Breaking the Protocol Bottleneck:

Digital Transformation with CDISC USDM and Structured Authoring

December 2, 2025

Meet Your Presenters

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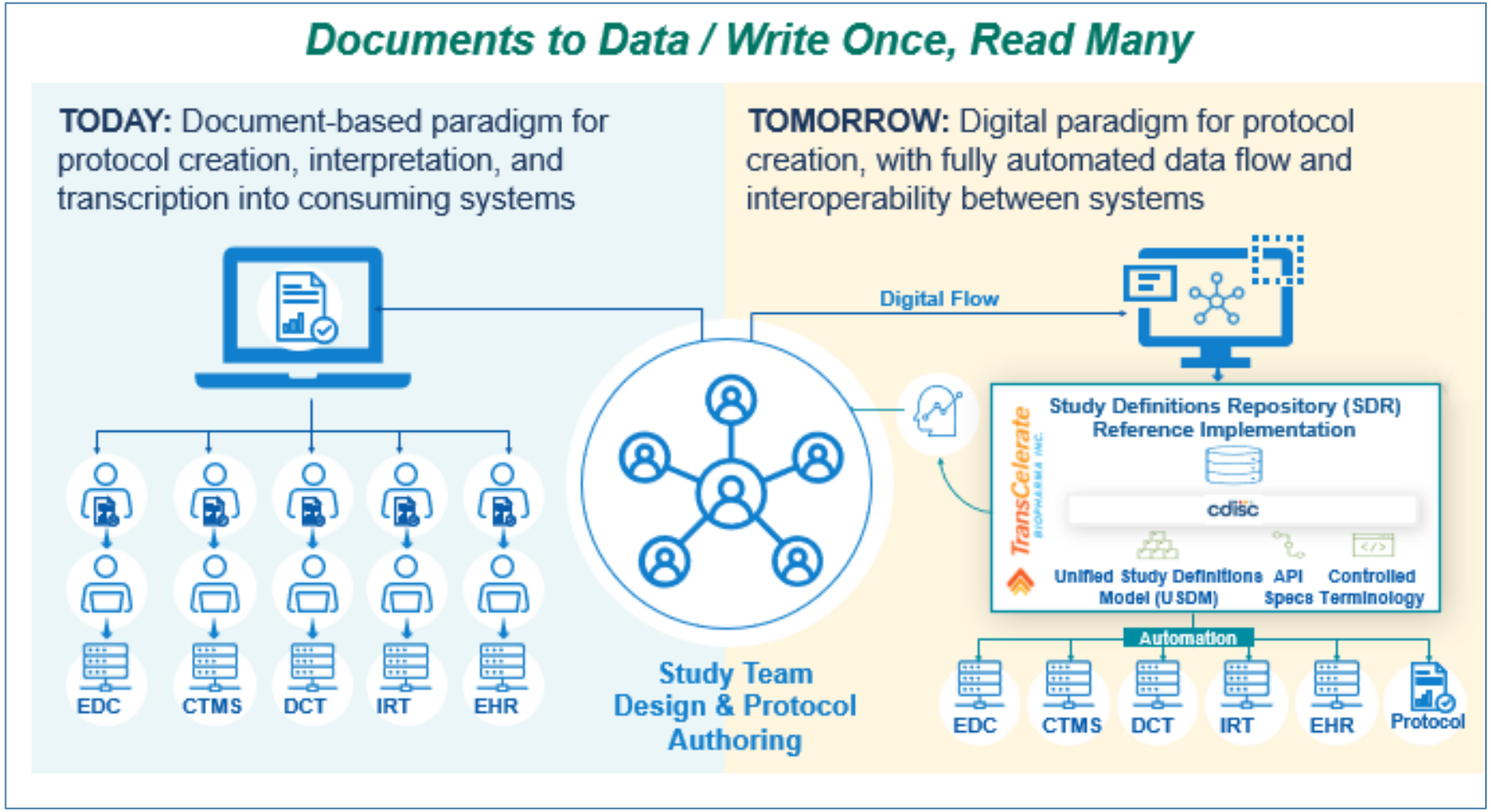
Agenda

- Introduction to OpenStudyBuilder
- Deep Dive into OSB
- Introduction to Docuvera
- Docuvera and OSB Integration
- Demonstration

