e-capture.net v2.9

user manual

TABLE OF CONTENTS

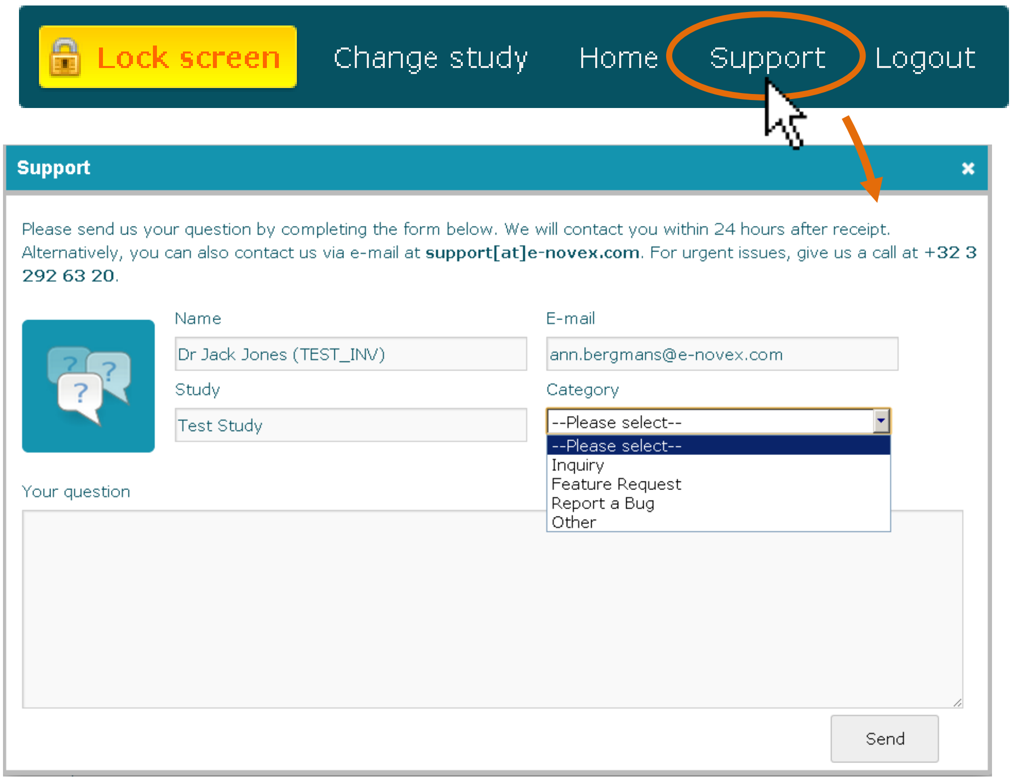
GETTING STARTED

e-capture.net has an intuitive and easy to use interface.

In order to help you navigate fluently through e-capture.net, this user manual will guide you through every window and every option in the program.
This will help you to understand the full functionality of the program, and learn how to use all its options and getting the job done with minimum effort.
There will be plenty of screenshots, which will help you to get a visual illustration of how things work. It is a good practice to read the manual, and try out the functionality of the program first hand. The best way to learn is to do, so take the time to navigate through the menus and discover the functions in this way.

1 SUPPORT

Support and information are provided via the support button on the top right hand side of the home screen:



2 ICONS

e-capture.net uses different categories of icons and marks to display important information to the end user: status marks, navigator icons and field marks. The tables below show the various icons you may see in your study.

Status marks (applicable for visits and forms)	
	Fully completed, no open queries.
	Not fully completed, or open queries.
	No data entered yet, not used yet.
	Fully completed, but answered queries still to close.

Navigator Icons			
	Form Signed		Waiting for SDV
	Signature invalidated by data update.		SDV partially completed or invalidated
	Form re-signed after invalidated signature, but signed by other user than initial signature.		SDV Completed
	Form Frozen ▪ Data update is NOT possible. ▪ Query open/answer/close is possible. ▪ Signature placing is possible.		Form Locked ▪ Data update is NOT possible. ▪ Query open/answer/close is NOT possible. ▪ Signature placing is NOT possible.
	Tick this icon to select any feature applicable for this form.		

Field marks	
	Question is completed, there are no queries.
	Question is not completed or has open queries.
	No data entered yet, question not processed yet.
	Question is completed with answered query still to close.
	Blue mark below: a memo is present on this question. Move the mouse arrow over the blue mark to see the memo text.

3 USER CREATION

Upon receipt of a correctly completed **User Request Form**, e capture.net will create your account, and you will receive an initial password mail.
If your study set-up includes the user management tool, the study sponsor or delegate will create all study user accounts.
You will receive access to the studies and sites that were indicated on the User Request Form.
New users receive an email that contains information about:

- URL: https://www.e-capture.net/*studyname/*
- Login ID: not case sensitive
- Initial password: Case sensitive!

Dear Dr Jack Jones,

A user account has been created.

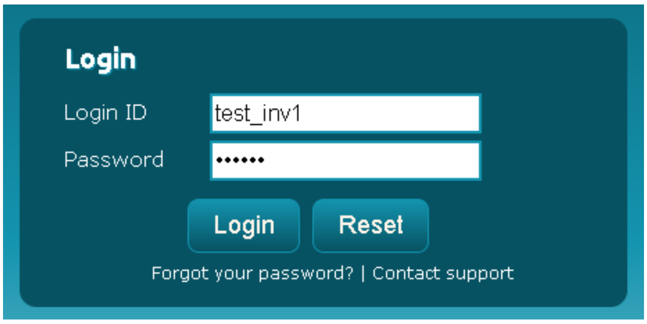
Study: TESTSTUDY1 (https://www.e-capture.net/)
Login ID: TEST_INV
Password: Prpg6$

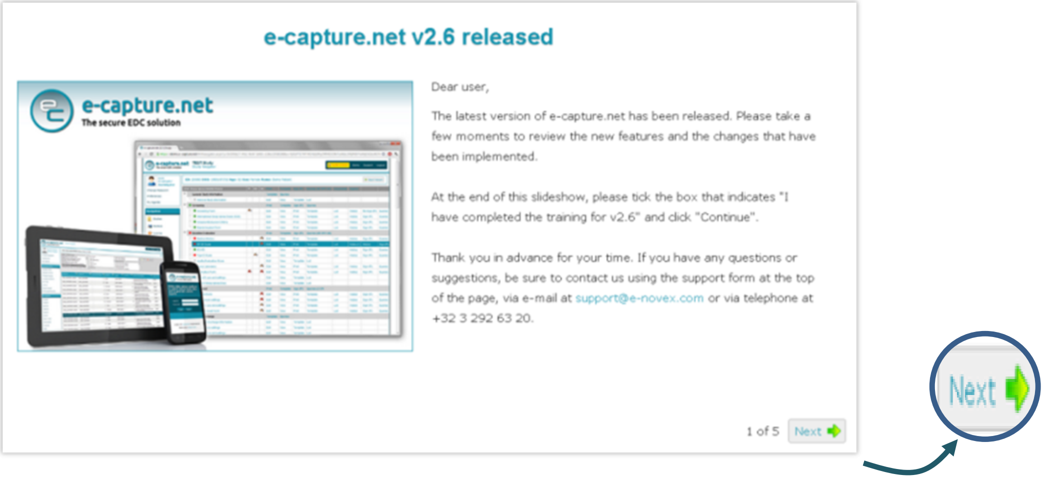
This password is temporary and needs to be changed at first logon.
Please note that the password is case-sensitive.

NOTE: YOU MUST CHANGE THE INITIAL PASSWORD AT FIRST LOGIN.

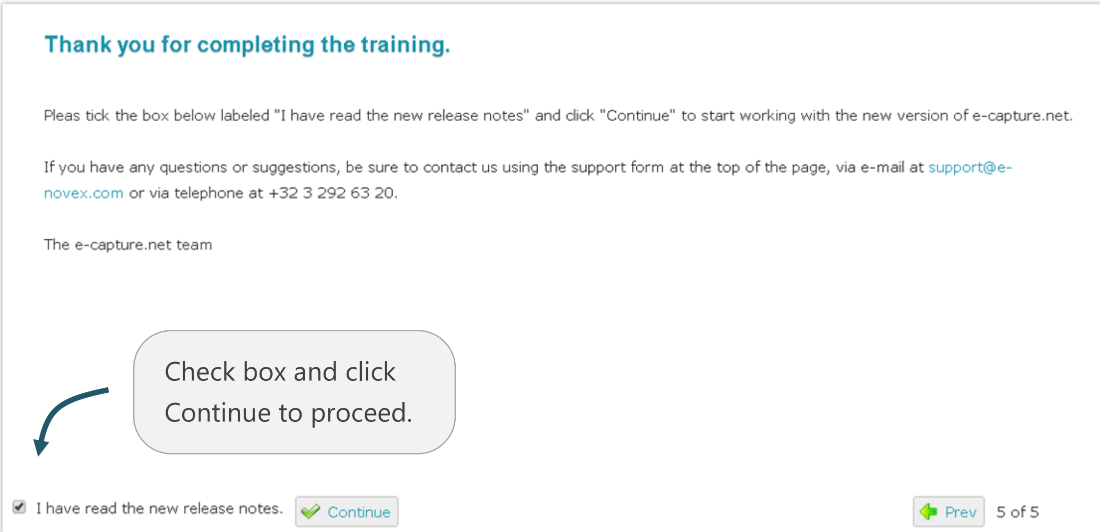
4 LOGIN

- Enter study URL: [https://www.e-capture.net/*studyname*/](https://www.e-capture.net/studyname/)
- Your study will open in e-capture.net. The lay out of the login screen depends on your study set-up but will be similar to the screen below:
- Enter Login ID and initial password and click the 'Login' button:
- You will be asked to process training slides about e-capture.net version 2.8 (only at first login!)

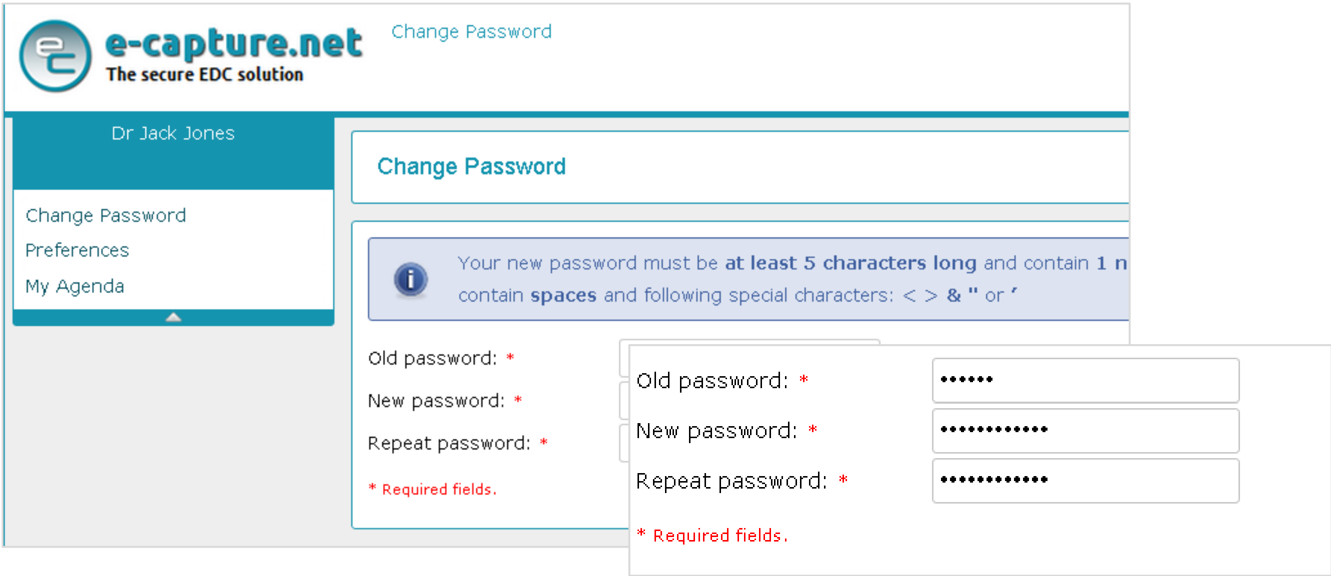




- Go through the slides with the 'Next' button and read them carefully.
- At page 5 of 5, click the checkbox: 'I have read the new release notes'. A 'Continue' button will appear
- Click the 'Continue button'.

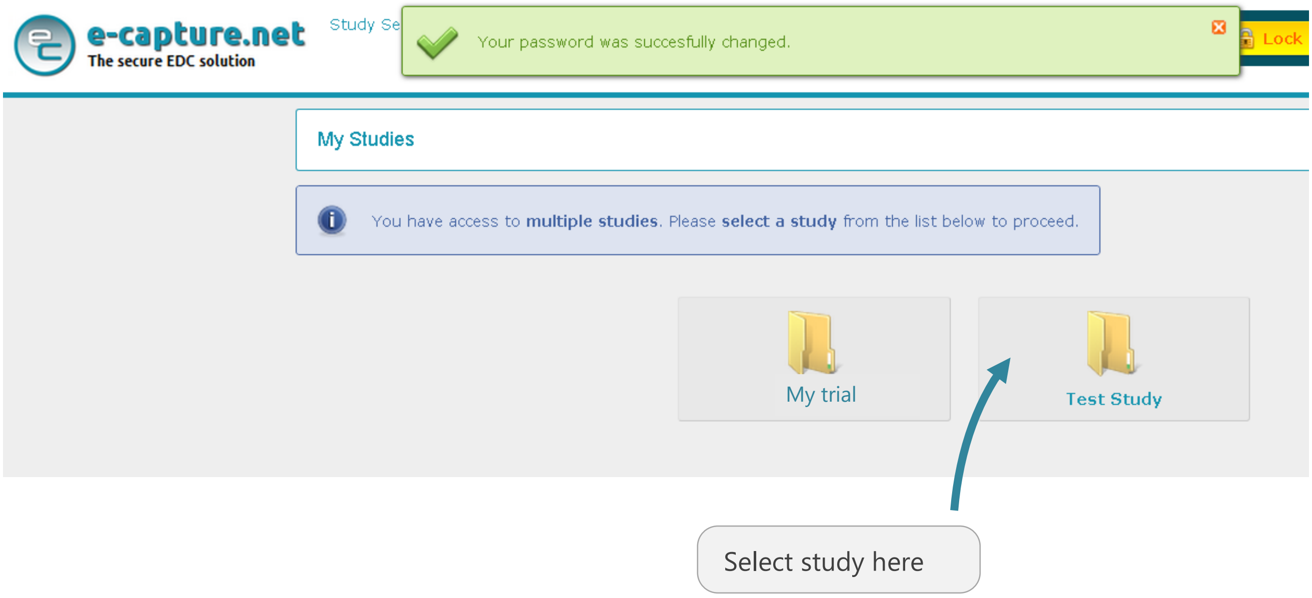


Upon first login, you must change the password prior to any study access:



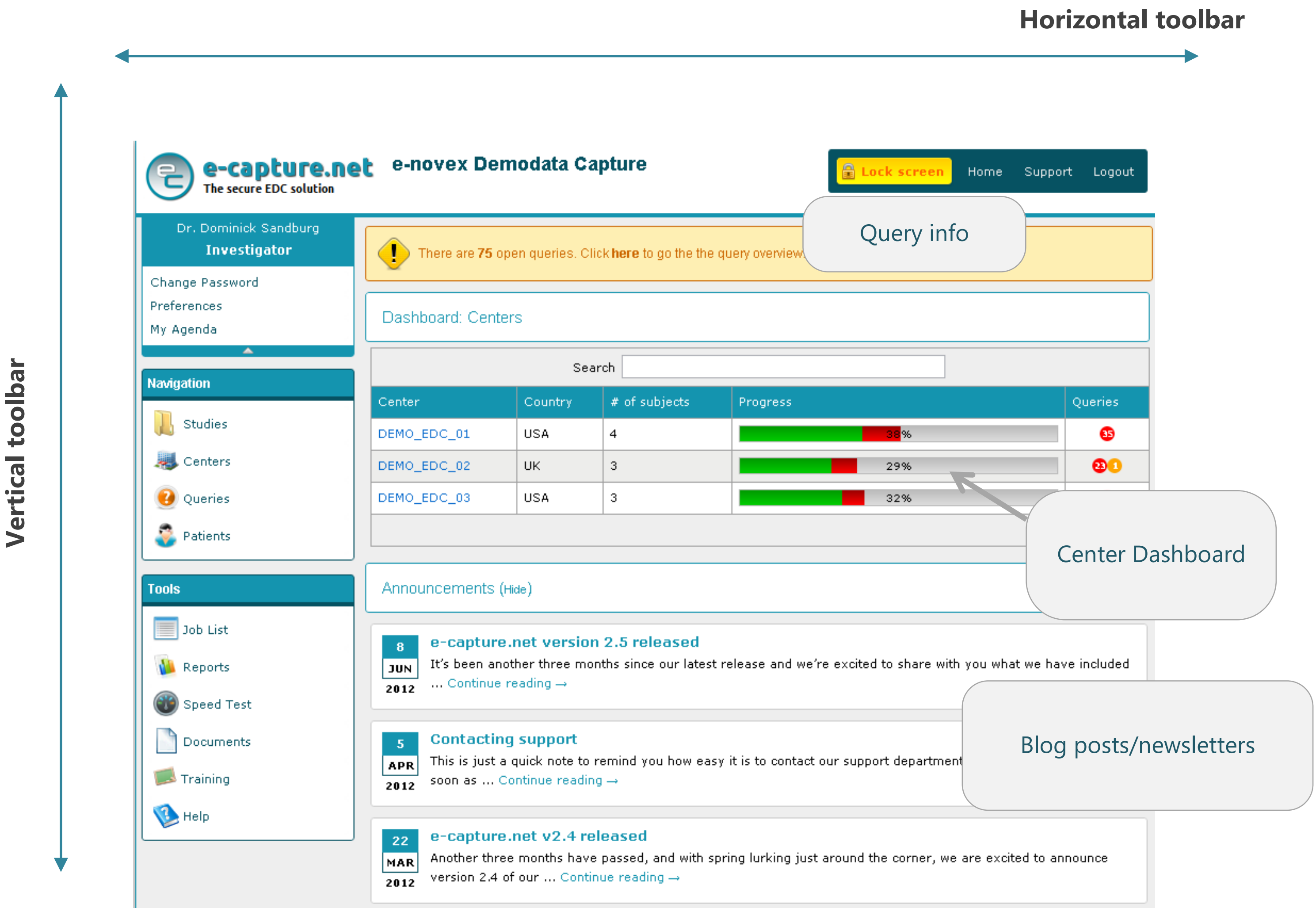
- Type your old password.
- Type and re-type your new password.
- Click the 'Save' button.

You will now navigate to the 'Studies' screen.
If you have access to more than one study, you must first select the study to work on:



5 HOME SCREEN

The first screen you see after choosing your study is the Dashboard or Home screen. The content of the dashboard may differ depending on your user role and study.

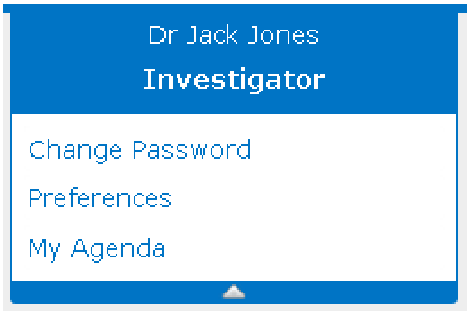


5.1 HORIZONTAL TOOLBAR

- Lock Screen: if you need to leave your computer or temporarily hide your screen, click this button to lock your screen. If you unlock within 1 hour, you return to the same e-CRF location.
- Home: return to Home screen.
- Support: create mail to e-capture.net help desk.
- Logout: click this button to log out of the study, next time you log in, you will return to the Home screen (automatic logout after 1 hour).

5.2 VERTICAL TOOLBAR

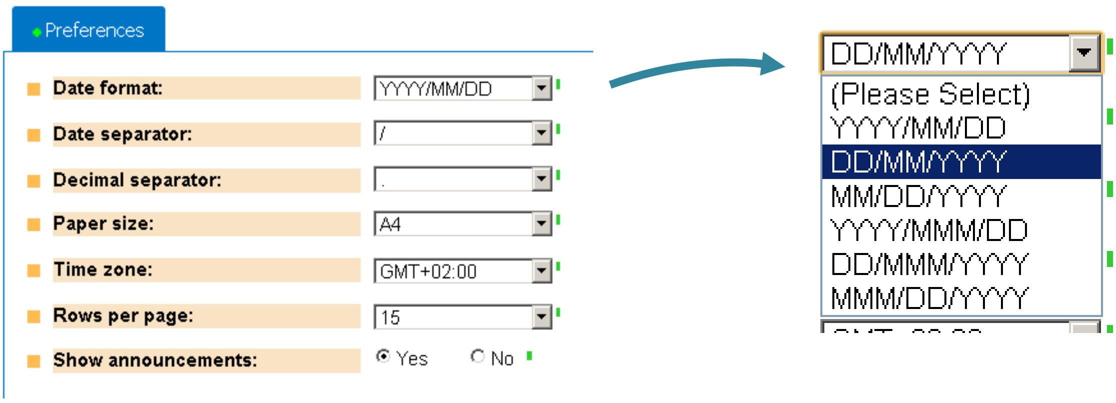
e-capture.net has three major menus on the vertical toolbar (left hand side): User tools, Navigation and Tools. Both menus have sub menus, and each of these have its specific tasks to help you work in a very intuitive and friendly environment.



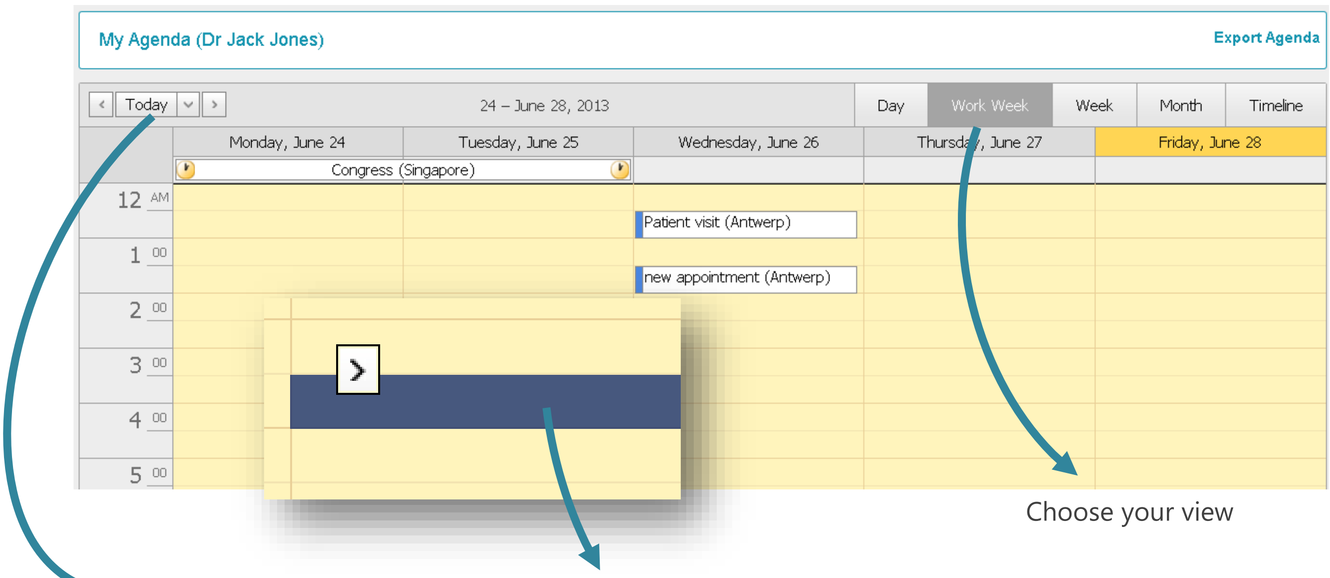
The **Preferences** window allows you to change the date format, date separator, decimal separator, paper size, time zone, rows per page and the visibility of announcements.

NOTE: FOR CORRECT DATA ENTRY, IT IS IMPORTANT TO SET THE DATE FORMAT IN THE WAY YOU ARE USED TO ENTER DATES. THE FREQUENTLY USED INTERNATIONAL DATE FORMATS ARE AVAILABLE IN A DROPDOWN LIST.

The system remembers saved preferences at future logins.



My Agenda enables you to maintain your calendar and appointments.

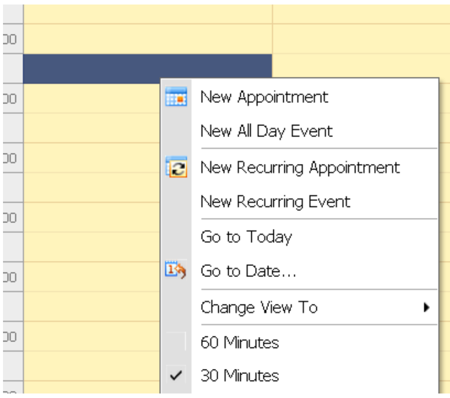


Choose your view

Browse through days

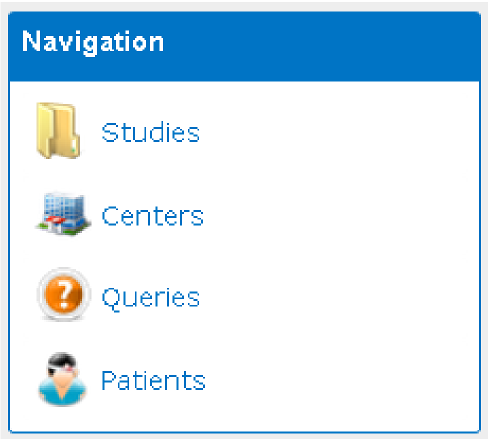
Add an appointment (hover with your mouse over the appropriate date and click the appearing arrow).

Back to top ↺



NOTE: RIGHT-CLICK ACTIVE FIELDS FOR HIDDEN OPTIONS.
THIS RULE APPLIES IN ALL CASES IN E-CAPTURE.NET. BY RIGHT CLICKING ON AN ACTIVE FIELD, YOU CAN SELECT ANY ONE OF THE AVAILABLE OPTIONS OF THAT PARTICULAR FIELD. IN CASE OF MY AGENDA, THE AVAILABLE OPTIONS ARE: NEW APPOINTMENT, NEW ALL DAY EVENT AND SO ON. IN THIS POPUP MENU, YOU ALSO HAVE THE "GO TO DATE..." WHICH COMES IN HANDY WHEN YOU NEED TO SCHEDULE APPOINTMENTS SEVERAL DAYS, WEEKS OR EVEN MONTHS AHEAD OF TIME. YOU CAN ALSO EXPORT YOUR CALENDAR ENTRIES FOR USE IN OTHER APPLICATIONS.

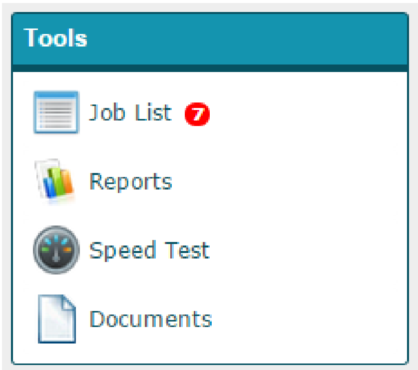
5.2.1 NAVIGATION

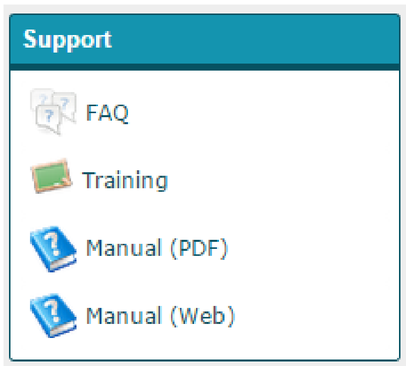


The Navigation tool provides access to all available study summaries, center summaries, query summaries and all the patients in the database. Most of the time, you will use the options in the Navigation section, which provides access to most of the data for your day-to-day work. This tool will be further discussed into detail in Part 2: Navigation.

5.2.2 TOOLS & SUPPORT

- Job list: compiles long running tasks, processed in the background. See also Chapter: Job List
- Report: view standard reports or create your own reports, selecting any study question (depending on your user role). See also Chapter: Reports
- Speed test: in case of speed issues, please perform a speed test and send the results to support. See also Chapter: Speed test
- Documents: all study related documents, if applicable.
- FAQ: frequently asked questions and answers.
- Training: video based e-capture.net training.
- Manual: a detailed user manual about e-capture.net.

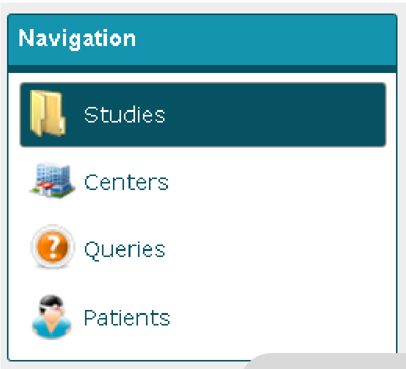




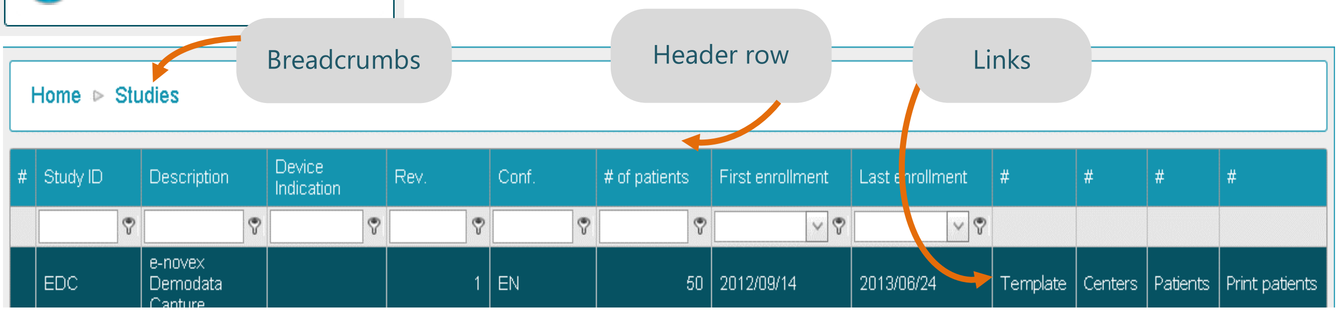
NAVIGATION

This chapter will discuss how to navigate between studies, centers, patients and queries within e-capture.net.

1 STUDIES



The **Studies** summary is the first screen in the **Navigation** menu. This window displays your study details.



The header row of the studies summary shows several attributes:

1. Study ID: the abbreviated, numerical ID of the study.
2. Description: the extended identification of the listed study.
3. Device indication: specifies the device that is examined in the study, if applicable.
4. Rev. (Revision): Study version.
5. Conf. (configuration): user language.
6. # Patients: total number of patients in the respective study.
7. Date of first and last patient enrollment.

NOTE: YOU CAN CUSTOMIZE ANY TABLE WITHIN E-CAPTURE.NET:

- DRAG THE COLUMN HEADERS IN THE HEADER ROW. (ALSO, SEE CHAPTER: SEARCH AND FILTER OPTIONS)
- USE THE AVAILABLE SEARCH AND FILTER OPTIONS (ALSO SEE CHAPTER: SEARCH AND FILTER OPTIONS)

1.1 LINKS

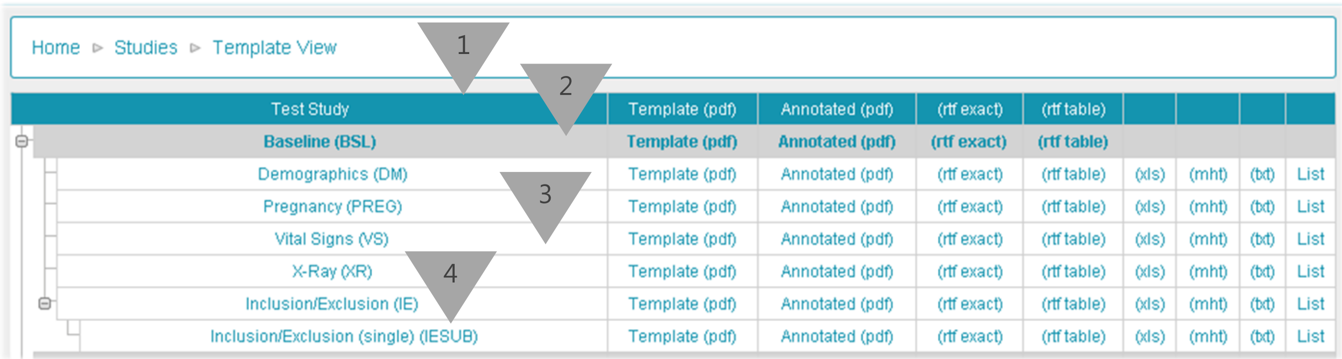
The **Studies** summary also provides links to the Centers and Patients Table and to several sets of study documentation:

NOTE: FOR MORE INFORMATION ON THE CENTERS AND PATIENTS TABLE, PLEASE SEE CHAPTER: CENTERS

1.1.1 TEMPLATE – ANNOTATED CRF

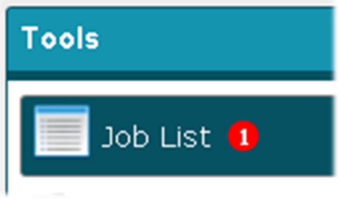
This window displays all pre-set e-CRF templates. You can download and print all (annotated) study e-CRF forms in PDF, data (xls) and text (rtf and txt) format.

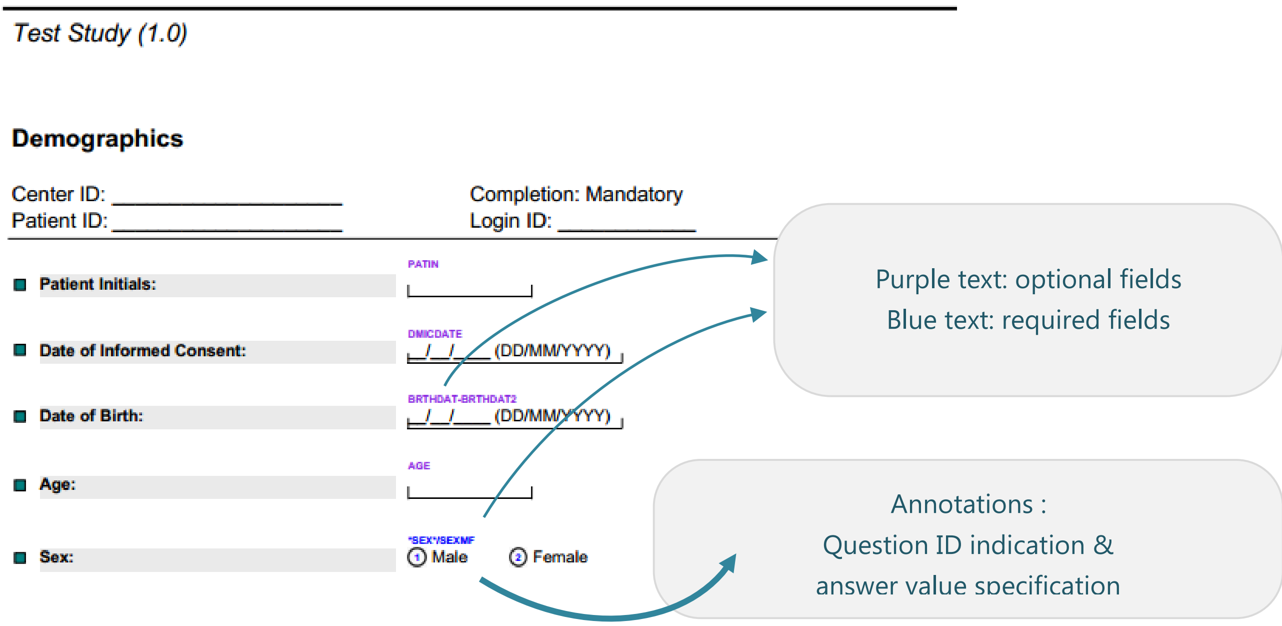
- You can consult all templates on study level①, visit level② and form level③.
- Sub-forms are indicated in the template study overview with suffix ‘SUB’④. In the annotated CRF, the form and fieldnames of sub-forms also contain ‘SUB’ in their naming.


Home ▹ Studies ▹ Template View

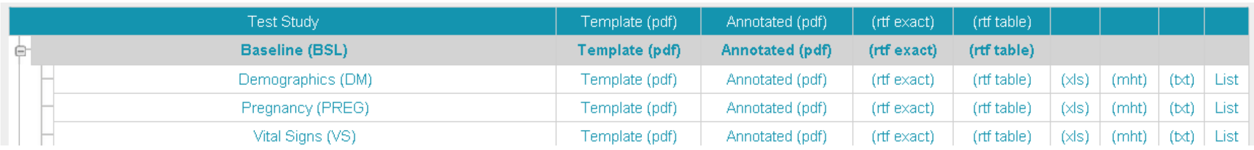
Test Study	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)				
Baseline (BSL)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)				
Demographics (DM)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)	(xls)	(mht)	(txt)	List
Pregnancy (PREG)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)	(xls)	(mht)	(txt)	List
Vital Signs (VS)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)	(xls)	(mht)	(txt)	List
X-Ray (XR)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)	(xls)	(mht)	(txt)	List
Inclusion/Exclusion (IE)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)	(xls)	(mht)	(txt)	List
Inclusion/Exclusion (single) (IESUB)	Template (pdf)	Annotated (pdf)	(rtf exact)	(rtf table)	(xls)	(mht)	(txt)	List

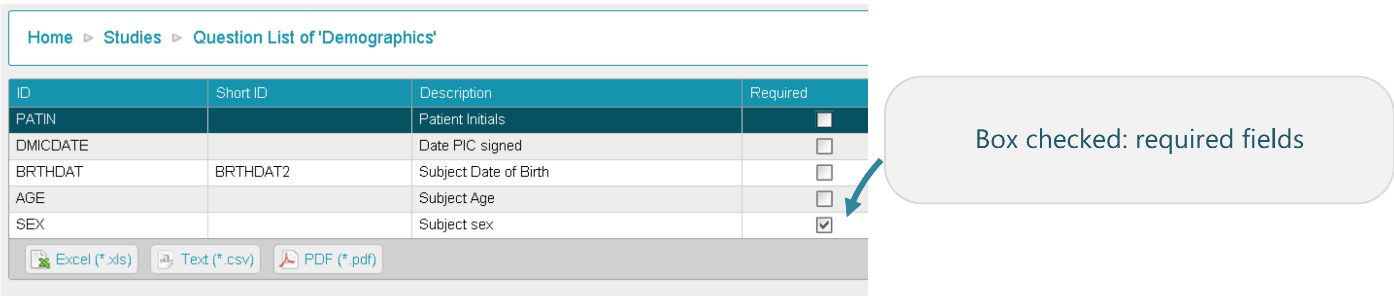
- If you click one of the template links, your request will be sent to the **Job list**. See: Chapter: Job List for more information.
- Once the Job is finished, you can retrieve and download your request from the Job list.





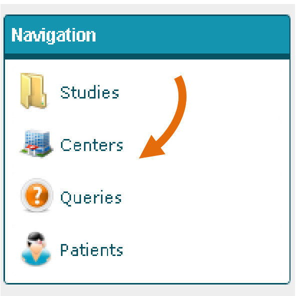
The **List** functionality also allows you to review all annotated field ID’s.

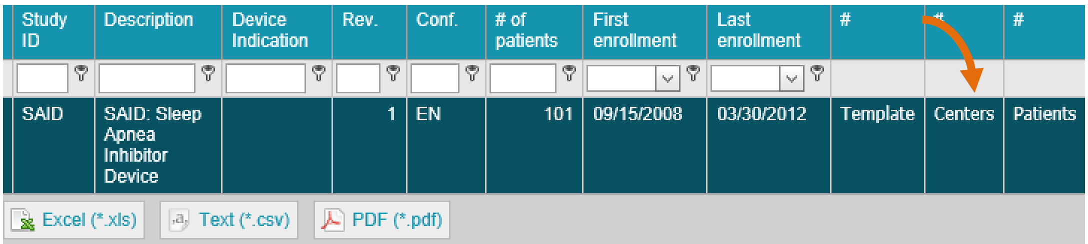




NOTE: THE STUDY ANNOTATED CRF FOLLOWS THE SEQUENCE OF DATA ENTRY, NOT DATA ANALYSIS.

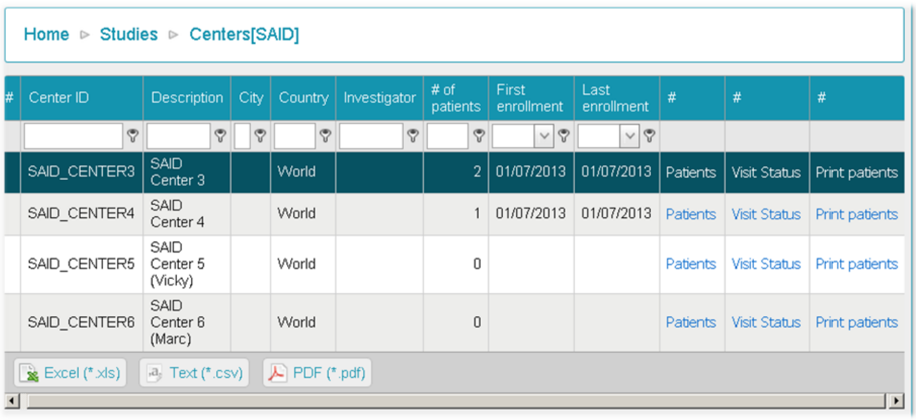
2 CENTERS





The **Centers** link within the Studies Summary as well as the **Centers Tab** within the Navigation tool brings you to an overview of all centers you have access to.

NOTE: YOU CAN ALSO ACCESS THIS OVERVIEW VIA THE DASHBOARD ON THE HOME SCREEN.



The header row shows the details and filter options that are listed for each site: Center ID, Description, City, and Country, number of patients and date of first and last enrollment.

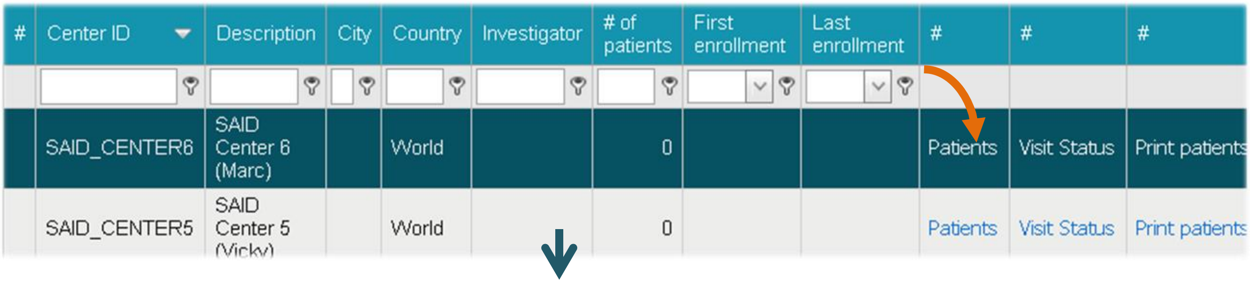
[Back to top ↺]

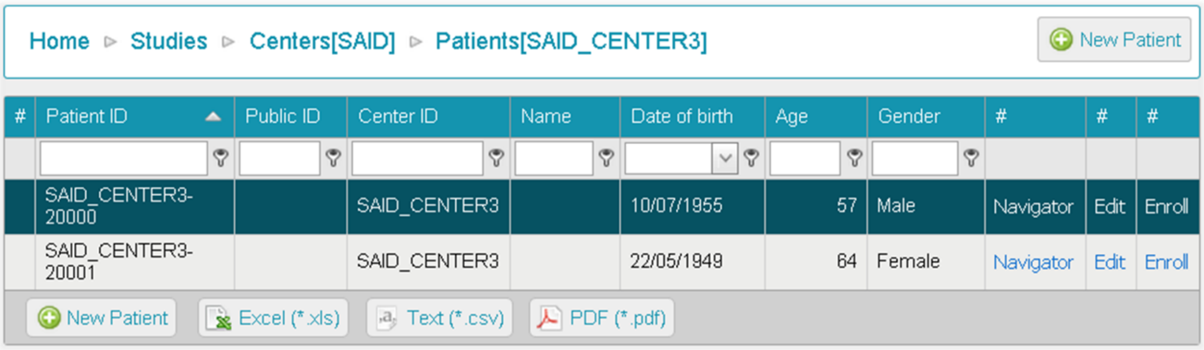
2.1 CENTERS – PATIENTS

The Patients link provides an overview of all patients **within the respective site** (see also the screenshots on next page).

NOTE: TO SEE AN OVERVIEW OF THE PATIENTS OF **ALL** THE SITES YOU HAVE ACCESS TO: CLICK 

WITHIN THE NAVIGATION TOOLS (SEE PART: NAVIGATION, CHAPTER 5: PATIENTS).





The header row shows the details and **filter options** that are listed for each patient: Patient ID, Public ID, Center ID, Name, date of Birth, Age and gender.

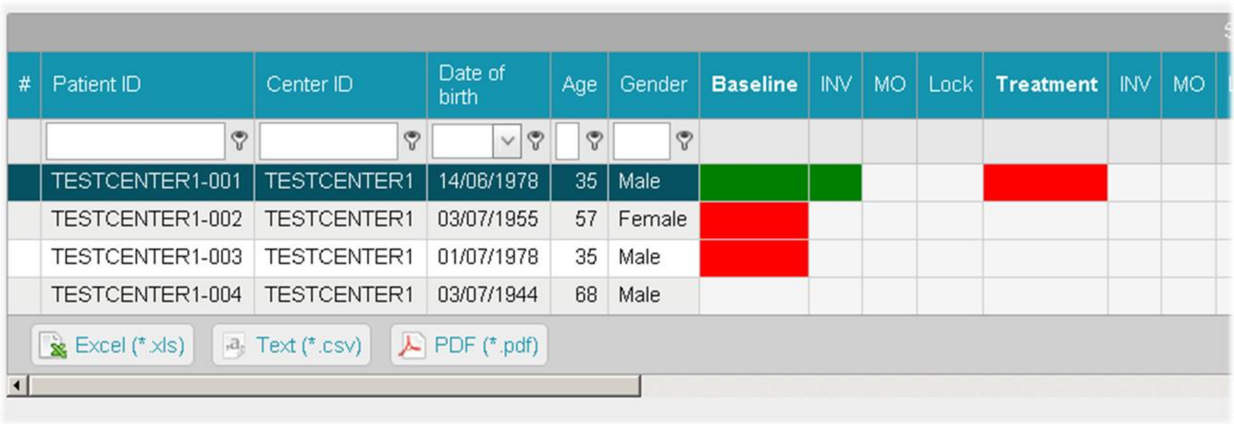
- 

: click this button to [create a new patient].
- **Navigator**: this link brings you to the [e-CRF pages] of the respective patient.
- **Edit**: this link brings you to the identification window of the respective patient.

Back to top ↺

2.2 CENTERS – VISIT STATUS

The Visit Status link provides an overview of all patient visits within the respective site.

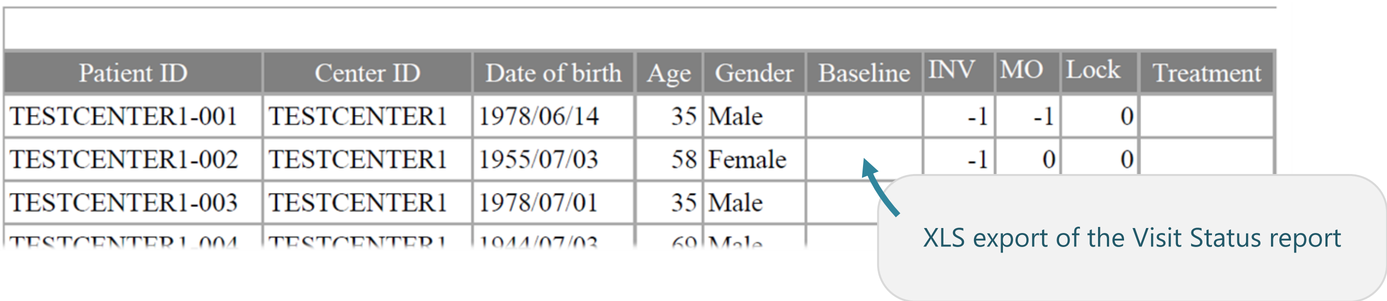


#	Patient ID	Center ID	Date of birth	Age	Gender	Baseline	INV	MO	Lock	Treatment	INV	MO
	TESTCENTER1-001	TESTCENTER1	14/06/1978	35	Male							
	TESTCENTER1-002	TESTCENTER1	03/07/1955	57	Female							
	TESTCENTER1-003	TESTCENTER1	01/07/1978	35	Male							
	TESTCENTER1-004	TESTCENTER1	03/07/1944	68	Male							

NOTE: YOU CAN ALSO ACCESS THIS AND OTHER OVERVIEWS WITHIN TOOLS ⇨ Reports

Similar to all table listings in e-capture.net, you can export the Visit Status listing to Excel, PDF or text format. In the report, the colors are indicated by numbers (see table below for a definition of the color indication):

Color	Description	Status
White	Not applicable/de-activated	-99 or empty
Grey	Not yet started/no data entered yet	0
Green	Complete: all required fields are completed/all forms are signed	1
Red	Not all required fields are completed /at least one signature missing on required forms	-1



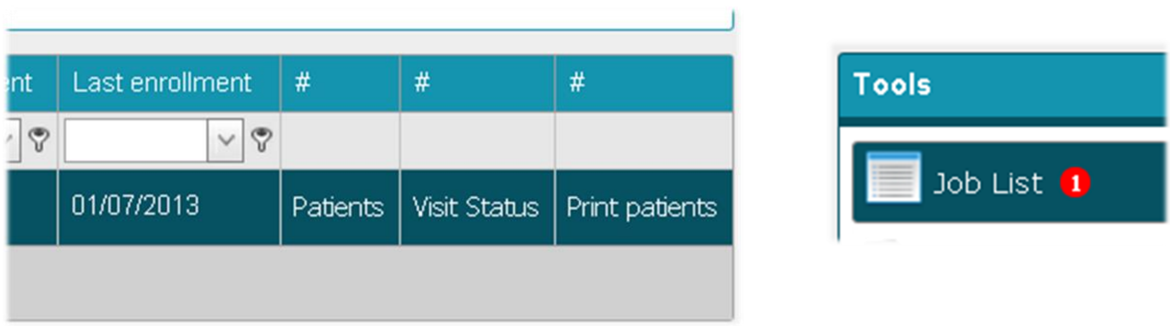
Patient ID	Center ID	Date of birth	Age	Gender	Baseline	INV	MO	Lock	Treatment
TESTCENTER1-001	TESTCENTER1	1978/06/14	35	Male		-1	-1	0	
TESTCENTER1-002	TESTCENTER1	1955/07/03	58	Female		-1	0	0	
TESTCENTER1-003	TESTCENTER1	1978/07/01	35	Male					
TESTCENTER1-004	TESTCENTER1	1944/07/03	69	Male					

Back to top ↺

2.3 CENTERS – PRINT PATIENTS

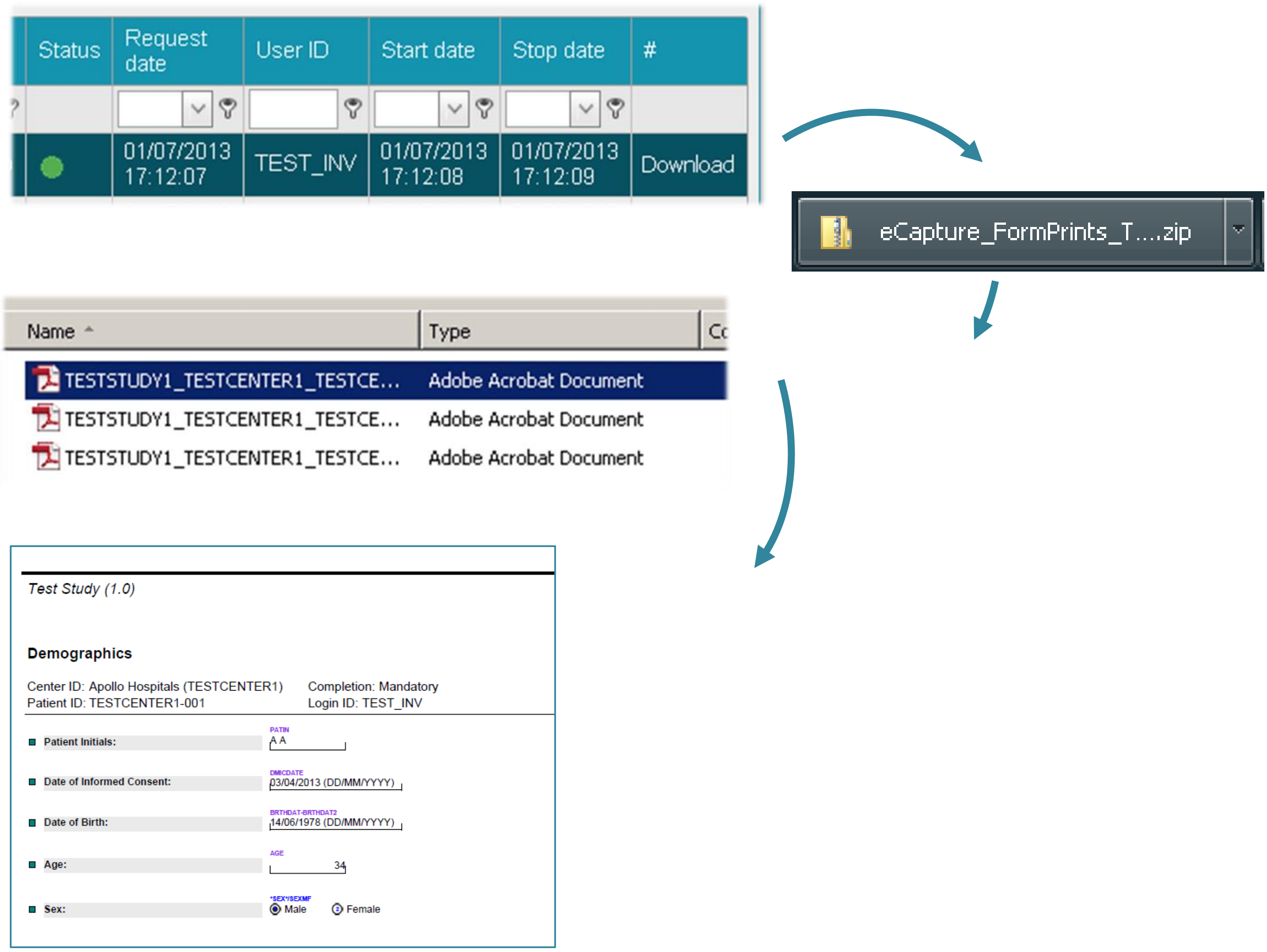
e-capture.net provides the possibility to print all study patients' e-CRF pages.

1. Click Print patients.



2. Your request will be sent to the Job list.
3. e-capture.net ensures that long running tasks are executed in the background. Once the Job is finished, you can retrieve and download your request from the Job list:
4. Click **Download** within the Job list:

The requested patient print outs will appear in a ZIP file that opens in your 'Downloads' folder.

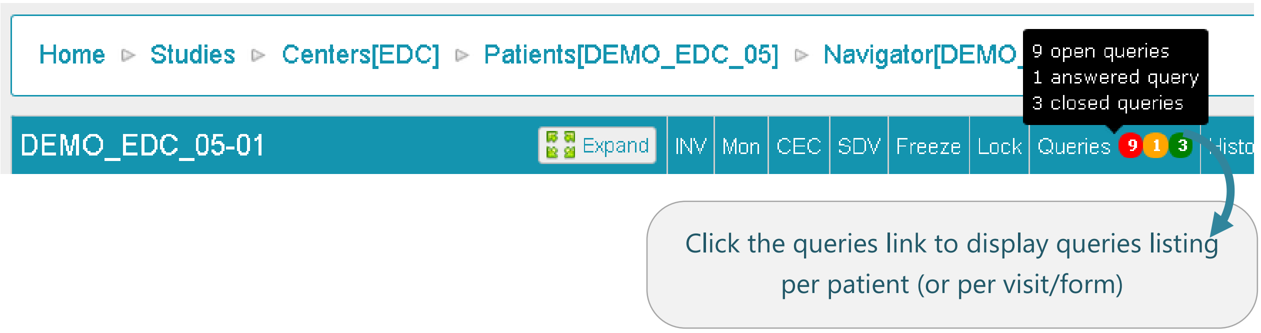


3 QUERY LISTING

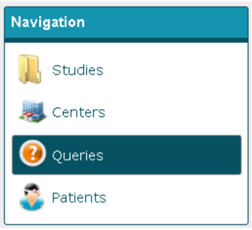
This chapter explains the structure and use of the query list. Details on how to manage queries are explained in the Chapter: Query Management.

3.1 QUERY LISTING PER PATIENT

Tick the query icons within a patient's navigator to view a query list, pre-filtered at patient, visit or even at form level. You can find more information on the query filter further in this chapter.
You can always move back from the query list to the patient navigator via the 'Go to form' button.

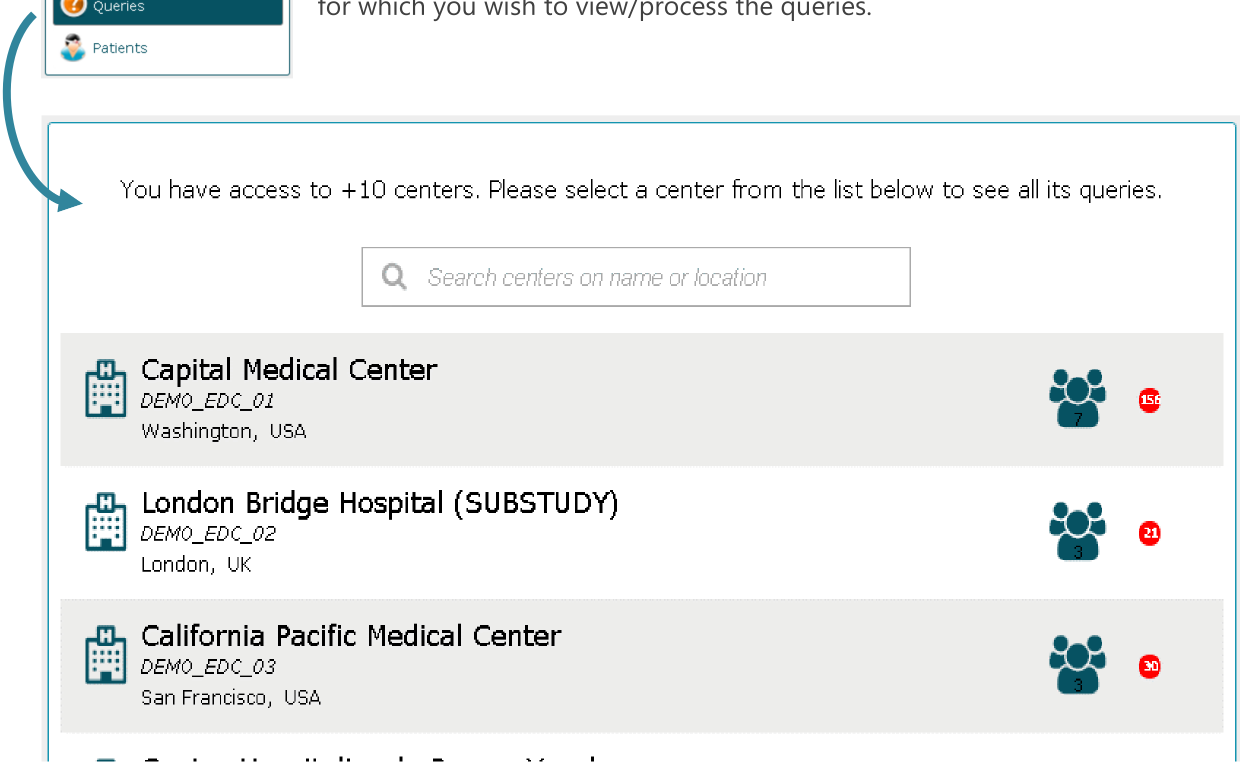


3.2 QUERY LIST PER CENTER



The **Queries** link within the navigation toolbar will direct you to the query list.

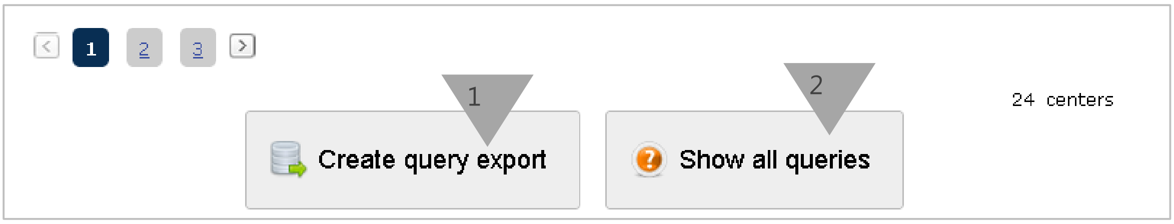
In case you have access to more than 10 centers (that have patients with queries), the query listing will be displayed per center. e-capture.net will ask you to select the center for which you wish to view/process the queries.



