# **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

#### Usernames 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:

Starfish
Dear Adam, You are receiving this email because you have been granted access to the Starfish Trial, and can now set up a Password for your account. Set New Password This set password link will expire in 24 hour(s). If you require a fresh link, please contact the Trial Team. Kind regards, Starfish Trial Team
If you're having trouble clicking the "Set New Password" button, copy and paste the URL below into your web browser: <u>https://starlish.bctu-staging.bham.ac.uk/reset-</u> password/?ebef704cb2a02aaeb3414f093847fe16c1d05e131c9f47cdc4e603516a0bbb72 email=STARFISH%40ftrials.bham.ac.uk
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- 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 <u>https://starfish.bctu.bham.ac.uk</u>
   (Please see: <u>Important General Information Web Browsers for more information</u>)
- Log in using your username and password.
- The log-in page will look like this:

## <u>Dashboard</u>

• 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 <u>STARFISH@trials.bham.ac.uk</u>. • 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).

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U DIMAINSCIPAN		Prondon Smith				Manage Account		
Dashboard	Verit	ed Account				Log Out	1	
( Activity								
🗠 User Management								
Site Management	Birmingham (	linical Trials Unit						
View Participants	Sta	fich						
C Manage Data Queries	Sta	11511						
Settings	An NIHR-fu	nded randomised controlled trial es	ploring hearing recovery with	1				
(2) Help	steroid treat	ments for idiopathic sudden senso	nneural nearing loss.					
Trial Website								
Privacy	Patients scree	ned Patients ran	ndomised Op	en data queries	Sites active			
	с Ш	ц Ш	()		0			
	Shortcuts							
	↔ Recruitme Enter a r	nt new Participant	<ul> <li>Trial Administration</li> <li>Add a new Researcher</li> </ul>	er	<ul> <li>Trial Administration</li> <li>Add a new Site</li> </ul>			
https://starfish.bctu.bham.ac.uk/user/profile								

• 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.

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$\leftarrow$ $\rightarrow$ C $\triangle$ $\stackrel{\text{\tiny B}}{}$ starfish.bctu-	staging.bham.ac.uk/user/profile		Ê	☆	*	🗆 🔇	:
UNIVERSITY OF BIRMINGHAM     Dashboard     Activity     View Participants     Manage Data Queries	Profile Information Update your account's profile information and email address.	First Name Alexandra Last Name Brown Email example@example.com					
<ul><li>Settings</li><li>Help</li></ul>			l	SAV	E		
<ul> <li>Trial Website</li> <li>Privacy</li> </ul>	Update Password Ensure your account is using a long, random password to stay secure.	Current Password           New Password           Confirm Password					
				SAV	E		

## Live/ Training Database

- You can access the STARFISH Training Database here: <a href="https://starfish.bctu-staging.bham.ac.uk/">https://starfish.bctu-staging.bham.ac.uk/</a>. 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: <u>https://starfish.bctu.bham.ac.uk</u>
- If you have any problems using or accessing the STARFISH Online Database then please get in contact with the STARFISH Trial team at <u>STARFISH@trials.bham.ac.uk</u>

#### 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.

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Dashboard	Participant List A list of all the Trial Participants wit	h Study Number and Site.		Add Participant
) Activity				
View Participants	STUDY MUMBER	CURDENT SITE	SMTDY DATE	
) Manage Data Queries	1016	Itaguemolestiaeet Hospital	29-03-2023	View
Settings	SZV3FZ	Itaquemolestiaeet Hospital	30-03-2023	View
Help	PYHCZR	Itaquemolestiaeet Hospital	30-03-2023	View
Trial Website	P6AGRE	Itaquemolestiaeet Hospital	04-04-2023	View
Privacy	62QY7T	Itaquemolestiaeet Hospital	06-04-2023	View
	1024	Itaquemolestiaeet Hospital	06-04-2023	View
	CARXXB	Itaquemolestiaeet Hospital	17-04-2023	View
/starfish.bctu-staging.bham.ac.uk/site-patients				

