Standard Operating Procedure (SOP)

OPTIMISE II Database User Guide

SOP 007

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Scope

- To provide guidance on the data entry using the OPTIMISE II database.

General data entry rules / Notes

- Always be careful when entering data, check each screen before saving.
- Always log out of the database when not in use.
- Always enter complete records and save, do not leave the form in the middle of data entry.
- The system will timeout after ~10 minutes of inactivity (keyboard and mouse activity will not count as 'active', in order to remain 'active' you will need to save or browse between forms).
- If accessing a drop-down list (via mouse or tab) and then using arrows on keyboard to select, the field must be exited clearly before the data is selected and stored until save. If you move keys whilst focus still on the field, the data changes.
- Please do ensure that at the end of each data entry session you clearly log out and close the browser.

Help and Contacts

- If you have any queries relating to data entry or the database, please contact:

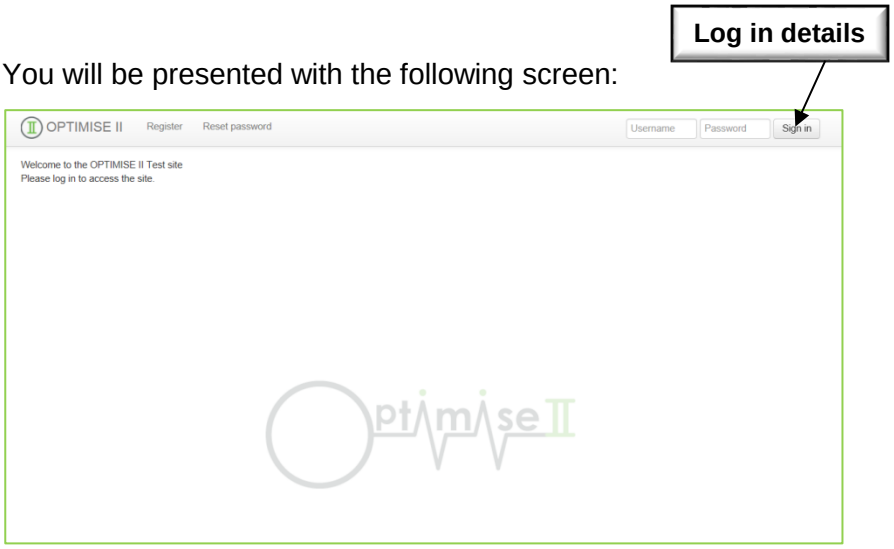
Priyanthi Dias; Trial Manager	admin@optimiseii.org	0203 594 0352
OR Doris Lanz; PCTU Trial Manager	d.lanz@qmul.ac.uk	0207 882 5636

So that we can handle your query quickly and efficiently, please include as much detail about the issue as possible in your first contact. Screen shots are useful. We may forward your query to the database manager, if appropriate.

Logging On To The System

- Open an internet browser and enter the following link:
  - For the TEST system: **https://optimiseiidev.research.its.qmul.ac.uk**
  - For the LIVE system: **https://trials3.pctu.qmul.ac.uk**

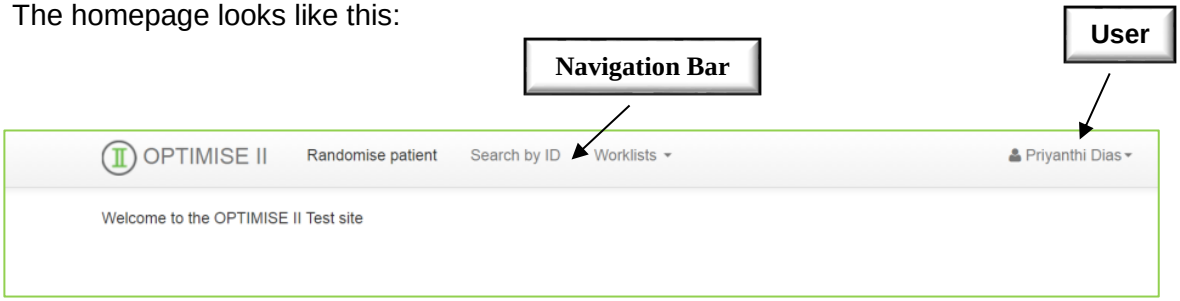
You will be presented with the following screen:



- Log in using the credentials supplied by the Trial Manager. If you experience any issues, please contact the central team (see cover page for contact details).
- **Please note users will be required to enter test data into the test database before being given access to the live database**.

Homepage And Navigation

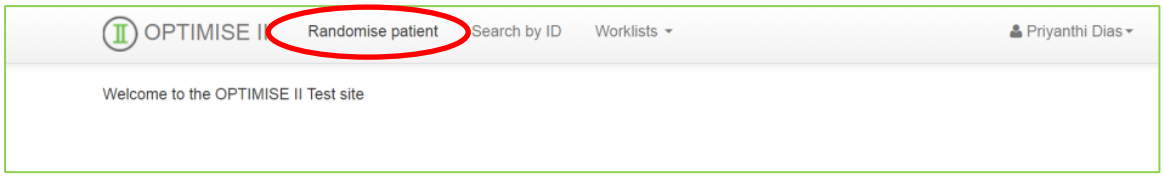
- The homepage looks like this:



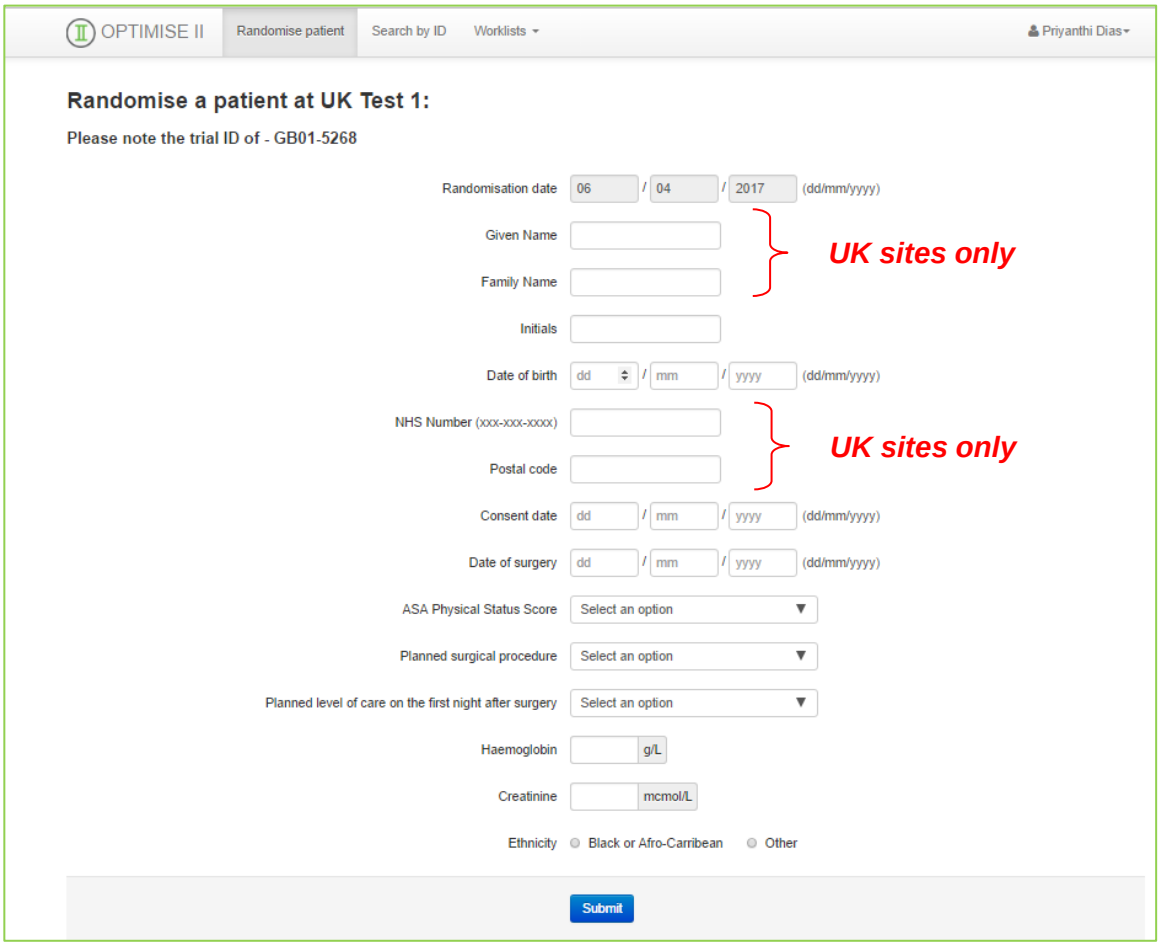
Navigation Bar – use this to navigate around the database

User – this displays the username and role of the person logged in

- To add a participant, click '**Randomise patient**' in the navigation bar circled below:

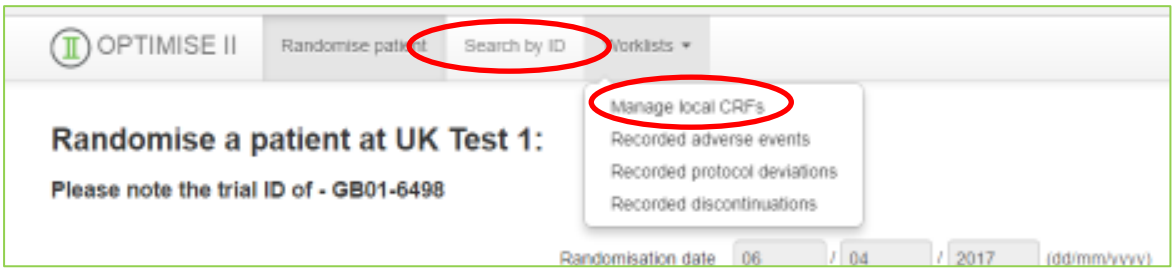


- A dropdown box will appear requesting the following information prior to randomisation:

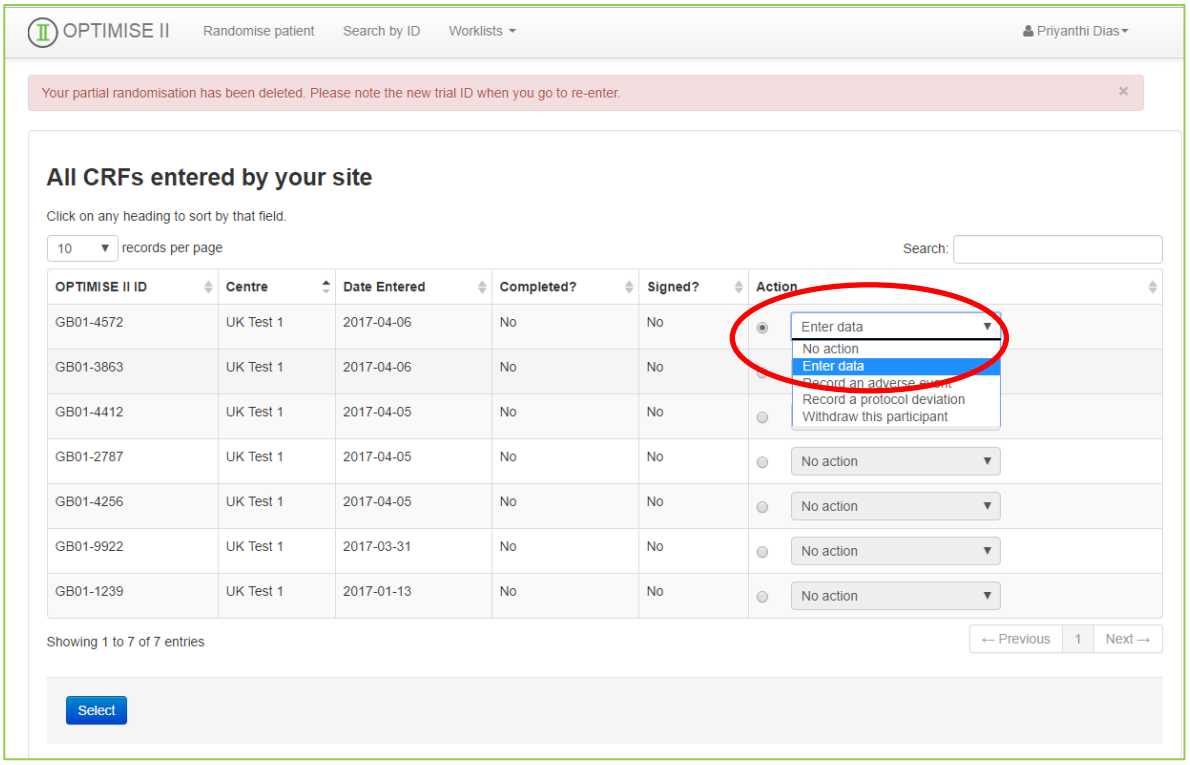


- An 8-digit trial ID will be automatically generated from your site ID; the first 4 digits are the unique Site ID (4 digits) followed by the unique Subject ID (4 digits). For example if your site ID is GB01, the format of your Study Subject IDs will be as follows: GB01-0001. Ensure that your site is displayed correctly and that you enter the trial ID on your paper CRF.

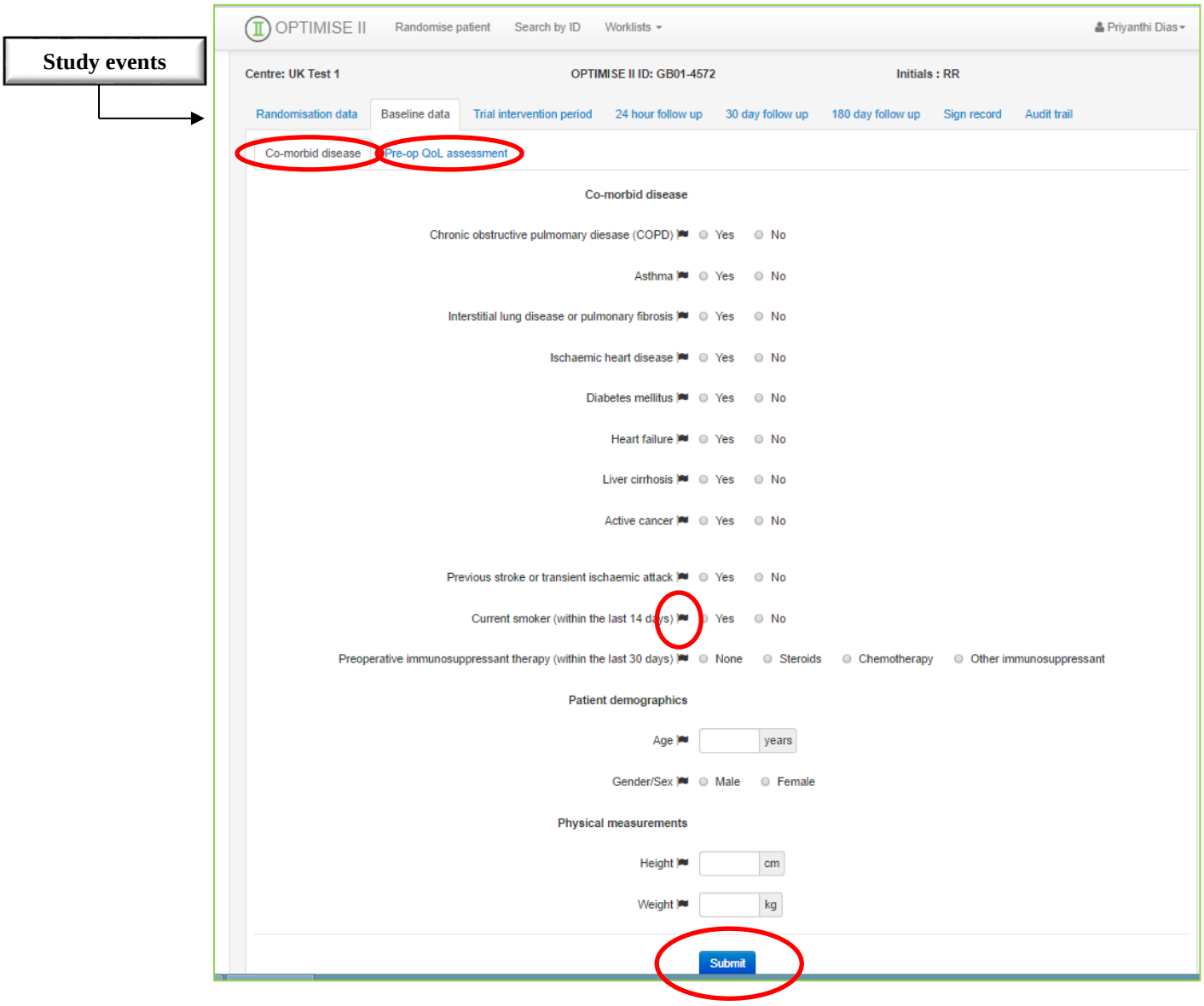
- All fields in the randomisation page are mandatory and must be completed for randomisation to take place.
- Once you have entered the data, click '**Submit'** which will generate an automated randomisation message sent to the email address the user registered the account with.
- Participants can be searched via '**Search by ID'** or under '**Worklists, Manage local CRFs**'.



- If you are ready to enter the baseline data, search for the participants using the trial ID and select the '**Action'** button. Then select the '**Enter data'** using the drop down menu, followed by '**Select'**.

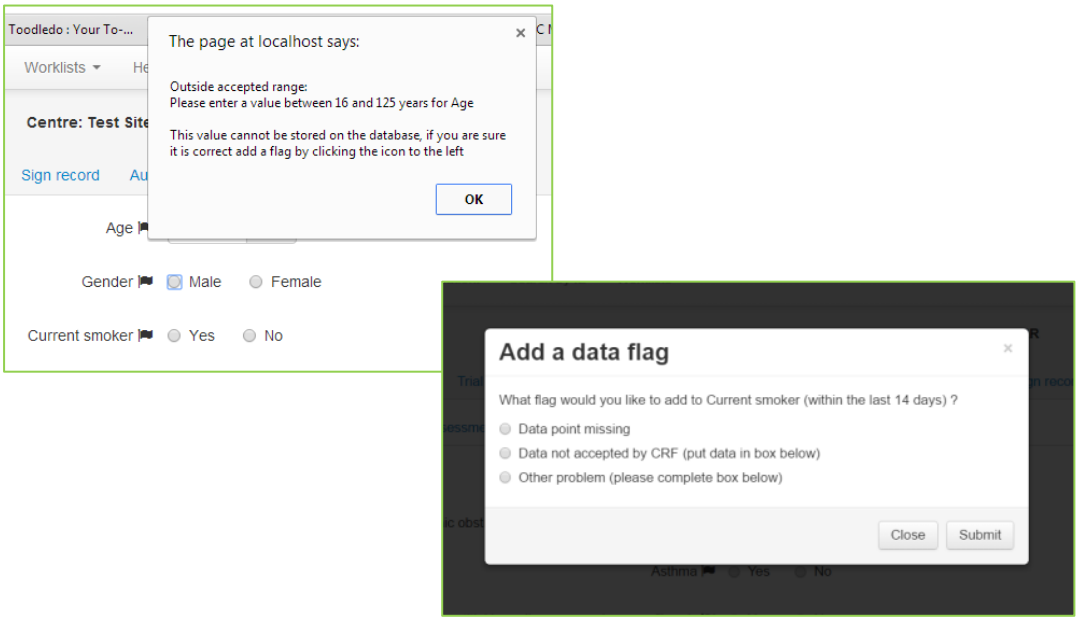


- Once you have selected the '**Enter data'** icon, the page below will appear containing all the study events (e.g. randomisation data, baseline, trial intervention period). Each study event is separated into different sections. For example the baseline data is split into two sections (circled below): 1) Co-morbid disease, patient demographics and physical measurements and 2) Pre-op Quality of Life (QoL) assessment (UK sites only).

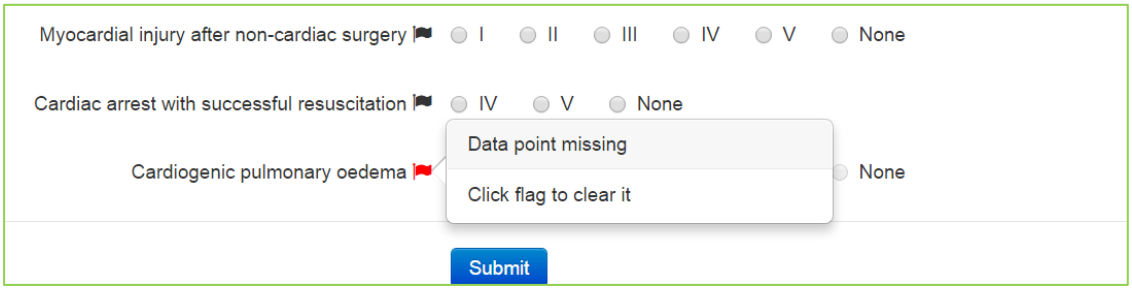


- Complete the form by filling in the text/numbers where required and click '**Submit**' to save the work before moving to another tab.

- Use the flag icon present in each field to record any anomalies or values that cannot be entered in the database because they are outside the normal range.

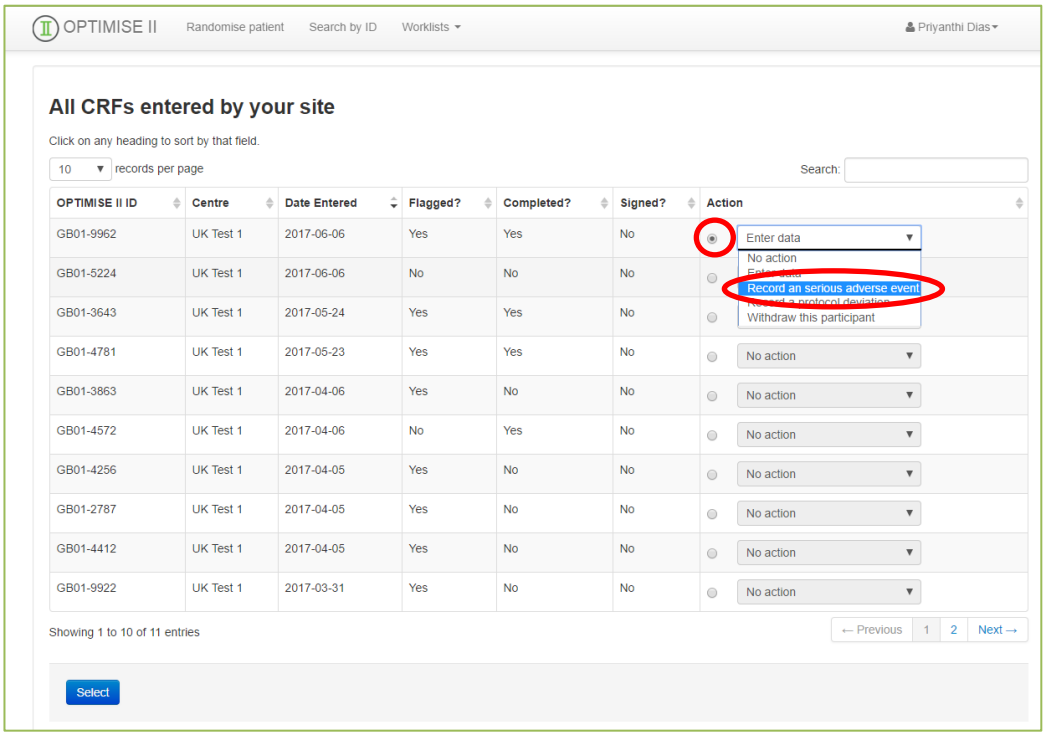


- All events should be entered in chronological order and any missed events must be recorded as '**Data point missing**' using the flag icon.
- If you have previously marked an event as '**Data point missing**' but would now like to enter data for that event, you can do so by clicking the flag and select '**Click flag to clear it**'.

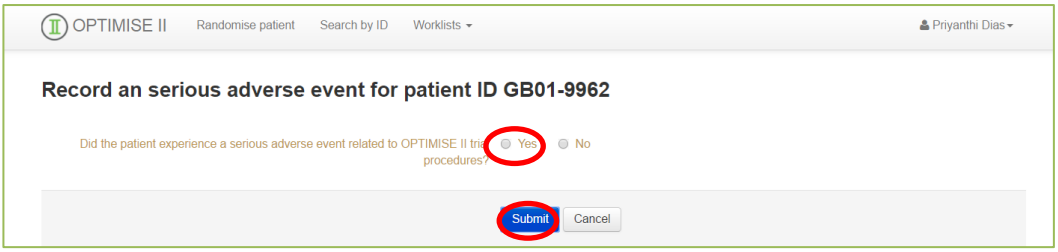


Recording Of Serious Adverse Events

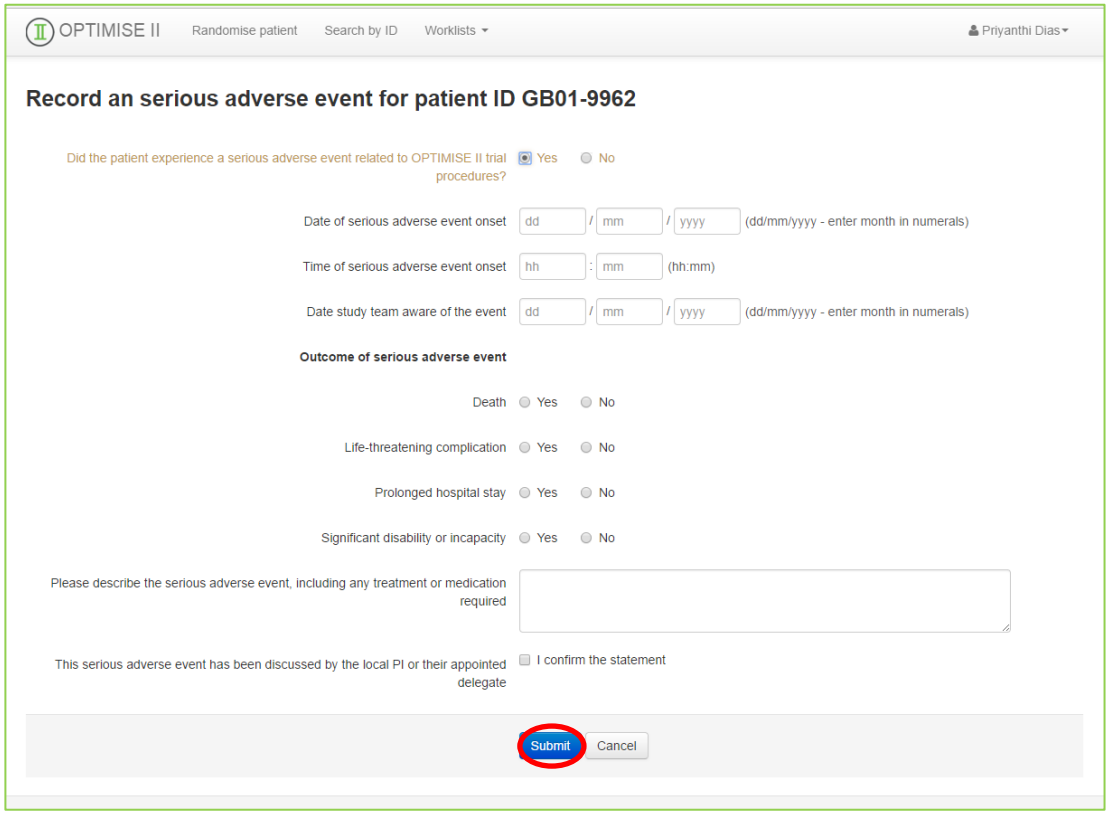
- Only Serious Adverse Events (SAE) will be recorded in this trial. To record an SAE, search for the participant by their trial ID, click the '**Action**' button, select "Record a serious adverse event" from the drop down menu, and click '**Select**'.



- This will take you to the screen below; to confirm that you do want to record an SAE for this participant, select '**Yes**' followed by '**Submit**'.

