York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
Pharm/S101

Delivering clinical trials prescriptions to patient's homes under exceptional circumstances

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Date:	17th September 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17th September 2024

This SOP will normally be reviewed at least 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	8th April 2020		
2.0	15th October 2024	Rachel Spooner	Change of Trust name. Removal of the COVID specific information. Added in things to consider before agreeing a delivery.

Contents

1 Introduction, Background and Purpose

Following the COVID-19 pandemic, procedures were created to accommodate clinical trials patients to continue to receive their trial medication, without having to attend a hospital site in person. This standard operating procedure is created to ensure there is a process in place for clinical trials patient's to have their treatment delivered to their homes or care facility under exceptional circumstances and following approval from the individual trial sponsor.

The deliveries of the clinical trials medication to clinical trials patients need to be done by members of staff qualified to do so.
Some sponsors may have made allowances for their trial IMP to be delivered to patients homes, there maybe approved couriers in place or they may reimburse a delivery fee. This must be clarified with the sponsor prior to agreeing to delivery IMP to a patient. Cost must be logged on the EDGE system.

2 Who Should Use This SOP

3 This SOP should be used by any member of the research and development team that is going to be involved in the delivery of clinical trial to the homes of patient who need them. When this SOP Should be Used

This SOP should be used whenever a delivery of clinical trial medication is required to a patient under exceptional circumstances.

4 Procedure(s)

Prior to agreeing to have to have a patient's IMP delivered to their home or care facility consider:

- Have other options been explored? Could a relative or carer collect or can the can it be collected on another day?
- Storage requirements – is there a need for a temperature logger and or a insulated cold chain shipper?
- The type of IMP – Is it a high risk drug or controlled drug?
- Are there any cautionary handling requirements? E.g. cytotoxic
- How long is the journey?
- Can you use a Trust pool car or have the correct insurance?
- Have you got sponsor approval if needed.

1. A patient needing a delivery will need to be identified by the research nurse who is dealing with the patient. When clinical trials medication is required,

they should let the clinical trials pharmacy know that this medication will need to be delivered.

2. The prescription and dispensing procedure remains the same and should be conducted as normal.
3. The Pharmacy clinical trials team will also check to see if the sponsor may have made other arrangements for getting medication to patient's homes. Some sponsors are providing a deliver service themselves.
4. When the medication is ready the pharmacy clinical trials will contact the qualified member of staff that is to be delivering the IMP to the patient's home or care facility.
5. Once the relevant member of staff has been selected to deliver the medications the clinical trials pharmacy staff will complete the pharmacy section on the Pharm/F92-Clinical Trials Delivery Form
    - The patient must be contacted before delivery to ensure they will be there to accept the medications. Patient consent must be given by the patient allowing the delivery of their medication by a research nurse or member of pharmacy clinical trials.
    - No information on the form must indicate the patient's care or treatment.

6. The medication will be placed in a pharmacy paper bag.
7. The member of staff collecting and delivering will complete the relevant section of the Pharm/F92-Clinical Trials Delivery Form
8. The member of staff delivering the medication must drive direct to the patient's address.
9. Once at the address,. Ask the patient or carer to confirm the patient's date of birth stated on the delivery form.
10. Complete the relevant section on the form and return it to pharmacy clinical trial when you are next on site.
11. The completed for must be store in the pharmacy site file for the study to maintain accountability.

If there are any problems with a planned delivery call the pharmacy clinical trials team on 01904 721684.

5 Related SOPs and Documents

Pharm/F92 Clinical Trials Delivery Form