Docuvera™
a cormeo brand

From Study Design to ICH M11 Protocol

Seamless Digital Transformation through CDISC USDM and Structured Component Authoring Integration

October - 2025

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:

- End-to-end digital workflow integrating Open Study Builder (OSB) with Docuvera
  - Automatically generated ICH M11-compliant protocols from CDISC USDM-structured study design
  - Utilized the TransCelerate Digital Data Flow technical frameworks for real-time integration between study design tools and protocol authoring systems
  - Supported component-based authoring with automated FHIR export capabilities (enabling data-driven workflows)
  - Generate the ICF from the Protocol (and other document types) using Docuvera GenAI

Potential for Up to

40%

Resource reduction in clinical study startup

Potential for Up to

20%

acceleration in trial execution timelines

From Strategy to Execution

Inconsult Portfolio

- Life science is our strategic growth and investment area
- Strong commitment to invest in patients, customers and partners
- Experiences and ready-to-go team with hands-on attitude and quality awareness
- Customer centricity
- Reliable and agile
- Deep domain knowledge in regulated industries

Healthcare is Changing - Again

Challenges & Opportunities

Exponential impacts of AI

Rapid acceleration in what we know about human biology

Continued push to cut drug prices

Empowered consumers

Crisis as a way of life

Standardization

Improves Patient Safety

Delivers Better Patient Outcomes

Enhances Efficiency

Provides Interoperable Data

Improves Cost Control

Increases Patient Confidence

Transcelerate's Program: Harmonize Process

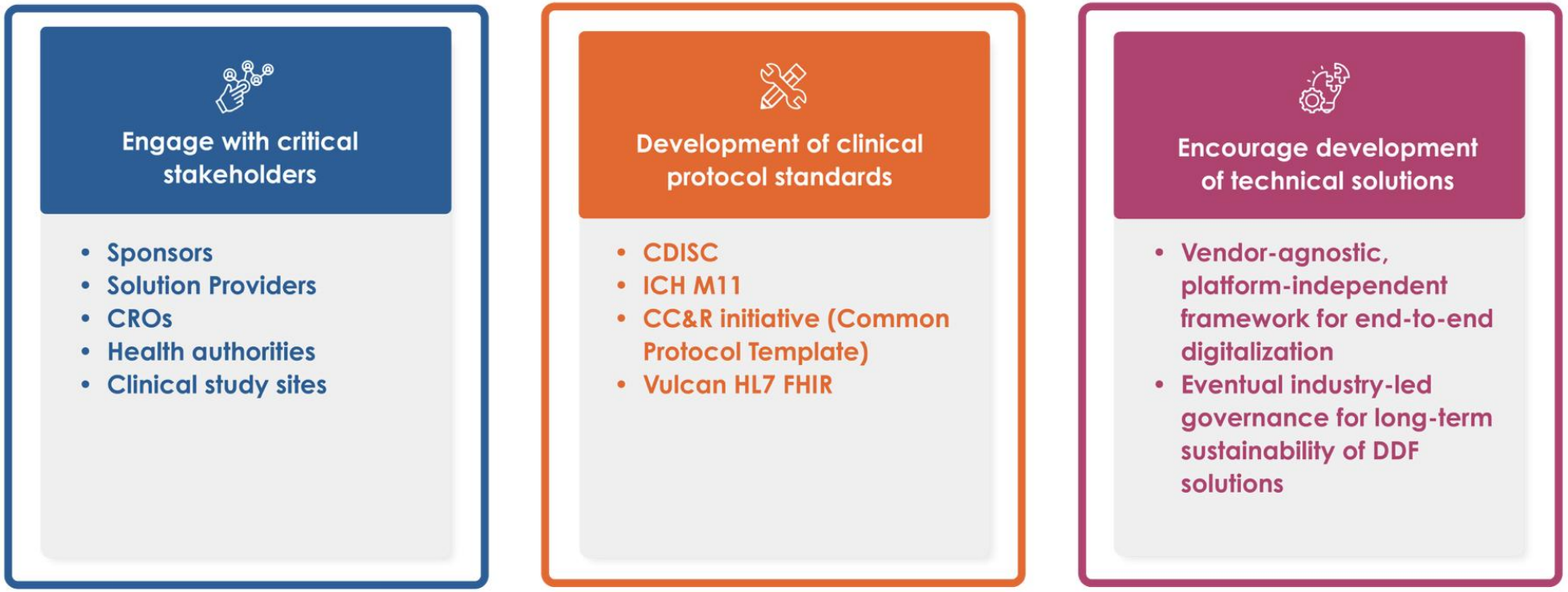
Goal: The Digital Clinical Protocol

"TransCelerate is a non-profit catalyst for change in clinical research. We unite diverse voices across biopharmaceutical R&D to drive innovation, simplify clinical trials and help bring new treatments to patients faster, safer and more efficiently" *copied from the Transcelerate website*

Transcelerate's Digital Dataflow (DDF) is an industry wide initiative to agree on standards to enhance efficiency and quality in clinical trials

Transcelerate/DDF Key Principles

Enabling Clinical Trial Protocol Digitalization



Source: Transcelerate website

DDF Gets Traction in the Industry

The Open Study Builder

Encourage development of technical solutions

- Vendor-agnostic, platform-independent framework for end-to-end digitalization
- Eventual industry-led governance for long-term sustainability of DDF solutions

Novo Nordisk took a lead in developing a meta data repository to control the clinical solution landscape

… and made it open source

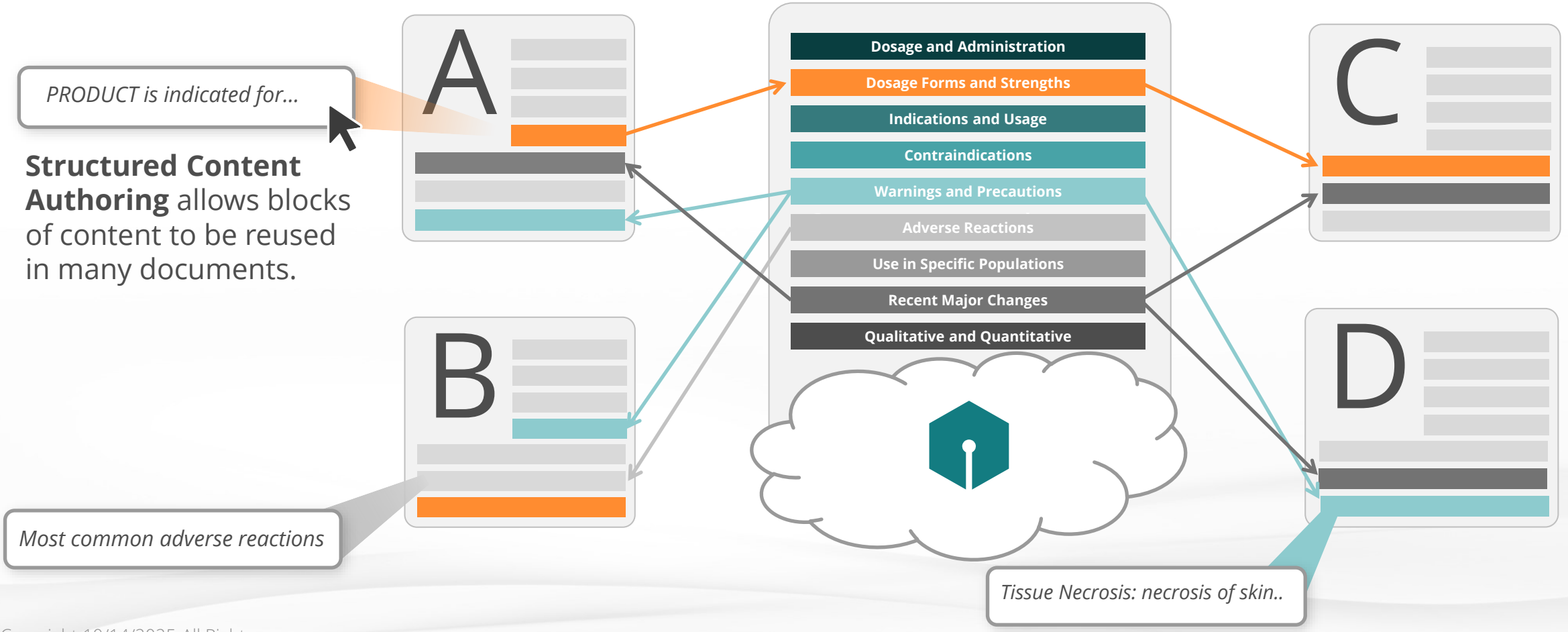
How will other key technology vendors react?

