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Using DDF to drive Clinical Data Automation

Presented by Suman Kumar, Deloitte

Meet the Speaker

Suman Kumar

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Organization: Deloitte

Suman Kumar has 20+ years of experience working for Life Sciences companies and brings a specific focus on creating specialized products offerings in areas of medicine development. He has a deep understanding of the Clinical R&D landscape having worked with large pharmaceuticals, contract research organizations, niche data vendors and more. He has led multiple large scale Clinical Data Analytics programs that aim to reduce cycle time and bring therapies faster to patients.

Disclaimer and Disclosures

- *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

1. Challenges with traditional approaches to managing clinical study data
2. Understand how an intelligent single source of truth can bring about more efficient clinical trials
3. Explore use cases that demonstrate opportunities across the clinical trial lifecycle
4. Review the potential benefits of using metadata-driven AI/ML to automate the clinical data flow

Challenges with traditional approaches to managing clinical study data

The current business challenge

Throughout the lifecycle of a clinical trial, a litany of critical artifacts are developed to establish the trial's structure, track patient data, and execute tasks – however the process to perform this work is highly manual/inefficient and increases cycle time

How can we create a **sustainable metadata backbone** for clinical trial data management to meet future digital demands of **greater agility and interoperability**, while improving trial execution?

Common Business Challenges

- **Fragmented** data and disconnected systems
- Extensive **manual effort**
- **Inconsistent** and **inaccurate** information
- **Rework** and repetition
- Challenges in enabling **innovative trial models**

Implications of the Business Challenges

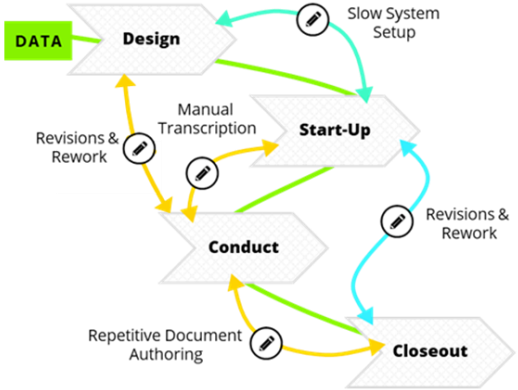
- Inputs for **trial artifacts** are **scattered** across numerous, **interoperable systems** and formats
- **Artifact creation** requires **manual data transcription** from documents and systems
- Manual transcription often leads to **data errors**
- Although trials typically reuse data components, the **same work is repeated across trials**
- Complexities and limitations related to **integrating data from new sources create** challenges with virtual trial designs

Transitioning to the Future of Clinical Trials

Artificial intelligence has the potential to significantly reduce clinical trial cycle times and costs while improving the outcomes of clinical development

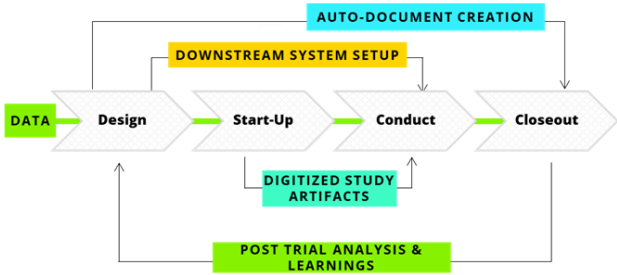
Traditional clinical trial data flow

A non-linear maze of manual effort, rework, and inefficiency



The future state vision

Streamlined interoperability of trial artifacts enabled through the standardization of data / vocabulary & learnings from AI & ML analysis



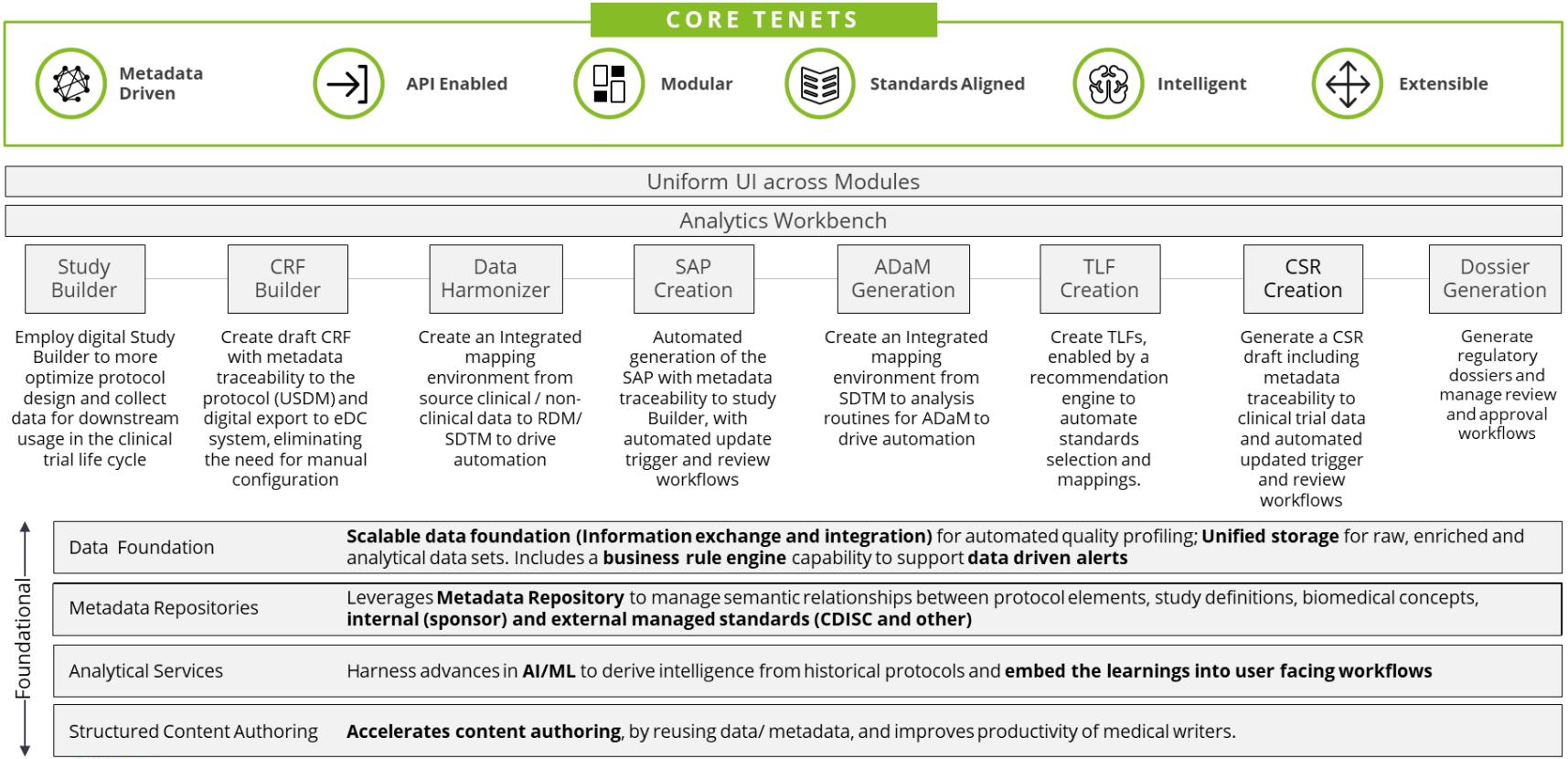
Future state benefits

- **Reduced Manual** Effort & Rework
- **Increased Interoperability** Across Multiple Systems
- **Improved Trial** Cycle Time
- **Optimized Use of Insights** to Improve the Next Trial
- **Reduced Errors in** Trial Artifacts

Understand how an intelligent single source of truth can bring about more efficient clinical trials

