

Recruitment Figures

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1 Introduction

- 1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).
- 1.2 The Chief Scientist Office (CSO) provides NHS Research Scotland (NRS) funding to NHSL based on the number of research projects undertaken and the number of study participants recruited. The upload of robust monthly study recruitment figures to the Scottish Research Data Application System (SReDa) is essential to ensure that NRS funding allocations accurately reflect activity levels.
- 1.3 For all commercial and non-commercial NRS eligibly funded studies actively recruiting within NHS Lothian the local study team must report monthly recruitment figures for all study locations (i.e., hospitals/ GP surgeries) within NHS Lothian to ACCORD.
- 1.4 Lothian recruitment data is collated from local researchers and the CRF via excel spreadsheet or from a bulk upload from EDGE, a cloud-based research management system used by many research teams to track patient activity. Within Scotland SReDa is linked to the NIHR Central Portfolio Management System (CPMS) to allow automated recruitment data upload to CPMS. Scottish Health Boards are responsible for capturing recruitment information on a monthly basis from all non-commercial and commercial portfolio studies which are active within their Health Board area. This includes both studies led by and hosted by the Board.
- 1.5 There is a confirmation step within CPMS allowing the data flowing into CPMS to be validated by the CI or a nominated representative of the study. The CI or a named representative will now be responsible for confirming the data entered onto CPMS.
- 1.6 Studies considered exemption studies (e.g., manual research upload studies) will continue to upload recruitment directly to CPMS. These are studies where the recruitment information is known at one site only in a multisite study, for example a questionnaire study where the sites provide the questionnaire, but the completed questionnaire is returned directly to a main centre for counting. Exemption studies are not required to confirm the recruitment information on CPMS.

- 1.7 Studies which collect tissue/data only, without any associated research question and without seeking consent from patients, should not be included in the return to the CSO. Where a study collects tissue/data, answers a research question and consents patients to take part in the study, it can be included.

2 Purpose

- 2.1 To describe the procedures for notifying ACCORD of monthly recruitment figures thus ensuring complete and accurate reporting to the CSO.

3 Scope

- 3.1 This Standard Operating Procedure (SOP) applies to all investigators responsible for reporting recruitment figures for commercial and non-commercial studies which are actively recruiting in NHS Lothian
- 3.2 This SOP also applies to ACCORD personnel who are responsible for collating and uploading recruitment data.

4 Responsibilities

- 4.1 It is the responsibility of the Investigator or designee, to report monthly recruitment figures for all study locations (i.e., hospitals/ GP surgeries) within NHS Lothian to ACCORD via the R&D Recruitment Mailbox (R&DRecruitmentUploads@nhslothian.scot.nhs.uk), or upload into EDGE, or in the case of exemption studies manually upload recruitment data for all study sites across the UK to the NIHR CPMS.
- 4.2 It is the responsibility of the Project Information Manager, (PIM) or designee, to:
- Create a new study record for most NHS Lothian /University of Edinburgh led non-commercial eligibly funded or extended review (adopted) studies on the NIHR CPMS.
 - Add the CPMS ID to the Scottish Research Database Application (SReDA).
 - Provide the Chief Investigator and their research teams (if applicable) with the NIHR documents regarding access and navigation.
 - Once recruitment starts in the first site of a Lothian led study it is the responsibility of the PIM or designee to provide the latest NIHR & NRS CMT guidelines with regards to the confirmation of recruitment activity in CPMS.
- 4.3 The NRS Portfolio Administration Officer, or designee, is responsible for;
- Tracking and collating recruitment figures via the R&D Recruitment Mailbox (R&DRecruitmentUploads@nhslothian.scot.nhs.uk), EDGE database, CRF Manager, or by contacting the study teams.
 - Ensuring recruitment figures are accurate and up to date

