MAPS-2

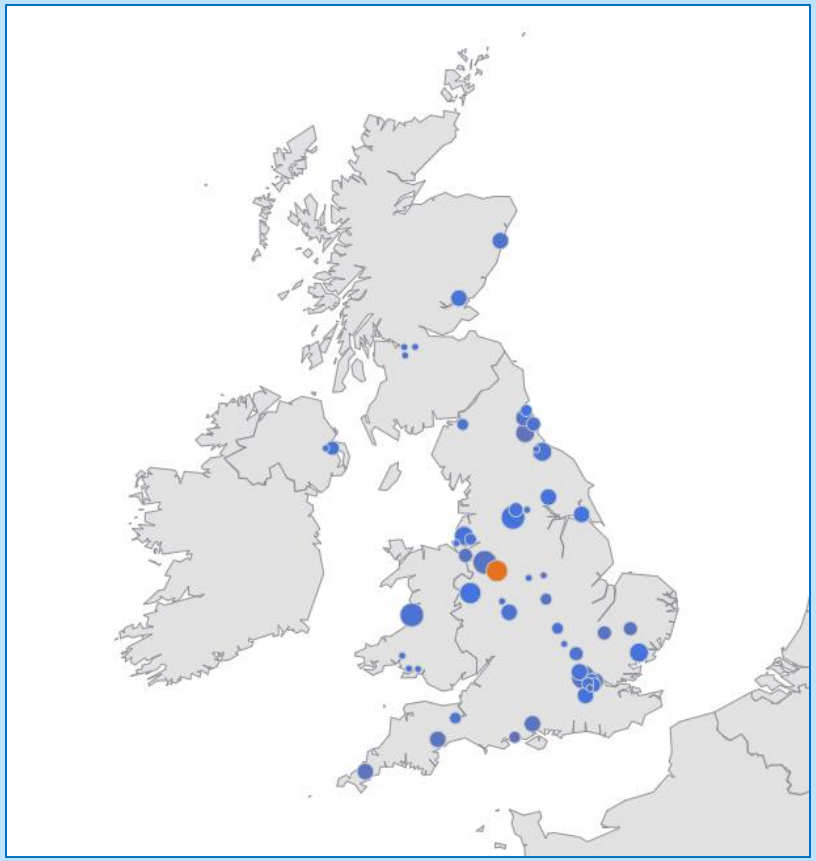
The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) Trial:

Investigator meeting (15)
24th September 2024

University of Nottingham
UK | CHINA | MALAYSIA

MAPS-2

Recruitment targets and status



Target participant number	= 2100
Current enrolment number	= 992
Completed follow up at 6 months	= 663
No. of recruiting sites open	= 68
No. of repatriation sites open	= 8

Still looking for new sites both recruiting and repat!

