

# STARFISH Database

## Guidelines for Data Entry and Randomisation



# Guidelines for STARFISH Database

## Introduction

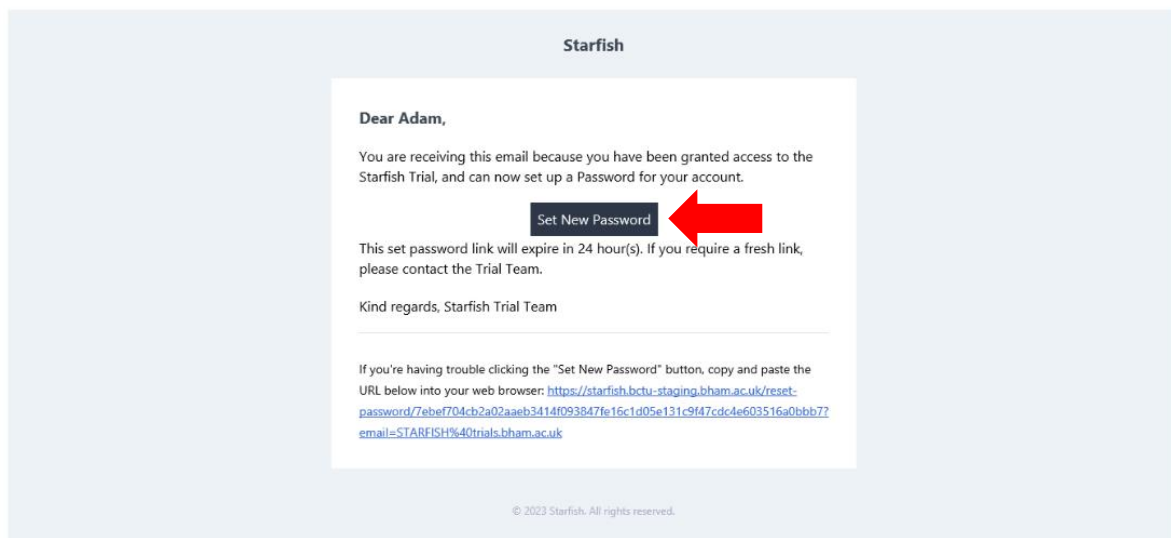
This document is intended to explain how to use the STARFISH Online Database. It does not go into the detail of either the protocol or the randomisation procedure itself, but provides essential information that will help you to use the Online Database for randomisation and data entry.

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## Accessing and Using the System

### Username and Passwords

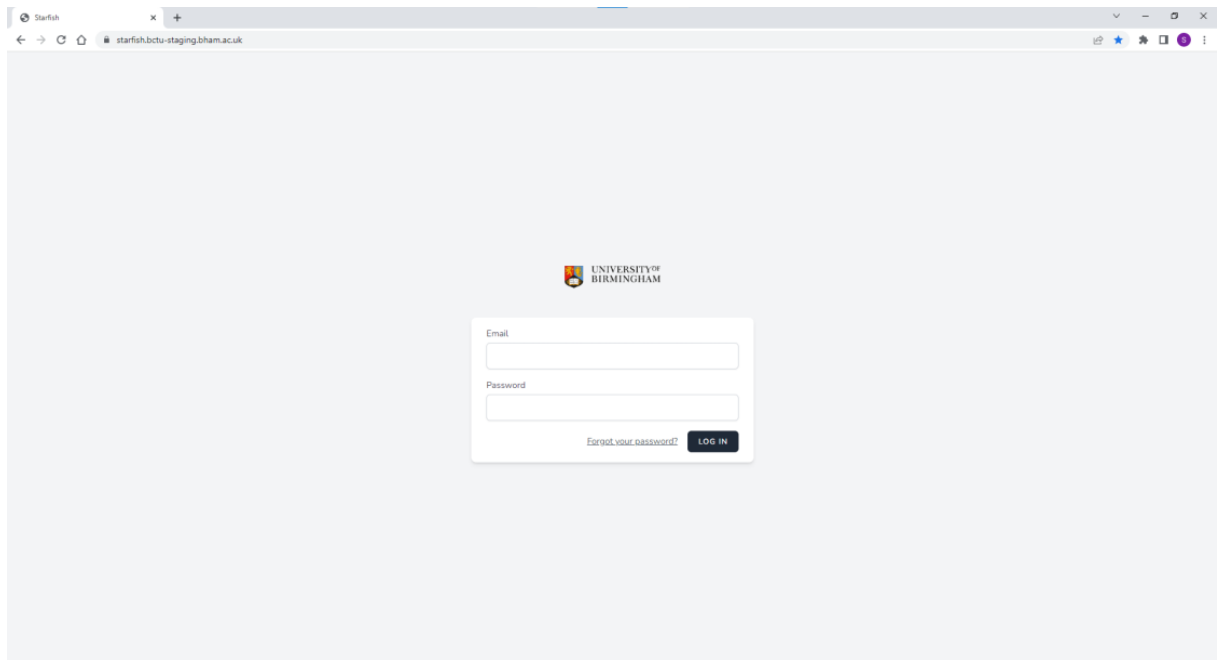
- You will receive an email from the Trials office containing a link to set a new password for your account. Passwords are individual and should be known only to you.
- The set new password email will look like this:



- You will be sent to a page to enter and confirm a new password. Once this is done, the page will refresh, informing you that your password has successfully been reset.
- You will be sent a verification email and the first time you log in you may be asked to verify your email address by clicking the link that has been emailed to you. If you do not receive any emails, you may find they have been directed to your 'Junk Email' folder.
- After verifying your email address, you can Login using your Username and Password.

