SOP number	**55.017**	Version	**2.0**
Title	**Sponsor Quality Control of SAEs Processed by the Pharmacovigilance Office**		

Prepared by Signature	Marc Jones Date
Approved by Signature	Caroline Watson Date
Released by Signature	Chloë Cowan Date

SOP category	NHS GG&C Sponsor Pharmacovigilance

Staff category

Staff Category	R	A	C	I
R&I Research Governance Manager		X		
R&I Pharmacovigilance	X			
R&I Innovation Lead			X	
Sponsor Research Co-Ordinators			X	
Project Managers			X	
Industry Collaboration Project Manager			X	
R&I Pharmacy			X	
R&I Monitoring			X	
Chief Investigator				X
Principal Investigator				X

1. Scope

This procedure applies to NHSGGC staff with sponsor safety reporting responsibilities.

Chief Investigators (CIs) will be provided with a copy (marked as an uncontrolled copy) of this SOP for their information.

2. Purpose

The purpose of this SOP is to describe the QC process for SAEs following processing by the PV Office. SAE levels and particularly the number of SAEs considered related to the IMP/trial procedure of medical device differ on a trial by trial basis. In addition for many trials there could be large proportions of SAEs that are due to the patients underlying medical condition rather than the trial intervention. For early phase studies where little is known regarding the safety profile of the IMPs/invasive medical devices it is important that SAEs are closely monitored, whereas in a phase IV trial using a well-established IMP the safety profile may be well known with little risk of events occurring that are unexpected for that IMP. Therefore the review and QC of these events will be carried out according to a risk based approach.

3. Procedures

For each trial or study handled by the PV Office the PV and Safety Manager will determine the level of QC review required for serious adverse events in a risk dependent manner and this initial level will be documented in the PV plan.

At a minimum 10% of SAEs received within the trial will be QC reviewed and this review will be documented using Form 55.017A. For all trials the first 10 SAEs will be reviewed to identify any issues quickly and to ensure measures are in place to mitigate any risk.

For high risk Phase I studies (as defined by the Sponsor) 100% checking of SAEs will be in place and documented via Form 55.017A.

The above checks are in addition to the standard review of expectedness of serious adverse reactions carried out by the Sponsor PV manager. This is mandatory for all trials as per SOP 55.001 but falls outside the scope of this SOP.

Where issues are identified during the QC process a decision may be made to temporarily increase IMP/trial procedures/medical devices the level of QC review until these issues are resolved. Similarly if no major issues are detected a decision may be made to reduce the level of QC review. Any decision to increase or decrease the level of QC review will be documented on Form 55.017A without a corresponding update to the PV Plan.

The QC review required for each study will be documented within the Sponsor safety reporting plan (Form 55.001A) detailing the initial level of review to be carried out and were appropriate the specific triggers for modifying the level of review throughout the trial.

4. Referenced documents

- Form 55.001A - Sponsor Safety Reporting Plan
- Form 55.017A - Sponsor QC Review Log
- SOP 55.001 - Pharmacovigilance in Clinical Trials of Investigational Medicinal Products (Glasgow Clinical Trials Unit)

5. Related documents

- Guideline - 55.001G PV Office Processing for Clinical Trials of Investigational Medicinal Products
- Guideline 55.007A - PV Office Processing for Clinical Investigations of Non CE Marked medical Devices

6. Document History

Version	Date	Description
1.0	23/11/2021	First Release
2.0	26/02/2025	Updated to new RACI matrix, and to amend level of QC minimum and add need to state in PV plan.