Guideline number	**Guideline 55.001C**	Version	**6.0**
Title	**PV Office – Submitting SUSAR reports to MHRA via ICSR**		

Purpose of document:
To outline the process for entering SUSAR reports onto the MHRA electronic reporting site for SUSARs (ICSR).

Personnel:
Pharmacovigilance Administrator
Pharmacovigilance and Safety Manager and Sponsor delegates

Background
Suspected Unexpected Serious Adverse Reactions (SUSARs) require expedited reporting to the regulatory authorities (MHRA) and the relevant Ethics Committee.

The regulations set time limits:
Fatal or Life Threatening SUSARs: not later than 7 days after the sponsor for Pharmacovigilance had information that the case fulfilled the criteria for fatal or life-threatening SUSAR and any follow-up information with a further 8 days.
All other SUSARs: not later than 15 days after the sponsor for Pharmacovigilance had information that the case fulfilled the criteria for a SUSAR.

SUSARs must be reported electronically to the MHRA via the ICSR website. This provides a method of electronic submission of UK and Third Country SUSAR reports to the MHRA.

Submit a SUSAR report

1. Log into ICSR Portal

   Note: All fields marked with “Required" are mandatory.

   Click Save Draft at any time to save a report for editing and/or submission at a later date.

2. Click on ‘Reports’
3. Click on ‘New Report’
4. Select ‘Standard E2B ICH R2 Medicines form” and press select
5. Complete the Admin section of the form. Only certain fields will be highlighted below,

   a. For the field ‘Message Type’ select ‘ICHICSR’

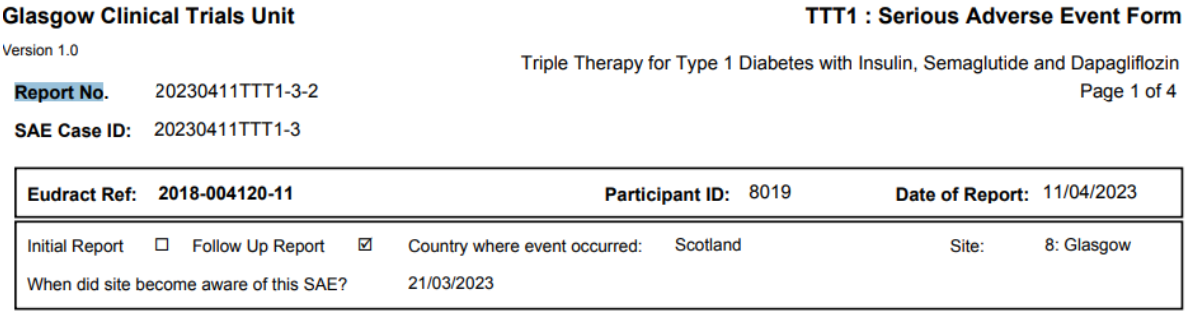
   b. For the field ‘Sender's Safety Report Unique Identifier’ enter the following:

   Country ID-Sponsor ID-SAE Report No.

   As an example:

   GB-NHSGGC-**20230411-TTT1-3-2**

   Where the bold text is taken from the SAE form field ‘Report No’ as highlighted below



Glasgow Clinical Trials Unit — **TTT1 : Serious Adverse Event Form**

Version 1.0

Triple Therapy for Type 1 Diabetes with Insulin, Semaglutide and Dapagliflozin

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Report No. 20230411TTT1-3-2

SAE Case ID: 20230411TTT1-3

Eudract Ref:	**2018-004120-11**		**Participant ID:**	8019	**Date of Report:**	11/04/2023	
Initial Report	☐	Follow Up Report ☑	Country where event occurred:	Scotland	Site:	8: Glasgow	
When did site become aware of this SAE?		21/03/2023					

   c. For the field ‘Message no’ this should reflect the number of reports submitted to the MHRA for this event i.e. for initial SUSAR report this should be 1, for the first follow up 2 etc. This is NOT the report no.

   d. For the field ‘Type of report’ select ‘Report from study’

   e. For the field ‘Regulatory authority's case report number’ enter ‘Sender's Safety Report Unique Identifier’’ as per 5b

   f. For the field ‘Was the case medically confirmed, if not initially from health professional?’ select ‘No’

6. Complete the Reporter (note: this refers to the PV office member) section of the form. Click add. Most fields are straightforward with the exception of the following:
    - 'literature reference' this should remain blank
    - Reporter organisation, this should state NHS Greater Glasgow and Clyde.
    - For reporter qualification state "Consumer of other non-health professional.
    - For study name use EudraCT number#TTT1 where TTT1 is the study short title.

7. Complete the Patient section. All fields are straightforward.

8. If applicable, complete the Patient History section. All fields are straightforward. Refer to medical history, concomitant medication etc.

9. If applicable, complete the Death section. All fields are straightforward.

10. Where the SAE involves an infant, and refers to a congenital anomaly or birth defect the Parent section should be completed. All fields are straightforward.

11. Complete a drug section for each IMP/drug involved. Certain fields are highlighted below

    a. For the field 'Drug characterisation' if the IMP is suspected to have a causal relationship with the event 'Suspect should be selected'
    b. If there is a suspected drug interaction that has caused the reaction the concomitant medication should also be entered in its own section. "Concomitant" should be selected under drug characterisation

    Most fields are optional but as much information as possible should be provided.
    Note: Medicinal product entry: A dictionary of drug terms and codes is associated with the ICSR reporting form. This is regularly updated with new terms that have been submitted to the MHRA in CTA applications. The term entered into the Drug Name field will be matched against the drug dictionary in real time. When no match is found, the user will be prompted to check and re-enter the term. When no match is found for a second time, the user will be permitted to continue and submit the report with an unmatched name.
    Note: If the patient is taking 200mg four times a day, this should be entered as "200mg" in drug dose and unit, with "4" as the drug interval and "day" as the drug interval unit.
    Complete the Reaction section for each reported term. All fields are straightforward

12. Complete the Causality section using the edit button for each reported reaction. Certain fields are highlighted below.

    a. For the field 'Source of Assessment" enter 'Investigator'
    b. For the field 'Method of Assessment' enter 'MHRA'
    c. For the field 'Result of Assessment' enter 'Related' or 'Unrelated' or 'Unknown'

13. Complete the Test section. All fields are straightforward.

14. Complete the Narrative section. All fields are straightforward.

    Under senders comments add any detail regarding disagreements between reviewers etc.

15. Select 'Validate and send'

16. From the Confirmation page, save a copy of pdf of the SUSAR report and the associated .xml form.

    Save a copy of all forms electronically into the Sponsor PV subfolder and the PV Office filestore subfolder electronic study file in a patient specific folder.

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17. Details of the report will appear on the Report Management page which is displayed on logging into ICSR.

Follow-up Report

Under report management on the ICSR dashboard select the required SUSAR and click update. Enter all necessary amendments to the report and submit as per above.

Guideline signatories

Prepared by Signature	Marc Jones Date
Approved by Signature	Caroline Watson Date

Document history

Version	Date	Description
1.0	02.09.10	Version 1.0 creation
2.0	30.08.11	Amendment after use of system
3.0	29/11/13	Updated to reflect changes to the eSUSAR system Guideline No. updated
4.0	18/09/14	Addition of process to document confirmation of submission of report to MHRA.
5.0	15/07/2016	Reviewed and released as part of SOPs reorganisation process. Guideline has moved to SOP category 55 NHS GG&C Sponsor Pharmacovigilance and renumbered (previously 18.001C). 'Prepared by' changed to Caroline Watson, 'Approved by' changed to Julie Brittenden.
6.0	31/05/2023	Amended in line with the introduction of the ICSR system