



association for **clinical data management**

# Clinical Data Manager – Past and Present

## ACDM eDigital Data Management Expert Group

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# Clinical Data Manager – Past and Present

Historically, Clinical Data Managers (CDMs) were only responsible for clinical data from collection to delivery for statistical analysis. Now, CDMs must design and project manage data flow, add technical expertise to improve data quality and integrity and generate insights from clinical data, adding to its interpretation and usability.

The CDM role is a varied and diverse role. Even if the label of a Data Manager (DM) is different across different companies and countries, the job specification is often similar as described on the next page of this document.

The main purpose of the DM role is to plan, manage and deliver clinical data of high quality and integrity. Activities related to this include:

- Communication of complex data issues with regards to end-to-end delivery of clinical trials
- Documentation (data management plans, edit check specifications, data transfer plans, risk and mitigation strategies, case report forms etc.)
- Data collection design and implementation
- Problem-solving and issue resolution
- Providing technical expertise in DM systems
- Project management
- Adherence to data standards
- Stakeholder management (e.g. reporting on study progress and data cleanliness to project managements or senior leadership)
- Additional tasks such as Medical Coding, programming and technical design could also come under the remit of the DM depending of the size or scope of the department

Changes in CDM roles have mostly been in regulatory and technological aspects, leading to a need to upskill in these areas. Examples of these changes include a focus on inspection readiness, data quality, risk management, oversight, data visualisation to detect patterns of missing data, outliers, trends and/or lack of variability, standards and the increase in range of data being collected. For example in addition to the clinical notes traditionally recorded in a clinical trial Case Report Form (CRF), trial data now often also includes data captured electronically such as novel laboratory or biomarker data, Electronic Clinical Outcome Assessment (eCOA), ECG monitoring and wearable data. The CDM not only has to be the subject matter expert (SME) but now also needs to look for new trends, technology and better ways of collecting, managing & delivering the good quality, fit-for-purpose data. These technical aspects are also impacted by various regulatory and geographical considerations. CDMs must understand complex protocols and trial design to accurately collect and deliver data in line with data standards. CDMs now have closer connections to other functions such as Clinical Scientists, Biologists, Biostatisticians, Regulatory Specialists and Tech Leads.

The CDM should also oversee study milestones. This involves:

- An understanding of requirements for data delivery
- Continuous risk assessments concerning the clinical data and data operations
- An appropriate data validation strategy (e.g. whether the data needs to be cleaned or not)
- A basic knowledge in statistics and statistical programming, for a general understanding of what is required from the data
- Promoting the use of data standards, as expected in CDISC
- Data conversion/integration
- A knowledge in the therapeutic area under research
- System administration/management, validations, review reports, system integrations (EDC, CTMS, PRO, etc)

Trial designs are becoming increasingly complex and innovative. Adaptive designs such as group sequential designs can involve a number of interim analysis and then there are umbrella, basket and even platform trials. Appropriate management of data, to have access to reliable robust data quickly is essential for these trial designs. The recent impact of COVID-19 has led to a serious consideration for more decentralised trials and the proposed use of wearables and eCOA amongst historic real-world data mean that the CDM now needs to consider how large data sets should be handled and what data collection methods truly add value to protocols. Going forward it is likely that the data from various sources will be used in the future, so additional aspects regarding subject consent and how the data will be stored and whether the full dataset or aggregated data will be used must be considered. Overall, these changes signify the need for Data Managers to be agile in response to evolving technology and clinical trial designs.

One major change has been providing and documenting proof of oversight of external service providers for sponsors and CROs developing good quality metrics or interactive dashboards. With this evolution, we have started to see the role change to a more strategic discipline, enabling data-driven clinical research approaches, ensuring participant protection, as well as improving the reliability and credibility of trial results and adapting to new technologies to help clinical scientists understand, explore and interpret data.

A major challenge remains being regarded as an equal partner in the study management team. There is a common perception that data management was not an integral part of study team and works in isolation. However, as described above, the DM works with a variety of stakeholders and are integral to the reporting of robust clinical trial data.

As technology continues to advance, we will find that the role of a DM continues to evolve. Today, there is such a diverse skillset within data management that careers in data governance, data science, strategic leadership roles, and technology/subject-matter experts may be considered.

## Conclusion

It's an exciting time to be part of the data community, with plenty of room to grow and learn whether that is part of your current role or because you are looking for a new challenge. However, there are 5 core data management principles that are synonymous across any of these types of roles, which are;

- Strategy
- Ownership/Stewardship
- Metadata
- Governance (including quality)
- Data Usage

Although the profession can seem to be in constant fluctuation, in an industry that is equally fast-paced, all data professionals can expect success when they remain focused on these concepts. As the clinical trial landscape constantly evolves it is only natural that the future of CDM will come further to the fore and by incorporating the above principles of data management, will be able to shape the future of clinical trials - ensuring better outcomes for all stakeholders.

