STANDARD OPERATING PROCEDURE FOR PREPARING AND SUBMITTING DEVELOPMENT SAFETY UPDATE REPORTS (DSUR) FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMP)

SOP NUMBER:	TASC SOP065 v2
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REVIEW DATE:	28 Sept 2025

1. PURPOSE

This SOP describes the procedure for preparing and submitting safety reports for Clinical Trials of Investigational Medicinal Products (CTIMP).
The report covered is:

Development Safety Update Report (DSUR)

From: Jointly from TASC and Chief Investigator (CI)
To: Medicines and Healthcare Products Regulatory Agency (MHRA) and Research Ethics Committee (REC)

2. SCOPE

This SOP applies to TASC staff members, investigators and research staff working on CTIMPs which are sponsored or co-sponsored by the University of Dundee and/or NHS Tayside.

3. RESPONSIBILITIES

This SOP complies with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004 and subsequent amendments.

TASC Pharmacovigilance (PV) Monitor on behalf of Sponsor is responsible for:

- Identification and advise to investigators of annual due dates for DSURs
- MedDRA coding of Serious Adverse Events (SAE) for DSURs.
- Completion of DSUR.
- Submission of DSUR to MHRA and REC, unless otherwise delegated to a third party.
- Submission of the DSUR to the competent authorities and the Ethics Committee of all of the countries for international studies, unless otherwise delegated to a third party.
- Follow-up on any actions or queries raised following review of the DSUR.

CI is responsible for:

- Review and sign-off of DSUR.

Progress reporting may be delegated to a third party, but this must be agreed between both parties and the responsibilities clearly documented before the study commences.

4. PROCEDURE

4.1 Preparing DSURs

4.1.1 TASC PV Monitor will maintain and check the DSUR tracker, held in the PV folder, to identify the annual dates for the DSURs for CTIMPs.

4.1.2 Send DSUR reminders to the CI by e-mail approximately 6 weeks prior to the Clinical Trial Authorisation (CTA) date.

4.1.3 If required, arrange SAE reconciliation as of end of the DSUR reporting period with the Data Management team.

4.1.4 MedDRA code SAEs for the DSUR and send to CI for review.

4.1.5 Create the report using the DSUR template (Doc Ref 099).

4.1.6 Once final content has been agreed, the DSUR will be signed by the CI and returned to the PV Monitor.

4.2 Submitting DSURs

4.2.1 For CTIMPs, the DSUR should be submitted annually.

- If at least one of the trials covered by the DSUR has gone through the Combined Review process (new single application system for CTIMPs and combined medicine and device) then the report should be submitted using the **Integrated Research Application System (IRAS)**.
- If none of the trials covered by the DSUR have gone through the Combined Review process, then the report must be submitted to the MHRA using the **MHRA Submissions** portal. The report should also be emailed to the REC together with a *CTIMPs Safety Report Form* (available from the Health Research Authority website).

4.2.2 The DSUR should be submitted annually on or within 60 days of the CTA anniversary date; no DSUR reporting period should be longer than 12 months.

4.2.3 Email receipts from **MHRA Submissions** system and REC shall be filed in the Sponsor File and Trial Master File.

4.2.4 A DSUR should be submitted on the due date even if the study has not started recruitment, and an explanation should be included.

4.2.5 The DSUR should continue to be submitted until End of Trial declaration has been submitted.

4.3 Shortened Format DSUR

A simplified procedure has been made available by MHRA for low-risk individual clinical trials authorised in the UK under the Notification Scheme (Type A trials), see MHRA website for full details.

4.3.1 As an alternative to producing a full DSUR for these trials, the *Annual Progress Report* (available from the Health Research Authority website) may be used.

4.3.2 The cover letter will state that this is an *Annual Progress Report* (APR) in lieu of a full DSUR and include the EudraCT number and CTA reference number. A list of all serious adverse reactions in section 6 of the APR should be included.

4.3.3 This should be submitted by the Sponsor to MHRA and REC.

5. ABBREVIATIONS & DEFINITIONS

APR	Annual Progress Report
CI	Chief Investigator
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Report
IRAS	Integrated Research Application System
MedDRA	Medical Dictionary for regulatory Activities
MHRA	Medicines and Healthcare Products Regulatory Agency
PV	Pharmacovigilance
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 099: DSUR template

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
1	Heather Barclay (TASC PV Monitor)	28/09/2021	New.
2	Joana Rocha (TASC PV Monitor)	28/09/2023	DSUR submission details updated; to include Combined Review process and shortened DSUR for low-risk individual trials.

8. APPROVALS

Approved by:	**Date:**
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 Sep 2023