Roles of Study Coordinator

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Roles of Study Coordinator

• Definition of Study Coordinator
  Anyone who acts as point person for the clinical-study site, overseeing all study operational responsibilities
Roles of Study Coordinator

- Pre-trial
- Trial
- Post Trial
Roles of Study Coordinator

• Study Coordinator must ensure that Essential Documents for the conduct of the clinical trial are prepared and kept safely.
• These documents serve as to demonstrate the compliance of the investigator with the GCP standards and applicable regulatory requirements.
Roles of Study Coordinator

• The documents includes trial master files (essential documents) and patients files (source files and CRF’s)

• These documents should be available for monitoring, audit by Sponsor auditors and inspection by regulatory authorities
Pre Trial Roles

- Coordinates the development of forms, questionnaires and the application of research techniques

- Assists in writing procedures manuals for data collection and coding.

- Informs patients or caregivers about study aspects and outcomes to be expected
During Trial Roles

• Plans and coordinates the initiation of research study protocol, and the establishment of operating policies and procedures
• Coordinates the day-to-day activities of the study
• Ensures the smooth and efficient day-to-day operations and data collection activities
During Trial Roles

• Ensures compliance with protocol guidelines and requirements of regulatory agencies
• Recruits participants, collects research data and manages calendars as they relate to the project.
During Trial Roles

• Coordinates and implements procedures to collect data from patient charts, medical records, interviews, questionnaires, diagnostic tests and other sources

• Monitors patients' progress to include documentation and reporting of adverse events
During Trial Roles

• Identify problems and/or inconsistencies and recommend corrective action as appropriate
• Ensures compliance with protocol guidelines and requirements of regulatory agencies
• Monitors study activities to ensure compliance with protocols and with all relevant local, state and federal regulatory and institutional polices
During Trial Roles

- Administers study drug(s) (if applicable)
- Obtains blood samples, respiratory samples, cultures, tissues and other specimens for laboratory analysis
- Maintains required records of study activity including case report forms, drug dispensation records and regulatory documents
During Trial Roles

• Acts as the primary administrative point of contact for internal research staff
• Acts as an operational liaison for other research organizations, funding agencies and regulating bodies
During Trial Roles

• Monitors the progress of research activities; develops and maintains records of research activities
• Prepares periodic and ad hoc reports, as required by investigators, funding agencies, and/or regulatory bodies
• Implements quality control process throughout the conduct of the trial/study
Post Trial Roles

• Plans, implements, and maintains data collection and analysis systems in support of research protocol; may coordinate the collection and analysis of research data

• Evaluates and interprets collected data and prepares appropriate documentation
Post Trial Roles

• Confers with PI to assist in developing plans for research projects and to discuss the interpretation of results

• Collaborate on the preparation of manuscripts for publication.
Post Trial Roles

• Prepares oral presentations or written reports and appropriate recommendations or conclusions.

• Submit final reports as required to regulatory authorities

• Ensure final trial close-out activities are completed and essential documents filed.
Roles of Study Coordinator

- Good listener and communicator
Thank you

- Multi tasking