York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S92

Prescribing and processing clinical trial prescriptions involving the satellite unit (York Hospital)

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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This SOP will normally be reviewed every 2 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	14th September 2015	

Contents

1 Introduction, Background and Purpose

This Standard Operating Procedure (SOP) should be used to ensure that all Investigational Medicinal Products (IMPs) and Non Investigational Medicinal Products (NIMPs) involving chemotherapy are prescribed correctly, clinically checked by a specialist oncology/haematology pharmacist, ordered and dispensed in accordance with the protocol, and returned to the patient in a safe and timely manner.

Clinical trial prescriptions involving chemotherapy require a clinical check due to the range and complexity of the regimes, and the toxicities and complications which may occur due to treatment with chemotherapy. The clinical check will ensure that clinical trial patients are receiving treatment as described in the protocol, and that their treatment is prescribed and dispensed safely.

2 Who Should Use This SOP

The procedures described should be followed by oncology/haematology clinical trial prescribers authorised to prescribe as documented on a trial specific delegation log, members of the oncology/haematology research team, trained and authorised oncology/haematology pharmacists and members of the satellite unit team, and the pharmacy clinical trials team within York Hospital.

3 When this SOP Should be Used

This SOP should be used when prescribing and processing clinical trial prescriptions involving the satellite unit at York Hospital.

4 Procedure(s)

4.1 Research team responsibilities for communicating clinical trial prescriptions to the pharmacy clinical trials team

The research team must ensure that the pharmacy clinical trials team are informed of any potential patients who may enter a trial involving IMPs and NIMPs as soon as possible. The pharmacy clinical trials team must also be informed when the patient is registered into the trial.

The research team must communicate all clinical trial prescriptions required to the pharmacy clinical trials team in the week prior to the clinic appointment. This will ensure that there is a sufficient quantity of stock available, and will allow the pharmacy clinical trials team to communicate with other areas of pharmacy involved in supplying doses. **Failure to inform the pharmacy clinical trials team of prescriptions may result in the dose being delayed or missed.**

If there are any cancellations or changes to appointments, the research team must inform the pharmacy clinical trials team.

4.2 Pharmacy clinical trials team responsibilities to provide the satellite unit with a list of clinical trial prescriptions required

The pharmacy clinical trials team must send an email to the lead pharmacist and lead pharmacy technician in the satellite unit on a weekly basis. This should contain the details of any prescriptions involving IMPs and NIMPs required over the following week.

The email should contain the date and time the patient is in clinic, name of the trial, participant trial ID number and their initials.

Any cancellations or changes to appointments must be communicated to the lead pharmacist and lead pharmacy technician in the satellite unit.

4.3 Pharmacy clinical trials team responsibilities to provide the satellite unit with trial randomisation/registration forms

When a new participant is randomised/registered into a clinical trial involving the satellite unit, a member of the pharmacy clinical trials team must scan the randomisation/registration form and save a copy in the trial specific folder on the X drive (X:\CANCER and CHEMOTHERAPY\Cancer Clinical trials).

4.4 Clinical trial prescriptions involving doses prepared by the aseptic unit

All clinical trial prescriptions requiring doses of chemotherapy to be prepared by the aseptic unit must be received in the aseptic unit at least 48 hours before the dose is due to be administered to the patient. All prescriptions will need to be clinically checked by the satellite unit prior to being sent to the aseptic unit.

The research team must contact the satellite unit and the pharmacy clinical trials team if a dose is required within less than 48 hours. This will be discussed with the aseptic unit, and doses cannot be guaranteed to be prepared in this case.

Depending on the arrangements discussed during trial setup, the satellite unit or the pharmacy clinical trials team will be responsible for ordering doses from the aseptic unit.

All aseptic order forms completed must be accompanied by a photocopy of the clinical trial prescription, and must be checked by an oncology/haematology specialist pharmacist.

Further guidance can be found in Pharm/S100 (Aseptic preparation of Investigational and Non Investigational Medicinal Products).

4.5 Clinical trial specific prescriptions for chemotherapy

Only prescribers with the appropriate competencies and listed on the trial delegation log as authorised to, can prescribe for a clinical trial.