Back to top ↺

3.3 FULL STUDY QUERY LIST – QUERY EXPORT

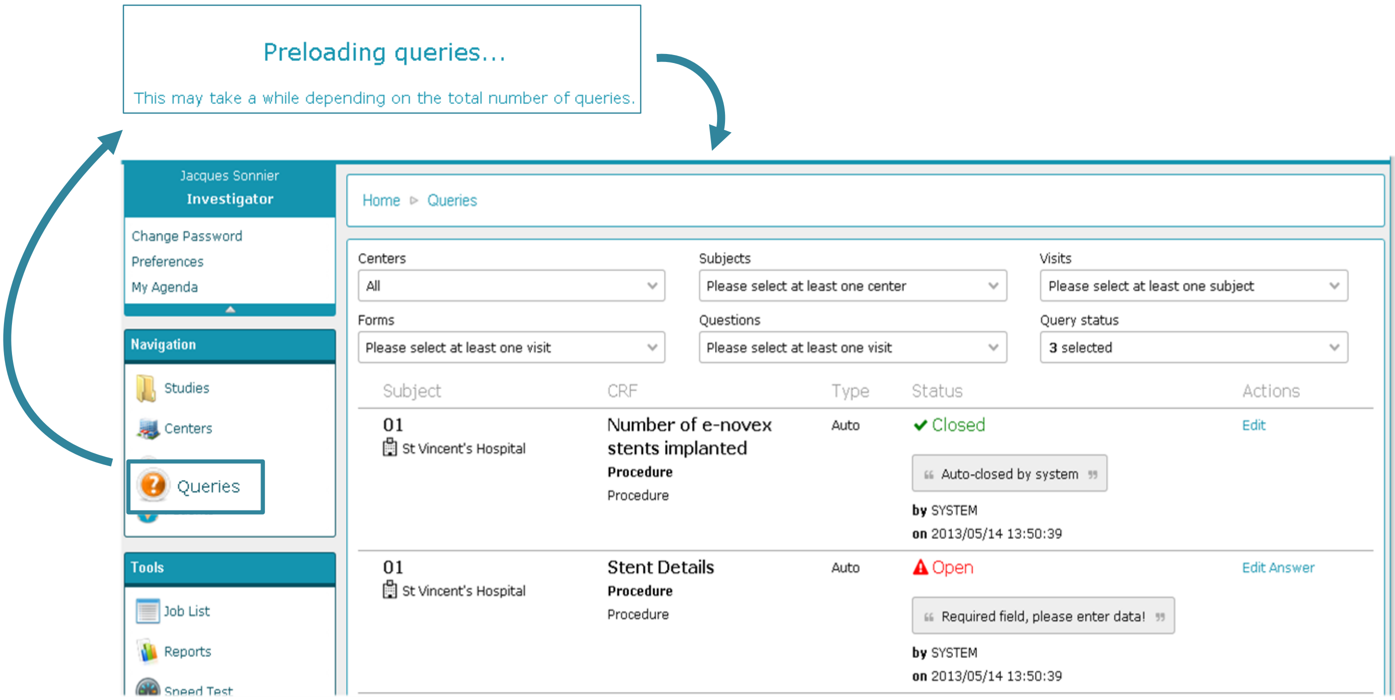
If you have access to less than 10 centers, you will automatically get the **full study** query list.
In case you have access to more than 10 centers with queried patients, it may be faster to work with a center query list.
You can always obtain the full **study query export** ① or **full study query list** ② via the query buttons below the query-centers list.



a) The query export will be created in the background and made available in the job list for download in excel format. You can continue working in e-capture.net while the query list processing.

b) You can manage all study queries at once by ticking the 'Show all queries' button. Loading the full study query list might take some time. You will initially start with a partially completed list, in which you can already manage the shown queries.

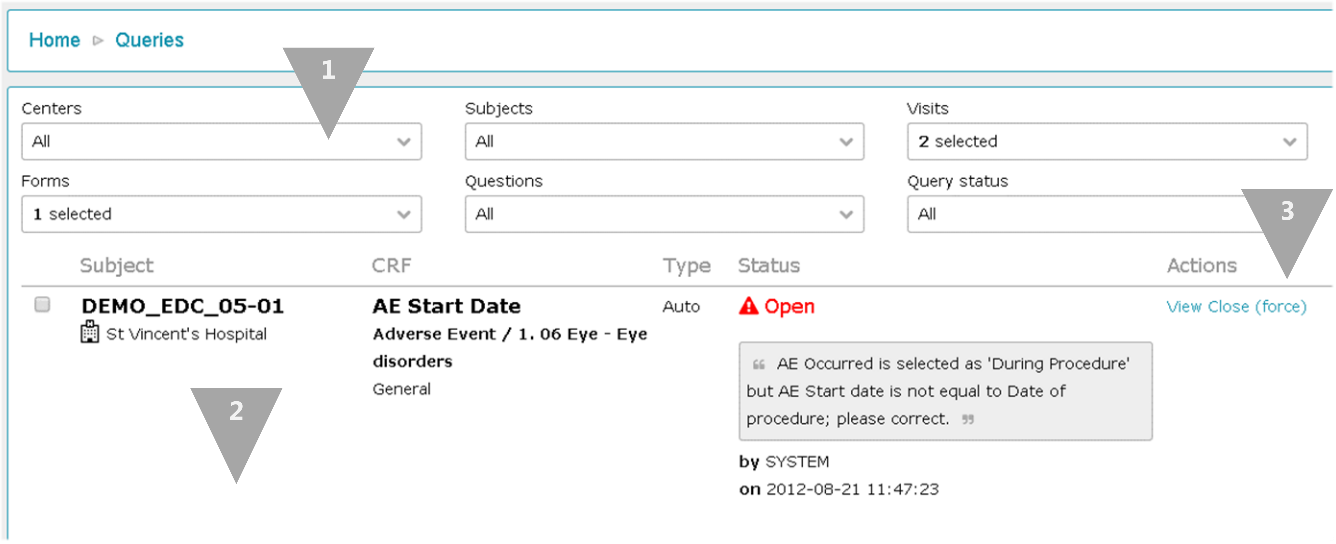
NOTE: A MESSAGE WILL INDICATE THAT THE QUERY LIST IS LOADING, DEPENDING ON THE SIZE OF YOUR STUDY OR NUMBER OF QUERIES; THIS MAY TAKE A FEW MOMENTS.



For more information regarding query details, please check the Query management chapter.

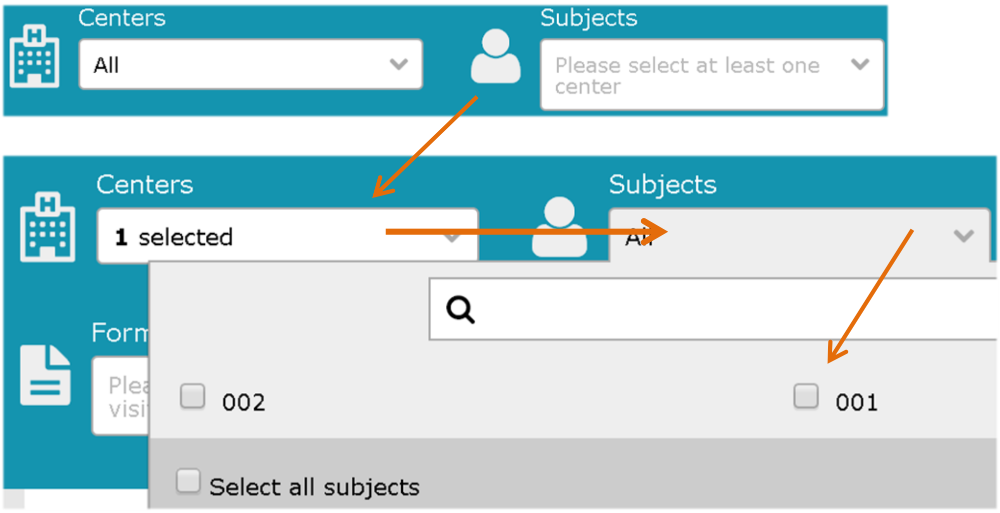
3.4 QUERY LISTING: SEARCH AND FILTER

The top row of the query list includes multiple search and filter functionalities, enabling easy search and batch query management.



1. search and filter box

- The Query status filter can used independently from the other query filters.
- Filters for Centers -> subjects -> visits -> Forms -> questions can only be applied in this fixed sequence.

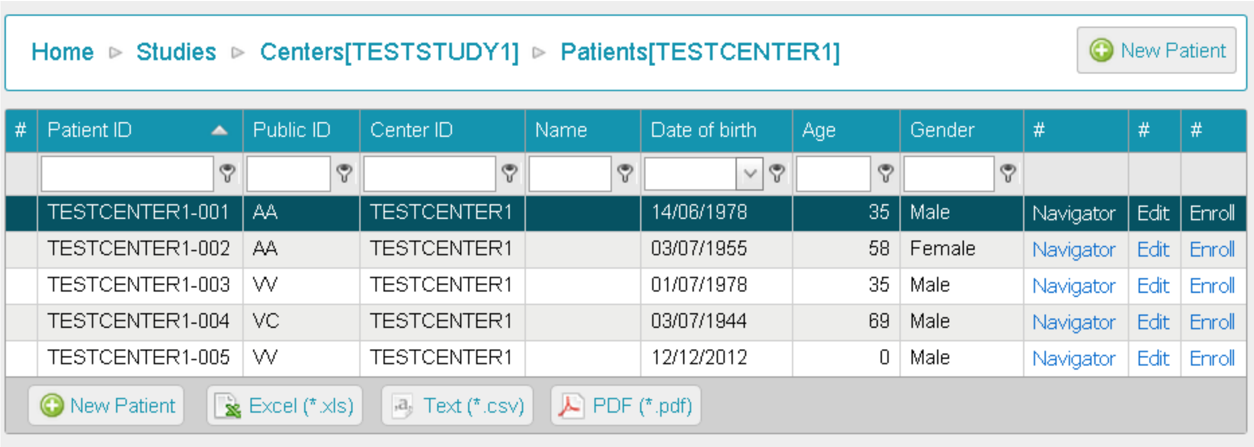


2. Results of filter/search action - information per shown query : see query list details
3. Possible query actions – the presence of these actions depends on the rights assigned to your user role.

NOTE: QUERY MANAGEMENT WILL BE EXPLAINED IN FURTHER DETAIL IN THE QUERY ACTIONS SECTION IN CHAPTER: MANAGE QUERIES.

4 PATIENTS

Once you have added patients to the study, they will appear in the Patients table.
The **Patients** tab within the Navigation tool brings you to a table view of the study Patients from all centers **you have access** to:

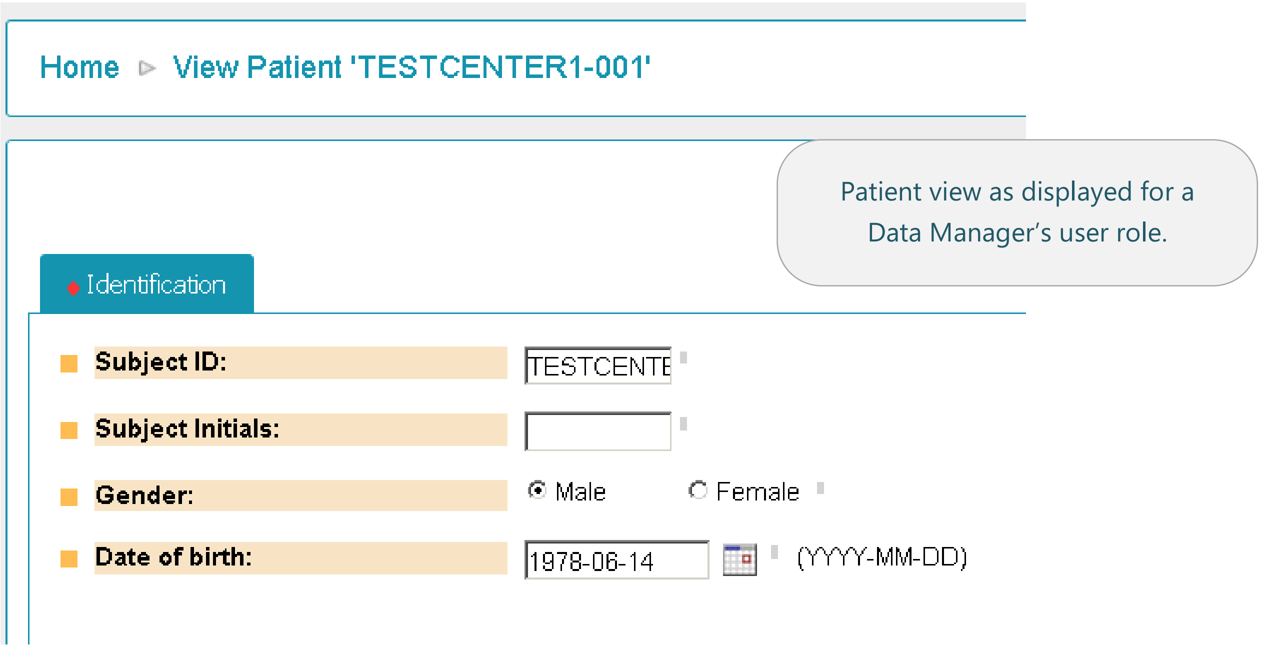


Home ▹ Studies ▹ Centers[TESTSTUDY1] ▹ Patients[TESTCENTER1]   New Patient

#	Patient ID	Public ID	Center ID	Name	Date of birth	Age	Gender	#	#	#
	TESTCENTER1-001	AA	TESTCENTER1		14/06/1978	35	Male	Navigator	Edit	Enroll
	TESTCENTER1-002	AA	TESTCENTER1		03/07/1955	58	Female	Navigator	Edit	Enroll
	TESTCENTER1-003	VV	TESTCENTER1		01/07/1978	35	Male	Navigator	Edit	Enroll
	TESTCENTER1-004	VC	TESTCENTER1		03/07/1944	69	Male	Navigator	Edit	Enroll
	TESTCENTER1-005	VV	TESTCENTER1		12/12/2012	0	Male	Navigator	Edit	Enroll

New Patient   Excel (*.xls)   Text (*.csv)   PDF (*.pdf)

- All patients are displayed in a table view with header details: Patient ID, Public ID, Center ID, Name, Date of Birth, Age and Gender.
- **Navigator**: the link to each patient's e-CRF pages.
- All patient information will be presented within the Patient View. You can access (and update) this view via an **Edit** (read and write) or **View** (read) link. The presence of this link depends on the rights assigned to each user role.



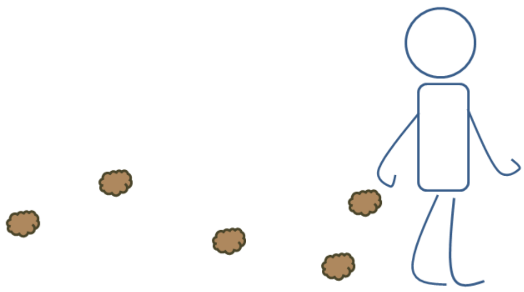
NOTE: SEE ALSO CHAPTER [CREATE PATIENTS].

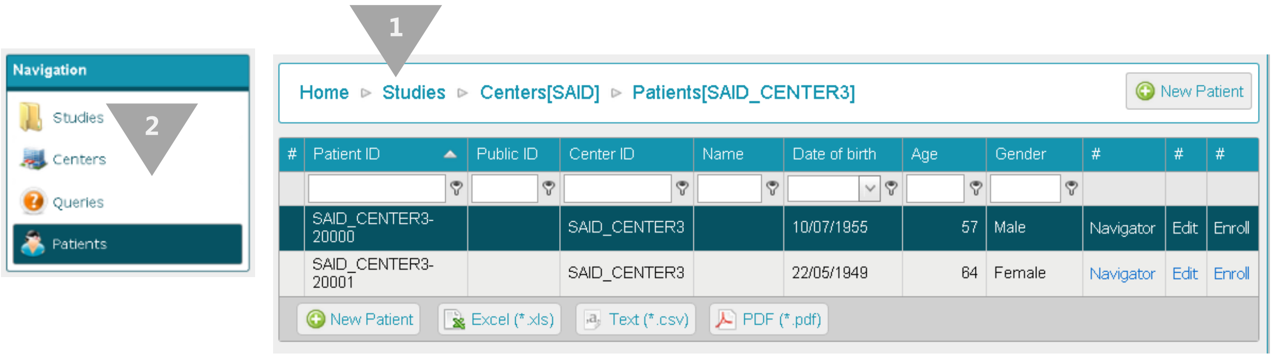
5 SEARCH AND FILTER OPTIONS

5.1 BREADCRUMBS

WHERE AM I?

e-capture.net provides a breadcrumb trail above each table view to allow you to keep track of you locations within the application.
Breadcrumbs enable you to retrace your steps and see how you arrived at the current page.
Each step within the breadcrumb path is a link to that specific location ①.
Within the navigation or tools menu, the blue color of the menu icon indicates your respective location ②.

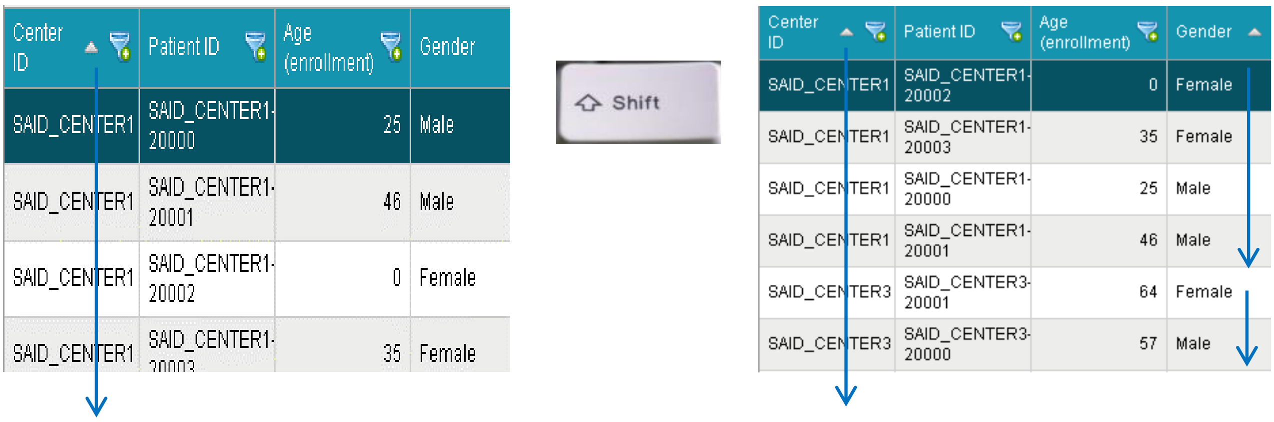




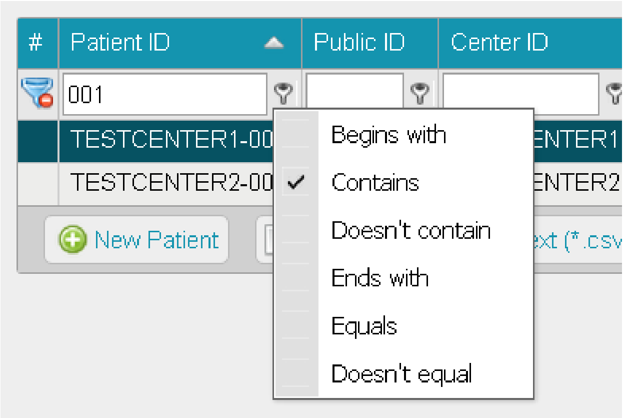
5.2 SORT LIST

Single click any of the column headers to order by that column (A-> Z or 1-> 9); Click again for reverse sorting (Z->A or 9 -> 1).

To add multi column sorting, press the Shift key when ticking the additional (lower level) column to sort. See also further in this manual for the sorting of subform grids.

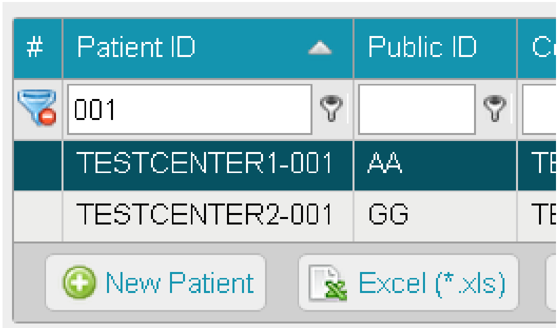


5.3 FILTER OPTIONS



Enter a search term in the appropriate field and click the icon to display all filter options.

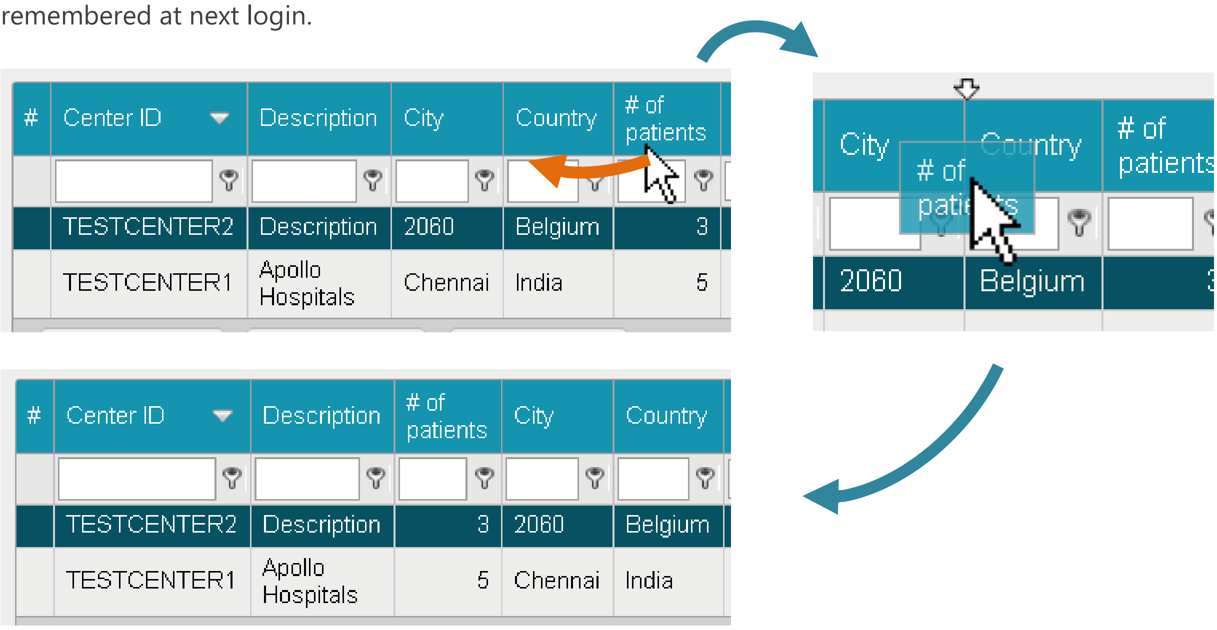
Click the icon on the left of the column headers to remove existing filters



NOTE: E- CAPTURE.NET PROVIDES SORT AND FILTER OPTIONS WITHIN EACH TABLE, REPORT OR EXPORT.
THE SYSTEM REMEMBERS ALL CURRENT FILTERS AND SEARCH TERMS AT NEXT LOGIN.

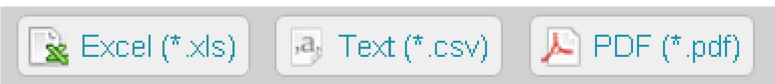
5.4 CUSTOMIZE LISTS

e-capture.net allows you to customize your tables via drag & drop of columns. The column sequence is remembered at next login.



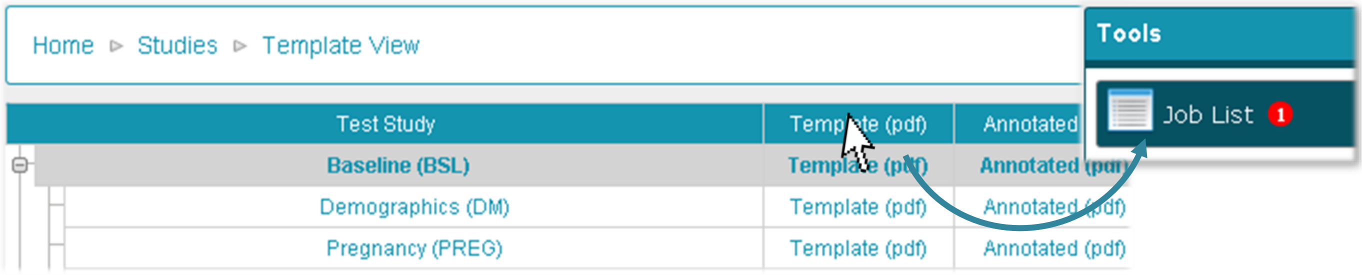
5.5 EXPORT LISTS

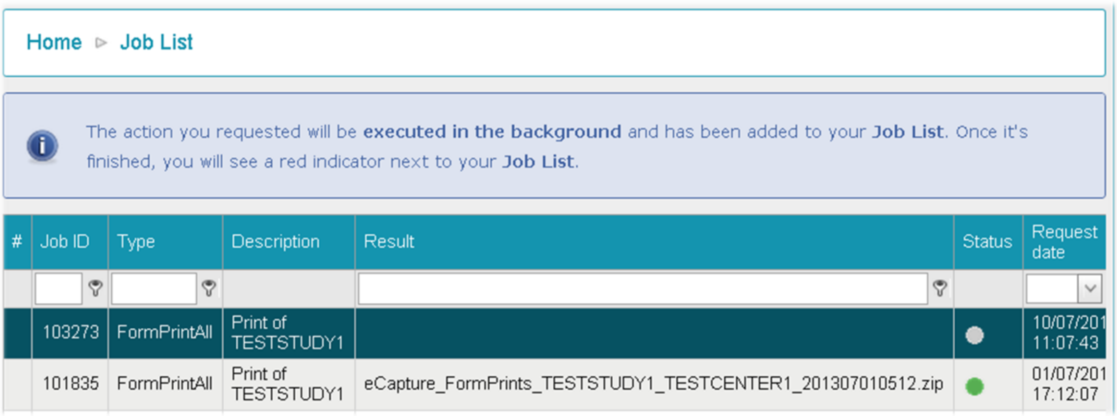
e-capture.net provides an export option (Excel, text and PDF) within each table.



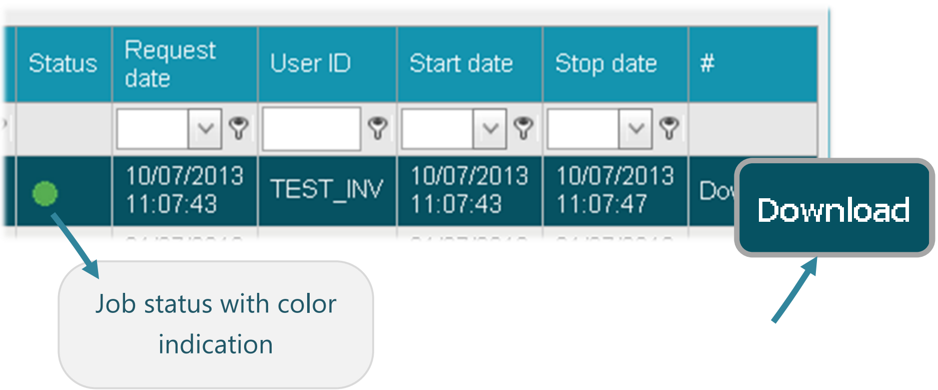
6 JOB LIST

- e-capture.net ensures that long running tasks/requests are executed in the background.
  These requests are added to a Job list.
  While Job list is running, you can continue working on your study.
- Examples of a long running task: download of a study template or printing of patient CRF's:





- The Job list will show if your request is ready (green status), in progress (yellow status), waiting (grey status = system is processing another job).
- Press the F5 key to refresh your internet page for updated job status.
- Once the Job is finished, you can retrieve and download your request from the Job list:



- In case of multiple requests, jobs will be performed one after the other, meaning you may have to wait a few moments before your job is processed. You can always continue working on the study and check the job status afterwards.

7 SPEED TEST

In case you experience slow performance of the platform, it's important to locate the origin of the slow performance. To do so, we need you to perform a speed test, and mail us the test results.

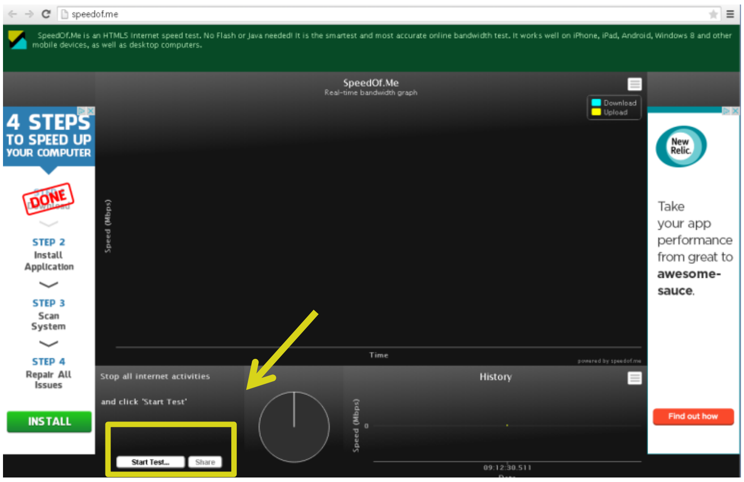
This can be done via the below 3 steps :

1. Click link http://speedof.me
2. Start test
3. Share your results via mail to :support@e-capture.net

Workflow in detail with screenshots

1. Click **link** http://speedof.me

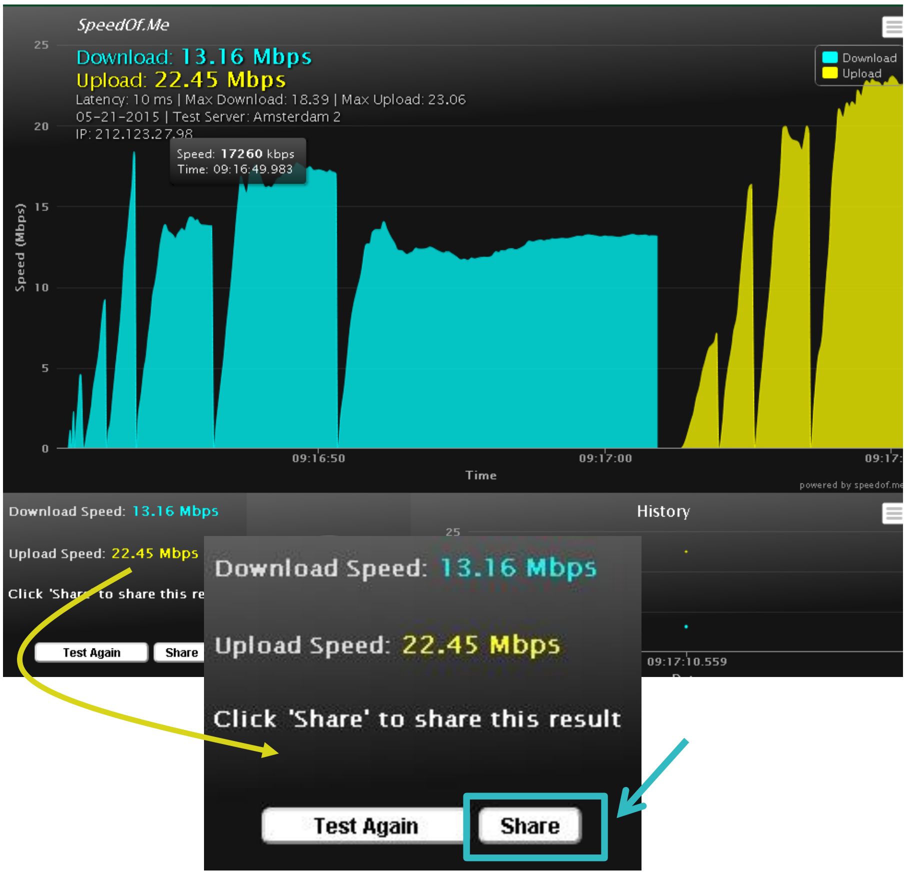
The internet page opens.

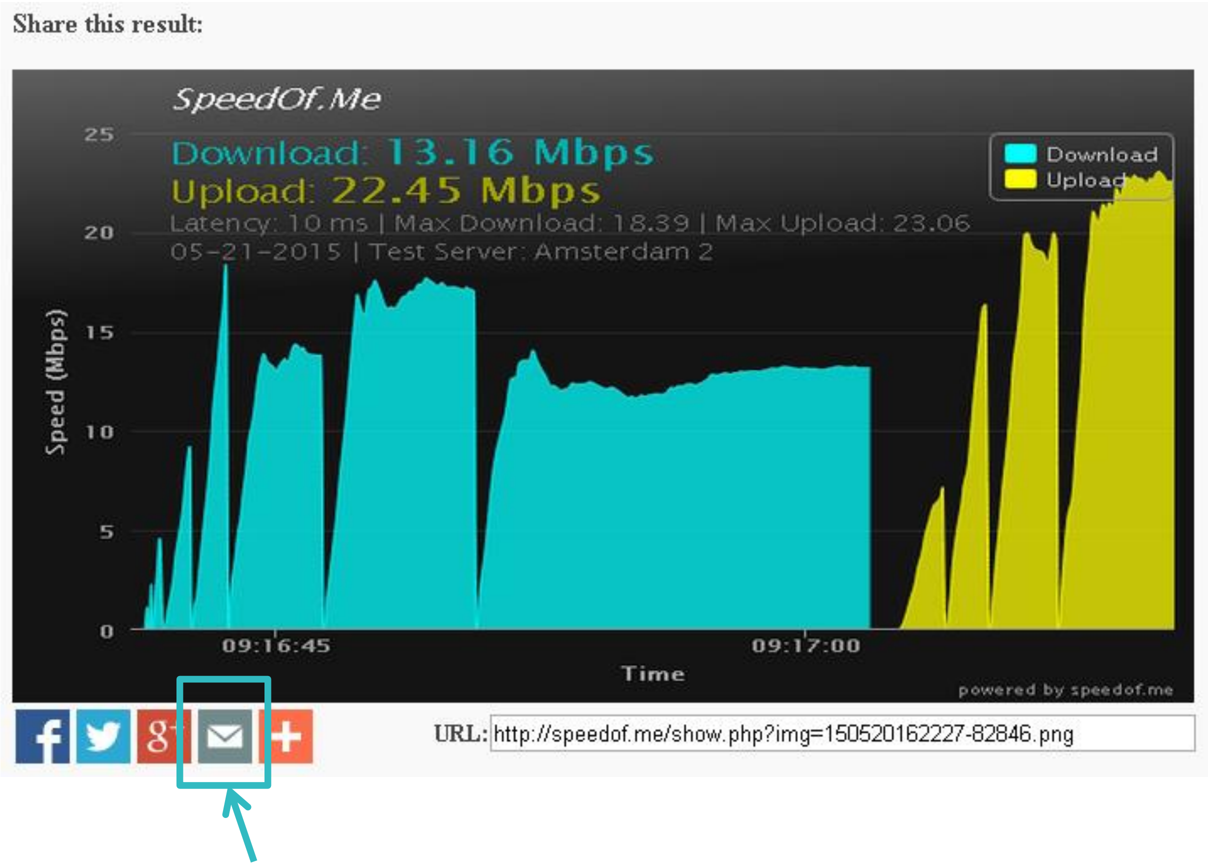


2. Click '**Start Test**'. This button is below your screen. And wait till the test has fully run.

Back to top ↺

3. When the test is completed, **share** your results with Support@e-capture.net



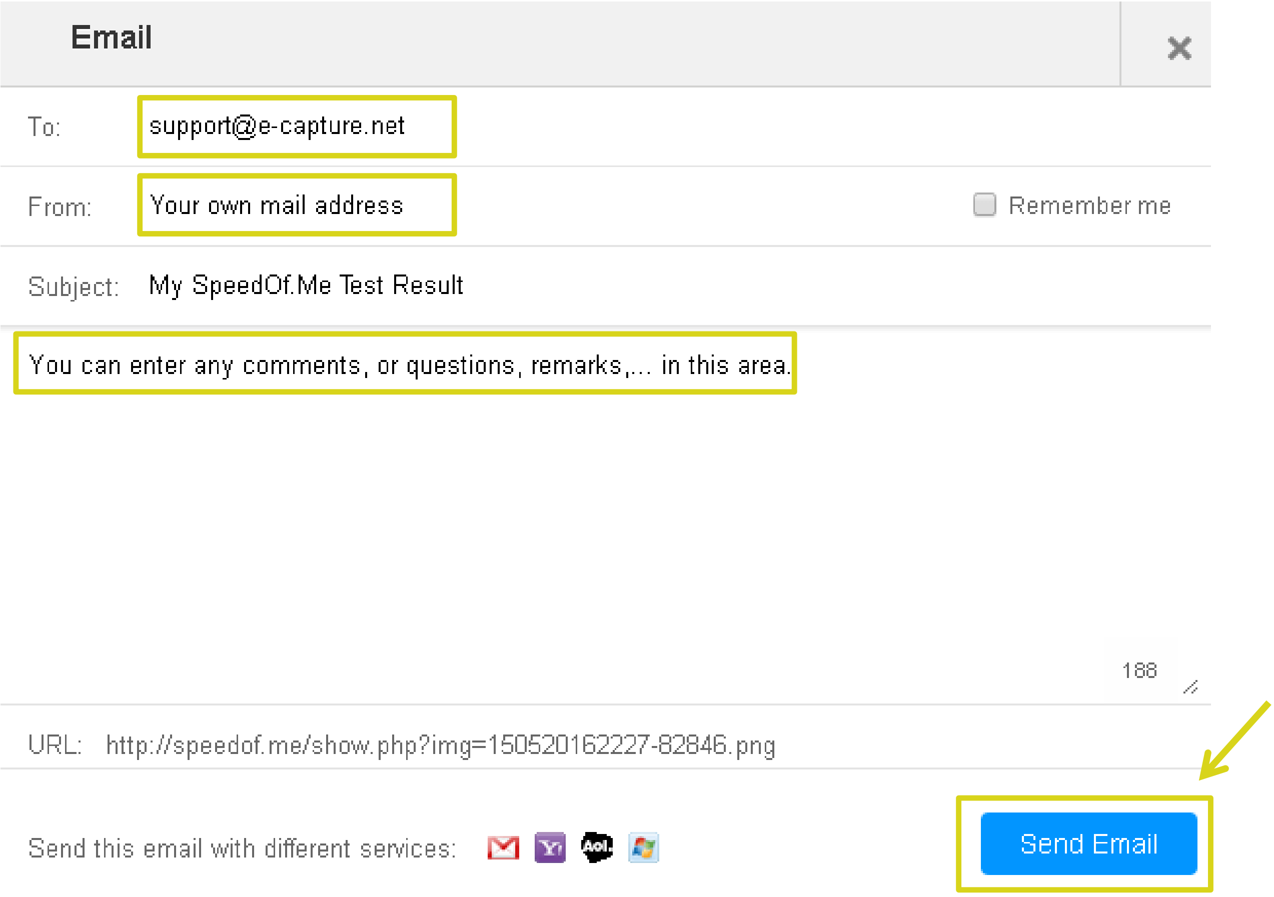


Back to top ↺

Enter following mail addresses

- To : support@e-capture.net
- From: enter your own mail address
- Type your comments in the comment area

Then Click 'Send Email'



Checklist for slow connections:

a) Perform speed test: if Download < 0.5MB → slow connection.

b) Compare to www.youtube.com or www.facebook.com: Equally slow? → slow connection.

c) Browser: IE6, IE7 of IE8? → please test in other browser.

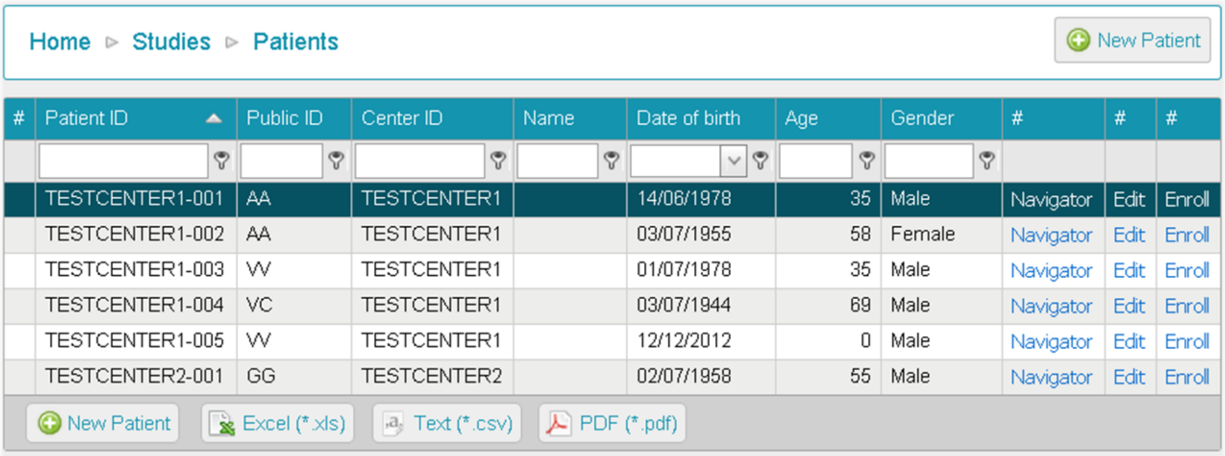
d) Do you have an anti-virus program installed? This could be could be blocking certain items.

e) Check Java script: go to www.isjavascriptenabled.com. If NO → java script is blocked.

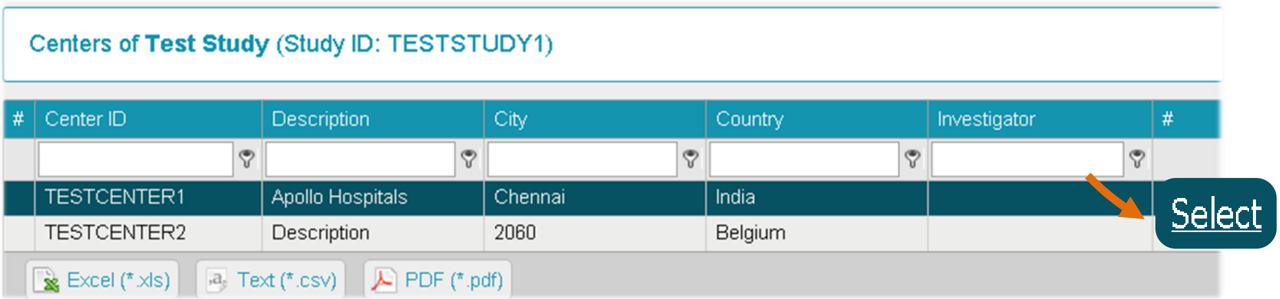
1 CREATE PATIENTS

To create a new patient in e-capture.net, follow these steps:

- Login to e-capture.net and select your study.
- Click **Patients** within the Navigation menu, this action will display the list of patients of all centers you have access to.



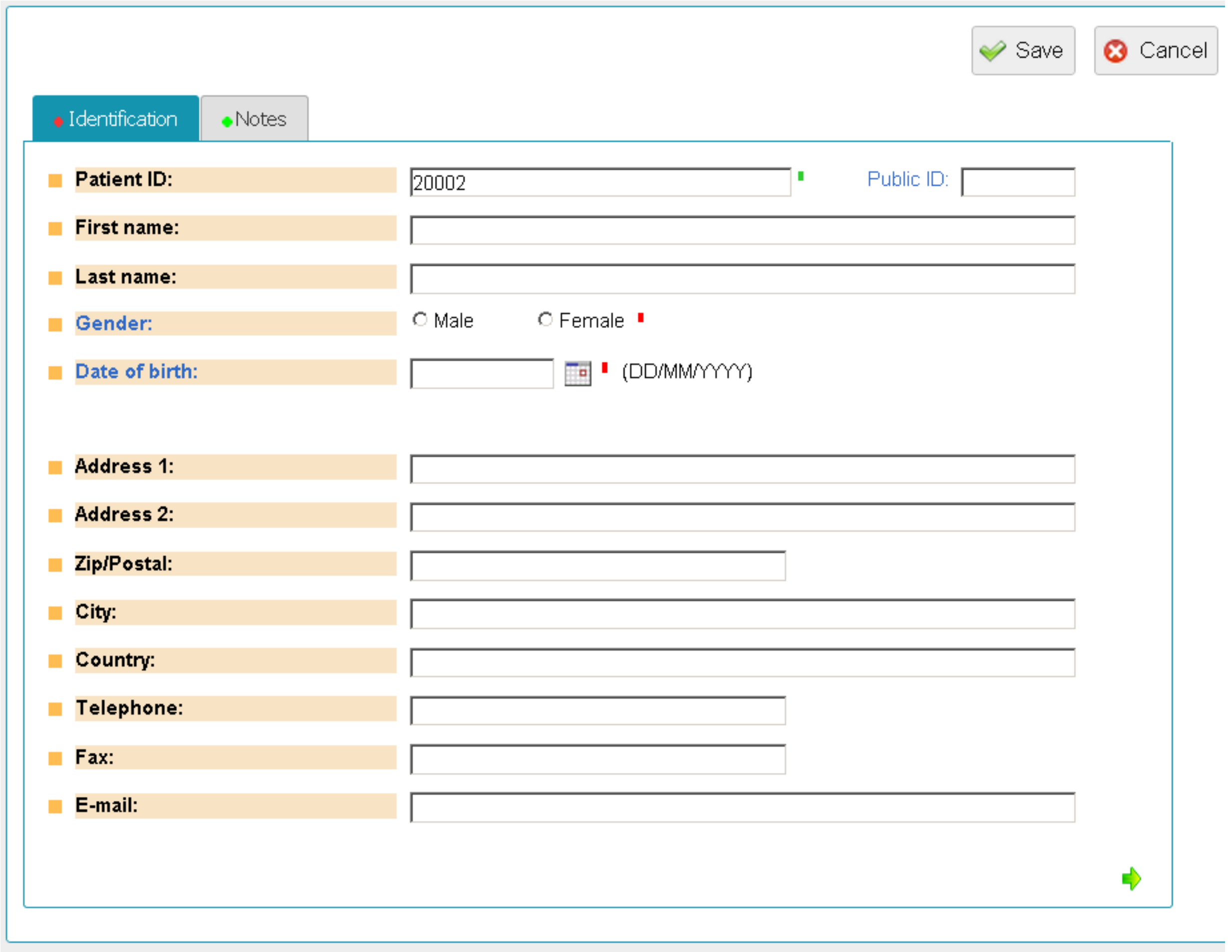
- Click the 'New patient' button. The availability of this button depends on the rights assigned to your user role. Typically, Investigator roles will be able to create new patients.
- If you have access to more than one center, the next step is to <u>select</u> the center to which you would like to add a patient:



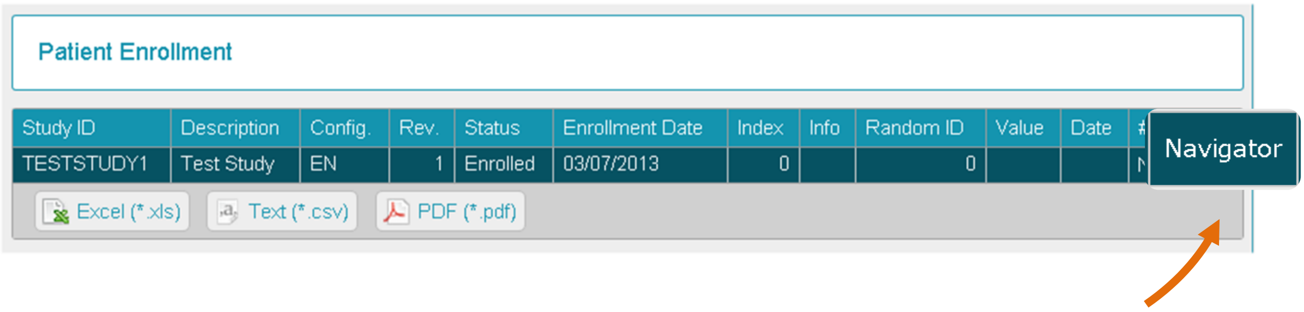
NOTE: THERE ARE TWO OTHER WAYS TO REACH THE PATIENTS PAGE THROUGH THE NAVIGATOR MENU:

STUDIES -> PATIENTS LINK TO SHOW ALL STUDY PATIENTS.
CENTERS - > PATIENTS LINK TO SHOW THE PATIENTS OF THAT CENTER.

- The New patient window will appear. The content of this page depends on your study set-up.



- Patient ID: may or may not be automatically generated by the system.
- Fields marked with a red icon (▮) are mandatory fields. This icon will become green upon a satisfactory data entry.
- Click the 'Cancel' button if you do not wish to save the information you have created.
- Click the 'Save' button after completion of all required fields to create the Patient. You will navigate to the created patient's enrollment page.
- Via the **Navigator** link on this page (and all other patient tables), you can navigate to the patient's e-CRF pages.

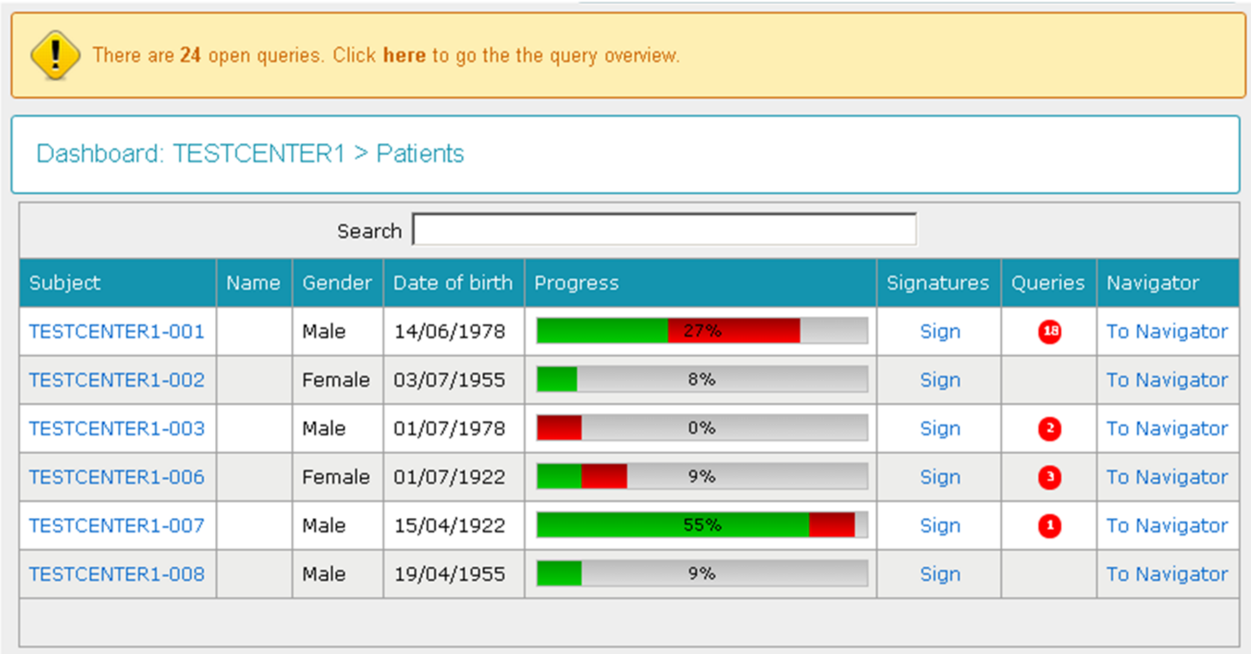


2 SEARCH PATIENTS

2.1 SEARCH FROM DASHBOARD

Your study dashboard is located on the Home screen. The content of this dashboard may depend on the rights assigned to your user role.

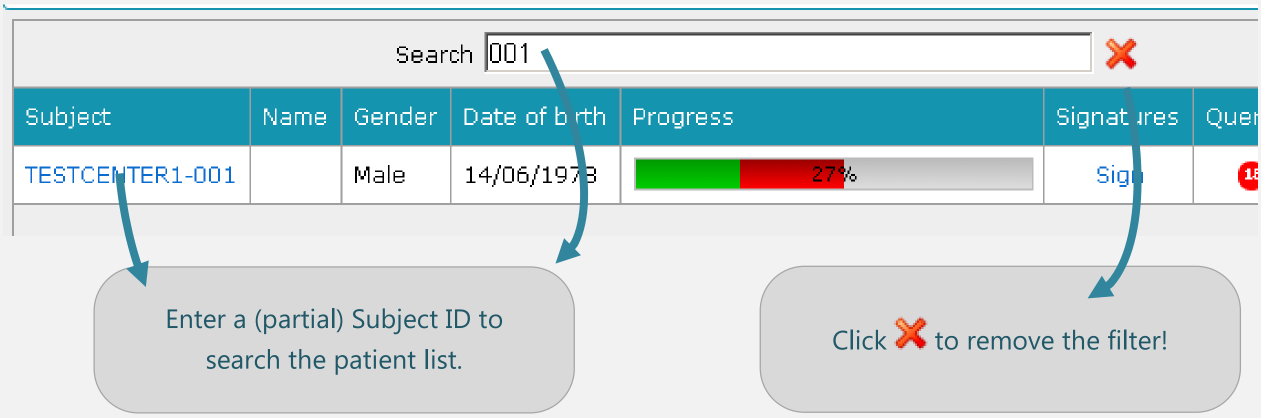
- If you have access to more than study center, the dashboard will initially show you these centers in table view. For each listed center, links are available to navigate to the Patients list of that center (As described in Part 2 Getting Started, Chapter: Home screen).
- If you have access to one study center, the dashboard will directly display your center's Patient list:



Subject	Name	Gender	Date of birth	Progress	Signatures	Queries	Navigator
TESTCENTER1-001		Male	14/06/1978	27%	Sign	18	To Navigator
TESTCENTER1-002		Female	03/07/1955	8%	Sign		To Navigator
TESTCENTER1-003		Male	01/07/1978	0%	Sign	2	To Navigator
TESTCENTER1-006		Female	01/07/1922	9%	Sign	3	To Navigator
TESTCENTER1-007		Male	15/04/1922	55%	Sign	1	To Navigator
TESTCENTER1-008		Male	19/04/1955	9%	Sign		To Navigator

For each patient, e-capture.net displays information about Name (optional), Gender, Date of Birth and the number of queries in the patient's e-CRF. Depending on your user role, link(s) to the patient's navigator are available in blue text color: Subject, Signatures and/or Navigator.

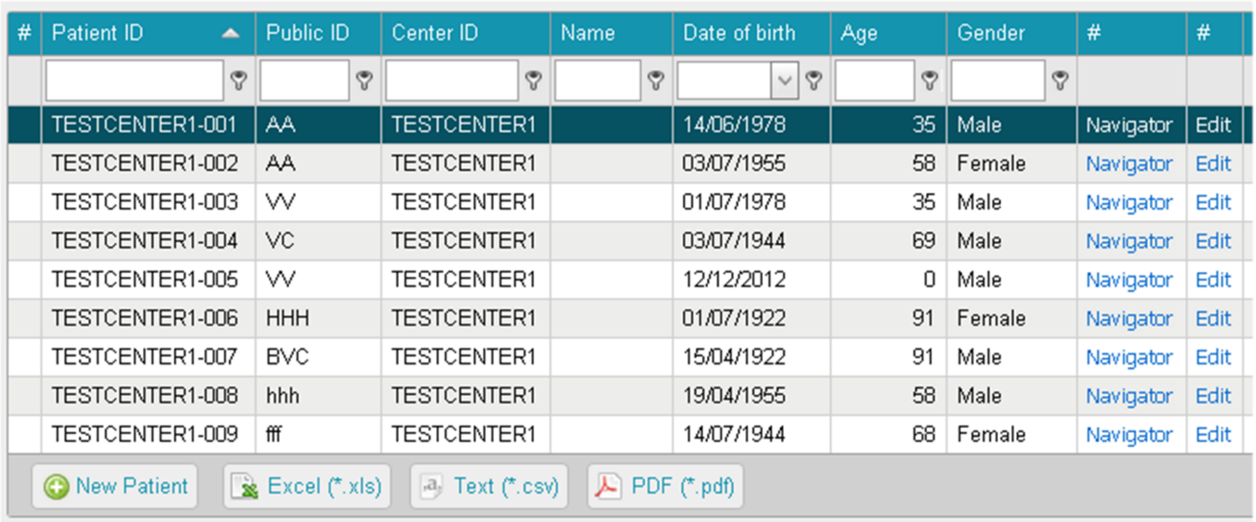
A **Search field** is available on top of the table in which you can enter a (partial) search term for **Subject**:



Back to top ↺

2.2 SEARCH FROM PATIENT'S TABLE

The Patients tab within the Navigation Tool provides a detailed Patients table in which you can use the general search, filter and navigation functionalities (see also Chapter: Search and Filter options):



#	Patient ID	Public ID	Center ID	Name	Date of birth	Age	Gender	#	#
	TESTCENTER1-001	AA	TESTCENTER1		14/06/1978	35	Male	Navigator	Edit
	TESTCENTER1-002	AA	TESTCENTER1		03/07/1955	58	Female	Navigator	Edit
	TESTCENTER1-003	VV	TESTCENTER1		01/07/1978	35	Male	Navigator	Edit
	TESTCENTER1-004	VC	TESTCENTER1		03/07/1944	69	Male	Navigator	Edit
	TESTCENTER1-005	VV	TESTCENTER1		12/12/2012	0	Male	Navigator	Edit
	TESTCENTER1-006	HHH	TESTCENTER1		01/07/1922	91	Female	Navigator	Edit
	TESTCENTER1-007	BVC	TESTCENTER1		15/04/1922	91	Male	Navigator	Edit
	TESTCENTER1-008	hhh	TESTCENTER1		19/04/1955	58	Male	Navigator	Edit
	TESTCENTER1-009	fff	TESTCENTER1		14/07/1944	68	Female	Navigator	Edit

New Patient | Excel (*.xls) | Text (*.csv) | PDF (*.pdf)

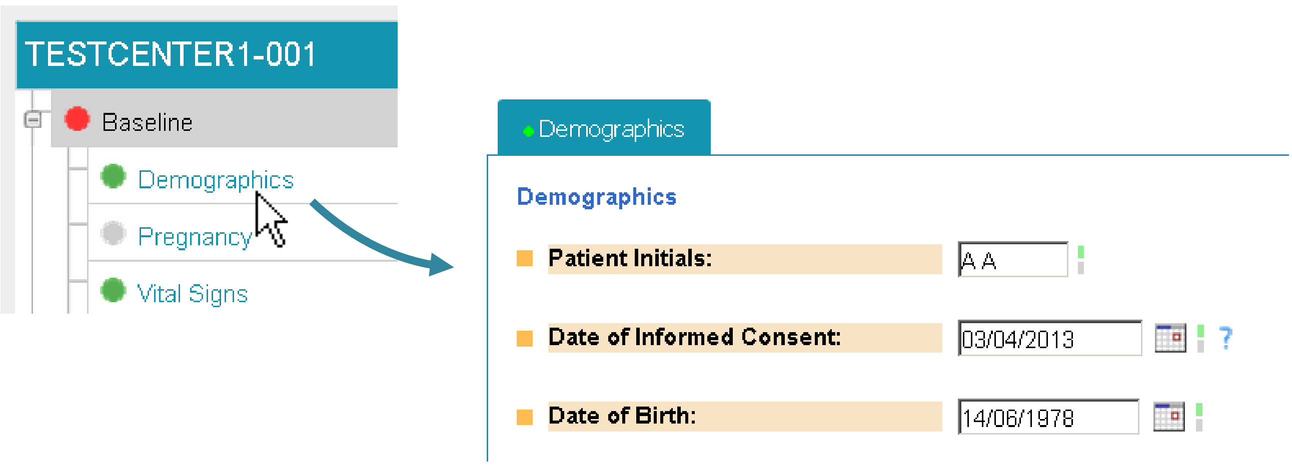
NOTE: SEE ALSO PART 2: GETTING STARTED, CHAPTER: PATIENTS

3 PATIENT CRF NAVIGATOR

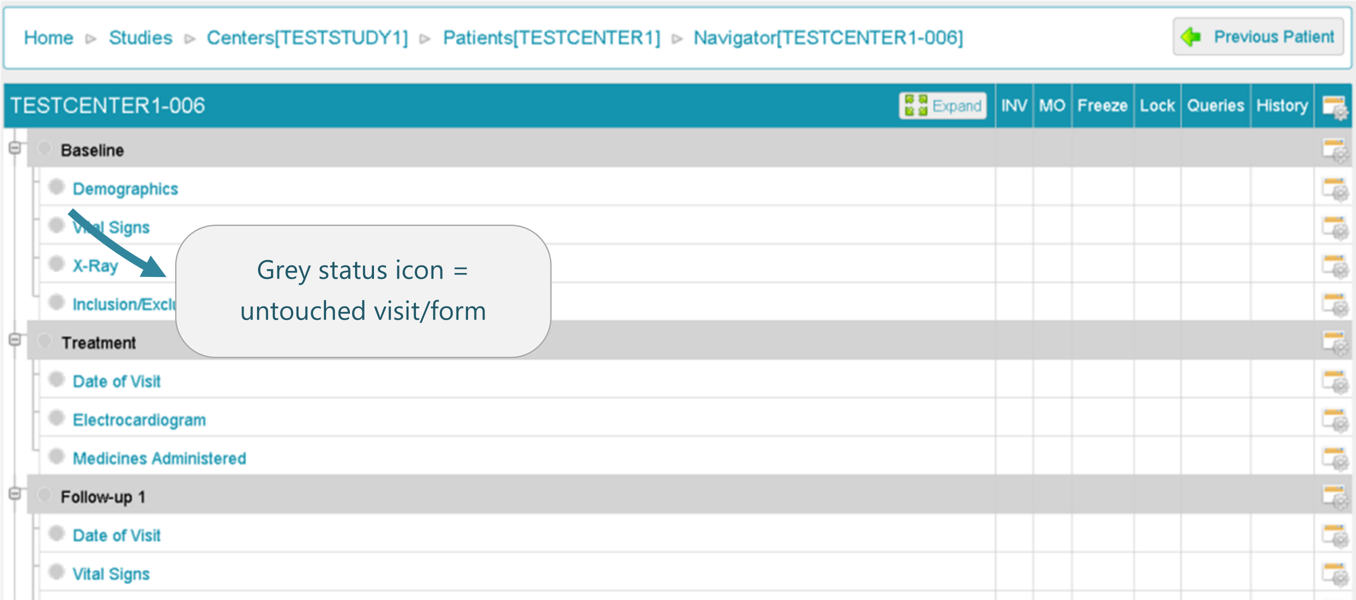
Entering and editing data in your study is done through the Navigator.

THE NAVIGATOR REPRESENTS THE PATIENT'S TIMELINE THROUGH THE STUDY FORMS AND VISITS.

- All study visits and forms are displayed in a tree view format and can be collapsed and expanded.
- Depending on your study settings, it is possible that the visibility of some forms/visits depends on the entries within other forms/visits.
- Clicking any of the forms within a visit will take you directly to the selected form.

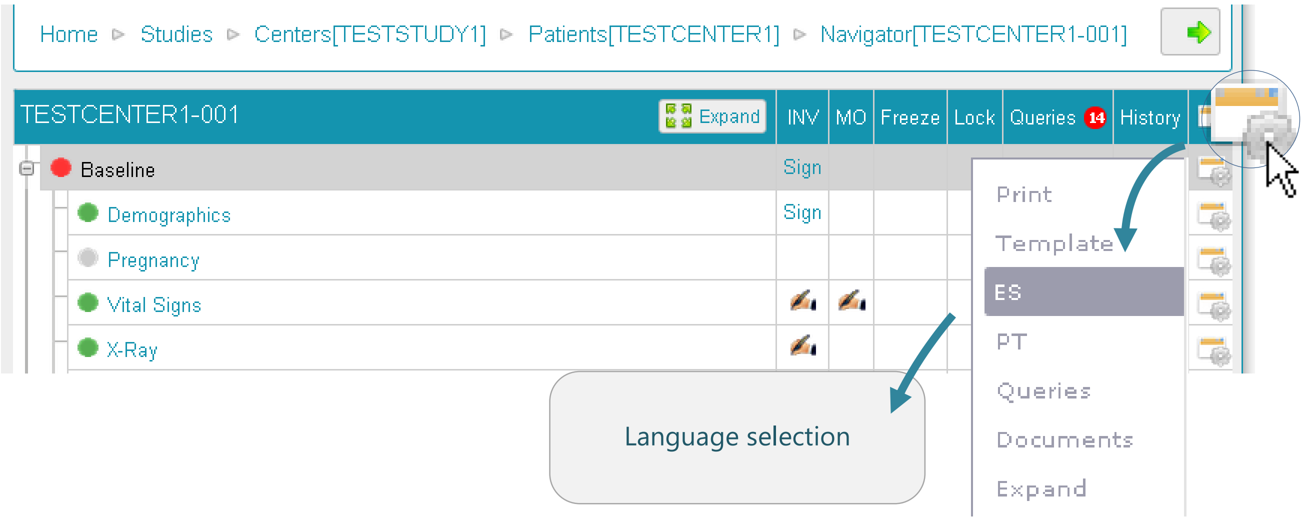


As presented in the image below, the CRF's are empty for a new patient, therefore the status indicators for each Navigator form are grey.



