

Entering Data into Forms

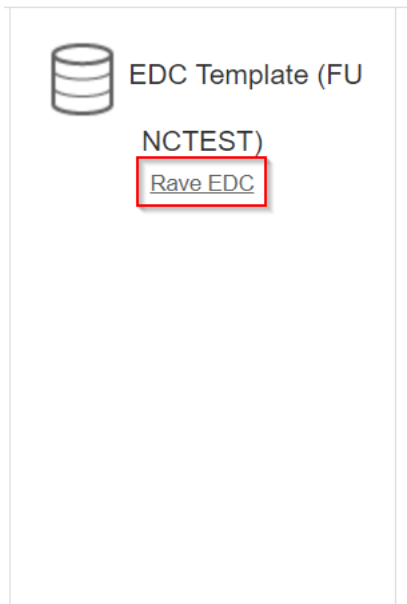
This guide will illustrate the steps in which different data types can be entered into **Standard** forms and **Log** forms in Rave.

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Accessing Forms

To access a form, log into Rave and select the **Rave EDC** link of a specific study.



If the chosen study is associated with multiple sites, a list of sites will then appear. Select a relevant site.

Note: If a study is linked to a singular site, the **Sites** page will not appear. The user will be directly taken to the **Subjects** page.

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STUDIES CCR - EDC Template - ACTIONS EDC - ENVIRONMENTS Development - Help - Clinical Research Asso...

Sites

Find a Site Find a Subject [View Study Reports](#)

Site Number	Site Name	Country	Investigator
BO TEST	BO TEST	United States	
PA TEST	PA TEST Site	United States	
Programmer_Test	Programmer_Test	United States	
T1	TEST	United States	

4 Total Results

The **Subjects** page will then appear which lists all the subjects in that site. Click on a subject to access its forms.

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STUDIES CCR - EDC Template - ACTIONS EDC - ENVIRONMENTS Functional Testing - SITES T1 - TEST - Help - Clinical Research Asso... Mahpara Nuzhat

TEST - Subjects

Enrollment Target 0 Enrolled 2 Completed 0

Filter By Subject Status: All Statuses Find Subject [View Site Reports](#)

Subject Information	Subject Status
1010001	Screened
1010002	Screened

2 Total / 1 Per page

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1010002 **1010002** Subject Status: Screened

Screening Course 1 Course 2 Course 3 Course 4 Course 5 Course 6 Labs Ongoing Off Treatment Follow Up **< COLLAPSE**

Actions [View Subject Reports](#)

[Primary Form](#)

	Subject	Screening	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6	Labs	Ongoing	Off Treatment
Subject Enrollment	●										
Enrollment		●									
Baseline Medical History		○									
Prior Radiation Supplement		●									
Prior Surgery Supplement		○									
Prior Therapy Supplement		○									
Prior Treatment Summary		○									
Physical Exam -		○									

Forms can be directly viewed from the grid window.

The screenshot shows the Rave interface with a grid window. The left navigation bar lists folders: Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Course 6, Labs, Ongoing, Off Treatment, and Follow Up. The main area displays a table with columns: Subject, Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Course 6, Labs, Ongoing, and Off Treatment. The rows include: Subject Enrollment, Enrollment, Baseline Medical History, Prior Radiation Supplement, Prior Surgery Supplement, Prior Therapy Supplement, and Prior Treatment Summary. A red box highlights a filled circle in the 'Subject' column for 'Subject Enrollment', and another red box highlights an empty circle in the 'Screening' column for 'Enrollment'.

This can also be done by selecting a folder on the left navigation bar and choosing a form.

The screenshot shows the Rave interface with the 'Screening' folder selected in the left navigation bar. The main area displays a table with columns: Subject, Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Course 6, Labs, Ongoing, and Off Treatment. The rows include: Subject Enrollment, Enrollment, Baseline Medical History, Prior Radiation Supplement, Prior Surgery Supplement, Prior Therapy Supplement, and Prior Treatment Summary. A filled circle is visible in the 'Subject' column for 'Subject Enrollment'.

The screenshot shows the Rave interface with the 'Enrollment' form selected in the left navigation bar. The main area displays a table with columns: Subject, Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Course 6, Labs, Ongoing, and Off Treatment. The rows include: Subject Enrollment, Enrollment, Baseline Medical History, Prior Radiation Supplement, Prior Surgery Supplement, Prior Therapy Supplement, and Prior Treatment Summary. A filled circle is visible in the 'Subject' column for 'Subject Enrollment'.

