

RAVE EDC USER GUIDELINES

iMedidata Rave EDC	https://www.imedidata.com
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For technical problems with the Rave EDC system, please contact the iMedidata help desk via e-mail at helpdesk@mdsol.com or by telephone.

For your local iMedidata help desk phone number, check <https://www.mdsol.com/en/contact-sales-and-support#contactsupport>

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1. General information

The data will be collected via the iMedidata Rave EDC system: <https://www.imedidata.com/>. The system allows authorized staff members to enter and edit clinical data about their patients on-line.



FOR COMPATIBILITY REASONS, WE RECOMMEND TO USE GOOGLE CHROME FOR ENTERING THE RAVE EDC SYSTEM. USING INTERNET EXPLORER CAN CAUSE FUNCTIONALITY LOSS.

These guidelines will provide a synopsis of main features available to provide the data. For more in depth information regarding the functionality of the Rave EDC system, please refer to eLearnings, accessible through the Tasks pane. An eLearning that has been completed, can always be retaken if necessary.

More information on getting help is detailed in the help section 6 of these guidelines.

For general questions regarding the study, the access rights or the CRF completion, please refer to study specific CRFs completion guidelines or contact EORTC via the study-specific e-mail address.

2. Navigation

Once logged on through the main iMedidata page using your unique username and password, you will be directed to the Rave EDC home page where you will have access to the study ***once all prerequisite eLearning has been completed***. Following and successfully completing the eLearning post-assessments are required before getting access to the study database.

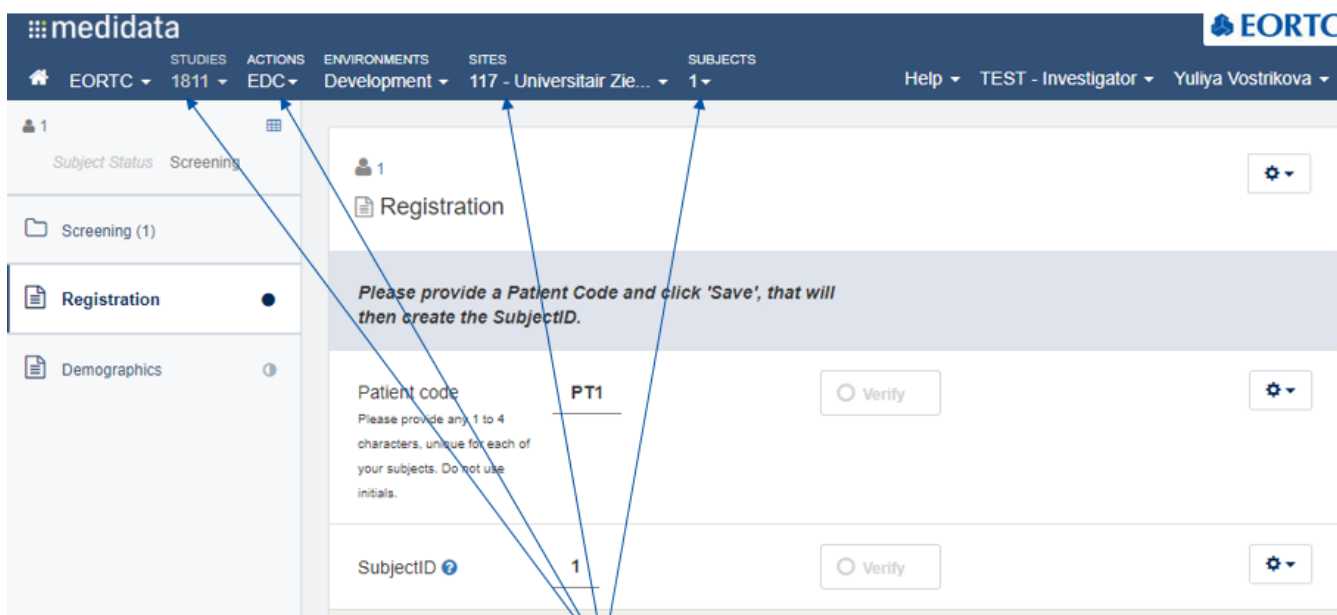
To access the EDC module, click on the relevant study icon link. A user is automatically logged out by the system after a period of inactivity, when that happens the iMedidata login page reappears.