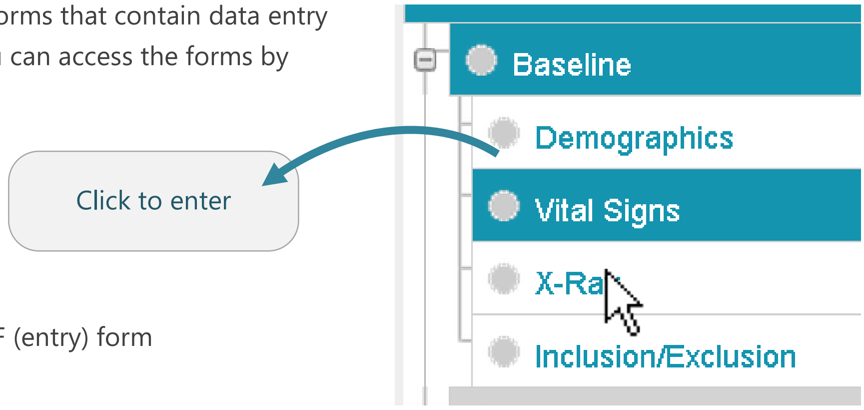
4 PATIENT CRF LANGUAGE

Depending on your study settings, 1 or in multiple languages will be available.
In case of multiple languages, you can select a language through the action icon within the patient Navigator.
The language is indicated by the international language code.
Once selected, the system remembers this language at next login.



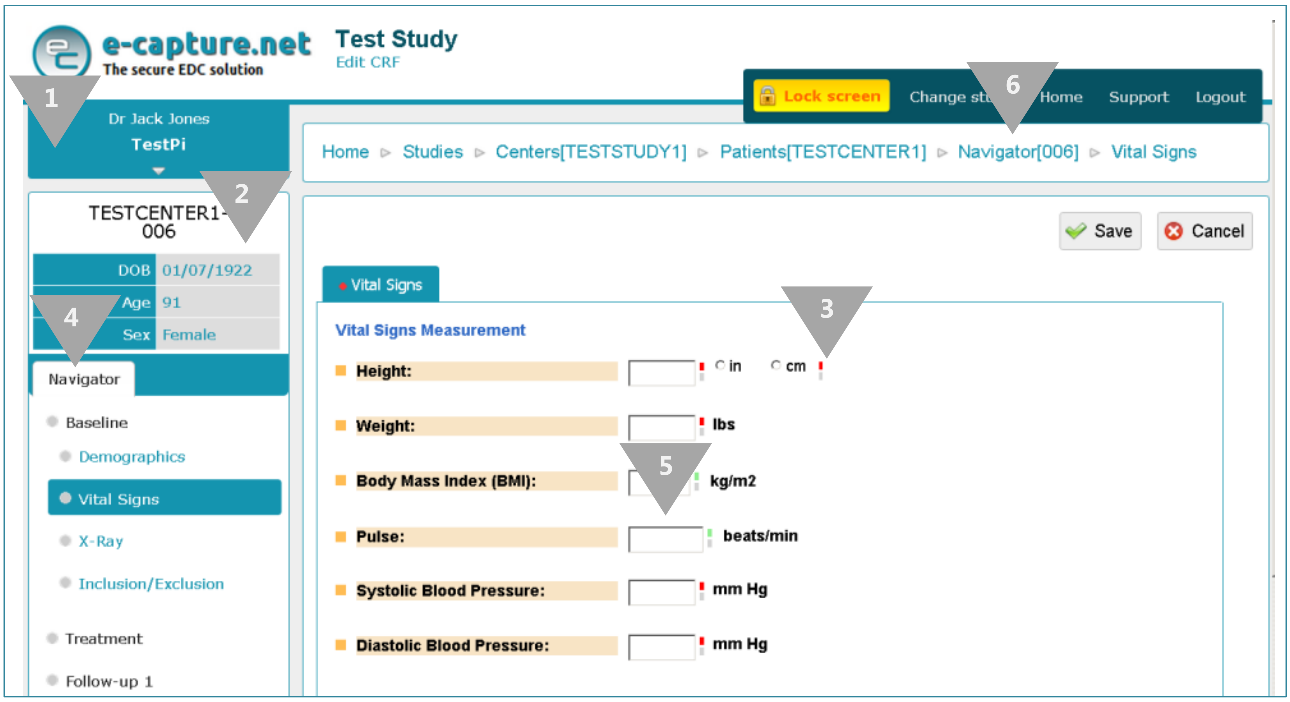
ENTER DATA

A study visit may consist of multiple forms that contain data entry fields or other interface elements. You can access the forms by clicking the applicable form name.



1 FORM LEVEL

The screenshot below shows an e-CRF (entry) form in e-capture.net:



1. User information
2. Patient information: the details shown in this box may depend on your study specifications.
3. Field Marks
4. Navigator: easy access to other visits and forms
5. Data entry fields
6. Breadcrumbs

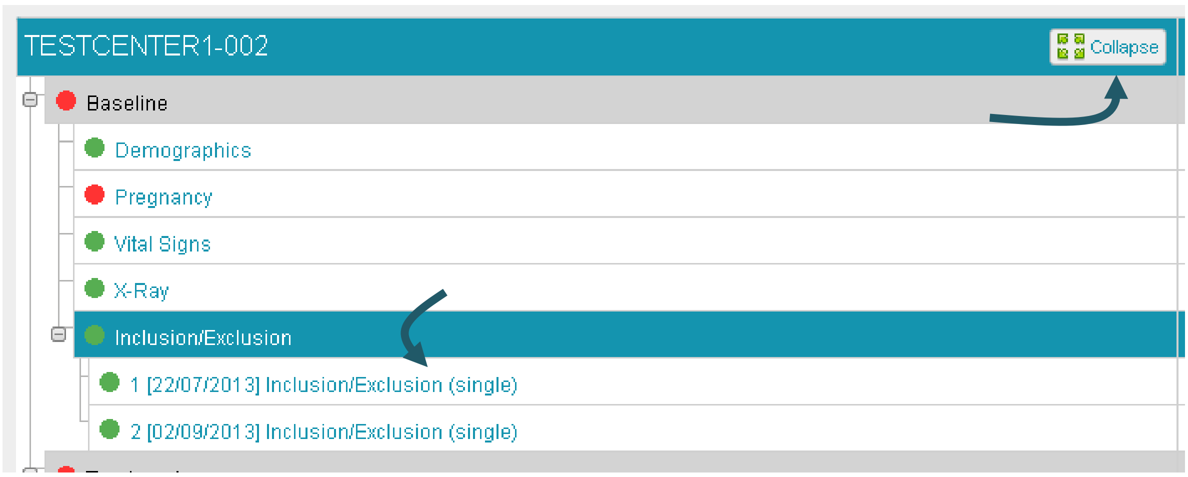
Back to top ↺

1.1 SUB- FORMS AND GRIDS

1.1.1 VIEW SUB-FORMS

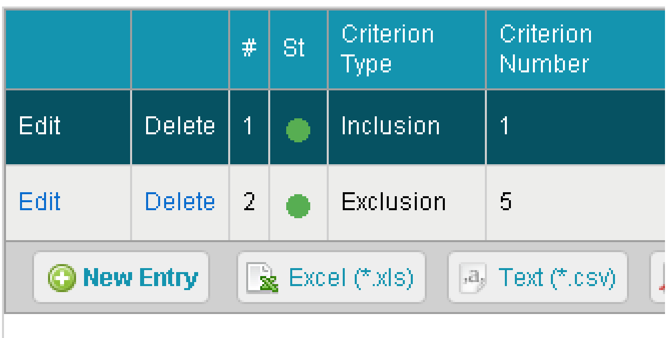
Sub-forms are forms that are embedded into a parent form. They may be activated upon certain data entry and are typically used to capture repetitive information (medication entries, device details...).
An example for the use of a sub-form is the entry of failed eligibility criteria:

- Click the 'Expand/Collapse' button on the top right hand side of the navigator to see all sub-forms.

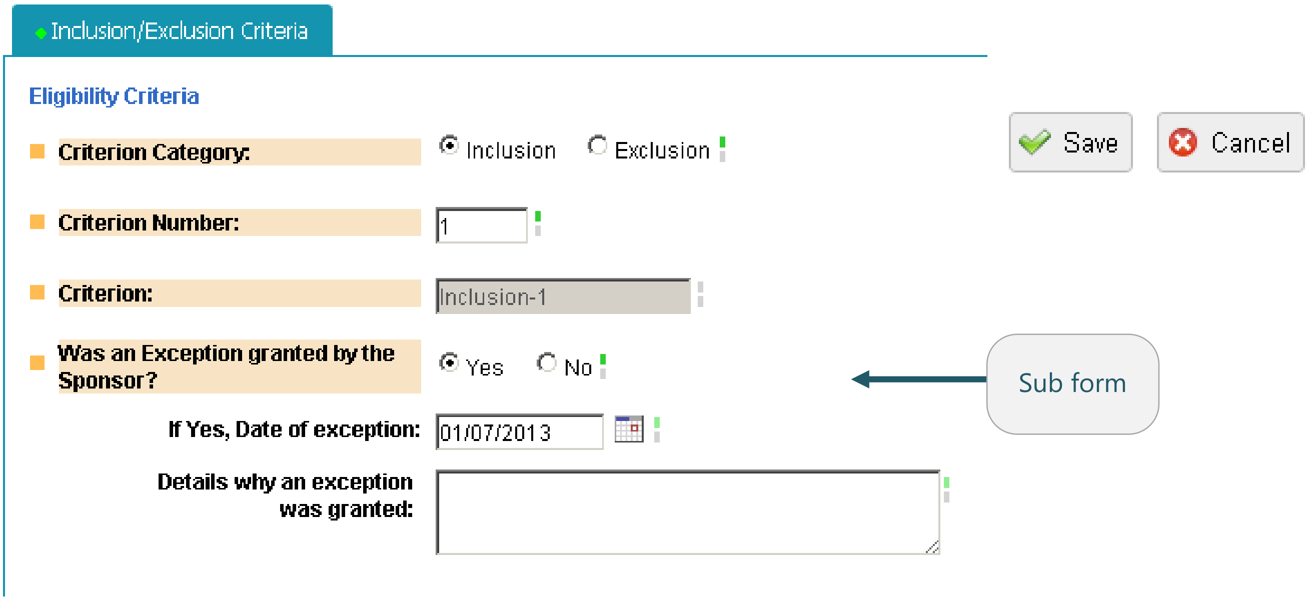


1.1.2 CREATE/DELETE SUB-FORMS

- Embedded sub-forms are displayed in a table format in the parent form.
- You can export the content of the sub-forms in Excel, csv or PDF format.
- Use the buttons 'New Entry', 'Edit' for data entry in the sub-forms.
- Use the button 'Delete' to remove a specific sub-form. 'Deleted' sub-forms will become invisible, but will remain in the study audit trail.



Back to top ↺



NOTE: UPON SAVING THE SUB-FORM, THE **PARENT** IS NOT AUTO SAVED. YOU MUST SAVE THE PARENT BEFORE MOVING TO ANOTHER LOCATION IN E-CAPTURE.NET.

1.1.3 SORT SUB-FORM GRIDS

By default, the sub-forms are sorted by the form (creation) number in the grid.

		#	St	Criterion Type	Criterion Number	Criterion	Exception Granted	Date of Exception
Edit	Delete	1	●	Inclusion	1	Inclusion-1	Yes	2013/07/01
Edit	Delete	2	●	Exclusion	5	Exclusion-5	Yes	2013/08/28
Edit	Delete	3	●	Exclusion	5	Exclusion-5	Yes	2013/07/02

You can sort the grid by any column, via ticking the applicable column header.
For example, sort by Criterion type:

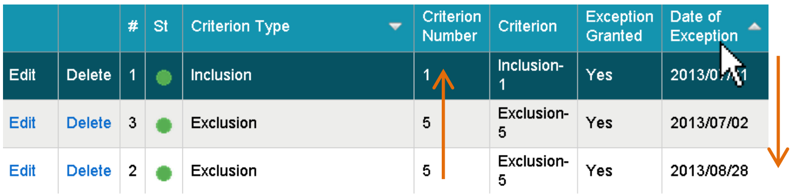
- Click once: the grid is sorted alphabetically (A-> Z) or numerical (1->9) depending on the column values.
- Click a second time : the grid is sorted alphabetically (Z -> A) or numerical (9->1)

		#	St	Criterion Type	Criterion Number	Criterion	Exception Granted	Date of Exception
Edit	Delete	2	●	Exclusion	5	Exclusion-5	Yes	2013/08/28
Edit	Delete	3	●	Exclusion	5	Exclusion-5	Yes	2013/07/02
Edit	Delete	1	●	Inclusion	1	Inclusion-1	Yes	2013/07/01

		#	St	Criterion Type	Criterion Number	Criterion	Exception Granted	Date of Exception
Edit	Delete	1	●	Inclusion	1	Inclusion-1	Yes	2013/07/01
Edit	Delete	3	●	Exclusion	5	Exclusion-5	Yes	2013/07/02
Edit	Delete	2	●	Exclusion	5	Exclusion-5	Yes	2013/08/28

You can create a **sub level sort** for any column, via Shift + ticking the applicable column header. For example, sort by Criterion type first and then sort by Date of Exception.

- Tick column header for level 1 sorting : the grid is sorted as indicated above:
- Press your ‘Shift’ key  + tick the ‘date of exception’ column header to create a sublevel sort.



		#	St	Criterion Type	Criterion Number	Criterion	Exception Granted	Date of Exception
Edit	Delete	1		Inclusion	1	Inclusion-1	Yes	2013/0?/?1
Edit	Delete	3		Exclusion	5	Exclusion-5	Yes	2013/07/02
Edit	Delete	2		Exclusion	5	Exclusion-5	Yes	2013/08/28

1.2 REPETITIVE FORMS

Repetitive forms are form templates that enable the creation of multiple, identical forms within a study in e-capture.net. Typical examples of repetitive forms are Adverse Events, Protocol Deviations or unscheduled visits.

Repetitive forms are indicated with this icon: 

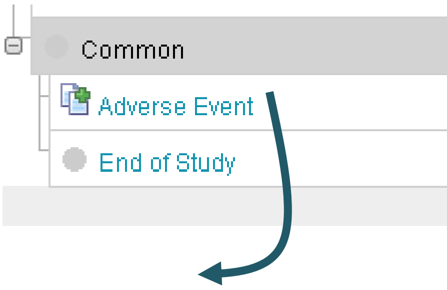
1.2.1 CREATE REPETITIVE FORMS

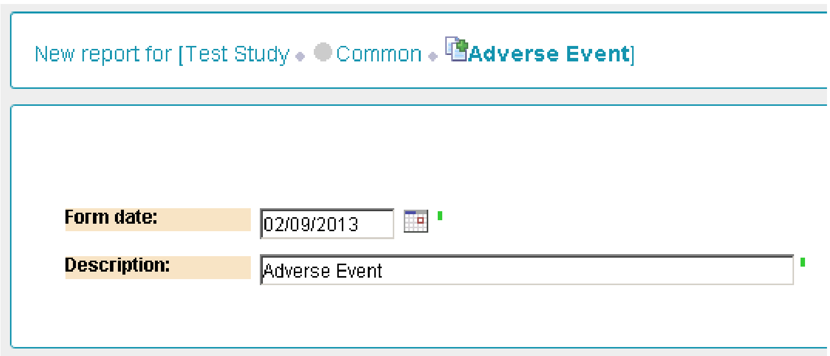
To create a repetitive form from a subject’s template, follow these steps:

a) Click the applicable form template:

- The form date will be auto populated with the date of creation.
- Description gets auto populated with the repetitive form name.

You can change both fields of this label when applicable.



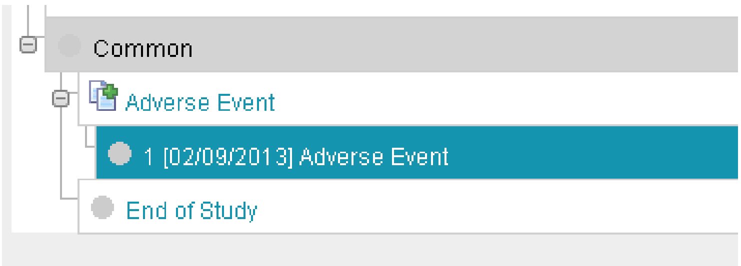


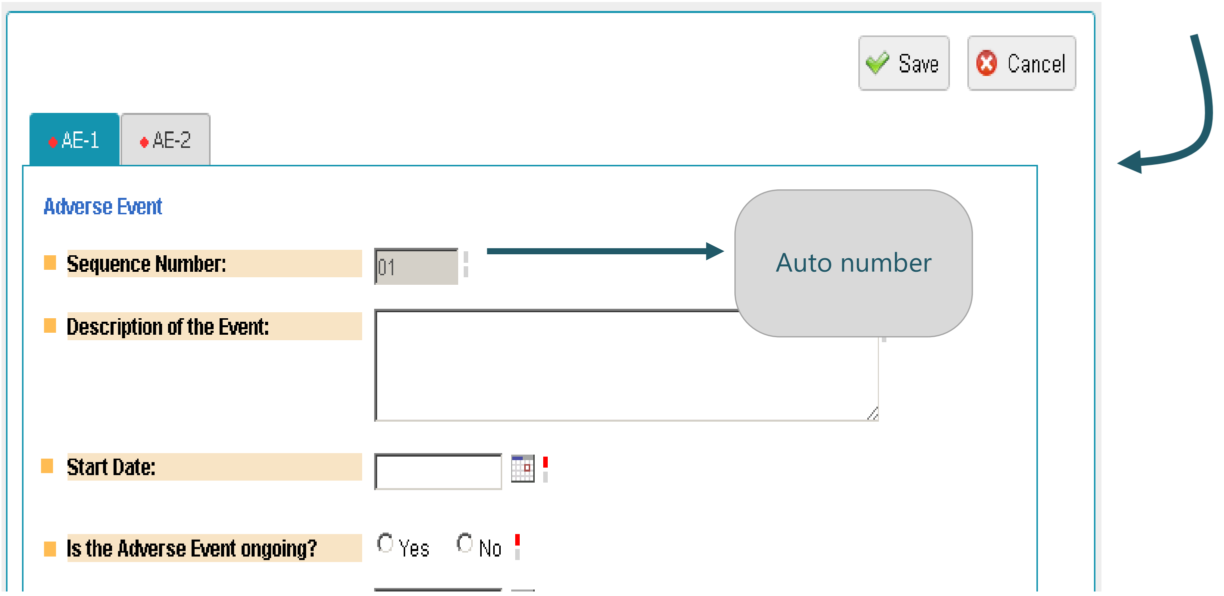
b) Click Save.

- A new form is created and displayed within the Navigator.
- All repetitive forms receive an auto-numbering, based on the order of creation.

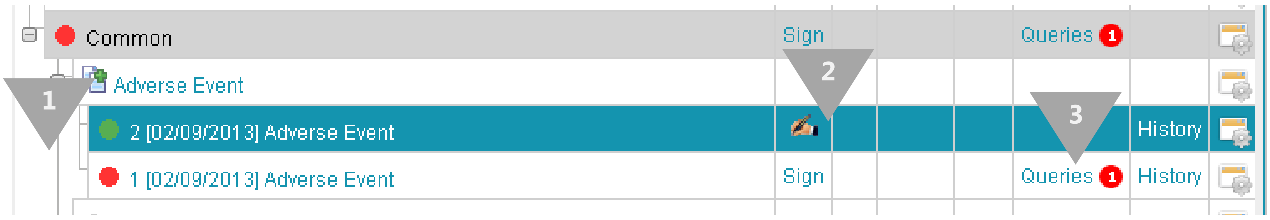
c) Click on the new form to open:

d) Complete the form and save your entries.





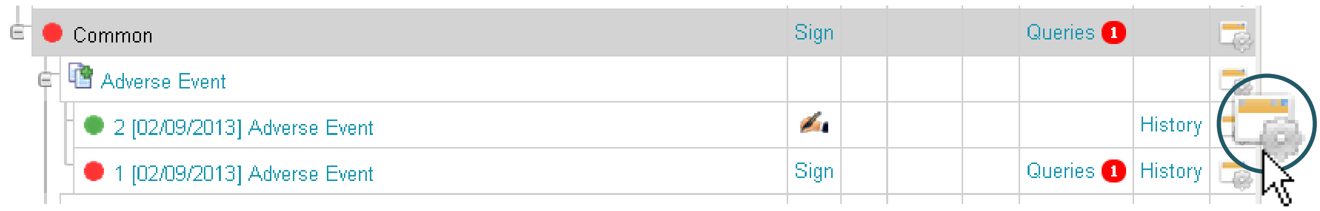
Form status indicators ①, sign status ②and query status ③ are indicated in general and for each individual repetitive form:



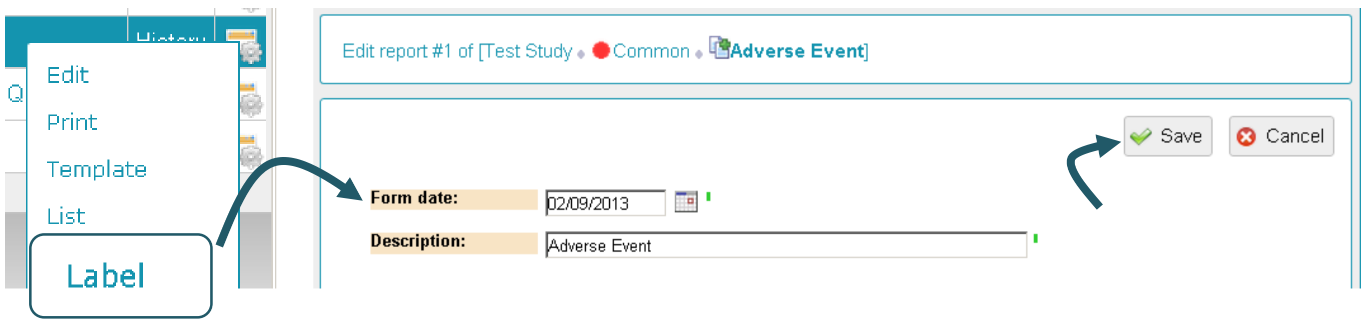
1.2.2 EDIT REPETITIVE FORM LABEL

To update the label of a repetitive form, follow these steps:

a) Click the actions icon  next to the form title you would like to update.



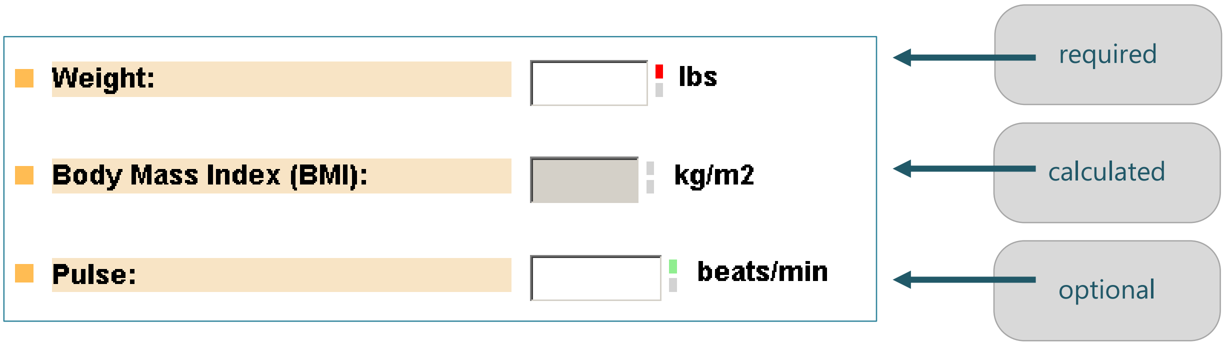
b) Click 'Label' within the dropdown, update the 'description' textbox and/or date and click Save.



1.3 FIELD STATUS INDICATORS ON DATA ENTRY FIELDS

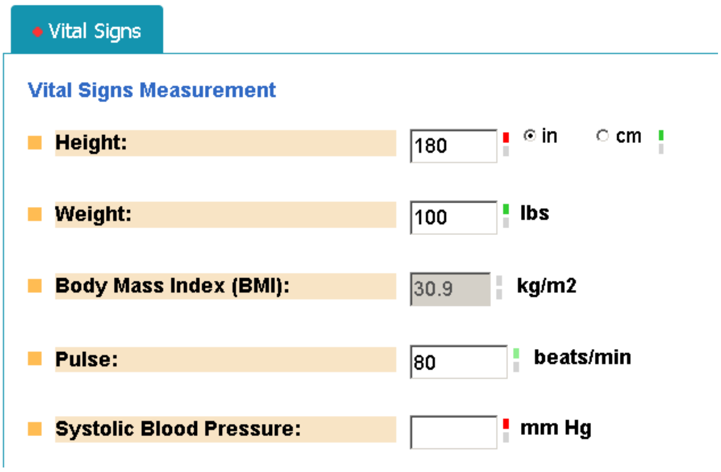
e-capture.net generates field marks to indicate the status of a field throughout the course of the patient in the study.

- Within an empty page:
- The required fields/questions are indicated with a red field mark.
- Optional, non-mandatory questions are indicated with a green field mark.
- De-activated or non-editable fields have a grey field mark.

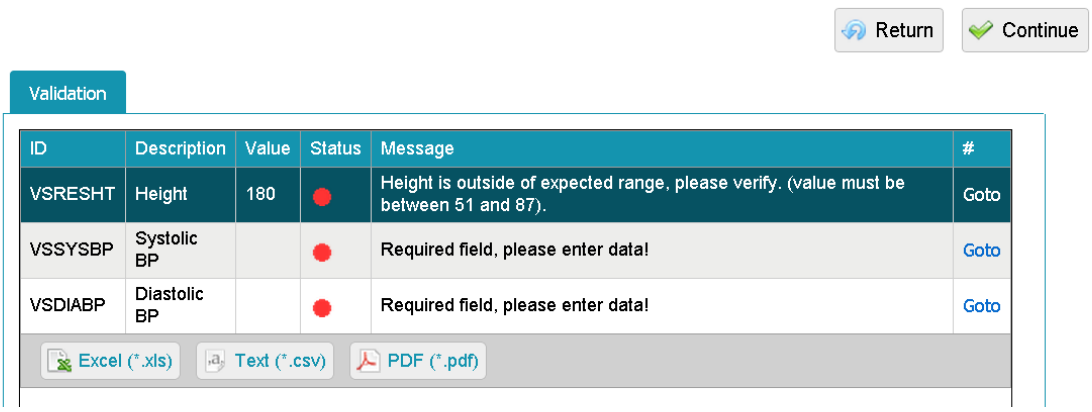


Upon entering data:

- If you complete a field with a value that lies within the ranges as specified by your study protocol, the field mark becomes **green**.
- If your entry is out of the range as specified in your study protocol or if the answer is contradictory to other questions, the field mark will be **red**
- If you leave a required field empty, the field mark will remain **red**.



NOTE: IF YOU CHOOSE TO SAVE A FORM THAT HAS MISSING DATA OR FIELDS WITH QUERIES, THE AUTOMATIC VERIFICATION OF E-CAPTURE.NET WILL DISPLAY A TABLE WITH MISSING OR QUERIED ENTRIES
(THIS WORKFLOW WILL BE DISCUSSED IN MORE DETAIL IN CHAPTER: SAVE DATA)



ID	Description	Value	Status	Message	#
VSRESHT	Height	180	●	Height is outside of expected range, please verify. (value must be between 51 and 87).	Goto
VSSYSBP	Systolic BP		●	Required field, please enter data!	Goto
VSDIABP	Diastolic BP		●	Required field, please enter data!	Goto

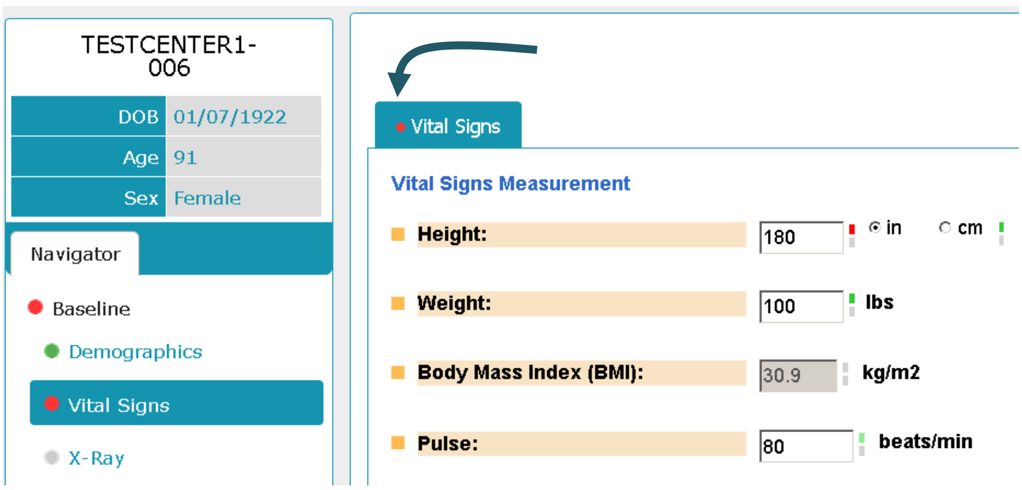
Memo's and queries

- e-capture.net also allows adding extra notes or comments to each field or question. The presence of a memo is indicated with a **blue field mark.**

- A question/field that has an answered query is indicated with an **orange field mark** (read more about query management in the respective chapter).

1.4 FORM STATUS INDICATORS (FORM MARKS)

Similar to the field marks, the status of a form is also indicated by a color mark:



- An untouched form has a grey mark.
- A correctly completed form has a green mark.
- A completed form with only answered queries present has a yellow mark (Site = no action needed / monitor-Data Manager = action needed).
- A form with unanswered required fields or fields with open queries will have a red mark.

NOTE: EVEN IF ONLY ONE REQUIRED QUESTION IS UNANSWERED OR ANY QUESTION HAS A QUERY, THE ENTIRE FORM WILL BE MARKED RED.

Back to top ↺

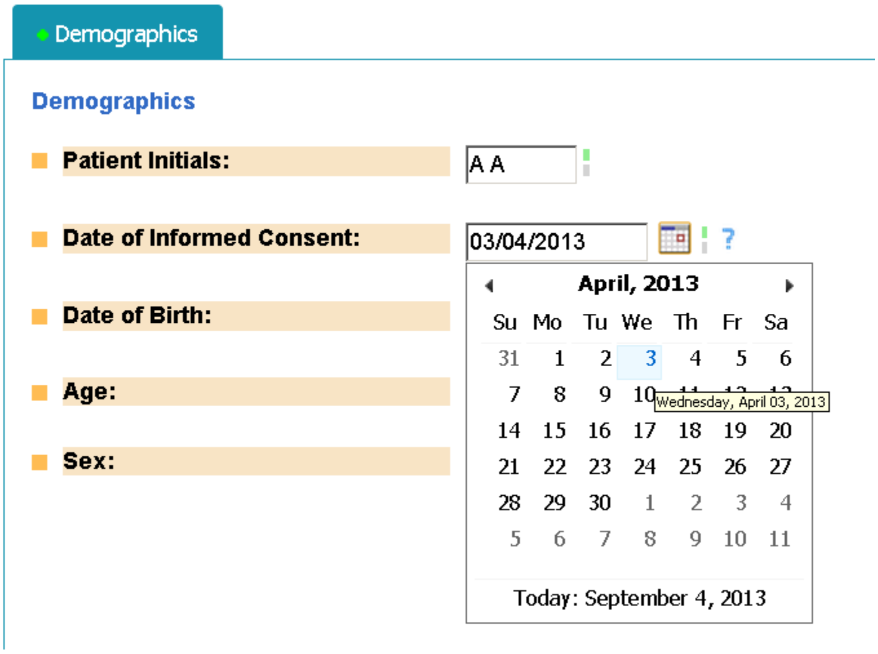
2 GENERAL DATA ENTRY FIELD TYPES

2.1 DIRECT DATA ENTRY

You can enter text or numeric data directly into a data field.

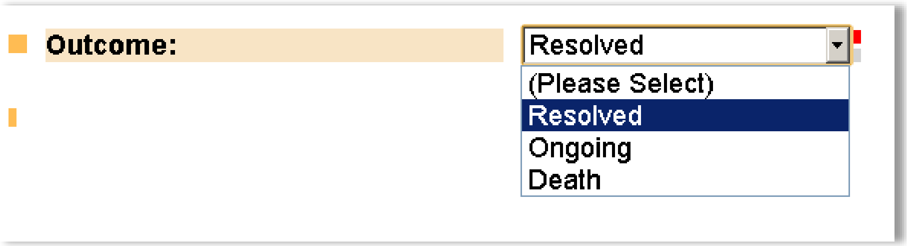
2.2 CALENDAR ENTRY

- Dates can be entered manually (if the pre-defined date format is respected).
- You can select a date from the calendar by clicking the calendar icon.



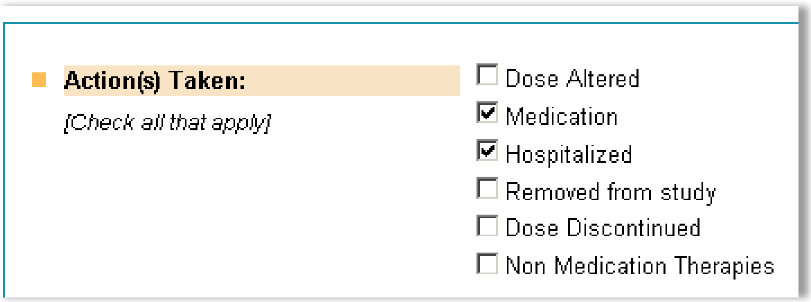
2.3 RADIO BUTTONS AND DROP DOWN LIST

Both fields allow the selection of **zero to one option** from a pre-defined list.



2.4 CHECK BOXES

Check boxes allow you to select zero to many options from a pre-defined list.

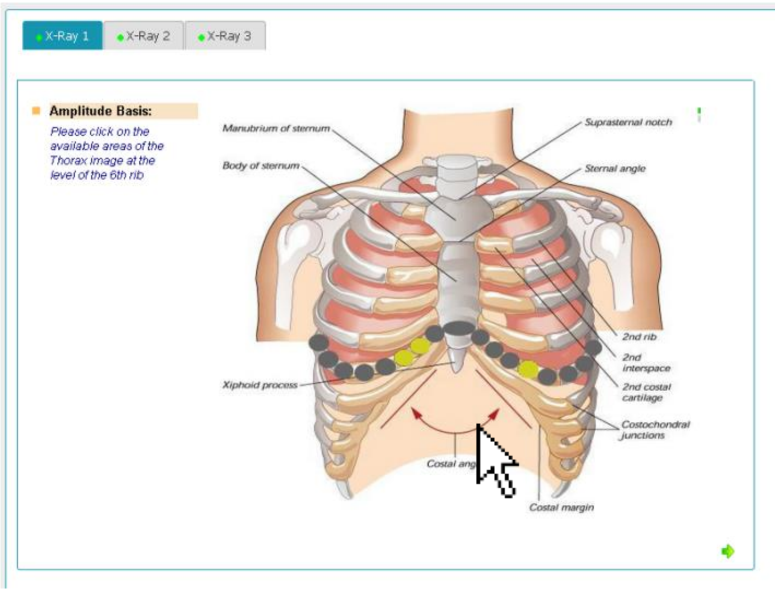


3 STUDY SPECIFIC DATA ENTRY

Following data-entry field types are stand-alone features in e-capture.net. The presence of these field types depends on the set-up of your study.

3.1 CLICKABLE IMAGES

This tool uses a photo, diagram, x-ray scan or alike (you can chose the image), with "live" areas on the image where you can set labels, indicate positions and so on. You can enter information by clicking on the available areas within a clickable image:



3.2 UPLOAD DOCUMENTS

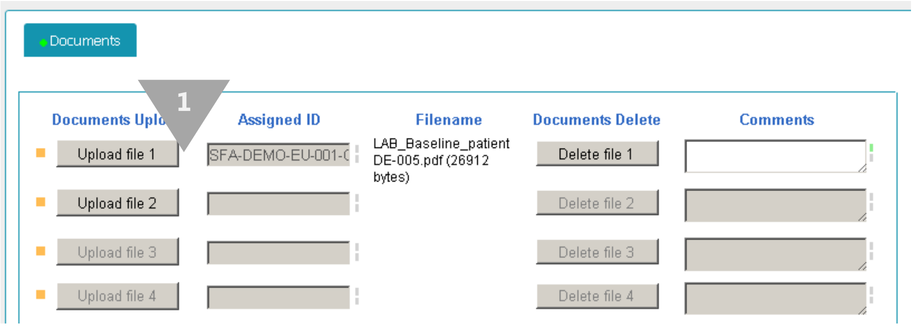
Enter data by uploading files/documents into your study's e-CRF. The set up and visibility of the document upload functionality depend on your study design and the rights assigned to your user role.
Restrictions for upload in e-capture.net :

- Max 10 MB per upload
- No moving images

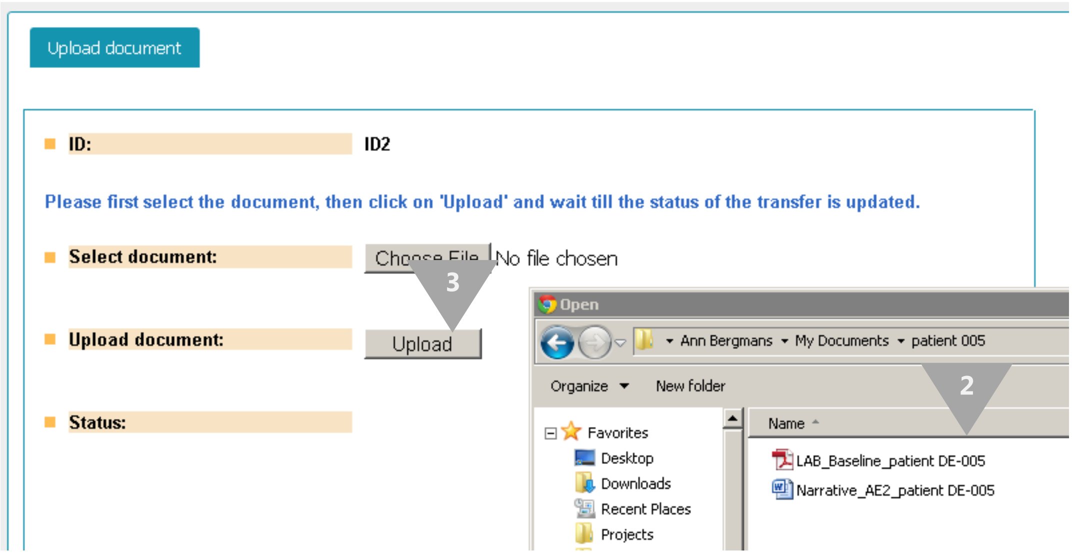
NOTE : FOR MOVING IMAGES OR FILES LARGER THEN 10 MB, PLEASE INQUIRE ABOUT USING THE CORE LAB TRACKER SYSTEM.

In general, these are the steps to be followed to upload an external document:

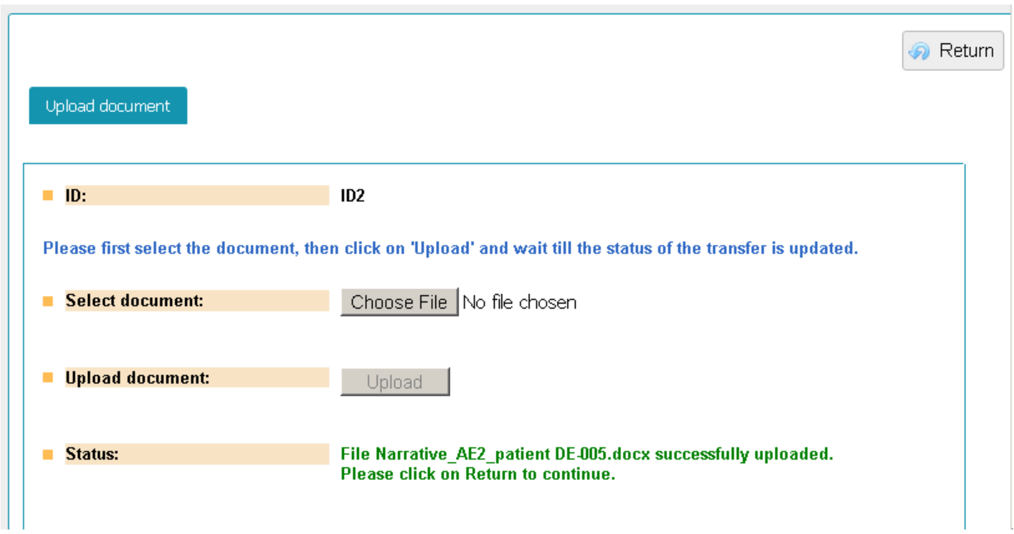
1. Click the button 'Upload File'.



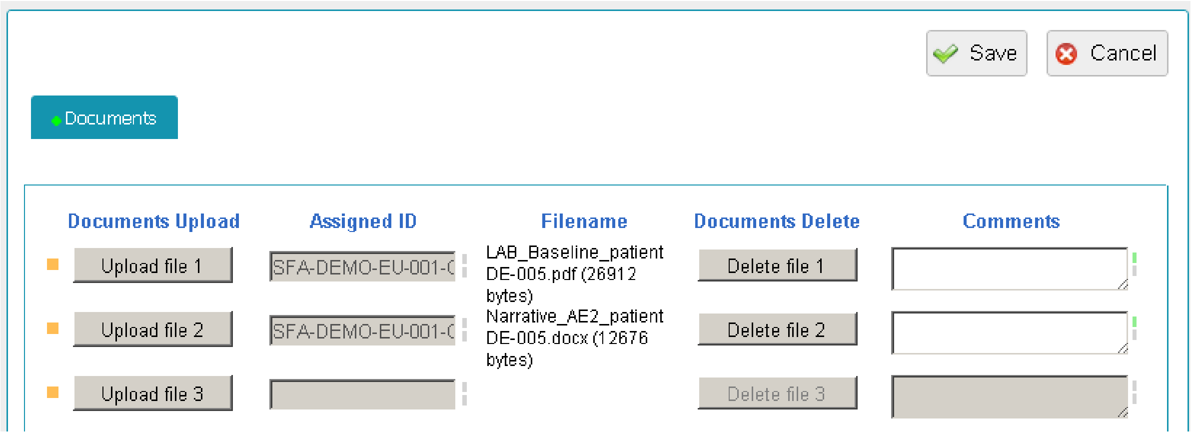
2. In the Upload Document window, click **Choose File**, browse to the applicable file location, and select the document to upload.
3. Click the 'Upload' button:



4. The Status field will indicate in green text the successful upload of the required document:



5. Click **Return** to navigate back to the Document upload form:



4. The 'Delete File' button allows you to delete uploaded documents.

5. Click 'Save' to return to the patient's Navigator.

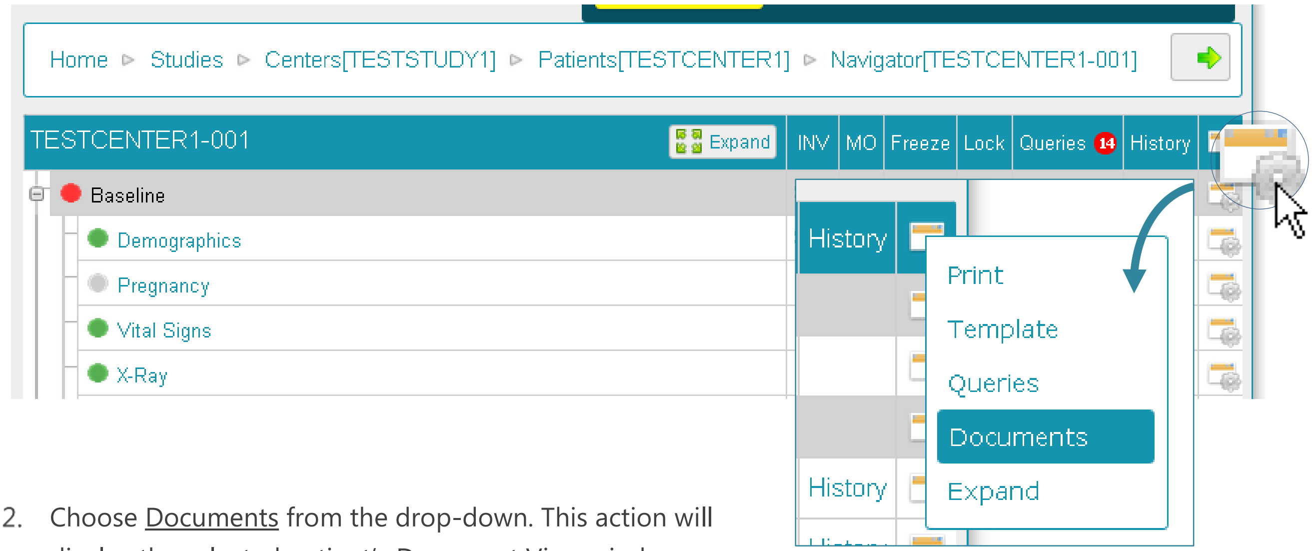
NOTE : E-CAPTURE ALSO ALLOWS UPLOAD OF ZIP FOLDERS, HOLDING ALL DOCUMENTS APPLICABLE FOR THIS UPLOAD PURPOSE. IF YOU RE-NAME THE ZIP FILE PRIOR TO UPLOAD, SPECIFYING THE UPLOAD REASON LIKE 'AE1' THIS WILL MAKE IT EASY FOR THE VIEW USERS TO FIND THE APPLICABLE FILE

Back to top ↺

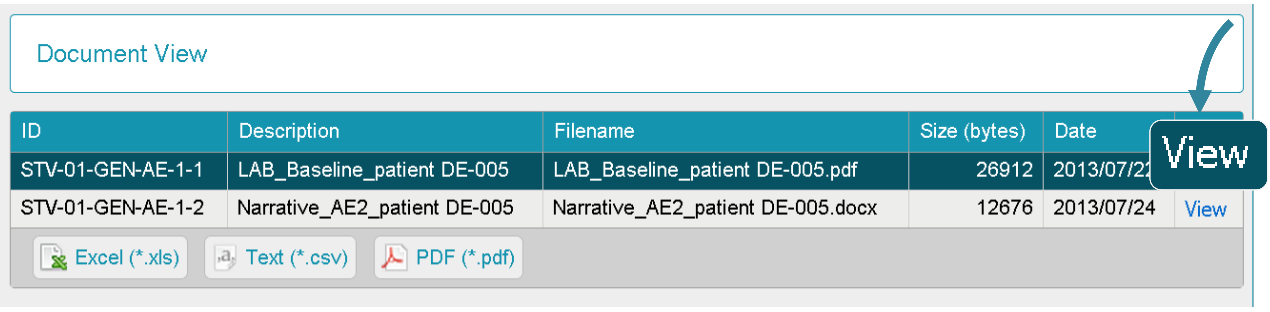
3.2.1 VIEW PATIENT – LINKED DOCUMENTS

All documents that are uploaded into the patient's forms are accessible to view on **Patient level.**
To view uploaded documents, follow these steps:

1. Click the action icon on the right of Navigator's **top row**:



2. Choose Documents from the drop-down. This action will display the selected patient's Document View window.
3. Click the **View** link of the selected Document to display its content.

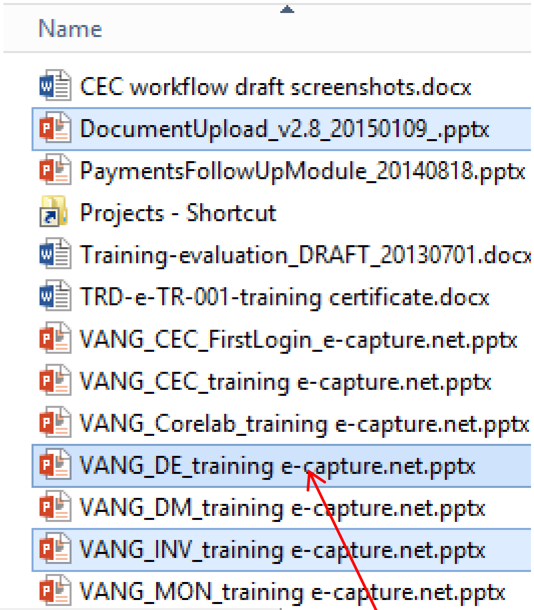


ID	Description	Filename	Size (bytes)	Date	
STV-01-GEN-AE-1-1	LAB_Baseline_patient DE-005	LAB_Baseline_patient DE-005.pdf	26912	2013/07/2	
STV-01-GEN-AE-1-2	Narrative_AE2_patient DE-005	Narrative_AE2_patient DE-005.docx	12676	2013/07/24	View

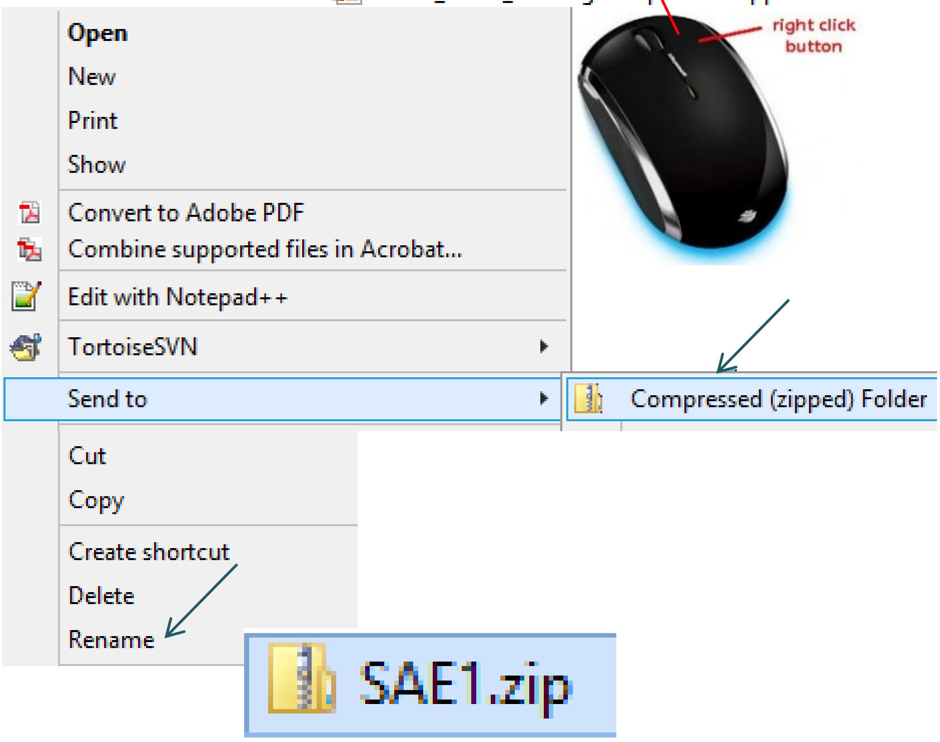
3.2.2 UPLOAD ZIP FILES

To optimize effectiveness in finding uploaded files, you might agree to upload all files for 1 certain event within 1 zip file. This is possible in case the total size of the zip file is max 10 MB.

Zip files can be created as follows :



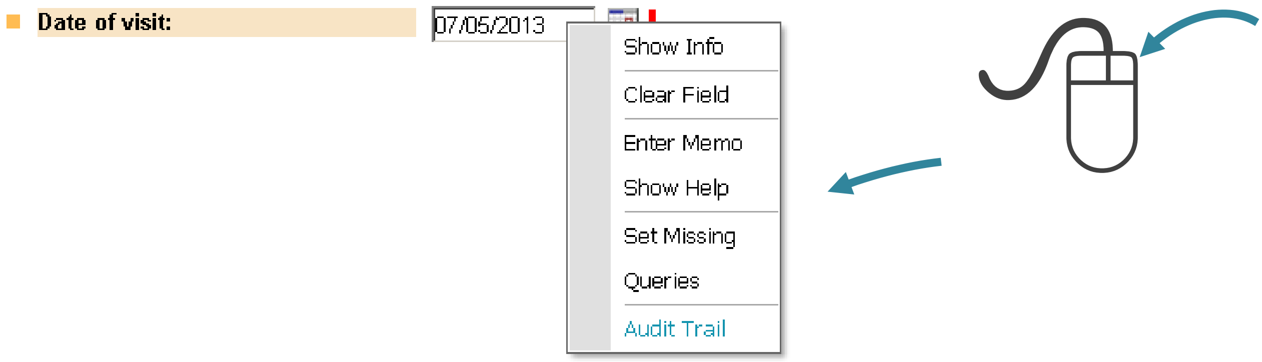
1. Open the folder from which you want to upload files.
2. Press the control key '**CTRL**' in your keyboard + click the applicable files in your patient folder
3. Click on a selected file with your right mouse button
4. Go to 'Send to' and move further to 'Compressed Zipped Folder'
5. Click 'compressed (zipped) folder'



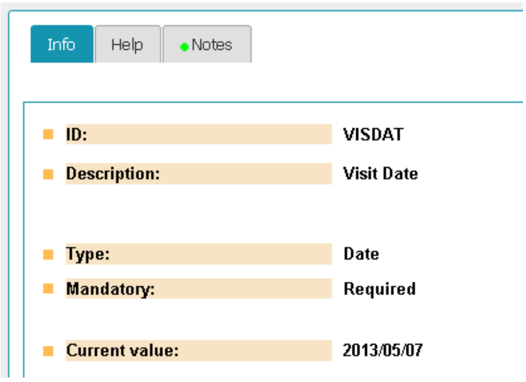
6. Right click the newly created folder
7. Click 'rename'
8. Rename following agreed study naming convention
9. Upload the zip file to the eCRF

4 THE USE OF THE RIGHT MOUSE BUTTON:

Additional question/field level options are available upon clicking you right mouse button. The content of this menu depends on the rights assigned to your user role.
The screenshot below shows the menu option available for an Investigator role:



4.1 SHOW INFO:



Select this option to consult specific information regarding the field, for example description, type, current value,…

4.2 CLEAR FIELD

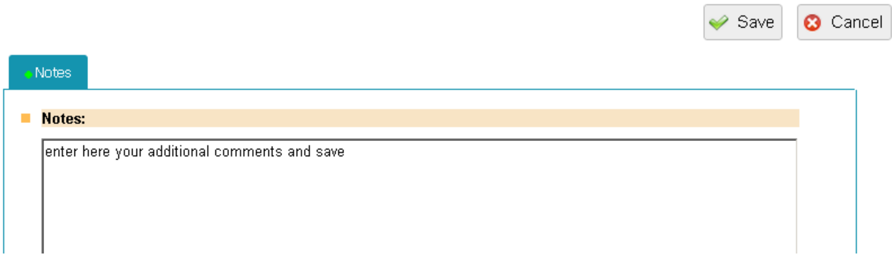
The entered value of the field will be cleared. Note that in case the value was saved, the deletion of that value will be logged in the audit trail.

4.3 ENTER MEMO'S

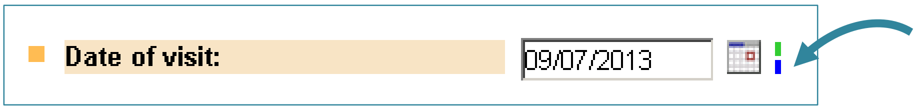
Memo's enable the user to add additional information to a field or question in an e-CRF form. Memos are visible to all users that have access to this patient. Only users that have the rights to enter data will be able to add memos.

NOTE: A MEMO IS NOT A QUERY AND HAS NO FOLLOW UP LISTS. IT MUST BE USED ONLY INFORMATIVE**.**

1. Make a right button click on the applicable field and choose the menu option: 'Enter memo' (see screenshot above).
2. Enter your comment in the displayed textbox.



3. Click the 'Save' button to save your entries and return to the form page or click 'Cancel' if you do not wish to add the entry to the respective field.
4. The blue field mark indicates the presence of a memo:



4.4 READ MEMO'S

To read a memo, move the mouse arrow over the blue mark. The memo text will pop up:

4.5 DELETE MEMO'S

Memos can only be deleted by users with data entry rights assigned to their user role.

1. Make a right button click on the applicable field and choose the menu option: 'Enter memo' (see screenshot above).
2. Remove the comment from the textbox.
3. Click the 'Save' button.

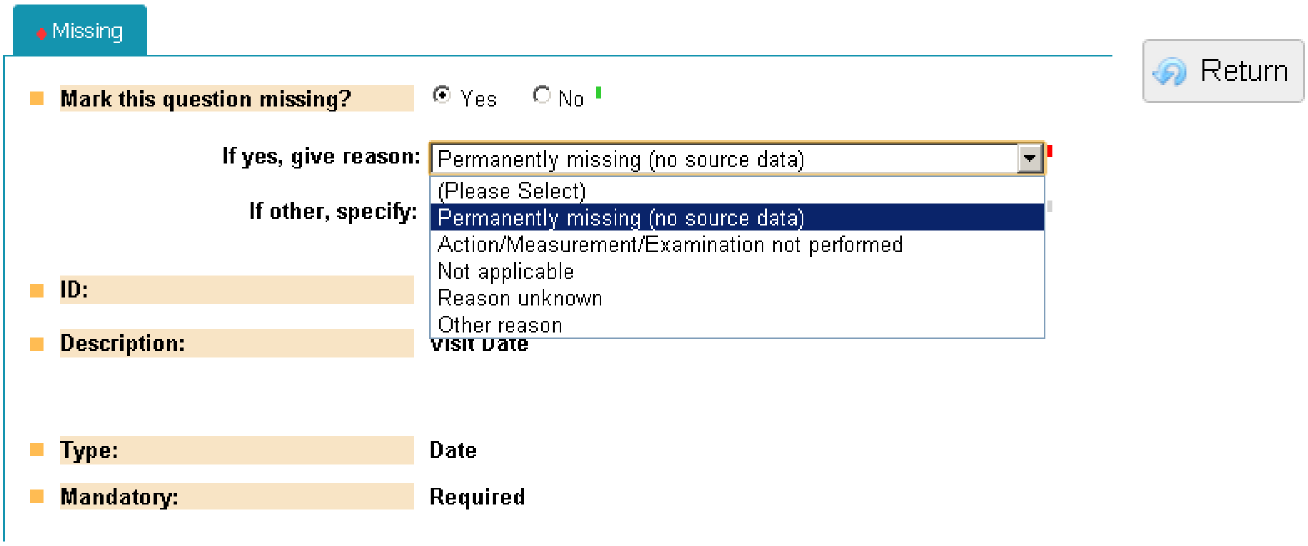
4.6 SET MISSING

Set missing can be used to ignore a (required) question in a form.

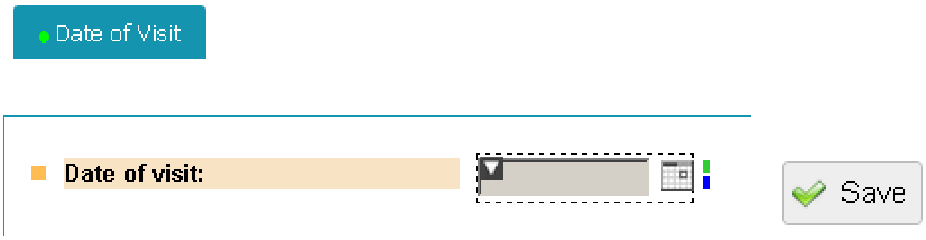
- The 'missing' question will no longer influence the form status mark.
- The 'missing data report' lists all questions marked as 'missing'.

NOTE: THIS FEATURE SHOULD ONLY BE USED WHEN DISCUSSED WITH AND IN FOLLOW UP BY THE STUDY SPONSOR OR MONITOR.

1. Selecting 'Set Missing' from the field menu opens a new window in which you must indicate the field or question as missing and provide a reason.



2. Click the 'Return' button on the top right hand corner of the screen to go back to the form you were working on.



3. The question is now marked 'missing'. This is indicated by a dotted line framework around this answer.
4. Click the 'Save' button.

4.7 UNDO SET MISSING

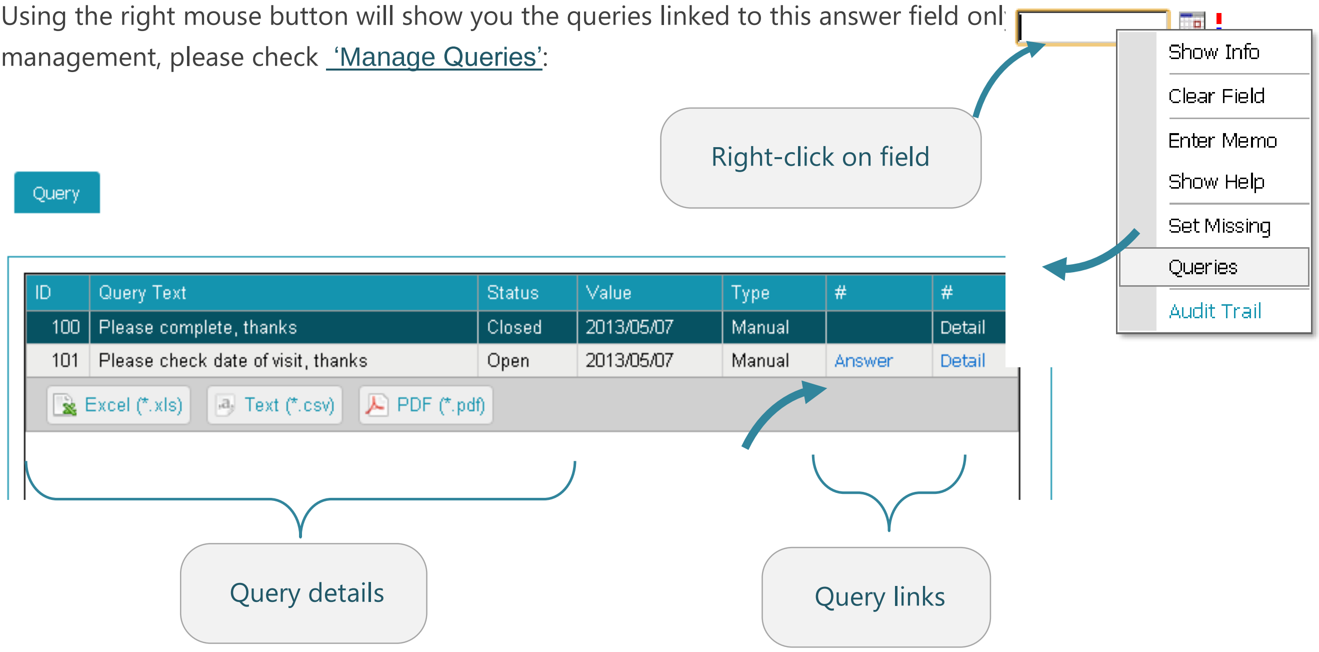
1. Right click on the applicable field and select 'Set Missing' from the menu.
2. Update the first question on the Missing window to 'No' and click the 'Return' button.

