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 TRIALS WITH PAPER QUERIES)

VERSION 3.1
June, 2014

Version history - RDC user guide for studies with paper queries

REVISION HISTORY			
Version	**Brief Description of Change**	**Author**	**Issue Date**
1.0	Initial Release	Antoine Briffaux	04/12/2003
1.1	Update of RDC form approval process and screenshots	Antoine Briffaux	22/06/2004
2.0	Reorganization of document and update to RDC 2	Joke De Wever	11/03/2008
3.0	Update to RDC 4 (for trials with paper queries)	Joke De Wever	08/04/2010
3.1	User guide imported in Confluence and document split into different pages that can be easily updated electronically in the system	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.

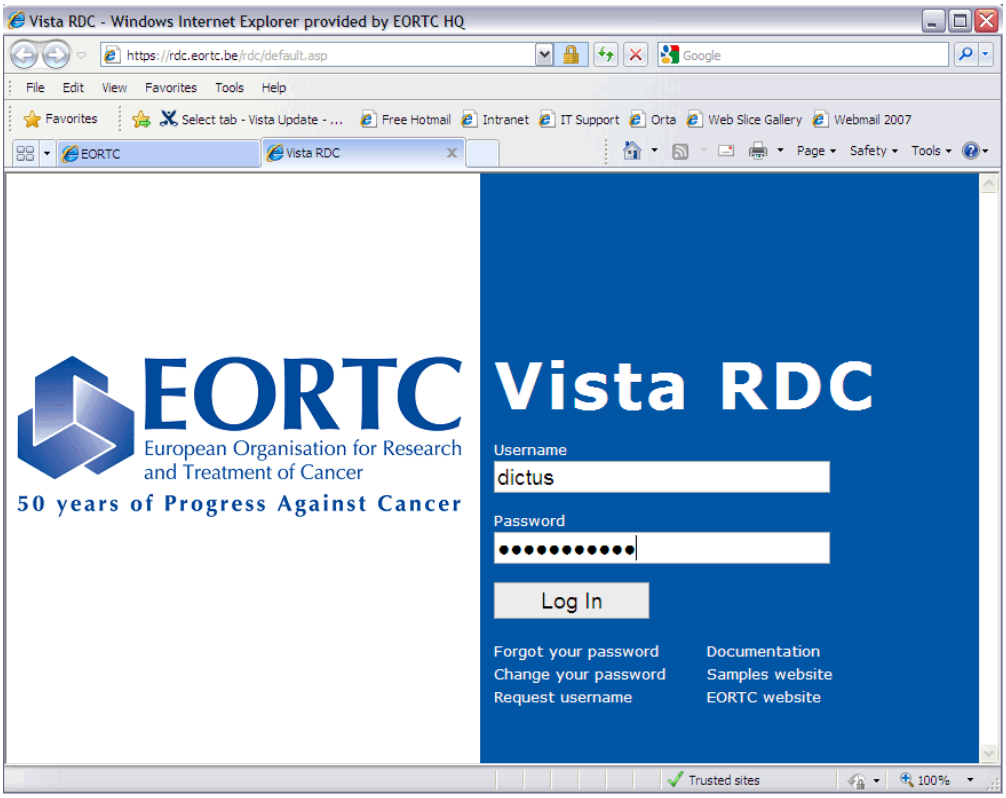
The EORTC VISTA-RDC system provides an electronic version of the CRFs and will enable you to enter and edit data on-line and, once completed, to directly transfer the data into the EORTC clinical database. Sent forms stay visible and accessible in VISTA RDC.
After the data transfer, the data reported 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. If queries are generated, they will be sent to you in PDF format, by e-mail. You should print this form, answer the questions on the printed query form, sign and date it and return it to EORTC.

Queries requesting an overdue form will result in a 'requested form' appearing on the 'blank' tab (see Forms status (studies with paper queries)).

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.

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

All investigators and implicated staff in activated centers will be provided with an ORTA/RDC username and password to access the VISTA RDC system. The type of access that will be given will depend on what was reported on the "Signature and delegation of responsibilities log" document that was provided to the EORTC HQ at time of site activation. Some users might have the right to complete, approve (sign) and send forms while other users might only be authorized to complete forms, without having the possibility to approve and send them.

⚠ **Important note**: forms that are not approved and not sent are not visible to the EORTC Data Managers. It is thus important to approve and send the forms as quickly as possible after completion in order to avoid delay in data validation by EORTC.

Users who are already member of the EORTC can use their existing ORTA/RDC username and password. For the other users, ORTA/RDC usernames and passwords will be attributed using the signature log.

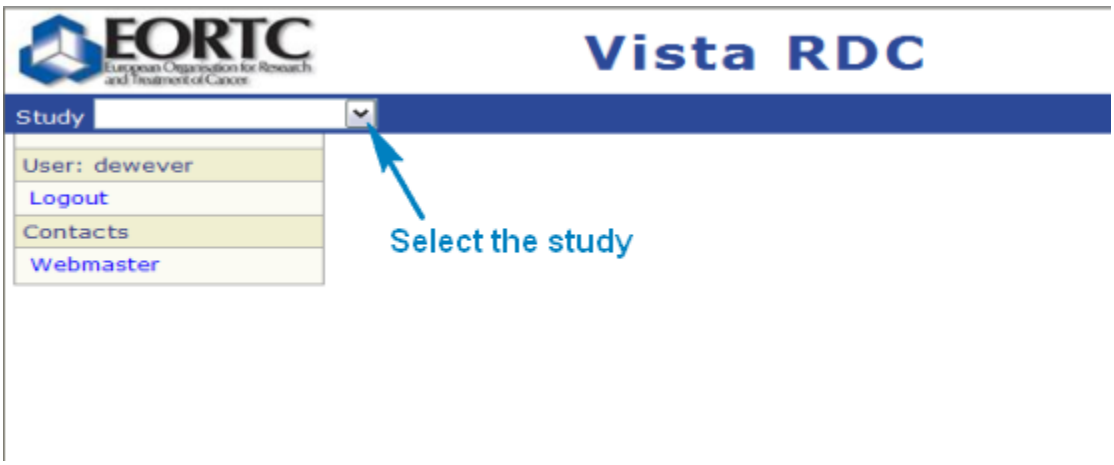
If needed however, a username and password can be requested on the RDC website (https://rdc.eortc.be; 'Request username'). An Account request form has to be completed with the details of the person, institution and study number. Your new username and password will be sent to you by e-mail within a few days.

> *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

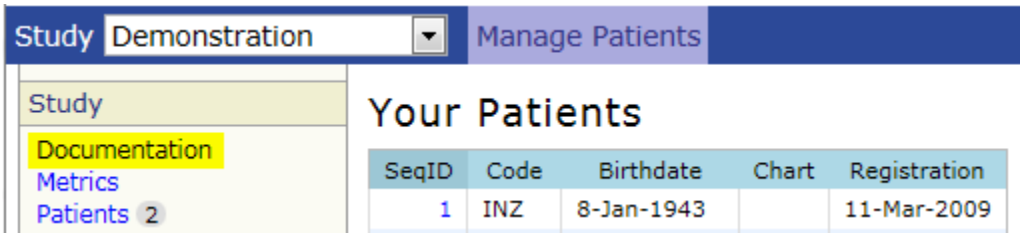
Once logged on, you can begin the actual RDC process. The first step is to identify the EORTC study.

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.

