WORK INSTRUCTION

WI 01 – How to Enter a Safety Report onto Q-Pulse Version 4

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DISCLAIMER

This generic R&D Work Instruction (WI) must be followed unless a study specific SOP/WI exists.

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Full History			
Version	**Date**	**Author**	**Reason**
V1.0	22 November 2012		
V1.1	14 November 2014	Lisa Treeby & Rhianne Lewis, R&D Facilitators and Joanne Lowe, Quality Assurance Coordinator	Minor clarifications to the process. Transferred content to new template.
V1.2	03 November 2015	Lisella Wilkinson, QA Coordinator	Minor additions to process to accommodate metrics required and report designing.
V2.0		Nikki Sawyer, Quality Assurance Coordinator and Elizabeth Watson R&D Facilitator	Minor additions to the process and new information on updating records. Transferred content to new template.
V3	13 July 2022	Quality Assurance Coordinator	Updated into current WI template and to reflect change in saving process.
V4	17 July 2025	Quality Assurance Coordinator	Routine review. Updates to job titles.

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1 INTRODUCTION

All safety reports which are reported to Research & Development (R&D) should be recorded on R&D's quality management system, Q-Pulse, and reviewed and followed-up appropriately. Safety reporting systems are subject to audit by the Sponsor/Host institution or inspection by the Medicines and Healthcare Products Regulatory Agency.

2. PURPOSE

The purpose of this Work Instruction (WI) is to describe the procedure for recording safety report forms on Q-Pulse.

3. SCOPE

This WI applies to the Quality Assurance (QA) Coordinator and, in their absence, the QA Team and Sponsorship Team. It also applies to the Sponsorship Manager in terms of oversight of the procedure.

4. DEFINITIONS & ABBREVIATIONS

CI	Chief Investigator
GOG	R&D Governance Oversight Group
PI	Principal Investigator
MHRA	Medicines and healthcare Products Regulatory Agency
SOP	Standard Operating Procedure
R&D	Research and Development
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
WI	Work Instruction
DTX	Datix Incident Report Number
CTIMP	Clinical Trial of an Investigational Medicinal Product
SAE	Serious Adverse Event

5. DUTIES AND RESPONSIBILITIES OF STAFF

QA Coordinator

It is the responsibility of the QA Coordinator to enter all safety reports received by R&D onto Q-Pulse in a timely manner. In the absence of the QA Coordinator, members of the wider QA Team or Sponsorship Team will assume this responsibility.

Sponsorship Manager

It is the responsibility of the Sponsorship Manager to oversee this procedure and to review all safety reports which are received and entered onto Q-Pulse. In the absence of the Sponsorship Manager, the R&D Senior Leadership Team will assume this responsibility. If clinical input is required, this will be sought from R&D Clinical Leads.

6. PROCEDURES

6.1 Guidance on Entering a Safety Report onto Q-Pulse

NB First check if Causality has been ticked; if not, you can't put the safety report on Q-Pulse.

Step 1	Open Q-Pulse and in the 'CAPA' module: • Open 'New' • Click 'From wizard' • Click 'Safety report' • Click 'Next'
Step 2	You should now be on the 'Initial Details' page. • **Details** – Enter in a line the title of the study followed by the patient ID, then the summary of the event detailed on the safety report form, divided by a few spaces. • **R&D Number** – Enter the R&D number, which should be located on the safety report (can also be searched for on EDGE) • **Keywords** – Enter the short title of the study • **Sponsored or hosted** – select • Click 'Next'
Step 3	This will take you to the 'Additional Details' page. • **Causality** – select the causality from the drop-down-list, this can be identified from the safety report. **NB:** If it's a registry study causality will always be not related (there is no intervention on the protocol). • **Source** – Select 'Datix' from the drop-down-list and expand the list. Select which type of report it is, this can be found on the safety report. • **Expected or Not** – Select whether the event/reaction was expected or unexpected, this can be found on the safety report. **NB**: Can be skipped over if not required (for Not Related or Unlikely). If causality is possibly, probably, or definitely related expectedness should always be ticked. Contact the person who submitted the form if not. • Click 'Next'
Step 4	This will take you to the 'Date incident occurred' page. • **Incident Date** – This is the 'date of onset' on the safety report. • **Target Date** – This is the 'date reported to R&D' on the safety report. **NB**: Remember to check the date as the month automatically comes up as the following month. • **Raised Date** – Select the date you are entering the safety report onto Q-Pulse. • **Investigator Aware Date** – next to date of onset on the safety report. • Click 'Next'

Step 5	The Safety Report Wizard is now complete. • Tick 'After Finish – Display Details' • Click 'Finish' • The safety report details will be displayed. Enter the 'DTX' number on the top left of the safety report form before saving in the R&D study folder and send a copy to the Assistant R&D Manager for review.

6.2 Updating Records on Q-Pulse

Open records on Q-Pulse

To search for a record, click on the CA/PA module on the LaunchPad Q-Pulse screen. This brings up a Filter screen. Enter the study name, a specific search word/number or the DTX number in the keyword search box.

Select the required AE/SAE by double clicking on it. It will open in a new screen.

Within 'Details' Box add the update. Type in 'Update received' and the date. Then add the extra information from the updated safety report. Save what has been entered before exiting the screen.

Enter the DTX number of the initial report and 'follow up' or 'final report' onto the top left corner of the form before saving and forward a copy to the Assistant R&D Manager to review.

Updates to closed records on Q-Pulse

Closed report will need re-opening. Select the required AE/SAE and open in a new screen, click on 'Actions', click 'Re-Open Record'. You will be prompted to enter a reason, write 'Update received'.

Within 'Details' Box add the update. Type in 'Update received' and the date. Then add the extra information from the updated safety report. Close the report with a final comment eg 'Issue resolved'. Save what has been entered before exiting the screen.

Enter the DTX number of the initial report and 'follow up' or 'final report' onto the top left corner of the form before saving and forward a copy to the Assistant R&D Manager to review.

6.3 Useful Information when entering Safety Reports on Q Pulse

Study specific safety report forms agreed by the Sponsor can be used to notify R&D in place of the R&D template forms.

If the CI/PI hasn't signed the safety report and isn't available to sign it the sub or co-investigator should sign instead (if delegated to do so).

If the safety report is for a CTIMP and the CI/PI has not signed, check if it is a first

report. If it is a first report the CI/PI needs to sign. If it is a follow up report and if no changes have been made to causality, expectedness or severity then no CI/PI signature is needed. The person submitting the report does however need to evidence that the CI/PI has seen and considered the updated report, this can be done by copying them into the email to R&D.

7. DISSEMINATION AND TRAINING

7.1 This WI and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this WI must ensure that they take time to read and understand the content of this WI.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

8.1 In order to monitor compliance with this WI, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Enter the 'DTX' number on the top left of the safety report form before saving in the R&D study folder.	Review forms saved on Research_Develop$ shared drive, study folders.
2.	Reports should be sent to the Sponsorship Manager for review.	Sponsorship Manager sign off on Q-Pulse

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format must be retained indefinitely.

10. REFERENCES

Royal Devon Website: https://www.royaldevon.nhs.uk/about-us/research-and-development/information-for-researchers/useful-documents/