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

The Impact of USDM

Bringing Clarity to Study Design

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SPEAKER

Dave Iberson-Hurst

Partner. data4knowledge

DIH has 40+ years' experience across several industries with the last 20 years spent in the pharmaceutical industry combining his technology and software development experience with clinical data standards. During this time, he has served as the CDISC CTO, worked on, and led, several CDISC teams, presented in many forums in Europe, the US, and elsewhere across the globe.

He has worked closely with the FDA, EMA, HL7, ISO, and other standards organizations and was was a member of CDISC's Blue Ribbon commission. He was the CDISC Product Owner for the Digital Data Flow / USDM project for four years until December 2025.

He is a partner at data4knoweldge in Copenhagen and is focused on using the USDM to drive efficiency across the clinical trial enterprise.

WHAT WE WILL DISCUSS

Three topics.

01

Why the SoA hides more than it shows.

02

What becomes possible when the logic is computable.

03

The USDM is the foundation.

THE REALITY

We have all stared at a Schedule of Activities and questioned the exact intent

How many of us have missed something important — buried in 8-point text, in the twelfth footnote?

Time is our friend

Like clockwork.

Very fine mechanisms keeping very accurate time. That is what we want for our studies. Precise. Predictable. No surprises.

01 · CHAPTER ONE

The problem.

Where the precision leaks out — and we don't notice.

A VERY SIMPLE SCHEDULE OF ACTIVITIES

Most studies are far more complex than this. The complexity is where problems hide.

	SCRN (a)	V1	V2	V3
	7 Days	Day 1	7 Days	21 Days
	-7 .. +6 Days		-2 .. +2 Days	-2 .. +2 Days
IC	X			
Med Hist	X			
DM	X			
Elig	X	X		
VS		X		X
PE				X
QS2				X (b)
ECG				X
Blood	X			X (c)
Dose		Dosing shall taking place every 7 days		

a) A daily diary shall be completed by the participant every day until day N once the ICF and been signed
b) QS2 shall be performed before ECG
c) Bloods shall be performed 2 hrs after the ECG

The table contains some of the logic.

	SCRN (a)	V1	V2	V3
	7 Days	Day 1	7 Days	21 Days
	-7 .. +6 Days		-2 .. +2 Days	-2 .. +2 Days
IC	X			
Med Hist	X			
DM	X			
Elig	X	X		
VS		X		X
PE				X
QS2				X (b)
ECG				X
Blood	X			X (c)
Dose		Dosing shall taking place every 7 days		

a) A daily diary shall be completed by the participant every day until day N once the ICF and been signed
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FOOTNOTES

(a) Daily diary, completed by the participant **every single day** until day N.

(b) QS2 must be performed **before** ECG.

(c) Bloods must be performed **2 hours after** the ECG.

Three footnotes. Three different kinds of timing logic. None of it is in the table.

THE THING NOT IN THE TABLE

Where is Day 14?

