MediCase eCRF version 5.2

MediCase eCRF version 5.2 will be released Sunday November 27, 2022.

Content

1. General

1.1. Subject status has been redefined

All subjects in MediCase have a *status*. We have now redefined the possible status values to make them more intuitive, and also introduced the possibility to have study specific subject statuses corresponding to different study phases. Previously, subjects progressed through the phases Screening, Included and Follow-up (where applicable). Now it will be possible to specify custom phases for each study, and the subjects' status will directly display in which phase it is.

Possible subject status values:

Status	Description	Change
Screening	The subject is in screening. The status name is the name of screening study phase the subject is in and can be customized for a study.	
Study	The subject is included and in progress. The status name is the name of included study phase the subject is in and can be customized for a study (e.g. can be "Study", "Run-in" or "Follow-up").	Was previously named "Included", or "Follow-up", depending on study phase. The previous "Included" study phase is now named "Study" (see "Redesigned subject page" for more information). To rename the default "Study" phase or to discuss configuration of named study phases in your ongoing study, please contact MediCase.
Completed	The subject is included, and all data on all visits is entered for the subject.	Was previously named "Finished", but then only used when monitoring and signing was complete for all visits.
Rejected	The subject has been rejected before screening (only applicable in studies using Rejection Log).	Was previously named "Unsuitable"
Waiting for informed consent	The subject has not yet given informed consent (applicable studies only).	
Screening failure	The subject was not included after screening.	Was previously named "Not included"

Excluded at randomization	The subject was randomized, but excluded as a result of randomization.	
Early terminated	The subject has been included, but has been early terminated.	Was previously named "Excluded"

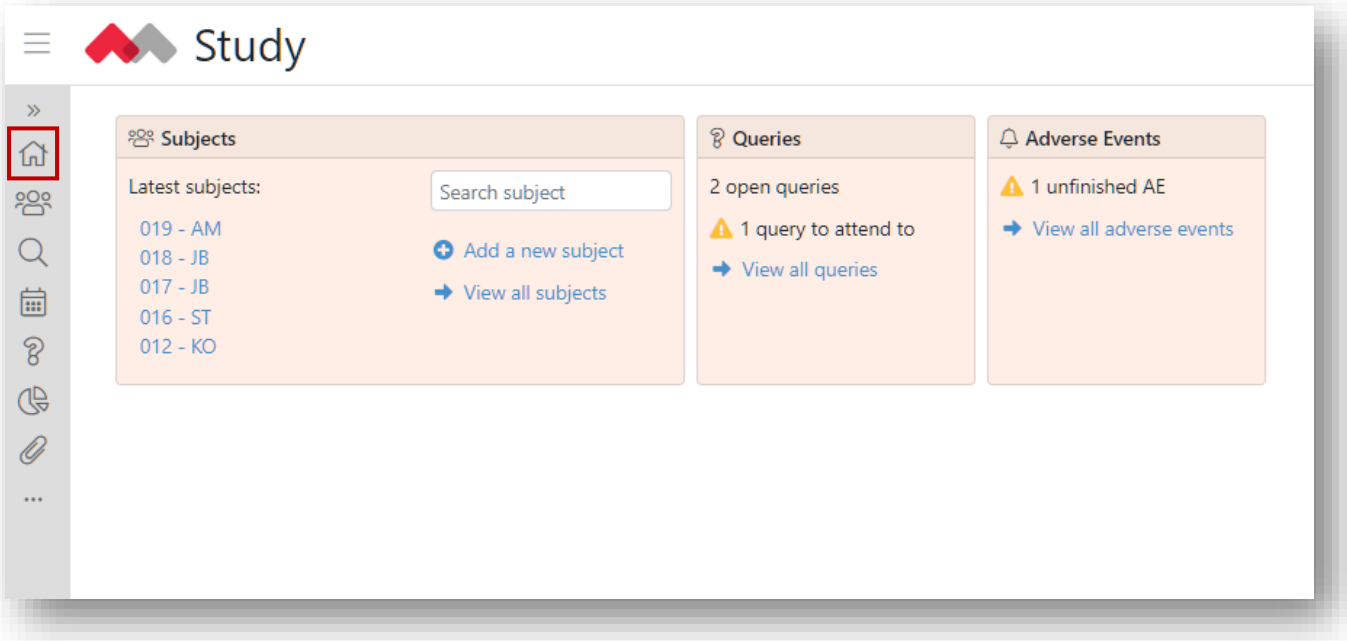
Included subjects now includes early terminated subjects

When filtering subject list for "Included subjects" or reviewing the number of "Included subjects" in the study statistics report, early terminated subjects were previously not considered as included. To be more consistent with how subjects are categorized in study reviews, early terminated subjects are now also accounted for when we use the term "included subjects".

1.2. Study dashboard

When opening a study's eCRF the start page is now a dashboard containing the most common features, along with useful information about open queries, unfinished adverse events etc.

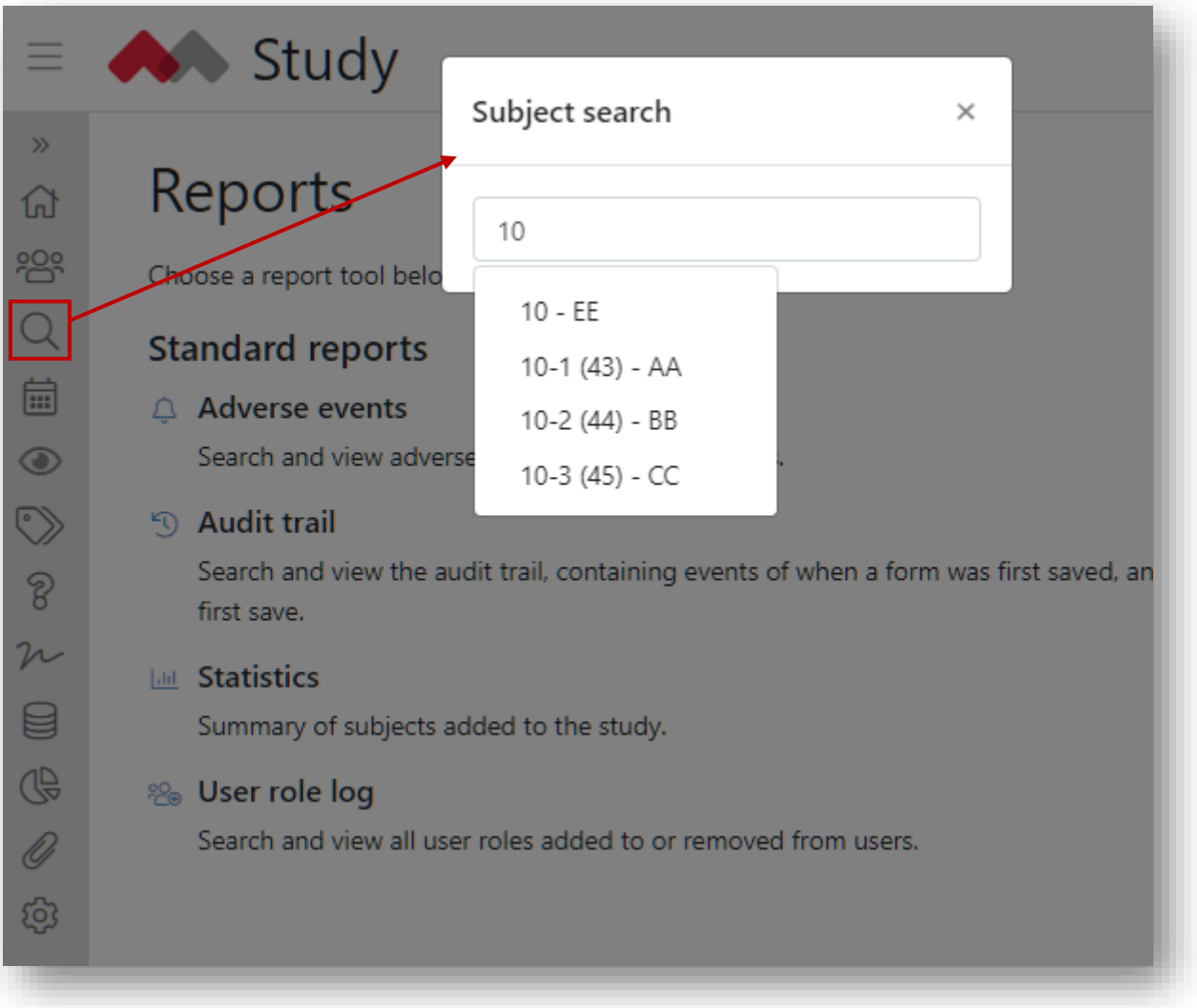
The dashboard will contain different sections depending on your user role. You can always return to the dashboard using the "Home" icon in the menu.



