

## Standard Operating Procedure (SOP)

### OPTIMISE II Database User Guide

### SOP 007

Authors: Priyanthi Dias & Ann Thomson  
Authorisation: Rupert Pearse (Chief Investigator)

#### Scope

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

#### General data entry rules / Notes

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- 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

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

Priyanthi Dias; Trial Manager	<a href="mailto:admin@optimiseii.org">admin@optimiseii.org</a>	0203 594 0352
<b>OR</b> Doris Lanz; PCTU Trial Manager	<a href="mailto:d.lanz@qmul.ac.uk">d.lanz@qmul.ac.uk</a>	0207 882 5636

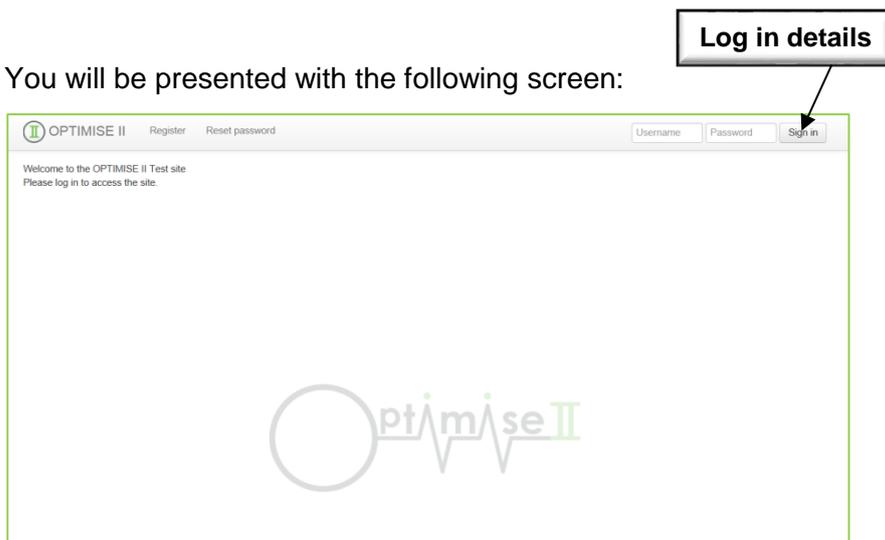
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Version 3.0

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>

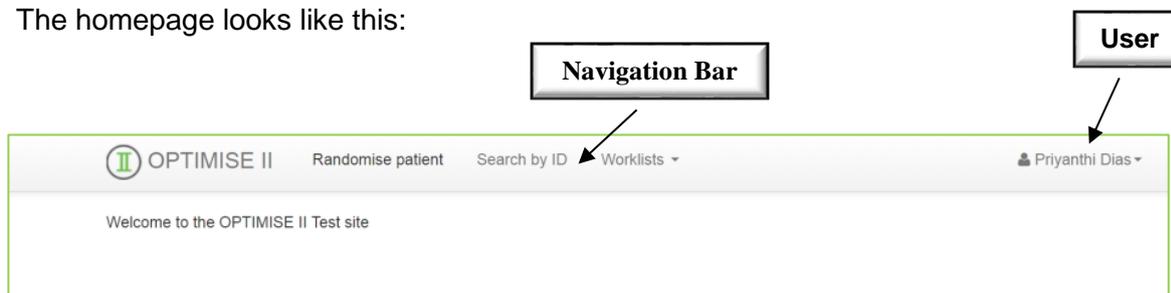
You will be presented with the following screen:



- 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:

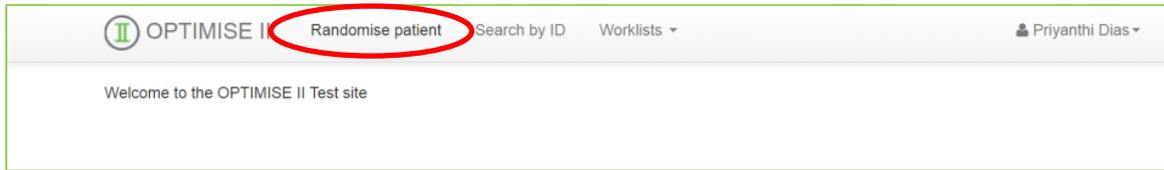


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**Navigation Bar** – use this to navigate around the database

