

Change Management from CDM to CDS

How to create a CDS Organization

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SCDM Live
annual conference

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SCDM Publication
Thought Leadership



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DRIVERS FOR CHANGE

Master Protocols
Umbrella, Basket and Platform

Adaptive Design

'Synthetic' Arms

Sensors &
Wearables

Home
Nursing

Telemedicine

Data
Quality

Risk-Based
Approaches

Critical to Quality Factors
Critical Data and Processes

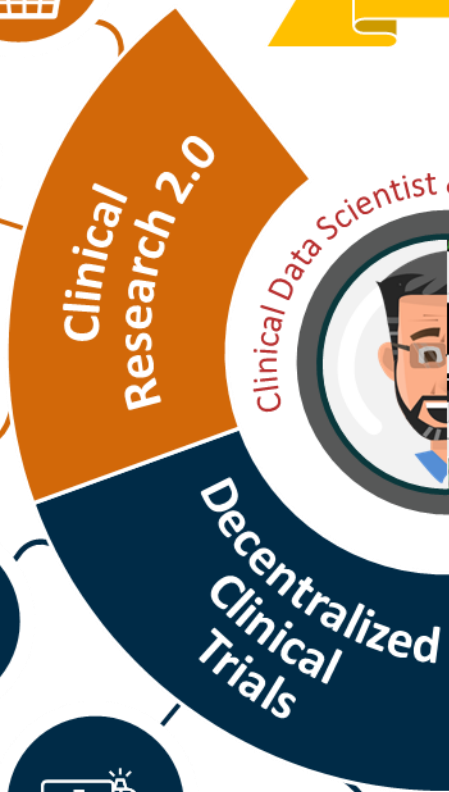
Quality Tolerance Limits

Quality by Design

BOTs

Predictive Data Review

ML, NLP, NLG &
Voice Recognition



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Our CDS Journey

Why?

What?

How?

Birth of Clinical Data Science
SCDM New Vision



Evolution Drivers
(June-2019)



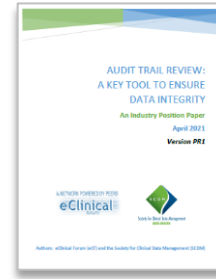
Technology Enablers
(March-2020)



DCT Topic Brief
(April 2020)



Role Evolution
(August-2020)



Audit Trail Review
(April 2021)



The evolution of Clinical Data Review



The Automation of CDM Driven Activities



Risk-Based CDM



The CDM Role Evolution

5 Topic Briefs
(April to Aug 2022)



How to create a CDS Organization
(Sep 2022)

2019 **Reflection**

2020

2021

2022

Position 2023

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CDS Portal
(April 2020)

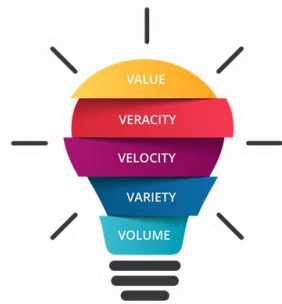
<https://scdm.org/clinical-data-science>

CDS Certification Program

Action

GCDS Chapters

2022 CDS Topic Briefs?



The 5Vs of Clinical Data

March



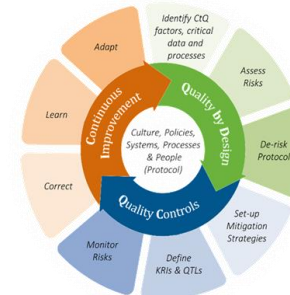
The evolution of Clinical Data Review

April



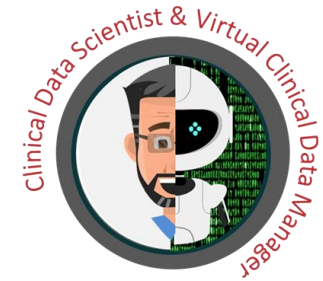
The Automation of CDM Driven Activities

June



Risk-Based CDM

July



The CDM Role Evolution

August



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https://scdm.org/clinical-data-science/#registration_topicbriefs

Best Practices

Risk-based CDM approaches
(Incl. Operational feasibility, QbD and CtQs)

Advanced Clinical Data Reviews
(incl. Story telling visualizations, systematic errors detection, Data Tagging, Exclusion and Curation)

Implementation of the 5Vs of Clinical Data
(Incl. Secondary data assets such a synthetic control arms and complex data Integrations)

Automation of CDM Activities
(Incl. Robotic and Intelligent Process Automation)

Soft Skills

Critical thinking

Influential leadership

Pragmatism

Ability to manage ambiguities

Ability to make and own decisions

Core competencies Areas

Risk Management

Vendor Oversight

Patient Centric Technologies Deployment

Process Management

RPA and ML Based SDLC

Advanced data exploration and interrogations
(e.g., non-SQL, R, Python)

Foundational Knowledge

New protocol designs (e.g., Master, Adaptive)

DCT approaches¹¹

Risk-Based methodologies and regulations

Health Care Data (RWD/RWE), Standard Models and Terminologies

Emerging Data Structures (e.g., Sensors)

Automation and Artificial Intelligence concepts



4 Interconnected evolution pillars remain but ...
resiliency has become a new imperative



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Publications

The Evolution of Clinical Data Management into Clinical Data Science

CDS DEFINITION

TOPIC BRIEFS

PART-1

PART-2

PART-3

OTHER

AUTHORS

INTERACTIVE PAPERS

Definition of CDS

First, **Clinical Data Science** is not to be confused with the general discipline of Data Science which applies across multiple industries. From an SCDM point of view and as expressed in the third reflection paper, Clinical Data Science is an evolution of Clinical Data Management. Clinical Data Science encompasses processes, domain expertise, technologies, data analytics and Good Clinical Data Management Practices essential to prompt decision making throughout the life cycle of Clinical Research. Clinical Data Science can be defined as the strategic discipline enabling the execution of complex protocol designs in a patient centric, data driven and risk-based approach ensuring subject protection as well as the reliability and credibility of trial results.

