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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

One Schedule of Activities (SoA) for All: A Layered Abstraction to Harmonize Protocol Schedules and Accelerate Digitization with USDM

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Speakers

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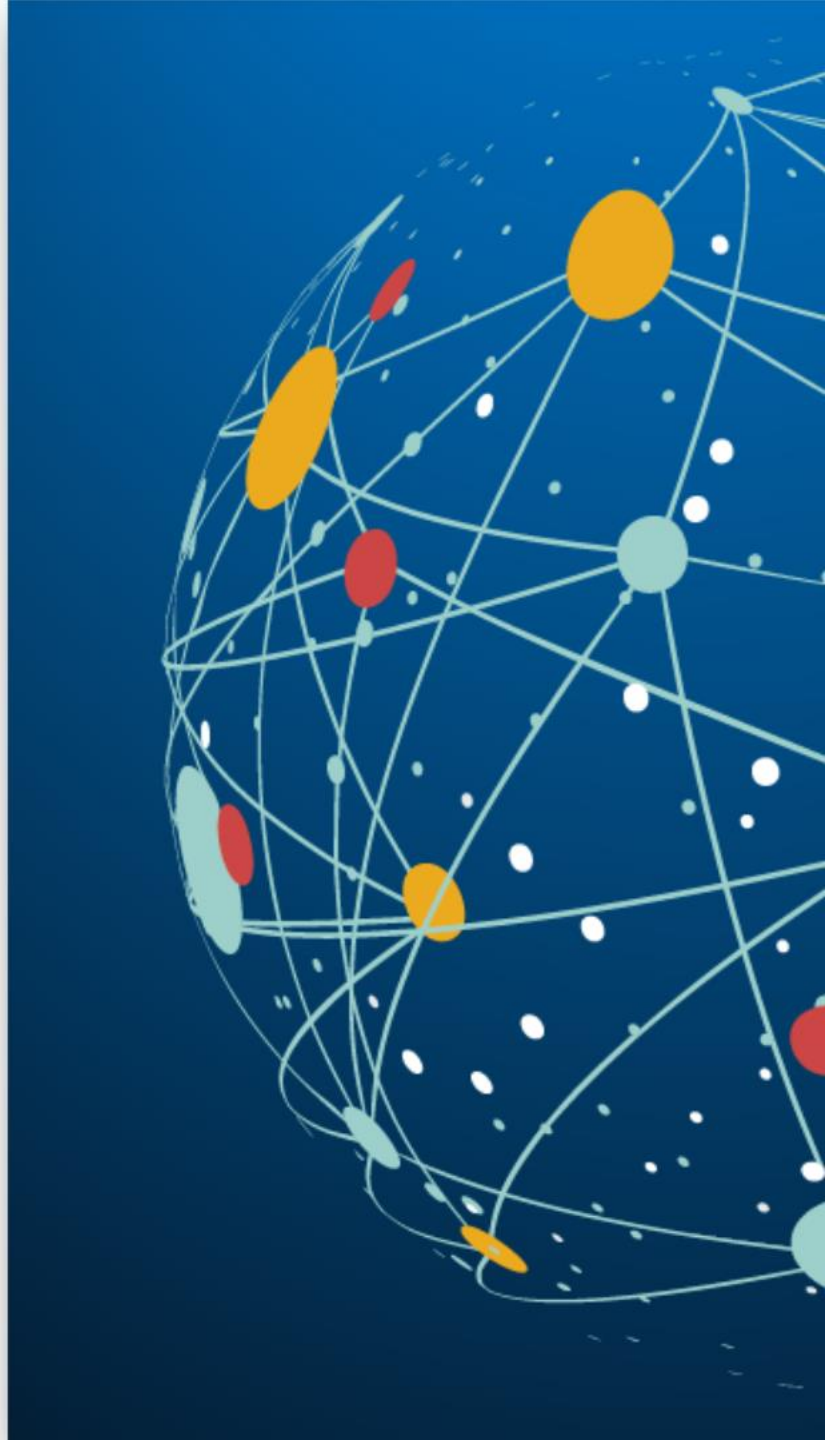
Agenda

- Why do we need a SoA Standard?
- The SoA Ontology and Metadata Model
- Automation Made Possible
- Wrap Up

