



USER TRAINING GUIDE FOR USE WITH NWORTH RANDOMISATION DATABASES



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TABLE OF CONTENTS

1 BEFORE YOU START ERROR! BOOKMARK NOT DEFINED.

2 LOGGING IN ERROR! BOOKMARK NOT DEFINED.

2.1 PERFORM RANDOMISATION..... 5

2.2 AFTER SUBMITTING THE DATA..... 6

2.3 DATA CONFIRMATION. 8

2.4 RANDOMISATION RESULT..... 9

3 Trouble shooting

All screen shots are taken from a mock trial, used for validation.

1 Before you start

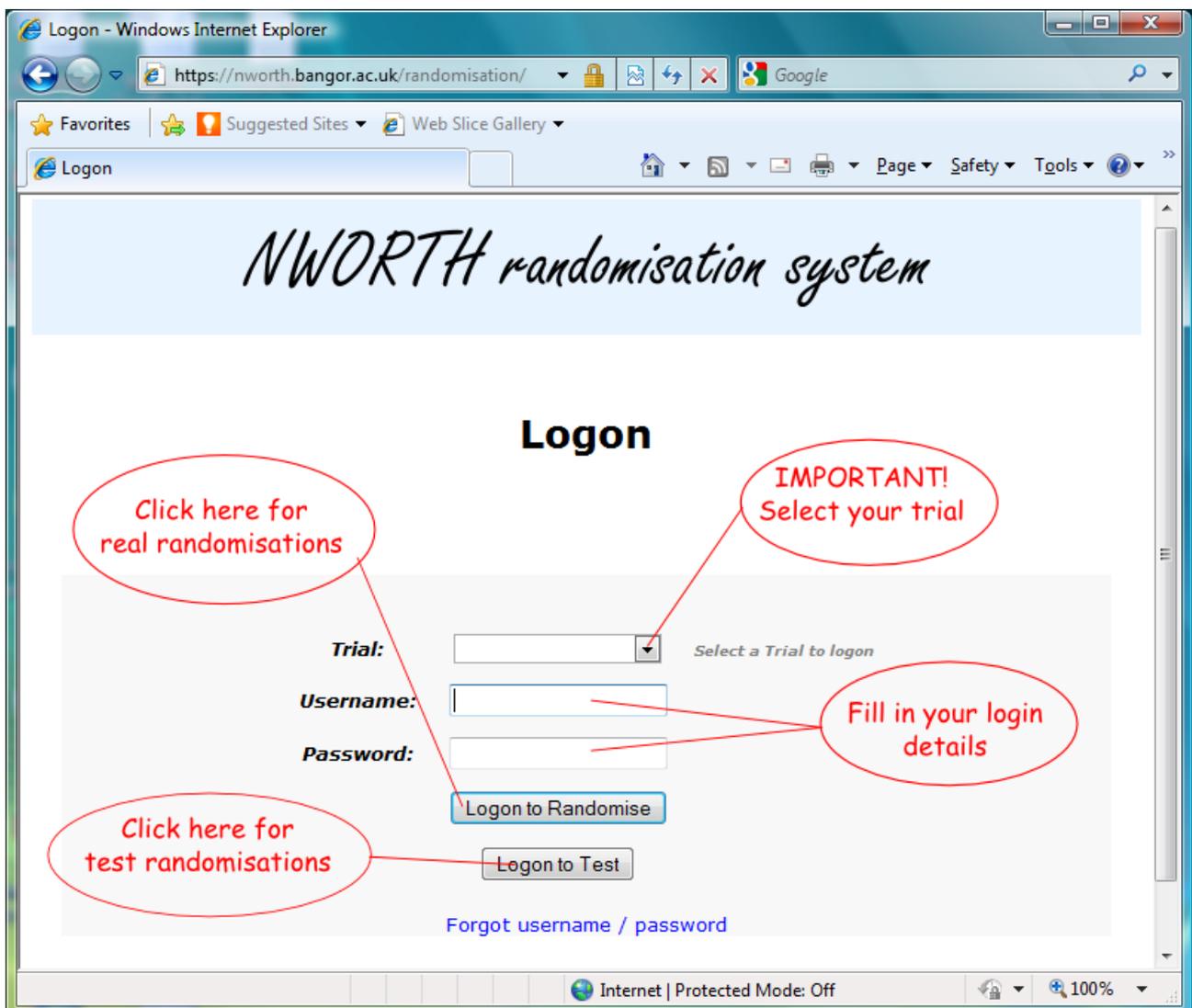
Your username and password will have been emailed to you by the NWORDH IT team.

If you have not been issued with a username and password, please contact the trial manager. They will confirm that you are to perform randomisations and pass on your name, title, phone number and email address to the NWORDH IT team.

2 Logging In

Enter the URL <https://nworth.bangor.ac.uk/randomisation/> into the address bar in your browser.

You should see a page that looks like the one shown below:



Select your trial and enter your username and password. Usernames and passwords are case-sensitive.

If you click the button "Logon to Randomise", you will be doing real randomisations: the database will be updated and email notifications will be sent.

If you click the button “Logon to Test”, you will be using the system in the test mode. In this case you will have the entire experience of performing randomisations, but the database will not be updated and email notifications will not be sent.

In case you have forgotten your login details, use the link “Forgot username / password” at the bottom of the login page. It will display the form shown below:

The screenshot shows a web browser window with the URL <https://nworth.bangor.ac.uk/randomisation/forgotPassword.jsp>. The page title is "Forgot Password". The main heading is "NWORDH randomisation system" in a cursive font. Below this is the "Forgot Password" section. It features a form with two fields: "Trial:" and "Email address:". The "Trial:" field is a dropdown menu with a red arrow pointing to it from a callout box that says "Select the trial you are associated with". The "Email address:" field is a text input with a red arrow pointing to it from a callout box that says "Enter the email address you have been registered with in the system". Below the fields is a "Submit" button. The browser's address bar and menu bar are visible at the top.

Fill in the form and submit. Make sure to enter the email address you were registered in the system with originally. You will receive an email with your username and a new automatically generated password. After logging on using the emailed details you can change your password.

2.1 Perform randomisation

After logging in you will see a form displaying the questionnaire for this trial:

NWORTH randomisation system

[Change Password](#) [Logoff](#)

Questionnaire

Trial: OQ_Test

Please fill in the form with the details of the participant and submit it.

Participant ID	<input type="text"/>	<i>Unique, 5 or 6 digits</i>
Participant DOB	<input type="text"/>	<i>DD MM YYYY</i>
Participant Initials	<input type="text"/>	<i>Required</i>
Type of oq_test repair	<input type="text"/>	<i>Select</i>
Age	<input type="text"/>	<i>Select</i>
Consent	<input type="text"/>	<i>Yes is required</i>
Inclusion Criteria Met	<input type="text"/>	<i>Yes is required</i>
Gender	<input type="text"/>	<i>Select</i>
Centre	<input type="text"/>	<i>Select</i>
Bilateral repair	<input type="text"/>	<i>Select</i>

All the fields are required.

On the left-hand side are the field captions. On the right-hand side are brief help texts, explaining the specific requirements for the corresponding data fields.

As displayed above the “Submit” button, all fields are required. The system does not accept incomplete data sets.

Fill in the questionnaire with the details of the participant and submit.

If you have logged on using the button “Logon to Test”, you will see the following screen:

https://nworth.bangor.ac.uk/randomisation/randomise/questionnaire.jsp

Questionnaire

File Edit View Favorites Tools Help

Meet the BBC Wildlife edit... DatabaseMetadata « Data... Page Safety Tools

N WORTH randomisation system - Test

Change Password Logoff

Indicates 'test' mode

Questionnaire

Trial: OQ_Test

Please fill in the form with the details of the participant and submit it.

Participant ID *Unique, 5 or 6 digits*

Participant DOB *DD MM YYYY*

Participant Initials *Required*

Type of oq_test repair *Select*

Age *Select*

Consent *Yes is required*

Inclusion Criteria Met *Yes is required*

Gender *Select*

Centre *Select*

Bilateral repair *Select*

All the fields are required.

Submit

In this instance you are using the randomisation system in test mode. The test mode is indicated on the top bar.

In test mode the database is not changed. The randomisations, performed in it are not saved. Email notifications will not be sent.

