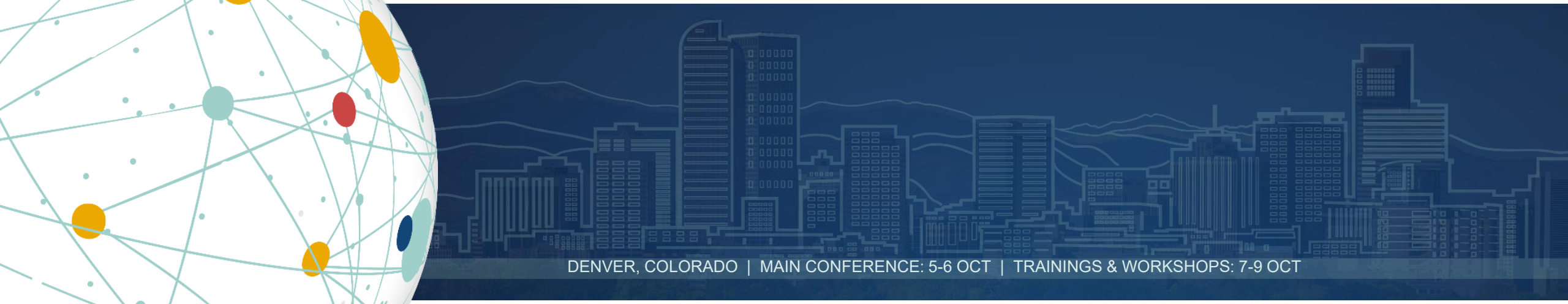


# 2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION




# A Guide to Utilizing USDM from Study Concept to Study Execution

Chris Damato, Associate Product Director, Evinova AG
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# Speakers



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# Agenda

1. Using USDM from Study Concept to Study Execution
2. Current Implementation Options
3. Lessons Learned along the way
4. Advancing the USDM Standard

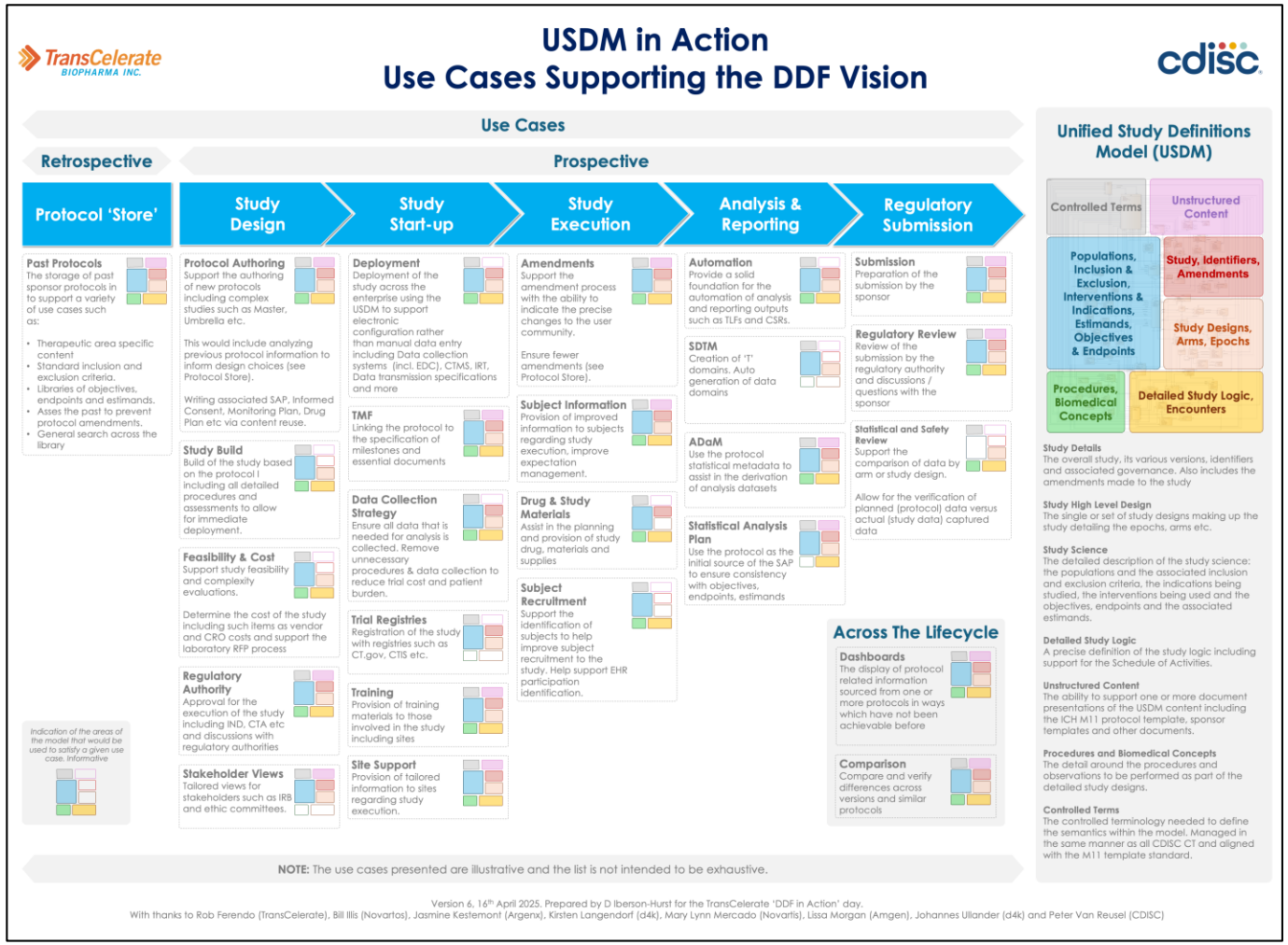
# Using USDM from Study Concept to Study Execution