Trial specific prescriptions are designed for all oncology/haematology clinical trial regimes involving IMPs. The ‘protocol’ and ‘course name’ heading on the prescription identify the name of the clinical trial, and the treatment that the patient has been allocated to receive. IMPs prescribed on a standard non-trial prescription should be returned to the prescriber, who should re-prescribe the treatment using the authorised trial specific regime.

Trial specific prescriptions should only be used for patients involved in a clinical trial. If a trial prescription is issued for a patient not involved in a clinical trial, it should be returned to the prescriber to be issued on a standard prescription. This decreases the risk of non-trial patients receiving IMPs and NIMPs.

The satellite unit will print prescriptions for IMPs and NIMPs involving parenteral administration. **The satellite unit pharmacist must add the patient's trial ID number and allergy status to the prescription. These can be added manually or electronically.**

Prescriptions for oral IMPs and NIMPs will be printed by the prescriber. **The prescriber should add the patient's trial ID number and allergy status to the prescription. These can be added manually or electronically.**

4.6 IVRS/IWRS kit/batch numbers to be added to a clinical trial prescription

For double-blind medication allocated by an Interactive Voice/Web Response System (IVRS/IWRS), the research nurse may allocate the treatment using the system. The kit numbers generated must be added to the prescription by the prescriber. All prescriptions must be accompanied by an electronic form confirming the kit numbers allocated.

For clinical trials that use an IVRS/IWRS for stock control purposes, the research nurse may allocate the kit/batch numbers using the system. A printed form confirming the kit/batch numbers generated must be sent to the satellite unit by either the research team or pharmacy clinical trials team (this must be discussed during trial setup). The pharmacist providing the clinical check must then add the kit/batch numbers onto the prescription manually.

4.7 Manual changes or additions to clinical trial prescriptions

Manual changes or additions to ChemoCare prescriptions will not be accepted by pharmacy (apart from those described in section 4.5 and 4.6, and changes to treatment dates that have been approved by the Satellite Unit Pharmacist who must confirm that the electronic ChemoCare record accurately reflects the manual change to the prescription). The patient's electronic ChemoCare record must always accurately reflect the hard copy of the prescription.

Any clinical trial ChemoCare prescriptions with manual changes not meeting the conditions above must be returned to the prescriber. The electronic ChemoCare record must be updated, and another prescription generated. Ensure the previous prescription is destroyed in accordance with standard procedures.

4.8 Presenting a clinical trial prescription for oral IMPs and NIMPs to the satellite unit

Clinical trial prescriptions for oral IMPs or NIMPs involving chemotherapy must be sent to the satellite unit to be clinically checked by an oncology/haematology specialist Pharmacist.

The prescription must be presented to the satellite unit, and must be accompanied by the following documentation;

- Trial randomisation/registration form
- Interactive Voice/Web Response System (IVRS/IWRS) confirmation (if applicable to the trial)

- Other documentation necessary for the trial (e.g. thalidomide treatment initiation form, lenalidomide/thalidomide Prescription Authorisation Form (PAF))

The research team must ensure that the documentation described above is available for the satellite unit.

As described in section 4.7, manual changes or additions to ChemoCare clinical trial prescriptions will not be accepted by pharmacy. The research team must check that manual changes or additions are not present on the prescription.

The research team must also check that the patient's trial identification number and allergy status are recorded on the prescription by the prescriber, and that the clinician is authorised to prescribe on the delegation log. The start date of treatment must also be checked. If the research team notice these are missing, incomplete or incorrect, the prescription must be returned to a prescriber on the delegation log to be amended.

A member of the research team must contact a member of the pharmacy clinical trials team to inform them that the prescription has been delivered to the satellite unit. Any relevant clinical information must be discussed with the pharmacist providing the clinical check and the pharmacy clinical trials team.

4.9 Satellite unit printing prescriptions for IMPs and NIMPs involving parenteral administration

The satellite unit will print prescriptions from ChemoCare for medication to be administered via a parenteral route. The prescription will be clinically checked in accordance with SOPSAT19 (Systemic anti-cancer therapy clinical check parameters) as described in section 4.10 of this SOP.