• 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:

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< → C △	) 🗎 starfish.bctu	-staging.bham.ac.uk/site-patients/create				남 ☆ 🛊 🛛 🌖 🗄
UNIVE BIRMI	RSITY <sup>OF</sup> NGHAM				Alexand	Ira Brown 🐱
🔓 Dashboard	ł	Add Participant				
() Activity						
😤 View Parti	cipants					
💬 Manage D	ata Queries		Create new Participant at Site:	Itaquemolestiaeet Hospital		
					Cancel Create	
Settings						
⑦ Help						
Trial Webs	site					
Privacy						

• 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.

Starfish × ← → C △ ê starfish.bctu-	+ -staging.bham.ac.uk/patients/3b811ced-	-5fbf-4803-b591-1bf2a39618f8						✓	- *	°	×
UNIVERSITY <sup>OF</sup> BIRMINGHAM							Alexandra Brown 👻				
Dashboard     Activity     View Participants		View Participant : ASKV5B Manage and Enter Data for this Participant					Cancel				
Manage Data Queries		Participant Summary Participant : ASKV58	Assessment Schedul Forms for this Participant c	e In be added or viewed v	ia the list below						
③ Settings		Recruiting Site : Itaquemolestiaeet Hospital Current Site : Itaquemolestiaeet Hospital Entry Date : 24-04-2023	Form	Date Due	Assessment Date	Status					
⑦ Help		Participant Record created by 24 Apr 23	Screening								
() Trial Website		Alexandra Brown	Screening Log	24-04-2023			Add				
Aumeda											

#### 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.

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UNIVERSITY® BIRMINGHAM				Adam David 🖌	
Dashboard	Participant List A list of all the Trial Participants with Stud	y Number and Site.		Add Participant	
C Activity					
😤 View Participants					
Manage Data Queries	STUDY NUMBER	CURRENT SITE	ENTRY DATE		
	1016	Itaquemolestiaeet Hospital	29-03-2023	View	
Settings	SZV3FZ	Itaquemolestiaeet Hospital	30-03-2023	View	
(7) Help	PYHCZR	Itaquemolestiaeet Hospital	30-03-2023	View	
Trial Website	PEAGRE	Itaquemolestiaeet Hospital	04-04-2023	View	
Privacy	62QY7T	Itaquemolestiaeet Hospital	06-04-2023	View	
	1024	Itaquemolestiaeet Hospital	06-04-2023	View	
	CARXXB	Itaquemolestiaeet Hospital	17-04-2023	View	
https://starfish.bctu-staging.bham.ac.uk/site-patients	0				

- 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:

Starfish x     ↔ C ☆ ≅ starfish.bctu-st	+ taging.bham.ac.uk/patients/3ec91c0c-71b	bb-42d2-a6de-3a5e201d15f1						Ŀ	~	v – ☆ \$1
UNIVERSITY <sup>®®</sup> BIRMINGHAM							Alexandra Brown 👻			
Dashboard     Activity     View Participants	N M	View Participant : 1016 Ianage and Enter Data for this Participant					Cancel			
Manage Data Queries		Participant Summary Participant : 1016	Assessment Schedule Forms for this Participant car	n be added or viewed via	the list below					
Settings		Current Site : Itaquemotestiaeet Hospital Current Site : Itaquemolestiaeet Hospital Entry Date : 29-03-2023	Form	Date Due	Assessment Date	Status				
<ul> <li>Help</li> <li>Trial Website</li> </ul>		Participant Record created by 29 Mar 23	Screening							
Privacy		Frank Moore     Screening Log indicates Participant is	Screening Log	29-03- 2023	30-03-2023	In Progress	View			
		Eligible     Participant is Eligible 30 Mar 23	Baseline							
		Participant Randomised 30 Mar 23     View Intervention Allocation	Informed Consent	29-03- 2023	30-03-2023	In Progress	View			
		V REVV INCELVENTION ALLOCATION	Contact Details	29-03- 2023	30-03-2023	Data Entry Finished	View			
			Randomisation	29-03- 2023	30-03-2023	In Progress	View			
			Clinic Visit	29-03- 2023	29-03-2023	In Progress	View			
			Participant Completed Booklet	29-03- 2023						
				29-03-						

