OpenClinica eCRF Completion Guideline

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Contents

1. OpenClinica help 6
1.1 OpenClinica Support 6
1.2 Study Specific Support 6
1.3 Study database access 6
1.4 Password Management 6
1.5 Multifactor Authentication (MFA) 7
2. General data entry guidelines 9
2.1 General data entry guidelines for PANTHER in OpenClinica 9
2.1.1 Browser – Google Chrome 9
2.2 Common formatting 9
2.2.1 Dates and Time 9
2.2.2 Values 9
3. Subject information 10
3.1 Navigation Toolbar 10
3.2 Home Page 10
3.3 Icon key 10
3.4 Adding a Participant 11
3.5 Adding data 11
3.6 Events (Visits) 11
3.6.1 Adding a Study Event 12
3.6.2 Resubmitting/Modifying Subject Information 14
3.6.3 Form Versioning 14
3.6.4 Scheduling a Study Event 15
3.6.5 Removing an Event 16
3.6.6 Restore an Event 17
3.6.7 Subjects: Visit View 18
3.6.8 Subjects: Form View 19

3.6.9 Navigating Between Pages 19
4. Entering data 19
4.1 Data Entry Directly into a Form 19
4.2 Navigating Between Forms 20
4.3 Marking the CRF Complete 20
4.4 Changes made to a CRF Form after being marked Complete 21
4.5 Specific Field Types: 21
4.5.1 Mandatory Fields 21
4.5.2 Empty non-mandatory fields 22
4.5.3 Date Fields 22
4.5.4 Auto Calculate 23
4.6 Repeating Forms 23
4.7 Adding Unscheduled Events 23
4.8 Signing Pages 24
4.9 Manual Randomisation 26
5. Query management 26
5.1 Answering System Queries 26
5.1.1 Answering System Queries: Modifying Data 28
5.1.2 Answering System Queries: Providing an Explanation 28
5.1.3 Answering Queries: Other Query Types 28
6. Study specific guidelines 29
6.1 Schedule Pre-randomisation Event 29
6.2 Eligibility – Platform form 30
6.3 Eligibility – Simvastatin form 32
6.4 Eligibility – Baricitinib form 35
6.5 Initial Consent form 37
6.6 Phenotyping 37
6.7 Schedule Randomisation Event 39

6.8 Randomisation 39
6.8.1 Randomisation Eligibility 39
6.8.2 Randomisation Assignment 40
6.9 Schedule Baseline Event 41
6.9.1 Consent 41
6.9.2 E-consent 42
6.9.3 Contact Details 45
6.9.4 Hospital Admission 46
6.9.5 Demography 47
6.9.6 Equality and Diversity 49
6.9.7 Baseline Data 50
6.10 Lab Parameters – 24hrs prior to Randomisation 54
6.11 Samples Baseline 54
6.11.1 IQCode 55
6.12 Day 0 (post randomisation) Event 56
6.12.1 GCS, Delirium and RASS Score 56
6.13 Daily data Day 0 to Day 6 57
6.14 Intervention Administration 60
6.14.1 Simvastatin – Administration 60
6.14.2 Baricitinib – Administration 60
6.14.3 Usual Care – Administration 61
6.15 Sample Collection 61
6.15.1 Samples D2 62
6.15.2 Samples D6 62
6.16 Daily data day 7 63
6.17 Daily data Day 8 to Day 28 66
6.18 Discharge from ICU 67
6.19 Discharge Hospital 68

6.19.1 Discharge from Hospital 68
6.19.2 Montreal cognitive assessment/MoCA 69
6.19.3 Short Physical Performance Battery 69
6.19.4 Safety Outcomes 70
6.19.5 Co-Enrolment 72
6.20 Day 90 72
6.20.1 Follow up Day 90 72
6.20.2 Labour Market Outcomes 73
6.20.3 BRIEF Health Literacy Screening 73
6.20.4 EQ-5D-5L 74
6.21 Hospital Anxiety and Depression Scale (HADS) 75
6.21.1 Social and Wellbeing SF-36 76
6.21.2 Impact of Events Scale 77
6.22 Day 180 78
6.22.1 Follow Up data - Day 180 78
6.23 Follow Up data - 1 year 79
6.24 Safety reporting 79
6.24.1 Adverse Event Form 79
6.24.2 Serious Adverse Event Form 79
6.25 Concomitant Medications 81
6.26 Protocol Deviations 82
6.27 Permanent Discontinuation of Study Treatment 83
6.28 Withdrawal Form 84
6.29 Pregnancy Notification 85
6.30 Death Form 86
7. CRF completion queries 86
8. Version history 86
9. AmendmentsS 87

1. OpenClinica help

1.1 OpenClinica Support

Contact the Clinical Data Systems (CDS) Production Support for any OpenClinica technical related queries, the help desk is available:

By e-mail: cds_support@imperial.ac.uk

By phone: +44 (0)207 5942614

The team are available Monday to Friday 09:00-17:00

Links to the OpenClinica training modules can also be found on the Website**:**

https://www.imperial.ac.uk/clinical-trials-unit/clinical-data-systems/cds-openclinica/training-openclinica-40/

For help with randomisation refer to the PANTHER Randomisation Guide.

1.2 Study Specific Support

For **study specific** OpenClinica queries please refer to this completion manual or contact the study team below:-

pantheruk@imperial.ac.uk

1.3 Study database access

Study URL: https://imperial.openclinica.io/OpenClinica

Upon successful completion of the OpenClinica role(s) based training, a user can request an OpenClinica account by completing the OpenClinica User Activation Form (UAF) accompanied by the relevant training certificate to your regional manager.

The form requires approval by either the Study Manager or Chief Investigator (CI). Once the form has been completed and sent to CDS Production Support by the PANTHER team, the requested role will be created in OpenClinica.

You will receive a time sensitive email from OpenClinica inviting you to the study, which includes details of the URL and a link to setup your password. You will have 14 days to click on the link to activate your account. If the time passes and the link becomes inactive, contact the CDS Production Support team and they will send you the invitation again. Please try to complete process in a timely manner. OpenClinica is a cloud-based system which is accessible via one URL to access all studies you are assigned to.

Once your account has been activated, to gain access to this study you will need to enter the unique “Username” and “Password” on the database:

**Please note: your username and password should not be recorded anywhere in this document. Passwords should never be shared with other users.*

1.4 Password Management

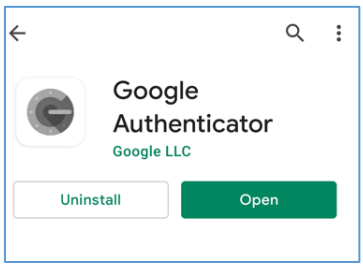
If you forget or enter an incorrect password more than twice you need to click on the **“Forgot Your Password?”** link on the login page and answer the questions provided, the answers are based on those set up when you first logged in. For forgotten password or log in details please contact the OpenClinica/ CDS help desk Support/Helpdesk who will be able reset your password.

A new temporary password will be sent by email to the account holder, you will be expected to change this upon next login.

1.5 Multifactor Authentication (MFA)

Please email the study team: pantheruk@imperial.ac.uk if you have any queries regarding resetting your MFA access.

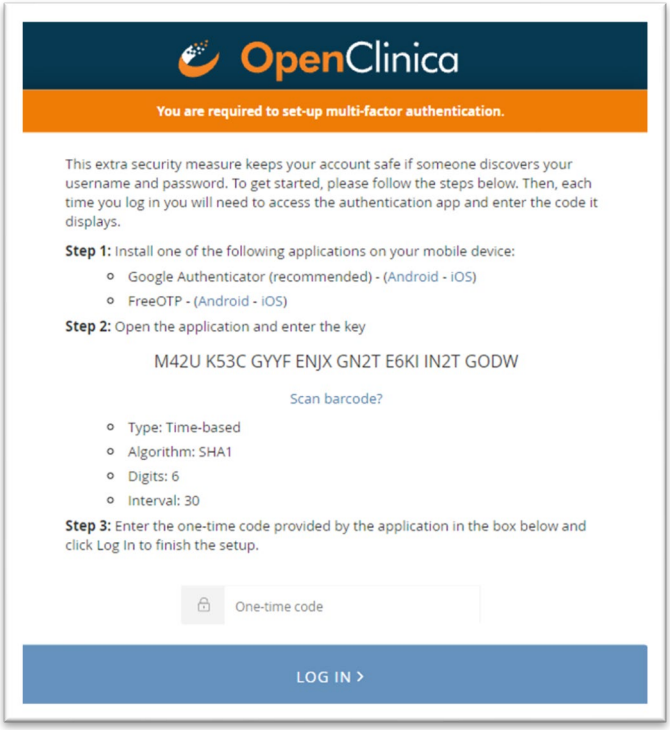
1. Firstly, install **Google Authenticator** on your mobile device. You will be required to use this app each time you sign in to OpenClinica.



2. Open OpenClinica webpage (https://imperial.openclinica.io/OpenClinica/MainMenu) on your computer and login to your account with your existing username and password. Open the **Google Authenticator** on your mobile phone and scan the QR code displayed on the next page.
3. You will be provided with a 6-digit code on your mobile device after scanning the QR code on the computer screen.
4. Enter the 6-digit code into the field on the OpenClinica login page and click on “Log in”.



If you are unable to scan a QR Code



5. For users that are unable to scan the QR code, click on "**Unable to scan**" link on OpenClinica webpage after entering your username and password. This will provide 32-key code.
6. On the mobile app (**Google Authenticator**), select "**Enter a setup key**" and enter the 32-key code provided in the step above. This will generate a 6-digit code that will need to be entered into the field on the OpenClinica login page and click on "Log in".
7. The scanning of the QR code (or entering the 32-digit key code) is a one-time step.

Once this is setup, the account is saved on Google Authenticator app and the 6-digit codes are generated automatically without the need for a QR Code or a key code each time you try to login.

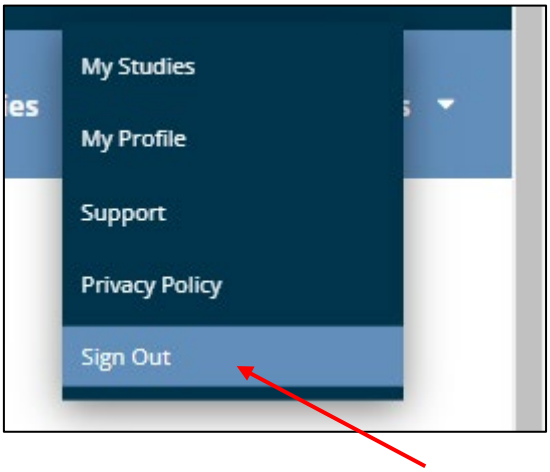
Once these details are entered, click "LOG IN". The system will then display another screen in which to enter your one time code, this is generated by the Google Authenticator app on your smartphone. You will be required to download the Google Authenticator app to retrieve this code before you can access your study. Enter the code that appears in the authenticator app into the and click "LOG IN"

The system will then display a **HOME** screen which is dependent on your user role. Monitor role will have a different home screen to Data Entry, CI and PI roles (Participant Matrix home screen will be displayed). The HOME screen showing this study information {Title, CI, Site etc.)

It is good practice to log out once you have finished using the OpenClinica application. This is particularly important if you are not using your own computer.

After a set period of inactivity (1 hour by default) you will be automatically logged out of the system.

To log out click on the 'Sign Out' button in the navigation bar at the top right hand side of the page.



2. General data entry guidelines

Data entry must be completed for ALL subjects. To adhere to **Good Clinical Practice (GCP)**:

- Data entry for a completed visit should be performed within **14** business days.Data queries should be answered within **14** business days.Data entry must only be completed by authorized personnel who have received trial specific and OpenClinica training and are competent in eCRF completion.
- Avoid using abbreviations in text fields (other than NA - **Not Applicable**, ND - **Not Done**, NK - **Not Known** and UNK - **Unknown**) and acronyms, unless they are approved medical abbreviations known to be acceptable.
- Avoid using abbreviations that are ambiguous or could be interpreted differently.

Anywhere on the eCRF that **'other (specify)'** is selected, there is usually an entry in the space provided describing what 'other' means.Subject identifiers **should not** be used anywhere on the eCRF, such as subject's name, initials, address, hospital number etc., in order to maintain the confidentiality of the subject.

2.1 General data entry guidelines for PANTHER in OpenClinica

2.1.1 Browser – Google Chrome

When using OpenClinica, Google Chrome is the preferred browser option set by the manufacturer, if possible, please use this browser during data entry.

2.2 Common formatting

2.2.1 Dates and Time

Enter date by choosing from the manual calendar, the format is year/month/day i.e., yyyy-mm-dd for example 13th August 1999 is 1999-08-13.

Enter time in a 24-hour clock format i.e., hh:mm e.g., 3:25pm would be entered as 15:25

2.2.2 Values

For values with decimal points, you may need to round the value up or down. To do this:

Decide which is the last number to keep.

Leave it the same if the next number is less than 5 (called rounding down) OR

Increase it by 1 if the next number is 5 or more (called rounding up)

Example 1: To round a value up or down to the nearest whole number

- 72.26 would be rounded down to 72 (as the next number is less than 5)
- 72.53 would be rounded up to 73 (as the next number is 5 or more)

Example 2: To round a value up or down to 2 decimal points

72.2638 would be rounded down to 72.26 (as the next number is less than 5)**72.2684 WOULD BE ROUNDED UP TO 72.27 (AS THE NEXT NUMBER IS 5 OR MORE)**

3. Subject information

3.1 Navigation Toolbar

The navigation toolbar can be found on the top right-hand corner of the OpenClinica main page:



Once logged in you will be able to see the homepage which is also the Participant Matrix. This displays all Participant added to the database at your site. The Navigation toolbar contains these links:

- **Home** – Used to navigate back to the home page/ participant matrix.
- **Participant Matrix** – Used to return to the participant matrix which displays the Participant's general information, Events, and Forms.
- **Add participant** – Used to add new participant.
- **Queries** – This shows a summary count of all queries for all participants and what the status of the query is.
    - **Tasks:**Schedule Study event- can be used to schedule events for a given participant, without entering into that particular participant page.

View Events- You can use this page to filter Study Events. The default view shows Study Events that apply to the current month. Participants for whom Events were scheduled but have not had data recorded as of the expected Event date will appear highlighted in yellow.

3.2 Home Page

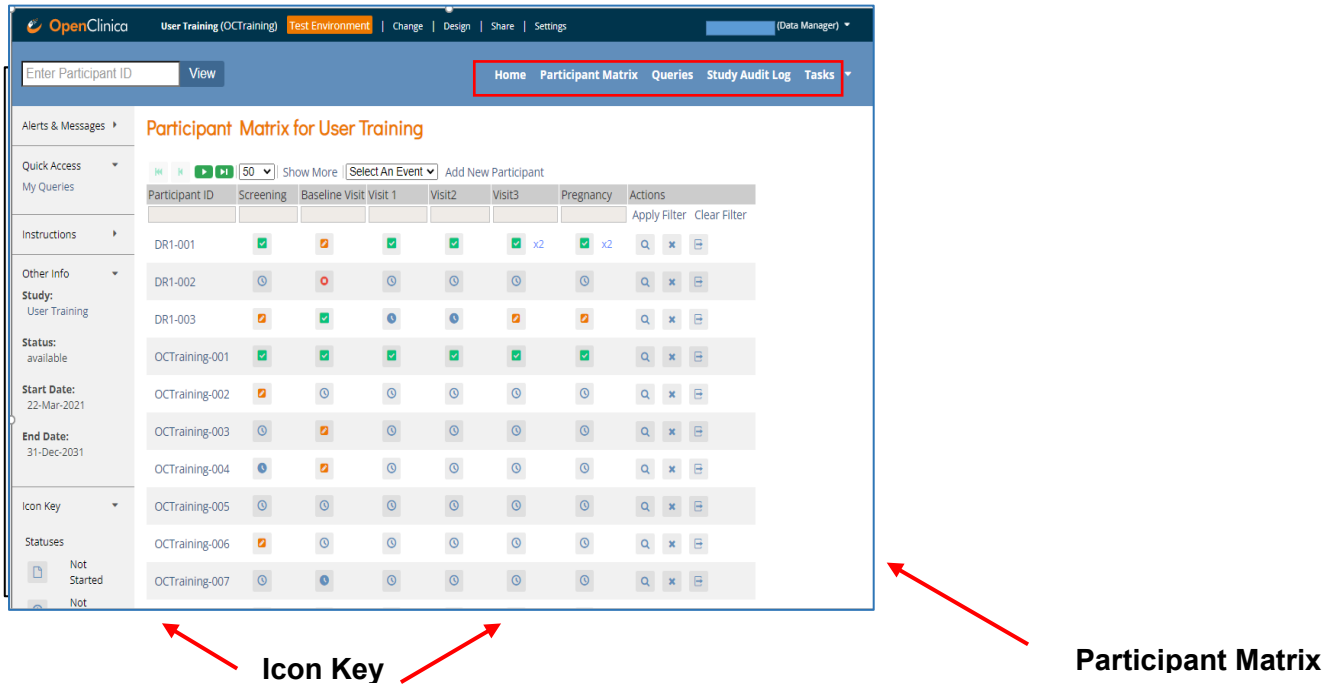
The homepage displays the participant matrix in the centre and an icon key on the left which explains the symbols in the participant matrix.

All added participants are found under the Participant ID column and specific participants can be searched for using their ID in the top square.

The 'Selects an Event' box can be used to search for individual visits. All participants that have the selected event data entered or partially entered will be shown.

3.3 Icon key

Below displays the icon definitions which show the status of an Event:



3.4 Adding a Participant

To add a participant click **'Add Participant'** on the homepage. For further details see section 6.

3.5 Adding data

When completing data entry for the first time, if you have missing information and will need to return back to the form, select the close option on the form and not the complete option, this will allow you to enter the form again without having to state a reason for the change.

3.6 Events (Visits)

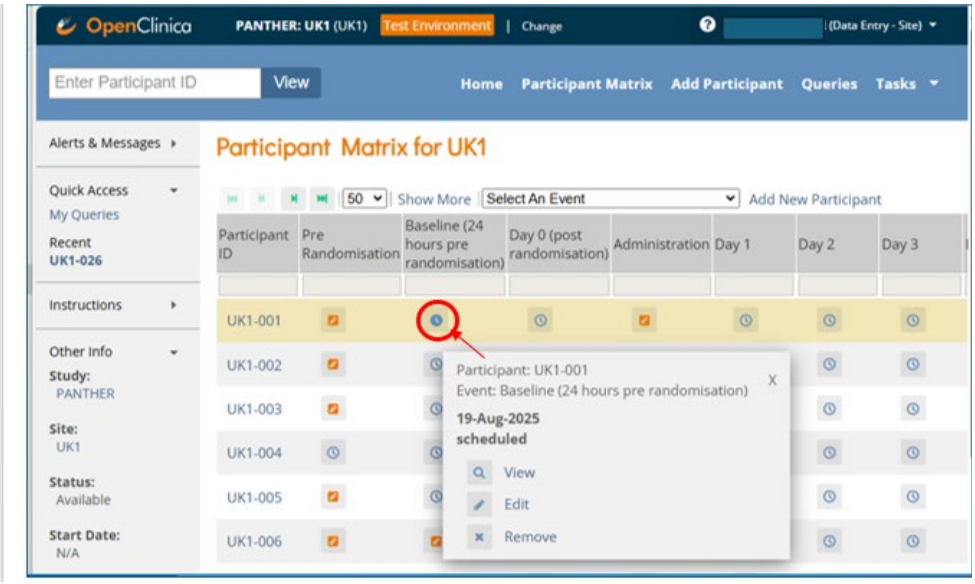
A (Study) Event (visit) is the timepoint in the study where data has to be entered in the eCRF. The following events are defined for PANTHER study:

- Pre Randomisation
- Randomisation PANTHER A; Randomisation PANTHER AB; Randomisation PANTHER B; Randomisation PANTHER C; Randomisation PANTHER CD; Randomisation PANTHER D
- Baseline (24 hours pre randomisation)
- Day 0 (post randomisation)
- Administration
- Day 1; Day 2; Day 3; Day 4; Day 5; Day 6; Day 7; Day 8; Day 9; Day 10; Day 11; Day 12; Day 13; Day 14; Day 15; Day 16; Day 17; Day 18; Day 19; Day 20; Day 21; Day 22; Day 23; Day 24; Day 25; Day 26; Day 27; Day 28
- Discharge ICU
- Discharge Hospital
- Day 90

- Day 180
- Day 365

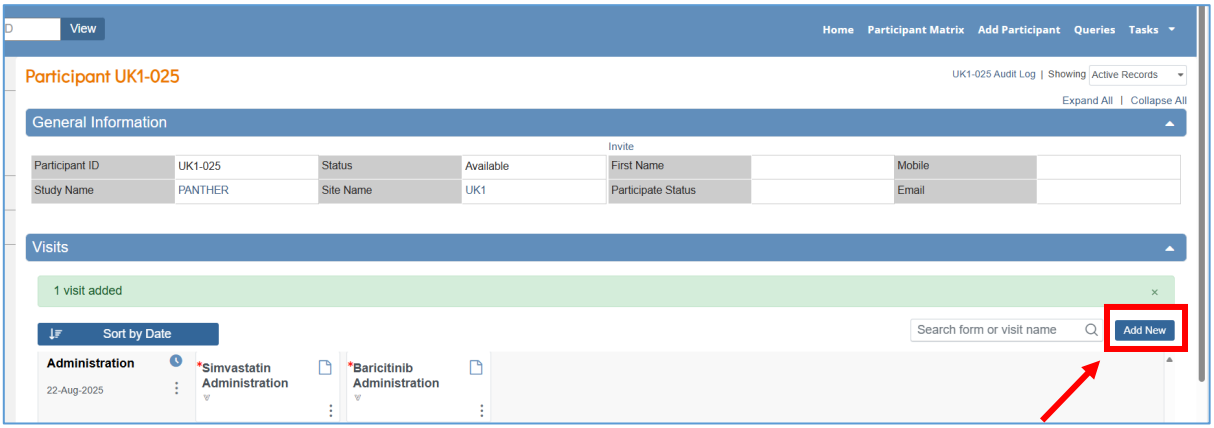
To view or Edit data for a participant

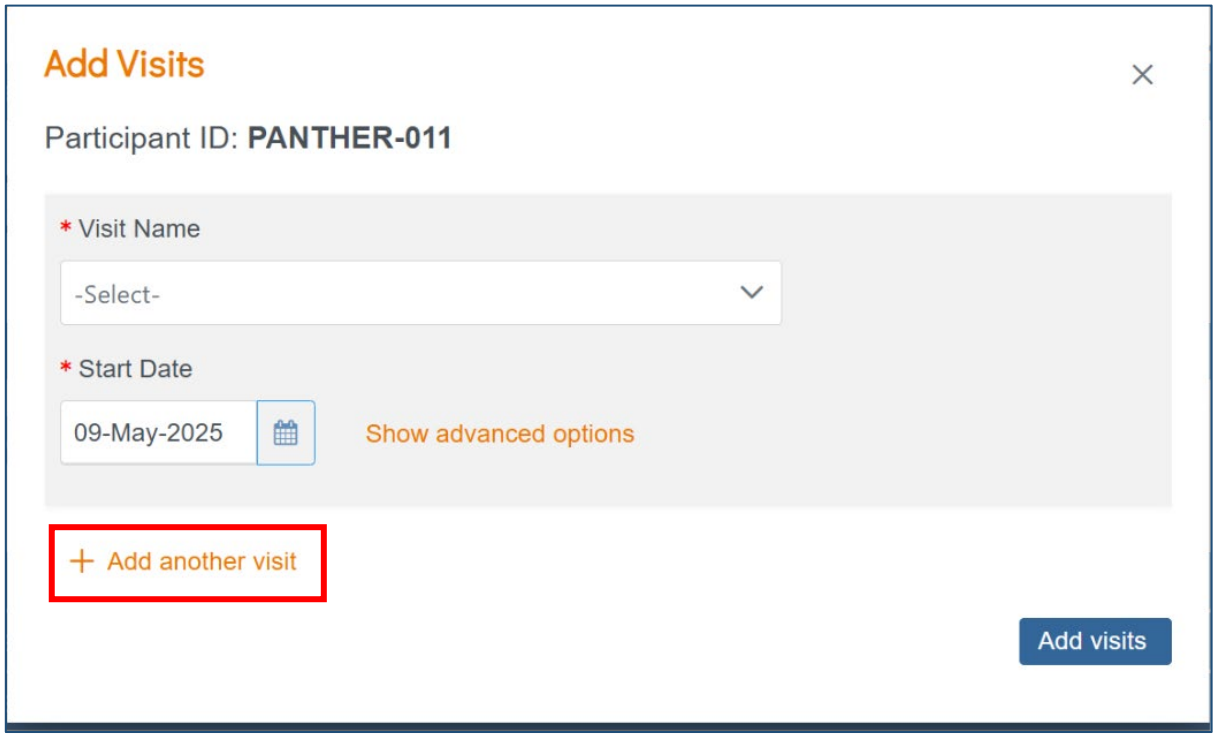
Click the icon for a **scheduled**, **data entry started**, or **completed** Event and select **View/Enter** to view the **Participant Details** screen



3.6.1 Adding a Study Event

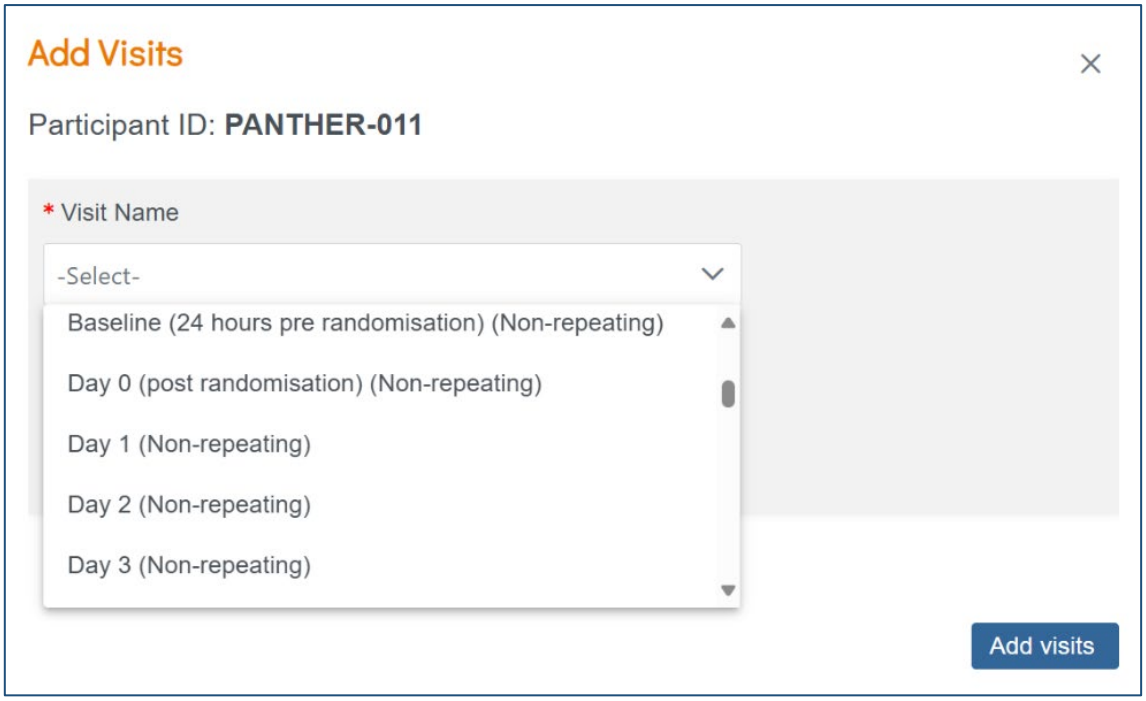
Once the patient ID has been generated, the patient visits can be added. Visits are added by clicking ‘Add New’ on the right-hand side of the Participant page. This generates the ‘Add Visits’ pop-up window.