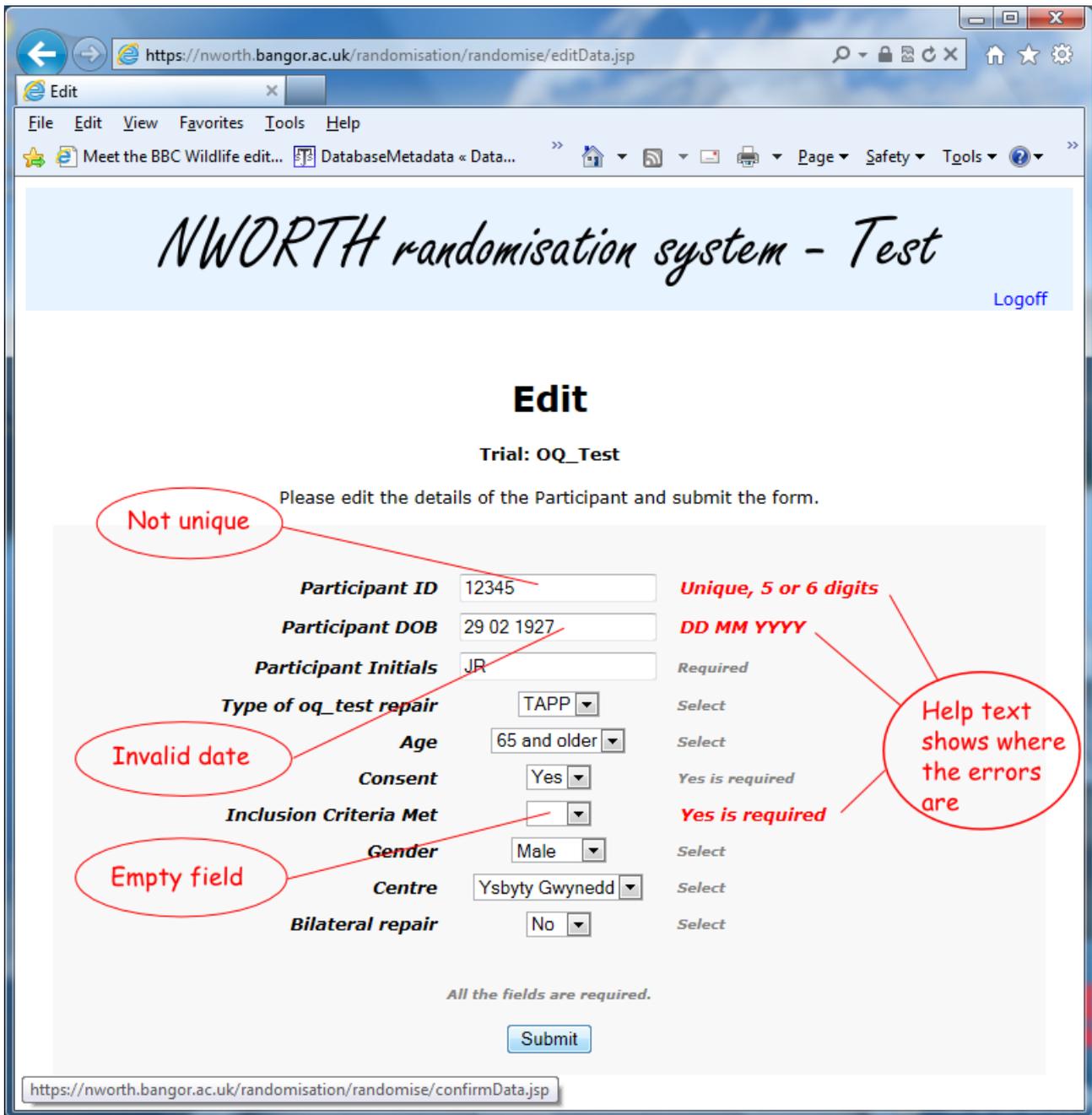
The test mode serves to familiarise you with the questionnaire and the reactions of the randomisation system to your actions.

In test mode you can experiment with the system in a safe way.

2.2 After submitting the data

Below is an example of submitting an incomplete and erratic data set. In this case the system will

go directly in the “Edit” mode, indicating the errors.



In the example above the “Participant ID” was not unique. In this case, there will be also an error if the ID contains symbols other than digits, or if it was shorter than 5 digits or if it were longer than 6 digits.

The system checks the dates for validity and correct format. In this case the format was correct, but the date was invalid.

The third error was because there was nothing selected for “Inclusion Criteria Met”.

All fields must be completed.

2.3 Data confirmation

After the data is corrected in the “Edit” mode and passes validation checks, the Confirm screen will be shown. An example of it is shown below:

NWORTH randomisation system - Test [Logoff](#)

Confirm

Trial: OQ_Test

Please Confirm the data or Edit to correct it. Confirmation will trigger the Randomisation process.