The screenshot shows the Rave EDC home page interface. It features a left sidebar with 'Apps' (CODER, EORTC, REPORTING, EORTC, RAVE Labs, EORTC), a central 'Studies (9)' section with a search bar and a list of study links (1811-E²-RADlatE, Rave EDC Labs, Rave Architect Security, Codex, Reporting, Rave Architect Roles, Rave Modules, Safety Gateway Mapping, Rave EDC), and a right sidebar with 'Tasks' (Invitations (0), No Pending Invitations, eLearning (0), No Pending eLearning). Three callout boxes provide instructions: 'Invitations to studies should be accepted here' points to the 'Invitations (0)' section; 'Prerequisite training will be listed here. Once you have completed the training and passed the assessments, you will be granted access to the study.' points to the 'eLearning (0)' section; and 'Access the study after completing the training' points to the 'Rave EDC' link in the study list.

2.1 Rave EDC

You can navigate between studies, modules (such as EDC, lab management and EDC task overview), sites and subjects from the dropdown menus at the top to perform the following actions:

- Click on your site name to add or modify subjects for that site
- Click **'Add Subject'** to enter a new subject
- Click on an existing subject ID to enter or update existing data for that subject
- Click on visit folders to access the forms that need to be entered for that visit
- Click on form names to enter data on a form



Use shortcuts at the top of the screen to navigate between studies, modules, site and subjects

2.2 Subject dashboard

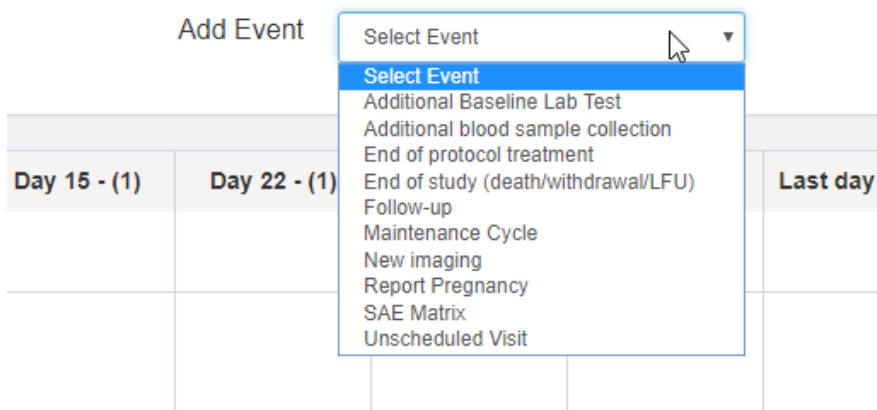
When first selecting a subject, the subject dashboard appears. This shows at a glance which data is already completed, which data is expected, if and where queries are etc. Clicking on any icon takes you to the form in question.

	Subject	Screening
Registration	●	
Demographics		✎
Non-Malignant Medical History		○
Malignant Medical History		○
Primary Disease		○
Pregnancy Test		○
Eligibility		✎
Randomization		●
Initial Measurements		

