

Outlined below are the Sponsor's key responsibilities:

Trial Design: Design the trial to protect participants, ensure it can be carried out effectively with focus on quality and include inputs from stakeholders involved

Resources: Provide sufficient resources such as qualified staff and suitable facilities to support the clinical trial

Allocation of Activities: Assign trial tasks clearly, document who is responsible for what and ensure proper supervision

Qualification and Training: Make sure all personnel are properly trained and qualified for their trial roles

Financing: Secure adequate funding for the trial and manage finances transparently with appropriate documentation

Agreements: Create clear, written agreements that define the roles, responsibilities and expectations with investigators, institutions and service providers

Investigator Selection: Select investigators who are skilled and qualified to handle all aspects of the trial

Communication with Ethics Committee and Regulatory Authorities: Maintain effective communication with ethics committees and regulatory bodies throughout the conduct of the trial

Sponsor Oversight: Continuously supervise all trial activities, including those done by outside service providers to ensure all activities are managed effectively

Quality Management: Set up a quality management system to control and oversee all essential trial processes effectively

Quality Assurance and Quality Control: Establish and uphold quality assurance and quality control systems with robust monitoring and comprehensive documentation practices

Noncompliance: Promptly address and record any non-compliance, take corrective actions and report significant issues to authorities, as required

Safety Assessment and Reporting: Ensure all safety information from the trial is properly collected, checked and reported to regulators and others as required

Insurance/Indemnification/Compensation: Provide appropriate insurance, indemnification and compensation for trial participants and investigators

Investigational Product(s): Manage all aspects of investigational product handling such as supply, storage, distribution, accountability and destruction in compliance with the protocol and regulatory requirements

Data and Records: Ensure trial data and records are accurate, secure, complete with full traceability and confidentiality and are accessible for inspections

Reports: Prepare detailed trial reports, whether interim or final, that meet regulatory submission requirements and keep investigators updated on any follow-up treatments or therapies when applicable

These responsibilities ensure that clinical trials are scientifically valid, ethically conducted and comply with applicable regulations and standards to protect participant safety and maintain data integrity