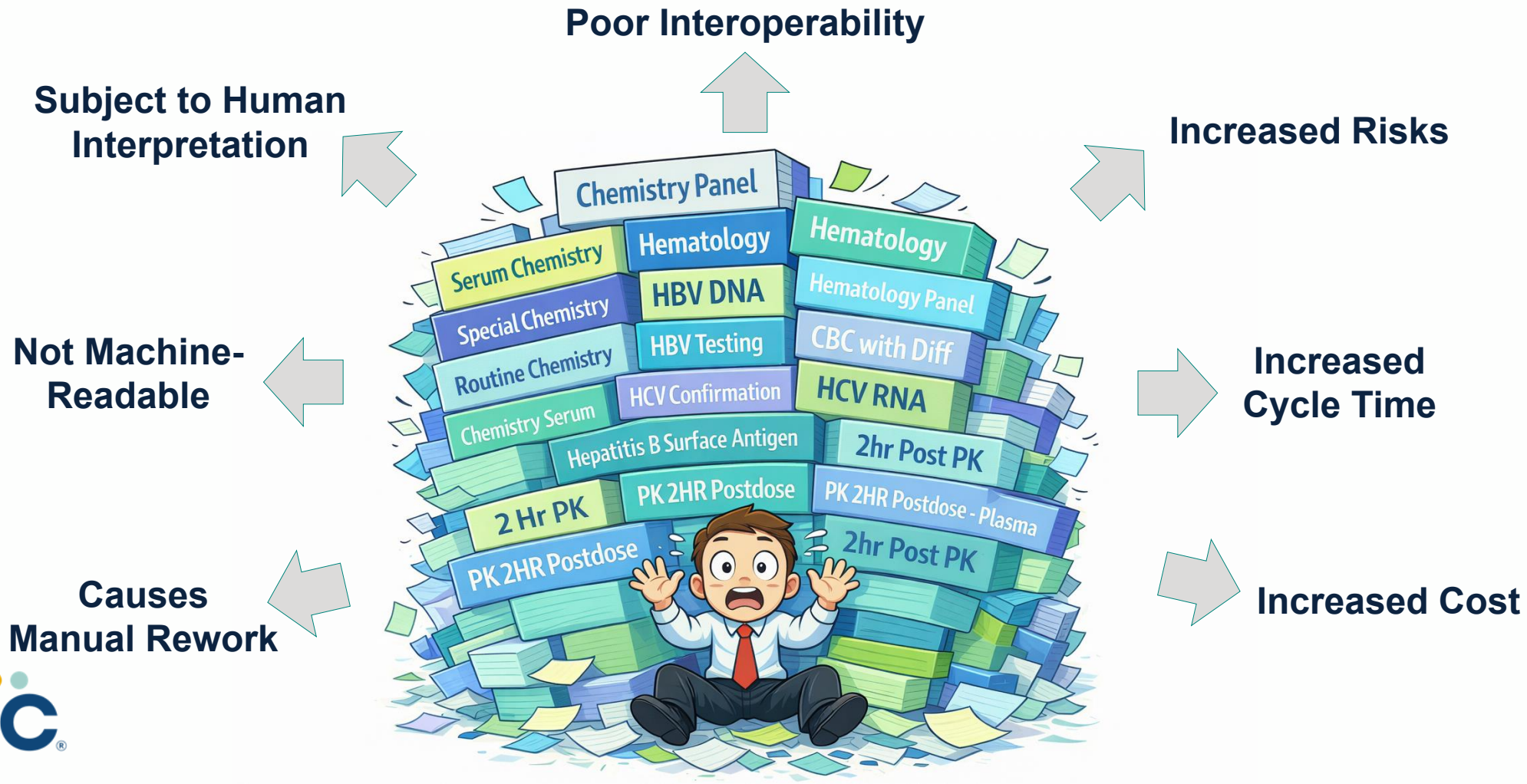


One SoA for All

Why do we need a SoA standard?

The Problem

Schedule of Activity (SOA) nomenclature varies across protocols resulting in nearly 300 Specimen, Assay, and Visit names manually mapped each month



Leveraging Industry and SOA Standards

1

ICH M11 Template

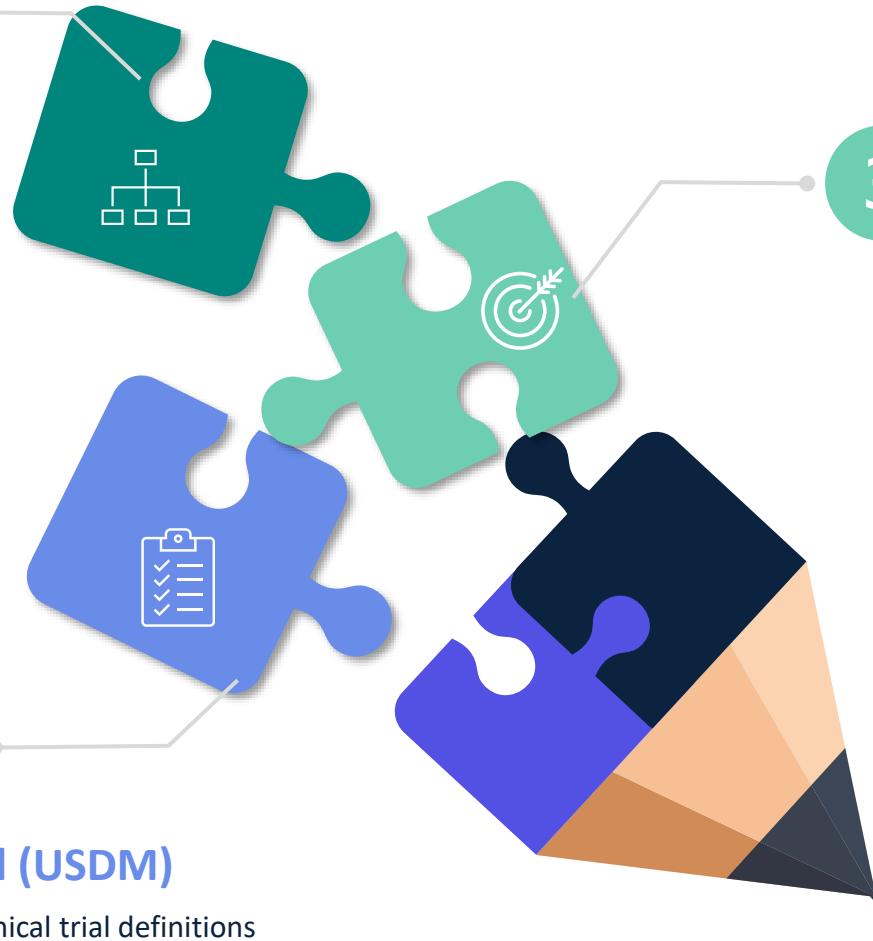
Modular Sections:

- Objectives
- Endpoints
- Participant Population
- Inclusion/Exclusion Criteria
- Safety
- Visits
- Assessments
- Etc.

Controlled Terminology:

Defines concepts within the protocol & provides standard terms and definitions

- e.g., Adaptive Trial Design, Control Types, Amendment Details, Amendment Scope, Analyses, etc.



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Structured SOA

- SOA Metadata Model
  - Visits: Structured Timepoints (visits, cycles, days, etc.)
  - Assessments: Standard Nomenclature
- Defines the ontology, data standards, business rules, and operational relationships for SOA representation and authoring within study protocols

2

Unified Study Definition Model (USDM)

- Machine Readable, standardized framework for clinical trial definitions
- Dynamic, structured, executable protocol

digital study design

How a Harmonized SOA Impacts Stakeholders

The standardized SOA – aligned to USDM – unlocks efficiency across ecosystem

Standardized SOA → Digital Study Design → Faster Startup → High Quality Trials

Study Teams

- Quality protocol development
- Fewer amendments from semantic issues
- Reusable
- Automation ready

Downstream Consumers & Service Providers

- Clear, unambiguous requirements
- Consistent Activities and Specimen definitions
- Enables study start up, service provider alignment

Clinical Sites

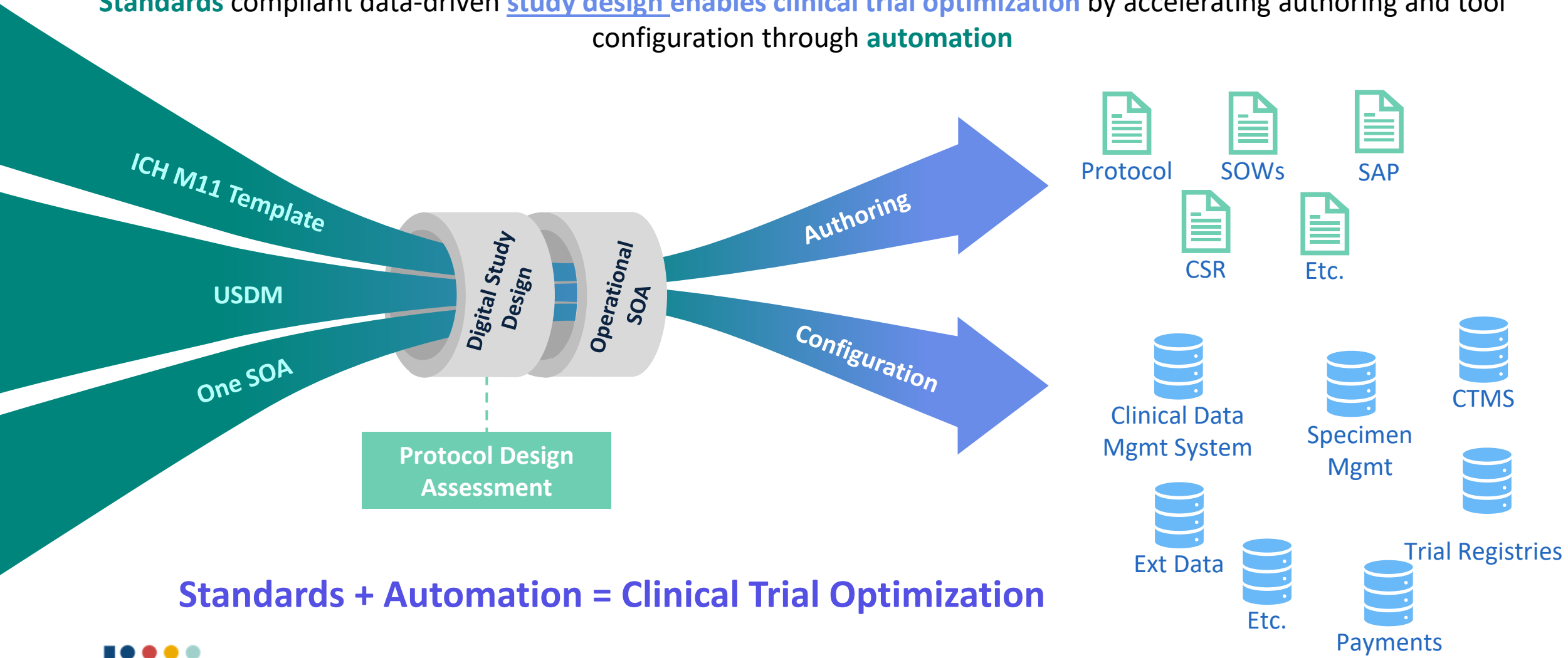
- Less confusion and fewer errors due to interpretation burden
- Clearer visit expectations
- Fewer opportunities for deviations

