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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Evinova's USDM-Driven Approach to Protocol Standardization and Study Design Optimization

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Speakers

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Our Evinova Study Designer mission is to…

Create a trusted agentic studio that accelerates trial design, authoring, and downstream system configuration to one week.

Our AI-native platform is the accelerant. ***USDM is the interoperability backbone that enables the transformation.***

Enabling ClinDev and ClinOps experts to accelerate drug development collaboratively requires standards

Initial Evinova Implementation

Idea — **Drug Development Lifecycle** — Submission

Context Infusion ····▶ **Intelligent Study Planning** ····▶ **Seamless Study Execution**

Historic CSP **Digitization**

Collaborative design iteration between ClinDev & ClinOps

Design

Cost

Feasibility

Authoring

Automated downstream customer system configuration

Unified Trials for execution

Evinova Pipeline Management for monitoring

An underlying USDM Data Plane serves as the source of truth for a study throughout the lifecycle – enabling a connected experience

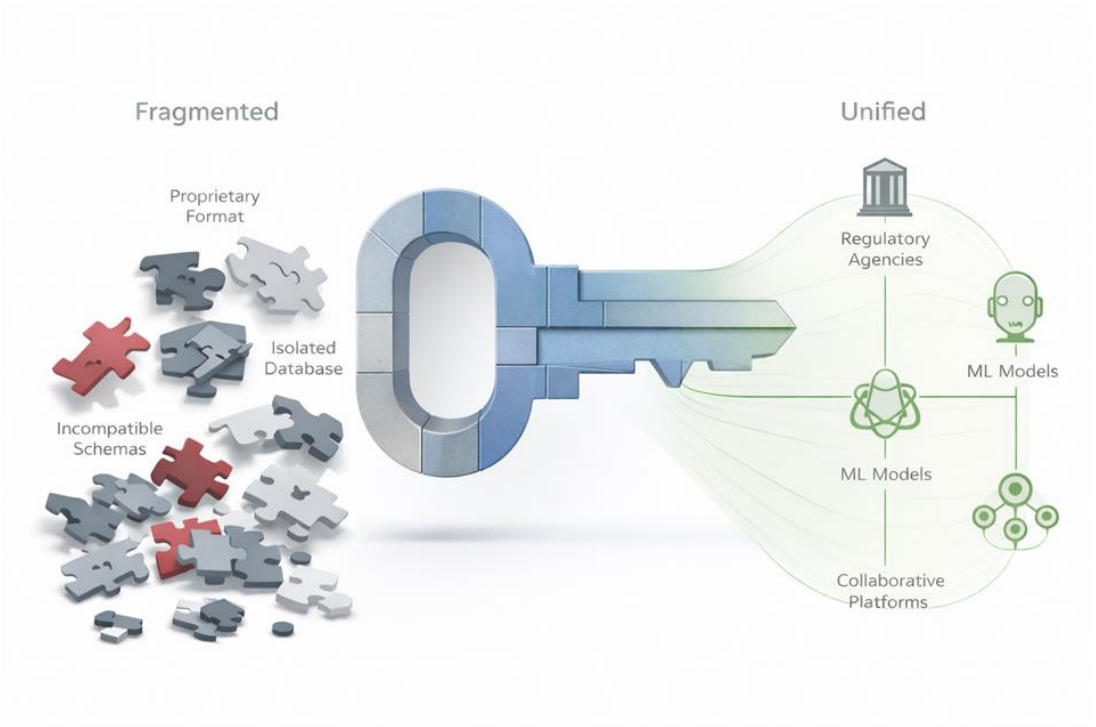
Digitization for context infusion is just the start; we are constantly digitizing user inputs across modules as user interact in parallel

It all started with protocol digitization…

- Clinical expertise was trapped in unstructured PDFs- inaccessible for systematic analysis or reuse
- Manual data extraction was prone to inconsistencies and infeasible for large volume of CSPs
- Without standardization, there was no cross-study analysis or institutional knowledge preservation
- **Decades of trial expertise was lost with no structured way to capture and transfer**

USDM was the natural choice.

- Vendor-neutral format prevents lock-in to proprietary systems
- Comprehensive coverage of all clinical trial elements
- Reusable library of standardized terms
- Enabler of downstream applications like cost estimation, EDC auto build, etc.



A team of AI agents parses PDF protocols into USDM

Document ingestion and section detection (synopses, objectives/endpoints, schedule of activities

AI extraction of entities and relationships using pattern + model prompts, constrained to USDM fields

Normalization via Evinova Grounding service: terminology alignment (e.g., CDISC USDM CVs), deduplication, and validation against USDM constraints

Review UI for SMEs to accept/modify; publication to the USDM registry

Goal: Transform unstructured protocol PDFs into USDM JSON with human-in-the-loop quality control

Safeguards:
Constrained schemas, validation rules, provenance tags, and audit logs

Integration:
Open-source components for parsing and validation; export as USDM JSON for downstream tools

Our published findings in Nature.com

In our **Nature.com** publication, we provided evidence that the implementation of digital health technology in clinical trials improves patient experience with accelerated timelines and reduced costs:

60%
improvement in patient experience

40%
of on-site visits could be eliminated(1)

15-30%
acceleration in timelines(2)

43%
reduction in cost(3)

Improved health outcomes

We have also shown that digital health technology can reduce carbon emissions by **20-45%**

https://www.nature.com/articles/s41591-023-02489-z

1. Assessment of 91 protocols across 50% of indications of total market, when utilising clinical validated devices.
2. Acceleration of 6 months in CRESCENDO Study
3. Cost reduction in DAPA-MI Study

nature medicine

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Comment | Published: 16 August 2023

Implementation of digital health technology in clinical trials: the 6R framework

Cristina Ortega Durán, Matthew Bonam, Elisabeth Björk, Rod Hughes, Serban Ghiorghiu, Cristian Massacesi, Alicyn Campbell, Emmette Hutchison, Menelas N. Pangalos & Susan Galbraith

Nature Medicine **29**, 2693–2697 (2023) | Cite this article

4613 Accesses | **114** Altmetric | Metrics

AstraZeneca has introduced digital health solutions into clinical trials, demonstrating improved patient experience, accelerated timelines and reduced costs.

