Senior Statistical Programmer " >

Job ID
329404BR
India

Job Description

5! The number of New Molecular Entities (NMEs) approvals of potential blockbusters, which Novartis obtained in 2019 alone. We advanced a breath of early programs in our pipeline that addresses significant unmet needs and are looking for passionate and enthusiastic Statistical Programmers with expertise in SDTMs, ADaMs & TFLs, and experience in Regulatory Submissions. As a part of the Statistical Programming unit, you will play a key role in supporting a growing pipeline across multiple therapeutic areas, with emphasis on regulatory submissions. An excellent opportunity to work end-to-end programming from CRF collections through Regulatory submission, you will have an exciting opportunity to learn new technologies (like R) and endorse Statistical Programming as a key contributor in driving the #GO-Digital vision of Novartis.

Your responsibilities include, but are not limited to:

Lead and coordinate activities of all statistical programmers as Trial Programmer for phase I to IV clinical studies or assigned project-level activities. Make statistical programming recommendations at study level.

Build and maintain effective working relationship with cross-functional teams, discuss status of deliverables and critical programming aspects (timelines, scope), e.g. as member of the Clinical Trial Team (CTT).

Review eCRF, discuss data structures and participate in data review activities in accordance with the company, department and industry standards (e.g. CDISC).
Processes, review and develop programming specifications as part of the analysis plans.

Provide input into statistical programming solutions and/or ensure their efficient implementation. Responsible for development of programming specifications of analysis datasets and pooled datasets.

Ensuring timely and quality development and validation of datasets and outputs for CSRs, regulatory submissions/interactions, safety reports, publications or exploratory analyses (as required) in the assigned drug development study/project according to specifications.

Responsible for quality control and audit readiness of all assigned statistical programming deliverables as well as accuracy and reliability of statistical analysis results.
Maintain up-to-date knowledge of programming software (e.g. SAS) as well as industry requirements (e.g. CDISC SDTM/ADaM, eCTD, Define.xml), attend functional meetings and trainings.

Establish successful working relationship on individual studies with external associates according to agreed contract and internal business guidelines. Contributes to assigned parts of process improvement, standardization and other non-clinical initiatives.

Diversity & Inclusion / EEO

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

Minimum Requirements

What you'll bring to the role:

BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field with Ideally 5+years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry.

Good SAS experience and proven skills in the use of SAS within a Statistical Programming environment to develop and validate deliverables. Good experience in contributing to statistical analysis plans and/or constructing technical programming specifications.

Good knowledge of industry standards including CDISC data structures as well as understanding of the development and use of standard programs.

Good understanding of regulatory requirements relevant to Statistical Programming (e.g. GCP, study procedures).
Good communications and negotiation skills, ability to work well with others globally.

Why Novartis?

769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.
We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.
We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!
Imagine what you could do here at Novartis!
Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network
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Global Drug Development
Business Unit
GDO GDD
Location
India
Site
Hyderabad, AP
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Functional Area
Research & Development
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Shift Work
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