

RAVE EDC USER GUIDELINES

Version 3 26/06/2026

Medidata Rave EDC	https://www.imedidata.com
<i>For technical problems with the Rave EDC system, please contact the iMedidata help desk via e-mail at helpdesk@mdsol.com or by telephone.</i> <i>For your local iMedidata help desk phone number, check https://www.mdsol.com/en/contact-sales-and-support#contactsupport</i>	

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1. General information

The data will be collected via the Medidata Rave EDC system: <https://www.imedidata.com/http://rdc.eortc.be/>. 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

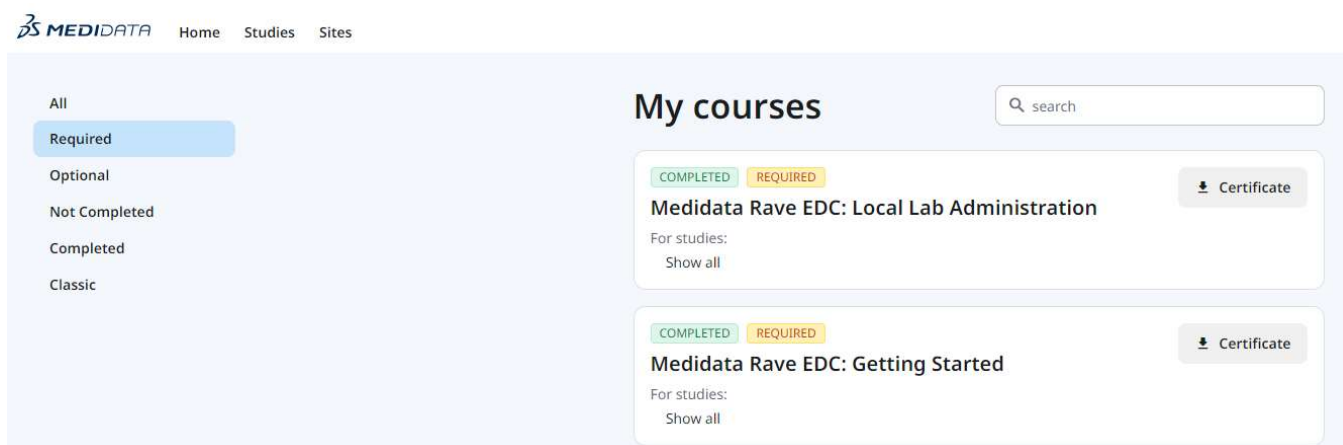
Once logged on through the main iMedidata page using your unique username and password, you will be directed to the Rave EDC home page where you will have access to the study **once all prerequisite courses have been completed**. Following and successfully completing the course post-assessments are required 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 for a user named Amy. At the top, there's a navigation bar with 'Home', 'Studies', and 'Sites'. Below the navigation bar, a greeting 'Hello, Amy' is displayed. A yellow warning box states: 'You must complete required courses. You cannot access 3 of your assigned studies until you successfully complete the required eLearning courses. View courses'. The main content area is divided into three columns: 'Studies', 'Sites', and 'History'. The 'Studies' column lists four studies: 'Safety and Feasibility of the EGlove Ph...', 'Development of an Intervention to En...', 'Rehabilitation After Breast Cancer', and 'F21046 - CancerTrial'. The 'Sites' column lists four sites: 'Livingston Hospital', 'Edinburgh Royal Infirmary II', 'New York Hospital', and 'Albany Medical Center'. The 'History' column shows a list of activities: 'All studies', 'Visits list', 'Actions list', and 'Task list'. Each item in the 'History' section has a timestamp indicating when it was last accessed.

The studies and sites you have recently worked on appear in the first two columns. Click on a recent study or site to open it or click on the three dots to access the EDC module. Your recent work activity is listed under 'History'.

