Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

Clinical trials involving pharmaceutical products

Ref PHARM-0002-005-v2

Status: Approved
Document type: Procedure

Contents

1 Purpose

Following this procedure will allow the Trust to:-

- Ensure the safe and ethical use of investigational medicines by our service users
- Comply with legal and regulatory requirements in the authorised supply of investigational medicines
- Ensure that the supply of clinical trial medicines to service users is done with knowledge and approval of R&D and Pharmacy
- Ensure compliance with Good Clinical Practice (GCP)
- Ensure research integrity and compliance with General Data Protection Regulations (GDPR)

Since April 2016, the Health Research Authority (HRA) has been the governing body for approving all research in the NHS, including that involving investigational medicinal products (IMPs).

The HRA approval system draws together the Research Ethics Committee (REC) recommendations and the clinical trial authorisation from the Medicines Healthcare Regulatory Authority (MHRA), the licensing authority.

Tees, Esk and Wear Valleys NHS Foundation Trust must comply with this regulatory framework for clinical trials involving medicines to ensure the safety of our service users recruited into clinical trials. The Research Governance Group, a sub-committee of QuAC, provides corporate assurance that research activity meets the required quality and governance standards.

TEWV hosts clinical trials involving medicines sponsored by pharmaceutical companies, universities, charities and other bodies. Working in partnership together, the departments of Pharmacy and Research and Development, ensure the safety, integrity and quality of research is maintained, to contribute to global evidence based medicine.

2 Related documents

This procedure describes what additional requirements are necessary for the safe and ethical use of investigational medicines, in the 'Clinical trials involving pharmaceutical products' section of the Medicines Overarching Framework.

The Medicines Overarching Framework defines compliance requirements for prescribing and initiating treatment safely which you must read, understand and be trained in before carrying out the procedures described in this document.

The Pharmacy Clinical Trial Service works to their own set of approved SOPs for every step and every task in clinical trial investigational medicinal product (CTIMP) management.

Research and Development work to their own set of approved SOPs covering every step of assessing, confirming, arranging and participating in clinical trial activity.

Management of suspected research fraud or misconduct R&D SOP 23

Other relevant documents and guidance:

- Safe and Secure Handling of Medicines: A Team Approach. Royal Pharmaceutical Society Guidance 2005
- Good Clinical practice Guide, MHRA, First published 2012
- Professional Guidance on Pharmacy Services for Clinical Trials, National Pharmacy Clinical Trials Advisory Group (NPCTAG) 2013

3 Issues relating to clinical trial investigational medicinal products (CTIMPs)

3.1 Approval of research involving medicines

All research, particularly that involving medicines MUST be approved by Research and Development and Pharmacy

- R&D can direct prescribers wishing to undertake their own research to appropriate sources for assistance, for example, with defining the research question, grant applications, and how to submit for ethical approval
- Research by any practitioner, even if using licensed medicines, MUST be assessed and approved by R& D from the outset
- Clinical trials of investigational medicinal products sponsored by pharmaceutical companies, universities, charities and other bodies will use the national HRA approval process, but still need local R&D and Pharmacy approval before commencement in TEWV.

All staff planning to conduct research should contact the Research and Development department with an initial email contact to tewv.researchanddevelopment@nhs.net to outline their proposal and confirm plans for seeking research approvals.

Research conducted without necessary approvals will be investigated, and the practitioner referred to HR and professional bodies as deemed appropriate.

3.2 Commencement of a clinical trial

Once a clinical trial involving medicines has been accepted by TEWV, R&D and Pharmacy will undertake a set of checks to ensure the study protocol, documentation and medicinal products comply with GCP.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human participants.

At the outset, before recruiting any service users to a study, brief guidance for ward staff on the specific study is prepared, that details what to do if a patient is admitted to a ward on a clinical trial medicine. This includes a summary of the study, how to prescribe, handle and store the investigational medicines, and contact details for the study team.

An up to date list of all current clinical trials involving medicines recruiting in TEWV is available on the intranet, following the link below:

http://intouch/SERVICES/CLINICAL/PHARMACY/Pages/ClinicalTrials.aspx

Most studies will have a mechanism in place for the continued supply of the investigational medicine beyond the end of the study, for those service users who have benefited from the treatment within the study.

Occasionally, a provision for this may not be included in the original protocol. Principal investigators may request to obtain a supply of the trial medicine on an individual basis, if this is possible and can be justified. The Drug and Therapeutics Committee should be approached at the commencement of the study, if this is deemed likely.

3.3 Storage of investigational medicines in clinics or departments

Due to logistics, and TEWVs large geography, it may require pharmacy to dispense and deliver a clinical trial medicine to a location remote from the Pharmacy Clinical Trial Service.

The following rules apply to comply with GCP:

- All areas required to store clinical trial medicines must be risk assessed at the outset
- Clinical trial medicines should be physically separated from other medicines
- The temperature of the storage area requires regular measurement.
- Access to the investigational products should be restricted to only those persons involved with the study.
- Monthly audit of the security, segregation and temperature monitoring will be undertaken on any remote storage area that holds investigational medicinal products for a specific study.

4 Responsibilities of the Pharmacy Department

Pharmacy and R&D will ensure that an adequate skill mix of personnel, are appointed/rostered to the Pharmacy Clinical Trial Service to ensure the safe running of clinical trials involving medicines in TEWV.
The Pharmacy Clinical Trial Service is responsible for ensuring that all clinical trial materials are of an appropriate quality for use in TEWV at the set-up of the trial: this includes both licensed and unlicensed medicines, their labelling, packaging and patient information leaflets. Pharmacy will ensure that relevant legislation and guidance is followed regarding the investigational medicinal products.
All pharmacy staff involved in approval, dispensing or checking of any clinical medicines will be provided with training either in-house or via the trial sponsor.
Clinical trial investigational medicinal products (CTIMPs) must be stored in dedicated temperature controlled and monitored facilities within TEWV, separate from routine pharmacy stock.
The Pharmacy Clinical Trial Service must have standard operating procedures in place covering all aspects of the clinical trial process including approval, receipt, temperature monitoring, storage, dispensing, maintaining and archiving trial documentation, and issue to service users or research staff.
The Pharmacy Clinical Trial Service is responsible for ensuring up to date information for out of hours use, in case of admission of trial patients, or the need to un-blind a patient in an emergency situation
Pharmacy Trial Files will be returned to sponsors at the close down of the trial. Any patient identifiable data will be obliterated or removed to comply with GCP and GDPR. Copies of prescriptions will be retained and archived for 15 years after the last patient completes the trial medicines.

6 Document control

Date of approval:	24th May 2018	
Next review date:	1st December 2021	
This document replaces:	PHARM-0002-005-v1	
Lead:	Name	Title
	Angie Hardy	Senior Clinical Pharmacist – R&D
Members of working party:	Name	Title
	Sarah Daniel Chris Williams	R&D Manager Chief Pharmacist
This document has been agreed and accepted by: (Director)	Name	Title
	David Brown	Acting Chief Operating Officer
This document was approved by:	Name of committee/group	Date
	Drug and Therapeutics Committee	24th May 2018
Amendment details:	V2 - May 2018 - Updated to include regulatory and in-house approval frameworks V2- May 2018 - Updated to include the role of the in-house Pharmacy Clinical Trial Service. V2- April 2021 – review date extended to 01 December 2021	