The study dashboard contains useful information and links to common features.

1.3. Subject search in menu

You can now search for study subjects directly in the menu, anywhere in the eCRF. Click the search icon in the menu and then search for subjects by screening number, subject number or any other part of the subject identification label. The subjects matching your search will be displayed in a list. Click on the subject in the list to navigate to the subject page for the selected subject.



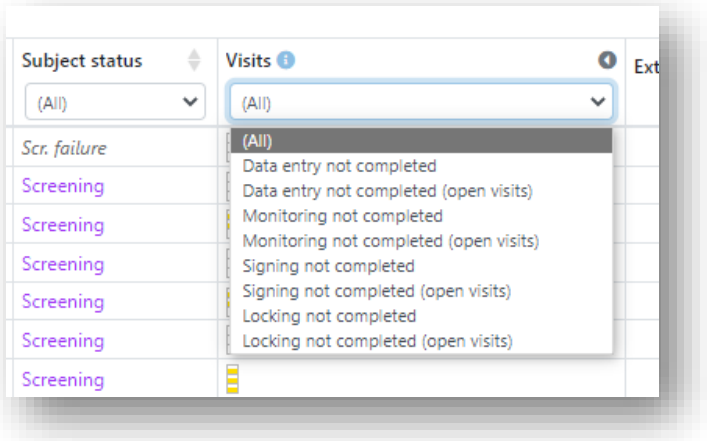
The subject search in the menu makes it easy to go to the subject page for any subject from any location in the eCRF.

1.4. Subject list updates

The subject list has been updated to better adjust to your screen size, and with some new features to make it easier to get an overview of the subjects in your study.

- The subject list better adjusts to your screen size

- The “Visits” column contains more filtering options for searching subjects that is not complete in data entry, monitoring, signing and/or locking.

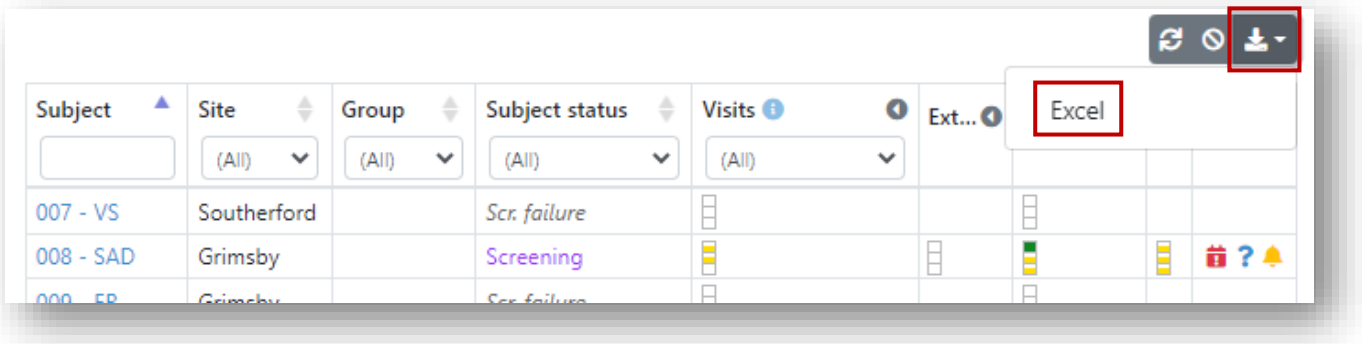


In the Visits column filter you can choose to only display subjects that are not completed in data entry, monitoring, signing and/or locking

- Omitted visits are distinguished by grey boxes in the progress icons.

Omitted visits are displayed with a grey box

- You can export the subject list as an Excel document.

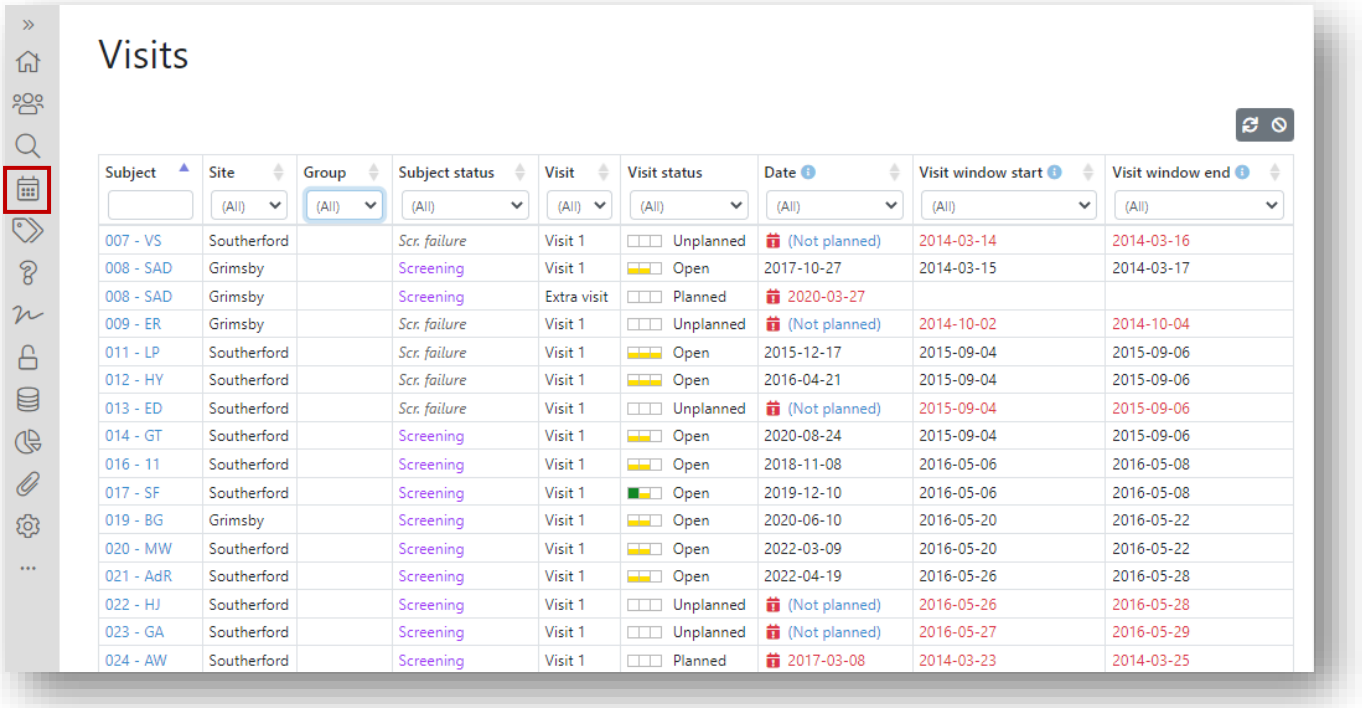


Click the Export button on the top right corner, and then select "Excel" to export the subject list as an Excel document

1.5. Visits tool

The *Visit planning* menu item has been replaced by *Visits*, where all visits for all subjects are listed, including the visit status, date planned and visit window (if applicable).

