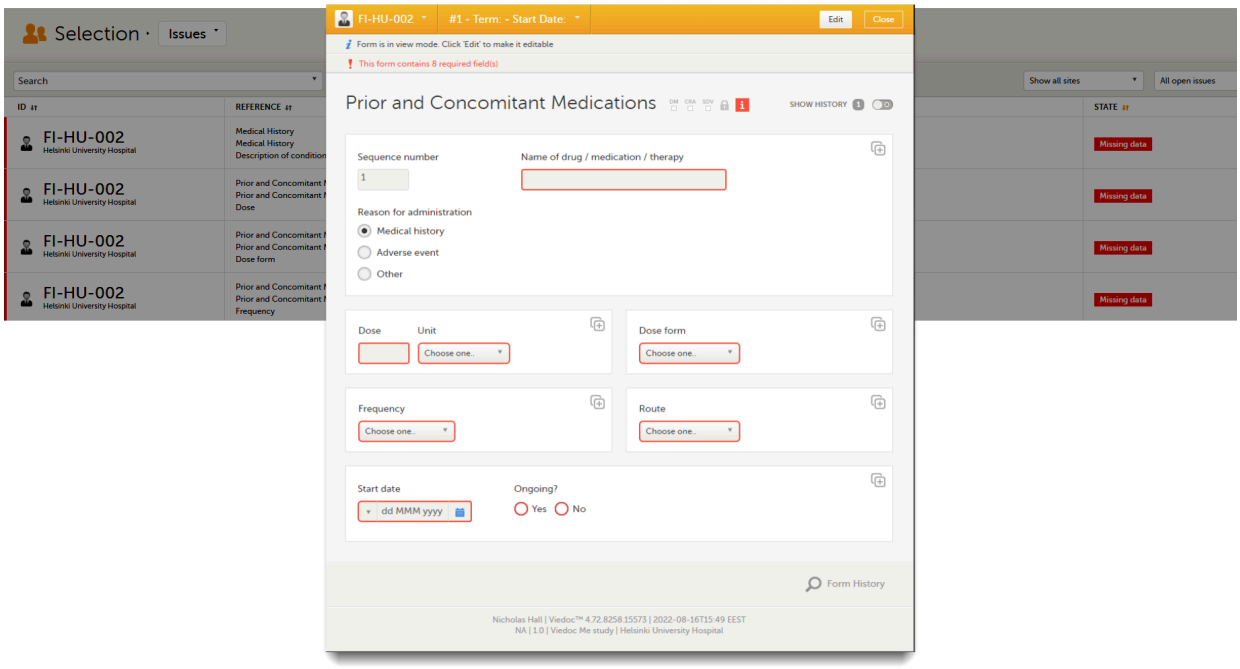
Note! The Selection page does not consider the role visibility except for task count; therefore, the subject status reflects the general status of the subject in the study, regardless of the user who has work to be performed. The subject details view reflects the subject status considering the role visibility.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

2.2 The issues view

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

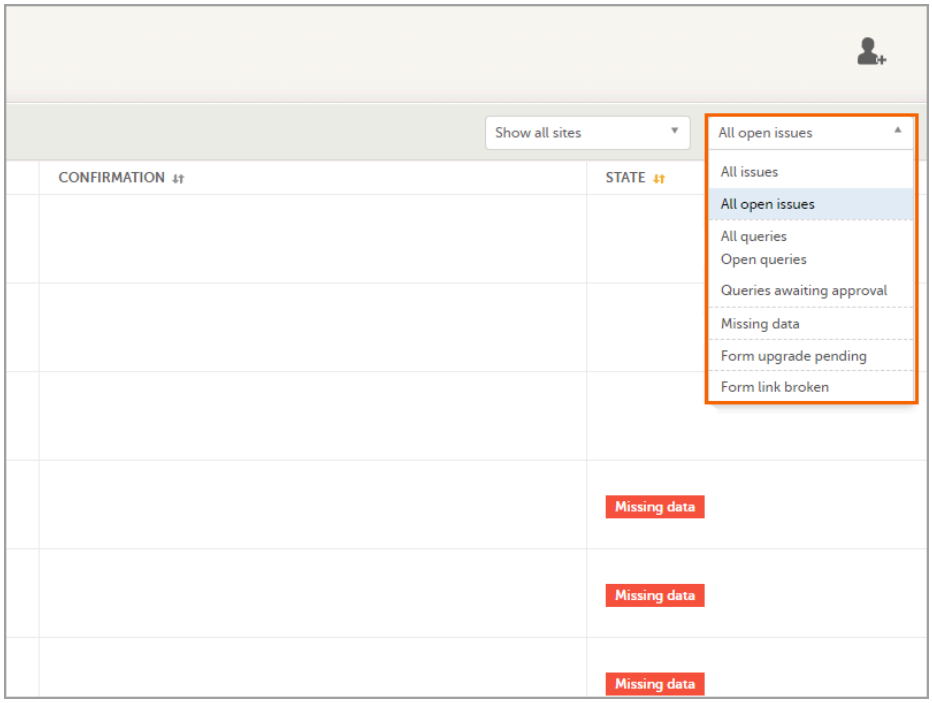


Click any row to open the form where the issue was raised:



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:

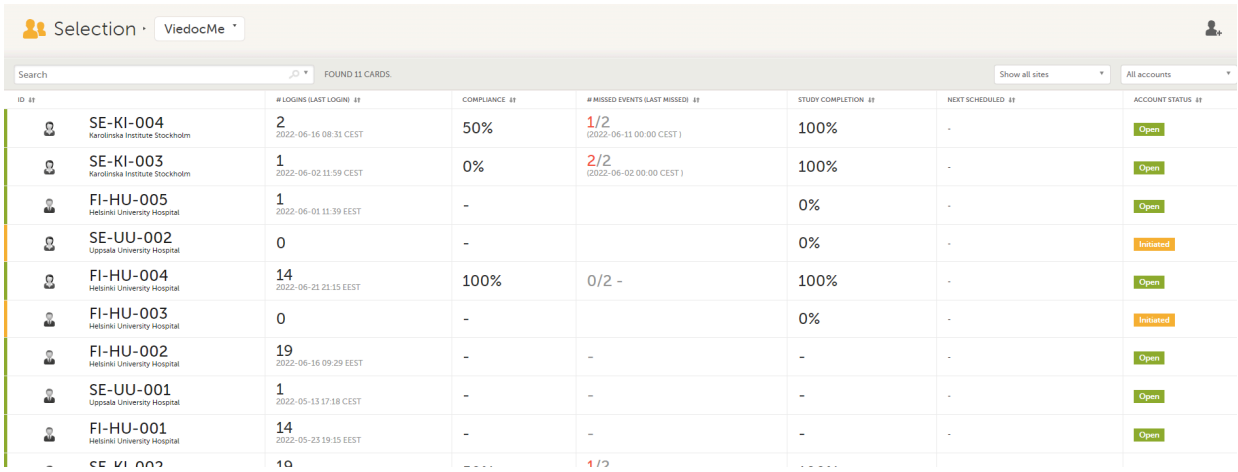


- By site - view data from a specific site or from all sites
    - Include deleted subjects
- By issue type/status:
    - **All issues**:
        a. Missing data
        b. All queries, regardless of status
        c. Form upgrade pending
        d. Pending reference data upgrade
    - **All open issues**: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

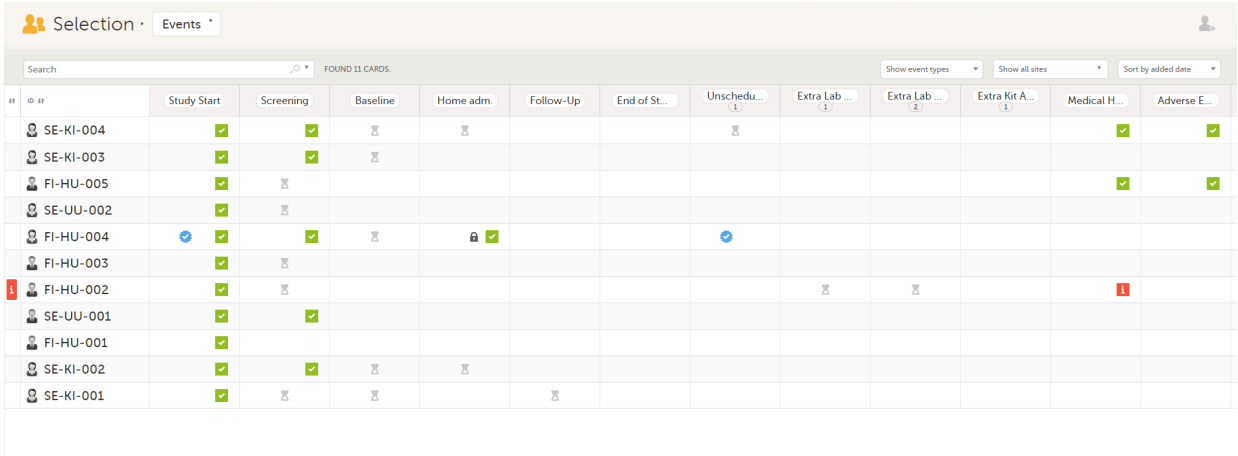


For each subject, the following information is listed:

- **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

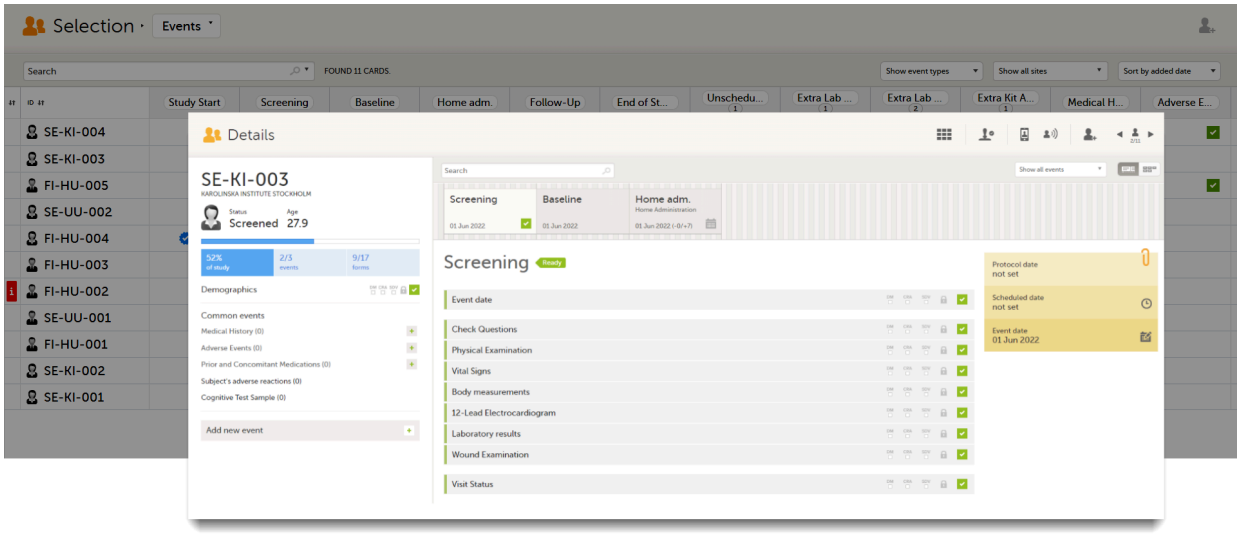
2.4 The Events view

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**

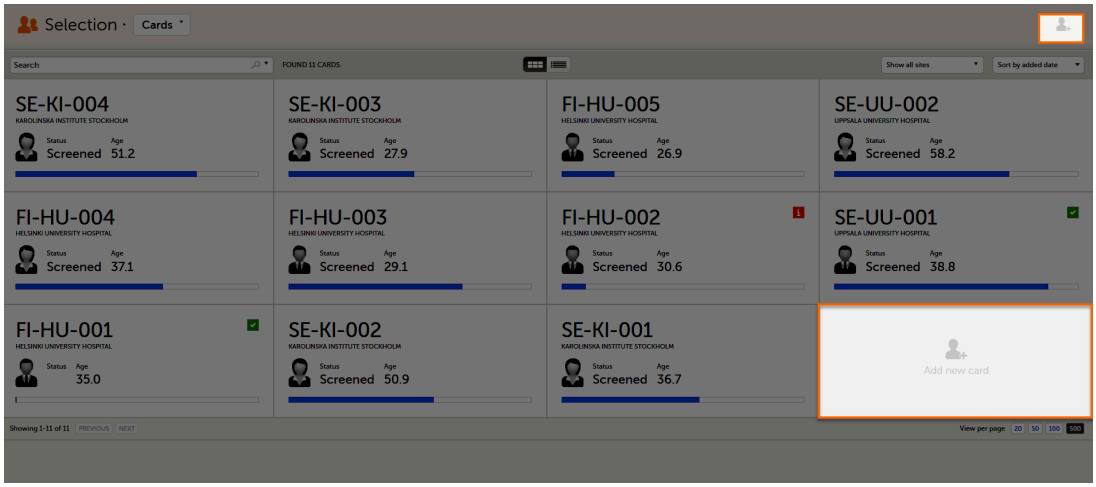
Note! On the selection page, in the **Events** view, the event name (as set in the Study event settings in the study design) is displayed. If there is a recurring event, a counter is shown under the event name, for example: Follow up 1, Follow up 2.

---

3 Adding a new subject

To add a new subject:

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



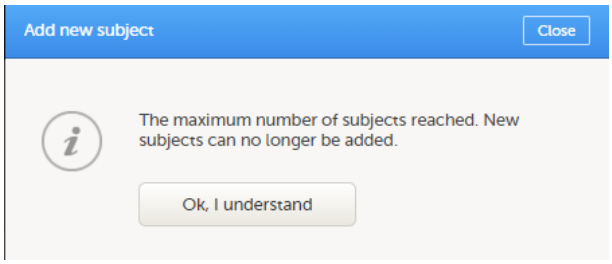
The first form in the study is displayed.

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

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

See also the video tutorial Add and select subjects.

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



Entering and editing data

Entering/Editing data

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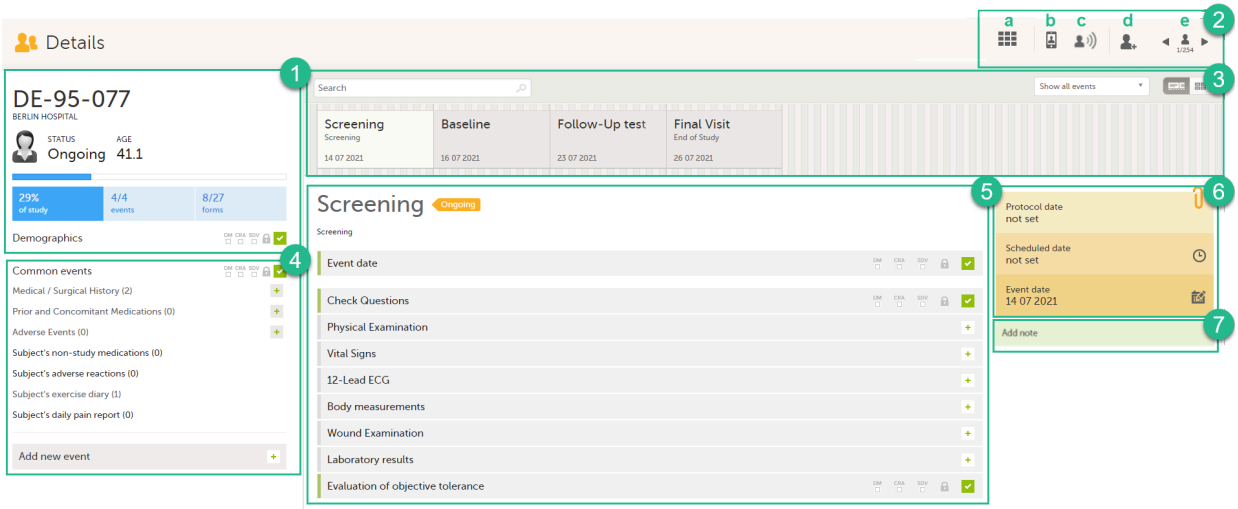
1 Overview

1.1 Details page

When you select a subject card in the Selection page, or add a new subject, the Details page opens.



Here you will find the following information:

1. Subject details - including subject ID, site name and a status summary.

Note! The subject details view reflects the subject status and the review flags considering the role visibility, while the Selection page does not take into account the role visibility. Therefore, the subject status on the Selection page reflects the general status of the subject in the study, regardless of the user who has tasks to be performed. This could result, for example, in a subject status in the subject details view where a subject could have a green check mark or being locked, while in the Selection page it is not (due to some other user role having unfinished work/forms to complete on the respective subject).

The following flags show the status of each form:

Flag	Description
DM	Shows if the data was reviewed by the Data Manager (DM) or other role with review permission. Green check-mark if performed, otherwise grey.
CRA	Clinical review indicator, reviewed by Clinical Research Associate (CRA) or other role with review permission. Green check-mark if performed, otherwise grey.
SDV	Source Data Verification (SDV) indicator. Green check-mark if performed, otherwise grey.
Lock	Black if the form was locked by the Monitor, otherwise grey.
Status	Shows the status of the data entered: ▪ Green check-mark if the form is completed ▪ Red [i] if the form has issues

Note! The flags are not displayed for the empty forms.

2. Toolbar with the following functions:

a. Return to the Selection page
b. Set up Viedoc Me
c. Initiate a Viedoc Connect call
d. Add a new subject
e. Toggle between subjects

Depending on the role and permissions you have, the following might also be available:

- Signing console (for details, see Signing data):

- Data review console, for user roles with data review permissions (for details, see Clinical review, SDV and Lock and Data review and Lock):

See also the video tutorial Enter data.

3. Event slider - a list of all the scheduled and unscheduled events for the subject.

From the top-left corner you can search for events. All events containing characters of the search string are filtered and shown in the slider.

From the top-right corner you can toggle the view and change the way the events are displayed: only by name or with detailed cards. Tip! Toggle to the "only by name" view to fit all events, if there are many matches in your search result.

From the dropdown list to the right you can select to:

- Show all events
- Show all initiated events
- Show all unplanned events
- Show / hide subject-initiated events
- Show / hide deleted events

4. Common events - here you can add events that cannot be scheduled in advance, such as adverse events, by clicking on the respective event name.

You can also add unscheduled events by clicking the **Add new event** link. The unplanned events will show up in the event slider inserted among the existing events according to the event date.

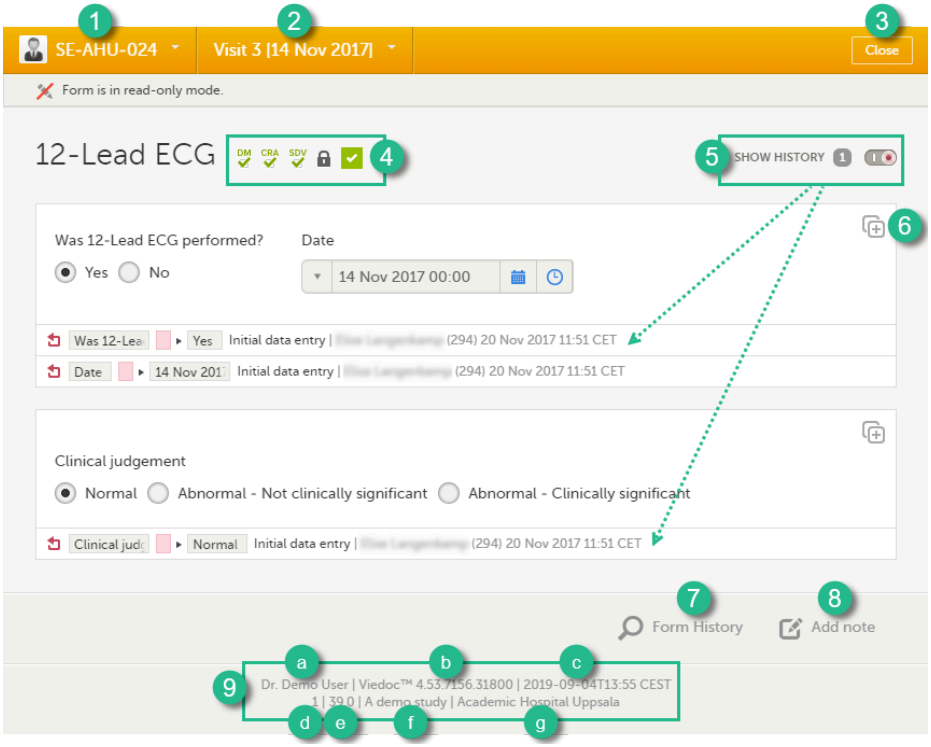
5. The list of the forms to be filled in for the event selected in the event slider (2). Click the form bar to open it and enter the data. Depending on the study setup, it may be necessary to initiate the event through the Event date form, to be able to enter data. For more information, see Initiating an event.

6. The protocol date, the scheduled date (if set), and the event date (if set).

7. Private notes. For details, see Adding private notes.

1.2 An example of a form

When you click on a form on the Details page, the form opens. The below image shows an example of a form:



1. Subject ID. You can use this dropdown list to navigate to other subjects within the same form, see Navigating between subjects/events within the same form.
2. Event name. You can use this dropdown list to navigate to other events within the same form, see Navigating between subjects/events within the same form.
3. **Close**. Click to close the form and return to the Details page.
4. Flags showing the status of the form, see the description of these flags above.
5. **Show history**. Activate the switch to display the history of each form item.
6. Action button. Click to select a field (item) and select the type of action you wish to perform, for example to confirm data as missing or to add a private note. For more information, see Confirm data as missing and Adding private notes.
7. Form history, see Form history PDF.
8. **Add note**. Click to add a private note to the form, see Adding private notes.
9. Footer of the form, containing the following information:

    a. User name
    b. Viedoc version number
    c. Date and time of last form edit
    d. The protocol version that the study is based on
    e. Study design version number of the version that is active on the moment the event is initiated
    f. Name of the study
    g. Name of the site

---

2 Initiating an event

There are two types of events that can be initiated for a subject:

- Scheduled events - events that were scheduled in advance. These can be events initiated in Viedoc Clinic or subject-initiated events. The subject-initiated events can be initiated only by the subject via Viedoc Me - the filled-in data is visible in Viedoc Clinic afterwards.
- Unscheduled events - events that cannot be scheduled in advance.

To start entering data on an event, the event must first be initiated.
The exception is when the event date is configured in the study design to be automatically set and based on the data entered within the event.

Note! When the event date is automatically set, the following apply to the Event date form based on the settings in the study design:

- The Event date form is visible and can be edited if this option is enabled for your study. Queries can be raised on the Event date form.
- The Event date form is not visible. This means that the Event date form is not shown on the Details page, in the Review console, in the Signing console, or in the Issues list, and that it is not possible to raise

queries on the event date. The Event date form is neither included in metrics but still available in the data export.

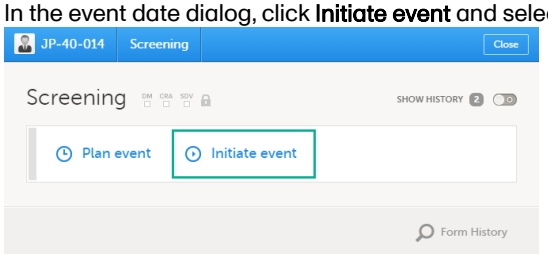
2.1 Scheduled event

To initiate a scheduled event:

1 Open the Event date form, in one of the following ways:

a - Next to the event name, click **Set an event date.**
b - On the form, click **Event date.**
c - On the right-side pane, click **Scheduled date.**
d - On the right-side pane, click **Event date.**

2 In the event date dialog, click **Initiate event** and select the date:



Note! For the events that are already scheduled, the protocol date is also displayed. Entering an event date that is outside the protocol date will raise a warning message.

3 Click **Save changes**.
The event date dialog closes and the event is initiated. The event status changes to **Ongoing**.

2.2 Unscheduled events

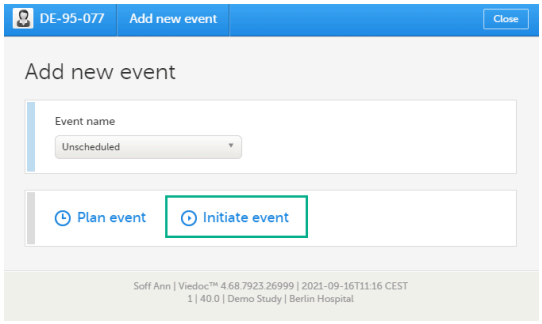
To add and initiate an unscheduled event manually:

1 On the Details page, click **Add new event** in the left-side pane.

The Add new event dialog opens.

2 Choose the **Event name** from the dropdown list. The events available are the ones that were configured by the study designer as unscheduled events.

3 Click **Initiate event** and select the date:



4 Click **Add event**.
The event date dialog closes and the event is added and initiated. The unplanned events will show up in the event slider inserted among the existing events according to the event date. The event status changes to *Ongoing*.

3 Entering data

3.1 Working in multiple browser tabs

Important! Working in multiple browser tabs when entering data may cause data conflicts and other serious problems. Therefore it is important to only work in one browser tab when entering or editing data.

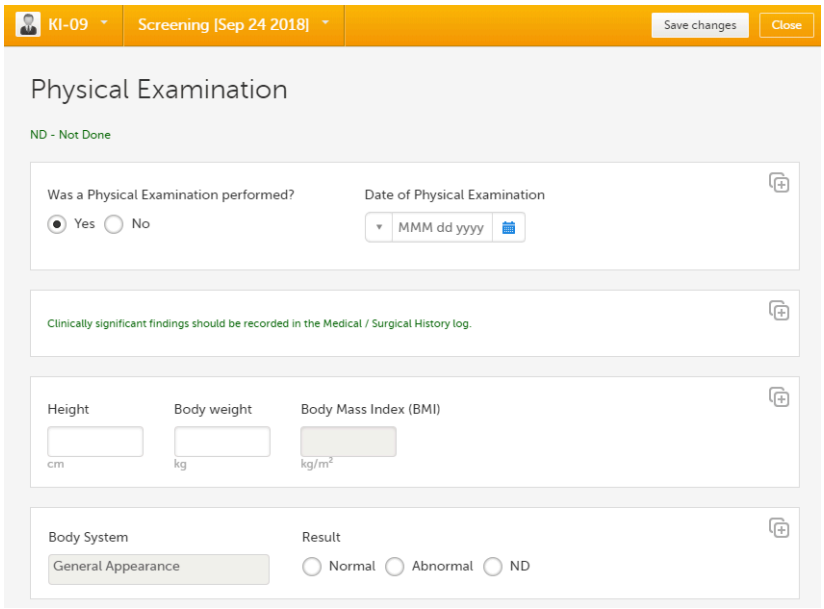
3.2 Entering data in a form

When the event date is set, automatically or manually, it is possible to start filling in the forms.

To enter data in a form:

1 Open a form by clicking the form bar:

2 Fill in the fields - most fields are self-explanatory when it comes to how they should be filled in:



3 Click **Save changes**.

When all the forms in one event are filled in, the event is considered completed and a green check mark appears on the event tab in the event slider.

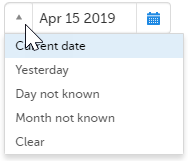
Below, we explain how to fill in some of the most common fields in a form:

- Dates
- Times
- Ranges
- File upload
- Linking between forms

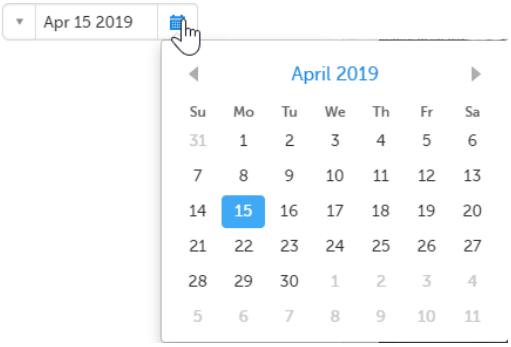
3.2.1 Dates

You can fill in the date field in two ways:

- Click the dropdown menu and select one of the following options:
  - **Current date**
  - **Yesterday**
  - **Day not known**
  - **Month not known**
  - **Clear** (remove date)



- Click the calendar icon to open the date picker and select a date. Click the arrows to change month.

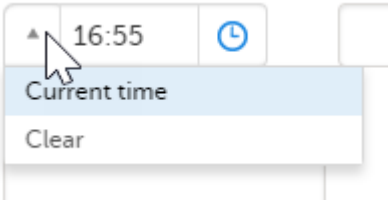


Tip! You can click the month/year header to view all months of the year, and then click the year header to view a range of years.

3.2.2 Times

You can fill in the time field in two ways:

- Click the dropdown menu to select the current time:



- Click the clock icon to open the time picker. Click the arrows to select the hour and minute (with a five minutes time interval), or double-click the hour and minute fields to manually enter any hour and minute:

3.2.3 Range

You can define a range of values by selecting a comparator symbol, and then enter the numeric value(s). You can chose between the following comparators:

- Inclusive in between
< Less than
≤ Less than or equal to
> Greater than
≥ Greater than or equal to
= Equal to

3.2.4 File upload

To upload a file to a form:

1 Click the arrow on the right side of the upload box or click the thumbnail if this is available.

2 Browse for the file to be uploaded and click **Open**.
During the upload process:
- A progress bar is showing the upload status.
- You can cancel the file upload by clicking the **X** button on the right side of the progress bar.
- You can continue editing the form.
- You cannot close the form until the upload process is completed.

3 The uploaded file(s) will be stored once the respective form is saved by clicking **Save changes**.

You can download an existing file by clicking the file name or by clicking the thumbnail (if it exists). If a drawing pad item was submitted from Viedoc Me it will be available as a downloadable file.

You can remove an uploaded file by clicking the trash can icon on the right side of the file name.

Note!

- The file upload icon will display a thumbnail of the image if a jpeg, gif or png file is uploaded. If other file types are uploaded, the icon will only show the file extension.
- The maximum allowed file size is 2 GB.

- The upload of password-protected zip files is not supported, as Viedoc cannot scan these files for viruses.
- For security reasons, it is not possible to upload executable files. See the complete list of unsupported file types in the end of this lesson, in Blacklisted file formats.

3.3 Linking between forms

When editing a form, you can add links between different types of forms with the Form link item. This can be useful for example, to quickly see when a medication was taken by a subject and for what reason.

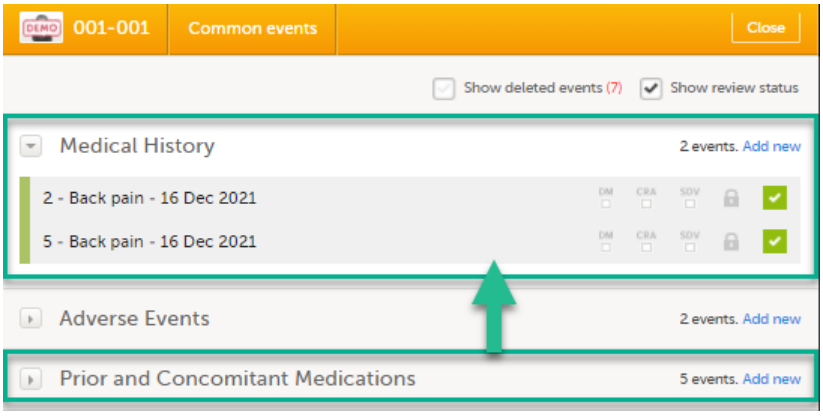
Note! To access the Form link item Clinic users must have access to whichever form type it is configured to link to, for example the Medical History, Adverse events or Prior and Concomitant Medications forms. Viedoc Me does not support forms with Form link items.

Forms can be linked with several instances of a specified form type. For example, while editing the Prior and Concomitant Medications form, links can be made to several registered Medical History events.

To link two forms:

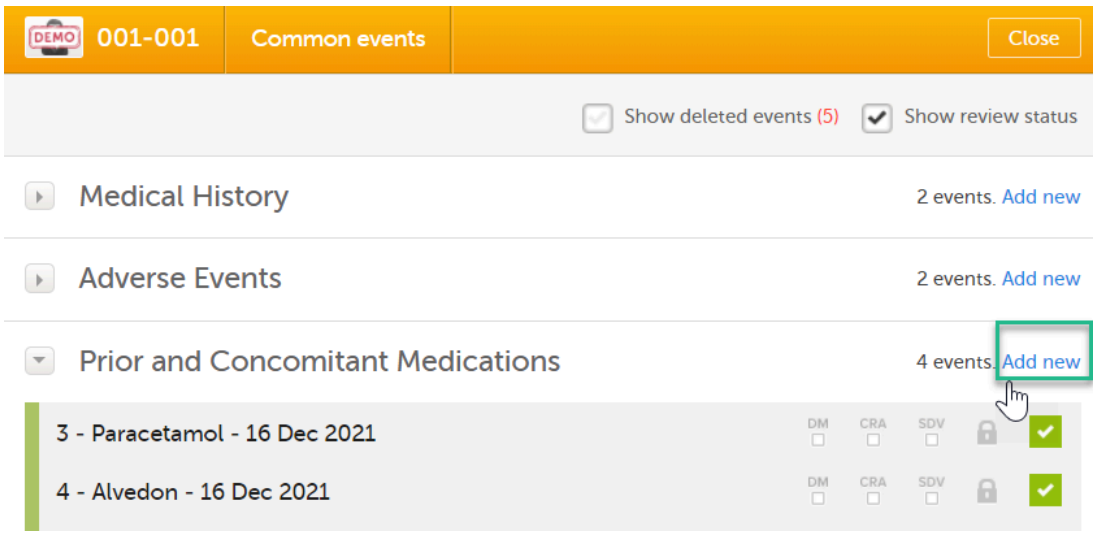
1 Open a subject card. In this card you can see two Medical History forms under Common events:

2 In this example, we will link the Prior and Concomitant Medications form to the existing Medical History form instances and enter the medication that the subject has taken for the Medical History event.



3 To link the Prior and Concomitant Medications form to the Medical History form instances:

Select **Add new** in the Prior and Concomitant Medications form.



4 In the Prior and Concomitant Medications forms, select **Medical history** to show all existing form instances of the same type. The available link items are shown in a dropdown list.

1. Enter the name of the drug/medication/therapy.

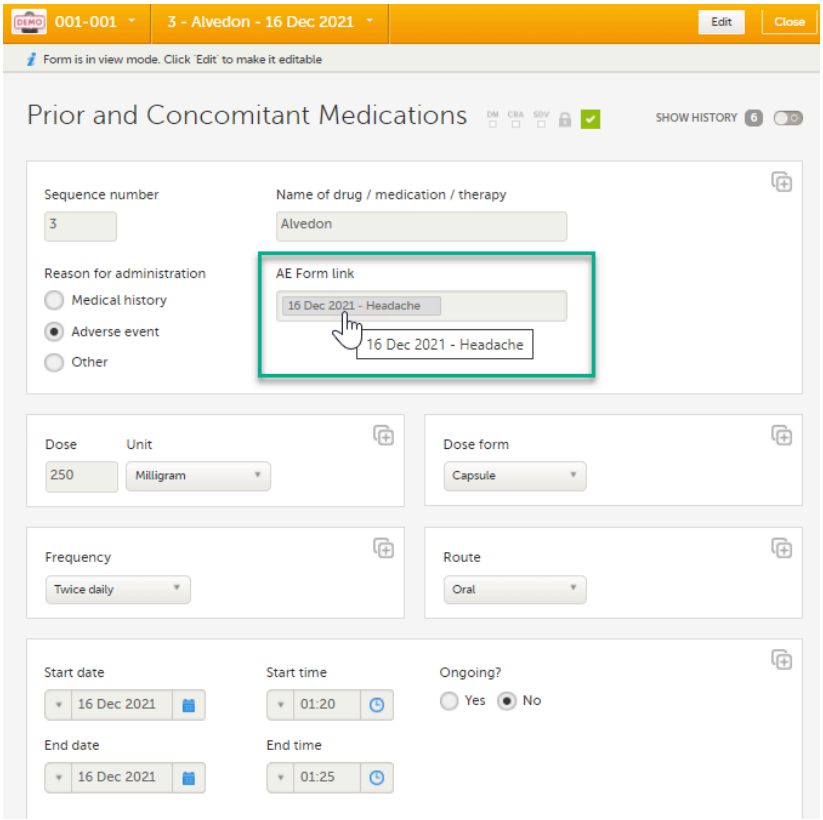
2. Select the relevant Medical history.

3. Select **Save changes** - the Prior and Concomitant Medications form is now linked to the Medical history form instance.

Notes!

- The forms in the link item are shown in the order of the earliest date first according to the event date, (and by the order of activities reflecting the order in the design) within each event.
- If a date item is used in the format of a form link item, then the date will be saved in the system language of that user. When the next user edits the form, the language of the date item is automatically updated to reflect the language setting of the editing user.

4 After saving the form, select any link item to open and read that form. In the example shown below, the Adverse events form. Closing the form returns you to the original form, in this example the Prior and Concomitant Medications form.

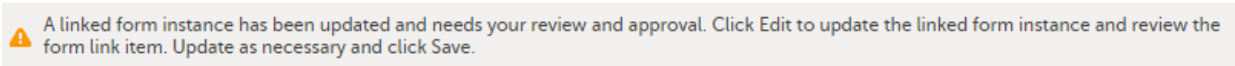


Note! You can also search in the form link item field. This can be useful to find a specific form instance if there are many adverse events for example.

3.3.1 Updates to linked forms

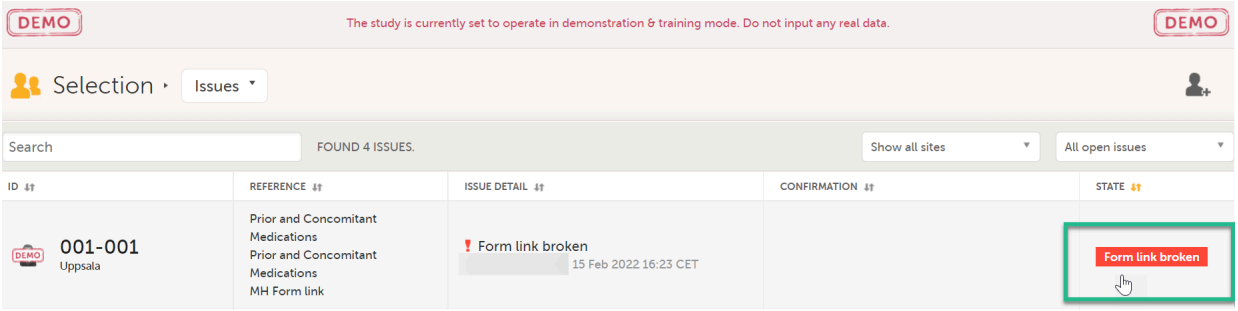
If you update a linked form by resetting, deleting, or changing data, the following occurs:

- The form containing the linked form instance is marked with an issue flag (the red [i] icon).
- An error message is displayed at the top of the form containing the link item:

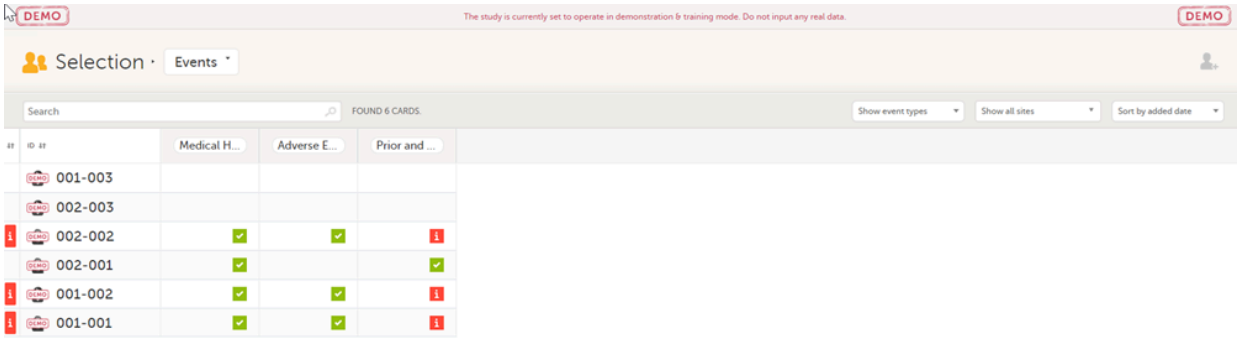


3.3.2 Locations of updated linked forms

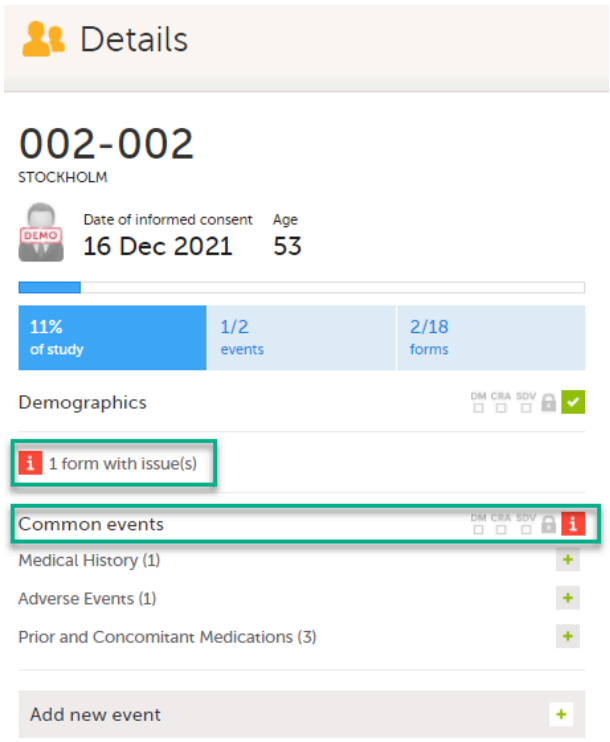
In the Issues view of the Selection page, forms are easily identified and are labelled **Form link broken**:



In the Events view of the Selection page, forms are easily identified and marked with an issue flag (the red [i] icon). Select the red [i] icon to open the subject card.

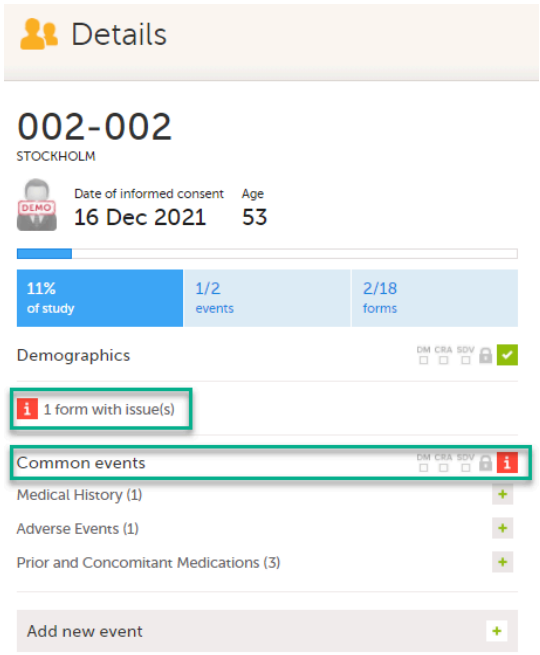


On the subject card, the issue is marked with an issue flag:

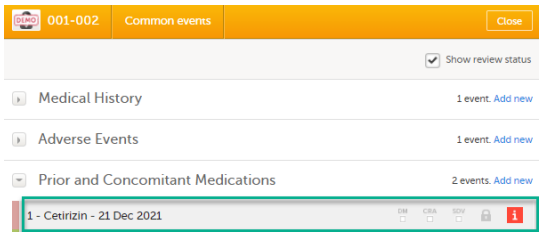


3.3.3 Updating a linked form

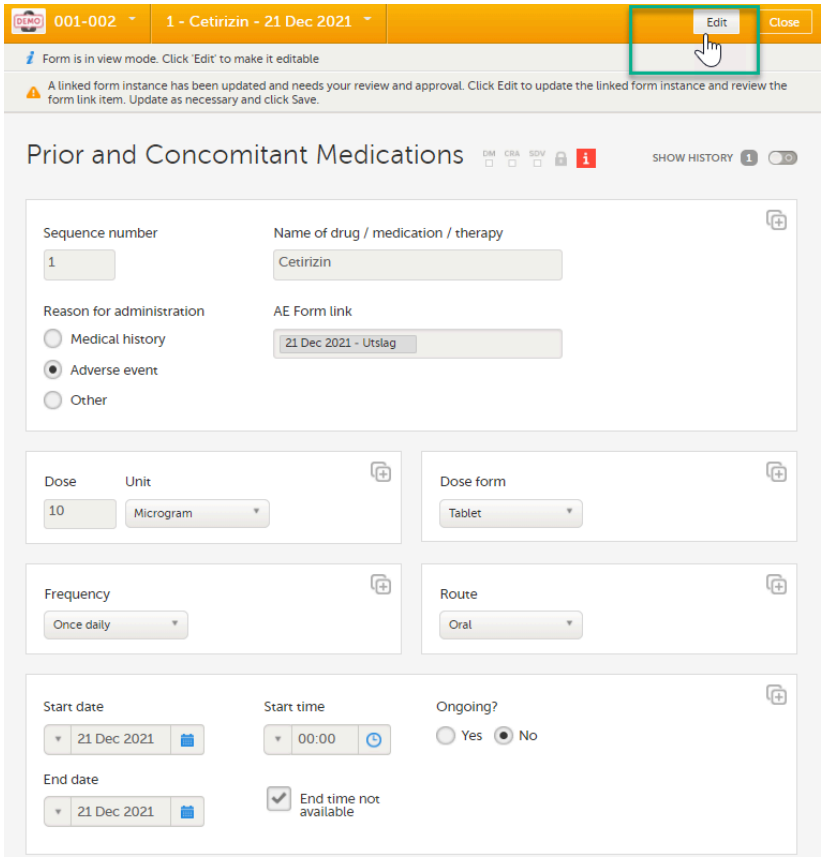
1 Select the red [i] icon to open the issue, (in this example under Common events).



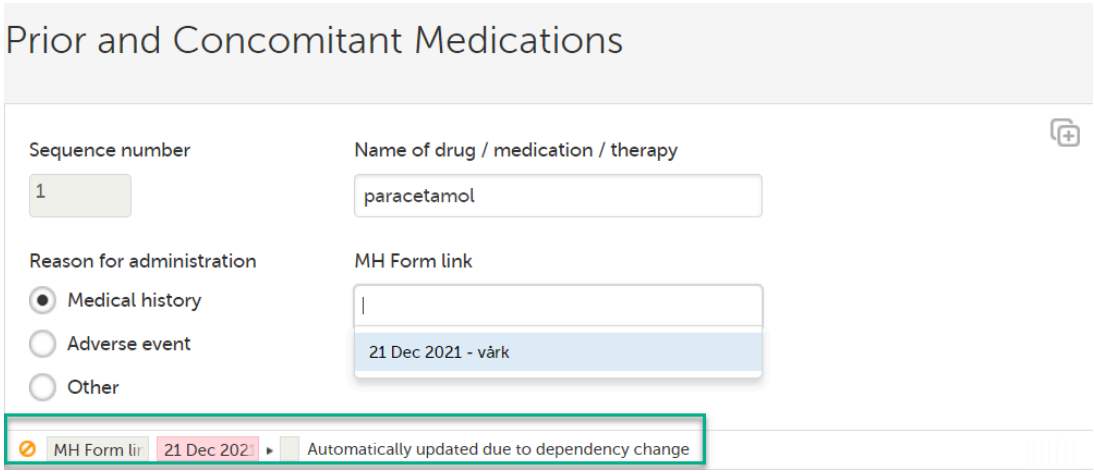
2 Select the red [i] icon (in this example under Prior and Concomitant Medications) to open the form with the issue.



3 Select **Edit** to update the form:



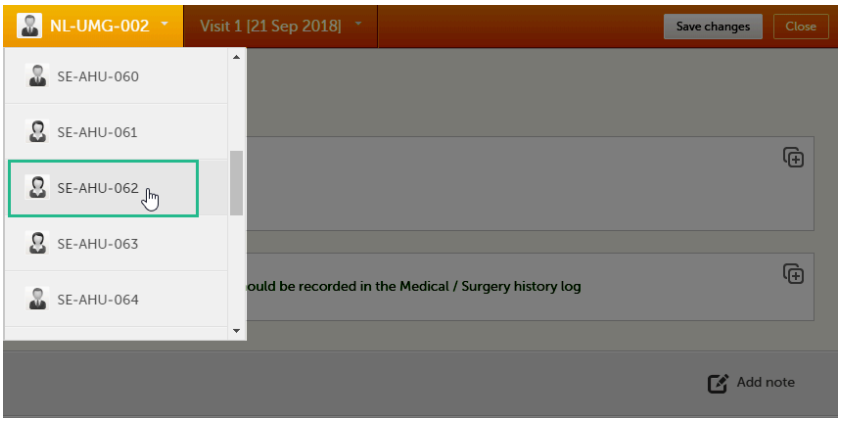
4 A message is displayed as part of the audit trail when the linked items are updated:



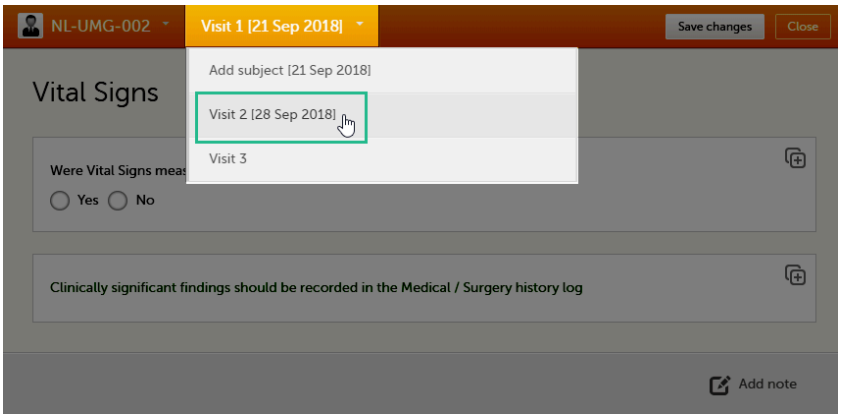
3.4 Navigating between subjects/events within the same form

Once you have a form open, it is possible to navigate through different subjects, or different events, if the form is included in other initiated events as well. This function is available through the dropdown lists in the form header, as illustrated below:

- Navigate through subjects:



- Navigate through events:



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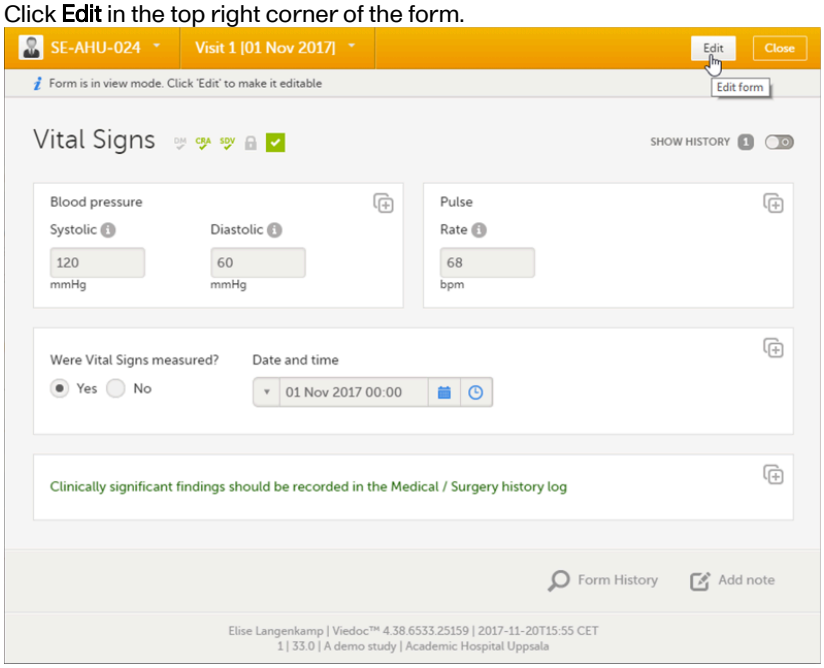
4 Editing data

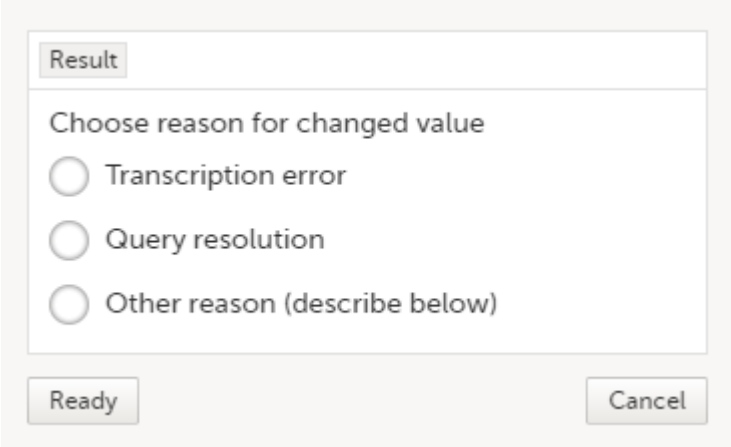
To edit data that already have been saved:

1 Open the form that contains the data you want to change.

2 Click **Edit** in the top right corner of the form.



3 Edit the data and click **Give reason**.
A dialog opens.



4 Select one of the pre-formulated reasons for change, or click **Other reason** and provide a description. Click **Ready** and **Save changes**.

Note!

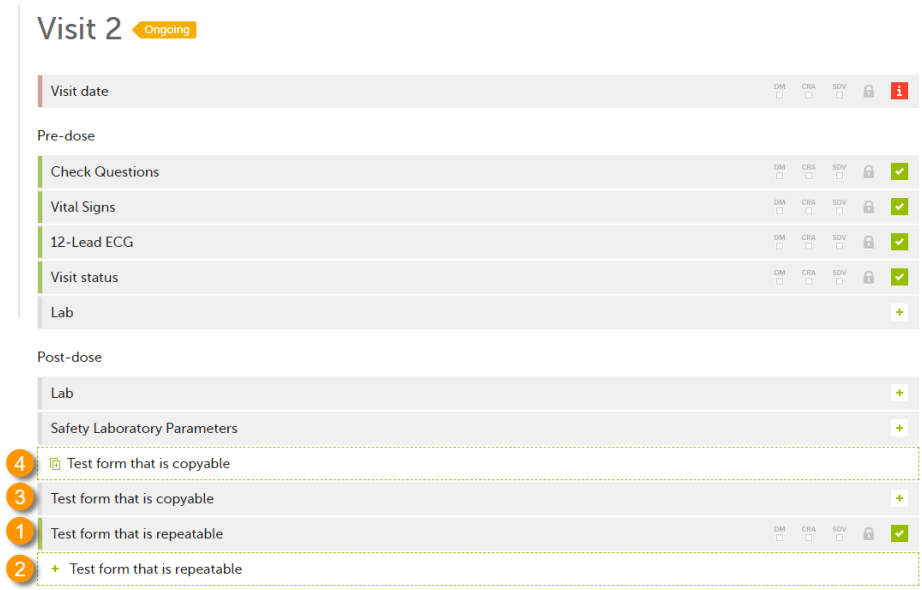
- A form that has been locked by the Monitor or Data Manager cannot be edited. If you anyway want to edit a locked form, contact your Monitor.
- Subject-submitted (Viedoc Me) forms are locked by default. If you, together with the subject, consider that changes need to be made to the answers in a subject-submitted form, contact your Monitor. Depending on the settings for your study, your Monitor might have the possibility to unlock the subject-submitted form.

5 Repeating forms

It is possible to create several instances of the same form within one activity. This can only be done if the form is set as repeating in the study design.

If a form is set as repeating, a ghost form will appear once you have filled in and saved the first instance of the form (see the lab form example in the image).

Note! The ghost form of a repeating form is displayed below the main form and marked with a + icon. If you see a ghost form above the main form, it is a copyable form. See the image below, and see Copyable forms.



1. Main form instance of repeating form
2. Ghost form of a repeating form, displayed below the main form instance and marked with a + icon
3. Main form instance of a copyable form
4. Ghost form of a copyable form, displayed above the main form instance and marked with a copy icon

To fill in an instance of a repeating form:

1 Click the ghost form. A new instance of the form opens.

2 Fill in the form instance and click **Save changes**.
If you have not reached the maximum allowed number of instances of a repeating form, a ghost form appears every time you save a new instance of the form. If the maximum number of instances of the repeating form is reached, no ghost form will appear upon saving a new instance of the form.

To delete an instance of a repeating form:

1 Open the respective instance of the form and click **Edit**.

2 Click **Delete form**.

3 Select or enter a reason for deleting the form and click **Delete**. The instance of the form is removed.

Note!

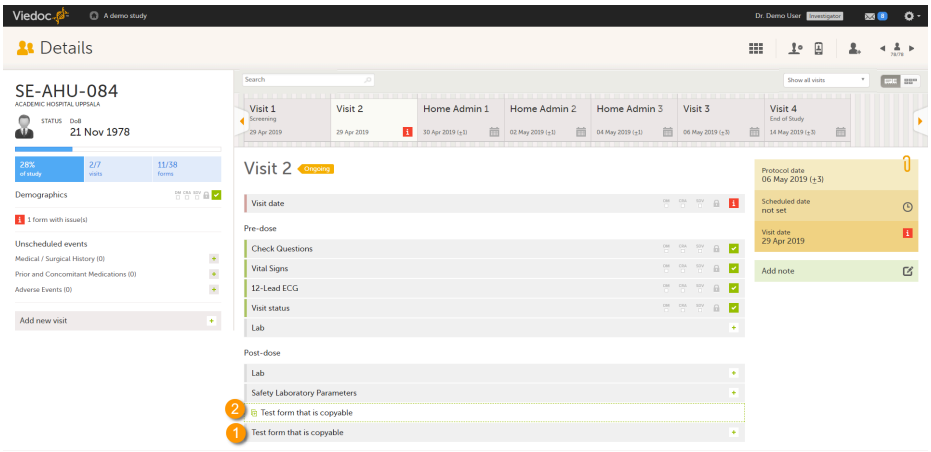
- It is not possible to reset a repeating form. If you wish to clear the data, it is only possible to completely delete that specific instance of a repeating form and create a new one again.
- In order for the event to be considered as completed, at least one instance of a repeating form must be filled in.

---

6 Copyable forms

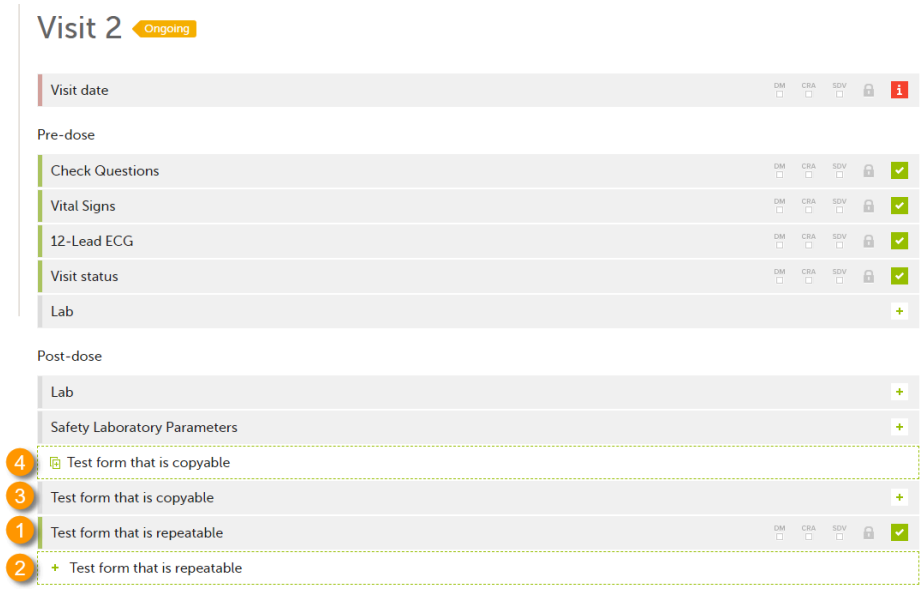
It is possible to initiate a form based on copied data from a previous event. This can only be done if the form is set as copyable in the study design.

If a form is set as copyable, a ghost form will appear above the main form.



1. Main form - click the main form to enter data manually. Data from the same form in a previous event will not be copied into this form in the current event.
2. Ghost form - click the ghost form to initiate the form by copying data from a previous event. See below for instructions.

Note! The ghost form of a copyable form is displayed above the main form, and marked with a copy icon. If you see a ghost form below the main form, it is a repeating form. See the image below, and see Repeating forms.

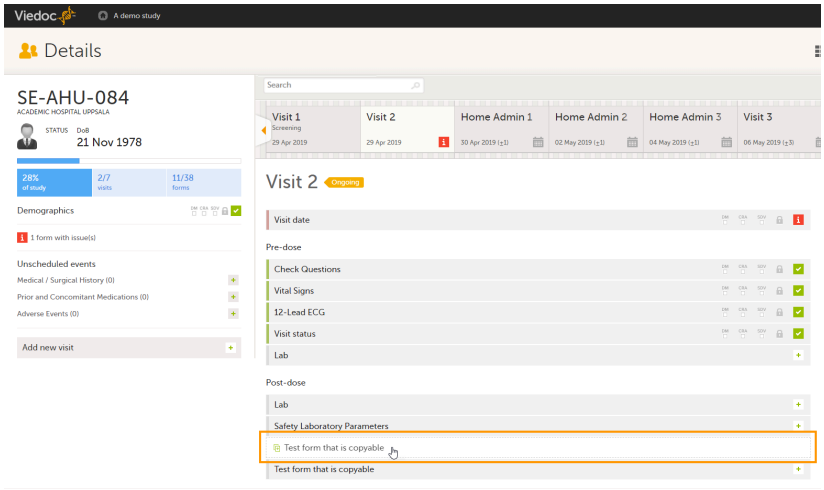


1. Main form instance of repeating form.
2. Ghost form of a repeating form, displayed below the main form instance and marked with a + icon.
3. Main form instance of a copyable form.
4. Ghost form of a copyable form, displayed above the main form instance and marked with a copy icon.

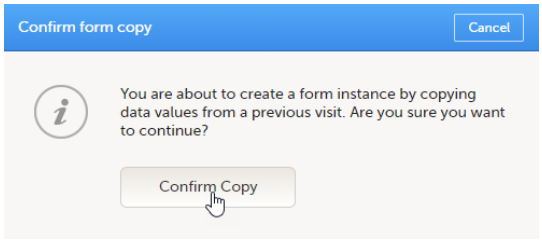
If the copyable form is also set as repeating (see Repeating forms), and in the previous event, three instances of that form have been initiated, then in the current event all three instances appear as ghost form. By clicking one of these ghost forms, you can select the instance from which the data are copied.

To initiate a form based on data copied from a previous event:

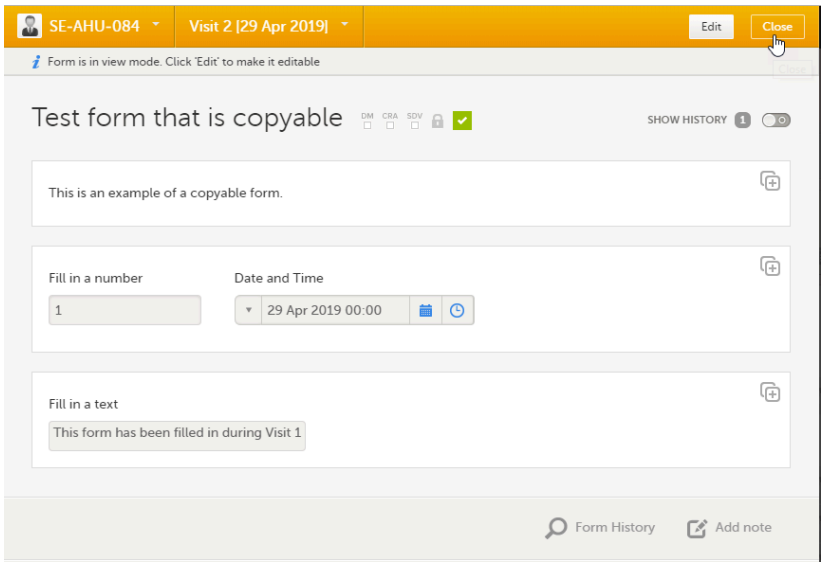
1 Click the ghost form.



A dialog opens asking you to confirm whether you want to create a form instance by copying data from a previous event.



2 Click **Confirm** to continue.
An instance of the form opens, pre-filled with data from the previous event.



3
- If you want to save the form as is, click **Close**. The form will be saved containing the copied data.
- If you want to make any changes, click **Edit**. Edit the fields you would like to change. Click **Give reason** and provide a reason for change. Click **Ready**, and **Save changes** to save the changes to the data.

The ghost form disappears and the form is displayed as initiated.

To delete a copied form:

1 Open the form and click **Edit**.

2 Click **Delete form**.

3 Select or enter a reason for deleting the form and click **Delete**. The copied form is removed and the ghost form re-appears.

Note!

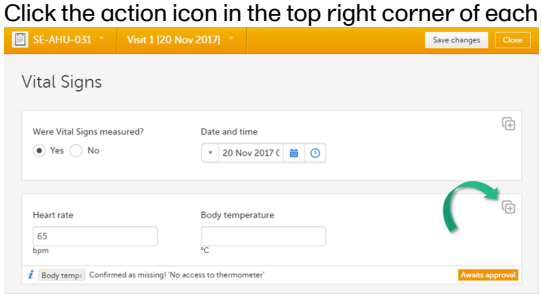
- A form instance based on copied data always contains the data of the previous event, even if data have been changed during that event. If a copyable form is included in Event 1, 2 and 3, and the data is copied from Event 1 to Event 2, edited during Event 2, and then copied to Event 3, the changes made during Event 2 are included in the data copied into Event 3.
- A form instance based on copied data always contains the latest saved data from the previous event at the moment of copying. Any changes performed to the form instance from which the data are copied (the source) after the copy action are not reflected in the form instance containing the copied data (the destination).

---

7 Confirming data as missing

To mark the data as missing, if you are not able to provide information in a field:

1 Click the action icon in the top right corner of each field group:



A dialog opens.

2 Select the field for which the data is missing in the dropdown menu.

3 Select **Confirm field is missing** and provide a reason.
Note! The **Confirm field is missing** action is only shown for the fields that are set as "Required" in the study design.

4 Click **Ready**. Below the field, the text **Confirmed as missing** is displayed, together with the reason provided above.

---

8 Adding private notes

You can add private notes for:

- Events
- Forms
- Single fields (items)

Note! It is only possible to add private notes if this feature is enabled for your role.

8.1 Private notes for events

You can add private notes to every event. Private notes are only visible to the user that created the notes, and can only be edited by that user. Adding or editing a private note does not break the signature. It is possible to add as many notes as you like. Notes are ordered according to date in descending order.

To add a private note for an event:

1 Click **Add note** on the right pane of the Details page.

2 Enter the note text and click **Ready**.

3 Click **Save changes**.
The notes dialog closes.

To add another note:

1 Click **Open notes**.

2 Click **Add another note**.

3 Enter the note text and click **Ready**.

4 Click **Save changes**.
The notes dialog is closed and the new note is displayed in the right pane of the Details page.

To edit an existing note:

1 Click **Open notes**.

2 Click the pen icon behind the note you want to edit.

3 Edit the note text and click **Ready**.

4 Click **Close**. The notes dialog is closed.

To delete a private note:

1 Click **Open notes**.

2 Click the trash can icon behind the note you want to delete.

3 Click **Save changes**. The notes dialog closes.

To see a history of changes to private notes, activate the **Show history** switch. Private notes are not recorded in the audit trail, neither included in the data export.

8.2 Private notes for forms

You can add private notes to every form. Private notes are only visible to the user that created the notes, and can only be edited by that user. Adding or editing a private note does not break the signature.

To add a private note for a form:

1 Click **Add note** on the bottom of the form.

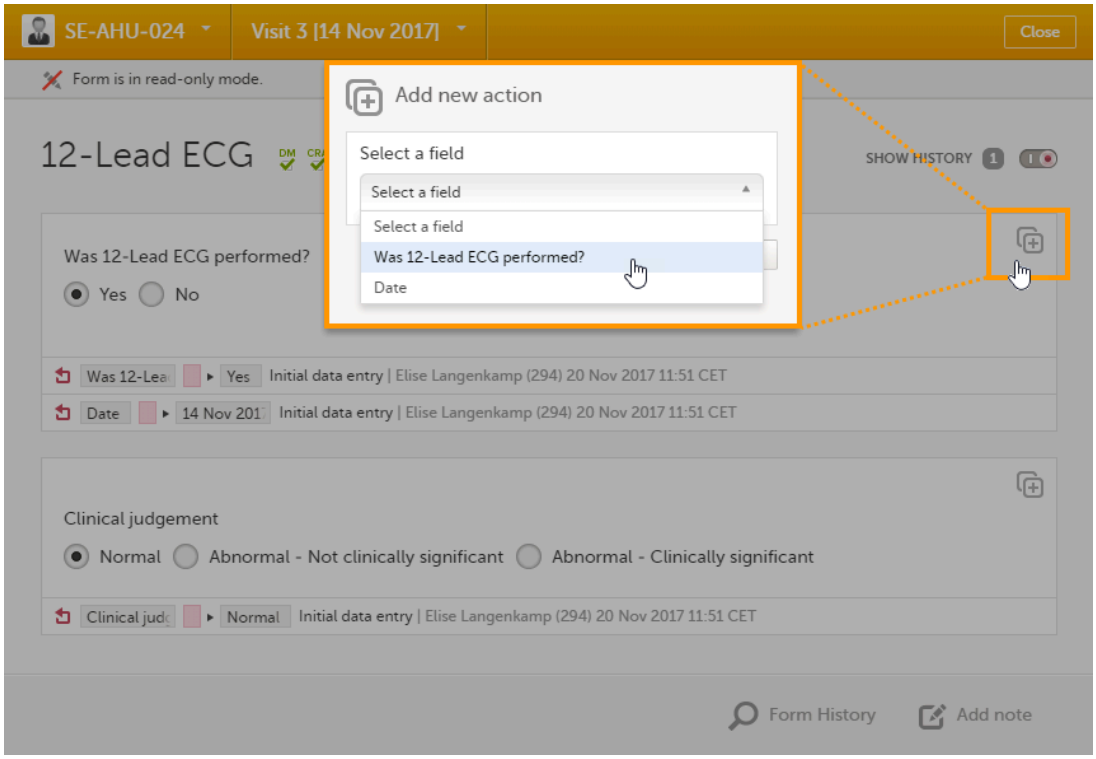
2 Enter the note text and click **Save note**. The note dialog closes and the note is displayed on the form.

8.3 Private notes for fields

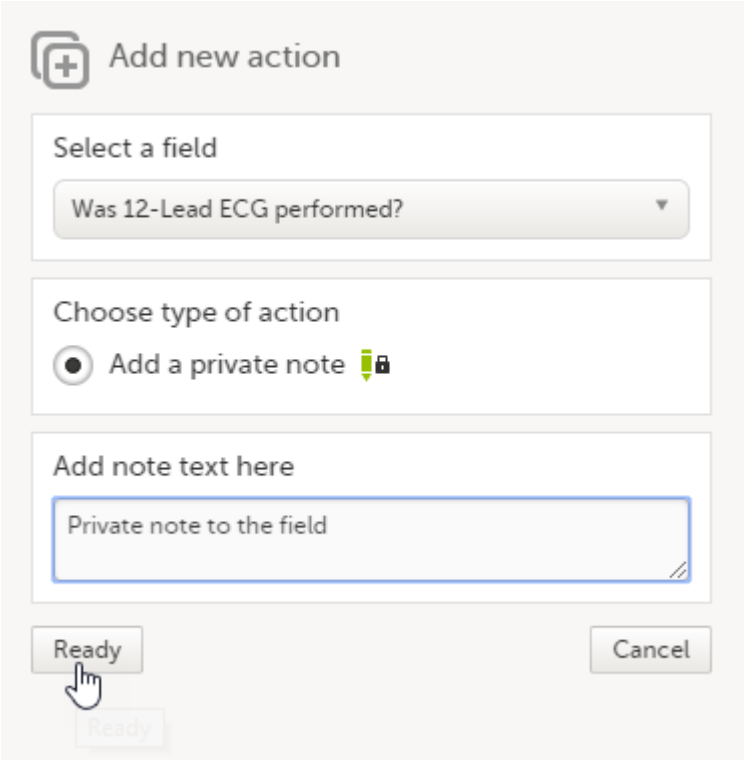
You can add private notes to single fields in a form. Private notes are only visible to the user that created the notes, and can only be edited by that user. Adding or editing a private note does not break the signature.

To add a private note for an event:

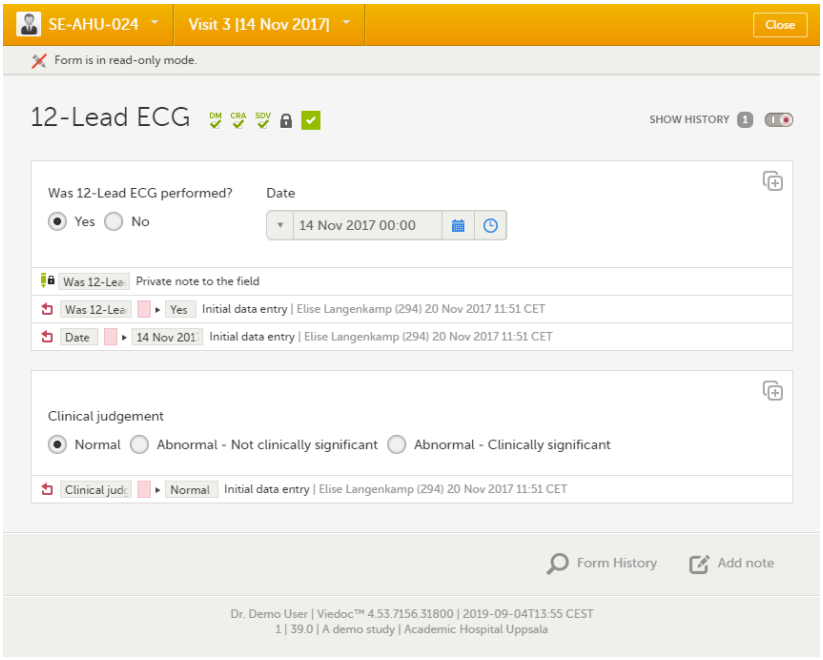
1 Click the action icon in the top right corner of the field group.
A dialog opens.
Select the field you would like to add the private note to.



2 Enter the note text and click **Ready**.



3 Click **Save changes**.
The notes dialog closes and the note is saved at the bottom of the field group.



9 Resolving a query

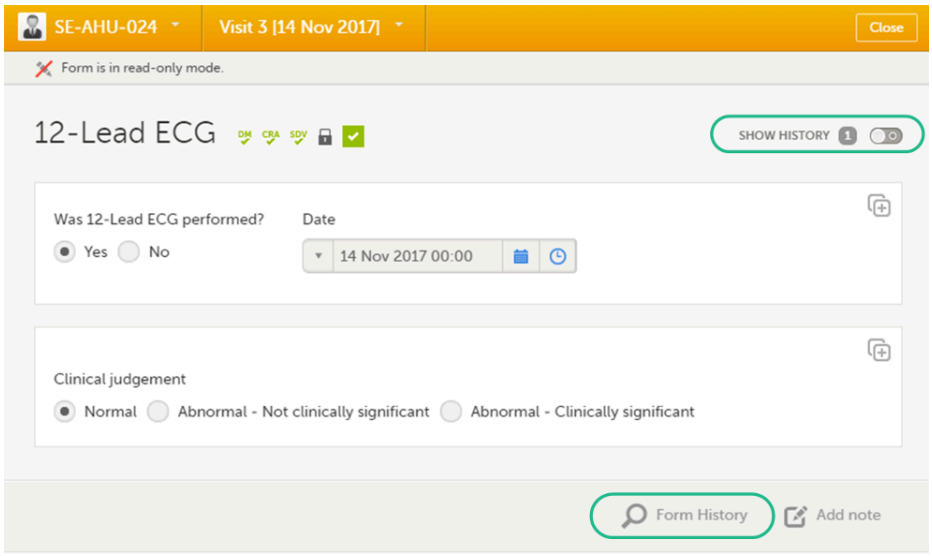
For complete instructions on how to resolve a query, see Resolving queries.

See also:

- The video tutorial Issues: Resolve a query
- Overview of the queries process and workflow in Viedoc - Queries overview

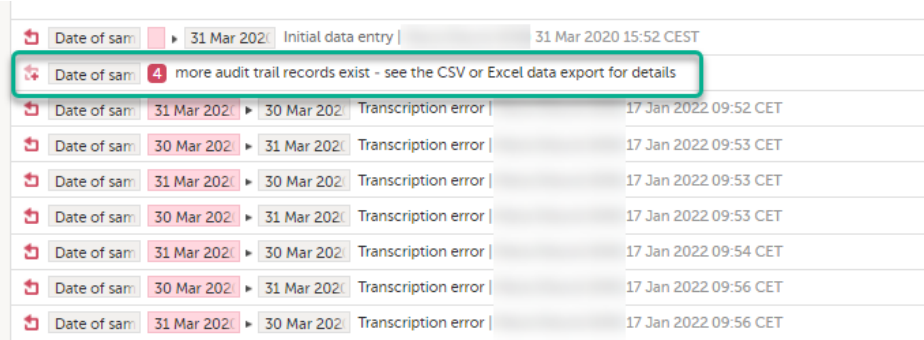
10 Audit trail and form history

You can view the history of a form, including information on who entered the initial data and who made any changes. To view the history, activate the **Show history** switch on the top right side of the form:



10.1 Limited number of audit trail records

To make the form history and the form history PDFs more manageable in terms of size, there is a limit to the number of displayed audit trail records. The history only displays the initial data entry and the latest 25 audit trail records. If there are more records, a message is displayed:



To see the complete form history, export to CSV or Excel. For more details on how to download and export the Admin Audit trail please select this link.

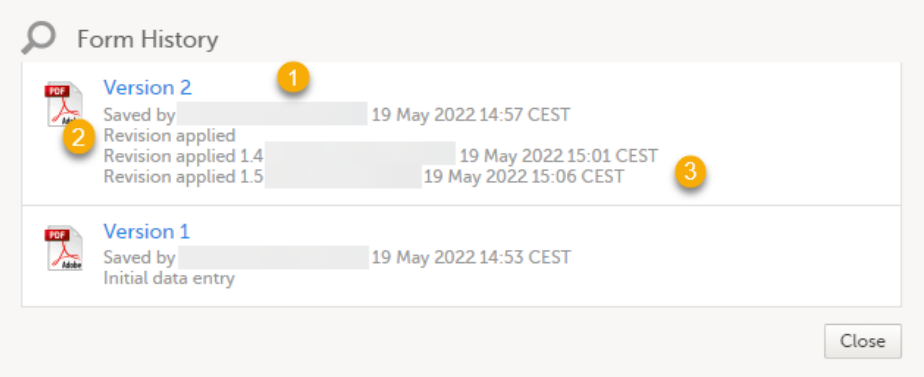
Note! It is not very likely that clinic staff would make more than 25 edits to a field. However, when working with JavaScript functions, that is a possibility.

10.2 Form history PDF

You can download PDFs of all the saved versions of the form by clicking **Form History** located on the bottom right side of the form.

If any of the fields in the form are hidden for your role, you are not able to see the form PDFs.

By clicking **Form History**, a list with all the form versions is displayed, and you can choose which version you want to download. There is one version of the form for each change performed on the eCRF.



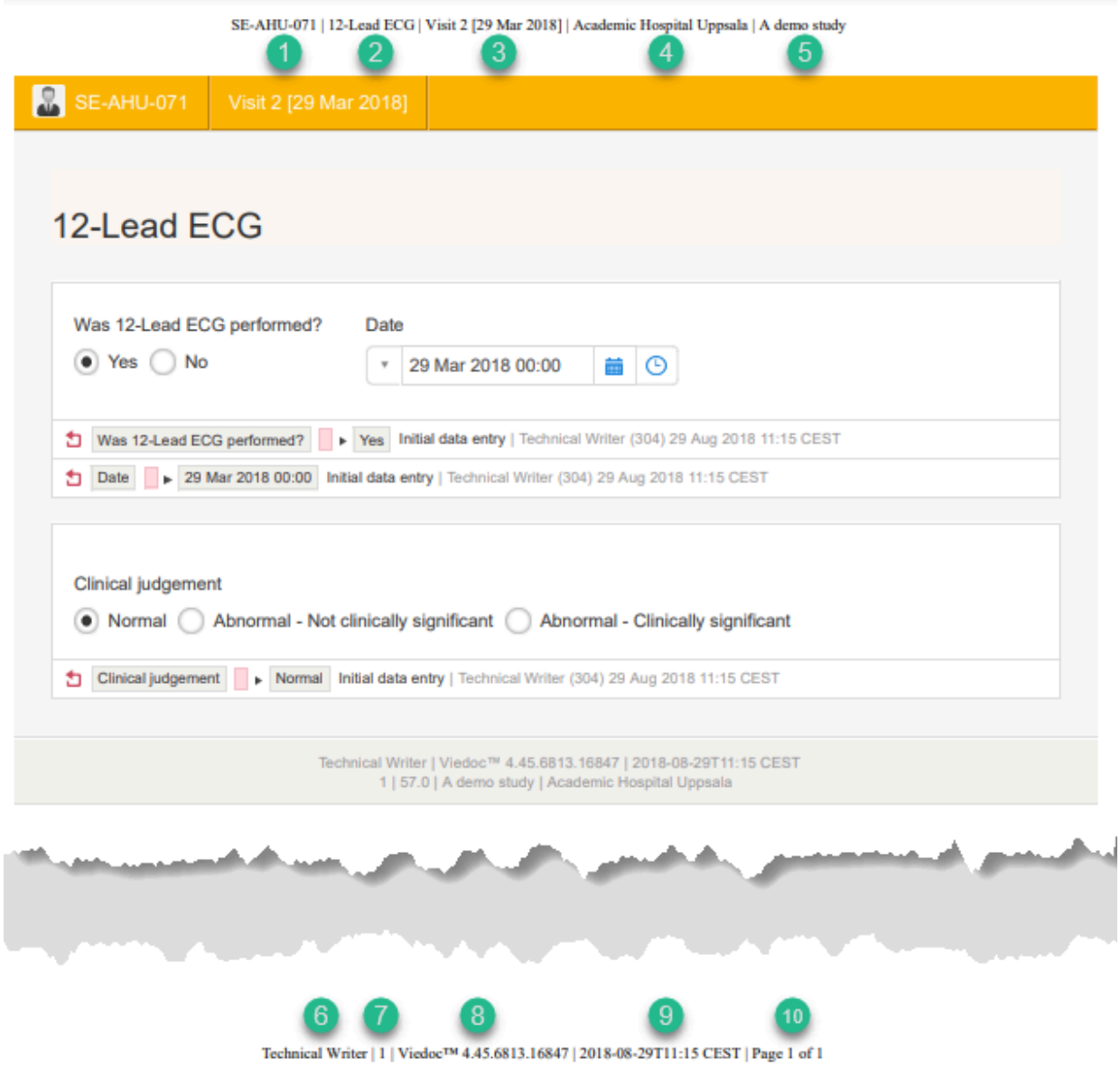
1. The user name of the user who saved the edited form.

