



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

SOP NUMBER:	TASC SOP065 v4
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for preparing and submitting the Development Safety Update Report (DSUR) for Clinical Trials of Investigational Medicinal Products (CTIMPs) which are sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST).

2. SCOPE

This SOP describes to the process of creating and submitting a DSUR and applies to TASC staff members, investigators and research staff working on CTIMPs which are sponsored or co-sponsored by the UoD and/or NHST.

The Sponsor procedure complies with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004 and the European Pharmacovigilance Regulations (effective 2012) and subsequent amendments.

3. RESPONSIBILITIES

Sponsor (TASC Pharmacovigilance (PV) Monitor):

- will identify and advise investigators of the annual due date of DSURs.
- must ensure fees applicable to the submission of the DSUR are paid prior to submission.
- will prepare the DSUR (where the preparation of the report has not been delegated to a third party).
- will submit the DSUR on behalf of the Chief Investigator (CI) to the licensing authorities Medicines and Healthcare products Regulatory Agency (MHRA) or other, unless otherwise delegated to a third party.
- will follow-up on any actions or queries raised following review of the DSUR.

Investigator (CI, Principal Investigator) or delegate:

- will review and sign off DSUR.

4. PROCEDURE

The Sponsor or delegate will provide the licencing authority (MHRA or other) with an annual safety report for CTIMPs which are sponsored or co-sponsored by the UoD and/or NHST, as per trial requirements or agreements.

The licensing authority will accept a trial-specific DSUR provided the sponsor submits appropriate justification.

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

4.1. Preparing DSURs

- 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.
- DSUR reminders will be sent to the CI by e-mail approximately 6 weeks prior to the Clinical Trial Authorisation (CTA) date.
- If required, SAE reconciliation will be done with the trial team or Tayside Clinical Trials Unit (TCTU) Data Management team.
- The CI will review Medical Dictionary for regulatory Activities (MedDRA) coded serious adverse events (SAEs), serious adverse reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs).
- TASC PV Monitor will draft the DSUR using the DSUR template (Doc Ref 099) and the DSUR cover letter.
- If applicable, DSUR submission fees will be paid prior to submission to the licensing authority (MHRA or others). The payment receipt must be filled in the Sponsor file and Trial Master File (TMF) as proof of payment.
- Once final content has been agreed, the DSUR will be signed by the CI and submitted by the TASC PV Monitor.

4.2. Submitting DSURs

- The DSUR should be submitted to the licensing authority (MHRA or others) within 60 days of the CTA anniversary date; no DSUR reporting period should be longer than 12 months.
- A copy of the DSUR and acknowledgement receipts from the licensing authority (MHRA or others) shall be filed in the Sponsor File and TMF.
- If a trial has a CTA approval and no participants have been enrolled at the time of the data lock point, an explanatory letter will be completed in place of the DSUR.
- The DSUR should continue to be submitted until Global End of Trial notification has been submitted.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Report
MedDRA	Medical Dictionary for regulatory Activities
MHRA	Medicines and Healthcare Products Regulatory Agency
NHST	NHS Tayside
PV	Pharmacovigilance
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TASC	Tayside Medical Science Centre
TCTU	Tayside Clinical Trials Unit
TMF	Trial Master File
UoD	University of Dundee

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.
3	Joana Rocha (TASC PV Monitor)	24/09/2025	MHRA Submissions system step removed. Payment prior to submission details added. APR details removed.
4	Joana Rocha (TASC PV Monitor)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	30 Mar 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 Mar 2026