

# Enterprise Reference Model Lead

Job ID  
REQ-10021499  
Sep 10, 2024  
USA

## Summary

This thought leader will establish strategic, best-in-class reference model standards across the enterprise. This includes design and implementation of a governance framework to maintain alignment of business units, system and functional strategies and priorities, by communicating the standards to all stakeholders and fostering feedback and engagement to continuously improve.

## About the Role

### Major accountabilities:

- Your responsibilities include, but are not limited to:
- Design and implement the Novartis CDM Reference Model management framework partnering with key business and technology stakeholders to ensure effective controls of essential documents lists, taxonomy and metadata management across multiple systems and processes.
- Lead the CDM Reference Model governance board, providing structure and process around it, facilitating effective decision-making and arbitrating across subject matter experts in multiple disciplines, line functions, and business units, creating/owning document content.
- Drive platform interoperability through metadata standard strategy that can adapt with the changing Novartis technology landscape.
- Lead strategic planning and assessment efforts across business units to support continuous improvement and ongoing release management efforts of deployed technology.
- Develop and deliver strategies to increase the adoption and improvement in TMF health and document management across stakeholder groups through the effective implementation of Reference standards, and contribution to filing guidance, learning material and templates.
- Lead external benchmarking exercises and maintain external visibility and connections to stay at the forefront of classification and standards management.
- Provide support in preparation for audits/inspections, contributes to root cause analysis identification and creation/delivery of CAPAs in relation to Reference Model standards.
- Timely, efficient and quality execution of TMF related activities within budget and resources within 5% of cost overruns
- Reduction and management of TMF risk with effective strategic, contingency and risk mitigation plans

### Minimum Requirements:

- Minimum of 7 years working in bio-pharmaceutical clinical research and development with specific experience in clinical operations processes and clinical systems data interoperability.
- In-depth knowledge of the TMF Reference Model, EDMS reference model, and other data governance standards.

- Demonstrated success in running cross functional initiatives, facilitating governance boards and/or leading matrixed teams.
  - Strong influencing and presentation skills. Ability to communicate effectively at all levels.
  - High organizational awareness, including experience working in multi-disciplinary teams, across cultures and geographies.
- Good negotiation, problem solving and conflict resolution skills.

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Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

Distant Employee - Distant Working Arrangement (DWA) (USA)

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1

East Hanover, USA

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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