**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:

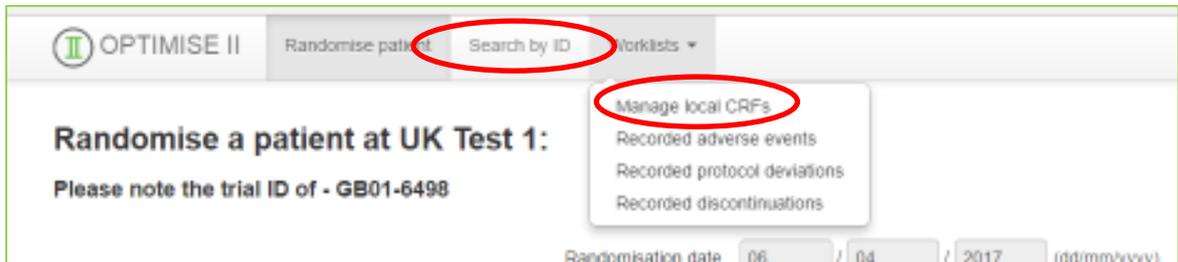


- A dropdown box will appear requesting the following information prior to randomisation:

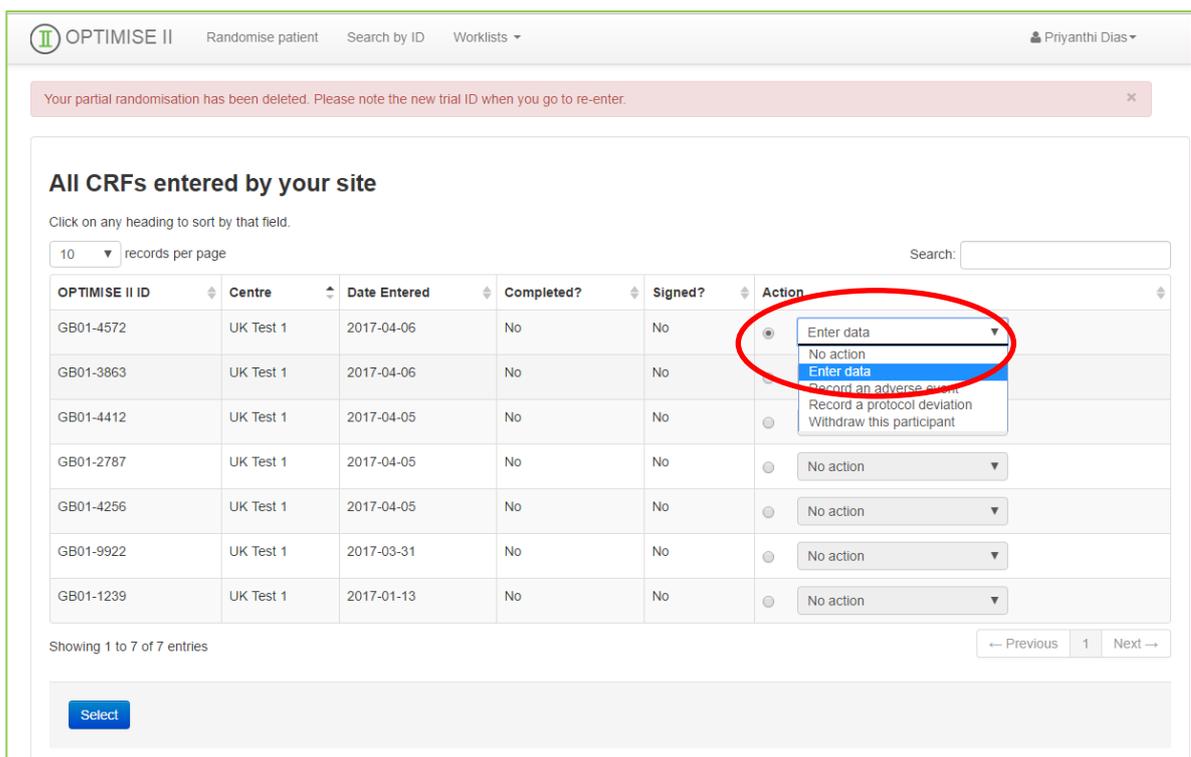
A screenshot of the 'Randomise a patient at UK Test 1' form. The form title is 'Randomise a patient at UK Test 1:'. Below the title, it says 'Please note the trial ID of - GB01-5268'. The form contains several input fields: 'Randomisation date' (06 / 04 / 2017), 'Given Name', 'Family Name', 'Initials', 'Date of birth' (dd / mm / yyyy), 'NHS Number (xxx-xxx-xxxx)', 'Postal code', 'Consent date' (dd / mm / yyyy), 'Date of surgery' (dd / mm / yyyy), 'ASA Physical Status Score' (dropdown), 'Planned surgical procedure' (dropdown), 'Planned level of care on the first night after surgery' (dropdown), 'Haemoglobin' (input with unit 'g/L'), 'Creatinine' (input with unit 'mcmol/L'), and 'Ethnicity' (radio buttons for 'Black or Afro-Caribbean' and 'Other'). A blue 'Submit' button is at the bottom. Red brackets on the right side of the form group 'Given Name', 'Family Name', and 'Initials' under the label 'UK sites only', and 'NHS Number' and 'Postal code' under another 'UK sites only' label.

- 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**'.



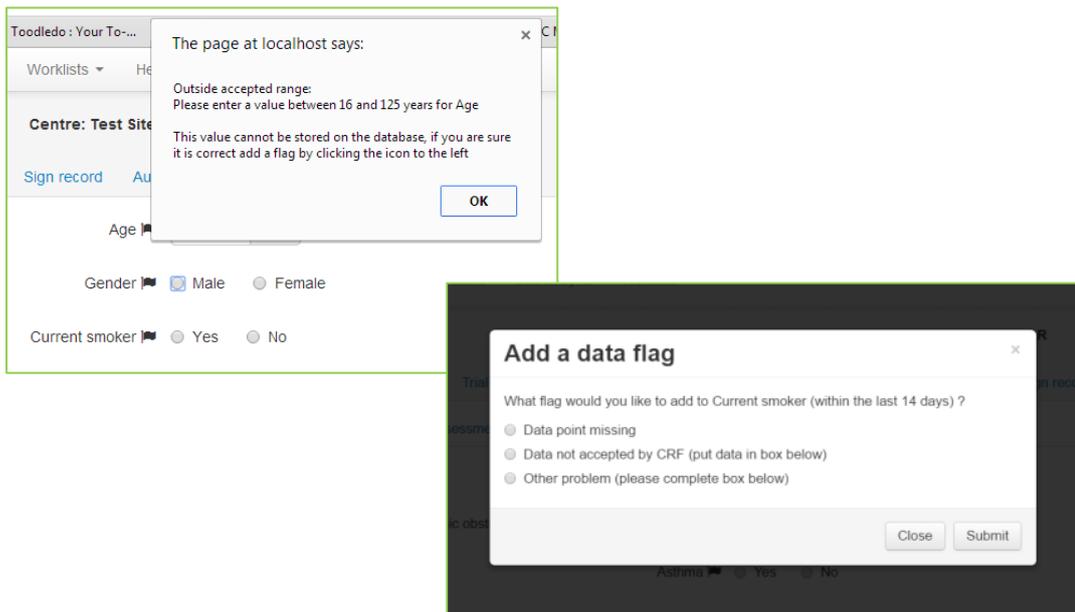
- Once you have selected the **'Enter data'** icon, the page below will appear containing all the study events (e.g. randomisation data, baseline, trial intervention period). Each study event is separated into different sections. For example the baseline data is split into two sections (circled below):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

**Study events**

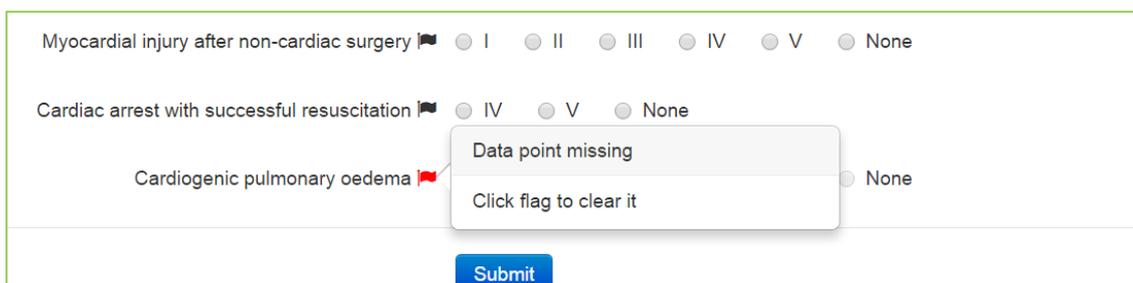
The screenshot displays the 'OPTIMISE II' web interface. At the top, there are navigation options: 'Randomise patient', 'Search by ID', and 'Worklists'. The user's name 'Priyanthi Dias' is visible in the top right. The main header shows 'Centre: UK Test 1', 'OPTIMISE II ID: GB01-4572', and 'Initials: RR'. Below the header, there are several tabs: 'Randomisation data', 'Baseline data', 'Trial intervention period', '24 hour follow up', '30 day follow up', '180 day follow up', 'Sign record', and 'Audit trail'. The 'Baseline data' tab is active and contains two sub-sections: 'Co-morbid disease' and 'Pre-op QoL assessment', both of which are circled in red. The 'Co-morbid disease' section lists several conditions with radio buttons for 'Yes' and 'No': Chronic obstructive pulmonary disease (COPD), Asthma, Interstitial lung disease or pulmonary fibrosis, Ischaemic heart disease, Diabetes mellitus, Heart failure, Liver cirrhosis, Active cancer, Previous stroke or transient ischaemic attack, and Current smoker (within the last 14 days). The 'Pre-op QoL assessment' section includes input fields for 'Age' (years), 'Height' (cm), and 'Weight' (kg). At the bottom of the form, a blue 'Submit' button is circled in red. A callout box on the left labeled 'Study events' has an arrow pointing to the 'Baseline data' tab.

- 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'**.

OPTIMISE II Randomise patient Search by ID Worklists Priyanthi Dias

### All CRFs entered by your site

Click on any heading to sort by that field.

10 records per page Search:

OPTIMISE II ID	Centre	Date Entered	Flagged?	Completed?	Signed?	Action
GB01-9962	UK Test 1	2017-06-06	Yes	Yes	No	Enter data No action <b>Record a serious adverse event</b> Withdraw this participant
GB01-5224	UK Test 1	2017-06-06	No	No	No	No action
GB01-3643	UK Test 1	2017-05-24	Yes	Yes	No	No action
GB01-4781	UK Test 1	2017-05-23	Yes	Yes	No	No action
GB01-3863	UK Test 1	2017-04-06	Yes	No	No	No action
GB01-4572	UK Test 1	2017-04-06	No	Yes	No	No action
GB01-4256	UK Test 1	2017-04-05	Yes	No	No	No action
GB01-2787	UK Test 1	2017-04-05	Yes	No	No	No action
GB01-4412	UK Test 1	2017-04-05	Yes	No	No	No action
GB01-9922	UK Test 1	2017-03-31	Yes	No	No	No action

Showing 1 to 10 of 11 entries

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'.

OPTIMISE II Randomise patient Search by ID Worklists Priyanthi Dias

### Record a serious adverse event for patient ID GB01-9962

Did the patient experience a serious adverse event related to OPTIMISE II trial procedures?  Yes  No

Submit Cancel

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

OPTIMISE II Randomise patient Search by ID Worklists ▾ Priyanthi Dias ▾

### Record an serious adverse event for patient ID GB01-9962

Did the patient experience a serious adverse event related to OPTIMISE II trial procedures?  Yes  No

Date of serious adverse event onset  /  /  (dd/mm/yyyy - enter month in numerals)

Time of serious adverse event onset  :  (hh:mm)

Date study team aware of the event  /  /  (dd/mm/yyyy - enter month in numerals)

**Outcome of serious adverse event**

Death  Yes  No

Life-threatening complication  Yes  No

Prolonged hospital stay  Yes  No

Significant disability or incapacity  Yes  No

Please describe the serious adverse event, including any treatment or medication required

This serious adverse event has been discussed by the local PI or their appointed delegate  I confirm the statement

## 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.

The screenshot shows the OPTIMISE II interface for a participant record. The trial ID 'OPTIMISE II ID: GB01-4572' is highlighted with a red circle and labeled 'Trial ID'. The 'Sign record' button is also circled in red. A callout box labeled 'Incomplete data' points to a list of incomplete sections: Co-morbid disease, Pre-op lab assessment, Timing and monitoring, Drugs, Procedure, 24 hour follow up, Primary outcome, Complications, Hospital stay, 30 day QoL assessment, and 180 day follow up. The interface also includes a 'Submit' button and a 'Delete Record' button.

## 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'.

The screenshot shows a table of participants in the OPTIMISE II system. The table has columns for Trial ID, Centre, Date, and Action. The first row is highlighted, and a dropdown menu is open for the 'Action' column, showing the option 'Record a protocol deviation' circled in red. A callout box labeled 'Record a protocol deviation' points to this option. The table also includes a 'Select' button at the bottom.

Trial ID	Centre	Date	Action
GB01-3863	UK Test 1	2017-04-06	Record a protocol deviation
GB01-4412	UK Test 1	2017-04-05	No action
GB01-2787	UK Test 1	2017-04-05	No action
GB01-4256	UK Test 1	2017-04-05	No action
GB01-9922	UK Test 1	2017-03-31	No action
GB01-1239	UK Test 1	2017-01-13	No action

- 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**'.

**Record a protocol deviation for patient ID GB01-4572**

Only complete this form if there is a protocol deviation

What type of deviation occurred?

Please indicate the reason

State when this occurred

Please describe the protocol deviation in detail

This protocol deviation has been discussed with the local PI or their appointed delegate  I confirm the statement

## 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**'.

**All CRFs entered by your site**

Click on any heading to sort by that field.

10 records per page

Search:

OPTIMISE II ID	Centre	Date Entered	Completed?	Signed?	Action
GB01-4572	UK Test 1	2017-04-06	No	No	No action
GB01-3863	UK Test 1	2017-04-06	No	No	Enter data
GB01-4412	UK Test 1	2017-04-05	No	No	No action
GB01-2787	UK Test 1	2017-04-05	No	No	Enter data
GB01-4256	UK Test 1	2017-04-05	No	No	Record an adverse event
GB01-9922	UK Test 1	2017-03-31	No	No	Withdraw this participant
GB01-1239	UK Test 1	2017-01-13	No	No	No action

Showing 1 to 7 of 7 entries

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

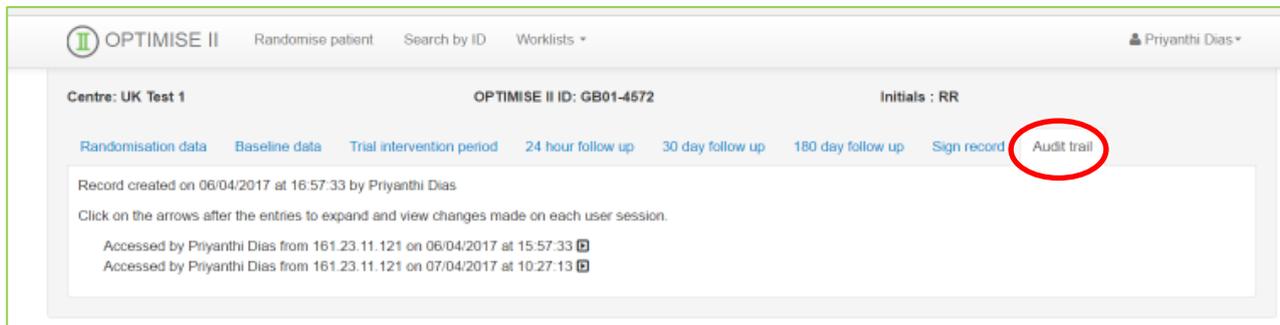
- Select the primary reason for discontinuation using the drop down menu as seen below and enter details about the withdrawal decision in the text box and once complete click '**Submit**'.

## Worklists

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

## Audit Trail

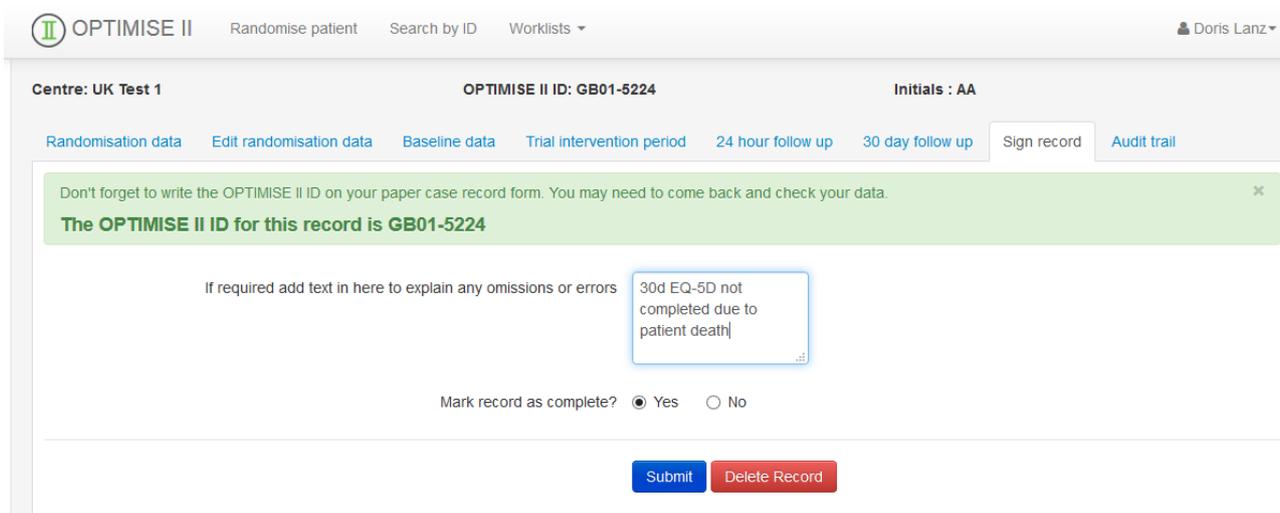
- The audit trail the entries and changes made under each session for the individual participant.



The screenshot shows the OPTIMISE II interface for a patient record. The top navigation bar includes 'OPTIMISE II', 'Randomise patient', 'Search by ID', and 'Worklists'. The user is logged in as 'Priyanthi Dias'. The patient details are: Centre: UK Test 1, OPTIMISE II ID: GB01-4572, and Initials: RR. A menu of tabs is visible: 'Randomisation data', 'Baseline data', 'Trial intervention period', '24 hour follow up', '30 day follow up', '180 day follow up', 'Sign record', and 'Audit trail'. The 'Audit trail' tab is highlighted with a red circle. Below the tabs, the record creation information is displayed: 'Record created on 06/04/2017 at 16:57:33 by Priyanthi Dias'. A note states: 'Click on the arrows after the entries to expand and view changes made on each user session.' Two access logs are shown: 'Accessed by Priyanthi Dias from 161.23.11.121 on 06/04/2017 at 15:57:33' and 'Accessed by Priyanthi Dias from 161.23.11.121 on 07/04/2017 at 10:27:13'.

## 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:



The screenshot shows the OPTIMISE II interface for a patient record. The top navigation bar includes 'OPTIMISE II', 'Randomise patient', 'Search by ID', and 'Worklists'. The user is logged in as 'Doris Lanz'. The patient details are: Centre: UK Test 1, OPTIMISE II ID: GB01-5224, and Initials: AA. A menu of tabs is visible: 'Randomisation data', 'Edit randomisation data', 'Baseline data', 'Trial intervention period', '24 hour follow up', '30 day follow up', 'Sign record', and 'Audit trail'. The 'Sign record' tab is active. A green notification box at the top states: 'Don't forget to write the OPTIMISE II ID on your paper case record form. You may need to come back and check your data. The OPTIMISE II ID for this record is GB01-5224'. Below this, there is a text area for 'If required add text in here to explain any omissions or errors' with the text '30d EQ-5D not completed due to patient death'. At the bottom, there is a question 'Mark record as complete?' with radio buttons for 'Yes' (selected) and 'No'. Two buttons are visible: 'Submit' and 'Delete Record'.

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