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COMMON CLINICAL RESEARCH JOB INTERVIEW QUESTIONS WITH ANSWERS



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What is a clinical trial (also called clinical research)?

Definition:

Clinical research is a Branch of healthcare science & research study that involves human volunteers designed to determine the safety and effectiveness of a drug, biologic (such as a vaccine), device (such as vagus nerve stimulator) or other treatment or behavioral intervention.

Carefully conducted clinical trials are the fastest and safest way to find treatments that improve health in people.

The Food and Drug Administration (FDA) requires that all new treatments be tested in clinical trials before they are reviewed for approval. Observational trials address health issues in large groups of people in natural settings.

Clinical research includes:

- Medical and behavioral research involving volunteer participants
- Investigations that are carefully developed and conducted with clinical outcomes recorded
- Identification of better ways to prevent, diagnose, treat, and understand human disease
- Trials that test new treatments, clinical management and clinical outcomes, and long-term studies
- Strict scientific guidelines
- Ethical principles to protect participants



Why participate in a clinical trial?

Because clinical trials are required of any new therapy prior to FDA approval, major improvements in healthcare would be impossible without volunteer participants. Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Why is clinical Research Important (Benefits)?

Research is important because:

- Clinical trials test how well new approaches and interventions work in people
- These approaches can be medical, behavioral, or management
- Each study answers scientific questions
- Each study helps scientists prevent, screen for, diagnose, manage, and treat a disease

People who take part in clinical trials contribute to the knowledge of how a disease progresses.

Some benefits of taking part in a clinical trial are:

- Participants have access to promising new approaches often not available outside the clinical trial setting
- The drug, vaccine or other intervention being studied may be more effective and/or efficacious than the standard approach (although there is no guarantee that participants will receive the experimental drug, vaccine, or other intervention)
- Participants receive careful medical attention from a research team of doctors and other health professionals
- Participants may be the first to benefit from the study
- Results from the study may help others in the future



Who can participate in a clinical trial?

All clinical trials have guidelines about who can participate. The factors that allow someone to participate in a clinical trial will vary from study to study. These criteria are based on the goals of the study and include such factors as age, the type and stage of a disease, previous treatment history, and other medical conditions. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. The criteria are used to identify appropriate participants needed to answer the scientific questions being asked while keeping them safe.

The main goal for using volunteers in a clinical trial is to prove, by scientific means, the effects and limitations of the experimental treatment on a wide variety of people. Research procedures with volunteers are designed to develop new knowledge, not to provide direct benefit to study participants. Before joining a clinical trial, a person must qualify for the study:

- Some research studies seek participants with illnesses or conditions to be studied in the clinical trial
- Some research studies need volunteers who do not have the disease being studied A person with the condition being studied is called a “patient volunteer” and:
 - Has a known health problem
 - Participates in research to better understand, diagnose, treat, or cure that disease or condition
 - Supports research procedures to help develop new knowledge (these procedures may or may not benefit the participant)

A person may also volunteer who is at risk for the condition being studied. A volunteer who does not have the condition being studied is called a “control” and:

- Participates in clinical research to test a new vaccine, microbicide, or other strategy or intervention
- Is needed when developing a new technique, such as a blood test or imaging device
- Helps define the limits of "normal"
- Serves as a control for participant groups and is often matched to participants on characteristics such as age, gender, or family relationship
- Receives the same test, procedure, vaccine, microbicide the participant group receives Some volunteers serve as controls by not taking the test vaccines, microbicides, or other strategies. Or these volunteers may receive doses large enough only to show that it is present, but not at a level that can treat the condition. Investigators learn about a disease process by comparing how each kind of volunteer reacts to the trial. Some studies require a major commitment in time and effort. Some studies may involve some discomfort. The research procedure may also carry some risk. The consent process for volunteers includes a detailed discussion of the study's procedures and tests.