The drop-down list can be seen below, the list is chronological, and you can select which visit you want to add from this.

When the visits have been added they can be seen on the participant page, starting with the first at the bottom moving up in a chronological order. The order can be flipped with the first at the top by clicking 'Sort by Date' on the top left-hand side. This means that the first visit 'Screening (Diagnostic and Fluid)' will now be at the top of the page.



When the visits have been added they can be seen on the participant page, starting with the first at the bottom moving up in a chronological order. The order can be flipped with the first at the top by clicking 'Sort by Date' on the top left-hand side. This means that the first visit will now be at the top of the page.

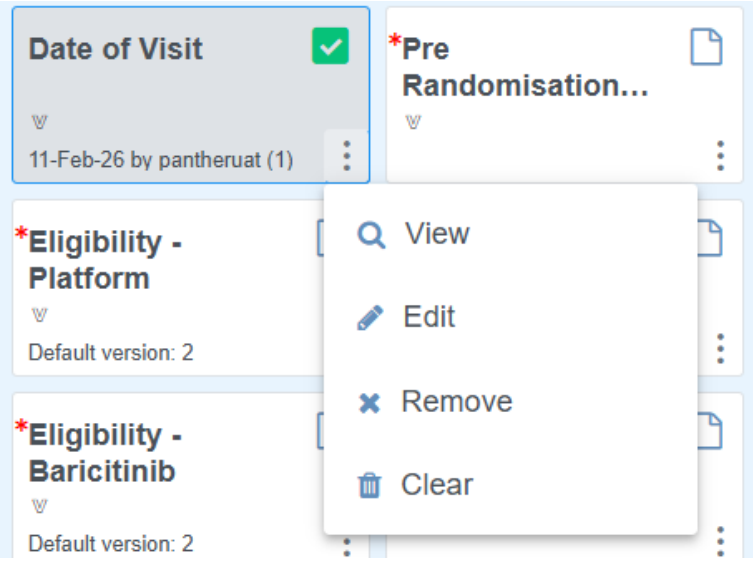
It is advised that only visits that are being completed at that moment should be added as any that are not needed can be removed however it can be problematic for the PI and CI sign off later on.

3.6.2 Resubmitting/Modifying Subject Information

You can modify a form at any time if the form has been closed **and not** saved.

If the form has been saved, you can still modify the data entered however you must give a reason for this. If your changes do not meet form requirements, such as constraints, you will see a message alerting you that specific values have errors and must be changed.

A saved form is one that has a green tick in the top right corner. To edit this form, find **the three dots** in the bottom right corner and choose '**edit**' from the list.



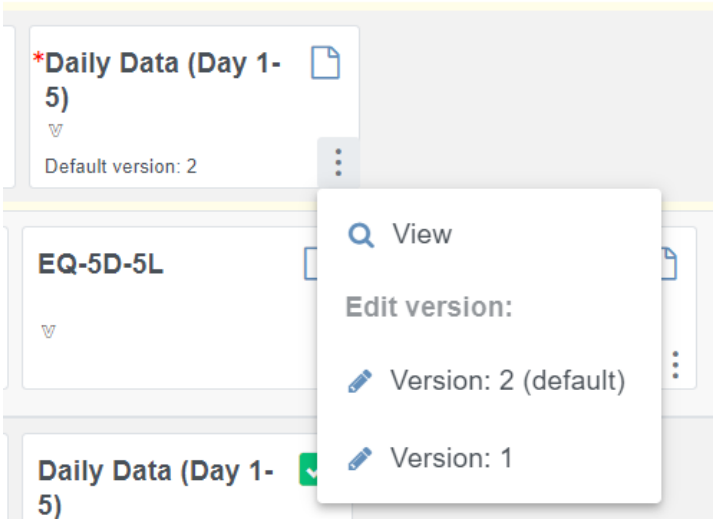
When editing a form to enter missing data/correct data, OpenClinica will ask the data entry user to enter a reason for the change. Depending on the internet browser used for data entry, this may show some auto-fill suggestions based on previous data entry. The auto-fill suggestions **should not be used** when entering a reason for change, as this saved data may be associated with other fields in the form and will change the data for those fields. Example given below: if the first option 'Updated' is selected, it will also change the dates in the form.



3.6.3 Form Versioning

If you have to edit a saved form, please follow the steps from section 3.4.

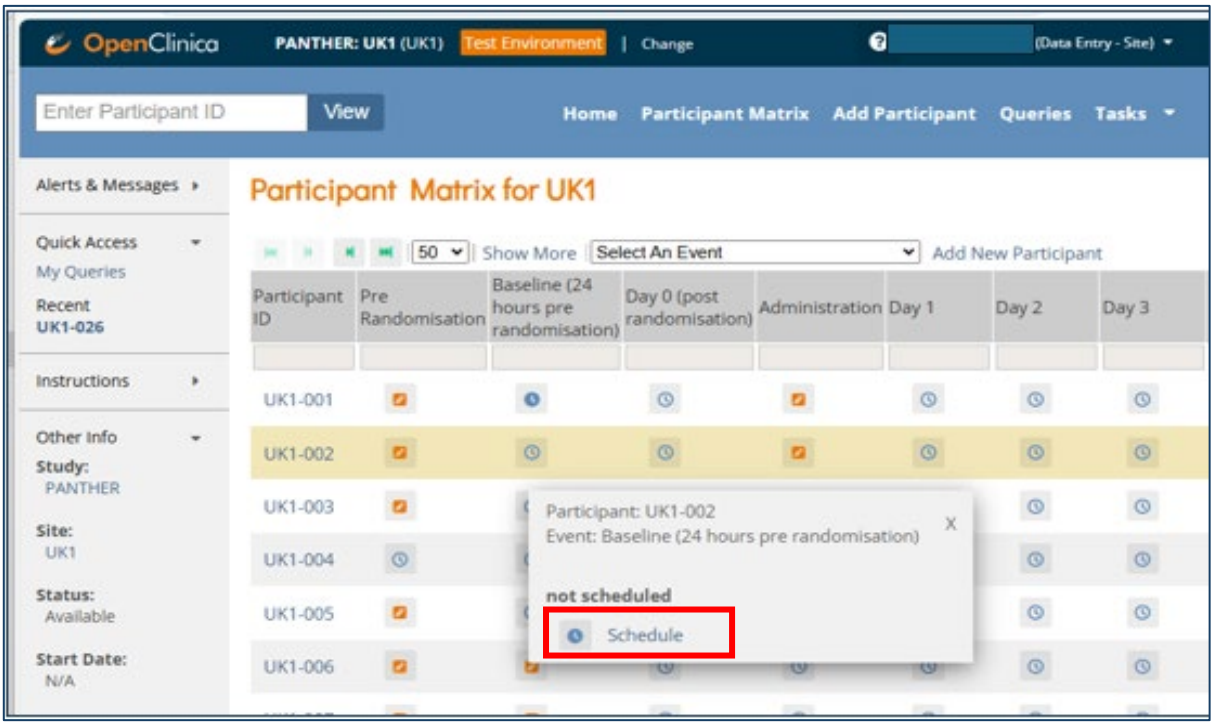
Due to database updates when clicking on the three dots to enter the edit function there are multiple versions of the form available.



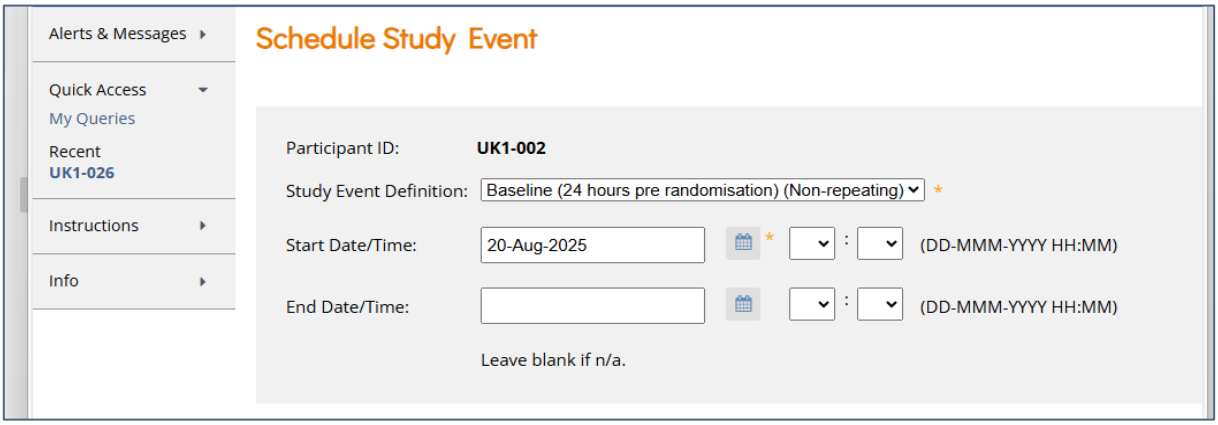
Please make sure to edit the latest version of the form – this prevents any data errors.

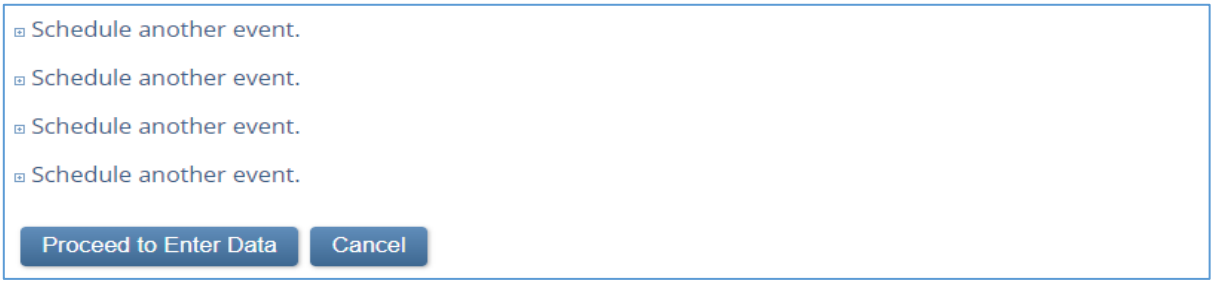
3.6.4 Scheduling a Study Event

If you want to enter data, you have to schedule the respective Event. This is done in the '**Participant Matrix'**. Please click on the Event you want to schedule. A window pops up and then click on '**Schedule'**.



The 'Schedule Study Event' screen appears.



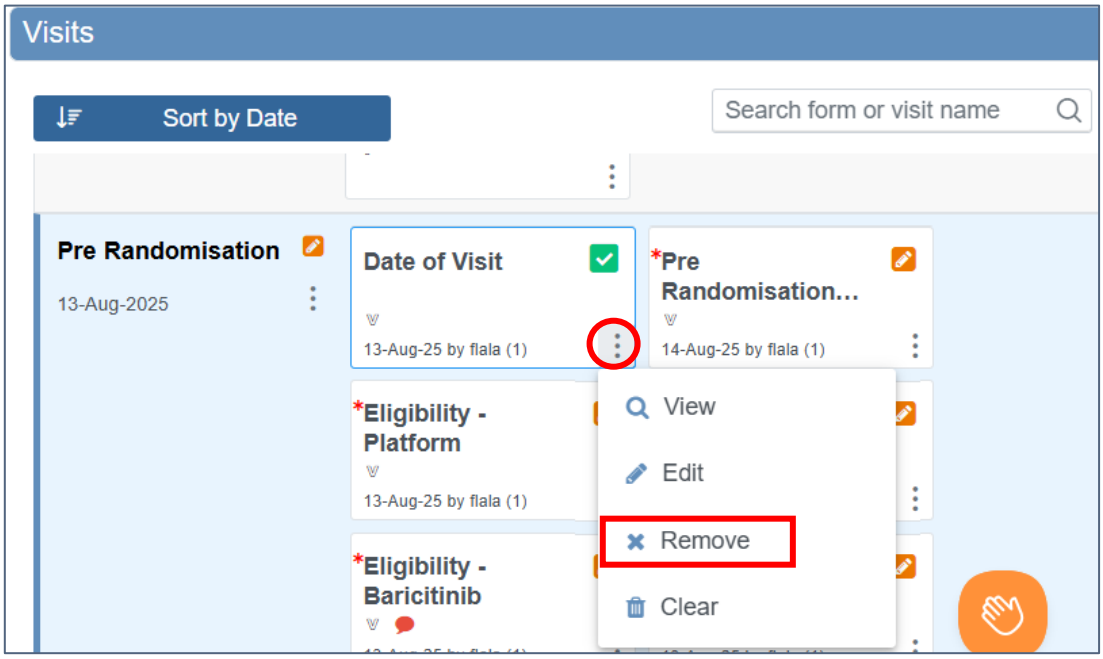


- Complete the screen details:
- **Study Event/Definition**: Select the respective event from the drop-down list.
- **Start Date/Time**: Default date is the current date when Event is scheduled in the eCRF or enter date required. This field is optional.
- **End Date/Time**: Enter date, this field is optional.
- Then click **'Proceed to Enter Data'** Now the respective event has been scheduled and you may start the data entry.

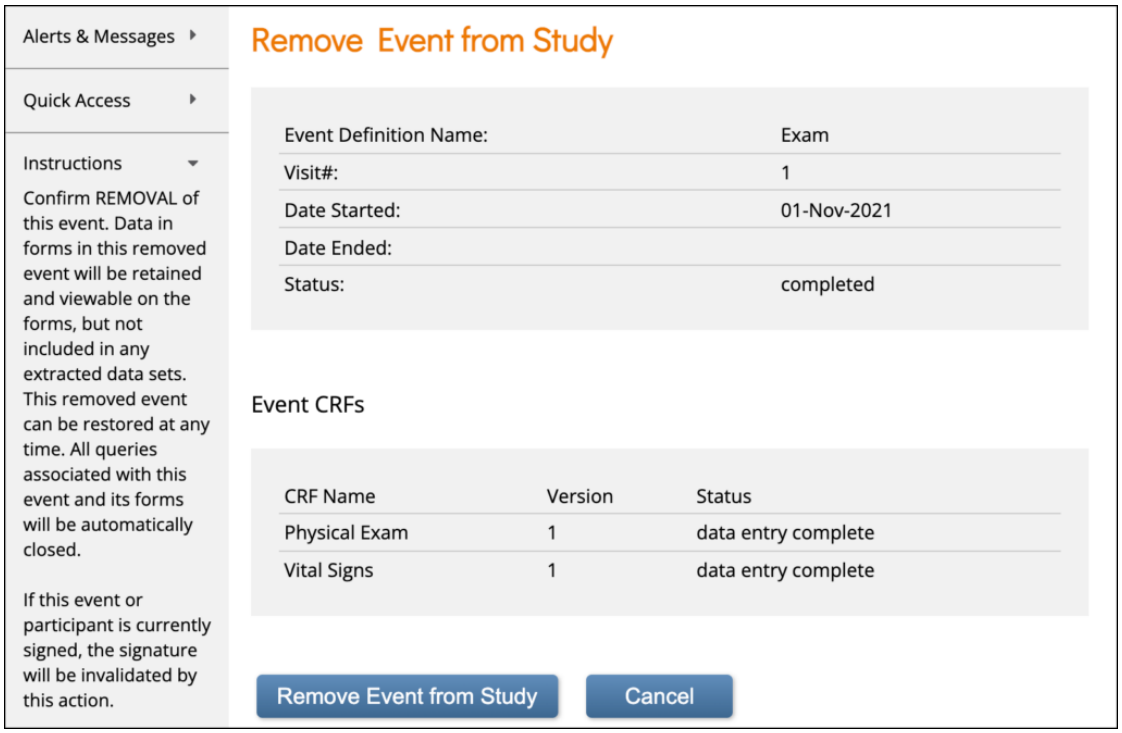
3.6.5 Removing an Event

If an Event has been entered in error, you can remove that event or form (examples below are shown for an Event).

To remove the event Click the **Remove** button in the **three dots** menu on the **Participant Details** screen. This is replaced with the **Restore** button.



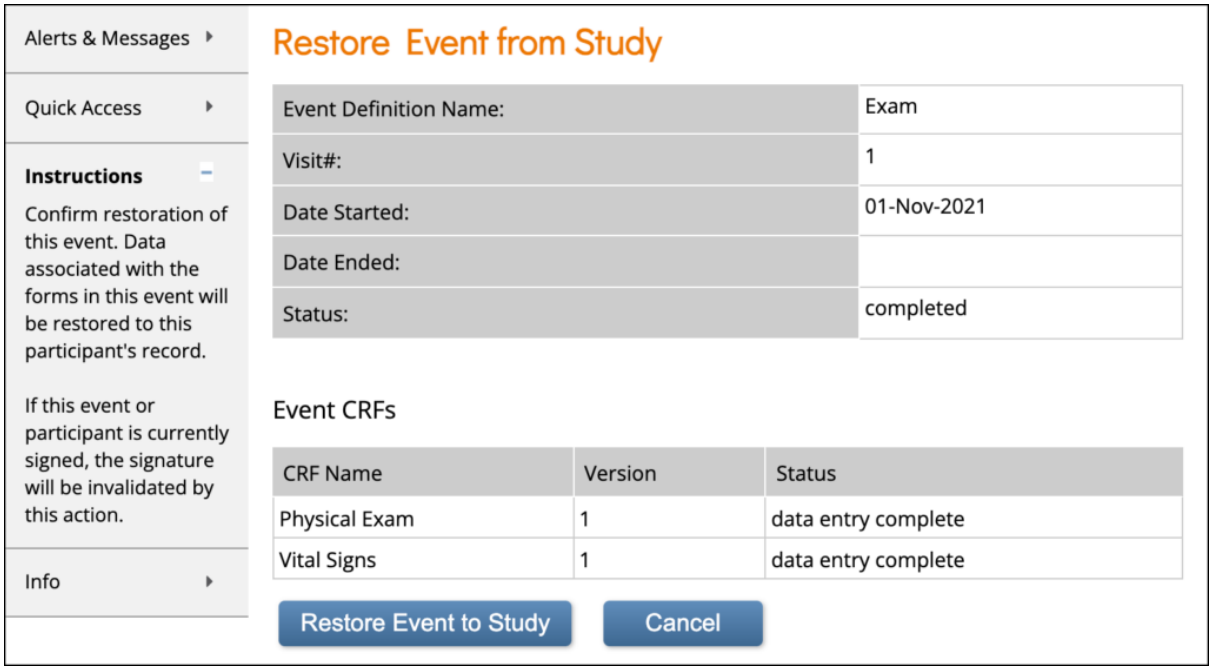
You will be taken to a form in which you must enter the reason for removing the form, complete this section and then select 'Remove event from study':



Note: If an Event is removed after being signed, the signature is invalidated, and if restored, the form must be signed again.

3.6.6 Restore an Event

If you have removed an Event you want to restore, click the **Restore** button in the three dot **Event Actions** menu on the **Participant Details** screen. This is replaced with the **Remove** button.



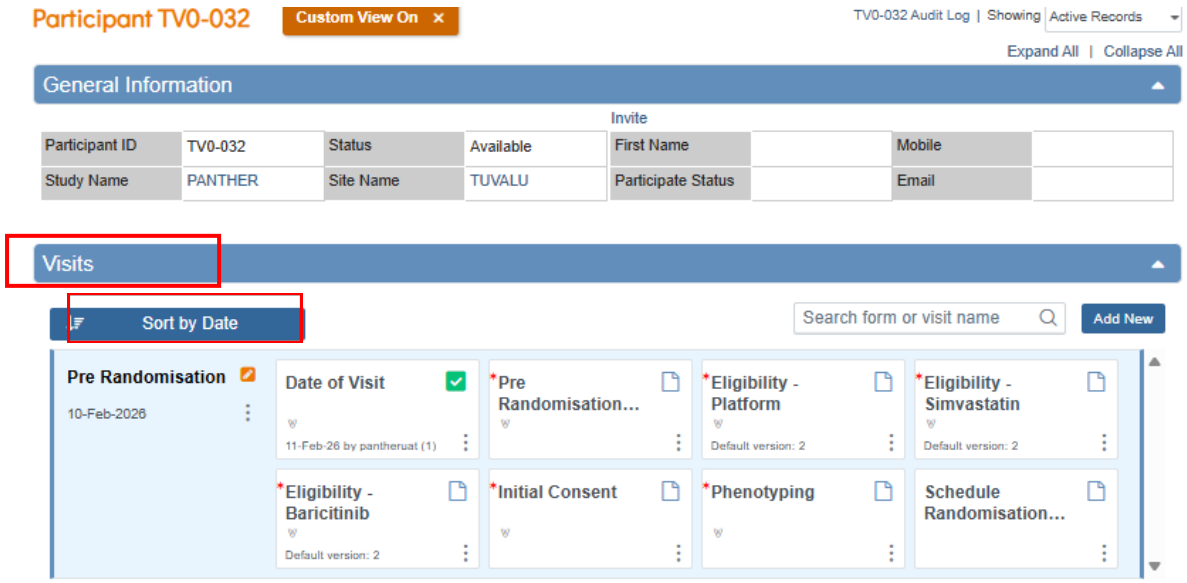
Please note: *If an Event is removed after being signed, the signature is invalidated, and if restored, the Form must be signed again. When data was entered on the Form prior to the Event being removed,* **The event this form is in has been removed *appears at the top of the Form.***

3.6.7 Subjects: Visit View

To view all visits that have been added to a patient's profile select the participant from the 'Participant Matrix'. On the patient page all assigned visits can be viewed under the Visits tab:

The visits will show up in **reverse-chronological** order, with the first visit: Screening (Diagnostic and Fluid) at the bottom of the page. The order in which the visits are viewed can be changed to chronological, where the first visit is at the top by selecting the 'Sort by Date'.

When the arrow on the 'Sort by Date' tab is facing up the visits will appear in a chronological order down



the page.



3.6.8 Subjects: Form View

When a visit is added to a subject's profile all the forms associated with that visit will be automatically visible. The forms have symbols in their top right corner that show the status of completeness. The date on the bottom is the day the data was entered and by who. The 'V' symbol show whether the data has been verified, and changes to black when the data has been verified.



Data entry not started **Data entry started** **Data entry completed**

3.6.9 Navigating Between Pages

For the PANTHER Trial all forms are one page with either a 'Close' or 'Complete' option.

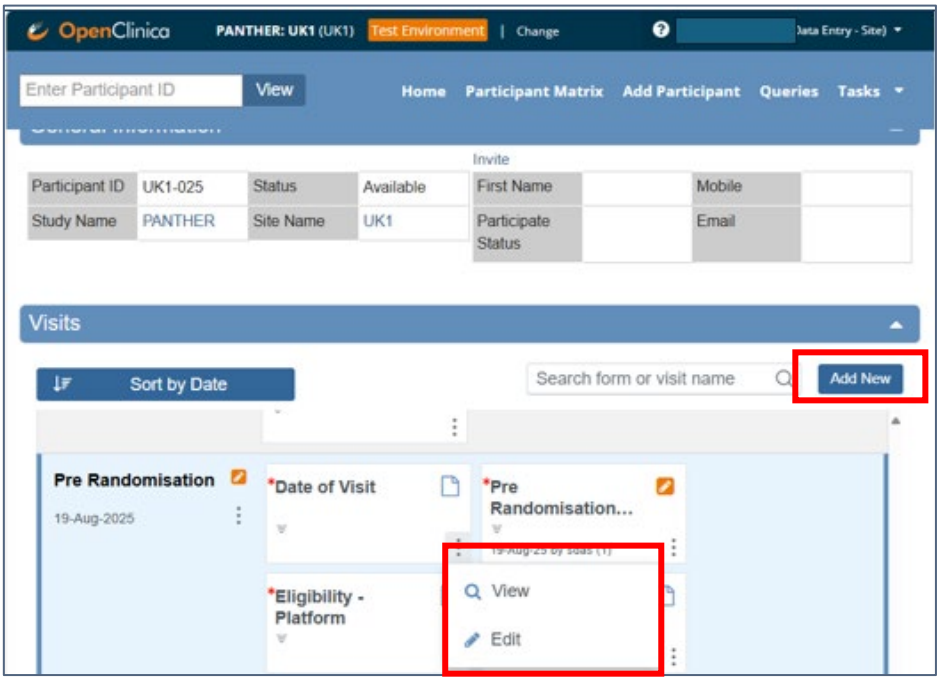
When a form is 'Closed' the data in the form is saved however you can enter back into the form and change the data without having to enter a reason for this data change.

When the form is 'Completed' the data is saved, when the form is opened again it will be in 'Review Mode' and if you would like to change data, please refer to section 3.4 and 3.5 of this manual: Adding Data and Resubmitting/Modifying Subject Information.

4. Entering data

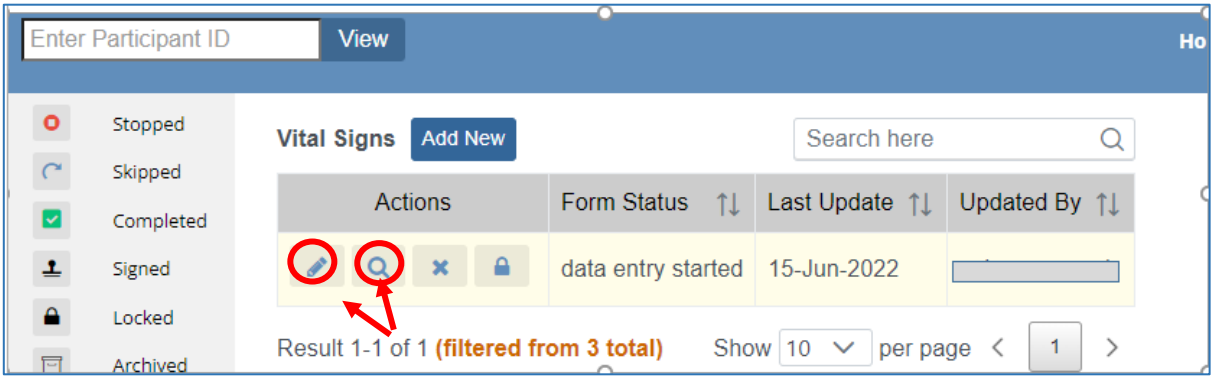
4.1 Data Entry Directly into a Form

1. Click the **Add New** button to add a form associated with the Event. This will open the form directly for you to document.
2. Click the **Edit** button in the **three dots** menu to open the form.
3. Enter information into each field.



