



Randomisation Guide

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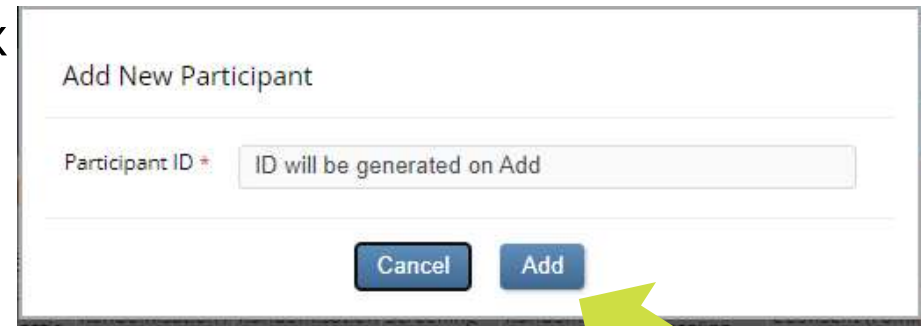
FUNDED BY
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Randomisation

- + Randomisation should be performed soon after confirming eligibility and prior to anticipated start of randomised treatment
- + Randomisation performed using a web-based system in 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
- + 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 New Participant'



Add New Participant

Participant ID * ID will be generated on Add

Cancel Add

- + The participant ID will be automatically generated

Participant UAT1-1064

UAT1-1064 Audit Log | Showing Active Records

Expand All | Collapse All

General Information				Invite			
Participant ID	UAT1-1064	Status	Available	First Name		Mobile	
Study Name	SepTIC	Site Name	UAT 1 Site 1	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 UAT1-1064 UAT1-1064 Audit Log | Showing Active Records

[Expand All](#) | [Collapse All](#)

General Information

Participant ID	UAT1-1064	Status	Available	First Name		Mobile	
Study Name	SepTIC	Site Name	UAT 1 Site 1	Participate Status		Email	

Invite

Visits

Sort by Date

Search form

There are no rows to display.

Completing a form

+ After adding a visit, you will need to click on the pencil icon to edit a form

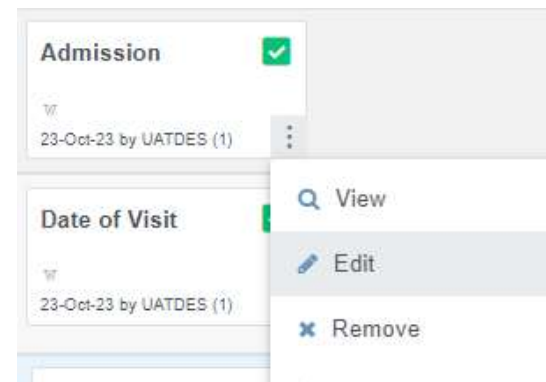
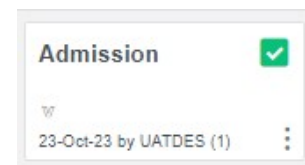
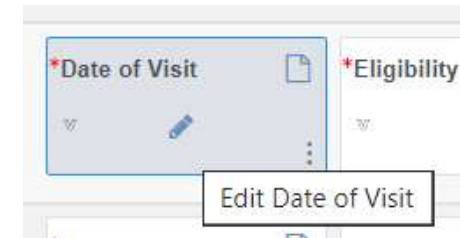
+ Clicking on the edit icon will open the form

+ 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

+ 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'



Randomising patients onto Trials 1 and 2: Diagnostic and Fluid

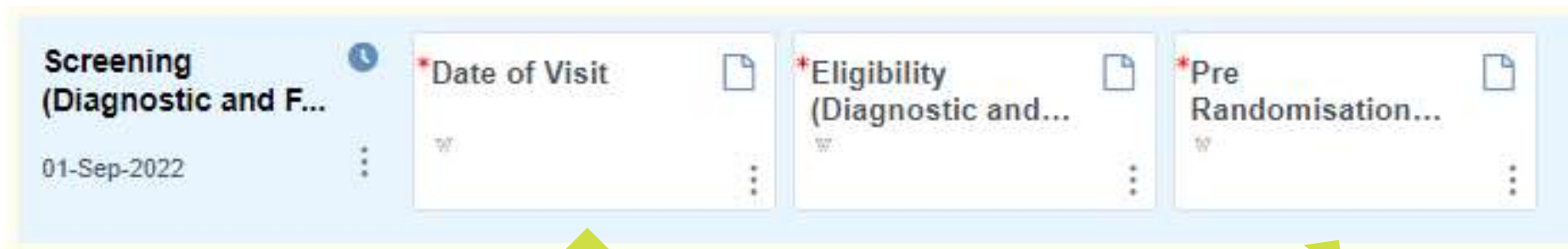
- + The screening visit **must be** completed prior to randomisation
- + This is to confirm eligibility of the patient
- + The system will not allow you to randomise before completing screening
- + A drop-down list should appear with all the visits
- + Select 'Screening (Diagnostic and Fluid)'

Select the correct visit

And then click 'Add visits'

Completing the screening visit

- + Once you have added the screening visit, there should be 3 forms to complete



The screenshot shows a form titled "Screening (Diagnostic and F..." with a date of "01-Sep-2022". Below the title are three form sections, each with a red asterisk and a document icon:

- *Date of Visit
- *Eligibility (Diagnostic and...
- *Pre Randomisation...

Should be today's date (date of randomisation)

Then complete both forms and mark as complete

Complete the Eligibility form

Participant Information

Month and Year of Birth	ⓘ *
yyyy-mm	↺
Age <small>(years)</small>	ⓘ
What is the patient's gender?	ⓘ *
<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Prefer to self-describe <input type="radio"/> Prefer not to disclose	
Is patient's gender the same as the sex assigned at birth?	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Prefer not to disclose	

Inclusion Criteria

Adults (≥16 years of age) admitted to ICU due to suspected sepsis and expected to stay for at least two calendar days (i.e. expected to still be in ICU the day after tomorrow)	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No	
Receiving intravenous antibiotics for suspected sepsis	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No	
According to local clinical judgement, patient has received adequate initial early fluid resuscitation	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No	

Exclusion Criteria

More than 24 hours since ICU admission (this does NOT apply for intervention 3, GM-CSF). Note: As early intervention in sepsis is important, the aim should be to enrol eligible patients as soon after ICU admission as is practically possible.	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No	
Previously admitted to ICU due to sepsis on this hospital admission	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No	

Confirm the participant is eligible for the study by selecting 'Yes' and click 'Complete'

Final Eligibility Check

Is the subject eligible to participate in the fluid and diagnostic trials of the study?	ⓘ *
<input type="radio"/> Yes <input type="radio"/> No	

All changes saved.

Close

✓ Complete

Complete the Pre-randomisation Data form

Has the patient been in hospital >48h or is known to have been readmitted within 30 days 🗨️ * <input type="radio"/> Yes <input type="radio"/> No	Is the patient receiving vasopressors? 🗨️ * <input type="radio"/> Yes <input type="radio"/> No
Is the patient receiving respiratory support? 🗨️ * <input type="radio"/> Yes <input type="radio"/> No	

Close

✔ Complete

- + You are now ready to randomise the patient once the screening visit is complete

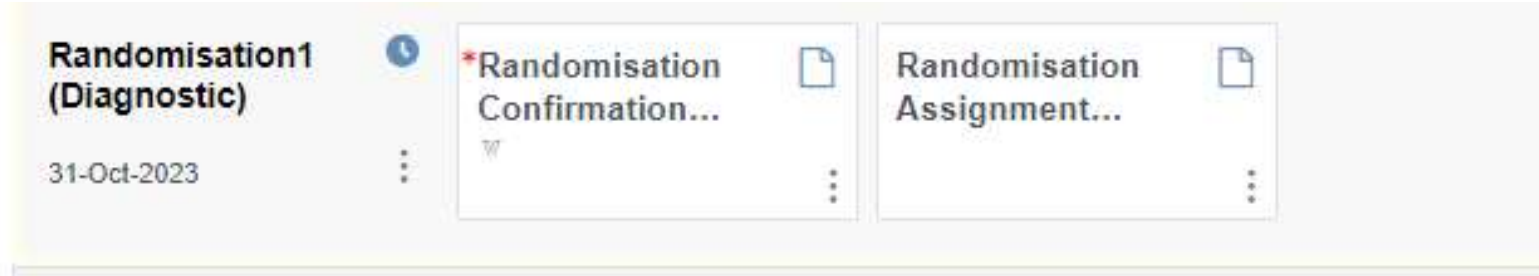
Visits

Sort by Date

Screening (Diagnostic and F... 23-Oct-2023	Date of Visit 23-Oct-23 by UATDES (1)	Eligibility (Diagnostic and... 23-Oct-23 by UATDES (1)	Pre Randomisation... 23-Oct-23 by UATDES (1)
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Add the randomisation visit for Trial 1: Diagnostic

- + To randomise patients onto Trial 1: Diagnostic, you will need to add the randomisation visit and complete the forms in the order below



The screenshot shows a trial management interface. On the left, there is a card for 'Randomisation1 (Diagnostic)' with a date of '31-Oct-2023'. To the right of this card are two form boxes. The first form is titled '*Randomisation Confirmation...' and the second is titled 'Randomisation Assignment...'. Both forms have a document icon and a vertical ellipsis menu icon. Below the forms, two green arrows point upwards towards the respective form boxes.

Complete the
randomisation
confirmation

The assignment will
be on this form

Complete the diagnostic randomisation confirmation to confirmation eligibility

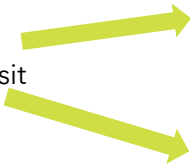
Confirm the participant details and eligibility in order to randomise this participant.

Study Name: <i>SepTIC</i>	Participant ID
Gender	Month and Year of Birth

Randomise

Has Consent been obtained	ⓘ*
<input type="radio"/> Yes <input type="radio"/> Enrolled without prior consent in emergency situation (Consent to be obtained later) <input type="radio"/> No	
Vasopressor use	ⓘ
<input type="radio"/> Yes <input type="radio"/> No	
Source of infection	ⓘ
<input type="radio"/> Community <input type="radio"/> Hospital	
Is the participant eligible for randomisation and stratifications completed?	ⓘ*
<input type="radio"/> Yes <input type="radio"/> No	
Date of Randomisation	ⓘ ⓘ*
yyyy-mm-dd	🔄
Select 'Randomise' below if participant is eligible and click 'Complete' to randomise the participant.	ⓘ
<input checked="" type="radio"/> Randomise	
Please click 'Complete' and the treatment will be populated in the Randomisation Assignment form.	

These questions will be automatically completed with answers from the screening visit



These questions will appear once the previous question is answered

View the randomisation assignment form to see the diagnostic treatment allocation

- + This form is **read-only**, no data will be entered on the form
- + The participants details will appear from the eligibility form
- + The allocation will be under 'Treatment'

Participant details:

Study Name: <i>SepTIC</i>	Participant ID UAT1-1085
Gender Male	Month and Year of Birth 1961-06

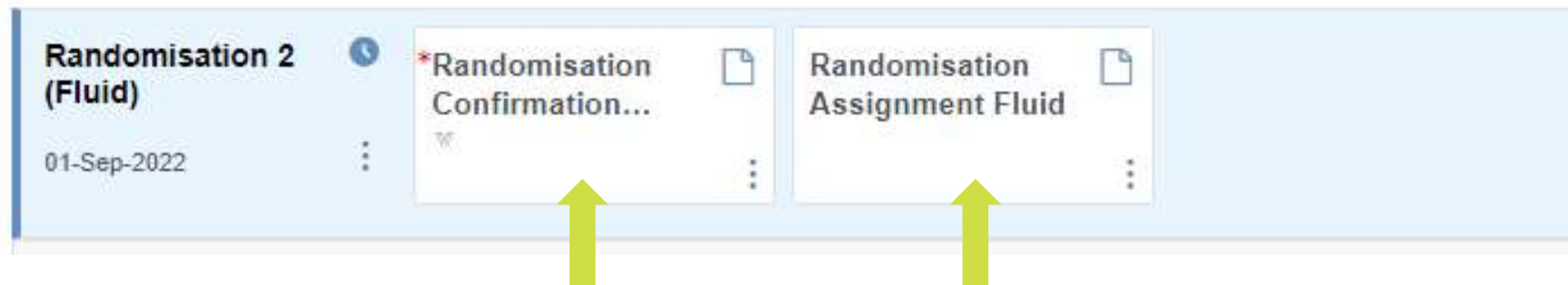
Example:

Allocation:

Date of Randomisation 2023-10-31
Treatment PCR-based pathogen testing and PCT

Repeat for Trial 2: Fluid

- + To randomise patients onto the Fluid Trial, there should be 2 forms to complete



Complete the
randomisation
confirmation

The assignment
will then appear
on this form

Complete the Fluid Randomisation Confirmation Form

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

Study Name: <i>SepTIC</i>	Participant ID
Gender	Month and Year of Birth

Randomise

Vasopressor use	
<input checked="" type="radio"/> Yes <input type="radio"/> No	
Receiving respiratory support	
<input checked="" type="radio"/> Yes <input type="radio"/> No	
Is the participant eligible for randomisation and stratifications completed?	
<input type="radio"/> Yes <input type="radio"/> No	

These questions will be automatically completed with answers from the screening visit



Date of Randomisation	
yyyy-mm-dd	

Select 'Randomise' below if participant is eligible and click 'Complete' to randomise the participant.	
<input type="radio"/> Randomise	

These questions will appear once the previous question is answered



View the randomisation assignment form to see the fluid treatment allocation

- + This form is **read-only**, no data will be entered on the form
- + The participants details will appear from the eligibility form
- + The allocation will be under 'Treatment'

Participant details:

Study Name: <i>SepTIC</i>	Participant ID UAT1-1085
Gender Male	Month and Year of Birth 1961-06

Example: **Allocation:**

Date of Randomisation 2023-10-31
Treatment Conservative fluid therapy with de-resuscitation

Randomising patients onto Trial 3 GM-CSF

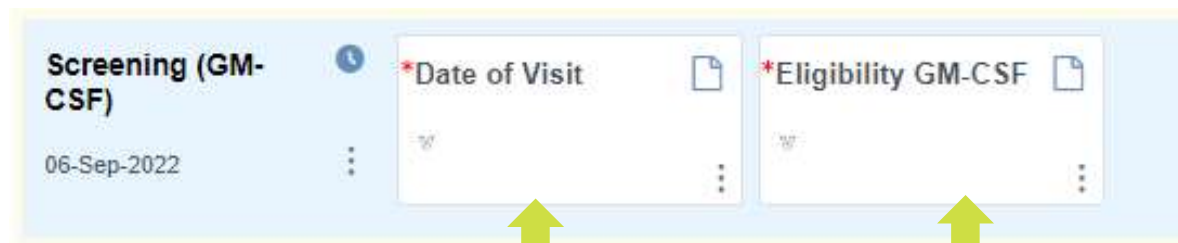
- + Ensure the patient meets the additional inclusion criteria and none of the additional exclusion criteria for GM-CSF
- + To randomise patients to the GM-CSF trial, the following events/forms must be complete:

Screening (Diagnostic and Fluid)

this visit must be completed regardless of whether the patient was randomised to the Diagnostic and Fluid trials

Complete screening visit for Trial 3: GM-CSF

- + The screening visit must be completed **before** randomising
- + Add the 'Screening (GM-CSF)' visit and complete the forms in the order shown below



The screenshot shows a form titled 'Screening (GM-CSF)' with a date of '06-Sep-2022'. It contains two main sections: '*Date of Visit' and '*Eligibility GM-CSF'. Each section has a document icon and a vertical ellipsis menu icon. Two green arrows point upwards from the text below to the input areas of these two sections.