NOTE: A USER WITH A DATA MANAGER ROLE IS ABLE TO RUN A REPORT THAT SUMMARIZES ALL QUESTIONS THAT HAVE BEEN MARKED AS MISSING. FOR MORE DETAILS, PLEASE SEE CHAPTER REPORTS).

Back to top ↺

4.8 QUERIES

Using the right mouse button will show you the queries linked to this answer field onl management, please check ['Manage Queries'](#):



4.9 AUDIT TRAIL – QUESTION LEVEL

Select 'Audit trail' from the field menu to see a detailed table overview of the respective field's audit trail. For more information on the Audit trail functionality in e-capture.net, please see Chapter: Audit Trail.

Audit trail [VISDAT]

Action	Change date	Reason for change/Query	Value	Changed by	User name	User profile
Update	12/07/2013 12:32:30	ok	(missing)	TEST_INV	Dr Jack Jones	TestPi
Open #101	02/07/2013 12:13:39	Please check date of visit, thanks		TEST_DM	Test Data Manager	TestDm
Close #100	02/07/2013 12:13:19	Data update verified		TEST_DM	Test Data Manager	TestDm
Answer #100	02/07/2013 12:13:19	Closed by force/Response overruled		SYSTEM		
Open #100	02/07/2013 12:13:03	Please complete, thanks		TEST_DM	Test Data Manager	TestDm
Insert	01/07/2013 16:48:25		07/05/2013	TEST_INV	Dr Jack Jones	TestPi

Excel (*.xls) Text (*.csv) PDF (*.pdf)

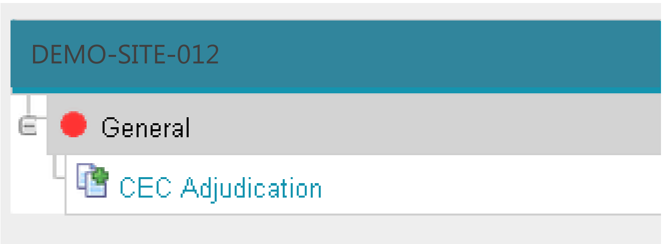
5 FORM VISIBILITY

e-capture.net supports a dynamic visibility of fields or forms depending on:

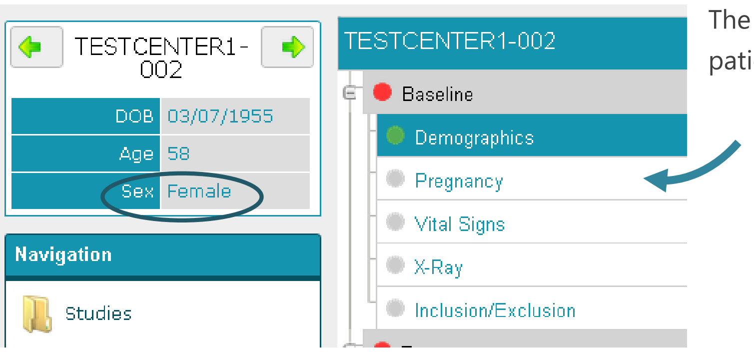
- The rights assigned to your user role.
- Patient specifications or randomization.
- Entered data.

5.1 USER ROLE VISIBILITY

Depending on the rights assigned to your user role, some study forms may or may not be visible to you. For example: a CEC user might **only** have access to the patient's CEC Adjudication forms:



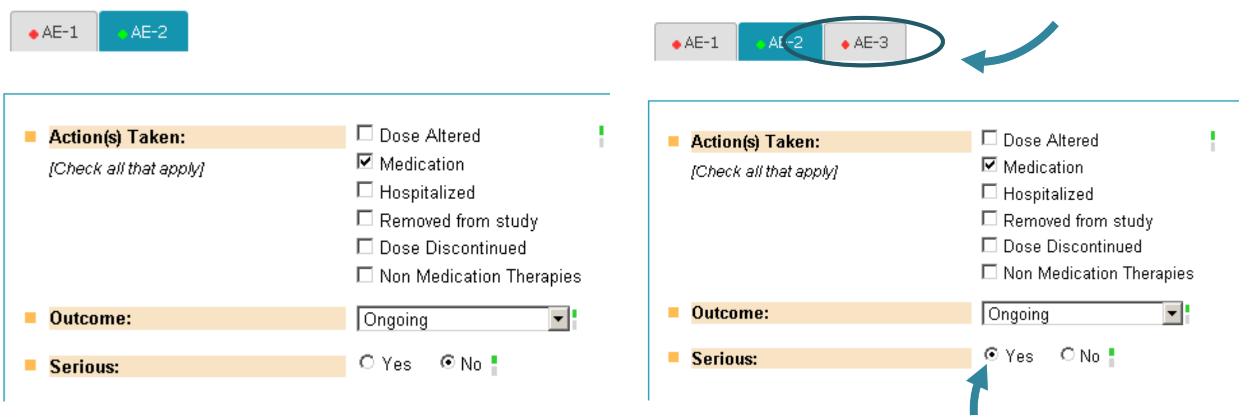
5.2 VISIBILITY DEPENDING ON PATIENT SPECIFICATION



The pregnancy form will only be visible for **female** patients:

5.3 VISIBILITY DEPENDING ON ENTERED DATA

If an Adverse Event is specified as 'Serious', an extra form will become available to enter extra details about the Serious Adverse Event:

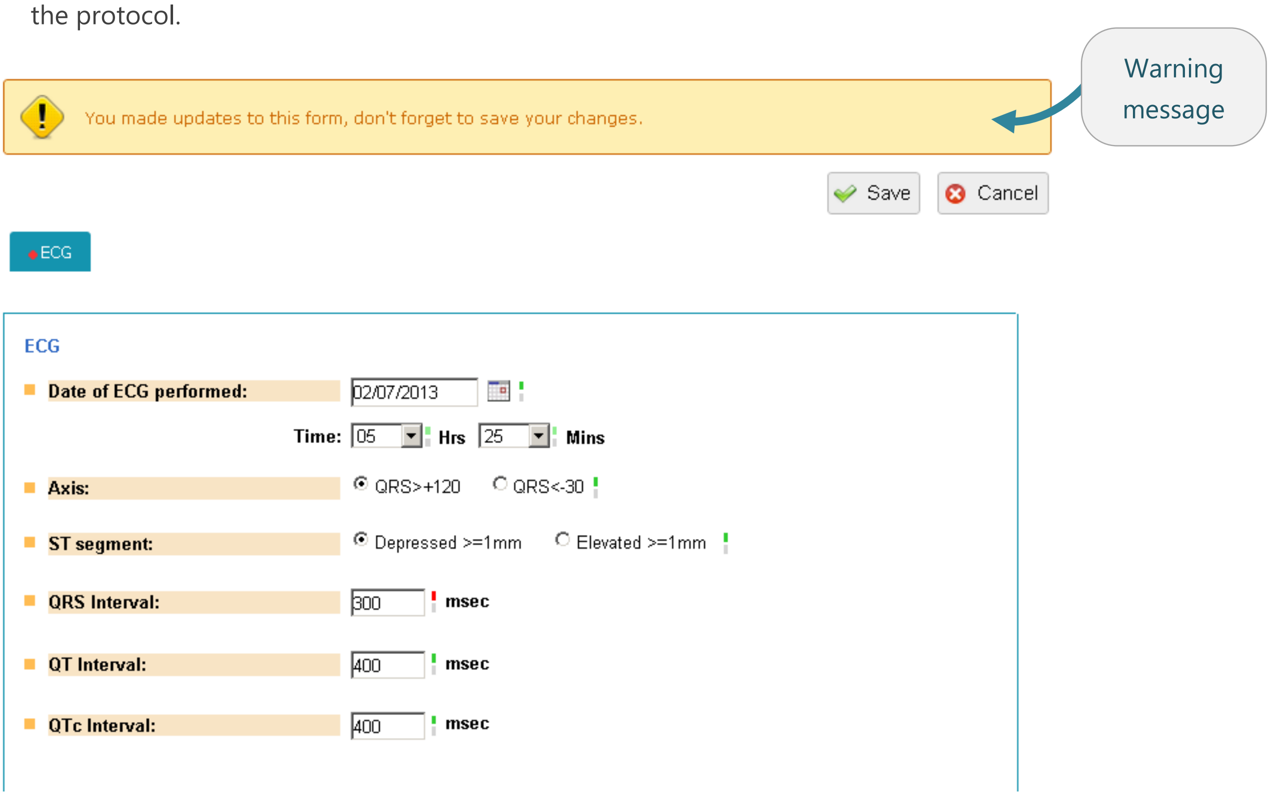


Back to top ↺

6 SAVE DATA

When entering date into the e-CRF forms of your study, it is important to follow the correct steps to ensure your data is saved before moving to another form or e-capture.net feature.

- When you enter the last question on a form, e-capture.net will check if your answers are within the range of the protocol.

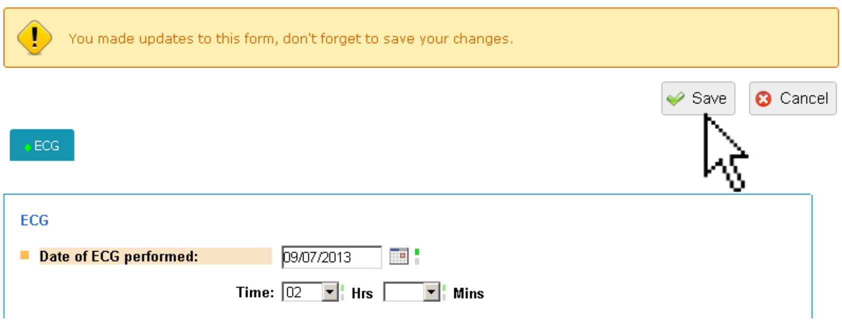


- Answers within protocol range will be marked **green.**
- Answers out of range, or contradictorily to other answers will be marked **red** and a **query** will be triggered at this question. The questions out of protocol range will be marked red.
- When at least one question has an open query (red mark), the e-CRF **form mark will turn red**.
- If all queries in a form are answered (yellow mark), then the form status will turn yellow.
- When all data is updated, and all queries closed, **field and form marks** will automatically turn to **green**.

6.1 SAVE A COMPLETE FORM (GREEN FORM MARK)

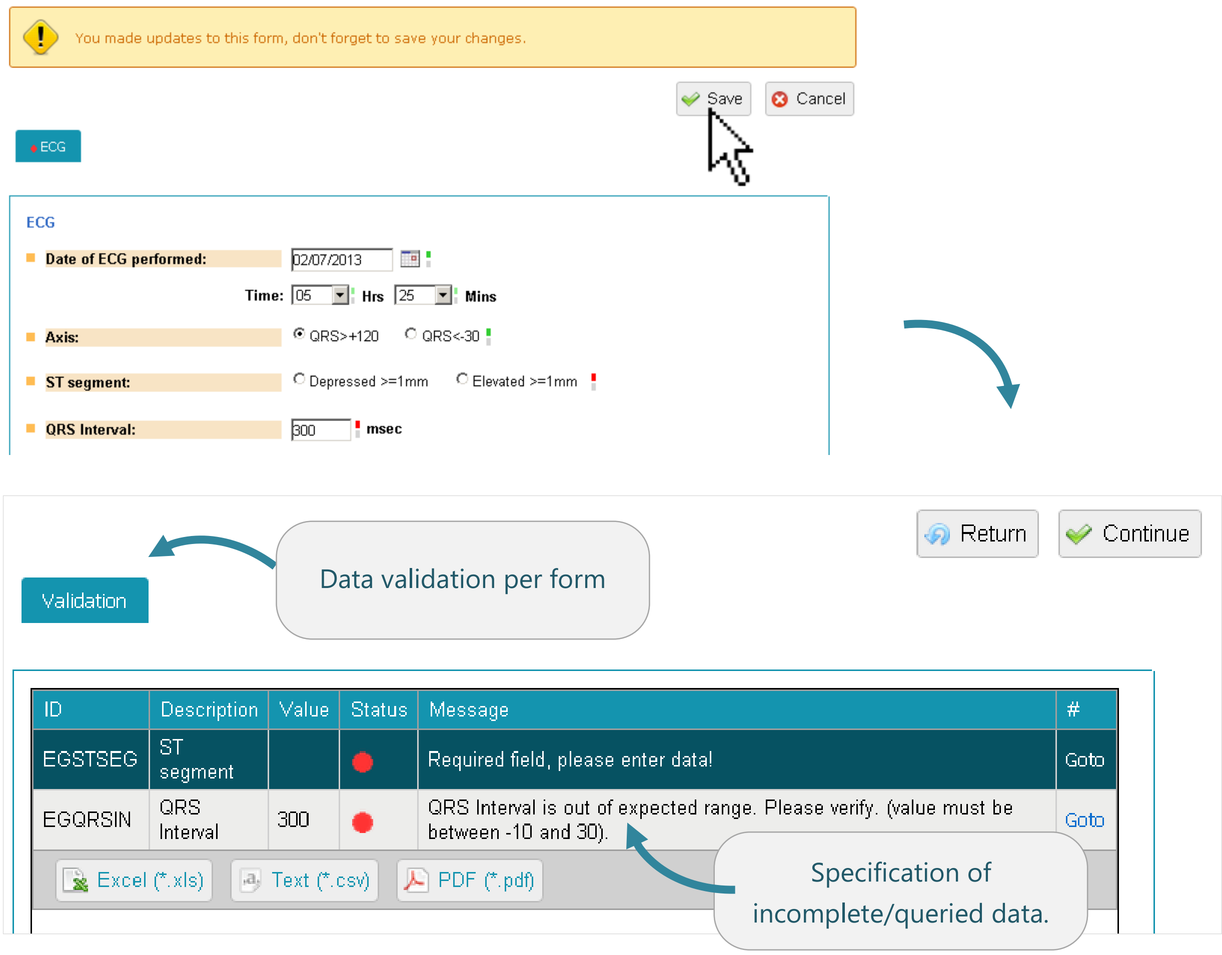
Click the 'Save' button to save your entries and return to the respective patient's Navigator:

In case you click 'Cancel'
all data of all tabs in the form that
was updated since last 'Save' will be lost.



6.2 SAVE AN INCOMPLETE FORM (RED FORM MARK)

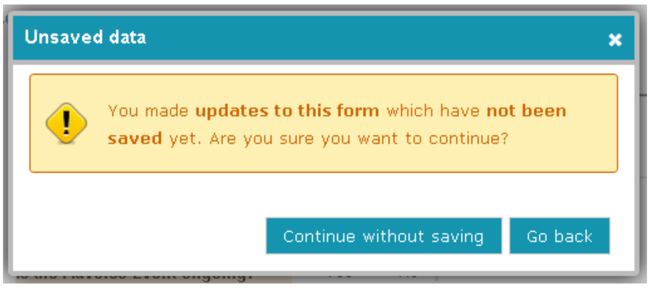
If you save a form that contains open queries or un-answered mandatory questions upon clicking the 'Save' button or the arrows to navigate to the next form, the system will display a **Validation overview** of the respective form. This overview indicates the required data entries or updates:



Possible actions:

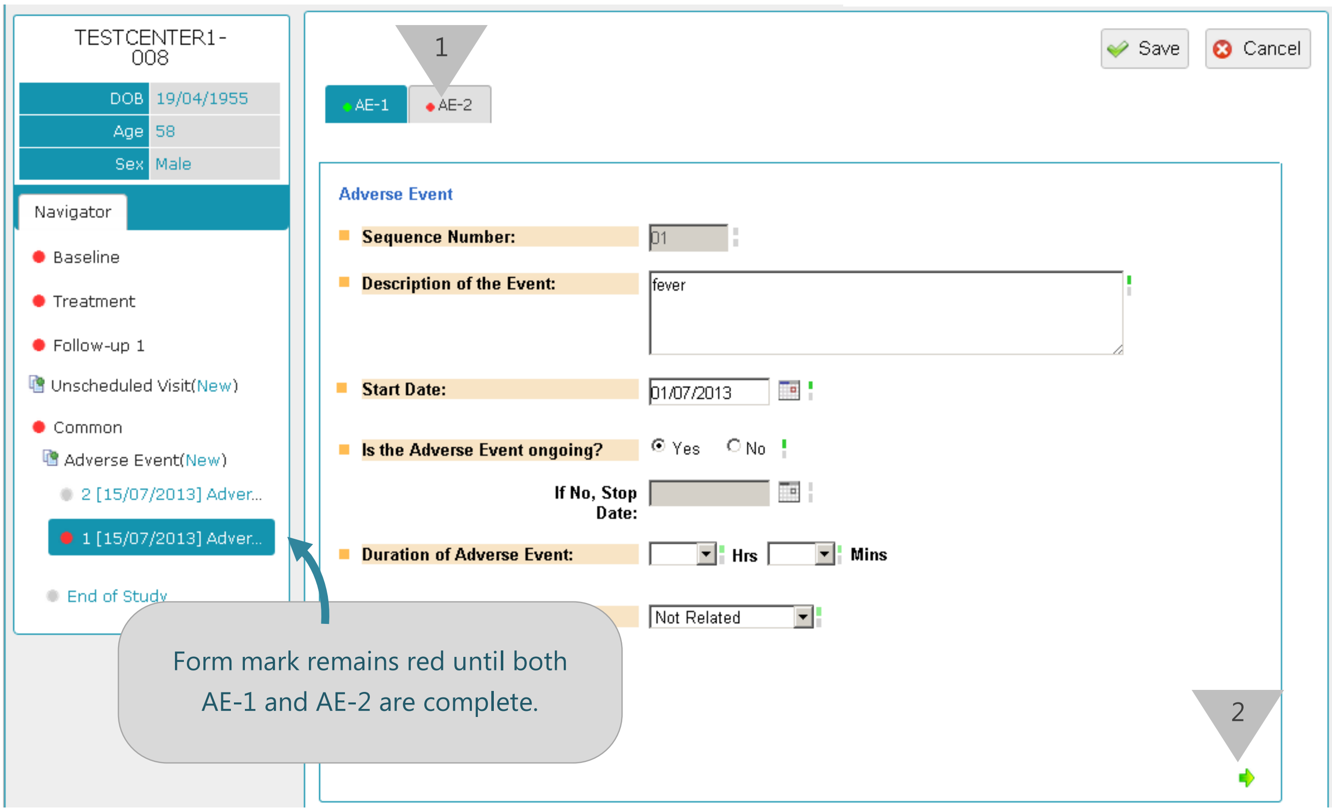
- Click the 'Goto' link: you will be directed to the selected question to update/enter data and/or answer queries. At this point, data is not saved yet.
- Click Return: You will navigate back to the respective form. At this point, data is not saved yet!
- **Continue**: your data is saved with red form mark and you will be returned to the patient's Navigator. You can return to this form later to update the red-marked data fields (see also the query workflow chart).

NOTE: IN CASE NAVIGATE AWAY FROM A PAGE WITHOUT SAVING, YOU WILL RECEIVE A WARNING MESSAGE:
- CLICK GO BACK IF YOU DO WISH TO SAVE YOUR ENTRIES,
- CLICK CONTINUE WITHOUT SAVING IF YOU DO NOT



6.3 SAVE FORMS WITH MULTIPLE TABS

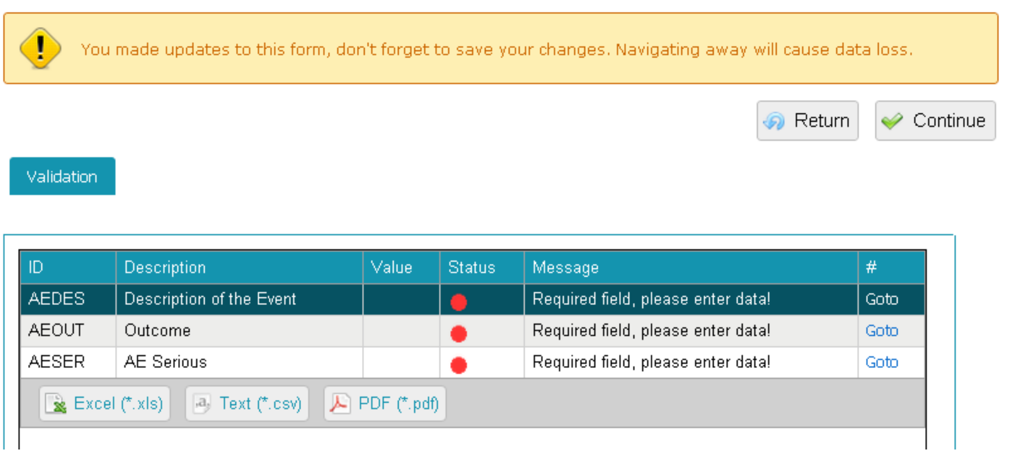
Large forms are often divided into separate tabs. All tabs must require a green mark to obtain a green form mark.



To navigate to the next tab, you can:

- Click the tab ①
- Click the arrow within the page ②

As mentioned in previous item: Save an incomplete form (red form mark), a Validation table will be displayed if you save an incomplete form:

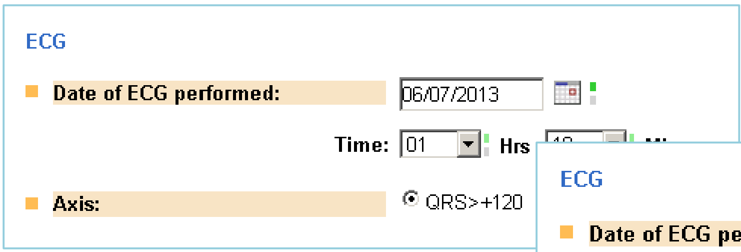


7 EDIT DATA – REASON FOR CHANGE

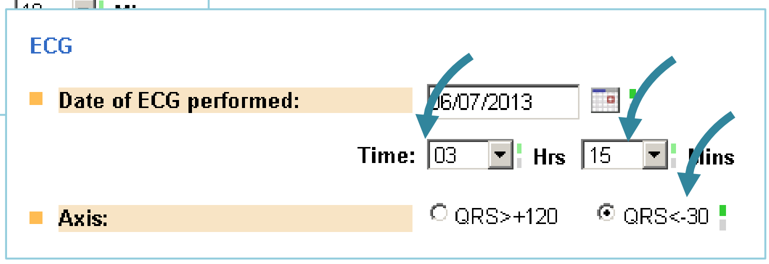
As long as a form in e-capture.net is not locked for editing by a freeze or lock action, it is possible to change any field or question that has been previously completed and saved.
For more information on the freeze and lock functionality, please see Chapter: Freeze and Chapter: Lock

Depending on your study settings, you may need to enter a **Reason for Change** before you can save the modified data.
To modify existing data and complete a Reason for change, you must follow these steps:

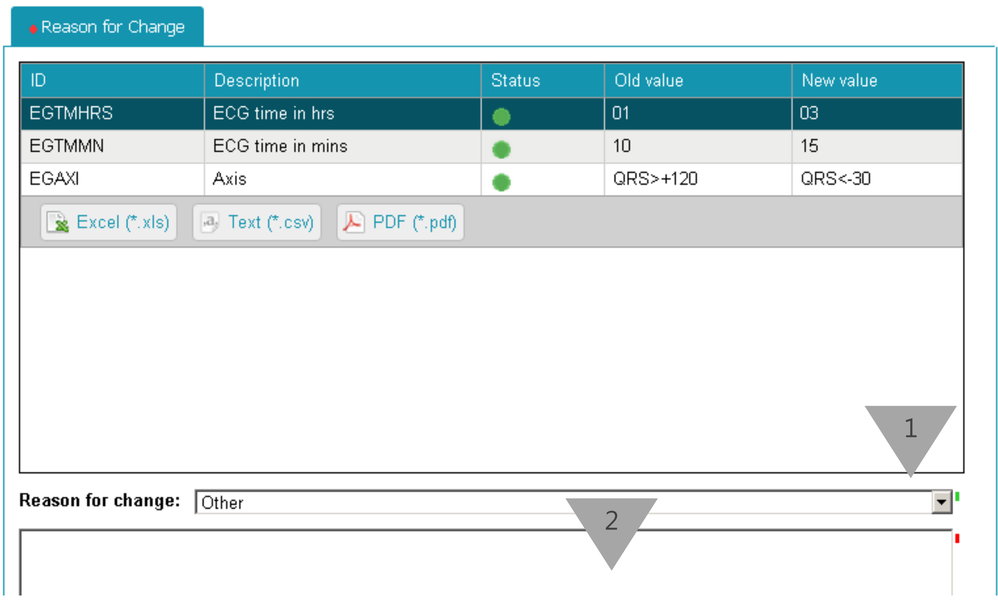
1. Navigate to the applicable visit and form you wish to modify and change the data:



2. Click **Save**



3. In case the Reason for Change functionality is enabled for you study and you save a form without queries, a list of the changed fields will be presented to you in this window:



5. In case of pending queries, you will first see the query overview screen.
6. Enter a reason for change, either by selecting a pre-defined option from the dropdown list ① or by entering a reason in the comment box ②.
7. Click **Save.**

Reason for change is not activated:

- When you reply to a query without actual data change in the CRF form
  - In case the values in the CRF have not changed, therefore reason for change is not needed (Queries are meta data, not CRF data).
- When entering data into fields that were not completed before.
  - If in a partially completed CRF, data is added to questions that were not entered before, then Reason for change is not needed.
- Change data that has not been saved before.
  - This date is not yet saved in the e-capture.net database; therefore, any data change at this point will not trigger a Reason for change.

MANAGE DATA

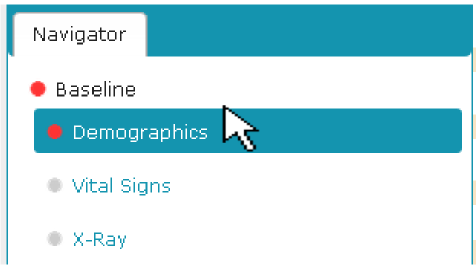
1 AUDIT TRAIL

e-capture.net maintains an audit trail both at form level and at question level. For every data update, the following is logged:

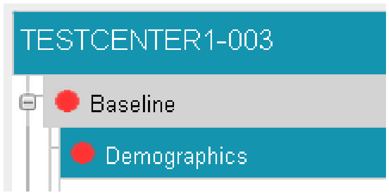
- ID, name and profile of the user(s) that performed an action.
- Specification of the performed action
- Time and date of the action
- Status of the form or question
- Value of the field or question (only for audit trail on question level).
- Reason for Change/Query (only for audit trail on question level).

1.2 QUESTION LEVEL AUDIT TRAIL

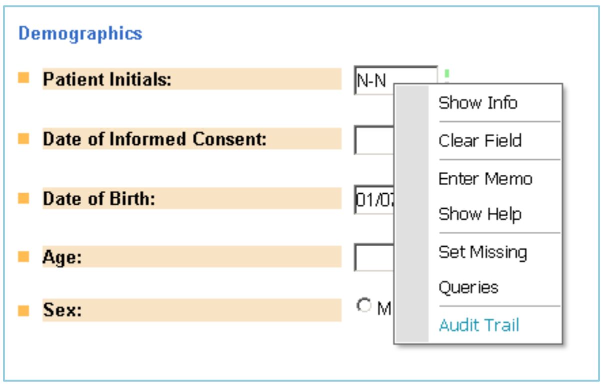
1. Click the form name to enter the applicable form:

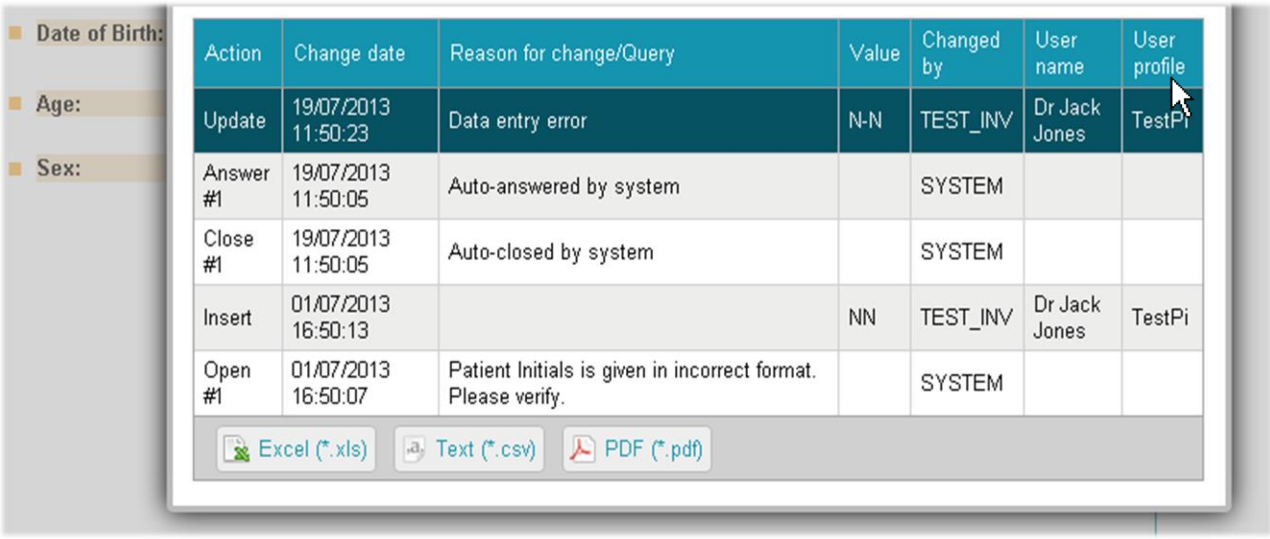


Or



2. Right mouse button click the answer field and choose '**Audit Trail**' from the pop-up menu: This action will display the Audit trail window for the indicated question.





Action	Change date	Reason for change/Query	Value	Changed by	User name	User profile
Update	19/07/2013 11:50:23	Data entry error	N-N	TEST_INV	Dr Jack Jones	TestPi
Answer #1	19/07/2013 11:50:05	Auto-answered by system		SYSTEM		
Close #1	19/07/2013 11:50:05	Auto-closed by system		SYSTEM		
Insert	01/07/2013 16:50:13		NN	TEST_INV	Dr Jack Jones	TestPi
Open #1	01/07/2013 16:50:07	Patient Initials is given in incorrect format. Please verify.		SYSTEM		

Excel (*.xls) Text (*.csv) PDF (*.pdf)

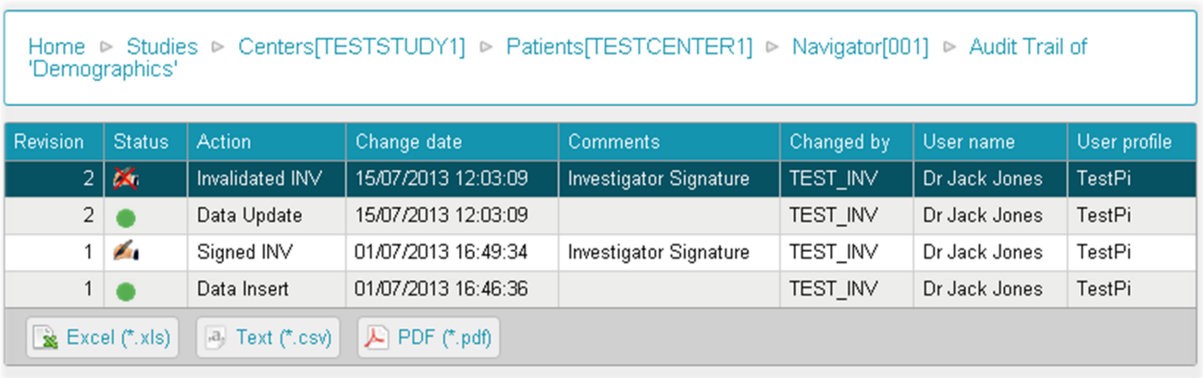
The most recent action is displayed on top. Details of either data entry and modification as well as status changes from Source Data Verification (if applicable to your study) are displayed in this table.

1.3 FORM LEVEL AUDIT TRAIL

You can access the Audit Trail on Form level through the Patient's Navigator:

- Tick **History** on the right hand side of each Navigator row:

This action will display the full Audit trail for the indicated form (Demographics in this example).



Revision	Status	Action	Change date	Comments	Changed by	User name	User profile
2		Invalidated INV	15/07/2013 12:03:09	Investigator Signature	TEST_INV	Dr Jack Jones	TestPi
2		Data Update	15/07/2013 12:03:09		TEST_INV	Dr Jack Jones	TestPi
1		Signed INV	01/07/2013 16:49:34	Investigator Signature	TEST_INV	Dr Jack Jones	TestPi
1		Data Insert	01/07/2013 16:46:36		TEST_INV	Dr Jack Jones	TestPi

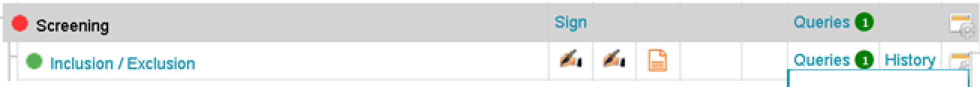
Excel (*.xls) Text (*.csv) PDF (*.pdf)

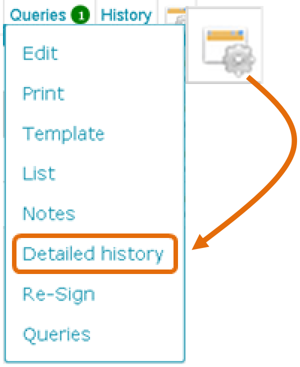
The most recent action is displayed on top. Details of either data entry and modification as well as status changes from Source Data Verification, Signatures and /or Freeze-Lock status (if applicable to your study) are displayed in this table.

NOTE: SIMILAR TO ALL TABLE LISTINGS IN e-capture.net, BOTH QUESTION AND FORM LEVEL AUDIT TRAILS CAN BE EXPORTED TO EXCEL, PDF OR TEXT FORMAT.

1.4 DETAILED HISTORY (COMBINED FORM AND QUESTION AUDIT TRAIL)

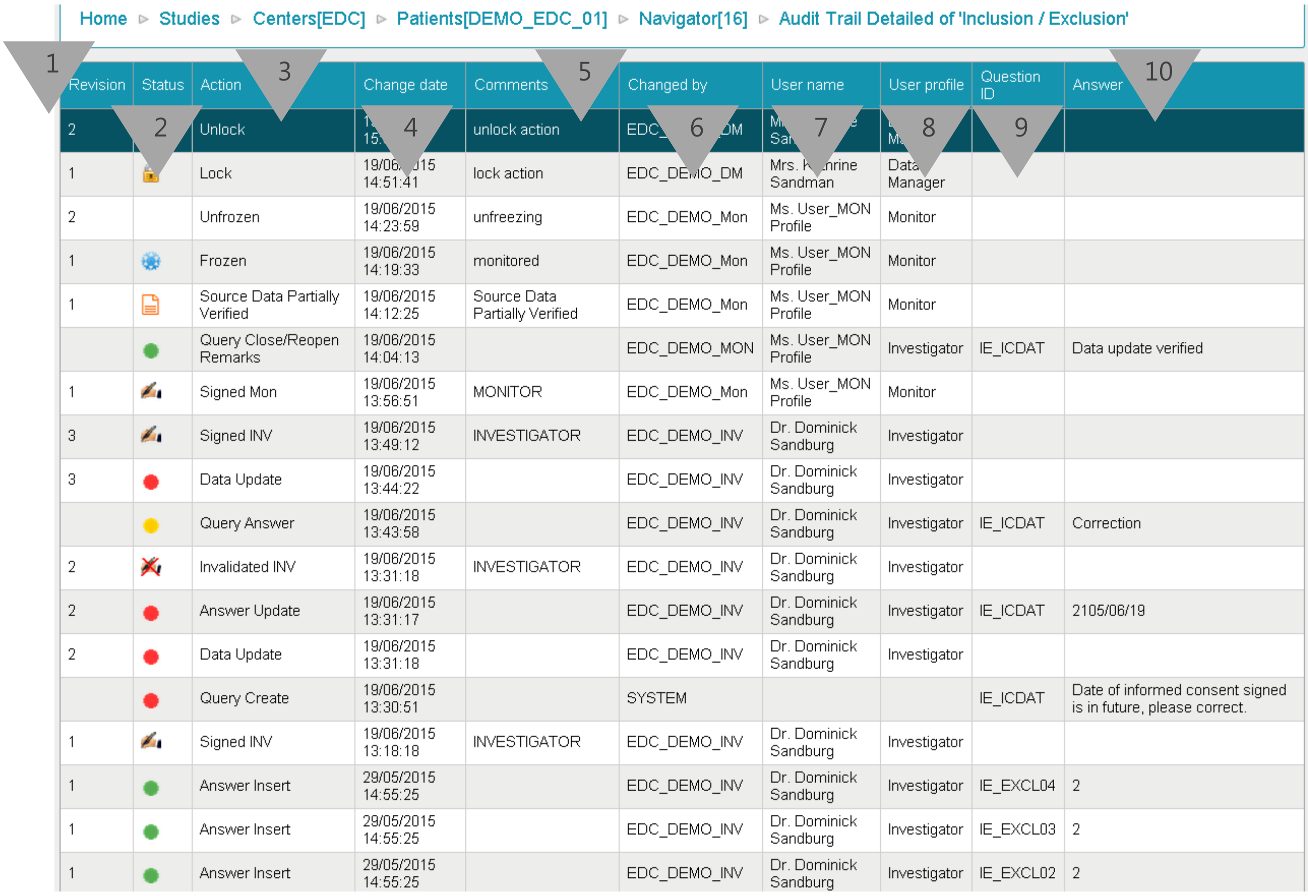
The 'Detailed History' is available for each form separately. The 'Detailed History' displays both form level and question level audit trail actions within the applicable form. To access the 'Detailed history' for a form,





1. select the icon to the right of the applicable form,
2. Tick 'Detailed History' in the pop up menubar

The Detailed History table displays



Revision	Status	Action	Change date	Comments	Changed by	User name	User profile	Question ID	Answer
2		Unlock	[illegible]	unlock action	[illegible]	[illegible]	[illegible]		
1		Lock	19/06/[illegible]15 14:51:41	lock action	EDC_DE[illegible]O_DM	Mrs. K[illegible]rine Sandman	Data Manager		
2		Unfrozen	19/06/2015 14:23:59	unfreezing	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Frozen	19/06/2015 14:19:33	monitored	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Source Data Partially Verified	19/06/2015 14:12:25	Source Data Partially Verified	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
		Query Close/Reopen Remarks	19/06/2015 14:04:13		EDC_DEMO_MON	Ms. User_MON Profile	Investigator	IE_ICDAT	Data update verified
1		Signed Mon	19/06/2015 13:56:51	MONITOR	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
3		Signed INV	19/06/2015 13:49:12	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
3		Data Update	19/06/2015 13:44:22		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
		Query Answer	19/06/2015 13:43:58		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	Correction
2		Invalidated INV	19/06/2015 13:31:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
2		Answer Update	19/06/2015 13:31:17		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2105/06/19
2		Data Update	19/06/2015 13:31:18		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
		Query Create	19/06/2015 13:30:51		SYSTEM			IE_ICDAT	Date of informed consent signed is in future, please correct.
1		Signed INV	19/06/2015 13:18:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL04	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL03	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL02	2

Each column in the table is explained in the following chapters :

1. Revision per Action item
2. Status
3. Action
4. Change date (Date & time)
5. Comments
6. Changed by (User ID)
7. User name
8. User profile
9. Question ID (if applicable)
10. Answer (question values, or query comments)

Back to top ↺

1.4.1 REVISION PER ACTION ITEM

The column ‘Action’ in the Detailed History, specifies the type of action performed. For each action type, the action revision is displayed in column ‘Revision’ The revision count is processed separately for each action type.

Home ▹ Studies ▹ Centers[EDC] ▹ Patients[DEMO_EDC_01] ▹ Navigator[16] ▹ Audit Trail Detailed of 'Inclusion / Exclusion'

Revision	Status	Action	Change date	Comments	Changed by	User name	User profile	Question ID	Answer
2		Unlock	19/06/2015 15:00:26	unlock action	EDC_DEMO_DM	Mrs. Kathrine Sandman	Data Manager		
1		Lock	19/06/2015 14:51:41	lock action	EDC_DEMO_DM	Mrs. Kathrine Sandman	Data Manager		
2		Unfrozen	19/06/2015 14:23:59	unfreezing	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Frozen	19/06/2015 14:19:33	monitored	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Source Data Partially Verified	19/06/2015 14:12:25	Source Data Partially Verified	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
		Query Close/Reopen Remarks	19/06/2015 14:04:13		EDC_DEMO_MON	Ms. User_MON Profile	Investigator	IE_ICDAT	Data update verified
1		Signed Mon	19/06/2015 13:56:51	MONITOR	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
3		Signed INV	19/06/2015 13:49:12	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
3		Data Update	19/06/2015 13:44:22		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
		Query Answer	19/06/2015 13:43:58		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	Correction
2		Invalidated INV	19/06/2015 13:31:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
2		Answer Update	19/06/2015 13:31:17		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2105/06/19
2		Data Update	19/06/2015 13:31:18		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
		Query Create	19/06/2015 13:30:51		SYSTEM			IE_ICDAT	Date of informed consent signed is in future, please correct.
1		Signed INV	19/06/2015 13:18:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL04	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL03	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL02	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL01	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL04	1
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL03	1
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL02	1
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2015/05/29
1		Answer Insert	29/05/2015 14:55:22		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL01	1
1		Data Insert	29/05/2015 14:55:26		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		

Form Level history

Question Level history

1. **Question Revision** : The revision count is done for each separate question ID

Example : revision for question ICDAT. Data entry (question rev.1) & Data update (rev.2)

For each revision, all audit trail items, including the answer value is specified in the table

Revisio	Action	Change date	Comment	Changed by	User name	User profile	Question I	Answer
2	Answer Update	19/06/2015 13:31		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2105/06/19
1	Answer Insert	29/05/2015 14:55		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2015/05/29

2. **Form** Revision : Each Form save triggers a new form revision,

Back to top ↺

The form level history is displayed without any specified question ID's. Each form save triggers a new form revision, but only in case there was a data update since the last save action.

NOTE: *Some actions (eg, closing a query) require a system forced form save.*
Example : When a Monitor closes all queries in a form, the form should be displayed as a green status. Since the Monitor cannot Save a form (read only access), the system auto-saves the form to update the form status. The automated form saves are not shown in the Detailed History..

NOTE: *It may be possible that the form revision is different from a question revision (eg data entry into the form -> form save 1 = Form Rev.1 // Data update only to question IE_ICDAT -> form save 2 = Form Rev.2)*
<u>Question IE_INCL01</u> was not changed after initial data entry (= question REV.1)
Even on form rev. 2, the question revision remains REV.1 (because there was no data update to this question)
<u>Question IE_ICDAT</u> was updated, so the question revision was updated rev.1 -> rev.2

---

3. **Sign** revision : Count per sign definition

   Every time a signature is placed, or invalidated, the sign revision is incremented by 1.
   Each sign definition has its own separate revision count.

Revisio	Action	Change date	Comments	Changed by	User name	User profile
1	Signed Mon	19/06/2015 13:56	MONITOR	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor
3	Signed INV	19/06/2015 13:49	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator
2	Invalidated INV	19/06/2015 13:31	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator
1	Signed INV	19/06/2015 13:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator

---

NOTE: *In the above screenshot, the INV signature was placed (rev1) -> invalidated (rev2) -> re-signed (rev3). the Montitor signature has its own revision count (starts at rev1)*

---

4. **Query** : No revision displayed

   Each query is linked to a specific question. Since the question ID is mentioned for the applicable query, and data update for a question triggers the question revision, the query revision is not displayed in the table.

5. **SDV** revision : Every 'Save SDV Status', triggers a new SDV revision.

6. **Freeze** revision : Every Freeze / Unfreeze action triggers a new Freeze revision

2		Unfrozen	19/06/2015 14:23:59	unfreezing	EDC_DEMO_Mon
1		Frozen	19/06/2015 14:19:33	monitored	EDC_DEMO_Mon

7. **Lock** revision : Every Lock / Unlock action triggers a new Lock revision

2		Unlock	19/06/2015 15:00:26	unlock action	EDC_DEMO_DM
1		Lock	19/06/2015 14:51:41	lock action	EDC_DEMO_DM

NOTE: *The Detailed History 'Revision' column displays the revisions for all action types in the same column. For an easy overview per item, please export the Detailed History to excel, and filter per action type.*

1.4.2 STATUS

The status column displays the form 'meta data' icons , which are also used in the patient eCRF navigator screen.

Home ⊳ Studies ⊳ Centers[EDC] ⊳ Patients[DEMO_EDC_01] ⊳ Navigator[16] ⊳ Audit Trail Detailed of 'Inclusion / Exclusion'

Revision	Status	Action	Change date	Comments	Changed by	User name	User profile	Question ID	Answer
2		Unlock	19/06/2015 15:00:26	unlock action	EDC_DEMO_DM	Mrs. Kathrine Sandman	Data Manager		
1		Lock	19/06/2015 14:51:41	lock action	EDC_DEMO_DM	Mrs. Kathrine Sandman	Data Manager		
2		Unfrozen	19/06/2015 14:23:59	unfreezing	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Frozen	19/06/2015 14:19:33	monitored	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Source Data Partially Verified	19/06/2015 14:12:25	Source Data Partially Verified	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
		Query Close/Reopen Remarks	19/06/2015 14:04:13		EDC_DEMO_MON	Ms. User_MON Profile	Investigator	IE_ICDAT	Data update verified
1		Signed Mon	19/06/2015 13:56:51	MONITOR	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		

1.4.3 ACTION

The Action column in the Detailed History table, specifies the type of action performed. For each action, a separate revision count is held in the study database.

For more details regarding each action type, please check the chapter on Lock, Freeze, Reason for change, SDV, and/or signing.

1.4.4 CHANGE DATE (DATE & TIME)

For each action processed, both date and time are registered into the database.

1.4.5 COMMENTS

Some database actions trigger a comment field, that will be completed manually by the user, or automated by the system :

- Manual : Lock or Freeze, or Reason for change.

These comments are entered by the user, when processing the action.

- Automated : SDV status save, Sign

These comments are pre-defined during study setup, and auto completed by the system when the action is executed.
For more information regarding each action type, please check the chapter on Lock, Freeze, Reason for change, SDV, and signing

1.4.6 CHANGED BY

The 'changed by' column specifies the user ID of the person that processed the action.

1.4.7 USER NAME

The 'User name' column specifies the full user name of the person that processed the action.

1.4.8 USER PROFILE

The 'User profile' column specifies the user role in which the user has access to the database; the user role definitions are customized specifically for every separate study, and may differ from project to study.

1.4.9 QUESTION ID

The 'question ID' column specifies the question to which the action is related . To link the question ID to the question label, please check the manual section on 'Annotated CRF'

Revision	Status	Action	Change date	Comments	Changed by	User name	User profile	Question ID	Answer
2		Unlock	19/06/2015 15:00:26	unlock action	EDC_DEMO_DM	Mrs. Kathrine Sandman	Data Manager		
1		Lock	19/06/2015 14:51:41	lock action	EDC_DEMO_DM	Mrs. Kathrine Sandman	Data Manager		
2		Unfrozen	19/06/2015 14:23:59	unfreezing	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Frozen	19/06/2015 14:19:33	monitored	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
1		Source Data Partially Verified	19/06/2015 14:12:25	Source Data Partially Verified	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
		Query Close/Reopen Remarks	19/06/2015 14:04:13		EDC_DEMO_MON	Ms. User_MON Profile	Investigator	IE_ICDAT	Data update verified
1		Signed Mon	19/06/2015 13:56:51	MONITOR	EDC_DEMO_Mon	Ms. User_MON Profile	Monitor		
3		Signed INV	19/06/2015 13:49:12	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
3		Data Update	19/06/2015 13:44:22		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
		Query Answer	19/06/2015 13:43:58		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	Correction
2		Invalidated INV	19/06/2015 13:31:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
2		Answer Update	19/06/2015 13:31:17		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2105/06/19
2		Data Update	19/06/2015 13:31:18		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
		Query Create	19/06/2015 13:30:51		SYSTEM			IE_ICDAT	Date of informed consent signed is in future, please correct.
1		Signed INV	19/06/2015 13:18:18	INVESTIGATOR	EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL04	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL03	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL02	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_EXCL01	2
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL04	1
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL03	1
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL02	1
1		Answer Insert	29/05/2015 14:55:25		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_ICDAT	2015/05/29
1		Answer Insert	29/05/2015 14:55:22		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator	IE_INCL01	1
1		Data Insert	29/05/2015 14:55:26		EDC_DEMO_INV	Dr. Dominick Sandburg	Investigator		

NOTE: *Form level action types do not have a linked question IS.*

1.4.10 ANSWER

The 'Answer' column specifies the database value that is linked to the selected answer and the query text related to a query action.
To link the answer value to the answer text label, please check the manual section on 'Annotated CRF'

1.5 QUERY AUDIT TRAIL

1.5.1 QUERY AUDIT TRAIL VIA THE PATIENT CRF

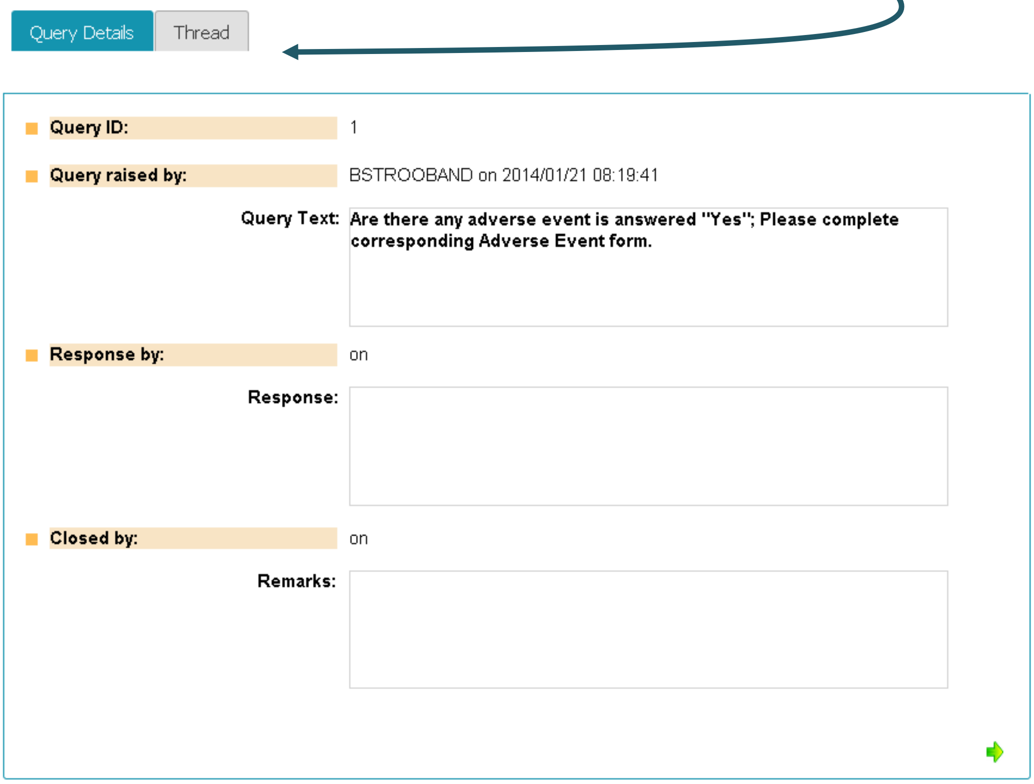
1. right button click on the answer field.
2. Select 'Queries'.
3. Tick 'Detail'.
4. Tick 'thread' (in case of a re-opened query).

Query

ID	Query Text	Status	Value	Type	#	#
1	Are there any adverse event is answered "Yes"; Please complete corresponding Adverse Event form.	Open	1	Auto	Answer	Detail

Excel (*.xls) Text (*.csv) PDF (*.pdf)

When an edit check is answered and afterwards **re-opened,** then a **second tab (Thread)** is shown.



The query thread contains the query audit trail. (showing the previous query text, remarks & answers)

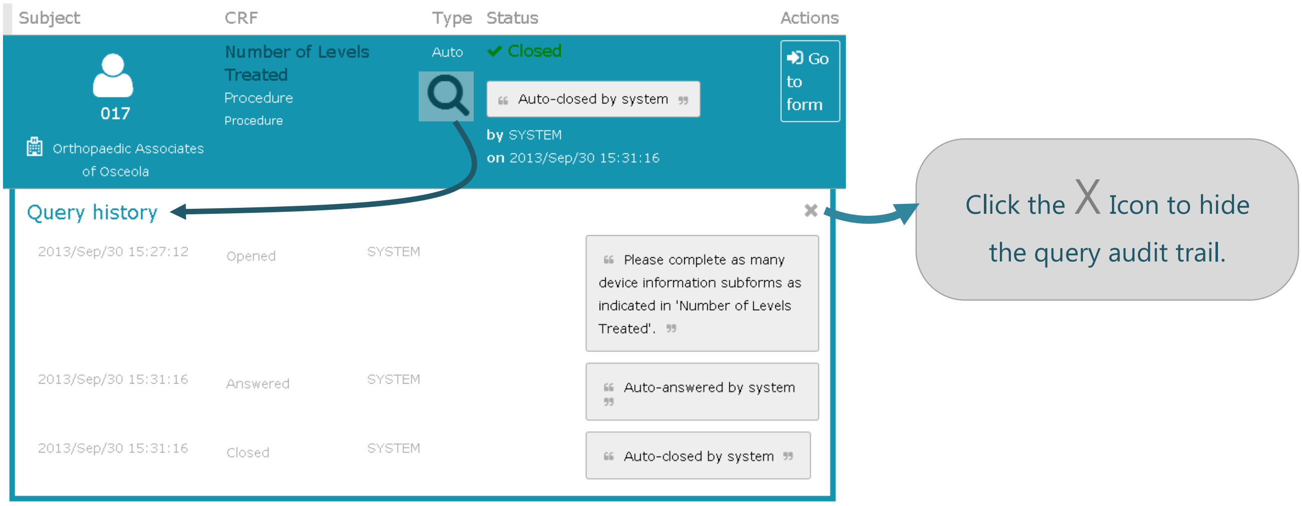
Query Details | Thread

ID	Action	Message	By	On
100	Remarks	please check again	BSTROOBAND	2014/01/21 08:19:41
100	Response	adverse event form has been completed	EGROCHENIG	2013/08/02 10:24:12
100	Query	Are there any adverse event is answered "Yes"; Please complete corresponding Adverse Event form.	SYSTEM	2013/07/31 16:29:01

Excel (*.xls) Text (*.csv) PDF (*.pdf)

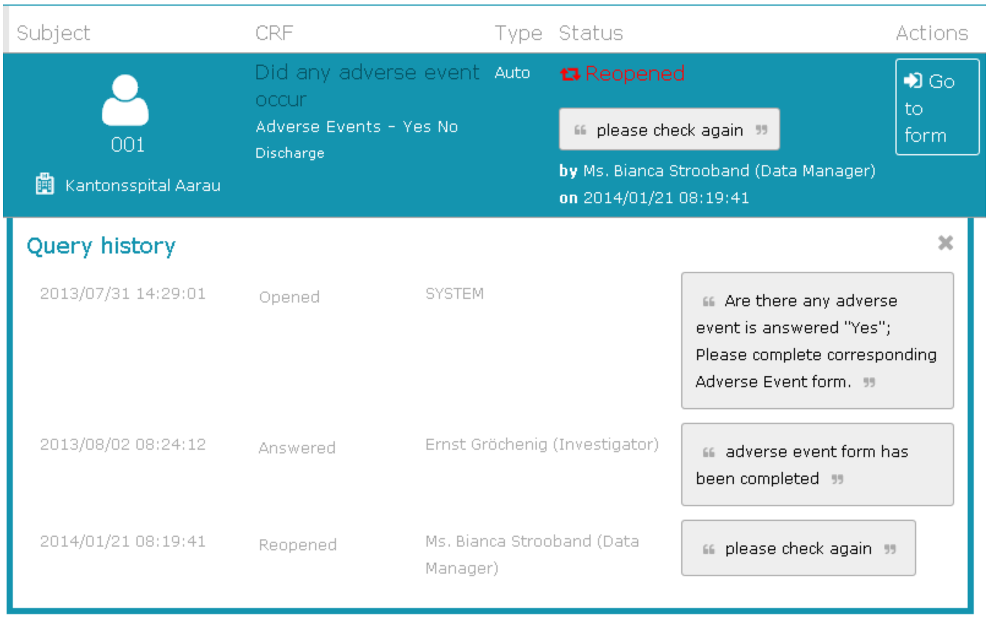
1.5.2 QUERY AUDIT TRAIL VIA THE QUERY LIST

Within the query list , click the magnifying glass to view the audit trail for a specific query.
Query audit trail for open / answered / closed queries in the query list.



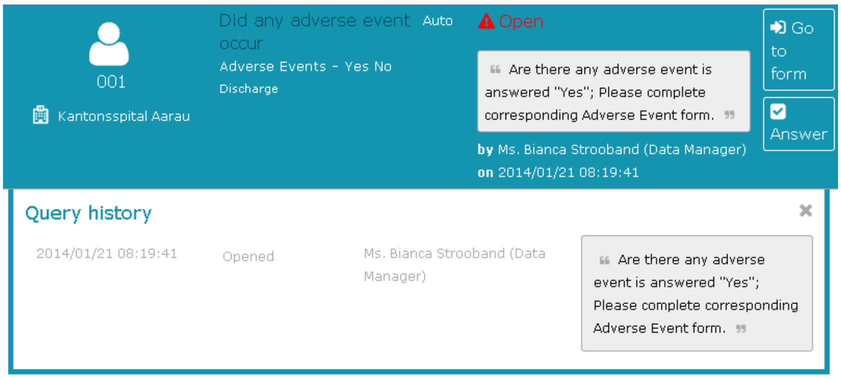
Query audit trail for re-opened queries in the query list

- For a re-opened query, the audit trail shows 2 separate query lines :
- To 'link' the query rows, please filter the query list to center/patient/visit/form and question.



'Reopened' query:
All items before the 're-open' action are shown in the audit trail of the 'reopened' query row (these are the items shown in the 'query thread' in the CRF query audit trail view). The 're-opened' part is considered fully processed, and no query actions are possible on the 'reopened' query row.

open/answered/closed status query:
For each 're-opened' query, there is a linked query row, where you can process query actions.
The first audit trail line indicates the same date/time and user id as the last audit trail line in the 'reopened' item.



2 FORM AND VISIT STATUS

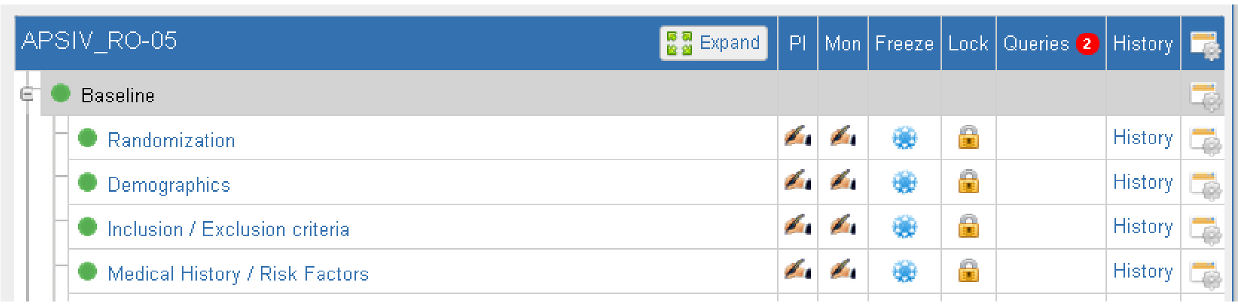
A page status is **manually set** to a form or visit to indicate the progress of the entered data of each patient throughout the study.
The study design and the rights assigned to the user roles will define which status can be set by which user.
You can define 'Status' as:

- A signature (multiple user role defined signatures possible within one study)
- Freeze or lock status

As an example: following study signatures can be defined:

Sign reason ID	Sign Reason	Sign reason description
1	INV	Investigator Signature
2	MO	Monitor Signature
7	CEC1	CEC Signature
8	CEC2	CEC Signature
9	CEC3	CEC Signature
5	CO1	Corelab1 signature
6	CO2	Corelab2 signature
4	CEC	CEC member

The screenshot below illustrates how the workflow and progress of a patient is indicated with statuses:



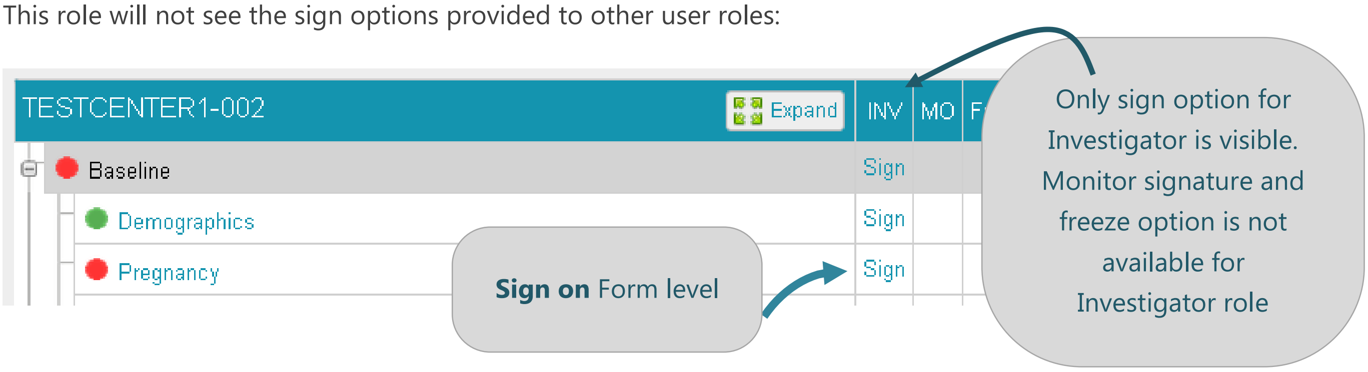
Back to top ↺

3 SIGN FORMS, VISITS OR PATIENTS

Depending on your study set-up, e-capture.net allows you to sign each form separately or multi-sign an entire visit or patient.

NOTE: YOU CAN ONLY SIGN FORMS THAT HAVE A GREEN ● OR RED ● STATUS. UN-OPENED FORMS WITH GREY ● STATUS CANNOT BE SIGNED.

