

7 Using OpenClinica as an Investigator

Before reviewing this section, make sure that you have read [Getting Started](#). In addition, please review the [Using OpenClinica as a CRC](#) section, as the document applies to Investigators as well as CRCs.

For Information on Using Information as an Investigator, See the Following Sections:

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7.1 Signing Participant Records

Investigators (a site-level role) and **Data Specialists** (a study-level role) can sign Participant records.

Participant records can be signed at three levels:

- Study Event level
- Participant level
- Bulk (multiple Participants at a time)

Events are eligible for signature once the following conditions are met:

- All required forms within an event are marked *Complete*
- All non-required forms within an event are either marked *Complete* or *Not Started*
- The Study Events in question are in a "final" state (*Not Scheduled, Complete, Stopped, or Skipped*). It is not possible to sign *Archived* or *Removed* records.

Additionally, Participants are eligible to be signed, individually or in bulk, if all of their events meet the event criteria above.

Sign a Study Event

1. On the **Participant Matrix**, click the **Event** you want to sign.
2. Select **Sign** from the drop-down list (**Sign** only appears if the event is in a final state).

Participant Matrix for New Test Site

50 Show More Select An Event Add New Participant

Sign	Participant ID	Eligibility & Consent	Exam	Treatment	Daily	Final Treatment	Actions
<input type="checkbox"/>							Apply Filter Clear Filter
	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a12345	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	DF-001				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
	site001				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

Results 1 - 5 of 5.

Participant: a12345
Event: Eligibility & Consent
30-Nov-2021
completed

- View
- Edit
- Remove
- Sign

Or

1. Click the **View** icon for the participant with an event you want to sign.
2. Locate the **Event** you want to sign, and select **Sign** in the **Actions** drop-down list.

Participant Matrix for New Test Site

50 Show More Select An Event Add New Participant

Sign	Participant ID	Baseline	Exam	Treatment	Follow up	Final Treatment	Actions
<input type="checkbox"/>							Apply Filter Clear Filter
	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

The screenshot shows the 'Visits' interface. At the top, there's a 'Sort by Date' button and a search bar. Below, visits are listed in a grid. The 'Exam (1)' visit on 01-Nov-2021 is selected, and a menu is open with 'Sign' highlighted. Other visits include 'Treatment (1)' with sub-items like 'Pre-Treatment Evaluation', 'Treatment Administration', and 'Post Treatment Evaluation'. The bottom bar is labeled 'Adverse Event'.

Or

1. Click **Edit** in the *Event Actions* menu to go to the *Update Study Event* screen.
2. Then, click **Sign Event** at the bottom.

Update Study Event

Participant ID: a1234

Event: Exam

Start Date/Time: * : (DD-MMM-YYYY HH:MM)

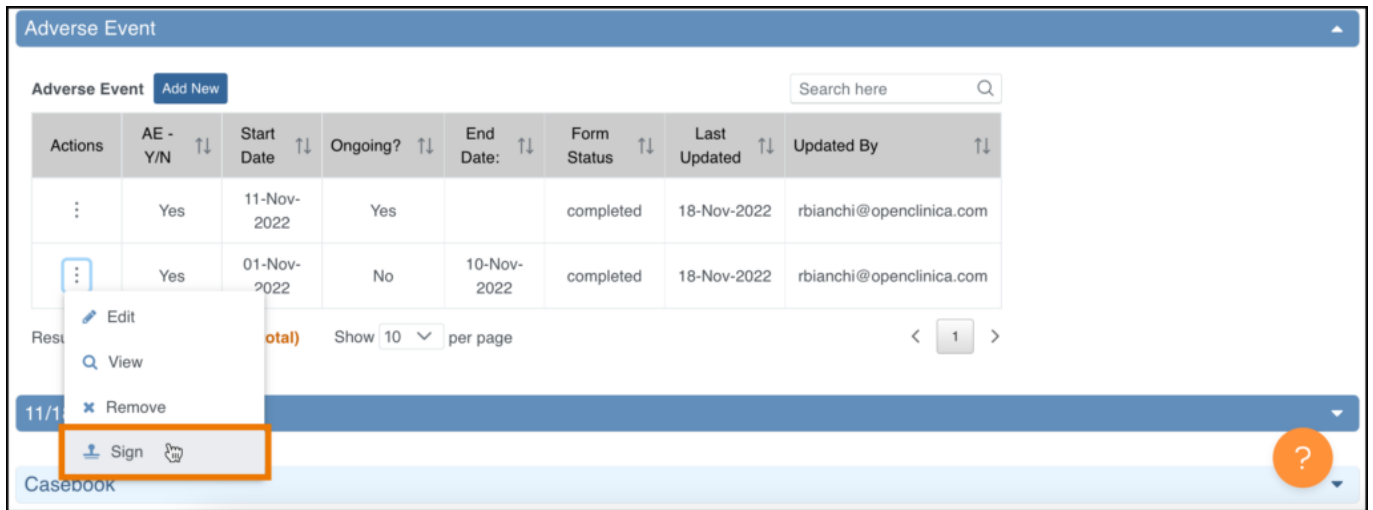
End Date/Time: : (DD-MMM-YYYY HH:MM)

Status:

Other Actions

Sign Event:

For Common Events, click the **Sign** icon in the menu of the *Actions* column on the *Participant Details* screen.



