The Institute of Clinical Research

Early Careers Clinical Researcher
May 2025

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Introduction to Clinical Research and the Early Careers Clinical Researcher (ECCR) membership

About the ICR

The Institute of Clinical Research (The ICR) is a **membership-led** independent association for **clinical research professionals**, in commercial and non-commercial environments.

Example of commercial organizations :
Pharmaceutical and biotechnological companies, CROS (contract research organizations).

Example of non-commercial organizations :
NHS and NIHR sites, academic institutions conducting research, charitable organizations.

What is the ECCR Membership?

- This membership is for those in education who are interested in a career within clinical research (Early Careers Clinical Researcher).
- It is a chance to understand more about clinical research, learn about the industry and connect with all the professional members of the industry.
- It is an annual membership of £10 per year.
- It is the ICR's newest category of membership and gives a valuable introduction to those wanting to learn more about clinical research and connect with experienced members within the industry.

What is Clinical Research?

Clinical Research is a branch of medical research that involves people and aims to determine two aspects...

the **safety** and **effectiveness** of medicines, devices, diagnostic products and treatment regimes.

The aim is for these to be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

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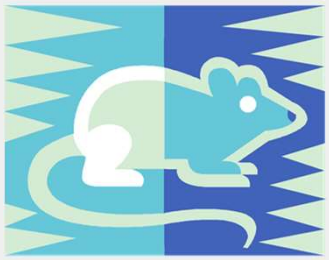
Phases in Clinical Trials



Phase I

Healthy volunteers
Small doses
Safety

Phase II

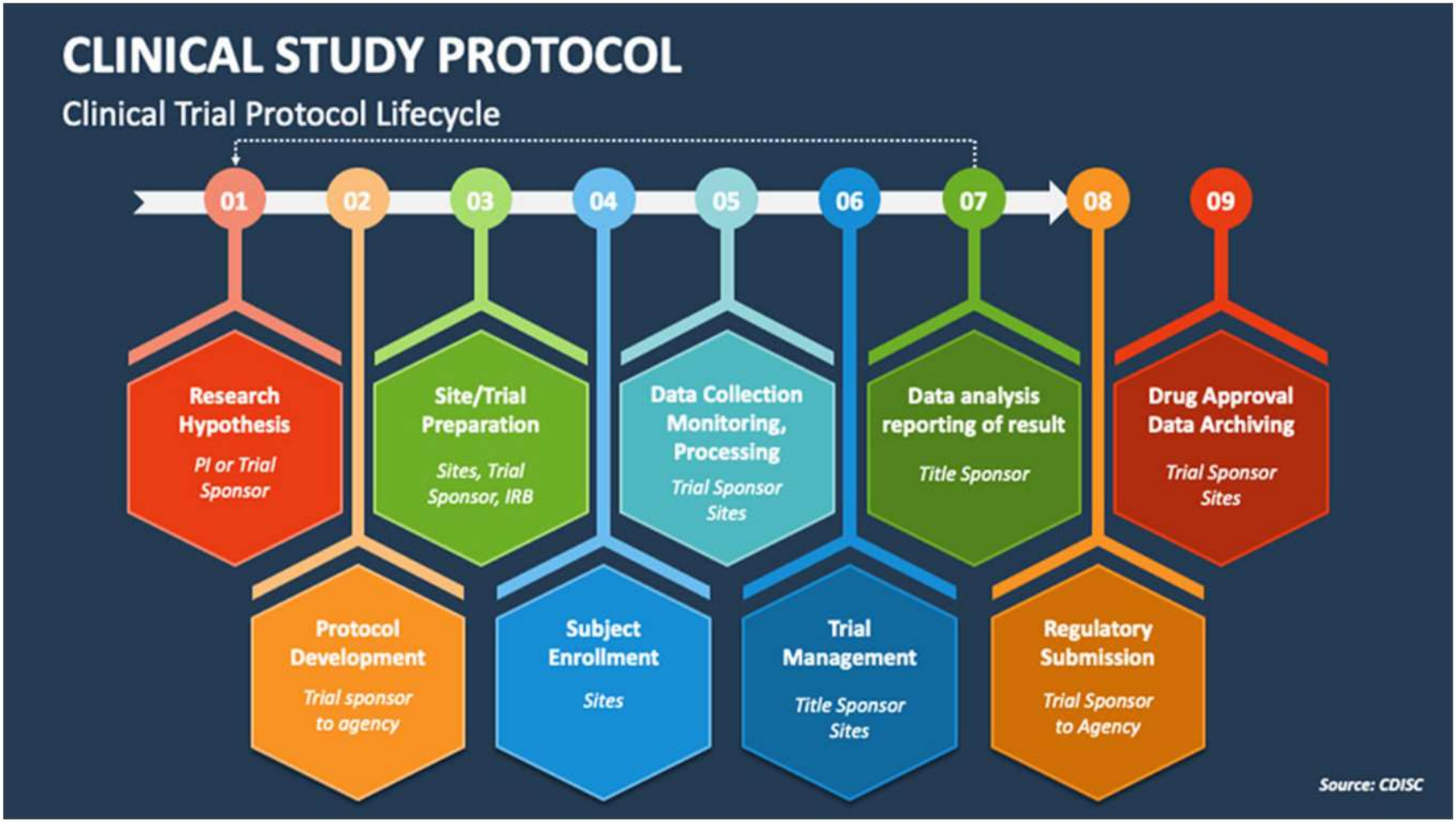
Patients
Safety and efficacy (does it work?)

