viedoc learning™

Viedoc User Guide for Site Users

35 Lessons ■ 35 from Viedoc System

General

5 lessons

- Overview of Viedoc Clinic 1.1
- System requirements 1.2
- Managing your Viedoc account 1.3
- Overview of the landing page 1.4
- Approving eCRF changes 1.5

Data entry

8 lessons

- Study start page 2.1
- Documentation & Training 2.2
- Selection page 2.3
- Entering/Editing data 2.4
- Resetting and deleting data 2.5
- Signing data 2.6
- Working with reference data 2.7
- Randomization, allocation, and emergency unblinding 2.8

Data review

1 lessons

- Issues and tasks 3.1

Queries

1 lessons

- Resolving queries 4.1

Data export

4 lessons

- Updated Exporting data 5.1
- Excel export 5.2
- PDF export output 5.3
- Archiving a study 5.4

Viedoc Me

3 lessons

- Managing Viedoc Me 6.1
- Using Viedoc Me (information for study participants) version 4.70 and earlier 6.2
- Using Viedoc Me (information for study participants) 6.3

Viedoc Connect

1 lessons

- Using Viedoc Connect 7.1

Video tutorials

12 lessons

- Site User training 8.1
- Create a user account 8.2
- Log in/Log out and reset password 8.3
- Landing page 8.4
- Add and select subjects 8.5
- Initiate and add visits 8.6
- Enter data 8.7
- Sign data 8.8

Overview of Viedoc Clinic

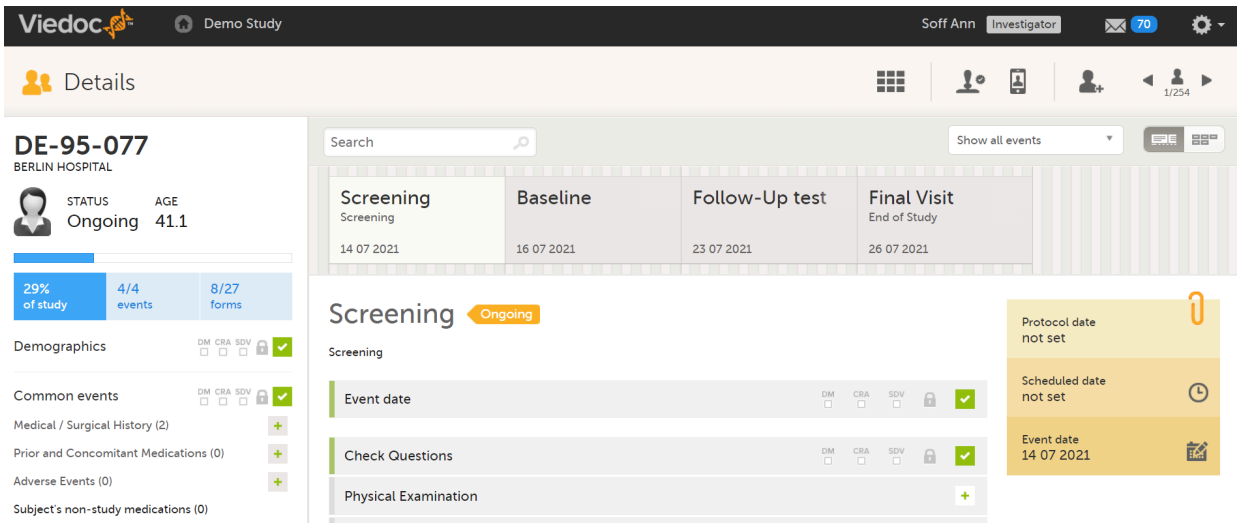
Overview of Viedoc Clinic

Published by Viedoc System 2025-04-24

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

System requirements

System requirements

Published by Viedoc System 2022-06-16

1 Customer computer requirements

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

1.1 Browser requirements

Viedoc supports the following browsers:

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

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

For Viedoc Designer:

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

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

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

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

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

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

1.2 Screen resolution

The following screen resolutions are required:

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

1.3 Internet connection

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

1.4 Firewall policy

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

---

2 Security

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

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

Managing your Viedoc account

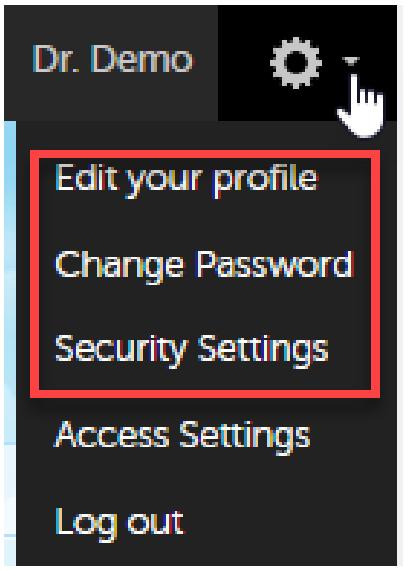
Managing your Viedoc account

Published by Viedoc System 2025-06-10

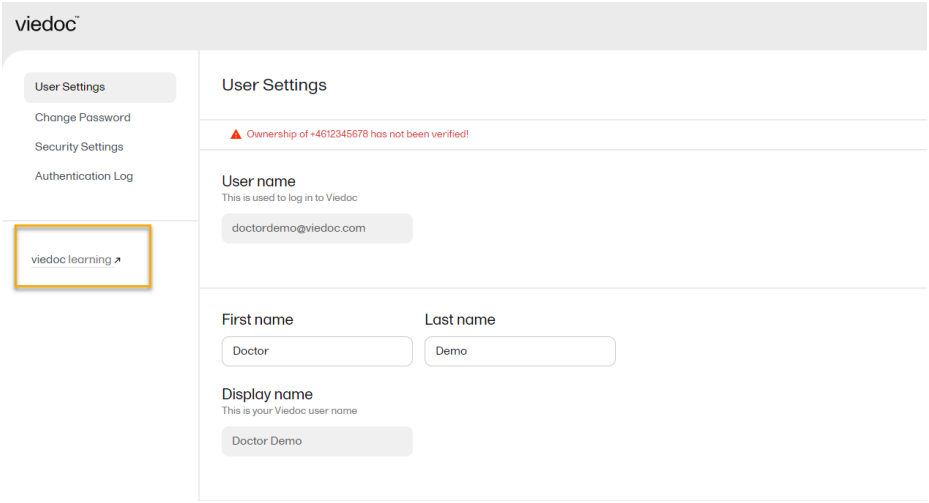
1 Viedoc user account management

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

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



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



2 User settings

Once logged in, you can edit your profile.

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

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

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

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

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

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

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

Notes!

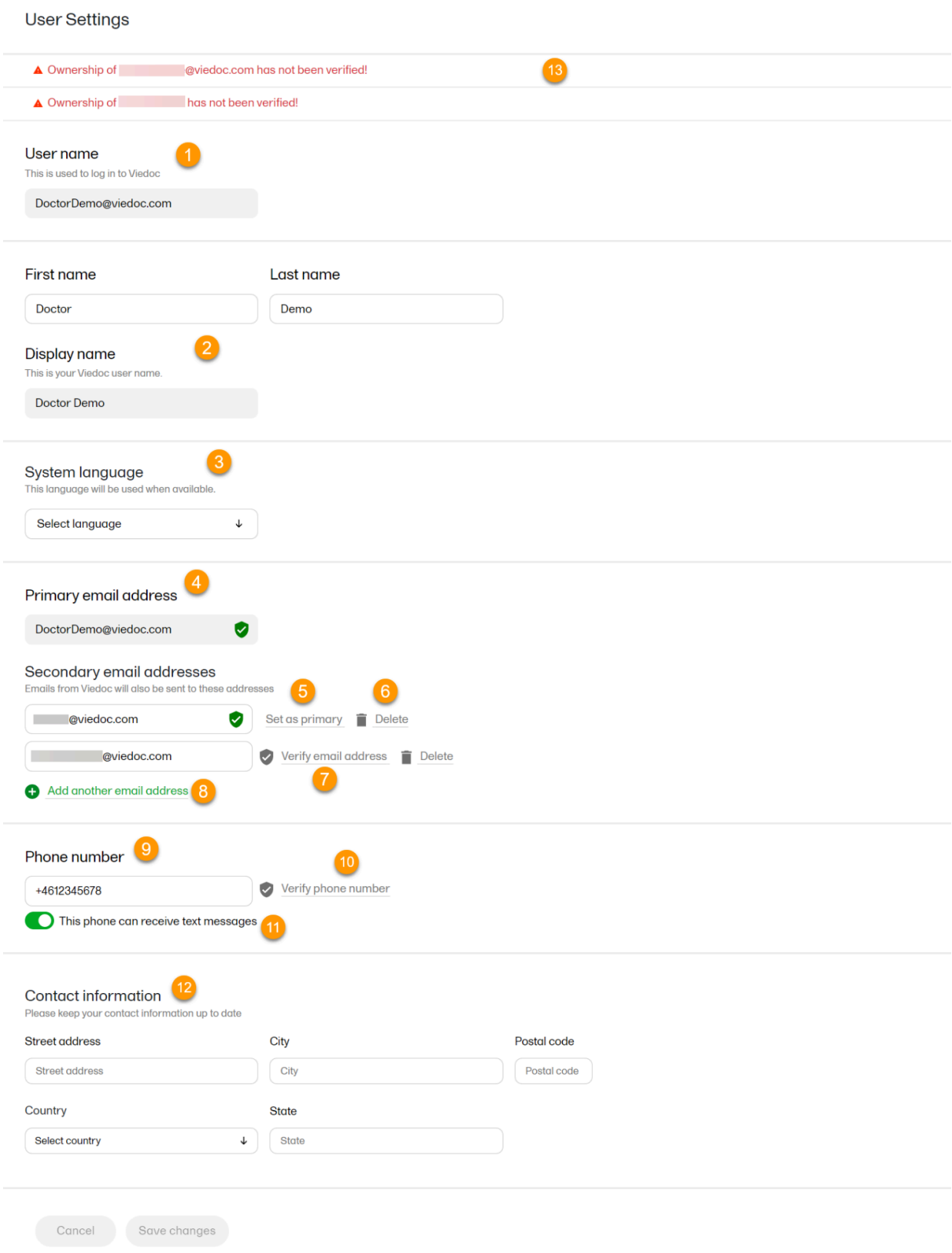
Phone number formats are also supported with:

- Separators between number groups, for example spaces, hyphens, and dots.
- Parentheses around area codes or other number groups.
- An optional country code with a plus sign is also permitted.
- Extensions marked by "x" or "ext"

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** window, 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** window 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:

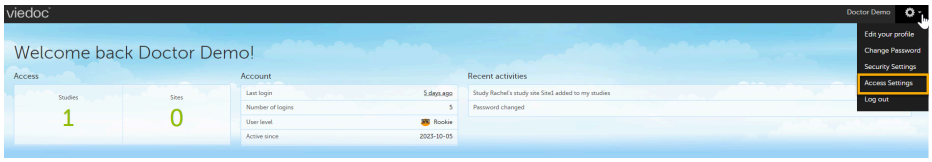
1 Make sure that the phone number is correctly entered and that the **Phone can receive text messages** option is selected.

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** window 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

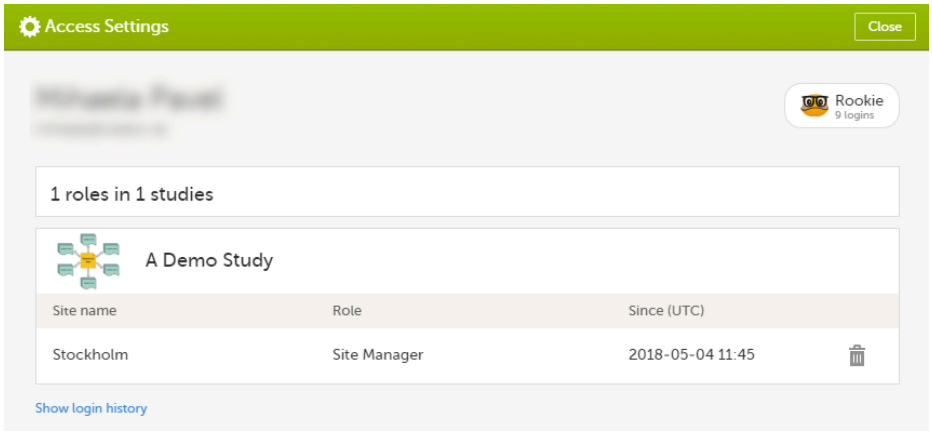
From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.



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)

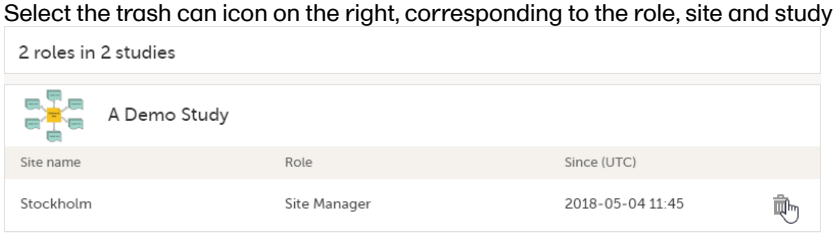
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

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

4.2 Deleting study access

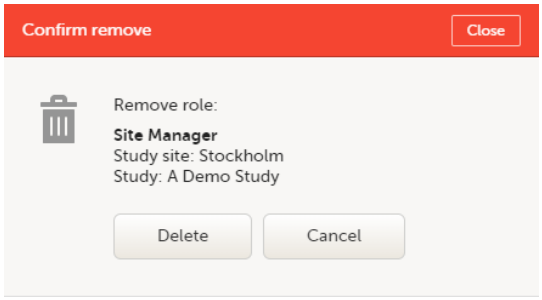
To remove yourself from a certain role within a study:

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



A confirmation window is displayed.

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



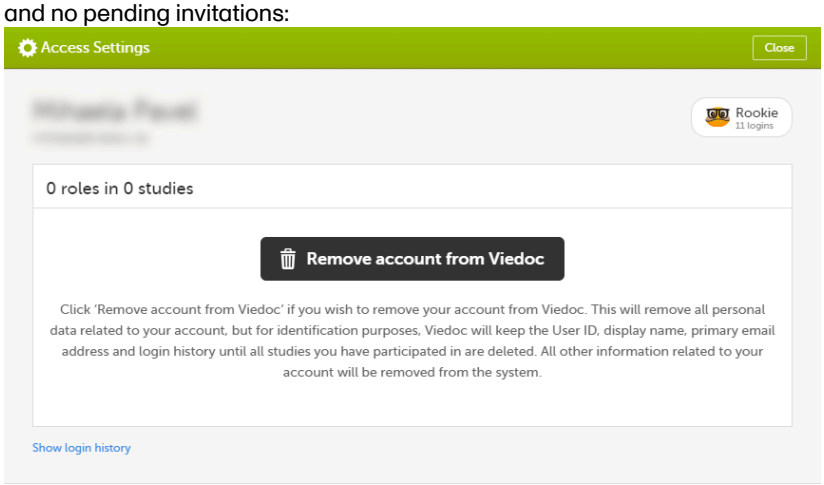
A notification email will be sent to all the Study Managers, or to the Site Managers if any roles are delegated.

4.3 Deleting your Viedoc account

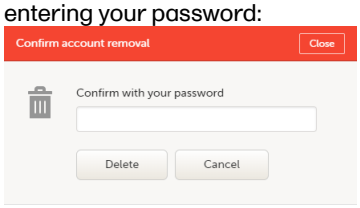
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

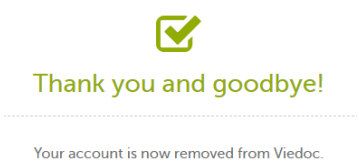
1 Go to **Access Settings**. To be able to remove your account, you should have no roles left in any study and no pending invitations:



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



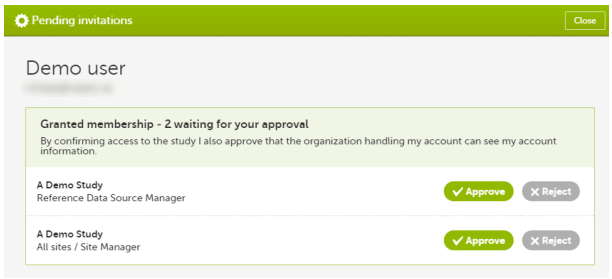
3 Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



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.

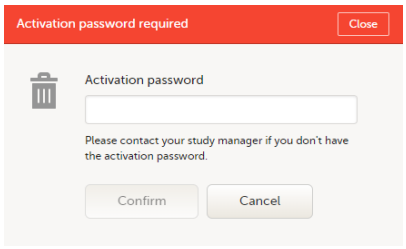
5 Pending invitations

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

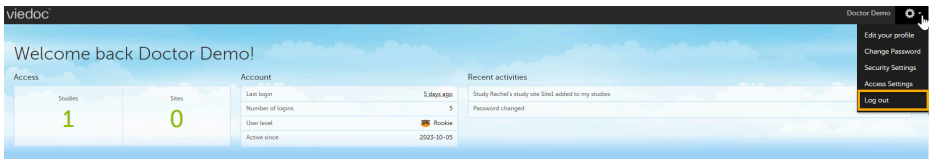
To postpone the approval or rejection of study invitations, select **Close** in the top right corner of the **Pending invitations** window and postpone providing an answer to the study invitation.
To access the pending invitations again, the **Pending invitations** window is shown:

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

---

6 Logging out

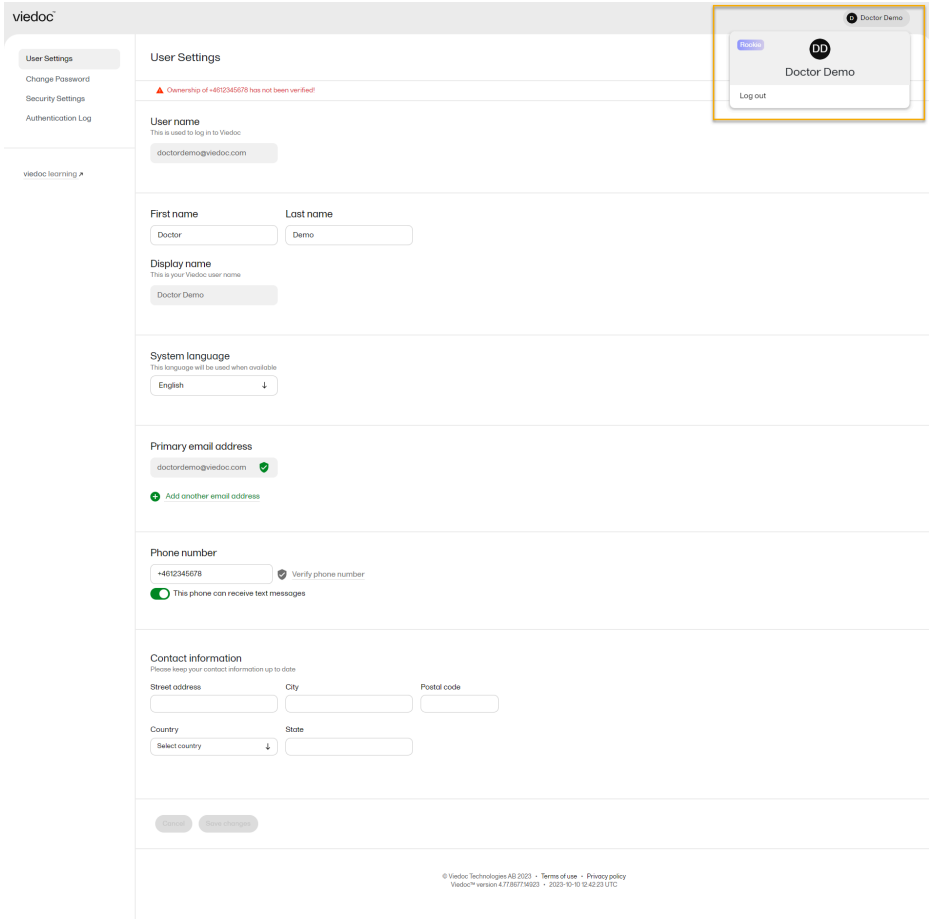
From Viedoc you can log out from different locations:



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

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

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


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
© Viedoc Technologies AB 2023 • Terms of use • Privacy policy
Viedoc™ version 4.77.867.74923 • 2023-10-10 12:42:23 UTC

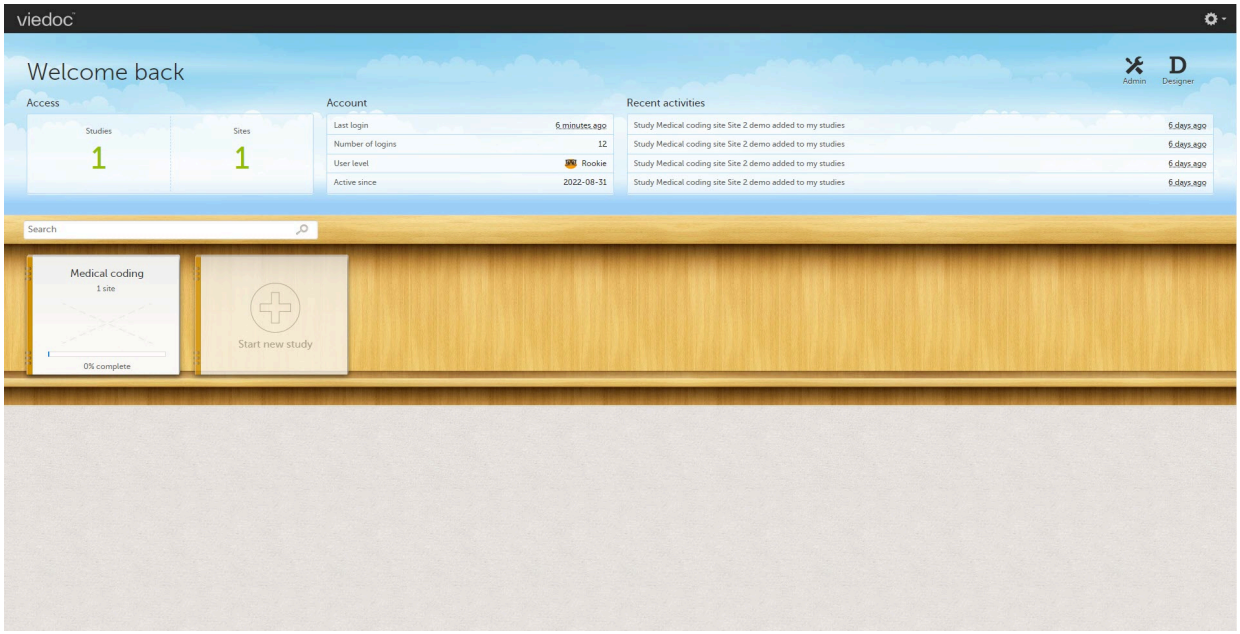
Overview of the landing page

Overview of the landing page

Published by Viedoc System 2025-06-10

1 Landing page

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



1.1 Summary information

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

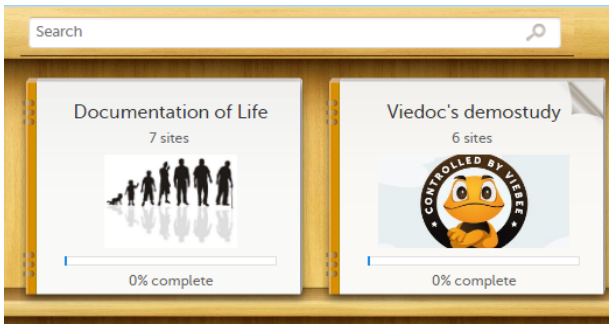
Skill level	Icon	Description
Semi-pro		21-100 logins
Pro		101-1000 logins
Legend		> 1000 logins

- **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.

1.1.1 Study slider

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.



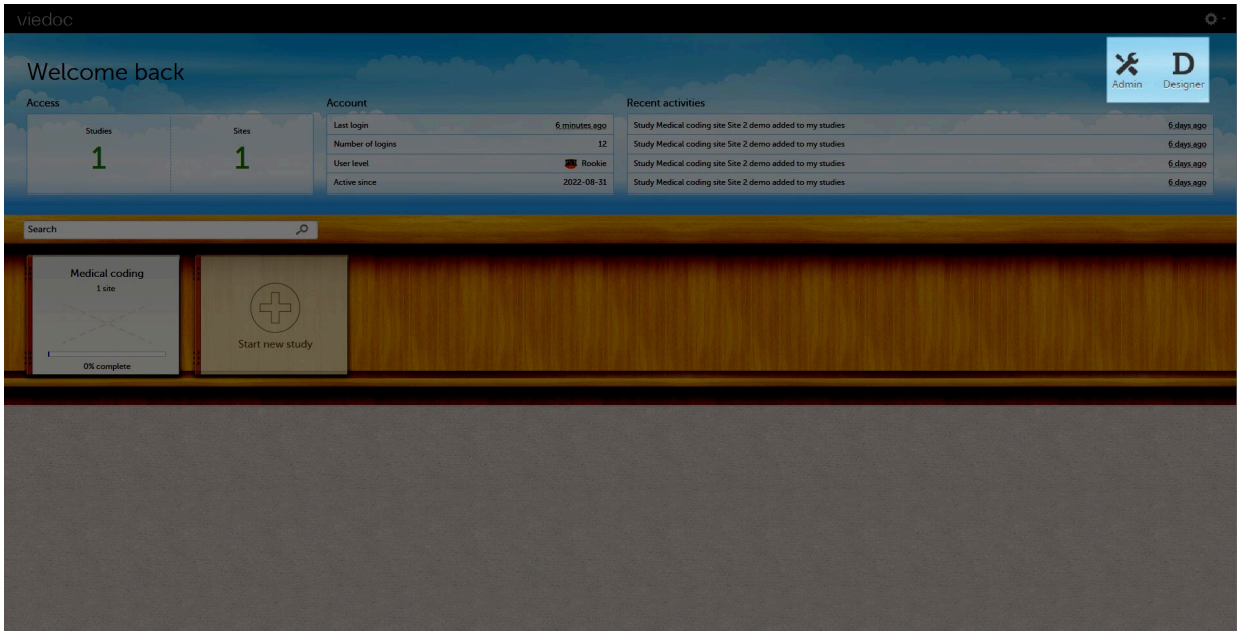
A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

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.

Select a study logo to select a study to work with. The study start page is loaded on the lower half of the screen, for more information, see Study start page.

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


viedoc
Welcome back
Admin
Designer
Access
Studies
1
Sites
1
Account
Last login
6 minutes ago
Number of logins
12
User level
Rookie
Active since
2022-08-31
Recent activities
Study Medical coding site Site 2 demo added to my studies
6 days ago
Study Medical coding site Site 2 demo added to my studies
6 days ago
Study Medical coding site Site 2 demo added to my studies
6 days ago
Study Medical coding site Site 2 demo added to my studies
6 days ago
Search
Medical coding
1 site
0% complete
Start new study

Approving eCRF changes

Approving eCRF changes

Published by Viedoc System 2021-11-24

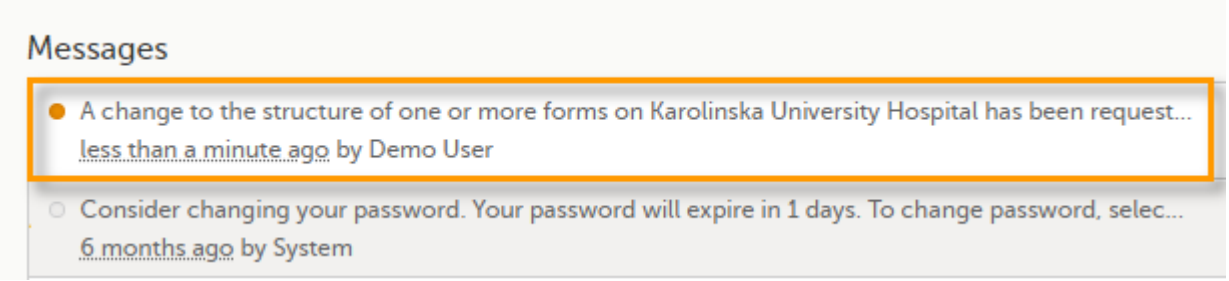
1 Introduction

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:

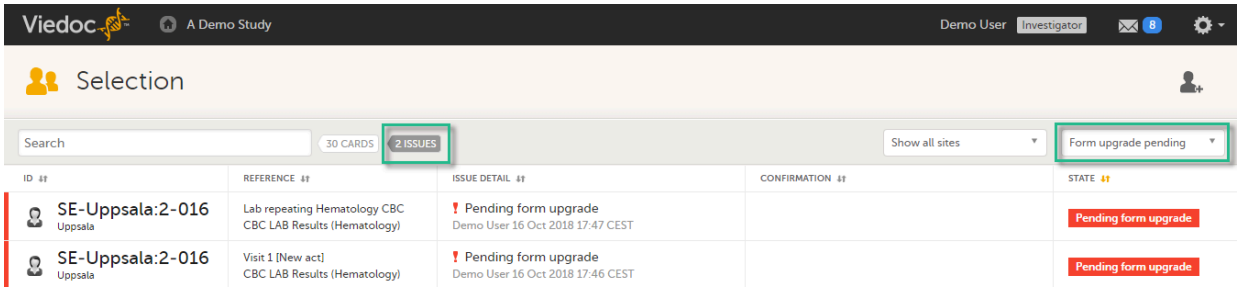


By clicking on the message, a detailed text is shown, that summarizes the changes to the eCRF as entered by the Study Manager.

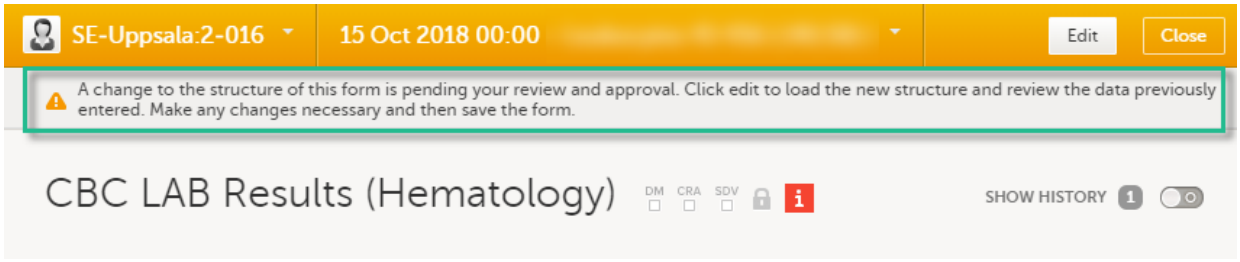
An approval is needed before the saved forms will be upgraded to the new version, for those types of changes that potentially affect data integrity, such as form names, field labels, instructions text, and so on.

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.

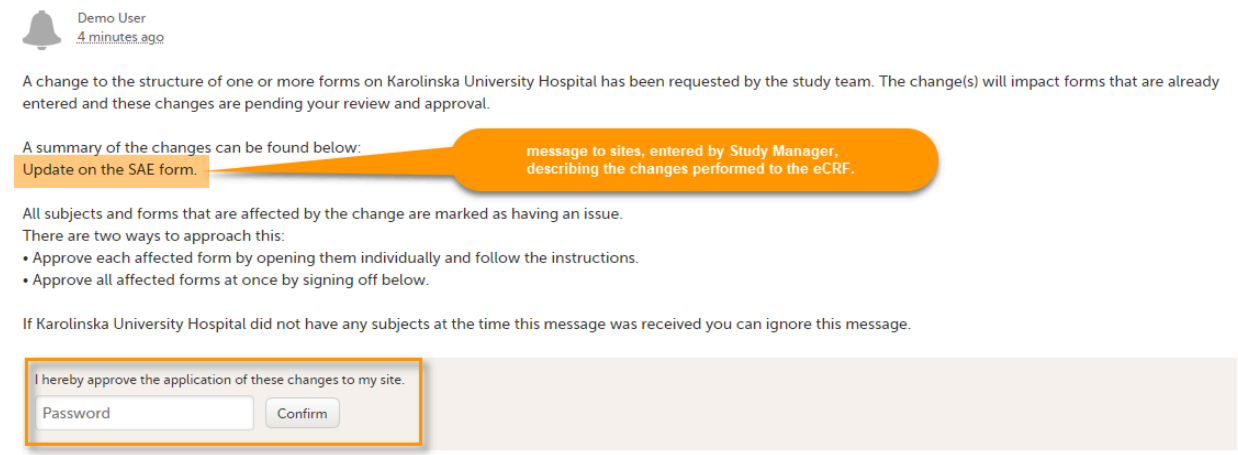
The forms affected by the upgrade are marked with an issue flag (the red **[i]** icon). A summary of the affected forms can be viewed in the Selection page, by selecting the **ISSUES** view and filtering from the drop-down list in the upper right corner by **Form upgrade pending**:



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.

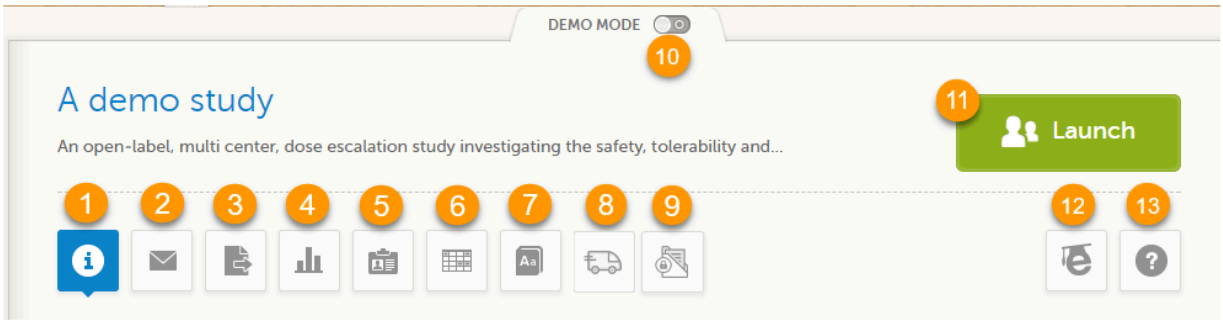
Study start page

Study start page

Published by Viedoc System 2025-09-24

1 Introduction

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



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

Notes!

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

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

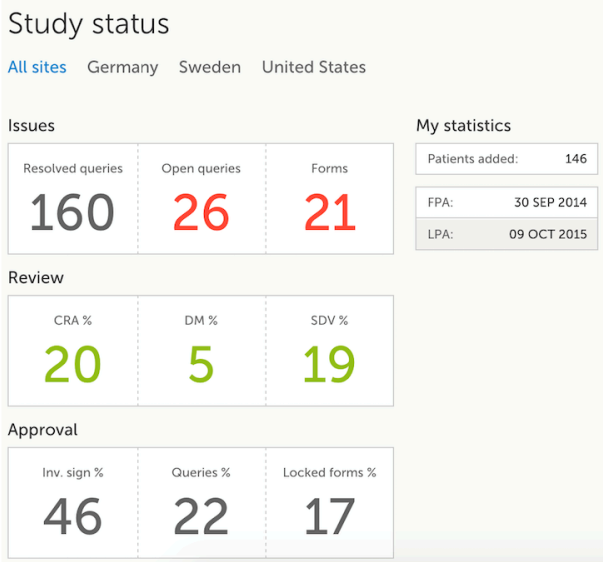
- If you have mandatory documentation pending to be read and signed, then the first page that opens is the Documentation & Training.

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

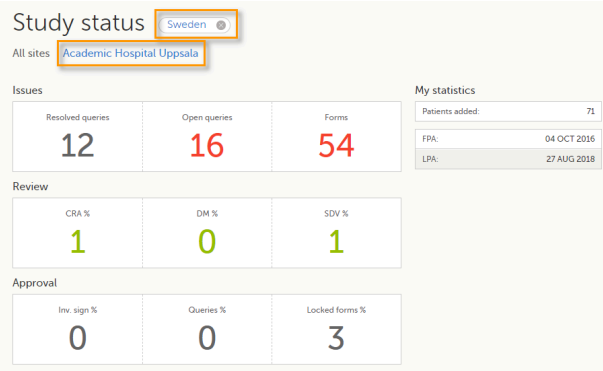
- If you do not have any mandatory documentation pending signing, then the first page that opens is the Study status page.

2 Study status

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



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



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

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

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

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

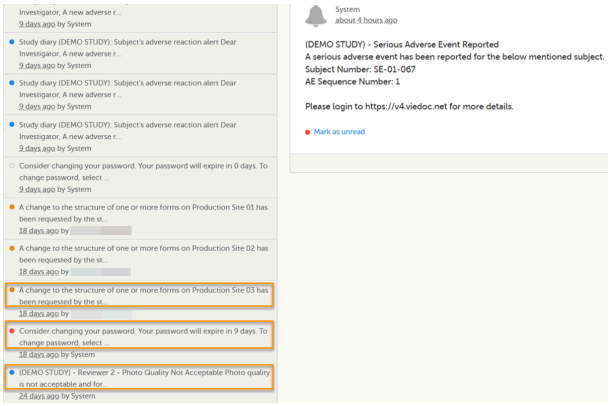
Note! All the numbers reflect the data entered in the selected operation mode (demo or production), that is, if demo mode is selected, then the numbers reflect only the data entered in demo mode.

---

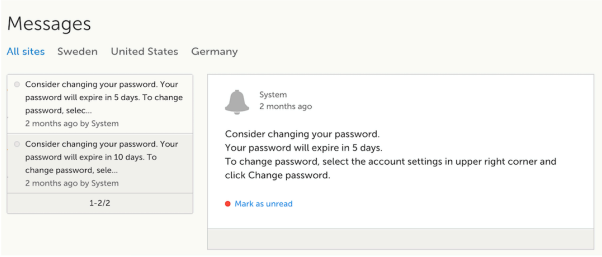
3 Messages

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

In the message window, a blue dot indicates a study-specific alert, a yellow dot indicates a form change requiring approval, and a red dot indicates an expiring password.



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



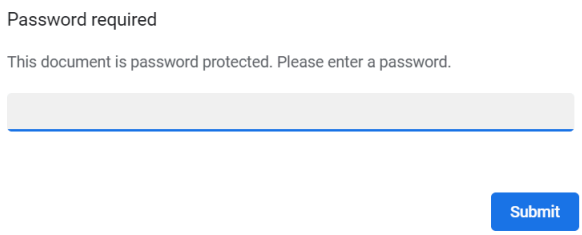
3.1 Alert messages

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 pop-up below where you can enter your password:



4 Data export

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

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

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

For more information about data export and preview, see Exporting data.

---

5 Metrics and Viedoc Reports

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

Note! Metrics might not be available to all users.

For a detailed description, see Metrics.

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

---

6 Roles

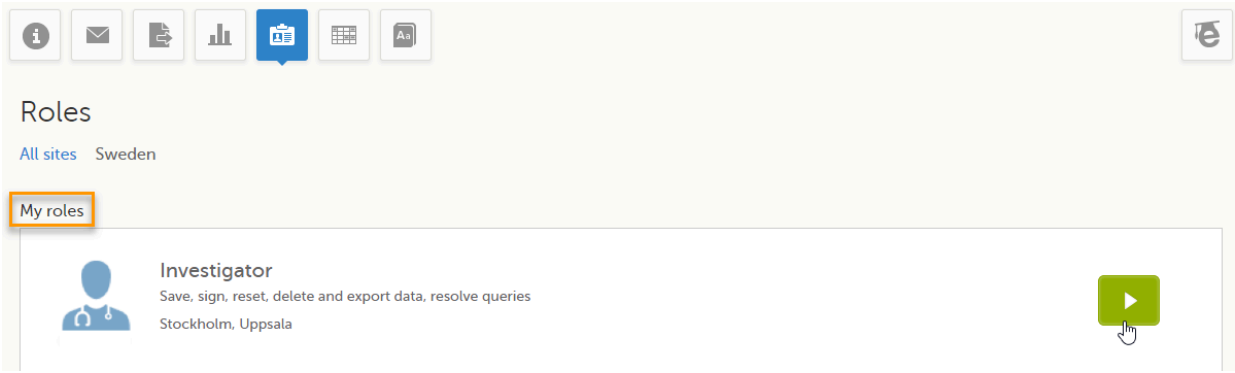
Note! The Roles page is only available for users with special permission to view roles, as per the study design.

The Roles page provides information on:

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

6.1 My roles

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



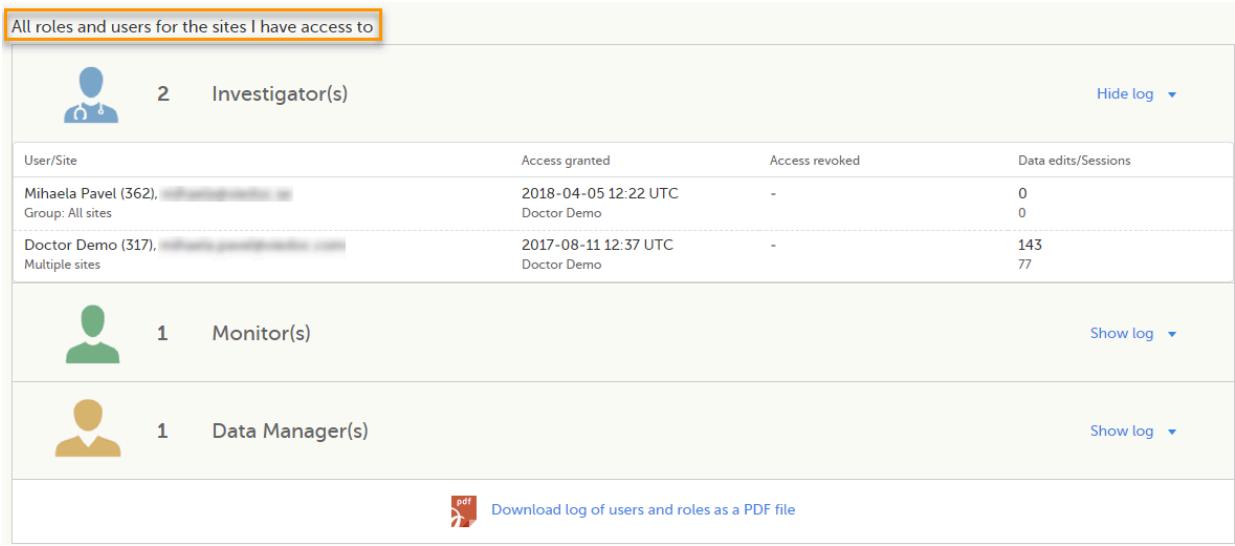
The following information is displayed (with *examples*):

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

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

6.2 All roles and users for my site(s)

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



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

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

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

6.2.1 User logs

For each study, you can download user logs in PDF and Excel format 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.

Notes!

- In Viedoc Clinic, both production sites and demo sites and roles/users for both production sites and demo sites can be included in the user administration log, depending on which mode (Production/ Demo mode) is enabled when the log is generated.
- System roles for a study (organization users are not included) are included in the user and administration log. For example, site managers for demo sites are included when a log is generated for a production site, as a site manager is a system role.

You can generate the log for the country/site selection in your current Viedoc language by selecting **Generate a PDF file / Generate an Excel file** at the bottom of the study start page:

Once the user log is generated you can:

- **Download the latest generated log** for the country/site selection (stored on the server with a date and time stamp) 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

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

1. Summary - the summary of active/inactive roles, active/inactive users as well as data contributors, grouped in one section per site.

- An **Active role** is the current distinct role all active users have for a site.
- An **Inactive role** is a role that was previously assigned but currently lacks any active user.
- An **Active user** is a user with at least one active role.
- An **Inactive user** is a user who had at least one role at a site, but all roles for the site have been revoked.

2. Roles - a list of the permissions associated with each role and corresponding history, grouped in one section per site.
3. User log per site - a list of all users who ever had access to data, including user activity, grouped in one section per site.
4. User account logs - a list of the change history of all user accounts for the users listed in the above sections of the log, grouped per user (identified by the user ID).

6.2.1.2 User administration log in Excel

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

1. Report Info - general information about when and by whom the log was generated, and some information about the study status. The following more detailed information is contained:

- The Organization name
- The Study name
- Production study GUID
- Demo study GUID
- For PMS studies: Sponsor side Production study GUID
- For PMS studies: Sponsor side Demo study GUID

2. User Access Log - a list with detailed information about user access, showing one row per site and role, including clinic roles and system roles.
   Note! The access granted date/time is the date/time when a user accepts the invitation to a study.
   Some columns in this sheet are further explained here:

- **Site Group** - indicates when a user is granted access to the site through a site group invitation. Possible values are *Training sites*, *Countries*, and *All sites*.
- **2FA** - indicates what level of two-factor authentication the user has. Possible values are *Study level*, *Account level*, or *No two-factor authentication enabled*.
- **Latest system login date/time** - information about the latest login of each user (for end users only, not API client users).
- **Certified** - indicates if the user is certified for the role. Possible values are *Yes, No*, or an empty cell for roles that don't have mandatory training sections to read.
  - If the user has signed the certification associated to their role, the column will display: Certified:Yes.
  - If the user has selected Read & Understood but not signed the associated certification, the column will display: Certified: No.
- **User type** - indicates the type of user. Possible values are *End User or API Client*, to indicate if the user is an end user that can log in to the system or a Web API Client that can access the API with a role.

3. User Invitation Log - a list with information about pending invitations and rejected invitations, including clinic roles and special roles.

Note! When an invitation has been accepted the user will no longer be included in the invitation log, but in the User Access Log.
Some columns in this sheet are further explained here:

- **Role** - role of the invited user.
- **Email Address** - Email address of each invited user.
- **Existing User** - indicates whether the invited user already has another role in the study, or is a new user. Possible values are *Yes*, *No*.
- **Initial Invitation Sent date/time** - information about the first invitation of each user
- **Initial Invitation Sent By ID** - the numeric user ID for the user
- **Initial Invitation Sent By Display Name** - initial invitation sent with the display name usedin Viedoc to identify the user.
- **Initial Invitation Sent By Email Address** - Email address of the initial invitation sent to the invited user.
- **Invitation Resend Count** - the number of times an invitation has been resent.
- **Latest Invitation Sent date/time** - information about the latest invitation of each user.
- **Status** - invitation status, possible values are *Pending*, *Rejected*.
- **Invitation Rejected date/time** - information about a rejected invitation for each user.

4. **Certification Log** - a list of certifications per user. Certifications performed before the release of 4.65 lack information about what roles the certification applies to. That is, the cells in column **Certified With Roles** are empty.
5. **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.
6. **Account Settings Log** - a list with all user accounts setting changes with user ID, change log, user name, and date/time.

---

7 Reference data

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

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

---

8 Medical coding

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

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

For more information about medical coding, see Medical coding.

---

9 Viedoc Logistics

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

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

---

10 Viedoc eTMF

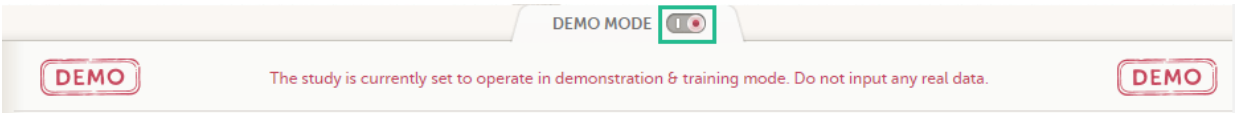
Viedoc eTMF is a digital repository for capturing, managing, sharing, and storing essential documents.

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

---

11 Demo mode

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



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

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

See also the video tutorial Activate demo mode.

12 Launch

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

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

13 eLearning / Documentation & Training

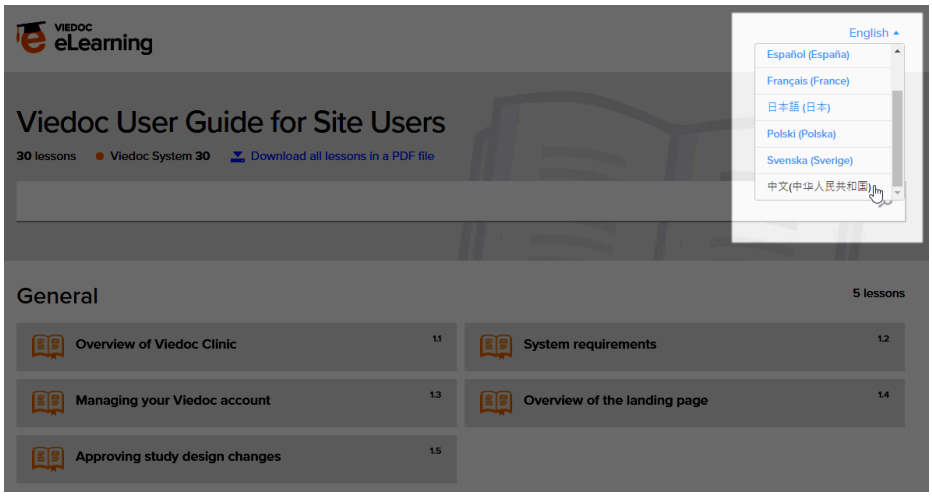
If you have mandatory documentation pending to be read and signed, this is the first page that is displayed when you access the study.

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

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

- English
- Chinese
- Japanese

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



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

14 Support

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

Back to top of page

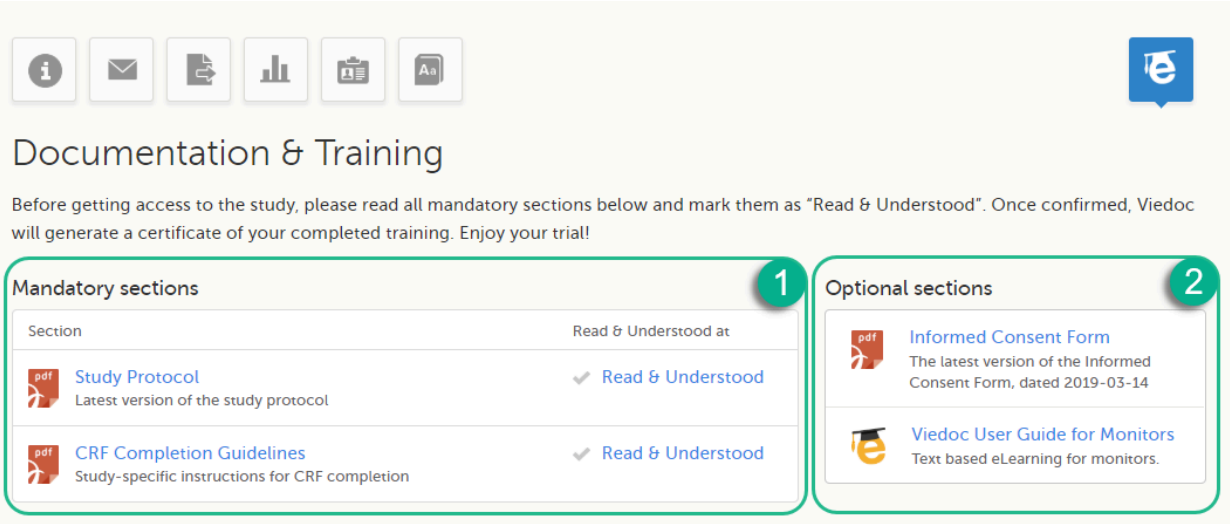
Documentation and Training

Documentation & Training

Published by Viedoc System 2020-06-04

1 Introduction

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



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

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

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

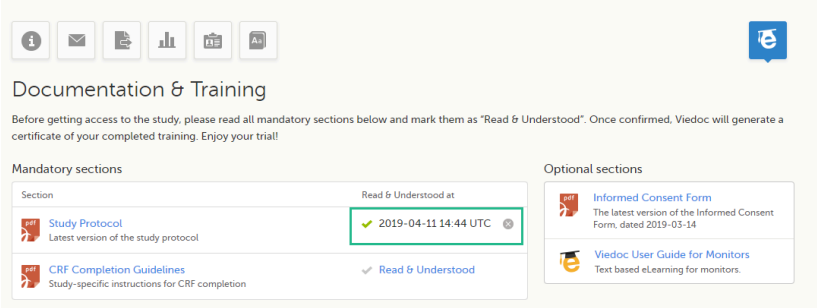
2. **Optional sections** - contains additional educational and reference materials that you have access to. Simply click on the link to open each of the available documents/links.

