Therapeutic Data Strategy Director

Job ID
REQ-10051031

May 14, 2025

India

Summary

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, , mitigated, and captured in the appropriate knowledge database. In collaboration with the GPT, GCT, and CTT, 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 creates and implements strategies for the end-to-end data product, ensuring application of Novartis clinical data standards and defining the clinical data acquisition and data review, strategy to support the submission of our clinical programs. The TDSD is responsible for ensuring that delivery and timelines are met with quality, whilst ensuring cost efficiencies and stakeholders ' satisfaction.

About the Role

Major Accountabilities (Describe the 10-14 main results of the role to be achieved)

Creation and Execution of operational data strategy:

- Collaborate with the Global Program Clinical Head (GPCH) to establish and maintain a data strategy for the clinical data standards of the assigned Therapeutic Area, as well as the design, collection, processing, transformation, of clinical data supporting the needs for reporting and submission.
- Impact assessment of proposed data collection and analysis
- 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 and ensures compliance with relevant Novartis processes
- Ensures the provision of resource with the skillset to develop robust & lean E2E specification.
- 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 minimum data requirements
- Ensure the minimum data requirements remain intact and understanding the operational impact e.g., 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, adaptive designs, pragmatic trials, decentralization, etc.).
- Work with COPH and Vendor Program Strategy Director (VPSD) to define the provision of ancillary data, including vendor capabilities.
- Author the Operational Data Strategy Section of Operational Execution Plan (OEP) (key customers, dataflow, and targets to generate Data-as-a-Product (DaaP) etc.).
- Establishes a "performance-oriented culture" that is driven / supported by analysis of real-time activity and quality metrics
- Contribute to the development of the Data Operations organization. Define/contribute to the development of long-term goals and operating policies through his/her leadership role on the management team.
- As an extended member of the Data Operations Leadership Team support functional excellence for Data Operations by contributing to the definition of the strategic goals and operating policies, and leading/contributing to strategic initiatives in line with the overall Data Operations strategy.
- Support the BD&L activities from CDO perspective.

End-to-End Ownership of the Clinical Data Flow:

- Ensures that data is collected and reviewed as efficiently as possible, and that extraneous data is not procured.
- 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.

- Accountable for managing operational strategy around data cleaning and data review at portfolio level.
- Drives standards and processes to facilitate data right the first time.
- Act as point of escalation for data specific project management issues and for broader data demands (e.g. changing scope, addition of analysis/reporting events).

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.
- Drives identification of needs, adoption and maintenance of data standards.

Operational Project Management:

- Develop, communicate, and drive implementation of a global data operationalization strategy to deliver value-adding data; CDS 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.
- Accountable for managing the strategy of the data cleaning, review, and data related specifications at portfolio and study level.
- Ensure high quality, timely and efficient Data Operation deliverables for projects and trials partnering with other Data Operations functions within assigned Development Unit or program.
- Work alongside the Operational Program Lead and Trial Lead to ensure all data related risks and issues are identified and mitigated.
- Link between business needs and technical development/deployment and technology usage in data operations.
- Influencer and interlocutor for adoption and compliance with company efficiency process and objectives within data workflow.
- Assesses / approves changes that impact the data collection strategy.

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Development

部門
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India

勤務地
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Mumbai (Office), India

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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