Rave consists of two types of forms: **Standard** and **Log**.

Standard forms have one record per form and each standard form consists of a set of data points.

The screenshot shows a standard form titled "Enrollment" for a subject with status "Screened". The form is organized into sections, with the "DISEASE AND CONSENT" section visible. It contains several data points:

- Lesion anatomic site description: A large text area with a character count of 0 / 200.
- Date of Diagnosis: A date picker showing dd, --, and yyyy.
- Histology: A dropdown menu.
- Grade of Histology: A dropdown menu.
- Dose Level: A dropdown menu.
- Disease Stage at Entry: A dropdown menu.
- Disease Stage at Diagnosis: A dropdown menu.
- Gleason Score: A text input field.

Log forms consist of multiple records of the same form data points. These records can be viewed horizontally in landscape mode or vertically in portrait mode. Log forms will be discussed further later on in this document.

The screenshot shows a log form titled "Adverse Events" for a subject with status "Screened" and study "1010002". The form displays a table of "Adverse Events, Log Lines" with the following columns:

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
1	5	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
2	3	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

Below the table, there are controls for adding new rows (1 New row(s), 10 per add max, Add), deleting rows (2 Row(s), 29 Column(s)), and pagination (Per page 10 25 50 100). A "Do you want to add comments?" prompt is also visible.

Entering Different Data Types

Text Fields: Text fields contain text boxes where data can be entered manually. Depending on the study configuration, characters and numbers can be submitted through them. The following screenshots demonstrate data being entered into a standard form.

Pick Lists: Certain data points have pick lists which consist of a set of fixed values. Click on the dropdown icon to generate the list.

Some pick lists can be long and extensive. In these cases, in addition to scrolling through a list and choosing a value, users can also start typing in their desired value. Selections that match the written term will then appear on the list.

Enrollment

DISEASE AND CONSENT

Lesion anatomic site description 0 / 200

Date of Diagnosis dd ... yyyy

Histology

- Pancreas-Undifferentiated Carcinoma
- Pancreas-Signet Ring Cell Carcinoma
- Pancreas-Medullary
- Pancreas-Hepatoid Carcinoma
- Pancreas-Colloid (mucinous non-cystic) Carcinoma
- Pancreas-Adenosquamous Carcinoma
- Pancreas-Adenocarcinoma Ductal Type

Grade of Histology

Dose Level

Disease Stage at Entry

Disease Stage at Diagnosis

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STUDIES: CCR - EDC-Template ACTIONS: EDC ENVIRONMENTS: Functional Testing SITES: T1 - TEST SUBJECTS: 1010002

Help Clinical Research Asso. Mahpara Nuzhat

1010002 Subject Status: Screened

Enrollment

DISEASE AND CONSENT

Lesion anatomic site description 27 / 200

Date of Diagnosis 2 Nov 2021

Histology

Grade of Histology

Dose Level

Disease Stage at Entry

Disease Stage at Diagnosis

Dates: A data point that has a date format can be entered in two different ways. It can be typed in manually or it can be entered by clicking on the calendar icon shown below.

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STUDIES: CCR - EDC-Template ACTIONS: EDC ENVIRONMENTS: Functional Testing SITES: T1 - TEST SUBJECTS: 1010002

Help Clinical Research Asso. Mahpara Nuzhat

1010002 Subject Status: Screened

Enrollment

DISEASE AND CONSENT

Lesion anatomic site description 0 / 200

Date of Diagnosis dd ... yyyy

Histology

Grade of Histology

Enrollment

DISEASE AND CONSENT

Lesion anatomic site description

Date of Diagnosis

Histology

Grade of Histology

Dose Level

Disease Stage at Entry

Disease Stage at Diagnosis

Calendar: November 2021. The 8th is highlighted with a red dashed box.

In some date fields, unknown or imprecise dates can be submitted. In that case, either the date itself or both the date and the month can be left as **unknown**. However, the year must always be specified.

1010002 **Ongoing**

Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Course #	Day in Course	Start Date	Stop Date	Agent Name
1		<input type="text" value="dd"/> <input type="text" value=""/> <input type="text" value="YYYY"/>	<input type="text" value="dd"/> <input type="text" value=""/> <input type="text" value="YYYY"/>	<input type="text"/>

Calendar: November 2021. The 8th is highlighted with a red dashed box.

Unknown Select all that are unknown (you can select up to 3):

- Day
- Month

1010002 **Ongoing**

Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Course #	Day in Course	Start Date	Stop Date	Agent Name
1		<input type="text" value="UN"/> Nov 2021	<input type="text" value="dd"/> <input type="text" value=""/> <input type="text" value="YYYY"/>	<input type="text"/>

Calendar: November 2021. The 8th is highlighted with a red dashed box.

Unknown Select all that are unknown (you can select up to 3):

- Day
- Month

1010002 Ongoing
Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Course #	Day in Course	Start Date	Stop Date	Agent Name
1		UN UNK	2020	

Unknown
Select all that are unknown
(you can select up to 3)

Day
Month

Radio Button: As illustrated below, another type of data point is represented by radio buttons. Users can make a selection among the options listed.

1010002 Screening
Prior Treatment Summary

Prior Treatment Summary, Log Lines

Back To Complete View < Previous Line Line 1 of 26 Next Line >

Therapy Type Anti-retroviral Therapy

Any Therapy? Yes No ⚠ This field is required. Please complete.

of Prior Treatments

Date of Last Dose dd ... yyyy

Back To Complete View < Previous Line Line 1 of 26 Next Line >

Derived fields: Certain data points will have no pick lists, dates or text boxes associated with them – there will be no method of input. These are derived from other data points in the form and can also be recognized by the **frozen** ❄ icon to the right of the field.

The screenshot shows a 'Baseline Symptom' form with the following fields:

- Onset Date: dd, --, yyyy (with a calendar icon)
- Date Resolved: dd, --, yyyy (with a calendar icon)
- AE/SOC: ... (with a search icon)
- SOC: [Red box] ❄
- CTCAE Term: [Red box] ❄
- Symptom Description: [Text box]
- Grade: -- (with a dropdown arrow)

Most forms include a **Comments** section near the end of the page, which can be accessed after responding to the prompt highlighted below. If answered 'Yes', new data points will appear where data can be submitted.

The screenshot shows a table with 18 rows and 3 columns. The table lists body parts and their corresponding input fields:

12	Breasts	--	[Text box]	[Print] ❄
13	Pelvis	--	[Text box]	[Print] ❄
14	Abdomen	--	[Text box]	[Print] ❄
15	Neurologic	--	[Text box]	[Print] ❄
16	Psychologic	--	[Text box]	[Print] ❄
17	Immune	--	[Text box]	[Print] ❄
18	Other	--	[Text box]	[Print] ❄

Below the table, there is a prompt: "Do you want to add comments?" with a dropdown menu showing "Yes" and "No" options. The "Yes" option is highlighted.

18 Other

18 Row(s)
3 Column(s)

Do you want to add comments? Yes

COMMENTS

Date dd -- YYYY

Notes
0 / 200

Save Cancel

Move to next task after save

If the data entered in a form is no longer wished to be saved, clicking **Cancel** will prevent data submission. This resets the form to its previously saved state and does not record audit history.

1010002
Subject Status Screened

M Stage

Date of Confirmation of Histology dd -- YYYY

Date of Informed Consent Version dd -- YYYY

Date from which to Start Including labs dd -- YYYY

NIH ADVANCE DIRECTIVES FORM

Collected? --

Collection Date dd -- YYYY

Comments
0 / 250

Save Cancel

Move to next task after save

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After entering all the intended data in a form, it can be saved by selecting the blue **Save** button at the end of the page.

1010002
Subject Status Screened

M Stage

Date of Confirmation of Histology dd -- YYYY

Date of Informed Consent Version dd -- YYYY

Date from which to Start Including labs dd -- YYYY

NIH ADVANCE DIRECTIVES FORM

Collected? --

Collection Date dd -- YYYY

Comments
0 / 250

Save Cancel

Move to next task after save

An easy way to navigate from one form to another is by clicking on the **Subject Grid** icon. This bypasses the need for a user to go back to the subject homepage. This overlay feature is available in all forms except the Primary Form.

Selecting the grid icon will open up the subject grid and from this view, a user can click on the next form that data has to be entered into. The current form location will be indicated by a blue dotted line.

	Subject	Screening	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6	Labs	Ongoing	Off Treatment
Subject Enrollment	●										
Enrollment		○									
Baseline Medical History		○									
Prior Radiation Supplement		○									
Prior Surgery Supplement		○									
Prior Therapy Supplement		○									
Prior Treatment Summary		○									
Physical Exam - Screening		○									
Consult		○									
Baseline Symptom		○									
Course Initiation			○	○	○	○	○	○			
Physical Exam - Cycles			○	○	○	○	○	○			

Log Forms

Log forms can be viewed in both **Portrait** and **Landscape** mode. They appear in landscape mode by default, where all the log records are displayed as individual rows.

