York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S92

Prescribing and processing oncology and haematology prescriptions for clinical trials

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Cheryl Donne & Poppy Cottrell-Howe
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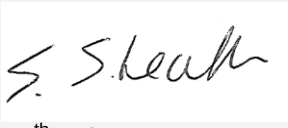
Approved by:	Name/Position:	Stuart Parkes Deputy Chief Pharmacist
	Signature:	
	Date:	14th July 2020
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
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This SOP will normally be reviewed every 3 years unless changes to the legislation require 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	Details of significant changes
1.0	14th September 2015	
2.0	11th August 2020	Change of author. Change of link to R&D website. Clarity of working processes to cover both York and Scarborough sites. All teams' responsibilities updated. Change of author. Updated flowcharts. Change of title.

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 given / administered to the patient in a safe and timely manner.

2 Who Should Use This SOP

The procedures described should be followed by oncology/haematology clinical trial prescribers who have been authorised to prescribe on the trial specific delegation log, members of the oncology/haematology research team, trained and authorised oncology/haematology pharmacists, members of the satellite unit team and the pharmacy clinical trials team.

3 When this SOP Should be Used

This SOP should be used when prescribing and processing clinical trial prescriptions involving oncology and haematology medication.

4 Procedure(s)

Flow charts for the order of processing Chemotherapy prescriptions for York & Scarborough Hospital sites are shown in Appendix 1 and 2 of this SOP.

All chemotherapy prescriptions will be generated on Chemocare unless prior exceptional agreement has been made at trial set-up.

Not all trials will be able to run in the format outlined below.
Some trials will have specific ways in which they will need dispensing due to blinding restrictions or other contributing factors. This will be communicated with the relevant research team when the study opens.

Research team responsibilities:

Contact the pharmacy clinical trials team as soon as a patient is booked in for a visit to collect/receive medication as part of a clinical trial this will also include any potential new patients that might enter into the study as well as all patients continuing on study treatment to allow for supplies to be ordered.

Failure to inform the pharmacy clinical trials team of prescriptions may result in the dose being delayed or missed.

For patients collecting their medication from Scarborough consider booking the patient in for their visit after 2pm if possible. This will allow for prescriptions to be sent on same day routine hospital transport if for any reason the prescription is unable to be generated in advance.

Inform the pharmacy clinical trials team if there are any cancellations or changes to appointments or treatments.

The research team must contact the oncology satellite unit directly when Chemocare prescriptions have been generated if the prescriber has not already done so. The sooner the prescription can be generated by the prescriber it will allow for more time for the rest of the processes and will help to reduce errors. The oncology satellite unit will then clinically check the prescription before releasing it to the pharmacy clinical trials team to be dispensed. **Failure to inform the satellite team of prescriptions will result in the prescriptions not being released for dispensing which will delay patient supply.**

The information required by the oncology satellite unit to locate and process the chemocare prescription will be: patient details, date and time of clinic visit or treatment & how many courses of treatment are expected. Also information the pharmacy clinical trials team so they can be ready to receive the prescription once checked.

At least 48 hours' notice is required for all products requiring preparation by the Aseptic unit. The research team must contact the oncology 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.

If a prescription is generated and printed in clinic (Usually Haematology prescriptions), the research nurse should ensure the pharmacy satellite unit are aware that the patient is waiting. The nurse can wait for the clinical check by an authorised Pharmacist and then bring it themselves to clinical trials pharmacy or make arrangements with the oncology satellite to get it to Pharmacy clinical trials for dispensing.

Collect completed prescriptions from the pharmacy clinical trials at York or from the main pharmacy reception at Scarborough. For prescriptions with space to sign for collection, sign the section when collecting from pharmacy.

A copy of the prescription will be provided for the patients notes. The original prescription will be kept in the pharmacy site file.

For patients collecting from **Scarborough** the original and any copies of the prescription will be kept by the research teams and will be collected regularly by the pharmacy clinical trials staff. The prescription will also be accompanied with a Transporting IMP between the York and Scarborough sites form Pharm/F84 this will require signing on collection and must be kept with the copies/original prescription for accountability. The completed forms will be collected by pharmacy clinical trials staff. If for any reason the prescription cannot be sent to the patient on routine transport liaise with the pharmacy clinical trials team to make arrangements to get the medication delivered to the patient. If the patient's prescription gets delivered to their house, obtain their signature on the Transporting IMP between the York and Scarborough sites form Pharm/F84.