You still have all the visit planning options for subjects' next visit as in the previous *Visit planning* tool, but you now also get an overview of the status of all previous and upcoming subject visits.



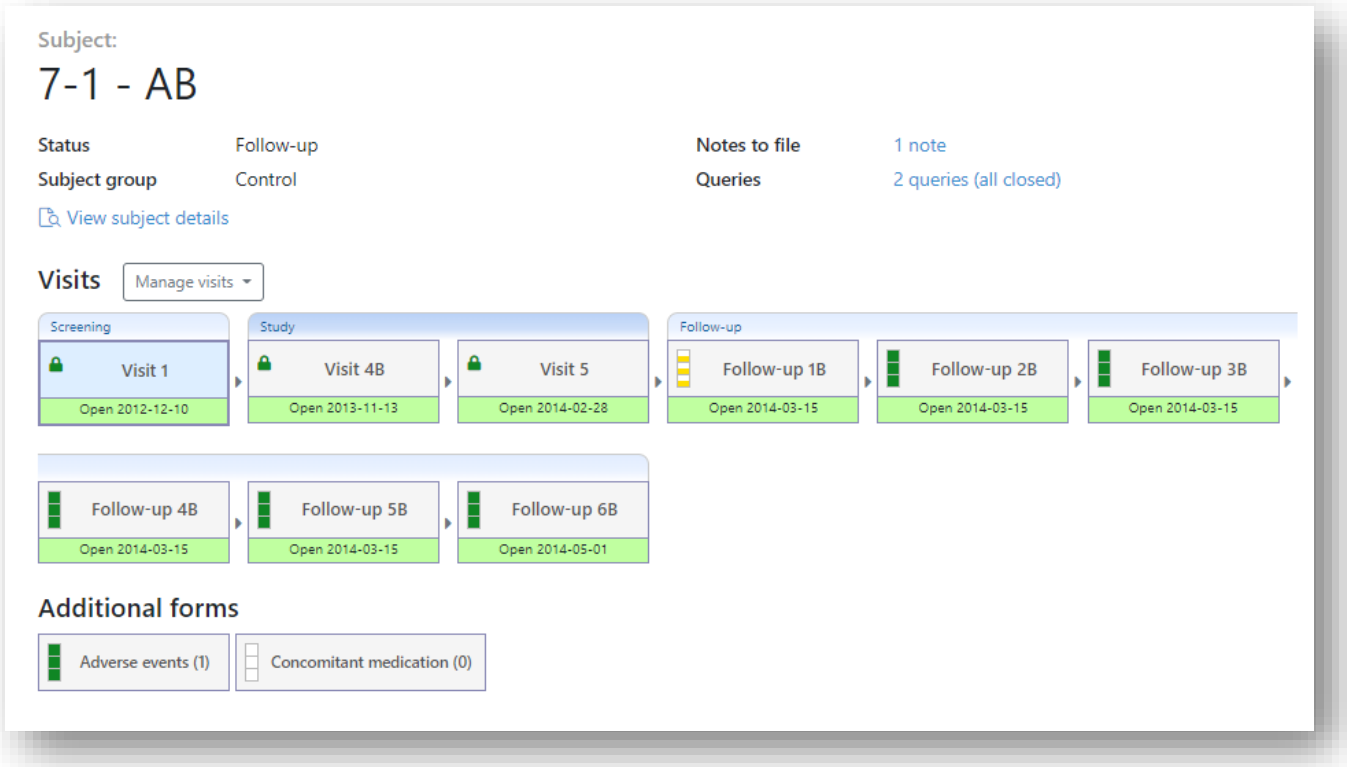
The Visits tool shows an overview of all known subject visits in the study – passed and upcoming.

1.6. Redesigned subject page

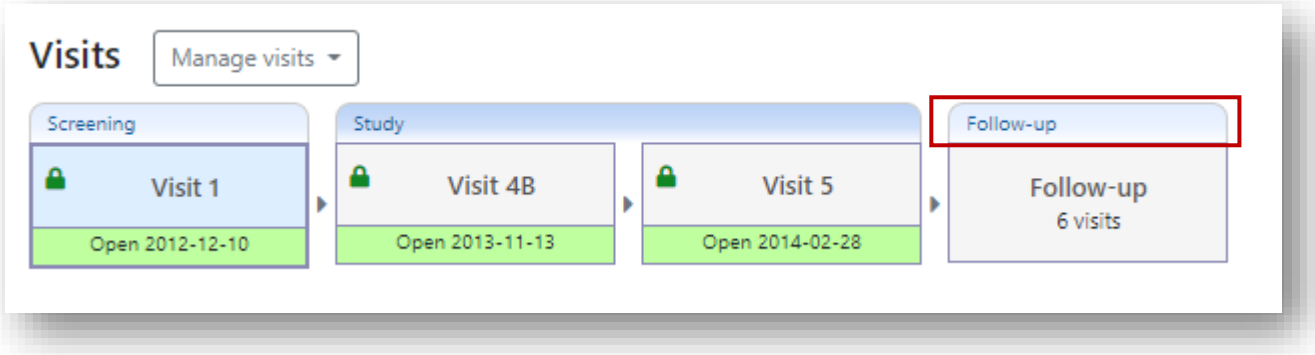
The subject page has been redesigned and has some new features added.

Note when reading the below: To rename the default "Study" phase or to discuss configuration of named study phases in your ongoing study, please contact MediCase.

- The visits are grouped by the study phase they belong to. The name of the study phase is displayed in a bar above the visit boxes. Clicking on the bars expand or collapse the whole study phase.



