



## Randomisation User Training

v1.0 01-NOV-2023

Sponsor: Imperial College London

Funder: NIHR

IRAS ID: 1005848

REC ref: 23/LO/0339

Chief Investigator: Prof Anthony Gordon

Study Coordination Centre:

Imperial Clinical Trials Unit

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# Coordinating Centre / Trial Management Team

- + Trial coordinated by Imperial Clinical Trials Unit
- + Chief Investigator: Prof Anthony Gordon
- + Trial Manager: Janis Best-Lane
- + Trial Monitor(s): Ravinder Dhaliwal and Paulina Kuswik

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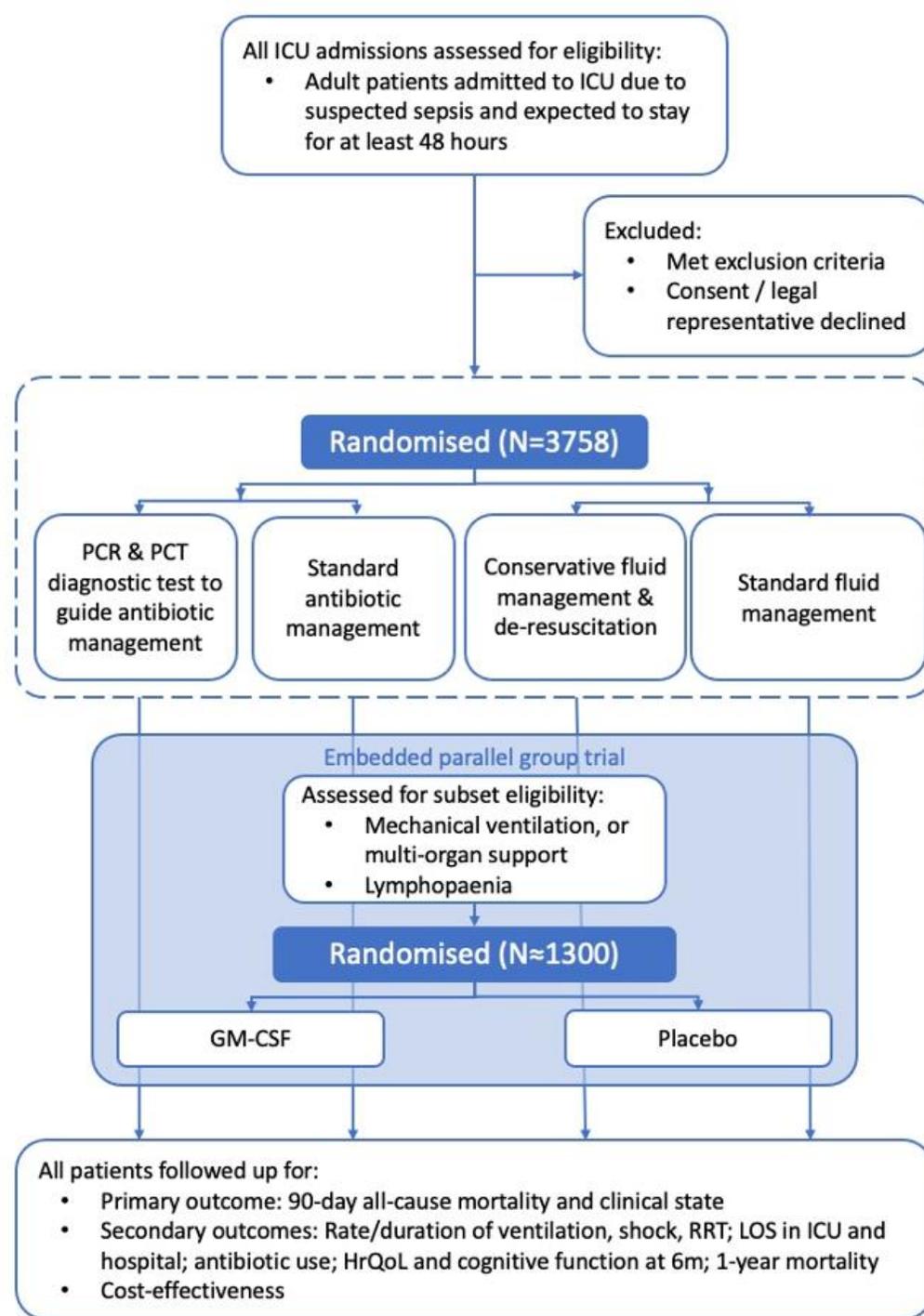
# Introduction to SepTiC

- + A multi-centre, pragmatic, multi-factorial, open-label randomised controlled trial, with an embedded randomised, double-blind, parallel group trial.

