NOVARTIS

Toxicology Study Monitor - Principal Scientist I/II

Job ID
REQ-10087192
сен 08, 2026
Китай

Сводка

The Preclinical Safety (PCS) department within the Biomedical Research (BR) - Translation-al Medicine Unit provides non-clinical safety strategy of products in -discovery, -development and -market, globally, with state-of-the-art regulatory compliance. As a Scien-tific Study monitor, you will join our PCS Toxicology team to oversee in-vivo and in-vitro toxicity studies conducted at CROs in China are following international scientific and regula-tory standards (GLP, ICH, etc) and acting as the primary scientific contact for the CRO Study Director. This role will support nonclinical research and safety for multiple projects across multiple disease areas.

About the Role

Key responsibilities:

- The Study Monitor is appointed to each outsourced preclinical study based on relevant technical expertise, designated disease area and/or scientific background knowledge and acts as the primary scientific contact for the Study Director at the Contract Research Organization (CRO).
- The Study Monitor is responsible for overseeing the progress of the study and for ensuring that the study is conducted, recorded and reported according to the study protocol. The Study Monitor should ensure that the study is compliant with the appropriate GLP regulations, Novartis policies (animal welfare, quality, and compliance), CRO in-house standard operating procedures, Novartis expert recommendations (where feasible) and all relevant international regulatory guidelines and requirements.
- Resolution of study related issues, liaisons with internal experts and informing the appropriate people in a timely manner is pivotal to the performance of this role. The study phases and sample delivery timelines should be strategically overviewed and tracked to ensure that internal contributor reports are delivered to the CRO on time and that the CRO meets its agreed main reporting timelines.
- Formulates and leads/co-leads novel projects with team or enables matrix collaboration on project/technology solutions to achieve creative results for impact on BR goals. Generates innovative ideas within own team and/or project team/functional community to meet new technical requirements and/or answer project key scientific/technical/development questions. Establishes target dates and priorities to enable data-driven advancements in project teams, within own team, and with collaborators, or within functional community.
- Communication skills are critical to this role in forming strong working relationships with other team members.
- Works closely with the PCS-Operations and PCS Project Team Member (PTM) to formulate a project outsourcing strategy.
- Has a working knowledge of HA regulations (Swiss medic, OECD, FDA) to support conduct of GLP compliant toxicology studies.
- May be PCS part-time PTM

Essential Requirements:

- PhD or MVSc/MS/M.Pharm with 7+ years of experiences in drug discovery and/or development, preferably as Study Director or Study Monitor in the early preclinical screening and GLP studies
- In-depth knowledge of toxicology assays in early development, Safety pharmacology and genotoxicity
- Working knowledge of drug design and development
- Excellent communicators, strong team players and have a high level of logistical/planning ability
- Registration and certification with one of the International Toxicology registers preferred

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)

Дивизион
Biomedical Research
Business Unit
Research
Место
Китай
Сайт
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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.china@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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