• 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:

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← → C ☆ 🔒 starfish.bctu-sta	ging.bham.ac.uk/patients/3ec91c0c-71bb-42d2-a6de-3a5e201d15f1				<i>Ŀ</i> ? ☆	* 🗆 🌍	) i
			2023				^
UNIVERSITY <sup>OF</sup> BIRMINGHAM		ICECAP-A	29+03- 2023				
Dashboard		Injection2					
( Activity		Clinic Visit	05-04- 2023	Add			
View Participants				_			
Manage Data Queries		Injection3					
(i) Settings		Clinic Visit	12-04- 2023	Add			
(7) Help		Week6					
Trial Website		Clinic Visit	10-05- 2023	Add			
Privacy		Participant Completed Booklet	10-05- 2023				
		Perception of Hearing Loss	10-05- 2023				
		SSQ12	10-05- 2023				
		Vestibular Rehabilitation Benefit	10-05- 2023				
		Tinnitus Functional Index	10-05- 2023				
		Showing 1 to 20 of 36 results		< 1 2 >			

# 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.

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UNIVERSITY <sup>OF</sup> BIRMINGHAM	new participant recordence, ) and when participants of property .					Alexandra Brown 👻	E H	<i>x</i> u
Dashboard Activity	View Participant : 62QY7T Menage and Erter Data for this Participant					Cancel		
View Participants Manage Data Queries	Participant Summary Participant : 620Y7T	Assessment Sche Forms for this Particip	i <b>dule</b> ant can be added or v	lewed via the list below				
Settings	Recruiting Site : Itaquemolestiaeet Hospital Current Site : Itaquemolestiaeet Hospital Fntry Date : 06-04-2023	Form	Date Due	Assessment Date	Status			
Help	Participant Record created by 06 Apr 23	Screening						
Trial Website	Alexandra Brown	Screening Log	06-04-2023	06-04-2023	Data Entry Finished	View		
r mary	Participant is Eligible	Baseline						
		Informed Consent	06-04-2023	24-04-2023	Data Entry Finished	View		
		Contact Details	06-04-2023	24-04-2023	Data Entry Fasahed	View		
		Randomisation	06-04-2023			Add		
							1	

• 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.

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UNIVERSITY <sup>OF</sup>	-staging.bnam.ac.uk/assessment/170/contactDetails/3/edit			Al	iexandra Brown ↓	Î
Dashboard	Edit Contact Detail	s Form				
Activity     View Participants     Manage Data Queries		Contact Details Form CRF Version: v1.0		Participant : 62QY7T Current Site : Itaquemolestisaet Hospital Entry Date : 06-04-2023		
<ul> <li>Settings</li> <li>Help</li> <li>Trial Website</li> <li>Privacy</li> </ul>		Visit Details Assessment Date	dd/mm/yyyy	٥		
		Preferred means of contact regardi	ng participation in this study			
		Post E-mail	Please Select Please Select	× ×		
		Mobile	Please Select	v		

• 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:

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UNIVERSITY <sup>OF</sup>	aging onam, acue assessment / //u/contactuetaile/syleait			Alexandra Brown 👻	EY	* 1		Î
Dashboard	Edit Contact Details Form							l
Activity     View Participants     Manage Data Queries	Contact Details Fo CRF Version: v1.0	n	Participant : 6207 Current Site : Itaquemolocistianet Hosp Entry Date : 06-04-20	7T tal 23				
<ul> <li>Settings</li> <li>Help</li> <li>Trial Website</li> <li>Privary</li> </ul>	Visit Details							
Privacy	There is one or The mobile fiel	or on this page that you must fix before o	ontinuing.					
	Assessment Date	24/04/2023	٥					
	Preferred mean	of contact regarding participation in th	nis study					
	Post	No	~					
	E-mail	Yes	•					

