



Generic Randomisation System User Guide – Role: Administrator

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1. Introduction

The generic randomisation system is a base system that is designed to be extended when developing web-based randomisation applications for CTRC.

The system includes common functionality that will be useful in web randomisation applications, including but not limited to: login functionality, randomisation form management, allocation list upload, randomisation number configuration management, permission management, site management, audit logging, database change tracking, scheduled tasks and email sending.

This user guide covers all functionality of the system of which some is restricted to administrators.

There is a separate user guide for researchers covering randomisation.

There are no other separate user guides for the other roles as roles may differ per project the template is used on, however this guide covers all functionality and can be used for the other role's user guides as required.

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2. Important Notes You Must Read

2.1. Initial User Accounts

When the live system is setup a single named account will be setup for the statistician and trial coordinator. In addition to any other requested names accounts. After which other users can be created using the admin pages in the website.

Once named accounts are created it is strongly recommended that the initial un-named accounts be disabled, which can be done via the edit user page for the respective user accounts.

2.2. Identifying Development/Test Site compared to Live Site

All pages on the development site will contain a red heading indicating that the site is the development site. The live site will not contain this header.



Login

Use a local account to log in.

Username

Password

[Forgot your password?](#)

2.2.1. Differences in Functionality on Development/Live sites

The following table details pages that are accessible in the development and live versions of the site.

Please note that access to certain pages will be restricted based on user permissions and not on whether the site is in development or live configuration.

Page	Development	Live
Manage Sites	Yes	Yes

Manage Permissions	Yes	Yes
Manage Roles	Yes	Yes
Manager Users	Yes	Yes
View Audit Log	Yes	Yes
Request Password Reset	Yes	Yes
Build Randomisation Form	Yes	No
View Randomisation Form	Yes	Yes
Configure System	Yes	No
Configure Automated Emails	Yes	No
Edit Randomisation Number Format	Yes	No
Manage Treatments	Yes	No
Manage Trial Arms	Yes	No
Clear Randomisations	Yes	No
Download User Test Plan	Yes	No
Test Minimisation Randomisation	Yes	Yes
Test Block Randomisation	Yes	Yes
Download Randomisation Details	Yes	Yes
View Current Imbalance	Yes	Yes
Edit Imbalance Factor	Yes	Yes
Release - Prepare	Yes	No
Release – Setup from release on test system	No	Yes
Allocation Upload	Yes	Yes

2.2.2. Initial Setup Configuration

When the test and live systems are setup by the IS team the following will be included in the systems:

Development

- A user account for the statistician for which the login details will be passed to the statistician upon setup.
- The default standard randomisation form will be included ready for editing
- The default configuration/email configuration will be included ready for editing.
- A sample trial arm and treatment will be included ready for editing.

Live

- A user account for the statistician for which the login details will be passed to the statistician upon setup.
- A user account for the trial co-ordinator for which the login details will be passed to the trial co-ordinator upon setup.
- Nothing else is setup on the live system - after updating the live system from a release prepared from the test system will be the point when it can be used properly.

2.2.3. System Validation

Aspects of the system that are not configurable have been tested via automated tests during the development of the software. However, tests which apply to elements of the system that are setup by the user cannot be subjected to these tests.

The ability to download automatically generated user tests which will provided guiding tests for the configurable elements of the system is provided.

2.3. Registration Systems

If the system is configured to act as a registration system instead of a randomisation system, then references to “randomisation” will appear as “registration” throughout the system. In addition some features that are not applicable for a registration system will not be accessible. Otherwise, functionality remains unaltered.

