

cdisc®

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

CDISC US INTERCHANGE · DENVER · 2026

From Protocol to CSR: Reimagining Clinical Trials with AI and Next-Gen CDISC Models

DENVER, COLORADO | MAIN CONFERENCE: 5-6 OCT | TRAININGS & WORKSHOPS: 7-9 OCT

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Session 7, Track B

Speaker



Bhavin Busa

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Bhavin Busa is the Principal & Co-founder of Clymb Clinical. He is recognized as a thought leader in the areas of data standards, programming, and regulatory submission. He serves on the CDISC Open-Source Alliance (COSA) Board. Additionally, Bhavin serves as a CDISC ARS Product Owner/Co-lead and an active contributor to the CDISC & PHUSE Community.

THE INFLECTION POINT

Clinical trials are at an inflection point.

Static standards must evolve into intelligent, executable frameworks.

THE FOUNDATION: EMERGING CDISC STANDARDS

USDM	Biomedical Concepts	AC / DC	ARS
Study definition	Data semantics	Analysis intent	Analysis results

THE STARTING OBSERVATION

Today's clinical data workflow is still fragmented



Each handoff: interpreted, copied, and recreated by hand

Silos

Documents, systems, standards, and AI each operate on their own.

Re-interpretation

The same intent is re-read at every step, from protocol to SAP to code to CSR.

Traceability after the fact

Links from intent to results are reconstructed after the fact.

THE FOUNDATION

Next-gen CDISC standards make study intent computable

USDM

Unified Study Definitions Model

A machine-readable model of the protocol: study design, objectives and endpoints, arms, epochs, and schedule of activities.

UNLOCKS

Computable study definitions

BCs

Biomedical Concepts

Reusable, standardized definitions of what is measured and how it is collected and analyzed.

UNLOCKS

Consistent data from collection to analysis

AC / DC

Analysis and Derivation Concepts

Formalize analysis intent: what is being analyzed (AC) and how it is derived (DC).

UNLOCKS

A structured, reusable SAP

ARS / ARD

Analysis Results Standard

Describes analyses, displays, and results as metadata, with results held as analysis results data (ARD).

UNLOCKS

Traceable outputs generated from metadata

THE BACKBONE FOR AGENTIC AI

One metadata spine, protocol to CSR

	1 Study definition	2 Data and datasets	3 Analysis intent	4 Analysis results	5 Reporting
WHAT STANDARDS DEFINE	**USDM + Biomedical Concepts**	**CDASH · SDTM · ADaM**	**Analysis + Derivation Concepts (AC/DC)**	**ARS + ARD**	**ARD + CSR templates**
WHAT AI AUTOMATES	Protocol optimization and computable study design	AI-assisted SDTM and ADaM mapping and code	Structured SAP and derivation logic	TFL, ARD, and program generation; real-time insights	In-text values and narrative drafting from ARD

Standards carry the intent. **Automation and AI carry it forward.**

WHAT 'AGENTIC' MEANS HERE

AI that works on structure, not guesswork



Machine-readable context

Agents draw on USDM, Biomedical Concepts, AC/DC, and ARS metadata rather than parsing documents.



Standards constrain, AI accelerates

Models and controlled terminology define what is valid. AI drafts specifications, code, and narrative within them.



Humans stay in control

Outputs are reviewed, versioned, and traceable inside a validated environment.

The metadata defines the intent.