Digital Data Flow Ambition

Breaking the Document Paradigm



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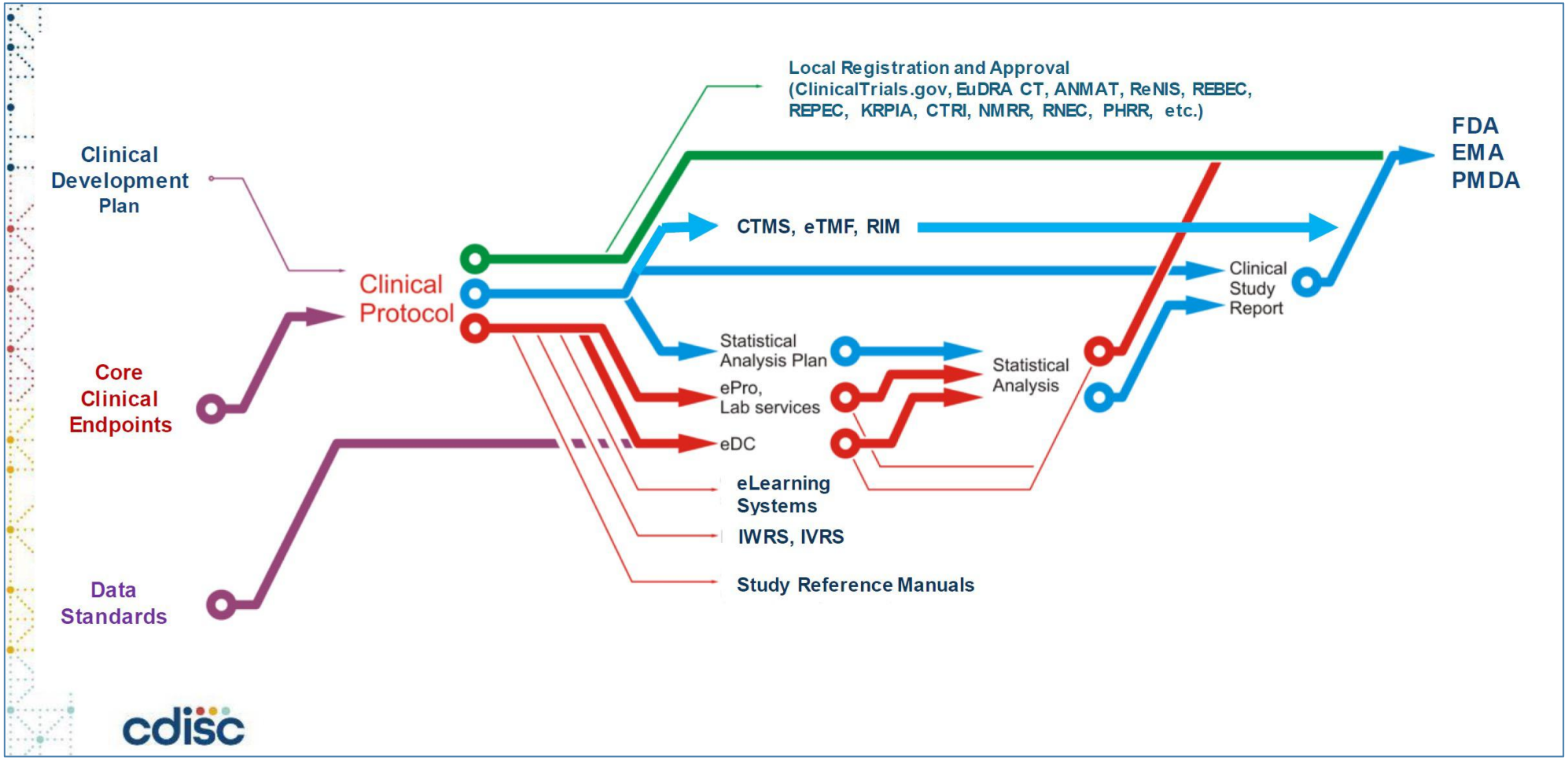
Digital Data Flow (TransCelerate & CDISC)



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What is OpenStudyBuilder?

Rethinking Clinical Development Through Digital Innovation

It's a **metadata** and
study definition repository

OpenStudyBuilder (OSB) is the open-source solution for the industry, establishing **a single, standardized source of truth for digital study design specifications,** unlocking data- and AI-driven operational and scientific excellence across clinical development.