Alternatively

- Click on the pen icon to enter or edit data in the form.
- Click on the magnifier to view data in the form.



When you select the 'Pen Icon', the CRF form opens and you can start to enter data. Please fill in the entire form. When you have finished entering data, you can close the CRF Form and continue to enter data later or select '**Next'** or **'Complete'**

If you forget to enter data in at least one mandatory field, when you click 'Complete', the section will highlight in pink and you will receive an error message alert: **This field is required.**

4.2 Navigating Between Forms

If you click **Next**, the system will automatically move you to the next page in the event form when it finishes saving the data. If you click **Back** you will go back to the previous section of the CRF. Closing the form saves all changes made.

4.3 Marking the CRF Complete

The CRF must be marked complete, after finishing data entry for the complete CRF. When all sections (of an event) are complete, select '**Complete**'.

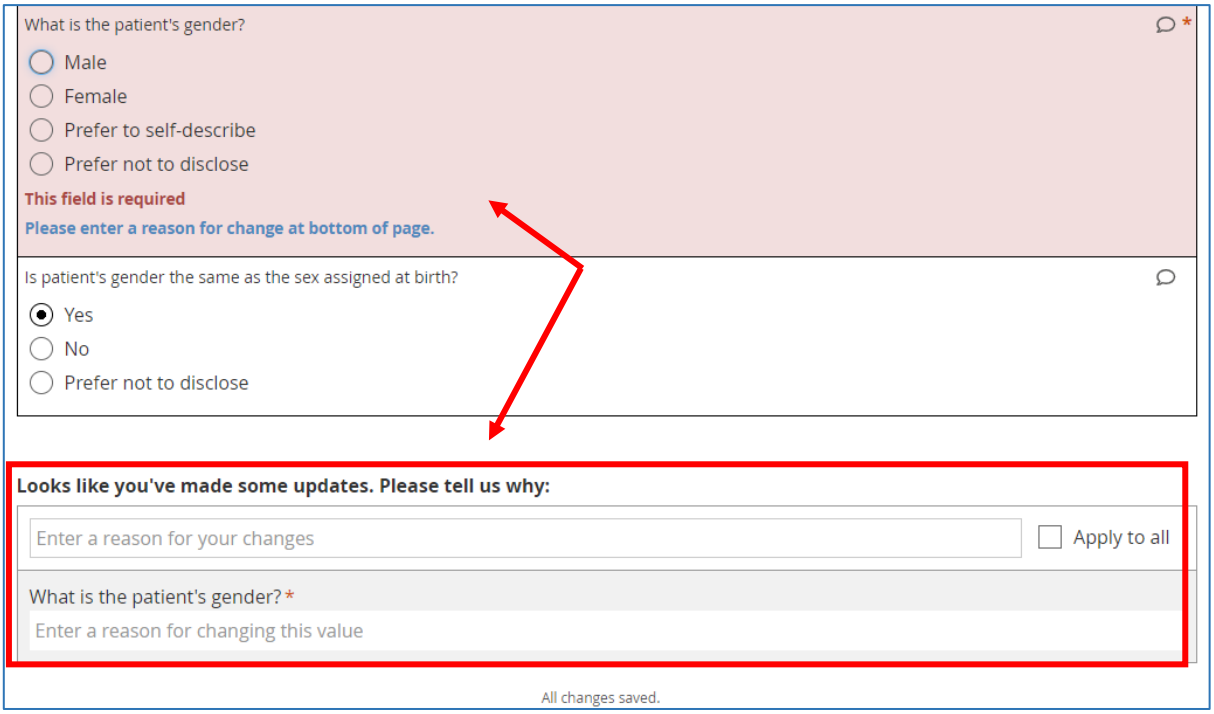
NOTE: Please only mark the form as 'Complete' when all the missing data has been entered. A query will only be raised when the form is marked as complete, so make sure you are happy with all the data before clicking complete.

This will change the status of the CRF from 'Data Entry Started' to 'Complete'. The Status of the CRF will remain complete, even if the data is changed afterwards.

4.4 Changes made to a CRF Form after being marked Complete

If you make any changes to the data after it has been marked complete, an alert occurs and you will be required to enter a note indicating the reason for change at the bottom of the form.

Complete both fields



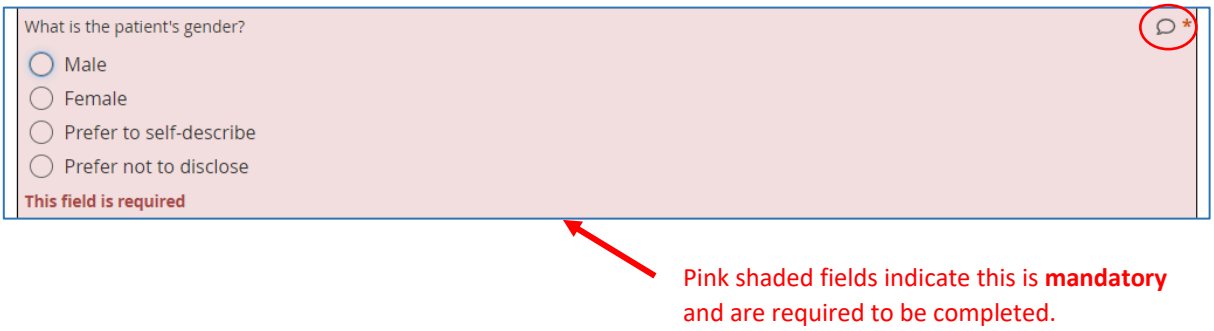
The Rights group roles that can perform data entry in OpenClinica are:

- Data Entry - Study
- CI
- PI
- Data Entry - Site

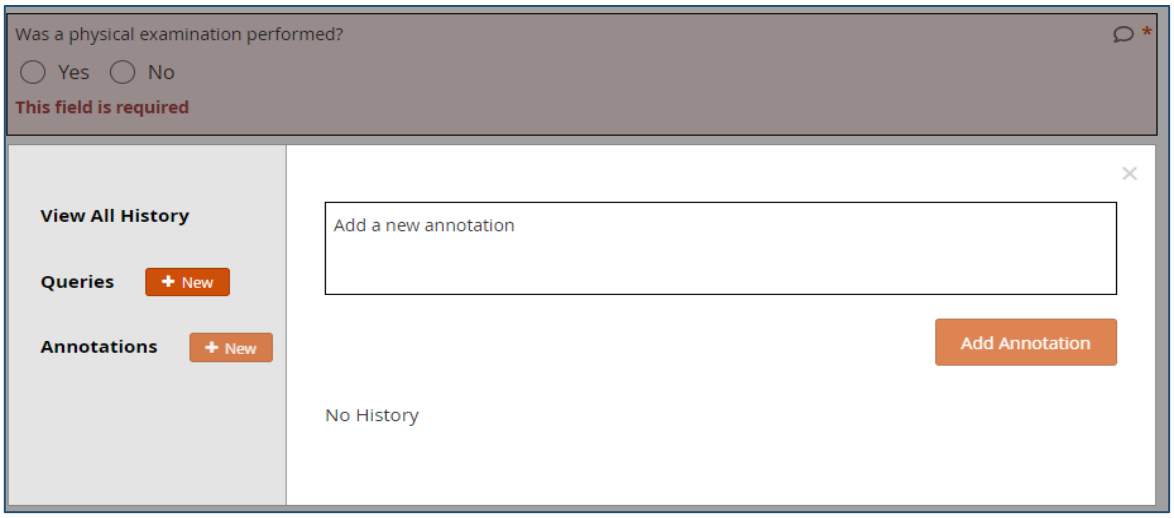
4.5 Specific Field Types:

4.5.1 Mandatory Fields

All mandatory fields will need to be completed – these fields will remain shaded with a pink background after the form has been submitted until they are completed. If any data are permanently missing because it is not done, unknown or not applicable, the site must click on the comment bubble icon and add an **'annotation'** in order to indicate this Although this site should make every effort to complete mandatory fields wherever possible.



An annotation is added to a field to make a note and keep track of workflow.



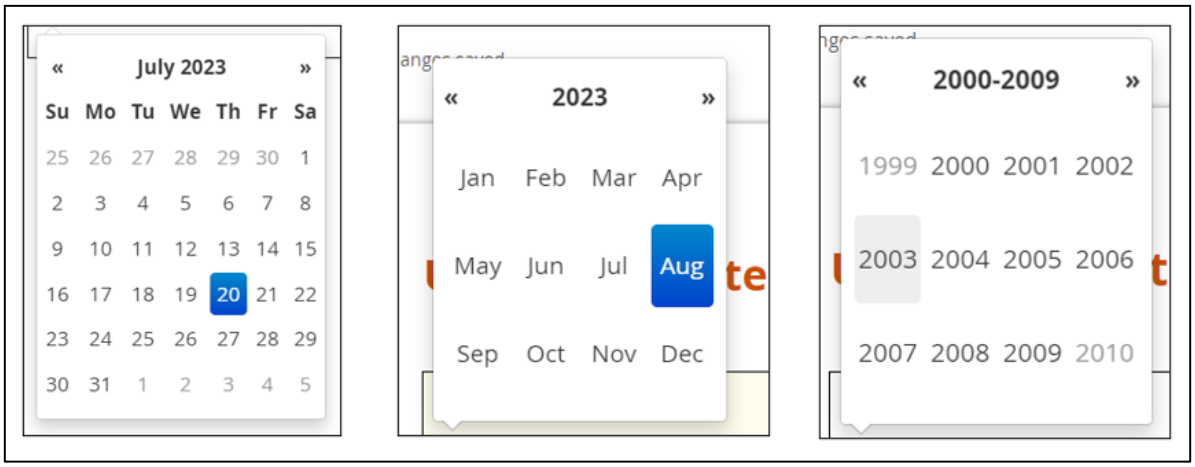
4.5.2 Empty non-mandatory fields

If for any reason a field is blank for any of the regular fields, within this field will be a comment bubble icon and add an annotation.

4.5.3 Date Fields

All date parts of the DATE field must be completed wherever possible, but there may be instances where this may not occur. Some dates are set up to allow partial dates to be entered. Where a date field is unknown, this should be entered on the system. Your study requirements will have pre-defined date formats where applicable on the CRF forms.

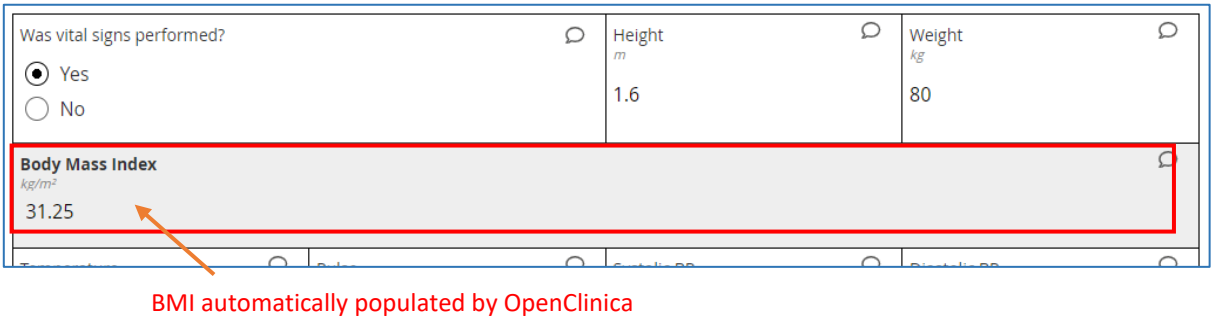
All date fields will be in the yyyy-mm-dd format. This can be either typed in or entered using the drop-down calendar, this appears automatically when you click on the date. Click on the month on top to move see all



months in that year and click on the year to see all years in that decade, the arrows on the sides can be used to move between decades or months.

4.5.4 Auto Calculate

You may see a field that does not have an area for you to enter data, but instead is a blank greyed out space. This is an auto calculated field i.e. either a mapping field from another entered field or a calculated field. When you enter the information, the system will take some of the information recorded and uses a formula to calculate a response for that field. You do not have to do anything except enter the data in the provided fields and submit.

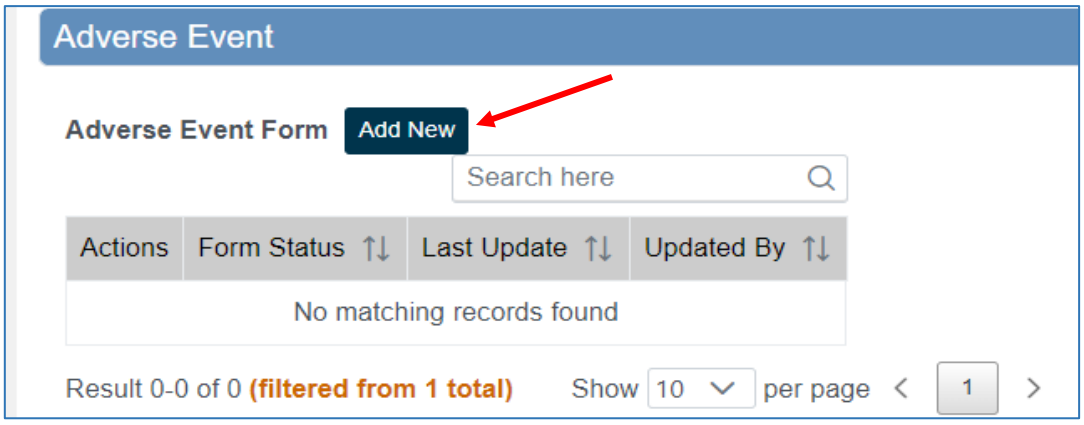


Data Entered and Saved - BMI has been calculated from entered height and weight.

4.6 Repeating Forms

Repeating Events are used for entering multiple records of data into the same form i.e., Adverse Events.

When you first access a repeating form, you will see an empty summary. Click the **Add New** button to access the questions and create one form for entry.



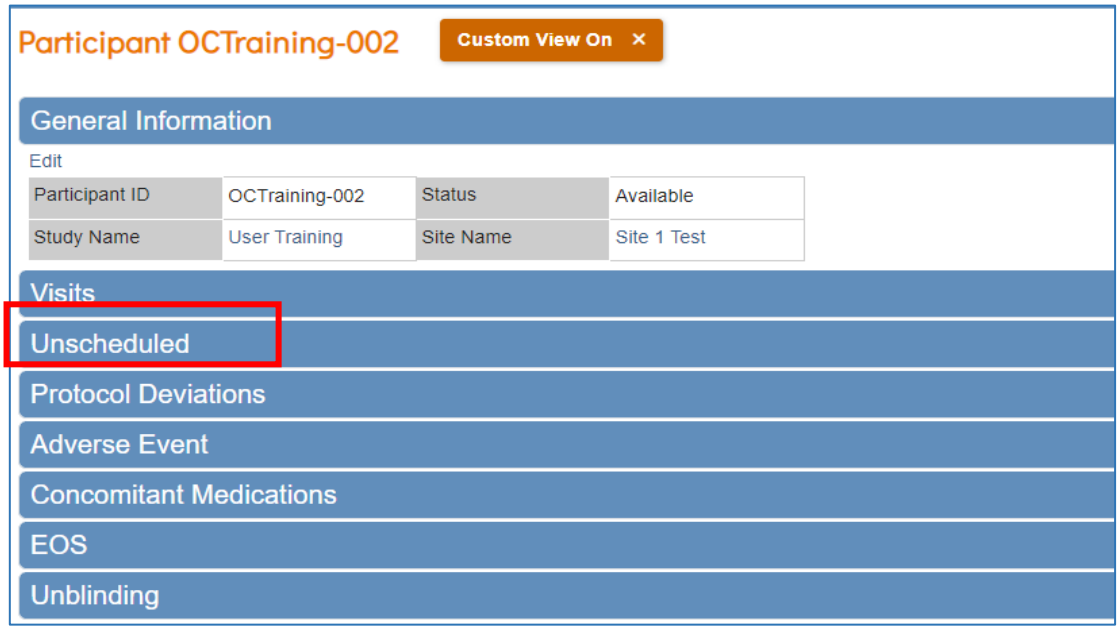
Once you have completed the questions on the form, click the **Complete** button to save the data.

The saved record will then appear on the summary entries.

Create new, additional forms by clicking on the '**Add New'** button for additional entries as needed.

4.7 Adding Unscheduled Events

If an unscheduled event is required to be added; the '**Participants Details** include an unscheduled section.



Navigate to an unscheduled visit for the participant, if the subject does not have any unscheduled visits, in the content pane, click '**Add New'** to display a blank event at the bottom of the page.

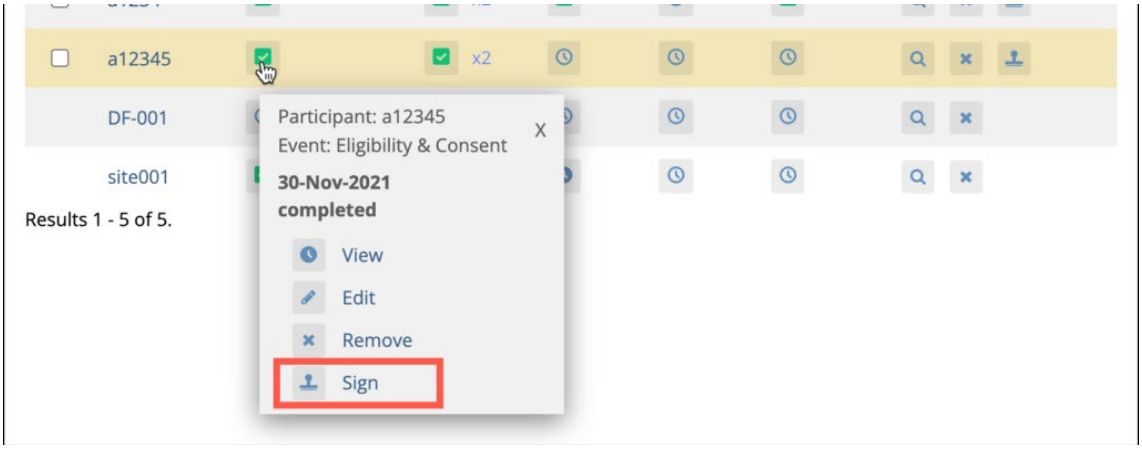
4.8 Signing Pages

After data entry of a CRF is completed, reviewed and all discrepancies are resolved, a PI (person of the site having the 'Investigator' rights in OpenClinica) must sign the CRF. When the PI signs an Event, they provide their approval of all CRF data for the CRF for the participant. CRFs are eligible for signature once the Study Events are in a "final" state i.e. (*Not Scheduled, Complete, Stopped, or Skipped)*

Please Note: If you update a signed form with a data update, OpenClinica will invalidate the previous signature and update the signature listings and each form to indicate that the form or case report book must be signed again.

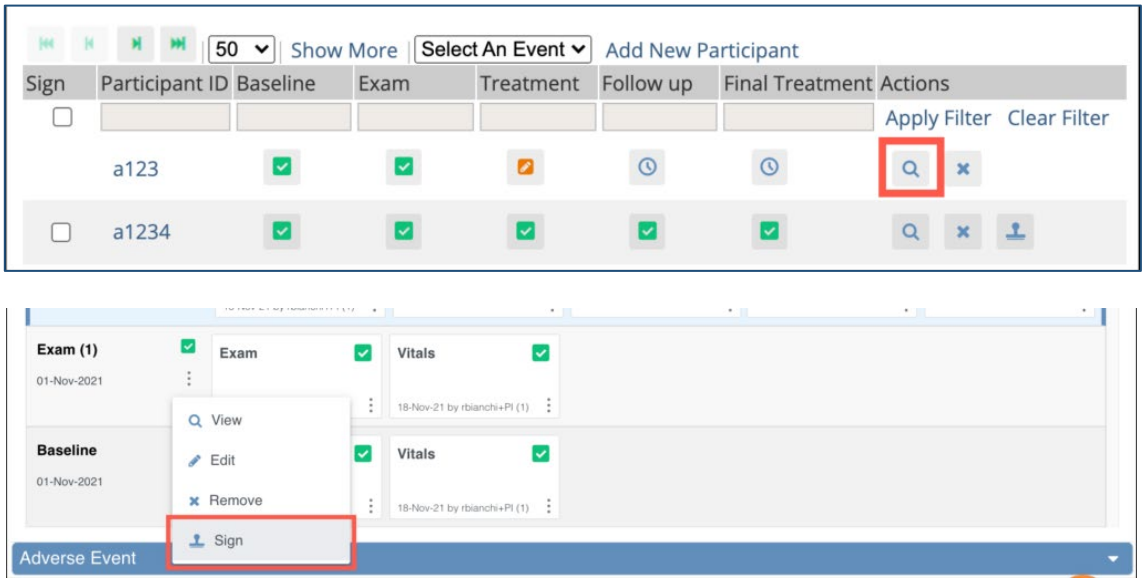
To sign a study event

- Go to the **Participant Matrix**, then click the **Event** you want to sign.
- Select **Sign** from the drop-down list (**Sign** only appears if the event is in a final state as stated above).

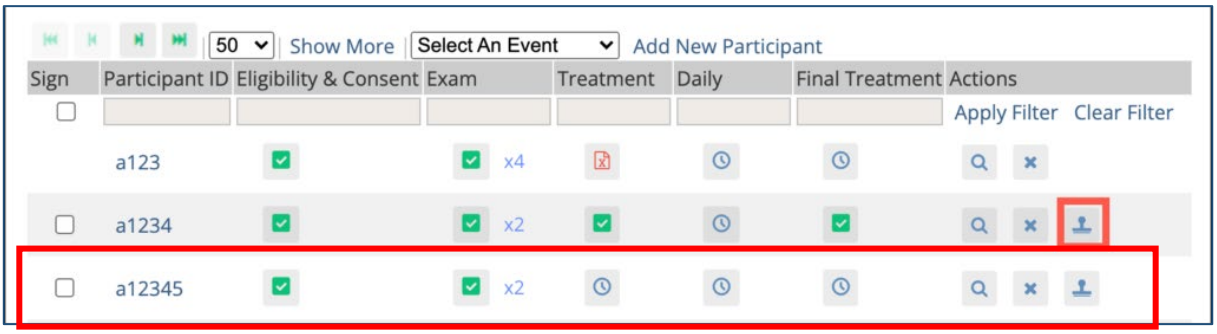


Or

- Click the **View** icon for the participant with an event you want to sign
- Find the **Event** you want to sign, and select **Sign** in the **Actions** drop-down list



If all Events for a participant are in a final state *(Not Scheduled, Completed, Stopped, or Skipped),* then the entire participant record can be signed.

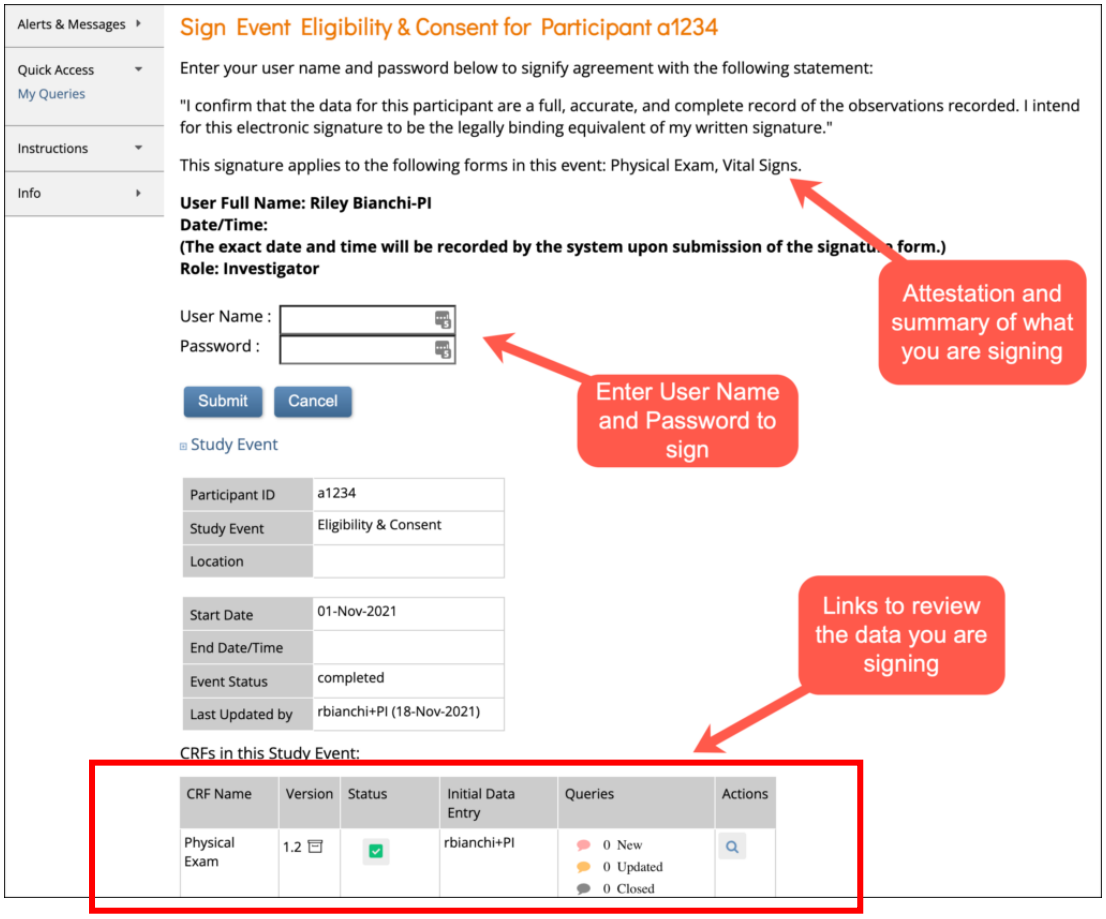


The Electronic signature screen appears.

Electronic signatures in OpenClinica are considered a legal signature and verification of the attestation provided. Signatures are applied through the use of an OpenClinica account and its associated username and password, so keep this information secure.

1. The **Electronic Signature** screen includes an attestation, your full name, a listing of the records you are signing, and a prompt to enter your username and password.
2. Scroll to the bottom of the page to see a list of forms in the Event and the status of queries for each of those Forms:

Enter your username and password and click **Submit** to complete the electronic signature process.



4.9 Manual Randomisation

Manual randomisation will be done on a case-by-case basis, if OpenClinica is down please contact the sponsor team/ monitor at pantheruk@imperial.ac.uk and we will advise you on the next steps.

5. Query management

5.1 Answering System Queries

Once data entry has been performed and you click the '**Complete'** button, the system compares the data to the system queries associated with the page. The system creates queries automatically if you close a form that has unaddressed errors. You can also manually create queries as needed.

There are two options to respond to this query.