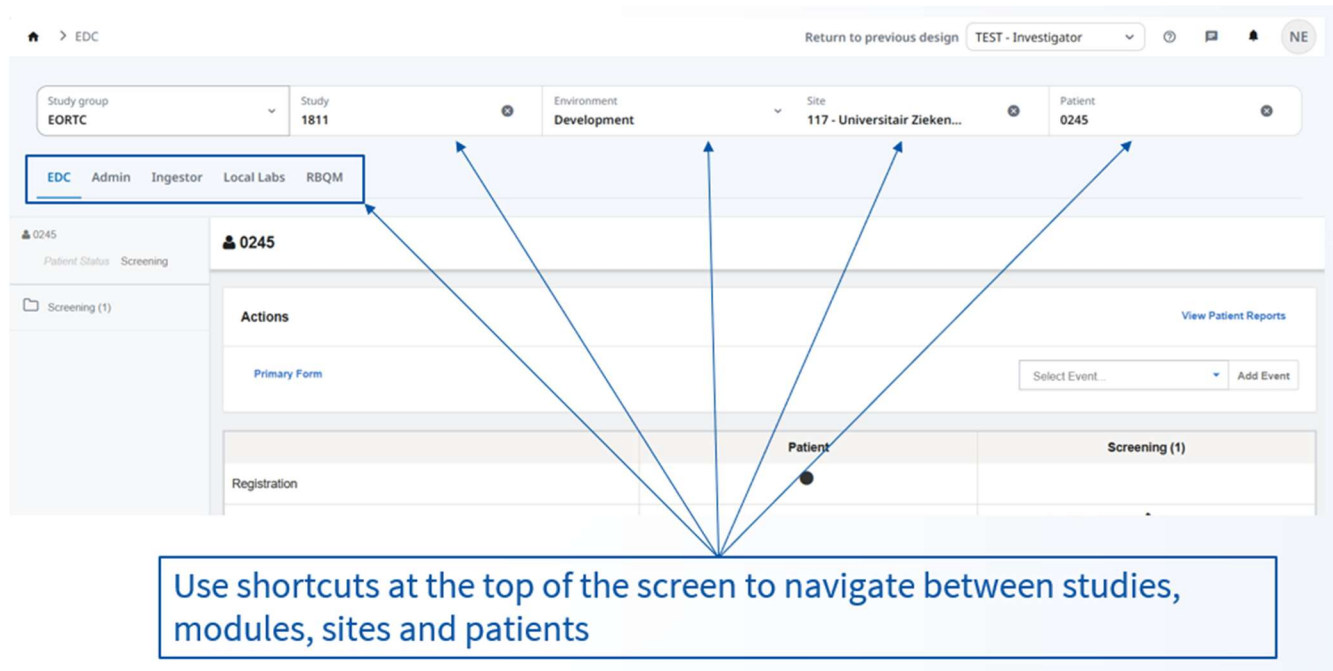
In the right upper corner of the page you can access online help, your profile and notifications. In your profile you will find "my courses" which lists the required training to get access to the study.



2.1 Rave EDC

You can navigate between studies, modules (such as EDC and lab management), 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 Patient'** 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



2.2 Patient grid

When first selecting a subject, the patient grid 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.

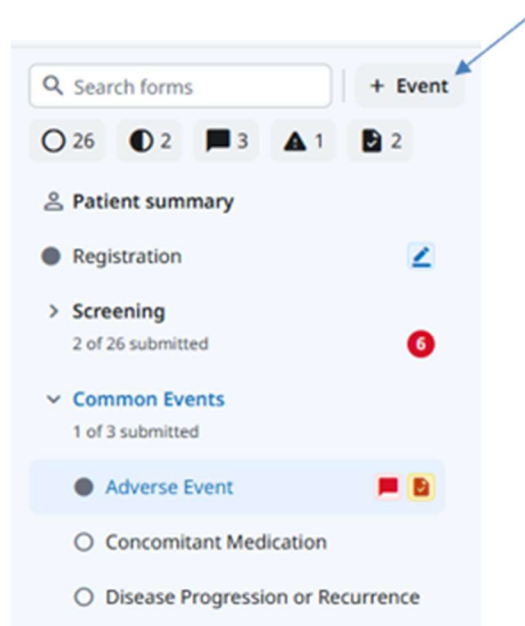
💬 : A speech balloon means one or more queries have been raised.

