

The primary responsibilities of a Clinical Research Coordinator include:

Feasibility and Site Selection: Complete and submit the site feasibility document received from the sponsor/ sponsor representative by coordinating with the investigator to gather required details. Assist sponsor/sponsor representative during site selection visit

Ethics Committee Submission: Submit all trial documents to the ethics committee, track the status, respond to queries and support communication between the principal investigator and ethics committee during review. Ensure secure and organized maintenance of all ethics committee related documents. During the conduct of a clinical trial, submit safety reports, progress updates and any changes to the documents such as protocol amendments to the ethics committee

Investigator Meeting: Attend investigator meetings as needed alongside the investigator and communicate key information to the other members from the site team

Site Initiation Visit: Organize and facilitate the visit, ensure site staff is trained on the protocol, confirm that all required documents and supplies are ready and support the site to be fully prepared to start the trial

Patient Recruitment: Assist in identifying and screening eligible participants, explaining the study protocol and maintain ongoing communication with participants throughout the trial to ensure retention and compliance. Work closely with the principal investigator to implement effective recruitment strategies

Informed Consent: Provide assistance during the informed consent process. Ensure participants understand the study, obtain and document their voluntary informed consent and maintain compliance with regulatory and ethical guidelines throughout the process

Data Maintenance: Responsible for accurately maintaining source documents and completing case report forms to ensure data integrity and compliance with study protocols and regulations. Facilitate monitoring visits, audits and inspections

Investigational Product Management: Ensure proper storage, handling, dispensation, accountability, return/destruction and documentation according to protocol and regulatory requirements throughout the clinical trial. Coordinate inventory control and assist with shipment and reconciliation of the investigational product

Essential Records: Maintain and organize all essential clinical trial records accurately and securely, ensuring regulatory compliance and keep them audit / inspection ready throughout the study and after its completion

Safety Reporting: Collect and document adverse events. Report serious adverse events in compliance with safety reporting timelines and regulatory requirements in a clinical trial

Study Close Out: Ensure all study documents are complete, ethics committee is notified about the study closure, resolve outstanding queries, manage investigational product return/destruction and secure archival of study records during the study close out.

Based on experience, clinical research coordinators may participate in developing SOPs, training and supervising staff, managing budgets, tracking finances and overseeing resource allocation.

Thus, clinical research coordinator plays a vital role in ensuring that the clinical trial is conducted ethically, safely and efficiently, while maintaining data integrity and prioritizing the welfare of participants