Notes:

This course will show Investigators how to sign in OpenClinica version 3.1.

The course is suitable for CTC or external staff in the following roles:
Clinical Investigators and Co-Investigators

Prerequisites

Basic knowledge of Clinical Trials processes.
Competence in using web-based software applications.
Completion of course: Introduction to OpenClinica for CTC studies.
Learning Objectives

At the completion of the course, successful participants will be able to:

- Sign an Event
- Sign a CRB

Notes:
Electronic Signatures

This section covers:
- Electronic Signatures Overview

Notes:
Electronic Signatures Overview

- Electronic signatures can only be performed by Investigators
- Some Events (e.g. SAEs) need signing during the study
- This is study-specific – refer to the Study Manual for details
- Events that have been signed will appear with a green stamp
- The CRB is required to be signed for EVERY subject ONCE at the end of the study
- CRBs that have been signed will appear with ALL events showing a green stamp
- For both Events and CRBs, check that all data is final before signing - any further Signatures will invalidate the signature, and require re-signing

Notes:
Electronic Signatures:
Signing an Event

This section covers:
- Signing an Event
Notes:

Click on the relevant Event and Occurrence in the Subject Matrix and select ‘View/Enter Data’, then:

1. Ensure that all started CRFs in the event are marked as complete

2. In the Event Summary, select ‘Edit Study Event’

3. In the ‘Update Study Event’ screen, select a status of ‘Signed’ – signed will only appear as an option if all started CRFs in the event are marked as complete, and the user is an Investigator.
Notes:

4. Enter your username and password and Submit.

The signed Event will appear with a ‘Sign’ (green stamp) icon in the Subject Matrix (visible to all users)
Electronic Signatures - Events

<table>
<thead>
<tr>
<th>Study Subject ID</th>
<th>Baseline</th>
<th>Surgery</th>
<th>Pathology</th>
<th>30 Day</th>
<th>SAE</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRN001</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>TRN002</td>
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</tr>
<tr>
<td>TRN003</td>
<td>x2</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

For multiple occurrences, click on the icon to see the status of each occurrence.

**Notes:**

If there is more than one occurrence of an event, the status of each individual occurrence can be viewed by clicking on the icon to view the summary.
Electronic Signatures: Signing a CRB

This section covers:
- Signing a Case Record Book

Notes:
Notes:

When a subject case book is ready to be signed (at the end of the study, when all of the events have been marked complete, skipped or have not been scheduled), *Investigators only* will see the green ‘Sign’ icon in the Actions column of the Subject matrix.

The green ‘Sign’ icon may also appear throughout the study, whenever the events meet the criteria – **Make sure that the study is completed before signing the CRB.**

Any Signatures, including answering queries, performed after signing the CRB will invalidate the signature, and require re-signing.

1. Once you are certain that the study has been completed, and the green ‘Sign’ icon is visible in the Actions column, click on the green ‘Sign’ icon.

2. Enter your username and password and Submit.
Electronic Signatures - CRB

Subject appears with green stamp for ALL events = Signed CRB

Notes:

Once the CRB is signed, ALL of the events will appear with a green Sign icon (visible to all users)
Summary of Signatures

- Some **Events** (e.g. SAE) are required to be signed during the study – see the Study Manual for details.

- The **CRB** is required to be signed for EVERY subject **ONCE** at the end of the study.

- For both Events and CRBs, check that all data is final before signing - any further Signatures will invalidate the signature, and require re-signing.

Notes: