Job Holder:
Job Title:*: Junior CRA*
Career Level: TBD
Department: Global Clinical Operations-SMM {Region}
Function: GMD
Reports To: Clinical Research Manager {Region}
Direct Reports: No
Indirect Reports: No

Description

The Clinical Research Associate (CRA) has local responsibility for the delivery of the studies at allocated centres and are active participants in the MC study team(s). The CRA works in close collaboration with other CRAs and the Local Study Delivery Team to ensure that quality and quantity commitments are achieved in a timely and efficient manner.

The CRA is responsible for the preparation, initiation, monitoring and closure of an agreed number of centres in clinical studies according to AZ Procedural Documents, international guidelines such as ICH and GCP as well as relevant local regulations. Deliver according to the commitment in the individual trials.

A CRA with longer tenure and experience may take on additional responsibilities that include additional tasks associated with with Lead CRA, Senior CRA , Local Study Team Leader (LSTL).

Major responsibilities

- Obtain and maintain essential documentation in compliance with ICH-GCP, AZ Procedural Documents and local regulations both in the office and at site.
- Actively participate in local Study Delivery Team meetings.
- Contribute to the selection of potential investigators.
- Train, support and advise Investigators and site staff in study related matters.
- Contribute to national Investigators meetings.
- Initiate, monitor and close study sites in compliance with AZ Procedural Documents. Share information on patient recruitment and study site progress within local Study Delivery Team.
- Drive performance at the sites. Proactively identify study-related issues and escalates as appropriate.
- Update IMPACT and other systems with data from centres as per required timelines.
- Manage study supplies (ISF, CRF, etc), drug supplies and drug accountability at study sites.
- Perform source data verification according to SDV plan.
- Ensure data query resolution.

- Ensure accurate and timely reporting of Serious Adverse Events.
- Prepare for activities associated with audits and regulatory inspections in liaison with local Study Delivery Team Lead and CA&A.
- Provide the required monitoring visit reports within required timelines.
- Work with data management to ensure quality of the study data.
- Ensure compliance with AstraZeneca's Code of Conduct and company policies and procedures relating to people, finance, technology, security and SHE (Safety, Health and Environment).

Additional Responsibilities May Include

- Ensure completeness of the Study Master File and ensure essential documents are sent to R&D site.
- Ensure timely delivery of proper applications/documents for submission to Regulatory Authorities.
- Ensure timely customization and completion of the CSA for designated studies
- Design draft budget for designated studies according to fSMA requirements
- Track and manage agreed payments at study site level.
- Participate in training and mentoring of new members of the local Study Delivery Team ensuring compliance with ICH/GCP and AZ Procedural documents.
- Ensure that all study documents are ready for final archiving and sign-off completion of local part of the Trial Master File.
- Contribute to process improvements, knowledge transfer and best practice sharing.
- Actively share applicable information that may be relevant to Marketing & Sales and the MC Medical Department and in accordance with Corporate Ethical guidelines.

Minimum Requirements and Preferred Background

- University degree in related discipline, preferably in life science, or equivalent qualification.
- Fluent knowledge of spoken and written English.
- Excellent knowledge of international guidelines ICH/GCP, basic knowledge of GMP/GDP.
- Good knowledge of relevant local regulations.
- Good medical knowledge in relevant AZ Therapeutic Areas.
- Basic understanding of the drug development process.
- Good understanding of Clinical Study Management including monitoring, study drug handling and data management.
- Ability to travel nationally as required.

Competencies and Skills

- Ability to deliver quality according to the requested standards.
- Ability to work in an environment of remote collaborators.
- Manages change with a positive approach for self, team and the business. Sees change as an opportunity to improve performance and add value to the business.
- Ability to look for and champion more efficient and effective methods/processes of delivering quality clinical trials with reduced budget and in less time.
- Excellent written and verbal communication skills, negotiation, collaboration and interpersonal skills.
- Good analytical and problem solving skills.
- Demonstrates ability to prioritize and manage multiple tasks with conflicting deadlines.
- Good cultural awareness.
- Ability to understand the impact of technology on projects and to use and develop computer skills while making appropriate use of systems/software in an e-enabled environment.
- Team oriented and flexible; ability to respond quickly to shifting demands and opportunities.