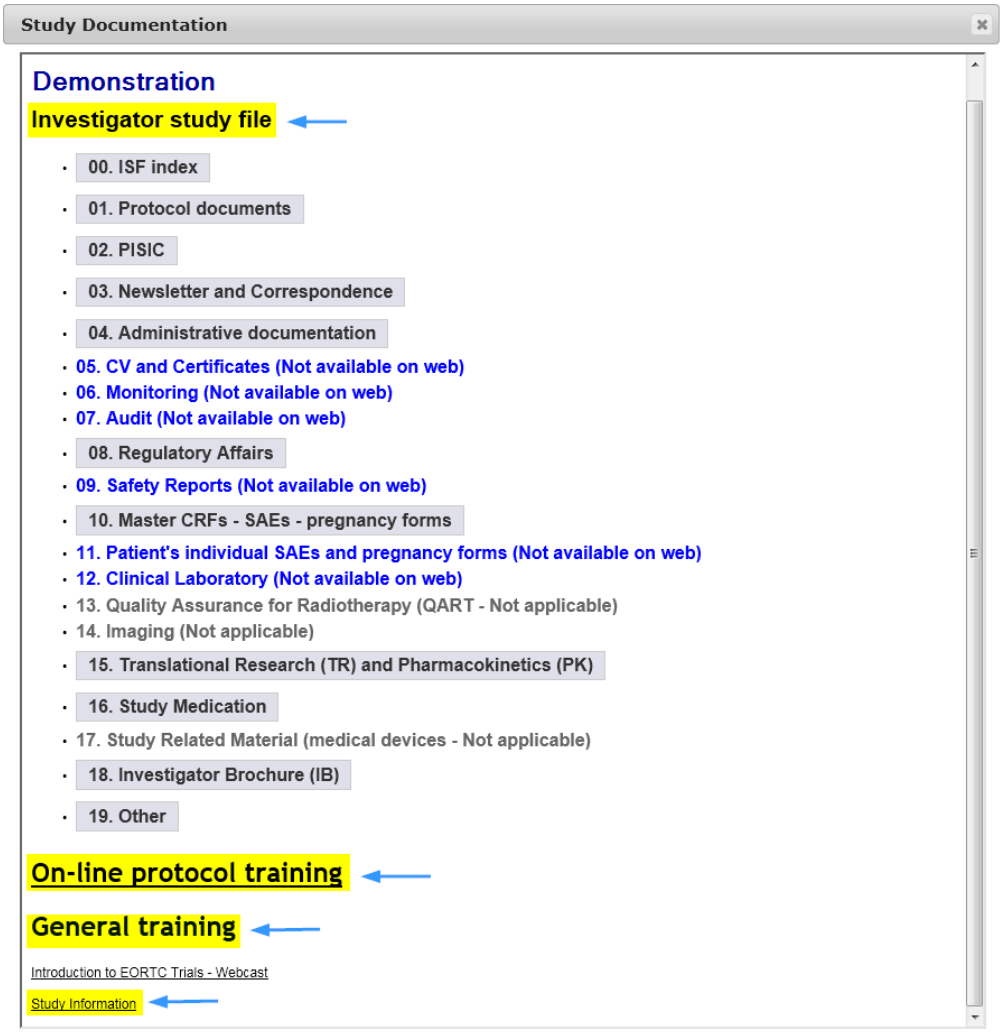


Study documentation

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



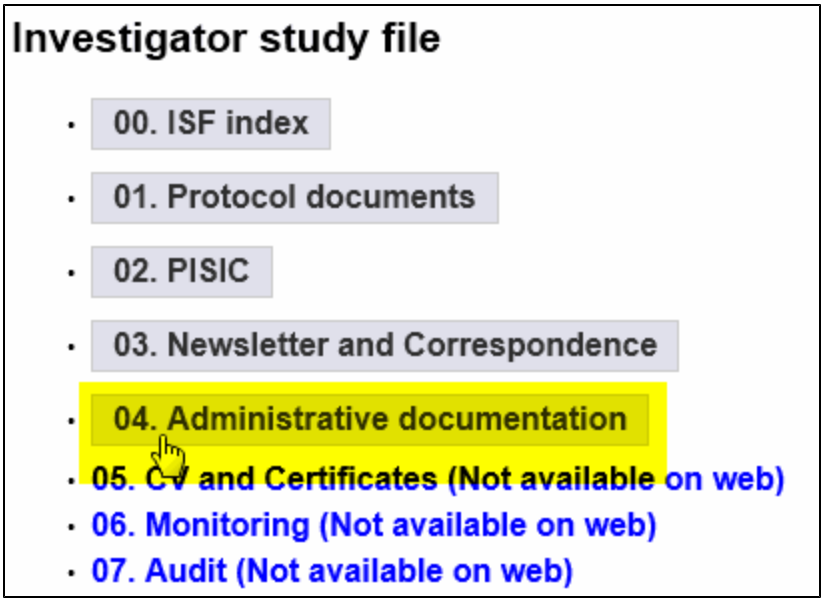
You will be redirected to the study documentation page where you can access the investigator study file, on-line protocol training (if available), general training on EORTC clinical trials activities and the study information page.

