The industry role evolution

Patrick Nadolny

Head, Global Data Management

Our CDS Journey

SCDM Live

Internal

The 5Vs of Clinical Data

The evolution of Clinical Data Review

The Automation of CDM Driven Activities

Risk-Based CDM

The CDM Role Evolution

eSource Part 1 Vendors/CROs
eSource Part 2 Sites'-eye view
eSource Part 3 Pharma
eSource Part 4 Regulators

Birth of **C**linical **D**ata **S**cience

SCDM New Vision
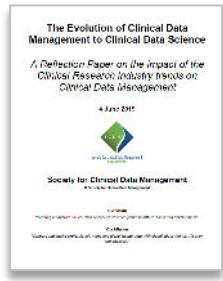
Evolution Drivers (June-2019)

DCT Topic Brief (April 2020)
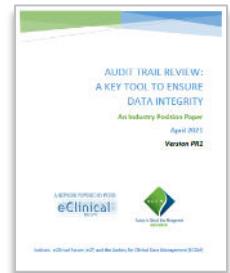
Audit Trail Review (April 2021)

5 Topic Briefs (April to Aug 2022)

4 eSource Topic Briefs 4 Perspectives !! (Sep 2023)

CCDA (Sep 2024)

GCDMP Chapter Rb-CDM

| 2019 | **Refection** | 2020 | 2021 | 2022 | **Position** | 2023 | **Action** | 2025 |

Technology Enablers (March-2020)
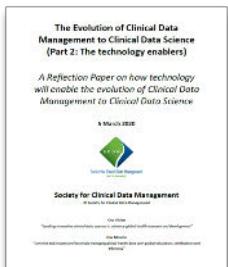
CDS Portal (April 2020)
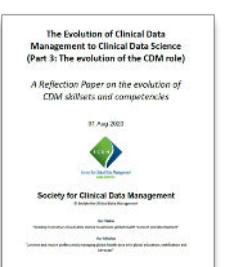
Role Evolution (August-2020)

CDS Position Paper (Sep 2022)

New Vision New Structure

13 eSource Podcasts (Sep 2023)

CCDS (Sep 2025)

elev8

Internal

Clinical Data Science Evolution Drivers

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Clinical Trial Diversity
DRAFT
Apr 2022

DHT in Clinical Trials
Dec 2023

Master Protocols
DRAFT
Dec 2023
Mar 2022

Adaptive Designs
Nov 2019

ICH E6 R3
Jan 2025

ICH E8 R1
Nov 2021

European DCT Recommendations
Dec 2022

Decentralized Clinical Trials
DRAFT
May 2023
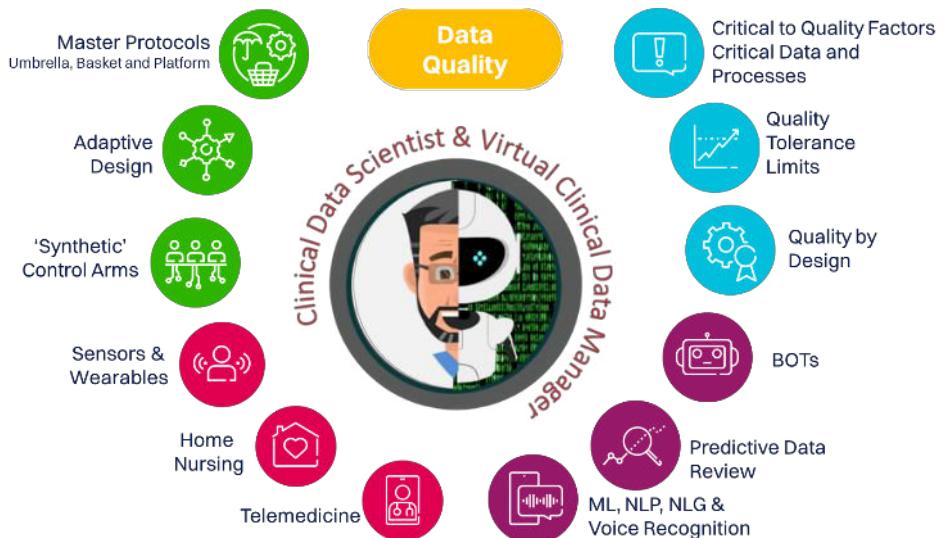
EMA Reflection Paper on the use of AI in the medicinal product lifecycle
July 2023

