








Instructions

Part 1: Filling in the baseline questionnaire

1. Log on to Open Clinica (www.openclinica.nl).
A username and password will be provided separately.
2. Click '**Subject Matrix**' in the blue toolbar (yellow square, print screen 1).
3. Click on the '**Scheduled**' icon in the '**Baseline**' column (red square).
4. Click '**View/Enter Data**' (green square).

Print screen 1: Subject matrix and Baseline questionnaire

The screenshot displays the 'Subject Matrix for BOLERO' interface. The top navigation bar includes 'Home', 'Subject Matrix' (highlighted with a yellow square), 'Notes & Discrepancies', 'Study Audit Log', and 'Tasks'. The left sidebar contains 'Alerts & Messages', 'Instructions', 'Info', 'Icon Key', 'Statuses', and 'Actions'. The main content area shows a table with the following structure:

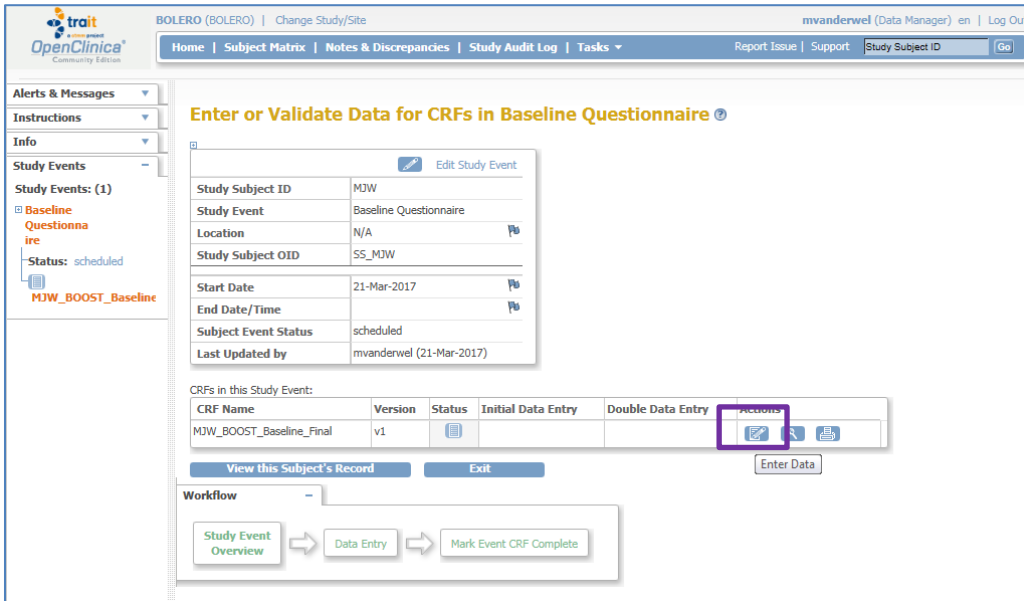
Study Subject ID	Baseline Questionnaire	Case Assessment	Actions
MJW			     

A tooltip is displayed over the 'Scheduled' icon, showing the following details:

- Subject: MJW
- Event: Baseline Questionnaire
- Status:scheduled
- View/Enter Data (green button)

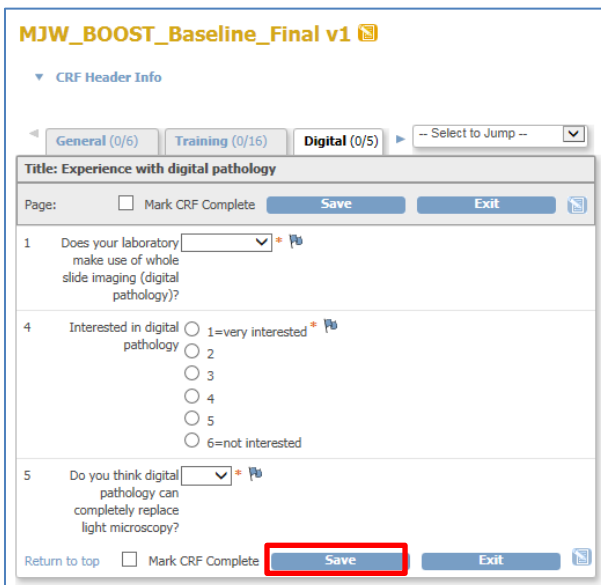
5. In the next screen, click 'Enter Data' (purple square, print screen 2).