Phase III

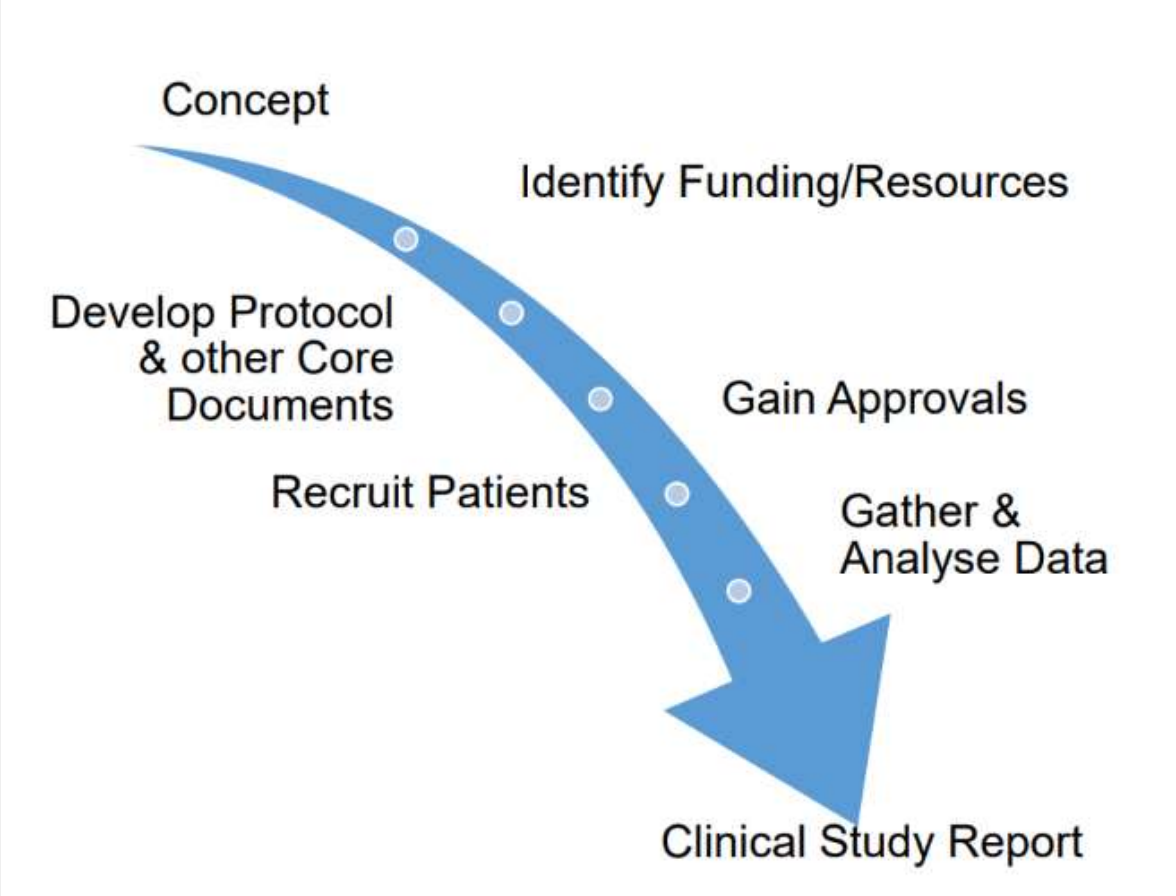
Larger studies
Many patients
Safety and Efficacy

