



# Pharmacy Technicians and their role in Clinical Trials

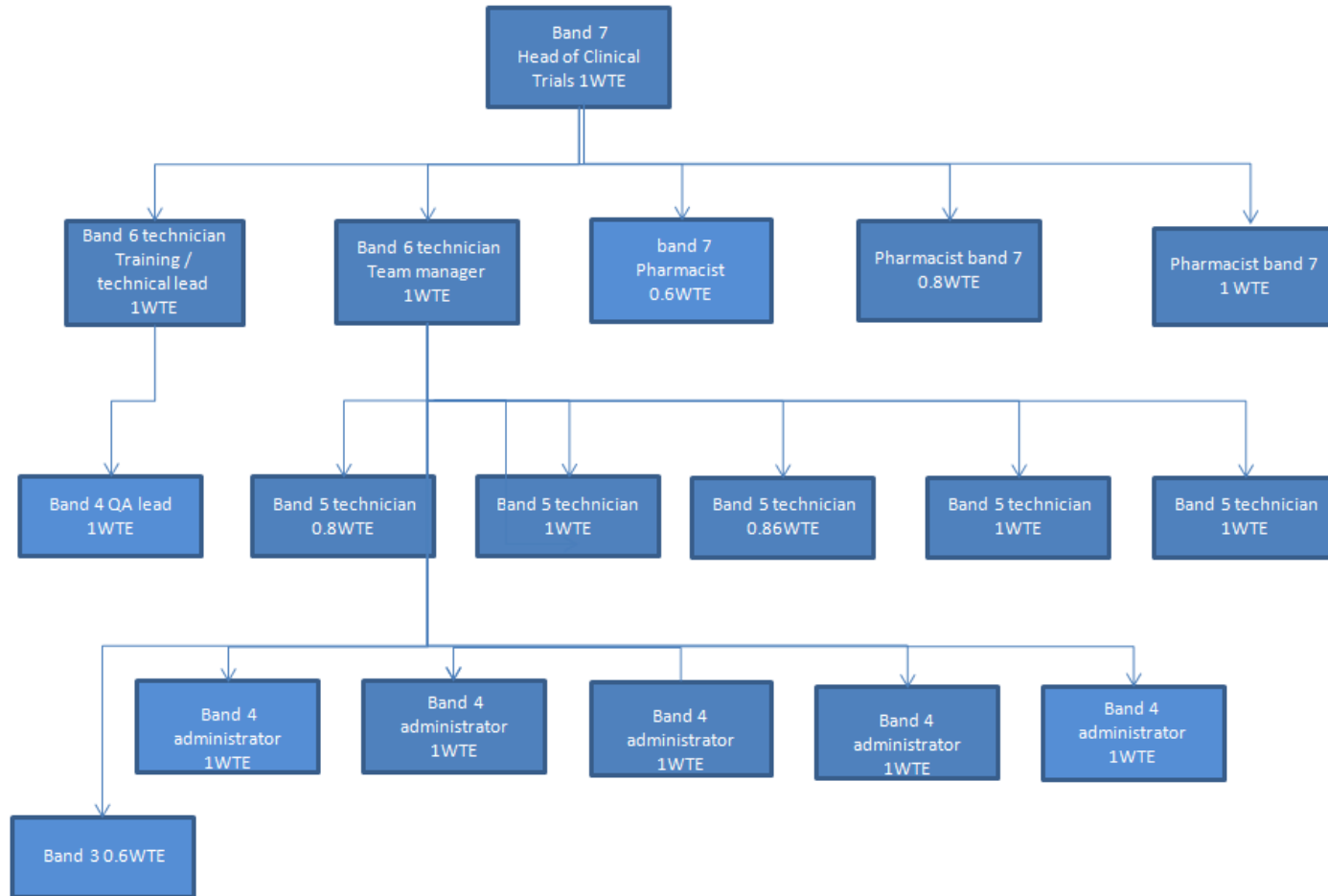
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# Introduction

- Clinical trials pharmacy team at Southampton
- Roles within the team
- Role of the pharmacy technician
- Day in the life of a clinical trials technician
- Patient safety and clinical trials
- Case studies
- Questions and answer session