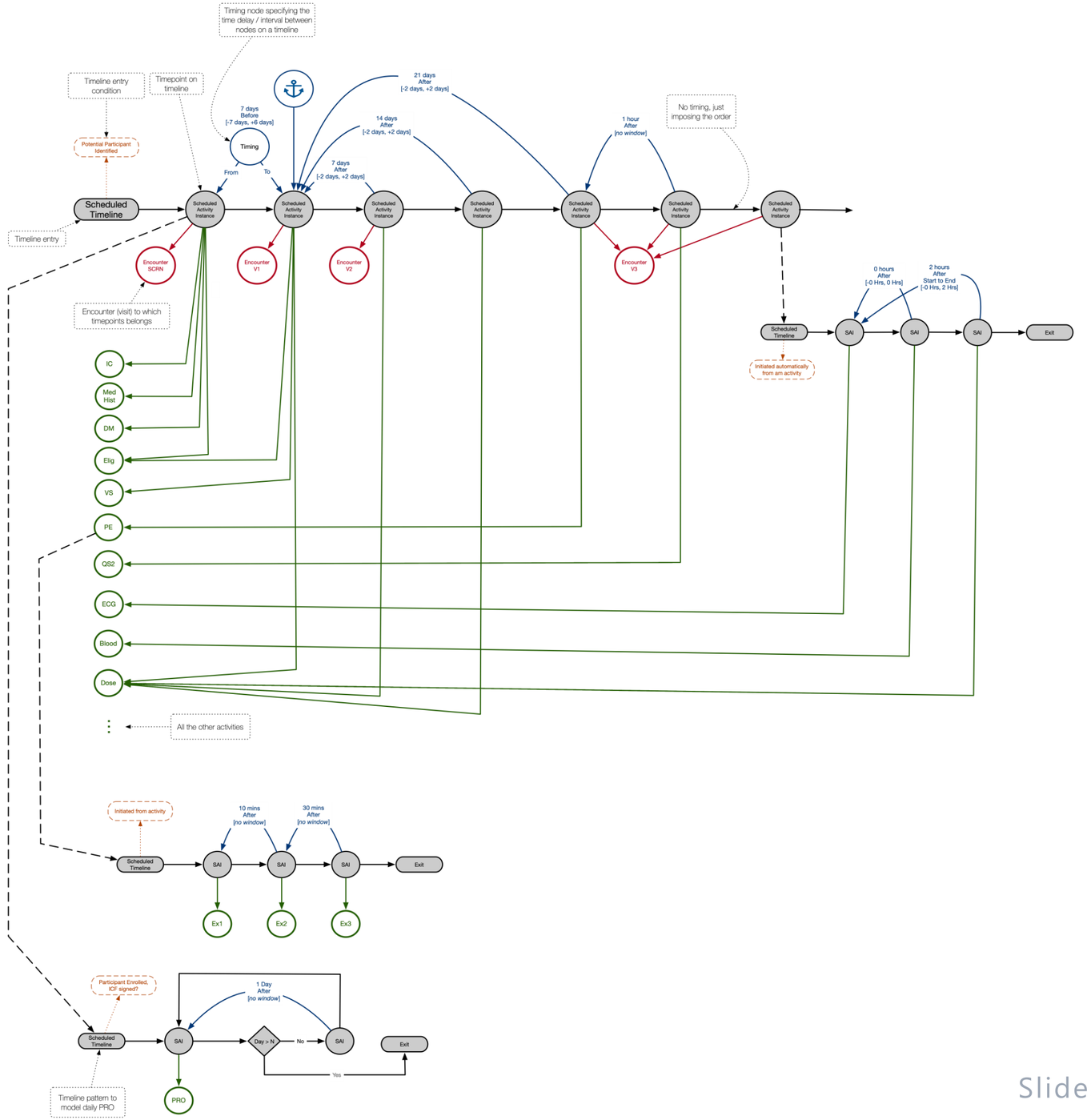
Visits at day 1, 8 and 22. Dosing every 7 days. The protocol says it. The SoA hides it. A dose with no visit.

02 · CHAPTER TWO

The model.

Where the logic comes out of the footnotes and into the machine.

USDM timelines, in one picture.



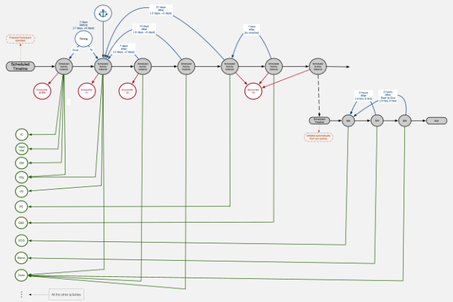
WHAT THE FOOTNOTES BECOME

Three timelines. One truth.

MAIN

Visit timeline

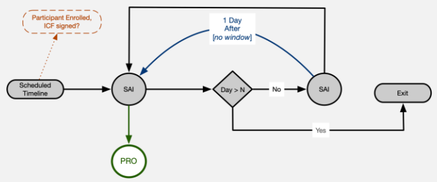
Drives encounters and dosing. SCRN → V1 → 14d → V3. The ghost is now a node.