Phase IV

How the product is used in real life after it has been licensed


CLINICAL STUDY PROTOCOL
Clinical Trial Protocol Lifecycle
01
02
03
04
05
06
07
08
09
Research Hypothesis
PI or Trial Sponsor
Site/Trial Preparation
Sites, Trial Sponsor, IRB
Data Collection Monitoring, Processing
Trial Sponsor Sites
Data analysis reporting of result
Title Sponsor
Drug Approval Data Archiving
Trial Sponsor Sites
Protocol Development
Trial sponsor to agency
Subject Enrollment
Sites
Trial Management
Title Sponsor Sites
Regulatory Submission
Trial Sponsor to Agency
Source: CDISC

A typical clinical trial



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How do we ensure our clinical trials are done safely and in accordance with the rules?

- All studies must be approved by a **Regulator** and an **Ethics Committee** before they can start
- We follow Good Clinical Practice (**GCP**)
- Study staff are appropriately qualified and **trained**
- We have **safety** reporting procedures
- We follow clear instructions for all tasks, these are called **SOPs** (standard operating procedures).

Different Roles in Clinical Research

The sponsor....

- Funds the trial
- Has overall responsibility to ensure the trial is conducted safely and complies with regulations.
- Can be a pharmaceutical or biotech company; an academic institution such as universities and research centres; or a charity such as Cancer Research UK.
- Will usually apply for a marketing application for the product to be licensed and used by patients in the real world population. This takes place after the clinical trials have been conducted and approved for use in humans.

Different Roles in Clinical Research

The Contract Research Organization (CRO)

- Works for the sponsor
- Runs the trial for the sponsor as part of a contractual partnership.
- Has regular meetings with the sponsor to discuss what is happening on the study and any potential issues.
- Some examples of the large CROs are : Syneos Health, IQVIA, Parexel, PPD, ICON, Fortrea, Medpace.

Different Roles in Clinical Research

The sites

- Are where the trials can take place
- Are usually a hospital or a GP/ health clinic.
- Will have a medically qualified professional responsible for the trial, called ‘The Investigator’.
- There will also be a study team that works on the trial, usually consisting of research nurses, coordinators and pharmacists.
- Some clinical trials have study nurses who visit the patients in their own homes, these studies are usually referred to as ‘decentralized trials’.

Technology / Remote Data / Real World Evidence / AI driven / Decentralised Trials

Different Career Roles in Clinical Research

- Clinical Research Associate
- Clinical Trial Administrator
- Medical Writer
- Data Manager
- Project Manager
- Quality Assurance Officer
- Regulatory Associate
- Statistician
- Site Staff Investigator / Nurse / Pharmacist
- Site Staff Administrator / Data Coordinator
- Study Start Up
- Pharmacovigilance Officer

Routes in to the industry

There are different options as to how you gain entry into the clinical research industry.

