

# Key Roles in Clinical Trials

## 1. Clinical Research Associate (CRA)

### What they do:

- They **monitor** clinical trials.
- Visit hospitals or sites where trials are happening to check:
  - Are patient records accurate?
  - Is the trial being done **according to protocol**?
  - Is data being recorded properly?
- CRAs **act like auditors** to ensure everything is compliant and accurate.

### Usually employed by:

- Pharma companies
- Contract Research Organizations (CROs)

### Think of them as:

Quality checkers for clinical trials.

## 2. Investigators (Doctors)

### What they do:

- These are **real doctors** (e.g., oncologists, cardiologists) running clinical trials in their hospitals or clinics.
- They **treat patients** and **record trial data**.
- They make sure that patient safety is protected.

 Called: *Principal Investigator (PI)* if they lead the site.

🧠 Think of them as: The "project manager" at the hospital site for the trial.

### 3. Study Coordinator

🔧 What they do:

- Works at the hospital/clinic under the investigator.
- Handles **daily work**:
  - Scheduling patient visits
  - Collecting informed consent
  - Sending reports to pharma company or CRA
- They are the **bridge between patients, doctors, and trial sponsors**.

🧠 Think of them as:

The "operations person" manages the site logistics.

### 4. Patients (Subjects/Participants)

🔧 What they do:

- These are people **volunteering** to try a new drug or treatment.
- They may:
  - Take the drug
  - Visit hospitals regularly
  - Report side effects
- Some get paid or reimbursed; others do it for access to new treatments.

🧠 Very important! Patient safety is the **#1 priority** in trials.

## 5. Regulatory Managers

### What they do:

- They work at pharma/biotech companies.
- Handle **submissions to health authorities** like:
  - FDA (USA)
  - EMA (Europe)
  - CDSCO (India)
- Make sure all trial documents, reports, and approvals are correct and submitted on time.

### Think of them as:

The legal & documentation experts keep the trial legal and ethical.