

## Signing Subjects and Forms

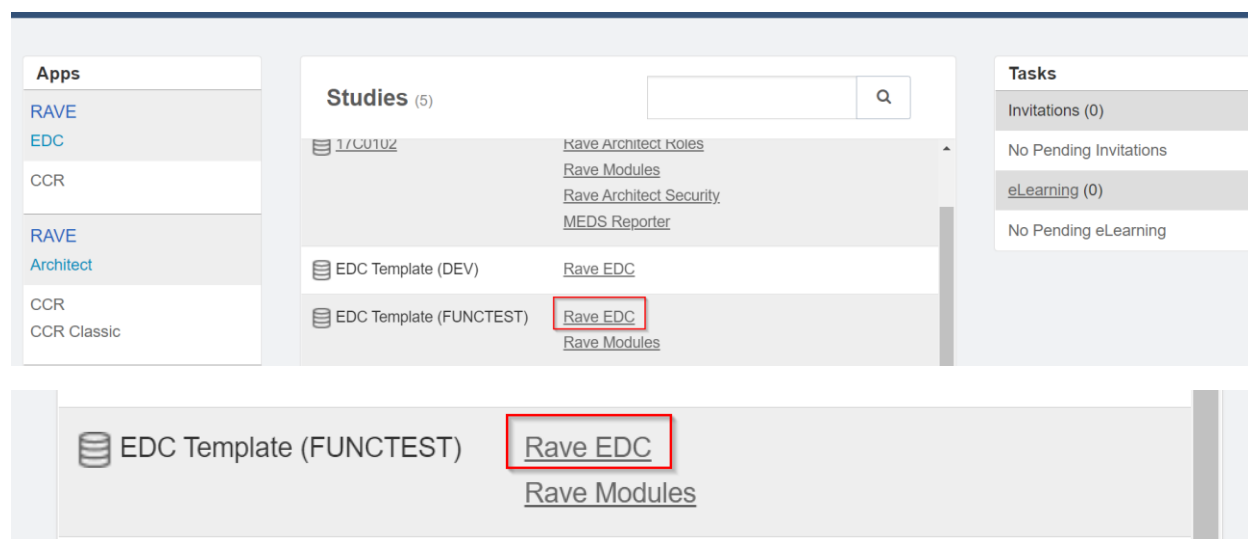
Principle Investigators can review and sign off on study subjects and forms. The data points in a form which require signatures must be verified by a Monitor before they can be signed, and a user must have an **Investigator** role to sign any forms or subjects. The username and password of the Investigator's Rave account are required to generate electronic signatures (eSignatures).

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### **Signing Subjects (Batch Signing)**

After logging into Rave, select the **Rave EDC** link for the desired study in the Studies list.



Navigate to the relevant site if there are multiple sites available and pick the subject that needs to be signed. As seen below, the user is accessing the study as an **Investigator**.

STUDIES: CCR - EDC Template - ACTIONS: EDC - Functional Testing - ENVIRONMENTS: T1 - TEST - SITES: Help - Investigator - Mahpara Nuzhat

### TEST - Subjects

Enrollment Target 6   Enrolled 4   Completed 0

Filter By Subject Status: All Statuses   Find Subject:    Reset   View Site Reports

Subject Information	Subject Status
1010001	Screened
1010002	Screened
1010003	Screened
1010005	Screened




4 Total   Page 1 / 1   Per page: 10 25 50 100

(Investigator)   Raw EDC 2021.2.0   Copyright © 1999-2021 Medidata Solutions, Inc.

Forms that require signatures are denoted by the  icon, as shown in the image below. In order to sign all the eligible forms of a subject at once, select the **Sign Subject** button near the top of the Subject homepage. Forms or fields which have not been configured to require signatures will not be signed.