The oncology/haematology specialist pharmacist providing the clinical check must add the patient's trial ID number and allergies if these are not already recorded on the prescription.

For clinical trials involving IVRS/IWRS for stock control purposes, a printed confirmation of the kit/batch numbers to be dispensed must be given to the satellite unit by the research team or pharmacy clinical trials team (arrangements to be discussed during trial setup). This may be sent via email or by giving a hard copy to the satellite dispensary team. The pharmacist providing the clinical check must use this to add the kit/batch numbers onto the prescription manually.

4.10 Pharmacy clinical trial team responsibilities for providing documentation to enable the clinical check of a clinical trial prescription

The pharmacy clinical trial team must ensure that the following are available on the X drive (X:\CANCER and CHEMOTHERAPY\Cancer Clinical trials) to enable the pharmacist to provide an accurate clinical check;

- Trial Status Inventory List (updated upon trial opening and monthly)
- Current version of the protocol (updated upon trial opening and amendments)
- Delegation log (updated when a new prescriber is added)
- Randomisation/registration forms (updated upon patient entry to trial or re-randomisation)

4.11 Clinical check of a clinical trial prescription

An oncology/haematology specialist pharmacist in the satellite unit will clinically check the prescription in accordance with SOPSAT19 (Systemic anti-cancer therapy clinical check parameters).

The pharmacist must clinically check the prescription against the current trial protocol, and the documentation provided with the prescription, such as;

- Trial randomisation/registration form
- Interactive Voice/Web Response System (IVRS/IWRS) confirmation (if applicable to the trial)
- Other documentation necessary for the trial (e.g. thalidomide treatment initiation form, lenalidomide/thalidomide Prescription Authorisation Form (PAF))

The pharmacist providing the clinical check must check that the clinician has been delegated the responsibility of prescribing by checking the study-specific delegation log available on the X drive (X:\CANCER and CHEMOTHERAPY\Cancer Clinical trials). If the clinician is not on the delegation log, or has not been delegated the role of prescribing, the pharmacist must contact the research team. The prescriber is the clinician who confirms the ChemoCare prescription.

If the prescriber has not added the patient's trial ID number or allergies to the prescription, these may be added by the pharmacist. These can be added manually or electronically.

If any of the required documentation is missing, the satellite unit should contact a member of the research team to obtain this.

Only prescriptions for IMPs and NIMPs that are to be ordered or dispensed by the pharmacy clinical trials team should be sent to the pharmacy clinical trials team. The pharmacist providing the clinical check must check which medication is to be supplied by the pharmacy clinical trials team by accessing the Trials Status Inventory List on the X drive (X:\CANCER and CHEMOTHERAPY\Cancer Clinical trials).

Requests for additional/supportive medication should be sent to the Healthcare At Home Pharmacy or supplied from TTO packs. If there are any queries as to who should supply the medication, contact a member of the satellite unit team.

The pharmacist providing the clinical check must annotate the ChemoCare chart to indicate where all medication is to be supplied from. This will ensure that the research team can easily collate all IMPs, NIMPs, and additional supportive medication.

4.12 Role of Healthcare at Home in clinical trials dispensing

IMPs and NIMPs must not be sent to the Healthcare at Home pharmacy within York Hospital, unless this is acceptable as defined by the trial protocol. The Trial Status Inventory List must be checked to ensure that IMPs and NIMPs are dispensed by the appropriate team to allow an accurate audit trail of dispensing to be created.

The items required to be dispensed by the Healthcare at Home team should be indicated on the prescription by the satellite unit team during the process of the clinical check, as described in SOPSAT23 (outsourced dispensing of oral chemotherapy and ancillary medication at Healthcare at Home).

4.13 Processing a clinical trial prescription in the satellite unit (IMPs/NIMPs to be ordered/dispensed by the pharmacy clinical trials team)

Once the prescription has been clinically checked, a member of the satellite unit team should contact a member of the pharmacy clinical trials team to make them aware of the prescription to be ordered/dispensed. A member of pharmacy (e.g. delivery ATO, satellite unit ATO, pharmacy clinical trials ATO etc) must deliver or collect the prescription and associated documentation, and give directly to a member of the pharmacy clinical trials team.

