

Clinical Trials Wardlist Check Instructions

Procedure to check the Core Patient Database (CPD) for inpatients taking part in a clinical trial


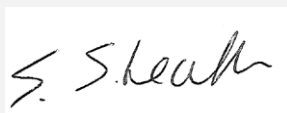
**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE
THAT THE CORRECT VERSION IS BEING USED**

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S97
Version Number:	3.0
Author:	Courtney Cole
Implementation date of current version:	3 rd September 2020

Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Signature:	
	Date:	6 th August 2020
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	6 th August 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	20 th August 2015	
2.0	21 st December 2017	Change of author. Reference to the electronic prescribing system.
3.0	3 rd 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.

Contents

		<u>Page No</u>
1	Introduction, Background and Purpose	1
2	Who Should Use This SOP	1
4	Procedure(s)	1
5	Related SOPs and Documents	3

1 Introduction, Background and Purpose

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.

This SOP details the procedure for identification of such patients and the actions to be taken by the Pharmacy clinical trials team.

This SOP details what course of action should be taken in the event of a patient being admitted to hospital who is 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.

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.

3 When this SOP should be used

This SOP should be used every weekday (except on Bank Holidays) to check for newly admitted patients or when notified of a patient on a ward participating in a clinical trial from outside of the Trust.

4 Procedure(s)

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)
 - Click on All Programs
 - 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 that have been admitted into hospital since the last check was done.

4.1.2 Identify which trial the patient is taking part in

1. Click on the exclamation mark (!) next to the patients 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 we have no patients on IMP's and /or NIMP's by annotating NA (not applicable) in the relevant fields. Click close then repeat this exercise for each patient.
2. Close CPD.
3. At the end of each month, file the completed form in the designated file. Forms should be retained for 12 months. Forms older than 12 months should be destroyed by placing into confidential waste.

4.2 Procedure to follow if a patient is on a clinical trial

1. Once a patient on a clinical trial has been identified, 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. The Senior Pharmacy Technician or Pharmacy Clinical trials manager 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.
4. 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

4.3 Procedure for insuring the patient's trial medication is added to EPMA.

If clinically appropriate the patient's trial medication should be added on to EPMA which is 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 4.3 above.

5 Related SOPs and Documents

Pharm/F102 Pharmacy Clinical Trials Wardlist Check Form