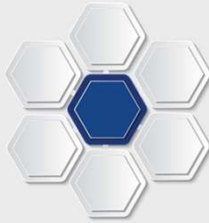




The Institute of Clinical Research

Early Careers Clinical Researcher





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



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?

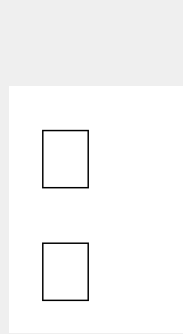
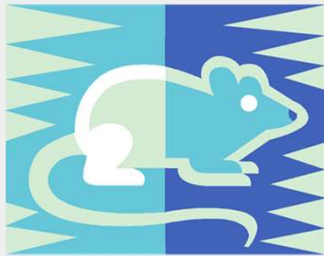
Clinical Research is a branch of medical research that involves people and aims to determine two aspects...

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

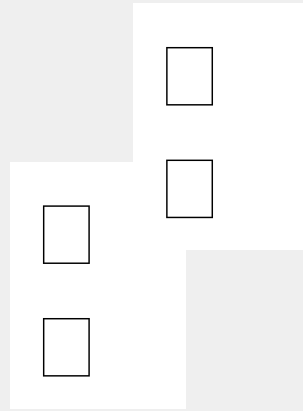
The aim is for these to be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.



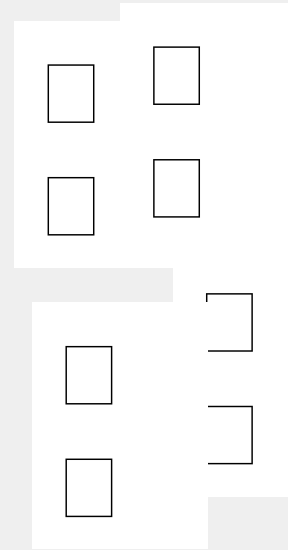
Phases in Clinical Trials



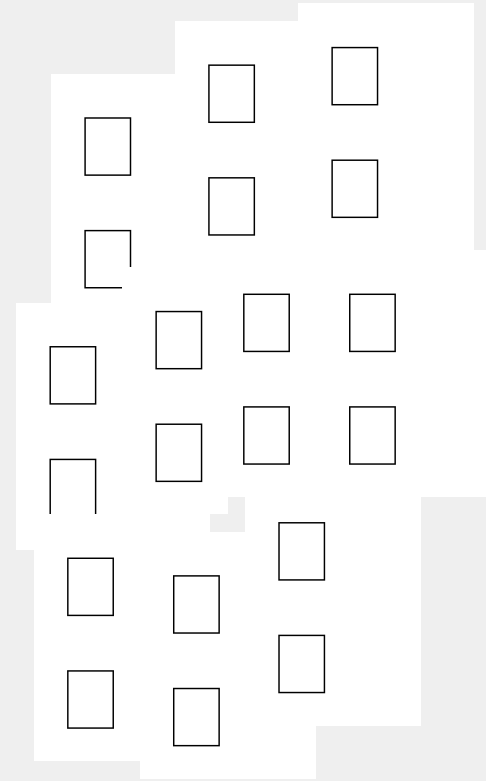
Phase I
Healthy
volunteers
Small doses
Safety



Phase II
Patients
Safety and
efficacy
(does it
work?)



