

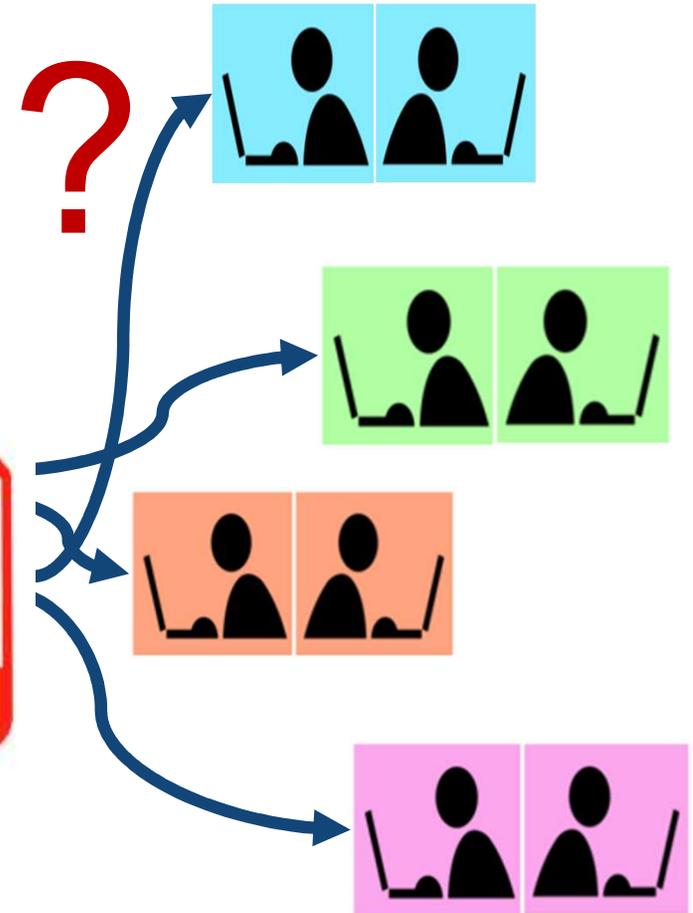
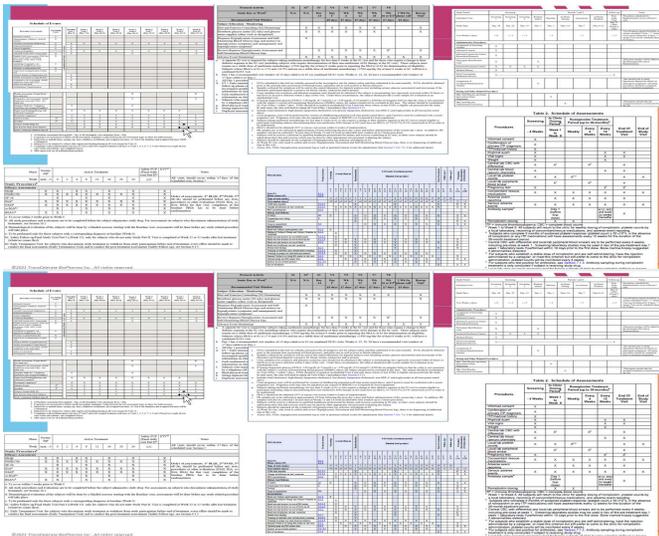
# Digital Data Flow Overview How AI and Standards Can Partner to Enable Study Design