This should be today's date (date of randomisation)

Then complete eligibility form

Inclusion Criteria GM-CSF

Intubated and mechanically ventilated and expected to continue for another 24 hours or requiring two organ support (i.e. vasopressors or renal replacement therapy) Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
An absolute lymphocyte count $< 1.2 \times 10^9/L$ on two consecutive calendar days at least 12 hours apart, with no values $> 1.2 \times 10^9/L$ in between. Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No

Exclusion Criteria for GM-CSF

More than 120 hours (5 days) since ICU admission Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
Already receiving G-CSF or GM-CSF Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
A total white blood cell count $> 50 \times 10^9/L$ Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
Known to be pregnant or breastfeeding Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
Known recent (required treatment within the last 5 years) haematological malignancy Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
Solid organ or bone marrow transplantation Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No
Patient weight $< 175kg$ Ⓟ*
<input type="radio"/> Yes <input type="radio"/> No

- + Complete the GM-CSF eligibility form
- + Confirm patient eligibility on the final eligibility check before continuing

Final Eligibility Check

Eligibility results from first eligibility check, is patient eligible:- Ⓟ	Is the subject eligible to participate in the GM-CSF trial of the study? Ⓟ
	<input checked="" type="radio"/> Yes <input type="radio"/> No

Add the Randomisation 3 GM-CSF visit

+ Then complete the forms as shown below

Complete the
randomisation
confirmation

The assignment will
appear on this form

The screenshot shows a light blue interface with three main components. On the left is a card titled 'Randomisation 3 (GM-CSF)' with the date '06-Sep-2022' and a vertical ellipsis icon. In the center is a white box titled '*Randomisation Confirmation G...' with a date '04-Sep-23 by UATDE (1)' and a vertical ellipsis icon. On the right is another white box titled 'Randomisation Assignment GM...' with a document icon and a vertical ellipsis icon. Two green arrows point downwards from the text above to the central and right-hand boxes.

Complete the GM-CSF randomisation confirmation page

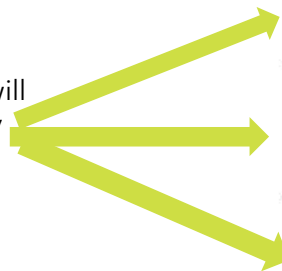
Confirm the participant details and eligibility in order to randomise this participant.

Study Name: <i>SeptIC</i>	Participant ID UAT1-1085
Gender Male	Month and Year of Birth 1961-06

Randomise

Treatment Allocation from Randomisation 1 <input type="radio"/> Standard care or Not Randomised <input checked="" type="radio"/> PCR/procalcitonin based diagnostics	D
Treatment Allocation from Randomisation 2 <input type="radio"/> Standard care or Not Randomised <input checked="" type="radio"/> Conservative fluid strategy	D
Source of infection <input type="radio"/> Community <input checked="" type="radio"/> Hospital	D
Is the participant eligible for randomisation and stratifications completed? <input checked="" type="radio"/> Yes <input type="radio"/> No	D
Date of Randomisation 2023-10-31	D
Select 'Randomise' below if participant is eligible and click 'Complete' to randomise the participant. <input checked="" type="radio"/> Randomise	D
Please click 'Complete' and the treatment will be populated in the Randomisation Assignment form.	

These questions will be automatically completed from previous forms



These questions will appear once the previous question is answered



The GM-CSF randomisation assignment form will have the fluid treatment allocation

Participant details:

Study Name: <i>SeptiC</i>	Participant ID UAT1-1090
Gender Female	Month and Year of Birth 1990-06

Example:

Allocation:

Date of Randomisation 2023-10-24	
Treatment SP66011	

The treatment will be the kit number that the patient has been assigned to. Make a note of the kit number.
Click 'Complete to close the form'

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, **refresh** the browser
- + And then open the assignment form
- + Or click 'edit' on the assignment form and submit again to refresh the page