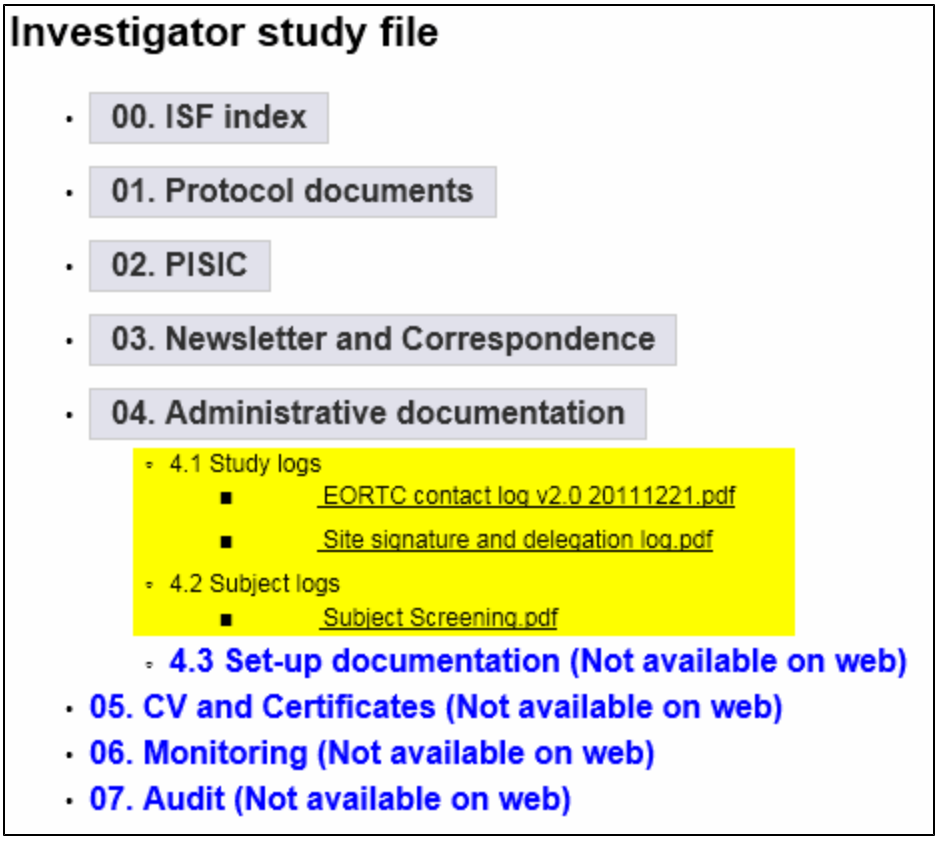


Investigator study file

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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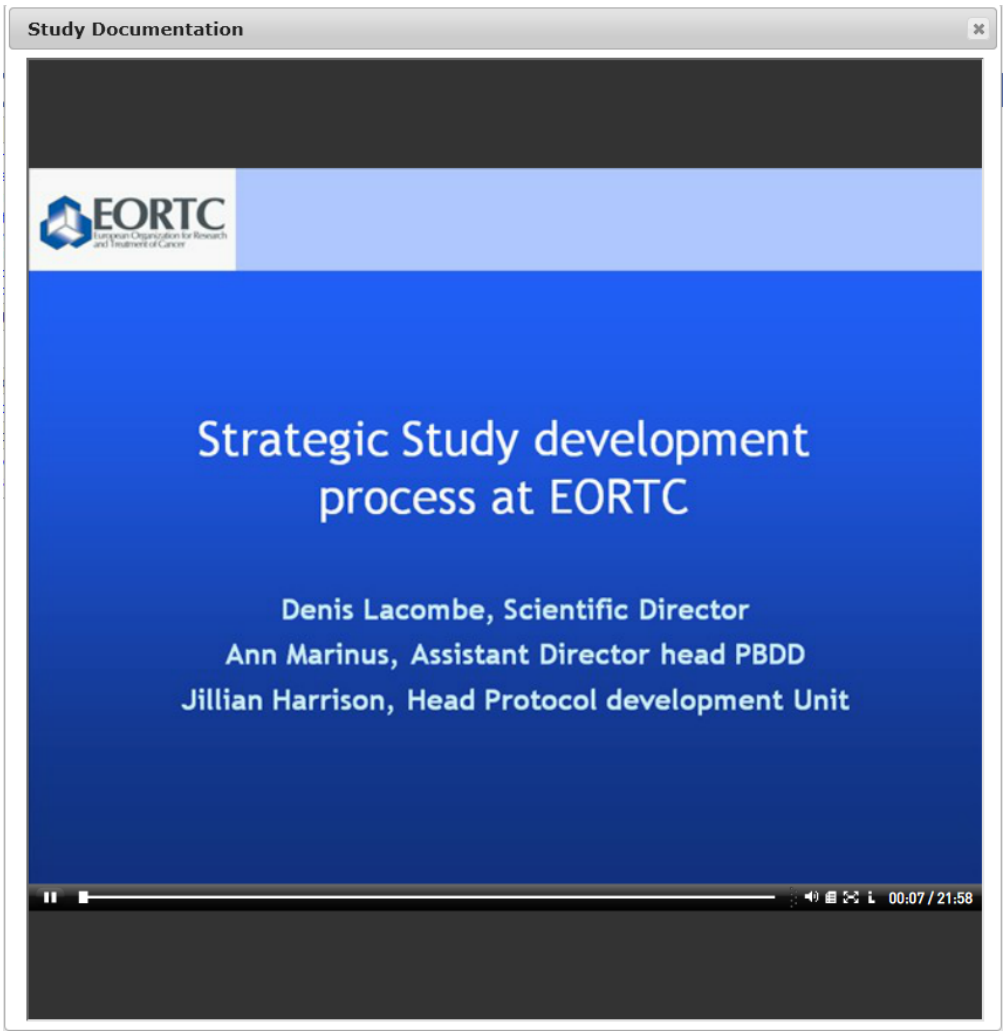
One Day Introduction to EORTC Trials

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, ...).

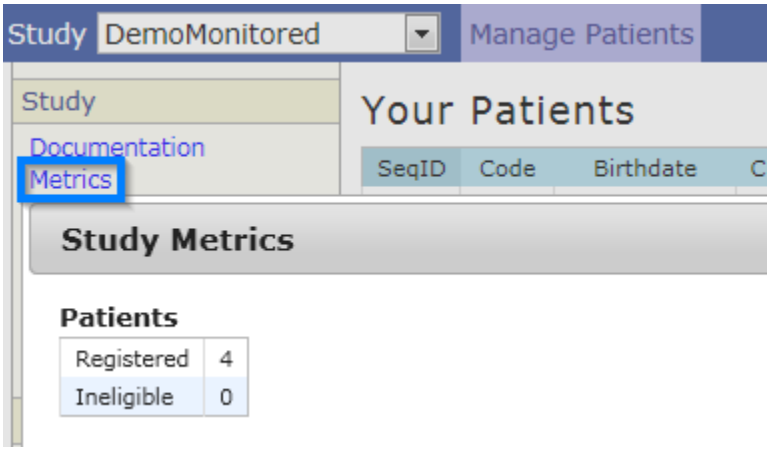
Study Documentation

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.

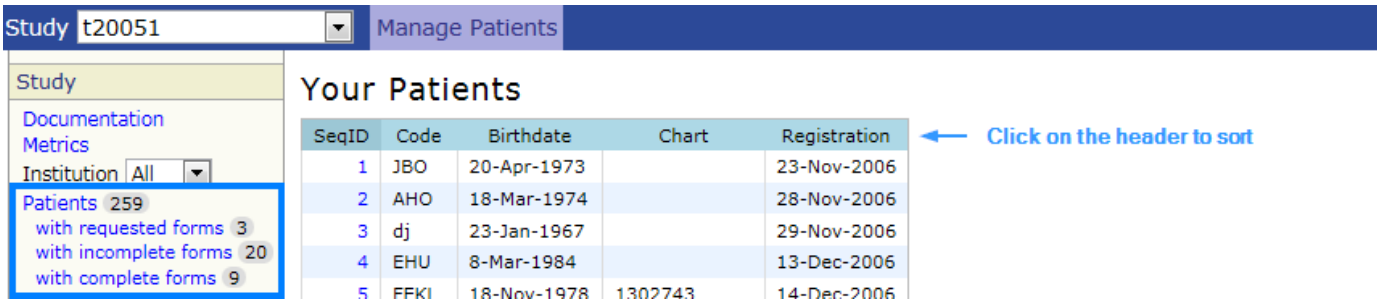
Request for help

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 enrolled by your institution will appear.
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.



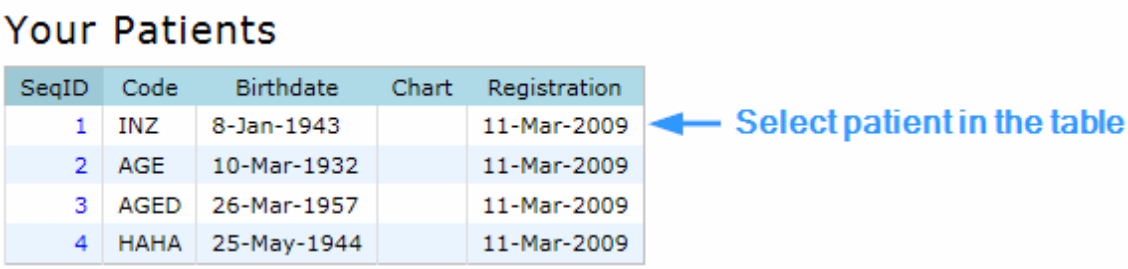
By default all the patients are shown. It is also possible to make a selection of patients based on the following criteria:

- Patients with requested forms
- Patients with incomplete forms
- Patients with complete forms

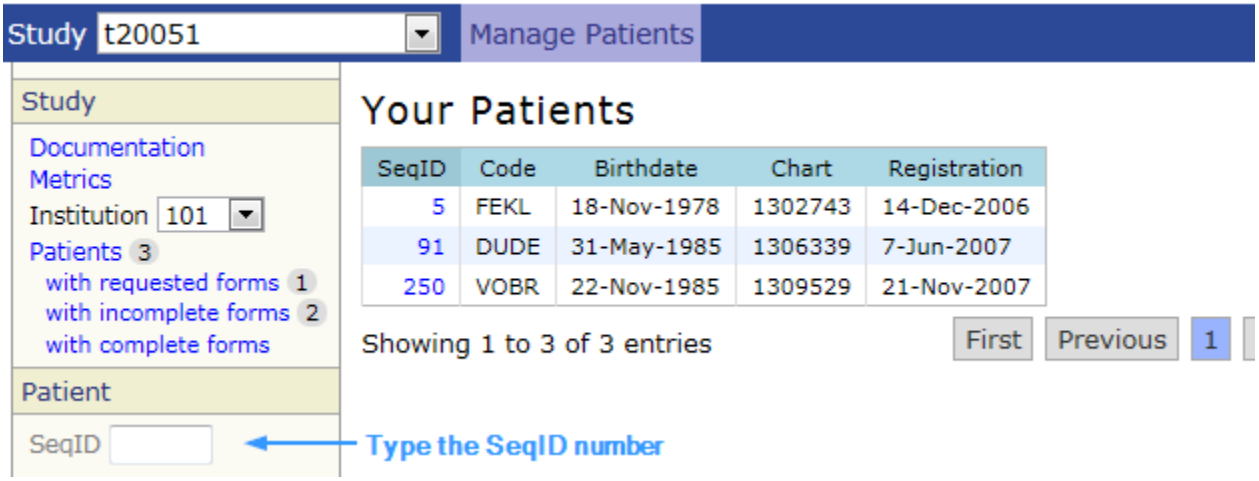
The numbers shown in the left panel are the number of patients in the selection.