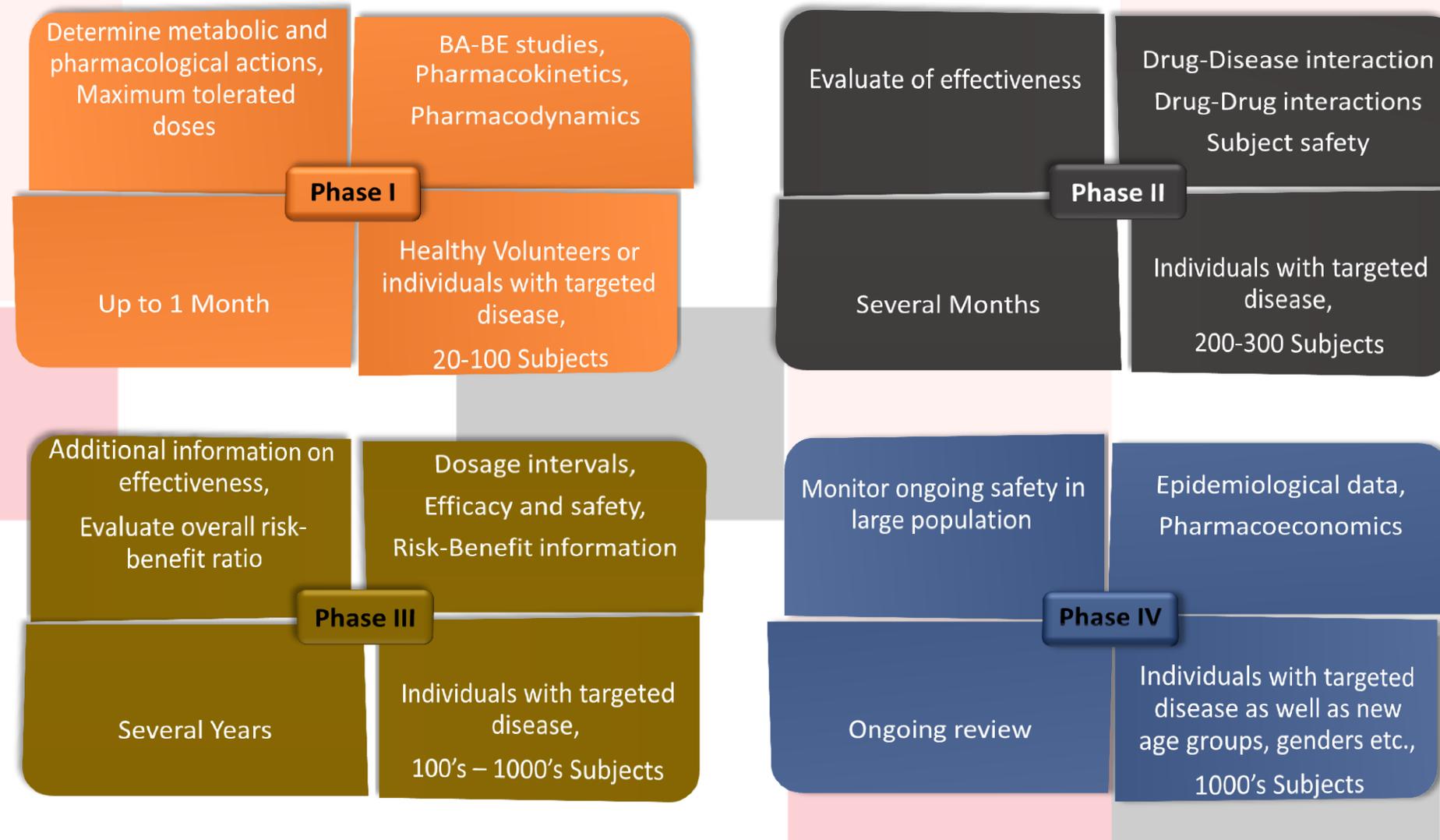
Purpose of Research

- Intended to increase knowledge about how well a diagnostic test or treatment works in a particular patient population.
- To test hypothesis formulated from observations and or intuition.
- Ultimately to understand better one’s world and make “Sense of it”.

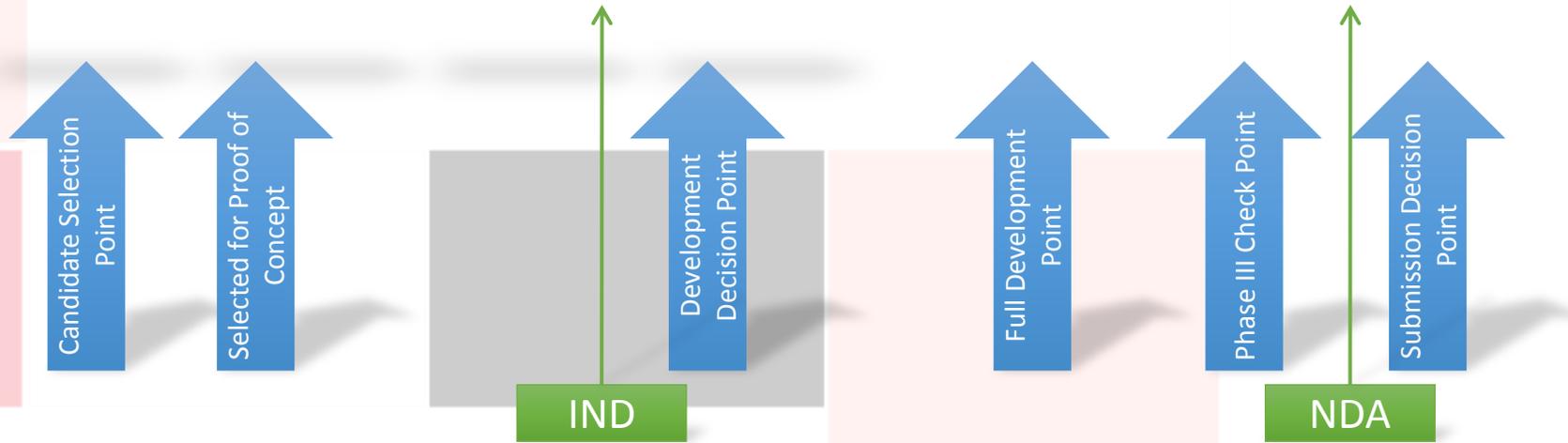


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Clinical Research - Phases



New Drug Development Process



R&D

- Research Target
- Discovery of Lead Compound
- Selection of Suitable Candidate

Preclinical

- Lab testing
- Animal Studies
- Toxicology Studies etc.,

Clinical (I & II)

- Biological Tests and Pharmacological test in humans
- Regulatory Clearance

Clinical (III&IV)

- Registration with Health Authorities
- Preparation for Launch
- Launch and Sales

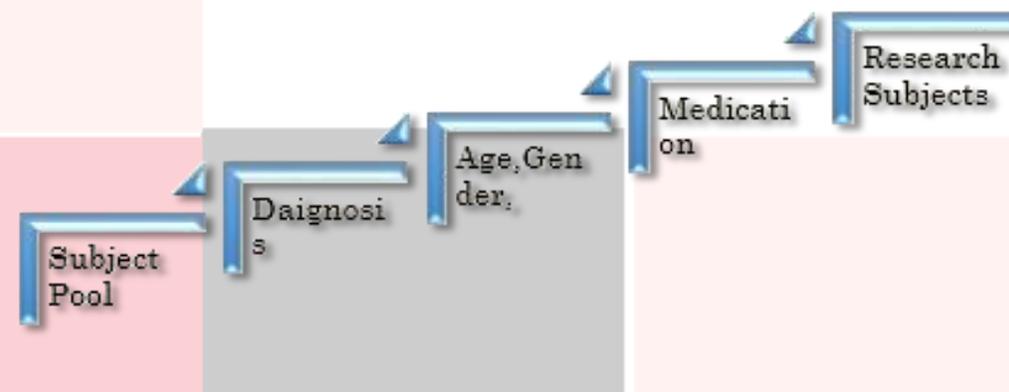
What Are Inclusion/Exclusion Criteria?

All clinical trials have guidelines about who can participate—these are specified in the inclusion/exclusion criteria:

- Factors that allow someone to participate in a clinical trial are "inclusion criteria"
- Factors that exclude or do not allow participation in a clinical trial are "exclusion criteria"

These factors may include:

- Age
 - Gender
 - The type and stage of a disease
 - Previous treatment history
 - Specific lab values
 - Other medical conditions
- Inclusion and exclusion criteria are not used to reject people personally. The criteria are used to:
- Identify appropriate participants
 - Keep them safe
 - Help ensure that researchers can answer the questions they want answered



What happens during a clinical trial?

The clinical trial study team, which includes doctors, nurses, and other health care professionals, checks the health of the participant at the beginning of the trial, gives specific instructions for participating in the trial, monitors the participant carefully during the trial, and stays in touch after the trial is completed. Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. Clinical trial participation is most successful when the study protocol is carefully followed, including frequent contact with the clinical trial team.

Usually, clinical trials compare a new product, vaccine, management strategy, or therapy with another that already exists. This comparison helps to determine if the new one is as successful as, or better than, the existing one. In some studies, participants may be assigned to receive a placebo (an inactive product that resembles the test product, but without its treatment value). Comparing a new product with a placebo can be the fastest and most reliable way to demonstrate the new product's therapeutic effectiveness and/or efficacy. Placebos are not used if a participant will be put at risk (standard of care)—particularly in the study of treatments for serious illnesses—by not having effective therapy. Potential participants are told if placebos will be used in the study before they enter a trial. For studies using placebos:

- Clinical trial investigators must be able to show that withholding active therapy from participants for a short time is unlikely to result in physical harm
- Participants must give voluntary, informed consent
- Investigators must closely monitor participants in these studies. For therapeutic trials, most studies compare new products or regimens with an approved therapy (for example, standard of care).

Randomization is when two or more alternative treatments are assigned to volunteers by chance instead of choice. The assigned treatment is administered with the highest level of professional care. The results of each treatment are compared at specific points during a trial, which may last for years. When one treatment is found superior, the trial is stopped so that the fewest participants possible receive the less beneficial treatment. In single- or double-blind studies (also called single- or double-masked studies), participants do not know which medicine is being used, so they can describe what happens without bias. Blind studies are designed to prevent members of the research team or study participants from influencing the results. Therefore, scientifically accurate conclusions are more likely. Members of the research team are not told which participants receive which medication, so their observations will not be biased. If medically necessary, it must always be possible to find out what participants have taken:

- In single-blind studies, only the participant is not told what is being administered
- In a double-blind study, the only person who knows what is being administered is the pharmacist

Where Do Clinical Trials Take Place?

Clinical trials take place all over the world:

- Health care providers' offices
 - Medical centers
 - Community and university hospitals and clinics
 - Veterans' and military hospitals
- Clinical trials may include participants at one or two highly specialized centers. Or they may involve hundreds of locations at the same time.

Good Clinical Practice (GCP) is an international quality standard that governments can transpose into regulations for clinical trials involving human subjects. GCP guidelines include protection of human rights as a subject in clinical trial and assurance of the safety and efficacy of the newly developed compounds. GCP guidelines also include standards on how clinical trials should be conducted and a definition of the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors. Good clinical laboratory practice (GCLP) guidelines focus on good laboratory practice and good clinical practice guidelines/standards for medical testing laboratories conducting clinical trials in developing countries

What Are Some of the Possible Risks Associated with Taking Part in a Clinical Trial?

Some risks of taking part in a clinical trial are:

- New vaccines, microbicides, and other strategies under study are not always better than the standard care to which they are being compared
- New treatments may have unexpected side effects or risks that are worse than those resulting from standard care
- Health insurance and managed care providers may or may not cover all participant care costs in a study
- Participants may be required to make more visits to the doctor than they would if not in the clinical trial
- Participants in randomized trials are not able to choose the kind of intervention they will Receive

What Is the Clinical Research Process?

The clinical research process includes:

- Pre-clinical testing
- Investigational New Drug Application (IND)
- Phase I (assess safety)
- Phase II (test for effectiveness)
- Phase III (large-scale testing)
- Licensing (approval to use)
- Approval (available for prescription)
- Post-marketing studies (special studies and long-term effectiveness/use)



What Are the Elements and Principles of Clinical Research?

The elements and principles of clinical research are:

- Protocol
- Protocol review
- Sponsor
- Eligibility criteria
- Informed consent
- Types of clinical trials
- Phases of clinical trials
- Activities during clinical trials
- Clinical trial participants

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I Agree

What Is Ethics?

Ethics means:

- Respect for persons
 - Beneficence, which means to do good—in clinical research, beneficence means even more— to do no harm, or maximize possible benefits and minimize possible harm
 - Justice, or fairness
- Scientific research has produced many social benefits, but it has also posed some troubling ethical questions.

Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments:

- During the Nuremberg War Crime Trials after World War II, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on prisoners. This code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.¹⁵
- The Tuskegee Study of Untreated Syphilis in the Negro Male (also known as the Tuskegee Syphilis Study, Public Health Service Syphilis Study, or the Tuskegee Experiment) was a clinical study, conducted between 1932 and 1972 in Tuskegee, Alabama by the U.S. Public Health Service. 399 poor, mostly illiterate African Americans with syphilis were recruited for research related to the natural progression of the disease if left untreated. The trial participants were not offered treatment for syphilis when it became available.¹⁶



Ethical Norms in Clinical Research

3 ethical principles guide clinical research

Respect for
Persons

- Treatment of person as autonomous

Beneficence

- Potential conflict between good of society Vs. individual

Justice

- Treatment of all fairly and all equally share benefits and risks

The Belmont Report¹⁷ was developed by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on April 18, 1979, to:

- Summarize the basic ethical principles identified by the Commission in the course of its deliberations
- State basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects Ethical principles must guide all research activities including:
 - All phases of research, including formation of research questions, design of the study, conduct of research, analysis of data, and interpretation of findings
 - Dissemination of new knowledge in the forms of presentations and publications..

What Is a Protocol?

Example..