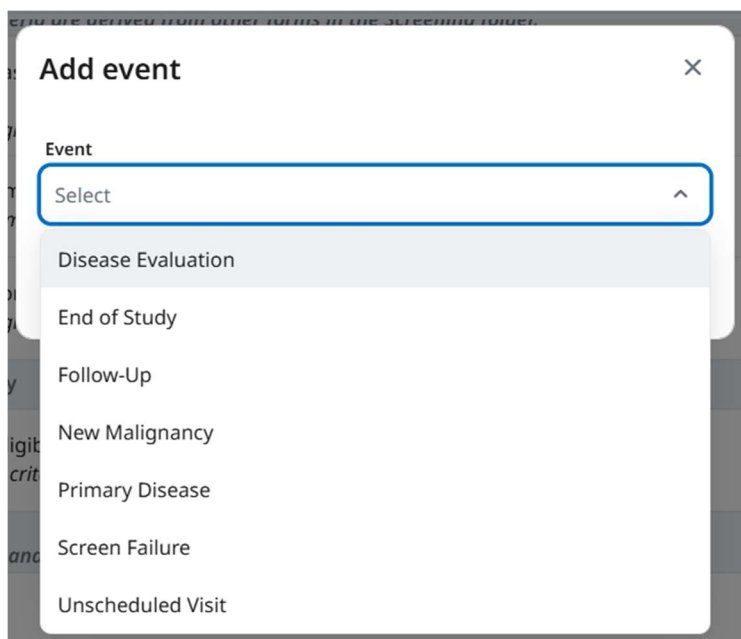
🚩 : A flag means an action is required.

✓ : A checkmark means that that data entry is complete and the data has been locked.

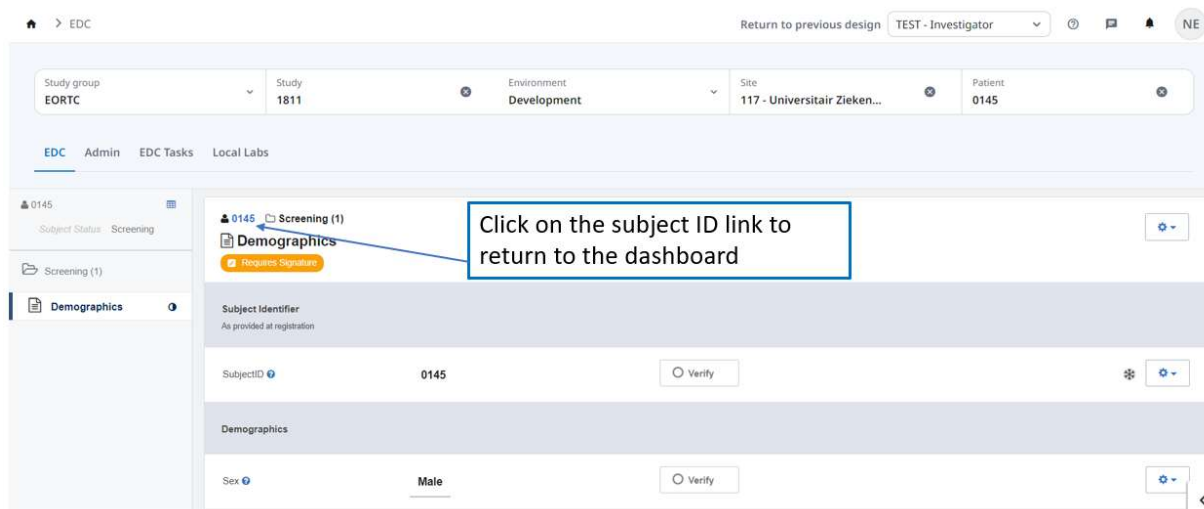
2.3 Add event

From the patient grid, 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.

Testing method

Verify

Save Cancel

☐ Move to next task after save

3.2 Change data

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).