Subject Status: Screened   View Subject Reports

Actions: **Sign Subject**

	Subject	Screening	Course 1	Course 2	Course 3	Course 4	Course 5	Course 6	Labs	Ongoing	Off Treatment
Enrollment											
Baseline Medical History		<input type="radio"/>									
Prior Radiation Supplement											
Prior Surgery Supplement		<input type="radio"/>									
Prior Therapy Supplement											
Prior Treatment Summary		<input type="radio"/>									
Physical Exam - Screening		<input type="radio"/>									
Consult		<input type="radio"/>									
Baseline Symptom		<input type="radio"/>									
Course Initiation			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			

Subsequently, the user will be directed to the Sign window where their Rave **Username** and **Password** has to be entered. Select the **eSign** button here to sign off on the subject.



As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

Username


Password

**Mahpara Nuzhat**

**24 Nov 2021 10:50:48 Eastern Standard**

Time



When a subject is signed successfully, all its relevant forms are marked by  icons in the Subject homepage. This means that the forms are now complete.

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


The signature can also be seen at the bottom of each of the signed forms. It consists of the Investigator's name, username and the timestamp of the signature.

The screenshot shows a form with various fields and a signature section at the bottom. The signature section is highlighted with a red box and contains the following text:




**Signature Applied**  
 Mahpara Nuzhat (nuzhatm5) - 24 Nov 2021 10:55:30 Eastern Standard Time

Buttons for 'Save' and 'Cancel' are visible below the signature section.

### Signing Standard Forms

The forms that require signatures can be viewed in the Subject homepage or Subject Grid, represented here by  icons.

The screenshot shows a Subject Grid table with the following columns: Subject, Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Course 6, Labs, Ongoing, and Off Treatment. The 'Screening' column contains a pencil icon in the 'Enrollment' row, which is highlighted with a red box. Other rows in the 'Screening' column contain empty circles.

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

Upon selecting a form, the data points that have to be reviewed and signed are marked by a **Requires Signature** key and **orange bars**.

1010003 Subject Status Screened

Screening

Enrollment

Requires Signature

DISEASE AND CONSENT

Lesion anatomic site description		Verify
Date of Diagnosis	3 Nov 2021	Verify
Histology	Sarcoma; synovial; monophasic fibrous	Verify
Grade of Histology	Low Grade	Verify
Dose Level	TAC1 : TAC1 Description	Verify
Disease Stage at Entry	II	Verify
Disease Stage at Diagnosis	IB	Verify
Gleason Score	2	Verify

When the form is ready to be signed, scroll to the bottom and select the **Sign** button.

1010003 Subject Status Screened

Screening

Enrollment

N Stage

M Stage

Date of Confirmation of Histology	9 Nov 2021	Verify
Date of Informed Consent Version	10 Nov 2021	Verify
Date from which to Start Including labs	11 Nov 2021	Verify

NIH ADVANCE DIRECTIVES FORM

Collected?	Verify
Collection Date	Verify
Comments	Verify

**Requires Signature**  
As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

**Sign**

Save Cancel

Move to next task after save

Similar to subject-level signing, the user will be directed to the Sign window. Enter Rave **Username** and **Password** and select **eSign**.