Welcome New Site – Manchester Trafford

MAPS-2

Extended recruitment end date – Oct 2026

August 2024 Recruitment

Top Recruiters

5	Hull Royal Infirmary
4	Wolverhampton (New Cross Hospital)
3	Kirkcaldy (Victoria Hospital)
3	Portadown (Craigavon)

49 Recruits in August 2024

September 2024 Recruitment

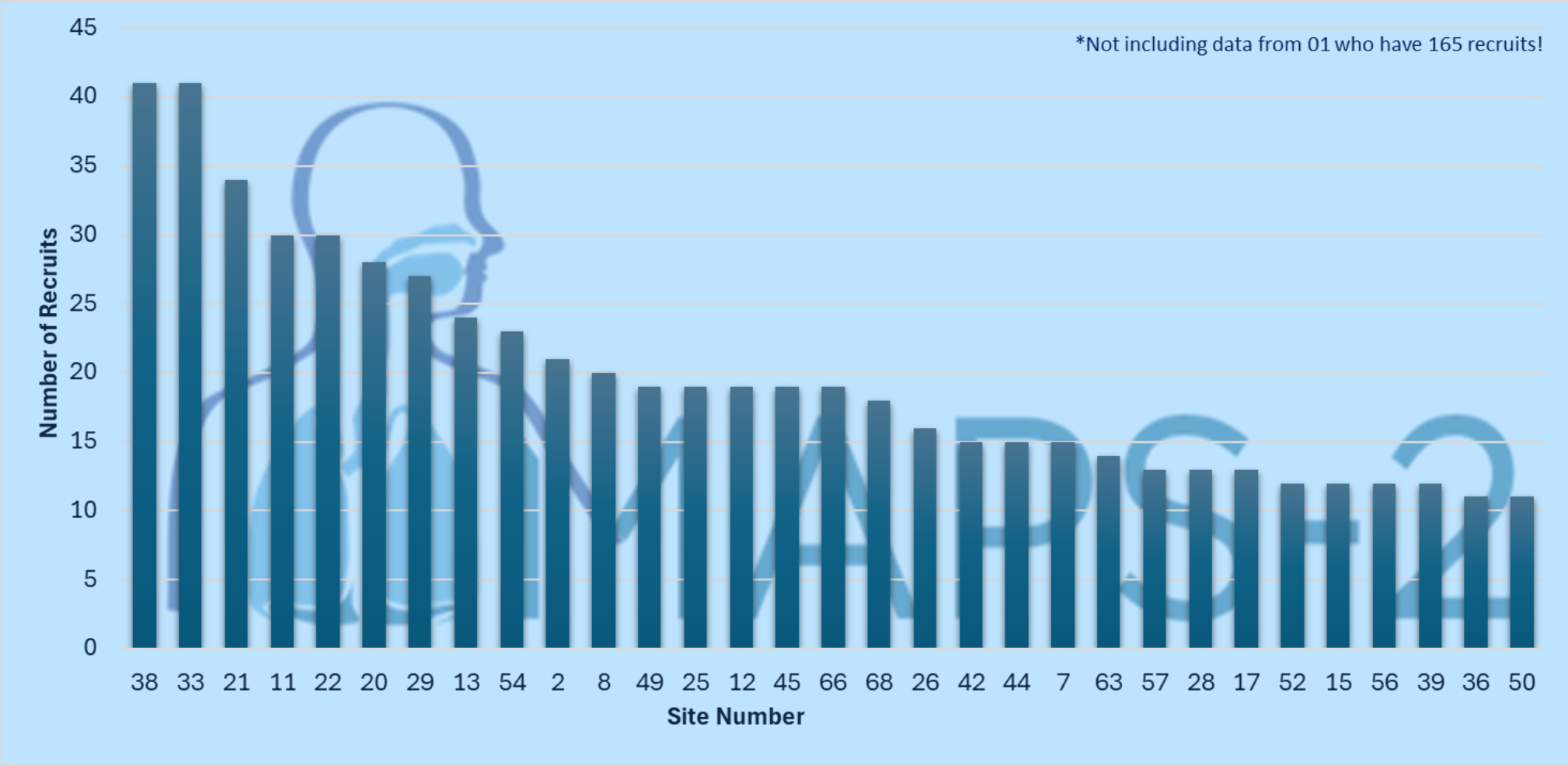
Top 5 Recruiters (so far!)