Resiliency to Disruptions
Sep 2023

CDS Evolution Drivers

Decentralized Clinical Trials — Apr 2020

The 5Vs of Clinical Data — Mar 2022

The CDM Role Evolution — Aug 2022

The evolution of Clinical Data Review — Apr 2022

Risk-Based CDM — Jul 2022

eSource — Vendors / CROs, Sites, Sponsors and Regulators — Sep 2023

The Automation of CDM Driven Activities — June 2022

CDS Evolution Drivers

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SCDM. CDM Industry Competency Framework

Risk-Based CDM (RB-CDM)

Quality by Design (QbD)
Controlling risks by building with the end in mind; Proactive planning

RB-study execution: Risk controls
Risk assessment; Quality checks & mitigation

RBQM
Incorporate QbD, Quality Controls and Continuous Quality Improvement; Use of RACT as a Risk Evaluation Tool

Soft Skills Inc. Leadership & Executive Skills

CDS-driven business models
CDS-based organization/ business structure

Change management
Skills to effectively implement change; Transition planning from CDM to CDS

People/Team development
High performing teams; Career development

Critical & strategic thinking
Skills to effectively analyze information plan according to objectives

Crisis management
Maintaining business continuity during a significant event

Clinical Trial Operations

Patient-driven development & inclusion
Patient/Site-driven development; For example: DCT, patient-centric designs

Emerging study execution
Patient/Site-driven development; For example: DCT, patient-centric designs

Trial design & logistics
Understanding study objectives and site/sample logistics

Protocol design, feasibility & review
Understanding protocol objectives and endpoints and how to review with a CDS eye/how to contribute to draft protocol design

Clinical Data Competencies & Cross-Functional Interactions

**Good Clinical Data Management Practices (GCDMP)**
Chapter topics/updates

CDM-role evolution
CDM to CDS

Partnership governance & oversight
Vendor management/governance

Stakeholder identification and management
Relationship building/interaction

Cross-functional collaboration
Relationship building/interaction

CDM ▷ CDS

Regulations & Standards

CDISC, FHIR, HL7

Global Regulatory Guidelines
For example: ICG-GCP

Country/Regional – specific regulations
For example: HGRAC China, GDPR

AI & Cognitive Tech

AI-driven technology platform
AI-driven DM workbenches

AI rb-SDLC
Risk-based approach to AI development life cycle

Generative AI
For example: Chat GPT, GPT 4.0

Data curation & insights generation
Spotfire, Power BI, visualization tools

Technology & Data Platforms

Data collection platforms
For example ECOA, EDC

Site eSource
EHR, Telemedicine, Home Care, DCT

Patient-tailored technology
For example: wearables, BYOD

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CDS 101

Everything you need to know about Clinical Data Science in an on-demand webinar – now on the SCDM Learning Hub!

Released April 17th 2024

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CCDS Certification

Dr. Deepak Kallubundi
Executive Director
Global Head of CDM Operations

Dr. Shobha Muniyappa
Associate Director
CDM Operations

Why Is Certification Needed?

Key Benefits of SCDM Certification

- **Validates expertise-** Provides an objective to validate professional knowledge and skills

- **Ensures Data Quality-** Certified Professionals are better equipped to implement best industry practices

- **Enhances professional credibility and career advancement** opportunities

- Demonstrates commitment to **continuous professional development**

- **Sets a Global Standards-** helps establish consistent, global benchmark for excellence and professional discipline

Job Analysis

*Job Analysis slides are Courtesy of Kryterion

Job Analysis – What?

- Study of a profession, occupation, or role to identify the *essential job duties* and *essential knowledge and skills* required for *competent* job performance

- Provides relative importance of tasks and knowledge or skills

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Job Analysis – Why?

- Content validity

- Legal defensibility

JOB ANALYSIS = FOUNDATION FOR EXAM

14

Brief Overview of JA and Exam Development Process

- Content Definition and Grouping Meetings
- Test Blueprint Finalization
- Write and Classify Items
- Administer Beta Exam
- Determine Passing Score

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Job Analysis – How?

