EORTC
European Organisation for Research and Treatment of Cancer
AISBL International Non-Profit Association under Belgian law IVZW

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VISTA RDC

VISTA REMOTE DATA CAPTURE
EORTC ELECTRONIC DATA CAPTURE SYSTEM

https://rdc.eortc.be

USER GUIDE
(FOR MONITORS)

VERSION 1.0
June, 2014

Version history - RDC user guide for monitors

REVISION HISTORY			
Version	**Brief Description of Change**	**Author**	**Issue Date**
1.0	Initial Release	Marlies Dictus	June 2014

Overview

VISTA Remote Data Capture (VISTA RDC) is used for the completion of most case report forms. These forms will be accessible from the EORTC website and have to be completed on-line (https://rdc.eortc.be). The system allows remote users to have access to the EORTC VISTA patient clinical database.

> *Note: Some CRF (e.g. pathology form, Quality of Life, SAE, etc.), could still have to be completed on paper. Please check for each study which forms (if any) need to be completed on paper. All other forms will have to be completed on-line.*

For further information regarding the timepoints of completion of the case report forms please refer to the study specific guidelines for CRF COMPLETION.

The EORTC VISTA-RDC system provides an electronic version of the CRFs and will enable users to enter and edit data on-line and, once completed, to directly transfer the data into the EORTC clinical database. Sent forms stay visible and accessible in VISTA RDC.
After the data transfer, the data reported on the Case Report Forms will be reviewed and validated by the EORTC Data Manager. In case of missing or contradictory data, queries will be raised (per patient) in order to obtain consistent data. These queries will appear in VISTA RDC. Queries requesting an overdue form will result in a 'requested form' appearing on the 'blank' tab. Other queries are displayed in the 'queries' tab.

VISTA RDC is NOT used to register, enroll or randomize patients. For the registration, enrollment or randomization of your patient, please go to: http://orta.eortc.be (via Internet at anytime). An ORTA user guide is available on the weblink.

RDC monitoring

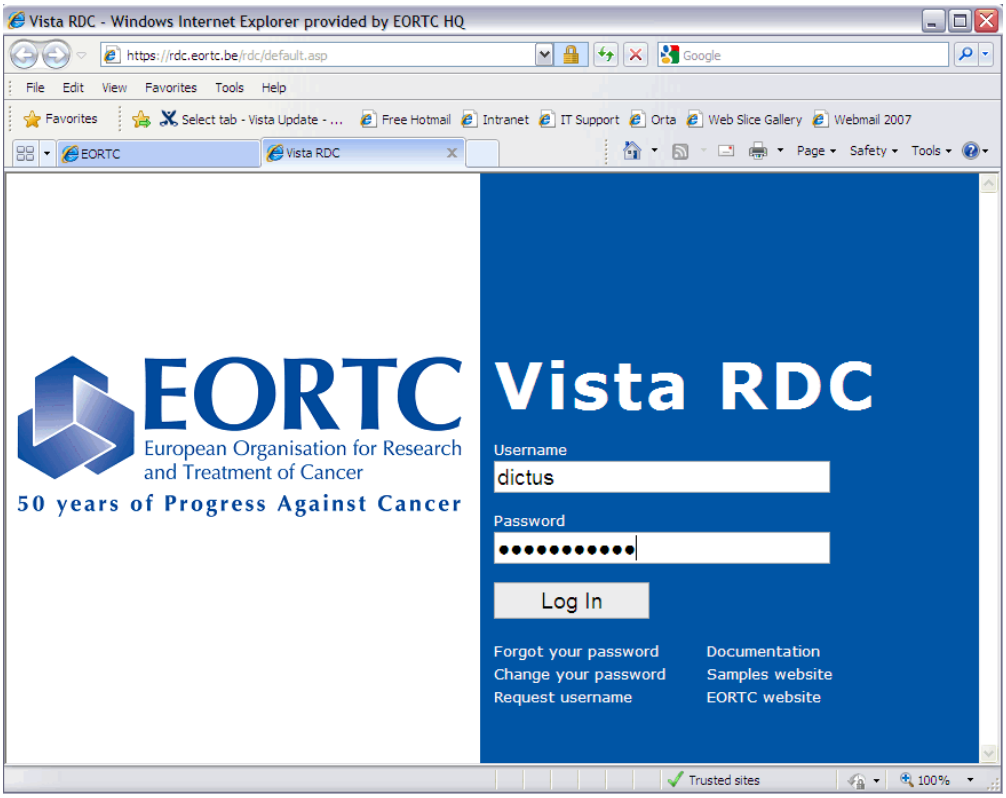
In studies using the RDC monitoring feature, Monitors can create electronic **CRA queries** and can electronically tick forms as **source data verified**.

The CRA queries are raised by the Monitor, should be answered by the Principal Investigator (or an authorized staff member). Once answered and validity of the answer marked by the monitor (by ticking the form as source data verified), the query will be closed by the EORTC Data Manager.

Source data verification by the Monitor can be done on 'complete' and 'sent' forms and CRA queries can be created on forms with the same status which are not yet ticked as 'source data verified'.

Access the RDC system

Access to the EORTC VISTA RDC system is possible at the following internet address: **https://rdc.eortc.be**/ or through the EORTC website (http://www.eortc.org), in the 'Investigator's Area'.
On this web page, you will be prompted to enter your EORTC ORTA Username & password (identical to the one used for registration/randomization of patients).



> *Note: If this screen does not appear or if you have problems after login, your browser might be too old to run the program. Install an upgraded version of your internet browser. These programs are free and available for download on the Internet.*

Username & password

An RDC username and password for monitors will be granted after completion of an **RDC access request form** by the Data Manager responsible of the study.

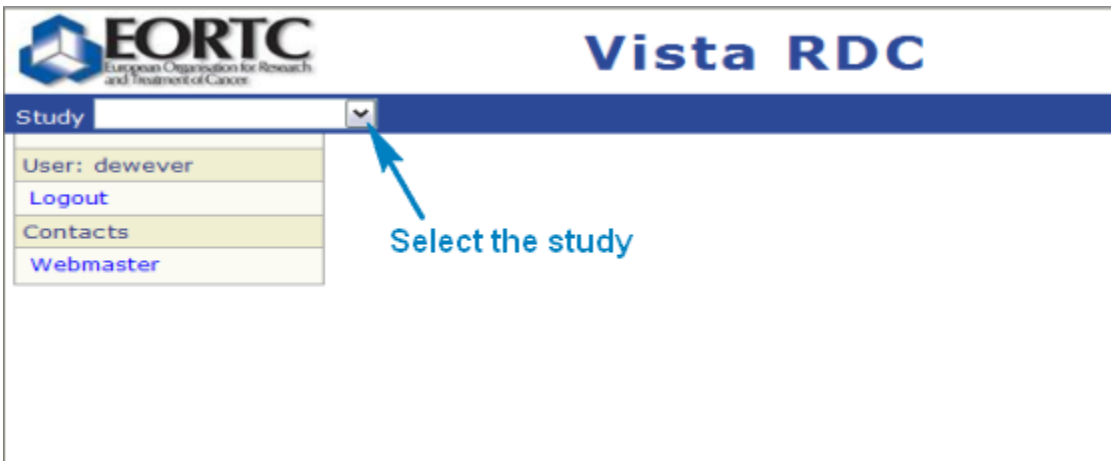
On this form, the type of access for the monitor should be defined (e.g. monitor rights for all patients, patients from (a) specific institution(s), patients from a particular physician).

> *Note: **Passwords expire after 90 days**. However, you don't need to connect every 3 months to change your password. When you connect with an expired password, the system will ask you to choose a new one. Changing the password periodically is a security feature of the system. Choose whatever password you like, but with **at least 6 characters**. A combination of alphanumeric characters is preferable.*
>
> *In case you have **forgotten your password**, a link is provided to request it. Your password will be sent to your email address.*

Study Identification

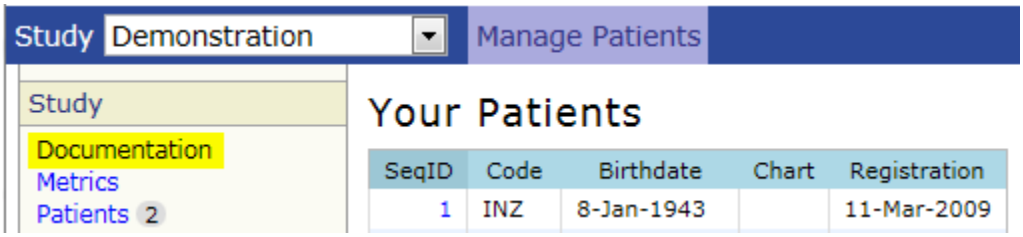
Once logged on, you can begin the actual RDC process. The first step is to identify the EORTC study.