As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

**Username**

**Password**

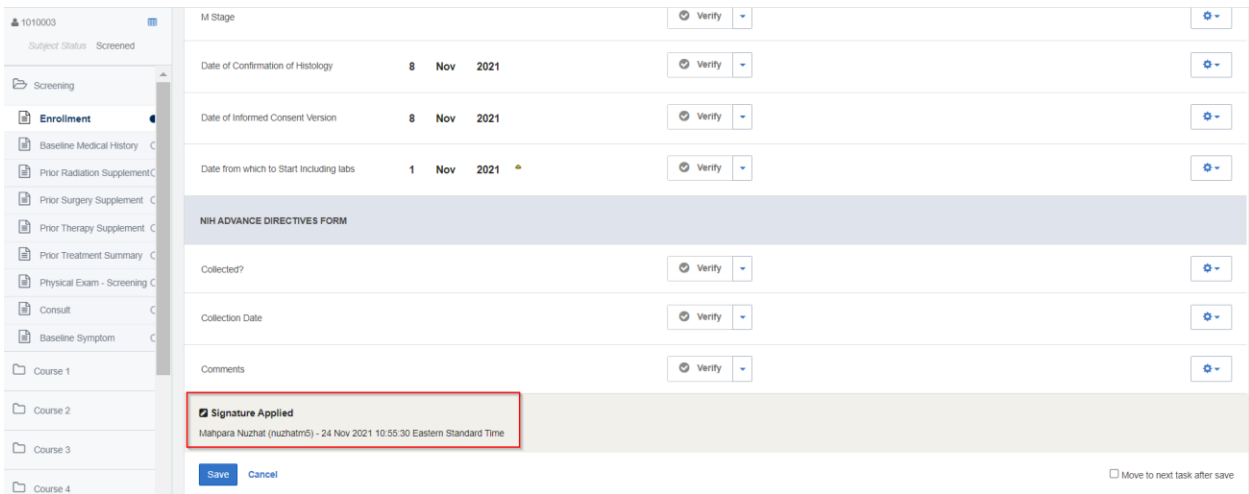
**Mahpara Nuzhat**

**24 Nov 2021 10:50:48 Eastern Standard**

**Time**



The signature status can be viewed at the bottom of the form. As shown below, the signature was applied successfully.



## Signing Log Forms

Log forms can be signed in both **Landscape** mode and **Portrait** mode. Log lines cannot be signed individually – applying a signature to one log record will sign all the other records in the log form.

One method of signing log forms is through landscape mode where all the log records appear as individual rows in the log form, as shown in the image below. Click on the **Sign** button at the end of the page to sign the form.

1010003 Subject Status Screened

Adverse Events

Requires Signature

Adverse Events, Log Lines

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
1	4	12 Nov 2021		Abdominal infection : Infections and infestations	Infections and infestations	Abdominal infection
2	10	16 Nov 2021	18 Nov 2021	Arterial thromboembolism : Vascular disorders	Vascular disorders	Arterial thromboembolism

2 Row(s)  
29 Column(s)

Do you want to add comments?  Verify

**COMMENTS**

Requires Signature  
As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

**Sign**

Save Cancel

Move to next task after save

Log forms can also be signed in portrait mode. Click on the highlighted icon to switch to portrait view.

1010003 Subject Status Screened

Adverse Events

Requires Signature

Adverse Events, Log Lines

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
1	4	12 Nov 2021		Abdominal infection : Infections and infestations	Infections and infestations	Abdominal infection
2	10	16 Nov 2021	18 Nov 2021	Arterial thromboembolism : Vascular disorders	Vascular disorders	Arterial thromboembolism

2 Row(s)  
29 Column(s)

Do you want to add comments?  Verify

**COMMENTS**

Requires Signature  
As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

**Sign**

Save Cancel

Move to next task after save

In this mode, each log line is displayed as a standard vertical form. Here, scroll to the bottom of the page and click on the **Sign** button. This action will not only sign the specific log line, it will also sign all the other log records in the form.

The screenshot shows a web interface for a clinical trial log. On the left is a sidebar with a tree view containing items like 'Screening', 'Course 1' through 'Course 6', 'Labs', 'Ongoing', 'Adverse Events', 'Concomitant Measures/Medications', and 'Extent of Disease- Lesions Identification'. The main area displays a list of log entries, each with a 'Verify' button. The entries include 'Action' (Dose Reduced), 'Therapy' (Support), 'Outcome', 'Expedited Report to IRB?' (Yes), 'Expedited Report to Sponsor' (No), and 'Comments'. Below the list is a navigation bar with 'Back To Complete View', 'Previous Line', 'Line 1 of 2', and 'Next Line'. A 'Do you want to add comments?' section with a 'Verify' button is also present. A 'COMMENTS' section is expanded, showing a 'Requires Signature' checkbox and a text area with a 'Sign' button highlighted in a red box. At the bottom of the comments section are 'Save' and 'Cancel' buttons.

On the Sign window, enter **Username** and **Password**. Then select **eSign**.



As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

Username

Password

**Mahpara Nuzhat**

**24 Nov 2021 12:16:19 Eastern Standard**

**Time**



The signature can be viewed in each of the individual log records in the form.

The image displays two screenshots of a clinical trial log form for subject 1010003, showing the 'Adverse Events' section. The form is divided into two lines of data.

**Line 1 (Top Screenshot):**

- Therapy: Support
- Outcome: Support
- Expedited Report to IRB?: Yes
- Expedited Report to Sponsor: No
- Comments: (Empty)
- Navigation: Back To Complete View, < Previous Line, Line 1 of 2, Next Line >
- Do you want to add comments?: (Radio button selected)
- COMMENTS: Signature Applied (highlighted with a red box)
- Signature: Mahpara Nuzhat (nuzhatm5) - 24 Nov 2021 12:17:15 Eastern Standard Time
- Buttons: Save, Cancel

**Line 2 (Bottom Screenshot):**

- Therapy: Support
- Outcome: Recovered
- Expedited Report to IRB?: Yes
- Expedited Report to Sponsor: No
- Comments: (Empty)
- Navigation: Back To Complete View, < Previous Line, Line 2 of 2, Next Line >
- Do you want to add comments?: (Radio button selected)
- COMMENTS: Signature Applied (highlighted with a red box)
- Signature: Mahpara Nuzhat (nuzhatm5) - 24 Nov 2021 12:17:15 Eastern Standard Time
- Buttons: Save, Cancel

The signature can also be seen in landscape mode. The **Requires Signature** badge and corresponding orange bars are consequently absent.

**Adverse Events, Log Lines**

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
1	2	12 Nov 2021		Abdominal infection : Infections and infestations	Infections and infestations	Abdominal infection
2	2	16 Nov 2021	18 Nov 2021	Arterial thromboembolism : Vascular disorders	Vascular disorders	Arterial thromboembolism

**COMMENTS**

- Signature Applied**  
Mahpara Nuzhat (nuzhatm5) - 24 Nov 2021 12:17:15 Eastern Standard Time

### Signature breaking

When a signed data point in a form is modified by another user, the signature will break. The field would then have to be verified by a Monitor and then reviewed and signed by an Investigator. The other data points in the form that remain unchanged do not need to be verified or signed again.

### Audit Trail View

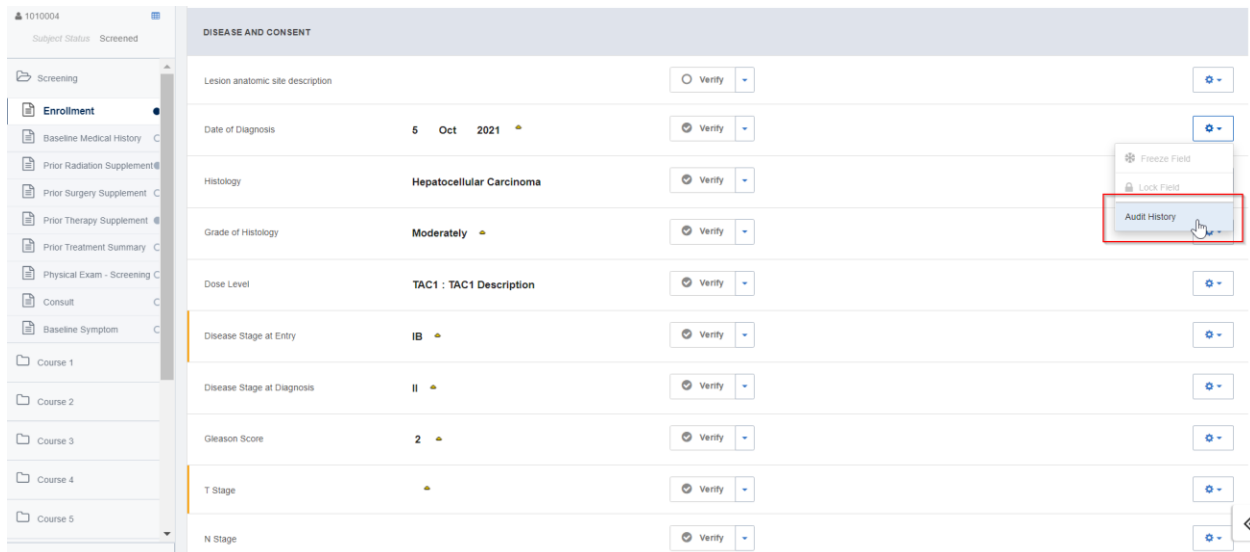
Rave Audit History keeps records of any changes made to a form or data point, including any signatures applied or broken. Click on the gear icon of a form or a specific data field and select **Audit History** to view its audit trail.

