

How to run Clinical Trials

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About me

- ❑ Registered Nurse since 1985
- ❑ Research Nurse since 1996
- ❑ 3 years as Research Nurse in Diabetic Neuropathy studies in Toronto, Canada
- ❑ Since 1999 have worked in HIV research at three different London Hospitals

Objectives

- ❑ General Understanding of
 - ❑ clinical trials
 - ❑ GCP (Good Clinical Practice) guidelines
 - ❑ EU Clinical trials directives
- ❑ Informed consent
- ❑ How to recruit and keep patients
- ❑ Case studies

Quick Overview of Clinical Trials

What is a Clinical Trial

- prospectively assigns human participants to interventions, e.g.
 - Drugs
 - cells and other biological products
 - surgical procedures
 - diagnostic procedures
 - Devices
 - behavioural treatments
 - process-of-care changes
 - preventive care
- evaluates effects on health outcomes.

Types of Clinical Trials

(Treatment trials)

- Randomised
- Blinded
- Open

Phases of Clinical Trials

- ❑ Pre-clinical studies
 - ❑ In vitro/vivo studies
- ❑ Phase 0
 - ❑ Single subtherapeutic doses, healthy volunteers, very small numbers
- ❑ Phase I
 - ❑ Pharmacokinetics, pharmacodynamics, tolerability, Healthy volunteers, (20-80 subjects)

Phases of Clinical Trials

□ Phase II

- Efficacy and Safety, (20-300 subjects)

□ Phase III

- Definitive assessment, safety (300-3,000 subjects)

□ Phase IV

- Post marketing, long term safety

Why do Clinical Trials

- First access to new medicines
- Greater quality of care
- Income and cost savings
- Advance knowledge

Who is involved?

The Research Team

Research Team

- Sponsor
- Ethics Committee
- R&D committee
- Chief Investigator
- Principal Investigator
- Pharmacist
- Study Coordinator/Research Nurse
- The Patient

Sponsor

- ❑ Individual, company, institution or an organisation

Sponsor Responsibilities

Ensures

- Scientific quality
- Ethics approval
- Management and monitoring
- Funding (not mandatory)

Ethics Committee

- Independent bodies
- Ethical review
- Ensures the dignity, rights, safety and well-being of participants

Research and Development (R&D) Committee

- ❑ A corporate function of the hospital or organisation
- ❑ Governance and management

Chief Investigator

- ❑ Primary responsibility for the design, conduct and reporting
- ❑ Same as Principal Investigator (if at one site)

Principal Investigator

- ❑ Designs, conducts and reports
- ❑ Seeks ethics approval
- ❑ Conducts in accordance with legal and local guidance
- ❑ Participants welfare and Feedback

Pharmacist

- ❑ Safeguards
- ❑ Investigative Medicinal Products (IMPs) are
 - ❑ Appropriate, procured, handled, stored and used safely and correctly.
 - ❑ Follows protocol and Local guidance

