

## Clinical Document Management Reference Model Manager

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Company: Novartis

Location: United Kingdom

Category: computer-and-mathematical

Clinical Document Governance Management (CDGM) is accountable for strategy and delivery of clinical document management (CDM) systems, processes, standards and operations of CDM services (including Trial Master File management (TMF), clinical submission readiness, record retention and archiving, Good Documentation Practice capability build) across Novartis globally. In addition, CDGM is driving the transformation of TMF at Novartis, through the introduction and adoption of new technologies, processes and ways of working.

This individual contributor role is accountable for the implementation of the governance framework to lead Novartis Clinical Document Management (CDM) Reference Model standards, including document taxonomy and metadata guidance, and to drive their adoption across the business and system configuration.

The role can be based in either in Dublin or United Kingdom.

### **Major responsibilities**

Your responsibilities include, but are not limited to:

- Set up and maintain Novartis CDM Reference Model management framework partnering with key business and technology collaborators to ensure effective controls of crucial 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 teams and line functions creating/owning document content.
- Support the development and delivery of strategies to increase the adoption and improvement in TMF health and document management across collaborator groups through the effective implementation of Reference standards, and contribution to filing guidance, learning material and templates.
- Provide support in preparation for audits/inspections, contributes to root cause analysis identification and creation/delivery of CAPAs in relation to Reference Model standards.

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