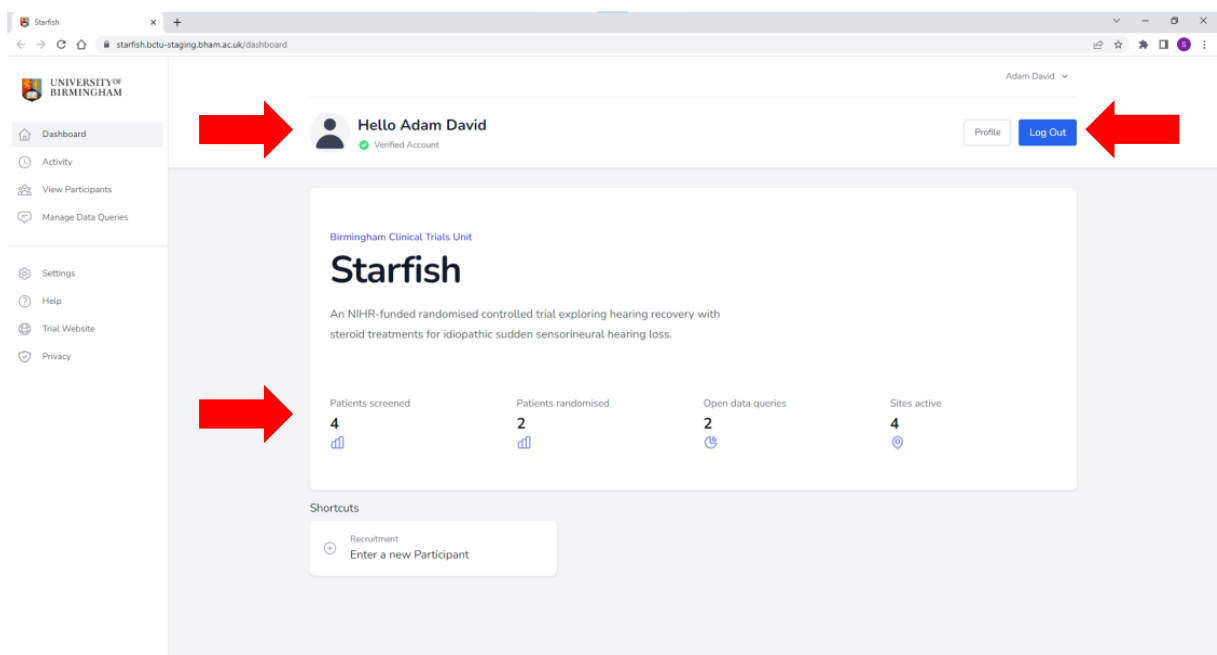
### Accessing the STARFISH Database

- Direct your web browser to <https://starfish.bctu.bham.ac.uk>  
(Please see: [Important General Information – Web Browsers for more information](#))
- Log in using your username and password.
- The log-in page will look like this:



## Dashboard

- Once you have logged in, the Dashboard/ Homepage will look like this:

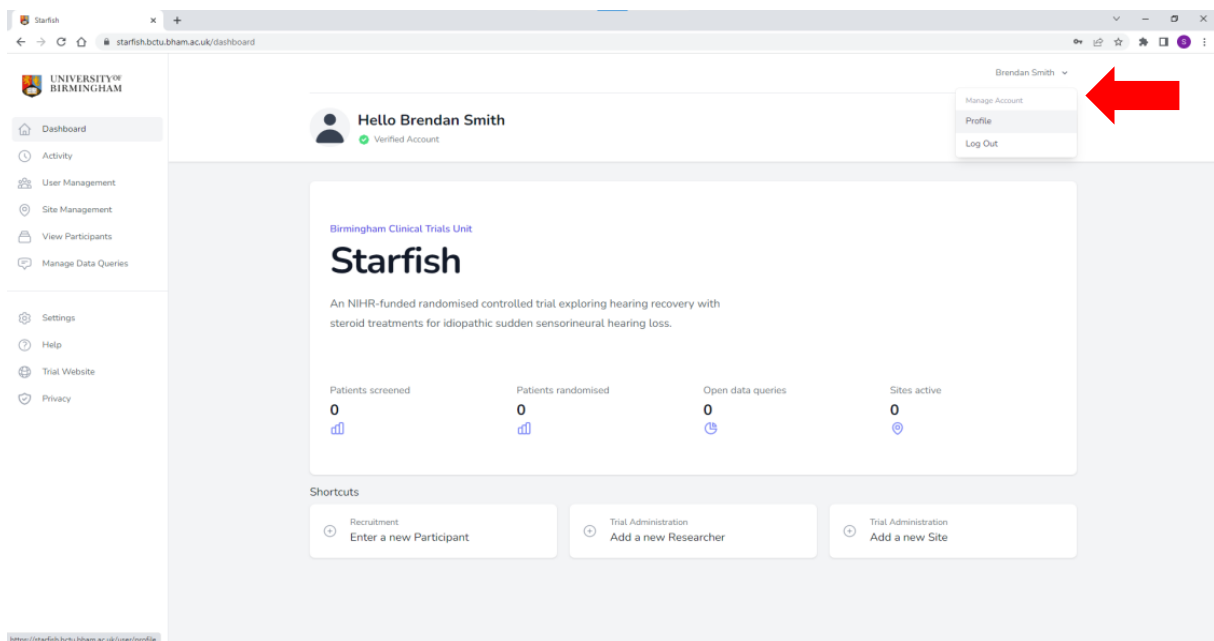


- You should be able to see your name at the top of the page with a 'Verified Account' label. Information on the STARFISH Trial will be on this page. If you have any problems logging in or accessing this STARFISH database please contact [STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk).

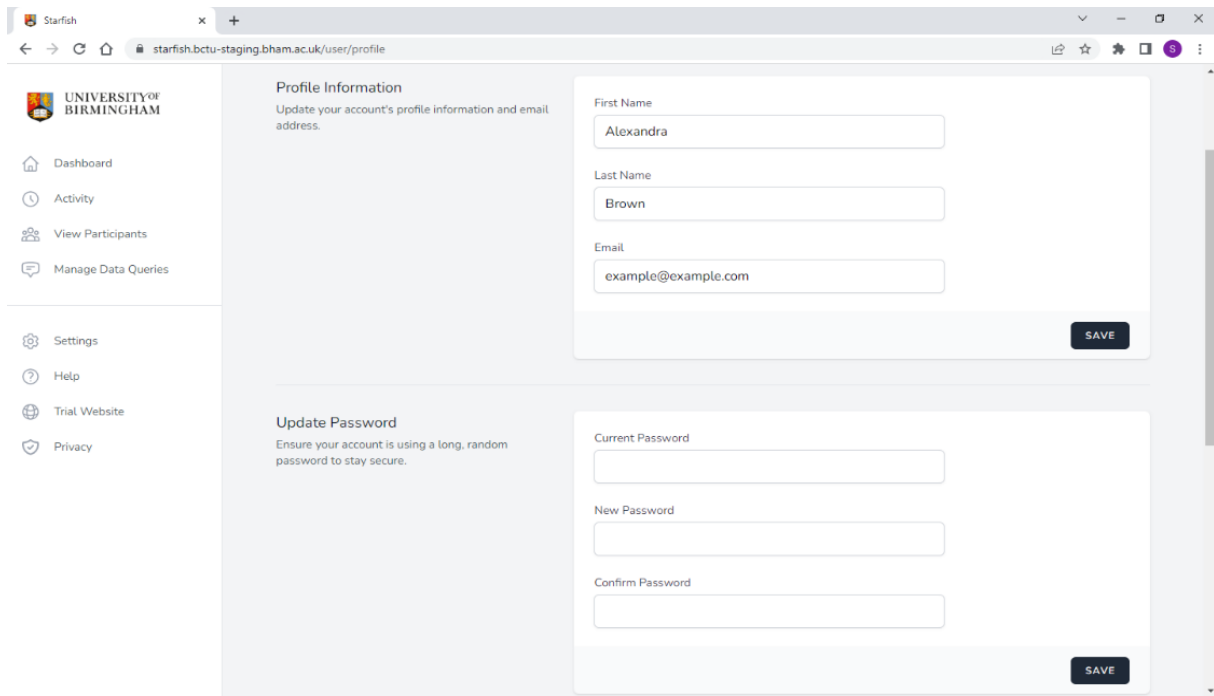
- You will be able to see overall information about the trial on this page. E.g. Patients screened, Patients randomised, open data queries and the number of active sites.

### Accessing Profile Page and Changing Password

- To access your profile page select your name in the top right hand corner of any page on the database, then from the resulting drop down menu select 'Profile'. *(You can also access this by selecting the 'Profile' button located in the top right hand corner of the Dashboard page).*



- On the Profile page you will be able to view and change your name and email address. You will also be able to change your password and set up two factor authentication if wanted.



## Live/ Training Database

- You can access the STARFISH Training Database here: <https://starfish.bctu-staging.bham.ac.uk/>. This will allow you to access everything you would be able to when in the live database like adding participants, forms and practising the randomisation process.
- You will be able to log in to the STARFISH Training Database using generic test log in details. Please request these from the trials office if you'd like to use the training system.
- Data entered onto the training system is cleared regularly but may be visible to other users, including users at University of Birmingham. Please do not enter real patient data into the training system.
- You can access the Live STARFISH Database here: <https://starfish.bctu.bham.ac.uk>
- If you have any problems using or accessing the STARFISH Online Database then please get in contact with the STARFISH Trial team at [STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk)

## Logging off

- To log off the system simply click the 'Log Out' button on the Dashboard or select your name in the top right hand corner of every page then select 'Log Out' from the drop down menu.

## Entering Data

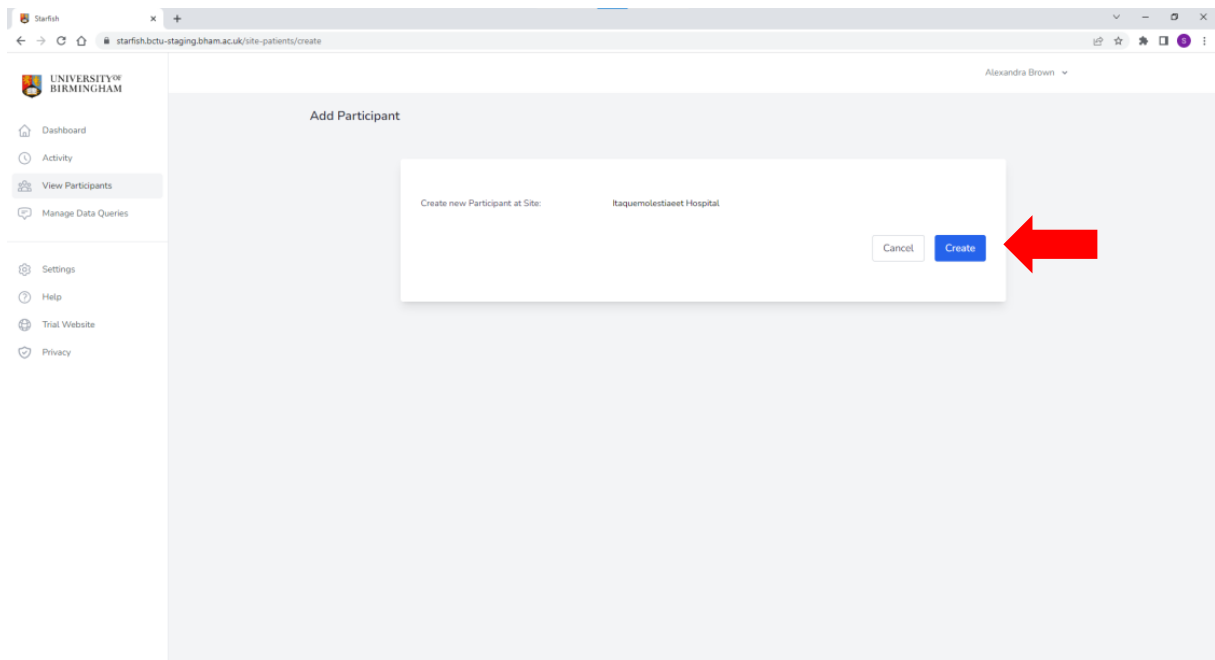
### Adding a participant record

- From the Dashboard select 'View Participants', this will show a list of any current participants that can be identified by their study number. You will also be able to see the current site the participant is registered with and the entry date they were added to the online database.

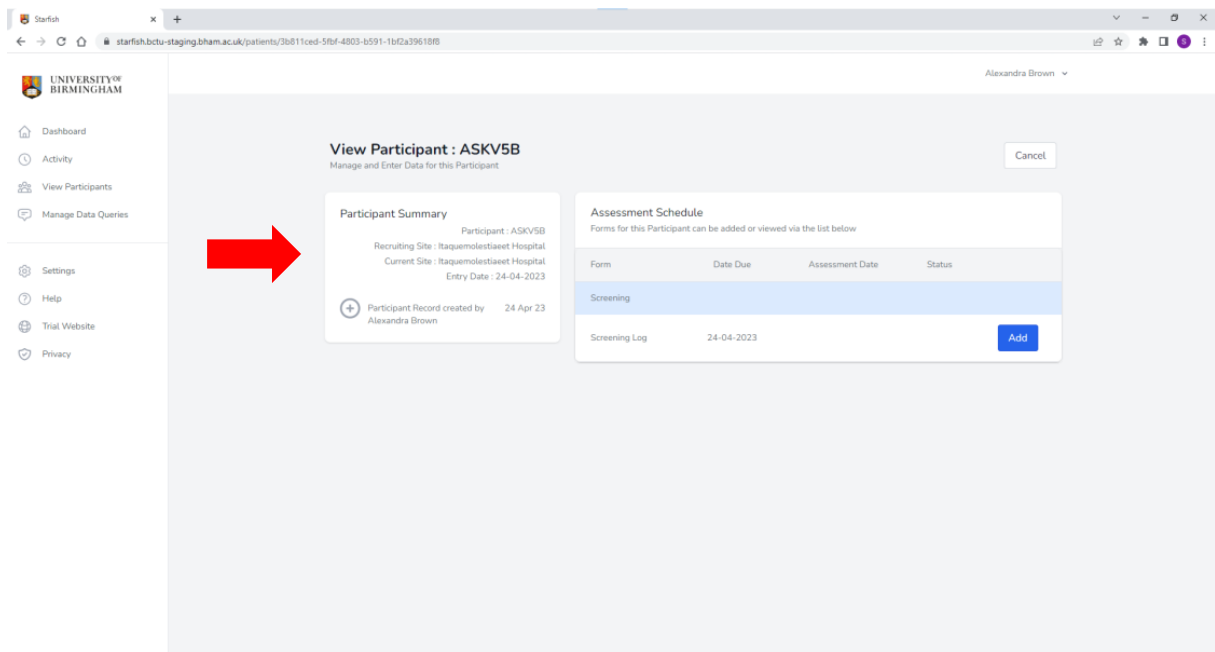
The screenshot shows the Starfish web application interface. On the left is a navigation sidebar with the University of Birmingham logo and menu items: Dashboard, Activity, View Participants (highlighted with a red arrow), Manage Data Queries, Settings, Help, Trial Website, and Privacy. The main content area is titled 'Participant List' and contains a table of trial participants. In the top right corner of the main area, there is an 'Add Participant' button, which is also highlighted with a red arrow. The table lists participants with their study numbers, current sites, and entry dates.

STUDY NUMBER	CURRENT SITE	ENTRY DATE	
1016	Itaquemolestaet Hospital	29-03-2023	<a href="#">View</a>
SZV3FZ	Itaquemolestaet Hospital	30-03-2023	<a href="#">View</a>
PHYCZR	Itaquemolestaet Hospital	30-03-2023	<a href="#">View</a>
P6AGRE	Itaquemolestaet Hospital	04-04-2023	<a href="#">View</a>
62QY7T	Itaquemolestaet Hospital	06-04-2023	<a href="#">View</a>
1024	Itaquemolestaet Hospital	06-04-2023	<a href="#">View</a>
CAR0XB	Itaquemolestaet Hospital	17-04-2023	<a href="#">View</a>

- To add a new participant select 'Add Participant' in the top right hand corner of the Participant List page. This will send you to a page which will give you the option to create a new participant, as shown below:



- Once you have created a new Participant you will be directed to the individual participant page, where you can manage and enter data. This page contains basic information about the participant and the list of assessments to be added, as shown below. Initially, only the screening log form will be shown. More forms will appear as you add each individual form.





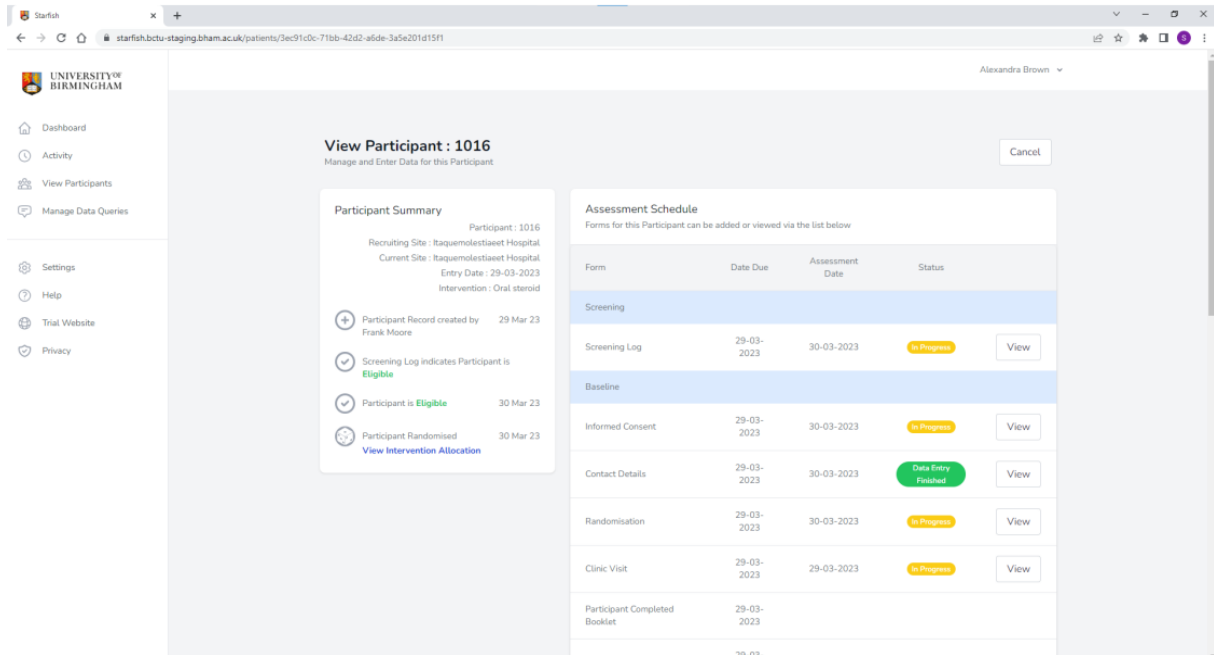
## Viewing a participant record

- From any page, select 'View Participants' in the database menu on the left hand side of the page.
- To view a record from the Participant List, select 'View' on the right hand side of the page next to the specific participant record you would like to view.

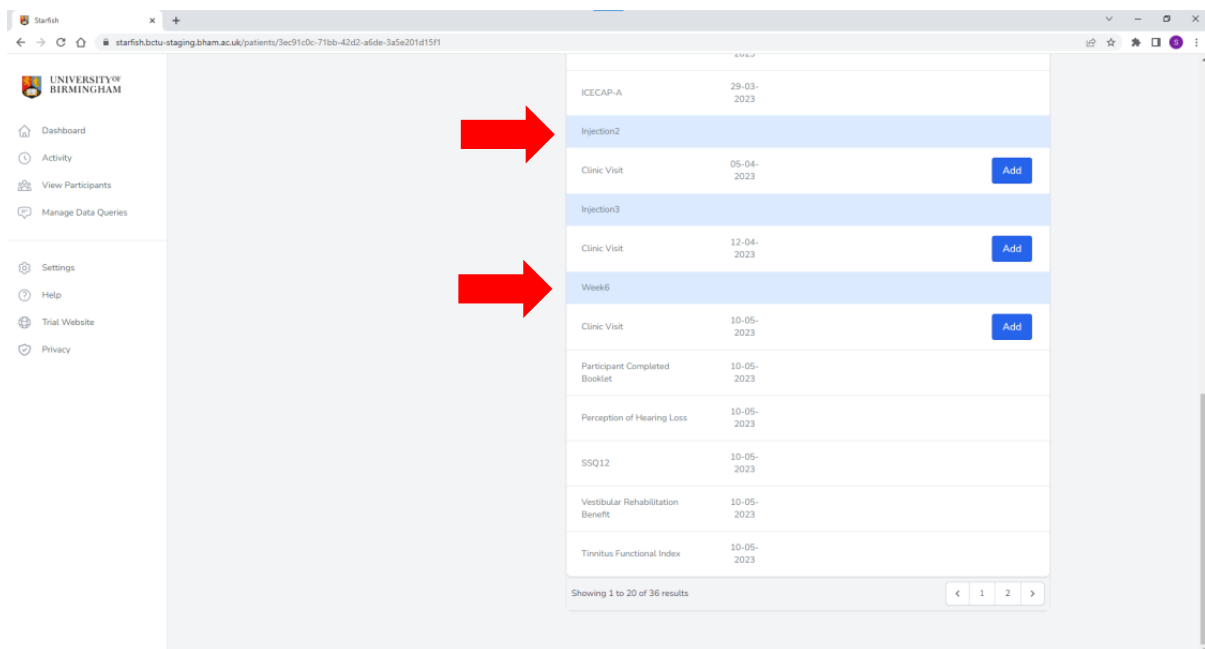
The screenshot shows the Starfish database interface. On the left, a sidebar menu includes 'View Participants', which is highlighted with a red arrow. The main content area is titled 'Participant List' and contains a table of participants. A red arrow points to the 'View' link in the first row of the table.