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 Forms, Incomplete forms, Complete Forms and Sent forms).

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.

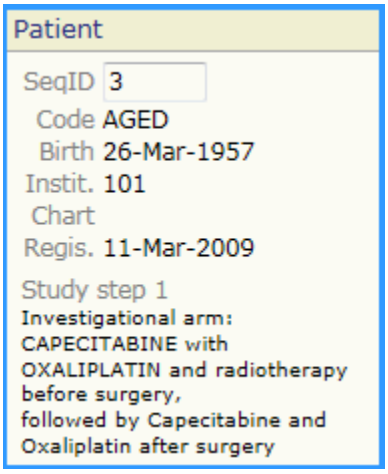
Your Patients

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

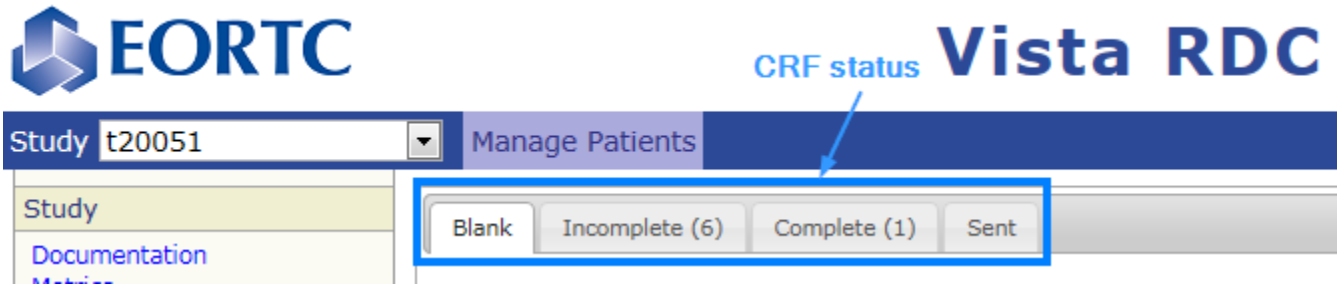
The patient's identification can be found on the left of the screen.



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

Four tabs are available in the **center of the screen**. Each tab corresponds to a different CRF status.

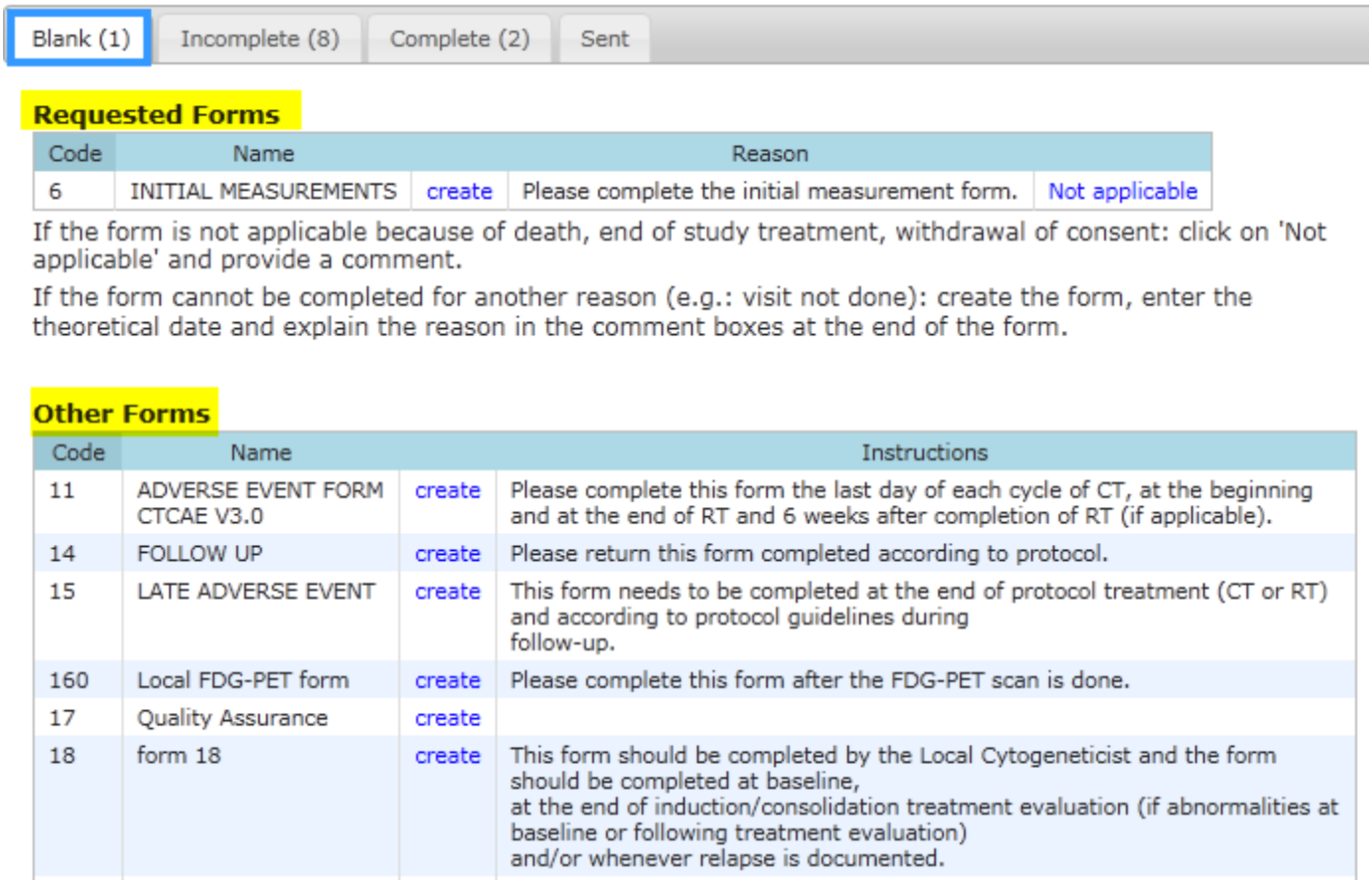


Blank forms

This tab contains 2 subsections (requested forms and other forms). If a form has not been sent in due time, it will be requested in the section '**req uested forms**'. Form code, name and reason for request will be displayed. The form can be created by clicking on 'create'. Once the form has been created, the request will disappear from the list. If a requested form cannot be completed, click on 'not applicable', enter the reason and click on 'Save'. The request will disappear.

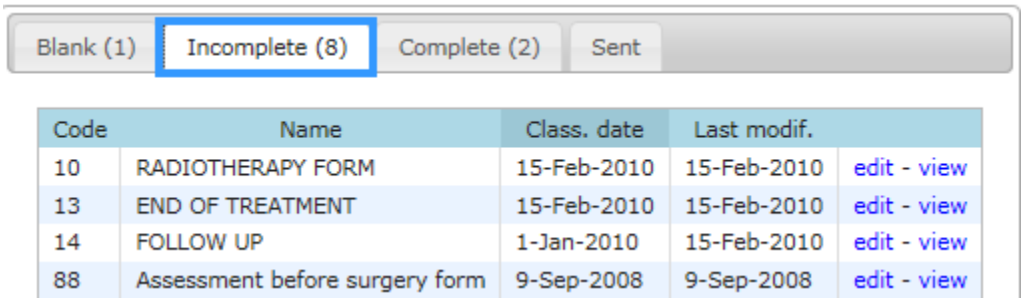
All forms remaining available for completion are displayed in the "**other forms**" section. In the 'Instructions' it is reported when the form has to be completed.

The number next to 'Blank' (in the tab) corresponds to the number of requested forms.



