NOVARTIS

Study Analyst

Job ID
REQ-10073988
мар 31, 2026
Индия

Сводка

We are seeking a Study Analyst to provide study level support for Novartis clinical trials, including all aspects of PK data collection, analysis, and reporting, with a focus on non-compartmental PK data analysis and reporting of PK results. This role requires an understanding of basic PK and statistical concepts and hands-on experience with use of Phoenix Nonlin for non-compartmental PK data analysis. Experience contributing to the PK section of clinical study protocols is desirable. Familiarity with other non-compartmental PK analysis tools and programming languages such as R is a plus. It is critical for the Study Analyst to be aware of and follow internal SOPs and regulatory requirements related to PK data analysis and reporting. Strong verbal and written communication skills and experience with drafting reports of PK results are highly desired.

The Study Analyst is expected to work in a matrix team environment with the PKS project representative (PTM) and clinical trial team (CTT) functional representatives, such as programming and data management, and may also be required to attend CTT meetings. Awareness of study timelines and ability to plan prospectively to ensure delivery of analysis datasets and timely delivery of PK results is a key requirement of the role. The ability to independently draft PK analysis plans for the study is desirable. The Study Analyst is considered a subject matter expert in PK data analysis and is expected to contribute toward ensuring that internal SOPs are followed and updated as needed. An innovative mindset with the flexibility to adapt to new tools and methods of analysis is expected.

Additional responsibilities may include other trial level PKS support, such as attending regular CTT meetings, QC support for PK analyses and/or regulatory documents, providing input in routine regulatory update submissions, such as IB and safety updates.

About the Role

Major accountabilities:

- Provide trial level support for all aspects of PK data collection, analysis and reporting in Novartis clinical trials as part of a matrix team consisting of the PTM and CTT members.
- Draft non-compartmental PK analysis plans and PK sections of clinical protocol. Perform PK analysis and draft results narrative for inclusion in clinical study reports or other documents.
- As subject matter expert, provide scientific leadership in PK data analysis, including adoption of value-added innovations, and adherence to internal SOPs.
- Attend CTT meetings to represent PKS and provide study level input as needed. Provide support for QC review of PK analyses or documents.
- Provide input in routine regulatory updates, such as IB and safety updates

Minimum Requirements:
B.S / M.S. with relevant experience (minimum 5+ yrs) in non-compartmental PK data analysis and reporting, preferably in an industry setting.

- Proficient in non-compartmental PK analysis using Phoenix Nonlin. Familiarity with other analysis tools and programming languages is a plus.
- Understanding of basic pharmacokinetic principles, experience working on project teams (preferably global) as well as awareness of regulatory guidance and recent innovations in non-compartmental PK analysis.
- Understanding of drug development and clinical trials in industry and awareness of key regulatory requirements at each stage of drug development
- Excellent verbal and written communication skills.

Languages:

- English.

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Biomedical Research
Business Unit
Development
Место
Индия
Сайт
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time

Employment Type
Regular
Shift Work
No

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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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