Prescriber's responsibilities:

Only prescribers with the appropriate duties detailed on the individual trial delegation log are authorised to prescribe for a clinical trial. **This is for all stages of Chemocare prescribing.** It is the prescribing doctor's responsibility to be aware if they are able to prescribe. Prescriptions will be checked by an oncology satellite

pharmacist and Pharmacy clinical trials and any changes required could delay the supply of medication to the patient.

Chemocare Prescriptions for oral IMPs and nIMPs can be either printed by the prescriber in clinic or by the oncology satellite unit. Aseptically prepared items must be printed in the oncology satellite unit. The prescriber should add the patient's trial ID number and allergy status to the prescription electronically.

If required for the trial the nurses must be contacted to perform any randomisation/allocation in the IWRS so that the correct IMP treatment pack number or treatment arm can be allocated by pharmacy.

The start date of treatment, cycle and visit number, and quantity of medication must be prescribed in line with the study protocol.

If a prescribing error/omission is detected by the oncology satellite unit, the prescription will be returned to the prescriber to be amended they will be contacted by the most suitable method as the prescriber maybe off site. 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. This may result in delays to the patient receiving treatment.

Serious errors will be reported through the DATIX System.

At least 48 hours' notice is required for all products requiring preparation by the Aseptic unit, if urgent items are needed, contact all the relevant parties to make arrangements to supply and prepare the items.
For patients that collect prescriptions from Scarborough consider that the prescription is dispensed on the York site and prescriptions and medication will be sent on routine hospital transport that leaves the York site at 12pm daily and will arrive at the Scarborough site at approximately 1.30pm/2pm the same day. Allow enough time for the prescription to be checked, dispensed and sent on transport for the patient to collect in clinic. (Minimum 24 hours' notice) Failure to give enough notice will result in patient's not being able to collect their medication and will require alternative delivery methods.

Pharmacy clinical trials team responsibilities:

When informed by the research teams of a patient attending clinic to collect/receive a prescription, add the appointment to the workflow diary to allow for correct planning.

Ensure there are adequate supplies available for the patient's visits.

Clinical trials pharmacy will be responsible for managing stock of IMP for all studies. Effective communication of patient's treatment dates and appointments will enable the IMP stock to be available when required.

When randomisations/allocations are generated by the research teams, forward a copy to the oncology satellite team if needed for clinical checking.

Only prescribers that have prescribing delegated duties on the trial delegation log can prescribe for a clinical trial. The clinical trials pharmacy team will check the prescription against the delegation log once the prescription is received in the department. The most up to date copy of the delegation can be obtained from the research teams.

Pharmacy clinical trials team will complete the required order paperwork to the aseptic team to allow them to create worksheets to make the requested product.

Pharmacy clinical trials will dispense the required items on the prescription, listed in the study protocol that are IMP or nIMP that require accountability which include:

Oral items:

- IMP or nIMP supplied by the sponsor
- Products classed by the sponsor as IMP and nIMP which is sourced, ordered, supplied and accounted for by the pharmacy clinical trials team.

  If there is any supply issues with standard/supporting elements of the chemocare prescription (medication not classed as IMP or nIMP as part of the study) that cannot be obtain from the standard route e.g. from TTO packs on the ward or from Lloyds pharmacy, then the pharmacy clinical trials team (if stock levels in the main hospital pharmacy allows) may supply these also if requested by the research team.

Aseptically prepared items:

- IMP or nIMP supplied by the sponsor - the raw elements and sundry items used to prepare the product will be dispensed to the aseptic team directly before the product is to be prepared to maintain accountability and temperature monitoring.
  Depending on the individual trial arrangements pharmacy clinical trials may need to supply trial specific labels for items being supplied by the oncology satellite unit or aseptics. Refer to the study specific SOPs in the pharmacy site file.

nIMP which are not supplied by the sponsor may require accountability to be completed by the pharmacy clinical trials. Complete the relevant accountability and patient specific logs retrospectively when the associated documentation is provided by the oncology satellite or aseptics. Refer to the study specific SOPs in the pharmacy site file for clarification if this is required.

The Pharmacy clinical trials team will perform accountability for IMP and nIMP for products made in the aseptic unit, photocopy/return processed worksheets and preform label accountability as required. Store the copied paperwork in the pharmacy site file with the patient's prescription and return the original to aseptics.

Pharmacy clinical trials may be required to deliver products directly to the treatment areas for some blinded studies; these arrangements will be made prior to the study opening.