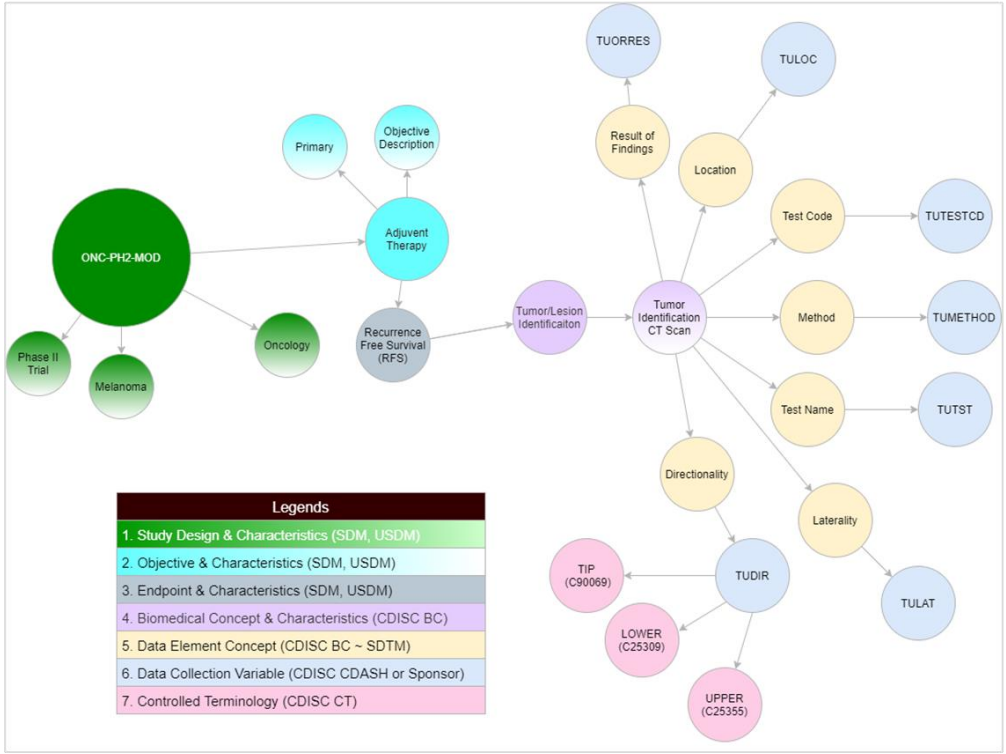
Realizing the future state vision

To help optimize impact, companies should explore opportunities to automate across the entire clinical trial life cycle.



Connecting the different Silos

Connect internal and external metadata; Provide end to end traceability across business processes



- **"Connective"** Tissue that links different metadata together – study design, data collection, biomedical concepts, data tabulation, analysis concepts etc.
- **Biomedical concepts** define assessments that need be performed to achieve an endpoint/ timepoint
- Biomedical concepts act as a unit of knowledge that **eliminates ambiguity** while performing CRF design
- Helps system/ application detect **correlations (impact analysis)** that humans cannot.
- Provides **vertical and horizontal scalability**
  - Integrate with **external ontologies**, vocabularies and dictionaries
  - Allows further enrichment from competitive intel (a lot of data available as **unstructured content**)

Explore use cases that demonstrate opportunities across the clinical trial lifecycle

Enabling disciplined automation

Three use cases demonstrate the opportunities across the lifecycle

USE CASES

PROTOCOL BUILDER
Use AI/ML and Biomedical Concepts in conjunction with the Common Protocol Template to enable creation of digitized protocol and traceability of common elements from protocol to CSR.

CRF BUILDER
Use metadata collected for each visit as defined in the study builder to generate an ODM/ALS import file to automate CRF build in EDC System.