Clinical research is conducted according to a plan (a protocol) or action plan. The protocol acts like a “recipe” for conducting the trial. The plan describes what will be done in the study, how it will be conducted, and why each part of the study is necessary. The protocol or plan is carefully designed to safeguard the participants’ health and answer specific research questions. The same protocol is used by every doctor or research center taking part in the trial. A protocol describes:

- Who is eligible to participate in the trial
 - Details about tests, procedures, medications, and dosages
 - The length of the study and what information will be gathered
- A protocol is led by a principal investigator. The principal investigator is often a doctor. Members of the research team regularly monitor the participants’ health to determine the study’s safety and effectiveness and/or efficacy.

A protocol is a study plan on which each clinical trial is based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

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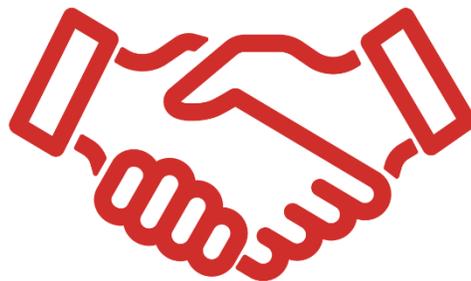
What Is a Protocol Review?

Clinical trials in the United States must be approved and monitored by an Institutional Review Board (IRB). The IRB ensures that the risks are minimal and are worth any potential benefits. An IRB is an independent committee. Physicians, statisticians, and members of the community belong to an IRB. The committee ensures that clinical trials are ethical and that the rights of all participants are protected. U.S. regulations require all research institutions in the United States that conduct or support biomedical research involving people to meet certain requirements. An IRB must initially approve and periodically review the research. Some research institutions have more than one IRB. During protocol reviews, networks review and assess what other networks are doing to see what information applies to what they are doing.

Major players in Research team

Sponsor

- Investigator
- Clinical Research Associate
- Clinical Research Coordinator
- Data Manager
- Statistician
- Patients
- IRB
- Regulatory Body



World Health Organization

Major players in Research team

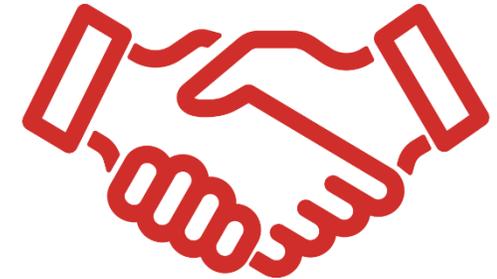
- Investigator
- Clinical Research Associate
- Clinical Research Coordinator
- Data Manager
- Statistician
- Patients
- IRB
- Regulatory Body



What Is a Sponsor?

Clinical trials are sponsored or funded by various organizations or individuals, including:

- Physicians
 - Foundations
 - Medical institutions
 - Voluntary groups
 - Pharmaceutical companies
 - Federal agencies such as the National Institutes of Health, the Department of Defense, Centers for Disease Control and Prevention (CDC), and the Department of Veterans Affairs
- Trials can occur at sites as varied as hospitals, universities, doctors' offices, or community clinics.





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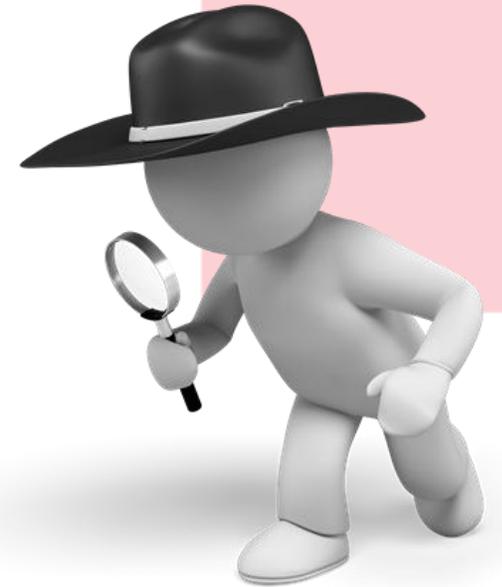
Principal Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Responsibilities : Investigator

- Investigators Qualifications
- Adequacy of Resources
- Medical Care of Study Participants
- Communication with the IRB / IEC
- Compliance with the Protocol
- Investigational Product care
- Records and Reports
- Progress Reports
- Safety Reporting
- Stopping or suspending a study
- Final report by investigator
- Randomization & unbinding
- The Informed Consent

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Institutional Review Board



CRC

- Person who handles most of the administrative responsibilities of a clinical trial, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor's visit.
- Functions as extension of Investigator.
- Involved in operational duties – recruiting, scheduling, completing CRF's, administering tests.

www.

CRA (Monitor)

- A person appointed by the Sponsor or Contract Research Organisation (CRO) for monitoring and reporting the progress of the trial and for verification of data.
- The monitor ensures that the trial is conducted, recorded and reported in accordance with the Protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements.

Responsibilities: Monitor

- Main line of communication between sponsor and site
- Site feasibility Training and support
- to site staff & selection
- Protocol & GCP Compliance
- Document completeness & maintenance
- Source Data Verification
- Trial material accounting
- Monitoring reports & other office documentations
- Prepare and assist in IRB, Regulatory and internal audit or inspection
- Assist in IRB and Regulatory Submission
- Assist in IRB and Regulatory Submission
 - Ensure timely AE & SAE reporting

What Is Informed Consent?

Informed consent is the process of providing potential participants with important facts about a clinical trial before they decide to participate. The process of informed consent, which means “providing additional information,” continues throughout the study. Members of the research team explain the details of the study.

This explanation helps people make a decision that is right for them. Informed consent is not a contract or just a piece of paper—it is a process.

Informed consent must be provided:

- In the participants’ native language
- At an appropriate educational level Translation or interpretive assistance can be provided for participants with limited language skills.