The study phases are displayed in bars above the visit boxes

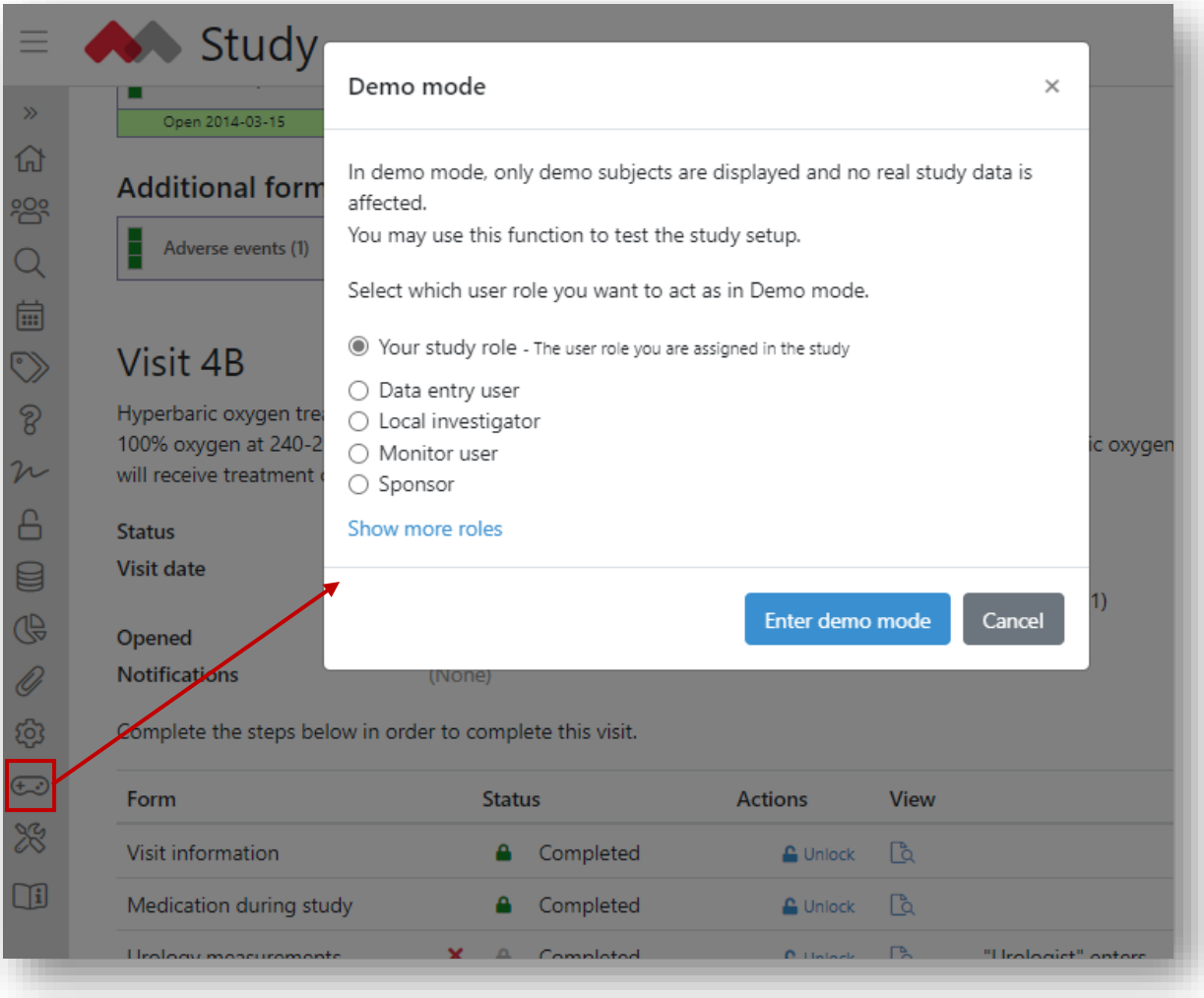


Clicking on a study phase bar collapses or expands all visits in the phase

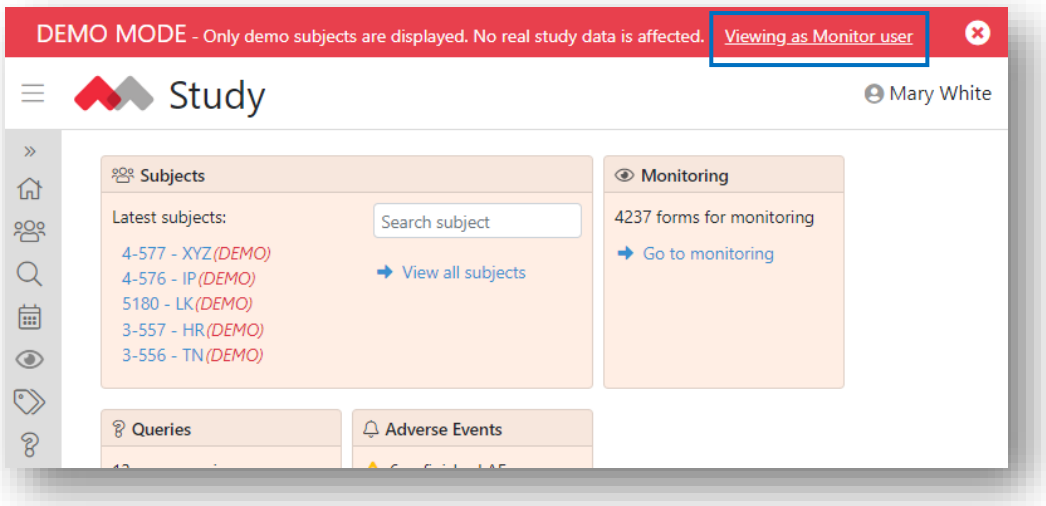
- The *Manage visits* menu contains actions for adding extra visits for the subject and a function for omitting multiple visits for the subject. Read more in the *Data Entry* section of these Release Notes.

1.7. User role can be selected in Demo and Draft Preview mode

When entering *Demo mode* to test the study setup or, e.g., train new staff to use the eCRF you may now choose which user role you want to enter Demo mode as. In this case you can test how the eCRF looks for another user role than your own (e.g. data entry user, monitor or investigator). The selected role will of course only be in effect while you are in Demo mode, and do not affect your user role when managing real subjects in the study.

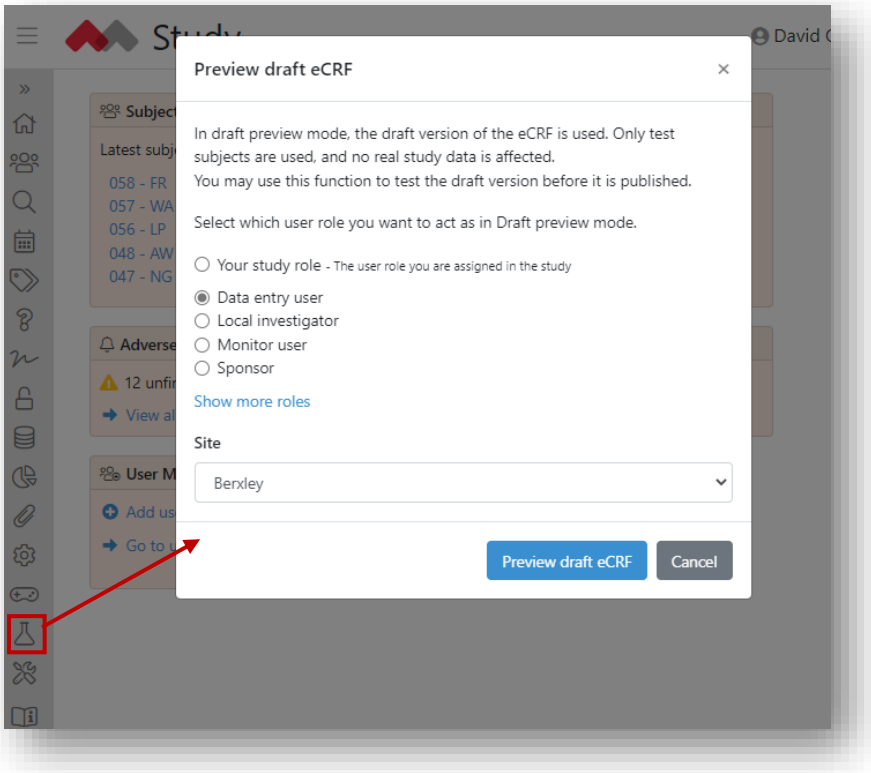


When entering Demo mode you may select which user role you want to have in Demo mode



When in Demo mode the selected role is displayed in the top bar. You can switch user role by clicking the link.