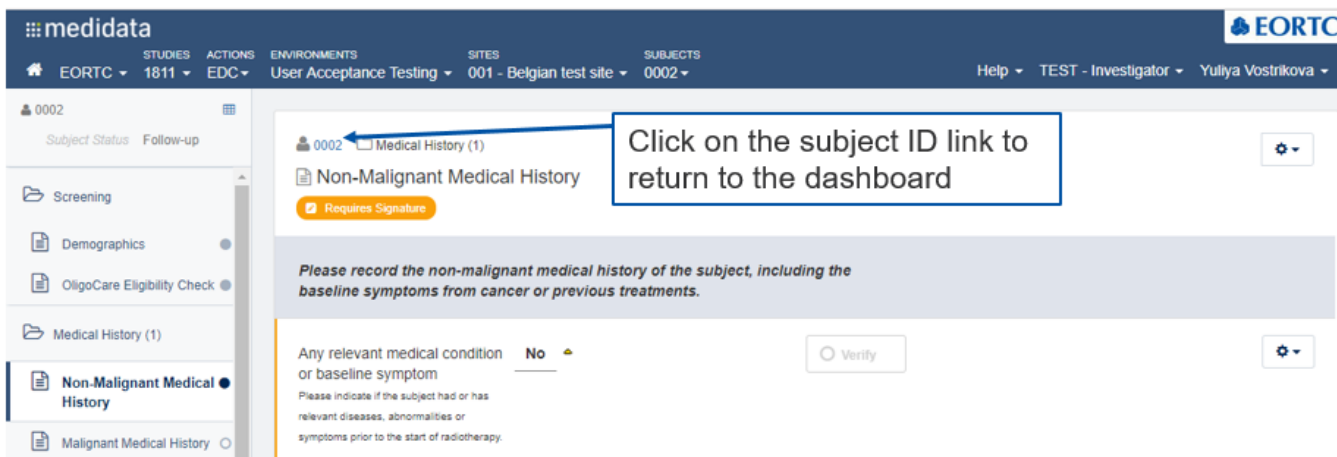
●	: A black circle means the form has been entered and has no queries.
○	: A white circle means the form is expected but has not been entered yet.
◐	: A black/white circle means the data has been partially completed with some empty fields. In case not all fields on a form are mandatory, this might be the final state.
✎	: A pencil means data has been entered and is pending signature.
💬	: A speech balloon means one or more queries have been raised.
🚩	: A flag means an action is required.
✓	: A checkmark means that that data entry is complete and the data has been locked.

2.3 Add event

From the subject dashboard, you can also add events outside of the normal visit structure, i.e. in case of unscheduled visits, additional lab tests to be reported, end of protocol treatment, end of study, etc. Adding an event will create a visit folder or a form for further completion. For more information about study specific visit folders and forms, please refer to study CRFs completion guidelines.



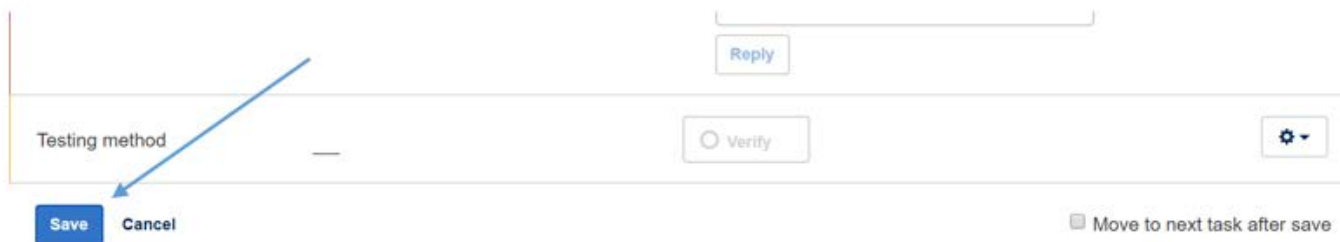
You can return to the dashboard by clicking on the subject ID hyperlink in the top left corner of the CRF screen.



3. Data completion

3.1 Save data

It is important to select ‘**Save**’ when new data has been entered or previously entered data has been changed. The save button is located underneath the final data entry field on a page. In case of many data entry fields on a form, it might be necessary to scroll down before the save button is visible.