Systolic blood pressure ?

125 mmHg

Data Entry Error

Data Entry Error
Per Query Resolution
New Information

A changed field can be identified by the presence of a delta icon.

Tumor Histology at Initial Diagnosis

Histopathologic type

Small cell neuroendocrine carcinoma (8041)



Please report the predominant WHO Tumor Classification.

Delta icon indicating a changed field

3.3 Audit trail

You can access the audit trail of any field by clicking on the 3 vertical dots icon (⋮) and selecting '**Audit history**'.

Diastolic blood pressure

75 mmHg

Clinical significance

No

Pulse rate

82 beats/min

Respiratory rate

Enter data

breaths/min

Data Entry Error

Audit history

Verify

Entry lock

Data lock

Add comment

Audit history ✕

Data Point - Diastolic blood pressure ▼

Queries

From newest to oldest ▼

 19 Jun 2026 10:05:35

System User

User closed query 'Data is required. Please complete.' (System to Site).

 19 Jun 2026 10:05:35

System User

Query 'Data is required. Please complete.' answered by data change (System to Site).

 19 Jun 2026 10:05:35

Maya Persoons

User entered '75' reason for change: Data Entry Error

 19 Jun 2026 10:04:49

System User

User opened query 'Data is required. Please complete.' (System to Site).

 19 Jun 2026 10:04:49

Maya Persoons

User entered empty.

Within the audit trail you can review any changes made to the data of the field, as well as any prior queries and query replies. At the top right of each CRF, you can access the audit trail on form level.

Vital Signs 19 Jun 2026

Screening

OPEN QUERY

Please record the results of the vital signs assessment.

Assessment done

Yes

Date of assessment

19 JUN 2026

Please record the date of first vital signs

Edit 

Audit history

Verify form 

Entry lock form 

Data lock form 

The form audit trail shows only details of changes happening on form level, e.g. date of creation, inactivation, changes to form name, ...

3.3.1. Comment

You can add comments by clicking on the 3 vertical dots icon (⋮) and selecting **'Add comment'**. An extra window will open to comment in case you want to provide more information on a data entry or data change.

3.4 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).

3.5 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’.

3.6 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 Concomitant medication form collects multiple medications, as many as needed.

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

Concomitant Medication

Common Events

Please record the concomitant medications of the Subject.

Any concomitant medication(s) ☐ No ☐ Yes
Data is required. Please complete.

Subject ever received Covid vaccine ☐ No ☐ Yes

Please complete an entry for each concomitant medication, and for any change to the dose, unit, frequency or route of these.

Log Records 1

All Search

#	TASKS	MEDICATION	INDICATION	AE INDICATION	MH INDICATION	SPECI
1		Enter data	...			

Portrait view button

Expand row

Audit history

Verify ☐

Entry lock ☐

Data lock ☐

Inactivate

Scroll to right

+ 1 more rows (10 add max)

Rows per page 50 1 of 1

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 (Expand row). To return from portrait view to the overview, click the escape button (X) or cancel. Make sure to first save the data encoded.

Concomitant Medication
Patient ID: 0002

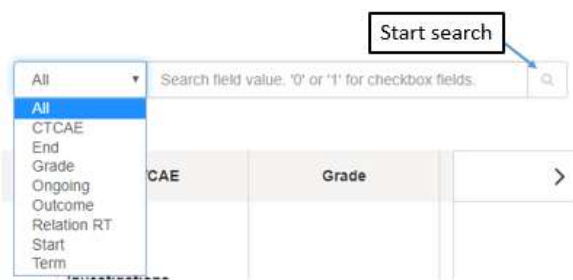
1 < > Edit ✎ ⋮

Medication name	Enter data			⋮
Indication	...			⋮
Dose	Enter data			⋮
Please record here only the dose, not the unit or frequency.				
Unit	...			⋮
Frequency	...			⋮
Route	...			⋮
Start date	dd	MMM	yyyy	📅
Ongoing	☐			⋮
End date	dd	MMM	yyyy	📅

Save **Cancel**

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'.

