NOVARTIS

Associate Clinical Trial Leader

Job ID
REQ-10011054
Juni 09, 2024
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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.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Indien
Site
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Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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