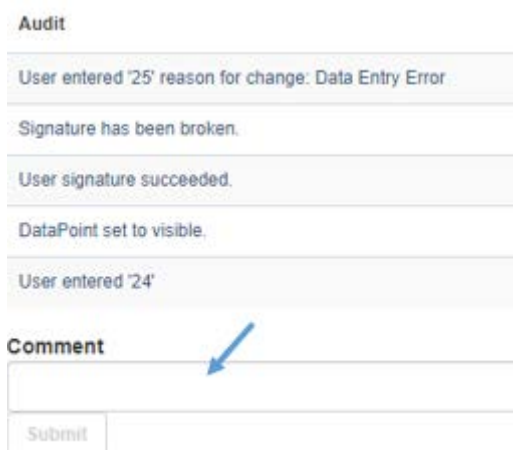
3.2 Change data and comment

In case of a data entry error, it is possible to change data that had been entered and saved by selecting the data point(s) to be updated and entering the new data. A reason for the correction has to be provided (by default, ‘Data Entry Error’ is selected).

A changed field can be identified by the presence of a delta icon. You can access the audit trail for that field by clicking on the cog icon and selecting ‘**Audit history**’.

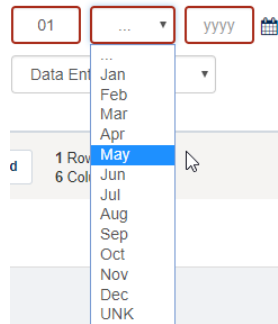


From inside the audit trail, you can add comments by using the **Comment** field available.



3.3 Dates

Dates are requested in a dd-MMM-yyyy format. To enter a date, enter one or two digits for the day, select the month from the dropdown and enter four digits for the year.



A partially unknown date can be entered by entering **“UN”** if the day is unknown and/or by selecting **“UNK”** for an unknown month. Alternatively, by clicking on the calendar icon, you can select the date using the calendar. This also allows for entering partially unknown dates.

Note that on some CRFs a fully unknown date will be allowed and can be entered as “UN/UNK/UNKN” (with “UN” for the day, “UNK” for the month and “UNKN” for the unknown year).

3.4 Missing data

In case a numeric or text result is expected to be entered a query will be raised automatically, requesting the information to be completed. When the information is confirmed in the query answer as not available (for example, a mandatory assessment was forgotten to be performed), EORTC HQ staff can enter one of the following missing codes, depending on the reason why the value was not available:

- ND – not done
- UN – unknown
- NA – not applicable

Example: if a Uric acid result is confirmed as not available as the lab test was not done, this result will be coded as not done with ‘ND’.

Uric acid mg/dL Verify

Data Entry Error Range: 2.4 - 6.2

Data is required. Please complete.

The test was not done

Reply

→

Uric acid ND - 'Not done' mg/dL Data Management

Range: 2.4 - 6.2

Data is required. Please complete.

The test was not done

3.5 Tables (Log forms)

A log form is used when more than one record of data needs to be reported on a form. For example 1 Adverse Event form collects multiple AEs, as many as needed.

Log forms look like tables and they allow the addition of new rows in the table, called log lines.

Adverse Event, Log Lines

Use Portrait View to make changes.

All Search field value: '0' or '1' for checkbox fields.

<	Term	CTCAE	Grade	Outcome	Start	Ongoing	>
1	-	-	-	-	- - - -	<input type="checkbox"/>	

Scroll to right

Portrait view button

If not all columns are visible on the page, you can click on an arrow icon which allows you to easily scroll from left to right. When adding, viewing or editing an entry in a log line, the entry can expand so all the data fields are fully visible (Portrait view). To return from portrait view to the overview, click **'Return to complete view'**.

SEARCHING IN LOG LINES

A search field is available allowing to search a certain value in all fields or in a specific field. To initiate a search, enter a search field value in the text box and click the magnifying glass. To clear the search filters, select 'Clear Filter'.

Start search

All Search field value: '0' or '1' for checkbox fields.