In contrast, **Clinical Data Management** is responsible for the life cycle of clinical data from collection to their delivery for statistical analysis in support of regulatory activities. Clinical Data Management is primarily focusing on dataflows and **data integrity** (i.e., data is managed the right way). Clinical Data Science broadens this focus by adding the data risk, data meaning and value dimensions for achieving **data quality** (i.e., data is credible and reliable). Clinical Data Science also expands the scope of Clinical Data Management beyond the study construct by requiring the ability to generate knowledge and insights from clinical data to support other clinical research activities which requires different expertise, approaches, and technologies.

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Clinical Data Science

New Position Paper

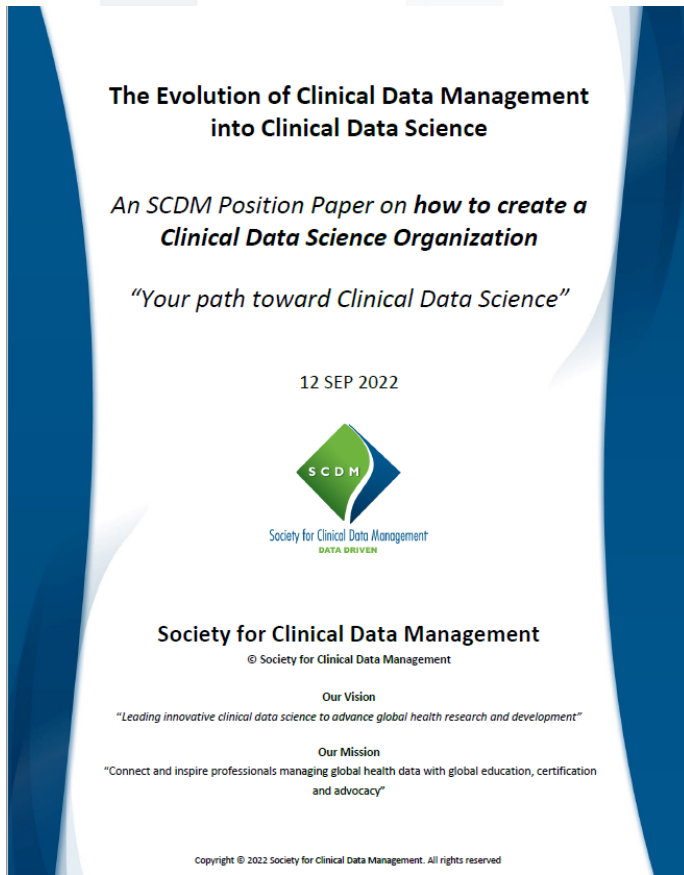
How to create a Clinical Data Science Organization

After publishing 3 reflection papers and multiple topic briefs on the evolution of Clinical data Management (CDM) toward Clinical Data Science (CDS), it is time to move from reflection to action. This position paper will clarify key CDS concepts and provides insights on how CDM professionals can efficiently set their path toward CDS and how they actually can make it happen.

While this paper is not meant to be an exhaustive change management guide, it will provide a concrete set of recommendations on how to evolve an organization toward CDS or simply build/rebuild a CDM organization.



How to create a CDS Organization



Need for Change

Change Management



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How to create a CDS Organization

The Evolution of Clinical Data Management into Clinical Data Science

An SCDM Position Paper on how to create a Clinical Data Science Organization

"Your path toward Clinical Data Science"

12 SEP 2022



Society for Clinical Data Management
DATA DRIVEN

Society for Clinical Data Management
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Our Vision
"Leading innovative clinical data science to advance global health research and development"

Our Mission
"Connect and inspire professionals managing global health data with global education, certification and advocacy"

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Growing our CDM tree

Cultivating the Right Actions

Enable informed, risk-based, and actionable decisions supporting studies and submissions

Growing the right team

Able to support all data aspects of clinical trials

Evolution of CDM Data Reviews

100% QC

Change Leadership adding Enrichment

Scaling the CDM team smartly through a fit for purpose roadmap tailored for your organization

Transformation to deliver Clinical Data Sciences roles and responsibilities

New operating model

Patient's driven data flows leveraging direct data capture

CDM Driven Automations

Traditional EDC Centric CDM Processes

Expansion of capabilities and operating model for the delivery of low hanging fruit

Upskill to build knowledge base and core competencies within internal and external resources

Sourcing the Right Data in the right context; optimized methods to accommodate the 5 Vs of clinical data

Drive adoption of innovative technology and methodologies

Sourcing the Right Talent

Maximize the power of data to enhance the speed of science utilizing of automation

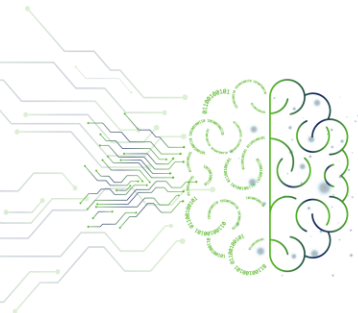
Secure strong CDM Foundations



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Q & A



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evolving industry

