NOVARTIS

Associate Director Clinical Sciences

Job ID
REQ-10057082
Jul 03, 2025
Mexico

Summary

Oversees the 6 clinical sciences resources & reports up to the NOCC Lead USMA Evidence Generation MXC. In addition, will have tactical responsibilities of assigned clinical research tasks related to IITs, RCs, MAPs and NIS/LIS.

About the Role

#LI-Hybrid

Location: Mexico City

This role is based in Mexico City, Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key responsibilities

- Oversees the 6 clinical sciences resources & reporting up to the NOCC Lead USMA Evidence Generation MXC, in addition will perform clinical sciences tactical responsibilities:
  - Accountable for the accuracy and timeliness of trial information in all trial databases and tracking systems.
  - Facilitate MRC and SRC review of concepts
  - Timely processing of MAP requests, maintenance of request and closure
  - Interfaces with the disease area(s), global and US clinical team members, regulatory affairs, drug supply, data management, finance and other relevant functional areas
  - Preparation of trial related documentation, TMF maintenance: 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.
  - Ensure key processes and documents are maintained/updated on time (e.g. TPSR, ICF Clinical Review, TMF)
  - Ensures TPSR & Pubs Review
  - Initiation of IND x-ref letter and IN & IB distribution
  - Establish charters for and support management of SC and EO
  - Conduct Pre-RC alignment and Ensure EPRM and TPIAT completion for RCs (internal and external interface management)
  - Responsible for the initial and subsequent drug supply across trials within a therapeutic area in collaboration with the Local Clinical Supply Manager.

    - Contributes to the preparation and review of clinical program documents (PowerPoint presentations, IND annual report, regulatory documents, clinical study reports, (CSR) and submissions) and other study related documents assuring quality and consistency.
    - Supports the management and tracking of trial budgets including payments working closely with the appropriate partners
    - Study close out execution, including financial reconciliation, creating approval and closure letters
    - Prepare for and support quarterly review meetings with TA teams
    - Understands and complies with company SOPs and GCPs; contributes to continuous improvement in SOPs and local Working Practices.
    - Any other clinical activities as assigned
- Oversees execution of assigned clinical research activities, ensuring key processes are completed with consistency, quality and compliance
- Liaison between US/MXC/HYD clinical sciences teams

Position Requirements Education:

Bachelor's degree in a science related field or a Registered Nursing certification or equivalent certification/licensure from an appropriately accredited institution.

Languages:

- Advanced English proficiency

Experience required:

- Significant clinical research or research monitoring experience (comparable to 8 years) that provides the required knowledge, skills and abilities and experience supervising, 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.

Technical Knowledge/Competencies:

- 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.
- Strong customer focus, Excellent interpersonal skills & Strong attention to detail.
- Good computer skills: good knowledge of Microsoft Office and the ability to learn appropriate software.
- Good English language and grammar skills.
- Effective presentation skills. Effective organizational and time management skills.
- Proven flexibility and adaptability. Excellent team player with team building skills.
- Ability to work independently as required
- Ability to utilize problem-solving techniques applicable to constantly changing environment

Commitment to Inclusion

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

Novartis is committed to work with and provide 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 tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Finance
Business Unit
Universal Hierarchy Node
Location
Mexico
Site
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Ajustes de accesibilidad

Novartis tiene el compromiso de trabajar y proporcionar adaptaciones razonables para personas con discapacidad. Si, debido a una condición médica o discapacidad, necesita una adaptación razonable para cualquier parte del proceso de contratación, o para des empeñar las funciones esenciales de un puesto, envíe un correo electrónico a tas.mexico@novartis.com y permítanos conocer la naturaleza de su solicitud y su información de contacto. Incluya el número de posición en su mensaje.

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