2. "Revision applied" is displayed when a user has updated the form according to a new design revision. This can be done in one of two ways:

   - Manually edit a specific form
   - Manually perform a batch update of all forms with a pending upgrade

3. "Revision applied X.Y <Study Manager user name> <date time>" is displayed when the system has automatically updated the form according to a new design revision. This happens if the update in the revision does not affect the data integrity.

The PDF shows a screenshot of the form with the editing history included:



The page header and footer provide the following information, as illustrated in the previous image:

1. Subject ID
2. Form name
3. Event info (in the format set in the study design)
4. Site name
5. Study name
6. User name - the user who last edited the form
7. Version number - the version of the eCRF
8. Viedoc version number
9. Date and time when the form was last edited
10. Page number out of total number of pages of the PDF document

10.3 Masking of sensitive data

If sensitive data has been entered into a form, it is possible to mask such data so that it is not visible in the form history (except for roles with the specific permission). Sensitive data can, for example, reveal information about a subject's name or gender.

To mask sensitive data in the form history, your role must have the permission to anonymize data. The permission is set up in Viedoc Designer.

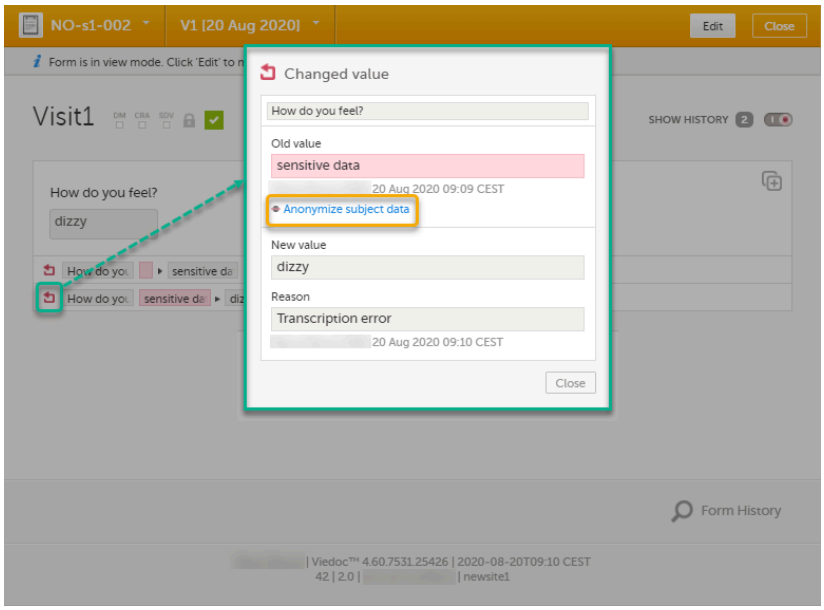
When sensitive data has been entered into a form, you first need to edit the data into something not sensitive, see Editing data. Then a record in the form history is created.

10.3.1 Masking text

To mask sensitive text data in the form history:

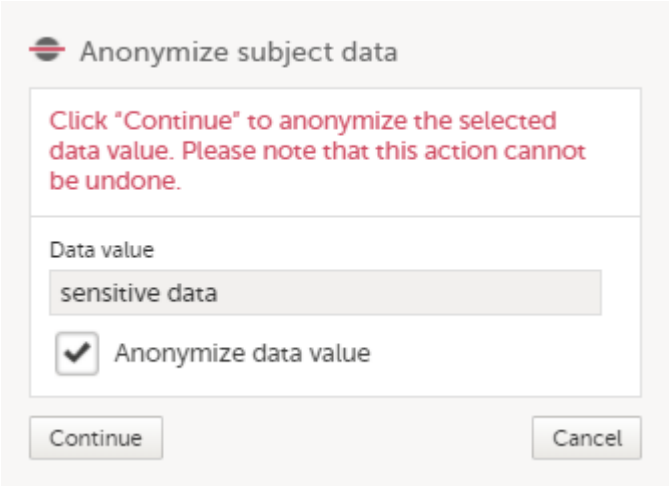
1 Click **Show history** in the top right corner of the form to open the form history.

2 For the history record with the sensitive data, click the **Changed value** icon.



3 Click **Anonymize subject data**.

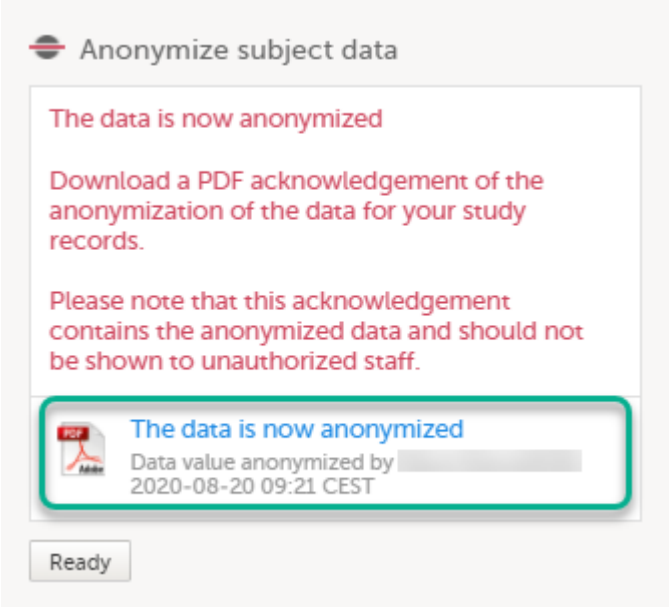
4 In the dialog that is displayed, select **Anonymize data value** and click **Continue**.



5 Enter your password and select **Submit**.

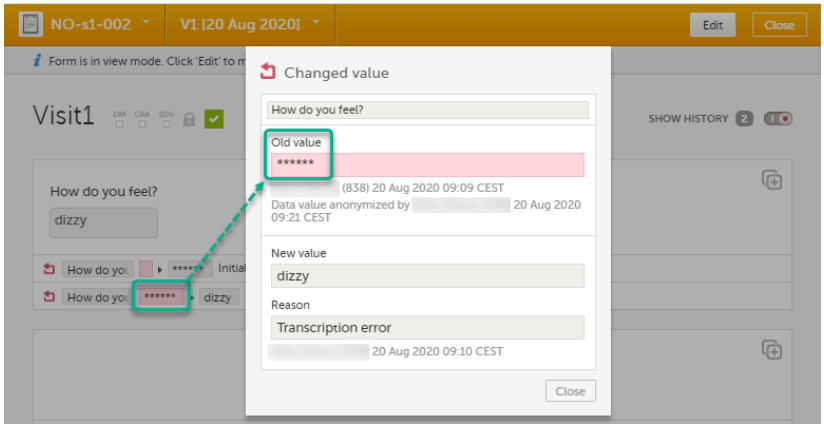
6 The dialog now displays a text confirming that the data is anonymized. Click **Ready**.

Note! All masking actions are logged so that it is possible to see when they were made and by whom.



Note! When the data has been masked, a PDF acknowledgement is created. The PDF contains information about what has been masked, when and by whom it was done. To download the PDF, click the link in the dialog. It is recommended to archive the PDF together with your study documentation.

7 The form history now displays asterisks in place of the sensitive data.



Note! The masked data will be masked also in an export.

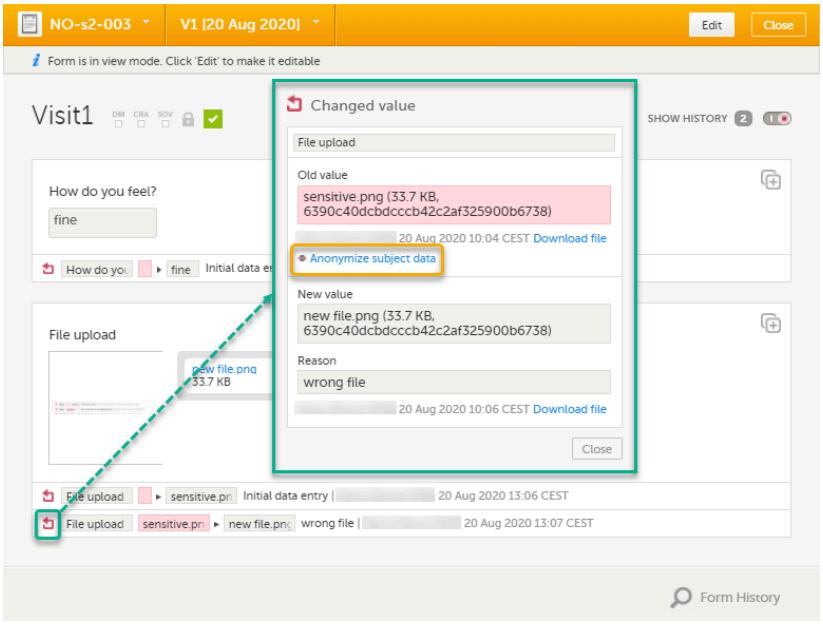
Note! Anonymization of data in linked forms does not affect the form link items, these have to be anonymized separately.

10.3.2 Masking a filename

To mask a sensitive filename in the form history:

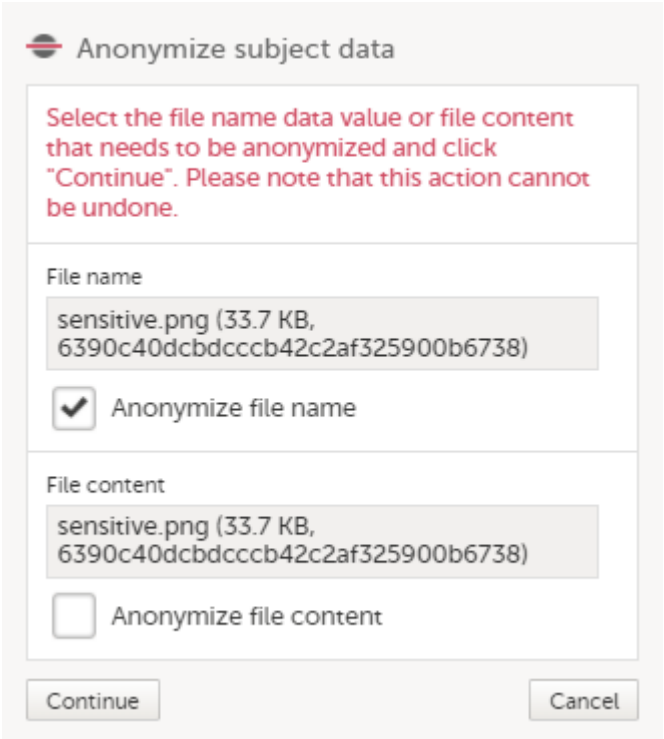
1 Click **Show history** in the top right corner of the form to open the form history.

2 For the history record with the sensitive filename, click the **Changed value** icon.



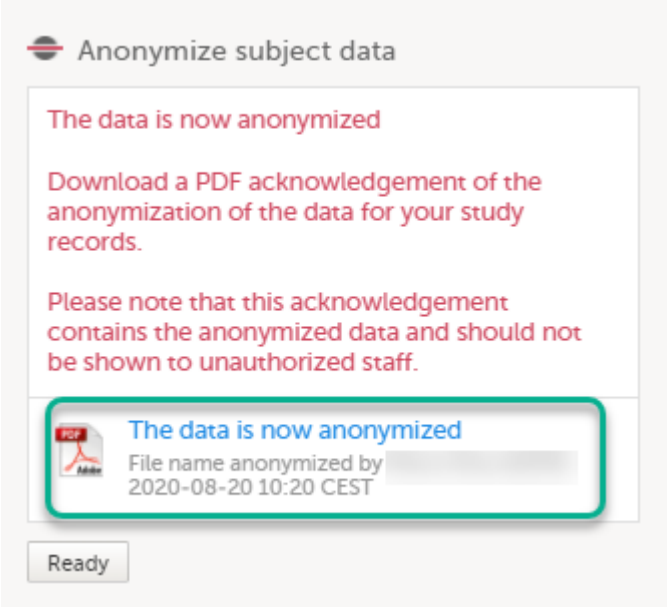
3 Click **Anonymize subject data**.

4 In the dialog that is displayed, select **Anonymize file name** and click **Continue**.



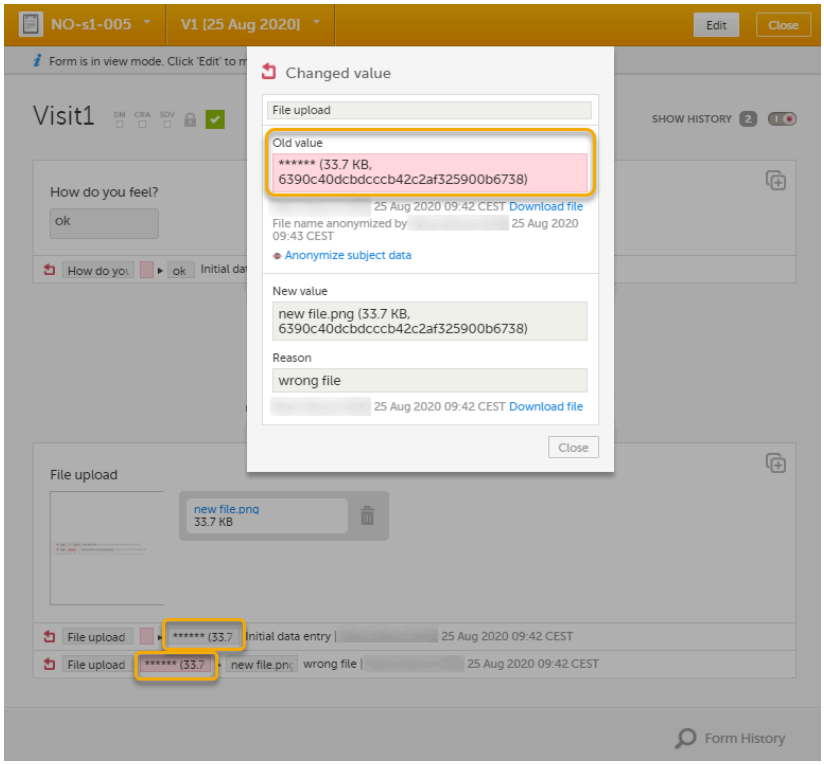
5 Enter your password and click **Confirm**.

6 The dialog now displays a text confirming that the filename is anonymized. Click **Ready**.



Note! When the filename has been masked, a PDF acknowledgement is created. The PDF contains information about what has been masked, when and by whom it was done. To download the PDF, click the link in the dialog. It is recommended to archive the PDF together with your study documentation.

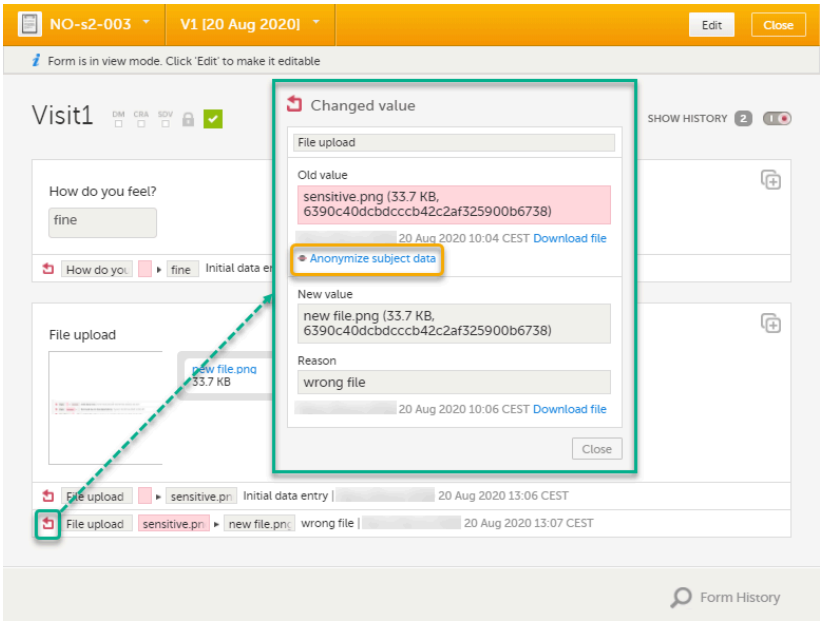
7 The masked filename is now no longer visible in the form history.



10.3.3 Masking file content

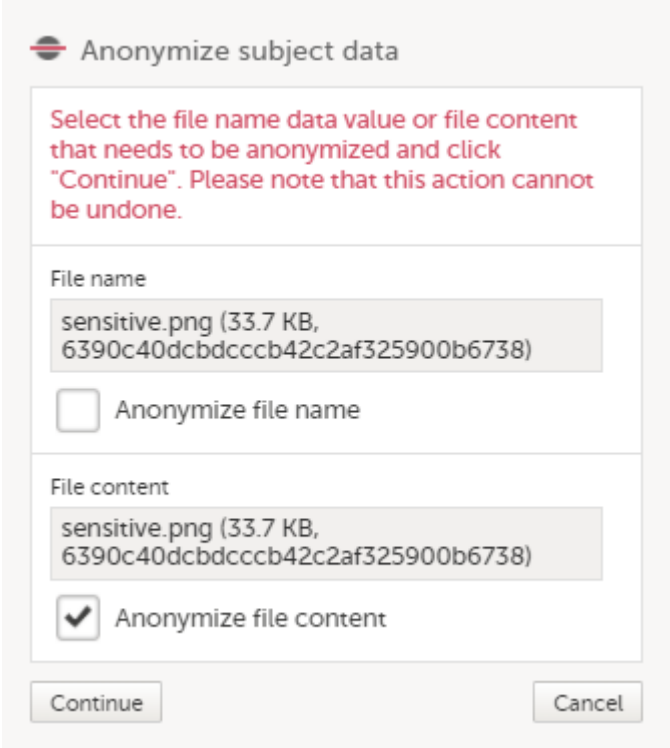
1 Click **Show history** in the top right corner of the form to open the form history.

2 For the history record with the sensitive file content, click the **Changed value** icon.



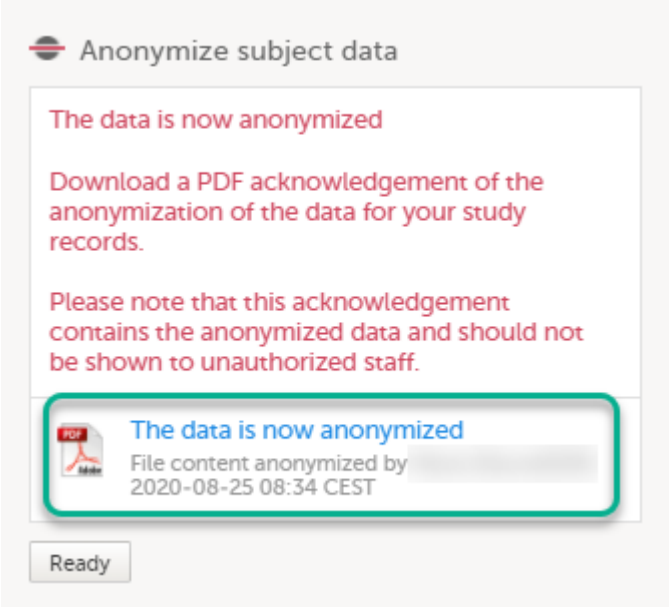
3 Click **Anonymize subject data**.

4 In the dialog that is displayed, select **Anonymize file content** and click **Continue**.



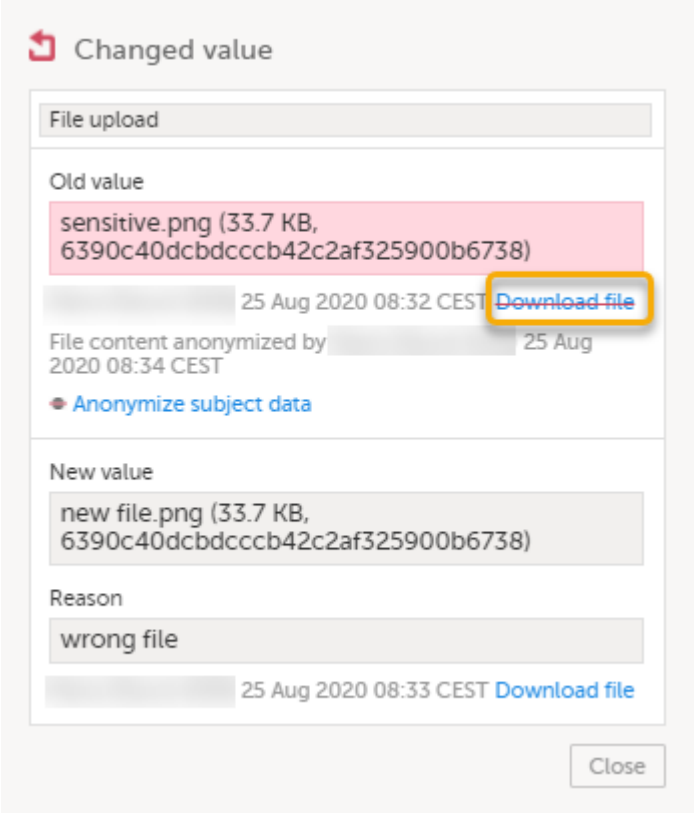
5 Enter your password and click **Confirm**.

6 The dialog now displays a text confirming that the data is anonymized. Click **Ready**.



Note! When the file content has been masked, a PDF acknowledgement is created. The PDF contains information about what has been masked, when and by whom it was done. To download the PDF, click the link in the dialog. It is recommended to archive the PDF together with your study documentation.

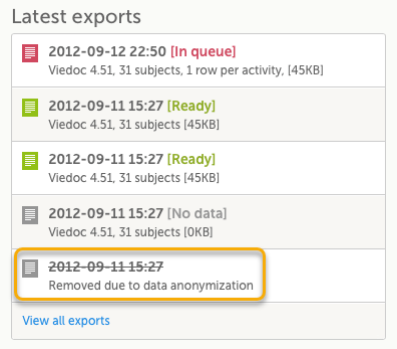
7 The masked file is now no longer accessible in the form history.



10.4 Consequences of masking data

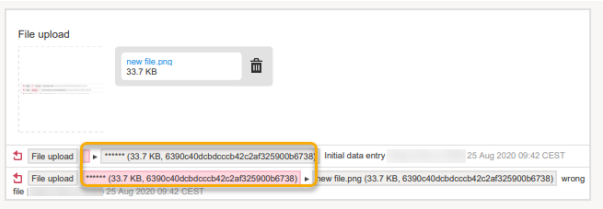
10.4.1 Data exports

Historical data exports that were created before the data masking can no longer be downloaded because such exports could include the data that was later masked.

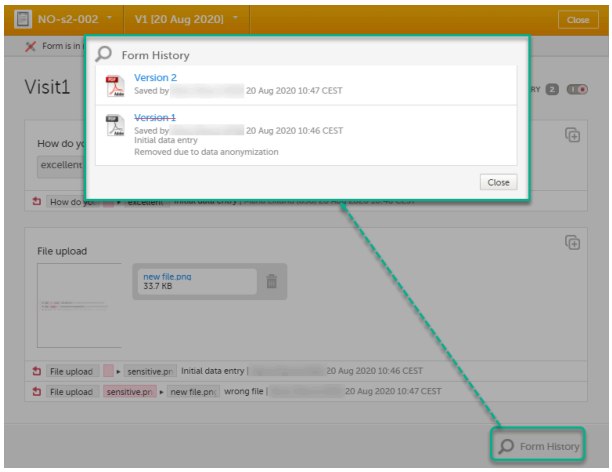


10.4.2 Form PDFs

When data has been masked, it is reflected in all form PDFs.



For a form version with masked data, and for all previous form versions, all form PDFs become unavailable because they could include the data that was masked.



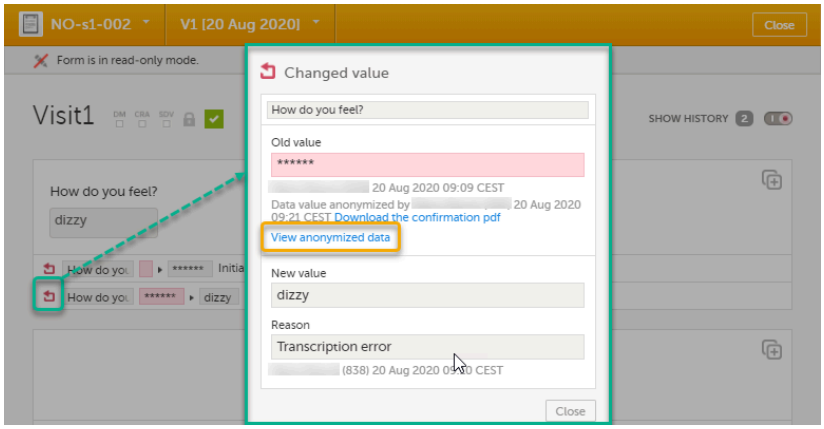
10.5 Viewing masked data

For roles with the permission to view anonymized data, it is possible to view masked data in the form history. The permission is set up in Viedoc Designer.

To view masked data:

1 Click **Show history** in the top right corner of the form to open the form history.

2 For the history record with the masked data, click the **Changed value** icon.

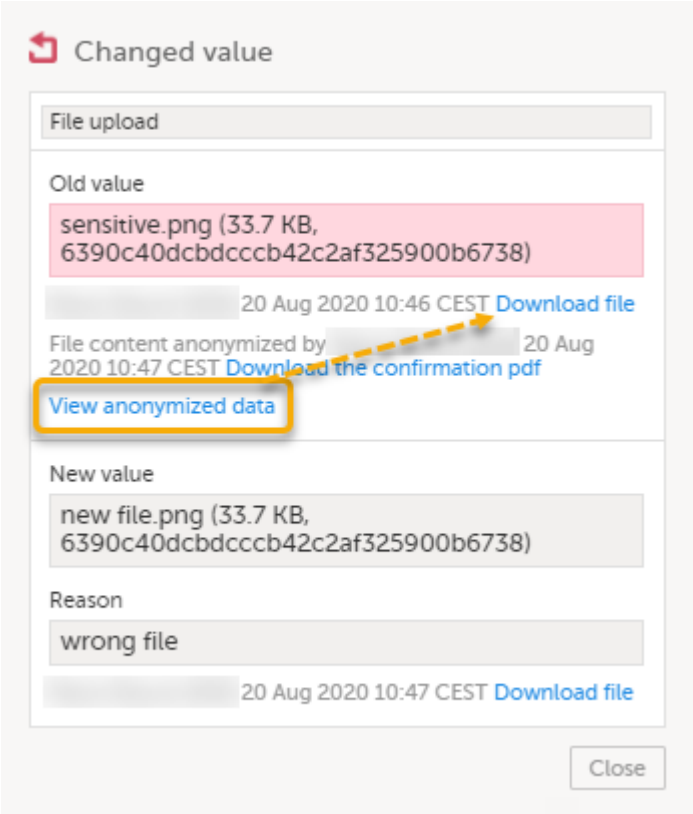


Note! You can download a confirmation PDF using the link in this dialog.

3 Click **View anonymized data**.

4 For masked text and filenames, the sensitive data is immediately displayed in the field **Old value**.

For masked file content, the disabled download link for the file is enabled.



Note! From this dialog, you can download a confirmation PDF. The PDF contains masked data and should not be shown to unauthorized staff.

---

11 Blacklisted file formats

The following executable file types are considered as high risk because essentially all computers with the listed operating system installed can carry out the commands contained in the executable file.

In other words, files with the extensions listed below can be executed with some basic part of Windows, Mac OS, Linux, and so on.

Due to this, the following file formats will not be accepted by Viedoc form file loader:

Extension	Format	Operating system(s)
ACTION	Automator Action	Mac OS
APK	Application	Android
APP	Executable	Mac OS
BAT	Batch File	Windows
BIN	Binary Executable	Windows, Mac OS, Linux
CMD	Command Script	Windows
COM	Command File	Windows
COMMAND	Terminal Command	Mac OS
CPL	Control Panel Extension	Windows
CSH	C Shell Script	Mac OS, Linux
EXE	Executable	Windows
GADGET	Windows Gadget	Windows
INF[1]	Setup Information File	Windows
INS	Internet Communication Settings	Windows
INX	InstallShield Compiled Script	Windows
IPA	Application	iOS
ISU	InstallShield Uninstaller Script	Windows
JOB	Windows Task Scheduler Job File	Windows
JSE	JScript Encoded File	Windows
KSH	Unix Korn Shell Script	Linux

Extension	Format	Operating system(s)
LNK	File Shortcut	Windows
MSC	Microsoft Common Console Document	Windows
MSI	Windows Installer Package	Windows
MSP	Windows Installer Patch	Windows
MST	Windows Installer Setup Transform File	Windows
OSX	Executable	Mac OS
OUT	Executable	Linux
PAF	Portable Application Installer File	Windows
PIF	Program Information File	Windows
PRG	Executable	GEM
PS1	Windows PowerShell Cmdlet	Windows
REG	Registry Data File	Windows
RGS	Registry Script	Windows
RUN	Executable	Linux
SCR	Screensaver Executable	Windows
SCT	Windows Scriptlet	Windows
SHB	Windows Document Shortcut	Windows
SHS	Shell Scrap Object	Windows
U3P	U3 Smart Application	Windows
VB	VBScript File	Windows

Extension	Format	Operating system(s)
VBE	VBScript Encoded Script	Windows
VBS	VBScript File	Windows
VBSCRIPT	Visual Basic Script	Windows
WORKFLOW	Automator Workflow	Mac OS
WS	Windows Script	Windows
WSF	Windows Script	Windows
WSH	Windows Script Preference	Windows

Resetting and deleting data

Resetting and deleting data

Published by Viedoc System 2022-02-10

1. Introduction
2. Resetting a form
    2.1 Resetting a radio button in a form
3. Deleting a common event
4. Deleting an unscheduled event
5. Resetting the event status
6. Deleting a subject

1 Introduction

This lesson describes how to delete a subject, a form, or an event.

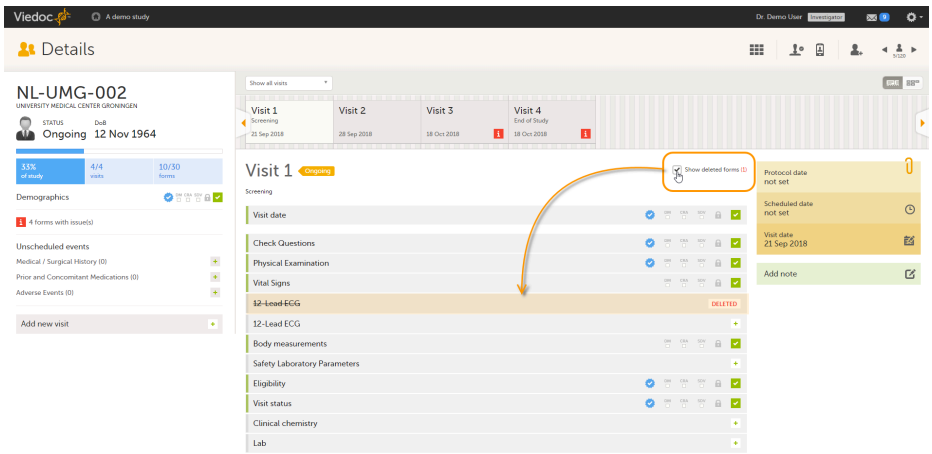
Note! No data, even if deleted or reset, is actually removed from the database. It is only marked as "deleted" and will not appear in the export output.

> Important! Although no data is deleted from the database, it is not possible to revert any deleted data. Therefore, please make sure to double-check the data before you delete the data. If any data is deleted by mistake, the deleted data is still available for preview and can be re-entered manually based on the old records.
>
> To view deleted forms, select **Show deleted forms** in the upper right corner of the form on the **Details** page.

2 Resetting a form

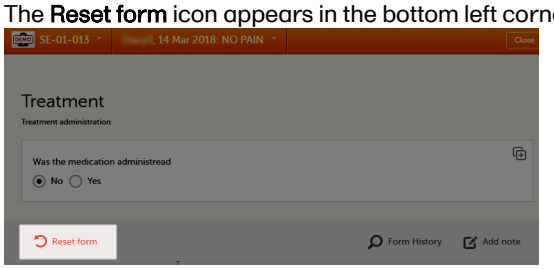
Resetting a form means that all data in the form is erased and the fields in the form appear empty again.

The old data in the form is still available for tracking purposes and can be accessed by activating the **Show deleted forms** checkbox on the **Details** page:

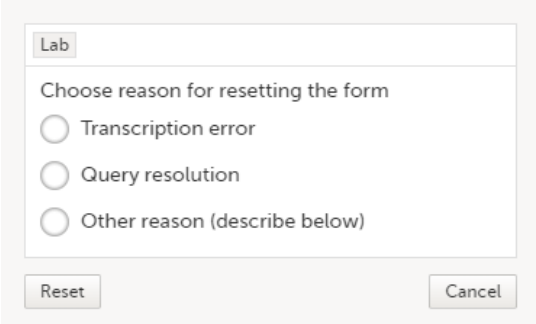


To reset a form:

1 Open the form and click **Edit** in the top right corner.
The **Reset form** icon appears in the bottom left corner of the form.



2 Click **Reset form**.
A pop-up appears asking for the reason for resetting the form.



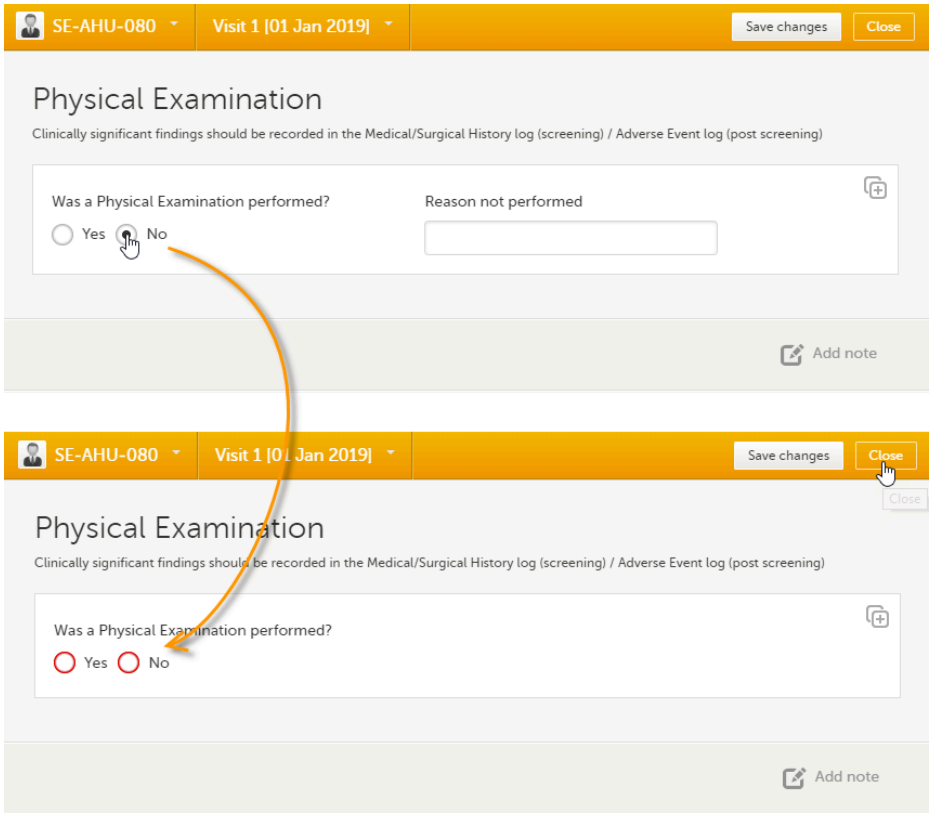
3 Enter the reason and click **Reset**.

Note!

- Any open queries in a form that is reset will automatically be closed by the system.
- If you cannot see the reset icon after clicking **Edit**, please contact your Site Manager or Study Manager for assistance. It might be possible that your role does not include permission to reset forms.

2.1 Resetting a radio button in a form

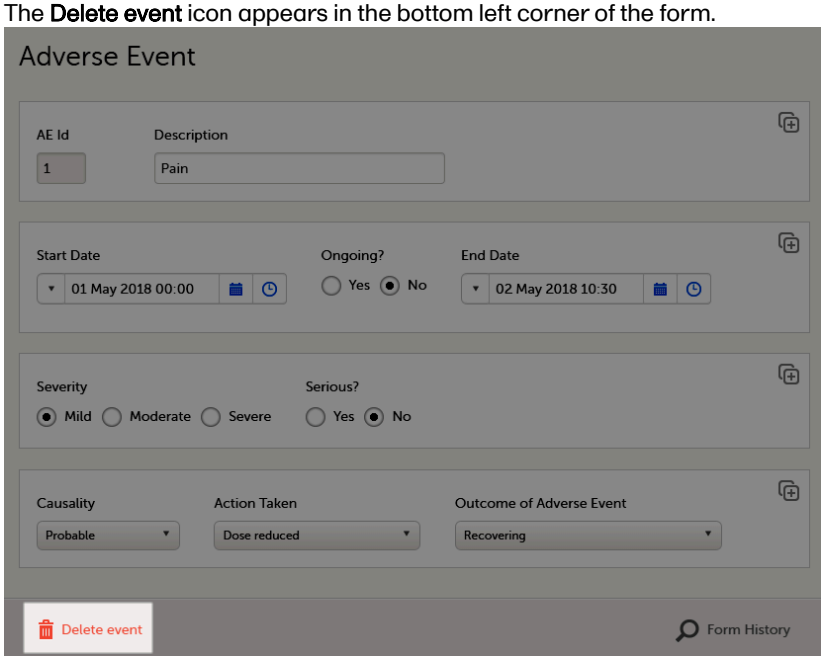
In case you made a selection in a radio button and want to return to the state in which no option is selected, you can reset the radio button. To reset a radio button, click the selected radio button again, and it will be deselected:



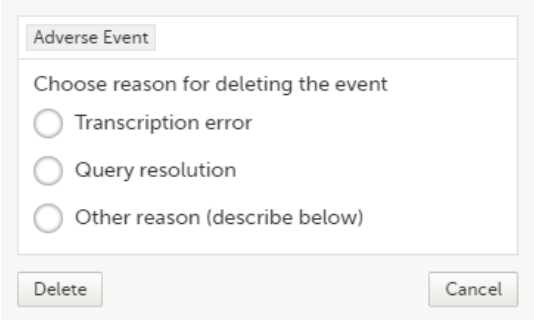
3 Deleting a common event

To delete a common event such as Adverse Event, Concomitant Medications or Medical History:

1 Open the event and click **Edit** in the top right corner.
The **Delete event** icon appears in the bottom left corner of the form.



2 Click **Delete event**.
A pop-up appears asking for the reason for deleting the event.



3 Provide the reason and click **Delete**.
The event is deleted but available for tracking purposes in the history.

Note!

- Any open queries in a deleted event will automatically be closed by the system.
- If you cannot see the delete icon after clicking **Edit**, please contact your Site Manager or Study Manager for assistance. It might be possible that your role does not include permission to delete events.

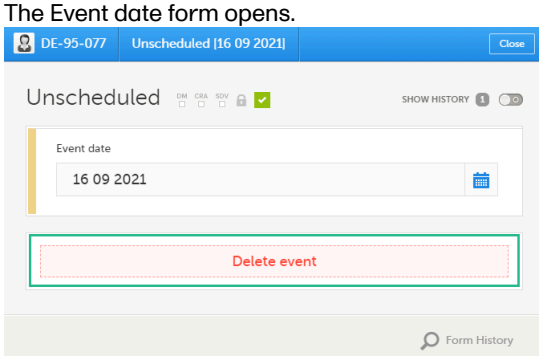
---

4 Deleting an unscheduled event

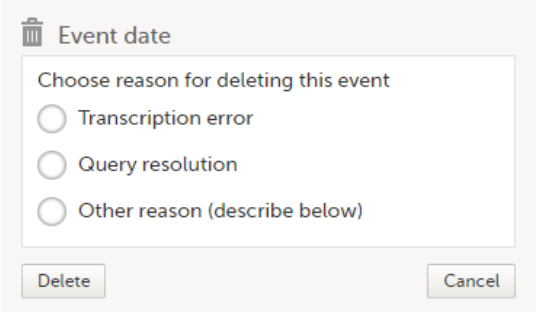
If you have added an event manually using the **Add new event** button (see Entering/Editing data), you can remove the manually added event if it does not contain any data. If any form within a manually added event is completed, the form needs to be reset before the event can be deleted.

To delete a manually added event:

1 Open the event and click **Event date**.
The Event date form opens.

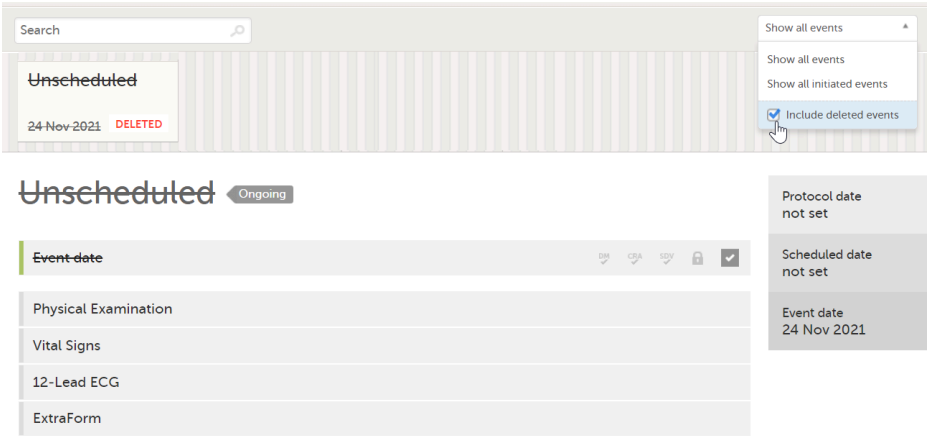


2 Click **Delete event**.
A pop-up appears asking for the reason for deleting the event.



3 Provide the reason and click **Delete**.

Once the event is deleted, the event gets a **DELETED** stamp, the event name appears in strikethrough, and the content of the event is displayed in grey. By default, all deleted events are still visible in the schedule. You can select to show or hide the deleted events by selecting or clearing the **Include deleted events** checkbox in the **Show all events** drop-down list:



5 Resetting the event status

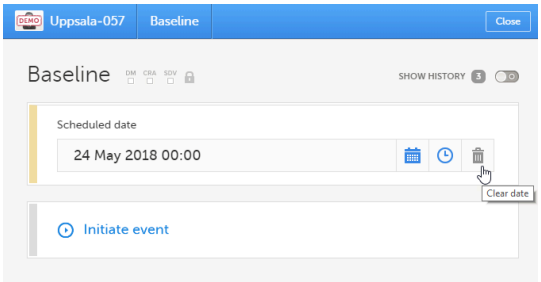
If you have initiated or planned a scheduled event by mistake, you can set it back to its previous status. If any data is entered on the event, the forms with data need to be reset before the event status can be reset.

Note! If a scheduled event with visibility conditions is reset and the conditions were not fulfilled, the event status is set as "Deleted".

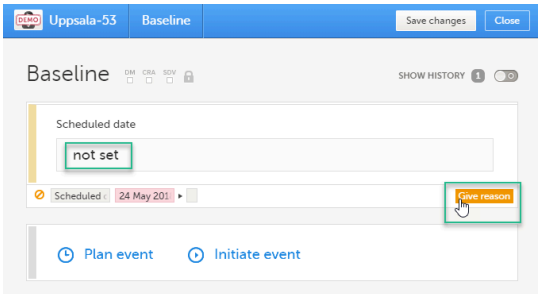
To reset the event status for a scheduled event that was initiated/planned:

1 Open the event and click **Event date**.
The Event date form opens.

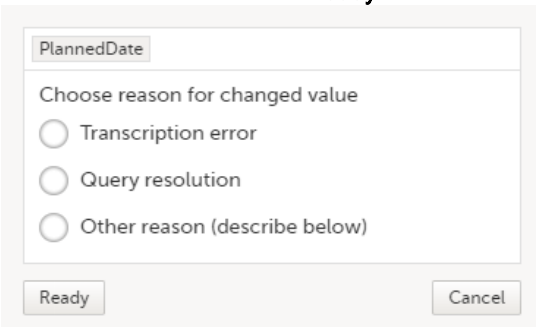
2 Click the trash can icon next to the date.



3 The date is now **not set**.
Click **Give reason**.



4 Provide the reason and click **Ready**:

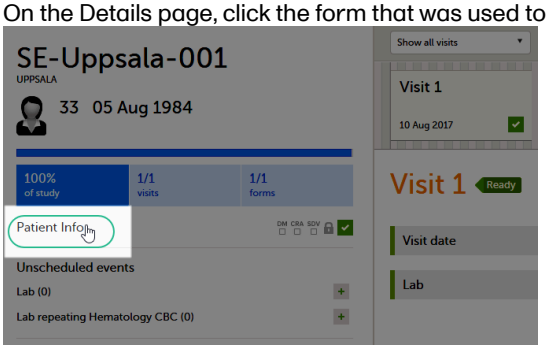


6 Deleting a subject

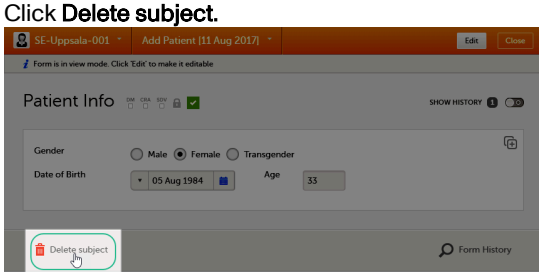
Note! A subject cannot be deleted if the form that was used to add the subject is locked.

To remove a subject from the study:

1 On the Details page, click the form that was used to add the subject.

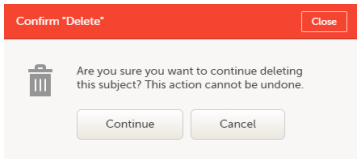


2 Click **Delete subject**.



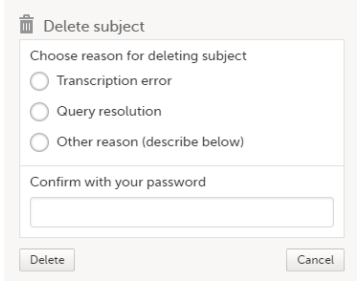
A confirmation dialog appears.

3 Click **Continue**.



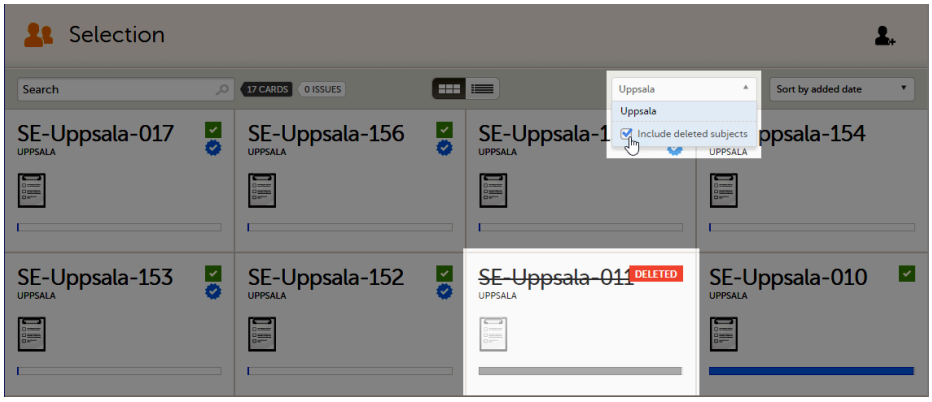
You will be prompted to enter the reason for deletion.

4 Provide a reason, enter your password and click **Delete**.



After deletion, the Details page is marked in grey, but all forms are still accessible.

The subject card is also still visible on the Selection page. You can select to remove the subject card from the Selection page by clearing the **Include deleted subjects** checkbox in the drop-down list of the site in the top right corner of the Selection page.



Signing data

Signing data

Published by Viedoc System 2023-10-10

1. Introduction
    1.1 Signature definition
2. Signing console

1 Introduction

Data is signed by the Investigator. Signing for a subject can be done on an individual form, event, or across a study through the signing console.

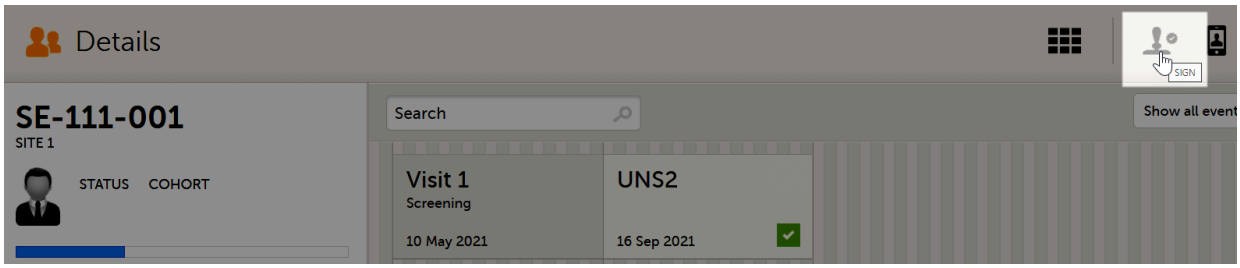
1.1 Signature definition

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.

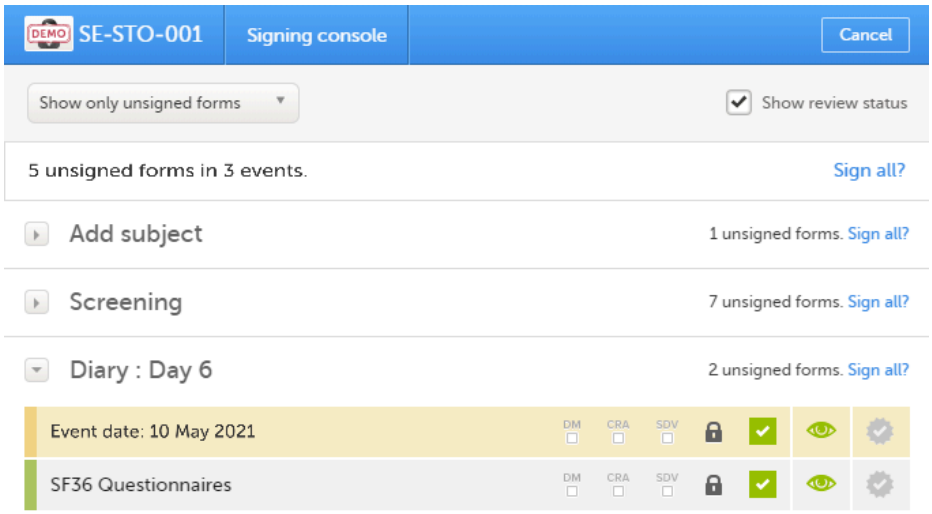
In Viedoc, the purpose/meaning of a signature is always “responsibility” as used in Sec. 11.50 of Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11. The signer is thereby acknowledging his/her responsibility for the entered data. Viedoc keeps account of what was signed,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

2 Signing console

To access the signing console, go to the Details page and click the **SIGN** icon in the top right corner of the page:



The signing console opens:



The signing console provides a list of all the initiated forms with no issues for the selected subject, grouped by event.

You can use the filter in the top of the page to:

- Show all forms
- Show only unsigned forms

The eye icons help you identify which forms you have visited (the most recent version of the form), the green eye icon means that you have visited the last version of the form, the grey eye icon means that you have not visited the latest version of the form.

To review a form, simply click the form bar. After closing the form, you will end up in the signing console again.

To view the review status of:

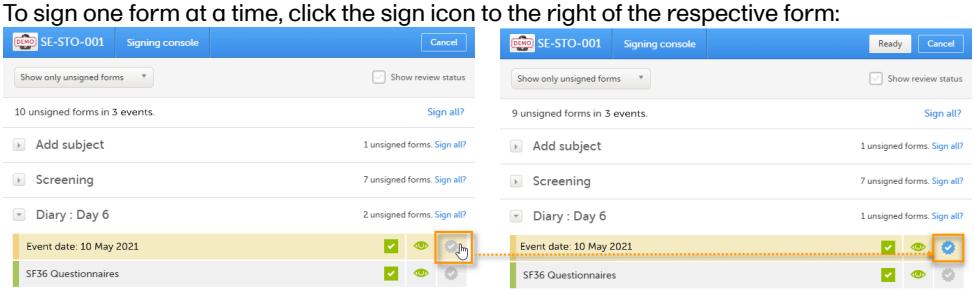
- **CRA** - reviewed by Clinical Research Associate (CRA) or other role with review permission
- **DM** - reviewed by Data Manager (DM) or other role with review permission
- **SDV** - performed Source Data Verification (SDV)

...for each form, check the **Show review status** checkbox in the top right corner of the page.

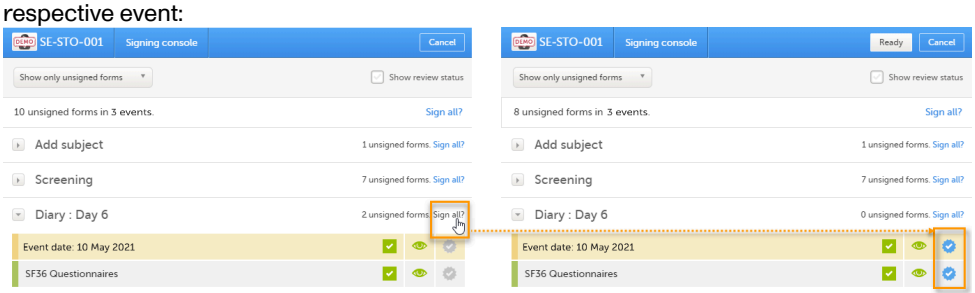
To sign the data:

1 Mark the form(s) to be signed in one of the following ways:

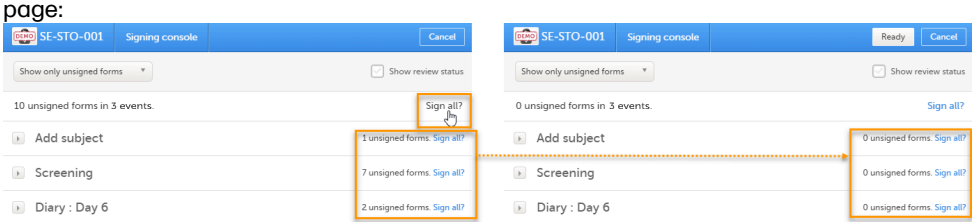
- To sign one form at a time, click the sign icon to the right of the respective form:



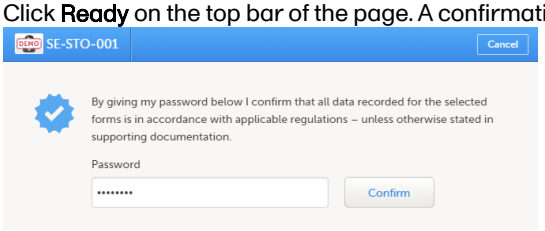
- To sign all unsigned forms within an event, click the **Sign all?** link to the right of the respective event:



- To sign all unsigned forms for the respective subject, click the **Sign all?** link in the top of the page:



2 Click **Ready** on the top bar of the page. A confirmation dialog is displayed:



The text explains the default meaning of the signature in Viedoc when the Investigator signs data. It is a generic text meant to cover all the regulations under which any study is conducted. The regulations are different according to the study, and it is the responsibility of the Study Manager/Study Coordinator (or any responsible for the study site) to inform the Investigator about the regulations.

3 Type in your password and click **Confirm**.

Important! If you enter an incorrect password 3 times in a row, your account will be locked.

See also the video tutorial Sign data.

Working with reference data

Published by Viedoc System 2021-11-24

1. Introduction
    1.1 About reference data
    1.2 Terminology
    1.3 Workflow
2. Reference data overview
    2.4 Overview of reference data on the landing page
    2.5 The reference data editor
        2.5.1 How to use the reference data editor
        2.5.2 Variables
        2.5.3 Factors
    2.6 How the reference data feature works within the forms
3. Entering and publishing reference data values
4. Editing reference data values

1 Introduction

1.1 About reference data

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

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

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

1.2 Terminology

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

1.3 Workflow

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

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

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

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

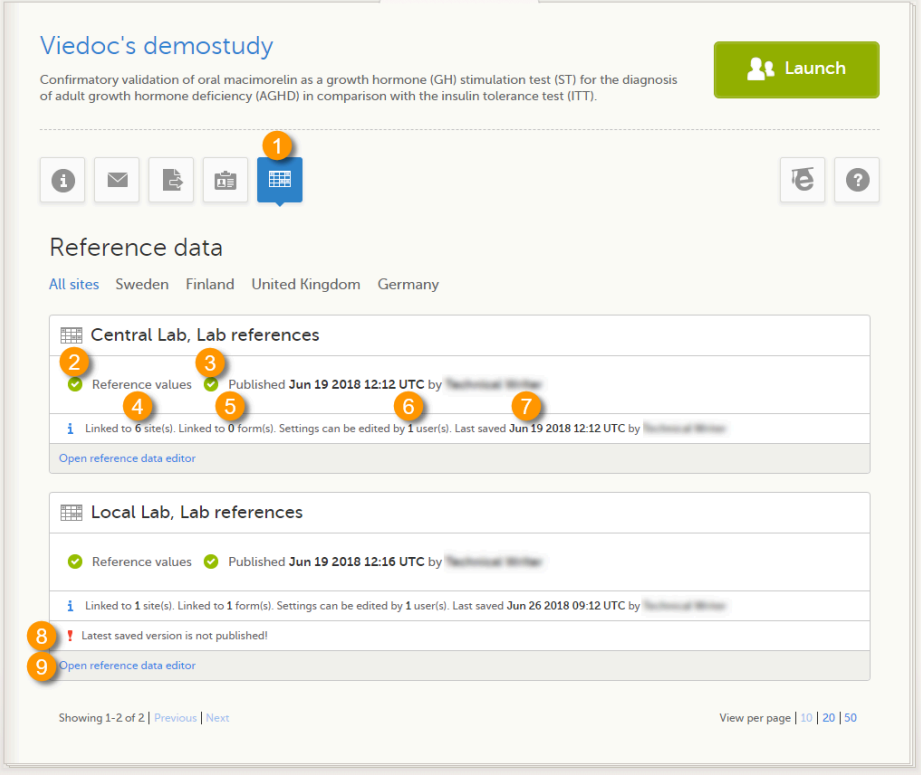
See also the video tutorial demonstrating how to work with reference data in Enter reference data.

---

2 Reference data overview

2.1 Overview of reference data on the landing page

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



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

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

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

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

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

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

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

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

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

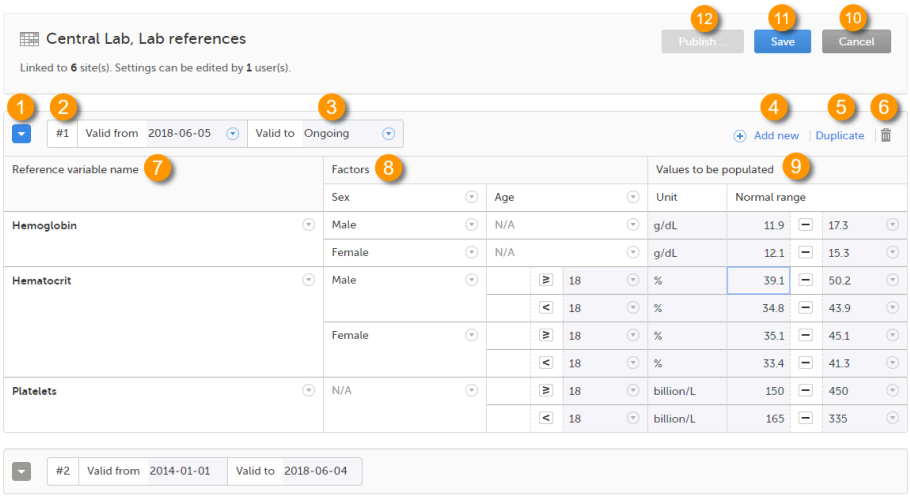
8. Warning message if the latest saved version was not published.

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

2.2 The reference data editor

2.2.1 How to use the reference data editor

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



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

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

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

3. The period the reference data set is valid.

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

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

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

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

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

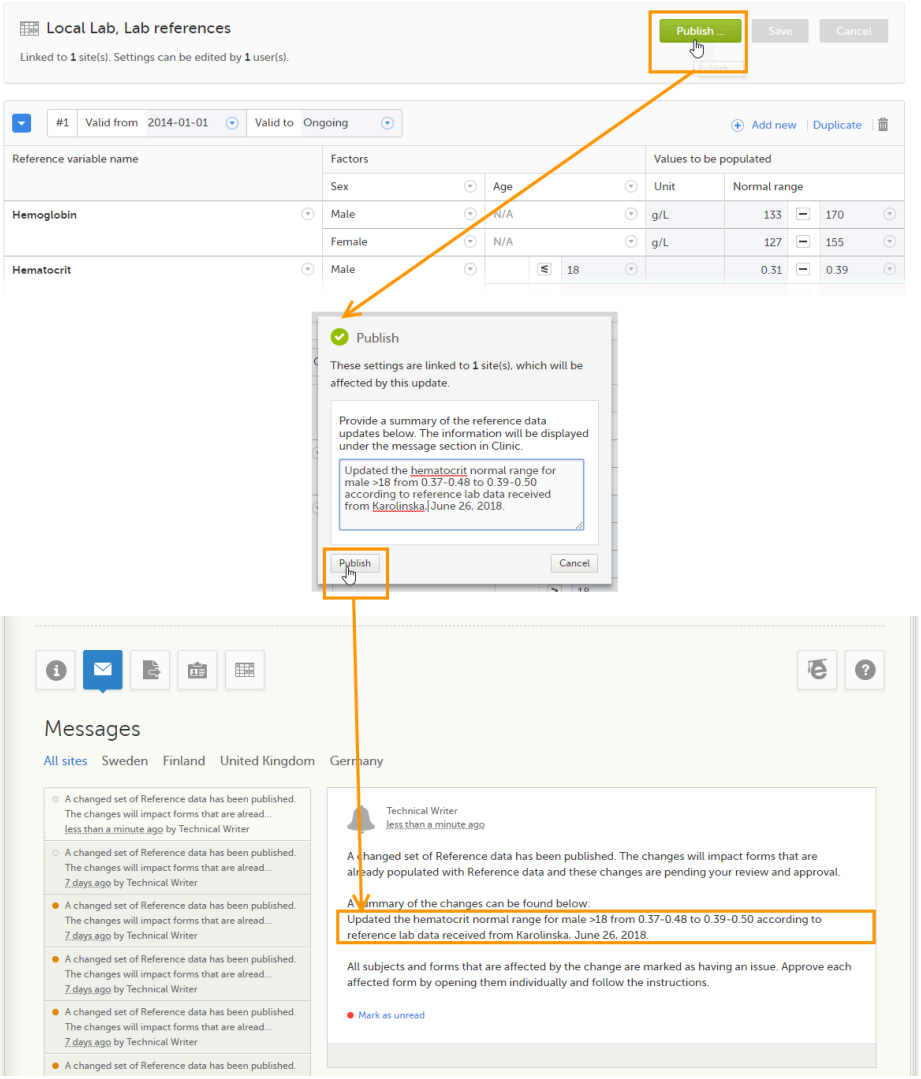
8. **Factors** - the factors that are defined in the scope. Factors are parameters that affect the reference data. See Factors for more information.

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

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

11. Click **Save** to save the changes performed.
Note! Only users with clinic roles that have permission to edit reference data can edit and save the reference data.
Upon save, the reference data set becomes available for publishing.

12. Click **Publish** to publish the reference data. A dialog appears asking you to enter a message. This message appears in the **Messages** section on the landing page.
Publishing makes the data available for auto-population into the subject forms.
Note! Only users with clinic roles that have permission to publish reference data can publish the reference data.



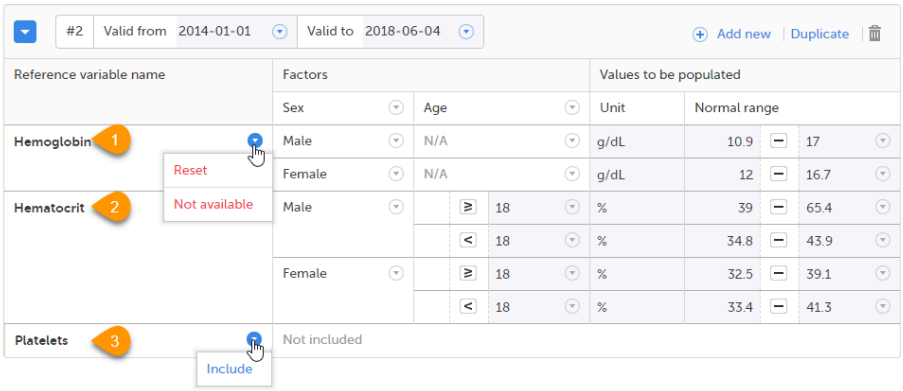
2.2.2 Variables

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

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

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

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



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

2.2.3 Factors

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

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

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

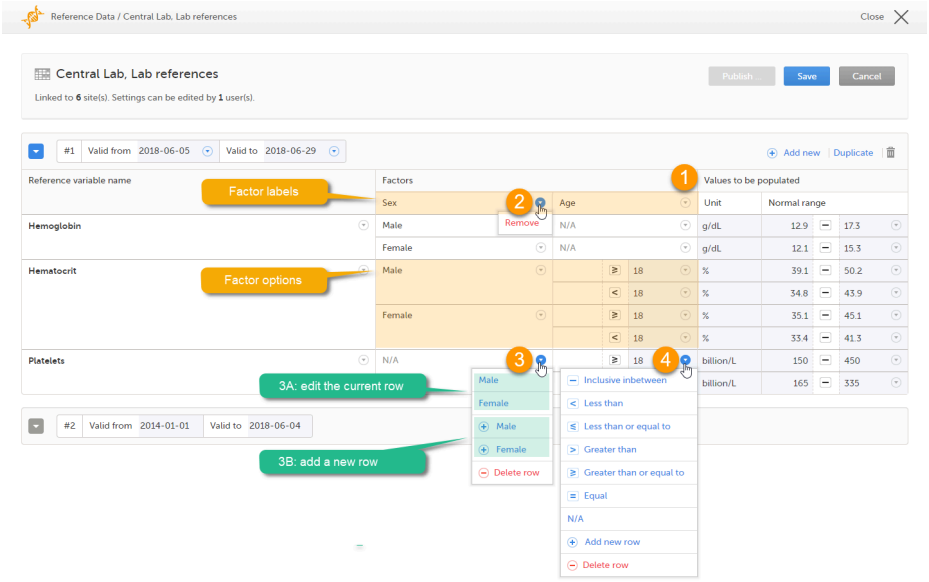
By default, a newly added factor is populated with *N/A* (not applicable) in the table. You can edit this by clicking the arrow to the right of *N/A* and select one of the options from the drop-down list. The drop-down list displayed varies depending on whether the factor has predefined factor options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

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

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

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

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



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

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

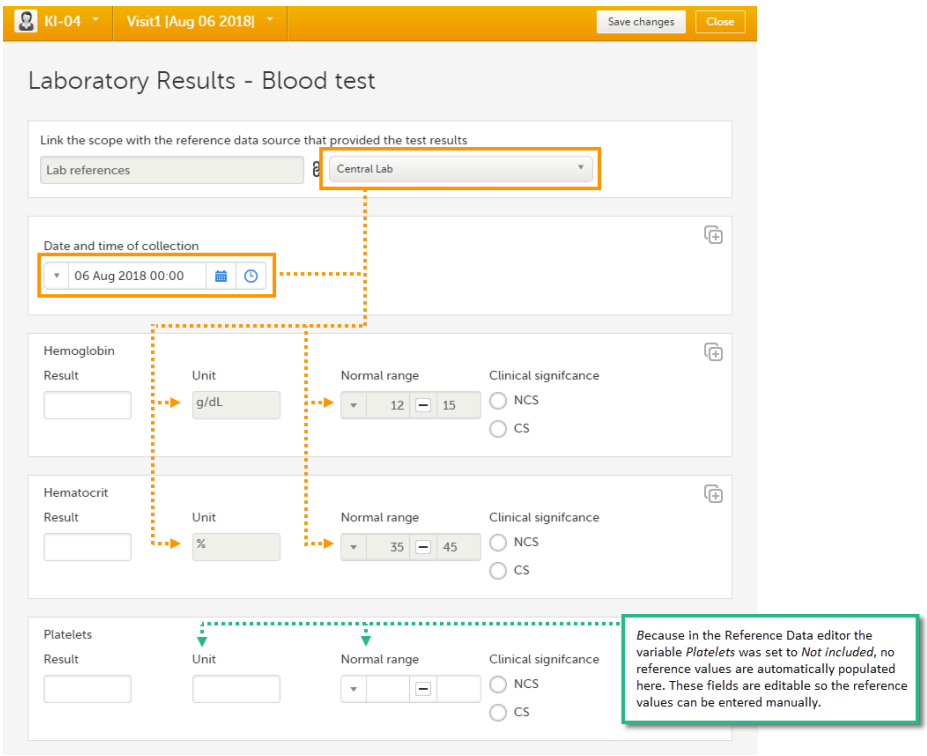
2.3 How the reference data feature works within the forms

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

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

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

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



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

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

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

---

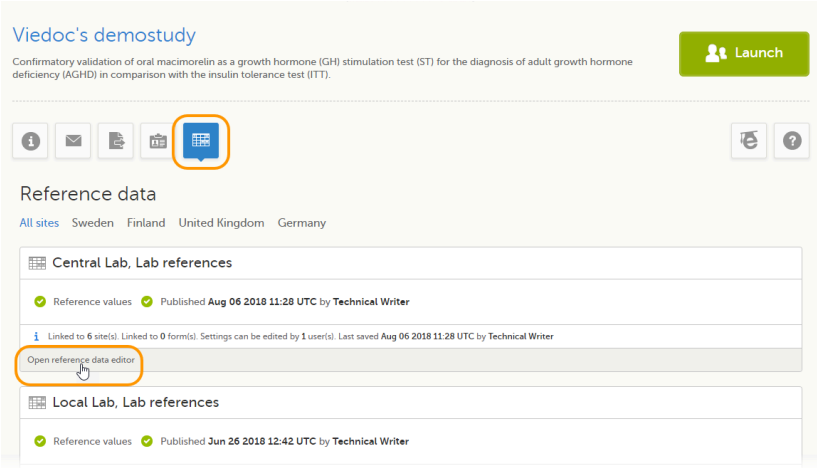
3 Entering and publishing reference data values

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

To enter a new set of reference values:

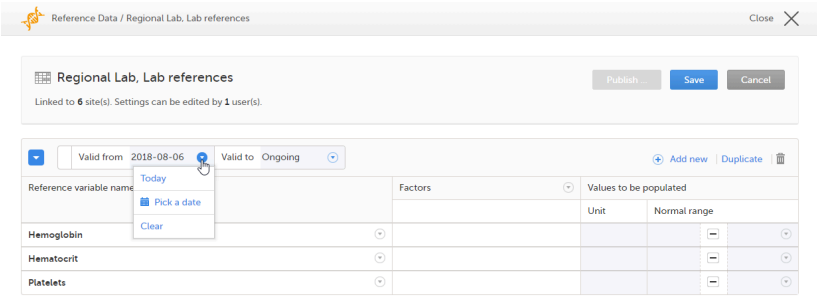
1 On the Viedoc landing page, click the **Reference data** icon.

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

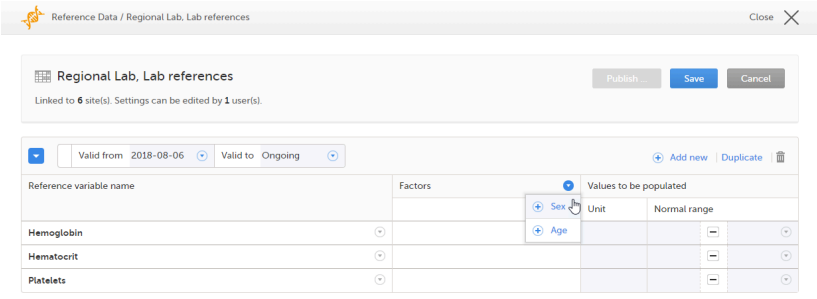


The reference data editor opens and displays the variables and the target types to be populated, as defined in the reference data scope. If you would like to exclude some of the variables, click the arrow to the right of the variable name and select **Not available**. See also Variables for more information.

3 Select the date from which, and to which, this set of reference values is valid in the **Valid to** and **Valid from** fields.

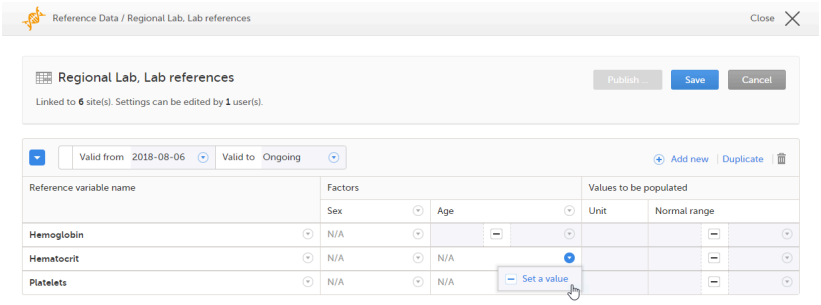


4 Click the arrow to the right of **Factors** and select the factors that should be included.

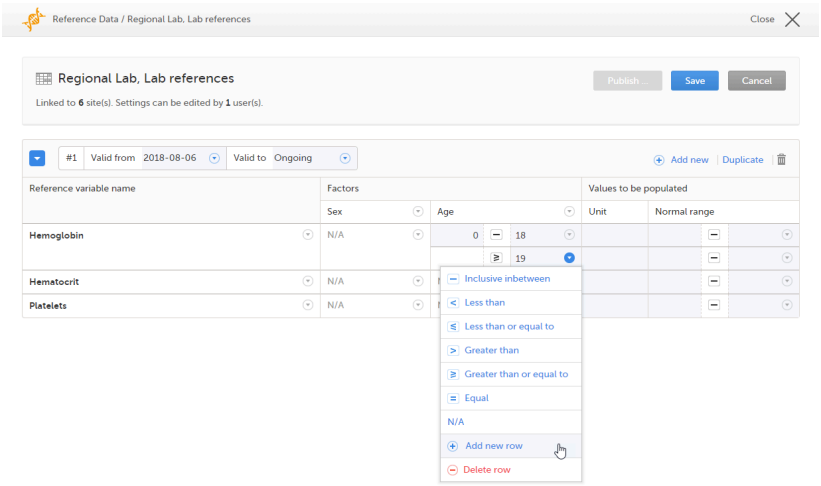


5 For every variable, and for every factor, click the arrow to the right of *N/A* and select the factor options that should be included.

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



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



See also Factors for more information.

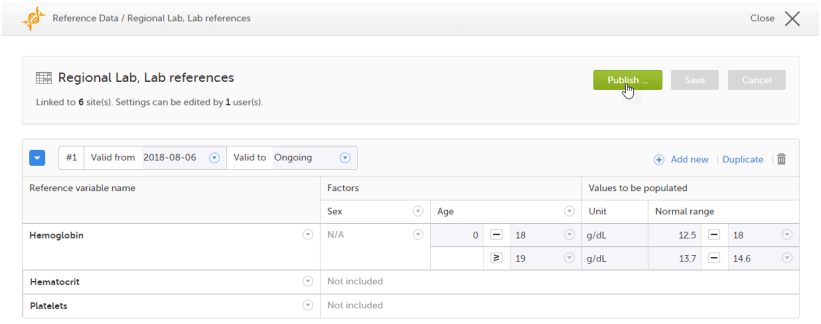
6 For every variable, and for every factor, enter the reference values that should be automatically populated to the forms.

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

To publish reference data:

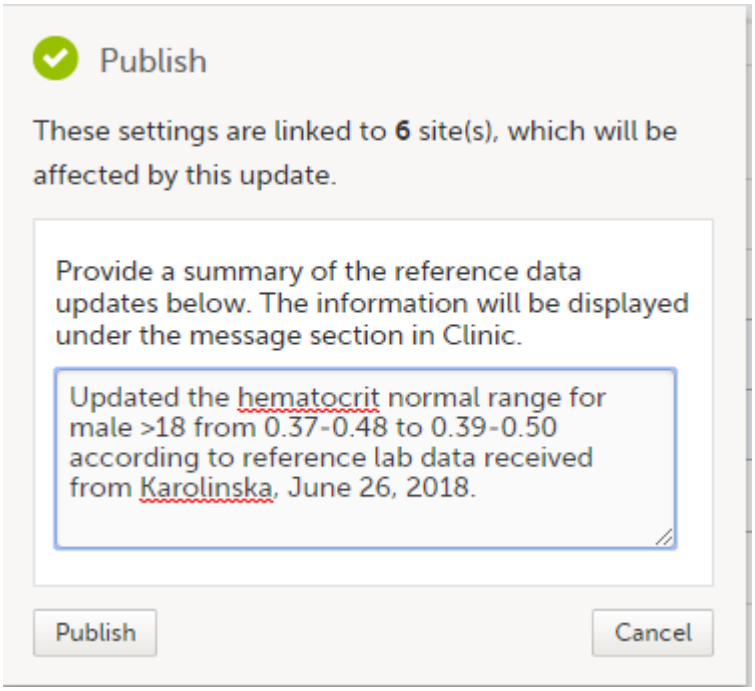
Note! You can only publish reference data when your role has permission to publish reference data.

1 Click **Publish**.



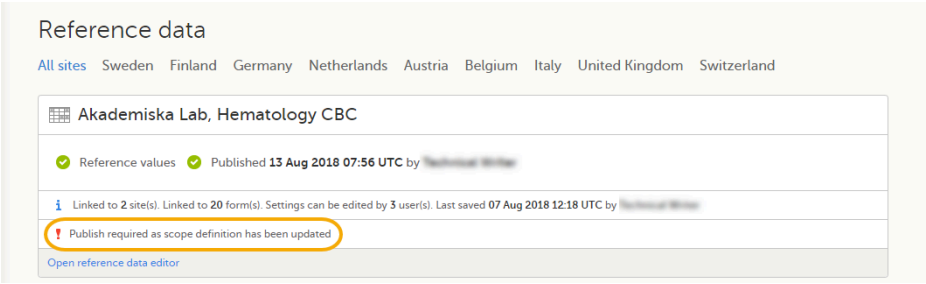
A dialog opens.

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



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

If the reference data scope is changed and published in Viedoc Designer after the reference values have been published in Viedoc Clinic, the following message will appear on the Reference data page.



The reference date source-scope combination needs to be updated and published again in Viedoc Clinic, for the reference values to become available for auto-population to the subject forms.

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

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4 Editing reference data values

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

To edit a set of reference values:

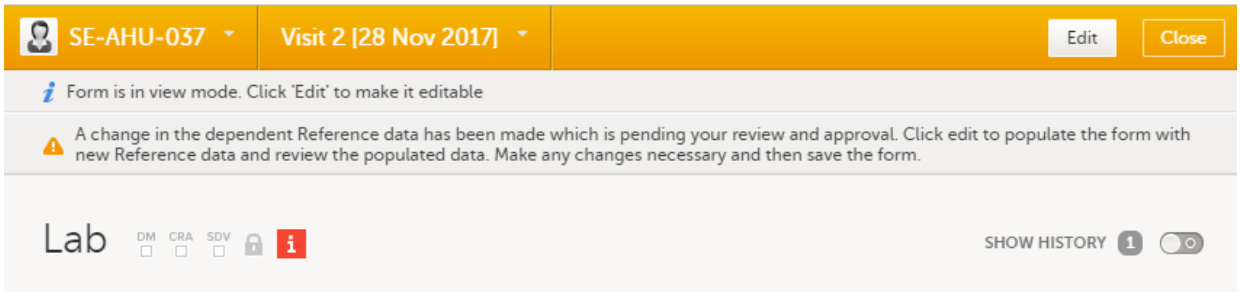
1 On the Viedoc landing page, click the **Reference data** icon.

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

3 Edit the variables (see Variables), factors (see Factors), or the reference values.

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

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



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

Randomization, allocation and emergency unblinding

Randomization, allocation, and emergency unblinding

Published by Viedoc System 2023-06-21

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2. Randomization
    2.1 Emergency unblinding
3. Allocation
    3.2 Undo allocation
    3.3 Replace allocation
    3.4 Allocation actions in audit trail

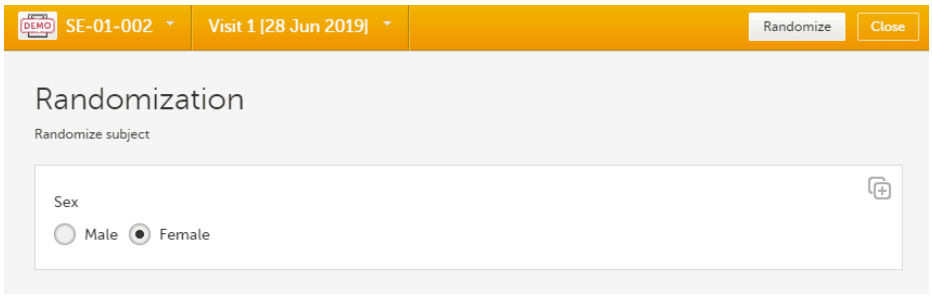
1 Introduction

If randomization and allocation are used in your study, some specific forms are used for randomization and allocation, that have a specific behaviour compared to the other forms. This lesson describes the particularities of the randomization and allocation forms and how to work with these.

2 Randomization

It is important to know that the randomization form will be locked after the randomization was performed, so the form won't be possible to edit.

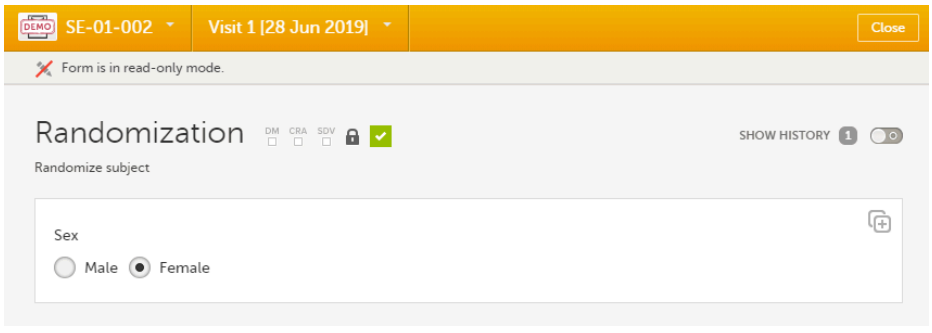
An example of a simple randomization form:



You can notice that, compared to the other forms, here the **Edit** option is replaced by the **Randomize** (or something else, depending on the configurations in your study).

Note! If the randomization is configured for the study start event, there is no **Randomize** button. Instead, the randomization happens when saving the form.