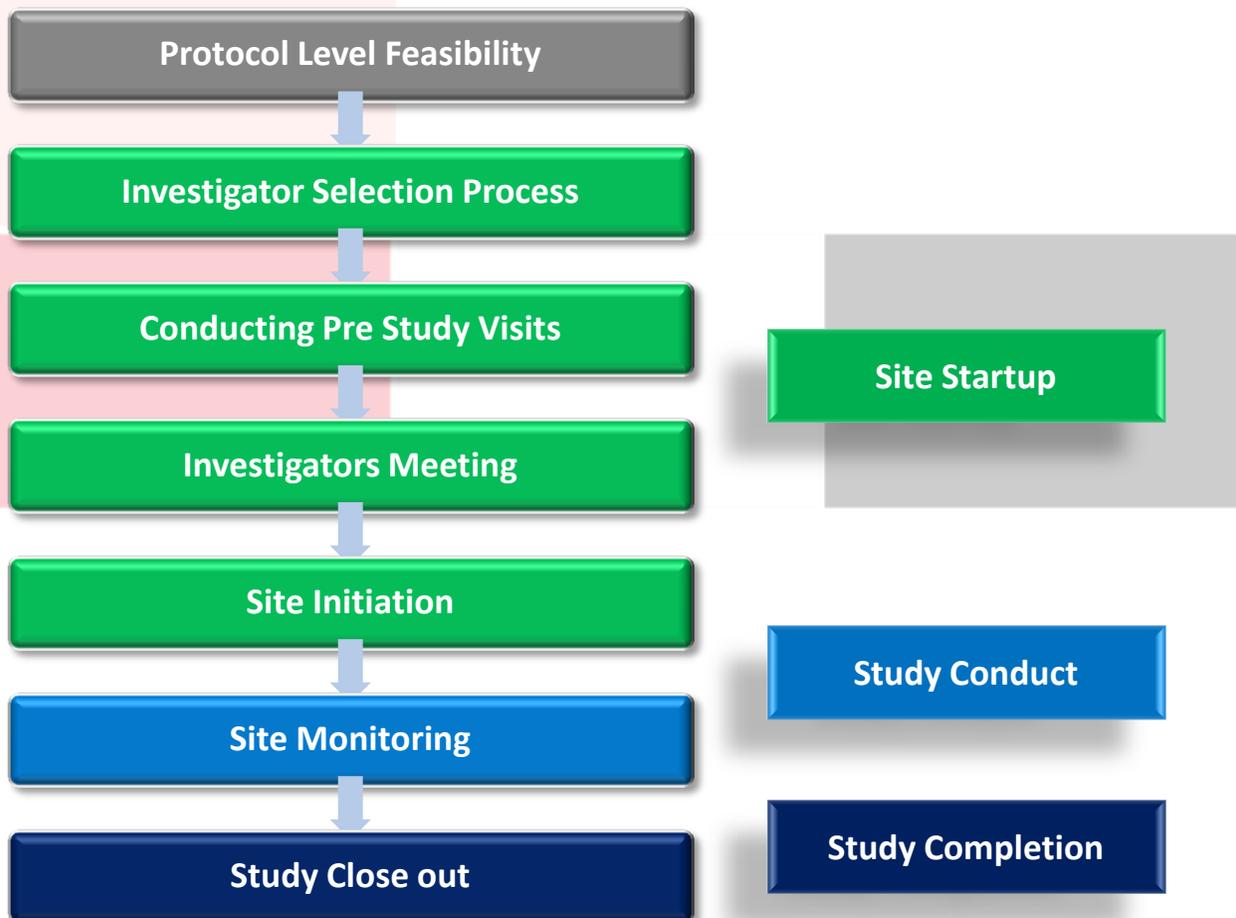
The research team provides an informed consent document that includes details about the study:

- Its purpose
- Duration
- Required procedures
- Who to contact for more information
- An explanation of risks and potential benefits The participant then decides whether to sign the document

In many communities, illiteracy and mistrust exist toward anyone who asks for a signature as a commitment. Sometimes people fear their signatures may lead to unexpected obligations, because they attach great importance to legal formalities. Volunteers are free to withdraw from a study completely or to refuse particular treatments or tests at any time (sometimes, however, this will make them ineligible to continue the study). Notes

COMMUNITY ADVISORY BOARDS (CABS) AND THE RESEARCH PROCESS and IRB....

Study Start Up



Feasibility Studies

- Protocol feasibility: To assess from the region(s)/country(ies) where the clinical study is to be conducted, agreement on important study criteria like inclusion exclusion criteria, comparator drug, and study procedures outlined in the Protocol Synopsis, to prevent the need for protocol amendments later in the planning process
- A secondary objective is to provide information to support finalization of the country/region allocation

Site feasibility: involves assessing site potential based on multivariate factors like Principal Investigators experience & interest in Clinical Research, patient inflow, accessibility to the site, availability of patients that meet the study criteria, and other related factors that affect the accrual rates and proper conduct of study related activities.

- This is done to ensure that appropriate sites/Principal Investigators are identified

Site Selection

- It can be defined as a systematic planned process to evaluate and select an investigator and site for conduct of clinical trial
- Factors involved in selection
 - Reputation in field
 - Facilities desirable for trial conduct
 - Access to patient population
 - Accessible geographic location
 - Anticipated time for initiation and completion of trial
 - EC–ability to process protocols fairly and expeditiously
- Relationship with sponsor
- Budgetary factors
- Past experience
- Experienced staff

Investigator Meeting

- Purpose
 - Achieve uniformity in approach by all investigators
 - Review and discuss the protocol
 - Answer questions
 - Generate enthusiasm
 - Get everyone to know each other and develop a sense of teamwork and trust
 - Review potential difficulties, issues and problems
 - Review administrative ground rules

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Site Initiation

- Study initiation is done to review protocol, processes and procedures to ensure that all site personnel understand requirements of trial
- Sites are initiated after all regulatory & ethical documentation is complete, after IP and other supplies are shipped and before any patients are enrolled

Monitoring

- Purpose
- To verify
 - protection of rights and well-being of subjects
 - reported trial data is accurate, complete, and verifiable
 - trial is in compliance with:
 - Protocol and amendments
 - Regulatory requirements
 - Enrolment
 - Drug supply

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Study Close Out

- All After ensuring the study is complete
- CRF received
- All study material is accounted for
- All investigational product is accounted for and balance returned to sponsor
- Ensure payment completion



Key Issues

Start Up

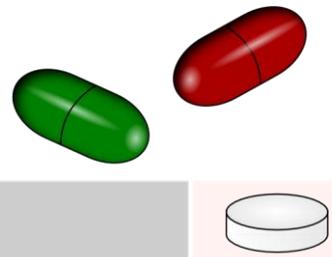
- Delegate responsibilities
- Educate research team
- Enrollment plan
- Study documents