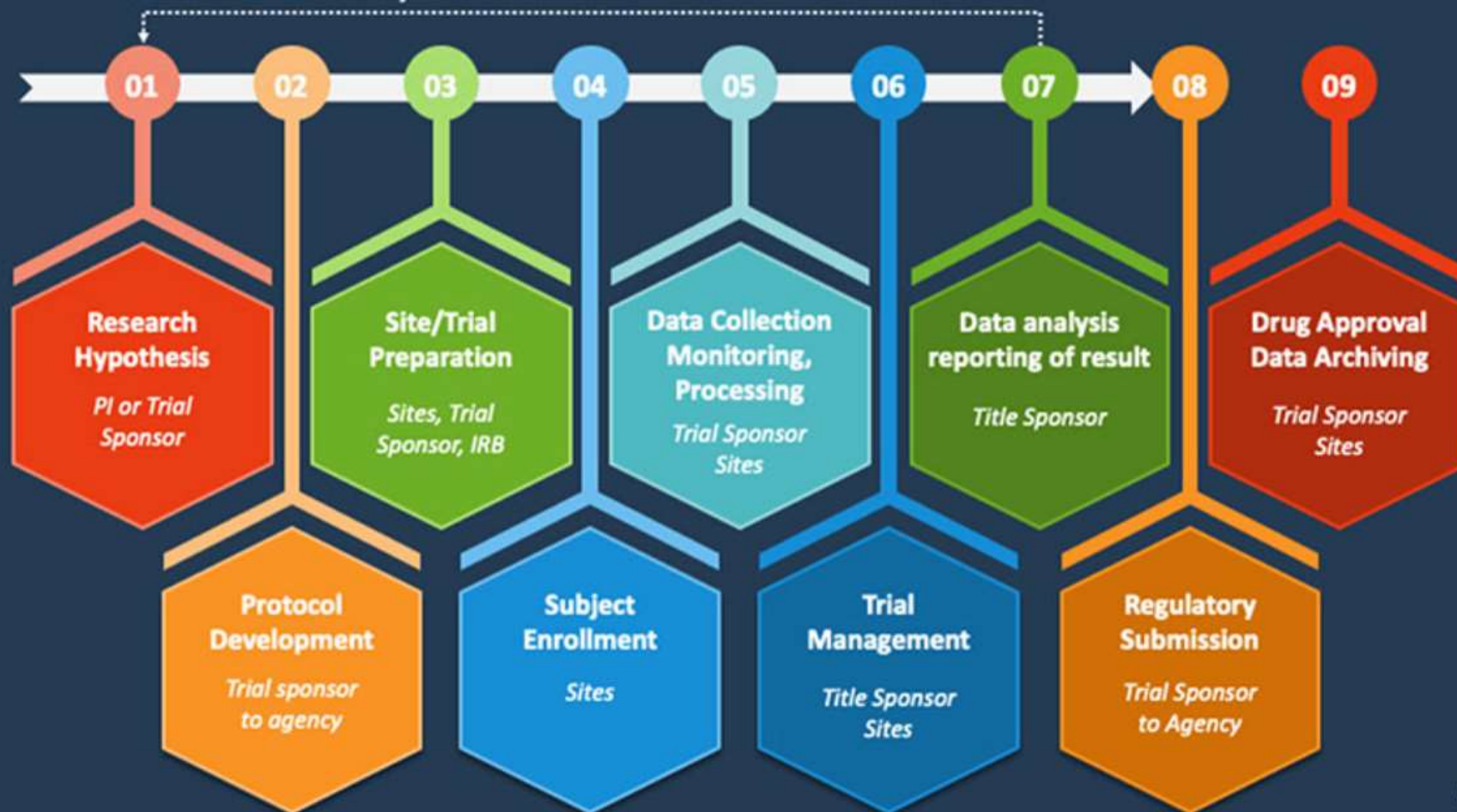
Phase III
Larger
studies
Many
patients
Safety and
Efficacy