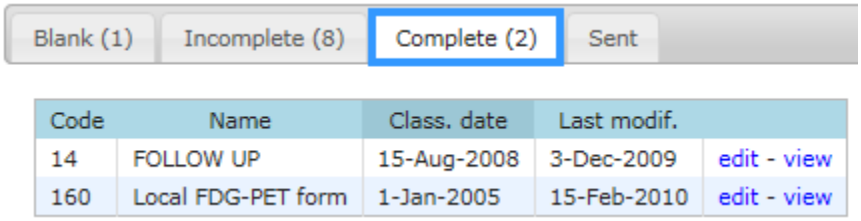
Incomplete forms

When created, a new form has an "incomplete" status. A form can be saved as "incomplete" at any time.



Complete forms

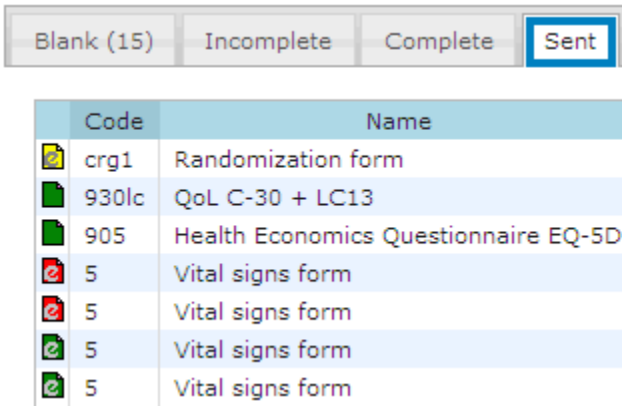
Once all required data on a form has been reported, the form should be saved as 'complete'. 'Complete' forms must be sent to the EORTC database by users that have the right to sign forms. You can edit complete forms as long as they are not yet sent.



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 can no longer be edited. If modifications are needed, report them on a paper Data Correction Form.

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 ( ).

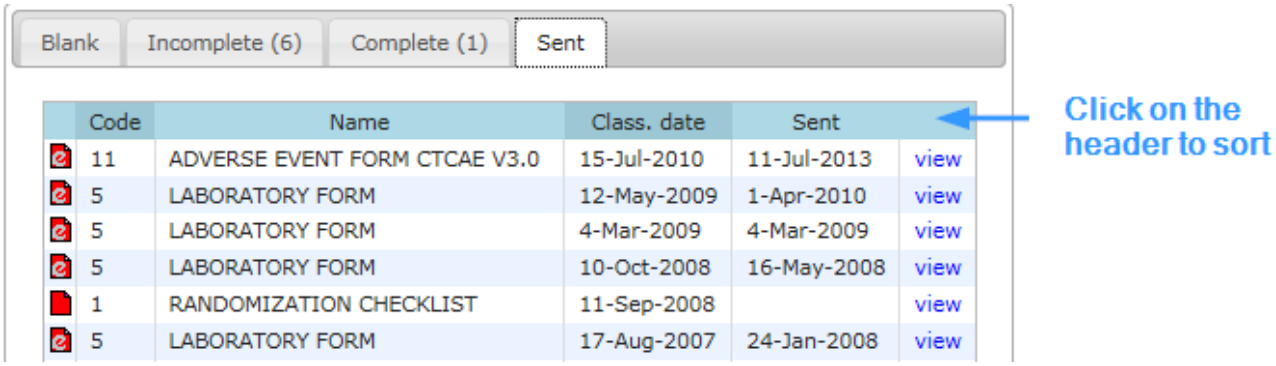


Order forms for a structured view

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

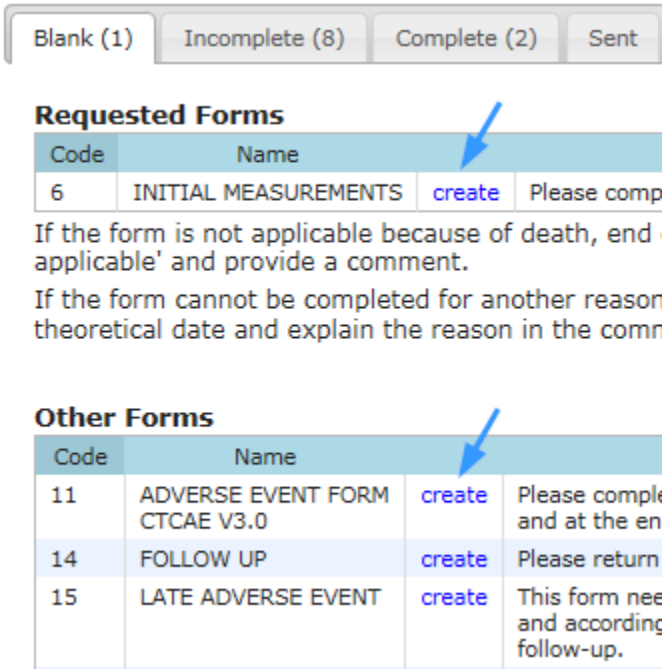
Form code: the reference number/letter code of the form (e.g. CRF '5' laboratory form/CRF 'LBHEM' hematology form)
Name: the name of the form (e.g. Adverse event form)
- **Class. date**: the classification date of the form (this is a date on the form that is used for the identification in the system, 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**.



Create a form

Click on the button **'Create'** next to the form you would like to complete in the tab 'Blank'. All available RDC forms are displayed in the table 'Other forms'. Instructions for the timely completion of the forms are mentioned in this table. To complete a form for which a request was issued, click on the button 'Create' in the table 'Requested forms'.



Uni-sequential forms

These forms can **only be created once** as they concern data collected once per patient. Once these forms have been created they will no longer be available in the 'Other forms' table (e.g. On study form, End of treatment form).

Sequential forms

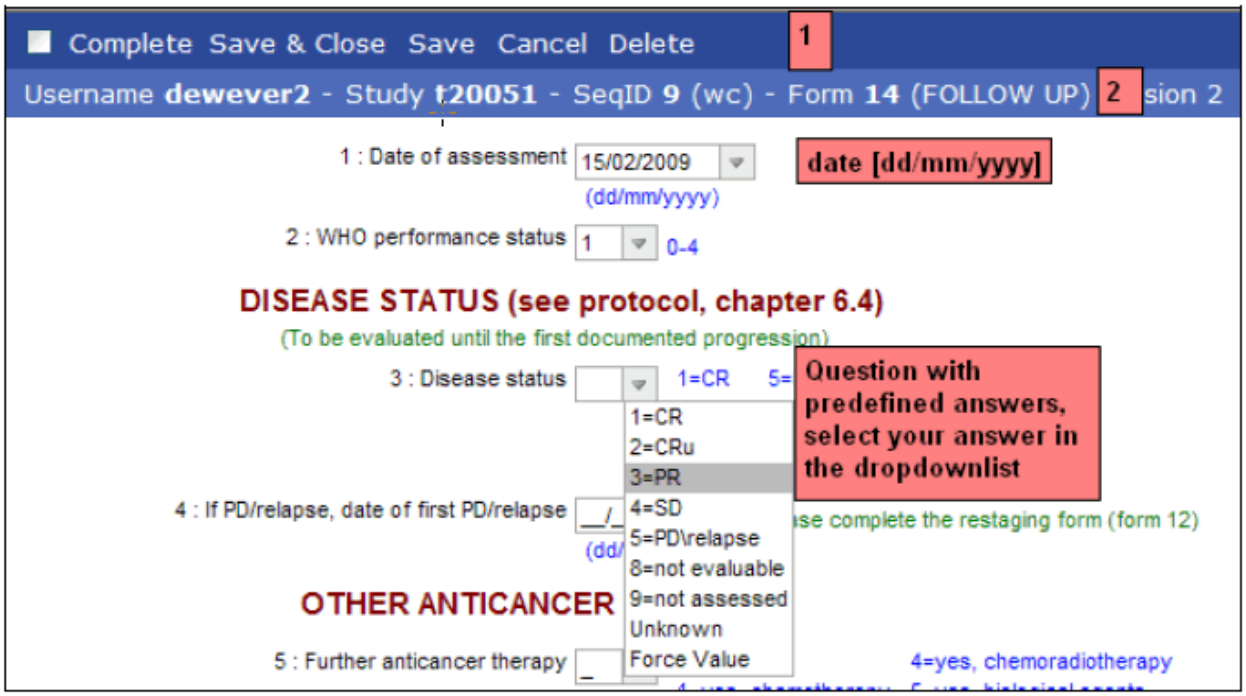
These forms can be created as many times as necessary as they concern data requested periodically for a patient. They will always be available in the 'Other Forms' section (e.g. Laboratory form, Adverse Events form, Follow-up form).