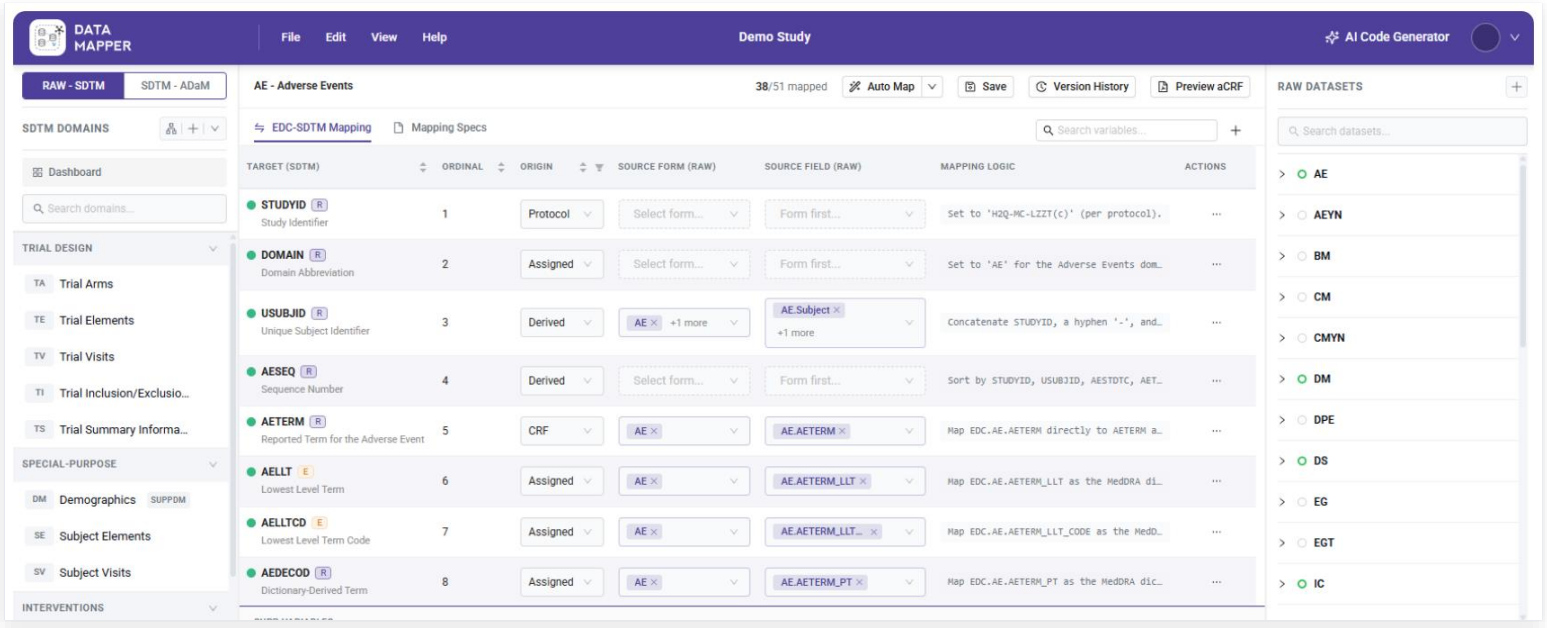
AI accelerates the implementation.

REAL-WORLD IMPLEMENTATIONS

DATA MAPPING (USDM · CDASH · SDTM · ADaM · AI)

Standards-driven SDTM and ADaM specifications

Raw and EDC metadata, standards, and controlled terminology drive the mapping. AI assists; the standards layer stays controlled.



50–60%

reduction in manual SDTM / ADaM mapping time

INPUTS

- Raw / EDC metadata
- SDTM + ADaM standards
- Controlled terminology

OUTPUTS

- SDTM / ADaM specs
- Define metadata
- aCRF information
- SAS / R code

SAP DEVELOPMENT (USDM · AC · AI)

From narrative SAP to structured metadata

TODAY

Narrative SAP

Written as a Word or PDF document for a human reviewer: rich, detailed, and hard to use downstream.

- Definitions live in paragraphs
- Each downstream consumer interprets it again
- Cannot be ingested by automation or AI

IN THE FRAMEWORK

Structured SAP

The same content as machine-readable specifications: endpoints, populations, parameters, timepoints, methods, and displays.

- AC defines what is being analyzed
- DC defines how it is derived
- Reusable across studies; usable by automation and AI

The narrative SAP does not go away. **It is paired with a structured twin that downstream systems can read.**

Prospective ARS: metadata is born with the shell

INPUT

Structured SAP metadata

Endpoints, populations, parameters, methods, and display requirements as ARS-aligned definitions.