- Move to more detailed

CCDS

CCDS Domain 1

CCDS Domain 2

CCDS Domain 3

CCDS Domain 4

CCDS Domain 5

Risk Based CDM

Job Task

Job Task

Job Task

Job Task

Job Task

Job Task

Job Task

Job Task

Job Task

Job Task

16

www.kryterion.com
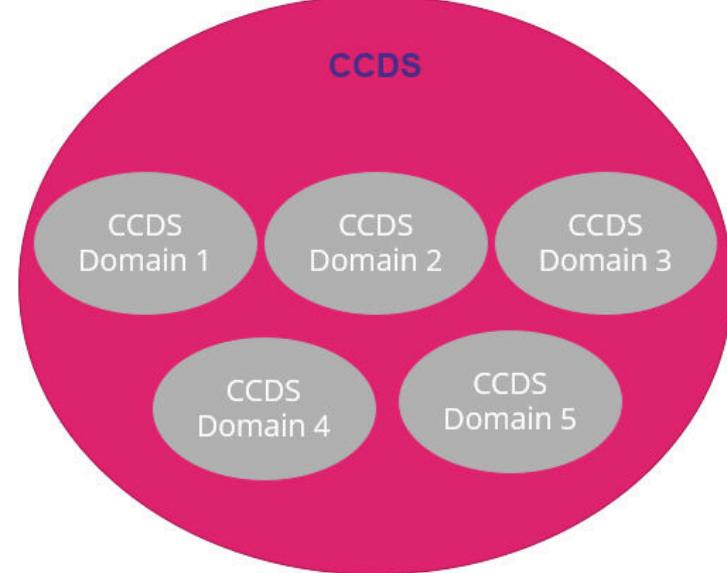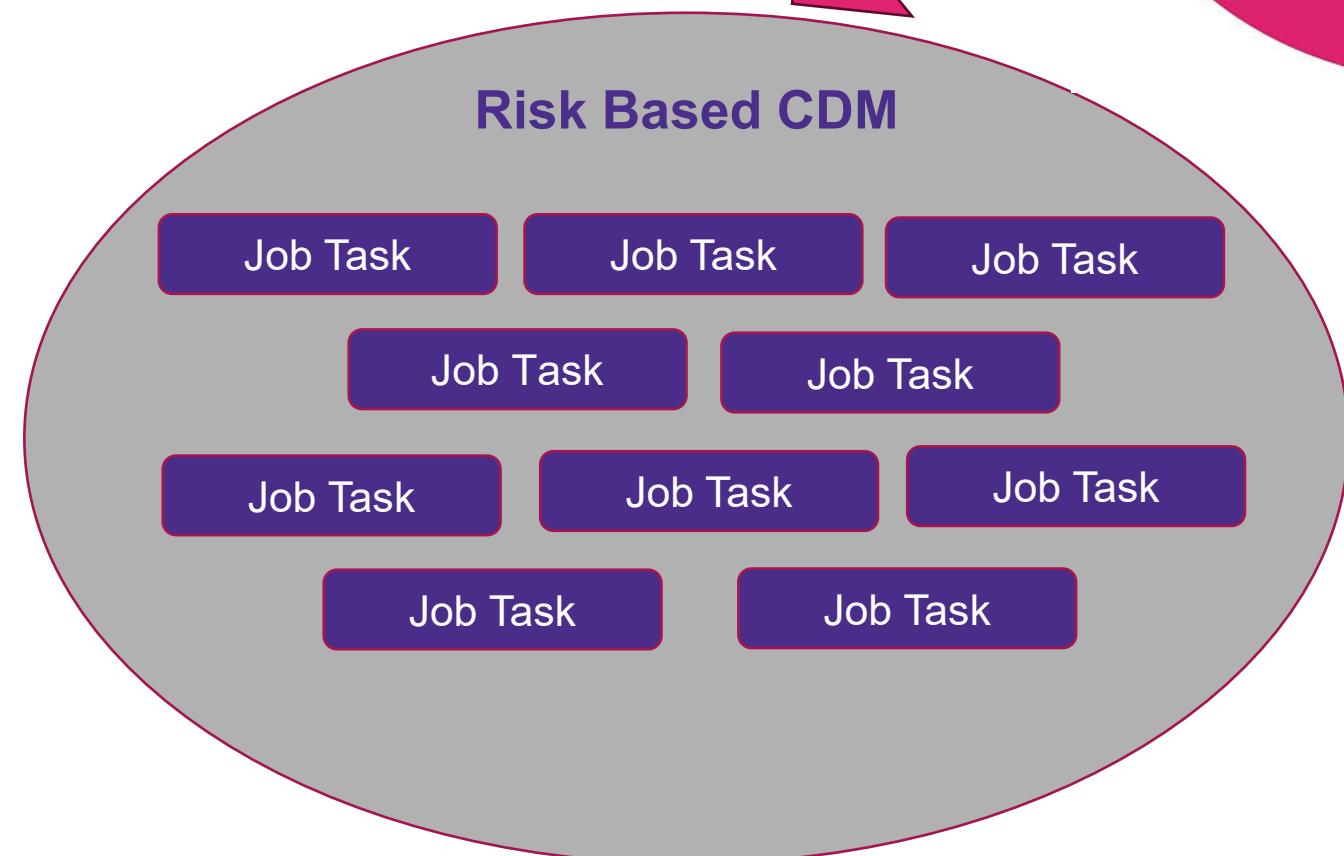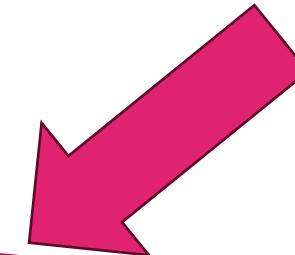
JA Step 1: Content Definition and Grouping