STUDY NUMBER	CURRENT SITE	ENTRY DATE	
1016	Itaquemolestaet Hospital	29-03-2023	<a href="#">View</a>
SZV3FZ	Itaquemolestaet Hospital	30-03-2023	<a href="#">View</a>
PYHCZR	Itaquemolestaet Hospital	30-03-2023	<a href="#">View</a>
PEAGRE	Itaquemolestaet Hospital	04-04-2023	<a href="#">View</a>
6ZQY7T	Itaquemolestaet Hospital	06-04-2023	<a href="#">View</a>
1024	Itaquemolestaet Hospital	06-04-2023	<a href="#">View</a>
CAR00B	Itaquemolestaet Hospital	17-04-2023	<a href="#">View</a>

- Once on the Participant's record page you can add, view and edit existing forms, in accordance with the permissions you have. On the left hand side you will be able to see whether the participant is eligible for the trial and whether they can be randomised. Once they have been randomised it will show you the allocation they have received.
- On the right hand side you will be able to see the status of the assessments (e.g. 'In Progress', 'Data Entry Finished'). As shown below:

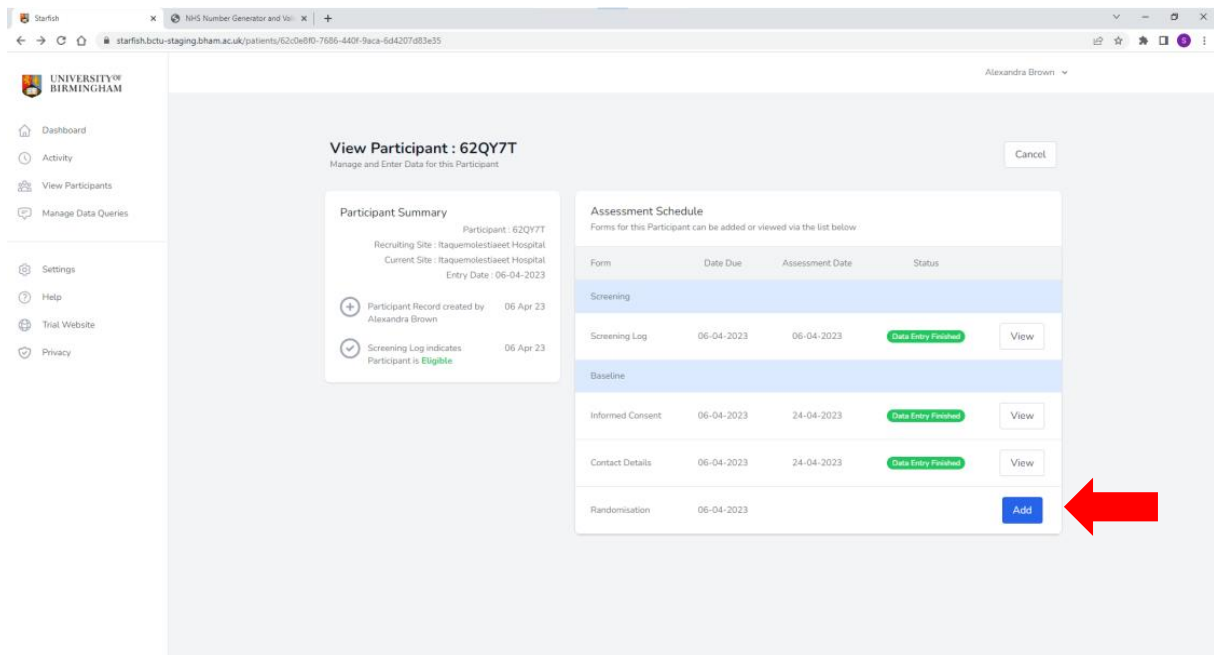


- The forms are separated into the different appointment visits (e.g. Injection 2, Injection 3, Week 6 Clinic Visit) to allow for ease when selecting the correct time point for each form. As seen below:

