ROLE PROFILE

General Information

Job Title : Clinical Research Associate

Acronym (filled in by HR) **:** AMCL **Review :** 2

Job Purpose

The main function of a Clinical Research Associate is to manage, and monitor the conduct of assigned clinical trials in compliance with established timelines, ICH/GCP, ISO 14155, Country regulations and Lima policies and procedures.

Major Accountabilities

- May assist in developing overall clinical strategy, including necessary regulatory requirements for key markets.
- Develop and manage designated clinical studies including all phases:Protocol study development, investigator/site selection, contract negotiation, preparation of trial related documentation and Ethics committee and/or other required Competent Authorities submissions with follow through to ensure successful outcome.
- Develop and maintain good working relationships with investigators and study staff.
- Build a strong relationship with KOLs and Investigators and provides support for Presentations and publications in cooperation with the Marketing and Scientific team.
- Track and report on progress of study including site activation, patient enrolment, monitoring visits.
- May assist in the preparation of clinical protocols, amendments, informed consent forms, study guides, case report forms and any other clinical research related documents.
- Set up the trial sites, train the study staff to trial-specific activities and close trial sites on completion.
- Verify data entered for consistency with original data source, track completed CRFs and timely respond to queries and requests.
- Monitor the trial throughout its duration, which involves both remote monitoring and visiting the trial sites on a regular basis.
- Liaise and communicate with study staff on conducting the trial.
- Maintain and update project files and documentation.
- Analyze data, discuss results and prepare reports/clinical presentations.
- Organize and participate in kick-off and investigator meetings to review progress of ongoing clinical trials.
- Review AEs and ensure that adverse event reporting is adequately internally and externally. communicated.
- May assist in selection and Coordination of the activities with Contract Research Organizations (if involved).
- Liaise and communicate with Lima Marketing and Sales teams and other external parties.

Background (State the required education, experience level, and competency profile)

Education : Bachelor/Master Degree in Life Sciences

Or Bioengineering (Biological Science, Pharmacy, or other health-related discipline preferred)

Experience : /

Professional Requirement : /

Technical/Soft Skills

Description	Advanced	Intermediate	Basic
Accuracy and attention to details	☑	☐	☐

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Technical/Soft Skills

Description	Advanced	Intermediate	Basic
Analytical thinking	☑	☐	☐
Effective communication (both written and oral)	☑	☐	☐
Visualization and presentation skills. Ability to tailor the information/communication style to the audience	☐	☑	☐
Flexibility	☑	☐	☐
Time management and priority setting	☐	☑	☐
Problem solving	☑	☐	☐
Ability to work cross-functionally	☑	☐	☐
Interpersonal skills	☑	☐	☐
Data analysis	☑	☐	☐
English language (spoken and written form)	☑	☐	☐
Knowledge of clinical research principles, ICH-GCP, ISO 14155 and applicable guidelines	☑	☐	☐
Proficiency in Office automation packages	☑	☐	☐
Availability to travel	☐	☑	☐

Read and Approved

Date: **Signature:**

Area Vice President's Signature : 18/05/2018 _____

Employee's Signature (for acknowledgement) **:** _____ _____