- All
- CTCAE
- End
- Grade
- Ongoing
- Outcome
- Relation RT
- Start
- Term

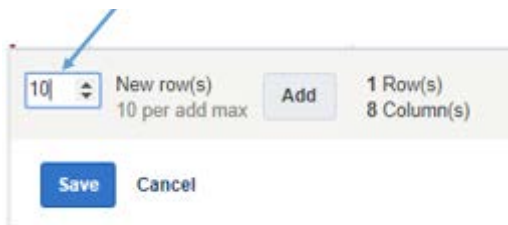
CAE	Grade	>
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SORTING COLUMNS ON LOG LINES

The log lines can be sorted based on the column. Click once on the name of the column to sort in ascending order and click twice to sort in descending order.

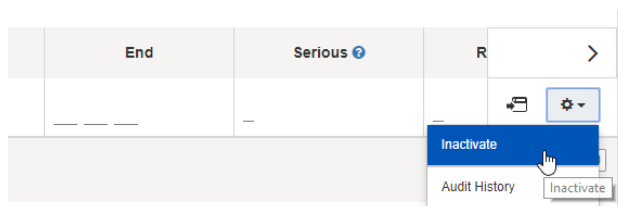
ADDITION OF A NEW LOG LINE

To add a log line, click on ‘Add’. If you want to add multiple new lines at once, you can add up to 10 lines at once by entering the desired number.

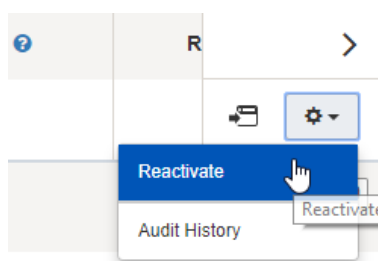


INACTIVATE A RECORD

A log line that has been entered can be inactivated from the complete view by selecting the cog icon and selecting “Inactivate”. The data will remain visible, but is scored through. A reason for inactivation will be requested.



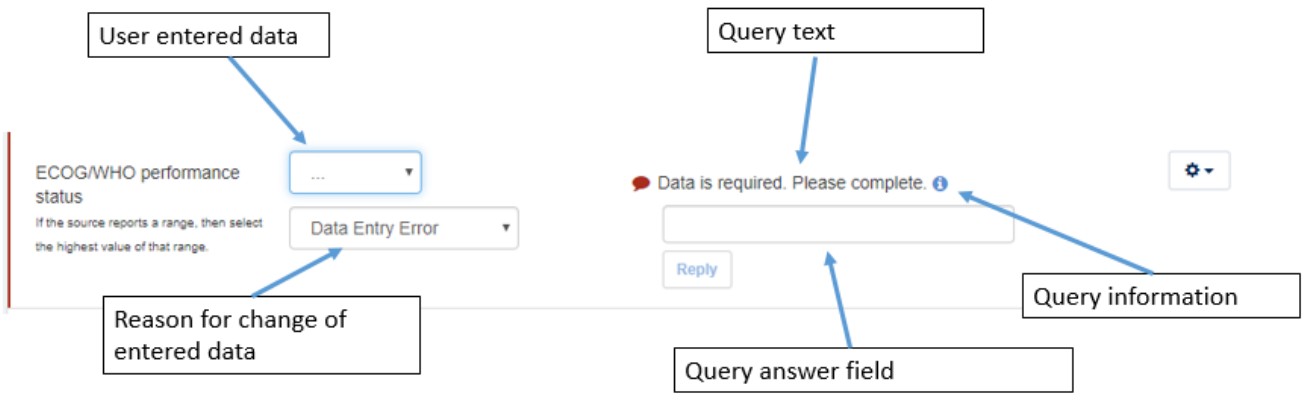
A log line that has been inactivated can be reactivated by the same procedure. A reason for reactivation will be requested.



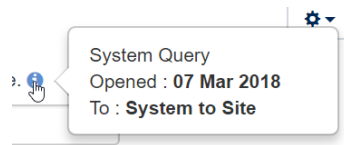
4. Queries

You can answer queries in two ways:

- 1 Modify the data in the data entry field. When changing entered data, a reason for the change also has to be selected. Typically, no additional response is required; however in some cases still an actual query response might be requested (clarification of a situation).
- 2 If the entered data is correct, you can provide clarification, justification, rationale, ... as a user response.



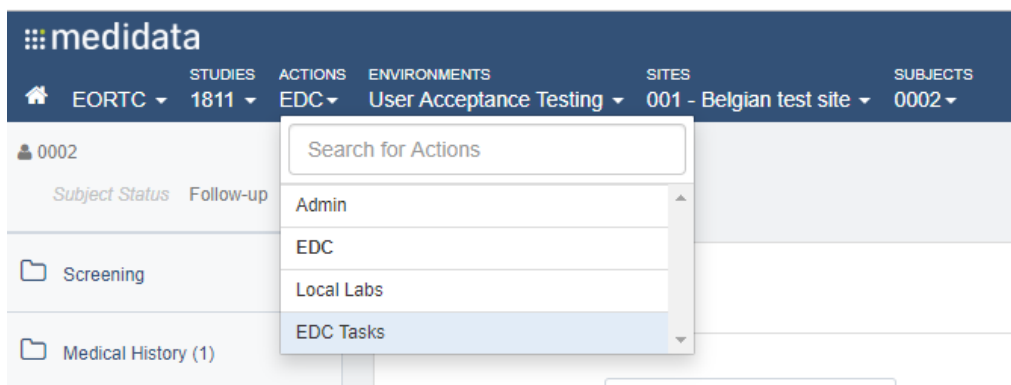
More information about the query (origin and type of the query, date query was opened) can be viewed by hovering over the query information bubble.



5. EDC tasks

The EDC tasks section gives you at any time an overview of pending actions for you to perform such as pages requiring signature, non-conformant data to be corrected, open queries to be answered or notes to acknowledge.

To find these tasks, click on **'Actions'** in the taskbar and select **'EDC tasks'**. This opens the overview, from where you can navigate through the different tasks and follow the hyperlinks to the actual action items. **Filters** can be applied to find back tasks on specific subjects, forms, folders, number of days a query has been open, or any combination thereof.



Task Overview

Pages Requiring Signature 136

Nonconformant Data 1

Open Queries 77

Notes 4

Overdue Data 0

Study Site Task List - balancetestsite

Open Queries

Filters Clear Filter

Subject	Subject Status	Folder	Form	Days Open
0001	Screening	Screening	Non-Malignant Medical History	2
0001	Screening	Screening	Demographics	7
0001	Screening	Screening	Vital Signs	2
0001	Screening	Lab Test	Coagulation	7
0001	Screening	Lab Test	Biochemistry 04 Apr 2018	7
0001	Screening	Common Events (AE/MED/PR)	Adverse Event	2
0001	Screening	Screening	Screen Failure	7
0002	Enrolled	Screening	Demographics	7
0002	Enrolled	Screening	Eligibility	7
0002	Enrolled	Screening	Vital Signs	7

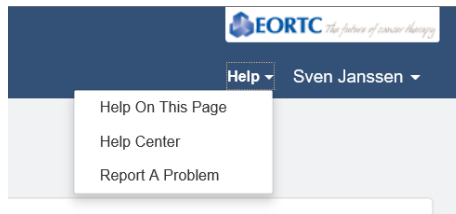
77 Total Result(s)

« 1 / 8 »

Per page 10 25 50 100

6. Help

Help regarding the use of the iMedidata Rave EDC system is available at any time from the help dropdown menu at the top right of the screen.



Several help options are available:

- **Help On This Page** takes you to a help page related to the page you are on (for example, if you access this link from the visit dashboard page, help about that topic shows up).
- **Help Center** takes you to the general help pages, where help regarding any topic is available.
- **Report A Problem** allows you to search for help, or to report a problem directly to iMedidata.