

AD, Clinical Sciences

Job ID
REQ-10077636
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Сводка

#LI-Remote

Novartis has an incredible opportunity for a talented individual to join our team as an Associate Director, Clinical Sciences. As the Associate Director, Clinical Sciences, you will support US efforts in the planning, execution and reporting of US Medical Affairs clinical trials.

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result.

This position will require 25% travel as defined by the business (domestic and/ or international).

About the Role

Responsibilities include:

- Responsible for the implementation of designated clinical trials including investigator selection, patient recruitment, preparation of trial related documentation, TMF maintenance, and organizing Ethics Committee submissions.
- May provide strategic input to protocol design based on operational feasibility and execution strategy as appropriate
- Accountable for the accuracy and timeliness of trial information in all trial databases and tracking systems.
- Serves as clinical trial leader for US Medical Affairs Trials (including Phase I-IV, Managed Access, Investigator Initiated, Research Collaborations and Registries).
- May serve as disease area(s) lead in support of Therapeutic Area Program Lead, Clinical Sciences.
- Interfaces with the disease area(s), global and US clinical team members, clinical operations, scientific operations, regulatory affairs, drug supply, data management, finance, quality, compliance, and other relevant functional areas.
- Liaises with study investigators, site research staff, and field-based colleagues to support clinical studies. Point of first contact when investigators/site personnel enquire about patient inclusion/exclusion criteria for ongoing trials.
- Organizes investigator's start-up meeting and study site initiation meetings.
- Drives study enrollment, plan advisory boards, and perform external study feasibility with investigators.
- May independently develop strategic trial execution plan (e.g., recruitment retention, contingency plans) and timeline commitments for the US as appropriate.
- Maintains project files including: ethics committee approvals; curricula vitae of investigators and study personnel; clinical investigators brochure; protocols; case report forms instructions; consent documents; clinical trial material shipping orders; start-up meeting attendance documentation; letters of agreement; lab reference ranges; all investigator and site correspondence; and schedules of payment.
- Understands and complies with company SOPs and GCPs; contributes to continuous improvement in SOPs and local Working Practices.
- Responsible for the initial and subsequent drug supply across trials within a therapeutic area in collaboration with the Local Drug Supply Manager.
- Contributes to the preparation and review of clinical program documents (PowerPoint presentations, IND annual report, Health Authority (HA) briefing books, clinical study protocol, regulatory documents, clinical study reports, (CSR) and submissions) and other study related documents assuring quality and consistency.
- Supports the development, management and tracking of trial budgets working closely with the appropriate partners.
- Facilitates vendor selection and performance. Manages all vendors (CRO, Central lab etc.): definition of responsibilities, communication plan, divisions of responsibility, milestones, , review monthly status reports, and the interactive management of all vendors to ensure project success.
- Coordinates the movement of laboratory samples and the resulting data when central laboratory facilities are used.
- Reviews all SAEs, ensures Medical Director sign-off, that sites are notified, and that all company procedures are complied with.
- Supports all scientific aspects of clinical trial(s) and program level activities as assigned.
- Provides mentorship to Managers and Specialists, Clinical Sciences, to ensure that their role and contribution is optimized.

Essential Requirements

- Bachelor's degree in a science related field or a Registered Nursing certification or equivalent certification/licensure from an appropriately accredited institution.
- A minimum of 8 years of significant clinical research or research monitoring experience that provides the required knowledge, skills and abilities and experience mentoring or training others. In some cases, an equivalent combination of education, professional training, and experience that provides the required Knowledge, Skills and Abilities may be considered. In some cases, an equivalent combination of education, professional training, and experience that provides the required Knowledge, Skills and Abilities may be considered.

- Excellent understanding and demonstrated application of FDA guidelines, Good Clinical Practices, and applicable Standard Operating Procedures.
- Ability to mentor and train other clinical associates in a positive and effective manner.
- Ability to evaluate medical research data and proficient knowledge of medical terminology.
- Effective oral and written communication skills, with the ability to communicate effectively with medical personnel.
- Effective presentation skills. Effective organizational and time management skills.
- Ability to utilize problem-solving techniques applicable to constantly changing environment.

The salary for this position is expected to range between \$152,600 and \$283,400 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people [click here](#).

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Дивизион

US

Business Unit

Marketing

Место

США

Состояние

Remote, US

Сайт

Remote Position (USA)

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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