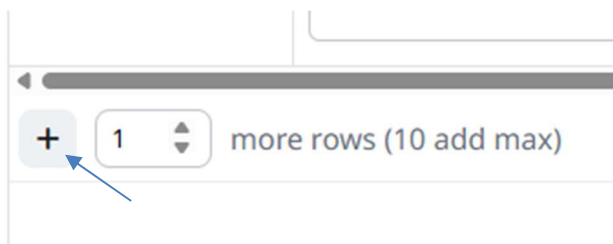


SORTING COLUMNS ON LOG LINES

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.

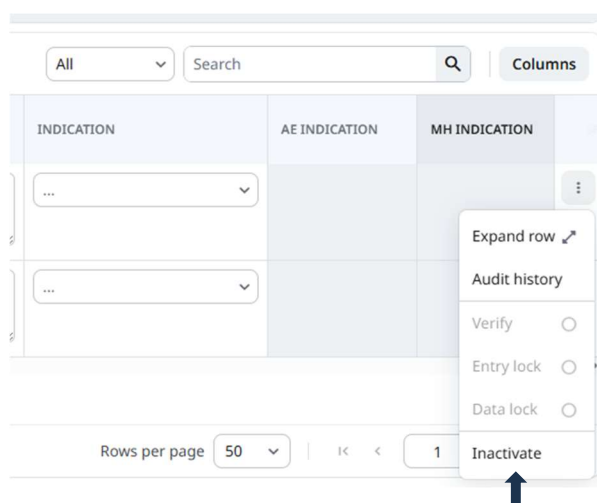
ADDITION OF A NEW LOG LINE

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

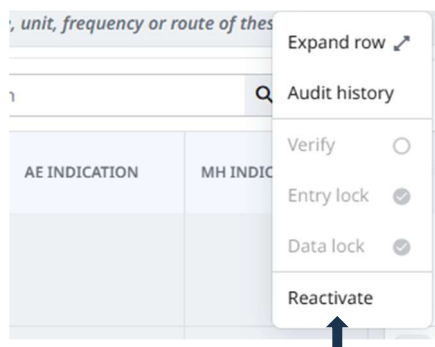


INACTIVATE A RECORD

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.

The screenshot displays a Rave EDC interface with several components and callouts:

- User entered data:** Points to a dropdown menu at the top of the form.
- Reason for change of entered data:** Points to a dropdown menu labeled "Data Entry Error".
- Query text and information on query type and date opened:** Points to a query message box containing the text "Data is required. Please complete." and "System to Site • 19 Jun 2026".
- Query answer field:** Points to the "Answer" label within the query message box.

The interface also includes a section titled "ECOG/WHO performance status" with a note: "If the source reports a range, then select the highest value of that range."

More information about the query (origin and type of the query, date query was opened) can be viewed under the query text.

5. Patient list page and EDC tasks

The EDC section gives you at any time an overview of sites, patients and pending tasks. These tasks are 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.

The screenshot shows the 'Patients' page in the Rave EDC system. The top navigation bar includes 'Return to previous design', 'TEST - Investigator', and a user profile icon. The main header shows filters for 'Study group: EORTC', 'Study: 1811', 'Environment: Development', and 'Site: 117 - Universitair Ziekenhuis Ant...'. The sidebar on the left has tabs for 'EDC', 'Admin', 'Ingestor', 'Local Labs', and 'RBQM'. Under 'EDC', there are links for 'Patients' (20), 'Your tasks' (195), and 'Others' tasks (2). The main content area is titled 'Patients' and shows a summary: 'Target: 0 Enrolled: 14 Completed: 1'. Below this is a filter bar with 'Patient ID', 'Patient status', and 'Manage filters'. A search bar and 'Clear filters' button are also present. The patient list table has columns for 'PATIENT ID', 'PATIENT STATUS', and 'ADD EVENT'. The list shows three patients: 0030 (SCREENING), 0031 (SCREENING), and 0062 (ENROLLED).

