York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S88

Creating, reviewing and approving a clinical trial prescription

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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-/.html and/or Q-Pulse

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Approved by:	Name/Position:	Kate Nixon – Deputy Chief Pharmacist
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	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17th September 2024

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	Reviewers	Details of significant changes
1.0	12th March 2015		
2.0	21st December 2017		Rewritten to provide clear instructions. Addition of instructions when dealing with sponsor produced prescriptions. Change of Author.
3.0	11th January 2021		Change of link to R&D website. Change of author. EPMA information added, sponsors electronic systems explained.
4.0	15th October 2024	Poppy Cottrell-Howe	Change of approver, who can create and approve, EPMA – new drugs, Metavision addition. Change from electronic to editable copies are permitted to be sent to research teams.

Contents

1 Introduction, Background and Purpose

The use of specific prescriptions for clinical trials enables prompt identification of those trials, facilitates accountability and ensures that Investigational Medicinal Products (IMPs) and Non-Investigational Medicinal Products (NIMPs) are prescribed and dispensed according to the appropriate protocol. Prescription design should be carefully considered during study setup at site.

A variety of prescriptions may be used to prescribe IMPs and NIMPs e.g. trial specific prescriptions, hospital inpatient (via EPMA), outpatient prescriptions, electronic prescriptions generated by the Sponsor or via ChemoCare. Prescription requirements are described in the Professional Guidance on Pharmacy Services for Clinical Trials produced by the National Pharmacy Clinical Trials Advisory Group (NPCTAG), York and Scarborough Teaching Hospitals NHS Foundation Trust Medicines Code, The Medicines, Ethics and Practice guide produced by the Royal Pharmaceutical Society, and the prescribing and dispensing guidance given in the MHRA Good Clinical Practice Guide.

This SOP aims to ensure the standardisation and quality of any clinical trial prescriptions produced within York and Scarborough Teaching Hospitals NHS Foundation Trust.

2 Who Should Use This SOP

This SOP should be followed by all members of the pharmacy clinical trials team in York and Scarborough Teaching Hospitals NHS Foundation Trust with the responsibilities to create/design and authorise clinical trials prescriptions.

3 When this SOP Should be Used

Follow this SOP when creating a clinical trial prescription, or when amending a sponsor provided prescription to ensure compliance with the Trust Medicines Code. Note that the associated prescription template (Pharm/T15) may not be suitable for oncology or haematology clinical trials, which may need to be prepared by a specialist pharmacist using ChemoCare.

If prescriptions are needed at ward level, then Electronic prescribing and Medicines Administration (EPMA) or Metavision may be used.

4 Procedure(s)

4.1 Creating a clinical trial prescription

The Pharmacy Clinical Trials Manager or Specialist Pharmacy Technician will create/design clinical trials prescription templates and the Deputy Chief pharmacist (the pharmacist responsible for pharmacy clinical trials) or delegate should authorise the prescription template.

Use the Clinical Trial Prescription Template (Pharm/T15) to create a clinical trial prescription if this is appropriate for the trial.

Ensure that the clinical trial identifiers at the top of the prescription are completed.

Adapt the template for clinical trials involving medication allocated through an IVRS/IWRS (Interactive Voice/Web Response System), or for clinical trials that do not utilise this system as appropriate for the designated trial.

Amend the template to further suit the needs of the clinical trial ensuring that sections which are not relevant to the trial are deleted.

Once the prescription is complete save it on the X:/ drive in the appropriate section of the trial electronic folder. The prescription should then be reviewed and authorised as described in section 4.3.

If the study requires the use of a ChemoCare prescription, place a file note stating this into the appropriate section of the pharmacy site file. Approved wet-signed copies of ChemoCare prescriptions are scanned on to ChemoCare.

Creating a clinical trials EPMA or Metavision prescription/order set

Some trials may need to be prescribed at ward level; depending on the nature of the study it may be suitable (if agreed with the sponsor) that the IMP/nIMP can be prescribed using EPMA. Arrange with the pharmacy EPMA team to add the required drugs to the EPMA system.

This may need to be done in a trial specific order set if the drug is on the approved list on EMPA. It must state that it is part of a clinical trial. Below is an example of how patient's trial medication can be prescribed on EPMA: "The ABC clinical trial – Aspirin or Placebo 75mg once a day – obtain from the pharmacy clinical trials".

Once the prescription has been checked and authorised as per the EPMA process, a copy of the order set should be sent to the PI and research team.

If the drug is new, it will not be on the approved list for adding to EMPA, this will need to be free typed by the prescriber on to the system at the time of prescribing. Prior to the trial opening a member of the pharmacy clinical trials team will prepare the exact wording for free typing prescription from the protocol/trial documentation. This will be approved by the PI and Deputy Chief pharmacist and documented in the trial specific SOP so that it can be prescribed in line with the requirements and remain standard prescribing for all participants for the duration of the trial.

For patients recruited on ICU the IMP is to be added to Metavision, this will be done by the designated ICU pharmacist following the standard way of adding drugs to the Metavison system. This will be approved by the PI and Deputy Chief pharmacist and documented in the trial specific SOP.

Place a file note stating that EPMA or Metavision prescribing has been used for this trial into the appropriate section of the pharmacy site.

4.2 Amending a clinical trial prescription provided by a Sponsor.

Sponsor prescriptions may be used in place of clinical trial prescriptions generated using template (Pharm/T15) providing they contain all the information required by the Trust Medicines Code.

If information is missing from the prescription, contact the sponsor to either request that they amend the prescription to include the missing information or to request permission to amend the prescription on site.

Some sponsors may wish to use their own electronic prescribing system. The system should be reviewed and assessed with a responsible pharmacist for clinical trials to ensure it meets the requirements of the Trusts medicines code.

4.3 Prescription review, authorisation and management

If amendments to a sponsor prescription are made by the clinical trials team, then the prescription must be reviewed and authorised by the sponsor before it is taken into use.

Prescriptions produced or amended by the pharmacy clinical trials team should always be reviewed and authorised by a responsible pharmacist for clinical trials prior to implementation.

The approved prescription should be version controlled. Laminate and file the wet signed copy in the pharmacy site file.

Send a photocopy of the wet signed prescription to the research team. Note that editable copies of prescriptions should never be distributed to research teams.

If changes need to be made to a prescription during the trial, amend the prescription and ensure that the amended version is reviewed and authorised as above including obtaining CRA/Sponsor approval where necessary.

Supersede the previous version held in the pharmacy file and replace it with the wet signed version of the new prescription.

Send a scanned copy of the wet signed prescription to the research team and request they replace all old copies with the new copy. Note that editable copies of prescriptions should never be distributed to research teams.

If the prescription is from a sponsor produced prescription pad, obtain permission to supersede the whole pad and/or its destruction. A single copy should be superseded and retained for reference within the pharmacy site file

4.4 Requests for new ChemoCare regimes, protocols and modifications

Requests relating to trial specific ChemoCare prescriptions must be requested from an authorised oncology satellite pharmacist.

In addition to the standard patient identifiers and clinical information required, the following information should also be captured at the time of preparing the prescription;

- The name of the clinical trial
- The treatment arm(s)/regimes

- Space to record patient trial ID number
- Space to record IVRS/IWRS pack numbers (if applicable)

5 Related SOPs and Documents

Pharm/T15 Clinical Trial Prescription Template

York and Scarborough Teaching Hospitals NHS Foundation Trust Medicines Code

MHRA Good Clinical Practice Guide