



Randomisation Guide

03 Feb 2026

Randomisation

- ❑ Once eligibility is confirmed begin completing the eligibility forms.
- ❑ Randomisation should be performed after receiving the result of the patient's subphenotype.
- ❑ Randomisation is performed using a web-based system, OpenClinica
- ❑ OpenClinica is a browser-based electronic data capture system (EDC) accessed via the link <https://imperial.openclinica.io/OpenClinica> with email address and password to log-in
- ❑ We advise site teams to use Google Chrome as a browser where possible
- ❑ Record each randomisation on screening/randomisation log and print randomisation form from the OpenClinica system
- ❑ Ensure the participant's trial ID is recorded in their medical records

Adding a new participant

❑ Navigate to the participant matrix

❑ Click 'Add Participant'

❑ The participant ID will be automatically generated

Home Participant Matrix **Add Participant** Queries Tasks

Add New Participant

Participant ID * ID will be generated on Add

Cancel Add



Participant ID	TV0-029	Status	Available	First Name		Mobile
Study Name	PANTHER	Site Name	TUVALU	Participate Status		Email

Adding a visit

- ❑ The forms on the database are organised into 'visits' which reflect the different timepoints of the study
- ❑ To add a visit click 'Add New'

Participant TV0-029

TV0-029 Audit Log | Showing Active Records

Expand All | Collapse All

General Information

				Invite			
Participant ID	TV0-029	Status	Available	First Name		Mobile	
Study Name	PANTHER	Site Name	TUVALU	Participate Status		Email	

Visits

Sort by Date

Search form or visit name

Add New

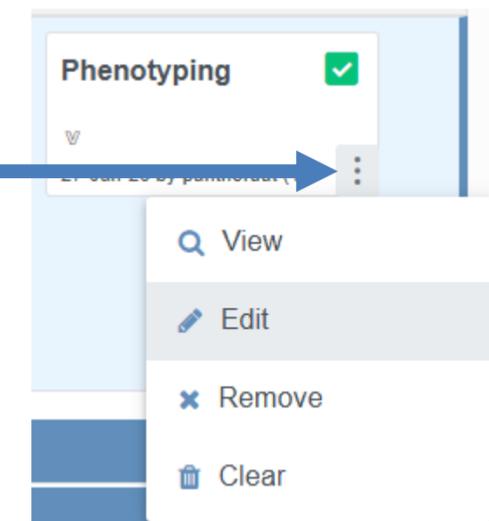
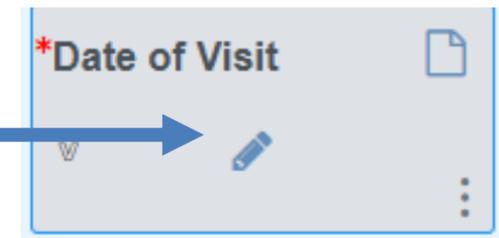
There are no rows to display.

Death

Serious Adverse Event

Completing a form

- ❑ After adding a visit, you will need to click on the pencil icon to edit a form
- ❑ Clicking on the edit icon will open the form
- ❑ Data entry is automatically saved, so even if you close a form the data will save
- ❑ Once you have completed data entry on a form, click the orange 'Complete' button. Please note that this will finalise the data, only select this once you are happy with the data
- ❑ Forms that are complete will have a green tick
- ❑ If you need to edit data on a form that is complete, click the three dots, and then click 'Edit'



Randomisation process

- ❑ The Pre-randomisation (screening) visit must be completed prior to randomisation
- ❑ This is to confirm eligibility of the patient
- ❑ The system will not allow you to randomise before completing pre-randomisation (screening)
- ❑ A drop-down list should appear with all the visits after selecting 'Add New'
- ❑ Select 'Pre-randomisation'

Select the correct visit

Add Visits

Participant ID: TV0-028

* Visit Name

Pre Randomisation (Non-repeating)

Pre Randomisation (Non-repeating)

Baseline (24 hours pre randomisation) (Non-repeating)

Day 0 (post randomisation) (Non-repeating)

Simvastatin Administration (Non-repeating)

Baricitinib Administration (Non-repeating)

