Exercise 1.

Logging on
Log in to the OpenClinica Training database, by going to: http://www.ctc.usyd.edu.au/our-research/clinical-trials/trials-data-systems.aspx, then scroll to the bottom of the dropdown list and select ‘Training’, then select ‘OpenClinica generic training system’.

The OpenClinica Login Screen will be displayed.
1. Enter your User Name: (provided via email from the Coordinating Centre)
2. Enter your Password: (provided via email from the Coordinating Centre).
3. Reset your password, set your challenge question and answer, then click ‘Change Password’

Remember both your password challenge question and answer – you will need them if you forget your password.

About passwords
• User Names and Passwords are case sensitive
• Passwords must be 8 characters in length and consist of at least 1 number
• Passwords must be changed every 90 days
• Passwords cannot be reused
• Passwords in an eCRF system are equivalent to your written signature
• Passwords must never be shared
• Whenever you log on using a centrally issued password you will be required to change your password i.e. centrally supplied passwords only allow the user to log onto the system to change their password.
Exercise 2.

The Subject Matrix – Browsing Data

1. Use the subject matrix to browse through a subject’s record for data already entered for the training study: Module A, pages 17, 20-22
   a. From the Subject Matrix page, click on the ‘View’ icon (magnifying glass) at the far right of any patient that has data (i.e. icons are not all blue)
   b. From the View Subject page, click on the ‘View’ icon next to any eCRF with data entry complete (i.e. green tick box)
c. Click through the eCRF sections to view the data (NB: CRFs that have only one section will show only one tab)
d. Click Exit to get back to the View Subject page

e. Click Subject Matrix button in the navigation bar, or ‘Go Back to Subject List’ at the bottom of the page, to get back to the Subject Matrix page
2. Practice drilling down from the Subject Matrix to specific events, then browsing through the eCRFs for that event, pages 17, 20-22
   a. Click on any Event that has data (i.e. icon is not blue)
   b. Click ‘View/Enter Data’ in the pop-up menu
   c. Click on the ‘View’ icon next to any eCRF with data entry complete (i.e. green tick box)
   d. Click through the eCRF sections to view the data (NB: CRFs that have only one section will show only one tab)
   e. Click Exit to get to the View Subject page
   f. Click Subject Matrix button in the navigation bar, or ‘Go Back to Subject List’ at the bottom of the page, to get back to the Subject Matrix page
3. Try using the Filters in the Subject Matrix: Module A, page 17
   a. In the grey box below the Study Subject ID, type in a study subject ID for any patient in the list
   b. Click ‘Apply Filter’ at the far right (or alternatively, press the Enter key of your keyboard)
   c. Click Clear Filter (at the far right) to clear the filter
   
   d. For any event, click the grey box below the Baseline event title and select Completed
   e. Click Clear Filter (at the far right) to clear the filter
4. Try using the View by Event tools in the Subject Matrix: Module A, page 19
   a. In the Select an Event dropdown menu, select Surgery/Pathology

   ![Subject Matrix for Training Site 2](image)

   b. Click on the ALC_PATH form for any patient, then select View from the pop-up menu

   ![Subject Matrix for Training Site 2](image)

   c. Click Exit to get back to the Subject Matrix page (unfiltered)
Exercise 3.

Signing an Event

Try signing an SAE event: Module S, pages 6-8
For the patient number assigned to you in the email from CTC:

1. Navigate to an SAE
   a. If not already in the subject matrix, click on the Subject Matrix button
   b. Locate the relevant patient number (you might find it easier to filter by the patient number
   c. Click on the SAE event
   d. Click View/Enter Data for the first SAE occurrence

2. Sign the Event
   a. Ensure that the SAE CRF in the event is marked as complete (green tick) in the the ‘Enter or Validate Data’ screen
   b. Click ‘Edit Study Event’ at the top of the ‘Enter or Validate Data’ screen
c. In the ‘Update Study Event’ screen, select a status of ‘Signed’

**NB:** ‘signed’ will only appear as a status option for an event if all started CRFs in the event are marked as complete, and the user is an Investigator.

d. Click ‘Submit Changes’

e. On the ‘Update Study Event’ screen, enter your username and password

f. Click Submit

g. Click on the ‘Subject Matrix’ and navigate to the relevant patient

h. The signed Event will appear with a ‘Sign’ (green stamp) icon in the Subject Matrix, and with a status of ‘signed’.

**NB:** Only the selected event is signed - any other events (e.g. other SAEs for this patient) will remain unsigned – each SAE must be signed individually.
Exercise 4.

**Signing a Case Record Book (CRB)**

Try signing a CRB: Module S, pages 10-11
For the patient number assigned to you in the email from CTC:

1. Sign the CRB
   a. Click on the Sign Action (green stamp) in the Actions column

   **NB:** To sign the CRB, ensure that you click on the Sign icon in the Actions column. Clicking on a Sign icon for an event will only navigate to that event.

   b. In the ‘Sign Subject’ screen, enter your username and password
   c. Click Submit

   d. The signed CRB will appear with a ‘Sign’ (green stamp) icon for ALL completed events in the Subject Matrix (Events that were never started will remain blue)
Exercise 5.

**Online Help (OpenClinica Reference Guide)**

1. Access OpenClinica online help: Module A, page 25
   a. Click on the help icon (question mark) next to the heading at the top of any age
   b. Briefly review the help available using the expandable menus at the left of the OpenClinica Reference Guide which appears in a new window
   c. Close the OpenClinica Reference Guide window
Exercise 6.  

Logging out

Always use the “logout” link to leave the system
Exercise 7.

Resetting a Forgotten Password

1. Click the ‘Forgot Password’ link

2. Enter your user name

3. Enter your email used for the training OpenClinica account – this was entered by CTC on your behalf. Contact CTC if you are uncertain.

4. Select password challenge question. This is the password challenge question that you selected when resetting your password upon logging in the first time

5. Enter the answer to the password challenge. This is the answer that you specified when resetting your password upon logging in the first time

6. Click "Submit Password Request"

7. The system will send a new password only if a correct combination of password challenge and answer are specified, and if the correct email address is used. Otherwise, the system will display an appropriate error message.

8. Once a correct password challenge question and answer are provided, together with the correct email address, the system will send a message to the associated email containing a temporary password. You will use this information to login to OpenClinica. When you log in using the temporary password, you will be prompted to change it. You will also need to re-select a challenge question and enter your answer.

This is the end of the exercises – please advise your CTC trial coordinator that you have completed the exercises, so that your data entry can be checked. Thank You.