1010002 Ongoing
Adverse Events

Adverse Events, Log Lines

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
1	5	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
2	3	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

Do you want to add comments?

All the fields in a log form can be observed by clicking on the arrow buttons to the right and left of the header titles.

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1010002 Ongoing
Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Agent Name	Procedure/Measure	Dose

Do you want to add comments?

COMMENTS

Save Cancel

Data entered into a log line in landscape view can be saved by clicking on the **Save** button.

1010002 Ongoing
Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Start Date	Stop Date	Agent Name	Procedure/Measure
1 Oct 2020	8 Oct 2020	9-AC	MRI, Endorectal

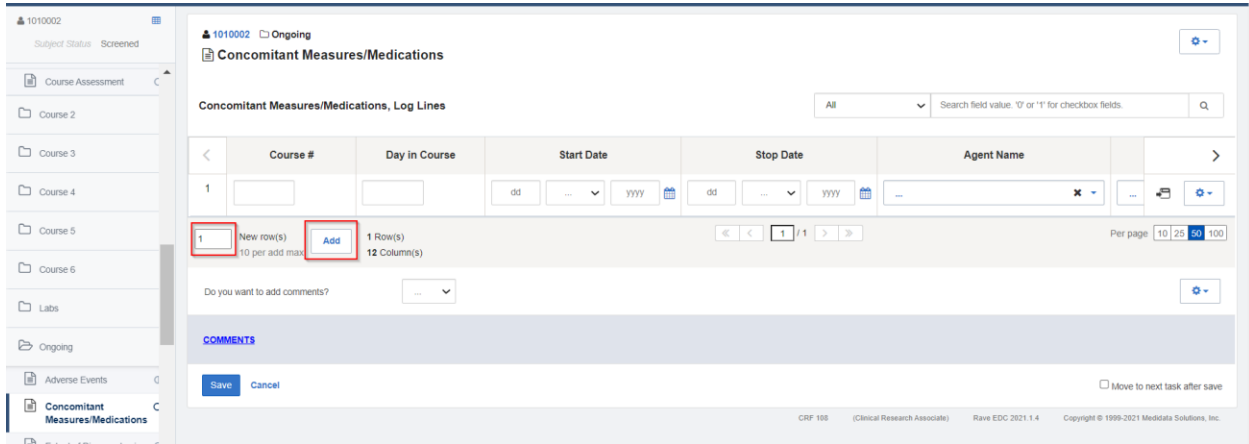
Do you want to add comments?

COMMENTS

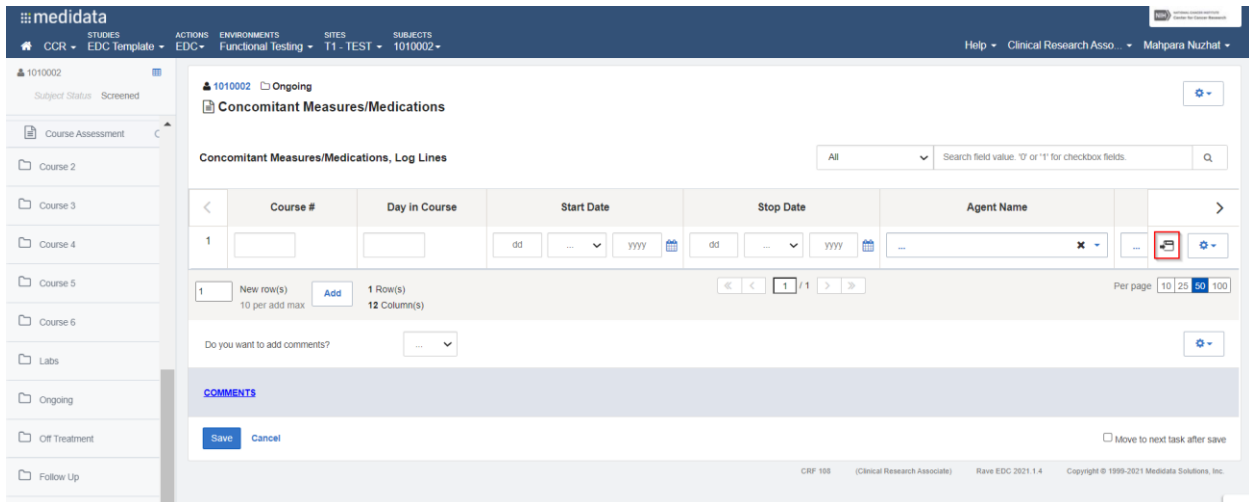
Save Cancel

After entering data in one log line, additional log lines can be added by selecting the **Add** button. The specific number of possible rows to be added also be entered. The feature of adding log lines is dependent on study configuration.

