NOVARTIS

Clinical Data Operations Lead

Job ID
REQ-10017214
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Summary

The Clinical Data Operations Lead is part of the data42 Clinical Data Pipeline team and is responsible for leading all data operations related to the Clinical Data assets for data42 and will report to the Clinical Data Pipeline Owner. A key aspect of the program is to centralize all clinical data collected across Novartis clinical studies to enable secondary research involving clinical trials data, including clinical raw and ready-to-be analyzed data of the clinical databases (EDC, lab and 3rd party data). The position is a key collaborator with other data42 teams. Ensures that clinical data are ingested, mapped and harmonized according to CDISC SDTM/ADaM standards, curated, medically recoded (WHODrug/MedDRA) and anonymized according to Good Clinical Data Management Principles efficiently with timely and high quality deliverables as per data42 user needs. To do so, the team lead will oversee all Subject Matter Expert (SME) squads operational data activities and will guarantee their excellence in execution across the Clinical Data Pipeline and check their achievement with business needs. Team Lead will onboard, train and ensure business continuity of the squads and will maintain/define use case portfolio lifecycle by applying Agile project management framework. Create and maintain processes and documentation. Create KPIs/Metrics/reports showing efficiency and quality improvements in the field of clinical data operations and will report them to Clinical Data Pipeline Owner on a regular basis.

About the Role

Major accountabilities:

- Lead Clinical Data operations for data42 across the Clinical Data Pipeline and be responsible for overall data delivery of the team aligned with use case needs and Clinical Data Pipelines releases.
- Act as functional manager for local associates including providing supervision and advice to the SME squads on functional expertise and processes.
- Make data transformation/standardization decisions/recommendations as required and translate use case needs into data operations.
- Ensure all practices are aligned with Good Clinical Data Management Principles related to Clinical Data Pooling activities
- Communication with stakeholders, ensuring the clinical data operations and reporting meets quality requirements and on-time delivery.
- Build and maintain effective working relationship with cross-functional teams, able to summarize and discuss status of deliverables and critical aspects (timelines, scope, resource plan) e.g. as Clinical Data Operations representative in project-level team.
- Comply with company, department and industry standards (e.g. CDISC, NCI) and processes (GCDMP, ICH-GCP), assess and clarify additional requirements at project-level.
- Ensure timely and quality data operations and validation of datasets and outputs.

- Responsible for quality control and audit readiness of all assigned data operations and data release deliverables involving clinical pipeline.
- Maintain up-to-date knowledge of Clinical Pipeline software and methodologies as well as industry requirements, attend functional meetings and trainings.
- As assigned, act as SME or contribute to process improvement project initiatives with a focus on anonymization and reporting procedures. Act as Clinical Data Management expert in problem-solving aspects.
- Maintain use cases portfolio involving data operations during their lifecycle.
- Recruiting, working with external provider of contractors.
- KANBAN Agile methodology application

Key performance indicators:

- Achievement of goals with high quality and timeliness of clinical data operations deliverables and contributions as assessed by the Clinical Data Pipeline Owner, internal and external customers.
- Adequate representation of the clinical data operations function as Clinical Data Operations Lead. Effectiveness of communication and team behaviors as assessed by the team members.
- Collaboration with other data42 product teams
- Ability and effectiveness in training, mentoring and coordinating internal and external analysts assigned to the same project as assessed by the functional/operational manager.

Job Dimensions:

Number of associates: Coordination of 5+ internal or external data managers. Acts as a functional manager locally for associates.

Impact on the organization:

- Successful delivery of assigned projects: Timely, high quality and efficiently produced Clinical Golden tables
- Innovative solutions and improvements to support timely and efficient Clinical golden data deliverables
- High quality and impactful work product to support the data42 Clinical Data Pipeline team
- Efficient team organization and environment

Minimum Requirements:
Education: BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field

Work Experience:

- Ideally 7+years in a clinical data management and /or warehousing role or related experience within the pharmaceutical, healthcare, supporting clinical trials/ or in pharmaceutical industry
- Strong understanding of data management methods. Provides input to Data Management strategy.
- Experience as Data Management lead for several studies or project-level activities, including coordination of team of internal or external programmers, ability to transfer own knowledge to others.
- Good knowledge of industry standards including CDISC data structures and WHODrug/MedDRA dictionaries as well as a solid understanding of the development and use of standard programs
- Advanced understanding of regulatory requirements relevant to Clinical Data Management (e.g. GCP, study procedures).
- Knowledge of Agile KANBAN Framework
- Passionate and deeply knowledgeable about data management, data anonymization and clinical data

structures
- Proven communications and negotiation skills, ability to work well with others globally and influence
- Established project management skills with a proven track record of leading and/or collaborating with teams in complex global matrix structures and business models.
- Some people management skills are required in this team lead role. Proven record of at least managing team members.
- Collaboration / teamwork
- Ideally AI/ML basic knowledge.

Languages :

- Fluent English (Oral and Written)

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