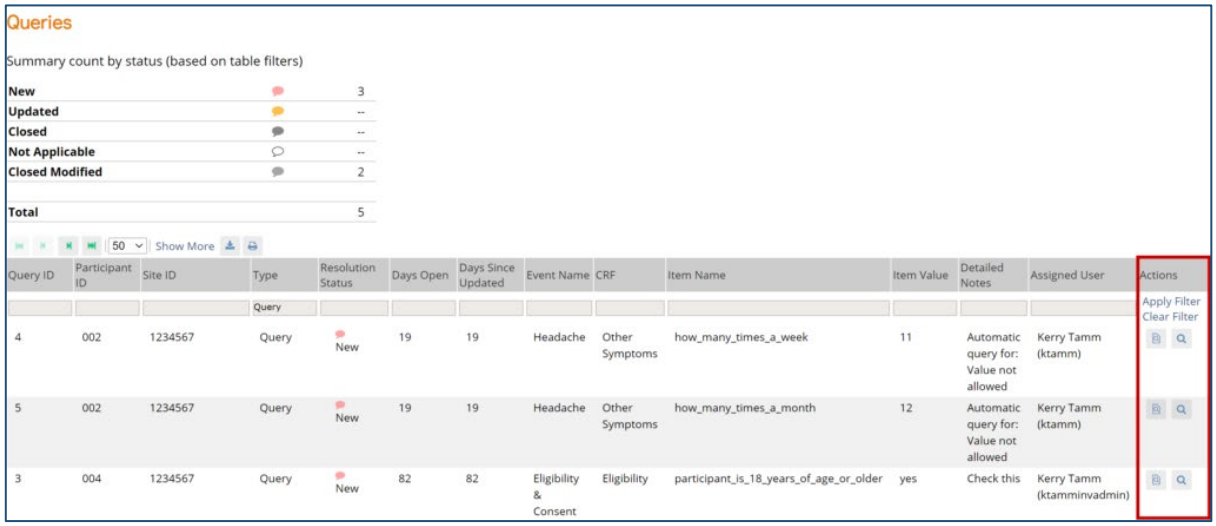
1. If the data was entered incorrectly, you can modify the data. If the updated data no longer meets the query conditions, the query will automatically close.
2. You can respond to the query with an explanation as to why the data is correct as entered. Query will then change to an "**Updated**" status.

To review data associated with a query You can either:

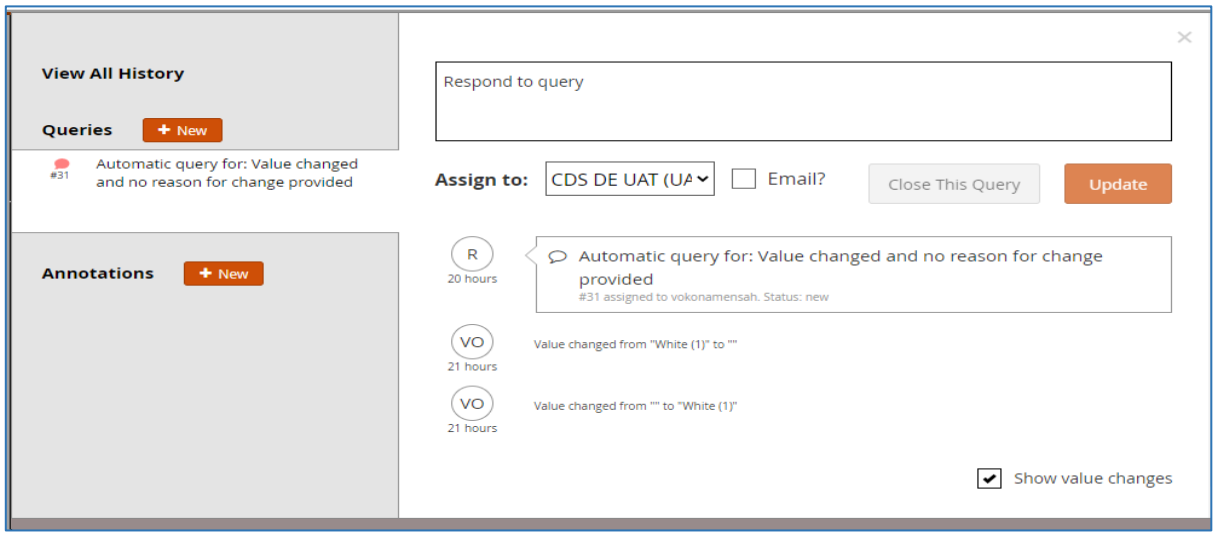
View Query Only

View Query within record

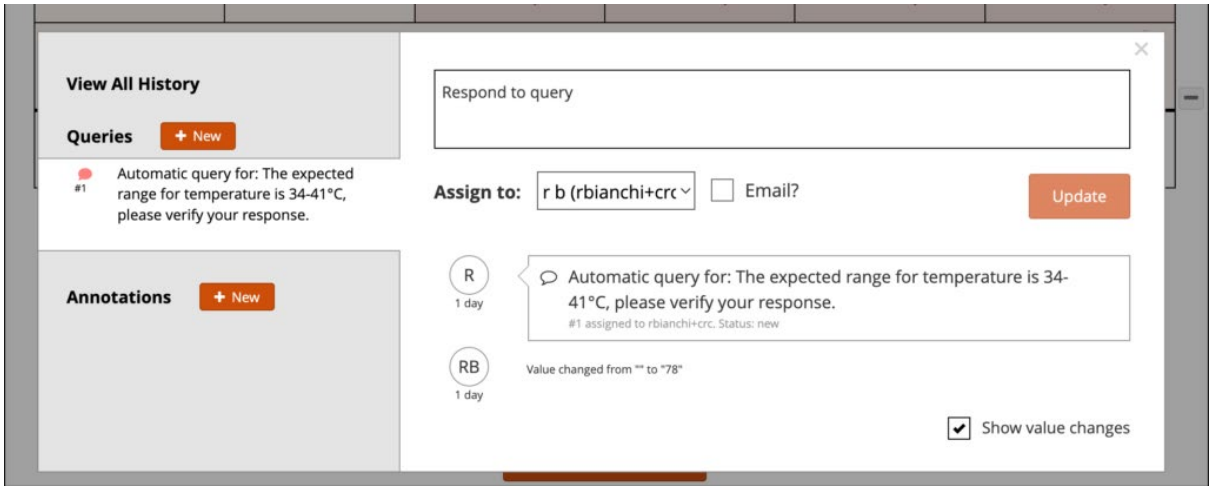
You can access these options from the **Actions** column of the **Queries** table



View Query Only



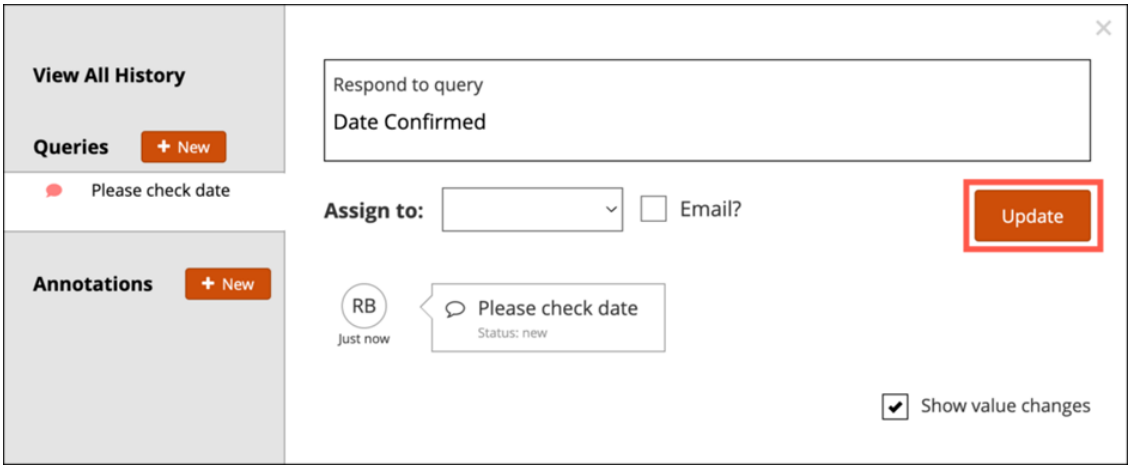
View Query Within Record



 Icon – indicates an Open query.

5.1.1 Answering System Queries: Modifying Data

- Open a Form.
- Click the **Query Bubble** in the field you want to create a query for.
- Select the query you want to respond to and/or update.
- If you need to change information in a form, close the **Query** widget, and make changes to the Form manually. You must provide a **Reason for Change** before completing the Form (Optional).
- In the **Respond to query** field, enter text explaining the query response.
- Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access (Optional)
- Click the **Update** button to add the response and leave the query open.

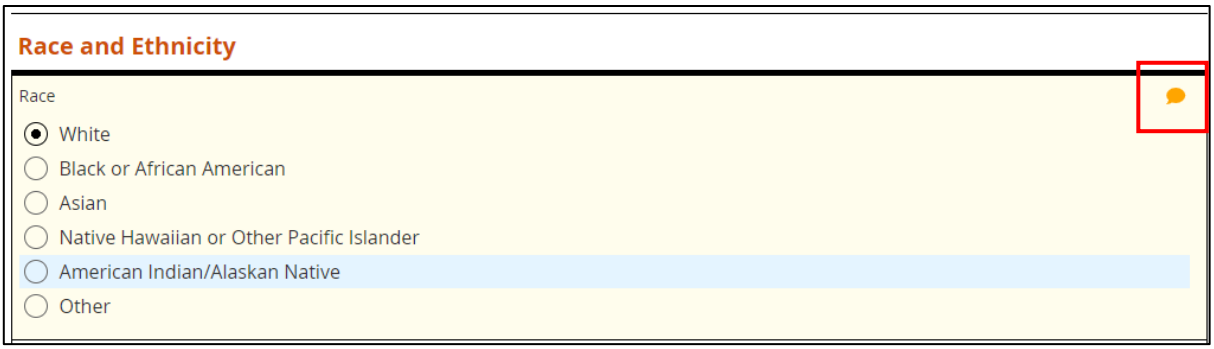


5.1.2 Answering System Queries: Providing an Explanation

If the data is correct as entered, you can respond by providing more details either by responding to the query and/or updating the field, and the query status will change. Click the **'Update'** button.

 Icon – indicates an Updated query.

Query status is now changed to **Updated.**



5.1.3 Answering Queries: Other Query Types

Manual Queries are entered by OpenClinica users that have permission rights, for example, a Monitor. Therefore, they do not open as an automatic query when the page is saved but may appear at any time during the conduct of the study. You have the same options to respond – to change the data or to provide an explanation. You will be required to respond to each of these queries.

6. Study specific guidelines

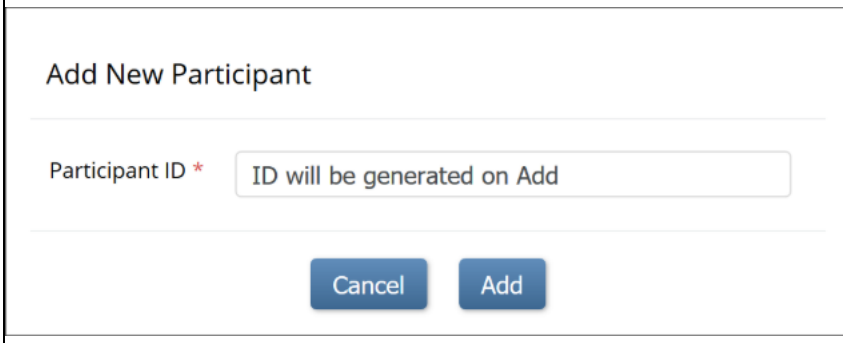
Please refer to section *Events (Visits)* for the schedule of visits for the study.

Adding a New Participant

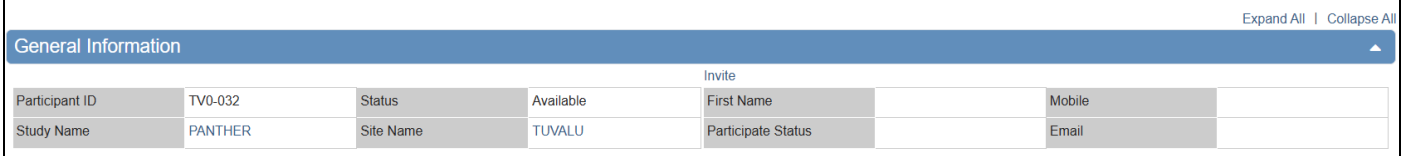
Click on '**Tasks'** in the Navigation Bar and then select **'Add Participant'**

To add a participant automatically:

1. Set the **Method of Creation** field to **System-generated** (see above).
2. From the **Tasks** menu, select **Add Participant,** or on the **Participant Matrix** screen, click **Add New Participant** above the matrix.
3. Click the **Add** button in the **Add New Participant** screen to generate a Participant ID.



Once your participant is added you will be directly brought to the participant page:



The participant page shows the patients ID at the top. This is the page where all study data for this particular patient will be added.

For this study the database will also act as the screening log. Both eligible and screened patients should be added.

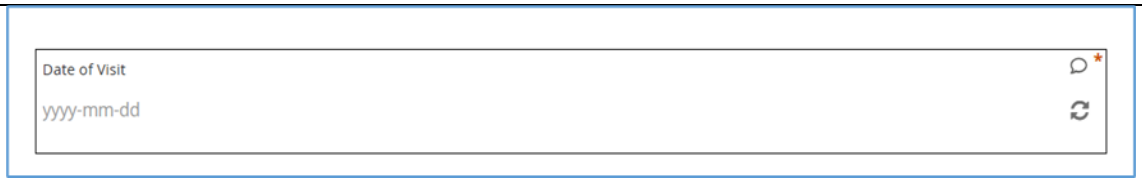
6.1 Schedule Pre-randomisation Event

Pre Screening Event

When entering data in this visit, it is important that each form is completed in order before the patient is randomised. If they are not completed in sequential order the randomisation may not be successful.

Date of Visit

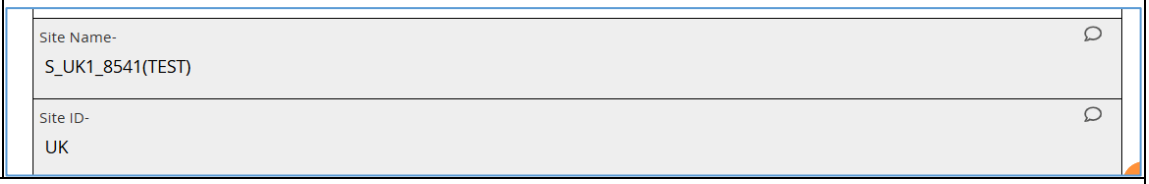
To begin screening navigate to the Date of Visit form



Enter the date screening completed. Screening should be completed **on the same day** as randomisation.

Click on 'Close' or 'Complete' to save the data.

Note – if close is selected, changes can be made and the form can be completed later. If complete is selected, any changes will require a reason for the changes.

Pre-Screening	
Month and Year of Birth	- Enter participant's Month & Year of Birth
Age	- The Age is auto populated on the system once the Month & Year of Birth and Date of Visit has been entered.
What is the participant's sex?	- Enter the sex of participant. **<u>If Participant is Female –</u>** - Indicate Yes or No whether a pregnancy test has been completed during this hospital admission - If No – Patient cannot be randomised and you would need to contact the study team - If Yes - Enter Date of Pregnancy Test - Select Result of Pregnancy Test – If Positive is selected this should be confirmed. -
Was a chest x-ray done?	- Indicate Yes or No whether a Chest x-ray was done - If Yes – Select the category of chest x-ray - If No - Patient cannot be randomised and you would need to contact the study team - If category of chest x-ray is 'Unilateral' or 'Normal' – Patient cannot be randomised, and you would need to contact the study team - Site Name & Site ID – is Read only and mapped from site details initially entered. 

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.

- **When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised.**

6.2 Eligibility – Platform form

Inclusion Criteria
The patient must meet the definition of ARDS prior to randomisation. Each criterion must be met within the same 24hrs. The date and time that the criteria is met should be entered. **All points on the eligibility form must be completed for correct randomisation**

YES, must be selected for ALL Inclusion Criteria for patient to be eligible for randomisation. Please make sure to fill in all of the data on the form or a query will be raised.	
Critically ill patients in hospital and the following: - **a) Acute respiratory distress syndrome (ARDS)***	- Indicate Yes or No whether the patient is critically ill in hospital with ARDS - If No – Participant should be excluded and will automatically be added to the screening log. - If Yes – complete the next inclusion question - *Please note participant must have been diagnosed within the last 48hrs*
***ARDS as defined by**	*(i) a known acute clinical insult or new or worsening respiratory dysfunction, and* *(ii) receiving respiratory support via invasive mechanical ventilation or non-invasive ventilation including continuous positive airway pressure, or high-flow nasal oxygen ≥30L/min and* *(iii) Within the same 24-hour time period:* *• bilateral opacities on chest imaging not fully explained by effusions, lobar/lung collapse/atelectasis, or nodules, and* *• respiratory failure not fully explained by cardiac failure, fluid overload, pulmonary embolism, acute airways disease, or interstitial lung disease and,* *• PaO2/FiO2 ratio ≤40 kPa from arterial blood gases, or SpO2/FiO2 ≤300 from pulse oximetry where SpO2 ≤97.* - Indicate Yes or No whether the patient fits the ARDS definition described - If No – Participant should be excluded and will be added to the screening log. - If Yes – complete the next inclusion question
The date of onset of ARDS is when the last criterion in (iii) is met	- Enter date of onset of ARDS from when the last criterion (iii) is met
The time of onset of ARDS is when the last criterion in (iii) is met *format (hh:mm [0-23] hrs [0-59] min)*	- Enter time of onset of ARDS from when the last criterion (iii) is met
Exclusion Criteria	
NO, must be selected for ALL Exclusion Criteria for patient to be eligible for randomisation. If Yes is selected participant is added to the screening log on the database.	
>48 hours from diagnosis of ARDS	- Indicate Yes or No whether it has been more than 48 hours since the patient's ARDS diagnosis - If Yes – Participant should be excluded and will be added to the screening log. - If No – complete the next exclusion question
Planned withdrawal of life-sustaining treatment within the next 24 hours	- Indicate Yes or No whether there is planned withdrawal of life-sustaining treatment within the next 24 hours - If Yes – Participant should be excluded and will be added to the screening log. - If No – complete the next exclusion question
Previous enrolment in the PANTHER	- Indicate Yes or No as to whether the patient has been enrolled in PANTHER within the last 12 months

trial in the last 12 months	- If Yes – Participant should be excluded and will be added to the screening log. - If No – complete the next exclusion question -
Declined consent	- Indicate Yes or No as to whether the patient/surrogate/legal representative has declined consent to take part in the PANTHER trial - If Yes – Participant should be excluded and will be added to the screening log. - If No – complete the final eligibility check
Final Eligibility Check	
Is the subject eligible to participate in the study?	- This question is auto populated once all questions are complete and depending on the answers to the inclusion and exclusion criteria.
Please specify	- Only appears if answer to above question is 'No'. - Please specify whether the inclusion or exclusion criteria was violated. Participant will not be eligible to participate in the study and cannot proceed with randomisation
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - **When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised**.	

6.3 Eligibility – Simvastatin form

Inclusion Criteria	
All points on the eligibility form must be completed for correct randomisation. If an exclusion criterion is met participant will be added to the screening log.	
Is the site participating in this intervention?	- Indicate Yes or No whether your site is participating in the Simvastatin intervention. - If No – select 'Close' or 'Complete'. - If Yes – complete the exclusion criteria questions.
Exclusion Criteria	
- Indicate Yes or No for all exclusion criteria. If any is answered Yes, participant has failed the exclusion and should be confirmed	
Aged <18 years	- This will auto-populate - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question
Patient is known to be pregnant	- This will appear if the patient is female as indicated on the 'pre-screening form. - Indicate Yes or No to whether the patient is known to be pregnant
Creatine kinase >10 times the upper limit of the normal range	- Indicate Yes or No whether the patient's Creatine kinase is greater than 10 times the upper limit of the normal range. The actual result must be checked/confirmed before randomisation. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question

Liver transaminases >8 times the upper limit of the normal range	- Indicate Yes or No whether the patient's Liver transaminases is greater than 8 times the upper limit of the normal range. The actual result must be checked/confirmed before randomisation. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Currently receiving ongoing treatment with any of the following: itraconazole, ketoconazole, HIV protease inhibitors, nefazodone, cyclosporine, amiodarone, verapamil, or diltiazem.	- Indicate Yes or No whether the patient is receiving any of the listed ongoing treatments with any of the following medications - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Severe renal impairment (eGFR < 30mL/min and not receiving renal replacement therapy).	- Indicate Yes or No whether the patient has severe renal impairment (eGFR < 30mL/min and not receiving renal replacement therapy). - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Current or recent treatment (within 2 weeks) with statins	- Indicate Yes or No whether the patient is currently or recently been treated with statins within 2 weeks. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Physician decision that a statin is required for proven indication	- Indicate Yes or No whether a physician has decided that a statin is required for proven indication - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Contraindication to enteral drug administration, e.g., patients with mechanical bowel obstruction. Patients with high gastric aspirates due to an ileus are not excluded	- Indicate Yes or No whether the patient has a contraindication to enteral drug administration - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Known hypersensitivity to simvastatin	- Indicate Yes or No whether the patient has a known hypersensitivity to simvastatin - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question

Any other medical condition or treatment that, at the clinical discretion of the investigator, is considered not in the participants best interest to start treatment with the IMP based on the approved version of the IMP SmPC	- Indicate Yes or No whether any other medical condition or treatment, in the investigator's clinical judgment, makes initiating the IMP (per the approved SmPC) not in the participant's best interest. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
***US Only** **Any other medical condition or treatment that, at the clinical discretion of the investigator, is considered not in the participants best interest to start treatment with the IMP based on the approved version of the IMP SmPC. In the US this specifically refers to the exclusion of the concomitant use posaconazole, erythromycin, clarithromycin, telithromycin, gemfibrozil, amlodipine, ranolazine or of all strong CYP3A4 inhibitors with simvastatin is contraindicated.**	- Indicate Yes or No whether any other medical condition or treatment, in the investigator's clinical judgment, makes initiating the IMP (per the approved SmPC) not in the participant's best interest. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion question
Consent declined for intervention	- Indicate Yes or No whether consent has been declined - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Final Eligibility Check	
Is the participant eligible to participate in the intervention?	- This question is auto populated once all question are complete and depending on the answers to the inclusion and exclusion criteria.
Please specify	- Only appears if answer to above question is 'No'. - Please specify which criteria was violated. Participant will not be eligible to participate in the study and cannot proceed with randomisation
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.	

- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised.

6.4 Eligibility – Baricitinib form

Inclusion Criteria	
All points on the eligibility form must be completed for correct randomisation. If an exclusion criterion is met participant will be added to the screening log.	
Is the site participating in this intervention?	- Indicate Yes or No whether your site is participating in the Baricitinib intervention. - If No – select 'Close' or 'Complete'. - If Yes – complete the exclusion criteria questions.
Exclusion Criteria	
- Indicate Yes or No for all exclusion criteria. If any is answered Yes, participant has failed the exclusion and should be confirmed	
Aged <18 years	- This will auto-populate - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Patient is known to be pregnant	- This will appear if the patient is female as indicated on the 'pre-screening form. - Indicate Yes or No to whether the patient is known to be pregnant
Neutrophil count less than (0.5x109/L) at the time of the eligibility assessment	- Indicate Yes or No whether the patient has a neutrophil count less than (0.5x109/L) at the time of the eligibility assessment. The actual result must be checked/confirmed before randomisation. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Liver transaminases >8 times the upper limit of the normal range	- Indicate Yes or No whether the patient's liver transaminases is greater than 8 times the upper limit of the normal range. The actual result must be checked/confirmed before randomisation. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Currently receiving ongoing immunosuppressants (high-dose corticosteroids, T-cell-targeted or B-cell-targeted therapies, interferon, or JAK inhibitors)	- Indicate Yes or No whether the patient is currently receiving ongoing immunosuppressants - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Severe renal impairment (eGFR < 15mL/min) or receiving renal replacement therapy	- Indicate Yes or No whether the patient has severe renal impairment (eGFR < 15mL/min) or is receiving renal replacement therapy - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.

Known active tuberculosis infection or, if known, latent TB treated for less than 4 weeks with appropriate anti-tuberculosis therapy per local guidelines.	- Indicate Yes or No whether the patient has known active tuberculosis infection or, if known, latent TB treated for less than 4 weeks with appropriate anti-tuberculosis therapy per local guidelines. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Known hypersensitivity to baricitinib	- Indicate Yes or No whether the patient has a known hypersensitivity to baricitinib - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Breast feeding	- This will auto populate if female has been selected on the pre-screening form. - Indicate Yes or No whether the patient is breast feeding
Known herpes zoster virus, hepatitis B virus, hepatitis C virus or human immunodeficiency virus (HIV)	- Indicate Yes or No whether the patient has a herpes zoster virus, hepatitis B virus, hepatitis C virus or human immunodeficiency virus (HIV) - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Any other medical condition or treatment that, at the clinical discretion of the investigator, is considered not in the participants best interest to start treatment with the IMP based on the approved version of the IMP SmPC.	- Indicate Yes or No whether any other medical condition or treatment, in the investigator's clinical judgment, makes initiating the IMP (per the approved SmPC) not in the participant's best interest. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
***US Only** **Any other medical condition or treatment that, at the clinical discretion of the investigator, is considered not in the participants best interest to start treatment with the IMP based on the approved version of the IMP SmPC. In the US this specifically refers to the exclusion of including an absolute lymphocyte count less than 0.2x 10^9/L.**	- Indicate Yes or No whether any other medical condition or treatment, in the investigator's clinical judgment, makes initiating the IMP (per the approved SmPC) not in the participant's best interest. - If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Consent declined for an intervention	- Indicate Yes or No whether consent has been declined

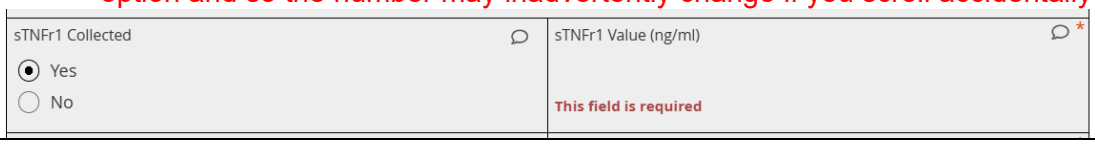
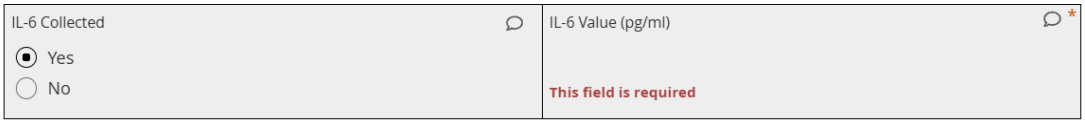
	- If Yes – Participant has failed exclusion and will be added to the screening log. - If No – complete the next exclusion criteria question.
Final Eligibility Check	
Is the participant eligible to participate in the intervention?	- This question is populated automatically once all question are complete and depending on the answers to the inclusion and exclusion criteria.
Please specify	- Only appears if answer to above question is 'No'. - Please specify which criteria was violated. Participant will not be eligible to participate in the study and cannot proceed with randomisation
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised.	