Conduct

- Protocol compliance
- Documentation
- Record retention
- Trial drug accountability
- Safety reporting

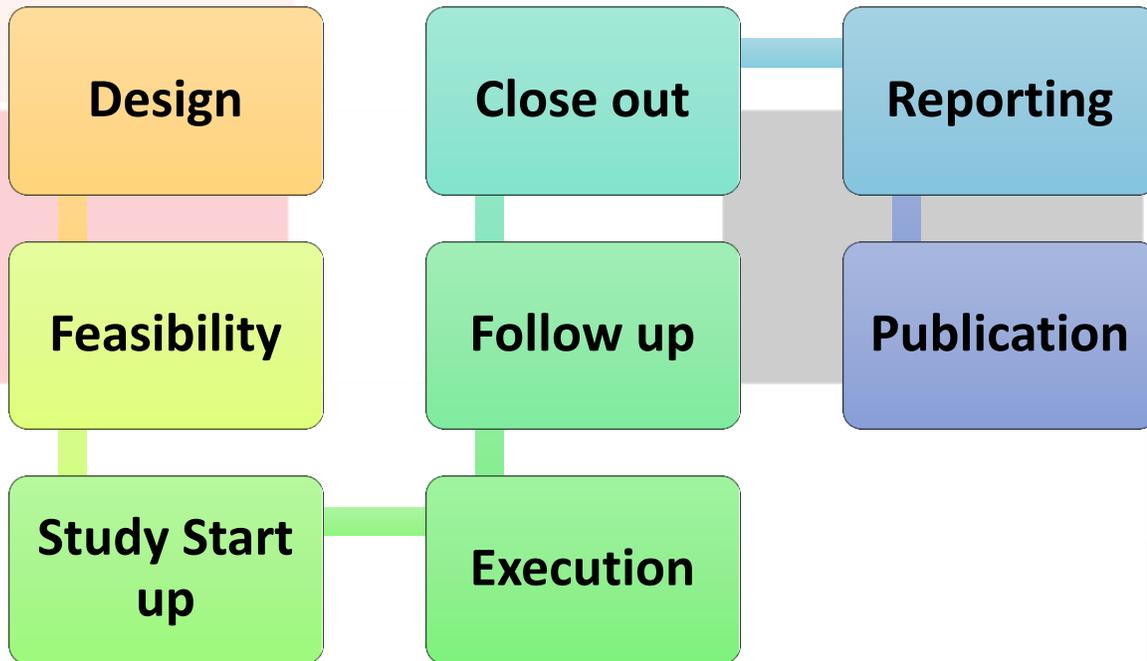
Close Out

- Final drug accountability
- Preparation of records for archiving
- Storage or destruction of lab samples
- Data query resolution
- Notification to governing regulatory body



Site Management

A structured & planned approach to manage various research activities/functions at a site to ensure execution through compliance and strict adherence to safety standards -through periodic monitoring per pre-determined/planned monitoring plan.