## Research questions

1. Do rapid PCR-based microbiological diagnostics plus procalcitonin improve outcomes and antibiotic stewardship compared to standard care in patients admitted to ICU with sepsis?
2. Does conservative fluid therapy with active removal of accumulated fluid (de-resuscitation) improve outcomes compared to standard care in patients ...with sepsis?
3. Does GM-CSF compared to placebo improve outcomes in a high-risk subset of patients ...with sepsis?
4. What is the relative cost-effectiveness of each of these interventions compared to current standard of care?

# Study Flowchart



# Inclusion Criteria

- + Adult patients ( $\geq 16$  yrs) admitted to ICU due to suspected sepsis and expected to stay for at least two calendar days (i.e. expected to still to be in ICU the day after tomorrow)
- + Receiving intravenous antibiotics for suspected sepsis
- + According to local clinical judgement, patient has received adequate initial early fluid resuscitation

# Exclusion Criteria

- + More than 24 hours since ICU admission (*not for GM-CSF*)
- + Previously admitted to ICU due to sepsis on this hospital admission
- + Not expected to survive 90 days, due to pre-existing chronic disease
- + Not expected to survive initial resuscitation (24 hours)
- + Neutropaenia due to chemotherapy / malignancy (but not due to sepsis)
- + A source of infection that will require a prolonged course of antibiotics, for >21 days (e.g. infective endocarditis, osteomyelitis, hepatic or cerebral abscess, tuberculosis)
- + DKA / HHS / DI / SAH (in last 21 days)
- + Weight <40Kg

# GM-CSF Trial - Inclusion criteria

+ Intubated, mechanically ventilated & expected to continue for another 24 hours

Or

+ Two organ support (Vasopressors, RRT)

**AND**

+ An absolute lymphocyte count  $<1.2 \times 10^9$  /L on two consecutive calendar days

*(at least 12 hrs apart with no values  $>1.2 \times 10^9$  /L in between)*

# Additional Exclusion criteria – GM-CSF

- + More than 120 hours (5 days) since ICU admission
- + Already receiving G-CSF or GM-CSF
- + A total white blood cell count (WBC)  $>50 \times 10^9 /L$
- + Allergy or adverse reaction to GM-CSF or yeast-product
- + Known to be pregnant or lactating
- + Known active haematological malignancy (*treated within last 5 years*)
- + Solid organ or bone marrow transplantation
- + Patient weight  $>125\text{kg}$

# Good Clinical Practice (GCP)

- + International, ethical and scientific quality standard to which all research involving human participants is conducted
- + Comprised of 13 core principles & applies to all clinical investigations that could affect safety and well-being of human participants, providing international assurance that:
  - Data and reported results of clinical investigations are credible and accurate
  - Rights, safety and confidentiality of participants in clinical research are respected and protected
- You are encouraged to obtain GCP certification, such as that available through NIHR:  
<https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>

# Principles of Good Clinical Practice (GCP)

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior Institutional Review Board (IRB)/ Independent Ethics Committee (IEC) approval/favourable opinion.

# Principles of Good Clinical Practice (GCP)

7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task.
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable [Good Manufacturing Practice\(GMP\)](#). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