Layout of a form

All forms are identified by their name (e.g. Adverse Event form, Follow-up Form, etc) and code (number or letter combination). On each form, data are to be completed in a 'numbered box system'. Each box can be identified (and queried) by its box number, listed to the left of the question. Text fields have the same numbering system.

The VISTA-RDC screens have an identical set-up for all forms. The VISTA-RDC screens are divided into 4 areas (see example below):

- **(1) Action buttons** that help you manage the VISTA-RDC form i.e. Save & close, Save, Cancel, Delete.
- **(2) Identification** of the current user (username), the EORTC study number (study), patient SeqID and form.
- **(3)** A series of **Boxes** to report the requested data.
- **(4) A drop down menu** next to each box.



Drop down menu to report the requested data

- ***Date***: contains only the 'force value' option and the 'unknown' option. If it concerns a classification date, you will not be able to put the date as 'unknown'.
- ***Question with predefined answers*** (labeled question: e.g. a no/yes question): contains the predefined answers, the 'force value' option and the 'unknown' option.
- ***Numeric question*** (e.g. value of WBC): contains only the 'force value' option and the 'unknown' option.
- ***Text field:*** contains only the 'force value' option and the 'unknown' option.

More details on how to complete data on a form can be found on the pages Edit a form (studies with paper queries) and Special issues for entering data (studies with paper queries).

Edit a form

Forms with an **incomplete or complete** status **can be modified** after creation ('edit'). Data reported on forms that have been **sent** to the EORTC database can **no longer be modified directly in the system** (only 'view'). In case data needs to be modified on 'sent' forms, please complete a paper Data Correction Form (DCF) and send it to the EORTC Data Manager.

Edit an unsent form

Once a form is created you can enter the data requested. Answer each question by typing your answer in the field allocated to the question or by selecting the answer in the dropdown list.
Activate the cursor in the answer field by clicking on it. You can go through the questions by either using the **TAB** button on your keyboard or by repositioning the cursor with your **mouse**.

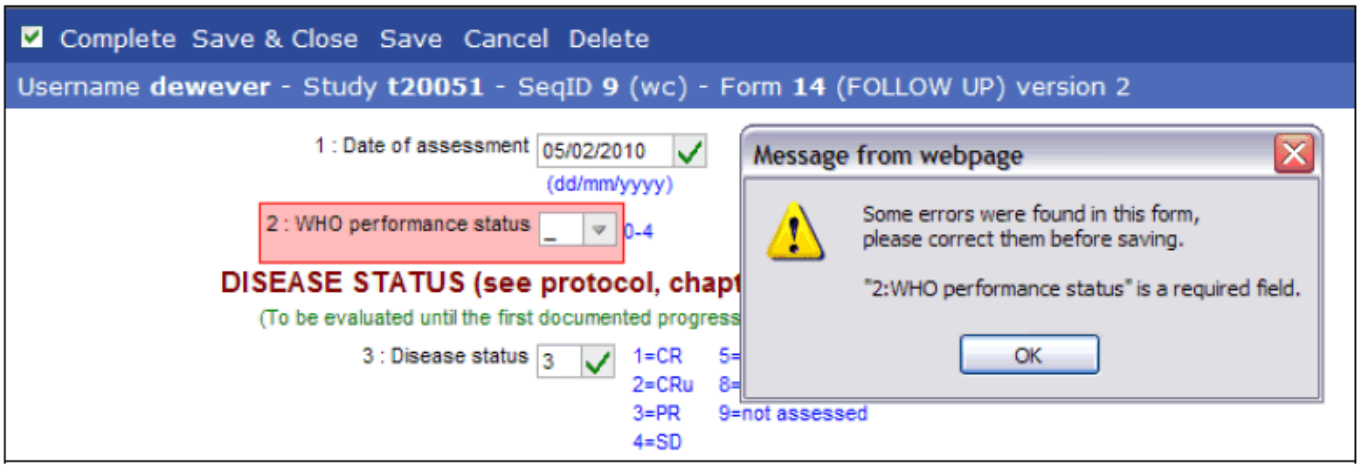
Answer boxes in the RDC forms have 2 levels of reporting importance.

- Mandatory data
- Other data

Mandatory data

The requested data may **not remain empty**.

- You can save a form as **incomplete** when mandatory data is missing
- The form can be set to a **complete** status if all mandatory data have been completed: if you try to save a form as complete when mandatory data is missing, a pop-up message will warn you which box(es) need to be completed before the form can be saved as complete (see example below).



Other data

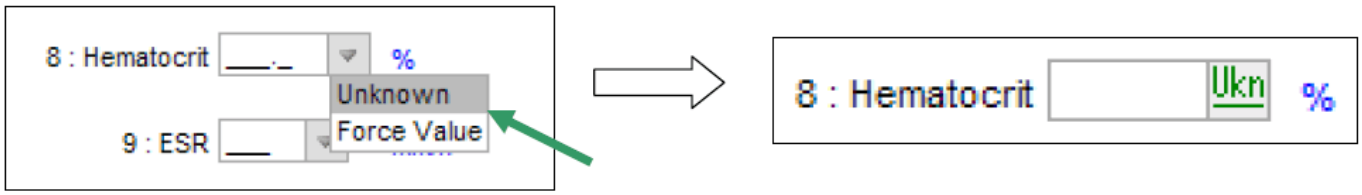
These data can not always be completed because**:**

- The requested information is not yet available
  e.g. "Date of first documented progression of disease" remains empty on the follow-up form until progression was diagnosed.
- The requested information is conditional to the answer of another variable
  e.g. for treatment information: only if there was a modification done, you'll have to provide the reason for this modification. If no modification was done, this box should stay empty.
- The data is not applicable
  e.g. Some lab values can be entered in 2 units, only one box has to be completed.

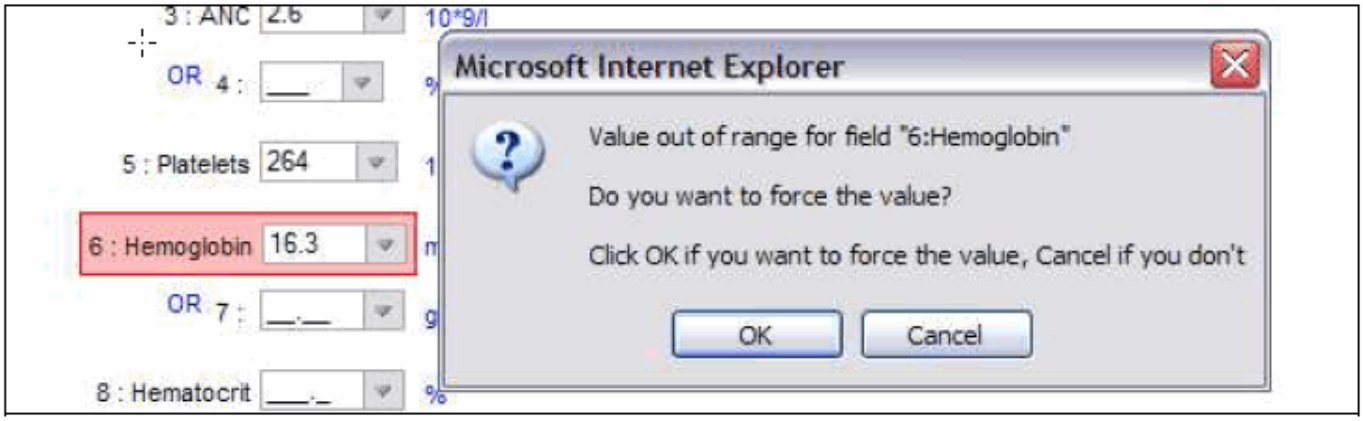
Special issues for entering data

General

Unless it is for a clear reason, do not leave applicable boxes empty otherwise a query will be issued to ascertain whether information was unknown or simply missing.
Where information is not known, select the corresponding box and flag it unknown by selecting UNKNOWN in the drop down menu. For example if a test was not performed or ~~a response or toxicity not assessed o~~r the patient source data are incomplete, do not leave the relevant box(es) empty but set them as "unknown"**.**

