

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S88
Version Number:	3.0
Author:	Poppy Cottrell-Howe
Implementation date of current version:	11 th January 2021

Approved by:	Name/Position:	Stuart Parkes – Deputy Chief Pharmacist
	Signature:	
	Date:	11 th December 2020
	Name/Position:	Sarah Sheath, SOP Controller
	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 March 2015	
2.0	21 st December 2017	Rewritten to provide clear instructions. Addition of instructions when dealing with sponsor produced prescriptions. Change of Author.
3.0	11 th January 2021	Change of link to R&D website. Change of author. EPMA information added, sponsors electronic systems explained.

UNCONTROLLED DOCUMENT WHEN PRINTED

Contents

	<u>Page No</u>
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	1
3 When this SOP Should be Used	1
4 Procedure(s)	1
4.1 Creating a clinical trial prescription	2
4.2 Amending a clinical trial prescription provided by a Sponsor	2
4.3 Prescription review, authorisation and management	2
4.4 Requests for new ChemoCare regimes, protocols and modifications	3
5 Related SOPs and Documents	3

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.

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) may be used.

4 Procedure(s)

4.1 Creating a clinical trial prescription

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 kept with the oncology team and can be provided upon request.

Creating a clinical trials EPMA 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. 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.

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

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.

Create a draft version of the prescription, save it in the appropriate folder on the X:/ drive and send it to a senior pharmacy technician and the pharmacy

clinical trials manager for review and comment. Comments received should be incorporated if appropriate.

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 electronic 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 photocopy of the wet signed prescription to the research team and request the return of any copies of the previous version. Note that electronic 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 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