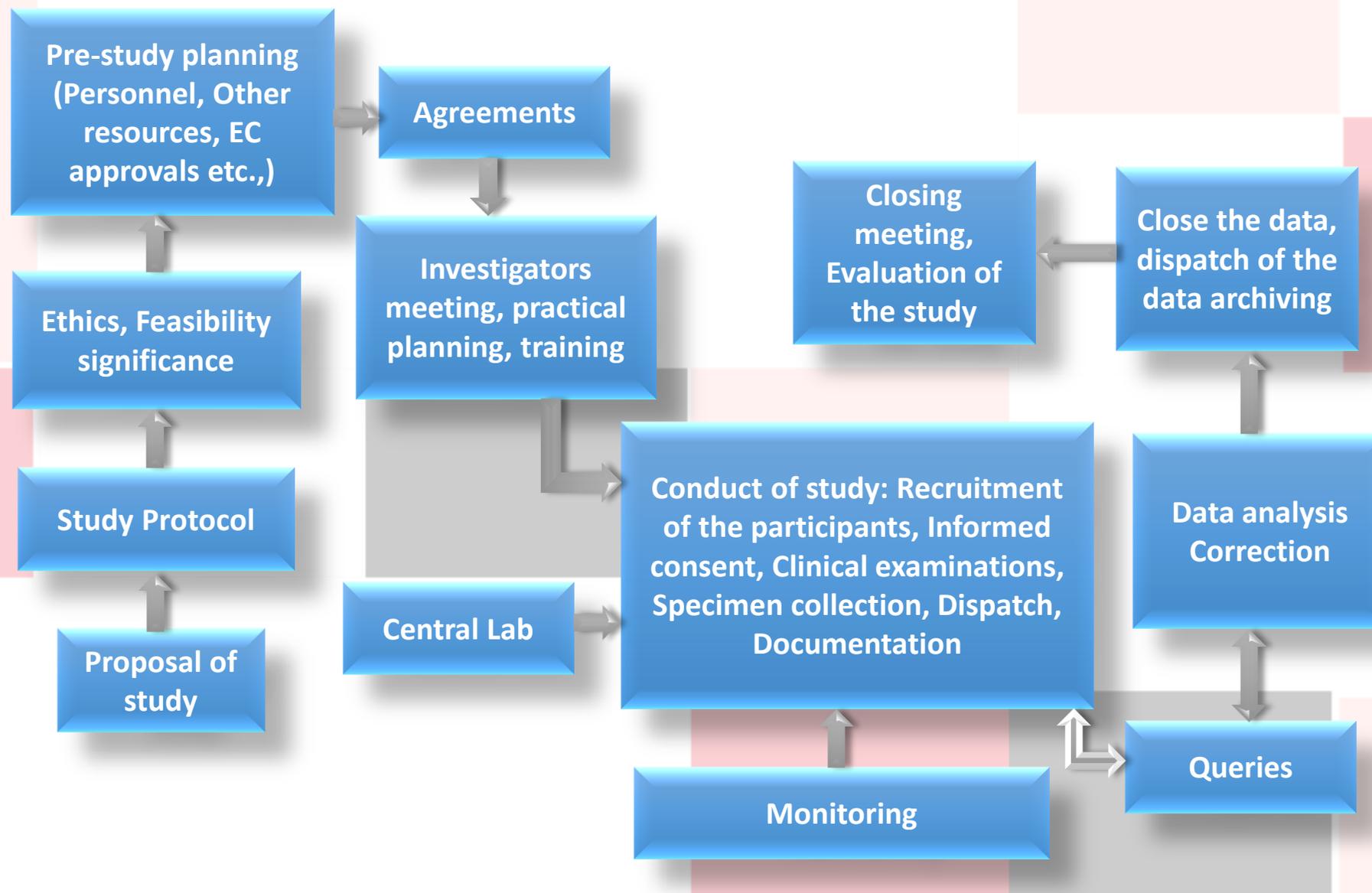


Study Documents

- Investigator's Boucher
- Protocol
- Informed Consent Form
- Case Report Form
- Financial Disclosure Form
- EC Approval Letter
- Clinical Trial Agreements and Budget
- Lab Normal Ranges
- Sample Labels
- Pre trial Monitoring Report
- Signed Agreements between 2 parties.



Process Flow





What are the types of clinical trial?

Type of Clinical Trial	Description
Treatment	Test new treatments, new combinations, new approaches to surgery or radiation therapy, or clinical management strategies.
Prevention	Look for better ways to prevent a disease in people who have never had the disease. In the case of diseases other than HIV/AIDS, to prevent the disease from returning. Better approaches may include medicines, vaccines, and/or lifestyle changes.
Diagnostic	Determine better tests or procedures for diagnosing a particular disease or condition.
Screening	Test the best way to detect certain diseases or health conditions.
Quality of Life (or Supportive Care)	Explore and measure ways to improve the comfort and quality of life of people with a chronic illness.



Pristyn Research Solutions

Pristyn Research Solutions is a leading global supplier of IT services to global enterprises to advance their IT applications. Apart from software development, we provide validated data for research & dedicated professionals. It has International Centers in all over the country for the purposes of recruitment to support research, training and development of Human Resource from Corporate, Pharma

Pristybase, Pharma/Clinical/ Medical Reporting System

Pristybase is a global safety data base and a platform containing spontaneous ADR reporting & Individual Case Safety Reporting (ICSR) can be submitted by the participating member Pristyn | Individual health care & Pharma professional | working professionals and researchers. It is promoted with the aim of awareness and safe use of the drug and medicinal products, also with the main mission of promotion of international regulations and guideline in the field of research and development. As per Indian Pharmacopoeia Commission (IPC) Pharmacovigilance is the need of society. Hence while designing & development of templates of Pristybase Indian and international regulatory body's formats and guideline are taken into considerations. Like Indian Drug Administration (IDA) previously known as CDSCO | Uppsala Monitoring Centre (UMC-Sweden) on behalf of WHO, a detailed considerations about guidelines of Indian GCP and CIOMS as well as ICH-GCP have been taken care while development of the same.

Pristybase will be used to obtain the information about a safety profile of a medicinal product. These data will be used by pharmaceutical industries, academic institutions and regulatory authorities for statistical signal detection, updating periodic reports (PSUR), and the latest and new version of Pristybase will be available soon on a server globally and professionals will be provided access to the case study for their reference and research protocols.

An overlay window titled 'Admin login' is shown over the website content. The window has a light blue border and contains two input fields: 'User Name' and 'Password'. Below the fields is a 'Login' button. The background of the window shows a laptop keyboard and a blue stethoscope on a white surface.

Admin login

User Name

Password

Login



C. SUSPECTED MEDICATION(S)

Report Number	<input type="text"/>	Exp. Date	<input type="text"/>	Therapy dates started	<input type="text"/>
Sr.No	<input type="text"/>	Dose used	<input type="text"/>	Therapy dates stopped	<input type="text"/>
8. Name (Brand/Generic)	<input type="text"/>	Route used	<input type="text"/>	Indication	<input type="text"/>
Manufacturer (if known)	<input type="text"/>	Frequency (OD, BD etc.)	<input type="text"/>	Causality Assessment	<input type="text"/>
Batch No. / Lot No.	<input type="text"/>				

Add

Report Number	S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates started	Therapy dates stopped	Indication	Causality Assessment

9. Action Taken(in Yes or No)

Report Number	<input type="text"/>	Dose increased	YES	Not applicable	YES
S.No as per C	1	Dose reduced	YES	Unknown	YES
Drug withdrawn	YES	Dose not changed	YES		

10. Reaction reappeared after reintroduction (please tick) YES

Effect unknown	YES
Dose (if reintroduced)	<input type="text"/>

Add

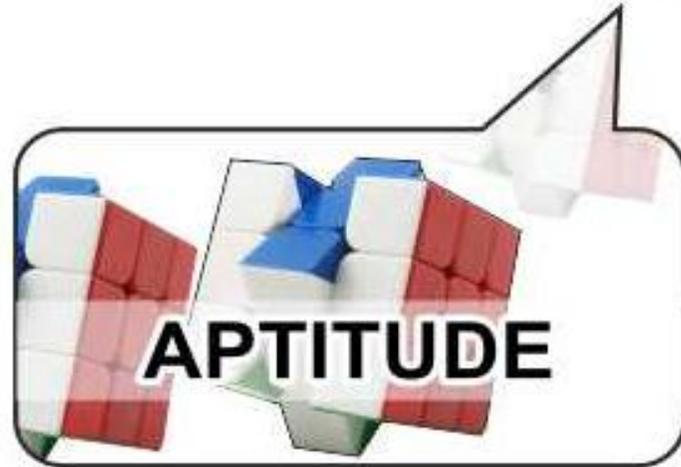
Report Number	S.No as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Reaction reappeared	Effect unknown	Dose (if reintroduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

Report Number	<input type="text"/>	Route Used	<input type="text"/>	Therapy dates stopped	<input type="text"/>
Sr.No	<input type="text"/>	Frequency (OD, BD, etc.)	<input type="text"/>	Indication	<input type="text"/>
Name (Brand/Generic)	<input type="text"/>	Therapy dates started	<input type="text"/>		