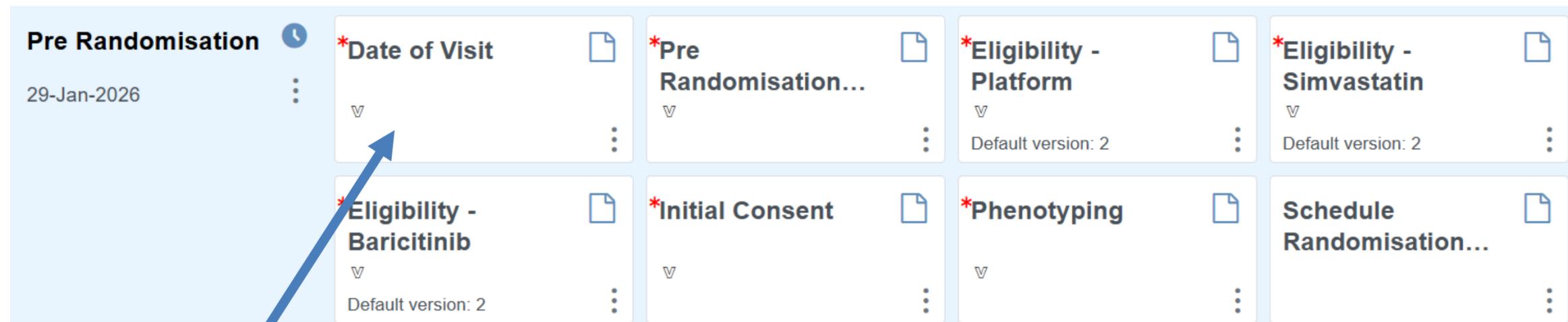
×

And then click 'Add visits'

Add visits

Completing the pre-randomisation visit

- ❑ Once you have added the Pre-randomisation visit, there should be 8 forms to complete
- ❑ Complete all forms in the pre-randomisation visit in sequential order.
- ❑ If they are not completed in sequential order the randomisation may not be successful.



The screenshot shows a grid of 8 forms for a 'Pre Randomisation' visit on '29-Jan-2026'. The forms are arranged in two rows of four. Each form has a title, a dropdown arrow, and a three-dot menu icon. A blue arrow points to the 'Date of Visit' form.

Form Title	Default Version
*Date of Visit	
*Pre Randomisation...	
*Eligibility - Platform	Default version: 2
*Eligibility - Simvastatin	Default version: 2
*Eligibility - Baricitinib	Default version: 2
*Initial Consent	
*Phenotyping	
Schedule Randomisation...	

Should be today's date (date of randomisation)

TV0-029: Eligibility - Platform

Inclusion Criteria

Critically ill patients in hospital and the following: - a) Acute respiratory distress syndrome (ARDS)*	Ⓟ *
<input type="radio"/> Yes <input type="radio"/> No	
*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 $\geq 30\text{L}/\text{min}$ 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, • $\text{PaO}_2/\text{FiO}_2$ ratio < 40 kPa from arterial blood gases, or $\text{SpO}_2/\text{FiO}_2 < 315$ from pulse oximetry where $\text{SpO}_2 < 97$.	Ⓟ *
<input type="radio"/> Yes <input type="radio"/> No	

Exclusion Criteria

>48 hours from diagnosis of ARDS	Ⓟ *
<input type="radio"/> Yes <input type="radio"/> No	
Planned withdrawal of life-sustaining treatment within the next 24 hours	Ⓟ *
<input type="radio"/> Yes <input type="radio"/> No	
Previous enrolment in the PANTHER trial in the last 12 months	Ⓟ *
<input type="radio"/> Yes <input type="radio"/> No	
Declined consent	Ⓟ *
<input type="radio"/> Yes <input type="radio"/> No	

Final Eligibility Check

Is the subject eligible to participate in the study?	Ⓟ *
<input type="radio"/> Yes <input checked="" type="radio"/> No	
Please specify	Ⓟ *
<input type="checkbox"/> Inclusion criteria violated	
<input type="checkbox"/> Exclusion criteria violated	

All changes saved.

Close

✓ Complete

Completing eligibility forms

There are 3 eligibility forms which require completion: Platform, Simvastatin & Baricitinib

The final eligibility check is auto populated depending on what you have answered. If no is selected, you will be unable to randomise the patient and will need to specify why the patient has been excluded.