4.14 Ready to administer (RTA) IMPs and NIMPs

Ready to administer (RTA) IMPs and NIMPs will be ordered and dispensed by the satellite unit team. The pharmacy clinical trials team must ensure that the satellite unit have any additional labels required to label the IMPs and NIMPs in accordance with European Union Good Manufacturing Practice (EU-GMP) Annex 13: Investigational Medicinal Products.

A member of the satellite unit team must photocopy the prescription, and give the copy to a member of the pharmacy clinical trials team.

The prescription must document the following information;

- Product dispensed (name, strength, form)
- Batch number
- Expiry date
- Manufacturer
- Signature/initials of individual who dispensed and checked each drug

The pharmacy clinical trials team must use the prescription to retrospectively complete the relevant IMP/NIMP accountability logs (if applicable). The prescription must be filed in the pharmacy clinical trial file.

4.15 Processing a clinical trial prescription involving the pharmacy clinical trials team

Clinical trial prescriptions from ChemoCare involving the pharmacy clinical trials team will be dispensed and checked as described in the trial specific Pharmacy Trial Instructions.

Once the prescription has been dispensed and checked, a member of the pharmacy clinical trials team will contact a member of the research team to inform them that the IMP is ready to be collected. Depending on the arrangements described in the Pharmacy Trial Instructions, the research team should either collect the IMP from the pharmacy clinical trials team, or the IMP may be returned to the satellite unit for collection.

When the medication is collected, the ChemoCare prescription must be signed and dated to confirm receipt of the medication.

A photocopy of the prescription and any accompanying documentation must be stored in the pharmacy trial file. If used during the trial, original thalidomide treatment initiation forms, and lenalidomide/thalidomide Prescription Authorisation Forms (PAF) must also be stored in the pharmacy trial file.

Additional/supportive medication may be supplied from Healthcare at Home, or TTO packs from clinic. It is the responsibility of the patient/research team to collect medication from Healthcare at Home.

4.16 Prescribing errors and non-compliance with prescription completion

If a prescribing error/omission is detected by the pharmacy department, the prescription will be returned to the prescriber via the research team/satellite unit to be amended. Any changes to the prescription must be completed by a prescriber named on the delegation log for the study. Changes must be made electronically using the ChemoCare system, and a new prescription generated. Ensure the previous prescription is destroyed in accordance with standard procedures.

Serious errors will be reported through the Adverse Incident Reporting System (AIRS).

5 Related SOPs and Documents

York Teaching Hospital NHS Foundation Trust Medicines Code

MHRA Grey Guide

EU-GMP Annex 13: Investigational Medicinal Products

International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines

Pharm/T25 Pharmacy Trial Instructions

Pharm/S100 Aseptic preparation of Investigational and Non Investigational Medicinal Products

SOPSAT23 Outsourced dispensing of oral chemotherapy and ancillary medication at Healthcare at Home

SOPSAT19 Systemic Anti-Cancer Therapy Clinical Check Parameters

6 Appendix A – Flowchart for processing a clinical trial prescription for oral IMPs and NIMPs involving the satellite unit

Key (responsibilities)	
Research team	**Prescriber**
Satellite unit team	**Pharmacy clinical trials team**

Inform the pharmacy clinical trials team when a patient is potentially going to enter a clinical trial involving Investigational Medicinal Product(s) (IMPs) or Non Investigational Medicinal Product(s) (NIMPs).

Inform the pharmacy clinical trials team when a patient is registered/randomised into a clinical trial involving IMPs or NIMPs.

Scan a copy of the registration/randomisation form to the trial specific file under X:\CANCER and CHEMOTHERAPY\Cancer Clinical trials.

Inform the pharmacy clinical trials team regarding all patient appointments requiring a prescription. If the appointment changes or is cancelled, inform the pharmacy clinical trials team as soon as possible.

A prescriber listed on the delegation log for the trial must prescribe all IMPs or NIMPs on a trial specific prescription. Handwritten amendments and/or additions are not acceptable.

Complete the patient's trial ID number and allergy status on the prescription.

Complete any additional required documentation (e.g. thalidomide treatment initiation form, lenalidomide/thalidomide Prescription Authorisation Form (PAF)).