The pharmacy clinical trials team will be responsible for liaising with the research teams to ensure the completed prescription is collected or transported ready for the patients visit.

For patient's collecting their prescription from the Scarborough site, follow the study specific SOPs in the pharmacy site file. Prescriptions will be sent with a Transporting IMP between the York and Scarborough sites form Pharm/F84. These completed forms will be collected regularly from the Scarborough research team and filed in the pharmacy site file upon return. Original and copies of the prescription will also be regularly collected from the research teams at Scarborough and filed in the pharmacy site file.

If the patient collects their prescription from pharmacy clinical trials/gets delivered to their house. Obtain their signature on either the prescription or Transporting IMP between the York and Scarborough sites form Pharm/F84. If a taxi is used follow the main pharmacy procedure. Store associated paperwork and correspondence with the patient's prescription in the pharmacy site file.

The oncology satellite unit responsibilities:

All clinical trials oncology and haematology prescriptions will be processed through the oncology satellite unit for a clinical check for both the York and Scarborough sites.

All prescriptions will be clinically checked in accordance with SOPSAT19 (Systemic anti-cancer therapy clinical check parameters)
The clinically checking pharmacist must be trained how to check clinical trial prescriptions.

All items supplied by the sponsor (IMP or nIMP) will be dispensed by the pharmacy clinical trials team; however other items on the prescription may need to be obtained through other routes, e.g. TTO packs or Lloyds. Standard of Care IV products (Items that are not IMP or nIMP that are not supplied by the sponsor/pharmacy clinical trials) requiring aseptic preparation will be ordered by the oncology satellite team and orders sent direct to the aseptic.
Ready to administer (RTA) products not supplied by the sponsor will be ordered and dispensed by the oncology satellite unit team.

A copy of the most up to date delegation log can be obtained from the pharmacy clinical trials team or the research team if required for checking or query purposes. The oncology satellite checking pharmacist will contact the pharmacy trials team to forward the patients randomisation when required.
The checking pharmacist can add the patient's trial number and allergy status to the prescription if the prescriber has not done so by using a suitable trial document or source such as the patient's randomisation paperwork. This can be done electronically or manually.
The oncology satellite unit will call pharmacy clinical trials when a checked prescription is ready for collection or hand it to the research nurse to take to pharmacy clinical trials
Requests for additional/supportive medication should be sent to the Lloyds pharmacy or supplied from TTO packs. This should be annotated on the prescriptions. If there are issues with this method of supply contact the pharmacy clinical trials team to see if they can facilitate supplying the items.

The oncology satellite unit will contact the prescriber directly to correct any prescribing issues regarding the prescriptions and feedback to the research nurses and pharmacy clinical trials team of possible delays.

The pharmacist providing the clinical check must sign the prescription either electronically or manually indicating the Clinical check is complete so dispensing can be done.

For all products supplied as part of a clinical trial that requires accountability by the sponsor order/dispensing paper work and worksheets should be supplied to the pharmacy clinical trials team for photocopying and saving in the pharmacy site file.

5 Related SOPs and Documents

York and Scarborough Teaching Hospitals 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

SOPSAT19 Systemic Anti-Cancer Therapy Clinical Check Parameters

Pharm/F84 – Transporting IMP between York and Scarborough Sites Form

Appendix 1) Processing research prescriptions at York

Patients booked in for a clinic visit where they will be collecting a prescription

Inform the pharmacy clinical trials team of the planned patient visit

Ask the clinician to prescribe the required treatment for the patient

Request that the prescription is written as early as possible, this is to allow for any corrections to be made.

Ensure you inform them of any additional information they may need to know e.g. how many cycles are needed

Check with the prescriber or on Chemocare that the prescription is prescribed

If it is a clinical trials prescription (paper copy)

Bring the completed original prescription to the pharmacy clinical trials dispensary

If a randomisation is needed ensure this is also completed and communicated with the pharmacy clinical trials team.

Print the randomisation allocation if needed

Dispense the prescription

If there are issues found with the prescription inform the research nurses to ask the prescriber to make the corrections as soon as they can.

Ring the research team to collect the prescription or make arrangements with the team as to when it will be collected or delivered to the patient/clinic.

Retain the original prescription within pharmacy and endure the research team as a copy of the prescription for their records.

Collect the prescription from pharmacy clinical trials and retain the photocopy of the prescription.