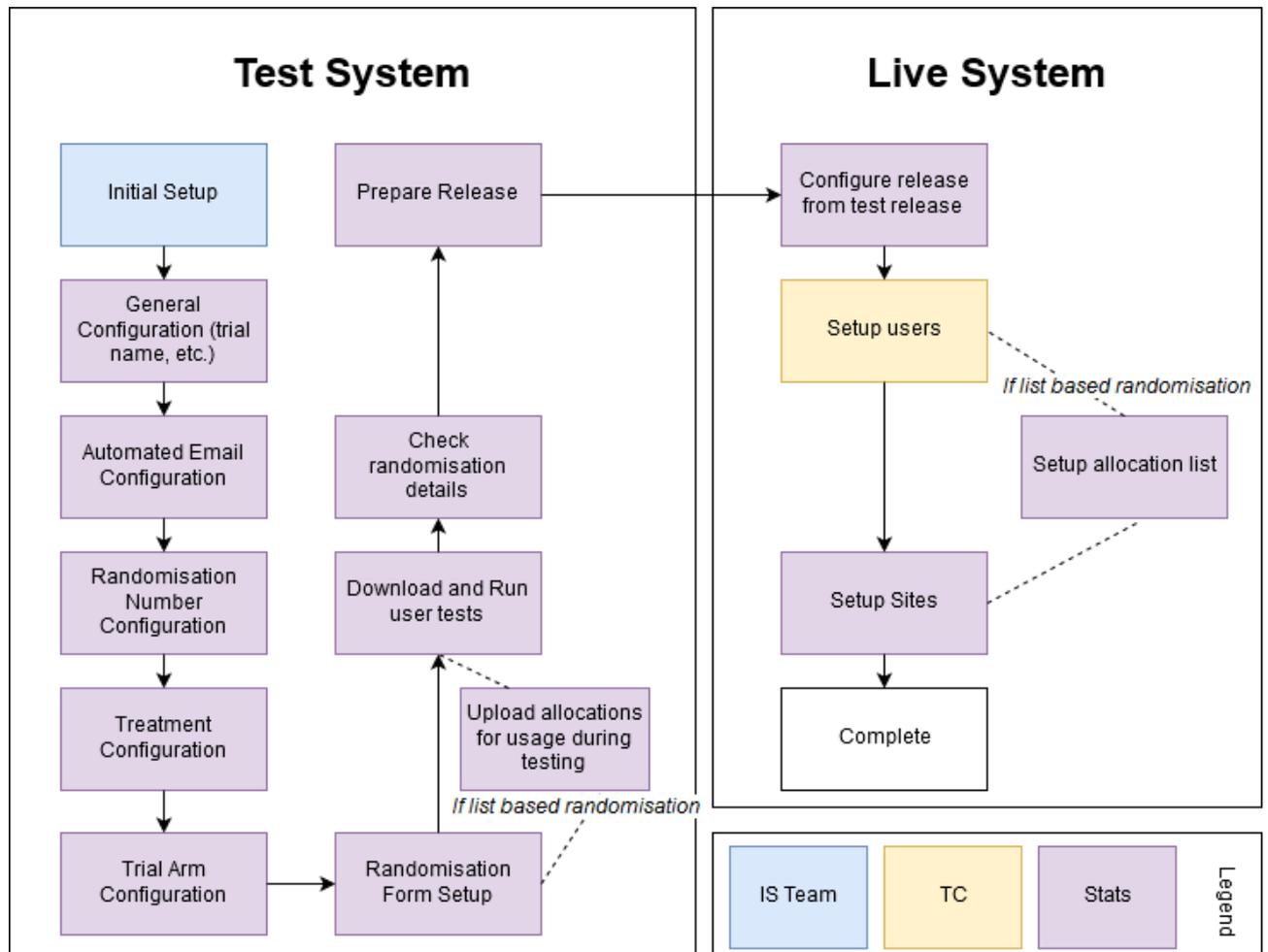
3. Access Guidelines

Access to the live system should only be provided once a user has been trained on the use of the system.

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

4. Suggested Workflow for configuring the system for usage

The flowchart below displays the suggested workflow for configuring the system. While some steps can be done in any order the below ordering is optimal.



5. Pages

The following pages are accessible to this user type.

5.1. Login

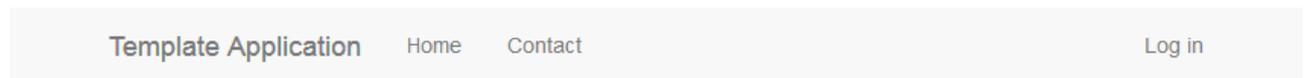
Using the login link will open the login page – you must enter both the username and password correctly to proceed.

The system will auto direct you here when accessing the root URL.

Should a user have forgotten their password, clicking the “Forgot your password?” will open a page where the user can enter their username. This will send an email to the user detailing how to reset their password.

Should an email not be received within 2 hours of the request or a user has forgotten their username please contact the named person on the contact page.

If the system uses multiple sites and the user logging in is associated to more than one site, then they will be prompted to select the site in which to log in to upon successful entry of their login credentials.



Login

Use a local account to log in.

Username

Password

[Forgot your password?](#)

Development Site
Please do not enter any live data into the development site.

Select Site

Logging in as: **admin**

Select the site you wish to login to: ▾

Select Site Cancel Login

Template Application • [Browser Requirements](#) • [Privacy Policy](#) • Framework Version 0.1

Upon successful login, the links that you can access will appear in the top navigation bar.

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 links on the top bar.

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

5.2. Switching Site

If the logged in user has more than one site associated to them, clicking the name of the site in the navigation bar will send the user to a page whereby they can reselect the currently logged in site.

5.3. Dashboard

Upon successful login, you will be presented with a screen showing the key pages you may wish to use in the system. The links displayed differ depending on the user's role, if the system is a test system and the type of randomisation the system is configured to use (i.e. minimisation or block).

Development Site
Please do not enter any live data into the development site.

Statistician Dashboard

Configuration

-  1. Edit Randomisation Number Format
Opens page that allows building of the randomisation form.
[1. Edit Randomisation Number Format](#)

Administration

-  1. View Audit Events
This page displays information regarding usage of the site.
[1. View Audit Events](#)

5.4. Manage Sites

These pages allow the addition, editing or deletion of sites in the system. Initially the listing page will be presented which shows all sites within the system.

Sites

[Create New Site](#)

Show entries Filter:

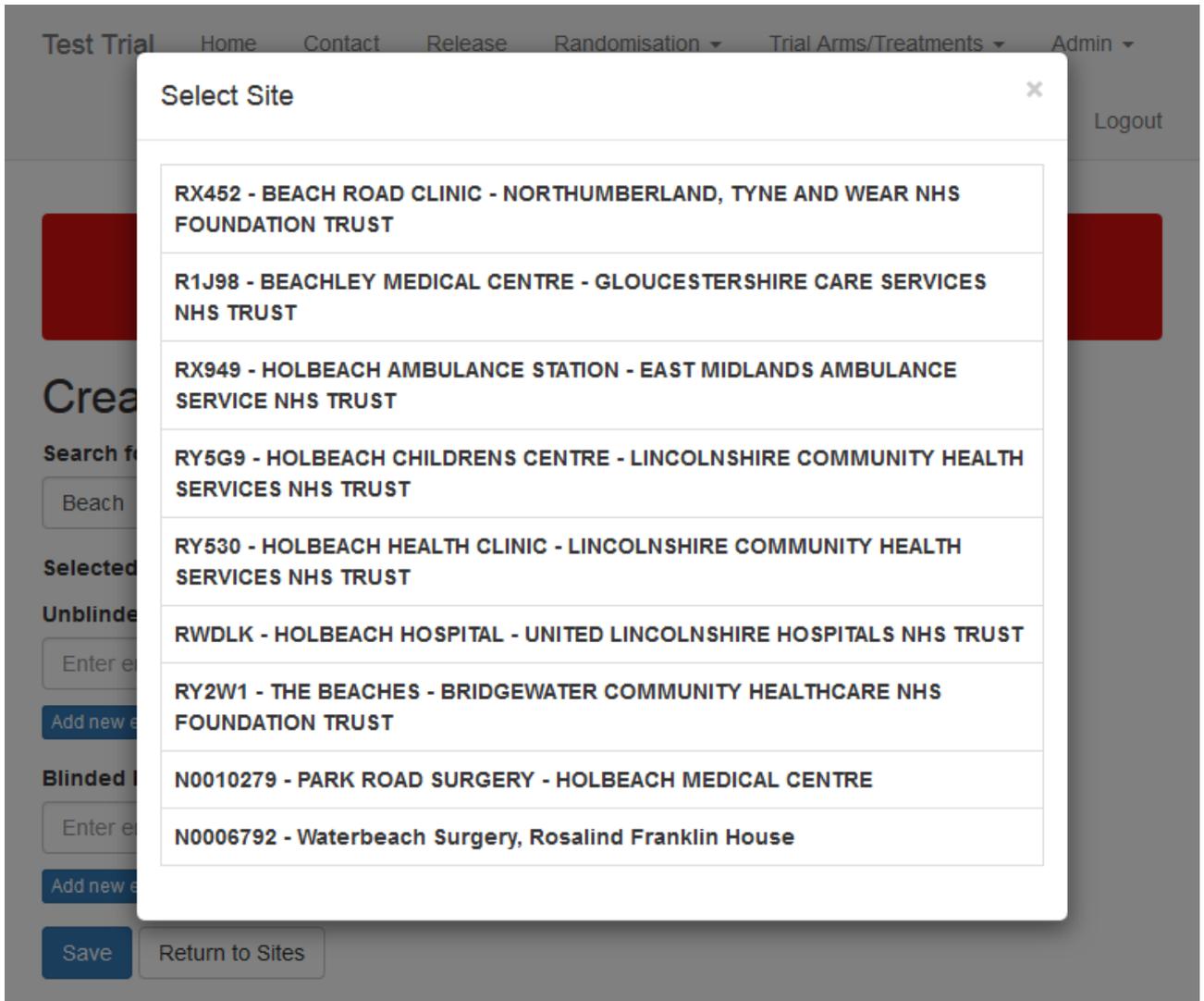
Code	Name	Randomisations	Actions
00000	CTRC	• Total Randomisations to site: 0	Edit Delete

Showing 1 to 1 of 1 entries [Previous](#) [1](#) [Next](#)

5.4.1. Create New Site

To add new sites click the 'Create New Site' button from the Sites page.

Sites must be linked to a Trust Site and can be done through searching for the name of the site or using its unique CPMS code or UKCRN number using the search bar. If you use a code then the system will assign the site automatically, if you use a search term (such as “Beach”) then you will be asked to select the trust site you mean from a list.



Pleasure ensure that you use the appropriate site codes as agreed for the study.

Create New Site

Site creation mode

Before you create a new site, have you completed **ST002TEM08 Randomisation request form**?
If not, this form can be downloaded from CRUMBS.

i Please ensure that you use the appropriate site codes as agreed for the study

Search for Trust Site using UKCRN/CPMS code or name

Selected site: RX452 - BEACH ROAD CLINIC

Randomisation Site Code (used with allocation upload list)

Unblinded Randomisation Email Contacts

Blinded Randomisation Email Contacts

You will also need to provide at least one email address for the unblinded/blinded emails that get sent out upon randomisation at this site. You cannot use the same address for both and also note that more than one email address can be added for each list.

If the trial is not blinded, only one list for email address is provided.

Warnings will be shown above the form should any fields require review before creation or updating can be completed.

If no warnings are generated when the save button is pressed, the site will be created and will be available to assign users to.

5.4.2. Creating custom site

Changing "Site creation mode" to custom opens the custom site creation page, whereby code and name can be specified.

Create New Site

Site creation mode

Site Code

Site Name

Registration Email Contacts

5.4.3. Edit Existing Site

To edit an existing site, click on the “Edit” link that is associated with the site that you wish to modify.

The code is uneditable as the site is bound to an existing one during creation.

You can edit the email addresses used for blinded/unblinded randomisation emails for randomisations done at the site.

The history button next to the text field is used to view a history of changes made to this field and will be discussed in further detail later on in this document.

5.4.4. Deleting Site

To delete an existing site, click on the “Delete” link that is associated with the site that you wish to modify.

The page will ask you to confirm the deletion action. The deletion cannot be performed if users are assigned to the site, a warning indicating this will appear if this is the case.

Template Application Home Contact Admin ▾ Logged in as: admin Site: A Logout

Development Site

Please do not enter any live data into the development site.

Delete Site

Are you sure you wish to delete **C**?

5.5. Manage Permissions

These pages allow the addition, editing or deletion of permissions in the system. Initially the listing page will be presented which shows all permissions within the system.

Development Site

Please do not enter any live data into the development site.

Permissions

Permission names must match the rule of `Controller-PageName`.

E.g. to create the permission for `Create` on a controller named `TestController`, then the name of the permission would be `Test-Create`.

Create New Permission

Show entries

Filter:

Name	Description	Actions
AuditEvent-Index		Edit Delete
Permission-Create		Edit Delete
Permission-Delete		Edit Delete
Permission-Edit		Edit Delete

5.5.1. Create New Permission

To add new permissions click the 'Create New Permission' button from the Permissions page.

Permissions have one required data field:

- Name

Permissions have one optional data field:

- Description

Development Site

Please do not enter any live data into the development site.

Create New Permission

Name

Description

Warnings will be shown above the form should any fields require review before creation or updating can be completed.

If no warnings are generated when the save button is pressed, the permission will be created and will be available to assign roles to.

Permissions, in order to be used by the system properly, must follow a naming convention.

Page-Action

For example, for /User/Create the permission must be named "User-Create", for /User/ the permission must be named "User-Index".

Note that the newly created permission will automatically be assigned to the role currently logged in to.

Wildcard

Permissions can use the wildcard "*" to denote all pages or all pages in a specific controller, e.g. "Controller-*" would work for all pages in that area.

5.5.2. Edit Existing Permission

To edit an existing site, click on the "Edit" link that is associated with the permission that you wish to modify.

Development Site

Please do not enter any live data into the development site.

Edit Permission

Name



Description



Save

5.5.3. Deleting Permission

To delete an existing permission, click on the “Delete” link that is associated with the permission that you wish to modify.

The page will ask you to confirm the deletion action. Deleting a permission will unlink it from all roles that use it.

Development Site

Please do not enter any live data into the development site.

Delete Permission

Are you sure you wish to delete **AuditEvent-Index**?

Delete

5.6. Manage Roles

These pages allow the addition, editing or deletion of roles in the system. Initially the listing page will be presented which shows all roles within the system.

Development Site

Please do not enter any live data into the development site.

Roles

Create New Role

Show 10 entries

Filter:

Name	Access Level	Description	Actions
Site Administrator	2		Edit Delete
System Administrator	1	Typically reserved for IS Staff.	Edit Delete
Test Role	3		Edit Delete
User	3		Edit Delete

Showing 1 to 4 of 4 entries

[Previous](#) [1](#) [Next](#)

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5.6.1. Create New Role

To add new role click the 'Create New Role' button from the Role page.

Roles have two required data fields:

- Name
- Level

Roles have two optional data fields:

- Description
- Permissions

Level refers to importance of the role. In the system the role "System Administrator" is level 1.

Level is used in several different places across the system, most notably in Managing Users, whereby a user cannot assign a role with a more important level than the one they hold. In addition, a user cannot manage another user who has a higher role level than themselves.

Development Site

Please do not enter any live data into the development site.

Edit Role

Name



Level



Description



Permissions

Permission changes will not affect currently logged in users until they logout and then login again.

Warnings will be shown above the form should any fields require review before creation or updating can be completed.

If no warnings are generated when the save button is pressed, the role will be created and will be available to assign users to.

5.6.2. Edit Existing Role

To edit an existing role, click on the "Edit" link that is associated with the role that you wish to modify.

Development Site
Please do not enter any live data into the development site.

Edit Role

Name

Level

Description

Permissions

Permission changes will not affect currently logged in users until they logout and then login again.

5.6.3. Deleting Roles

To delete an existing role, click on the “Delete” link that is associated with the role that you wish to modify.

The page will ask you to confirm the deletion action. You cannot delete a role that users are assigned to, a warning will appear if this is the case and not allow the deletion action to occur.

Development Site
Please do not enter any live data into the development site.

Delete Role

Are you sure you wish to delete **Test Role**?

5.7. Manage Users

Add or edit users of the system from this area. Initially the listing page will be presented which shows all users within the site logged into and that hold a role of equal or lower level than the user viewing the page.

Template Application Home Contact Admin ▾ Logged in as: admin Site: A Logout

Development Site
Please do not enter any live data into the development site.

Users

Create New User

Show 10 entries Filter:

Username	Title	Forename	Surname	Email Address	Actions
A-Admin	-	-	A Admin	A-Admin@example.com	Details Edit Delete

5.7.1. Creating User

To add new role click the 'Create New User' button from the Users page.

The following data fields are mandatory for each user (at least one site field or 'All Sites data field must be selected):

- Username - Used by user to login to the system (once saved this field cannot be changed)
- Title
- Forename
- Surname
- Email Address
- Confirm Email Address
- Password - Used by user to login to the system (minimum size 6 characters)
- Sites assigned to and what role to be assigned to for the site
 - The sites selectable will match the sites the 'Currently Logged in' (the user performing the create User) user is assigned to i.e. If the currently logged in user only has access to site "A" then they can only create/edit users to be in site "A"
 - The roles selectable will match the roles of equal or lower level than the currently logged in user's role for the site being assigned to the user

A warning will be shown above the details form should any fields require review before creation or updating can be completed.

Development Site

Please do not enter any live data into the development site.

Create New User

Username

Title

Forename

Surname

Email Address

Confirm Email Address

Password

User Role

All

Assign to all sites

A

Assign to site A

B

Assign to site B

C

Assign to site C

Save

5.7.2. Edit User

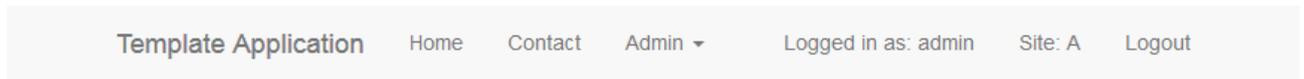
To edit an existing user, from the “Users” page click on the “Edit” link that is associated with the user you wish to modify.

You can alter all fields except for username and password from this page.

In addition, you can alter the “Enabled” field from the edit page, which if unchecked, will prevent the user logging into the system.

5.7.3. User Details

To view details of an existing user, from the “Users” page click on the “Details” link that is associated with the user you wish to view.



User Detail

Name	-- A Admin
Email Address	A-Admin@example.com
Enabled	<input checked="" type="checkbox"/>

5.8. View Audit Log

The audit log shows a summary of all activity within the system (with timestamp and user involved). The page will show 200 of the most recent events but all events can be accessed by using the date filter functions provided. Additional logged data is stored within the logs folder of the website and accessible by IS developers. Additionally temporal tables store past copies of data altered within the database and time + user stamps which can be reviewed if required by IS developers.

Development Site

Please do not enter any live data into the development site.

Audit Events

Date From:

Date To:

Filter Using Dates

Show entries

Filter:

Date	Description	User ID
21/09/16 2:14:12 PM	Login	2
21/09/16 2:14:14 PM	Site selected for login (A)	2
21/09/16 2:29:09 PM	Login	2
21/09/16 2:29:13 PM	Site selected for login (A)	2
21/09/16 2:38:40 PM	Login	2
21/09/16 2:38:42 PM	Site selected for login (A)	2

5.9. Request Password Reset

Clicking the text on the navigation bar which reads “Logged in as: <user>” will display a menu, one of the links directs to the reset password page.

Development Site

Please do not enter any live data into the development site.

Manage Account

[Reset Password](#)

[Switch Site](#)

Development Site
Please do not enter any live data into the development site.

Reset Password

Enter new password here:

Password

5.10. Changes Made on Edit Pages

Edit pages will display a clock icon next to editable fields. Clicking the icon reveals a history of how that field has been changed over time.

Edit Permission

Name

The screenshot shows a modal window titled "Changes Made" with a close button (X) in the top right corner. The modal contains a table with the following data:

Old Value	New Value	Modified By	Modified On	Action	Reason for Modification
	Allocation page for block randomisation.	Mr Trial Administrator	12/01/2017 15:24:16	Modified	Description Edit For User Guide.

6. Randomisation Pages

6.1. Build Randomisation Form Page

The build randomisation form page allows for the editing of the randomisation form used in the system. In this page you can configure:

- Sections (such as "Screening Data")
- Questions within sections (of varying types, such as a date question or a text question) – questions must be contained in a section

- Question text
- Question options (if the question is an option question, i.e. it uses a dropdown menu to select pre-defined answers)
- Validation rules (e.g. date question can be configured to not accept a future date)
- Indicating that a question and its answers are to be used as a stratification factor in the randomisation system. This has numerous implications on elements of the system such as the minimisation algorithm.

The page utilises a drag-and-drop interface to build the form. The sections and the different types of questions can be found on the left of the page and can be dragged toward the right side of the page which is the representation of the form.

Development Site
Please do not enter any live data into the development site.

Form Builder

Form Title

Randomisation Form

Screening Data

Screening Number Rules: 1 Options Drag Remove

Patient Initials Rules: 0 Options Drag Remove

Consent Date Stratification Factor Rules: 1 Options Drag Remove

Date of Birth Stratification Factor Rules: 3 Options Drag Remove

Site Stratification Factor Options Drag Remove

Section Drag

Yes/No question Drag

No/Yes question Drag

Text entry question Drag

Decimal number entry question Drag

Numeric entry question Drag

Option selection question Drag

Site Drag

When you are happy with the form, the save button can be located at the bottom.

6.2. View Randomisation Form Page

This page displays the randomisation form that is ready to be completed. Upon successful completion of the form, you will be presented with an overview of the form before submission. Upon successful submission of the form the subject will be randomised and the emails will be sent to the email addresses assigned to the randomising site.

All questions in the form are mandatory and each answer will be validated against the assigned validation rules that were created during the build form phase of the process.

The below screenshot displays the form with a validation error message.

Development Site
Please do not enter any live data into the development site.

Randomisation Form

Before completing the below eligibility criteria, these must have been fully reviewed and confirmed by a qualified doctor.

Screening Data	
1: Screening Number	<input type="text" value="123"/>
2: Patient Initials	<input type="text" value="KMK"/>
3: Consent Date	<input type="text" value="02/01/2008"/> <small>The field must be after or equal to "Date of Birth".</small>
4: Date of Birth	<input type="text" value="06/01/2015"/>
5: Site	<input type="text" value="CTRC"/>

Once completed an overview will appear:

Form Entry

Screening Data

1: Screening Number	002
2: Patient Initials	KMK
3: Consent Date	01/01/2017
4: Date of Birth	05/01/2015
5: Site	CTRC

Inclusion Criteria

1: Yes/No question	Yes
--------------------	-----

Exclusion Criteria

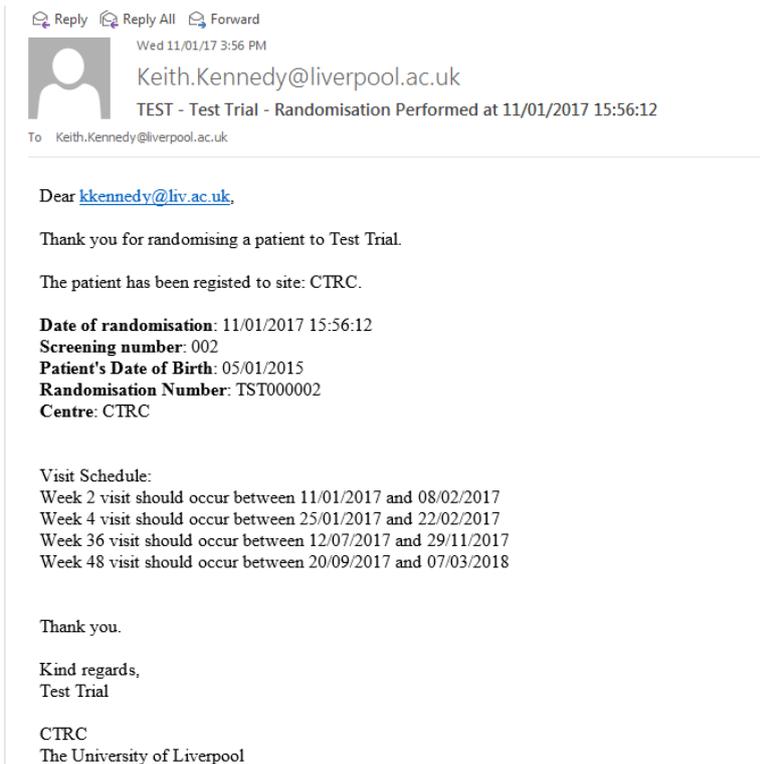
1: No/Yes question	No
--------------------	----

Central Randomisation Override

1: Reason for central randomisation	Test
-------------------------------------	------

Cancel Randomise

Clicking randomise here will randomise the subject and send the email messages which will look like the following:



You will also be presented with a small page confirming the randomisation has been completed.

Randomisation Submission Completion

Randomisation has been completed. Emails have been sent to the appropriate email address, including your own email address.

If an email is not received in four hours, please contact your trial coordinator.

Randomisation Details

Date of randomisation: 11/01/2017 15:56:12

Screening number: 002

Patient's Date of Birth: 05/01/2015

Randomisation Number: TST000002

Centre: CTRC

Allocation: Treatment A

[Randomise another patient](#)

6.3. Configure System

The configure system page allows for the configuration of variables relating to the trial.

You can change the following:

- Trial Name (used in page header and email correspondence)
- Trial email address (copied into all emails)
- Trial URL (used in emails)
- Trial Phone number (used in emails and contact page)
- Trial Fax Number (used in emails and contact page)
- Trial Postal Address (used in emails and contact page)
- Blinded trial checkbox – used to indicate if the trial is blinded. This is used to determine whether to send unblinded and blinded treatment allocation details in emails upon randomisation. If unchecked, emails will be sent out without treatment details as default.
- Uses site based count for randomisation number – if checked the randomisation number will increment based on number of subjects at the site in question, if not checked the number will increment based on total number of subjects in the entire study.
- Randomisation type – this is used to specify if the trial is minimisation or block (list) based, this has implications into how the randomisation is performed.
- Auto Generate Randomisation Code - this is only applicable for block randomisation where the randomisation code cannot come from the upload list – this option if checked will auto generate the randomisation number for an allocation based randomisation.
- Dental trial checkbox – this is used to specify if the trial is a dental trial. This affects the information text that appears above the randomisation form only at this time.

Please note that after a release is prepared on the test system, you will not be able to edit:

- Blinded trial checkbox

- Uses site based count for randomisation number
- Randomisation type
- Dental trial checkbox

6.4. Configure Automated Emails

This page allows for the configuration of variables relating to automated emails sent out by the system.

You can change the following:

- The text used in the email send to new users upon account creation
- The text used in the email sent to unblinded email addresses of a site upon randomisation of a subject to said site
- The text used in the email sent to blinded email addresses of a site upon randomisation of a subject to said site
 - It is important to note that if the trial is setup not to be a blinded trial – only one randomisation email box appears here
- The text used in emails can use variables which are listed on the page, these are denoted by the # character.
- Variables enclosed within [] are randomisation form question variables, the email text can also use these variables. Changes made to the randomisation form will also be made to these variables. If you add, remove or rename a question then this will also be applied to the variables.

<p>New Account Email</p> <p>Dear #newusername,</p> <p>A new account has been created for you on the #trialname system.</p> <p>You can access the system here</p> <p>Send Test Email</p>	<table border="1"> <thead> <tr> <th>Variable</th> <th>Explanation</th> </tr> </thead> <tbody> <tr> <td>#name</td> <td>Full name of the person the email is being sent to.</td> </tr> <tr> <td>#signature</td> <td>Email signature, consisting of trial name, phone, fax, email and postal address.</td> </tr> <tr> <td>#newusername</td> <td>Username of the new system user.</td> </tr> <tr> <td>#trialname</td> <td>Name of the trial.</td> </tr> <tr> <td>#randomisationdetails</td> <td>Details of randomisation - this will be adjusted accordingly based on if it is being used in a blinded or unblinded email message.</td> </tr> <tr> <td>#visitschedule</td> <td>Details of visit schedule - this will use Visit schedule range in combination with the date of randomisation to build the text of the visit schedule.</td> </tr> <tr> <td>#site</td> <td>Name of randomisation site.</td> </tr> <tr> <td>#randomisationsystemurl</td> <td>URL to randomisation application.</td> </tr> <tr> <td>#trialurl</td> <td>URL to trial site (comes from configuration page).</td> </tr> <tr> <td>[Screening Number]</td> <td>Screening Number - The value given for Screening Number on the randomisation form</td> </tr> <tr> <td>[Patient Initials]</td> <td>Patient Initials - The value given for Patient Initials on the randomisation form</td> </tr> <tr> <td>[Consent Date]</td> <td>Consent Date - The value given for Consent Date on the randomisation form</td> </tr> <tr> <td>[Date of Birth]</td> <td>Date of Birth - The value given for Date of Birth on the randomisation form</td> </tr> <tr> <td>[Site]</td> <td>Site - The value given for Site on the randomisation form</td> </tr> <tr> <td>[Yes/No question]</td> <td>Yes/No question - The value given for Yes/No question on the randomisation form</td> </tr> <tr> <td>[No/Yes question]</td> <td>No/Yes question - The value given for No/Yes question on the randomisation form</td> </tr> <tr> <td>[Reason for central randomisation]</td> <td>Reason for central randomisation - The value given for Reason for central randomisation on the randomisation form</td> </tr> </tbody> </table>	Variable	Explanation	#name	Full name of the person the email is being sent to.	#signature	Email signature, consisting of trial name, phone, fax, email and postal address.	#newusername	Username of the new system user.	#trialname	Name of the trial.	#randomisationdetails	Details of randomisation - this will be adjusted accordingly based on if it is being used in a blinded or unblinded email message.	#visitschedule	Details of visit schedule - this will use Visit schedule range in combination with the date of randomisation to build the text of the visit schedule.	#site	Name of randomisation site.	#randomisationsystemurl	URL to randomisation application.	#trialurl	URL to trial site (comes from configuration page).	[Screening Number]	Screening Number - The value given for Screening Number on the randomisation form	[Patient Initials]	Patient Initials - The value given for Patient Initials on the randomisation form	[Consent Date]	Consent Date - The value given for Consent Date on the randomisation form	[Date of Birth]	Date of Birth - The value given for Date of Birth on the randomisation form	[Site]	Site - The value given for Site on the randomisation form	[Yes/No question]	Yes/No question - The value given for Yes/No question on the randomisation form	[No/Yes question]	No/Yes question - The value given for No/Yes question on the randomisation form	[Reason for central randomisation]	Reason for central randomisation - The value given for Reason for central randomisation on the randomisation form
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<p>Visit Intervals</p> <p>Text will be used as visit name (optional)</p> <p>Interval</p> <p>2</p> <p>Margin</p> <p>2</p> <p>Text will be appended onto visit detail (optional)</p> <p>Delete</p>																																					

- Visit schedule details:
 - You can specify if the schedule is measured in weeks or days and you can specify the intervals for each visit using intervals and margins.
For example a visit with interval 4 and margin 1 will display a visit between 3 weeks and 5 weeks.
 - You can add as many intervals as required.
 - You can also add text before and after the visit schedule that will appear before and after that visit detail respectively on the automated emails that are sent out

6.5. Edit Randomisation Number Format

The randomisation number format that is used for the generated numbers for the randomised subjects can be configured here.

The elements of the number that can be changed are:

- Free Text – this is limited to 3 characters
- Uses site code – this will use the site code for the site being randomised to
- Uses arm code – this will use the code specified for the arm that is being used for the subject in the number if checked (the code is set when the arm is created is details in the Trial Arm section of this document)
- Uses Strata Code – this uses the value for the stratification, all values can be viewed on the “Stratification Map” page
- Sequential number length – this is the number of digits used for the incrementing part of the number
- Part separator – this is the character(s) that are used in between the components of the number (this can be empty)

Please note that the setting in the “Configuration” page – “Uses Site Based Count for Randomisation Number” will be used when generating the incrementing count portion of the randomisation number

You are free to rearrange to order of the component parts.

An example preview of this code will appear on the page itself.

Please note that after a release is prepared on the test system, this page will no longer be editable.

Edit Randomisation Number Format

Randomisation Number Preview

ARM01-S0001-00001

Arm CodeSite CodeIncrementing Number

Free Text (optional)

Uses Site Code

Uses Arm Code

Uses Strata Code

6.6. Manage Treatments

By default there will be two generic treatments in the system. You are able to add, edit and delete treatments as needs require while working on the test system.

Treatments consist of a name and description and must be created before Trial Arms are created. The reason for this is because to create a trial arm, you must select the treatments that are assigned to the arm.

Please note that after a release is prepared on the test system, you will only be able to remove treatments.

Treatment Options

Create New Treatment Option

Show entries

Filter:

Name	Trial Arms	Description	Actions
Treatment A	• Arm A		Edit Delete
Treatment B	• Arm A		Edit Delete

Showing 1 to 2 of 2 entries

Previous **1** Next

Create New Treatment Option

Name

Description

6.7. Manage Trial Arms

Managing trial arms is very similar to managing treatments. As discussed in the previous section, trial arms must be created with a list of treatments.

By default the system includes one sample trial arm and it's important to note that if the trial has one arm then using the default trial arm with the trial specific treatments would be the recommended approach. While the trial has one arm, it will be excluded from details such as the randomisation email as it is redundant information. The system must include at least one trial arm to function correctly.

When creating a trial arm you are asked for:

- Code – this can be used in the randomisation number
- Name
- Treatments in arm (if the trial has no separate arms – then including all treatments in the sole arm of the study is recommended)
- Max Randomisations – number representing maximum number of randomisations that can be assigned to a trial arm
- Description

Create New Trial Arm

Code

Name

Treatments

Max Randomisations

Description

6.8. Clear Randomisations

This page, only accessible on the test system, will remove all previous randomisations. This is useful for resetting the system before user tests are run, for instance.

6.9. Download User Test Plan

This page, only accessible on the test system, allows the downloading of a word document containing user tests for the randomisation form.

The test document has the following sections:

1. Test plan details – these are prepared with the logged in user's details
2. Test Plan QA and Approval – left blank
3. Test plan
 - a. Randomisation Form Validation – this section contains tests that test the validation rules added to each question
 - b. Randomisation Submission Validation – this section contains tests for completion and submission of the randomisation form
 - c. Randomisation Email Confirmation – this section contains tests relating to receiving the automated emails sent out upon randomisation
 - d. Statistical Tests – this section contains tests that check if the minimisation algorithm is working as expected
 - e. Contact Page Configuration – this section contains tests relating to ensuring the system configuration is correct and the correct details appear on the contact page
 - f. Additional User Tests – empty test section for additional tests
4. Validation completion – left blank
5. QA testing results and approval to proceed with release – left blank

Please note that after a release is prepared on the test system, you will only be able to remove treatments from trial arms.

6.10. Test Minimisation Randomisation

This page allows for the testing of the minimisation routine by uploading a CSV file representing a series of simulated randomisations.

This page will only appear in a study that uses minimisation randomisation which is configured on the Configuration page.

It is important to note that these simulated randomisations are not saved to the database.

The page allows you to download a sample CSV file prepared with the appropriate headings.

Each heading will correspond to a stratification factor question from the form and will require a valid answer in the rows below to be processed correctly.

The following types of question require as an answer:

- Date question – if there the ranges that correspond to stratification factors (e.g. 0-16, 17+) then “1” and “2” will correspond to the ranges, respectively.
- Dropdown option – the text of the option is required
- Site – the site code is required

Upon successful upload of a valid CSV file you will be presented with a table that looks like the following:

Test Minimisation Results

Filter results:

Number	Imbalance	Initial Allocation	Initial Random Number	Second Random Number	Treatment
1	0;0;	Treatment B	62.1613175897679	59.119081943817	Treatment B
2	0;9;	Treatment A	35.5903719251931	66.0311316447477	Treatment A
3	9;18;	Treatment A	59.6478045264482	10.1783614653062	Treatment A
4	27;27;	Treatment B	9.01942626061822	72.9431813456785	Treatment B
5	45;45;	Treatment A	58.3910479947883	35.7080012260508	Treatment A
6	72;63;	Treatment B	82.4484805960434	79.8552310466092	Treatment B
7	99;90;	Treatment B	31.8201023302135	42.6200509269815	Treatment B
8	126;126;	Treatment B	55.8775349314686	86.76728074754	Treatment B
9	153;171;	Treatment A	79.9349675327237	30.9145105680984	Treatment A
10	189;216;	Treatment A	29.3065892668937	93.6793304484707	Treatment A

Showing 1 to 10 of 15 entries

Previous **1** 2 Next

Excel

The “Excel” button at the bottom allows for the download of the entire table.

6.11. Allocation Stratification Map

If, during the form building process, questions outside the “Site” questions were defined as stratification factors then this page can be used to view the permutations of those factors into a map.

The map can be used when populating the allocation upload spreadsheet such that the “StratID” column can be used to define a combination of stratification factors.

The below screenshot displays an example from this page.

Allocation Stratification Mapping

Please be aware that as the randomisation form and stratification factors can be altered that this map is subject to change.

When the initial release is prepared, stratification factors will be locked and at that point the displayed map can be considered final.

Filter results:

StratID	 Date of Birth	 Hair Colour	
1	0 - 17	Red	
2	18 - Max	Red	
3	0 - 17	Green	
4	18 - Max	Green	

Showing 1 to 4 of 4 entries

Previous **1** Next

Here we have two questions defined as stratification factor, DOB and Hair Colour. Each permutation of answers is displayed along with the “StratID”. This ID can be used in the allocation upload form.

6.12. Allocation Upload

The upload allocation page is only available in studies that use list based randomisation.

The page accepts a CSV file representing the allocations that will be available. Each row on the spreadsheet requires the following:

- StratID – this is a value representing the combination of stratification factors for the allocation, the values that can be used for this page can be found on the map page previously discussed. If there are no combinations of stratification factors that can be used, this column needs to default to “1”.
- Centre – this is the randomisation code that will be given to a site. The site doesn’t have to be setup at the time the allocation is uploaded but the code used here will need to be assigned to a site before randomisation can occur.
- allocation – this must match a name of a treatment added to the system
- randomum – this is the randomisation number that will be assigned to the randomisation that uses this allocation

The page provides a sample CSV file and the format rules for the uploaded document.

Upload Allocations

Upload Allocation List

No file selected.

Example CSV file format:

```
StratID,Centre,allocation,randomum
1,1,Treatment A,1001,
3,1,Treatment B,1002,
3,2,Treatment B,2001
```

A list of valid IDs for StratID can be found [here](#). Please note that if no stratification factors are defined outside of site the default for StratID is 1.

