A clinical research coordinator (CRC) **manages and coordinates the day-to-day activities of clinical trials**. Their responsibilities include:

- Ensuring compliance: CRCs ensure that clinical studies comply with regulations, Good Clinical Practice (GCP), and Institutional Review Board (IRB) requirements.
- Protecting human subjects: CRCs are responsible for protecting human subjects involved in the study.
- Training participants: CRCs train study participants and monitor their eligibility.
- Managing study conduct: CRCs manage the day-to-day running of the study, including recruiting and screening participants, scheduling study visits, and managing laboratory procedures.
- Financial management: CRCs review and accept the billing matrix, and coordinate payments to participants.
- Collecting data and producing reports: CRCs collect data and produce reports.
- Tracking patient health and progress:

Auditors in clinical data have several roles, including:

- Ensuring data accuracy: Auditors review the process of collecting and documenting data to ensure it's correct.
- Verifying compliance: Auditors review documents like the trial protocol and informed consent forms to ensure compliance with regulations.
- Verifying subject consent: Auditors ensure that subjects enrolled in the study are doing so voluntarily and through proper consent.
- Identifying non-compliance: Auditors identify any non-compliance with the study protocol and regulations.
- Taking corrective action: Auditors report back to the sponsor on any necessary corrections.
- Protecting human subjects: Auditors ensure that the study protects human subjects.

Investigator Selection

- Interest in the research question.
- Experience and qualifications of the investigator.
- Sufficient staff to conduct the study and their experience and qualifications.
- Availability of suitable patient population: ...
- Adequate time to conduct and oversee the trial.
- Adequate facilities:

Protocol

- A protocol is a document that states the reasoning behind and structure of a research project

- Protocol also defined as a document that describes the background, rationale, objectives, design, methodology, statistical consideration and organization of trial

- The Study protocol can be viewed as a written agreement between the investigator , the participants and the scientific community

Impartial Witness

- A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative
- cannot read, and who reads the informed consent form and any other written
- information supplied to the subject.

What is confidentiality?

- 'Confidentiality' means making sure that information is only available to those who are authorised to have access.
- Usually, this will mean keeping things secret between the client and you, the worker.
- As a worker, you will find out things that should not be shared amongst your family, your community or the client's family.

Assent vs Consent

Comparison Table

Characteristics	Assent	Consent
Meaning	Agreeing with something, a request, or to participate in an activity	Giving permission to be involved in an activity
Age	Obtained from people who are not of legal age to give a consent	Obtained from adults (people above the legal age)
In research	Willingness to participate in a study	Legally entered agreement for a subject to participate in a study
In law	Not a legally binding permission	Legally binding permission

DB Difference Between.net

A waiver of consent is a request to not include a specific element of consent or to not obtain consent at all, usually in the context of research. A waiver of consent can be granted in certain circumstances, such as when:

- Research is essential: The use of identifiable information or human biological materials is required for the research.
- Research poses minimal risk: The research poses no more than minimal risk to participants.
- Research has important social value: The research has important social value.
- Research is not feasible without a waiver: The research would not be feasible or practicable to carry out without the waiver.
- Emergency settings: Treatment must be provided quickly, patients are incapacitated, or a legally authorized representative is not readily available.

A Data and Safety Monitoring Board (DSMB) is an independent group of experts that monitors the safety of participants in clinical studies. Their responsibilities include:

Reviewing data

DSMBs periodically review data to ensure the safety of participants, the conduct of the study, and its progress.

Making recommendations

DSMBs make recommendations to the sponsor or a steering committee about whether to continue, modify, or terminate the trial.

Providing written reports

DSMBs provide written reports to the sponsor that summarize their oversight activities, recommendations, and any concerns about subject safety.

Reviewing the protocol

DSMBs review the initial protocol to ensure it will capture the information needed to evaluate the study's safety and efficacy.

Content

The content of a document connects the audience with the information being provided.

Feedback

Feedback from readers is important for improving the content of documentation. It helps to monitor the satisfaction of end users.

Form validation

Form validation is important to ensure that the data entered by users meets the required criteria. If the validation rules are not met, error messages are used to communicate the issues to the user.

Template

It is a good idea to design a template for each type of documentation being developed. Standardizing templates based on documentation type can help users easily identify which document they're looking at.

Audience

The audience is the person or people who will read the document.

Document structure

Document structure describes the organization of a document into graphical

There are a number of forms used for reporting adverse drug reactions (ADRs) globally, including:

- Medwatch: A protocol form for collecting and reporting ADRs
- Yellow Card: A protocol form for collecting and reporting ADRs
- CDSCO form: A protocol form for collecting and reporting ADRs
- CIOMS form: A form used for reporting foreign events, developed by the World Health Organization's Council for International Organizations of Medical Sciences
- Adverse Event Reporting System (AERS): A computerized database used by the FDA to support its post-marketing safety surveillance program for approved drugs and therapeutic biologic products

Unexpected Adverse Drug Reaction. **An adverse reaction, the nature or severity of which is not consistent with the applicable product information** (e.g., Investigator's Brochure for an unapproved investigational medicinal product).

The minimum criteria for reporting an adverse drug reaction (ADR) are:

- An identifiable patient
- A suspect medicine or medicines
- A suspected reaction
- Reporter details, including name and contact information

The U.S. Food and Drug Administration (FDA) defines a serious adverse drug reaction (ADR) as one that results in any of the following outcomes:

- Death
- Life-threatening condition
- Hospitalization, either initial or prolonged
- Disability, which can be significant, persistent, or permanent
- Congenital abnormality

PvPI stands for **Pharmacovigilance Programme of India**. It's an initiative by the Central Drugs Standard Control Organization (CDSCO) in collaboration with the Indian Pharmacopoeia Commission (IPC). The program is run under the Ministry of Health and Family Welfare, Government of India.

PSUR stands for **Periodic Safety Update Report**. It's a document that provides an update on the worldwide safety of a medicinal product to regulatory authorities at specific times after authorization.

SUSAR is an abbreviation for **Suspected Unexpected Serious Adverse Reaction**. It can refer to an adverse reaction that occurs during research with a medicinal product. An adverse reaction is considered unexpected if its nature and severity are not consistent with the information about the medicinal product.

Collects and processes reports

The UMC collects and processes adverse drug reaction (ADR) reports from member countries of the WHO Programme for International Drug Monitoring.

Identifies potential hazards

The UMC's primary goal is to identify potential sources of harm to patients.

Communicates information

The UMC shares information about drug safety with a wide range of audiences to improve patient safety.

Maintains the VigiBase database

The UMC maintains the VigiBase database, the world's largest collection of Individual Case Safety Reports (ICSRs).

Provides technical support

The UMC offers technical support and guidance to national centers for pharmacovigilance.

Develops tools

The UMC develops and supports countries with reporting and data management tools.

Provides a drug coding reference guide

The UMC offers a complete reference guide for drug coding.