Clinical trials usually follow a site-based model that is centered around in-person patient visits for recruitment, interventions, assessments and follow-up[1]. Although patients benefit from in-person contact, reliance on clinical visits can represent a large burden for many patients, who must navigate challenges due to the time, logistics and cost of attendance[2]. The use of digital technology has been proposed to address some of the potential inefficiencies associated with the site-based clinical trial model, with the broad aim of optimizing the experience of participants in clinical trials[3].

The Result: USDM driven efficiency

enabling faster study design build times

Study Designer

- Design
- Costing
- Benchmarks
- Feasibility
- Document Authoring AI

Design studies with the power of data and AI, to accelerate **productivity and study outcomes.**

- Fewer design iterations through explicit, shared semantics
- Reduced handoffs and rework via a single source of truth
- Earlier feasibility and burden checks to streamline decisions
- Instant querying of existing protocols to inform decisions and enable downstream automation

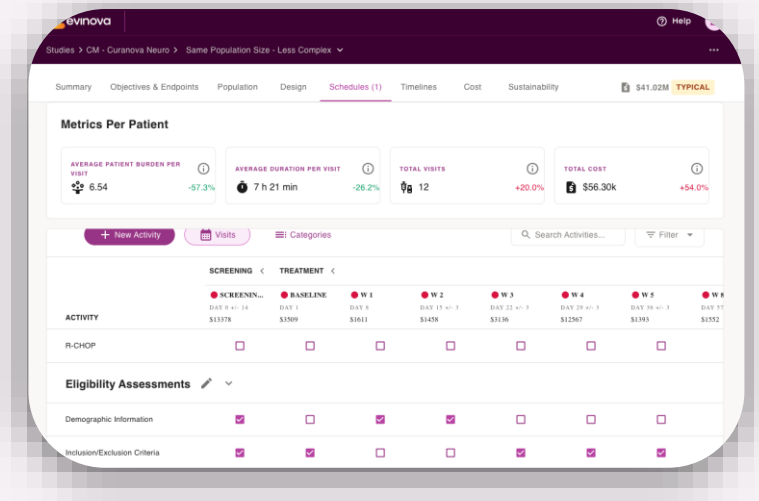
Delivered benefits for large pharma

>$100M in first year and **$354M** by year 4

30% improvement patient experience

14% improvement carbon emissions

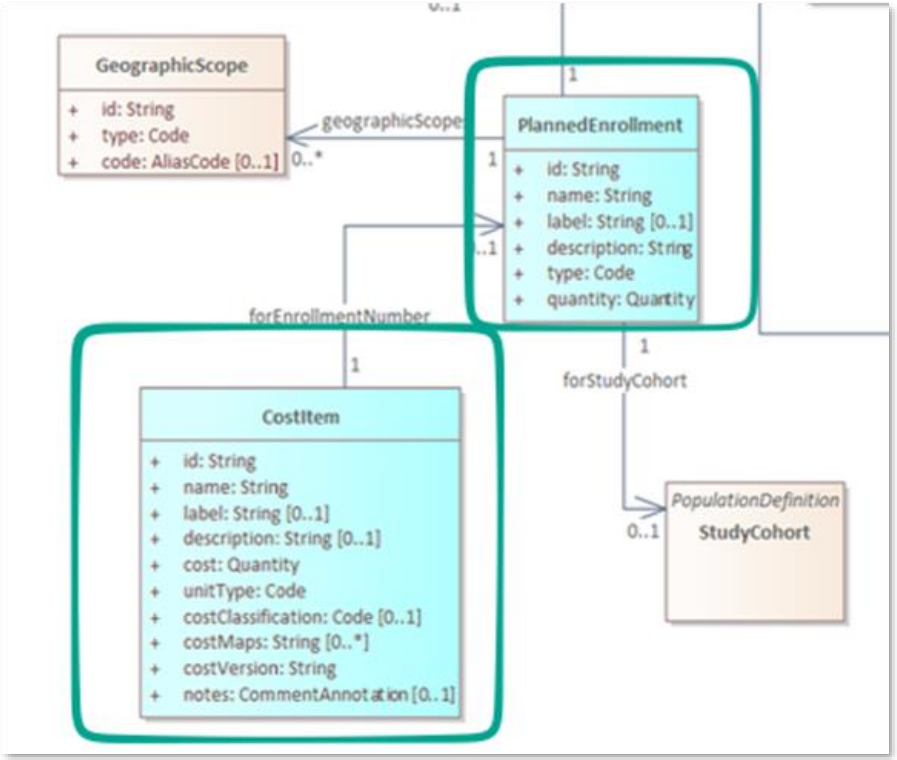
26% improvement patients per site



Exploring Extensions of USDM

Our biggest challenge is extending the data model to contemplate broader study context, such as cost and other operational data.

Based on our learnings collaborating with CDISC, we are in the process of implementing a CostItem Class which would allow USDM to capture various study costs such as Labs and Procedures in a standard way.



We look forward to engaging with you at the…

- 360i Technology Vendor Roundtable
- Innovator Council
- DDF Solution Collaboration Forum

Questions?

Thank You!