Format rules

The entire file must contain no validation errors to be uploaded.

- Rule 1: Each allocation should be on a separate line with fields separated using comma characters
- Rule 2: The file must be saved as a .csv file format with the file extension .csv
- Rule 3: The first line must contain the header format as shown in the example above
- Rule 4: Allocation options are: {Treatment A | Treatment B}
- Rule 7: Allocation already uploaded

Available and assigned allocations can be viewed on the site management page afterward.

Sites

Show entries

Filter:

Code	Name	Randomisations	Actions
00000	CTRC	<ul style="list-style-type: none">• Available allocations: 3• Total Randomisations to site: 0	<input type="button" value="Edit"/> <input type="button" value="Delete"/>

Showing 1 to 1 of 1 entries

6.13. Test Block Randomisation

This page allows for the testing of the allocation routine by uploading a CSV file representing a series of simulated randomisations.

This page will only appear in a study that uses block randomisation which is configured on the Configuration page.

It is important to note that these simulated randomisations are not saved to the database.

Currently, this page works on the assumption that site is the sole stratification factor for allocations. If you upload a CSV with a series of site codes then the routine will try to randomise a simulated subject for each row to the site specified. If there is a failure the page will notify the user.

Upon successful simulated randomisations you will see a page like the following, details each allocation's randomisation code and treatment assigned.

Test Block Randomisation Upload

This page performs a simulation of block allocations given a list of randomisation details. This does not save to the test database.

Upload Sample Randomisation List

No file selected.

Test Block Randomisation Results

Filter results:

Number	Treatment
1001	Treatment A
1002	Treatment B

Showing 1 to 2 of 2 entries

6.14. Download Randomisation Details

This page displays details of all current randomisation in the system, including the values that were filled into the form. This page is only accessible to statisticians and does include treatment allocation information.

Randomisation Details

Filter results:

 Site	 Randomisation Number	 Treatment	 Screening Number	 Patient Initials	 Consent Date	 Date of Birth	 Site	 Yes/No question
CTRC	TST000001	Treatment B	001	KMK	2017-01-01 00:00	2016-12-04 00:00	CTRC	Yes
CTRC	TST000002	Treatment A	002	KJM	2017-01-03 00:00	2017-01-02 00:00	CTRC	Yes
CTRC	TST000003	Treatment B	003	JML	2017-01-17 00:00	2017-01-02 00:00	CTRC	Yes

Showing 1 to 3 of 3 entries

Previous **1** Next

Excel

6.15. View Current Imbalance

This page details the distribution of randomisations across each arm and each stratification factor in the study.

If the study is a block based randomisation you will not see the current imbalance factor nor the link to edit it.

This page also contains a link to get to the Edit Imbalance Factor page which is discussed in the next section.

View Current Imbalance

Total randomisations: **3**

Current imbalance factor: **100**

[Edit Imbalance Factor](#)

Arm A

Randomisations: **3**

Calculated imbalance factor: **0**

Stratification Factor	Treatment A	Treatment B	Total
All	1	2	3
Date of Birth	1	2	3
0 - 21	1	2	3
22+	0	0	0
Site	1	2	3
CTRC	1	2	3

6.16. Edit Imbalance Factor

If the study is a block based randomisation this page will be disabled and you will see the appropriate message.

This page allows for the editing of the imbalance factor used in the minimisation algorithm.

The value must be between 0-100.

7. Release

The release procedure is as follows:

- Configure test system for trial
 - Configuration page
 - Automated email configuration
 - Treatments
 - Trial arms
 - Randomisation form
 - Randomisation number format
- Save the state of the test system (i.e. the above configurable components) into a release
- Login to the live system
- Select the release you wish to configure the live system from and save

- At this point the live system will have been configured to match the configurable components of the test system.

7.1.1. Saving the State of the Test System for a new Release on the Live System

Clicking the release link on the test system will allow you to open a page for preparing a new release.

Development Site

Please do not enter any live data into the development site.

Before you prepare this release please check you have configured and are satisfied with the following:

- Main configurations (inc. trial name, type of randomisation and contact details). Click [here to edit](#)
- Email configurations (inc. email text sent out upon randomisation and visit schedule details). Click [here to edit](#)
- Randomisation form - including indications of stratification factors and validation rules on questions. Click [here to edit](#)
- Format of automatically generated randomisation number. Click [here to edit](#)
- Imbalance factor. Click [here to edit](#)
- Treatments. Click [here to edit](#)
- Trial Arms. Click [here to edit](#)
- The test plan for the randomisation form has been downloaded, completed and filed. Click [here to download the test plan](#)

Please also be aware that once the release is prepared, you will no longer be able to edit the following:

- Stratification factor questions in the randomisation form build page.
- Trial arm and treatment configuration will be limited - only treatments can be removed.
- Configuration settings such as randomisation type and if the trial is blinded will not be editable.

Are you happy with the configuration of the system? The current configuration will be prepared for release to the live system.



Prepare Release

Return to Home

The page asks the user to confirm they are happy with the state of the system and that the user tests have been downloaded, completed and filed.

If the user is happy with everything listed, they may prepare the release.

Upon preparation of a release, the user will see a page confirming this. It is also worth noting that the footer displayed on all pages will not display the latest release prepared.

Development Site

Please do not enter any live data into the development site.

Release Has Been Prepared

Test Trial • [Browser Requirements](#) • [Privacy Policy](#) • Framework Version 1.0.0.0 • Release 1 - 12/01/2017 11:20:07

7.1.2. Configuring the live system

Upon preparing of a release of the system on the test server, the user will be able to login to the live system and configure that system based on the saved configuration of the test system.

Clicking the release button on the live system will allow the user to navigate to the page that can set the live system up with a new release configuration.

Configure for Release

Updating to a new release will update the following based on the configuration of the test system at the time the release was prepared:

- Configuration (trial name, contact details and type of randomisation)
- Text of emails sent upon randomisation inc. visit schedule details
- Randomisation form - including all validation rules and stratification factors
- Trial arms
- Treatments
- Imbalance factor
- Randomisation number format

Select Release to Deploy

1 : admin - 12/01/2017 11:20:07

Save

Return to Home

Upon selecting a release and saving the live system will now be configured. The footer here will also display details of the latest release.