Core Components of OSB:

- The OpenStudyBuilder application (web-based user interface)
- The clinical Metadata Repository and Study Definition Repository - MDR & SDR (central storage, graph database)
- The API layer (enabling interoperability with other systems)

#PoweredByOpenStudyBuilder

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OpenStudyBuilder Values

Enhanced **Quality** and **Compliance**

Optimized **Resource** Utilization

Reduced **Cycle Times**

AI Enablement

Improved **Automation**

Smart **Integrations**

Lower Development **Costs**

What Will OSB Actually Be Capable Of?

Specify and manage key clinical study concepts and related standards

Input

Enable systems and users to **input advanced clinical meta data on key study concepts** digitally

Standardize

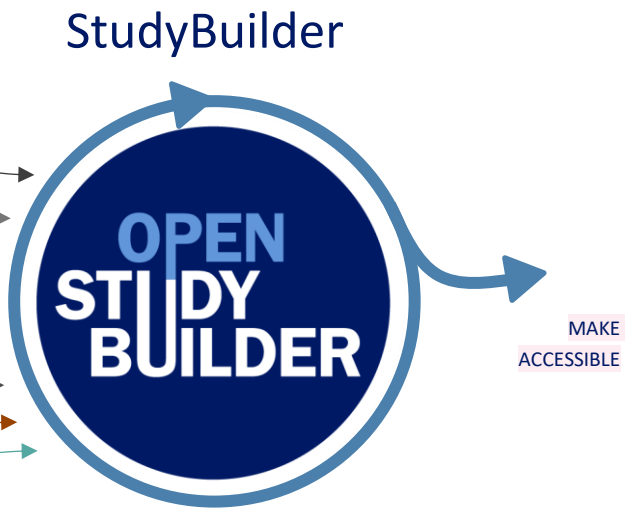
Ensure **compliance to standards**
Resolve inconsistencies
Harmonize lanugage

Make accessible

Enabling users and digital products to **parallelize, optimize** and **automate** across downstream business processes

Study concepts

- 0. Regulatory data standards requirements
- 1. Study Design Structure
- 2. Study Outcome
- 3. Study Criteria
- 4. Schedule of Activities
- 5. External Data Transfer Specifications
- 6. UI Driven Data Collection Specification
- 7. Data Quality Elements



Business processes

1. Study Planning
2. Protocol Authoring
3. Data Collection Enablement
4. Data Transformation and Sharing
5. Study Monitoring and Quality
6. SDTM Generation
7. Statistical Analysis, ADaM generation and TFL
8. Clinical Disclosure
9. Clinical Study Reporting
10. Submission

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What Is OSB Actually Capable of **Now**?

Specify and manage key clinical study concepts and related standards

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Enable systems and users to **input advanced clinical meta data on key study concepts** digitally

Standardize

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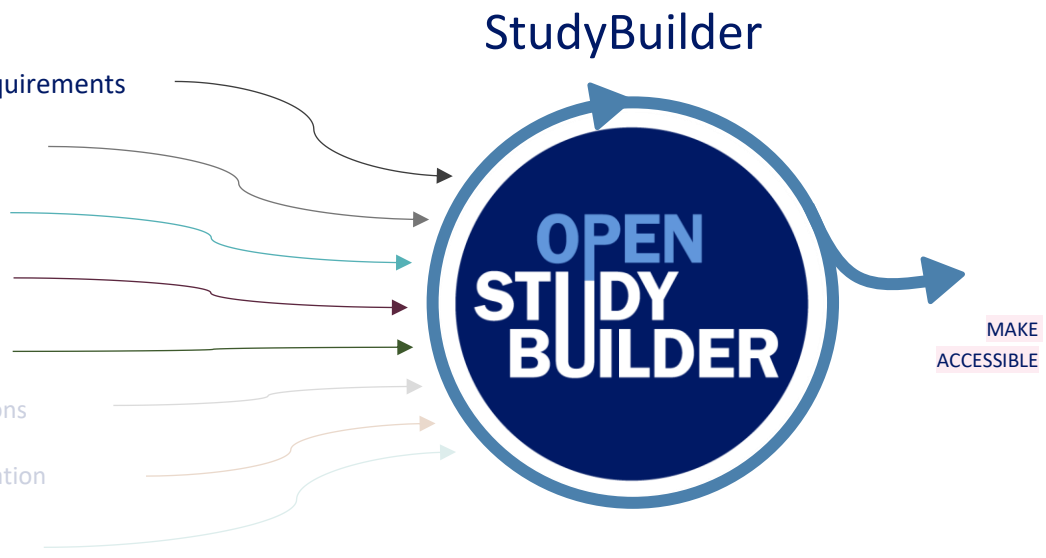