- Review the current CCDS body of knowledge, tasks, and other documentation SCDM has developed

- Sort into a structure that can reliably and fairly assess candidates for the CCDS credential

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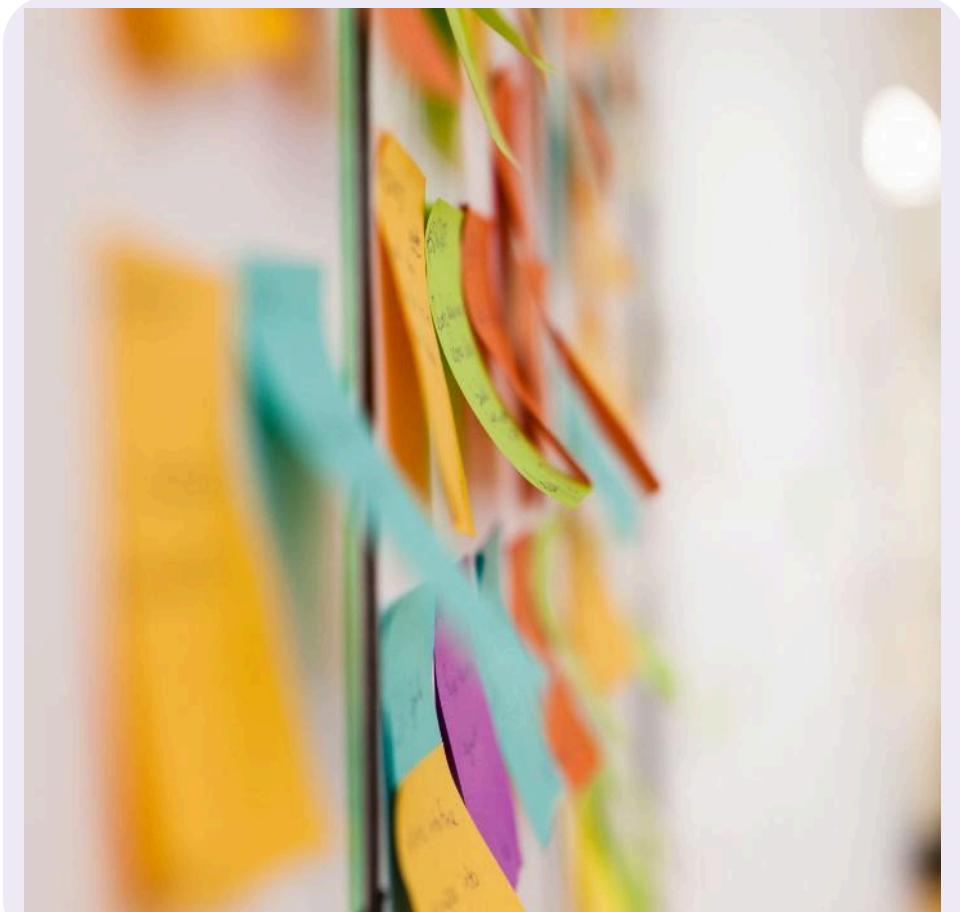
TASK DOMAINS & STATEMENTS

- Identify job domains

- Write task statements for each domain
  - Comprehensive list relative to scope of certification program
  - No overlap or repetition
  - Consistent with purpose and level of credential