5	Hull Royal Infirmary
4	Stoke on Trent
4	Harrow (Northwick Park Hospital)
2	Belfast (Royal Victoria Hospital)
2	Derby

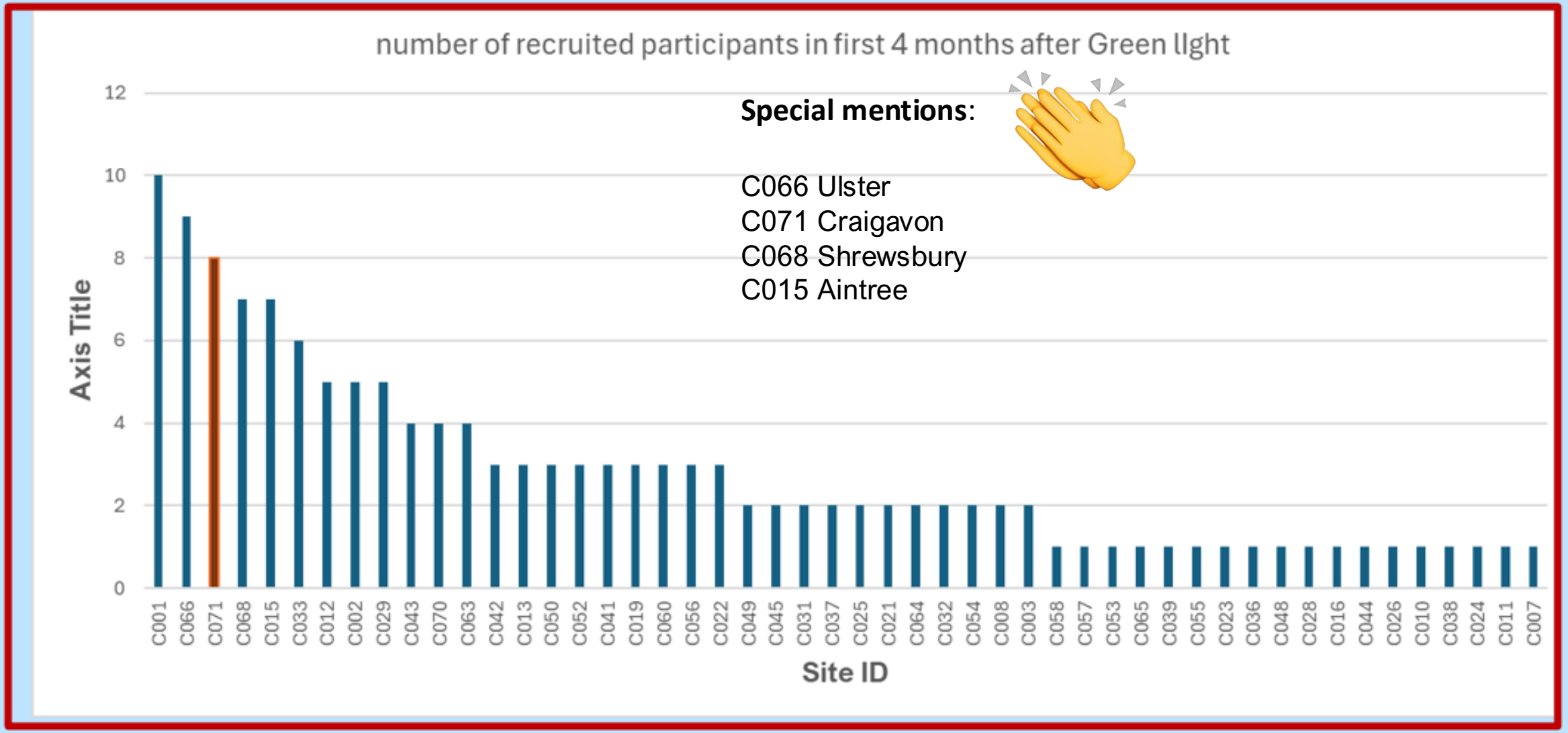
28 Recruits and counting!

Could **YOU** be the one to get us to

Sites with >10 Recruits



Number of recruits within 4 months after GL



SA03 – 1. Safety Reporting

- **Pneumonia** and **death due to presenting stroke** are trial outcomes and are not reportable as SAEs.

  They have separate CRFs: Pneumonia Diagnosis CRF; Vital status-Death Notification CRF

- **Adverse events that are either expected as part of the stroke condition (Appendix 3) or known side effects of the IMP (Appendix 1) do not need to be expedited as Serious Adverse Events.**
  These will be recorded in the patients' notes.