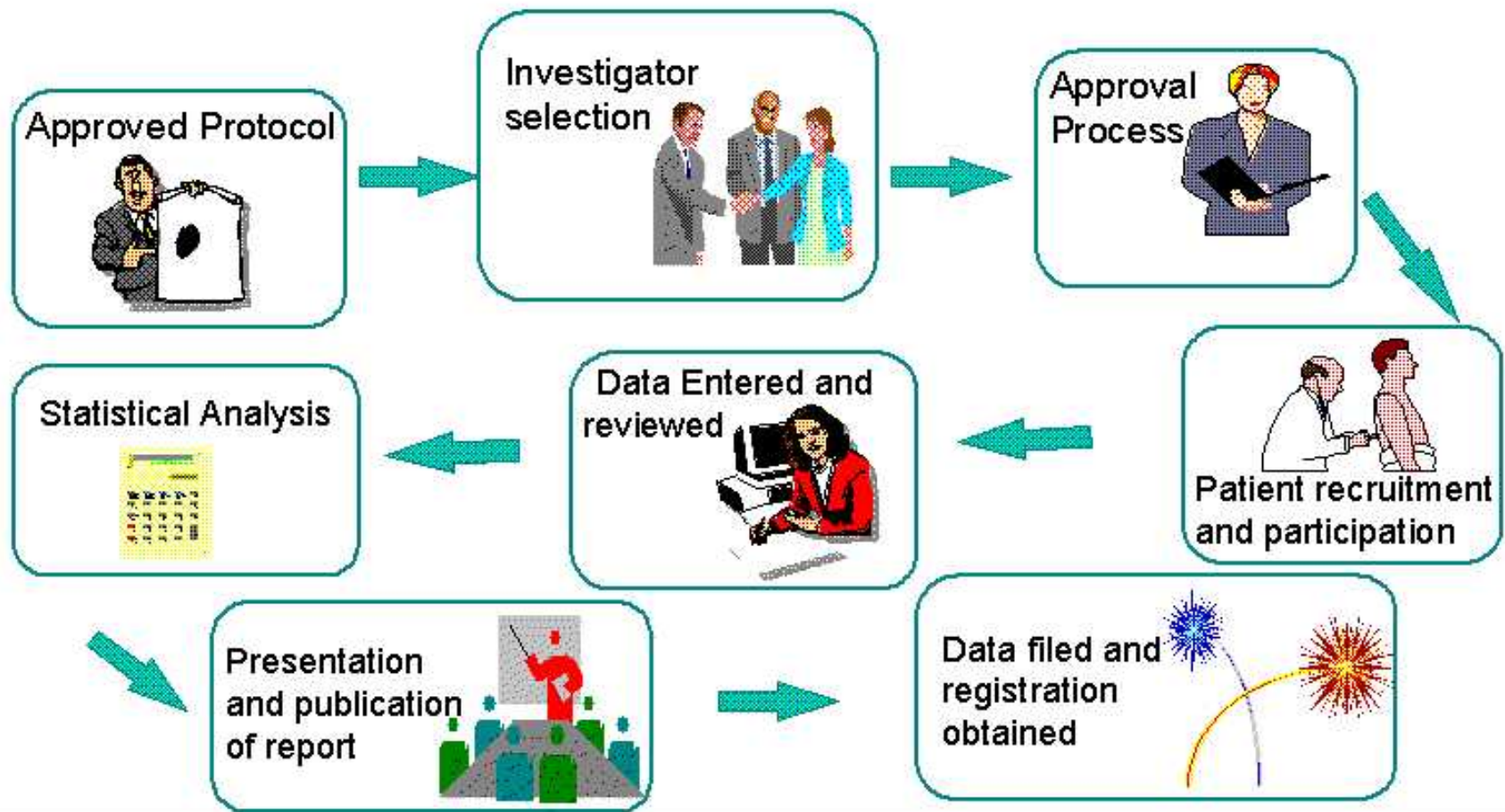
Study Coordinator/Research Nurse

- Administration
- Liaison
- Collection and recording of data
- Recruitment and screening of patients
- Ensures informed consent completed
- Patient follow up
- Staff training

The Patient

- ❑ Most important part of the team.
- ❑ Their role is to know what is expected of them throughout the study.

Clinical Trials in a Nut Shell



Quick Overview of GCP Guidelines

ICH Guidelines for Good Clinical Practise

- ❑ International Conference on Harmonisation (ICH)
- ❑ Human clinical trials
- ❑ International ethical and scientific quality standards
- ❑ Design, conduct, recording and reporting

Principles of GCP

- Risks and benefits
- Rights of trials subjects
- Scientifically sound
- Protocol
- Informed consent
- Confidentiality

Quick Overview of EU Clinical Trials Directives

Two European Union Directives

- ❑ EU Clinical Trials Directive
(2001/20/EC)
- ❑ EU Good Clinical Practice Directive,
(2005/28/EC)

Purpose

- ❑ Protect the Patients
- ❑ Administrative provisions
- ❑ Principles and guidelines for IMP
- ❑ Harmonise trial conduct in the EU
- ❑ Credibility of results.

Overview

- ❑ Sponsors
- ❑ Legal obligations for investigators and sponsors
- ❑ "own account" or non commercial studies affected

What types of trials does it cover

- Medicinal Products
- Clinical, pharmacological or pharmacodynamic effects, adverse reactions
- Safety and efficacy

Informed Consent

Informed Consent

- The most important document in the trial?
- ICH GCP guidelines
- EU Clinical Trials Directive

Principles

- Ethics approval of informed consent form
- No Coercion
- Person obtaining informed consent must fully inform subject

Principles

- Understandable language
- Ample time and opportunity to ask questions
- Prior to any study procedures

Special Considerations

- Visual impairments
- Literacy
- Learning disabilities
- Capacity to decide
- Unresponsive patients
- Prisoners

How to recruit and keep study patients

Recruiting

- Create a study friendly environment
- Have realistic goals
- Work with sponsors/monitors
- Staff familiar with studies

Recruiting

- Refer patients
- Flag up eligible patients
- Use recruitment information i.e. posters
- Know what works best for the culture of the patients

Keeping patients

- Treat your study patients special
- Be Flexible
- Have a friendly efficient research team

CASE STUDIES