To find these tasks and the site and patient list page, click on **'EDC'**. In the patient list page you can find an overview of the registered subjects. Follow the hyperlinks to the subject in Rave EDC.

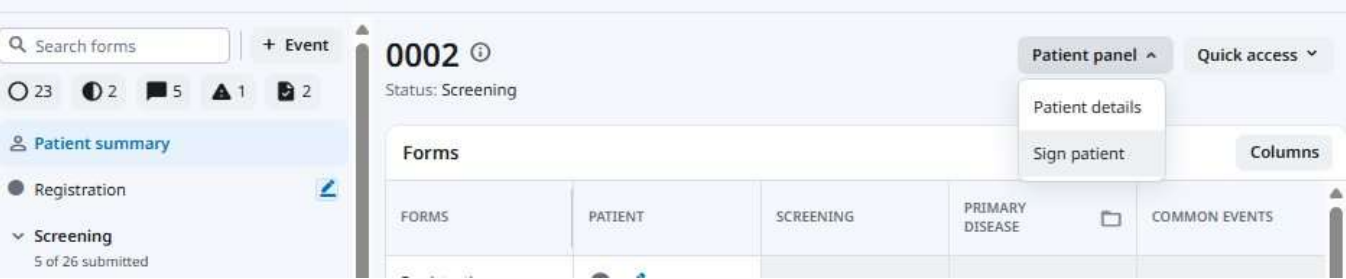
Pending actions for the registered subjects are available under **'Your tasks'**. This opens the overview, from where you can navigate through the different tasks and follow the hyperlinks to the actual action items. **Filters** can be applied to find back tasks on specific subjects, forms, folders, number of days a query has been open, or any combination thereof.

The screenshot shows the 'Your open queries' page in the Rave EDC system. The top navigation bar is the same as the previous screenshot. The main header shows the same filters. The sidebar on the left has tabs for 'EDC', 'Admin', 'Ingestor', 'Local Labs', and 'RBQM'. Under 'EDC', there are links for 'Patients' (20), 'Your tasks' (119), 'Non-conformant data' (1), 'Overdue data', 'Signatures' (73), and 'Notes' (2). The main content area is titled 'Your open queries' and shows a summary: 'List: 28'. Below this is a filter bar with 'Patient ID', 'Patient status', and 'Manage filters'. A search bar and 'Clear filters' button are also present. The query list table has columns for 'FORM', 'FOLDER', 'COUNT', 'MAX DAYS OPEN', 'PATIENT ID', and 'PATIENT STATUS'. The list shows five queries: Demographics, Radiotherapy Tre..., Colorectal Cance..., Progression/Rec..., and Colorectal Cance....