**Enrollment**

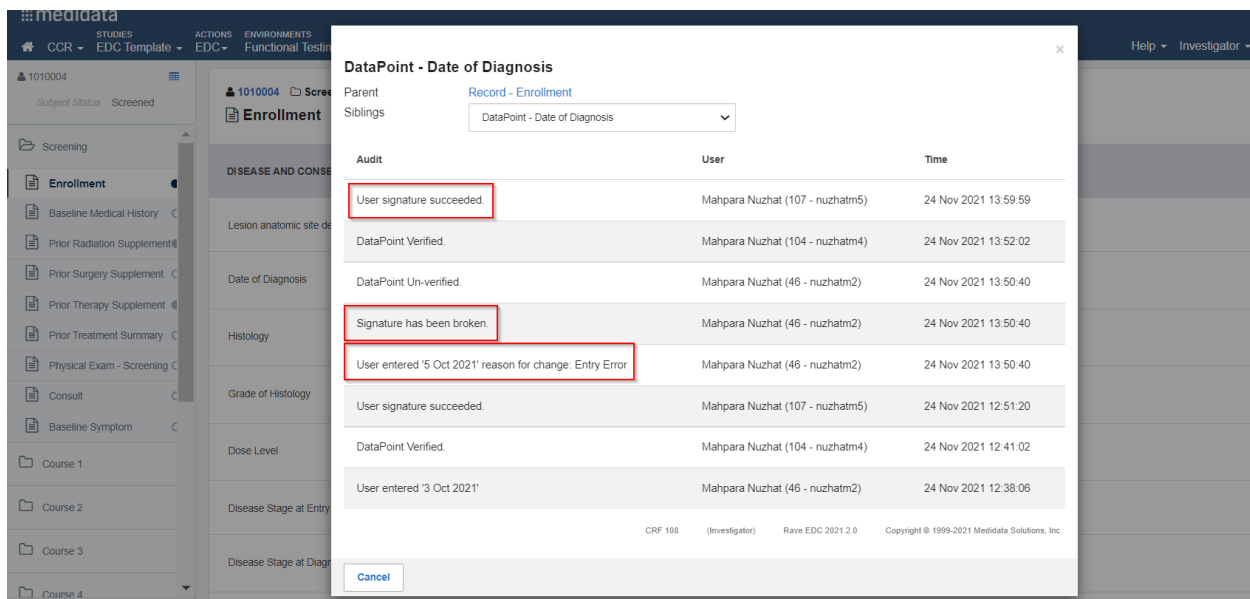
**DISEASE AND CONSENT**

Lesion anatomic site description		Verify
Date of Diagnosis	5 Oct 2021	Verify
Histology	Hepatocellular Carcinoma	Verify
Grade of Histology	Moderately	Verify
Dose Level	TAC1 : TAC1 Description	Verify
Disease Stage at Entry	IB	Verify
Disease Stage at Diagnosis	II	Verify

**Audit History**



As seen below, each time a form is signed or a signature is broken, the relevant activity, user information and timestamps are logged.



## Bulk Signing Forms and Subjects

Forms and subjects can also be signed in bulk. To do so, use the **Actions** dropdown on the top navigation bar and select **EDCTasks**.

