viedoc learning™

Viedoc User Guide for Medical Coders

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Overview of Viedoc Clinic

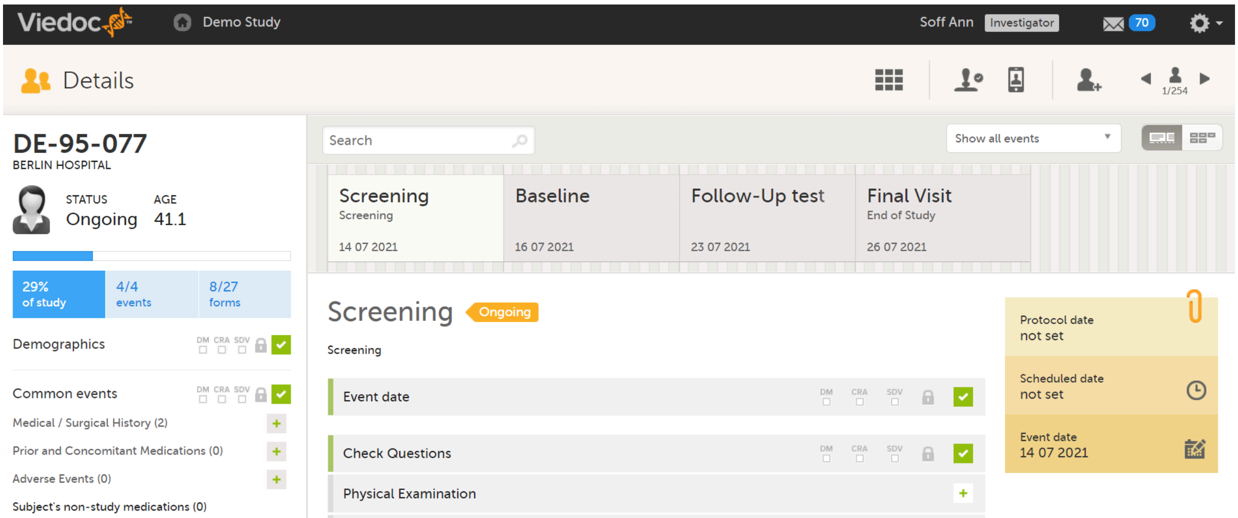
Overview of Viedoc Clinic

Published by Viedoc System 2024-10-10

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

1 Introduction

Viedoc Clinic is the interface for the end user, and is primarily used by site and study staff (Investigators, Study Coordinators, Monitors, Data Managers and so on) and keeps track of all the activities performed by the site.



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

The following main actions can be performed in Viedoc Clinic:

- Data entry - covered by the following lessons:
  - [Selection page](#)
  - [Entering/Editing data](#)
  - [Resetting and deleting data](#)
  - [Signing data](#)
  - [Working with reference data](#)
- Raise and resolve queries - described in [Resolving queries](#)
- Data export - described in [Exporting data](#)
- Medical coding - described in [Medical coding](#)
- View study metrics - described in [Metrics](#) and [Viedoc Reports](#)

2 Languages

Viedoc Clinic is available in the following languages:

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

System requirements

System requirements

Published by Viedoc System 2022-06-16

1 Customer computer requirements

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

1.1 Browser requirements

Viedoc supports the following browsers:

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

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

For Viedoc Designer:

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

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

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

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

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

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

1.2 Screen resolution

The following screen resolutions are required:

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

1.3 Internet connection

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

1.4 Firewall policy

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

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2 Security

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

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

Managing your Viedoc account

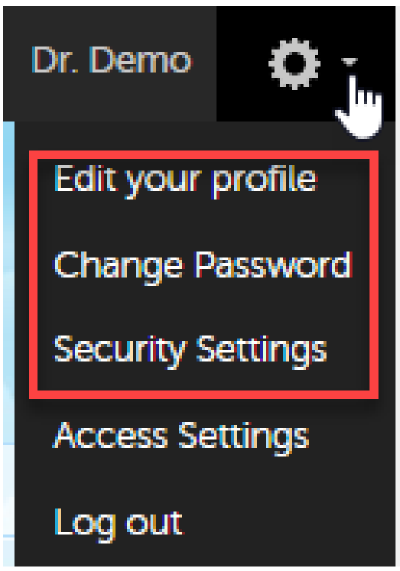
Managing your Viedoc account

Published by Viedoc System 2024-10-10

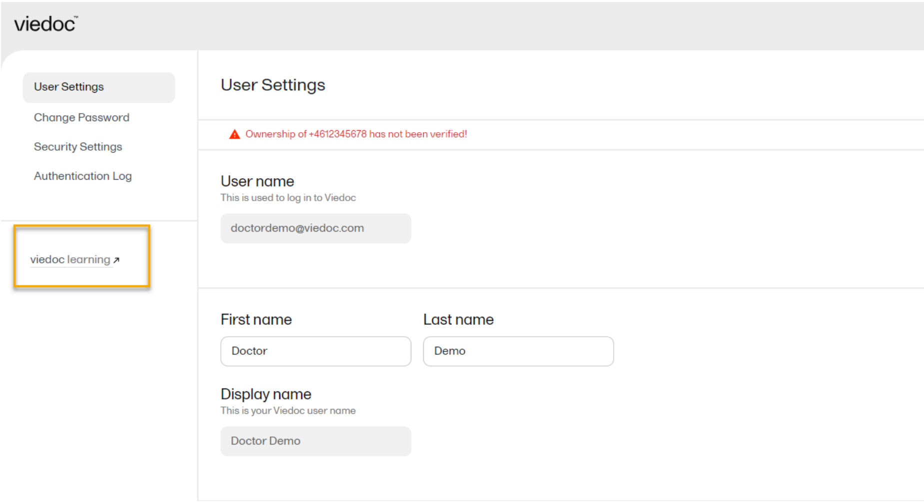
1 Viedoc user account management

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

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



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



2 User settings

Once logged in, you can edit your profile.

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

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

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

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

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

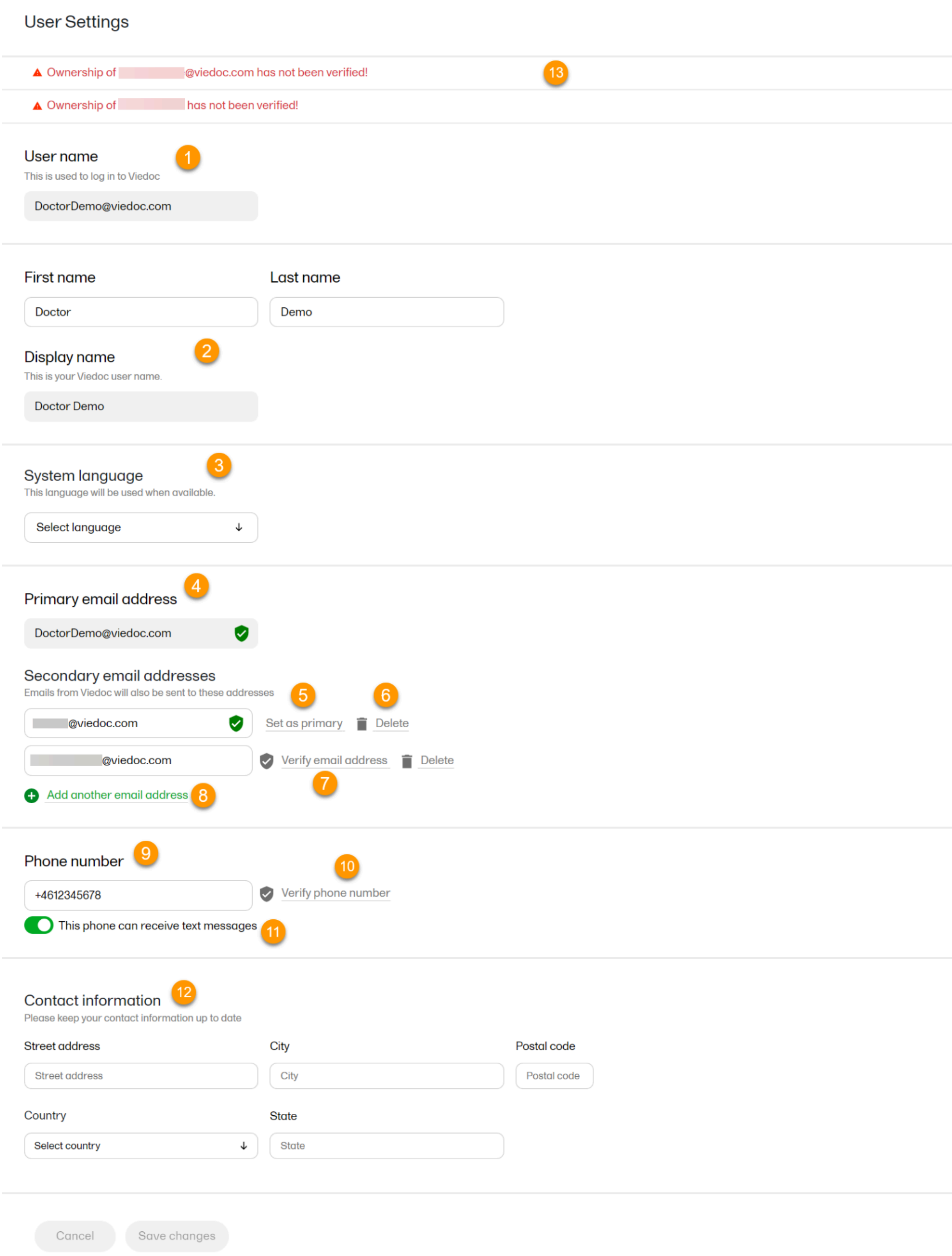
5, 6, 7, 8. **Secondary email addresses** - you can add up to 3 additional email addresses that will be used by Viedoc to send notifications on alerts and trackers as configured in Viedoc Designer. Viedoc alert emails will be sent to all the primary and verified secondary email addresses set up for your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

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

Important!

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

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



2.1 Adding a secondary email address

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

1. Select **Add another email address** link (8) next to the current primary email address.
2. Enter the email address in the new field under **Secondary email addresses**.
3. Select **Save changes**. A notification email is sent to both the primary email address and to the newly added email address to inform you about the change. At the top of the **Edit your profile** dialog box, you will see a warning message saying that the newly entered email address is not verified (13).

2.2 Verifying a secondary email address

To verify a secondary email address:

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

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

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

2.3 Changing the primary email address

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

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

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

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

2.4 Editing your phone number

To edit your phone number:

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

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

2.5 Verifying your phone number

To verify your phone number:

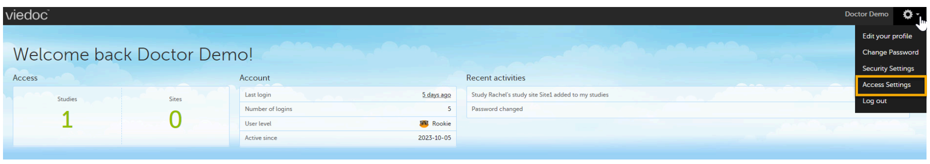
1. Make sure that the phone number is correctly entered and that the **Phone can receive text messages** option is selected.

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

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

3 Study access management

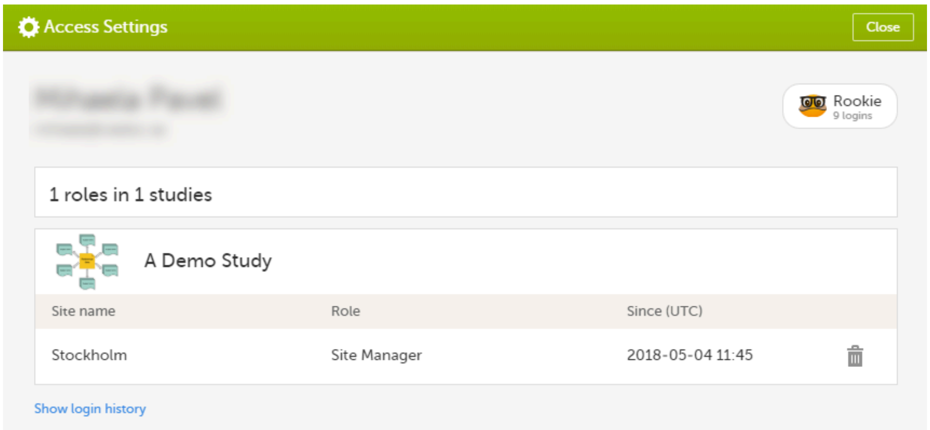
From the settings button (wheel) you can perform all actions related to study access management in **Access Settings**.



4 Access settings

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

4.1 Study membership



The following information is provided, grouped by study:

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

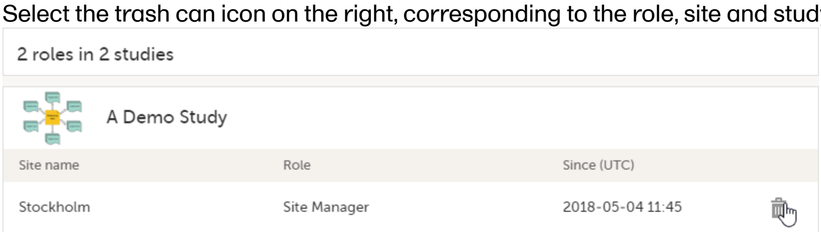
For users with organization roles, these are listed in the top of the page, in a separate section, providing the following information:

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

4.2 Deleting study access

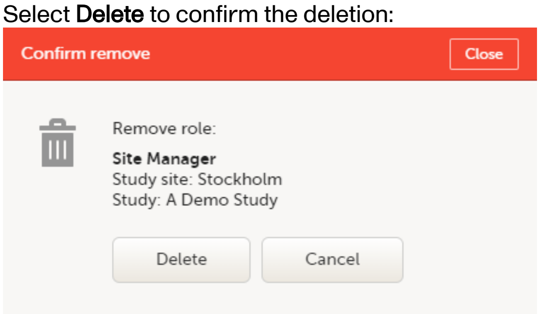
To remove yourself from a certain role within a study:

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



A confirmation dialog is displayed.

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



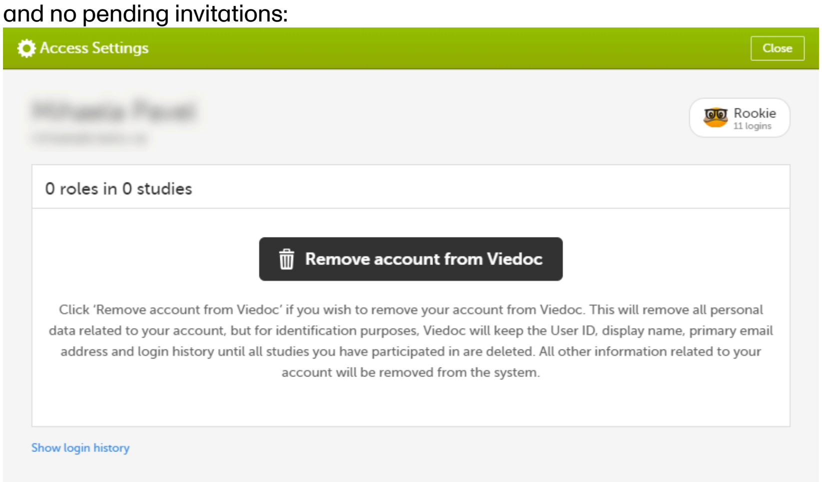
A notification email will be sent to all the Study managers, or to the Site managers if any roles are delegated.

4.3 Deleting your Viedoc account

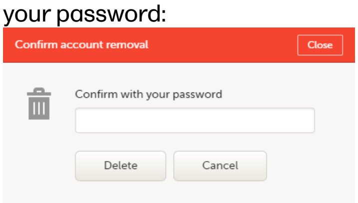
You can remove your Viedoc account when you have no study memberships left, that is, 0 roles in 0 studies.

To delete your Viedoc account:

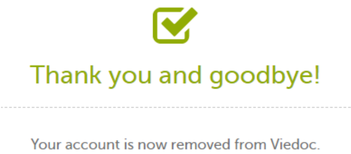
1. Go to **Access Settings**. To be able to remove your account, you should have no roles left in any study and no pending invitations:



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



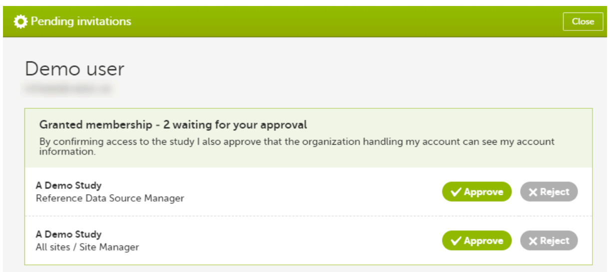
3. Enter your password and select **Delete**. A confirmation message is displayed and a notification email will be sent to your primary email address:



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

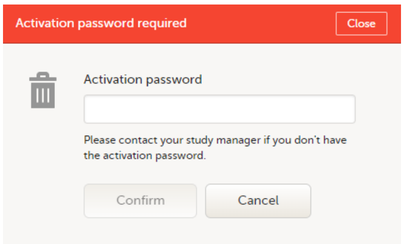
5 Pending invitations

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



5.1 Approving a study invitation

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



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

5.2 Rejecting a study invitation

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

5.3 Postponing the approval/rejection of a study invitation

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

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

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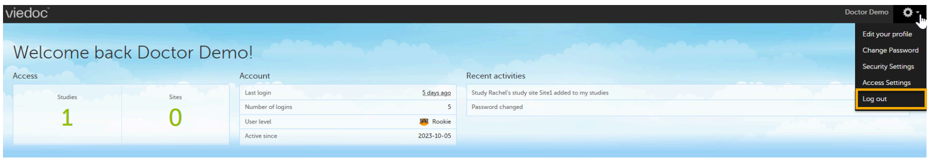
6 Logging out

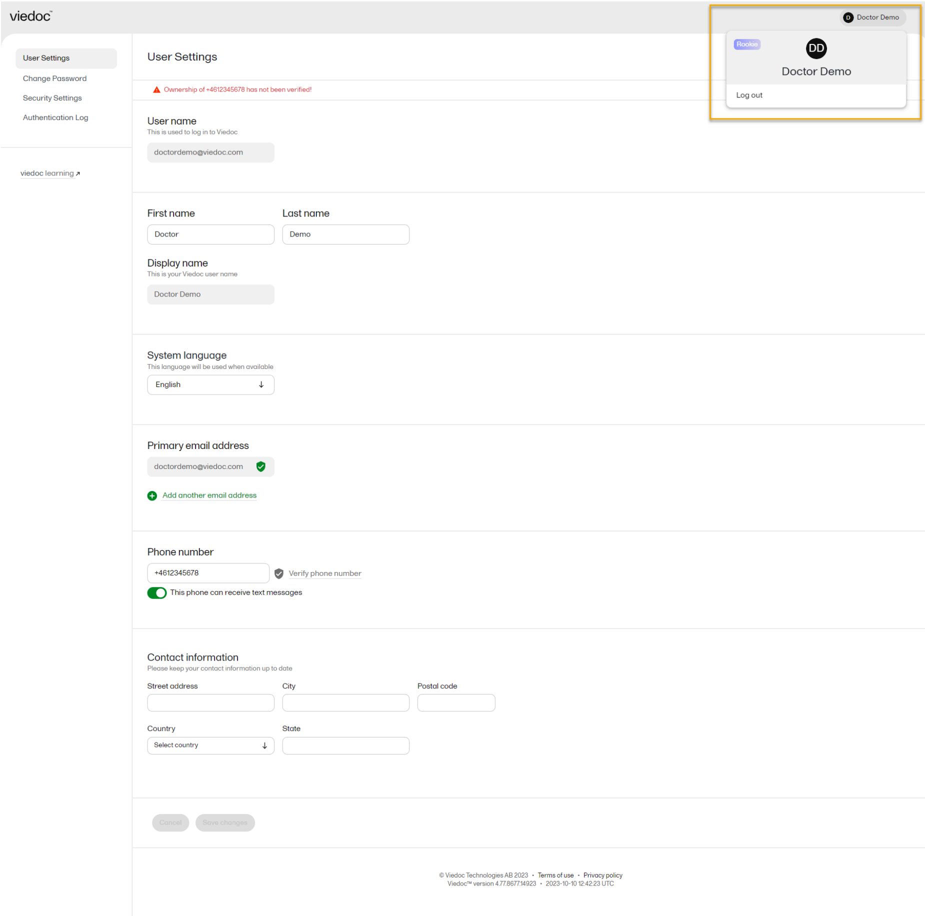
From Viedoc you can log out from different locations:



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

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

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


viedoc
Doctor Demo
Rookie
DD
Doctor Demo
Log out
User Settings
Change Password
Security Settings
Authentication Log
viedoc learning
User Settings
Ownership of +4612345678 has not been verified!
User name
This is used to log in to Viedoc
doctordemo@viedoc.com
First name
Doctor
Last name
Demo
Display name
This is your Viedoc user name
Doctor Demo
System language
This language will be used when available
English
Primary email address
doctordemo@viedoc.com
Add another email address
Phone number
+4612345678
Verify phone number
This phone can receive text messages
Contact information
Please keep your contact information up to date
Street address
City
Postal code
Country
Select country
State
Cancel
Save changes
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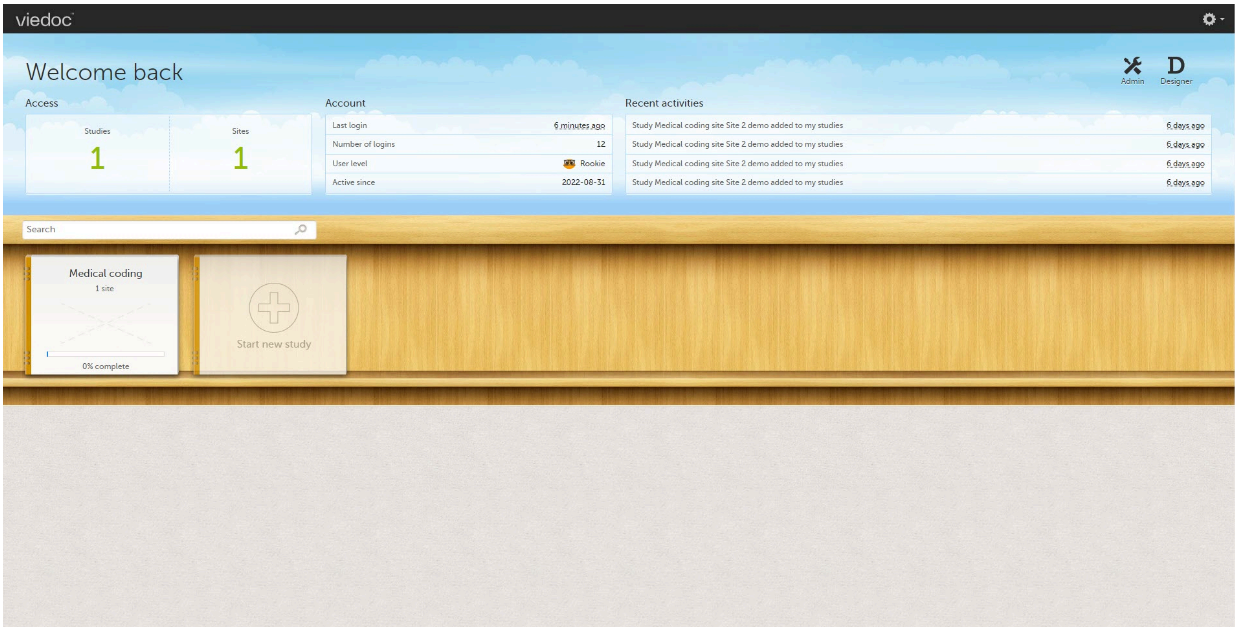
Viedoc™ version 4.77.8677.14923 • 2023-10-10 12:42:23 UTC

Overview of the landing page

Published by Viedoc System 2024-10-10

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



The landing page provides the following summary information:

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

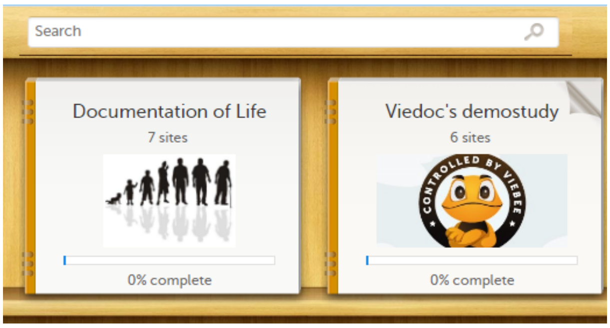
Skill level	Icon	Description
Rookie		≤ 20 logins
Semi-pro		21-100 logins
Pro		101-1000 logins

Skill level	Icon	Description
Legend		> 1000 logins

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

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

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



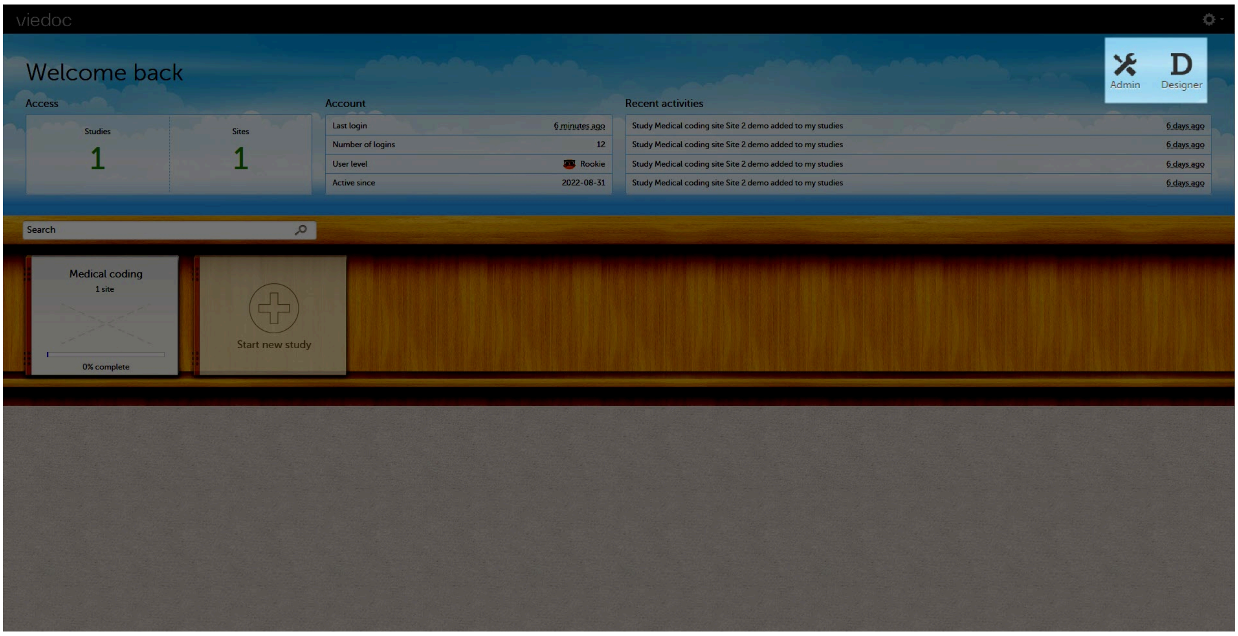
A progress bar is shown below each study logo. The percentage displayed is calculated by the mean completion of each subject (rounded down). Thus, it measures the total completion of the study.

Note!

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

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

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



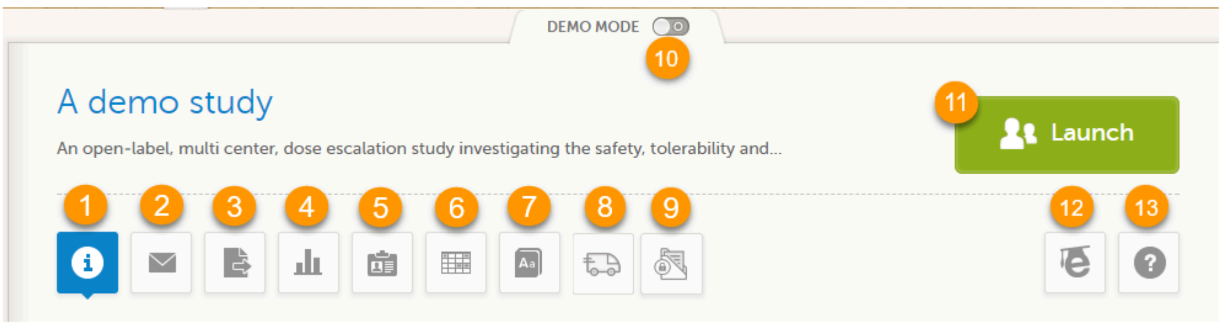
Study start page

Study start page

Published by Viedoc System 2024-12-03

1 Introduction

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.

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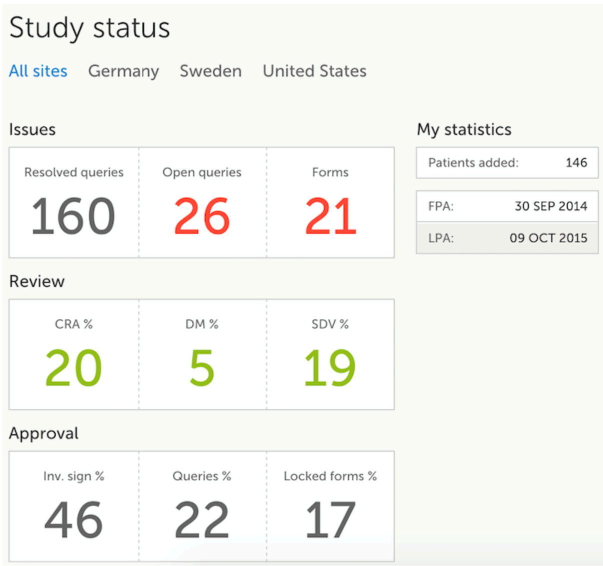
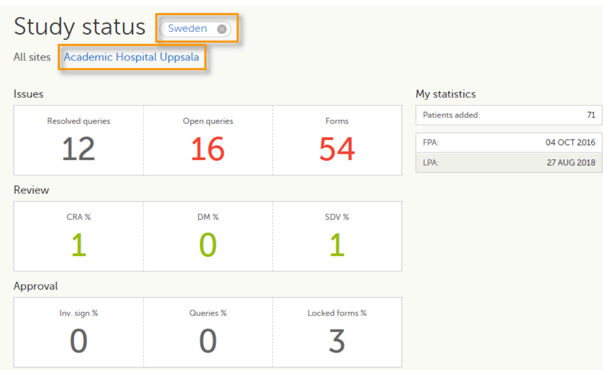
2 Study status

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



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



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

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

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

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

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

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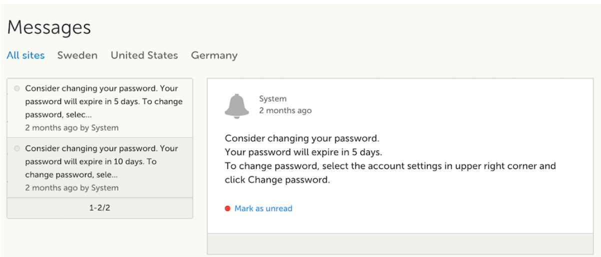
3 Messages

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

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



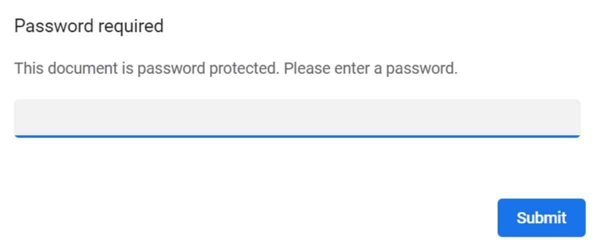
3.1 Alert messages

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

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

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

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



4 Data export

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

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

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

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

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5 Metrics and Viedoc Reports

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

Note! Metrics might not be available to all users.

For a detailed description, see Metrics.

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

---

6 Roles

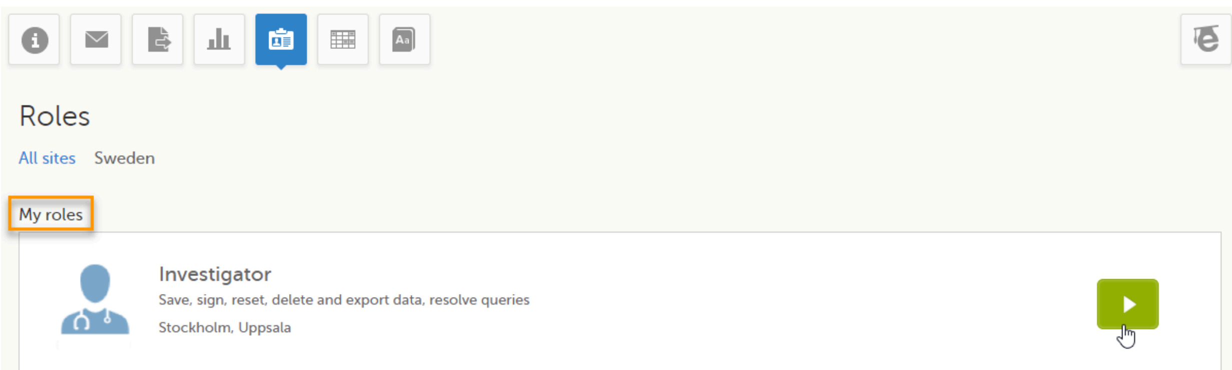
Note! The Roles page is only available for users with special permission to view roles, as per the study design.

The Roles page provides information on:

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

6.1 My roles

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



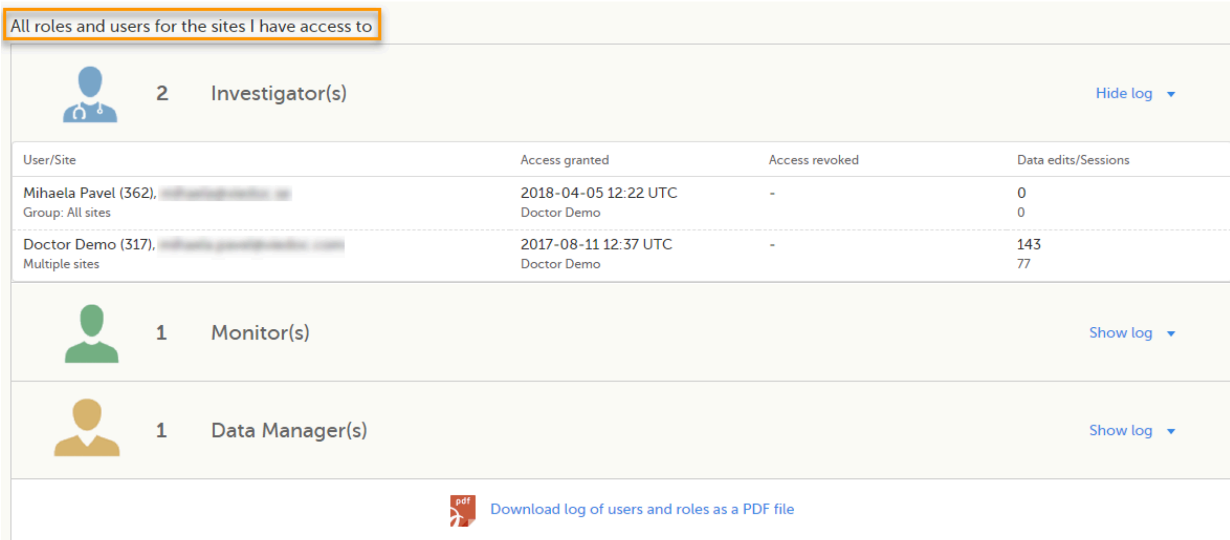
The following information is displayed (with *examples*):

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

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

6.2 All roles and users for my site(s)

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



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

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

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

6.2.1 User logs

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

- Log of users and roles in PDF format
- User administration log in Excel format

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

After the user log was generated you can choose to:

- Download the latest generated log for the country/site selection - the most recent version generated has a date and time stamp and is stored on the server, making it possible to directly download the file instead of generating a new one, or
- Select **Regenerate** - if you need a more recent version than the one available for download.

6.2.1.1 Log of users and roles in PDF format

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

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

6.2.1.2 User administration log in Excel format

The User administration log contains the following sheets:

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

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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.

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8 Medical coding

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

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

For more information about medical coding, see Medical coding.

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9 Viedoc Logistics

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

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

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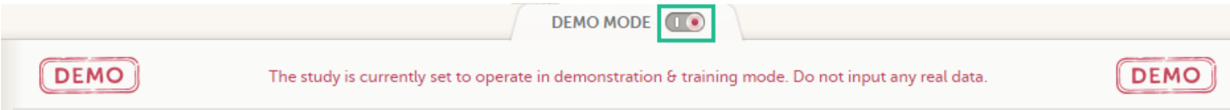
10 Viedoc eTMF

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

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

11 Demo mode

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



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

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

See also the video tutorial Activate demo mode.

12 Launch

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

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

13 eLearning / Documentation & Training

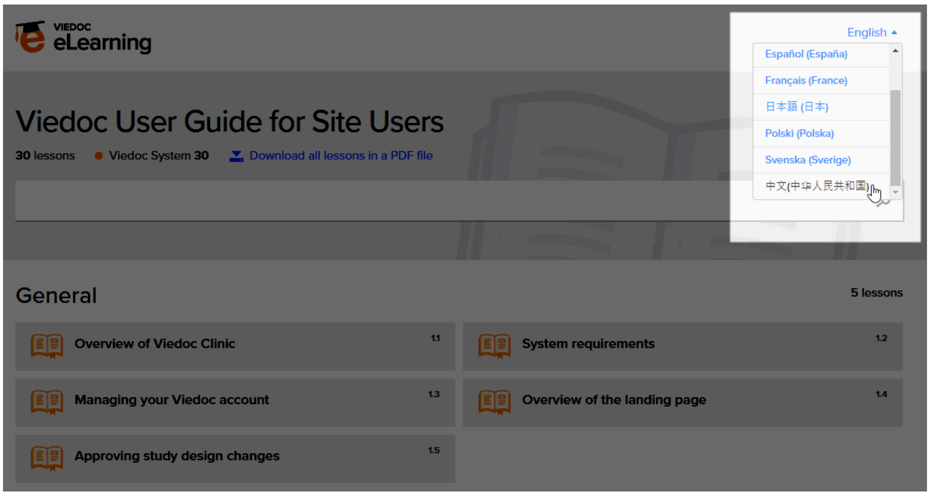
If you have mandatory documentation pending to be read and signed, this is the first page that is displayed when you access the study.

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

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

- English
- Chinese
- Japanese

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



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

---

14 Support

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

[Back to top of page](#)

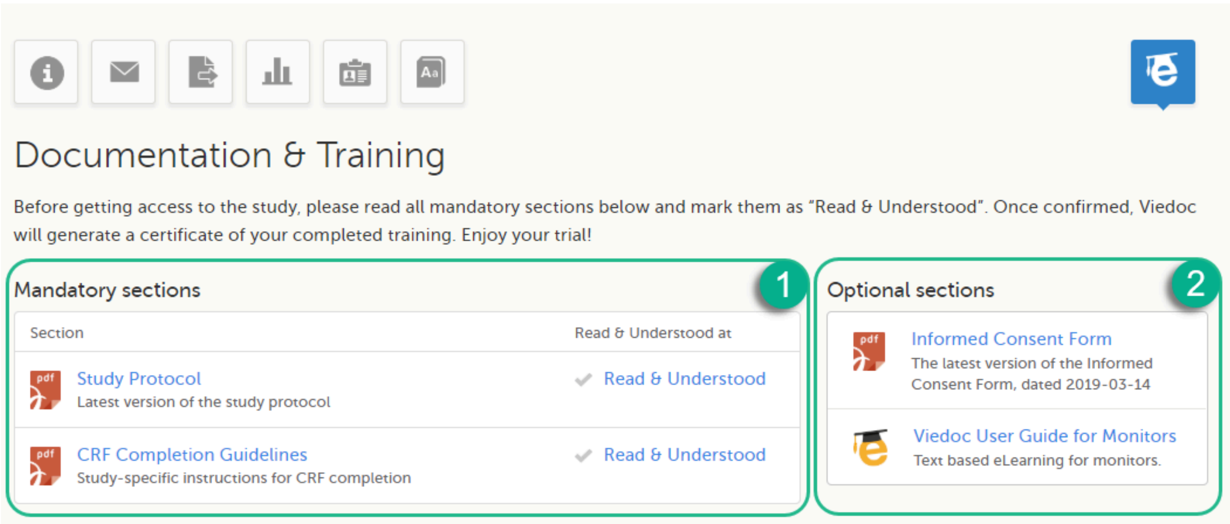
Documentation and Training

Documentation & Training

Published by Viedoc System 2020-06-04

1 Introduction

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



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

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

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

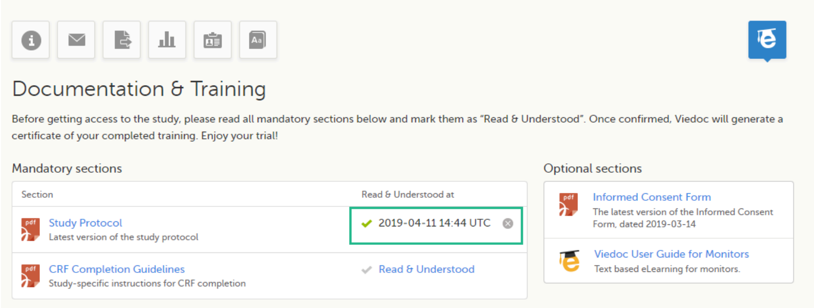
2. **Optional sections** - contains additional educational and reference materials that you have access to. Simply click on the link to open each of the available documents/links.

2 Becoming a certified user

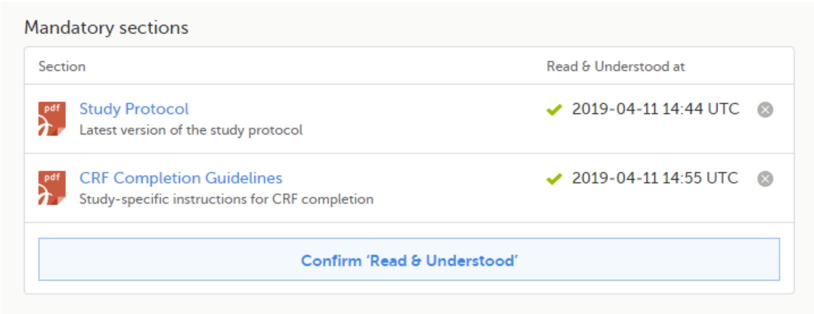
To work within a study for which mandatory training sections were assigned, you need to read, understand and sign all the sections listed as mandatory.

To obtain the user certificate:

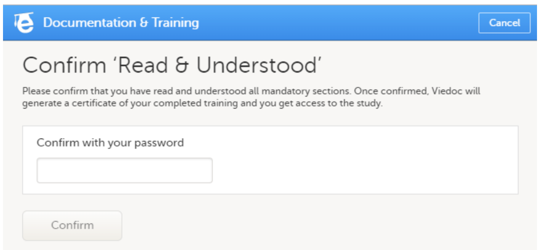
1 Click the link to open the section. Read through and, when you're done, go back to the Documentation and Training page and click **Read & Understood**. A date and time stamp in Coordinated Universal Time (UTC) will be shown in the **Read & Understood at** column:



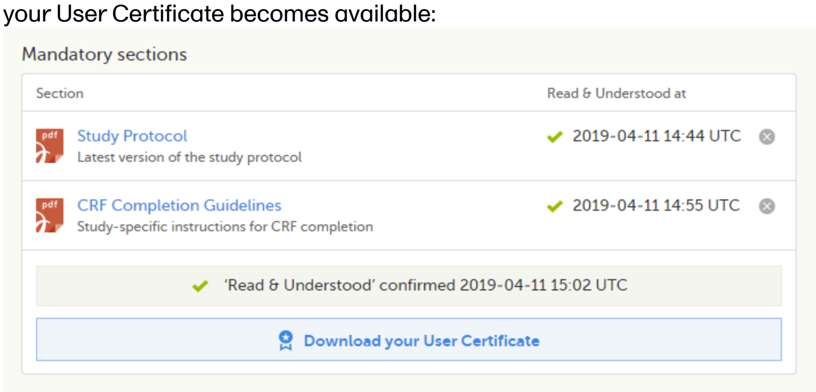
2 Repeat step 1 for each of the mandatory sections. When all the mandatory sections are marked as "Read & Understood", a Confirm 'Read & Understood' link becomes available:



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



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



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

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

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

3 Downloading your user certificate

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

The following information is provided on the certificate:

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

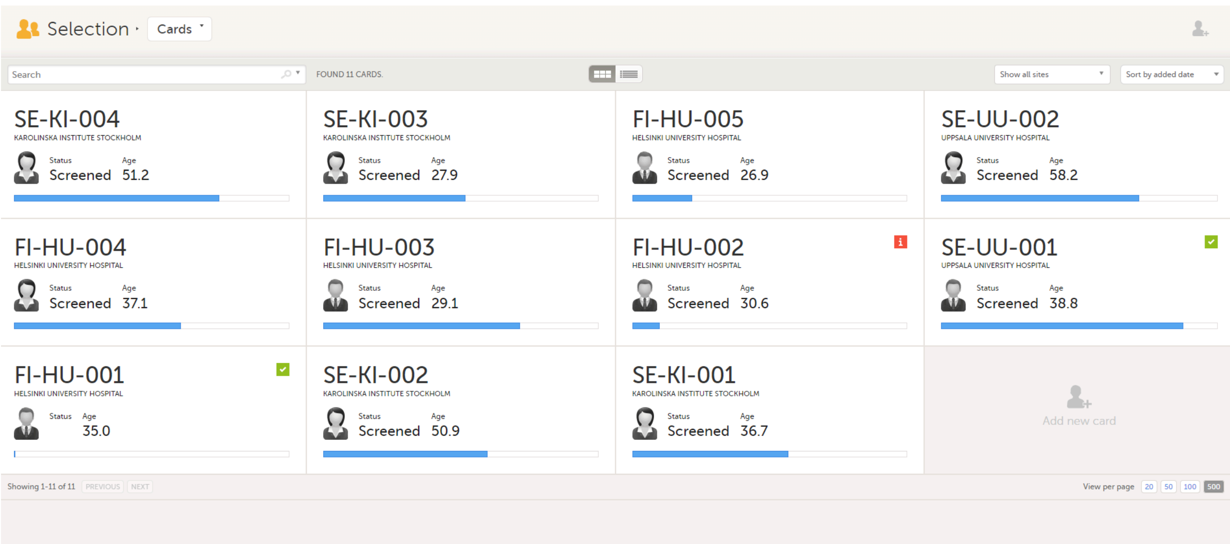
Selection page

Selection page

Published by Viedoc System 2023-10-09

1 Introduction

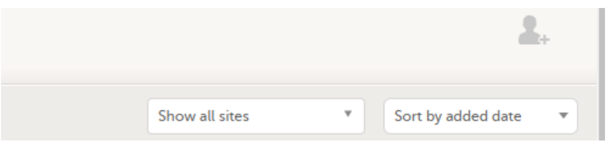
The Selection page displays all the subjects from all the sites you have access to:



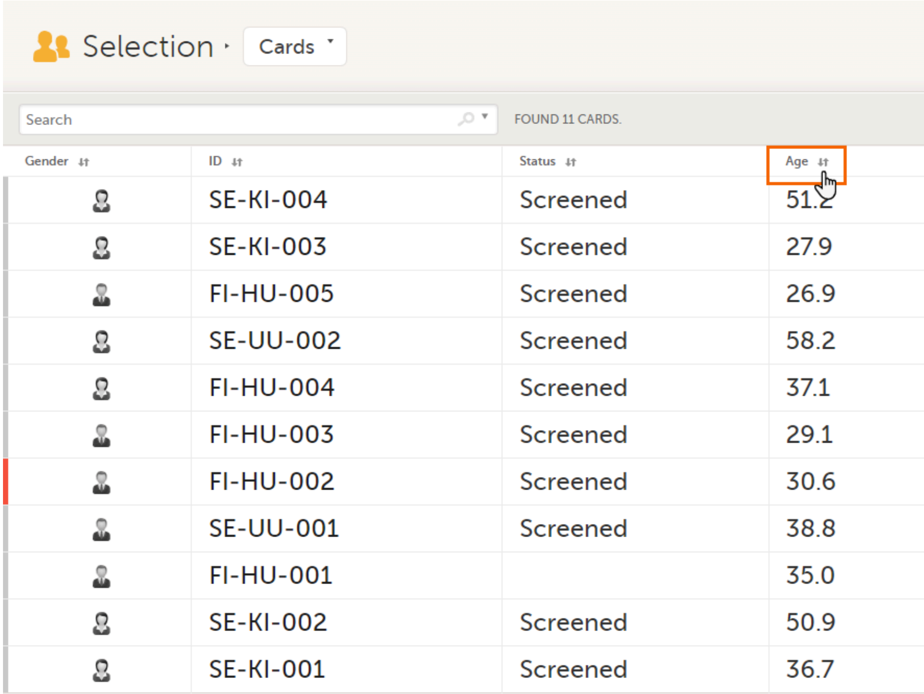
In the default view, each subject is represented by a card. Depending on your study setup, the Selection page can be displayed in several ways. See Views of the Selection page.

1.1 Sorting and filtering

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



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



1.2 Searching

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

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

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

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

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

1.3 Icons

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

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

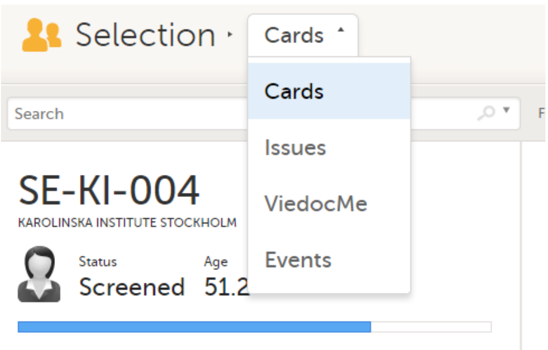
Icon	Description
	Signed - all data that is possible to sign has been signed
	Read-only - the card is being open for edit by another user. Note that the subject card can still be accessed for review or SDV by a user without edit permissions, for example a monitor or a data manager.
	In progress - the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

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

2 Views of the Selection page

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

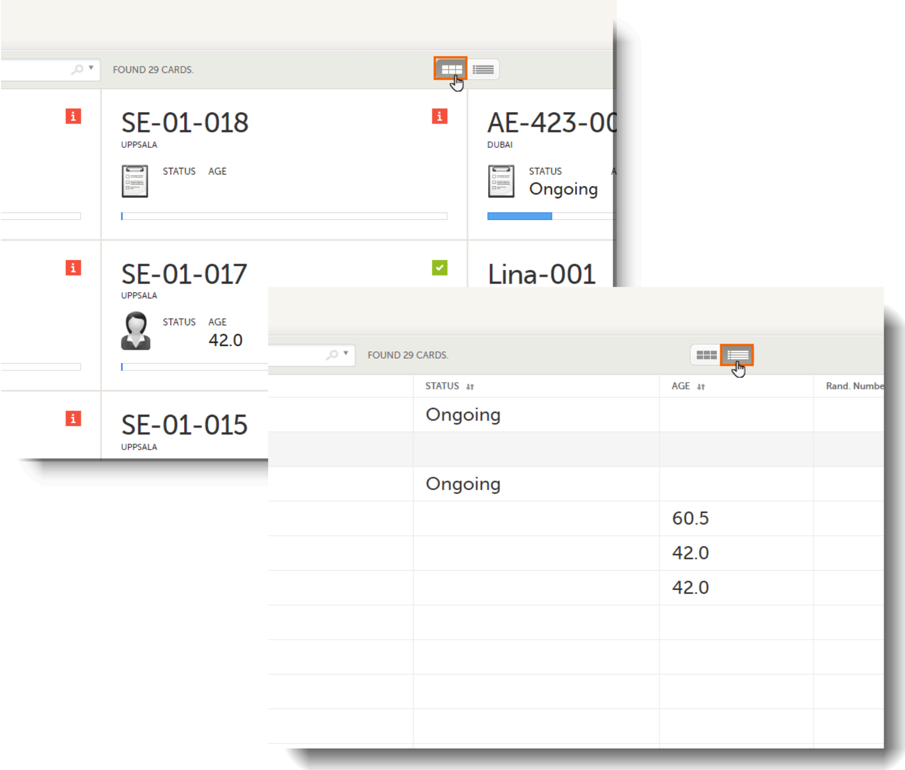
- If the study is configured with extended selection pages, you can select a view at the top of the page. Select **Cards**, **Issues**, **Viedoc Me** or **Events** from the dropdown menu to open the view. The Viedoc Me view is only available to select if the Viedoc Me feature is included in your study.



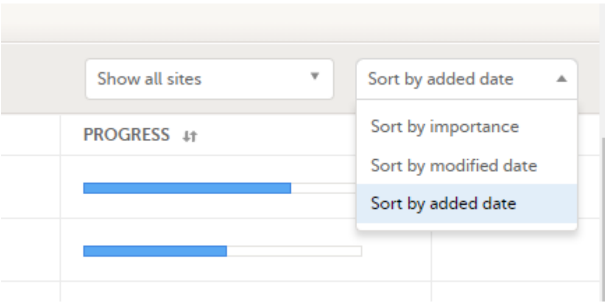
- If the study is not configured with extended selection pages, you can select between the views **Cards** and **Issues** by clicking the buttons next to the search field.

2.1 The Cards view

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

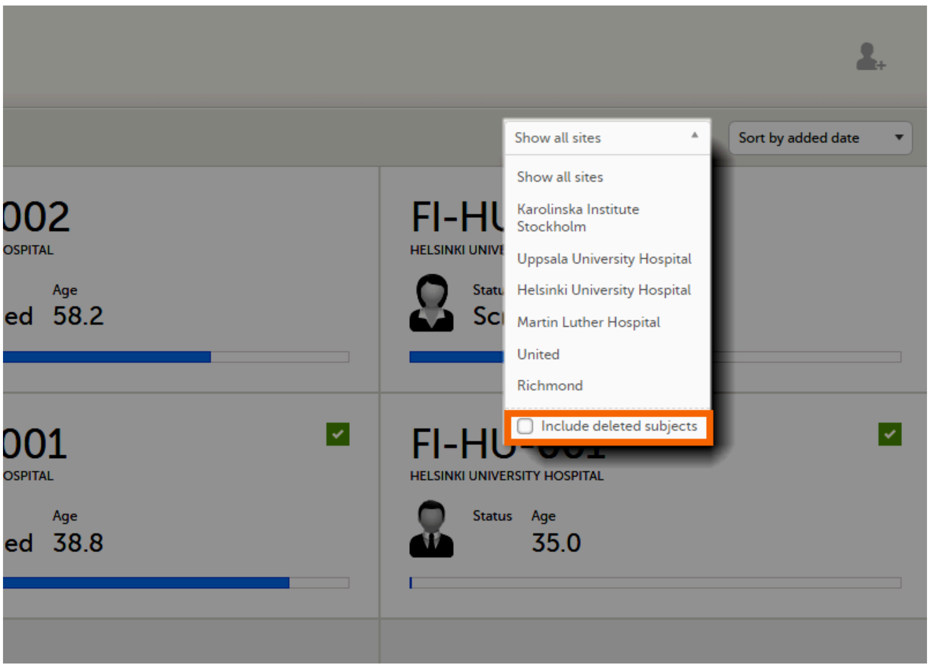


The subjects are sorted by added date, where the most recently added subject is displayed first. You can sort the subject cards by selecting an option in the upper right corner:



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

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

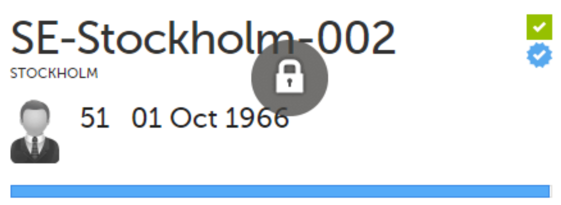


2.1.1 The subject card overview

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

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

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

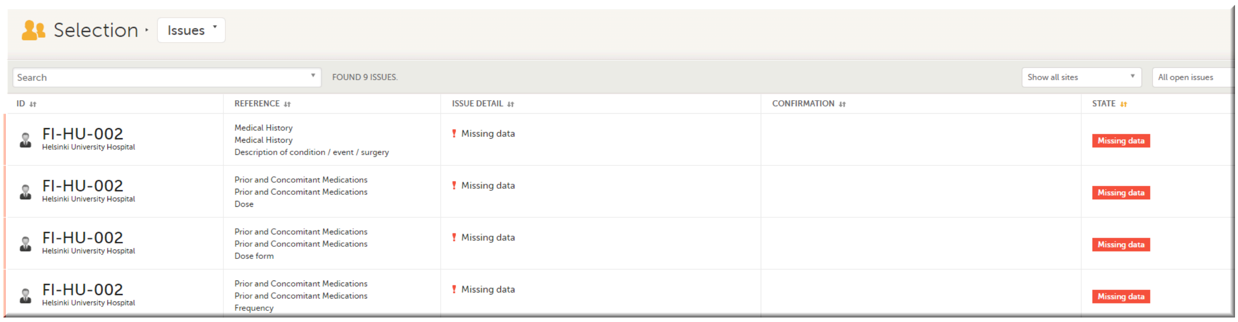


- Progress bar indicating the completion status (in blue)

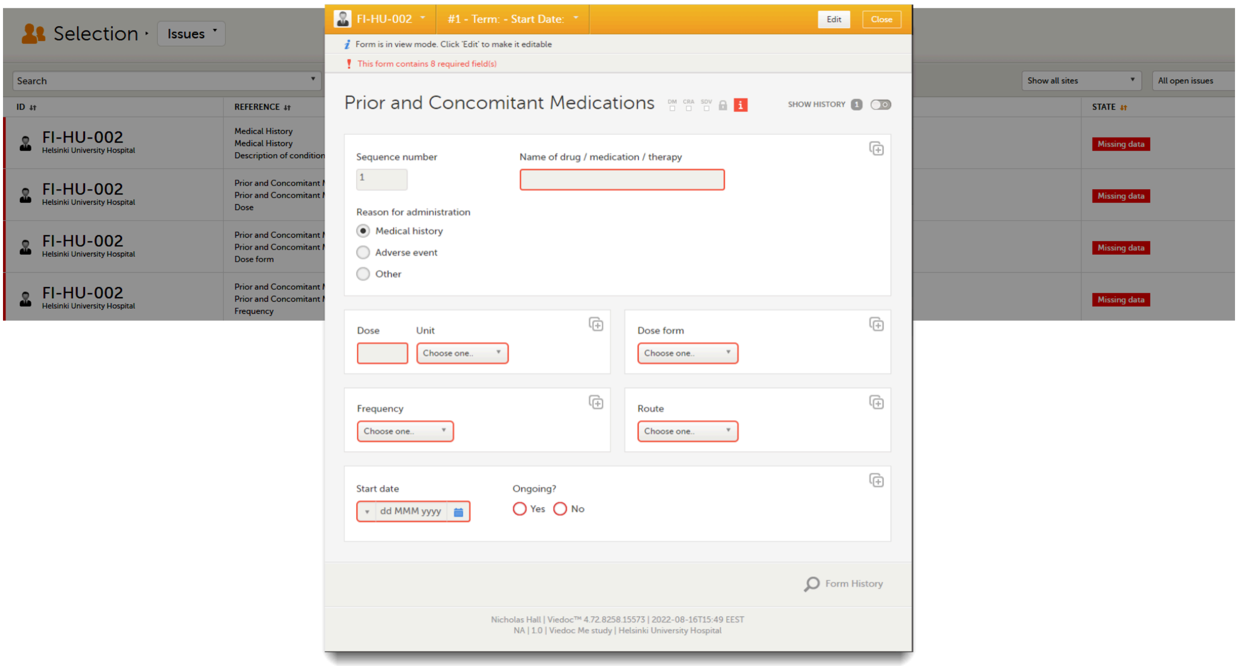
Note! The Selection page does not consider the role visibility except for task count; therefore, the subject status reflects the general status of the subject in the study, regardless of the user who has work to be performed. The subject details view reflects the subject status considering the role visibility.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

2.2 The issues view

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

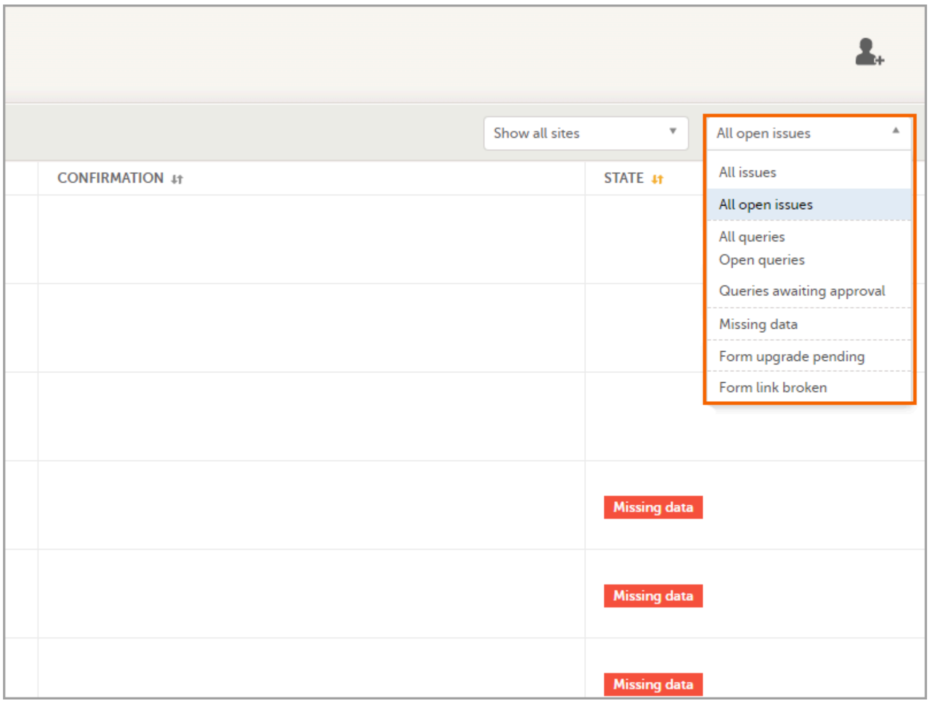


Click any row to open the form where the issue was raised:



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

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

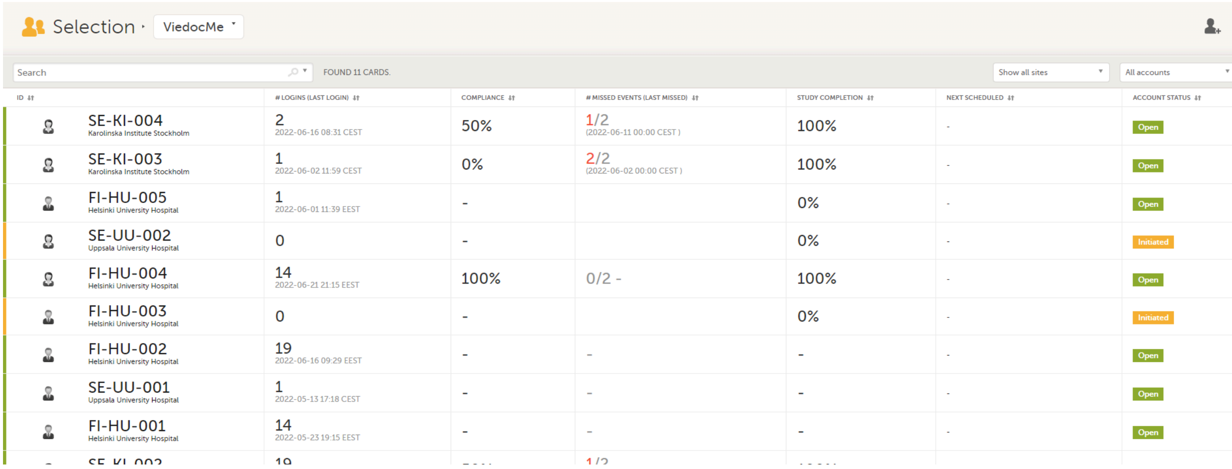


- By site - view data from a specific site or from all sites
  - Include deleted subjects
- By issue type/status:
  - **All issues**:
    a. Missing data
    b. All queries, regardless of status
    c. Form upgrade pending
    d. Pending reference data upgrade
  - **All open issues**:
    a. Missing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

- **Form upgrade pending**
- **Form link broken**

2.3 The Viedoc Me view

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

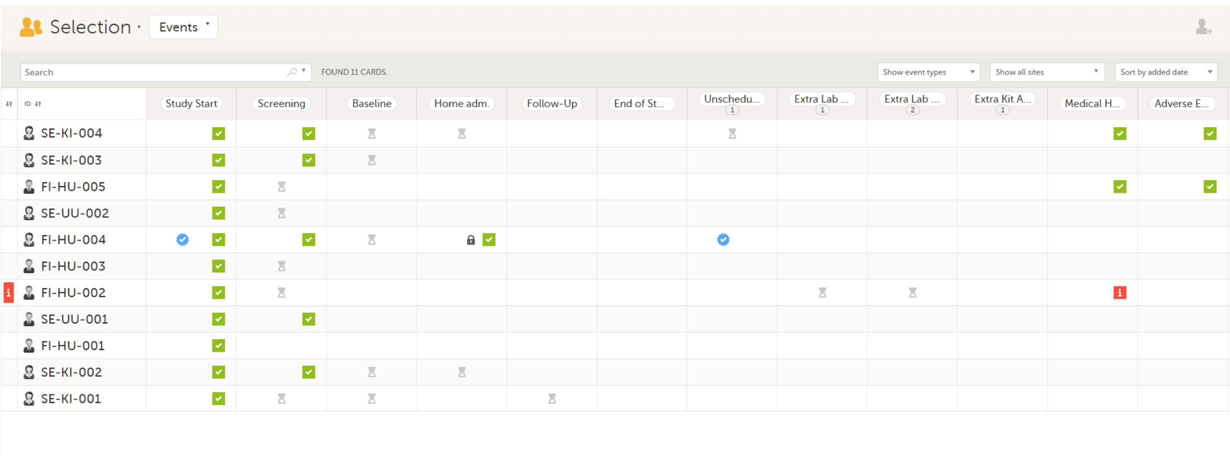


For each subject, the following information is listed:

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

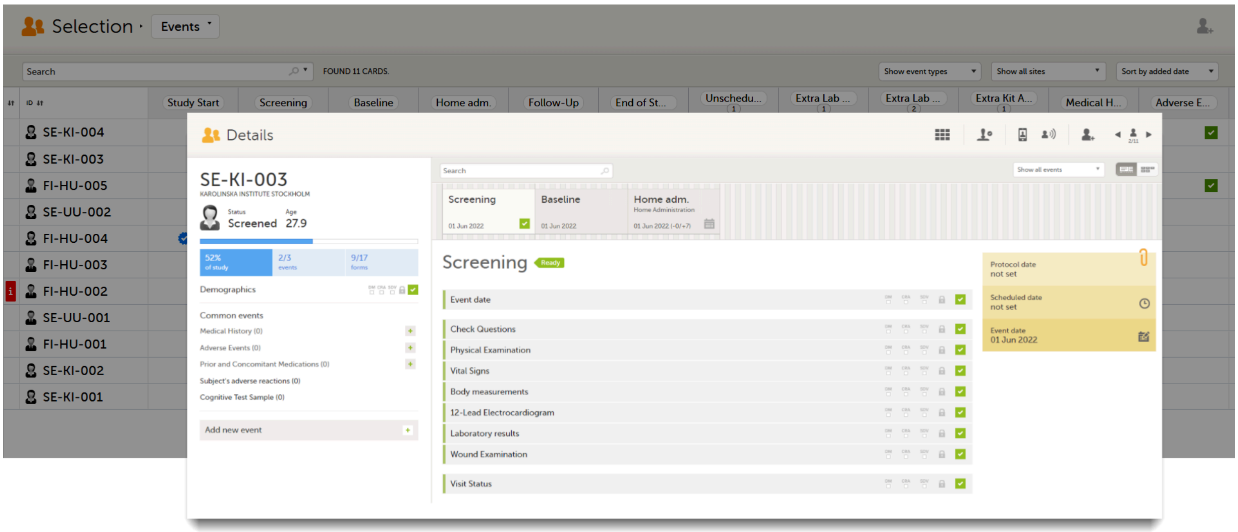
2.4 The Events view

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



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

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



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

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

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

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

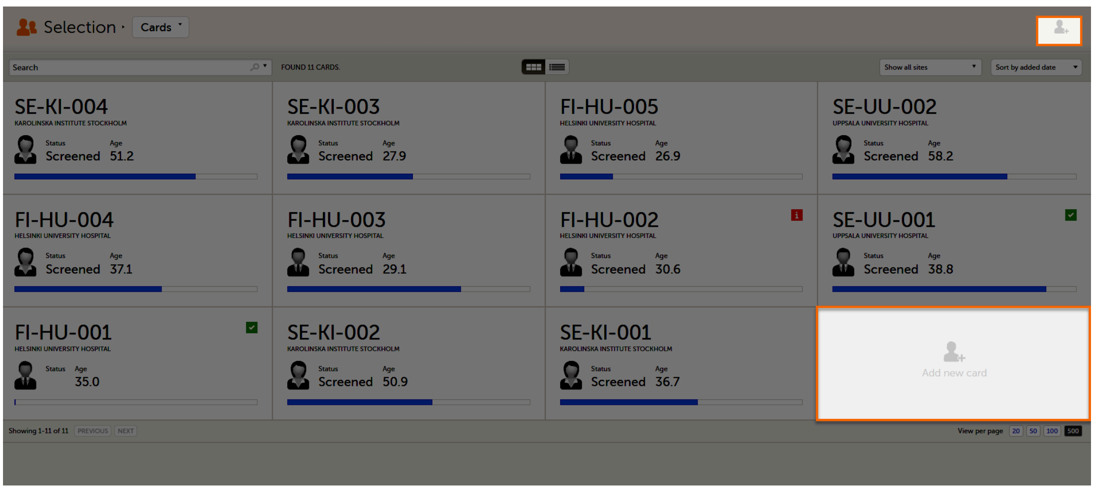
Note! On the selection page, in the **Events** view, the event name (as set in the Study event settings in the study design) is displayed. If there is a recurring event, a counter is shown under the event name, for example: Follow up 1, Follow up 2.

---

3 Adding a new subject

To add a new subject:

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



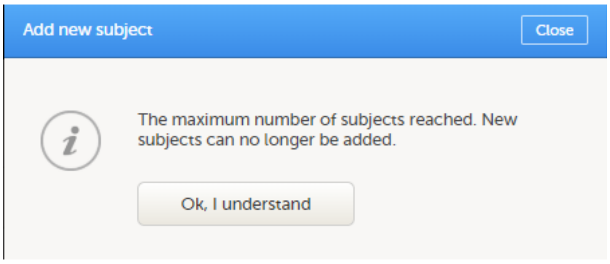
The first form in the study is displayed.

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

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

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

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



Queries overview

Published by Viedoc System 2024-10-10

1 Introduction

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

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

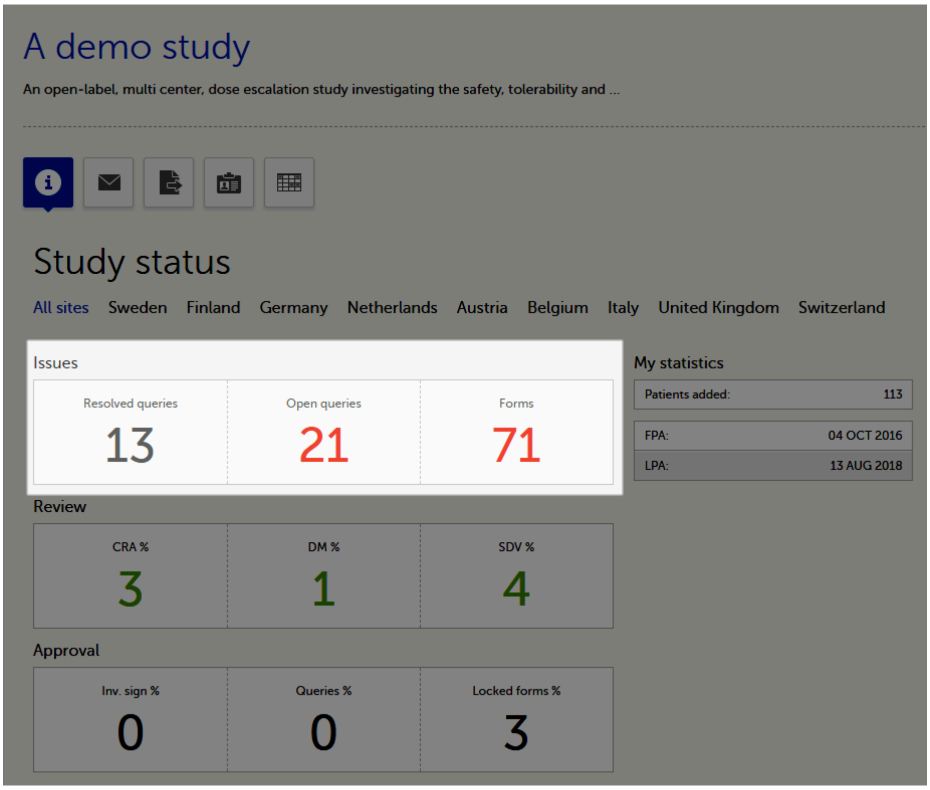
Note! All the related queries are automatically closed, when:

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

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

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

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



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

2 Role-based queries

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

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

Notes!

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

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

3 Manually raised queries

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

Manually raised queries can be:

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

3.1 Pre-queries

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

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

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

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

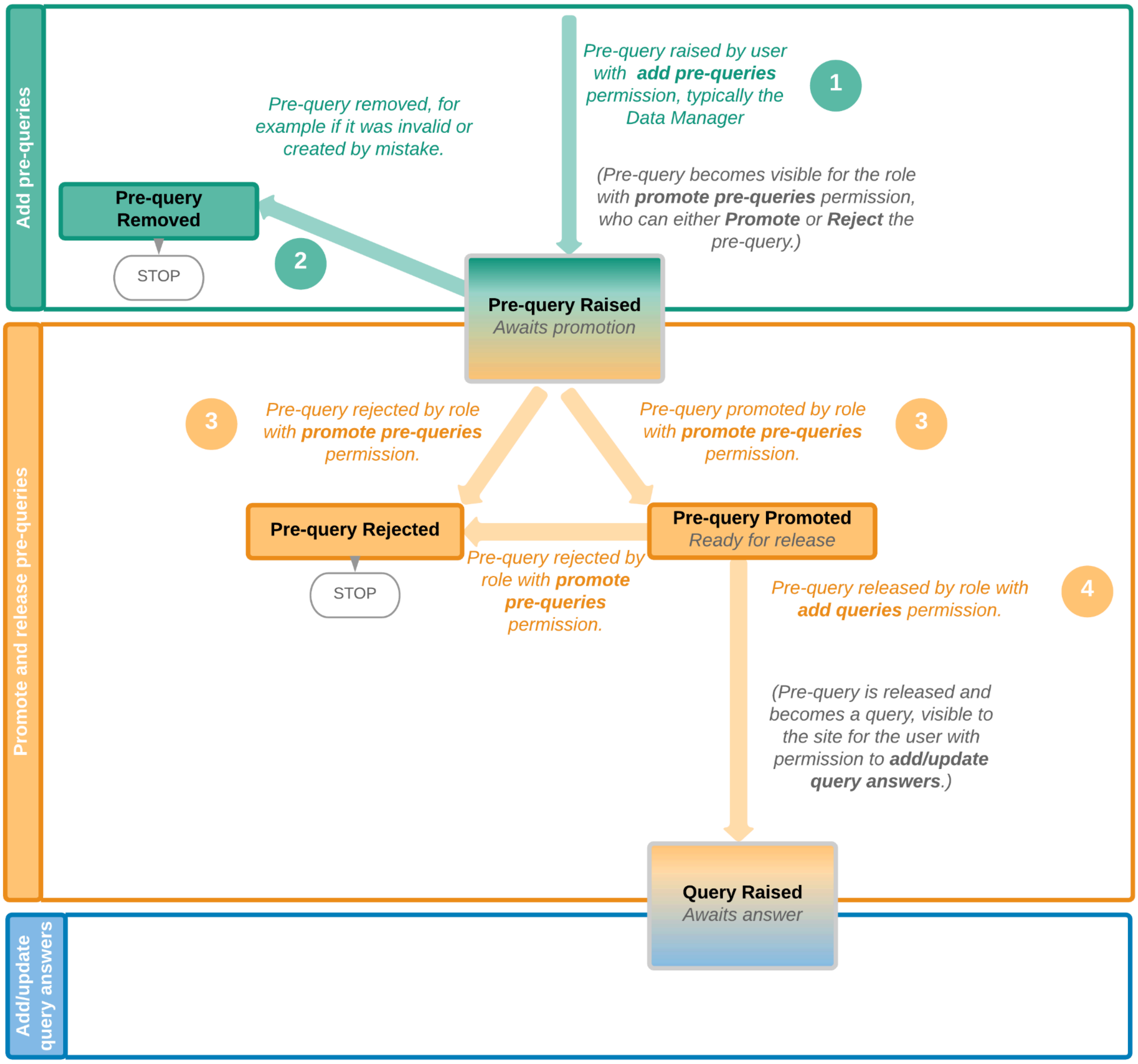
The following image illustrates the main actions that can be performed on a pre-query and all the states the pre-query goes through before it is released as a query:

1. The pre-query is added by the user with permission to add pre-queries, typically the Data Manager.
As a result, a pre-query is raised, becoming visible for the Viedoc Clinic user with permission to promote pre-queries, typically the Monitor.

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

3. The raised pre-query is promoted or rejected by the Viedoc Clinic user with permission to promote pre-queries, typically the Monitor.

4. The promoted pre-query is released by the Viedoc Clinic user with permission to add queries (typically the Monitor), becoming a raised query that is visible for the Viedoc Clinic user with permission to add/update query answers (typically the Investigator), who will be responsible for resolving the query, as described in [Queries](#).



3.1.1 Pre-query states

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

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

3.2 Queries

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

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

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

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

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

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

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

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

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

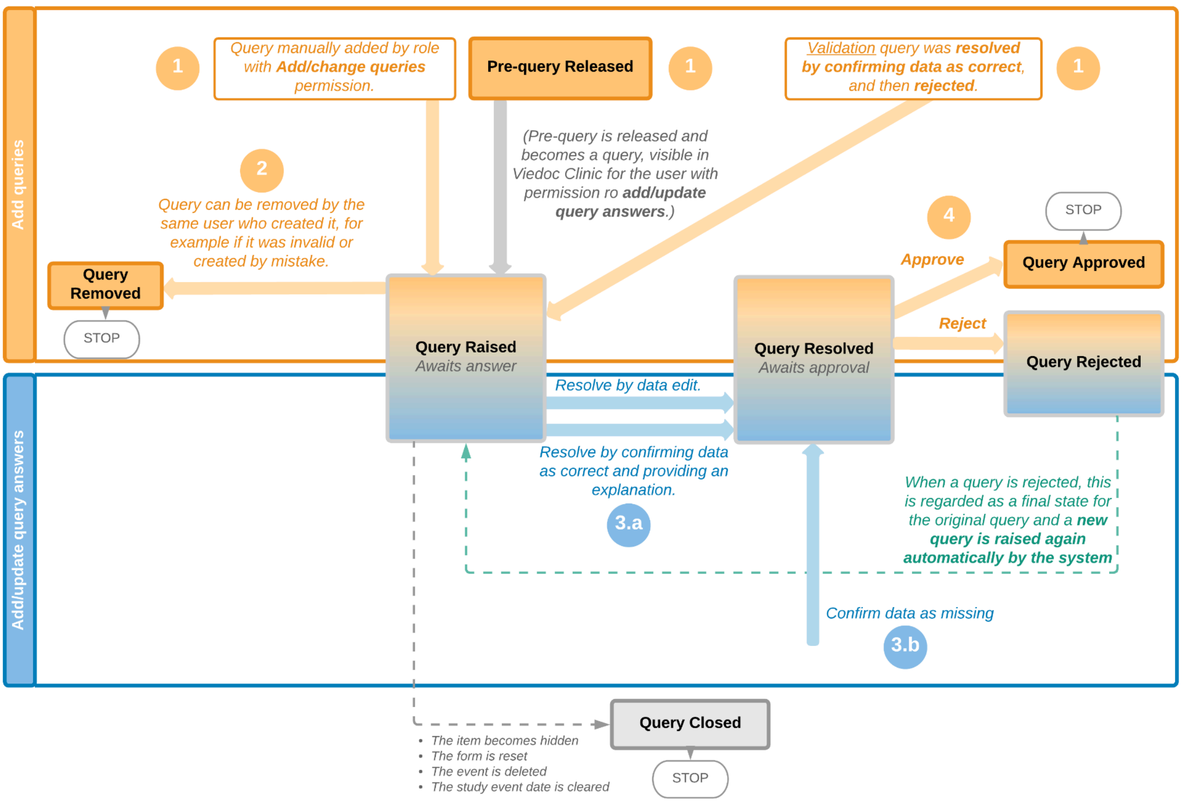
- Editing the data
- Confirming the data is correct and providing an explanation

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

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

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

See also [Query states]().



4 Validation queries

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

1. A query is raised as a result of a validation performed by the system.

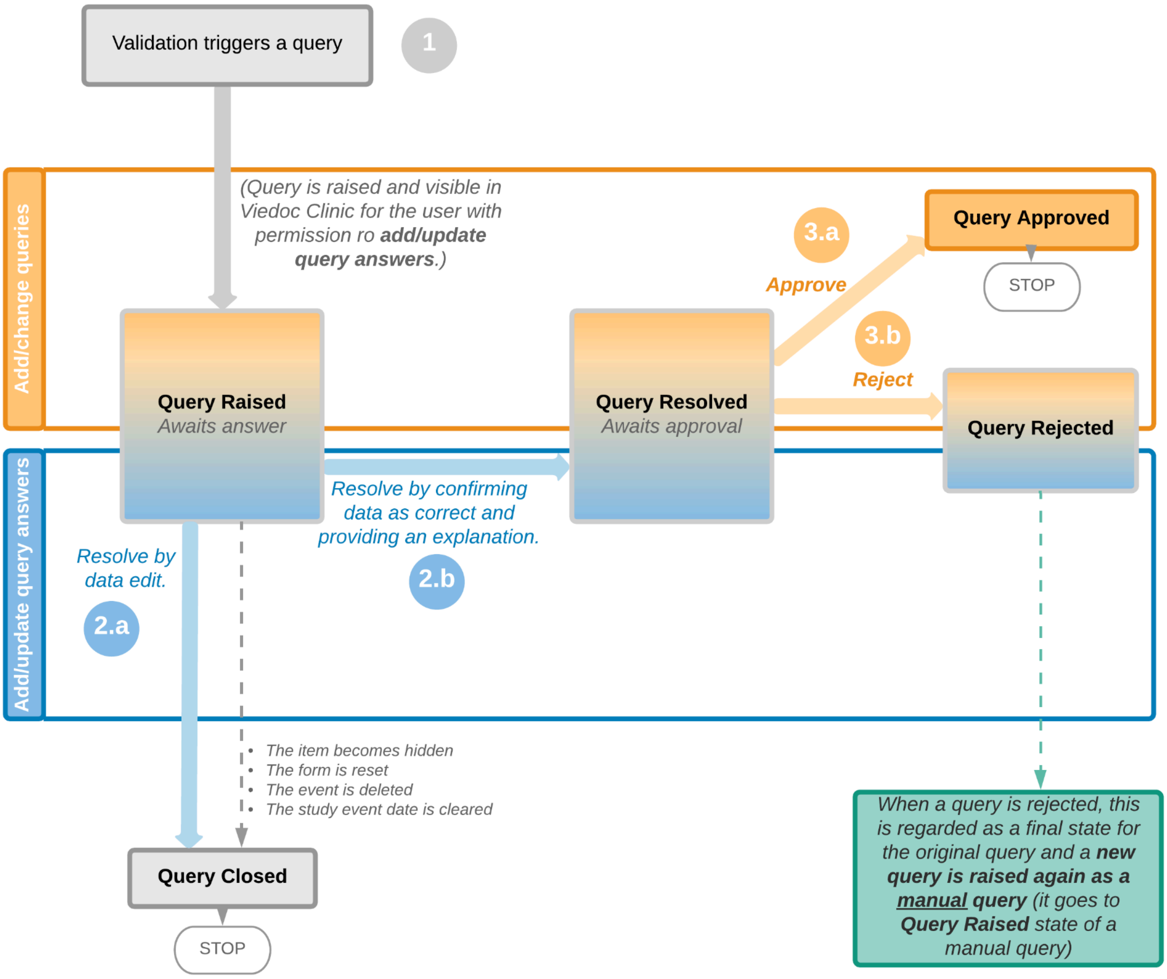
2. The user with permission to add/update subject/event/form data and query answers, typically the Investigator, resolves the query by one of the following:

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

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

a. **Approve** the resolved query.
b. **Reject** the resolved query. The old query becomes **Rejected** and a new query is raised and becomes a manual query. So from here it will follow the path of a manual query from the **Query Raised** state, as described earlier in Manual queries > Queries.

See also Query states.



5 Query states

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

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

- The item becomes hidden

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

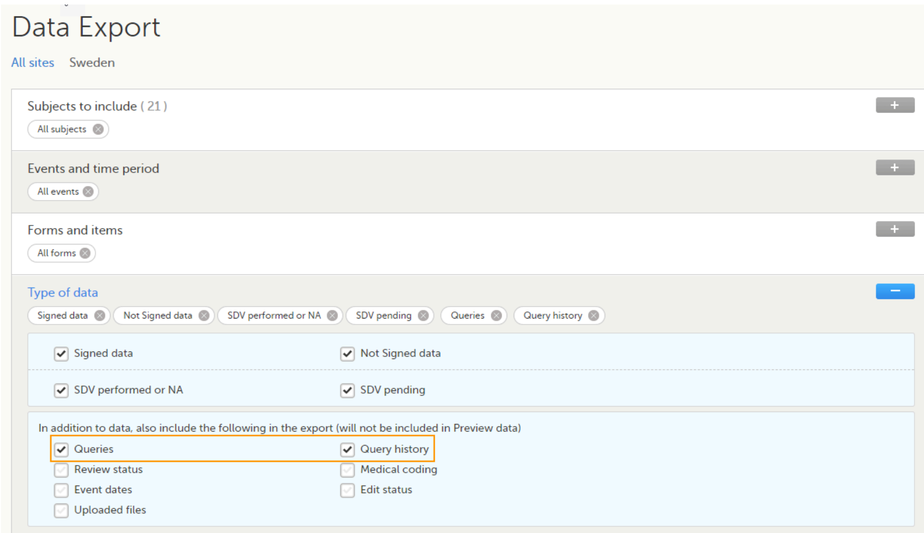
In Viedoc Clinic	In export output	Through...	Becomes...
Awaits answer	QueryRaised	Remove query (by Monitor)	QueryRemoved (**Removed**)
		Edit query (by Monitor)	QueryRaised (Awaits answer)
		Resolve query (by Investigator)	QueryResolved (Awaits approval)
Awaits approval	QueryResolved	Approve query (by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

6 Queries in export output

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

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

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



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

6.1 Queries in ODM export

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

6.2 Queries in Excel export

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

---

7 Related topics

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

Raising and promoting pre-queries

Published by Viedoc System 2024-10-10

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

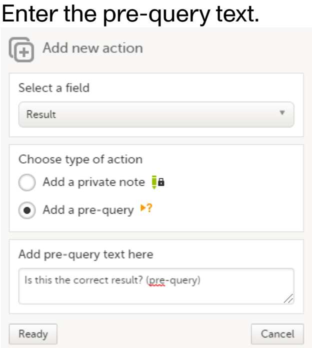
1 Raising a pre-query

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

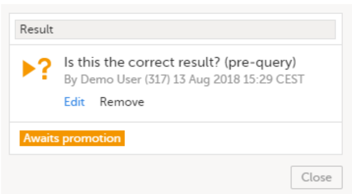
To add a pre-query:

1. Open the form that contains the field the pre-query will be raised on.

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



3. Click **Ready**. The pre-query is created and needs to be promoted and released by the user with permission to promote pre-queries (typically the Monitor), in order to be visible as a query for the site staff.
The pre-query can be edited or removed (if invalid or created by mistake) by clicking the **Edit** or **Remove** links:



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

A pre-query is always marked by this icon:

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

---

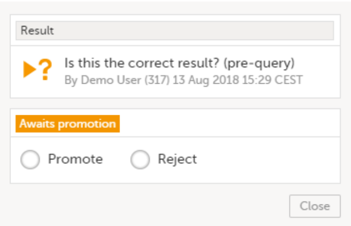
2 Promoting/Rejecting a pre-query

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

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

To promote a pre-query:

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



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

---

3 Releasing/Rejecting a pre-query

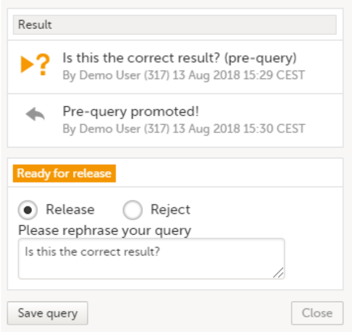
A pre-query can be released after it has been promoted, that is, a pre-query in Ready for release state.

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

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

To release a pre-query:

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



2

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

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

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

For more information on pre-queries, see Queries overview.

Raising/Approving/Rejecting queries

Published by Viedoc System 2024-10-10

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

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

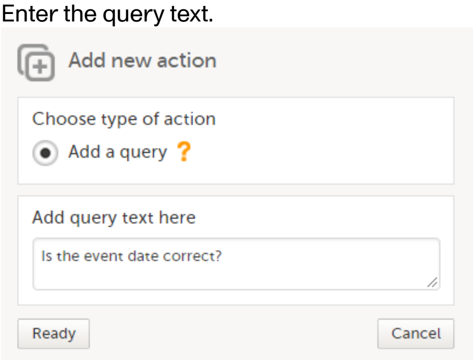
Note! When the role-based queries option is enabled for your study, all of the above actions are restricted to the same role as the role who raised the query. For more information, see Role-based queries.

1 Adding a query

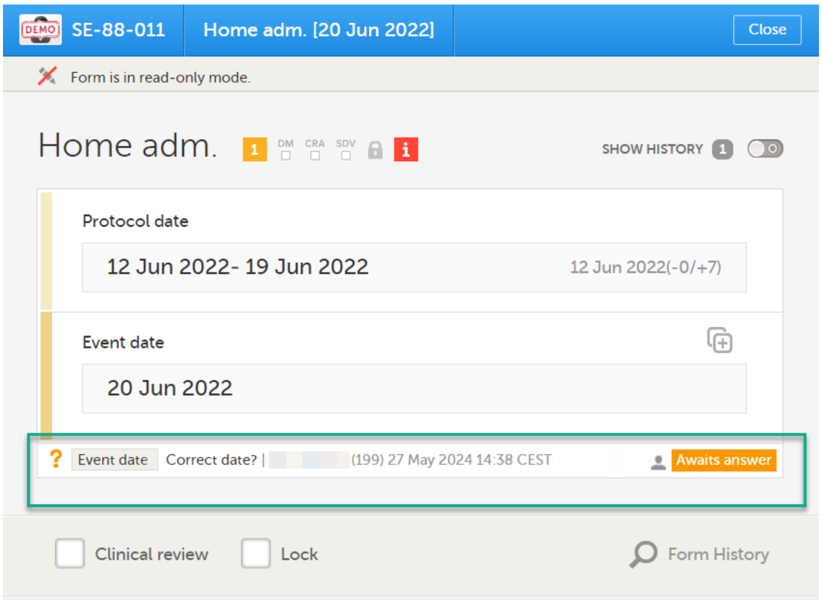
To raise a query:

1. Open the form that contains the field the query will be raised on.

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



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



After the query has been raised it can be:

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

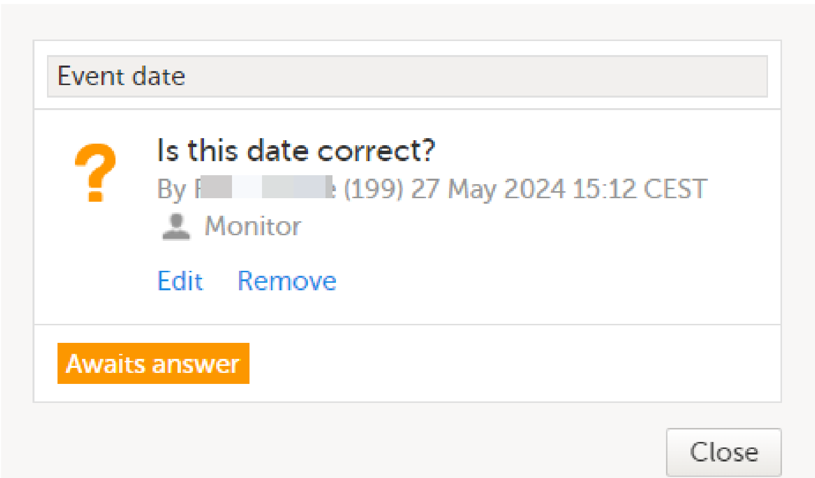
---

2 Editing a query

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

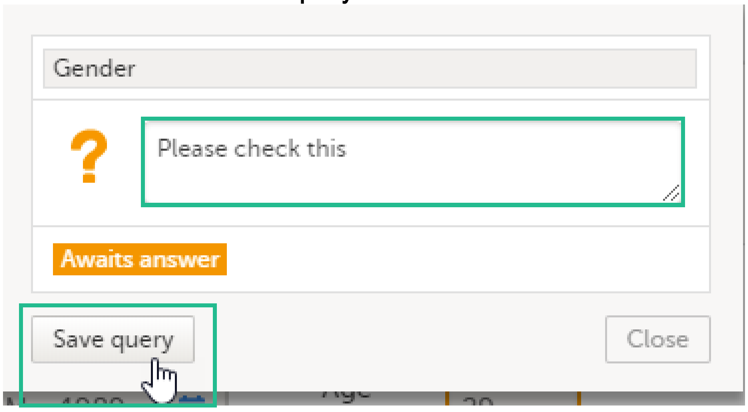
To edit a query:

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



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

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



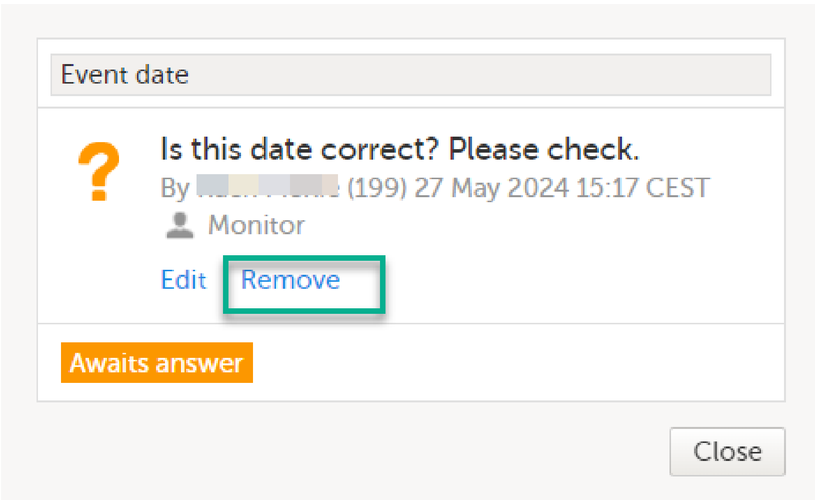
The query text is now updated.

3 Removing a query

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

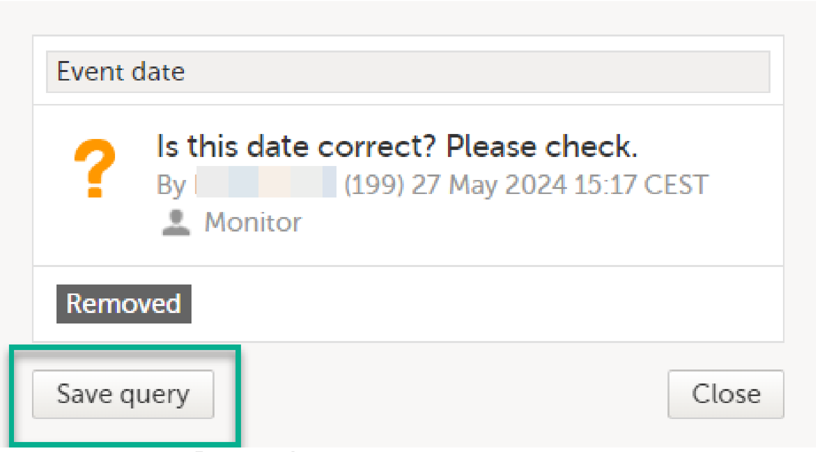
To remove a query:

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



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

2 Click **Save query** to confirm:

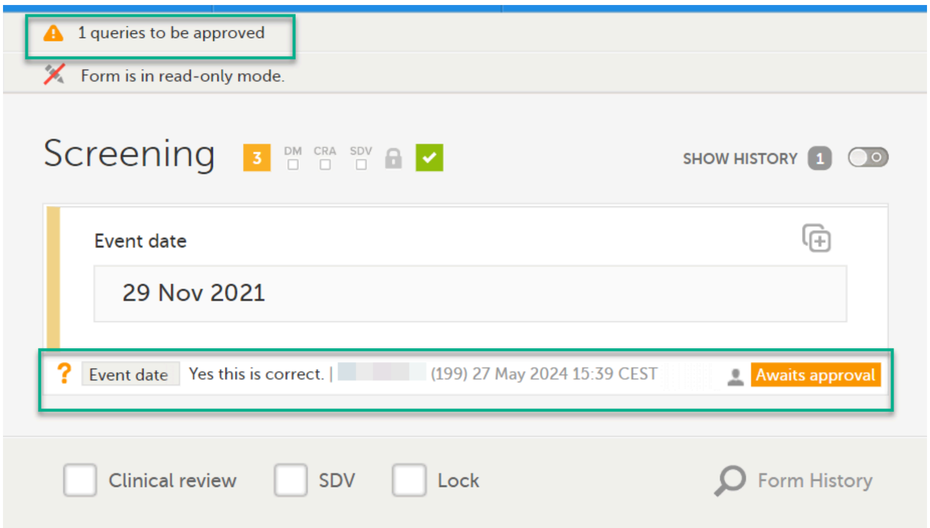


The query state is **Removed**. This is a final state for a query.

4 Approving/Rejecting a query

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

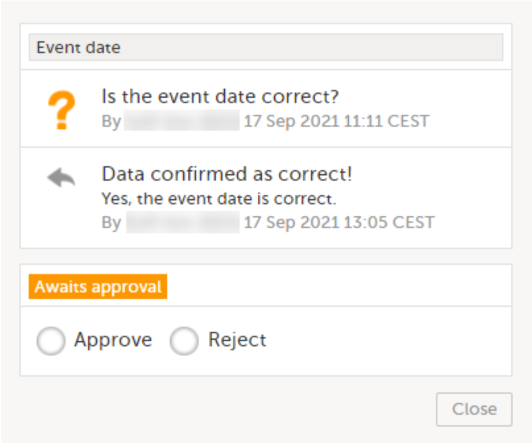
Note! An exception is a query raised as a result of confirming data as missing by the site user. This type of query can only be approved.



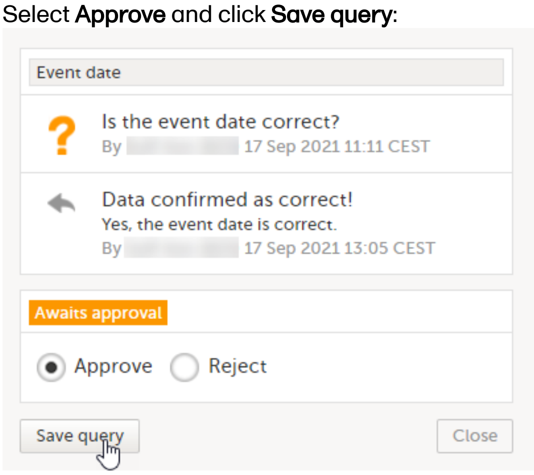
4.1 Approving a query

To approve a query:

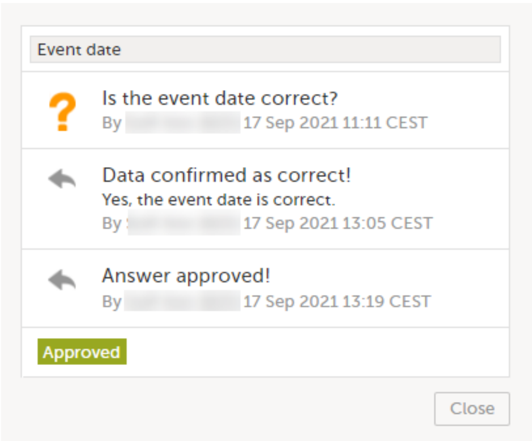
1 Open the query. The query pop-up opens displaying the list of the query history:



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



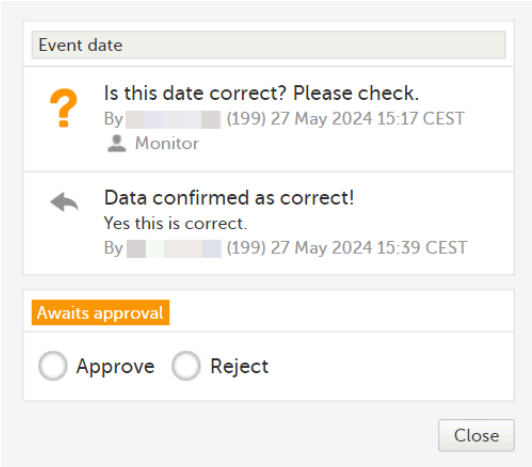
The query is now **Approved**. This is a final state for a query:



4.2 Rejecting a query

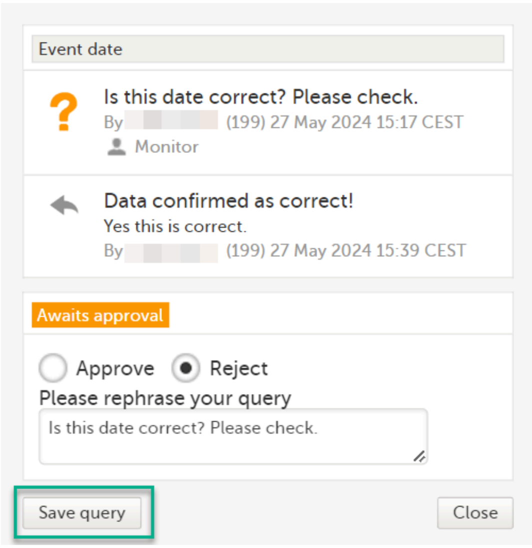
To reject a query:

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

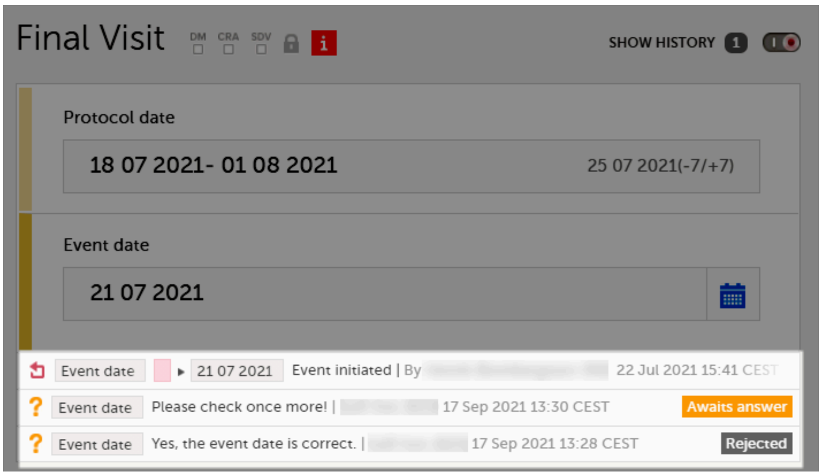


Note! The avatar icon and the user role who raised the query is only visible if role-based queries is enabled for the study. For more information, see Role-based queries.

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



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



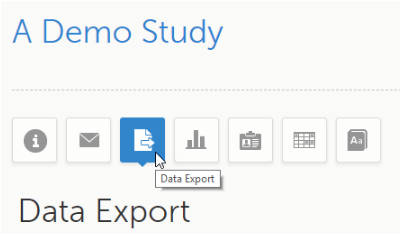
Exporting data

Exporting data

Published by Viedoc System 2025-02-18

1 Introduction

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



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

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

---

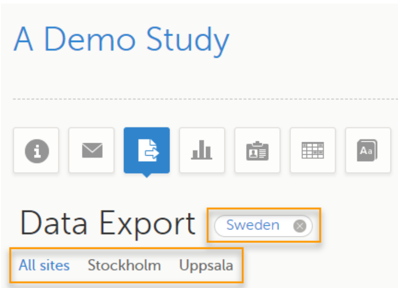
2 Filtering the data to be previewed/exported

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

2.1 Filtering data by country and site

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

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



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

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

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

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

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

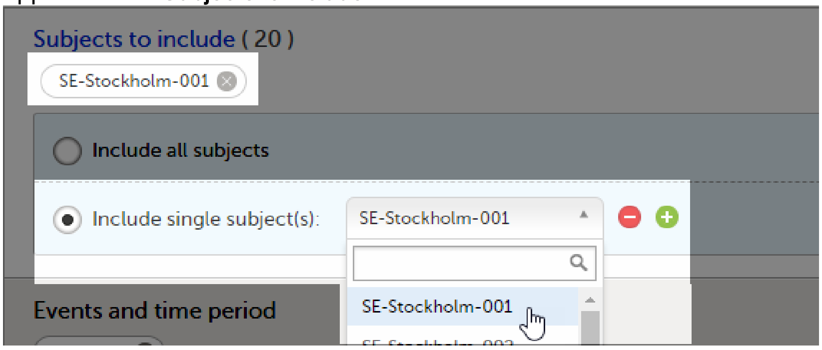
2.2 Including subjects

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

To select which subjects to include:

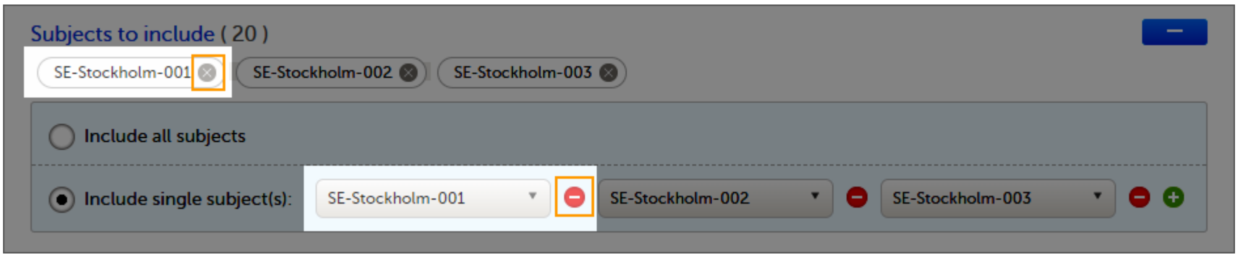
1 Select **Include single subject(s)**.

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



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

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



2.3 Events and time period

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

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

2.3.1 Selecting events

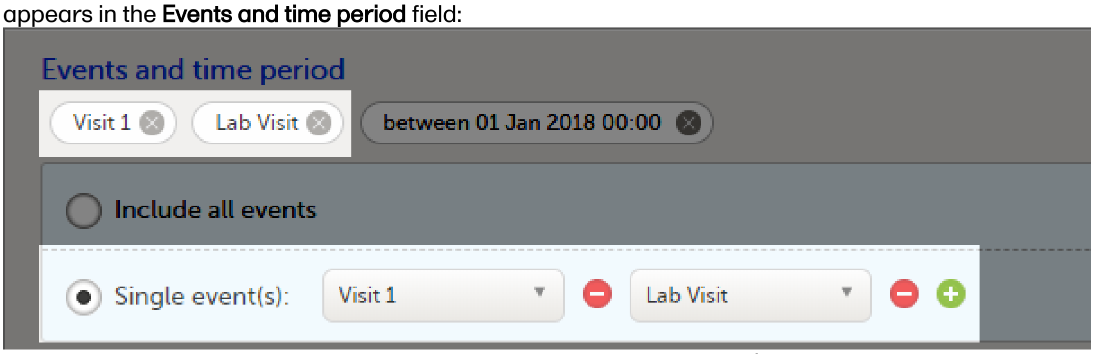
You can choose to:

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

To select which events to include:

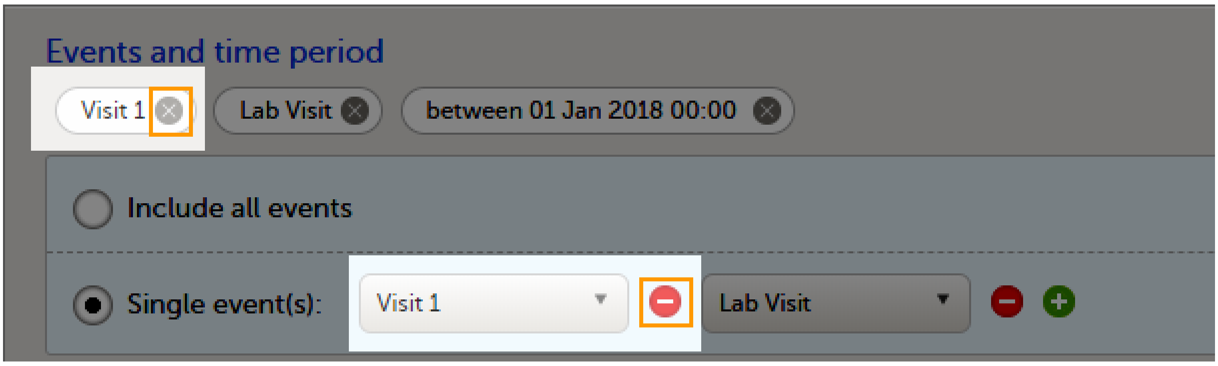
1 Select **Single event(s)**.

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



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

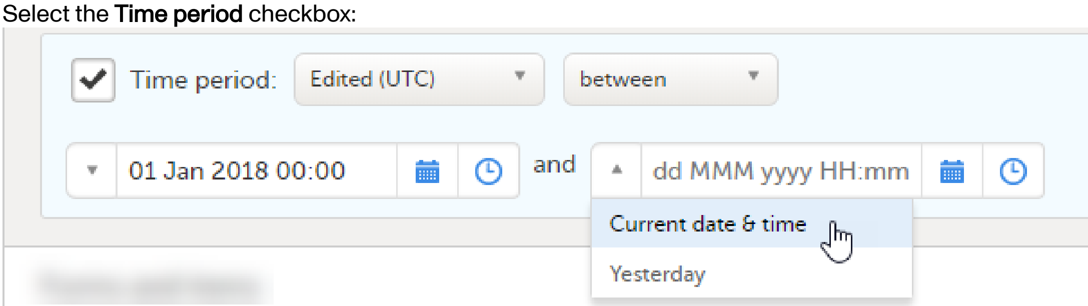
To undo the selection of certain events, click the - icon, or click the cross x icon next to the event:



2.3.2 Selecting a time period

To include data from a specific time period:

1 Select the **Time period** checkbox:



2 Select one of the following options from the first drop-down list:

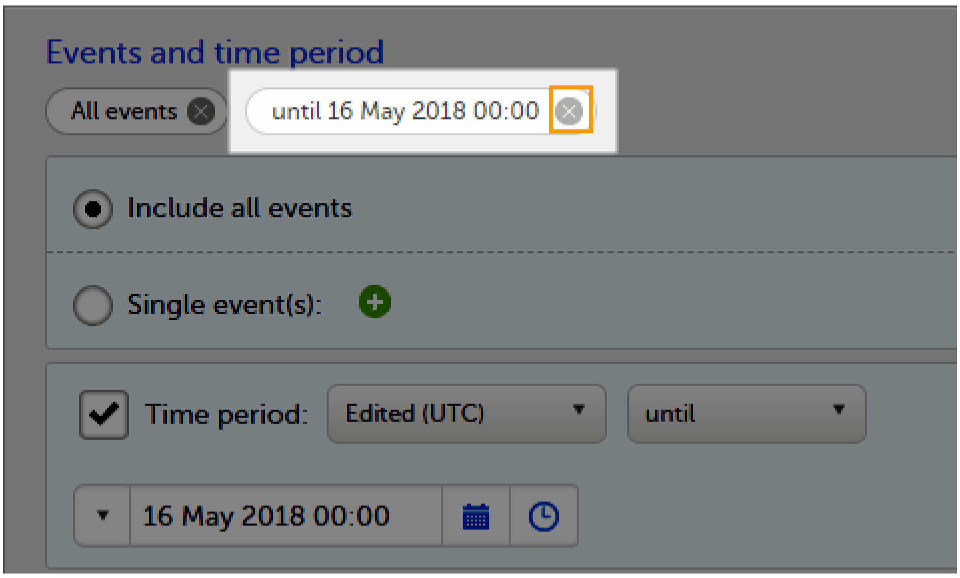
- **Edited (UTC)** - to include data based on the date they were added or last edited.
Note! This feature includes data based on Coordinated Universal Time (UTC), not on the local time a user has added or edited data. Note that also the time period should be specified in UTC.
- **Event date** - to include data based on the event date.

3 Select whether to define the time period **until** a certain date, **from** a certain date, or **between** two dates.

4 Select the date(s).

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

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



2.4 Forms and items

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

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

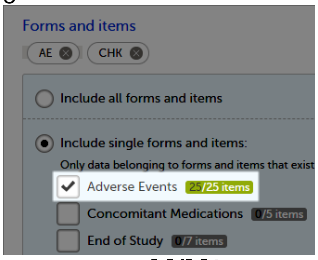
Note! Only data belonging to forms and items that exist in the latest effective design applied to the first of the selected sites will be included in the export. Also note that the forms and fields available to choose from are determined by the visibility settings for your user role.

To include data from specific form(s):

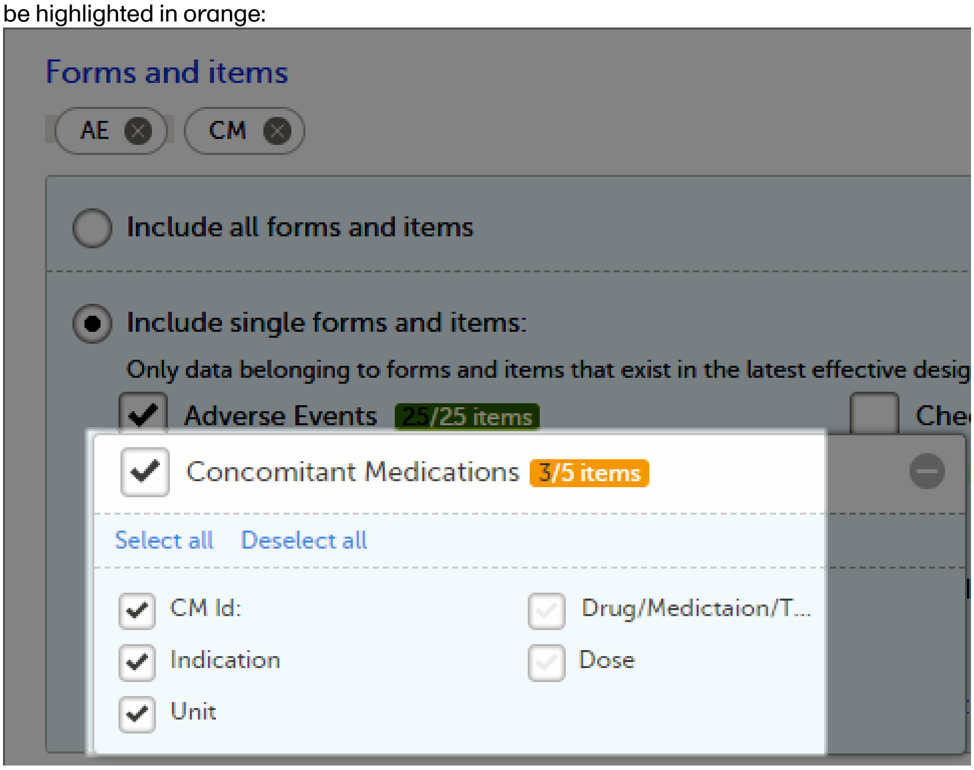
1 Select **Include single forms and items**.

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

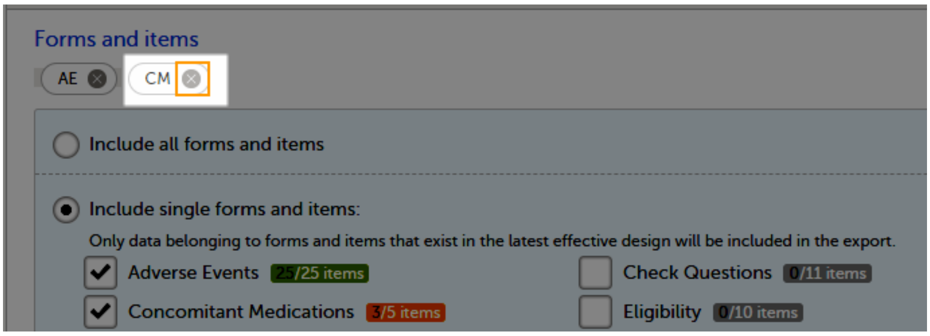
- Select the checkbox corresponding to a form in the list displayed, to include the respective form with all the items contained. The selected/total number of items will be highlighted in green:



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



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



2.5 Type of data

2.5.1 Filter data by review status

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

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

2.5.2 Additional information

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

2.5.2.1 Booklet status

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.5.2.2 Queries and Query history

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

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

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

See also:

- Queries in ODM export
- Queries in Excel export

2.5.2.3 Review status

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

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

See also:

- Review status in ODM export
- Review status in Excel export

2.5.2.4 Event dates

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

- Microsoft Excel - Office Open XML
- CSV
- ODM

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

Column name	Description
Site sequence number	A counter that identifies the site globally within the study
Site name	The site name, as set in Viedoc Admin
Site code	The site code, as set in Viedoc Admin
Subject sequence number	A counter that identifies the subject within the site
Subject Id	The Subject ID, in the format configured in Viedoc Designer. The Subject ID is the subject identifier displayed in Viedoc Clinic on the subject card, subject details page, and so on.
Event Id	The event ID, as set in the study design (in Viedoc Designer)
Event name	The event name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Event repeat key	For recurring events, the counter that identifies different occurrences of the same event (identified by the Event ID). Available for output versions Viedoc 4.39 and onward.
Event status	The current status of the event. It can be one of the following: ▪ *Initiated* ▪ *Proposed* ▪ *Not Initiated* ▪ *Planned*
Event date	The event date, as set in Viedoc Clinic when the event is initiated
Planned date	The event planned date, as set in Viedoc Clinic when the event is planned
Proposed date	The proposed date for the event, if set in the study design
Window start date	The event time window start date, if set in the study design.
Window end date	The event time window end date, if set in the study design
Initiated by	The name and ID of the user who initiated the event
Initiated date (UTC)	The date and time (UTC) when the event was initiated
Last edited by	The name and ID of the user who last edited the event
Last edited date (UTC)	The date and time (UTC) when the event was last edited

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

2.5.2.5 Uploaded files

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

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

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

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

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

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

2.5.2.6 Pending forms

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

- Microsoft Excel - Office Open XML
- CSV

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

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

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

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

2.5.2.7 Medical coding

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

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

2.5.2.8 Edit status

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

- Microsoft Excel - Office Open XML
- CSV
- PDF - PDF/A
- ODM

2.5.2.9 Subject status

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

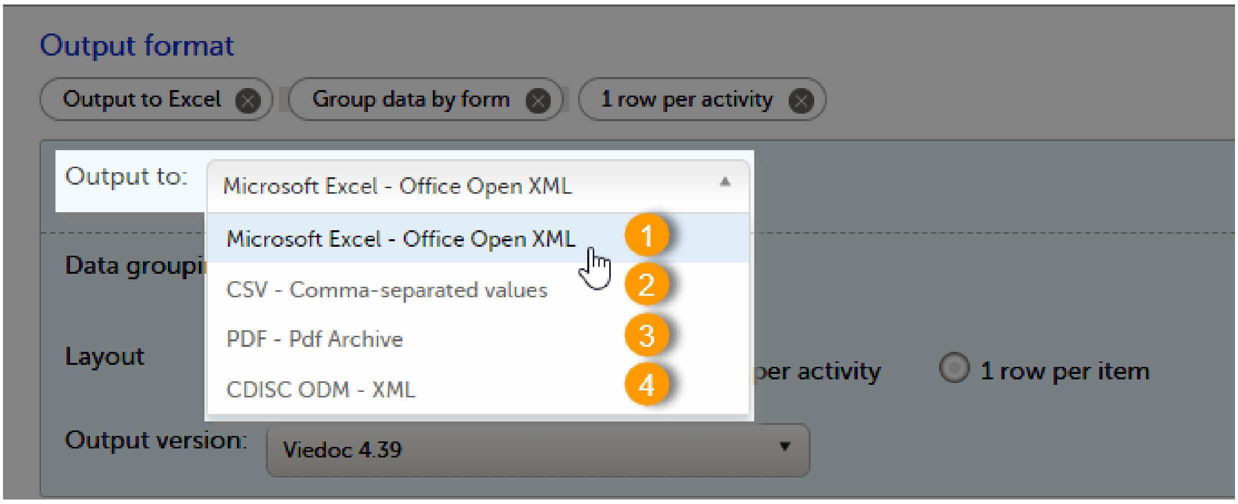
- Microsoft Excel - Office Open XML
- CSV
- ODM

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

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

3 Export output formats

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



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

1. Microsoft Excel - Office Open XML

2. CSV

3. PDF - PDF/A

4. ODM

3.1 Microsoft Excel / CSV

Viedoc uses Microsoft Excel Open XML format which is compatible with Excel version 2007 and later.

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

3.2 CSV

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

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

3.3 PDF

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

3.4 CDISC ODM

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

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

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

The ODM export file is built up as follows:

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

See also:

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

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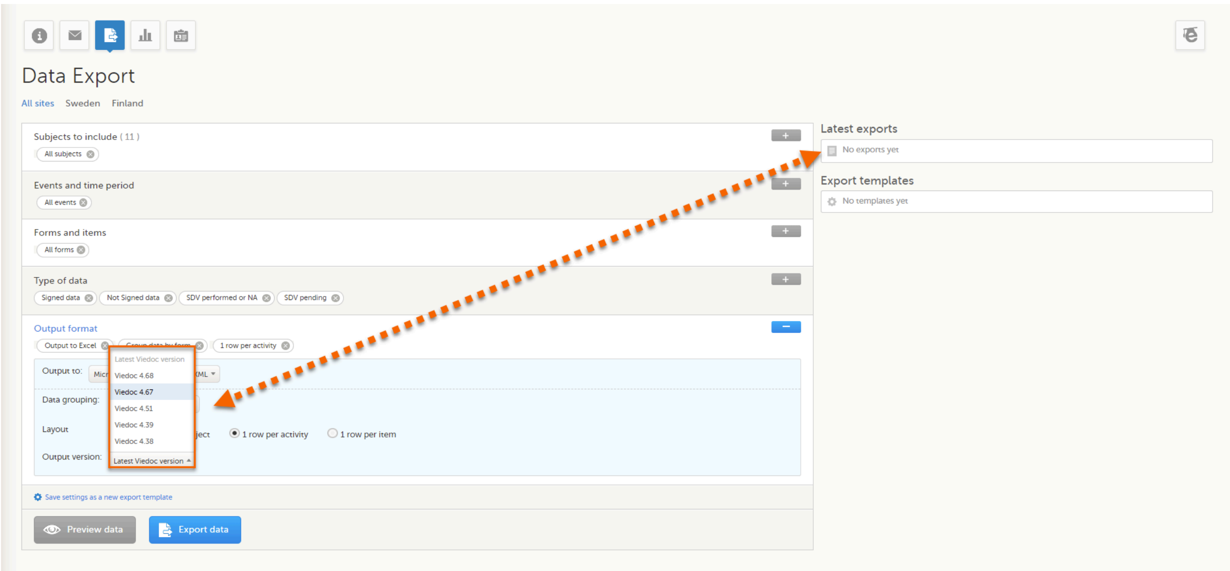
4 Export compatibility with previous Viedoc versions

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

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

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



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

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

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

4.1 Output versions

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

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

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

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

File type	Changes in the export output format
ODM	Introduction of support for partial datetime, date, and time. This is now the default type when exporting designs and data in ODM format. Partial dates as per the ISO 6801 standard are written up to the most detailed value available. This makes the export compliant with CDISC ODM.
ODM	When exporting a design to ODM, multi-selection code lists are handled as follows: Checkbox item definitions are split by code list items. • During metadata export, checkbox ItemDef is replaced with one for each code list item. • For clinical data export, the comma-separated values are replaced for the checkbox with ItemData for each respective value. For example, when splitting a checkbox ItemDef with OID="CHK" and code list IDs "Yes" and "No", the split checkbox ItemDefs will have the OIDs "__CHK__Yes" and "__CHK__No", respectively. That is, the original OIDs and the code list IDs are prefixed with two underscore characters and separated by two underscore characters. In Viedoc Designer, checkbox items are exported as multiple ItemDefs - one for each selection value. In Viedoc Clinic and the Viedoc API: In the latest export version, checkboxes are exported as separate items for metadata and clinical data. In previous export versions, checkboxes are exported as one item. This has been introduced to be compliant with CDISC ODM.

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

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

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

File type	Changes in the export output format
Excel	Addition of three columns for the new form sequence numbers introduced: • `SubjectFormSeqNo` – Counter that uniquely identifies the instance of a specific form on a subject level, that is, it starts with 1 and is incremented each time a new instance of the form is created for that subject. • `OriginSubjectFormSeqNo` – For a copied form instance, it identifies the form instance from which data was copied for the first time. For the first instance of the form (that is, not copied) it gets the value of the `SubjectFormSeqNo` . • `SourceSubjectFormSeqNo` – For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the `SubjectFormSeqNo` from which the form instance was copied. For the first instance of the form (that is, not copied) it is empty.
ODM	Three new form sequence numbers were introduced, as Viedoc extensions: `v4:SubjectFormSeqNo` , `v4:OriginSubjectFormSeqNo and v4:SourceSubjectFormSeqNo` , within the `FormData` , right after the `FormRepeatKey` .
PDF	A table of contents was added to the PDF archive, starting on page 2 of the file.

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

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

5 How study design impacts data export

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

What happens when study designs differ?

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

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

What does "first selected site" mean?

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

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

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

Selecting multiple sites with different study designs

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

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

Best practices to ensure accurate exports:

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

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

Example scenario: How study design affects data export

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

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

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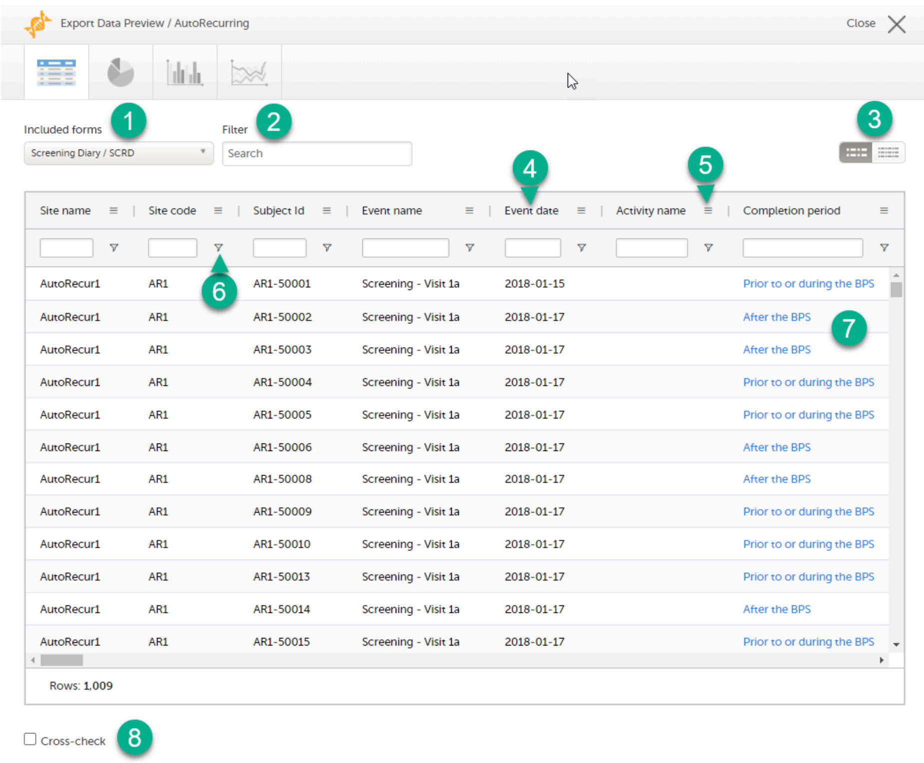
6 Previewing data

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

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

6.1 Data table

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



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

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

3. Toggle between spacious view and compact view.

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

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

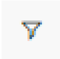
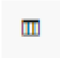
6. Click to access the column filter. For more information, see Column filter.

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

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

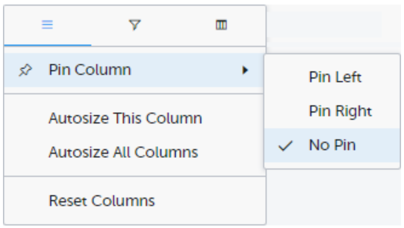
6.1.1 Column menu

The column menu contains:

- column display options 
- column filter 
- column selection options 

For more information, see the following sub-sections.

6.1.1.1 Column display options



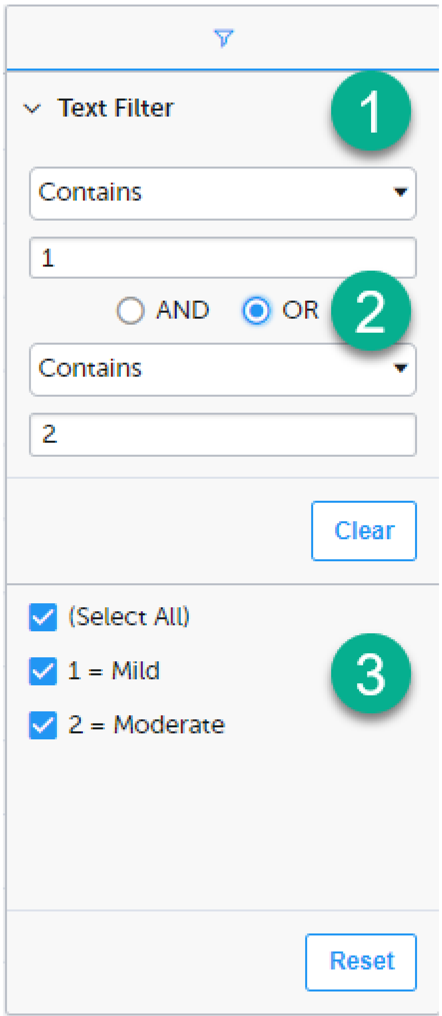
Pin Left/Right makes a column remain visible in the leftmost or rightmost position when you scroll sideways. Select **No Pin** to unpin the column.

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

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

6.1.1.2 Column filter

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



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

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

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

  Note! The text filters are case-insensitive.

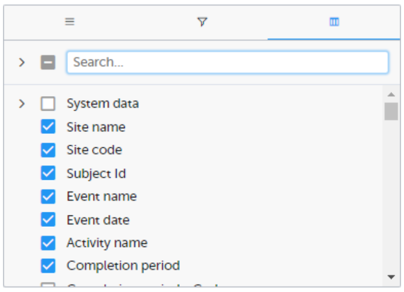
- Number filter with the following filter operators:
  - Equals
  - Not equal
  - Less than
  - Less than or equals
  - Greater than
  - Greater than or equals
  - In range

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

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

6.1.1.3 Column selection options

Select the columns to be displayed in the preview table.

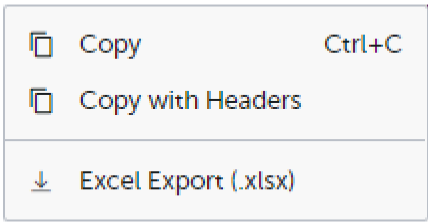


Use the **Search** field to search for columns.

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

6.1.2 Data table context menu

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



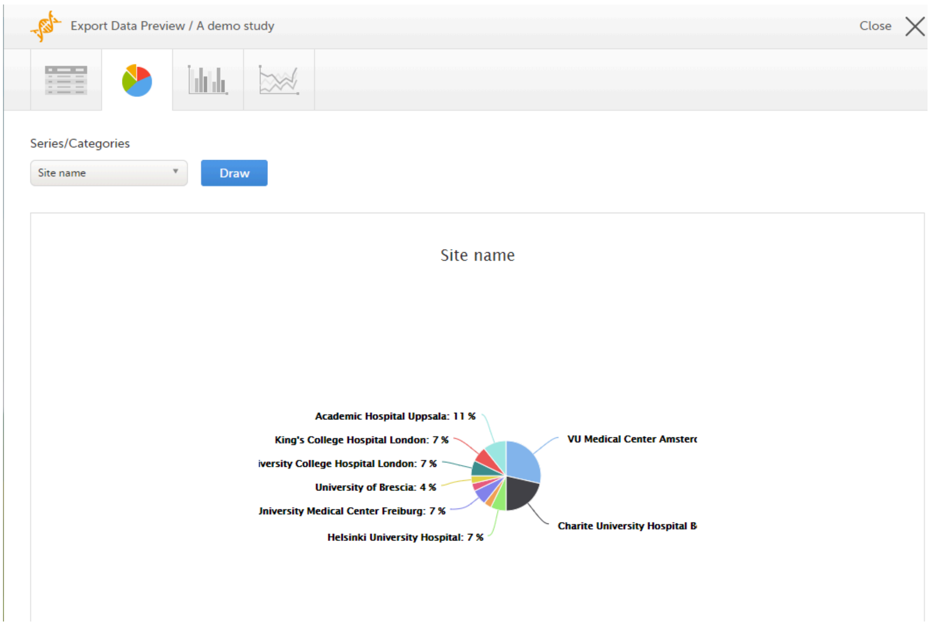
Copy: Copies the cell value to your clipboard.

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

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

6.2 Pie chart

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



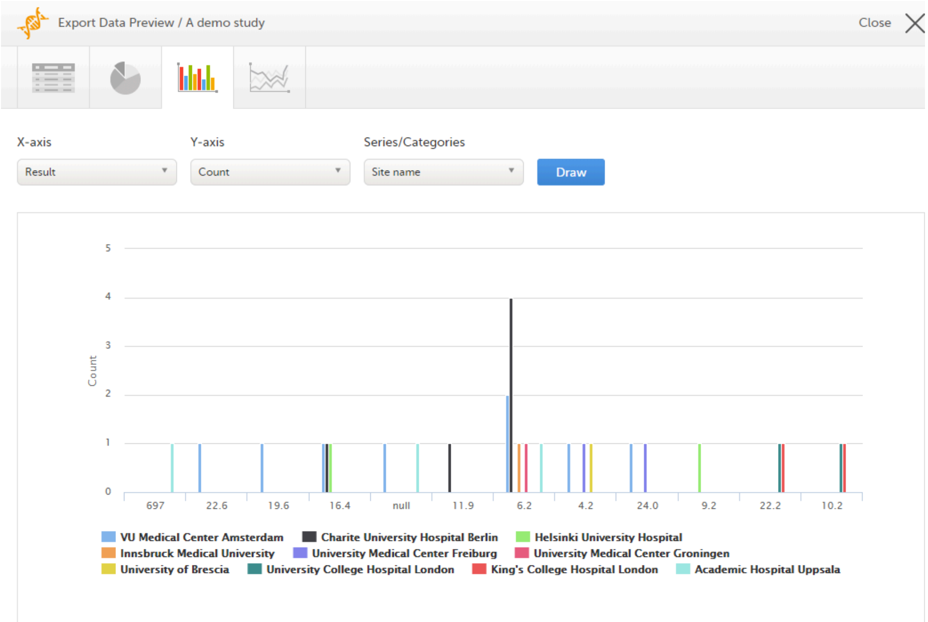
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any data point to view its details.

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

6.3 Column chart

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



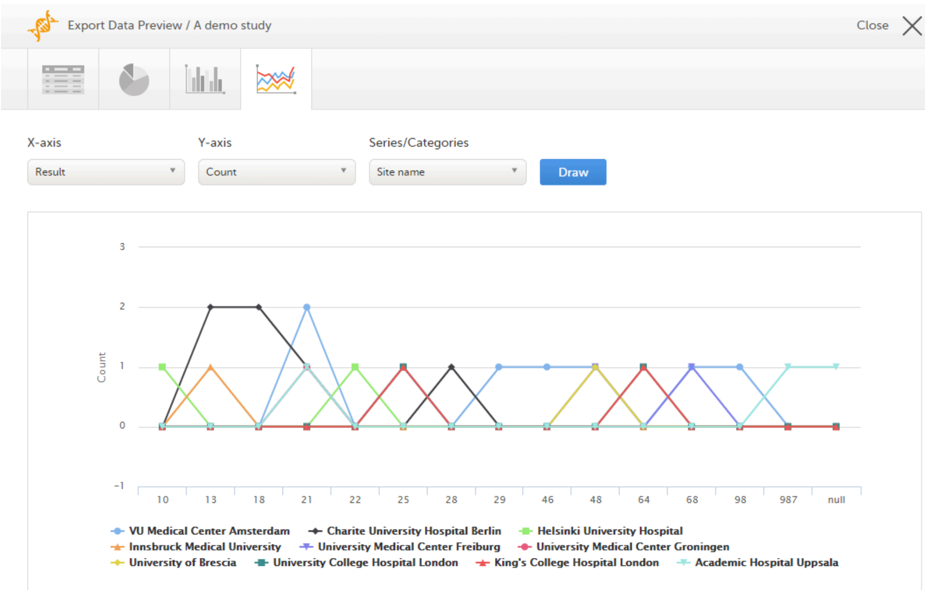
If you have selected **Group data by form**, you can only choose data sets from the form you have selected on the data table tab.

Click any column to view details of the data.

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

6.4 Line chart

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



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

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

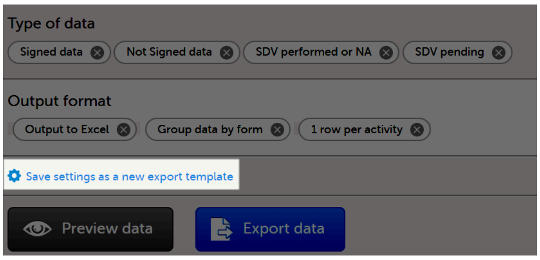
7 Data export templates

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

7.1 Saving export settings as a template

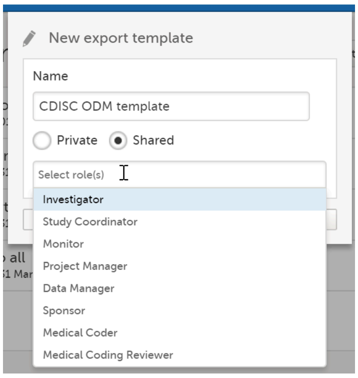
To save your settings as a template:

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

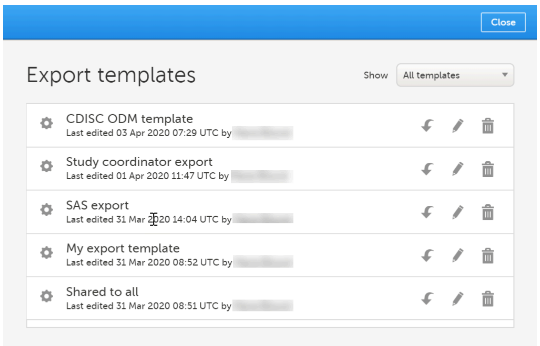


2. In the pop-up that is displayed, enter a name for the template and select whether it should be private or shared.

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



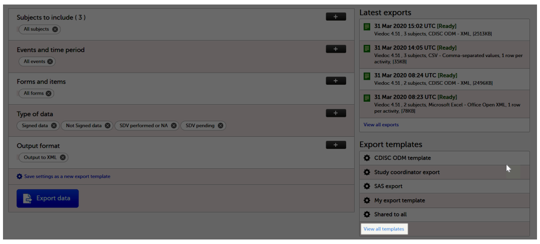
3. Click **Save**. Now the **Export templates** list is displayed, with your newly created template at the top of the list:



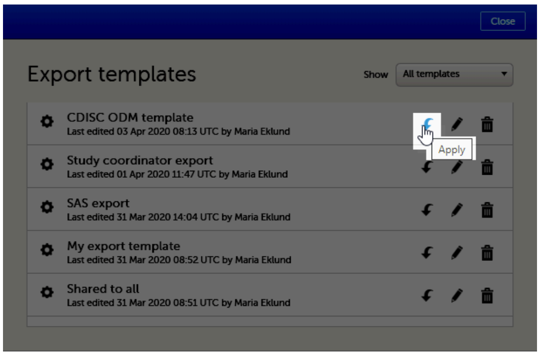
7.2 Applying a data export template

To apply a data export template:

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

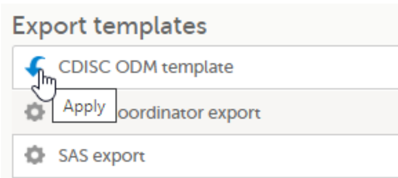


2 Click the apply icon for the template that you want to apply.



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

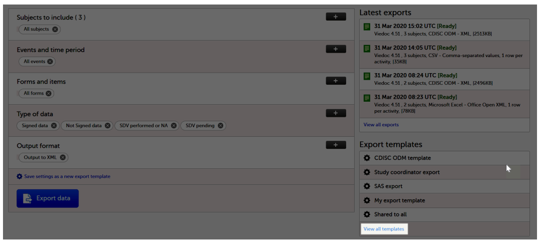
Tip! Alternatively, you can use the quick access apply, available in the **Export templates** area:



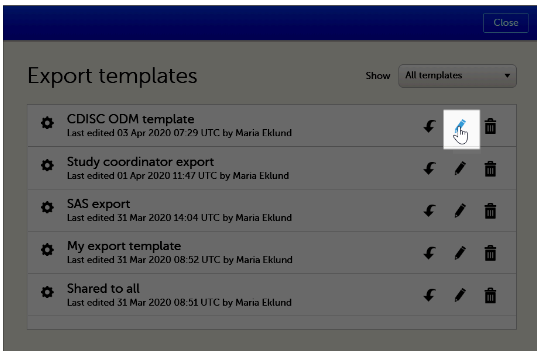
7.3 Editing a data export template

To edit a data export template:

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



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



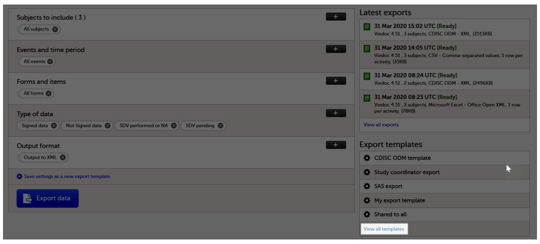
3 In the pop-up that is displayed, you can edit the name of the export template and the settings for **Private/Shared**.

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

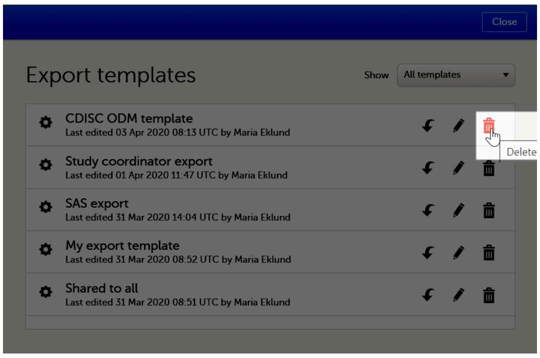
7.4 Deleting a data export template

To delete a data export template:

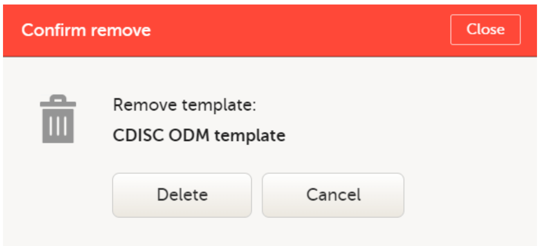
1 Click **View all templates** in the **Export templates** area of the **Data export** page.



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



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



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

8 Exporting data

To perform a data export:

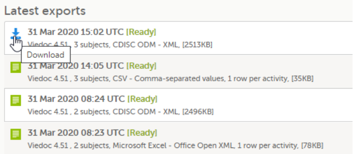
1 Filter the data to be exported. See Filtering the data to be exported.

2 Select the Output format.

3 Optionally, select the Output version.

4 Optionally, preview the data to be exported.

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



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

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

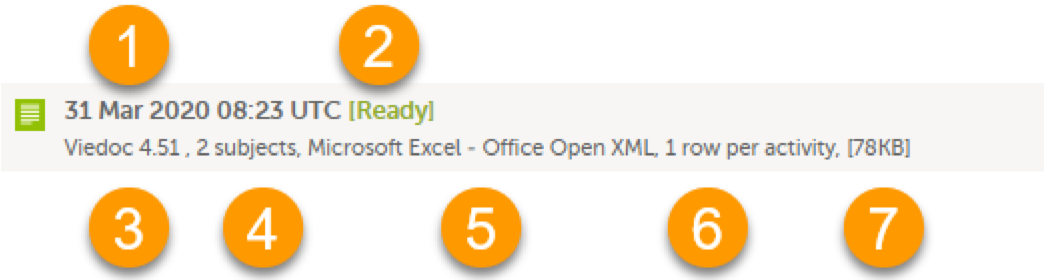
Note! If any of the characters that are invalid for a filename in Windows are used within any of the *SponsorCode* or *SiteCode*, these characters will be automatically replaced with **-** within the exported filename.

8.1 Latest exports

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

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

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



Each log entry provides the following information:

1. The date and time when the export was initiated.

2. The export status:

- **In Queue** - the export request is in queue, waiting to be processed.
- **In Progress** - the exported started and is in progress.
- Ready - the file was successfully exported and is ready for download.
- Error - an error was encountered and the export was not performed.

3. Viedoc output version - see Output versions.

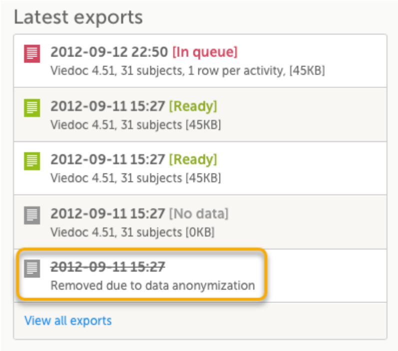
4. The number of exported subjects.

5. The format of the output file.

6. The selected layout, if applicable.

7. File size

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



9 Exporting Data FAQ

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

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

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

Q: Is there a size limit to exports?

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

Q: Can I schedule exports automatically?

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

Q: How is missing data handled?

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

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

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

Excel export

Excel export

Published by Viedoc System 2024-12-03

1 Introduction

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

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

For general information about data export in Viedoc, see Exporting data.

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

2 File structure

The Excel export contains the following sheets:

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

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

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

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

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

2.1 Header rows

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

1. Human-readable format

2. Machine-readable format

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

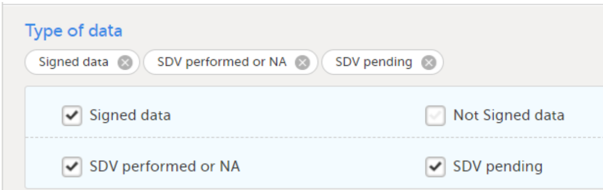
An item that was changed within a new/revised study design version will have a "__*n*" suffix added, where *n* is incremented for each study design version where the respective item was changed:

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

3 Data filtering - Type of data

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

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



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

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

4 Data grouping

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

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

4.1 Group data by form

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

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

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

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

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

4.2 Do not group data

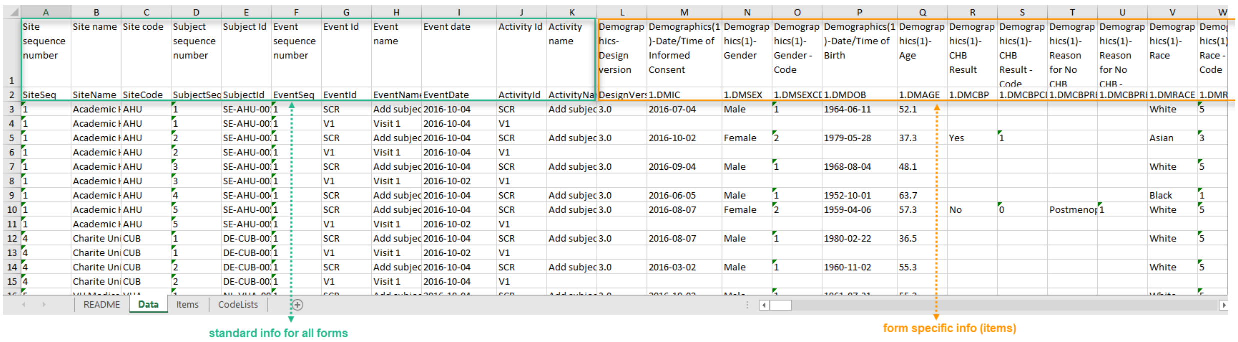
If you choose not to group the data, then all data from all forms will be exported in the same sheet (**Data**) of the output file.

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

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

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

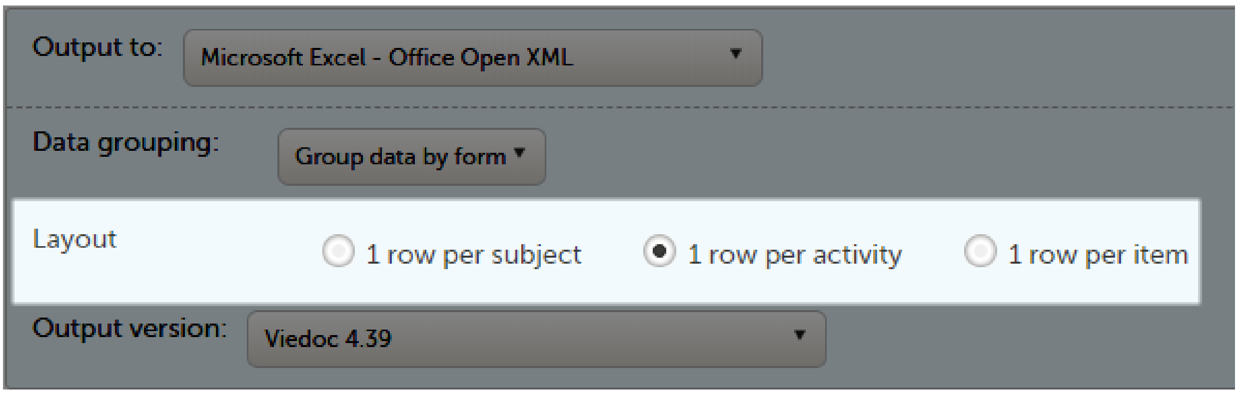
- <*FormName>_Design Version* - the form name, as set in the study design (in Viedoc Designer) and displayed in Clinic. In the example in the image, the form name is *Demographics.*
- *<FormName>(<Form Repeat Key>)_<ItemName>* - for each item in the respective form. The form name and item name, as set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



5 Layout

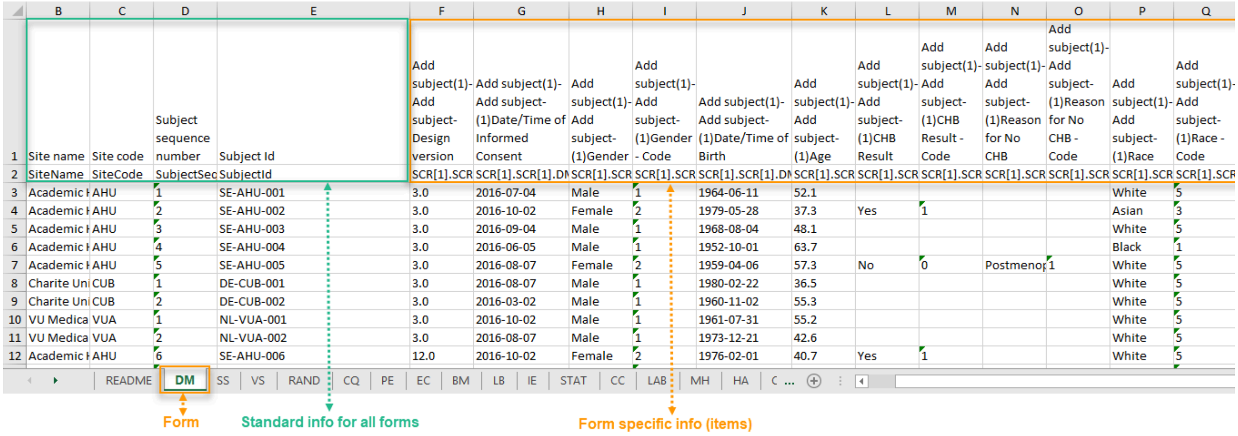
In the **Layout** section, you can select whether the data should be organized in the output file as:

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



5.1 One row per subject

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



	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Site name	Site code	Subject sequence number	Subject Id	Add subject(1)-Add subject-Design version	Add subject(1)-Add subject-(1)Date/Time of Informed Consent	Add subject(1)-Add subject-(1)Gender	Add subject(1)-Add subject-(1)Gender - Code	Add subject(1)-Add subject-(1)Date/Time of Birth	Add subject(1)-Add subject-(1)Age	Add subject(1)-Add subject-(1)CHB Result	Add subject(1)-Add subject-(1)CHB Result - Code	Add subject(1)-Add subject-(1)Reason for No CHB	Add subject(1)-Add subject-(1)Reason for No CHB - Code	Add subject(1)-Add subject-(1)Race	Add subject(1)-Add subject-(1)Race - Code
2	SiteName	SiteCode	SubjectSec	SubjectId	SCR[1].SCR	SCR[1].SCR[1].DM	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR[1].DM	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR	SCR[1].SCR
3	Academic H	AHU	1	SE-AHU-001	3.0	2016-07-04	Male	1	1964-06-11	52.1					White	5
4	Academic H	AHU	2	SE-AHU-002	3.0	2016-10-02	Female	2	1979-05-28	37.3	Yes	1			Asian	3
5	Academic H	AHU	3	SE-AHU-003	3.0	2016-09-04	Male	1	1968-08-04	48.1					White	5
6	Academic H	AHU	4	SE-AHU-004	3.0	2016-06-05	Male	1	1952-10-01	63.7					Black	1
7	Academic H	AHU	5	SE-AHU-005	3.0	2016-08-07	Female	2	1959-04-06	57.3	No	0	Postmenop	1	White	5
8	Charite Uni	CUB	1	DE-CUB-001	3.0	2016-08-07	Male	1	1980-02-22	36.5					White	5
9	Charite Uni	CUB	2	DE-CUB-002	3.0	2016-03-02	Male	1	1960-11-02	55.3					White	5
10	VU Medica	VUA	1	NL-VUA-001	3.0	2016-10-02	Male	1	1961-07-31	55.2					White	5
11	VU Medica	VUA	2	NL-VUA-002	3.0	2016-08-07	Male	1	1973-12-21	42.6					White	5
12	Academic H	AHU	6	SE-AHU-006	12.0	2016-10-02	Female	2	1976-02-01	40.7	Yes	1			White	5

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

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

The first columns provide information on the site and subject:

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

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

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

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

5.2 One row per activity

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

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

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

	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	EventNam	EventDate	ActivityId	ActivityNa	FormSeq	DesignVers	PEYN	PEYNCD
3	1	Academic	AHU	11	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		1	32.0	Yes	1
4	1	Academic	AHU	14	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		1	33.0	No	0
5	1	Academic	AHU	14	SE-AHU-014	1	UNS_1	Unschedul	2017-11-13	UNS_1		1	34.0	Yes	1
6	1	Academic	AHU	18	SE-AHU-018	1	V1	Visit 1	2017-11-14	V1		1	36.0	Yes	1
7	1	Academic	AHU	22	SE-AHU-022	1	V1	Visit 1	2017-11-14	V1		1	39.0	Yes	1
8	1	Academic	AHU	23	SE-AHU-023	1	V1	Visit 1	2017-10-16	V1		1	27.0	Yes	1
9	1	Academic	AHU	23	SE-AHU-023	1	V3	Visit 3	2017-10-27	V4		1	33.0	Yes	1
10	1	Academic	AHU	24	SE-AHU-024	1	V1	Visit 1	2017-11-01	V1		1	33.0	Yes	1
11	1	Academic	AHU	24	SE-AHU-024	1	V3	Visit 3	2017-11-14	V4		1	39.0	Yes	1
12	1	Academic	AHU	32	SE-AHU-032	1	V1	Visit 1	2017-11-21	V1		1	44.0	Yes	1
13	1	Academic	AHU	34	SE-AHU-034	1	V1	Visit 1	2017-11-21	V1		1	46.0	Yes	1
14	1	Academic	AHU	36	SE-AHU-036	1	V1	Visit 1	2017-11-20	V1		1	44.0	Yes	1
15	1	Academic	AHU	43	SE-AHU-043	1	V1	Visit 1	2018-01-01	V1		1	51.0	Yes	1
16	1	Academic	AHU	44	SE-AHU-044	1	V1	Visit 1	2018-01-02	V1		1	51.0	Yes	1
17	1	Academic	AHU	50	SE-AHU-050	1	V1	Visit 1	2018-01-06	V1		1	55.0	Yes	1
18	1	Academic	AHU	73	SE-AHU-073	1	V1	Visit 1	2018-03-20	V1		1	57.0	Yes	1
19	1	Academic	AHU	75	SE-AHU-075	1	V1	Visit 1	2018-08-13	V1		1	59.0	Yes	1

README | DM | SS | VS | RAND | CQ | PE | EC | BM | LB | IE | STAT

5.3 One row per item

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

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

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

	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	Subject Id	Event sequen	Event Id	Event name	Event date	Activity Id	Activity name	Form Id	Form name	Form sequence number	Item group Id	Item group sequ	Item Id	Item export label
2	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormId	FormName	FormSeq	ItemGroupId	ItemGroupSeq	ItemId	ItemExportLabel
3	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG__10217_1	1	PEYN	Physical Examination performed
4	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	IG__10217_1	1	PEDT	Date/Time of Examination
5	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
6	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
7	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
8	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
9	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result
10	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG7	1	PECARES	Cardiovascular - result
11	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG8	1	PEABRES	Abdomen - result
12	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG9	1	PELYRES	Lymph nodes - result
13	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG10	1	PEEXRES	Extremities - result
14	SE-AHU-011	1	V1	Visit 1	2017-10-20	V1		PE	Physical Examination	1	PEG11	1	PEOTHRES	Other - result
15	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG__10217_1	1	PEYN	Physical Examination performed
16	SE-AHU-014	1	V1	Visit 1	2017-11-10	V1		PE	Physical Examination	1	IG__10217_1	1	PENDREA	Examination not performed reas
17	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG__10217_1	1	PEYN	Physical Examination performed
18	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	IG__10217_1	1	PEDT	Date/Time of Examination
19	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG2	1	PEHERES	HEENT - result
20	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG3	1	PESKRES	Skin - result
21	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG4	1	PETHRES	Thyroid - result
22	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG5	1	PENERES	Neurological - result
23	SE-AHU-014	1	UNS_1	Unscheduled	2017-11-13	UNS_1		PE	Physical Examination	1	PEG6	1	PERERES	Respiratory - result

... | RAND | SS | DM | VS | LB | EC | CQ | PE | BM | IE | STAT | LAB | CC | MH | ExampleForm ...

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

5.3.1 Include history

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

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

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

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

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

5.3.2 Checkboxes

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

Item OID index

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

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

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

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

5.3.3 Reference ranges

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

6 Form link items in the export output

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

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

6.1 One row per activity

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

In the example below:

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

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

There are also two header rows in the output:

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

6.2 One row per item

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

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

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

6.3 One row per subject

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

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

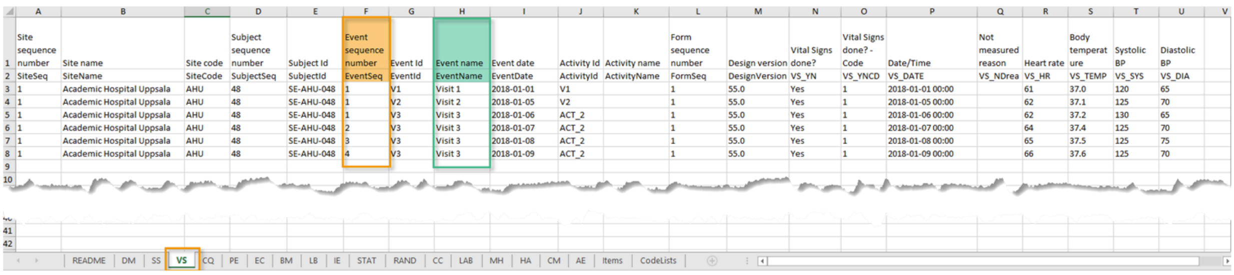
There are also two header rows in the output:

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

7 Recurring events in the export output

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

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



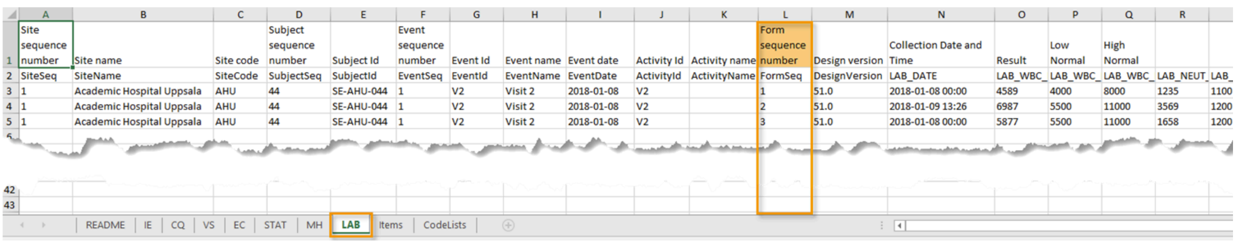
Site sequence number	Site name	Site code	Subject sequence number	Subject Id	Event sequence number	Event Id	Event name	Event date	Activity Id	Activity name	Form sequence number	Design version	Vital Signs done?	Vital Signs done? - Code	Date/Time	Not measured reason	Heart rate	Body temperature	Systolic BP	Diastolic BP
SiteSeq	SiteName	SiteCode	SubjectSeq	SubjectId	EventSeq	EventId	EventName	EventDate	ActivityId	ActivityName	FormSeq	DesignVersion	VS_YN	VS_YNCD	VS_DATE	VS_NDrea	VS_HR	VS_TEMP	VS_SYS	VS_DIA
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V1	Visit 1	2018-01-01	V1		1	55.0	Yes	1	2018-01-01 00:00		61	37.0	120	65
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V2	Visit 2	2018-01-05	V2		1	55.0	Yes	1	2018-01-05 00:00		62	37.1	125	70
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	1	V3	Visit 3	2018-01-06	ACT_2		1	55.0	Yes	1	2018-01-06 00:00		62	37.2	130	65
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	2	V3	Visit 3	2018-01-07	ACT_2		1	55.0	Yes	1	2018-01-07 00:00		64	37.4	125	70
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	3	V3	Visit 3	2018-01-08	ACT_2		1	55.0	Yes	1	2018-01-08 00:00		65	37.5	125	75
1	Academic Hospital Uppsala	AHU	48	SE-AHU-048	4	V3	Visit 3	2018-01-09	ACT_2		1	55.0	Yes	1	2018-01-09 00:00		66	37.6	125	70

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

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

9 Forms initiated by copying data from previous event

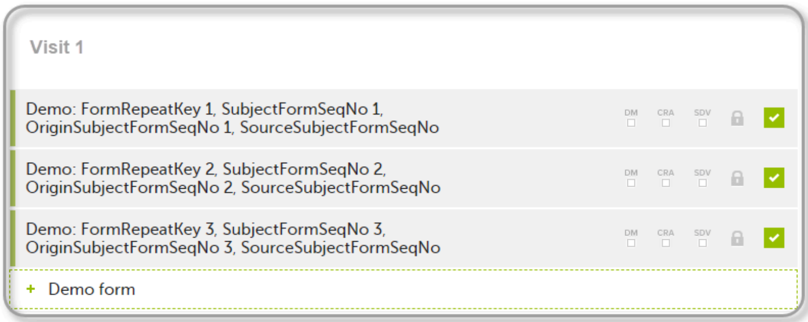
The following form sequence numbers are used to make it easier to track different form instances at subject level, which are useful especially for the form instances initiated by copying the data from previous event.

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

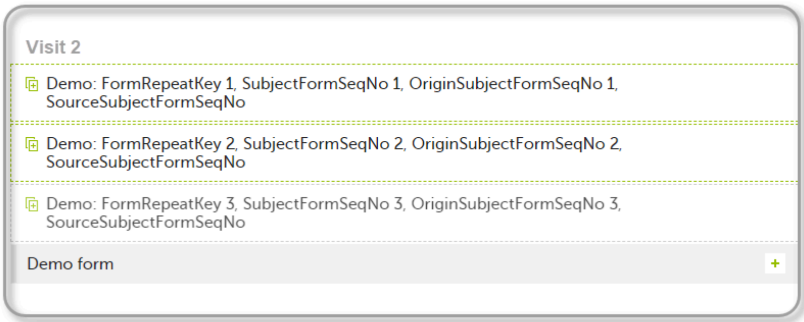
The example below illustrates how the values for these sequence numbers are assigned. The demo form used is set as repeatable and copyable and is included in Visit 1, Visit 2 and Visit 3.

We perform the following actions in Viedoc Clinic:

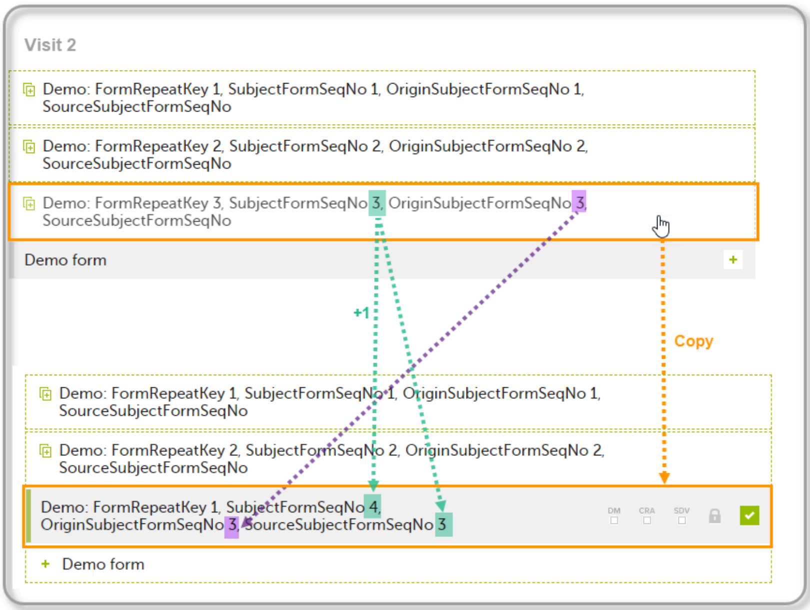
1 Initiate Visit 1 and fill-in three instances of the Demo form, these instances will get the sequence numbers as illustrated below:



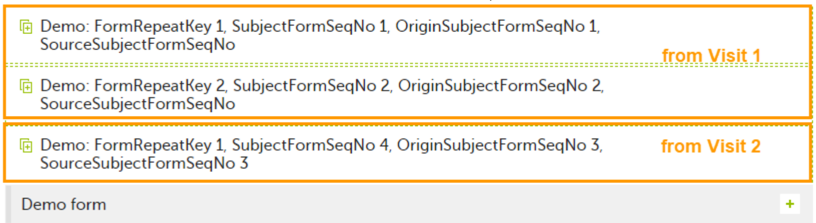
2 Initiate Visit 2. Demo form will be available to be initiated by copying data from one of the previously filled-in form instances within Visit 1, so all the three instances will be shown as ghost forms:



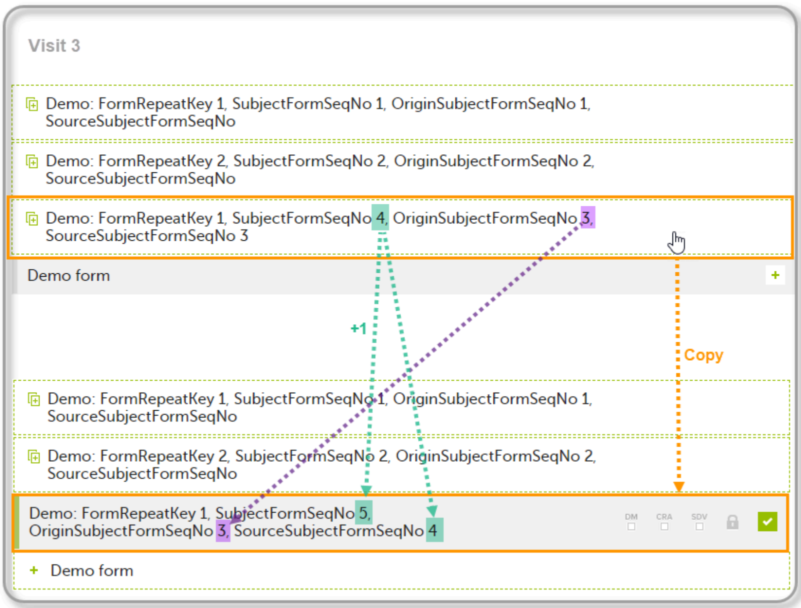
3 Create an instance of Demo form within Visit 2 by copying the data from the third instance of the form filled in within Visit 1. This will result in the new form instance getting the sequence numbers as illustrated below:



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



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



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

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

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

Notes!

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

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

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

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

PDF export output

PDF export output

Published by Viedoc System 2022-02-10

1 Introduction

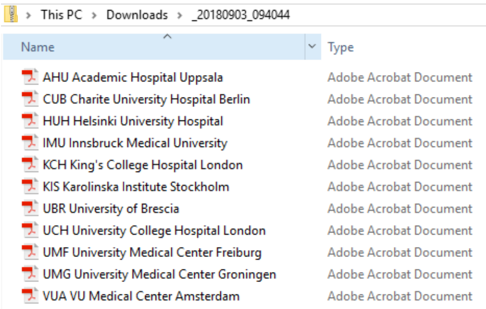
When choosing **PDF** as output format, you have the following options:

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

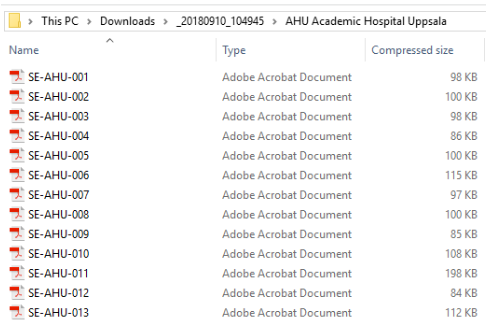
2 Output file(s)

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

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

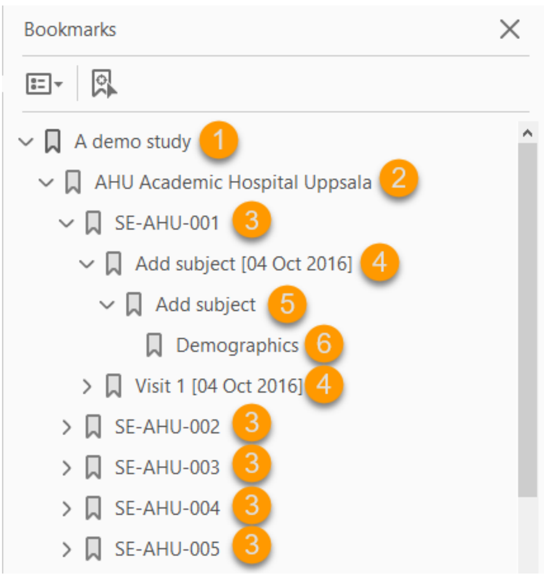


- For the **FDA submission format (eCTD)**, there is one folder for each site, and each folder contains one separate PDF file for each subject (file name is the same as the subject ID):



3 PDF file structure/content

This section describes the structure of the exported PDF file.



The file is structured as follows:

1. A study summary on the first page.

2. A site summary page.

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

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

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

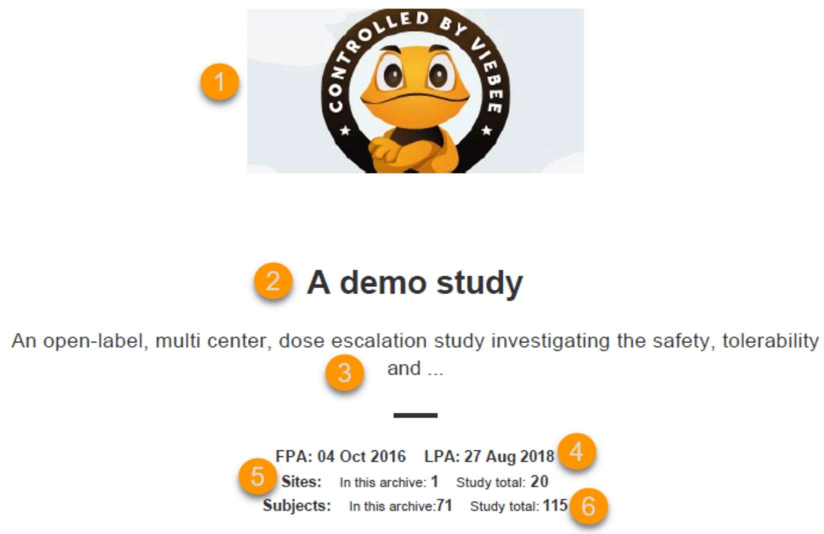
6. For each activity, one sub-section for each form. The latest version of the form PDFs are included here. See also **Audit trail and Form History** section in Entering/editing data.

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

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

- ## 3.1 First page

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



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

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

3. Study description, as set in Viedoc Designer.

4. The dates for:

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

5. The number of **sites**:

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

6. The number of **subjects**:

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

3.2 Site summary page

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

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

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

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

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

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

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

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

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

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

3.3 Subject summary page

The subject summary page provides the following information:

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

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

3. The date and time the subject was added.

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

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

3.4 Event summary page

The event summary page provides the following information:


A demo study / Academic Hospital Uppsala 1

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

Contents 3

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

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

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

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

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

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

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

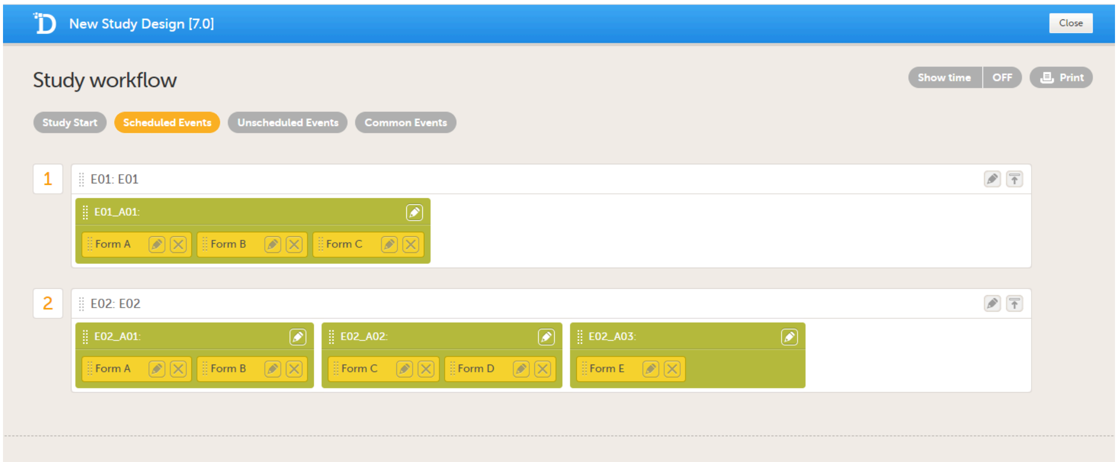
3.4.1 The sort order of the forms

The forms in the PDF are sorted by these characteristics:

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

The following example illustrates the sort order.

Suppose the study design looks like this:



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

- Form A
- Form B
- Form C

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

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

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

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

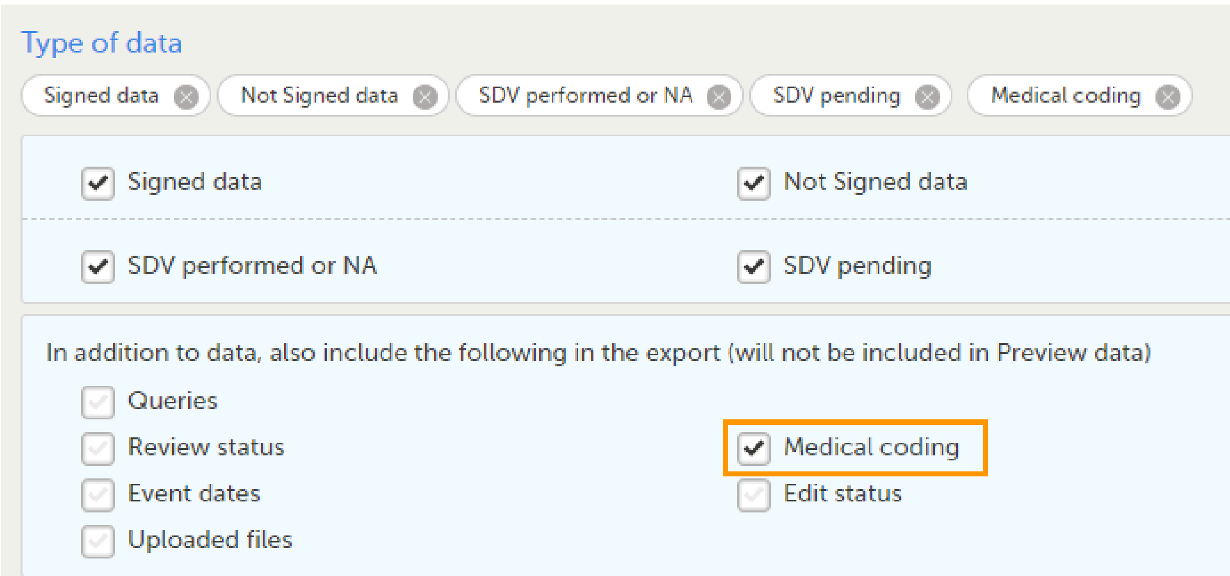
Medical coding in Excel export

Published by Viedoc System 2024-06-26

1 Introduction

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

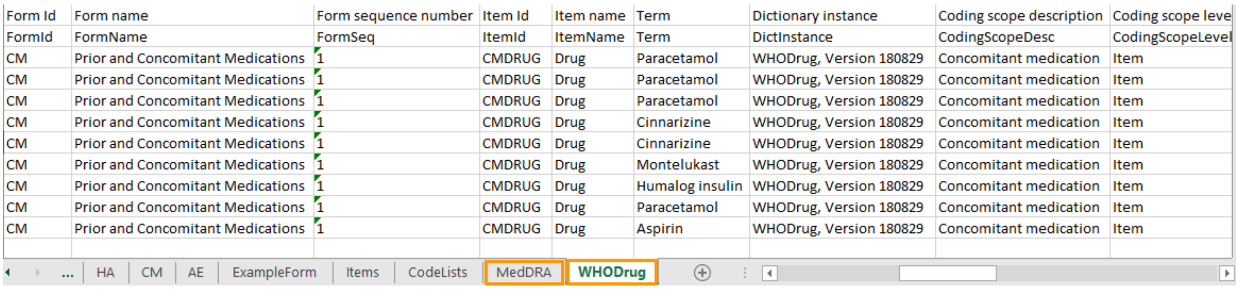
To include the medical coding information in the exported file, you need to select **Medical coding** under **Type of data** in the Data Export page:



For general details about data export, see Exporting data.

2 Medical coding information in Excel

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



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

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

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

Column name	Description
Source Subject form sequence number	For a copied form instance, a counter that identifies the source of a copied form instance (the form instance the data was copied from). It gets the value of the `SubjectFormSeqNo` from which the form instance was copied. For the first instance of the form (not copied) it is empty (null).
Item Id	The item ID, as set in the study design (in Viedoc Designer)
Item Name	The item name, as set in the study design (in Viedoc Designer) and displayed in Viedoc Clinic
Medical coding-specific information	
Term	The coded term
Dictionary instance	The description of the dictionary instance, as set in Viedoc Admin when uploading the dictionary
Version	The dictionary version.
Coding scope description	The coding scope description, as defined in Viedoc Designer
Coding scope level	The coding scope level, as defined in Viedoc Designer, can be one of the following: ▪ Event ▪ Activity ▪ Form ▪ Item group ▪ Item
Code sequence number	A counter that identifies the code for those values with more than one code
Dictionary-specific information	

<table>
<tr><th>Column name</th><th colspan="3">Description</th></tr>
<tr>
<td>WHODrug:
DrugCode
DrugName
NameSpecifier
OldForm
Ingredients
ATCCodes
CountryCode
CountryName
MAH (MAH)
PharmForm
Strength
MedProdId
Generic
PreferredCode
PreferredName
Name</td>
<td>MedDRA:
soc_code
soc_name
soc_abbrev
hlgt_code
hlgt_name
hlt_code
hlt_name
pt_code
pt_name
pt_soc_code
llt_code
llt_name
llt_currency</td>
<td>ATC without DDD:
L1 code
L1 name
L2 code
L2 name
L3 code
L3 name
L4 code
L4 name
L5 code
L5 name</td>
<td>IDF:
L1 薬剤コード
L1 薬剤名
L1 薬剤名カナ
L2 薬剤コード
L2 薬剤名
L2 薬剤名カナ
L3 薬剤コード
L3 薬剤名
L3 薬剤名カナ
L4 薬剤コード
L4 薬剤名
L4 薬剤名カナ
L5 薬剤コード
L5 薬剤名
L5 薬剤名カナ
L5 一般名
L5 一般名カナ
L5 使用区分1
L5 使用区分2
L5 基準名コード
L5 メーカーコード
L5 メーカーの略称
L5 剤形コード
L5 薬剤コード区分1
L5 メンテ年月
L6 薬剤コード
L6 薬剤名
L6 薬剤名カナ
L6 一般名
L6 一般名カナ</td>
</tr>
</table>

Column name	Description
	▪ L6 使用区分1 ▪ L6 使用区分2 ▪ L6 基準名コード ▪ L6 メーカーコード ▪ L6 メーカーの略称 ▪ L6 剤形コード ▪ L6 薬剤コード区分1 ▪ L6 メンテ年月
Interpretation	The medical coder's interpretation of the applied coding value
Coded by user	The name of the user who performed the coding, followed by the user ID in parentheses
Coded on date	The date and time when the coding was performed
Approved by user	The name and ID of the user who approved the items
Approved on date (UTC)	The date and time (UTC) when the item was approved

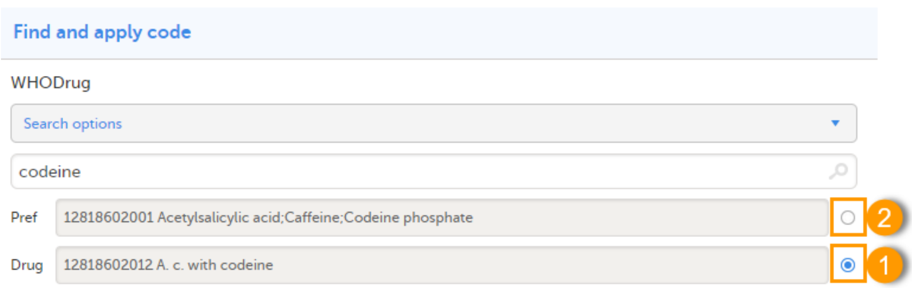
3 An example - WHODrug in Excel exported file

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

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

1. **Drug** (default)

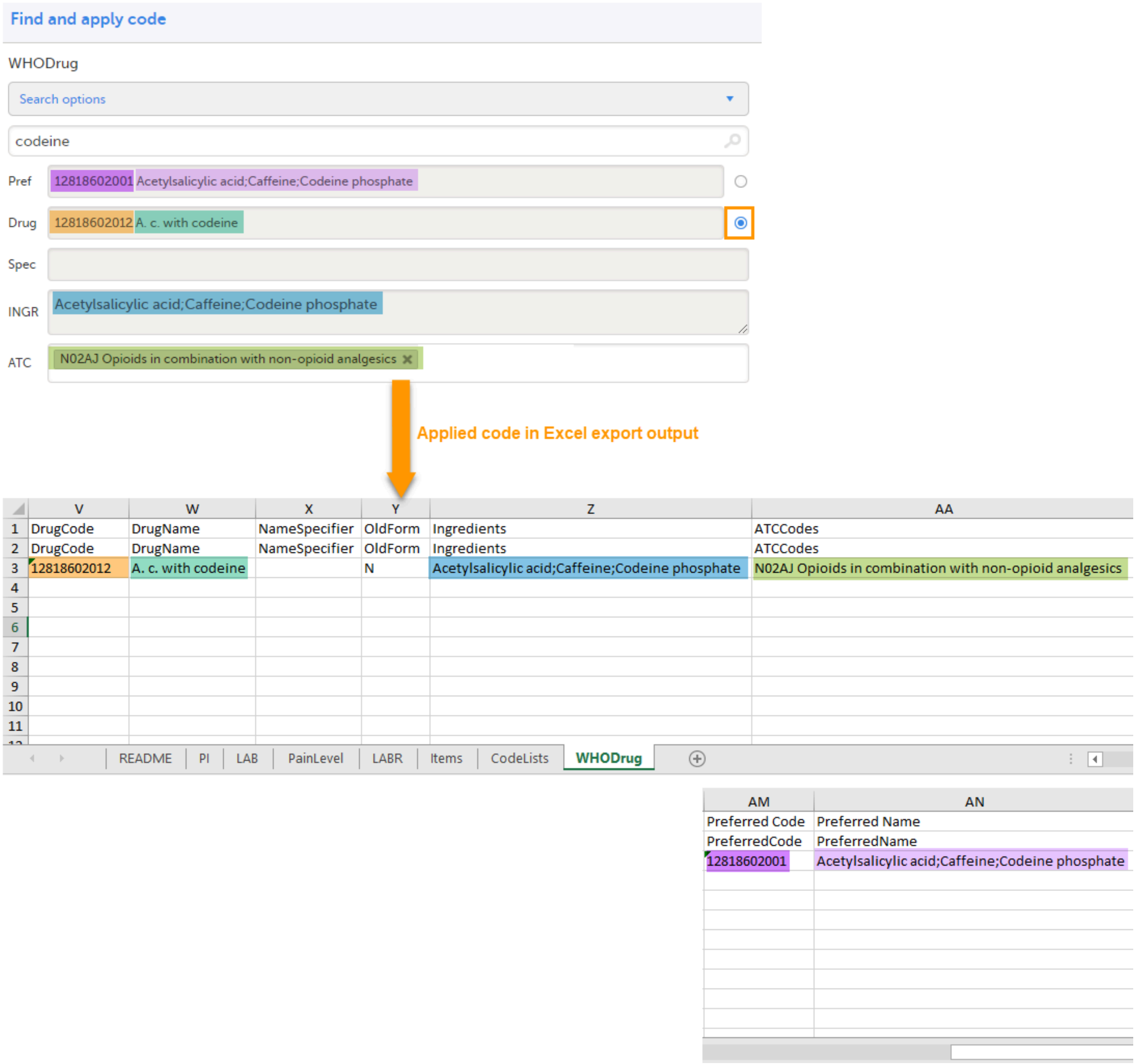
2. **Pref**erred name



3.1 When selecting Drug

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

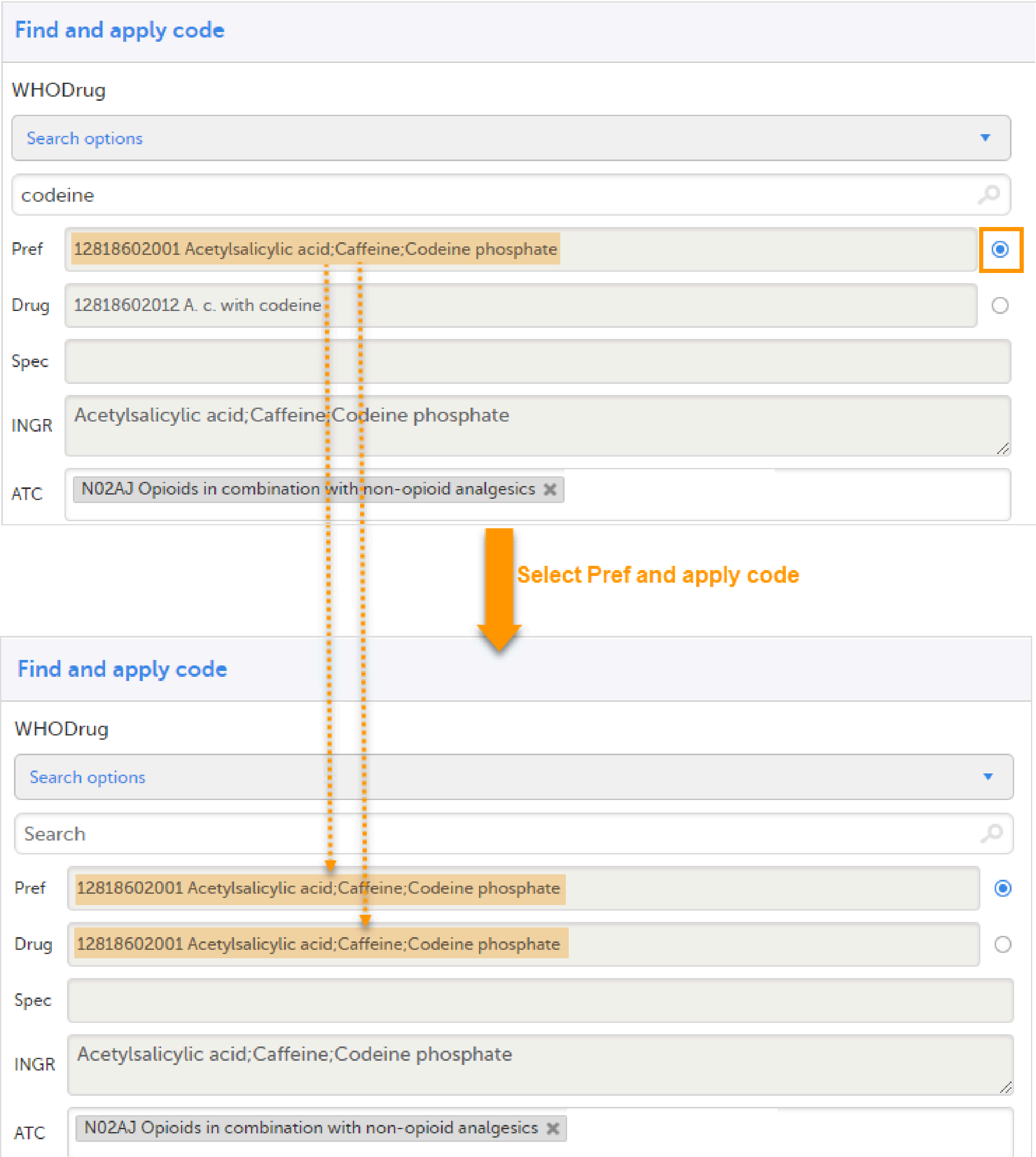
When **Drug** is selected, the **Preferred code** and **Preferred name** come out in the export as well, in the last columns, as illustrated in the image.

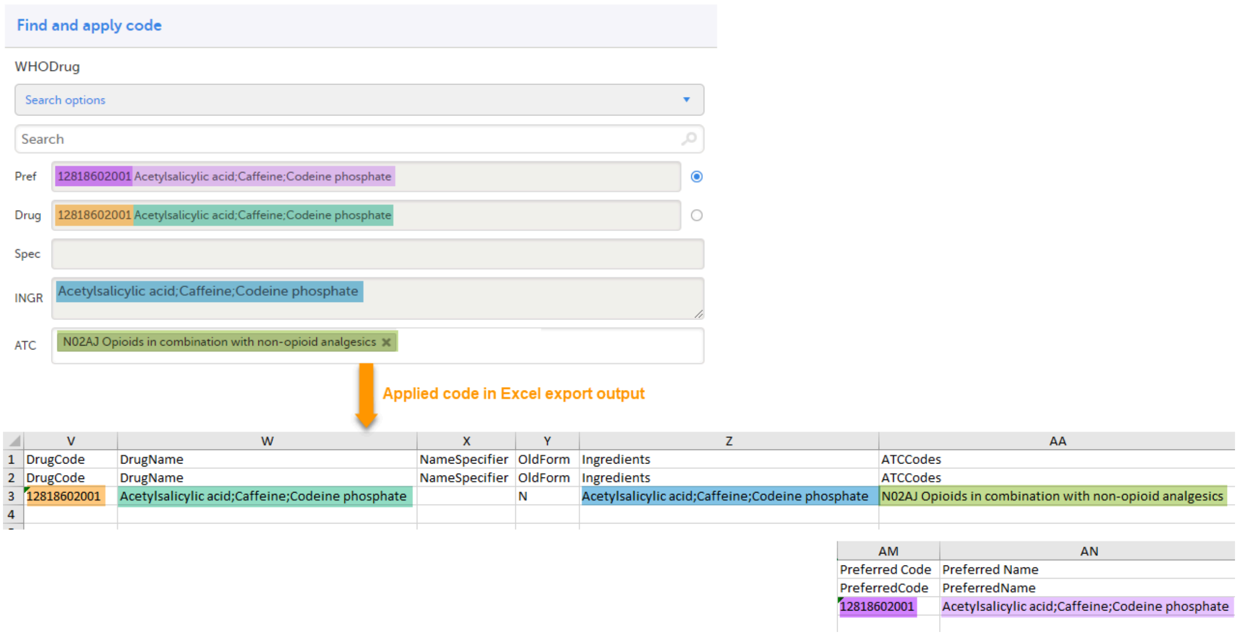


3.2 When selecting Preferred name

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

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


Find and apply code
WHODrug
Search options
codeine
Pref
12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate
Drug
12818602012 A. c. with codeine
Spec
INGR
Acetylsalicylic acid;Caffeine;Codeine phosphate
ATC
N02AJ Opioids in combination with non-opioid analgesics
Select Pref and apply code
Find and apply code
WHODrug
Search options
Search
Pref
12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate
Drug
12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate
Spec
INGR
Acetylsalicylic acid;Caffeine;Codeine phosphate
ATC
N02AJ Opioids in combination with non-opioid analgesics


Find and apply code
WHODrug
Search options
Search
Pref 12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate
Drug 12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate
Spec
INGR Acetylsalicylic acid;Caffeine;Codeine phosphate
ATC N02AJ Opioids in combination with non-opioid analgesics
Applied code in Excel export output
V W X Y Z AA
1 DrugCode DrugName NameSpecifier OldForm Ingredients ATCCodes
2 DrugCode DrugName NameSpecifier OldForm Ingredients ATCCodes
3 12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate N Acetylsalicylic acid;Caffeine;Codeine phosphate N02AJ Opioids in combination with non-opioid analgesics
4
AM AN
Preferred Code Preferred Name
PreferredCode PreferredName
12818602001 Acetylsalicylic acid;Caffeine;Codeine phosphate

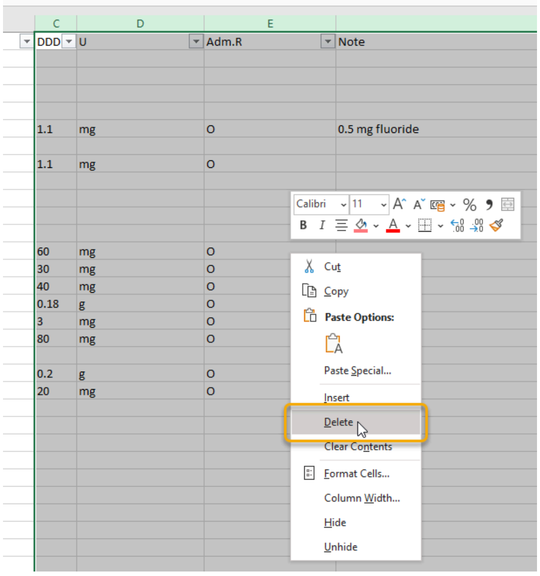
Converting an ATC dictionary from Excel format to ASCII format

Published by Viedoc System 2022-02-10

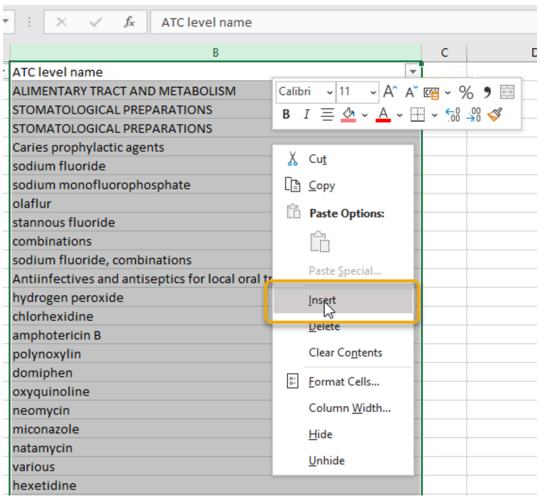
To convert an Anatomic Therapeutic Chemical classification system (ATC) dictionary:

1. Open the `xlsx` file in Microsoft Excel.

2. If Defined Daily Dose (DDD) is included in the file (columns C, D, E, and F), delete these columns, as well as the note column if there is one.



3. Insert a new column B.

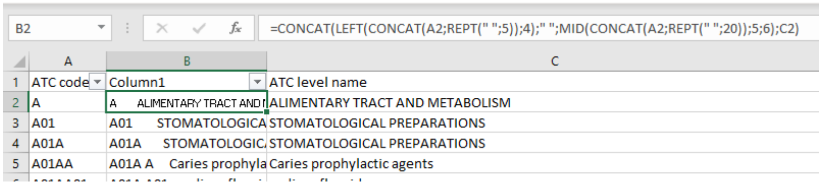


4 In cell B2, write a formula. To add a formula, start by typing an equal sign (=). Then Excel interprets the text in that cell as a formula (unless otherwise specified).

The formula will look different depending on the language of your Excel installation. These are some examples:

- English: =CONCAT(LEFT(CONCAT(A2;REPT(" ";5));4);" ";MID(CONCAT(A2;REPT(" ";20));5;6);C2)
- French: =CONCAT(GAUCHE(CONCAT(A2;REPT(" ";5));4;" ";STXT(CONCAT(A2;REPT(" ";20));5;6);C2)
- Spanish: =CONCAT(IZQUIERDA(CONCAT(A2;REPETIR(" ";5));4);" ";EXTRAE(CONCAT(A2;REPETIR(" ";20));5;6);C2)
- German: =TEXTKETTE(LINKS(TEXTKETTE(A2;WIEDERHOLEN(" ";5));4);" ";TEIL(TEXTKETTE(A2;WIEDERHOLEN(" ";20));5;6);C2)
- Swedish: =SAMMAN(VÄNSTER(SAMMAN(A2;REP(" ";5));4);" ";EXTEXT(SAMMAN(A2;REP(" ";20));5;6);C2)

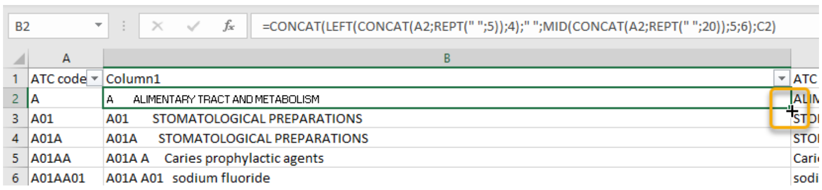
Note! Depending on the regional settings in your operating system, you might need to replace the semicolons with commas.



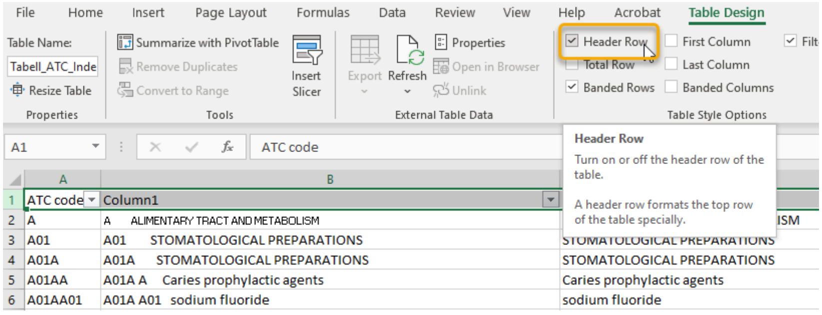
The formula does the following:

1. It takes the first four characters from column A (padded right with spaces unless the text is four characters long).
2. It adds one space character.
3. It adds characters 5, 6, and 7 from column A (padded right with spaces unless the text is seven characters long).
4. It adds three space characters.
5. It adds all of column C.

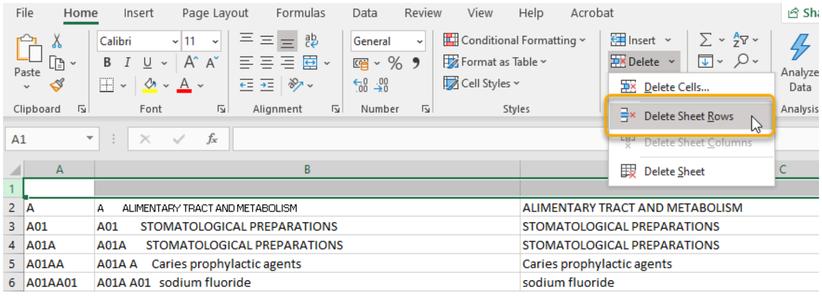
5 Fill all cells in the B column with the same formula, for example by dragging the small plus sign (+) downwards to cover the entire column.



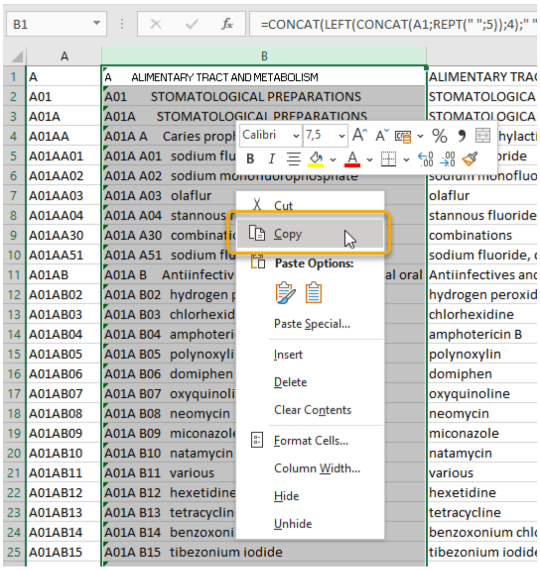
6 Remove row 1 (the header row). Do to this, you might first need to turn off the header row on the **Table Design** page.



Then you can delete the sheet row from the **Home** page.

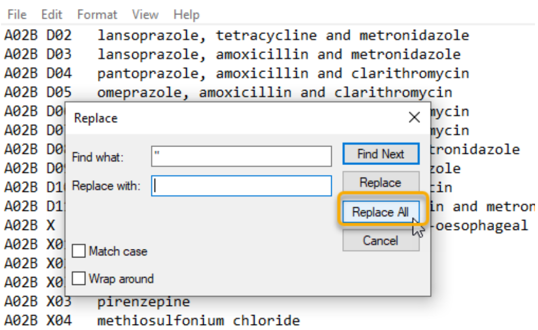


7 Select column B and copy it.



8 Paste the copied column into a raw text editor such as Windows Notepad. It is important to use an editor that does not add any formatting.

9 In the raw text editor, search for the quotation mark character (") and remove any such occurrences.



10 If there are empty lines at the end of the file, remove them.

```
V10X X03    radium (223Ra) dichloride
V10X X04    lutetium (177Lu) oxodotreotide
V20         SURGICAL DRESSINGS
```

11 Save your file with an appropriate filename that reflects the ATC version and with the filename extension `asc` .

12 Upload the file to Viedoc according to these instructions: Creating a dictionary instance.

Medical coding

Medical coding

Published by Viedoc System 2025-02-18

1 Introduction

Viedoc Coder allows you to code data, such as Adverse Events, Medical History, and Concomitant Medications, in a standardized way. You can access Viedoc Coder on the landing page.

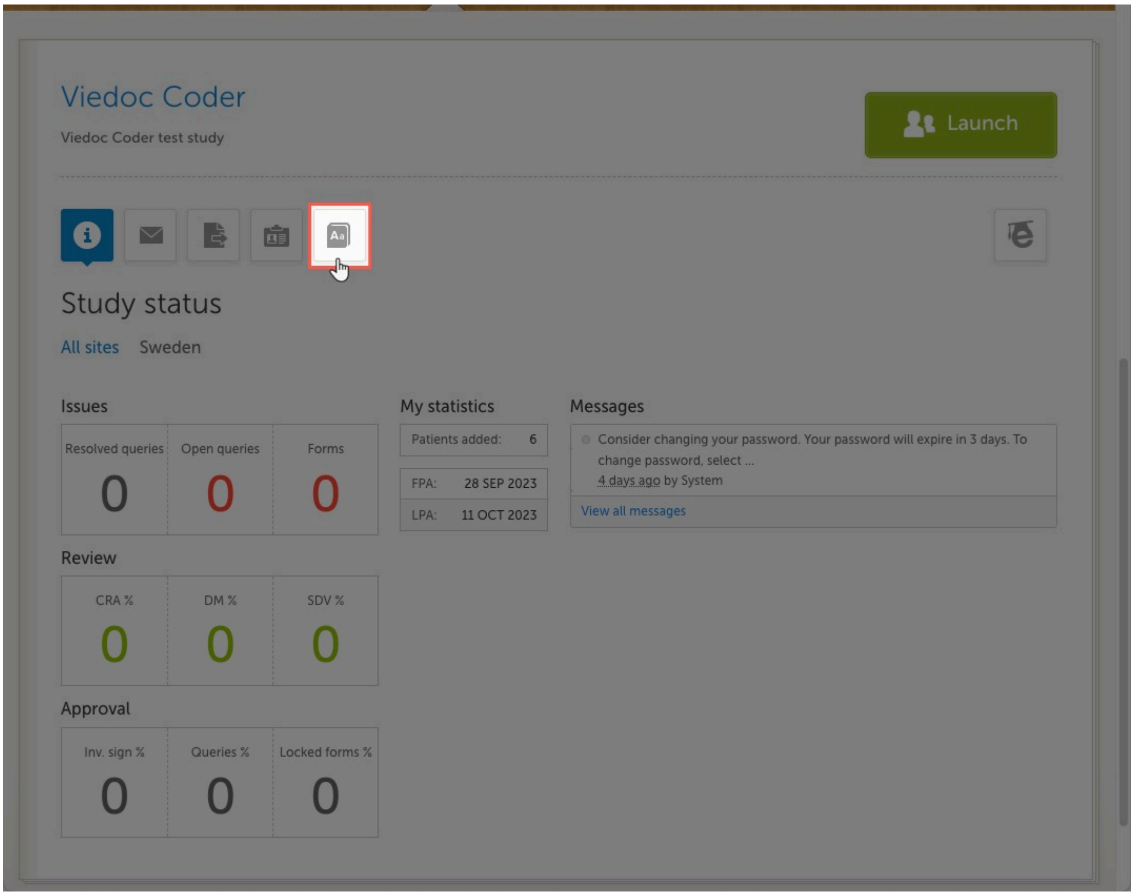
The Viedoc Coder page displays metrics about coding, for example, the number and percentage of items that have been coded and approved. There is one set of metrics for each coding scope. The metrics displayed are based on the data and sites that you have permission to view.

Note! You can only access Viedoc Coder if permission to view, perform, and/or approve medical coding is activated for your role. If you do not see the medical coding icon, you do not have a role with medical coding permissions.

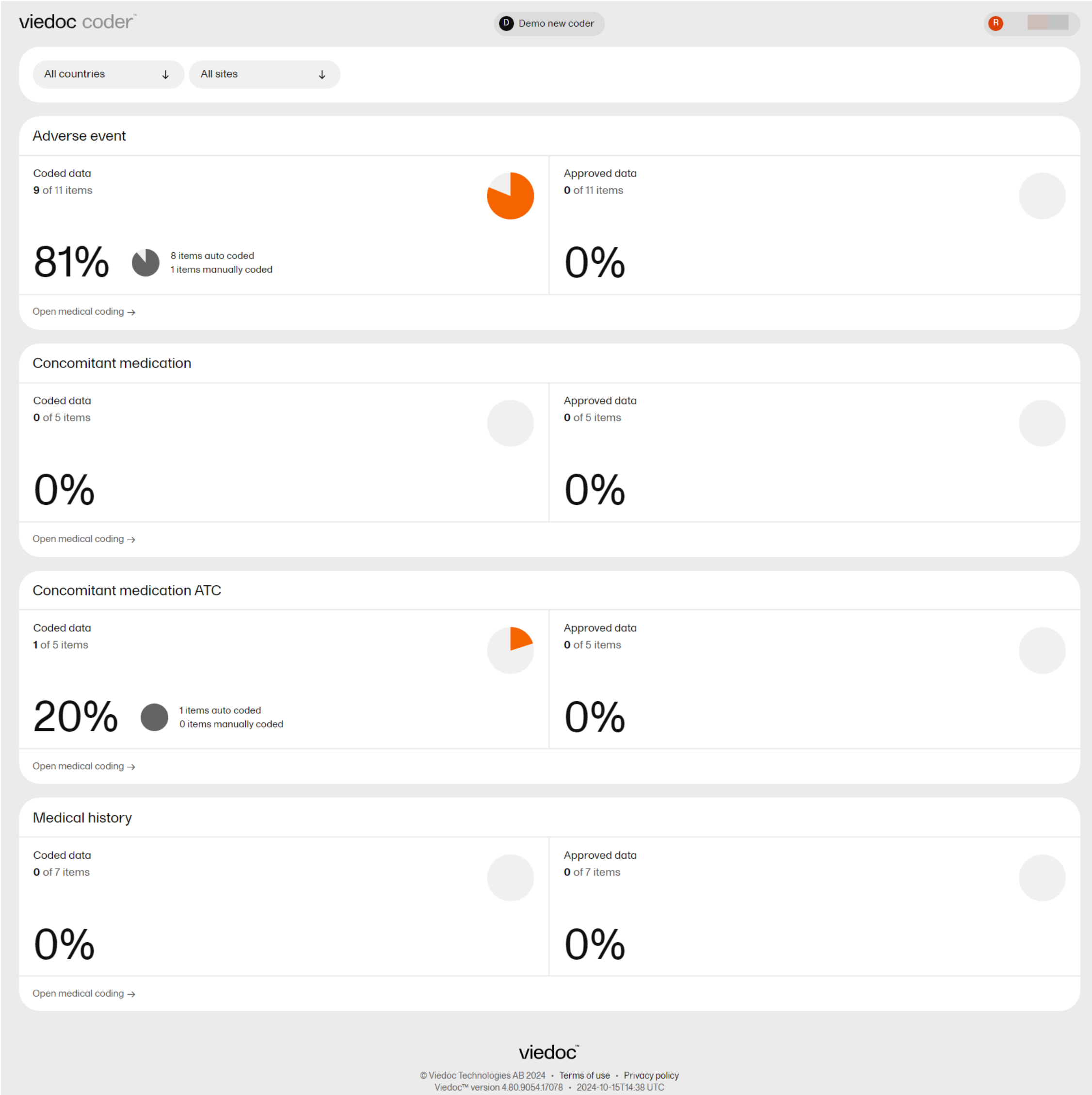
2 Viedoc Coder

2.1 Overview

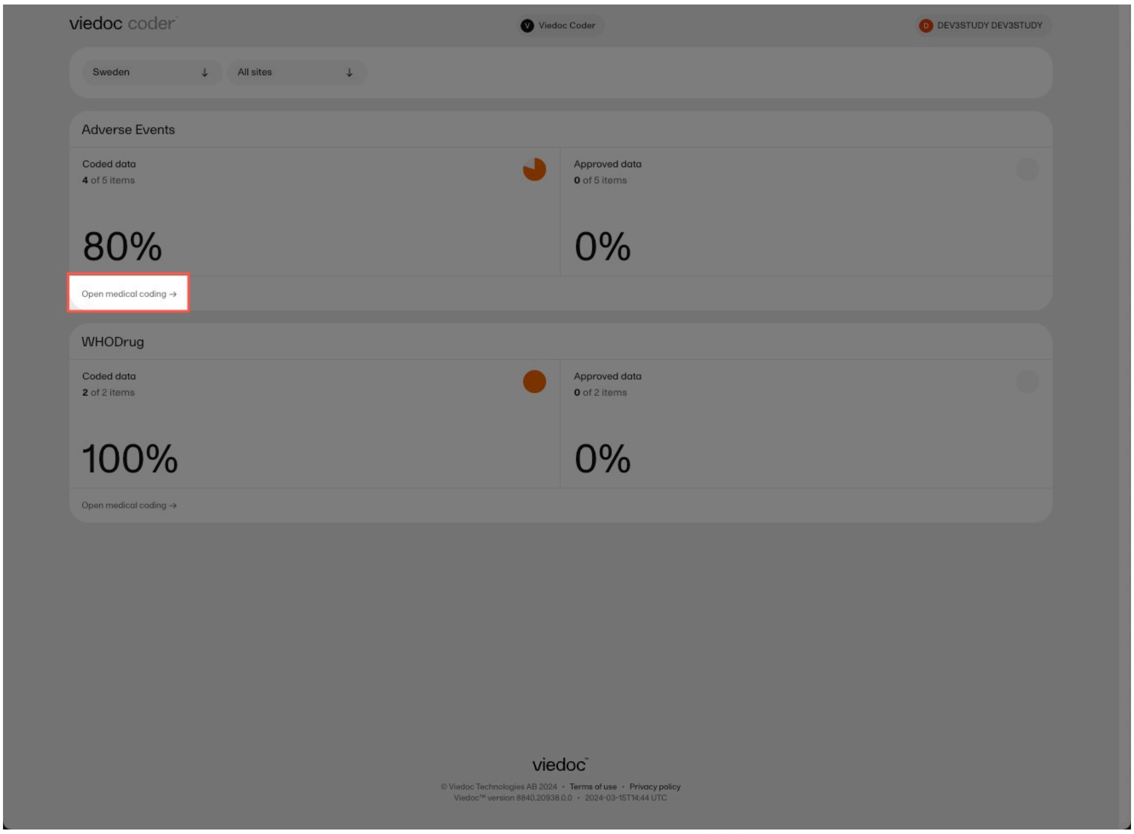
1. To open Viedoc Coder select the **dictionary icon**:



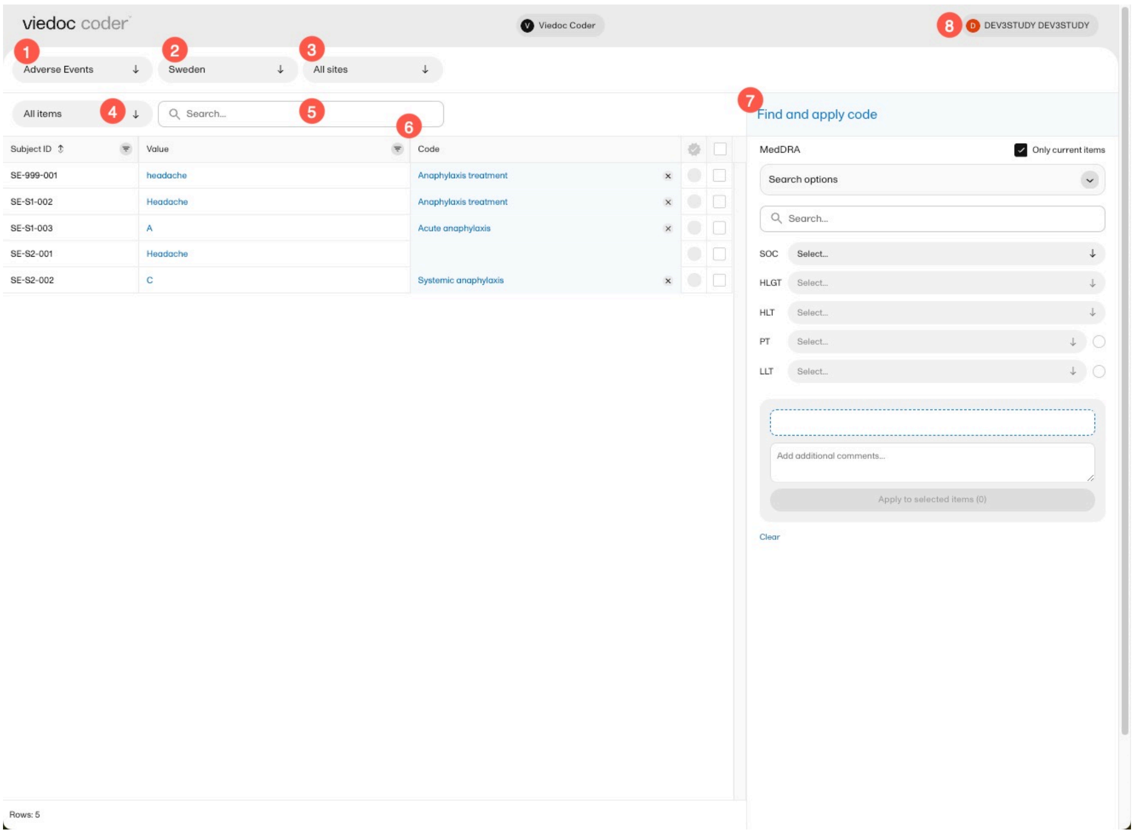
Viedoc Coder opens in a new window:


viedoc coder
Demo new coder
All countries
All sites
Adverse event
Coded data
9 of 11 items
81%
8 items auto coded
1 items manually coded
Approved data
0 of 11 items
0%
Open medical coding →
Concomitant medication
Coded data
0 of 5 items
0%
Approved data
0 of 5 items
0%
Open medical coding →
Concomitant medication ATC
Coded data
1 of 5 items
20%
1 items auto coded
0 items manually coded
Approved data
0 of 5 items
0%
Open medical coding →
Medical history
Coded data
0 of 7 items
0%
Approved data
0 of 7 items
0%
Open medical coding →
viedoc
© Viedoc Technologies AB 2024 • Terms of use • Privacy policy
Viedoc™ version 4.80.9054.17078 • 2024-10-15T14:38 UTC

2. Select **Open medical coding** on a scope:



Viedoc Coder displays a table that lists all items to be coded in the **Value** column.



In Viedoc Coder, you can:

1. Select the coding scope (the data) to be coded.
2. Select to display items from all countries or from an individual country.
3. Select to display items from all sites or from an individual site.

4. Select to display all uncoded (and rejected) items, all coded items, all approved items, or all items.

5. Perform a text search among all values of the items.

6. If configured for your study, there can be additional columns included with supporting values for the coding, for example route, indication, or other.

7. Find and apply codes (see Finding and applying a medical code).

8. Select here to change the settings of Viedoc, access the help center, or logout of Viedoc.

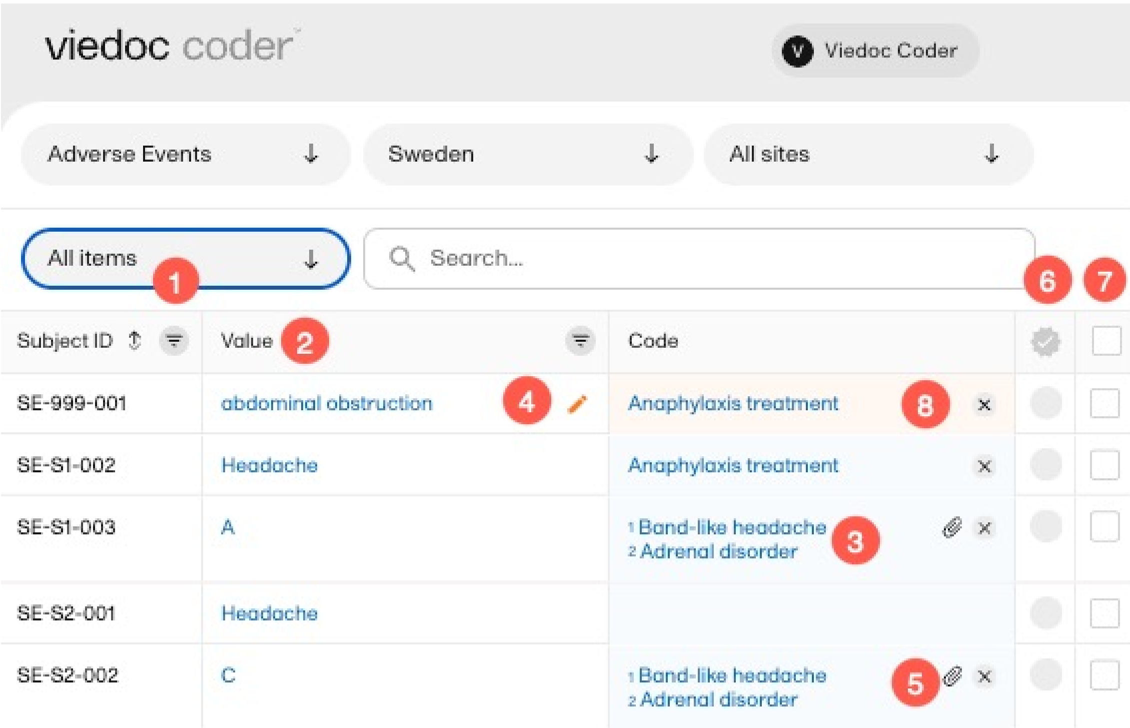
When applying codes, it is possible to:

- Add a comment - an interpretation or explanation of the value that you have assumed in order to code.
- Add multiple codes to one value.

See Finding and applying a medical code.

2.2 What do the symbols and colors mean?

In Viedoc Coder, you can find the following symbols:



1. The three horizontal lines is a filter function. Click the symbol to open a dropdown list with a search field and a list of selectable items.

2. Fields have a sorting function which will list its contents in ascending and descending order. This function is not available for all columns.

3. A numbered list in the code field means that there is more than one medical code applied to that value.

4. An orange pen icon in the value field, together with a light orange background in the code field, means that the value (form item) has been changed in Viedoc Clinic by the Investigator after the item was coded. The applied code may not be correct anymore and the item should be re-coded.

5. A clip icon in the code field means that an interpretation has been added. Move the mouse pointer over the clip icon to view the contents of the interpretation.

6. An activated tick mark indicates that the coding has been approved.

7. The checkbox is used to mark the values to which a selected code should be applied.

8. The white cross in a grey circle is used to delete the applied code.

3 Finding and applying a medical code

This section gives an example of medical coding of adverse events using the Medical Dictionary for Regulatory Activities (MedDRA) and an example of medical coding of concomitant medication using the World Health Organization Drug Dictionary (WHO DD). The coding procedure is similar even if you are using other types of dictionaries.

3.1 A use case for coding with the MedDRA dictionary

3.1.1 Searching for a code

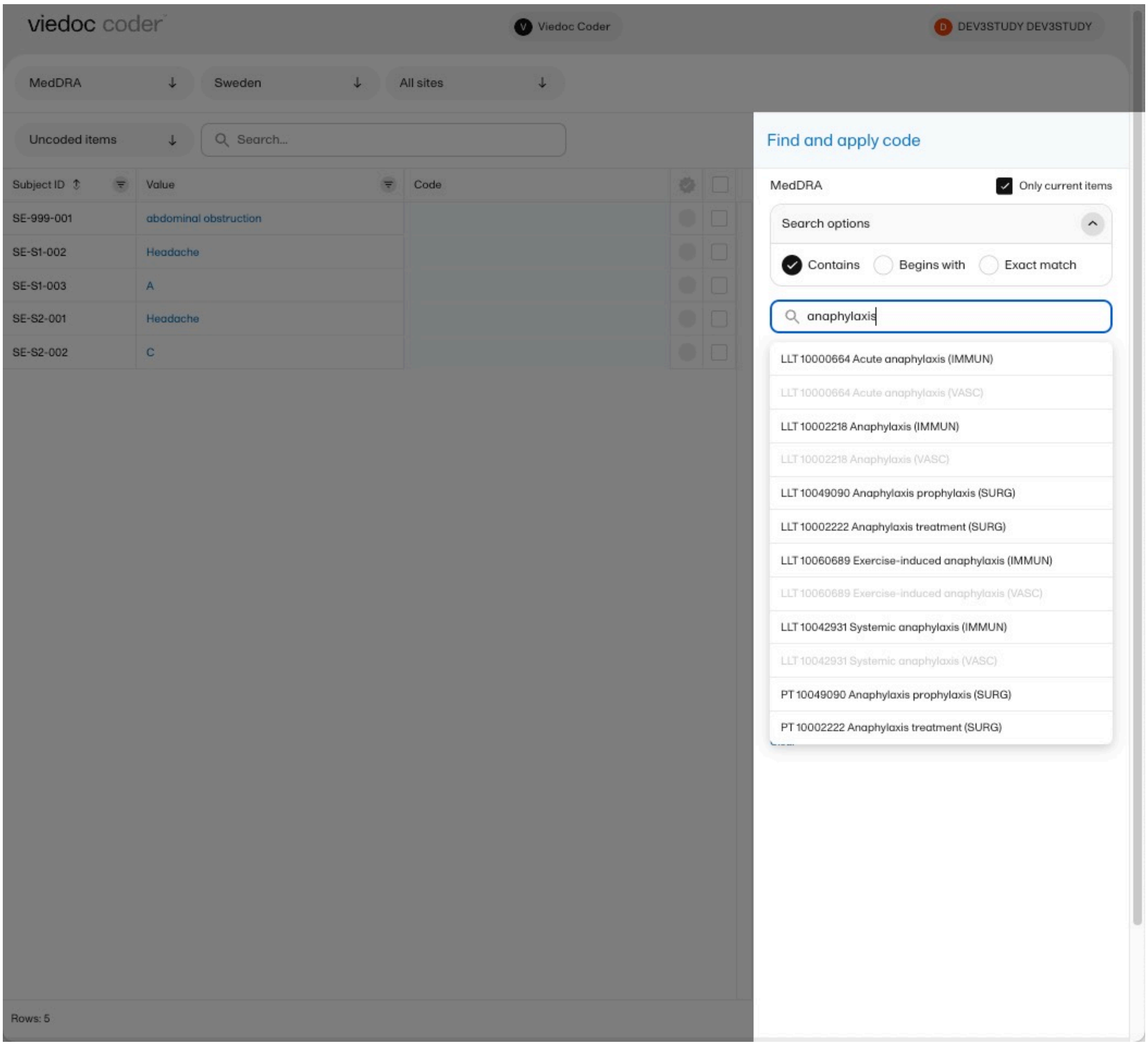
To find a code that you want to apply to a value, use the **Find and apply code** section.

There are three search options available:

- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.

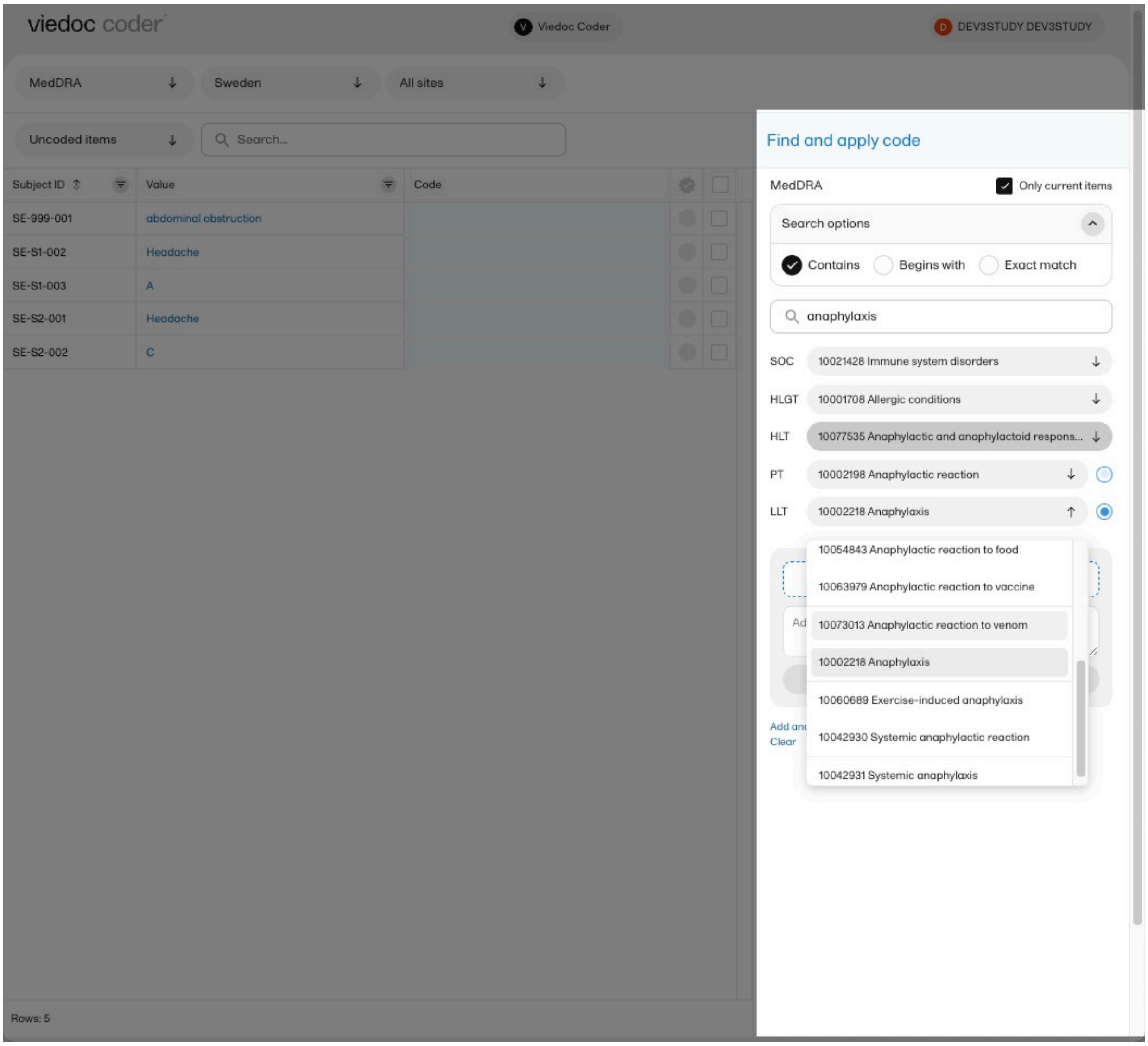
You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a dropdrown list that deploys from the **Search** field. If a term is linked to multiple System Organ Classes (SOCs), the code that links to the primary SOC is displayed in black, while the codes that link to secondary SOCs are displayed in grey.

Searching is not case sensitive. If you type in "Anaphylaxis", the search can return results such as "anaphylaxis" and "Anaphylaxis".



You can also search a code by selecting the System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Preferred Term (PT) and Low Level Term (LLT) using the dropdown lists below the search field.

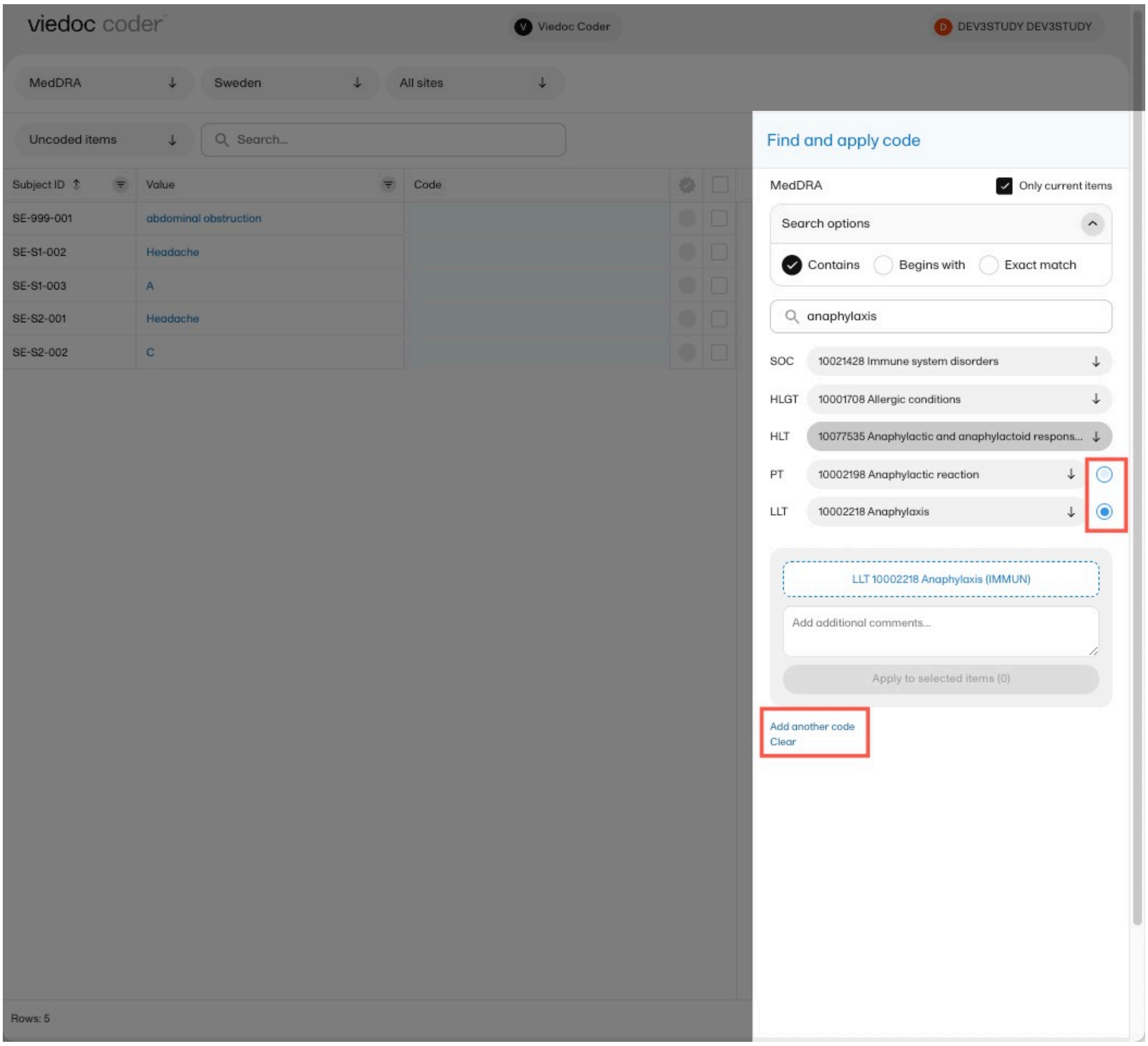
By default, the search returns low level terms (LLTs) that have the status 'current' in the MedDRA dictionary. It is possible to search among non-current MedDRA codes (that is, terms that are vague, ambiguous, truncated, abbreviated, out-dated, or misspelled and thus no longer used), by clearing the checkbox for **Only current items**.



3.1.2 Selecting a code

Select the code you would like to apply. The details of this code appear in the fields below the search field.

You can select to use the Preferred Term (PT) or the Low Level Term (LLT) by clicking one of the blue radio buttons next to the **PT** and **LLT** fields, as shown below:

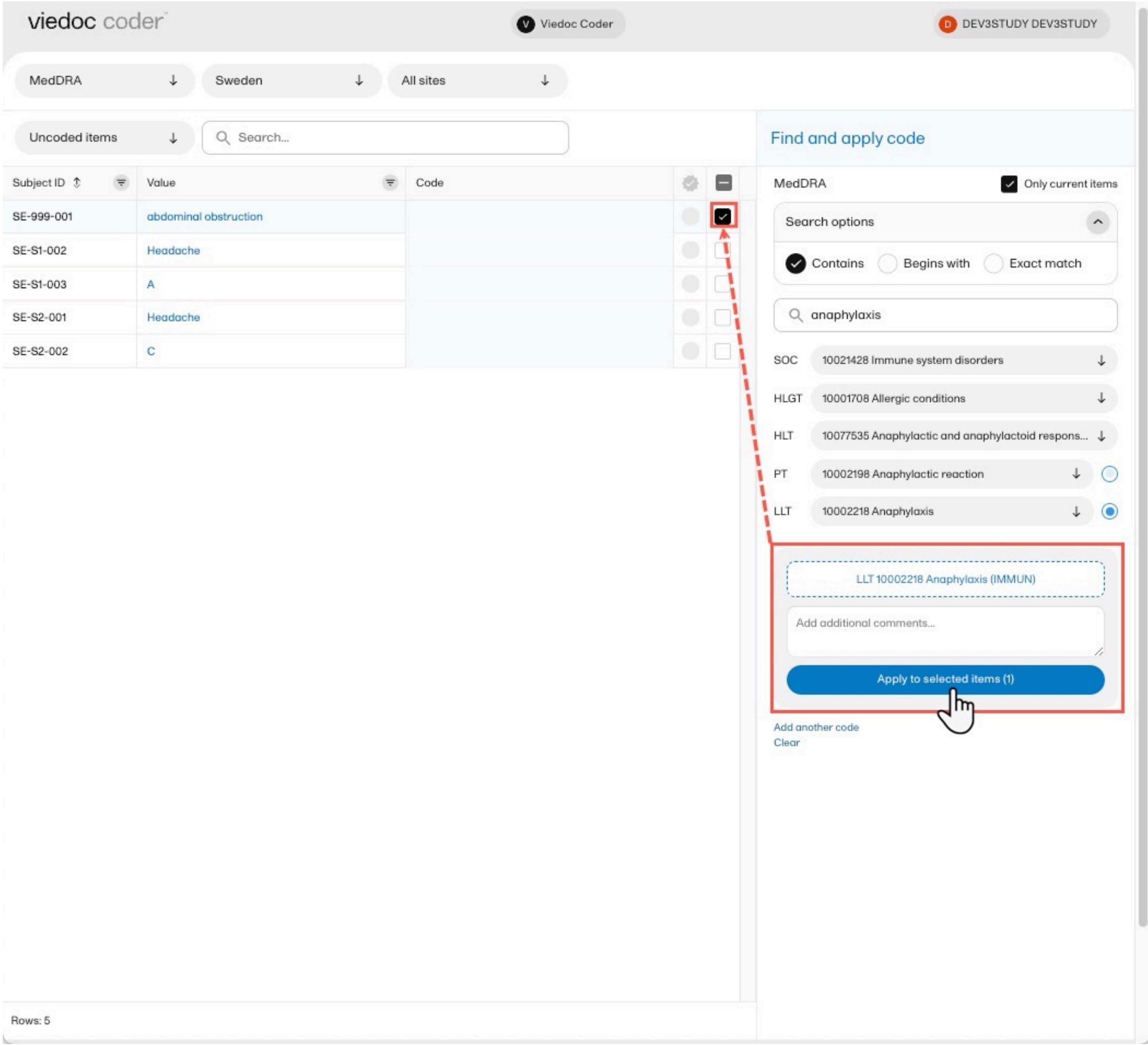


If you would like to add more than one code to the same value, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset your selections by clicking **Clear**.

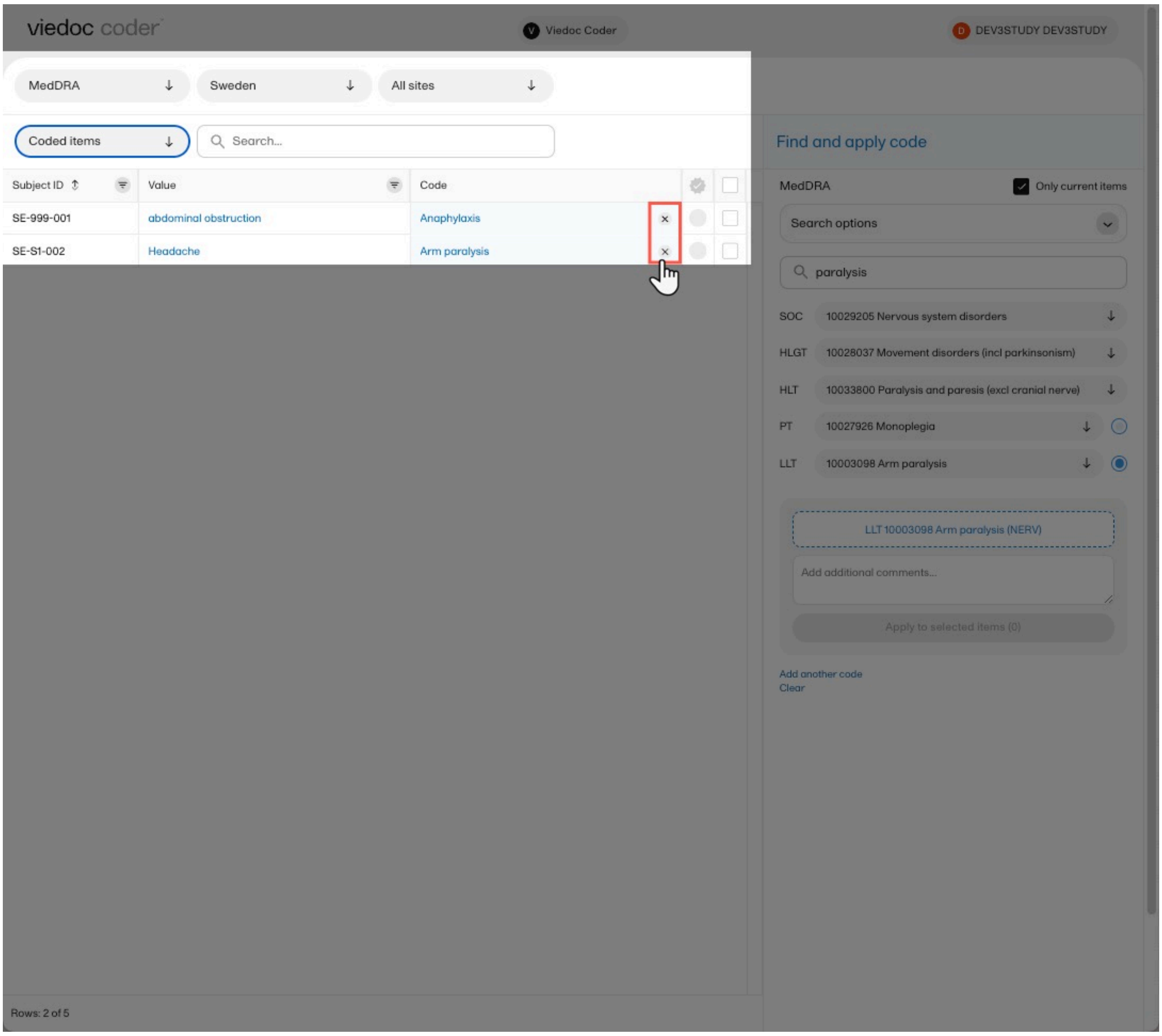
Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code.

3.1.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values.



Note! You can remove an applied code by clicking the cross icon to the right of the applied code.



3.2 A use case for coding with the WHO Drug Dictionary

3.2.1 Searching for a code

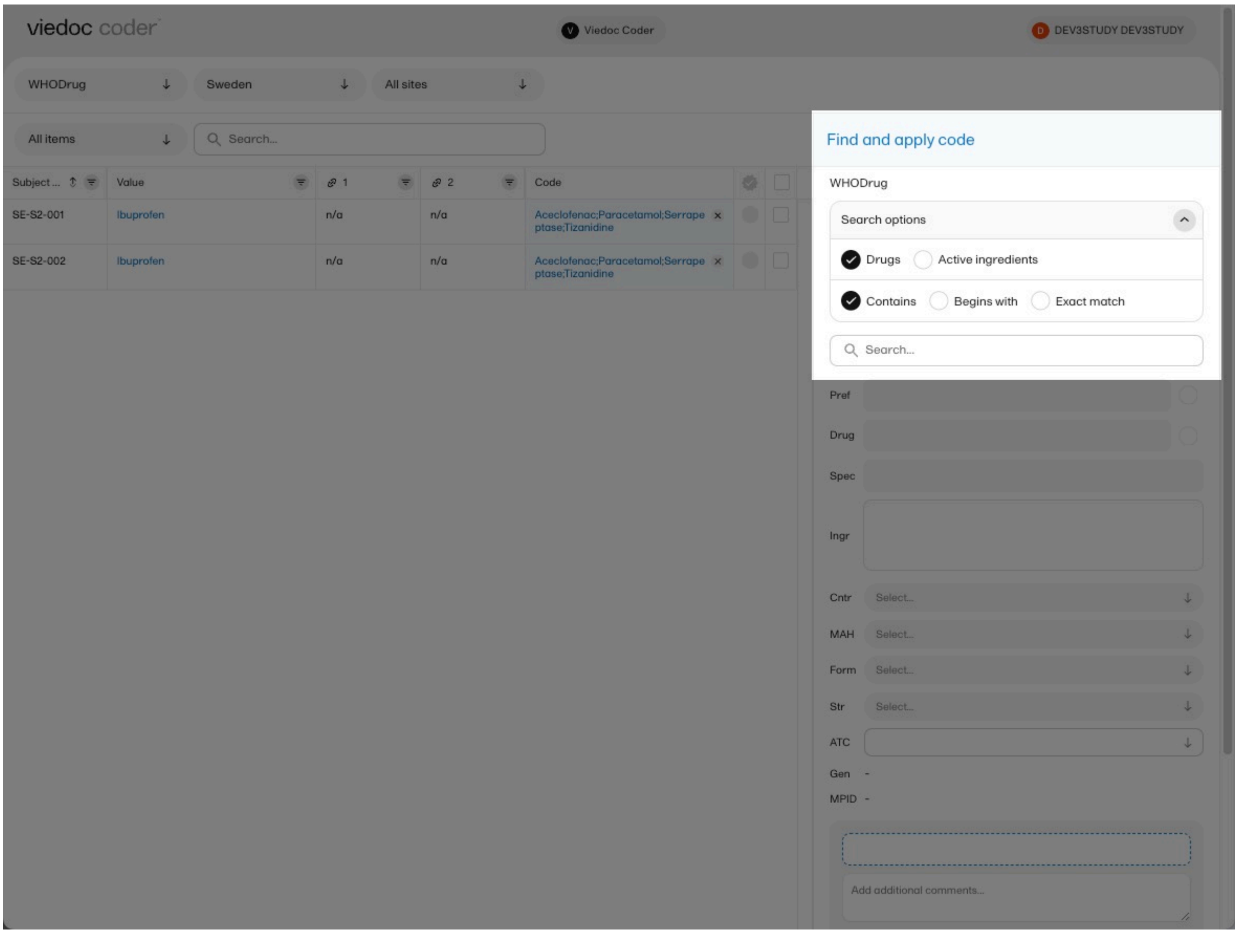
To find a code that you want to apply to a value, use the **Find and apply code** section.

When using the WHO DD, you can select to search by:

- **Drugs** - to search for drugs by their name. This is the default option.
- **Active ingredients** - to search for drugs by their active ingredients. You can enter multiple ingredients in the search field, separated by **;** and the search will return all drugs that contain all specified ingredients.

There are three search options available:

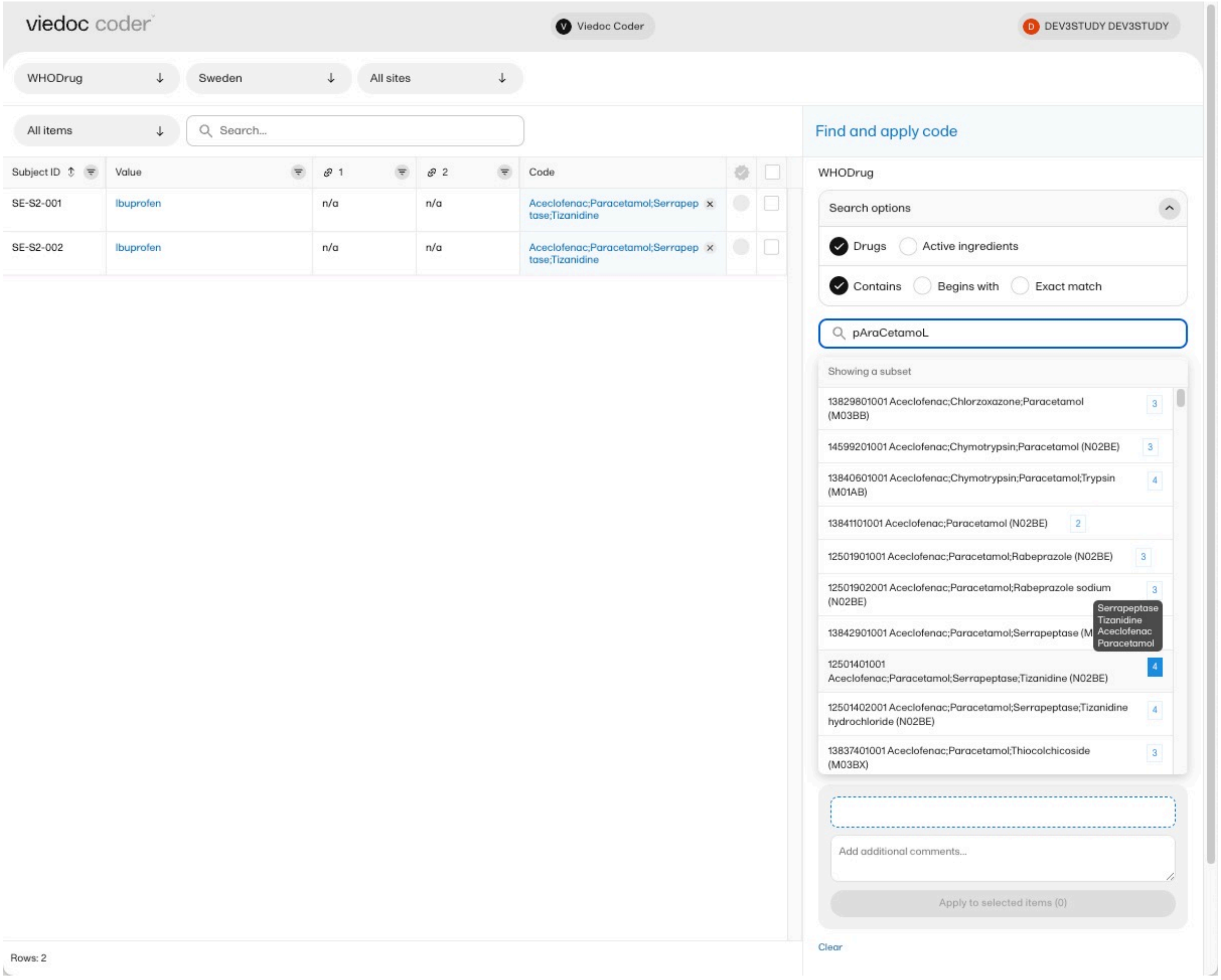
- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.



You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a dropdrown list that deploys from the **Search** field.

Searching is not case sensitive. If you type in "paRacetaMol", the search can return results such as "paracetamol" or "Paracetamol".

The number behind the entries in the list depicts the number of active ingredients. If you hover the cursor over the number, a dialog box appears that lists the active ingredients.

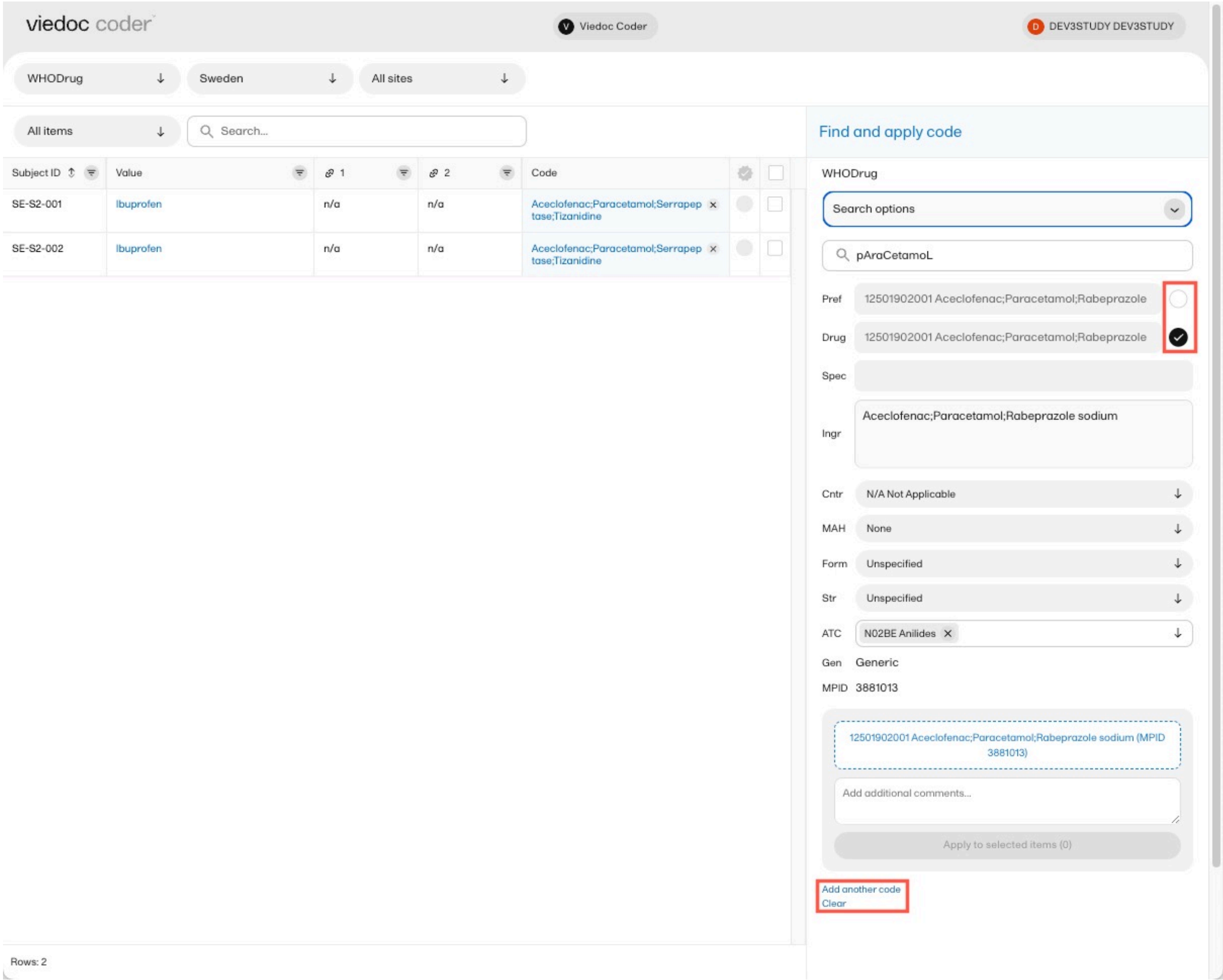


3.2.2 Selecting a code

Select the code (drug) you would like to apply. The details of this drug will appear in the fields below the search field.

In the WHO DD, all drugs have a preferred drug. You can select to use the Preferred drug (Pref) or the Drug name by clicking one of the blue radio buttons next to the **Pref** and **Drug** fields. **Drug** is the default.

Note! When exporting medical coding, both the preferred drug and drug name are included in the export (in separate columns). But if you select to apply **Pref** while coding, the preferred name ends up in both columns in the export. This is to provide consistency for the data managers, so that they only have to look in one column to find their data.

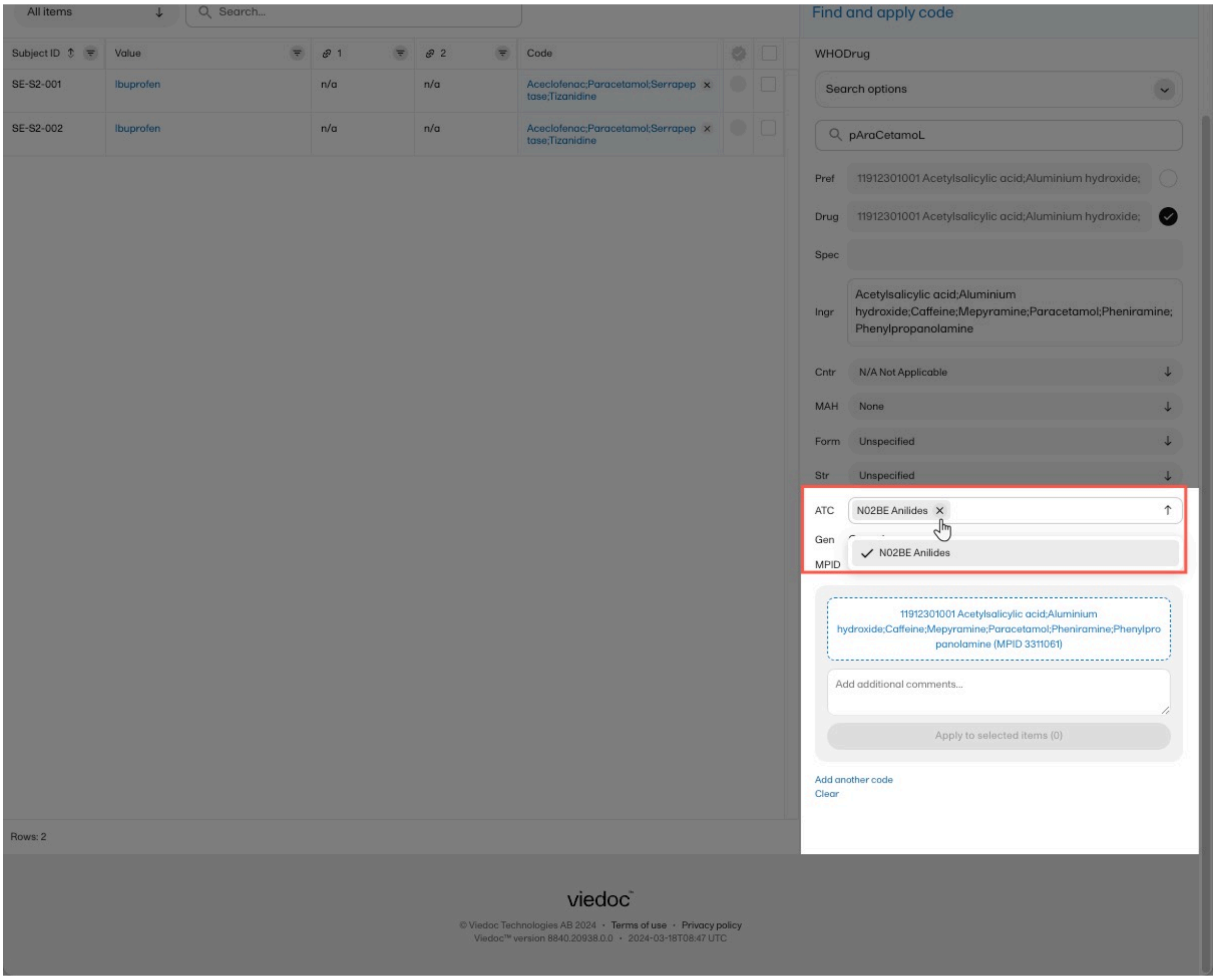


Use the dropdown lists to select Country (Cntr), Marketing Authorization Holder (MAH), Pharmaceutical Form (Form), Strength (Str), or Medicinal Product ID (MPID), if applicable.

If you would like to add more than one code to the same field, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset you selections by clicking **Clear**.

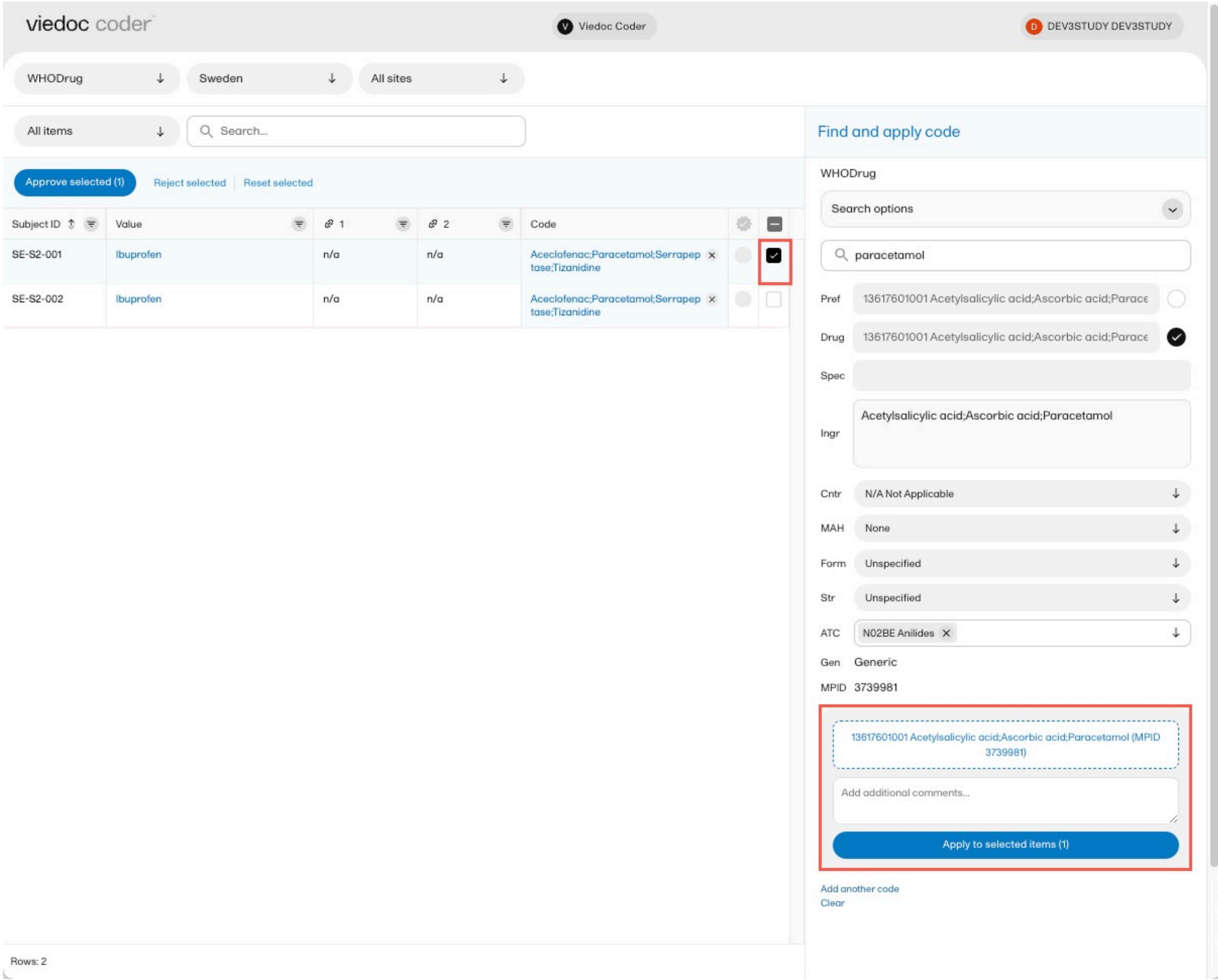
Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code..

If you selected a drug that carries multiple Anatomic Therapeutic Chemical Classification System (ATC) codes, all ATC codes will be displayed in the **ATC** field. You can define whether to include all ATC codes in the coding or only a selection. Select the ATC code to include it or select the X icon to remove an ATC code.



3.2.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values.



You can remove an applied code by clicking the cross icon to the right of the applied code.

---

4 Approving the medical coding

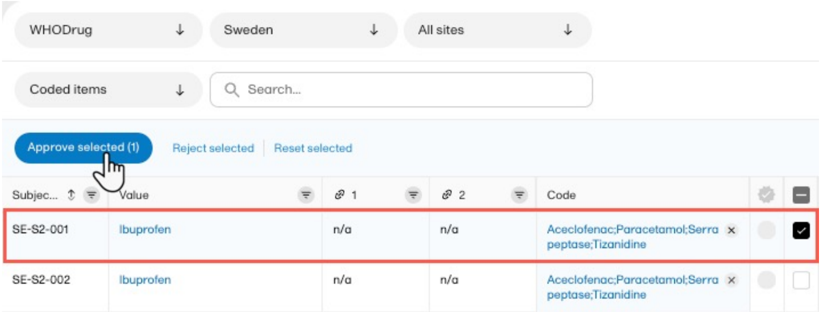
After applying codes to the items, it is possible to approve/reject/reset the items as shown in the below table.

Action	Current state/found in list	New state/found in list
Approve	Coded Rejected	Approved items
Reject	Coded Approved	Uncoded items
Reset	Approved Rejected	Coded items

Tip! To see all items in one list, select the filter **All items**.

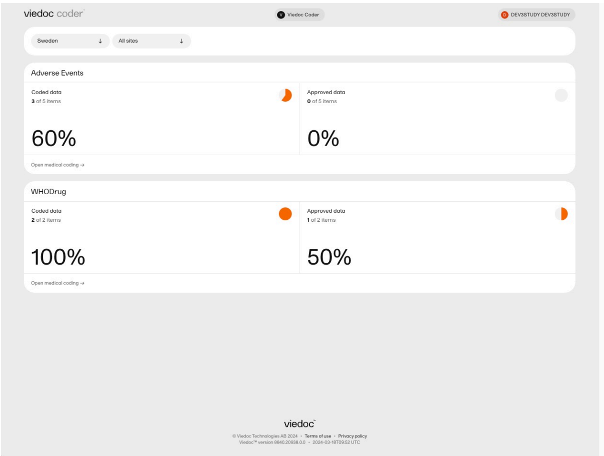
To approve items that have been coded:

1 Select the item(s) that you want to approve and click **Approve selected**.



2 The selected item(s) now disappear from the list and are found with the blue "Approved" symbol in the Approved items list.

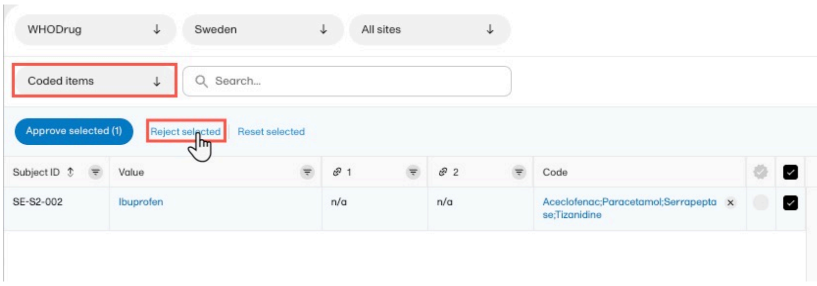
Tip! The metrics of the medical coding that have been approved can be seen on the landing page:



4.1 Rejecting the medical coding

To reject items that have been coded:

1 Select the items that you want to reject and select **Reject selected**.

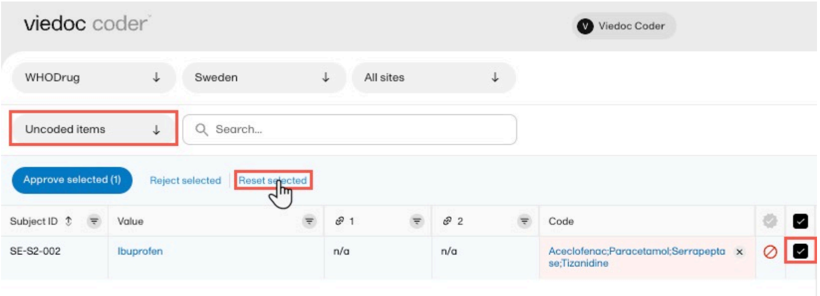


2 The selected item(s) now disappear from the list and are found with the red "rejected" symbol in the Uncoded items list for re-evaluation.

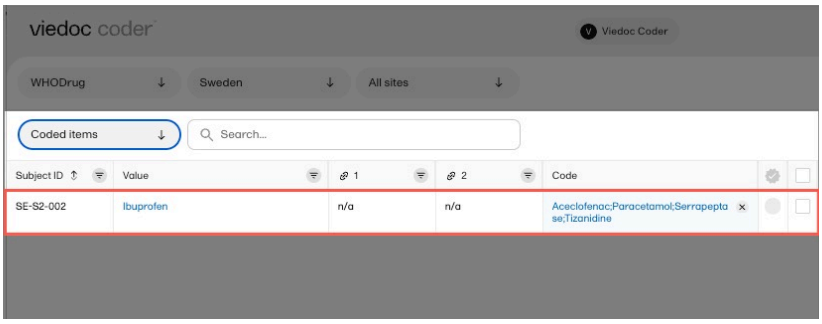
4.2 Resetting the medical coding

To reset items that have been approved or rejected:

1 Select the item(s) that you want to reset and click **Reset selected**.

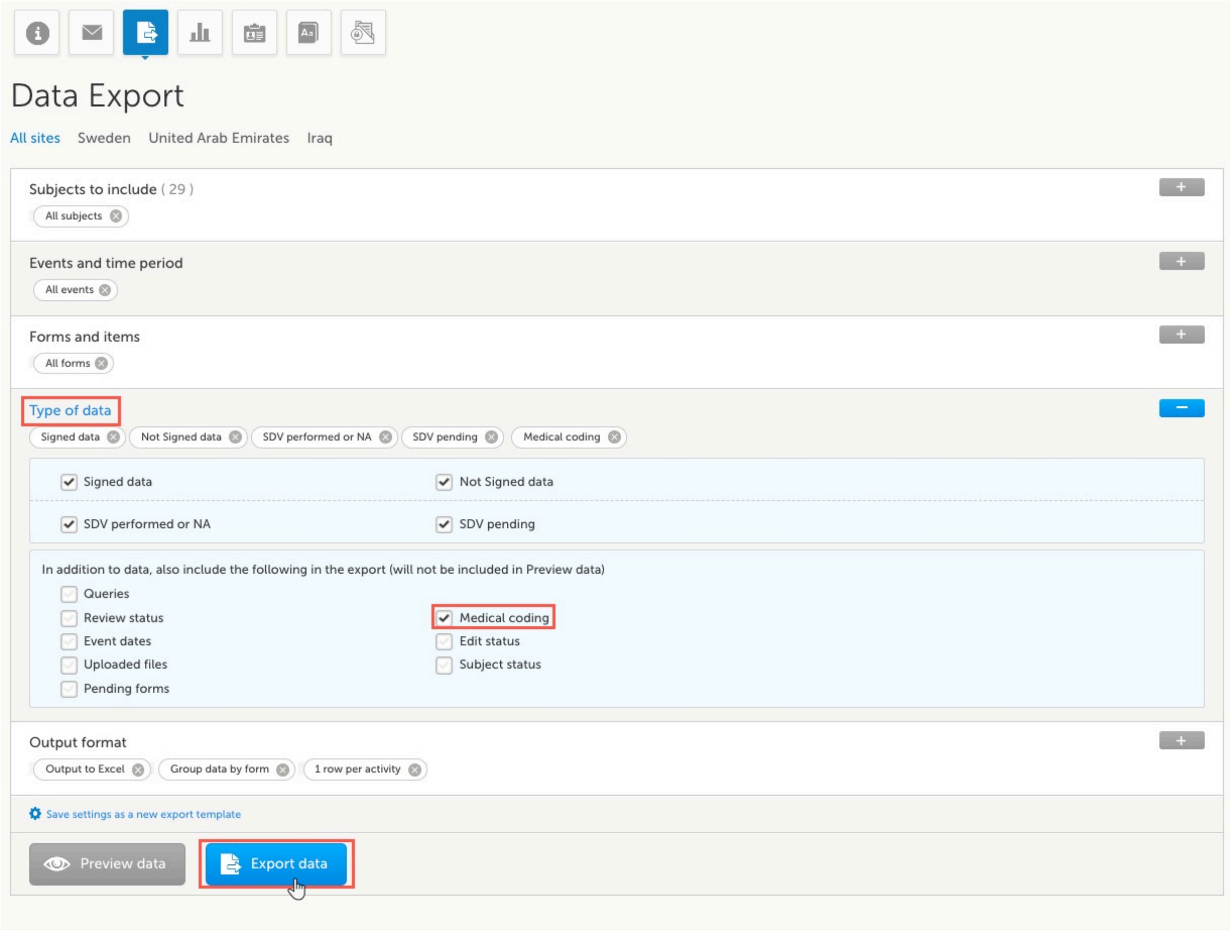


2 The selected item(s) now disappear from the list and are found in the Coded items list without the approved/rejected flag.



5 Exporting the medical coding

It is possible to export medical coding using Viedoc's data export feature, for more information, see Exporting data.



To export the medical coding, select the checkbox in front of **Medical coding** in the **Type of data section**.

For more information about how medical coding is exported, see:

- Medical coding in ODM export
- Medical coding in Excel export

Note! You can only export medical coding if permission to export data is activated for your role. If you do not see the data export icon, you do not have a role with export permissions.

6 Auto coding

In Viedoc Coder, you can choose to enable auto coding.

We support auto coding for the MedDRA and ATC dictionaries. Auto coding can be enabled and disabled for individual scopes within the MedDRA/ATC terminology. Currently, auto coding includes an exact match to MedDRA, any language and ATC.

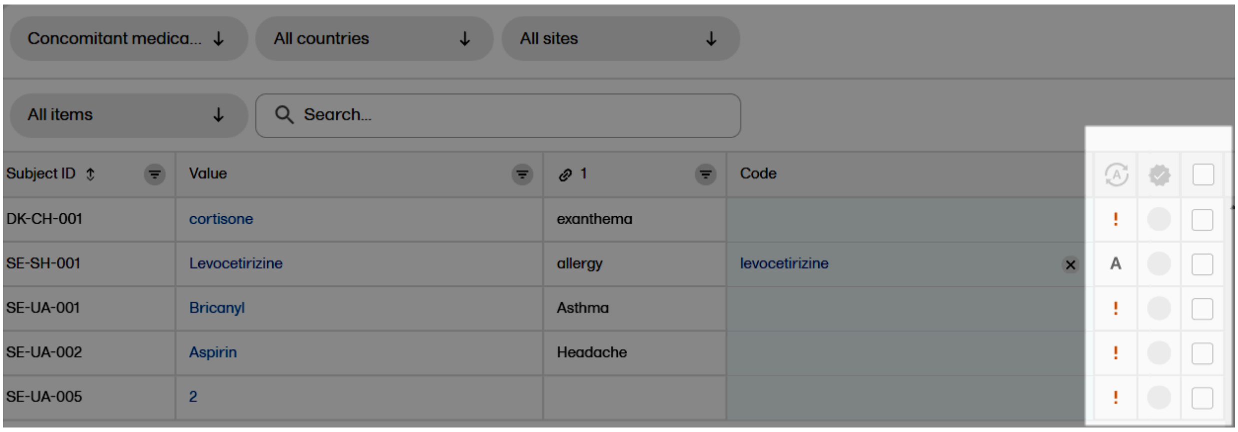
Note! MedDRA-J is scheduled to be included in the future.

Note! By default, auto coding is disabled for ongoing studies and enabled for new studies. However, it can be disabled for new studies. The auto coding setting is always available in Viedoc Admin, however is only functional for the new Viedoc coder and not the old Viedoc Coder console. If you wish to update to the new Viedoc Coder, please contact your Viedoc representative.

When auto coding is enabled, all existing uncoded items will be auto coded and all new items will be auto coded without any manual steps. However, items that are auto coded without a match will be flagged, and will need to be manually coded.

An auto coded item is indicated within the table for coded items:

- **A** = auto coded with a match
- ! = auto coded without match and needs to be manually coded.



[Back to top of page]

Medical coding version 4.78 and earlier

Medical coding version 4.78 and earlier

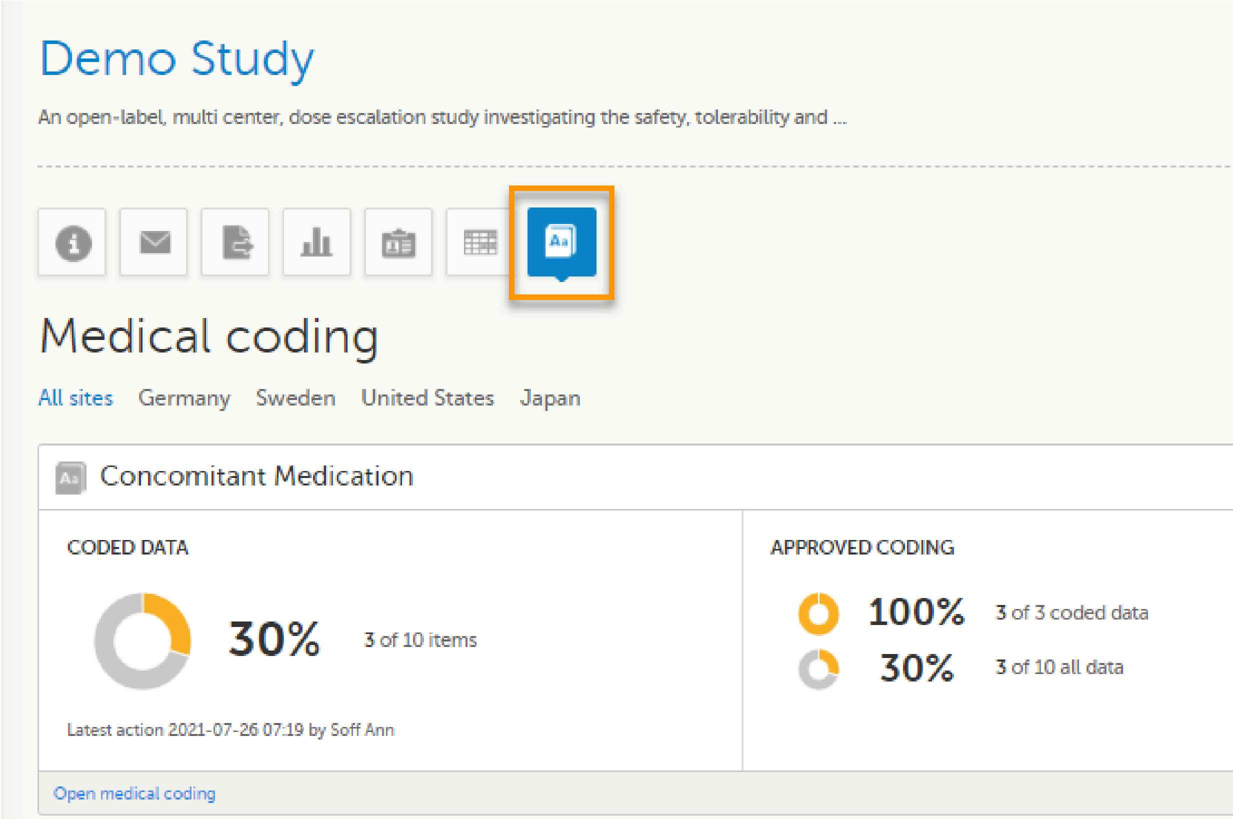
Published by Viedoc System 2024-06-27

1 Introduction

Viedoc Coder allows you to code data, such as Adverse Events, Medical History, and Concomitant Medications, in a standardized way. You can access Viedoc coder on the landing page.

The Viedoc Coder page displays metrics about coding that tell the user the number and percentage of items that have been coded and approved. There is one set of metrics for each coding scope. The metrics displayed are based on the data and sites that you have permission to view.

Note! You can only access Viedoc Coder if permission to view, perform, and/or approve medical coding is activated for your role. If you do not see the medical coding icon, you do not have a role with medical coding permissions.



You can select to display the metrics of:

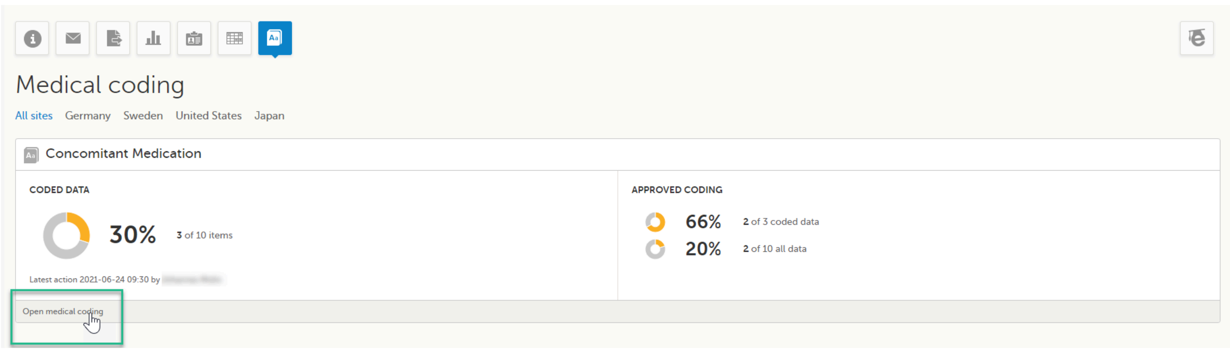
- All sites
- All sites in an individual country
- An individual site

---

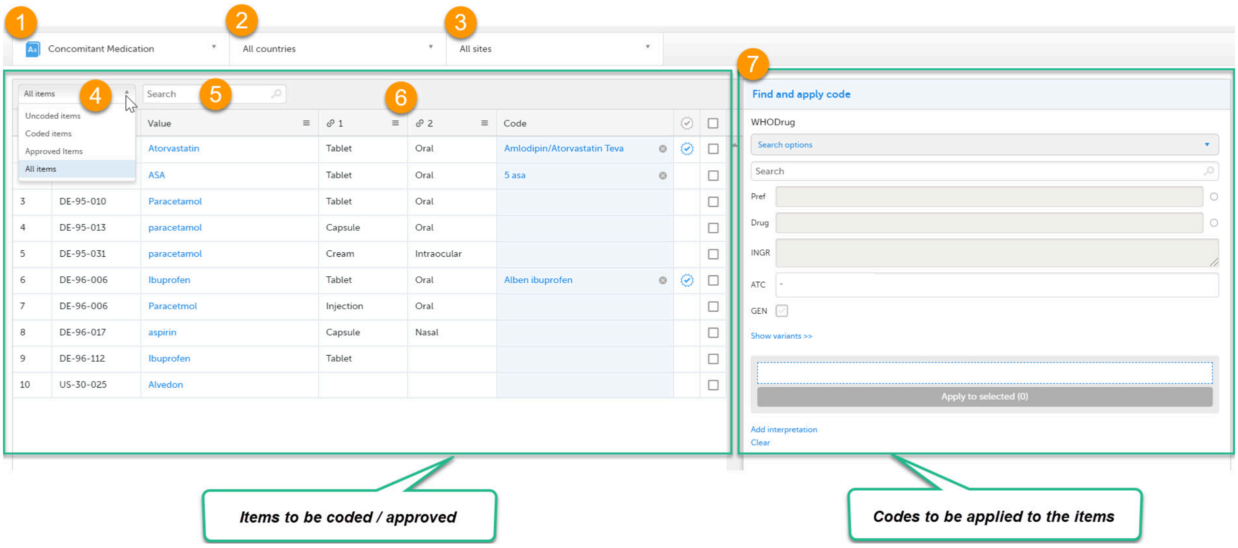
2 The Viedoc Coder console in Viedoc Clinic

2.1 Overview of the medical coding console

To enter the medical coding console, click **Open Viedoc Coder** in the lower left corner of the coding scope.



The Viedoc Coder console opens in the same window:



The Viedoc Coder console displays a table that lists all items to be coded in the **Values** column. You can view the corresponding form (Electronic Case Report Form (eCRF)) of an item by clicking on the value.

On the Viedoc Coder console, you can:

1. Select the coding scope (that is, data) to be coded.

2. Select to display items from all countries or from an individual country.

3. Select to display items from all sites or from an individual site.

4. Select to display all uncoded (and disapproved) items, all coded items, all approved items, or all items.

5. Perform a text search among all values of the items.

6. If configured for your study, there can be additional columns included with supporting values for the coding, for example route, indication, or other.

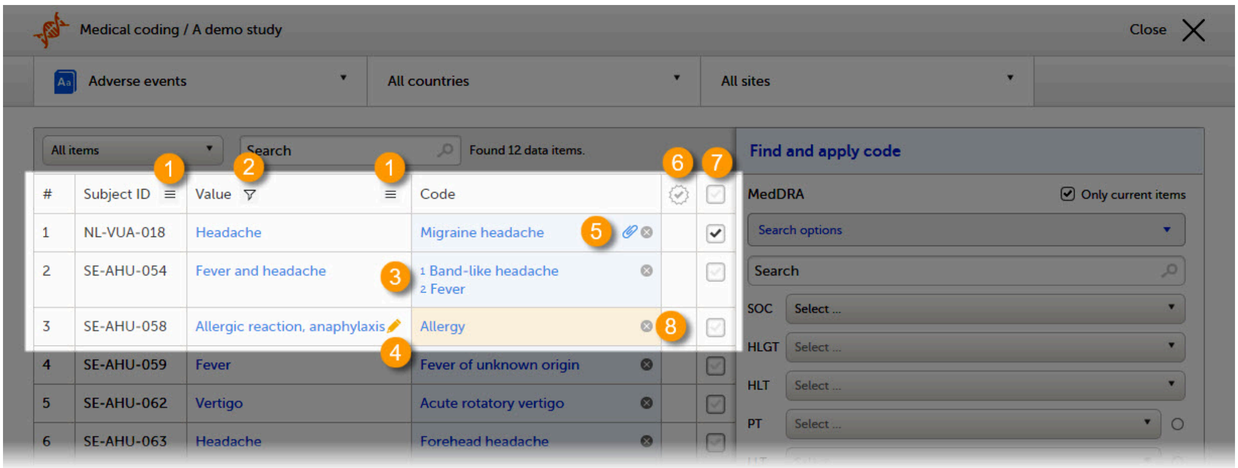
7. Find and apply codes (see Finding and applying a medical code).

When applying codes, it is possible to:

- Add an interpretation - a comment or explanation of the value that you have assumed in order to code.
- Add multiple codes to one value.

See Finding and applying a medical code.

2.2 What do the symbols and colors mean?



On the Viedoc Coder console, you can find the following symbols:

1. The three horizontal lines is a filter function. Click the symbol to open a drop-down list with a search field and a list of selectable items.

2. A filter symbol indicates that a selection has been made and the column only displays your filtered items.

3. A numbered list in the code field means that there is more than one medical code applied to that value.

4. An orange pen icon in the value field, together with a light orange background in the code field, means that the value (form item) has been changed in Viedoc Clinic by the Investigator after the item was coded. The applied code may not be correct anymore and the item needs to be re-coded.

5. A clip icon in the code field means that an interpretation has been added. Move the mouse pointer over the clip icon to view the contents of the interpretation.

6. An activated tick mark indicates that the coding has been approved.

7. The checkbox is used to mark the values to which a selected code should be applied.

8. The white cross in a grey circle is used to delete the applied code.

---

3 Finding and applying a medical code

This section gives an example of medical coding of adverse events using the Medical Dictionary for Regulatory Activities (MedDRA) and an example of medical coding of concomitant medication using the World Health Organization Drug Dictionary (WHO DD). The coding procedure is similar even if you are using other types of dictionaries.

3.1 A use case for coding with the MedDRA dictionary

3.1.1 Searching for a code

To find a code that you want to apply to a value, use the **Find and apply code** section.

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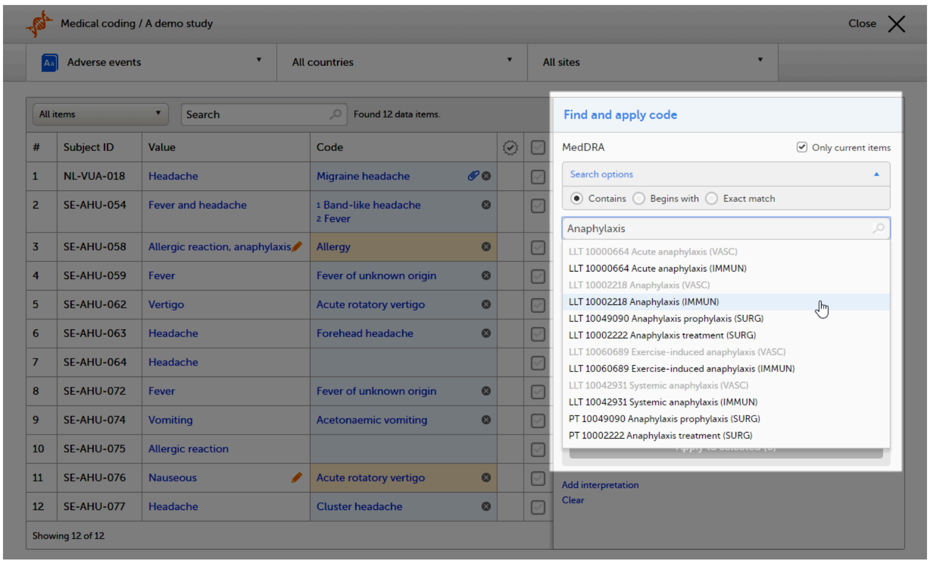
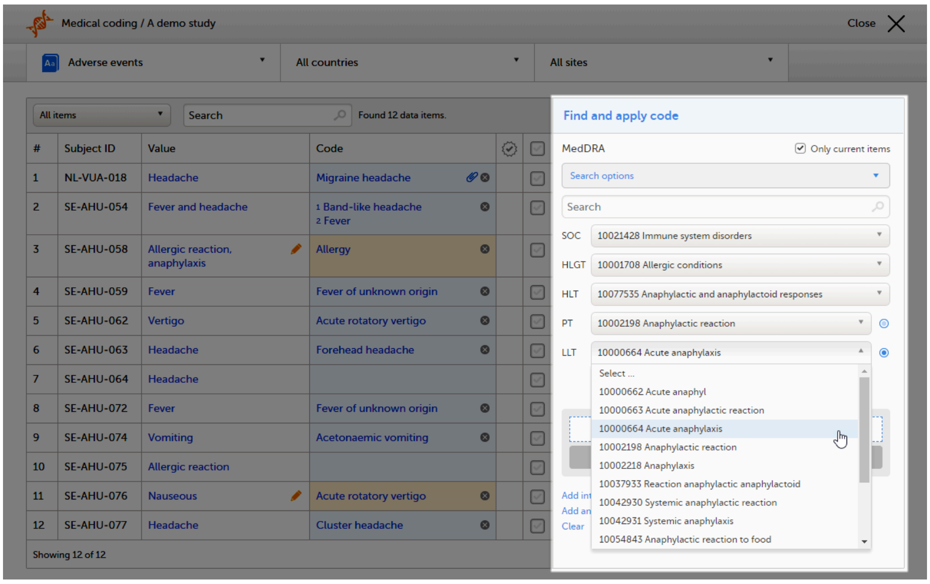
Searching is not case sensitive. If you type in "Anaphylaxis", the search can return results such as "anaphylaxis" and "Anaphylaxis".



You can also search a code by selecting the System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Preferrred Term (PT) and Low Level Term (LLT) using the drop-down lists below the search field.

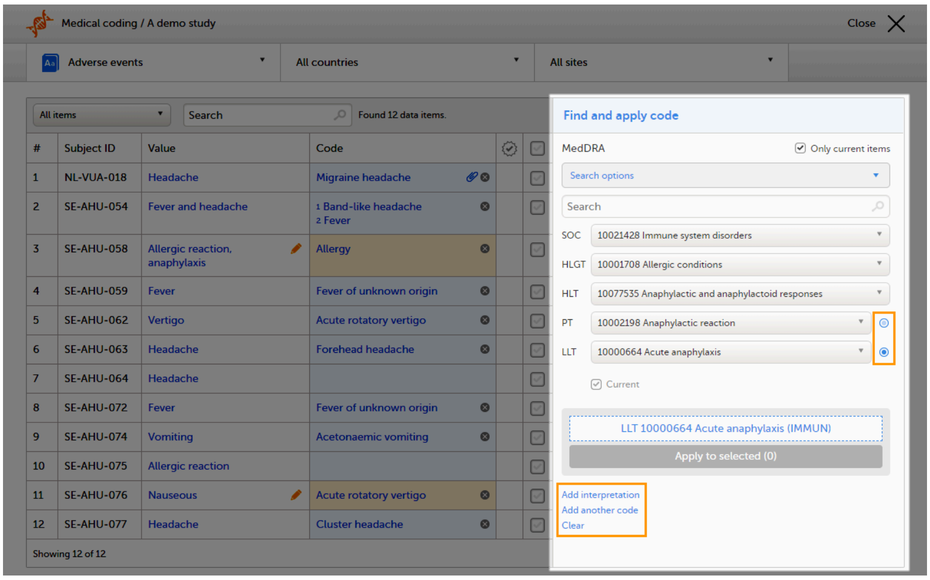
By default, the search returns low level terms (LLTs) that have the status 'current' in the [MedDRA]() dictionary. It is possible to search among non-current MedDRA codes (that is, terms that are vague, ambiguous, truncated, abbreviated, out-dated, or misspelled and thus no longer used), by clearing the checkbox for **Only current items**.



3.1.2 Selecting a code

Select the code you would like to apply. The details of this code appear in the fields below the search field. The checkbox **Current** displays whether the selected Low Level Term (LLT) has the status *current* in the [MedDRA]() dictionary or not.

You can select to use the Preferred Term (PT) or the Low Level Term (LLT) by clicking one of the blue radio buttons behind the **PT** and **LLT** fields, see image.

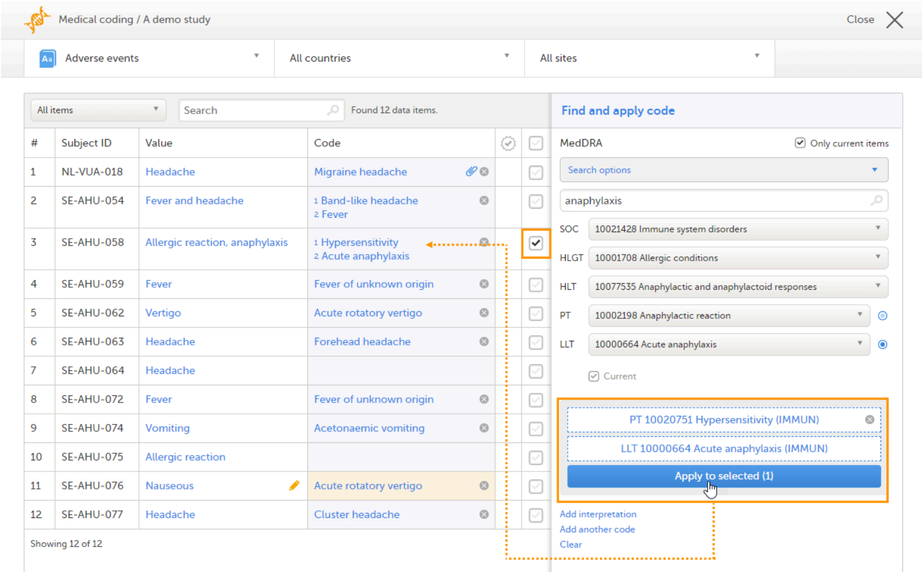


If you would like to add more than one code to the same field, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset your selections by clicking **Clear**.

Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code.

3.1.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values. In the example in the image, we applied two codes to the value *Allergic reaction, anaphylaxis* for subject *SE-AHU-058*.



You can remove an applied code by clicking the cross icon to the right of the applied code.

3.2 A use case for coding with the WHO Drug Dictionary

3.2.1 Searching for a code

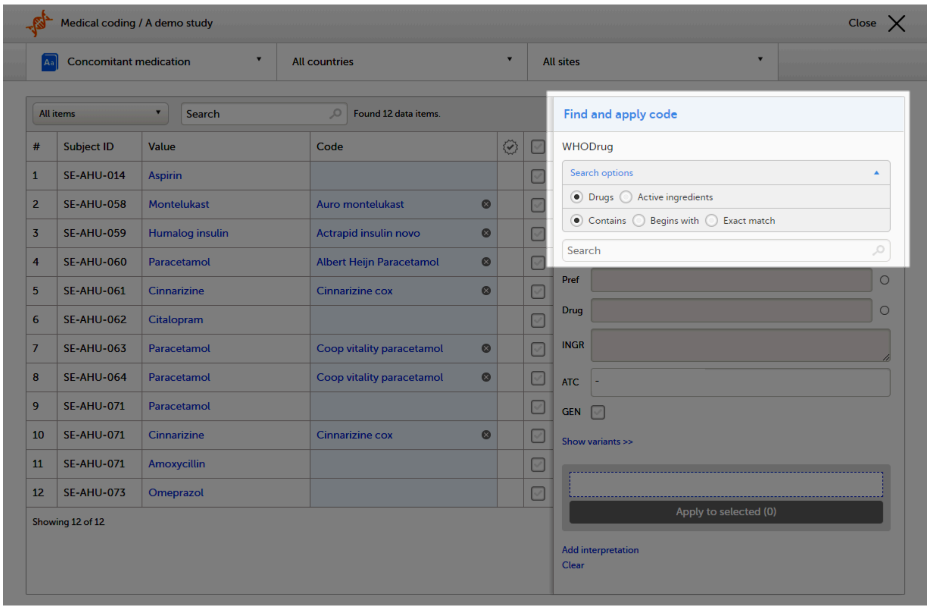
To find a code that you want to apply to a value, use the **Find and apply code** section.

When using the WHO DD, you can select to search by:

- **Drugs** - to search for drugs by their name. This is the default option.
- **Active ingredients** - to search for drugs by their active ingredients. You can enter multiple ingredients in the search field, separated by **;** and the search will return all drugs that contain all specified ingredients.

There are three search options available:

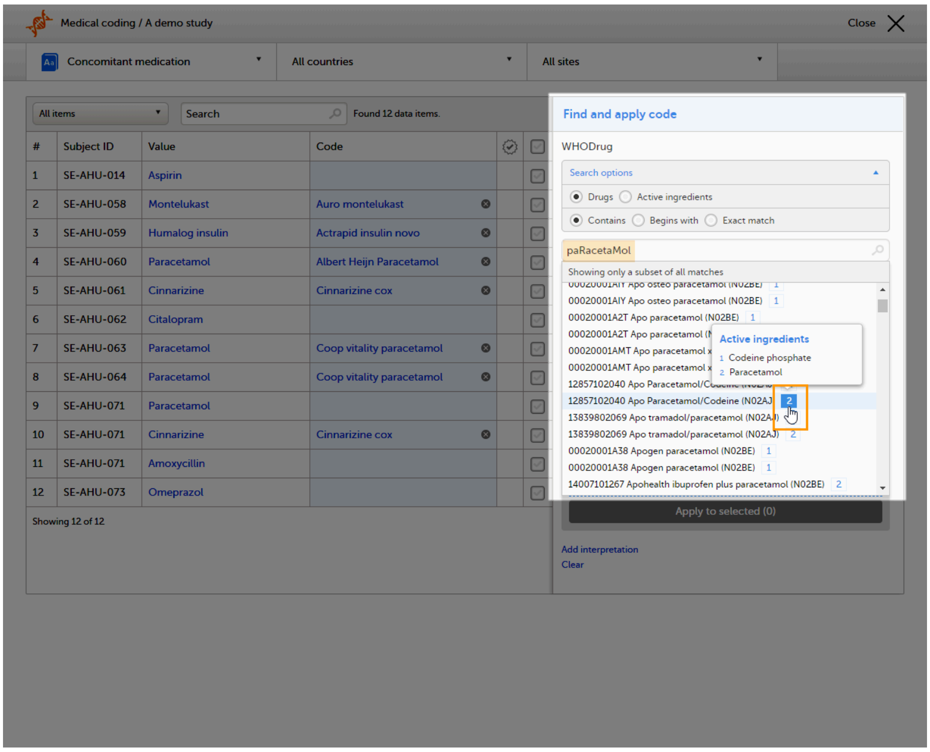
- **Contains** - the search will return all entries that contain the text typed in the search field. This is the default option.
- **Begins with** - the search will return all entries that begin with the text typed in the search field.
- **Exact match** - the search will return all entries that exactly match the text typed in the search field.



You can search for codes or (substrings of) terms in the **Search** field. Codes matching the term will be listed in a drop-drown list that deploys from the **Search** field.

Searching is not case sensitive. If you type in "paRacetaMol", the search can return results such as "paracetamol" or "Paracetamol".

The number behind the entries in the list depicts the number of active ingredients. If you click that number, a pop-up appears that lists the active ingredients.

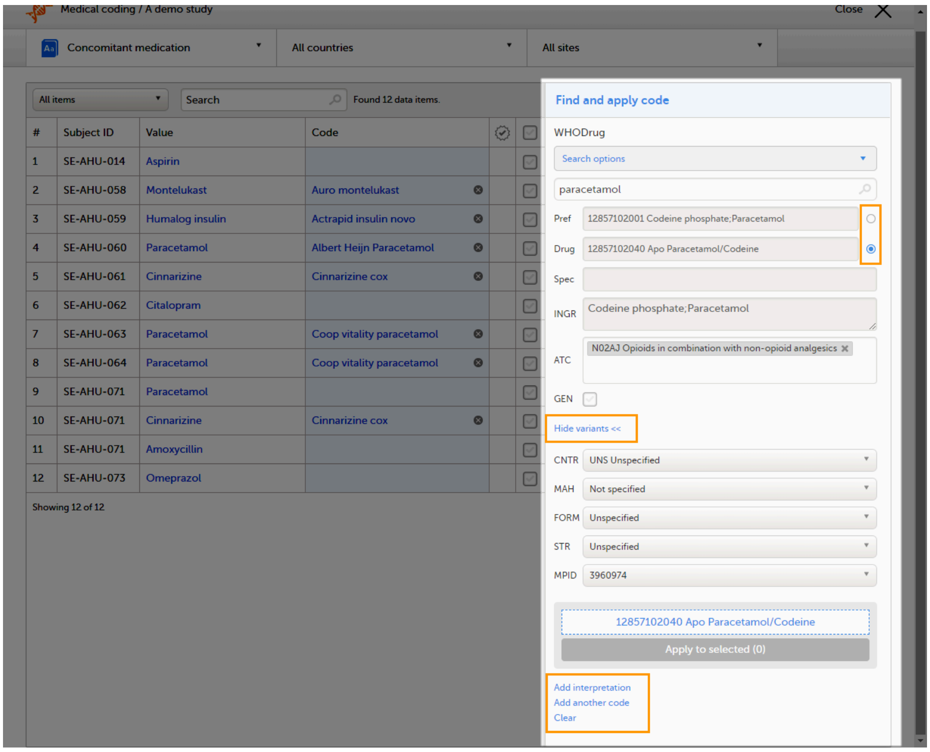


3.2.2 Selecting a code

Select the code (drug) you would like to apply. The details of this drug will appear in the fields below the search field.

In the WHO DD, all drugs have a preferred drug as parent. You can select to use the Preferred drug (Pref) or the Drug name by clicking one of the blue radio buttons behind the **Pref** and **Drug** fields. Drug is the default.

Note! When exporting medical coding, both the preferred drug and drug name are included in the export (in separate columns). But if you select to apply **Pref** while coding, the preferred name ends up in both columns in the export. This is to provide consistency for the data managers, so that they only have to look in one column to find their data.

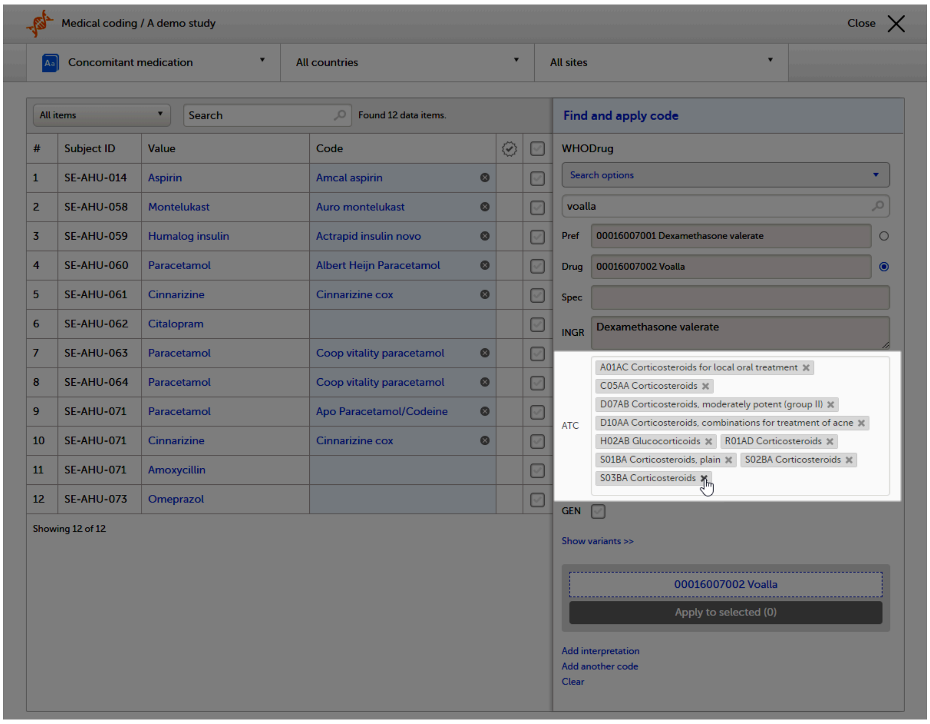


Click **Show variants** to display and specify variants of the selected code (drug), and use the drop-down lists to select Country (CNTR), Marketing Authorization Holder (MAH), Pharmaceutical Form (FORM), Strength (STR), or Medicinal Product ID (MPID), if applicable. Click **Hide variants** to hide the variants, see image.

If you would like to add more than one code to the same field, click **Add another code**.
If you would like to add an interpretation, that is, a comment or explanation of the selected code, click **Add interpretation** and type your interpretation in the field.
You can reset you selections by clicking **Clear**.

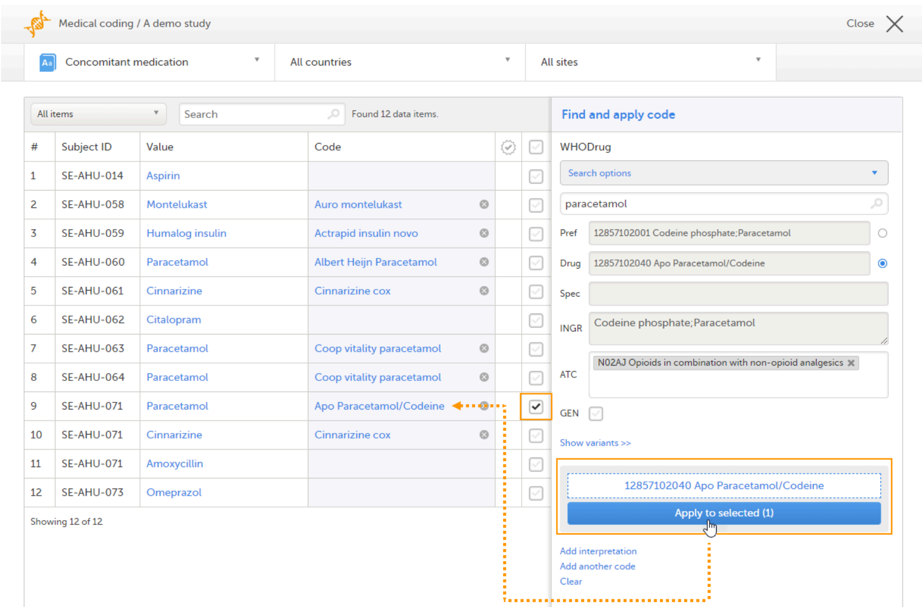
Tip! If you want to apply a code that has been used before, click that code in the left side of the table. The **Find and apply code** section is then automatically populated with the selections for that code..

If you selected a drug that carries multiple Anatomic Therapeutic Chemical Classification System (ATC) codes, all ATC codes will be displayed in the **ATC** field. You can define whether to include all ATC codes in the coding or only a selection. Click the cross to remove an ATC code, or click the **ATC** field to add ATC codes.



3.2.3 Applying a code

To apply a selected code, select the checkboxes for the value or values you want to apply that code to, and click **Apply to selected**. The selected code will be applied to the selected subjects and values.



You can remove an applied code by clicking the cross icon to the right of the applied code.

4 Approving the medical coding

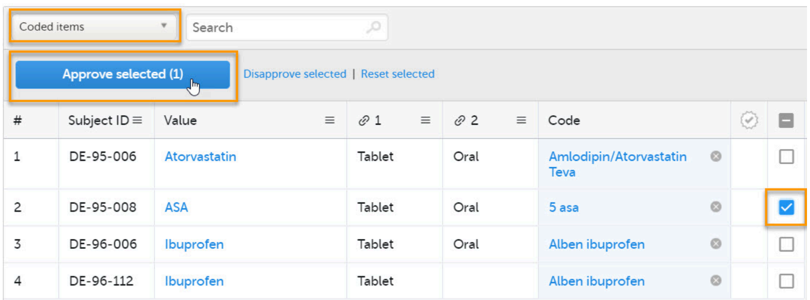
After applying codes to the items, it is possible to approve/disapprove/reset the items as shown in the below table.

Action	Current state/found in list	New state/found in list
Approve	Coded Disapproved	Approved items
Disapprove	Coded Approved	Uncoded items
Reset	Approved Disapproved	Coded items

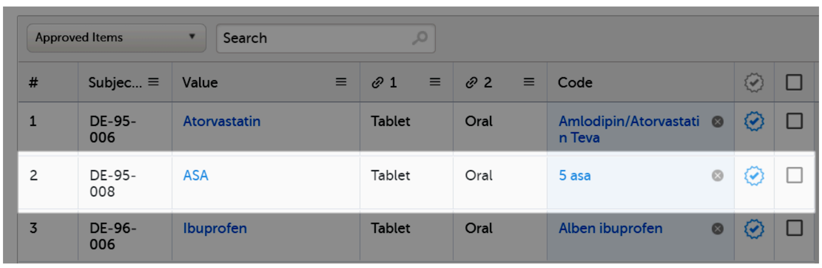
Tip! To see all items in one list, select the filter **All items**.

To approve items that have been coded:

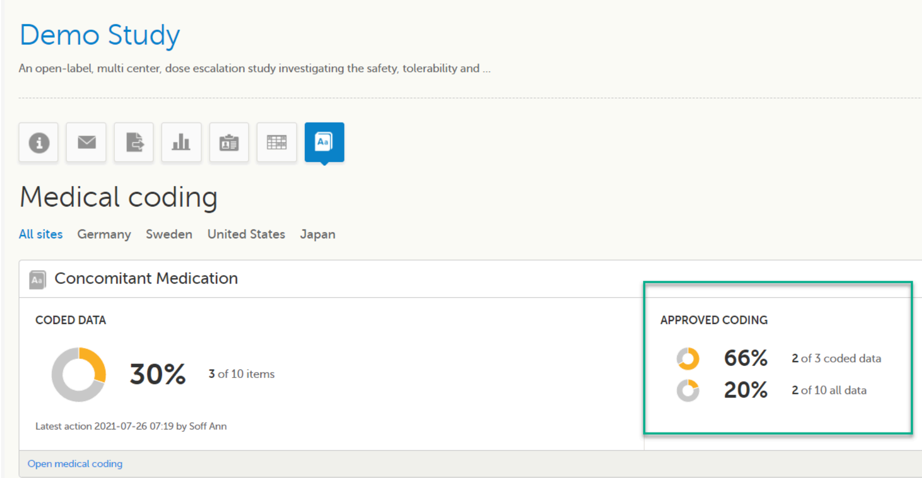
1 Select the item(s) that you want to approve and click **Approve selected**.



2 The selected item(s) now disappear from the list and are found with the blue "Approved" symbol in the Approved items list.



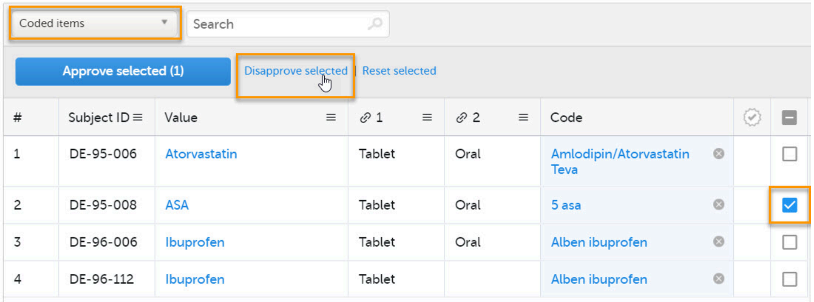
Tip! The metrics of the medical coding that have been approved can be seen on the landing page:



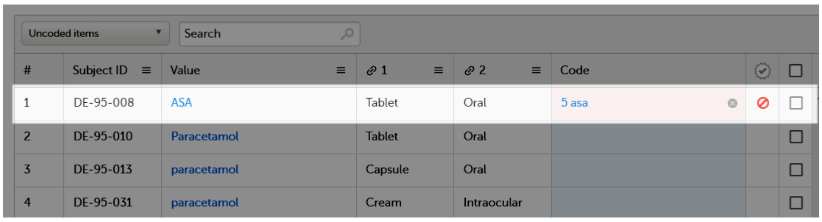
4.1 Disapproving the medical coding

To disapprove items that have been coded:

1 Select the items that you want to disapprove and click **Disapprove selected**.



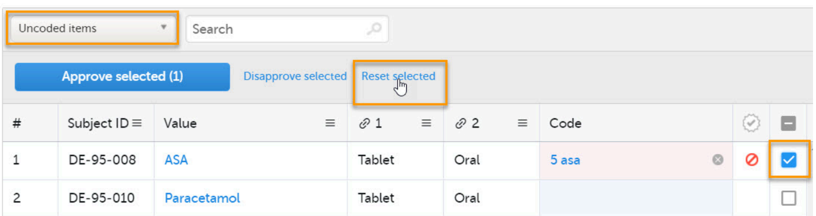
2 The selected item(s) now disappear from the list and are found with the red "Disapproved" symbol in the Uncoded items list for re-evaluation.



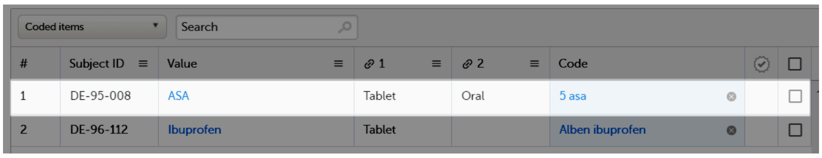
4.2 Resetting the medical coding

To reset items that have been approved or disapproved:

1 Select the item(s) that you want to reset and click **Reset selected**.

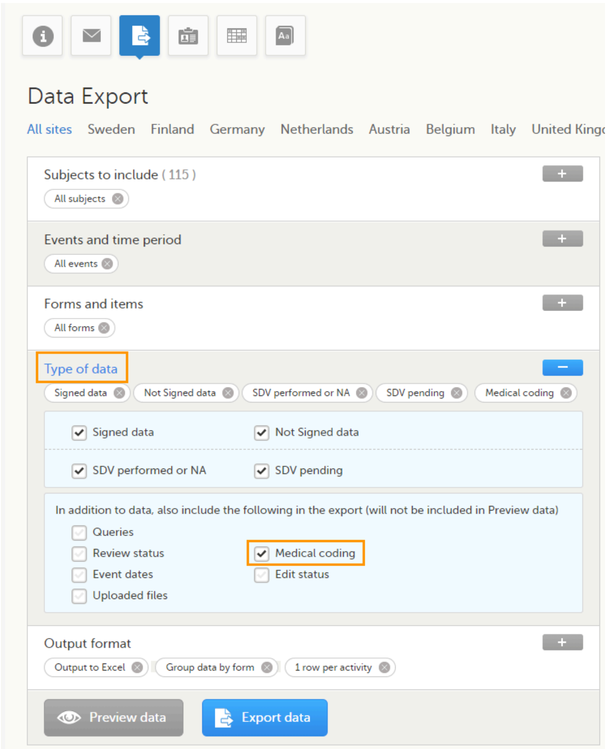


2 The selected item(s) now disappear from the list and are found in the Coded items list without the approved/disapproved flag.



5 Exporting the medical coding

It is possible to export medical coding using the export feature of Viedoc, see [Exporting data](#).



To export the medical coding, select the checkbox in front of **Medical coding** in the **Type of data section**.

For more information about how medical coding is exported, see:

- [Medical coding in ODM export](#)
- [Medical coding in Excel export](#)

Note! You can only export medical coding if permission to export data is activated for your role. If you do not see the data export icon, you do not have a role with export permissions.

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

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

Published by Viedoc System 2018-11-07

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

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

Activate demo mode

Activate demo mode

Published by Viedoc System 2018-11-07

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

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

Version 2.1