SUB · CYCLICAL

Daily PRO diary

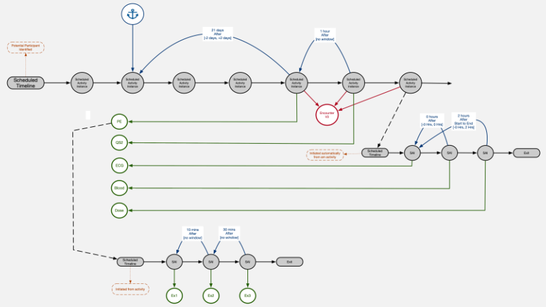
Kicked off when ICF is signed. Runs every day. Stops at day N.



SUB · ORDERED

V3 ordering

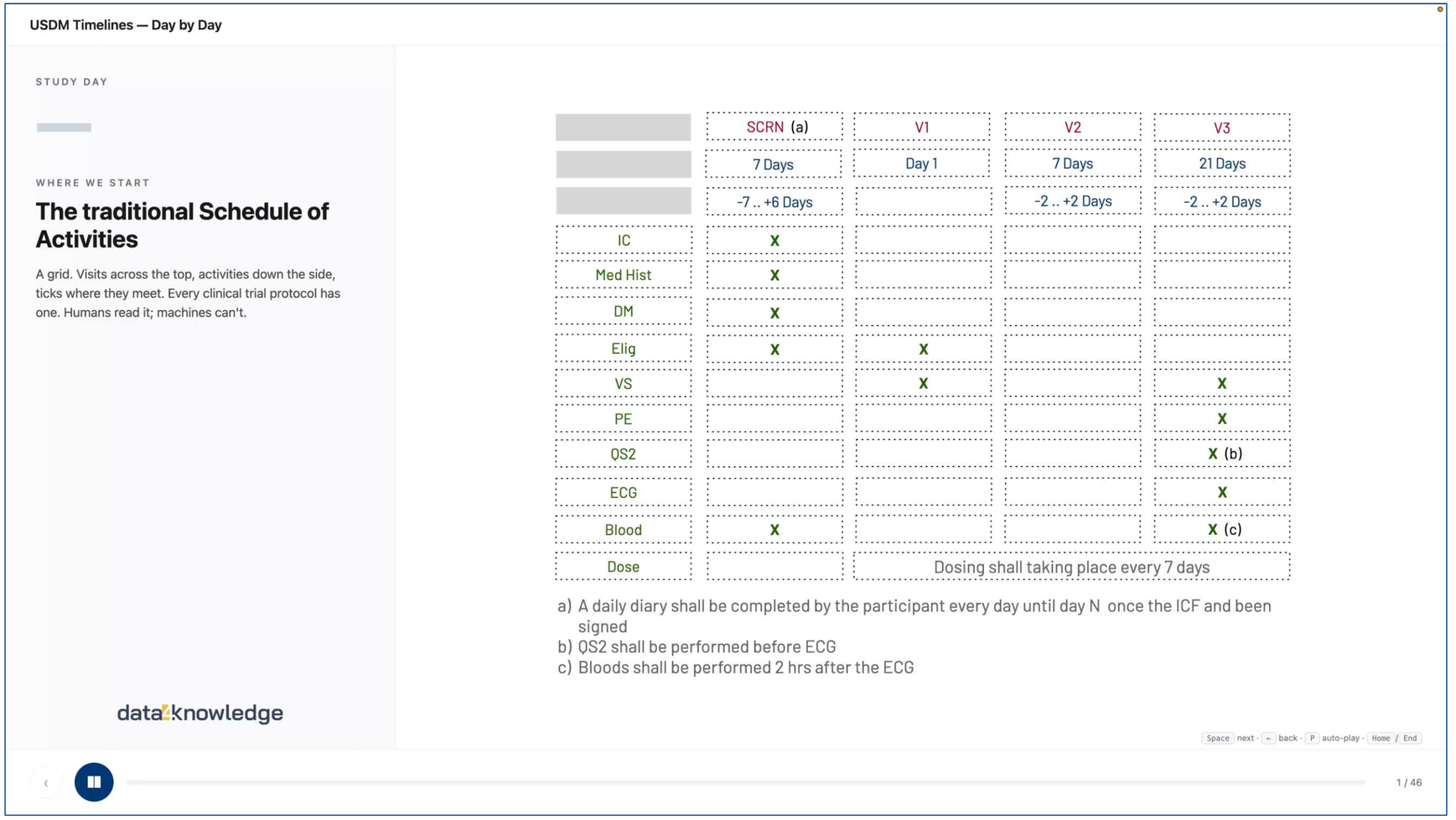
QS2 before ECG. Bloods two hours after ECG. Order and timing — explicit.



The footnotes are gone. The logic is in the model.

WHAT THE MACHINE CAN NOW DO

Day-by-day expansion. Generated.



03 · CHAPTER THREE

The payoff.

What you get for free, once the logic is computable.

ONE SOURCE OF TRUTH

One model. Many use cases

SOURCE / USDM

Protocol Store

The Study Definition Repository — one model that every view downstream is generated from.

DOWNSTREAM →

1 DESIGN & PLAN

Study Concept

- Optimization Scores
- Enrollment Forecasting
- Resourcing & Cost Predictions
- Country & Site Selection
- Timeline Forecasting
- Design Study
- Author Protocol
- Render Stakeholder View

2 START-UP & BUILD

Study Start-Up

- Study Build
- Central Analysis Services
- Clinical Trial Materials
- Interactive Response Technology
- Clinical Trial Management
- Draft Study Budget
- Draft Site-Level Budgets

3 EXECUTION

Study Execution

- Report Protocol Changes
- Estimate Trial Site Inventory Needs
- Query Patient Screening Facilities
- Populate Trial Site Data Systems
- Verify Site Compliance

4 ANALYSE & REPORT

Analysis & Reporting

- SDTM Trial Domains
- SDTM Data Domains
- SDTM → ADaM
- Perform Study Analysis
- Draft Statistical Analysis Plan

5 SUBMIT

Regulatory Submission

- Transmit Study Protocol
- Review Study Protocol
- Compare Actual to Planned Treatment Progression