- A university degree* (life sciences, numerical or health science)
- A health sciences qualification (nursing)
- In an administrative role at the site
- Internship opportunities
- Work placement opportunities

- *Some roles don't require a degree – there are a number of routes by which you could enter the clinical research space without any degree. This is especially true of Investigator site or hospital based roles.

Entry Role – CTA (Clinical Trial Administrator)

- Supports the project team with administrative tasks
- Managing clinical trial documentation
  - Distribution of important documents e.g. protocol, Investigator brochure (safety information about the medicine)
  - Filing of documentation to the correct place within the TMF (trial master file, central place for the clinical trial documentation).
  - Tracking of variables
    - Participant metrics (recruitment, screen failures, withdrawals, completed).
    - Distribution of the investigational product (medicines, devices)
    - Important documents such as reports and minutes from meetings
- ***Ideal for those with good organizational and prioritization skills who like to be office based / homebased and working with teams of people.***
- Some CTAs choose to become Clinical Research Associates (CRAs), see next slide.

Entry role – Clinical Research Associate/Monitor

- May join as a trainee CRA
- Acts as the contact between the 'Investigator' (doctor) and the 'Sponsor' (pharma/biotech).
- Manages and visits the 'site' (place of trial, usually a clinic).
- Checks that the Investigator is conducting the trial according to the study protocol (instructions) and the regulations.
- Reviews the participant documentation to check that the trial data is correct
- Reviews all safety reports to ensure the participant is safe.
- ***Ideal for those with good organizational, prioritization and communication skills who like to travel and work with teams of people.***

Entry role – Data Manager

- The participant in the trial follows the protocol and takes the investigational product (medicine), we then collect **data** such as blood pressure readings, blood tests, physical symptom observations. This data helps us to determine of the medicine (or device) is **safe** and if it **works** (effective).
- The data manager role is to ensure that the data on the clinical study is reliable.
- Data managers will review data for mistakes and to ensure the data matches against the protocol requirements.
- Data Managers will write, run and use validation programs to do this.
- Any anomalies in the clinical trial data will result in a 'data query' that the Data manager will ensure is resolved and re-entered into the database.
- ***Ideal for those with good organizational and prioritization skills; and who enjoy maths, statistics and data patterns.***

Useful definitions and terms

There are lots of abbreviations in the clinical research industry. The most common ones we use are :

- GCP – good clinical practice, the ethical framework we apply to how we manage our tasks and conduct the study. You can read more on GCP here : https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

- IMP - the investigational medicinal product, sometimes also called the IP, the product, the drug. It is the drug / device / technique that we are testing to see if it is safe and does it work.

Useful definitions and terms contd.

- SOPs – Standard Operating Procedures, these are the detailed instructions that companies use to complete working tasks.

- MHRA – This is the regulatory authority in the UK, Medicines & Healthcare products
  Regulatory Agency. Each country has their own Regulatory authority, for example in the US, it is the Food and Drugs Administration (FDA).

You can see more of the common terms on our website here :
https://icr-global.org/clinical-research-definitions/

What is the (Early Careers Clinical Researcher) ECCR Membership?

- **It is an annual membership of £10 per year (compared to £95 professional MICR)**
- It is for those in education/other industries who are interested in a career within clinical research.

The benefits of The ICR ECCR membership

- Access to specific ECCR materials such as introductory webinars and training slides.