• 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:

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$\leftrightarrow$ $\rightarrow$ $\mathbb{C}$ $\triangle$ $\stackrel{\text{\tiny B}}{=}$ starfish.bctu-	staging.bham.ac.uk/assessment/162/screeningLog/5	<i>Ŀ</i> ☆	*		) 1
UNIVERSITY <sup>OF</sup> BIRMINGHAM		Alexandr	a Bro	wn 🗸	ĺ
Dashboard	View Screening Log Form				
View Participants     Manage Data Queries	Screening Log Form CRF Version: v3.0	Participant : PYHCZR Lurrent Site : Itaquemolestiaeet Hospital			
<ul> <li>Settings</li> <li>Help</li> <li>Trial Website</li> </ul>	Back to Participant	Entry Date : 30-03-2023 Mark as Data Entry Finished			
Privacy	<ul> <li>Participant is Ineligible</li> <li>The selected age over eighteen is invalid.</li> <li>The selected new onset issnhl is invalid.</li> <li>The selected onset hearing loss is invalid.</li> </ul>				
	Section 1 - General				
	Assessment Date 27/04/2023				

#### 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.

→ C ① ■ starfish.bctu-staging.bham	.ac.uk/assessment/171/randomisation/create				* @ \$ * <b>0</b> ()
UNIVERSITY <sup>08</sup> BIRMINGHAM				Alexand	ra Brown 🐱
) Dashboard	Add Randomisation	Form			
) Activity					
View Participants		Randomisation Form			
Manage Data Queries	,	RF Version: v2.0		Participant : 62QY7T Current Site : Itaquemolostiaeet Hospital Entry Oate : 06-04-2023	
Settings					
Help					
Trial Website		Visit Details			
Privacy		Assessment Date	dd/mm/yyyy	•	
		Inclusion criteria			
		>=18 years old	Yes		
		Diagnosis of new-onset ISSNHL- sensorineural hearing loss of 30 decibes (dBHL) or greater over 3 contiguous pure-tone frequencies (out of 0.5, 1.0, 2.0, 4.0 kibhertz (kHz)] confirmed with a pure tone	Yes		

- 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:

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← → C ☆ 🗎 starfish.bctu	staging.bham.ac.uk/assessment/171/randomisation/create				<b>0</b> 7 년	\$ <b>\$</b>		
UNIVERSITY <sup>00</sup> BIRMINGHAM		Eligibility assessed by: Must be on SS&DL. Remember to document to and time of assessment, person performing a	Atexandra Brown v the assessment of eligibility in the patients medical ssessment, and the name of the trial.	notes. This should include the date				•
Dashboard     Activity								
C Manage Data Queries		Confirmation of selected eligibility of Year of birth provided on screening form: 199	criteria and minimisation variables					
Settings		Date of birth:	18/05/1999					
(?) Help		Must correspond to age ≥18 years						
<ul> <li>Trial Website</li> <li>Privacy</li> </ul>		Date this episode of ISSNHL first noticed: Within 4 weeks prior to randomisation. Used	21/04/2023	of hearing loss".				
		Time since onset of hearing loss:	≤14 days ∨					
		New vertigo since onset of hearing loss: Patient reported. Used to inform minimisation	No ~					
		Side of hearing loss:	Left ~					
		Please provide the data from the Pure Tone A	udiogram used to confirm ISSNHL					