The study identification screen prompts you to select a study number. Only the studies for which you have fulfilled the necessary requirements for participation will be listed in the drop-down menu.

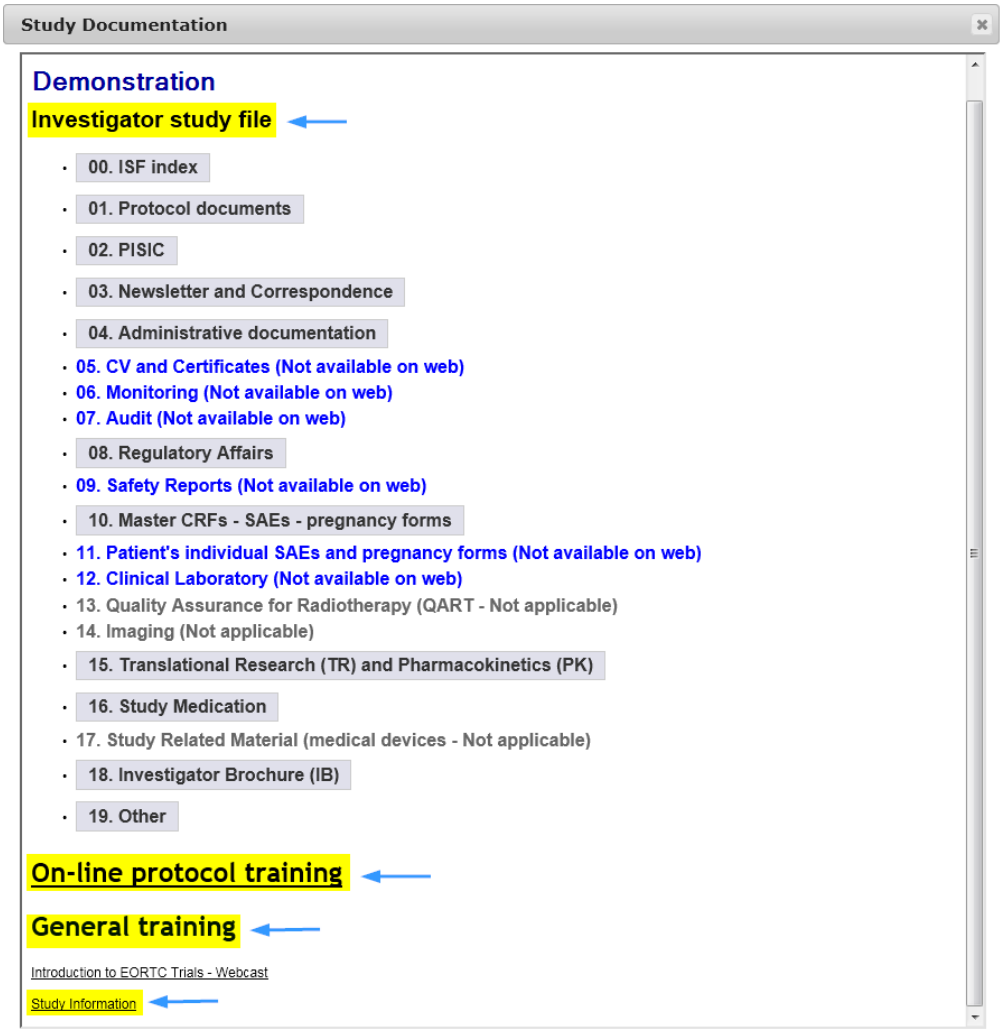


Study documentation

After selecting the study, information on the study can be retrieved by clicking on 'Documentation' in the left part of the screen.



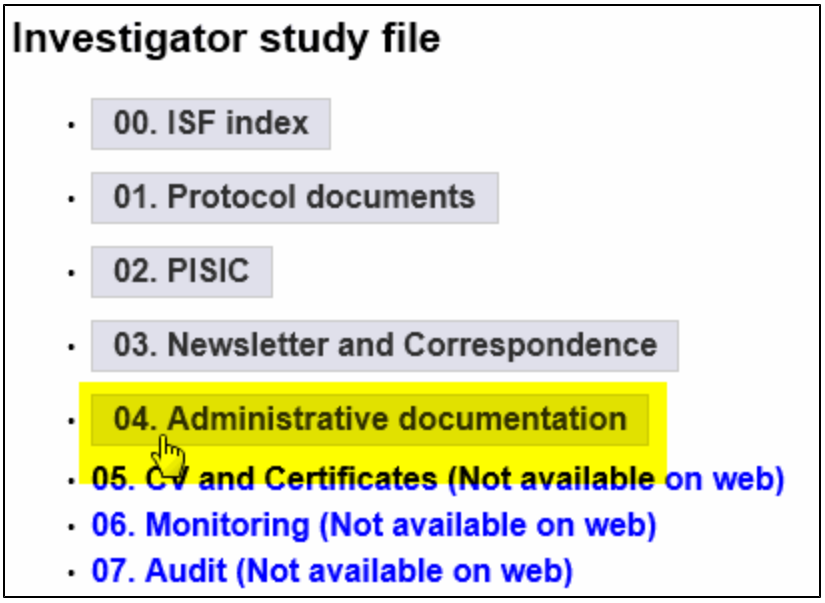
You will be redirected to the study documentation page where you can access the investigator study file, on-line protocol training (if available), general training on EORTC clinical trials activities and the study information page.

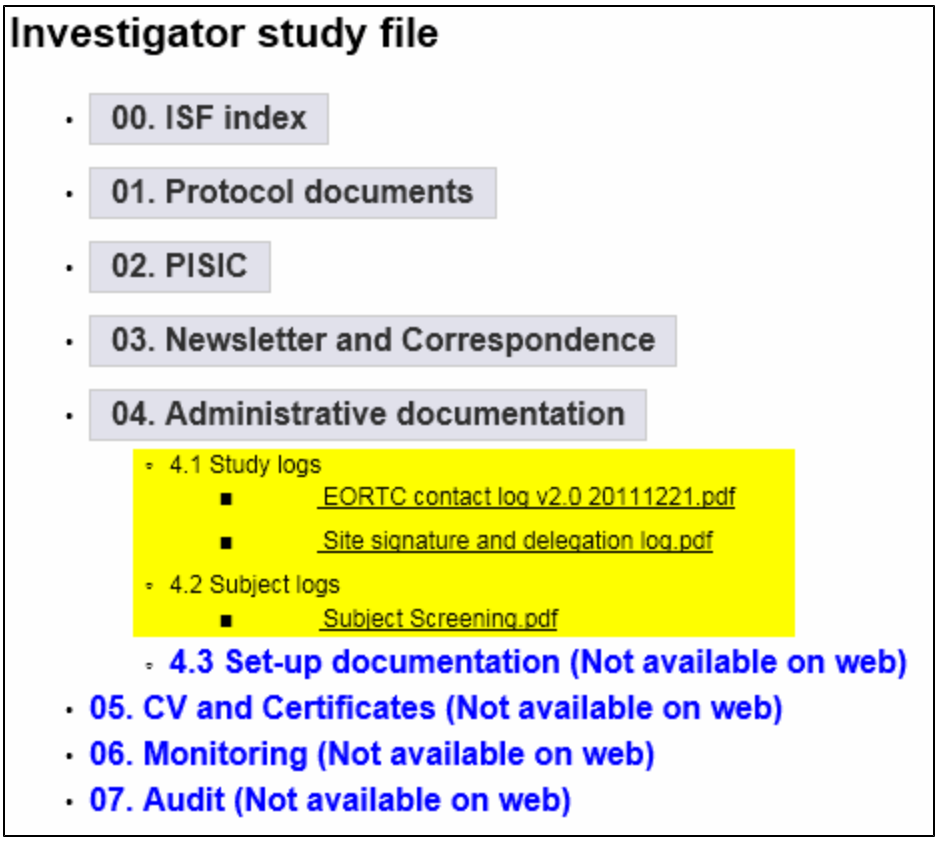


Investigator study file

This part is showing the structure and contents the investigator study file should have on site. The investigator study file consists of all the documents which should be kept at the site in the investigator study file (e.g. protocol documents, CRF completion guidelines, IB, ...). The general documents (not site specific) are directly available on-line on this study documentation page. This is the case of **blank paper forms** such as quality of life or SAE forms, **CRF completion guidelines**, which can thus be easily consulted during data entry in RDC.