Patients

- Fewer unnecessary visits or procedures
- Clearer understanding of what to expect
- More consistent care across sites

Changing the Authoring Paradigm

Standards compliant data-driven **study design enables clinical trial optimization** by accelerating authoring and tool configuration through **automation**



Standards + Automation = Clinical Trial Optimization

The SoA Ontology and Metadata Model

The Building Blocks

Layers 1-3: Overview on SOA Structured Frame and Ontology

"What is the operational and semantic truth under all the implementation noise and chaos?"

SOA Model L1-L3: Structured Frame and Ontology

1. Anchored in Global Standards & Evidence

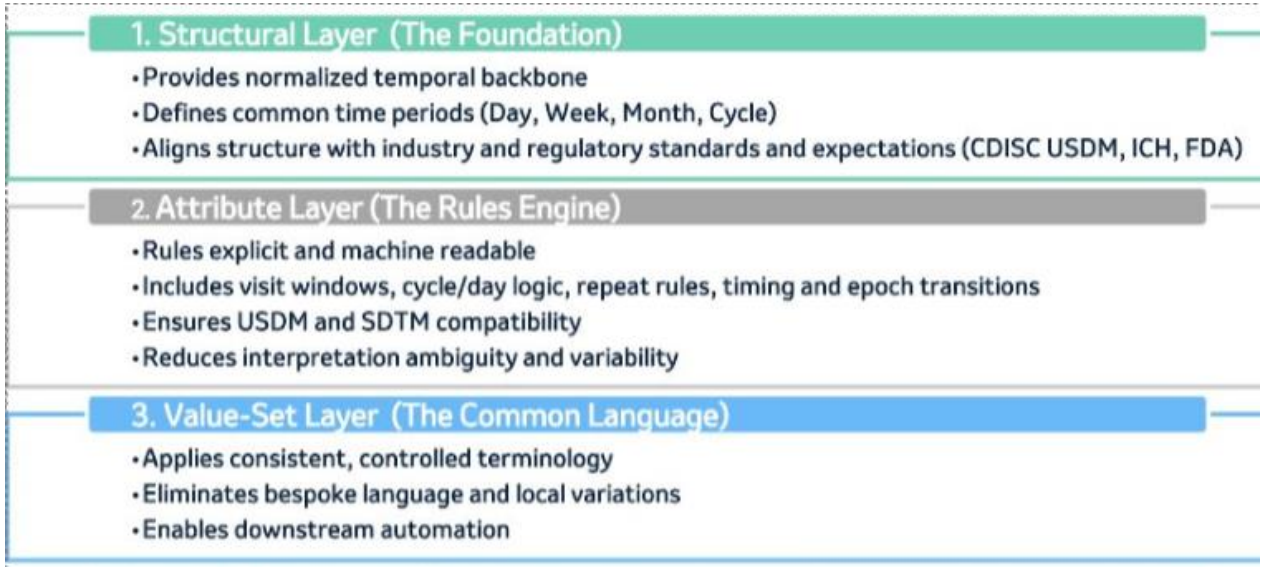
- Foundation: Built from 80+ real-world protocols (Public and MSD-internal protocols) and leading templates.
- Regulatory Alignment: Strictly anchored in FDA, ICH, NIH, and CDISC requirements.
- Scalability: Designed for universal *reuse* across all study phases, study types, and Therapeutic Areas.