STUDIES: CCR - EDC Template | ACTIONS: EDC - Functional Testing | ENVIRONMENTS: T1 - TEST | SUBJECTS: 1010003 | Help - Investigator - Mahpara Nuzhat

1010003  
Subject Status: Screened

EDC Tasks

DISEASE AND CONSENT

Lesion anatomic site description

Date of Diagnosis: 3 Nov 2021

Histology: Sarcoma; synovial; monophasic fibrous

All the forms in the study that require signatures can be seen by clicking on the **Pages Requiring Signature** link on the left Task Overview bar.

STUDIES: CCR - EDC Template | ACTIONS: EDC Tasks - Functional Testing | ENVIRONMENTS: T1 - TEST | SUBJECTS: 1010003 | Help - Investigator

Task Overview

Pages Requiring Signature 4

Pages Requiring Signature

Study Site Task List - TEST

Please select a task category on the left side.

(Investigator) Rave EDC 2021 2.0 Copyright © 1999-2

Task Overview

Pages Requiring Signature 4

Study Site Task List - TEST

Pages Requiring Signature

Filters

Select All	Subject	Subject Status	Folder	Form
<input type="checkbox"/>	1010003	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Prior Radiation Supplement
<input type="checkbox"/>	1010004	Screened	Screening	Prior Therapy Supplement

4 Total Result(s)  / 1

Multiple patients and forms can be signed by using the **Select All** button or the checkboxes placed to the left of each row.

The screenshot shows the 'Study Site Task List - TEST' interface. At the top, there is a 'Task Overview' tab and a 'Pages Requiring Signature' tab with a count of 4. Below this is a 'Pages Requiring Signature' section with a 'Filters' input field and a 'Clear Filter' button. The main area is a table with the following columns: 'Select All', 'Subject', 'Subject Status', 'Folder', and 'Form'. The table contains four rows of data, all with a status of 'Screened'. The 'Select All' button is highlighted with a red box. At the bottom, there is a 'Sign Pages' button and a pagination control showing '4 Total Result(s)' and 'Per page 10 25 50 100'.

Select All	Subject	Subject Status	Folder	Form
<input type="checkbox"/>	1010003	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Prior Radiation Supplement
<input type="checkbox"/>	1010004	Screened	Screening	Prior Therapy Supplement

Select **Sign Pages** to sign all the checked forms at once.

The screenshot shows the same 'Study Site Task List - TEST' interface, but now all checkboxes in the 'Select All' column are checked. The 'Sign Pages' button is highlighted with a red box. The table data remains the same as in the previous screenshot.

Select None	Subject	Subject Status	Folder	Form
<input checked="" type="checkbox"/>	1010003	Screened	Screening	Enrollment
<input checked="" type="checkbox"/>	1010004	Screened	Screening	Enrollment
<input checked="" type="checkbox"/>	1010004	Screened	Screening	Prior Radiation Supplement
<input checked="" type="checkbox"/>	1010004	Screened	Screening	Prior Therapy Supplement

The pages to be signed can also be filtered by **Subject, Subject Status, Folder** and **Form**. In this example, the objective is to only sign forms for the subject 1010004. By checking the checkbox for that subject on the Filters list and selecting the **Filter** button, the list will be updated with the new parameter.

**Pages Requiring Signature**

Filters Clear Filter

Subject

All Subjects  
 1010003  
 1010004

Subject Status  
 All Statuses  
 Screened

Folder

All Folders  
 Screening

Form

All Forms  
 Enrollment  
 Prior Radiation Supplement  
 Prior Therapy Supplement

«

Using **Select All** and selecting **Sign Pages** will therefore sign all the forms for patient 1010004.