By clicking on the grey bars, additional information appears and the PDF documents can be opened directly and printed for filing.





On-line protocol training

When available for the study, on-line protocol training can be followed from the study documentation page by clicking on the link 'On-line protocol training'. Different training slides can be accessed and when the training is finished, the trainee can confirm online that the training has been followed and a training certificate will be provided by email.

General training

The general training on EORTC clinical trials activities consists of a webcast training which is recorded from the one day introduction to EORTC trials. Specific presentations on EORTC's study development, study activation, patients safety, randomization and data management, ... can be viewed directly from the link.

Study Documentation

EORTC
European Organisation for Research and Treatment of Cancer

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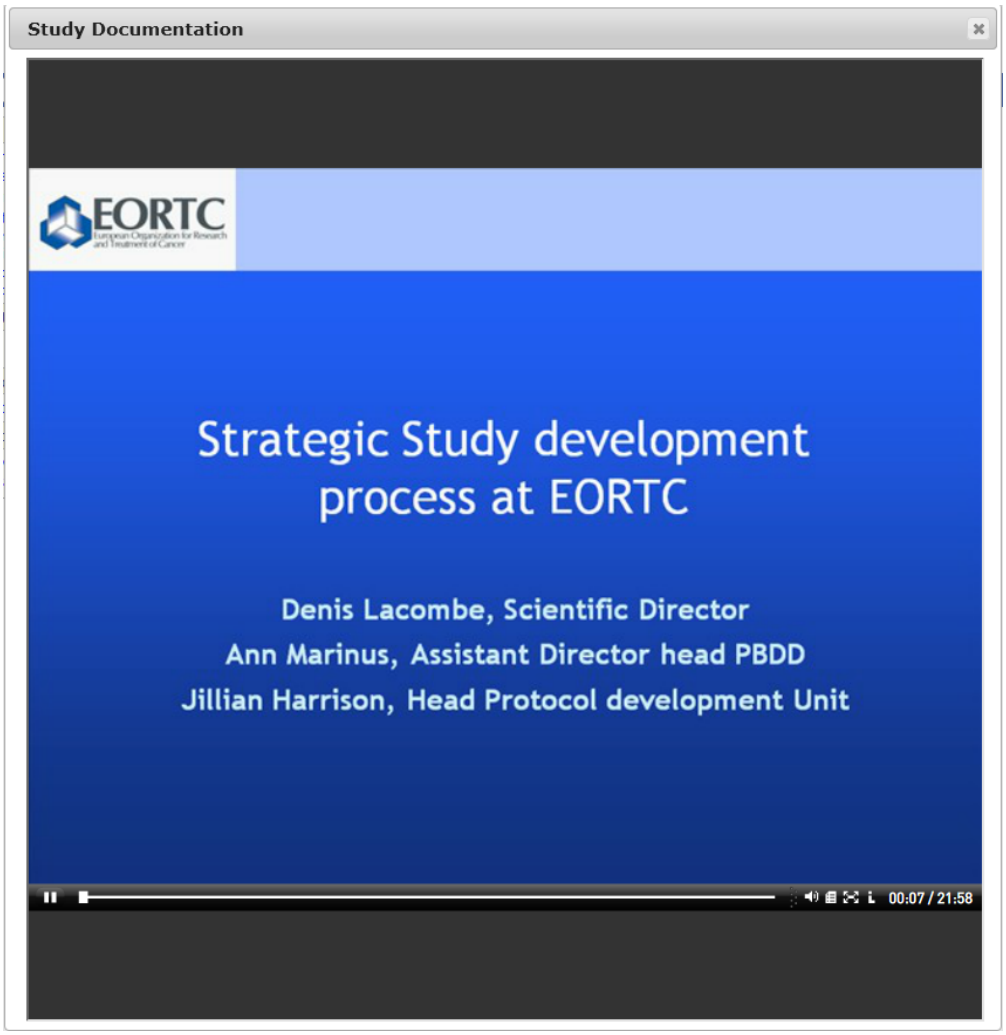
One Day Introduction to EORTC Trials

This course is dedicated to newly participating members (investigators, data managers, research nurses, etc.), and industry representatives. The purpose of this introductory workshop is to give guidance for participating in EORTC clinical trials activities. The following recordings were made before a live audience in October 2010.

The following streaming videos requires JavaScript to be enabled and the latest version of the Macromedia Flash Player. If you are you using a browser with JavaScript disabled please enable it now. Otherwise, please update your version of the free Flash Player by downloading here.

	Title	Length	Content	Presenter
1.	Introduction	35 mins	General Introduction, structure and activities, scientific strategy and perspectives	Francoise Meunier (Director General)
2.	Study Development	22 mins	Strategic Study Development Process at EORTC	Denis Lacombe (Scientific Director)
	Project and Budget	9 mins	Project and Budget Development	Ann Marinus (Head of Project and Budget Development)
	Protocol Review	8 mins	Protocol Review Process / Protocol Development	Jillian Harrison (Head of Protocol Development)
	Study Activation	12 mins	Study Activation Timelines	Ann Marinus
3.	Trial Methodology	70 mins	Phase I, II and III trial design, randomization, selection of endpoint, sample size, statistical methods, reporting, monitoring and publication	Richard Sylvester (Senior Statistical Scientist)



Study information page

The study information page contains information on the specific protocol (trial status, targeted sample size, drug, study staff, ...).

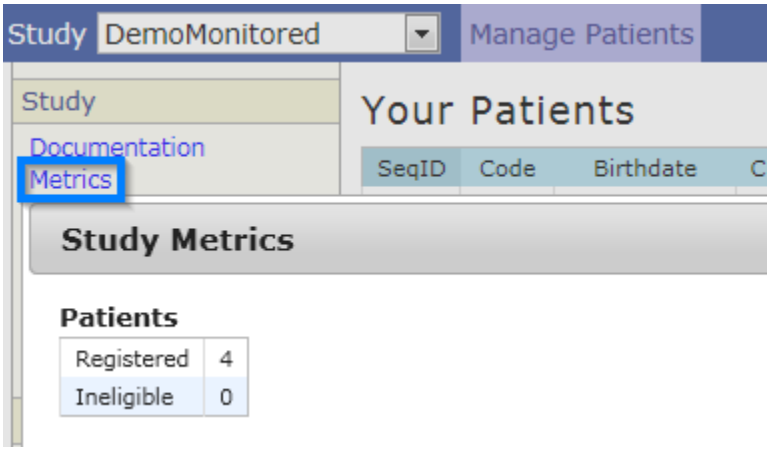
Study Documentation

Demonstration

Trial Status	Closed for recruitment
Dates	Date of activation: 18-Jul-11 Date Step1 close: 05-Aug-13
Data management at EORTC	Full
Phase	3
Randomized trial	Yes
Type	-
Targeted Sample size	EORTC Groups: 587 - All Groups: 587
Number of steps	2
Drug	Pazopanib Blind trial medication
Study Staff	Name (Study Coordinator) - Royal Marsden Hospital - Sutton, Surrey, Sutton Name (Statistician) - EORTC Headquarters, Brussels Name (Data Manager) - EORTC Headquarters, Brussels Name (Project Manager) - EORTC Headquarters, Brussels, Name (Clinical Research Associate) - EORTC Headquarters, Brussels Name Clinical Research Associate) - EORTC Headquarters, Brussels Name Clinical Research Associate) - EORTC Headquarters, Brussels
Type of cancer	Lung
Participating Groups	EORTC Lung Cancer Group(Coordinating Group)
Protocol summary	Cancer.gov (PDQ) ClinicalTrials.gov
NCT number	NCT01208064
EudraCT	2010-018566-23
Protocol documents in	

Metrics

After selecting the study, the number of patients randomized/registered (step 1) in the study can be seen by clicking on 'metrics' in the left part of the screen.



!! Please do not take the 'ineligible' number into account, as this is not applicable for studies using randomization by ORTA.