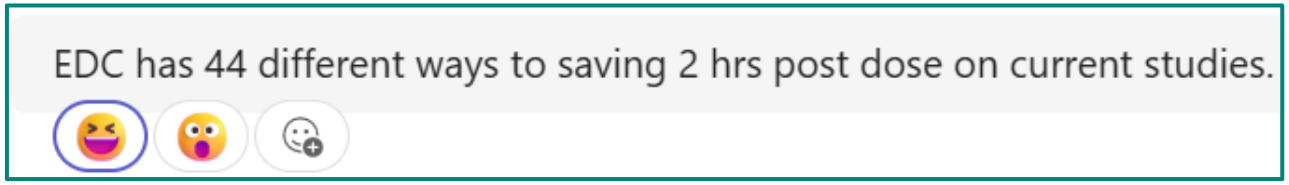
2. Methodology: The Entity Canonical Data Model (ECDM)

- A process of “Conceptual Abstraction” and “Semantic Compression”
- A structured flow from Entity -> Attribute -> Valueset.
- Created common attributes and their valuesets: Study Day/Week/Month/Cycle, Visit Number, Cycle Day, Window, etc...

3. The Impact: Operational Precision

- Canonical Structure: Reveals a dense, semantically rich structure that is both operationally precise and machine-readable.
- Elimination of Variability: Replaces "bespoke" naming with a single, unified language to enable downstream automation and data consistency.





In a nutshell, layers 1-3 provides the normalized temporal backbone and standardize our terminology, ensuring there is **only one way** to say: 'POST-DOSE 2 HOUR'.

SOA Model L2-3: Controlled Attributes and Valuesets

Summary of Structured SOA Attributes:

- Total structured SOA attributes defined: **23**
- Attributes with controlled terminology: **19**
- Attributes with input format control (no controlled term): **4**
- Protocol-agnostic definitions written for SOA attributes and their associated valuesets to ensure cross-study *reusability* and *semantic stability and consistency*.
- Using Existing CDISC SDTM CT where applicable and referencing the CDISC DDF and Protocol Terminology

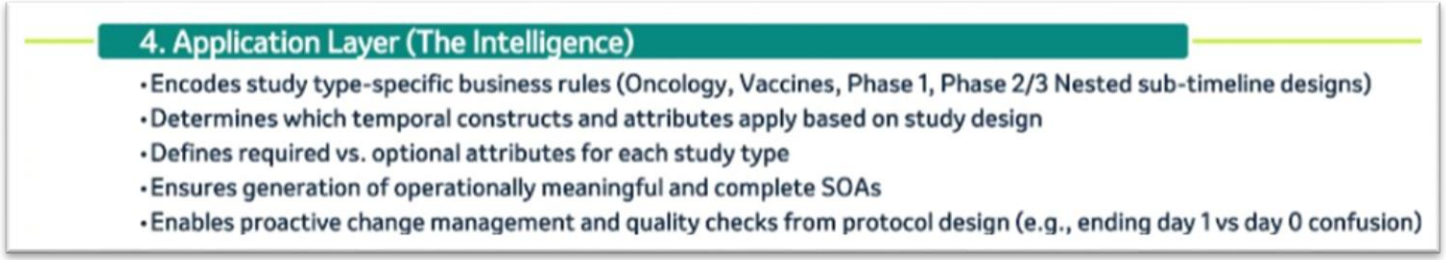
Structured SOA Attributes	Has Controlled Valueset	Control Input Format
STUDY PERIOD DURATION	No	Yes
STUDY PERIOD RANGE	No	Yes
PARTICIPANT PLANNING	Yes	
VISIT LABEL	Yes	
VISIT NUMBER	Yes	
STUDY CYCLE	Yes	
CYCLE DURATION	No	Yes
CYCLE DAY	Yes	
STUDY MONTH	Yes	
MONTH INTERVAL CONVENTION	Yes	
MONTH INTERVAL RANGE	No	Yes
STUDY WEEK	Yes	
STUDY DAY	Yes	
WINDOW	Yes	
WINDOW ANCHOR TYPE	Yes	
DISPOSITION AND MILESTONE EVENT	Yes	
ANCHOR EVENT	Yes	
EVENT-ANCHORED RELATIVE POSITION	Yes	
EVENT-RELATIVE TIME OFFSET	Yes	
EVENT-ANCHORED SUB-TIMELINE FLAG	Yes	
CONTACT MODE	Yes	
ENVIRONMENTAL SETTING	Yes	
SCHEDULED ACTIVITIES	Yes - Pending List	

Study Design Requirements

Layer 4: Encoding Business Logic and Operational Requirements and Constraints

"We have the building blocks – how do we connect them to construct a clinically and operationally meaningful SOA?"

Minimal Viable Metadata – What must be included in a SOA so we have a clear and meaningful schedule?



Minimal Viable Metadata (MVM):

- Information Theory: "**What is the minimum information needed so a computer can reconstruct reality?**"
- For SOAs this means:
  - What **required attributes/fields** do we need to reliably construct the schedule for a given **study type and therapeutic area**?
  - What are **optional attributes** on top of that?
- For those familiar with SDTM, this is analogous to defining **Required vs Expected vs Permissible variables** for each SOA type.
- Clarifies **human interpretation**
- Enables true **machine readability and automation**

Vaccine SOA Modeling, Mock Example and MVM Requirements

Vaccine SOA Mock Example – Main Timeline

Mock Vaccine SOA

Example 1: 3-Regimen Vaccine - Globel Timeline/Main SOA - Followup Visits built on nominal study day

Scheduled Planning = used for protocol-defined, prospectively planned visits and milestones that form the standard schedule of activities applicable across participants.