Print screen 2: Opening screen



6. Please answer all questions in the questionnaire that opens up.
7. After you have answered all questions, click 'Save' (red square, print screen 3).

Print screen 3: Baseline questionnaire



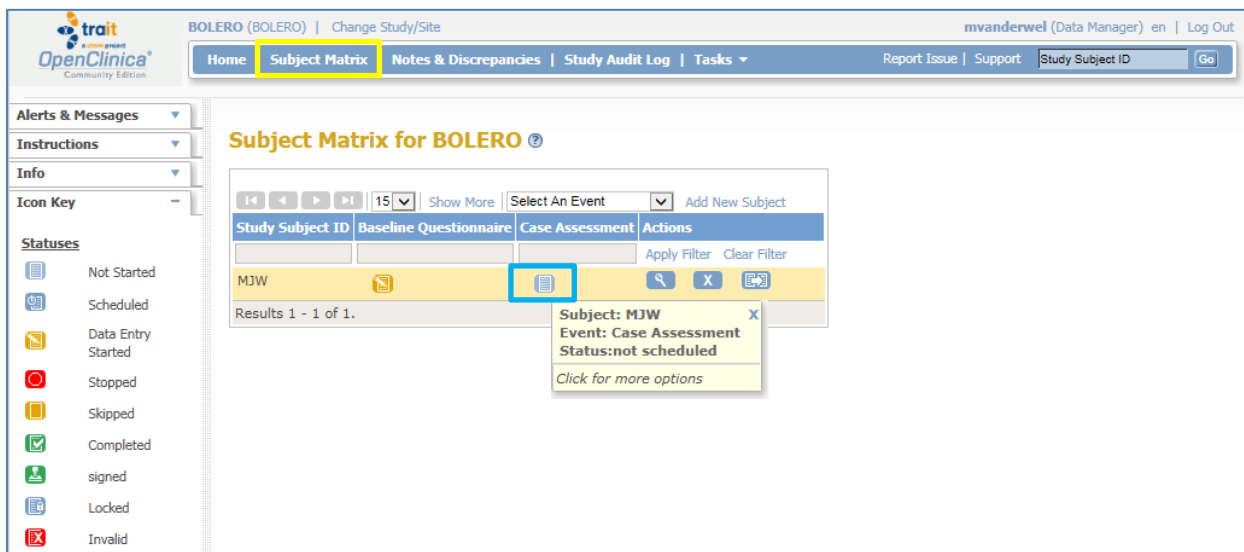
Part 2: Case Record Forms

1. Log on to Open Clinica (www.openclinica.nl) with your username and password (provided separately).

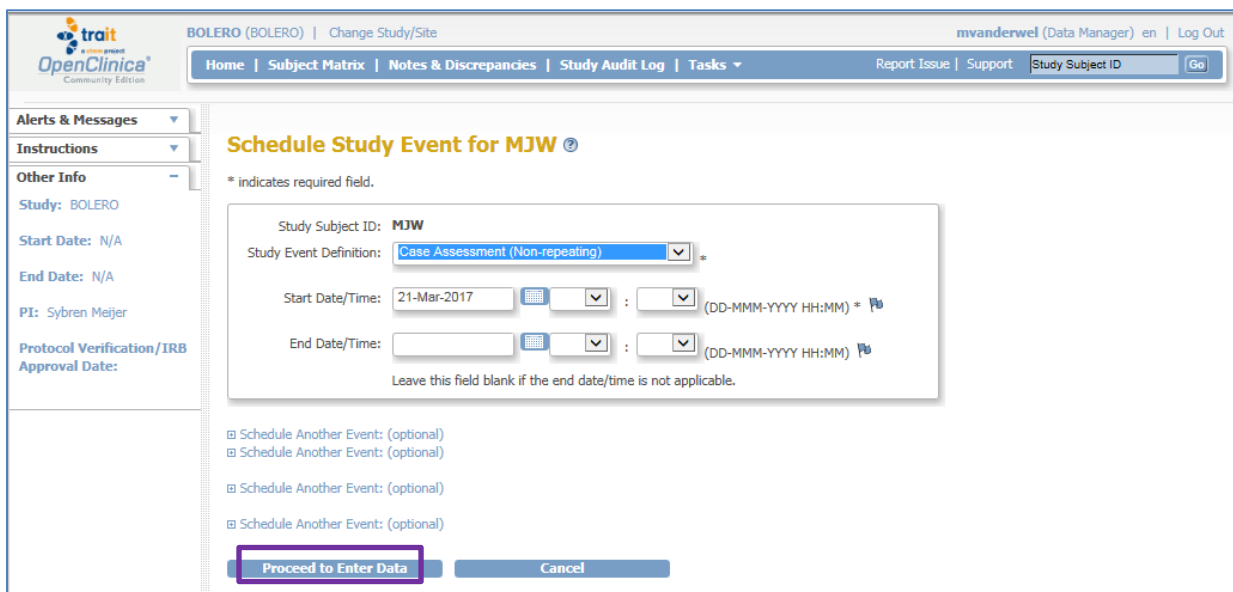
Before you are able to start the case assessment, you first need to schedule the cases for assessment.

2. Click **'Subject Matrix'** in the blue toolbar on the top of the screen (yellow square, print screen 3).
3. Click on the **'Not Started'** icon in the **'Case Assessment'** column (blue square, print screen 3)
4. Click **'Schedule'**
5. Click **'Proceed to enter data'** (purple square, print screen 4)