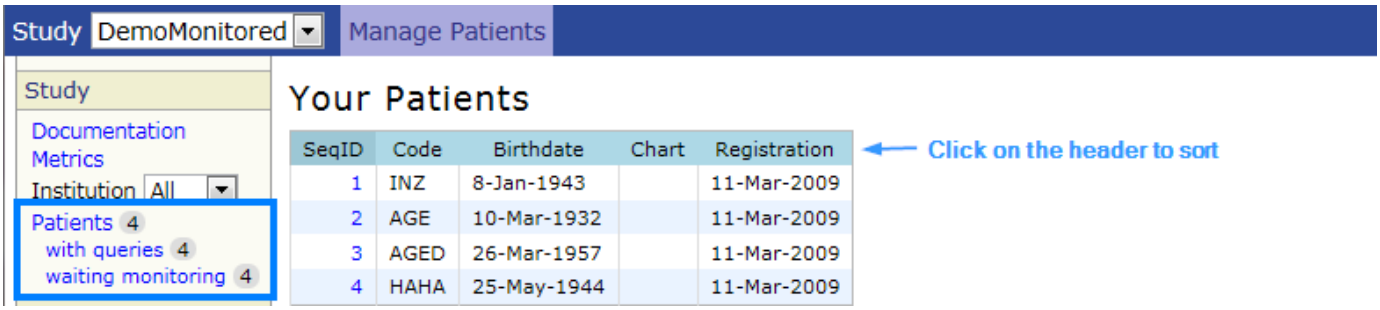
Request for help

Would you encounter a technical problem with VISTA RDC, please contact either the EORTC webmaster or the study team.
For protocol related issues you can always contact the EORTC Data Manager.

Both the webmaster and the EORTC Data Manager responsible for your trial can be directly contacted by e-mail via the following links in the left part of the screen:

Select a patient

Once you have selected the study number, a table listing the patients for which you have access will be shown.
The table 'Your Patients' shows the patient's SeqID allocated at the end of the registration/randomization procedure, the patient code, date of birth, chart number (not applicable anymore since 01/01/2008) and date of registration. By default, the table is sorted by Seqid. To sort by code, date of birth or date of registration, click on this field in the header of the table.



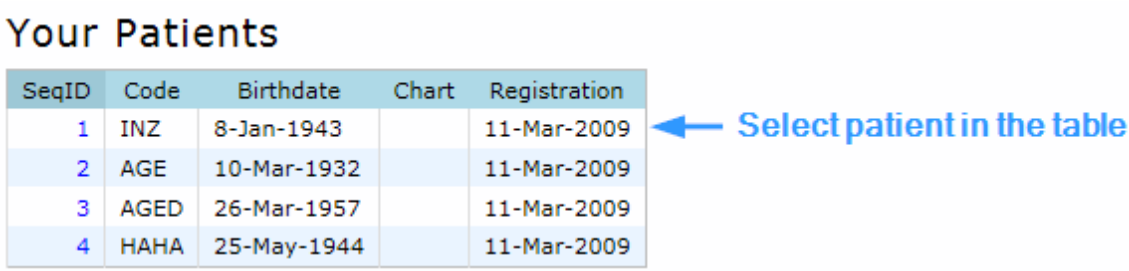
By default all the patients are shown. It is also possible to make a selection of patients based on the following criteria:

- Patients with queries
- Patients waiting monitoring

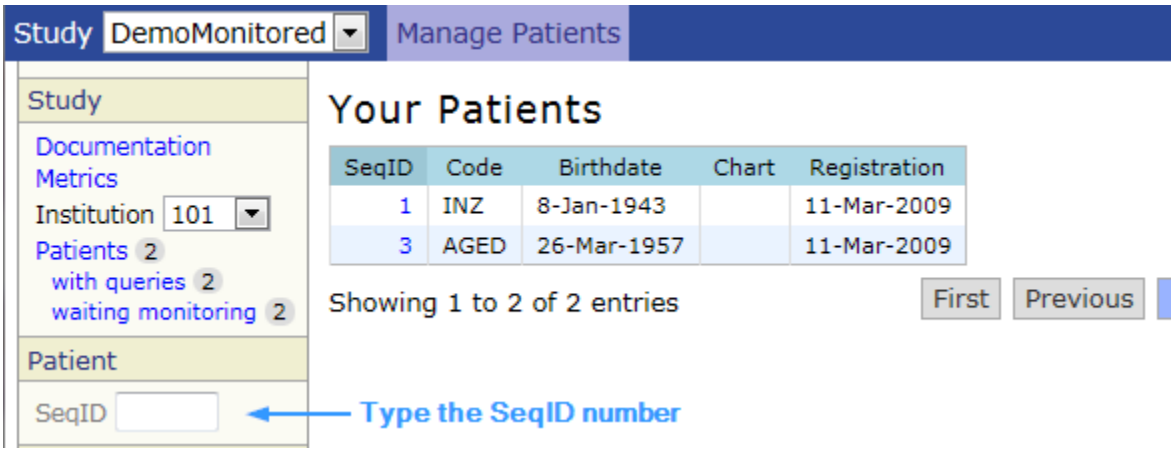
The numbers shown in the left panel are the number of patients in the selection.

Open the patient's file

To open a patient's file, you may either select the patient in the table or type in the SeqID number (followed by the Enter button) in the SeqID field on the left part of the screen.



OR



Selecting the patient SeqID will give you access to the patient's file. This on-line file compiles all forms for the selected patient ('Blank', 'Incomplete', 'Complete' and 'Sent') as well as the unresolved queries.

Entries shown in the table

A maximum of 25 entries is shown in the table with 'your patients'. With the buttons 'previous' and 'next' you can go the previous/next list of entries. With the buttons 'first' and 'last' you can go the first/last list of entries.

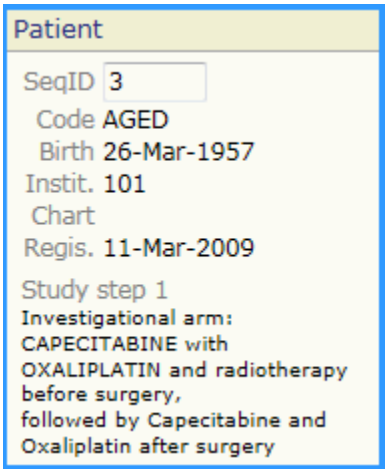
Your Patients

SeqID	Code	Birthdate	Chart	Registration
1	ELSK	6-Nov-1946		15-Nov-2011
2	SMA	7-Oct-1956		11-Dec-2011
3	LEGE	28-May-1962		4-Jan-2012
4	EF01	18-Jul-1938		27-Jan-2012
5	HEA	15-Mar-1950		31-Jan-2012
6	DU	30-Aug-1934		2-Feb-2012
7	BOKO	16-Aug-1954		9-Feb-2012
8	DMA	31-Mar-1981		15-Feb-2012
9	mbr	19-Jul-1962		22-Feb-2012
10	MG	11-Aug-1952		29-Feb-2012
11	AW	30-Jun-1931		1-Mar-2012
12	MD	19-Aug-1939		7-Mar-2012
13	RAAR	6-Jun-1947		27-Mar-2012
14	AHH	3-Apr-1982		28-Mar-2012
15	HMA	23-Oct-1953		1-Apr-2012
16	MAA	18-Aug-1962		2-Apr-2012
17	E-C	6-Mar-1945		23-Apr-2012
18	WY	26-Jun-1955		23-Apr-2012
19	JG	13-Feb-1945		24-Apr-2012
20	PG	1-Feb-1947		26-Apr-2012
21	JD02	10-Jan-1961		30-Apr-2012
22	WBR	5-Nov-1955		11-May-2012
23	MAB	6-May-1947		11-May-2012
24	J-M	9-Sep-1965		15-May-2012
25	MAPI	4-Jan-1946		16-May-2012

Showing 1 to 25 of 102 entries First Previous 1 2 3 4 5 Next Last

Patient identification

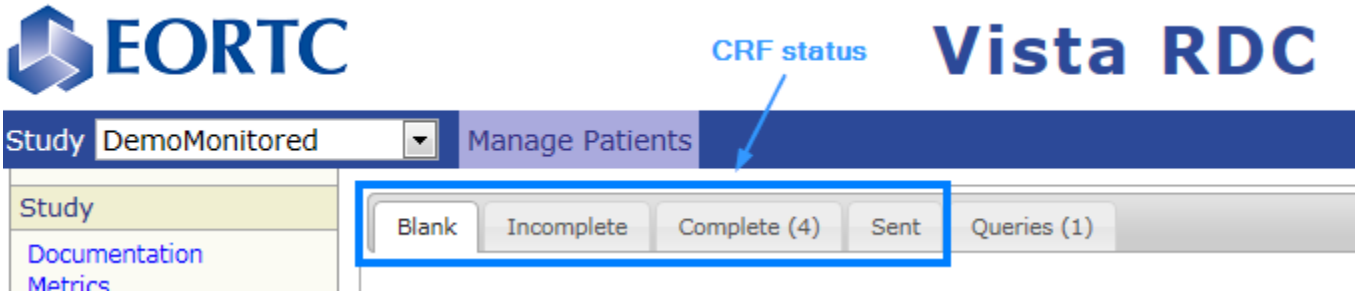
The patient's identification can be found on the left of the screen.



Code: the patient code (chosen at registration, 4 characters at maximum)
Birth: the patient's date of birth (dd/mm/yyyy)
Instit: the EORTC reference number for the institution that registered/randomized the patient
Chart: the patient's chart number (not applicable anymore since 01/01/2008)
Regis: the date the patient was registered in the trial (for the first step)
Study step 1: the treatment that was allocated during the registration/randomization of the patient for step 1 (depending on the study multiple steps can be displayed)

Forms status

Five tabs are available in the **center of the screen**. Four of them are related to the CRFs status while the last one is dedicated to the unresolved queries of the patient.



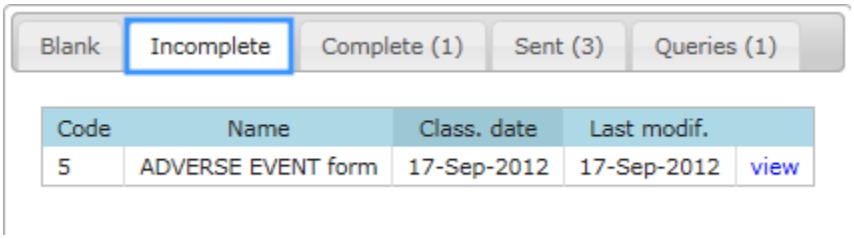
Blank forms

This tab is **not applicable** for the monitor and contains no information.

Incomplete forms

When created by the principal investigator (or an authorized staff member), a new form has an 'incomplete' status. A form can be saved as 'incomplete' at any time.

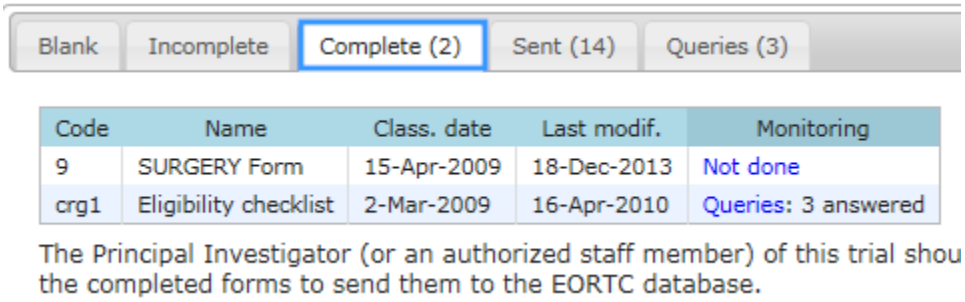
The monitor can **view** the forms that have status 'incomplete' but cannot make CRA queries on this type of form, neither mark it as source data verified "SDV done".



Complete forms

Once all required data on a form has been reported, the form will be saved by the principal investigator (or an authorized staff member) as 'complete'. 'Complete' forms must be sent to the EORTC database by users that have the right to sign forms. 'Complete' forms can be edited as long as they are not yet sent, without CRA queries and not yet source data verified by the monitor.

The monitor can create **CRA queries** on 'complete' forms and can mark this type of form as **source data verified (SDV done)**.

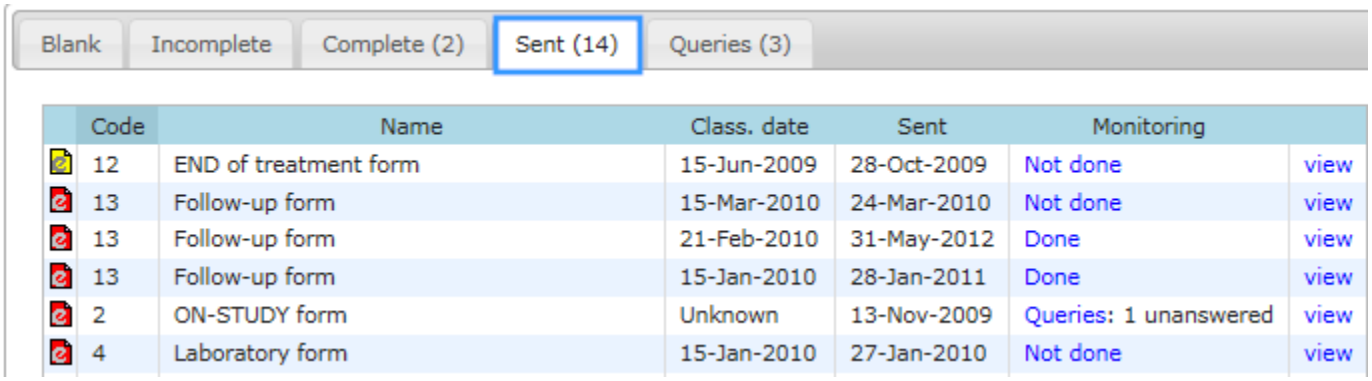


Sent forms

Once a form is approved and sent, it is made visible to the EORTC Data Manager. The form arrives with an on-hold status in the EORTC database. Forms that have been sent by the principal investigator (or an authorized staff memeber) can no longer be edited by them; however they can create an electronic Data Correction.

In the sent tab also the sent paper forms are shown (e.g. Quality of Life forms). The forms that are entered and sent through VISTA RDC ( ) have a different logo than the paper forms ( ).

The monitor can create **CRA queries** on 'sent' forms and can mark them as **source data verified (SDV done)**.



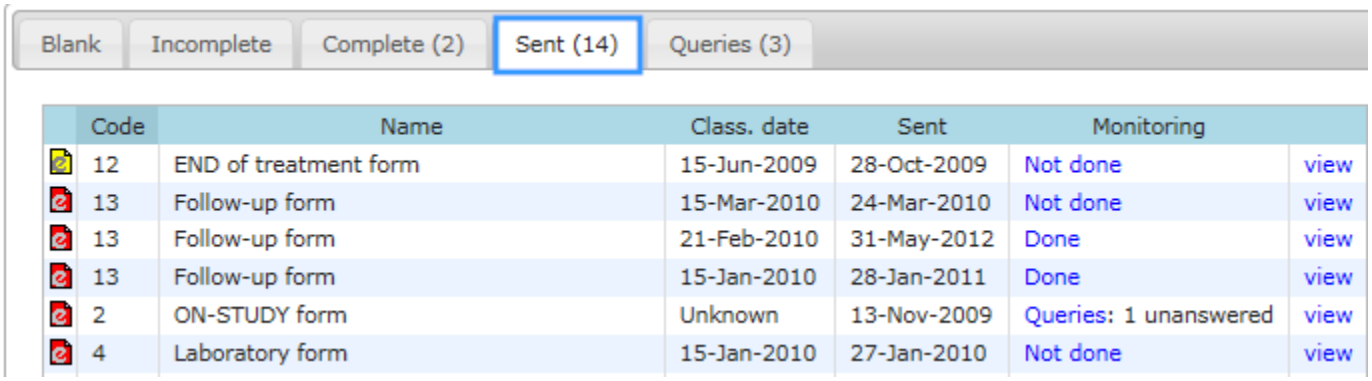
Monitoring status

The **monitoring status** can be seen in the 'complete' and the 'sent' tab.

There are 3 possible statusses:

- Not done: source data verification by the Monitor is not done
- Done: source data verification by the Monitor is done
- Queries: number of (un) answered queries

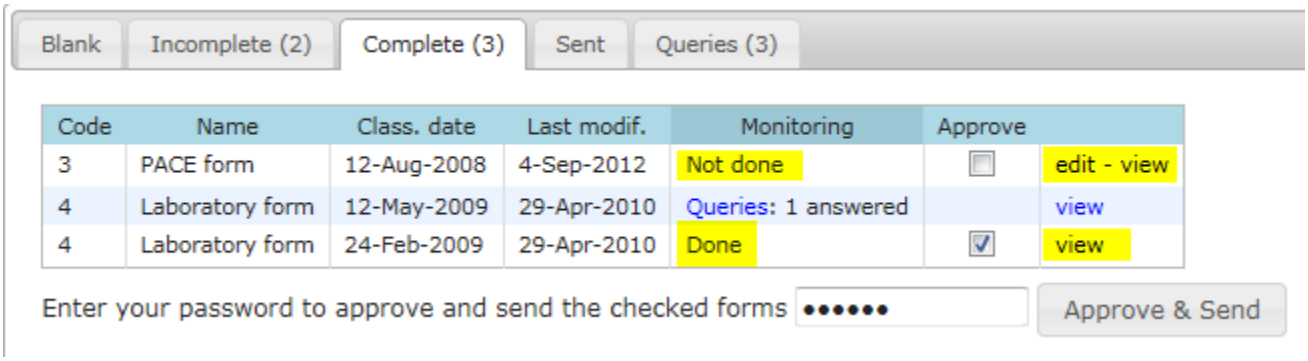
By clicking on 'not done', 'done' or 'queries' in the monitoring column, a form can be source data verified and CRA queries can be created.



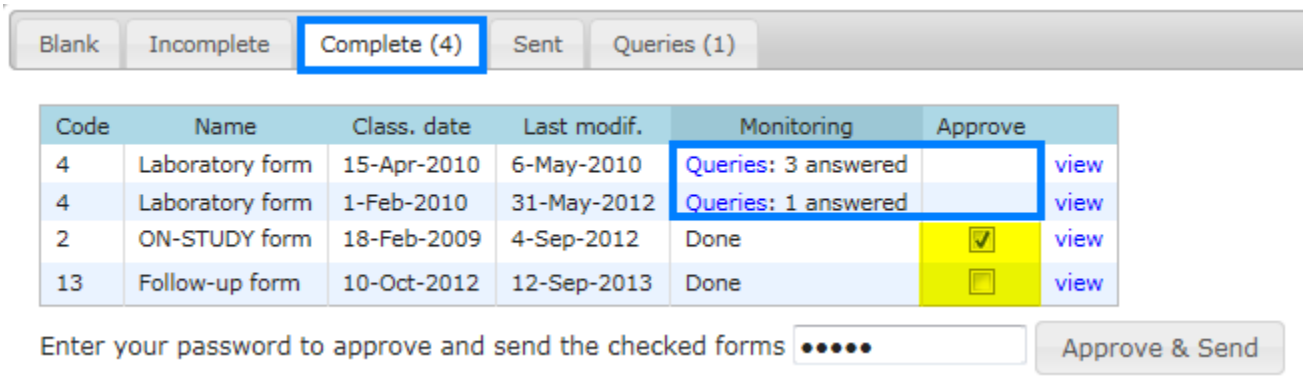
	Code	Name	Class. date	Sent	Monitoring	
	12	END of treatment form	15-Jun-2009	28-Oct-2009	Not done	view
	13	Follow-up form	15-Mar-2010	24-Mar-2010	Not done	view
	13	Follow-up form	21-Feb-2010	31-May-2012	Done	view
	13	Follow-up form	15-Jan-2010	28-Jan-2011	Done	view
	2	ON-STUDY form	Unknown	13-Nov-2009	Queries: 1 unanswered	view
	4	Laboratory form	15-Jan-2010	27-Jan-2010	Not done	view

In the 'queries' tab, monitors can only view the DM, DCF and/or CRA queries.

In the 'complete' tab: when monitoring is done, the form cannot be modified anymore by the site ('view' only) and must be sent.



in the 'complete' tab: when there is an unanswered query, the form cannot be approved/sent by the site until the query is resolved and the monitor has marked the forms as "SDV".

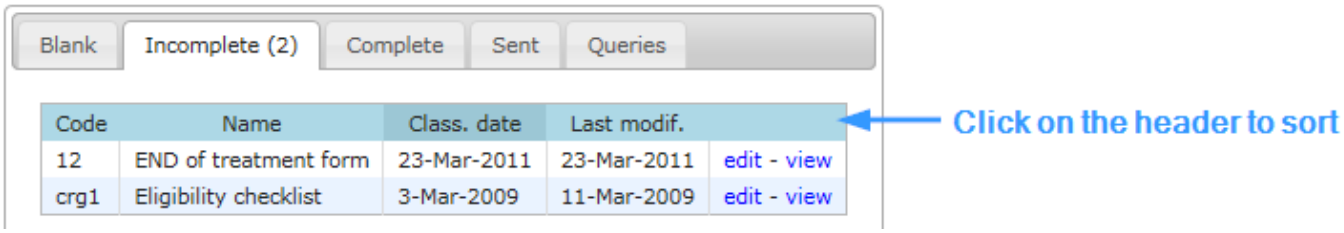


Order forms for a structured view

In each table of all the tabs the forms can be ordered by the following:

- **Form code**: the reference number/letter code of the form (e.g. form '4' laboratory form/form 'LBHEM' hematology form)
- **Name**: the name of the form (e.g. Adverse event form)
- **Class. date**: the classification date of the form (this is a date on the form that is used for the identification in the system, e.g. the classification date of the Follow-Up form, is the date last known to be alive).
- **Last Modif.** *(in tab 'Incomplete' and 'Complete')***:** the date on which the last modification was done
- **Sent** *(in tab 'Sent')***:** the date the form was sent

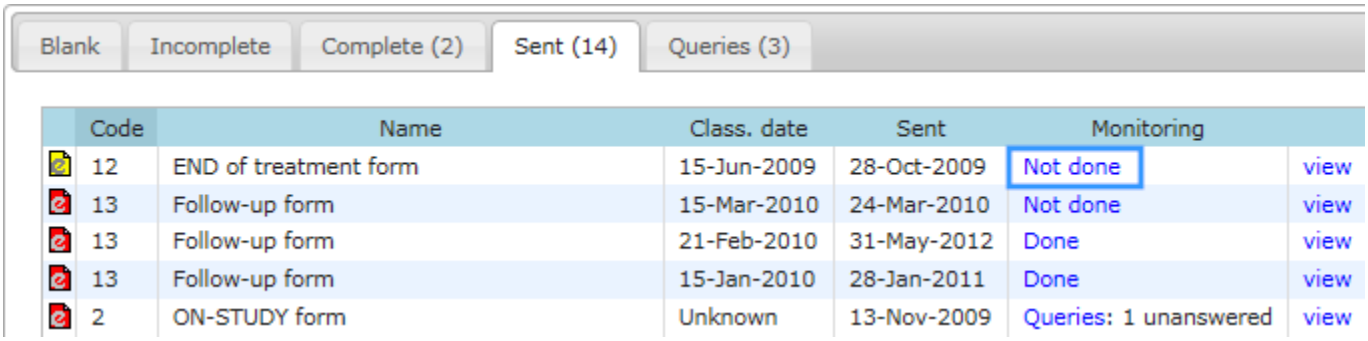
To order the forms within a table according to one of the above-mentioned criteria, click on the related **table headers**.



Source data verification

Source data verification can be done by the monitor on forms with 'complete' and 'sent' status.

The monitor can select the forms where monitoring has not yet been done by clicking on 'Not done' in the 'monitoring' column (Monitoring status (for monitors)).

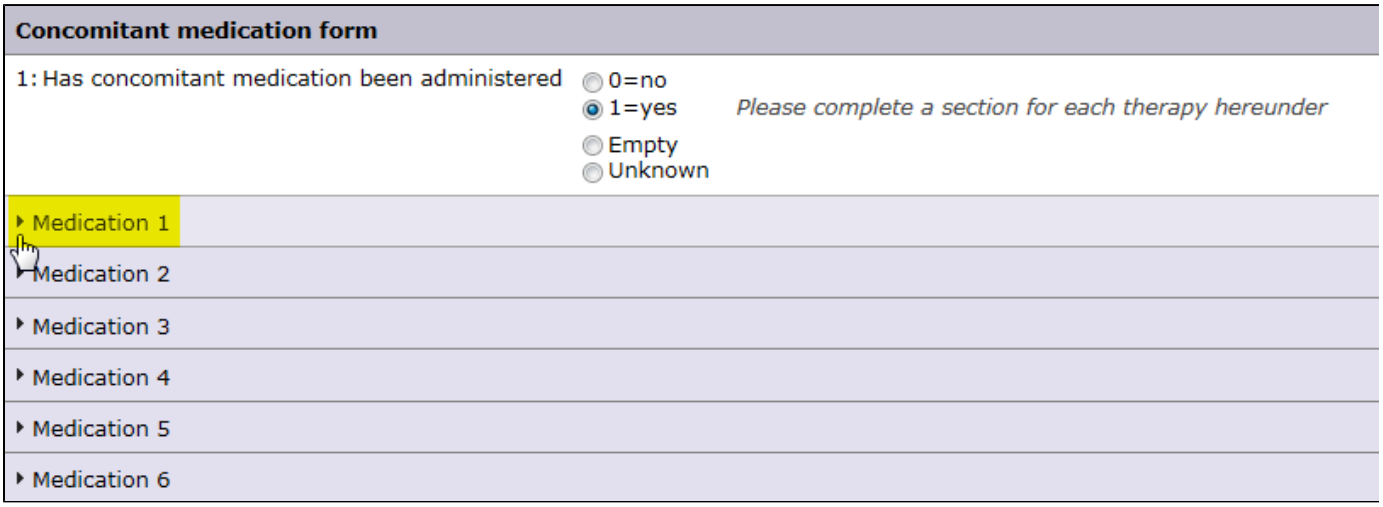


The values should be verified against the source data as described in the monitoring plan. If there are no discrepancies, the form can be ticked as 'source data verified' (**SDV**). It is not possible to mark each item as SDV separately. It can only be done at the form level.

