



PREVAIL Randomisation System

User Guide – Role: Researcher

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Version 1.0

1. Introduction

The PREVAIL randomisation system is a web based application used by researchers and trial staff to randomise within the PREVAIL trial

The web address for the staging / test system is: <https://ctrc.liv.ac.uk/Staging/PrevailRandomisationTest/>

The web address for the live system is: <https://ctrc.liv.ac.uk/Randomisation/PREVAIL>

User Roles:

- Users in the administrator role are able to undertake any activity within the system.
- Users in the trial coordinator role can add/edit sites and users as well as randomise subjects.
- Users in the statistician role can add/edit sites and upload allocation lists.
- Users in the researcher role can only randomise subjects.

This document is a guide for users who have been assigned the ‘researcher’ role.

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2. Access Guidelines

Access to the live system should only be provided once a user has been trained on the use of the system and successfully randomised a test subject.

It is strongly suggested that copies of all test randomisations by users are filed as evidence that they have been adequately trained in the use of the application.

When providing access to the test system it is strongly advised that the username contains the word TEST.

3. Pages

The following pages are accessible to this user type.

3.1. Login

On accessing the system users will be presented with the login screen – the username and password (case sensitive) must be entered correctly to proceed.

Should a user have forgotten their password click the ‘Reset my Password’ link at the bottom of the login form to access the password reset page – users can enter their username and trigger an email to the Principal Investigator’s registered email address within the system. The email contains details for resetting the password. The user should ensure the Principal Investigator is available to access their email to obtain the details for resetting the password.

Should an email not be received within 2 hour of the request or a user has forgotten their username please contact the trial coordinator – the details are shown on the login page.

University: [Home](#) | [A-Z Index](#) | [Staff](#) | [Students](#)

PREVAIL

You are here: [University Home](#) > [PREVAIL](#) > [Web Randomisation](#)

Home Page
Log in

Useful Links
Biostatistics
[PREVAIL Trial Website](#)
MCRN CTU

Study Coordinator Contact
E-Mail: prevail@liverpool.ac.uk
Phone: +44 (0) 151 282 4716

PREVAIL - PREventing infection using Antimicrobial Impregnated Long lines

To access these pages you need to login.

If you do not have credentials to access this system please contact the trial coordinator email: prevail@liverpool.ac.uk or telephone +44 (0) 151 282 4716.

Login

Username

Password

Forgotten password - [Reset my password](#)
Forgotten username - [Contact the PREVAIL trial coordinator](#)

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For security passwords should not be stored for this page on any computer or computer user account which does not require a password to access.

The pages within the system follow a consistent layout structure with the navigation and useful links and details on the left, trial header and page content on the right.

The staging / test system will always include 'TEST System' in the top left heading – this will not appear on the live system, **please always check the accessed system is the one you intended before proceeding.**

3.2. Randomise Participant

The randomisation procedure has been broken down into 3 steps as outlined below:

3.2.1. Eligibility/randomisation – Randomisation Details

The first step within patient randomisation is the randomisation details check – all fields must be completed before proceeding.

The screenshot shows the 'TEST System:: PREVAIL' web interface. At the top right, there are navigation links: 'University: Home | A-Z Index | Staff | Students'. Below this is a breadcrumb trail: 'You are here: University Home > PREVAIL > Web Randomisation'. The main content area is titled 'TEST System:: PREVAIL - PREventing infection using Antimicrobial Impregnated Long lines'. It features a sidebar with 'Home Page' (Randomise Participant, Manage Sites, Manage Users, Upload Allocations, View Audit Log, Reset My Password, Log out) and 'Useful Links' (Biostatistics, PREVAIL Trial Website, MCRN CTU). The main form is titled 'Eligibility / randomisation' and contains several sections: 'Randomisation Details' with fields for Centre (dropdown), Name of Person Randomising, Email of Person Randomising, Dob of Person Randomising, Screening Number, Baby's date of birth (dd/mm/yyyy), and Date of Consent (dd/mm/yyyy); 'Inclusion Criteria' with one item: '1. Baby requires a PICC (Premicath 1 Fr.)' with Yes/No radio buttons; 'Exclusion Criteria' with two items: '1. Baby has been previously entered into the trial' and '2. Baby has a known allergy or hypersensitivity to rifampicin or miconazole', both with Yes/No radio buttons; and 'Central Randomisation Override' with a text field for 'Reason for central randomisation'. A 'PROCEED' button is located at the bottom right of the form.

- The screening number must be unique.
- All of the fields in the Randomisation Details section must be completed
- No dates can be in the future
- The date of consent can only be within the last 14 days and must be after the baby's date of birth.
- All inclusion criteria should be set to 'Yes' while all exclusion criteria must be 'No' in order to proceed.
- For randomisations being completed by administrators or trial coordinators the central randomisation reasons should also be provided.

On completing all the criteria questions click the 'Proceed' button to proceed to the second stage.

If a field has not been entered, or information is incorrect a warning message will be displayed at the top of the page:

Eligibility / randomisation

- The 'Dob of Person Randomising' field cannot be in the future

3.2.2. Confirmation

The second step is to confirm that the randomisation details are correct and that all the inclusion/exclusion criteria are correct.

University: [Home](#) | [A-Z Index](#) | [Staff](#) | [Students](#)

TEST System:: PREVAIL

You are here: [University Home](#) > [PREVAIL](#) > [Web Randomisation](#)

Home Page

- Randomise Participant
- Manage Sites
- Manage Users
- Upload Allocations
- View Audit Log
- Reset My Password
- Log out

Useful Links

- Biostatistics
- PREVAIL Trial Website
- MCRN CTU

Study Coordinator Contact

E-Mail: prevail@liverpool.ac.uk
Phone: +44 (0) 151 282 4716

TEST System:: PREVAIL - PREVENTing infection using Antimicrobial Impregnated Long lines

Confirm Randomisation Details

Please review the details entered below, if these are correct click the 'Randomise' button below.

Randomisation Details

Centre	Birmingham Women's Hospital
Name of Person Randomising	Duncan Appelbe
E-Mail of Person Randomising	dea@liv.ac.uk
Dob of Person Randomising	22/07/1969
Screening Number	679
Baby's date of birth (dd/mm/yyyy)	26/07/2015
Date of Consent (dd/mm/yyyy)	27/07/2015

Inclusion criteria

1. Baby requires a PICC (Premicath 1 Fr).	Yes
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Exclusion criteria

1. Baby has been previously entered into the trial	No
2. Baby has a known allergy or hypersensitivity to rifampicin or miconazole	No

Central Randomisation Override

Reason for central randomisation

RANDOMISE

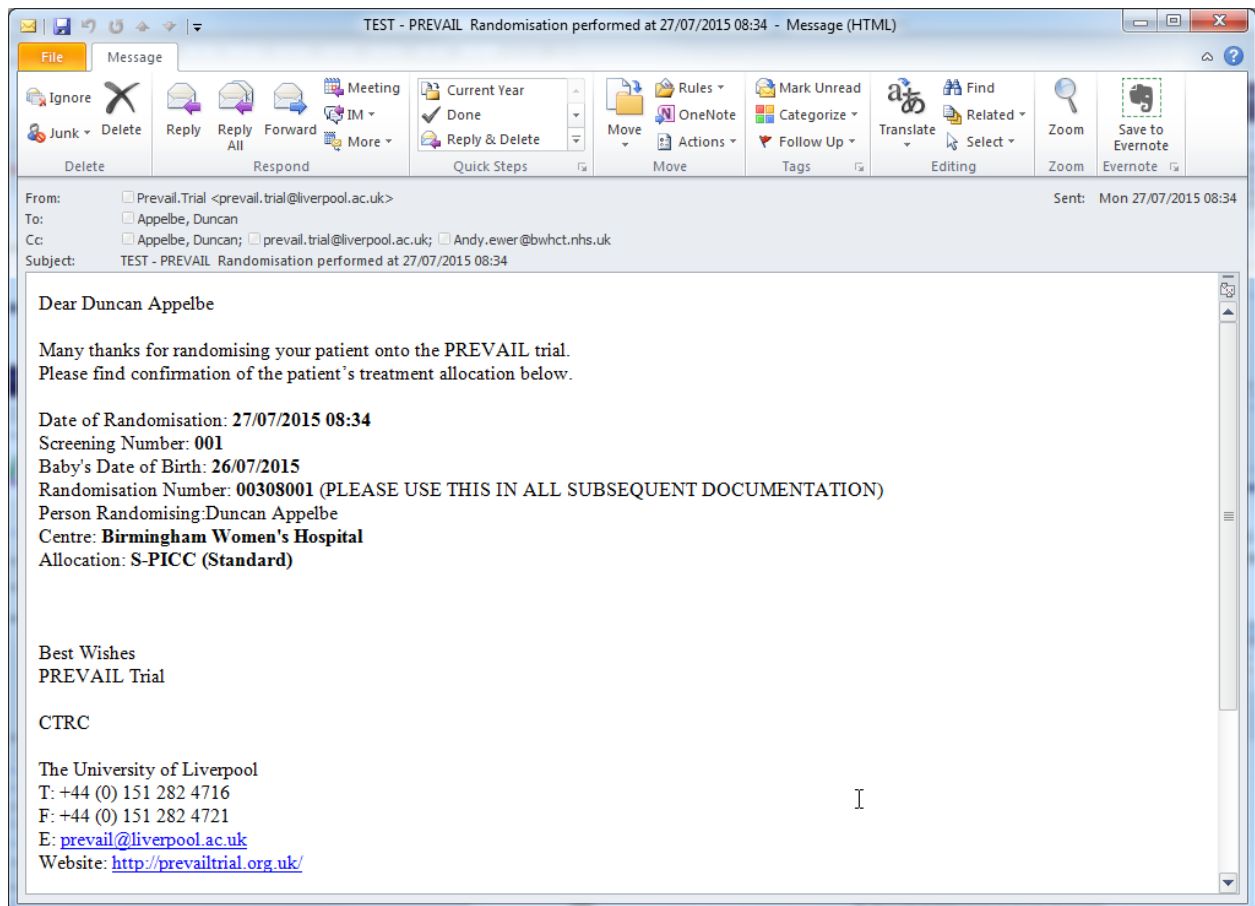
If all is correct, click on the Randomise button.

3.2.3. Randomisation Complete

On completion the following page will be shown which confirms the centre, screening number, patient initials, randomisation number, date of randomisation and treatment allocation.

The screenshot displays the 'TEST System:: PREVAIL' web interface. At the top right, there are navigation links: 'University: Home | A-Z Index | Staff | Students'. Below this is a dark blue header with the text 'TEST System:: PREVAIL'. A breadcrumb trail reads 'You are here: University Home > PREVAIL > Web Randomisation'. On the left, a 'Home Page' menu lists: 'Randomise Participant', 'Manage Sites', 'Manage Users', 'Upload Allocations', 'View Audit Log', 'Reset My Password', and 'Log out'. Below this is a 'Useful Links' section with 'Biostatistics', 'PREVAIL Trial Website', and 'MCRN CTU'. A 'Study Coordinator Contact' section provides 'E-Mail: prevail@liverpool.ac.uk' and 'Phone: +44 (0) 151 282 4716'. The main content area features the 'PREVAIL' logo (with two stars) and the title 'TEST System:: PREVAIL - PREVENTing infection using Antimicrobial Impregnated Long lines'. Below the logo, it states 'Randomisation Complete' and 'You should receive an eMail confirmation of these details. If the eMail is not received within 4hrs contact the study coordinator.' An 'Allocation Details' box contains the following information: Centre: **Birmingham Women's Hospital**; Screening Number: **001**; Date of Randomisation: **27/07/2015**; Randomisation Number: **00308001**; Treatment Allocation: **S-PICC (Standard)**. The footer includes the University of Liverpool address and contact information on the left, and a copyright notice '© University of Liverpool - a member of The Russell Group' with links for 'Contacts | Map | Legal | Accessibility' on the right.

An email confirming these details will be sent to the user randomising, trial coordinator and any other emails configured for the site (i.e. PI). If an email is not received within 4 hours confirming the details please contact the trial coordinator.



3.3. Request Password Reset

This page allows users to trigger an email containing details for resetting a password