Print screen 3: Subject matrix and Assessment round

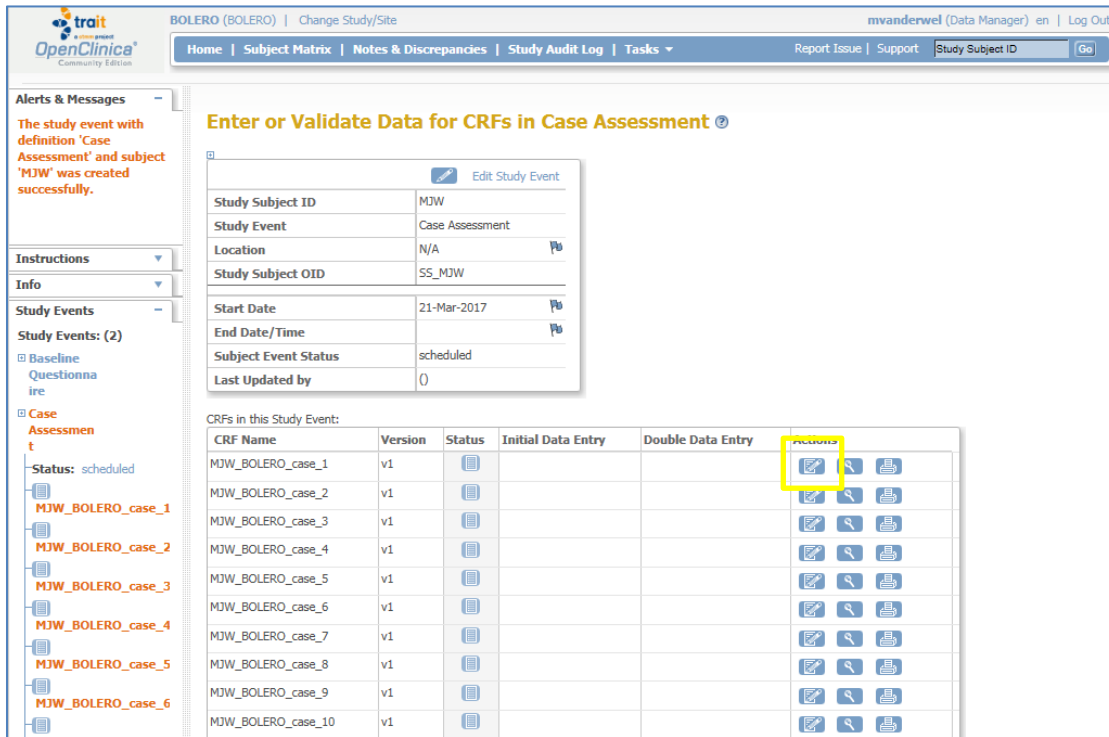


Print screen 4: Scheduling of Case Assessment round



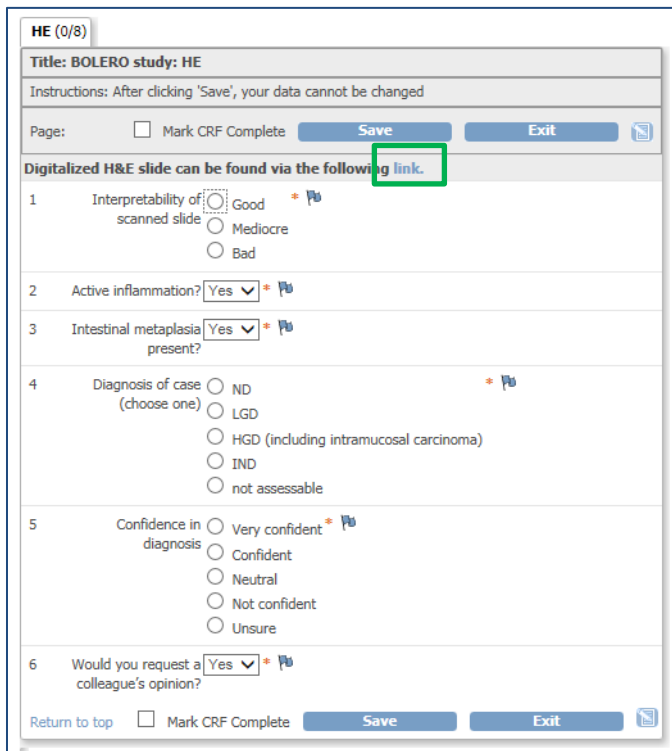
6. You have now reached the overview page for 'Case assessment'
7. To start on the first case, click the '**Enter Data**' icon to the right of the CRF of case 1 (yellow square, see print screen 5)

Print screen 5: Entering data into Case Assessment round after scheduling



8. Links to digitalized slides are contained within the CRF (green square, Print screen 6).

Print screen 6: CRF with dynamic links to digitalized slides



9. First, evaluate the H&E slide by clicking the link provided in the CRF.
10. A digital slide viewer will automatically open up and take you to the relevant slide. All slides have been scanned at 20x resolution.
















If the dynamic link does not open up, your pop-up blocker might be disabled, or there might be a problem with browser compatibility. The viewer uses Flash player, which is disabled in Google Chrome. Therefore, it works on Internet Explorer or Firefox.

11. Please answer the questions after you have finished your evaluation of the H&E slide.
12. After you have answered all questions, click 'Save'.
13. A new tab will now open, containing the link to the slide viewer for the H&E slide and complementary p53 IHC slide.
14. Please answer the questions after you have finished your evaluation of the p53 IHC slide.
15. After you have answered all questions, click 'Save'.
16. You will now return to the overview page to assess the next case. Please note that the assessed cases will move to the bottom of the list.

Again, you can exit the study at any time and continue at a later timepoint.

APPENDIX I

Symbols used within Open Clinica

Statuses	
	Not Started
	Scheduled
	Data Entry Started
	Stopped
	Skipped
	Completed
	signed
	Locked
	Invalid
Actions	
	View
	Edit
	Remove
	Restore
	Reassign
	Sign