In case of discrepancies with the source data, a **CRA query** should be created.

Collapsible sections

For some studies collapsible optional sections are incorporated into the electronic forms. To access the fields for a collapsed section, click on the panel with arrow.



The fields for that section will appear. As soon as data is completed in these sections or queries are made, the section will always appear as uncollapsed.

Concomitant medication form

1: Has concomitant medication been administered
- ○ 0=no
- ◉ 1=yes
- ○ Empty
- ○ Unknown

Please complete a section for each therapy hereunder

▾ Medication 1

2: Drug name: Fluconazole ☐ Unknown

3: Route
- ◉ 1=Per os
- ○ 2=Intravenous
- ○ 3=Intramuscular
- ○ 4=Subcutaneous
- ○ 5=Rectal
- ○ 6=Transdermal (patch)
- ○ 7=Other *Specify below*
- ○ Empty
- ○ Unknown

4: If other, specify route: ☐ Unknown

5: Dose/Units/Schedule: 200mg OD ☐ Unknown

6: Indication for use
- ◉ 1=Adverse event
- ○ 2=Prophylaxis
- ○ 3=Other
- ○ Empty
- ○ Unknown

7: Specify indication for use: Fungal infection ☐ Unknown

8: Start date: 01 Mar 2013 ☐ Unknown

9: Ongoing ○ 0=no ◉ 1=yes ○ Empty ○ Unknown

10: End date: day month year ☐ Unknown

▸ Medication 2

▸ Medication 3

▸ Medication 4

▸ Medication 5

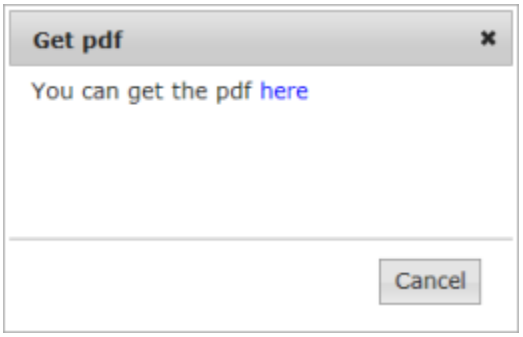
▸ Medication 6

Save a form as PDF

When opening a form by clicking on 'view' next to the form in the 'Incomplete', 'Complete' or 'Sent' tabs, the button 'Save as pdf' is available.

Click on the button 'Save as pdf' to print the form to PDF. A dialog window 'get pdf' will appear.

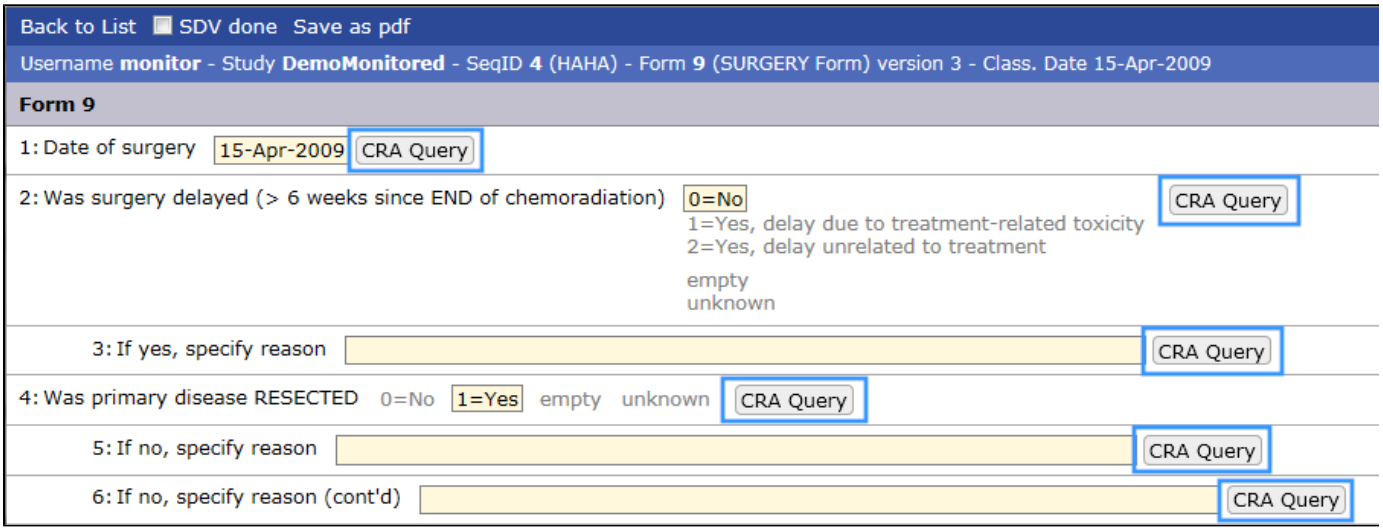
The pdf version of the form is displayed when clicking on 'here' in the text 'You can get the pdf here'.
You can save or print the PDF document.



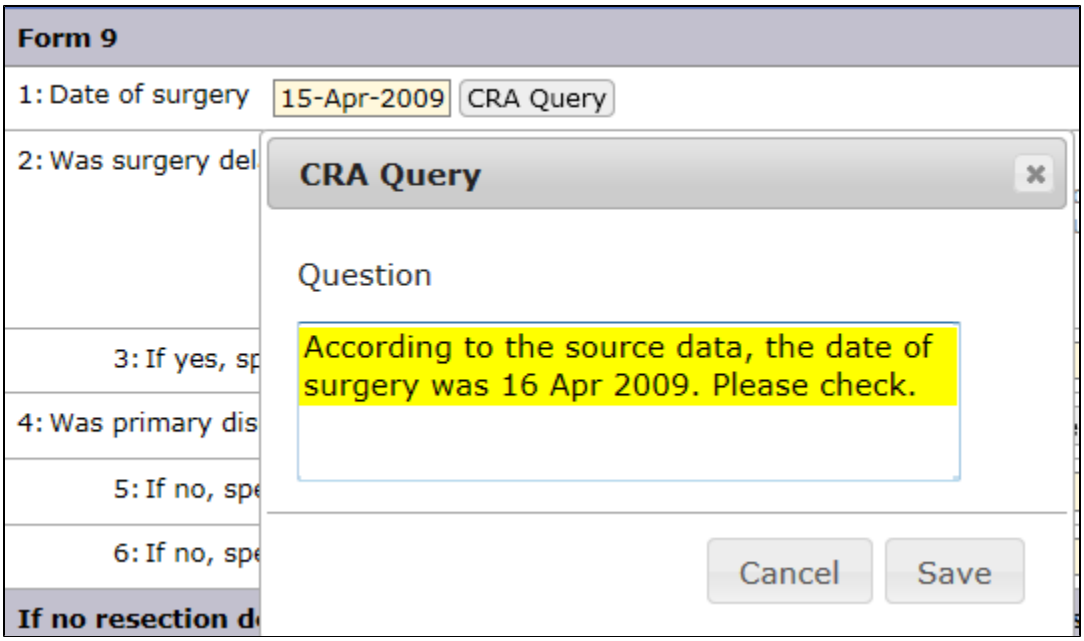
Create an electronic CRA query

When during the source data verification of a form discrepancies are found between the data reported in the form and the source data, an **electro nic CRA query** should be created for the applicable field.

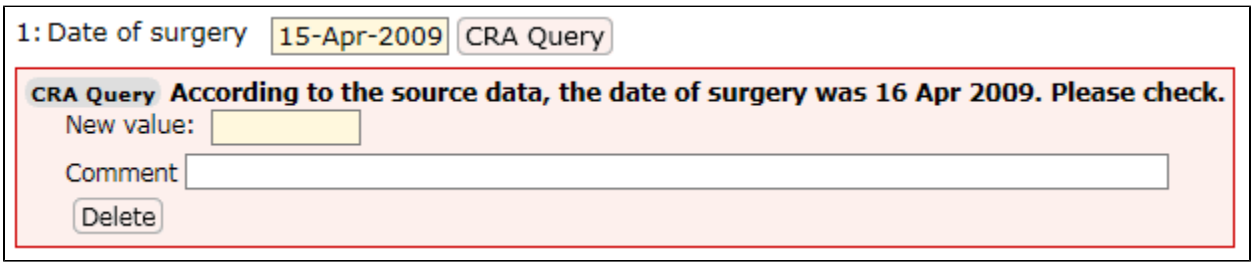
A CRA query can be created on each field of each form with status 'complete' or 'sent' which is not yet ticked as 'source data verified'.



