# PhEAST Working Practice Document 012
## Title: Randomisation

Patients who consent (individually, or by personal/professional legal representative) to participate in the trial will be randomised by a member of their local research team within **4 to 31 days** of stroke onset. Randomisation is done via bespoke, secure web-based system, maintained by the central Stroke Trials Unit in Nottingham.

Randomisation FAQs:

Q: What if we're unable to obtain certain data points?
A: Please click the 'M' symbol next to the question, and click not done or not known. If there is a not an 'M' symbol next to it, this information is required in order to proceed to randomisation

Q: Which forms need completing prior to randomisation?
A: Eligibility, Day 000, Day 000 Clinical and Day 000 EQ-5D-5L – please complete Day 000 cognition and Day 000 IQCODE as close as possible to randomisation (if incomplete this will not stop randomisation, but we like them to be done as close together as possible)

Q:Who can randomise?
A: Anyone who is delegated to do so on the log. Ensure it's not someone who will be completing blinded follow ups, as the randomisation result will blind them.

1. You will need to login into REDCap and then select the 'PhEAST' project. Once you're in PhEAST REDCap, head towards the column on the left-hand side of the page and select 'Add/Edit Records'
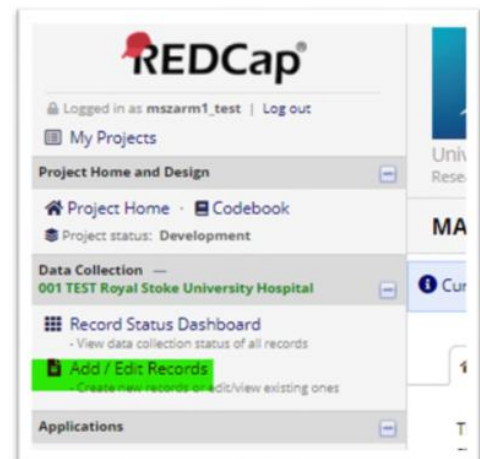


2. Then proceed to 'Add new record'.



3. In the new data entry, select 'Eligibility' and then complete this form.

## NEW Record ID C001-0015

| Data Collection Instrument | Status |
|---|---|
| Eligibility | ⊚ |
| Day 000 | ⊚ |
| Day 000 Clinical | ⊚ |
| Day 000 EQ-5D-5L | ⊚ |
| Day 000 Cognition | ⊚ |

📋 **Eligibility**

Adding new Record ID **C001-0015**

| Record ID | C001-0015 |
|---|---|

**Eligibility form**

**Trial Identifiers:**
Name: Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)
UK ISRCTN98886991
UK IRAS306761
UK CPMS 50913
AT national data registry *
WHO UTN U1111-1273-9942

**Participant initials (e.g. ABC or A-C)**
* must provide value
3 uppercase letters, or 2 separated by a hyphen (-)

**Age >=18 years? (Must be Yes to be eligible)**
* must provide value
○ Yes  ○ No
Choose one answer
reset

**Recent stroke between 4 and 31 days previously? (Must be Yes to be eligible)**
* must provide value
○ Yes  ○ No
Choose one answer
reset

**Clinical dysphagia defined as a functional oral intake scale (FOIS) score of 1 (nothing by mouth, feeding by NGT/PEG) or 2 (tube dependent with minimal attempts of food or liquids)? (Must be Yes to be eligible)**
* must provide value
○ Yes  ○ No
Choose one answer
reset

**Non-stroke dysphagia, e.g. due to traumatic brain haemorrhage, subarachnoid haemorrhage, brain tumour, Parkinson's disease, multiple sclerosis, severe dementia, head or neck cancer? (Must be No to be eligible)**
* must provide value
○ Yes  ○ No
Choose one answer
reset

**Pre-stroke dysphagia? (Must be No to be eligible)**
* must provide value
○ Yes  ○ No
Choose one answer
reset

4. Once complete, click 'Save & Exit Form'

**Assessor information**

| Please enter your name? | John Doe |
|---|---|
| * must provide value | Free text |