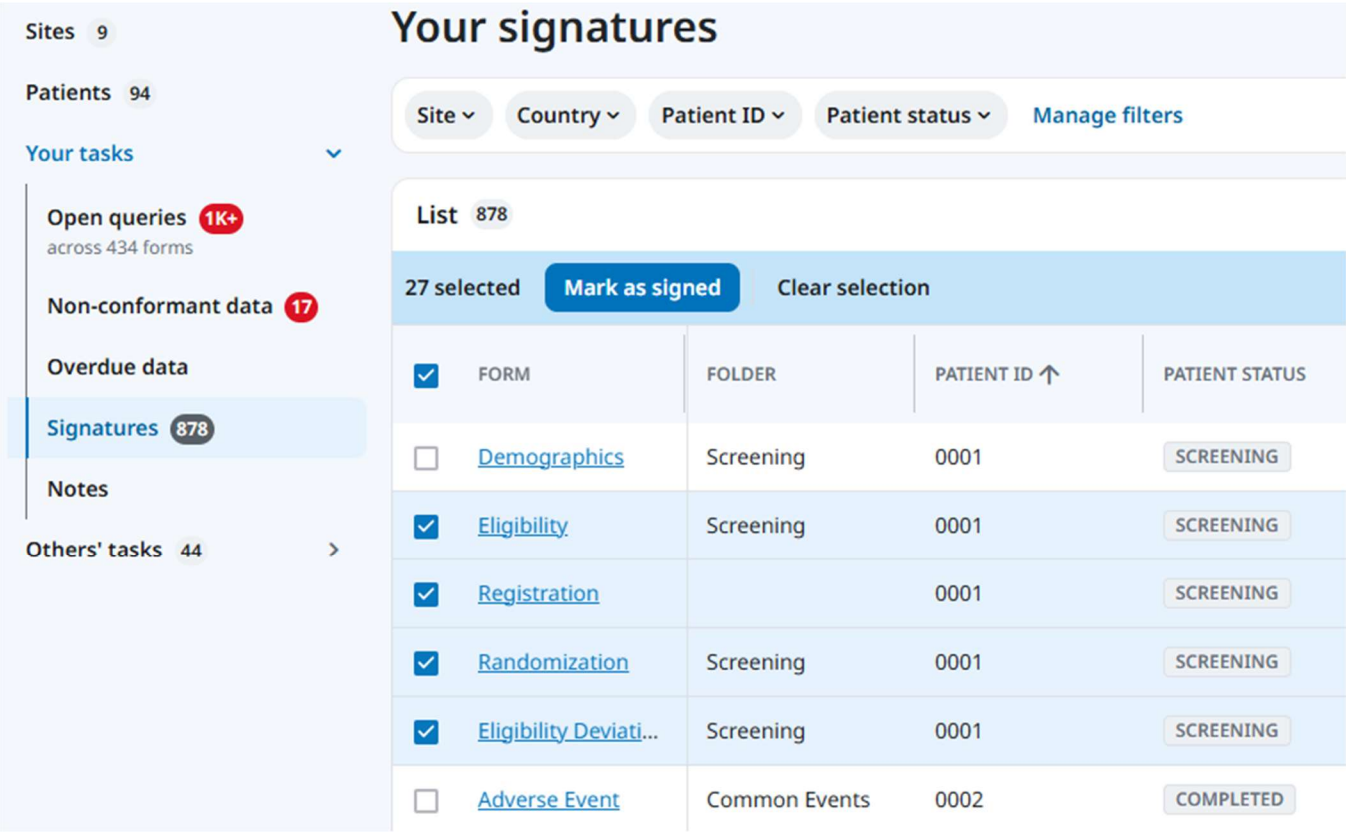
6. Signing of eCRFs

The Principal Investigator, or a delegate, is responsible for endorsement of the reported data by signing the eCRFs in Rave EDC.

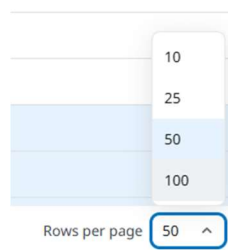
Signature can be applied per patient, by clicking the Sign patient button at the patient’s homepage:



Alternatively, forms can be signed in bulk from the EDC tasks menu:



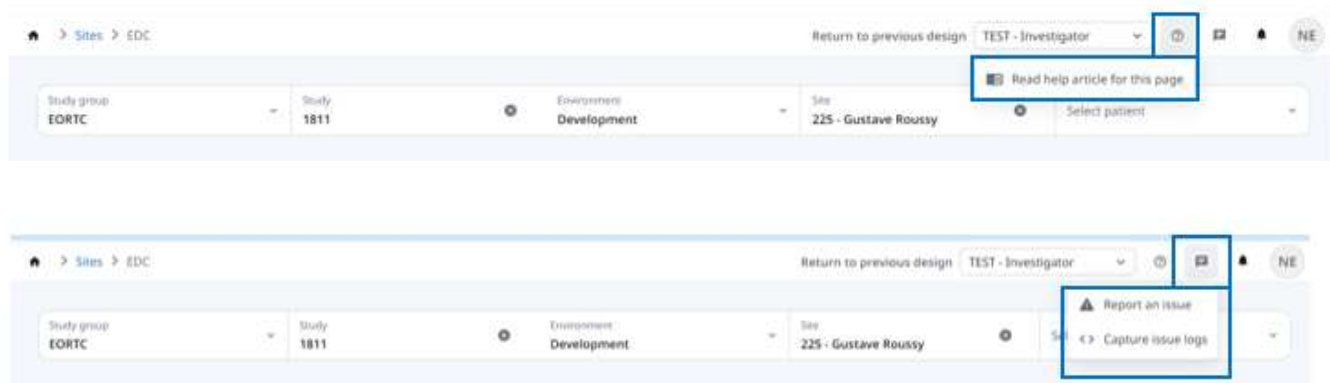
By ticking box at the top of the table, all eCRFs that are ready can be signed by clicking the “Mark as signed” button. Forms that are not ready to be signed, e.g. due to pending queries, will automatically not be selected.