18
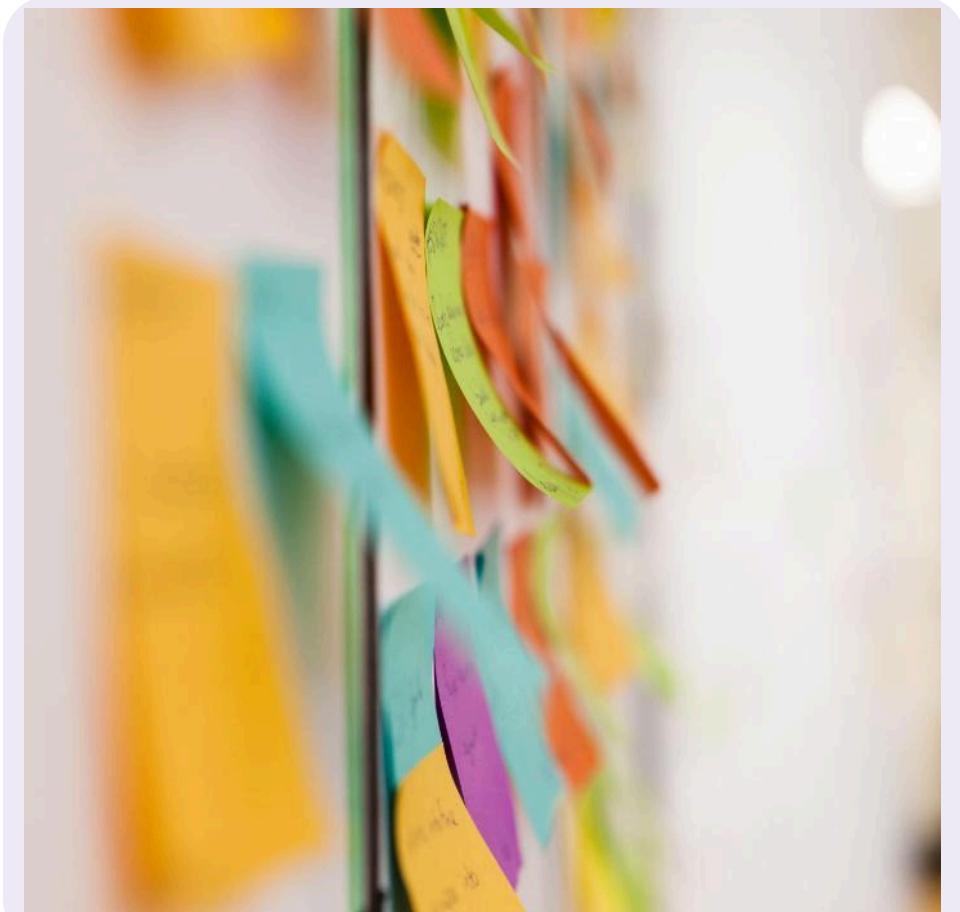
TASK STATEMENTS

Each task statement should include:

- **Who** is doing the action? (implied)

- **What** is the action?

- **To whom/what** is the action directed?

- **Why** is the action being done?

- **How** is the action being done?

- **What work products**, if any, result from the action?
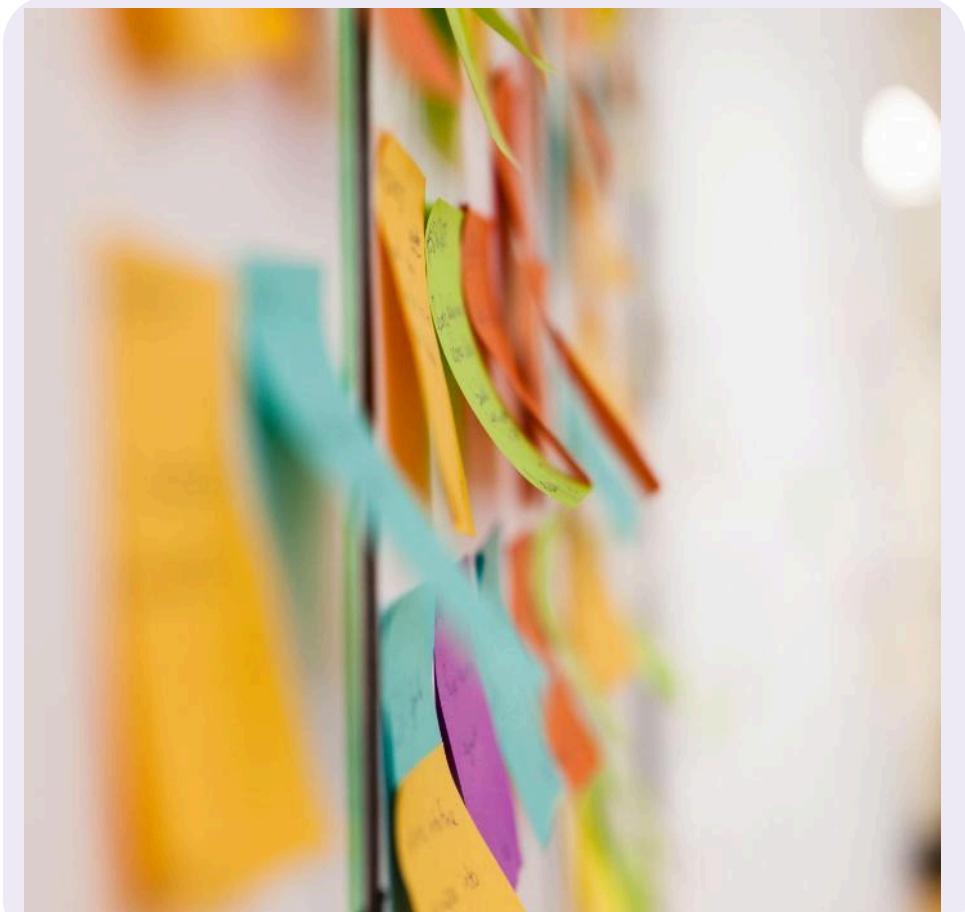
JA Step 2: Test Blueprint Finalization
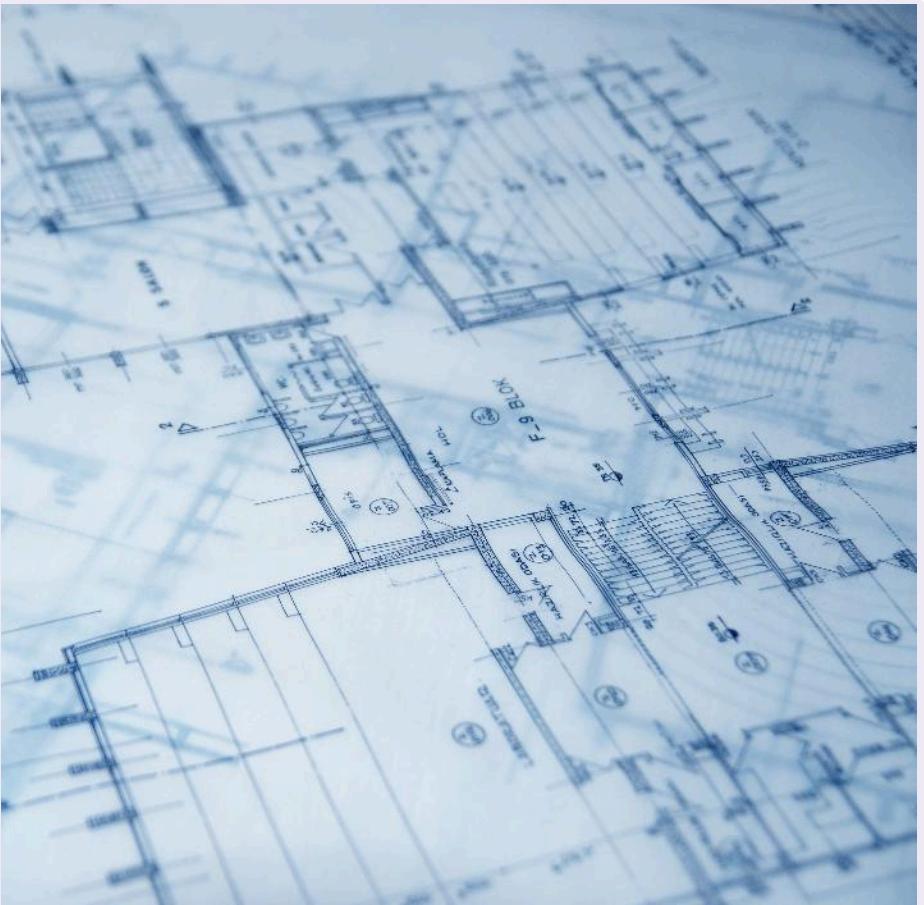
- Goal is to design assessment that will result in VALID inferences and RELIABLE measurement

- Includes content areas for exam and weights, types of items, how exam will be scored, how scores will be used, etc.

