WORK INSTRUCTION

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

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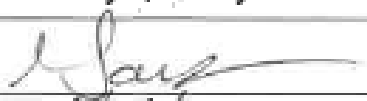
Signature	
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Controlled document

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It is the responsibility of all users of this Work Instruction to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

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

Associated Trust Policies/ Procedural documents:	*S22 Safety Reporting*
Key Words:	R&D Work Instruction AE/AR/SAE/SAR/SUSAR Safety Reporting Q Pulse
In consultation with: Quality Assurance Group (June 2019) Directorate Governance Group	

Contents

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 R&D Facilitators. It also applies to the Assistant R&D Manager in terms of oversight of the procedure.

4. DEFINITIONS

CI	Chief Investigator
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, the R&D Facilitators will assume this responsibility.

Assistant R&D Manager

It is the responsibility of the Assistant R&D Manager to oversee this procedure and to review all safety reports which are received and entered onto Q-Pulse. In the absence of the Assistant R&D Manager, the Research Management and Governance Manger will assume this responsibility.

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 as ticked. • 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 research nurse 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 • 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. Write the 'DTX' number on the top of the safety report form and provide to the Assistant R&D Manager. **NB**: If the safety report is for a CTIMP request the Sponsor SAE form from the research nurse if it hasn't been sent with the safety report.

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 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.

On the hard copy of the updated safety report, write the DTX number of the initial report and 'update received'. Attach it to the initial report before forwarding to the Assistant R&D Manager to review.

Closed records on Q-Pulse

Closed report will need re-opening. Select the required 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.

On the hard copy of the updated safety report, write the DTX number of the initial report and 'update received'. Attach it to the initial report (if available) before forwarding to the Assistant R&D Manager to review.

6.3 *Useful Information when entering Safety Reports on Q Pulse*

If the PI hasn't signed the safety report for a CTIMP study but has signed the sponsor's form then it isn't necessary to get the safety report signed as well.

If the PI hasn't signed the safety report and isn't available to sign it the co-investigator should sign instead.

If the safety report is for a CTIMP and the PI has not signed, check if it's a first report. If it is a first report the PI needs to sign. If it is not a first report and if no changes have been made to causality, expectedness or severity then no PI signature is needed.

If it is an AE form then it will be a sponsored study. Hosted studies will only be SAEs.

If it's a hosted study and the Sponsor does not need to know about an event it does not need to be logged on Q-Pulse.

7. DISSEMINATION AND TRAINING

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

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

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

8.1 This WI will be audited in line with the relevant SOP and in agreement with the R&D audit process.

8.2 Outcomes from audit will be presented to the R&D Quality Assurance Group 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 the R&D Divisional Governance Group.

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 RDE Research website.

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

10. REFERENCES

RDE Research: https://rderesearch.co.uk/home/