Participant ID	123456	Unique, 5 or 6 digits
Participant DOB	28 02 1927	DD MM YYYY
Participant Initials	JR	Required
Type of oq_test repair	TAPP	Select
Age	65 and older	Select
Consent	Yes	Yes is required
Inclusion Criteria Met	Yes	Yes is required
Gender	Male	Select
Centre	Ysbyty Gwynedd	Select
Bilateral repair	No	Select

Entered values

The system accepted the data, but it still could be wrong in a way the system cannot recognise.

Here is a final chance to check whether the entered values are correct and edit the data if they are not. After each edit, the system will require confirmation before performing the randomisation with the data set.

If you click the button “Confirm”, this will trigger the randomisation process.

When you are happy the data is correct, confirm to perform the randomisation.

2.4 Randomisation result

After the randomisation is performed, the following screen will be shown:

The screenshot shows a web browser window with the URL <https://nworth.bangor.ac.uk/randomisation/randomise/randomise.jsp>. The page title is "Randomise". The main heading is "NWORTH randomisation system - Test" with a "Logoff" link. Below this is the "Randomisation Result" section for "Trial: OQ_Test".

The participant details are as follows:

Participant ID	123456
Participant DOB	28 02 1927
Participant Initials	JR
Type of oq_test repair	TAPP
Age	65 and older
Consent	Yes
Inclusion Criteria Met	Yes
Gender	Male
Centre	Ysbyty Gwynedd
Bilateral repair	No

Was randomised into group **No OQ.**

This was a *test randomisation*. It wasn't saved and email notifications were not sent.

[Another Randomisation](#)

Red annotations in the image:

- A red circle around the participant details list with the text: "For real randomisation these values will be added to the database".
- A red circle around the "group No OQ." field with the text: "Group - only shown to non-blinded users".

The screen shows the data which was used for the randomisation and the result of the randomisation.

For blinded users the group to which the participant was assigned will not be displayed.

When the randomisation is performed in live (not in test) mode, the email notifications will be sent and the randomisation will be added to the database.

In test mode nothing is added to the database and notification emails are not sent.

You can perform another randomisation if you click on the link "Another Randomisation" at the

bottom of the page.

If you are finished randomising, click “logoff” at the top right of the page. This action will destroy your session with the server and will prevent possible unauthorised access to the trial’s randomisations.

2.5 Changing your Password

To change your password, click “Change password” at the top right of the pages displaying the questionnaire. The link will display the following screen:

NWRTH randomisation system

Change Password

The password should consist of at least 6 characters and use only letters and digits. It should contain at least one capital letter, one small letter and one digit, for example aXb2sd.

All the fields are required

Current Password: *Required*

New Password: *Required*

New Password: *Confirm*

Enter your current password in the field titled “Current Password” and then enter your new password in the fields with caption “New Password”. If what you have entered in the field “Current Password” matches your current password and the entries in the fields “New Password” are

identical, your password will be changed.

Note that the system will **not** send you any email notifications in connection to the change of the password. You should take care to remember your new password.

3 Trouble-shooting

If you experience any problems accessing the system or performing randomisations, please check this section of the guide.

3.1 Logon problems

- Make sure you have selected your trial correctly;
- Apply the right capitalisation in the username and password: the system is case sensitive and “mac15N” is different from “Mac15n “.
- When using the “Forgot username / password” feature of the system, you will be identified by the email address and the trial. Make sure you select the right trial and the email address with which you have been registered as a user. An alias to that email address will not work.

If you are still having trouble, contact your trial manager. It may be that you have not been registered as a user in the system and the trial manager will send your details to the NWORTH IT team with a request to create you an account.

3.2 Problems randomising

- Check the mode you are using the randomisation system. Test mode is indicated on the top bar of the pages and in it you cannot perform real randomisations: the database will not be updated and email notifications will not be sent.
- Check the dates in the questionnaire are the required formats. If the date is not in the required format, or it is not a valid date e.g. 36/11/1987, the system will not accept it.
- In fields where integer numbers are required, numbers containing a fraction part will be rejected.
- Where digits are required, only digits will be accepted.
- Participant IDs must be unique. When an ID is rejected, but it is otherwise correct in terms of format, length, value and character set, this is an indication that it is not unique.