The screenshot below illustrates the sign options in a patient's Navigator as provided for on Investigator role. This role will not see the sign options provided to other user roles:

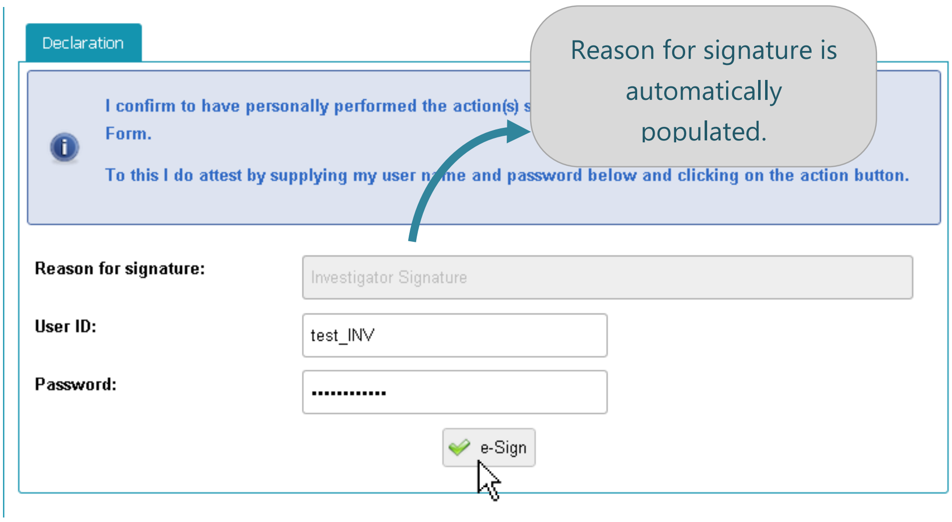


If specified in your study definitions, it might be possible that you can sign only under certain specific conditions (see also Item: Sign dependency rules).

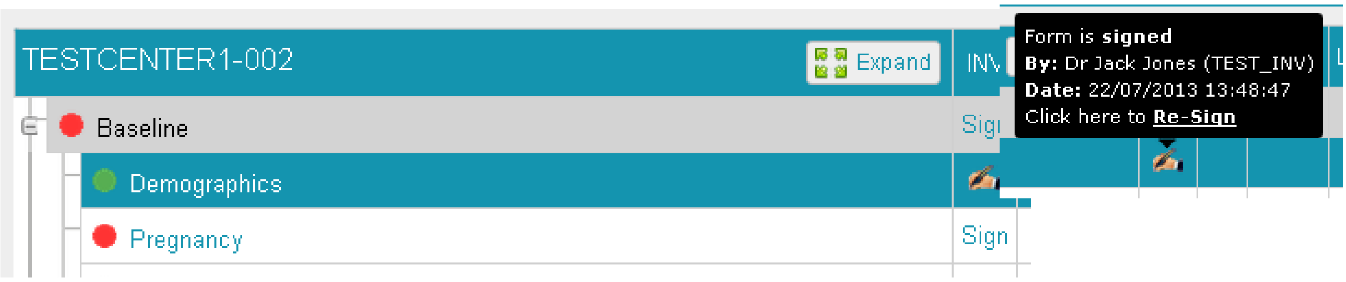
3.1 FORM SIGNATURE

To sign a form, follow these steps:

1. Starting in the Patient's Navigator, Click the 'Sign' button that is located on the right of the applicable form.
2. A Sign Declaration window opens in which you need to confirm the reason for signing by entering your **User ID** and **Password**:
3. Click the 'e-Sign' button. The sign icon indicates that the form has been signed correctly.



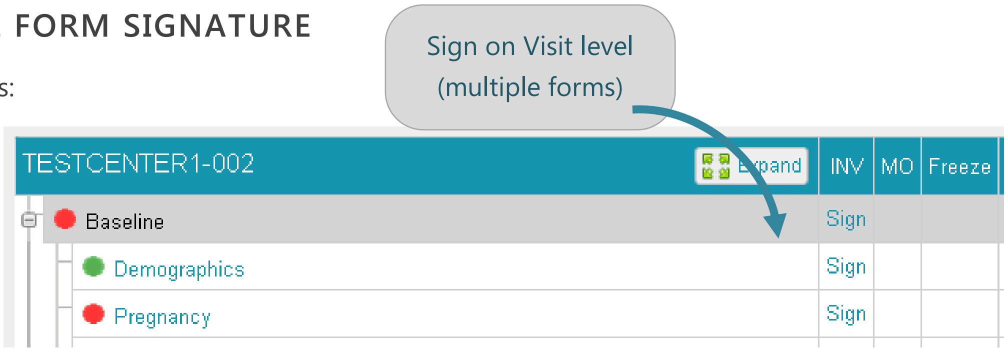
4. Hover with your mouse over this Icon to see the signature details.



3.2 VISIT / MULTIPLE FORM SIGNATURE

To sign a visit, follow these steps:

1. Starting in the Patient's Navigator, Click the 'Sign' button that is located on the right of the applicable **visit**.

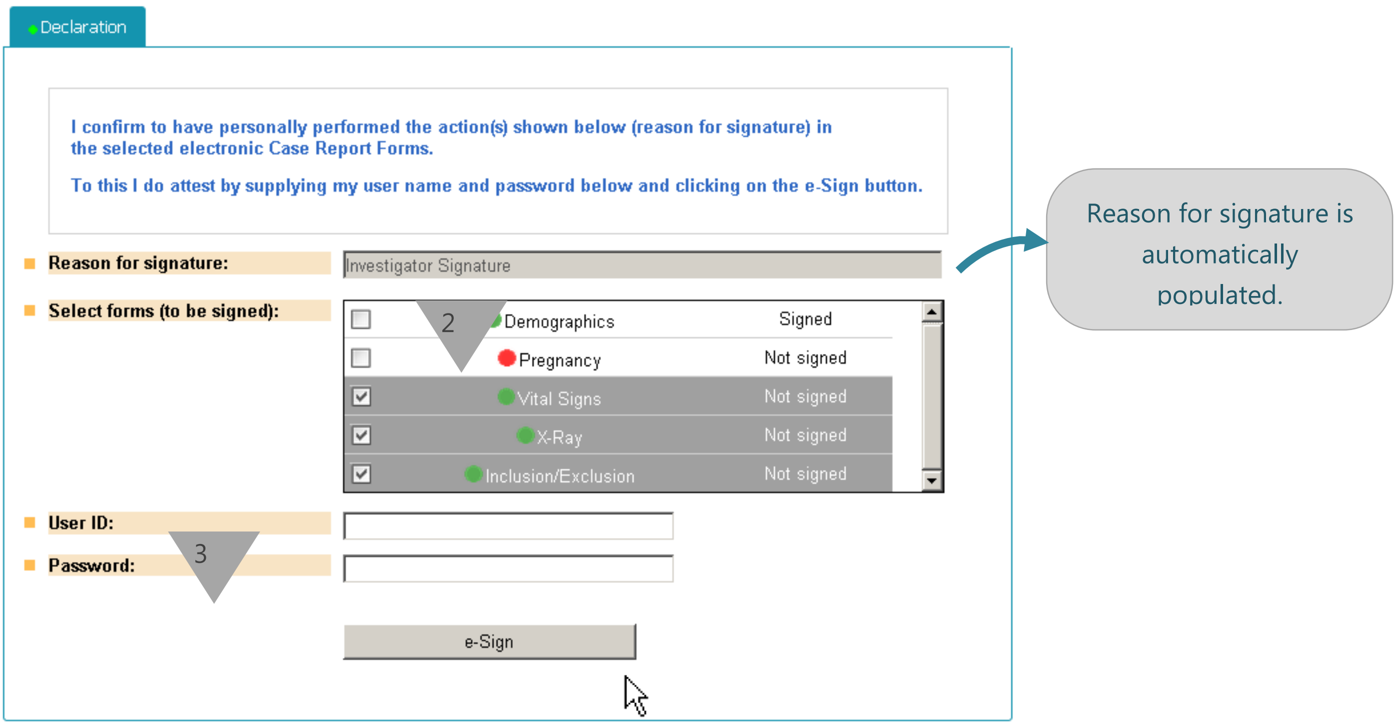


A Sign Declaration window opens in which you need to:

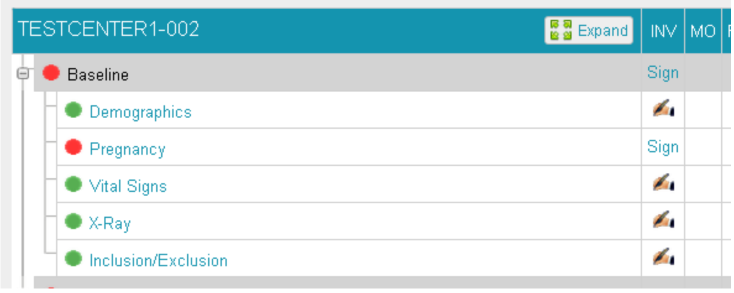
2. Select the forms you wish to sign:

- All forms available for signing will be checked by default.
- Forms that have already been signed will not be checked
- Forms that do not need to be signed (yet) must be un-checked.

3. Confirm the reason for signing by entering your **User ID** and **Password.**

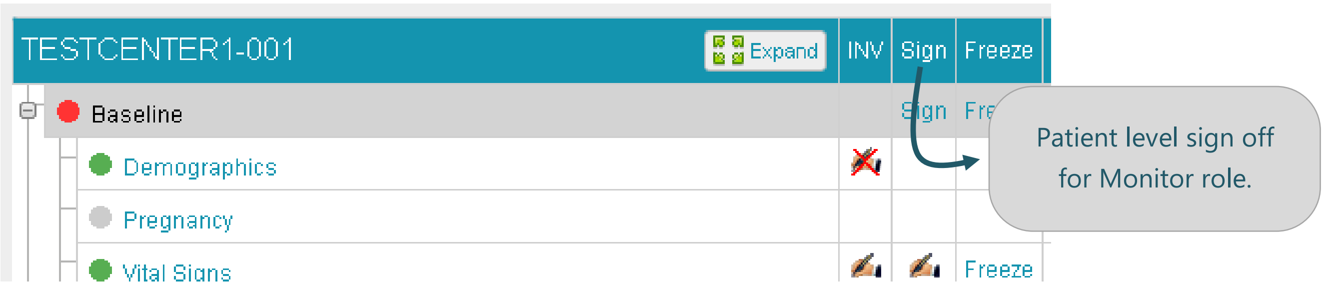


4. Click the e-Sign button. The sign icon on each indicated form of the applicable visit indicates that these forms have been signed correctly.



3.3 PATIENT LEVEL SIGNATURE

Depending on the study set-up and the rights assigned to your user role, it may be possible to sign off for an entire patient.
In this case, there will be 'Sign' button available on the top cell of the sign column in each patient's navigator:

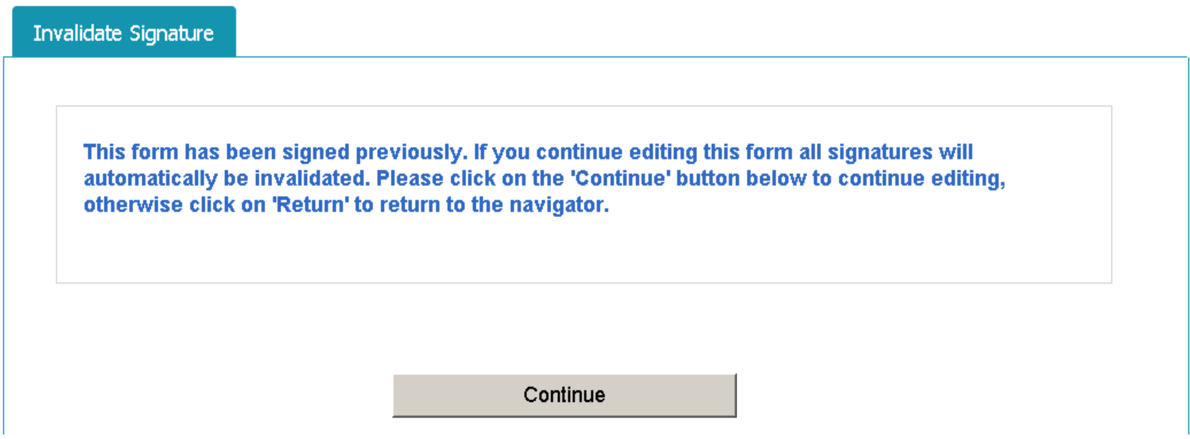


The next steps of the patient sign process are similar as explained in item [Visit / multiple form Signature](#).

3.4 INVALIDATE SIGNATURES (ONLY FOR USERS WITH WRITE ACCESS)

If there is need to **edit** a signed form, the signature will be invalidated. The form can be re-signed after editing.

- A warning message will appear when you click to open a signed form:



- After editing and saving the change, the signature has become invalidated and is indicated by the icon.
- Hover over the icon with the computer mouse to reveal the specifications about the invalidation:

NOTE: IN CASE YOU CLICK THE 'CONTINUE' BUTTON TO VIEW THE FORM AND SAVE IT WITHOUT CHANGING THE EXISTING DATA, THE ORIGINAL SIGNATURE WILL REMAIN VALID.

3.5 RE-SIGN

To re-sign a form or visit, you need to follow the same steps as initial signing (see item: Form signature).

- If a form is re-signed by the same user as the initial signature, the sign icon will be shown .
- In case another user (with the same profile) re-signs, this will be indicated with a sign icon with a grey cross :

3.6 SIGN DEPENDENCY RULES

Depending on study set-up, sign dependency rules may be implemented. In this case, it might be possible that a monitor can only sign when the investigator has signed, or if other conditions for signoff are implemented.

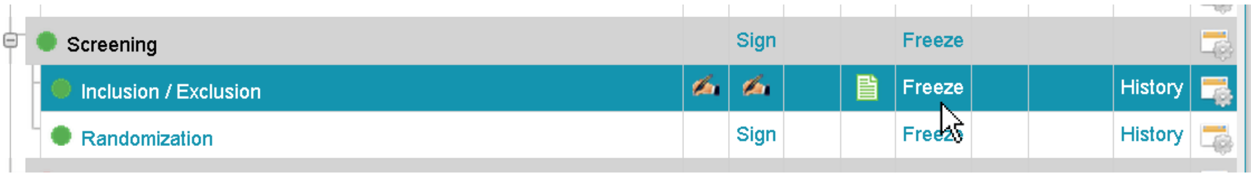
4 FREEZE

The Freeze action is generally performed by a user with a Monitor role. A freeze action makes a form read-only however, it is still possible to open, answer or close queries and sign forms.

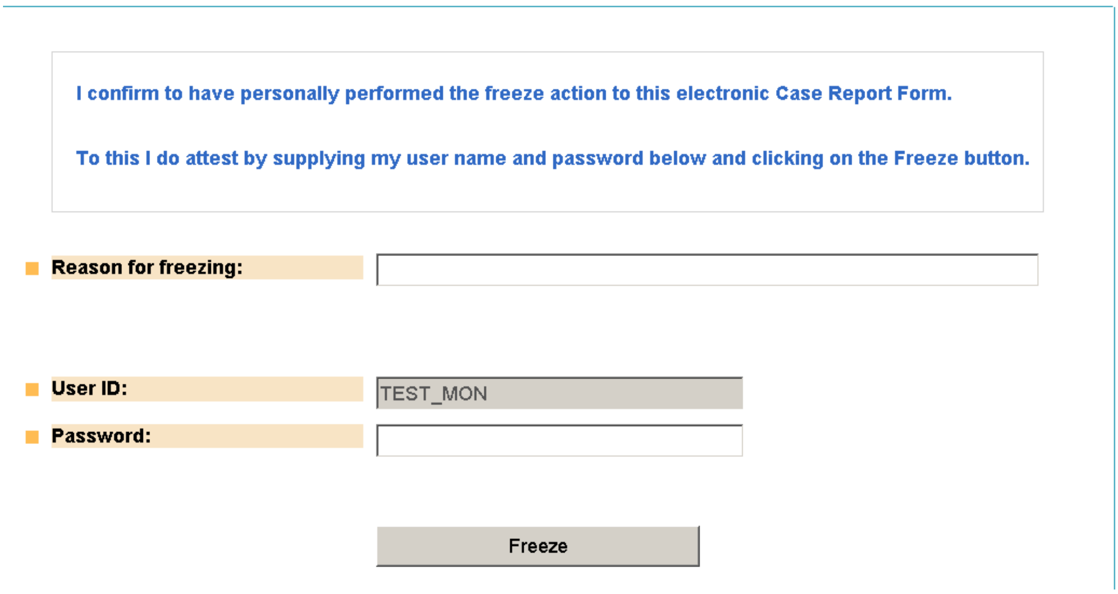
4.1 FREEZE A FORM

To freeze a form, follow these steps:

1. Starting in the Patient's Navigator, click the **freeze** link that is located on the right of the applicable form. This link will only be visible to the users that have freeze rights assigned to their role.



2. A Freeze window opens.

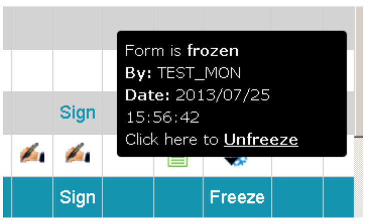


- You can enter a reason for freezing, but is not mandatory.
- Your **User ID** will be pre populated.

3. Enter your **Password** and click **Freeze**

The freeze icon indicates that the form is frozen.

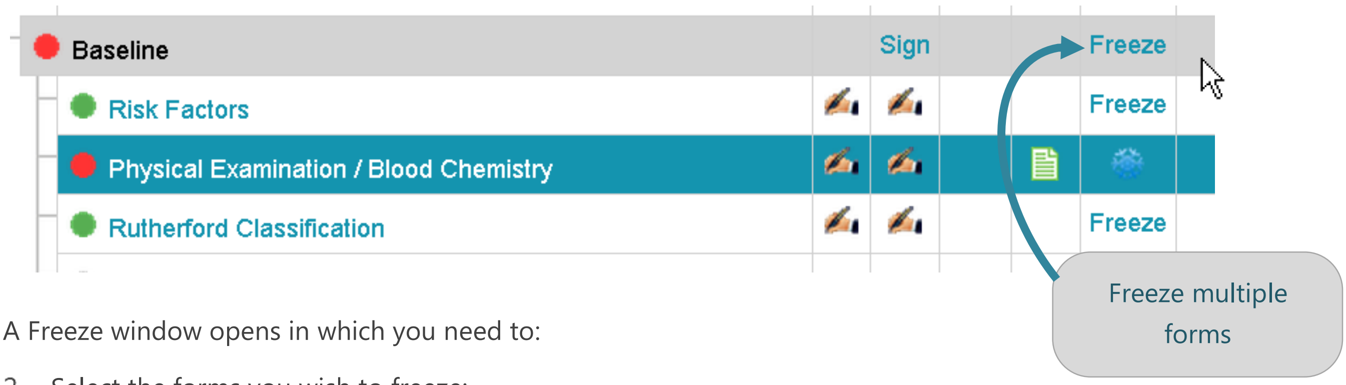
4. Hover with your mouse over this Icon to see the freeze details.



4.2 FREEZE MULTIPLE FORMS

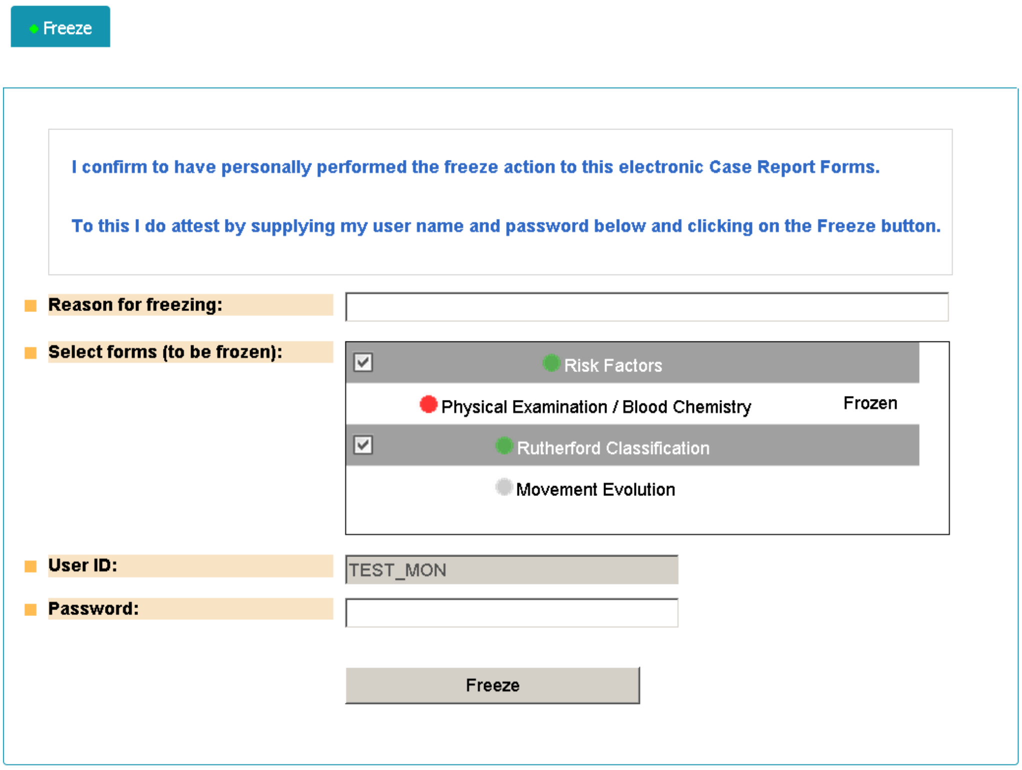
Similar as signing multiple forms, e-capture.net provides the possibility to freeze multiple forms simultaneously:
To freeze multiple forms, follow these steps:

1. Starting in the Patient's Navigator, Click the **Freeze** link that is located on the right of the applicable **visit**.



A Freeze window opens in which you need to:

2. Select the forms you wish to freeze:



- Forms that have already been frozen cannot be checked
- Forms with a grey status cannot be checked.
- It is possible to freeze a form with open or answered queries.

3. Enter your **Password** and click **Freeze.**

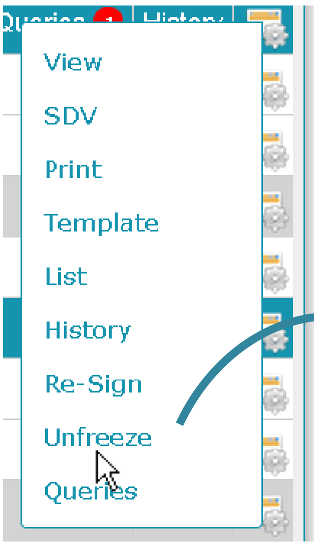
4.3 UN-FREEZE

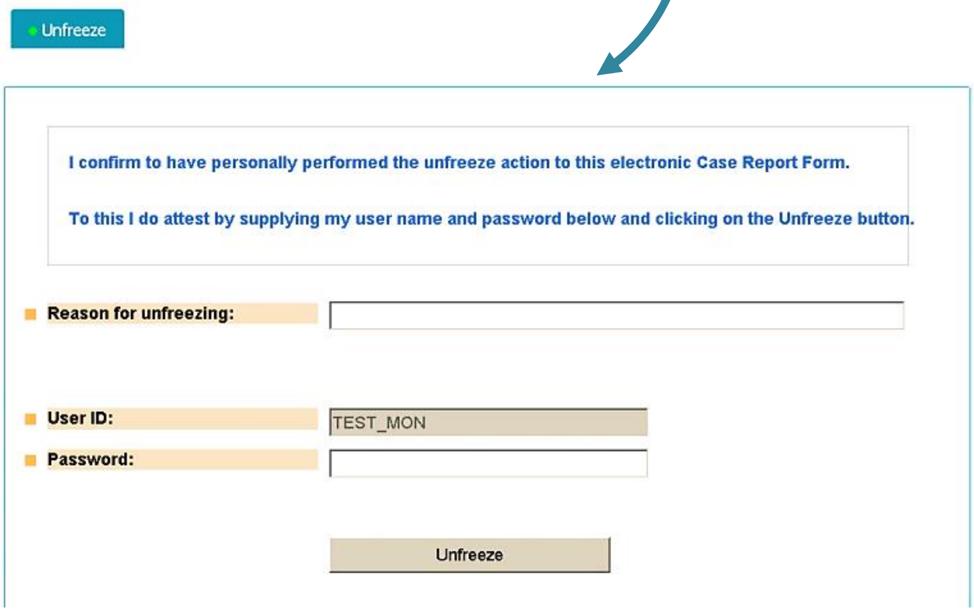
A Freeze action makes a form read-only. In case the site needs to update a formb, it is possible to un-freeze:

- Hover with your mouse over the freeze Icon and click: '<u>Unfreeze</u>'

OR

- Click the Icon of the applicable form and choose Unfreeze from the dropdown menu.
- Enter your password in the Unfreeze window and click **Unfreeze**





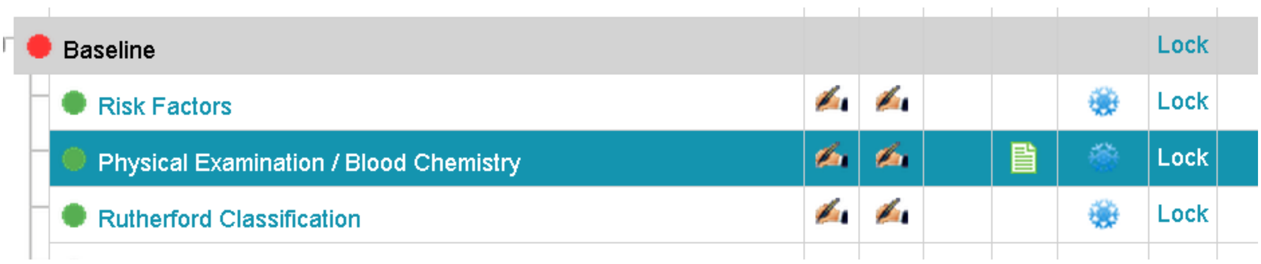
5 LOCK

The Lock action is generally performed by a user with a Data Manager role. A lock action makes a form read-only with no access to query, sign or freeze actions.

5.1 LOCK A FORM

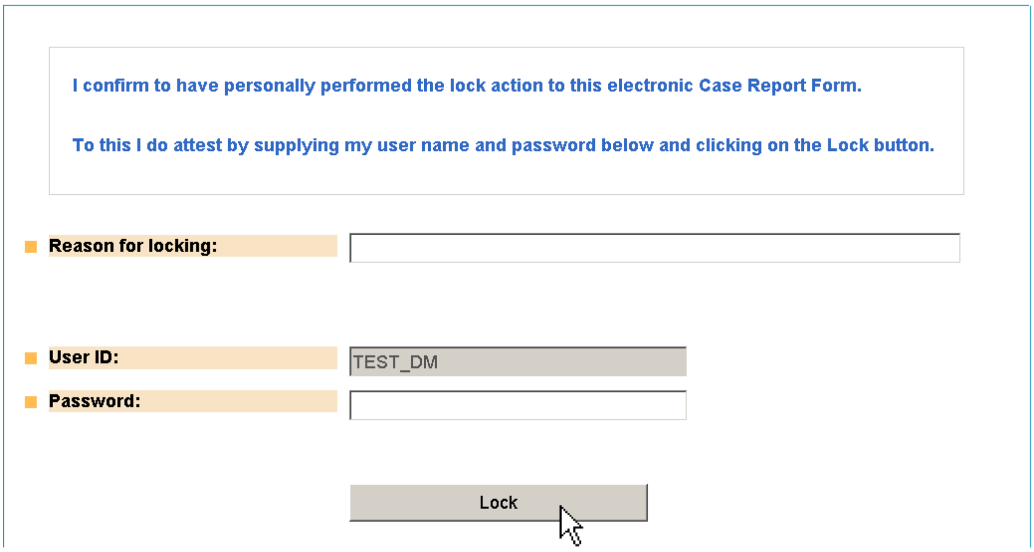
To lock a form, follow these steps:

1. Starting in the Patient's Navigator, click the **lock** link that is located on the right of the applicable form. This link will only be visible to the users that have lock rights assigned to their role.

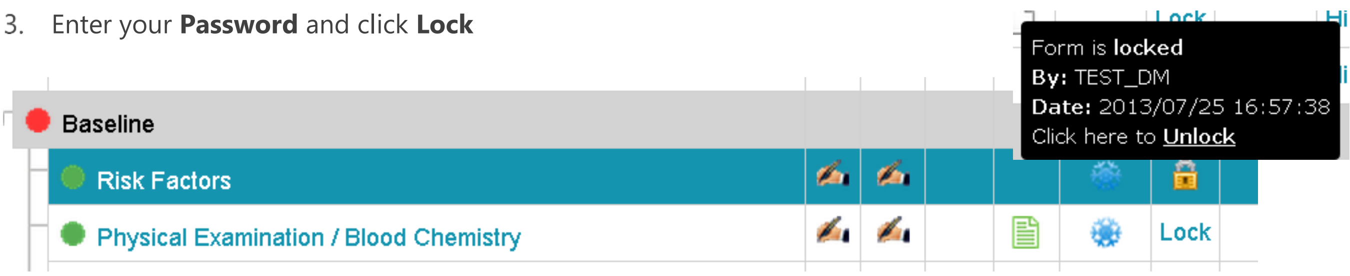


2. A Lock window opens.

- You can enter a reason for locking but this is not mandatory.
- Your **User ID** will be pre populated.



3. Enter your **Password** and click **Lock**



The Lock icon indicates that the form is locked.

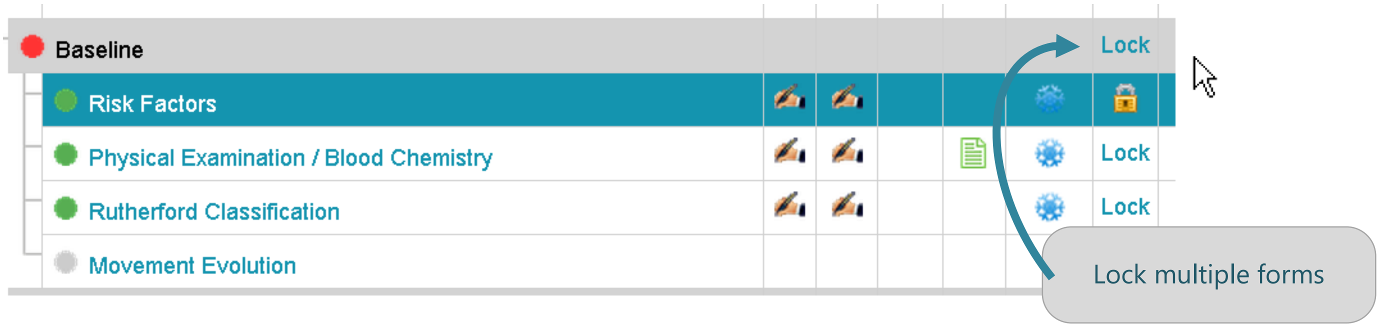
4. Hover with your mouse over this Icon to see the lock details.

5.2 LOCK MULTIPLE FORMS

Similar as signing or freezing multiple forms, e-capture.net provides the possibility to lock multiple forms simultaneously:

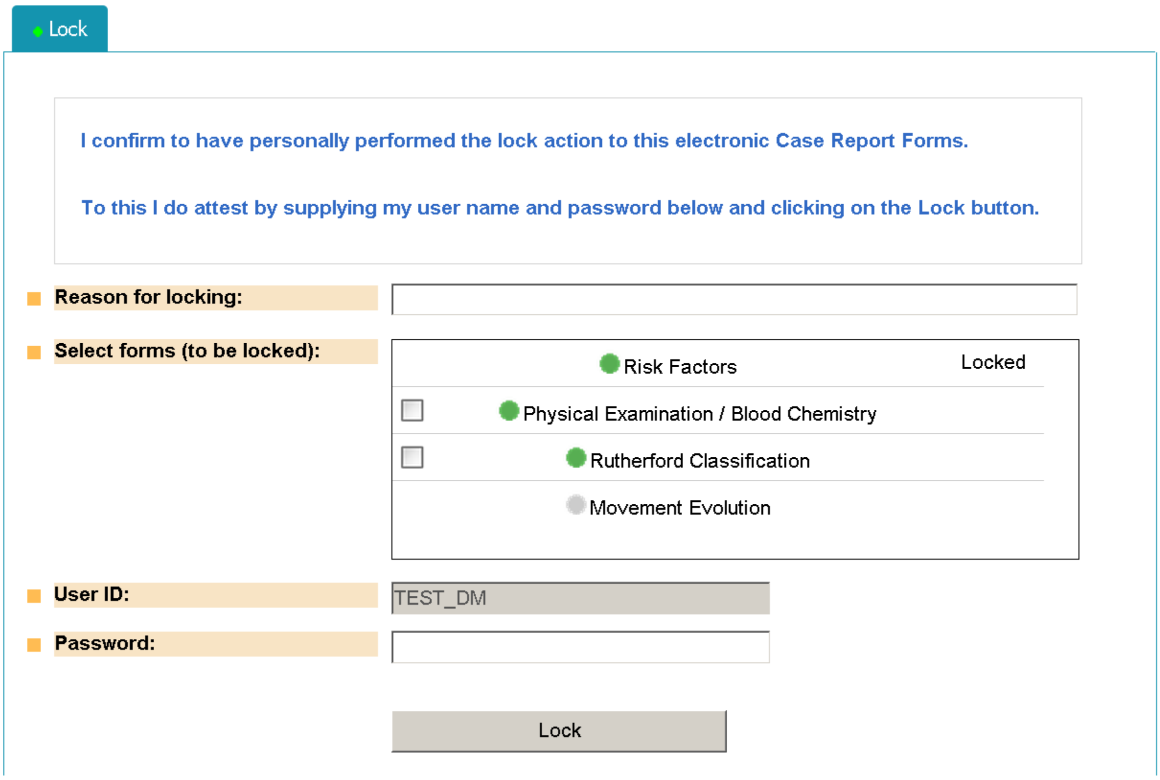
To lock multiple forms, follow these steps:

1. Starting in the Patient's Navigator, Click the **Lock** link that is located on the right of the applicable **visit**.



A Lock window opens in which you need to:

2. Select the forms you wish to lock:

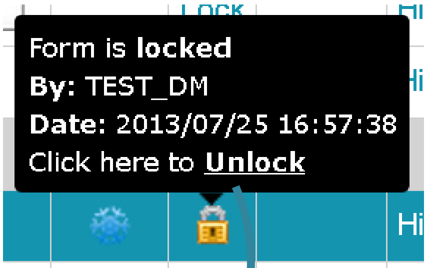


- Forms that have already been locked cannot be checked
- Forms with a grey status cannot be checked.
- It is possible to lock a form with open or answered queries.

3. Enter your **Password** and click **Lock.**

5.3 UN-LOCK

A lock action makes a form read-only. In case the site needs to update a form, it is possible to un-lock:

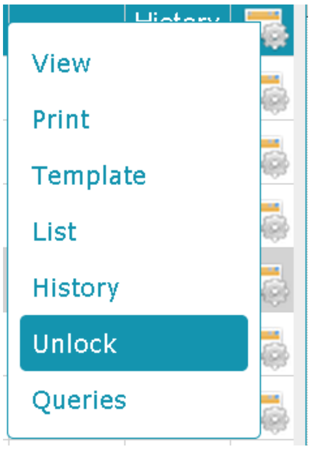


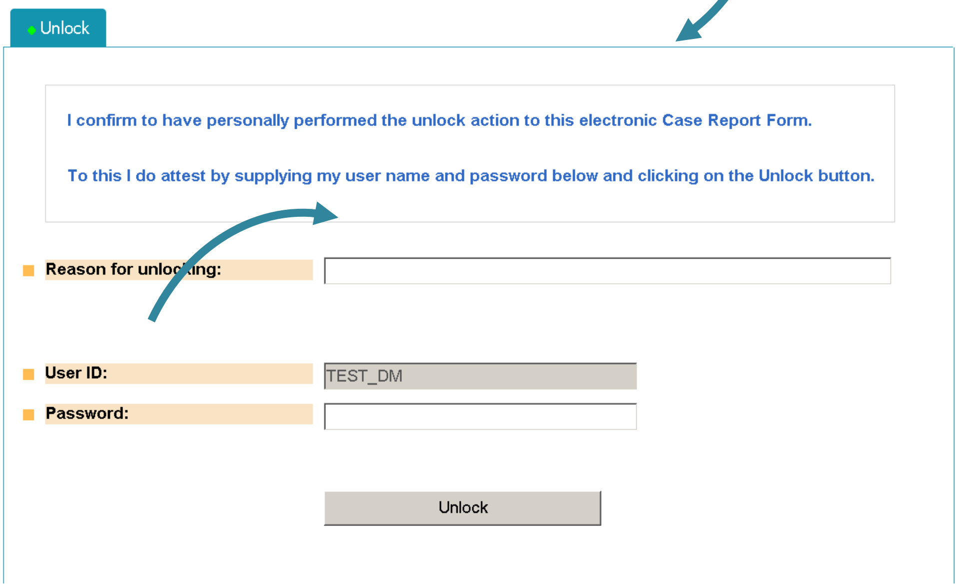
- Hover with your mouse over the freeze Icon and click: '<u>Unlock</u>'

  OR

- Click the Icon of the applicable form and choose Unlock from the dropdown menu.

- Enter your password in the Unlock window and click **Unlock**





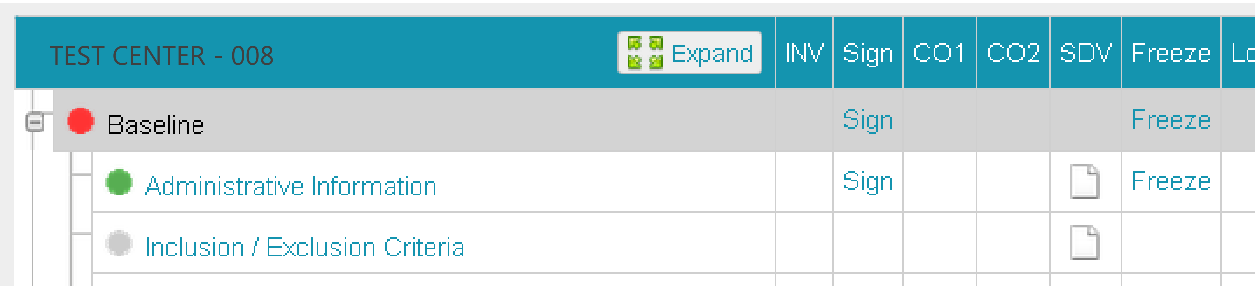
6 SOURCE DATA VERIFICATION

Source Data Verification (SDV) is the evaluation of the conformity of the data represented in the e-CRF with source data to ensure validity and integrity of clinical study data.
The SDV functionality of e-capture.net allows the documentation of this process by indicating the SDV status of all or certain pre-defined data fields in the e-CRF.
SDV is a stand-alone feature in e-capture.net and its presence depends on the set-up of your study (recommended to be only used when <100% SDV required).

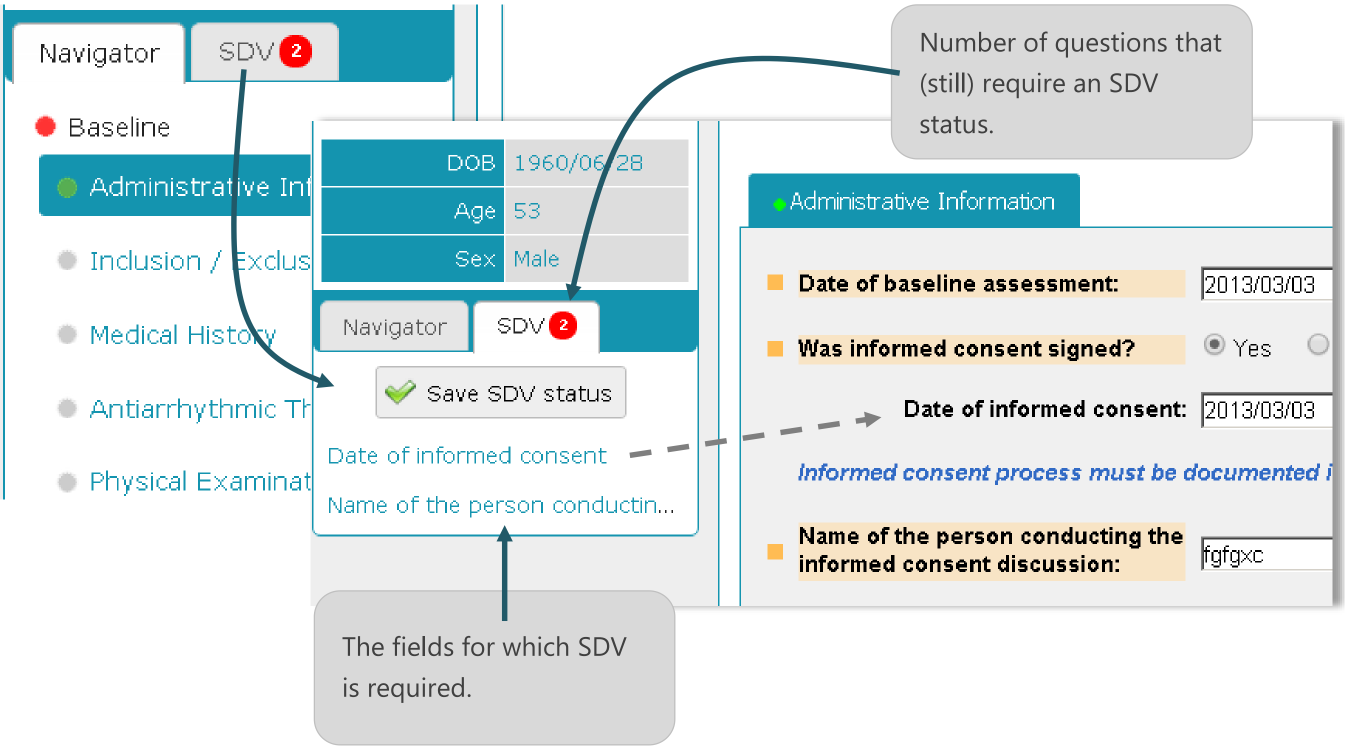
6.1 VERIFY SOURCE DATA

Users with the appropriate rights assigned to their user role (typically a Monitor role) are able to verify source data in e-capture.net
To perform Source Data Verification, follow these steps:

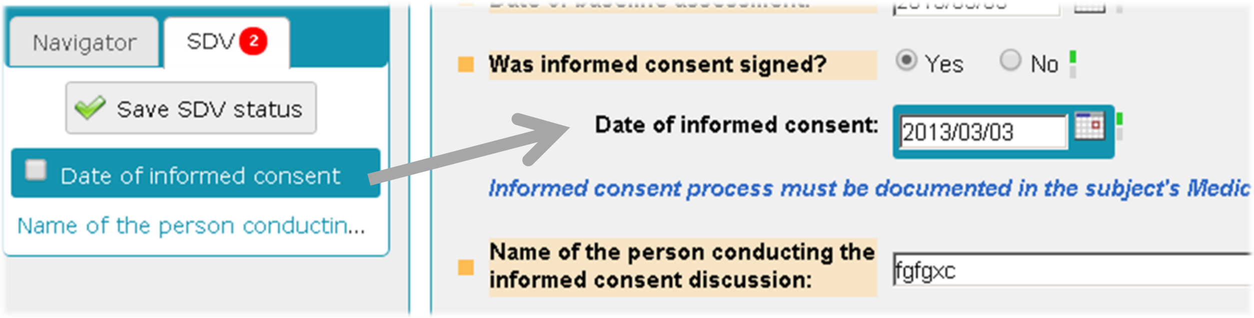
1. Open a patient navigator.
2. Click the applicable form to open:



3. Click the SDV tab:

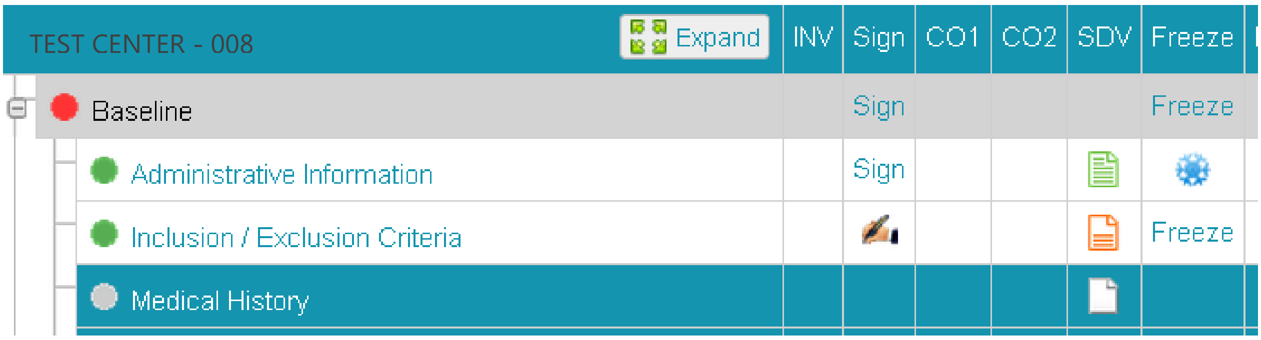


4. Tick the applicable question(s) within the SDV tab.
5. This question will become highlighted in the e-CRF form:



6. Check the box in front of the question(s).
7. Click 'Save SDV status'.

8. The SDV status of each applicable form is indicated with an SDV icon in the patient navigator.
9. Hover with your mouse over this Icon to see the SDV details:



10. When SDV is performed on all required fields of an e-CRF form, the form will be frozen automatically.

If any updates are required, the form should be manually un-frozen by a user with appropriate rights to do so (typically a monitor role).

- Updated items will lose SDV indication  (invalidated) and present signatures will become invalid.

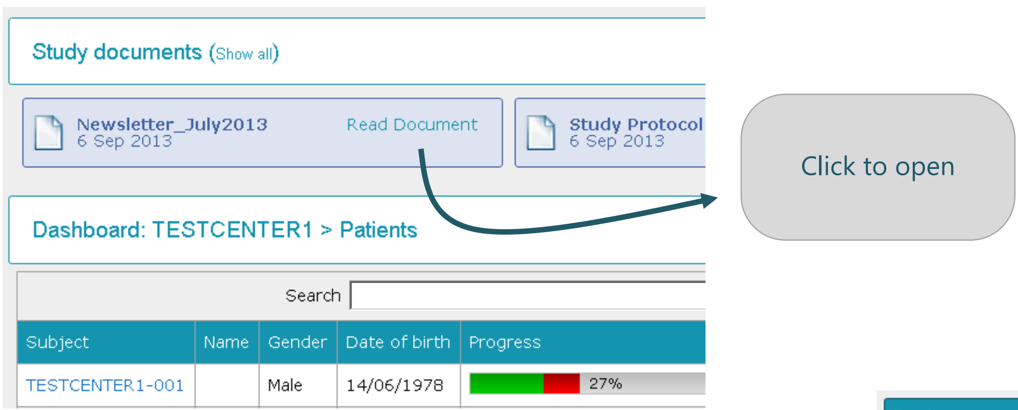
6.2 SDV STATUS

Icon	Meaning	Consequences
	No SDV performed yet	▪ The e-CRF form can still be updated. ▪ Signing is allowed ▪ Query actions are allowed
	Partial SDV Invalidated SDV	▪ The e-CRF form can still be updated. ▪ Updated items will lose SDV indication (invalidated) ▪ Updates will invalidate signatures, if present. ▪ Query actions are allowed
	Completed SDV	▪ Automatic form freeze ▪ The form cannot be updated ▪ Signing is allowed ▪ Query actions are allowed

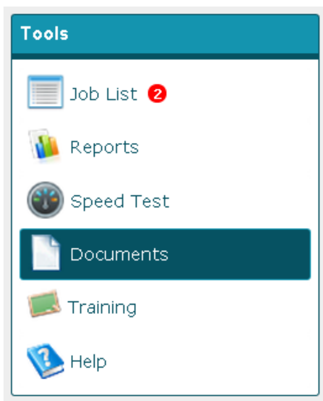
7 CONSULT DOCUMENTS

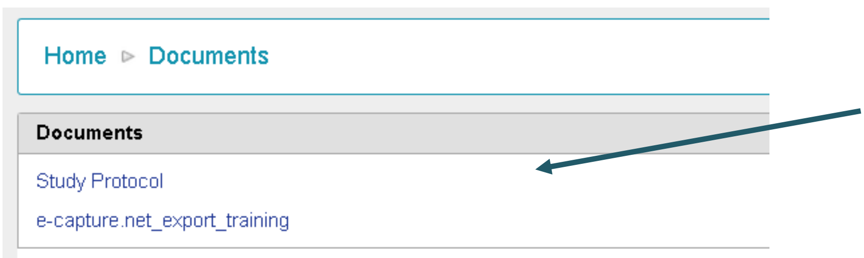
If applicable to your study, documentation (newsletters, PIC, Protocol) can be added and opened within e-capture.net

3. Embedded on the home page:



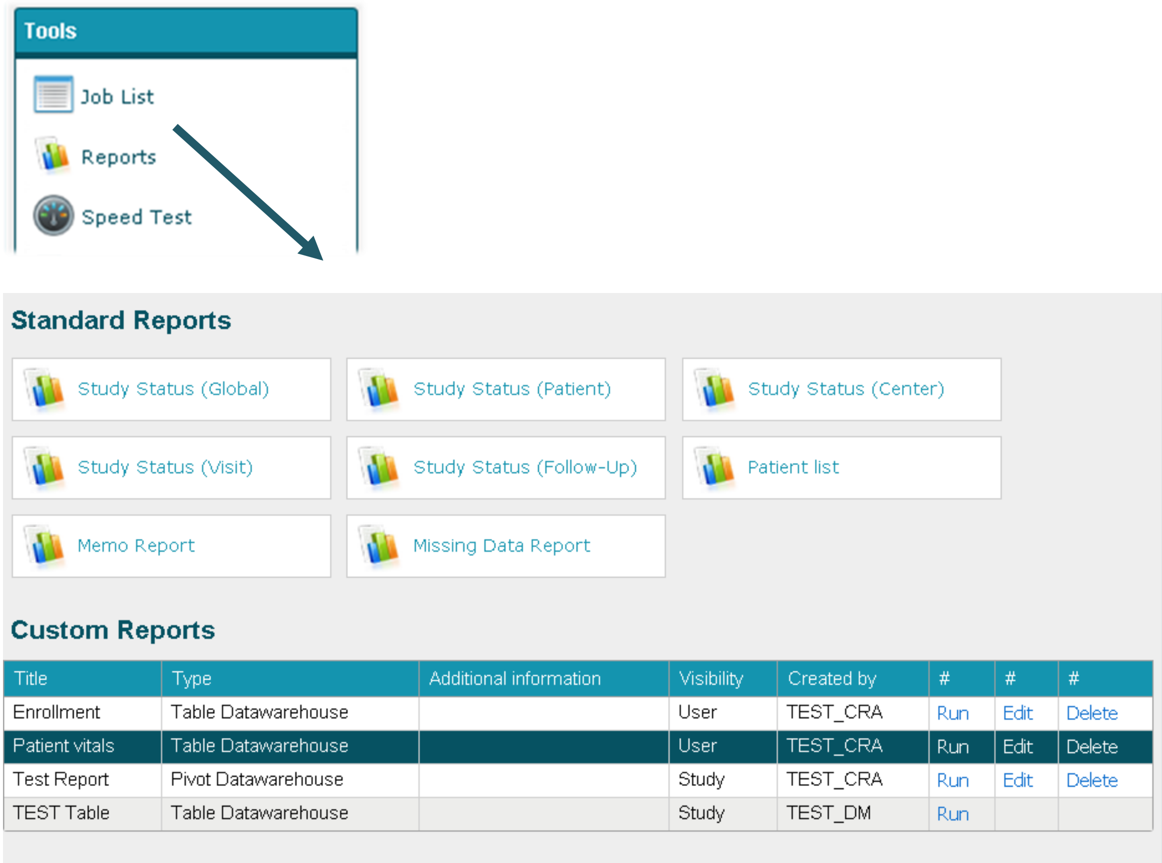
4. Within the Documents tab in the Tools list:





8 REPORTS:

The Reports functionality offers both a list of general reports and customized (implemented) reports.
Click the **Reports** link in Tools to navigate to this page:



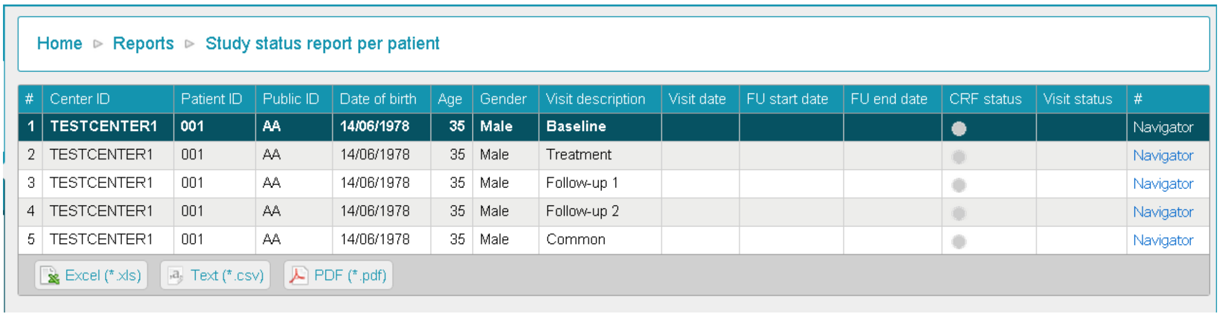
8.1 GENERAL REPORTS

General reports area standard functionality in e-capture.net.
As presented in the image above, there are several reports, starting from a **global study report**, which includes all the patients and all the centers, to more specific study reports **by patient, by center,** or by **visit**.
These reports are available for all user roles.
The reports: **Memo Report** and **Missing Data report** will only be available for user roles that do not have data entry access.
Standard reports are ready-made reports updated to real time data when running.

NOTE: REPORTS ARE GENERATED FOR ALL STUDY DATA, BUT ONLY THE STUDY DATA OF THE CENTERS YOU HAVE ACCESS TO WILL BE AVAILABLE FOR YOU WHEN RUNNING A GENERAL REPORT.

Back to top ↺

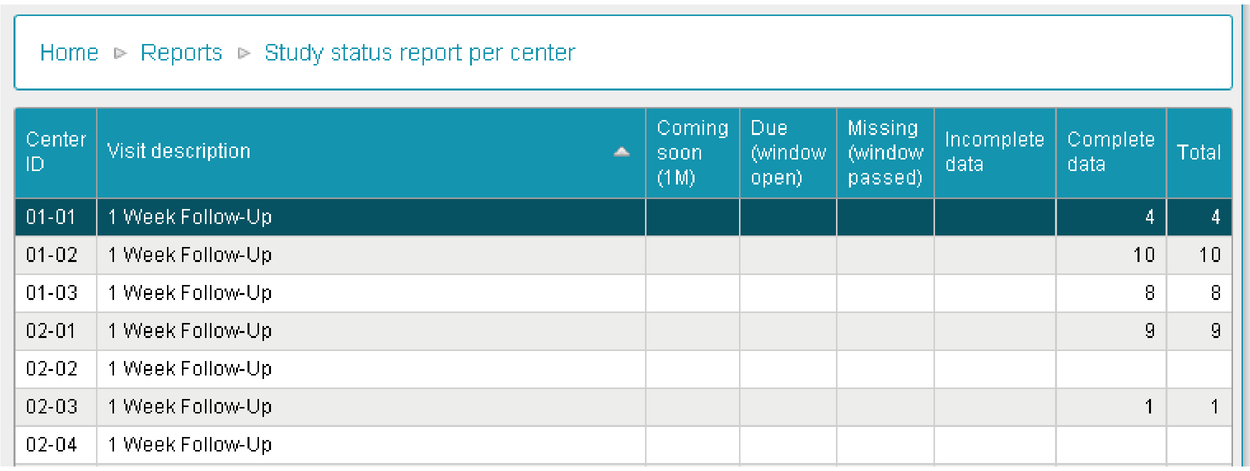
The screenshot below shows an example of the Study Status per patient as shown for a user with access rights to one study center.



#	Center ID	Patient ID	Public ID	Date of birth	Age	Gender	Visit description	Visit date	FU start date	FU end date	CRF status	Visit status	#
1	TESTCENTER1	001	AA	14/06/1978	35	Male	Baseline						Navigator
2	TESTCENTER1	001	AA	14/06/1978	35	Male	Treatment						Navigator
3	TESTCENTER1	001	AA	14/06/1978	35	Male	Follow-up 1						Navigator
4	TESTCENTER1	001	AA	14/06/1978	35	Male	Follow-up 2						Navigator
5	TESTCENTER1	001	AA	14/06/1978	35	Male	Common						Navigator

NOTE: THE LAST COLUMN OF THE REPORT FORESEES A LINK TO THE E-CRF OF THE RESPECTIVE PATIENT (**NAVIGATOR**).

The screenshot below shows an example of the Study Status per center as shown for a user with access rights to all study centers.



Center ID	Visit description	Coming soon (1M)	Due (window open)	Missing (window passed)	Incomplete data	Complete data	Total
01-01	1 Week Follow-Up					4	4
01-02	1 Week Follow-Up					10	10
01-03	1 Week Follow-Up					8	8
02-01	1 Week Follow-Up					9	9
02-02	1 Week Follow-Up						
02-03	1 Week Follow-Up					1	1
02-04	1 Week Follow-Up						

NOTE: SIMILAR TO ALL TABLE LISTINGS IN E-CAPTURE.NET, ALL REPORTS CAN BE EXPORTED TO EXCEL, PDF OR TEXT FORMAT.
YOU CAN DRAG & DROP COLUMN HEADERS TO CHANGE THE ORDER OF THE COLUMNS AND LIST THE ENTRIES BY COLUMN HEADER. SEE ALSO CHAPTER: SEARCH AND FILTER OPTIONS

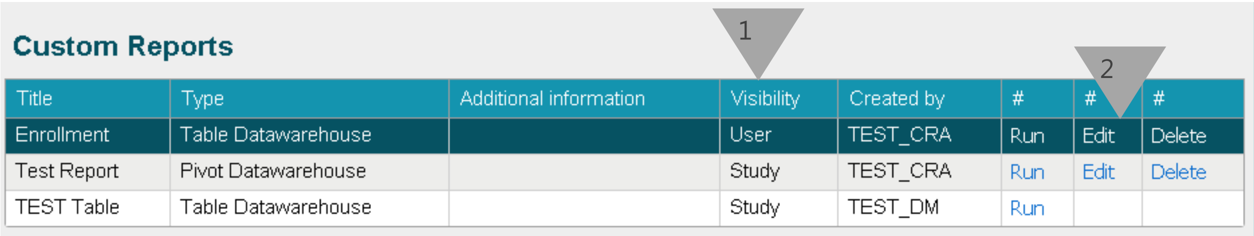
8.2 CUSTOM REPORTS

Depending on the study set up and the rights assigned to your user role, you might have read-only, no access or create access to Customized reports. When running a report, the system will always respect your user center access definitions. The report will show data only for your applicable patients, even if the report is created by another user who has different patient access rights.

8.2.1 CREATE ACCESS

If your user role has write access to the custom reports, you can do the following:

- Create, run, update and delete your own study reports ①.
- Run public reports from other users ②.
- You will be able to edit other user's reports and run these to get updated information. You can however not save any changes made to reports that you did not create by yourself.



Custom Reports

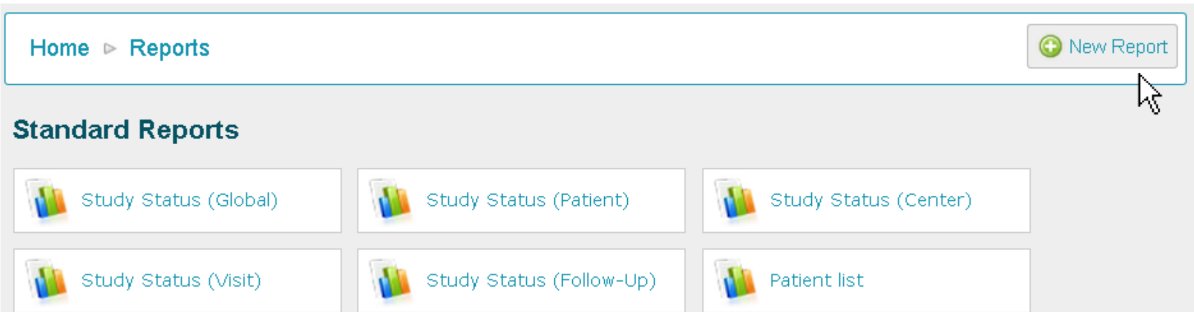
Title	Type	Additional information	Visibility	Created by	#	#	#
Enrollment	Table Datawarehouse		User	TEST_CRA	Run	Edit	Delete
Test Report	Pivot Datawarehouse		Study	TEST_CRA	Run	Edit	Delete
TEST Table	Table Datawarehouse		Study	TEST_DM	Run		

8.2.2 READ-ONLY ACCESS

If your user role has read access to the custom reports, you can run the public reports that other users have created. Data shown in these reports will respect your patient access limitations.

8.2.3 CREATE CUSTOM REPORTS (ONE FORM)

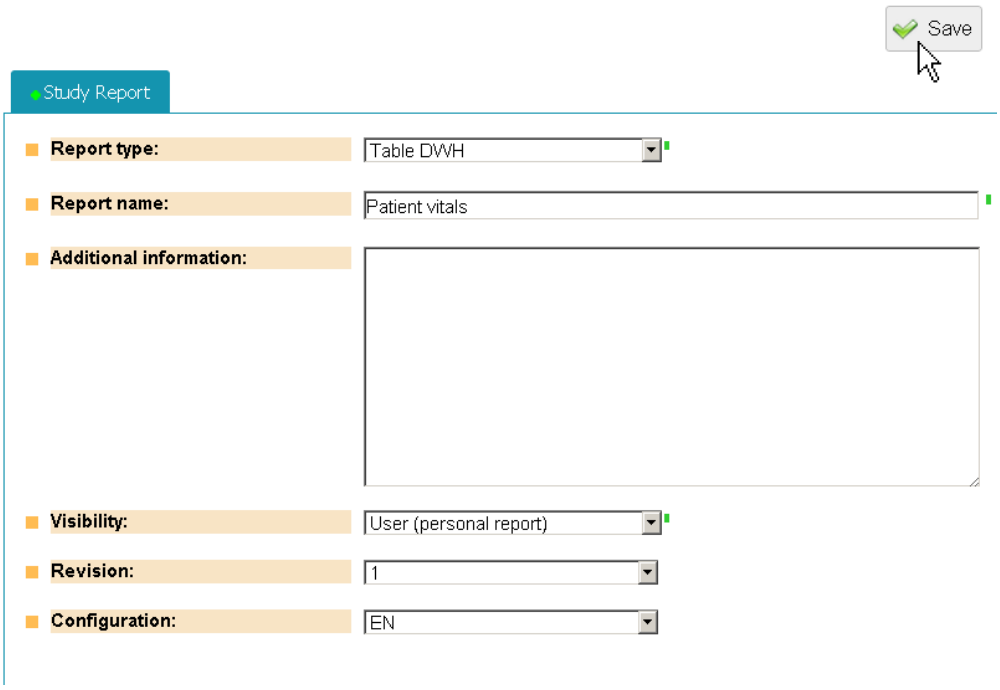
1. Click ' New Report' on the right top of the page to add a new row to the custom report list:



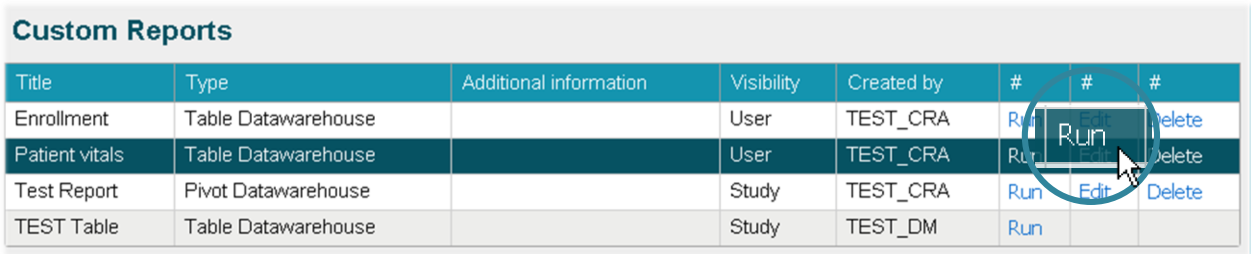
2. Before you can start selecting the content of your report, you first need to create a 'table frame'.
3. Within the Study Report window:

- Select the applicable report type: Table DWH (each selected question indicated one column) or Pivot DWH (DWH= Data Warehouse).
- Enter a report name
- Select the visibility: user (personal) or study (public for all users with access to Custom Reports).
- Click Save.

