SCDM CCDS

# CCDS Exam

# Study Guide

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# CCDS EXAM STUDY GUIDE

This document is a study guide to help test takers prepare for the CCDS Exam by listing the resources that align with the core CCDS exam domains and associated tasks.

**Please note this guide is a supplemental study aid.**

## CONTENTS

# 1 CCDS: Exam Format

The Certified Clinical Data Scientist (CCDS) exam is designed to evaluate the candidate's interpretation of best-fit responses based on practical industry experience and review of the references provided in this study guide.

The exam employs a time-based, multiple-choice format for various question types, including scenario-based and fact-based questions.

## 2 CCDS Exam Domains and Tasks

### AI & Cognitive Tech

Tasks

1. AI-Driven Technology Platform
2. Data Visualization & Machine Learning Tools
3. Generative AI
4. Responsible AI (Ethical Considerations, Privacy, Regulations)

Resources

| Task | Resource(s) & Alignment |
|---|---|
| **AI-Driven Technology Platform** | Artificial Intelligence Applied to Clinical Trials: Opportunities and Challenges - Explains how AI platforms can optimize clinical trial processes, highlighting practical opportunities and limitations |
| **Data Visualization & Machine Learning Tools** | FDA AI/ML for Drug Development Discussion Paper - Provides regulatory insights on applying ML models, including training, validation, and visualization of data for decision-making |
| **Generative AI** | GenAI in Clinical Trials - Explores use cases of generative AI in clinical research, such as drafting protocols, patient-facing content, and synthetic data generation |
| **Responsible AI (Ethical Considerations, Privacy, Regulations)** | • Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Outlines regulatory expectations for responsible AI supporting decision-making<br>• EMA Reflection Paper on Use of AI in Medicinal Product Lifecycle - Provides EU guidance on AI integration across the drug lifecycle, emphasizing risk management<br>• Ethics and Governance of Artificial Intelligence for Health: Guidance on Large Multi-Modal Models - Focuses on ethical deployment, governance, privacy, and fairness in health AI<br>• FDA (CDER) Position on AI in Drug Development - Clarifies FDA's stance on trustworthy AI use and compliance in drug development |

## Clinical Data & Cross Functional Interactions

Tasks

1. CDM Role Evolution
2. Partnership Governance & Oversight
3. Stakeholder Identification, Management & Collaboration

Resources

| Task | Resource(s) & Alignment |
|---|---|
| **CDM Role Evolution** | • The Evolution of Clinical Data Management into Clinical Data Science (Part 3: The evolution of the CDM role) - Directly addresses how the CDM role is evolving into data science, highlighting required skills and responsibilities<br>• The Evolution of Clinical Data Management into Clinical Data Science - Provides broader context on how CDM is transitioning toward data science, with implications for AI adoption, analytics, and decision support<br>• Clinical Data Warehousing: A Scoping Review - Shows how centralized data strategies reshape CDM responsibilities, requiring advanced data integration and analytics skills |
| **Partnership Governance & Oversight** | • FDA (CDER) Position on AI in Drug Development - Defines regulatory expectations for oversight and governance when sponsors and partners use AI in drug development<br>• FDA: Conducting Clinical Trials with Decentralized Elements - Highlights the governance and oversight needed for decentralized and partner-led clinical trial models<br>• FDA Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Outlines governance considerations to ensure AI use is transparent, explainable, and appropriately overseen |
| **Stakeholder Identification, Management & Collaboration** | • Clinical Data Warehousing: A Scoping Review - Emphasizes collaboration among stakeholders (data managers, statisticians, IT, regulators) in centralized data strategies<br>• FDA: Conducting Clinical Trials with Decentralized Elements - Identifies stakeholder roles and coordination needs in decentralized clinical trials<br>• The Evolution of Clinical Data Management into Clinical Data Science - Discusses the collaborative nature of CDM's evolution, requiring engagement with cross-functional stakeholders (clinicians, data scientists, regulators, technology partners) |

## Clinical Trial Operations

Tasks

1. Automation of Clinical Trial Activities (including Coding)
2. Data Reuse / Repository / Archival
3. Emerging Study Execution
4. Patient-driven Development & Inclusion
5. Protocol Design, Feasibility & Review
6. Trial Design & Logistics

