Clinical Trials Daily Tasks

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

All staff should regularly check the R&I Department'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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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&I Department 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&I Department website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	4th December 2024
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	Date:	12th December 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	20th August 2015		
2.0	21st December 2017		Change of author. Reference to the electronic prescribing system.
3.0	3rd September 2020		Change of link to R&D website. Change of author. Removed non-relevant procedures. Changed procedure to remove drug charts but to include EPMA. Changed procedure to not have pharmacy clinical trial staff going on to the ward but to liaise with the ward pharmacy staff as EPMA can be viewed remotely.
4.0	21st February 2024	Rachel Spooner	Change of author. Addition of check of ePMA prescribing.
5.0	6th January 2024	Rachel Spooner	Change of SOP name. Reference to daily temperature checks, wardlist checks and EDGE calendar checks.

Contents

1   Introduction, Background and Purpose

There are 3 tasks that must be performed on the morning of each weekday within Pharmacy Clinical Trials. These tasks are:

- Daily Temperature Checks and Monitoring
- Daily Wardlist check
- Daily EDGE calendar check

These tasks are essential to ensure that IMP is stored correctly and is safe to be used, that any trial patients admitted to hospital are identified as soon as possible so that appropriate steps can be taken, and that any prescription visits planned and logged on the EDGE calendar are reviewed by a member of Pharmacy Clinical Trials.

This SOP details the process for checking the CPD wardlist and the actions to be taken following the identification of any trial patients admitted to hospital. This SOP also details how to access the EDGE calendar and the steps to take when trial patient visits requiring prescriptions are booked in and logged on EDGE. The process for completing the daily temperature checks is detailed in Pharm/S48.

2   Who Should Use This SOP

This SOP should be used by all members of the pharmacy clinical trials team within York and Scarborough Teaching Hospitals NHS Foundation Trust who need to check the CPD wardlist for newly admitted clinical trial patients or have been notified of a patient on a clinical trial from outside of the Trust, and who need to track trial patients' prescription visit using the EDGE system.

3   When this SOP should be used

This SOP should be used every weekday (except on Bank Holidays) to check for newly admitted patients, to check the prescribing/administration of any IMP on ePMA for current clinical trial inpatients, or when notified of a patient on a ward participating in a clinical trial from outside of the Trust. This SOP should also be used to view any planned trial patient visits using EDGE which require clinical trial prescriptions to be dispensed so that this can be accounted for in the clinical trials team's workload planning and capacity.

4   Wardlist check procedure

Patients that are participating in Trust sponsored/hosted clinical trials could be admitted into hospital. Identification of these patients is crucial so that any Investigational Medicinal Product (IMP) or Non-Investigational Medicinal Product (NIMP) can still be administered to the patient if appropriate. Identification of these patients will be done using the Core Patient Database (CPD), as all clinical trial patients will have an alert put on their CPD record. The pharmacy clinical trials team will assess whether the patient has sufficient IMP/NIMP supply for the duration of their hospital stay, and confirm

that any prescribing/administration of IMP on ePMA is correct and uses the approved ePMA clinical trial order sets (if applicable for the study).

4.1 Access wardlist on CPD and view current in-patients on a clinical trial

1. Log onto the Core Patient Database (CPD)
   - Click on Start (on the task bar)
   - Search for, and click on, 'CPD'.
2. Go to Forms, Inpatients and then List patients on ward (Wardlist).
3. Type YD (for York) and SH (for Scarborough) in the Hospital box.
4. Click Filters.
5. Click on the clipboard next to Select Alerts.
6. Click Drug Trial and click OK.
7. Click Save and Close.
8. Check the results for newly admitted patients since the last check was done, and any clinical trials patients previously identified that are still currently an inpatient.

4.1.2 Identify which trial the patient is taking part in

1. Click on the exclamation mark (!) next to the patient's name to determine which trial they are participating in and if it involves IMPs and/or NIMPs. Document accordingly on a Pharmacy Clinical Trials Wardlist Check Form (Pharm/F102). This form must be completed even if there are no patients on IMP's and /or NIMP's by ticking 'No new patients'. Click close then repeat this exercise for each patient.
2. Close CPD

4.2 Procedure to follow for a newly-identified clinical trial patient:

1. Once a new patient on a clinical trial has been identified since the last check was completed, check the relevant clinical trials file to determine whether the patient is currently receiving treatment with IMPs or NIMPs. Record patient and medication details on form Pharm/F102.
2. The Pharmacy clinical trials team do not need to take any further action if the patient is not currently receiving trial specific medication other than record this on Pharm/F102.
3. Inform a clinical trials pharmacy technician of the new patient and the trial involving IMPs/NIMPs they are on.
4. A clinical trials pharmacy technician should inform the ward Pharmacist/Meds Man Technician of any trial patient(s) on their ward, the medication involved, including the dose, duration and date of last dispensing episode.
5. Ask the ward pharmacist to confirm that the patient has their trial medication with them and that there is an appropriate quantity to cover their stay in hospital. If a sufficient supply of medication isn't available, then the research team should be contacted.
6. For patients on clinical trials that require ePMA prescribing, refer to section 4.3.