- Defined adverse events (**S**afety **E**ndpoint **o**f **I**nterest) will continue to be summarised as AEs on section C of the Day14/discharge follow up CRF where you will be prompted to complete more details in the Safety Endpoint of Interest CRF. These data will be monitored by the DMC and TSC.

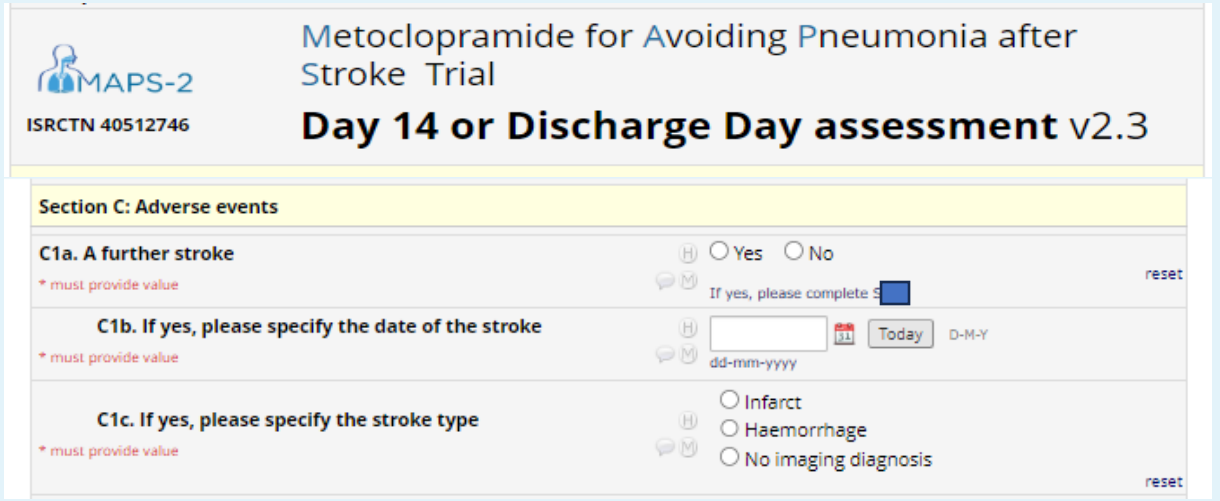
- A new SAE/Safety Reporting WPD will be uploaded to our documents page.

SA03 – 1. Examples

- Defined adverse events (**S**afety **E**ndpoint **o**f **I**nterest) will continue to be summarised as AEs on section C of the Day14/discharge follow up CRF where you will be prompted to complete more details in the Safety Endpoint of Interest CRF.
  These data will be monitored by the DMC and TSC.

Example:

  - **Epileptic seizure after ICH. This does not need to be reported as an SAE.**
    Report as event of special interest.



MAPS-2
ISRCTN 40512746

Metoclopramide for Avoiding Pneumonia after Stroke Trial

Day 14 or Discharge Day assessment v2.3

Section C: Adverse events

C1a. A further stroke * must provide value	○ Yes ○ No reset If yes, please complete S
C1b. If yes, please specify the date of the stroke * must provide value	Today D-M-Y dd-mm-yyyy
C1c. If yes, please specify the stroke type * must provide value	○ Infarct ○ Haemorrhage ○ No imaging diagnosis reset

Safety endpoints

These will be recorded at the end of treatment (14 days) and include:
Stroke Recurrence
Cardiorespiratory arrest requiring resuscitation
Severe bradycardia requiring atropine or pacemaker insertion
Definite epileptic seizure (focal or general)
Oculogyric crises
Tardive dyskinesia
A new diagnosis of Parkinson's disease
Adverse events
Discontinuations due to adverse events

SA03 – 1. Examples – NOT SAE

- **Pulmonary embolism** - listed in Appendix 3 so will be recorded in the medical notes
  NOT REPORTABLE, NOT AN SAE