# Randomisation

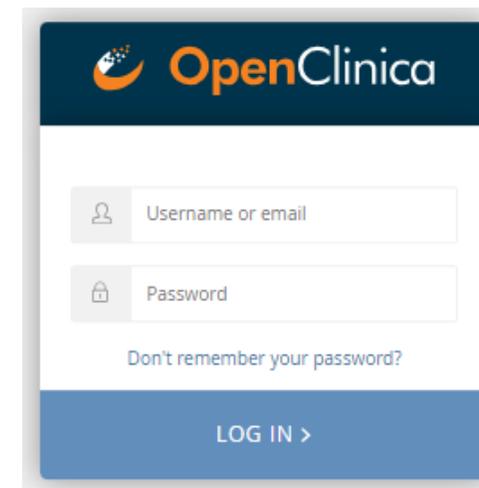
- + Randomisation should be performed soon after confirming eligibility and prior to anticipated start of randomised treatment
- + Randomisation performed using a web-based system in OpenClinica
- + Record each randomisation on screening/randomisation log and print randomisation form from the OpenClinica system
- + Ensure the participant's trial ID is recorded in their medical records

# Randomisation Users – Access to 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
- + **Please sign the combined training log / access request form** to complete your training and request a user account
  - ❖ Completing this training and signing training log means randomisation only users do not then need to be on Delegation Log, complete full GCP training, complete full OpenClinica training, or provide CV for SepTiC
- + Site trial team will submit the log to Trial Management at [septic@imperial.ac.uk](mailto:septic@imperial.ac.uk) for us to set-up your OpenClinica randomisation account
- + You will receive confirmation of your user account and log-in details by email

# Logging in to OpenClinica for the first time

- + Every time you login to the OpenClinica database, you will need to use the **Google Authenticator** app on your mobile device
- + This is also known as multi factor authentication (MFA) which is another way of confirming your identity when you login
- + To use the **Google Authenticator** app, you will first need to download it onto your mobile device
- + Download **Google Authenticator** from the App Store (for iOS) or Google Play Store (Android)
- + Go to the **OpenClinica** database and login to your account with your username and password



Open **Google Authenticator** on your mobile device and scan the QR code



**OpenClinica**

You are required to set-up multi-factor authentication.

This extra security measure keeps your account safe if someone discovers your username and password. To get started, please follow the steps below. Then, each time you log in you will need to access the authentication app and enter the code it displays.

**Step 1:** Install one of the following applications on your mobile device:

- Google Authenticator (recommended) - (Android - iOS)
- FreeOTP - (Android - iOS)

**Step 2:** Open the application and scan the barcode:

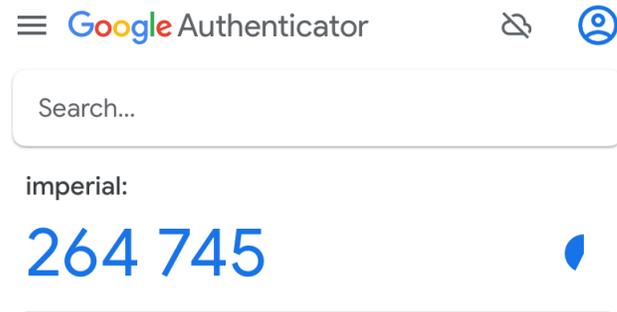


Unable to scan?

**Step 3:** Enter the one-time code provided by the application in the box below and click Log In to finish the setup.

LOG IN >

You will then receive a 6-digit code on your mobile device after scanning the QR code



**OpenClinica**

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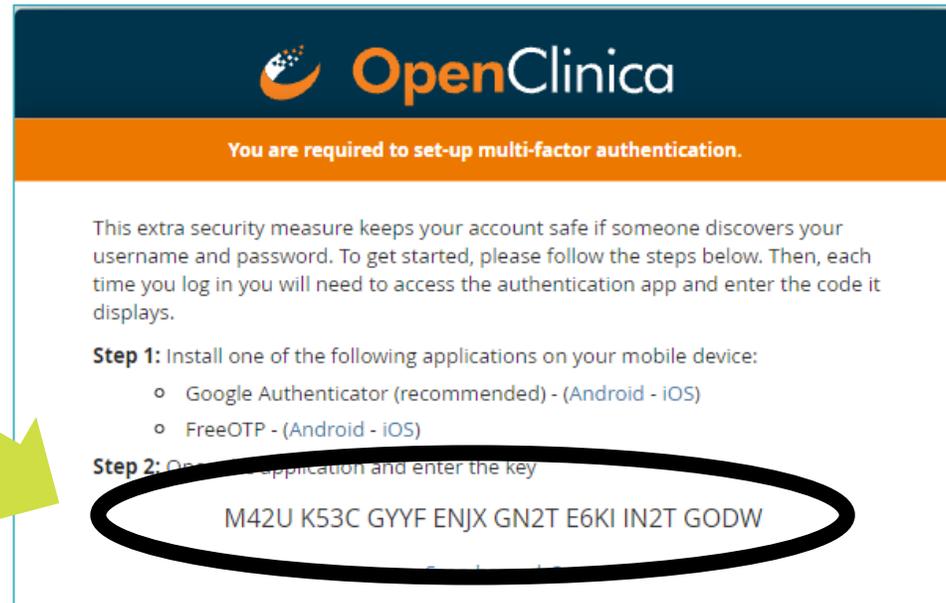
LOG IN >