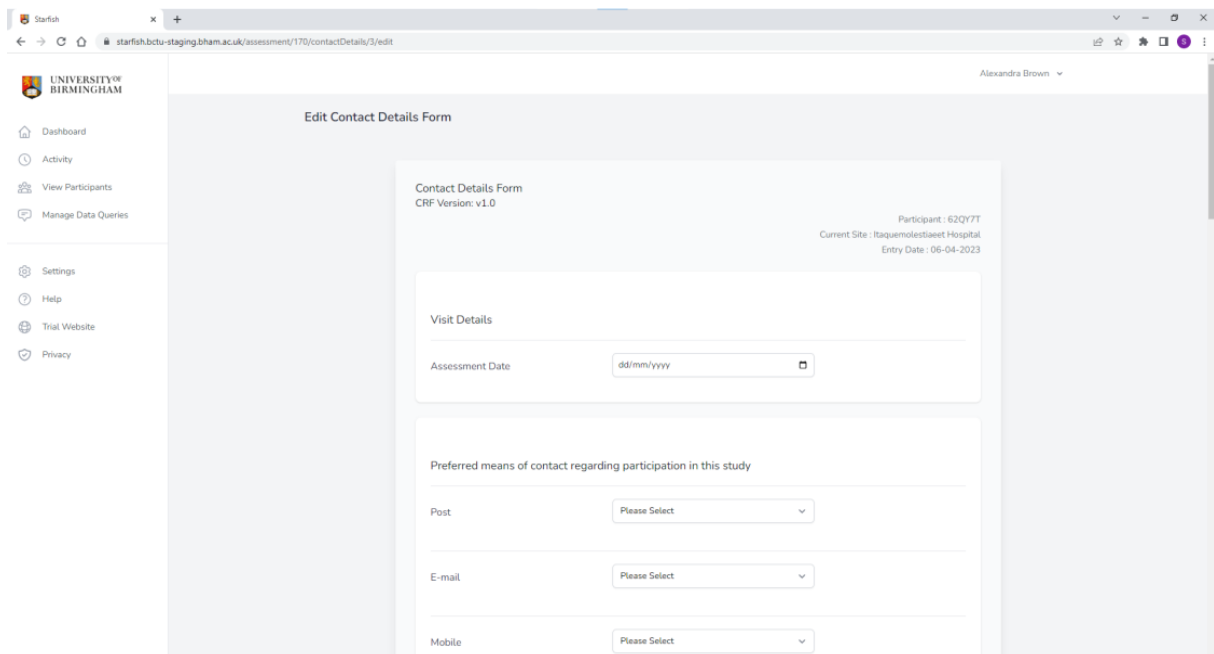


### Adding a form, Entering data and Submitting a form

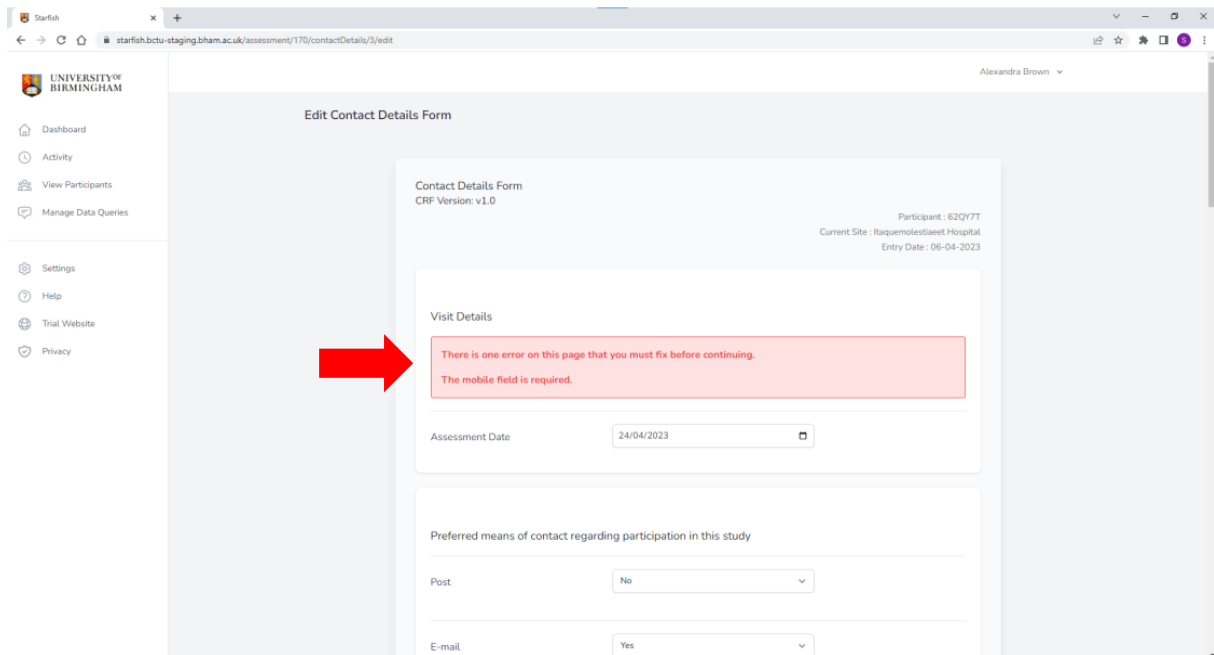
- From the Participant form, click 'Add' for the desired form. Some forms will only appear once you have entered other forms.



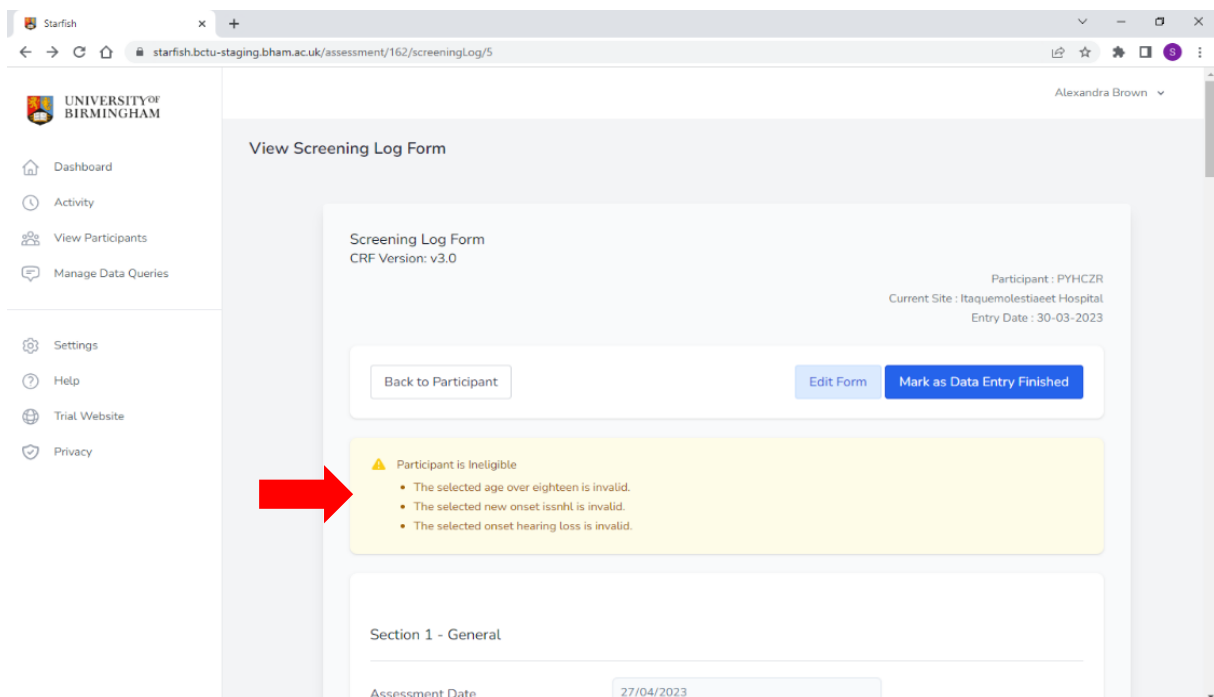
- The next page you will see is the form you have added. Complete the form by entering the data in each field and selecting 'Save Form'. The forms will include questions with drop down menus, text fields and numerical fields. Clicking 'Cancel' will undo any information you have entered since the last save.



- Some fields are required and you will not be able to submit the form until the data is entered. You will get a prompt at the top of the page when this happens informing you what the error is or which field is missing, as shown below:



- If you have entered and submitted data that would suggest the participant is not eligible for the trial then you will see a 'Participant is Ineligible' message at the top of the form bullet-pointing the fields that make the participant ineligible. As shown below:



## Notes on entering data and using the online database

- All forms must be completed online via the STARFISH Database, excluding the Participant Questionnaire Booklet, which will be completed by the participant, overseen by site staff. For the Questionnaire Booklet, please take a copy for your local records, then send them in the provided pre-paid envelopes to the trials unit.
- Forms to be completed by site staff are as follows: Screening Log, Informed Consent, Randomisation, Clinic Visit, SAE and Change of Status. They are completed at the following time points: Baseline, Injection 2 (if applicable), Injection 3 (if applicable), Week 6 and Week 12. Some forms need only be completed if relevant and can be added at any time (e.g. an SAE form should be completed if a reportable SAE has occurred).
- All forms associated with the Participant Questionnaire Booklet such as: Participant Completed Booklet, Perception of Hearing Loss, SSQ12, Vestibular Rehabilitation Benefit, Tinnitus Functional Index, Health Utilities Index 3 and ICECAP-A will be completed on the online database by a member of the Trial team once the Participant Questionnaire Booklet has been posted to BCTU. You will be able to view the data in the system once it has been entered at BCTU.
- Some fields are programmed to have acceptable limits and query ranges. This is to detect unexpected or implausible data, e.g. a date of birth that would give a patient an age of 150 years. An error message will show if you enter data that is outside the permitted range.
- Some fields are required and you will see an error message if you try to save the form without entering the required data. All data at randomisation is required.
- If you have any queries (shown at the top/ bottom of the page) please resolve the issues, e.g. by adding any missing data, before you submit the form. Staff at BCTU will query any missing or invalid data if the form is received before these issues are addressed.
- Contact the STARFISH trial office (STARFISH@trials.bham.ac.uk) if you have any issues or need to add a form that isn't currently available to you.