What do we mean?

# Using USDM to Implement DDF Use Cases

## Use Cases in Focus:

- Protocol Store
- Study Design
  - Study Build / Concept
  - Protocol Authoring
  - *Feasibility & Cost*
- Study Start-up
  - Deployment




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# Requirements to Implement These Use Cases

## Protocol Store

- Collection of historical Protocols to leverage
- USDM Aligned Data Store
- Systematic Method to create the USDM versions of the Protocols

## Concept / Build

- Key Study Design aspects captured digitally
- Application /Product aligned to USDM
- Ability to natively communicate using partial USDM Payloads

## Protocol Authoring

- Digital first solution
- Consumes and builds on a USDM Record
- Creates the complete USDM Entity

## Start-Up - Deployment

- Translation of the USDM record with SDTM/CDASH to create an initial configuration file

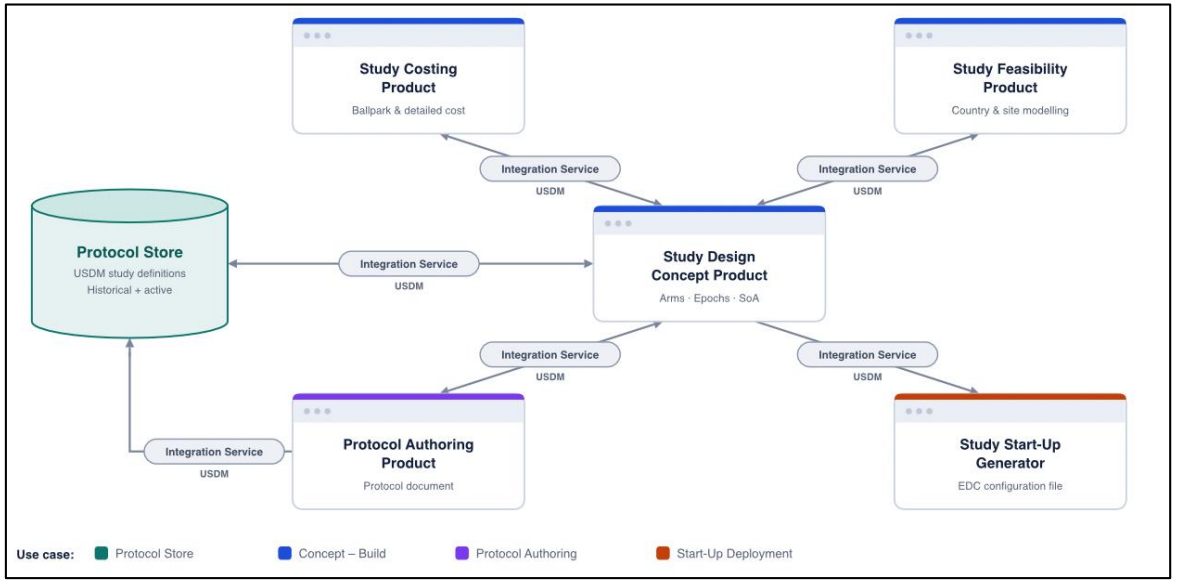
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# Current Implementation Options