- Access ALL the other materials that Professional members see
  - The annual GCP and Ethics Forum
  - Monthly hot topic webinars
  - Recordings from some of the events, so you can listen to clinical researchers discussing trials

- Coming soon, resources on :
  - How to get into the industry, exploring career pathways
  - Real life case studies and experiences from those who work in the clinical research industry.
  - A typical day in the life of a …..CRA
  - Ask an expert – access to Clinical Research experts

The benefits of ECCR membership contd

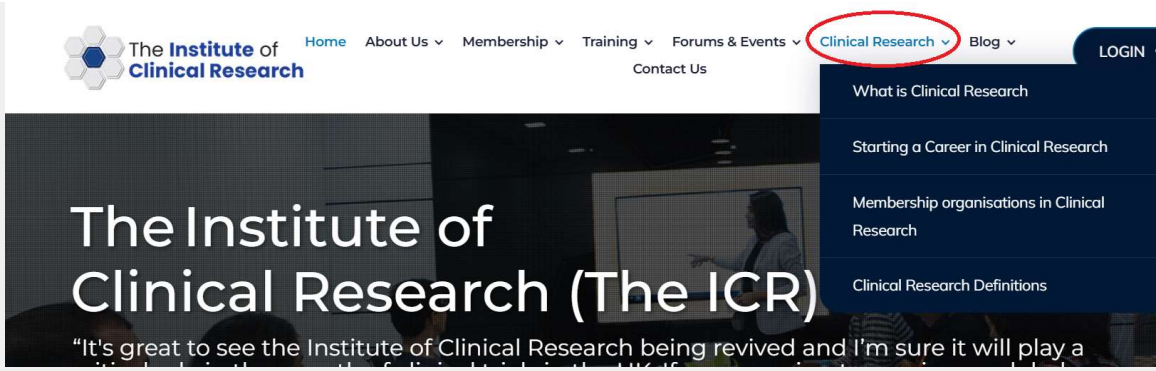
- **We are piloting a mentoring programme with a University, life science students with experienced clinical researchers.**
- Being kept informed of the latest industry developments and networking events – **Cambridge, Scotland, Wales, London.**
- **Quarterly newsletter –** industry updates, new regulations "Compliance Corner", future events, Special Interest groups

What can you do?

- Join ICR as a member
- Subscribe to our newsletter
- Follow us on LinkedIn : https://www.linkedin.com/company/institute-of-clinical-research
- Join our LinkedIn Group: https://www.linkedin.com/groups/3385539/
- Follow us on our Instagram @the_icr

- Let us know what you might find helpful and we will see if we can develop it for you and others.
- Stay in touch and if you have any questions, ask us!
- Office@icr-global.org / Fiona@icr-global.org

Resources



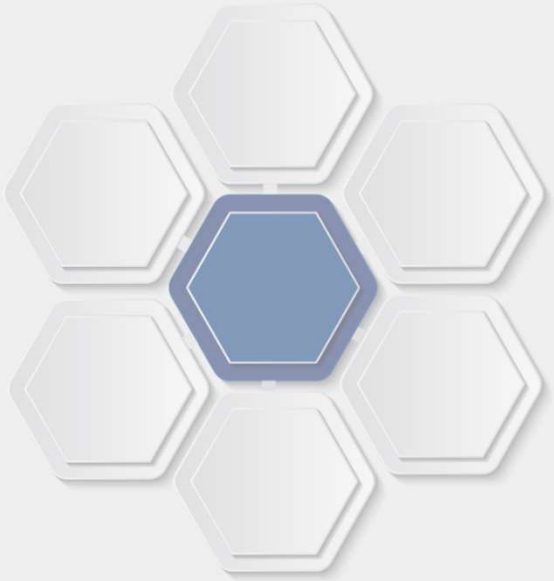
- www.icr-global.org
- https://icr-global.org/what-is-clinical-research/
- [DOWNLOADABLE RESOURCES]

- www.ich.org
- GCP Guideline is here : https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

- Health Research Agency UK (NHS)
- https://www.hra.nhs.uk/

- NIHR interactive tool kit https://www.ct-toolkit.ac.uk/

- Medicines and Healthcare regulatory Agency
- https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- Blog: https://mhrainspectorate.blog.gov.uk/



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