- **Death due to deterioration of presenting stroke** – NOT AN SAE
  Please record Notification of Death CRF

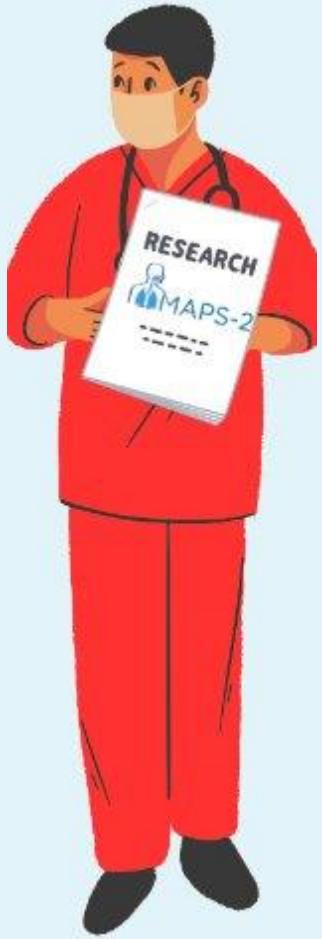
APPENDIX 3: Expected Stroke Symptoms and Complications

- Pneumonia: complete the Pneumonia Diagnosis form
- Death due to the presenting stroke or its complications: complete a Notification of Death form

***All other expected stroke symptoms and complications* to be recorded in patient notes but not subject to expedited reporting**
These events are aspects of the original qualifying disease and do not constitute adverse events.

- Stroke symptoms (reduced level of consciousness, confusion, hemianopia, double vision, facial paresis, other cranial nerve palsies, hemiparesis, hemi sensory loss, ataxia, incoordination, speech problems, dysarthria, hemi inattention, dysphagia
- Extension of the initial stroke
- Haemorrhagic transformation of the stroke
- Malignant cerebral oedema
- Venous thromboembolism
- Atrial fibrillation
- Carotid artery stenosis
- Decubitus ulcer
- Shoulder pain
- Other musculoskeletal pains
- Urinary incontinence
- Urinary retention

SA03 – 2. Co-enrolment



- Co-enrolment with observational studies is encouraged BUT must still be authorised by the Chief Investigator.
- There are current CTIMPS that are investigating trial treatments, that if accepted into clinical practice, will be used together.

  Therefore, co-enrolment with such CTIMPS, even if not sponsored by University of Nottingham, will be considered.

HOWEVER

- UoN Sponsor templated assessment needs to be completed for both trials.
- An agreement signed by both the CI's and both Sponsors **prior to co-enrolment.**

Reminder - REDCap® Accounts

- Your REDCap account is valid for **1 year** as per the University of Nottingham Sponsor Policy.
- You will automatically receive an email notifying you when your account is approaching expiry.

Subject heading **[REDCap] xxxxx's account will expire in 14 days (University of Nottingham)**
[This message was automatically generated by REDCap]

Dear REDCap user,

This email is to inform you that your REDCap account with username "user id" (**User's name**) will expire on **Friday, June 21, 2024 (4:46 PM)**. Your account has been set to expire because it meets the criteria set forth by your organizational policy. At the time of expiration, your account will be suspended, after which you will no longer be able to log in to REDCap at https://cdss.nottingham.ac.uk/redcap/ using that user account until the access is restored at the request of the Sponsor. Your projects or data will not be lost. Please reply to this email and request the account extension, and our team will contact you shortly to verify additional details. Thank you!

- **Failure to acknowledge this email will lead to your account being deactivated.**

Please reply to any of the automated emails to confirm that your account is still in use to - daniel.simpkins@nottingham.ac.uk

Finance payments delay – new system UNICORE

- The UoN is moving all HR and Payment systems to a new platform called Unicore.
- There will be a period where **no transactions** can be made:

16th October – 20th November

Open Discussion