4. Current state of the Clinical Data Management role

As the industry's leading CDM organization, the SCDM has created anchor points for our discipline such as the Good Clinical Data Management Practice[4] (GCDMP©) and the certification program for Clinical Data Managers[5]. Together, they have been defining for almost two decades, the expected competencies, foundational knowledge and best practices of today's CDM roles.

First published in 2000, the GCDMP© provides a reference for CDM organizations in their implementation of high quality CDM processes for paper and EDC based studies. Its twenty-eight (28) chapters guide Clinical Data Managers preparing for CDM training and education.

GCDMP Chapters	
Data Privacy	External Data Transfers
Data Management Plan	Patient-Reported Outcomes
Project Management for the Clinical Data Manager	CDM Presentation at Investigator Meetings
Vendor Selection and Management	Training
Data Management Standards in Clinical Research	Metrics in Clinical Data Management
Design and Development of DCIs	Assuring Data Quality
Edit Check Design Principles	Measuring Data Quality
EDC - Concept and Study Start-up	Data Storage
EDC - Conduct	Data Entry Processes
EDC - Study Closeout	Coding Dictionary Management & Maintenance
CRF Completion Guidelines	Safety Data Management and Reporting
CRF Printing and Vendor Selection	Serious Adverse Event Data Reconciliation
Database Validation, Programming & Standards	Database Closure
Laboratory Data Handling	Clinical Data Archiving

Fig 1. List of GCDMP Chapters

The SCDM certification program launched in 2004, identifies seventy (70) competencies organized into the eight (8) core domains (see figure 2). The number of competencies in the **Design, Project Management, Data Processing and Programming** domains represent over 85% of all those identified in the certification program which aligns by design well with the GCDMP© chapters.

Competency domain	# of competencies	% of total competencies
Design	21	*30.0%*
Project Management	16	*22.9%*
Data Processing	15	*21.4%*
Programming	8	*11.4%*
Testing	2	*2.85%*
Training	2	*2.85%*
Personnel Management	3	*4.3%*
Review	3	*4.3%*

Fig 2. List of SCDM Certification domains

The SCDM Task Analysis Survey conducted in September 2018 re-confirmed the relevance of all competencies included in the survey. At a high level, the competencies included in each of the eight (8) domains cover the following areas:

Study Design	Identification and set-up of all data collection instruments (DCIs) such as EDC and eCOA, data handling and reporting tools leveraging clinical data standards. It also includes core CDM documents such as the Data Management Plan (DMP) and Case Report Form (CRF) Completion Guideline
Programming	Creation of the required tools defined during study design. Scope includes programming of the eCRF (Screens and Edit Checks), reports, ad-hoc querying, data imports, transformations and extracts
Data Processing	Data Lifecycle from collection to archival. Includes the collection, transfer, import, cleaning, coding, reconciliation and quality assessment of clinical study data
Testing	Definition and execution of testing strategies for required tools
Training	Ensuring understanding of CDM processes across the organization
Personnel Management	Ensuring CDM staff oversight
Project Management	Ensuring oversight of CDM activities from study initiation to study close-out including vendor management
Review	Expert review of study and CDM deliverables

In addition to the competencies themselves, twenty-five (25) foundational knowledge topics have been confirmed by the 2015 and 2018 Task Analysis Surveys as necessary to the performance of the CDM competencies. Those include but are not limited to the topics listed below:

- Therapeutic development and clinical research fundamentals
- Scientific method
- Good Clinical Practices (GCP) and other guidance
- Software Development Life Cycle (SDLC) concepts
- Audit methodologies
- Project management fundamentals
- Basic statistical concepts
- Data and metadata models, standards and terminologies (incl. medical terminology)
- Workflow design, analysis, and control fundamentals

Last, beyond those competencies, foundational knowledge and best practices, the following are commonly expected **soft skills** considered as essential building blocks for Clinical Data Managers.

- Attention to details
- Logical thinking
- Adaptability
- Ability to articulate complex concepts to the trial teams
- Ability to investigate and troubleshoot complex data trends
- Ability to work with cross-functional teams

While there are some variations across companies, the CDM role framework below, based on core competency domains, foundational knowledge, best practices and soft skills represents the core expectations from Clinical Data Managers today.
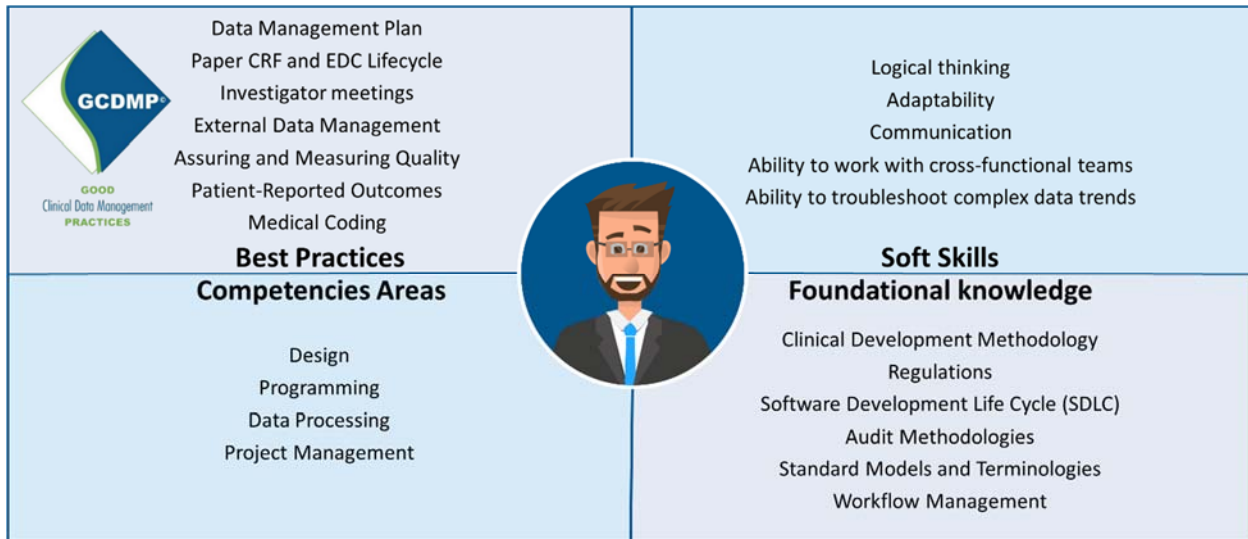

Fig 3. CDM role framework

In summary, even if some companies may have started to expand the scope of their CDM responsibilities, they are still revolving their activities around the following:

- The lifecycle of DCIs and Clinical Data Standards
- The end to end data flow from collection to archival
- The review and reconciliation of clinical study data
- The management of third-party data and related vendors
- One harmonized set of best practices (i.e., GCDMP© Chapters)
- One main CDM tool (i.e., EDC)
- The project management and documentation for all the responsibilities above

This SCDM framework has robustly anchored the CDM discipline for many years. While those will remain critical for years to come, the SCDM has initiated the journey toward CDS and is preparing our discipline to successfully support the evolving needs of clinical research. The following sections will expand on the two first reflection papers and address the impact of this evolution to CDM roles.