SCAN TO EXPLORE

TransCelerate Use Case Library

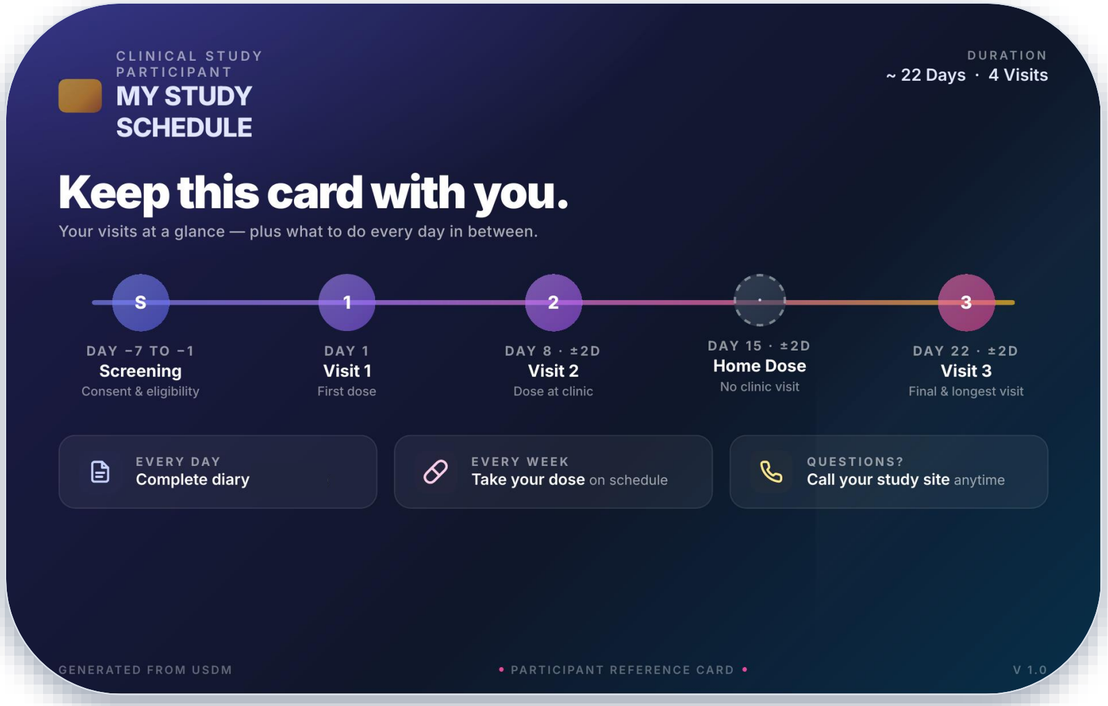
29 use cases · full catalog & rationale

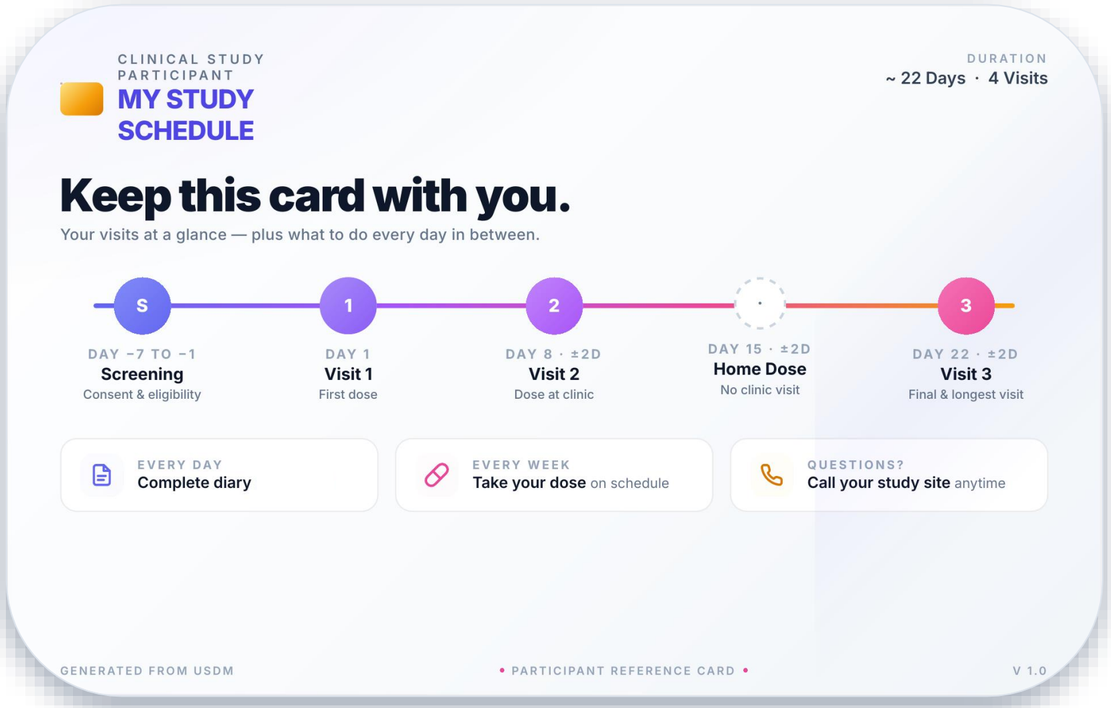
Same source · Single source of truth

OUTPUT · WALLET SIZED · PARTICIPANT

Your guide to the study.

Plain language. Visit by visit.





— THE PRINCIPLE —

The better the USDM,
the better the precision in our studies,
the better the automation.

USDM is the foundation. Everything after — EDC, operations, participant guides, site guides, regulatory … — is built on it.

KEY LESSONS

Three key messages.

01

USDM is the foundation for all that follows

02

The SoA is a view — not the source.

03

Precision in the model unlocks downstream automation.

Thank you, Milano.

Find me afterwards.

SCAN TO CONNECT
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SPEAKER
Dave Iberson-Hurst

FROM
data4knowledge ApS