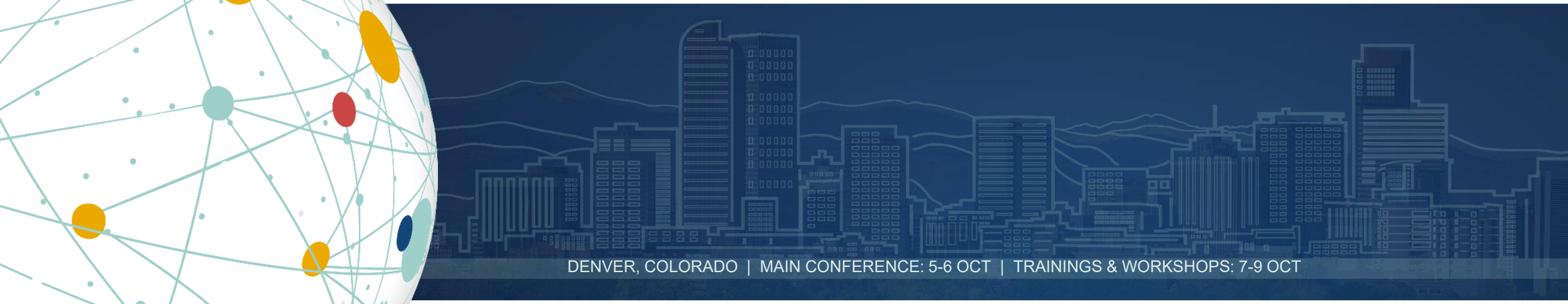


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



What It Actually Takes

Lessons from Production USDM Adoption and the Path to Digital Data Flow

Bill Lynch, CTO, HumanTrue

Speaker



Bill Lynch

CTO and co-founder
HumanTrue

linkedin.com/in/billjive/

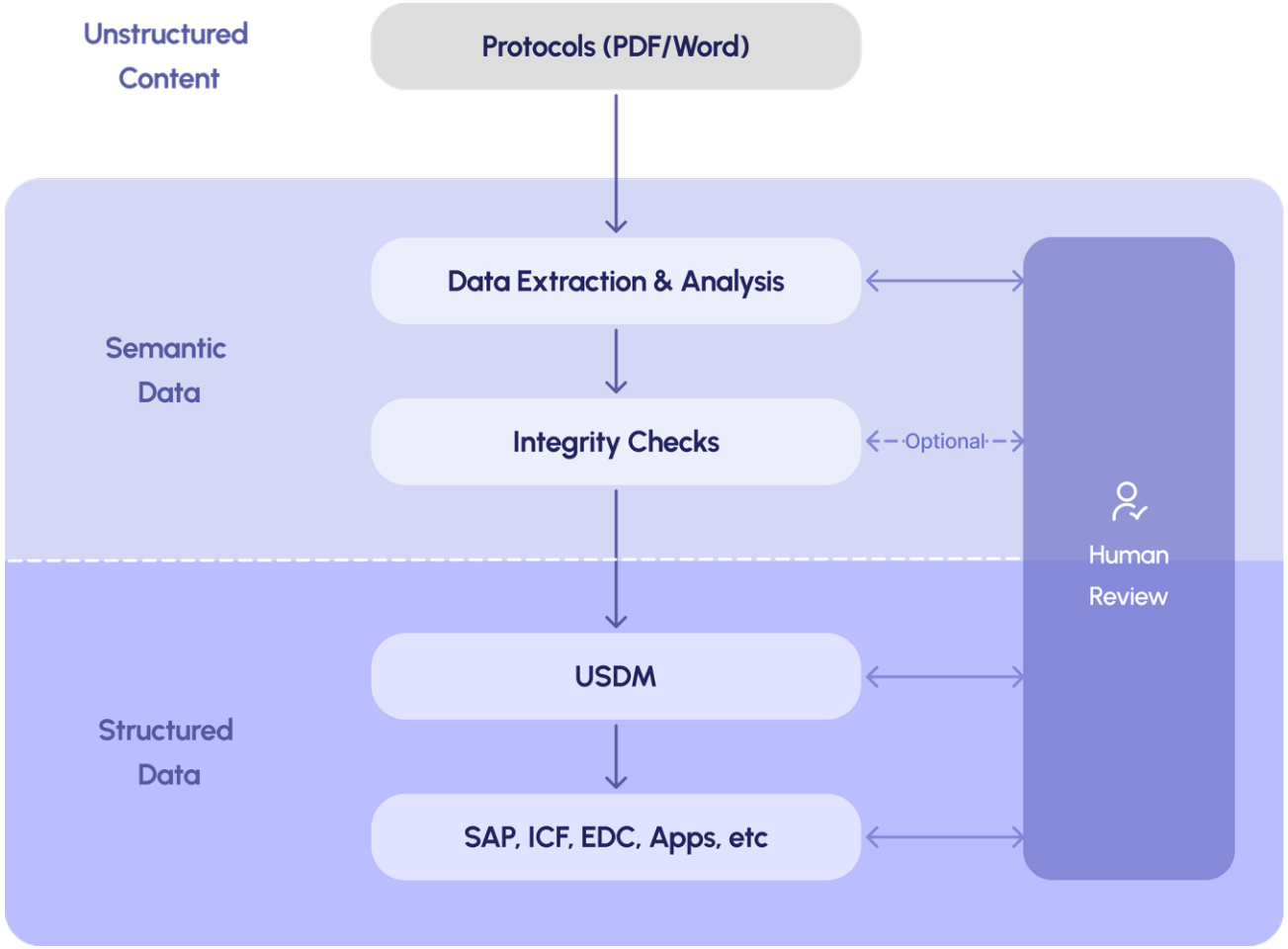
- Software entrepreneur, advisor, nonprofit board member
- Co-Founder, Jive Software, HumanTrue
- Member, USDM Governance Group