William Illis

Novartis & TransCelerate



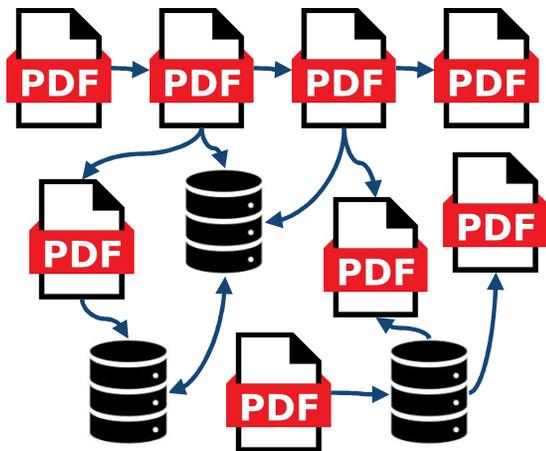
# Clinical Study Protocols *Broken...*



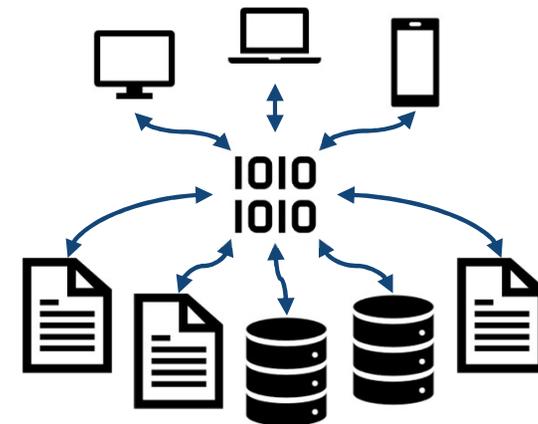
# Why Digital Data Flow? – The Vision

*Break the Document Paradigm*

From document-first



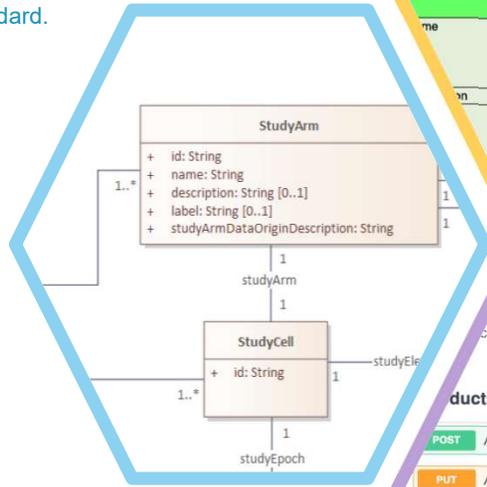
To data-first



# The USDM Standard

## Logical Model

The UML logical model (a class diagram) that provides the basis for the USDM standard.



## API Specification

Provides the means to exchange a single study between machines using a JSON API

## CDISC Controlled Terminology

Provides further semantics, complementing the UML model. Includes the definition of classes, attributes, and value sets

	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Description
	C188827	Study Arm Type
dataOriginDescription	C188828	Study Arm Data Origin Description
originType	C188829	Study Arm Data Origin Type
label	CNEW	Study Arm Label
studyEpoch	C71738	Study Epoch
name	C93825	Study Epoch Name
description	C93824	Study Epoch Description
type	C188830	Study Epoch Type
label	CNEW	Study Epoch Label

## CORE Rules

Specification of the rules that define USDM compliance

Rule ID	Warning/ Error	Entity	Applies
1	ERROR	All	All
2	ERROR	All	All
3	ERROR	All	All
4	ERROR	All	All
5	ERROR	All	All
6	ERROR	All	All
7	ERROR	All	All
8	ERROR	All	All
9	ERROR	All	All
10	ERROR	All	All
11	ERROR	All	All
12	ERROR	All	All
13	ERROR	All	All
14	ERROR	All	All
15	ERROR	All	All
16	ERROR	All	All
17	ERROR	All	All
18	ERROR	All	All
19	ERROR	All	All
20	ERROR	All	All
21	ERROR	All	All
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98	ERROR	All	All
99	ERROR	All	All
100	ERROR	All	All

## API for DDF

Celerate Digital Data Flow (DDF) Study Definitions Repository API.

**Introduction** Routes that form the production specification.

POST	/v3/studyDefinitions	Create a study
PUT	/v3/studyDefinitions/{studyId}	Update a study
GET	/v3/studyDefinitions/{studyId}	Return a study
GET	/v3/studyDefinitions/{studyId}/history	Returns the study history
POST	/v3/studyDesigns	Study designs for a study

Expand all object

## Implementation Guide

Guidance on using the USDM model and ensuring conformance with the standard

## Examples

Example protocols implemented in the USDM with associated JSON files and visualisations

```

studyArms: [
  {
    "id": "StudyArm_1",
    "name": "Placebo",
    "label": "",
    "description": "Placebo",
    "type": {
      "id": "Code_61",
      "code": "C174268",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Placebo Comparator Arm"
    },
    "studyArmDataOriginDescription": "Data collected within study",
    "dataOriginType": {
      "id": "Code_62",
      "code": "C188866",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Data Generated Within Study"
    }
  },
  {
    "id": "StudyArm_2",
    "name": "Xanomeline Low Dose",
    "label": "",
    "description": "Active Substance",
    "type": {
      "id": "Code_63",
      "code": "C174267",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Xanomeline Comparator Arm"
    }
  }
]
  
```

on 2.0 Draft for Internal Review)

**Unified Study Definitions Model Implementation Guide (USDM-IG)**

**Version 2.0 (Draft for Internal Review)**

Prepared by the DDF Team

Notes to Readers

- This is the draft version 2.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v2.0). It is intended for Internal Review only and is not a final version.

History

Version	Release Date
2.0 Draft for Internal Review	

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# Digital Data Flow Progress and Plans

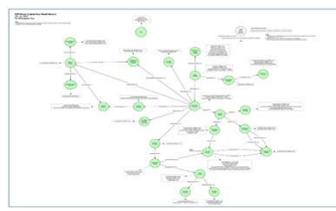


2025

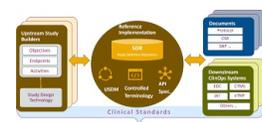
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USDM 4.0



Model Updates USDM 4.1



Study Definition Repository



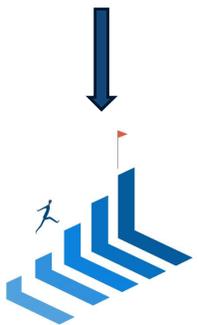
Executable Conformance Rules



USDM Extensions Registry



Adoption Stories



More Adoption Stories



Use Case Library



Use Case Handbooks



Solution Collaboration Forum and Showcase Webinar Series & Challenge Events

Overall Goals for Governance

Category	Conform/Manage Standards	Enable/Platform's Tech	Enable Conformance	Enable Community
Purpose	Define and maintain CDISC's USDM Reference Architecture (RA) USDM API Stack, Conformance Technology and Implementation Guide to ensure conformance per conformance implementer trust	Define and/or manage the USDM Reference Architecture (RA) and accelerate for early implementation of reference architectures, for conformance with the USDM Reference Architecture	Provide a mechanism for sponsors, CROs, tech vendors and others to demonstrate early conformance of products, for standards in CDISC Reference Architecture, for ability to bring and play	Secure, activate & create ongoing support to the conformance community. Provide opportunities for collective support in the future through USDM awards and standards
Relevance/ Timing	Relevant during full lifecycle of standard use	Relevant during early to mid stages of adoption across ecosystem	Relevant during full lifecycle of standard use	Relevant during full lifecycle of standard use

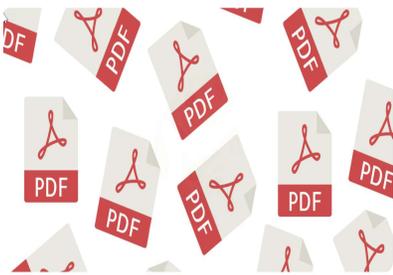
Design, Goals & Capabilities



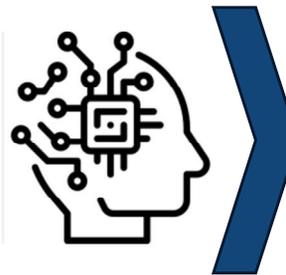
USDM Governance Group DDF Advisory Board



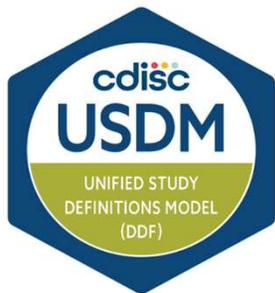
# Better Data, Better AI



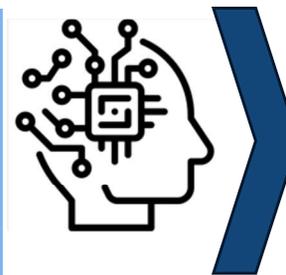
Unstructured, free text  
Inconsistent naming  
One-off interpretations  
Missing information



- Plausible Inferences
- AI Assistants
- Helpful, sometimes impressive
- Limited, sometimes wrong
- Incremental gains