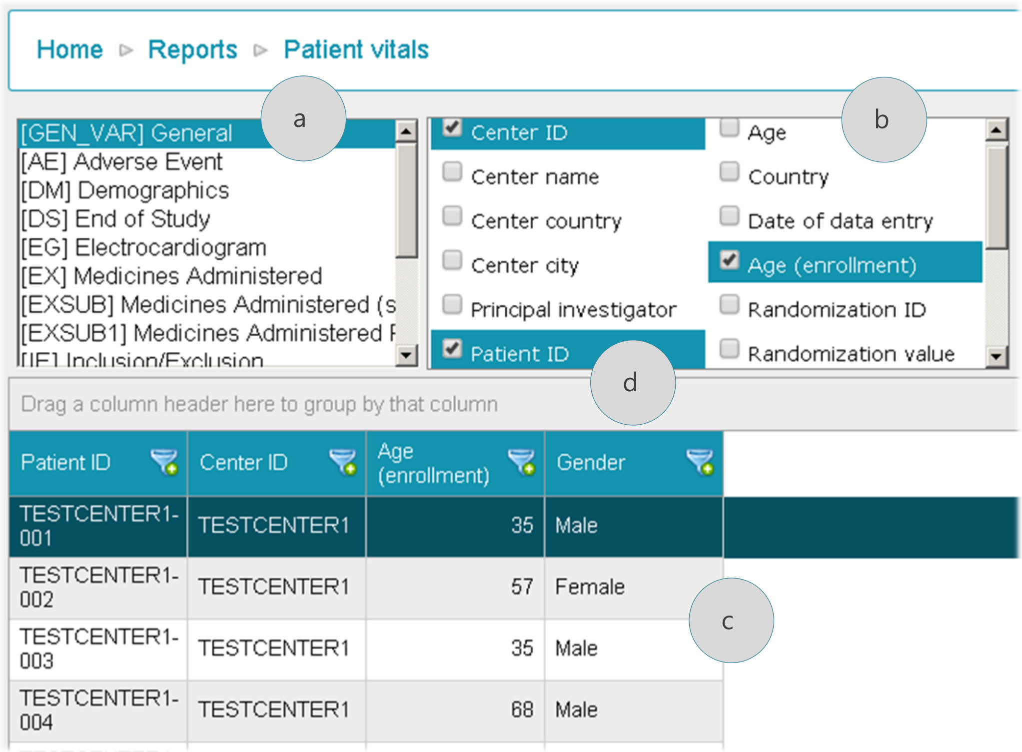
NOTE: PATIENT ACCESS LIMITATIONS ARE RESPECTED FOR EACH USER. DIFFERENT USERS MIGHT GET LESS/MORE PATIENTS IN THE SAME REPORT.



You will be redirected to the previous screen, where the table title is now added to the custom reports.



4. Click 'Run' to select content for your report:



The top left selection box holds a list with all study forms.

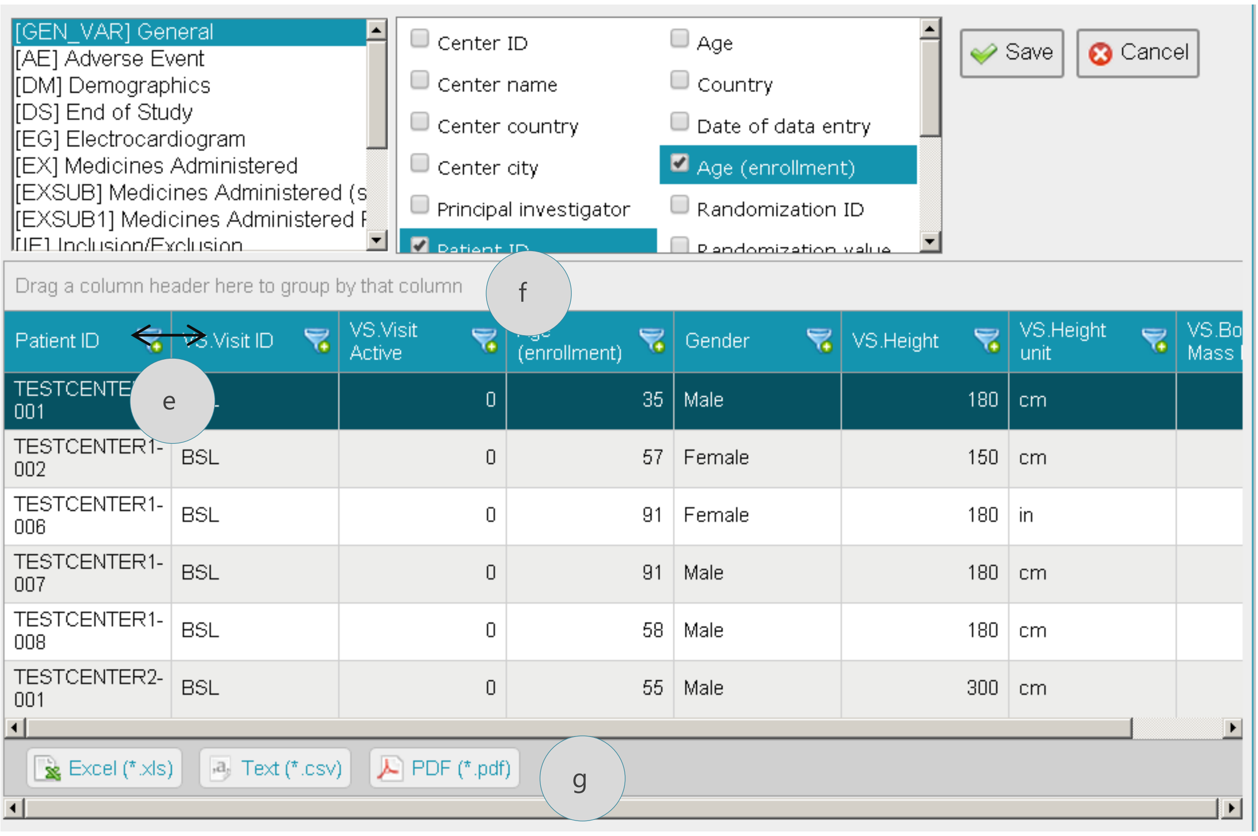
- The top right selection box contains the listing of all question and status ID's within the selected forms in (a).

Below these columns is the actual report table.

- Question ID's : Patient ID, Center ID, Age and Gender are included by default. You can easily remove these ID's by unchecking the checkboxes in (b).
- Select the form to analyze from the left selection box (a)
- Select the questions or status indicators you want to display in your table at the right selection box (b).
- Selected items are immediately visible in the report (c).

NOTE: ALL QUESTIONS WITHIN THE E-CRF CAN BE SELECTED TO CREATE TABLES, IF THE REQUIRED QUESTION IS NOT SHOWN, USE THE SLIDE BAR ON THE RIGHT

IN CASE A FORM IS USED IN MULTIPLE VISITS, SELECT 'VISIT DESCRIPTION' IN THE QUESTION BOX, TO SPECIFY THE VISIT FOR WHICH THE DATA IS APPLICABLE.



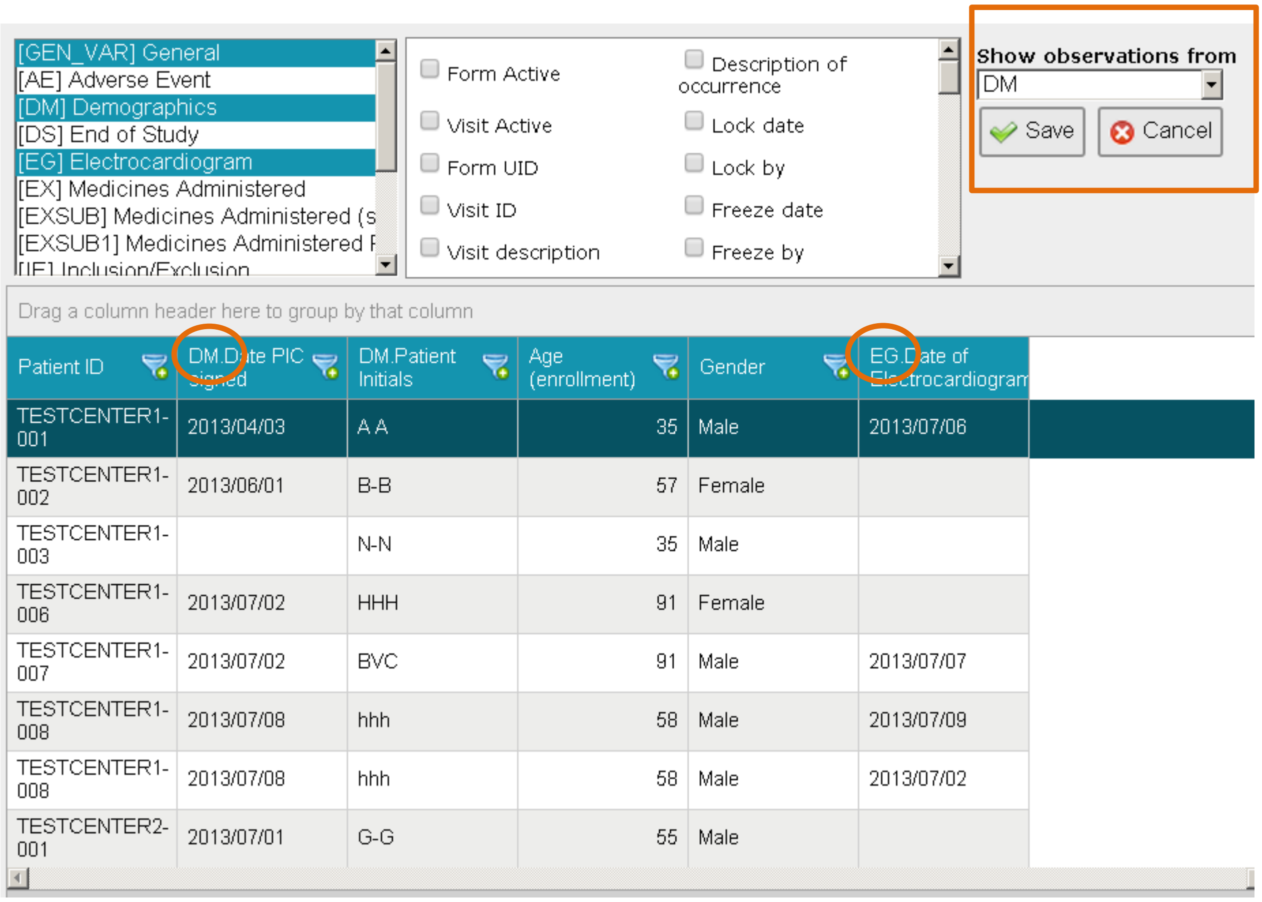
- You can adjust the column widths for better viewing and as in all tables within e-capture.net, you can change the order of the columns by drag & dropping the header rows (e).
- Search and filter options are available for each column header (f).
- You can export all reports in Excel, PDF or csv (g).

If you need to report questions from one form only, your table is ready (see next item for creating reports with multiple forms)

5. Click save.

8.2.4 CREATING A REPORT WITH MULTIPLE FORMS

When you create a data warehouse report, you can select multiple forms and multiple questions.
All selected items will be displayed in your report, every ID in 1 column.
When you have selected items on more than one e-CRF form, you need to select the **observations form** you wish to analyze.

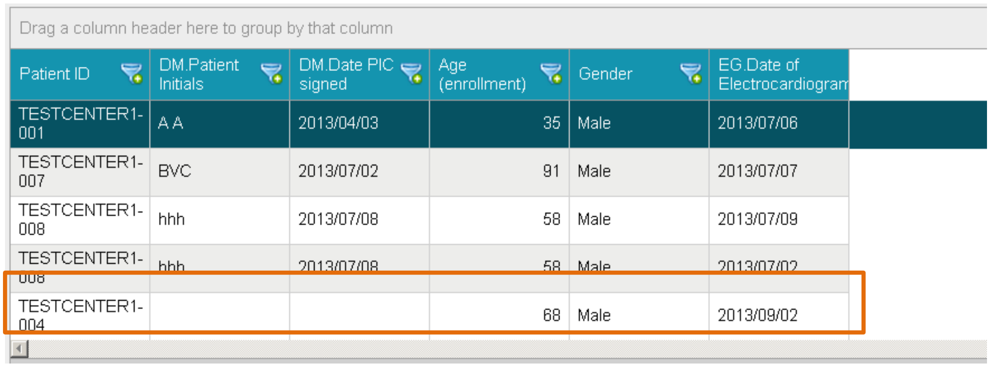


Patient ID	DM.Date PIC signed	DM.Patient Initials	Age (enrollment)	Gender	EG.Date of Electrocardiogram
TESTCENTER1-001	2013/04/03	A A	35	Male	2013/07/06
TESTCENTER1-002	2013/06/01	B-B	57	Female	
TESTCENTER1-003		N-N	35	Male	
TESTCENTER1-006	2013/07/02	HHH	91	Female	
TESTCENTER1-007	2013/07/02	BVC	91	Male	2013/07/07
TESTCENTER1-008	2013/07/08	hhh	58	Male	2013/07/09
TESTCENTER1-008	2013/07/08	hhh	58	Male	2013/07/02
TESTCENTER2-001	2013/07/01	G-G	55	Male	

The screenshot above shows the report with ID's from Demographics (DM) and Electrocardiogram (EG).
Observations are shown from DM, meaning that all applicable records from the DM form are listed.

- Patients that have an entry for DM but not for 'Date of Electrocardiogram' (EG) will be listed (priority = DM). Patients that do not have entries for DM, but do have a date entered for Electrocardiogram will not be listed.

The screenshot below shows the same report, but now **observations are shown from EG**:



Patient ID	DM.Patient Initials	DM.Date PIC signed	Age (enrollment)	Gender	EG.Date of Electrocardiogram
TESTCENTER1-001	A A	2013/04/03	35	Male	2013/07/06
TESTCENTER1-007	BVC	2013/07/02	91	Male	2013/07/07
TESTCENTER1-008	hhh	2013/07/08	58	Male	2013/07/09
TESTCENTER1-008	hhh	2013/07/08	58	Male	2013/07/02
TESTCENTER1-004			68	Male	2013/09/02

In this view, only the records are listed for which there is a Date of Electrocardiogram present.

- The first 4 rows were also present in the first view (Show observations for DM), but there is also a new record that was not shown in the first view (a patient that does not have entries for 'initials' or 'date of PIC signed' (DM), but does have a date entered for Electrocardiogram).
- The records from the first view with an empty 'Date of Electrocardiogram' or also not listed in this view.

NOTE: IF YOU NEED A REPORT THAT LISTS THE OBSERVATIONS OF (A) CERTAIN FIELD(S) FOR ALL PATIENTS (EVEN EMPTY RECORDS), YOU NEED TO MAKE SURE TO INCLUDE AN ID IN THE REPORT THAT IS LIKELY TO HAVE CONTENT FOR ALL PATIENTS (EXAMPLE: DATE PIC SIGNED OR SCREENING DATE). IN THIS CASE, BY CHOOSING **SHOW OBSERVATIONS** FOR THE FORM THAT INCLUDES THIS ID, ALL PATIENTS WILL BE LISTED IN THE REPORT.

Selecting what to analyze

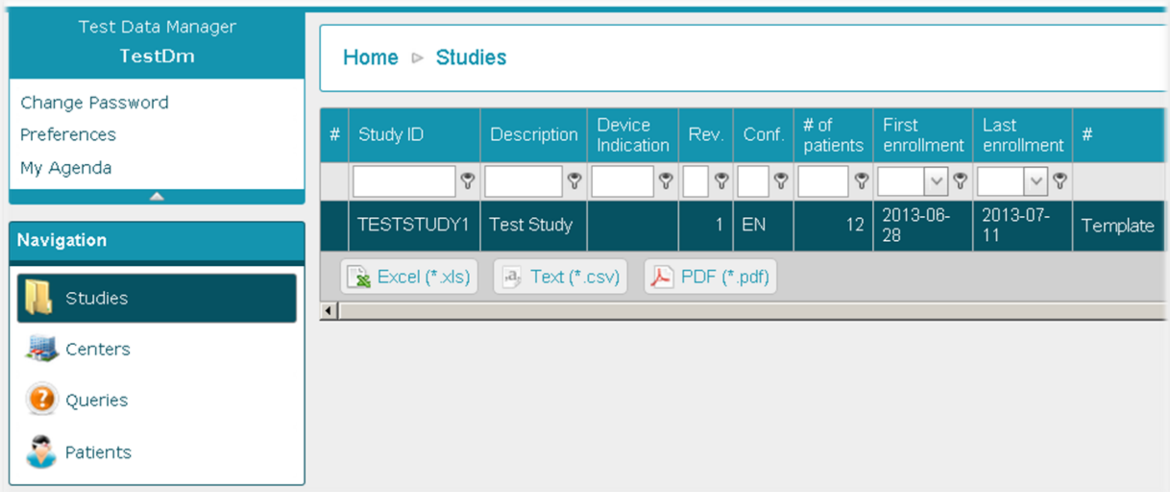
As mentioned in items above, the right selection box contains all question and status ID's of the selected form. You can select following items:

- Question ID: adding a question ID in your report will generate for each patient and each visit where the respective form is present the data that was entered for this question.
- Example: Question ID= Age will generate a column in your report in which the entered or calculated age of each patient is present.
- Status ID: adding a status ID in your report will generate for each patient and each visit where the respective form is present, the selected status of this form.
- Example: Lock date, Freeze by, SDV status, Sign date,...
- Form Active: this ID indicates if a form is active (value = 0) or inactive (value = 1).
- Visit Active: this ID indicates if a visit is active (value = 0) or inactive (value = 1).

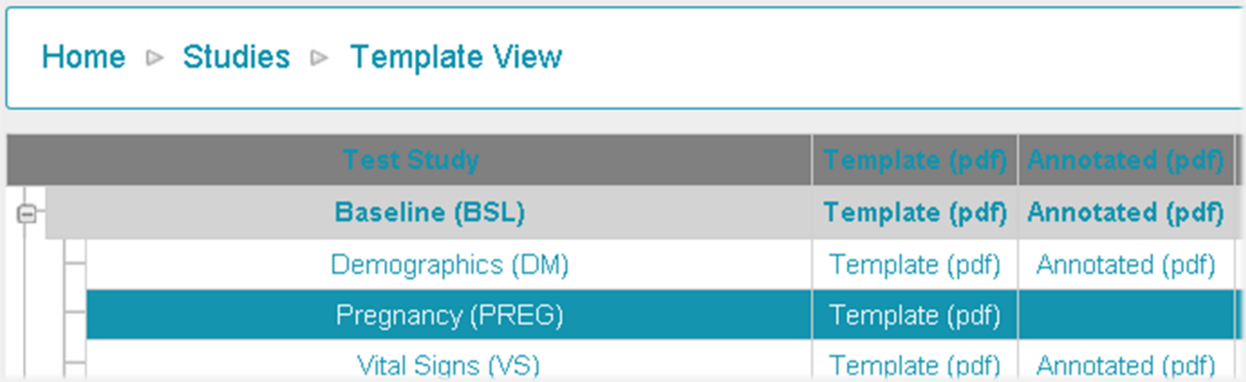
Finding form names and question ID's

Before you start creating your table, it is best to check the form names at the template navigator.

1. Click 'Study' at the left toolbar.



2. Click 'template' at the study information table to view all form names and ID's



Make sure there is only one form ID for the form you would like to create your report.

- A form that has identical question content in multiple visits will have the same ID for each visit. Including this ID in a report will generate records for this form of each applicable visit.

To visualize these forms in your report, it is recommended to select 'visit description' in the question selection box.
A 'visit description' column will be added to the report, allowing you to filter per visit.

- A form that does not have identical question content between visits will be indicated with a different form name (example: VS1, VS2).

Including <u>one of these</u> ID's in a report, will only generate the occurrences of the visits with the selected form ID in your report.

- In this last case you have two options :

1. create a Single form report on each of the form ID's
2. create a Multiple form report (see guidelines on Multiple form Creation)

8.2.5 CREATING PIVOTAL TABLES

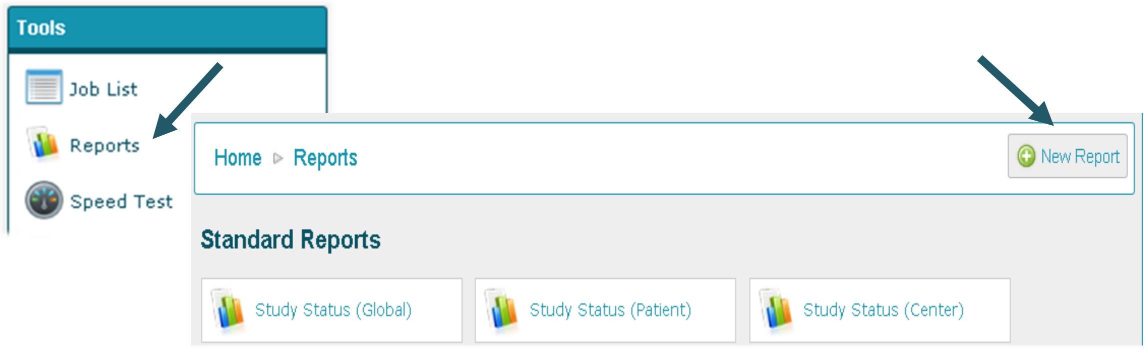
A pivotal table will not show you any entered data, but will give you a count on the specified table item. Before creating your pivotal, it's important to know what you want to count number of patients where this occurred, or the number of occurrences completed ?

3 steps are needed to create your pivotal table :

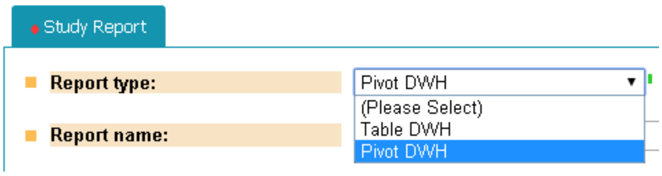
1. Create your pivotal table (without data).
2. Select items to add to your table.
3. Create your table layout.

A. **Create your pivotal table** :

- click 'Reports' in the left toolbar
- click 'new report' in the right upper corner of the e-capture.net screen



- Select 'pivotal' as report type
  And also specify report name
  and report visibility



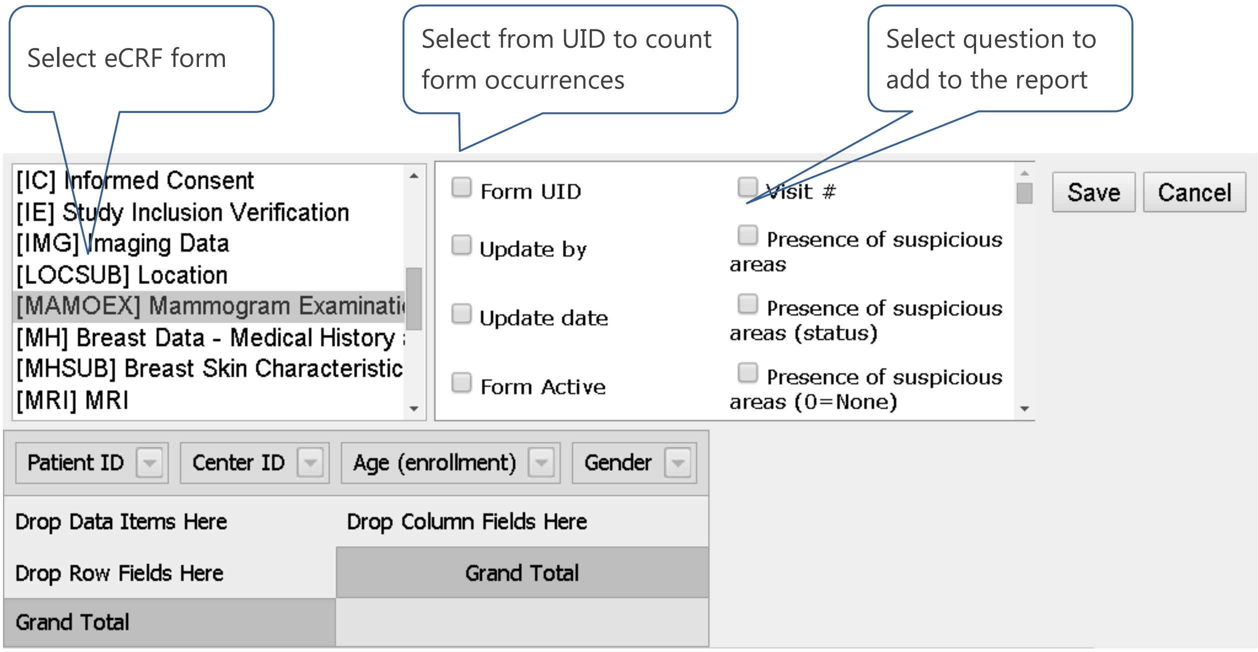
Before you start adding content to your table, it's important to reflect on what exactly you want the table to count. If you want a report on Adverse Events, you want to list all AE's occurred, not the number of patients that events.

NOTE: SELECT 'PATIENT (COUNT)' FROM THE 'GENERAL' ITEMS TO COUNT THE NUMBER OF PATIENTS FOR WHICH A CERTAIN QUESTION WAS COMPLETED (COUNT = 1 PER PATIENT, EVEN IF THE FORM WAS COMPLETED MULTIPLE TIMES.

SELECT 'FORM UID' IN THE QUESTION BOX OF THE SELECTED FROM TO COUNT ALL FORM OCCURRENCES FOR WHICH A QUESTION WAS COMPLETED.

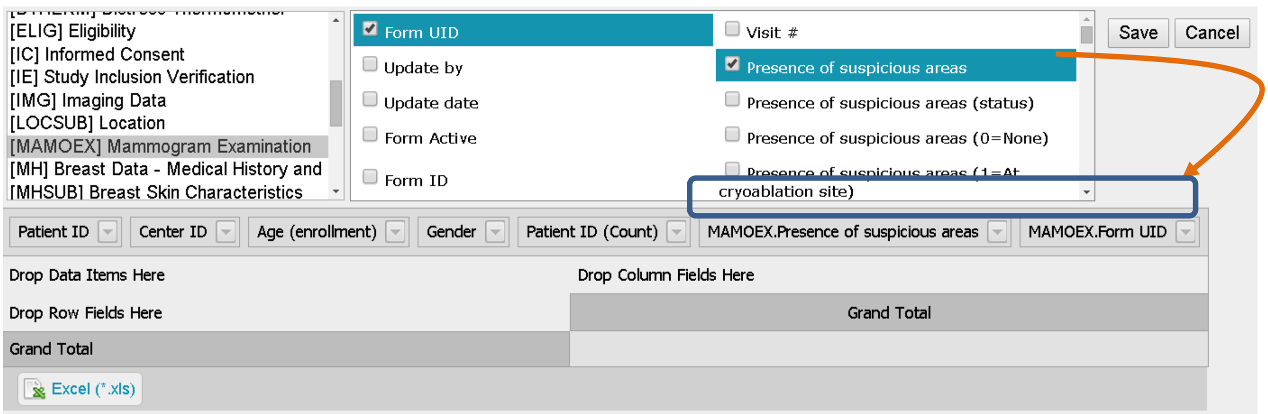
APART FROM COUNTING OCCURRENCES (# FORMS COMPLETED OR # OF PATIENTS), YOU CAN ALSO CREATE PIVOTALS FOR MAXIMA, MINIMA, ETC. FOR THIS, SELECT THE QUESTION WITH '(MAX)' OR '(MIN)' ADDED TO THE QUESTION LABEL.

B. Select content for your Pivot table



- Select the form you want to create a report on.
- Select the applicable questions to add to the report.
- Select the form UID in case you need to count all form occurrences (important if the form is used multiple times per patient.

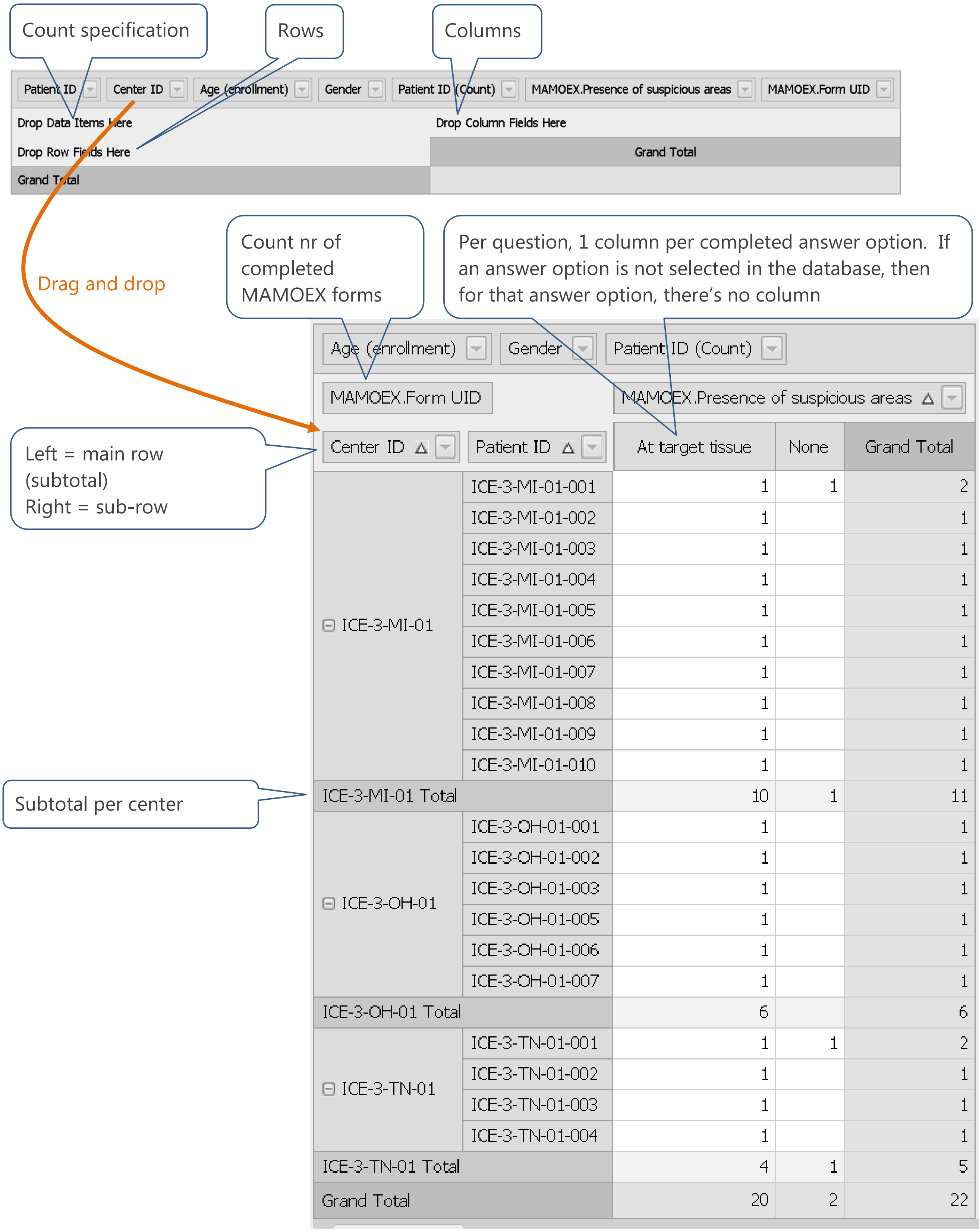
All selected items are added to the selection row on top of your table.



C. Create table layout

Via drag & drop, you can create your table layout

- Rows & sub-rows to show (eg, subtotal per center)
- Columns to show (& sub-columns if applicable)
- Items to count



Center ID	Patient ID	At target tissue	None	Grand Total
ICE-3-MI-01	ICE-3-MI-01-001	1	1	2
	ICE-3-MI-01-002	1		1
	ICE-3-MI-01-003	1		1
	ICE-3-MI-01-004	1		1
	ICE-3-MI-01-005	1		1
	ICE-3-MI-01-006	1		1
	ICE-3-MI-01-007	1		1
	ICE-3-MI-01-008	1		1
	ICE-3-MI-01-009	1		1
	ICE-3-MI-01-010	1		1
ICE-3-MI-01 Total		10	1	11
ICE-3-OH-01	ICE-3-OH-01-001	1		1
	ICE-3-OH-01-002	1		1
	ICE-3-OH-01-003	1		1
	ICE-3-OH-01-005	1		1
	ICE-3-OH-01-006	1		1
	ICE-3-OH-01-007	1		1
ICE-3-OH-01 Total		6		6
ICE-3-TN-01	ICE-3-TN-01-001	1	1	2
	ICE-3-TN-01-002	1		1
	ICE-3-TN-01-003	1		1
	ICE-3-TN-01-004	1		1
ICE-3-TN-01 Total		4	1	5
Grand Total		20	2	22

Back to top ↺

8.3 CUSTOM IMPLEMENTED REPORTS

Custom reports can be created for your study specifically, and added at the general report section. The visibility of these reports depends on the rights assigned to your user role.

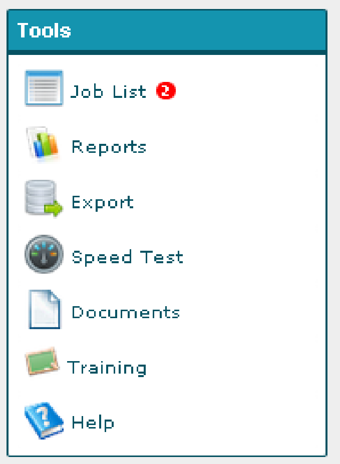
Example: CEC and Safety report for user profiles: CEC member and safety Officer:

TEST STUDY – CEC Report

TEST STUDY – Safety Report

Name	Date of birth	Age	Gender	AE category	CEC label	CEC date	CEC signed by	CEC sign date
	1950/12	62	Male	SADE	CEC-1 on AE-2	2012/03/01	BFII_CEC1	2012/11/15
	1950/12	62	Male	SADE	CEC-2 on AE-2	2012/03/01	BFII_CEC2	2012/11/15
	1950/12	62	Male	SADE	CEC-3 on AE-2	2012/03/01	BFII_CEC3	2012/11/15
	1950/12	62	Male	Seriousness unknown	CEC-1 on AE-3	2012/03/26		
	1950/12	62	Male	Seriousness unknown	CEC-2 on AE-3	2012/03/26	BFII_CEC2	2013/07/26

9 EXPORTS

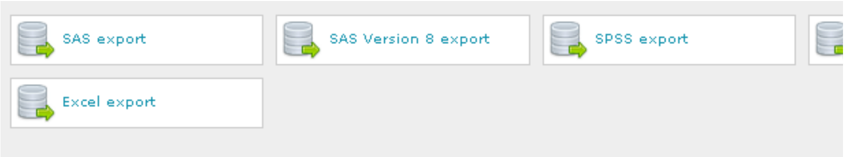


The Export tool allows you to export full study datasets in excel, SAS, CDISC ODM or SPSS format.
Access to this tool depends on the rights assigned to your user role.

9.1 CREATE DATA EXPORTS

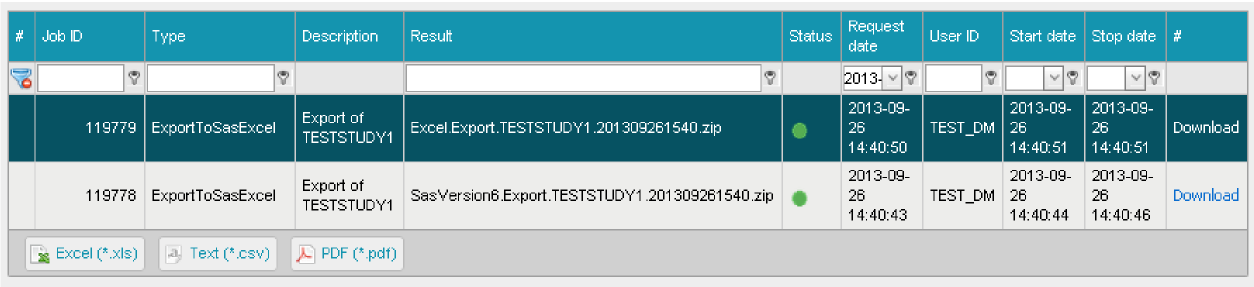
To create an export, follow these steps:

1. Click Export in the Tools menu (left toolbar).
2. Select the required export format in the displayed window:



e-capture.net will create the requested export in the background. The task will be added to the Job list.
You are able to continue working with your study while the export is running.
To check the job status, please click the 'F5' key on your keyboard. When the job marker is green, the export is ready for download.

3. Download the export from the Job list:



#	Job ID	Type	Description	Result	Status	Request date	User ID	Start date	Stop date	#
	119779	ExportToSasExcel	Export of TESTSTUDY1	Excel.Export.TESTSTUDY1.201309261540.zip		2013-09-26 14:40:50	TEST_DM	2013-09-26 14:40:51	2013-09-26 14:40:51	Download
	119778	ExportToSasExcel	Export of TESTSTUDY1	SasVersion6.Export.TESTSTUDY1.201309261540.zip		2013-09-26 14:40:43	TEST_DM	2013-09-26 14:40:44	2013-09-26 14:40:46	Download

Excel (*.xls) Text (*.csv) PDF (*.pdf)

4. Save the ZIP file in an appropriate location

NOTE: TO CREATE A STUDY QUERY EXPORT, PLEASE CHECK THE SECTION 'FULL STUDY QUERY LIST – QUERY EXPORT' .

Back to top ↺

9.2 OPEN EXPORTS

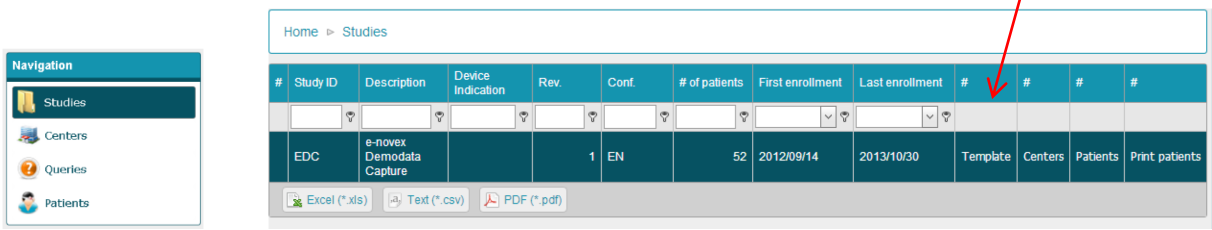
Depending on your computer settings, you may need to specify with which program you would like to open your export.

1. Click on the saved ZIP file.
2. Click the applicable export file to open via the applicable program.

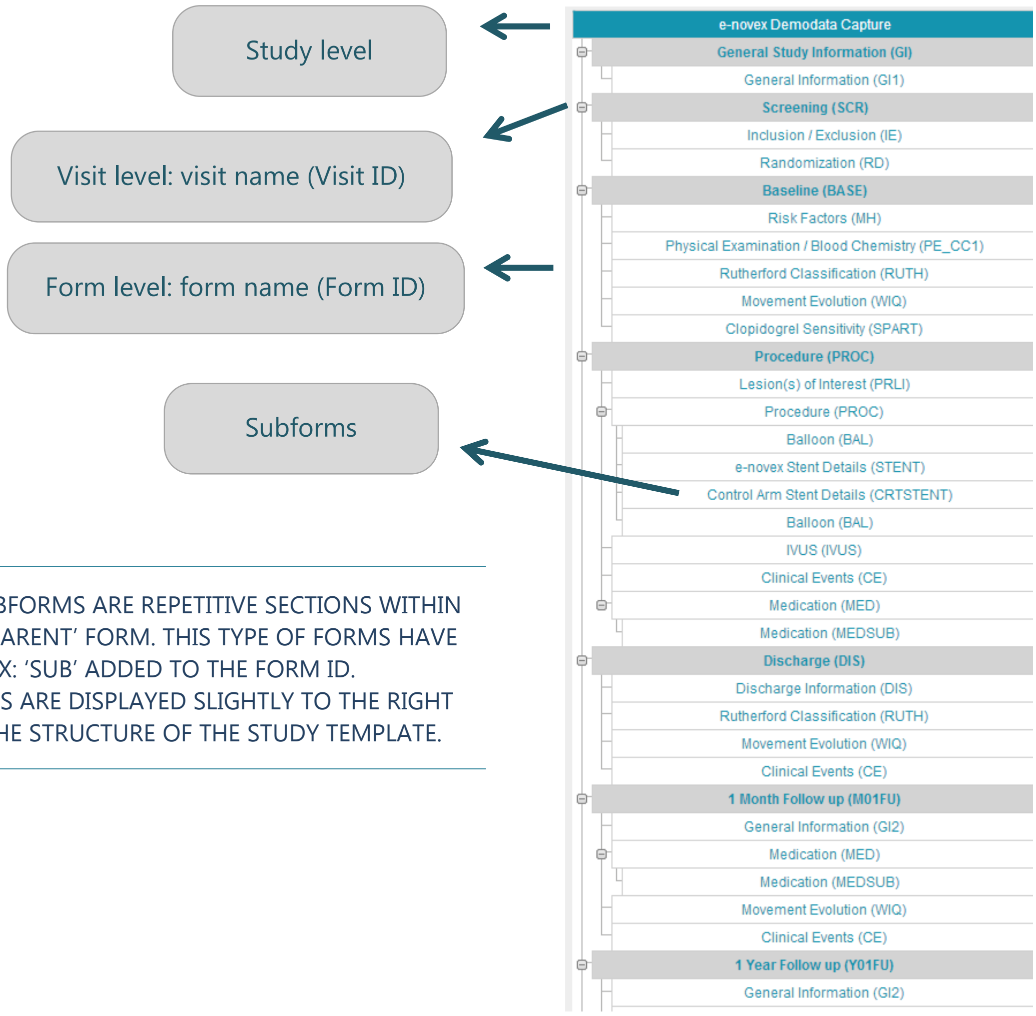
9.3 TOOLS TO READ AN EXPORT

9.3.1 THE STUDY TEMPLATE

The study template shows the study structure, and indicates which export files are related
You can find the study template via the left toolbar 'studies' and next click the 'template' link



In the template, the study level is indicated in color, the visits are indicated in grey, and the forms are white rows



NOTE: SUBFORMS ARE REPETITIVE SECTIONS WITHIN A MAIN 'PARENT' FORM. THIS TYPE OF FORMS HAVE THE PREFIX: 'SUB' ADDED TO THE FORM ID. SUBFORMS ARE DISPLAYED SLIGHTLY TO THE RIGHT WITHIN THE STRUCTURE OF THE STUDY TEMPLATE.

9.3.2 ANNOTATED CRF

The Annotated CRF holds all questions ID's that are present within the eCRF forms that are shown in the study template. For each question, the answer values are shown before each answer text, OR the code list is indicated next to the question ID. (eg *AECODE*/AECODE = *Question ID*/Codelist)
Follow these steps to print the annotated CRF of your study:

- Click the 'Annotated PDF' link in the study template. The annotated CRF can be obtained at following levels :
- at study level for the entire study Annotated CRF
- at visit level for 1 specific visit
- at form level for 1 specific form

Specifications

a) 1 Form ID = 1 export file

In the study template, all forms are displayed on the correct location following the study structure.

- Some forms may seem very similar, but are actually different forms with different form ID's. each separate form has a separate export file (eg, GI1,GI2 in the study template).
- If a form is present in multiple visits, the data for all visits is included in the same form export file (example MED in the study template).

b) Relations between forms (Parent forms / subforms / repetitive forms)

Some forms have repetitive sections (subforms). Subforms have their own form ID and therefor create a separate export file.

- For most subforms, the form name is the same as the parent form, with 'SUB' added to the subform ID (eg 'MED' and subform 'MEDSUB'), but this is not always the case. Please check the study template to see the links between the forms/subforms.
- To find the link between the subform and linked parent form, please create a link between the column **'parent_id' in the subform-export file and the question ID for the subform in the parent form**. Both columns will show the same number for the link between the parent & child.
- Each subform or repetitive form can be completed multiple times. Therefor a repetitive (sub) form has a form number, which is indicated in the export column **'form_occurrence'.**
- **Fixed forms** can only be completed once per visit (eg DIS). The 'form_occurrence' for fixed forms is '0'.
- A repetitive visit (ex. free follow up) has a visit number, indicated in export column '**visit_occurrence**
  If the 'visit occurrence' is '0', then this is a fixed visit (not repetitive).

c) Forms similar, but with separate export files

Some CRF forms look very similar, and may even have multiple question ID's identical in the annotated CRF, but when there are any differences, the form will have a different form ID (eg: GI1, GI2 in the study template).
When analyzing these forms as a grouped item, please create links between the identical (or similar) questions in each form export.

d) To which visit belongs a form

Some forms are present in multiple visits (eg CE in the study template).

- The export file indicates the visit ID (column '**visit_id'**)
- The visit ID will be clear for forms in fixed visits (procedure, discharge, follow-up, …)
- Filtering the export file to one specific visit _id value, gives all results for this one specific visit.
- The **'GEN'** indication at the 'visit_id' column means that these are forms that can be used during the entire study, or the time point of this form is not known at study start. (eg Adverse Event).
- When the 'visit_id' = 'GEN', **consult the annotated CRF of this form for a time - point indicating question.** You can then link this time point to visit_id's of other export files.

e) Answer values / code list values

- On the left side of each answer in the annotated CRF, the answer value is shown, OR the **code list** is indicated next to the question ID. (eg *AECODE*/AECODE = *Question ID*/Codelist)
- You find the **Code list values via search in** the 1 export file in different formats
- **.sas file** in the SASv6 / SASv8 export
- **.inf file** in the Excel export

Example : the code list for the AECODE dropdown =

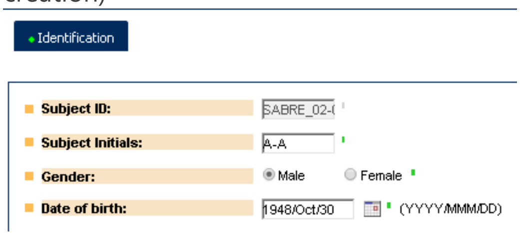
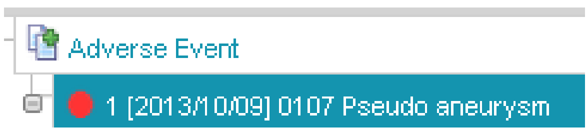
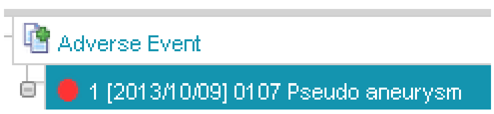
VALUE AECODET
1 = "01 Blood - Blood and lymphatic system disorders"
2 = "02 Card - Cardiac disorders"
3 = "03 Cong - Congenital, familial and genetic disorders"
4 = "04 Ear - Ear and labyrinth disorders"
5 = "05 Endo - Endocrine disorders"
6 = "06 Eye - Eye disorders"
7 = "07 Gastr - Gastrointestinal disorders"
8 = "08 Genrl - General disorders and administration site conditions"
9 = "09 Hepat - Hepatobiliary disorders"
10 = "10 Immun - Immune system disorders"
11 = "11 Infec - Infections and infestations"
12 = "12 Inj&P - Injury, poisoning and procedural complications"
13 = "13 Inv - Investigations"
14 = "14 Metab - Metabolism and nutrition disorders"
15 = "15 Musc - Musculoskeletal, connective tissue and bone disorders"
16 = "16 Neopl - Neoplasms benign, malignant and unspecified (incl cysts and polyps)"
17 = "17 Nerv - Nervous system disorders"
18 = "18 Preg - Pregnancy, puerperium and perinatal conditions"
19 = "19 Psych - Psychiatric disorders"
20 = "20 Renal - Renal and urinary disorders"
21 = "21 Repro - Reproductive system and breast disorders"
22 = "22 Resp - Respiratory, thoracic and mediastinal disorders"
23 = "23 Skin - Skin & subcutaneous tissue disorders"
24 = "24 SocCi - Social circumstances"
25 = "25 Surg - Surgical and medical procedures"
26 = "26 Vasc - Vascular disorders"

NOTE: THE LABELS IN THE .INF OR .SAS FILE ARE LIMITED TO 250 CHARACTERS .

9.3.3 GEN VAR – COLUMNS IN ALL EXPORT FILES

a) Column ID's added to each export file (not in the annotated CRF)

Some fields are not part of the CRF questions, but are still added to each export file. These additional export columns are explained in detail in this chapter, and can help linking data between different export files.

Column header	Value	meaning
center_id	xxx	xx = the center number
subject_id	xxx-yy	xxx = center ID yy = patient number within the center
public_id	3 digit textbox	Patient initials – availability depends on the wet-up of your study. (question during the patient creation) 
calc_gender	1 = Male 2 = Female	
birthdate	Date field	Date of birth
enroll_date	Date field	Date of patient creation in the database
calc_age	Numeric field	Auto calculated current patient age
enroll_age	Numeric field	Auto calculated : age at patient creation in the database
study_id	demo data capture	The study ID is identical for all patients. It is the ID of the database
visit_id	See visit ID in the study template	The (visit ID) is a specific abbreviation of the visit name.
visit_occurrence	Numeric field ▪ Fixed visits : value = '0' ▪ Repetitive visit : value = visit number	See repetitive visits Eg: an unscheduled follow up visit can be completed multiple times. Each unscheduled visit is numbered. The visit number = visit_occurrence
form_occurrence	Numeric field ▪ Fixed form : value = '0' ▪ Repetitive form : value = form number	Eg : adverse event number 1 
form_occurrence_des	Text ▪ Fixed visits : empty ▪ Repetitive visit : value = visit name shown in the patient navigator	Eg, 0107 Pseudo aneurysm 

Column header	Value	meaning
parent_id	Numeric ▪ 0 in case no parent form is linked ▪ [number] in case of a subform export file	Parent ID is the unique form ID of the parent form linked to this specific subform. More details to create links between parent form and subform : see relations between forms - subforms
visit_active	0/1	In your export files this is not applicable (used in the database audit trail)
form_active	0/1	In your export files this is not applicable (used in the database audit trail)
insert_date	Date field	The date the form was 1st saved
insert_by	text	The user account ID that did the 1st form save
change_date	Date field	The date the form was last saved
change_by	text	The user account ID that performed the final form update & form save
lock_date	Date field	The date the form was last locked
lock_by	text	The user account ID that performed the most recent form lock
freeze_date	Date field	The date the form was last frozen (no more data updates are allowed in the form = read only modus, but one can still sign the form or process queries)
freeze_by	text	The user account ID that performed the most recent form freeze
sdv_date	Date field	only completed when the SDV Stand alone feature is activated
sdv_by	text	only completed when the SDV Stand alone feature is activated
sdv_status	text	only completed when the SDV Stand alone feature is activated
sign1_date	Date field	Date of most recent investigator signature on this form
sign1_by	text	The user account ID that performed the most recent investigator signature

NOTE: ALL OTHER COLUMN HEADERS RESEMBLE QUESTION ID'S THAT CAN BE FOUND IN THE ANNOTATED CRF

b) GEN_VAR file

The SASv6 and SASv8 exports hold an additional export file 'GEN_VAR' these variables are not part of any of the CRF forms, but are general values allocated to each created user, linked to the user creation action.
Some of those ID's are also present at each export file.
Not all field ID's in the GEN_VAR will be meaningful for data analysis. Some may even not be in use for your study.

Column header	Value	meaning
SUBJLID	numeric	
SUBJUID	numeric	Unique number allocated to a patient, unrelated to the center ID (database level numbering)
SUBJID	numeric	Equals the 'yy' in the subject_id column in each form export file. To link the SUBID to the Subject_ID, combine with centerID as follows : 'CENTERID –SUBJID' = subject_id
PUBLID		Is linked to the patient initials field in the export files
GENDER	1 = Male 2 = Female	Patient gender = equals 'calc_gender' in the form export files
BRTHDAT	Date Field	Equals the 'birthdate' in the form export files
SUBJAGE	numeric	Identical to the 'calc_age' in each form export file
CENTRLID	Numeric	Unique numeric center number
CENTRUID	Numeric	Unique numeric center number
SUBJSLID	Numeric	Unique numeric patient number
SUBJSUID	Numeric	Unique numeric patient number
ENRLDAT	Date field	Date the patient was created and linked to a specific study center
CENTERID	text	Equals the 'center_id' from the study crf form export files
CENTRDES	Text	Center name The center name is indicated in the center list (shown when ticking 'centers' in the left toolbar
CENTRCTR	Text	Center country The center country is indicated in the center list (shown when ticking 'centers' in the left toolbar
CENTRCTY	Text	Center city The center city is indicated in the center list (shown when ticking 'centers' in the left toolbar

Column header	Value	meaning
CONTACT	Text	Information regarding to contact person at the center. Mostly left blank during center creation
ENRLAGE	numeric	Age at time point of patient creation Equals ‘enroll_age ‘ in the study CRF form export files

MANAGE QUERIES

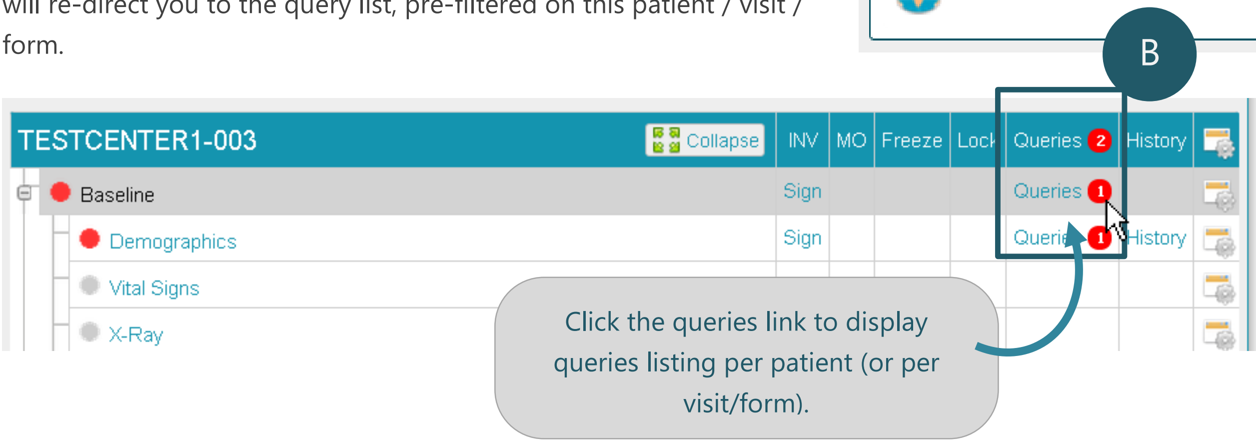
Queries may be raised automatically by the system as a result of a violation of a pre-defined restriction (data entry errors that are inconsistent or outside expected protocol parameters) or set manually by users with appropriate rights to create a query.

1 VIEW QUERIES

1.1 VIEW QUERIES IN THE QUERY LIST

Click the Queries link:

A: In the Navigation box of the left tool bar: this action creates a query list for all patients appointed to you in this study.
B: In the patient navigator: on form/visit or study level → this action will re-direct you to the query list, pre-filtered on this patient / visit / form.



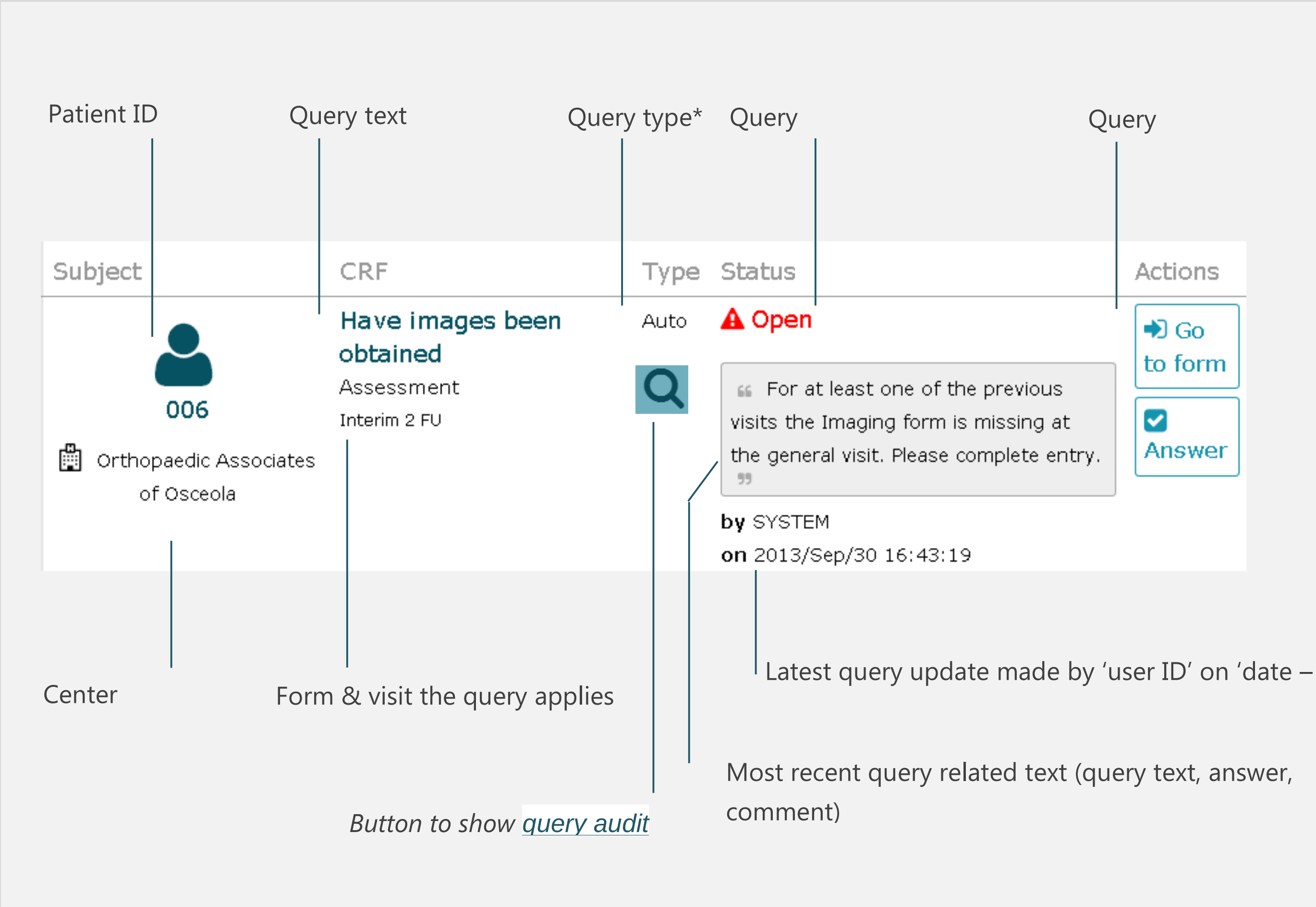
The status of a query is indicated by the color of the query status icon:

- 1 : the visit/form/field contains one or more answered, none closed queries.
- 2 : the visit/form/field contains open, unanswered queries.
- 3 : the visit/form/field contains closed queries.

The number of queries is indicated within the status icon.

NOTE: NAVIGATION , AND SEARCH AND FILTER FOR QUERIES, IS EXPLAINED IN SECTION 'QUERY LISTING'.

1.1.1 QUERY LIST DETAILS



*Query type :

- System queries are auto generated by the system if the entered answer or value is out of protocol range.
- Manual queries are created by monitors, data managers, ...

**Query status

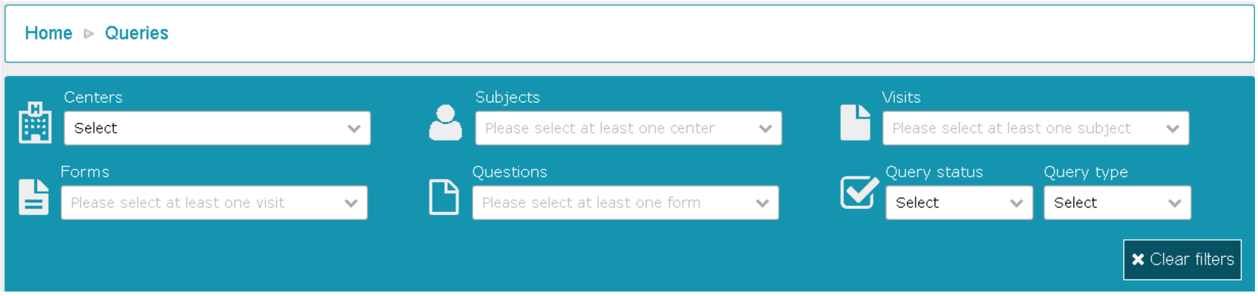
- **Open** : action is required from the data entry users.
- **Answered** : the query is to be reviewed and closed by the Monitor / Data Manager.
- **Closed** : the query is fully processed, no further action is required.
- **Re-opened** : The initial answer did not satisfy the Monitor/ Data Manager, and the question is re-activated via a new linked query. The 're-opened' query row contains the query audit trail of the initial question query. Linked to this question, a second query row indicates the active query part. (Please filter center/patient/visit/form and question in the query list).

***Query actions applicable for your user role .

- The button 'Go to form', brings you to the query location in the eCRF.
- The visibility of the button 'Answer / Close' depends on the rights assigned to your user role.

1.1.2 QUERY LIST FILTERS

Within the query list, you can use the query list filters to search for certain queries.