## Further Reading

SDTM's Interactive Paper – Drivers on Clinical Data Science

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# The Role of a Data Manager

Clinical Data Management (CDM) role is made up of lots of different tasks but mainly it is to manage the data being collected for the purpose of the clinical trial. CDM is responsible for the success of clinical trials. The goal of clinical trials is to evaluate the safety and effectiveness of pharmaceuticals, medical devices, or in-vitro diagnostic (IVD) devices to support regulatory submissions or marketing claims.

A CDM role is to manage all aspects of clinical data collection and dissemination. To successfully conduct a clinical trial, a CDM leads the decision making for data collection options and the development of data collection tools best suited for the clinical trial protocol. They also lead teams that ensure the clinical trial data are collected, validated, and complete as per the requirements in the clinical protocols. These protocols also receive approvals and review from Institutional Review Boards (IRB) and Regulatory Agencies, so it is critical that CDM follow the protocols strictly. Maintains a proactive attitude towards regulations and best practices updates, Ensuring the project is progressing according to internal SOPs or other guidelines to fulfill regulations.

CDM are responsible for creating and maintaining both the case report forms, data management plan, change control logs and risk plans/logs, they are also typically responsible for reporting on the study progress and identifying risks to project managers, study team and/or leadership team and lead the resolution of issues with the clinical data collection, because the data is the first indicator of study progress. At the conclusion of a clinical trial, the clinical data manager is responsible for ensuring all data management activities have been completed correctly, within budget (for some organisations) and on time.

CDM working in smaller organisations may also be responsible as for the analysis of the data, per the clinical protocols.

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Number of years experience	DM Role	Outline of Tasks (but not limited)	Organisation					Country Specific information
			Sponsor	CRO	Site	Vendor	Lab	
New- 1yr	Clinical Data Coordinator	Graduate Clinical Data Manager, support DM related tasks		x	x		x	
1-2+ yrs	Data Manager	DM related tasks such as cleaning data. Preparation of trial documents. Coding of medical terms, reconciliation of SAE's and non-CRF data and perform user acceptance testing. Archiving and maintaining logs.		x	"X [Role may include data entry]"	x	x	Data Managers maybe be graded in levels e.g. I. II. III, etc
2-3+ yrs	Clinical Data Manager /Clinical Data Associate/Analyst/Coordinator/ CDA-1	Assist in DM related tasks such as cleaning data. Preparation of trial documents, assist in study set-up activities. Coding or review of medical terms, reconciliation of SAE's and non-CRF data and perform user acceptance testing. Archiving and maintaining logs.	x	x	x	x	x	
2-4+ yrs	Snr Clinical Data Manager/Senior Clinical Data Associate/Analyst/Coordinator/CDA-2	Lead and be responsible for all data management activities relating to assigned clinical trial projects, handling medium type studies. Provide DM deliverables internally and externally. Participate in team meetings, monitor project scope and supervise jnr DM members.	x	x	x	x		
2-5+ yrs	Data Acquisition Lead/Data Engineer	Provide technical solutions in assigned functional areas, including but not limited to: eCRF build programming, data validation specification, database specifications creation, Test Data Review, programming for Post-Go-Live changes, analyze and visualize clinical data, provide technical expertise about EDC system and SDTM mapping.	x	x				This could be where a programming group sits within DM
5+yrs	Lead Data Manager/Study Data Manager/ Lead Clinical Data Associate/Analyst/ Coordinator/CDA-3	Technical leader on all DM aspects form start-up to close out, handling complex studies. Develop plans, provide metrics. Serve as a project and client liaison for DM issues and concerns. Provide support and identify improvements in process and efficiency. Lead study set-up activities, provide DM deliverables internally and externally. Participate in team meetings, monitor project scope and supervise jnr DM members.	x	x		x		
6+yrs	Project Data Manager	Lead, co-ordinate, review and approve related tasks/documents. Ensure projects stay on time and budget	x	x		x	x	
6+yrs	Data Quality Manager/Data Quality Management Lead	Subject matter expert (SME), oversight, lead, co-ordinate, review and approve related tasks/documents. Responsible for quality and integrity of the data being provided.	x	x				
6+yrs	Global Data Management Lead/Data Management Expert	Subject matter expert (SME), oversight, lead, co-ordinate, review and approve related tasks/documents. Work with external partners. Awareness of trends and changes in the industry, ensuring standards are utilized. Monitoring quality, risks and performance measures.	x	x				
10+ yrs	Principal Data Manager/Manager, Clinical Data Management	Represent DM team, act as a subject matter expert (SME) and attend Bid defence meetings. Oversight, lead, co-ordinate, review and approve related tasks/documents. Work with external partners. Awareness of trends and changes in the industry, ensuring standards are utilized. Monitoring quality, risks and performance measures.	x	x				
10+ yrs	Assocaite Manager/Snr Manager of DM	Managing/leading projects or portfolio	x	x				
10+ yrs	Assocaite Director/Director (Head) of DM	Management of people, projects and portfolio	x	x		x		