Add

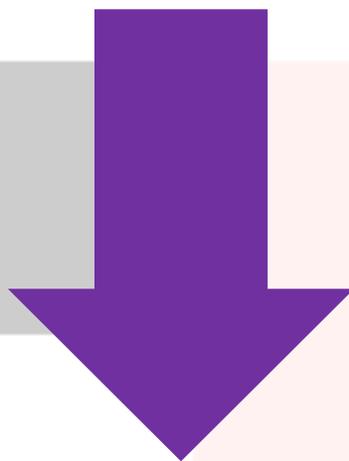
Current Standard Hiring Process of Companies





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Short Term Courses with placements
assistance and guarantee Kindly call us**



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Medical Transcription | Medical Writing | Research Publications

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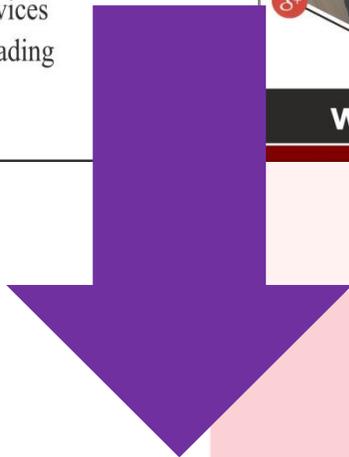


Wobble Base Bio Research



CORPORATE SERVICES

CDMS| e-CRF| EDC| Protocol| SAS| Oracle| Hadoop | ERP| CRM| ADRs and SAE fillings
 e-CRT| I.B| Medical Coding | PSUR| RMP| Systematic Review and Meta-Analysis
 Medical and Clinical Data Entry Pharma and Medical Translation |
 Employee Development Programs | Software Development and Frame-work services
 Outsourcing for compilation of research data | Regulatory Submission | Proof Reading
 Pharma | Medical Digital Marketing Research Publications
 Arrangement of Placement Drives



LAST

Our Trainees/ Students are placed in:



STUDENT SPEAK ABOUT PRISTYN TRAINING & PLACEMENT PROGRAM

"If you have joined Pristyn, your career and you, both are in good hands! Pristyn had a solution for every problem of mine. Joining here was the best decision. After coming here, I came to know what it takes being the best and stand out from the rest. Pristyn helped me to challenge any interview with my training and technical knowledge."

Komal.Choukhande, SGRS College of Pharmacy Saswad , Pune.



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Shivaji College of Pharmacy, Deori



Guests present at the workshop.

A DAYLONG workshop on "Students Industrial Pre-Placement Programme" was organised by Chhatrapati Shivaji College of Pharmacy, Deori in association with MSBTE, Mumbai and Pristyn Research Solution, Pune. The

main objective behind organising the workshop is to create awareness among the student about the industrial demand for skilled manpower to have employability. Pristyn Director Pathan Azhar Khan guided on Drug Discovery to Approval process with latest requirements and international regulations. The delegates were acquainted with role and responsibilities, interview techniques and job requirement. Pristyn Counselor Pavitra Shibad and Vinod Nair explains about the importance of having pleasant personality, soft skills and communication skills. In this workshop, Zhamsing B. Yerne, President Krushna Sahyptgi Tantra Shikshan Sanstha (Deori) Presided over while Dr. Milind Umekar, Principal SKB College of Pharmacy, Kamptee and Dr. Dinesh Biyani Associate Prof. were chiefly present alongwith Anil Z. Yerne, Secretary and Jayshree Yerne. Dr Milind Umekar also spoke on the occasion. Earlier, Upadesh Bhimrao Lade, Principal of Chhatrapati Shivaji College of Pharmacy, Deori delivered inaugural speech. Meenakshi Mhaske conducted the proceedings while Co-ordinator Sandipkumar Agrawal proposed vote of thanks.

Shri Shivaji College, Akola

About Pristyn Research Solutions:

Pristyn Research Solutions is a leading global supplier of I.T, Clinical, Pharmaceutical services and Knowledge processing services. We help global enterprises to advance their IT applications. Apart from software developments and frame-work global services Pristyn provide corporate training in profession and skills development. We strive to produce validated data for research & dedicated professionals. It has International affiliations and regional government approvals for organizing training programs, all over the country - for the purposes of recruitment to superior posts. It has huge associations of individuals and group involved in the area of training and development of Human Resource from Corporate, Public, Private Sector Organization & other Professional Bodies. For us every candidate is important & every company is unique. This is a place where a candidate identifies his/he career loopholes, overcome those & match the principle of RIGHT CANDIDATE FOR RIGHT JOB.

Short-Term Industrial & Corporate Training on: (Life-Science)

(A) Domain	(B) Domain	(C) Domain
1. Clinical Research	1. Pharma Q.A/Q.C	1) Medical Coding
2. Pharmacovigilance	2. Pharma Production	2) Medical Writing [MS]
3. Clinical data Management	3. DRA Ph-Digital Marketing	3) P.V Research Publications
4. Drug Regulatory Affairs	4. R & D	4) DRA
Duration= 3 Months	Duration= 3 Months	Duration= 3 Months



28 Days Job Training

- Technical Terminologies used in Interviews and Job Workplace.
- H.R and Company Communication Skills
- Mock Interviews and Professionalism
- Aptitude Training and Brain Boosting
- Group Discussion and Teamwork
- Job Search/Job Applying Tools and Tricks
- Computer & Online literacy required for Job
- Job and companies Applications /Email Writing
- Resume/C.V and Profile Building
- Motivational Lectures by industry Persons
- Career Guidance/ Self-Confidence Boosting
- Brush up-on English language.
- Soft Skills and communication
- Personality Development & Presentation Skills
- Placement Tools and Assistance
- Other Customize and personal Support

Advanced PGD & Professional Internship Program (Life-Science)



(Drug Discovery to Approval)

All Domains

Duration= 4+ 2 Months

2 Months Project & Placement

Short-Term Industrial & Corporate Training on: (I.T)

Domain	Domain	Duration=3 M
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 1 Month

Advanced PGD & Professional Internship Programed (I.T)

Domain	Domain	Duration= 6 Months
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 2 Month

