Therapeutic Data Strategy Director

Job ID
385231BR
Juli 02, 2024
USA

Summary

100,000. That’s how many patients participate in our clinical trials at any given time. Global Clinical Operations (GCO) touches patients’ lives every day acting as a link between science and medicine. Envision the impact you could have as the Therapeutic Data Strategy Director!
The Therapeutic Data Strategy Director (TDSD) bridges science and operations by defining how the clinical data strategy is operationalized across the complete data flow within GCO. The TDSD is responsible for ensuring data regulatory compliance, the availability of End-to-End (E2E) standards, that instruments and devices are thoroughly discussed, defined, and finalized prior to the database build and that the operational impact of any new changes are known, costed, mitigated, and captured in the appropriate knowledge database. In collaboration with the GPT, the TDSD aligns on the fit for purpose data package as part of a program / indication level quality by design to support data strategy needs in the drug development lifecycle of a molecule or across therapeutic area (TA) within an assigned unit in Novartis. This role is accountable for the end-to-end data product, ensuring application of Novartis clinical data standards and defining the clinical data acquisition and data review, analysis, and reporting strategy to support the submission of our clinical programs. So, if creating a program level data strategy for operations that embodies agility, cycle time reduction and ultimately reduces costs excites you, then you should apply.

Your Key Responsibilities:
Operational Execution of the Program Strategy:
• Lead, establish and maintain a data strategy for the design, collection, processing, transformation, reporting and submission of clinical data
• Cost and impact assessment of proposed data collection, analysis, and reporting
• Drive capability inputs to data team’s resource algorithm based on future incoming demands
• Matrix data operations leader who is the single focal point for the sustained industry leading cycle time for data product
• Ensures the provision of resource with the skillset to develop robust & lean E2E specification during the initial set up stage.
• Leads the full spectrum of standard development and compliance across their portfolio.
• Consults to drive quality into the study protocol and operational processes.
• Driving implementation of a lean global data strategy and define fit for purpose data requirements
• Ensure the fit for purpose data requirements remain intact and understanding the operational impact e.g., cost, resources, and time of any amendments as well as work with clinical development, analytics, and regulatory line functions to understand the scientific, clinical, statistical and regulatory impacts.
• Support assessment on opportunity to capitalize on non-traditional options (e.g., historical data, synthetic

data, cross-sponsor shared control arms IMI EU-PEARL, adaptive designs, pragmatic trials, decentralization, etc.).
• Work with Clinical Operational Program Head (COPH) and Vendor Program Manager (VPM) to define the provision of ancillary data, including vendor capabilities.
• Author the Clinical Data Section of Operational Execution Plan (OEP) (key customers, dataflow, and targets to generate Data-as-a-Product (DaaP) etc.).

End-to-End Ownership of the Clinical Data Flow:
• Drives implementation of a lean global data strategy and defines fit for purpose data quality requirements sufficient to support good decision making and meet regulatory requirements.
• Collaborates cross-functionally to define quality by design review process to ensure fit for purpose data quality sufficient to support good decision making.
• Drives standards and processes to facilitate data right the first time.

End-to-End Standards Oversight & Lifecycle Management:
• Responsible for compliance with data requirements and the availability of end-to-end clinical data standards (data collection through analysis) for a program/molecule/indication.
• Influence and support the design of new clinical data standards as required at the enterprise/ therapeutic area level.
• Final governance decision maker for adoption and maintenance of data standards.
• Drives / defines program level vendor data transfer specifications.

Operational Project Management:
• Develop, communicate, and drive implementation of a global data operationalization strategy to deliver value-adding data; TDSD supports and guides the Data Team (as part of the CTT) in ensuring the overall program /OEP strategy is aligned with execution.
• Establish key customers of Clinical Data and establish approach for future consumption.
• Works with the business to ensure adherence to timelines, adoption of the data strategy and delivery of the target data product quality.
• Influencer and interlocutor for adoption and compliance on business process and objectives related program data strategy.
• Assesses / approves changes that impact the data collection, analysis and reporting strategy.

About the Role

Minimum: Bachelor’s degree in life sciences, preferably with a statistics module.
• A minimum of 15 years in a R&D regulated environment in a relevant pharmaceutical or health care company. Strongly Preferred
• Excellent understanding of end-to-end clinical data processing and the clinical trial operations space.
• Extensive knowledge and experience in ICH-GCP Process Control or ICH-GCP Quality Assurance systems and Health Authority regulations; Clinical Operations experience in these areas is preferred.

The company provides reasonable accommodations for otherwise qualified individuals with medical restrictions if an accommodation can be provided without eliminating the essential function of driving.

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $192,000-288,000; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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