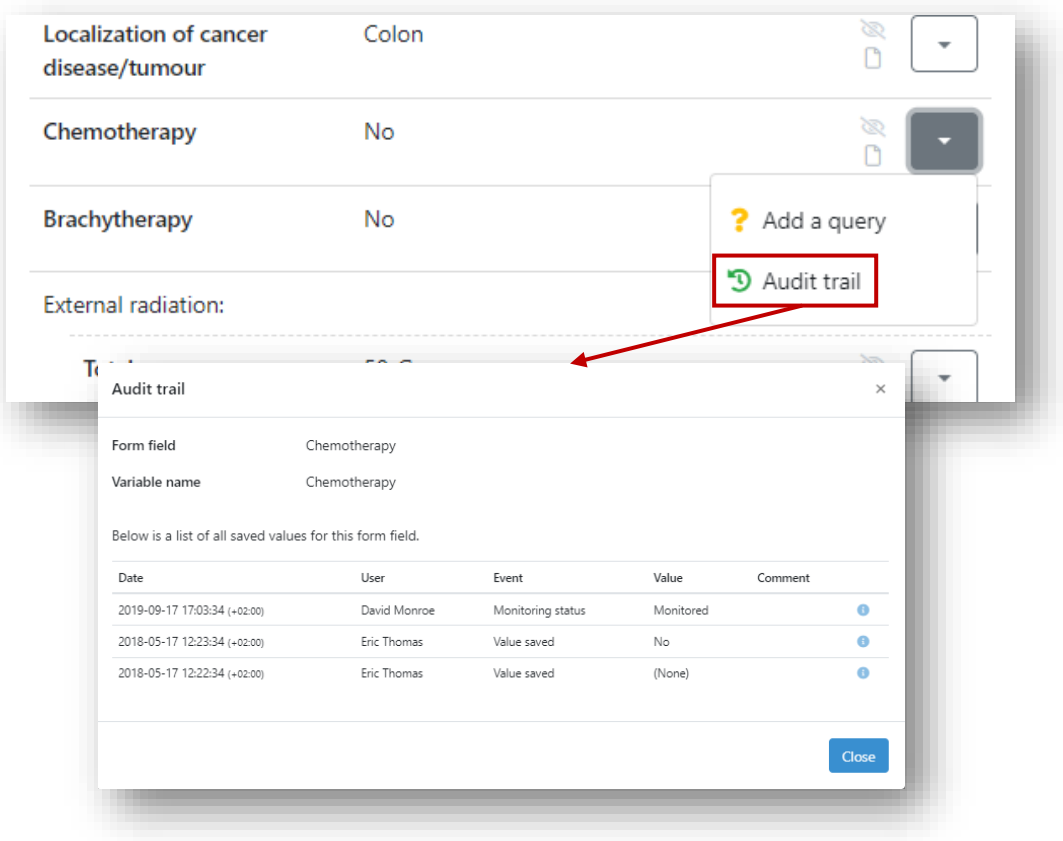
When previewing the draft version of the CRF, if a draft version exists and is ready for preview, you have the same option to select user role to preview as.



When previewing the draft version of the eCRF you may also select which user role to enter as

1.8. *View log* has been renamed to *Audit trail* in forms

When viewing or entering forms, the audit trail of a form field is accessed by the *Audit trail menu* option. This was previously named *View log*.

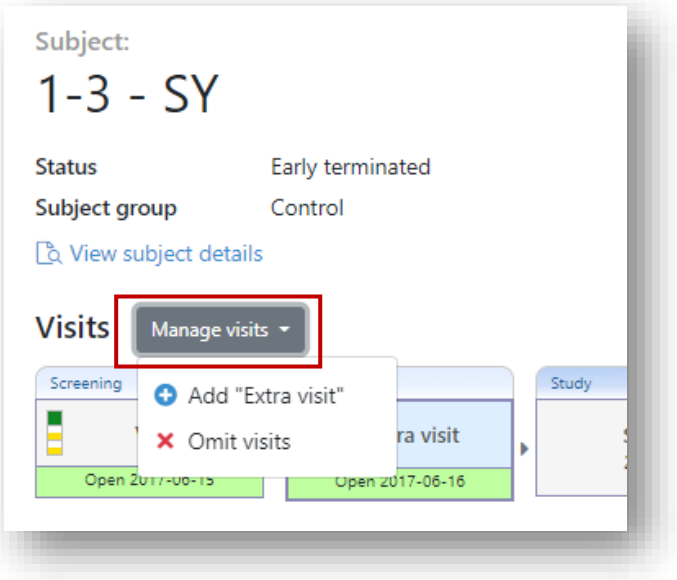


The audit trail for a form field is access by the "Audit trail" menu option

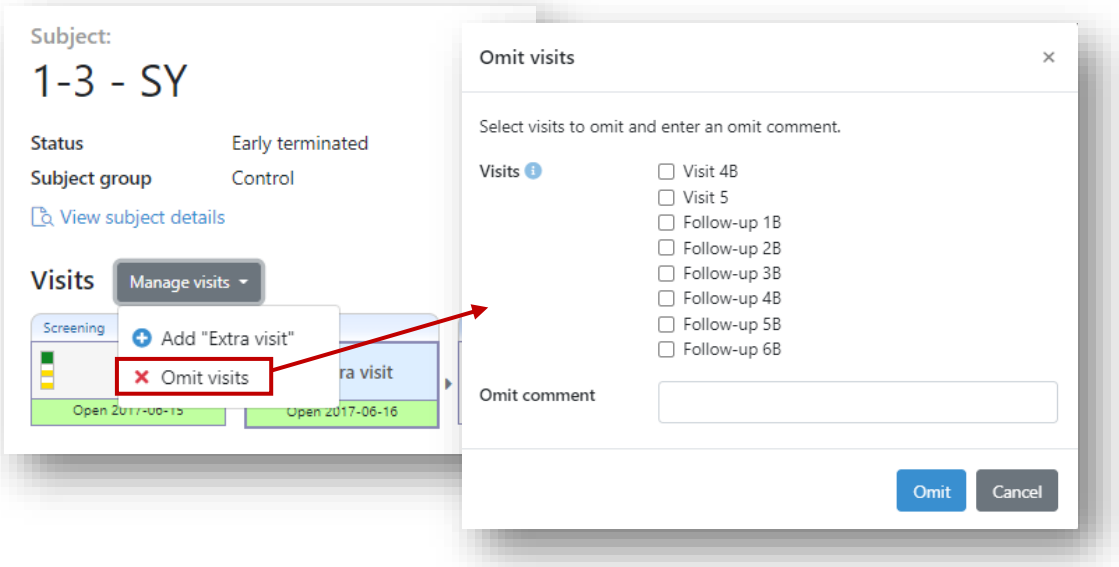
2. Data entry

1.9. Function for omitting multiple visits

The *Manage visits* menu on the subject page contains an action for omitting multiple visits for the subject.