The query question should be typed in the 'question' field and should be saved.



The CRA query is automatically sent to the principal investigator (or an authorized staff member), but can still be deleted in case of mistakes.



Important: 'Complete' forms with pending CRA queries and which are not marked as 'SDV done' cannot be sent to EORTC so it is important that

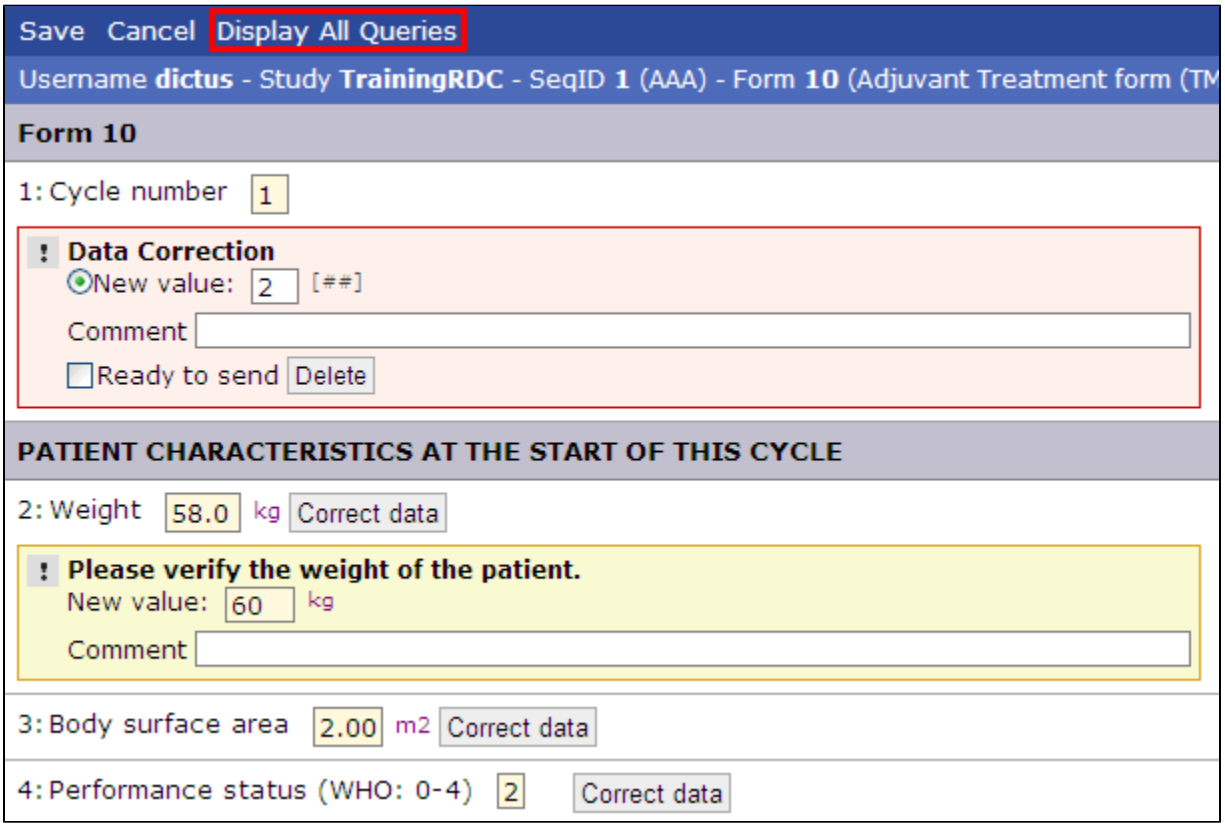
the monitor marks the forms as 'SDV done' when the answer of the query is satisfactory.

Display of electronic queries / data corrections

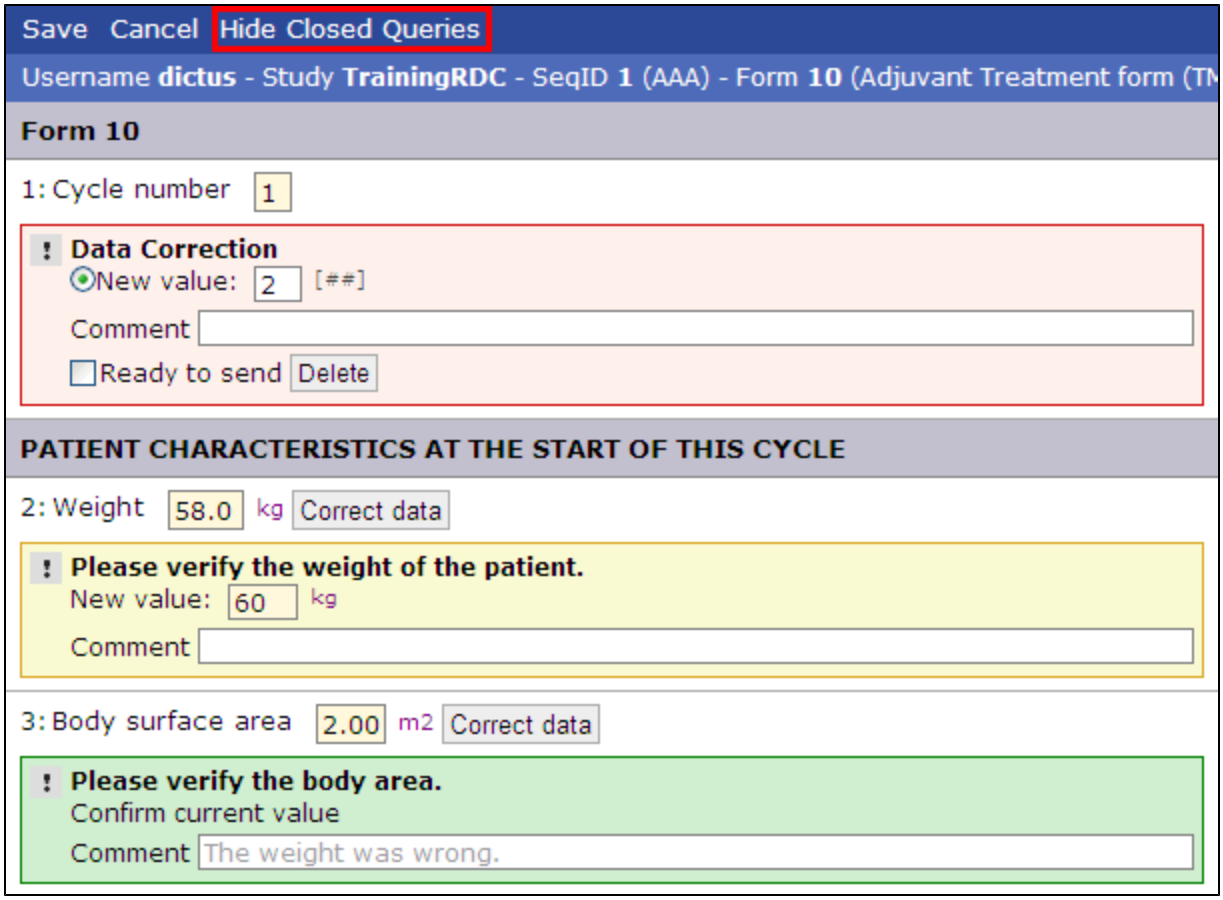
All queries / data corrections can be displayed when opening a form in the 'Sent' tab by clicking on 'view' next to the form.

- **(Un)answered** queries or data corrections not yet sent will appear highlighted in **red**
- **Answered** queries and sent data corrections **not yet processed** by the EORTC Data Manager will appear in **yellow**.

Query answers / data corrections that were sent and processed by the EORTC Data Manager do not appear by default. They can be made visible by clicking the button 'Display All Queries' if available at the top of the form. If this button is not available, it means that there are no such "closed" queries on this form. These queries / data corrections can be hidden again by clicking on the button 'Hide Closed Queries' that appears instead of the 'Display All Queries' button once ticked.



versus



Summary of color codes for queries

Color	Label	Description
Red	Unsent	Query answer / data correction that still needs to be sent
Yellow	Sent	Query answer / data correction that has been sent but not yet processed by the EORTC Data Manager
Green	Closed	Query answer / data correction that has been sent and processed by the EORTC Data Manager