ENGINE

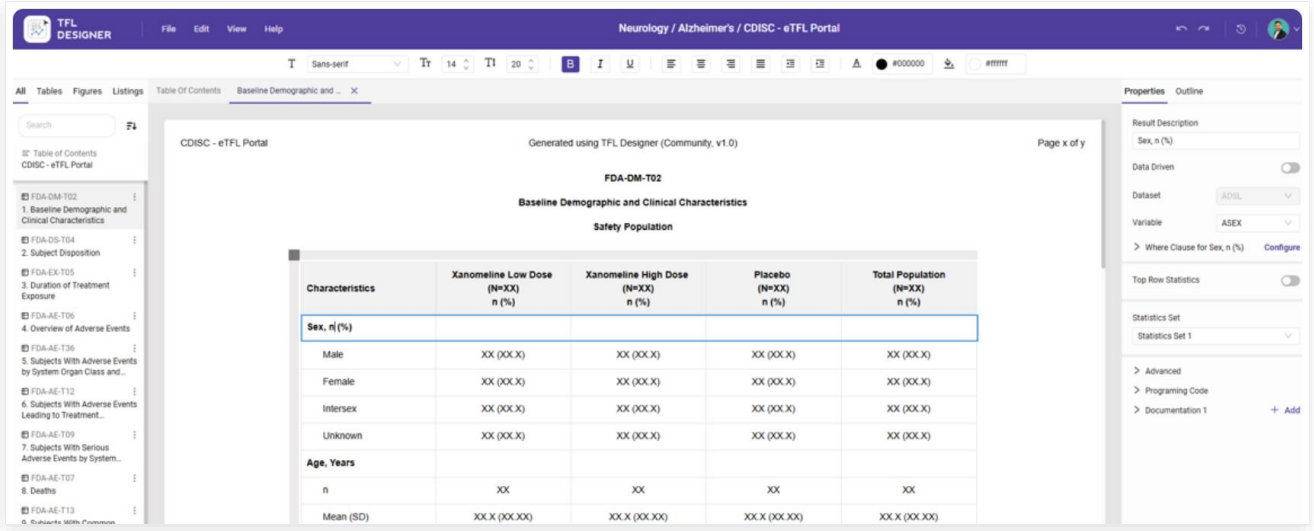
Template-driven generator

Templates carry layout, titles, footnotes, and formatting. Metadata supplies the analysis content.

OUTPUT

TFL shell + ARS metadata

Emitted together, so the metadata is never retrofitted.



A human-readable shell with machine-readable ARS and display metadata underneath.

No retrospective mapping. Outputs align with standardized metadata from the moment they exist.

METADATA-DRIVEN PROGRAMMING (SAS & R FRAMEWORKS)

From analysis intent to executable code



R-BASED FRAMEWORK

siera (open source)

Analysis-ready functions for population-level summaries, descriptive statistics, and standard ADaM-driven outputs. Composable, testable, and metadata-aware.

SAS-BASED FRAMEWORK

atlas

The SAS counterpart: same primitives, same metadata bindings, same outputs. Programmers in either ecosystem produce comparable artifacts.

AI CODE GENERATOR

SDTM, ADaM, ARD, and TFL programs

A layer of automation on top of the metadata-driven frameworks. Models read the same structured inputs and produce executable programs aligned with predefined standards.

Standards do the work. The model does the typing.

1

Translate specs into code

SDTM and ADaM mapping specifications and ARS metadata become SAS or R code.

2

Generate derivation logic

DC definitions become the derivation steps for ADaM generation.

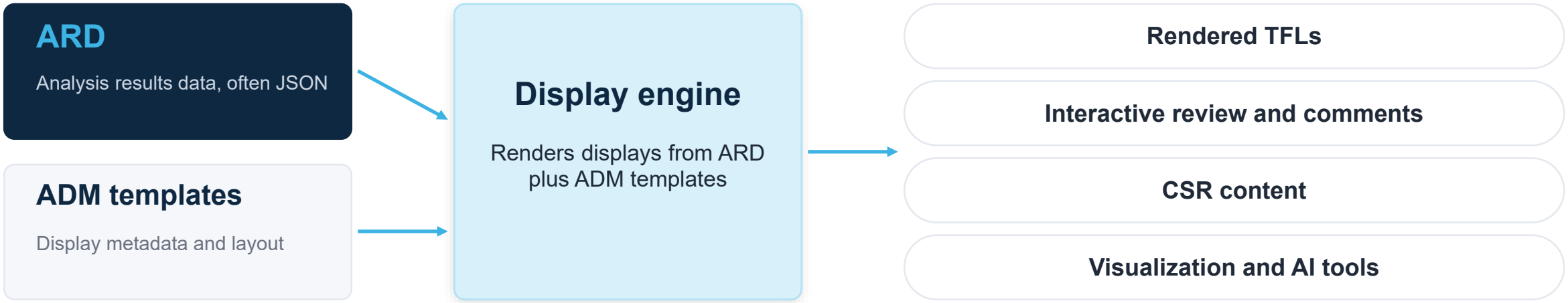
3

Construct display programs

ADM specifications drive the rendering programs for TFLs and ARD.