2 Becoming a certified user

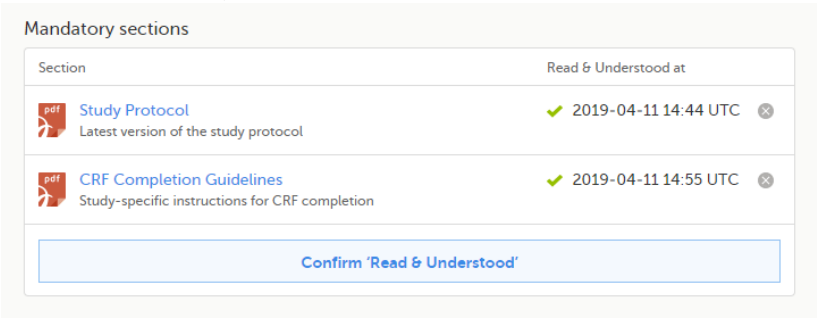
To work within a study for which mandatory training sections were assigned, you need to read, understand and sign all the sections listed as mandatory.

To obtain the user certificate:

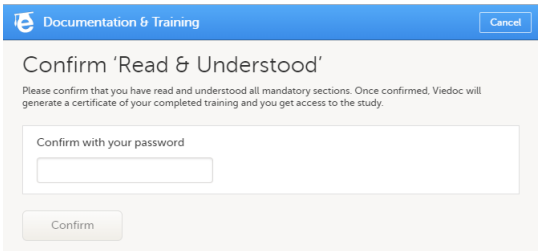
1 Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:



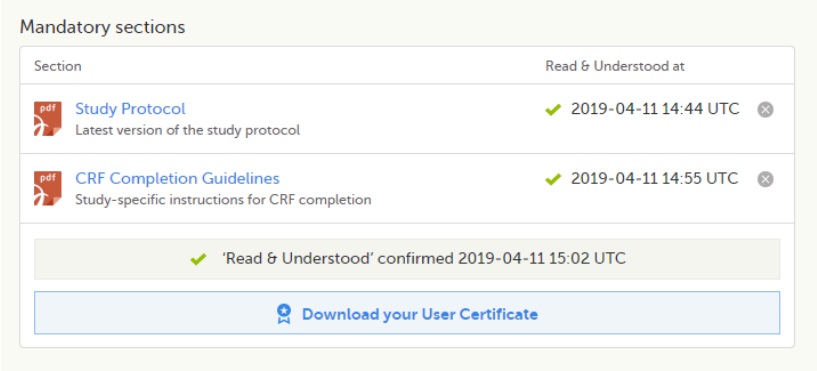
2 Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:



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



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



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

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

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

3 Downloading your user certificate

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

The following information is provided on the certificate:

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

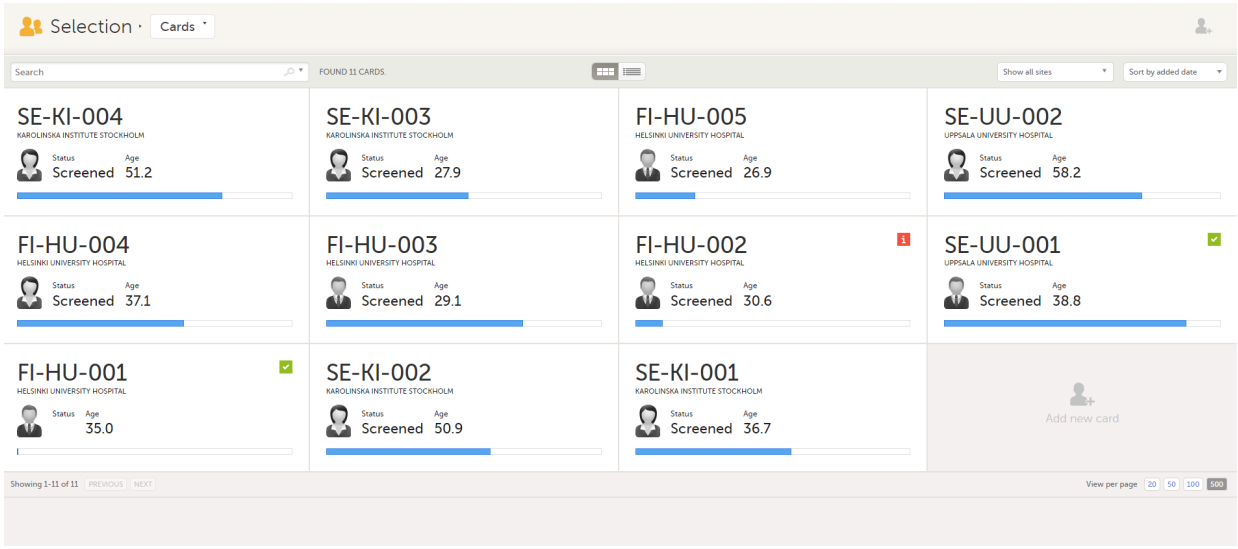
Selection page

Selection page

Published by Viedoc System 2025-04-24

1 Introduction

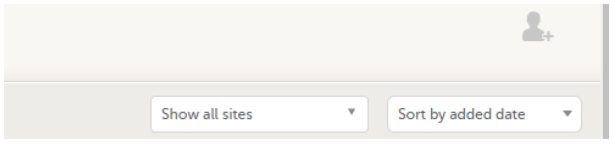
The Selection page displays all the subjects from all the sites you have access to:



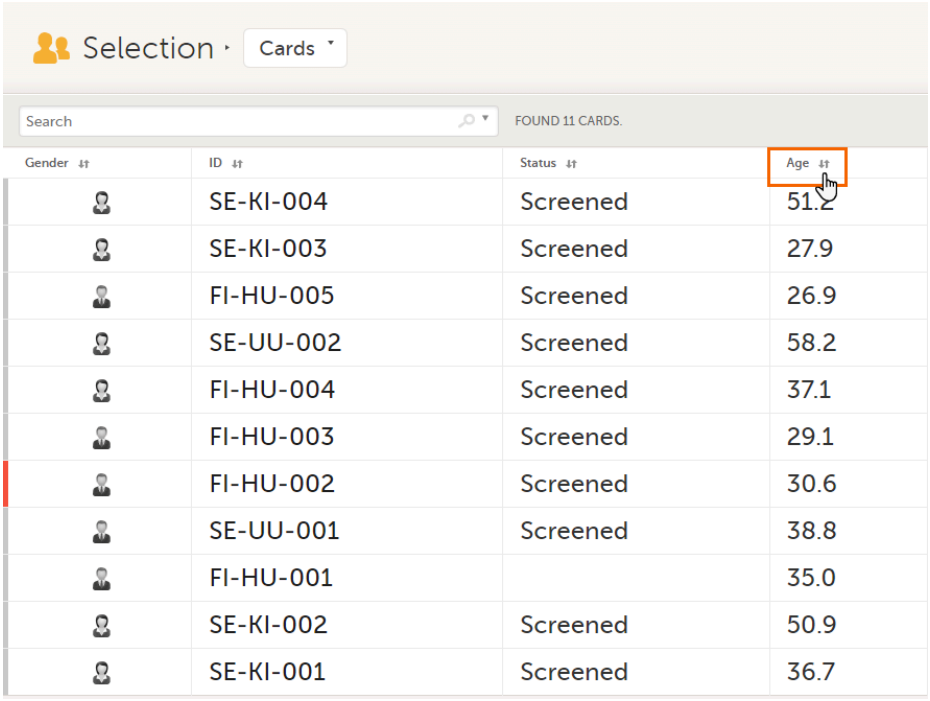
In the default view, each subject is represented by a card. Depending on your study setup, the Selection page can be displayed in several ways. See Views of the Selection page.

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:

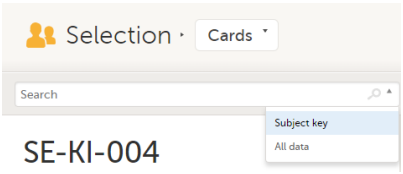


Notes!

- 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).

1.2 Searching

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



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

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

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

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

1.3 Icons

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

Icon	Description
i	**Issue** - at least one open query and/or missing data
7	**Task** - there are tasks to be completed, the number indicates the number of tasks

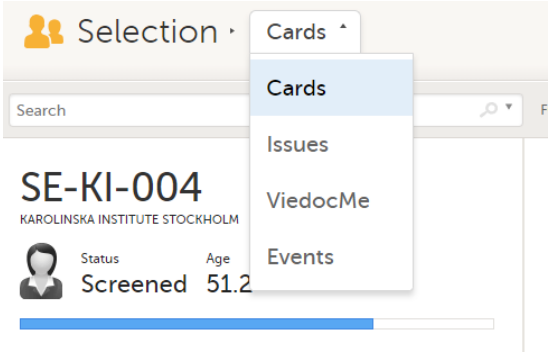
Icon	Description
	Complete - all initiated events have been completely filled in
	Signed - all data that is possible to sign has been signed
	Read-only - the card is being open for edit by another user. Note that the subject card can still be accessed for review or SDV by a user without edit permissions,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

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

2 Views of the Selection page

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

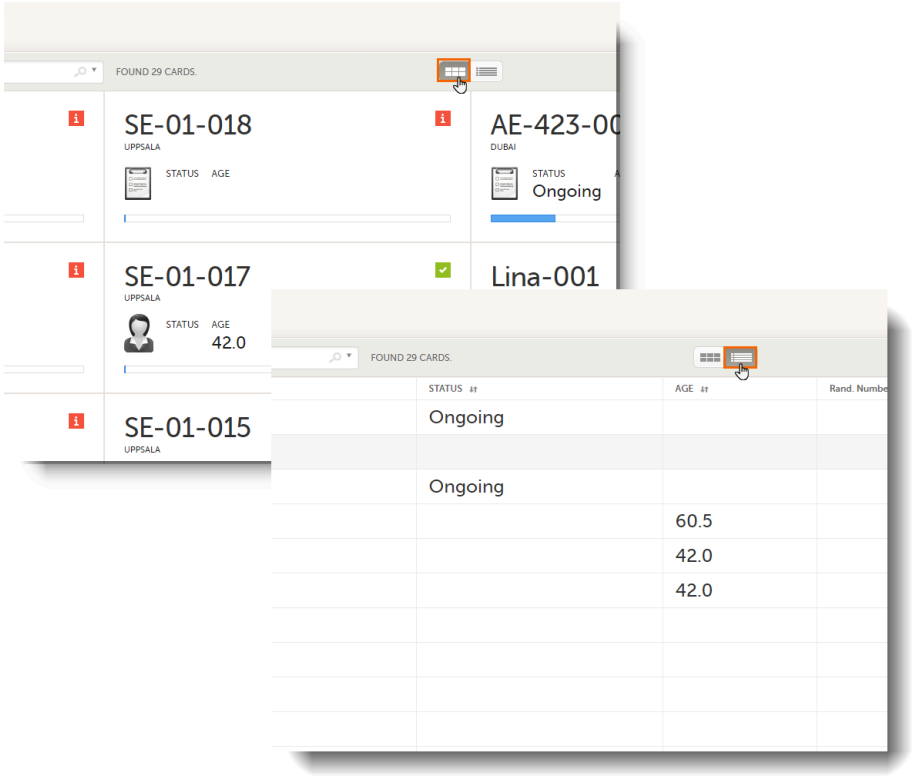
- If the study is configured with extended selection pages, you can select a view at the top of the page. Select **Cards**, **Issues**, **Viedoc Me** or **Events** from the dropdown menu to open the view. The Viedoc Me view is only available to select if the Viedoc Me feature is included in your study.



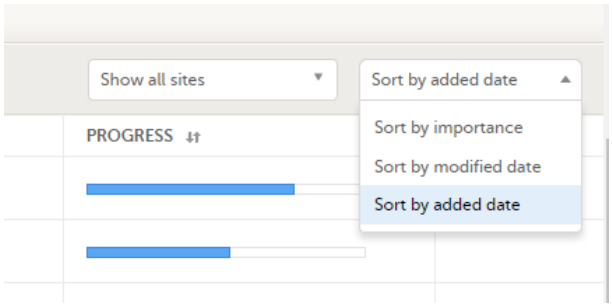
- If the study is not configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

2.1 The Cards view

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

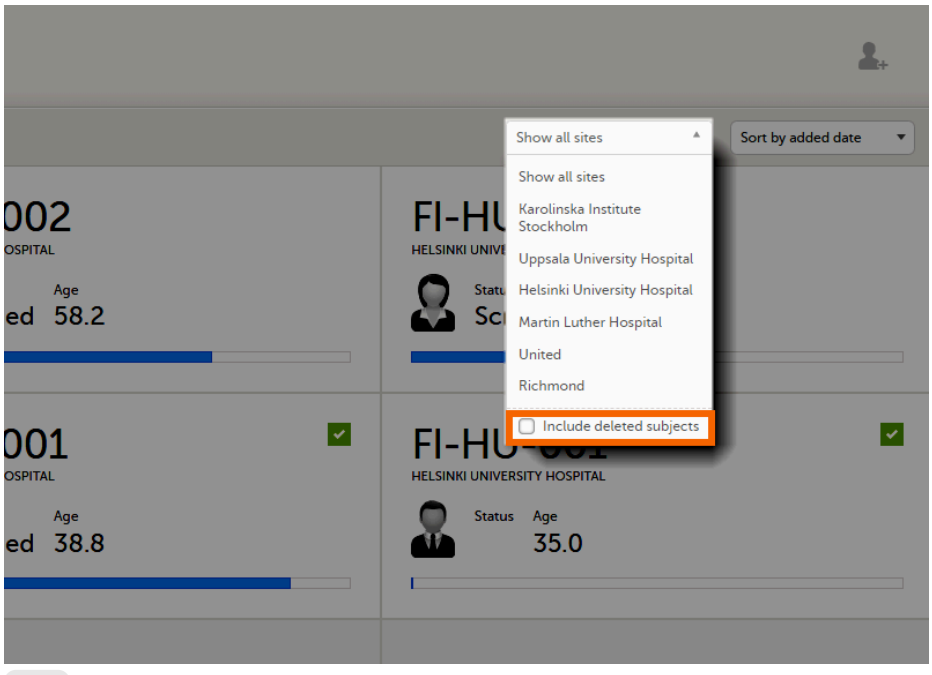


The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:



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

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

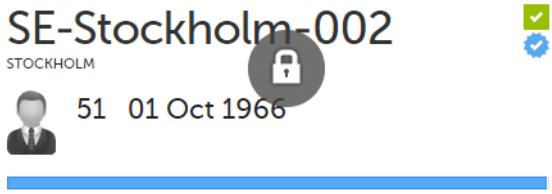


2.1.1 The subject card overview

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:

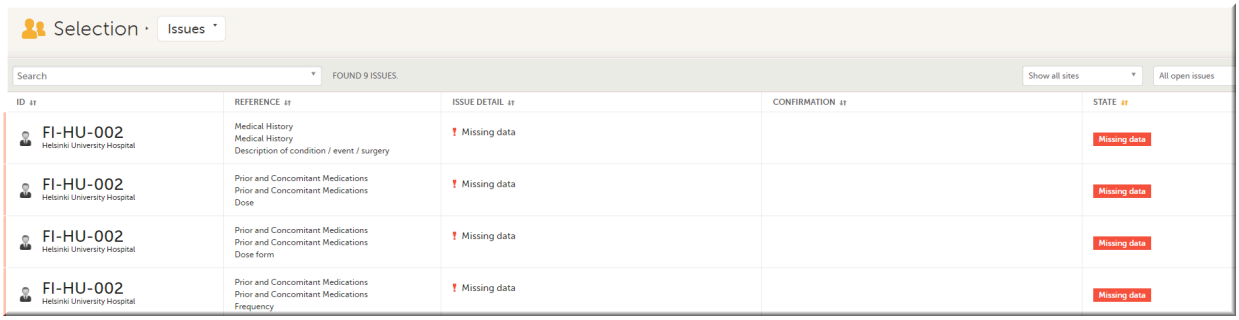


- Progress bar indicating the completion status (in blue)

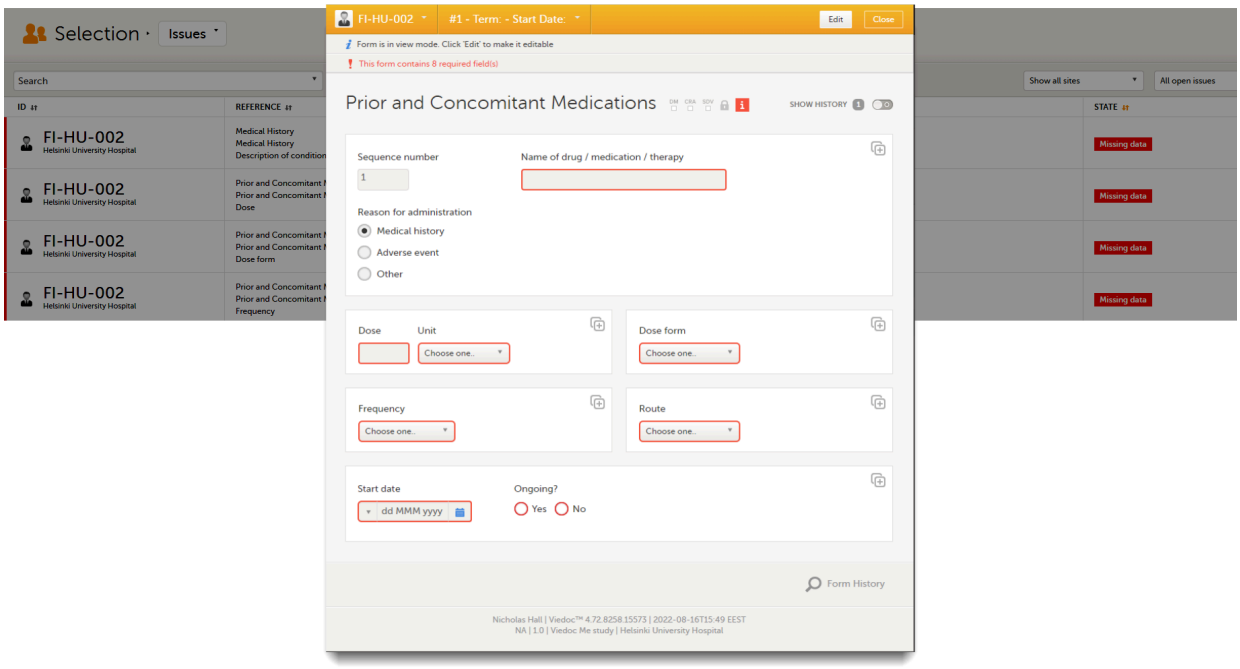
Note! The Selection page does not consider the role visibility except for task count; therefore, the subject status reflects the general status of the subject in the study, regardless of the user who has work to be performed. The subject details view reflects the subject status considering the role visibility. 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:

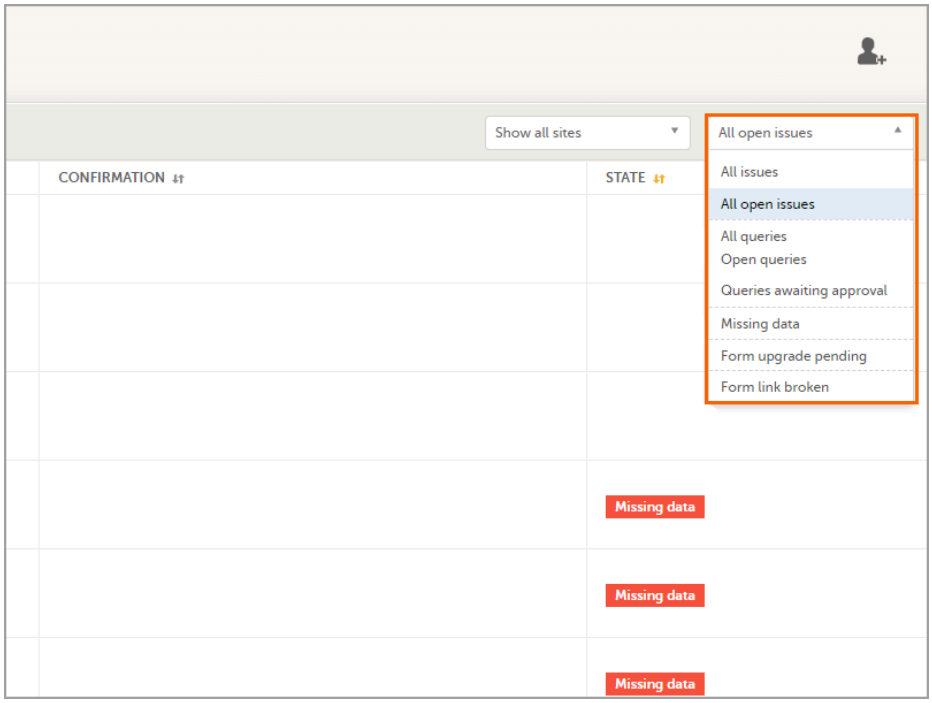


Click any row to open the form where the issue was raised:



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:

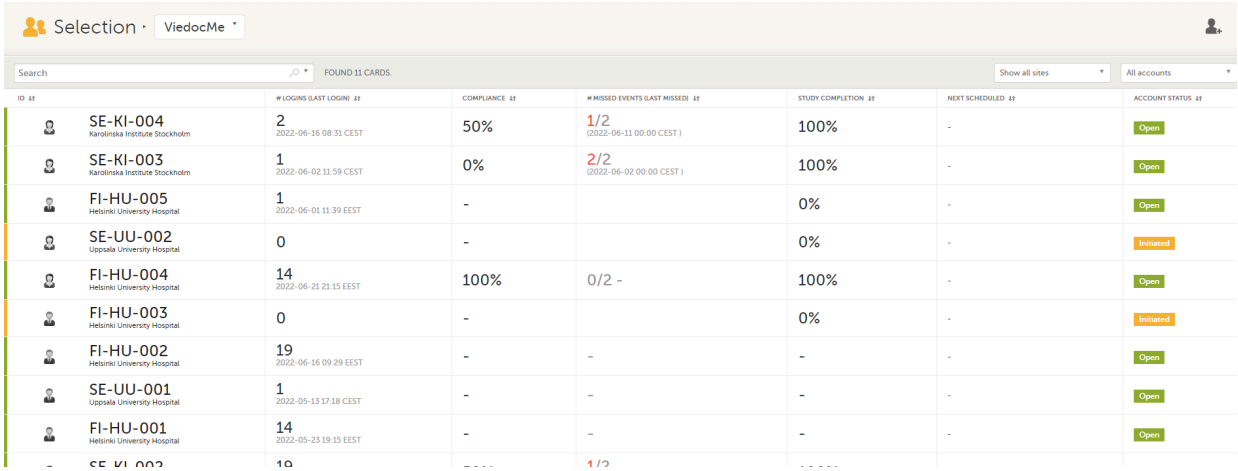


- By site - view data from a specific site or from all sites
  - Include deleted subjects
- By issue type/status:
  - **All issues**:
    a. Missing data
    b. All queries, regardless of status
    c. Form upgrade pending
    d. Pending reference data upgrade
  - **All open issues**:
    a. Missing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

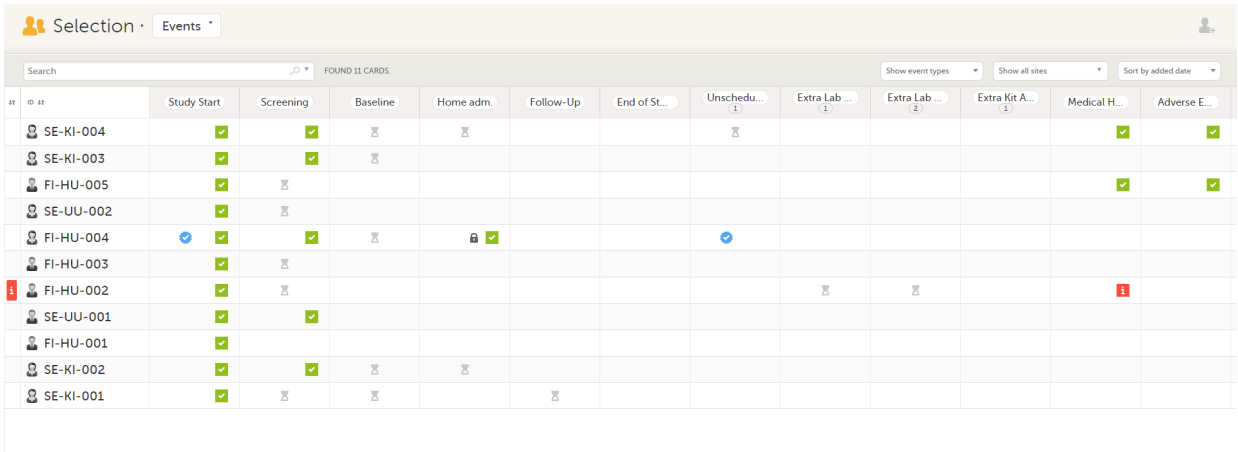


For each subject, the following information is listed:

- **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. The number in red is the number of missed assessments, and the number in grey is the total number of pending assessments. An assessment is counted as the number of pending activities within each event.
- **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

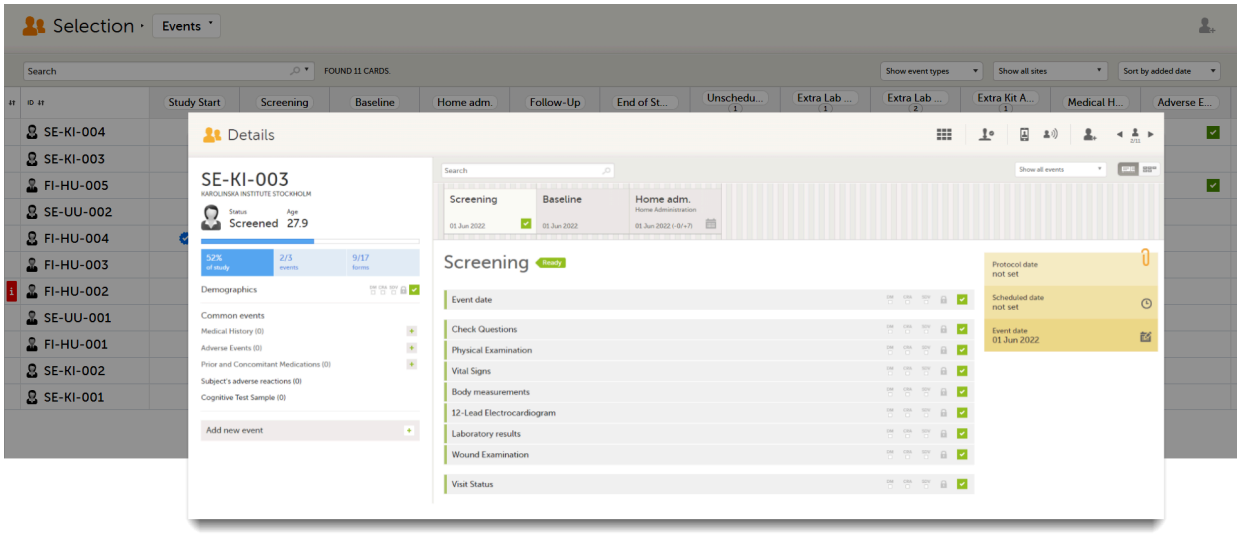
2.4 The Events view

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**

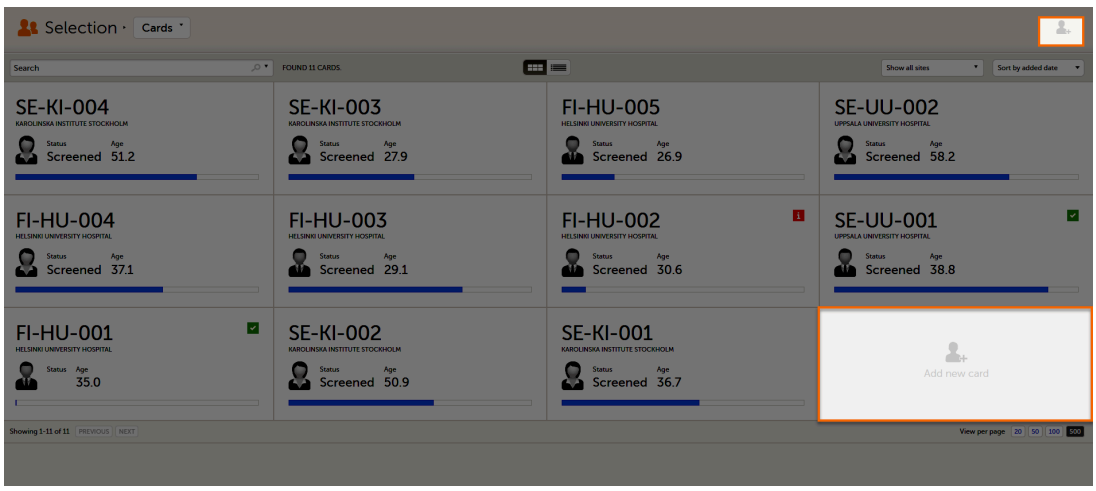
Note! On the selection page, in the **Events** view, the event name (as set in the Study event settings in the study design) is displayed. If there is a recurring event, a counter is shown under the event name, for example: Follow up 1, Follow up 2.

---

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:



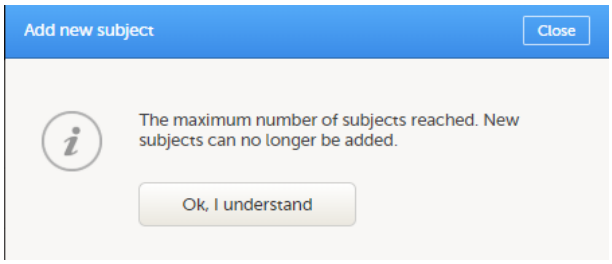
The first form in the study is displayed.

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

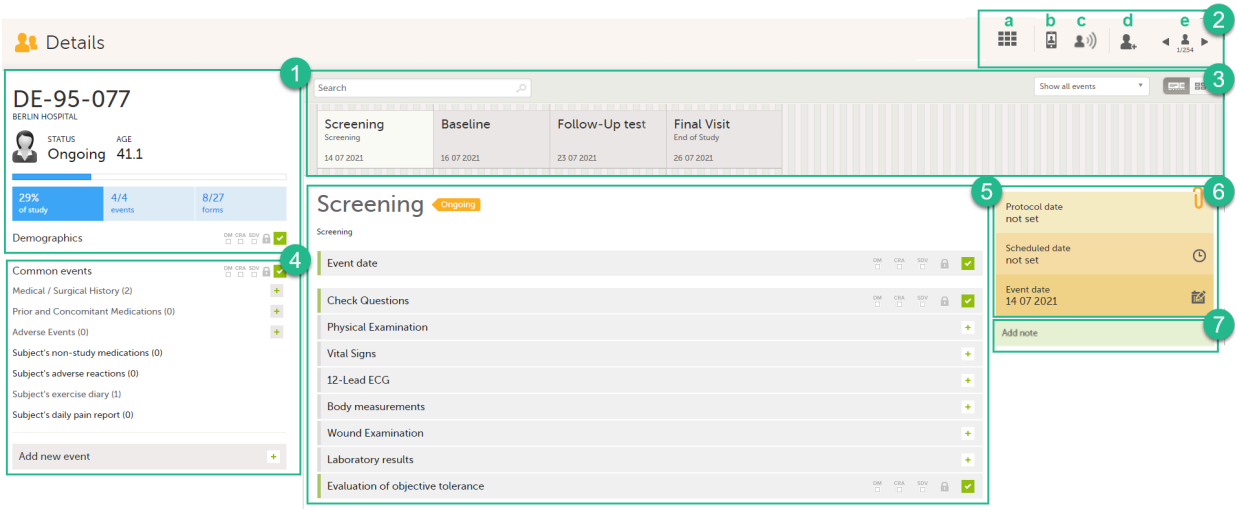
Entering/Editing data

Published by Viedoc System 2025-11-04

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.

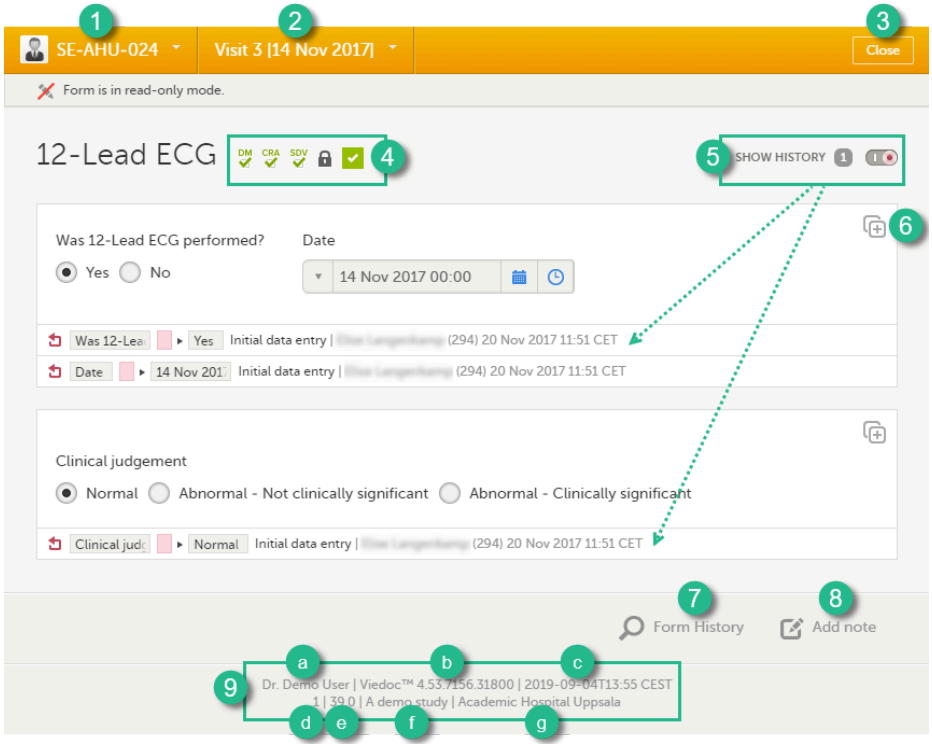
5. The list of the forms to be filled in for the event selected in the event slider (**2**). Click the form bar to open it and enter the data. Depending on the study setup, it may be necessary to initiate the event through the Event date form, to be able to enter data. For more information, see Initiating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

When initiatiating an event, you can either plan the event for a future date or you can initiate the event immediately.

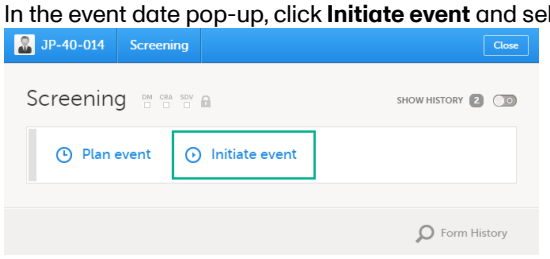
You might need to plan the event based on the study workflow. For example, some studies may need a series of Viedoc Me assessments before a visit. The Viedoc Me events will not be made visible until the you have planned the next visit.

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 pop-up, 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 pop-up closes and the event is initiated. The event status changes to **Ongoing**.

2.2 Unscheduled events

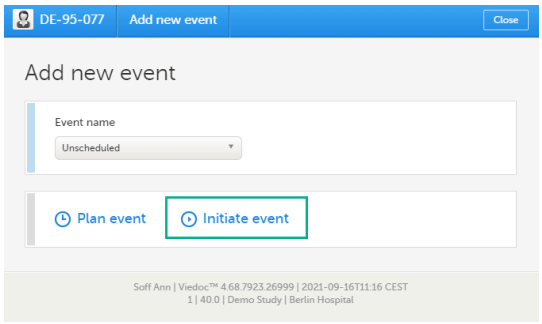
To add and initiate an unscheduled event manually:

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

The Add new event pop-up 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 pop-up 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.

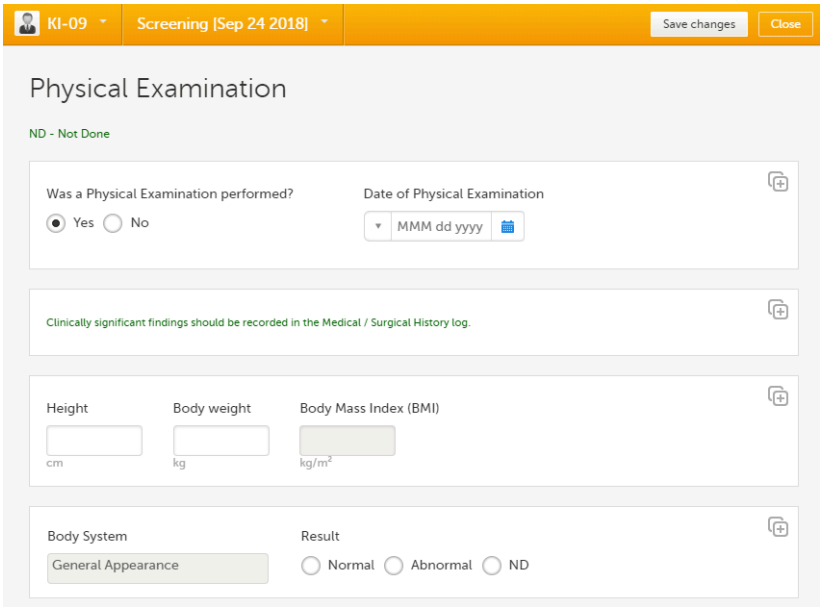
3.2 Entering data in a form

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.

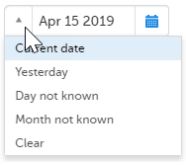
Below, we explain how to fill in some of the most common fields in a form:

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

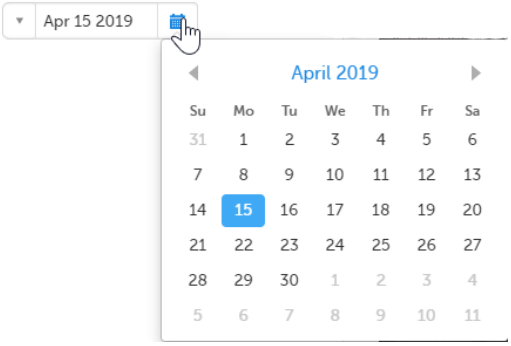
3.2.1 Dates

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.

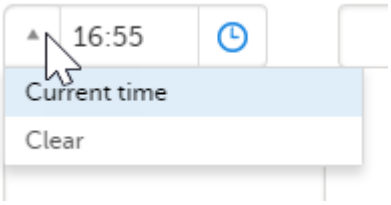


Tip! You can click the month/year header to view all months of the year, and then click the year header to view a range of years.

3.2.2 Times

You can fill in the time field in two ways:

- Click the dropdown menu to select the current time:

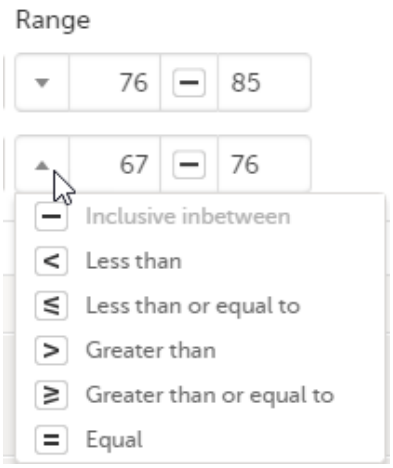


- Click the clock icon to open the time picker. Click the arrows to select the hour and minute (with a five minutes time interval), or double-click the hour and minute fields to manually enter any hour and minute:

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:

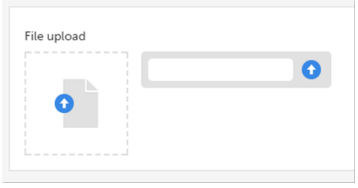
- Inclusive in between
< Less than
≤ Less than or equal to
> Greater than
≥ Greater than or equal to
= Equal to



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.

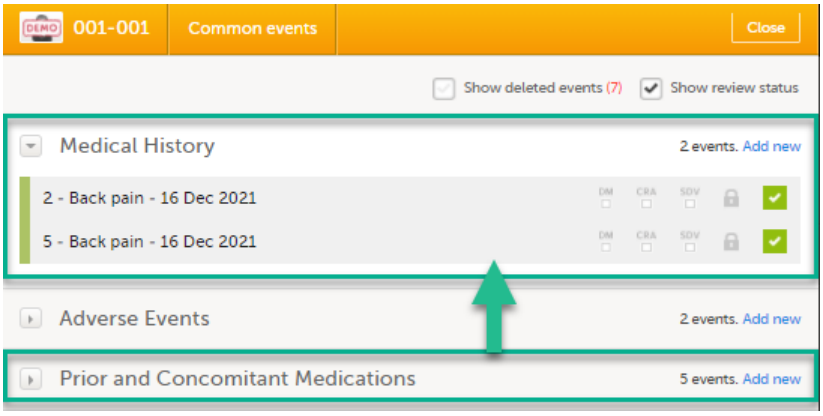
Note! To access the Form link item Clinic users must have access to whichever form type it is configured to link to, for example the Medical History, Adverse events or Prior and Concomitant Medications forms. Viedoc Me does not support forms with Form link items.

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:

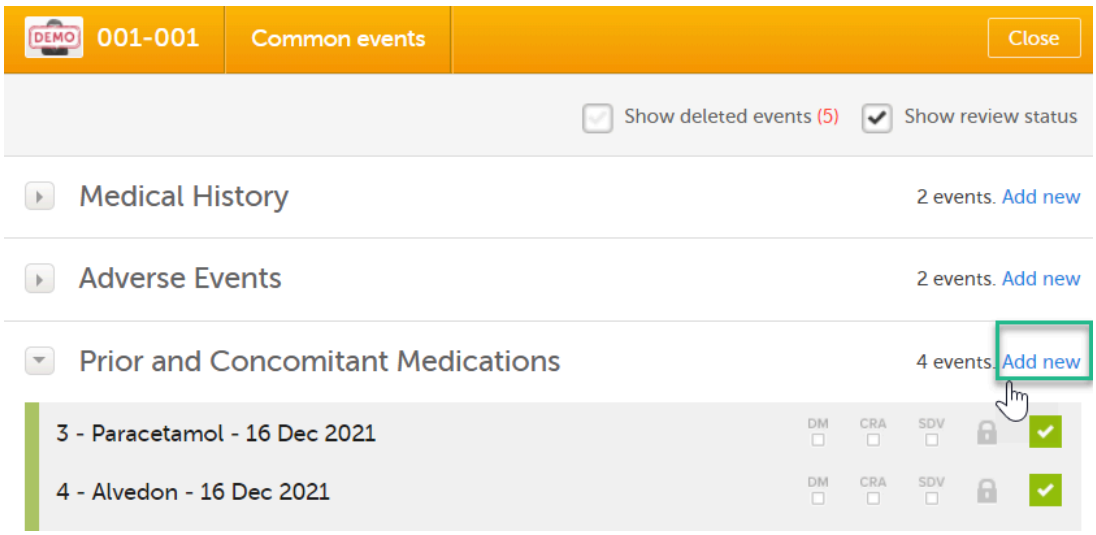
1 Open a subject card. In this card you can see two Medical History forms under Common events:

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.

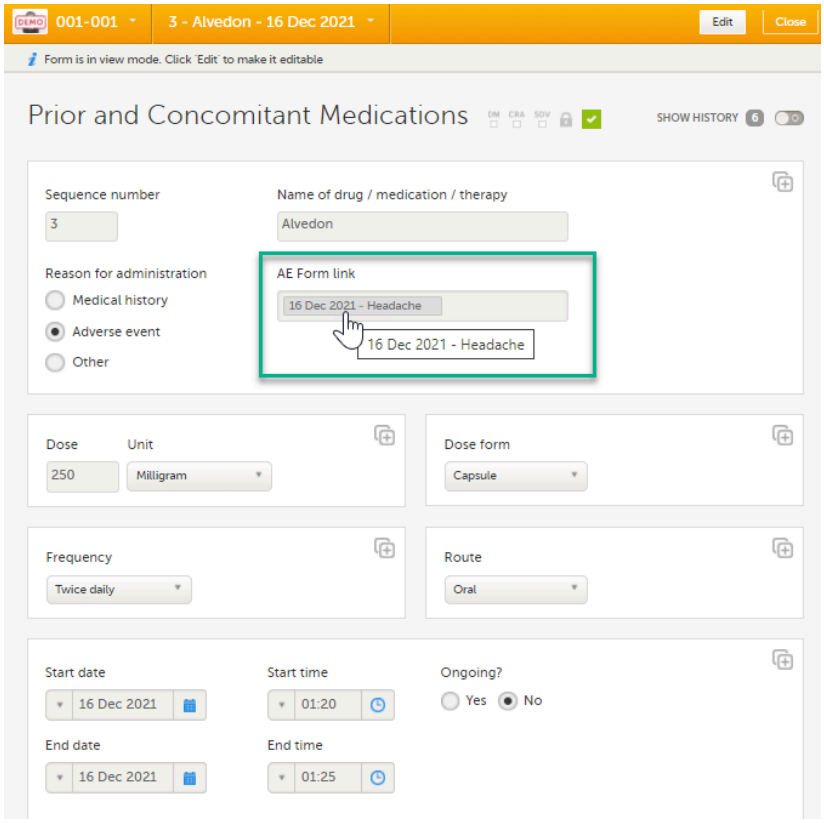
2. Select the relevant Medical history.

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.

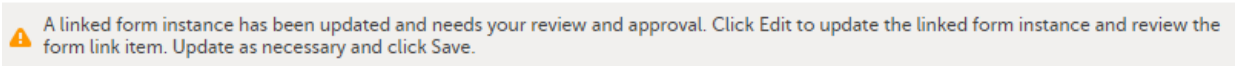


Note! You can also search in the form link item field. This can be useful to find a specific form instance if there are many adverse events for example.

3.3.1 Updates to linked forms

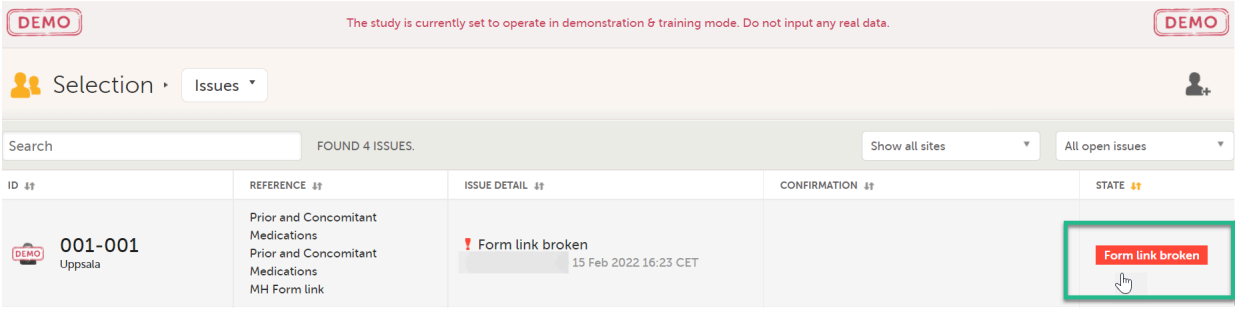
If you update a linked form by resetting, deleting, or changing data, the following occurs:

- 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:

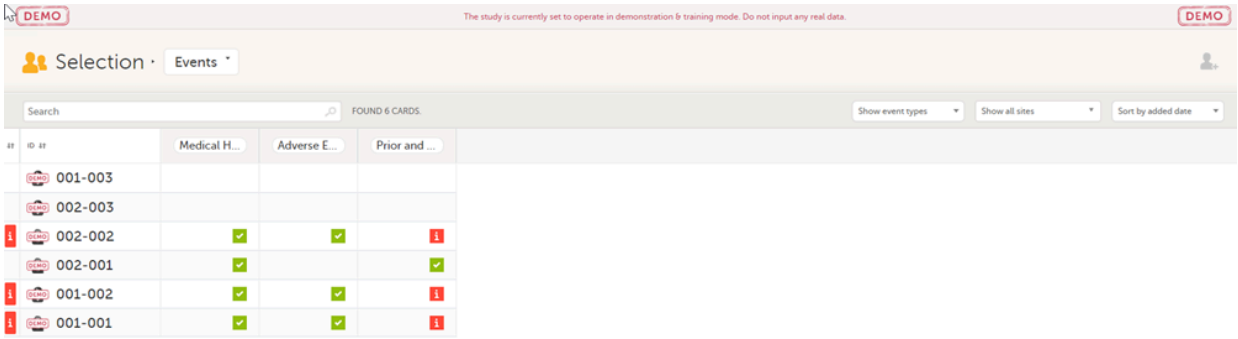


3.3.2 Locations of updated linked forms

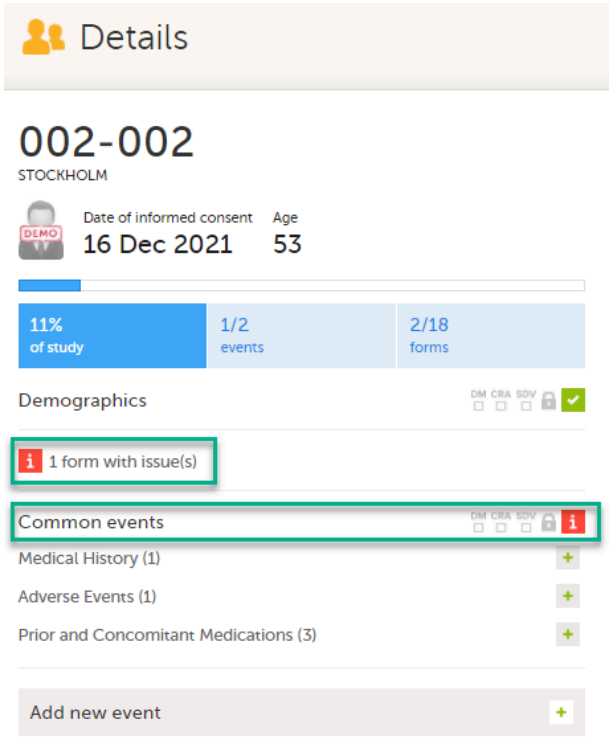
In the Issues view of the Selection page, forms are easily identified and are labelled **Form link broken**:



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.