Enter the 6-digit code here and click 'LOG IN'

# If you are unable to scan a QR code

- + Click on **“Unable to scan”** link on OpenClinica webpage after entering your username and password.

This will provide  
32-key code



- + Go on to google authenticator on your mobile device and select **“Enter a setup key”** and enter the 32-key code from the previous step
- + This will generate a 6-digit code



You are required to set-up multi-factor authentication.

This extra security measure keeps your account safe if someone discovers your username and password. To get started, please follow the steps below. Then, each time you log in you will need to access the authentication app and enter the code it displays.

**Step 1:** Install one of the following applications on your mobile device:

- Google Authenticator (recommended) - (Android - iOS)
- FreeOTP - (Android - iOS)

**Step 2:** Open the application and enter the key

M42U K53C GYYF ENJX GN2T E6KI IN2T GODW

Scan barcode?

- Type: Time-based
- Algorithm: SHA1
- Digits: 6
- Interval: 30

**Step 3:** Enter the one-time code provided by the application in the box below and click Log In to finish the setup.

Enter the 6 digit code here



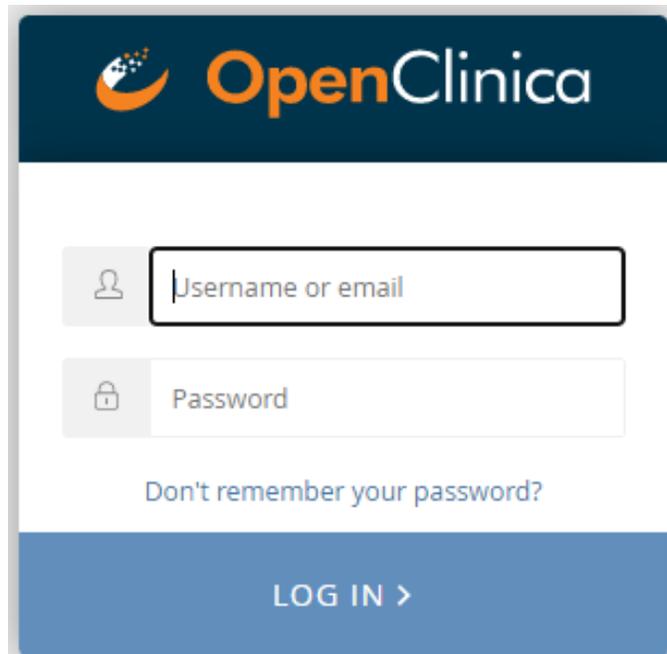
LOG IN >

And click here to log in

# You should now be set-up for MFA

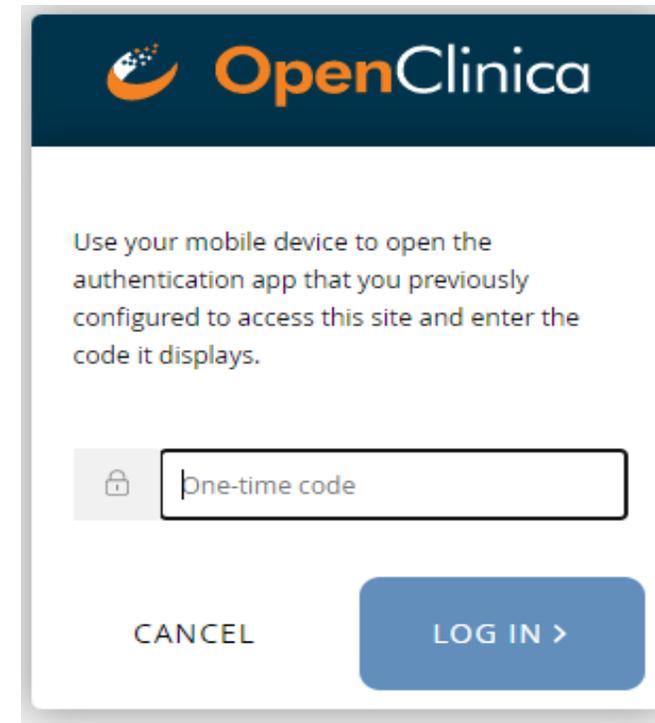
- + Once this is setup and you have the account saved on Google Authenticator, you do not need to scan the QR code again
- + Each time you login to OpenClinica, you will only need to use your username and password and then the 6 digit code from **Google Authenticator**

Now when you login to OpenClinica