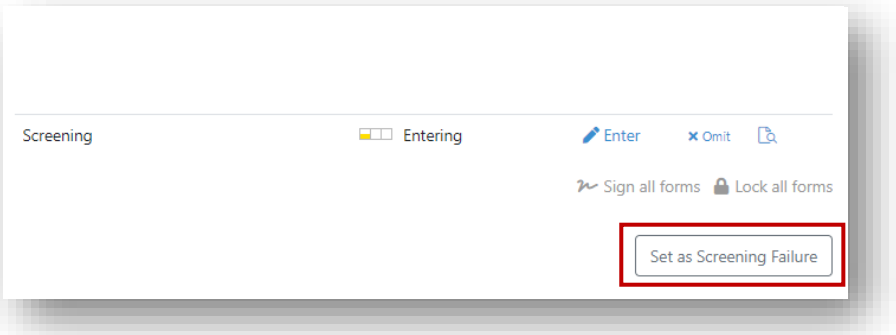
The "Manage visits" contains options for adding extra visits and omitting multiple visits



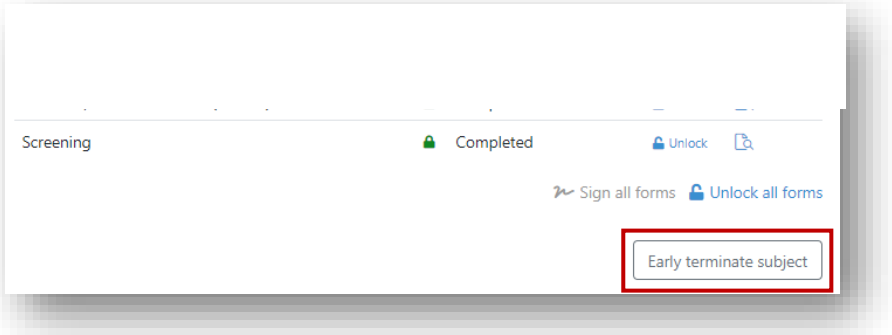
When selecting "Omit visits", you may select any number of visits to omit for the subject (that are in the state for omit), enter an omit comment and click "Omit".
Tip: You may select a range of visits by selecting the first, hold the Shift key and select the last.

1.10. Buttons to exclude subjects are renamed

The buttons for excluding a subject on the subject page has been renamed to align with the new subject status names. Screening subjects have a *Set as Screening Failure* button, and included subjects have an *Early terminate subject* button.



Screening subjects have a "Set as Screening Failure" button

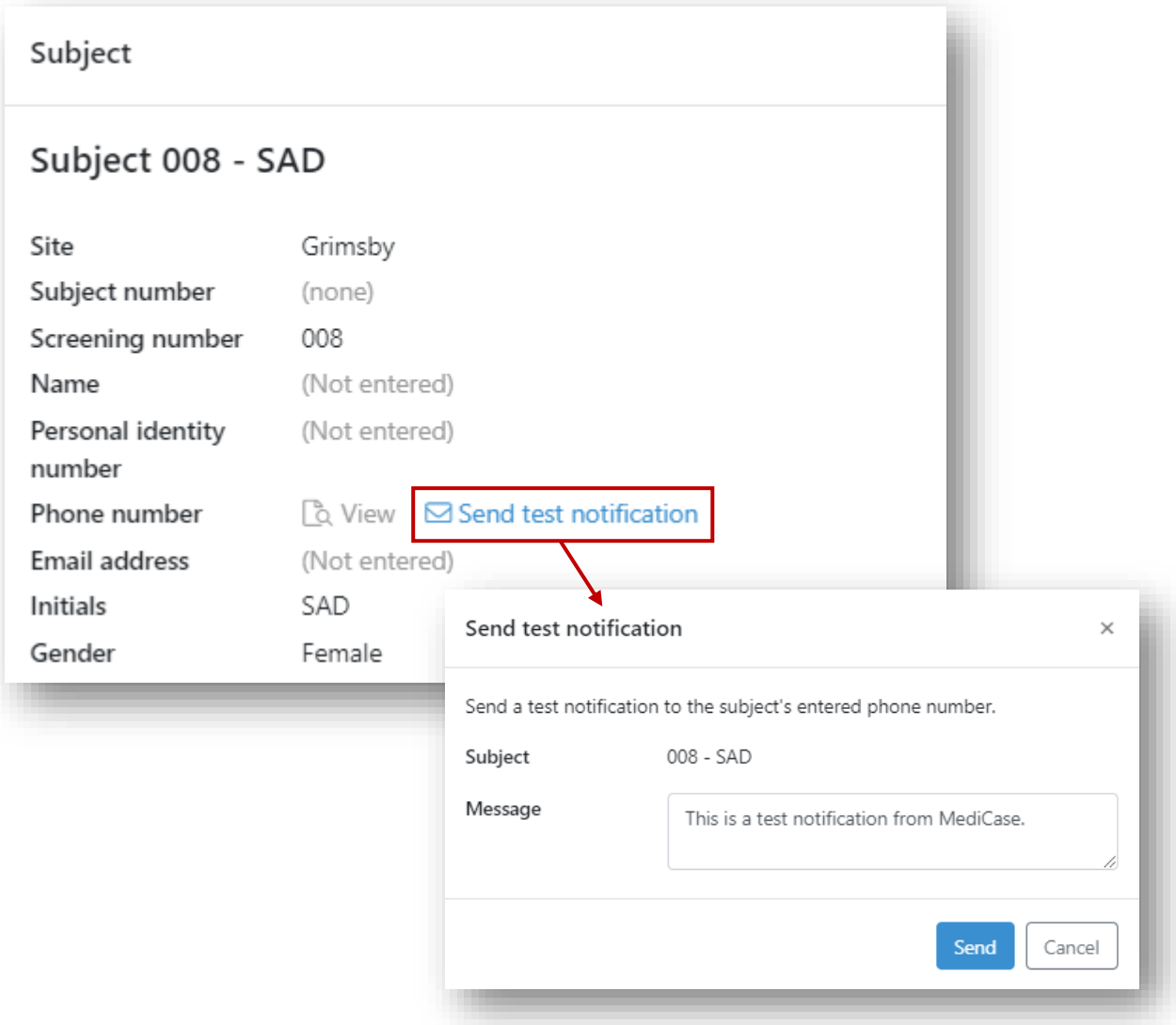


Included subjects have an "Early terminate subject" button

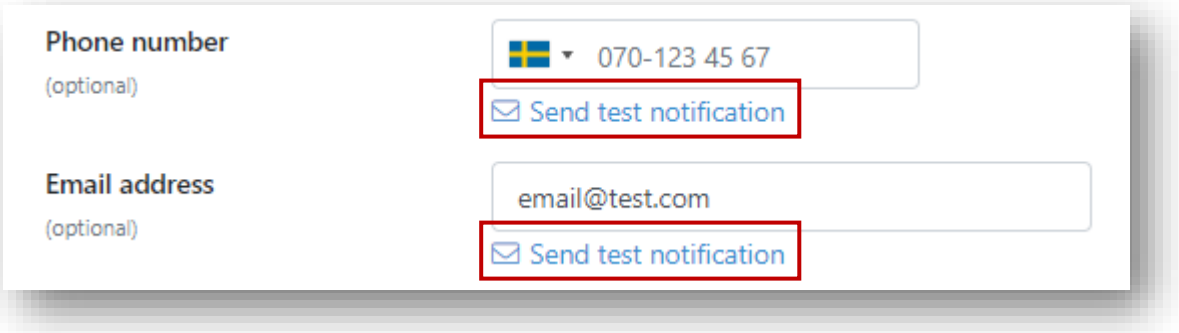
1.11. Send test notifications to subjects

In studies that collect email addresses or phone numbers for subjects to be used to send visit reminders, you can now send a test notification to a subject to verify that the correct email address or phone number is entered.