## **Randomisation**

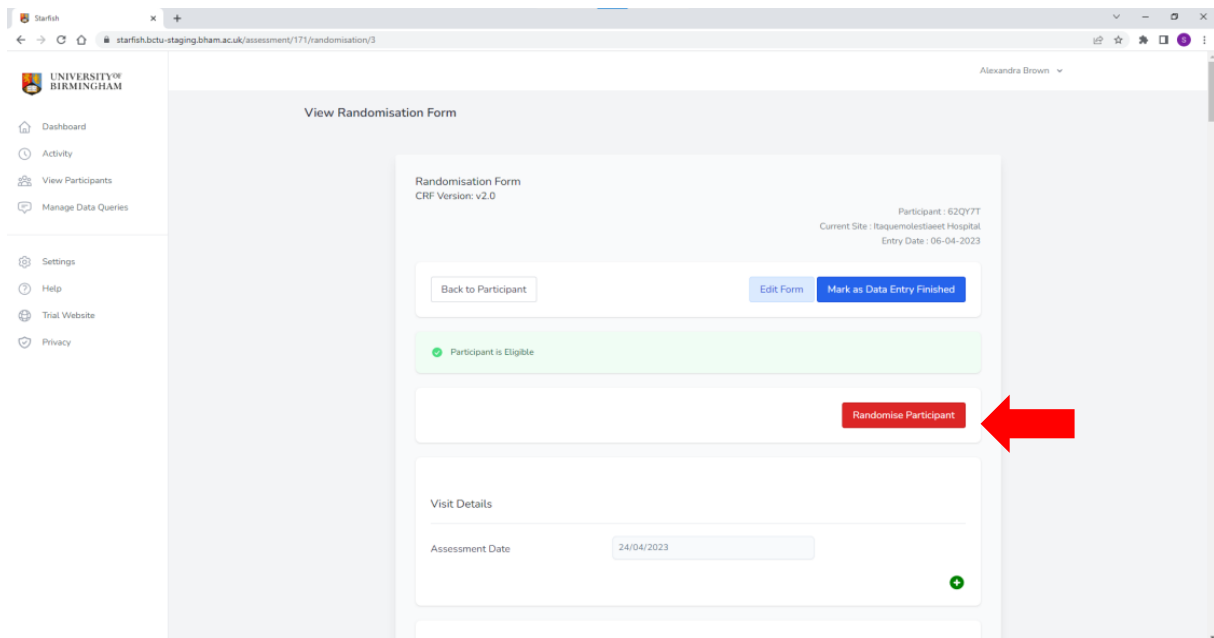
### Randomisation Form

- From the Participant List select 'Add' next to the Randomisation assessment to start the randomisation process. The randomisation form will open and you can start the data entry process.

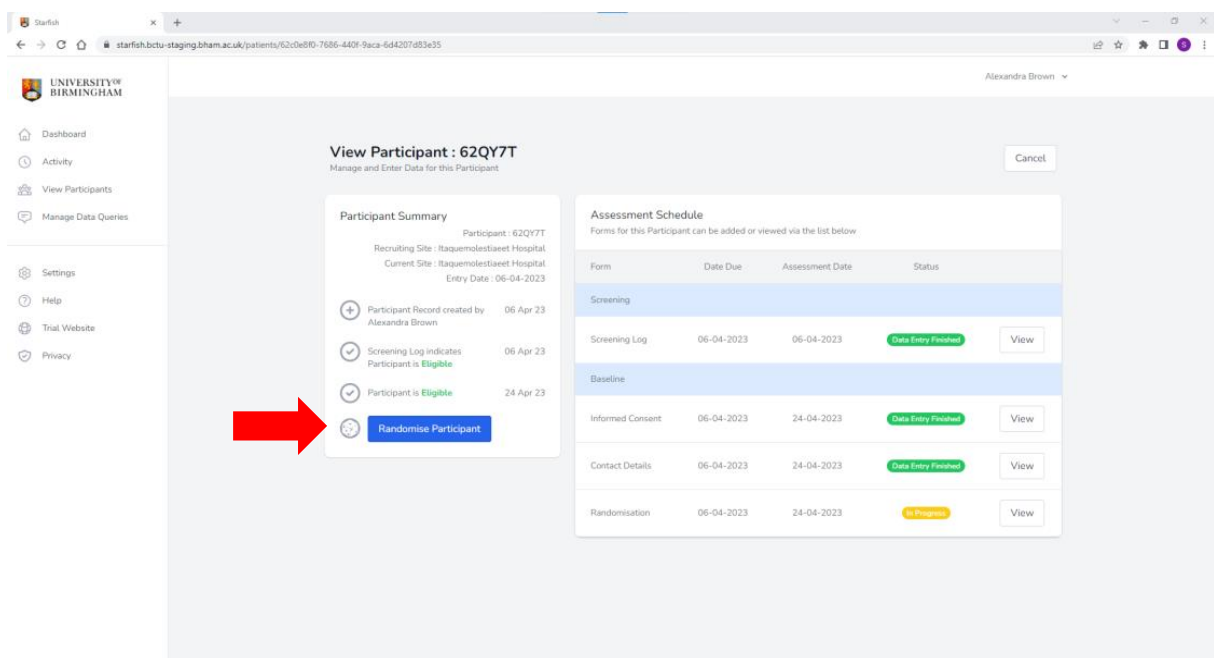
- Only people that have Informed Consent appropriately delegated will be listed in the 'Form Completed By & Sign Off' section. Please send a copy of your updated delegation log, along with a signed CV and GCP certificate to BCTU to add other clinicians to this list.
- As data is entered throughout the randomisation form, eligibility checks will be performed on certain fields to check the participant is eligible for the trial. Green text beneath selected fields will provide tips and indicate the checks being performed, as shown below:

## Randomising a Participant

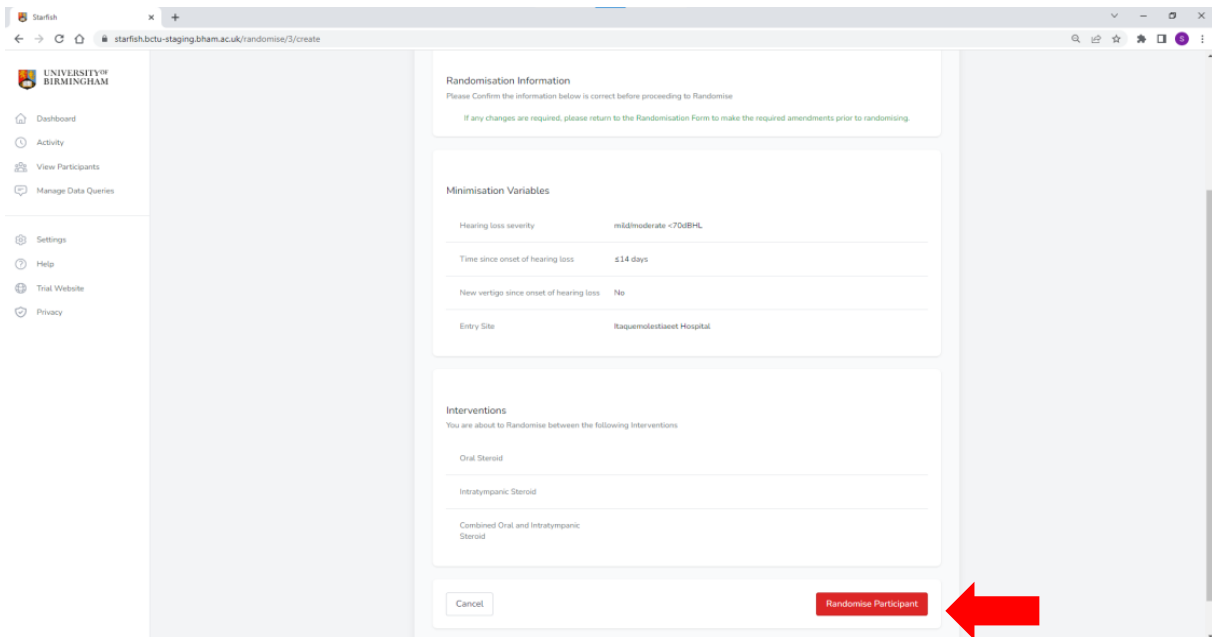
- When the data entry is complete and the randomisation form is submitted you will then be shown a red 'Randomise' button *at the top* of the randomisation form. As shown below:



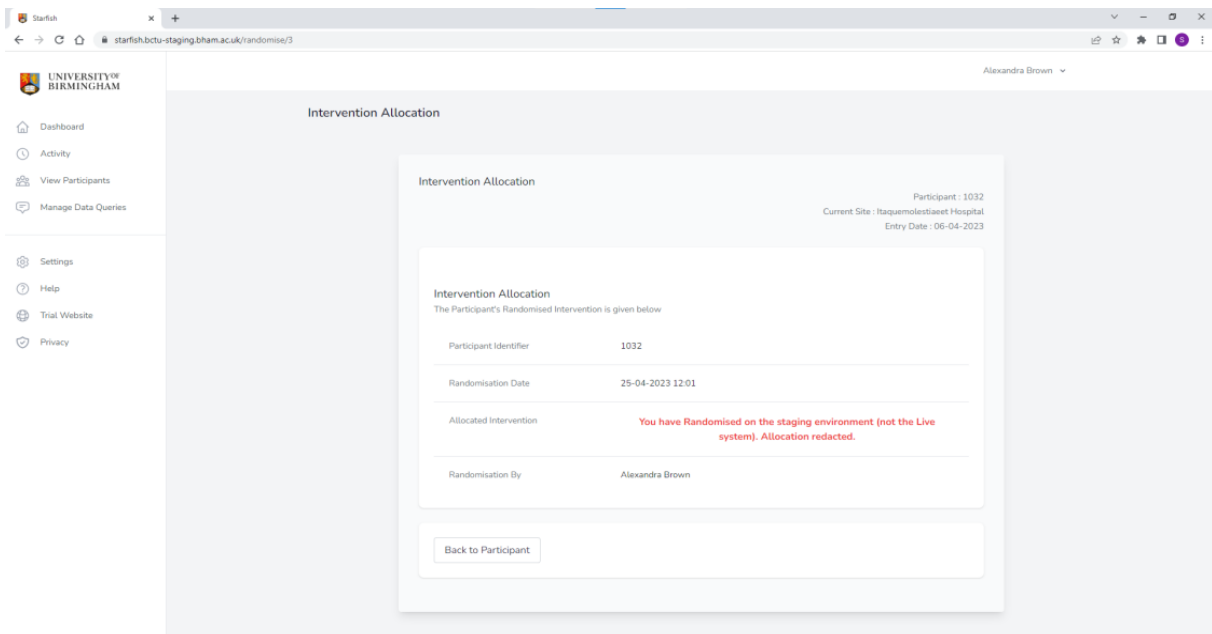
- You can also go back to the 'View Participant' page and find a randomise button on the left hand side.



- Once on the randomisation page, please confirm the information shown is correct. The three potential trial interventions are at the bottom of the page. Press the 'Randomise Participant' button to randomise the patient.



- Once randomised you will see the Participant Identifier Number, Randomisation Date, the Allocated Intervention and who randomised the participant.



The 'Allocation Intervention' field in the above image is what would be shown in the test database. On the live system this will show you the allocated treatment.



- After the randomisation process has begun, you will be able to add extra forms (e.g. Clinic visit). There will also be a 'Date Due' by each form showing when it should be completed by, in line with the Protocol visit schedule.

Form	Date Due	Assessment Date	Status
<b>Screening</b>			
Screening Log	06-04-2023	06-04-2023	Data Entry Finished
<b>Baseline</b>			
Informed Consent	06-04-2023	24-04-2023	Data Entry Finished
Contact Details	06-04-2023	24-04-2023	Data Entry Finished
Randomisation	06-04-2023		In Progress
Clinic Visit	25-04-2023		Add
Participant Completed Booklet	25-04-2023		
Perception of Hearing Loss	25-04-2023		
SSQ12	25-04-2023		

## Notes on Randomisation

You need to have completed the Screening Log, Informed Consent and Contact Details forms to be able to add and submit the Randomisation form. You can add the screening record as soon as you encounter a potential participant with suspected ISSNHL, even several days before the randomisation.

Following randomisation, an email will automatically be sent to the person randomising, the PI, and other named members of site staff. A notification will also be sent to the STARFISH Trial Office at BCTU. The confirmation e-mail will state the patient's details, trial number and trial treatment allocation. Please file this as evidence of the participant's treatment allocation.

You cannot go back once the patient has been randomised and the trial number is given, as the patient has been entered into the trial. If you realise that data has been entered incorrectly during randomisation, please contact the STARFISH trial office at BCTU ([STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk)).

## **Important General Information**

### Security

When using the STARFISH Online Database, all data that is sent over the Internet is encrypted. There should be no danger of anyone being able to intercept the information and use it. However, if anyone has your user name and password then they can use the system as you do. Please do not reveal your user name and password to anyone. Each person using the STARFISH Online Database

will have their own user name and password. Please contact the STARFISH Trials Office ([STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk)) if you have any difficulty in accessing the system.

### Web Browsers

The system is usable by the most common browsers: Google Chrome, Internet Explorer, Firefox and Opera. The database has been tested most extensively with Google Chrome but as far as we are aware the browsers listed above should be able to use the system. Please let us know about any compatibility issues you may have.

### **Questions or Problems**

If you have any problems please contact the Trials Team on 0121 415 9133 or email at [STARFISH@trials.bham.ac.uk](mailto:STARFISH@trials.bham.ac.uk).