#### **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:

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← → C ☆ 🗎 starfish.bctu-	staging.bham.ac.uk/assessment/171/randomisation/3					🖻 🖈 🖪 🌖 E
UNIVERSITY <sup>00</sup> BIRMINGHAM					Alexandra Brown 👻	Î
Dashboard	View Randomisat	tion Form				
<ul> <li>Activity</li> <li>View Participants</li> </ul>		Randomisation Form				
Manage Data Queries		CRP Version: V2.0		Participar Current Site : Itaquemolestiae Entry Date : 0	nt : 62QY7T eet Hospital 16-04-2023	
<ul> <li>Settings</li> <li>Help</li> <li>Trial Website</li> </ul>		Back to Participant		Edit Form Mark as Data Entry Finis	shed	
Privacy		Participant is Eligible				
				Randomise Partici	pant	
		Visit Details				
		Assessment Date	24/04/2023		0	

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

C Q isstarfish.bctu-staging.bham.ac.uk/p	atients/62c0e8f0-7686-440F-9aca-6d4207d83e35						ピ ☆	* 🗆 🚯
UNIVERSITY <sup>00</sup> BIRMINGHAM						Alexandra Brown 👻		
) Deshboard	View Participant : 62QY7T Manage and Enter Data for this Participant					Cancel		
View Participants Manage Data Queries	Participant Summary Participant : 620Y7T Bernition Site : Brancenolestiaet Homital	Assessment Sche Forms for this Particip	dule int can be added or vi	ewed via the list below				
Settings	Current Site : Itaquemolestiaeet Hospital Entry Date : 06–04–2023	Form	Date Due	Assessment Date	Status			
) Help	(+) Participant Record created by D6 Apr 23	Screening						
) Trial Website ) Privacy	Alexandra Brown Screening Log indicates 06 Apr 23	Screening Log	06-04-2023	06-04-2023	Data Entry Finished	View		
	Participant is Eligible 24 Apr 23	Baseline						
	Randomise Participant	Informed Consent	06-04-2023	24-04-2023	Data Entry Finished	View		
		Contact Details	06-04-2023	24-04-2023	Oata Entry Finished	View		
		Randomisation	06-04-2023	24-04-2023	(In Progress)	View		

• 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.

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← → C û 🔒 starfish.bctu-staging.bham.ac.uk/randomise/3/create		옥 순 ☆ 🛸 🖬 🌖 🗄
UNIVERSITY <sup>OF</sup> BIRMINGHAM	Randomisation Information Please Carifient the information below is correct before proceeding to Randomise	·
Dashboard	If any changes are required, please return to the Randomisation Form to make the required amendments prior to randomising.	
() Activity		
2 View Participants		
C Manage Data Queries	Minimisation Variables	
Settings	Hearing loss sevenity mild/moderate <70dBHL	
⑦ Help	Time since onset of hearing loss £14 days	
Trial Website	New vertigo since onset of hearing loss No	
Privacy		
	Entry Site Itaquemolestiaeet Hospital	
	Interventions	
	You are about to Randomise between the following interventions	
	Oral Steroid	
	Intratympanic Steroid	
	Combined Oral and Intratympanic	
	Steroid	
	Cancel Randomise Participant	
		-

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

<ul> <li></li></ul>	- ^
LINUKERSTING     Attended a Brown v       Deathboard     Intervention Allocation       Activity     Intervention Allocation       Yewy Participants     Intervention Allocation       Manage Data Dearies     Participants: 1032	<b>S</b> :
Intervention Allocation Deshboard De	
Activity     Wiew Participants     Intervention Allocation     Participant: 1032	
Current Site : Itaquemolectiaeet Hospital Entry Date : 06-04-2023	
Image: Imag	

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.



#### 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 (<u>STARFISH@trials.bham.ac.uk</u>).

# **Important General Information**

#### <u>Security</u>

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 (<u>STARFISH@trials.bham.ac.uk</u>) 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 <u>STARFISH@trials.bham.ac.uk</u>.