When adding a new subject, or viewing the subject details of an existing subject, you can click the *Send test notification* link next to the email address or phone number field. You may then enter a test message to be sent to the subject, without disclosing the entered email address or phone number.



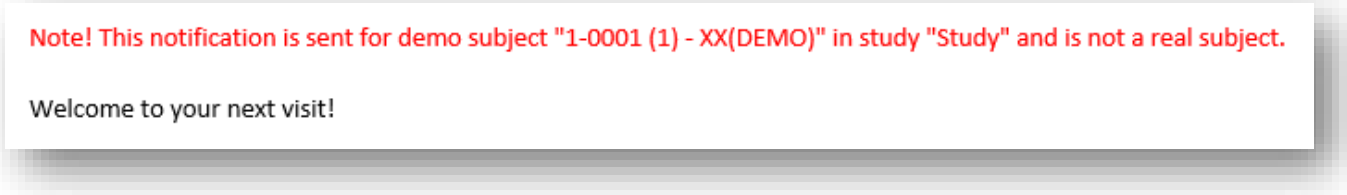
In the subject details dialog, you may send a test notification to the entered email address or phone number for a subject.



When adding a new subject, a test notification may be sent when you enter the subject's phone number or email address.

1.12. Visit notifications are marked with a disclaimer for demo and test subjects

If visit notifications are sent for demo or test subjects (subjects added in Demo, Draft Preview or Design mode), the notification will contain a disclaimer informing the recipient that the notification doesn't concern a real subject. The identification of the subject is also included in the disclaimer to make it easy to identify where the email address or phone number is entered. The disclaimer is added to both email and SMS notifications.

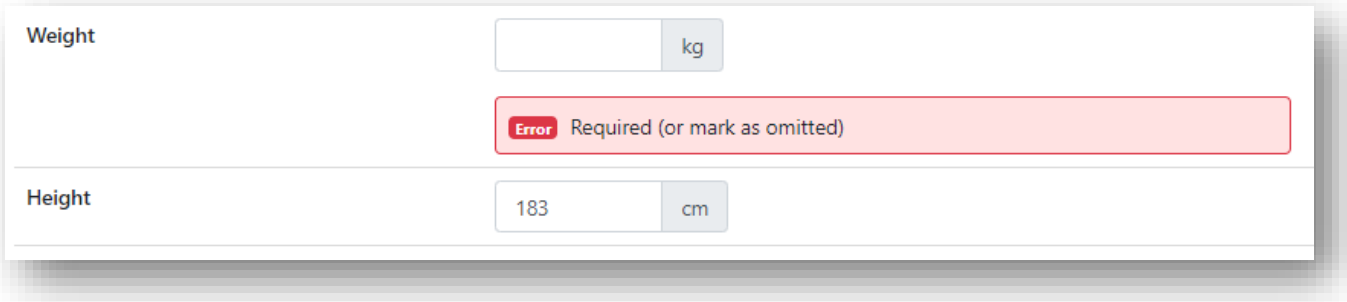


Visit notifications for demo and test subjects contain a disclaimer

1.13. When entering forms, the *Required* warning is displayed less frequently

When entering a form for a subject, fields that are non-optional trigger a *Required* warning when left blank. This warning has sometimes been displayed even though the actual field has never been visited due to dependencies between different fields in the form.

To avoid unnecessary warnings, *Required* warnings are now only displayed when you save the form as completed, or a previously entered field has been cleared.

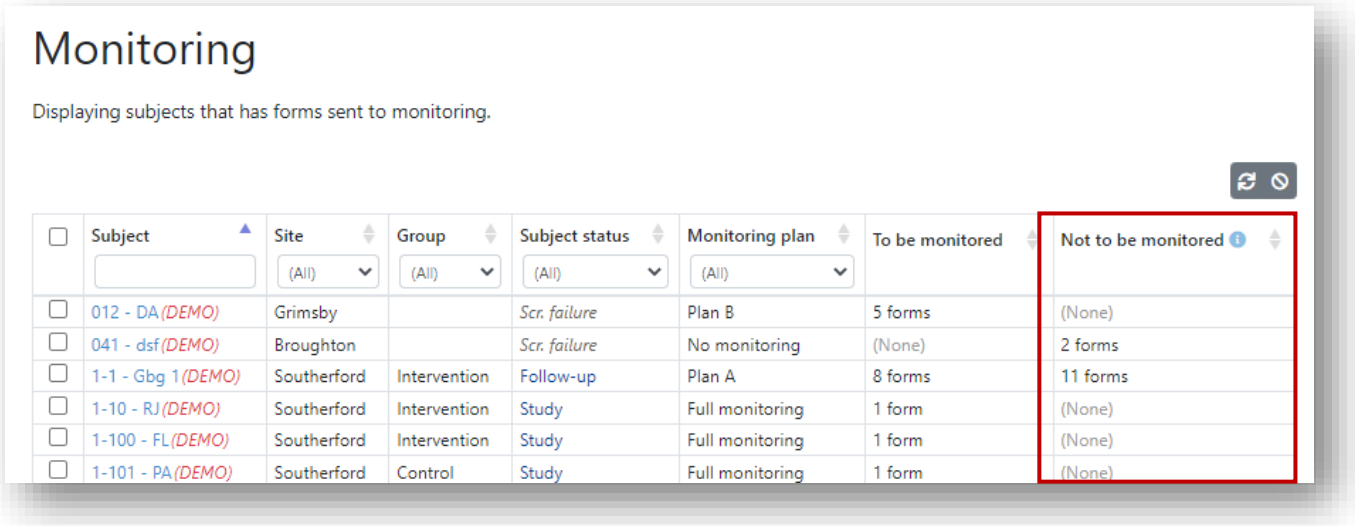


The "Required" warning is now displayed less frequently

3. Monitoring

1.14. New column *Not to be* monitored in monitoring list

When monitoring subjects, a new column named *Not to be monitored* is displayed in the monitoring list. This column contains the number of forms sent for monitoring but where the form is not included in the monitoring plan. This is only applicable to studies where the monitoring plan is configured in the eCRF.