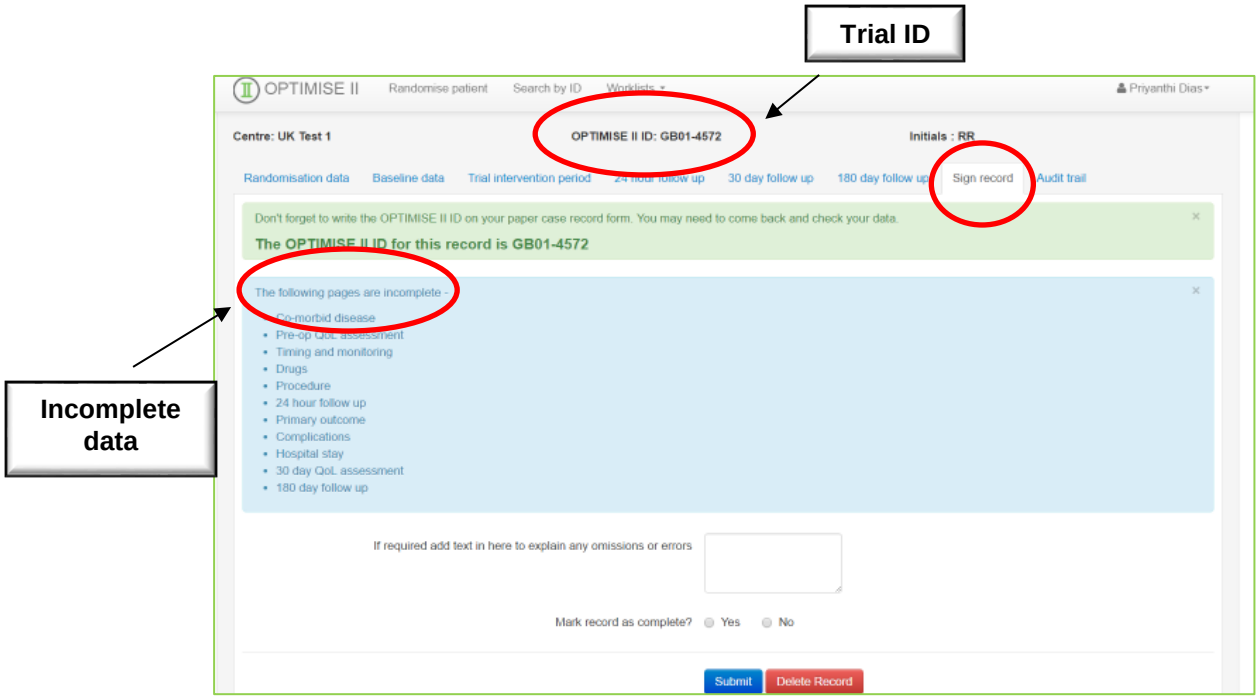


- Details of the SAE will need to be entered in form below, and once completed, click '**Submit**'.



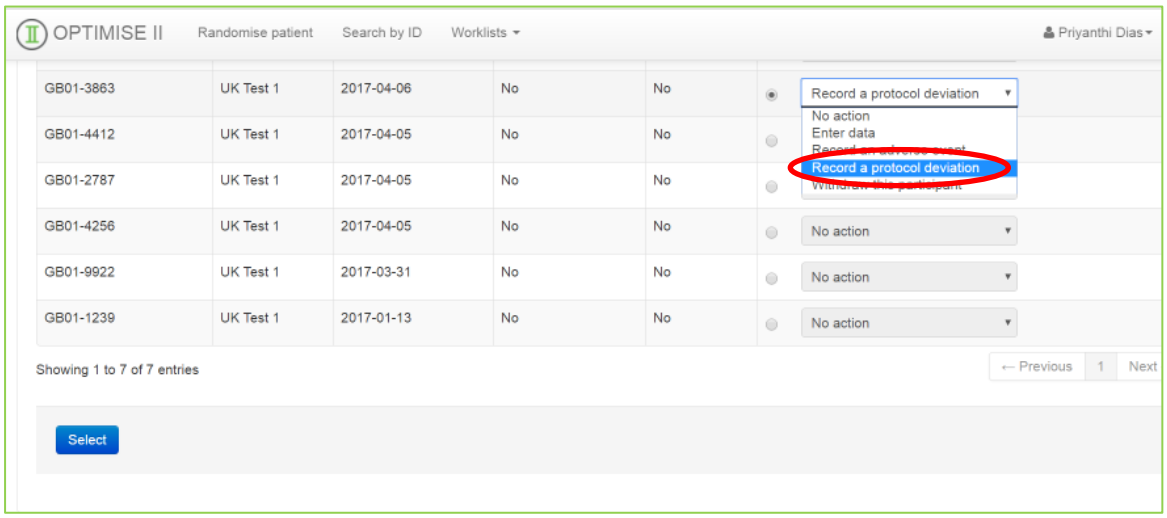
Missing Data

- Any missing data can be seen by selecting the appropriate participant by the trial ID, select '**Sign record'** and a summary the incomplete sections can be found.