Resources

| Task | Resource(s) & Alignment |
|---|---|
| **Automation of Clinical Trial Activities (including Coding)** | • The Evolution of Clinical Data Management into Clinical Data Science - Highlights how automation is central to the CDM-to-data science transition, including coding and data cleaning tasks<br>• FDA AI/ML for Drug Development Discussion Paper - Discusses automation through AI/ML for data processing, annotation, and model-driven trial activities<br>• FDA (CDER) Position on AI in Drug Development - Provides regulatory expectations on automated AI-driven processes in trial conduct |
| **Data Reuse / Repository / Archival** | • Clinical Data Warehousing: A Scoping Review - Reviews methods for centralized data warehousing, reuse, and archival to maximize trial value<br>• The Evolution of Clinical Data Management into Clinical Data Science - Explains how CDM is shifting toward stewardship of reusable clinical data for secondary use<br>• FDA: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Addresses how curated, reusable datasets support transparency and regulatory confidence |
| **Emerging Study Execution** | • FDA: Conducting Clinical Trials with Decentralized Elements - Covers innovations in execution models such as decentralized and hybrid trials<br>• FDA AI/ML for Drug Development Discussion Paper - Highlights the role of AI/ML in enabling adaptive and novel trial designs and execution<br>• FDA (CDER) Position on AI in Drug Development - Outlines oversight of AI-driven methods supporting innovative study execution |

| Task | Resource(s) & Alignment |
|---|---|
| **Patient-driven Development & Inclusion** | • FDA: Conducting Clinical Trials With Decentralized Elements - Emphasizes patient-centric approaches in decentralized trials, broadening inclusion<br>• FDA: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Highlights the importance of fairness and bias reduction in AI, ensuring inclusive patient representation<br>• The Evolution of Clinical Data Management into Clinical Data Science - Notes the shift toward patient engagement and patient-generated data in modern CDM practices |
| **Protocol Design, Feasibility & Review** | • FDA AI/ML for Drug Development Discussion Paper - Provides examples of AI/ML applications in protocol optimization, feasibility assessments, and trial planning<br>• FDA (CDER) Position on AI in Drug Development - Sets expectations for regulatory compliance in AI-supported protocol design and feasibility work<br>• The Evolution of Clinical Data Management into Clinical Data Science - Shows how data-driven methods are shaping protocol feasibility assessments and early-stage planning |
| **Trial Design & Logistics** | • Clinical Data Warehousing: A Scoping Review - Supports efficient trial design and logistics through centralized data access and reuse<br>• FDA: Conducting Clinical Trials with Decentralized Elements - Addresses operational logistics and design considerations in decentralized trial execution<br>• FDA (CDER) Position on AI in Drug Development - Provides regulatory perspective on the use of AI for optimizing trial design and operational logistics |

## Regulations & Standards

Tasks

1. Audit & Inspection
2. CDISC, FHIR, HL7
3. Global/Country/Regional Regulatory Guidelines

Resources

| Task | Resource(s) & Alignment |
|---|---|
| **Audit and Inspection** | • FDA: Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices - Provides guidance on identifying, reporting, and managing protocol deviations, a key focus during audits and inspections<br>• Good Clinical Practice (GCP) ICH E6(R3) - Establishes global standards for audit readiness and inspection practices in clinical research<br>• General Considerations for Clinical Studies (ICH) E8(R1) - Reinforces principles for study quality that support compliance during audits and inspections |
| **CDISC, FHIR, HL7** | • SCDM RB-CDM Draft Abstract - Discusses reference models for clinical data management, with implications for standard data structures such as CDISC<br>• Clinical Data Warehousing: A Scoping Review - Explores centralized data management approaches that depend on interoperability standards like CDISC, FHIR, and HL7 for integration<br>• MHRA Data Strategy 2024–2027 - Highlights the role of modern data standards and interoperability frameworks (including HL7 and FHIR) in regulatory data strategies |

| Task | Resource(s) & Alignment |
|---|---|
| **Global/ Country/ Regional Regulatory Guidelines** | • Clinical Data Warehousing: A Scoping Review - Provides evidence of global approaches to centralizing and managing clinical data, relevant to regulatory expectations<br>• FDA: Conducting Clinical Trials with Decentralized Elements - US-specific guidance on decentralized trial execution with global implications<br>• FDA: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Establishes FDA expectations for AI use in regulatory decision support<br>• EMA Reflection Paper on Use of AI in Medicinal Product Lifecycle - Provides the European Medicines Agency's perspective on AI integration throughout the product lifecycle<br>• General Considerations for Clinical Studies (ICH) E8(R1) - A foundational global guidance setting quality-by-design expectations for clinical studies<br>• Good Clinical Practice (GCP) ICH E6(R3) - Defines international ethical and scientific quality standards for designing, conducting, and reporting trials<br>• MHRA Data Strategy 2024–2027 - U.K. regulatory vision for modern data use, governance, and innovation in clinical research<br>• SCDM RB-CDM Draft Abstract - Provides professional society insight into evolving data management practices, complementing regulatory guidelines |