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CCDS Domains

CCDS Domain
Risk-Based CDM
Clinical Trial Operations
Regulations & Standards
AI & Cognitive Tech
Technology & Data Platforms
Clinical data & Cross Functional Interactions
Soft Skills

CCDS exam competencies are re-validated periodically in a job analysis called the SCDM Task Analysis Survey.

Item Creation & Review, Exam Launch

High Level Plan

AI Triggered Items

Regulatory documents, SCDM articles and various other sources

Item Review and Edit

Validation of items and finalize (human in loop)

System Check

User Testing with Prolydian system

Beta Test

Beta Exam Go-Live for a defined population

Regular CCDS Launch

CCDS certification exam is open for all

CCDS Item Banking | Lifecycle

System/AI (LLMs-GPT4/Gemini)

Start → Extract Key domain competencies from the corpus → Generate Questions for each identified competencies → Categorize items into Chapter/Task wise

Item Reviewers

Review the item and edit to fit for purpose → Share and cross review items between two cohort groups

Psychometrician

Feedback

Approved or Feedback? ← Review and Validate the items

Complete Result and Analysis

No

Beta Exam Ready?

Yes

Prolydian

Approved

Upload items into Prolydina system → Complete UAT in Prolydian system

Complete Regular Exam Release

Approved

Item Writers

Approve and Release? ← Redefine and Modify failed items ← Investigate and Further analyse failed items ← Monitor failed items

No

Thank You for Your Attention

- Appreciate your interest in clinical data management certifications

- Encourage continuous professional development and learning

- Contact us for further questions and support info@scdm.org

# Learning Continuity with elev8 by SCDM

Eva Martin
Education Director

Shaping the future of Clinical Data Management and Science Learning

This year, we've reached important milestones

✓ Full implementation of the new learning experience platform

✓ New strategic available CCDA, CCDM and RBQM Programs and learning support for 20+ GCDMP chapters

✓ Over 100 new courses designed around emerging learning trends

✓ More than 200 learners onboarded in May 2025

✓ Seamless user journey across membership, education, and certification, now with single sign-on

This journey begins with YOU, Your role, Your path, Your pace
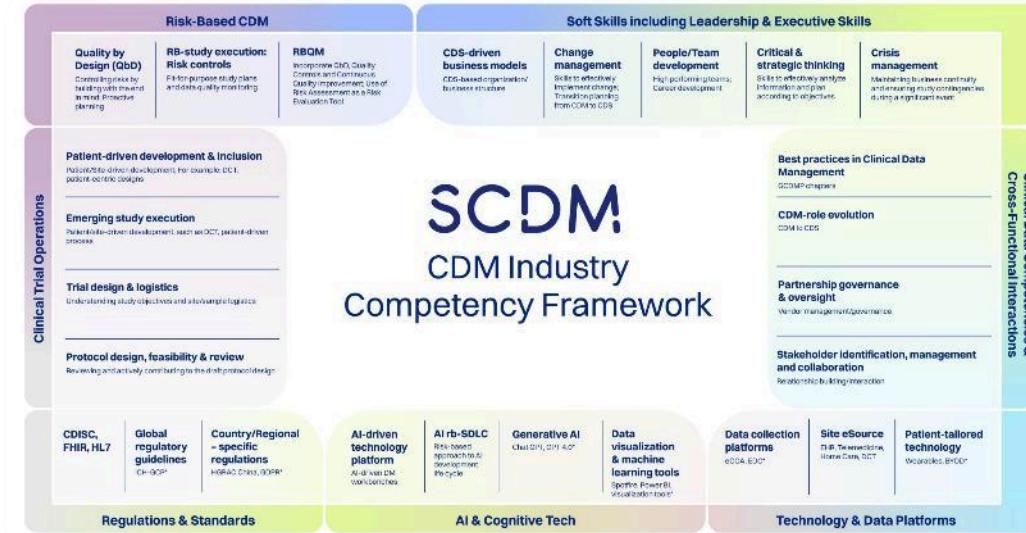
Competencies

