

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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Author:	Sacha Honour
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Approved by:	Name/Position:	Jax Westmoreland, Principal Pharmacist, Clinical Trials and Research
	Signature:	Signed copy held by R&D Unit
	Date:	23 <sup>rd</sup> November 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	23 <sup>rd</sup> November 2017

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 <sup>th</sup> August 2015	
2.0	21 <sup>st</sup> December 2017	Change of author. Reference to the electronic prescribing system.

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## 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 Teaching Hospital 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 Teaching Hospital 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.

#### 4.1.1 Check for newly admitted patients

1. Tick Admin (this then displays how long a patient has been in Hospital).
2. Tick LoS (Length of stay) button (this will put the number of days a patient has been in hospital in ascending/descending numerical order as you click).

3. Check 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 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. The Senior Pharmacy Technician will go to the ward and 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 by the Senior Pharmacy Technician

#### **4.3 Procedure for ward Pharmacists to follow when checking a patient drug chart**

1. The pharmacist must ensure all trial medication has been prescribed appropriately on the drug chart if clinically appropriate (this includes the electronic prescribing system).
2. A clinical trial inpatient label (which will be provided by the pharmacy clinical trials team on request) or an annotation should be placed/entered on the drug chart in an appropriate space by the ward Pharmacist. The clinical trials inpatient label hand written annotation should be completed with the name of the clinical trial the patient is participating in and the location of the trial specific medication (e.g. patient's own locker). If there is space available in the 'additional instructions' section of the drug chart, next to each trial specific drug, write 'Use trial specific medication' or add a note on the electronic prescribing system.
3. The Pharmacist should inform the Nurse involved in the patients care or Ward Sister that they have a patient on a pharmacy clinical trial and where the trial medication is being stored.

#### **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 Teaching Hospital 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, a senior pharmacy technician from the clinical trials team will go to the ward and see the patient if possible to obtain the following information.

- 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

If the patient has an insufficient supply of IMP/NIMP the senior pharmacy technician will have to contact the Research Team at the hospital that is hosting the clinical trial and request a further supply and arrange delivery of the medication (this may be that the patient has a representative that can collect this medication).

If further advice or assistance is required contact the relevant research nurse for that speciality.

## **5 Related SOPs and Documents**

Pharm/F102 Pharmacy Clinical Trials Wardlist Check Form