6.5 Initial Consent form

Initial Consent	
Refer to your Human Research Ethics Committee (HREC)/Institution Review Board (IRB) approval to determine the consent practices you should follow. In most jurisdictions to participate in the study, agreement must be obtained. Only patients who meet all inclusion criteria and none of the exclusion criteria will be randomised.	
Has consent been obtained before randomisation?	- Indicate Yes or No whether consent has been obtained prior to randomisation. - If 'Yes' is selected you will be advised to complete the details in the Consent Form within the Baseline Event. - If No is selected, you will need to complete the consent refused question.
Has consent been refused?	- If 'Yes' – you will be asked who refused consent. - If 'No' – you will need to complete the delayed consent question.
Confirm if delayed consent is allowed in the country?	- Indicate Yes or No whether delayed (also known as deferred in the UK) consent is allowed in the country. *If unsure, please reach out to your country specific study team.* - If 'Yes' – you will be asked to ensure consent is obtained and entered on the Baseline Event. - If 'No' – the participant cannot be randomised.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised.	

6.6 Phenotyping

Phenotyping Form	
Patients will be stratified into different sub-phenotype strata prior to randomisation.	
Was phenotyping completed?	- Indicate Yes or No whether phenotyping was completed, a patient cannot be randomised without phenotyping - If phenotyping is not possible, please select 'no' and the following options will appear:

	• Assay run failed • Kit expired • Kit not received • Software outage • Delay due to courier • Courier service failures • Needs engineer visit • Other *If 'other' is selected a text box will appear to capture other reasons not listed here.* *If one of these options is selected, the patient will not be randomised and considered a screen failure. These incidences will be monitored throughout the trial* If Yes – complete the next phenotyping question
Device type?	Select the device type for the device that is used: • Randox • Randox-courier • Ella
Date the sub phenotyping was completed	- Enter the date subphenotyping was completed
Time the sub phenotyping was completed **format (hh:mm [0-23] hrs [0-59] min)*	Enter the time subphenotyping was completed using the format described
Bicarbonate - lowest in prior 24 hrs (mmol/L)	- Enter the lowest Bicarbonate value in mmol/L from the previous 24 hrs.
sTNFr1 Collected	- Indicate Yes or No whether the sTNFr1 was collected - If No – Participant cannot be randomised. If Yes – enter the sTNFr1 value in the units requested ng/ml or pg/ml – this will vary depending on the device selected. - Ensure you check the value entered as due to the data point there is a scroll option and so the number may inadvertently change if you scroll accidentally 
IL-6 Collected	- Indicate Yes or No whether the IL-6 was collected - If No – Participant cannot be randomised. If Yes – enter the IL-6 value in pg/ml - Ensure you check the value entered as due to the data point there is a scroll option and so the number may inadvertently change if you scroll accidentally 

	Initial subphenotypes will be hyper- and hypo-inflammatory subphenotypes described in ARDS. The determination of the subphenotype of the participant will be dependent on the sTNFr1 and IL-6 values. *Note – the patient subphenotype will not be displayed on the database.*
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised.	

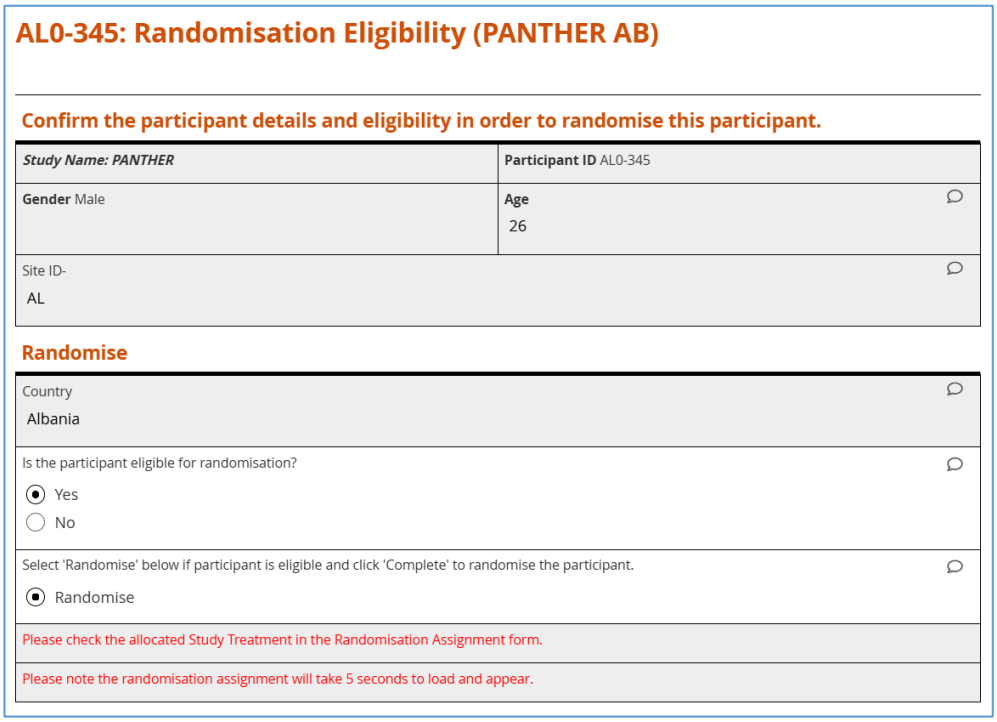
6.7 Schedule Randomisation Event

Schedule Randomisation Event Form	
Ensure all the Pre-Randomisation CRF forms have been completed and in sequential order otherwise you will not be able to complete the Schedule Randomisation Event form.	
Is the participant ready to schedule the Randomisation Events	- Indicate Yes or No whether the patient is ready to schedule the Randomisation Event. If Yes, the patient is ready to be randomised into one of the Randomisation Events. Please navigate back to the main page and the randomisation events will automatically appear. If No, the following options will appear:- o Patient improved o Patient deteriorated o Cannot co-enrol with another study - If any of these options are selected, the patient is not able to be randomised and does not meet the criteria. If the patient is not eligible for the trial the below message will appear. After clicking complete the patient will be added to the screening log. The participant does not meet the criteria for randomisation at this time. Please review. Please Click "Complete"
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.8 Randomisation

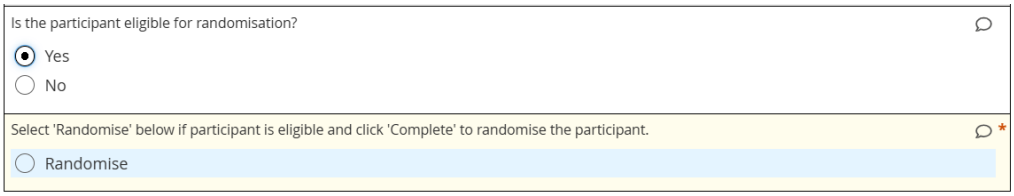
6.8.1 Randomisation Eligibility

Randomisation Eligibility Form
The Randomisation Eligibility form will automatically appear once the schedule randomisation event form has been completed. - For information only one of the following forms will appear: - Randomisation PANTHER A; Randomisation PANTHER AB; Randomisation PANTHER B; Randomisation PANTHER C; Randomisation PANTHER CD; Randomisation PANTHER D. *Note - This is part of the automated randomisation*
- Confirm that the patient details and eligibility to the study is correct before randomising participant. The Study Name, Participant ID, Gender, Age, Site ID and country are auto populated and read only fields mapped from the Pre-Randomisation form previously completed.

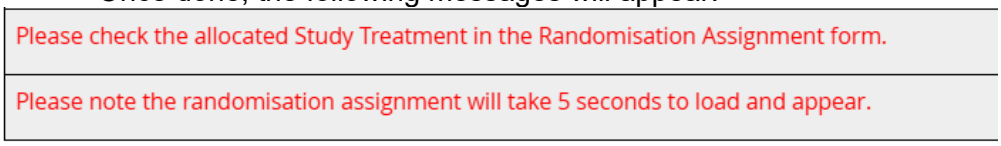


Is the participant eligible for randomisation?

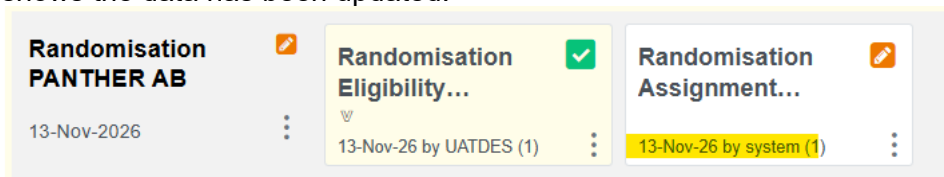
- Indicate Yes or No whether the patient is eligible for randomisation.
- If Yes – Select 'Randomise' radio button if participant is eligible



- Once done, the following messages will appear:



Please note it is important that you wait 5 seconds before opening the Randomisation Assignment form.
Wait until the audit trail appears at the bottom of the assignment form, this shows the data has been updated:-

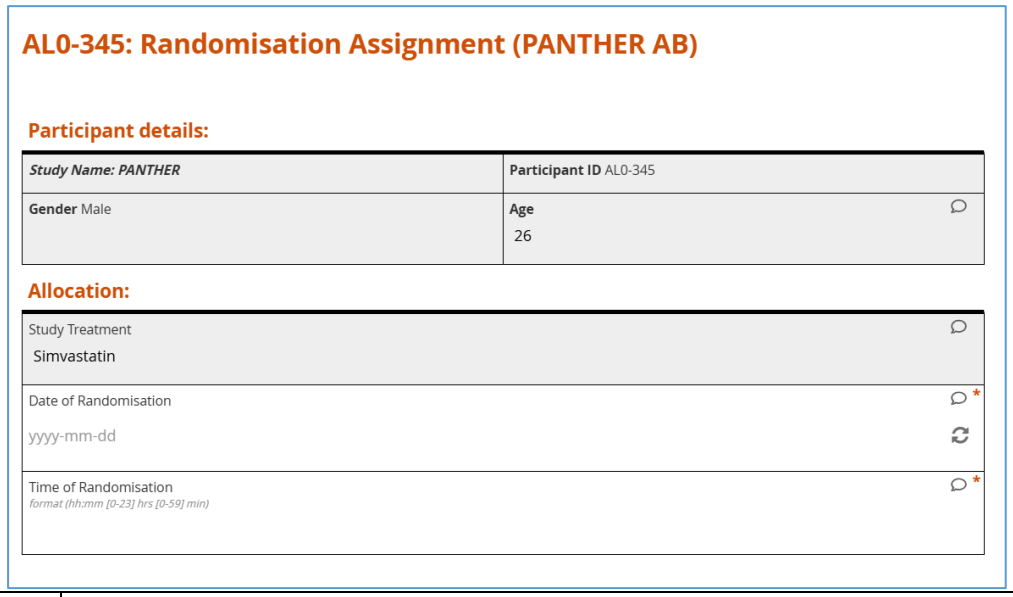


- Click **'Complete'** to randomise the participant. If the patient is not ready to be randomised click **'Close'** to save changes only.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.8.2 Randomisation Assignment

Randomisation Assignment Form

- This form details the allocated study treatment for the participant and will automatically appear.
- The Study Name, Participant ID, Gender, Age and Site ID are auto-populated and read only fields mapped from the Pre-Randomisation form previously completed.
- Study Treatment - Treatment allocation to which the patient is randomised using the Sealed Envelope automated online system.



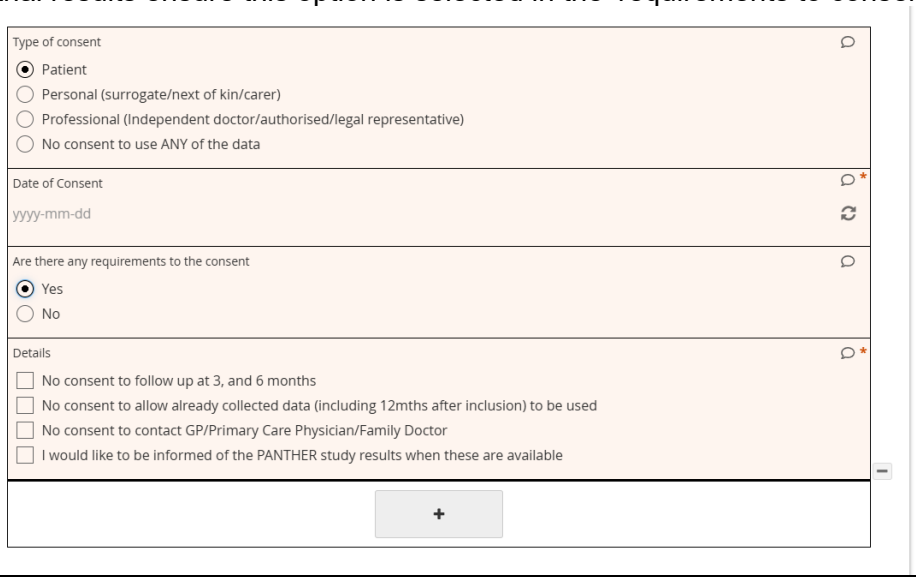
Date of Randomisation	- Enter the Date of Randomisation* - *There are restrictions to these fields to ensure that the current date and time is entered. A date in the past nor a date in the future can be randomised. Please ensure that when you randomise the patient you are able to start the treatment as soon as possible
Time of Randomisation	- Enter the Time of Randomisation

- Click on **'Close'** or **'Complete'** at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

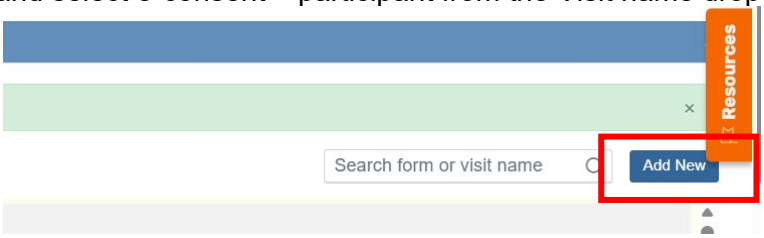
6.9 Schedule Baseline Event

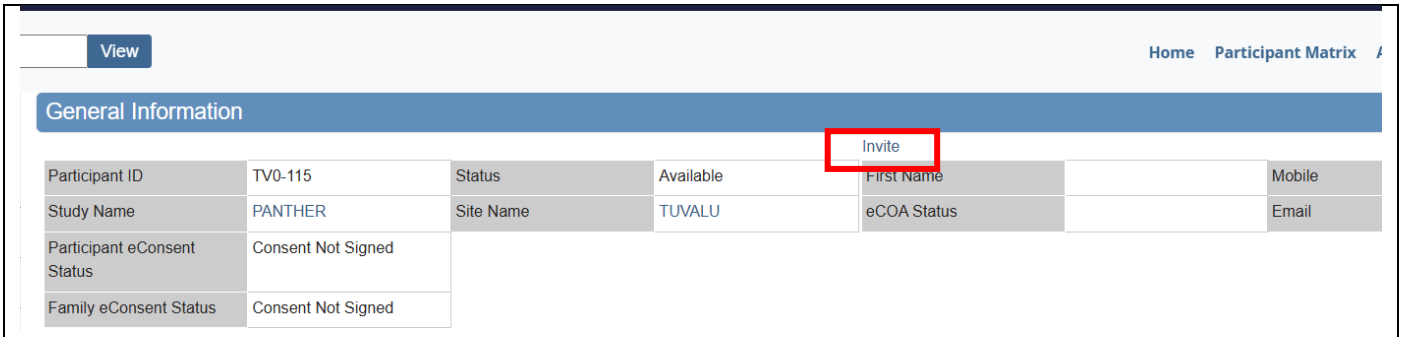
6.9.1 Consent

Consent Form	
Type of consent	Select the type of consent from the following: - Patient - Personal (surrogate/next of kin/carer) - Professional (Independent doctor/authorised/legal representative) - No consent to use ANY of the data - eConsent (UK only) – if eConsent is to be used ensure the eConsent visit is added. All consents must be included, if a professional consent is obtained and a retrospective consent obtained from the patient later, ensure both consent forms are added. To add more consents use the '+' symbol at the bottom.

Date of Consent	- Enter the date the consent was taken
Are there any requirements to the consent	- In the UK ensure yes is selected, if on the consent form certain points have been agreed, such as:- - If on the consent form the patient/family/professional is happy to receive the trial results ensure this option is selected in the 'requirements to consent'. 
- Click on **'Close'** or **'Complete'** at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

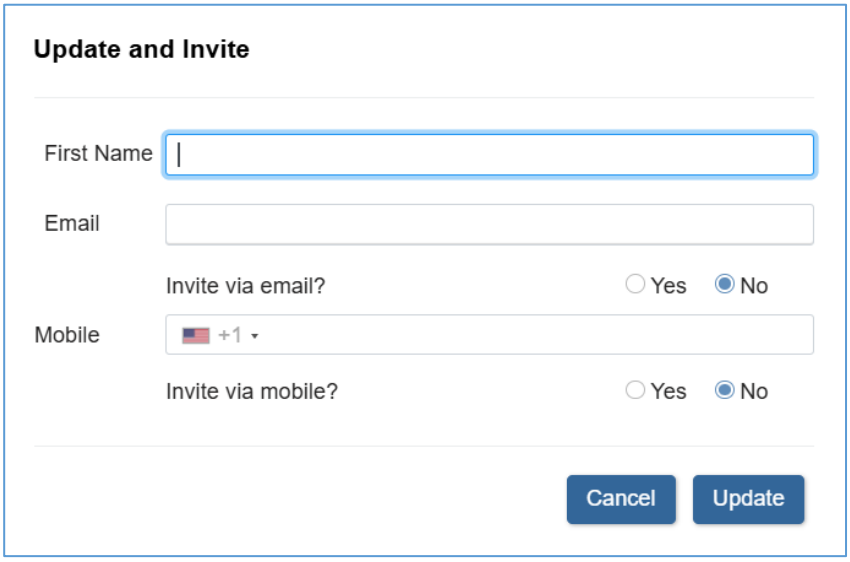
6.9.2 E-consent

E-consent - participant
To use participant e-consent add the visit on the patient homepage. - Click Add New and select e-consent – participant from the Visit name drop down.  - It will then appear as a visit  - To send the e-consent to the patient click "Invite" on the patient homepage:

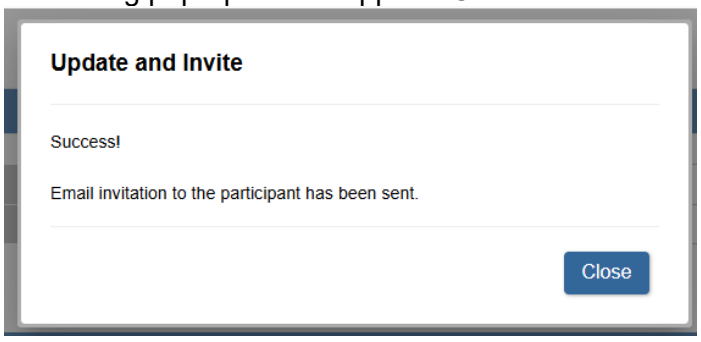


- In the pop-up box fill in the patients' first name and email and mark "Invite via email?" as "Yes".

Note – e-consent is only available for email and not mobile.



- Once complete, the following pop-up should appear. Click close.



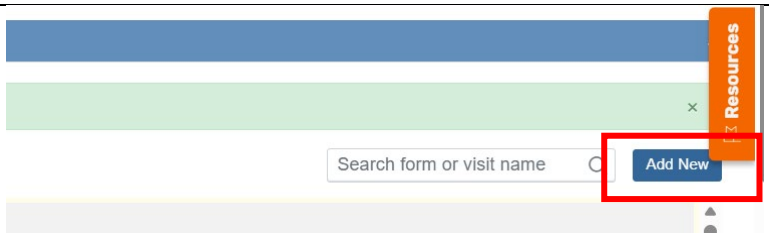
Note – the patient will receive the eConsent form via email. The eConsent – Participant form is read- only and will be marked as complete once the participant has provided the consent.

Once the consent is signed by the participant this needs to be countersigned by the site member who explained the study to them. This can be updated by clicking on the three dots and selecting countersign.

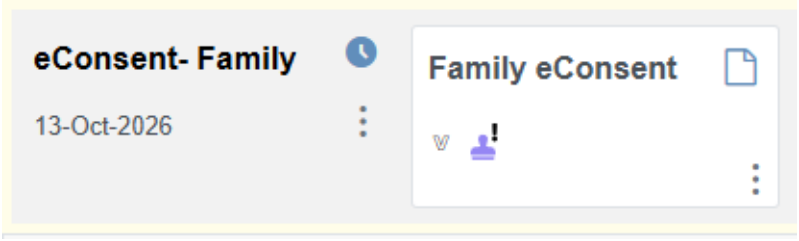
Scheduling eConsent - Family

To use family e-consent add the visit on the patient homepage.

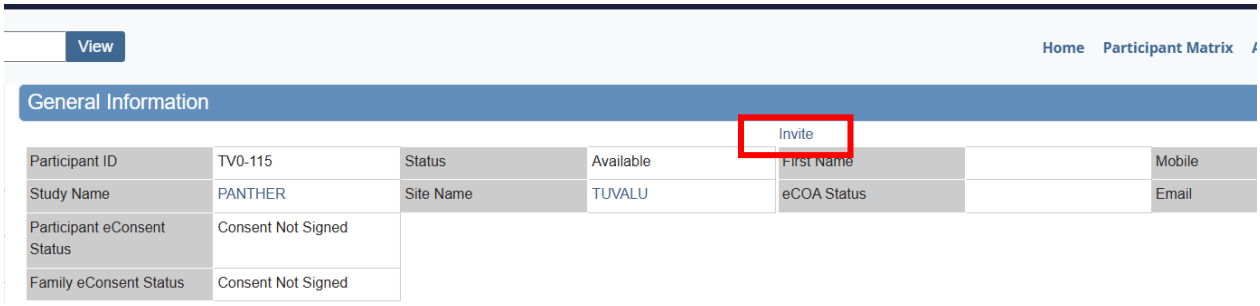
- Click Add New and select e-consent – participant from the Visit name drop down.



- It will then appear as a visit

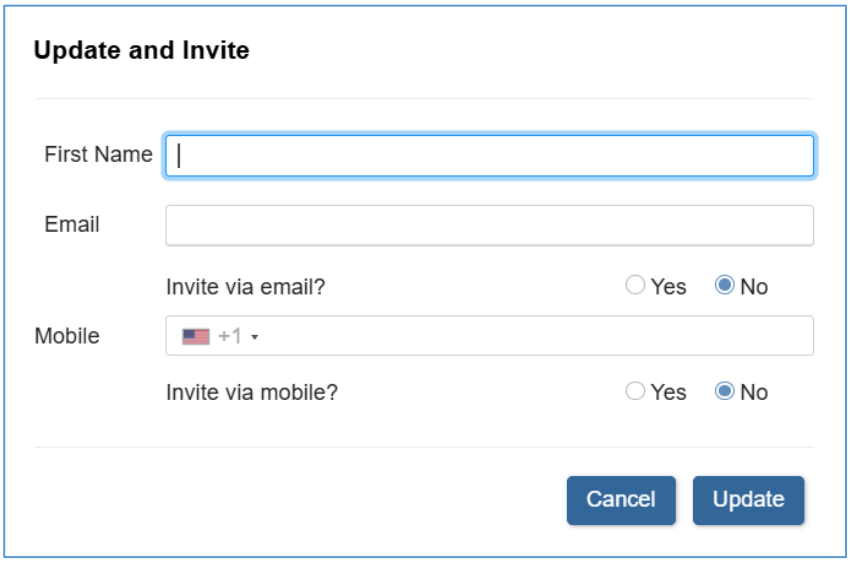


- To send the e-consent to the participants family click “Invite” on the patient homepage:

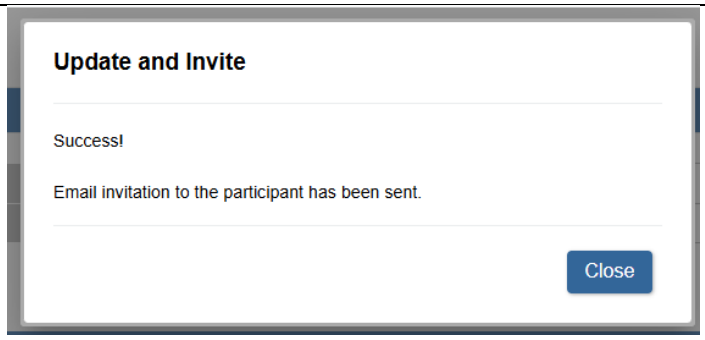


- In the pop-up box fill in the family members first name and email and mark “Invite via email?” as “Yes”.

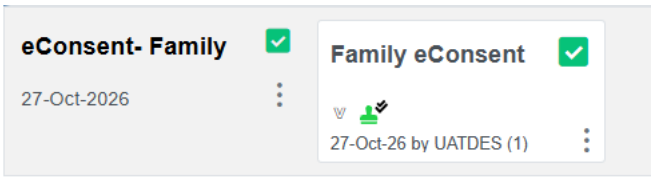
Note – e-consent is only available for email and not mobile.



- Once complete, the following pop-up should appear. Click close.



Note – the family member will receive the eConsent form via email. The eConsent – Family form is read- only and will be marked as complete once the family member has provided the consent.

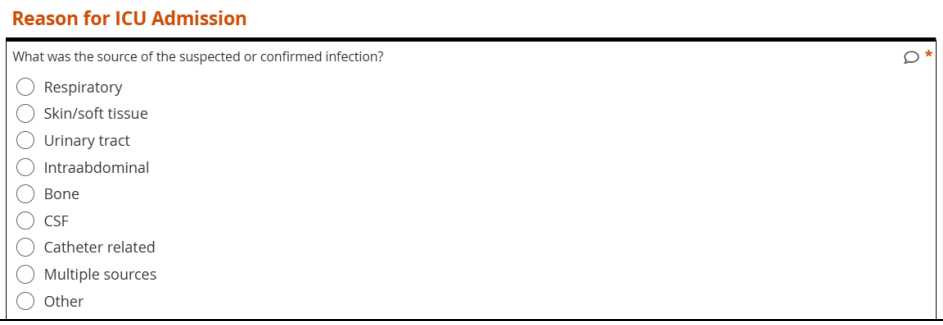


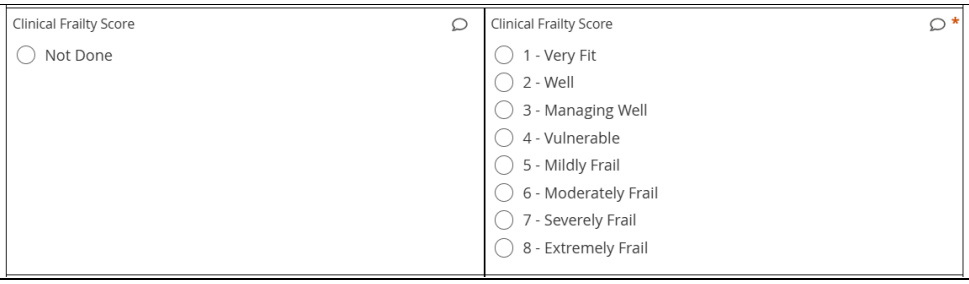
Once the consent is signed by the participant this needs to be countersigned by the site member who explained the study to them. This can be updated by clicking on the three dots and selecting countersign – see image above.

6.9.3 Contact Details

Contact Details	
- UK only - If consent is received for follow up, please complete the contact details form in the database to enable the patient to be contacted. *Note – Two email fields will show on the form. One is auto populated from eConsent and the other is to be used to add the patients email address.*	
Telephone number	- Enter patient's telephone number for contact purposes
Email address	- Enter patient's email address for contact purposes *Note – This is autopopulated from the 'invite' email field on eConsent, if this is not the email address for the participant please add in the box below*
Email address:	- Enter patient's email address for contact purposes if the previous email address has not auto-populated or is incorrect
Postal address	- Enter patient's postal address for contact purposes
Participant's name	- Enter patient's name - *Note – This is auto populated from the eConsent form once completed by the patient*
Date of birth:	- Enter the patients date of birth
Hospital number:	- Enter the patients hospital number
- Click on **'Close'** or **'Complete'** at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.9.4 Hospital Admission

Hospital Admission Form	
Hospital Admission Date	- Enter the Date Patient was admitted to hospital
Hospital Admission time *format (hh:mm [0-23] hrs [0-59] min)*	- Enter the Time Patient was admitted to hospital in the requested format
ICU Admission Date	- Enter the Date Patient was admitted to ICU
ICU Admission time *format (hh:mm [0-23] hrs [0-59] min)*	- Enter the Time Patient was admitted to ICU
Did the patient have a confirmed or suspected infection?	- Indicate whether the patient has a: • Confirmed infection, • Suspected but not confirmed infection • or Infection not suspected
What was the source of the suspected or confirmed infection?	*Note –This question will only appear if confirmed or suspected was selected in the previous question.* Please indicate the source of infection by completing the Reason for ICU Admission section. - Select from the list what was the source of the suspected or confirmed infection - If Other please provide details - If an infection is suspected but not confirmed please select the source of the suspected infection and for the microbiology test select 'not confirmed' from the list 
If an infection was confirmed, please select the positive microbiology test/s that identified the infectious pathogen	- Select all that apply from the list. - If Other please provide details
Clinical Frailty Score	- Select the result for Clinical Frailty Score, if test was not performed select **'Not Done'**

	
Confirmed SARS-CoV-2 positive in this admission	- Indicate Yes or No whether the patient had a confirmed SARS-CoV-2 positive in this admission
Was the patient a non-operative or operative patient?	- Select whether the patient was a non-operative or operative patient - Select a diagnostic category from the list below

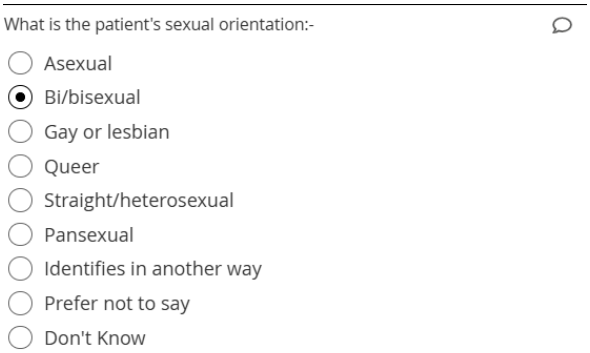
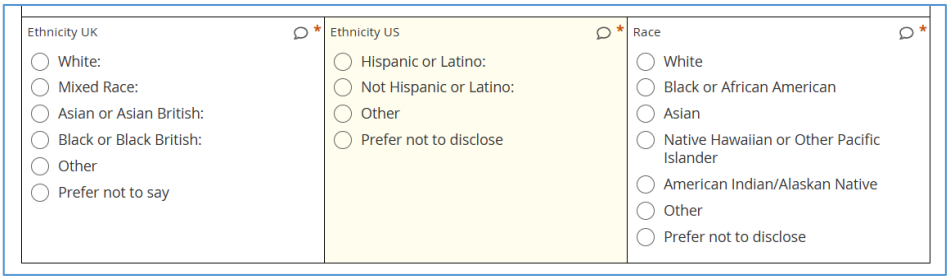
If Non-Operative – Select which diagnostic category from list	**If Operative - Select which diagnostic category from list**
Non-Operative: Cardiovascular	Post Operative: Cardiovascular
Non-Operative: Respiratory	Post-Operative: Respiratory
Non- Operative: Gastrointestinal	Post- Operative: Gastrointestinal
Non-operative: Neurologic	Post-operative: Neurologic
Non-operative Sepsis	Post-operative Sepsis
Non-operative: Trauma	Post-operative: Trauma
Non-operative: Metabolic	Post-operative: Metabolic
Non-operative: Hematologic	Post-operative: Hematologic
Non-operative: Renal and Genitourinary	Post-operative: Renal and Genitourinary
Non-operative: Musculoskeletal/ Skin disease	Post-operative: Musculoskeletal/ Skin disease
Non-operative: Other Medical Diseases	Post-operative: Other Medical Diseases
Non-operative: Undefined/ Unknown	Post-operative: Undefined/ Unknown

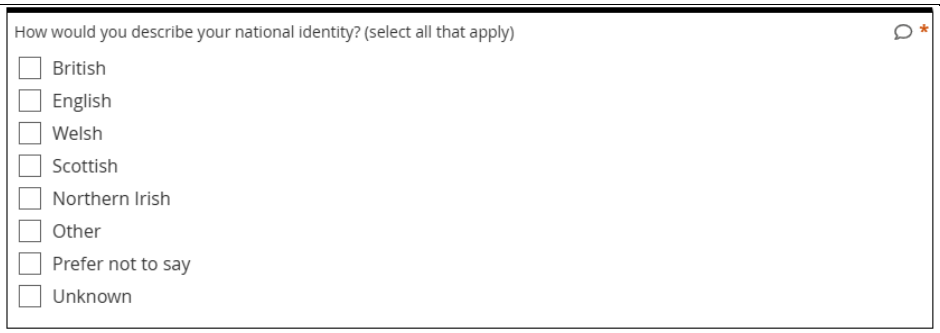
UK Only – Enter ICANRC details below	
ICNARC CMP Number	- Enter ICNARC CMP Number
ICNARC Ward Number	- Enter ICNARC Ward Number
APACHE II Score	- Select APACHE II score if known - Enter APACHE II Score - Select unknown if APACHE II score unavailable

- Click on **'Close'** or **'Complete'** at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.9.5 Demography

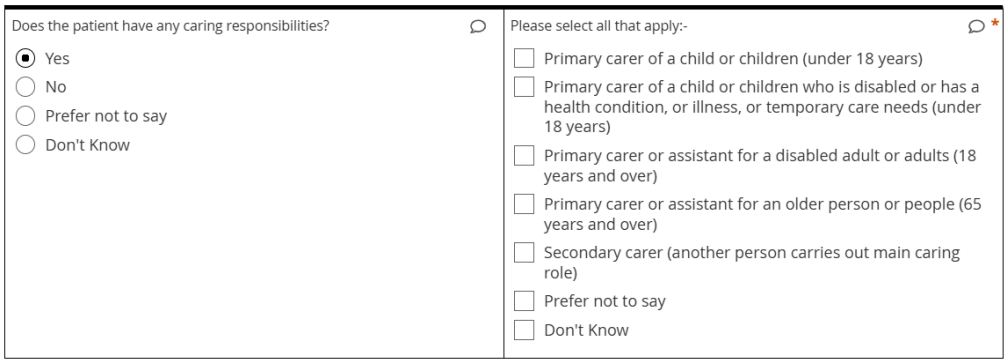
Demography Form
- **The patient's country will be auto populated on this page.**

What is the patient's gender?	- Enter the participant's gender from the list provided. A 'don't know' option is available if the data cannot be obtained. 
What is the patient's sexual orientation:	- Enter the participant's sexual orientation from the list provided. A 'don't know' option is available if the data cannot be obtained. 
Country	- This field will auto populate
Ethnic Group or Background	
National Identity: What is the participants race?	**Please note the below may look different depending on which country you are in.** - For UK sites – Select from the Ethnicity UK categories - For US sites –Select from the Ethnicity US and Race categories - If Other is selected for any of the questions, a 'Please specify' field will automatically appear for you to complete. 
Ethnicity: How would you describe your national identity? (select all that apply)	**Please note the below may look different depending on which country you are in.** - Enter the participant's national identity from the list provided. An 'other' and 'prefer not to say' and 'Unknown' options are available.

	
Education: What was your highest educational level?	- Enter the highest educational level the patient has achieved from the list provided
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.9.6 Equality and Diversity

Equality and Diversity	
Please note that this form will not appear in the US	
Religion	
What is the patient's religion, if any	- Select the patient's religion from those listed, if this information is not known, please select the 'don't know' option If Any Other Religion is selected this can be specified if they wish to disclose. - There is also an option if they would prefer not to say
Marriage/Civil Partnership	
Is the patient currently?	- Select the patient's marital status from those listed, if this information is not known, please select the 'don't know' option.
Parental leave	
In the last 12 months has the patient taken any of the following types of leave (select all that apply)	- Select type of parental leave patient has taken over the past 12 months, if this information is not known, please select the 'don't know' option.
Caring responsibilities	
Does the patient have any caring responsibilities?	- Indicate whether the patient has any caring responsibilities If yes, indicate types of responsibility

	
Socioeconomic background	
What was the occupation of the patient's main household earner when they were about aged 14?	- Indicate the occupation of the patient's main household earner when patient was aged 14 from the list provided
Would the patient consider themselves disabled?	- Indicate Yes or No as to whether the patient would consider themselves disabled
Does the patient have any physical or mental health conditions or illnesses lasting or expected to last for 12 months or more?	- Indicate whether the patient has any physical or mental health conditions lasting 12 months or expected to last longer than 12 months.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.9.7 Baseline Data

Baseline data	
Test Results: Closest result to time of inclusion. If a test was not done, please select 'Not Done'	
Type of Respiratory Support	- Select type of respiratory support the patient is receiving from the list provided: • CPAP/NIV • IMV • HFNC ≥30L/min
Respiratory support start date	- Enter date Respiratory support started If CPAP/NIV is selected – For Mode of Ventilation – Select the ventilation mode listed: CPAP(CPAP: Continuous positive airway pressure (non-invasive ventilation [NIV]) *Please note that delayed is listed as an IMV)

	- <u>If IMV is selected:</u> For Mode of Ventilation – Select one of the ventilation listed:- • A/C: Assist control (also known as V/C or AC/VC) • SIMV (Vol): Synchronized intermittent mandatory ventilation (volume) • SIMV (Pressure): Synchronized intermittent mandatory ventilation-pressure • PRVC: Pressure regulated volume control • APRV: Airway pressure release ventilation • PCV: Pressure control ventilation (also known as P/C or AC/PC) • PSV: Pressure support ventilation • VSV: Volume support ventilation • HFO: High frequency oscillation • Jet: Jet ventilation • BiPAP: Bilevel positive airway pressure • PAV: Proportional assist ventilation • NAVA: Neurally adjusted ventilatory assist • ASV: Adaptive Support Ventilation - If HFNC ≥30L/min is selected: • For Mode of Ventilation – Select the ventilation listed: HFNC (Optiflow); HFNC: High-flow nasal cannula (or Optiflow) *Enter the results closest to randomisation for each test, if a test was not performed select 'Not Done' for that test. Please note that different tests will appear depending on the type of ventilation that has been selected.*
Tidal Volume	- In many forms of mechanical ventilation, a predetermined volume of gas, or tidal volume, is delivered with each ventilator breath. Record in mL. This will appear if CPAP/NIV or IMV has been selected. -
Total Respiratory Rate Value	- Total respiratory rate (breaths per minute), enter the highest respiratory rate. This will appear if CPAP/NIV or IMV has been selected.
Minute Volume	- This value will be auto calculated from the tidal volume and Total Respiratory Rate results are entered. Please note this result will only appear when type of respiratory support has been selected as either CPAP/NIV or IMV.
Predicted Tidal Volume	- This value will be auto calculated from the predicted body weight and height. Please note this result will only appear when type of respiratory support has been selected as either CPAP/NIV or IMV.
PEEP	- Positive End Expiratory Pressure (measured in centimetres of H_2O, cmH_2O). PEEP provides a pressure at the end of exhalation to help improve oxygenation. This will appear if CPAP/NIV or IMV has been selected.
Plateau Pressure	- Will appear only when IMV option is selected, please enter value in cmH_20

PaO2	- Select either mmHg or kPa - Enter the partial pressure of oxygen in arterial blood
FiO2	- Enter the percentage of oxygen delivered when the arterial blood gas was obtained. This value should only be obtained from the ABG, (%) value
Mean Airway pressure	- The airway pressure measured at the airway opening during the administration of positive airway pressure, averaged over an entire ventilatory cycle, please enter in cmH_20
Occlusion Pressure	- Enter Occlusion Pressure (Pocc) value This is the negative pressure generated during a single inspiratory effort (or up to 5 s) following an end-expiratory airway occlusion. - The Pocc value represents the magnitude of the swing in airway pressure. It is the magnitude of the swing that should be entered into the database. - Enter the Pocc value obtained in the morning. If multiple values are available, take the Pocc and/or p0.1 value closest to 10 a.m. Ensure the respiratory support setting values entered coincide with the settings the patient was on when the Pocc/p0.1 values were obtained.
Airway Occlusion Pressure	- Enter the first 100 ms (P0.1) value - This is the negative pressure generated during a single inspiratory effort (or up to 5 s) following an end-expiratory airway occlusion. - The Pocc value will always be a negative integer and represents the magnitude of the swing in airway pressure. It is the magnitude of the swing that should be entered into the database. - Enter the Pocc value obtained in the morning. If multiple values are available, take the Pocc and/or p0.1 value closest to 10 a.m. Ensure the respiratory support setting values entered coincide with the settings the patient was on when the Pocc/p0.1 values were obtained.
Inspiratory Positive Airway Pressure (IPAP)	- Record the set Inspiratory Positive Airway Pressure in cmH_2O. - If IPAP not recorded, IPAP = PEEP + PS - Record actual inspiratory pressure/pressure support (not IPAP) if patient is receiving SIM-V with pressure (PS or PC) NIV. If a patient is receiving NIV via a NIV-only machine (i.e., Vision, i-vent, BiPAP or S/T, not a traditional MV) then you must calculate it: (Inspiratory pressure) / (PS) = plateau pressure – PEEP
ARDS Risk Factors	- Select one the ARDS Risk Factors - if 'Other' is selected you will be required to specify in the text field provided.
Vital Signs	- Enter the patient's height in cm - Enter the patient's weight in kg at ICU admission - BMI will be auto-calculated and populated by the system - Enter the patient's temperature, selecting degrees C or Fahrenheit F - Enter the lowest Systolic blood pressure value - Enter the Diastolic blood pressure value - Enter the lowest Heart Rate value

	- *Normal Ranges for some vital signs parameters on the form are listed below:*

Parameter	Low range	High range
Height (cm)	130	200
Weight (kg)	40.0	250.0
Temperature (ºC)	36.0	38.0
Temperature (ºF)	80.0	100.0
Heart Rate (bpm)	0	300
BP Systolic mmHg	90	150
BP Systolic mmHg (lowest)	0	150
BP Diastolic mmHg	45	90
BP Diastolic mmHg (lowest)	0	130

PaCO2 *kPa or mmHg*	- Partial pressure of carbon dioxide in arterial blood, select the correct units either kPa or mmHg and enter the value.
pH (arterial)	- Enter the pH (arterial) value, select either pH or H ions (nmol/L)
Mean Arterial Pressure (MAP)	- Enter the value in mmHg
Was the patient receiving vasopressors/inotropes at the time of randomisation?	- Indicate Yes or No whether the patient received vasopressors/inotropes at the time of randomisation, if yes, select which Vasopressor/Inotrope was received. - Then indicate Yes or No to confirm the selection in next question, then you will be required to enter the result, note for some drugs we require the highest value. If the highest dose has not been requested, please enter the dose closest to randomisation.
Was the patient receiving RRT at the time of randomisation?	- Indicate Yes or No whether the patient received Renal Replacement Therapy at the time of randomisation.
Did the patient receive continuous Neuromuscular Blocking Agent?	- Indicate Yes or No whether the patient received continuous Neuromuscular Blocking Agent.
Has the patient been in prone position in the last 24hrs?	- Indicate Yes or No whether the patient has been in prone position in the last 24hrs, if Yes, state the amount of many hours.
Is the patient receiving ECLS/ ECMO/has received in the last 24hrs?	- Indicate Yes or No whether the patient is receiving or has received ECLS/ECMO in the last 24hrs.
Has the patient received any steroid in the 24hrs prior to randomisation?	- Indicate Yes or No whether the patient has received any steroid in the 24hrs prior to randomisation. - If Yes, enter the total daily dose and route of administration.
Comorbidities	- *Note: There must be documented evidence that the condition existed or that the patient received therapy for the condition in the six months prior to admission to ICU.* - Indicate whether the patient has any past medical history for the following conditions listed Hypertension, Obesity, Diabetes, Congestive heart failure. Alcohol Abuse and Active Smoking.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.	

- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.10 Lab Parameters – 24hrs prior to Randomisation

Laboratory Results
Enter the worst/abnormal results received in the 24hrs prior to randomisation.
- For each test, please confirm whether the sample was taken - Record each test result - If a specific test was not performed or the result was affected, please select "Not Done," which appears next to each test name
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.11 Samples Baseline

Samples Baseline	
- Select the sampling tier your site will be participating in, this can be selected per patient. Sites in the UK can access the Sampling manual Document by clicking the link on the form and selecting > manuals > sample manual. - Where aliquots are collected for a sample, ensure that the number of aliquots are selected and each aliquot ID is added by clicking the + button. - For sites with a barcode scanner, scan the barcode on the sample which will auto-populate the aliquot ID on the database.	
Which sampling tier is the site participating in?	Tier 0 - No samples will appear as this refers to the subphenotyping sample only which is used and discarded. Tier 1 - Indicate **Yes or No** whether the following samples were collected: Li Heparin; Serum; EDTA; PAXgene; Nasal swab; Tracheal Aspirate - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. Tier 2 - Indicate **Yes or No** whether the following samples were collected: Li Heparin; Serum; EDTA; PAXgene; Nasal swab; Tracheal Aspirate - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. Tier 3 - Indicate **Yes or No** whether the following samples were collected: Li Heparin; Serum; EDTA; CPT Heparin; PAXgene; Nasal swab; Tracheal Aspirate.

	- If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. <u>Tier 4</u> - Indicate **Yes or No** whether the following samples were collected: Li Heparin; Serum; EDTA; CPT Heparin; PAXgene; Nasal swab; Tracheal Aspirate; BAL - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected.
Were these samples placed directly in a -80 freezer for storage?	- Indicate **Yes, No or Not Applicable** whether the samples were placed directly in -80 freezer for storage. If not applicable, please select.
Were these samples placed directly in a -20 freezer for storage then transferred to -80	- Indicate **Yes, No or Not Applicable** whether the samples were placed directly in -20 freezer for storage. If not applicable, please select.
Other comments?	- Any further information that should be known please enter in the 'Comments' field provided.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.11.1 IQCode

IQCode	
Was the questionnaire completed?	- Indicate **Yes, or Not done** - If Not Done, indicate reason as Outside of window or Unable to contact patient. - If yes, complete the form
Date	- Complete the date the questionnaire was completed
The IQ Code survey is administered as close to enrolment, following consent execution, as possible. If the participant is consented directly, the coordinator requests permission from the participant to ask a caregiver/family member to complete the survey *The assessment* *Now we want you to remember what your friend or relative was like 10 years ago and to compare it with what he/she is like now. 10 years ago was 20__. On* *the next page are situations where this person has to use his/her memory or intelligence and we want you to indicate whether this has improved, stayed the* *same or got worse than in that situation over the past 10 years. Note the importance of comparing his/her present performance with 10 years ago. So if 10* *years ago this person always forgot where he/she had left things and he/she still does this, then this would be considered 'Not much change'. Please indicate* *the changes you have observed by circling the appropriate answer.*	
Please indicate	- For each question select the box that best represents the given response: - 0 - Not answered

the changes you have observed by circling the appropriate answer.	- 1 - Much improved - 2 - A bit improve - 3 - Not much change - 4 - A bit worse - 5 - Much worse
Total Score of answered questions	- The total score of answered questions will automatically fill-in when all questions have been completed
Missing Answer/Not Answered	- The Missing answer/ Not Answered box will auto-populate based on the answers to the questions
Total Scores.	- The overall score will automatically fill-in when all questions have been completed
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.12 Day 0 (post randomisation) Event

6.12.1 GCS, Delirium and RASS Score

GCS and Delirium	
For GCS and delirium, this is the worst score in the previous 24 hours. **For GCS, if a patient is sedated and the only score available is when they are sedated record the three components from that score. If there is no score whilst the patient is sedated record the last known scores before sedation. If not taken prior to sedation then this should be marked as "not done".** *Note - If the only GCS score available is one for which the patient is sedated, record the three individual component scores from that total.*	
Glasgow Coma Scale Complete?	- Indicate whether the Glasgow Coma Scale was Complete - If Yes: - Select the Eye opening score - Select the Verbal response score - Select the Motor response score - The Total GCS Score will be auto-calculated from the scores provided from the Eye opening; Verbal response and Motor response scores. *Please note: the Total GCS Score will not show if any of the three scores are blank.*
Delirium screening tool	- Enter the Delirium screening tool or if not completed select 'not known' - If ICDSC Score is selected – Enter the Highest ICDSC for day and Highest ICDSC for night - If CAM-ICU is selected – Enter the Highest CAM-ICU for day and Highest CAM-ICU for night
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	
RASS Score	- Enter if the RASS score was conducted, yes or no - Record the patient's Richmond Agitation-Sedation Scale (RASS) score. - The RASS score ranges from **+4 (combative) to -5 (unarousable)**, with **0 indicating alert and calm**

6.13 Daily data Day 0 to Day 6

Daily data Day 0 to Day 6	
- **This form should be used to record Daily Data from Randomisation Day 0 to Day 6 and must be completed for each day the patient is in ICU** - **The values should be recorded closest to 8am on this day as possible up until the SOFA score details which should be the worst values from the previous 24 hours**	
Day 0 is from the time of randomisation to the end of the (ICU chart) day **Day 1 is the next (ICU chart) day and assuming they stay in the ICU each subsequent day is also each ICU chart day.** **Example:** **- Patient is randomised at 1pm on the 25/08** **- Day 0: 1pm 25/08 – 25/08 23:59/ End of ICU Chart Day** **- Day 1: 26/08 00:01/Start of Chart Day – 26/08 23:59/ End of ICU Chart Day**	
Patient Status	- Indicate the Patient Status If patient status is **Continuing in the trial** please complete the remaining questions on the form If patient died, ensure a Death form has been completed. If patient has been discharged from ICU – Indicate whether participant is receiving organ support, if Yes complete organ support questions. Ensure ICU discharge visit and form are also completed. If patient withdrew - Please complete the study withdrawal form
Date of visit day	- Enter the date of visit day – day 0 will be the day of randomisation (short day), and day 1 will be the day after randomisation.
Is the patient receiving respiratory support?	- Indicate yes or no if patient is receiving respiratory support: - If yes, select the type of support. If **O2 therapy** is selected: Select one of the following modes of O2 therapy:- - FM: Face mask - NP: Nasal Prongs - TM: Trach mask - T-piece If **CPAP/NIV** is selected: - Select CPAP **Please note that BiPAP is listed as an IMV* If **IMV** is selected: - Select from the following:- - **A/C**: Assist control (also known as V/C or AC/VC) - **SIMV (Vol):** Synchronized intermittent mandatory ventilation (volume) - **SIMV (Pressure):** Synchronized intermittent mandatory ventilation-pressure - **PRVC:** Pressure regulated volume control - **APRV:** Airway pressure release ventilation - **PCV:** Pressure control ventilation (also known as P/C or AC/PC) - **PSV:** Pressure support ventilation

	- **VSV:** Volume support ventilation - **HFO:** High frequency oscillation - **Jet:** Jet ventilation - **BiPAP:** Bilevel positive airway pressure - **PAV:** Proportional assist ventilation - **NAVA:** Neurally adjusted ventilatory assist - **ASV:** Adaptive Support Ventilation If **HFNC ≥30L/min** is selected: - Select **HFNC** (Optiflow) *Enter the results closest to 8am for each test, if a test was not performed select 'Not Done' for that test*
PaO_2	- Arterial pressure of Oxygen, select the preferred units:- kPa, mmHg.
FiO2	- Enter the percentage of oxygen delivered when the arterial blood gas was obtained. This value should only be obtained from the ABG, (%) value
Flow rate L/min	- Enter the flow rate, the volume of gas/air delivered per minute, *this option will only appear for HFNC*
Inspiratory positive airway pressure (IPAP) *cm H20*	- Record the set Inspiratory Positive Airway Pressure in cmH2O. If IPAP not recorded, IPAP = PEEP + PS - Record actual inspiratory pressure/pressure support (not IPAP) if patient is receiving SIM-V with pressure (PS or PC) NIV. If a patient is receiving NIV via a NIV-only machine (i.e., Vision, i-vent, BiPAP or S/T, not a traditional MV) then you must calculate it: (Inspiratory pressure) / (PS) = plateau pressure – PEEP *Will only appear if IMV has been selected*
Mean airway pressure	- The airway pressure measured at the airway opening during the administration of positive airway pressure, averaged over an entire ventilatory cycle, please enter in cmH_20 *Will only appear if IMV has been selected*
Absolute neutrophils	- Enter the absolute neutrophils result in $x10^9/L$
Bicarbonate	- Select the units either mmol/L or mEq/L
Did the patient receive continuous Neuromuscular Blocking Agent	- Indicate **Yes or No** whether the patient received continuous Neuromuscular Blocking Agent.
Is the patient receiving Extracorporeal Membrane Oxygenation (ECMO)	- Indicate **Yes or No** whether the patient is receiving or has received ECMO in the last 24hrs.
Was the patient receiving any steroids today?	- Indicate **Yes or No** whether the patient has received any steroid in the 24hrs prior to randomisation, Enter the total daily dose and route of administration.
SOFA Score Details – please enter details from previous 24hrs	
SOFA Score	The SOFA score is derived from six variables, each representing an organ system. Each organ system is assigned a point value from 0 (normal) to 4 (high degree of dysfunction/failure). The "worst" physiological variables are collected serially every 24 hours of a patient's ICU admission. The "worst" measurement is defined as the measure that correlated to the highest number of points. The SOFA score ranges from 0 to 24.