Check the prescription has been fully completed (e.g. trial ID number and allergy status) and ensure all addition documentation required is present (e.g. randomisation/registration form, IWRS confirmation form, PAF).

Deliver the prescription to the satellite unit team in a blue folder.

Contact the pharmacy clinical trials team to make them aware of the prescription.

Pharmacist checks prescriber is on the trial delegation log and conducts clinical check in accordance with the protocol, randomisation/registration form, SOPSAT19 and any additional documentation. Check the allergy status and patient's trial ID number have been added by the prescriber. Any errors/omissions must be referred to the prescriber. Ensure the pharmacy clinical trials team and research nurse are aware of any delays.

Use the Trial Status Inventory List to indicate on the prescription where all medication is to be supplied from (clinical trials, TTO packs, Healthcare at Home).

Once clinically checked, contact the pharmacy clinical trials team to make them aware the prescription is ready to be ordered/dispensed.

Collect the prescription from the satellite unit.

If the patient is waiting, dispense the prescription as soon as possible and obtain an accuracy check from the dispensary pharmacist.

Contact the research team when the IMPs or NIMPs are ready for collection. The research team must sign and date the prescription to confirm collection. IMPs and NIMPs will only be delivered to the satellite unit if agreed during trial setup. Take a photocopy of the prescription and any additional documentation, and give the research team the original.

Collect IMPs and additional/supportive medication (if applicable) in accordance with standard procedures. Check that all prescribed medication is present. Research/specialist nurse to give the medication to the patient and counsel.

7 Appendix B – Flowchart for processing a clinical trial prescription for IMPs and NIMPs involving parenteral administration

Key (responsibilities)	
Research team	**Prescriber**
Satellite unit team	**Pharmacy clinical trials team**

Inform the pharmacy clinical trials team when a patient is potentially going to enter a clinical trial involving Investigational Medicinal Product(s) (IMPs) or Non Investigational Medicinal Product(s) (NIMPs).

Inform the pharmacy clinical trials team when a patient is registered/randomised into a clinical trial involving IMPs or NIMPs.

Scan a copy of the registration/randomisation form to the trial specific file under X:\CANCER and CHEMOTHERAPY\Cancer Clinical trials.

Inform the pharmacy clinical trials team regarding all patient appointments requiring a prescription. If the appointment changes or is cancelled, the research team must inform the pharmacy clinical trials team as soon as possible.

A prescriber listed on the delegation log for the trial must prescribe all IMPs or NIMPs on a trial specific prescription.

Check Chemolist and print clinical trial prescription confirmed by prescriber.

Pharmacist checks prescriber is on the trial delegation log and conducts clinical check in accordance with the protocol, randomisation/registration form, SOPSAT19 and any additional documentation.

Check the allergy status and patient's trial ID number have been added by the prescriber, add if these are missing. Any errors/omissions must be referred to the prescriber. Ensure the pharmacy clinical trials team and research nurse are aware of any delays.

If applicable, add IVRS/IWRS kit/batch numbers to prescription using printed confirmation form.

Use the Trial Status Inventory List to indicate on the prescription where all medication is to be supplied from (clinical trials, TTO packs, Healthcare at Home).

Once clinically checked, if the pharmacy clinical trials team are involved in ordering/dispensing, contact them to make them aware that the prescription is ready for collection.

If the IMP/NIMP is an RTA, dispense according to standard procedures. Ensure any additional labels required are obtained from the pharmacy clinical trials team.

Collect the prescription from the satellite unit.

If required, order and dispense the IMPs/NIMPs and obtain an accuracy check from the dispensary pharmacist.

Ensure the satellite dispensary have any additional labels they require.

Take a photocopy of the prescription and any additional documentation for the pharmacy trial file and give the satellite unit the original prescription on the day the dose is due to be administered.

As per standard procedure, the dose will be sent from the aseptic unit to the satellite unit without involvement of the pharmacy clinical trials team. Any alterations to standard procedure must be discussed during trial setup.

Collect IMPs and additional/supportive medication (if applicable) in accordance with standard procedures. Check that all prescribed medication is present. Sign and date the prescription to confirm collection. Research/specialist nurse to give the medication to the patient and counsel.