A Central Hub for Digital Data Flow

Open Study Builder

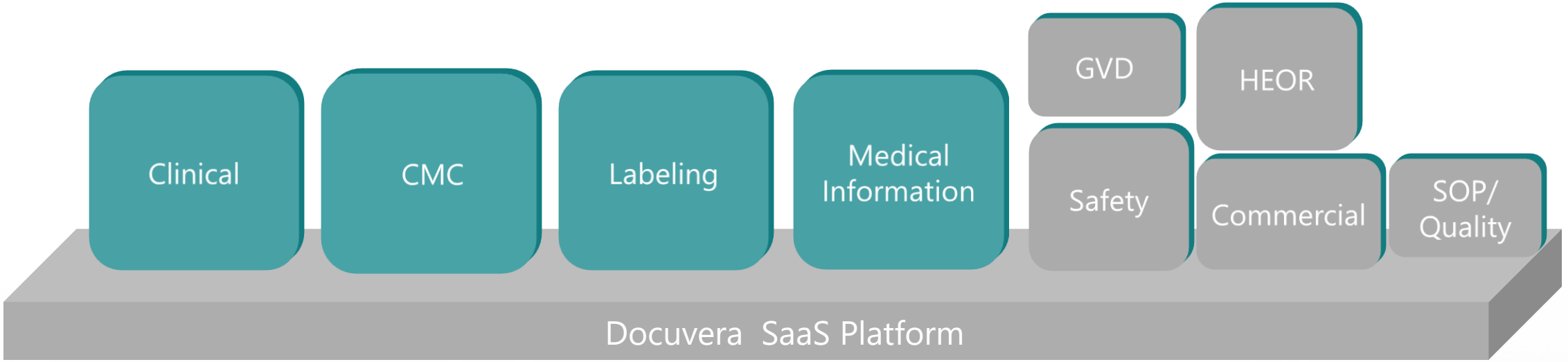
Structured Content Authoring

Lower Costs • Increased Compliance • Reduced Time-to-Market



Docuvera™

The Docuvera Platform



Horizontal Application Delivering Content Management Efficiencies through Core Content Reuse across the Drug Development Lifecycle

Start with a Single Use Case. Gain Early Wins and Expand!

Our Differentiation

- Template Authoring
- Review & Approval
- Localization
- Versioning & Archiving
- Omni-channel Publishing
- Task Notifications
- RESTful Services
- Search
- Auditing & Reporting
- Content Migration
- 21 CFR Part11 Compliant
- Permissions

Single Integrated Solution

Intuitive interface drives high level of user adoption.

Integrated platform and governance layer lower compliance risk and accelerate time to submission.

