Posting Title: Senior Principal Statistical Scientist

Job Description

The Senior Principal Statistical Scientist is responsible for proposing and leading the statistical strategy, and directly influencing cross-functional decision making on a project or an indication (or equivalent) within (pre/early/full) clinical development.

As the global lead for their project or indication, they are responsible for the discussion and implementation of modern and innovative trial designs, statistical model-based drug development approaches, data analysis and exploration methodologies that optimally address the research objectives of the clinical trials and support the goals of the project or indication, in line with a thorough understanding and implementation of all project operational aspects.

They provide statistical strategies for regulatory submissions, and contribute to drug development decisions with internal and external partners.
They may act as CSU Statistician.

1. Provide strategic statistical scientific global leadership to clinical project or indication (or equivalent) development, comprising all relevant technical, operational and disease area knowledge
2. Drive and steer the strategic quantitative framework for the suite of clinical trials in close collaboration with (early) project teams
3. Represents the GPT/GCT/CTT (or equivalent) internally and externally as the statistical scientist with leading quantitative skills, including regulatory interfaces, with objective and transparent clinical trial quantitative risk/probability of success assessments
4. In collaboration with clinical counterparts (Global Brand/Project Medical Directors/ Translational Medicine Experts) and Global Project Teams/GCT/CTTs, influence and negotiate clinical trial designs aligned with the CDPs/TPPs. Leads the quantitative evaluation of competing trial/analysis strategies assuring robust support to clinical development planning and execution. Contributes to the clinical development plan of the project or indication Contributes to the statistical strategic and quantitative contributions to regulatory/submission strategy and related documents (e.g.: Target Product Profile, sPOC document, CDP, Briefing Books, Risk Management Plan and responds to HA questions).
5. Across the multiple trials within the project or indication (or equivalent), is responsible for the full integration of modern aspects of drug development including model-based drug development and statistical methodologies in collaboration with partners.
6. Contributes to the statistical scientific requirements, synthesis and integration of information to support transition of drug development milestones / decision boards.
7. Contributes to ongoing data exploration of trials pre- and post-database lock data, of related trial data, of relevant available external data, with a sense of urgency and pragmatism, to address risks on patient safety and trial quality, to understand trial results and put them in a broader perspective, to prepare trial reporting, submission planning and health authority interactions.
8. May lead statistical scientific evaluation of in-licensing opportunities
9. Represents IIS at project or indication level internal/external meetings for strategic statistical scientific inputs
10. Identifies opportunity and integrates Statistical Methodology where necessary, make sure that the IIS team (statisticians, data management, database programming, statistical programming, medical and scientific writing) are aligned on the statistical scientific part.
11. Ensure high quality and timeliness for all deliverables and processes, including the development and the consistency of standards and plans for the project or indication.
12. Interacts with Health Authorities and external key opinion leaders as the recognized Novartis expert at project or indication (or equivalent) level for all quantitative aspects of the program. represents IIS at across global regulatory hearings/advisory committee meetings and other global regulatory interfaces
13. Provides biostatistics and drug development expertise to infrastructure and process improvement initiatives
14. Provides technical statistical expertise, identifies opportunity for influencing internal discussions for white papers/regulatory policy. Establishing external presence for technical / strategic areas
15. May serves as mentor and may undertake role of development/appraisal coordinator for selected IIS Franchise associates
16. May act as CSU statistical scientist

Minimum requirements
. PhD in Statistics (or equivalent degree/knowledge)

. Fluent in English (oral and written).
. 5+ years industry experience
. 2+ years influencing at least indication level clinical development programs with global leadership of the statistical sciences within the clinical development plans. Good disease area and guidelines knowledge.
. Contributes to external white-papers/policy shaping best practice statistical science. Is establishing track record of developing/ embedding statistical excellence. Established experience in contributing to global scientific improvement/change initiatives
. Very good interpersonal and communication skills (verbal and writing) bridging scientific and business needs – integrating quantitative sciences, strong disease area knowledge and appropriate market/competitive intelligence
. Expert scientific leadership skills demonstrated in facilitating and optimizing indication strategy. Good track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies
. Natural modern leadership style building partnerships and collaborative working environments
. Strong skills to facilitate and enable the contribution of quantitative teams
. Hands-on experience in contributing to the interface to regulatory agencies/leading the indication-level early clinical development campaign

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