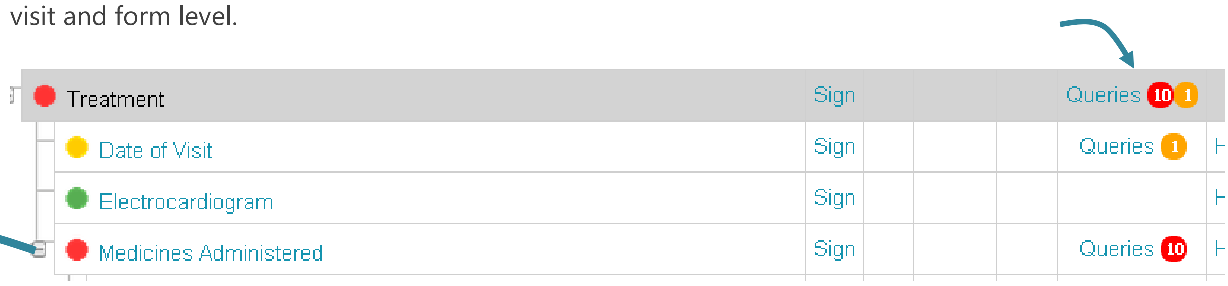


- Centers : filter on one or more centers
- Subjects : filter for one ore more subjects within the range of the filtered centers
- Visist : filter for one ore more Visits within the range of the filtered patients
- Forms : filter for one ore more Forms within the range of the filtered Visits
- Questions : filter for one ore more questions within the range of the filtered Forms .
- Query status : filter for open / answered / closed queries
- Query type : filter for manual and/or auto (= system generated) queries

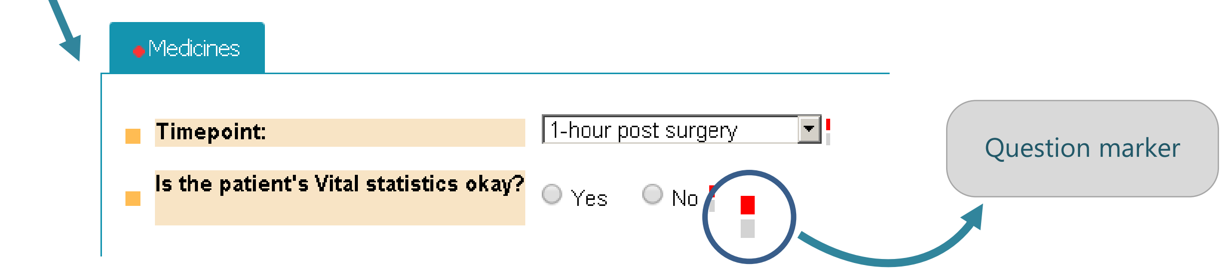
Back to top ↺

1.2 VIEW QUERIES VIA THE E-CRF FORM

As mentioned in item 'View queries in the query list', queries are displayed in the patient navigator on a study, visit and form level.



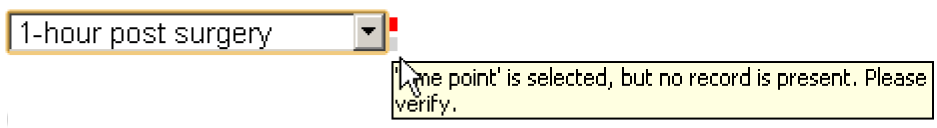
Within an e-CRF form, queries on question level are indicated by a question marker Icon. The status of a query is indicated by the same colors as mentioned in the item above.



The Query text of both automated and manual queries can be shown in 3 different ways :

1. Move your mouse arrow over the upper question marker.

When a query is open for this question, the query text will be shown in a pop up when bringing the arrow on this marker.

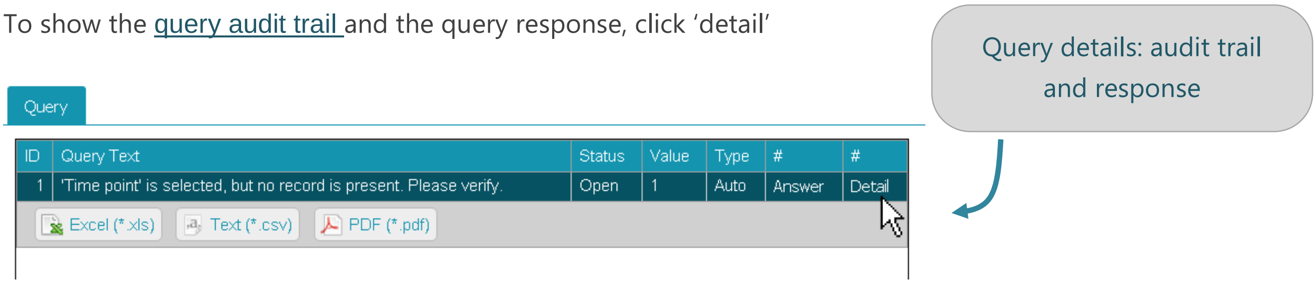


NOTE: TO SHOW THE ANSWER OF AN ANSWERED QUERY, RETURN TO THE NAVIGATOR AND CLICK 'QUERIES' AT FORM LEVEL, OR FOLLOW THE NEXT STEPS.

---

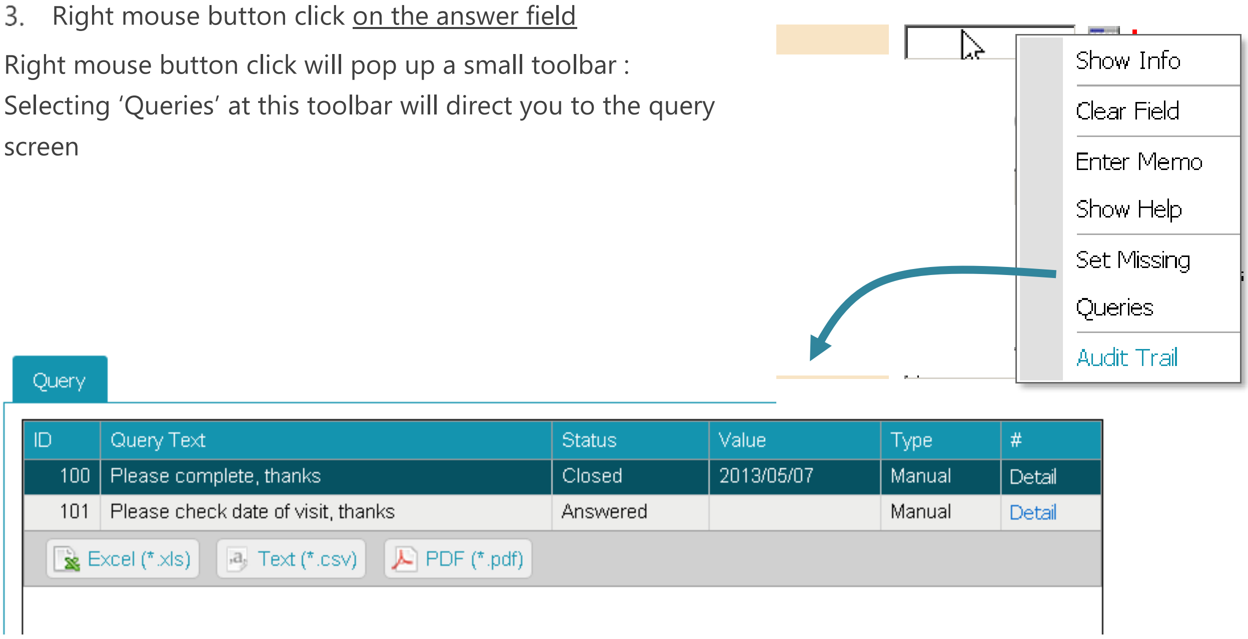
2. Single click on the upper question marker

Single clicking the question marker will show you the query screen. Within this screen, all queries that were raised on this field will be listed.
Depending on the rights assigned to your user role, this screen enables viewing, answering or closing a query (or queries) linked to the respective field.
To show the query audit trail and the query response, click 'detail'



3. Right mouse button click on the answer field

Right mouse button click will pop up a small toolbar :
Selecting ‘Queries’ at this toolbar will direct you to the query screen

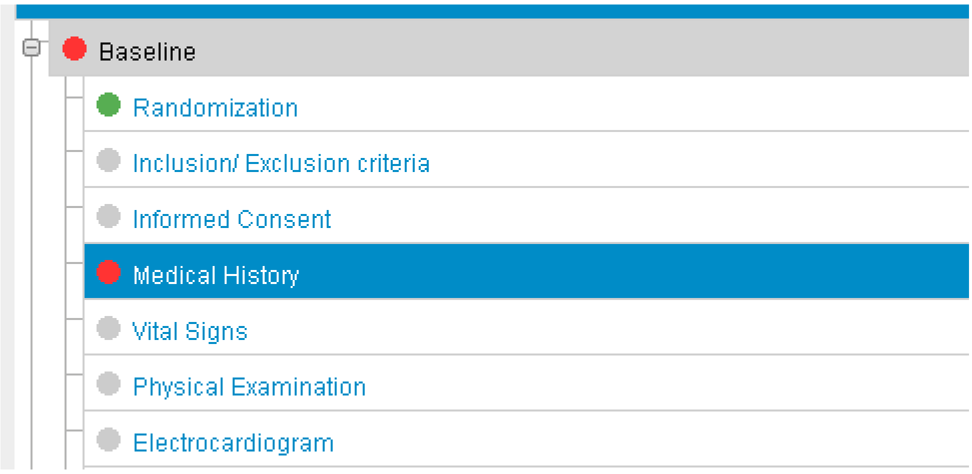


2 QUERY ACTIONS

Query actions can be performed through two workflows: at field level (in the e-CRF) or starting from the query list:

2.1 QUERY HANDLING AT FIELD LEVEL

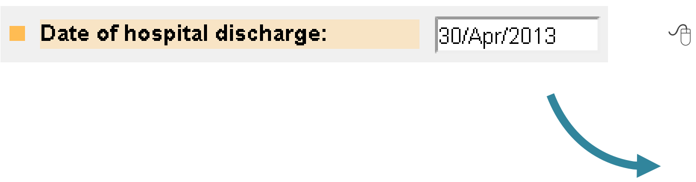
Open the form that contains queries, or where you want to create a query.

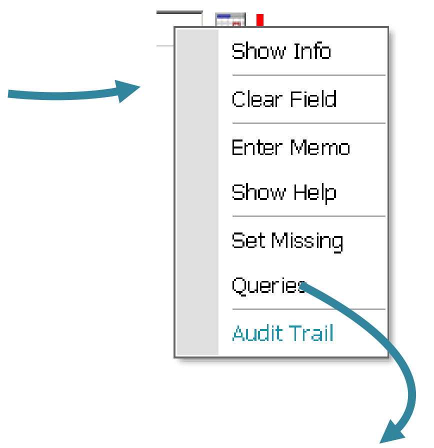


2.1.1 CREATE A QUERY – FIELD LEVEL

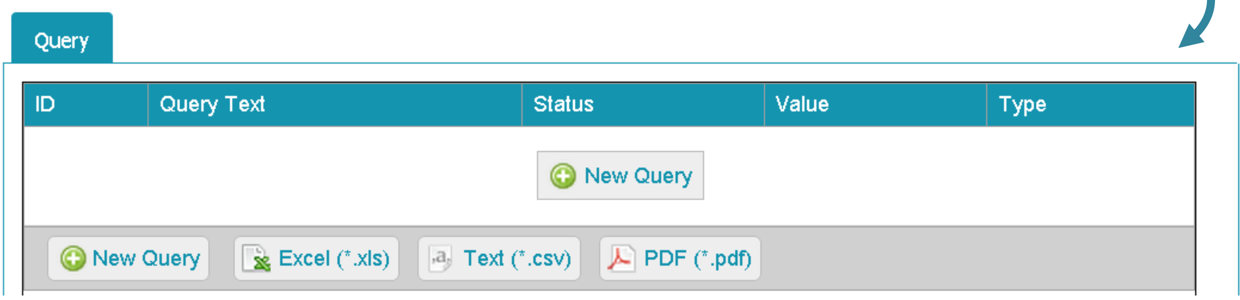
The ability to create queries depends on the rights assigned to your user role.. When query creation is activated for your user profile, the following steps will lead to creating a manual query :

1. enter the CRF form by ticking the form name in the navigator.
2. Within the form, tick the answer field with the right mouse button.
3. Select ‘queries’ from the menu.



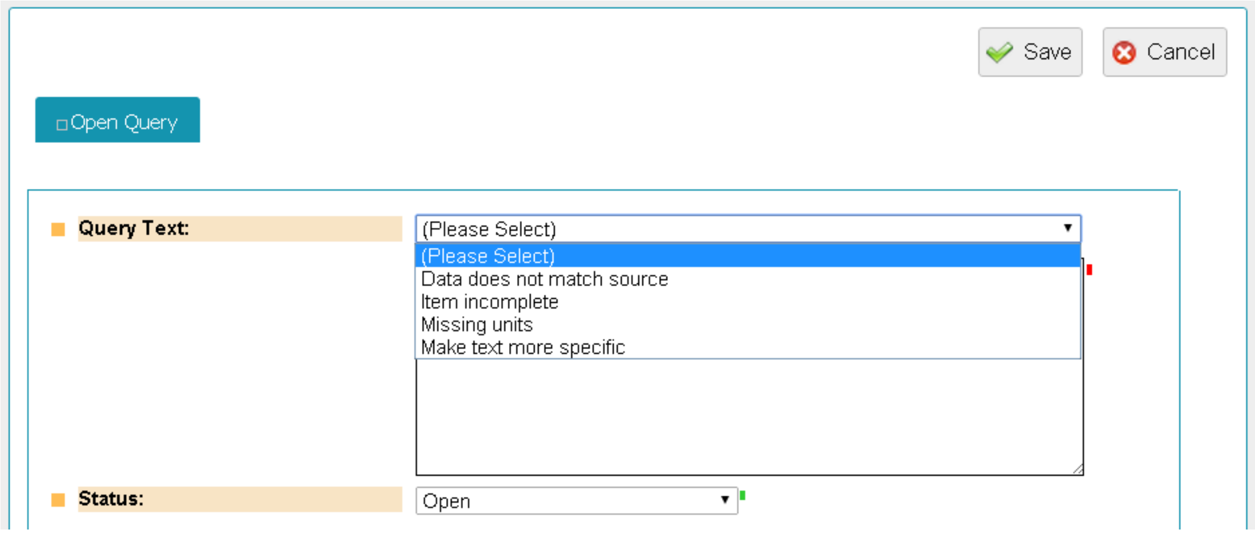


4. Click the ‘new query’ button.

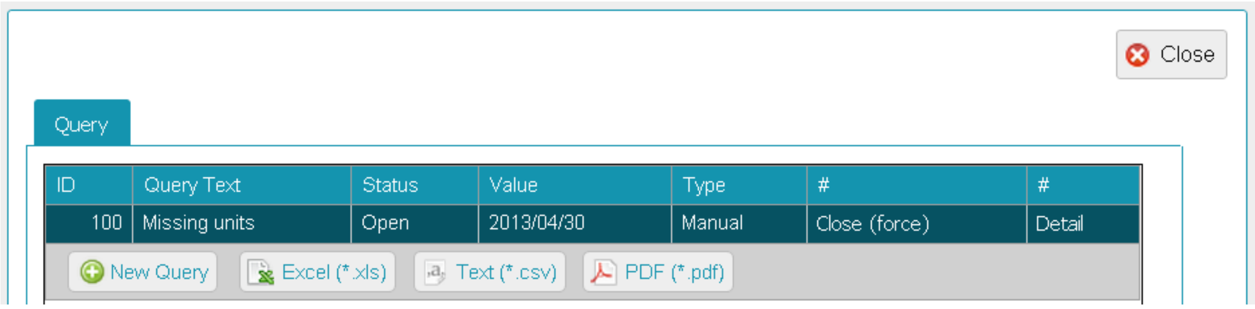


Back to top ↺

5. Enter the query text by selecting the pre-defined query texts, or type your own comment in the query textbox
6. Tick Save



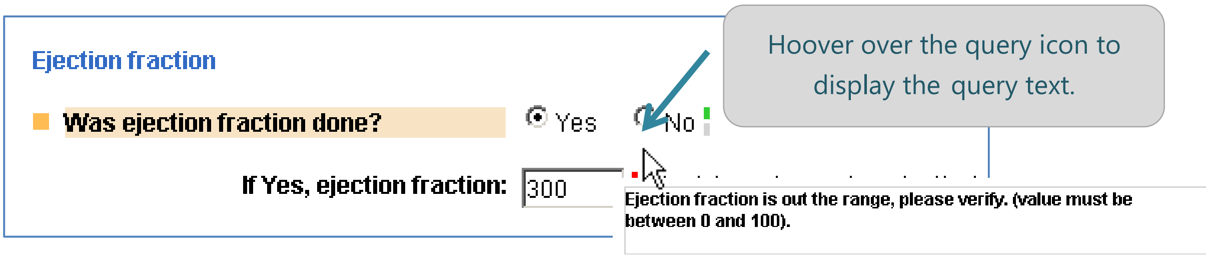
7. Close the query overview to navigate back to the eCRF form



8. The question status is now red and indicates your query.

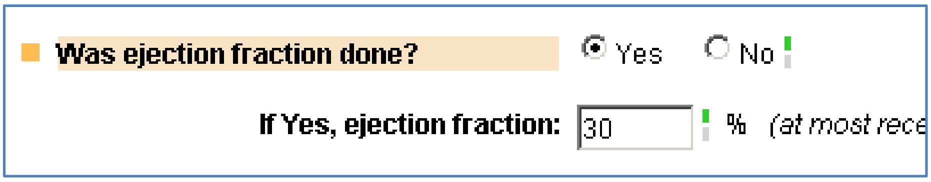
2.1.2 IMMEDIATE DATA CORRECTION TO 'AUTO-CLOSE-QUERY' – FIELD LEVEL

You can either correct the data immediately, without opening the query or open the query in case you need to confirm the value.



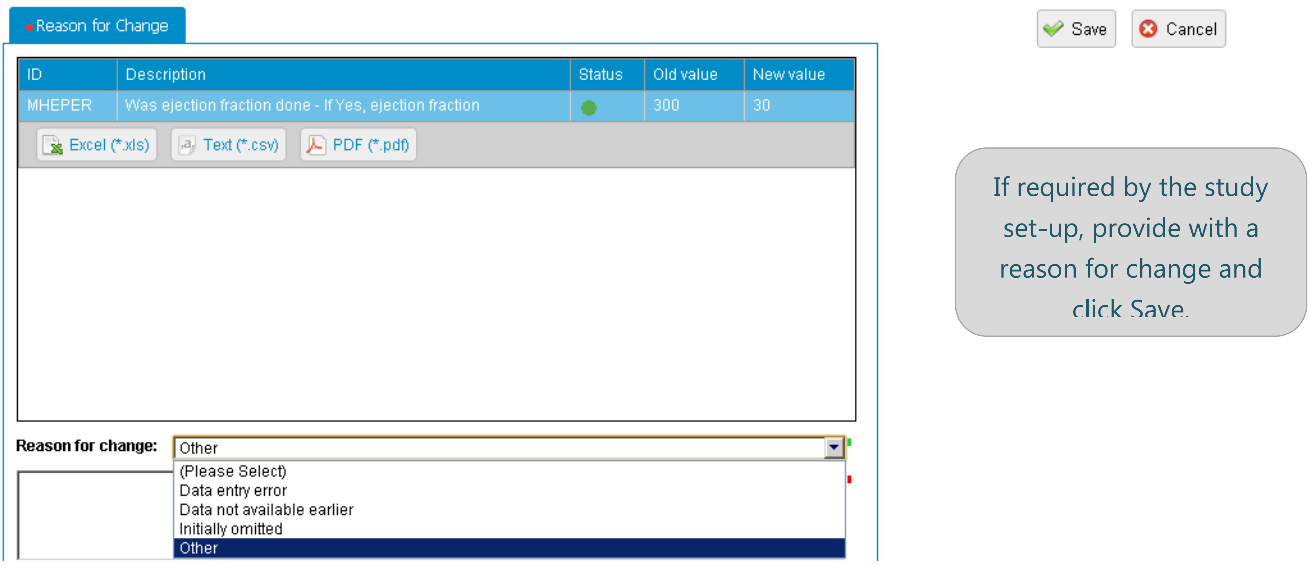
In case of **system generated queries**, a data update to 'values within the pre-defined ranges' will **auto-close the query by data entry/update**. In this case, there is no need to open and answer the query.

1. Correct the applicable data (in this case, the ejection fraction). If the newly entered data satisfies the pre-set protocol ranges, the query will become closed.
2. Click Save.



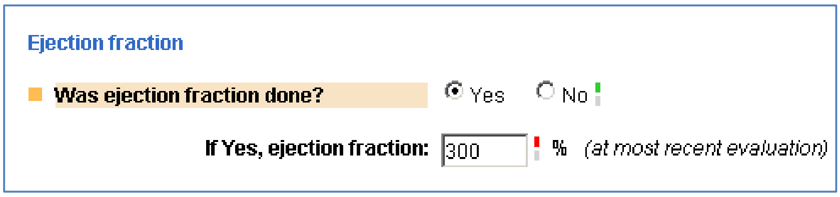
NOTE: MANUAL QUERIES WILL NEVER AUTO CLOSE. IN CASE OF A MANUAL QUERY YOU NEED TO UPDATE THE ANSWER VALUE AND ALSO **ANSWER** THE QUERY.

Depending on the set up of your study, you may need to enter a reason for change upon form save (or see an overview of other pending queries in this form). You must provide a reason here to be able to continue.

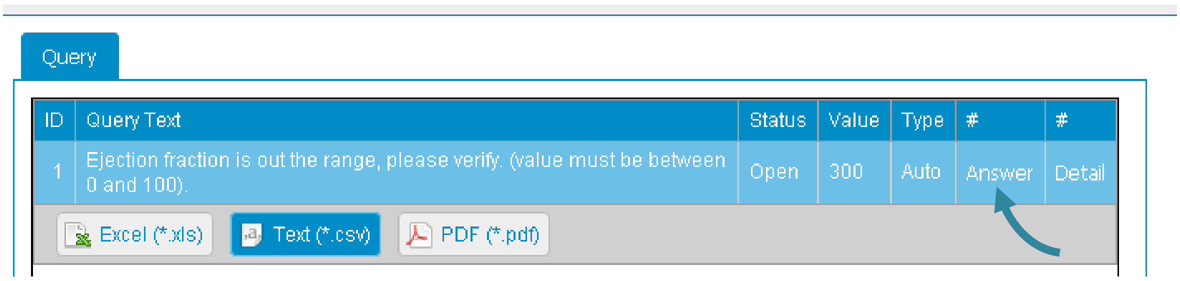


2.1.3 ANSWER THE QUERY – FIELD LEVEL

1. Click on the query icon to open the query



9. Within the query window, click ‘Answer’.



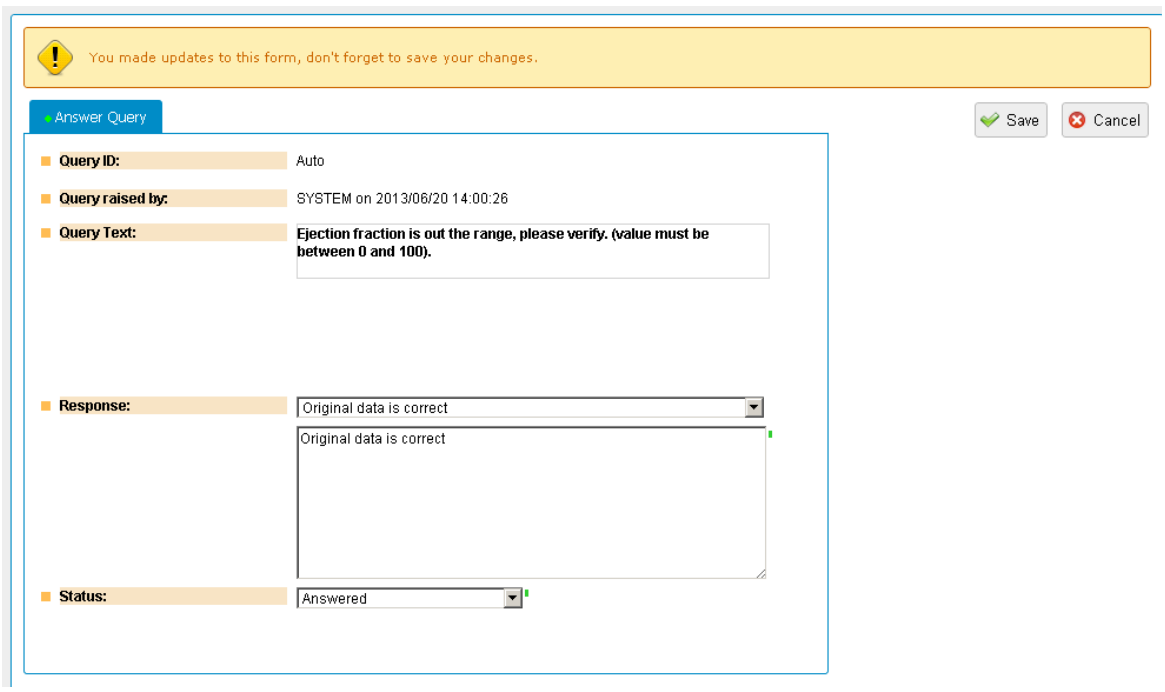
An Answer query window will open (see screenshot below).

10. Provide with a response to answer the query and click Save.

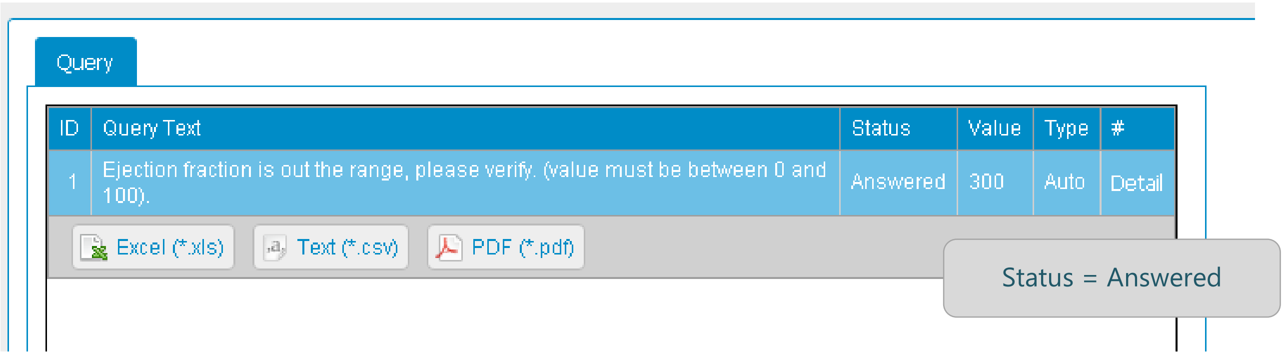
- Select a pre-set response or formulate a response in the comment box.

NOTE: THE RED STATUS ICON INDICATES THAT ‘RESPONSE’ IS A REQUIRED FIELD, YOU WILL NOT BE ABLE TO PERFORM ANY QUERY ACTION IF THIS FIELD IS NOT COMPLETED.

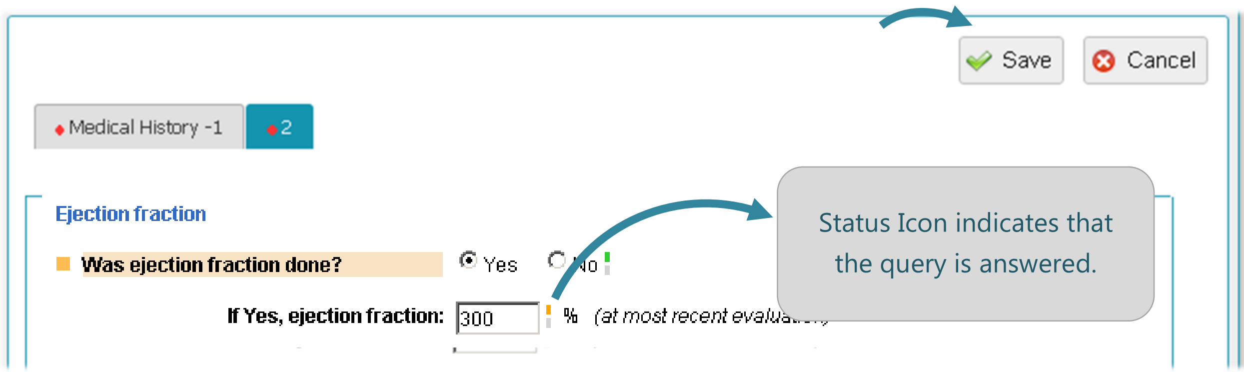
- The Status drop down will be auto populated with ‘Answered’ unless your user role allows you to perform multiple response types.



The query window will be displayed again:



11. Click return to navigate back to the form that contains the answered query:



12. Save the CRF form.

IMPORTANT NOTE: IF YOU DO NOT SAVE THE CRF FORM; THE QUERY ANSWER WILL NOT BE SAVED!

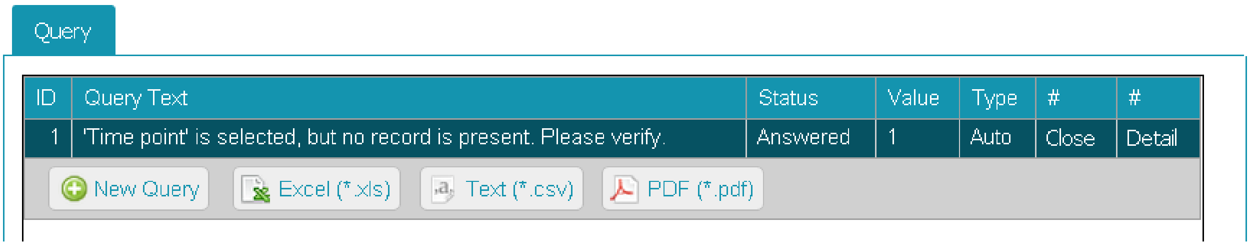
2.1.4 CLOSE QUERIES – FIELD LEVEL

'close queries' is a user role defined feature. Some user roles will not be able to close any queries. Some user roles will be able to close answered queries, while they cannot close unanswered queries.

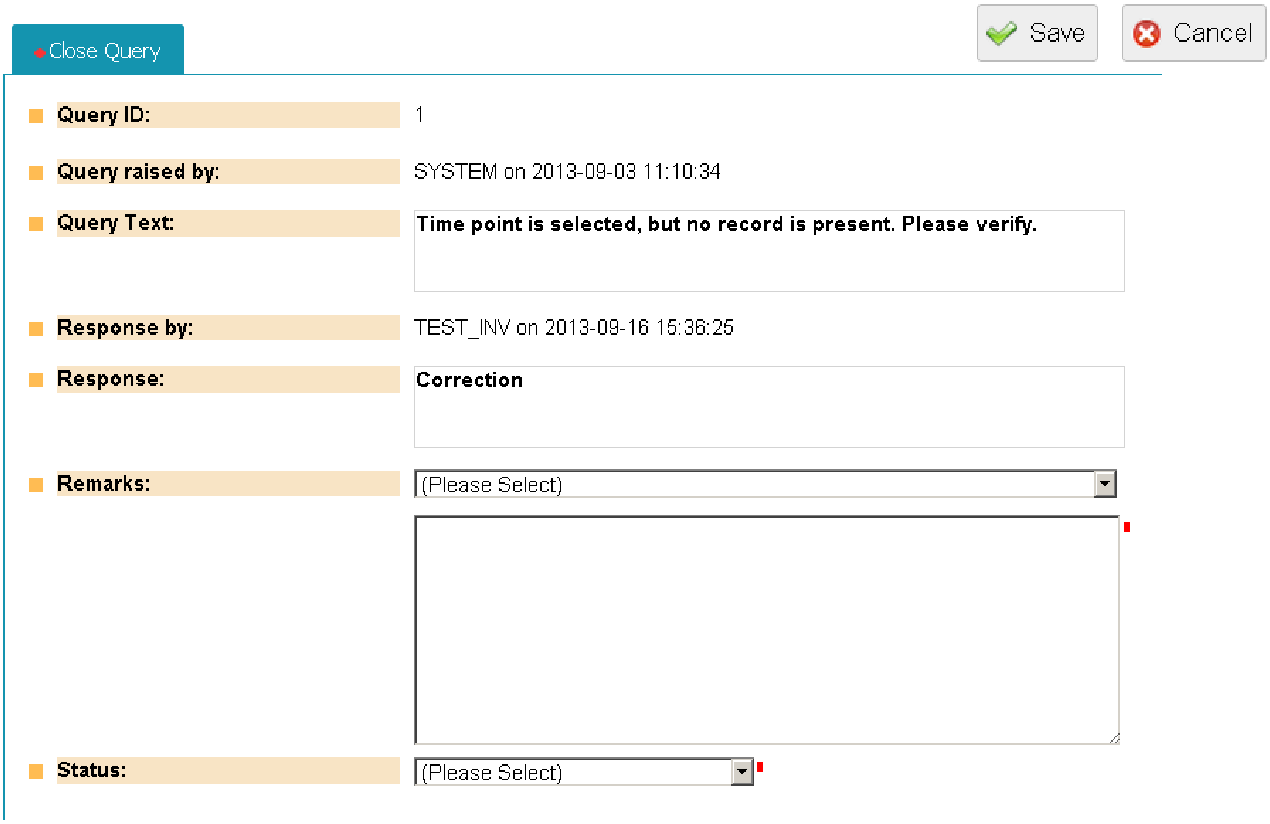
1. Click on the query icon to open the query.

2. Within the query window, click 'Close'.

- This link will only be available if you have the appropriate rights assigned to your user role.
- If you do not have this option, and a query should be closed, please request query closing in your query answer.



A Close query window will open.
This window displays the query text ① and response② and their respective audit trail③.



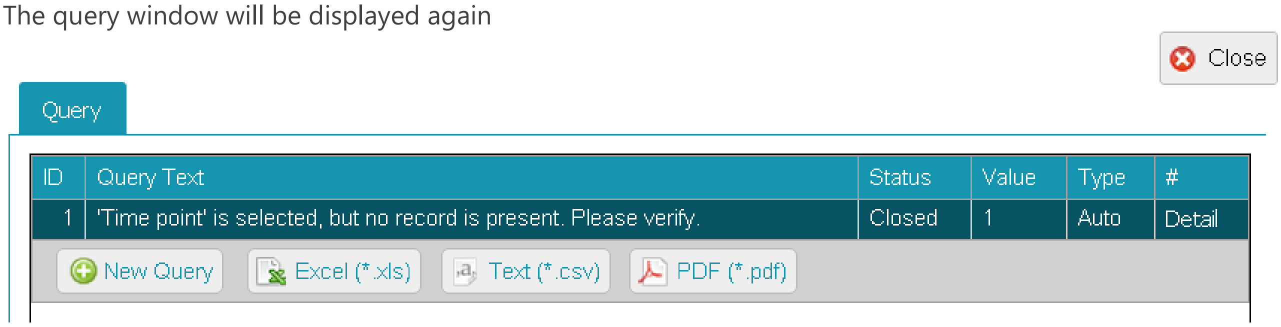
13. Provide with a remark by selecting a pre-set value from the drop down list or by entering a comment in the text box.

NOTE: THE RED STATUS ICON INDICATES THAT BOTH REMARKS AND STATUS ARE REQUIRED FIELDS, YOU WILL NOT BE ABLE TO PERFORM ANY QUERY ACTION IF THESE FIELDS ARE NOT COMPLETED.

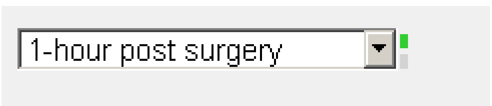
14. Set the status in the drop down to Closed or Reopen.

15. Click Save.

The query window will be displayed again



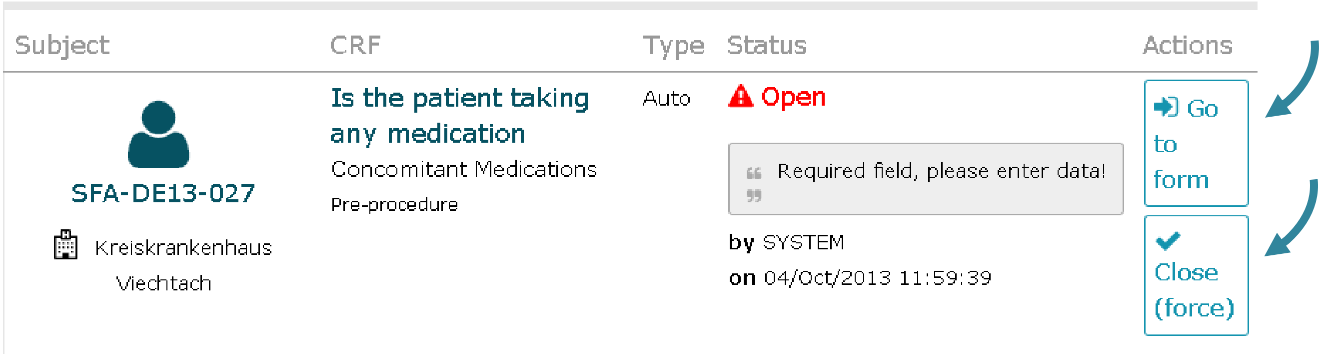
16. Click Close to navigate back to the form that contains the closed query.



Back to top ↺

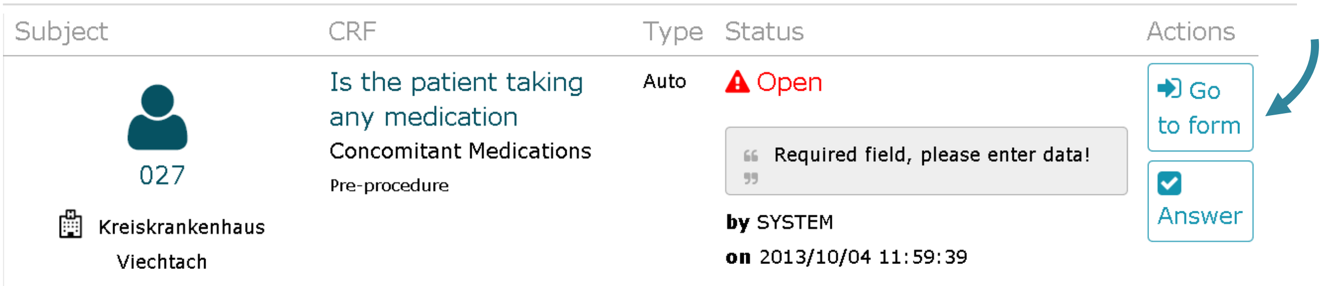
2.2 QUERY HANDLING FROM THE QUERY LIST

Depending on the rights assigned to your user profile, the query list will display certain action buttons. These buttons enable you to manage your patient queries. The available **query actions are shown on the right hand side of each query**.in the query list.
For more details about navigating to the query list, see item 'Query listing : Search and filter'



2.2.1 DIRECT DATA CORRECTION VIA QUERY LIST - 'GO TO FORM'

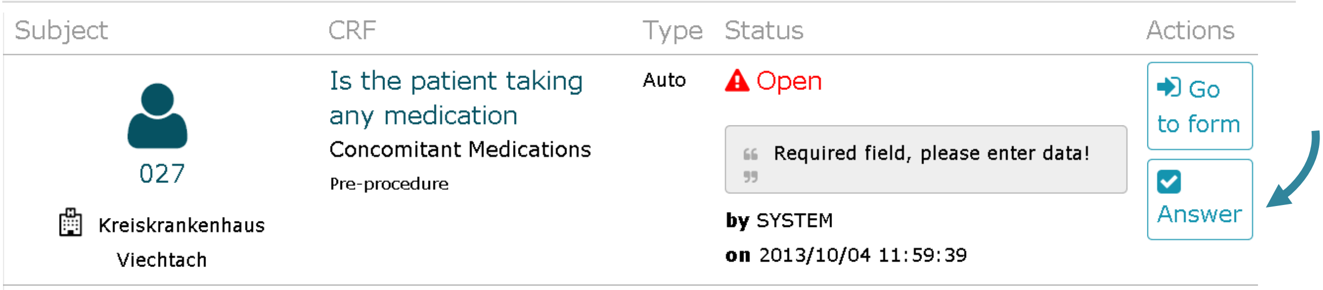
As mentioned in item 'Immediate data correction', queries can be immediately closed by data entry or update. Clicking 'Go to form', within the query list brings you to query location in the eCRF. From this point, the same workflow as Query management at field level is applicable.



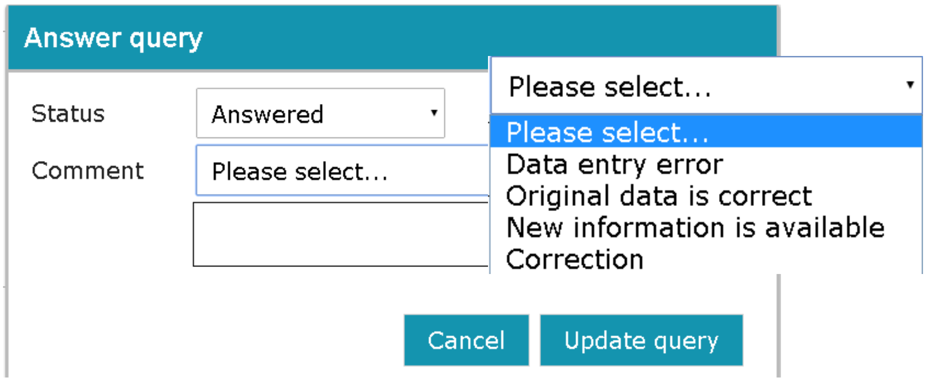
2.2.2 ANSWER QUERY - QUERY LIST

1. Click the Answer link within the study query list.

This link will only be available if you have the appropriate rights assigned to your user role.



An Answer Query window will open:

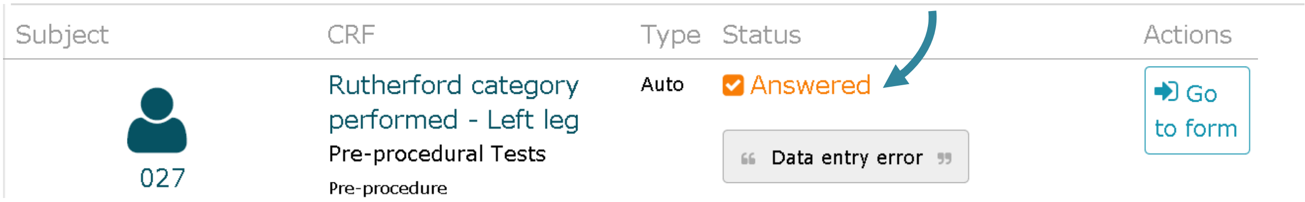


17. Provide with a response to answer the query.

- Select a pre-set response or formulate a response in the comment box.
- The Status drop down will be auto populated with 'Answered' unless your user role allows you to perform multiple response types.

18. Click 'Update Query'.

The query status will now be updated to 'Answered'

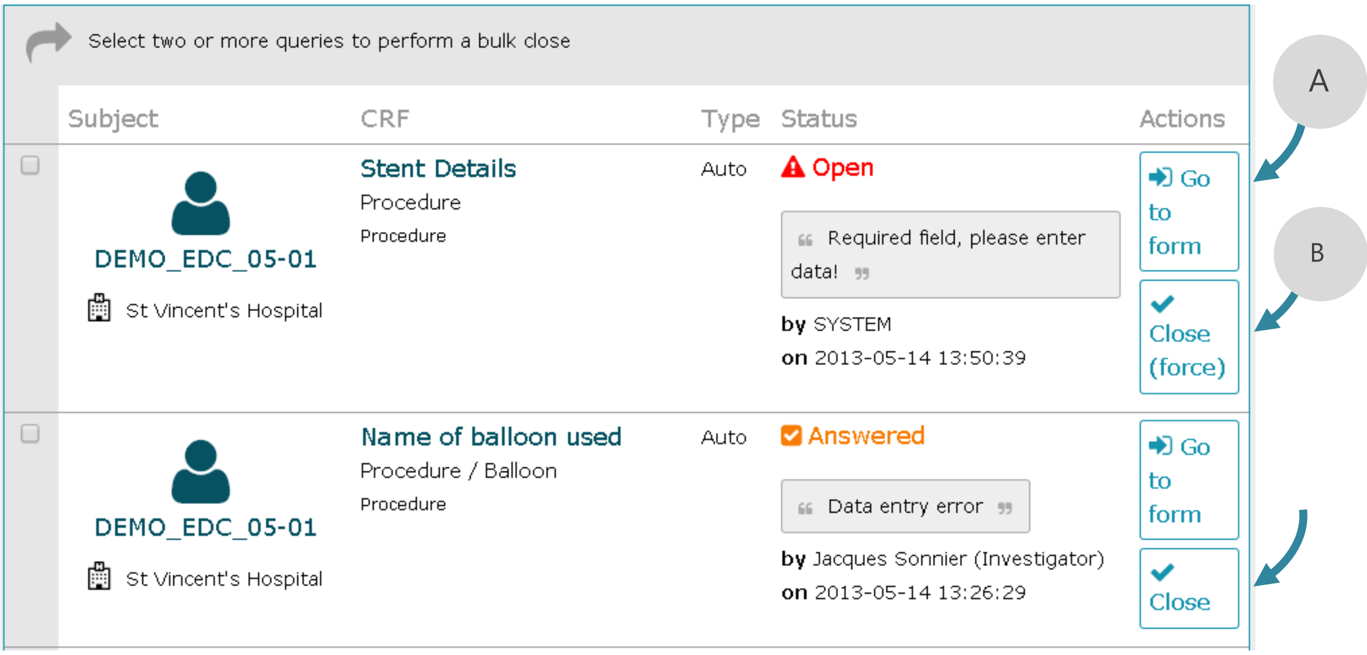


NOTE 1 : IF YOU CANNOT FIND THE ANSWERED QUERY, PLEASE CHECK THE QUERY STATUS FILTER, AND MAKE SURE THE ANSWERED QUERIES ARE SHOWN IN THE QUERY STATUS FILTER.

NOTE 2 : ANSWERING QUERIES CAN BE DONE ONLY QUERY PER QUERY, NOT IN BATCH

2.2.3 CLOSE QUERIES – QUERY LIST

'Close queries' is a user role defined feature. Some user roles will not be able to close any queries. Some user roles will be able to close answered queries, while they cannot close unanswered queries.

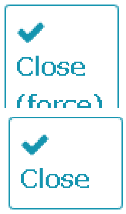


A: Close queries via 'Go to form'

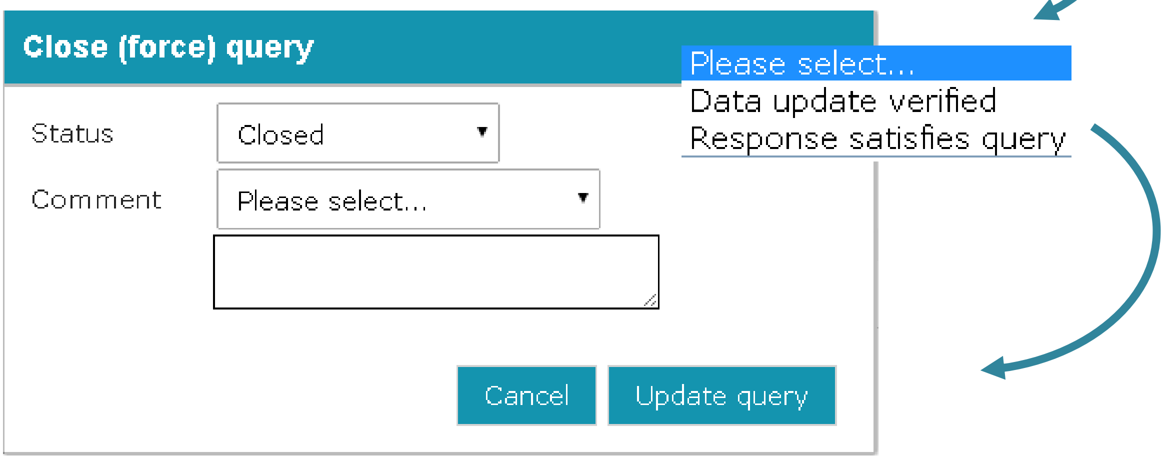
Clicking 'Go to form', within the query list brings you to query location in the eCRF. From that point, the same workflow as Query handling at field level is applicable.

B: Close queries via 'Close (force)' or 'Close'.

'Close (force)' and 'Close' have the same query close workflow and result.



- 'Close (force)' applies to unanswered, open queries.
- 'Close' applies to answered queries.
- Select a pre-set comment or formulate one in the comment box.
- The Status drop down will be auto populated with 'closed'.
- Click 'Update Query'.



The query status will now be updated to 'Closed' in the query list.

Back to top ↺

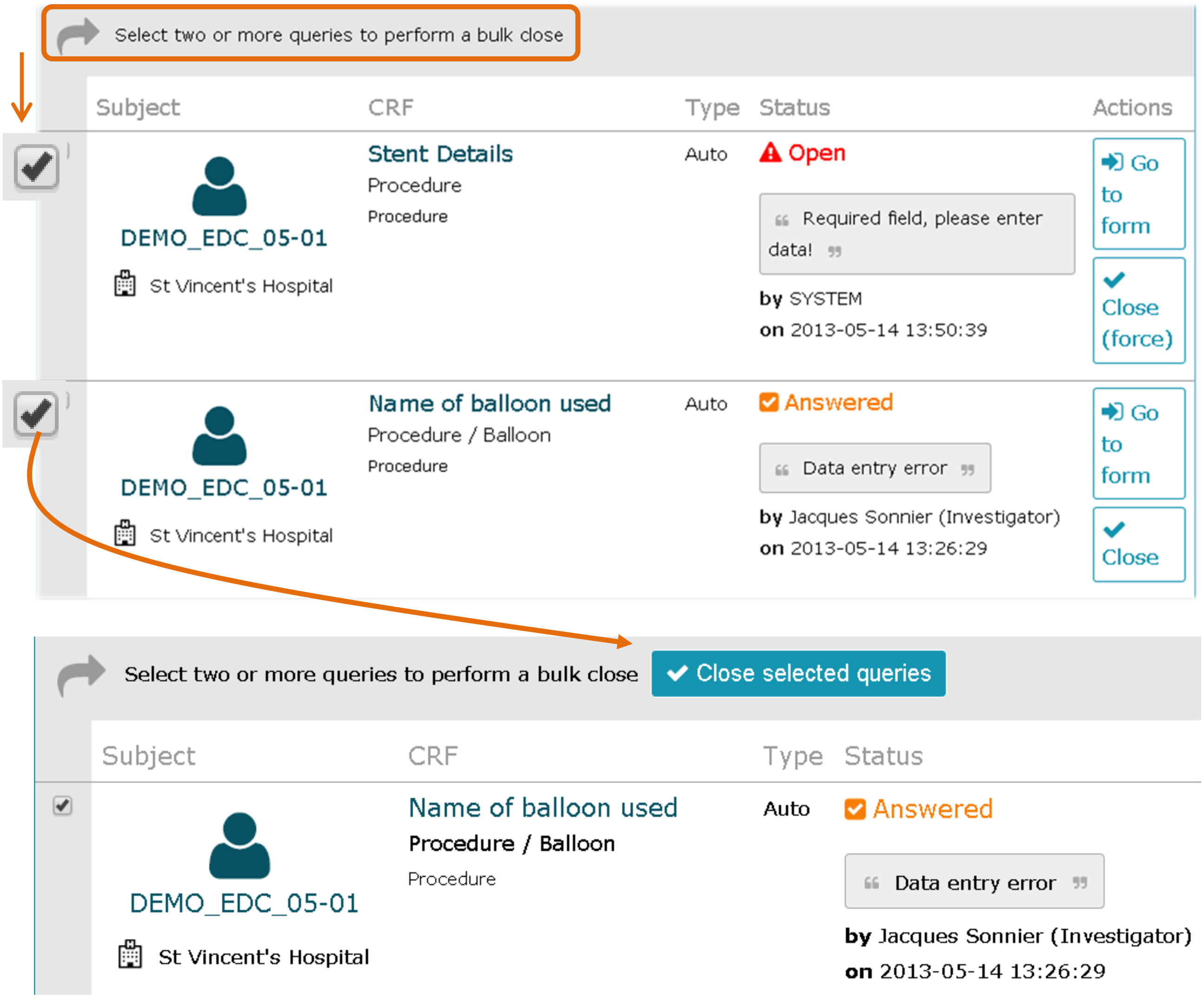
Subject	CRF	Type	Status	Actions
DEMO_EDC_05-01 St Vincent's Hospital	**Stent Details** Procedure Procedure	Auto	✔ Closed “ Data update verified ” **by** Michael Douglas (Data Manager) **on** 2014-01-20 16:08:01	Go to form

NOTE 1 : IF YOU CANNOT FIND THE CLOSED QUERY, PLEASE CHECK THE QUERY STATUS FILTER, AND MAKE SURE THE CLOSED QUERIES ARE SHOWN IN THE QUERY STATUS FILTER.

NOTE 2 : E-CAPTURE.NET ALSO ALLOWS YOU TO CLOSE QUERIES IN BATCH.

2.2.4 CLOSE QUERIES IN BATCH – QUERY LIST

e-capture.net allows you to close multiple (open or answered) queries in batch. This action is possible only via the query list. Depending on your user profile, you will be able to select queries for the 'Close' and/or 'Close (force)' action.



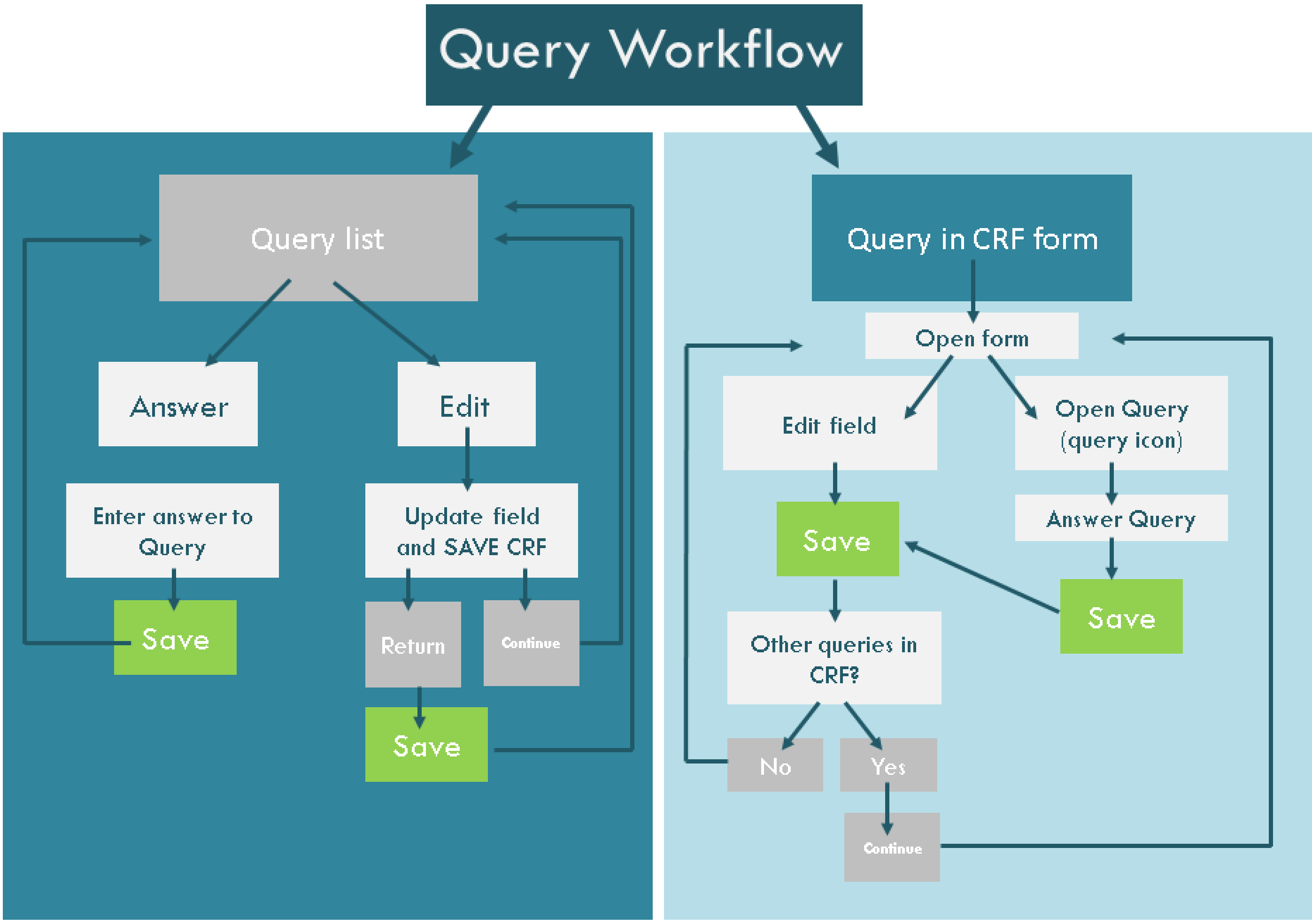
- Select the queries you wish to close in batch via the checkbox on the left hand side of the query description
- Click the button ' Close selected queries'.

From this point , the same workflow applies as if you would close a single query via the query list

- Select a pre-set comment or formulate one in the comment box.
- The Status drop down will be auto populated with 'closed'.
- Click 'Update Query'

NOTE 1 : RE-OPENED QUERIES NEED TO BE CLOSED ONE BY ONE, THEY CANNOT BE CLOSED IN BATCH

3 ANSWERING QUERIES: FLOW CHART PER WORKFLOW



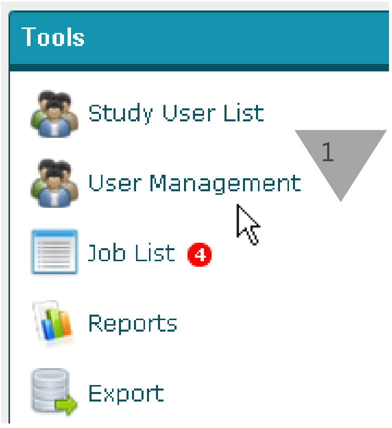
MANAGE USERS

As mentioned in chapter 1.3: User creation, e-capture.net provides user access upon receipt of a valid and completed User Request Form. The User Management feature however, allows you to perform these tasks yourself.

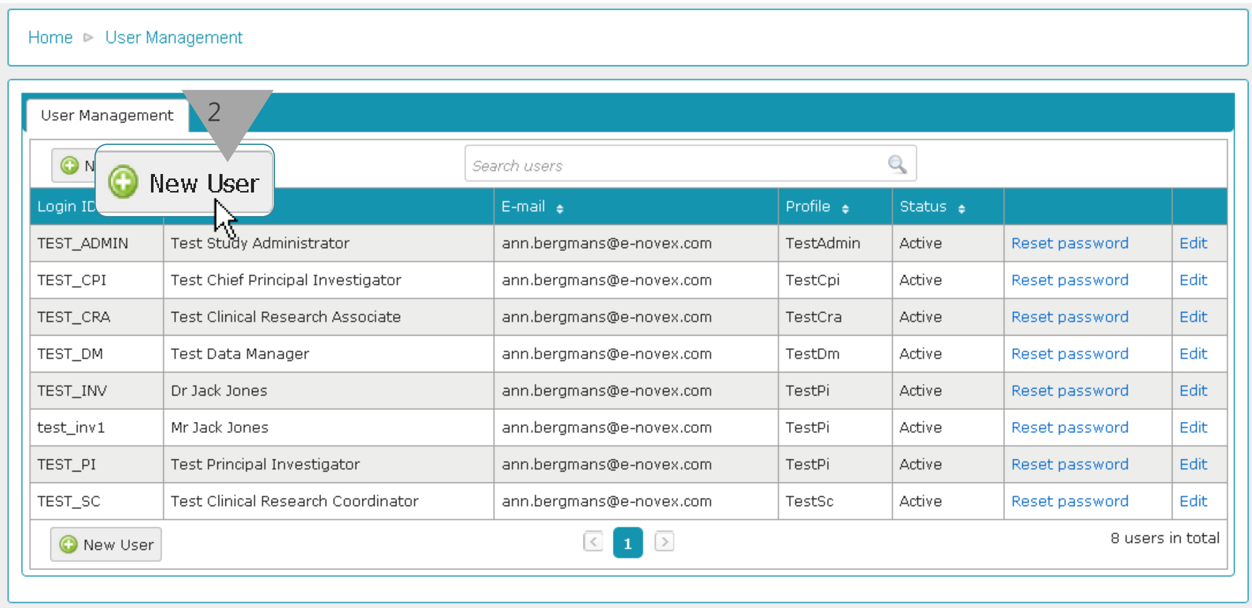
User Management is a stand-alone feature and will therefore not be applicable for all studies. If included in your study, access to User Management is linked to a specific user profile.

1 CREATE A NEW USER

1. Click the User Management link in the Tools section of the vertical toolbar. As mentioned above, the availability of this link depends on your study set up and the rights assigned to your user role.

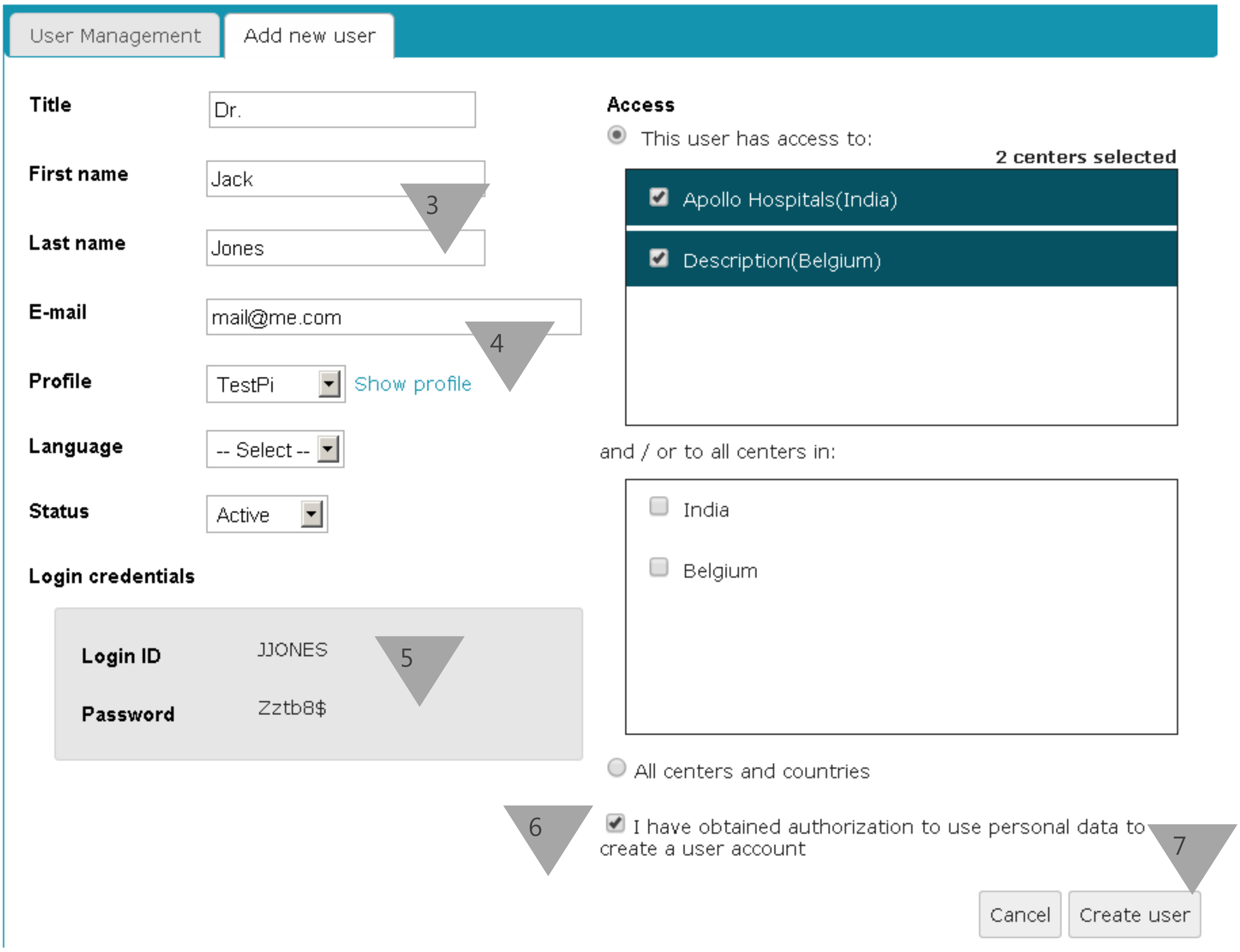


A user Management window will open. Existing users are displayed in table view.