To randomize the subject, click **Randomize**. The randomization is performed and the form is locked:

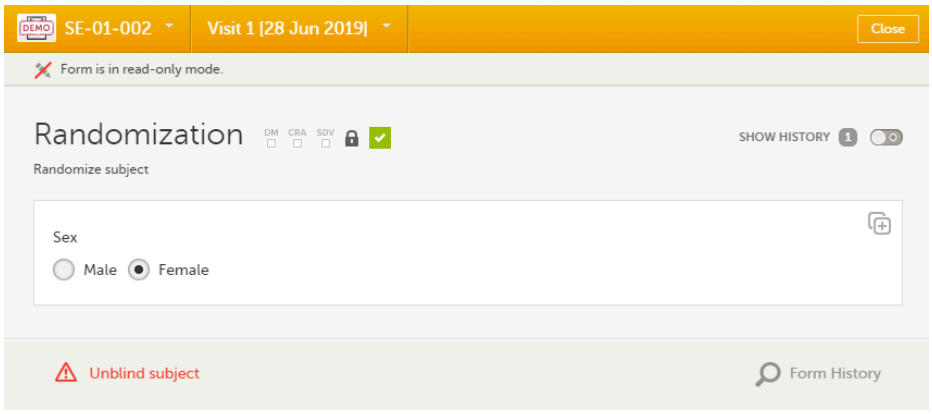


2.1 Emergency unblinding

In case of any medical emergency or serious medical condition that occurs while the participant is taking part in a study, the participant may not be able to be treated adequately unless it becomes known which treatment they have been receiving. In such situations, unblinding may become necessary.

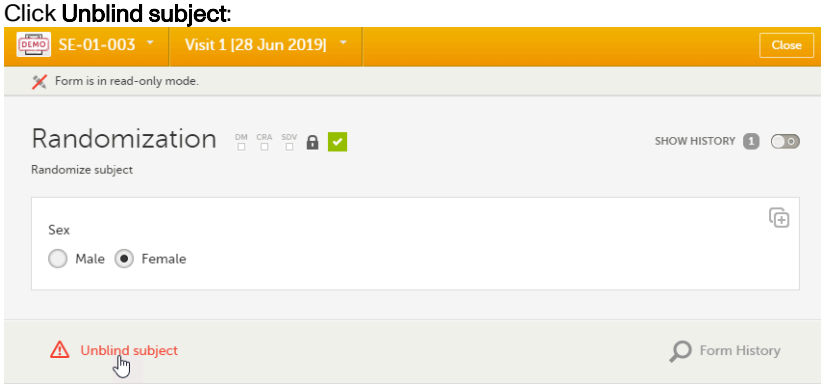
> Important! Unblinding a subject will reveal the subject's treatment and unblind all personnel with permission to view this data in the study.

If you have permission to perform an emergency unblinding, the **Unblind subject** appears on the randomization form, after the subject was randomized:



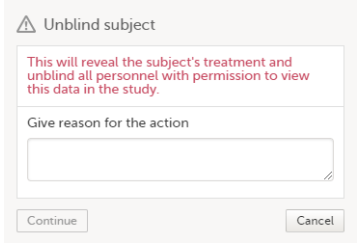
To unblind a subject:

1 Click **Unblind subject**:

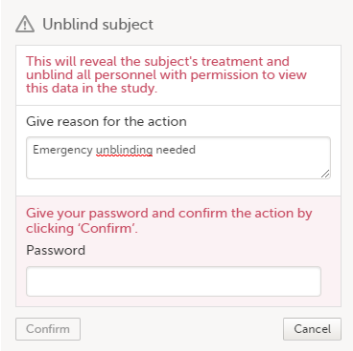


The Unblind subject dialog will be displayed.

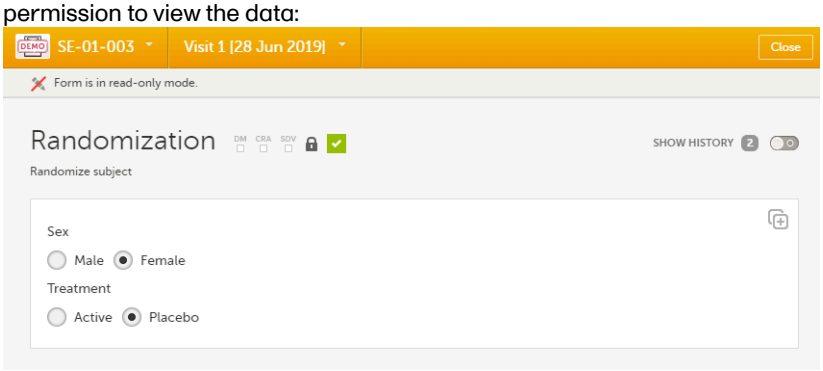
2 Type the reason for unblinding and select **Continue**.



3 Enter your password and select **Confirm**.



The treatment is now visible in the randomization form for the unblinded subject, for all the roles with permission to view the data:



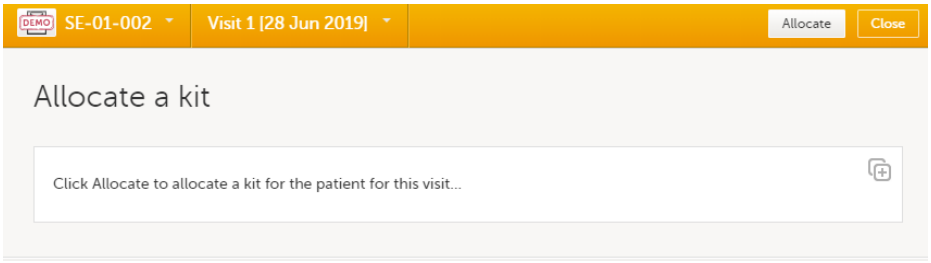
3 Allocation

If configured for your study, allocation can be performed additionally to the randomization. This can be performed within the same form as the randomization or in a separate allocation form.

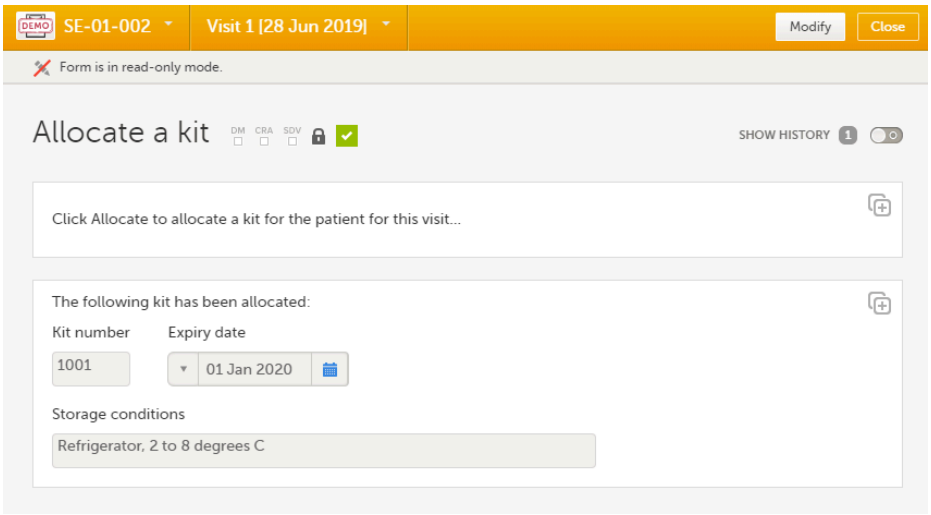
It is important to know that the allocation form will be locked after the allocation is performed, so the form won't be possible to edit. Still, the following actions can be performed after the allocation:

- Undo allocation - if the allocation was performed by mistake, for example at the wrong time. This will remove the existing allocation by reverting the allocation to its previous state and making the previously allocated kit available for other subjects.
- Replace allocation - allocate a new kit, for example if the subject loosed the previous one. This will replace the existing allocated kit with a new one. The previously allocated kit will continue to be allocated to the same subject.

An example of an allocation form:



To perform the allocation for the first time to a subject, click **Allocate** (or something else, depending on the configurations in your study). The allocation is performed and the form is locked:



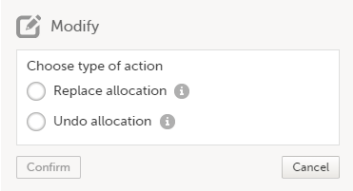
The action is registered in the audit trailed as **Initial data entry** and a new version of the form PDF is generated (see Allocation actions in audit trail).

Note! To perform an allocation after the existing allocation was undone, see Undo allocation.

3.1 Undo allocation

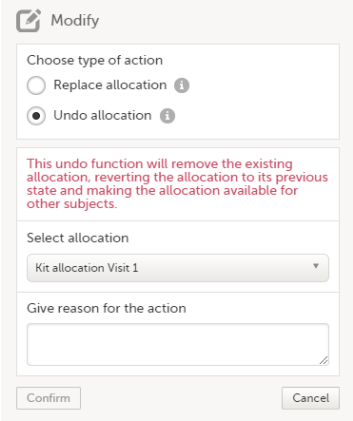
To undo an existing allocation:

1 Open the allocation form and click **Modify**. A dialog is displayed:

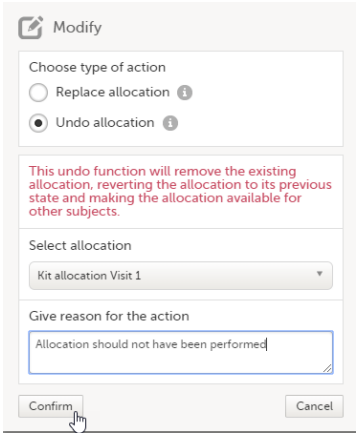


2 Select **Undo allocation**.

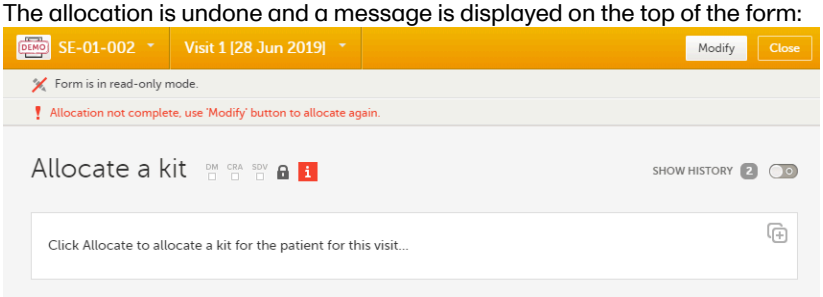
3 If multiple allocations are performed within the same form, select from the dropdown list the allocation you want to undo under **Select allocation**:



4 Type the reason for undoing the allocation (this text will be shown in the audit trail afterwards, see Allocation actions in audit trail) and select **Confirm**:



The allocation is undone and a message is displayed on the top of the form:



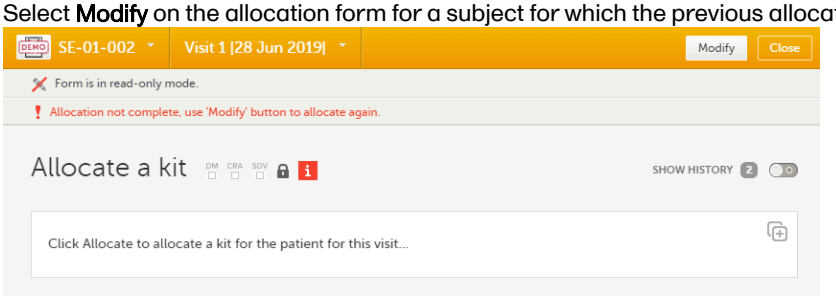
This will remove the existing allocation by reverting the allocation to its previous state and making the previously allocated kit available for other subjects.

A new version of the form PDF is generated (see Allocation actions in audit trail).

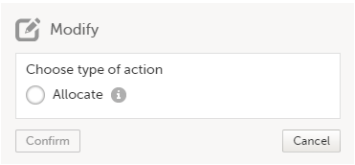
A new allocation can be performed for the subject, as described below.

To perform a new allocation, for a subject for which a previous allocation was undone:

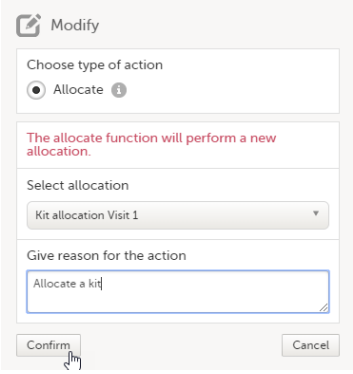
1 Select **Modify** on the allocation form for a subject for which the previous allocation was undone:



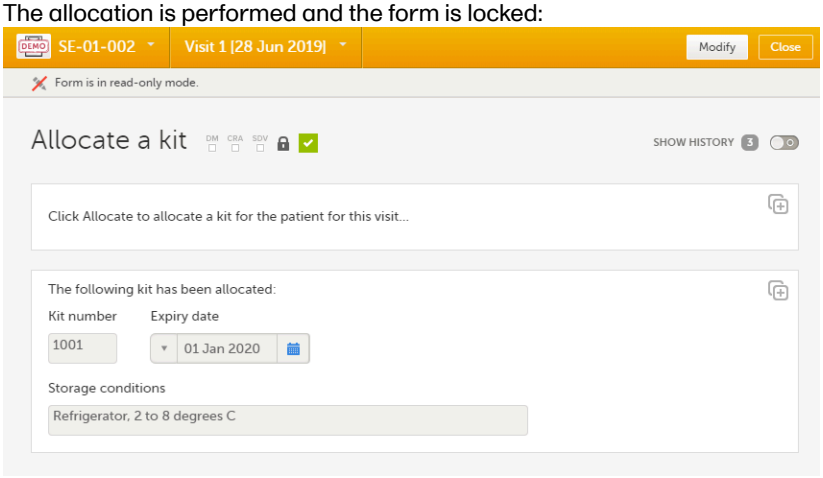
The Modify pop-up is displayed:



2 Select **Allocate**. If multiple allocations are performed within the same form, select from the dropdown list the allocation to be performed, enter the reason (this text will be shown in the audit trail afterwards, see Allocation actions in audit trail) and select **Confirm**:



3 The allocation is performed and the form is locked:

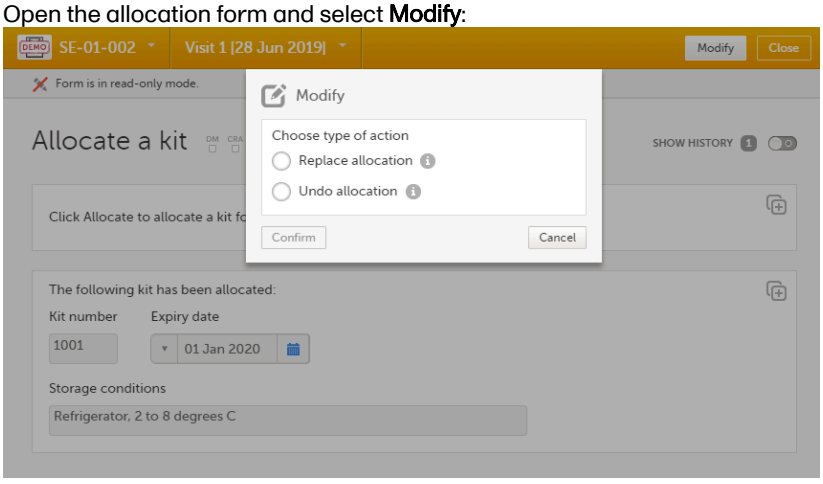


A new version of the form PDF is generated (see Allocation actions in audit trail).

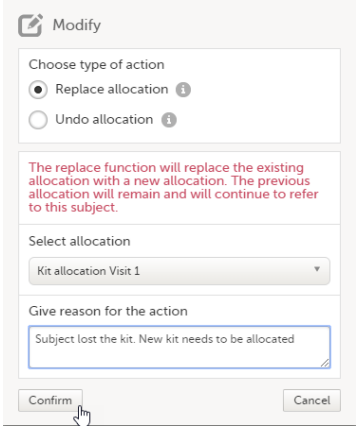
3.2 Replace allocation

To replace an existing allocation with a new one, that is, to assign a new kit to a subject:

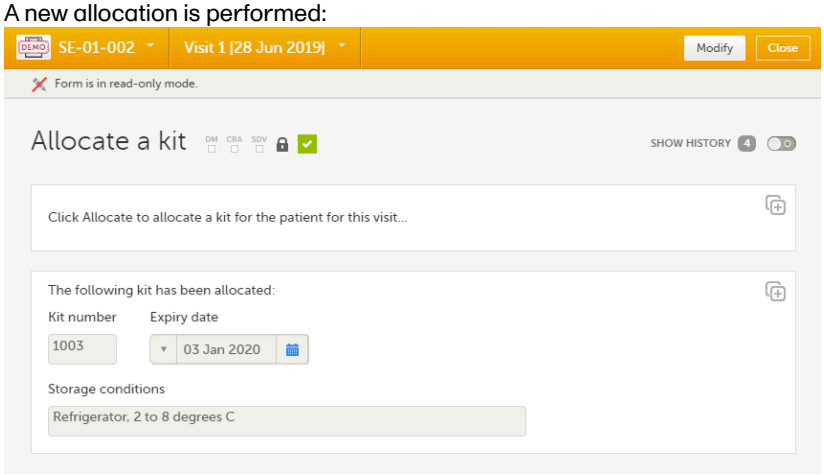
1 Open the allocation form and select **Modify**:



2 Select **Replace allocation**. If multiple allocations are performed within the same form, select from the dropdown list the allocation to be replaced, enter the reason (this text will be shown in the audit trail afterwards, see Allocation actions in audit trail) and click **Confirm**:



A new allocation is performed:

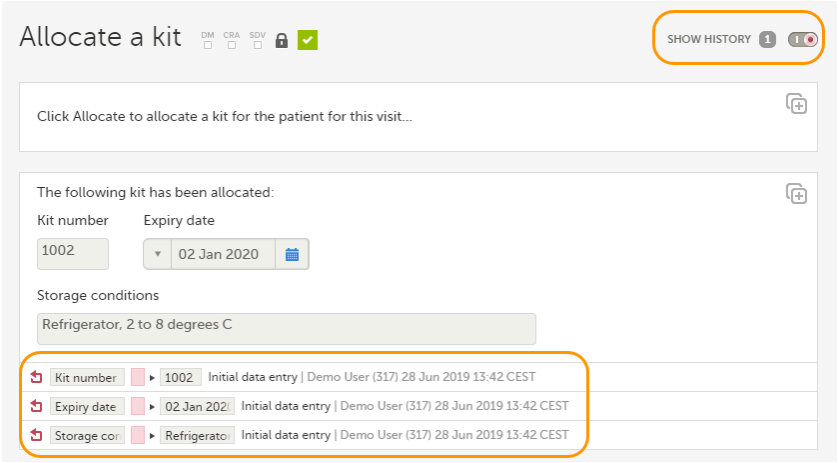


This will replace the existing allocated kit with a new one. The previously allocated kit will continue to be allocated to the same subject.
A new version of the form PDF is generated (see Allocation actions in audit trail).

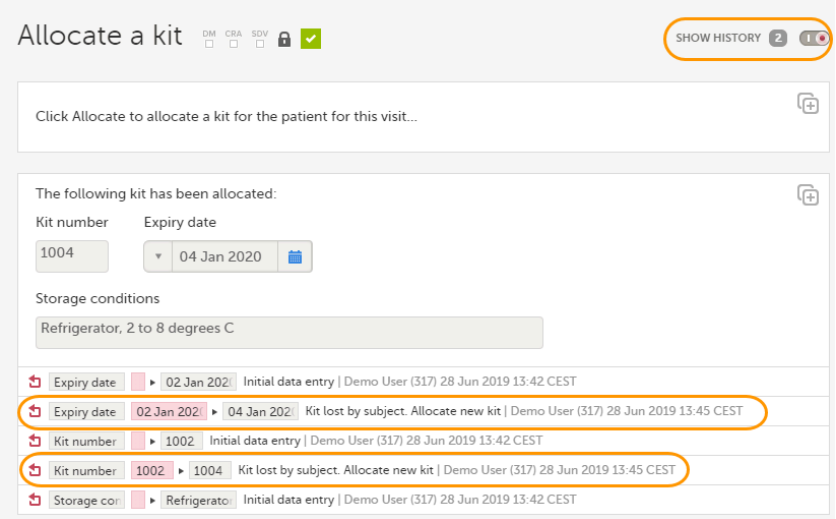
3.3 Allocation actions in audit trail

All the actions performed on allocation are recorded in the audit trail as follows:

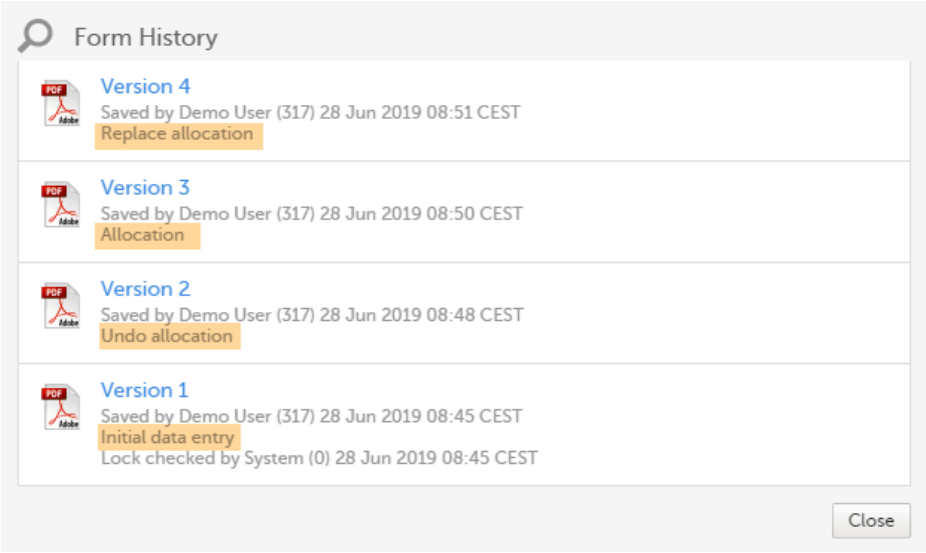
- The first time the allocation is performed, it is recorded as **Initial data entry**:



- The other actions performed (undo allocation, replace allocation) are recorded in the audit trail with the text entered as reason when the action was performed:



The allocation actions performed within a form are also shown in the Form History:



Issues and tasks

Issues and tasks

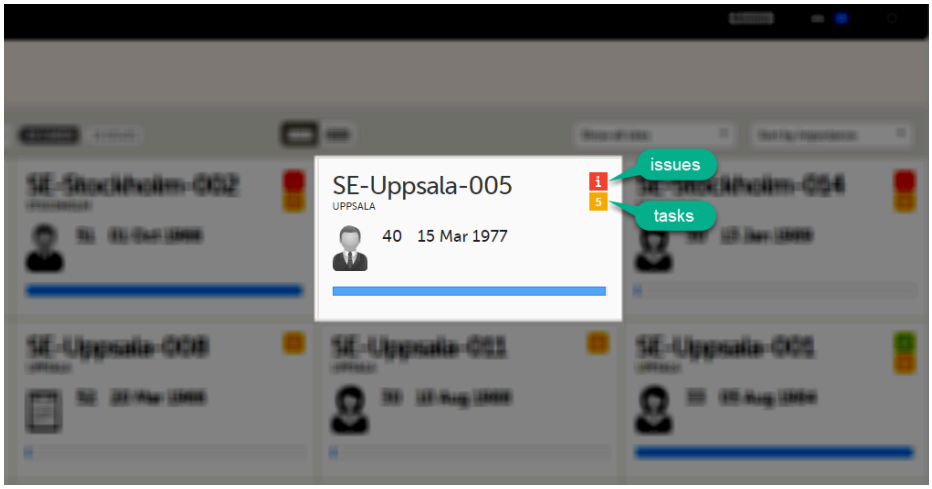
Published by Viedoc System 2024-10-10

1. Introduction
2. Issues
3. Tasks

1 Introduction

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

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

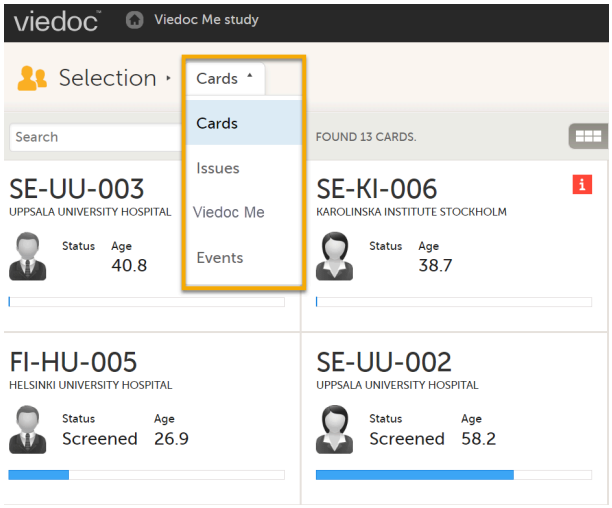


- Red icon: **Issues** - indicating that the subject has open queries and/or unconfirmed missing data. Both open queries and unconfirmed missing data should be handled and resolved by the site but, as a Monitor or Data Manager, it is important for you to be aware of these issues as well. For more details,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

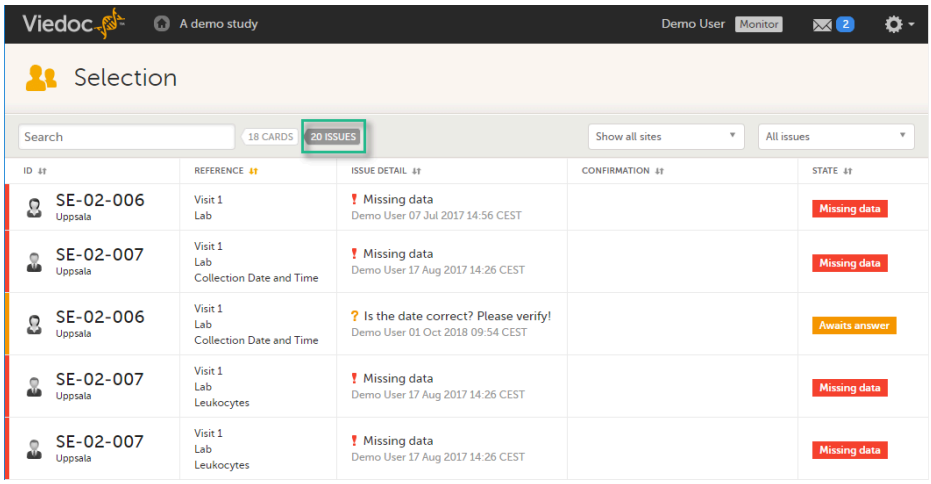
All issues and tasks should eventually disappear but while being present they help you identify where action is needed.

2 Issues

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



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



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

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

- By site - select to view data from a specific site or from all sites.
- By issue type/status:
  - **All issues** - all the issues regardless of the status, except for pre-queries
  - **All open issues** (default if role-based queries is not enabled for your study) - all the issues with an open status:
    - Missing data
    - Pending form upgrade
    - Pending reference data upgrade
    - Open queries (with status *Awaits answer*)
  - **All queries** - all queries regardless of the status
  - **Open queries** - only queries with status *Awaits answer*
  - **Queries awaiting approval** - only queries with status *Awaits approval*
  - **My queries** -
    Note! The following applies only if role-based queries is not enabled for your study:(default for users with permissions to Add/change queries, Add pre-queries, Promote pre-queries):
    - For user with permissions to Add pre-queries - all pre-queries that were raised by the user, regardless of the status
    - For user with permissions to Promote pre-queries - all pre-queries promoted by the user and all pre-queries raised regardless by whom they were raised
    - For user with permissions to Add/change queries - all queries raised or updated by the user, all queries awaiting approval regardless by whom they were raised, show all pre-queries promoted regardless by whom they were promoted
  - **Pre-queries** - all pre-queries regardless of status
  - **My role's queries** -
    Note! When role-based queries is enabled for a study, for user roles with permission to Add/change queries, such as Monitors and Data Managers, this filter is applied by default when opening the **ISSUES** list. My role's queries lists all the open manually raised queries that were raised by the same role with the status Awaits approval *or* Awaits answer.
  - **Missing data** - all unconfirmed missing data

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

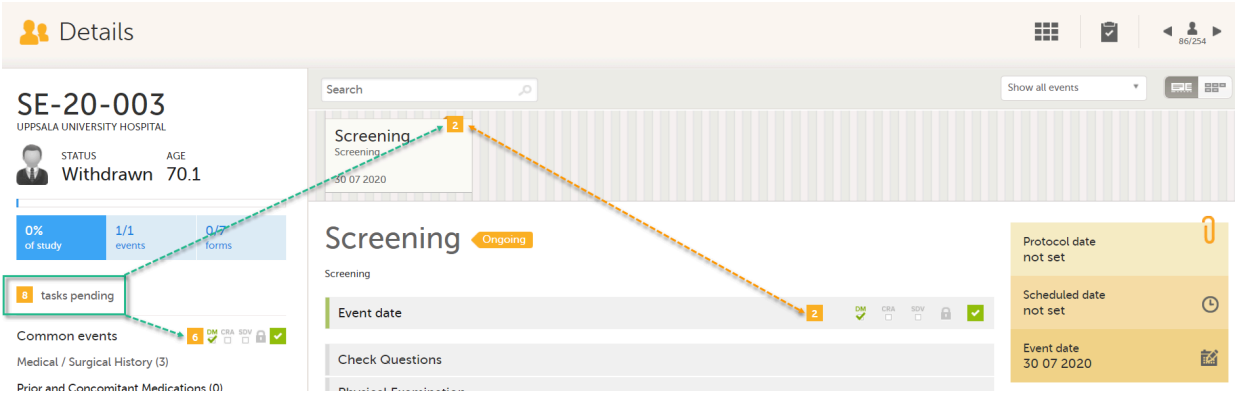
---

3 Tasks

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

Tasks are tracked on three levels:

- Subject
- Event
- Form



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

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

Clinical review, SDV, and Lock

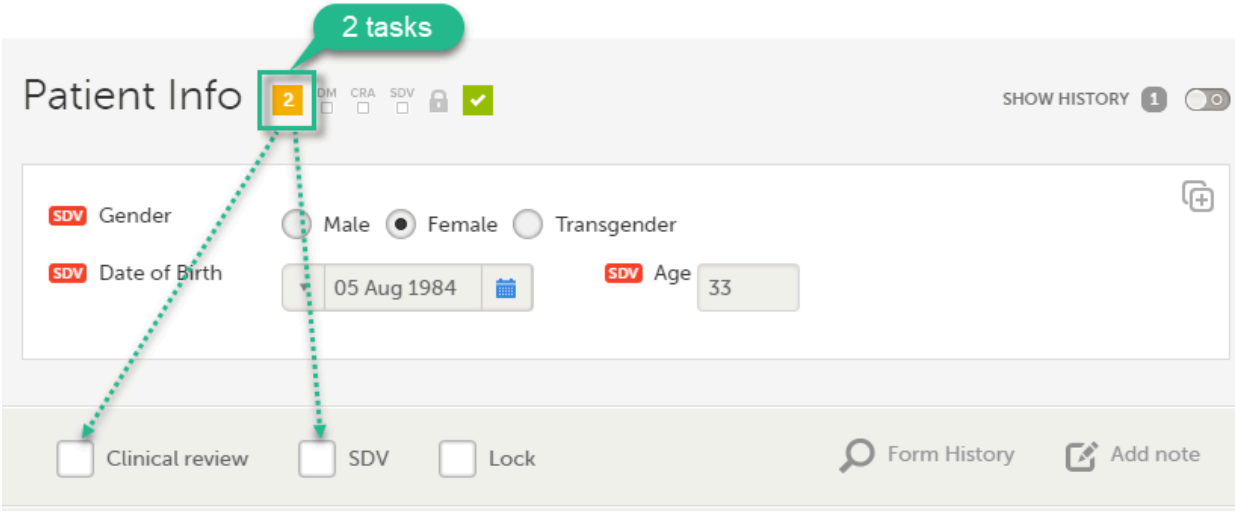
Published by Viedoc System 2023-10-09

1. Introduction
2. Clinical review
3. SDV
    3.1 SDV on item level
4. Lock
    4.2 Locking a form
    4.3 Unlocking a form
    4.4 Locking/unlocking a subject-submitted (Viedoc Me) form
5. Data review console
6. Study status and metrics

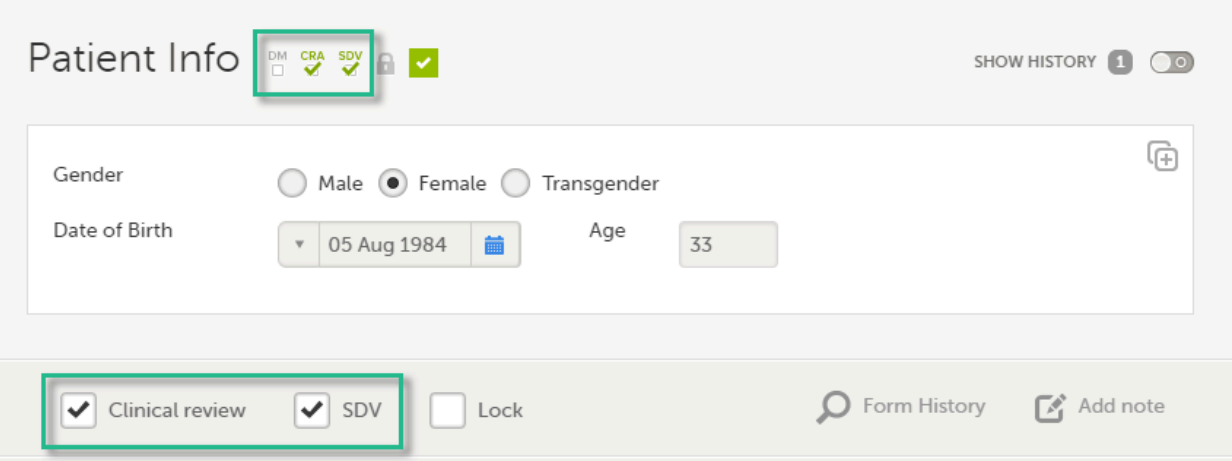
1 Introduction

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

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



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



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

---

2 Clinical review

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

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

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

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

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

---

3 SDV

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

SDV can be performed in one of the following ways:

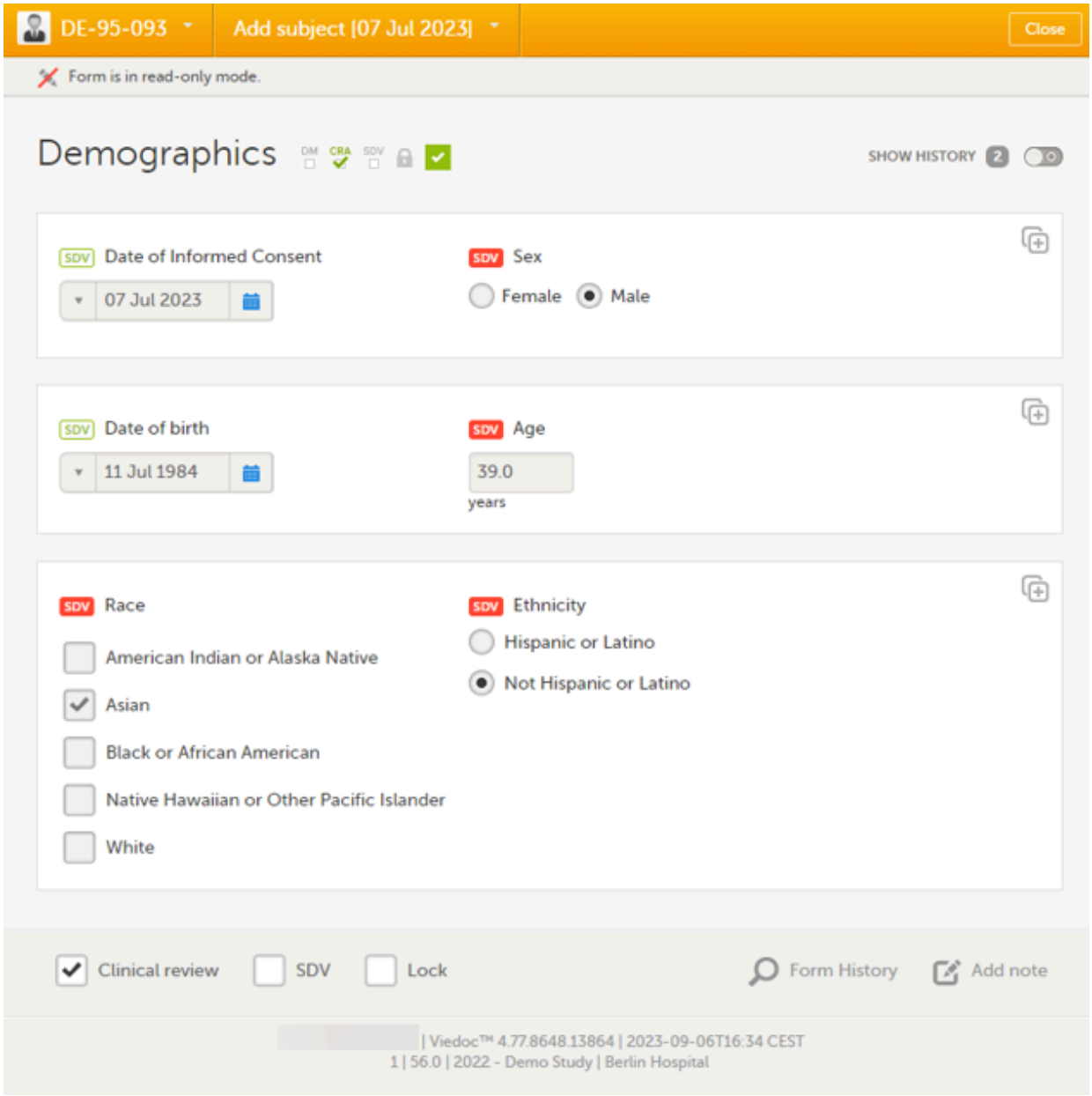
- On item level, by clicking on the SDV flag for the item in the form.
- On form level, by selecting **SDV** at the bottom of the form.
  Note! If there are items in the form that require SDV and are hidden due to data visibility conditions in the study design, you will not be able to apply SDV on form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

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

3.1 SDV on item level

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

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



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

Notes!

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

---

4 Lock

4.1 Locking a form

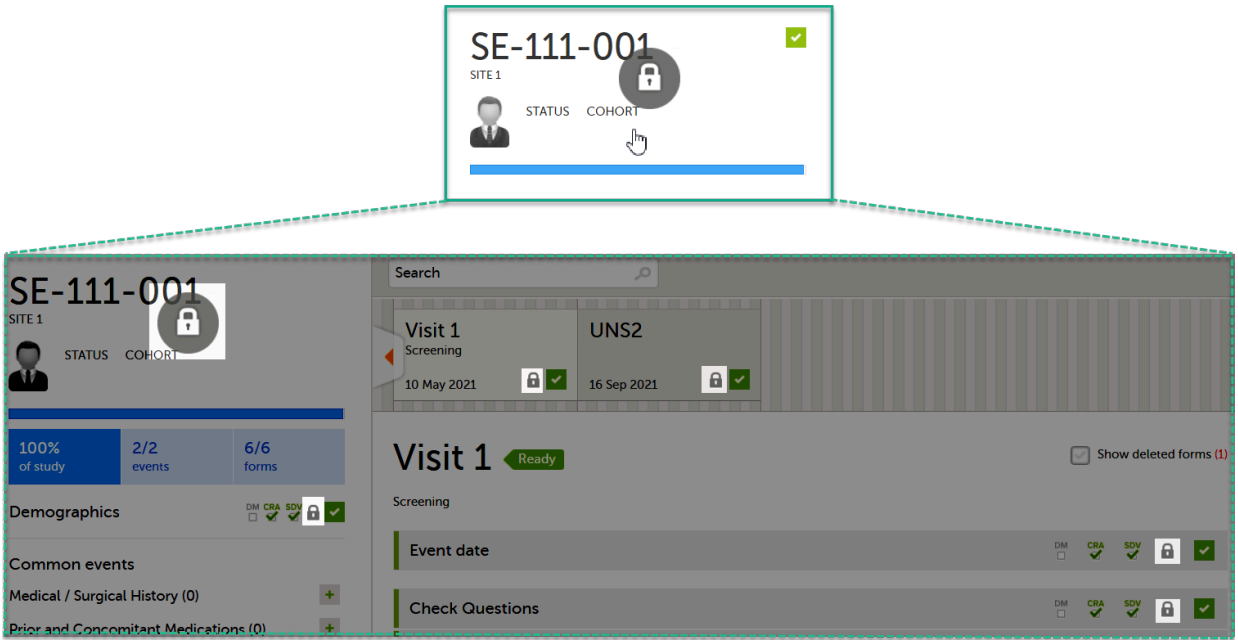
Locking data in a form can be performed in one of the following ways:

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

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

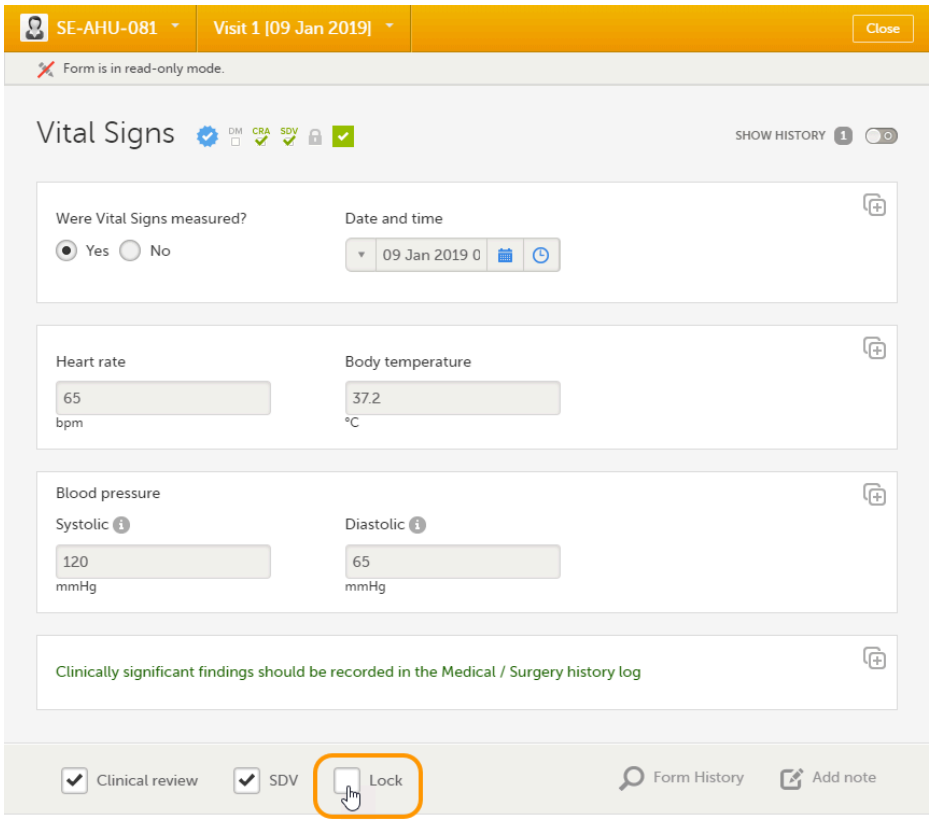
Important! Updates to the electronic Case Report Form (eCRF) are not applied to locked forms. If you are aware of any upcoming changes to the eCRF that potentially affect already saved and locked forms, make sure that these are unlocked before the new design version is published to the site.

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



4.2 Unlocking a form

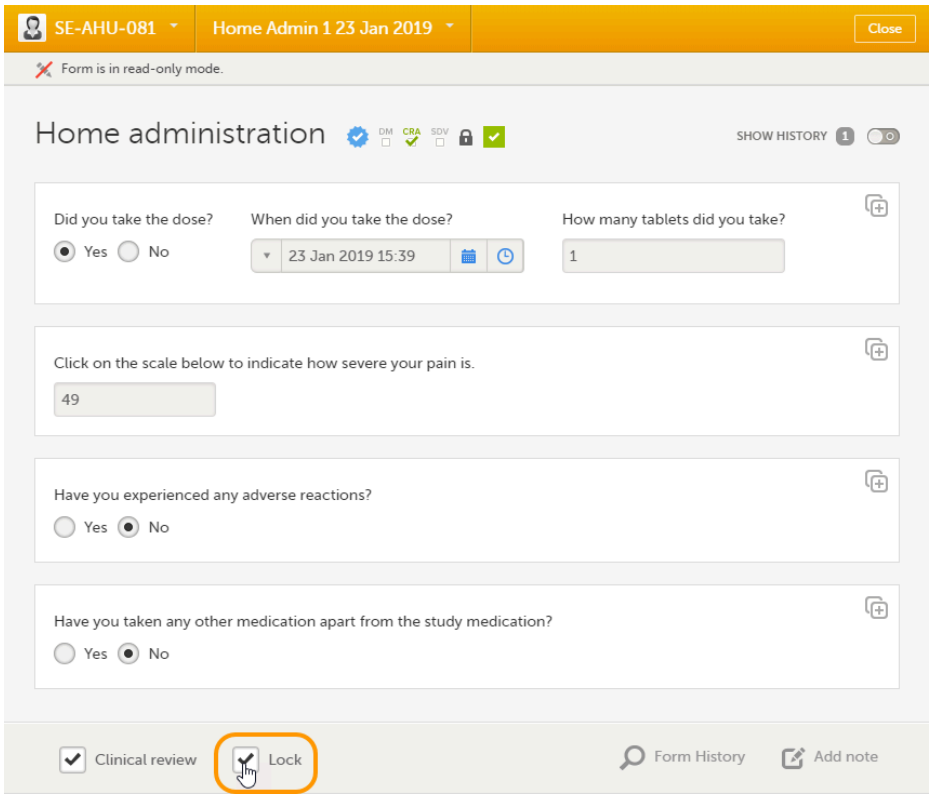
Regular clinic forms can be unlocked by clearing the **Lock** checkbox at the bottom of a form. Unlocking a form opens it up for editing by users with edit data permission (for example the Investigator).



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

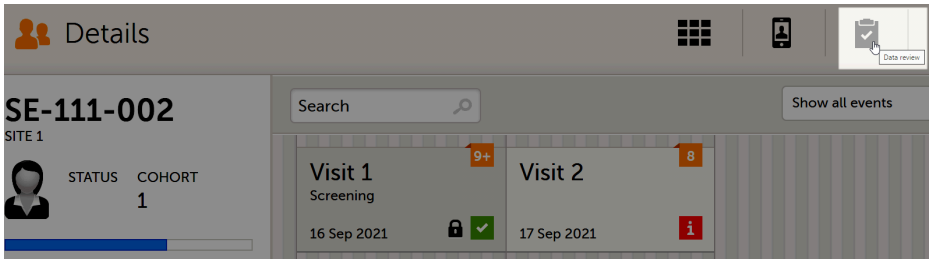
Subject-submitted (Viedoc Me) forms that are filled in by the subject are locked by default.

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

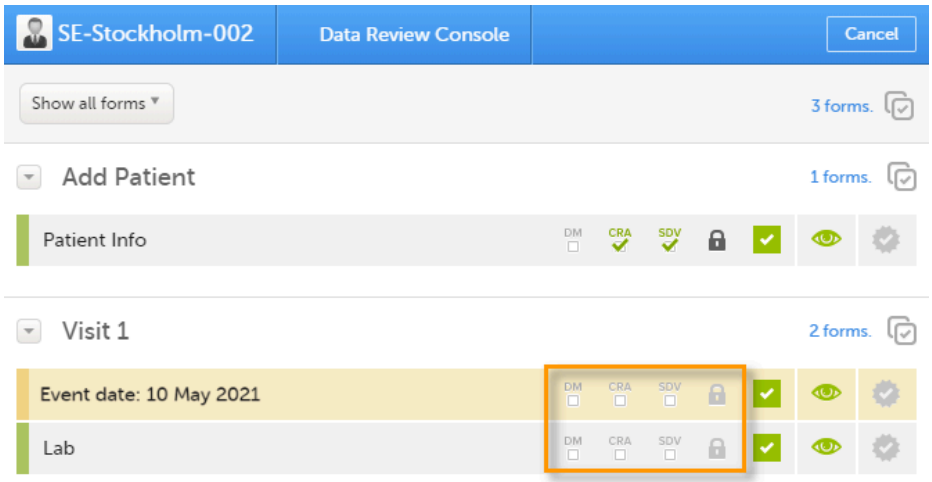


5 Data review console

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



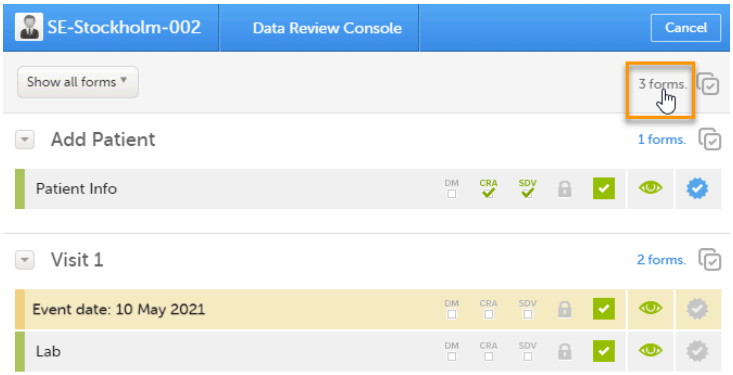
The data review console displays an overview of all forms of a subject that require data review, SDV, or lock. It shows which forms have been reviewed, SDV'ed, or locked. The green and grey eye icons help you identifying forms that you have not previously visited: the green eye icon marks the forms that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



To review and/or lock the forms:

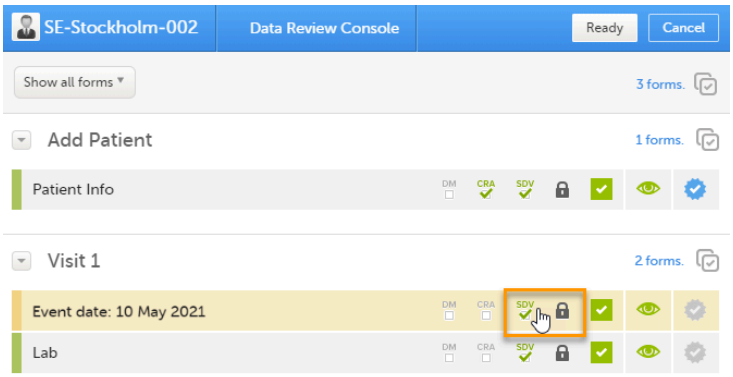
1 Select the form(s) to be reviewed in one of the following ways:

- Select all forms by clicking the ***n* forms** link on the top of the page:

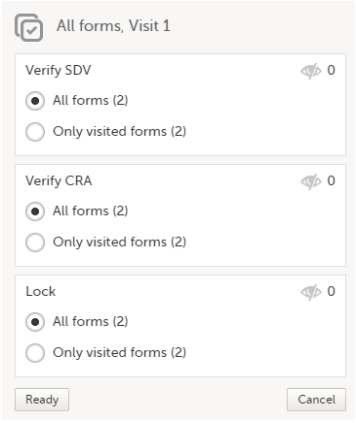


- Select all forms within an event, by clicking the ***n* forms** link to the right of the respective event:

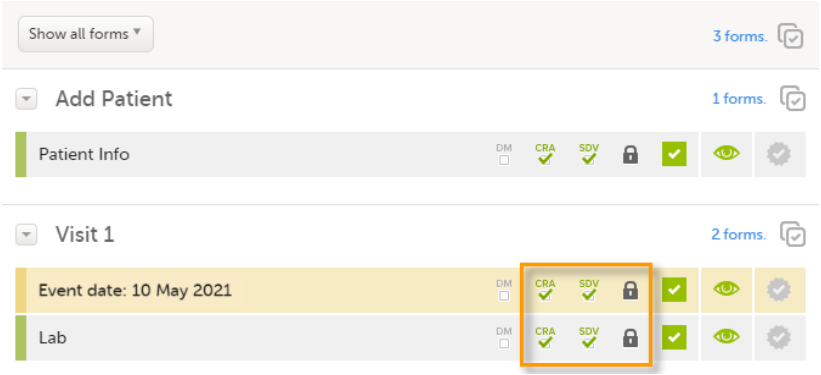
- Individually, check the review and/or lock icon for each individual form. Step 2 is not applicable in this case.



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



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



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

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

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6 Study status and metrics

The current workload can be checked on the Study status or the Metrics pages.

Data review and Lock

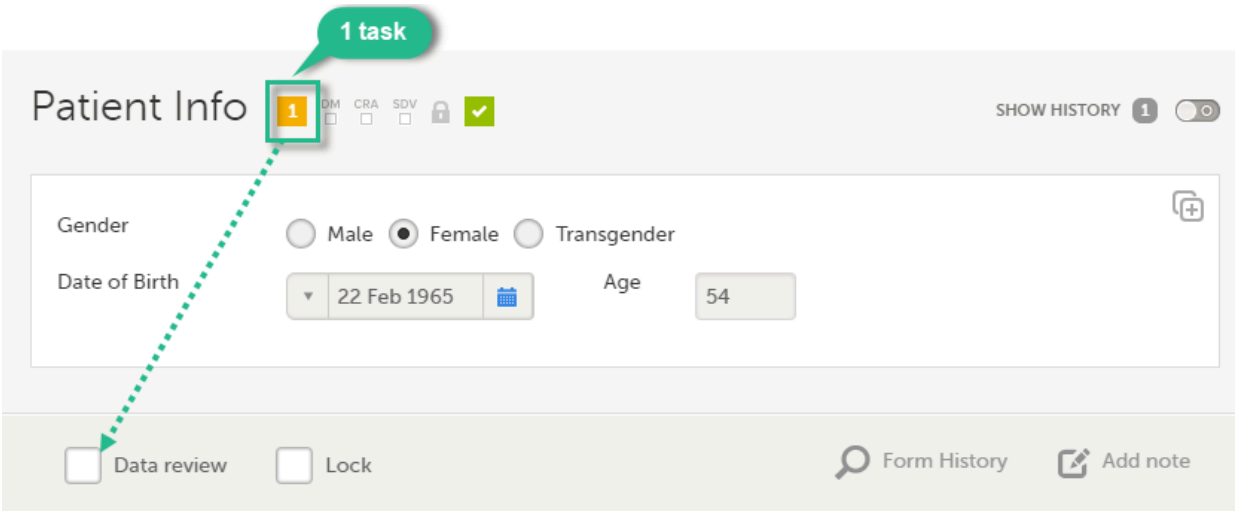
Published by Viedoc System 2023-10-09

1. Introduction
2. Data review
3. Lock
    3.1 Locking a form
    3.2 Unlocking a form
    3.3 Locking/unlocking a subject-submitted (Viedoc Me) form
4. Data review console
5. Study status and metrics

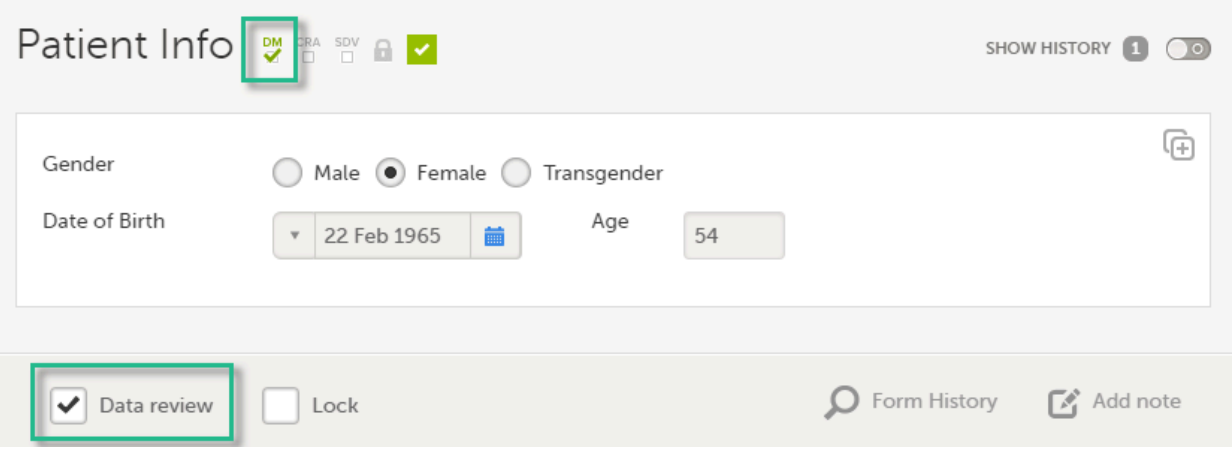
1 Introduction

The requirements on data review and source data verification vary between studies. This lesson describes what is possible in Viedoc.

If applicable for your study, data review is a task to be completed. The number of tasks to be completed is displayed in the orange task icon:



The orange task icon disappears when the checkboxes for clinical review and Source Data Verification (SDV) are selected and the task is completed.



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

---

2 Data review

The purpose of data review is to give the Data Manager the possibility to mark forms as reviewed.

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

- At the bottom of each form, by checking the **Data review** checkbox.
- Batch-wise through the review console. Read more about the review console below.

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

---

3 Lock

3.1 Locking a form

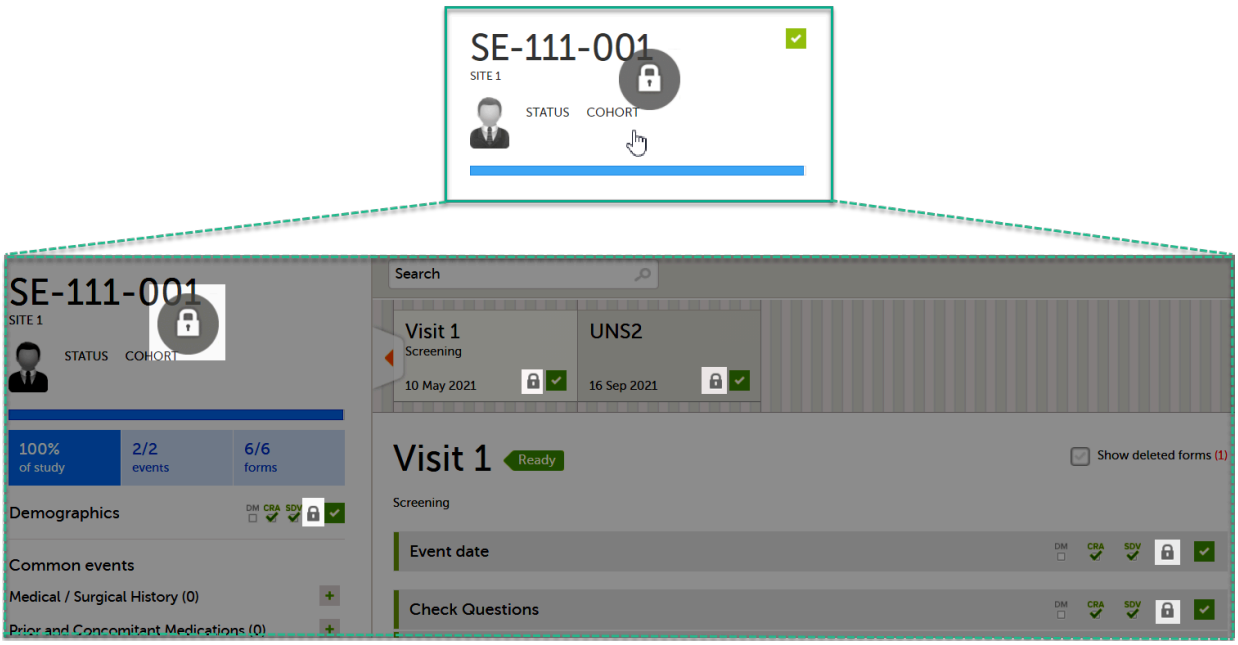
Locking data in a form can be performed in one of the following ways:

- At the bottom of every form, by checking the **Lock** checkbox.
- Batch-wise using the review console. Read more about the review console below.

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

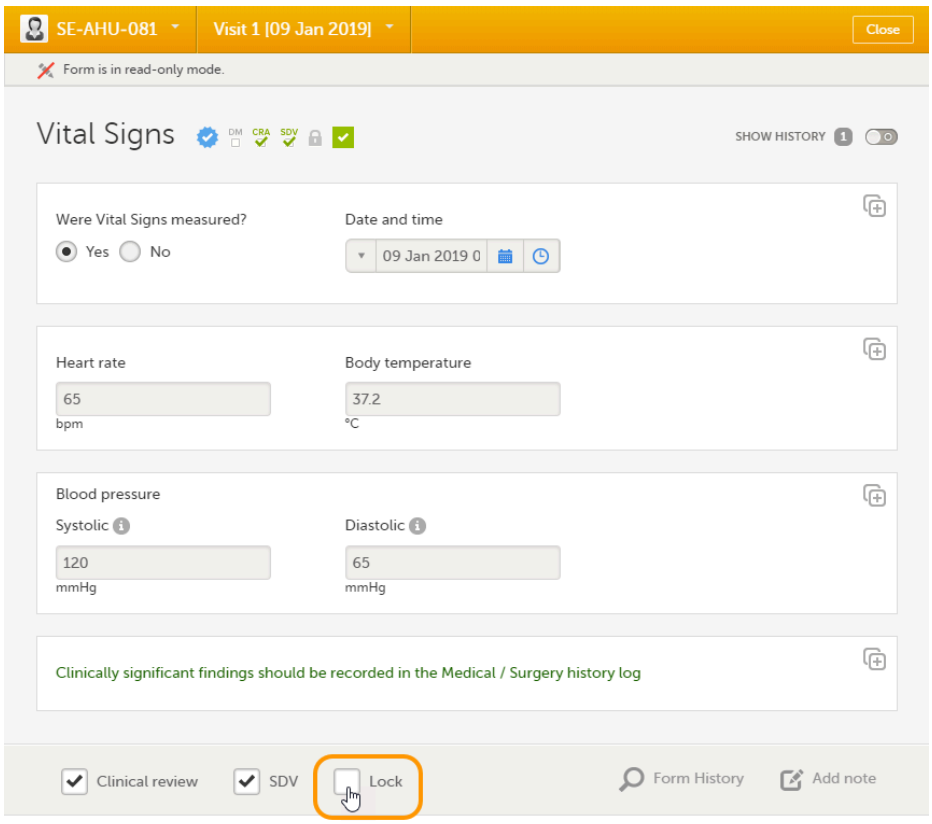
> Important! Updates to the electronic Case Report Form (eCRF) are not applied to locked forms. If you are aware of any upcoming changes to the eCRF that potentially affect already saved and locked forms, make sure that these are unlocked before the new design version is published to the site.

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



3.2 Unlocking a form

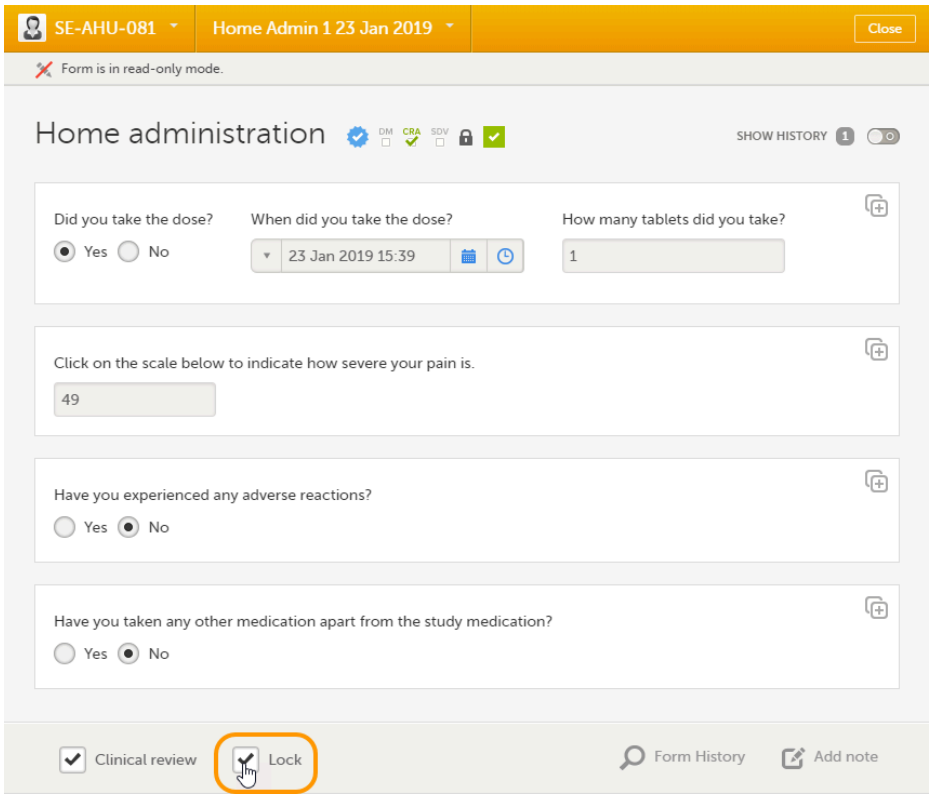
Regular clinic forms can be unlocked by clearing the **Lock** checkbox at the bottom of a form. Unlocking a form opens it up for editing by users with edit data permission (for example the Investigator).



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

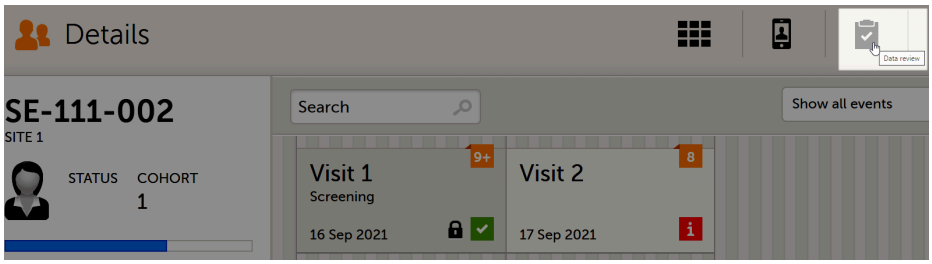
Subject-submitted (Viedoc Me) forms that are filled in by the subject are locked by default.

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

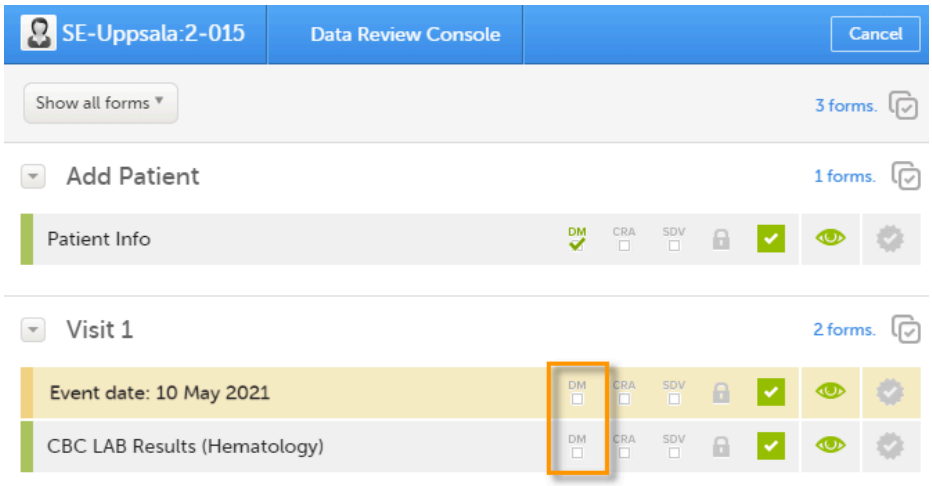


4 Data review console

You can perform data review and lock of the forms batch-wise, by using the data review console. To open the data review console, click the icon in the top right corner of the Details page.



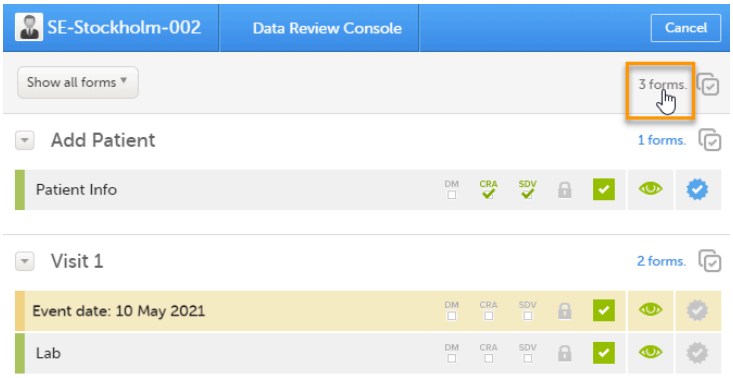
The data review console displays an overview of all forms of a subject that require data review, SDV or lock. It shows which forms have been reviewed, SDV'ed or locked. The green and grey eye icons help you identify which forms you have visited (the most recent version of the form): the green eye icon means that you have visited the last version of the form, the grey eye icon means that you have not visited the latest version of the form.



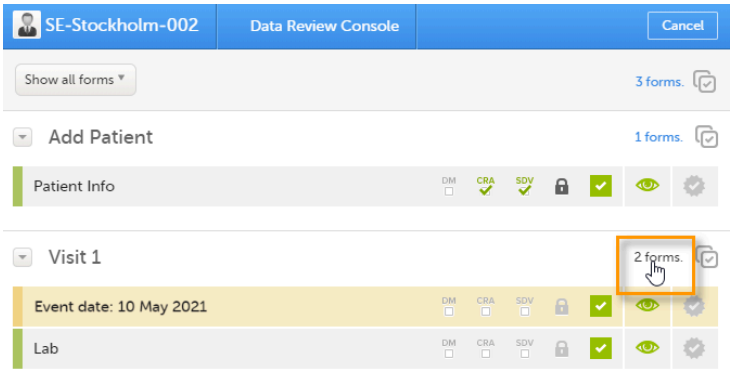
To review and/or lock the forms:

1 Select the form(s) to be reviewed in one of the following ways:

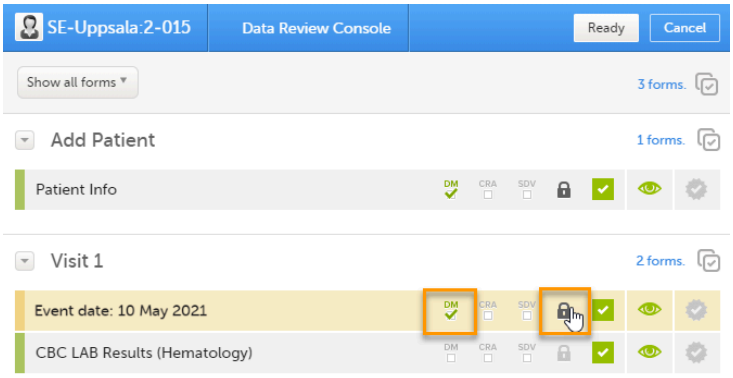
- Select all forms by clicking the ***n* forms** link on the top of the page:



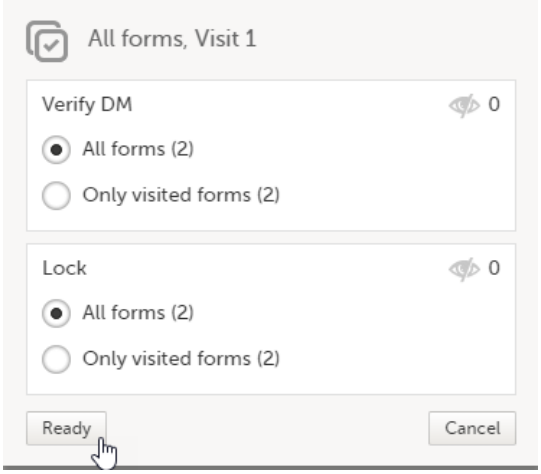
- Select all forms within an event, by clicking the ***n* forms** link to the right of the respective event:



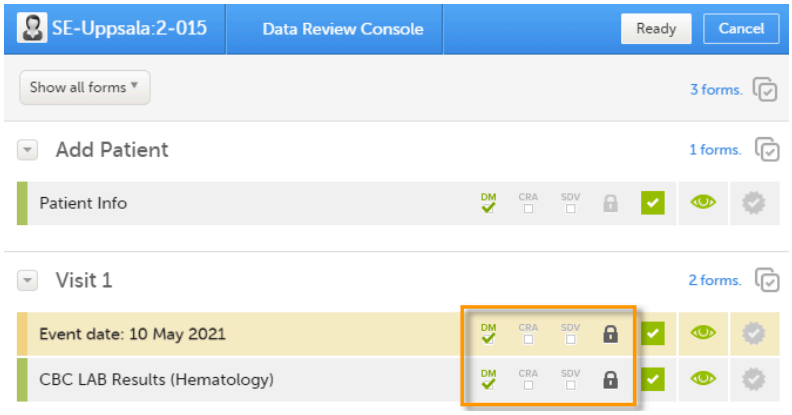
- Individually, check the review and/or lock icon for each individual form. Step 2 is not applicable in this case.



2 In the pop-up that opens, mark with **Data review** and/or **Lock** as needed, and click **Ready**:



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



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

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

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5 Study status and metrics

The current workload can be checked on the Study status or the Metrics pages.

Queries overview

Published by Viedoc System 2024-10-10

1. Introduction
2. Role-based queries
3. Manually raised queries
    3.1 Pre-queries
        3.1.1 Pre-query states
    3.2 Queries
4. Validation queries
5. Query states
6. Queries in export output
    6.3 Queries in ODM export
    6.4 Queries in Excel export
7. Related topics

1 Introduction

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

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

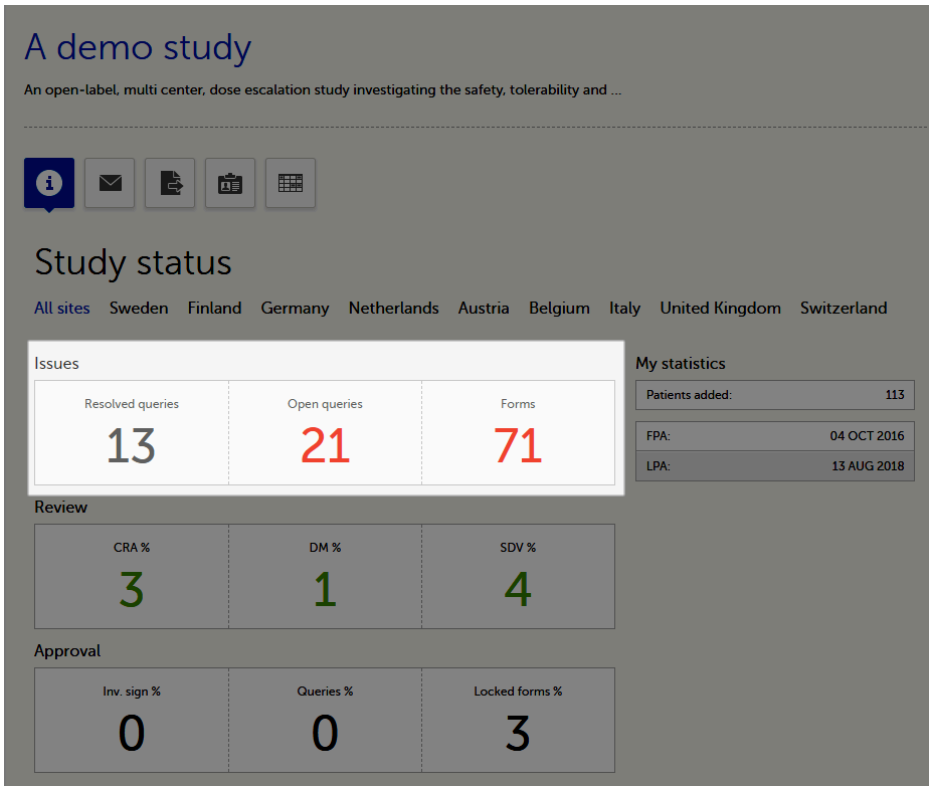
Note! All the related queries are automatically closed, when:

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

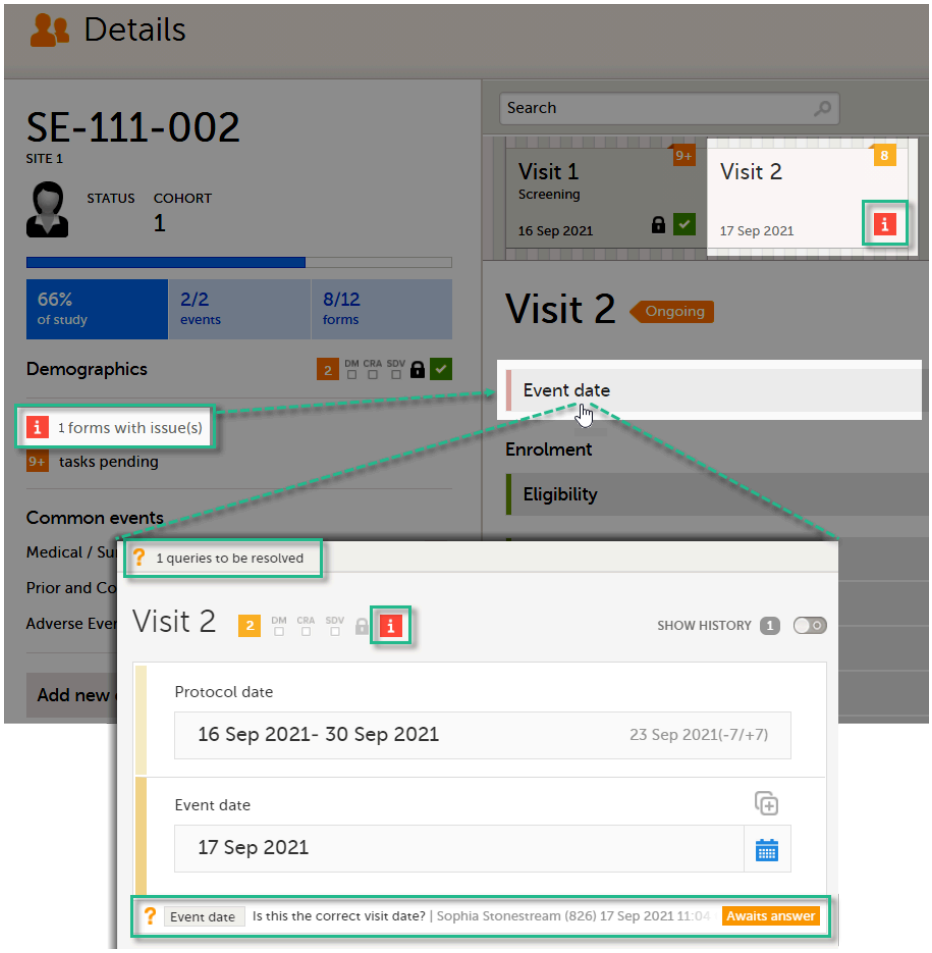
In case of a validation query, when this is resolved by data edit, it is automatically closed. See Validation queries.

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

A summary of the number of queries is displayed on the study start page, as illustrated below.
Note! This is a summary of the whole study and it does not take into consideration the role visibility conditions.



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



2 Role-based queries

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

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

Notes!

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

For more information, see the eLearning lesson on Role-based queries.

3 Manually raised queries

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

Manually raised queries can be:

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

3.1 Pre-queries

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

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

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

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

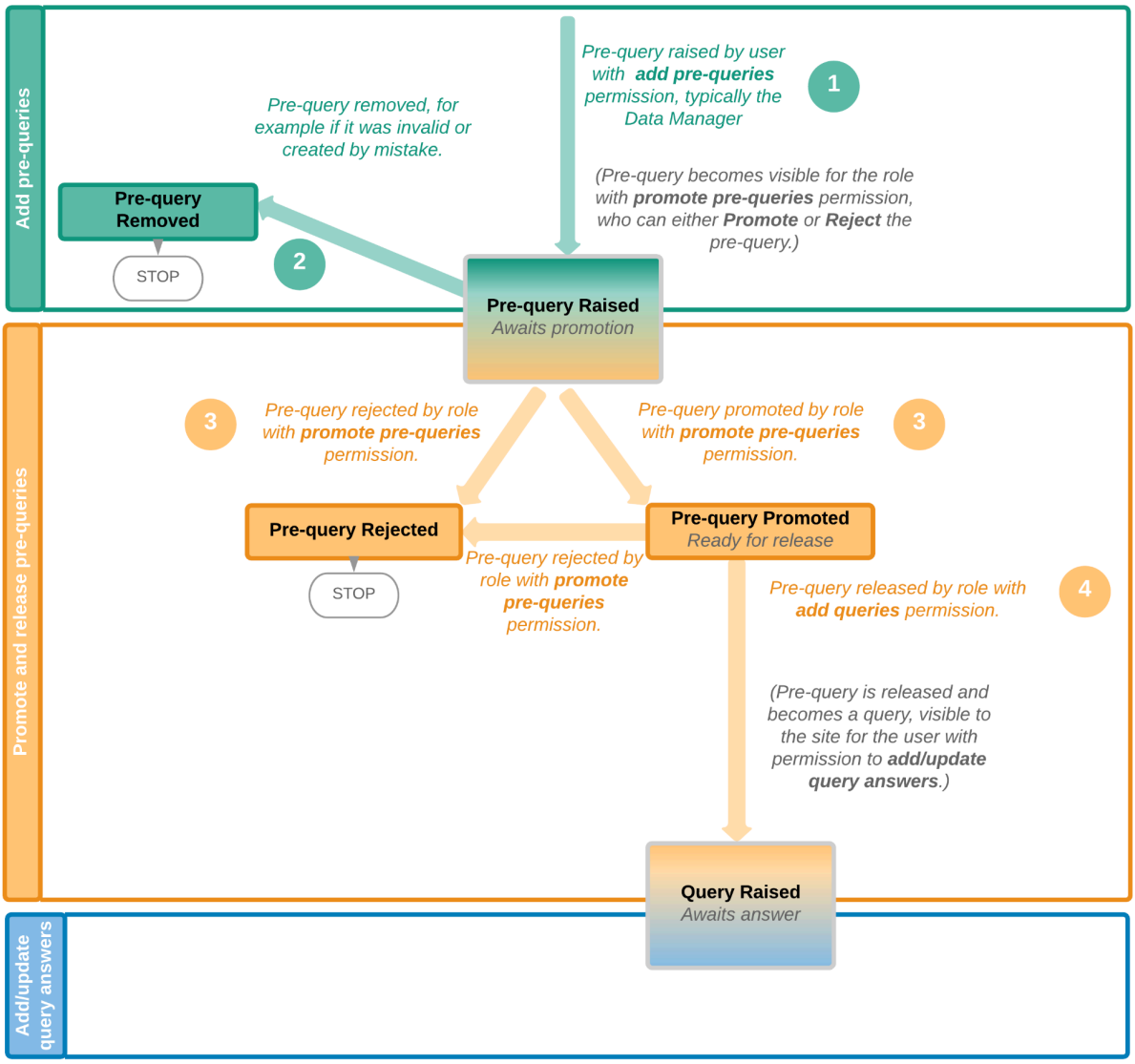
The following image illustrates the main actions that can be performed on a pre-query and all the states the pre-query goes through before it is released as a query:

1. The pre-query is added by the user with permission to add pre-queries, typically the Data Manager.
As a result, a pre-query is raised, becoming visible for the Viedoc Clinic user with permission to promote pre-queries, typically the Monitor.

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

3. The raised pre-query is promoted or rejected by the Viedoc Clinic user with permission to promote pre-queries, typically the Monitor.

4. The promoted pre-query is released by the Viedoc Clinic user with permission to add queries (typically the Monitor), becoming a raised query that is visible for the Viedoc Clinic user with permission to add/update query answers (typically the Investigator), who will be responsible for resolving the query, as described in Queries.



3.1.1 Pre-query states

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

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

3.2 Queries

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

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

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

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

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

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

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

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

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

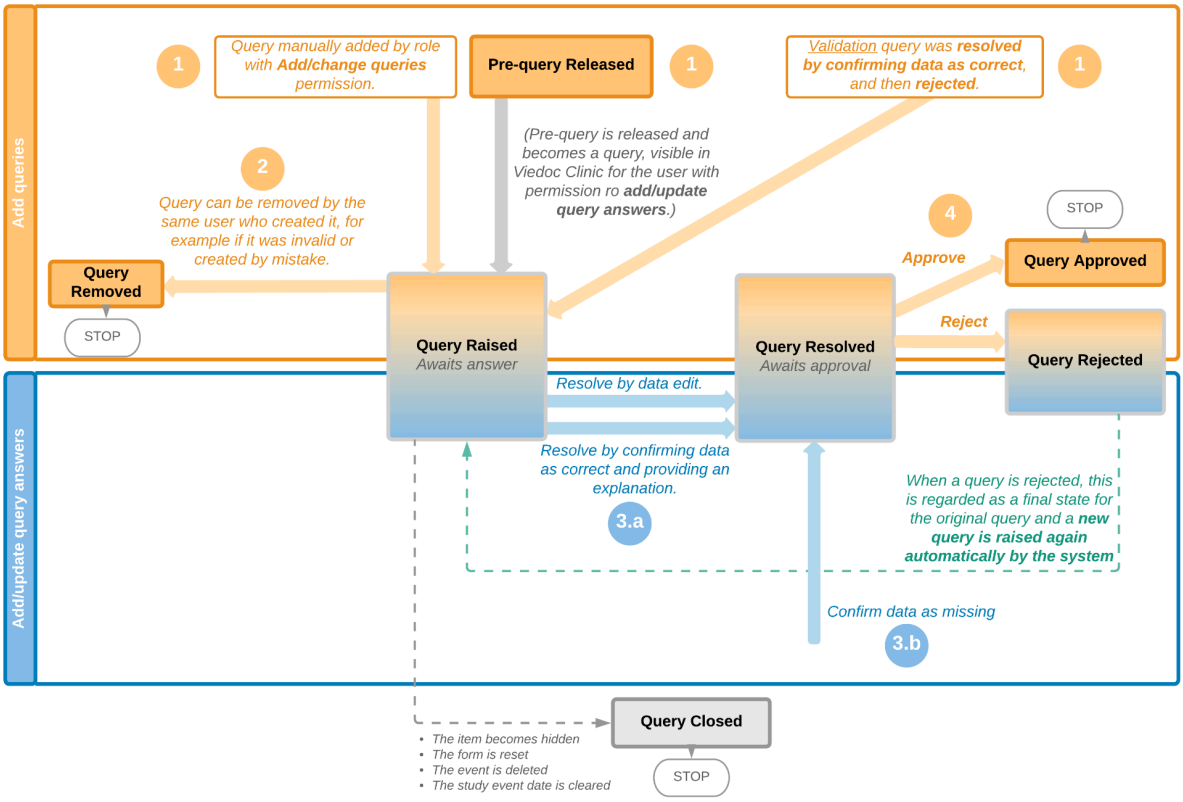
- Editing the data
- Confirming the data is correct and providing an explanation

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

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

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

See also Query states.



4 Validation queries

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

1. A query is raised as a result of a validation performed by the system.

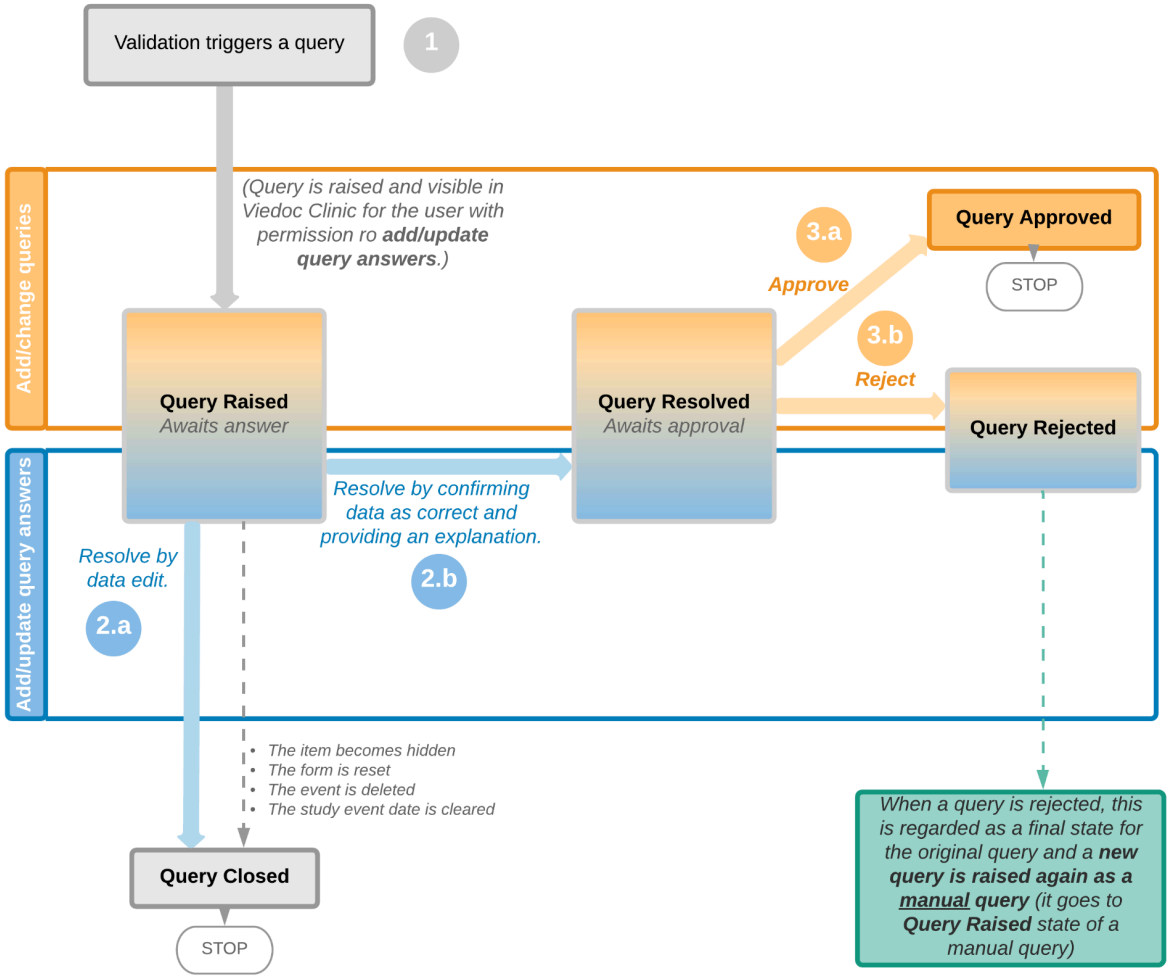
2. The user with permission to add/update subject/event/form data and query answers, typically the Investigator, resolves the query by one of the following:

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

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

a. **Approve** the resolved query.
b. **Reject** the resolved query. The old query becomes **Rejected** and a new query is raised and becomes a manual query. So from here it will follow the path of a manual query from the **Query Raised** state, as described earlier in Manual queries > Queries.

See also Query states.



5 Query states

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

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

- The item becomes hidden

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

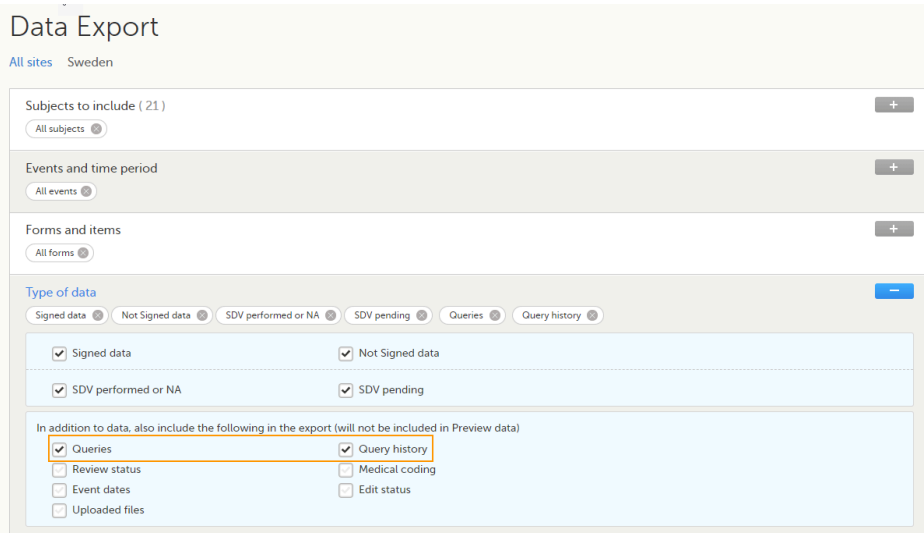
In Viedoc Clinic	In export output	Through...	Becomes...
Awaits answer	QueryRaised	Remove query (by Monitor)	QueryRemoved (**Removed**)
		Edit query (by Monitor)	QueryRaised (Awaits answer)
		Resolve query (by Investigator)	QueryResolved (Awaits approval)
Awaits approval	QueryResolved	Approve query (by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

6 Queries in export output

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

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

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



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

6.1 Queries in ODM export

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

6.2 Queries in Excel export

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

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7 Related topics

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

Raising and promoting pre-queries

Published by Viedoc System 2024-10-10

1. Raising a pre-query
2. Promoting/Rejecting a pre-query
3. Releasing/Rejecting a pre-query

For an overview of the entire query process see Queries overview.

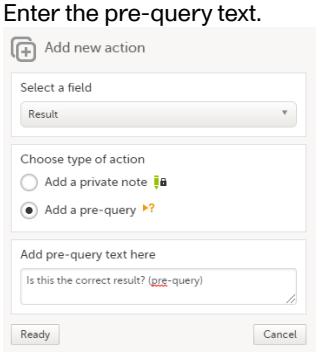
1 Raising a pre-query

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

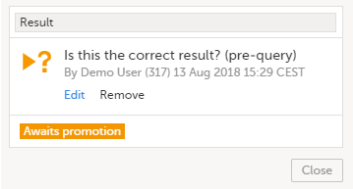
To add a pre-query:

1 Open the form that contains the field the pre-query will be raised on.

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



3 Click **Ready**. The pre-query is created and needs to be promoted and released by the user with permission to promote pre-queries (typically the Monitor), in order to be visible as a query for the site staff.
The pre-query can be edited or removed (if invalid or created by mistake) by clicking the **Edit** or **Remove** links:



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

A pre-query is always marked by this icon:

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

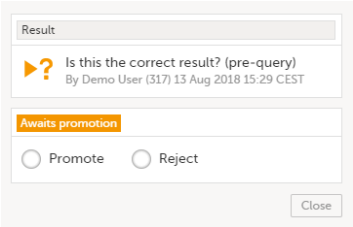
2 Promoting/Rejecting a pre-query

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

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

To promote a pre-query:

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



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

3 Releasing/Rejecting a pre-query

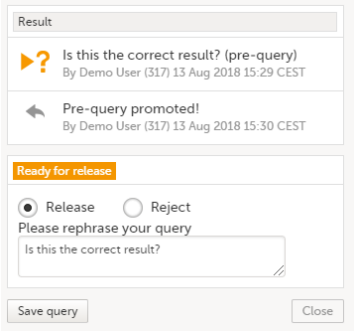
A pre-query can be released after it has been promoted, that is, a pre-query in Ready for release state.

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

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

To release a pre-query:

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



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

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

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

For more information on pre-queries, see Queries overview.

Raising/Approving/Rejecting queries

Published by Viedoc System 2024-10-10

1. Adding a query
2. Editing a query
3. Removing a query
4. Approving/Rejecting a query
    4.1 Approving a query
    4.2 Rejecting a query

For an overview of the entire query process see Queries overview.

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

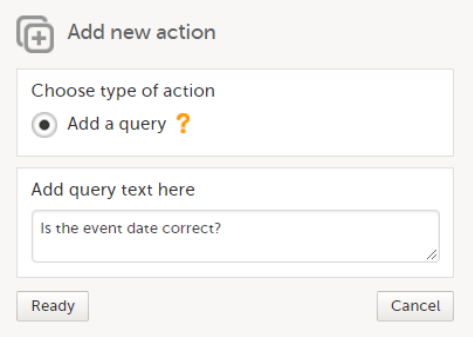
Note! When the role-based queries option is enabled for your study, all of the above actions are restricted to the same role as the role who raised the query. For more information, see Role-based queries.

1 Adding a query

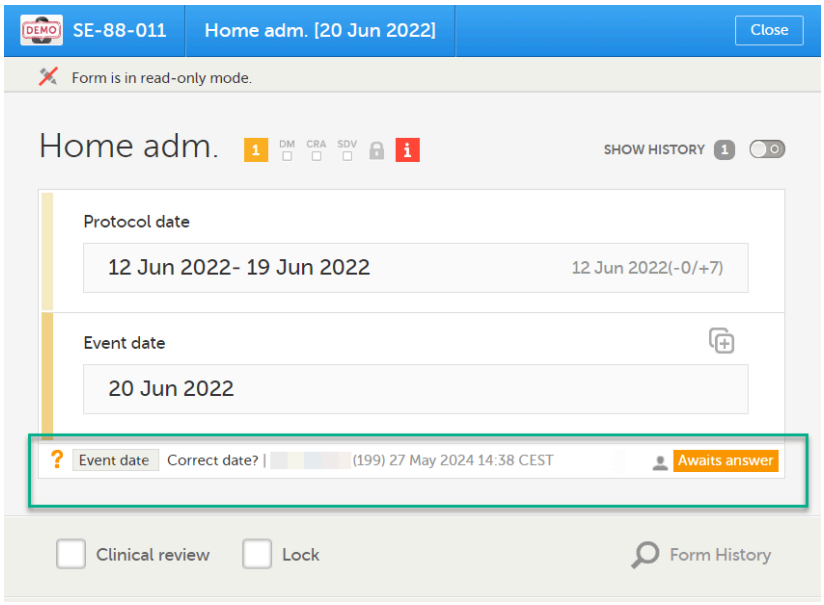
To raise a query:

1 Open the form that contains the field the query will be raised on.

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



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



After the query has been raised it can be:

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

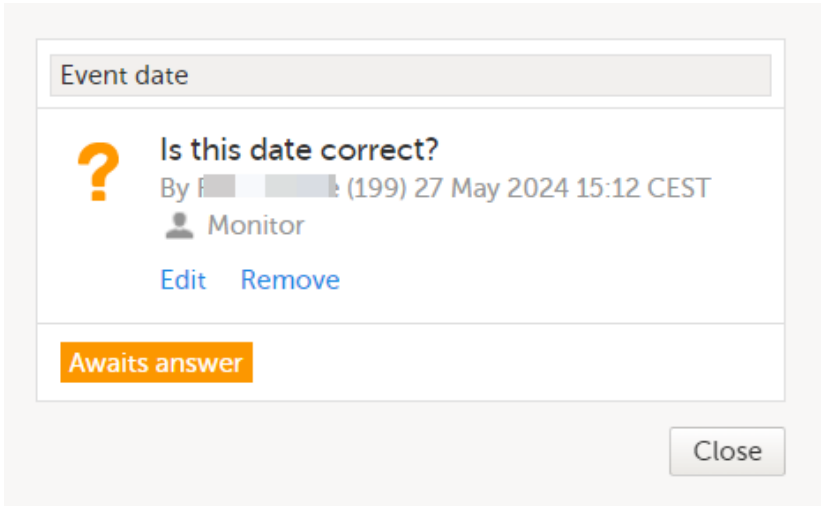
---

2 Editing a query

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

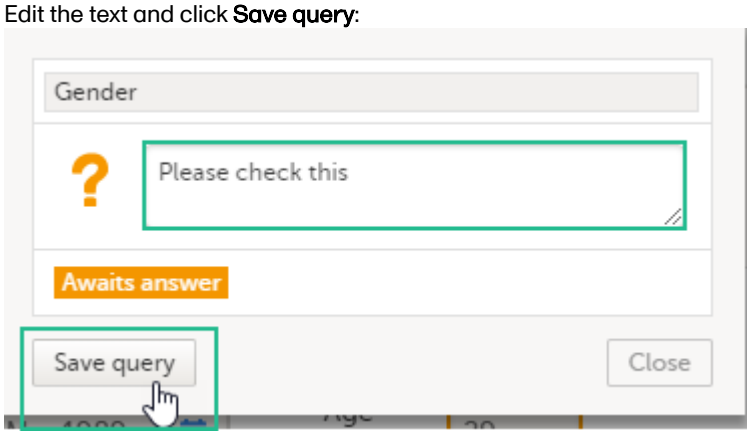
To edit a query:

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



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

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



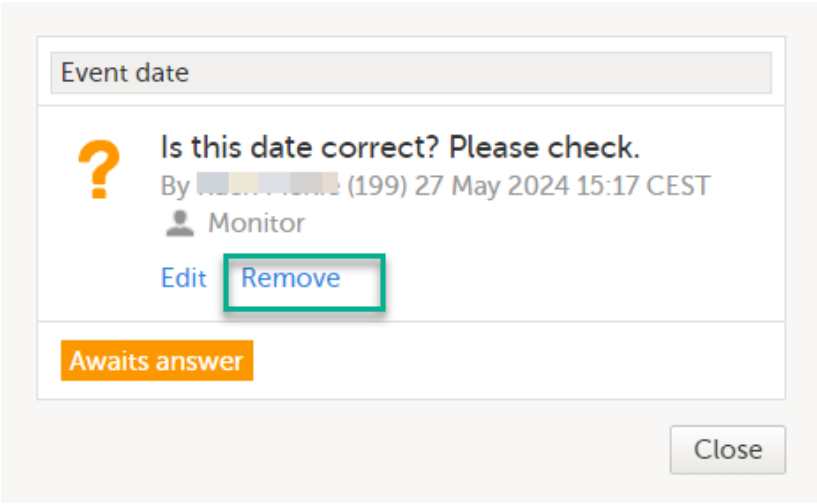
The query text is now updated.

3 Removing a query

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

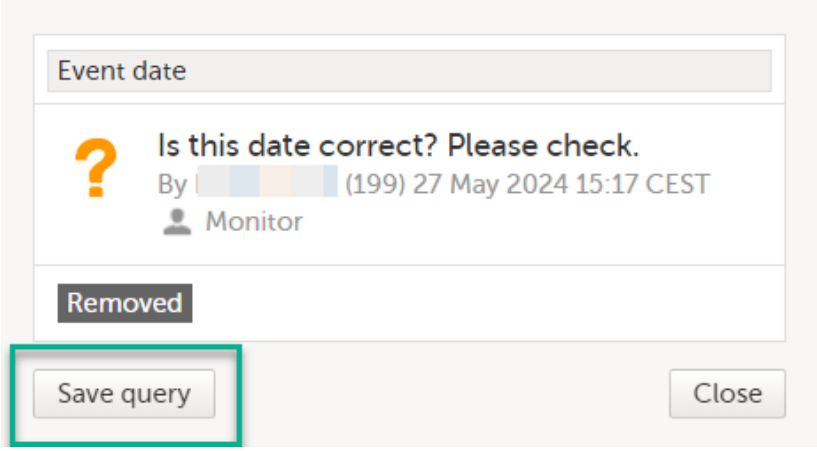
To remove a query:

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



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

2 Click **Save query** to confirm:



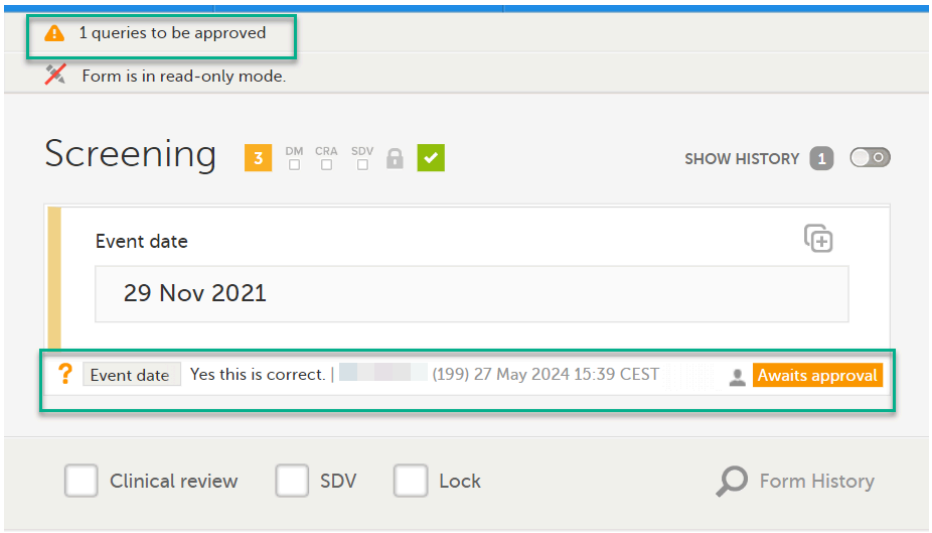
The query state is **Removed**. This is a final state for a query.

---

4 Approving/Rejecting a query

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

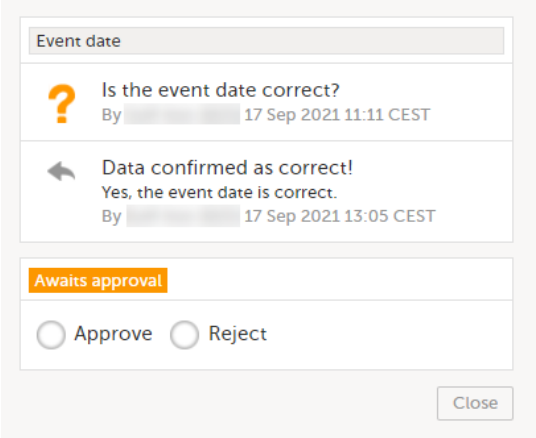
Note! An exception is a query raised as a result of confirming data as missing by the site user. This type of query can only be approved.



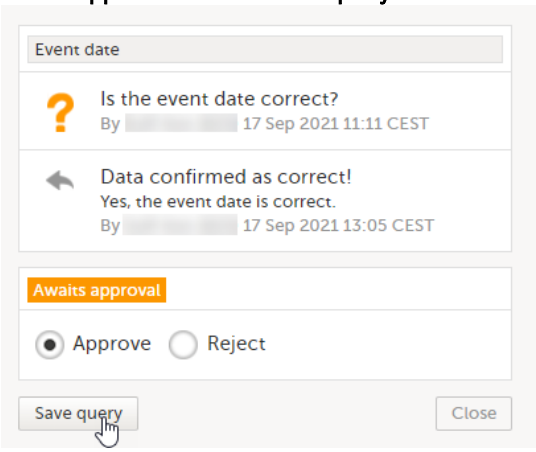
4.1 Approving a query

To approve a query:

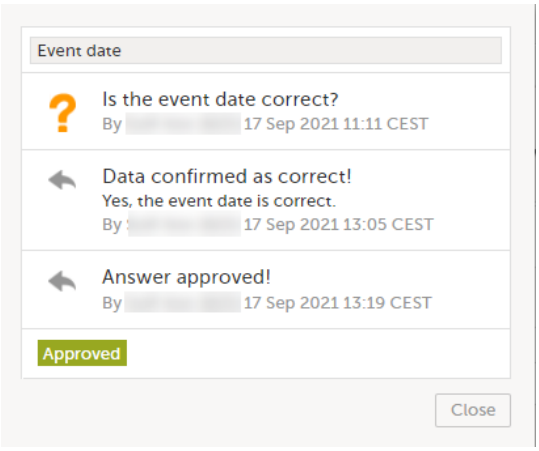
1 Open the query. The query pop-up opens displaying the list of the query history:



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



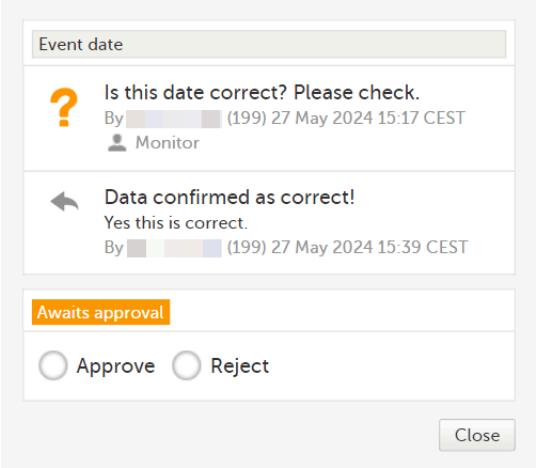
The query is now **Approved**. This is a final state for a query:



4.2 Rejecting a query

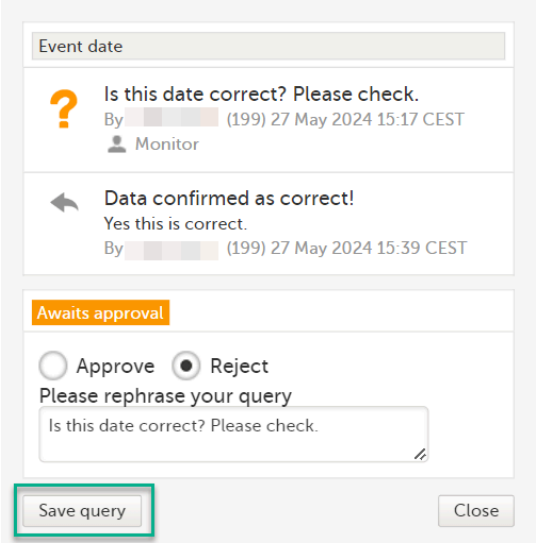
To reject a query:

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

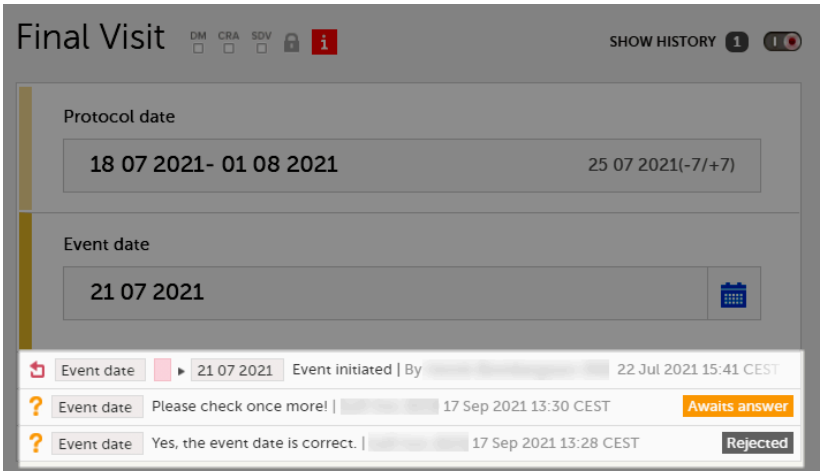


Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see Role-based queries.

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



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



Resolving queries

Published by Viedoc System 2024-10-10

1. Resolving a query
    1.1 Hard checks

1 Resolving a query

For an overview of the entire query process see Queries overview.

If a query is raised during data entry, a query message will appear as soon as you leave the field. To resolve the query, click the query message for more details, or correct the data directly before you continue entering data in the rest of the form.

If a query is raised after the form has been saved, the form is marked with a red issue icon `i` .

To resolve a query:

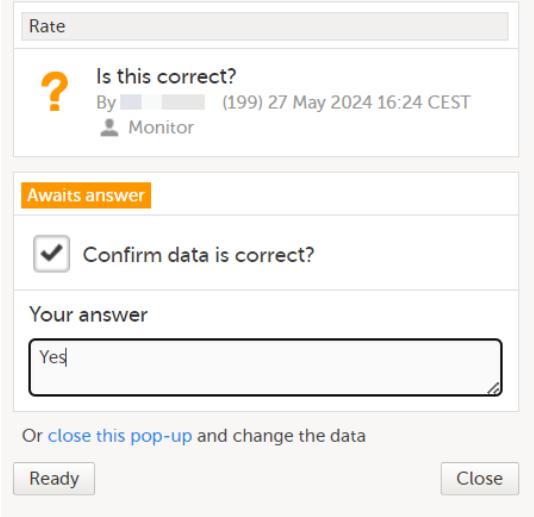
1 Open the form that contains a query.

2 Click **Edit** in the top right corner of the form.

3 Depending on if the entered data is correct or not:

- If the entered data is not correct, enter the correct value in the field that has a query.
- If the entered data is correct, click the query message, check the **Confirm data is correct** checkbox, and enter an answer.

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



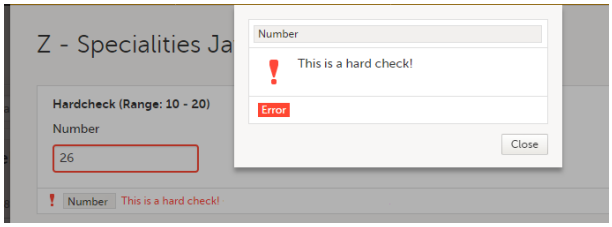
4 Click **Ready**.

5 Click **Save changes**.

1.1 Hard checks

If you add an edit check to an item, you have the option to allow saving of the form. If you allow it, a query is raised. You can save the form and then take care of the query later.

If you don't allow it, you have to solve the edit check immediately or you cannot save the form. We call this a **hard check**.



See also the video tutorial Issue: Resolve a query.

Role-based queries

Role-based queries

Published by Viedoc System 2024-10-10

1. Introduction
2. Manually raised queries
   - 2.1 Pre-queries
   - 2.2 Role-based queries in the Issues list
   - 2.3 Task count updates
   - 2.4 Role-based queries in the Excel and ODM export

1 Introduction

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

Notes!

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

For more information on validation queries and missing data and the entire query process, see Queries overview.

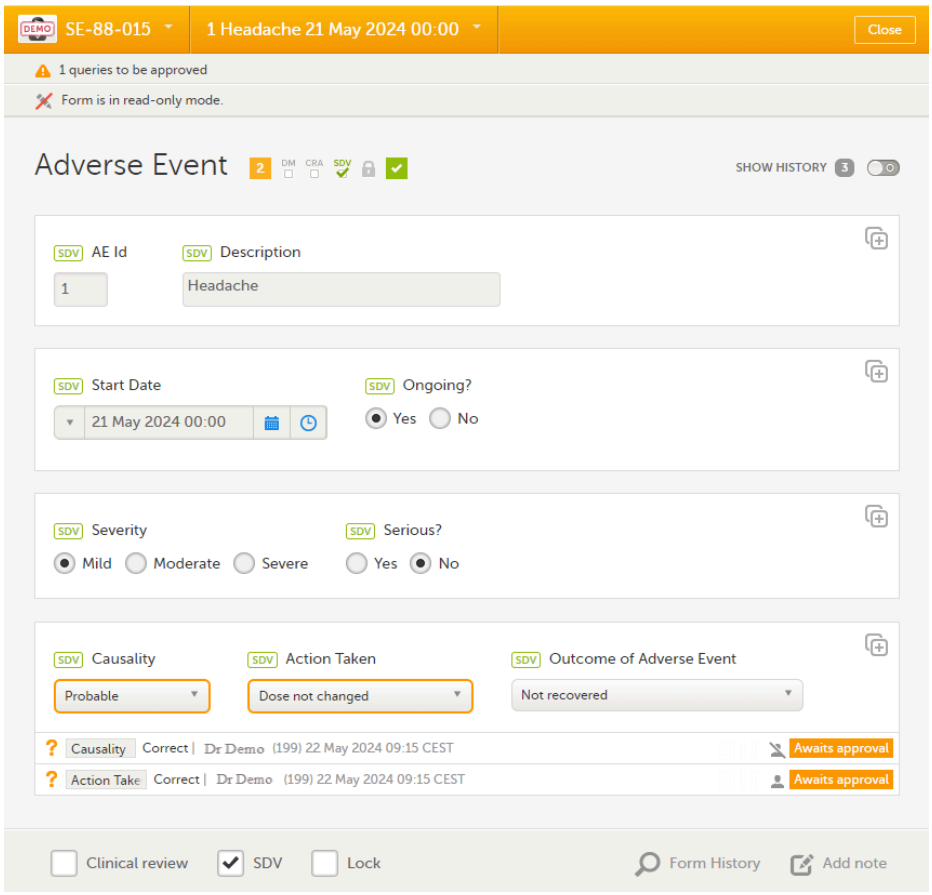
> Important!
> For all new studies started after Viedoc release 4.80, the default setting **Enable role-based queries** checkbox is selected.
> For studies started before release 4.80, the default setting **Enable role-based queries** checkbox is cleared. For studies started before release 4.80, all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

When role-based queries is enabled for a study, there are some updates to the information that is displayed in Viedoc Clinic. This is to support easily identifying which role raised a query, (if a query was raised by the same role as the current active user). This applies to pre-queries and for manually raised queries in forms, in the query history pop-up, in the **Issues** view and in the export output, as described below.

2 Manually raised queries

When role-based queries is enabled:

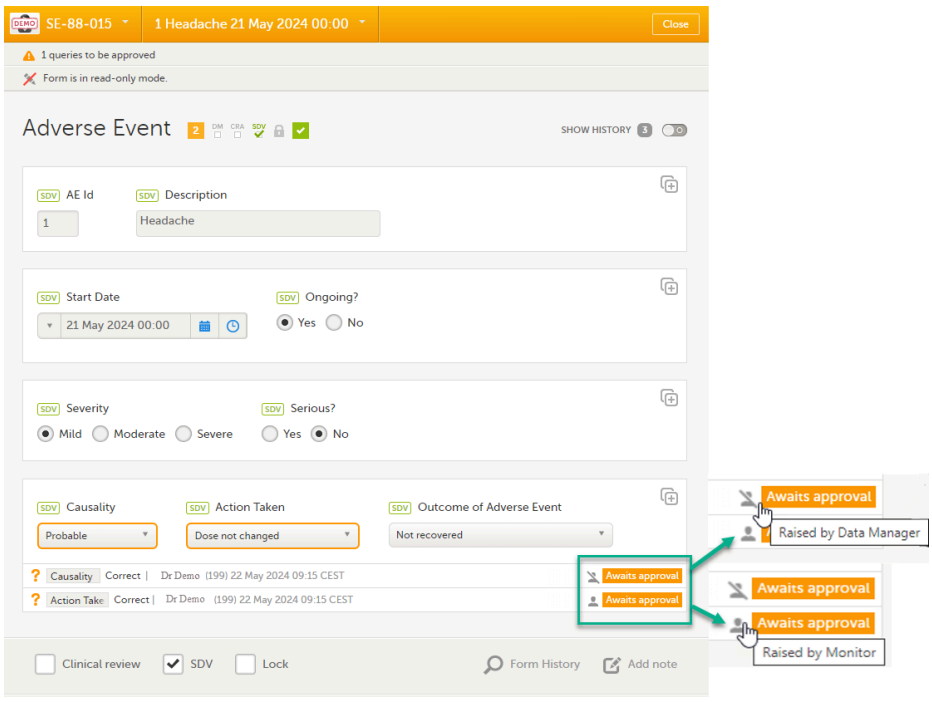
- A user role with permission to add/change queries can only perform actions on queries raised by their role, for example, a Monitor can only perform actions on queries, for example approve/reject/edit a manual query raised by a user with the Monitor role.
- Users with permission to add/change queries, for example Data Managers or Monitors, can still see which role has raised a query. For these roles, the user name and which user role raised/answered/approved/rejected a query is shown at form level.



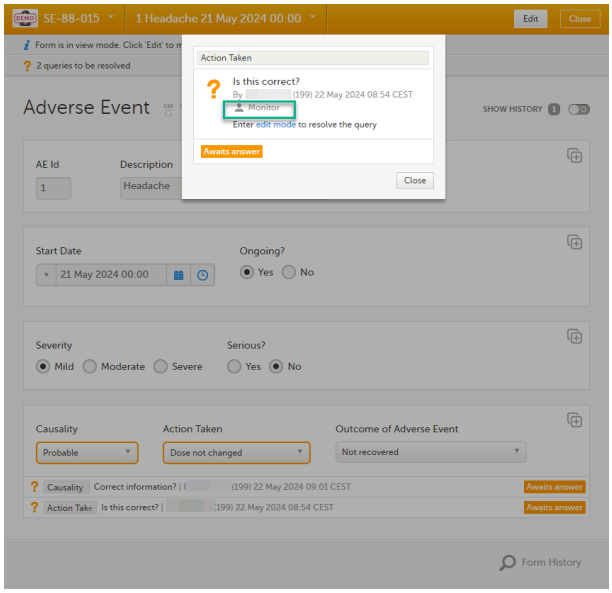
If a query was raised by a different user role, one that also has permission to add/change queries, the query will still be visible in the form. The user can see another role's actions on a query, however the query action will be flagged with a strikethrough avatar icon to indicate that no actions can be performed.

Note! The user role who raised the query is displayed by hovering over the avatar icon, as in the image below - **Raised by** (user role), and also in the query history pop-up, as shown below.

In the example below, the user is a Monitor and can only perform actions on the query raised by another user with the Monitor role, shown with the avatar with no strikethrough.



For the roles with permission to add/update query answers (such as Investigators), the role which raised the query is not shown on the form, however, it is shown in the query history pop-up which shows the query history:



2.1 Pre-queries

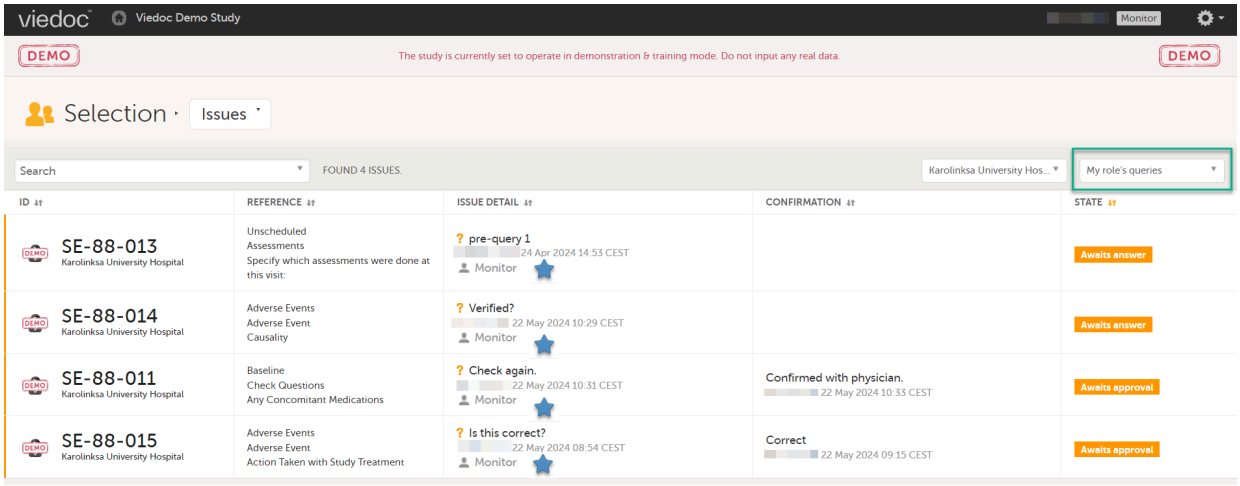
When role-based queries is enabled, when a raised pre-query is released, (typically by the Monitor), the resulting new query visible for the Viedoc Clinic user with permission to add/update query answers, typically the Investigator), is considered as being raised by the same role that released the pre-query.

For more information on pre-queries, see Queries overview.

2.2 Role-based queries in the Issues list

When opening the **ISSUES** list, for user roles with permission to add/change queries, such as Monitors and Data Managers, there is a filter available which is applied by default: **My role's queries**.

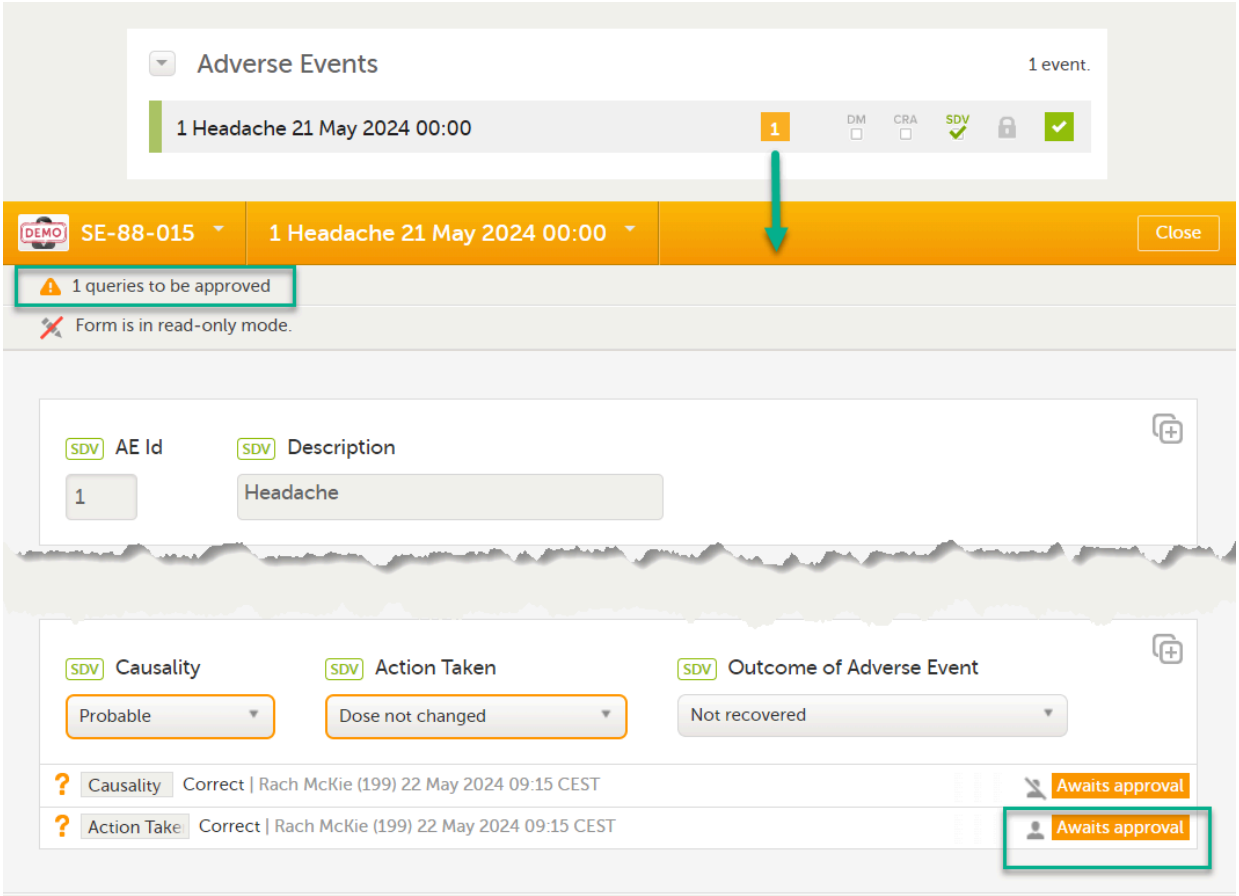
This filter lists all the open manually raised queries that were raised by the same role and that have the status **Awaits approval** and **Awaits answer**:



The role who raised a query is is shown in the Issue list as part of the **ISSUE DETAIL**, for all users regardless of their role or permissions.

2.3 Task count updates

The number of tasks to be performed counts only the queries that the user is allowed to perform actions on, based on their user role:



2.4 Role-based queries in the Excel and ODM export

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)

After the Viedoc 4.80 release, in the Excel export output, two extra columns are added to the Queries sheet, the two rightmost columns. These are added to existing export versions regardless of whether role-based queries is enabled or not for the study.

These columns contain:

- Information about the user role – the role of the user who performed the action on the query. This can be different for the different actions performed on the same query. For example, a Monitor raised the query, an Investigator answered, and a Monitor approved the query.
- Query raised by role – the role of the user who raised the query – this is always the same for all the actions performed on the same query.

Exporting data

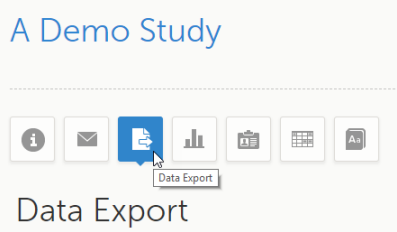
Exporting data

Published by Viedoc System 2025-02-18

1. Introduction
2. Filtering the data to be previewed/exported
    2.1 Filtering data by country and site
    2.2 Including subjects
    2.3 Events and time period
        2.3.1 Selecting events
        2.3.2 Selecting a time period
    2.4 Forms and items
    2.5 Type of data
        2.5.3 Filter data by review status
        2.5.4 Additional information
            2.5.4.1 Booklet status
            2.5.4.2 Queries and Query history
            2.5.4.3 Review status
            2.5.4.4 Event dates
            2.5.4.5 Uploaded files
            2.5.4.6 Pending forms
            2.5.4.7 Medical coding
            2.5.4.8 Edit status
            2.5.4.9 Subject status
3. Export output formats
    3.6 Microsoft Excel / CSV
    3.7 CSV
    3.8 PDF
    3.9 CDISC ODM
4. Export compatibility with previous Viedoc versions
    4.10 Output versions
5. How study design impacts data export
6. Previewing data
    6.11 Data table
        6.11.5 Column menu
            6.11.5.10 Column display options
            6.11.5.11 Column filter
            6.11.5.12 Column selection options
        6.11.6 Data table context menu
    6.12 Pie chart
    6.13 Column chart
    6.14 Line chart
7. Data export templates
    7.15 Saving export settings as a template
    7.16 Applying a data export template
    7.17 Editing a data export template
    7.18 Deleting a data export template
8. Exporting data
    8.19 Latest exports
9. Exporting Data FAQ

1 Introduction

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



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

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

---

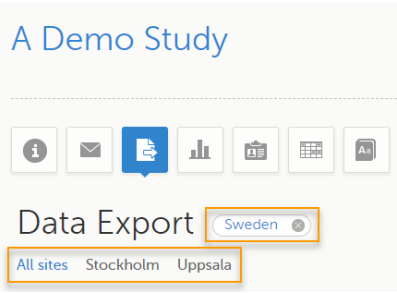
2 Filtering the data to be previewed/exported

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

2.1 Filtering data by country and site

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

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



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

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

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

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

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

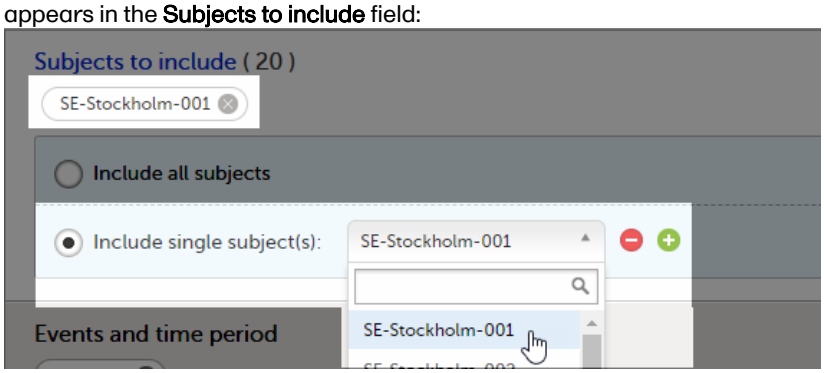
2.2 Including subjects

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

To select which subjects to include:

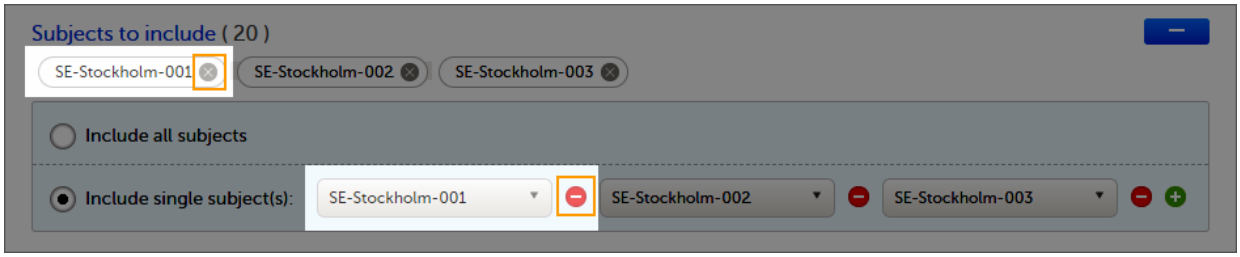
1 Select **Include single subject(s)**.

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



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

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



2.3 Events and time period

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

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

2.3.1 Selecting events

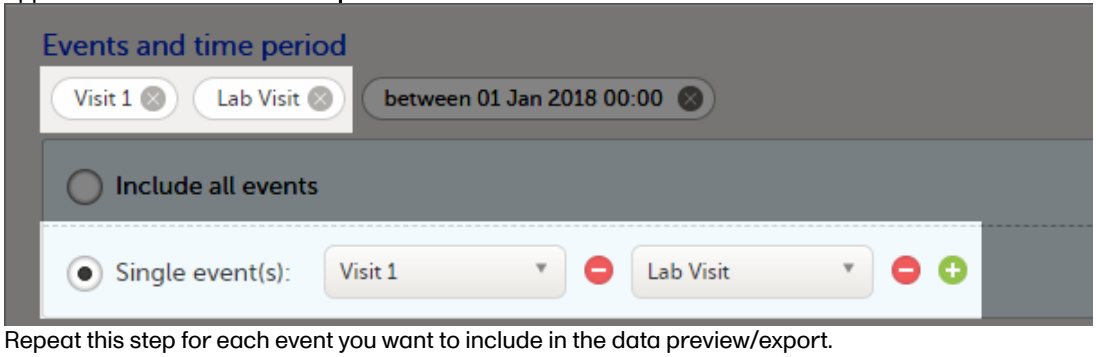
You can choose to:

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

To select which events to include:

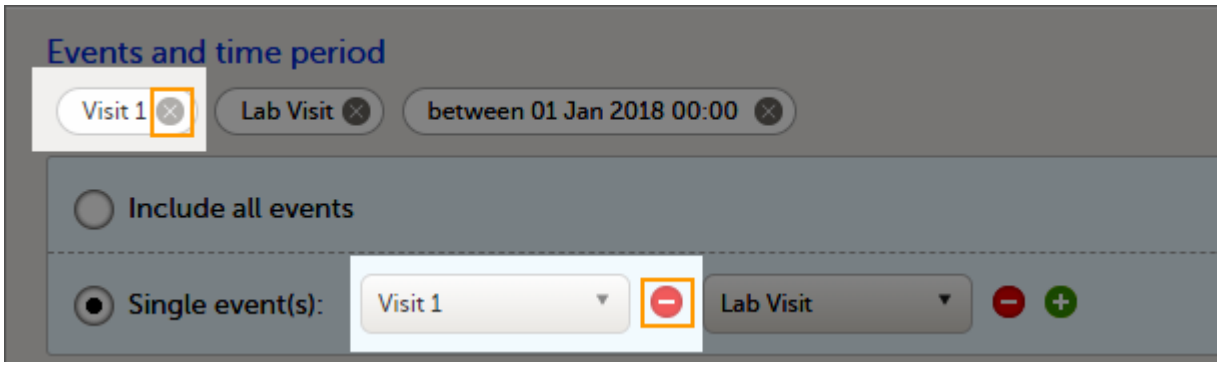
1 Select **Single event(s)**.

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



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

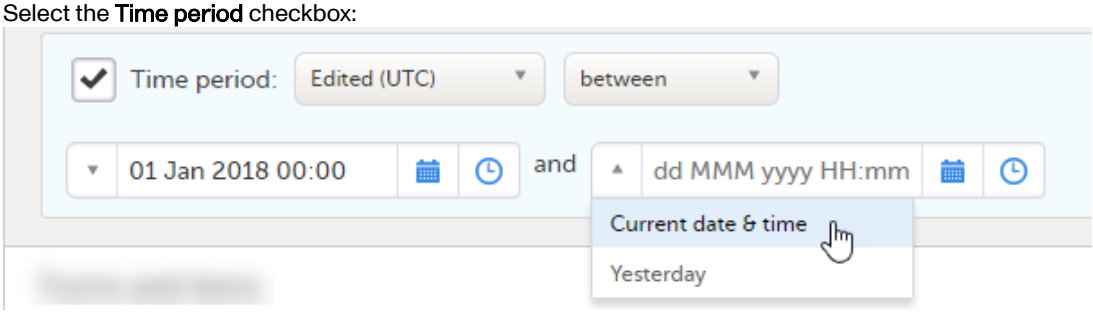
To undo the selection of certain events, click the - icon, or click the cross x icon next to the event:



2.3.2 Selecting a time period

To include data from a specific time period:

1 Select the **Time period** checkbox:



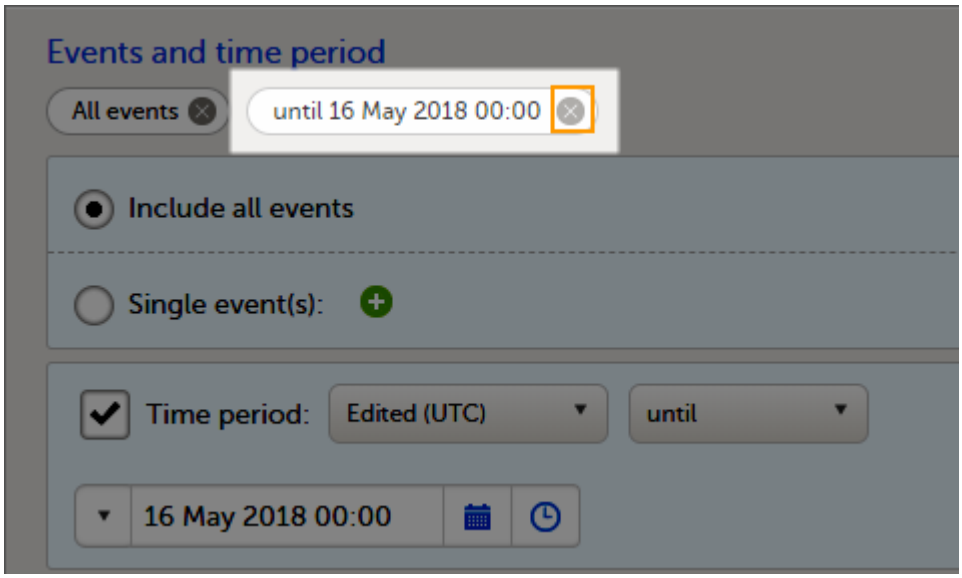
2 Select one of the following options from the first drop-down list:
- **Edited (UTC)** - to include data based on the date they were added or last edited.
  Note! This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note that also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

3 Select whether to define the time period **until** a certain date, **from** a certain date, or **between** two dates.

4 Select the date(s).

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

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



2.4 Forms and items

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

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

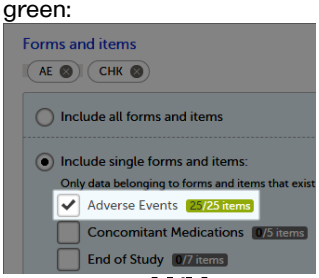
Note! Only data belonging to forms and items that exist in the latest effective design applied to the first of the selected sites will be included in the export. Also note that the forms and fields available to choose from are determined by the visibility settings for your user role.

To include data from specific form(s):

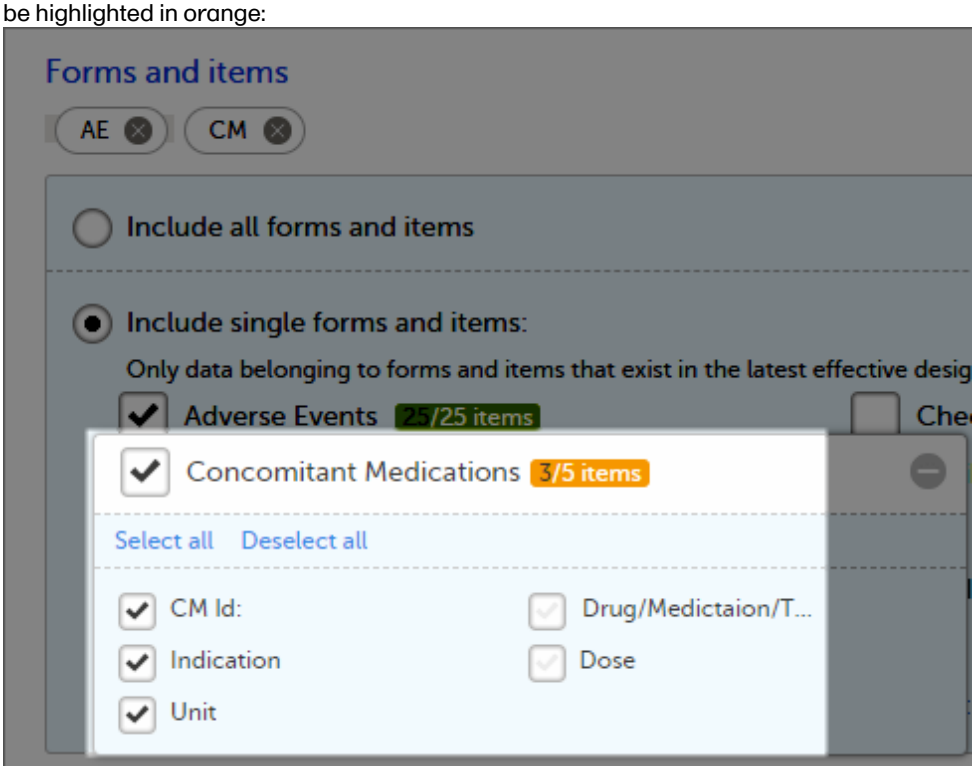
1 Select **Include single forms and items**.

2 Select the forms and items to be included, in one of the following ways:

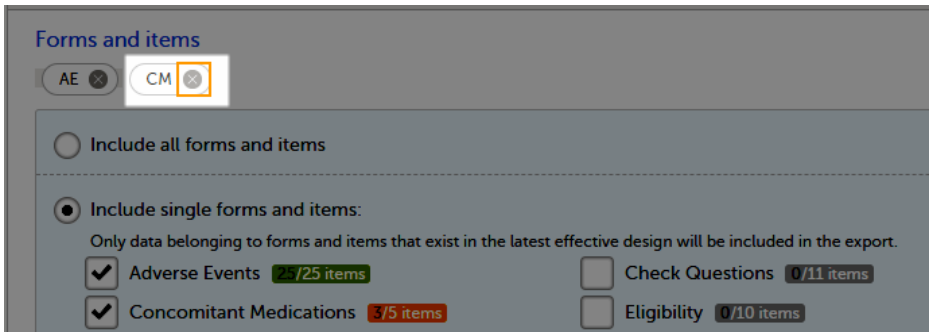
- Select the checkbox corresponding to a form in the list displayed, to include the respective form with all the items contained. The selected/total number of items will be highlighted in green:



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



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



2.5 Type of data

2.5.1 Filter data by review status

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

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

2.5.2 Additional information

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

2.5.2.1 Booklet status

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.5.2.2 Queries and Query history

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

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

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

See also:

- Queries in ODM export
- Queries in Excel export

2.5.2.3 Review status

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

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

See also:

- Review status in ODM export
- Review status in Excel export

2.5.2.4 Event dates

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

- Microsoft Excel - Office Open XML
- CSV
- ODM

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

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

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

2.5.2.5 Uploaded files

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

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

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

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

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

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

2.5.2.6 Pending forms

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

- Microsoft Excel - Office Open XML
- CSV

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

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

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

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

2.5.2.7 Medical coding

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

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

2.5.2.8 Edit status

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

- Microsoft Excel - Office Open XML
- CSV
- PDF - PDF/A
- ODM

2.5.2.9 Subject status

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

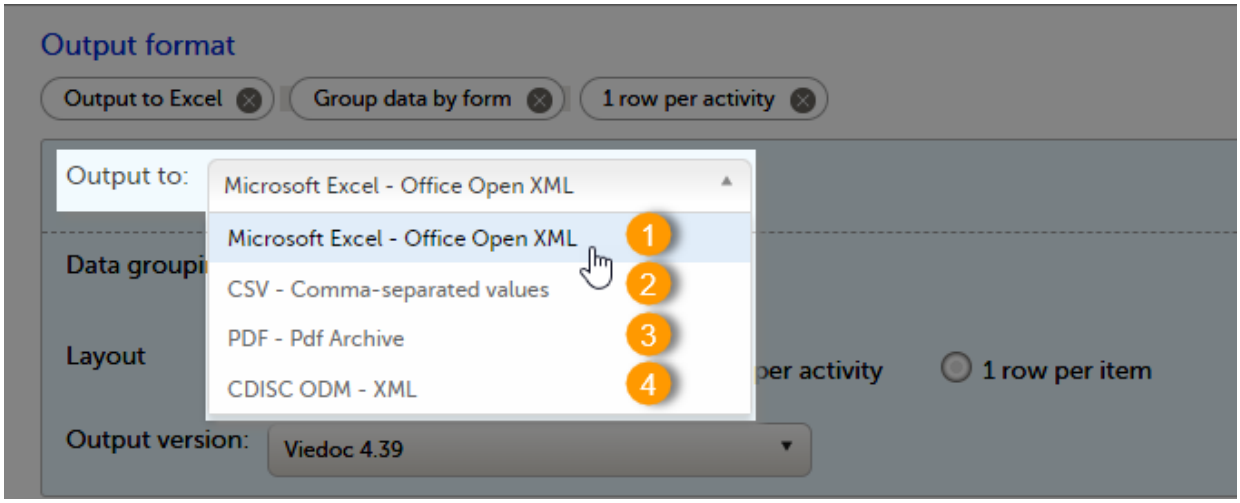
- Microsoft Excel - Office Open XML
- CSV
- ODM

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

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

3 Export output formats

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



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

1. Microsoft Excel - Office Open XML

2. CSV

3. PDF - PDF/A

4. ODM

3.1 Microsoft Excel / CSV

Viedoc uses Microsoft Excel Open XML format which is compatible with Excel version 2007 and later.

For details about the Excel export options and the format/structure of the output file, see Excel export.

3.2 CSV

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

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

3.3 PDF

For details about the PDF export and the format/structure of the output file, see PDF export output.

3.4 CDISC ODM

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

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

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

The ODM export file is built up as follows:

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

See also:

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

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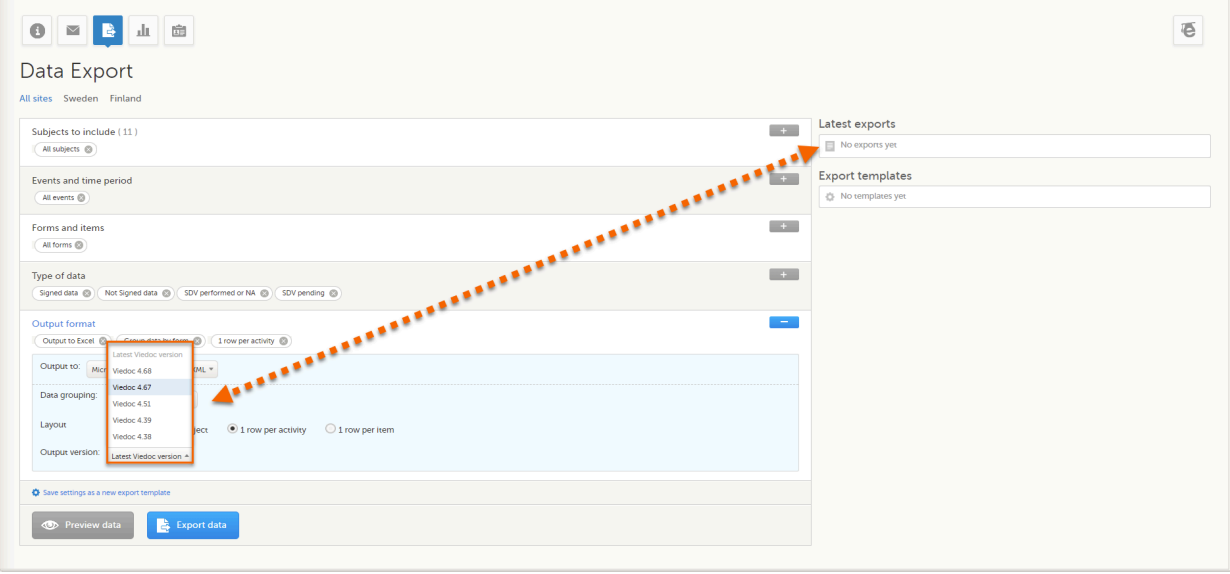
4 Export compatibility with previous Viedoc versions

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

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

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



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

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

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

4.1 Output versions

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

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

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

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

File type	Changes in the export output format
ODM	Introduction of support for partial datetime, date, and time. This is now the default type when exporting designs and data in ODM format. Partial dates as per the ISO 6801 standard are written up to the most detailed value available. This makes the export compliant with CDISC ODM.
ODM	When exporting a design to ODM, multi-selection code lists are handled as follows: Checkbox item definitions are split by code list items. ▪ During metadata export, checkbox ItemDef is replaced with one for each code list item. ▪ For clinical data export, the comma-separated values are replaced for the checkbox with ItemData for each respective value. For example, when splitting a checkbox ItemDef with OID="CHK" and code list IDs "Yes" and "No", the split checkbox ItemDefs will have the OIDs "__CHK__Yes" and "__CHK__No", respectively. That is, the original OIDs and the code list IDs are prefixed with two underscore characters and separated by two underscore characters. In Viedoc Designer, checkbox items are exported as multiple ItemDefs - one for each selection value. In Viedoc Clinic and the Viedoc API: In the latest export version, checkboxes are exported as separate items for metadata and clinical data. In previous export versions, checkboxes are exported as one item. This has been introduced to be compliant with CDISC ODM.

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

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

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 How study design impacts data export

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

What happens when study designs differ?

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

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

What does "first selected site" mean?

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

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

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

Selecting multiple sites with different study designs

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

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

Best practices to ensure accurate exports:

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

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

Example scenario: How study design affects data export

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

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

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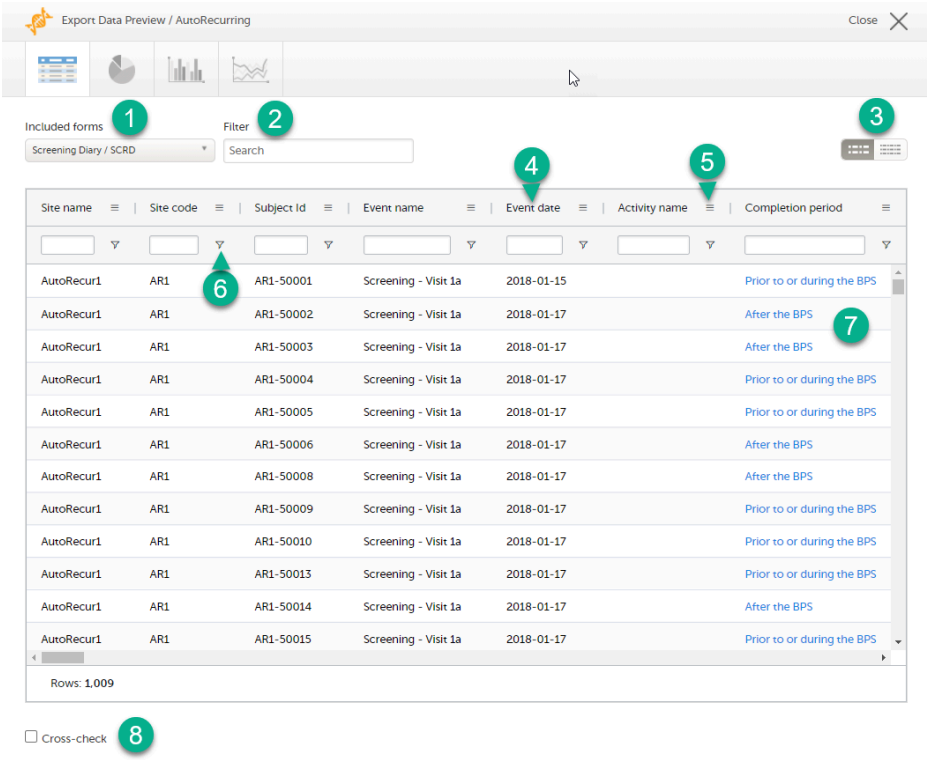
6 Previewing data

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

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

6.1 Data table

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



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

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

3. Toggle between spacious view and compact view.

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

5. Click to open the column menu. For more information, see Column menu.

6. Click to access the column filter. For more information, see Column filter.

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

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

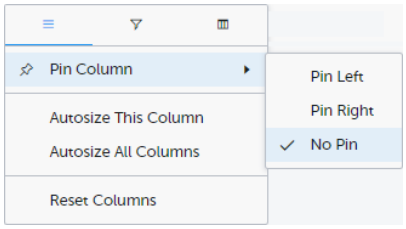
6.1.1 Column menu

The column menu contains:

- column display options
- column filter 
- column selection options 

For more information, see the following sub-sections.

6.1.1.1 Column display options



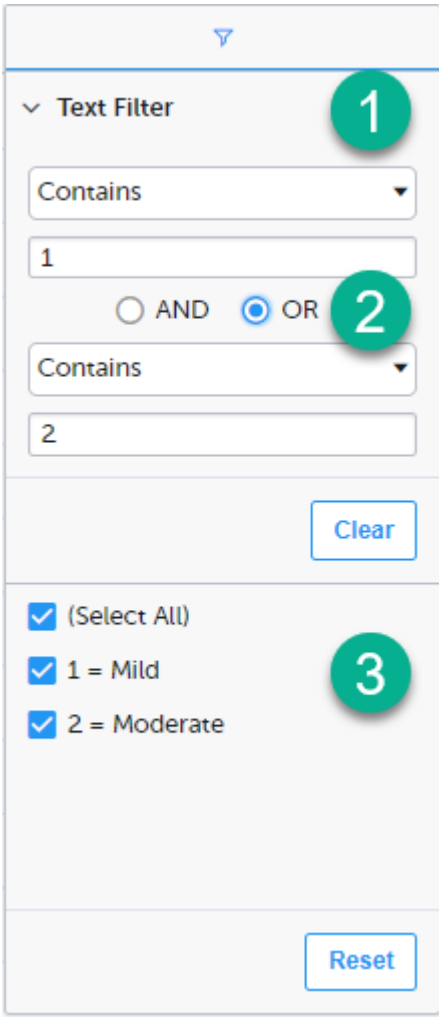
Pin Left/Right makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select **No Pin** to unpin the column.

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

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

6.1.1.2 Column filter

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



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

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

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

  Note! The text filters are case-insensitive.

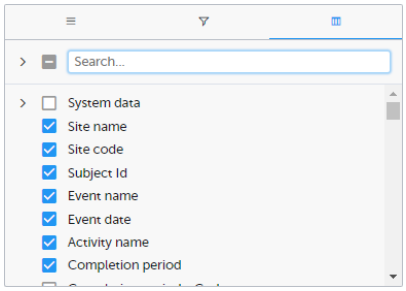
- Number filter with the following filter operators:
  - Equals
  - Not equal
  - Less than
  - Less than or equals
  - Greater than
  - Greater than or equals
  - In range

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

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

6.1.1.3 Column selection options

Select the columns to be displayed in the preview table.



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

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

6.1.2 Data table context menu

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

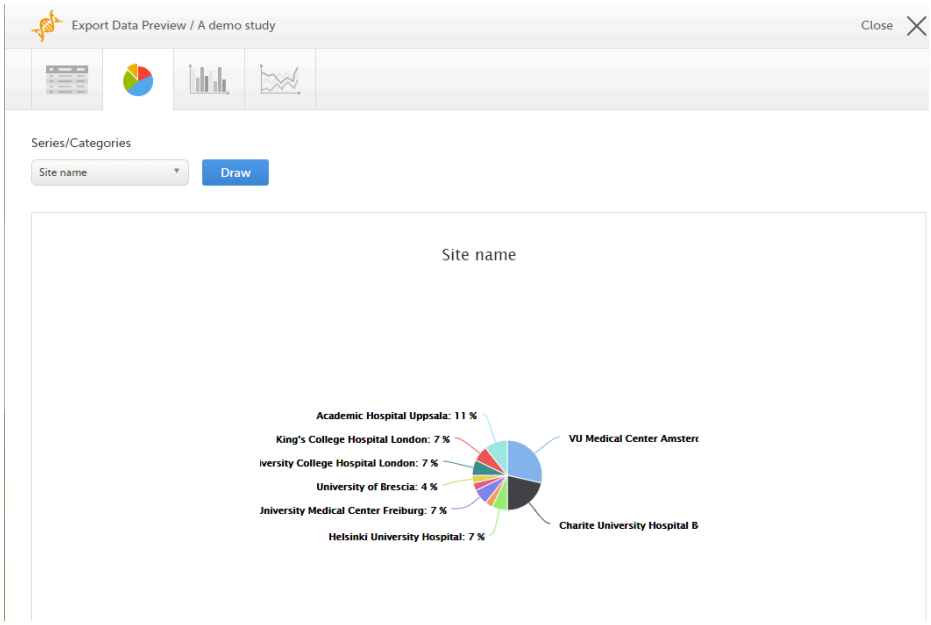
Copy: Copies the cell value to your clipboard.

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

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

6.2 Pie chart

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



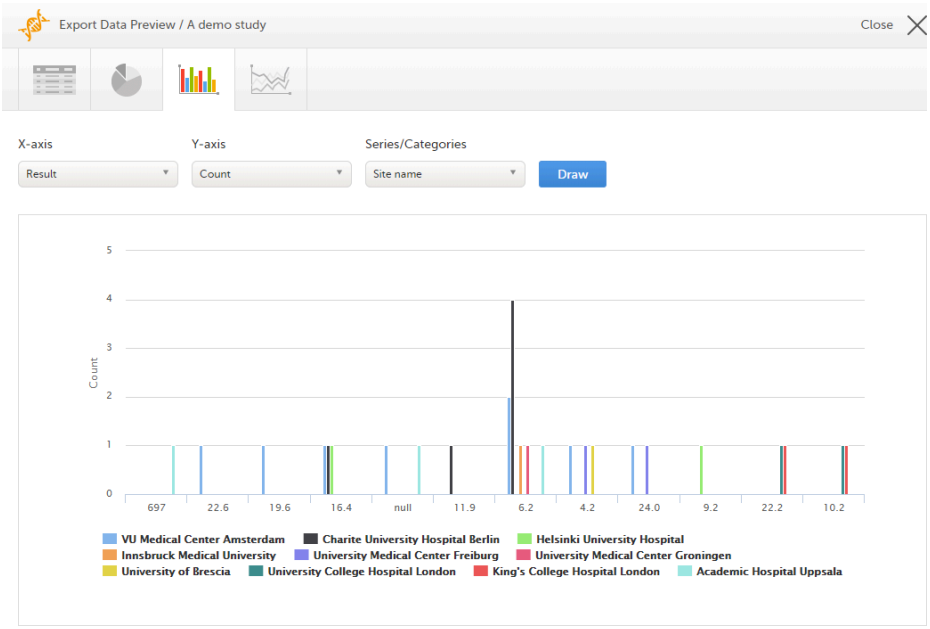
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any data point to view its details.

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

6.3 Column chart

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



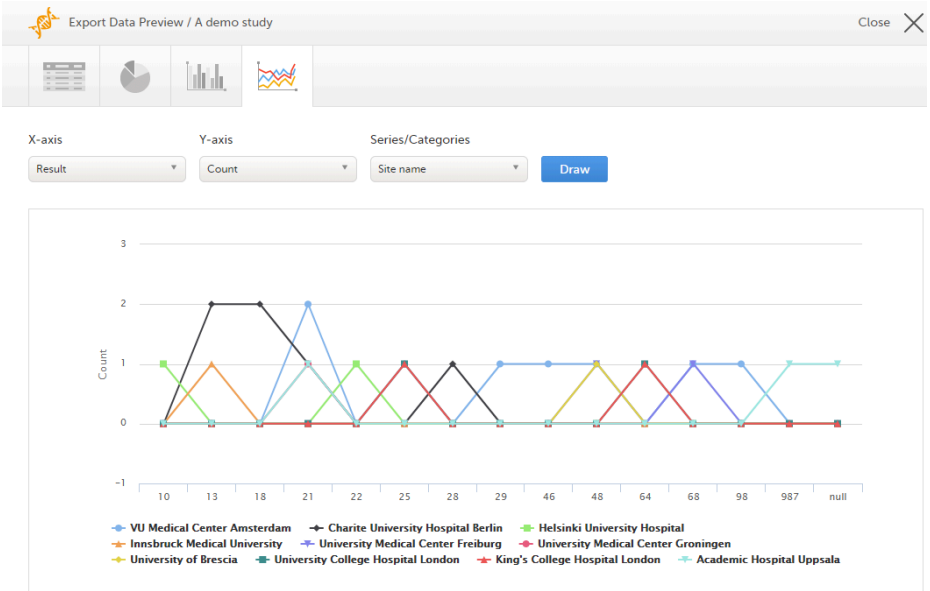
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any column to view details of the data.

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

6.4 Line chart

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



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

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

---

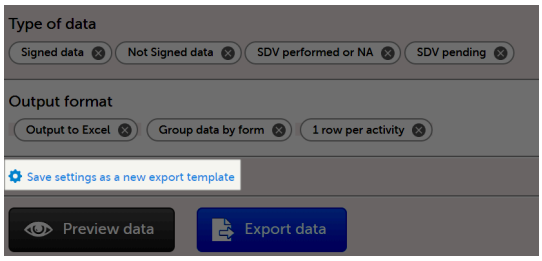
7 Data export templates

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

7.1 Saving export settings as a template

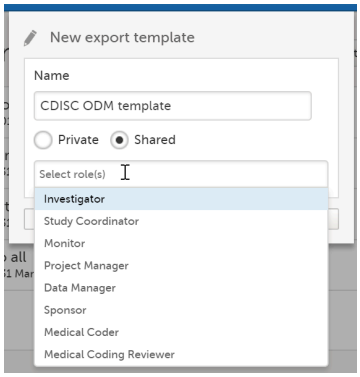
To save your settings as a template:

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

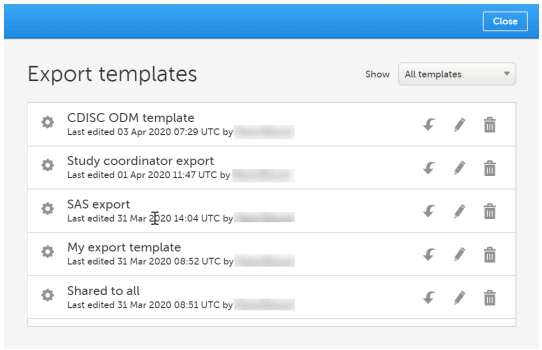


2 In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

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



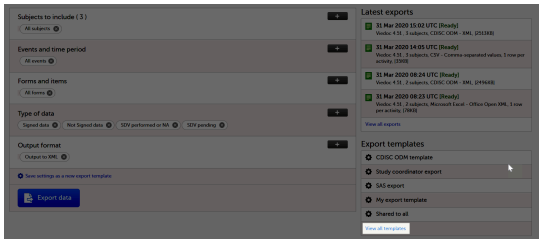
3 Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:



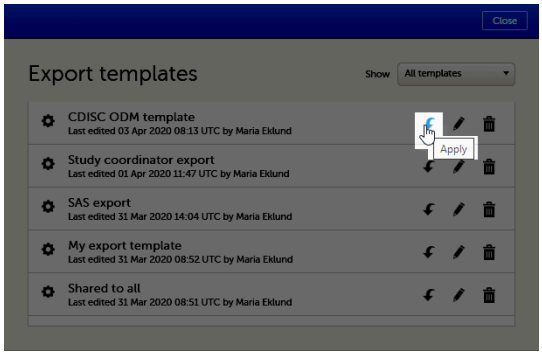
7.2 Applying a data export template

To apply a data export template:

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

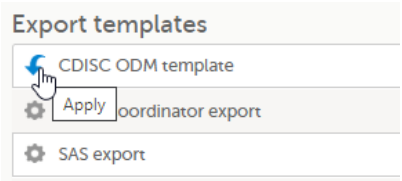


2 Click the apply icon for the template that you want to apply.



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

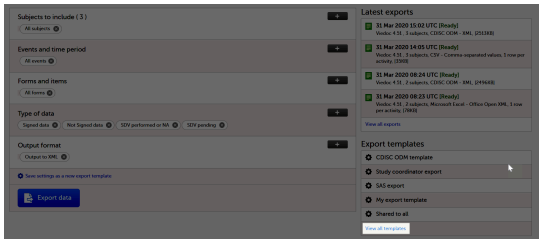
Tip! Alternatively, you can use the quick access apply, available in the **Export templates** area:



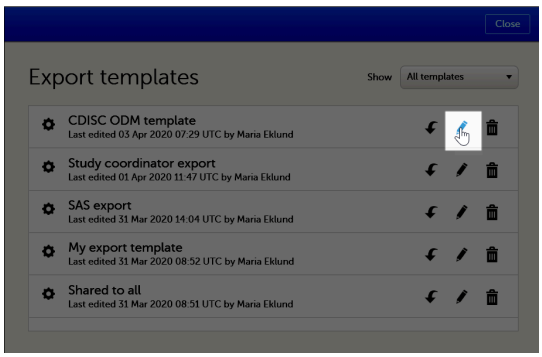
7.3 Editing a data export template

To edit a data export template:

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



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



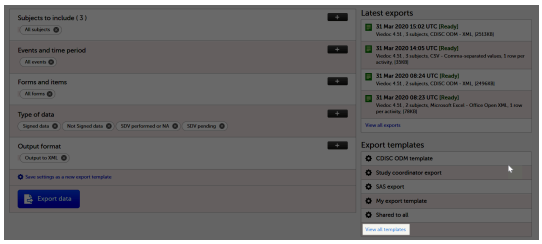
3 In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

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

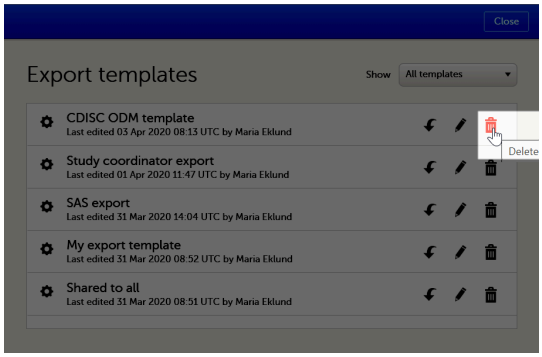
7.4 Deleting a data export template

To delete a data export template:

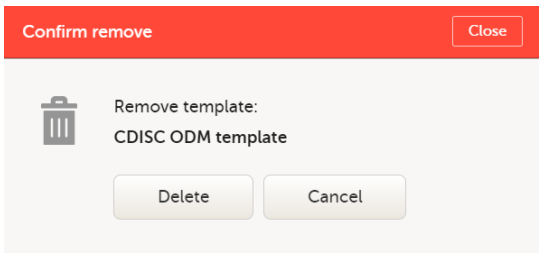
1 Click **View all templates** in the **Export templates** area of the **Data export** page.



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



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



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

8 Exporting data

To perform a data export:

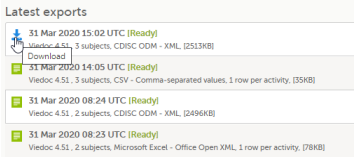
1 Filter the data to be exported. See Filtering the data to be exported.

2 Select the Output format.

3 Optionally, select the Output version.

4 Optionally, preview the data to be exported.

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



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

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

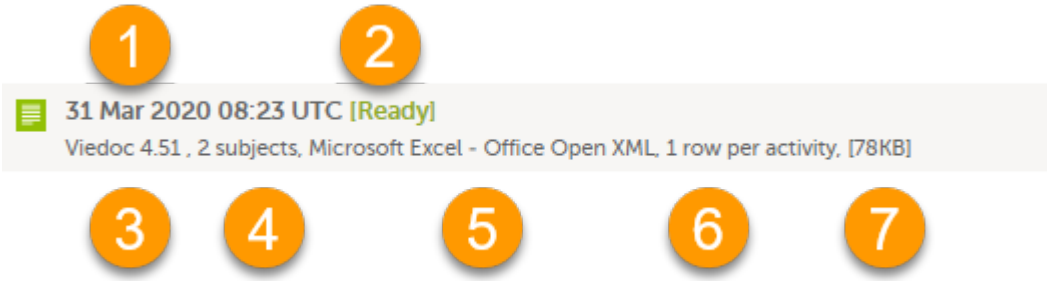
Note! If any of the characters that are invalid for a filename in Windows are used within any of the *SponsorCode* or *SiteCode*, these characters will be automatically replaced with **-** within the exported filename.

8.1 Latest exports

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

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

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



Each log entry provides the following information:

1. The date and time when the export was initiated.

2. The export status:

- **In Queue** - the export request is in queue, waiting to be processed.
- **In Progress** - the exported started and is in progress.
- **Ready** - the file was successfully exported and is ready for download.
- **Error** - an error was encountered and the export was not performed.

3. Viedoc output version - see Output versions.

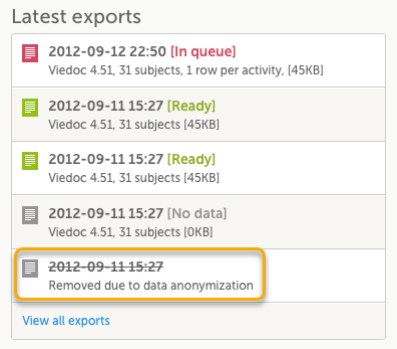
4. The number of exported subjects.

5. The format of the output file.

6. The selected layout, if applicable.

7. File size

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



9 Exporting Data FAQ

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

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

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

Q: Is there a size limit to exports?

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

Q: Can I schedule exports automatically?

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

Q: How is missing data handled?

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

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

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

Excel export

Excel export

Published by Viedoc System 2024-12-03

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4. Data grouping
    4.2 Group data by form
    4.3 Do not group data
5. Layout
    5.4 One row per subject
    5.5 One row per activity
    5.6 One row per item
        5.6.1 Include history
        5.6.2 Checkboxes
        5.6.3 Reference ranges
6. Form link items in the export output
    6.7 One row per activity
    6.8 One row per item
    6.9 One row per subject
7. Recurring events in the export output
8. Repeating forms in the export output
9. Forms initiated by copying data from previous event

1 Introduction

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

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

For general information about data export in Viedoc, see Exporting data.

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

2 File structure

The Excel export contains the following sheets:

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

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

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

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

	Group data by form	Do not group data
one row per subject	▪ *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

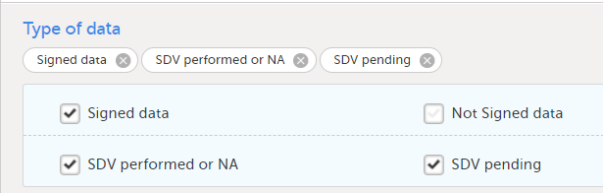
An item that was changed within a new/revised study design version will have a "__*n*" suffix added, where *n* is incremented for each study design version where the respective item was changed:

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	ActivityNa	FormSeq	DesignVer	GENDER	GENDERCD	DOB	AGE	PI2	HAS_FILTERED_VALUES
1	Stockholm	D8	2	EH-D8-002	1	AP	Add Patien	2017-08-11	APA		1	2.0	Male	M	1966-10-01	51		
2	Uppsala	Uppsala:2	2	SE-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

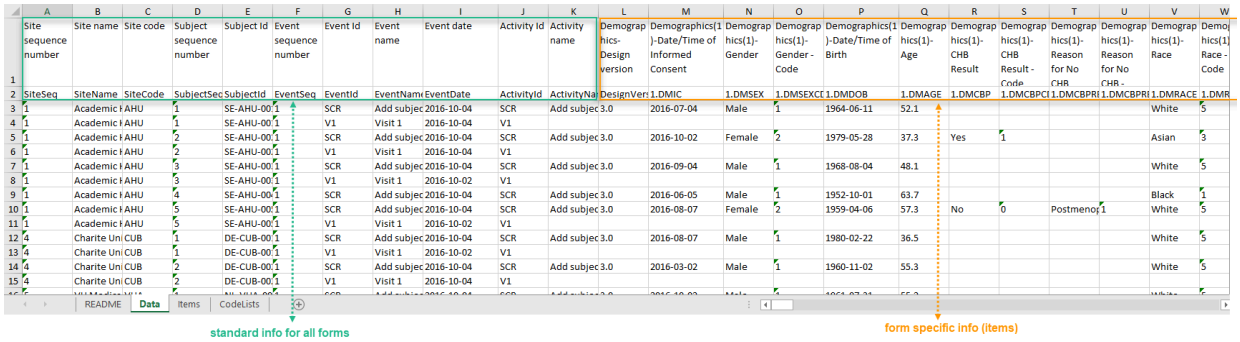
If you choose not to group the data, then all data from all forms will be exported in the same sheet (**Data**) of the output file.

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:

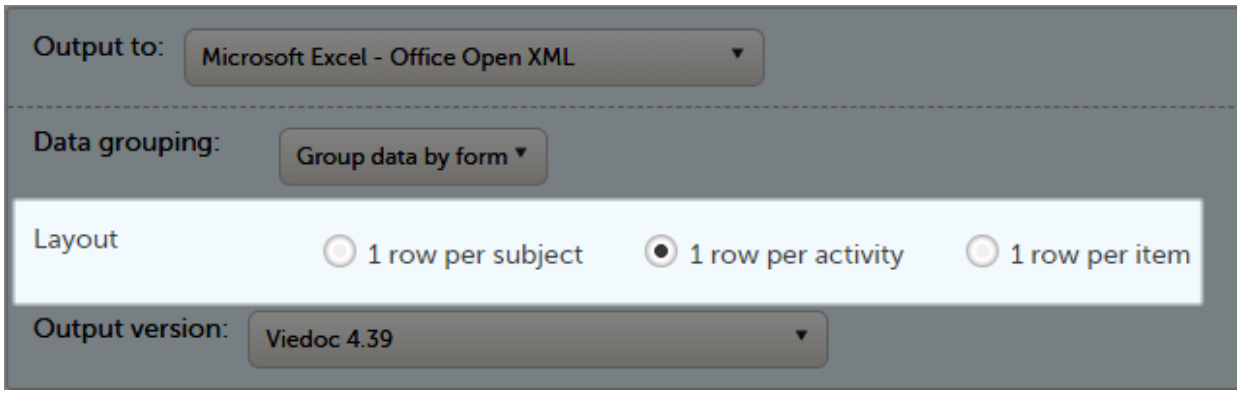
- <*FormName*>_*Design Version* - the form name, as set in the study design (in Viedoc Designer) and displayed in Clinic. In the example in the image, the form name is *Demographics.*
- *<FormName>(<Form Repeat Key>)_<ItemName>* - for each item in the respective form. The form name and item name, as 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

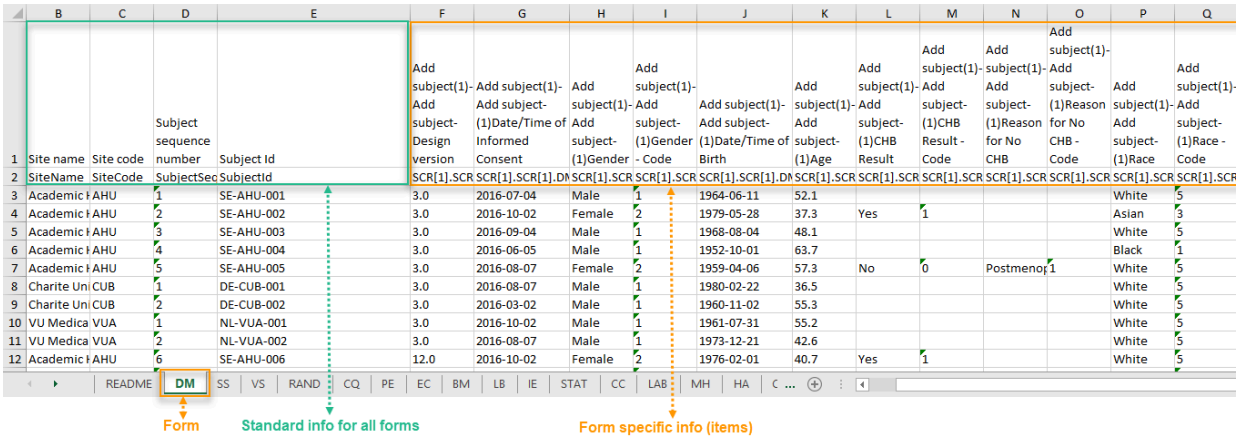
In the **Layout** section, you can select whether the data should be organized in the output file as:

- 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.

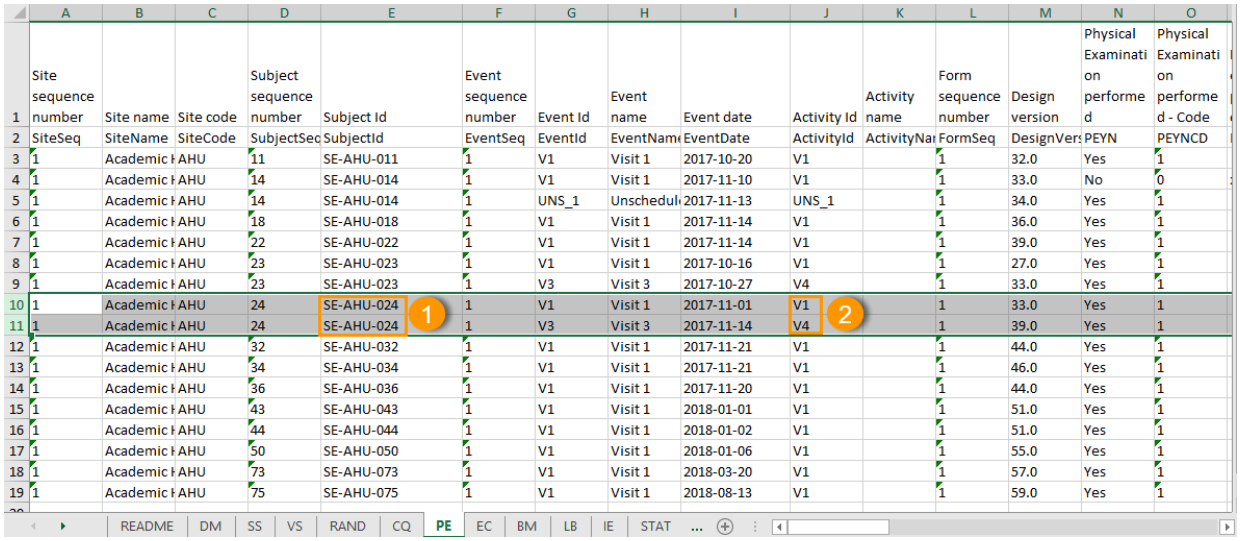
Note! The columns Event sequence number, Event Id, Activity Id, Form sequence number, Subject form sequence number, Origin Subject form sequence number, and Source Subject form sequence number are not included when you have selected **1 row per subject**.

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).



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

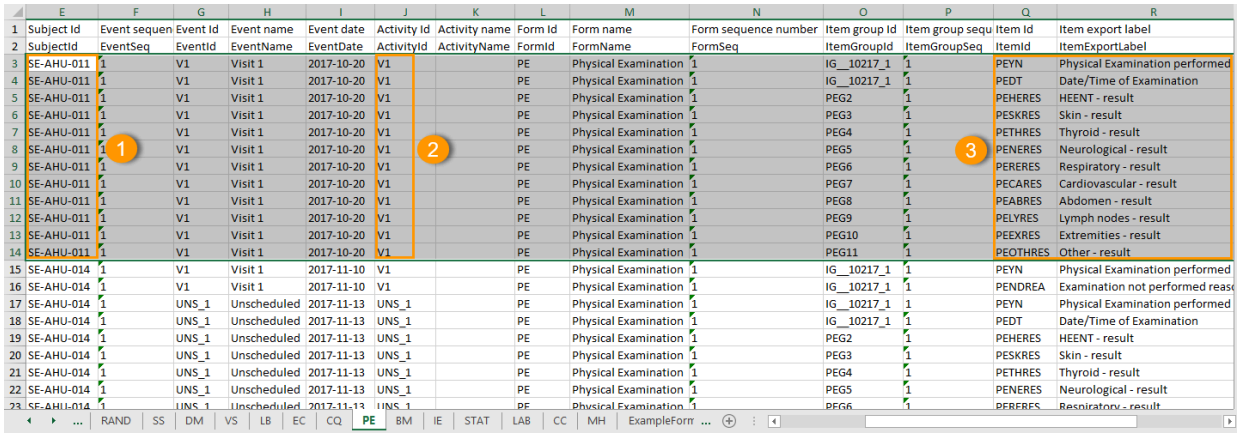
README | DM | SS | VS | RAND | CQ | PE | EC | BM | LB | IE | STAT

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).



	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	Subject Id	Event sequen	Event Id	Event name	Event date	Activity Id	Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequ	Item Id	Item export label
2	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId	ItemExportLabel
3	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG__10217_1	1	PEYN	Physical Examination performed
4	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG__10217_1	1	PEDT	Date/Time of Examination
5	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
6	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
7	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
8	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
9	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result
10	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG7	1	PECARES	Cardiovascular - result
11	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG8	1	PEABRES	Abdomen - result
12	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG9	1	PELYRES	Lymph nodes - result
13	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG10	1	PEEXRES	Extremities - result
14	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG11	1	PEOTHRES	Other - result
15	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG__10217_1	1	PEYN	Physical Examination performed
16	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG__10217_1	1	PENDREA	Examination not performed reas
17	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG__10217_1	1	PEYN	Physical Examination performed
18	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG__10217_1	1	PEDT	Date/Time of Examination
19	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
20	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
21	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
22	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
23	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result

RAND | SS | DM | VS | LB | EC | CQ | PE | BM | IE | STAT | LAB | CC | MH | ExampleForm

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

5.3.1 Include history

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

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

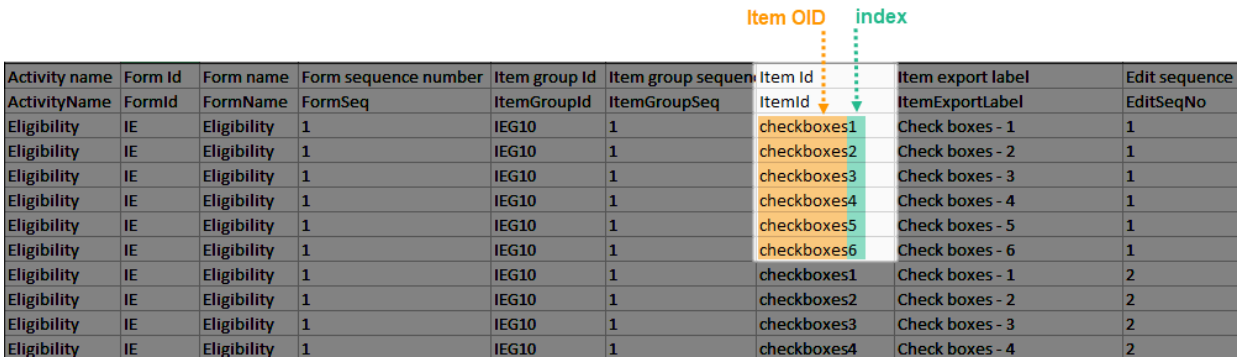
- **Edit sequence number** - a counter for each change per item.
- **Edit reason** - reason for change (initial or given reason at data edit). The edit reasons are the following:
  - Initial data entry
  - Function execution
  - Transcription error
  - Confirmed as missing!
  - Automatically updated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

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

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

5.3.2 Checkboxes

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



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

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

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

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

5.3.3 Reference ranges

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

---

6 Form link items in the export output

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

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

6.1 One row per activity

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

In the example below:

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

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

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

6.3 One row per subject

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

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

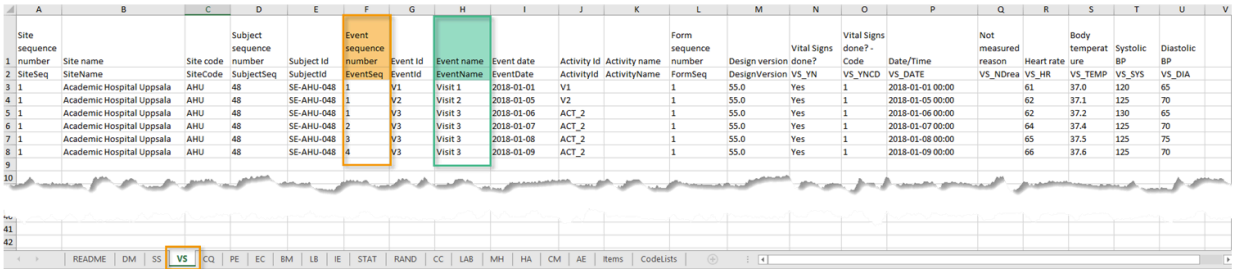
There are also two header rows in the output:

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

7 Recurring events in the export output

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

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



Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Vital Signs done?	Vital Signs done? - Code	Date/Time	Not measured reason	Heart rate	Body temperature	Systolic BP	Diastolic BP
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	VS_YN	VS_YNCD	VS_DATE	VS_NDrea	VS_HR	VS_TEMP	VS_SYS	VS_DIA
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V1	Visit 1	2018-01-01	V1		1	55.0	Yes	1	2018-01-01 00:00		61	37.0	120	65
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V2	Visit 2	2018-01-05	V2		1	55.0	Yes	1	2018-01-05 00:00		62	37.1	125	70
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V3	Visit 3	2018-01-06	ACT_2		1	55.0	Yes	1	2018-01-06 00:00		62	37.2	130	65
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	2	V3	Visit 3	2018-01-07	ACT_2		1	55.0	Yes	1	2018-01-07 00:00		64	37.4	125	70
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	3	V3	Visit 3	2018-01-08	ACT_2		1	55.0	Yes	1	2018-01-08 00:00		65	37.5	125	75
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	4	V3	Visit 3	2018-01-09	ACT_2		1	55.0	Yes	1	2018-01-09 00:00		66	37.6	125	70

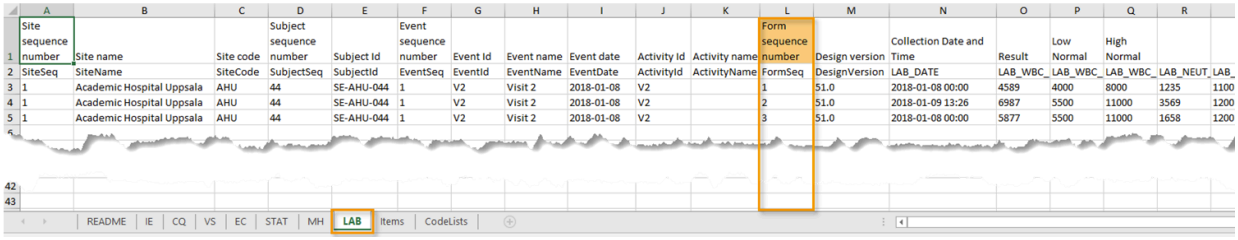
README | DM | SS | VS | CQ | PE | EC | BM | LB | IE | STAT | RAND | CC | LAB | MH | HA | CM | AE | Items | CodeLists

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

8 Repeating forms in the export output

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

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



Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Collection Date and Time	Result	Low Normal	High Normal		
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	LAB_DATE	LAB_WBC_	LAB_WBC_	LAB_WBC_	LAB_NEUT_	LAB_
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		1	51.0	2018-01-08 00:00	4589	4000	8000	1235	1100
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		2	51.0	2018-01-09 13:26	6987	5500	11000	3569	1200
1	Academic Hospital Uppsala	AHU	44	SE-AHU-044	1	V2	Visit 2	2018-01-08	V2		3	51.0	2018-01-08 00:00	5877	5500	11000	1658	1200

README | IE | CQ | VS | EC | STAT | MH | LAB | Items | CodeLists

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

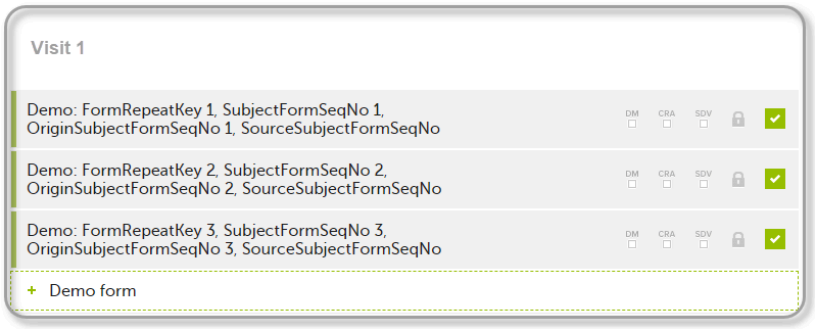
The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

- 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.

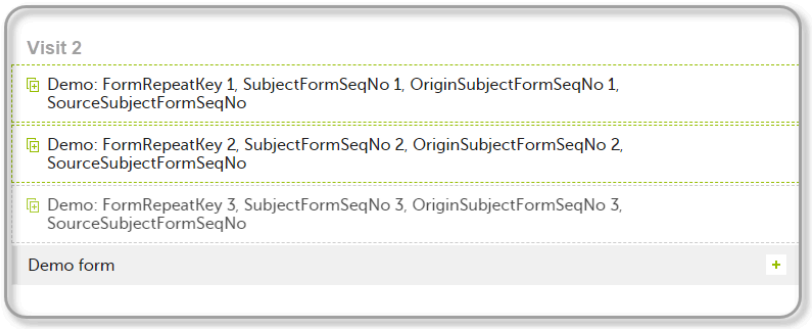
The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

We perform the following actions in Viedoc Clinic:

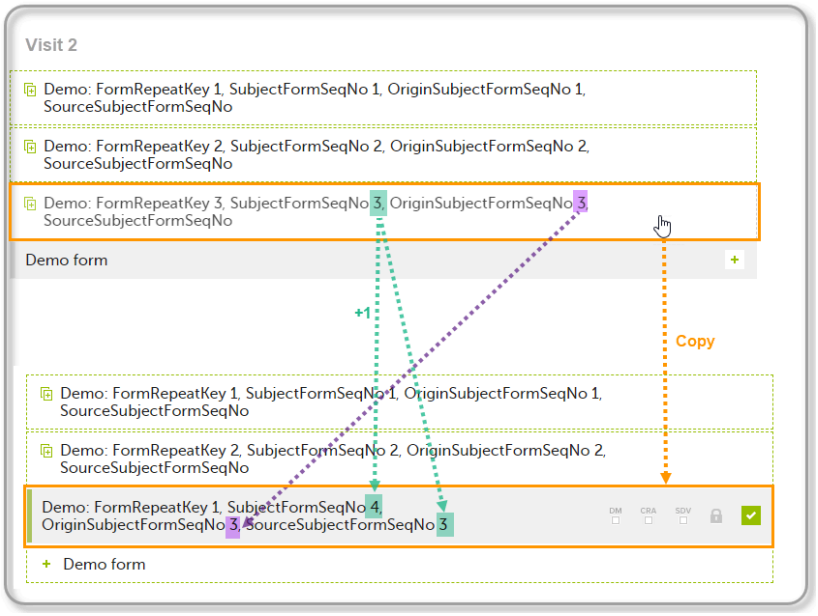
1 Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:



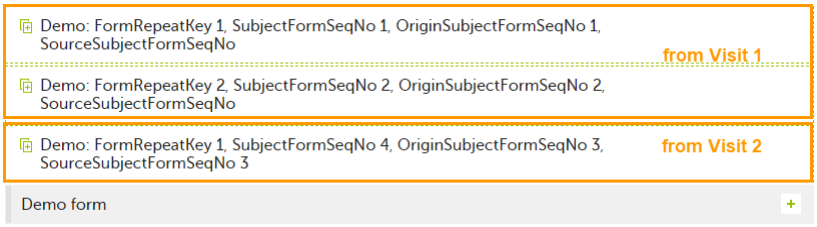
2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:



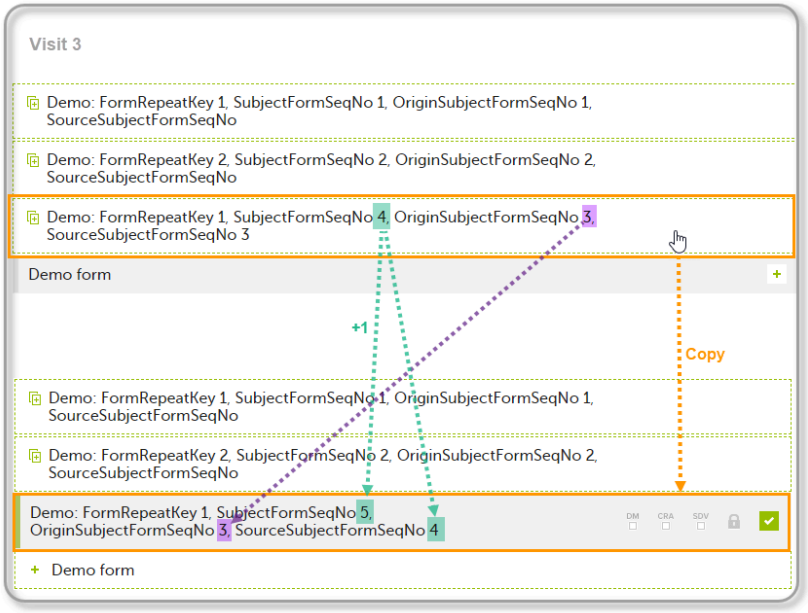
3 Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



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

Published by Viedoc System 2022-02-10

1. Introduction
2. Output file(s)
3. PDF file structure/content
    3.1 First page
    3.2 Site summary page
    3.3 Subject summary page
    3.4 Event summary page
        3.4.1 The sort order of the forms

1 Introduction

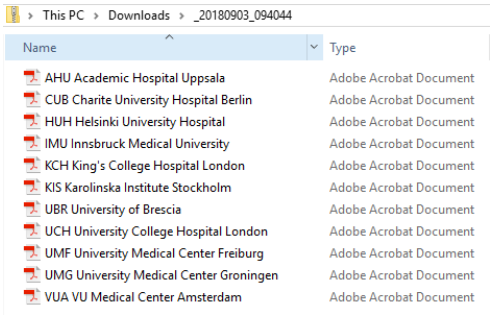
When choosing **PDF** as output format, you have the following options:

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

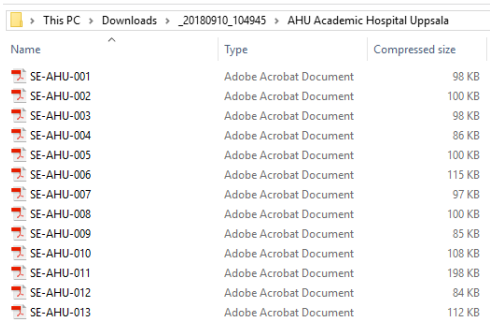
2 Output file(s)

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

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

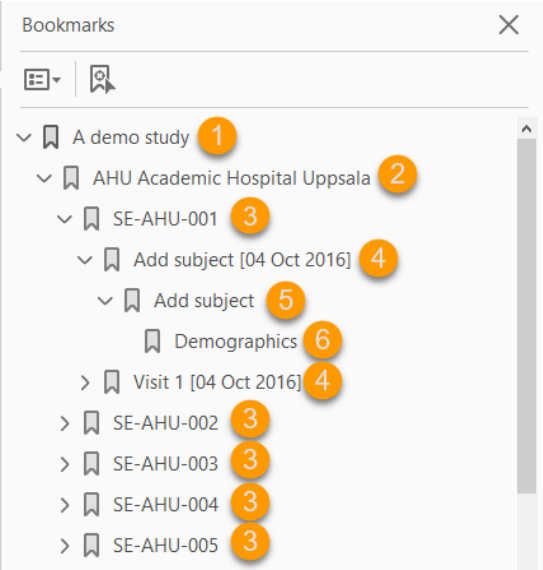


- For the **FDA submission format (eCTD)**, there is one folder for each site, and each folder contains one separate PDF file for each subject (file name is the same as the subject ID):



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:

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:

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.

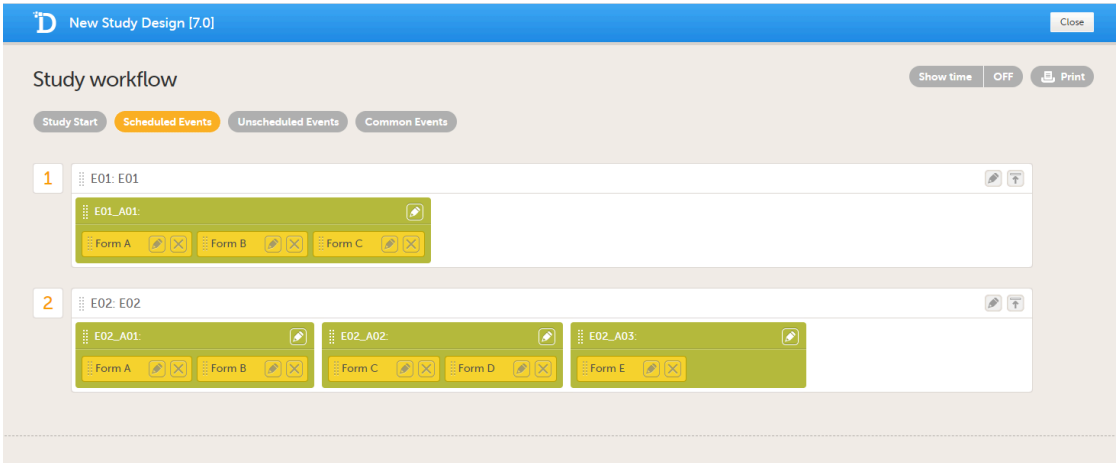
3.4.1 The sort order of the forms

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 ODM export

Published by Viedoc System 2020-06-04

1. Introduction
2. Association
    2.1 Annotation
        2.1.1 Comment
        2.1.2 "CL_ANNOTATION_TYPE"
        2.1.3 "CL_QRY_STATE"
        2.1.4 "CL_QRY_ITEM_SEQ_NO"
        2.1.5 v4:AuditRecord
3. Sorting the entries for a query

1 Introduction

To include the query information in the exported file, you need to select **Queries** under **Type of data** in the Data Export page.

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

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

This lesson describes how and where to find the query related information in the ODM export.

2 `Association`

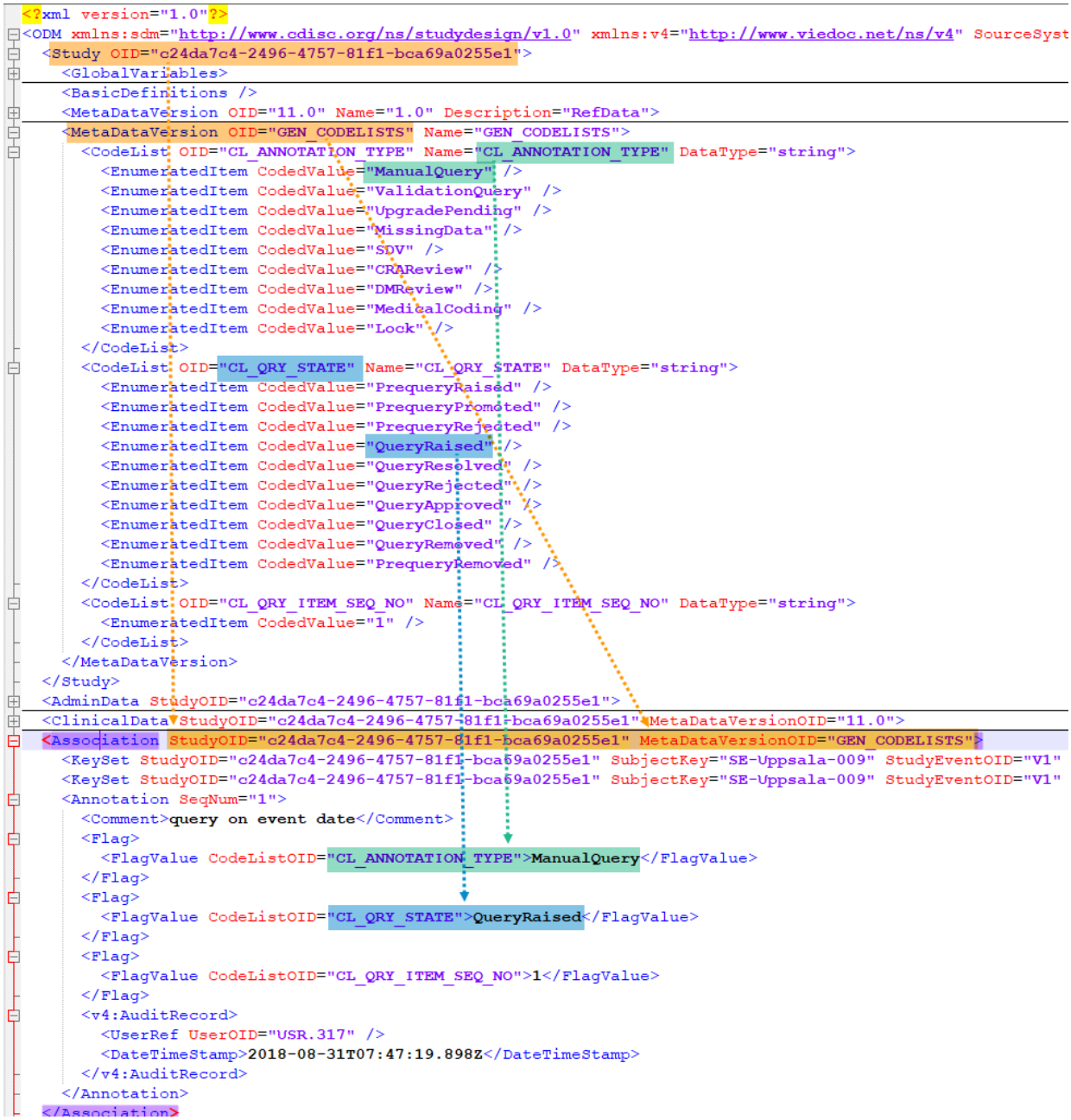
In the ODM export output file, the queries are stored under the `Association` tag.

As the query history is always included in the ODM export, there is an `Association` entry for each query state (for example if there is one query that has been through 3 different states namely raised, resolved and approved, there will be 3 different `Association` entries).

Note! All association elements are sorted by the AuditRecord datetime stamp.

Each `Association` links an item (identified by the `KeySet` , see the description below) to a set of properties related to a specific query wrapped under the `Annotation` tag (see detailed description below).

The image illustrates an example of an ODM export output, with the information within the `Study` tag at the top of the image and a query information under the `Association` tag at the bottom of the image:



For each `Association` entry, the following information is provided:

- The `StudyOID` and the `MetaDataVersionOID` indicate where the respective information is defined.
- The `KeySet` is generally used to identify the start and end of the annotated "link". For queries, both key sets are identical, as they identify the same item, namely the item the respective query corresponds to. It contains the following:
  - `StudyOID`
  - `SubjectKey`
  - `StudyEventOID`
  - `StudyEventRepeatKey`
  - `FormOID`
  - `FormRepeatKey`
  - `ItemGroupOID` - applicable only for queries on item level.
  - `ItemOID` - applicable only for queries on item level.

2.1 `Annotation`

The `Annotation` tag wraps the specific information of the respective query, as described below. Since there is only one `Annotation` within an `Association`, the `SeqNum` is always "1".

2.1.1 `Comment`

The `Comment` value depends on the query state and is set as follows:

- If the query state is `QueryRaised` or `PrequeryRaised`, the query text is specified here.

- If the query state is `QueryRejected` or `QueryResolved`, the resolution text is specified here, as in our example "*I am confirming the data*".

- No comment element is present for other cases than the ones mentioned above.

2.1.2 `"CL_ANNOTATION_TYPE"`

`CodeListOID="CL_ANNOTATION_TYPE"` indicates the annotation type, for example `"ManualQuery"`:

All the possible annotation types can be found under the `Study` tag, under the respective `StudyOID` and `MetaDataVersionOID`, respectively:

- `"ManualQuery"`
- `"ValidationQuery"`
- `"UpgradePending"`
- `"MissingData"`
- `"SDV"`
- `"CRAReview"`
- `"DMReview"`
- `"MedicalCoding"`
- `"Lock"`

Of all the above, only the following refer to queries:

- `"ManualQuery"`
- `"ValidationQuery"`
- `"UpgradePending"`
- `"MissingData"`
  Note! The `"MissingData"` annotation type is used both for unconfirmed missing data and missing data, there is no distinction between those in the ODM export.

2.1.3 `"CL_QRY_STATE"`

`CodeListOID="CL_QRY_STATE"` indicates the query state, for example `"QueryRaised`.

All the possible query states can be found under the `Study` tag, under the respective `StudyOID` and `MetaDataVersionOID`, respectively:

1. `"PrequeryRaised"`
2. `"PrequeryPromoted"`
3. `"PrequeryRejected"`
4. `"QueryRaised"`
5. `"QueryResolved"`
6. `"QueryRejected"`
7. `"QueryApproved"`
8. `"QueryClosed"`
9. `"QueryRemoved"`
10. `"PrequeryRemoved"`

For more details about the query and pre-query states, see Queries overview.

2.1.4 `"CL_QRY_ITEM_SEQ_NO"`

`CodeListOID="CL_QRY_ITEM_SEQ_NO"` indicates the sequence number of the respective query for the linked item. This is used to identify the query, meaning that all the `Annotation` entries corresponding to different states of the same query, will have the same value of `CodeListOID="CL_QRY_ITEM_SEQ_NO"` and same `KeySet`.

2.1.5 `v4:AuditRecord`

`v4:AuditRecord` contains the audit record for the respective annotation.

---

3 Sorting the entries for a query

Since the same query can go through many query states, there can be many `Annotations` with the same value of `CodeListOID="CL_QRY_ITEM_SEQ_NO"` and same `KeySet`. In order to get the latest entry for the same query, you can sort as follows:

1. First by date and time of the audit record.

2. For the entries having the same date and time stamp, order by the value of the `CodeListOID="CL_QRY_STATE"` , as listed above.

Queries in Excel export

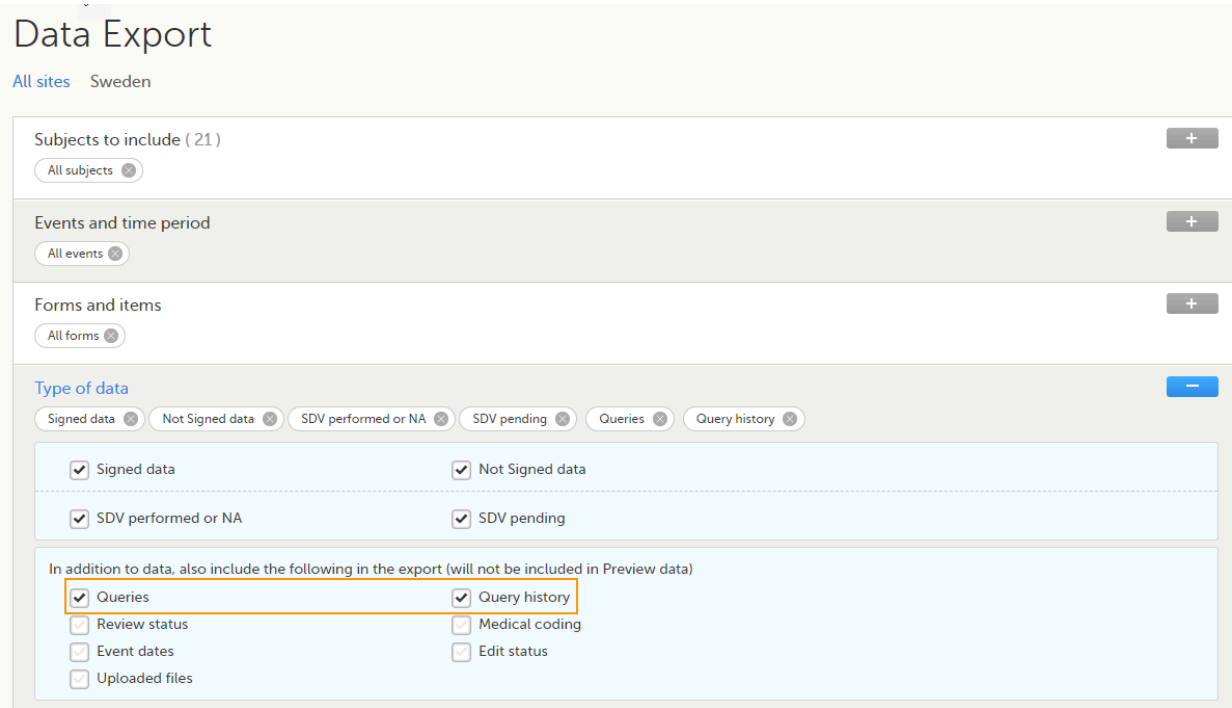
Queries in Excel export

Published by Viedoc System 2024-10-10

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.



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

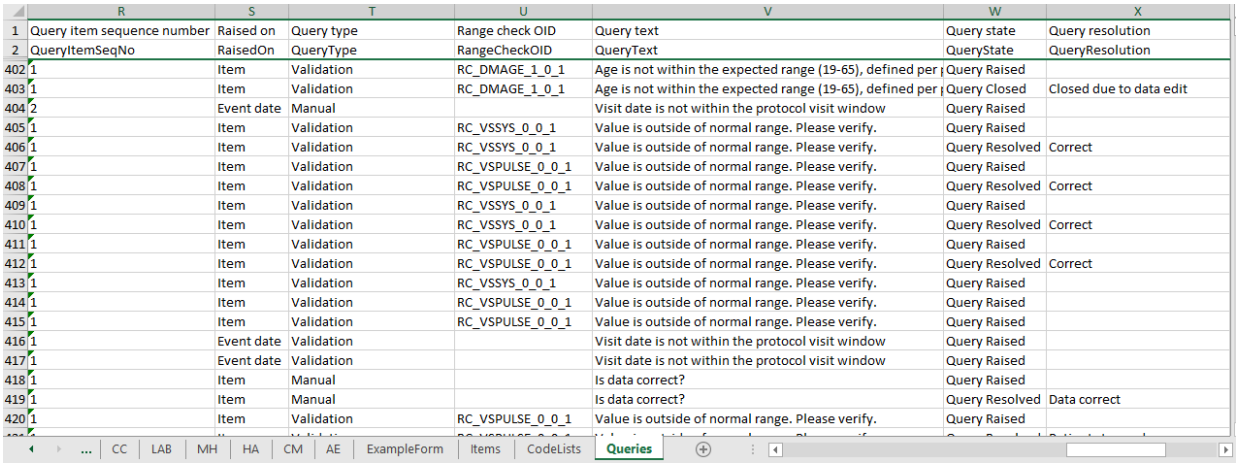
- Without **Query history** - there is one row for each query, providing information on the current state of the query.
- With **Query history** - there is one row for each change in a query state, that is, there can be many rows for one and the same query.

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	

... | 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: ▪ *Manual* - for manually raised queries. ▪ *Missing data* - data confirmed as missing ▪ *Pending form upgrade* - forms pending upgrade as a result of applying a revision of the study design ▪ *Unconfirmed missing data* ▪ *Validation* - for automatically raised queries, as a result of validation.
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.
User role	The role of the user who performed the action on the query
Query raised by role	The role of the user who raised the query

Medical coding in ODM export

Published by Viedoc System 2020-06-04

1. Introduction
2. Codelists
    2.1 Dictionary type
    2.2 Dictionary instance
    2.3 Dictionary properties
    2.4 Coding scopes
3. Medical coding items
    3.5 Association
    3.6 KeySet
    3.7 Annotation
        3.7.1 Flags
        3.7.2 AuditRecord

1 Introduction

This lesson describes how the medical coding information is structured within an Operational Data Model (ODM) file exported from Viedoc.

For general details about data export, see Exporting data.

2 Codelists

2.1 Dictionary type

There is one `CL_DICT_TYPE` codelist that contains one entry for each dictionary type present in the exported data:

```
<CodeList OID="CL_DICT_TYPE" Name="CL_DICT_TYPE" DataType="string">
  <EnumeratedItem CodedValue="MEDDRA" />
  <EnumeratedItem CodedValue="WHODRUG" />
</CodeList>
```

2.2 Dictionary instance

There is one codelist for each dictionary instance present in the exported data, which contains one `<ExternalCodeList>` element pointing to a specific dictionary version, that specifies:

- Dictionary type - `Dictionary`
- Version description - `Version`
- Source hash - `ref`

```
<CodeList OID="CL_MEDDRA_VERSION_19.0" Name="CL_MEDDRA_VERSION_19.0" DataType="string">
  <ExternalCodeList Dictionary="MEDDRA" Version="Version 19.0" ref="2A04E4B5D79A838E64DF1A18FF23400A" />
</CodeList>
<CodeList OID="CL_WHODRUG_WHO_DDE_C3_SEPTEMBER_1_2017" Name="CL_WHODRUG_WHO_DDE_C3_SEPTEMBER_1_2017" DataType="string">
  <ExternalCodeList Dictionary="WHODRUG" Version="WHO DDE C3 September 1, 2017" ref="A43B613AD1CCBFE9CE8E324FF0037398" />
</CodeList>
```

2.3 Dictionary properties

There is one codelist with dictionary properties for each dictionary present in the exported data. Each such codelist contains items for each property the dictionary defines:

```
<CodeList OID="CL_MEDDRA_PROP" Name="CL_MEDDRA_PROP" DataType="string">
  <EnumeratedItem CodedValue="soc_code" />
  <EnumeratedItem CodedValue="soc_name" />
  <EnumeratedItem CodedValue="soc_abbrev" />
  <EnumeratedItem CodedValue="hlgt_code" />
  <EnumeratedItem CodedValue="hlgt_name" />
  <EnumeratedItem CodedValue="hlt_code" />
  <EnumeratedItem CodedValue="hlt_name" />
  <EnumeratedItem CodedValue="pt_code" />
  <EnumeratedItem CodedValue="pt_name" />
  <EnumeratedItem CodedValue="pt_soc_code" />
  <EnumeratedItem CodedValue="llt_code" />
  <EnumeratedItem CodedValue="llt_name" />
  <EnumeratedItem CodedValue="llt_currency" />
</CodeList>
```

2.4 Coding scopes

There is one codelist for each dictionary coding scope present in the exported data, specifying:

- Coding scope ID
- Coding scope name

```
<CodeList OID="CL_CODING_SCOPE" Name="CL_CODING_SCOPE" DataType="string">
  <CodeListItem CodedValue="253">
    <Decode>
      <TranslatedText xml:lang="en">Adverse events</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="381">
    <Decode>
      <TranslatedText xml:lang="en">Concomitant medication</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
```

---

3 Medical coding items

3.1 `Association`

For each medical coding item, there is one `<Association>` entry.

Each `Association` links an item (identified by the `KeySet` , see the description below) to a set of properties related to a specific `Annotation` (see detailed description below).

3.2 `KeySet`

The `KeySet` is generally used to identify the start and end of the annotated "link". In this case, both key sets are the same, as they identify the same entity, namely the one the respective action (defined under the `Annotation`) corresponds to.

The `KeySet` specifies the following attributes:

- `StudyOID`
- `SubjectKey`
- `StudyEventOID`
- `StudyEventRepeatKey`
- Depending on the medical coding scope (Event/Activity/Form/Item group/Item), the following may be specified:
  - `FormOID` - not applicable for event scope
  - `FormRepeatKey` - not applicable for event scope
  - `ItemGroupOID` - applicable for item group and item scope
  - `ItemOID` - applicable only for item scope

3.3 Annotation

The `Annotation` consists of a set of `<Flag>` elements, and an audit record if the export was set to include the Viedoc extensions.

3.3.1 Flags

```
<Annotation SeqNum="1">
  <Flag>
    <FlagValue CodeListOID="CL_ANNOTATION_TYPE">MedicalCoding</FlagValue>
  </Flag>
  <Flag>
    <FlagValue CodeListOID="CL_DICT_TYPE">MedDRA</FlagValue>
  </Flag>
  <Flag>
    <FlagValue CodeListOID="CL_CODING_SCOPE">253</FlagValue>
  </Flag>
  <Flag>
    <FlagValue CodeListOID="CL_CODE_SEQ_NO">1</FlagValue>
  </Flag>
  <Flag>
    <FlagValue CodeListOID="CL_MEDDRA_VERSION_19.0">10013993</FlagValue>
    <FlagType CodeListOID="CL_MEDDRA_PROP">soc_code</FlagType>
  </Flag>
  <Flag>
    <FlagValue CodeListOID="CL_MEDDRA_VERSION_19.0">Ear and labyrinth disorders</FlagValue>
    <FlagType CodeListOID="CL_MEDDRA_PROP">soc_name</FlagType>
  </Flag>
  <Flag>
    <FlagValue CodeListOID="CL_MEDDRA_VERSION_19.0">Ear</FlagValue>
    <FlagType CodeListOID="CL_MEDDRA_PROP">soc_abbrev</FlagType>
  </Flag>
```

1. One flag element for the annotation type, with a `<FlagValue>` that is always `MedicalCoding` in this case.

2. One flag element for the dictionary type, with a `<FlagValue>` set to one of the `CL_DICT_TYPE` items.

3. One flag for the medical coding scope, with a `<FlagValue>` set to one of the `CL_CODING_SCOPE` items.

4. One flag element for the code sequence number, with a set to one of the `CL_CODE_SEQ_NO` items.

5. One flag element for each dictionary property set, with a `<FlagValue>` set to the dictionary property codelist (for example `CL_MEDDRA_PROP`) and a `<FlagValue>` set to the property value.

3.3.2 AuditRecord

The `<v4:AuditRecord>` is a Viedoc extension and is included in the output file only if the option to **Include extensions** was selected at export time.

It contains information on the user ID and the date/time stamp.

In the example image below the user ID = 304:

```
<v4:AuditRecord>
  <UserRef UserOID="USR.304" />
  <DateTimeStamp>2018-08-29T11:43:30Z</DateTimeStamp>
</v4:AuditRecord>
```

Medical coding in Excel export

Medical coding in Excel export

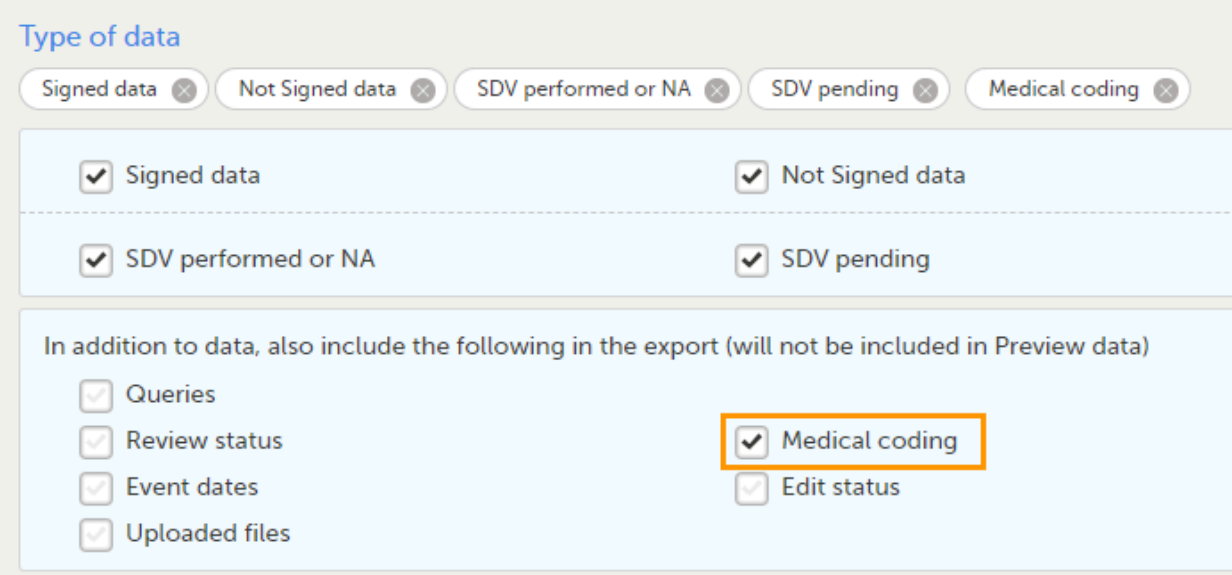
Published by Viedoc System 2024-06-26

1. Introduction
2. Medical coding information in Excel
3. An example - WHODrug in Excel exported file
   3.1 When selecting Drug
   3.2 When selecting Preferred name

1 Introduction

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

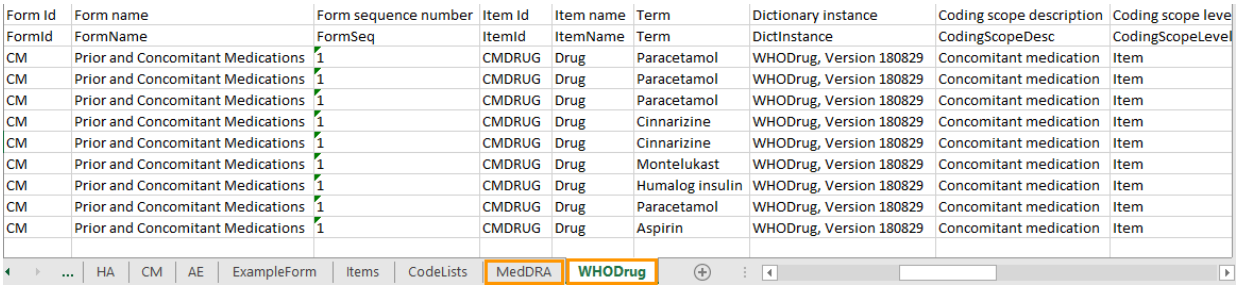
To include the medical coding information in the exported file, you need to select **Medical coding** under **Type of data** in the Data Export page:



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

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.
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` .

Column name	Description
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).
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
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
Version	The dictionary version.
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
Dictionary-specific information	

Column name	Description		
WHODrug: ▪ DrugCode ▪ DrugName ▪ NameSpecifier ▪ OldForm ▪ Ingredients ▪ ATCCodes ▪ CountryCode ▪ CountryName ▪ MAH (MAH) ▪ PharmForm ▪ Strength ▪ MedProdId ▪ Generic ▪ PreferredCode ▪ PreferredName ▪ Name	**MedDRA**: ▪ soc_code ▪ soc_name ▪ soc_abbrev ▪ hlgt_code ▪ hlgt_name ▪ hlt_code ▪ hlt_name ▪ pt_code ▪ pt_name ▪ pt_soc_code ▪ llt_code ▪ llt_name ▪ llt_currency	**ATC without DDD**: ▪ L1 code ▪ L1 name ▪ L2 code ▪ L2 name ▪ L3 code ▪ L3 name ▪ L4 code ▪ L4 name ▪ L5 code ▪ L5 name	**IDF**: ▪ 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 ▪ 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

Column name	Description		
			▪ L6 使用区分1 ▪ L6 使用区分2 ▪ L6 基準名コード ▪ 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
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	The date and time when the coding was performed		
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		

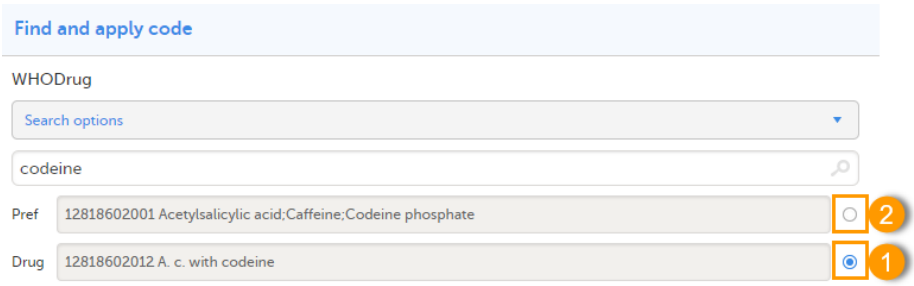
3 An example - WHODrug in Excel exported file

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)

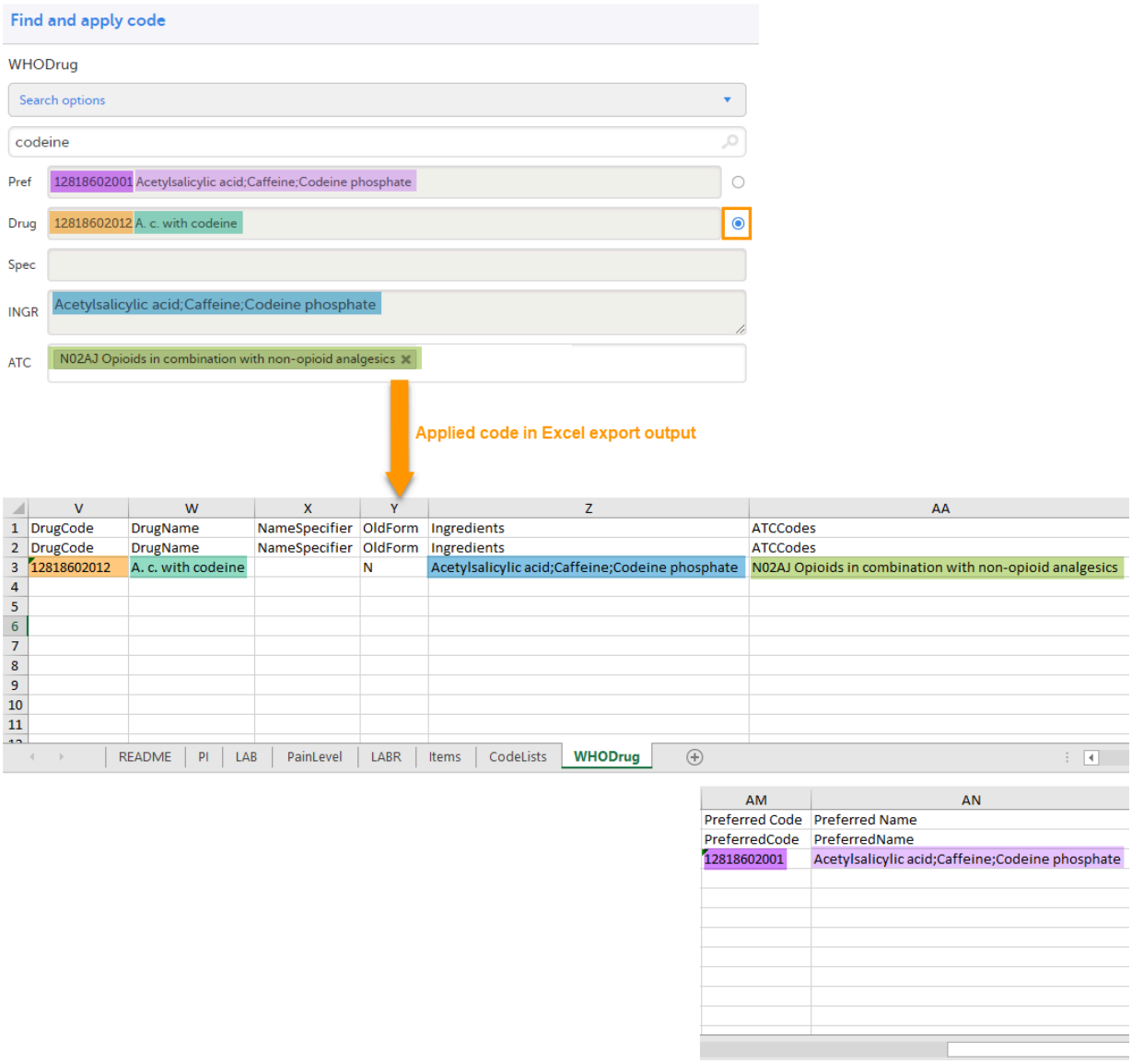
2. **Pref**erred name



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.

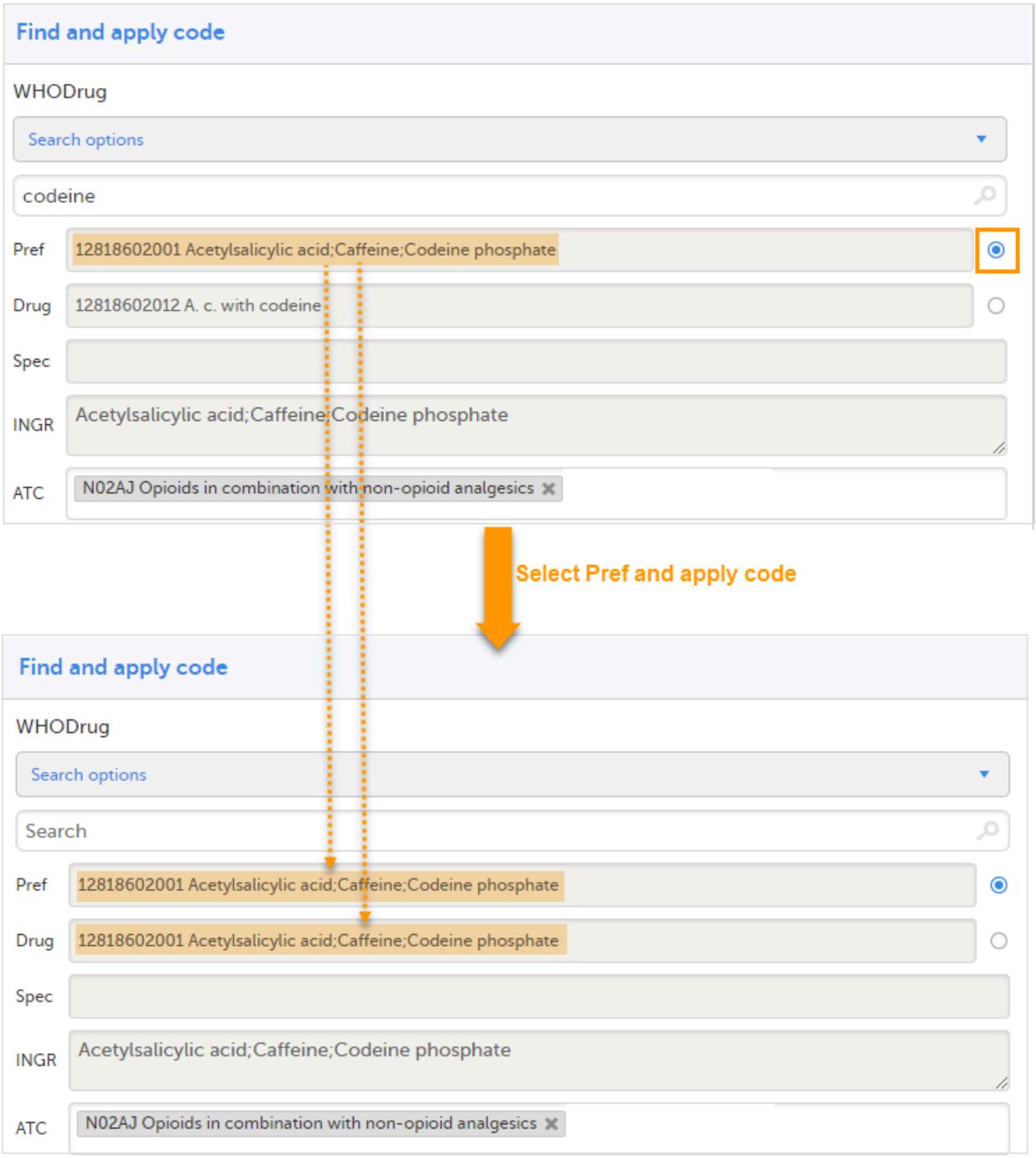
When **Drug** is selected, the **Preferred code** and **Preferred name** come out in the export as well, in the last columns, as illustrated in the image.

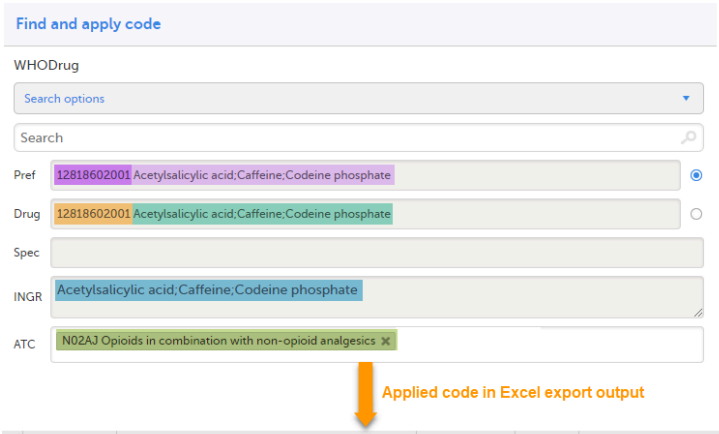


3.2 When selecting Preferred name

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



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 ODM export

Review status in ODM export

Published by Viedoc System 2023-06-21

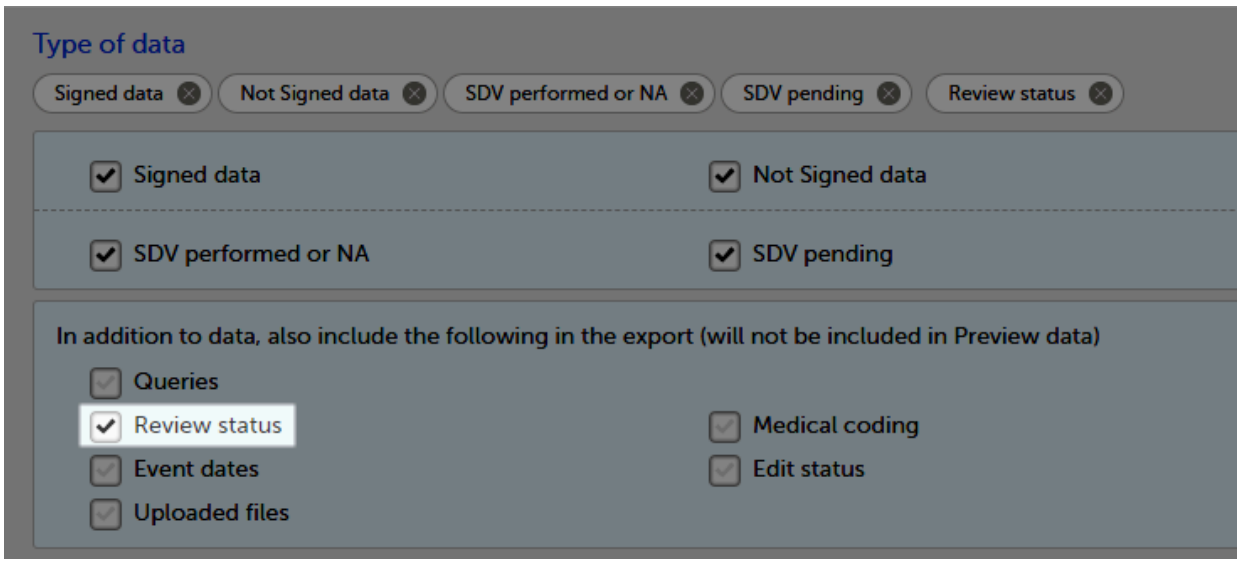
1. Introduction
2. Codelists
    2.1 Review type
    2.2 Review state
3. Review actions
    3.3 Association
    3.4 KeySet
    3.5 Annotation
        3.5.1 Flags
        3.5.2 AuditRecord

1 Introduction

This lesson describes how the review status information is structured within an Operational Data Model (ODM) file exported from Viedoc.

For general details about data export, see Exporting data.

To include the review status in the export, you need to select the **Review status** under **Type of data** in the Data Export page:



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

Note! Source Data Verification (SDV) status is only exported on study event and item level. SDV on form level is excluded from the export.

2 Codelists

2.1 Review type

The following annotation types are relevant for the review status and are listed in the `CL_ANNOTATION_TYPE` codelist:

- SDV
- CRAReview
- DMReview
- Lock
- Signature

```
<MetaDataVersion OID="GEN_CODELISTS" Name="GEN_CODELISTS">
  <CodeList OID="CL_ANNOTATION_TYPE" Name="CL_ANNOTATION_TYPE" DataType="string">
    <EnumeratedItem CodedValue="ManualQuery" />
    <EnumeratedItem CodedValue="ValidationQuery" />
    <EnumeratedItem CodedValue="UpgradePending" />
    <EnumeratedItem CodedValue="MissingData" />
    <EnumeratedItem CodedValue="SDV" />
    <EnumeratedItem CodedValue="CRAReview" />
    <EnumeratedItem CodedValue="DMReview" />
    <EnumeratedItem CodedValue="MedicalCoding" />
    <EnumeratedItem CodedValue="Lock" />
  </CodeList>
```

2.2 Review state

There is a `CL_REVIEW_STATE` codelist that indicates the review state, which is always `Checked` for the annotation types mentioned above. If the respective review was not performed in Viedoc, there is simply no entry for it in the ODM file.

```
  <CodeList OID="CL_REVIEW_STATE" Name="CL_REVIEW_STATE" DataType="string">
    <EnumeratedItem CodedValue="Checked" />
  </CodeList>
```

---

3 Review actions

3.1 `Association`

For each review action, there is one `<Association>` element.

Each `Association` links an item (identified by the `KeySet` , see the description below) to a set of properties related to a specific `Annotation` (see detailed description below).

3.2 `KeySet`

The `KeySet` is generally used to identify the start and end of the annotated "link". In this case, both key sets are the same, as they identify the same entity, namely the one the respective action (defined under the `Annotation`) corresponds to.

- `StudyOID`
- `SubjectKey`
- `StudyEventOID`
- `StudyEventRepeatKey`
- `FormOID`
- `FormRepeatKey`
- `ItemGroupOID`
- `ItemOID`

3.3 `Annotation`

The `Annotation` consists of a set of `<Flag>` elements, and an audit record if the export was set to include the Viedoc extensions.

3.3.1 Flags

```
<Annotation SeqNum="1">
  <Flag>
1   <FlagValue CodeListOID="CL_ANNOTATION_TYPE">DMReview</FlagValue>
  </Flag>
  <Flag>
2   <FlagValue CodeListOID="CL_REVIEW_STATE">Checked</FlagValue>
  </Flag>
  <v4:AuditRecord>
    <UserRef UserOID="USR.294" />
    <DateTimeStamp>2017-01-02T08:30:56Z</DateTimeStamp>
  </v4:AuditRecord>
</Annotation>
```

1. One flag element for the review type, with a `<FlagValue>` set to one of the `CL_ANNOTATION_TYPE` items.

2. One flag element for the review state, with a `<FlagValue>` set to one of the `CL_REVIEW_STATE` items.

3.3.2 AuditRecord

The `<v4:AuditRecord>` is a Viedoc extension and is included in the output file only if the option to **Include extensions** was selected at export time.

It contains information on the user ID and the date/time stamp.

In the example image below, the user ID = 294:

```
  <v4:AuditRecord>
    <UserRef UserOID="USR.294" />
    <DateTimeStamp>2017-01-02T08:31:03Z</DateTimeStamp>
  </v4:AuditRecord>
</Annotation>
```

Notes!

- The audit records for Viedoc Me actions have the `User OID="USR.0"`. This is applicable, for example, for the Lock action.
- The audit records for system actions have the `User OID="SYSTEM"`. This is applicable, for example, when the form is locked due to randomization.

Review status in Excel export

Review status in Excel export

Published by Viedoc System 2023-10-09

1. Review status
2. SDV

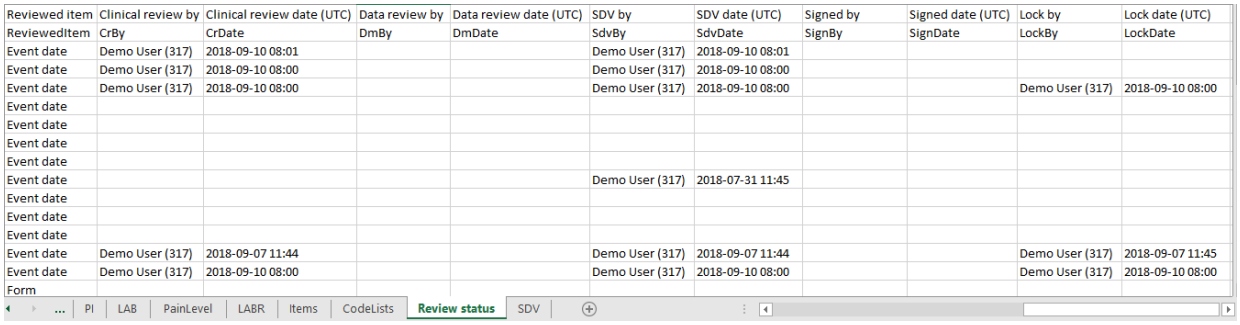
This lesson describes how the review status information is structured within an Excel file exported from Viedoc.

For general details about data export, see Exporting data.

1 Review status

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

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



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

... | PI | LAB | PainLevel | LABR | Items | CodeLists | Review status | SDV

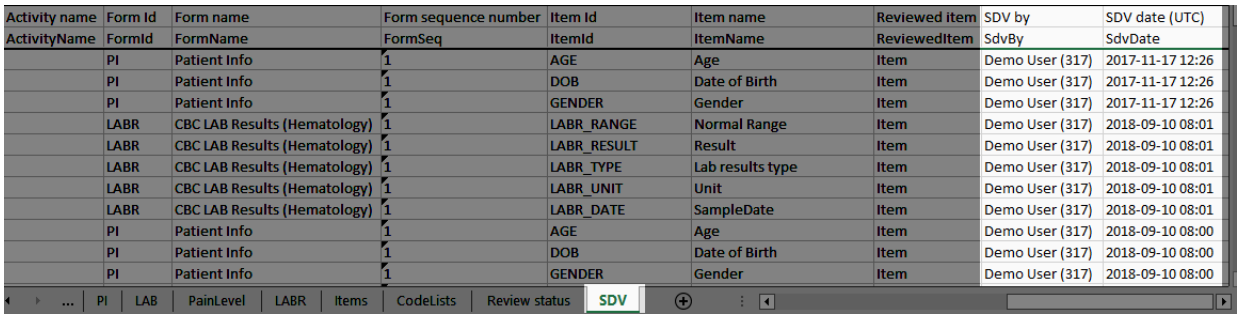
The first columns provide information for identifying the form that was reviewed, followed by the review information, as listed in the following table:

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.

Exporting for SAS

Exporting for SAS

Published by Viedoc System 2024-12-03

In Viedoc, it is possible to export data in a Statistical Analysis System (SAS) format, so that the data can be analyzed in SAS.

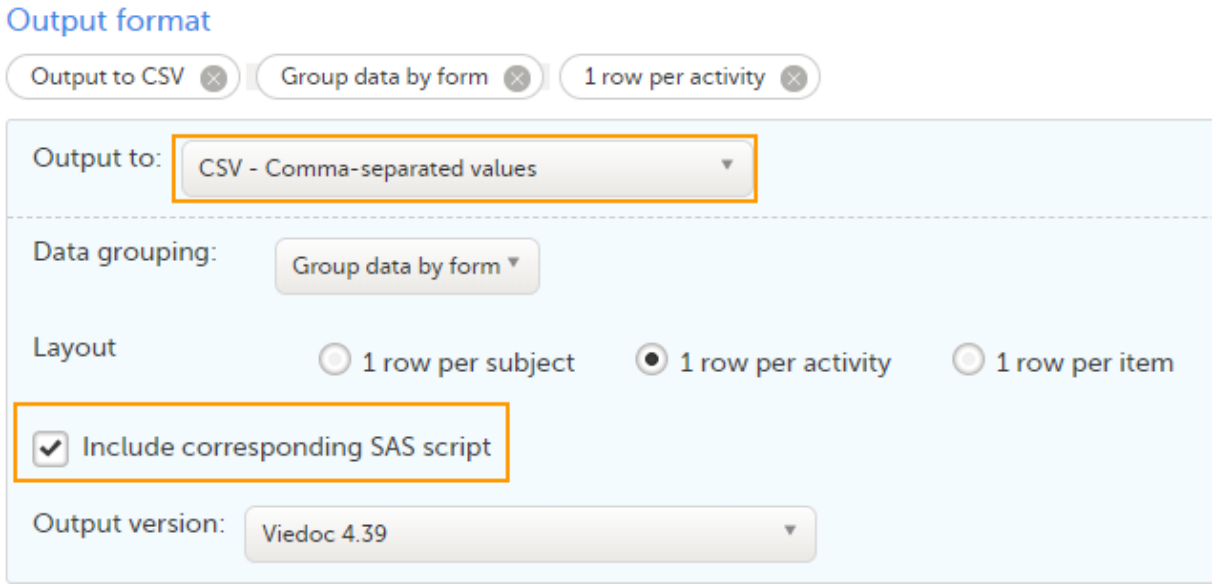
> Important! Only SAS in Unicode mode is supported.

To export data from Viedoc that is formatted for SAS, you have to make the following selections on the Data Export page, under **Output format**:

- In **Output to**, select **CSV - Comma-separated values**
- Select to **Include corresponding SAS script**

Notes!

- Linebreaks in paragraph text are converted to spaces when the output format is CSV.
- The option to Include corresponding SAS script is available only for **CSV** output, **Group data by form**, and **1 row per activity** layout.



The export output is a zip file, containing:

- A README text file - with general information about:
  - The Viedoc output version (for details see Exporting data).
  - The time zones used for date/time fields.
  - The meaning of the signature, only if the **Review status** was selected to be included in the export.
- One CSV file for (the generated data sets match the sheets of the equivalent Excel export):
  - Each form in the exported data.
  - **Items** - one Comma-Separated Values (CSV) file with general information about the items present in the exported data.
  - **CodeLists** - one CSV file with general information about the code list items (radio button/dropdown/checkbox) in the exported data.
- Two SAS files:
  - **_RunMe.sas** - this is the file to be run in SAS in order to import the data.

- **CSV2SAS.sas** - this is a generic file, not study specific, that is used by the **_RunMe.sas** file to convert the data to SAS format.

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

To import to SAS the data exported from Viedoc:

1. Export the data from Viedoc including the SAS script (the settings are described above).
2. Open SAS.
3. Run the **_RunMe.sas** file (see description above).

   The data types from the **Items** file and the **CodeLists** formats will be converted to the SAS formats.

Archiving a study

Archiving a study

Published by Viedoc System 2021-11-24

1. Introduction
    1.1 Prerequisite
2. Archiving the study

1 Introduction

When data collection at a study site has been confirmed and completed, each site should export and archive the study data and site-related documentation.

1.1 Prerequisite

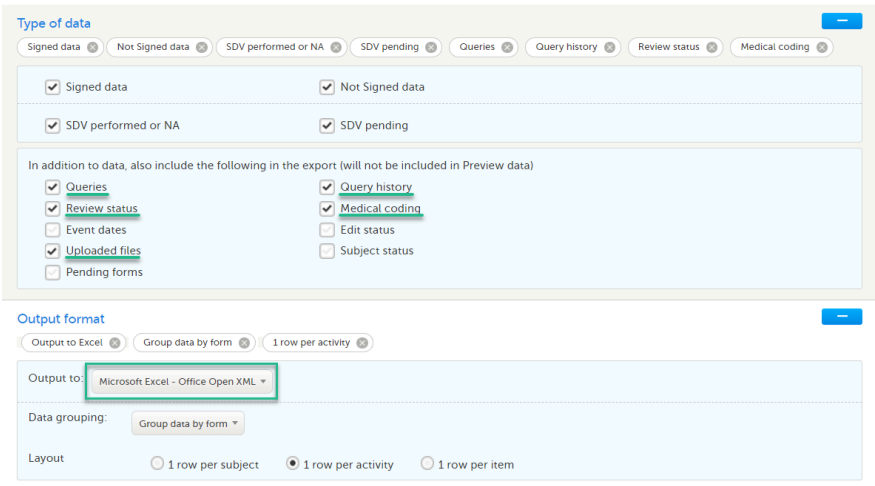
Site users must have the role permission to export data for the sites where the archiving should be performed. For more information, see the *Data export* lessons in Viedoc Clinic User Guide.

If Viedoc eTMF is used, see the following lesson eTMF-EMS repository.

2 Archiving the study

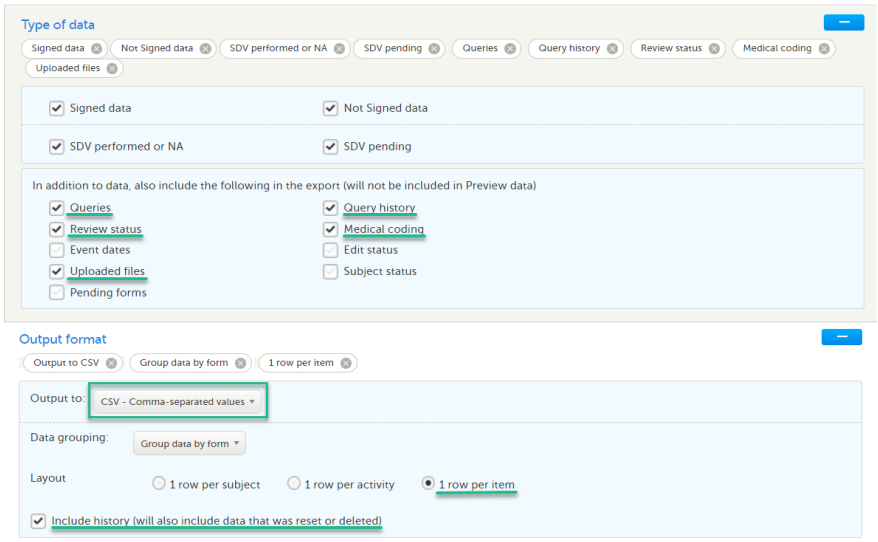
The following documentation is recommended to export when archiving a study at site. Export of data is still possible for locked studies.

- The user logs (available in PDF and Excel). For more information, see the *User logs* section in Study start page.
- The CRF data in all available formats (including all visits and forms). For each format, it is advisable to select the following:
    - Excel
        - Queries, Query history, Review status, Medical coding, Uploaded files

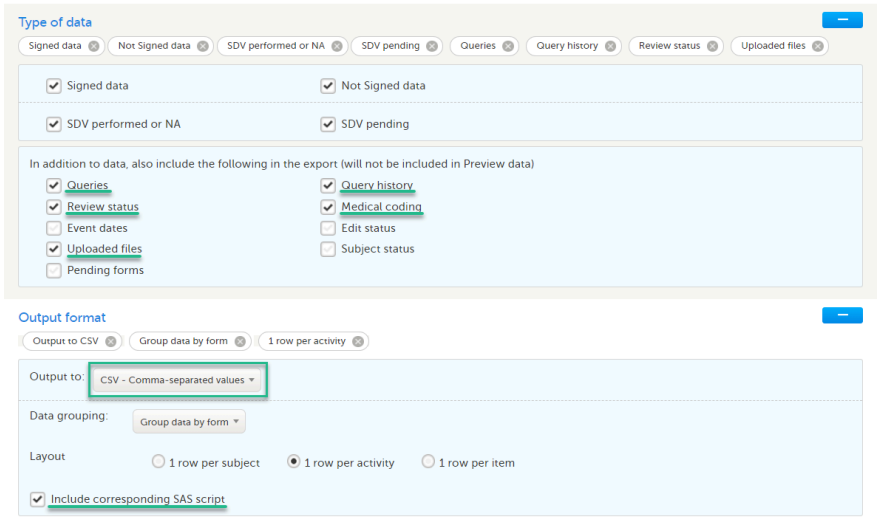


    - CSV
        - 1 row per item

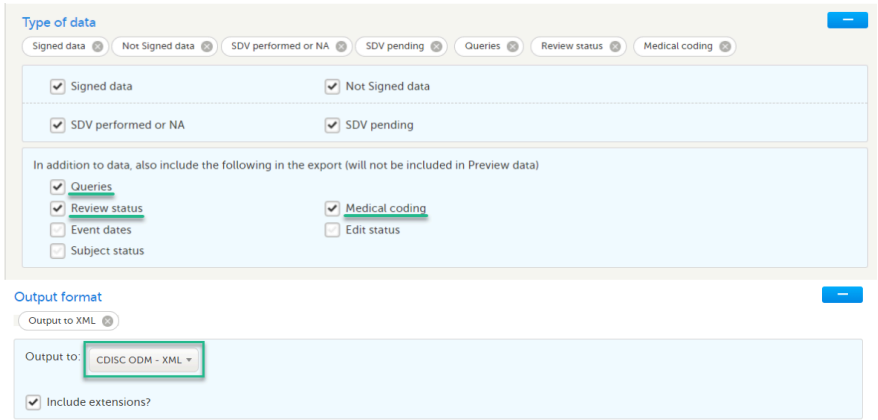
- Include history (will also include data that was reset or deleted)
- Queries, Query history, Review status, Medical coding, Uploaded files



- CSV
  - Include corresponding SAS script
  - Queries, Query history, Review status, Medical coding, Uploaded files

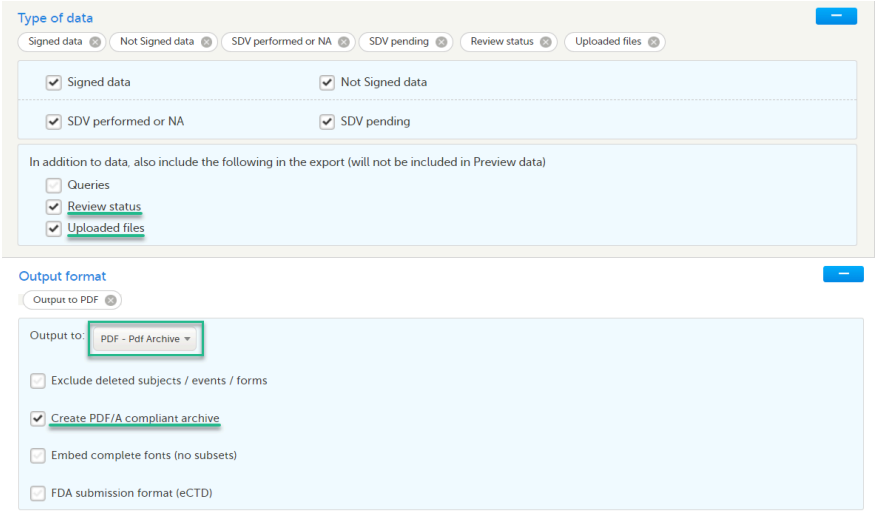


- ODM
  - Queries, Medical coding, Review status



- PDF
  - Create PDF/A compliant archive

- Review status, Uploaded files



The data export in Viedoc supports all file formats that are required for archiving and regulatory purposes, including these formats:

- Portable Document Format Archive (PDF/A) - an International Organization for Standardization (ISO)-standardized version of the PDF format, specialized for archiving and long-term preservation of electronic documents.
- Office Open Extensible Markup Language (XML) - a zipped, XML-based file format for spreadsheets (for example Excel), charts, presentations, and word processing documents.
- Statistical Analysis System (SAS) - a format used for statistical analysis in the SAS software suite. A SAS script to import CSV datasets into SAS can be included in the CSV export.
- Operational Data Model (ODM) - a vendor-neutral, platform-independent format for exchanging and archiving clinical research data, along with their associated metadata, administrative data, reference data, and audit information.

Medical coding

Published by Viedoc System 2025-02-18

1. Introduction
2. Viedoc Coder
    2.1 Overview
    2.2 What do the symbols and colors mean?
3. Finding and applying a medical code
    3.3 A use case for coding with the MedDRA dictionary
        3.3.1 Searching for a code
        3.3.2 Selecting a code
        3.3.3 Applying a code
    3.4 A use case for coding with the WHO Drug Dictionary
        3.4.4 Searching for a code
        3.4.5 Selecting a code
        3.4.6 Applying a code
4. Approving the medical coding
    4.5 Rejecting the medical coding
    4.6 Resetting the medical coding
5. Exporting the medical coding
6. Auto coding

1 Introduction

Viedoc Coder allows you to code data, such as Adverse Events, Medical History, and Concomitant Medications, in a standardized way. You can access Viedoc Coder on the landing page.

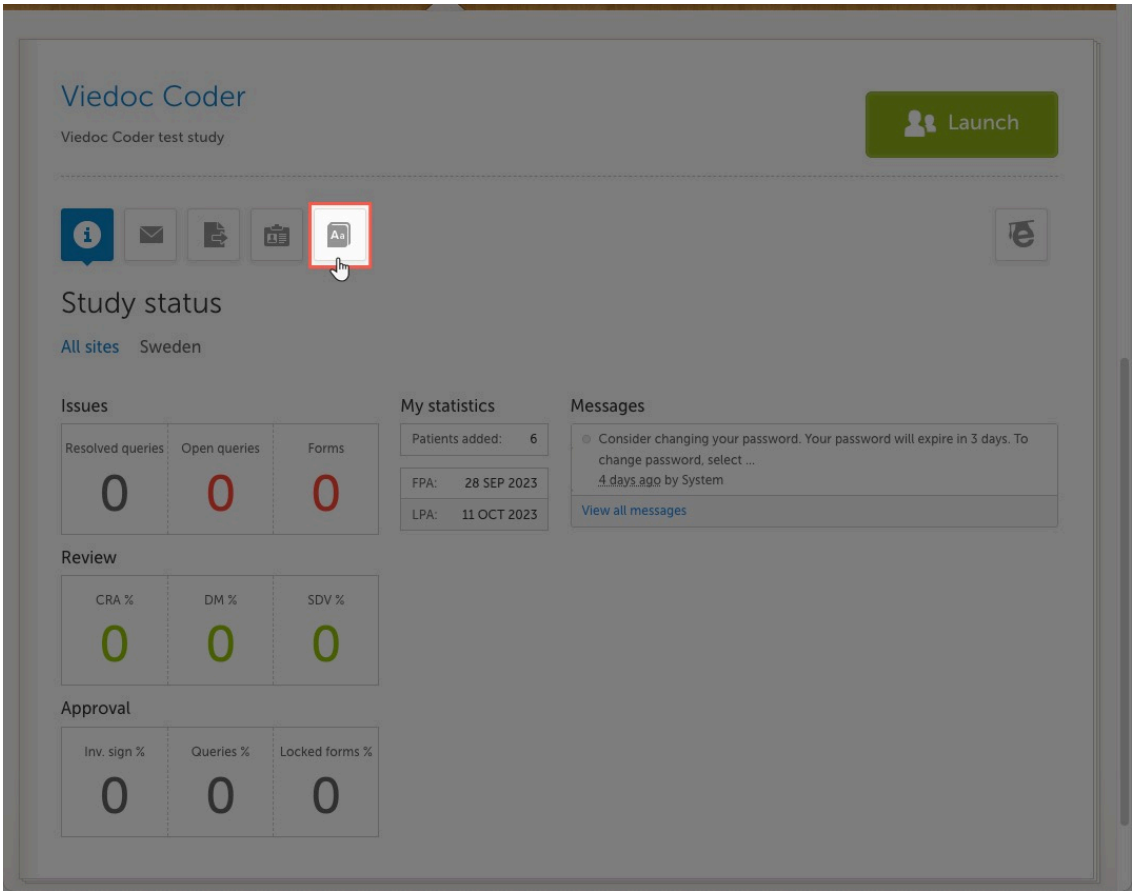
The Viedoc Coder page displays metrics about coding, for example, the number and percentage of items that have been coded and approved. There is one set of metrics for each coding scope. The metrics displayed are based on the data and sites that you have permission to view.

Note! You can only access Viedoc Coder if permission to view, perform, and/or approve medical coding is activated for your role. If you do not see the medical coding icon, you do not have a role with medical coding permissions.

2 Viedoc Coder

2.1 Overview

1. To open Viedoc Coder select the **dictionary icon**:



Viedoc Coder opens in a new window:

viedoc coder

Demo new coder

All countries ↓ | All sites ↓

Adverse event

Coded data
9 of 11 items

81%

8 items auto coded
1 items manually coded

Approved data
0 of 11 items

0%

Open medical coding →

Concomitant medication

Coded data
0 of 5 items

0%

Approved data
0 of 5 items

0%

Open medical coding →

Concomitant medication ATC

Coded data
1 of 5 items

20%

1 items auto coded
0 items manually coded

Approved data
0 of 5 items

0%

Open medical coding →

Medical history

Coded data
0 of 7 items

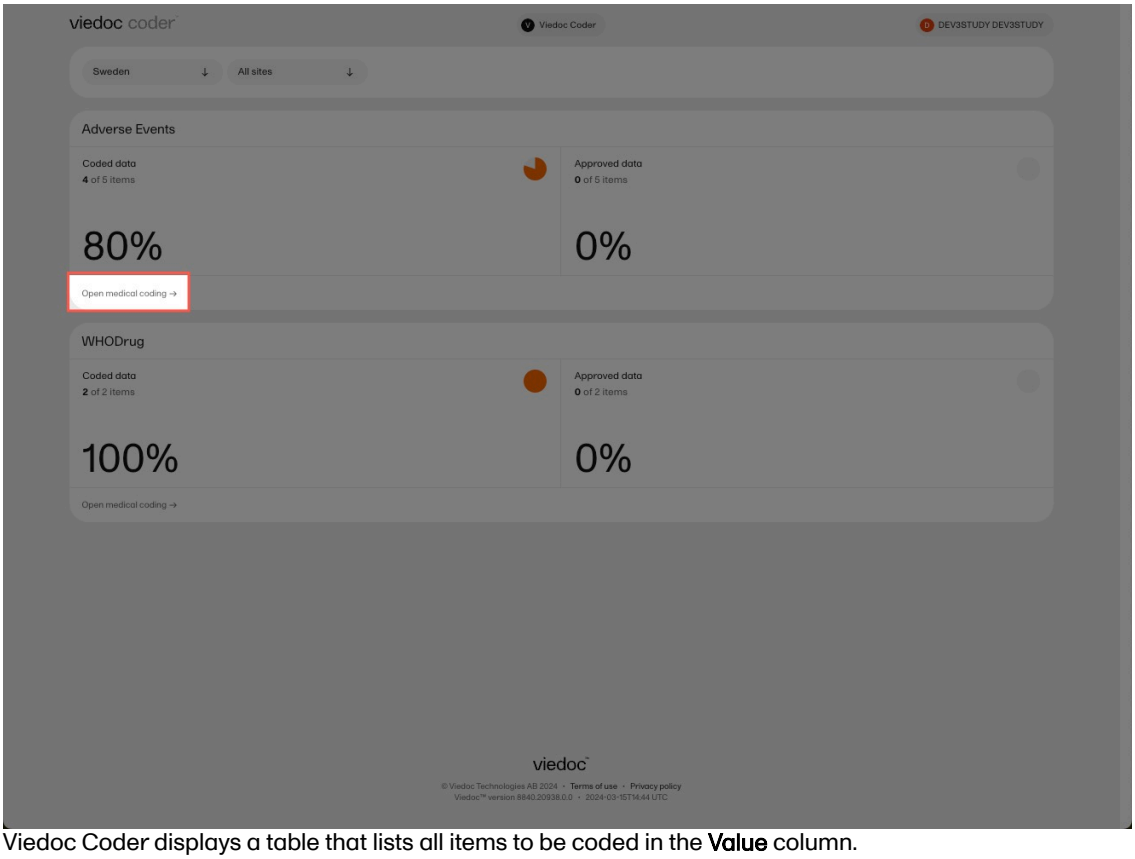
0%

Approved data
0 of 7 items

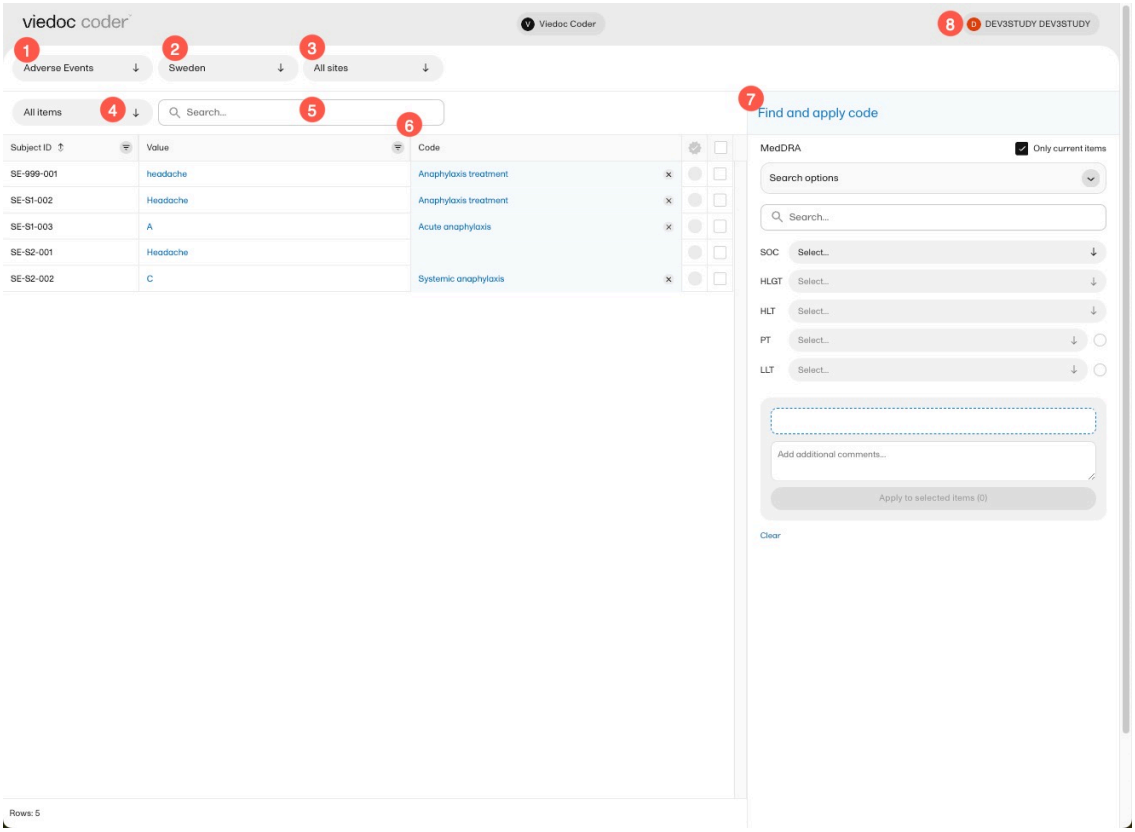
0%

Open medical coding →

2. Select **Open medical coding** on a scope:



Viedoc Coder displays a table that lists all items to be coded in the **Value** column.



In Viedoc Coder, you can:

1. Select the coding scope (the data) to be coded.

2. Select to display items from all countries or from an individual country.

3. Select to display items from all sites or from an individual site.

4. Select to display all uncoded (and rejected) items, all coded items, all approved items, or all items.

5. Perform a text search among all values of the items.

6. If configured for your study, there can be additional columns included with supporting values for the coding, for example route, indication, or other.

7. Find and apply codes (see Finding and applying a medical code).

8. Select here to change the settings of Viedoc, access the help center, or logout of Viedoc.

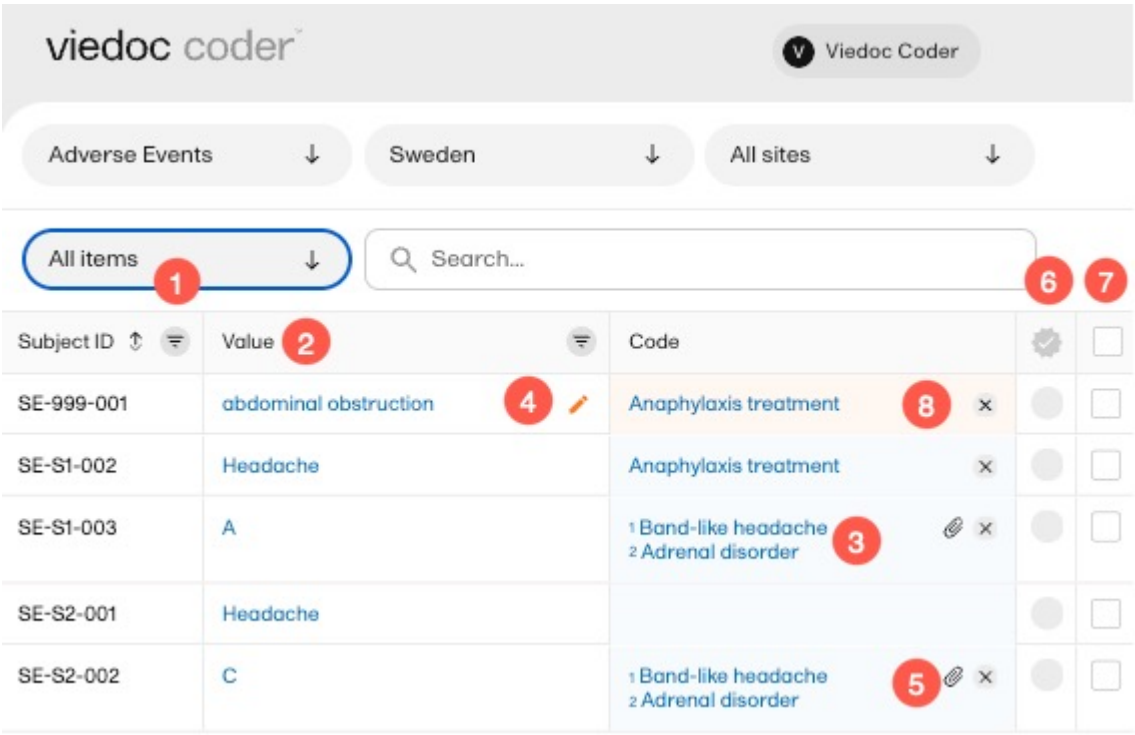
When applying codes, it is possible to:

- Add a comment - an interpretation or explanation of the value that you have assumed in order to code.
- Add multiple codes to one value.

See Finding and applying a medical code.

2.2 What do the symbols and colors mean?

In Viedoc Coder, you can find the following symbols:



1. The three horizontal lines is a filter function. Click the symbol to open a dropdown list with a search field and a list of selectable items.

2. Fields have a sorting function which will list its contents in ascending and descending order. This function is not available for all columns.

3. A numbered list in the code field means that there is more than one medical code applied to that value.

4. An orange pen icon in the value field, together with a light orange background in the code field, means that the value (form item) has been changed in Viedoc Clinic by the Investigator after the item was coded. The applied code may not be correct anymore and the item should be re-coded.

5. A clip icon in the code field means that an interpretation has been added. Move the mouse pointer over the clip icon to view the contents of the interpretation.

6. An activated tick mark indicates that the coding has been approved.

7. The checkbox is used to mark the values to which a selected code should be applied.

8. The white cross in a grey circle is used to delete the applied code.

3 Finding and applying a medical code

This section gives an example of medical coding of adverse events using the Medical Dictionary for Regulatory Activities (MedDRA) and an example of medical coding of concomitant medication using the World Health Organization Drug Dictionary (WHO DD). The coding procedure is similar even if you are using other types of dictionaries.

3.1 A use case for coding with the MedDRA dictionary

3.1.1 Searching for a code

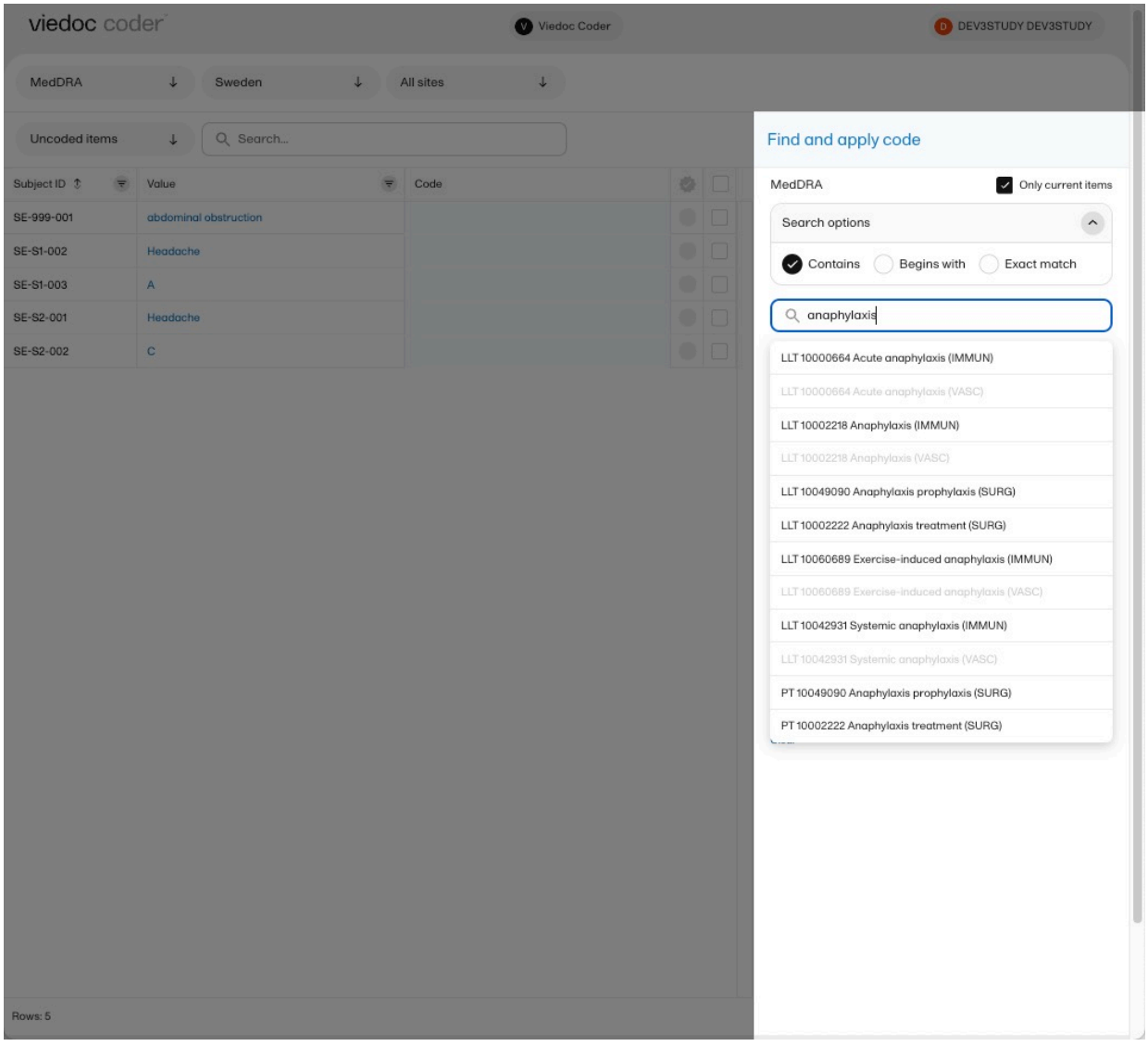
To find a code that you want to apply to a value, use the **Find and apply code** section.

There are three search options available:

- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.

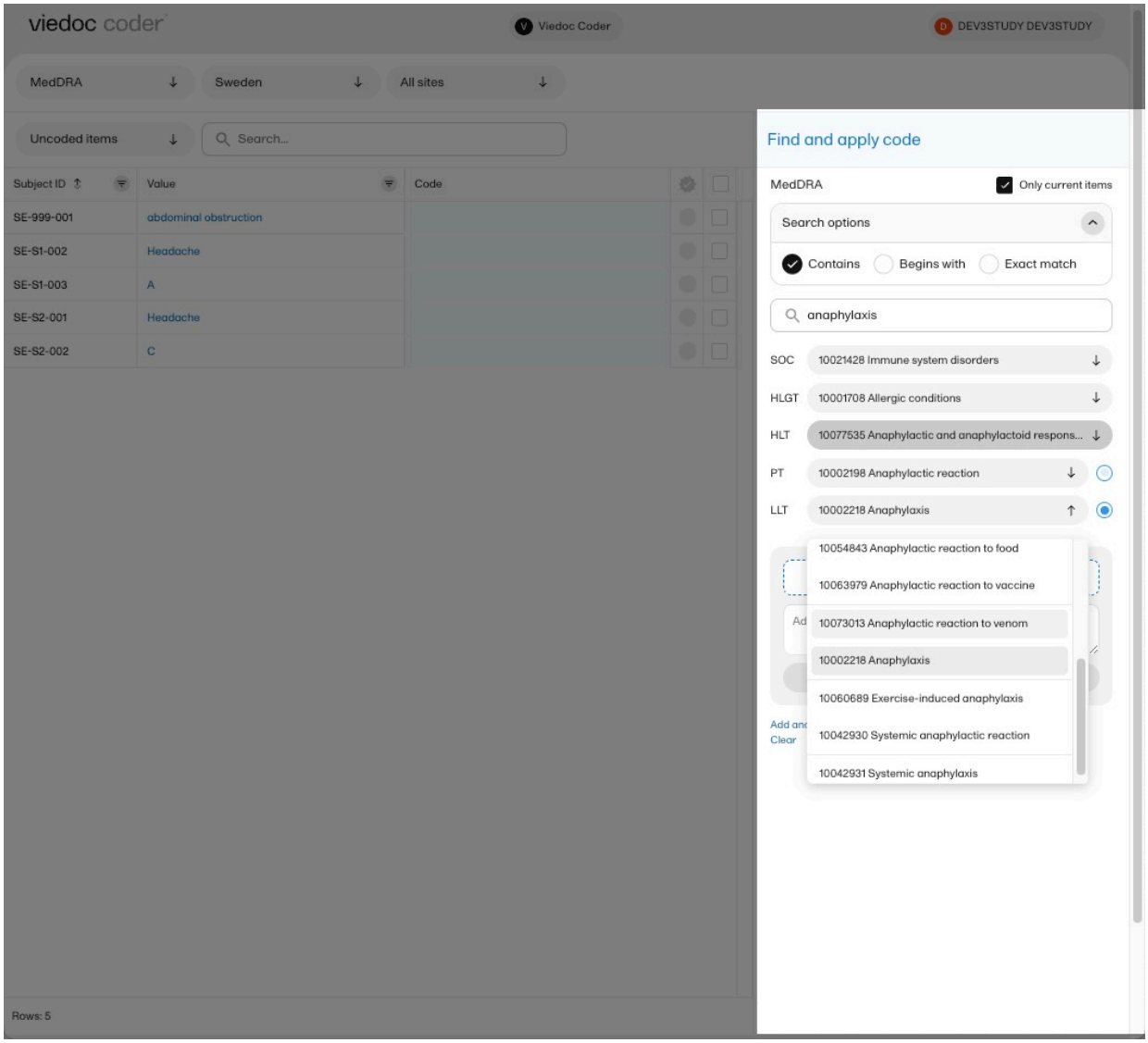
You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a dropdrown list that deploys from the **Search** field. If a term is linked to multiple System Organ Classes (SOCs), the code that links to the primary SOC is displayed in black, while the codes that link to secondary SOCs are displayed in grey.

Searching is not case sensitive. If you type in "Anaphylaxis", the search can return results such as "anaphylaxis" and "Anaphylaxis".



You can also search a code by selecting the System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Preferred Term (PT) and Low Level Term (LLT) using the dropdown lists below the search field.

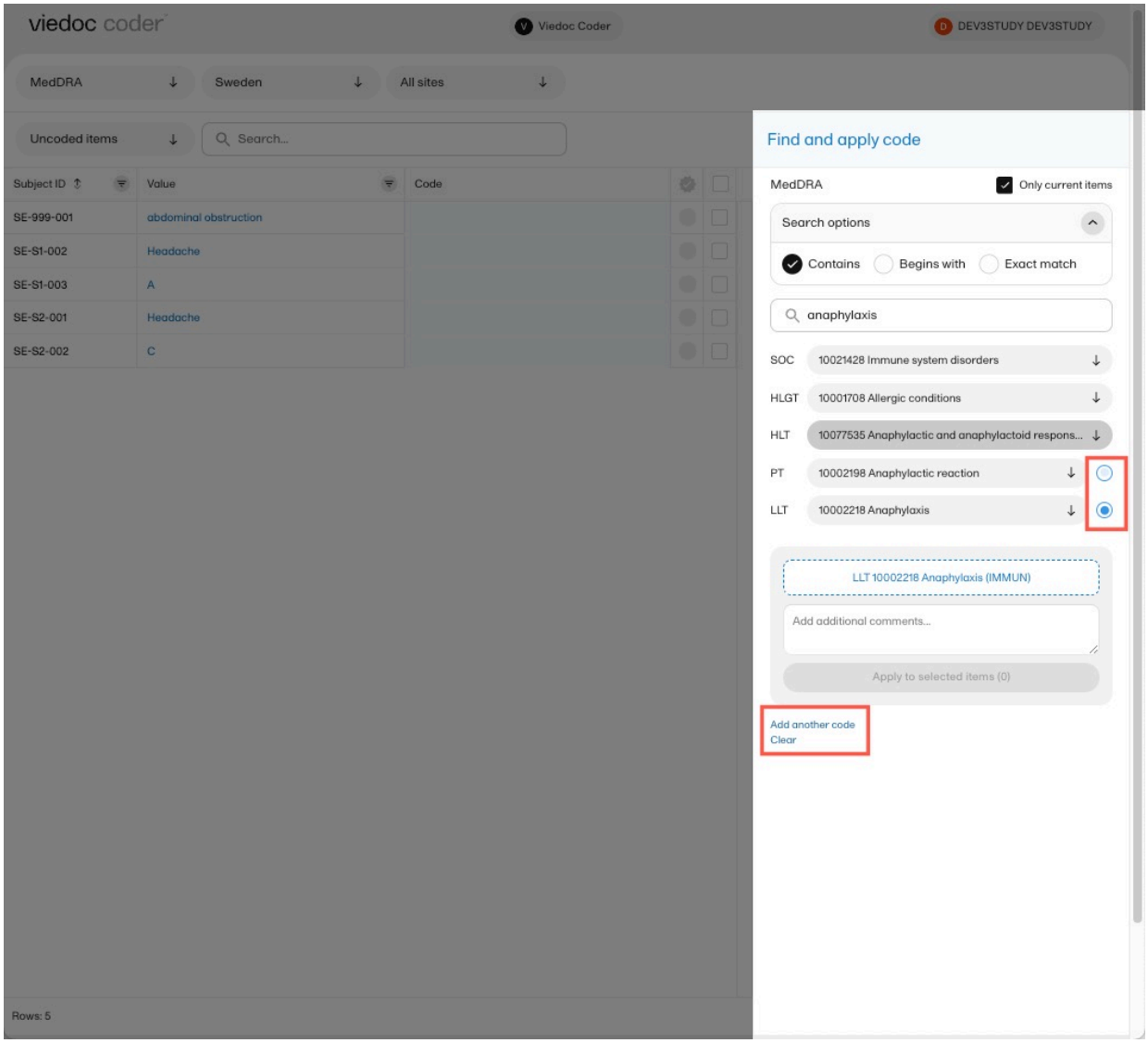
By default, the search returns low level terms (LLTs) that have the status 'current' in the MedDRA dictionary. It is possible to search among non-current MedDRA codes (that is, terms that are vague, ambiguous, truncated, abbreviated, out-dated, or misspelled and thus no longer used), by clearing the checkbox for **Only current items**.



3.1.2 Selecting a code

Select the code you would like to apply. The details of this code appear in the fields below the search field.

You can select to use the Preferred Term (PT) or the Low Level Term (LLT) by clicking one of the blue radio buttons next to the **PT** and **LLT** fields, as shown below:

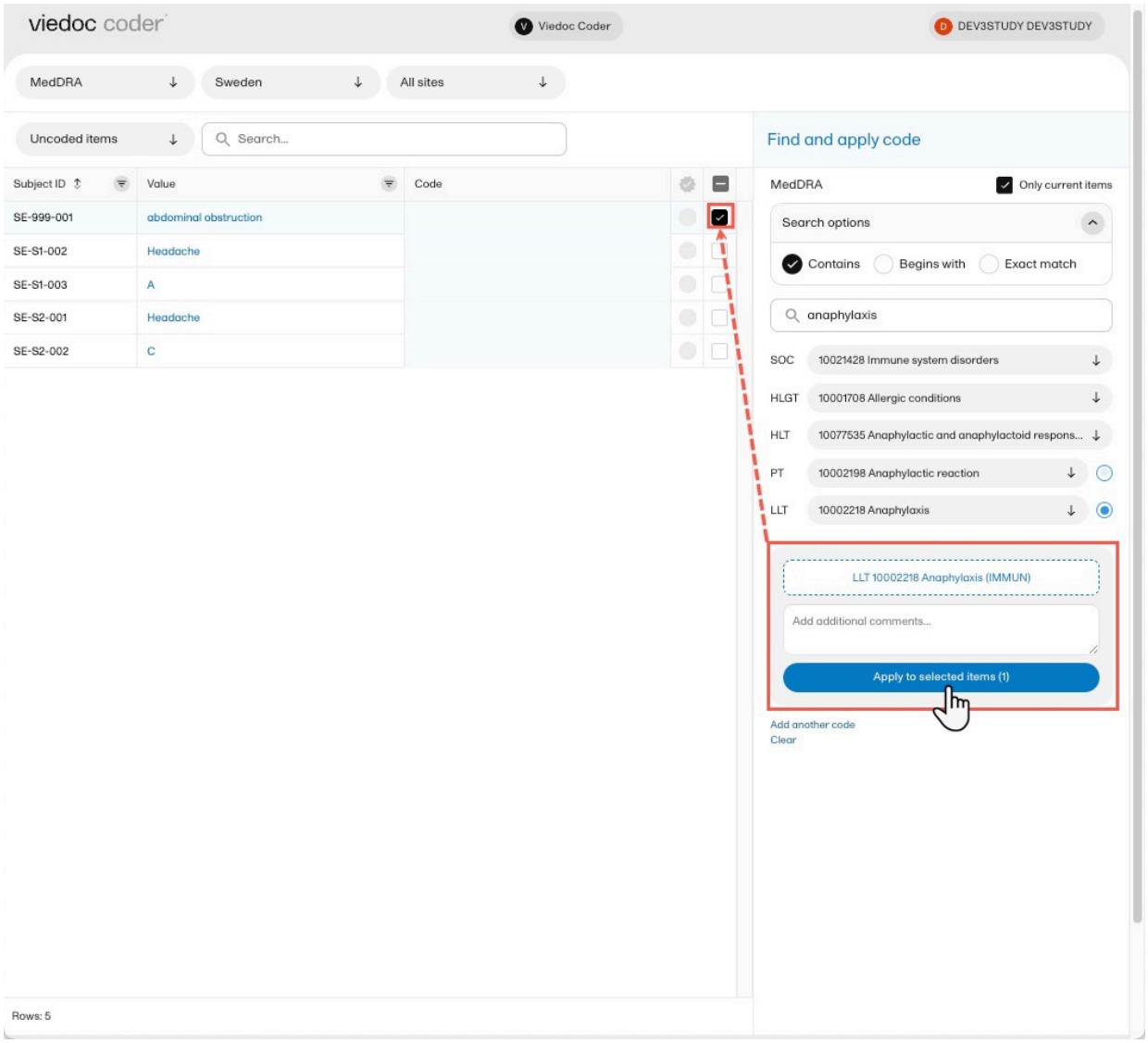


If you would like to add more than one code to the same value, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset your selections by clicking **Clear**.

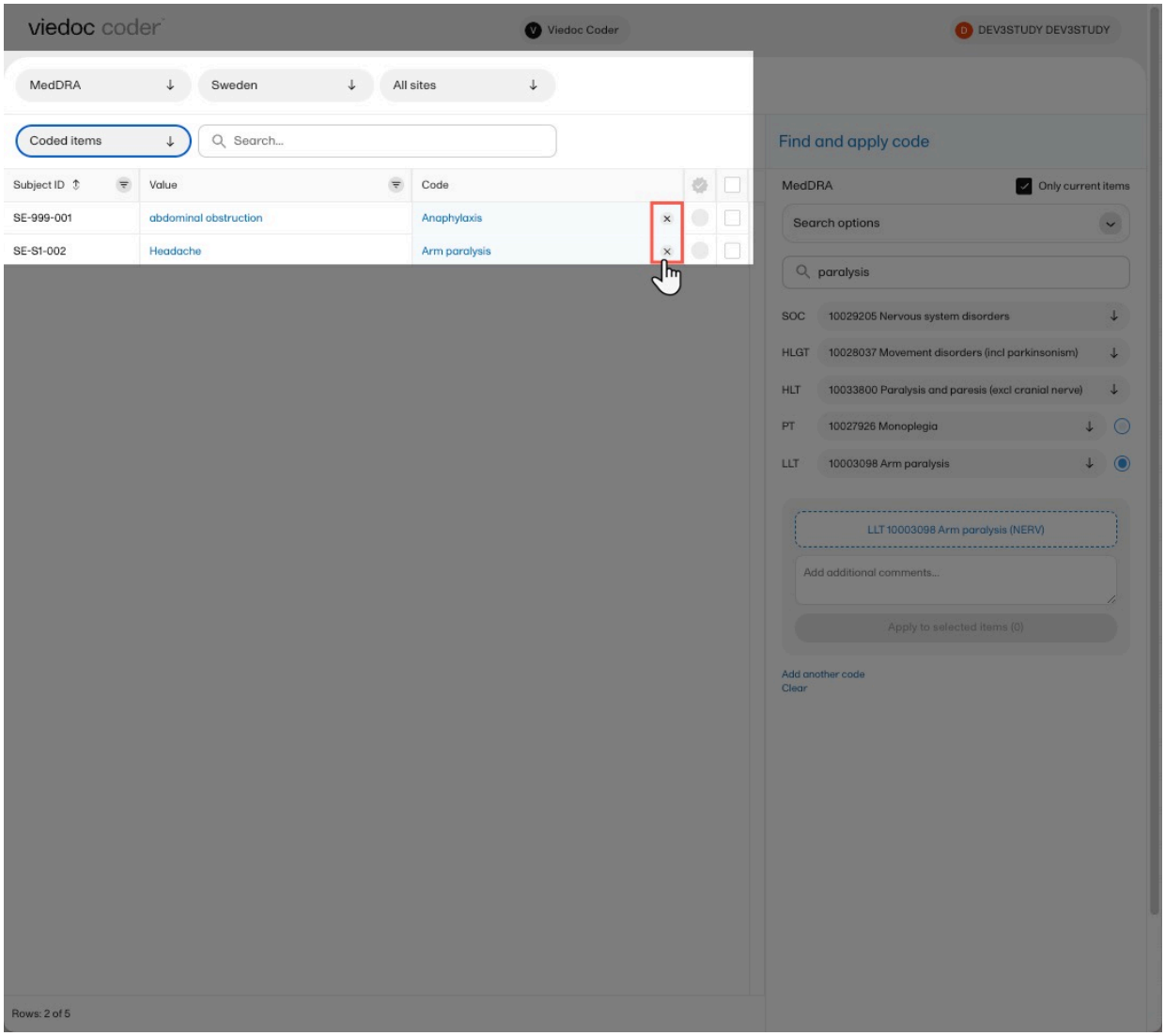
Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code.

3.1.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values.



Note! You can remove an applied code by clicking the cross icon to the right of the applied code.



3.2 A use case for coding with the WHO Drug Dictionary

3.2.1 Searching for a code

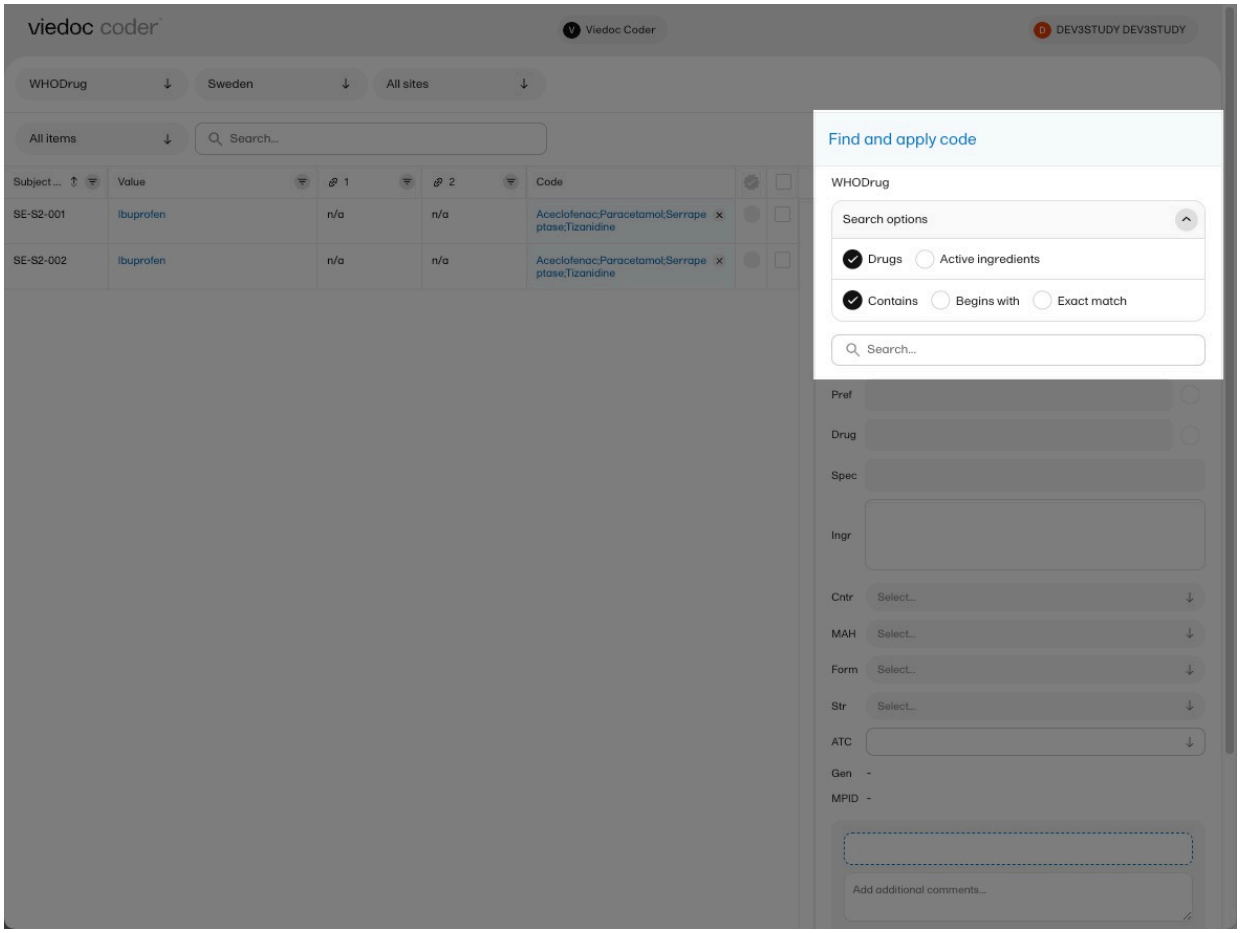
To find a code that you want to apply to a value, use the **Find and apply code** section.

When using the WHO DD, you can select to search by:

- **Drugs** - to search for drugs by their name. This is the default option.
- **Active ingredients** - to search for drugs by their active ingredients. You can enter multiple ingredients in the search field, separated by ; and the search will return all drugs that contain all specified ingredients.

There are three search options available:

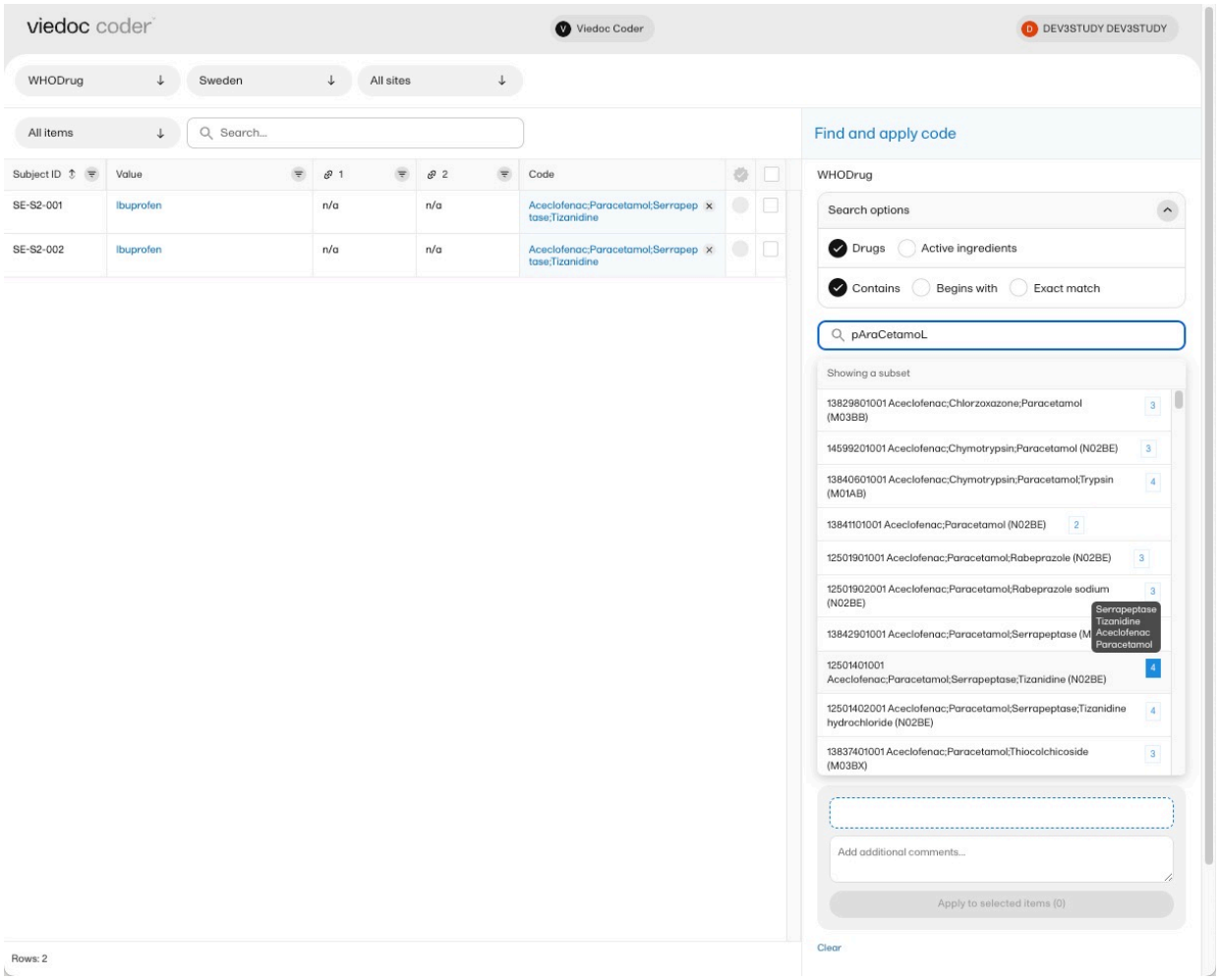
- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.



You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a dropdown list that deploys from the **Search** field.

Searching is not case sensitive. If you type in "paRacetaMol", the search can return results such as "paracetamol" or "Paracetamol".

The number behind the entries in the list depicts the number of active ingredients. If you hover the cursor over the number, a dialog box appears that lists the active ingredients.

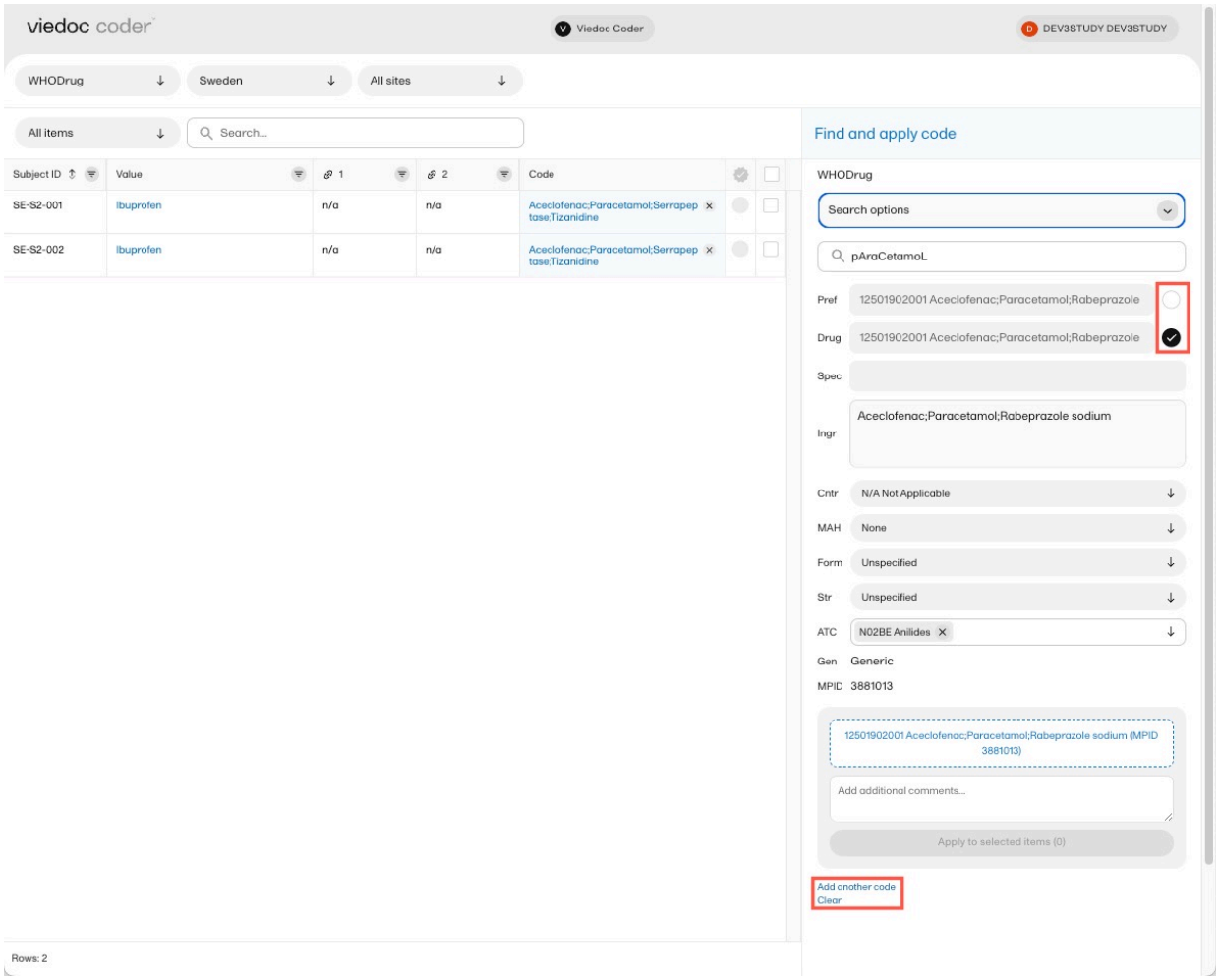


3.2.2 Selecting a code

Select the code (drug) you would like to apply. The details of this drug will appear in the fields below the search field.

In the WHO DD, all drugs have a preferred drug. You can select to use the Preferred drug (Pref) or the Drug name by clicking one of the blue radio buttons next to the **Pref** and **Drug** fields. **Drug** is the default.

Note! When exporting medical coding, both the preferred drug and drug name are included in the export (in separate columns). But if you select to apply **Pref** while coding, the preferred name ends up in both columns in the export. This is to provide consistency for the data managers, so that they only have to look in one column to find their data.

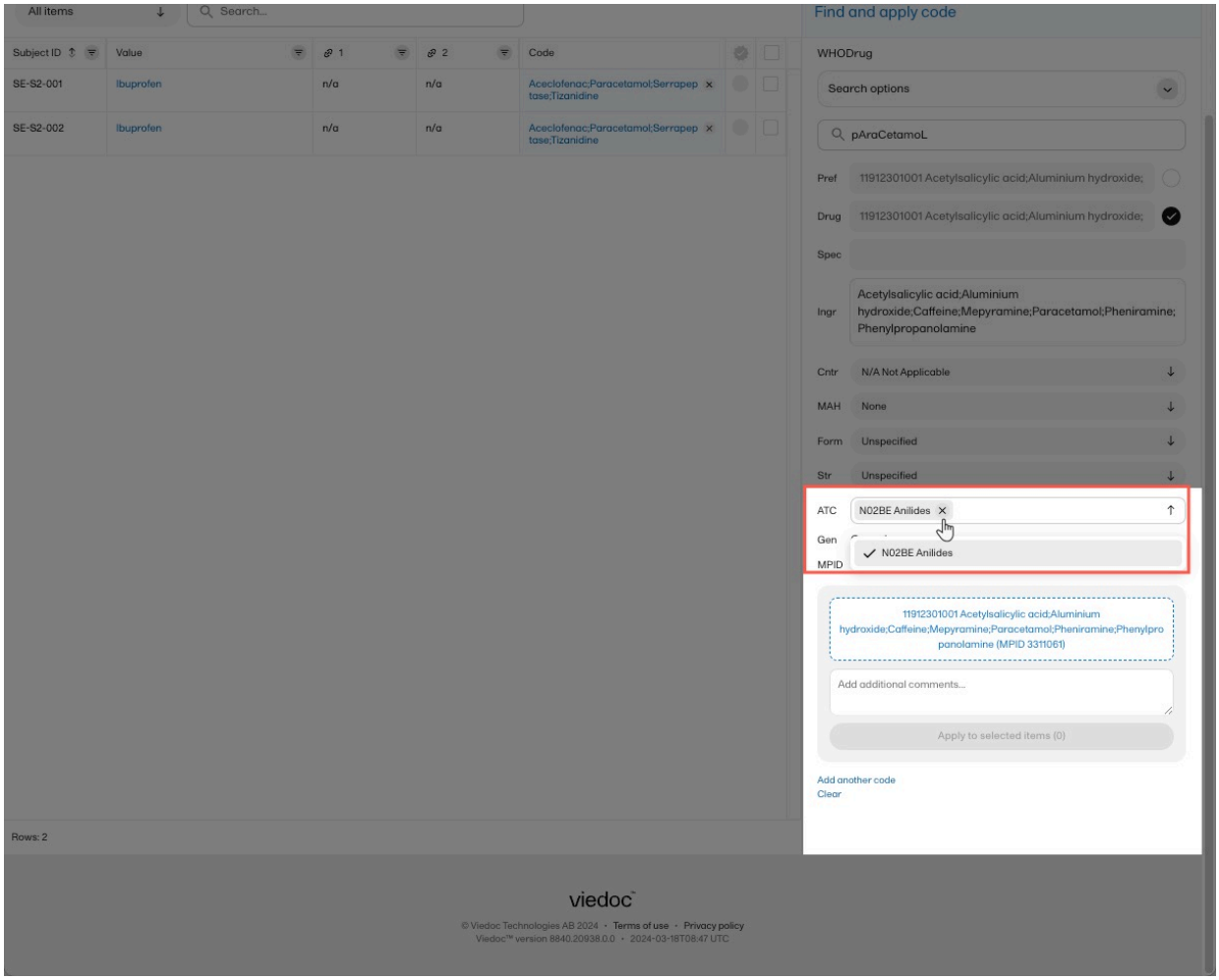


Use the dropdown lists to select Country (Cntr), Marketing Authorization Holder (MAH), Pharmaceutical Form (Form), Strength (Str), or Medicinal Product ID (MPID), if applicable.

If you would like to add more than one code to the same field, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset you selections by clicking **Clear**.

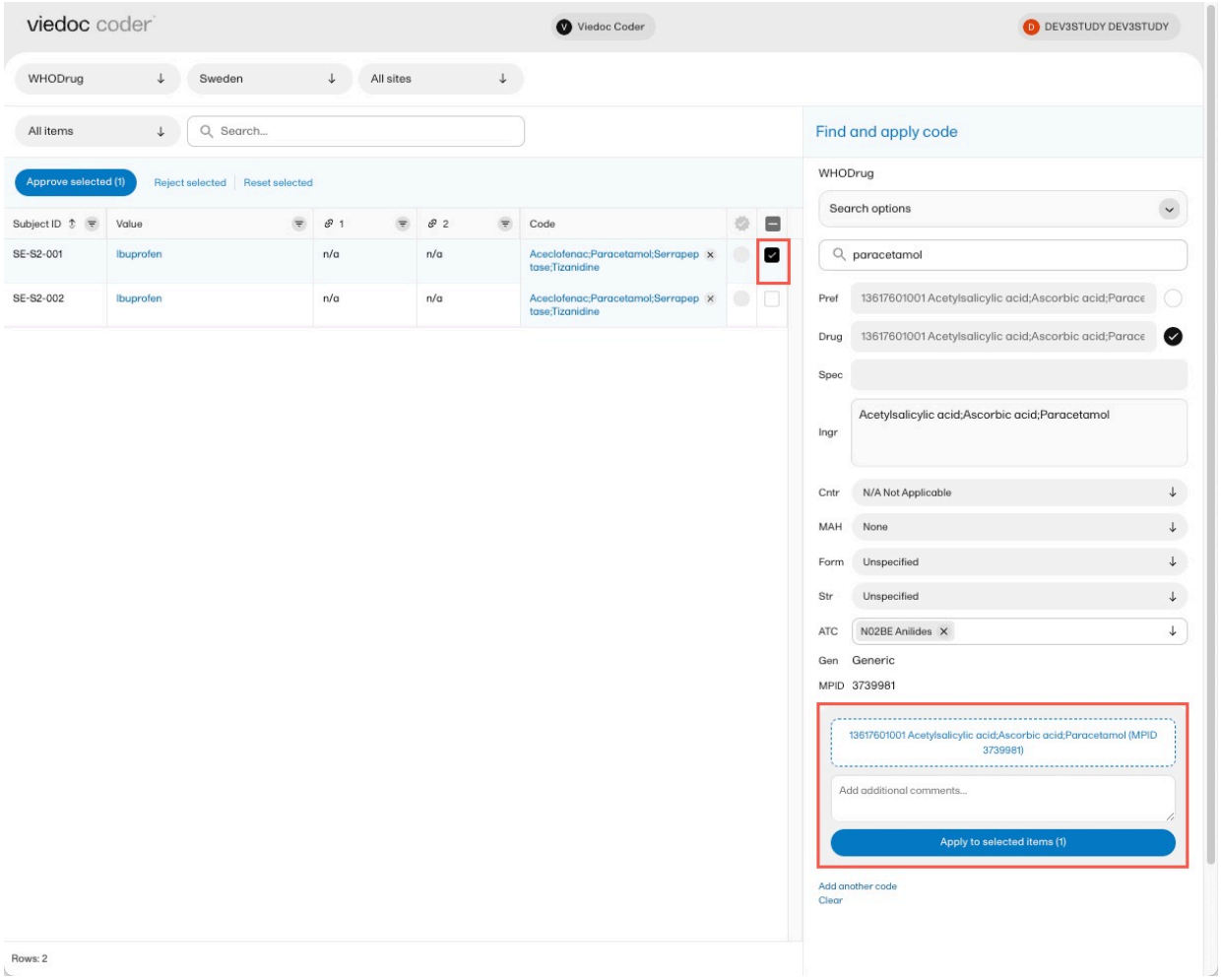
Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code..

If you selected a drug that carries multiple Anatomic Therapeutic Chemical Classification System (ATC) codes, all ATC codes will be displayed in the **ATC** field. You can define whether to include all ATC codes in the coding or only a selection. Select the ATC code to include it or select the X icon to remove an ATC code.



3.2.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values.



You can remove an applied code by clicking the cross icon to the right of the applied code.

---

4 Approving the medical coding

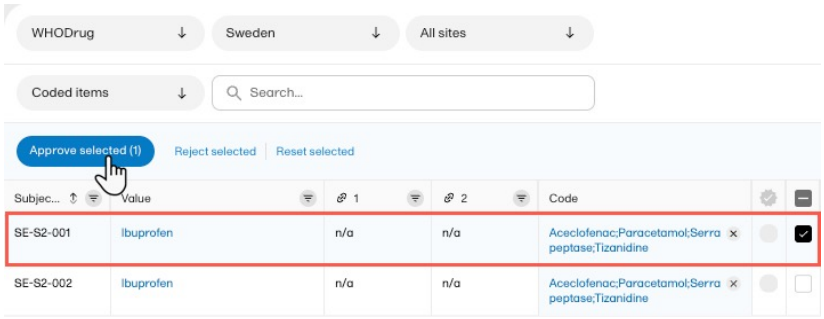
After applying codes to the items, it is possible to approve/reject/reset the items as shown in the below table.

Action	Current state/found in list	New state/found in list
Approve	Coded Rejected	Approved items
Reject	Coded Approved	Uncoded items
Reset	Approved Rejected	Coded items

Tip! To see all items in one list, select the filter **All items**.

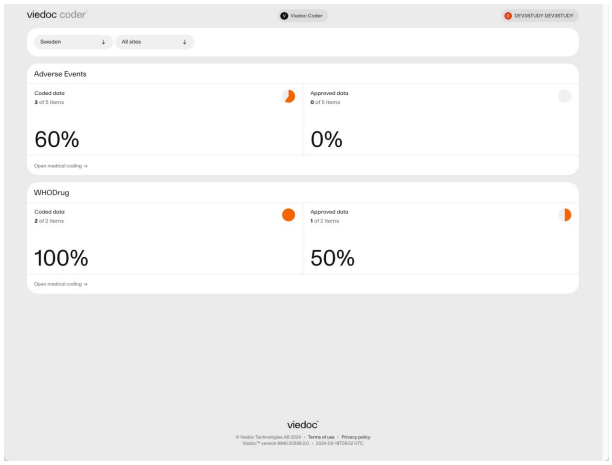
To approve items that have been coded:

1 Select the item(s) that you want to approve and click **Approve selected**.



2 The selected item(s) now disappear from the list and are found with the blue "Approved" symbol in the Approved items list.

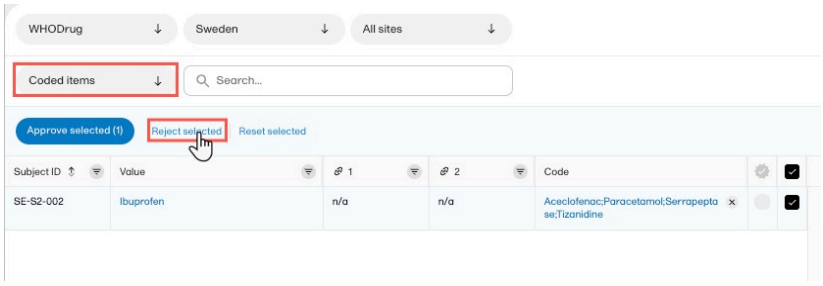
Tip! The metrics of the medical coding that have been approved can be seen on the landing page:



4.1 Rejecting the medical coding

To reject items that have been coded:

1 Select the items that you want to reject and select **Reject selected**.

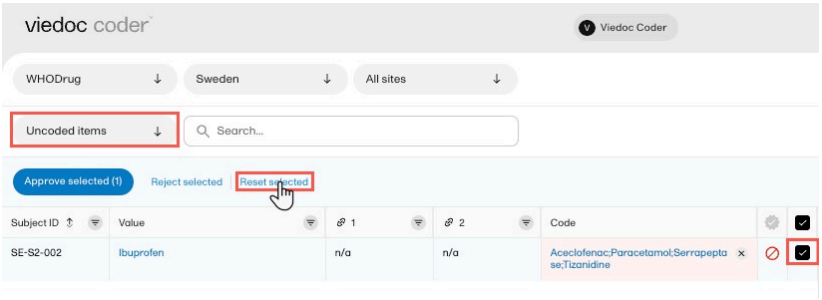


2 The selected item(s) now disappear from the list and are found with the red "rejected" symbol in the Uncoded items list for re-evaluation.

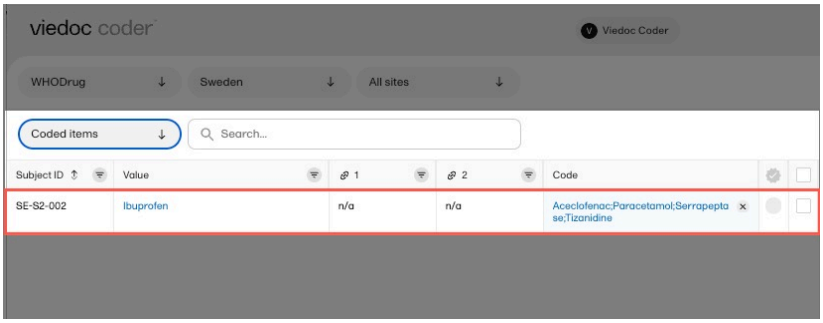
4.2 Resetting the medical coding

To reset items that have been approved or rejected:

1 Select the item(s) that you want to reset and click **Reset selected**.



2 The selected item(s) now disappear from the list and are found in the Coded items list without the approved/rejected flag.



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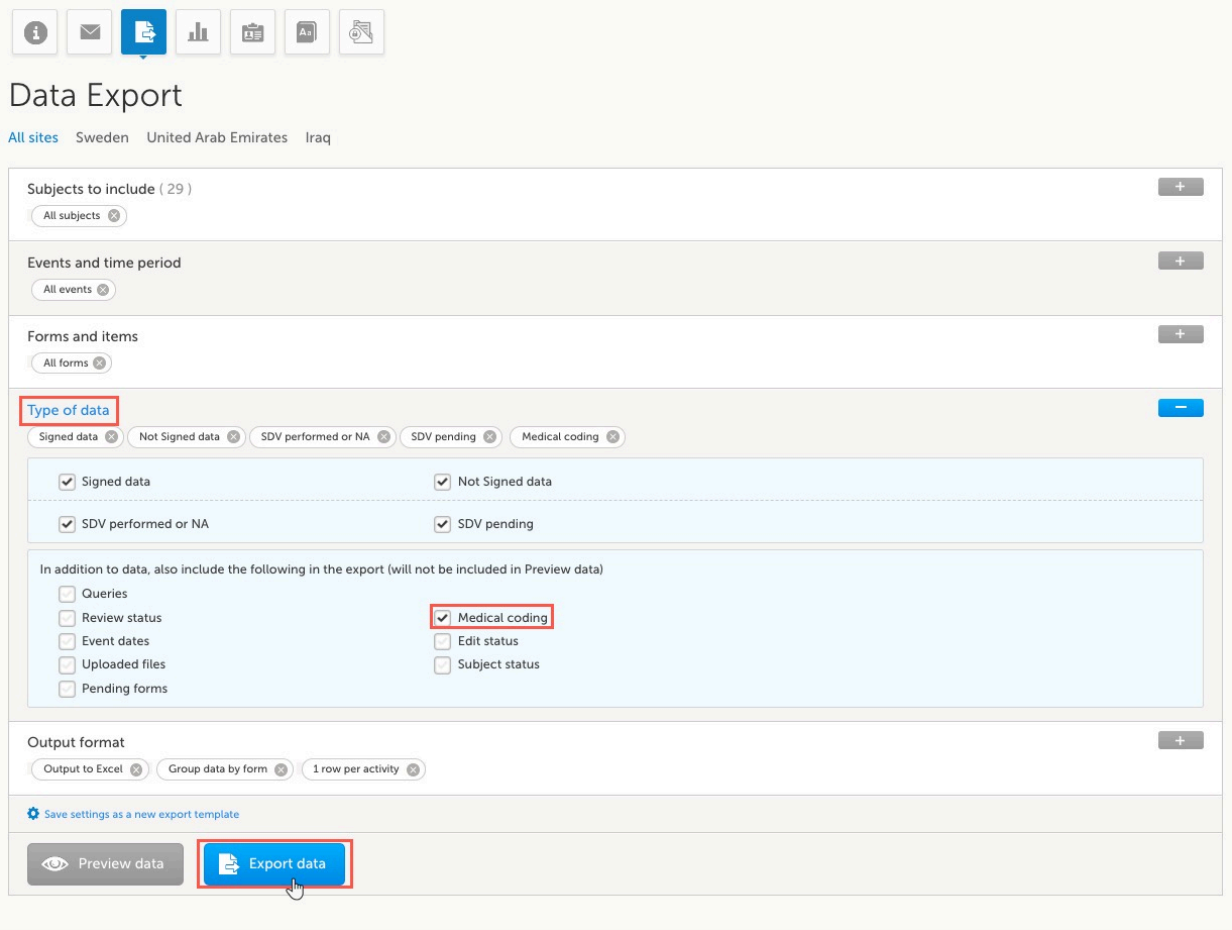
5 Exporting the medical coding

It is possible to export medical coding using Viedoc's data export feature, for more information, see Exporting data.



To export the medical coding, select the checkbox in front of **Medical coding** in the **Type of data section**.

For more information about how medical coding is exported, see:

- Medical coding in ODM export
- Medical coding in Excel export

Note! You can only export medical coding if permission to export data is activated for your role. If you do not see the data export icon, you do not have a role with export permissions.

6 Auto coding

In Viedoc Coder, you can choose to enable auto coding.

We support auto coding for the MedDRA and ATC dictionaries. Auto coding can be enabled and disabled for individual scopes within the MedDRA/ATC terminology. Currently, auto coding includes an exact match to MedDRA, any language and ATC.

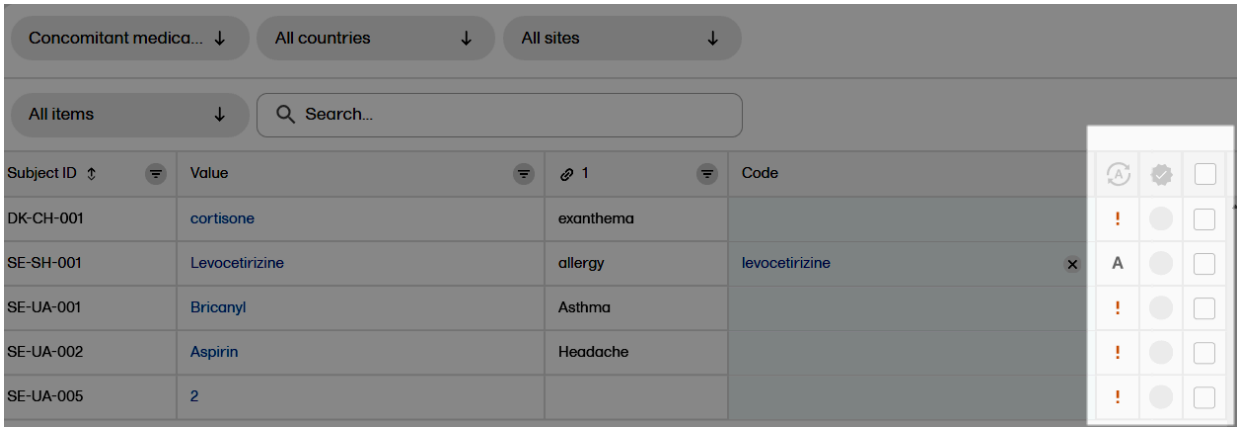
Note! MedDRA-J is scheduled to be included in the future.

Note! By default, auto coding is disabled for ongoing studies and enabled for new studies. However, it can be disabled for new studies. The auto coding setting is always available in Viedoc Admin, however is only functional for the new Viedoc coder and not the old Viedoc Coder console. If you wish to update to the new Viedoc Coder, please contact your Viedoc representative.

When auto coding is enabled, all existing uncoded items will be auto coded and all new items will be auto coded without any manual steps. However, items that are auto coded without a match will be flagged, and will need to be manually coded.

An auto coded item is indicated within the table for coded items:

- **A** = auto coded with a match
- **!** = auto coded without match and needs to be manually coded.



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Medical coding version 4.78 and earlier

Published by Viedoc System 2024-06-27

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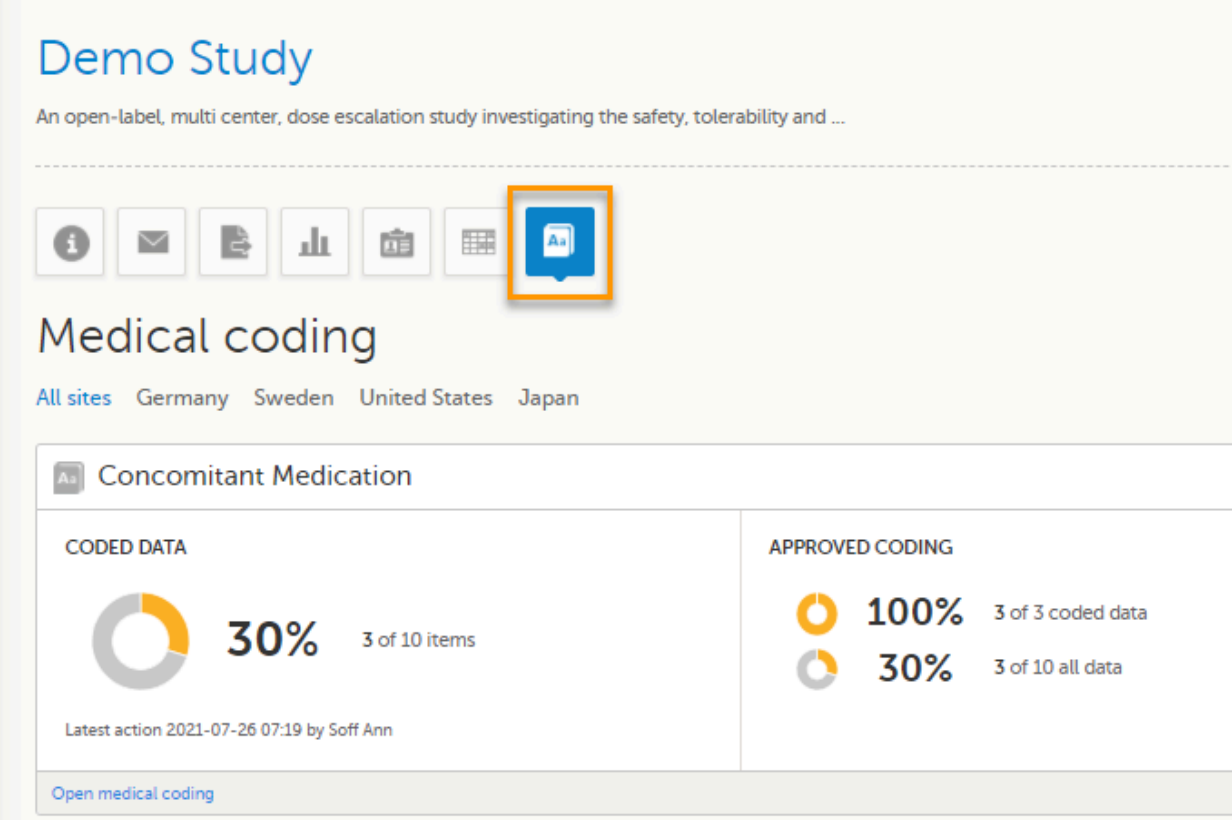
1 Introduction

Viedoc Coder allows you to code data, such as Adverse Events, Medical History, and Concomitant Medications, in a standardized way. You can access Viedoc coder on the landing page.

The Viedoc Coder page displays metrics about coding that tell the user the number and percentage of items that have been coded and approved. There is one set of metrics for each coding scope. The metrics displayed are based on the data and sites that you have permission to view.

Note! You can only access Viedoc Coder if permission to view, perform, and/or approve medical coding is activated for your role. If you do not see the medical coding icon, you do not have a role with medical coding permissions.



You can select to display the metrics of:

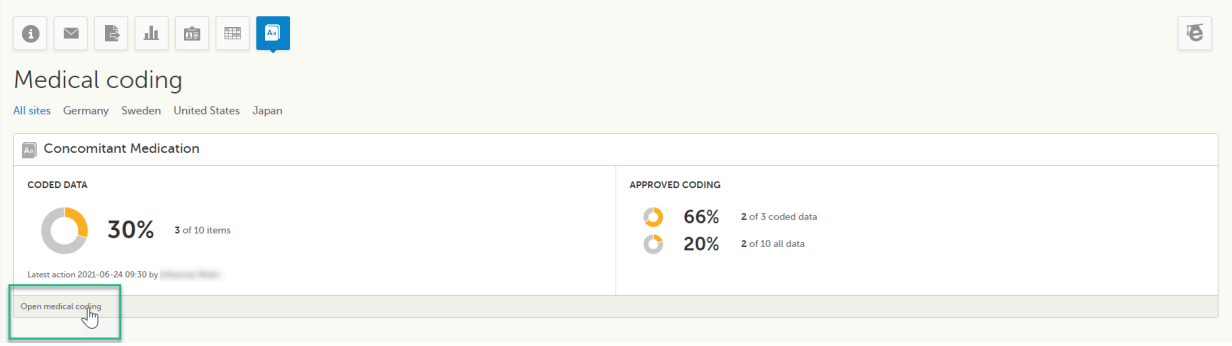
- All sites
- All sites in an individual country
- An individual site

---

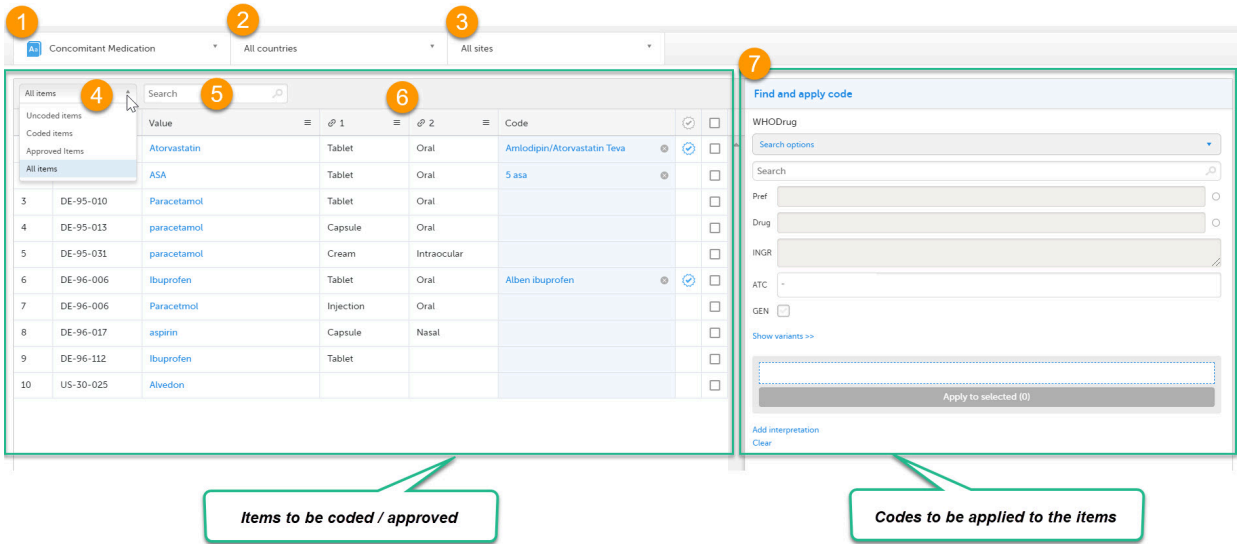
2 The Viedoc Coder console in Viedoc Clinic

2.1 Overview of the medical coding console

To enter the medical coding console, click **Open Viedoc Coder** in the lower left corner of the coding scope.



The Viedoc Coder console opens in the same window:



The Viedoc Coder console displays a table that lists all items to be coded in the **Values** column. You can view the corresponding form (Electronic Case Report Form (eCRF)) of an item by clicking on the value.

On the Viedoc Coder console, you can:

1. Select the coding scope (that is, data) to be coded.

2. Select to display items from all countries or from an individual country.

3. Select to display items from all sites or from an individual site.

4. Select to display all uncoded (and disapproved) items, all coded items, all approved items, or all items.

5. Perform a text search among all values of the items.

6. If configured for your study, there can be additional columns included with supporting values for the coding, for example route, indication, or other.

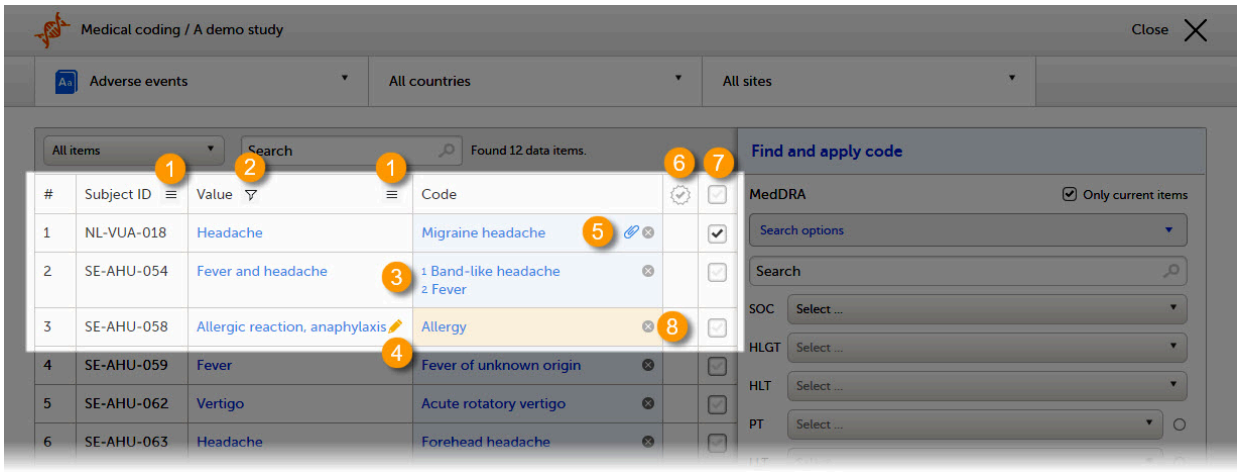
7. Find and apply codes (see Finding and applying a medical code).

When applying codes, it is possible to:

- Add an interpretation - a comment or explanation of the value that you have assumed in order to code.
- Add multiple codes to one value.

See Finding and applying a medical code.

2.2 What do the symbols and colors mean?



On the Viedoc Coder console, you can find the following symbols:

1. The three horizontal lines is a filter function. Click the symbol to open a drop-down list with a search field and a list of selectable items.

2. A filter symbol indicates that a selection has been made and the column only displays your filtered items.

3. A numbered list in the code field means that there is more than one medical code applied to that value.

4. An orange pen icon in the value field, together with a light orange background in the code field, means that the value (form item) has been changed in Viedoc Clinic by the Investigator after the item was coded. The applied code may not be correct anymore and the item needs to be re-coded.

5. A clip icon in the code field means that an interpretation has been added. Move the mouse pointer over the clip icon to view the contents of the interpretation.

6. An activated tick mark indicates that the coding has been approved.

7. The checkbox is used to mark the values to which a selected code should be applied.

8. The white cross in a grey circle is used to delete the applied code.

---

3 Finding and applying a medical code

This section gives an example of medical coding of adverse events using the Medical Dictionary for Regulatory Activities (MedDRA) and an example of medical coding of concomitant medication using the World Health Organization Drug Dictionary (WHO DD). The coding procedure is similar even if you are using other types of dictionaries.

3.1 A use case for coding with the MedDRA dictionary

3.1.1 Searching for a code

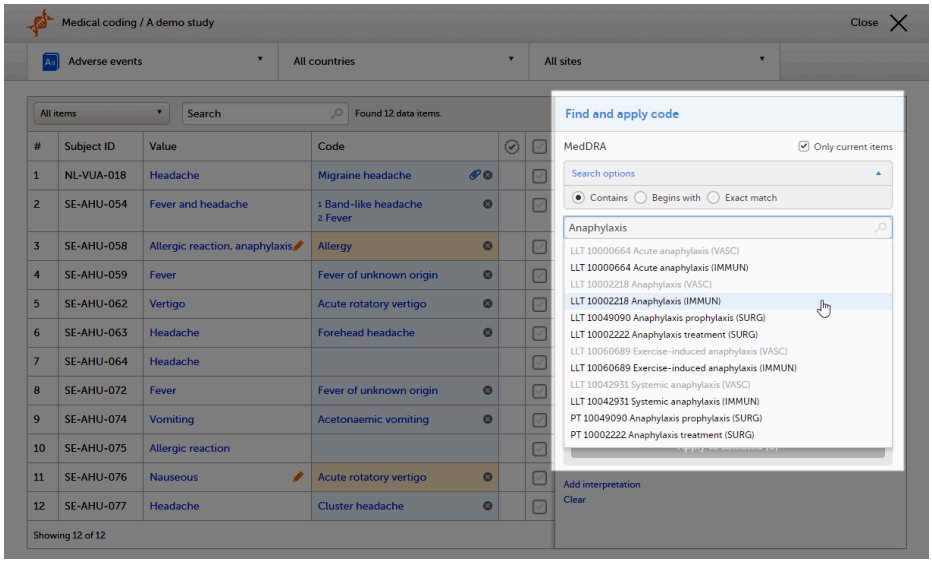
To find a code that you want to apply to a value, use the **Find and apply code** section.

There are three search options available:

- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.

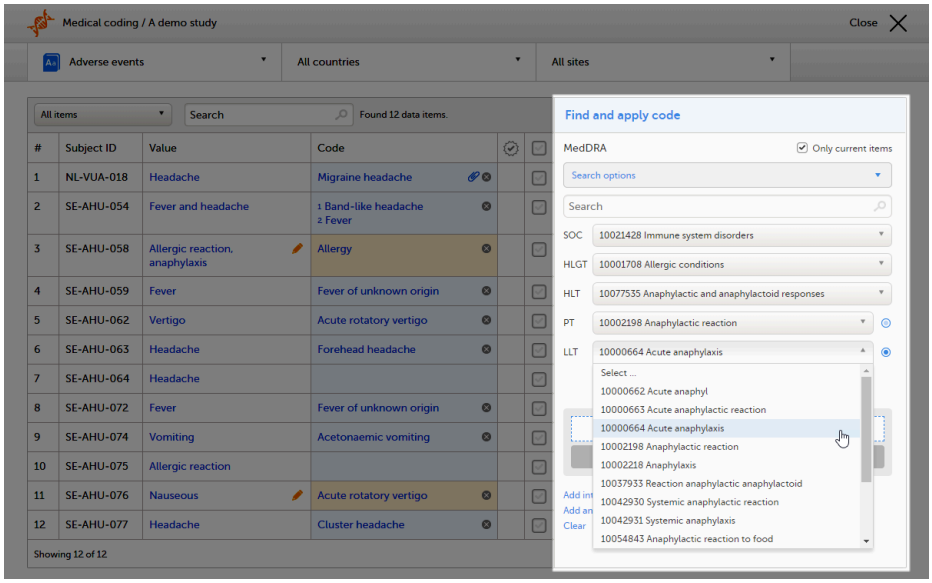
You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a drop-drown list that deploys from the **Search** field. If a term is linked to multiple System Organ Classes (SOCs), the code that links to the primary SOC is displayed in black, while the codes that link to secondary SOCs are displayed in grey.

Searching is not case sensitive. If you type in "Anaphylaxis", the search can return results such as "anaphylaxis" and "Anaphylaxis".



You can also search a code by selecting the System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Preferrred Term (PT) and Low Level Term (LLT) using the drop-down lists below the search field.

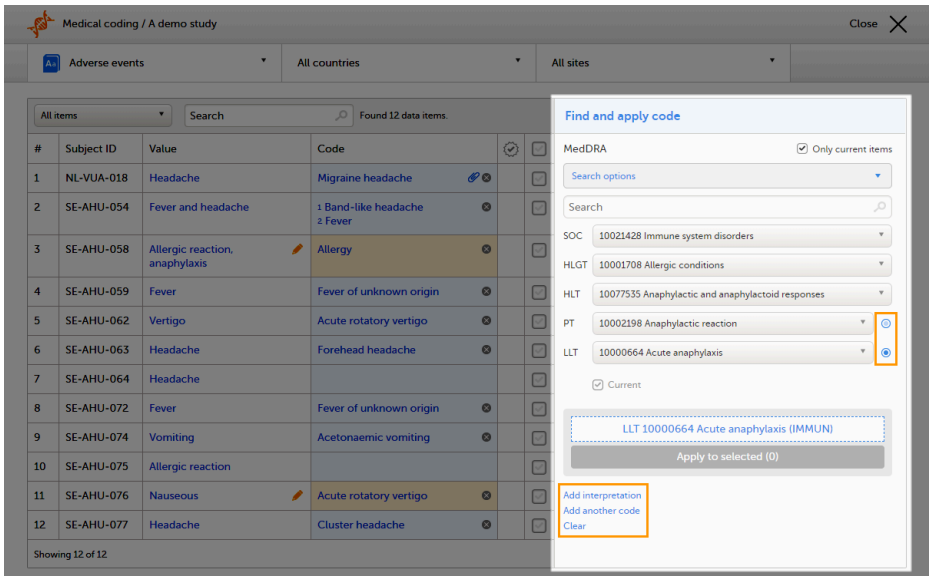
By default, the search returns low level terms (LLTs) that have the status 'current' in the MedDRA dictionary. It is possible to search among non-current MedDRA codes (that is, terms that are vague, ambiguous, truncated, abbreviated, out-dated, or misspelled and thus no longer used), by clearing the checkbox for **Only current items**.



3.1.2 Selecting a code

Select the code you would like to apply. The details of this code appear in the fields below the search field. The checkbox **Current** displays whether the selected Low Level Term (LLT) has the status *current* in the MedDRA dictionary or not.

You can select to use the Preferred Term (PT) or the Low Level Term (LLT) by clicking one of the blue radio buttons behind the **PT** and **LLT** fields, see image.

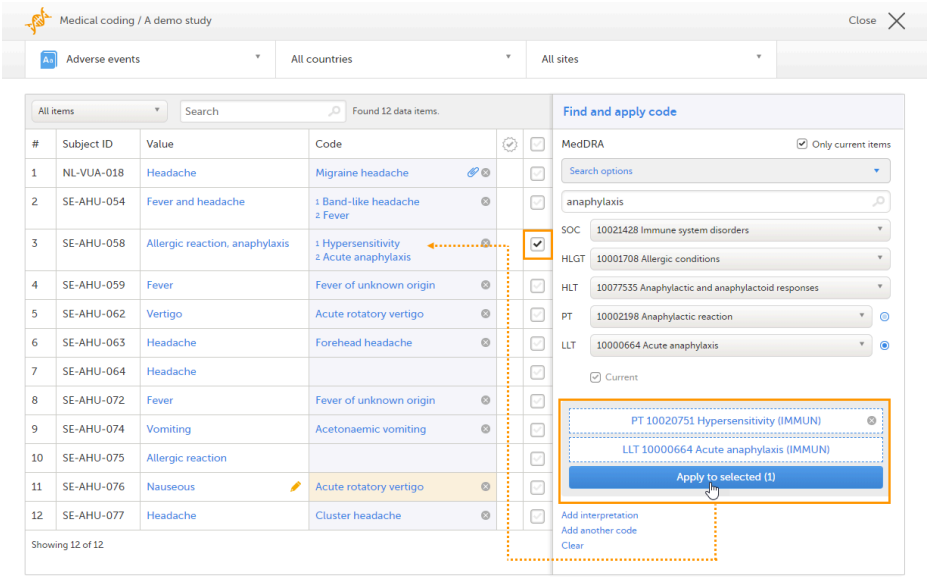


If you would like to add more than one code to the same field, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset your selections by clicking **Clear**.

Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code.

3.1.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values. In the example in the image, we applied two codes to the value *Allergic reaction, anaphylaxis* for subject *SE-AHU-058*.



You can remove an applied code by clicking the cross icon to the right of the applied code.

3.2 A use case for coding with the WHO Drug Dictionary

3.2.1 Searching for a code

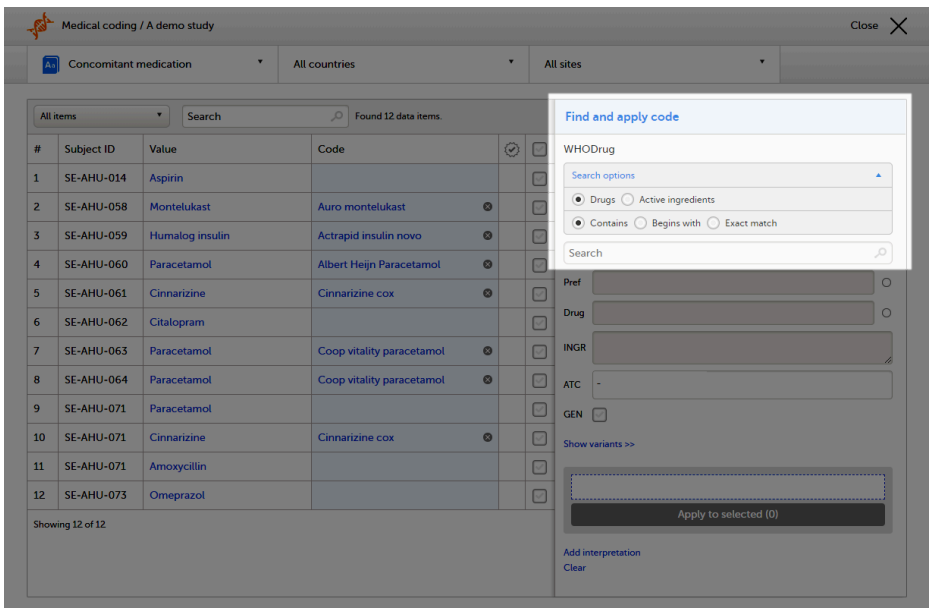
To find a code that you want to apply to a value, use the **Find and apply code** section.

When using the WHO DD, you can select to search by:

- **Drugs** - to search for drugs by their name. This is the default option.
- **Active ingredients** - to search for drugs by their active ingredients. You can enter multiple ingredients in the search field, separated by ; and the search will return all drugs that contain all specified ingredients.

There are three search options available:

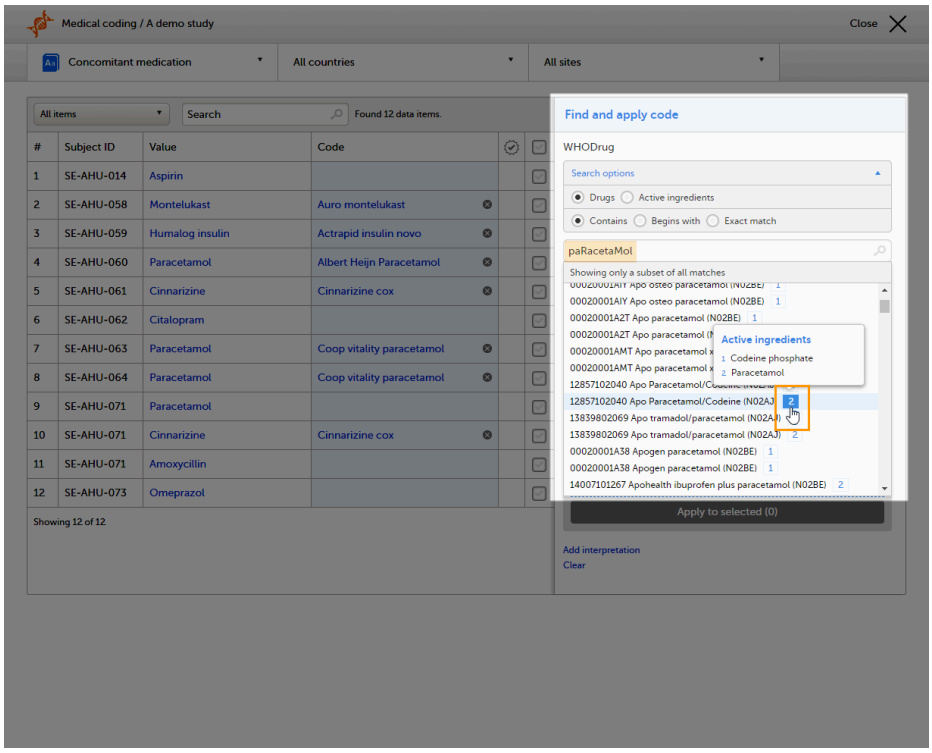
- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.



You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a drop-drown list that deploys from the **Search** field.

Searching is not case sensitive. If you type in "paRacetaMol", the search can return results such as "paracetamol" or "Paracetamol".

The number behind the entries in the list depicts the number of active ingredients. If you click that number, a pop-up appears that lists the active ingredients.

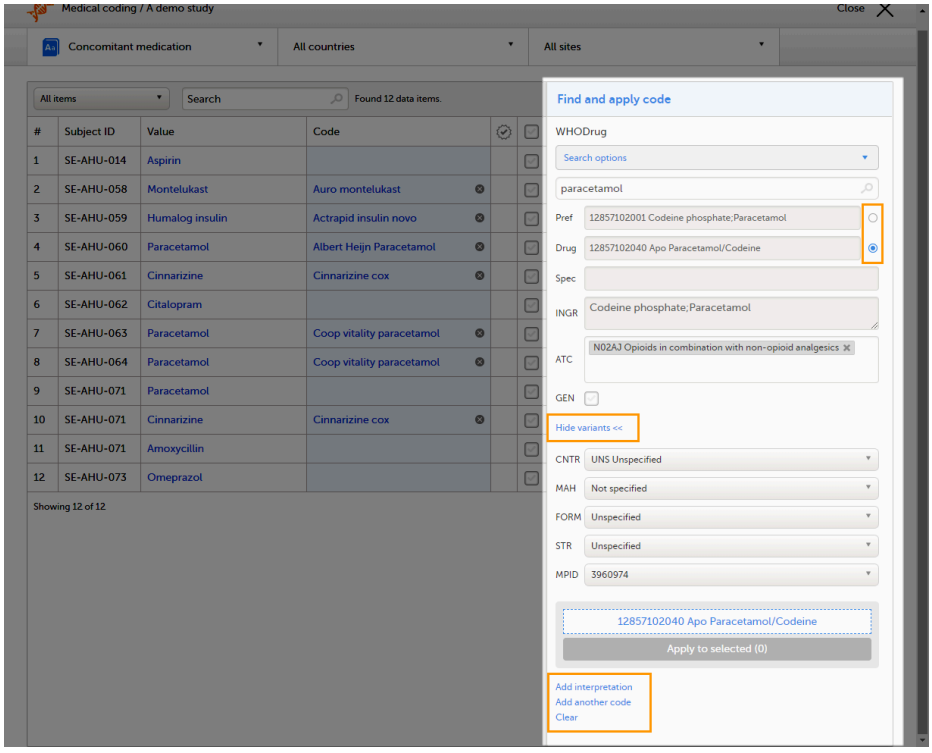


3.2.2 Selecting a code

Select the code (drug) you would like to apply. The details of this drug will appear in the fields below the search field.

In the WHO DD, all drugs have a preferred drug as parent. You can select to use the Preferred drug (Pref) or the Drug name by clicking one of the blue radio buttons behind the **Pref** and **Drug** fields. Drug is the default.

Note! When exporting medical coding, both the preferred drug and drug name are included in the export (in separate columns). But if you select to apply **Pref** while coding, the preferred name ends up in both columns in the export. This is to provide consistency for the data managers, so that they only have to look in one column to find their data.

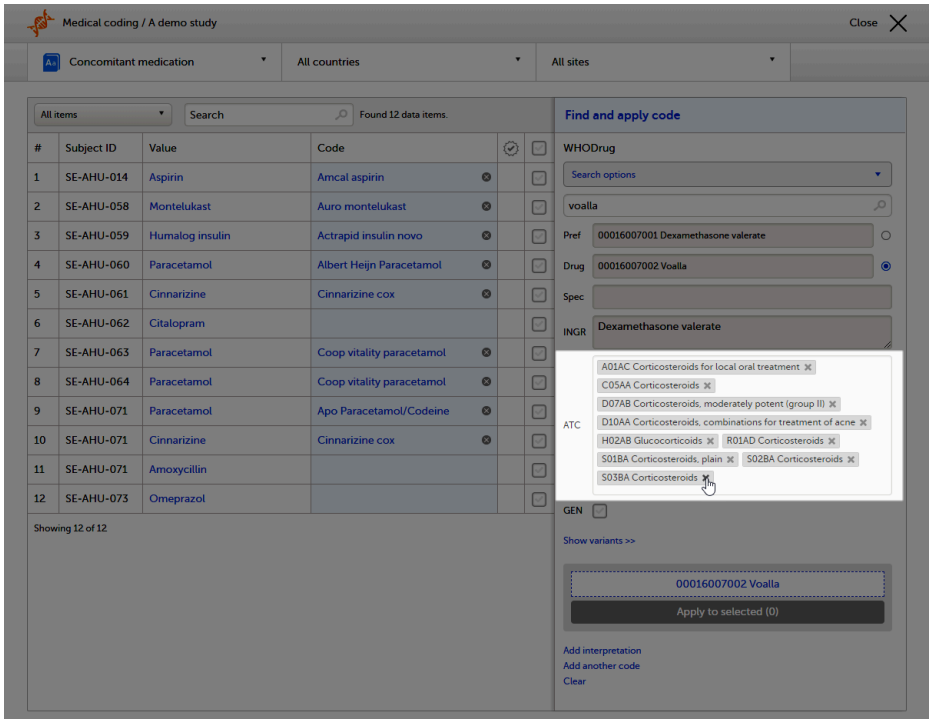


Click **Show variants** to display and specify variants of the selected code (drug), and use the drop-down lists to select Country (CNTR), Marketing Authorization Holder (MAH), Pharmaceutical Form (FORM), Strength (STR), or Medicinal Product ID (MPID), if applicable. Click **Hide variants** to hide the variants, see image.

If you would like to add more than one code to the same field, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset you selections by clicking **Clear**.

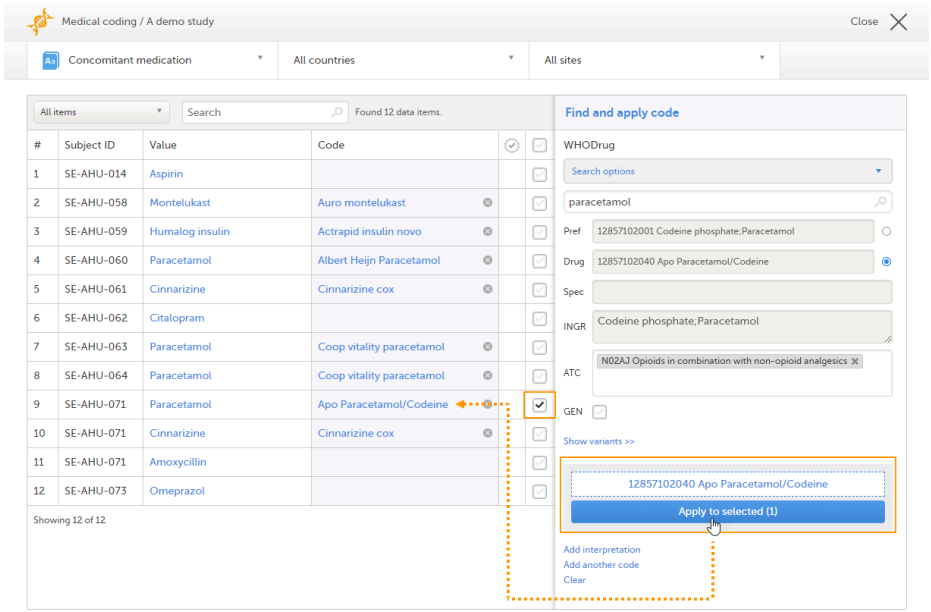
Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code..

If you selected a drug that carries multiple Anatomic Therapeutic Chemical Classification System (ATC) codes, all ATC codes will be displayed in the **ATC** field. You can define whether to include all ATC codes in the coding or only a selection. Click the cross to remove an ATC code, or click the **ATC** field to add ATC codes.



3.2.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values.



You can remove an applied code by clicking the cross icon to the right of the applied code.

4 Approving the medical coding

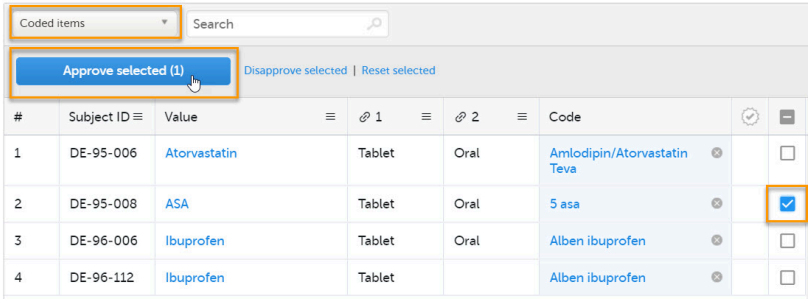
After applying codes to the items, it is possible to approve/disapprove/reset the items as shown in the below table.

Action	Current state/found in list	New state/found in list
Approve	Coded Disapproved	Approved items
Disapprove	Coded Approved	Uncoded items
Reset	Approved Disapproved	Coded items

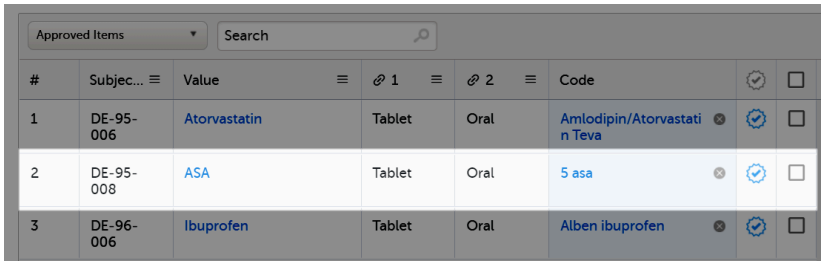
Tip! To see all items in one list, select the filter **All items**.

To approve items that have been coded:

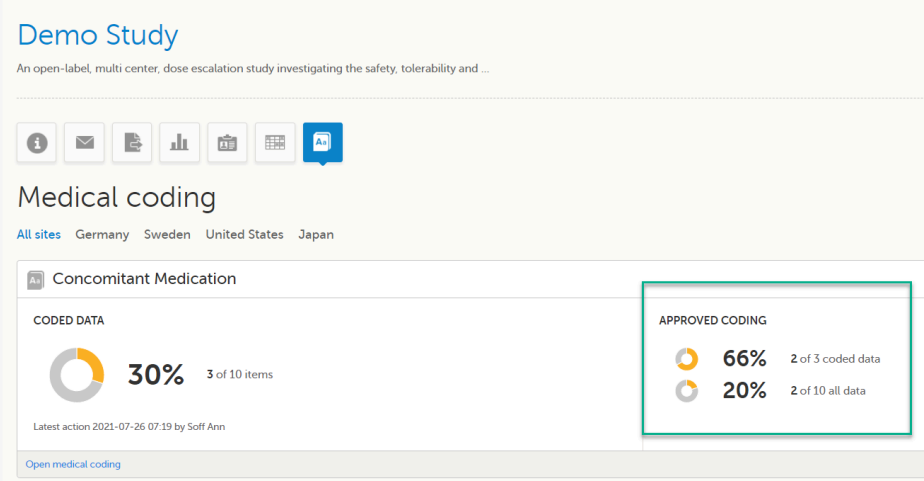
1 Select the item(s) that you want to approve and click **Approve selected**.



2 The selected item(s) now disappear from the list and are found with the blue "Approved" symbol in the Approved items list.



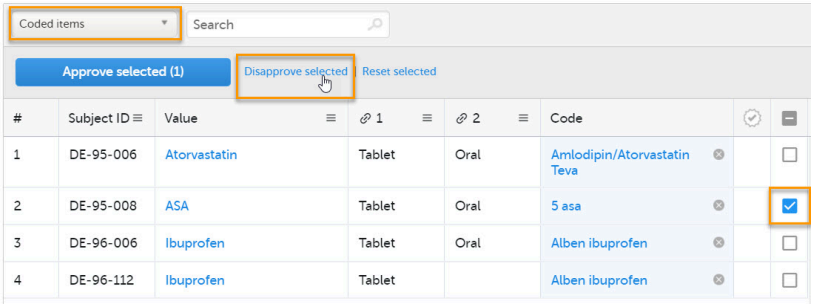
Tip! The metrics of the medical coding that have been approved can be seen on the landing page:



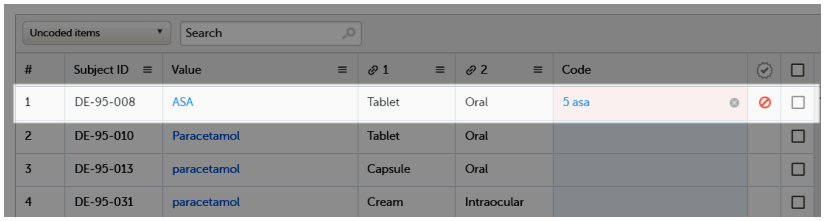
4.1 Disapproving the medical coding

To disapprove items that have been coded:

1 Select the items that you want to disapprove and click **Disapprove selected**.



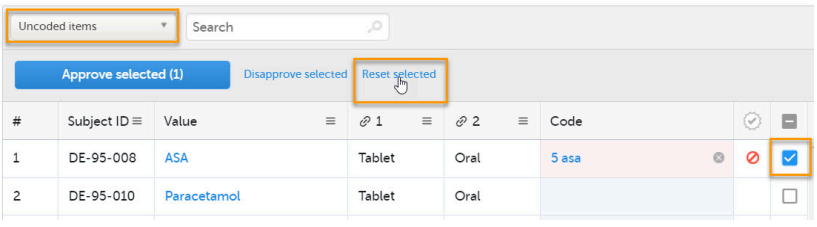
2 The selected item(s) now disappear from the list and are found with the red "Disapproved" symbol in the Uncoded items list for re-evaluation.



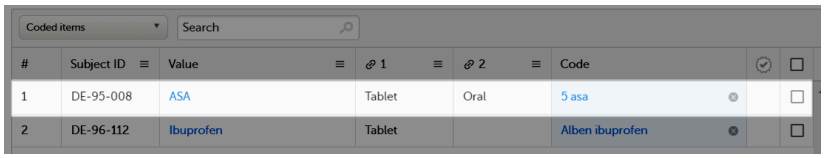
4.2 Resetting the medical coding

To reset items that have been approved or disapproved:

1 Select the item(s) that you want to reset and click **Reset selected**.

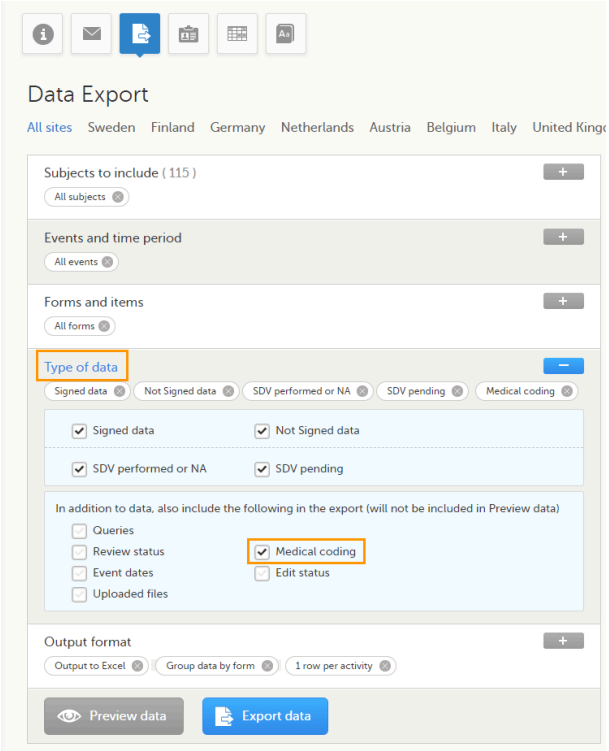


2 The selected item(s) now disappear from the list and are found in the Coded items list without the approved/disapproved flag.



5 Exporting the medical coding

It is possible to export medical coding using the export feature of Viedoc, see Exporting data.



To export the medical coding, select the checkbox in front of **Medical coding** in the **Type of data section**.

For more information about how medical coding is exported, see:

- Medical coding in ODM export
- Medical coding in Excel export

Note! You can only export medical coding if permission to export data is activated for your role. If you do not see the data export icon, you do not have a role with export permissions.

Managing Viedoc Me

Managing Viedoc Me

Published by Viedoc System 2024-10-10

1. Introduction
2. Activating the Viedoc Me account
    2.1 Sharing Viedoc Me Account Login Info with the subject
    2.2 Verifying the subject's contact information
    2.3 Resetting the PIN Code
    2.4 Quick access to Viedoc Me
3. Locking and unlocking the Viedoc Me account
4. Checking the status and subject activity
    4.5 Download log
    4.6 Viedoc Me account overview

This lesson applies to site staff managing the Viedoc Me application.

1 Introduction

If applicable for the study, a Viedoc Me account can be activated, allowing the subject to submit data to the study through any device using a web browser (phone, tablet, computer).

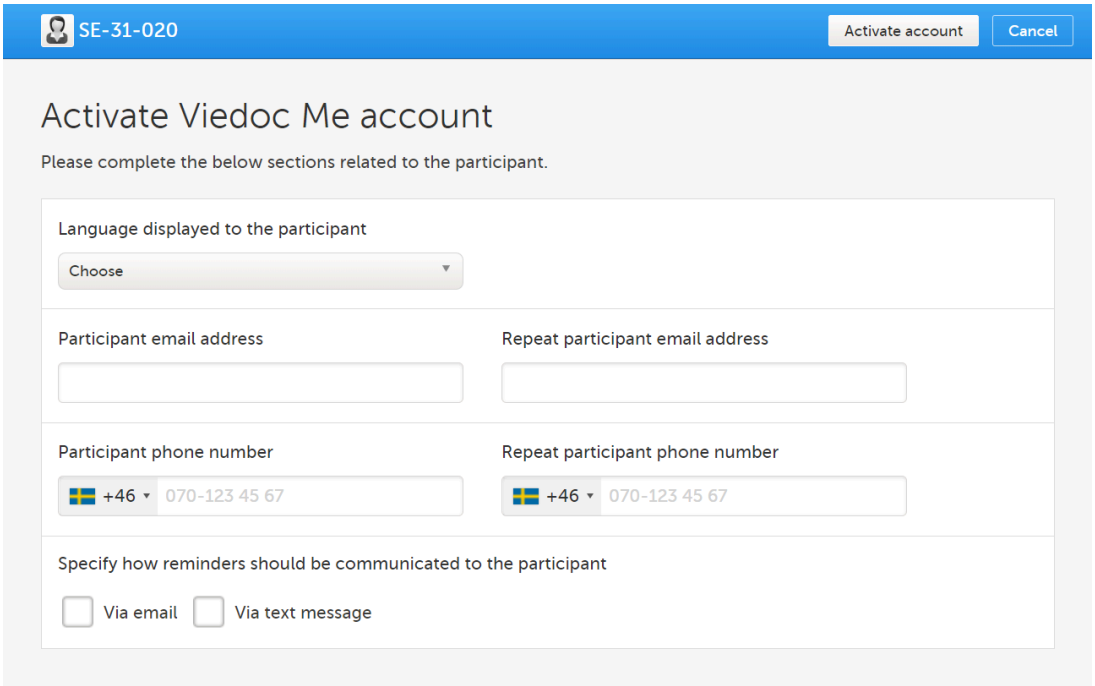
Note! Only user roles with editing permissions for the study start event form can activate a Viedoc Me account. If you do not have editing permissions, the phone icon (as seen in the image below) will not be visible on the Details page.

2 Activating the Viedoc Me account

To activate a Viedoc Me account for a subject:

1 Open a subject card and select the **phone icon** located in the top right corner of the Details page:

The **Activate Viedoc Me account window** opens:



2 **Language displayed to the participant**

Choose the language that should be displayed to the subject by selecting the language from the dropdown list.

3 **Participant email address** and **Participant phone number**

Enter the subject's email and/or phone number. These must be entered twice to ensure correct data entry.

Note! These options are only visible if the functionality for "sharing of access details" (login info) via email and/or text message has been enabled in the study settings. Please contact your study manager to have this option enabled.

4 **Specify how reminders should be communicated to the participant**

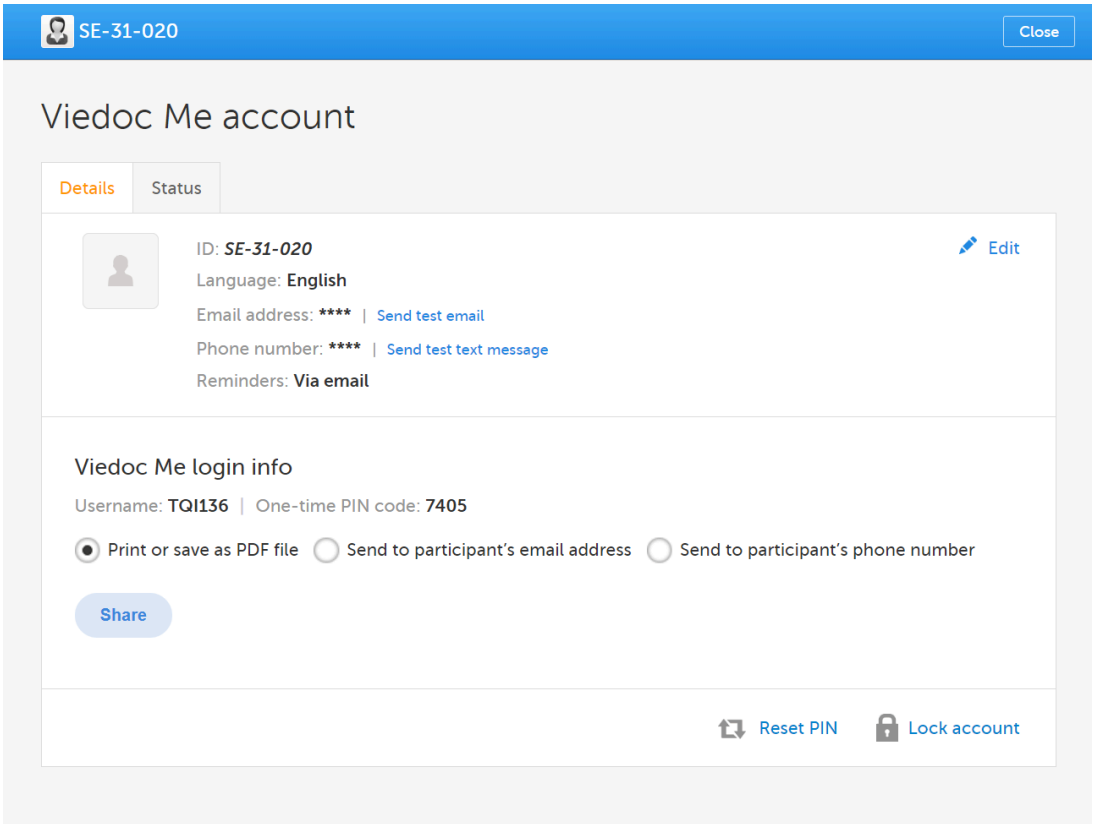
Select whether to send reminders via email and/or via text message.

Note! These options are only visible if the functionality for "allow activity reminders" via email and/or text message has been enabled in the study settings. Please contact your study manager to have this option enabled.

The reminder settings can also be changed at any time after the Viedoc Me account activation.

Test messages can be sent out to the entered email address and/or phone number, see Verifying subject email address and phone number.

5 Select **Activate account** at the top right. The **Viedoc Me Account window** will display the subject's account details and login info:



The Viedoc Me Account activation process is now complete.

To share the login info with the subject, please continue with the steps below.

Note! You may only activate one subject's Viedoc Me account at a time.

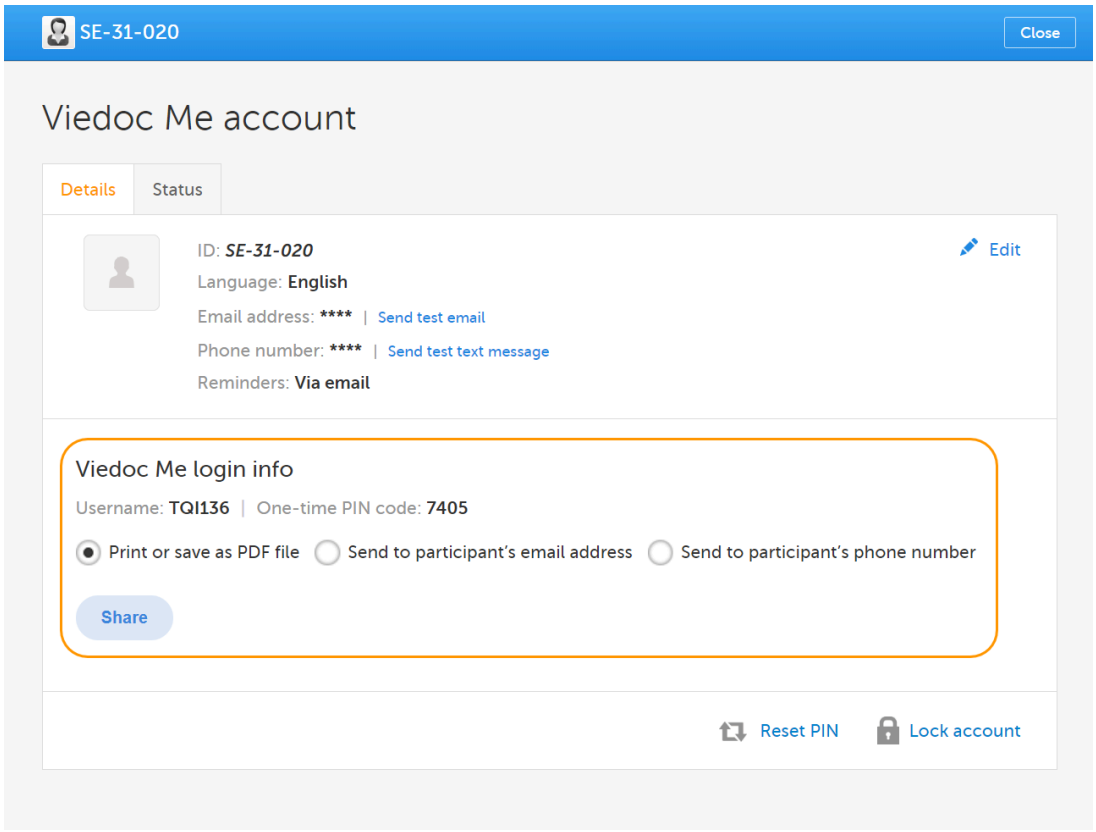
2.1 Sharing Viedoc Me Account Login Info with the subject

After the Viedoc Me account has been activated, there are several options to share the login info with the subject. This may be done at any time and repeated as often as needed.

To share login info with a subject:

1 Open a subject card and select the **phone icon** located in the top right corner of the Details page:

The **Viedoc Me Account window** is displayed:



2 Select the options for sharing the Viedoc Me login info with the subject:

- Select **Print or save as PDF file** to download a PDF with the Viedoc Me login info. This can be printed and given to the subject on paper, or shared as a PDF through other means.
- Select **Send to participant's email address** to send the Viedoc Me login info via email.
- Select **Send to participant's phone number** to send the Viedoc Me login info via text message.

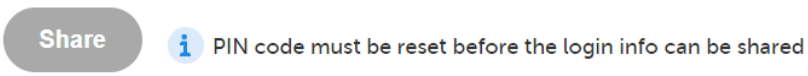
Note! If the functionality to "share Viedoc Me access details" (login info) via email and/or text message has not been enabled in the study settings, then only the option to Print or Save as PDF file will be visible here. Please contact your study manager to have this option enabled.

Note! The Viedoc Me login page URL always contains the string "idp". This is expected behavior.

3 Once the sharing method has been selected, select **Share** to complete the action:

- If **Print or save as PDF file** was selected, a PDF with the Viedoc Me login info will be downloaded in your browser.
- If **Send to participant's email address** was selected, an email with the Viedoc Me login info will be sent to the subject.
- If **Send to participant's phone number** was selected, a text message with the Viedoc Me login info will be sent to the subject.

Note! After sharing the login info, if you wish to share again with the subject you will receive a message next to the share button stating that the PIN must be reset before sharing the login info again:



Follow instructions on Resetting the PIN code below.

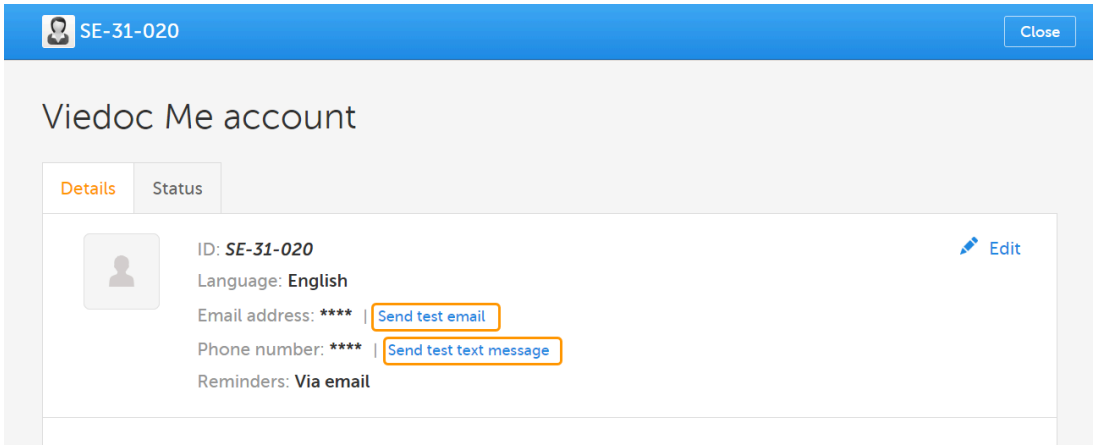
2.2 Verifying the subject's contact information

To verify a subject's contact information is correct, a test email/text message can be sent. The test emails and text messages sent from Viedoc cannot be replied to.

Note! Sending a test email or text message is only possible if the functionality for "sharing of access details" (login info) and/or "allow activity reminders" via email and/or text message has been enabled in the study settings.

To send a test email and/or text message:

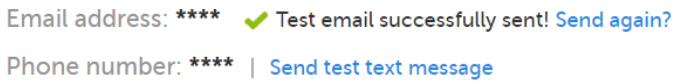
1 In the subject's details page, select the phone icon to open the **Viedoc Me Account window**. Select **Send test email** and/ **Send test text message**.



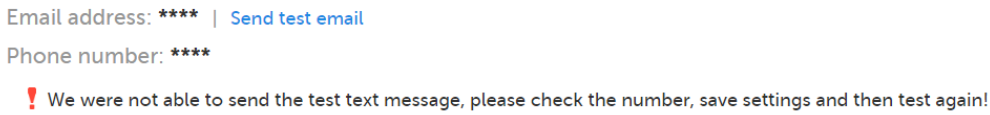
Note! The Send Test links are available only after the email address and/or the phone number was entered and **saved**. All changes done in the Viedoc Me account window must be saved in order for the test links to be available.

2 The result of sending out the test email/text message is displayed by a message.

If a test message was **successfully** sent:



If a test message **failed** to send:



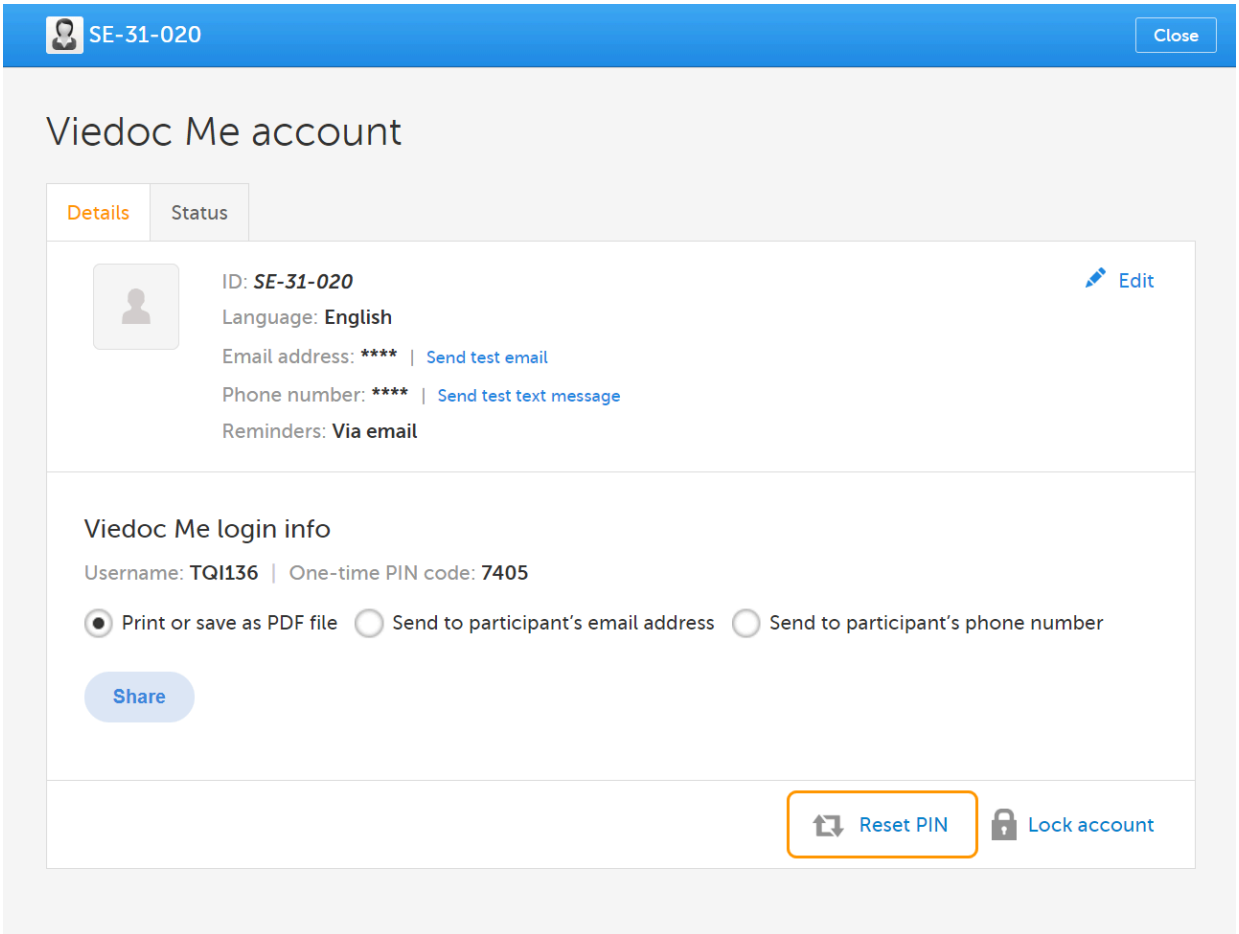
In this case you might want to enter the email address/phone number again by selecting **edit**, save the changes, and try to send the test message again.

Note! A successfully sent message does not confirm the correct email/phone number, only that it was sent out successfully from Viedoc. Please confirm with the subject that the message was received to ensure the email/ phone number is correct.

3 The test message(s) may be sent again by selecting **Send again** (for example, if the subject cannot confirm they have received the message).

2.3 Resetting the PIN Code

The subject's PIN can be reset at any time by selecting **Reset PIN**:



After the PIN is reset, you will need to share the login details again via PDF, email or text message by following steps 5 and 6 above.

Important! The account must be unlocked before the new PIN can be used for login. See Locking and Unlocking the Viedoc Me Account below for more information.

2.4 Quick access to Viedoc Me

If the subject is using Viedoc Me on a mobile phone, saving the URL as a shortcut on the home screen of the device can make future logins easier. Similarly, the Viedoc Me URL can be saved as a bookmark/favorite on a computer. Instructions on how to do this, and other valuable information for Viedoc Me users can be found in the Using Viedoc Me (Information for study participants) lesson.

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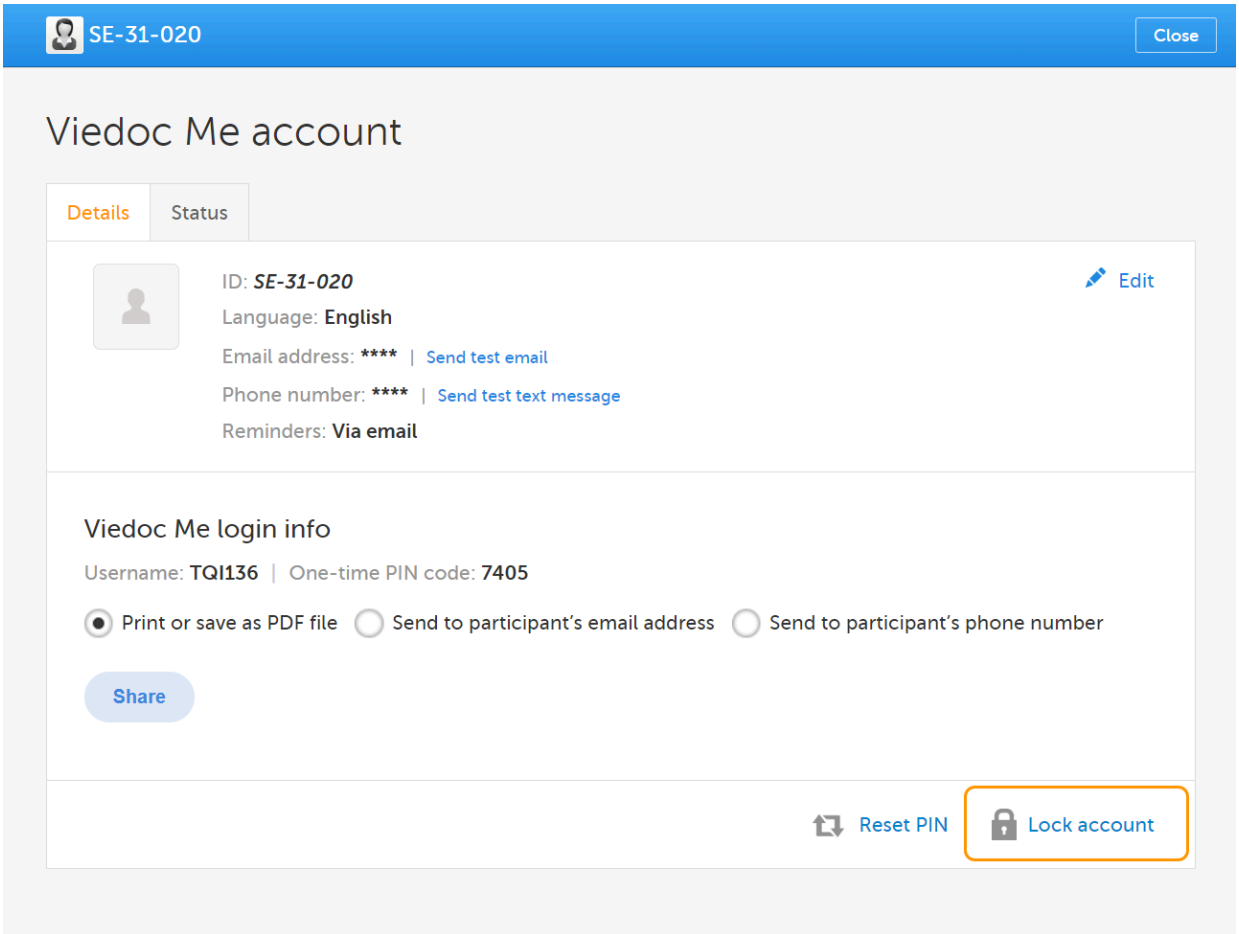
3 Locking and unlocking the Viedoc Me account

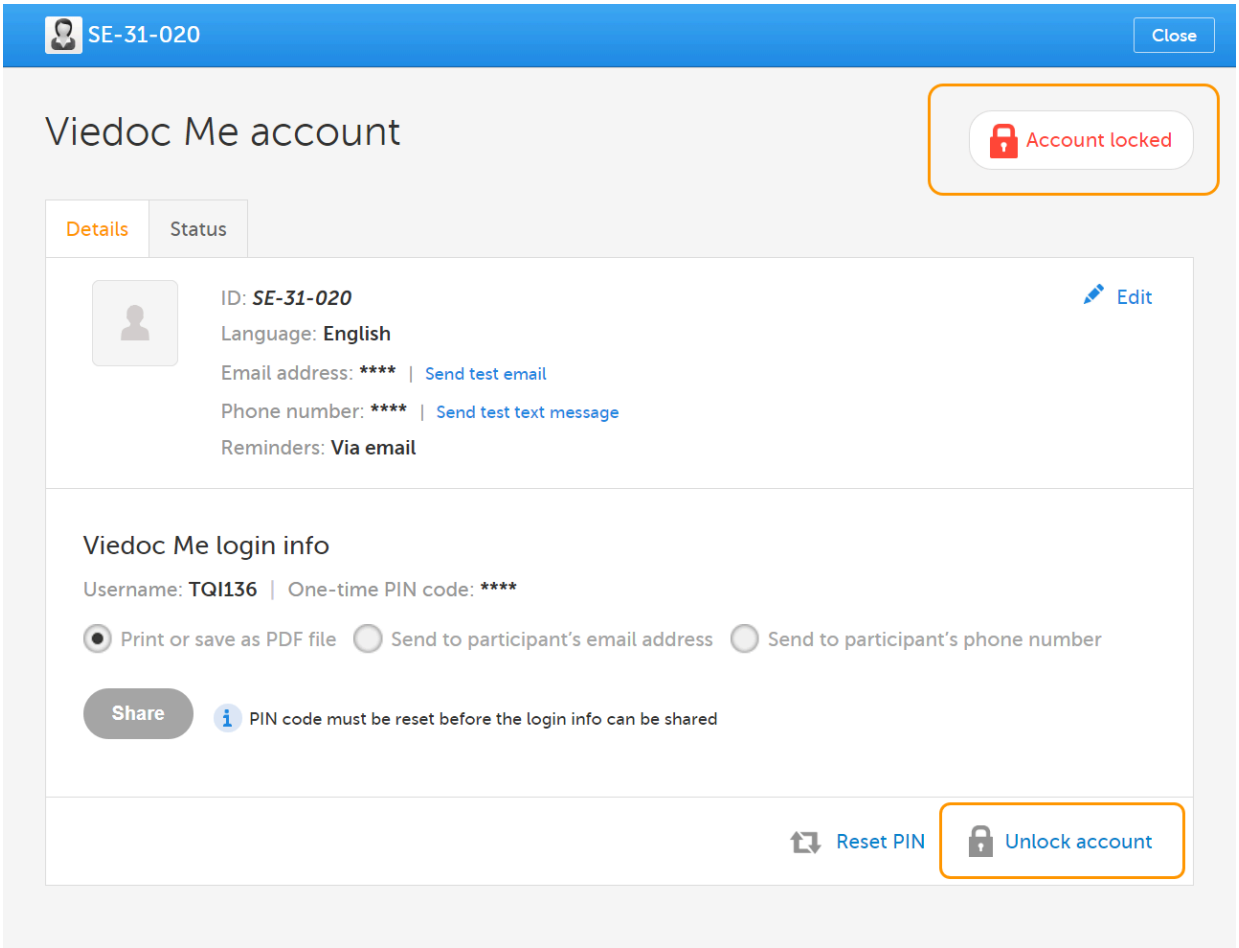
The Viedoc Me account can be locked/unlocked by selecting the **Lock/Unlock account** link in the Viedoc Me account details window:



Note! The account is automatically locked if the subject enters incorrect login details more than 3 times. If this occurs, an alert email is sent out with information about the locked account. The users that receive this email are site and monitoring staff, if their user role is configured with:

- access to the same site as the subject
- either data entry permissions and/or Clinical Review/SDV permissions, where data entry permissions is defined as any data entry permissions. and not only permissions for the study start event.

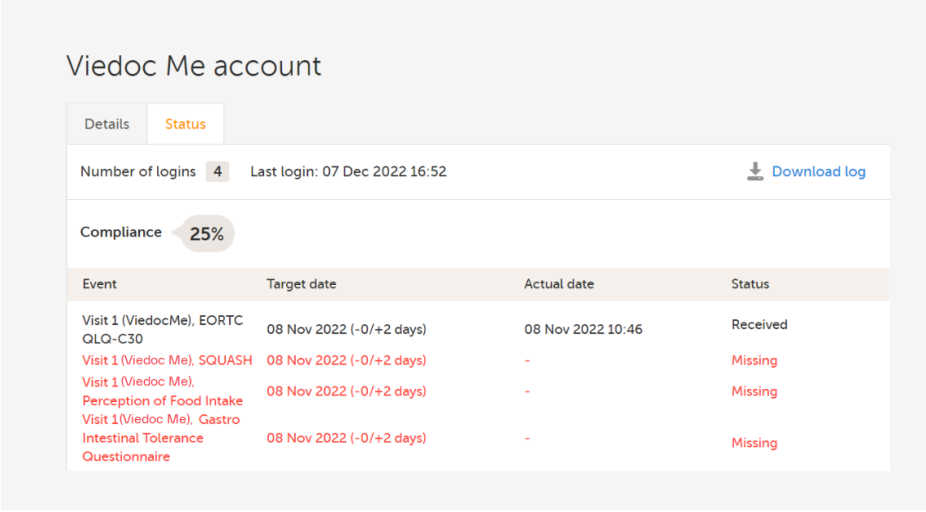
When the account is locked (either manually or automatically), this is marked by a red **Account locked** icon in the top-right corner of the Viedoc Me account details window. To unlock it, select the **Unlock account** link in the bottom-right corner:



4 Checking the status and subject activity

You can check the **Status** tab of the **Viedoc Me account window** for status of incoming questionnaires and activity.

Here you can see how many times the subject logged in, when they last logged in, compliance, and when incoming questionnaires are expected:



4.1 Download log

All activities related to the Viedoc Me account can also be downloaded as an Excel file by selecting **Download log**.

The Excel file contains the following sheets: the Account Activities sheet and the Communication log sheet.

In the Account activities sheet, the following activities are saved, with the latest activity saved in the top row of the Excel file:

- *Date**
- *Time**
- *Activity*
- *User name (site user at Clinic or subject)*
- *Submitted data/event name*
- *Submitted data/form name*
- *Submitted data/target date**
- *Submitted data/actual date**
- *Submitted data/status*
- *Login result*
- *PIN (Hashed)*
- *Change email (Hashed)*
- *Change phone (Hashed)*
- *Change reminder settings (email on/off, text message on/off)*

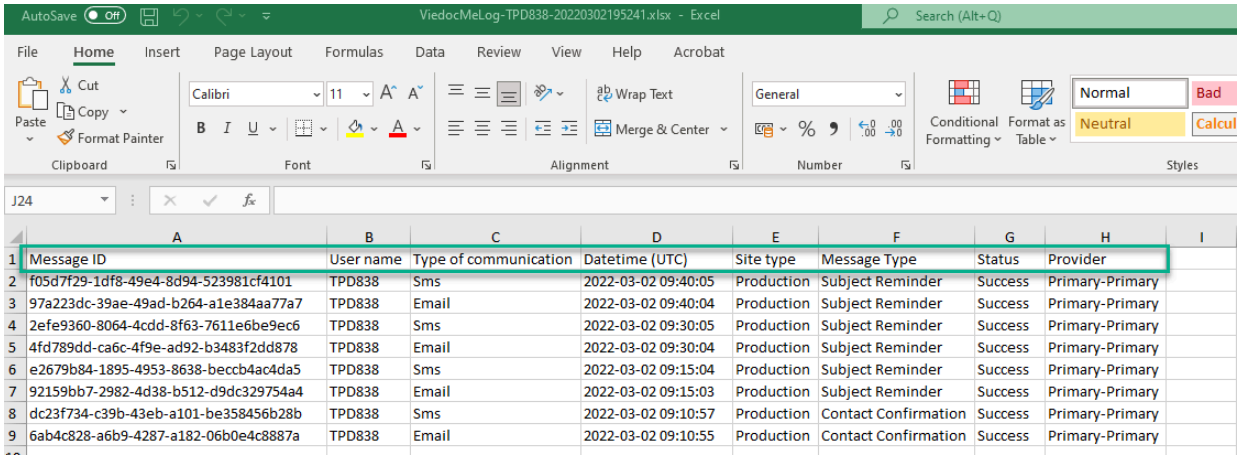
**Date and time of the site*

To the right of the Account activities sheet is the Communications log sheet which contains information about all the emails and SMS messages sent to that subject.

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

The Communications log contains the following information:

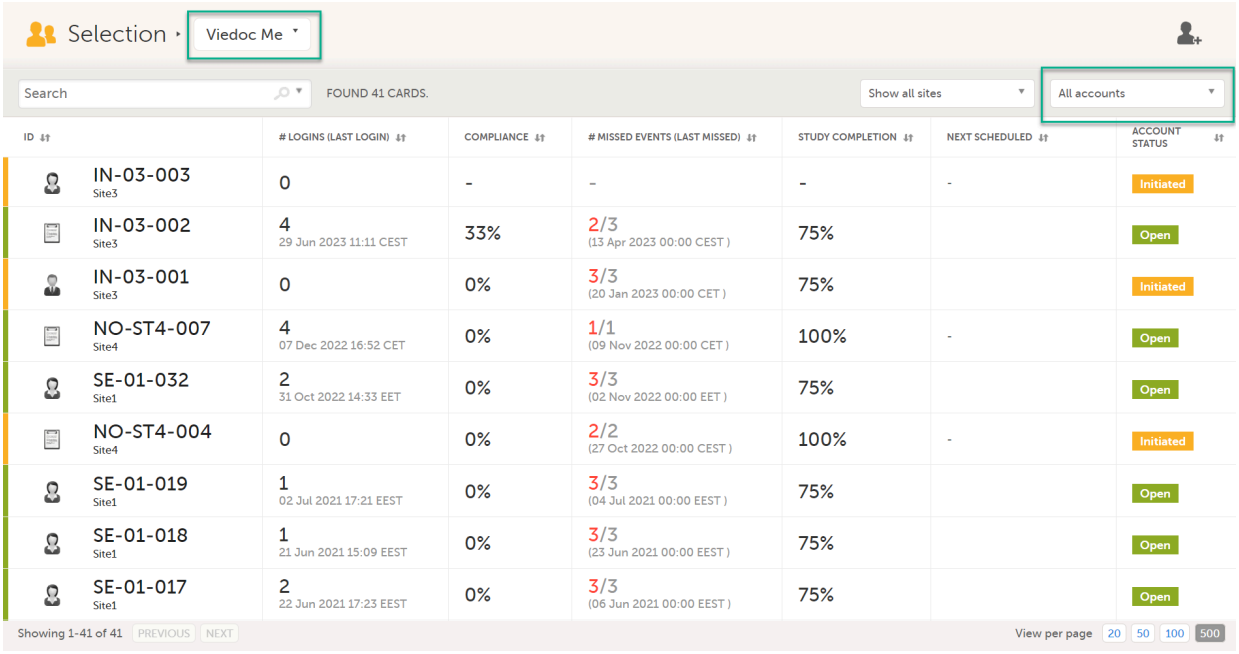
- *Message ID - GUID*
- *User name - (as in Viedoc Me account)*
- *Type of communication - SMS/Email*
- *Datetime (UTC) - datetime for when the communication happened*
- *Site type - Training/Production*
- *Message Type - (Subject Reminder/Contact Confirmation)*
- *Status - Success/Failed*
  Note! **Success** 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**.
- *Provider - Proxy (Primary/Secondary) - the provider that was used to send the message. (This information is used if needed for troubleshooting purposes).*



	A	B	C	D	E	F	G	H	I
1	Message ID	User name	Type of communication	Datetime (UTC)	Site type	Message Type	Status	Provider	
2	f05d7f29-1df8-49e4-8d94-523981cf4101	TPD838	Sms	2022-03-02 09:40:05	Production	Subject Reminder	Success	Primary-Primary	
3	97a223dc-39ae-49ad-b264-a1e384aa77a7	TPD838	Email	2022-03-02 09:40:04	Production	Subject Reminder	Success	Primary-Primary	
4	2efe9360-8064-4cdd-8f63-7611e6be9ec6	TPD838	Sms	2022-03-02 09:30:05	Production	Subject Reminder	Success	Primary-Primary	
5	4fd789dd-ca6c-4f9e-ad92-b3483f2dd878	TPD838	Email	2022-03-02 09:30:04	Production	Subject Reminder	Success	Primary-Primary	
6	e2679b84-1895-4953-8638-beccb4ac4da5	TPD838	Sms	2022-03-02 09:15:04	Production	Subject Reminder	Success	Primary-Primary	
7	92159bb7-2982-4d38-b512-d9dc329754a4	TPD838	Email	2022-03-02 09:15:03	Production	Subject Reminder	Success	Primary-Primary	
8	dc23f734-c39b-43eb-a101-be358456b28b	TPD838	Sms	2022-03-02 09:10:57	Production	Contact Confirmation	Success	Primary-Primary	
9	6ab4c828-a6b9-4287-a182-06b0e4c8887a	TPD838	Email	2022-03-02 09:10:55	Production	Contact Confirmation	Success	Primary-Primary	

4.2 Viedoc Me account overview

If applicable for your study, you can see an overview of the Viedoc Me accounts on the Selection page:



For more information, see Views on the Selection page in the lesson Selection page.

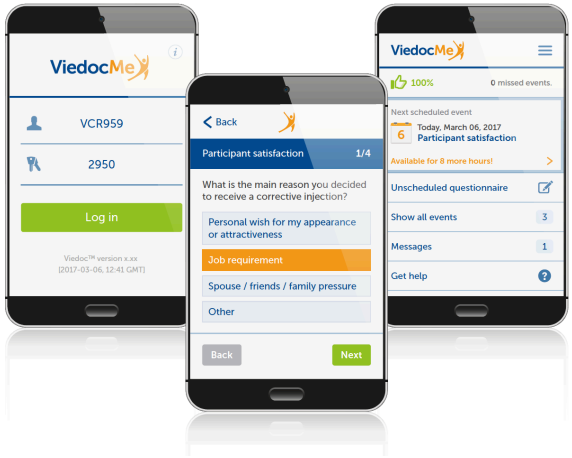
Using Viedoc Me (information for study participants) version 4.70 and earlier

Published by Viedoc System 2024-06-26

1. Introduction to Viedoc Me
2. Access to Viedoc Me
    2.1 Document with login details
    2.2 Logging in to Viedoc Me
    2.3 Quick access to Viedoc Me
3. Events
    3.4 Filling in a questionnaire of a scheduled event
    3.5 Filling in a questionnaire of an unscheduled event
4. Video calls
5. Good to know
    5.6 Reminders via email or text message
        5.6.1 Setting reminders and changing your contact information
    5.7 Changing your PIN code
    5.8 Help
    5.9 Log out
    5.10 If you lose internet connection

1 Introduction to Viedoc Me

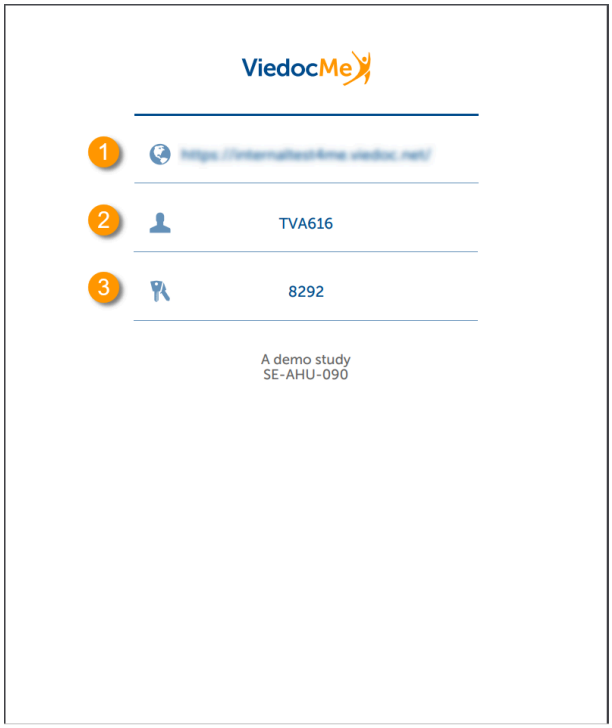
Viedoc Me is a web application used for collecting data from patients participating in clinical trials. It works on any device: a computer, tablet, or mobile phone, as long as the device has a browser and access to the Internet. The application enables you to fill in questionnaires and submit them.



2 Access to Viedoc Me

2.1 Document with login details

Access to Viedoc Me is provided by your doctor, nurse, or other contact at the clinic. You will be provided with a document that looks as follows:



The document contains the following info:

1. The URL (web address) to Viedoc Me.
2. Your user name. The user name consists of three characters followed by three numbers, for example *TVA616*.
3. Your PIN code. The PIN code consists of four numbers.

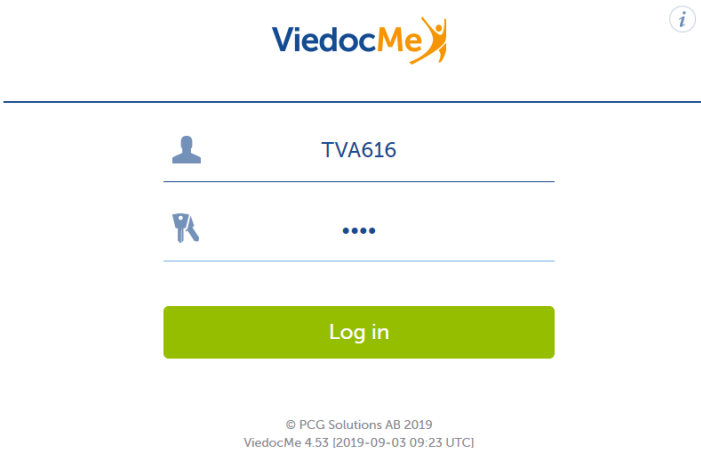
Note! When you enter the URL (web address) from the login information PDF in a browser, you are redirected to a URL that looks slightly different and that contains the string "idp". This is the expected behavior.

2.2 Logging in to Viedoc Me

To log in to Viedoc Me:

1 Open a web browser on your device. Type the URL that is stated on your document in the address bar.

The Viedoc Me login page opens.



2 Type your user name in the field next to the person symbol.

3 Type your PIN code in the field next to the key symbol.

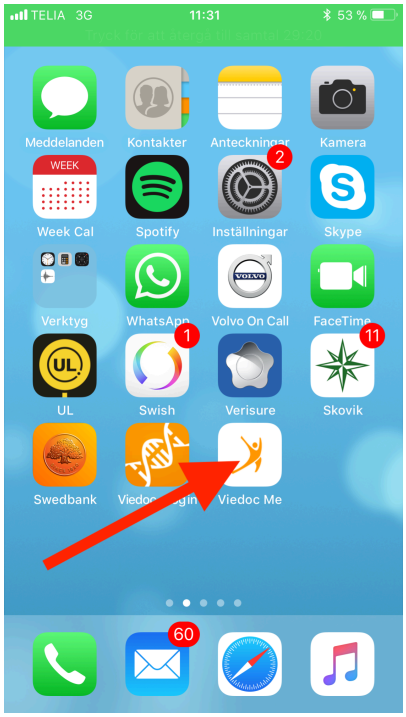
4 Select **Log in**.

Note! When logging in for the first time, you may be prompted to change you PIN code, if applicable for the study you are participating in. This will also be the case if the clinic staff have reset your PIN code:

Enter a new PIN code and select **Save** and then select **Continue** in the next window.

2.3 Quick access to Viedoc Me

If you are using Viedoc Me on a mobile phone, future logins can be done easier by saving the URL. It will appear as an app on the home screen of the device:



To save Viedoc Me as an app:

1 Open a web browser on the phone and navigate to the URL that is stated in the document provided to you.

2 Select the option *Save to home screen* or anything similar to that, depending on the device.

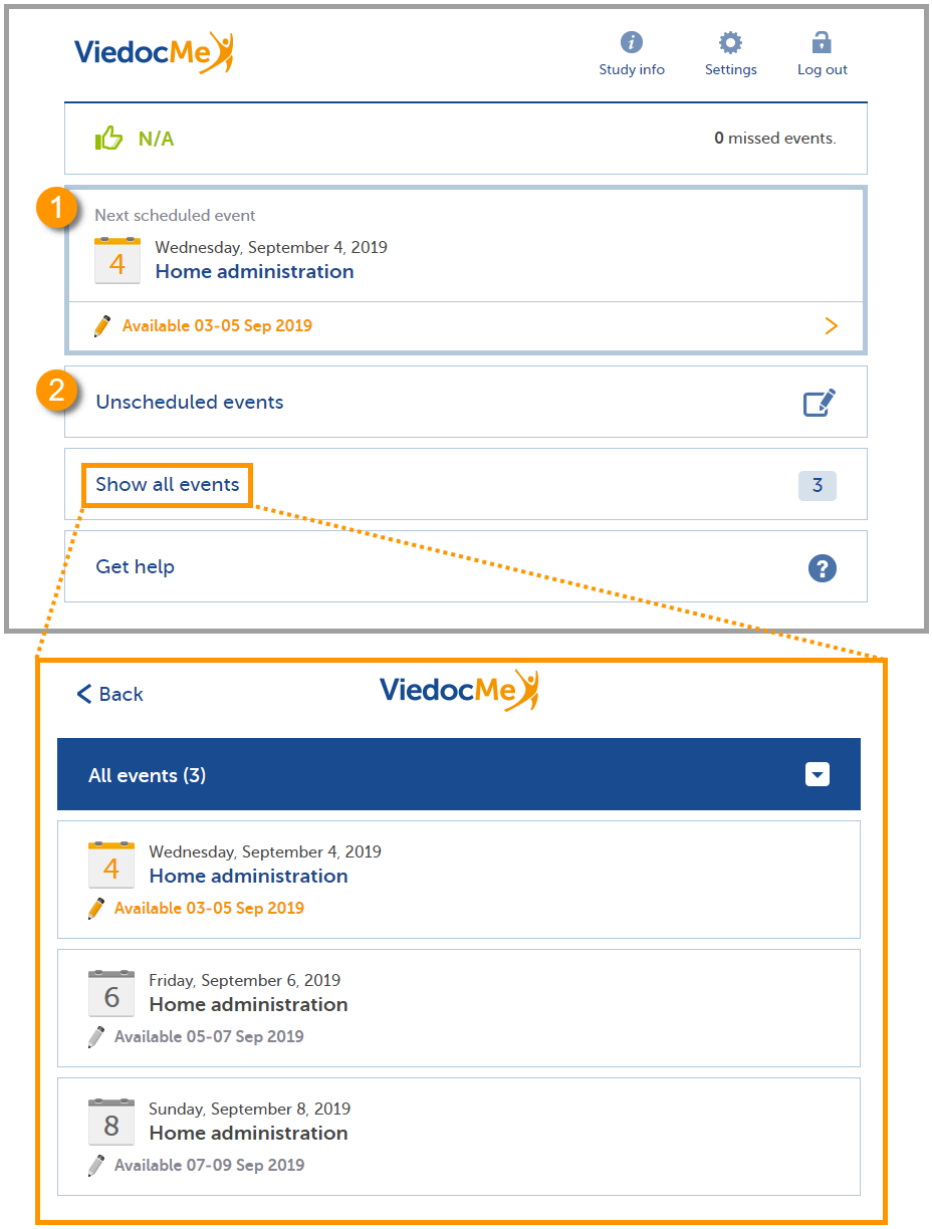
The Viedoc Me application is now available as an app on the phone.

Similarly, you can save the Viedoc Me URL as a bookmark/favorite on your computer.

3 Events

There are two types of events:

1. Scheduled events
   Under **Next scheduled event** (1), you see the next questionnaire that is to be filled in, and the time during which it is available. This questionnaire is part of the scheduled events that are planned for the study. These scheduled events are displayed on the Viedoc Me start page, one at a time, in the order in which they are scheduled. If you want to see all scheduled events, select **Show all events**, and a list of all scheduled events appears (see image).
2. Unscheduled event
   For some studies, you can spontaneously report data outside of the time frames of the scheduled events. These reports/questionnaires are called **Unscheduled events** (2), and can be added at any time, in an unlimited number of times. Note that unscheduled events are not used in all studies, so they might not be available for the study you are participating in.



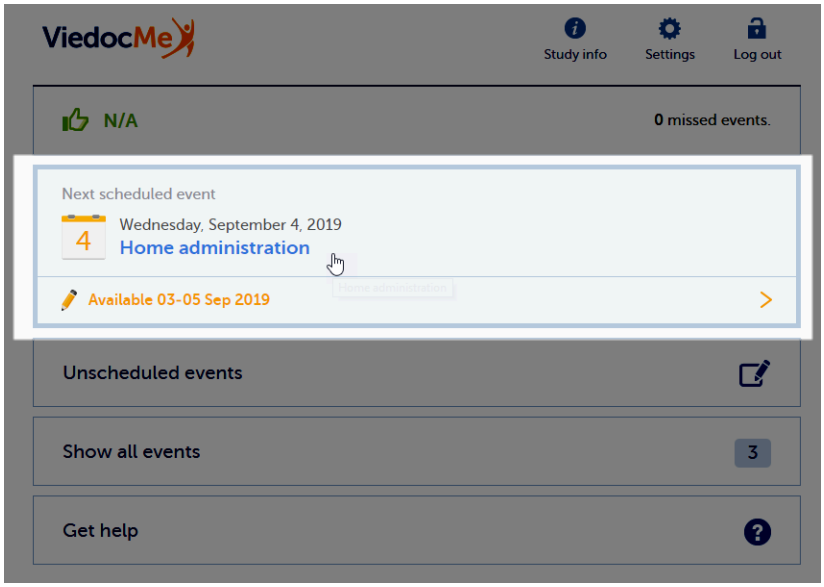
Note! The names of the questionnaires differ depending on the study. The above image is just an example!

3.1 Filling in a questionnaire of a scheduled event

To fill in a questionnaire of a scheduled event:

Note! You can only fill in a scheduled event (questionnaire) during the period it is available.

1 Select the **Next scheduled event**.
In the example below, the event name is *Home administration*. Note that it may have another name in your study.



The questionnaire opens.

2 Enter your answers to the questions. If there are multiple pages, you can navigate to the previous page by selecting **Back**, or to the next page by selecting **Next** (only if you have provided an answer to the question).

3 When you have answered the last question, select **Send** to submit the data.
The date and time of submission will be saved together with the data.

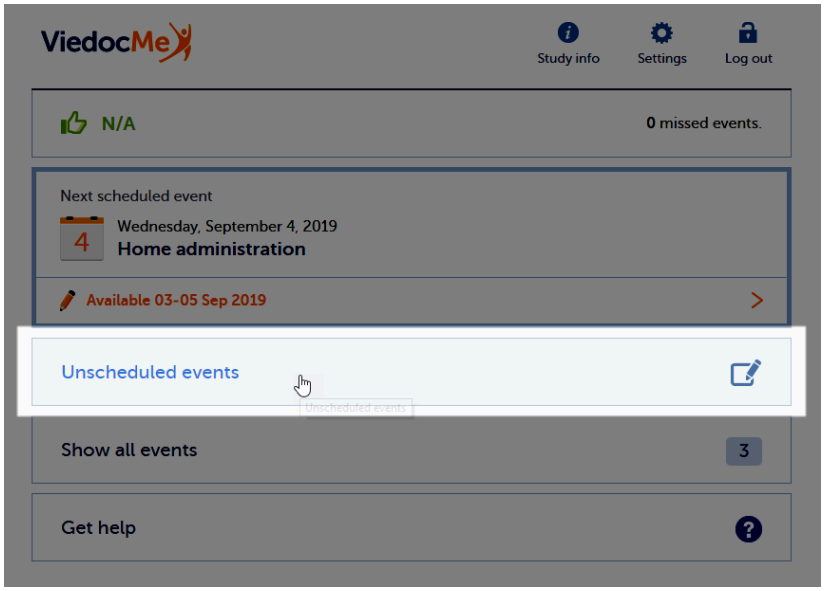
4 Select **Go to startpage** to return to the Viedoc Me start page.