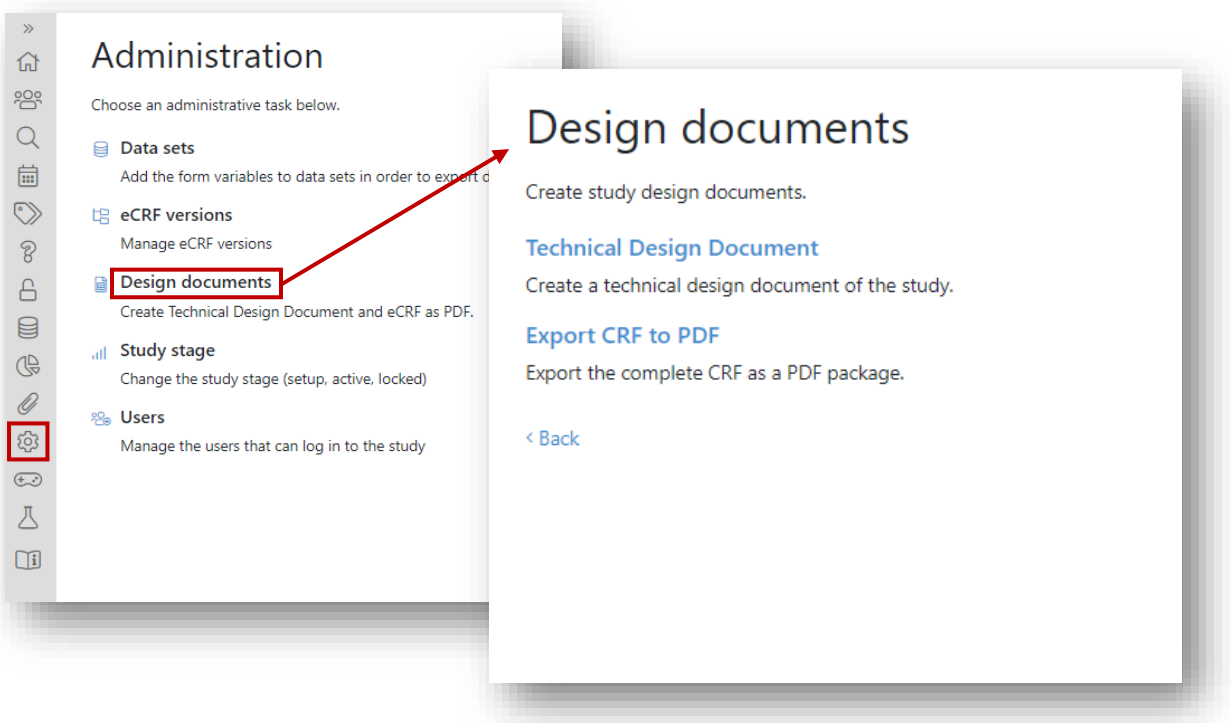


In the monitoring list the "Not to b e monitored" columns displays the number of forms sent for monitoring that are not included in the monitoring plan

4. Data Management

1.15. Design tool "Design documents" (DM)

As a Data Manager, you now have access to a new *Design documents* tool in the *Administration* section. In the Design documents tool you may create Technical Design Document (TDD) and export the CRF as an PDF package.



In the "Design documents" tool you can create a Technical Design Document and export the CRF as an PDF package

Technical Design Document

A Technical Design Document (TDD) is an Excel file containing information about the study design, including visits, forms and variables collected in the study.

Export CRF to PDF

For e.g. archiving purposes, you can export the CRF as PDF, with or without annotations (technical information about variables). Each form entered in the study will be included in the package. The package can be created as a ZIP package of all forms as individual PDF documents, or a combined PDF document containing all forms.

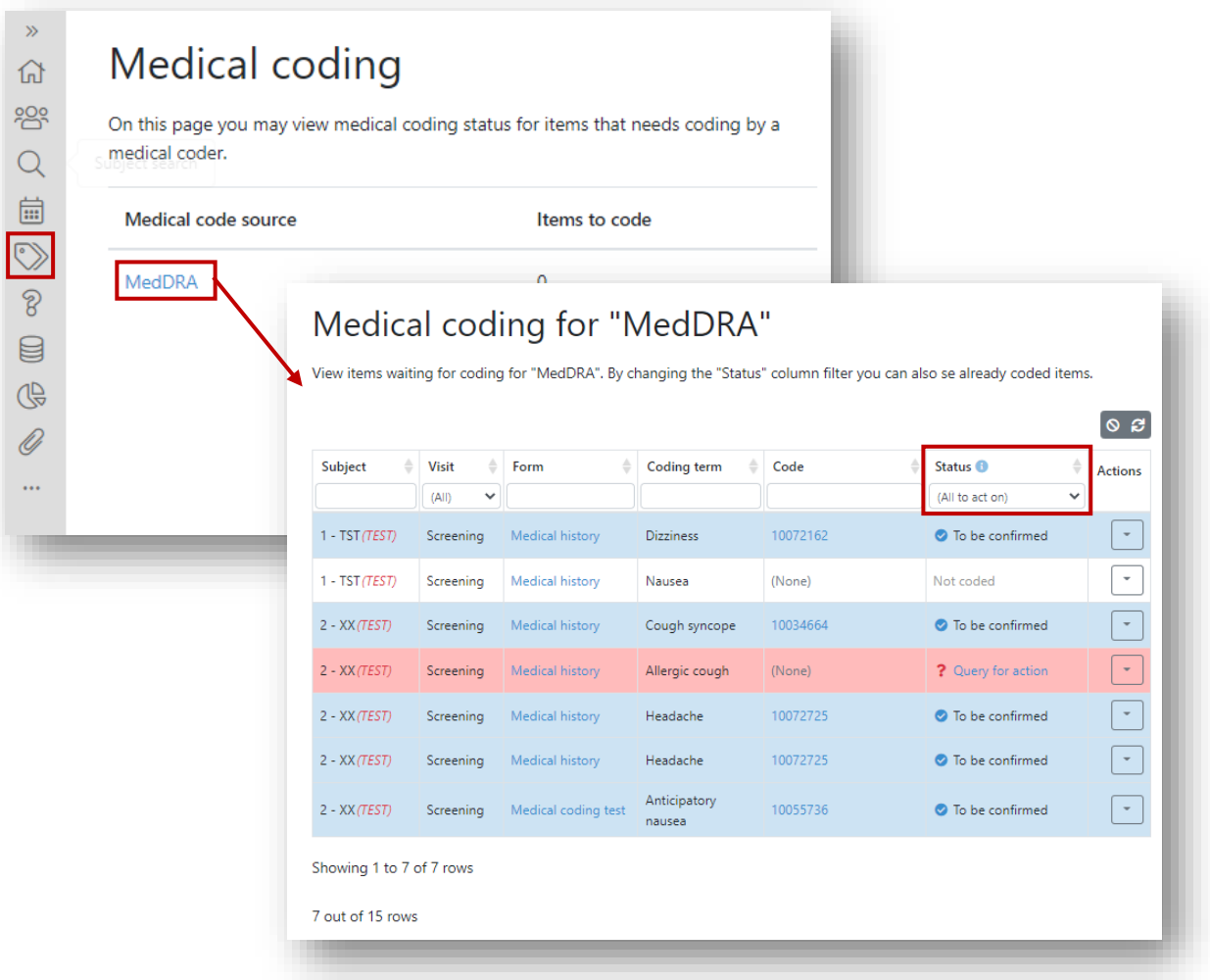
1.16. Multiple option variables in custom reports will be empty when no option is selected

When a custom report contains multiple options variables such as checkboxes or list boxes, they have previously been displayed as "(None)" in the result if no option is selected. To avoid mixing this up with an actual selected option called "None", we now display an empty result if no option is selected.

5. Medical Coding

1.17. Medical Coding tool in read-only mode for Data Managers, Monitors and Sponsors

When medical coding is performed by Medical Coder users in the study, the medical coding tool is used by the medical coders to code entered coding terms in the study. We now expose the medical coding tool also to Data Manager, Monitor and Sponsor users, but in read-only mode. Using this tool, the users may see how medical coding is progressing in the study.



In the "Medical Coding" tool you get an overview about medical coding progress in the study. When entering the tool all uncoded terms are displayed – use the "Status" filter to view already coded items.

1.18. Medical Coding queries not allowed on medical code fields

As a Medical Coder, adding a “Medical coding query” on an actual medical code field is now prevented. As a Medical Coder, you should add any query on the inputs to the medical code fields, where data entry has entered coding terms, to allow data entry users to respond to the query.

6. Bug Fixes

1.19. Filtering doesn’t work in the form signing and locking tools

In the tools for signing and locking forms, filtering the form list did not work properly in the previous release. This issue is now fixed.

7. What do you think?

At MediCase, we always strive to make our system more powerful and easier to use. Your point of view is valuable – if you have requests for improvements or other comments, please don’t hesitate to tell us what you think. Contact your MediCase contact person or send an email to support@medicase.se.