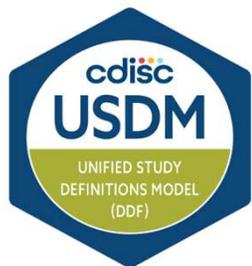


Structured objects  
Defined relationships  
Controlled terminology  
Machine readable

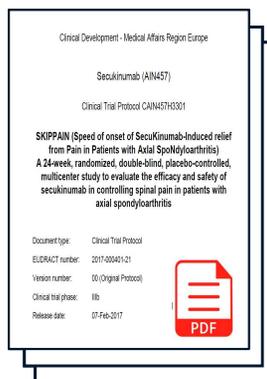


- Trusted outcomes that can be explained and defended
- Improved performance, accuracy and reliability
- Transformational gains

# Using AI to Produce USDM Protocol Outputs



+



```
{
  "protocolDefinition": {
    "id": "PROT-123",
    "studyTitle": "A Phase 2 Study of X in Patients with Y",
    "epochs": [
      {
        "id": "Screening",
        "type": "Screening"
      },
      {
        "id": "Treatment",
        "type": "Treatment"
      }
    ],
    "scheduleOfActivities": {
      "timepoints": [
        { "id": "V1", "description": "Day 1" },
        { "id": "V2", "description": "Week 4" }
      ],
      "activities": [
        { "id": "ACT1", "name": "Vital Signs" },
        { "id": "ACT2", "name": "Blood Draw" }
      ],
      "scheduledActivityInstances": [
        { "timepoint": "V1", "activity": "ACT1" },
        { "timepoint": "V1", "activity": "ACT2" }
      ]
    }
  }
}
```



# USDM + AI: Study Design and Execution Examples

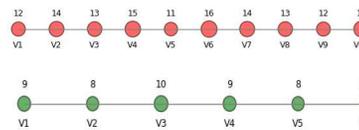
```

{
  "protocolDefinition": {
    "id": "PROT-123",
    "subTitle": "A Phase 2 Study of X in Patients with Y",
    "epochs": [
      {
        "id": "Screening",
        "type": "Screening"
      },
      {
        "id": "Treatment",
        "type": "Treatment"
      }
    ]
  },
  "scheduledActivities": [
    {
      "timepoint": [
        { "id": "M1", "description": "Day 1" },
        { "id": "M2", "description": "Week 4" }
      ]
    },
    {
      "activities": [
        { "id": "ACT1", "name": "Vital Signs" },
        { "id": "ACT2", "name": "Blood Draw" }
      ]
    }
  ],
  "scheduledActivityInstances": [
    {
      "timepoint": "M1",
      "activity": "ACT1"
    }
  ]
}
    
```

+



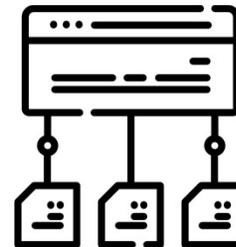
**SoA Optimization**



**Amendment Impact**



**Downstream Config**

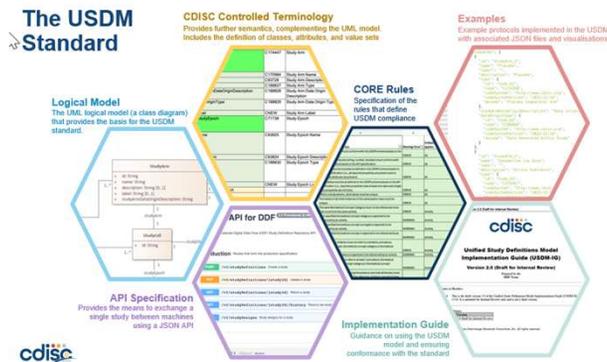


- ✓ Analyze activity density per visit
- ✓ Flag high-burden visits
- ✓ Make visit consolidation recommendations

- ✓ Identify affected activities changed visits, impacted cohorts
- ✓ Generate site-specific change lists, updated ICF language

- ✓ Translate USDM activities → EDC forms, eCOA screens
- ✓ Map USDM visits → EDC visit structure
- ✓ Alignment, Auto-configuration
- ✓ Self-assembling SDTM, ADaM, TFL's

# CDISC Standards Provide Data That Is AI Ready



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Without USDM AI guesses

With USDM AI understands