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2023 US INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER

From Medical Writing to Data Management: Key Considerations for Successfully Adopting the United Study Definitions Model (USDM) and Enabling Digital Data Flow (DDF)

Presented by Akash Trivedi, Life Sciences R&D Senior Manager, Accenture

Meet the Speaker

Akash Trivedi

Title: Life Sciences R&D Management Consulting Senior Manager

Organization: Accenture

Akash is a Management Consulting Senior Manager with 15+ years of experience working with Life Science companies, healthcare providers, and health startups. His areas of focus include developing business strategies and value models for digitalizing Life Sciences R&D (e.g., DDF, DCT, RWD) and Health Care Delivery (e.g., decentralized care, virtual health, connected health).

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

01 Value of Digital Data Flow

02 Impacted Stakeholders

03 USDM Overview and Value

04 Barriers to Adoption

05 Q&A

Digital Data Flow can drive operational efficiencies across the value chain

Trial Design	Study Start-up	Study Conduct	Results & Analysis	Submission & Approval
• Reduce trial design time by learning from previous studies and reusing existing templates • Reduce cost and cycle time by simulating the impact of the design and embed changes to reduce the need for amendments	• Reduce time and effort related to site selection, contracting, and budgeting by automating most of the effort • Reduce time and costs associated by automating the build studies in data acquisition and study management systems	• Accelerate cycle times by capturing data from digital sources (i.e., eCOA) allowing for more frequent data cuts/ interim analysis • Accelerate cycle times, improve data quality, and reduce cost by leveraging Direct Data Capture from digital sources (i.e., eCOA, Direct Lab feeds, Devices) and reducing the need for queries	• Accelerate cycle times by automating STDM transformations and data harmonization activities • Reduce effort by automating/ autogenerating various SAS programing activities • Improve talent acquisition and retention by transition to R	• Reduce time from Last Patient, Last Visit to Submission by automating document generation

Value Generated

Simplification and Interoperability

Enhanced efficiency, data quality and foundation for interoperability

Optimization of Clinical Protocol

Improved data management and increased insights

Improvement of Patient Outcomes

Consistent care and increased patient engagement

Highlighting the key benefits of digitalization to each stakeholder is necessary to drive buy-in and engagement

Study Team

Roles

Data Analyst, Therapeutic Area Leader(s), Clinical Research & Development Lead, Clinical Science Lead

Digitalization Benefits

- ✓ Enables relevant and comprehensive data sources to inform protocol and study design
- ✓ Increases ability to access real-time data
- ✓ Reduces time spent populating protocol creation

Protocol Author and Reviewer

Roles

Medical Writer, Study Delivery Lead, Regulatory Lead, Data Manager, Study Delivery Lead, Statistician

Digitalization Benefits

- ✓ Streamlines authoring process through instant coordination with cross-functional members and digitizing routine processes
- ✓ Reduces time spent authoring the protocol
- ✓ Improves productivity and efficiency through tailored review cycles
- ✓ Increases quality and compliance of protocol / protocol versioning
- ✓ Standardizes protocol terms according to controlled terminologies

Study Startup

Roles

Feasibility Team, Country/ Site Contracting, Budgeting/ Finance

Digitalization Benefits

- ✓ Leverages data to help identify the appropriate sites
- ✓ Automates the creation of budget frameworks
- ✓ Enables understanding of previous contracts to negotiate for new studies
- ✓ Calculate study cost while protocol is being drafted

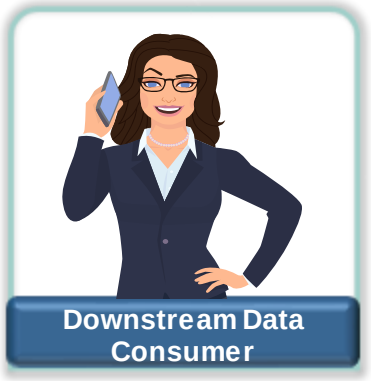
Study Build

Roles

Study Build Teams, Data Acquisition, Data Management

Digitalization Benefits

- ✓ Streamlines communication with study teams to ensure most recent protocol is being used
- ✓ Automate receptive, low-value takes so teams can focus on higher-value customizations
- ✓ Enables downstream activities to occur in parallel earlier



Downstream Data Consumer

Roles

Data Management, Data Harmonization, Data Analysis

Digitalization Benefits

- ✓ Reduces barriers that prevent database lock
- ✓ Expedites data cleaning for repetitive data discrepancies through automated queries
- ✓ Accelerates data manipulation through automated SDTM transformation
- ✓ Receive faster data cuts to monitor study progress

CDISC Unified Study Definitions Model (USDM)

Overview

USDM is a **Framework** developed by CDISC to create a common digital data model and method for exchanging protocol information

Objective

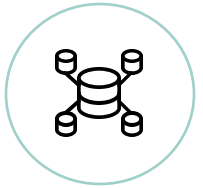
Provides the technical architecture to support the DDF goal of **complete automation** from beginning to end for clinical research

What is provided?