Our Platform

Our team builds a protocol intelligence platform for clinical study operations.

We start from the protocol as written, in Word or PDF, and make it digital.

Structured output is USDM and HumanTrue data. Downstream outputs are the documents and builds a study needs.



The Two Sides of the Production Coin





Heads: Operations	Tails: Trust
Conformance & Validation	Is it true, and valid?
Pipelines & Throughput	Did it see this kind of protocol?
Lineage & Logs	Are claims clear about how they were made?
Content Review	Did anyone check and can you tell?
Consuming Systems	Is it sufficient for downstream systems?

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Five topics

Conformance · Throughput · Lineage · Review · Consumers

Conformance

Make conformance cheap so it can be run all the time.

Fast

Fast enough for CI, the eval loop, and every emitted document.

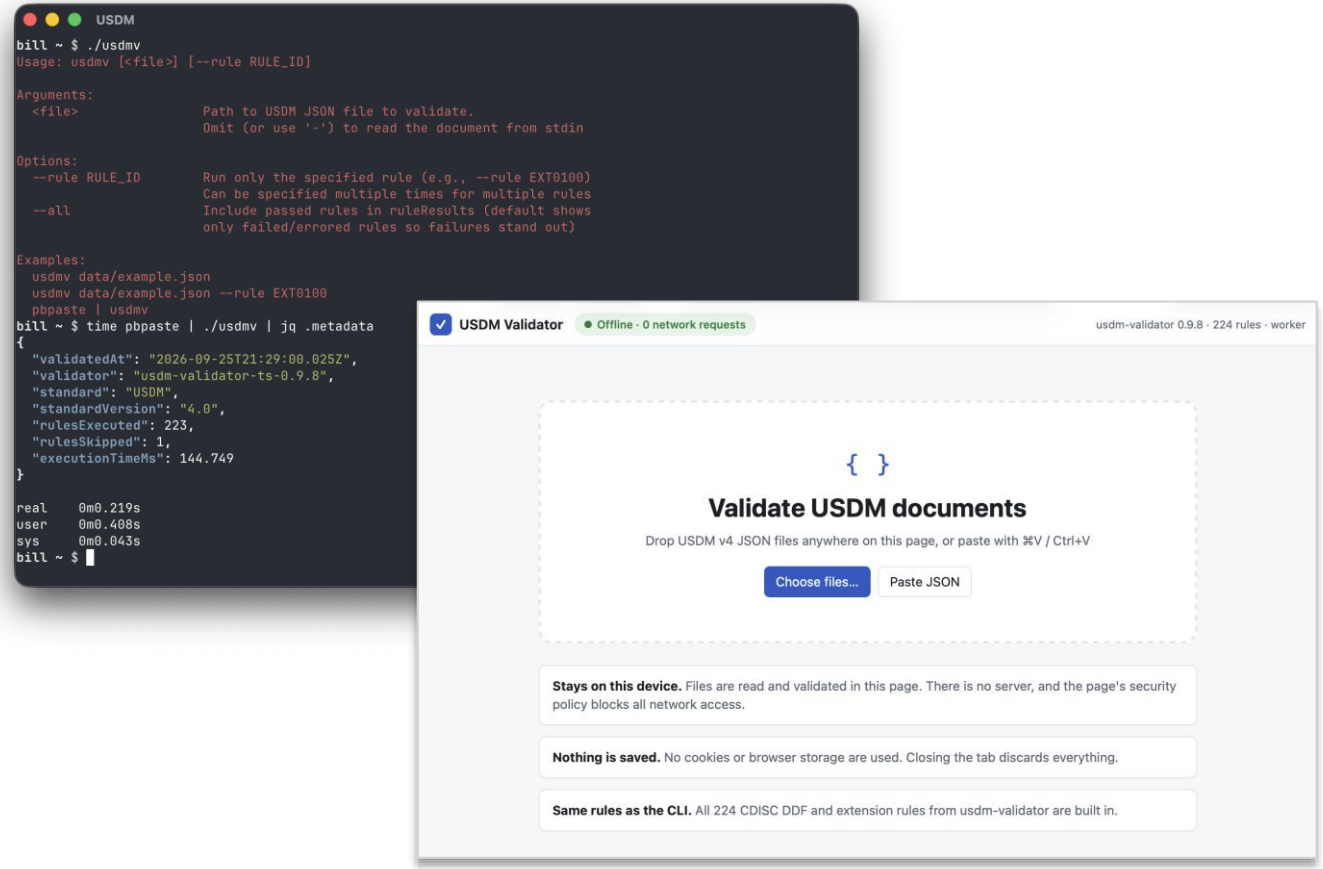
Test extensions

Core rules and extension rules together. A validator that cannot see your extensions gives a false pass.

Anywhere

Command line, or offline in a browser.

We built our own. Happy to talk about it. (Or share it)



Valid is not true



A validator checks schema and rules conformance, but encoded values might be wrong.

The protocol says	Valid, and right	Valid, and wrong
“Day 1 first dose, Day 8 visit"	Anchor (Day 1); Day 8 After P7D	Anchor (Day 1); Day 8 After P8D
“Safety follow-up 30 days after last dose"	After P30D, relative to the end-of-treatment dosing instance.	After P30D, relative to the anchor.
“Holter from 24 h before first dose to 72 h after"	One instance, one 96-hour span	Four instances, one per X in the grid

What to do

Recompute what the protocol states
Derive study days, windows, and spans. Compare them to the text.

View as a downstream system
EDC example: build the visit and form matrix, examine vs the schedule.

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Throughput



How many *different* protocol cases

Protocol types

Variety over volume

Phase 1 minute-level PK, phase 3 pragmatic designs, sub-studies

Therapeutic-area conventions

Across sponsors and templates

Oncology cycles, vaccine Day 0, dialysis-relative timing

Document conditions

Inputs as they arrive

Clean Word, a scanned PDF, a table split across pages

We are happy to work with the industry to publish more examples of protocol -> USDM.

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Did it see this kind of protocol?

The protocol says	One convention	Another
“End of treatment visit"	A scheduled visit	A visit triggered by an exit condition
“Month 6 visit"	P6M	P182D
“Cycles 1 to 6, Day 1"	One cycle timeline, repeated	Six separate visits

A random error is an incident.
A reproducible error is a policy, applied to every protocol of that shape.

Undeclared, they look the same.
A correct file and a consistently wrong one.

What to do

Ask for quality by protocol type
Whether built or bought, ask for more than one number.

Keep a hard-case list
One per shape. Run every change.

Declare your conventions
In the file, or alongside it.

Why does a protocol have an abbreviations list?

So that everything referenced in the document is in the document. A protocol is self-contained by convention.

10.3 Abbreviations

Abbreviation	Full Term
AE	Adverse Event
aMT6s	6-Sulfatoxymelatonin
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CTCAE	Common Terminology Criteria for Adverse Events
CTIS	Clinical Trials Information System (EU)
CTR	Clinical Trials Regulation (EU) No 536/2014
CYP	Cytochrome P450
D	Study Day (cohort-relative; D0 = departure)
DLMO	Dim-Light Melatonin Onset
DSHEA	Dietary Supplement Health and Education Act (US, 1994)
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FAS	Full Analysis Set
FDA	Food and Drug Administration (US)
FWA	Federal-Wide Assurance
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
GPS	Global Positioning System (player tracking)
HIPAA	Health Insurance Portability and Accountability Act
IACS	Institute for Applied Chronobiology in Sport (fictional Sponsor)
ICH	International Council for Harmonisation
ICSD-3	International Classification of Sleep Disorders, 3rd edition
IMP	Investigational Medicinal Product
IND	Investigational New Drug application
IRB	Institutional Review Board
IRT	Interactive Response Technology

Lineage

A USDM file will be read without its producer.

In the file

Every extracted value references the passage it came from, inside the same file.

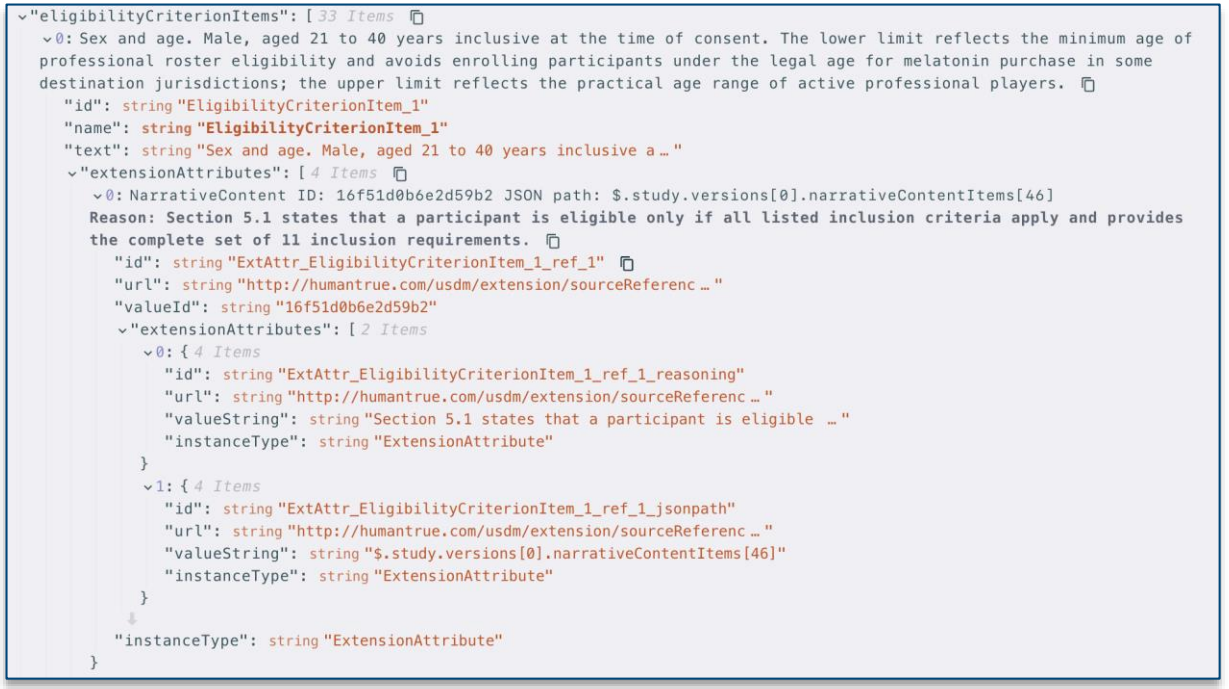
Checked

Validation fails the file when a reference does not resolve.

Recorded

Every run: document version in, models and versions, when, and who changed what.

GAMP's AI guidance increasingly expects this kind of evidence.



Cited, maybe not settled

A document can say two things. A file can only say one.

Synopsis
Ages 18 to 65

Inclusion criterion 1
Ages 18 to 75

Age range
18 to 65

Cited to the synopsis.
The conflict with criterion 1 is not recorded

How was this value made?

Read	a Day 8 visit, from the schedule grid
Inferred	a Day 8 visit, from “one week after the first dose”
Defaulted	a fixed duration, where the protocol says it varies
Synthesized	an epoch, because the USDM requires one
Chosen	ages 18 to 65, over criterion 1’s 18 to 75

What to do

Review side by side
Then pick, split, or send back.

Mark what was not read
Inferred, defaulted, synthesized.

No filler that reads like the protocol
If the schema demands it, say so.

Review

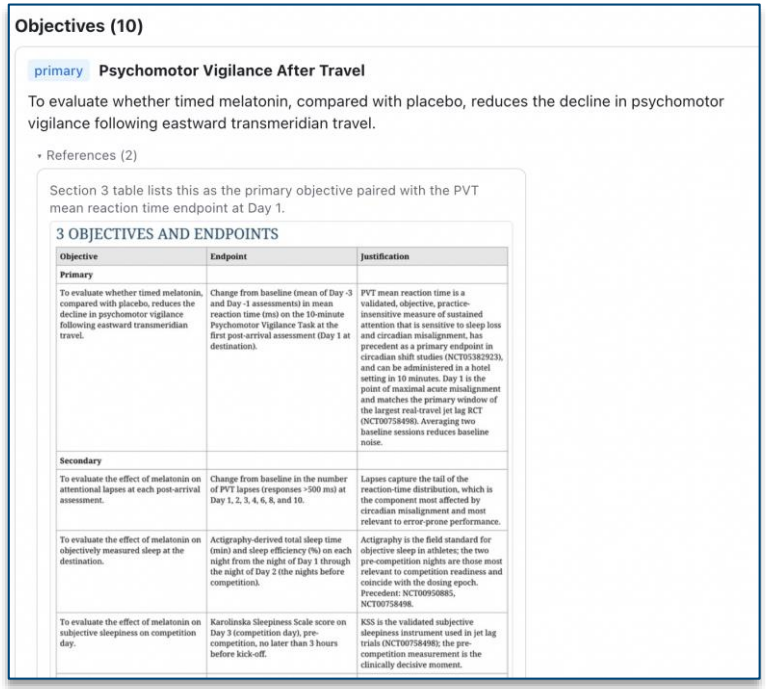
Nobody reviews a 1.6 MB JSON file.

Source beside the result
Surfaces built for the question being answered.

Every edit logged
Before, after, who, why. Re-extraction invalidates review.

Two reviewers
When the downstream use demands it.

Authors keep Word
Structure and review come after the document.



Objectives (10)

primary **Psychomotor Vigilance After Travel**

To evaluate whether timed melatonin, compared with placebo, reduces the decline in psychomotor vigilance following eastward transmeridian travel.

▪ References (2)

Section 3 table lists this as the primary objective paired with the PVT mean reaction time endpoint at Day 1.