4.3 Procedure for checking patient's ePMA records and clinical trial prescribing – Clinical Trials Pharmacy Technicians or appropriately trained and competent Clinical Trials Pharmacy assistants only.
1. This procedure is relevant for patients identified as being on a clinical trial that requires ePMA prescribing as per the study specific SOPs, for example for

studies requiring doses to be administered on the ward using approved clinical trial ePMA order sets.

2. Log on to CPD using the procedure in section 4.1, and locate the previously or newly identified patient on a relevant clinical trial using the procedure in section 4.1.2.
3. Double click on the patient's name on CPD
4. At the bottom of the newly opened CPD window, select the 'medication' button.
5. The patient's ePMA record will then open, displaying their 'current medications'.
6. Check that IMP/NIMP has been prescribed correctly on ePMA as per the study specific SOP in the relevant PSF and using the approved clinical trial order set (if appropriate). It is important to check that the prescribing is clear, accurate and that any protocol-defined medication durations are clearly documented.
7. For the IMP/NIMP prescribed, select the small calendar icon ('audit information') to view the administration of IMP on the ward, and confirm that any specific administration requirements, such as form or route of administration, are being adhered to.
8. If any issues are highlighted, contact the research team or ward pharmacist to review.
9. All clinical trial inpatients receiving IMP/NIMP on the wards **must have their ePMA records checked on a daily basis** to confirm that administration/prescribing continues to be accurate until the patient's discharge or treatment end. This includes for if the patient is transferred to a different site, for example SGH, Bridlington or Whitecross Court.
10. Once checked, select the check box 'ePMA check completed' on Pharm/F102 for that date to confirm all relevant clinical trial patients have had their ePMA records checked.

4.4 Procedure for ensuring the patient's trial medication is added to EPMA.

For clinical trial patients admitted to hospital, if clinically appropriate and/or specified in the study specific SOPs in the Pharmacy site files, the patient's trial medication should be prescribed on ePMA (the electronic prescribing system used for inpatients at both York and Scarborough sites).
Check with the research team and ward pharmacist if the trial medication should be continued and prescribed for the patient during their inpatient stay.

If it is to be continued, explain to the ward pharmacist how it should be prescribed on to EPMA using the free text function. It must state that it is part of a clinical trial and a note can be added to inform of the location of the trial medication. 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 – clinical trial supplies kept in patient's locker".

4.4 Procedure to follow when a patient is admitted into hospital whilst taking part in a clinical trial not hosted by York Hospital or Scarborough Hospital which form part of the York and Scarborough Teaching Hospitals NHS Foundation Trust.

If a patient is admitted into hospital and is currently taking part in a clinical trial not hosted through York Hospital or Scarborough Hospital, this would not

show up on CPD. The ward Pharmacist/Meds Man Technician would inform the Pharmacy clinical trials team of any such patient.

Upon notification of such a patient, ask the ward pharmacist/MMT to obtain the following information if possible

- The IMP/NIMP that the patient is taking
- The hospital name that is hosting the clinical trial
- The clinical trial name and the Sponsor
- How much medication the patient has

Pass this information on to the relevant research nurse for that speciality where they will investigate further. Work together with the research team to ensure the patient has the enough trial drug during their impatient stay and if clinically appropriate request it to be added on to EPMA following the procedure in 4.4 above.

At the end of each month, file the completed forms in the designated file. Forms should be retained for 12 months. Forms older than 12 months should be destroyed by placing into confidential waste.

5   Daily Temperature Checks procedure

Refer to Pharm/S48 (Temperature Monitoring (Clinical Trials)) for details on how to complete the daily temperature checks within Pharmacy Clinical Trials.

6   Checking the EDGE system for clinical trial prescription visits

The EDGE system is used by both Pharmacy Clinical Trials and the Research teams to track various study information, study finances and clinical trials patient visits.
The research teams also log patient visits on to the calendar on the EDGE system, attaching the 'Pharmacy team' to the visit a prescription or IMP supply is required.

As such, it is essential for this calendar to be checked daily to ensure that the Pharmacy Clinical Trials team are aware of any new upcoming appointments so that this can be planned into the team's workload and capacity.

1. Log onto the EDGE system at www.edge.nhs.uk using your personal username and password.
2. From the Home page, click on the 'Calendar' button on the left-hand side.
3. Select the dropdown button under 'My Team's Calendars'.
4. Select 'Pharmacy Team'. This adds all appointments and visits to the calendar that have been linked to the Pharmacy team by the research team when booking in the visit. These appointments should all involve Pharmacy in some way, whether that be a requirement to issue IMP, or dispense a clinical trial prescription.
5. Review the next 7 days, and check to see what appointments have been booked in. **Note:** clicking on the appointment itself will open further details regarding the visit, including the patient details, trial details, the staff involved in the visit, and any comments added by the research team.
6. On the Outlook Calendar for the joint pharmacy clinical trials team mailbox, check that all appointments logged on EDGE for the next 7 days have been noted in the outlook calendar. This ensures that all members of the pharmacy

clinical trials team can view what prescription visits are upcoming and plan accordingly.

7. If any new appointments have been added to EDGE, add this to the correct date/time on the joint outlook calendar, ensuring that the name of the study, and patient trial ID or initials are added to the description. Ensure the visit is categorised in the 'Prescription visit' colour for clarity.

8. Logout of EDGE.

7   Related SOPs and Documents

Pharm/F102 Pharmacy Clinical Trials Wardlist Check Form

Pharm/S48 Temperature Monitoring (Clinical Trials)