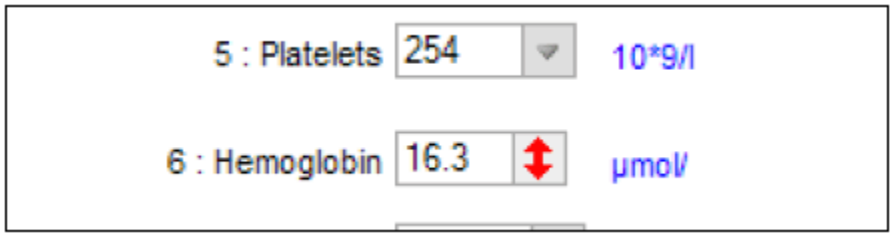


In case the value reported is out of the range defined in the database, the related question will be highlighted and a pop-up message will appear and request that you verify the data reported and force the value if it is correct. You can correct the value or force the answer by clicking on the button 'Force value'.

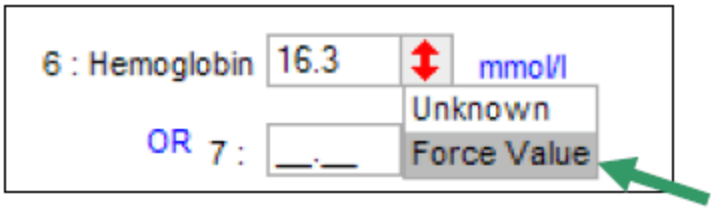


By clicking OK, the value will be forced. A forced value is recognizable by the arrow next to the related box.

If you do not want to force the value, press cancel.



To force a value, set your cursor on the relevant box and select “Force Value” in the drop down list next to the box.

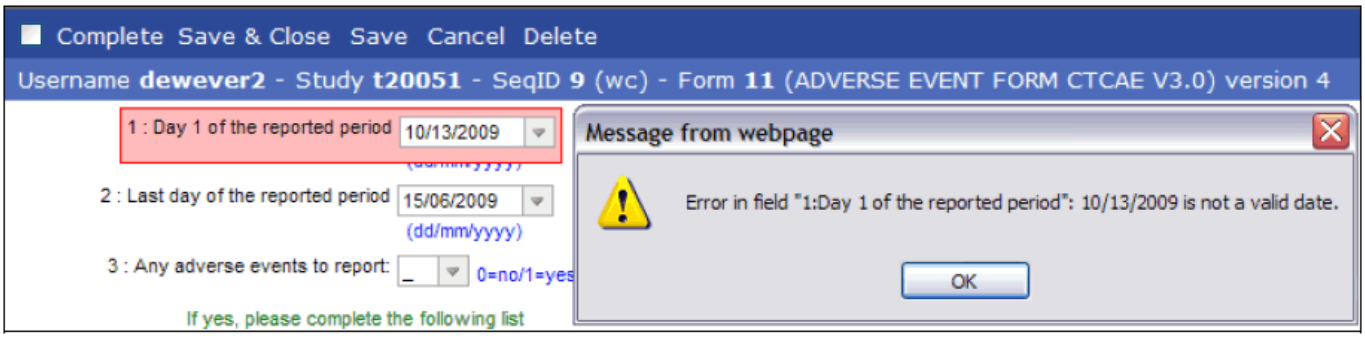


Text boxes

Text boxes have to be completed in **ENGLISH**

Dates

All dates to be completed consist of 8 characters in the sequence of day/month/year (i.e. **dd/mm/yyyy,** e.g. 03/01/2008). **Make sure you use slashes (/) and NOT dashes (-) or dots (.)** because wrong entries may block you when entering dates!



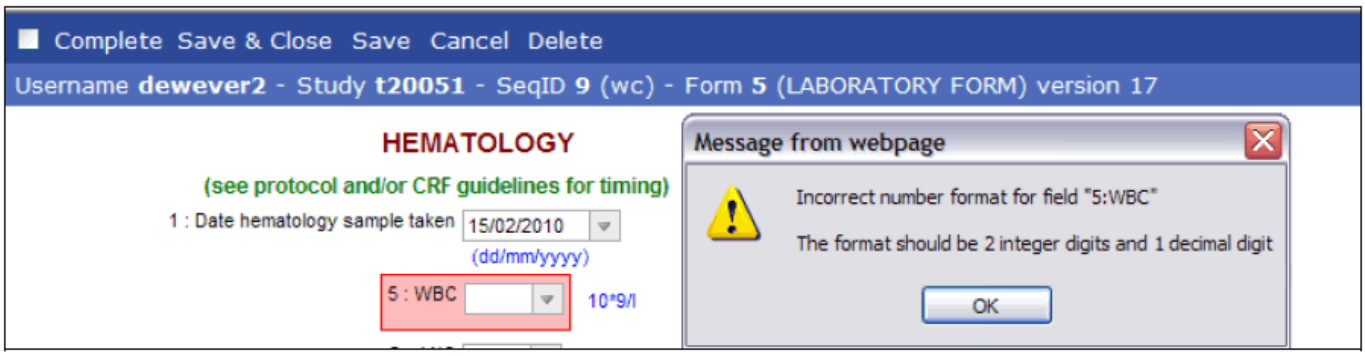
It is not possible to enter partial dates. If the day (and month) is not available, tick the checkbox 'unknown' and put the box number and the available info in the comment fields at the bottom of the form.

Numeric boxes

Depending on the laboratory of your institution, some parameters can be expressed in different units: e.g. Hemoglobin can be expressed in "mmol/l" or "g/dl". Choose the box corresponding to the unit used by your laboratory and **leave the other box blank** (no need to flag it UNKNOWN).

- If your laboratory uses other units, make the easiest conversion: e.g. "g/l" to "g/dl".
- If your laboratory provides results in both units, select and document one unit only, but consistently.

Never report values in a different unit than the one(s) provided on the VISTA-RDC form!
Warning messages will inform you if the wrong format has been used, informing you about the expected format.



Numbers with decimals

- Only use the number of spaces foreseen in each data box. When excess precision in numbers with decimals is observed, adjust the number according to the following **rounding rules** (ref: *NIST Guide to SI Units*):

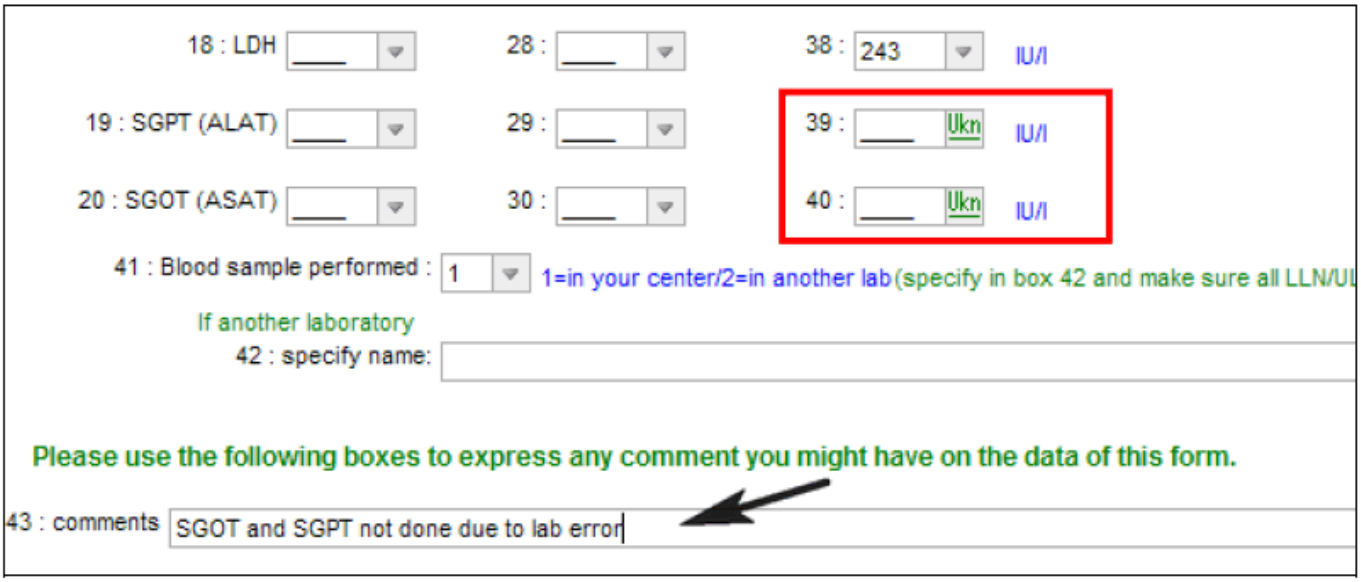
  For rounding xxx,ab**c** where a, b, c, x are figures