3 OBJECTIVES AND ENDPOINTS

Objective	Endpoint	Justification
Primary		
To evaluate whether timed melatonin, compared with placebo, reduces the decline in psychomotor vigilance following eastward transmeridian travel.	Change from baseline (mean of Day -3 and Day -1 assessments) in mean reaction time (ms) on the 10-minute Psychomotor Vigilance Task at the first post-arrival assessment (Day 1 at destination).	PVT mean reaction time is a validated, objective, practice-insensitive measure of sustained attention that is sensitive to sleep loss and circadian misalignment, has precedent as a primary endpoint in circadian shift studies (NCT05382923), and can be administered in a hotel setting in 10 minutes. Day 1 is the point of maximal acute misalignment and matches the primary window of the largest real-travel jet lag RCT (NCT00758498). Averaging two baseline sessions reduces baseline noise.
Secondary		
To evaluate the effect of melatonin on attentional lapses at each post-arrival assessment.	Change from baseline in the number of PVT lapses (responses >500 ms) at Day 1, 2, 3, 4, 6, 8, and 10.	Lapses capture the tail of the reaction-time distribution, which is the component most affected by circadian misalignment and most relevant to error-prone performance.
To evaluate the effect of melatonin on objectively measured sleep at the destination.	Actigraphy-derived total sleep time (min) and sleep efficiency (%) on each night from the night of Day 1 through the night of Day 2 (the nights before competition).	Actigraphy is the field standard for objective sleep in athletes; the two pre-competition nights are those most relevant to competition readiness and coincide with the dosing epoch. Precedent: NCT00950885, NCT00758498.
To evaluate the effect of melatonin on subjective sleepiness on competition day.	Karolinska Sleepiness Scale score on Day 3 (competition day), pre-competition, no later than 3 hours before kick-off.	KSS is the validated subjective sleepiness instrument used in jet lag trials (NCT00758498); the pre-competition measurement is the clinically decisive moment.

Reviewers get surfaces built for their question. Authors keep their tools.

Did anyone check, and can you tell?



Review records stay in the tool that made the file.

USDM Review ✓ 8/8 reviewed

Review the USDM-mapped sections against their source references, then approve.

Review sections

▸ History (8 approvals)

Objectives & Endpoints	Reviewed by Thom Yorke on Sep 22, 2026, 1:15 PM	Reviewed
Indications	Reviewed by Thom Yorke on Sep 22, 2026, 1:19 PM	Reviewed
Eligibility Criteria	Reviewed by Thom Yorke on Sep 22, 2026, 1:27 PM	Reviewed
Population	Reviewed by Ed O'Brien on Sep 22, 2026, 4:19 PM	Reviewed
Compounds & Drugs	Reviewed by Ed O'Brien on Sep 22, 2026, 4:28 PM	Reviewed
Devices	Reviewed by Ed O'Brien on Sep 22, 2026, 5:17 PM	Reviewed
Abbreviations	Reviewed by Ed O'Brien on Sep 22, 2026, 5:32 PM	Reviewed
Biomedical Concepts	Reviewed by Ed O'Brien on Sep 22, 2026, 6:17 PM	Reviewed

What could travel with the file

Section	**Eligibility criteria**
Reviewed by	**Thom Yorke (Clinical Scientist)**
When	**2026-09-15**
Outcome	**Edited**
Covers	**File version 3**
Full record	**Pointer to the review system**

(Illustrative. We are building this as an extension.)

What to do

Carry a summary
Per section: who, when, outcome.

Point to the record
Keep the detail out of the file.

Tie it to a version
A change voids the old review.

Consumers: ask
Which parts did a person review?

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Consumers



Consuming USDM is reconciliation, not conversion.

USDM

Encounters
Activities
Timelines
Biomedical concepts

Reconciliation

Matched against the sponsor's library

Exact match first, then ranked candidates, then a person decides

Decisions carry forward on amendment

The sponsor's build

Its folders and visits
Its library forms
Its matrices
Fields, with SDTM lineage

USDM says what the study needs. Each consumer's standards say how it is built there.

Is USDM enough?



Mostly yes. The bigger gaps are in how to use it.

WHAT WORKS

The EDC build works from plain USDM.

Rave ALS and ODM from the CDISC reference file, no extensions.

GAP

Timing to target day and window is a policy.

USDM leaves that mapping open. Each consumer writes its own.

GAP

Some of the schedule has no home.

Footnote conditions need extensions today.

A spec is as sufficient as the examples that show how to use it.

What we want to help build

- **Encoding cookbook** — Protocol concepts, worked
- **Consumption examples** — With the policy stated
- **Offline validator** — Runs locally, no upload
- **Shared extensions** — Offered as proposals
- **A way to compare** — Two USDMs, one protocol

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Questions?