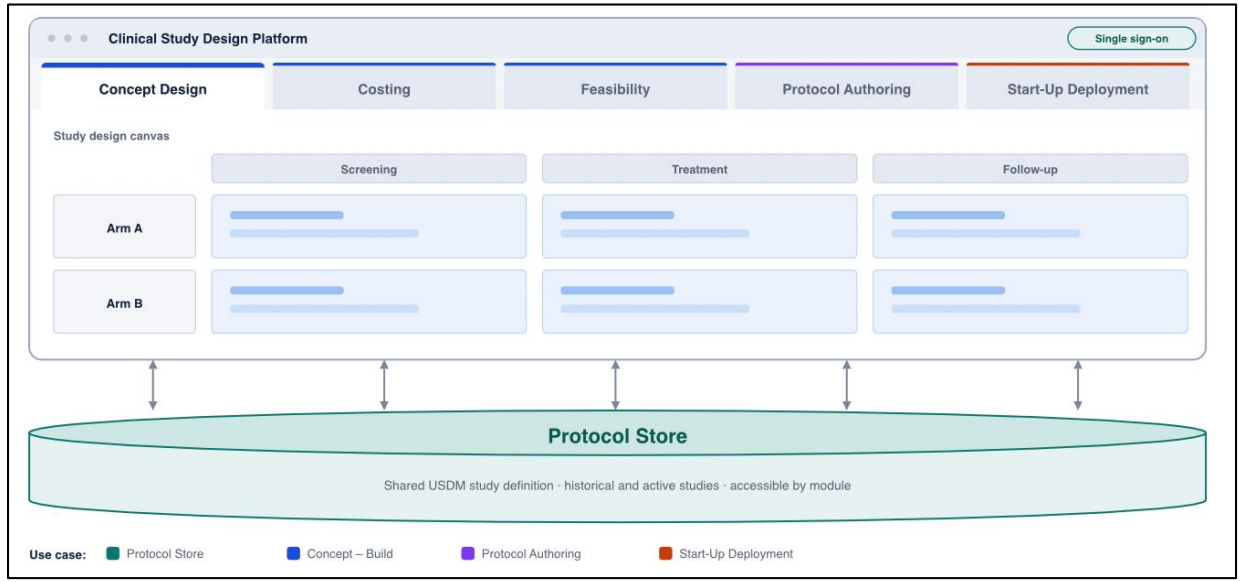
How can it be done?