Note: A maximum of 10 log lines can be added at a time.



Data can be entered in the landscape view shown above or in portrait view. To access portrait view, click on the highlighted icon.



The precise log line would then appear as a vertical standard form.

The screenshot shows a software interface for entering data. On the left is a sidebar with a tree view containing items like 'Course Assessment', 'Course 2' through 'Course 6', 'Labs', 'Ongoing', 'Adverse Events', and 'Concomitant Measures/Medications'. The main area is titled '1010002 Ongoing Concomitant Measures/Medications'. Below the title is a section 'Concomitant Measures/Medications, Log Lines'. It features a navigation bar with 'Back To Complete View', '< Previous Line', 'Line 1 of 1', 'Next Line >', and 'Add Another Line'. The form fields include: 'Course #' (text input), 'Day in Course' (text input), 'Start Date' (calendar picker), 'Stop Date' (calendar picker), 'Agent Name' (dropdown menu), 'Procedure/Measure' (dropdown menu), 'Dose' (text input), and 'UOM' (dropdown menu). Each field has a small gear icon to its right.

Just like a standard form, any data entered in this mode can be saved by clicking on the **Save** button at the bottom of the page.

This screenshot shows the same form as above, but with more fields filled in: 'UOM' is set to 'mg : Milligram', 'Route' is 'PO:Oral', and 'Reason' is 'Acidity'. The 'Comments' field is a text area with '0 / 200' characters. Below the form is a 'COMMENTS' section with a 'Do you want to add comments?' dropdown. At the bottom, a 'Save' button is highlighted with a red box, next to a 'Cancel' button. The navigation bar at the bottom of the form area includes 'Back To Complete View', '< Previous Line', 'Line 1 of 1', 'Next Line >', and 'Save and Add Another Line'.

We can return to landscape mode by selecting the blue **Back to Complete View** link.

The screenshot shows the 'Concomitant Measures/Medications' form in landscape mode. The left sidebar contains a navigation menu with items like 'Course Assessment', 'Course 2' through 'Course 6', 'Labs', 'Ongoing', 'Adverse Events', and 'Concomitant Measures/Medications'. The main content area is titled 'Concomitant Measures/Medications, Log Lines'. At the top, there is a navigation bar with '< Previous Line', 'Line 1 of 1', and 'Next Line >'. A red box highlights the 'Back To Complete View' link on the left side of this bar. On the right side of the bar, there is an 'Add Another Line' button. Below the navigation bar, the form fields are arranged in a grid. Each field has a 'Reset' icon (a square with a circle and a minus sign) to its right. The fields include: 'Course #' (text input), 'Day in Course' (text input), 'Start Date' (calendar picker), 'Stop Date' (calendar picker), 'Agent Name' (dropdown menu), 'Procedure/Measure' (dropdown menu), 'Dose' (text input), and 'UOM' (dropdown menu).

New log lines can also be added from this mode by selecting the **Add Another Line** button.

The screenshot shows the 'Concomitant Measures/Medications' form in landscape mode, similar to the previous one. The left sidebar is the same. The main content area is titled 'Concomitant Measures/Medications, Log Lines'. The navigation bar at the top is the same, but the 'Back To Complete View' link is now blue and not highlighted. The 'Add Another Line' button on the right side of the navigation bar is highlighted with a red box. The form fields below are identical to the previous screenshot.

Different log lines can be accessed by using the highlighted fields to go back and forth between the portrait view of the logs.

1010002
Subject Status: Screened

1010002 Ongoing
Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Course # ⚙️

Day in Course ⚙️

Start Date ⚙️


Stop Date ⚙️

Agent Name ⚙️

Procedure/Measure ⚙️

Dose ⚙️

Modifying Forms


Form entries can be modified when needed and any data point that has been updated is represented by a delta icon .


1010002
Subject Status: Screened

1010002 Screening
Enrollment


DISEASE AND CONSENT

Lesion anatomic site description Detailed lesion anatomic site description ⚙️

Date of Diagnosis 6 Nov 2021  ⚙️

Histology Pancreas-Hepatoid Carcinoma  ⚙️

Grade of Histology — ⚙️

Dose Level TAC1 : TAC1 Description  ⚙️

Disease Stage at Entry — ⚙️