Skills

Level

Personalization

We guide your journey in a structured, practical and clear way

1 Getting Started

Course	Course	Test

2 Deep dive into Learning

Course & Test	Course & Test	Course & Test

3 Hands-on practice

Practice	Optional Resources	Final Test

Coaching

Every step is immersive, dynamic, and designed to make education last

📌 Key points that stick

💬 Share, express & connect with peers

🤖 Ask, learn and save time

🎭 Practice real-life situations Key

🧘 Pause and think deeply

🧩 Apply what you've learned

Engagement

Your learning continues, across formats, moments and connections

Feedback

Community

Podcast

Conferences

Online Education

Journal

Virtual events

AI Tutor

Continuity
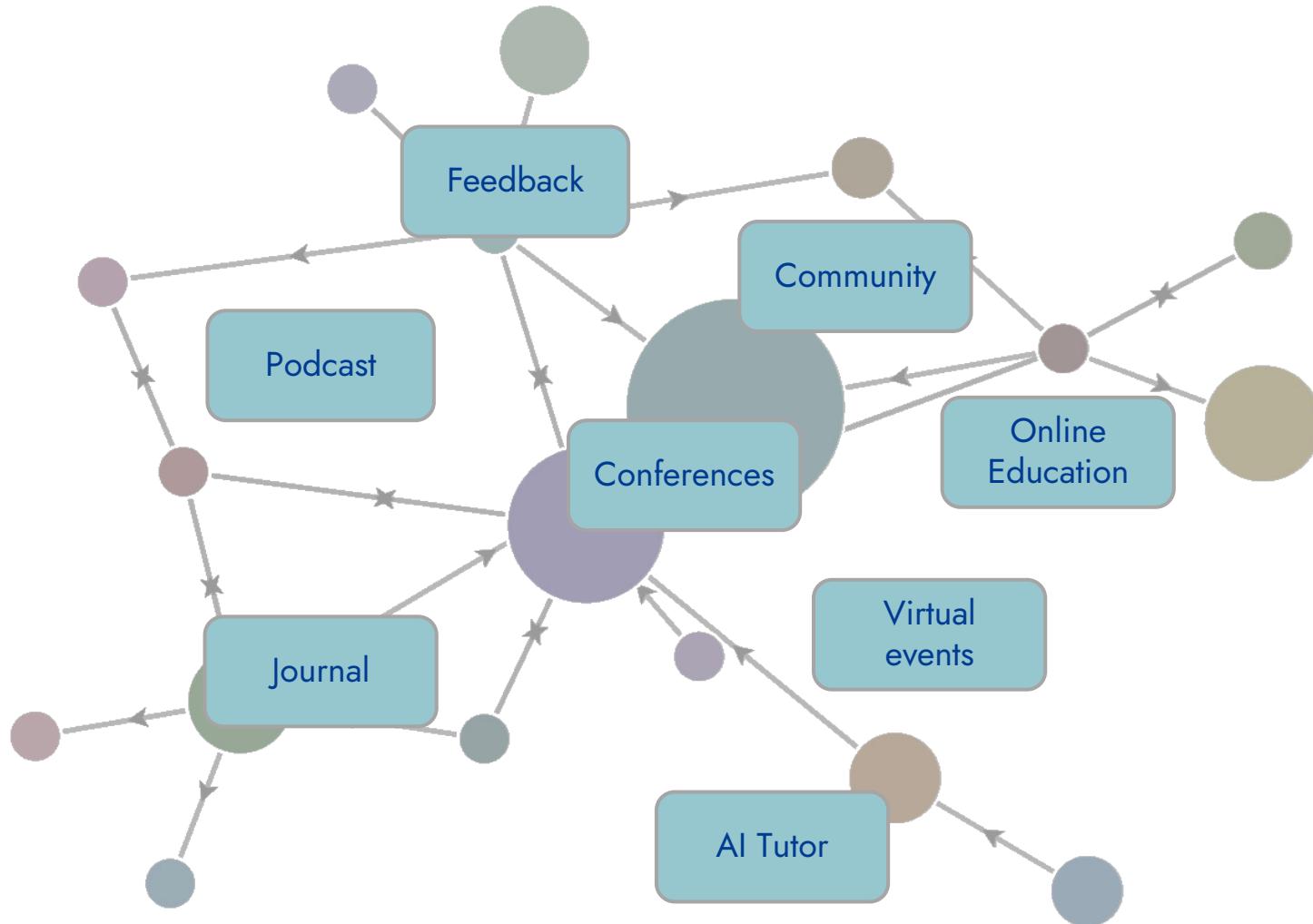
Learning is not just a moment. It is a journey

What was once fragmented is now structured, immersive, and supports continuous growth