

PREPARING AND SUBMITTING PROGRESS AND SAFETY REPORTS

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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 It is a requirement of maintaining both Research Ethics Committee (REC) approval and a Clinical Trials Authorisation (CTA), that Development Safety Update Reports (DSURs) are submitted annually.

2 Purpose

- 2.1 To document the procedure for preparing and submitting DSURs. It also outlines in what instances they are applicable and who is responsible for their completion and dissemination to relevant parties.

3 Scope

- 3.1 This Standard Operating Procedure (SOP) applies to Chief Investigators (CIs), or designees, for all studies sponsored by NHSL and/or the UoE. The SOP also applies to ACCORD Research Governance staff and Pharmacovigilance Team.

4 Responsibilities

- 4.1 For studies that require a CTA, it is the responsibility of the CI to complete DSURs.
- 4.2 It is the responsibility of the Pharmacovigilance Officer, or designee, to identify and advise Investigators of annual due dates for DSURs, and to submit DSURs to the

appropriate REC and to the Competent Authorities (CA) and other third parties specified in agreements.

- 4.3 It is the responsibility of the Pharmacovigilance Manager, or designee, to review the DSUR prior to the submission to the CA and REC.

5 Procedure

5.1 Development Safety Update Reports (DSURs)

- 5.1.1 For all studies that require a CTA, a DSUR must be submitted. The Sponsor is responsible for submitting DSURs to the Competent Authorities (CA) and the REC that approved the study, and any other third parties as per agreements.
- 5.1.2 The report period to which each DSUR relates runs for one year, from the Development International Birth Date (DIBD, the first date of Clinical Trial Authorisation and the annual 'data lock point' for the study) up to, and including, the day before the DIBD in the next calendar year.
- 5.1.3 The Pharmacovigilance Officer or designee, will send DSUR reminders to the CI by email approximately 1 month before the last day of the reporting period.
- 5.1.4 Within 5 working days of the DIBD, the Pharmacovigilance Officer, or designee, will provide to the study team line listings of all Serious Adverse Events (SAEs) reported to the Sponsor. The listings will not include MedDRA coding at this stage. Where applicable, line listings will remain blinded and will not include unblinded details of treatment allocation.
- 5.1.5 The report will be prepared by the CI using the DSUR template (CR008-T01), unless otherwise agreed. Additional guidance on how to complete the DSUR can be found by visiting the [MHRA](https://www.mhra.gov.uk) website.
- 5.1.6 The draft DSUR should be forwarded to the Pharmacovigilance Manager, or designee, within 30 calendar days after the DIBD, for review. The Pharmacovigilance Manager, or designee, will review the DSUR and provide MedDRA coded SAE/SAR/SUSAR line listings and SAE summary tabulations from the ACCORD safety database, unless this task has been contracted to a third party.

- 5.1.7 For blinded studies, only a blinded DSUR should be sent to the CI or trial team for review. The Pharmacovigilance Officer, or designee, will ensure that any unblinded information is inserted into the report prior to the submission to the CA and REC.
- 5.1.8 Once final content has been agreed, the DSUR will be signed by the CI and returned to the Pharmacovigilance Manager, or designee. The CI should supply a signature, wet or electronic. The Pharmacovigilance Manager, or designee, will then enter the unblinded information into the DSUR when appropriate.
- 5.1.9 The DSUR should be submitted within 60 calendar days of the DIBD data lock point. Reports must be submitted every year until completion of the trial. If the study closes prior to the DSUR date and an end of trial notification has already been submitted, no DSUR need be submitted.
- 5.1.10 If a clinical trial has not started before the first anniversary of approval, no DSUR needs to be submitted. However, a covering letter signed by the CI must be submitted to safety@accord.scot clearly explaining the reasons why the trial has not started. This letter will be submitted to the CA and REC by the Pharmacovigilance Officer or designee, in lieu of a DSUR.
- 5.1.11 For studies that require a CTA lasting less than a year, a DSUR must be submitted with a Declaration of the End of Trial Notification Form within 90 days of the trial ending or within 15 days if the trial is stopped early.
- 5.1.12 Signed DSURs will be submitted to the CA, REC and other relevant parties, by the Pharmacovigilance Officer, or designee, as per PV002 (Sponsor Overview and Trend Analysis) and as per the study-specific requirements detailed in study protocols or agreements.
- 5.1.13 The Pharmacovigilance Officer or designee, will ensure that a copy of the DSUR and acknowledgements of receipt from the REC and CA are filed in the TMF and/or Sponsor File. Where a receipt or acknowledgement is expected, the Pharmacovigilance Officer, or designee, will follow up with the REC or CA if acknowledgement has not been received.

6 References and related documents


- EMEA, “Note for Guidance on Good Clinical Practice” (E6) R2, CPMP/ICH/135/95.
- MHRA : Clinical trials for medicines: manage your authorisation, report safety issues
- ICH E2F guidance

- The Medicines for Human Use (clinical trials) Regulations 2004.
- CR008-T01 DSUR Template
- PV002 Sponsor Overview and Trend Analysis

7 Document History

Version Number	Effective Date	Reason for Change
1.0	22 MAR 2011	DSUR requirements
2.0	14 SEPT 2011	Update of procedure
3.0	20 FEB 2014	Update of procedure
4.0	10 MAY 2017	Update of procedure to align with PV002. WI made obsolete. Creation of a DSUR template (CR008-T01) added.
5.0	07 JUN 2019	Minor administrative changes and clarifications throughout
6.0	03 FEB 2022	Change of author. Pharmacovigilance Manager replaces Research Governance Manager post. Minor administrative changes. Updates to references
7.0	15 FEB 2024	Pharmacovigilance Officer responsibilities added. Updates following the HRA website update concerning APR: addition of submission timeline in 5.1.2 and addition of point 5.1.3 about studies that require an APR. CR008-T01 updated to v2.0, to include cumulative total SARs reported
8.0	15 JUL 2024	Update of section 5.1: Following the HRA update for APR submission: APR are not required for studies that received their favourable ethics opinion from a REC in England or Wales.
9.0	24 SEP 2024	Removal of all mentions of Annual Progress Reports (APR) – Following HRA update effective on 01-Aug-2024 APR submission to the REC are not required anymore. SOP moved over to new SOP template.

8 Approvals

Sign	Date
<p><i>Camille Bach</i></p> <p>AUTHOR: Camille Bach, Pharmacovigilance Manager, UoE, ACCORD</p>	<p>Sep 16, 2024</p>
<p> Gavin Robertson (Sep 13, 2024 15:46 GMT+1)</p> <p>APPROVED: Gavin Robertson, QA Coordinator, NHSL, ACCORD</p>	<p>Sep 13, 2024</p>
<p><i>L. Mackenzie</i></p> <p>AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD</p>	<p>Sep 16, 2024</p>











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