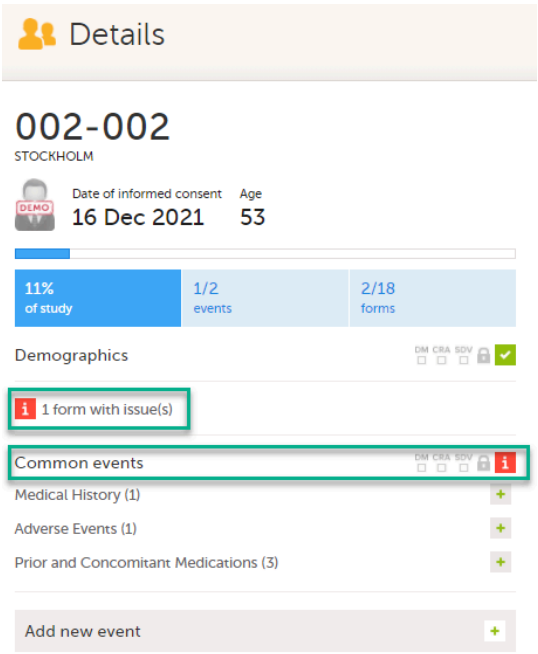


On the subject card, the issue is marked with an issue flag:

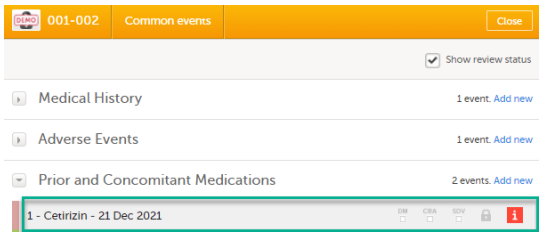


3.3.3 Updating a linked form

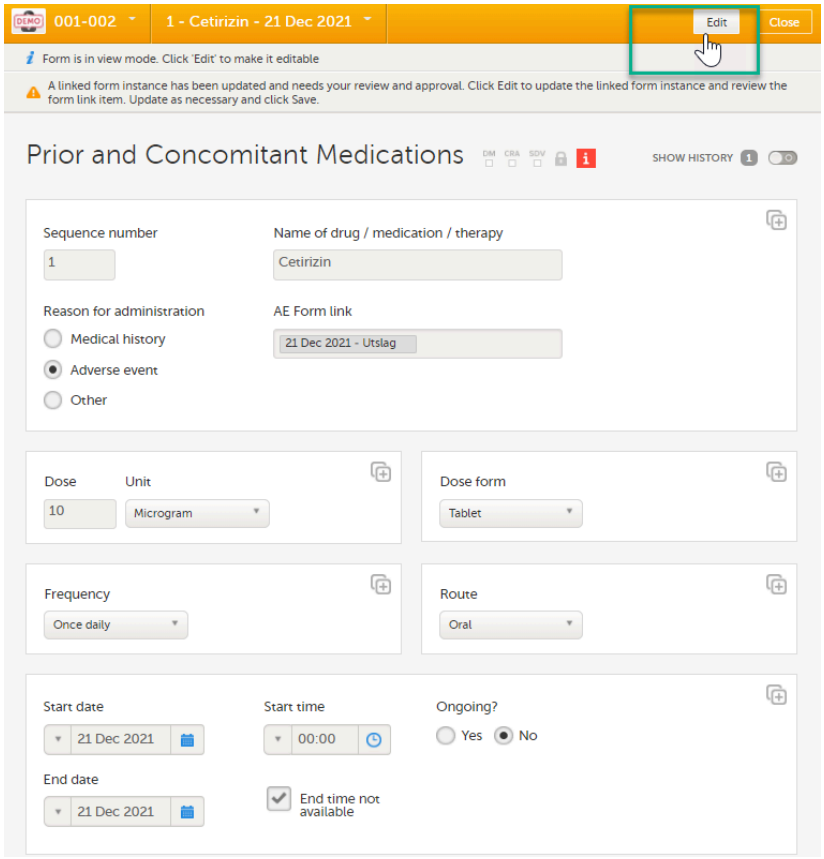
1 Select the red [i] icon to open the issue, (in this example under Common events).



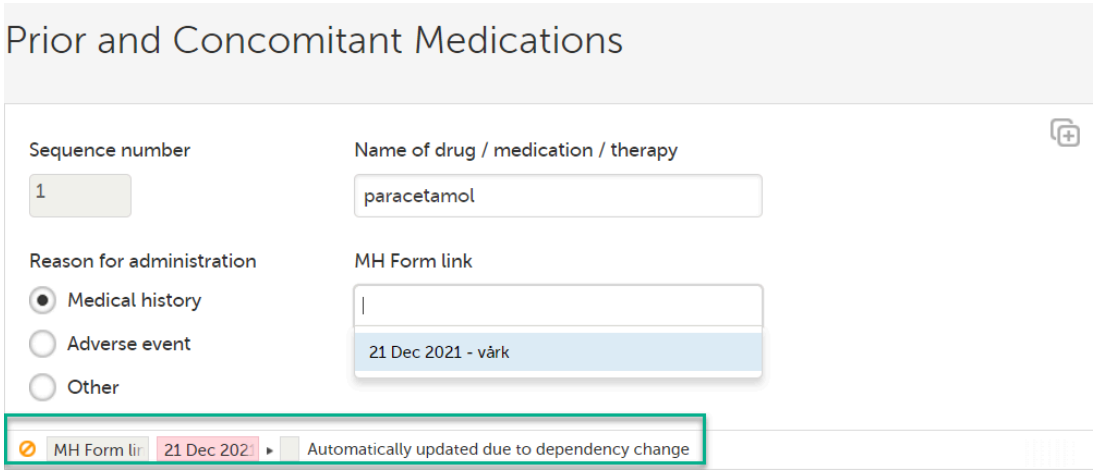
2 Select the red [i] icon (in this example under Prior and Concomitant Medications) to open the form with the issue.



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



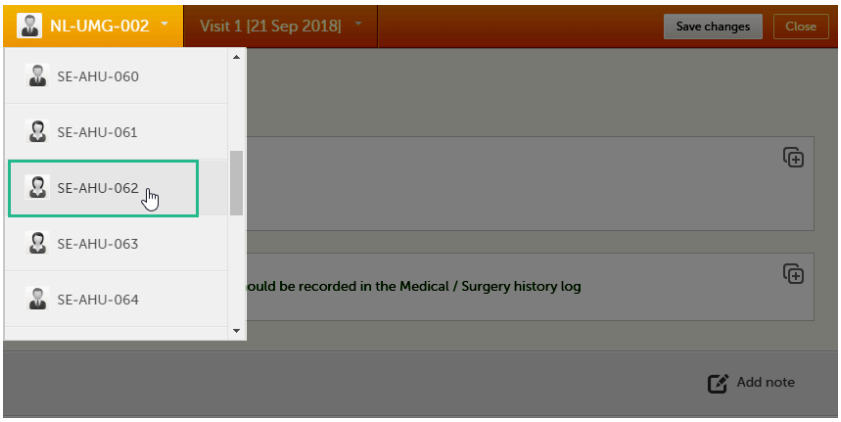
4 A message is displayed as part of the audit trail when the linked items are updated:



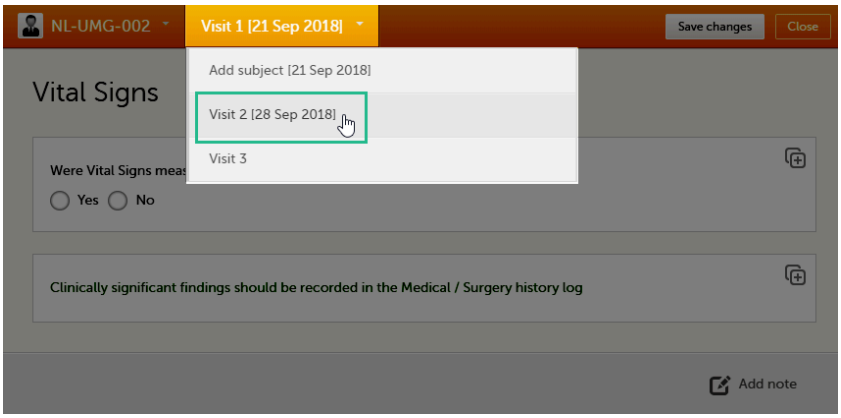
3.4 Navigating between subjects/events within the same form

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:

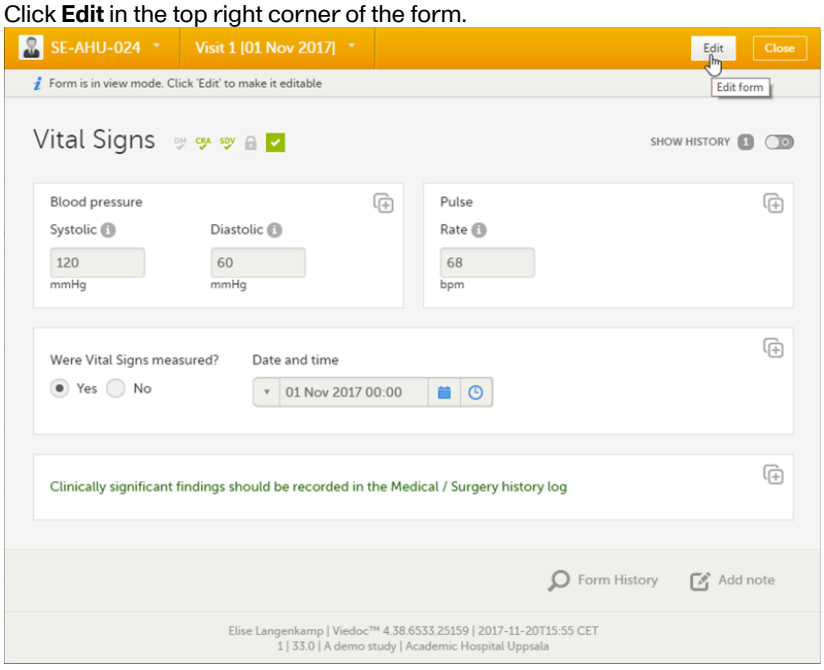


4 Editing data

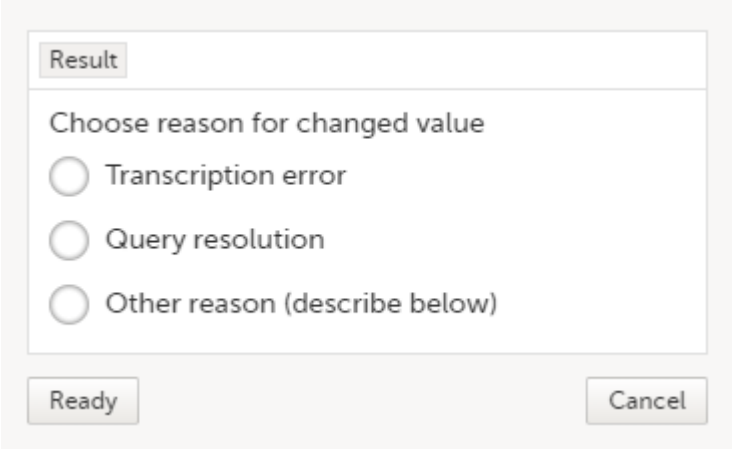
To edit data that already have been saved:

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 pop-up opens.



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

Notes!

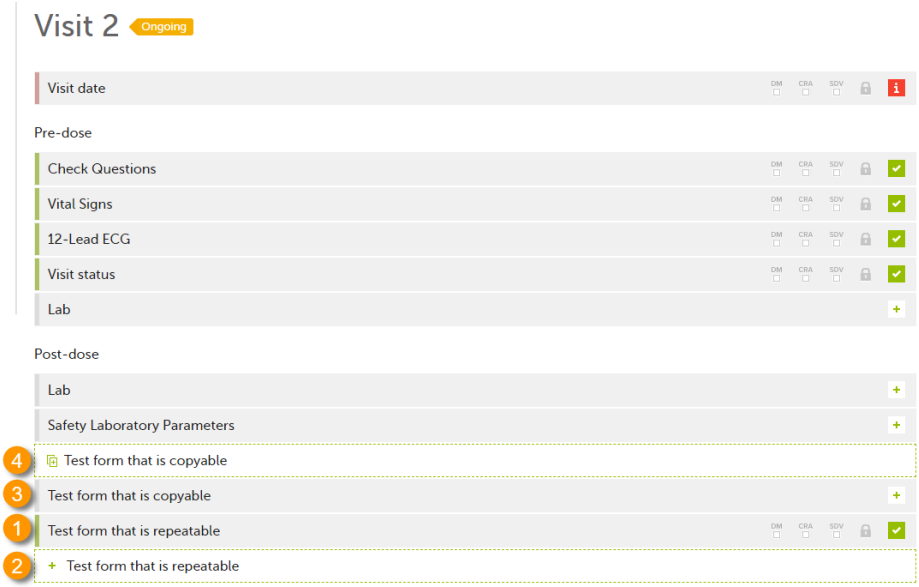
- A form that has been locked by the Monitor or Data Manager cannot be edited. If you still want to edit a locked form, contact your Monitor.
- Subject-submitted (Viedoc Me) forms are locked by default. If you, together with the subject, consider that changes need to be made to the answers in a subject-submitted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

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.

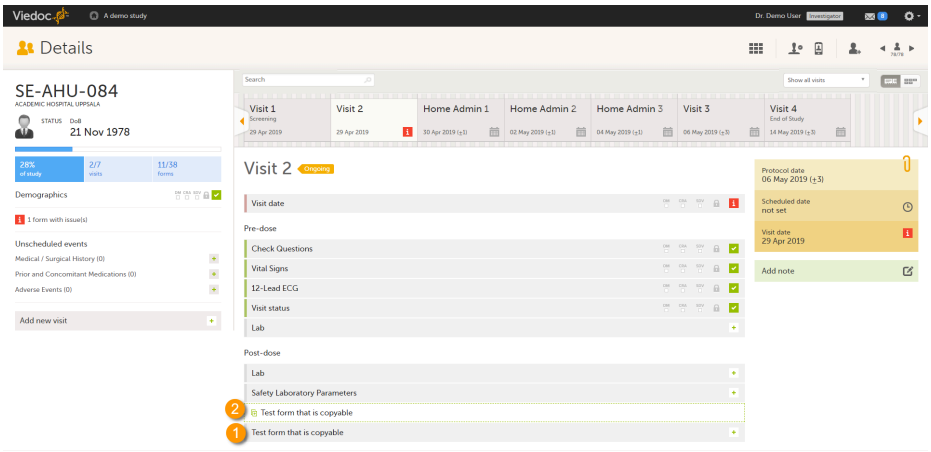
Note!

- 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

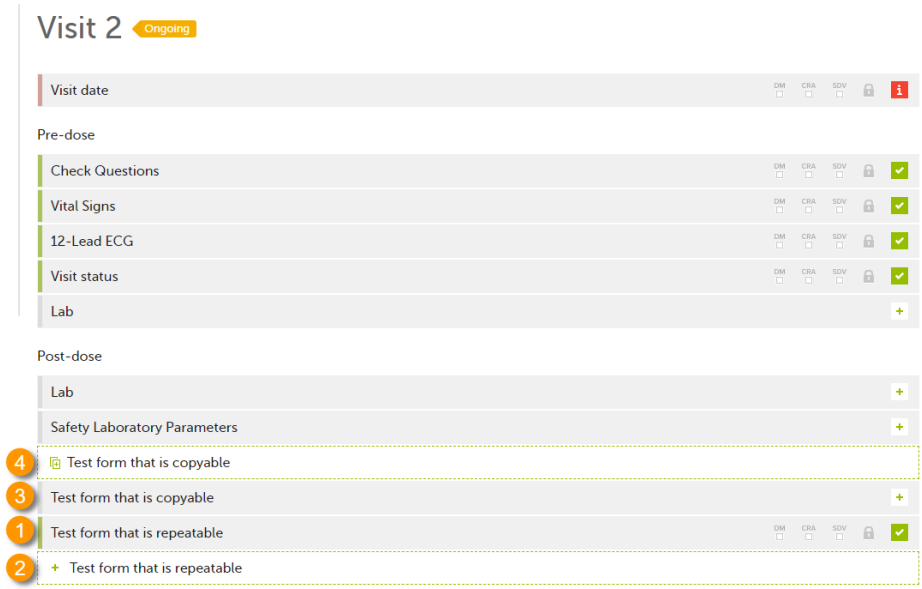
It is possible to initiate a form based on copied data from a previous event. This can only be done if the form is set as copyable in the study design.

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.

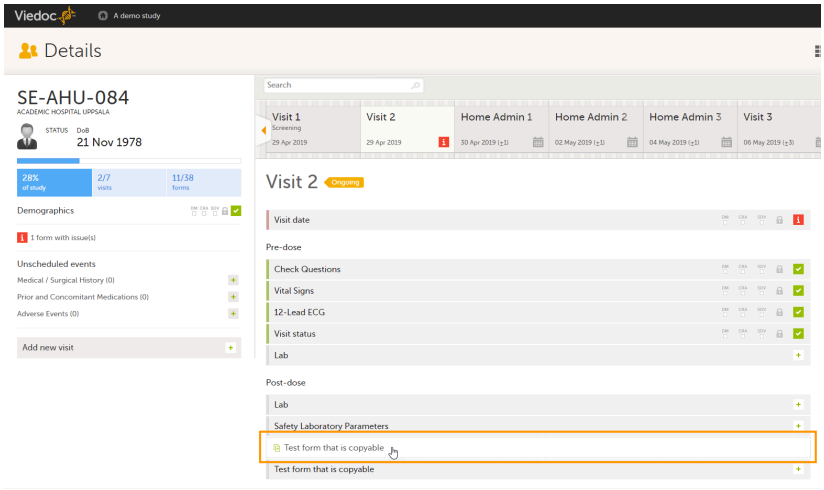


1. Main form instance of repeating form.
2. Ghost form of a repeating form, displayed below the main form instance and marked with a + icon.
3. Main form instance of a copyable form.
4. Ghost form of a copyable form, displayed above the main form instance and marked with a copy icon.

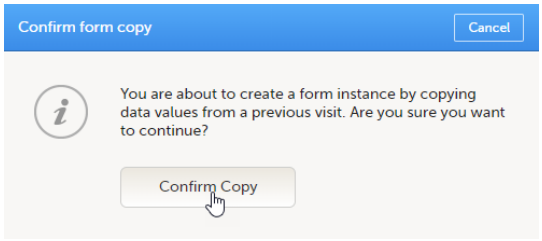
If the copyable form is also set as repeating (see Repeating forms), and in the previous event, three instances of that form have been initiated, then in the current event all three instances appear as ghost form. By clicking one of these ghost forms, you can select the instance from which the data are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

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

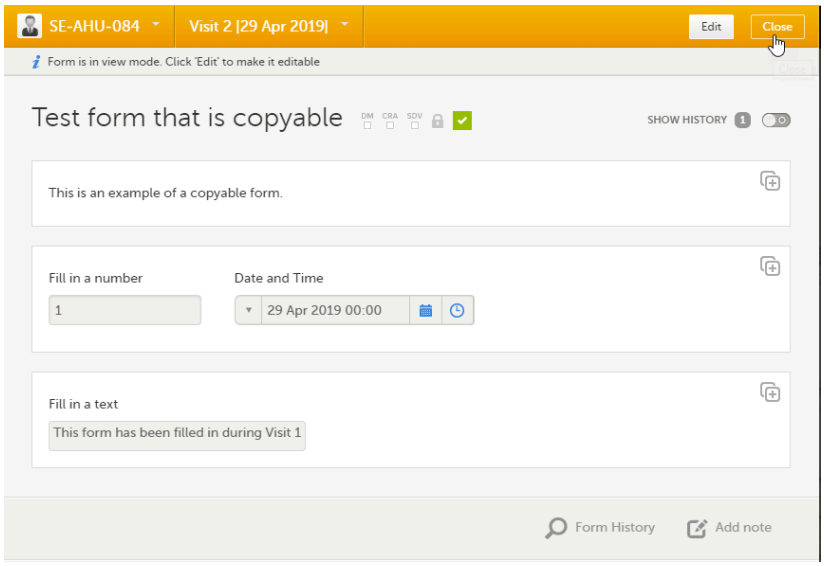
1 Click the ghost form.



A pop-up 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.

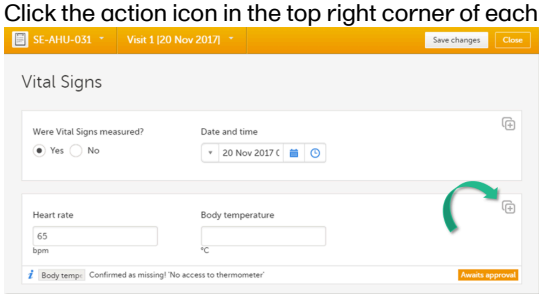
Note!

- 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 pop-up 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 pop-up 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 pop-up 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 pop-up 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 pop-up 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.

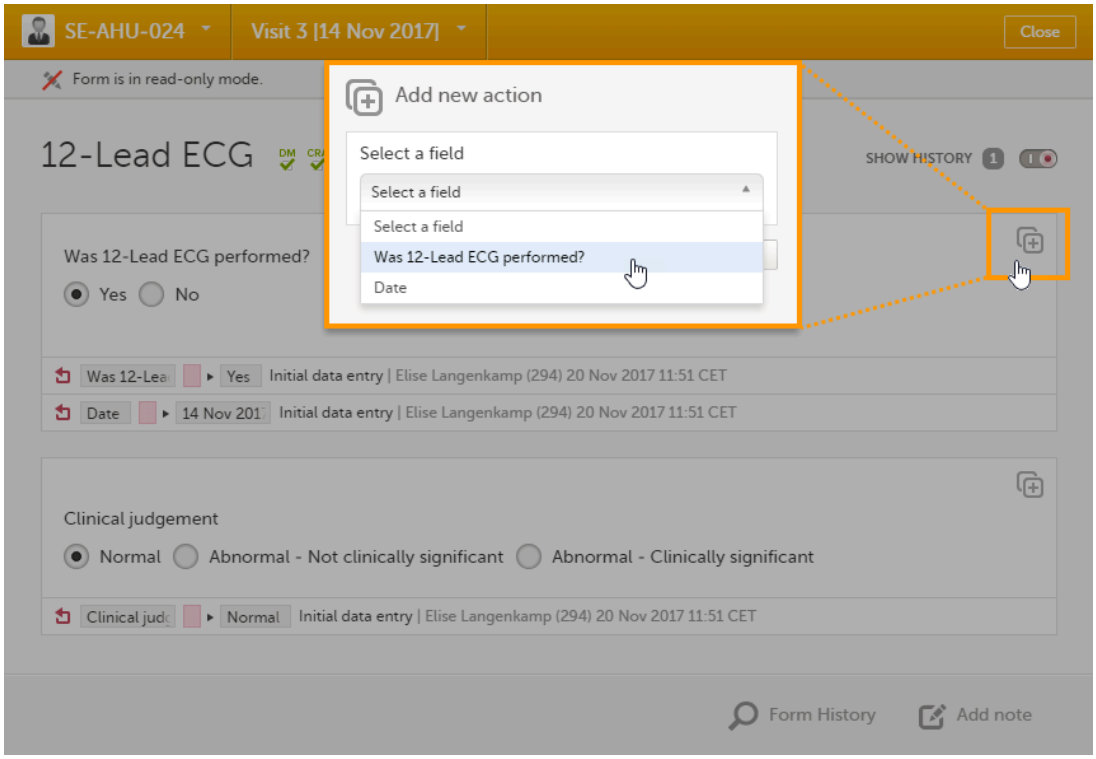
2 Enter the note text and click **Save note**. The note pop-up closes and the note is displayed on the form.

8.3 Private notes for fields

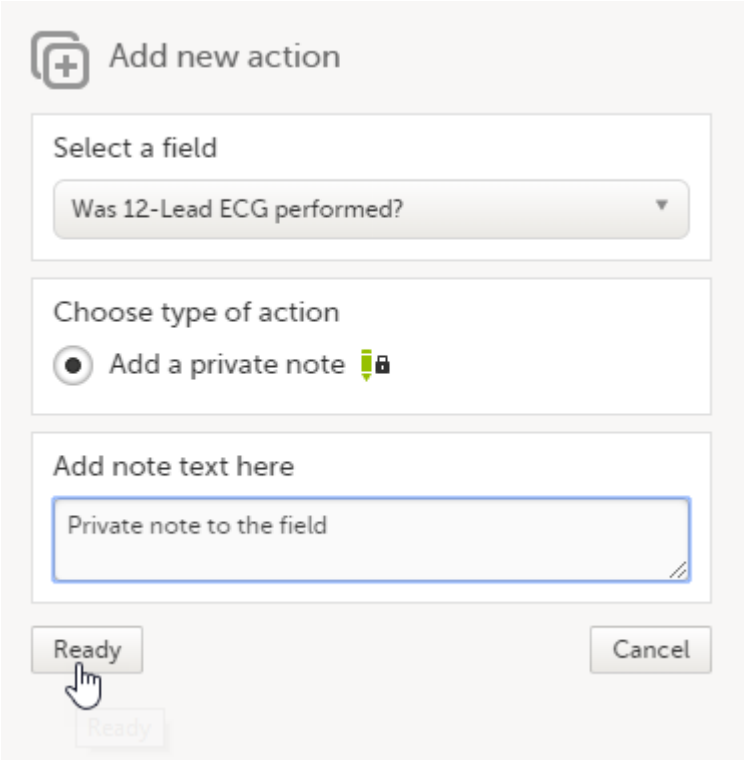
You can add private notes to single fields in a form. Private notes are only visible to the user that created the notes, and can only be edited by that user. Adding or editing a private note does not break the signature.

To add a private note for an event:

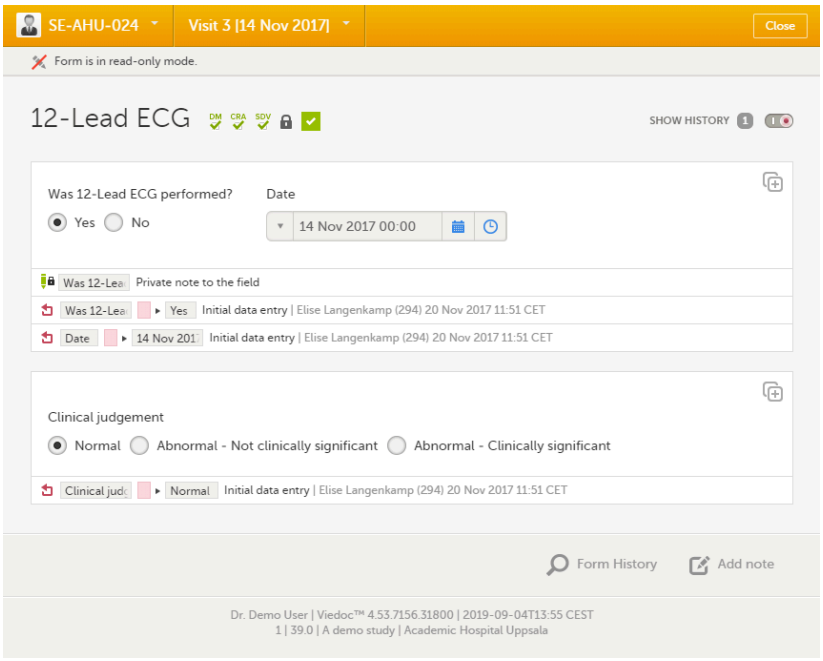
1 Click the action icon in the top right corner of the field group.
A pop-up opens.
Select the field you would like to add the private note to.



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



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



9 Resolving a query

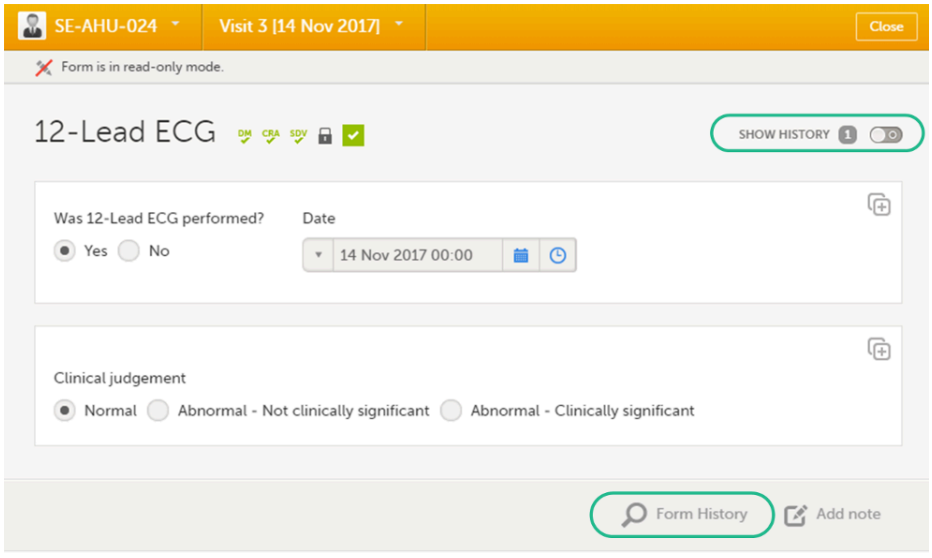
For complete instructions on how to resolve a query, see Resolving queries.

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:

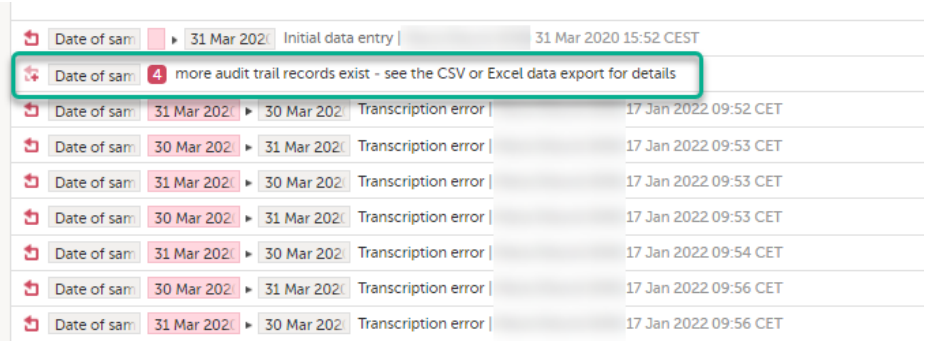


Note!

- If an item *without a value is confirmed as missing*, the audit trail export displays the query response as the edit reason.
- If an item *that already has a value is confirmed as missing*, the audit trail will display **Confirmed as missing!** as the reason for clearing the value.

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.

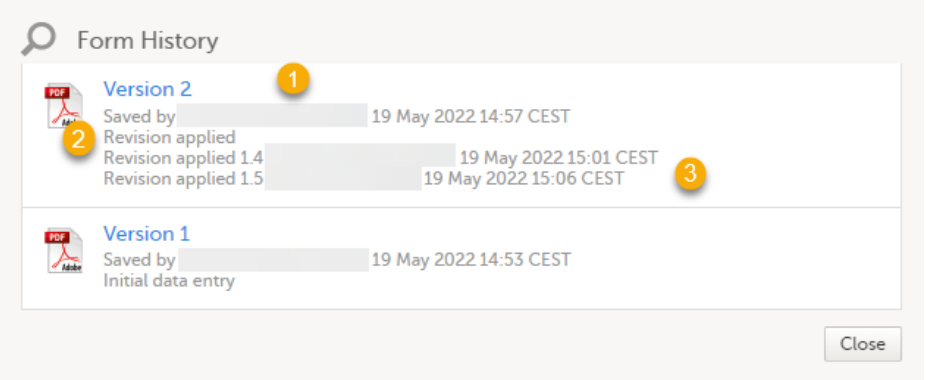
Note! It is not very likely that clinic staff would make more than 25 edits to a field. However, when working with JavaScript functions, that is a possibility.

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.



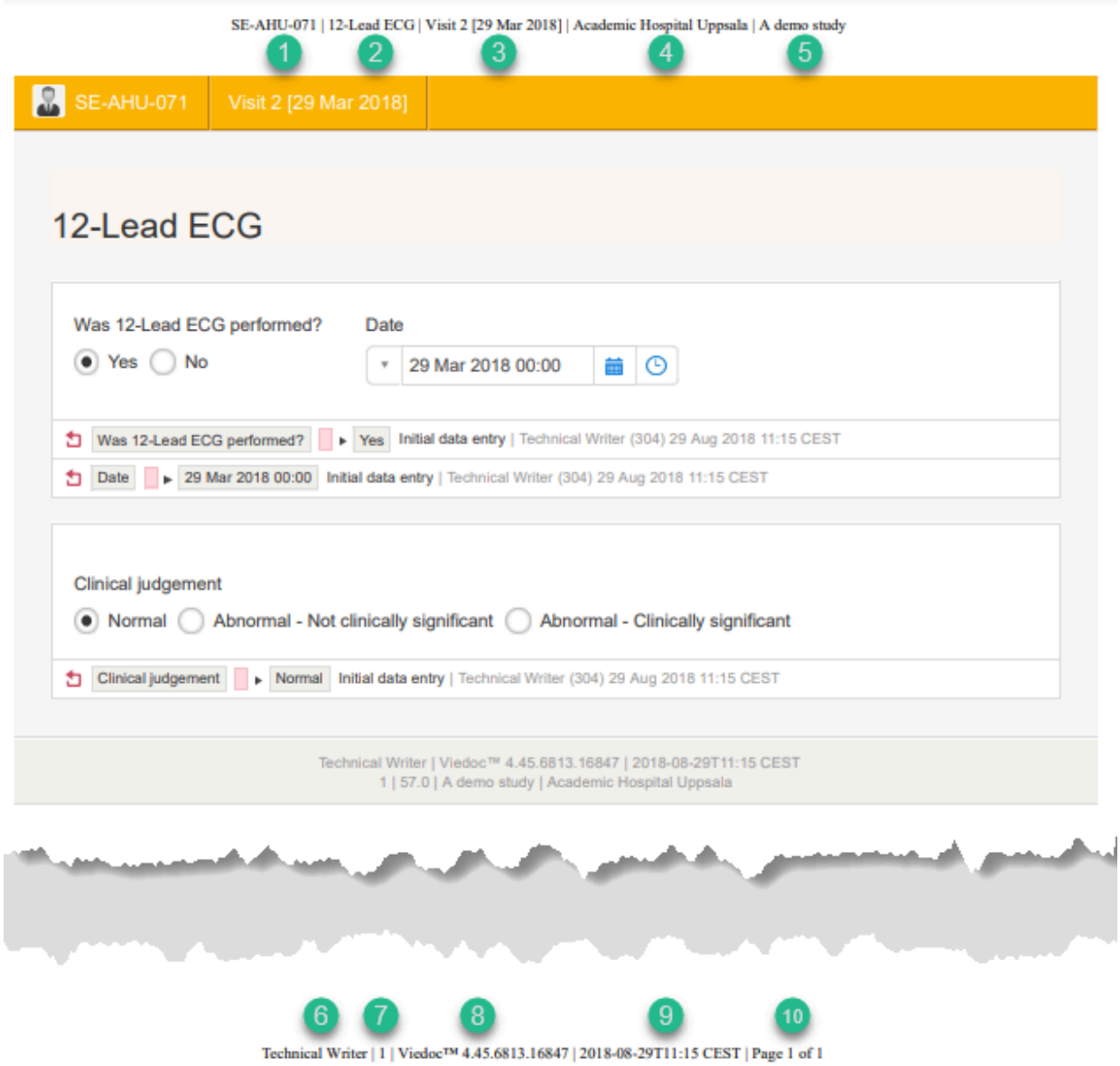
1. The user name of the user who saved the edited form.

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.

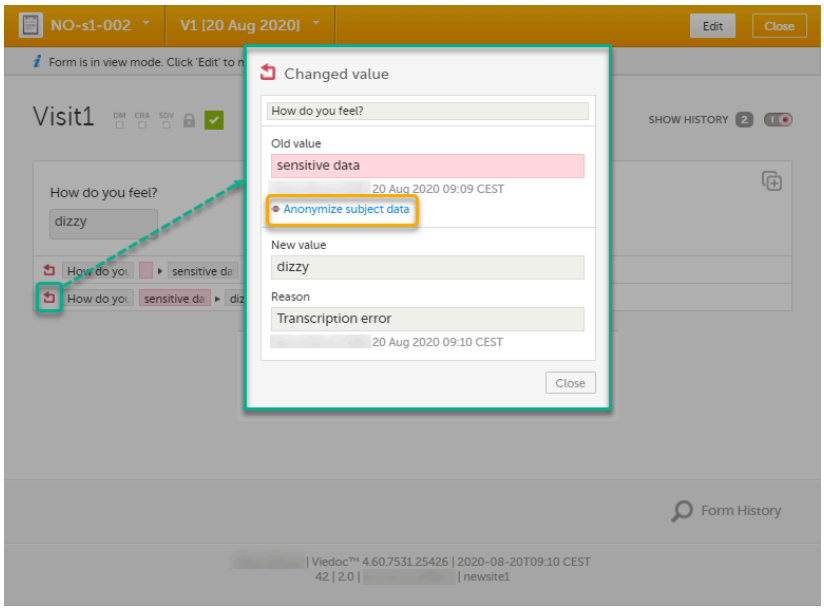
When sensitive data has been entered into a form, you first need to edit the data into something not sensitive, see Editing data. Then a record in the form history is created.

10.3.1 Masking text

To mask sensitive text data in the form history:

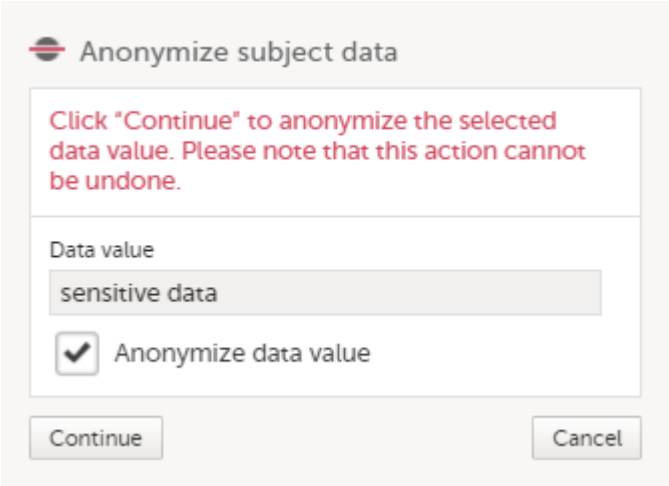
1 Click **Show history** in the top right corner of the form to open the form history.

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



3 Click **Anonymize subject data**.

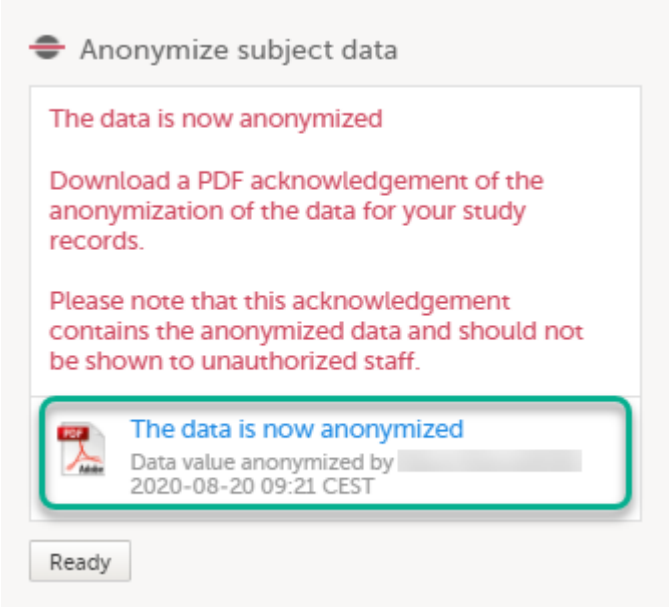
4 In the pop-up that is displayed, select **Anonymize data value** and click **Continue**.



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

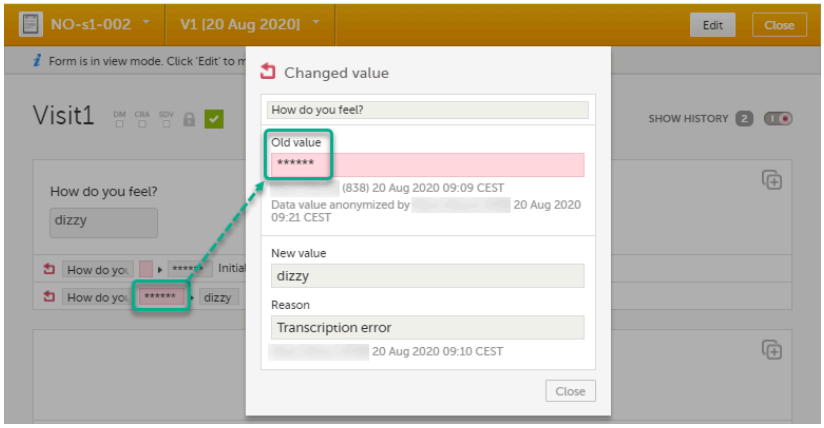
6 The pop-up now displays a text confirming that the data is anonymized. Click **Ready**.

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 pop-up. 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.

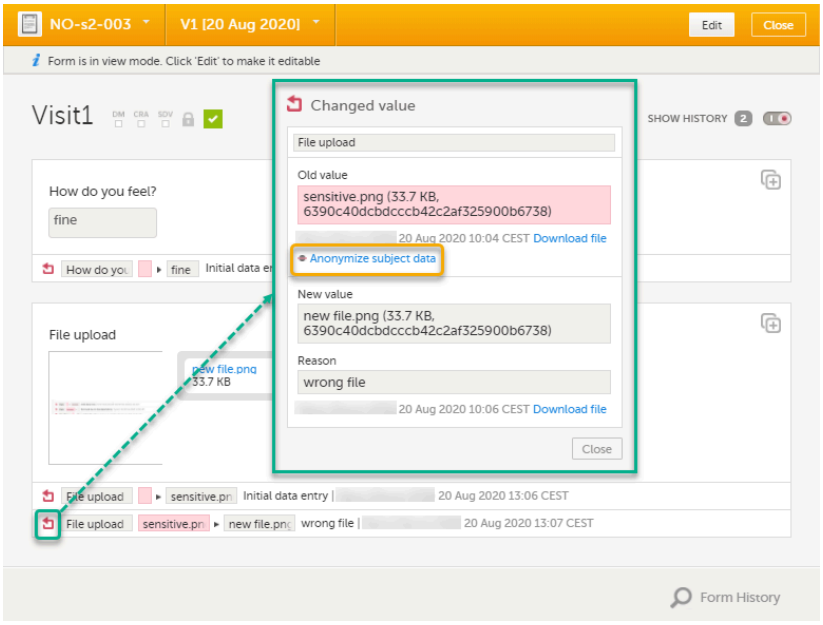
Note! Anonymization of data in linked forms does not affect the form link items, these have to be anonymized separately.

10.3.2 Masking a filename

To mask a sensitive filename in the form history:

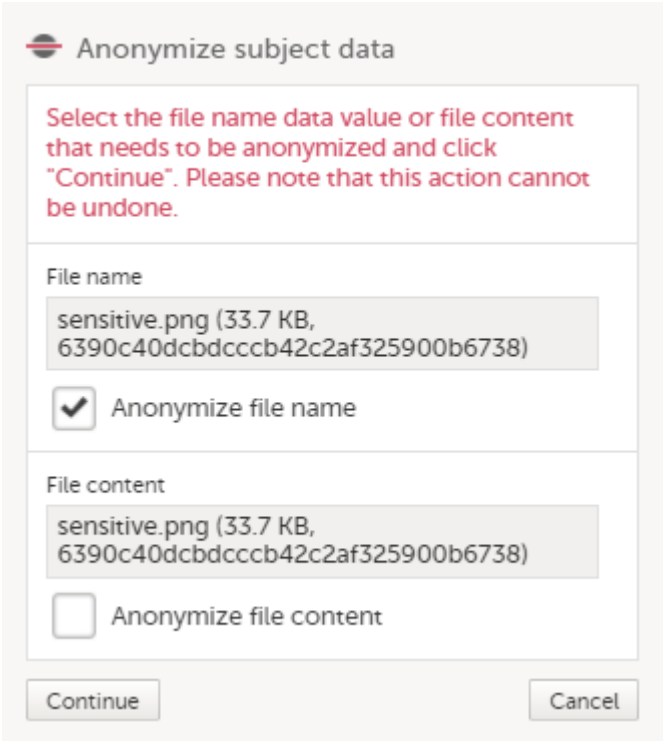
1 Click **Show history** in the top right corner of the form to open the form history.

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



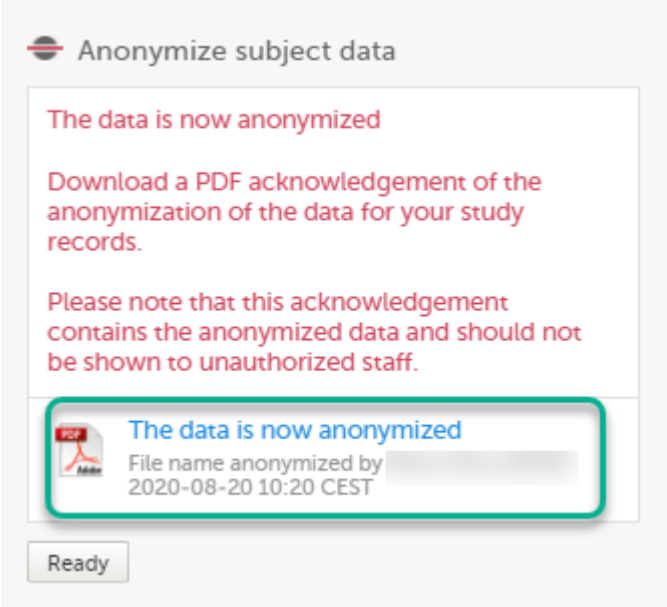
3 Click **Anonymize subject data**.

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



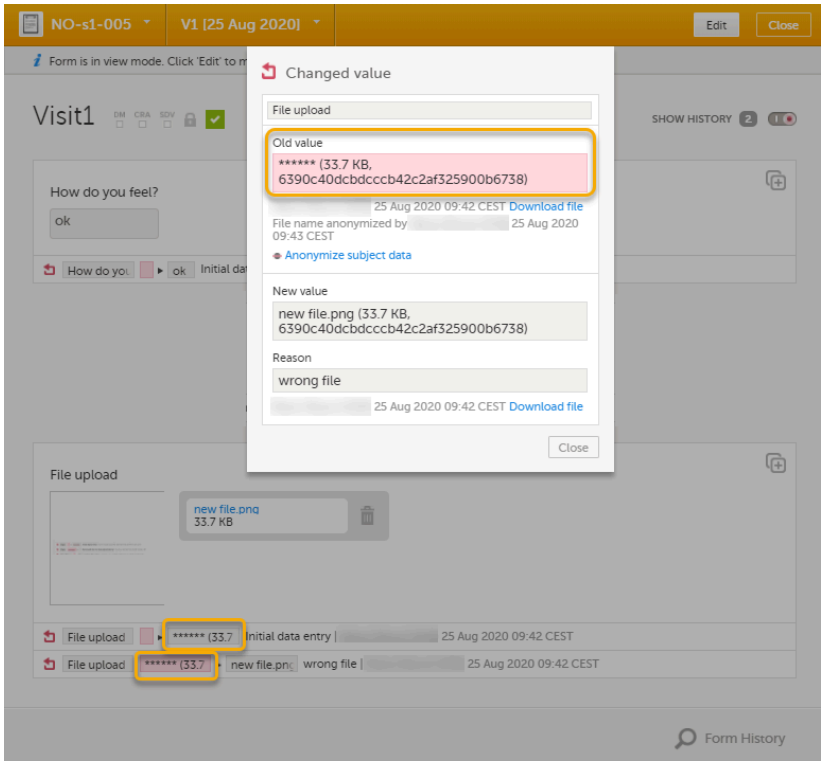
5 Enter your password and click **Confirm**.

6 The pop-up 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 pop-up. It is recommended to archive the PDF together with your study documentation.

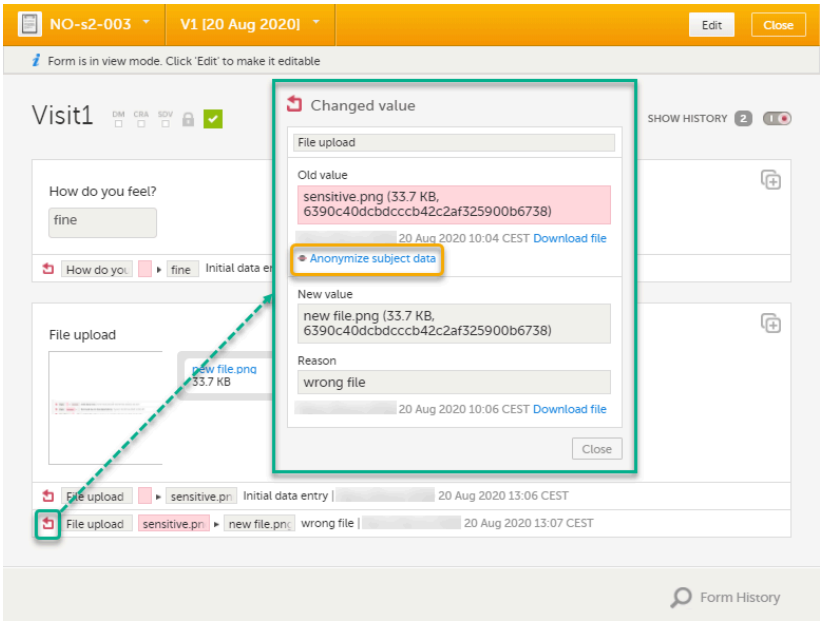
7 The masked filename is now no longer visible in the form history.



10.3.3 Masking file content

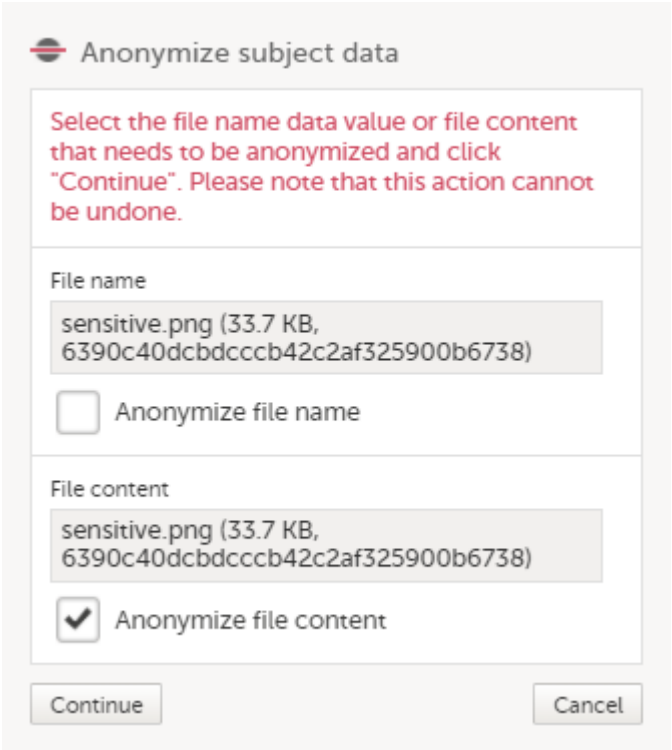
1 Click **Show history** in the top right corner of the form to open the form history.

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



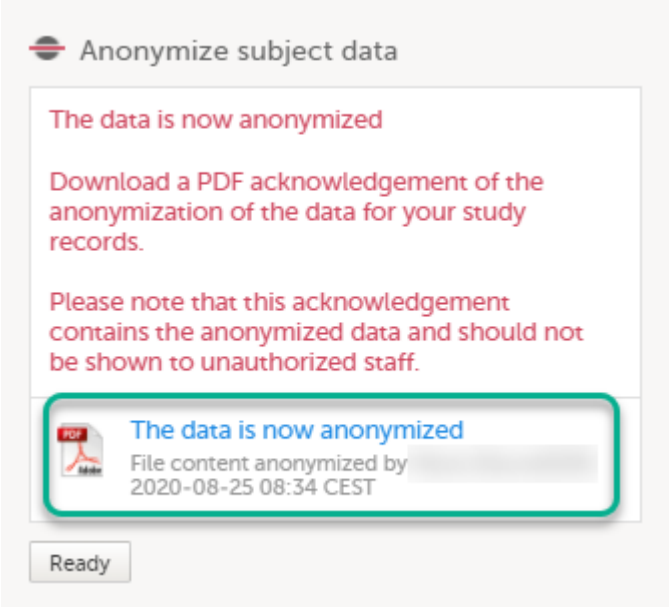
3 Click **Anonymize subject data**.

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



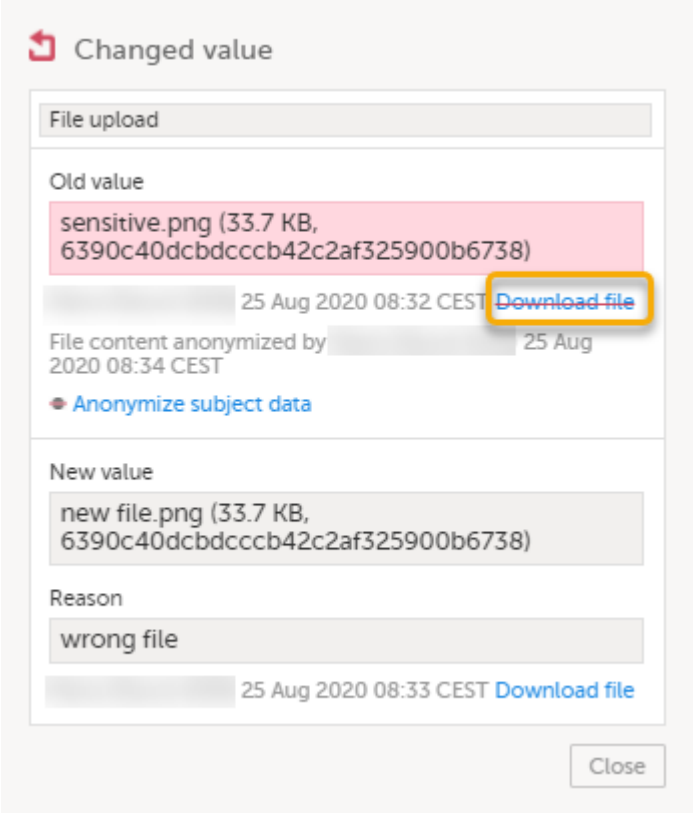
5 Enter your password and click **Confirm**.

6 The pop-up 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 pop-up. It is recommended to archive the PDF together with your study documentation.

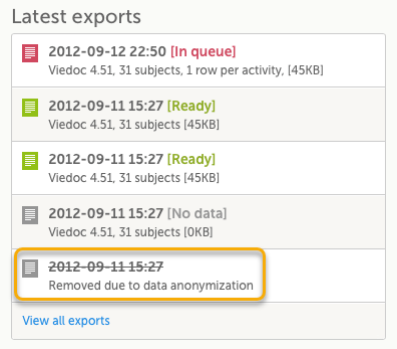
7 The masked file is now no longer accessible in the form history.



10.4 Consequences of masking data

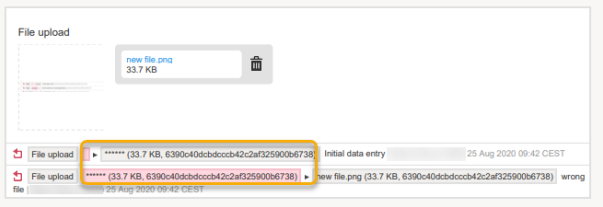
10.4.1 Data exports

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.

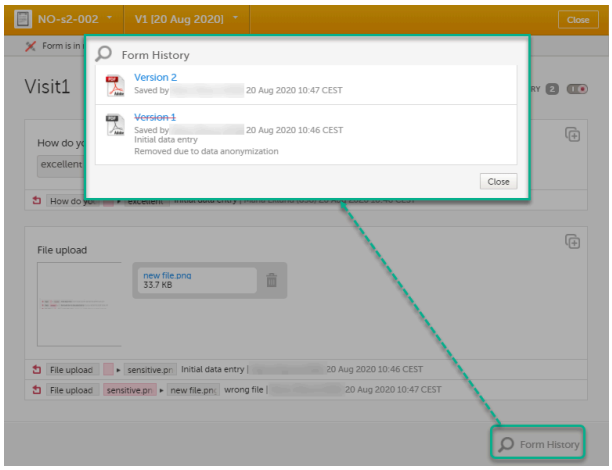


10.4.2 Form PDFs

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.



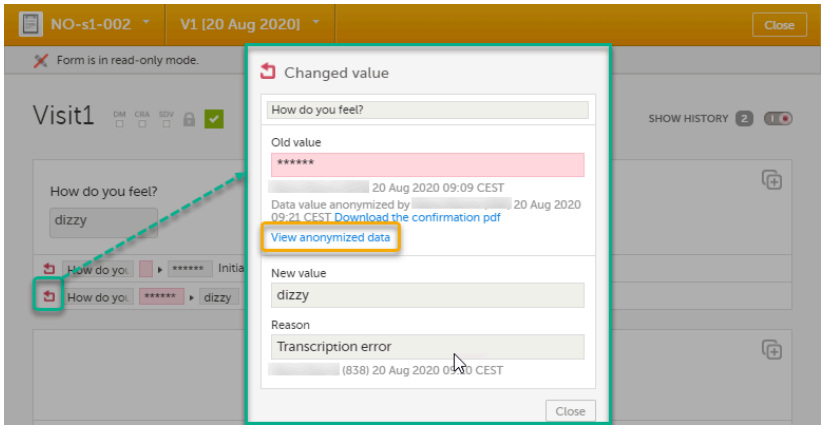
10.5 Viewing masked data

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.

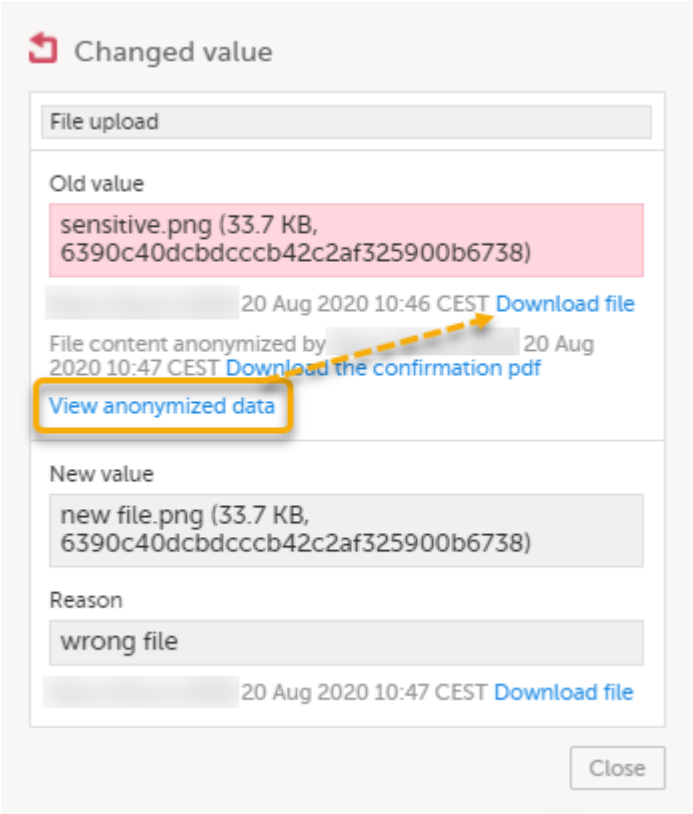


Note! You can download a confirmation PDF using the link in this pop-up.

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 pop-up, 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 2025-06-10

1 Introduction

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

Notes!

- 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.
- It is not possible to delete unscheduled events if automatic event dates are enabled.

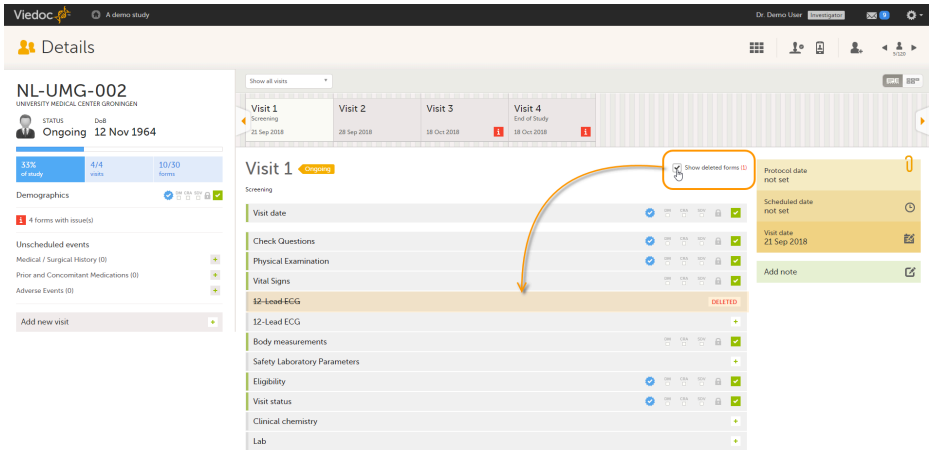
Important! Although no data is deleted from the database, it is not possible to revert any deleted data. Therefore, please make sure to double-check the data before you delete the data. If any data is deleted by mistake, the deleted data is still available for preview and can be re-entered manually based 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

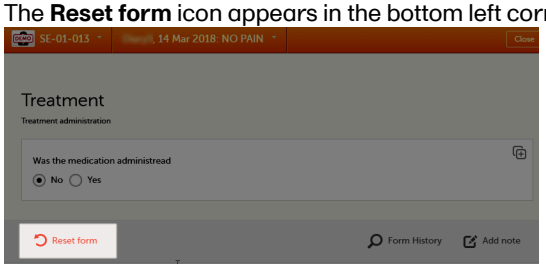
Resetting a form means that all data in the form is erased and the fields in the form appear empty again.

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:

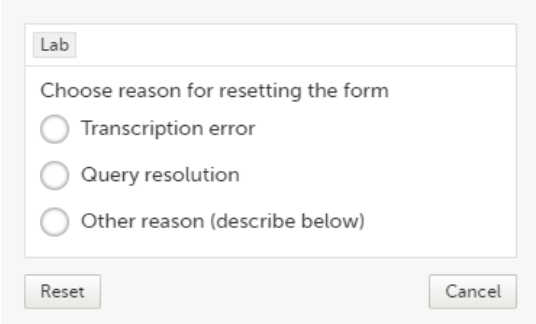


To reset a form:

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



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



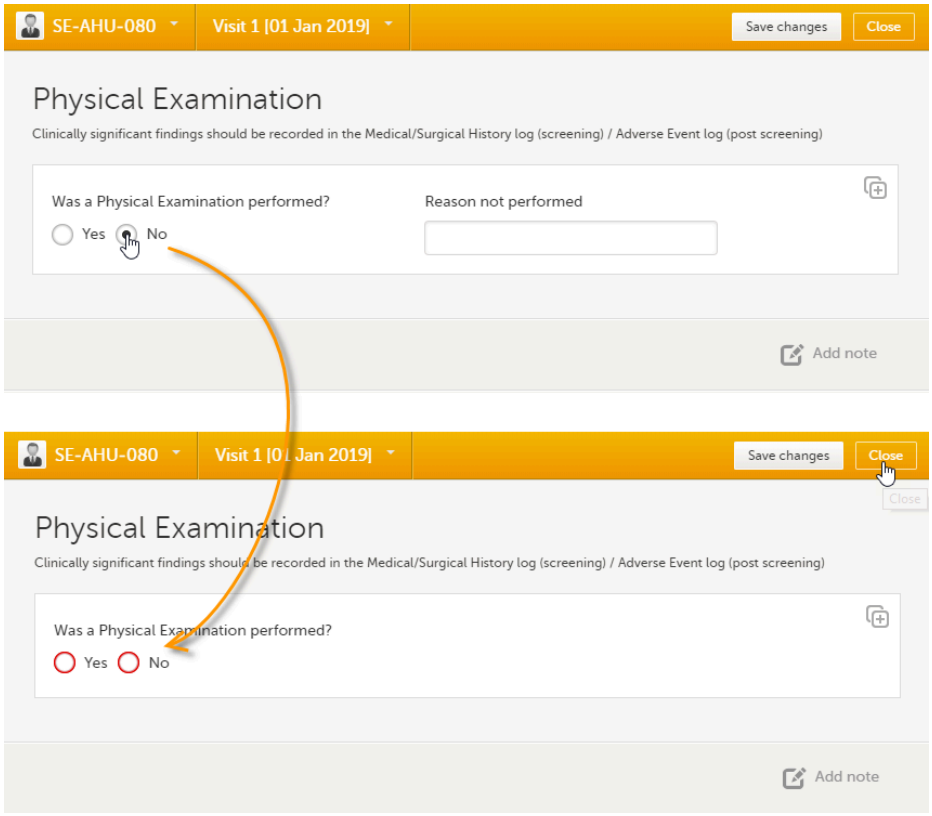
3 Enter the reason and select **Reset**.

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 selecting **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

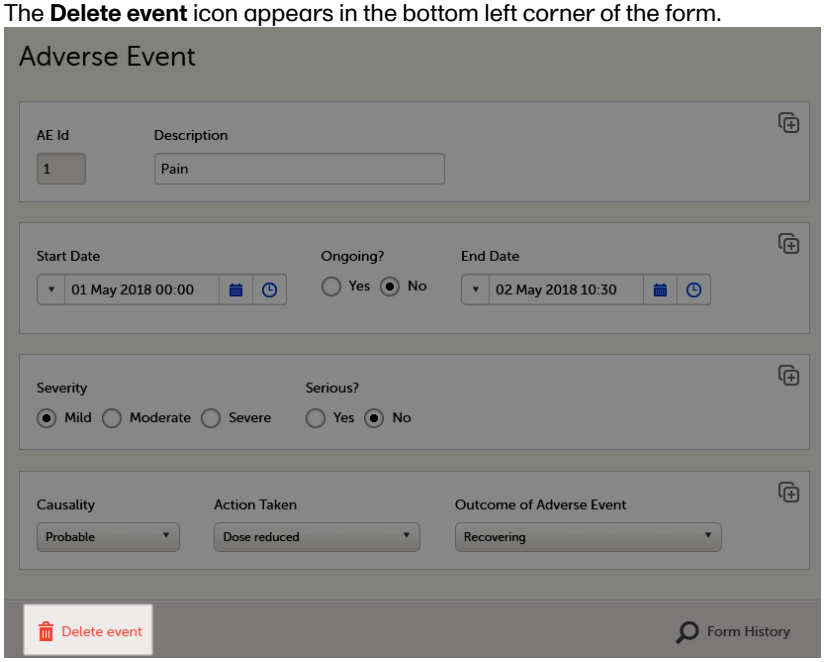
In case you made a selection in a radio button and want to return to the state in which no option is selected, you can reset the radio button. To reset a radio button, select the selected radio button again, and it will be deselected:



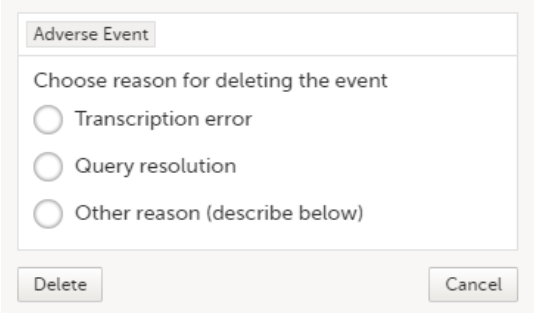
3 Deleting a common event

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

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



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



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

Note!

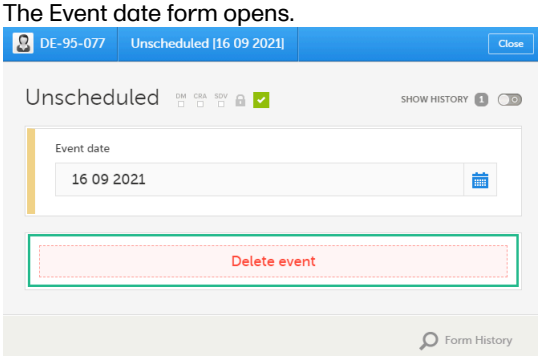
- Any open queries in a deleted event will automatically be closed by the system.
- If you cannot see the delete icon after selecting **Edit**, please contact your Site Manager or Study Manager for assistance. It might be possible that your role does not include permission to delete events.

4 Deleting an unscheduled event

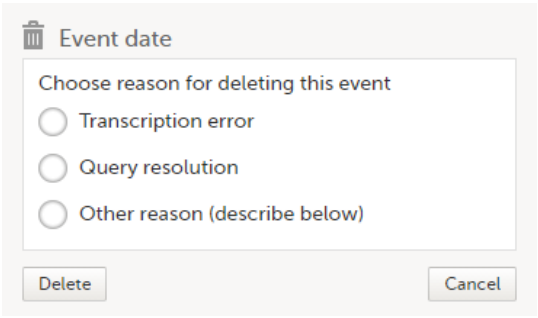
If you have added an event manually using the **Add new event** button (see Entering/Editing data), you can remove the manually added event if it does not contain any data. If any form within a manually added event is completed, the form needs to be reset before the event can be deleted.

To delete a manually added event:

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

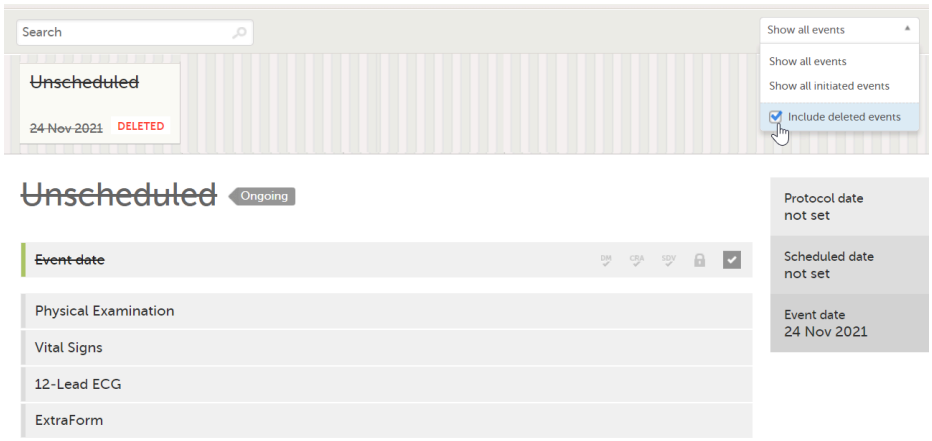


2 Select **Delete event**.
A pop-up appears asking for the reason for deleting the event.



3 Provide the reason and select **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

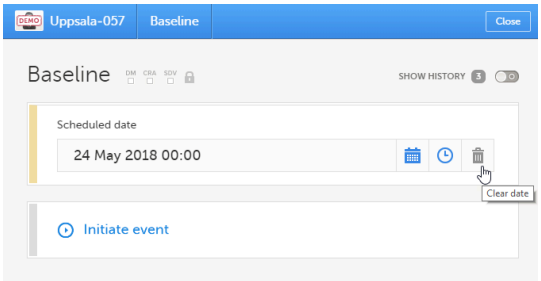
If you have initiated or planned a scheduled event by mistake, you can set it back to its previous status. If any data is entered on the event, the forms with data need to be reset before the event status can be reset.

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

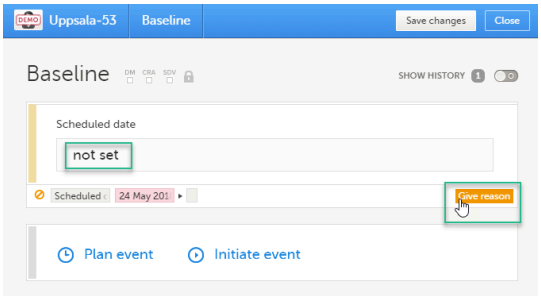
To reset the event status for a scheduled event that was initiated/planned:

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

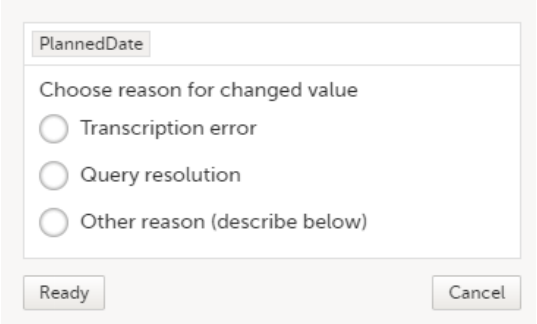
2 Select the trash can icon next to the date.



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



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

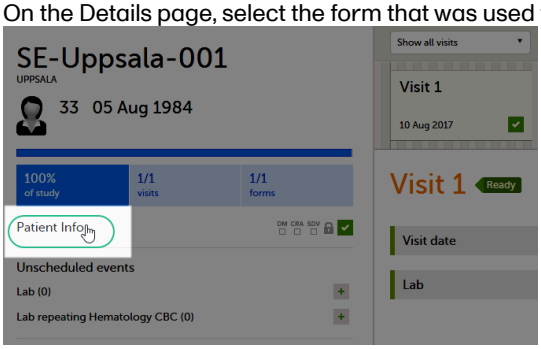


6 Deleting a subject

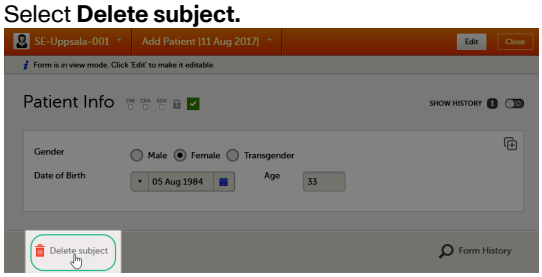
Note! A subject cannot be deleted if the form that was used to add the subject is locked.

To remove a subject from the study:

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

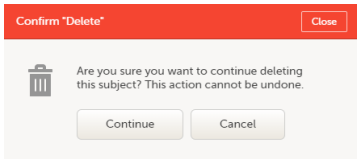


2 Select **Delete subject.**



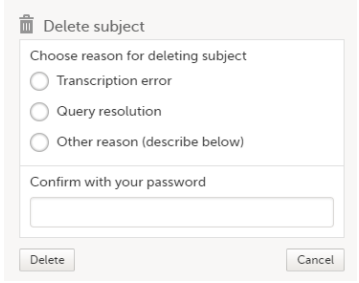
A confirmation pop-up appears.

3 Select **Continue**.



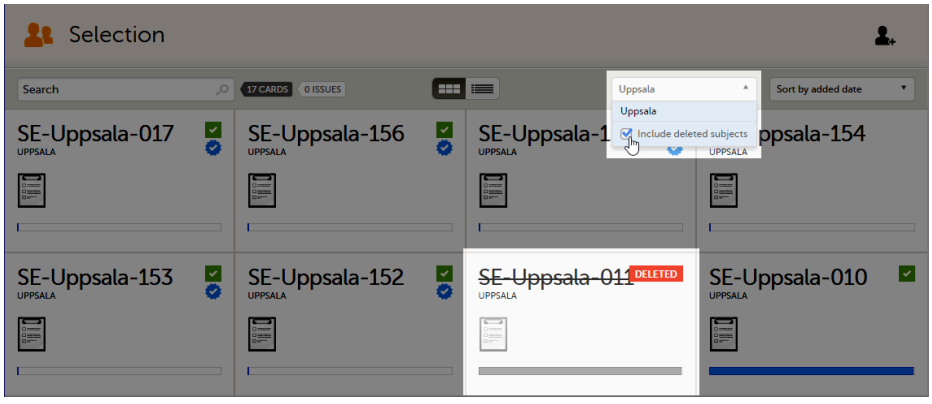
You will be prompted to enter the reason for deletion.

4 Provide a reason, enter your password and select **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 2025-08-19

1 Introduction

The **Investigator** signs the data. Signing for a subject can be done on an individual form, event, or across a study using the signing console.

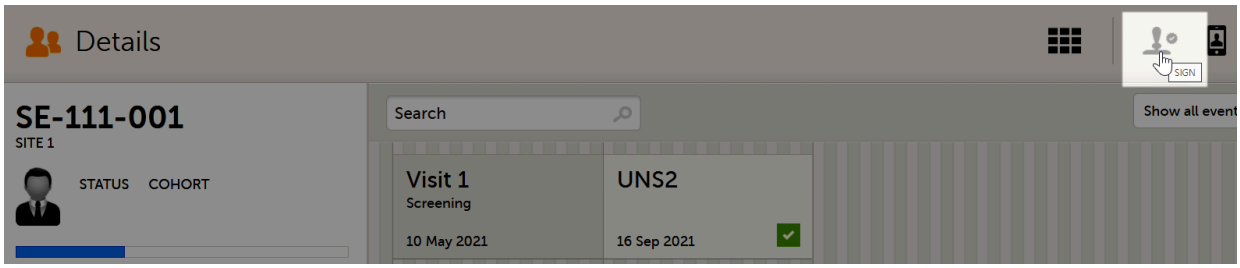
1.1 Signature definition

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.

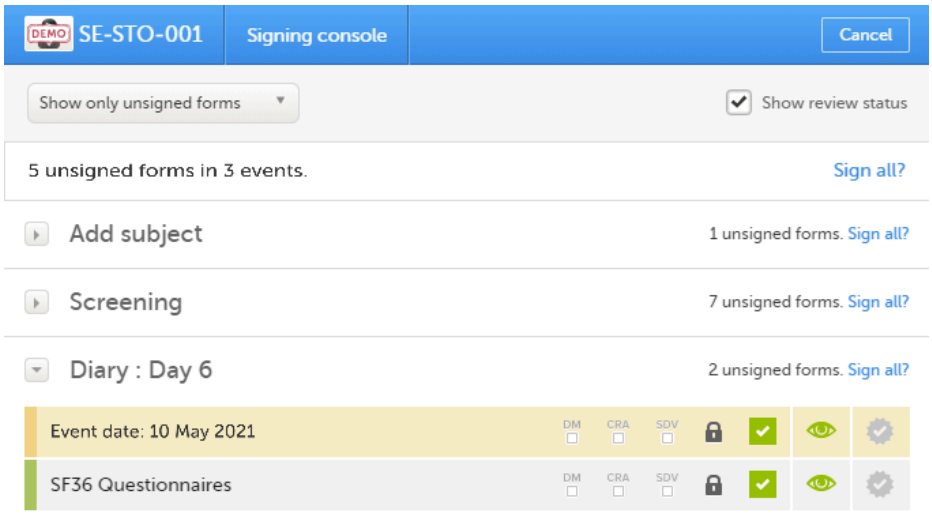
In Viedoc, the purpose/meaning of a signature is always “responsibility” as used in Sec. 11.50 of Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) part 11. The signer is thereby acknowledging his/her responsibility for the entered data. Viedoc keeps account of what was signed,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

2 Signing console

To access the signing console, go to the Details page and select the **SIGN** icon:



The signing console opens:



The signing console lists all of 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, select the form bar. Closing the form takes you back to the signing console.

To view the review status of:

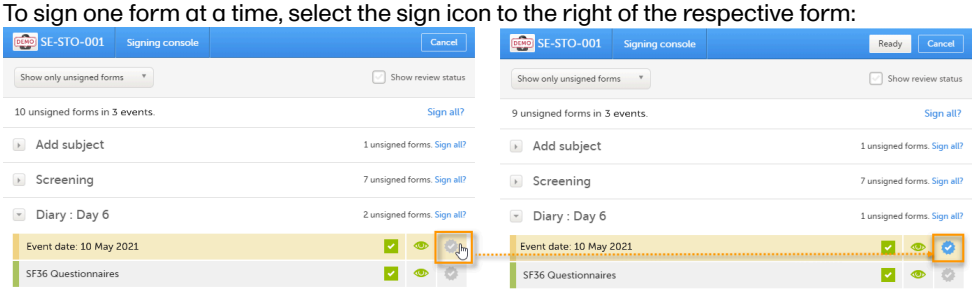
- **CRA** - reviewed by Clinical Research Associate (CRA) or another role with review permission
- **DM** - reviewed by Data Manager (DM) or another role with review permission
- **SDV** - performed Source Data Verification (SDV)

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

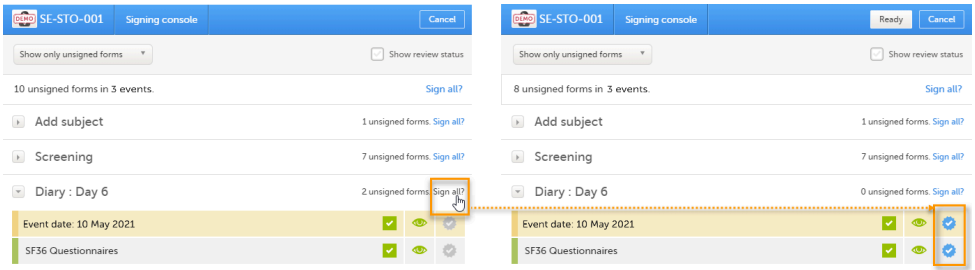
To sign the data:

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

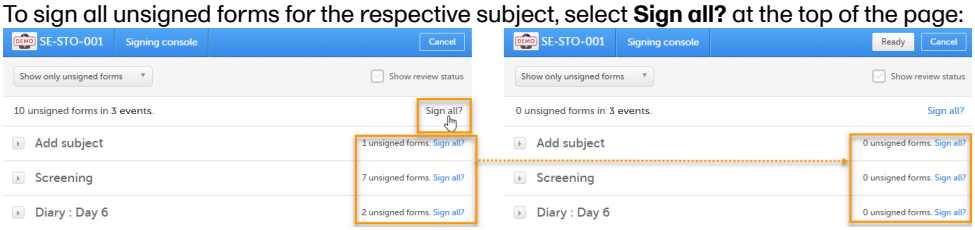
- To sign one form at a time, select the sign icon to the right of the respective form:



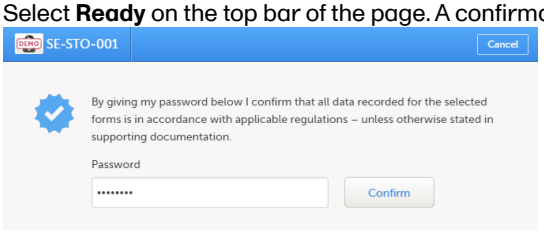
- To sign all unsigned forms within an event, select **Sign all?** to the right of the respective event:



- To sign all unsigned forms for the respective subject, select **Sign all?** at the top of the page:



2 Select **Ready** on the top bar of the page. A confirmation pop-up appears:



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

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

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

Note! For scheduled and unscheduled events, the event date form (`$EVENT`) still counts, even when it is excluded when you use automatic event dates.

- In the signing console, the counter (number of forms) for a event includes the `$EVENT` form. This cannot be selected to be signed but can be signed if you select **Sign all** (for subject or event).
- If you sign forms on an event individually, you will not be able to sign the `$EVENT` form. As a result, the sign symbol for the event is not visible, even though it looks as though all forms have been signed.

See also the video tutorial: Sign data.

Working with reference data

Working with reference data

Published by Viedoc System 2025-06-10

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.

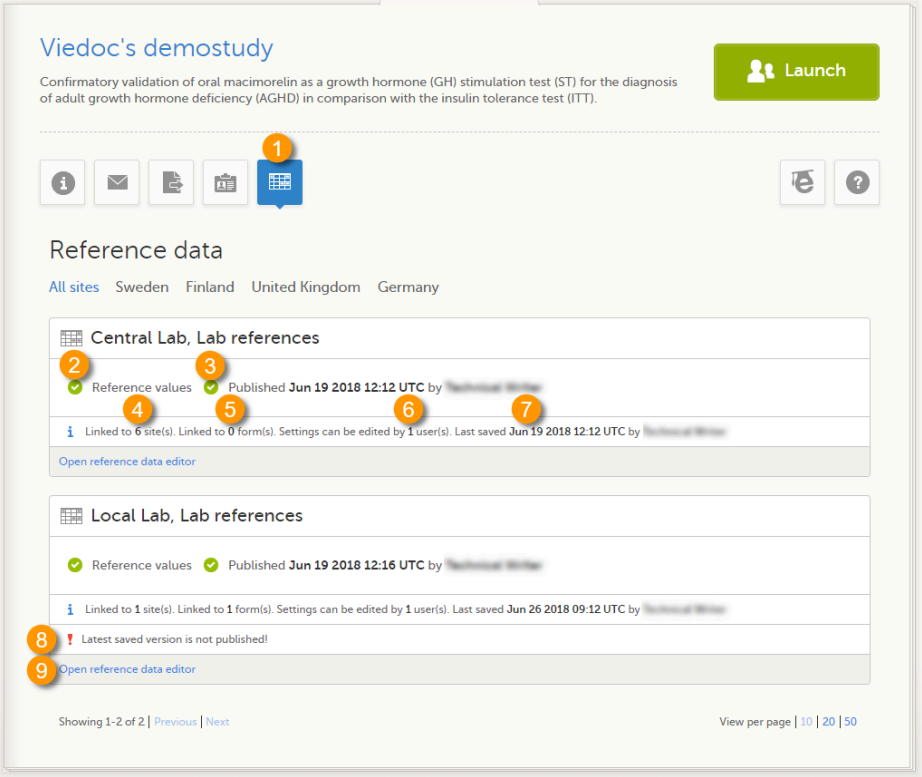
See also the video tutorial demonstrating how to work with reference data in Enter reference data.

---

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.

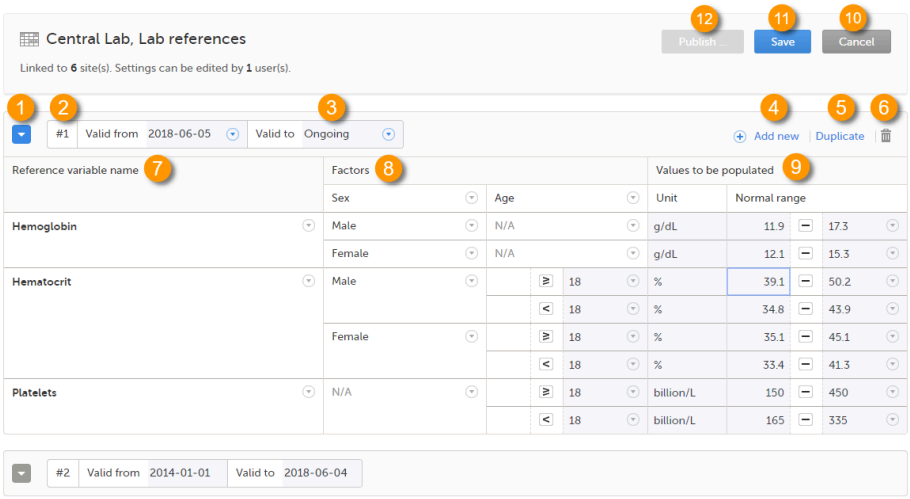
8. Warning message if the latest saved version was not published.

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 at 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.

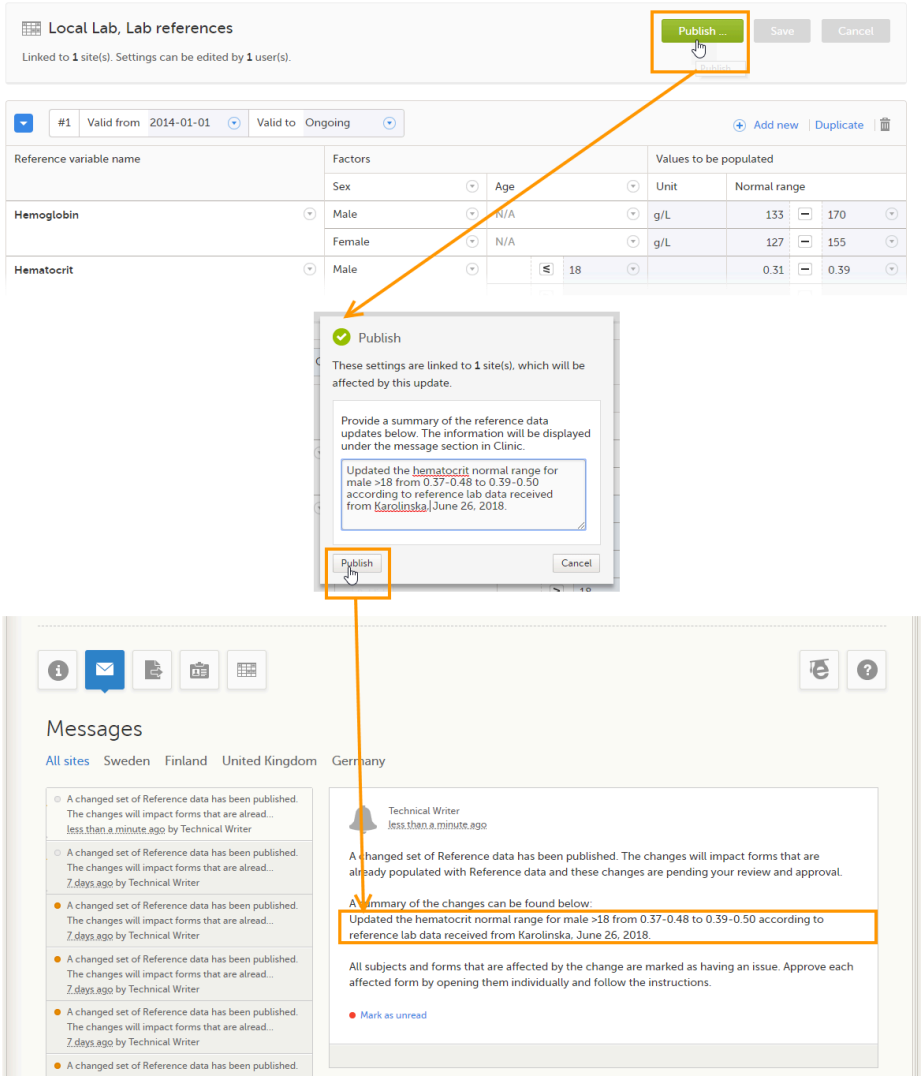
8. **Factors** - the factors that are defined in the scope. Factors are parameters that affect the reference data. See Factors for more information.

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 pop-up 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.



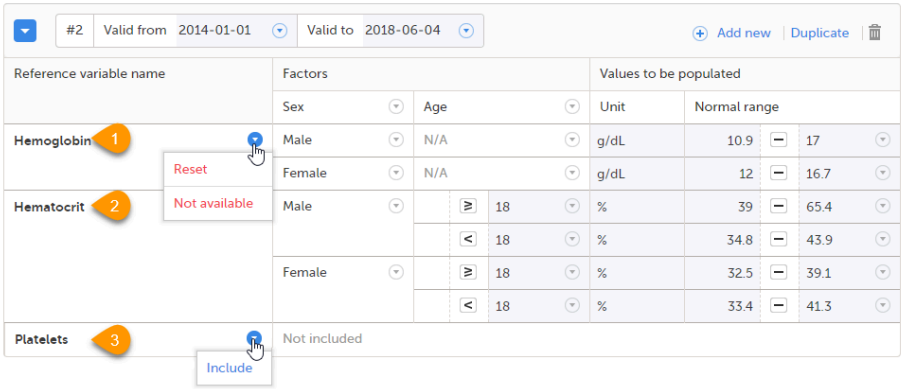
2.2.2 Variables

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.

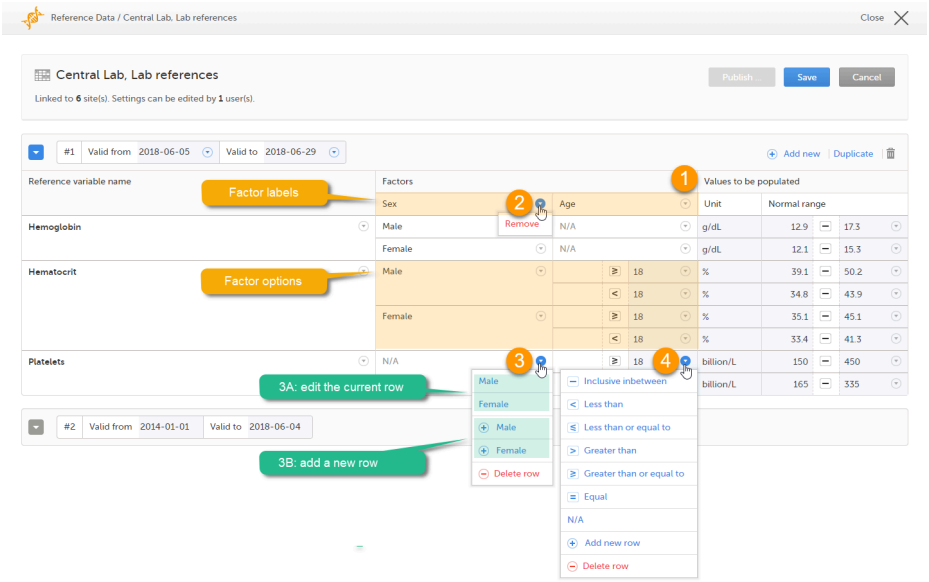
By default, a newly added factor is populated with *N/A* (not applicable) in the table. You can edit this by clicking the arrow to the right of *N/A* and select one of the options from the drop-down list. The drop-down list displayed varies depending on whether the factor has predefined factor options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

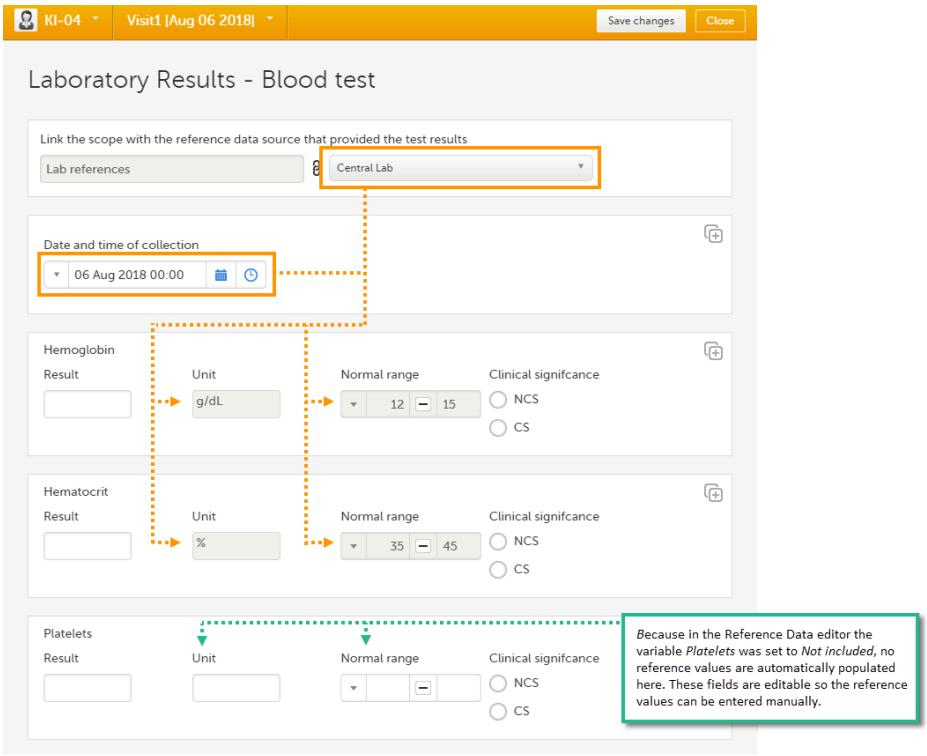
2.3 How the reference data feature works within the forms

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! When populating **numeric fields** using functions and reference data, they automatically receive the number of decimals configured in the design.

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.

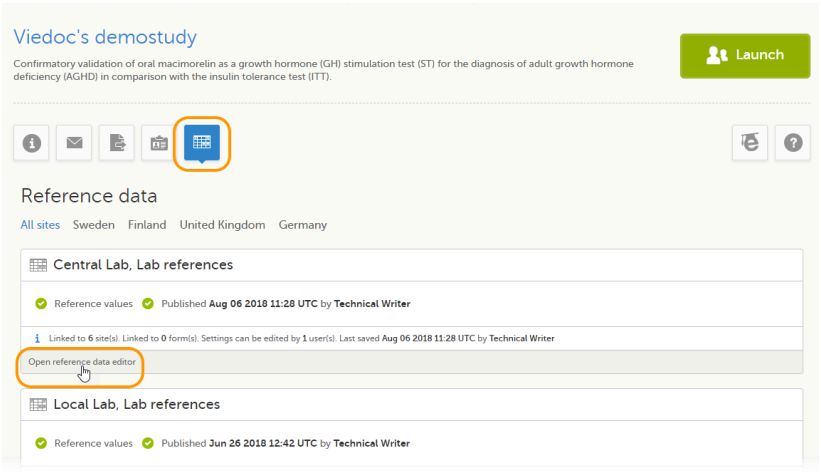
3 Entering and publishing reference data values

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

To enter a new set of reference values:

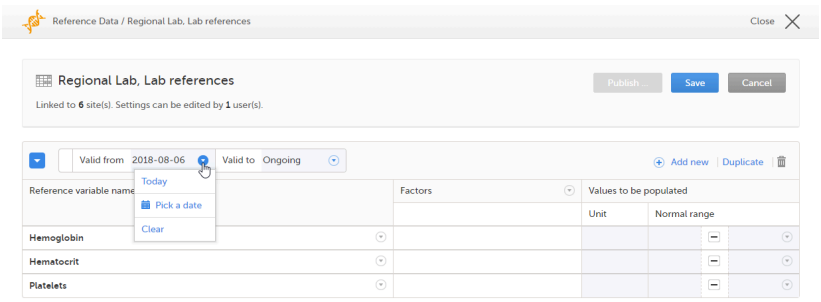
1 On the Viedoc landing page, click the **Reference data** icon.

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

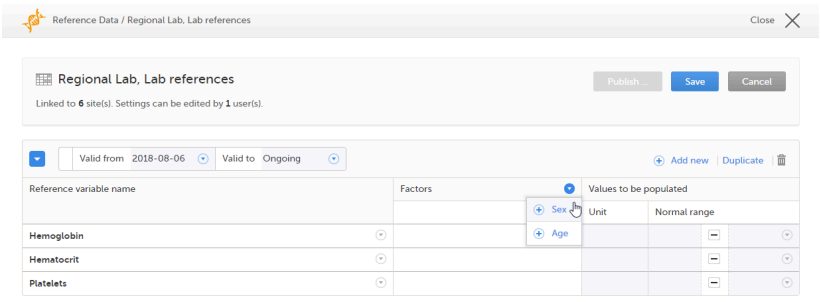


The reference data editor opens and displays the variables and the target types to be populated, as defined in the reference data scope. If you would like to exclude some of the variables, click the arrow to the right of the variable name and select **Not available**. See also Variables for more information.

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

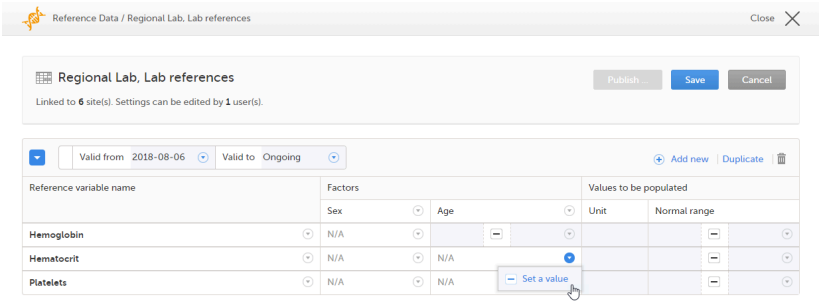


4 Click the arrow to the right of **Factors** and select the factors that should be included.

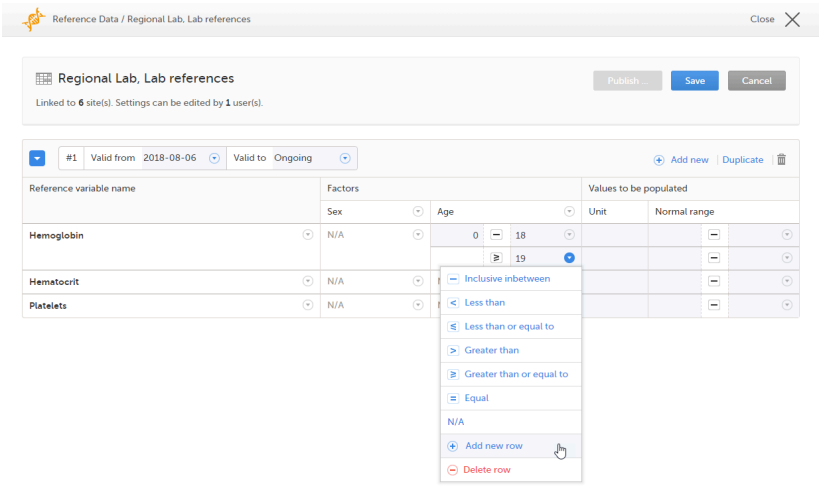


5 For every variable, and for every factor, click the arrow to the right of *N/A* and select the factor options that should be included.

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.

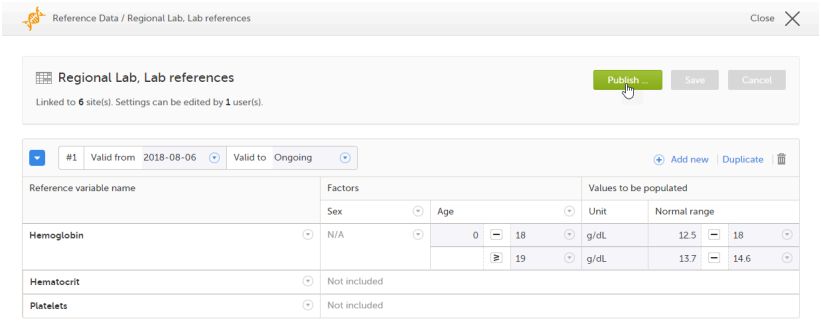
6 For every variable, and for every factor, enter the reference values that should be automatically populated to the forms.

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

To publish reference data:

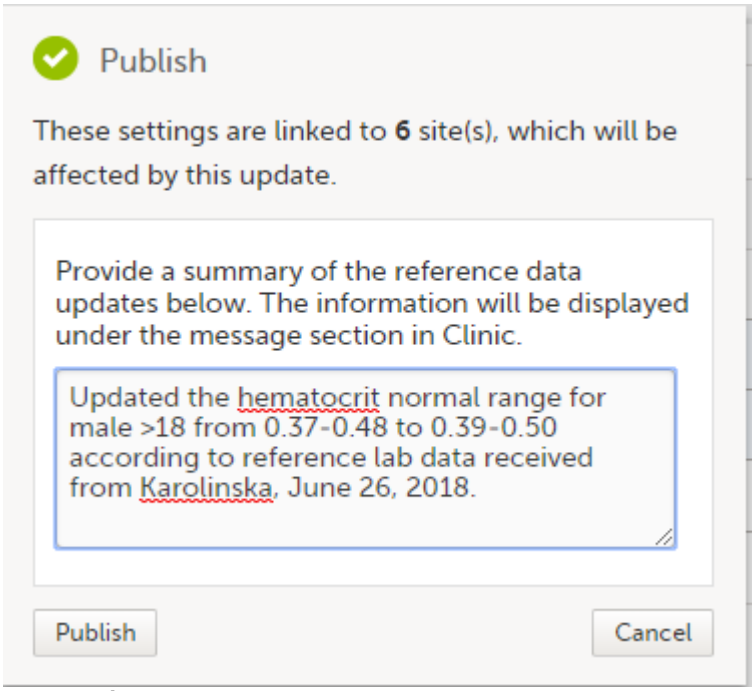
Note! You can only publish reference data when your role has permission to publish reference data.

1 Click **Publish**.



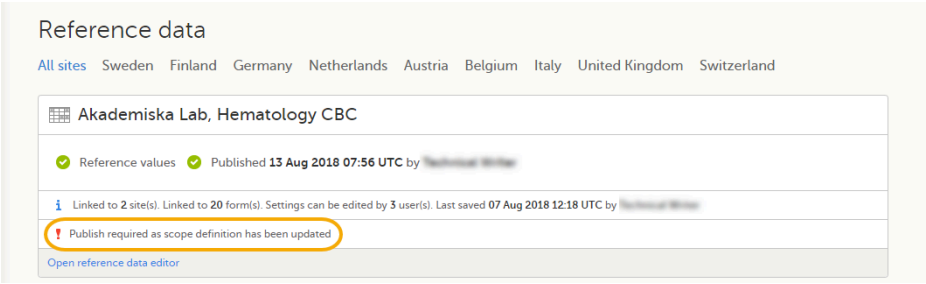
A pop-up opens.

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]**.

---

4 Editing reference data

4.1 Editing existing reference data

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

To edit a set of reference values:

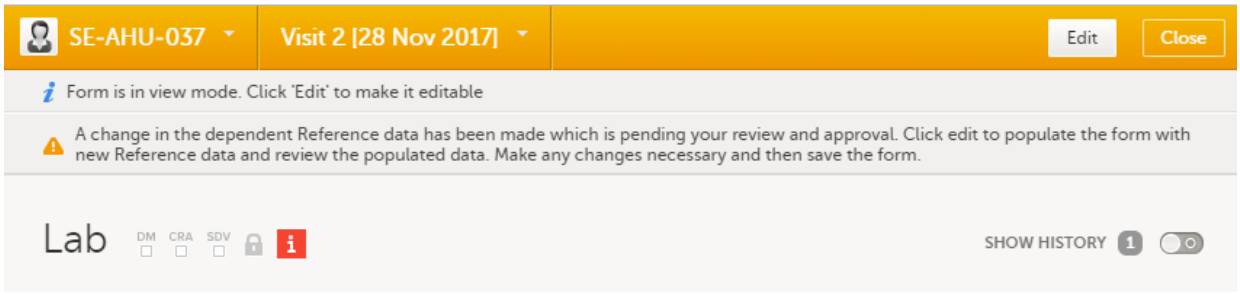
1 On the Viedoc landing page, click the **Reference data** icon.

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 during a study for already populated data, **ALL** 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:



Note! To avoid causing all forms to get issues, you can follow the alternative procedure as described in the next section.

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

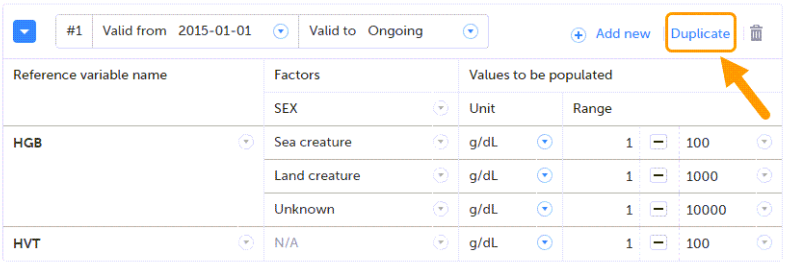
4.2 Making changes to reference data in a duplicate set

To make changes to a reference data set during a study and without causing all affected forms to get issues, you can create a copy of the existing reference data set and make the changes there.

To create a duplicate of your reference data set::

1 Open the reference data editor.

2 Select **Duplicate**.



The original set is displayed at the bottom of the list and the new set at the top.

3 Make your changes in the new set.

4 Set the dates for when you want the two sets to apply.

Note! The stop date of the previous set cannot overlap the start date of the new set. It is recommended to make the new set start on the day after the old set ends.

5 Save the changes.

6 Select **Publish...** and write a note to the site staff, explaining what has been changed.

7 Select **Publish**.

Randomization, allocation and emergency unblinding

Randomization, allocation, and emergency unblinding

Published by Viedoc System 2025-06-10

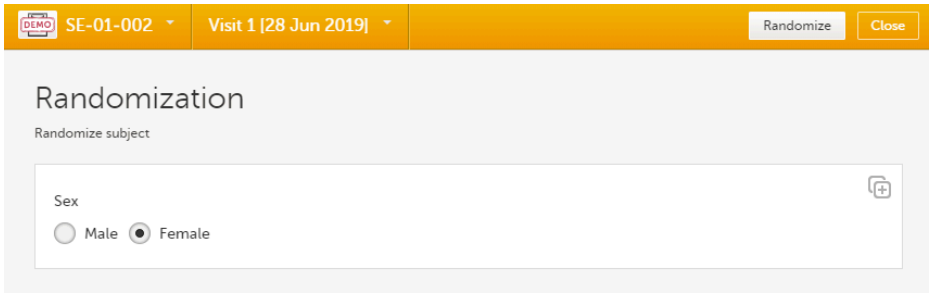
1 Introduction

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.

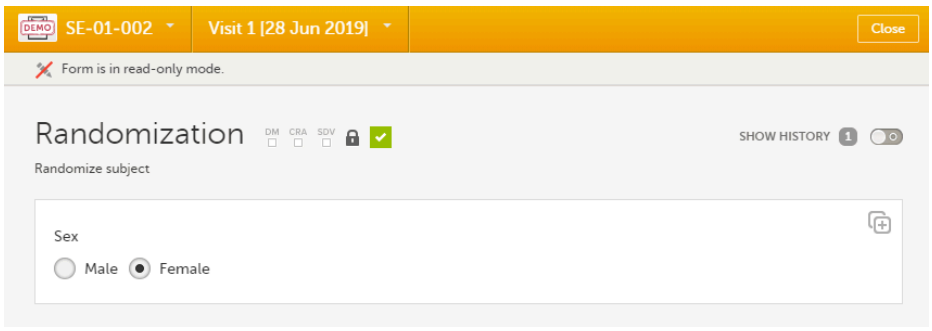
An example of a simple randomization form:



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:

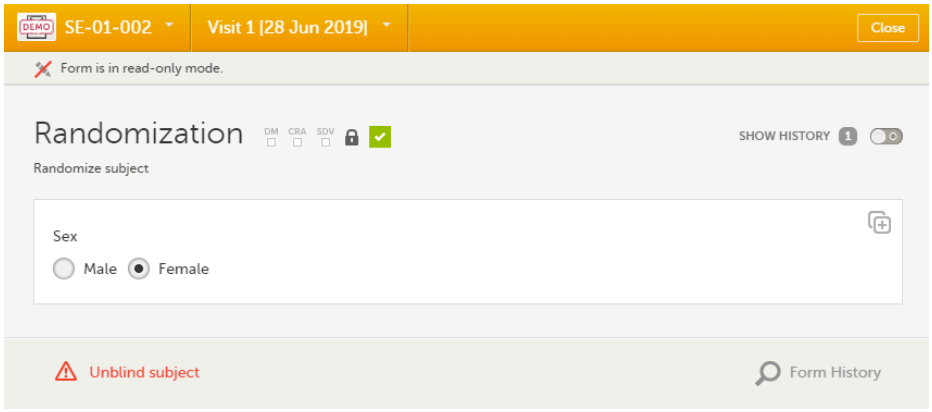


2.1 Emergency unblinding

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.

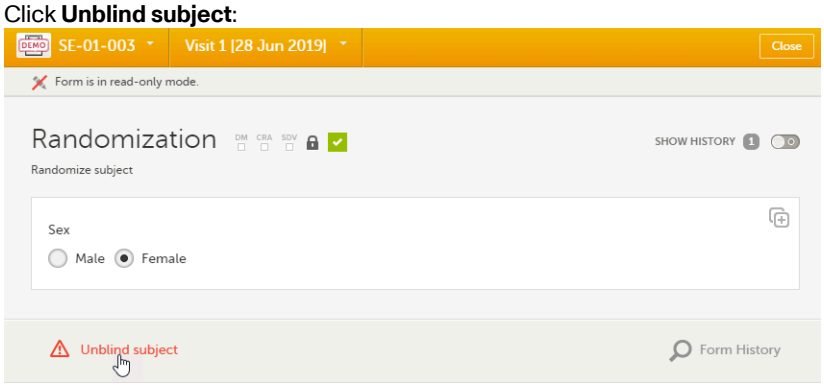
> **Important!** Unblinding a subject will reveal the subject's treatment and unblind all personnel with permission to view this data in the study.

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



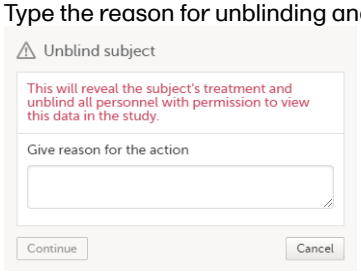
To unblind a subject:

1 Click **Unblind subject**:

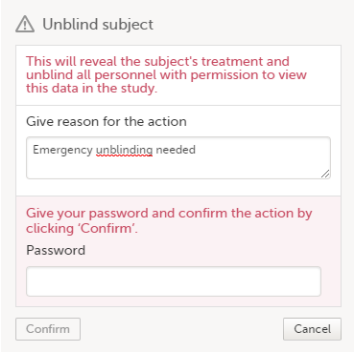


The **Unblind subject** pop-up will be displayed.

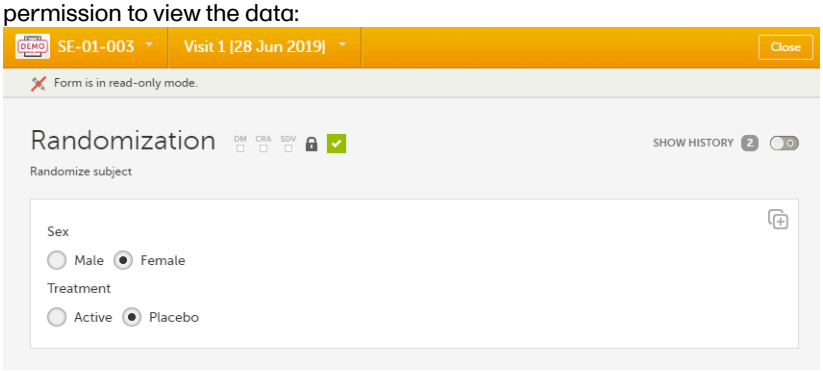
2 Type the reason for unblinding and select **Continue**.



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:



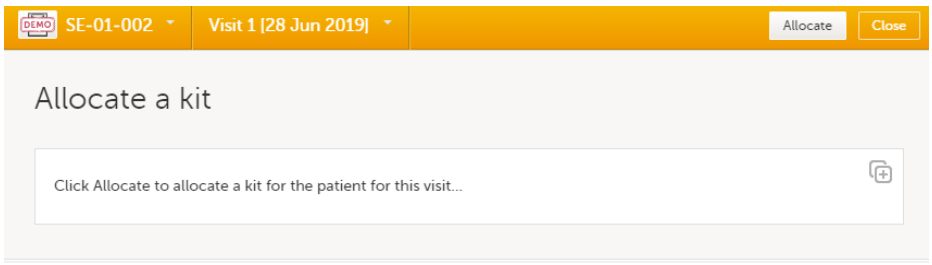
3 Allocation

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.

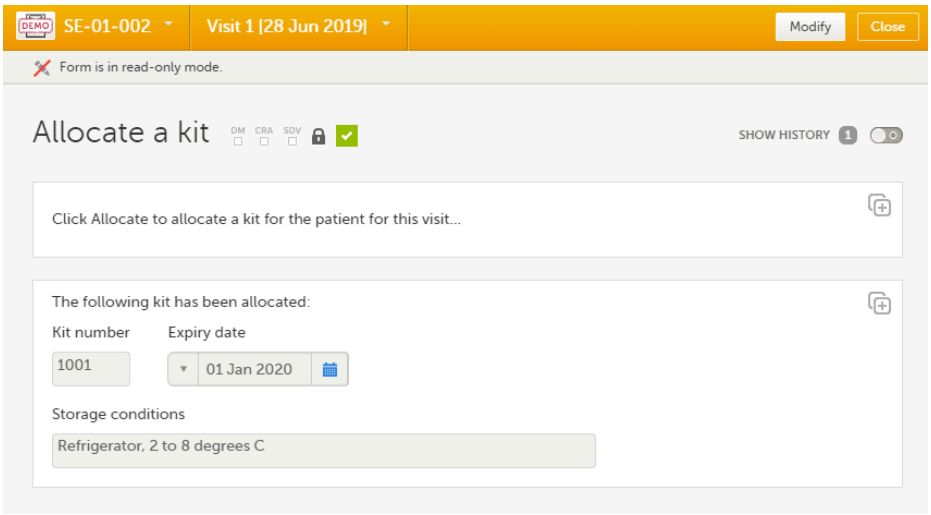
It is important to know that the allocation form will be locked after the allocation is performed, so the form won't be possible to edit. Still, the following actions can be performed after the allocation:

- 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:



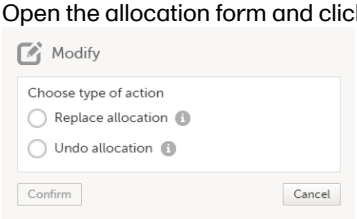
The action is registered in the audit trailed as **Initial data entry** and a new version of the form PDF is generated (see Allocation actions in audit trail).

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

3.1 Undo allocation

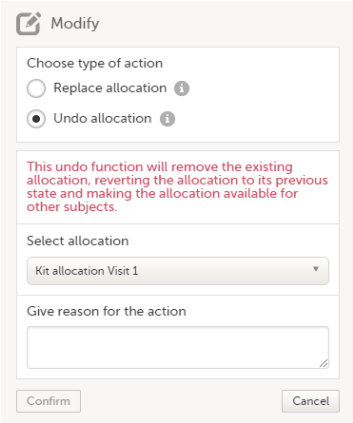
To undo an existing allocation:

1. Open the allocation form and click **Modify**. A pop-up is displayed:

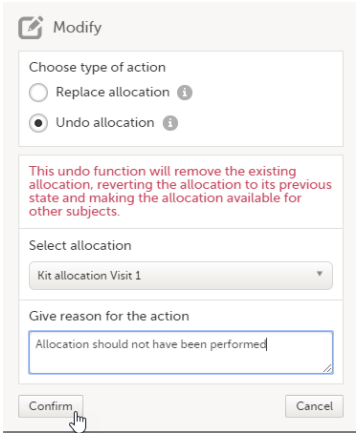


2. Select **Undo allocation**.

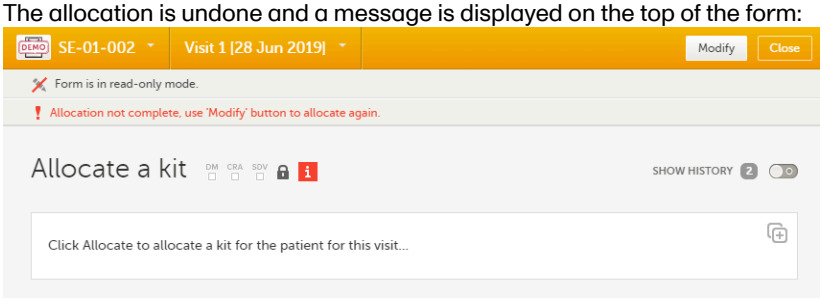
3. If multiple allocations are performed within the same form, select from the dropdown list the allocation you want to undo under **Select allocation**:



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:



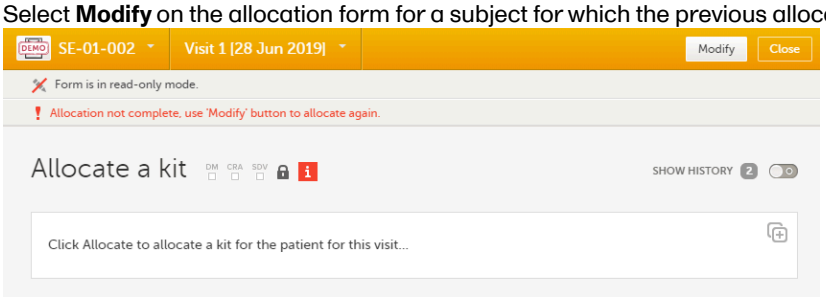
This will remove the existing allocation by reverting the allocation to its previous state and making the previously allocated kit available for other subjects.

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

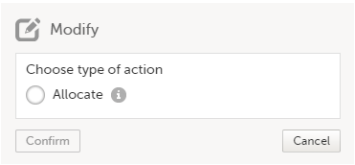
A new allocation can be performed for the subject, as described below.

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

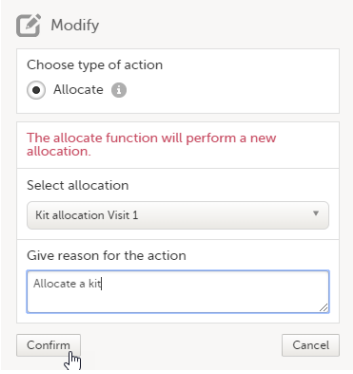
1 Select **Modify** on the allocation form for a subject for which the previous allocation was undone:



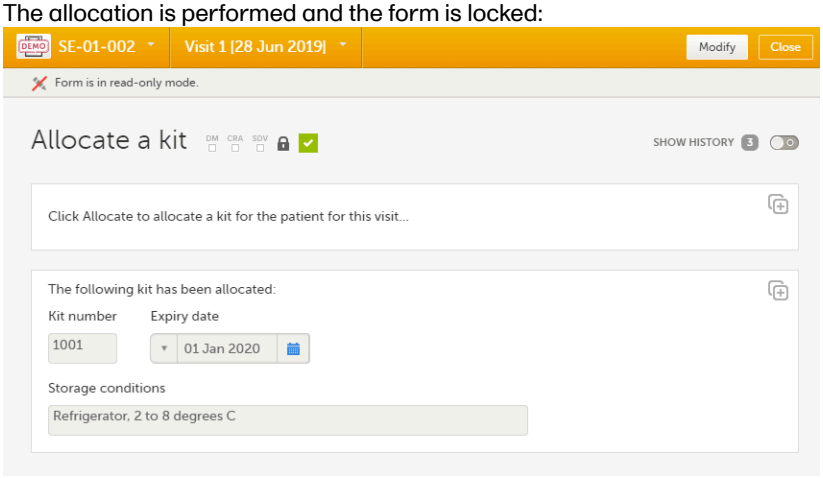
The Modify pop-up is displayed:



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:

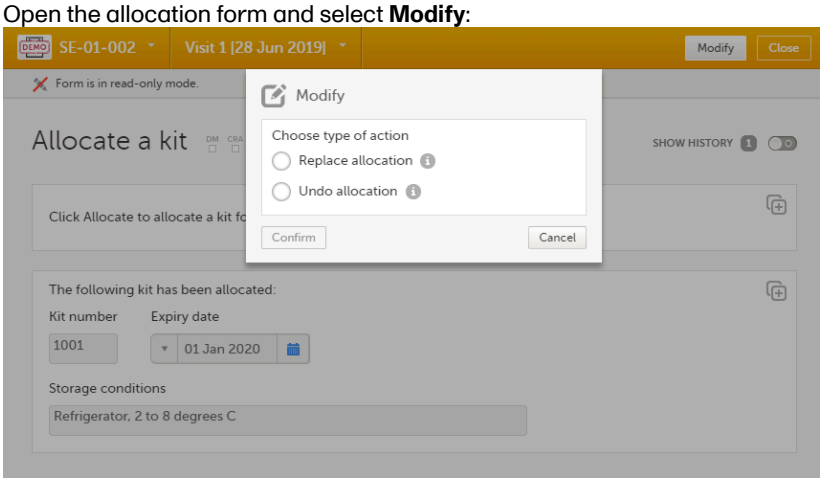


A new version of the form PDF is generated (see Allocation actions in audit trail).

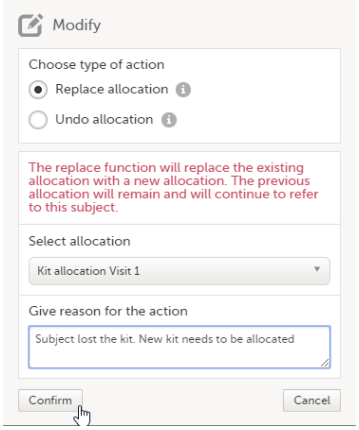
3.2 Replace allocation

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

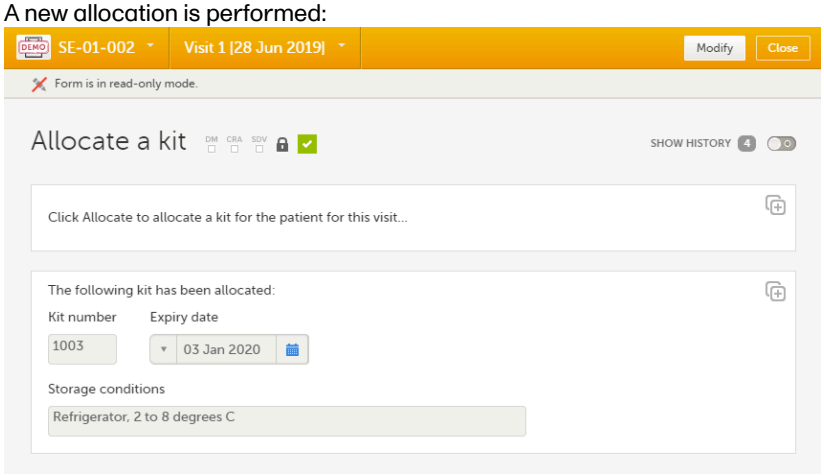
1 Open the allocation form and select **Modify**:



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:

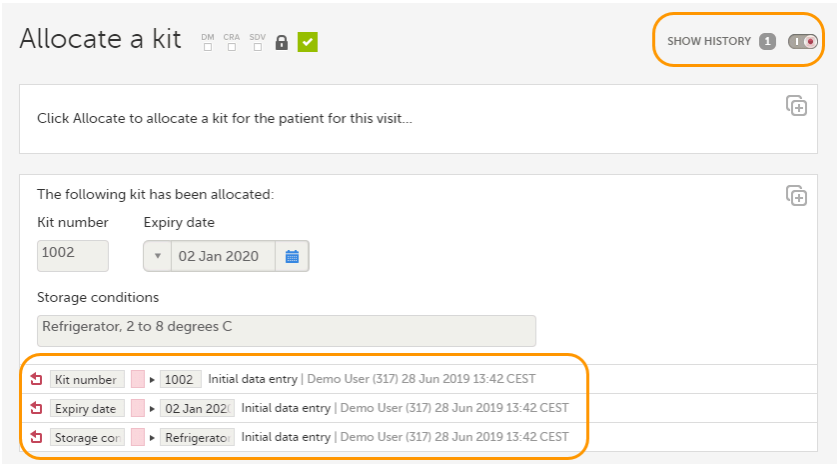


This will replace the existing allocated kit with a new one. The previously allocated kit will continue to be allocated to the same subject.
A new version of the form PDF is generated (see Allocation actions in audit trail).

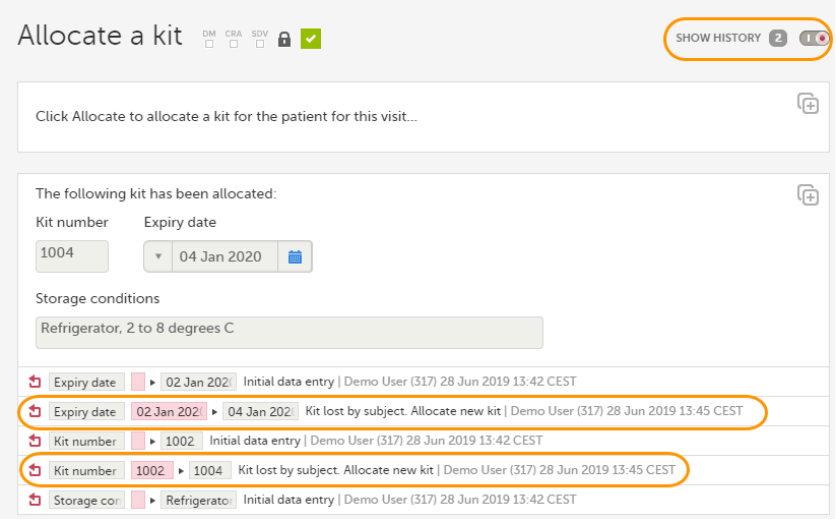
3.3 Allocation actions in audit trail

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

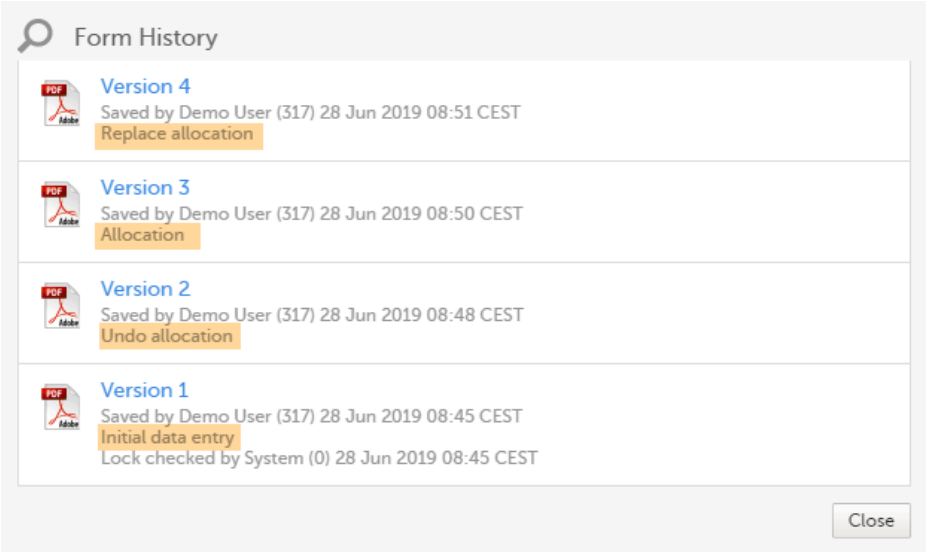
- The first time the allocation is performed, it is recorded as **Initial data entry**:



- 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

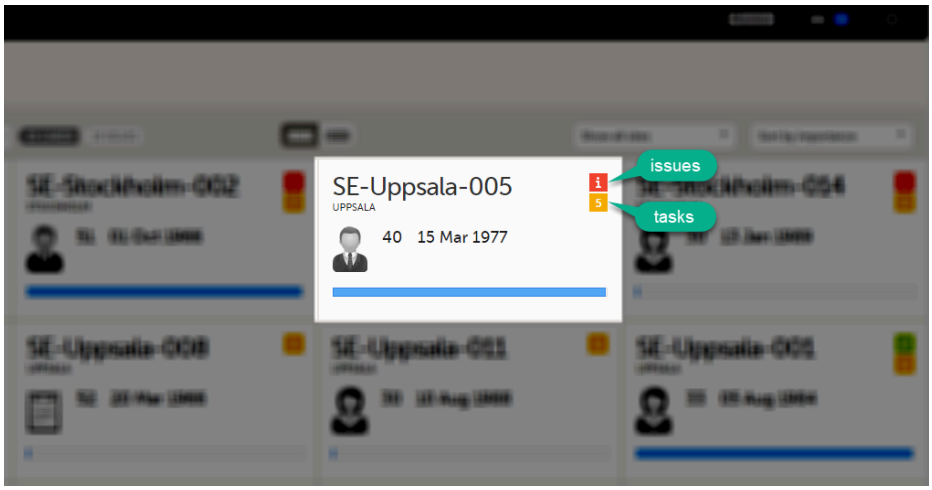
Issues and tasks

Published by Viedoc System 2025-04-24

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 upper-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 to identify where actions are needed.



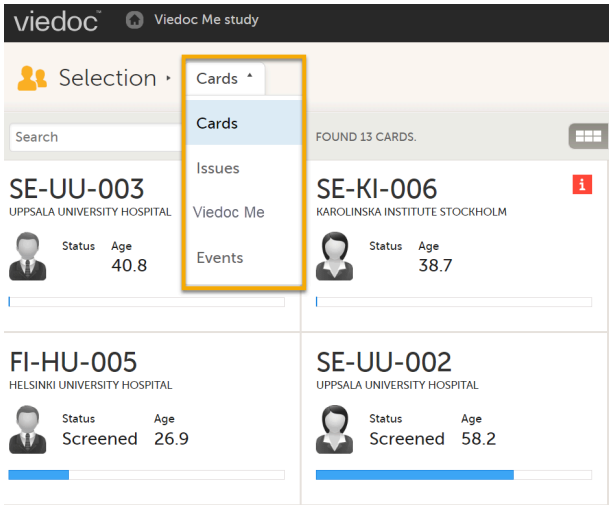
- **Red icon: Issues** - indicating that the subject has open queries and/or unconfirmed missing data. Both open queries and unconfirmed missing data should be handled and resolved by the site but, as a Monitor or Data Manager, it is important for you to be aware of these issues as well. For more details, 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 when present they help you identify where action is needed.

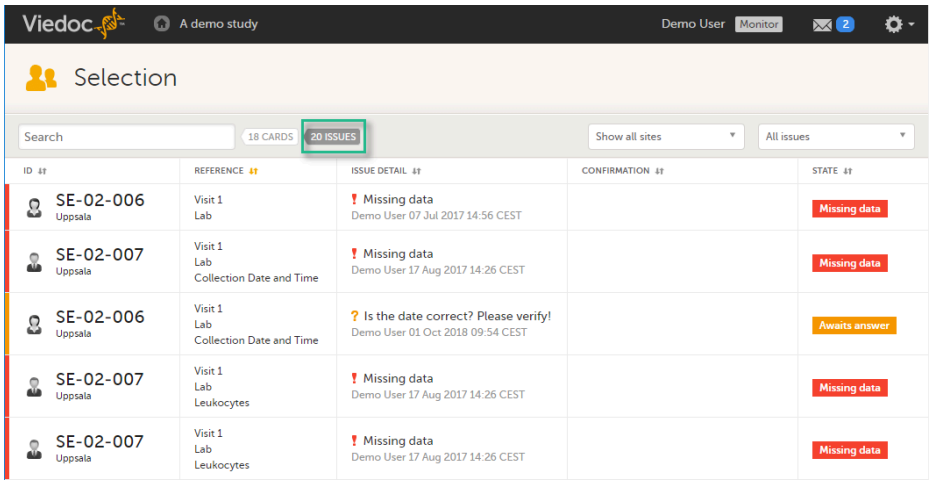
Note! The issue list will not be visible for sites that have more than 1000 subjects.

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 has been raised. If you close the form, you will return to this issue list again.

The list of issues can be filtered by using the dropdown lists on the upper-right 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

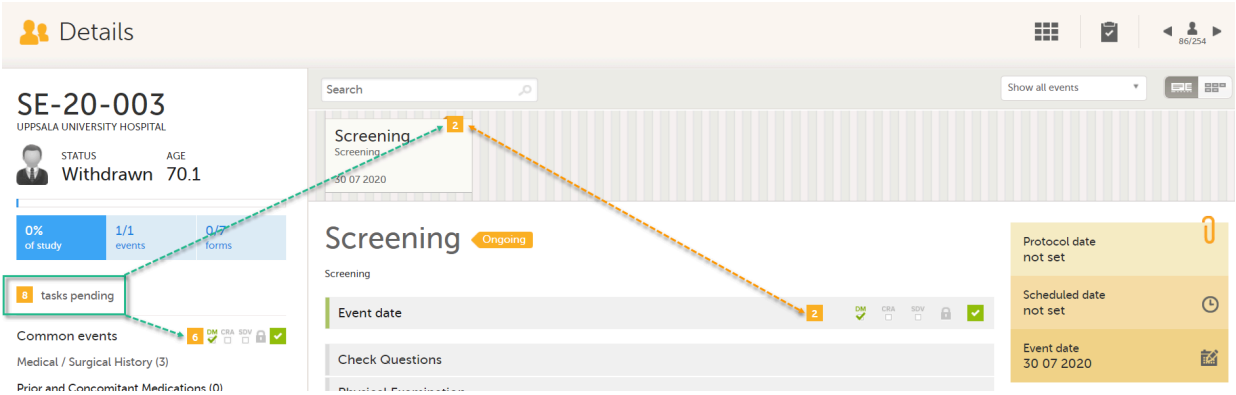
- **Form upgrade pending** - forms pending upgrade as a result of applying a revision of the study design

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.

Resolving queries

Resolving queries

Published by Viedoc System 2024-10-10

1 Resolving a query

For an overview of the entire query process see Queries overview.

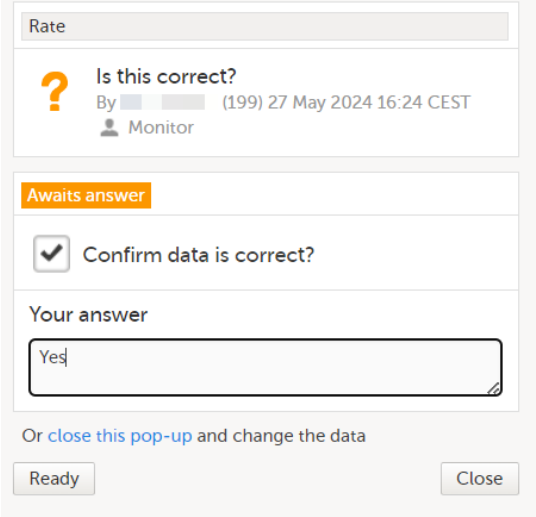
If a query is raised during data entry, a query message will appear as soon as you leave the field. To resolve the query, click the query message for more details, or correct the data directly before you continue entering data in the rest of the form.

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.
   .

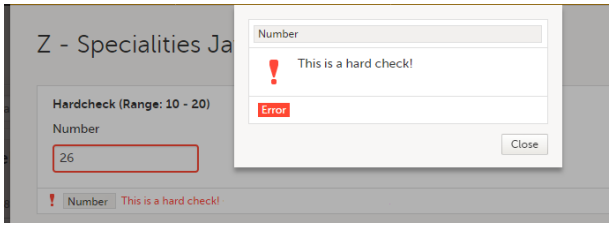


4. Click **Ready**.
5. Click **Save changes**.

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.

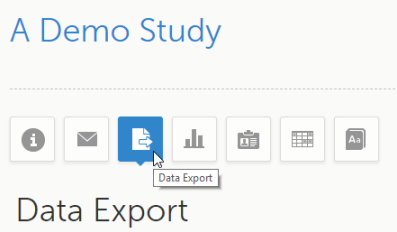
Exporting data

Exporting data

Published by Viedoc System 2025-12-02

1 Introduction

The Data Export page can be accessed by selecting 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)

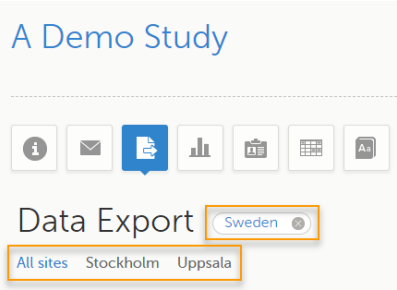
2 Filtering the data to be previewed/exported

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, select 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, select **All sites**.

To undo the selection of a country, select 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.

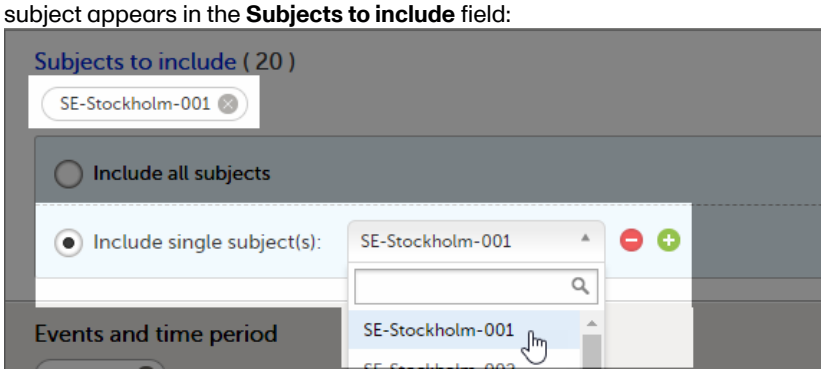
2.2 Including subjects

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:

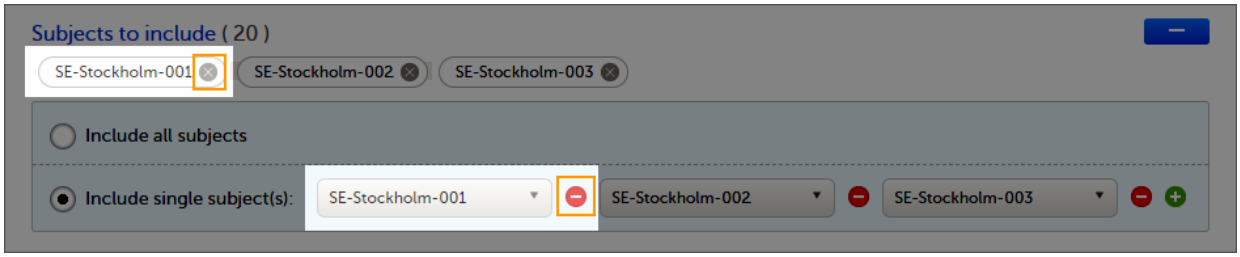
1 Select **Include single subject(s)**.

2 Select 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, select the - icon, or select 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

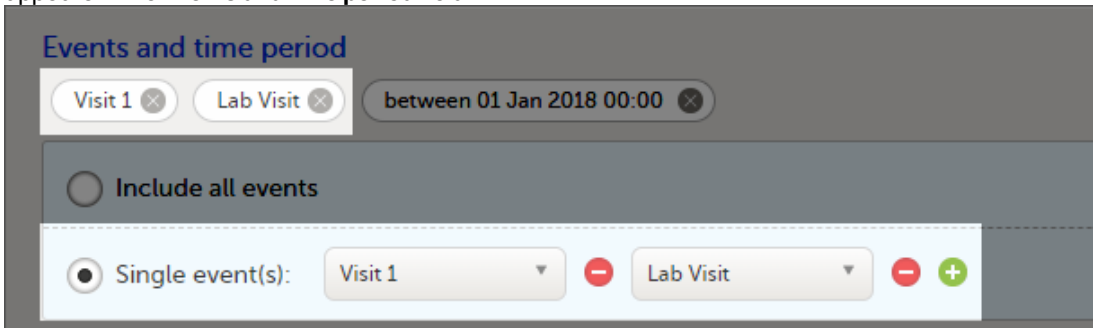
You can choose to:

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

To select which events to include:

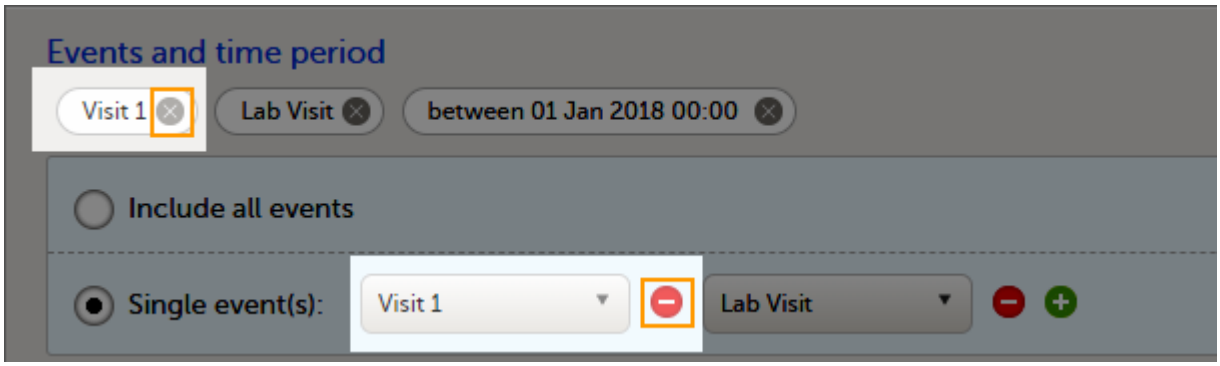
1 Select **Single event(s)**.

2 Select 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.

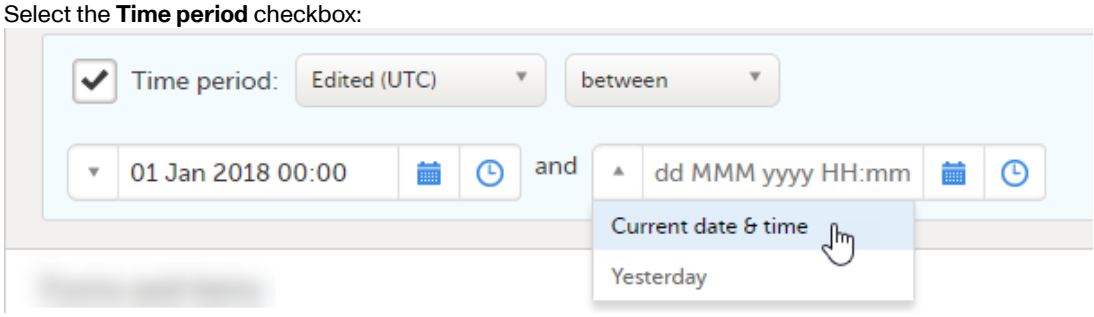
To undo the selection of certain events, select the - icon, or select the cross x icon next to the event:



2.3.2 Selecting a time period

To include data from a specific time period:

1 Select the **Time period** checkbox:



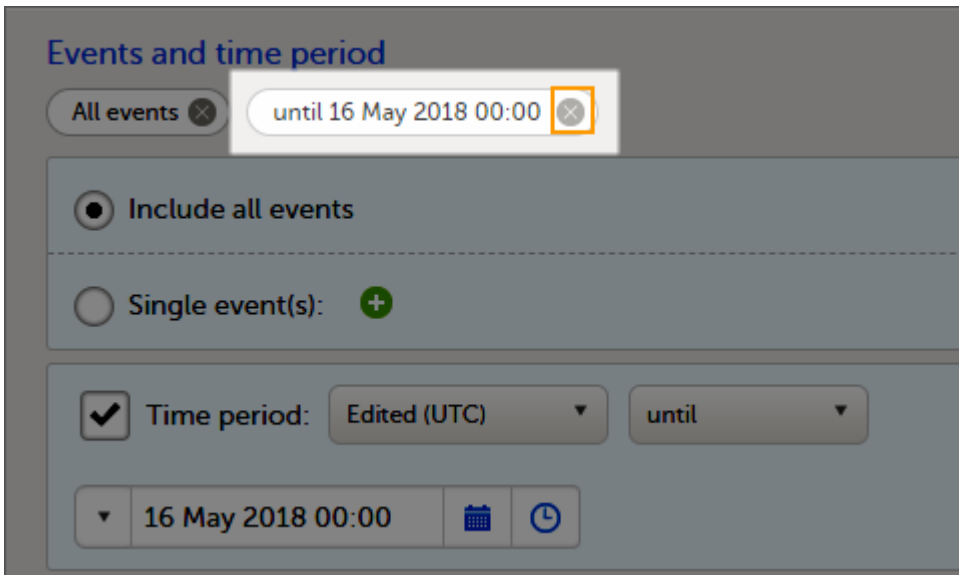
2 Select one of the following options from the first drop-down list:
- **Edited (UTC)** - to include data based on the date they were added or last edited.
  Note! This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note that also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

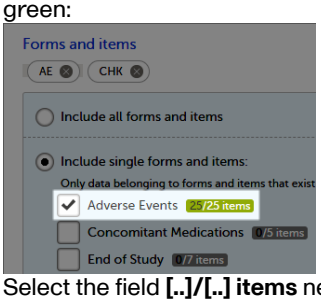
Note! Only data belonging to forms and items that exist in the latest effective design applied to the first of the selected sites will be included in the export. Also note that the forms and fields available to choose from are determined by the visibility settings for your user role.

To include data from specific form(s):

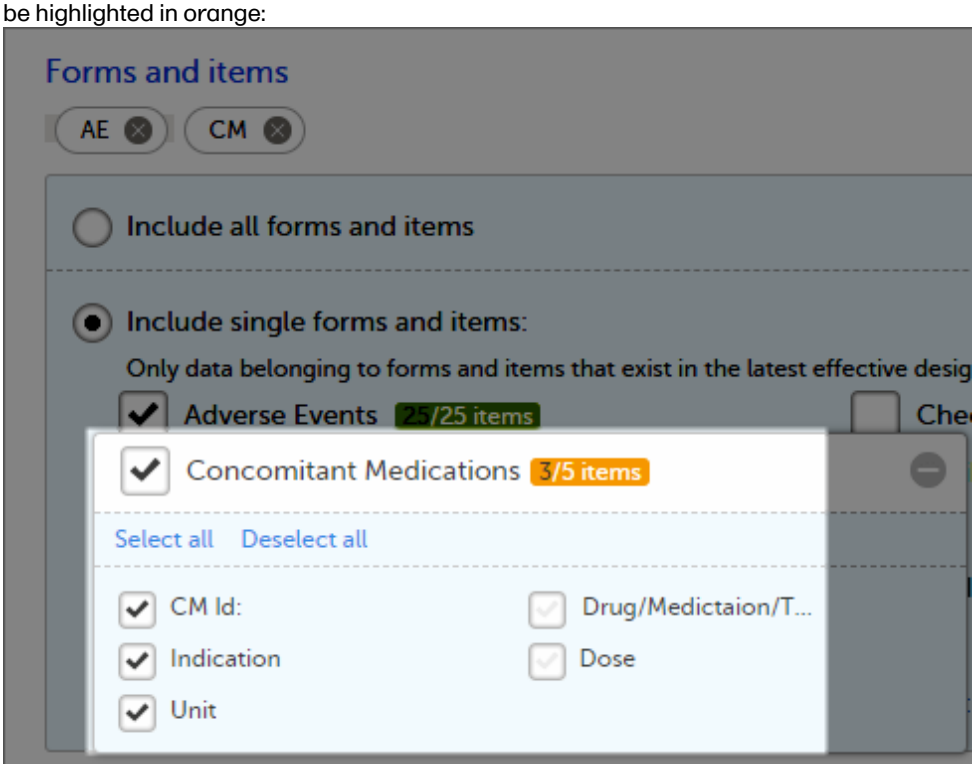
1 Select **Include single forms and items**.

2 Select the forms and items to be included, in one of the following ways:

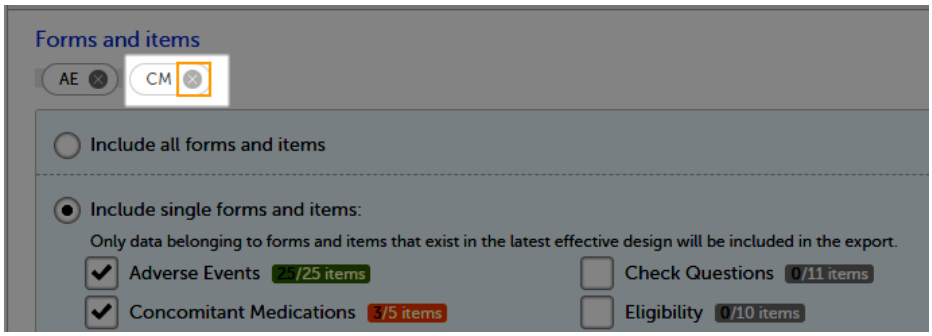
- Select the checkbox corresponding to a form in the list displayed, to include the respective form with all the items contained. The selected/total number of items will be highlighted in green:



- Select 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, select 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

Column name	Description
Last edited by	The name and ID of the user who last edited the event
Last edited date (UTC)	The date and time (UTC) when the event was last edited
Design version	The design version/revision that is active for the event

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 folder structure obtained when you unzip the file is as follows:

- SponsorCode_YYYYMMDD_HHmmss (date and time in UTC format)
  - FileData
    - StudySite (SiteCode)
      - SubjectKey
        - StudyEventOID
          - EventRepeatKey
            - ActivityOID
              - ActivityRepeatKey
                - FormOID
                  - FormRepeatKey (if any)
                    - ItemGroupOID
                      - ItemGroupRepeatKey (if any)
                        - ItemDefOID
                          - FileName.extension (original filename)
                            - FileName_tn.extension (thumbnail filename)

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

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

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

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

- File Hash (MD5)
- Link to file

2.5.2.6 Pending forms

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

- Microsoft Excel - Office Open XML
- CSV

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

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

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

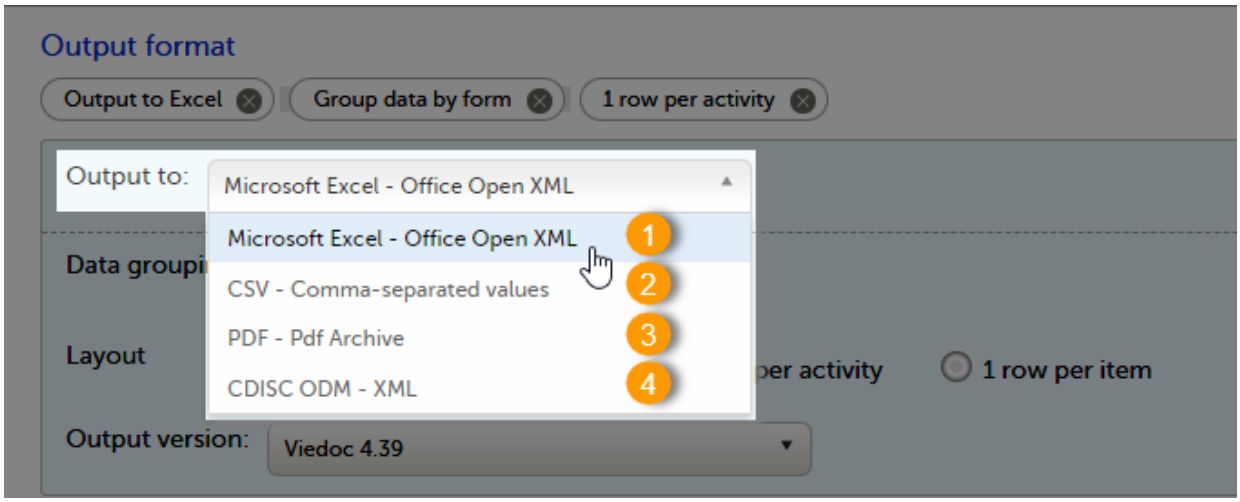
- Microsoft Excel - Office Open XML
- CSV
- ODM

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.

Notes! The export to CSV fails if the same OID was used in Viedoc Designer in different design versions withdifferent casing (for example, an OID defi ned 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 singleform is selected for export.

3.3 PDF

For details about the PDF export and the format/structure of the output file, see PDF export output.

3.4 CDISC ODM

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

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

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

The ODM export file is built up as follows:

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

See also:

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

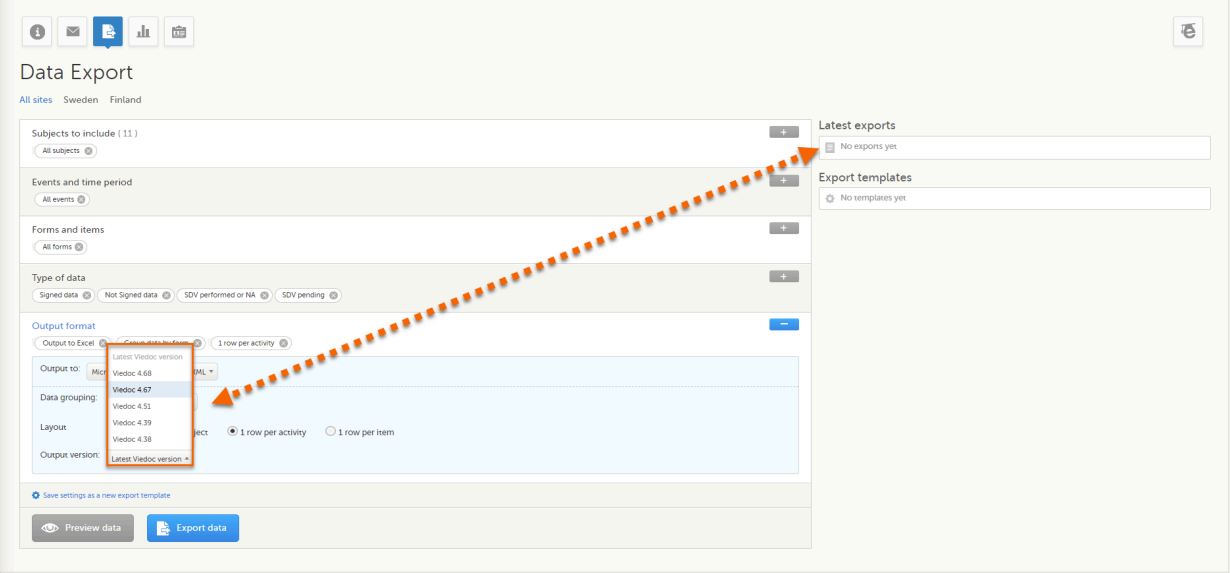
---

4 Export compatibility with previous Viedoc versions

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

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

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



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

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

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

4.1 Output versions

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

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

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

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

File type	Changes in the export output format
ODM	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.
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.

File type	Changes in the export output format
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.
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.

File type	Changes in the export output format
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 or complete configuration report of the design version to ensure completeness and consistency.

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

Example scenario: How study design affects data export

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

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

---

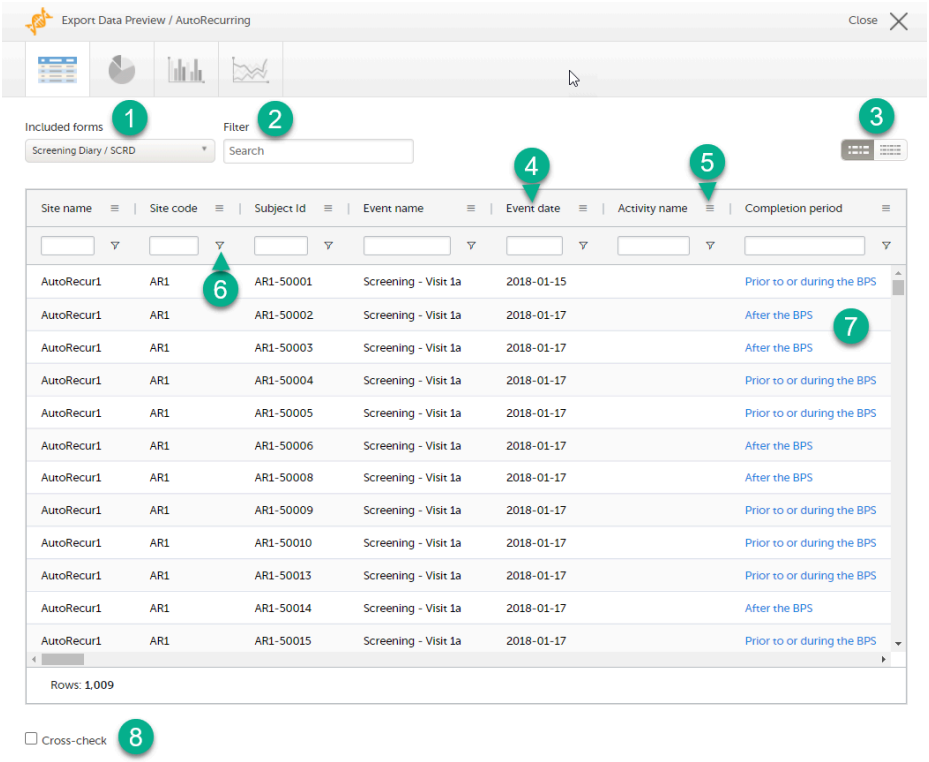
6 Previewing data

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

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

6.1 Data table

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



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. Select a column header to sort the data in ascending order. Select again to sort in descending order. Selecting a third time removes the column sort order. To rearrange the order of the columns in the table, simply select a column header and drag the column sideways.

5. Select to open the column menu. For more information, see Column menu.

6. Select to access the column filter. For more information, see Column filter.

7. Select 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.

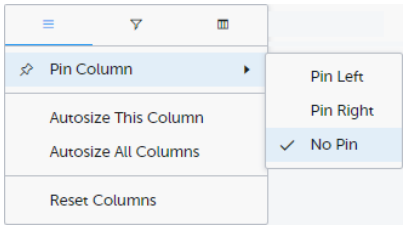
6.1.1 Column menu

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



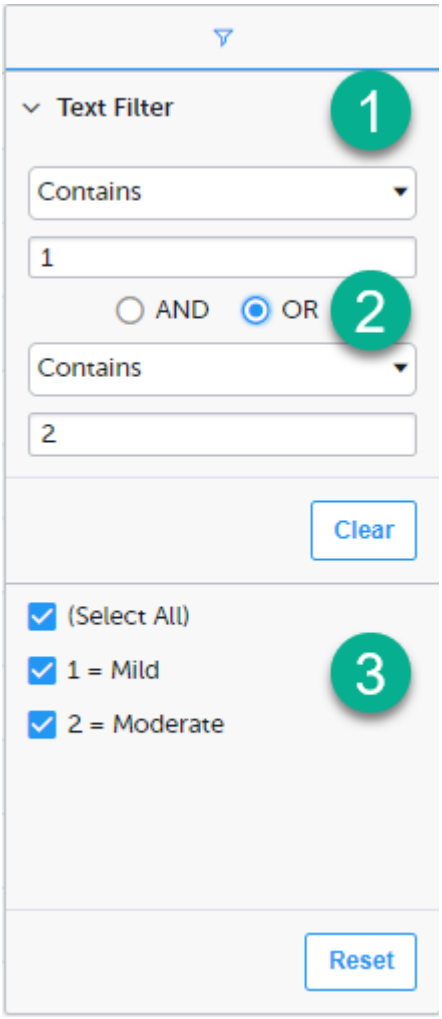
Pin Left/Right makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select **No Pin** to unpin the column.

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:

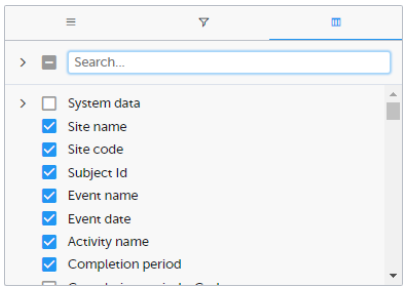
- Equals
- Not equal
- Less than
- Less than or equals
- Greater than
- Greater than or equals
- In range

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:

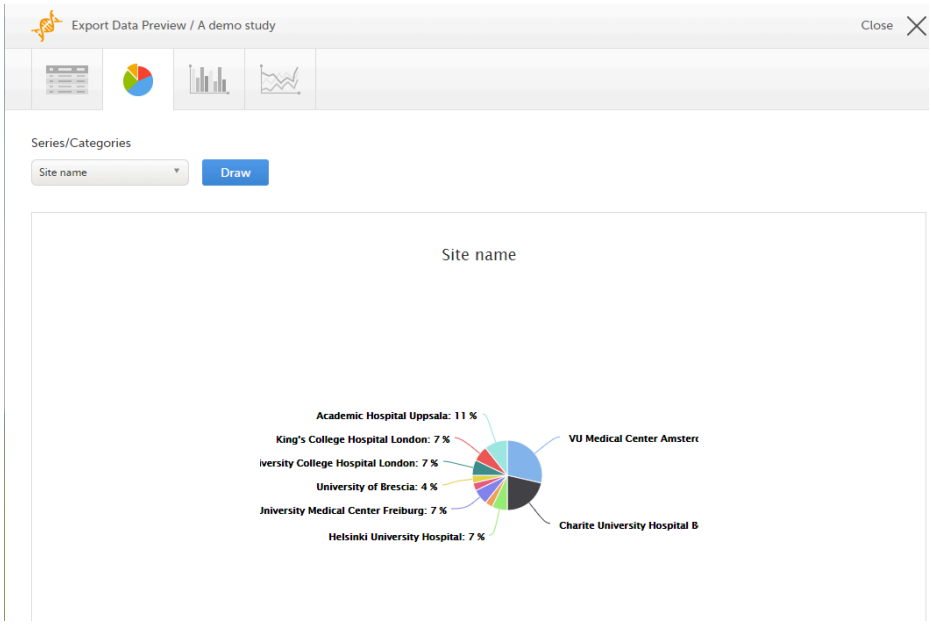
Copy: Copies the cell value to your clipboard.

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 select **Draw**:



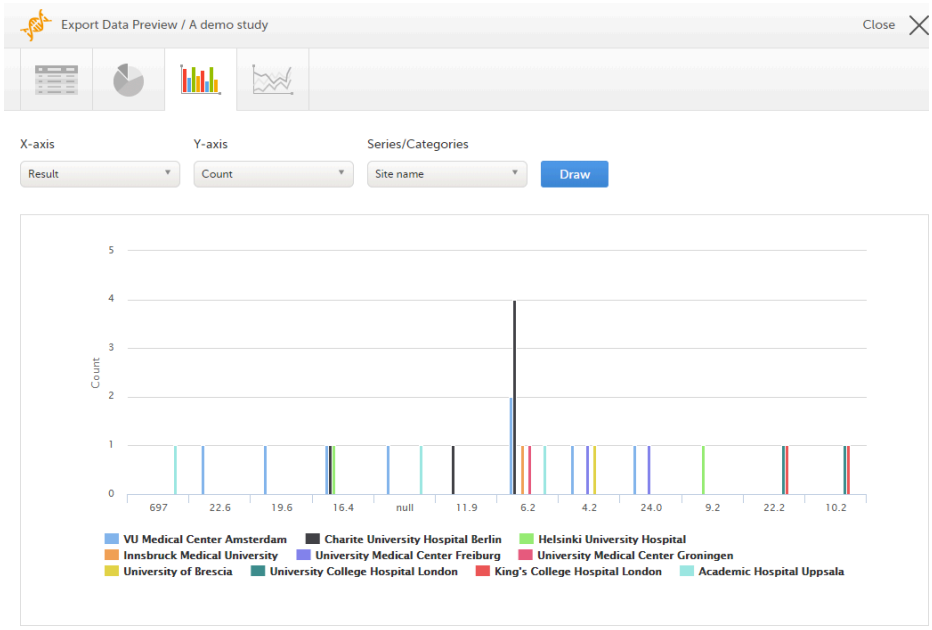
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Select 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 select **Draw**:



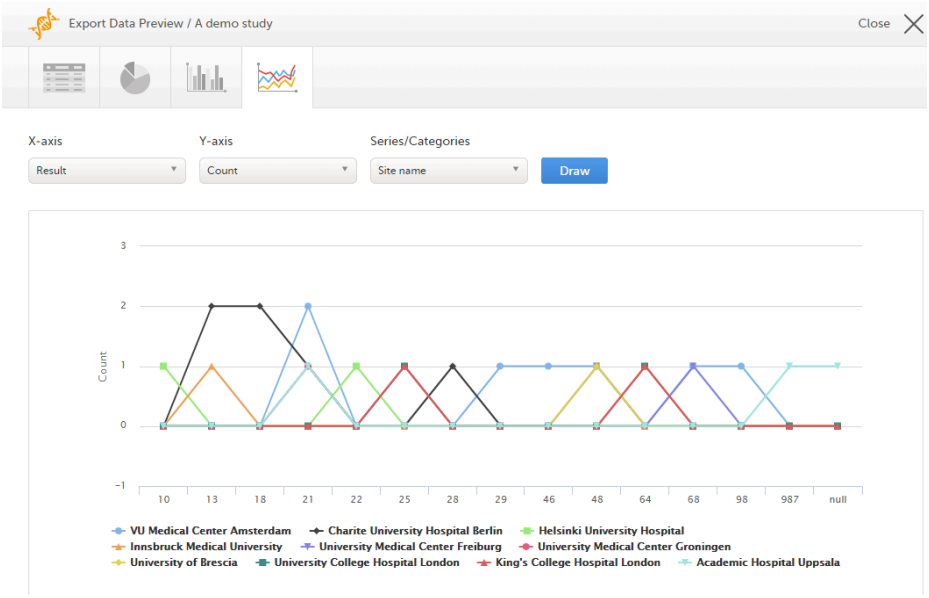
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Select 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 select **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.

---

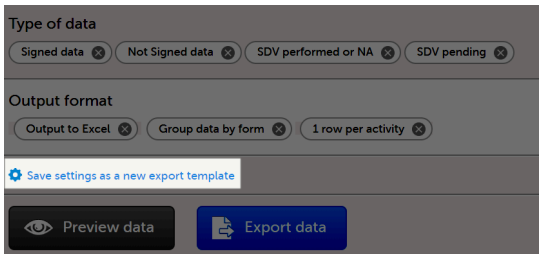
7 Data export templates

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

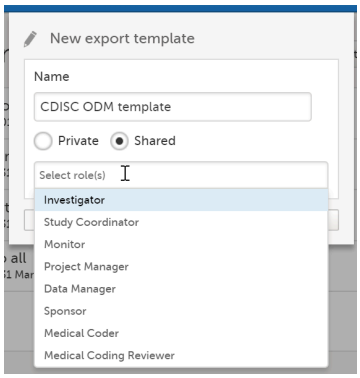
To save your settings as a template:

1 Select **Save settings as a new export template**.

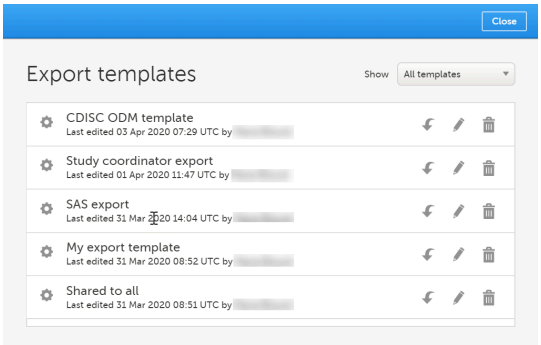


2 In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

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.



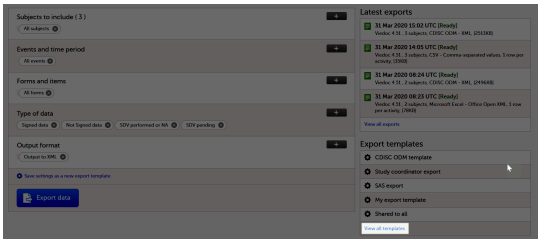
3 Select **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:



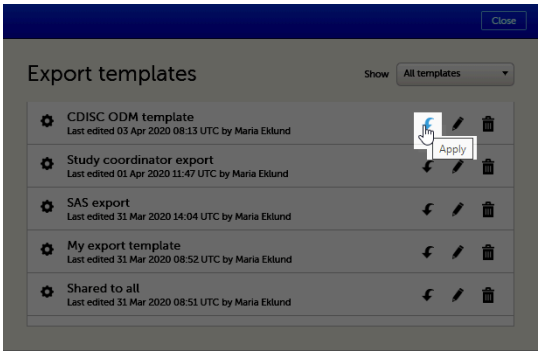
7.2 Applying a data export template

To apply a data export template:

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



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



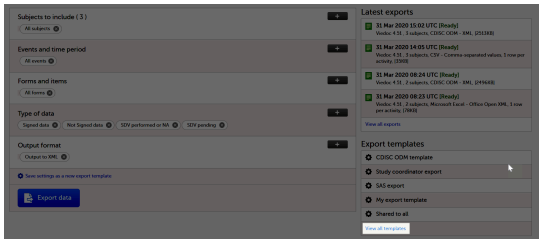
3 Select **Export data** to perform an export with the settings in the template.

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

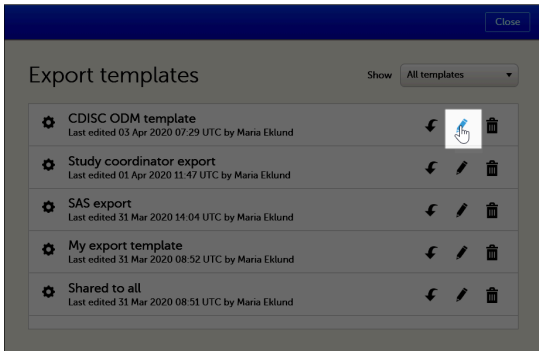
7.3 Editing a data export template

To edit a data export template:

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



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



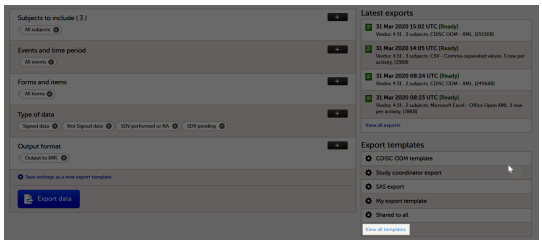
3 In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

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

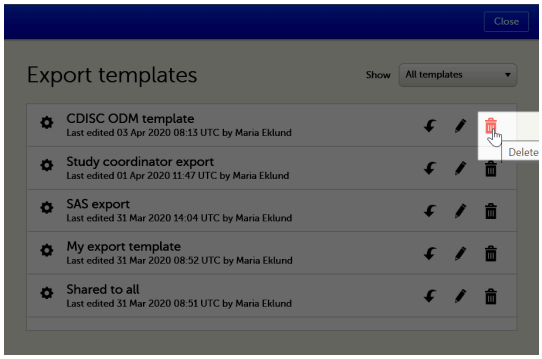
7.4 Deleting a data export template

To delete a data export template:

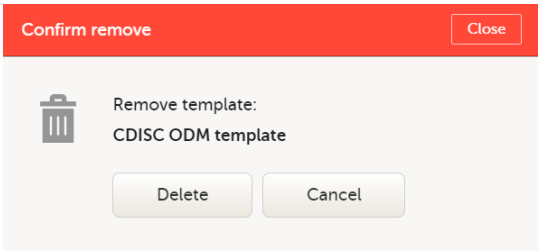
1 Select **View all templates** in the **Export templates** area of the **Data export** page.



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



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



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

8 Exporting data

To perform a data export:

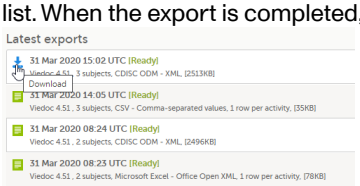
1 Filter the data to be exported. See Filtering the data to be exported.

2 Select the Output format.

3 Optionally, select the Output version.

4 Optionally, preview the data to be exported.

5 Select **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*.

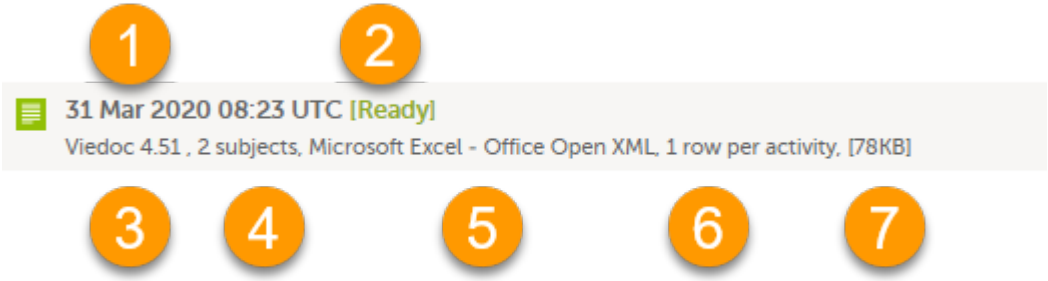
Note! If any of the characters that are invalid for a filename in Windows are used within any of the *SponsorCode* or *SiteCode*, these characters will be automatically replaced with **-** within the exported filename.

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, select 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.

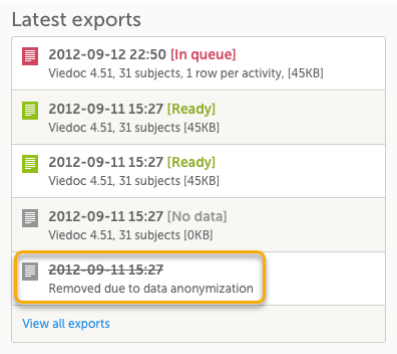
4. The number of exported subjects.

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.

Back to top of page

Excel export

Excel export

Published by Viedoc System 2025-04-24

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
            - time
            - 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

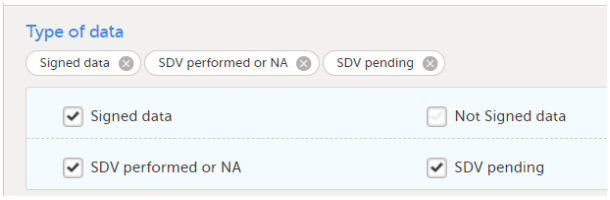
An item that was changed within a new/revised study design version will have a "__*n*" suffix added, where *n* is incremented for each study design version where the respective item was changed:

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` .

Column	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).
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

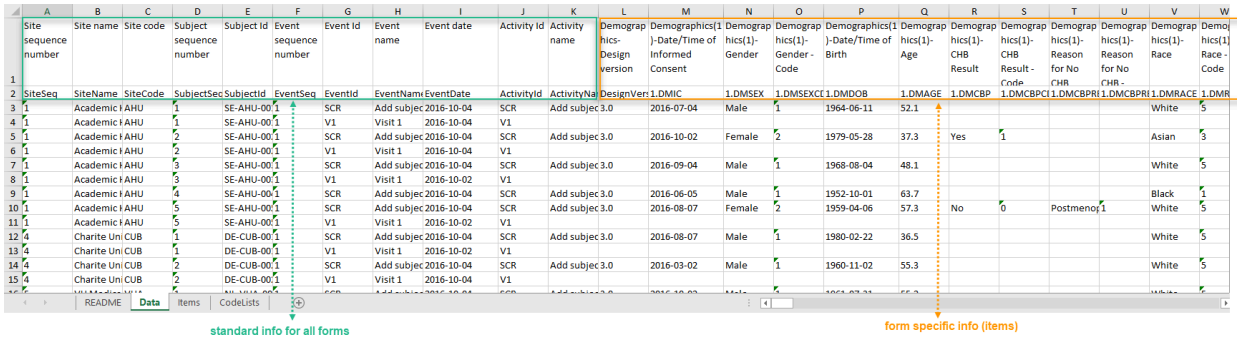
If you choose not to group the data, then all data from all forms will be exported in the same sheet (**Data**) of the output file.

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:

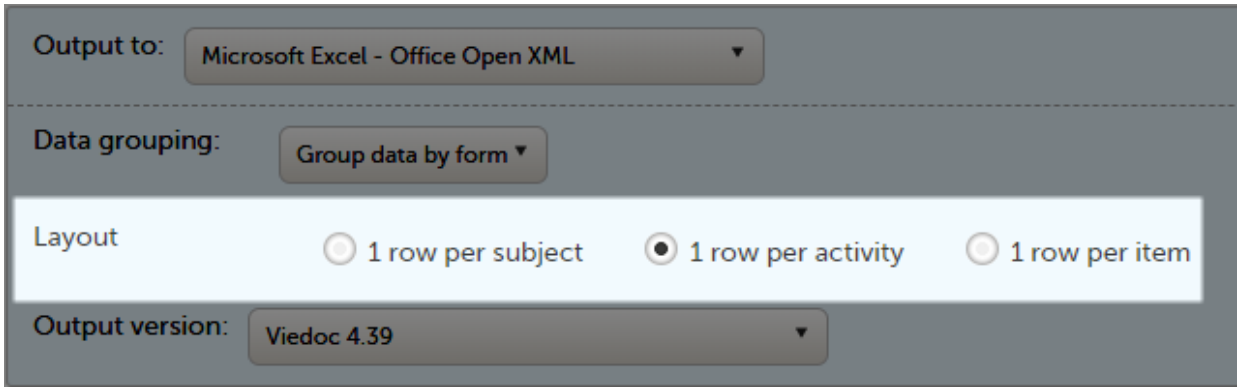
- <*FormName*>_*Design Version* - the form name, as set in the study design (in Viedoc Designer) and displayed in Clinic. In the example in the image, the form name is *Demographics.*
- <*FormName*>(<*Form Repeat Key*>)_<*ItemName*> - for each item in the respective form. The form name and item name, 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

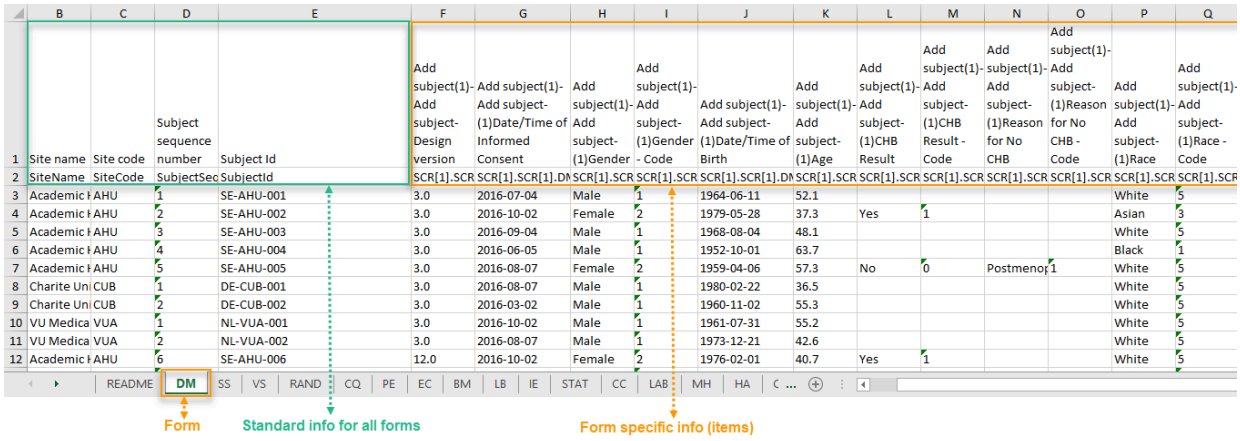
In the **Layout** section, you can select whether the data should be organized in the output file as:

- 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	ActivityNar	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 | ...

5.2.1 Checkboxes

5.2.1.1 Structure

All checkbox responses for an activity are exported within a single row, with each code list option occupying distinct columns. The items that have a code list assigned are output to an additional row with the ID suffixed with "CD", for the code.

5.2.1.2 Output columns

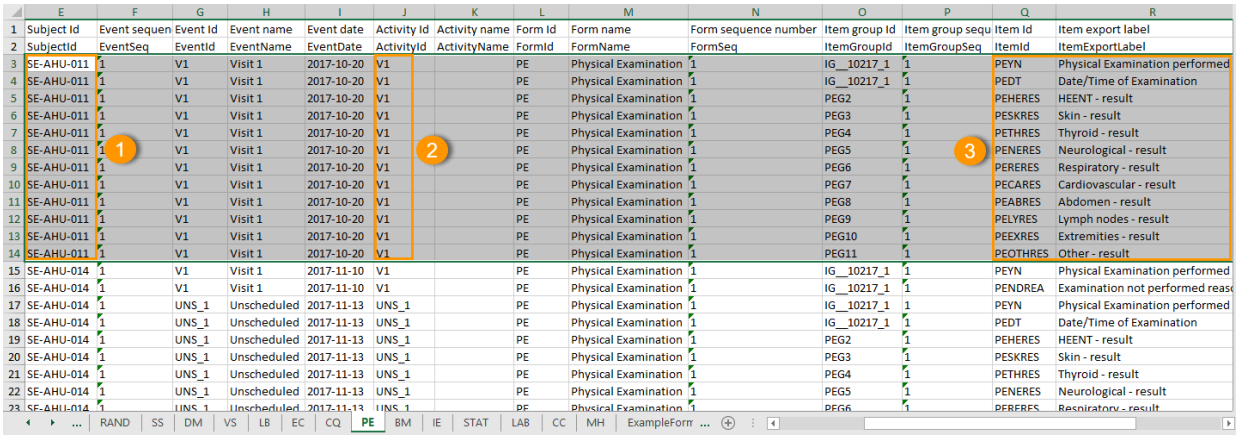
For each code list option, two columns are included: one for the label and one for the code value. Column headers use the item's OID and Export Label, each suffixed with a 1-based index (for example, CHECKBOXOID_LABEL1, CHECKBOXOID_LABEL1CD). Only the selected code list values are populated in the corresponding columns. Unselected options are left empty.

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

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

5.3.2.1 Structure

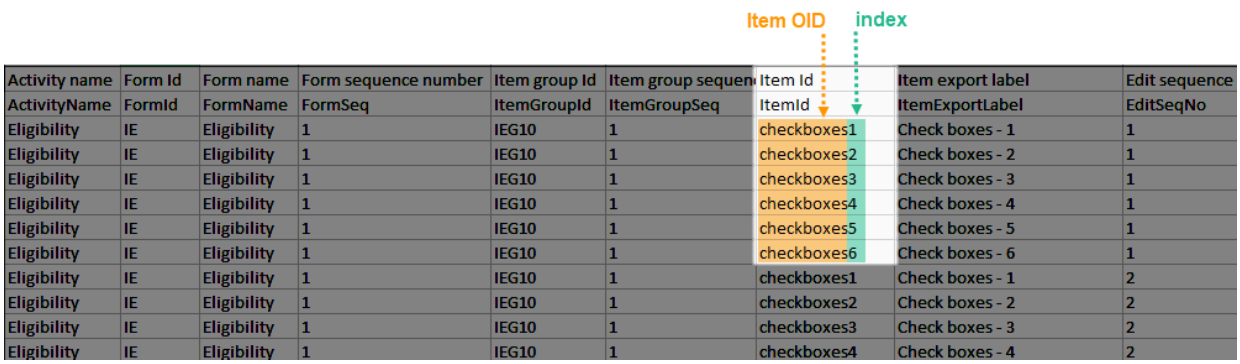
Checkbox items are output as one row per code list item. The items that have a code list assigned are output to an additional row with the ID suffixed with "CD", for the code.

5.3.2.2 Inclusion

All code list items are included in the output, regardless of whether they were selected or not.

5.3.2.3 Labeling

The **Item Id** column contains the item's Object Identifier (OID) with a 1-based index appended, 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

The **Item Export Label** column similarly includes the Export Label with the same 1-based index.

5.3.2.4 Output columns

Two columns are generated per code list item: one for the code label and one for the code value. If a code list value is selected, its corresponding value appears in these columns. Otherwise, they may remain empty.

5.3.2.5 Sort order

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**).

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-Activtyld-Formld-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

Header rows, one row per activity	
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

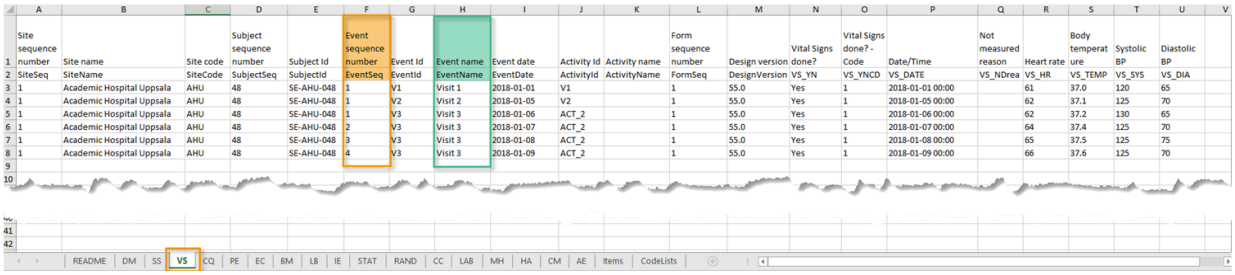
There are also two header rows in the output:

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

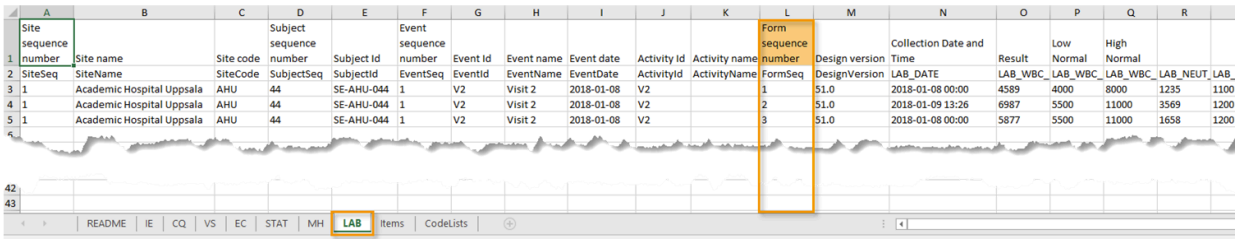
README | DM | SS | VS | CQ | PE | EC | BM | LB | IE | STAT | RAND | CC | LAB | MH | HA | CM | AE | Items | CodeLists

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

10 Tracking form instances using form sequence numbers

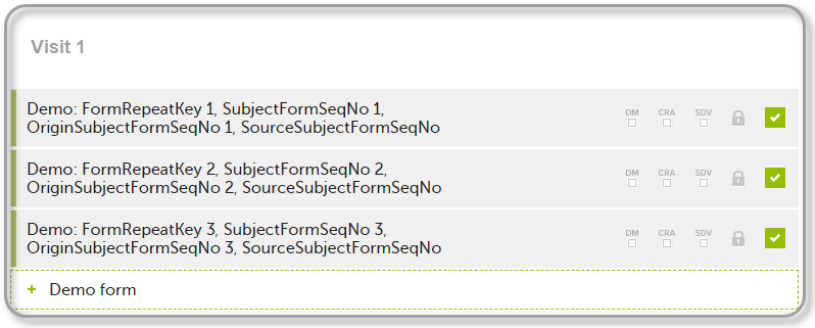
The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

- `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.

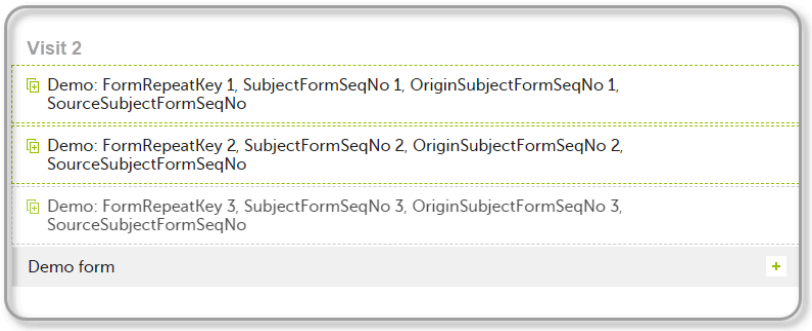
The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

We perform the following actions in Viedoc Clinic:

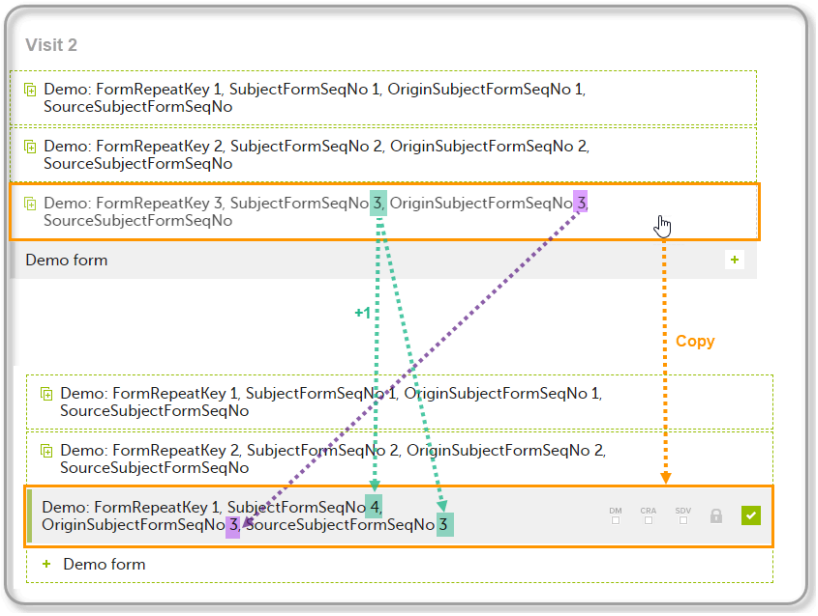
1 Initiate Visit 1 and fill in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:



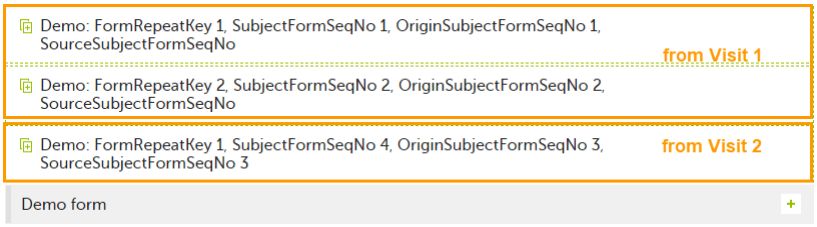
2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:



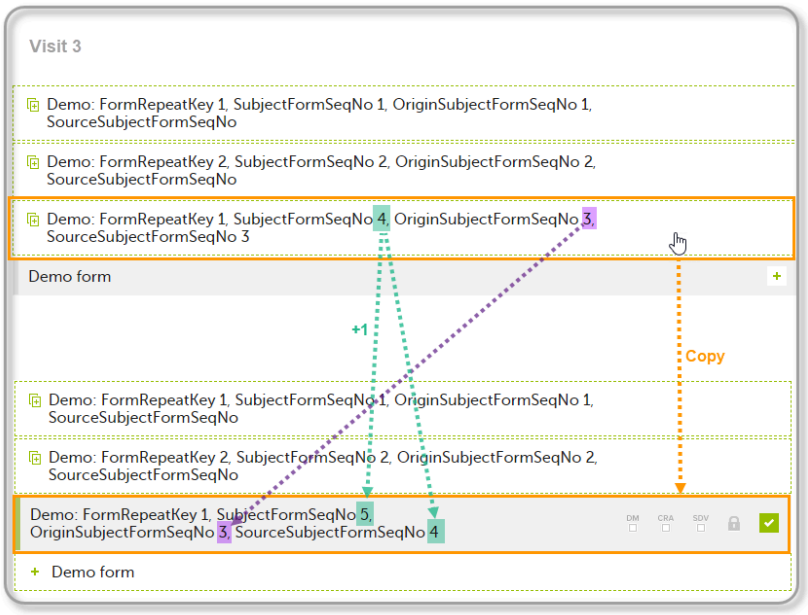
3 Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



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 2025-04-24

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.

Notes!

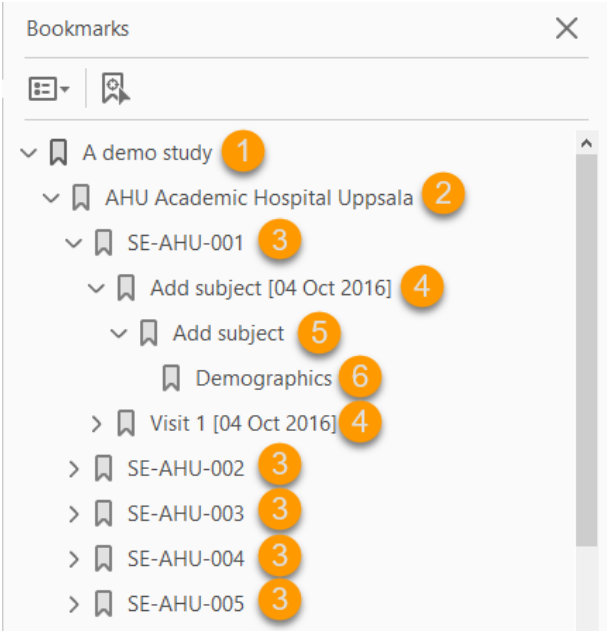
- For *non-production* data, the number of subjects in the PDF archive are limited to improve performance. The most recently added subjects are included according to the date the subject card was created. An information message is displayed: **For this mode the PDF Archive is limited to a sample of [X] subjects.**
- Visit date form history will not be included in the PDF export if no forms were filled in, or if forms were initiated from Viedoc Me.
- 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.

2 Output file(s)

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

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.

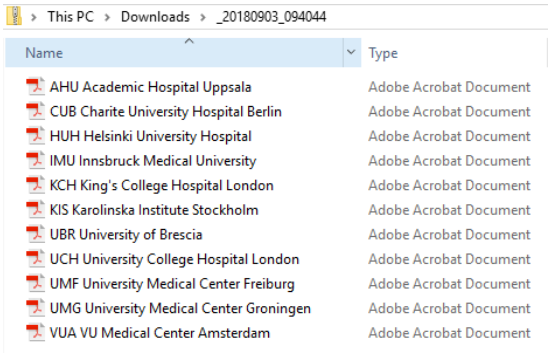
5. For each event, one sub-section for each activity.

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.

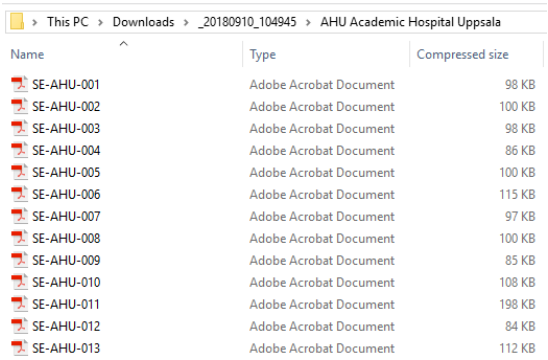
The meaning of the signature in Viedoc is included on the last page.

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.

- 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.

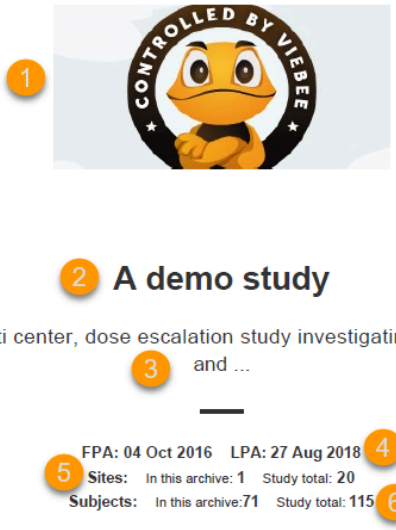


- For the **FDA submission format (eCTD)**, there is one folder for each site, and each folder contains one separate PDF file for each subject (file name is the same as the subject ID):



3.1 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:

5. The number of **sites**:

6. The number of **subjects**:

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.

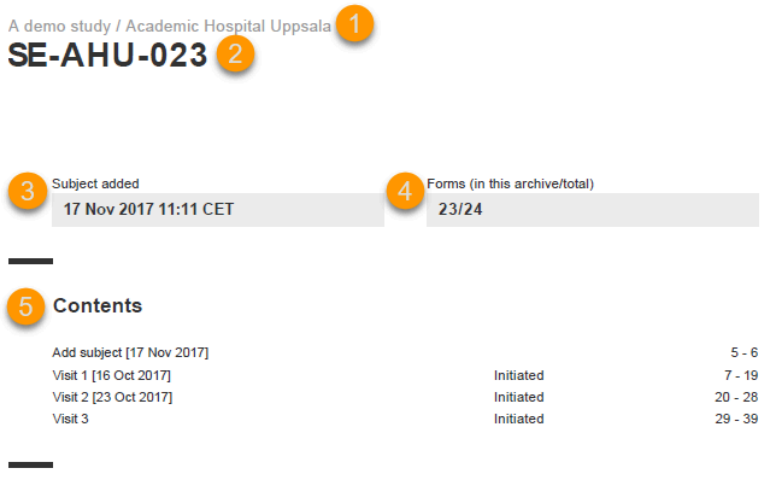
7. Date of Last Patient Added (LPA) to the site, in the site timezone.

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:

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

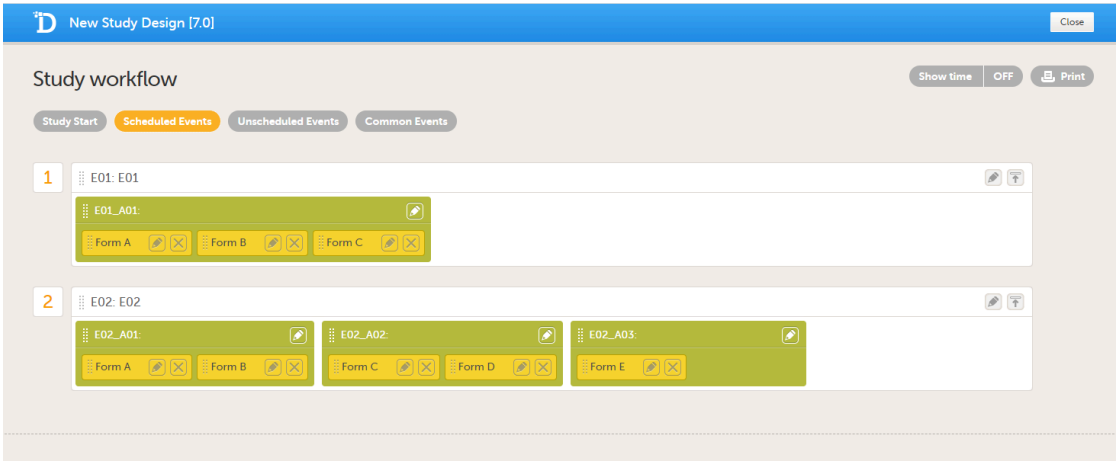
For each form, the form PDF is included, in the same format as for the form history pdf file. For details, see **Form history PDF** in Entering/editing data.

3.4.1 The sort order of the forms

The forms in the PDF are sorted by these characteristics:

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:

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:

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

- First Patient Added (FPA) in the study
- Last Patient Added (LPA) in the study
- In this archive - the number of sites selected to be included in the export.
- Study total - the total number of sites in the study.
- In this archive - the number of subjects selected to be included in the export.
- Study total - the total number of subjects in the study.
- 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.

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

- Form A
- Form B
- Form C

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

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

Archiving a study

Archiving a study

Published by Viedoc System 2021-11-24

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

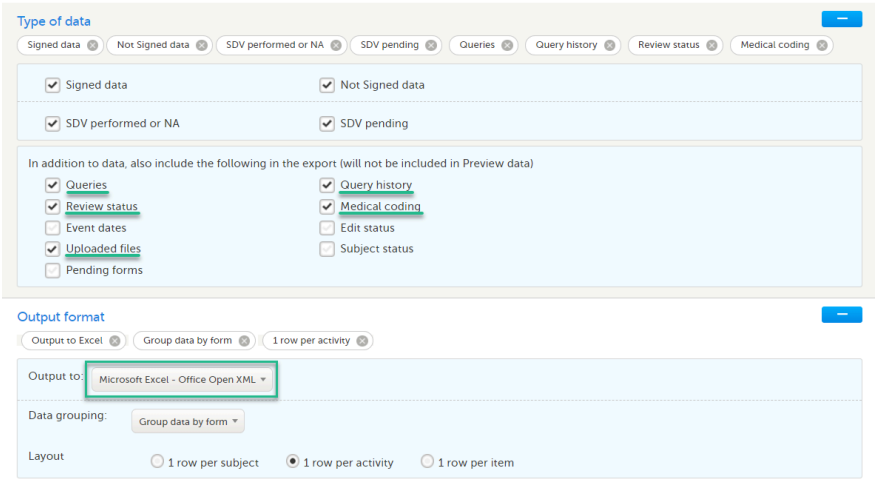
Site users must have the role permission to export data for the sites where the archiving should be performed. For more information, see the *Data export* lessons in Viedoc Clinic User Guide.

If Viedoc eTMF is used, see the following lesson eTMF-EMS repository.