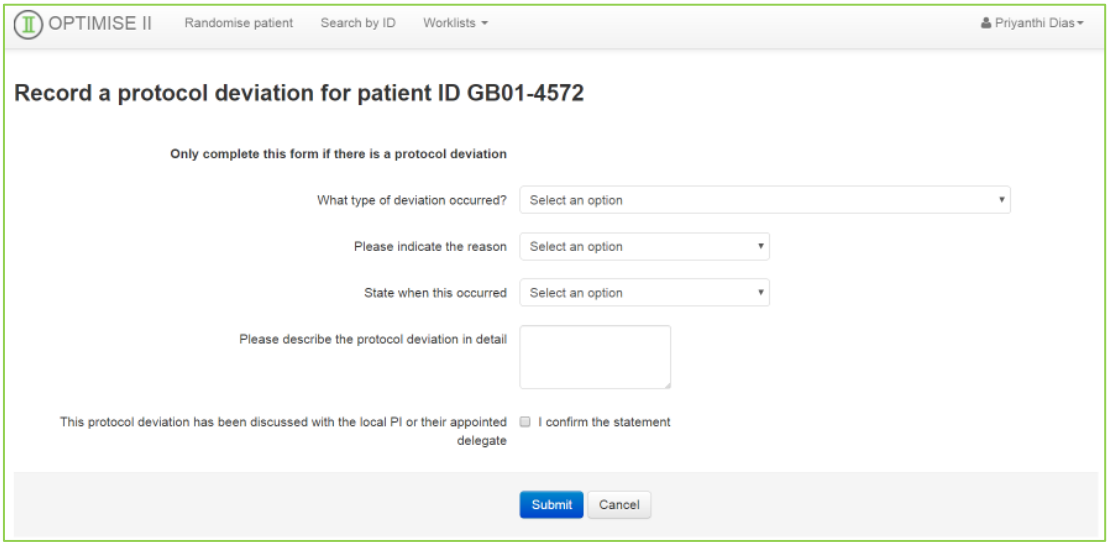


Recording Of Protocol Deviations

- You can record protocol deviations by selecting the participant via the trial ID, select '**Record a protocol deviation**' in the '**Action**' icon and click '**Select**'.

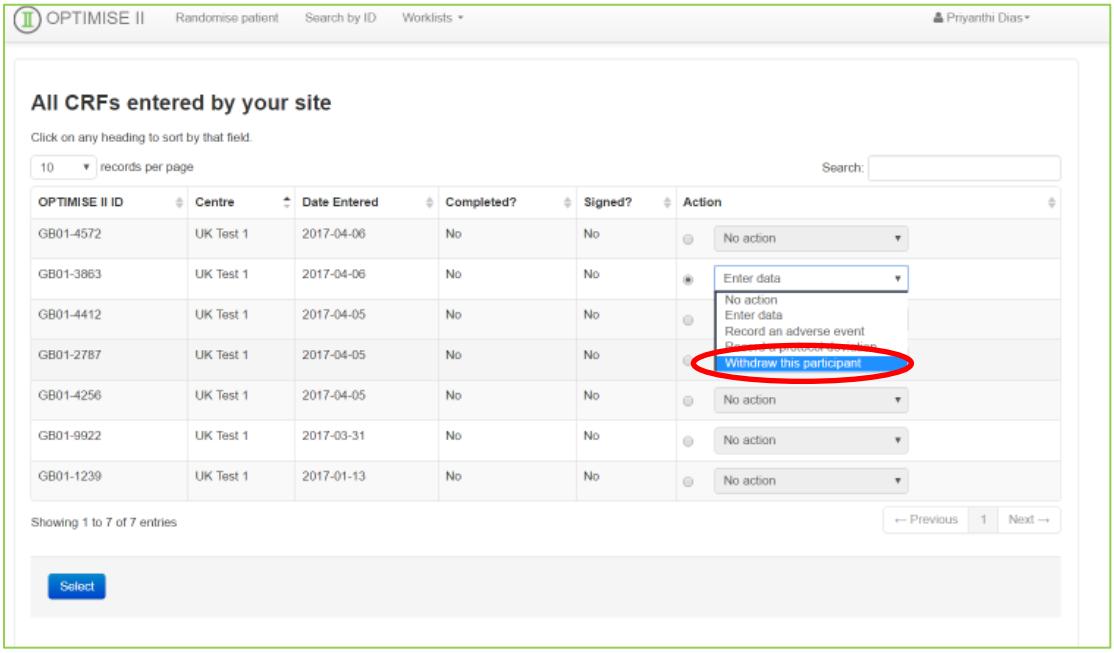


- Details of the SAE will need to be entered in the form below using the drop down menus and text box. Once completed click '**Submit**'.

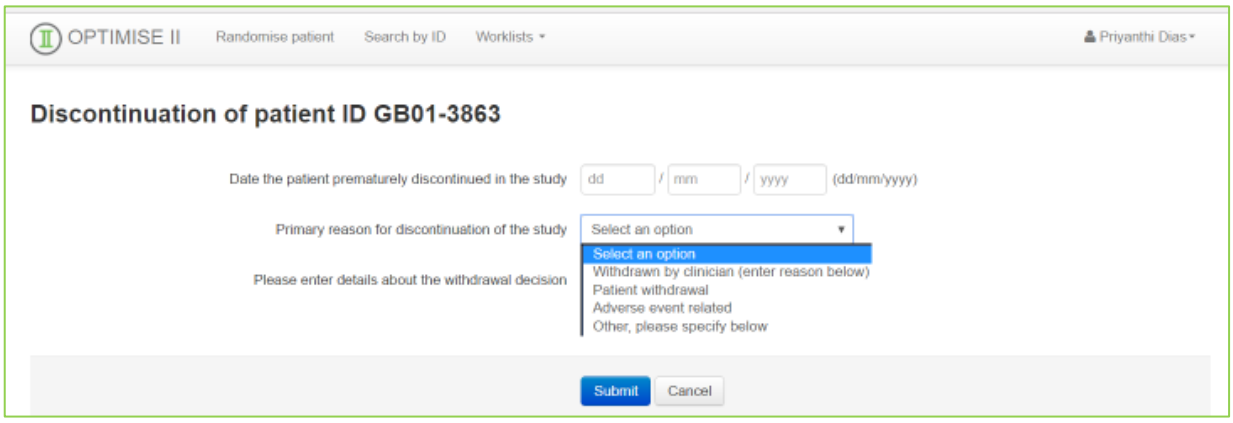


Participant Withdrawal

- You can withdraw a patient at any stage by selecting the participant via the trial ID, select '**Withdraw this participant**' in the '**Action**' icon and click '**Select**'.