2. Click the ‘New User’ button.

A new tab 'Add new user' will open in the User management window.



3. Enter the user specifications as mentioned in the user request form:

- Name (required)
- mail address (required)
- Profile (required)
- Center access
- Language: can only be selected in case the study has Multilanguage e-CRF forms.
- Status: 'Active' by default.

4. Click the Show Profile link to view all profile attributes:

TestPi profile attributes

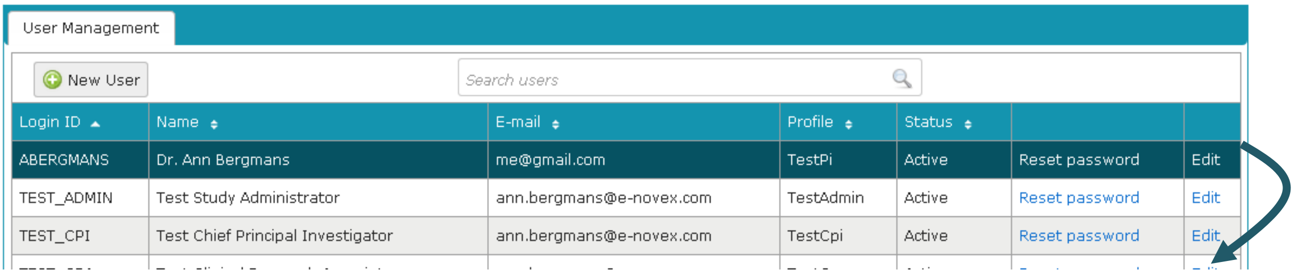
Signature	Investigator Signature	Create notes	✗
Sign level	Form/Visit	View random codes	✗
Create queries	✗	Unfreeze	✗
Close queries	No	Freeze forms	✗
Answer queries	✓	Edit random codes	✗
Lock	✗	(Un)Freeze level	Form/Visit
Unlock	✗	DDE level	Form/Visit
(Un)lock level	Form/Visit	Data access	Write
Source Data Verification (SDV)	✗	View Corelab	✗
View userlist	✗	Import Corelab	✗
Access reports	No	Upload Corelab	✗
Data exports	✗	Upload Documents	✗

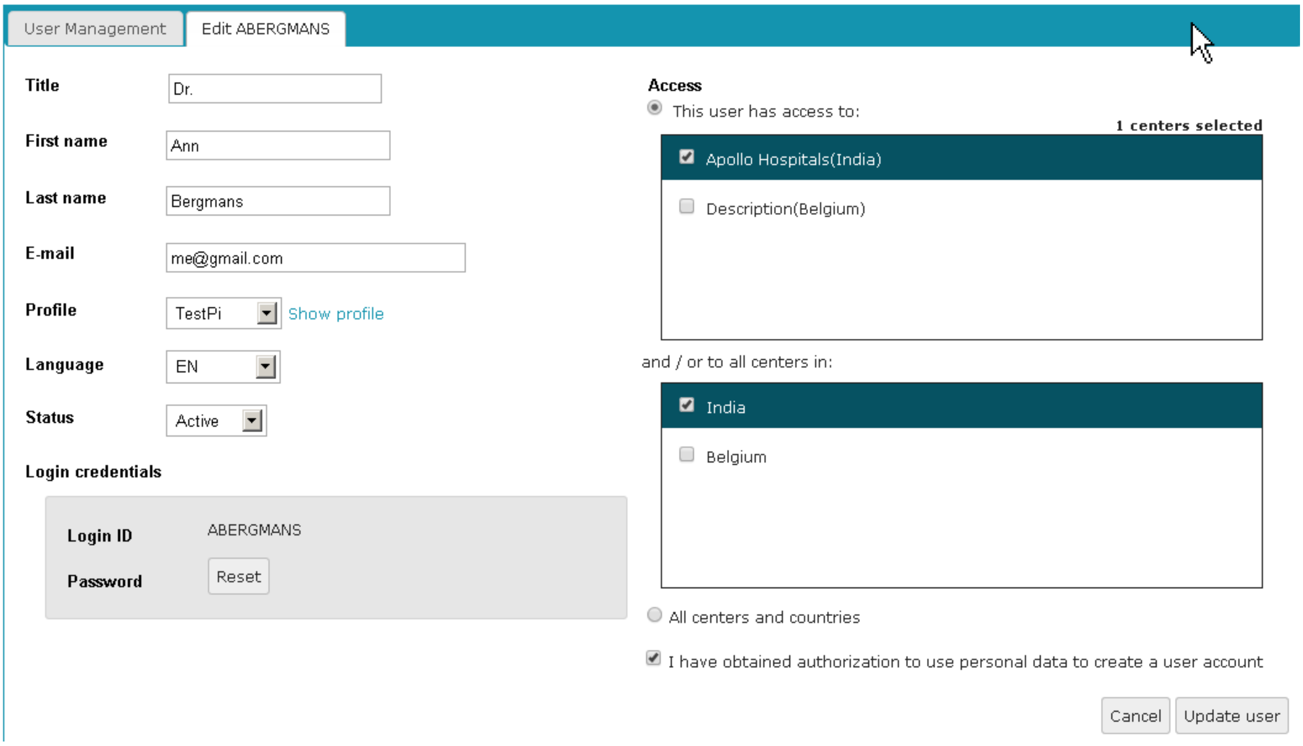
5. Only if all required fields are completed, the system will create and display the login credentials of the new user.
6. Check the box: "I have obtained authorization to use personal data to create a user account" to activate the 'Create user' button.
7. Click 'Create user'.

The new user will be added to the users table and will receive an automated email from e-capture.net that contains the study URL and the user's Login ID and password.

2 EDIT A USER ACCOUNT

1. Starting from the User Management window, click the Edit link within the users list:

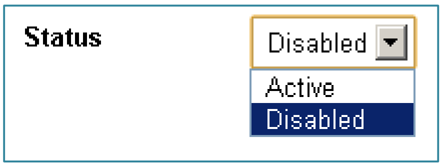


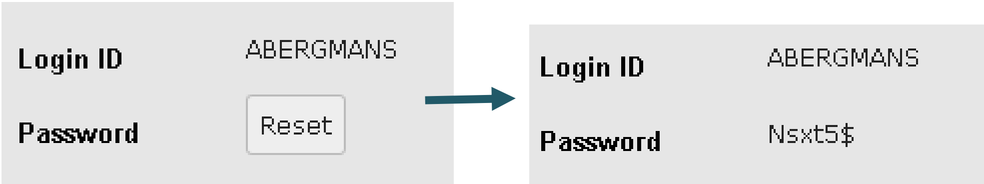


Back to top ↺

Available actions:

- Edit user specifications
- Disable a user with **Status** drop-down
- Reset password

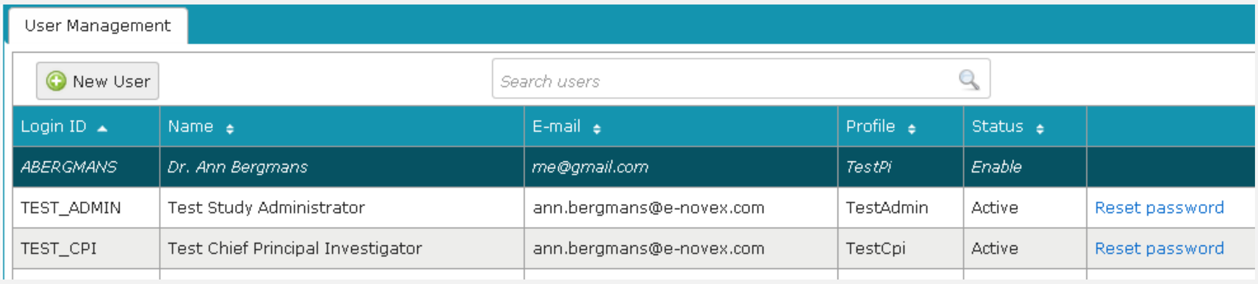




When ticking password 'Reset', a password mail is automatically sent to the user's mailbox.

8. Click the 'Update user' button to save your edits.

- Re-setting a password can also be done by directly clicking the Reset Password link within the users table.
- A disabled user (indicated in Italic text in the users table) will no longer be allowed to login to the study. To enable a disabled user, click 'Enable' within the Status column.



User Management

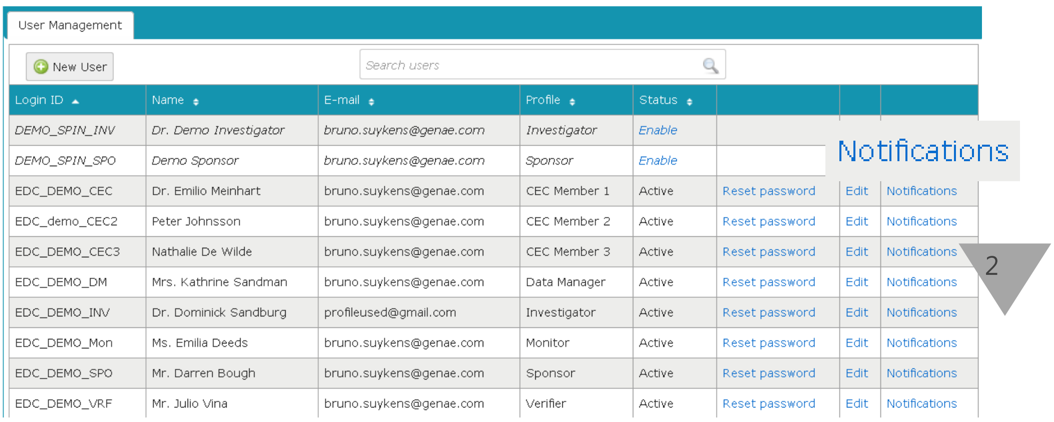
New User | Search users

Login ID	Name	E-mail	Profile	Status	
ABERGMANS	*Dr. Ann Bergmans*	*me@gmail.com*	*TestPi*	*Enable*	
TEST_ADMIN	Test Study Administrator	ann.bergmans@e-novex.com	TestAdmin	Active	Reset password
TEST_CPI	Test Chief Principal Investigator	ann.bergmans@e-novex.com	TestCpi	Active	Reset password

3 UPDATE NOTIFICATION ACTIVATION FOR A USER ACCOUNT

During study setup, the design team specifies which user profile should receive which type of notifications.
When creating a patient, automatically the notifications for his user profile are activated.
The study manager can activate/revoke notification receipt at user level via the user management tool.

1. Create / edit the user as specified above
2. Click 'Notifications' for the applicable user

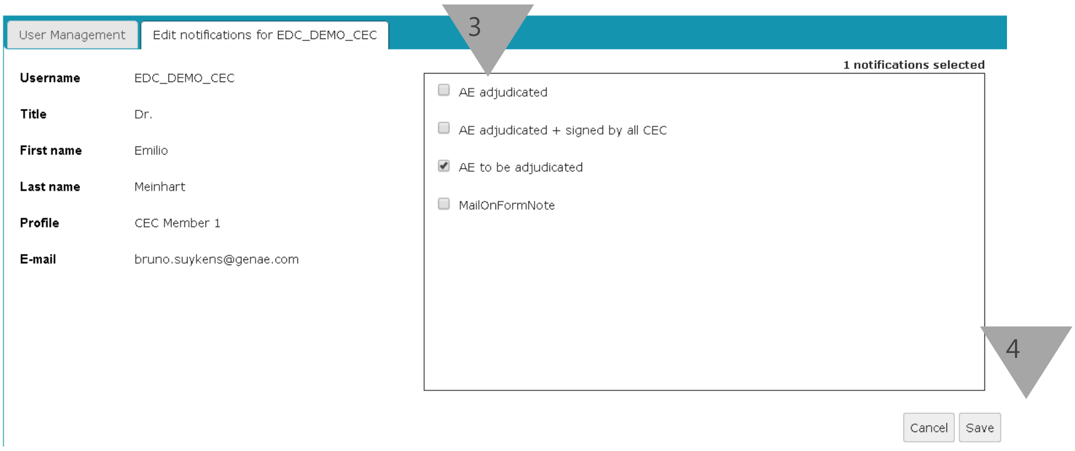


User Management

New User | Search users

Login ID	Name	E-mail	Profile	Status			
DEMO_SPIN_INV	*Dr. Demo Investigator*	*bruno.suykens@genae.com*	*Investigator*	*Enable*			
DEMO_SPIN_SPO	*Demo Sponsor*	*bruno.suykens@genae.com*	*Sponsor*	*Enable*			
EDC_DEMO_CEC	Dr. Emilio Meinhart	bruno.suykens@genae.com	CEC Member 1	Active	Reset password	Edit	Notifications
EDC_demo_CEC2	Peter Johnsson	bruno.suykens@genae.com	CEC Member 2	Active	Reset password	Edit	Notifications
EDC_DEMO_CEC3	Nathalie De Wilde	bruno.suykens@genae.com	CEC Member 3	Active	Reset password	Edit	Notifications
EDC_DEMO_DM	Mrs. Kathrine Sandman	bruno.suykens@genae.com	Data Manager	Active	Reset password	Edit	Notifications
EDC_DEMO_INV	Dr. Dominick Sandburg	profileused@gmail.com	Investigator	Active	Reset password	Edit	Notifications
EDC_DEMO_Mon	Ms. Emilia Deeds	bruno.suykens@genae.com	Monitor	Active	Reset password	Edit	Notifications
EDC_DEMO_SPO	Mr. Darren Bough	bruno.suykens@genae.com	Sponsor	Active	Reset password	Edit	Notifications
EDC_DEMO_VRF	Mr. Julio Vina	bruno.suykens@genae.com	Verifier	Active	Reset password	Edit	Notifications

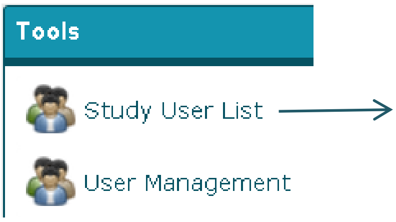
All Notifications for this user profile will be automatically activated

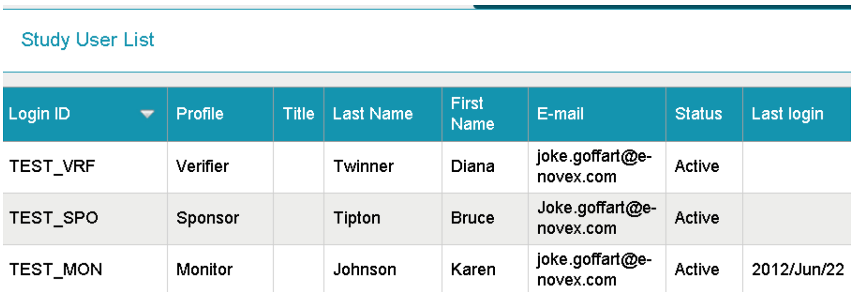


3. To add/remove a notification for this user, check/uncheck the notification in the list
4. Click 'Save'

4 VIEW THE STUDY USER LIST

Depending on the rights in your user role, the study user list will be available to you or not. The user list will show you all user accounts linked to your study.



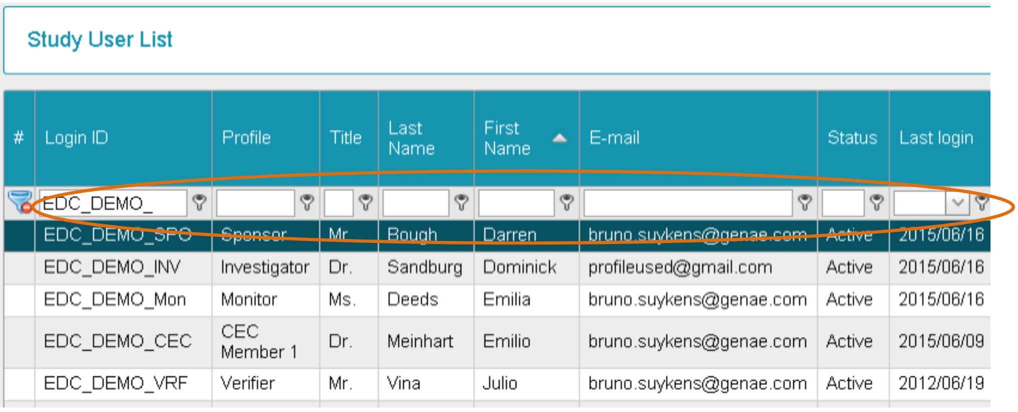


Study User List

Login ID	Profile	Title	Last Name	First Name	E-mail	Status	Last login
TEST_VRF	Verifier		Twinner	Diana	joke.goffart@e-novex.com	Active	
TEST_SPO	Sponsor		Tipton	Bruce	Joke.goffart@e-novex.com	Active	
TEST_MON	Monitor		Johnson	Karen	joke.goffart@e-novex.com	Active	2012/Jun/22

5 SEARCH USERS IN THE STUDY USER LIST

In the study user list, each column holds a search area to filter & search for users.



Study User List

#	Login ID	Profile	Title	Last Name	First Name	E-mail	Status	Last login
	EDC_DEMO_							
	EDC_DEMO_SPO	Sponsor	Mr.	Bough	Darren	bruno.suykens@genae.com	Active	2015/06/16
	EDC_DEMO_INV	Investigator	Dr.	Sandburg	Dominick	profileused@gmail.com	Active	2015/06/16
	EDC_DEMO_Mon	Monitor	Ms.	Deeds	Emilia	bruno.suykens@genae.com	Active	2015/06/16
	EDC_DEMO_CEC	CEC Member 1	Dr.	Meinhart	Emilio	bruno.suykens@genae.com	Active	2015/06/09
	EDC_DEMO_VRF	Verifier	Mr.	Vina	Julio	bruno.suykens@genae.com	Active	2012/06/19

Please check the chapter 'filter options' for more details.

MANAGE PAYMENTS

e-capture.net's Payment module allows you to enter and track payments that need to be made to your study centers.
Payments can be triggered per study visit and can be defined in different currencies per center.
The Payment module is a stand-alone feature and will therefore not be applicable for all studies. If included in your study, access to Payments is linked to a specific user profile.

1 INTRODUCTION: PAYMENT TABLE

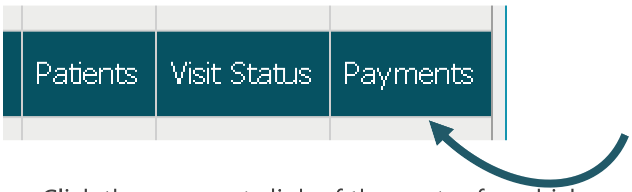
A payment table is implemented per study center. You can access each table per center via the 'Centers' button within the Navigation tool, or access the entire study payment table via the 'studies' button.

- Click 'Studies' , followed by 'Payments' to see the study payment overview of all your
- Click 'Centers' to see the overview of all centers you have access to, followed by 'payments' to see all payments for this center:

Home ▹ Studies ▹ Centers[EDC]

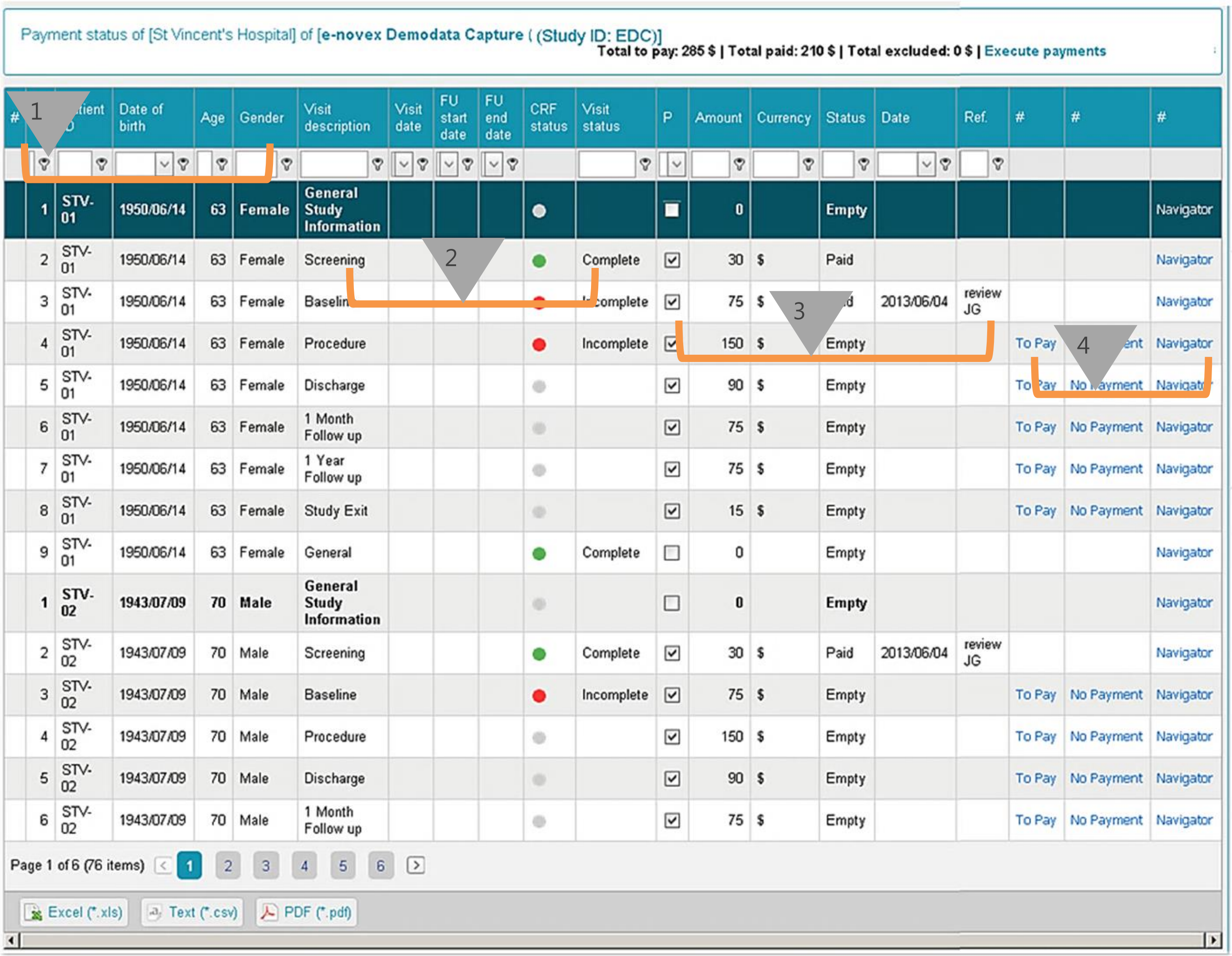
#	Center ID	Description	City	Country	Investigator	# of patients	First enrollment	Last enrollment	#	#	#
	CAP	Capital Medical Center	Olympia - Washington	USA		24	2012/09/14	2013/06/24	Patients	Visit Status	Payments
	LON	London Bridge Hospital (SUBSTUDY)	London	UK		3	2012/09/14	2012/09/14	Patients	Visit Status	Payments
	CAL	California Pacific Medical Center	San Fransisco - California	USA		3	2012/09/14	2012/09/14	Patients	Visit Status	Payments
	CEN	Centre Hospitalier de Perray Vaucluse	Paris	France		3	2012/09/14	2012/09/14	Patients	Visit Status	Payments
	STV	St Vincent's Hospital	New York	USA		10	2012/09/14	2013/06/23	Patients	Visit Status	Payments
	TOK	Tokyo Medical University Hospital	Tokyo	Japan		1	2012/10/01	2012/10/01	Patients	Visit Status	Payments

If your user role allows access to the Payments module (edit or view), a 'Payments' link will be available per center next to the Patients and Visit Status link (see also Chapter: Centers).



- Click the payments link of the center for which you wish to add or track payments:

Back to top ↺



Payment status of [St Vincent's Hospital] of [e-novex Demodata Capture ((Study ID: EDC)]
Total to pay: 285 $ | Total paid: 210 $ | Total excluded: 0 $ | Execute payments

#	tient D	Date of birth	Age	Gender	Visit description	Visit date	FU start date	FU end date	CRF status	Visit status	P	Amount	Currency	Status	Date	Ref.	#	#	#
1	STV-01	1950/06/14	63	Female	General Study Information						☐	0		Empty					Navigator
2	STV-01	1950/06/14	63	Female	Screening					Complete	☑	30	$	Paid					Navigator
3	STV-01	1950/06/14	63	Female	Baselin					complete	☑	75	$	d	2013/06/04	review JG			Navigator
4	STV-01	1950/06/14	63	Female	Procedure					Incomplete	☑	150	$	Empty			To Pay	ent	Navigator
5	STV-01	1950/06/14	63	Female	Discharge						☑	90	$	Empty			To Pay	No ayment	Navigat
6	STV-01	1950/06/14	63	Female	1 Month Follow up						☑	75	$	Empty			To Pay	No Payment	Navigator
7	STV-01	1950/06/14	63	Female	1 Year Follow up						☑	75	$	Empty			To Pay	No Payment	Navigator
8	STV-01	1950/06/14	63	Female	Study Exit						☑	15	$	Empty			To Pay	No Payment	Navigator
9	STV-01	1950/06/14	63	Female	General					Complete	☐	0		Empty					Navigator
1	STV-02	1943/07/09	70	Male	General Study Information						☐	0		Empty					Navigator
2	STV-02	1943/07/09	70	Male	Screening					Complete	☑	30	$	Paid	2013/06/04	review JG			Navigator
3	STV-02	1943/07/09	70	Male	Baseline					Incomplete	☑	75	$	Empty			To Pay	No Payment	Navigator
4	STV-02	1943/07/09	70	Male	Procedure						☑	150	$	Empty			To Pay	No Payment	Navigator
5	STV-02	1943/07/09	70	Male	Discharge						☑	90	$	Empty			To Pay	No Payment	Navigator
6	STV-02	1943/07/09	70	Male	1 Month Follow up						☑	75	$	Empty			To Pay	No Payment	Navigator

Page 1 of 6 (76 items) 1 2 3 4 5 6

Excel (*.xls) Text (*.csv) PDF (*.pdf)

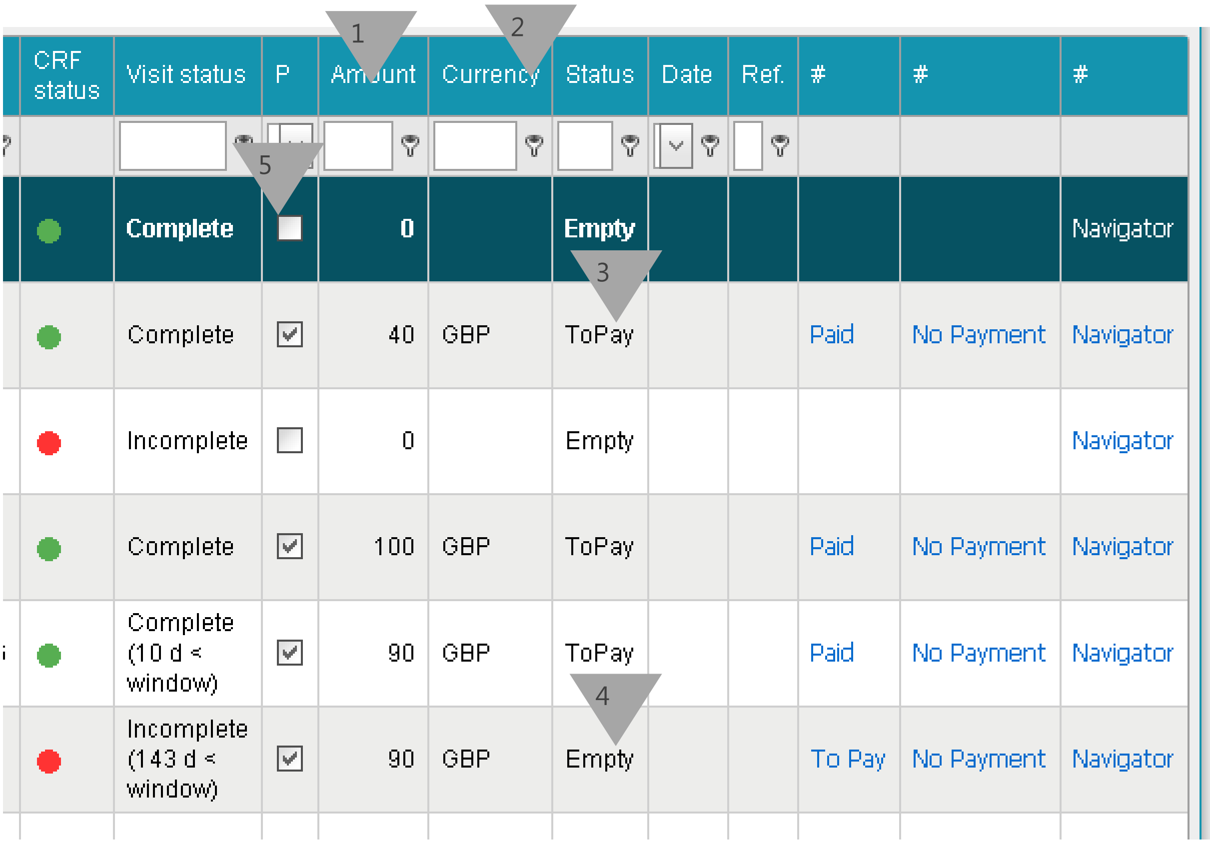
1. Patient information
2. Visit information
   - Description, date and follow up windows
   - CRF status: green, red or grey
   - Visit status: complete or incomplete, indication of time window if applicable.
3. Payment information
   - Payment required Yes/No
   - Amount
   - Currency
   - Status
4. Links
   - To pay (only for payment edit access).
   - Overrule payment (only for payment edit access).
   - Goto Patient navigator (for payment view or edit access).

Back to top ↺

2 AUTOMATED PAYMENT PROPOSALS

The Payment table displays an overview of automated payment proposals for each patient and each applicable visit.

1. Amount can differ per visit and site.
2. Currency can differ per site.
3. A payment status ‘to pay’ is displayed for each visit that has a green visit mark.
4. A payment status ‘empty’ is displayed for each visit that has a red or grey visit mark.
5. Payments are only applicable to visits for which the ‘P’ checkbox is checked.



CRF status	Visit status	P	Amount	Currency	Status	Date	Ref.	#	#	#
●	Complete	☐	0		Empty					Navigator
●	Complete	☑	40	GBP	ToPay			Paid	No Payment	Navigator
●	Incomplete	☐	0		Empty					Navigator
●	Complete	☑	100	GBP	ToPay			Paid	No Payment	Navigator
●	Complete (10 d < window)	☑	90	GBP	ToPay			Paid	No Payment	Navigator
●	Incomplete (143 d < window)	☑	90	GBP	Empty			To Pay	No Payment	Navigator

The status of a visit is indicated by the color of the visit mark:

- ● : visit has incomplete forms or has open queries: empty payment proposal.
- ● : un-opened visit empty payment proposal.
- ● : visit is complete with no open queries: Payment proposal.

Back to top ↺

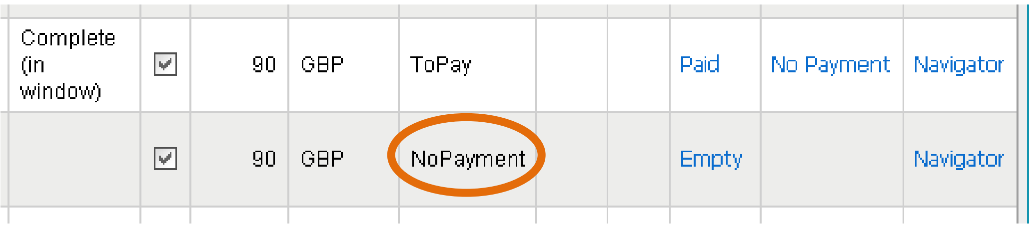
2.1 OVERRULE PAYMENTS

Payment proposals can be manually overruled for all visits for which a payment amount is specified, regardless of the visit status (green, red or grey).

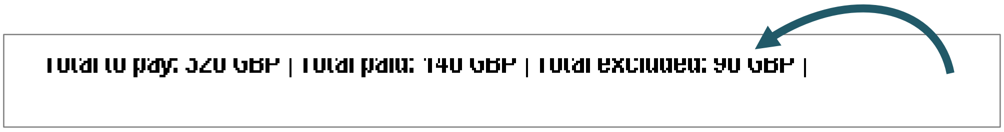
2.1.1 DO NOT PAY

1. Click the 'No Payment' link of the applicable visit to (temporarily) overrule payment:

5. The status of the visit changes to 'NoPayment' and the link changes to 'Empty':



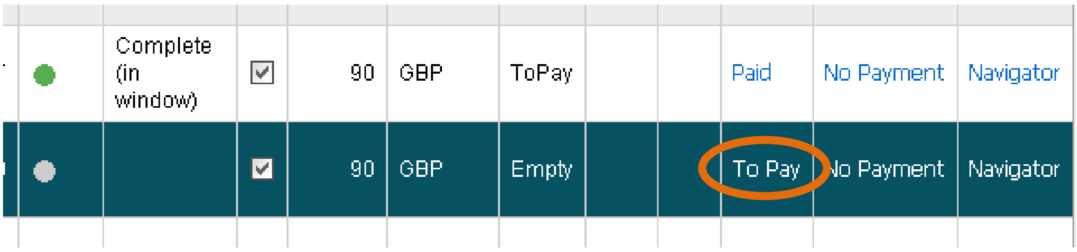
6. The overruled amount is added in the Payment table header to 'Total excluded':



7. Click the 'Empty' link to re-set to the automated payment proposal status.

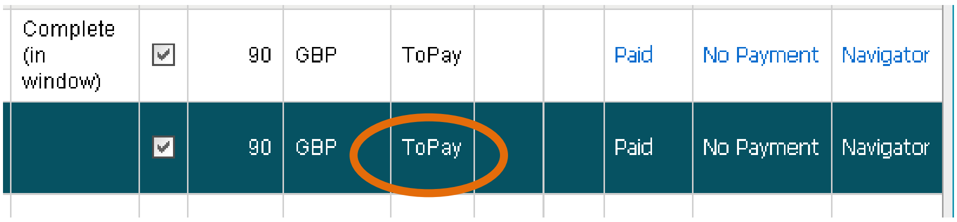
2.1.2 PAY ANYWAY

1. Click the 'ToPay' link of the applicable visit (grey or red status):



8. The status of the visit changes to 'ToPay' and the link changes to 'Paid'

9. Click 'No Payment' to return to the automated payment proposal status.

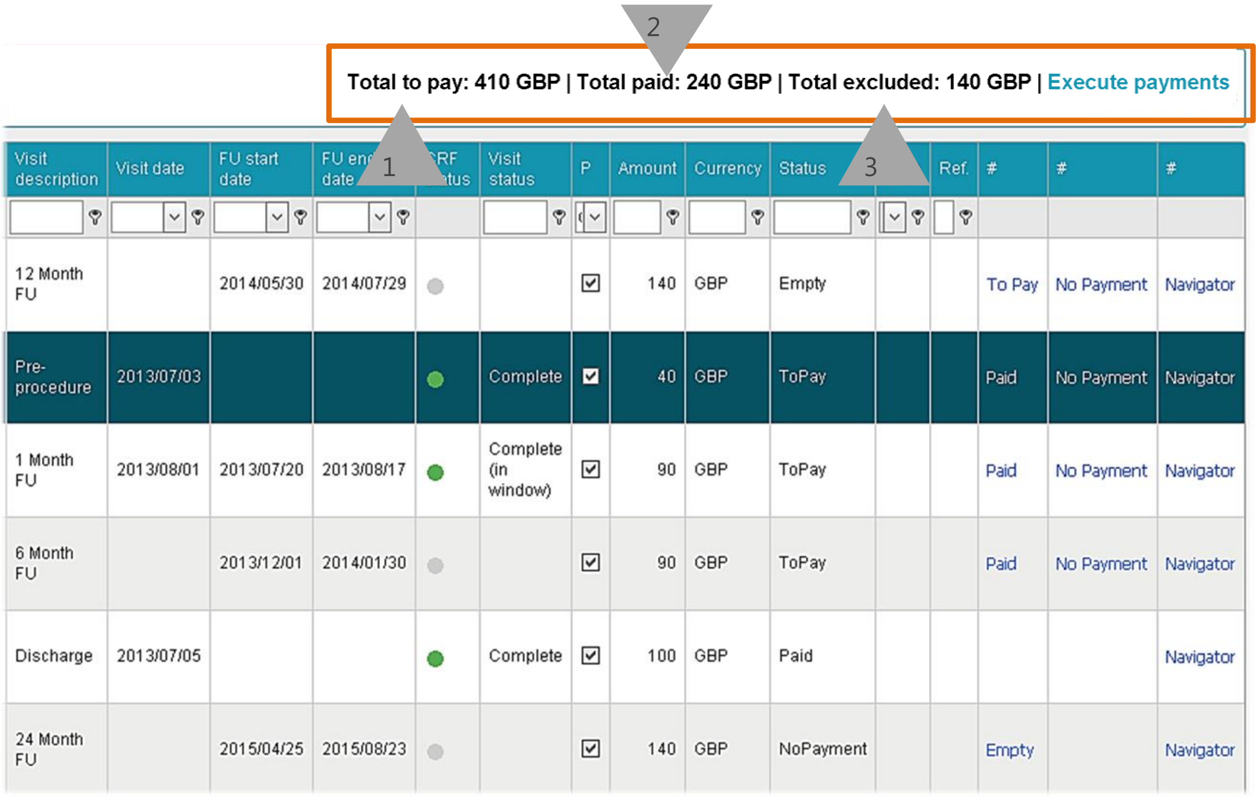


10. The extra 'To Pay' amount is added in the Payment table header to 'Total to pay':

Total to pay: 410 GBP | Total paid: 140 GBP | Total excluded: 0 GBP

NOTE: THE AUTOMATED STATUS OF A PAYMENT CAN BE OVERRULED AS LONG AS THE PAYMENT HAS NOT YET BEEN EXECUTED.

2.2 PAYMENT TABLE HEADER IN DETAIL



Total to pay: 410 GBP | Total paid: 240 GBP | Total excluded: 140 GBP | Execute payments

Visit description	Visit date	FU start date	FU end date	CRF status	Visit status	P	Amount	Currency	Status		Ref.	#	#	#
12 Month FU		2014/05/30	2014/07/29			☑	140	GBP	Empty			To Pay	No Payment	Navigator
Pre-procedure	2013/07/03				Complete	☑	40	GBP	ToPay			Paid	No Payment	Navigator
1 Month FU	2013/08/01	2013/07/20	2013/08/17		Complete (in window)	☑	90	GBP	ToPay			Paid	No Payment	Navigator
6 Month FU		2013/12/01	2014/01/30			☑	90	GBP	ToPay			Paid	No Payment	Navigator
Discharge	2013/07/05				Complete	☑	100	GBP	Paid					Navigator
24 Month FU		2015/04/25	2015/08/23			☑	140	GBP	NoPayment			Empty		Navigator

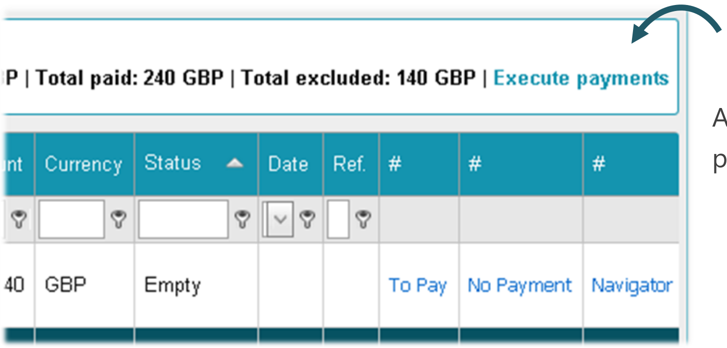
1. Total to pay = sum of amounts in the chosen center of all items with status 'ToPay'.
2. Total paid = sum of amounts in chosen center with status 'Paid'.
3. Total excluded = sum of amounts in chosen center with status: 'No payment'.

NOTE: THE AMOUNTS AS SPECIFIED ABOVE ARE TOTALS PER CENTER; THESE AMOUNTS DO NOT CHANGE WHEN YOU FILTER THE DATA IN THE PAYMENT TABLE.

2.3 EXECUTE PAYMENTS

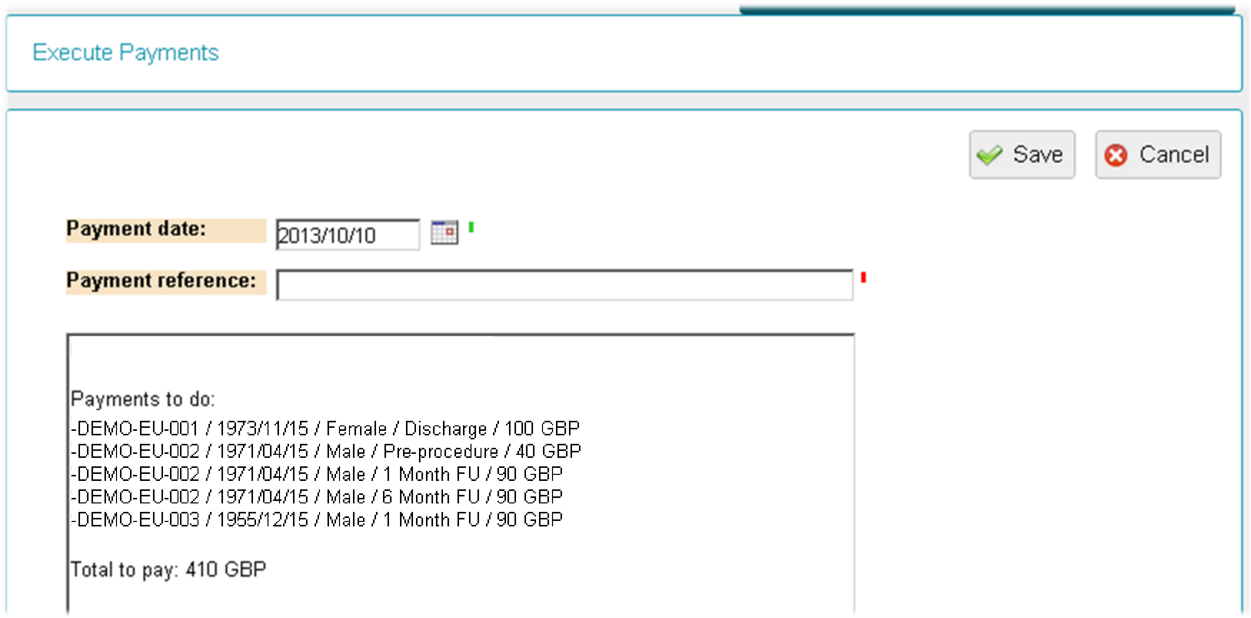
Payments can only be executed for visits with status 'ToPay'
When you agree with all proposed (and overruled) payments, follow these steps to execute payments:

1. Click Execute payments on the top right hand side of the Payments table.



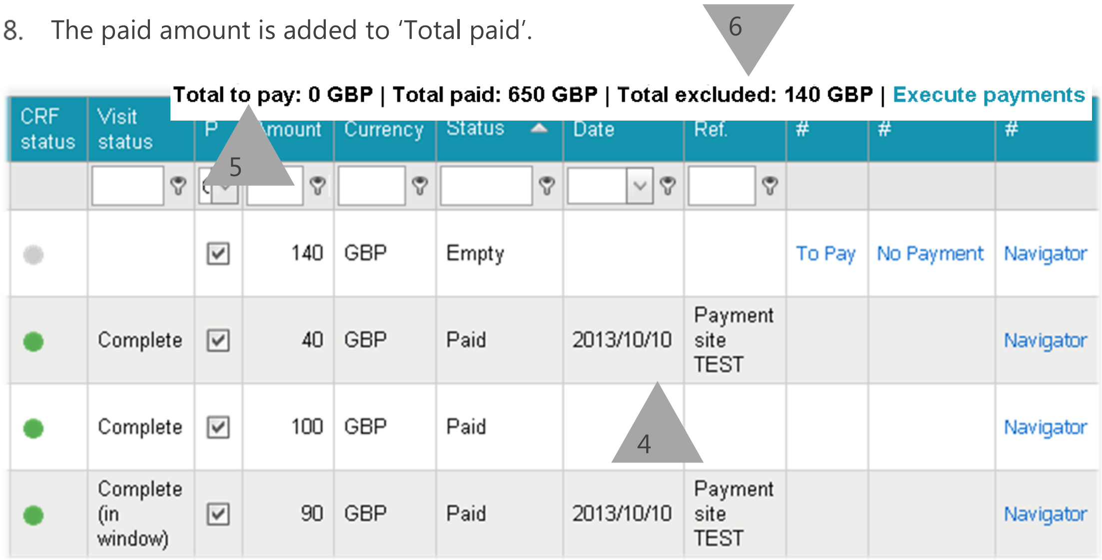
A window is displayed with all details per payment.

4. Add a payment reference and if needed, copy the details for further payment processing by your accountancy department.
5. Click Save.



IMPORTANT NOTE:
THE PAYMENT FUNCTIONALITY IS AN INFORMATIVE TRACKING TOOL. ACTUAL PAYMENT TRANSFERS ARE STILL TO BE EXECUTED.
THE PAYMENT DETAILS IN THE WINDOW ABOVE CAN BE USED TO FORWARD TO THE APPLICABLE PAYMENT DEPARTMENT.

6. Upon clicking Save, the date of payment and the reference are added to the Payment table.
7. Total to Pay is set to '0'.
8. The paid amount is added to 'Total paid'.

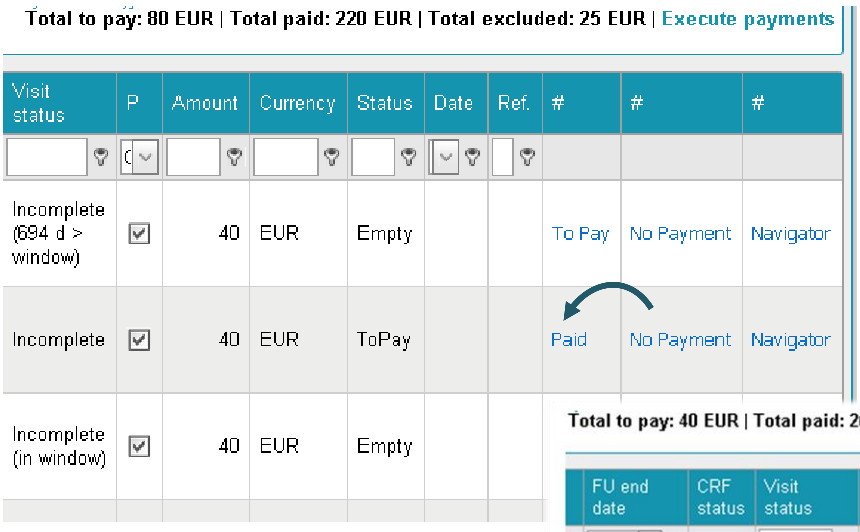


9. Possible actions to pay/ no payment are disabled for the visits for which payment was executed.

2.4 PROCESS A SINGLE PAYMENT

In case you do not wish to execute all payments at the same time, the Payment module allows you to process payments per single visit.

To do so, simply click the 'Paid' link for the applicable visit with status 'ToPay'.
The visit status becomes 'Paid' and the amount is deducted from 'Total to pay' and added to 'Total paid'.



! DO NOTE THAT IN THIS CASE, NO PAYMENT DETAILS WILL BE SHOWN UPON EXECUTION NOR WHEN PROCESSING A FOLLOWING OVERALL PAYMENT EXECUTION AS SPECIFIED IN THE SECTION ABOVE.

Back to top ↺

3 PAYMENT VIEW ACCESS

A payment table is implemented per study center. You can access each table via the 'Centers' button within the Navigation tool.
If your user profile has 'Payment view' access only, you'll be able to see the payment status for your patients, but you will not be able to manage the payments.

Visit description	Visit date	FU start date	FU end date	CRF status	Visit status	P	Amount	Currency	Status	Date	Ref.	#
Baseline Core Lab					**Incomplete**	☑	**300**	**USD**	**Empty**			Navigator
Baseline	2011/07/10				Incomplete	☑	270	USD	Paid	2013/07/18	1st payment round	Navigator
Procedure Core Lab					Incomplete	☑	300	USD	Empty			Navigator
Procedure	2011/07/12				Incomplete	☑	120	USD	Paid	2013/07/18	1st payment round	Navigator
1-Month Follow-Up Core Lab						☐	0		Empty			Navigator
1-Month Follow-Up	2011/08/11	2011/07/28	2011/08/25		Incomplete (in window)	☑	240	USD	Empty			Navigator
3-Month Follow-Up Core Lab						☐	0		Empty			Navigator
3-Month Follow-Up		2011/09/26	2011/10/24		Missing (window passed)	☑	240	USD	Empty			Navigator

DOUBLE DATA ENTRY

Reducing data entry errors

Transferring data from paper source documents into an eCRF is a critical step that may influence the accuracy of your study data.

Double data entry (or Two-pass verification) is a data entry quality control with a high degree of accuracy.

The Double Data Entry (DDE) module in e-capture.net is a stand alone feature and will therefore not be applicable for all studies. If included in your study, access to DDE is linked to a specific user profile.

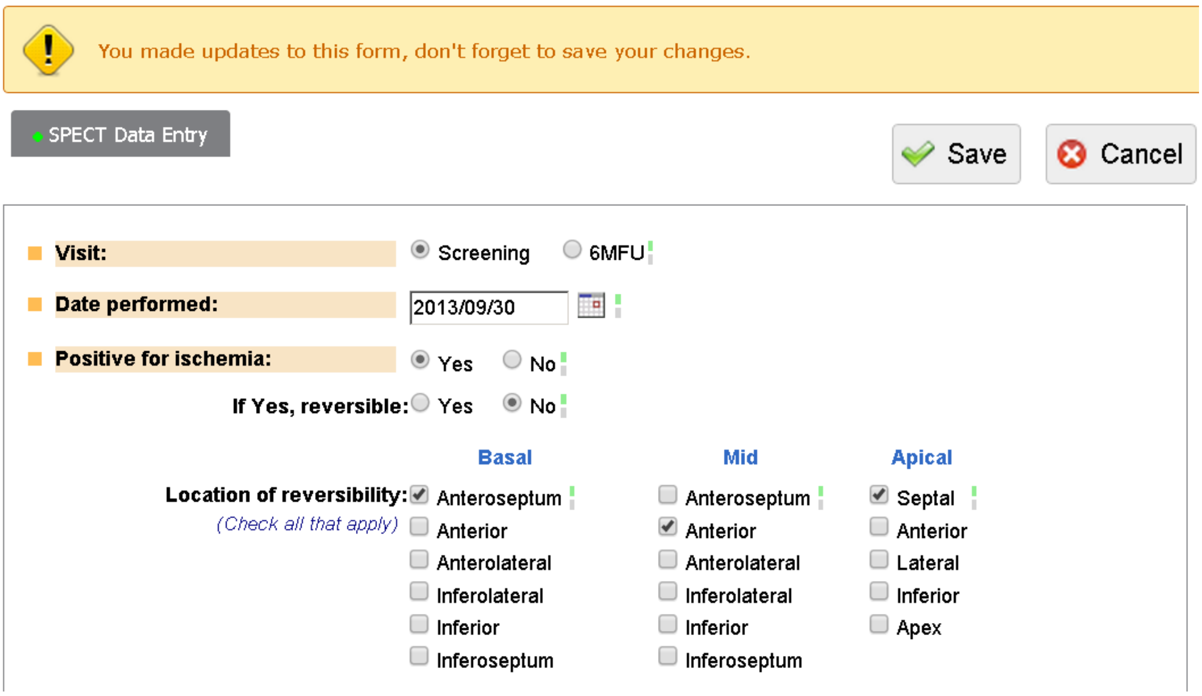
DDE - Method

Using this method, data will be entered twice into the eCRF forms of your study. During the second entry process, the entries are compared against the first data.

In case the entry of a value conflicts, e-capture.net alerts the data entry person, enabling verification and correction in real time during data entry.

1 FIRST DATA ENTRY

Enter data for the first time in the eCRF forms and save your entries (for more information, see Chapter: Enter Data).

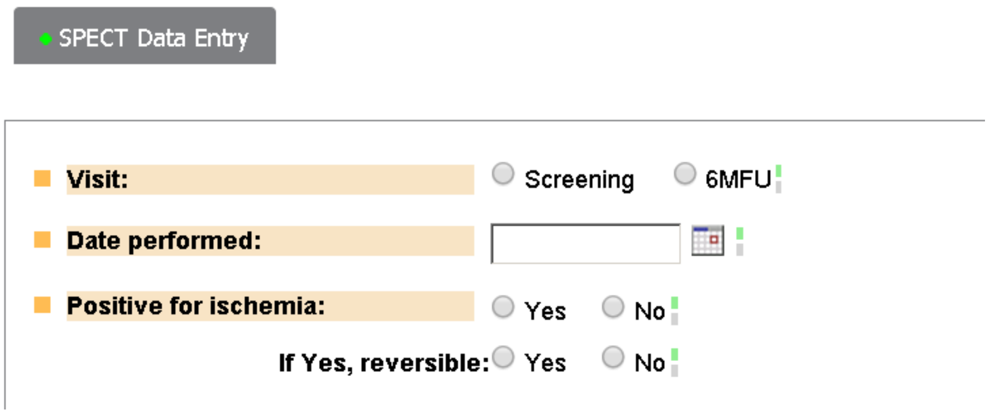


2 SECOND DATA ENTRY

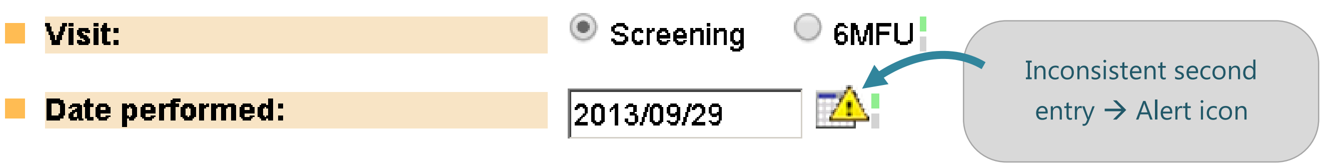
The second data entry is performed by a user which has verification rights assigned to it's user role. This user completes the same forms as the first entry person, using the same source documentation.

2.1 FORM COMPLETION

- Initially, the form is displayed with no entries:

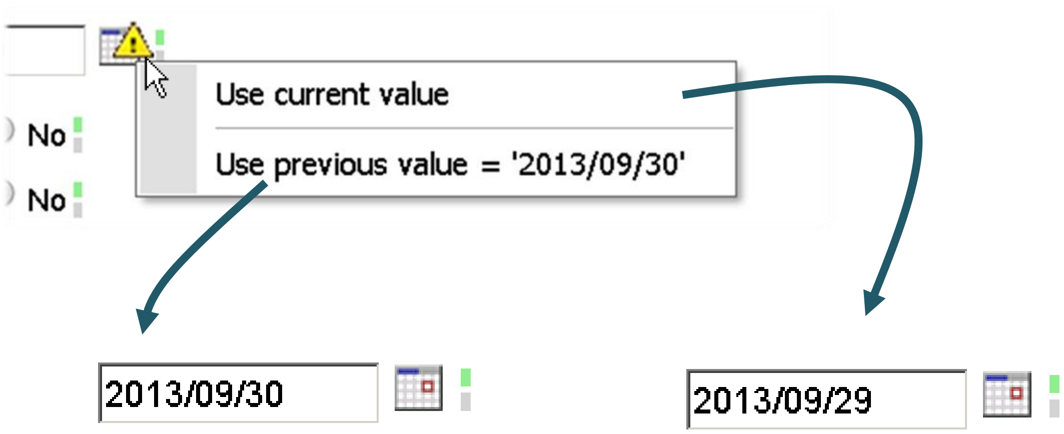


- The verification user completes the eCRF form for the second time. The system compares per field the second entries with the first.
- The system accepts correct entries but shows an **alert icon** in case of inconsistent entries on a field.



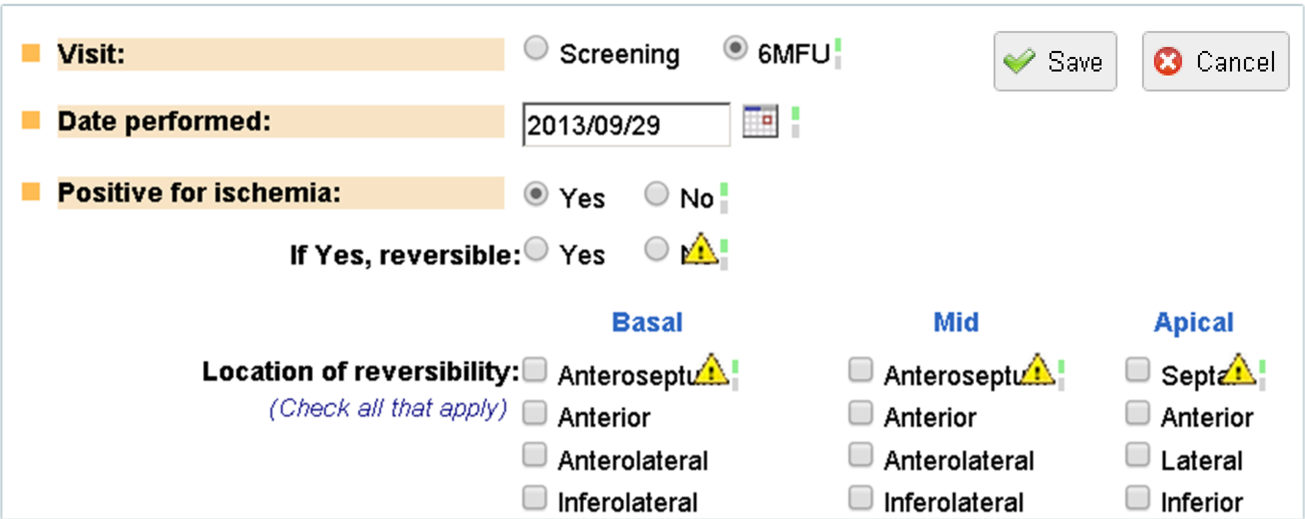
2.2 VERIFICATION

- Click on the alert icon. A window displays the options to accept either the current or the previous value.

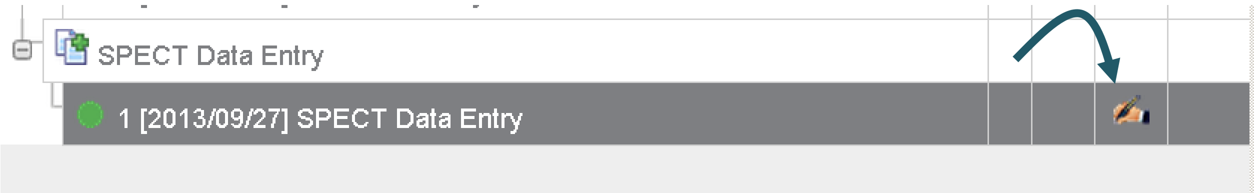


- Click 'Save' when all data is entered.

- Depending on the set up of your study, you might be requested to complete a [reason for change](#) in case a first entry is overruled by the second.
- If not all fields are completed or not all discrepancies are resolved, the message: "Verification not complete" is displayed when trying to save the form.



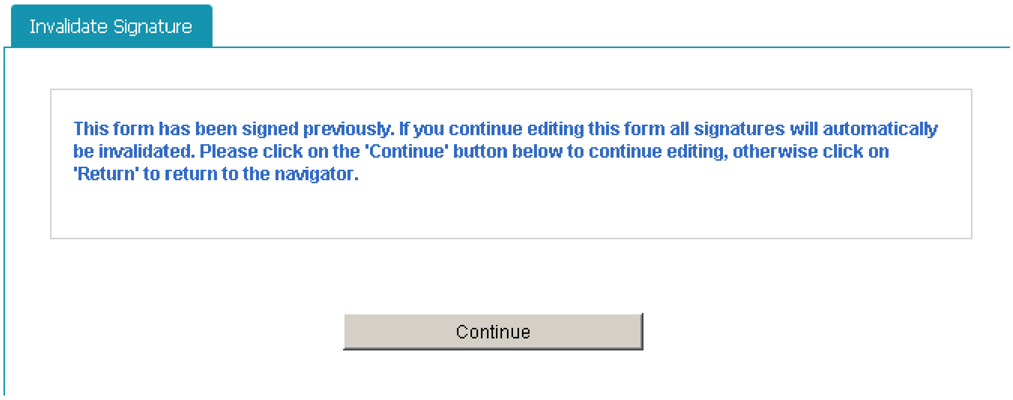
- Resolve all alert icons and save the form. If not, the partial verification will be lost for this page and needs to be re-done on re-entry.
- When second data entry is complete and saved, the form receives an automated signature in the navigator.



2.3 UPDATES AFTER DOUBLE DATA ENTRY

2.3.1 FIRST ENTRY USER

When you attempt to open a form that holds a DDE signature, you will first be prompted with a warning message.



- Click the 'Continue' button to open the form.
- In case you close the form without saving any changes, the DDE signature on the form will remain intact.
- If you update and save any data on the form, the signature will become invalidated.
  The Double Data Entry process must be repeated to re-install the signature.

2.3.2 SECOND ENTRY USER

When a second entry user returns to a signed form and clicks the 'Continue' button, the form will be opened with empty fields, forcing the verification user to repeat the entire second entry.