2 Archiving the study

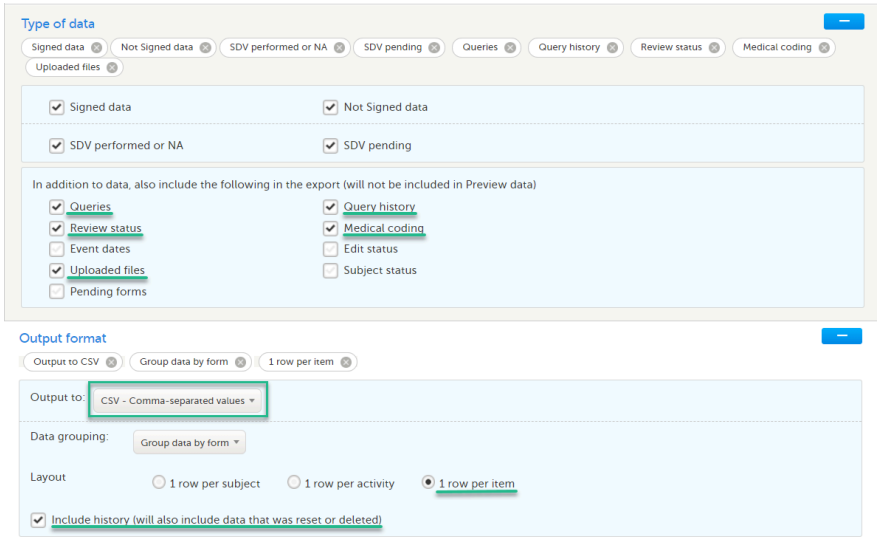
The following documentation is recommended to export when archiving a study at site. Export of data is still possible for locked studies.

- 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

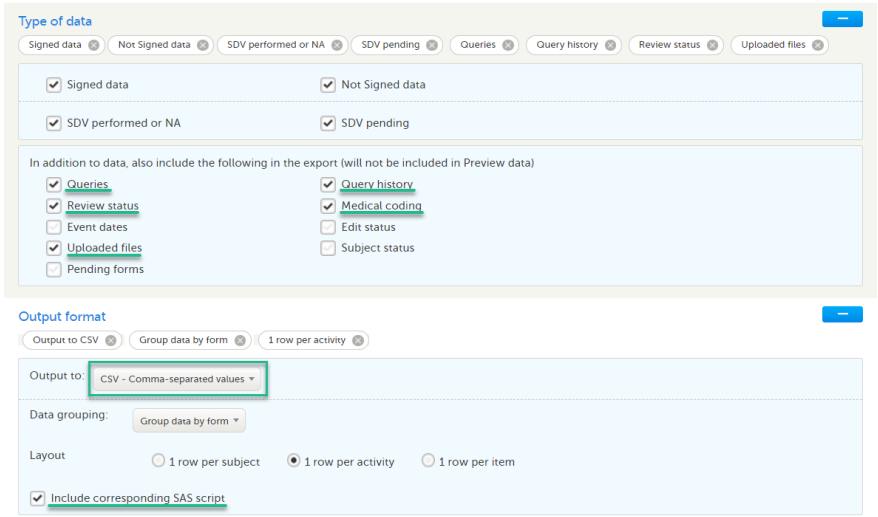


  - CSV
    - 1 row per item
    - Include history (will also include data that was reset or deleted)

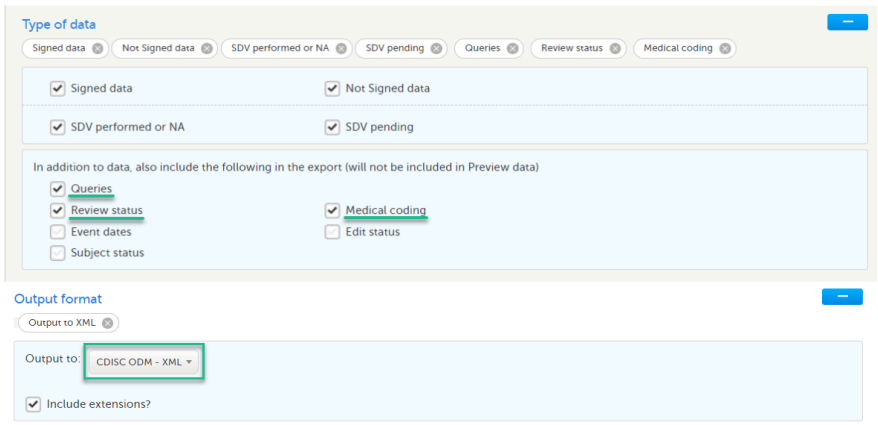
- Queries, Query history, Review status, Medical coding, Uploaded files



- CSV
  - Include corresponding SAS script
  - Queries, Query history, Review status, Medical coding, Uploaded files

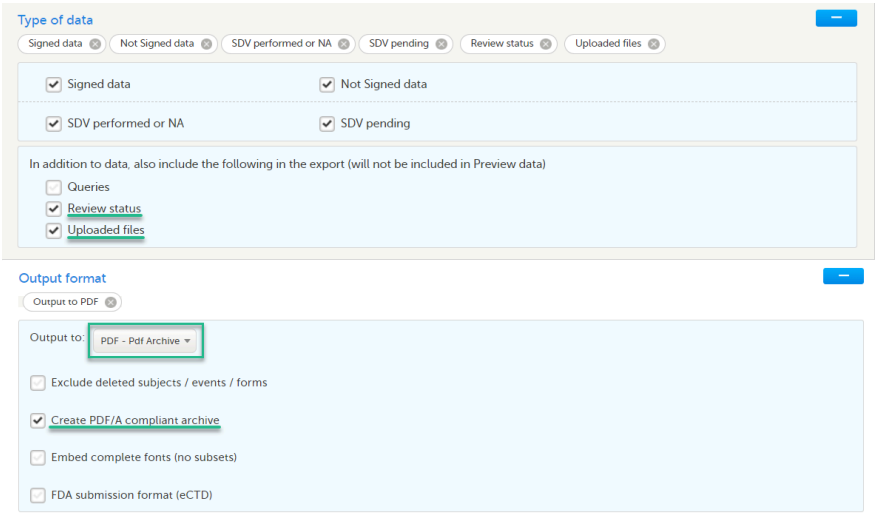


- ODM
  - Queries, Medical coding, Review status



- 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.

Managing Viedoc Me

Managing Viedoc Me

Published by Viedoc System 2025-09-24

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).

To access the platform:

- The device must have an active internet connection.
- If the subject chooses to receive text message reminders, the device must also be able to receive text messages.

Please make sure patients are aware of these requirements before they start using Viedoc Me. You can share the following information with them as needed: Using Viedoc Me - (information for study participants)

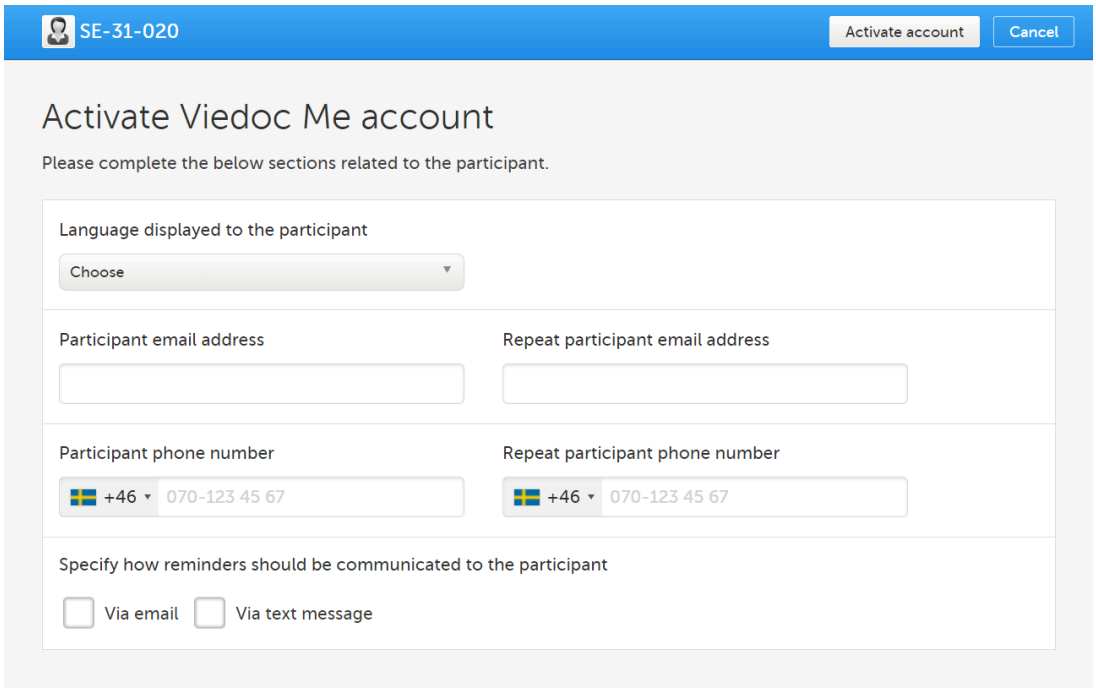
Note! Only user roles with editing permissions for the study start event form can activate a Viedoc Me account. If you do not have editing permissions, the phone icon (as seen in the image below) will not be visible on the **Details** page.

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.

Note! The languages Cebuano (ceb), Hiligaynon (hil), and Tagalog (tl) are available in when inviting subjects to Viedoc Me in Viedoc Clinic when added as additional languages in Viedoc Designer. These languages are currently displayed as: Unknown language (tl), Unknown language (ceb) Unknown language (hil).

3 **Participant email address** and **Participant phone number**

Enter the subject's email address 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 information) 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**

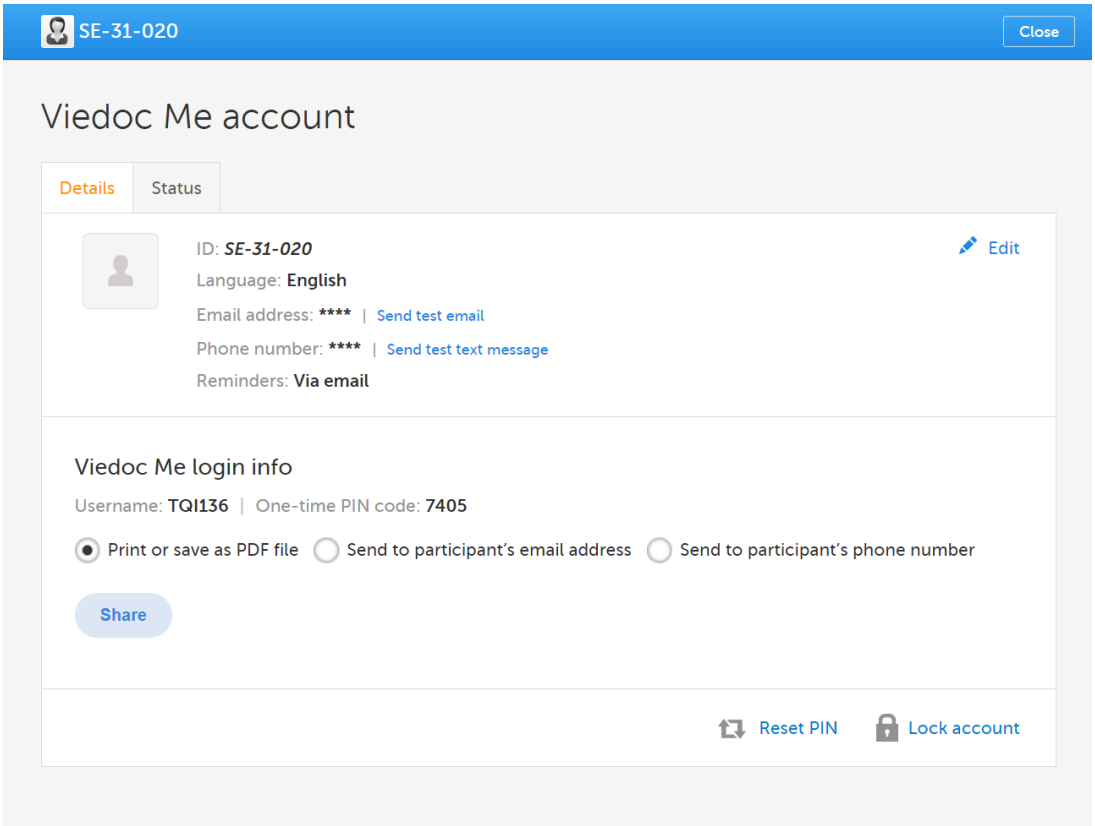
Select whether to send reminders via email and/or via text message.

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 information:



The Viedoc Me Account activation process is now complete.

To share the login information with the subject, please continue with the steps below.

Note! You may only activate one subject's Viedoc Me account at a time.

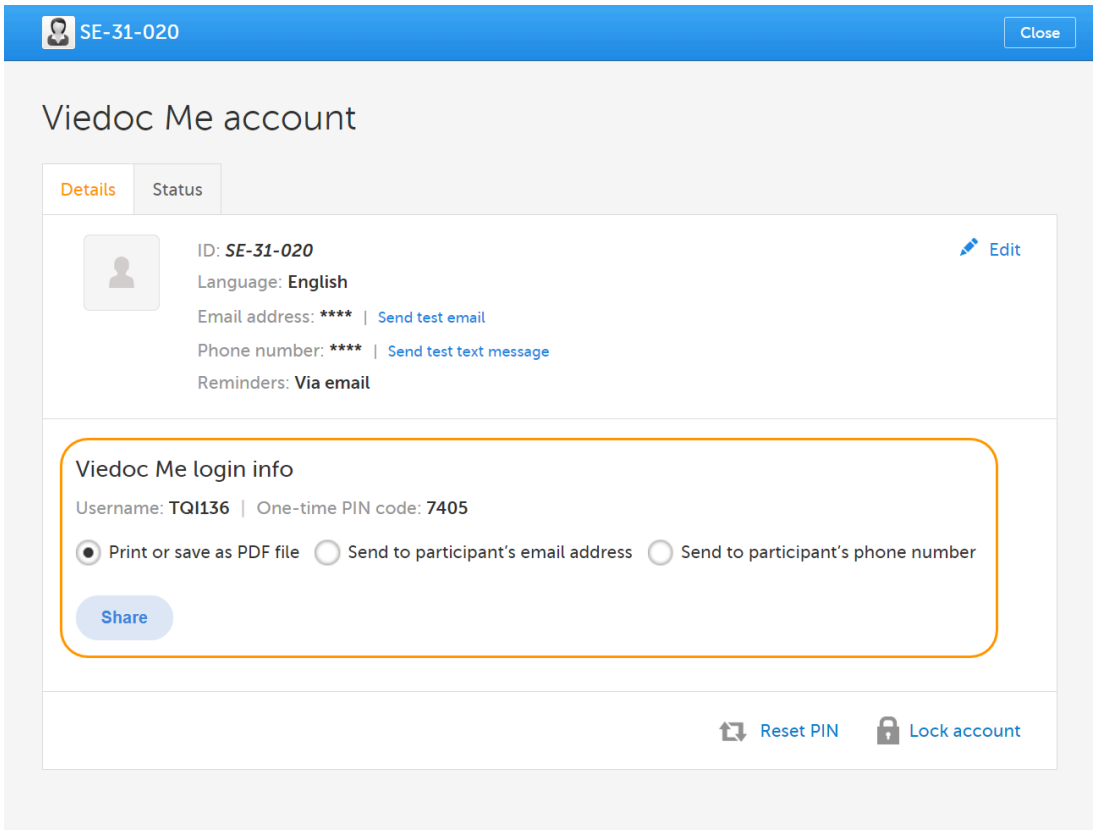
2.1 Sharing Viedoc Me account login information with the subject

After the Viedoc Me account has been activated, there are several options to share the login information with the subject. This may be done at any time and repeated as often as needed.

To share login information 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 information. 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 information via email.
- Select **Send to participant's phone number** to send the Viedoc Me login information via text message.

Note!

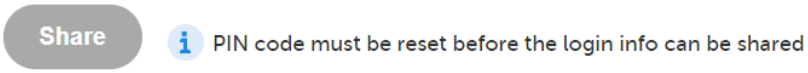
- If the functionality to "share Viedoc Me access details" (login information) via email and/or text message has not been enabled in the study settings, then only the option to Print or Save as PDF file will be visible here. Please contact your study manager to have this option enabled.
- The PDF file with the access details 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.

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 information will be downloaded in your browser.
- If **Send to participant's email address** was selected, an email with the Viedoc Me login information will be sent to the subject.
- If **Send to participant's phone number** was selected, a text message with the Viedoc Me login information will be sent to the subject.

Note! After sharing the login information, if you wish to share again with the subject you will receive a message next to the share button stating that the PIN code must be reset before sharing the login information again:



Follow instructions on Resetting the PIN code below.

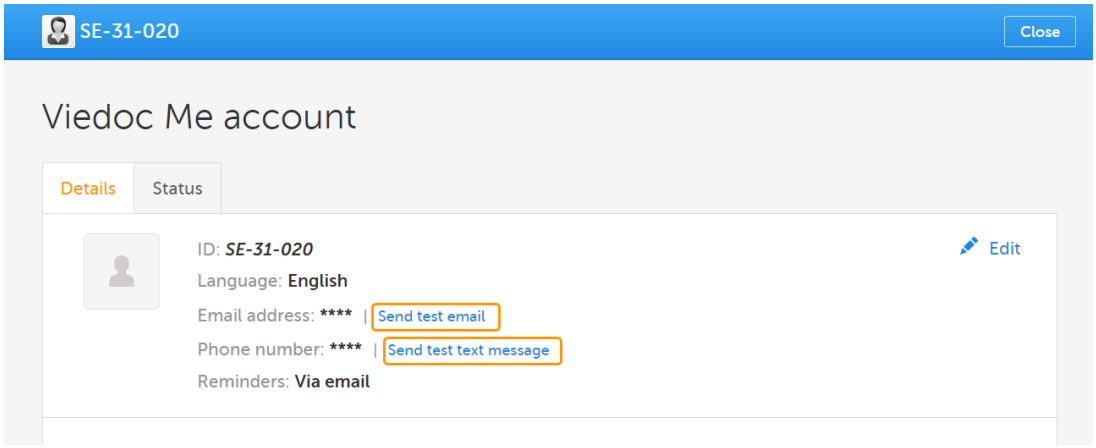
2.2 Verifying the subject's contact information

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 information) 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:

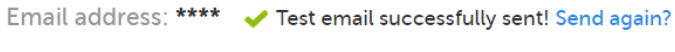
1 In the subject's details page, select the phone icon to open the **Viedoc Me Account window**. Select **Send test email** and/ **Send test text message**.



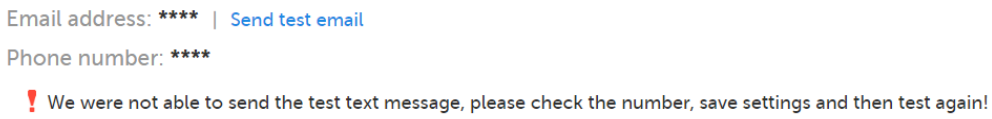
Note! The Send Test links are available only after the email address and/or the phone number was entered and **saved**. All changes done in the Viedoc Me account window must be saved in order for the test links to be available.

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:



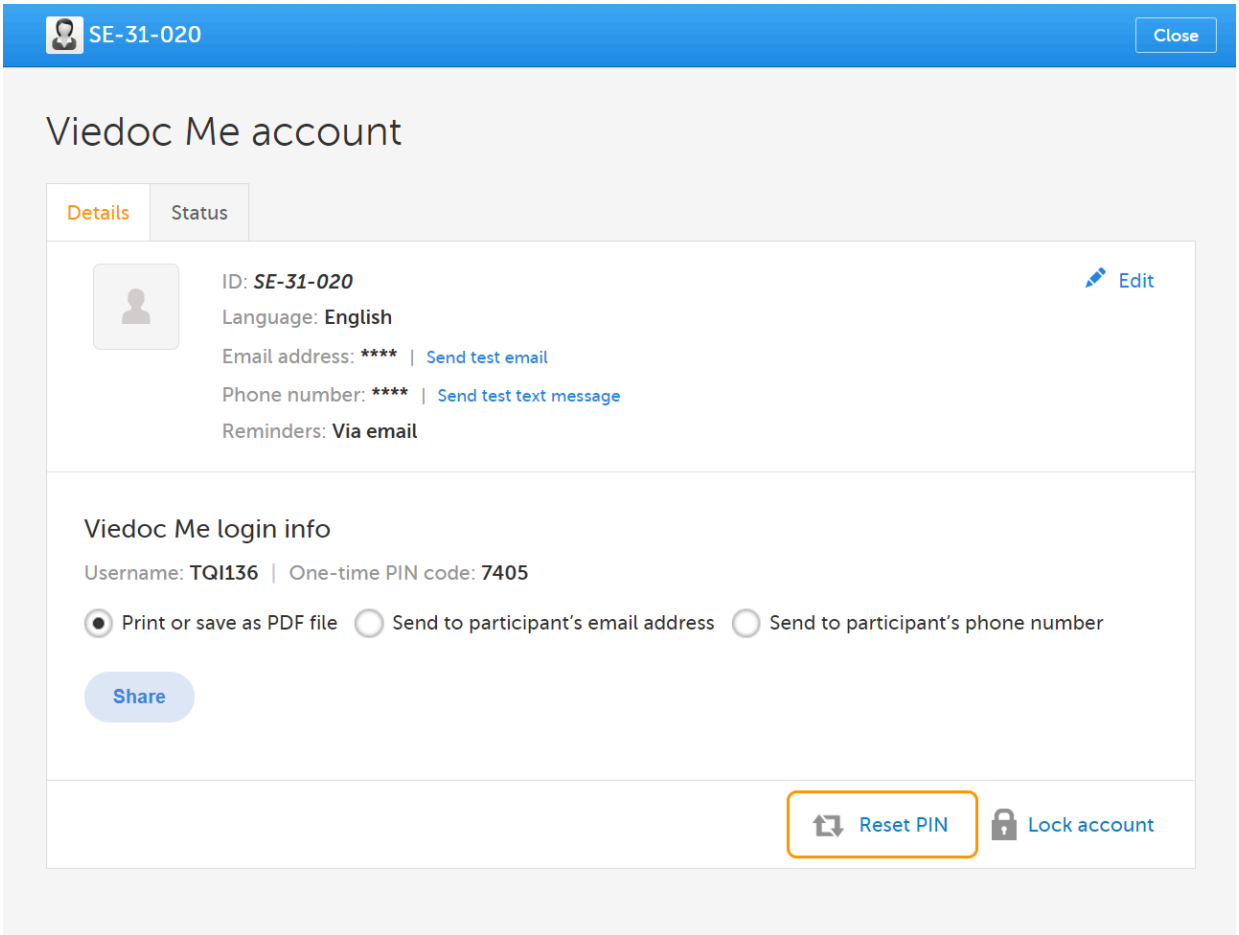
In this case you might want to enter the email address/phone number again by selecting **edit**, save the changes, and try to send the test message again.

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 address/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 code can be reset at any time by selecting **Reset PIN**:



After the PIN code 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 code 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.

---

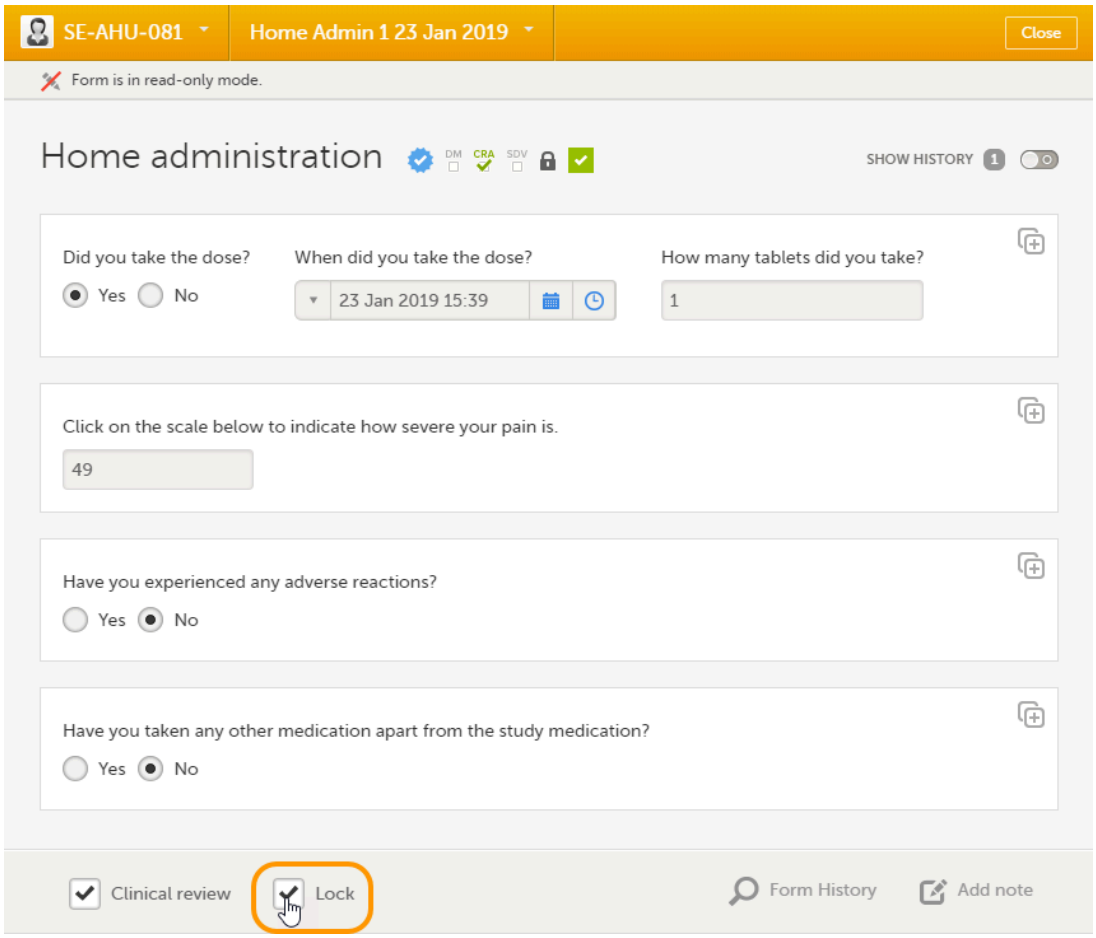
3 Editing form data in Viedoc Me (ePRO data)

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

There might be a 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 form.

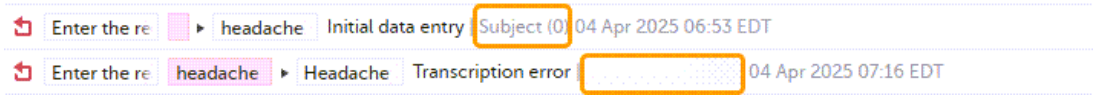
To edit a form in Viedoc Me:

1 A user with lock data permission (typically a Monitor) unlocks the form by clearing the **Lock** checkbox at the bottom of the form.



2 A user with edit data permission (for example, an Investigator) edits the form data according to these instructions: Editing data.

3 To see the audit trail of the edit, select **Show history** at the top-right corner of the form.

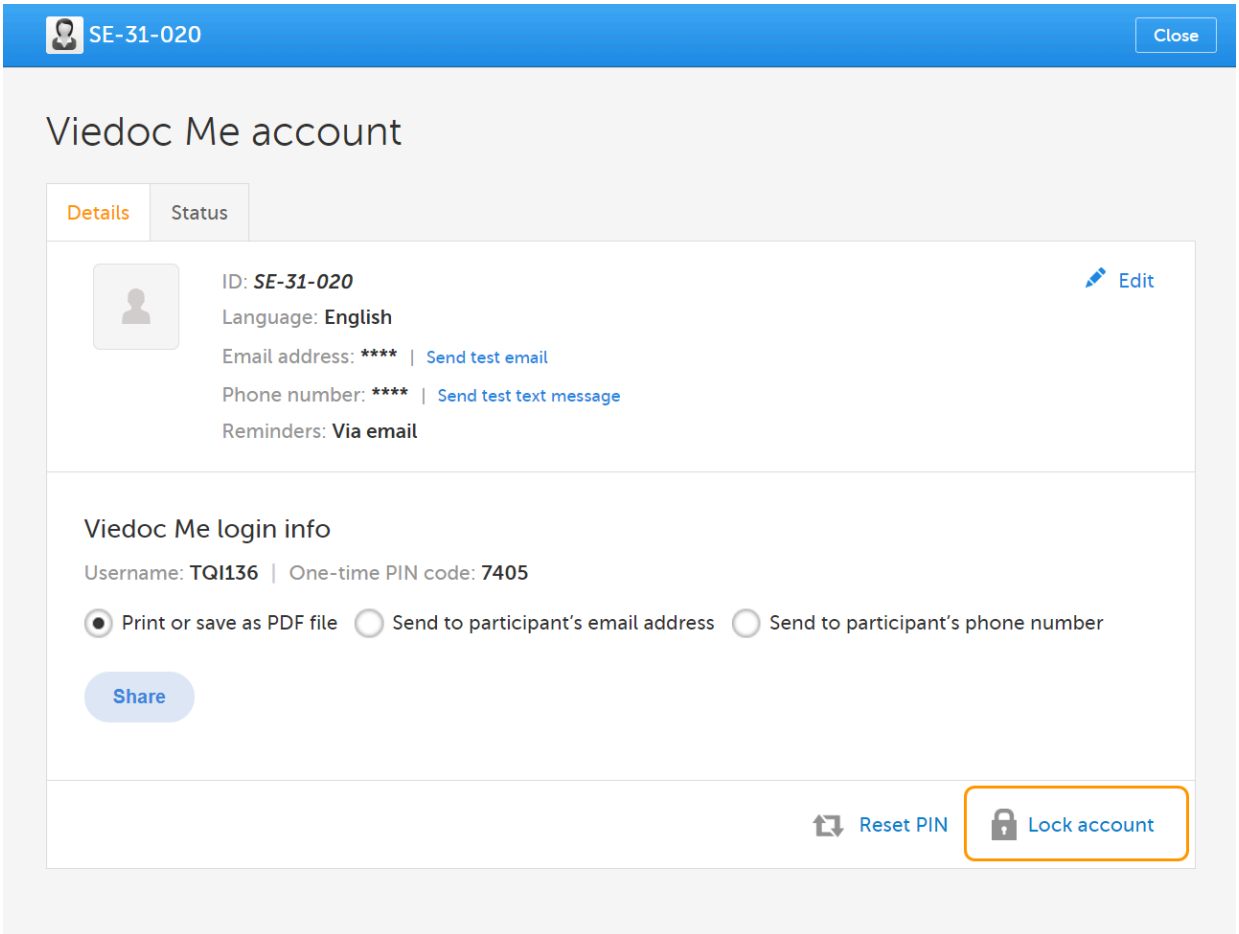


The subject who made the initial data entry is called Subject (0) in the audit trail. For the data edit, the user name is displayed (blurred in the image above for information security reasons).

4 A user with lock data permission locks the form for editing.

4 Locking and unlocking the Viedoc Me account

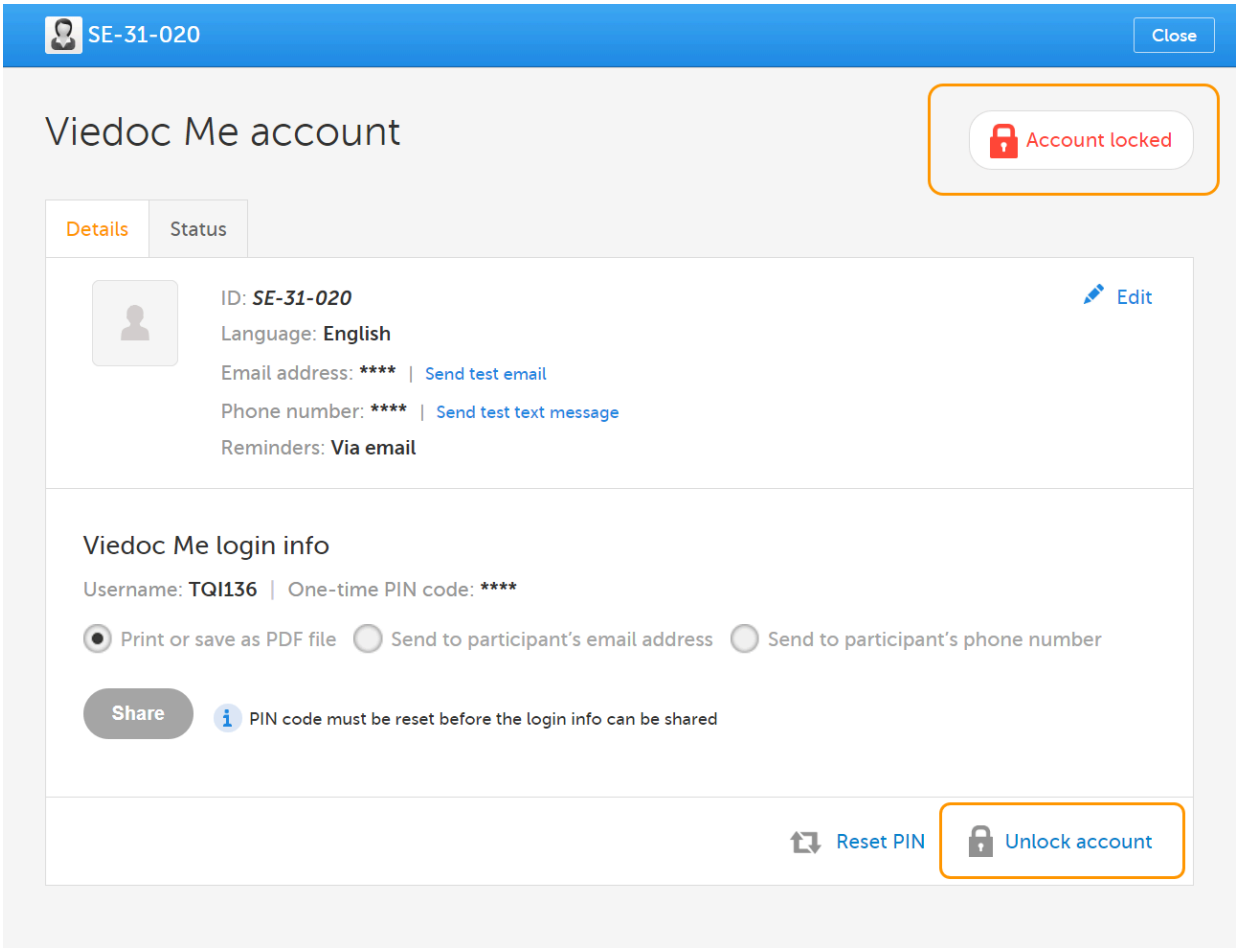
The Viedoc Me account can be locked/unlocked by selecting the **Lock/Unlock account** link in the Viedoc Me account details window:



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.

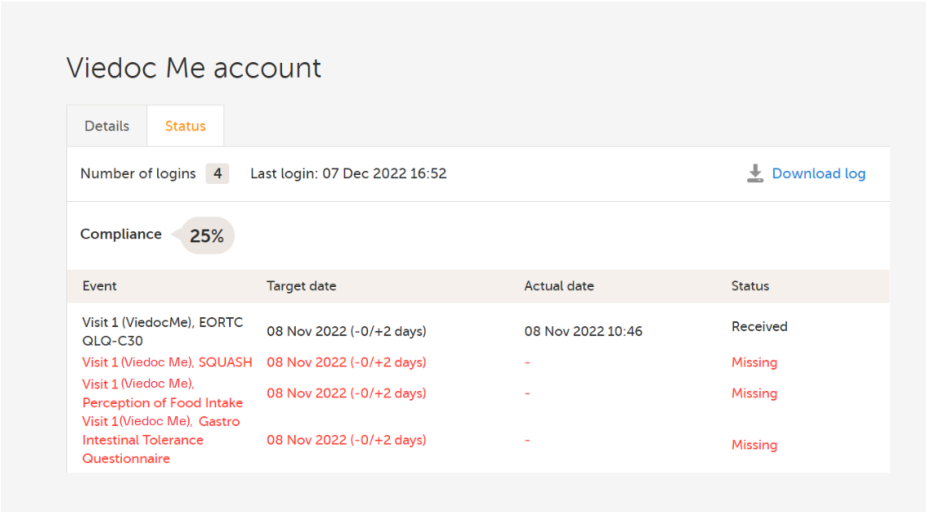
When the account is locked (either manually or automatically), this is marked by a red **Account locked** icon in the top-right corner of the Viedoc Me account details window. To unlock it, select the **Unlock account** link in the bottom-right corner:



5 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:



5.1 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)*

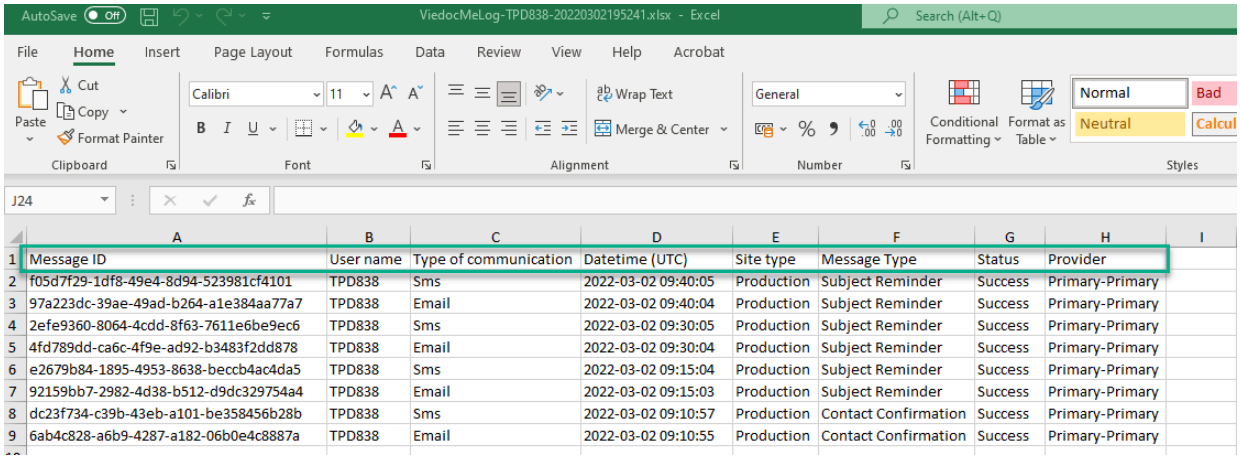
**Date and time of the site*

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:

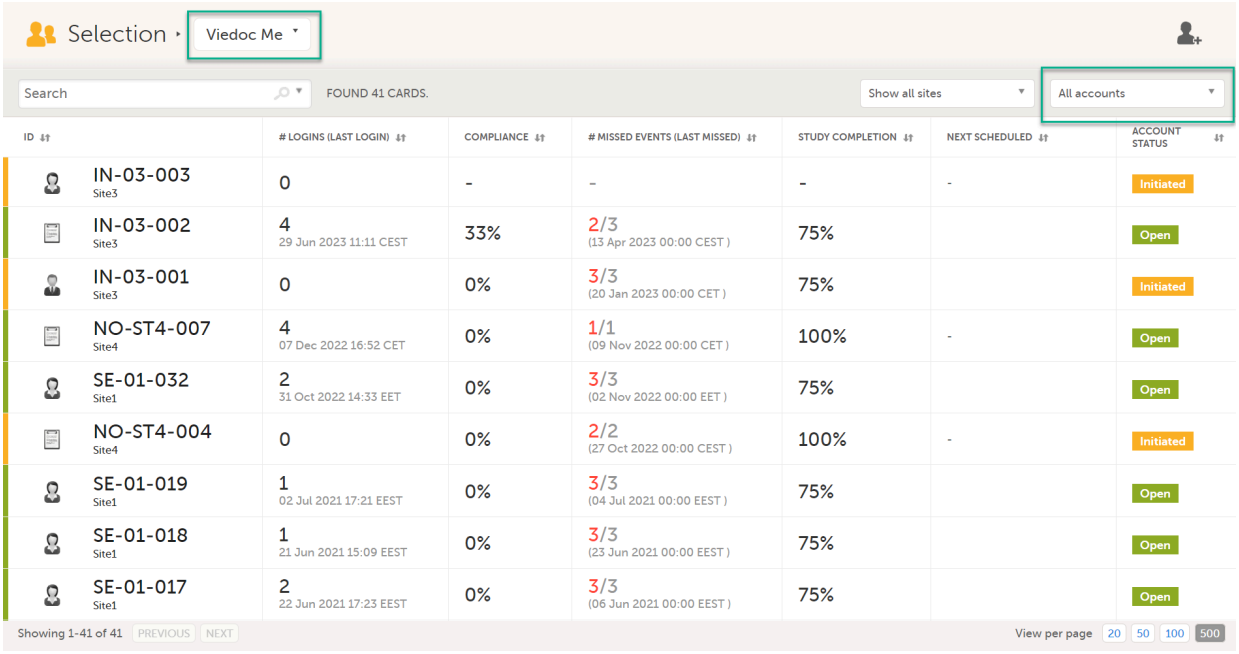
- *Message ID - GUID*
- *User name - (as in Viedoc Me account)*
- *Type of communication - SMS/Email*
- *Datetime (UTC) - datetime for when the communication happened*
- *Site type - Training/Production*
- *Message Type - (Subject Reminder/Contact Confirmation)*
- *Status - Success/Failed*
  Note! **Success** 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	

5.2 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.

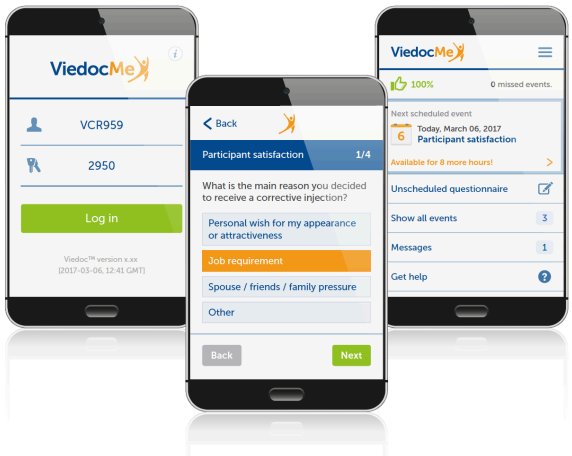
Using Viedoc Me (information for study participants) - version 4.70 and earlier

Using Viedoc Me (information for study participants) version 4.70 and earlier

Published by Viedoc System 2024-06-26

1 Introduction to Viedoc Me

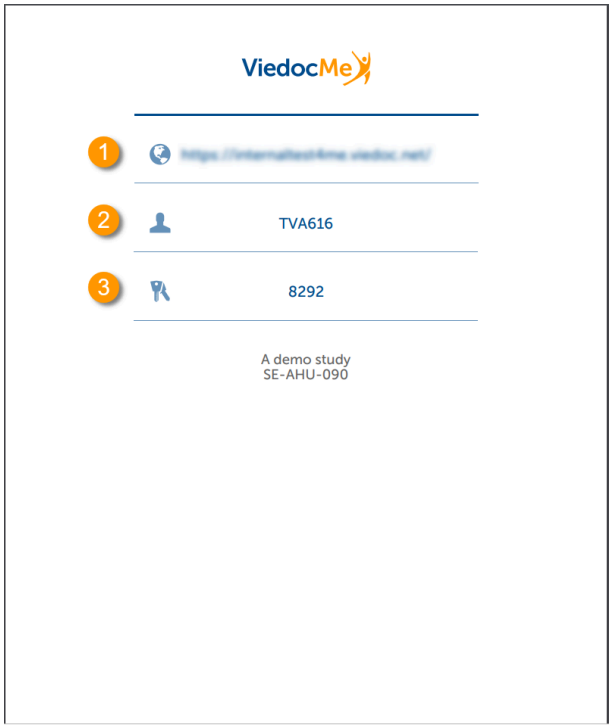
Viedoc Me is a web application used for collecting data from patients participating in clinical trials. It works on any device: a computer, tablet, or mobile phone, as long as the device has a browser and access to the Internet. The application enables you to fill in questionnaires and submit them.



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.

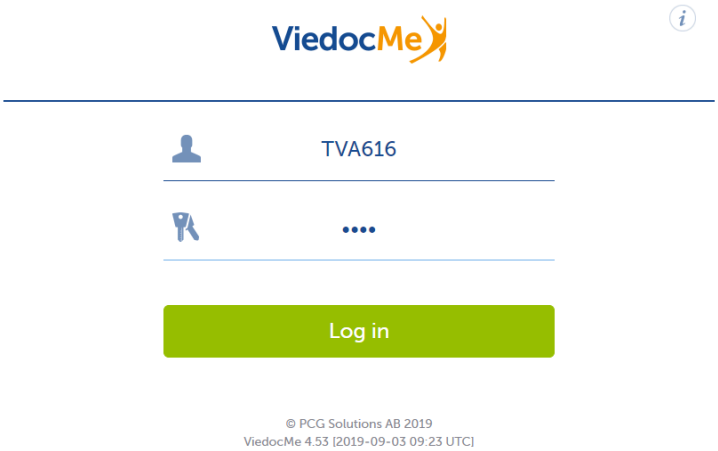
Note! When you enter the URL (web address) from the login information PDF in a browser, you are redirected to a URL that looks slightly different and that contains the string "idp". This is the expected behavior.

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.

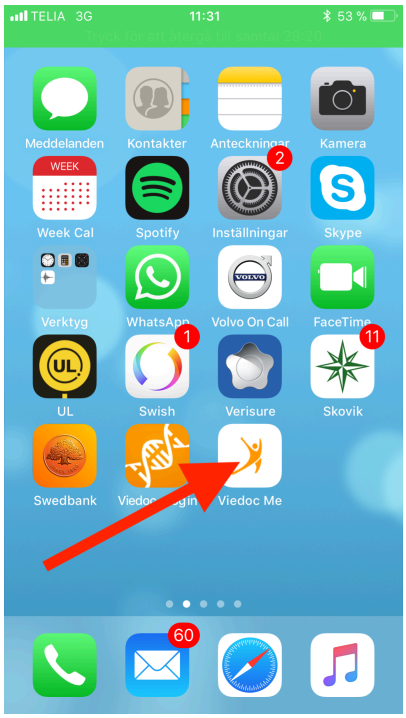
4 Select **Log in**.

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.

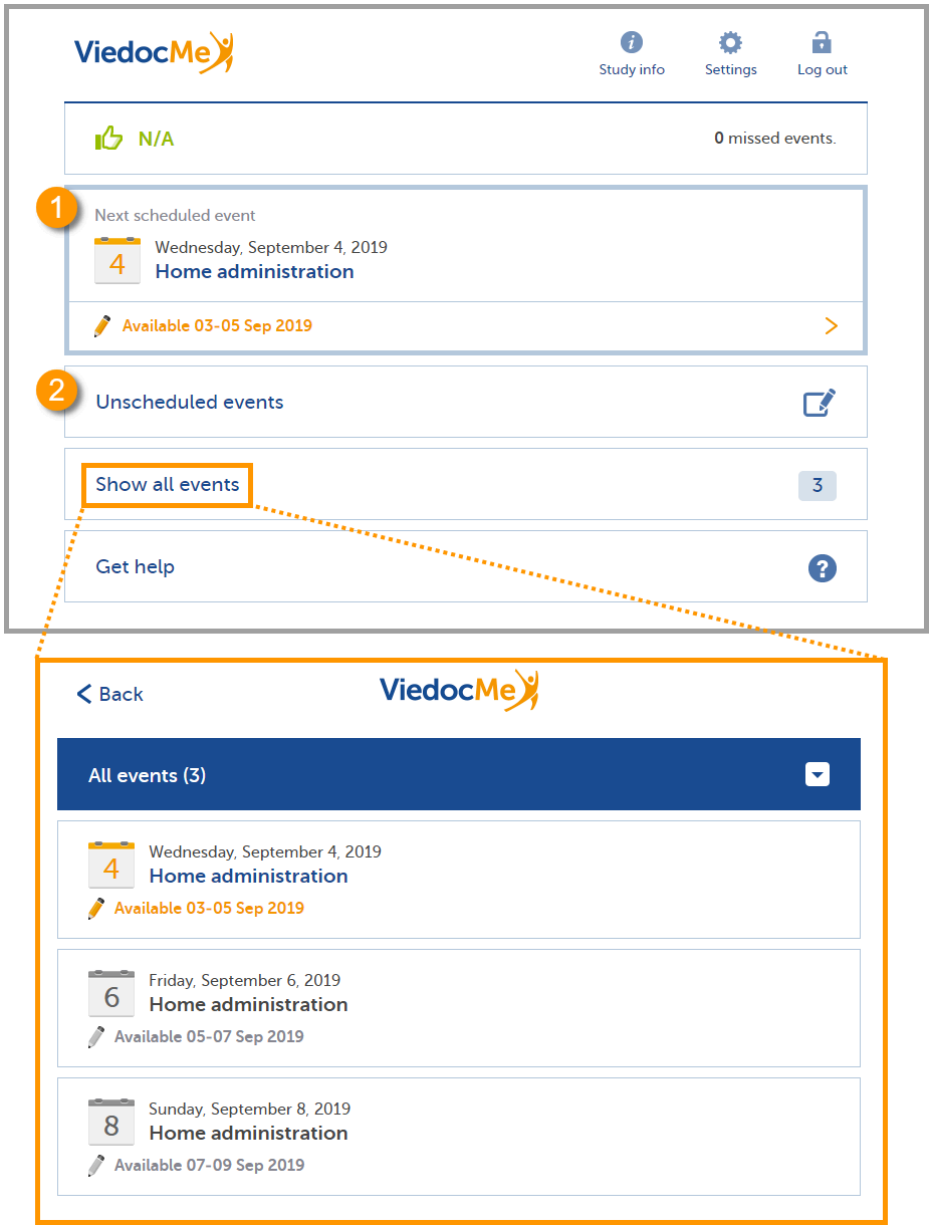
The Viedoc Me application is now available as an app on the phone.

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.



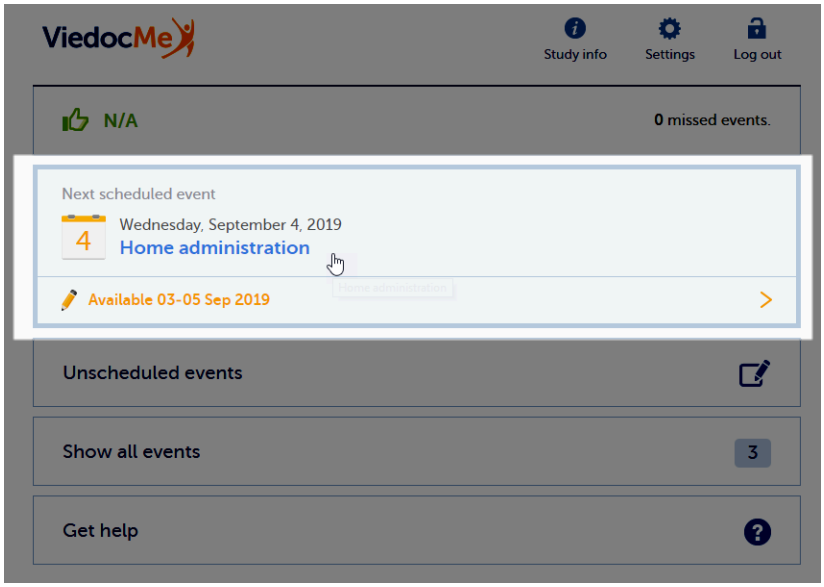
Note! The names of the questionnaires differ depending on the study. The above image is just an example!

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.

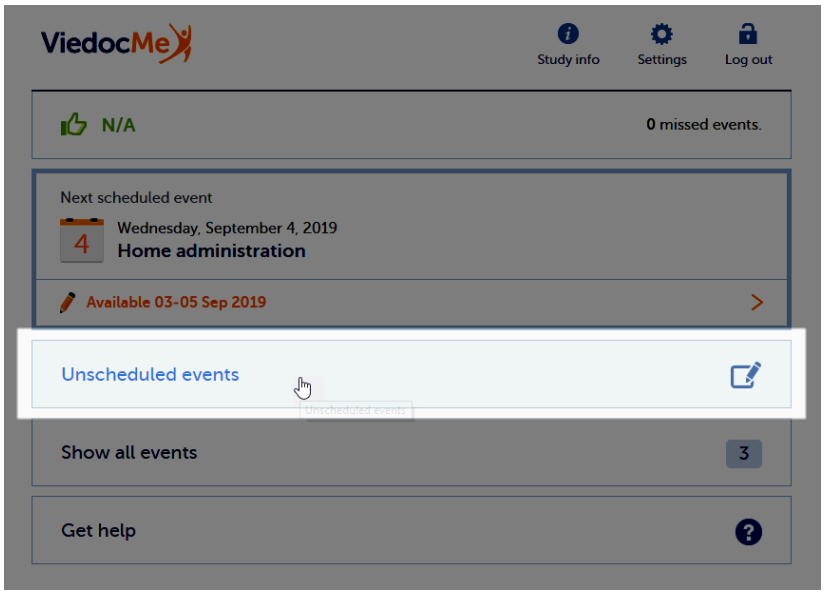
4 Select **Go to startpage** to return to the Viedoc Me start page.

3.2 Filling in a questionnaire of an unscheduled event

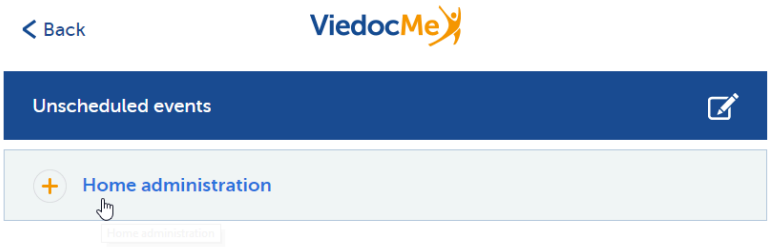
If the study allows, you might be able to spontaneously report data at any time.

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).

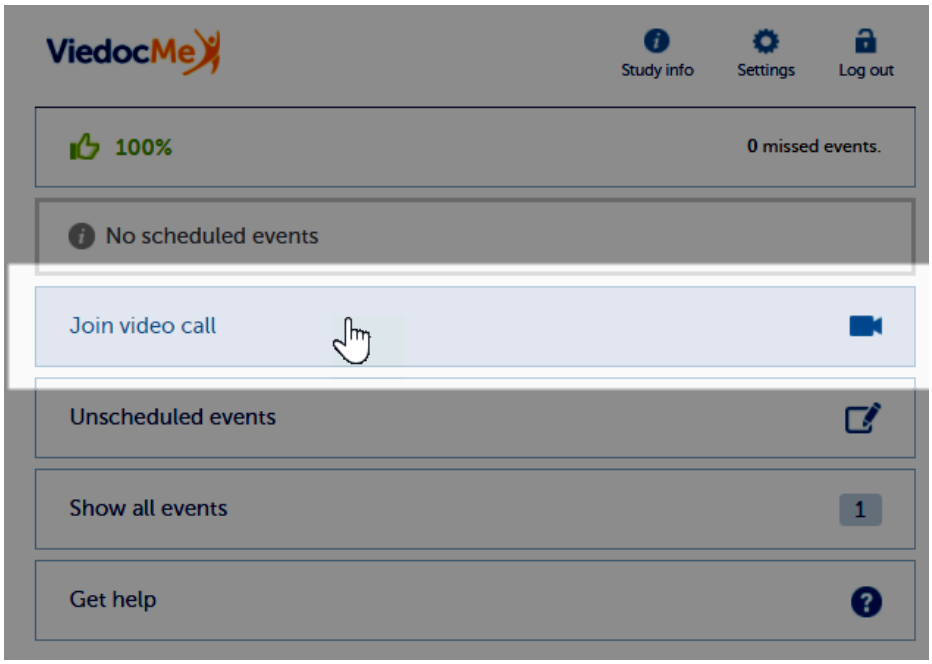
4 When you have answered the last question, select **Send** to submit the data.
The date and time of submission will be saved together with the data.

5 Select **Go to startpage** to return to the Viedoc Me start page.

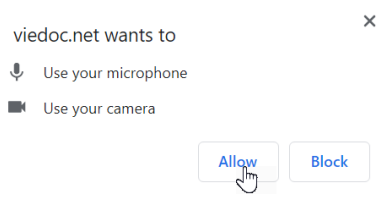
4 Video calls

The Viedoc Connect application allows the clinic staff to initiate a video call with you.

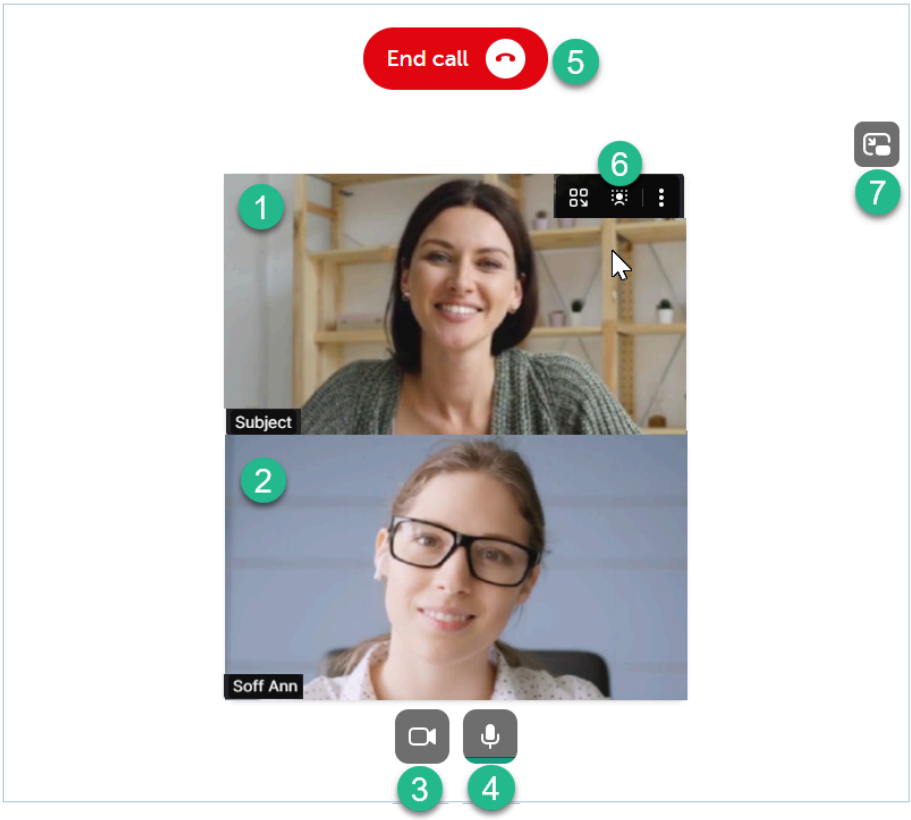
When your doctor has initiated a call, the video call module in Viedoc Me flashes in blue with the text **Join video call**. Select anywhere on the module to join the call.



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

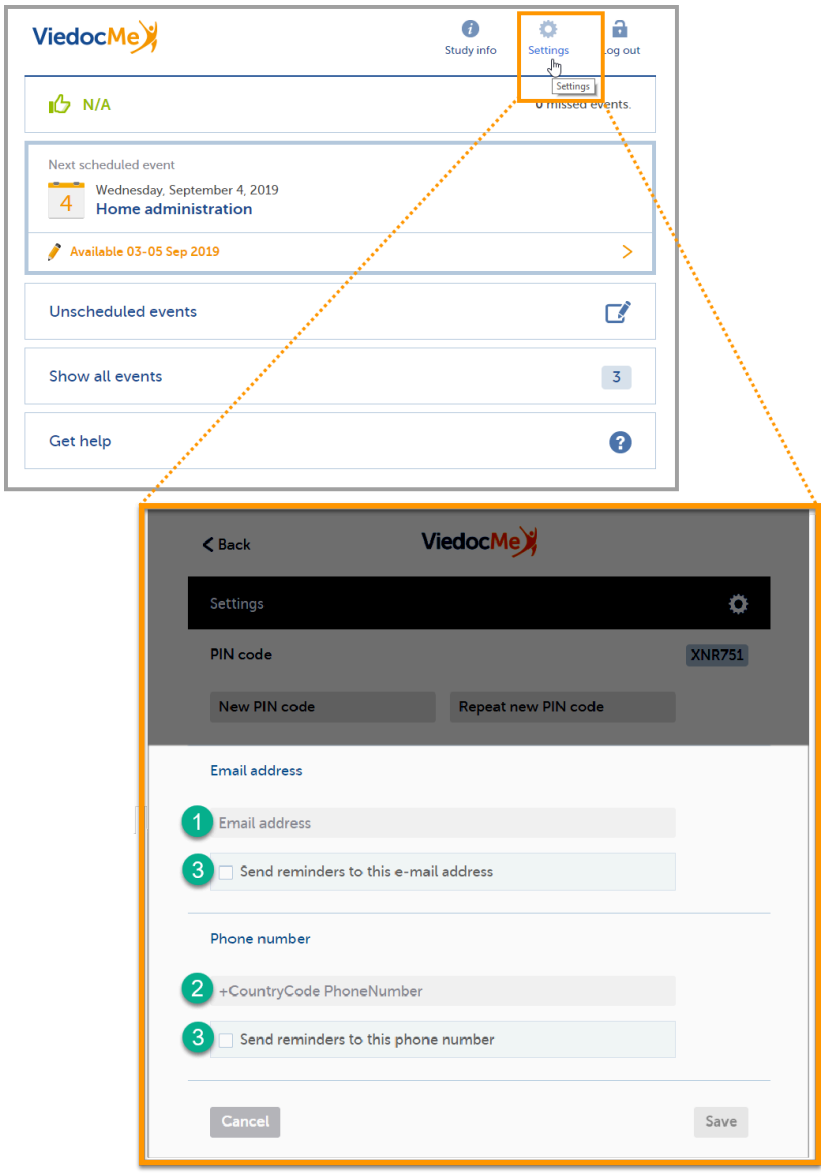
The Viedoc Me application can send reminders to remind you of upcoming scheduled events. These reminders are configured by the study staff at the clinic and can be sent as an email and/or a text message (sms). Note that you cannot reply to emails sent from Viedoc.

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.

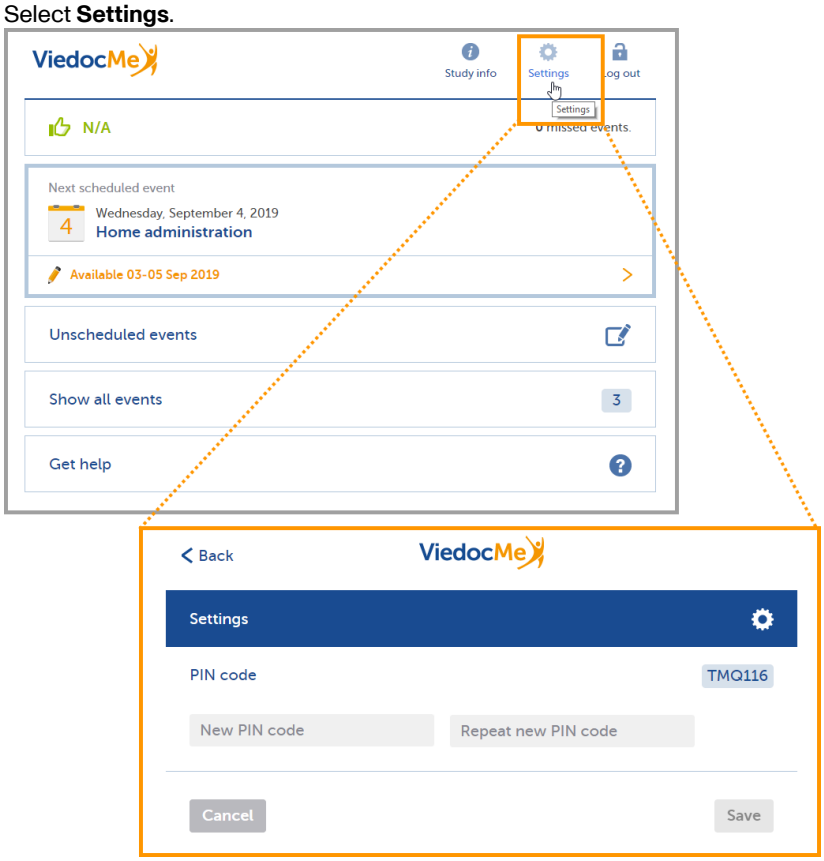
3 Select **Save** to save the changes.

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.

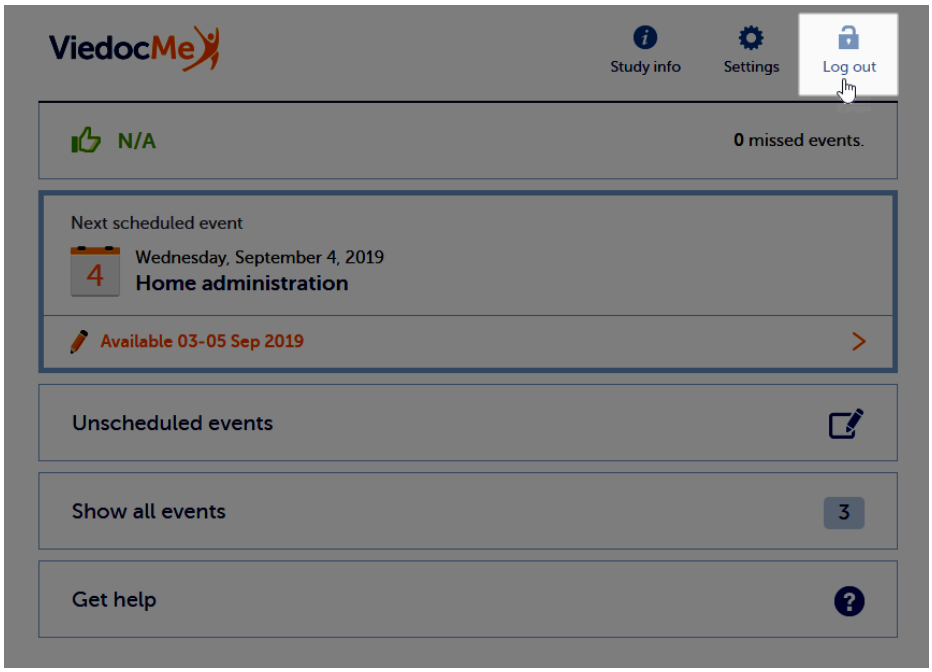
5.3 Help

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)

Using Viedoc Me (information for study participants)

Published by Viedoc System 2025-06-10

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.

In Viedoc Me you can 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).

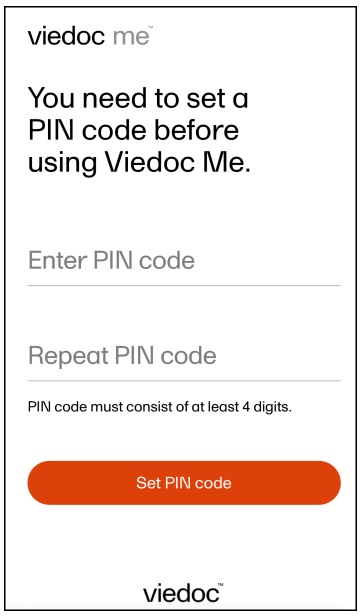
If your clinic contact shared your Viedoc Me login info via a **document**, you will receive either a paper document or a digital PDF file that contains the URL (web address) to Viedoc Me, a QR code that can be scanned by your mobile device for easy access to the URL, your user name, and your PIN code.

- 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

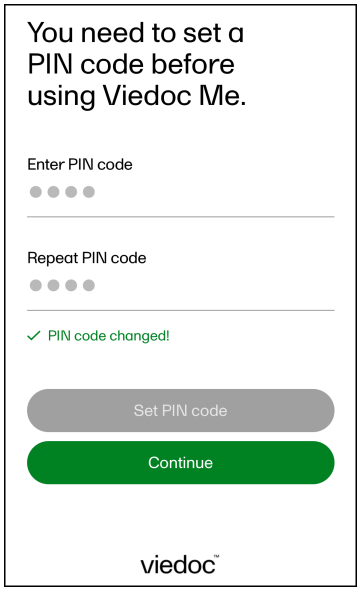
Note! When you enter the URL (web address) from the login information PDF in a browser, you are redirected to a URL that looks slightly different and that contains the string "idp". This is the expected behavior.

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**.

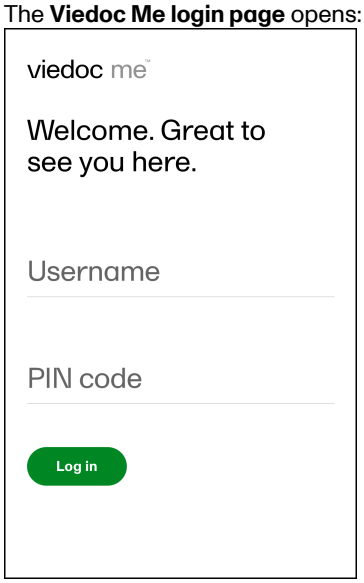
Your account is now activated! Please see Viedoc Me Start Screen below for more information on using the application.

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**.

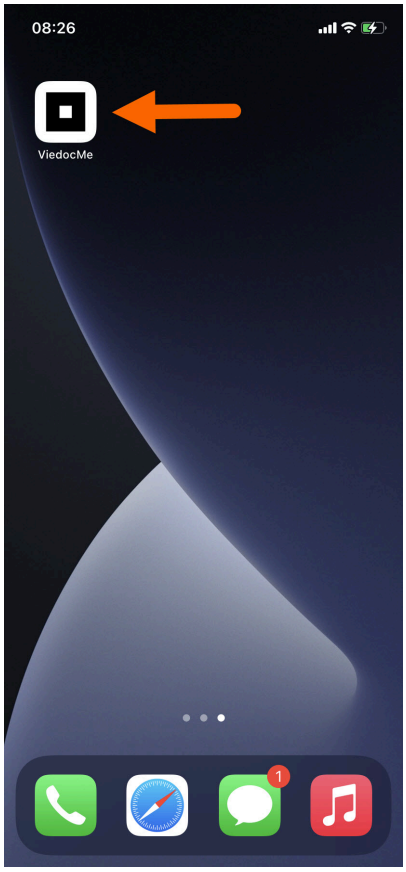
3 Enter your **PIN code**.

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:

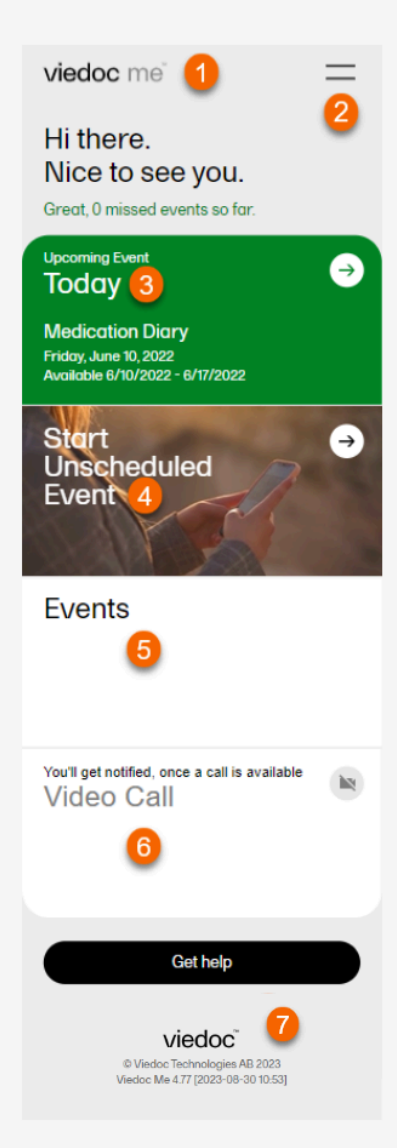
1. Open a web browser on the phone and navigate to the URL that is stated in the document provided to you.
2. Select the option to **Add to Home Screen**

   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.

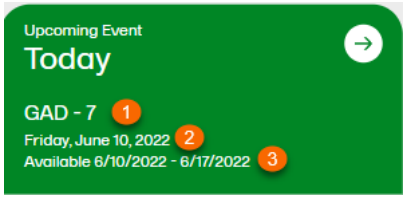
7. **The get help button** - select for information on how to contact clinical staff.

---

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.

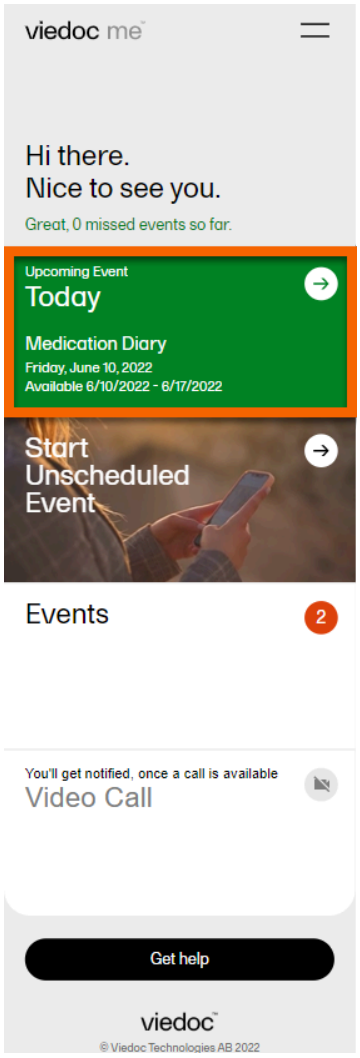
3. The dates of availability for the event.

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.

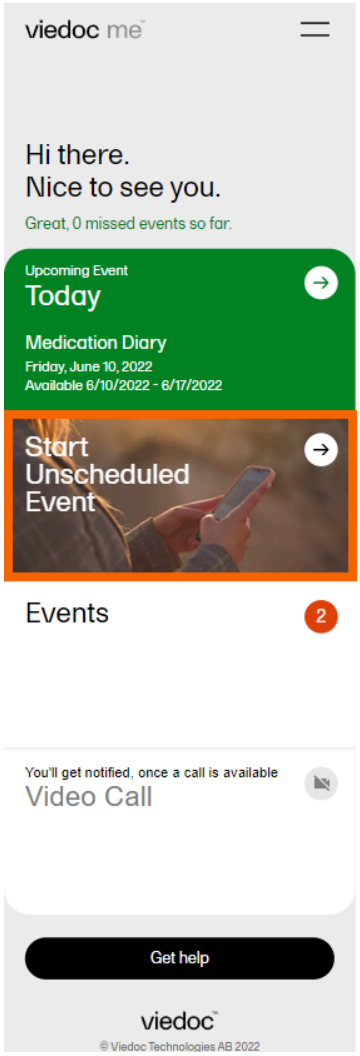
4 Select **Go to startpage** to return to the Viedoc Me home page.

4.3 Filling in an unscheduled event

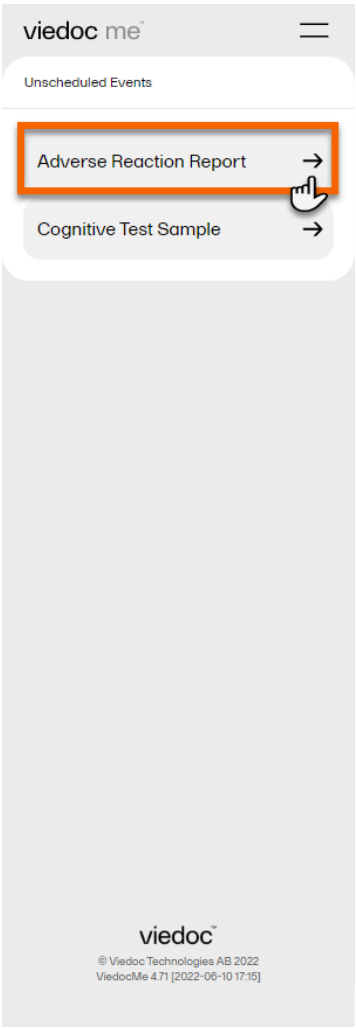
If the study allows for it, you will be able to report data at any time.

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.

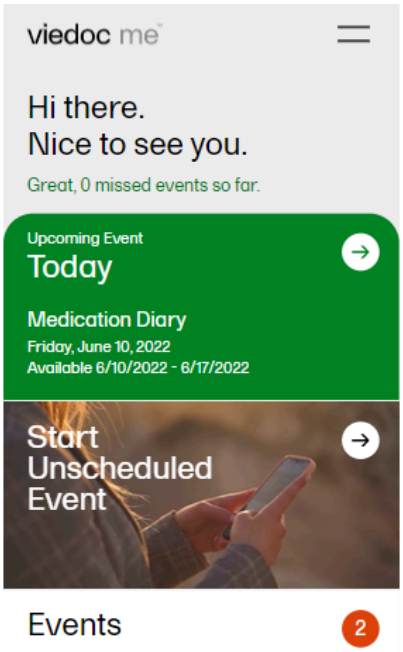
5 Select **Go to startpage** to return to the Viedoc Me home page.

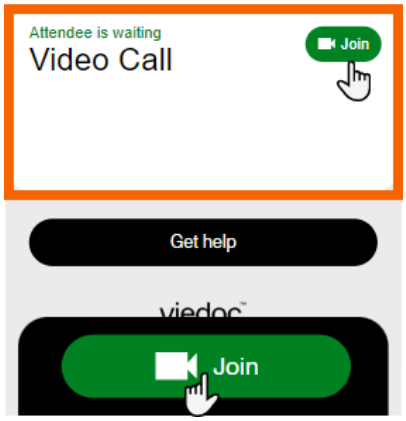
5 Video calls

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.

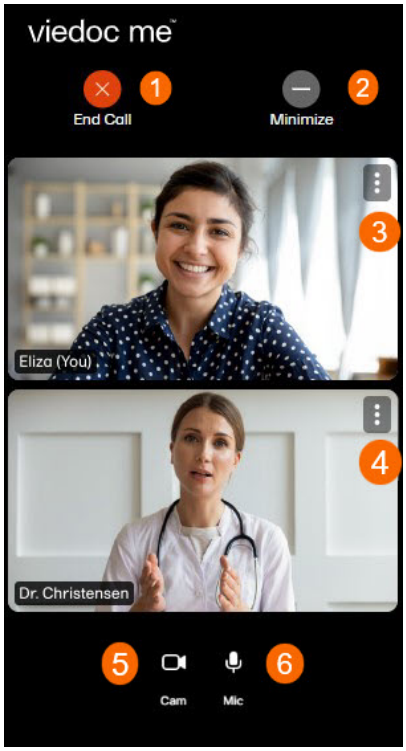




Note! If prompted, please select **Allow** so Viedoc Connect can access your camera and microphone through the browser.

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

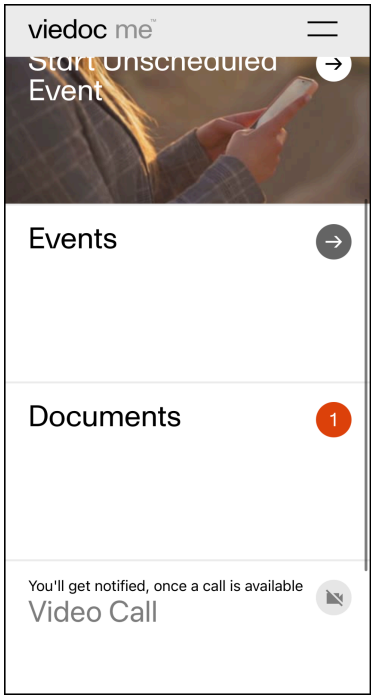
To open a document that has been shared with you:

1 If you received an email or text message with a notification that a document was shared with you, select the **link** in the email or text message to go to your document list in **Viedoc Share** (skip to step 3 below). Depending on the email you received, the link may open the document directly.

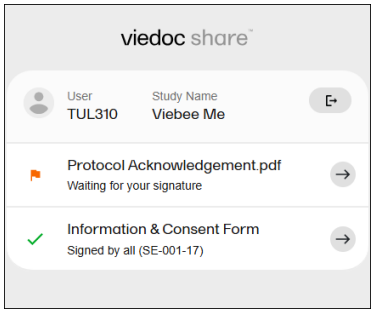
2 If you did not receive an email or text message, you can view shared documents by logging into your Viedoc Me account. If you have a new document a red circle is displayed next to the documents section, indicating how many new documents are available for you to view and/or sign.

Note! 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** is 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.

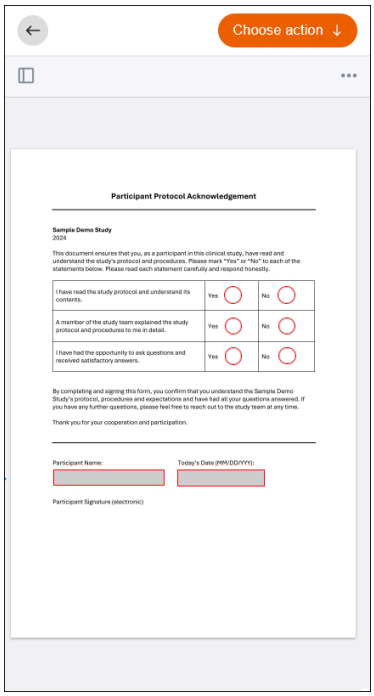
5 Review the contents of the document.

6.2 Filling in document fields

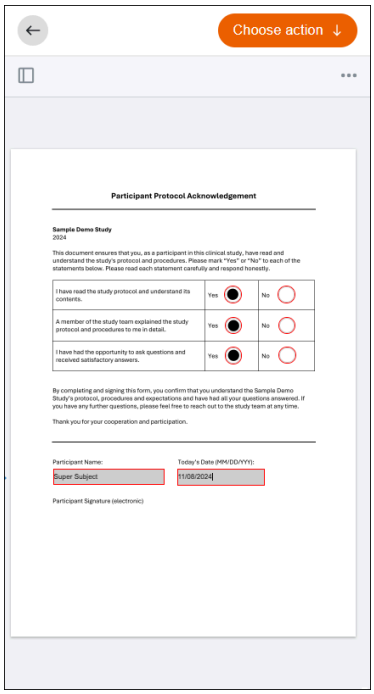
The document may include questions to answer or fields to fill in. If they are required, the fields must be completed before you are able to sign the document.

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).

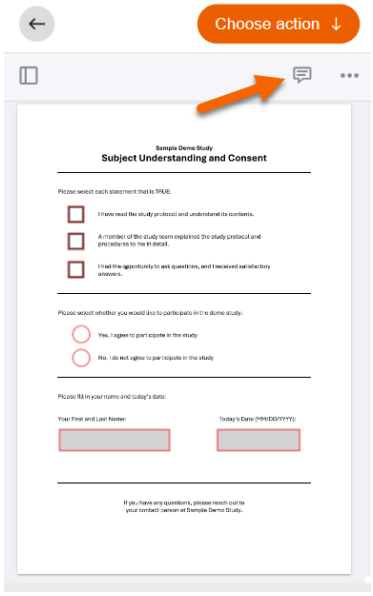
6.3 Using notes in documents

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.

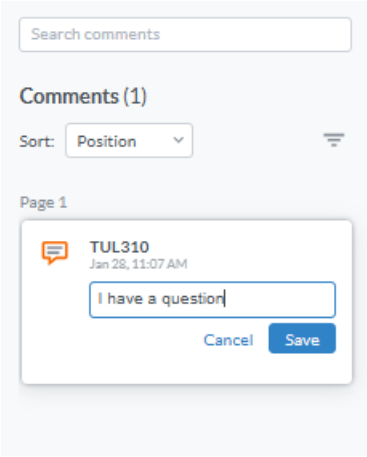
Note! You can only add notes to documents that require a co-signatory.

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:



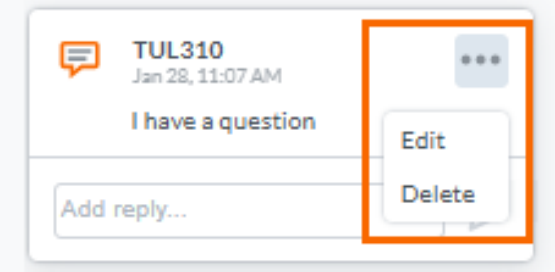
Note! Notes more than 240 characters may not display correctly in the browser after they are downloaded. They will display correctly when the downloaded document is viewed in a PDF viewer.

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:

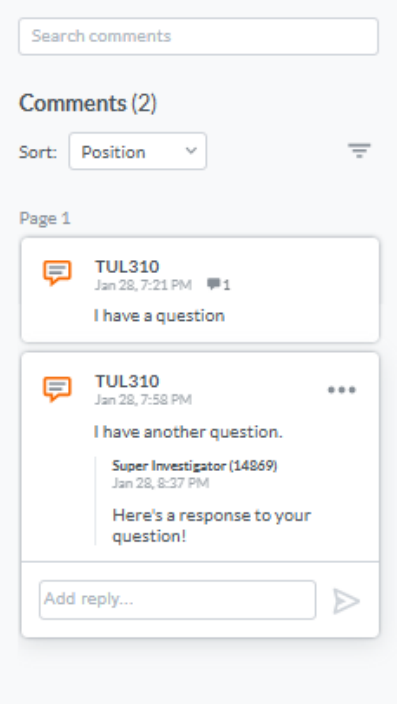
1 Select the note you want to edit or delete. Select the **options menu** in the top right corner of the note:



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.

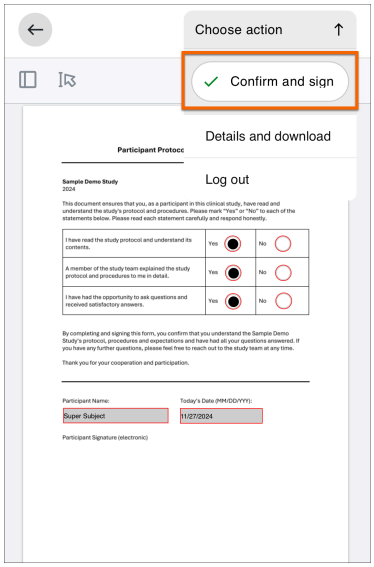
When you receive a reply to your note, you can add more replies as needed:



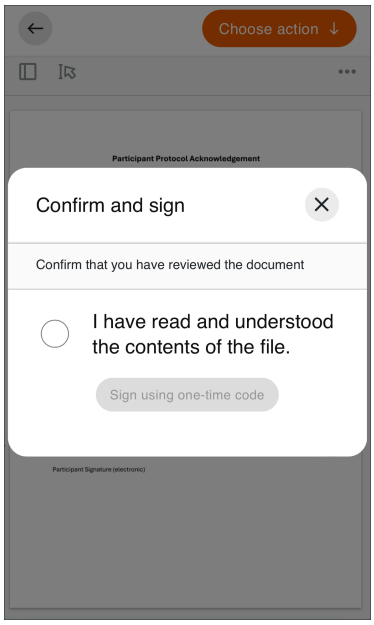
6.4 Signing a document

To sign a document:

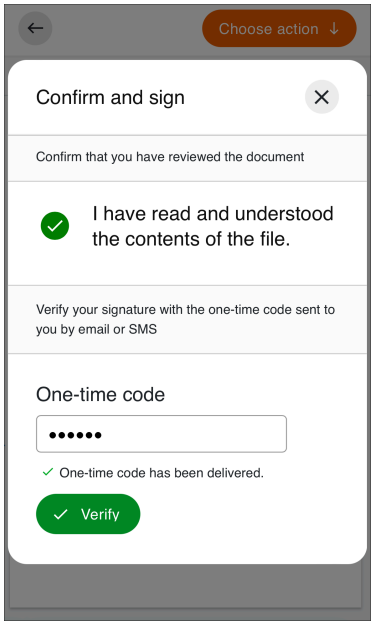
1 Select **Choose action** at the top right of the screen. If your signature is required, and any required fields have been completed, the **Confirm and sign** option is displayed:



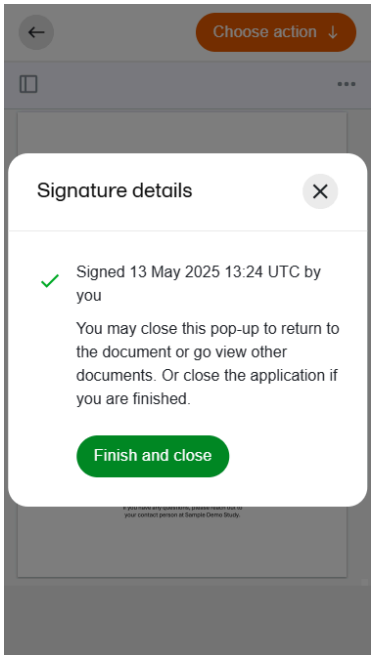
2 Select **Confirm and sign**. To confirm that you have reviewed the document, select the round button to the left of the confirmation statement and a green check mark will appear. Select **Sign using one-time code**.



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 pop-up to return to the document view. From there you can complete other actions such as downloading the document, or navigating to the document list to view other documents.

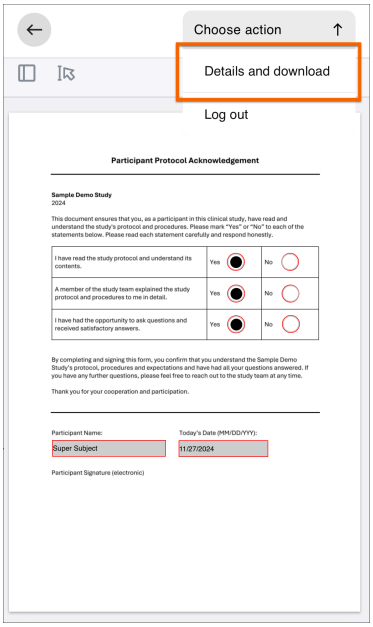
If you are finished, select **Finish and close** to close the application and sign out of Viedoc Me.

6.5 Downloading a document

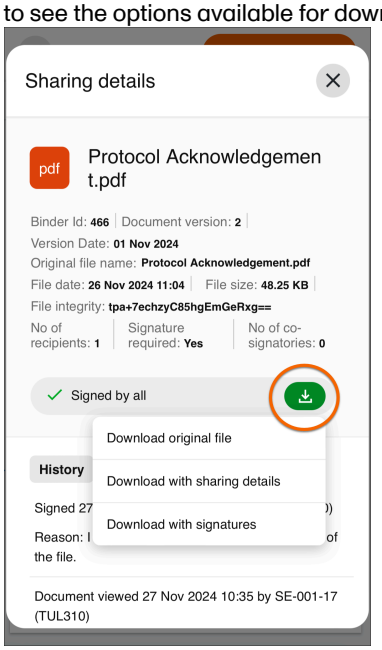
You can always download a copy of the document, whether the document requires a signature or not.

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.

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.

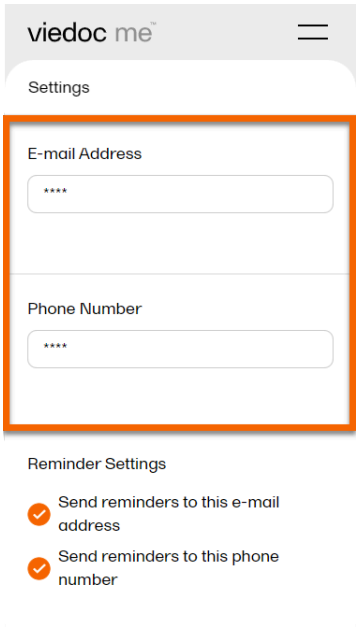
7.1.1 Setting reminders and changing your contact information

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.

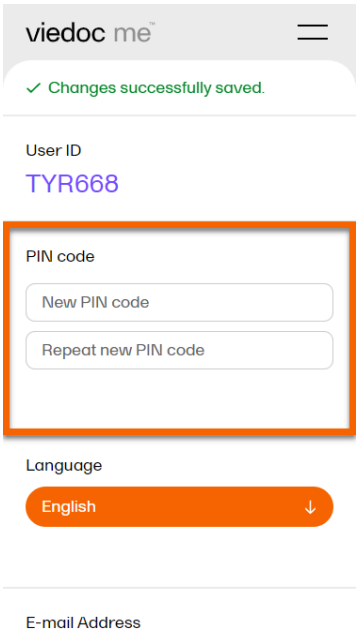
7.2 Changing your PIN code

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

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

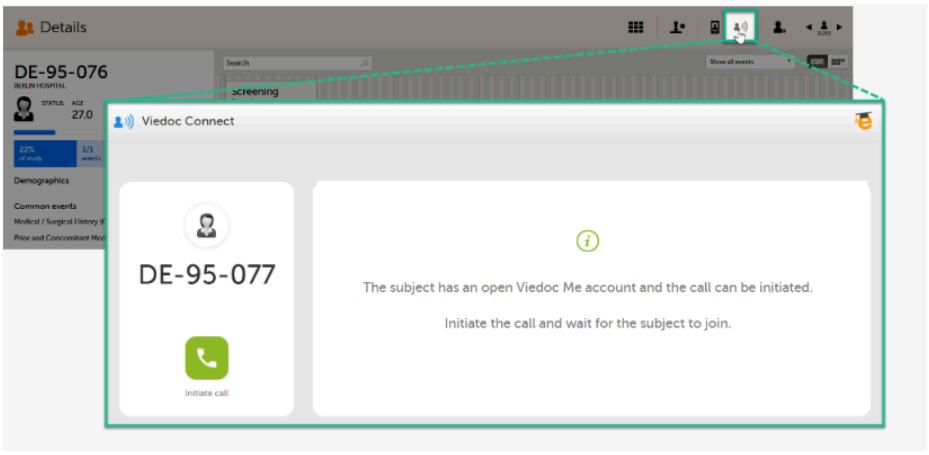
To use Viedoc Connect:

- 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

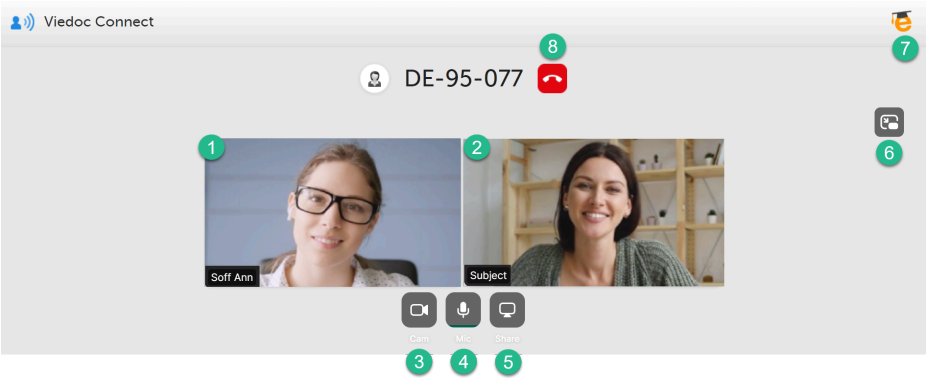
To open Viedoc Connect, select the icon on the Selection page. Viedoc Connect opens in a new tab:



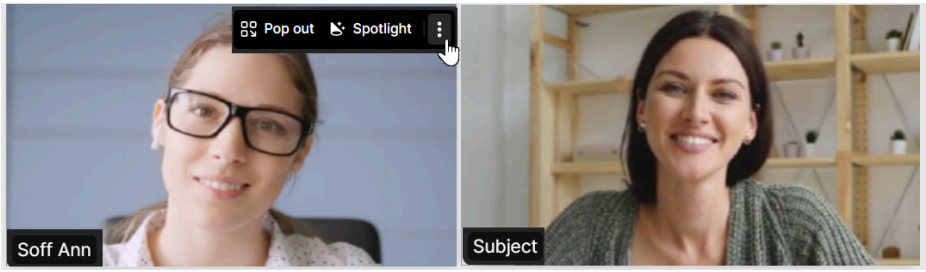
3 Initating a call

To initiate a call, click the **green** phone icon.

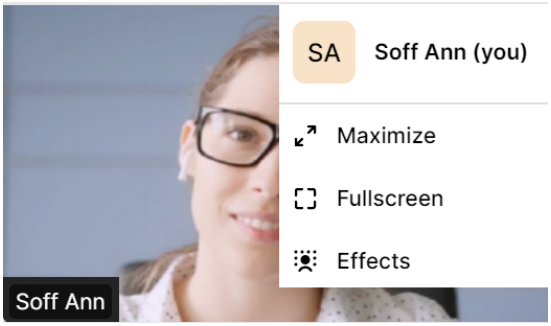
When the subject joins the call, you will see the following view:



1. To show the screen settings on the site user screen (you), hover over the screen:



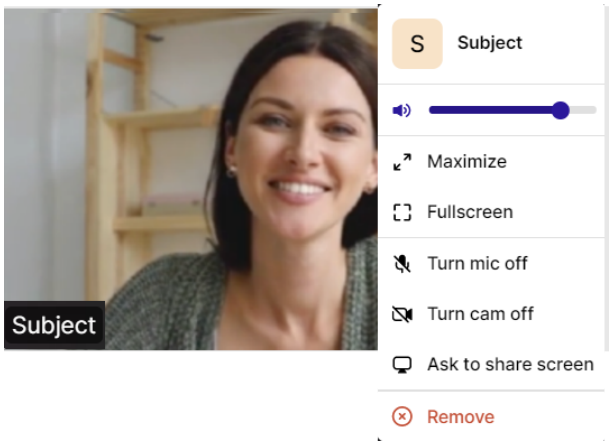
- Select **Pop out** to move the screen of you to the bottom right corner.
- Select **Spotlight** to put the spotlight on you.
- Select the three dots to show more settings:



- 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:



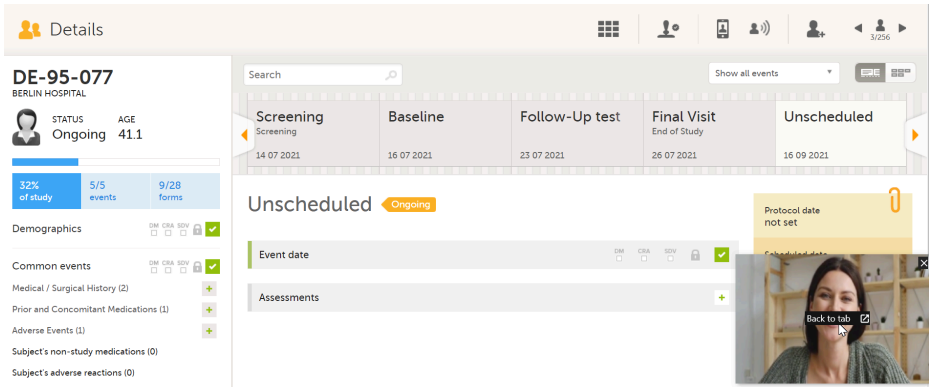
- Pull the bar to increase/decrease their volume.
- Select **Maximize** to make both screens larger.
- Select **Fullscreen** to make their screen cover the whole screen.
- Select **Turn mic off/Turn cam off** to disable their microphone/camera. To enable them, click **Ask to turn mic on/Ask to turn cam 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.

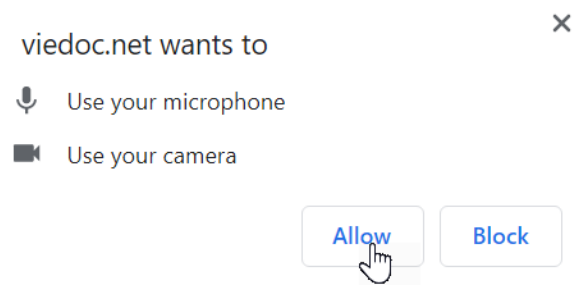
8. End call button - select to end the call.

---

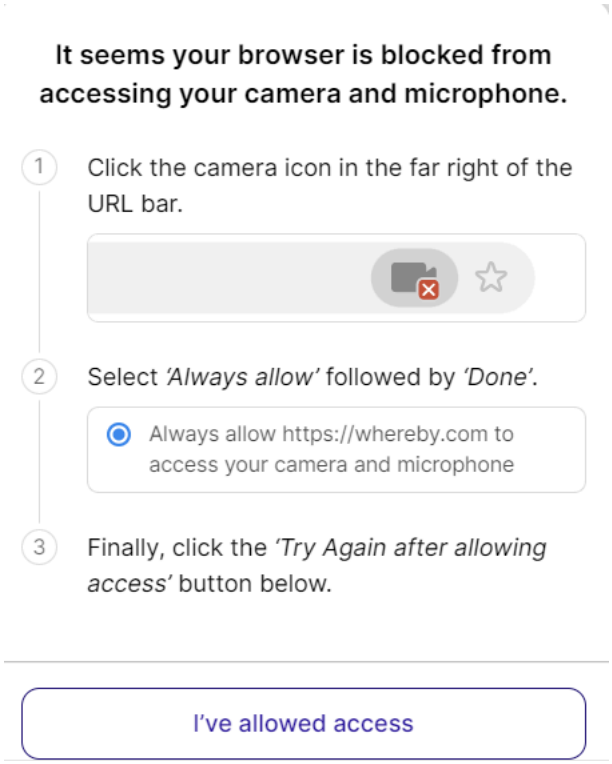
4 Troubleshooting

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 allllowed access** to enter Viedoc Connect.

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

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

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.

Viedoc "Working Smarter Series" webinars

Viedoc "Working Smarter Series" webinars

Published by Viedoc System 2025-11-04

1 Introduction

Our Working Smarter webinar series is designed to help Viedoc users get the most out of the platform, from practical tips and feature deep dives to best practices and expert insights. Each session addresses topics for our users including highlighting new features, sharing useful tips, best practices, or deeper insights into specific areas of Viedoc.

Whether you're new to the system or an experienced user, these webinars are here to help you work smarter.

2 Webinar recordings and Q&A

The full list of webinars in Viedoc's *Working Smarter Series*, including recordings and Q&A, is provided below.

2.1 Viedoc 4.80 Release Webinar

October 2024

https://help.viedoc.net/l/a29eab/en/

2.2 Viedoc Custom Reports in R Webinar Q&A

November 2024

https://help.viedoc.net/l/04c262/en/

2.3 Viedoc VIRP Webinar Q&A

January 2025

https://help.viedoc.net/l/893419/en/

2.4 Using GitHub Webinar Q&A

February 2025

https://help.viedoc.net/l/bb2d9a/en/

2.5 Design ODM Basics & Design Version Compare Webinar Q&A

March 2025

https://help.viedoc.net/l/027d45/en/

2.6 ePRO Tips and Tricks Webinar Q&A

April 2025

https://help.viedoc.net/l/f94362/en/

2.7 Randomization Webinar Q&A

June 2025

https://help.viedoc.net/l/227838/en/

2.8 Post-Live Changes Webinar Q&A

September 2025

https://help.viedoc.net/l/b01136/en/

Version 2.1.2