SDTM CONVERSION
Automate data quality checks and mapping from source clinical / non-clinical data (CRF, EHR, device, ePRO etc.) to SDTM and SEND, and analysis routines to drive automation

OUTPUTS

DIGITAL PROTOCOL INCLUDING SoA
Metadata is passed along to design CRF in an automated manner and minimal manual intervention

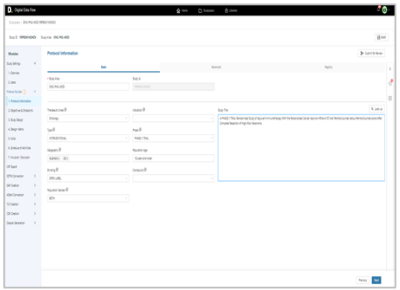
EDC SYSTEM DESIGN METADATA
Metadata is passed along to define the SDTM domain, variables, and lookups

SDTM CDISC COMPLIANT DATA & DOCUMENTATION
Enable conformation with third-party systems that the data is continually compliant

Use Case 1 : Study Designer

Use of AI/ML and metadata to automatically generate a digital protocol

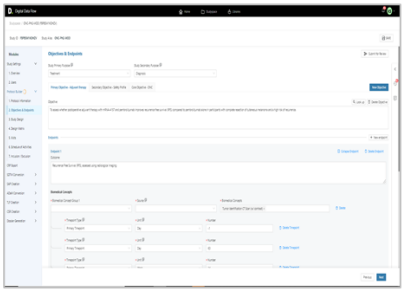
Study information & design



Metadata-Driven Automation

Utilize AI/ML/Metadata to assist with the defining of a study in the system by using each piece of supplied information to help select the next piece

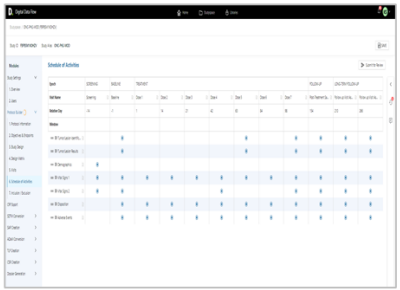
Objectives & endpoints



Library-Based Suggestions

Utilize system supplied relationships to suggest study endpoints and associated collection, storage, analysis, and reporting needs (CDASH/SDTM/ADaM/TLFs)

Schedule of activities



SoA Generation from Endpoints & Biomedical Concepts

Autogenerate the Schedule of Activities (SoA) based on defined endpoints and timing

Protocol

Protocol Generation and Metadata for Downstream Consumption

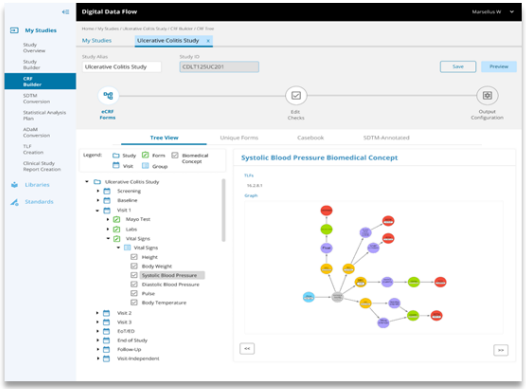
Autogenerate using the metadata and libraries

- Protocol
- A study definition import file that can be used by client's EDC tool to define the visit schedule, forms, fields, and edits

Use Case 2 : CRF Builder

Generate the machine-readable format to create the EDC design

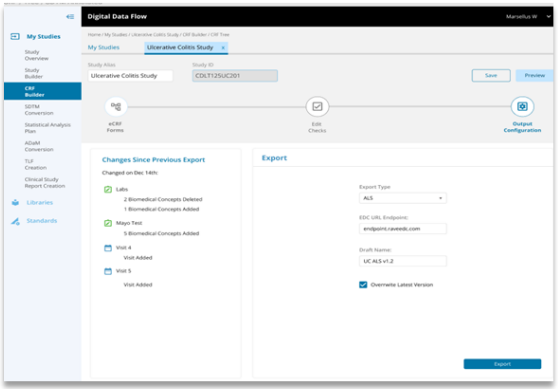
eCRF Tree



Visual Representations

Provide the ability to view the forms and fields at each visit for data managers, programmers, and statisticians to better understand the structure of the incoming data. Define the form order within each visit to support data collection at the sites.

