

Publishing Clinical Trial Standard Operating Procedures on Q-Pulse

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: <https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/> and/or Q-Pulse

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Version Number:	4.0
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Signature:	
	Date:	11 th December 2020
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	Signature:	
	Date:	14 th December 2020

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	12 th July 2013	Removal of section 4.2 detailing the distribution of trial instructions to Pharmacists through Q-pulse.
2.0	20 th July 2015	
3.0	19 th December 2017	Change of author Change of control procedure and distribution of SOPs Other minor word changes for clarity
4.0	11 th January 2021	Change of link to R&D website. Change of author. Updated who can approve SOPs.

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1 Introduction, Background and Purpose

Q-Pulse is an electronic software application used by York and Scarborough Teaching Hospitals NHS Foundation Trust to ensure that the most recent version of standard operating procedures (SOPs) and associated documents are available to and used by pharmacy clinical trials staff.

2 Who Should Use This SOP

This procedure should be followed by all members of the pharmacy clinical trials team within York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used to ensure that all pharmacy clinical trial SOPs and associated documents are published on the York and Scarborough Teaching Hospitals NHS Foundation Trust R&D website (www.research.yorkhospitals.nhs.uk) and the Q-Pulse distribution system. There may also be a requirement for an SOP to be published on the pharmacy Q-Pulse system.

Q-Pulse can be used to generate a list of the SOPs and the versions which have been acknowledged by relevant pharmacy staff. This list may be used to update personal training files or to prepare for an audit or MHRA inspection and can be prepared by the R&D department and/or the pharmacy quality assurance department where appropriate.

4 Procedure(s)

Publishing SOPs via R&D

1. New or updated SOPs and/or associated documents should be approved by either the Pharmacy Clinical Trials Manager or the Deputy Chief Pharmacist (who is the responsible pharmacist for pharmacy clinical trials).
2. Following approval, the SOP needs to be sent to the R&D SOP controller along with a tracked changes copy.
3. The R&D SOP controller will publish the SOP on the R&D website and on the Q-Pulse system.
4. A Q-Pulse generated email will inform designated recipients of the existence of new or amended SOPs which they should read and acknowledge.
5. A period of one month is allowed for training in use of the new/amended SOP before the procedure is formally implemented and accepted into practice.

6. A list of staff that have read and acknowledged the SOP on Q-Pulse can be generated by the R&D department when needed.

Publishing SOPs via the pharmacy Q-Pulse system

1. There may be a requirement to publish SOPs on the both the R&D and pharmacy Q-Pulse systems e.g. where such a SOP involves general pharmacy staff.
2. When the SOP has been published on the R&D website, send the link to the to the pharmacy quality assurance department with a list of the pharmacy personnel/staff groups who should read and acknowledge the SOP.
3. Pharmacy quality assurance staff will then publish the SOP on the pharmacy Q-Pulse system. This will consist of a just the link to the R&D website to ensure only the most recent version is in circulation.
4. Designated staff will be notified via Q-Pulse email that the document is available to read and acknowledge.
5. A list of staff that have read and acknowledged the SOP on Q-Pulse may be generated by the pharmacy quality assurance department when needed.

5 Related SOPs and Documents

York and Scarborough Teaching Hospitals NHS Foundation Trust R&D website
([http:// www.research.yorkhospitals.nhs.uk/sops-and-guidance-/](http://www.research.yorkhospitals.nhs.uk/sops-and-guidance/))