3. The **Electronic Signature** screen includes an attestation, your full name, a listing of the records you are signing, and a prompt to enter your username and password.
4. Scroll to the bottom of the page to see a list of Forms in the Event and the status of queries for each of those Forms:

Alerts & Messages ▾

Quick Access ▾
[My Queries](#)

Instructions ▾

Info ▾

Sign Event Eligibility & Consent for Participant a1234

Enter your user name and password below to signify agreement with the following statement:

"I confirm that the data for this participant are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

This signature applies to the following forms in this event: Physical Exam, Vital Signs.

User Full Name: Riley Bianchi-PI
Date/Time:
 (The exact date and time will be recorded by the system upon submission of the signature form.)
Role: Investigator

User Name :

Password :

▣ Study Event

Participant ID	a1234
Study Event	Eligibility & Consent
Location	

Start Date	01-Nov-2021
End Date/Time	
Event Status	completed
Last Updated by	rbianchi+PI (18-Nov-2021)

CRFs in this Study Event:

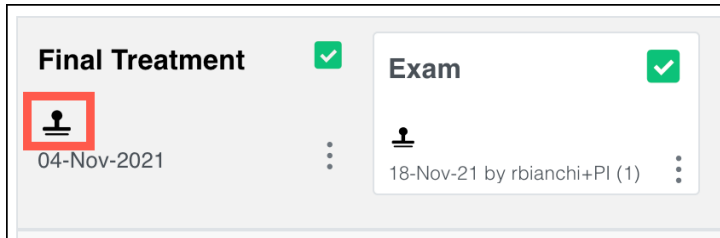
CRF Name	Version	Status	Initial Data Entry	Queries	Actions
Physical Exam	1.2	✔	rbianchi+PI	● 0 New ● 0 Updated ● 0 Closed	🔍

Attestation and summary of what you are signing

Enter User Name and Password to sign

Links to review the data you are signing

5. Enter your username and password and click **Submit** to complete the electronic signature process. You return to the **Participant Details** screen to view the Signed icon on the event.



Note: The attestation that appears when signing the Participant Event includes the forms listed above the User's Full Name on the Sign Event screen. The forms available to sign include all forms for the event, except the following:

- Forms the signing user cannot access due to permission tags or the Hidden attribute of the form
- Forms that were started in the event occurrence but are currently Archived or Removed
- Forms in the event occurrence that were never started or have Not Started status

Sign Participant Records for All Events for a Participant

If all Events for a Participant are in a final state (*Not Scheduled, Completed, Stopped, or Skipped*), then the entire Participant record can be signed.

Participant Matrix for New Test Site

50 Show More Select An Event Add New Participant

Sign	Participant ID	Eligibility & Consent	Exam	Treatment	Daily	Final Treatment	Actions
<input type="checkbox"/>							Apply Filter Clear Filter
	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
<input type="checkbox"/>	a12345	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

To sign for multiple Events for that Participant, click the **Sign** button on the **Participant Matrix**.

Bulk Sign Multiple Participant Records for All Events

When multiple Participants are ready to be signed (all Events for the Participant are in a final state), a checkbox appears in the Sign column in addition to the Sign button which is available in the Actions column. This checkbox allows you to select multiple Participants to sign in bulk.

Participant Matrix for New Test Site

50 Show More Select An Event Add New Participant

Sign	Participant ID	Eligibility & Consent	Exam	Treatment	Daily	Final Treatment	Actions
<input type="checkbox"/>							Apply Filter Clear Filter
<input type="checkbox"/>	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a12345	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Multiple User Signatures

Multiple users can sign an Event, so even if an Event has already been signed, the **Sign** action will still be available. If there are multiple signatures, all active signatures that have been added since the Event last became signed will display on the Form as well as in the Audit Log.

Unsigned Events

Events are unsigned if:

- A user makes changes to an item on a Form after the Form was signed.
- The Event status was changed from **Completed**, **Stopped**, **Skipped** or **Not Scheduled** after being signed. (This also changes the Participant status from **Signed** to **Available** and the Event Status to **Completed**.)
- A user archives/unarchives the Form, unless the Form had a status of **Not Started**.
- A user removes/restores the Form.

Note: Changing the version of a Form will only unsign the Form if a user changes data.

Functional approval by Elizabeth Prager. Signed on 2023-07-19 11:20AM

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