Automated Output



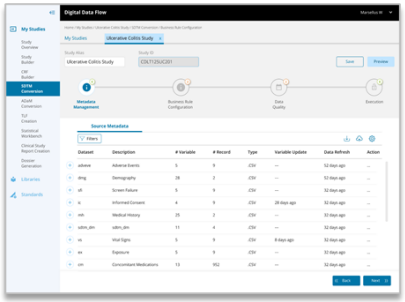
Automated EDC Design Metadata

Ensure consistency by providing detailed specifications that align with the study design. Enable the creation of design specification files to automatically generate the visit schedule, forms, and variables that will be used in the EDC tool.

Use Case 3: SDTM Conversion

Use of AI and libraries to automate the conversion of data

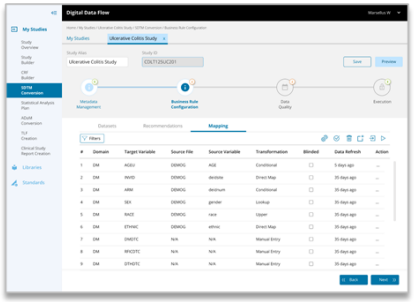
Study Metadata Sync



Identification of Study Metadata

Utilize study metadata from CRF builder and Digitized Protocol, including
EDC fields to define SDTM requirements

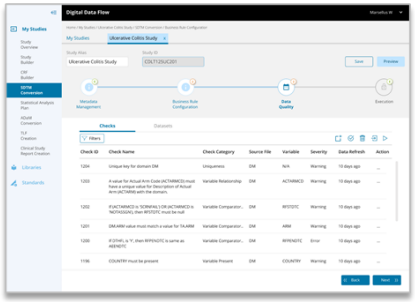
Business Rule Configuration & Data Quality Checks



Library-Based Population of Business Rules and Data Quality Checks

Consume study metadata to automatically generate source-to-target mappings

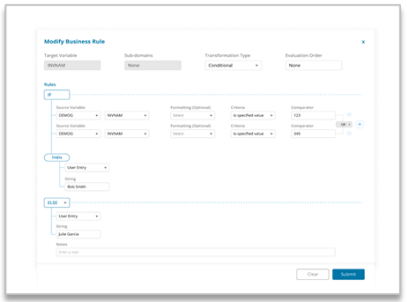
Data Conversion & Report



End-to-end Conversion and Report Generation

Run the end-to-end conversion (SDTM) including data quality checks as data is captured in source systems like EDC, labs etc. Solution should automatically produce output SDTM data and a data quality report

Business Rule Refinement



Updating Business Rules based on Report

Review the business rules suggested by solution, any errors and data quality reports. User will update the business rules if not satisfied with system recommendations, and provide feedback to relevant team for any data quality error

Review the potential benefits of using metadata-driven AI/ML to automate the clinical data flow

Potential benefits of AI & Metadata Driven End to End DDF

Albeit the possibility of potential benefits will grow as the technologies continue to mature, below are the initial benefits which can be aimed for during a build along each step of the data's transformation journey

Clinical Trial Value Chain	Design		Start-Up		Conduct		Analyze		Closeout
Solution Modules	Protocol Digitization	CRF Builder	SDTM Conversion	Adam Conversion	TLF Creation	Clinical Study Report Creation	Dossier Generation
Pain Points Addressed							
Quality Improvement	☑	☑			☑		
Productivity Enhancement	☑	☑	☑	☑	☑	☑	
Reduction in Cycle Time *(Days)*	>4	>14	>13	>5	>9	>7	>50
Reduction in Manual Work	70%	70%	95%	95%	70%	70%	
Reduction in Cost *(Late-Stage Study)*	$35k	$107k	$137k	$60k	$102k	$59k	

Thank You!