



STOPPIT-3 & STOPPIT-M NEWSLETTER

M

October 2023



HELLO!

We hope everyone has had a fantastic summer!

Recruitment total is now **32!** We had **4 recruits in September**, which means June 2023 is still our best month with 5 total recruits.

We now have **20 sites** open! A big welcome to our new sites **Princess Royal Maternity Hospital, Queen Elizabeth University Hospital**, both in Glasgow, and to **University Hospitals Coventry and Warwickshire NHS Trust!** See page 2 for a proper introduction.



Photo from Unsplash stock images



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DATES FOR THE DIARY



Tuesday, 10th October at 16:30 STOPPIT-3 PI Meetings

These new monthly meetings will be a chance for STOPPIT-3 PIs to speak to the STOPPIT-3 Chief Investigator Team (Professor Sarah Stock and Dr Sarah Murray). Although aimed at PIs, other members of the research team are welcome to attend.

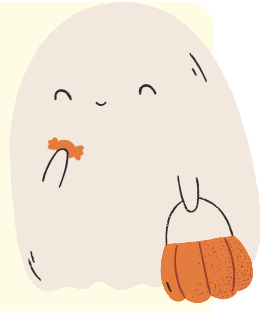
Thursday, 26th October 2023 at 12.30pm Monthly Drop-In Chat

Our monthly drop in chats are relaxed online Teams meetings where you can raise any questions, and teams can share recruitment tips.

SEPTEMBER RECRUITMENT SHOUT-OUT!

We had 4 new recruits to STOPPIT-3 in September! A big thank you to:

- **Musgrove Park Hospital, Somerset** team who had their first two recruits!
- **Sunderland Royal Hospital** team
- **Royal Infirmary of Edinburgh** team.



A WARM WELCOME TO THE NEW STOPPIT-3 SITES

A big welcome to:

- **Princess Royal Maternity Hospital, Glasgow** team - Dr Dawn Kernaghan (PI), Dr Amy Sinclair (Associate PI), Dr Rachel Bradnock (Investigator), Michele Shaw (Senior Research MW), Isobel Crawford (Research MW) and Catherine Clayton (Research Nurse)
- **Queen Elizabeth University Hospital, Glasgow** team - Dr Marie Anne Ledingham (PI), Kirsteen Paterson, Siobhan Moore, Therese McSorley (Research Midwives), Laura Dempster (Research Nurse) and Ann Marie Jordan (CTA).
- **University Hospitals Coventry and Warwickshire NHS Trust, Coventry** team - Miss Soma Mukherjee (PI), Midwifery Sister Joanna Clark, Jane Hillen, Lyndsey Prue and Gemma Suddick (Research Midwives).



Photo from Unsplash stock photos



SAE REPORTING

A brief reminder on reporting SAEs – full details can be found in the current STOPPIT-3 protocol, V7, Section 11.

When reporting an SAE:

- Please give as much information about SAEs as you can so that the QA team are clear about the event.
- As soon as you are aware of an SAE, for example, a major antepartum or postpartum haemorrhage (>1500 mL), this must be reported to ACCORD via QA@accord.scot within 24 hours. The database should prompt you if you tick 'Yes' in the SAE box. If in doubt, contact the Trial Team.
- There is a separate ACCORD form to complete as well as the REDCap database form. Currently this is CR005-T01 CTIMP SAE Form v5.0 and can be found on the ACCORD website.

Adverse Events

Assign record to a Data Access Group? -- select a group --

Adding new 34. (Instance #1)

Event: Adverse Events

34

This AE applies to: Mother

Adverse Event: Other

If other, please describe adverse event: PPH >1,500ml

Start Date: 02-10-2023 Today D-M-Y

SAE: Yes

Please report this event following the sponsor safety reporting procedures described in ACCORD SOP CR005

REDCap SAE Reporting Form

accord NHS Lothian
Academic and Clinical Central Office for Research and Development

SERIOUS ADVERSE EVENT (SAE) FORM

Clinical Trial of Investigational Medicinal Product (CTIMP)

TO BE COMPLETED BY ACCORD

Date received by ACCORD:	Time Received by ACCORD:
Date acknowledged by ACCORD:	Acknowledged by:
Report Stage: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Final	

