



Sealed Envelope (Unblinded Pharmacist) Training

V1.0 14-Mar-2024

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

Email: septic@imperial.ac.uk

(DO NOT SEND UNBLINDED INFORMATION TO THE SEPTIC INBOX)

Clinical Data Systems (CDS) Team:

cds_support@imperial.ac.uk

The SepTiC Trial

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

All study documentation and answers to frequently asked questions can be found on the SepTiC trial website:

<https://septictrial.co.uk/for-site-staff/>

Associated Documents:

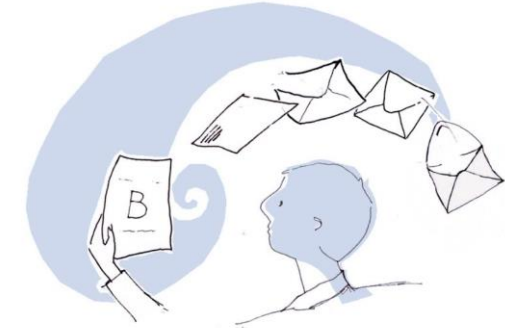
- + **SepTiC IMP Handling Manual** - describes procedures involved in all aspect of IMP management by site staff
- + **SepTiC IMP Management Plan** - describes the procedures involved in the management of all aspects of IMP order, delivery, use and destruction.
- + **SepTiC Sealed Envelope (Unblinded Pharmacist) Training Log** - Complete to confirm training on these slides

Sealed Envelope

- + For the SepTiC GM-CSF trial, kits will be allocated using the Sealed Envelope database.
- + Link to system: <https://www.sealedenvelope.com/access/>
- + Complete the Sealed Envelope User Activation Form (UAF) and email completed form to septic@imperial.ac.uk in order to request access
- + Unblinded pharmacist must be signed off on the delegation log and completed training log before access will be granted
- + Login details will be provided by the Clinical Data Systems (CDS) team at Imperial: cds_support@imperial.ac.uk

sealed envelope™

★ THE ORIGINAL INTERNET RANDOMISATION SINCE 2001



**RANDOMISATION AND ONLINE DATABASES
FOR CLINICAL TRIALS**

Sealed Envelope at Imperial College London
User Activation Form (UAF)

Please complete the form to gain access to Sealed Envelope on the OpenClinica studies at Imperial College London.

User Information for Access

1. Does the user have a Sealed Envelope account: Yes No
2. Full Name: Click or tap here to enter text.
3. Email Address: Click or tap here to enter text.

How did you complete your training?

Log In

Users with existing Sealed Envelope accounts will receive an invitation email to the study.

Dear Smita,

You have been invited to access **SepTIC 3 (TEST)** with Unblinding privileges.

Use the button below to log in and accept or decline this invitation. **Please note this invitation will only be active for 2 weeks.** After this time you will need to contact Smita (smita.das@imperial.ac.uk) to request another invitation.

Log in to SepTIC 3 (TEST)

If you have any difficulties please contact Smita (smita.das@imperial.ac.uk) by replying to this email.

— Sealed Envelope

Login to Sealed Envelope

Access

Please log in

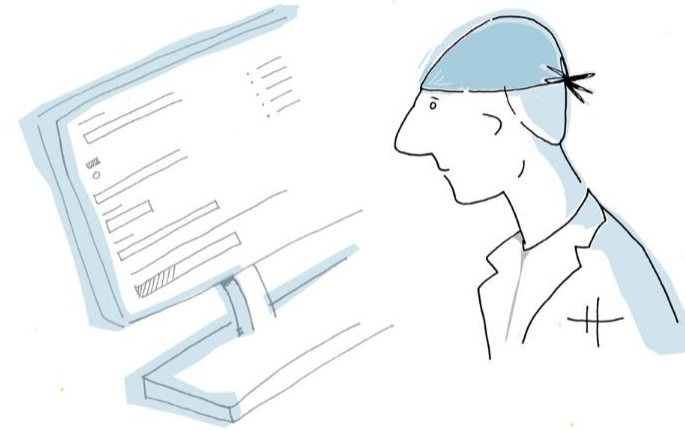
To log in you must enter your registered email address and password.

Email address:

Password:

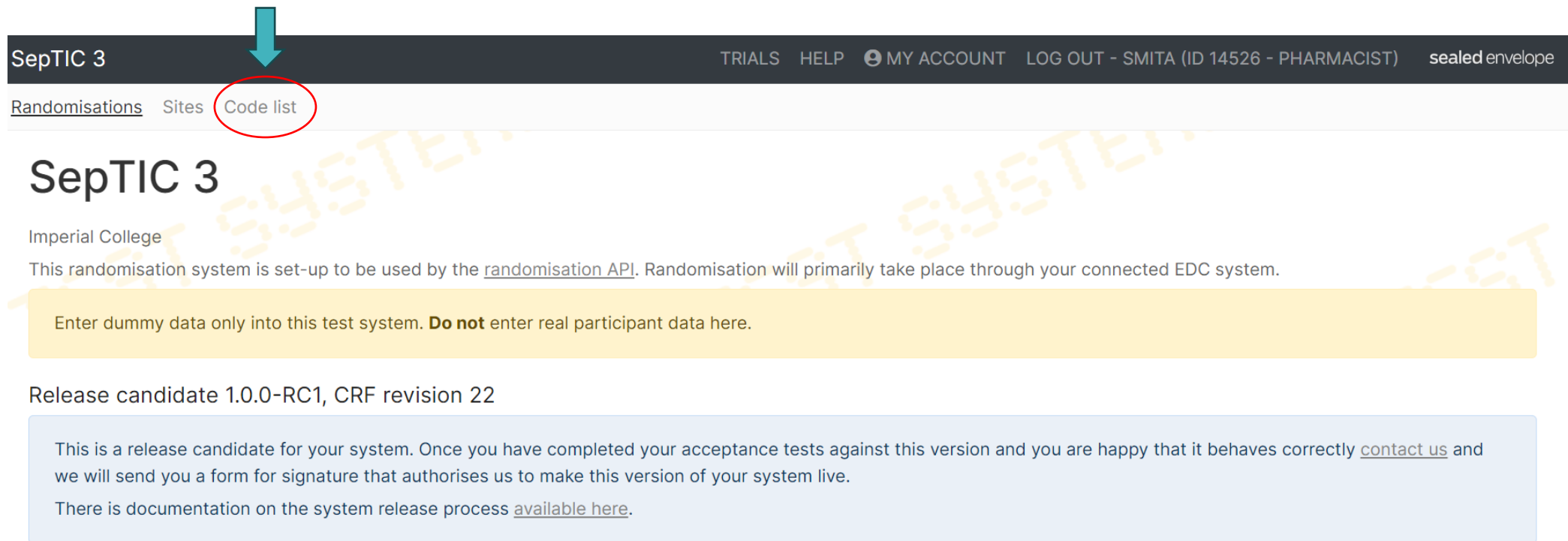
Log in

[Forgot your password?](#)



Programs and data held on this server are PRIVATE PROPERTY. Unauthorised access is prohibited and is contrary to the Computer Misuse Act 1990, which may result in criminal offences and a claim for damages. Users are reminded to keep their log in details confidential and never to share them with any other person. Users must [contact Sealed Envelope Ltd](#) immediately if they become aware of any suspicious activity.

Select 'Code list'



SepTIC 3 TRIALS HELP MY ACCOUNT LOG OUT - SMITA (ID 14526 - PHARMACIST) sealed envelope

[Randomisations](#) [Sites](#) [Code list](#)

SepTIC 3

Imperial College

This randomisation system is set-up to be used by the [randomisation API](#). Randomisation will primarily take place through your connected EDC system.

Enter dummy data only into this test system. **Do not** enter real participant data here.

Release candidate 1.0.0-RC1, CRF revision 22

This is a release candidate for your system. Once you have completed your acceptance tests against this version and you are happy that it behaves correctly [contact us](#) and we will send you a form for signature that authorises us to make this version of your system live.

There is documentation on the system release process [available here](#).

Once the CDS team has activated the kits, unblinded pharmacist will be able to see all kits assigned to their site, view the kit allocations and dispense to ICU

SepTiC 3 TRIALS HELP MY ACCOUNT LOG OUT - SMITA (ID 14526 - PHARMACIST AT UAT 1 SITE 1) sealed envelope

Randomisations Sites Code list

Code list

The code list shows the current location and details about all the kits in the trial. A kit is a unit of the investigational product or placebo that will be given to a single participant. In practice a kit may be a vial, a bottle containing pills, a pack containing multiple vials etc. Columns can be filtered using ranges, e.g.:

- [1-3] - to select values within the range of 1 to 3
- ([1-3],[7-10]) - to select values within the range of 1 to 3 or 7 to 10

Sequence	Kit Block	Kit code	Unblinded drug details	Kit type	Batch	Expiry date	Buffer, days	Status	Location	Site	Distributor	Last update	Notes
1		SP66001	Placebo	Standard		8 Nov 2024		0 New	Site	UAT 1 Site 1			
2		SP66002	Placebo	Standard		8 Nov 2024		0 New	Site	UAT 1 Site 1			
3		SP66003	GM-CSF	Standard		8 Nov 2024		0 New	Site	UAT 1 Site 1			
4		SP66004	GM-CSF	Standard		8 Nov 2024		0 New	Site	UAT 1 Site 1			

Showing 1 to 4 of 4 entries

Note: The GM-CSF intervention is double blinded. The site PI and site team are blinded to the IMP allocations. Do not disclose the unblinded drug details to any site staff or the SepTiC Trial Management team.

Managing IMP kit levels at site

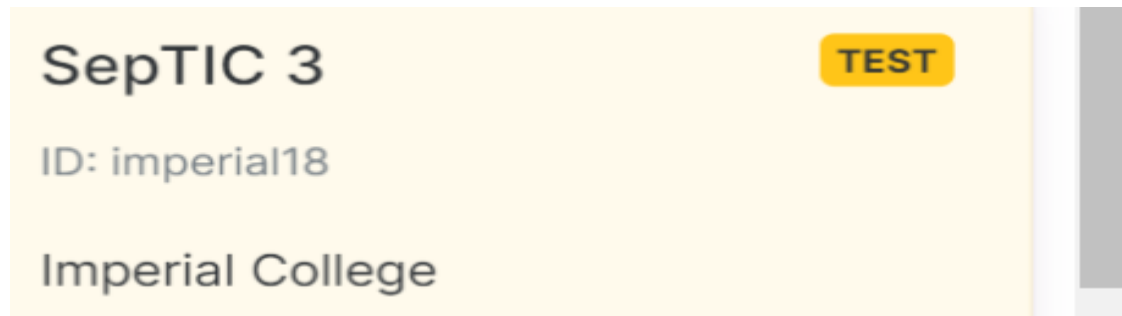
- + The unblinded pharmacist will need to monitor kit levels at site.
- + The ICU team will inform the pharmacy team when more kits are to be activated on Sealed Envelope
- + Please refer to the **SepTiC IMP Management Plan** for the full detailed process

Emergency Unblinding Instructions

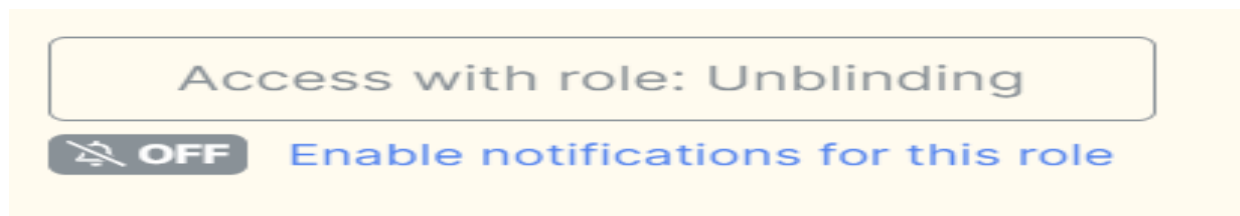
- + On the rare occasion that an emergency unblinding is required, the unblinded pharmacist will be able to perform this function.
- + The unblinded IMP allocation details should **only** be provided to the staff member who has requested the emergency unblinding
- + The SepTiC trial team should be informed of any emergency unblinding requests but **do not** email the unblinded kit allocation to the septic trial inbox as this will risk unblinding the team.
- + Please refer to the **SepTiC IMP Handling Plan** in the first instance

Unblinding on Sealed Envelope

- + The following process should be followed to unblind on Sealed Envelope to ensure an audit trail of the process is generated
- + **Do not** provide the unblinded allocation from the code list without following these steps first



1. Under the relevant study, click **Access with role: Unblinding.**



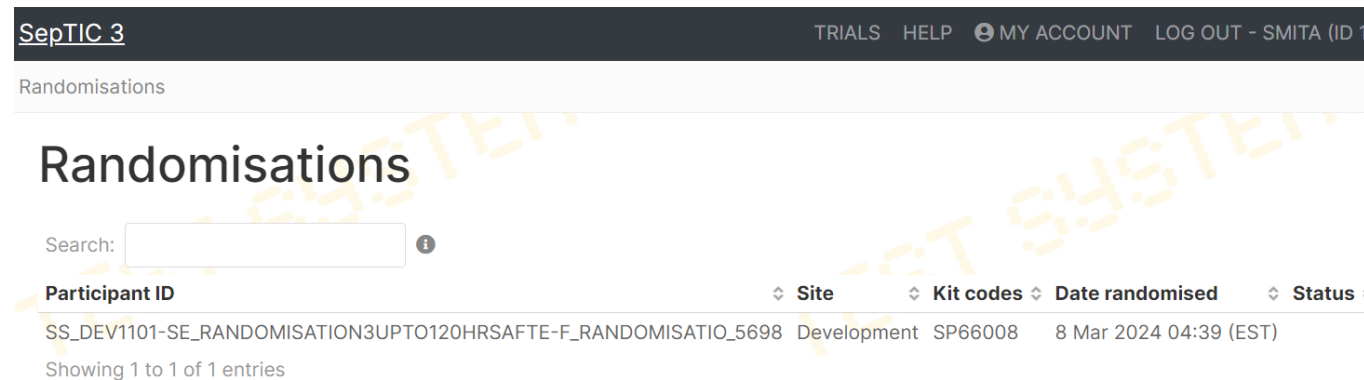
Unblinding on Sealed Envelope

2. Click Randomisations in the top left navigation bar. This shows a list of all randomised participants.



SepTIC 3

Imperial College



SepTIC 3 TRIALS HELP MY ACCOUNT LOG OUT - SMITA (ID 1

Randomisations

Randomisations

Search:

Participant ID	Site	Kit codes	Date randomised	Status
SS_DEV1101-SE_RANDOMISATION3UPTO120HRSAFTE-F_RANDOMISATIO_5698	Development	SP66008	8 Mar 2024 04:39 (EST)	

Showing 1 to 1 of 1 entries

Unblinding on Sealed Envelope

3. Click the participant to unblind, then click Unblind.

Randomisations

Randomisations

Search:

Participant ID	Site	Kit codes	Date randomised	Status
SS_DEV1101-SE_RANDOMISATION3UPTO120HRSAFTE-F_RANDOMISATIO_5698	Development	SP66008	8 Mar 2024 04:39 (EST)	

Showing 1 to 1 of 1 entries

Randomisation details

Participant ID SS_DEV1101-SE_RANDOMISATION3UPTO120HRSAFTE-F_RANDOMISATIO_5698

Site S_DEV_444: Development

Randomisation kit code SP66008

Date randomised 8 Mar 2024 04:39 (EST)

[View randomisation form](#)

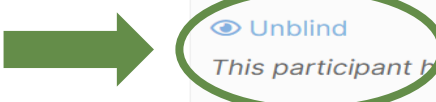
Unblinding

[Unblind](#)

This participant has not been unblinded

Kits

Kit code	Kit type	Expiry date	Date/time assigned	Reason
SP66008	Standard	28 Mar 2026	8 Mar 2024 04:39 (EST)	Randomisation by sdas



Unblinding on Sealed Envelope

4. After Clicking on Unblind the User will see the details below.

Unblind

Participant ID SS_DEV1101-SE_RANDOMISATION3UPTO120HRSAFTE-F_RANDOMISATIO_5698
Site S_DEV_444: Development
Randomisation kit code SP66008
Date randomised 8 Mar 2024 04:39 (EST)

By entering your password below you will reveal the treatment group to yourself on screen for the selected participant (shown above)

Please do not proceed unless it is absolutely necessary to unblind this subject. The unblinding will be recorded.

Reason

Reason*

Declaration

By entering my password below, I confirm I wish to unblind this participant.

Name

Smita (ID 14526 - Unblinding)

Date

8 Mar 2024 10:13 (UTC)

Password*

Confirm

Unblinding on Sealed Envelope

5. Providing details for Reason and Declaration click on Confirm.

Reason

Reason*



Enter reason for unblinding

Declaration

By entering my password below, I confirm I wish to unblind this participant.

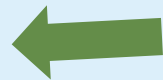
Name

Smita (ID 14526 - Unblinding)

Date

8 Mar 2024 09:59 (UTC)

Password*



Enter user password and click 'confirm'

Confirm

Unblinding on Sealed Envelope

6. After clicking on confirm, the unblinding details will show.

Randomisations

Participant ID SS_DEV1101-SE_RANDOMISATION3UPTO120HRSAFTE-F_RANDOMISATIO_5698 |
S_DEV_444: Development

[Return to participant](#)

The participant has been unblinded

Unblinding details

Randomised to **Placebo**

Note you will not be able to return to this screen and see the unblinded treatment again, unless you complete another unblinding form.

- + Complete the **SepTiC Sealed Envelope (Unblinded Pharmacist) Training Log** to confirm the Sealed Envelope training has been completed.
- + Send the completed training log alongside the Sealed Envelope UAF to the SepTiC inbox in order to request access.

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