The image shows the OpenClinica login interface. At the top is the OpenClinica logo. Below it are two input fields: one for 'Username or email' and one for 'Password'. A link 'Don't remember your password?' is located below the password field. At the bottom is a blue button labeled 'LOG IN >'.

It should ask you to enter your 6-digit code from Google Authenticator



The image shows the OpenClinica MFA verification screen. At the top is the OpenClinica logo. Below it is a text prompt: 'Use your mobile device to open the authentication app that you previously configured to access this site and enter the code it displays.' Below the prompt is a text input field labeled 'One-time code'. At the bottom are two buttons: 'CANCEL' and 'LOG IN >'.

# Once you have successfully logged in, navigate to the participant matrix

OpenClinica User Training (OCTraining) Test Environment | Change | Design | Share | Settings (Data Manager)

Enter Participant ID View Home **Participant Matrix** Queries Study Audit Log Tasks

### Participant Matrix for User Training

50 Show More Select An Event Add New Participant

Participant ID	Screening	Baseline Visit	Visit 1	Visit 2	Visit 3	Pregnancy	Actions
DR1-001	✓	⚠	✓	✓	✓ x2	✓ x2	🔍 ✕ 📄
DR1-002	⌚	⚠	⌚	⌚	⌚	⌚	🔍 ✕ 📄
DR1-003	⚠	✓	⌚	⌚	⚠	⚠	🔍 ✕ 📄
OCTraining-001	✓	✓	✓	✓	✓	✓	🔍 ✕ 📄
OCTraining-002	⚠	⌚	⌚	⌚	⌚	⌚	🔍 ✕ 📄
OCTraining-003	⌚	⚠	⌚	⌚	⌚	⌚	🔍 ✕ 📄
OCTraining-004	⌚	⚠	⌚	⌚	⌚	⌚	🔍 ✕ 📄
OCTraining-005	⌚	⌚	⌚	⌚	⌚	⌚	🔍 ✕ 📄
OCTraining-006	⚠	⌚	⌚	⌚	⌚	⌚	🔍 ✕ 📄
OCTraining-007	⌚	⌚	⌚	⌚	⌚	⌚	🔍 ✕ 📄

Alerts & Messages

Quick Access My Queries

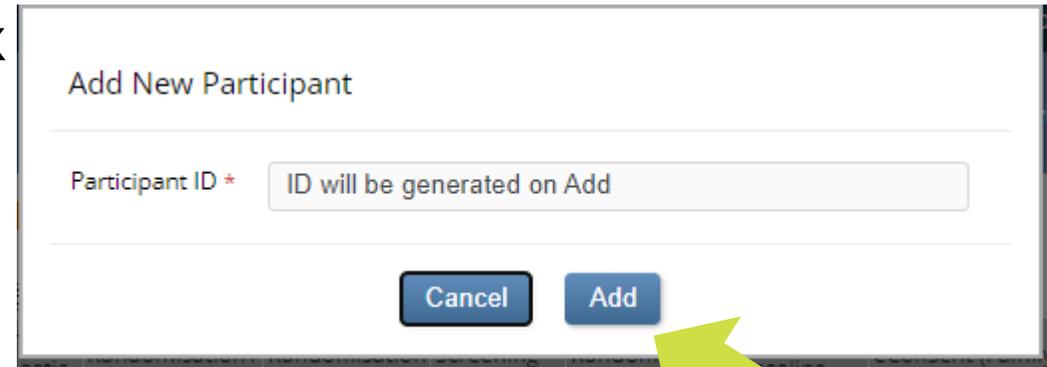
Instructions

Other Info  
Study: User Training  
Status: available  
Start Date: 22-Mar-2021  
End Date: 31-Dec-2031

Icon Key  
Not Started  
Not

# 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

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 ▲

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

Visits ▲

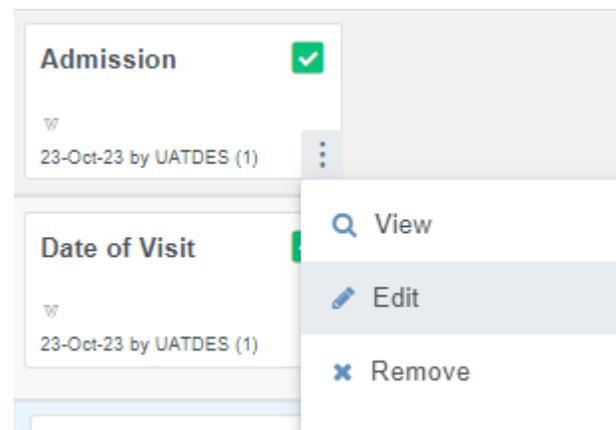
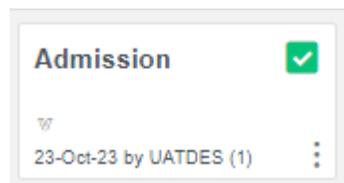
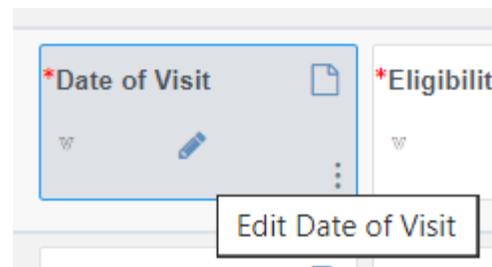
Sort by Date

Add New

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
- + The admission event will also need to be added to enter the patient's hospital and ICU admission details
- + A drop-down list should appear with all the visits
- + Select 'Screening (Diagnostic and Fluid)'

Select the  
correct visit



**Add Visits** ×

Participant ID: **UAT1-1064**

\* Visit Name

Screening (Diagnostic and Fluid) (Non-rep... ▼

Screening (Diagnostic and Fluid) (Non-repeating)

Randomisation1 (Diagnostic) (Non-repeating)

Randomisation 2 (Fluid) (Non-repeating)

Screening (GM-CSF) (Non-repeating)

Randomisation 3 (GM-CSF) (Non-repeating)

**Add visits**

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 record for a 'Screening (Diagnostic and F...)' visit on '01-Sep-2022'. To the right of the record are three form fields, each with a document icon and a vertical ellipsis menu:

- \*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 (years)	🗨 *
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)	🗨 *
Receiving intravenous antibiotics for suspected sepsis	🗨 *
According to local clinical judgement, patient has received adequate initial early fluid resuscitation	🗨 *

## 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.	🗨 *
Previously admitted to ICU due to sepsis on this hospital admission	🗨 *

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

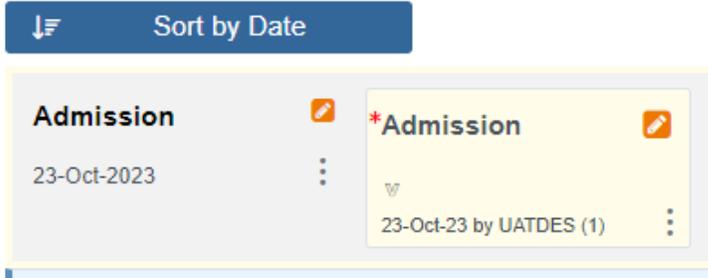
<p>Has the patient been in hospital &gt;48h or is known to have been readmitted within 30 days <span>🗨️ *</span></p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>	<p>Is the patient receiving vasopressors? <span>🗨️ *</span></p> <p><input type="radio"/> Yes</p> <p><input type="radio"/>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