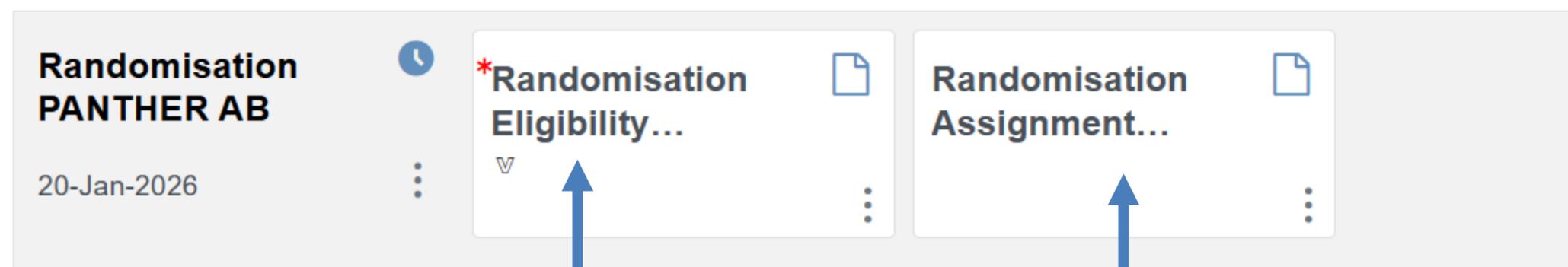
- ❑ You will need to mark the pre-randomisation event as complete once all forms have been completed
- ❑ You are now ready to randomise the patient once the pre-randomisation visit is complete

Pre Randomisation ✓ 27-Jan-2026	Date of Visit ✓ 27-Jan-26 by pantheruat (1)	Pre Randomisation... ✓ 27-Jan-26 by pantheruat (1)	Eligibility - Platform ✓ 27-Jan-26 by pantheruat (2)	Eligibility - Simvastatin ✓ 27-Jan-26 by pantheruat (2)
	Eligibility - Baricitinib ✓ 27-Jan-26 by pantheruat (2)	Initial Consent ✓ 27-Jan-26 by pantheruat (1)	Phenotyping ✓ 27-Jan-26 by pantheruat (1)	Schedule Randomisation... ✓ 27-Jan-26 by pantheruat (1)

Please click here and select 'edit', this will take you to the update study event page where you will need to change the status of the event to complete and a green tick will appear.

The randomisation visit

- ❑ The Randomisation Event will automatically appear above the pre-randomisation visit.
- ❑ A letter will also appear, such as A, AB, etc, please ignore these letters, these relate to the randomisation groups in the back end of the database.



Complete the randomisation eligibility form

The treatment allocation will appear here. You will also need to enter the date and time of randomisation here

Completing Randomisation eligibility

TV0-029: Randomisation Eligibility (PANTHER D)

Confirm the participant details and eligibility in order to randomise this participant.

Study Name: PANTHER	Participant ID TV0-029
Gender Male	Age 26
Site ID- TV	

Randomise

Country Tuvalu
Is the participant eligible for randomisation? <input type="radio"/> Yes <input type="radio"/> No

All changes saved.

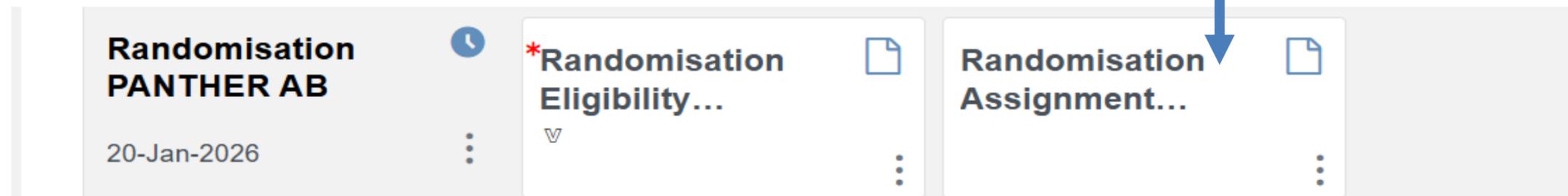
Close

✓ Complete

This form acts as a final check to confirm eligibility.

The greyed-out questions have been populated using answers from the pre-randomisation visit.

The randomisation allocation will not appear immediately on the assignment form



This is because there is a small lag between the assignment being generated and then appearing on the form.

Once you close any randomisation confirmation page, **WAIT** for the assignment form to change to orange and show that the system has updated the form.



If the assignment page does not update, refresh the browser

Only open the assignment form once it shows that it has updated

View the randomisation assignment form to see the treatment allocation

TV0-029: Randomisation Assignment (PANTHER D)

Participant details:

Study Name: PANTHER	Participant ID TV0-029
Gender Male	Age 26

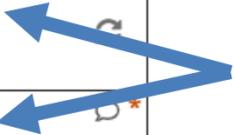
Allocation:

Study Treatment	Baricitinib
Date of Randomisation	yyyy-mm-dd
Time of Randomisation	Hint: format (hh:mm [0-23] hrs [0-59] min)

Treatment allocation will be shown here



The date and time of randomisation should be entered here.