# Team Structure



# Pharmacy Technician Role

Co-ordinate with R&D

Site Initiation Visit

Request documents from sponsor

Create prescriptions

Dispense

IMP management

Answer queries

Co-ordinate with research team

Create pharmacy trial specific procedure

Negotiations

Update pharmacy documents

Resolve issues

Write worksheets for aseptics

ACPT

Answer queries from admins

Respond to emails

Testing code break procedures

Co-ordinate items prepared in our TSU department

# Setting up a study

- Requesting documents
- Preparing local pharmacy documents
  - SOP, Accountability logs, Prescriptions, Worksheets, JAC entries
- Organising approval of local pharmacy documents
- Co-ordinating with
  - R&D, Research team, PI, Sponsor, CRA, Other sections of pharmacy
- Resolving issues that occur
- Site initiation visit
- Testing code break
- Gathering other documentations
  - MHRA approval, R&D approval, Delegation log
- Update EDGE on progress
- Issue pharmacy Green Light

# Open studies

- ACPT
- Dispense
- Answer queries
  - Research team, CRA, Other sections of pharmacy
- Resolve issues with prescriptions and dispensing
- Co-ordinate the preparation of TSU studies
- IMP management

# Amendments

- Request tracked changes copies or summary of changes
- Request review by pharmacist
- Update any pharmacy documents required
- Request R&D approval
- Update electronic records
- Update pharmacy file

# Other projects

- Transferring processes to EDGE
- Updating SOP
- Changing processes
- Individual projects



# Clinical trials and Patient Safety

## Good Clinical Practice

- Patient safety
- Integrity of the study data

Drug trial victim is like Elephant Man, says girlfriend

## Verdict confirms fate of 'elephant man' drug volunteers

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Researchers verify 'cytokine storm' theory of troubled trial.

# The lifelong shadow hanging over the Elephant Man drug trial victims after the human guinea pigs were left horribly disfigured and fighting for their lives

- In March 2006, eight volunteers signed up for a medical trial in London
- None of the eight volunteers could have known what lay ahead for them
- It became known as the Elephant Man trial because of its shocking side-effects
- New BBC documentary revisits dramatic events that left men fighting for life

# Man who died in French drug trial had 'unprecedented' reaction, say experts

Experts investigating the French drug trial that left one man dead and five hospitalised have published a report laying blame on the substance tested

New clues to why a French drug trial went horribly wrong

## France drug trial: Brain-dead man dies in hospital

French company bungled clinical trial that led to a death and illness, report says

By [Martin Enserink](#) | Feb. 5, 2016 , 1:00 PM

# Case Study 1

A trial with a novel drug that will be dose escalated in patients. In week 1 patients will receive 10mg once daily, week 2 50mg once daily, week 3 100mg once daily and week 4 400mg once daily.

When the dose is escalated patients must receive Day 1 and Day 2 treatment in clinic.

Bloods results must be reviewed prior to Day 1 of each escalation.

Bloods must be taken after the Day 1 dose and reviewed prior to Day 2 dose.

Local policy is that a pharmacist must review blood results.

Study drug is supplied in weekly packs.

# Case Study 2

The sponsor for a trial has stated that they do not want a local pharmacy dispensing label to be placed on the study medication when dispensed.

The sponsor label contains

- Drug name, formulation, strength
- Quantity
- Trial identifier
- Sponsor name and address
- Directions
- Temperature storage
- Blank to be filled in for Patient trial number
- Blank to be filled in for Date dispensed

# Case Study 3

Study is investigating Methotrexate (MTX) in combination with a novel agent. The novel agent will be a fixed dose throughout the study.

Each patient will receive weekly MTX as stated below:

Week number dose starts	Visit (V) dose dispensed	Dose
Week 1	V2	10mg
Week 4	V3	15mg
Week 7	V4	20mg
	V5	20mg

Dose escalation of MTX is dependent on blood results from the patient.

At visit 3 the patient will be reviewed by the doctor and bloods taken. The next supply of medication will be dispensed from pharmacy.

The bloods will be sent to a central lab for processing. Results will be available for the doctor to review 3 days later. The research team will then phone the patient to tell them their dose.

There is no patient compliance chart provided by the study.

# Case Study 4

A novel agent will be prepared in the aseptic unit.  
The final container is a syringe that will be administered via a syringe driver.

The sponsor is providing the syringes that will be used as the final container.

The syringes are CE marked, however, they are manufactured in the US.

# Case Study 5

For this study the study drug is packaged in a kit that contains 4 bottles of 30 tablets. This is sufficient study drug for a patient on full dose for one cycle.

The sponsor will assign a kit to each patient at each dispensing visit. Any unused medication should be returned by the patient at their next visit.

Patients can have dose reductions that will mean that they will only need 30 tablets or 60 tablets for each cycle of treatment.



## Useful links

Good Clinical Practice e-learning for Pharmacy

<https://learn.nihr.ac.uk/>

Improving Healthcare Through Clinical Research

<https://www.futurelearn.com/courses/clinical-research>

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