Close

✓ Complete

# Completing the admission visit

- + There is only one form to complete for the admission visit
- + Add the admission visit from the drop-down menu
- + Complete the form and mark as complete



Hospital Admission Date yyyy-mm-dd	<input type="text"/> *	Hospital admission time <i>format (hh:mm [0-23] hrs [0-59] min)</i>	<input type="text"/> *
ICU Admission Date yyyy-mm-dd	<input type="text"/> *	ICU Admission time <i>format (hh:mm [0-23] hrs [0-59] min)</i>	<input type="text"/> *
ICNARC CMP Number	<input type="text"/> *	APACHE II Score	<input type="text"/> *
SICSAG Number (For Scotland Sites Only)			
<input type="radio"/> SICSAG Number			
<input type="radio"/> Not Applicable			

- + You are now ready to randomise the patient once the screening and admission visits are complete

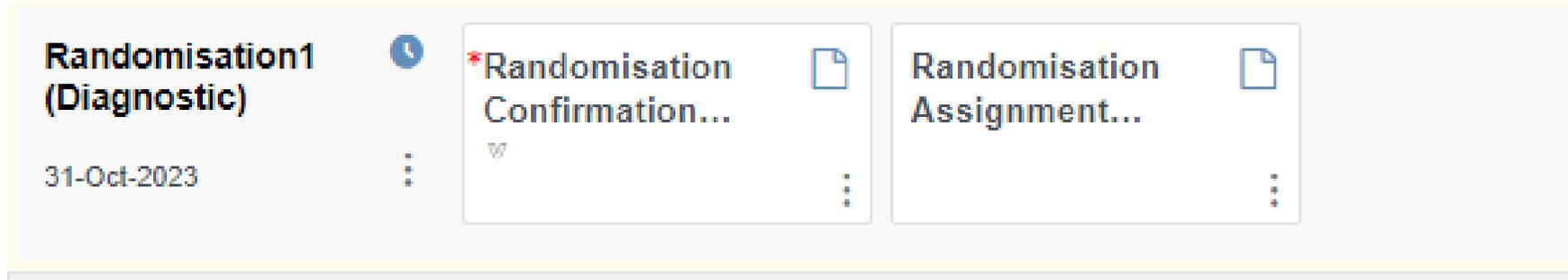
Visits

Sort by Date

<b>Admission</b> 23-Oct-2023	✓ ⋮	<b>Admission</b> 23-Oct-23 by UATDES (1)	✓ ⋮
<b>Screening (Diagnostic and F...)</b> 23-Oct-2023	✓ ⋮	<b>Date of Visit</b> 23-Oct-23 by UATDES (1)	✓ ⋮
		<b>Eligibility (Diagnostic and...)</b> 23-Oct-23 by UATDES (1)	✓ ⋮
		<b>Pre Randomisation...</b> 23-Oct-23 by UATDES (1)	✓ ⋮

# 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



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

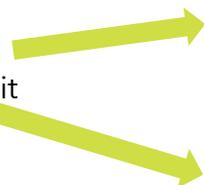
## Randomise

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

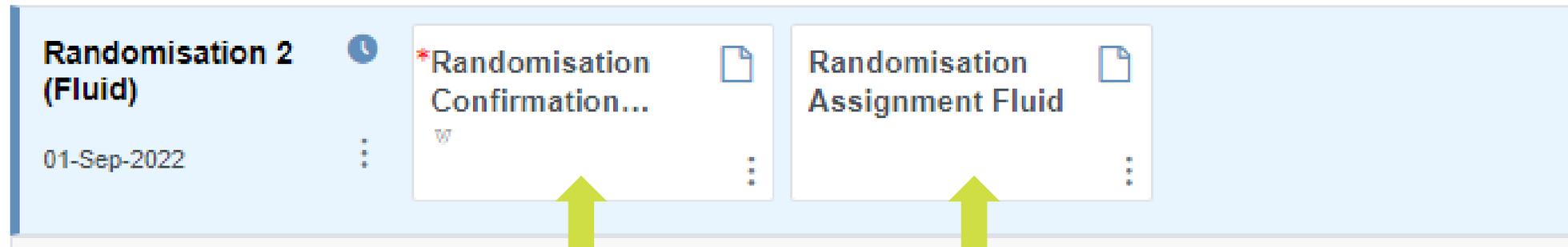
Example:

## 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	

These questions will appear once the previous question is answered

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

# 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

## **Admission**

# 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'. There are two main input fields, each with a red asterisk indicating it is required. The first field is labeled '\*Date of Visit' and the second is '\*Eligibility GM-CSF'. Both fields have a document icon in the top right corner and a dropdown arrow in the bottom right corner. Below the form, two green arrows point upwards towards the two input fields.

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) <span>🗨 *</span>
<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. <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No

### Exclusion Criteria for GM-CSF

More than 120 hours (5 days) since ICU admission <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No
Already receiving G-CSF or GM-CSF <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No
A total white blood cell count $> 50 \times 10^9/L$ <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No
Known to be pregnant or breastfeeding <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No
Known recent (required treatment within the last 5 years) haematological malignancy <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No
Solid organ or bone marrow transplantation <span>🗨 *</span>
<input type="radio"/> Yes
<input type="radio"/> No
Patient weight $> 125kg$ <span>🗨 *</span>

- + 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:- <span>🗨</span>	Is the subject eligible to participate in the GM-CSF trial of the study? <span>🗨</span>
	<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



Randomisation 3 (GM-CSF) 06-Sep-2022

- \*Randomisation Confirmation G... 04-Sep-23 by UATDE (1)
- Randomisation Assignment GM...

# Complete the GM-CSF randomisation confirmation page

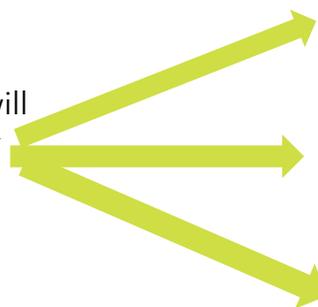
Confirm the participant details and eligibility in order to randomise this participant.

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	
Treatment Allocation from Randomisation 2 <input type="radio"/> Standard care or Not Randomised <input checked="" type="radio"/> Conservative fluid strategy	
Source of infection <input type="radio"/> Community <input checked="" type="radio"/> Hospital	
Is the participant eligible for randomisation and stratifications completed? <input checked="" type="radio"/> Yes <input type="radio"/> No	
Date of Randomisation 2023-10-31	
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 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	

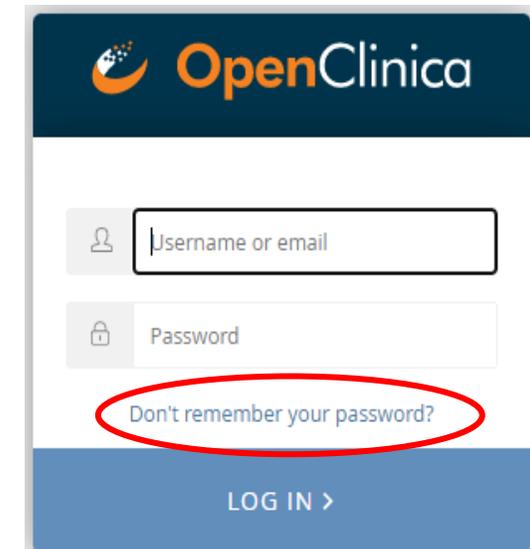
The treatment will be the kit number that the patient has been assigned to. Make a note of the kit number.  
Click 'Complete to close the form'

# 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

# If you have forgotten your password

- + Click 'Don't remember your password?'
- + Then you will have to enter your email address
- + OpenClinica will send an automatic email to the registered email address with a link to reset the password
- + On your mobile device, delete the current MFA code
- + Once you click the link to reset your password, it will ask you to scan the new code
- + You will then be asked to set your new password



The screenshot shows the OpenClinica login interface. At the top is the OpenClinica logo. Below it are two input fields: 'Username or email' and 'Password'. A link labeled 'Don't remember your password?' is circled in red. At the bottom of the page is a blue button labeled 'LOG IN >'.