

Associate Clinical Trial Leader

Job ID
REQ-10011054
Jun 09, 2024
India

Summary

Responsible for supporting, under the guidance of the Lead Clinical Trial Leader and/or Clinical Trial Leader (CTL) and the Clinical Program Leader (CPL), all aspects of TCO clinical trial(s) as assigned.

About the Role

Major accountabilities:

- May lead studies in maintenance or in closeout phase or ongoing studies post primary database lock with the oversight of the LCTL/CTL, as assigned.
- Support the clinical protocol development process in collaboration with the CTL/Lead CTL and the Clinical program Leader (CPL): contribute to the development of clinical protocols, amendments and related documents; drive and/or contribute to the development of trial-related documents and processes
- Contribute, with the support of a CTL/Lead CTL and the CPL, to the development of clinical section of regulatory documents like Investigator's Brochure, safety updates, IND/NDA submission documents, responses to Health Authorities questions.
- Under the guidance of the CTL/Lead CTL, support the global multidisciplinary CTT to ensure all trial deliverables are met according to timelines, budget, quality standards and operational procedures: attend CTT meetings, assist in report study progress and issues.
- In collaboration with the CPL, support the CTL/Lead CTL, in the ongoing review and cleaning of the clinical trial data, support final analysis and interpretation including the development of clinical trial reports, publications and internal/external presentations.
- Under the supervision of the CTL/Lead CTL coordinate the real time availability of quality clinical trial data, including safety, efficacy, pharmacokinetic, imaging and biomarker data, to provide consolidated information for dose escalation meetings with investigators.
- Responsible for accuracy of trial information in all trial databases and tracking systems.
- Attend relevant meetings to support ongoing execution of clinical trial and program level activities.
- Under the guidance of a CTL/Lead CTL ensure that program specific standards/activities (e.g., CRFs, UAT testing, database specifications, Data Handling plan, outsourcing specifications including imaging, biomarkers, PK, data monitoring, validation plans and data transfer specifications) are applied to the clinical trial, where applicable.
- Under the guidance of the CTL/Lead CTL develop clinical outsourcing specifications to facilitate bid templates and selection of CROs and other 3rd parties including central lab and imaging vendors; manage interface with external vendors in cooperation with the CRO; Management Department as well as with the Assay Research Lab. This also includes the set-up, logistics, documentation and clinical supplies needed for the clinical trial(s).
- Support the implementation of best practices and standards for trial management, including sharing

lessons learned.

Key performance indicators:

- Support of CTL/CTLs on the planning, executing and closing of early phase trials on time and within budget
- Adherence with guidance of GCP/ICH to ensure high quality trial conduct
- Support of ongoing data review to promote trial decisions and strategic planning

Minimum Requirements:

- Advanced degree or equivalent education/degree in life science/healthcare

or Bachelor degree or equivalent education/degree qualification in life science/healthcare required if accompanied by at least 2 years of involvement with clinical study planning, execution, reporting and publishing activities (either at a local medical organization, investigational site, pharmaceutical company/CRO, or clinical fellowship program).

Work Experience:

- Good communication, organization and tracking skills.
- Basic knowledge of Good Clinical Practice; basic knowledge of scientific principles.

Skills:

- Clinical Trials.
- Conflict Management.
- Contract Management.
- Effective Communication.
- Financial Analysis.
- Negotiation Skills.

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Division

Biomedical Research

Business Unit

Pharma Research

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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