*STUDY PERIOD:	SCREENING	INTERVENTION						FOLLOW-UP		
STUDY PERIOD RANGE	SD-14 to SD-1	SD1 to SD150						SD181 to SD300		
*STUDY PLANNING SCOPE	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Trial Completion Planning
*DISPOSITION AND MILESTONE EVENT		FIRST DOSE					PLANNED END OF TREATMENT			PLANNED END OF TRIAL
VISIT LABEL	SCR VST							SFU VST	SFU VST	SFU VST
VISIT NUMBER	V1									
STUDY MONTH		M1	M2	M3	M4	M5	M6	M7	M8	M10
*MONTH INTERVAL CONVENTION		NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS
*MONTH INTERVAL RANGE		SD1 to SD30	SD31 to SD60	SD61 to SD90	SD91 to SD120	SD121 to SD150	SD151 to SD180	SD181 to SD210	SD211 to SD240	SD271 to SD300
*STUDY DAY		SD1	SD60	SD90	SD120	SD150	SD180	SD210	SD240	SD300
*WINDOW			-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY
*WINDOW ANCHOR TYPE			SD	SD	SD	SD	SD	SD	SD	SD
*ANCHOR EVENT		FIRST DOSE	SECOND DOSE				THIRD DOSE			
*EVENT-ANCHORED SUB-TIMELINE FLAG		YES	YES				YES			
Scheduled Activities										
Study Vaccine Administered		X	X				X			
Informed Consent										
Medical History	x									
Physical Exam	x	x	x	x	x	x	x			x
Urinalysis	x	x	x	x	x	x	x			x
Safety Laboratory Blood draw	x	x	x	x	x	x	x	x	x	x
Serology Blood draw	x	x	x	x	x	x	x	x	x	x

Schedule visits by **Nominal Study Day (REQUIRED)** rat her than month to ensure every activity translates to a precise calendar date.

Trial Completion Planning = used for trial-level milestones or rules that define the scheduled conclusion of the entire clinical trial. These are study design decisions made at protocol authoring and are not tied to individual participant schedules or emergent events.

Event-Anchored Relative Timeline Modeling, MVM Requirements, and Mock Example

- Also known as...the USDM Model Chapter 4: Sub-timeline

Problems We Saw: Event-Anchored Relative Timelines

Sub-timeline

- A sub-timeline reflects a more detailed sample or assessment scheme that can be found in:
  - an assessment specific SoA
  - footnotes
  - protocol narrative text
- Sub-timelines can be referred to from an
  - Activity
  - ScheduledActivityInstance
- Timings and instances are specific within each (sub-)timeline.
- Sub-timelines can be reused within the study design
  - For example, PK profile assessments in cross-over studies

Study Period	Screening/ Rescreening[a]	Treatment																			Notes
Scheduled Month		0					1	2				3	6					7	12	18	To calculate visit windows, assume 1 month=28 days
Scheduled Day	-28 to -1	1		2	3	8	29	57		58	59	64	85	169		170	171	176	197	337	505	
Permitted Visit Window		n/a						±2 weeks						±2 weeks								Permitted window related to Day 1 vaccination.
				±6hr		±1 d	±2 d			±6hr		±1 d	±2 d			±6hr		±1 d	±2 d	±2 wk	±4 wk	Permitted window based on latest vaccination
Predose or Postdose		Pre	0hr	Post				Pre	0hr	Post				Pre	0hr	Post						
Administrative/Study Procedures																						
Informed Consent	X																				Includes optional Additional Research Consent Section 5.1, 8.1.1, 8.1.1.3
Optional Informed Consent for Blood for	X																				Section 8.1.1.2

- Weak linkage to the main SOA.
- Relative Positions (Pre-Dose, 0-hour/At-Dose, Post-Dose) around a dosing event is defined inconsistently.
- Sample collection timepoints like “0.5, 1, 2, 4, 8, 12, 24 hours post-dose” exist only as narrative often found in footnotes.
- Unclear Windows defined around the sample collection timepoints.
- Day-crossing ambiguity: Longer collection timepoints (e.g., 24, 48, 72 hours) can span multiple calendar days with no explicit Study Day recorded in the Global and Matin Time Frame.
- Underspecified event context
  - Anchoring events (“first dose”, “last dose”, “SOI/EOI”) are described in text but not captured as structured reference events.