All changes saved.

Close

✓ Complete

If you do not wait for the system to sync, the allocation will not appear

If you open the form before waiting for it to update, the treatment allocation will be blank

Participant details:

Study Name: PANTHER	Participant ID TV0-029
Gender Male	Age 26

Allocation:

Study Treatment

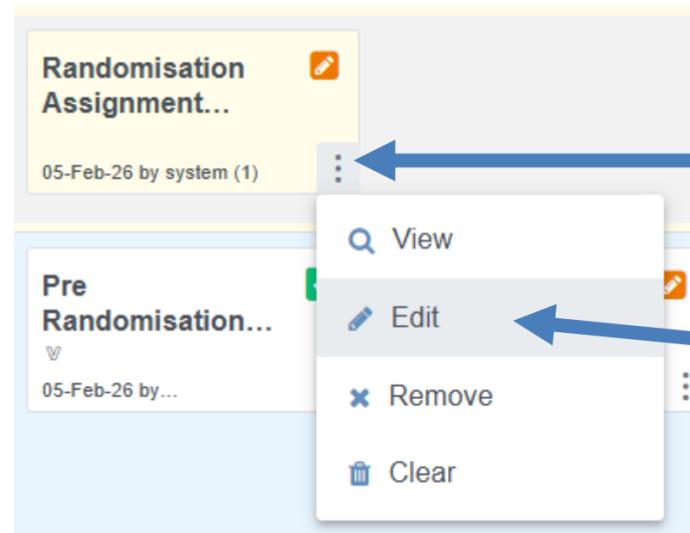
All changes saved.

Close

If this happens, do not panic. There are steps to take to allow the data to sync.

First click '**CLOSE**' to exit the form
Do not click 'Complete' as this will lock the form.

Re-open the form in 'Edit' mode



Click on the 3 dots next to the randomisation assignment form

Click 'Edit'

This will re-open the form in edit mode

Allocation:

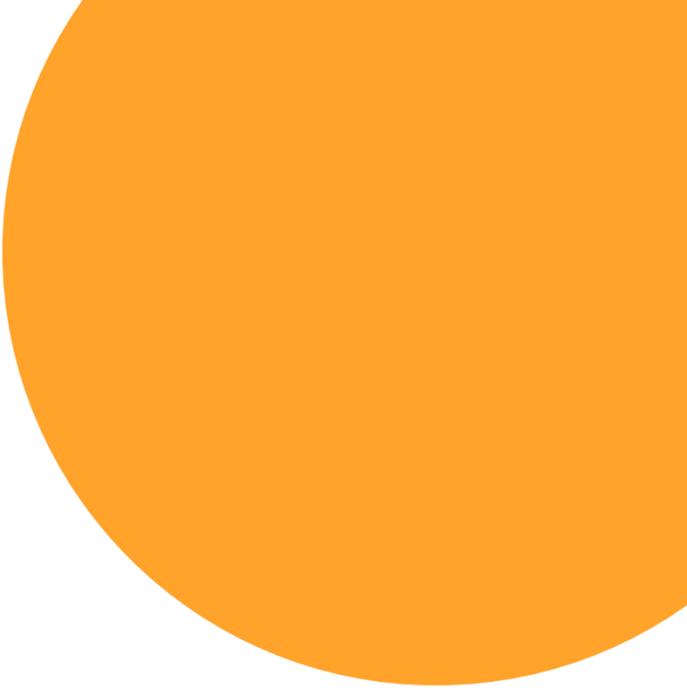
Study Treatment Baricitinib	🗨
Date of Randomisation yyyy-mm-dd	🗨* 🔄
Time of Randomisation <small>Hint: format (hh:mm [0-23] hrs [0-59] min)</small>	🗨*

The treatment allocation will now appear

You will need to complete the date and time of randomisation and click 'complete' once all data has been entered.

Randomisation Reminders

- ❑ After completing the confirmation page **WAIT** for the system to show the assignment form has updated
- ❑ Then open the form to view the assignment
- ❑ If the assignment is BLANK – close the form (do not click complete) and wait a moment before re-opening in edit mode
- ❑ OpenClinica have informed us if this does not work, do not try again
- ❑ Call a member of the PANTHER trial team to guide you through clearing the forms and randomising again



Contact the PANTHER team if you have any issues



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