GUIDANCE FOR THE PERSON COMPLETING THIS FORM

- Forms must be submitted to ACCORD **within 24 hours** of the site research team becoming aware of the SAE.
- Do not include** personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form.
- Do not include any supplementary information or documents unless requested by ACCORD.
- Complete the form as far as possible. The form can be updated/changed and re-submitted as new information becomes available.
- Any updates should be added to the original form - **DO NOT** create a new form for each update to this SAE.
- Forms must be submitted via one of the following routes:
 - Emailed as a PDF to safety@accord.scot (S) In person to the ACCORD Pharmacovigilance Team (S) Faxed to +44 (0)131 242 3447

ACCORD CR005-T01 CTIMP SAE Form v5.0



Recruitment Update – September 2023



Recruiting Team

	Total Recruits	Recruits this month
NHS Lothian, Edinburgh Royal Infirmary & St John's Hospital Livingstone	9	1
The Mid Yorkshire Trust, Pinderfields Hospital	7	
Bradford Teaching Hospitals NHS Foundation Trust, Bradford Royal Infirmary	4	
South Tees NHS Foundation Trust, The James Cook University Hospital	3	
Ninewells Hospital, Dundee	2	
 Somerset Foundation Trust, Musgrove Park Hospital, Taunton 	2	2
South Tyneside & Sunderland NHS FT, Sunderland Royal Hospital	2	1
Chesterfield Royal Hospital NHS Foundation Trust	1	
Royal Bolton Hospital. Bolton	1	
Royal Devon University Healthcare NHS FT, Royal Devon & Exeter Hospital	1	
Total	32	4

Recruitment Shout Outs!

Special mention to Somerset Foundation Trust, Musgrove Park Hospital who recruited the

30th

STOPPIT-3 participant! Thank you to Research Nurse Tessa Dean, PI Dr Katarina Harrison-Tvorozkova, Emma Robjohns and Mark Verdant (Clinical Trials Administration & Support). This was also their first recruit... and they had a total recruitment of two in September!

STOPPIT-3 and STOPPIT-M Sites

Birmingham Heartland's Hospital

Bradford Teaching Hospitals NHS Foundation Trust, Bradford Royal Infirmary

Chesterfield Royal Hospital NHS Foundation Trust

East Lancashire NHS Trust, Royal Blackburn and Burnley Hospitals

Leeds St James' Hospital

Liverpool Women's Hospital

The Mid Yorkshire Trust, Pinderfields Hospital

NHS Lothian, Edinburgh Royal Infirmary & St John's Hospital Livingstone

Ninewells Hospital, Dundee

North Lincolnshire & Goole NHS Foundation Trust

North Tyneside General Hospital, Northumbria Healthcare NHS FT

Princess Royal Maternity Hospital, Glasgow

Queen Elizabeth University Hospital, Glasgow

Royal Bolton Hospital. Bolton

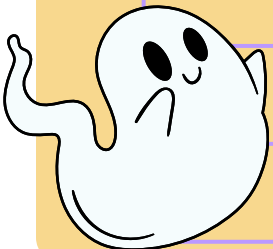
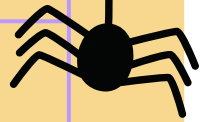
Royal Devon University Healthcare NHS FT, Royal Devon & Exeter Hospital

Somerset Foundation Trust, Musgrove Park Hospital, Taunton

South Tees NHS Foundation Trust, The James Cook University Hospital

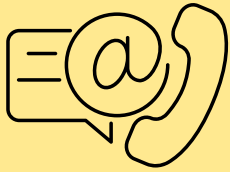
South Tyneside & Sunderland NHS FT, Sunderland Royal Hospital

University Hospitals Coventry and Warwickshire NHS Trust

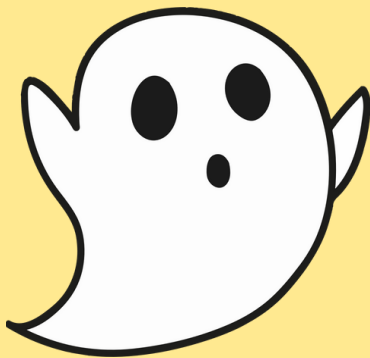




October 2023



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