Vaccine SOA Mock Example – Dose Administrations Trigger Sub-Timeline for Time-Sensitive Activities

Mock Vaccine SOA

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*DISPOSITION AND MILESTONE EVENT		FIRST DOSE					PLANNED END OF TREATMENT			PLANNED END OF TRIAL
VISIT LABEL	SCR VST							SFU VST	SFU VST	SFU VST
VISIT NUMBER	V1									
STUDY MONTH		M1	M2	M3	M4	M5	M6	M7	M8	M10
*MONTH INTERVAL CONVENTION		NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS	NOMINAL MONTH, 30 DAYS
*MONTH INTERVAL RANGE		SD1 to SD30	SD31 to SD60	SD61 to SD90	SD91 to SD120	SD121 to SD150	SD151 to SD180	SD181 to SD210	SD211 to SD240	SD271 to SD300
*STUDY DAY		SD1	SD60	SD90	SD120	SD150	SD180	SD210	SD240	SD300
*WINDOW			-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY	-14/+14 DAY
*WINDOW ANCHOR TYPE			SD	SD	SD	SD	SD	SD	SD	SD
*ANCHOR EVENT		FIRST DOSE	SECOND DOSE				THIRD DOSE			
*EVENT-ANCHORED SUB-TIMELINE FLAG		YES	YES				YES			
Scheduled Activities										
Study Vaccine Administered		X	X				X			
Informed Consent	x									
Medical History	x									
Physical Exam	x	x	x	x	x	x	x			x
Urinalysis	x	x	x	x	x	x	x			x
Safety Laboratory Blood draw	x	x	x	x	x	x	x	x	x	x
Serology Blood draw	x	x	x	x	x	x	x	x	x	x

Trial Completion Planning = used for trial-level milestones or rules that define the scheduled conclusion of the entire clinical trial. These are study design decisions made at protocol authoring and are not tied to individual participant schedules or emergent events.

Sub-timeline: PK Sampling, Gene Expression Profile at Pre/Post- Dose Administrations

3-Regimen Vaccine: Event-Anchored Subtimeline for time-sensitive activities

*** this can also be used as the primary timeline for early phase studies, same modeling and structure.**

*STUDY PERIOD:	INTERVENTION																	
*ANCHOR EVENT	FIRST DOSE						SECOND DOSE						THIRD DOSE					
*EVENT-ANCHORED RELATIVE POSITION	PRE-DOSE	AT-DOSE	POST-DOSE	POST-DOSE	POST-DOSE	POST-DOSE	PRE-DOSE	AT-DOSE	POST-DOSE	POST-DOSE	POST-DOSE	POST-DOSE	PRE-DOSE	AT-DOSE	POST-DOSE	POST-DOSE	POST-DOSE	POST-DOSE
*EVENT-RELATIVE TIME OFFSET	1 HOUR	0 HOUR	2 HOUR	4 HOUR	8 HOUR	24 HOUR	1 HOUR	0 HOUR	2 HOUR	4 HOUR	8 HOUR	24 HOUR	1 HOUR	0 HOUR	2 HOUR	4 HOUR	8 HOUR	24 HOUR
*WINDOW			+15 MINUTE	+1 HOUR	+2 HOUR	+2 HOUR			+15 MINUTE	+1 HOUR	+2 HOUR	+2 HOUR			+15 MINUTE	+1 HOUR	+2 HOUR	+2 HOUR
*WINDOW ANCHOR TYPE			ERTO	ERTO	ERTO	ERTO			ERTO	ERTO	ERTO	ERTO			ERTO	ERTO	ERTO	ERTO
*STUDY DAY	SD1					SD2	SD60					SD61	SD180					SD181
Scheduled Activities																		
Serum/Plasma PK Sampling	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Gene Expression Blood Sampling	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
xxx Acitvity	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

- **Removing Footnotes where Possible**: Used for time-sensitive activities such as PK/PD sampling, infusion safety monitoring
- **Stable Conceptual Model for Reusable Study Design**: can also be used as the Early Phase **Primary** timelines: e.g, phase 1 dose modification timeline.
- **Captures Day Overlaps**: Especially important for full representation because the 24-hour time point falls onto the next study day—typically not **included** in the main timetable because it is not a day-level visit but a **granular** sample collection time point.
- **Directional Clarity**: Relative Position consistently indicates/represents the "**directionality**" of time positions around an anchor event, thus keeping the offsets "unsigned."
  - Avoid "double negative" naming convention: e.g., Pre-Dose, –2 Hour
- **Error Prevention**: Clear representation of windows and anchoring logic helps **prevent unnecessary protocol deviation**s for clustered assessments and sample collection time points.

Oncology and Additional Study Design Requirements

We performed a similar analysis for Oncology SOAs using Study Cycle and Cycle Days:

- Consulted with our oncology clinical group.
- "Participant-event driven" ad-hoc schedules play a major role in oncology study design (i.e. Subject-level disposition events triggering 'contingency' planning, often referred to as 'unplanned/unscheduled' visits)
- Infinite study cycles as a "risk-adaptive" strategy.
- Study Day is an impractical time reference in Oncology/Cyclic Study Design due to truncated timelines or gaps causing "calendar drift."