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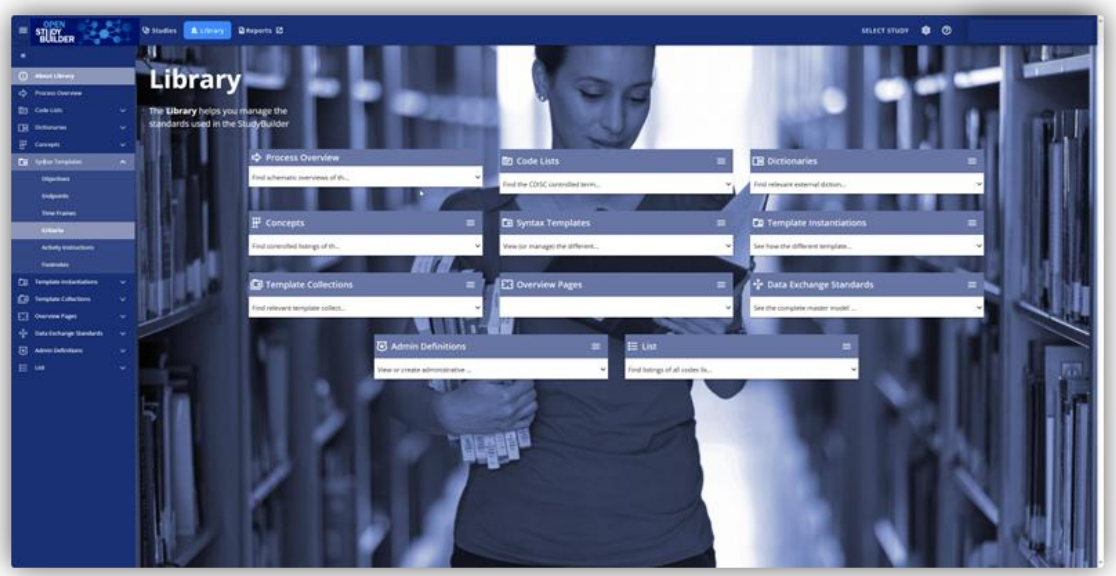
What Can You Do With OSB?

LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

REPORTS	
DASHBOARDS OF ACTIVITIES/ASSESSMENTS	STUDY COMPARE REPORT
OVERVIEW OF STUDY CRITERIA, ENDPOINTS & OBJECTIVES	



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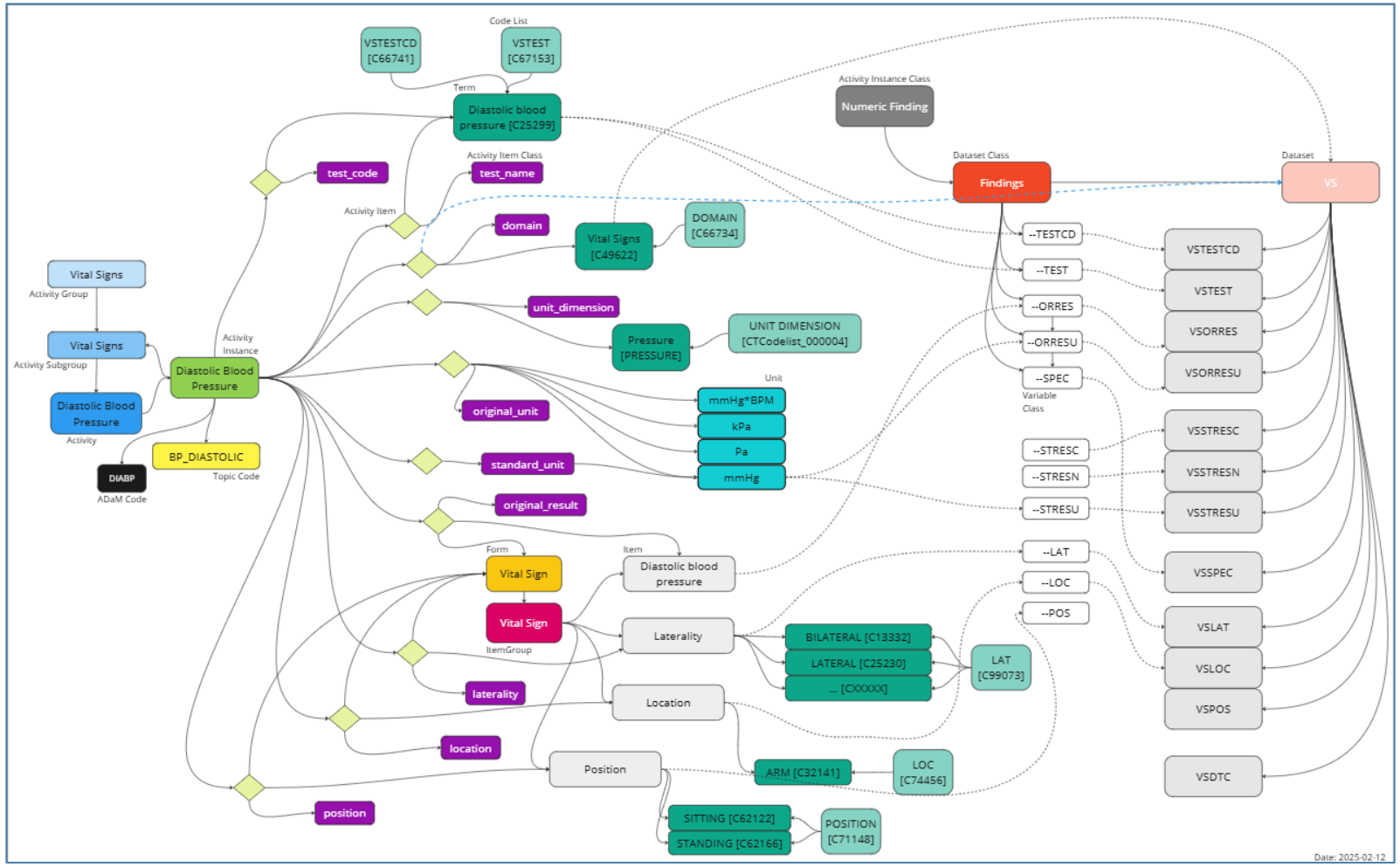
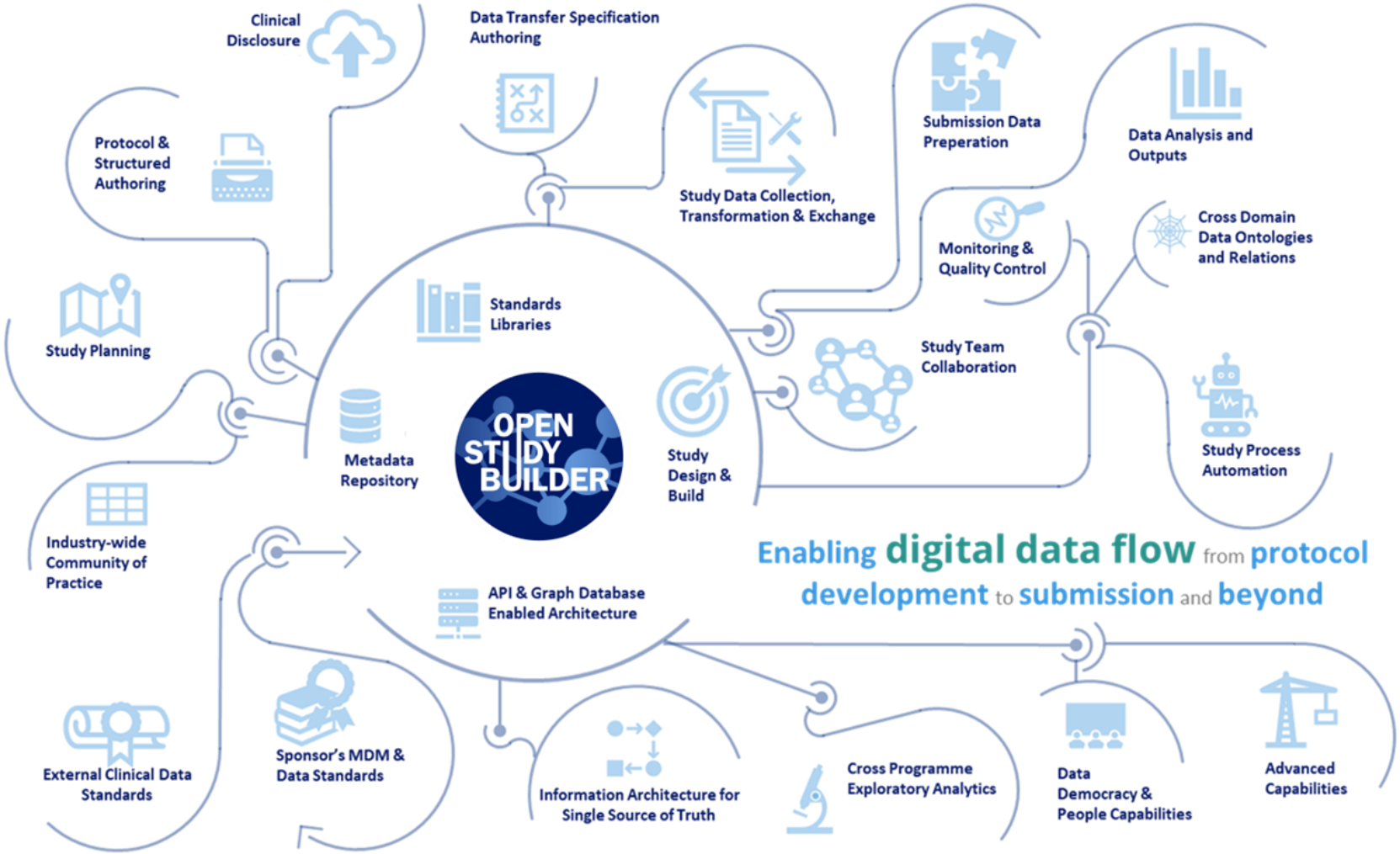
Connect To **Flow**: Define Once and Reuse

- Protocol Definition
- CRF Utilization
- EDC Specification
- SDTM Definition
- ADAM Definition



Opportunity Map



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The Market Imperative

Pharma's Digital Transformation Is Sluggish

Key Insight:
Transformation will continue to underperform until the content itself becomes structured, governed, and reusable.

- 70% of life sciences executives cite digital transformation as a top priority, but less than one-third report meaningful ROI (McKinsey, 2023).
- Fragmented systems, manual authoring, and static PDFs remain the biggest barriers to speed and compliance (Deloitte, 2024).
- Global regulators — EMA, FDA, Health Canada, PMDA — are progressing toward data-centric submissions (e.g., eCTD v4.0), alongside initiatives like ePI (FHIR), IDMP, ICH M11, and PQ-CMC.

The Docuvera Solution

Scalable, Structured Authoring Platform

Governance-first, **metadata-driven** content aligned with global frameworks.

AI Co-Writer with Safeguards

Keeps **humans in-the-loop ,** accelerates authoring workflows and compliance.

Digital Outputs

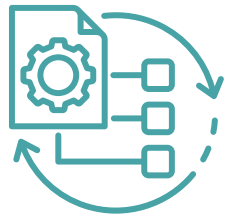
Produces **compliant exports** across **eCTD**, **FHIR**-based **ePI, ICH M11 protocols, PQ-CMC** plus Word, PDF, and **XML**.

Lifecycle Connectivity

Integrates with RIM, Study Builder, Translation Services, LIMS, Safety, and Artwork systems.

What Docuvera Does

Docuvera replaces fragmented document systems with **structured, governed, and reusable content**:



Created once.
Approved once. Reused everywhere.

Interoperable by design: aligned to standards such as eCTD 4.0, IDMP, FHIR-based ePI, ICH M11, PQ-CMC

Governed at creation:
compliance is built-in, not bolted on.

AI-enabled:
structured content provides the substrate for safe, compliant automation.

It’s Not About One Submission. It’s About **Every Update**.