**What is your professional role?**
* must provide value
○ Doctor
○ Coordinator, research
○ Nurse, clinical
○ Nurse, research
○ Physiotherapist
○ Occupation therapist
○ Speech & Language therapist
● Other
Choose one answer
reset

**Does your role involve working on stroke wards?**
* must provide value
○ Yes  ● No
Choose one answer
reset

**Please sign the form**
* must provide value
〜 Add signature
Signature

**Form Status**

| Complete? | Complete ▾ |
|---|---|

Save & Exit Form    Save & Go To Next Form ▾

-- Cancel --

5.  Repeat steps 3-4 for 'Day 000', 'Day 000 Clinical' and 'Day 000 EQ-5D-5L' forms. Once all these 4 forms are complete on the picture you can move onto the next step.

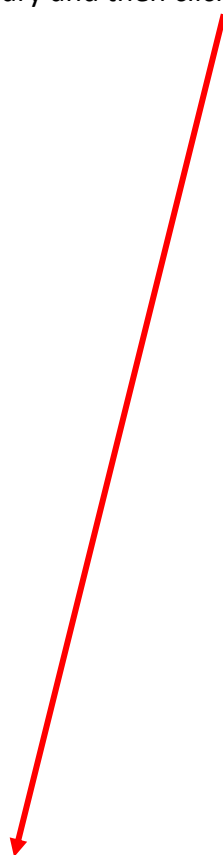Record ID **C001-0015** LKI
001 TEST Royal London Hospital

| Data Collection Instrument | Status |
|---|---|
| Eligibility | ● |
| Day 000 | ○ |
| Day 000 Clinical | ○ |
| Day 000 EQ-5D-5L | ○ |

6.  Head back towards the left-hand side of the page and click the 'Randomisation' link under 'Project Bookmarks'

**Project Bookmarks**

➡ Randomisation
➡ Supporting site
➡ Delegation log
➡ Trial documents

7.  Check the information in the randomisation summary and then click 'Randomise this participant'.

**PhEAST trial — DEVELOPMENT SITE**
**Pharyngeal Electrical Stimulation for Acute Stroke dysphagia Trial**

ISRCTN 98886991

Room S/D2108, Stroke Trials Unit
School of Medicine, University of Nottingham
Queen's Medical Centre, Derby Road
Nottingham NG7 2UH, United Kingdom
PhEAST trial office <mszlh@nottingham.ac.uk>

**TEST Royal London Hospital, London   Investigator: Athfi Mufied**

Log out

« Back to participant list

« Return to REDCap site

### PhEAST randomisation

| — Participant details — | |
|---|---|
| Participant ID: | **C001-0015** |
| Centre name: | **London, TEST Royal London Hospital, UK** |
| Initials: | **LKI** |
| Age: | **32 years old** |
| Sex: | **Female** |
| DSRS: | **5** |
| NIHSS: | **22** |
| Stroke type: | **Ischaemic stroke (IS)** |
| Circulation: | **Anterior** |
| Date stroke: | **14 Mar 2022** **(23 days ago)** |
| Date/time randomised: | - |
| Randomising investigator: | - |
| Days to randomisation: | - |
| Treatment group: | **Not randomised** |

[ Randomise this participant ]

8. Once complete, the following page should appear on your screen. Please click the link to get to the 'Success page'

**PhEAST trial — DEVELOPMENT SITE**
**Pharyngeal Electrical Stimulation for Acute Stroke dysphagia Trial**

ISRCTN 98886991

Room S/D2108, Stroke Trials Unit
School of Medicine, University of Nottingham
Queen's Medical Centre, Derby Road
Nottingham NG7 2UH, United Kingdom
PhEAST trial office <mszlh@nottingham.ac.uk>

**Redirect page**

**TEST Royal London Hospital, London   Investigator: Athfi Mufied**

Log out

« Back to start page

**Please click the following link to continue.**

- Success page

9. The next page should be displayed, which shows a summary of all of the participant's randomisation information. This shows:

- Participant's trial ID number
- The name of the randomising investigator
- Participant's their allocated treatment arm.

10. Click into the secure vault site to enter the participant's contact details, which will be required for follow-up.

11. Identifiable data will be kept separately in the secure vault, whereas all other data will be kept in the REDCap database.