## Risk-Based CDM

Tasks

1. Quality by Design (QbD)
2. RBQM
3. RB-Study Execution Risk Controls

Resources

| Task | Resource(s) & Alignment |
|---|---|
| **Quality by Design (QbD)** | • The Evolution of Clinical Data Management into Clinical Data Science (Part 3: The evolution of the CDM role) - Explains how CDM's role is evolving to embed quality into processes upfront, aligning with QbD principles<br>• The Evolution of Clinical Data Management into Clinical Data Science - Provides the broader framework for QbD in data management, emphasizing proactive design for quality<br>• FDA: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Outlines the importance of transparency and reliability of AI systems, reinforcing QbD approaches for regulatory confidence |
| **RBQM (Risk-Based Quality Management)** | • SCDM RB-CDM Draft Abstract - Directly addresses risk-based clinical data management principles that align with RBQM strategies<br>• Audit Trail Review: A Key Tool to Ensure Data Integrity - Demonstrates how audit trail reviews can serve as a monitoring and risk-mitigation activity within RBQM frameworks<br>• Clinical Data Warehousing: A Scoping Review - Highlights how centralized data systems support risk detection and monitoring, key to RBQM implementation |
| **RB-Study Execution Risk Controls** | • SCDM RB-CDM Draft Abstract - Discusses risk-based approaches for study execution, providing a framework for implementing risk controls<br>• Audit Trail Review: A Key Tool to Ensure Data Integrity - Serves as a practical risk control mechanism to detect anomalies and maintain study data integrity<br>• The Evolution of Clinical Data Management into Clinical Data Science - Shows how evolving CDM practices emphasize proactive risk management and data-driven execution controls |

## Technology and Data Platforms

Tasks

1. Data Collection Platforms (including External Data, All Source of Data)
2. Patient-Tailored Technology
3. Site eSource

Resources

| Task | Resource(s) & Alignment |
|---|---|
| **Data Collection Platforms (including External Data, All Sources of Data)** | • Clinical Data Warehousing: A Scoping Review - Explores centralized approaches for managing diverse data sources, supporting integration of external and real-world data<br>• The Evolution of Clinical Data Management into Clinical Data Science (Part 3: The evolution of the CDM role) - Highlights how CDM roles are expanding to oversee multi-source data collection and harmonization<br>• The Evolution of Clinical Data Management into Clinical Data Science - Provides the broader framework for managing heterogeneous data sources in modern trials<br>• FDA: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products - Stresses the need for reliable, traceable, and explainable multi-source data when supporting regulatory decisions<br>• General Considerations for Clinical Studies (ICH) E8(R1) - Reinforces principles of data quality and integrity across all sources of data collection<br>• Good Clinical Practice (GCP) ICH E6(R3) - Defines global standards for compliant and reliable data collection |
| **Patient-Tailored Technology** | • FDA: Conducting Clinical Trials with Decentralized Elements - Emphasizes the role of patient-centric technology in decentralized and hybrid trial model<br>• Ethics and Governance of Artificial Intelligence for Health: Guidance on Large Multi-Modal Models - Provides ethical principles for deploying patient-facing technologies, focusing on fairness, inclusivity, and transparency<br>• FDA: AI/ML for Drug Development Discussion Paper - Discusses patient-tailored applications of AI/ML in clinical trial design, monitoring, and data collection<br>• General Considerations for Clinical Studies (ICH) E8(R1) - Stresses patient-centered approaches and quality-by-design principles, aligning with tailored technologies |

| Task | Resource(s) & Alignment |
| --- | --- |
| **Site eSource** | • Audit Trail Review: A Key Tool to Ensure Data Integrity - Demonstrates how audit trail reviews ensure reliability of eSource data at sites<br>• FDA: Conducting Clinical Trials with Decentralized Elements - Highlights site responsibilities and expectations for implementing eSource solutions in decentralized environments<br>• Good Clinical Practice (GCP) ICH E6(R3) - Provides standards for accurate, attributable, and verifiable eSource records<br>• The Evolution of Clinical Data Management into Clinical Data Science - Explains how site eSource fits into the broader transition to modern data practices in CDM |

## LINKED RESOURCES

Artificial Intelligence Applied to Clinical Trials: Opportunities and Challenges

Audit Trail Review: A Key Tool to Ensure Data Integrity

Clinical Data Warehousing: A Scoping Review

EMA Reflection Paper on Use of AI in Medicinal Product Lifecycle

Ethics and Governance of Artificial Intelligence for Health: Guidance on Large Multi-Modal Models

FDA (CDER) Position on AI in Drug Development

FDA AI/ML for Drug Development Discussion Paper

FDA: Conducting Clinical Trials with Decentralized Elements

FDA: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

FDA: Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices

GenAI in Clinical Trials

General Considerations for Clinical Studies (ICH) E8(R1)

Good Clinical Practice (GCP) ICH E6(R3)

MHRA Data Strategy 2024 - 2027

SCDM RB-CDM Draft Abstract

The Evolution of Clinical Data Management into Clinical Data Science

The Evolution of Clinical Data Management into Clinical Data Science (Part 3: The evolution of the CDM role)

# 3 CCDS Study Guide Updates

| Date | Notes |
|---|---|
| 22 Sept 2025 | New version |
| 3 Feb 2026 | Page 13, added link to *"SCDM RB-CDM Draft Abstract"* |
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