	Please note, the total SOFA score may not appear at the bottom but will be calculated. - Enter the Mean Arterial Pressure (MAP), if test was not performed select 'Not Done' - Please Note: - if MAP score is greater or equal to 70 then the Cardiovascular Score will be 0 and if less than 70 then the Cardiovascular Score will be 1
Is the patient receiving vasopressors or inotropes?	- Indicate **Yes or No** whether the patient is receiving vasopressors or inotropes, - If yes, select **Yes or No** for which Vasopressors/Inotropes was received. - You will be required to choose which one from the following: o Highest Dopamine (mcg/kg/min) value. o Highest Dobutamine (mcg/kg/min) value o Highest Adrenaline (mcg/kg/min) value - *Please Note: This value is not accounted for in the calculation, e.g. If MAP Score and this value are added it will take the score of MAP into account.* o Highest Noradrenaline (mcg/kg/min) value o Highest dose Epinephrine (mcg/kg/min) value - *Please Note: This value is not accounted for in the calculation, e.g. If MAP Score and this value are added it will take the score of MAP into account.* - The dose of Vasopressin, Levosimendan; Milrinone are not required.
P/F Ratio	- P/F Ratio (PaO2/FiO2) – This is auto-calculated and read only so will be calculated when the PaO2 & FiO2 are entered.
Lowest Platelets (x10^9/L)	- Enter the Lowest Platelets (x10^9/L) value, if test was not performed select **'Not Done'** - Lowest Platelets (x10^9/L) Score – This is auto-calculated and read only so will be calculated when the Lowest Platelets (x10^9/L) is entered
Highest Bilirubin (umol/L)	- Enter the Highest Bilirubin (umol/L) Value, if test was not performed select 'Not Done' - Highest Bilirubin (umol/L) Score – This is auto-calculated and read only so will be calculated when the Highest Bilirubin (umol/L) value is entered.
Is the patient receiving Renal Replacement Therapy?	- Indicate Yes or No whether the patient is receiving Renal Replacement Therapy. - If Yes Renal Score – This is auto-calculated and read only so will be calculated when Yes is selected. - If No, Enter Highest Creatinine Result and Total Urine Output (ml/d): - Renal Score – This is auto-calculated and read only so will be calculated when Highest Creatinine Result and Total Urine Output is entered

Glasgow Coma Scale	- GCS Score – This is read only and mapped from the GCS and Delirium form - Total GCS Score – This is a read only field.
Total SOFA Score	- Total SOFA Score – This is auto-calculated and read only so will be calculated from the Respiration, Coagulation, Liver & Cardiovascular scores are entered. Please note this may not be displayed on the form but will be calculated.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.14 Intervention Administration

6.14.1 Simvastatin – Administration

Day 0 (First day of treatment)	
Please note: This visit will auto populate if the participant is assigned to this treatment	
Has Simvastatin been administered?	- Indicate Yes or No whether Simvastatin has been administered on first day of treatment (Day 0). Please complete for each day (up to Day 28) If Yes, complete the next few questions. - Enter the Date of Administration - Enter the Time of Administration - Enter the Creatinine kinase (CK) result (U/L) on D6, D13, D20 & D27, if test was not performed select 'Not Done' and raise a protocol violation - Enter the Alanine aminotransferase (ALT) result (U/L) on D6, D13, D20 & D27, if test was not performed select 'Not Done' and raise a protocol violation if AST was not done or - Enter the Aspartate aminotransferase (AST) result (U/L) on D6, D13, D20 & D27, if test was not performed select 'Not Done and raise a protocol violation if ALT was not done If No - Select the Reason Simvastatin was not administered for each day (up to Day 28) - If Patient died - ensure a Death form has been completed. - If patient has been discharged from ICU – ensure the discharge form has been completed. - If patient withdrew - ensure the study withdrawal form has been completed.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - **Please note: You can enter data for each day of treatment and can click 'Close' on the form for that day if not all data has been entered.* - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.14.2 Baricitinib – Administration

Day 0 (First day of treatment)	
Please note: This visit will autopopulate if the participant is assigned to this treatment	
Has Baricitinib been administered?	- Indicate Yes or No whether Baricitinib has been administered on first day of treatment (Day 0). Please complete for each day (up to Day 10) If Yes - Enter the Date of Administration - Enter the Time of Administration If No: - Select the Reason Baricitinib was not administered for each day (up to Day 10)If Patient died - ensure a Death from has been completed. - If Patient died - ensure a Death from has been completed. - If patient has been discharged from ICU – ensure the discharge form has been completed - If patient withdrew - ensure the study withdrawal form has been completed.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.14.3 Usual Care – Administration

Usual Care (if eligible to simvastatin)	
Please note: This visit will autopopulate if the participant was Eligible to Simvastatin but randomised to Usual Care.	
Was the usual care treatment followed?	- Indicate Yes or No whether usual care treatment followed. Please complete for D6, D13, D20 & D27 If Yes - Enter the CK, ALT and or AST values If No: - Select Yes or No if Simvastatin was given - If Simvastatin was given a protocol deviation would need to be raised - Enter the CK, ALT and or AST values
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.15 Sample Collection

6.15.1 Samples D2

Samples D2	
This form should be completed at Day 2 visit	
Which sampling tier is the site participating in?	- Select the sampling tier your site will be participating in. Site can access the Sampling Tier Document by clicking the link on the form also. Tier 0 - No samples will appear on the form. Tier 1 - No samples will appear on the form. Tier 2 - Indicate Yes or No whether the following samples were collected: - Li Heparin; Serum; EDTA; PAXgene; Tracheal Aspirate. - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. Tier 3 - Indicate Yes or No whether the following samples were collected: - Li Heparin; Serum; EDTA; PAXgene; CPT Heparin; Tracheal Aspirate. - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. Tier 4 - Indicate Yes or No whether the following samples were collected: - Li Heparin; Serum; EDTA; CPT Heparin; PAXgene; Tracheal Aspirate; BAL - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected.
Were these samples placed directly in a -80 freezer for storage	- Indicate **Yes, No or Not Applicable** whether the samples were placed directly in -80 freezer for storage. If not applicable, please select.
Were these samples placed directly in a -20 freezer for storage then transferred to -80	- Indicate **Yes, No or Not Applicable** whether the samples were placed directly in -20 freezer for storage. If not applicable, please select.
Other comments?	- Any further information that should be known please enter in the 'Comments' field provided.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.15.2 Samples D6

Samples D6	
This form should be completed at Day 6 visit	
Which sampling tier is the site participating in?	- Select the sampling tier your site will be participating in. Site personnel can access the Sampling Tier Document by clicking the link on the form also. Tier 0 - No samples will appear on the form Tier 1 - No samples will appear on the form Tier 2 - Indicate Yes or No whether the following samples were collected: - Li Heparin; Serum; EDTA; PAXgene; Tracheal Aspirate - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. Tier 3 - Indicate Yes or No whether the following samples were collected: - Li Heparin; Serum; EDTA; PAXgene; Tracheal Aspirate - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected. Tier 4 - Indicate Yes or No whether the following samples were collected: - Li Heparin; Serum; EDTA; PAXgene; Tracheal Aspirate; CPT Heparin - If Answer is 'Yes' for any of the samples enter the Sample ID; Number of aliquots collected; the aliquot ID and the Date & Time sample was collected.
Were these samples placed directly in a -80 freezer for storage	- Indicate **Yes, No or Not Applicable** whether the samples were placed directly in -80 freezer for storage. If not applicable, please select.
Were these samples placed directly in a -20 freezer for storage then transferred to -80	- Indicate **Yes, No or Not Applicable** whether the samples were placed directly in -20 freezer for storage. If not applicable, please select.
Other comments?	- Any further information that should be known please enter in the 'Comments' field provided.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.16 Daily data day 7

Daily Data Day 7
This form should be used to record Daily Data for Day 7. And must be completed when the patient is in ICU.

The values should be recorded closest to 8am on this day as possible up until the SOFA score details which should be the worst values from the previous 24 hours	
Patient Status	- Indicate the Patient Status If patient status is **Continuing in the trial** please complete the remaining questions on the form If patient died, ensure a Death form has been completed. If patient has been discharged from ICU – Indicate whether participant is receiving organ support, if Yes complete organ support questions. Ensure discharge form is also completed. If patient withdrew - Please complete the study withdrawal form
Date of visit day	- Enter the date of visit day
Is the patient receiving respiratory support?	- Indicate yes or no if patient is receiving respiratory support: - If yes, select the type of support. If **O2 therapy** is selected: Select one of the following modes of O2 therapy:- - FM: Face mask - NP: Nasal Prongs - TM: Trach mask - T-piece If **CPAP/NIV** is selected: - Select CPAP **Please note that BiPAP is listed as an IMV* If **IMV** is selected: - Select from the following:- - **A/C**: Assist control (also known as V/C or AC/VC) - **SIMV (Vol):** Synchronized intermittent mandatory ventilation (volume) - **SIMV (Pressure):** Synchronized intermittent mandatory ventilation-pressure - **PRVC:** Pressure regulated volume control - **APRV:** Airway pressure release ventilation - **PCV:** Pressure control ventilation (also known as P/C or AC/PC) - **PSV:** Pressure support ventilation - **VSV:** Volume support ventilation - **HFO:** High frequency oscillation - **Jet:** Jet ventilation - **BiPAP:** Bilevel positive airway pressure - **PAV:** Proportional assist ventilation - **NAVA:** Neurally adjusted ventilatory assist - **ASV:** Adaptive Support Ventilation If **HFNC ≥30L/min** is selected: - Select **HFNC** (Optiflow) *Enter the results closest to 8am for each test, if a test was not performed select 'Not Done' for that test*
PaO_2	- Arterial pressure of Oxygen, select the preferred units:- kPa, mmHg.
FiO2	- Enter the percentage of oxygen delivered when the arterial blood gas was obtained. This value should only be obtained from the ABG, (%) value

PaO2/FiO2 ratio	- This is an automatically calculated field derived from PaO2/FiO2
Flow rate L/min	- Enter the flow rate, the volume of gas/air delivered per minute, *this option will only appear for HFNC*
Mean airway pressure	- The airway pressure measured at the airway opening during the administration of positive airway pressure, averaged over an entire ventilatory cycle, please enter in cmH_20 *Will only appear if IMV has been selected*
Inspiratory positive airway pressure (IPAP) *cm H20*	- Record the set Inspiratory Positive Airway Pressure in cmH2O. *Will only appear if IMV has been selected*
Absolute neutrophils	- Enter the absolute neutrophils result in $x10^9/L$
Bicarbonate	- Enter the bicarbonate in mmol/L
Was the patient receiving any steroids today?	- Indicate **Yes or No** whether the patient has received any steroid in the 24hrs prior to randomisation, - Enter the total daily dose and route of administration.
Is the patient receiving vasopressors or inotropes?	- Indicate **Yes which one or No** whether the patient is receiving vasopressors or inotropes, - If yes, select which Vasopressors/Inotropes was received. **Please enter worst rate within the previous 24hrs** - You will be required to choose which one from the following: ○ Highest Dopamine (mcg/kg/min) value. ○ Highest Dobutamine (mcg/kg/min) value ○ Highest Adrenaline (mcg/kg/min) value - *Please Note: This value is not accounted for in the calculation, e.g. If MAP Score and this value are added it will take the score of MAP into account.* ○ Highest Noradrenaline (mcg/kg/min) value ○ Highest dose Epinephrine (mcg/kg/min) value - *Please Note: This value is not accounted for in the calculation, e.g. If MAP Score and this value are added it will take the score of MAP into account.* - Indicate Yes or No whether the patient received Vasopressin, Levosimendan; Milrinone
Is the patient receiving Renal Replacement Therapy?)	- Indicate Yes or No whether the patient is/has received Renal Replacement Therapy in the previous 24hrs.
Did the patient receive continuous Neuromuscular Blocking Agent	- Indicate Yes or No whether the patient received continuous Neuromuscular Blocking Agent.
Is the patient receiving Extracorporeal Life Support (ECLS), including Extracorporeal Membrane Oxygenation (ECMO)	- Indicate Yes or No whether the patient received Extracorporeal Life Support (ECLS), including Extracorporeal Membrane Oxygenation (ECMO)
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.	

- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.17 Daily data Day 8 to Day 28

Daily Data Day 8 - 28	
This form should be used to record Daily Data at Day 8 through to Day 28 Visit, any values entered on this form should be those that were done closest to time 8:00 am.	
Patient Status	- Indicate the Patient Status If patient status is **Continuing in the trial** please complete the remaining questions on the form If patient died, ensure a Death form has been completed. If patient has been discharged from ICU – Indicate whether participant is receiving organ support, if Yes complete organ support questions. Ensure discharge form is also completed. If patient withdrew - Please complete the study withdrawal form
Date of visit day	- Enter the date of visit day
Is the patient receiving respiratory support?	- Indicate yes or no if patient is receiving respiritaory support: - If yes, select the type of support. If **O2 therapy** is selected: Select one of the following modes of O2 therapy:- - FM: Face mask - NP: Nasal Prongs - TM: Trach mask - T-piece If **CPAP/NIV** is selected: - Select CPAP **Please note that BiPAP is listed as an IMV* If **IMV** is selected: - Select from the following:- - **A/C**: Assist control (also known as V/C or AC/VC) - **SIMV (Vol):** Synchronized intermittent mandatory ventilation (volume) - **SIMV (Pressure):** Synchronized intermittent mandatory ventilation-pressure - **PRVC:** Pressure regulated volume control - **APRV:** Airway pressure release ventilation - **PCV:** Pressure control ventilation (also known as P/C or AC/PC) - **PSV:** Pressure support ventilation - **VSV:** Volume support ventilation - **HFO:** High frequency oscillation - **Jet:** Jet ventilation - **BiPAP:** Bilevel positive airway pressure - **PAV:** Proportional assist ventilation - **NAVA:** Neurally adjusted ventilatory assist - **ASV:** Adaptive Support Ventilation If **HFNC ≥30L/min** is selected:

	- Select **HFNC** (Optiflow) *Enter the results closest to 8am for each test, if a test was not performed select 'Not Done' for that test.*
PaO_2	- Arterial pressure of Oxygen, select the preferred units:- kPa, mmHg.
FiO2	- Enter the percentage of oxygen delivered when the arterial blood gas was obtained. This value should only be obtained from the ABG, (%) value
PaO2/FiO2 ratio	- This is an automatically calculated field derived from PaO2/FiO2
Flow rate L/min	- Enter the flow rate, the volume of gas/air delivered per minute, *this option will only appear for HFNC*
Mean airway pressure	- The airway pressure measured at the airway opening during the administration of positive airway pressure, averaged over an entire ventilatory cycle, please enter in cmH_20 *Will only appear if IMV has been selected*
Inspiratory positive airway pressure (IPAP) *cm H20*	- Record the set Inspiratory Positive Airway Pressure in cmH2O. - If IPAP not recorded, IPAP = PEEP + PS - Record actual inspiratory pressure/pressure support (not IPAP) if patient is receiving SIM-V with pressure (PS or PC) NIV. If a patient is receiving NIV via a NIV-only machine (i.e., Vision, i-vent, BiPAP or S/T, not a traditional MV) then you must calculate it: (Inspiratory pressure) / (PS) = plateau pressure – PEEP *Will only appear if IMV has been selected*
Absolute neutrophils	- Enter the absolute neutrophils result in $x10^9/L$
Is the patient receiving vasopressors or inotropes?	- Indicate **Yes which one or No** whether the patient is receiving vasopressors or inotropes,
Did the patient receive continuous Neuromuscular Blocking Agent	- Indicate Yes or No whether the patient is received continuous Neuromuscular Blocking Agent.
Is the patient receiving Extracorporeal Life Support (ECLS), including Extracorporeal Membrane Oxygenation (ECMO)	- Indicate Yes or No whether the patient is receiving Extracorporeal Life Support (ECLS), including Extracorporeal Membrane Oxygenation (ECMO).
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.18 Discharge from ICU

Intensive Care Unit Outcome
Please note that a move to High Dependency Unit (HDU) should not be regarded as a discharge from the Critical Care environment. An ICU transfer is not considered a discharge from critical care.

Has the patient been discharged from the Intensive Care Unit	- Indicate Yes or No whether the patient has been discharged from the Intensive Care Unit
Date of First Intensive Care Unit Discharge (if applicable)	- If yes enter the Date of First Intensive Care Unit Discharge (if applicable)
Time of First Intensive Care Unit Discharge (24 hour clock) (if applicable) *format (hh:mm [0-23] hrs [0-59] min)*	- Enter the Time of First Intensive Care Unit Discharge (24 hour clock) (if applicable)
Hand grip strength dynamometry	- Enter Hand grip strength dynamometry value kg or lbs of force, if a test was not performed select 'Not Done' for that test
Maximal inspiratory pressure	- Enter Maximal inspiratory pressure value cmH20, if a test was not performed select 'Not Done' for that test
Manual Muscle Strength Testing (MMST)	- Select the grade (0-5) for Manual Muscle Strength Testing (MMST), if a test was not performed select 'Not Done' for that test - Enter date MMST completed
Length of Stay	
- Length of ICU Stay – this is auto-calculated from the date entered for ICU Admission on the hospital admission form	
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.19 Discharge Hospital

6.19.1 Discharge from Hospital

Discharge from Hospital	
Please schedule this visit if a safety outcome occurs. **Hospital discharge will be the first date that the patient is discharged to home/community/rehab/hospice. A transfer between hospitals is not considered as a hospital discharge.**	
Has the patient been discharged from Hospital	- Indicate Yes or No whether the patient been discharged from Hospital
Date of First Hospital Discharge (if applicable)	- If Yes, Enter the date of first hospital discharge (if applicable)
Time of First Hospital Discharge (24 hour clock) (if applicable) *format (hh:mm [0-23] hrs [0-59] min)*	- Enter Time of First Hospital Discharge (if applicable)

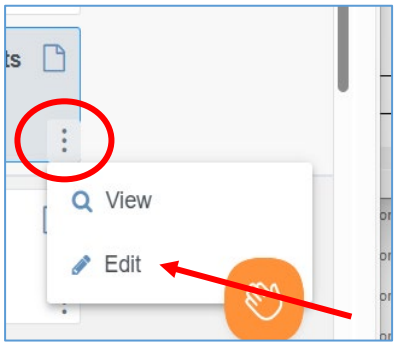
Hand grip strength dynamometry	- Enter Hand grip strength dynamometry value kg or lbs of force, if a test was not performed select 'Not Done' for that test
Maximal inspiratory pressure	- Enter Maximal inspiratory pressure value cmH20, if a test was not performed select 'Not Done' for that test
Manual Muscle Strength Testing (MMST)	- Select the grade (0-5) for Manual Muscle Strength Testing (MMST), if a test was not performed select 'Not Done' for that test - Enter date MMST completed
Length of stay	
Length of Hospital Stay – this is auto-calculated from the date entered for Hospital Admission on the Hospital Admission form	
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.19.2 Montreal cognitive assessment/MoCA

MoCA	
Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Not Done – Select Reason it was not done
Date questionnaire completed	- Input date the questionnaire was completed
1. Memory/Attention - Was this completed?	- Indicate Yes, or No whether Memory/Attention was completed
2. Verbal Fluency	- If 0-2 words select 0 points; - If 3-5 words select 1 point; - If 6-9 words select 2 points; - If 10-13 words select 3 points; - If 14 words or more select 4 points - Select the score given for this question (0 - 4) or select 'Not Done'
3. Orientation	- Select the score given for this question (0 - 6) or select 'Not Done'
4. Memory	- Select the score given for this question (0 - 5) or select 'Not Done'
Total Score	- Read-only field. The total score is automatically calculated by the system according to the scores given in previous questions.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.19.3 Short Physical Performance Battery

Short Physical Performance Battery
Please note: This form may be hidden/not required depending on your jurisdiction
- To complete the questionnaire please click the Actions tab these are the 3 dots located on the right side of form and then select Edit



Was the test completed?	- Indicate Yes, or No whether the test was completed if Yes, complete the remaining questions
Chair Stand Test	- Select the score given for this question (0 - 4)
T Balance Test	- Select the score given for this question (0 - 4)
Gait Speed Test	- Select the score given for this question (0 - 4)

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.19.4 Safety Outcomes

Safety Outcomes	
Has the patient experienced any of the following safety outcomes during their hospital stay	- Indicate Yes or No whether the patient has experienced any of the following safety outcomes during their hospital stay. - If Yes, complete the next questions.
Elevated Creatine Kinase more than 10 times the upper limit of normal	- Indicate Yes or No for question Elevated Creatine Kinase was more than 10 times the upper limit of normal - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If no, enter the end date of the event
Alanine Transaminase or Aspartate Transaminase more than 8 times the upper limit of normal	- Indicate Yes or No for question Alanine Transaminase or Aspartate Transaminase was more than 8 times the upper limit of normal more than 10 times the upper limit of normal. - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event
Severe thrombocytopenia, out of keeping with clinical disease *Clinicians should report any significant drop in platelet count out of keeping with clinical disease. In all cases of platelets <20 x109 cells/L these must be reported as a safety outcome*	- Indicate Yes or No for question Severe thrombocytopenia, out of keeping with clinical disease. - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event

Severe neutropenia, out of keeping with clinical disease *Clinicians should report any significant drop in neutrophil count out of keeping with clinical disease. In all cases of neutrophils <0.5 x109 cells/L these must be reported as a safety outcome*	- Indicate Yes or No for question Severe neutropenia, out of keeping with clinical disease. - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event.
Serious infection defined as a positive blood cultures requiring treatment and pulmonary aspergillosis requiring treatment	- Indicate Yes or No for question Serious infection defined as a positive blood cultures requiring treatment and pulmonary aspergillosis requiring treatment. - If Yes Enter the description of the event and Date of occurrenc - Indicate Yes or No if event was ongoing, If No, enter the end date of the event
Venous thromboembolism	- Indicate Yes or No for question Venous thromboembolism - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No. enter the end date of the event.
Stroke	- Indicate **Yes or No** for question **Stroke** - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event.
Myocardial infarction	- Indicate Yes or No for question Myocardial infarction - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event.
Ischaemic bowel	- Indicate **Yes or No** for question **Ischaemic bowel** - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event.
Gastrointestinal perforation	- Indicate Yes or No for question Gastrointestinal perforation - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event
Clinically important gastrointestinal (GI) bleeding. Defined as overt bleeding on GI endoscopy, developing as a complication in the ICU and accompanied by 1 or more of the following features within 24 hours - Spontaneous drop of systolic, mean arterial pressure or diastolic blood pressure of 20mmHg or more - Start of vasopressor or a 20% increase in vasopressor dose	- Indicate Yes or No for question Clinically important gastrointestinal (GI) bleeding. - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event

- Decrease in haemoglobin of at least 2 g/dl - Transfusion of 2 units of packed RBC or more	
New-Onset Atrial Fibrillation (NOAF)	- Indicate Yes or No - If Yes Enter the description of the event and Date of occurrence - Indicate Yes or No if event was ongoing, If No, enter the end date of the event
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.19.5 Co-Enrolment

Co-Enrolment	
Was the patient co-enrolled in any other clinical research studies?	- Indicate Yes or No whether the patient is co-enrolled in any other clinical research studies If yes, answer the next questions.
Study Name / Acronym	- Enter the Study Name/Acronym of study
Participant ID for the study co-enrolled	- Enter the participant ID for the study co-enrolled
Trial Intervention (if known)	- Enter the trial Intervention (if known)
Date of enrolment in the study co-enrolled?	- Enter the date of enrolment in the study co-enrolled?
If participant is enrolled on additional studies click '+' and enter details.	
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

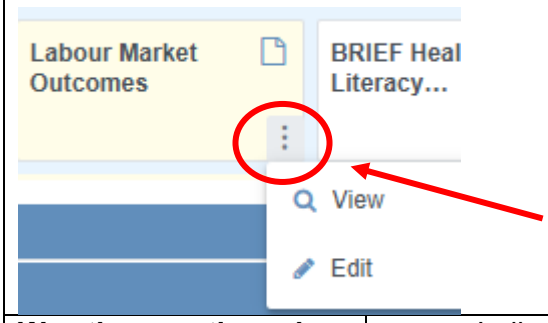
6.20 Day 90

6.20.1 Follow up Day 90

Follow Up Day 90	
Is the patient alive 90 days after randomisation?	- Indicate Yes, No or Unknown whether the patient is alive 90 days after randomisation - If Yes, enter date this was confirmed. - Confirm whether participant has had anu hospital readmissions since discharge and enter how many. - If No, enter date patient died.

- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

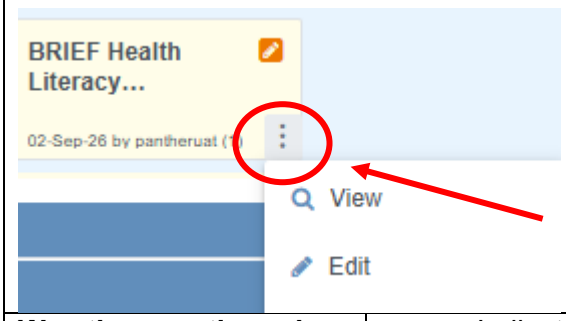
6.20.2 Labour Market Outcomes

Labour Market Outcomes	
This Questionnaire should be completed within +14 Days of Follow Up Visit. In some regions including the UK this will be completed centrally.	
- To complete the questionnaire please click the **Actions** tab these are the 3 dots located on the right side of form and then select **Edit** 	
Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Not Done – Select Reason it was not done - If the patient has died please select 'not done' and 'unable to contact patient'.
Date questionnaire completed	- Enter date the questionnaire was completed
Were you in employment before your admission to critical care?	- Indicate Yes, or No - If Yes, continue with the remaining questions. - If No, complete the "Describe Status" field and select "Complete".
Have you returned to work since discharge from hospital?	- Indicate Yes, or No - If Yes, continue with the remaining questions. - If No, select "Complete".
Are you working the same number of hours as before your admission to critical care?	- Indicate Yes, or No - If Yes, continue with the remaining questions. - If No, Describe the changes (including change to working hours).
Have you had to take any other unplanned time off work?	- Indicate Yes, or No - If Yes, Please describe this time off work (including hours). - If No, select "Complete".
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.20.3 BRIEF Health Literacy Screening

BRIEF Health Literacy Screening
This Questionnaire should be completed within +14 Days of Follow Up Visit. In some regions including the UK this will be completed centrally.

- To complete the questionnaire please click the **Actions** tab these are the 3 dots located on the right side of form and then select **Edit**



Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Yes, complete date questionnaire was completed and the remaining questions - If Not Done – Select Reason it was not done *Note if the patient has died please select 'not done' and 'unable to contact patient'.*
Date questionnaire completed	- Enter date the questionnaire was completed
Please circle the answer that best represents your response	- For each question select the box that best represents the patients response.
Total Score	- The overall score will automatically fill-in when all questions have been answered
Interpret Scores	- An interpretation for the score will appear hear based on the toal score, taken from the BRIEF questionnaire.

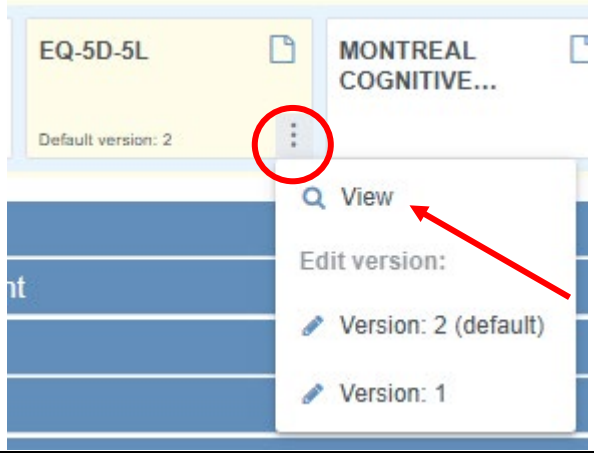
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.20.4 EQ-5D-5L

EQ-5D-5L

This Questionnaire should be completed within +14 Days of Follow Up Visit. In some regions including the UK this will be completed centrally.

- To complete the questionnaire please click the **Actions** tab these are the 3 dots located on the right side of form and then select **Edit**



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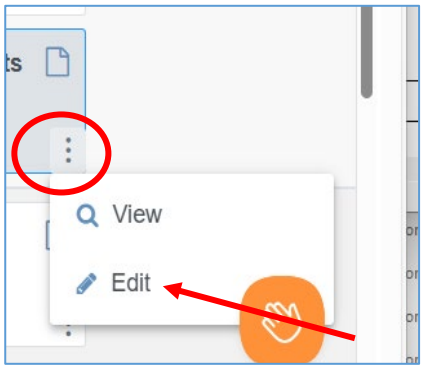
Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Not Done – Select Reason it was not done - If the patient has died please select 'not done' and 'unable to contact patient'.
Date questionnaire completed	- Enter date the questionnaire was completed
MOBILITY	- Select the option that the patient has described/selected
SELF-CARE	- Select the option that the patient has described/selected
USUAL ACTIVITIES	- Select the option that the patient has described/selected
PAIN/ DISCOMFORT	- Select the option that the patient has described/selected
ANXIETY/ DEPRESSION	- Select the option that the patient has described/selected
We would like to know how good or bad your health is TODAY. Please indicate on the scale (0-100) to indicate how your health is TODAY.	- On the right side scale, please tap to indicate how the patient rated their health today. The value will show in the black box titled "Your Health Today". - This scale is numbered from 0 to 100. - 100 means the best health you can imagine. - 0 means the worst health you can imagine.
Living Environment	
Do you live alone?	- Indicate Yes or No based on patients answer - If No, enter How many people the patient lives with.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised.	

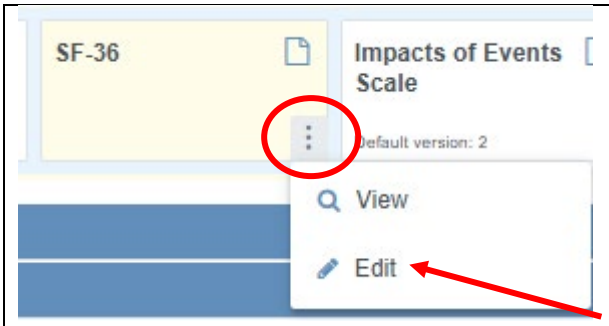
6.21 Hospital Anxiety and Depression Scale (HADS)

Hospital Anxiety and Depression Scale (HADS)	
This Questionnaire should be completed within +14 Days of Follow Up Visit. In some regions including the UK this will be completed centrally.	
- To complete the questionnaire please click the **Actions** tab these are the 3 dots located on the right side of form and then select **Edit** 	
Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Not Done – Select Reason it was not done - If the patient has died please select 'not done' and 'unable to contact patient'.
Date questionnaire completed	- Input date the questionnaire was completed

I feel tense or 'wound up':	- Select the option that the patient has described/selected
I still enjoy the things I used to enjoy:	- Select the option that the patient has described/selected
I get a sort of frightened feeling as if something awful is about to happen:	- Select the option that the patient has described/selected
I can laugh and see the funny side of things:	- Select the option that the patient has described/selected
Worrying thoughts go through my mind:	- Select the option that the patient has described/selected
I can sit at ease and feel relaxed:	- Select the option that the patient has described/selected
I feel as if I am slowed down:	- Select the option that the patient has described/selected
I get a sort of frightened feeling like 'butterflies' in the stomach:	- Select the option that the patient has described/selected
I have lost interest in my appearance:	- Select the option that the patient has described/selected
I feel restless as I have to be on the move:	- Select the option that the patient has described/selected
I look forward with enjoyment to things:	- Select the option that the patient has described/selected
I get sudden feelings of panic:	- Select the option that the patient has described/selected
I can enjoy a good book or radio or TV program:	- Select the option that the patient has described/selected
Total Score: Depression	- Read-only field. The total sum of all Depression Questions is automatically calculated by the system according to the scores given in previous questions.
Total Score: Anxiety	- Read-only field. The total sum of all Anxiety Questions is automatically calculated by the system according to the scores given in previous questions
Total Score:	- Read-only field. The total sum of all Anxiety Questions and all Depression Questions are automatically calculated by the system according to the scores given in previous questions
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.21.1 Social and Wellbeing SF-36

Social and Wellbeing SF-36
This Questionnaire should be completed within +14 Days of Follow Up Visit. In some regions including the UK this will be completed centrally.
- To complete the questionnaire please click the **Actions** tab these are the 3 dots located on the right side of form and then select **Edit**

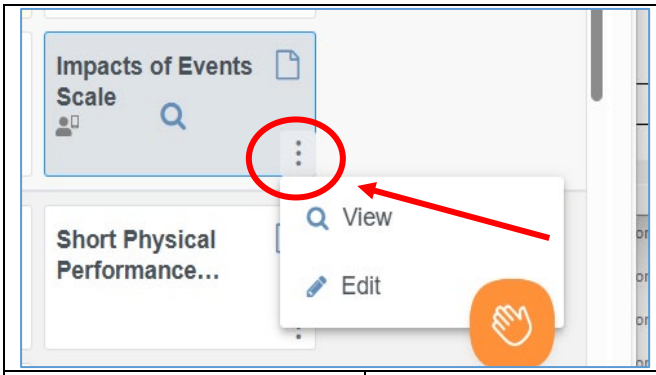


Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Not Done – Select Reason it was not done - If the patient has died please select 'not done' and 'unable to contact patient'.
Date questionnaire completed	- Enter date the questionnaire was completed
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?	- Select Yes or No that the patient has described/selected for all questions in this section.
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?	- Select the answer that the patient has described/selected for all questions in this section.
Welfare Benefits Question Set	- Select the answer that the patient has described/selected for all questions in this section.
Care Needs (adapted from Griffiths et al (2013)	- Indicate **Yes** or **No** for Q. Do you receive care (depend on other people for help) to undertake to undertake your normal activities? - If 'Yes' is selected answer all the questions in this section. - Select the option that the patient has described/selected.

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.21.2 Impact of Events Scale

Impact of Events Scale
This Questionnaire should be completed within +14 Days of Follow Up Visit. In some regions including the UK this will be completed centrally.
- To complete the questionnaire please click the **Actions** tab these are the 3 dots located on the right side of form and then select **Edit**



Was the questionnaire completed?	- Indicate Yes, or Not Done whether the questionnaire was completed. - If Not Done – Select Reason it was not done - If the patient has died please select 'not done' and 'unable to contact patient'.
Date questionnaire completed	- Enter date the questionnaire was completed
DURING THE PAST SEVEN DAYS with respect to (the event). How much were you distressed or bothered by these difficulties?	- Select the option [0 – 4] that the patient has described/selected for each question on the form. - 0 - Not at all; 1 - A little bit; 2 – Moderately; 3 - Quite a bit; 4 – Extremely]
Total Score	- This field will complete automatically based on the answers selected for the previous questions.

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.22 Day 180

6.22.1 Follow Up data - Day 180

Follow Up data - Day 180	
Date of Visit	- Enter Date this visit was performed
Was the patient contacted at D180?	- Indicate Yes or Not Done whether the patient contacted at Day 180 - If Not Done – Select Reason it was not done. *Note if the patient has died before this date, then please enter the date of death as the date of visit, this will flag a query, please answer the query explaining that the patient has died. Then for 'was the patient contacted' select 'not done' and 'unable to contact patient'.* -

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

The follow-up questionnaires at Day 180 will be completed centrally in some regions including the UK.

EQ-5D-5L, MOCA, HADS, SF-36, Impact of Events Scale, Labour Market Outcomes

Please refer to the Day 90 section as these assessments are repeated at Day 180

6.23 Follow Up data - 1 year

Follow Up data - 1 year	
Is the patient alive 1 year after randomisation?	- Indicate Yes, No or Unknown whether the patient is alive 1 year after randomisation. - If Yes, Enter Date this was confirmed. - If No, Enter Date patient died

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.24 Safety reporting

6.24.1 Adverse Event Form

Adverse Event Form

Please note: This form may be hidden/not required depending on your jurisdiction.

Section 4.6 details the location of adverse event and how to Add New.

Answer all questions on the form

- The AE number will be auto populated by the system.
- Enter the description/name of the adverse event in the "Adverse Event Term" field and complete the rest of the form.
- Only one event should be reported per page
- If AE is not ongoing, enter End date and ensure Outcome has been completed.
- If action taken is "Medication", ensure that the medication is recorded on the Concomitant Medication form.
- If "Does this adverse event meet the criteria for a Serious Adverse Event?" question is yes, complete a SAE form.
- Use the "Comments" field to record any additional information that has not previously been recorded on the eCRF regarding this AE.
- The Medical Coding section is not applicable for site staff to complete please leave blank.

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.24.2 Serious Adverse Event Form

Serious Adverse Event Form

- Section 4.6 details the location of adverse events and how to Add New
- Once an SAE has been added you will see a summary of the SAE on this page.
- Answer all questions on the form by completing each section.

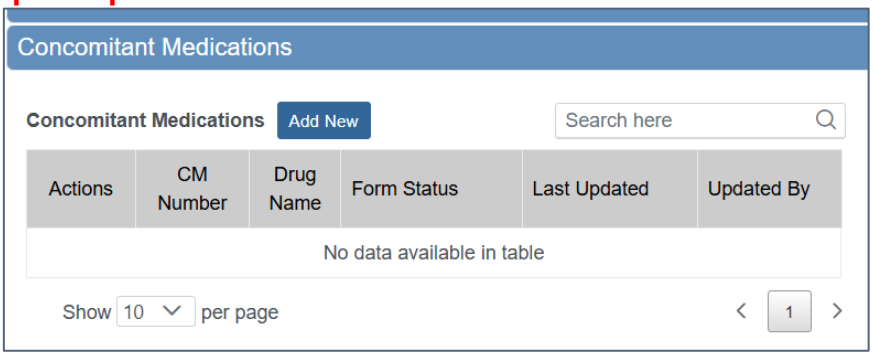
SAE Number	- The SAE reference number will be auto-populated by the system
Related to AE Number	- State whether related to an AE by entering the AE number*

	- *For UK Sites only – Please enter '0' for AE number
Type of Report	- Select Type of Report
Date of last trial treatment given prior to SAE	- Enter Date of last trial treatment given prior to SAE
Was the trial treatment given at full protocol dose prior to event?	- Indicate Yes or No - If No, provide details
Why was the event serious?	- Enter the Event seriousness
Where did the SAE take place?	- Select where the SAE took [lace - If place of SAE occurrence is Other, please specify.
Briefly describe SAE *(Include relevant symptoms, body site, lab tests and treatments received for management of the SAE)*	- Enter a narrative description of the event that occurred in the 'Briefly describe SAE' field. - Only one event should be reported per page
Serious Adverse Event Term	- Enter the description/name of the event in the "Serious Adverse Event term" field and complete the rest of the page.
Date of Notification	- Enter Date of Notification
Date of Onset	- Enter Date SAE started
Ongoing	- Indicate Yes or No if SAE is ongoing, If AE is not ongoing, enter 'End date' and ensure SAE status has been completed.
Severity	- Enter the severity of SAE – Mild, Moderate or Severe
CTCAE Grade	- Enter CTCAE grade
SAE Status	- Enter SAE status. If SAE Status is selected as "Recovered/Resolved", "Resolved with sequelae" or "Fatal" enter End date.
Trial Treatment/IMP	
Include details of the treatment the participant was receiving at the time of the event. Complete one entry per Treatment/IMP	
Dosage	- Enter the dosage of IMP that was given to the patient
Units	- Select the units from the drop-down
Frequency	- Select how often the IMP was given from the drop-down
Route of Administration	- Select the route of administration from the drop-down
Start Date of Most Recent Cycle	- Enter the start date of the most recent cycle
Ongoing	- Indicate Yes or No as to whether the IMP administration is ongoing
PI Assessment (TO BE COMPLETED BY PI ONLY)	
Expectedness	- Select Expected or Unexpected
RSI Version used to assess (IB/SmPC) **IB/SmPC - Investigator's Brochure/Summary of Product Characteristics*	- Enter the RSI version used to assess
Causal Relationship to Event	- Select the causal relationship to the event
Action Taken	- Select the action taken
Did reaction abate after stopping Treatment/IMP?	- Select Yes, No or Not applicable
Did reaction reappear after reintroduction?	- Select Yes, No or Not applicable

Other Treatments at Time of Event	
Are there other treatments at time of event?	- Enter any Other Treatment if additional treatment was given click '+' details in the 'Other Treatments at Time of Event' section and enter details.
Protocol Required Treatments (NIMPs)	
Are there any protocol required treatments (NIMPs)?*NIMP - Non-Investigational Medicinal Product*	- Enter any Protocol Required Treatment (NIMPS), if additional treatment was given click '+' details in the 'Protocol Required Treatment (NIMPS)' section and enter details
Other Treatments at Time of Event	
Any Other Relevant Information *(Such as the participant's medical history, drug or alcohol abuse, family history, findings from special investigations etc)*	- Complete 'Other Relevant Information' section.
Was this event expected in view of the patient's clinical history?	- Select Yes or No
Medical Coding	
SAE Verbatim	- Enter a description of the SAE
The remaining fields for this section will be completed by the study team.	
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.25 Concomitant Medications

Concomitant Medications	
This form should be completed if a participant is randomised to simvastatin and received baricitinib or if a participant is randomised to baricitnib and receives simvastatin.	

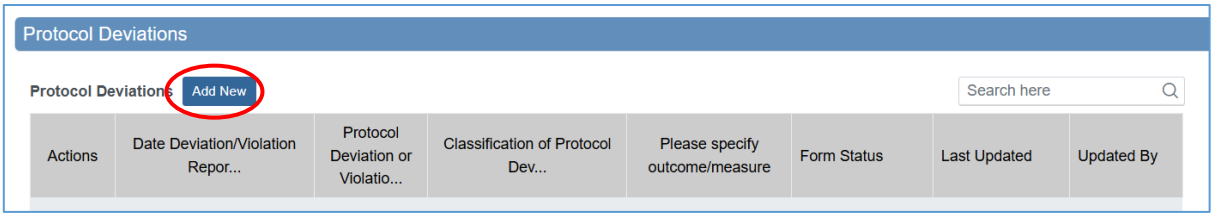


- To add a new medication, click on the 'New' button and a new Concomitant Medication page (see below) will open

Drug Name	- Select Simvastatin or Baricitnib
Start Date Format (Enter full date if known)	- Enter full date if know

	- If start date is unknown; use the "unknown" field to select the part of the date that is unknown (day or month).
Ongoing	- Select yes or no - If no, enter stop date
Indication	- Record the indication. If indication is an adverse event, ensure that the description is the same as what is recorded on the AE page -
Dosage	- Enter 'Dose' - If 'Other' provide specification.
Units	- Select 'Dose Unit' from the list. - If unit is not in the list, select 'Other' and specify
Frequency	- Select frequency from the list. If not on the list, select "Other" and specify details.
Route of Administration	- Select Route from the list. If Route is not on the list, select "Other" and specify details.
- Click on 'Close' or 'Complete' at the bottom of the page to save the data. - When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised	

6.26 Protocol Deviations

Protocol Deviations	
To add a Protocol Deviation/Violation form, click on the 'Add New' button for the Protocol Deviation page will open 	
Date Deviation/Violation Reported	- Enter the date the protocol deviation/violation has been reported.
Protocol Deviation or Violation	- Select whether this was a protocol deviation or violation: - **Deviation:** a protocol deviation occurs when a process or criteria has not been actioned in line with the approved protocol. - **Violation:** a protocol violation occurs when there is a consistent variation in practice from the defined protocol. Non-compliance with the inclusion and exclusion criteria is always classed as a significant protocol violation. Please refer to the relevant Study Manuals or the study team for guidance.
How was Deviation / Violation Identified?	- Select how the deviation/violation was identified, if none apply, select 'Other' and specify in the 'Please specify' box

Classification of Protocol Deviation/Violation	- Select one of the classifications. Only one can be selected.
Description of Deviation/Violation	- Describe in detail the deviation/violation. - Select how the deviation/violation was identified, if none apply, select 'Other' and specify in the 'Please specify' box
Date of Deviation/Violation	- Enter the date the deviation/violation occurred.
Response to Deviation / Violation (e.g. CAPA) *CAPA - Corrective Action Preventive Action*	- Enter any Corrective Action Preventive Action that have been taken/implemented as a response to this deviation/violation.
Is this a serious breach?	- Select 'Yes' or 'No' to confirm if deviation/violation was a serious breach question
Study Manager review (if applicable)	- Select 'Yes' or 'Not applicable for Study Manager Review

If multiple deviations are being entered at once, you can add another form automatically by selecting 'Add another Protocol Deviations' above the 'Close' form button.

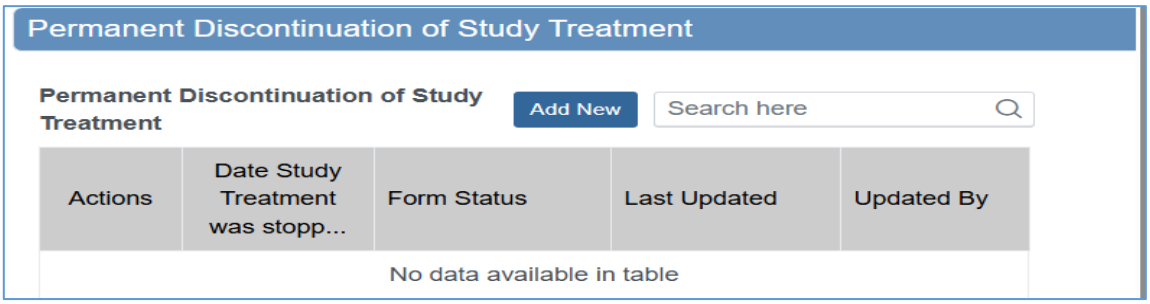
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.27 Permanent Discontinuation of Study Treatment

Permanent Discontinuation of Study Treatment

This form should only be completed if it is evident that a participant has permanently discontinued Study Treatment before the end of the study

- To add a Permanent Discontinuation of Study Treatment form, click on the 'Add New' button for the Permanent Discontinuation of Study Treatment page will open



Date Study Treatment was stopped	- Enter date participant permanently discontinued study treatment
Primary reason Study Treatment was stopped	- Select Reason for discontinuation - If reason is due to Significant Adverse Event or unacceptable toxicities (not captured via safety outcomes) please complete a Serious Adverse Event form

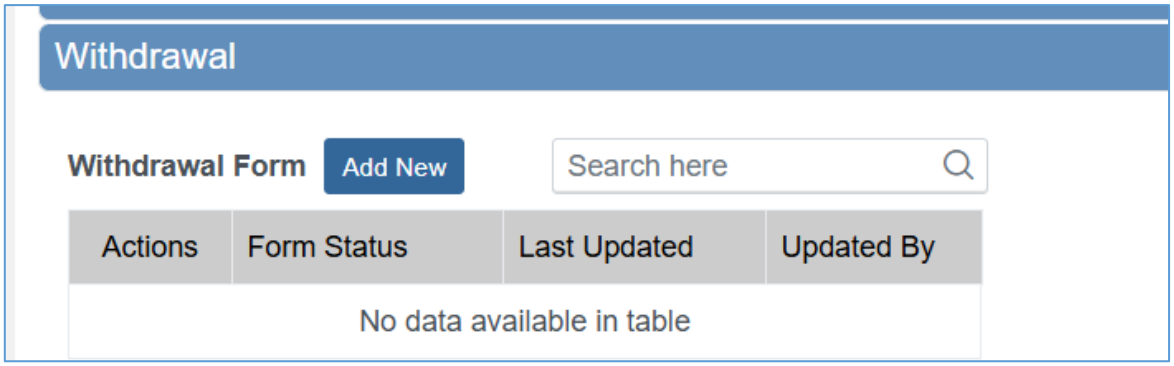
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.28 Withdrawal Form

Withdrawal Form

- To add a Withdrawal form, click on the 'Add New' button for the Withdrawal page will open
- This form should be completed for patients who withdraw from the study prior to end of study, a permanent discontinuation from study treatment form should also be completed.

- Otherwise, this form should be completed for all patients who complete the study

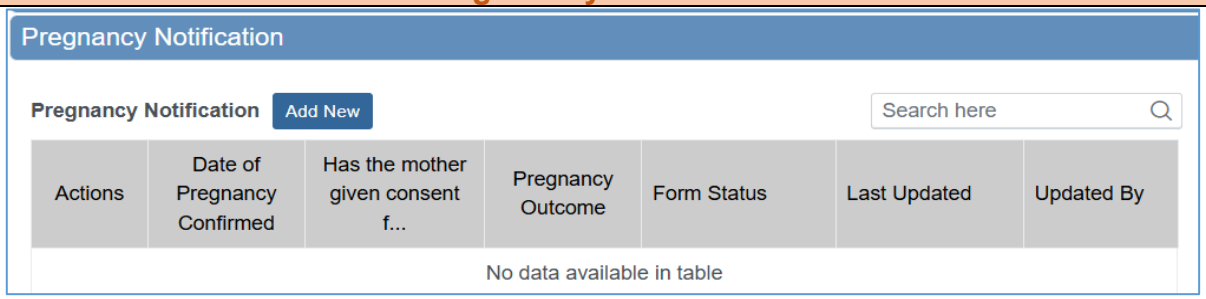


Did the subject complete the study according to the protocol?	- Select Yes or No - If the participant died, please select yes, as the participant completed the study according to the protocol
Date of Completion	- If the answer to the previous question is Yes, enter the 'Date of Completion' and the 'Consent' question -
Date of Withdrawal	- If the answer to the first question is No please enter the 'Date of Withdrawal'
Type of Withdrawal	- Select the type of withdrawal - If type of Withdrawal is selected as 'Other', please specify details in the box provided.
Primary reason for the Withdrawal.	- Select the Primary reason for the Withdrawal. - If Primary Reason for Withdrawal is selected as 'Other', please specify details in the box provided.
Consent	- The Consent question on the form should be completed to confirm participant consent.

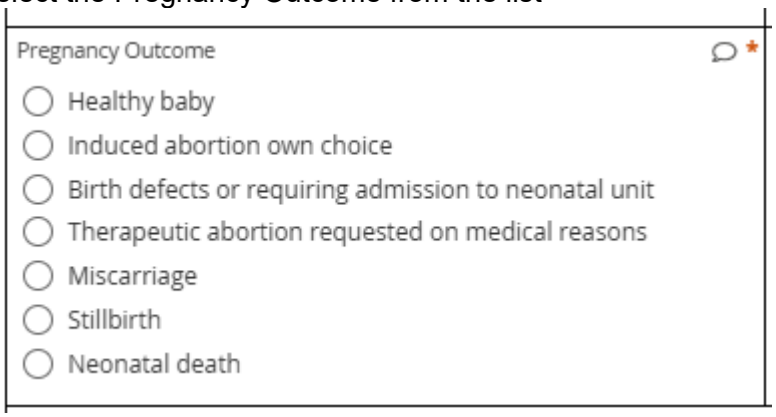
- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

6.29 Pregnancy Notification

Preganancy Notification



- Complete this form to report details of any pregnancy from the time of informed consent experienced by trial participant where such reporting is required by the trial protocol.

Report Date	- Enter Date of report
Initial or final report	- Indicate whether report is Initial or final report.
Has the mother given consent for pregnancy monitoring?	- Indicate **Yes or No** whether the mother has given consent for pregnancy monitoring
Date of Last Menstrual Period	- Enter the Date of Last Menstrual Period
Date of Pregnancy Confirmed	- Enter the Date pregnancy was confirmed
Expected Delivery Date	- Enter the Date of Expected Delivery
Onset of Labour (for deliveries after 22 weeks gestation)	- Indicate whether onset of Labour was Spontaneous or Induced -
Pregnancy Outcome	- Select the Pregnancy Outcome from the list  -
Date of Outcome	- Enter Date of Outcome
Comments	- Provide any additional information related to the pregnancy in the comments field provided.

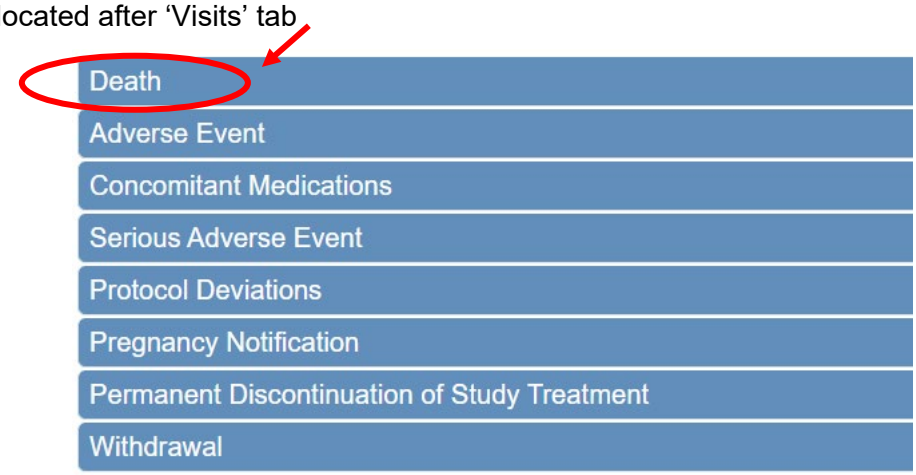
- Click on ‘Close’ or ‘Complete’ at the bottom of the page to save the data.

- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

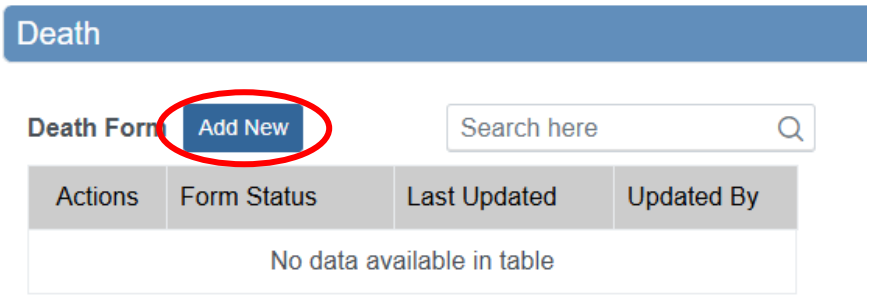
6.30 Death Form

Death Form

Death Form is located after 'Visits' tab



Select add new:



Complete this form when a participant has died. Answer all questions

- If Participant died during the study enter the Date & Time of death.

- Click on 'Close' or 'Complete' at the bottom of the page to save the data.
- When completing data entry please only 'complete' the form when all data has been entered. If data is missing from the form only 'close' the form – this prevents unwanted missing data queries from being raised

7. CRF completion queries

If you have any questions, please contact your trial management team.

8. Version history

Version Number	Date	Author	Description
1.0	17-Oct-2025	Vivienne Okona-Mensah	New document

2.0	18-Nov-2026	Elizabeth Fagbodun and Lucy Stronach	Formatting changes and updated due to changes made in the database

9. Amendments

Section	Amendment