- Tracking and uploading Regulatory Green Light/ Current Target Recruitment End (CTRE) dates.
- 4.4 The ACCORD Administration team is responsible for;
- Contacting study teams at the start of the study for their Regulatory Green Light (RGL) date and Current Target Recruitment End (CTRE) date.
 - Contacting study teams at the end of the study for their accurate study end date and recruitment end date if status still active.
- 4.5 It is the responsibility of key R&D personnel, including but not limited to, the Deputy R&D Director, the Principal R&D Manager, the Head of Research Governance (NHSL), the Champion Support Manager and the NRS Portfolio Performance Manager to review data quality reports provided by NRS CMT to determine any key trends as well liaise with relevant teams within R&D to agree on an action plan as and when required.
- 4.6 It is the responsibility of the NRS Generic Review Manager to call a meeting to discuss, plan and finalise submissions for Research Activity and Expenditure (RAE) reports in line with the CSO reporting schedule.
- 4.7 The ACCORD Clinical Trials Monitor (where applicable) is responsible for providing training on the reporting of recruitment figures at Site Initiation Visits (SIV) to study teams for studies Sponsored by NHSL/UoE and subject to a combined risk assessment (GS002).

5 Procedure

5.1 Study Start-Up

- 5.1.1 Recruitment is the enrolment of an individual person meeting specific inclusion criteria into a research study. Each study participant who has both provided informed consent to join a study and is taking part in the study (i.e. participants who count towards the sample size of the study as set out in the study protocol), should be recorded as a participant (<https://www.nihr.ac.uk/nihr-crn-recruitment-policy-document> V2.2 July 2023).
- 5.1.2 Prior to a research site commencing recruitment the Sponsor must ensure that all equipment (e.g., lab kits, drug supplies) and necessary documentation (e.g. approvals, contracts) are in place. Once this process is complete, this is known as the Regulatory Green Light (RGL) date.
- 5.1.3 Once a study has received R&D Management Approval, the Administration team will contact the Principal Investigator (PI), or designee, to confirm the RGL and CTRE dates and upload this information on SReDA.

- 5.1.4 The NRS Portfolio Administration Officer, or designee, will review monthly reports from SReDA to identify missing information for example RGL dates, CTRE dates, PI information etc.
- 5.1.5 The PIM or designee will create a new study record on CPMS for all NHS Lothian non-commercial led studies, which are eligibly funded and seeking informed consent from participants. The Project Information Manager must contact the CI with guidance on how to review and update the study record on CPMS as well as provide training on the new confirmation step within CPMS. The PIM will review the NIHR Open Data Platform (ODP) monthly to ensure that the lead team is confirming the recruitment for all participating sites.
- 5.1.6 The PIM, or designee, will run reports on SReDA at least fortnightly to identify eligible and/or adopted studies which have not yet received a CPMS ID. For NHS Lothian hosted studies, the Project Information Manager, or designee, will update the Project ID on SReDA with the CPMS ID.
- 5.1.7 For studies subject to a combined risk assessment (GS002), The ACCORD Clinical Trials Monitor will inform teams of the requirement and the process for recruitment reporting at SIV (where applicable)

5.2 Ongoing Management of Studies

- 5.2.1 For all actively recruiting eligibly funded studies led by or hosted within NHS Lothian, the Principal Investigator, or designee (Research Activity Contact), must report recruitment including where no recruitment has taken place (i.e. zero) for all study locations (i.e. hospitals/ GP surgeries) within NHS Lothian to ACCORD via R&DRecruitmentUploads@nhslothian.scot.nhs.uk, or by directly uploading onto EDGE.
- 5.2.2 The NRS Portfolio Administration Officer, or designee, will receive monthly reports from the Clinical Research Facility (CRF) and EDGE highlighting recruitment data. The NRS Portfolio Administration Officer, or designee, will manually or bulk upload these figures into SREDA.
- 5.2.3 The NRS Portfolio Administration Officer, or designee, will review data on SReDA regularly to identify missing recruitment figures and follow up with study teams for these figures. If a response is not received from the Investigator, or designee, after three attempts of contact via email, telephone, the CI will be copied into the email communication. If this does not elicit a timely response, the NRS Portfolio Administration Officer, or designee, will escalate this to the NRS Portfolio Performance Manager for action/guidance.
- 5.2.4 The PIM is responsible for checking that the recruitment for non-commercial "Exemption" studies led by NHS Lothian is uploaded on a monthly basis directly to CPMS by the lead research team. The recruitment information will be reviewed on

ODP on a monthly basis to identify any missing data. The PIM will send email reminders to the lead study team requesting that recruitment is uploaded to CPMS.