Task Overview

Pages Requiring Signature Study Site Task List - TEST

**Pages Requiring Signature**

Filters Clear Filter

Subject 1010004

<input type="button" value="Select All"/>	Subject	Subject Status	Folder	Form
<input type="checkbox"/>	1010004	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Prior Radiation Supplement
<input type="checkbox"/>	1010004	Screened	Screening	Prior Therapy Supplement

3 Total Result(s) « 1 / 1 » Per page 10 25 50 100

»

Task Overview  
Pages Requiring Signature 3

### Study Site Task List - TEST

Pages Requiring Signature

Filters Clear Filter

Subject 1010004

Select None	Subject ▲	Subject Status	Folder	Form
<input checked="" type="checkbox"/>	1010004	Screened	Screening	Enrollment
<input checked="" type="checkbox"/>	1010004	Screened	Screening	Prior Radiation Supplement
<input checked="" type="checkbox"/>	1010004	Screened	Screening	Prior Therapy Supplement

3 Total Result(s) « 1 / 1 » Per page 10 25 50 100

The signature is confirmed by the completed dot icons ● in the Subject homepage.

1010004  
Subject Status Screened

**1010004**

Actions View Subject Reports

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

If each form on the list needs to be accessed separately, click on the form row. This will direct the user to the chosen form.

Task Overview  
Pages Requiring Signature 4

### Study Site Task List - TEST

Pages Requiring Signature

Filters Clear Filter

Select All

Select All	Subject ▲	Subject Status	Folder	Form
<input type="checkbox"/>	1010003	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Enrollment
<input type="checkbox"/>	1010004	Screened	Screening	Prior Radiation Supplement
<input type="checkbox"/>	1010004	Screened	Screening	Prior Therapy Supplement

4 Total Result(s) « 1 / 1 » Per page 10 25 50 100

From this view, the user can navigate to other pages on the EDC Tasks list by using the highlighted links on the right. They can also return to the EDC Tasks view by selecting **Task List**, shown on the left.

1010004  
Subject Status: Screened

< Task List Pages Requiring Signature 4

< 1010004 - Screening - Enrolme... 1010004 - Screening - Prior Th... >

1010004 Screening

Prior Radiation Supplement

Requires Signature

Prior Radiation Supplement, Log Lines

	Date of First Dose	Date of Last Dose	Radiation Type	Other, Specify	Radiation extent	Site	Schedule
1	1 Feb 2021	21 Apr 2021	Radiofrequency Ablation		Limited Radiation	Bone, Non-Spine	

1 Row(s)  
11 Column(s)

Do you want to add comments?  Verify

COMMENTS

Requires Signature

As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

Sign

Save Cancel

Move to next task after save

The chosen form can be signed by clicking on the **Sign** button at the bottom of the page.

1010004  
Subject Status: Screened

< Task List Pages Requiring Signature 4

< 1010004 - Screening - Enrolme... 1010004 - Screening - Prior Th... >

1010004 Screening

Prior Radiation Supplement

Requires Signature

Prior Radiation Supplement, Log Lines

	Date of First Dose	Date of Last Dose	Radiation Type	Other, Specify	Radiation extent	Site	Schedule
1	1 Feb 2021	21 Apr 2021	Radiofrequency Ablation		Limited Radiation	Bone, Non-Spine	

1 Row(s)  
11 Column(s)

Do you want to add comments?  Verify

COMMENTS

Requires Signature

As PI, I understand and certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

Sign

Save Cancel

Move to next task after save



As demonstrated below, the signature was applied successfully.

▲ 1010004 ☐ Screening ⚙️

📄 **Prior Radiation Supplement**

Prior Radiation Supplement, Log Lines All  🔍

<	Date of First Dose	Date of Last Dose	Radiation Type	Other, Specify	Radiation extent	Site	Schedule	>
1	1 Feb 2021	21 Apr 2021	Tomotherapy		Limited Radiation ⚠️	Bone, Non-Spine		📄 ⚙️

1 Row(s) Per page

11 Column(s)

Do you want to add comments? ○ Verify ⌵ ⚙️

**COMMENTS**

**Signature Applied**

Mahpara Nuzhat (nuzhatm5) - 24 Nov 2021 12:51:20 Eastern Standard Time

Move to next task after save