ARD AND AI

Results become data, not static files



WHY ARD CHANGES EVERYTHING

Traceability

Direct linkage between results and metadata

Reproducibility

Consistent representation across runs

Reusability

One ARD for review, reporting, and the CSR

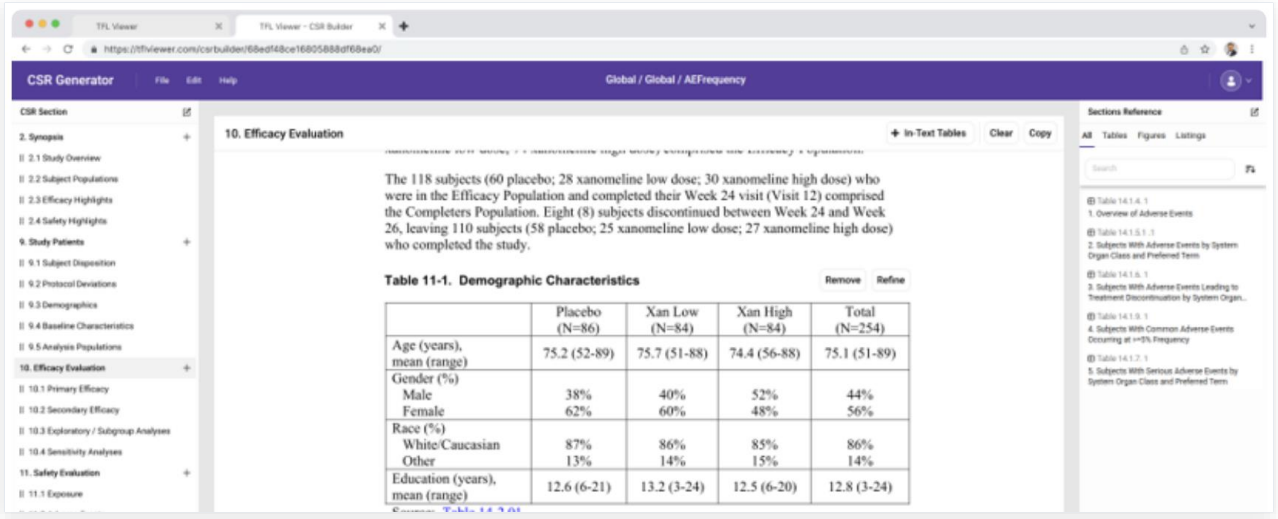
Interoperability

Compatible with downstream and AI tools

Changes to data or metadata appear immediately; static RTF or PDF files no longer need regenerating.

CSR DEVELOPMENT

From ARD to CSR



Approved results feed in-text tables and AI-assisted narrative.

In-text values

Statistics quoted in the narrative pull directly from ARD, so body text and tables cannot drift apart.

Post-text outputs

TFLs are referenced, not copy-pasted. Updates propagate from the specification layer.

AI-generated narrative

Section structures and standard prose blocks are metadata-aware, giving cross-study consistency.

No manual transcription. The narrative and the numbers stay aligned because they share a source.

GOVERNED BY DESIGN

Automation inside the regulated process

Validated environment

One Statistical Computing Environment for SAS and R execution, code, and output management.

Version control

Specifications, programs, and results are versioned with full execution history.

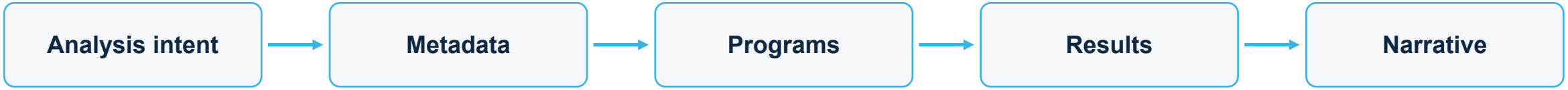
Access and review

Role-based access, review workflows, and e-signatures aligned with Part 11 and Annex 11.

Audit trail

A property of the system, not a deliverable produced after the fact.

TRACEABLE END TO END



MEASURED IMPACT

Numbers from real programs

50–60%

Reduction in manual SDTM / ADaM mapping time

80%

Less SAP authoring effort with SAP Builder

85%

Faster TFL shell creation, review, and approval

60%

Reduction in output programming and QC

70%

Less TFL review and approval time in TFL Viewer

40–50%

Cost savings on a medium-complexity Phase II study

Based on Clymb Clinical program experience.

WHERE THIS IS GOING · CDISC 360i

Toward a computable path from study design to submission

Computable study design

USDM and Biomedical Concepts define the study once; downstream specifications follow from it.

Analysis intent as metadata

AC/DC and ARS carry endpoints, populations, and methods into shells, code, and results.

Insight in real time

Results held as ARD stay live, supporting protocol optimization and real-time insight.

CDISC 360i: standards-driven automation across the lifecycle, from study design through analysis to submission.

KEY TAKEAWAYS

1

Standards are becoming executable.

USDM, Biomedical Concepts, AC/DC, and ARS turn documents into machine-readable intent.

2

Agentic AI needs that structure.

Metadata gives models the context and constraints to automate SDTM, ADaM, TFL, and CSR work.

3

Connected pipelines change the work.

Generating code and results from metadata reduces effort, improves quality, and preserves traceability.

Thank you.

Questions, conversation, and follow-up are welcome.

Bhavin Busa· Principal & Co-Founder, Clymb Clinical