3.2 Filling in a questionnaire of an unscheduled event

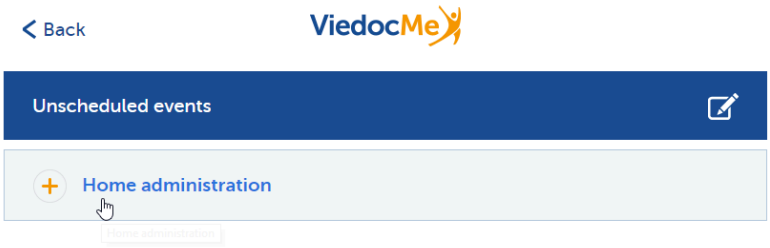
If the study allows, you might be able to spontaneously report data at any time.

To fill in a questionnaire of an unscheduled event:

1 Select **Unscheduled events**.



2 Select the name of the questionnaire next to the orange + icon.
In the example below, the name is *Home administration.* Note that it may have another name in your study.



The questionnaire opens.

3 Enter your answers to the questions. If there are multiple pages, you can navigate to the previous page by selecting **Back**, or to the next page by selecting **Next** (only if you have provided an answer to the question).

4 When you have answered the last question, select **Send** to submit the data.
The date and time of submission will be saved together with the data.

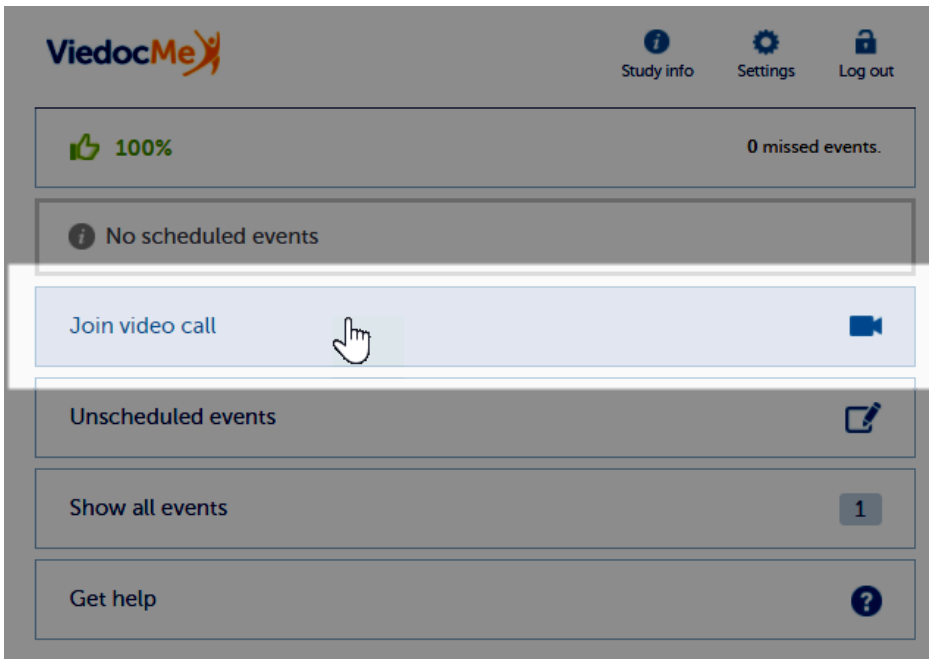
5 Select **Go to startpage** to return to the Viedoc Me start page.

---

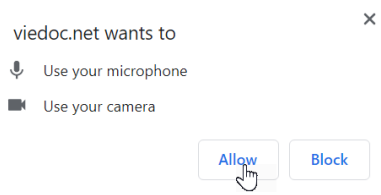
4 Video calls

The Viedoc Connect application allows the clinic staff to initiate a video call with you.

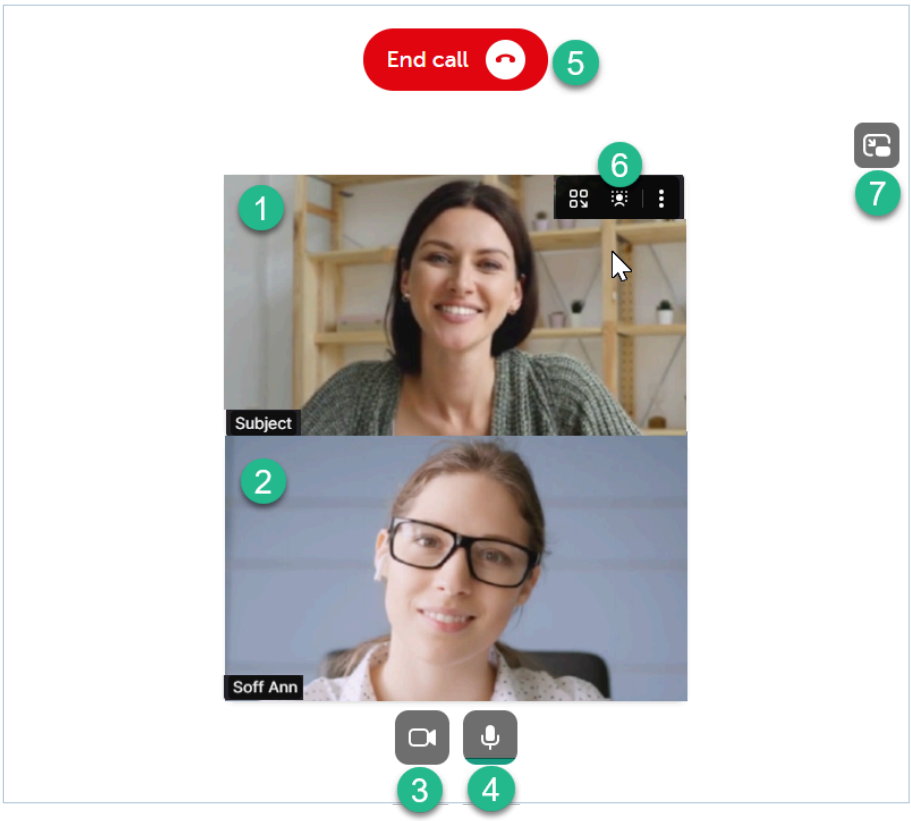
When your doctor has initiated a call, the video call module in Viedoc Me flashes in blue with the text **Join video call**. Select anywhere on the module to join the call.



Note! It's important to allow your web browser to access your camera and microphone, if prompted:



During the call, you will see the following screen:



1. The subject's screen (you)

2. The doctor's screen

3. Camera settings - select to disable the camera, hover to see more settings.

4. Microphone settings - select to mute your mic, hover to see more settings.

5. End call button - select to end the call.

6. More screen settings - hover over the participant's screen to show available options in the upper right corner.

7. Picture-in-picture - select to continue the video call with a remotable screen that will be shown even if you switch tab. Hover over the mini-screen and select **Back to tab** to return to the video call main screen.

---

5 Good to know

5.1 Reminders via email or text message

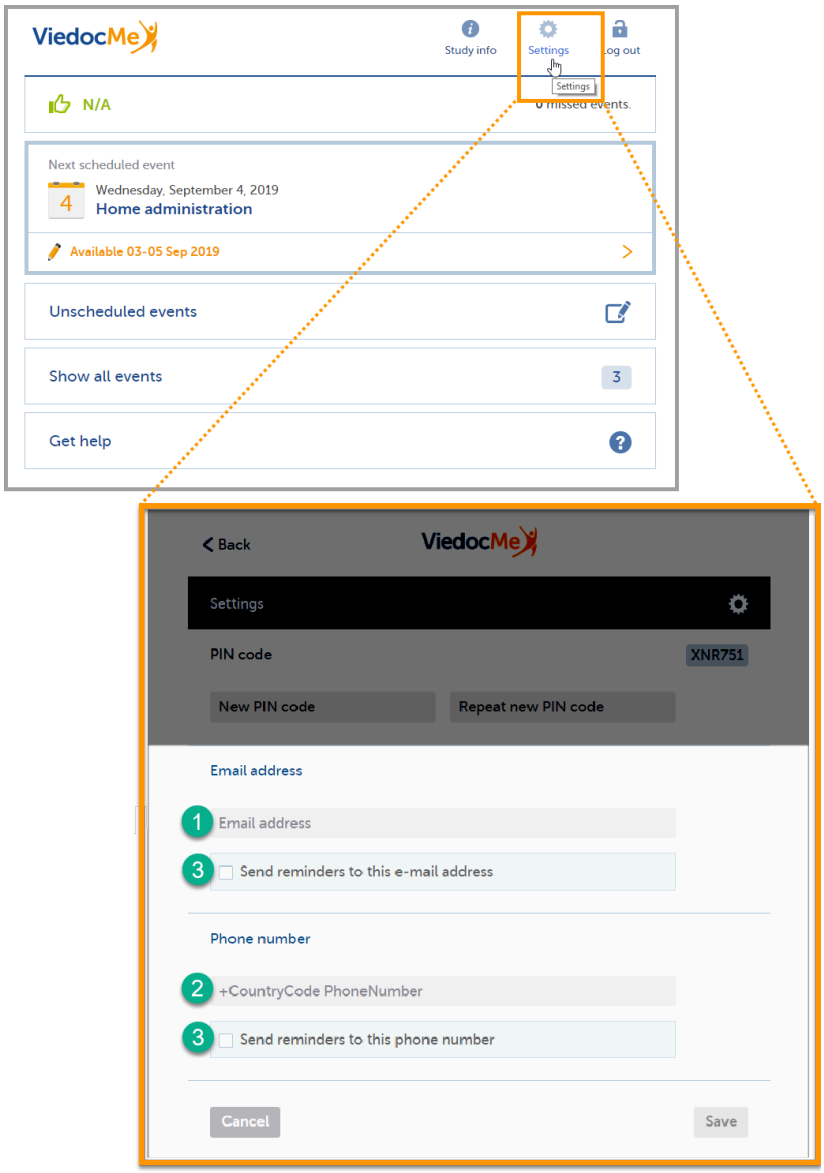
The Viedoc Me application can send reminders to remind you of upcoming scheduled events. These reminders are configured by the study staff at the clinic and can be sent as an email and/or a text message (sms). Note that you cannot reply to emails sent from Viedoc.

If applicable for the study you are participating in, you can change your email, phone number, and reminder settings if needed. If this option is not configured for your study, please inform the study staff at the clinic if you need to update your contact information and/or reminder settings.

5.1.1 Setting reminders and changing your contact information

To change your contact information and reminder settings, if applicable for the study you are participating in:

1 Select **Settings** and enter a new email address (1) and/or phone number (2). Make sure to include the country code in format `+[CountryCodePhoneNumber]` .



2 Check the box(es) (3) to allow Viedoc to send reminders to the email and/or phone.

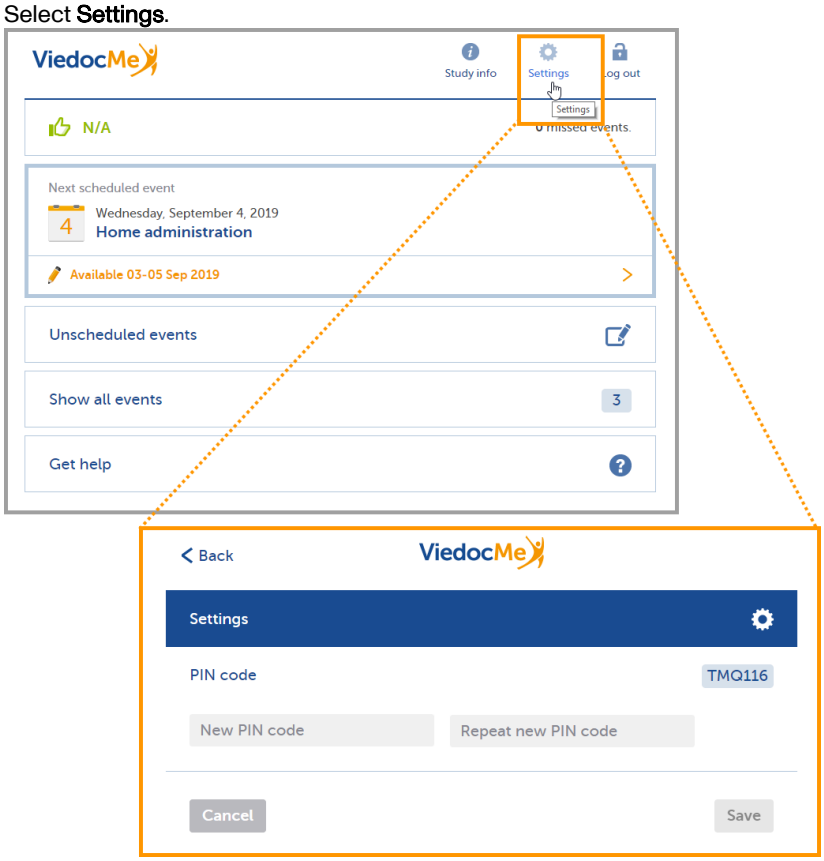
3 Select **Save** to save the changes.

5.2 Changing your PIN code

You can change the PIN code that was provided to you.

To change the PIN code:

1 Select **Settings**.



2 Enter a new PIN code in the field **New PIN code**, and repeat it in the field **Repeat new PIN code**.

3 Select **Save** to save the changes.

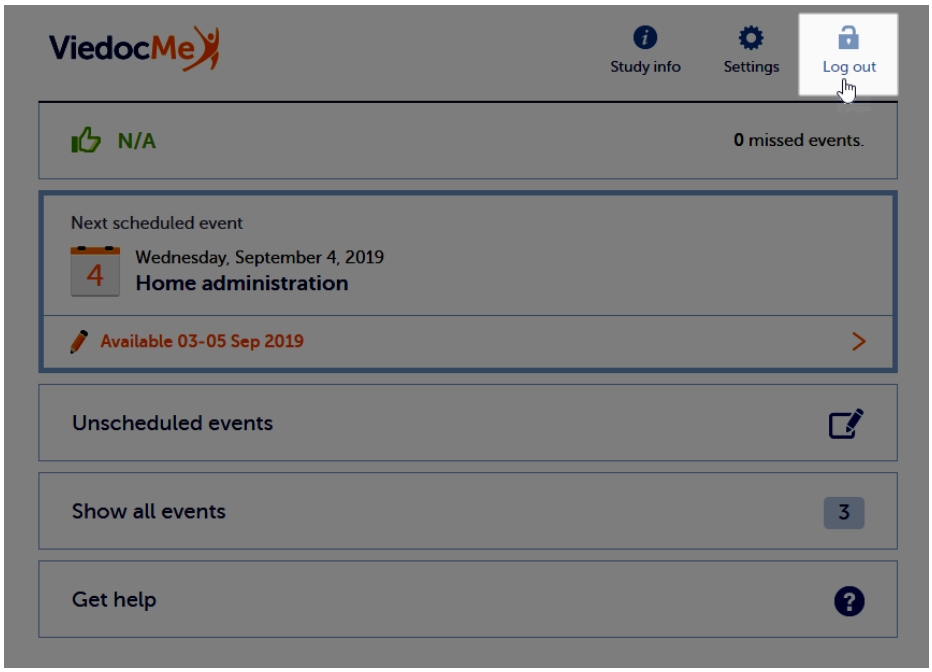
5.3 Help

If you forget how to log in to Viedoc Me or if you have lost the document with the login details, please contact your doctor/nurse or site staff at the clinic. They can create a new document with your login details for you.

5.4 Log out

You will automatically be logged out from Viedoc Me after 20 minutes of inactivity. Yet, we recommend you to always log out when you are done with the questionnaires, to avoid that anyone else can gain access to your device and submit data using your account.

Select **Log out** in the upper right corner to log out from Viedoc Me.



5.5 If you lose internet connection

While logged in to Viedoc Me, the system tolerates loss of internet connection up to one minute. If you lose internet connection for more than one minute, you will be automatically logged out. Any data that has not been submitted at that time will be lost.

Using Viedoc Me (information for study participants)

Published by Viedoc System 2025-02-18

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2. Access to Viedoc Me
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    2.2 Logging in to Viedoc Me
    2.3 Quick access to Viedoc Me
3. Start screen
4. Events
    4.4 Upcoming event
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    4.6 Filling in an unscheduled event
5. Video calls
    5.7 Viedoc connect settings
6. Receiving and signing documents with Viedoc Share
    6.8 Opening a document
    6.9 Filling in document fields
    6.10 Using notes in documents
    6.11 Signing a document
    6.12 Downloading a document
7. Expanded functions
    7.13 Reminders via email or text message
        7.13.1 Setting reminders and changing your contact information
    7.14 Changing your PIN code
    7.15 Help
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1 Introduction to Viedoc Me

Viedoc Me is a web application used for collecting data from patients participating in clinical trials. It works on computers, tablets, or mobile phone devices, as long as the device has a browser and access to the internet.

Viedoc Me helps you fill in questionnaires and submit them, keep track of events, connect with a physician through **Viedoc Connect**, or receive and sign documents through **Viedoc Share**.

2 Access to Viedoc Me

Access to Viedoc Me is provided by your physician, nurse, or other contact at the clinic. Depending on the study, your Viedoc Me login information will be shared via **email**, **text message**, and/or a **document** (paper document or PDF file).

2.1 Activating your Viedoc Me Account

To activate your Viedoc Me account and log in for the first time:

1 Open Viedoc Me:

If your clinic contact shared your Viedoc Me login info via **email or text message**, you will receive a message with a link to activate your account.

- Select the **link** in the email or text message you received. A page opens where you can set your PIN code (continue to step 2 below).

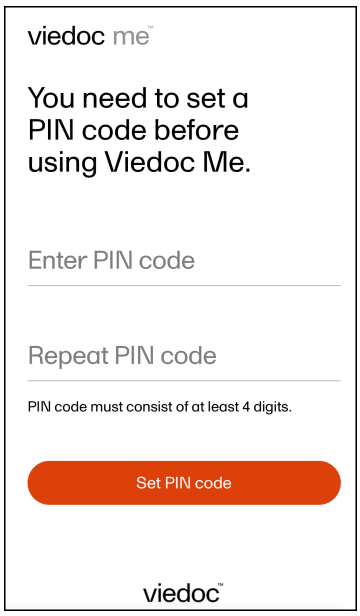
If your clinic contact shared your Viedoc Me login info via a **document**, you will receive either a paper document or a digital PDF file that contains the URL (web address) to Viedoc Me, a QR code that can be scanned by your mobile device for easy access to the URL, your user name, and your PIN code.

- Open a web browser on your device and enter the **URL** (web address), or scan the **QR code** on the document with your mobile device.
- Enter your **User Name** and your **PIN code** as they appear on your document.
- Select **Log in**.
- Depending on your study's settings you may be required to change your PIN code the first time you log in. In that case, you will be automatically directed to the Set PIN code page (continue to step 2 below).
- If your study *does not* require you to change your PIN code, your Viedoc Me account is now activated and you will be taken directly to the Start Screen. Please see Viedoc Me Start Screen below for more information on using the application

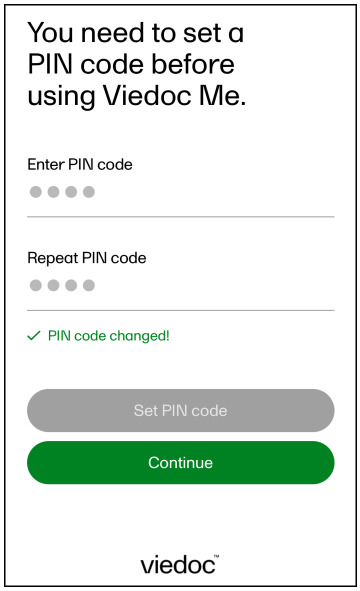
Note! When you enter the URL (web address) from the login information PDF in a browser, you are redirected to a URL that looks slightly different and that contains the string "idp". This is the expected behavior.

2 Change your PIN code:

The first time you log in to Viedoc Me you may be required to set a new PIN code. Enter your new **PIN code** twice. Make sure you remember or save your PIN code, you will need it to log in to Viedoc Me in the future.



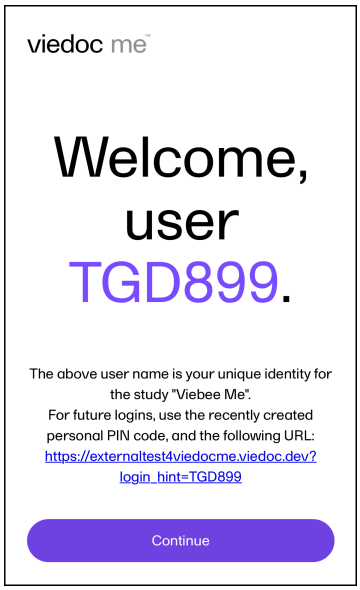
3 Select **Set PIN code** to save. The "PIN code changed!" confirmation message is displayed:



4 Select **Continue**.

5 **Account activation is complete!**

A Welcome screen is displayed:



6 Please remember to save your PIN code and the URL for future logins. For tips on saving the URL as an icon on the home screen of your device see Quick Access to Viedoc Me below.

Note! Your PIN code can be reset at any time, for example if you forget it. Please reach out to your contact at the clinic for help resetting your PIN code.

Select **Continue**.

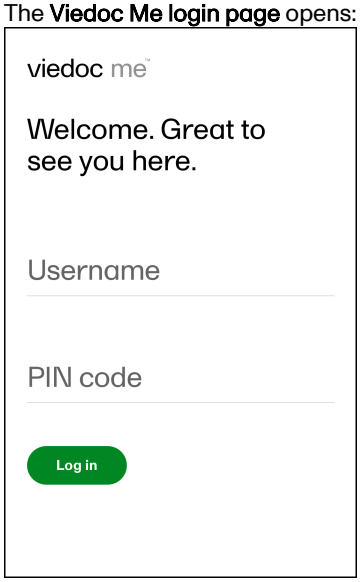
Your account is now activated! Please see Viedoc Me Start Screen below for more information on using the application.

2.2 Logging in to Viedoc Me

To log in to Viedoc Me:

1 Open a web browser on your device. Type the **URL** that you received via email, text message or in a document. For tips on saving the URL as an icon on the home screen of your device see Quick Access to Viedoc Me below.

The **Viedoc Me login page** opens:



2 Enter your **user name**.

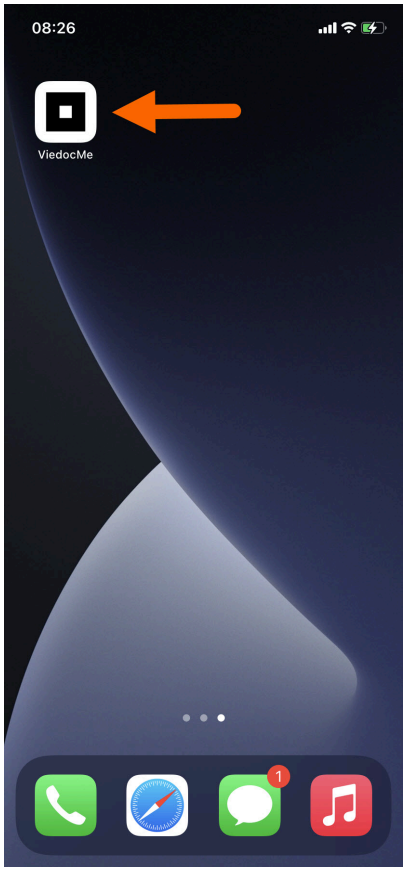
3 Enter your **PIN code**.

4 Select **Log in.**

The **Viedoc Me Start Screen** is displayed. Please see Viedoc Me Start Screen below for more information on using the application.

2.3 Quick access to Viedoc Me

If you are using Viedoc Me on a mobile device, future logins can be made easier by saving the URL as a shortcut. It will appear as an icon on the home screen of your device:



To save Viedoc Me to the home screen:

1 Open a web browser on the phone and navigate to the URL that is stated in the document provided to you.

2 Select the option to **Add to Home Screen**

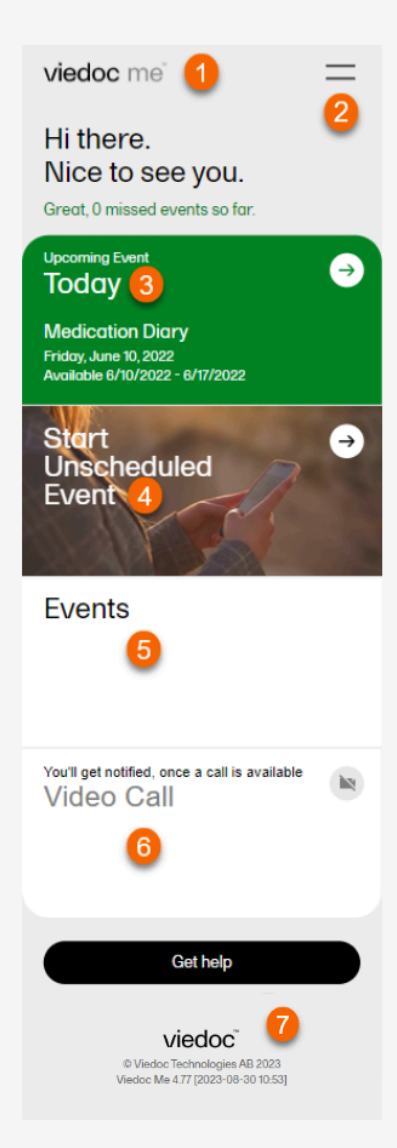
The Viedoc Me application is now available to select on your device.

Similarly, you can select the Viedoc Me URL and add it to the Favorites menu on your computer.

---

3 Start screen

When you log into Viedoc Me you will see the following start screen:



1. **The Viedoc Me logo** - select from anywhere in the app to return to the start screen.

2. **The menu** - select to see study info, change your settings, get help, or to log out.

3. **The upcoming events tile** - select to see which upcoming events you must fill in.

4. **The start unscheduled event tile** - select to start an unscheduled event.

5. **The events tile** - select to see past and future events.

6. **The video call tile** - select when a call becomes available to join a video call.

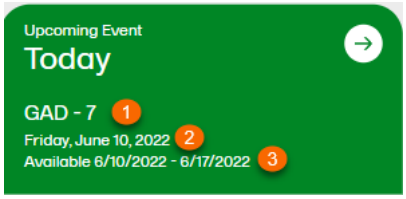
7. **The get help button** - select for information on how to contact clinical staff.

---

4 Events

4.1 Upcoming event

In **Upcoming Event**, you will see the next events that your study has scheduled for you.



1. The title of the event.

2. The date the event is to be started.

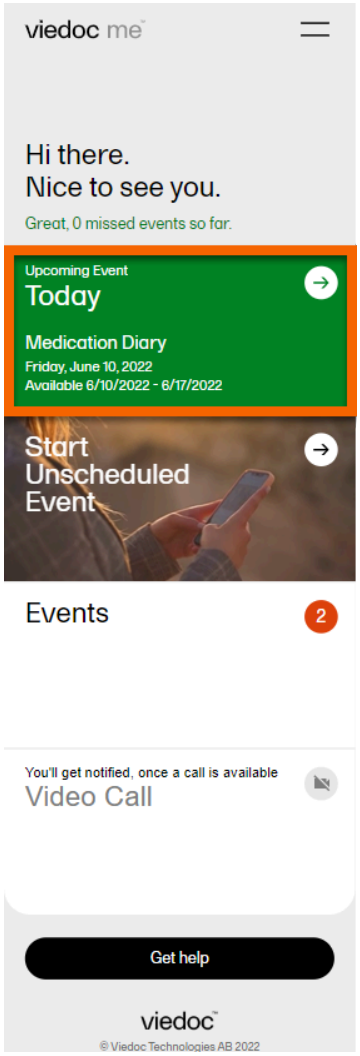
3. The dates of availability for the event.

4.2 Filling in an event

To fill in a scheduled event:

Note! You can only fill in an event during the availability period.

1 Select the **Upcoming Event** tile.



2 Select your answer to the questions. If there are multiple pages, you can navigate by using the arrow buttons.

3 Complete the event and then select **Submit.**
Note! Before you select **Submit,** you will be prompted to ensure your answers are set. You can select the back arrow button if you need to edit your answers.

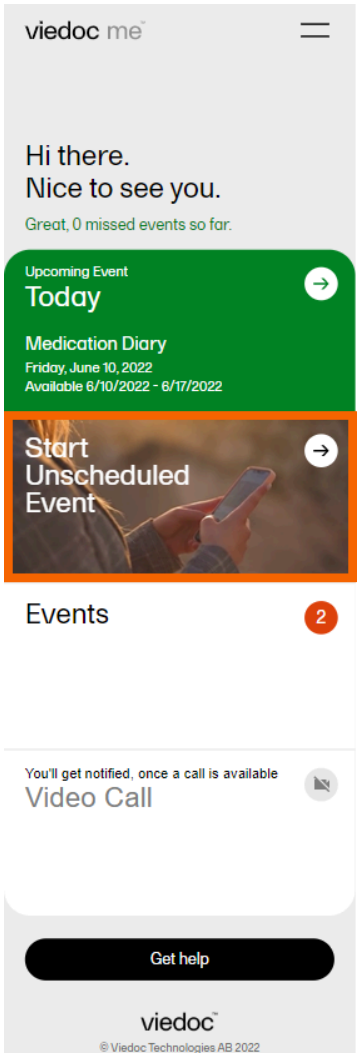
4 Select **Go to startpage** to return to the Viedoc Me home page.

4.3 Filling in an unscheduled event

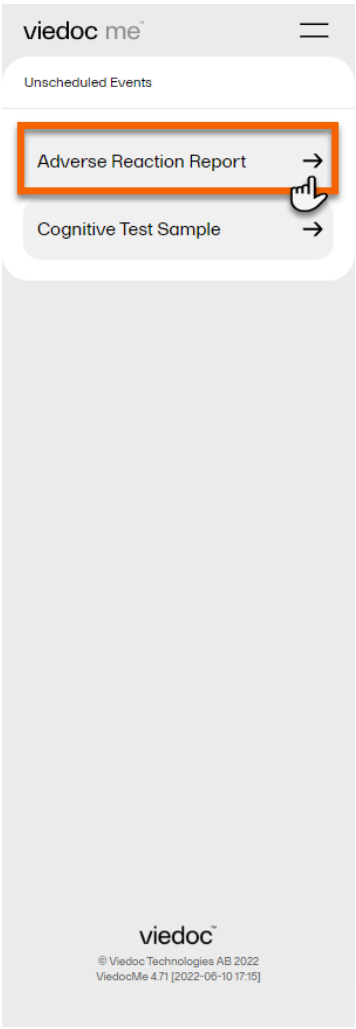
If the study allows for it, you will be able to report data at any time.

To fill in an unscheduled event:

1 Select **Start Unscheduled Event**.



2 Select the name of the event.



Note! You might have different report names in your study.

3 Select your answers to the questions. If there are multiple pages, you can navigate using the arrow buttons.

4 Complete the event and then select **Submit.**
Note! Before you select **Submit,** you will be prompted to ensure your answers are set. You can select the back arrow button if you need to edit your answers.

5 Select **Go to startpage** to return to the Viedoc Me home page.

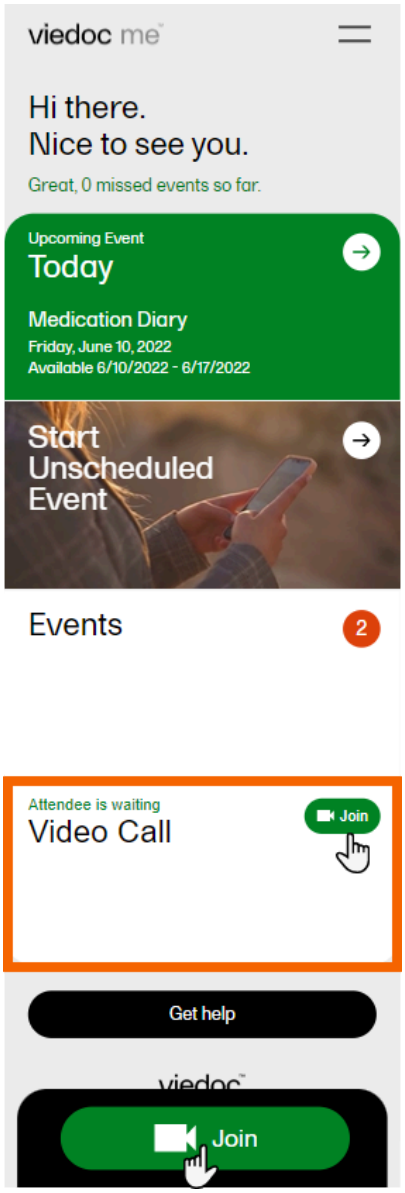
---

5 Video calls

The Viedoc Connect application allows the clinic staff to initiate a video call with you.

When your physician or nurse has initiated a call, the video call button will appear at the bottom of the screen.

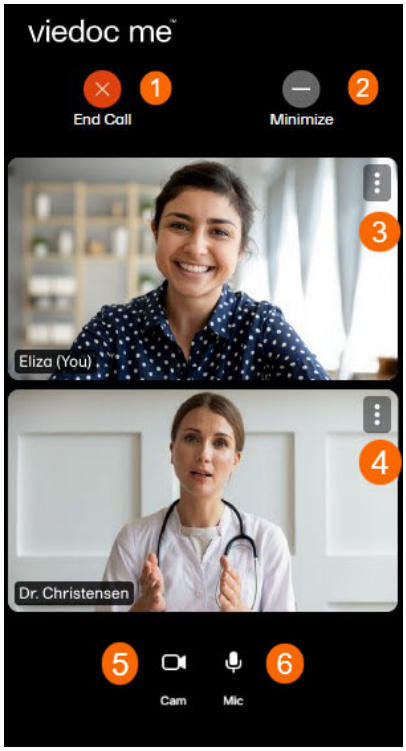
Select **Join** anywhere in the app to join the call. Alternatively, you can select the **Video Call** tile to join a call.



Note! If prompted, please select **Allow** so Viedoc Connect can access your camera and microphone through the browser.

5.1 Viedoc connect settings

During the call, you will see the following screen:



1. End call button - select to end the call.

2. Minimize button - select to minimize the Viedoc Connect window and continue in the app or in another window while speaking with the physician or nurse. Select Full screen in the app to bring the video window back into view.

3. Screen settings for subject - select to see more settings.

4. Screen settings for clinician - select to change screen and volume settings for clinician window.

5. Mic symbol - select to mute and unmute your microphone.

6. Cam symbol - select to turn your video stream off and on.

---

6 Receiving and signing documents with Viedoc Share

Depending on your study, you may be able to receive and sign documents in Viedoc Me. If a document is shared with you, you may receive a notification via email, text message, and/or directly in the Viedoc Me application.

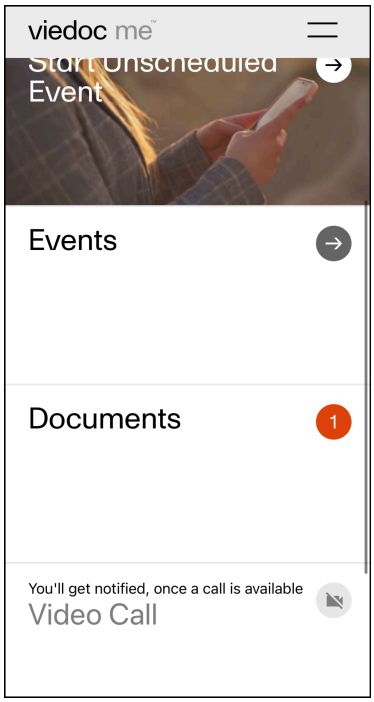
6.1 Opening a document

To open a document that has been shared with you:

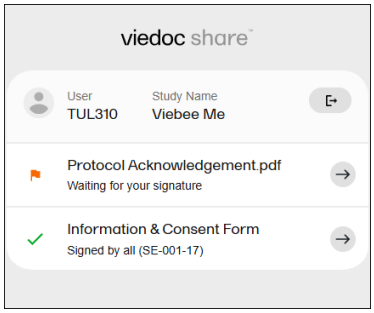
1 If you received an email or text message with a notification that a document was shared with you, click the link in the email or text message to go directly to Viedoc Share (skip to step 3 below).

2 If you did not receive an email or text message, you see your documents by logging into your Viedoc Me account. When you log in to Viedoc Me, if you have a new document there will be a red circle next to the documents section indicating how many new documents there are for you to view and/or sign. The tiles may be arranged slightly differently depending whether you are on a mobile device or computer, but the sections will look the same.

Select **Documents**.



3 Viedoc Share will be displayed with a list of documents that have ben shared with you, indicating any actions that you need to complete:



The icons displayed to the left of each document indicate a status and any required actions:

A **blue circle** indicates that the document has not yet been viewed, and there are no required signatures.

A **gray circle** indicates that the document has been viewed, and there are no required signatures.

An **orange flag** indicates that the document requires your signature.

A **green checkmark** indicates that the document has been signed by all required people.

A **gray checkmark** indicates that the document has been signed by you, but still requires a signature from a co-signatory.

4 Select a **document** to open it.

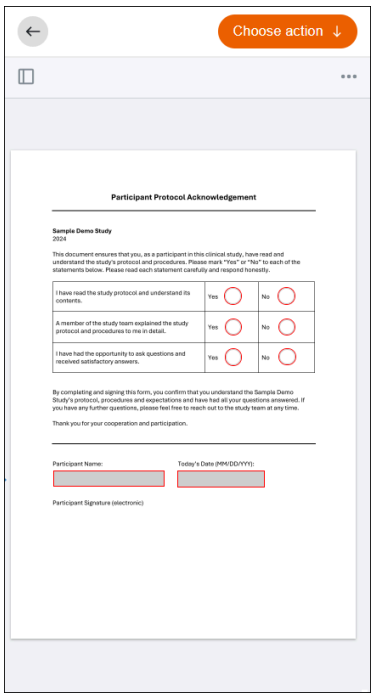
5 Review the contents of the document.

6.2 Filling in document fields

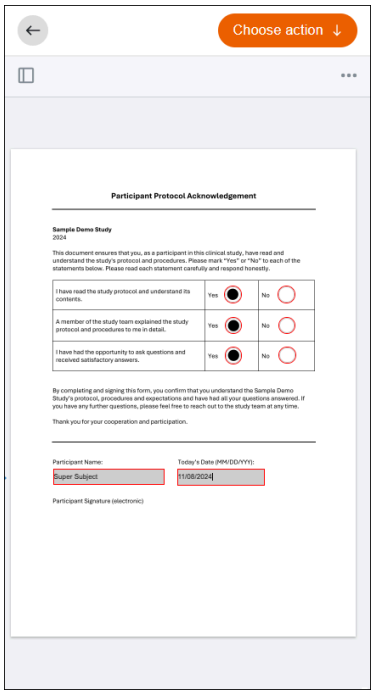
The document may include questions to answer or fields to fill in. If they are required, the fields must be completed before you are able to sign the document.

To fill in document fields:

1 If there are options or fields for you to complete, they will be displayed in the document. Required fields are outlined in red.



2 Select the round or square buttons by tapping with your finger (on a mobile device) or clicking on them with your cursor (on a desktop computer). If there are text fields, select the field to begin typing in it.



3 When all of the required fields have been completed you will be ready to sign the document (if required).

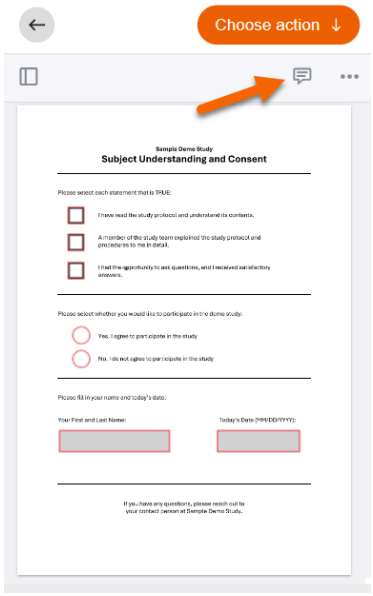
6.3 Using notes in documents

If you would like to add a question or comment to the document that was shared with you, you can add notes to a document that has not yet been signed. Once a note is added, someone on the study team is able to respond to your note.

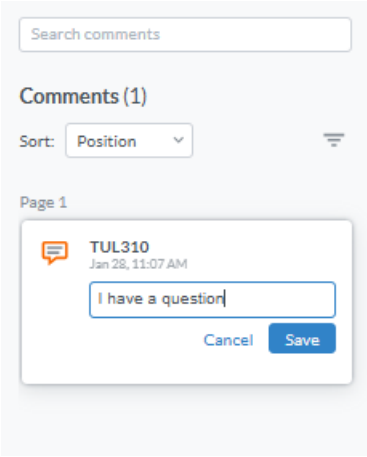
Note! You can only add notes to documents that require a co-signatory.

To add a note to a document:

1 Select the **Notes** icon on the top right of the document. If you do not see this icon, there is no co-signatory for this document and you will not be able to add notes.



2 Click or tap anywhere on the document to place your note. A textbox will be displayed where you can type in your text:



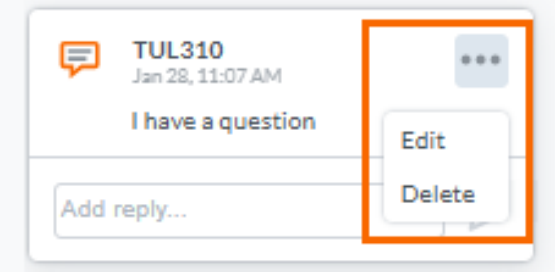
Note! Notes more than 240 characters may not display correctly in the browser after they are downloaded. They will display correctly when the downloaded document is viewed in a PDF viewer.

3 Select **Save** when you are finished typing your note.

You may add multiple notes to the document by repeating the same process.

To edit or delete a note:

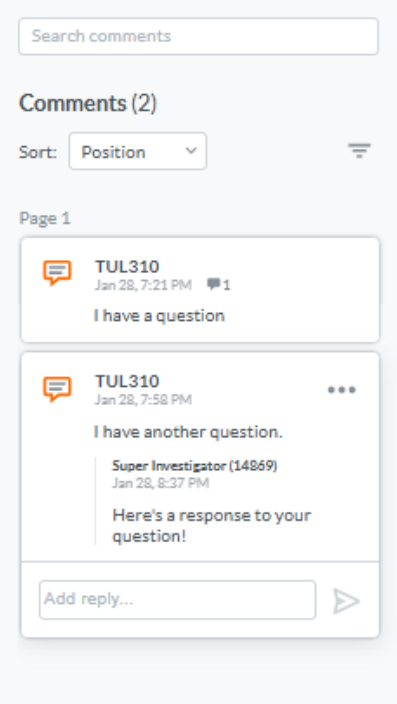
1 Select the note you want to edit or delete. Select the **options menu** in the top right corner of the note:



2 Edit the text and select **Save** when you're finished. Or select **Delete** to delete the note.

Note! Only notes that have not received a reply yet can be edited or deleted.

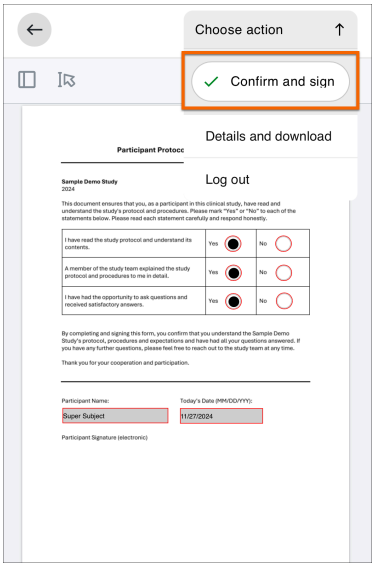
When you receive a reply to your note, you can add more replies as needed:



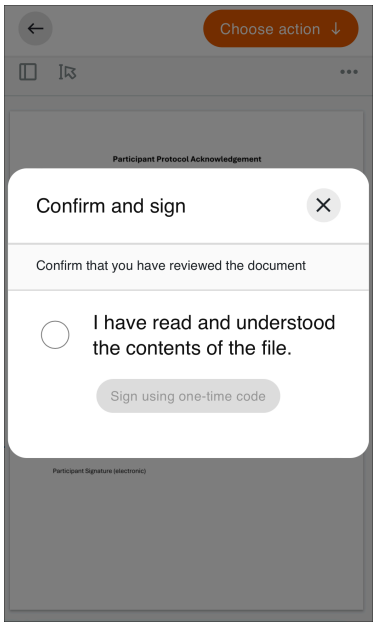
6.4 Signing a document

To sign a document:

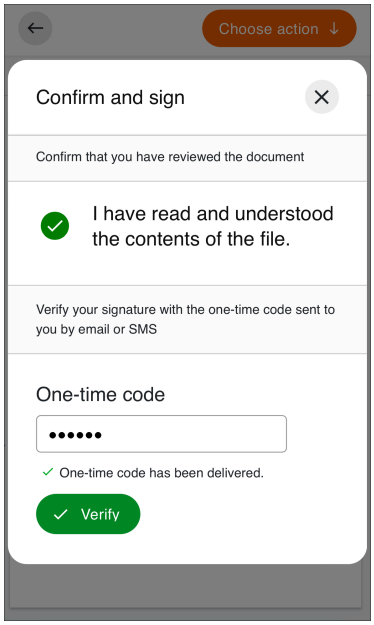
1 Select **Choose action** at the top right of the screen. If your signature is required, and any required fields have been completed, the **Confirm and sign** option is displayed:



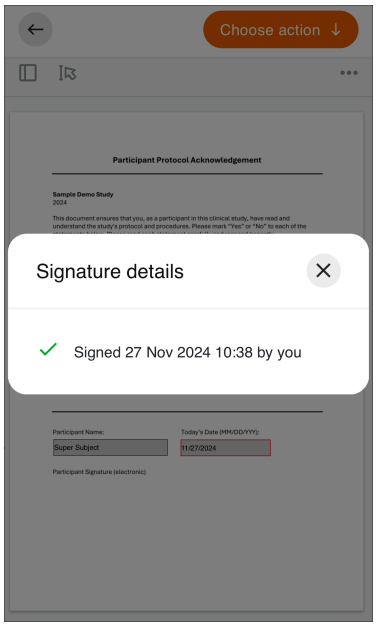
2 Select **Confirm and sign**. To confirm that you have reviewed the document, select the round button to the left of the confirmation statement and a green check mark will appear. Select **Sign using one-time code**.



3 A one-time passcode with six numbers will be sent to you via email or text message. Check the message and enter the code. Select **Verify**.



4 **Signature details** will be displayed, confirming that you have signed the document. Close this popup to return to the document view.

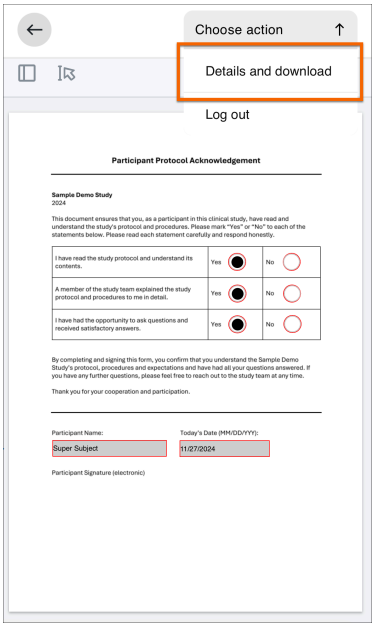


6.5 Downloading a document

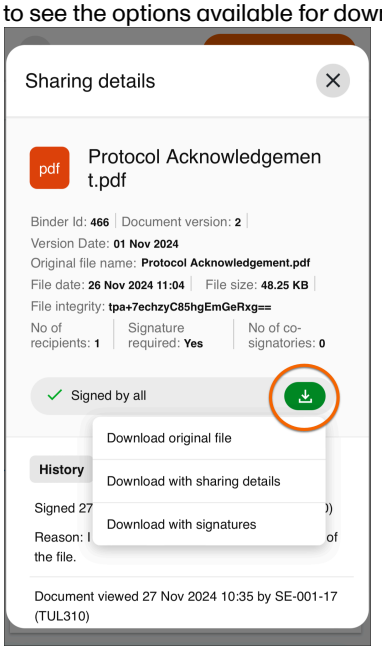
You can always download a copy of the document, whether the document requires a signature or not.

To download a copy of the document:

1 While viewing the document select **Choose action** at the top right, and select **Details and download**:



2 Sharing details and document history will be displayed. Under the details select the green **download** icon to see the options available for downloading:



The following options are available for downloading the document:

- **Download original file**: will download a copy of the original document. Any fields (ie. radio buttons, checkboxes or text fields) in the document will be empty in this version.
- **Download with sharing details**: will download a zipped folder which contains a copy of the document with any completed fields, and a separate file with sharing details and document history.
- **Download with signatures**: will download a copy of the document which includes a cover page containing signature details. Any completed fields completed will also be visible in this version. (Note! this option is only available if ALL of the required people have signed the document).
- **Download with notes**: will download a copy of the document which contains any notes added to the document, as well as any completed fields.

Note! In some cases notes may not display correctly when viewing the downloaded document in a browser, please try to open the document in a PDF viewer instead.

3 Select an option to begin downloading the document.

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7 Expanded functions

7.1 Reminders via email or text message

The Viedoc Me application can send event notifications to your email or as a text message (SMS) to your mobile device. These notifications are configured by the study managers. It is important to know that you cannot reply to these reminders sent from Viedoc.

If your study allows, you can change your email, phone number, and reminder settings from the settings option in the menu. If these options are not available to you, please inform the study managers at the clinic if you need to update your contact information or reminder settings.

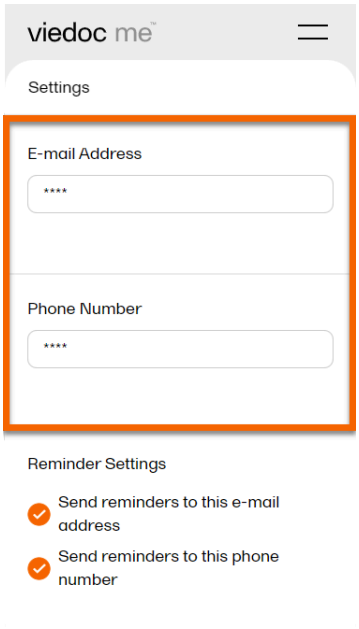
7.1.1 Setting reminders and changing your contact information

Change your contact information and reminder settings in the application when available:

1 **Select** the menu symbol on the start page.

2 **Select** settings.

3 Enter your updated email address and phone number.



4 Select **Save Changes** and your information will be updated.

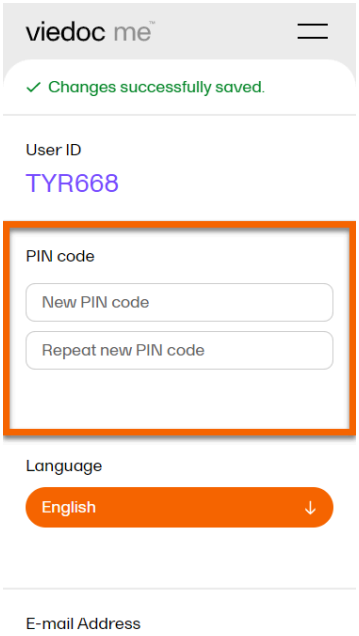
7.2 Changing your PIN code

You can update your PIN code anytime.

To update the PIN code:

1 **Select** the menu symbol on the start page of the app.

2 Enter a new PIN code in **New PIN code.** Re-enter your new PIN code in **Repeat new PIN code.**



3 Select **Save Changes** and your PIN code will be updated.

7.3 Help

If you forget how to log in to Viedoc Me or if you have lost your login document, please contact your physician, nurse, or site staff for your study. They can reset your PIN code and create a document with new login details for you.

7.4 Log out

The application will automatically log you out from Viedoc Me after 20 minutes of inactivity. However, we recommend you always log out when you are done with your questionnaires to avoid someone else gaining access to your device and submitting false data.

To log out, select the menu icon, and then select **Log out.**

Using Viedoc Connect

Using Viedoc Connect

Published by Viedoc System 2024-10-10

1. Introduction
    1.1 Prerequisites
2. Opening Viedoc Connect
3. Initating a call
4. Troubleshooting

1 Introduction

Viedoc Connect enables meetings between Clinic and Viedoc Me users through video calls. The video calls are started from Clinic, and the call is opened in a new tab that is the Viedoc Connect application. Once the call is initiated/ongoing, subjects can join the video call through the Connect module which is available in Viedoc Me.

A video call that has been started is valid/open to join within 60 minutes. Users can also leave and re-join the video call. The users are free to navigate in the Clinic tab to other pages during the call, and the subjects can navigate within Viedoc Me and submit questionnaires during the call.

Viedoc Connect only allows one active video call at a time, meaning that only the latest started video call is shown in Viedoc Connect.

1.1 Prerequisites

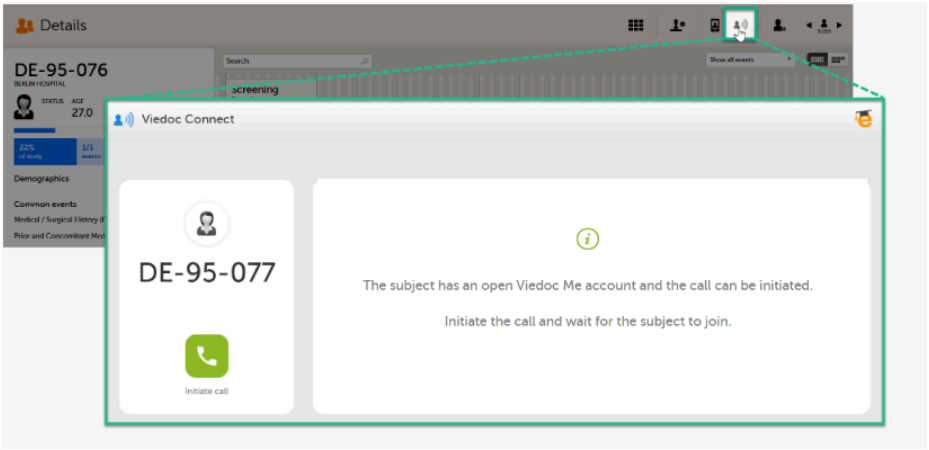
To use Viedoc Connect:

- the feature must be encluded in the study license
- the feature must be enabled in Viedoc Admin
- the subject must have an open Viedoc Me account

Note! For information about supported versions of iOS and Android, and other system requirements for Viedoc Connect use, please refer to System requirements for the Viedoc system and Supported Browsers & Devices for information about the desktop and mobile browsers and devices supported by the Whereby platform.

2 Opening Viedoc Connect

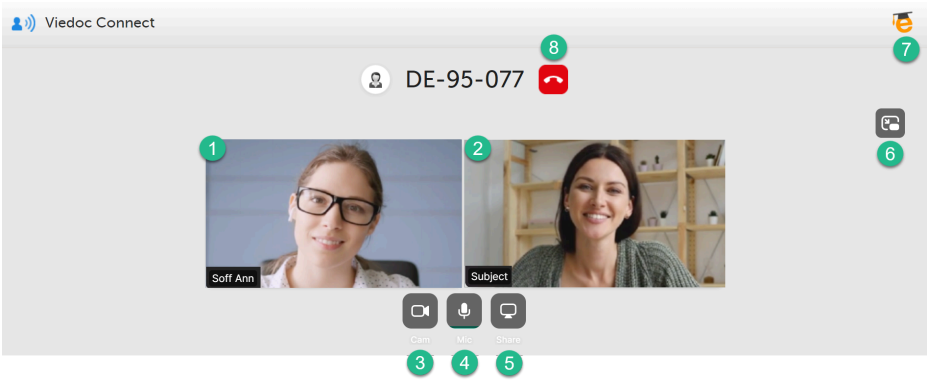
To open Viedoc Connect, select the icon on the Selection page. Viedoc Connect opens in a new tab:



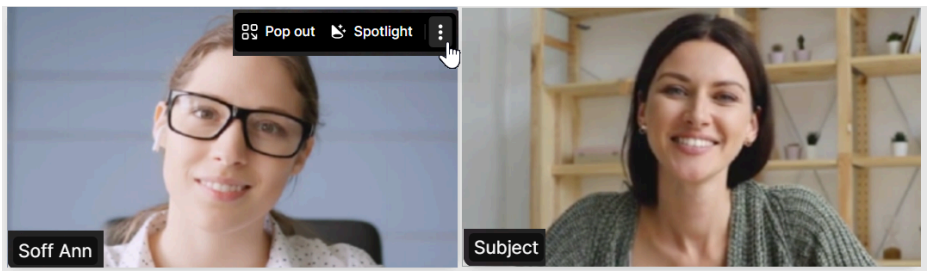
3 Initating a call

To initiate a call, click the green phone icon.

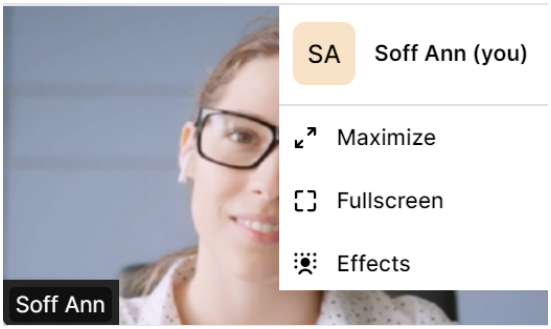
When the subject joins the call, you will see the following view:



1. To show the screen settings on the site user screen (you), hover over the screen:



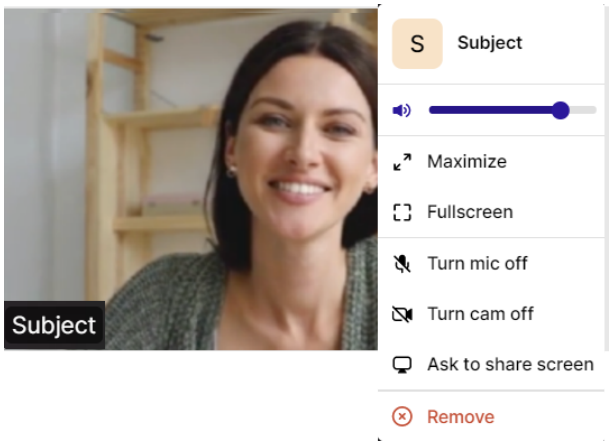
- Select **Pop out** to move the screen of you to the bottom right corner.
- Select **Spotlight** to put the spotlight on you.
- Select the three dots to show more settings:



- Select your name to edit it.
- Select **Maximize** to make both screens larger.
- Select **Fullscreen** to make your screen cover the whole screen.
- Select **Effects** to open a menu with more settings.

2. To show the screen settings on the subject's screen, hover over the screen:

- Select **Spotlight** to put the spotlight on the subject.
- Select the three dots to show more settings:



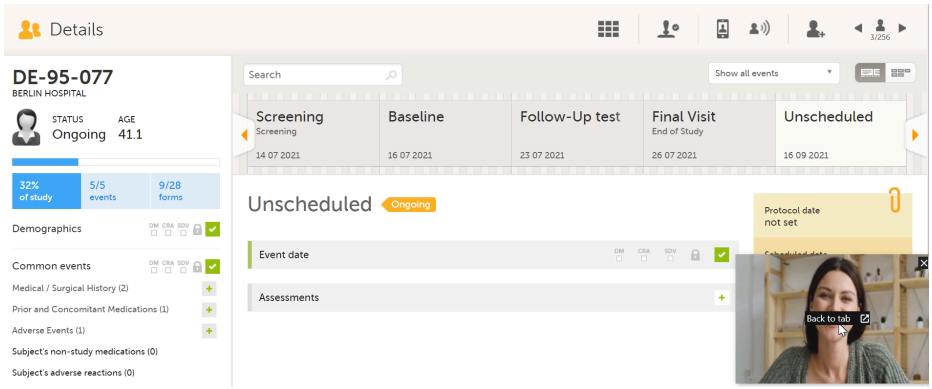
- Pull the bar to increase/decrease their volume.
- Select **Maximize** to make both screens larger.
- Select **Fullscreen** to make their screen cover the whole screen.
- Select **Turn mic off/Turn cam off** to disable their microphone/camera. To enable them, click **Ask to turn mic on/Ask to turn cam on**. The participant will be notified and needs to enable their mic/cam.
- Select **Ask to share screen**. The participant will be notified to share their screen.
- Select **Remove** to end the call with the participant.

3. Camera settings - select to turn off the camera. Hover to see more camera settings.

4. Microphone settings - select to mute. Hover to see more microphone settings.

5. Screen settings - select to share your screen.

6. Picture-in-picture - select to continue the video call with a remotable screen that will be shown even if you switch tabs. Hover over the mini-screen and select **Back to tab** to return to the Viedoc Connect main screen.



7. eLearning - select to open this lesson whenever you need help with Viedoc Connect.

8. End call button - select to end the call.

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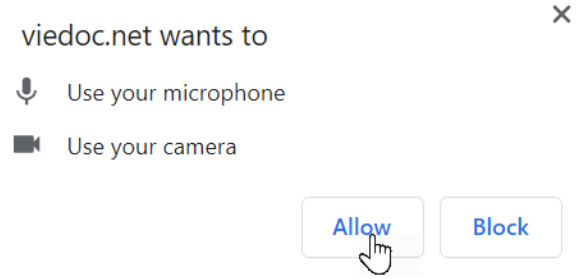
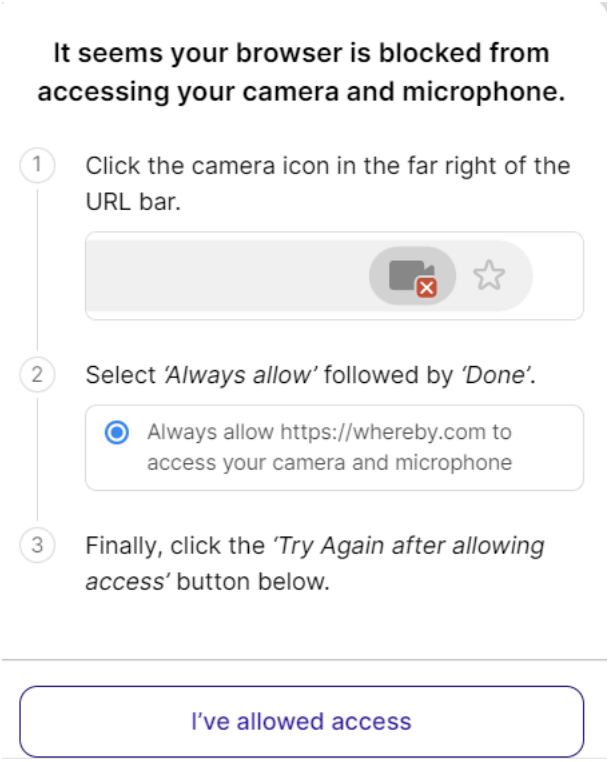
4 Troubleshooting

When launching Viedoc Connect, your browser may notify you to enable your microphone and camera.

To enable access to your microphone and camera, select **Allow**:



If you don't allow access, you will be prompted again:



Follow the instructions and select **I've alllowed access** to enter Viedoc Connect.

Receiving Documents with Viedoc Share

Published by Viedoc System 2025-02-18

1. Reviewing and signing documents
2. Replying to notes
3. Downloading documents

1 Reviewing and signing documents

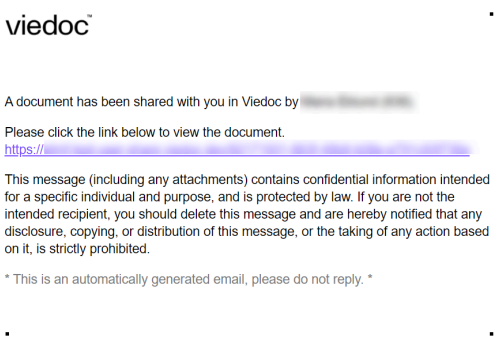
As a Viedoc Clinic user, documents can be shared with you directly in Viedoc to review and/or sign.

You may receive:

- A document that can be viewed, but does not need your signature.
- A document that requires your signature
- A document that requires your signature as a co-signatory, which can only be signed after the other recipient (for example, a study participant) has completed required document fields and/or signed the document first. The participant also has the option to add notes to ask questions, which you can reply to directly in the document (see replying to notes).

To review and sign documents:

1 If a document has been shared with you, you will receive an email notification similar to this example:


viedoc™

A document has been shared with you in Viedoc by [redacted]

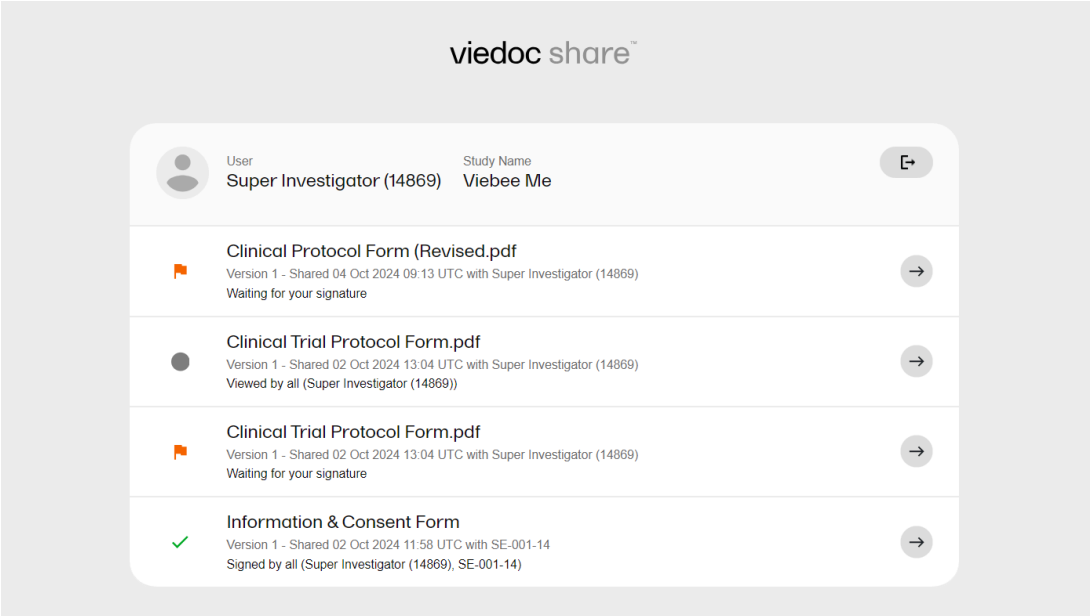
Please click the link below to view the document.
https://[redacted]

This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and are hereby notified that any disclosure, copying, or distribution of this message, or the taking of any action based on it, is strictly prohibited.

* This is an automatically generated email, please do not reply. *

2 To open the document, select the link in the email.

3 If you are logged into Viedoc, **Viedoc Share** is displayed with a list of documents that have been shared with you. If you are not already logged in, you will be directed to the login page first.



The icons displayed to the left of each document indicate a status and any required actions:

A **blue circle** indicates that the document has not yet been viewed, and there are no required signatures.

A **gray circle** indicates that the document has been viewed, and there are no required signatures.

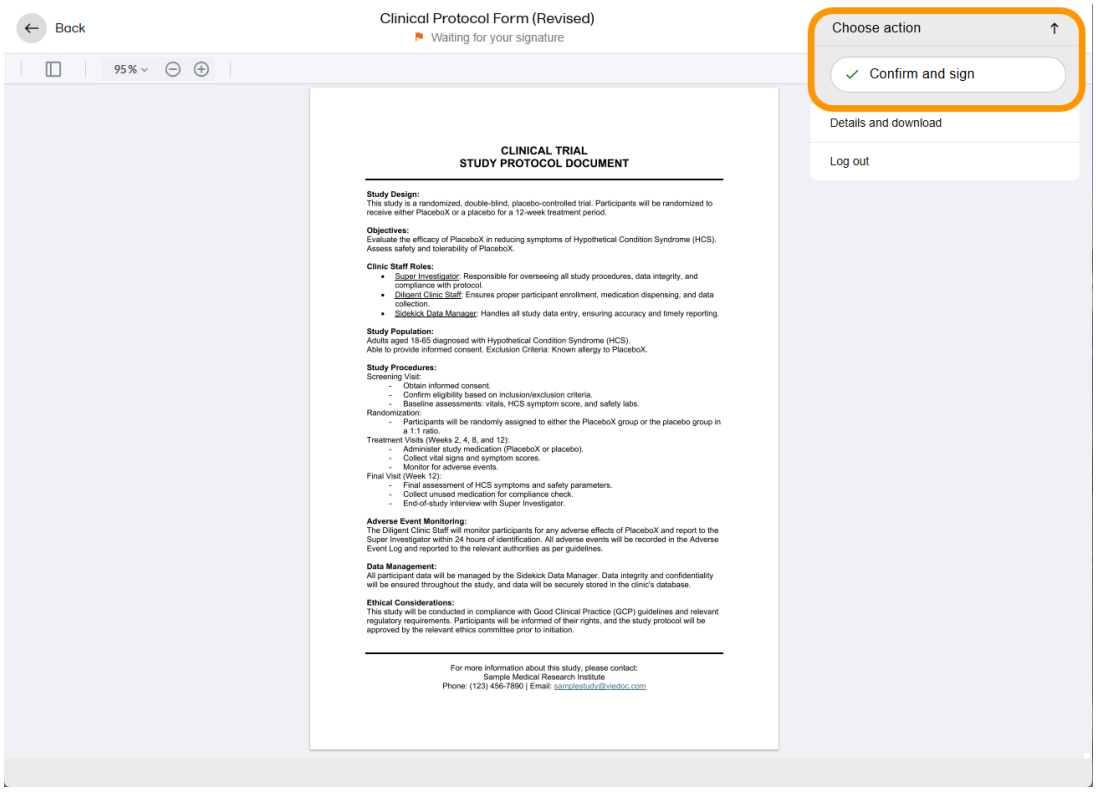
An **orange flag** indicates that the document requires your signature.

A **green checkmark** indicates that the document has been signed.

A **gray checkmark** indicates that the document has been signed by you, but still requires a signature from a co-signatory.

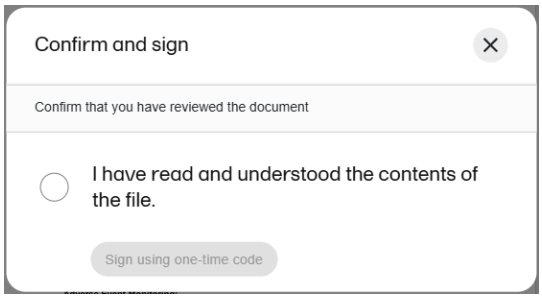
4 Select the document you would like to open and view.

After you have reviewed the document, select **Choose action** at the top right of the screen. If your signature is required, there will be an option to select **Confirm and Sign**. **Note!** If you have been designated as a co-signatory, the recipient must sign the document first, before you are able to sign it.

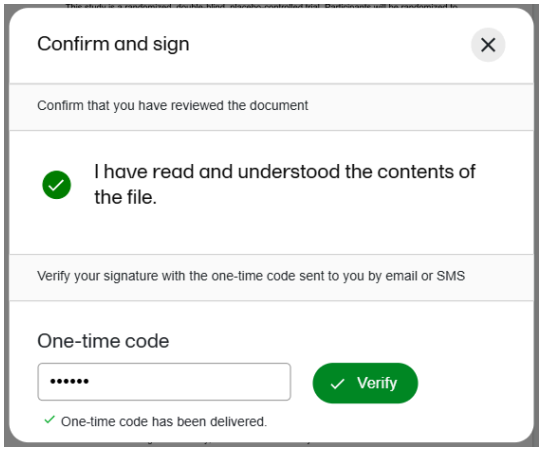


5 Select **Confirm and Sign**.

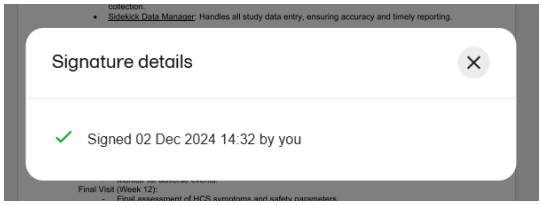
6 Select the round button to the left of the confirmation statement and a green check mark will appear. select **Sign using one-time code**.



7 A one-time passcode with six numbers will be sent to you via email or text message. Check the message and enter the code. Select **Verify**.



8 Signature details will be displayed, confirming that you have signed the document.



9 Close this popup to return to the document view.

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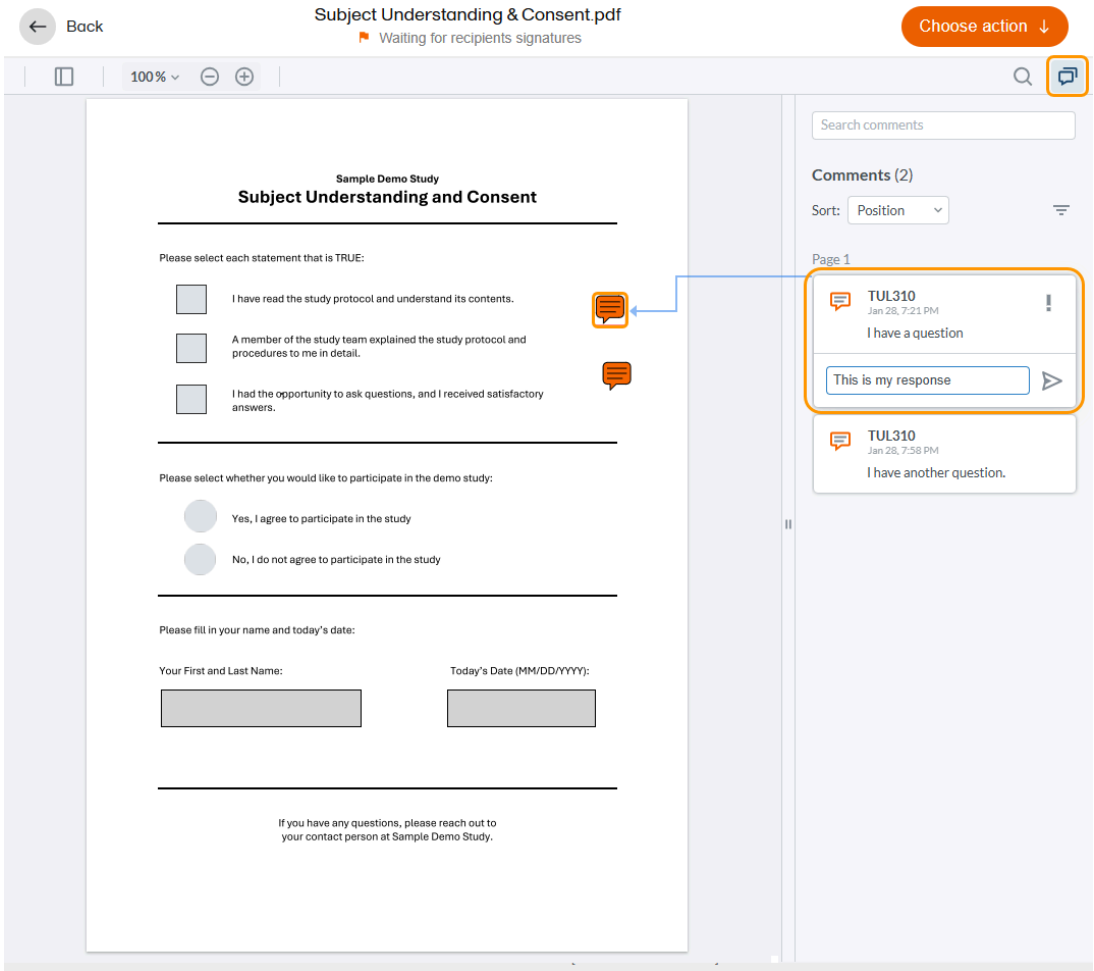
2 Replying to notes

Documents that are shared with a recipient and a co-signatory have the option for users to add and reply to notes. For example if a study participant has a question on a document, they can add a note to the document, and the co-signatory can reply to the note.

To reply to a note:

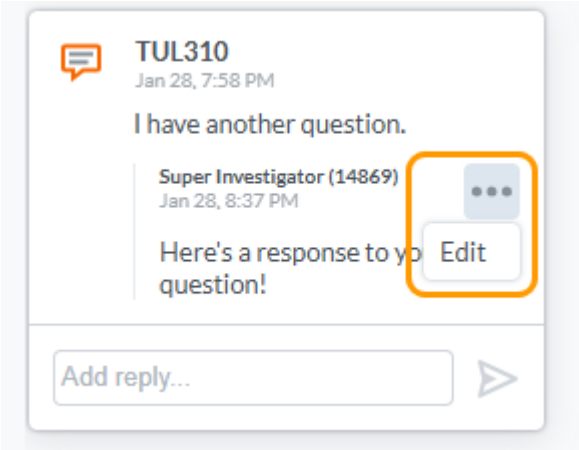
1 Navigate to the document by clicking on the link in the email you received, and/or selecting the document from the document list in Viedoc Share (see section 1 above).

2 Select the **Comments** icon on the top right of the document screen, or select the comment icons directly in the document. The notes added by the participant will be displayed on the right side of the screen:



3 Select the comment and type your reply. Select the **Send** icon to the right of the text field when you are finished.

4 To edit your reply, select the **options menu** to the right or your text and select **edit**. Edit your text and select **Send** when you are finished.

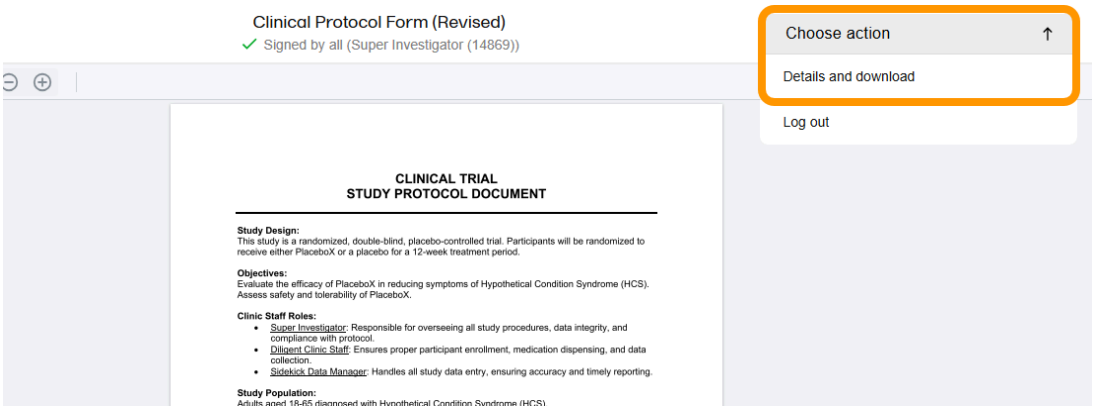


3 Downloading documents

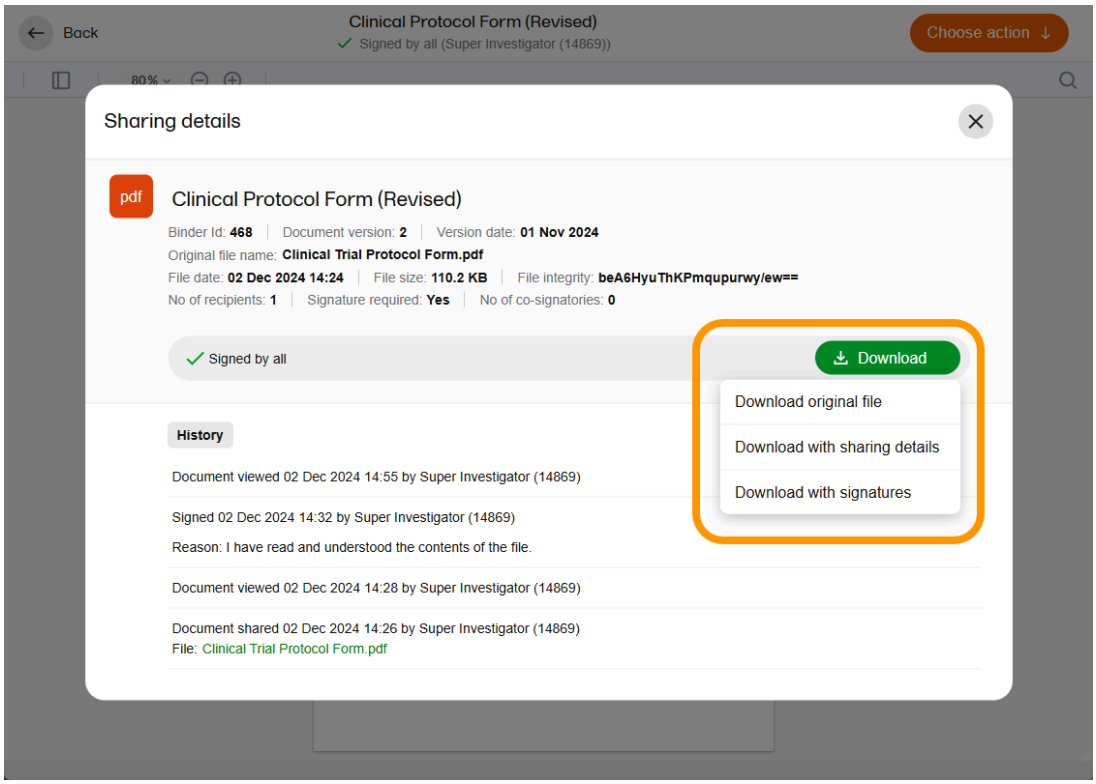
Whether or not the document requires a signature, you can download a copy of the document.

To download a copy of the document:

1 While viewing the document select **Choose action** at the top right, and select **Details and download**:



2 Sharing details and document history are displayed. Under the details select the green **Download** button to see the options available for downloading:



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Site User training video

Site User training

Published by Viedoc System 2022-05-06

This video is an introduction to Viedoc Clinic for the Site User.

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

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.

Add and select subjects

Published by Viedoc System 2018-11-07

This video provides a quick overview of the subjects **Selection** page and shows how to add new subjects.

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

Initiate and add visits

Initiate and add visits

Published by Viedoc System 2018-11-07

This video demonstrates how to initiate a visit in Viedoc, as well as how to add an unscheduled visit.

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

Enter data

Enter data

Published by Viedoc System 2018-11-07

This video demonstrates how to enter data in Viedoc, including filling in various data types and confirming data as missing.

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

Sign data

Sign data

Published by Viedoc System 2018-11-07

This video demonstrates how data can be signed by the Investigator, using the signing console.

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

Issues: Resolve a query

Published by Viedoc System 2018-11-07

This video demonstrates how to resolve a query in Viedoc.

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

Activate demo mode

Activate demo mode

Published by Viedoc System 2018-11-07

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

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

Enter reference data

Enter reference data

Published by Viedoc System 2019-01-07

This video demonstrates how to enter reference data in Viedoc Clinic.

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

Monitor training video

Published by Viedoc System 2021-05-05

This is a Viedoc introductory video for monitors.

If you encounter difficulties in viewing this video click here.

Version 2.1