Intuitive User Experience

Lilly

*"Docuvera is **completely intuitive**"*

Boehringer Ingelheim

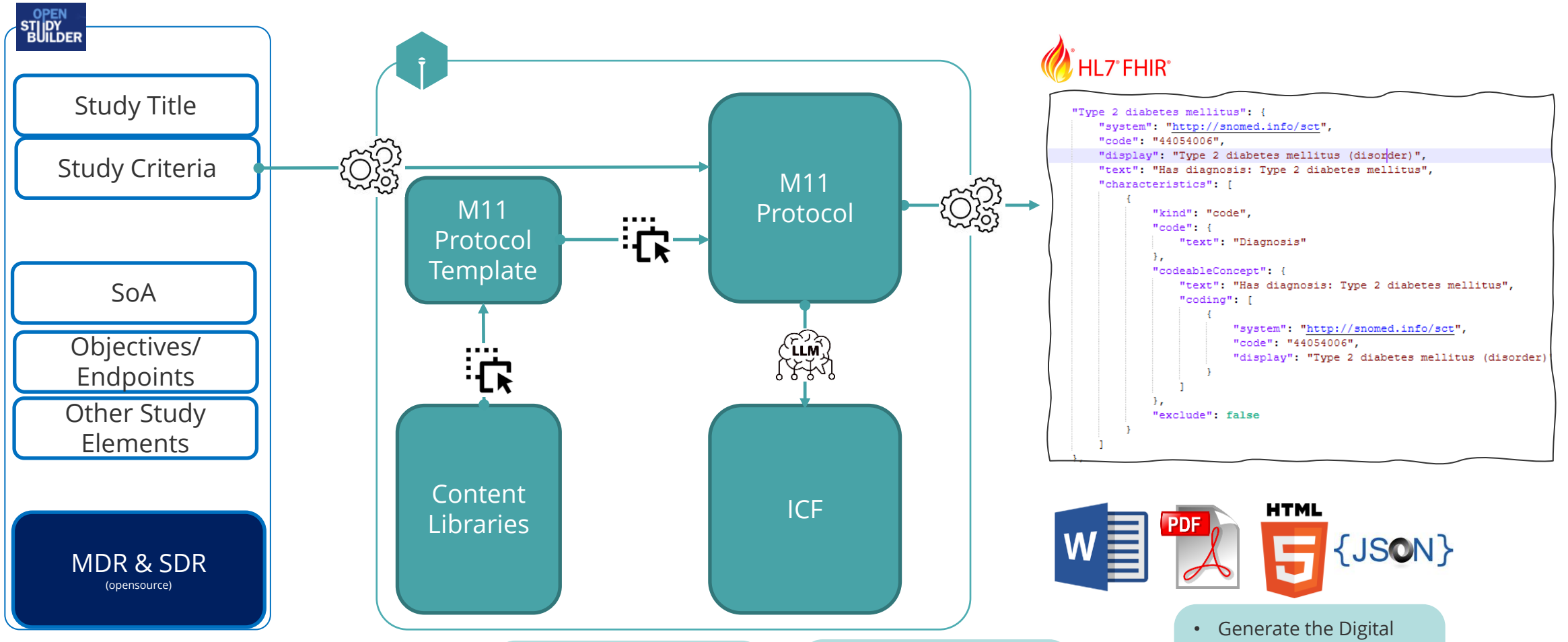
*"Docuvera is unique in delivering a superior user experience. We look forward to expanding its use across the company to **drive efficiencies** within and across functional areas."*

AstraZeneca

*"We selected Docuvera because of the success that they have had with our peers, their **experience in medical/labeling/clinical** and the intuitive interface."*