  - If (**c < 5**), xxx,a**bc** is rounded into xxx,a**b**: example: 7,124 7,12
  - If (**c 5**), xxx,a**bc** is rounded into xxx,a(**b+1**):example: 7,128 7,13

- If some decimals are not filled in, it will automatically filled in with 0 by the system after saving. example: 46,-- 46,00

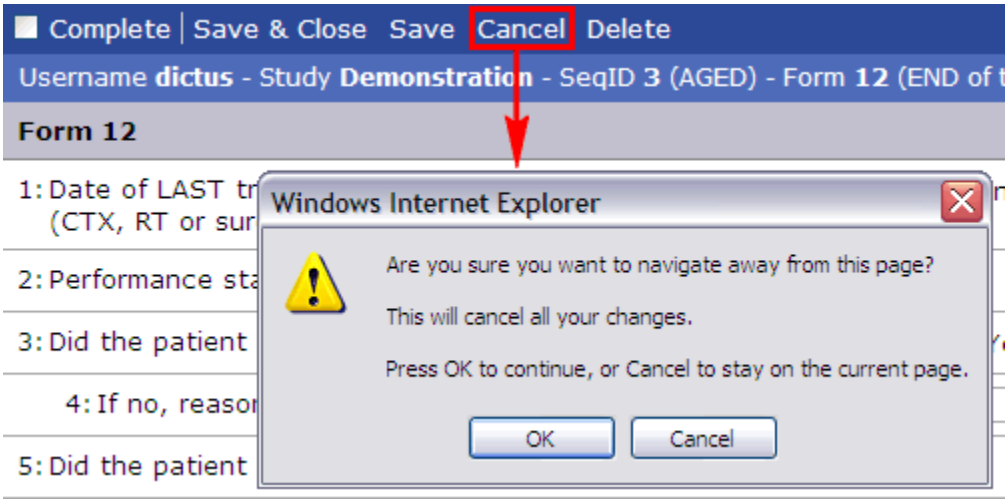
Comments

At the end of each RDC-form there is a space for writing down **comments.** These fields can be used to mention remarks (example: give reason why a lab value is not available). This could help to reduce the number of queries, but make sure that all information that should be reported in one of the RDC-fields is also mentioned in the appropriate field(s) and not only in these comment fields.



Cancel changes

In case you do not wish to save your changes, click on the 'cancel' button at the top of your screen.



Save a form as incomplete

A form may be saved without being complete and without the mandatory values being reported. To save a form as incompleye, click on the **Save** or on the **Save & Close** button at the top of your screen.

Save a form as complete

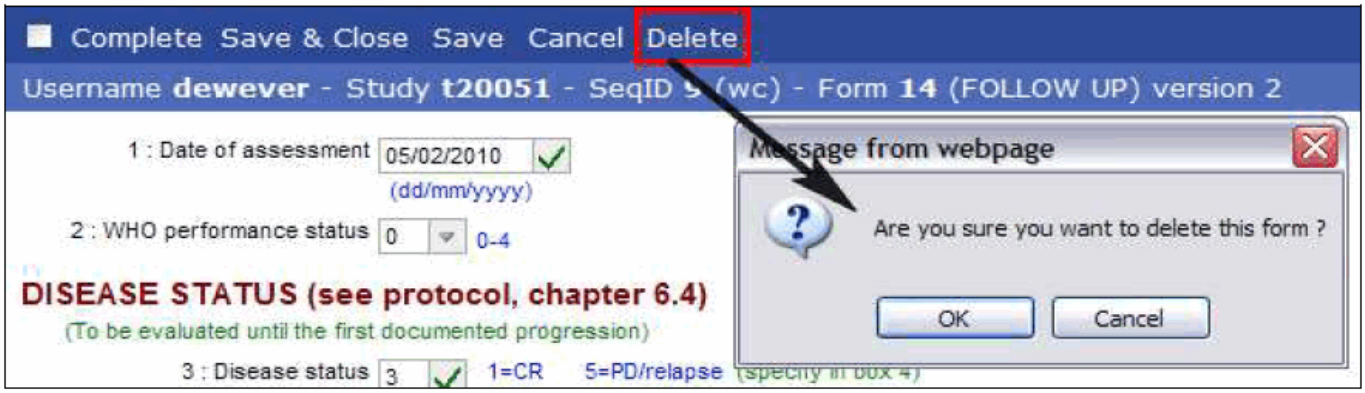
A form may be set as complete only if all mandatory questions (required fields) have been correctly answered and if all out-of-range data have been corrected or confirmed and forced. To save a form as complete, tick the field next to 'Complete' and click on the **Save** or on the **Save & Close** button at the top of your screen.

Delete a form

Forms can be deleted by the local Data Manager/Investigator if they were not yet sent to the EORTC (status 'Incomplete' or 'Complete'). In order to delete a form that has already been sent, the EORTC Headquarters should be notified by means of a paper Data Correction Form. Only the EORTC Data Manager is authorized to delete a form that has already been sent to the EORTC.

Delete an unsent form

A form can be deleted before it has been sent. In case data have already been reported on the form, these data will be deleted as well. To delete an unsent form, click on the 'delete' button at the top of the screen.

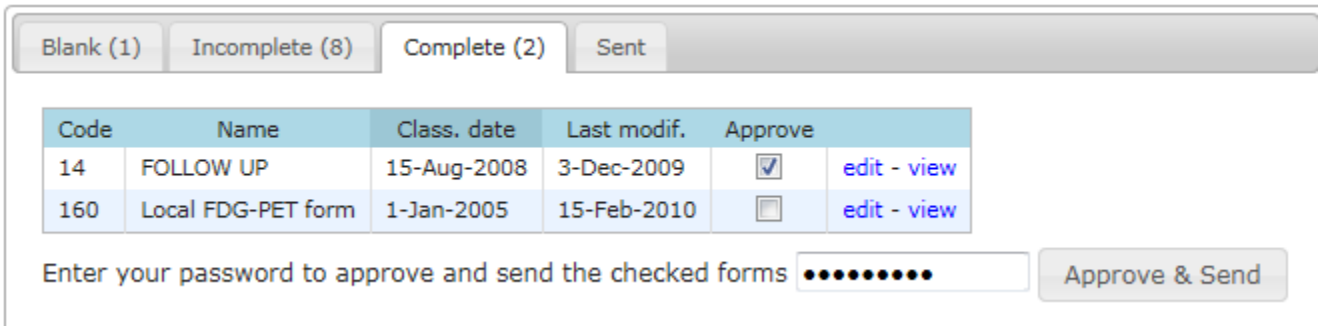


Approve & send a form

Authorization to approve and send forms is given on the signature and delegation of responsibilities log of the study. Forms can be approved and sent from the 'complete' tab.

Users entitled to approve and send forms

Users entitled to approve and send forms will see the message below. Tick the boxes next to the forms you wish to approve, enter your password and click the 'approve & send' button.



Users not entitled to approve and send forms

Users not entitled to approve and send the forms will see the following message: