SOP number	**51.031**	Version	**2.0**
Title	**Corrective and Preventative Action Plan Management**		

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SOP category	NHS GG&C Sponsor R&I
Staff category	

Staff Category	R	A	C	I
R&I Research Governance Manager	X			
R&I Lead Pharmacist Clinical Trials	X			
Quality Assurance Manager		X		
Chief Investigators				X

1. Scope

This SOP applies to all clinical research conducted within NHS GGC and clinical research sponsored by NHS GGC/ University of Glasgow that may occur on external sites.

2. Purpose

This SOP describes the process for the management of corrective and preventative action (CAPA) plans arising from all non-compliances logged within the Q-Pulse system as described in SOP 51.008.

3. Procedures

3.1. Raising a Non-Compliance

All non-compliances raised in accordance with SOP 51.008 that have a severity of Category 3 or Category 4 will be recorded on Q-Pulse using the Escalated Non-Compliance Wizard in the CAPA module. In some instances, Category 2 Non-Compliances may be recorded and follow the same process. This wizard has been designed to capture the required information to ensure full traceability of issues and enable successful resolution of non-compliances.

Table 1 details the information that is captured at the stage of raising the non-compliance.

Information Captured	Explanation
Details of the Non-compliance	This is a summary field in which a written explanation of the reported non-compliance can be captured.
Fault Category	This is used to give a general categorisation to the issue to enable trend analysis
Severity	By default, a CAPA will generally relate to a Category 3 or Category 4 non-compliance. However, this can be later downgraded if further investigation reduces the classification and in some instances a Category 2 may be raised.
Source	By default this will be given the identified of "Non-Compliance", however if a non-compliance is later determined to be escalated to a Serious Breach it will be changed to this tag or tagged as "Systems" if it relates to a systems issue.
Raised By	This is used to record the source of the non-compliance has been identified by providing the name of the individual reporting.
CI/PI	This is used to capture the name of the relevant CI/PI for the non-compliance
Raised Against	This is used to report the department, vendor or site which is impacted by the non-compliance.
Trial	This is used to record the specific trial impacted by the non-compliance, if more than one is impacted this can be recorded in the summary.
Sponsor	This is used to record who the sponsor of the associated trial is.
Owner	All non-compliances will be assigned to either the Lead Pharmacist or Research Governance Manager as detailed in section 5.1.1.

Table 1 – Q-Pulse Details

3.1.1. Ownership of Non-Compliances

For all non-compliances relating to issues with IMP or Labs, ownership will be assigned to the Lead Pharmacist Clinical Trials. All other Non-Compliances will be assigned to the ownership of the Research Governance Manager.

In instances of variation from this split of ownership, the R&I Director can determine who a CAPA is assigned to for Ownership.

3.1.2. Documenting Non-Compliance in TMF

It is not required to file information relating to the CAPA within an individual TMF for an affected trial, unless in the form of a file note to refer to containment actions taken specific to that trial. If

the containment action involves updates to information within a TMF then this is not required, only in the instance to offer an explanation for a gap in recorded information.

3.2. Managing Non-Compliance

All Non-Compliances will be managed through the Q-Pulse application, it is the responsibility of the assigned owner to maintain up to date information within the CAPA record and ensure timelines are maintained and achieved.

3.2.1. Workflow

The Q-Pulse application has an assigned workflow which must be followed to properly address the non-compliance.

Actions

This is used to capture details of any actions already taken by those associated with the issue either at site or with an associated department.

Implement Corrective Action

In this field, actions are detailed which will contain the immediate issue. This relates to the steps to "put right" the issue identified.

For example, if a study was to start without an e-CRF in place, what steps are to be taken relative to that trial and its start to address the fact the e-CRF is not in place?

The scope of this action is not to fully resolve the issue, but to limit its impact.

Investigate and Identify Root Cause

In this stage, consideration and investigation is carried out to determine why these circumstances came to pass. At what point in the process did the issue materialise? What factors contributed to this?

Implement Preventative Action

This stage will relate to the identified root cause(s), when it has been established why something happened steps can then be taken to ensure it will not happen again. This stage is concerned with the more holistic and long term impact of the non-compliance.

Follow Up

The follow up stage is used to ensure that the issue identified has been adequately addressed and all remedial steps have been taken to properly evidence and document the steps taken and where possible, ensure their effectiveness.

3.2.2. Retaining Evidence

As mentioned previously, it is essential to gather and retain evidence of the steps and actions taken to address a non-compliance. This can include updated documentation, reports, communications etc. This information will be gathered by the CAPA owner and added to the Q-Pulse record to enable reconstruction of the activity at a future date. E-Mail correspondence relating to the Non-Compliance may be retained in outlook and some of the more major emails can be saved and added to the Q-Pulse record.

3.2.3. Reminders

The Q-Pulse application has built in reminder and escalation functionality to alert assigned owners of forthcoming target dates, it is the responsibility of the owners of CAPAs to manage the target dates within Q-Pulse and appropriately respond to reminders by making the relevant updates within Q-Pulse.

3.2.4. Individual Non-Compliance Report

In the event it is required to produce an extract report on the overall status of an individual non-compliance, an embedded template in Q-Pulse may be used to present the summary of the information.

3.3. Closing Non-Compliance

It is the responsibility of the CAPA owner to close off the Q-Pulse record when all actions associated to the CAPA have been adequately addressed and sufficient evidence has been recorded. When a CAPA has been closed, evidence of the completed CAPA must be shared with the relevant stakeholders.

3.4. Reporting to Glasgow Health Science Partnership Regulatory affairs Group (GHSP RAG)

The Research Governance Manager or Lead Pharmacist Clinical Trials will present a report on the status of all Non-Compliances to the GHSP RAG. This will present the status of actions, identifying newly opened, still open and recently closed actions while also separating into the require categories. This information will be generated using data in Q-Pulse.

3.5. Reporting to Glasgow Health Science Partnership (GHSP) Delivery Board

The Chair of the GHSP RAG, or a GHSP RAG representative, will provide the GHSP Delivery Board with a summary of all Serious Breach Notifications, and relevant governance issues arising as a result, via the GHSP RAG report at each GHSP Delivery Board Meeting.

4. Referenced documents

- SOP 51.008 - Handling non-compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde
- SOP 51.009 - Notification of serious breaches of Good Clinical Practice or the trial protocol for clinical trials of investigational medicinal products

5. Related documents

- None

6. Document history

Version	Date	Description
1.0	17/12/2018	First Release
2.0	09/06/2023	Change of Author, significant update to content to reflect introduction of Q-Pulse.

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