Preparing and Submitting Progress and Safety Reports

DOCUMENT NO.:	CR008 v10.0
AUTHOR:	Camille Bach
ISSUE DATE:	17 FEB 2026
EFFECTIVE DATE:	28 APR 2026

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 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.

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 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 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 submission due 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 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 is not required. All safety information should be included in the Clinical Study Reporting.

5.1.12 Signed DSURs will be submitted to the CA 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 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 CA if acknowledgement has not been received.

5.1.14 For International studies: The procedure for reporting the DSURs to CAs and RECs will be included in any agreements between international groups performing the study.

6 References and related documents

- MHRA: Clinical trials for medicines: collection, verification, & reporting of safety events
- ICH E6 (R3): GUIDELINE FOR GOOD CLINICAL PRACTICE
- ICH E2F guidance

- The Medicines for Human Use (clinical trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.
- 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.
10.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). Removal of mention to submit DSUR to REC 5.1.5 update of the MHRA website link 5.1.11 No requirement to submit a DSUR for studies lasting less than 1 year.

		5.1.14 Addition of this paragraph for international studies. CR008 T01 updated: Addition of the ISRCTN number i Addition of the IRAS Trial ID Addition that attaching the IB/SPC is now mandatory in Appendix 1.

8 Approvals

Sign	Date
Camille Bach AUTHOR: Camille Bach, Pharmacovigilance Manager, UoE, ACCORD	13-Feb-2026
Sweta Rath APPROVED: Sweta Rath, Pharmacovigilance Officer, UoE, ACCORD	13-Feb-2026
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	13-Feb-2026

CR008 Preparing and Submitting Progress and Safety Reports v10.0

Final Audit Report 2026-02-13

Created:	2026-02-13 (Greenwich Mean Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAACc-6lvDxNjIBoIkaXaLPo9XRW9IFevg8

"CR008 Preparing and Submitting Progress and Safety Reports v10.0" History

Document created by Roisin Ellis (v1relli8@exseed.ed.ac.uk)
2026-02-13 - 12:04:30 PM GMT- IP address: 62.253.82.244

Document emailed to Camille Bach (Camille.Bach@ed.ac.uk) for signature
2026-02-13 - 12:06:38 PM GMT

Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2026-02-13 - 12:06:38 PM GMT

Document emailed to Sweta Rath (Sweta.Rath@ed.ac.uk) for signature
2026-02-13 - 12:06:38 PM GMT

Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2026-02-13 - 12:07:11 PM GMT- IP address: 52.102.18.37

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2026-02-13 - 12:07:22 PM GMT - Time Source: server- IP address: 62.253.82.242

Email viewed by Sweta Rath (Sweta.Rath@ed.ac.uk)
2026-02-13 - 12:22:43 PM GMT- IP address: 104.47.11.126

Document e-signed by Sweta Rath (Sweta.Rath@ed.ac.uk)
Signature Date: 2026-02-13 - 12:22:55 PM GMT - Time Source: server- IP address: 86.167.218.218

Email viewed by Camille Bach (Camille.Bach@ed.ac.uk)
2026-02-13 - 2:25:26 PM GMT- IP address: 104.47.11.62

Document e-signed by Camille Bach (Camille.Bach@ed.ac.uk)
Signature Date: 2026-02-13 - 2:25:42 PM GMT - Time Source: server- IP address: 81.109.241.151

Agreement completed.

2026-02-13 - 2:25:42 PM GMT