Docuvera™ a cormeo brand

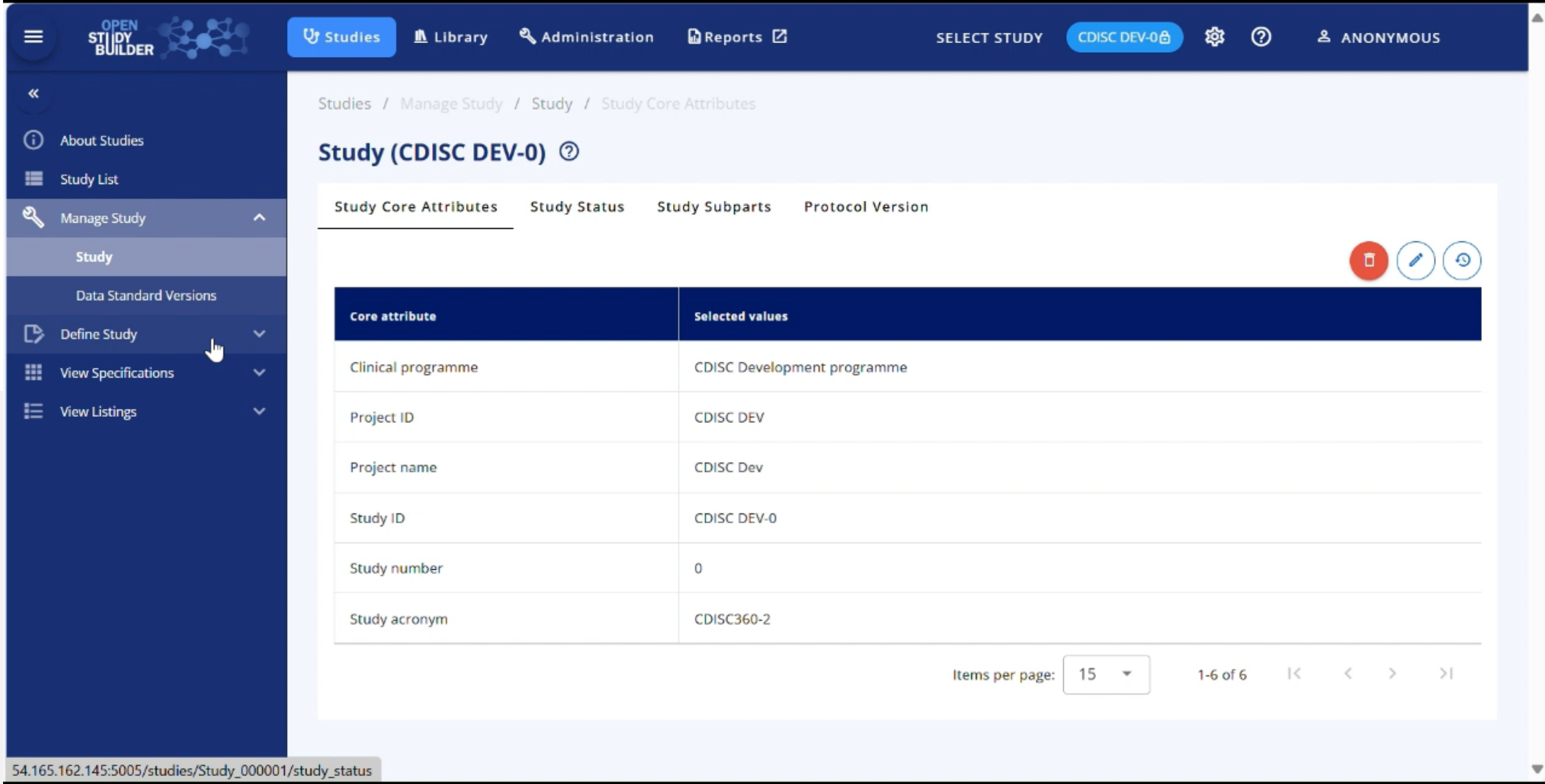
OSB – Docuvera Digital Data Flow



- Review Study Title & Inclusion Criteria ❶
- Review the M11 Protocol structure in Docuvera ❷
- Synch study data using the OSB connector
- Observe study criteria component and metadata ❸
- Modify study criteria & re-synch
- Observe study criteria component and metadata ❹
- Generate the Digital FHIR protocol ❺

Docuvera™ a cormeo brand

Demonstration


OPEN STUDY BUILDER
Studies
Library
Administration
Reports
SELECT STUDY
CDISC DEV-0
ANONYMOUS
About Studies
Study List
Manage Study
Study
Data Standard Versions
Define Study
View Specifications
View Listings
Studies / Manage Study / Study / Study Core Attributes
Study (CDISC DEV-0)
Study Core Attributes
Study Status
Study Subparts
Protocol Version
Core attribute
Selected values
Clinical programme
CDISC Development programme
Project ID
CDISC DEV
Project name
CDISC Dev
Study ID
CDISC DEV-0
Study number
0
Study acronym
CDISC360-2
Items per page:
15
1-6 of 6
54.165.162.145:5005/studies/Study_000001/study_status

Thank you

Murali Menon | murali.menon@docuvera.com

Guido Radack | gra@inconsult-online.de

Docuvera™
a cormeo brand