Roles of Study Coordinator

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H3Africa Consortium Meeting

Dar-es-Salaam, Tanzania

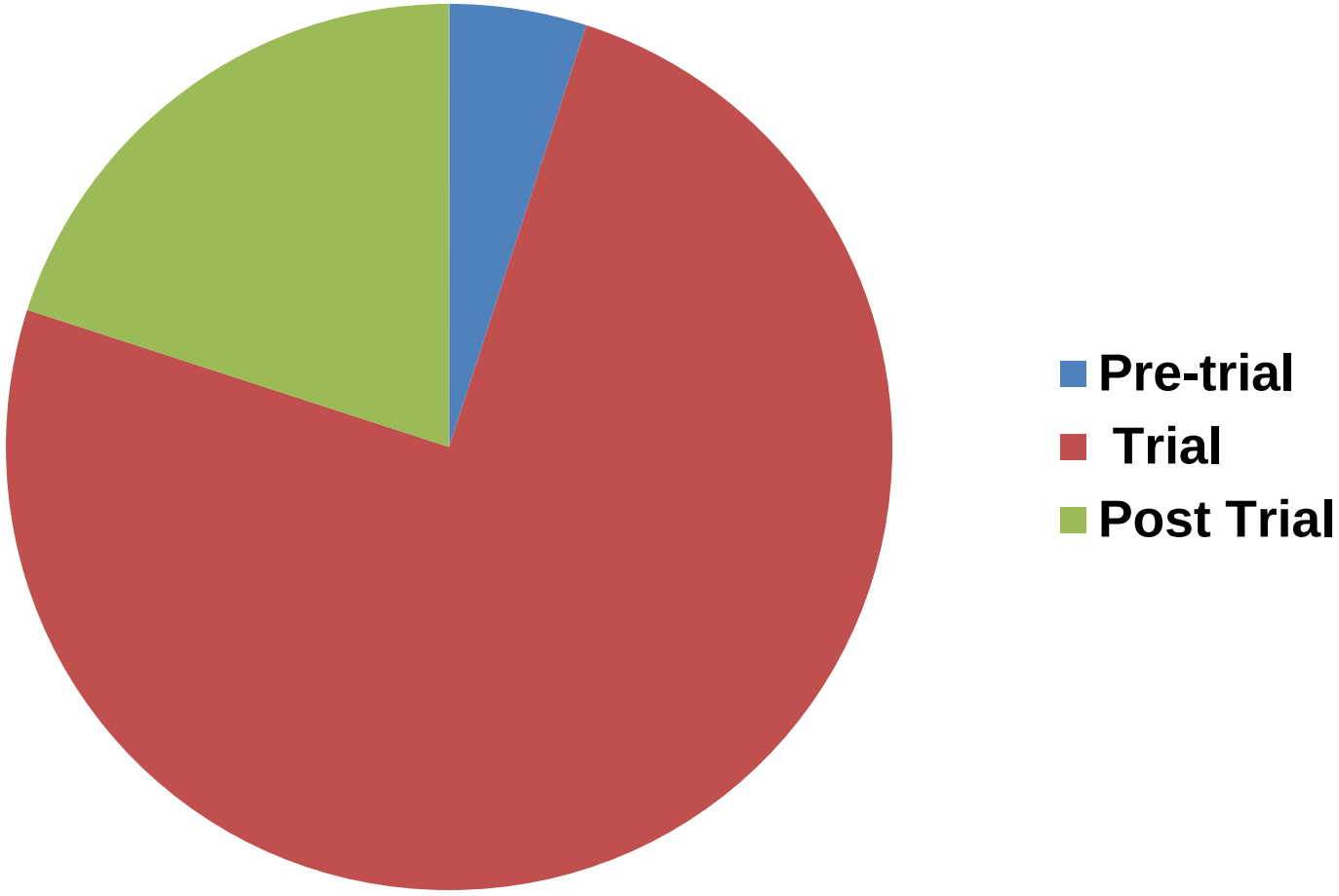
October 10, 2014

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



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

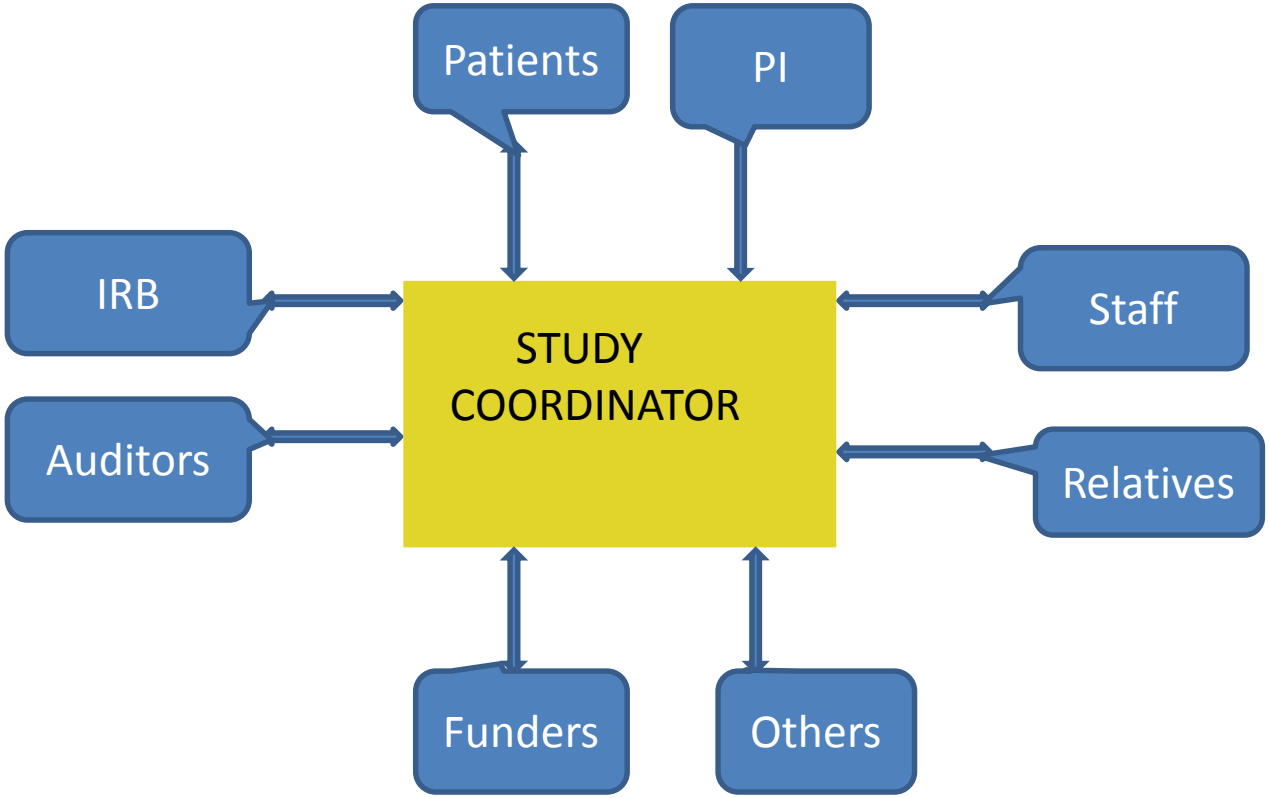
- Confers with PI to assist in developing plans for research projects and to discuss the interpretation of results
- Collaborate on the preparation of manuscripts for publication.

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**