

INVESTIGATOR

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An investigator is a person responsible for conducting the clinical trial and overseeing the participants involved in the trial. If the trial involves a team, this person leads the team and is called the principal investigator



Investigator Site is the location(s) where clinical trial activities such as participant care and data collection take place and/or coordinated under the supervision of the investigator or institution

The roles and responsibilities assigned to the investigator inherently apply to the investigator site as well, since the investigator is ultimately responsible for all trial activities conducted at that site

The key responsibilities assigned to the investigator are summarized below:

Qualifications and Training: Must be qualified by education, training and experience to properly conduct the trial and should provide proof of these qualifications. The investigator must be knowledgeable about the investigational product and the trial Protocol

Resources: Should be capable of recruiting the necessary number of eligible participants and must have adequate time, qualified staff and suitable facilities to conduct the trial effectively

Responsibilities and Delegation: May delegate trial-related tasks but remains ultimately responsible for participant safety and data accuracy. All delegations must be clearly documented and supervised appropriately with supervision levels proportionate to the risk and importance of the delegated tasks

Communication with Ethics Committee: Maintain prompt and continuous communication with the ethics committee for obtaining approvals and submitting required reports

Participant Recruitment and Informed Consent: Ensure that participants are recruited ethically and that informed consent is obtained according to the study protocol and regulatory requirements

Medical Care of Participants: Confirm that participants receive proper medical care throughout the trial, including managing any adverse events that occur

Safety Reporting: Report serious adverse events promptly to sponsors and regulatory authorities, with appropriate causality assessment. For deaths, the investigator must provide the sponsor, the ethics committee and regulatory authorities with any additional requested information, such as autopsy or medical reports, when available

Record Keeping: Maintain accurate, complete and secure source and trial records accessible for audits and inspections

Randomisation Procedures and Unblinding: Must follow the trial's randomization plan and only unblind treatment when necessary for participant safety or trial integrity, reporting the unblinding properly

Investigational Product Management: Responsible for managing the handling, storage, dispensing and accountability of investigational product(s) during the trial. While the sponsor may provide assistance, the investigator retains ultimate oversight and responsibility for these activities

Data Handling and Reporting: Ensure that data collected are accurate, timely, verifiable and reported according to the study protocol and regulatory standards

Compliance with Protocol and GCP: Conduct trial according to the approved protocol, good clinical practice standards and applicable regulatory requirements

Premature Termination or Suspension: Manage early trial suspension / termination by ensuring proper follow-up care for the participants and inform institution, sponsor, ethics committee, regulatory authority about suspension/ termination as Applicable

End of Participation in a Clinical Trial: Ensure proper follow-up care for participants after their trial involvement ends and protect all collected data according to the trial protocol and regulations

Final Report and Communication: Participate in preparing trial reports and maintain open communication about trial results and participant care as needed

These responsibilities highlight the importance of diligent oversight, ethical conduct, participant safety and maintaining data integrity throughout the clinical trial process