TIP: Expand the table by setting the number of rows as 100

7. Help

Help regarding the use of the Medidata Rave EDC system is available at any time in the question mark or the speech bubble icon at the top right of the screen.



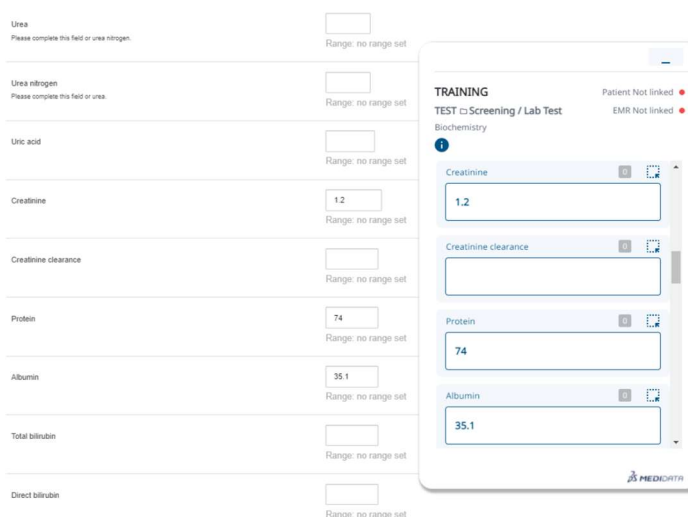
Several help options are available:

- **Read help article 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).
- **Report an issue** allows you to search for help, or to report a problem directly to Medidata.

8. Rave Companion

Rave Companion is free software that enables Rave EDC site users to transcribe patient data from an EHR/EMR into a Rave study form with greater efficiency and accuracy.

It has a floating window that mirrors the CRF. Any entry done in Companion is entered in EDC and vice versa.



Rave Companion can stay on top of other windows. It is useful for transcribing data from EMR/HER into Rave EDC, without constantly having to change focus between them.

TESTS	RESULT	FLAG	UNITS	REFERENCE
Renal Panel (10)				
Glucose	93		mg/dL	
BUN	14		mg/dL	
Creatinine	0.91		mg/dL	
eGFR	84		mL/min/1.73m2	
BUN/Creatinine Ratio	15			
Sodium	135		mmol/L	
Potassium	4.4		mmol/L	
Chloride	104		mmol/L	
Carbon Dioxide, Total	28		mmol/L	
Calcium	9.0		mg/dL	
Phosphorus	3.2		mg/dL	
Albumin	3.9		g/dL	

Click Data Capture allows to highlight text to automatically copy/paste this text into Rave EDC and minimize data transcription errors. When using this feature, please exercise caution not to introduce personal data that is not requested.

TESTS	RESULT	FLAG	UNITS	REFERENCE
Renal Panel (10)				
Glucose	93		mg/dL	
BUN	14		mg/dL	
Creatinine	0.91		mg/dL	
eGFR	84		mL/min/1.73m2	
BUN/Creatinine Ratio	15			
Sodium	135		mmol/L	
Potassium	4.4		mmol/L	
Chloride	104		mmol/L	
Carbon Dioxide, Total	28		mmol/L	
Calcium	9.0		mg/dL	
Phosphorus	3.2		mg/dL	
Albumin	3.9		g/dL	

For more information, demo videos and installation instructions, visit [Medidata Rave Companion Knowledge Hub](#).