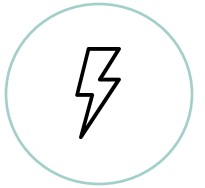
1. **USDM Class Diagram**
2. **API Specification**
3. **Essential User Stories**
4. **CDISC Controlled Terminology**
5. **Reference Architecture Conformance Tests**
6. **Supporting Materials**

BENEFIT

Controlled and Standard Vocabulary that aims to align with other CDISC standards



Consistent and harmonized trial data across systems



Enablement of study automation and optimization

Digitalization will have unique impacts on each stakeholder across the study lifecycle

	Study Startup	Study Conduct	Study Closeout
 **Dan** *Medical Writer*	I will use the CDISC USDM **structured and standardized terminology** to **digitally** write my protocol	I can expect **minimized protocol amendments** due to **standardized data and terminology** across systems and workstreams	I can **save cycle time** by leveraging content authoring tools for the **CSR** and other study-closeout documents
 **Brian** *Clinical Data Manager*	I can now utilize our pre-configured SDR **to program our EDC system and build the statistical analysis plan**	I can **minimize duplicate data entry** from various systems by improving standards in a **USDM-compliant format**	I can **enable common data integrations** between systems that share study design data needs
 **Maria** *Study Manager*	I can leverage the same attributes from Dan's digital protocol to set up my study in CTMS, with **minimal manual effort** required	I can **minimize the manual data reconciliation** for protocol deviations	I can **minimize the barriers** which prevent database lock

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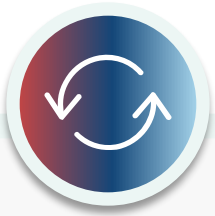
Barriers to Adoption



Insufficient Change Management

- Not engaging the right stakeholders early enough
- Lack of communication and shared understanding of benefits

Existing Technology Landscape

- If technology is not USDM CDISC compliant, you may need to build adaptors or change out technology to enable future way of working

Organizational Readiness

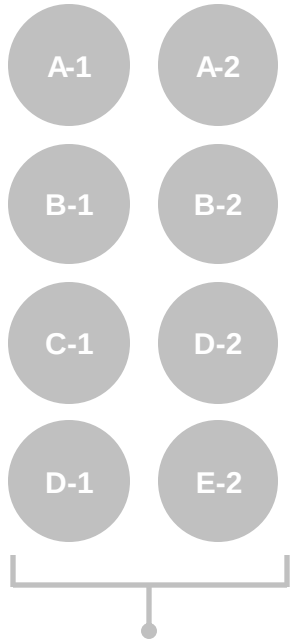
- Enterprise standards are required for successful implementation

Sponsors can overcome these barriers by engaging the right stakeholders early and often, communicating the value and benefits effectively, and ensuring your current tools & technologies are equipped to derive the most value from CDISC USDM.

We recommend using an agile, use case driven approach to realize automation and digitalization benefits sooner

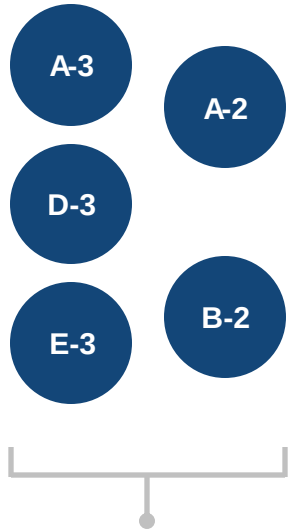
While the promise of digitalization across the end-to-end value chain is persuasive, proceeding with a use case driven approach will enable **focused automation and intelligence** to realize value faster.

It is essential to prioritize use cases by **optimized feasibility and organizational value** while also acknowledging **enabling and restrictive dependencies** that may inform their sequencing.



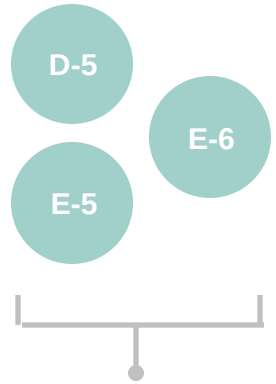
Starter Use Cases

Complete list of potential automation and digitalization use cases across the full clinical development value chain.



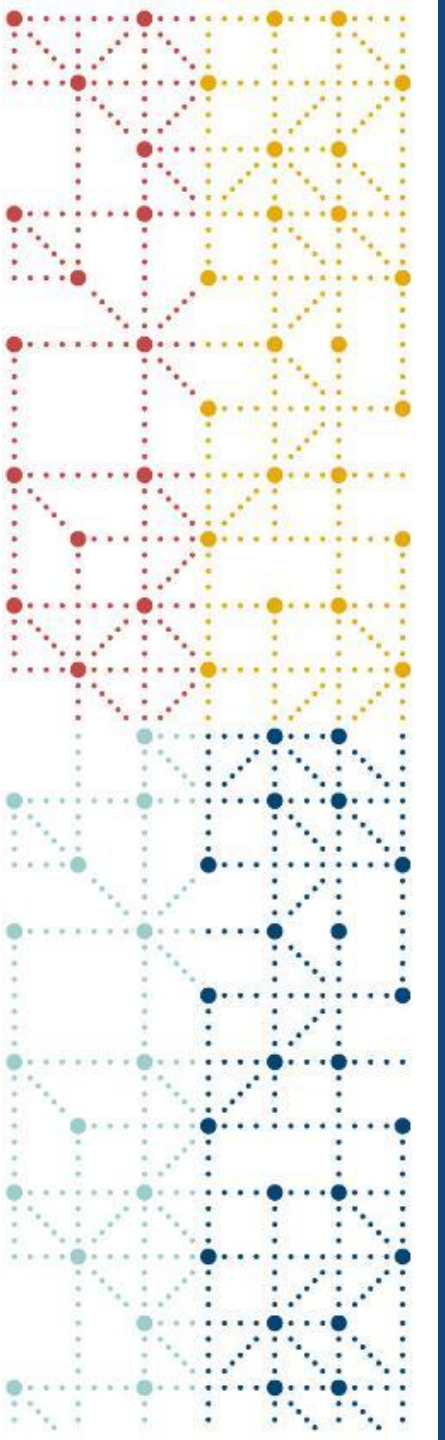
Prioritized Use Cases

Prioritized and down-selected use cases based on implementation feasibility and expected organizational return-on-investment.



Dependency-driven Use Cases

Immediately actionable use cases leveraging a combination of dependencies, resource capacity, and foundationally required capabilities.



Q&A

Thank You!