One governed source of truth

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About This Solution

Solving the legacy issue of maintaining compliance and long cycle times for protocol approval and study start in clinical trials

What you will see today:

- An integrated digital workflow integrating Open Study Builder (OSB) with Docuvera
  - Generate ICH M11compliant protocols in Docuvera from CDISC USDM enabled study designer (OSB)
  - Enables Digital Data Flow framework for real-time integration and synchronization between the two systems
  - Use component-based authoring workflows to manage Protocol lifecycle and amendments
  - Digital protocol generation, FHIR-based XML export with relevant Controlled Vocabularies, Codes

Potential for Up to

40%

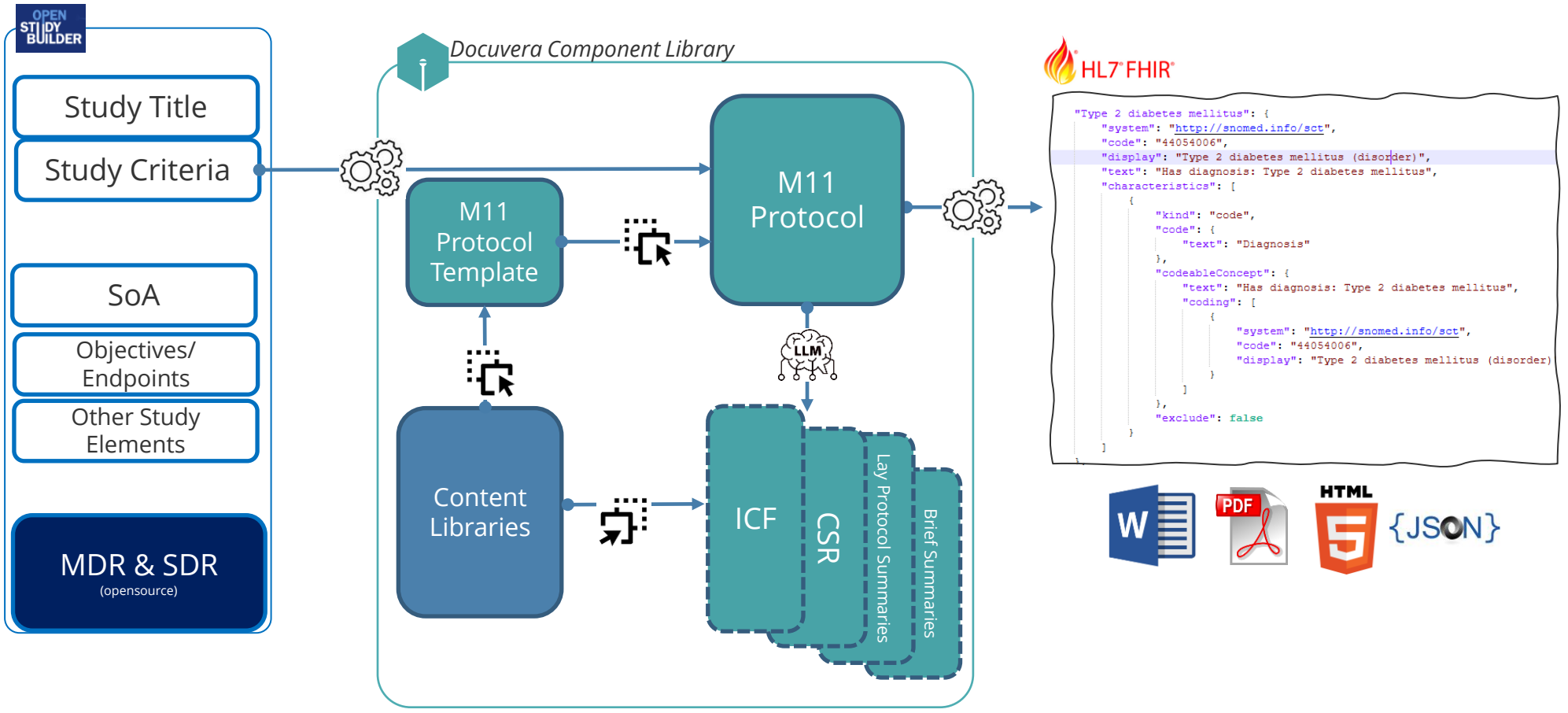
Resource reduction in clinical study startup

Potential for Up to

20%

acceleration
in trial execution timelines

OSB – Docuvera Digital Data Flow



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Demonstration

OpenStudyBuilder Links

Getting Started

Check out these resources!

- Project website: https://openstudybuilder.com
- Newsletter: LinkedIn
- Demonstration Videos: Overview (2025), Details (2023)
- Demonstration Flow: Homepage
- Repository: GitHub
- Slack: Join
- Email: openstudybuilder@gmail.com
- Request sandbox access: Sandbox
- Status Page: Status

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Thank You!