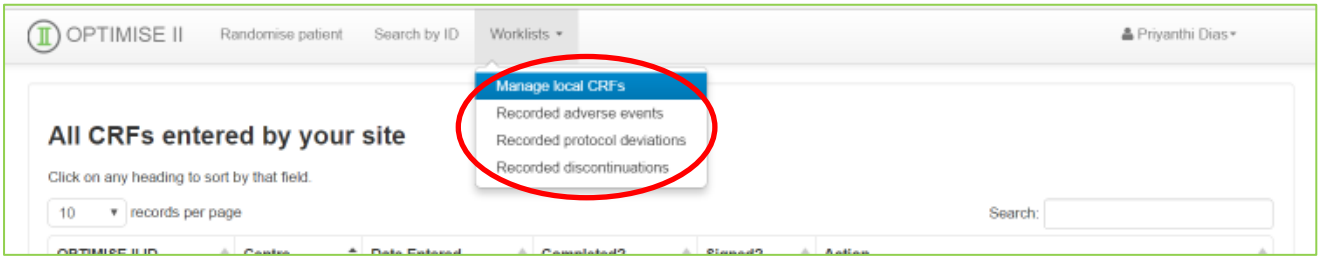
- This will take you to the screen below to enter the subsequent details.



- Select the primary reason for discontinuation using the drop down menu as seen below and enter details about the withdrawal decision in the text box and once complete click '**Submit**'.

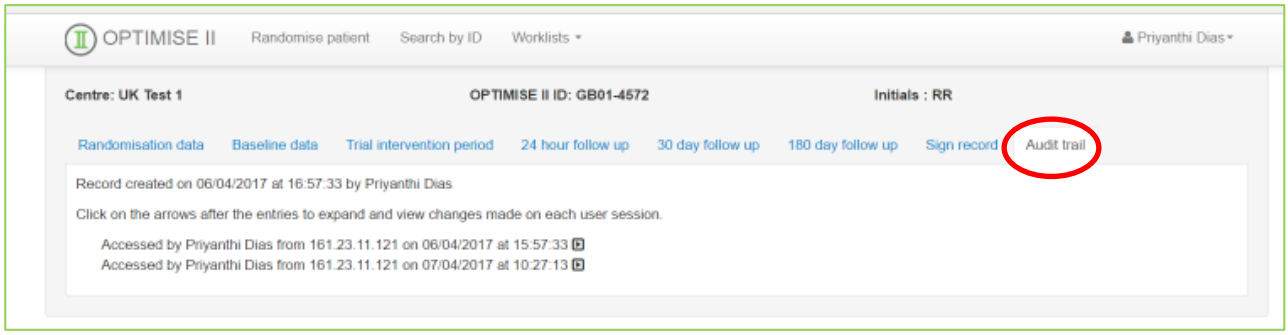
Worklists

- A list of all the recorded CRFs, adverse events, protocol deviations and withdrawals can be found under '**Worklists**'.



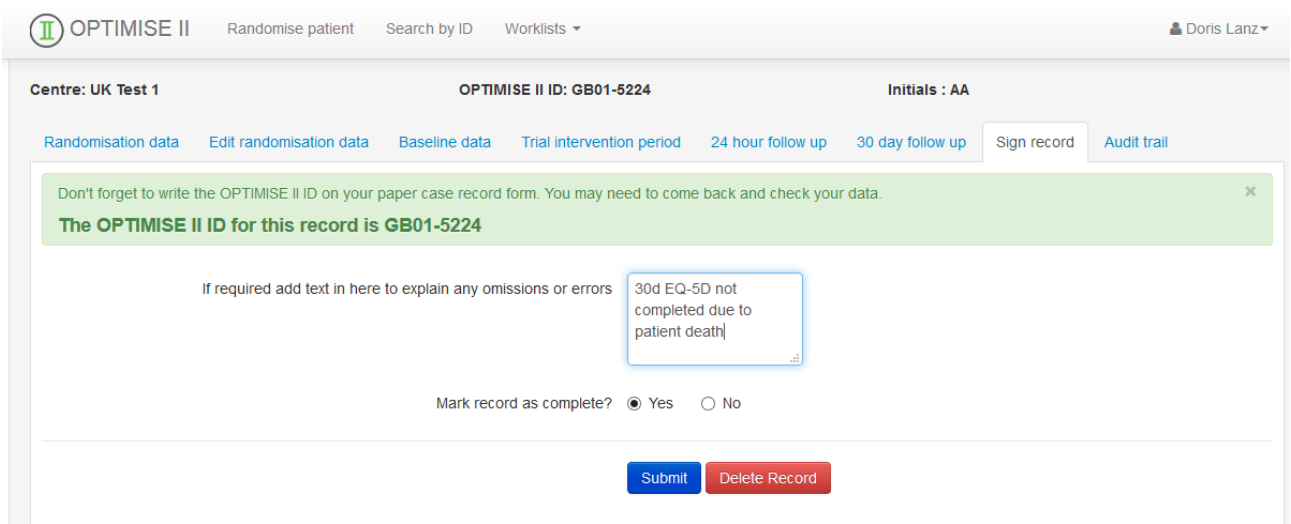
Audit Trail

- The audit trail the entries and changes made under each session for the individual participant.



Marking CRFs As Complete / Signing Off CRFs

- Once you are confident all the data entered is correct, go to the “Sign Record” section.
- Verify that you have not missed any data points.
- If you are confident the entire patient record is complete and accurate (or any missing data points are confirmed missing), mark the record as complete:



- After completion, CRFs will need to be signed-off by the Principal Investigator