

Clinical Trial Prescription Risk Assessment – Professional verification & Final Check of Clinical Trial Prescriptions

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

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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	28 th September 2020		
2.0	21 February 2024	Rachel Spooner	Change of senior to specialist pharmacy technician as who can preform a prescription risk assessment for clinical trials.

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1 Introduction, Background and Purpose

This SOP describes how individual clinical trial prescriptions will be risk assessed to determine if they require a professional verification and if a qualified, registered, accuracy checking pharmacy technician for clinical trials will be able to final check the prescription based on the risk associated with the prescription.

2 Who Should Use This SOP

All qualified, registered accuracy checking pharmacy technicians that work as part of the pharmacy clinical trials team at York and Scarborough Teaching Hospitals NHS Foundation Trust. The Deputy Chief Pharmacist who over sees the pharmacy clinical trials services and who is responsible signing off the final risk assessment.

3 When This SOP Should Be Used

This SOP should be used when assessing the risk of new or existing clinical trials prescriptions to establish if the risk requires a registered pharmacist to perform a professional verification and final check or if the risk is reduced sufficiently enough to allow for a qualified, registered, accuracy checking pharmacy technician (ACT) for clinical trials to perform the final check for the prescription.

4 Procedure(s)

4.1 Clinical Trial prescription types

New and existing clinical trials which are hosted at York and Scarborough Teaching Hospitals NHS Foundation Trust will have their prescription method risk assessed to determine how the prescription is to be checked prior and after dispensing.

The majority of clinical trial prescriptions differ from other pharmacy related prescriptions as they are usually trial specific prescriptions supplied by the sponsor or created following a Trust template (Pharm/T15 - Clinical Trial Prescription Template) in line with the protocol/sponsor requirements.

Clinical trial specific prescriptions only permits the IMP or nIMP stated in the protocol to be prescribed and dispensed to the patient, the risk is sometimes reduced further with the addition of an IVRS/IWRS allocated pack number generated by the sponsor's IVRS/IWRS programme to specify the exact product, batch number, expiry date and quantity to be given to the patient.

Exceptions to a standard clinical trial specific prescription would be if the IMP or nIMP is to be prescribed on the Trust's electronic prescribing systems such as Chemocare or EPMA, using an outpatient/FP10 prescription, or an inpatient specific drug chart/documentation. In these cases the risk can be increased as the prescriber has the opportunity to prescribe other items on the prescription which might not be in line with the trial protocol.

4.2 Clinical Trial prescription risk assessment

Either during the trial set up stage or when reviewing currently open trials a Clinical Trial prescription risk assessment form Pharm/F04 will be completed to determine the risk.

A Specialist Pharmacy Technician for clinical trials or the Pharmacy Clinical Trials Manager will complete the form, starting with the trial information.

Professional verification Assessment

The professional verification assessment is to be completed to determine if the prescription needs to be professional verification prior to dispensing. As with all clinical trial prescribing only clinicians signed on to the delegation log are allowed to prescribe for the specific study and it is their responsibility to confirm that the patient meets all the inclusion criteria before enrolling them on to the trial and that the study medication is still appropriate for the patient every time they complete a study prescription.

If 'yes' is given as the answer to any of the questions in the professional verification assessment section of the form, the prescription must be professionally verified by a registered Pharmacist. If the prescription is for systemic anticancer therapy it must be professionally verified by a suitably trained registered Pharmacist competent to check chemotherapy.

Final Check Assessment

The final check assessment is to be completed to establish if the sponsor has any specific requirements regarding a pharmacist performing the final check, this will be outlined in the pharmacy manual, study protocol or stated on the studies delegation log if this is to be a requirement.

The Deputy Chief Pharmacist will also list any concerns which can be addressed in this section if they believe the study to be a high risk and requires a pharmacist to perform the final check. If these concerns can be overcome to reduce the risk then the Senior Pharmacy Technician for clinical trials or the Pharmacy Clinical Trials Manager will work to find a solution and the study's final check assessment can be re-reviewed by the Deputy Chief Pharmacist.

If it was established in the professional verification assessment section that the study's prescription will contain systemic anticancer therapy and **will be** professionally verified by a suitably trained registered Pharmacist competent to check chemotherapy. Then you must confirm on the form that Clinical Trial Pharmacy Technicians who are ACT accredited will be finally checking the prescription.

Risk assessment outcome

The study will be categorised as either Low or High risk based on the questions stated on the form relating to how the study drugs are to be prescribed, professionally verified and final checked.

If the study is categorised as low risk then a Clinical Trials Pharmacy Technician who is ACT accredited to check clinical trial prescriptions or a registered Pharmacist may carry out the final check of the prescription, without the need for a professional verification.

If categorised as high risk then the trial prescription must be final checked by a registered Pharmacist only.

If study is stated as low risk, it is not valid in the following circumstances:

If the prescriber has made an amendment to the prescription, which moves the medication prescribed (e.g. item, dose, directions, and quantity) away from that quoted within the dispensing details/study protocol.

In these instances this must be brought immediately to the attention of a member of the Clinical Trials Pharmacy Team.

The protocol or sponsor must be referred to in this situation and, if necessary, the prescriber or Principal Investigator contacted if the medication prescribed is not that referred to in the protocol and is not covered by any allowed modifications.

Once the Clinical Trial prescription risk assessment form is completed it should be stored in section 4 of the pharmacy site file along with a copy of the study's sample prescription.

4.3 Study specific SOP's

The study specific SOP's should be tailored to accommodate the risk score the study has. Ensure the Accuracy and clinical checklist template Pharm/T43 and Dispensing instructions template Pharm/T42 correctly states if a professional verification is required and who can perform the final check of the prescription.

4.4 Training

Registered pharmacy technicians that hold an accuracy checking technician qualification allowing them to accuracy check in the main pharmacy department who are part of the pharmacy clinical trials team must complete a 20 item Clinical Trials specific checking log, prior to performing final checks on clinical trials prescriptions. The final sign off of the log is to be completed by the deputy chief pharmacist. The 20 item log is to be kept in the staff members Clinical Trials Training package & Competency workbook.

5 Related SOPs and Documents

Pharm/T42	Dispensing instructions template
Pharm/T43	Accuracy and clinical checklist template
Pharm/T15	Clinical Trial Prescription Template
Pharm/F115	Clinical Trials Training package & Competency workbook
Pharm/F04	Clinical Trials Prescription Assessment Form