NOVARTIS

HEOR Operational Study Manager (3 roles)

Job ID
REQ-10080978
июл 08, 2026
Мексика
Available in: English

Сводка

#LI-Hybrid

Location: Mexico City, Mexico

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

We are hiring for 3 HEOR Operational Study Managers who will be accountable for the end-to-end operational execution and management of assigned US Medical Affairs non-interventional studies, including retrospective analyses, prospective observational studies, Phase IV studies, Research Collaborations (RCs), and associated projects conducted on behalf of US MA HEOR.

This role supports US study teams by ensuring the planning, implementation, maintenance and closeout of all operational aspects, from concept through final report/manuscript, in compliance with timelines, budget, quality standards, and applicable regulations (GCP, SOPs, Work Practices).

The Operational Study Lead works closely with US MA HEOR leads, Evidence Generation Program Excellence, internal cross functional colleagues, and third-party vendors to ensure consistent, high-quality study delivery and effective risk, quality, and vendor performance management.

About the Role

Key Responsibilities:

- Accountable for operational execution and management of assigned US MA HEOR non interventional studies (including RCs and Phase IV) and associated projects as applicable.
- Support HEOR teams for operational and administrative tasks related to all study phases, from concept development to final report/manuscript.
- Coordinate and facilitate the flow of the administrative processes for development and review of study protocols, Informed Consent Forms (ICFs), Institutional Review Board (IRB) submissions (as applicable), and related data plans (i.e. data management and data monitoring plans).
- Coordinate study concepts through submission, review and approval process, partnering with HEOR Leads and Medical Review Committee (MRC) Leads; facilitate tracking and reporting of timelines, budgets, operational plans, and quality standards.
- Lead and document third party onboarding activities and may manage and oversee vendors (i.e. Contract Research Organisation (CRO), central lab etc.), including vendor responsibilities, communication plans, milestones, status reporting, quality concerns, and vendor activities.
- Track and report study related activities and payments to collaborators and vendors; coordinate contract preparation, review, and finalization with internal stakeholders and external service providers.
- Ensure regular interaction with vendors; monitor performance, deliverables, quality, and issue resolution; support the development, management, and tracking of trial budgets and Purchase Order (PO) service confirmations.
- Track and manage key trial milestones, monthly project status, key deliverables, and study information; maintain trial data in Clinical Trial Management Systems (CTMS), Novartis Clinical Vault (NCV), and related tracking systems.
- Collect, review, QC, and appropriately archive all study documentation throughout the study lifecycle; support documentation requirements for audits, inspections, internal reviews, and clinical disclosure activities in collaboration with HEOR Leads and the Clinical Disclosure Office (CDO).
- Identify, track, and manage study specific operational risks, issues, and CAPA activities; ensure handover/transition documentation is completed and archived; understand and comply with company SOPs and GCPs; contribute to continuous improvement in SOPs and local Working Practices; leverage AI tools to streamline tasks, generate content, and support decision-making.

Essential Requirements:

- Bachelor’s degree required; scientific or health related degree preferred, with significant experience in non interventional study operations, health outcomes research, or Medical Affairs.
- Strong knowledge of Good Clinical Practice (GCP), applicable Standard Operating Procedures, vendor oversight, and experience with systems (e.g., CTMS, DMS, financial tracking tools).
- Demonstrated ability to manage complex, cross functional operational activities with minimal oversight; ability to work independently and demonstrate mid-to-high-level competency.
- Strong organizational, documentation, stakeholder management, organizational and time management skills, with strong attention to detail.
- Fluent in English with good English language and grammar skills; effective oral and written communication skills, presentation skills, and the ability to communicate effectively with medical personnel.
- Strong customer focus, excellent interpersonal skills, and excellent team player with team building skills.
- Ability to utilize problem-solving techniques applicable to a constantly changing environment; proven flexibility and adaptability; good computer skills including knowledge of Microsoft Office and the ability to learn appropriate software.
- Availability and willingness to work and be available during US business hours, ensure US Holiday coverage, and be on call for critical matters based on business needs; employees are typically expected to be in their current role for at least 12–24 months before applying for a different role, subject to local guidelines and required approvals.

Accessibility and Accommodation:

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.

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 desempeñar 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.

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)

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Marketing
Место
Мексика
Сайт
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

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