Chemocare prescriptions only –
Ensure the prescription has been marked as complete on chemocare

If the prescription is on Chemocare (Oncology/haematology prescriptions only)

If a randomisation is needed ensure this is also completed and communicated with the pharmacy clinical trials team so they can print and give to the oncology satellite team

Phone the oncology satellite team that the prescription is ready to be clinically checked and handed to the pharmacy clinical trials team for dispensing or bring it to the pharmacy clinical trials team once printed and ready to dispense.

Clinically check the requested Chemocare prescription

Inform the pharmacy clinical trials team of any delays due to issues/corrections with the prescription as this might impact on transport times

Any issues with the prescription are communicated with the prescriber

Give the clinically checked chemocare prescription to the pharmacy clinical trials team

Inform the research team if delays will impact on the patient's visits/clinic appointment

Dispense the prescription

For IV aseptic products only
Coordinate with the pharmacy aseptics team when they need to make the product for the patient's visit and ensure they have the raw product available on the morning or afternoon of preparation.

Prepared IV products will be delivered to the ward/unit by the aseptics department and given by the nurses on the ward/unit

For IV aseptic products only
Obtain copies of the worksheets and any other paperwork related to the prescription that aseptics or the oncology satellite may have and store in the PSF.

Key:

Blue – responsibility/actions for Research Nurses/Team

Green - responsibility/actions for Pharmacy Clinical Trials Team

Purple - responsibility/actions for Oncology Satellite Team

Please note that not all trials will be able to run in the format outlined above.
Some trials will have specific ways in which they will need dispensing due to blinding restrictions. This will be communicated with the relevant research team when the study opens.

Phone numbers

Pharmacy Clinical Trials office – 72 1684

Oncology Satellite office - 72 1298

Pharmacy Aseptics – 72 5977

Appendix 2) Processing research prescriptions at Scarborough

Patients booked in for a clinic visit where they will be collecting a prescription

Where possible plan visits for after 1.30pm this will allow for prescriptions to be sent on transport the same day if needed

Key:

Blue – responsibility/actions for Research Nurses/Team

Green - responsibility/actions for Pharmacy Clinical Trials Team

Purple - responsibility/actions for Oncology Satellite Team

Inform the pharmacy clinical trials team of the planned patient visit

Ask the clinician to prescribe the required treatment for the patient

Request that the prescription is written as early as possible, this is to allow for any corrections to be made.

Ensure you inform them of any additional information they may need to know e.g. how many cycles are needed

Check with the prescriber or on Chemocare that the prescription is prescribed

If it is a clinical trial prescription (paper copy)

If the prescription is on Chemocare

If a randomisation is needed ensure this is also completed and communicated with the pharmacy clinical trials team so they can print and give to the oncology satellite team

Email the prescription to the pharmacy clinical trials team joint mailbox
Retain the original prescription

If a randomisation is needed ensure this is also completed and communicated with the pharmacy clinical trials team

Phone the oncology satellite team that the prescription is ready to be clinically checked and handed to the pharmacy clinical trials team for dispensing

Clinically check the requested Chemocare prescription

Print the prescription (and randomisation if needed)

Any issues with the prescription are communicated with the prescriber

Inform the pharmacy clinical trials team of any delays due to issues/corrections with the prescription as this might impact on transport times

Dispense the prescription

Give the clinically checked chemocare prescription to the pharmacy clinical trials team

Inform the research team if delays will impact on the prescription missing the planned transport and make alternative plans if needed

If there are issues found with the prescription inform the research nurses to ask the prescriber to make the corrections when they are next on site

The original prescription will need to be amended by the prescriber. Ask them to make the corrections and email the updated prescription back to the pharmacy clinical trials team

Dispense the prescription

Send on the next available hospital transport

If for any reason the prescription cannot be placed on hospital transport arrange for another method of transport with the research nurse/patient

The prescription is received by Scarborough pharmacy staff members

If a temperature excursions or damage has occurred during transit, arrange for more supplies to be sent.
Communicate this with the research team as it might impact on the patients visit.

Collect the prescription from Scarborough pharmacy

Sign the accompanying form indicating you have collected the prescription. Retain the form and original prescription, a member of the pharmacy clinical trials team will collect these when they next visit Scarborough.

Important information

Hospital transport times leaves York at 12 noon arrives at SGH approximately 1.30/2pm

Phone numbers

Pharmacy Clinical Trials office – 772 1684

Oncology Satellite office – 772 1298

Chemocare only –
Ensure the prescription has been marked as complete on chemocare

Collect original prescriptions and accompanying paperwork on next site visit to SGH