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

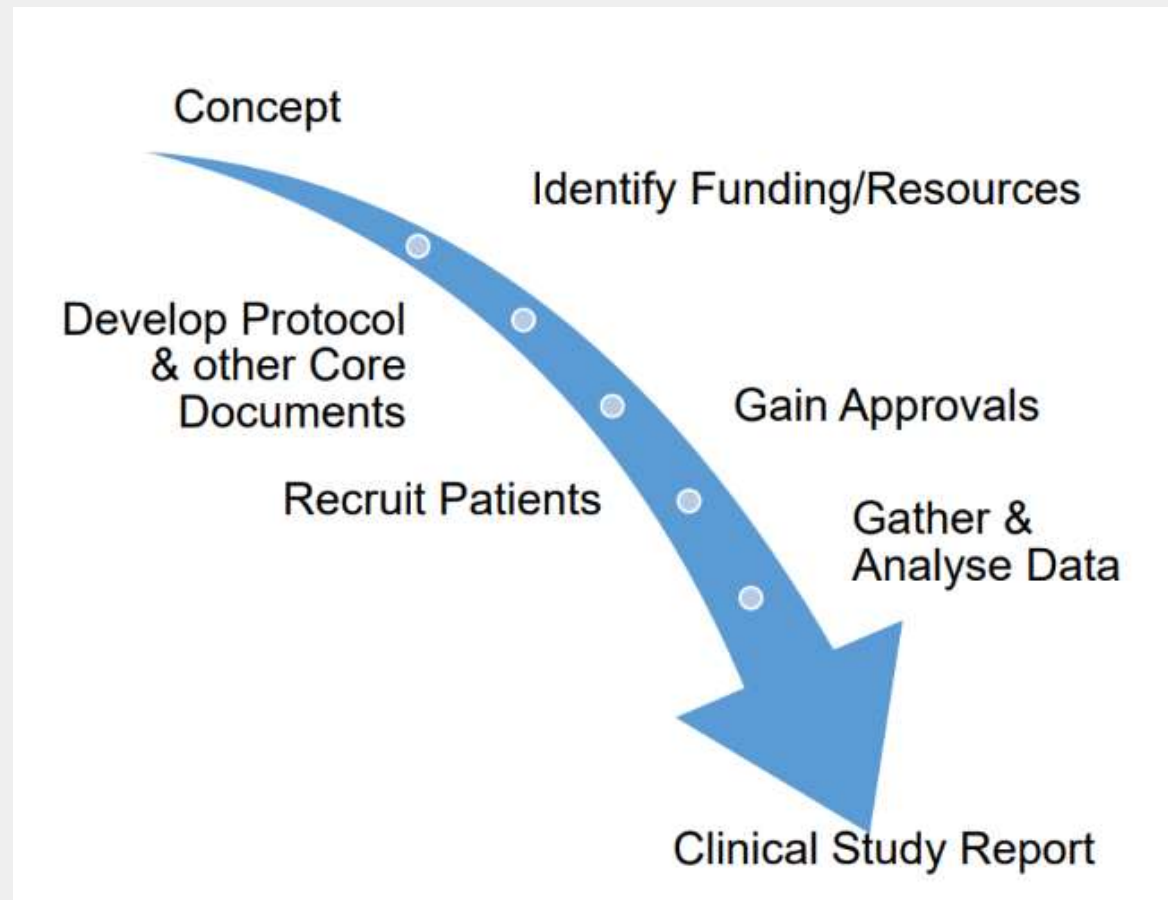
CLINICAL STUDY PROTOCOL

Clinical Trial Protocol Lifecycle



Source: CDISC

A typical clinical trial





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'.



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 (merge into next)

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.



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/>



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.

The benefits of ECCR membership

- You can log in on the website and then you will have access to specific ECCR materials such as introductory webinars and slides.
- You can also access the other materials that Professional members see.
- Materials include slides from important networking events such as :
 - 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



The benefits of ECCR membership contd

- ICR will also be developing further materials for ECCR members, such as :
 - 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 aCRA
- Being kept informed of the latest industry developments and networking events.



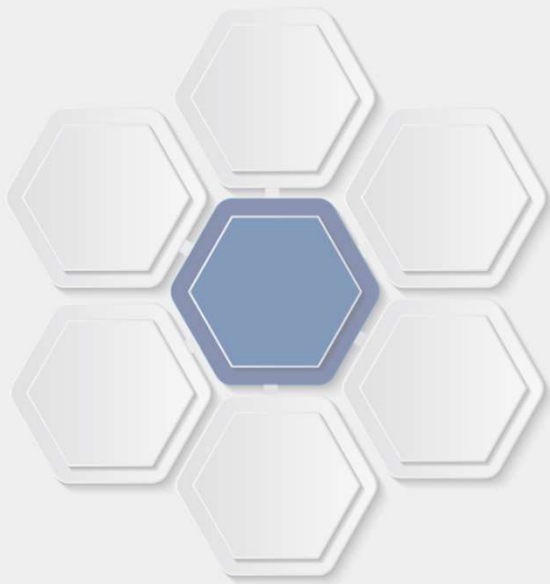
The Institute of
Clinical Research



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!



The **Institute** of **Clinical Research**