# Typical Implementation Patterns

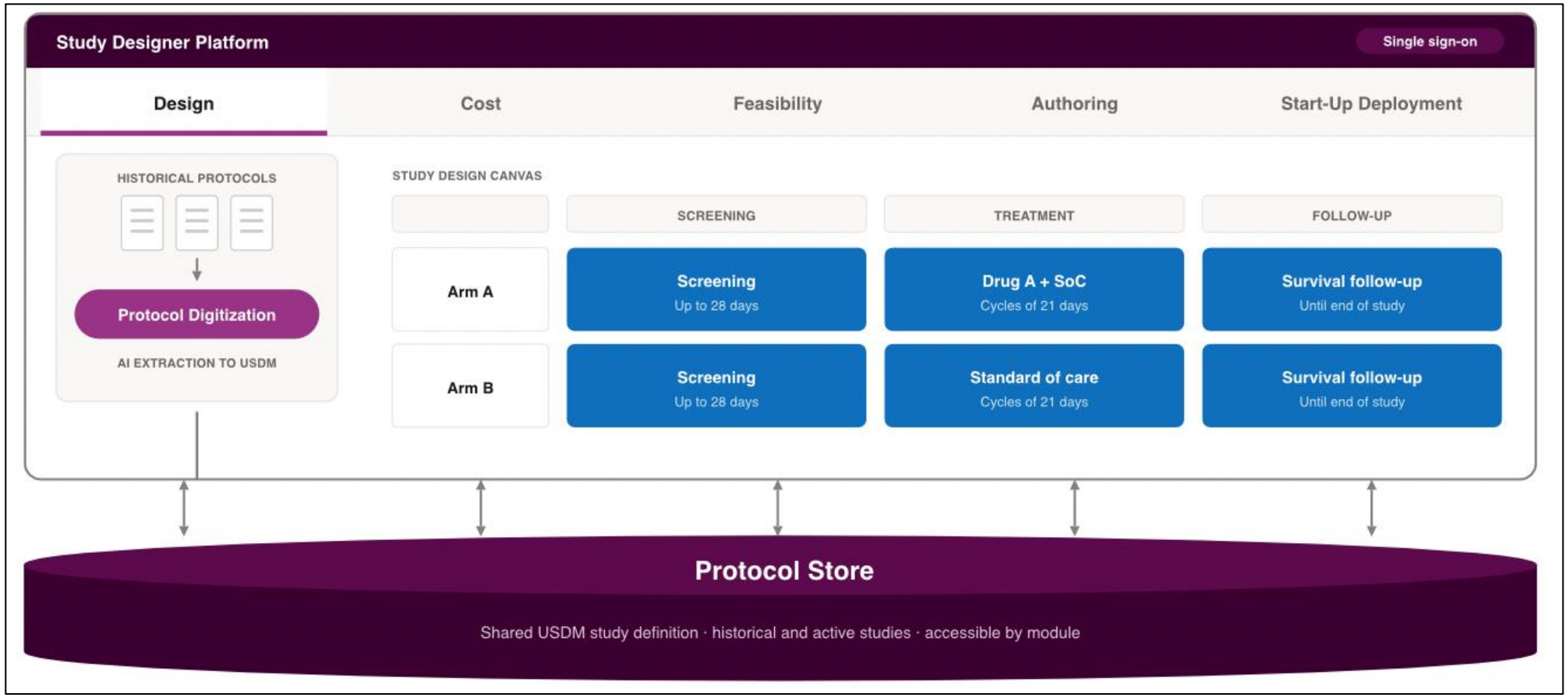
## Point to Point Integrations




## Integrated Ecosystem



# Evinova's Ecosystem Approach



# Lessons Learned along the way

What have been the bumps along the way?

# Lessons Learned



## Start with the USDM UML for the data model starting point

We had a product which we were building and pivoted to USDM alignment

Strategically focused on SOA first, then moved to the Study Schema



## Understand Your Controlled Terminology sets

What code sets are used for Clinical Activities, Labs, etc. ?

What are "your own" sets?

Leverage CDISC/SDTM code sets as much as possible



## Understand Your Partners Controlled Terminology Sets

How will other systems ingest your data files?

Do your partners/vendors use the same code sets?

# Advancing the USDM Standard

Where can USDM grow in the future?

# Options for Future Growth

## Extensions / Classes

- Costs
  - Activity Level
  - Study Wide
- Population Allocations
  - Country Allocations
  - SF & Drop Out Rates
- Milestones
  - Study
  - Country

## Document Types

- CSR
- SAP

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# Questions?



# Thank You!