5.3 End of Study

- 5.3.1 The administration team will create a monthly report to assess which active studies are past their proposed end date. The administration team will contact research teams to ensure the study end date and CTRE is accurately reflected in SReDA. The administration team will inform the NRS Portfolio Administration Officer, or designee, of any updates or extensions to study end dates.
- 5.3.2 The study team is responsible for informing the NRS Portfolio Administration Officer of the Recruitment End date for each study location (hospital, GP practice, etc.) where recruitment is taking place within NHS Lothian.
- 5.3.3 The PIM is responsible for updating the Recruitment End date and updating the Recruitment Status to 'No Longer Recruiting' by adding the 'Date of Status Change' on SReDA as well as updating the Project Status and Location Status.
- 5.3.4 For NHS Lothian led studies, the study team must confirm the Recruitment End date for all participating sites within the UK so that the study record on CPMS can be updated and the relevant Health Boards in Scotland informed. The Project Information Manager is responsible for updating the study record on CPMS with the correct study status and Study End date.
- 5.3.5 The study team is responsible for submitting necessary end of study documentation such as the End of Study Declaration Form and Final Report to accord@nhslothian.scot.nhs.uk so that the study record on SReDA can be updated.

5.4 Recruitment Data Report

- 5.4.1 RAG (red/amber/green) reports for all eligibly funded studies which have received R&D approval from any health board in Scotland are generated monthly by the NRS Central Management Team. These reports are shared with the portfolio and network performance managers as well R&D personnel who oversee recruitment for their boards.
- 5.4.2 RAG reports for Lothian studies are reviewed by key members of the R&D department at meetings, at least once a quarter, to determine if figures are accurate, on target and whether Investigators require any support from the department.

5.5 CSO Returns

- 5.5.1 The Project Information Manager, NRS Portfolio Performance Manager and NRS Portfolio Administration Officer will receive regular reports including the monthly RAG reports from the NRS Information Services Manager highlighting incomplete

and/or missing Minimum Dataset (MDS) data on SReDA. The Project Information Manager is responsible for coordinating R&D personnel to resolve any data discrepancies and provide regular updates to R&D Senior Management before the deadline set by NRS. MDS data can also be reviewed on Power BI (a metric reporting tool) by key R&D personnel. Any necessary changes must be made before the NRS Information Services Manager submits the final report to the CSO.

6 References and Related Documents




- [NIHR CPMS](#)
- [NIHR Open Data Platform \(ODP\)](#)
- [NIHR Clinical Research Network Recruitment Policy](#)
- [Temp Guidance for Boards CPMS-LPMS 11_04 version 1.docx.pdf \(nhsresearchscotland.org.uk\)](#)
- [Research Activity Confirmation Guidance \(PDF\).pdf \(nihr.ac.uk\)](#)
- [Manually Uploading Recruitment or No New Activity Data for Non-Commercial Studies \(nihr.ac.uk\)](#)
- [EDGE](#)
- [NHS Research Scotland Addition of Scottish Led Studies to CPMS](#)
- [Adoption of non-commercial Scottish-only studies](#)
- [Annex 2 NRS Eligible Funders List](#)
- NRS-GUI-003 ReDA 3 Minimum Dataset
- NRS-GUI-020 NRS ReDA – CPMS Recruitment User Guide
- GS002 Combined Risk Assessment

7 Document History

Version Number	Effective Date	Reason for Change
1.0	16 May 2017	New SOP
2.0	20 DEC 2018	Minor updates following ACCORD audit 77 (Recruitment Figures). Inclusion of details of non-commercial Nodal Reports and clarification on frequency of RAG meetings.
3.0	29 JUN 2021	Investigator responsibility to report recruitment figures to ACCORD added at 4.1. Project Information Manager post replaces Information and Knowledge Manager, with updated responsibilities. Additional information provided in Introduction. Updates to processes throughout. Updated references and links in section 6. Change of author.
4.0	29 JUN 2023	Introduction updates at 1.1 and 1.5, Section 5.1.5 further criteria regarding the creation of CPMS

		records, Updated 5.4.2 and 5.5. Updated reference list for broken links
5.0	01 OCT 2025	Sections 1.2, 4.1 and 5.2.1 updated, as now permitted to upload monthly recruitment figures onto the EDGE database. Minor changes at sections 1.2 and 4.3.

8 Approvals

Sign	Date
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