- Cyclic SOA Analysis and MVM requirements, plus a MOCK Oncology SOA, are in the "Backup Slides" section of this presentation.
- Additional Study Design Requirements, Concerns and Considerations are also in the "Backup Slides" section.

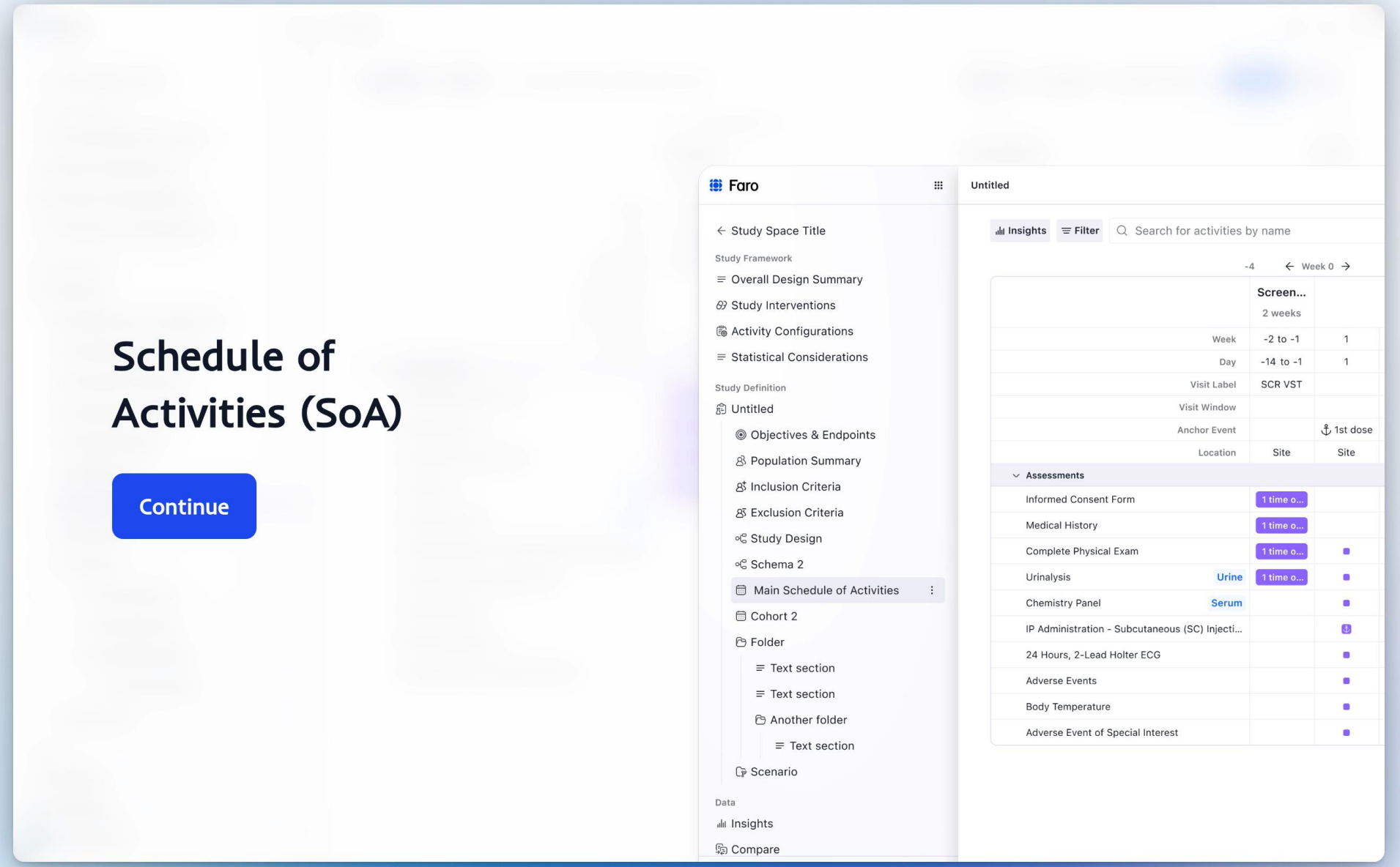
Execution & Automation

Layer 5: Transforms metadata into operational reality through automation

"We have a structured SOA – how can it be turned into a living, automated study schedule that runs itself?"

When the Theoretical Becomes Reality

Demonstration:



Let's Work Together

Your Voice Matters

Sponsors, regulators, solution providers, CROs, and sites — the SOA standard will only succeed with broad industry participation. Connect with CDISC to help shape the path forward.

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SoA Project

- Define Industry-Aligned Implementation Practices for SOA
- Bridge the Gap Between USDM Model and Real-World Use
- Standardize SOA Representation to Enable Consistency and Automation
- Drive Cross-Industry Collaboration and Adoption

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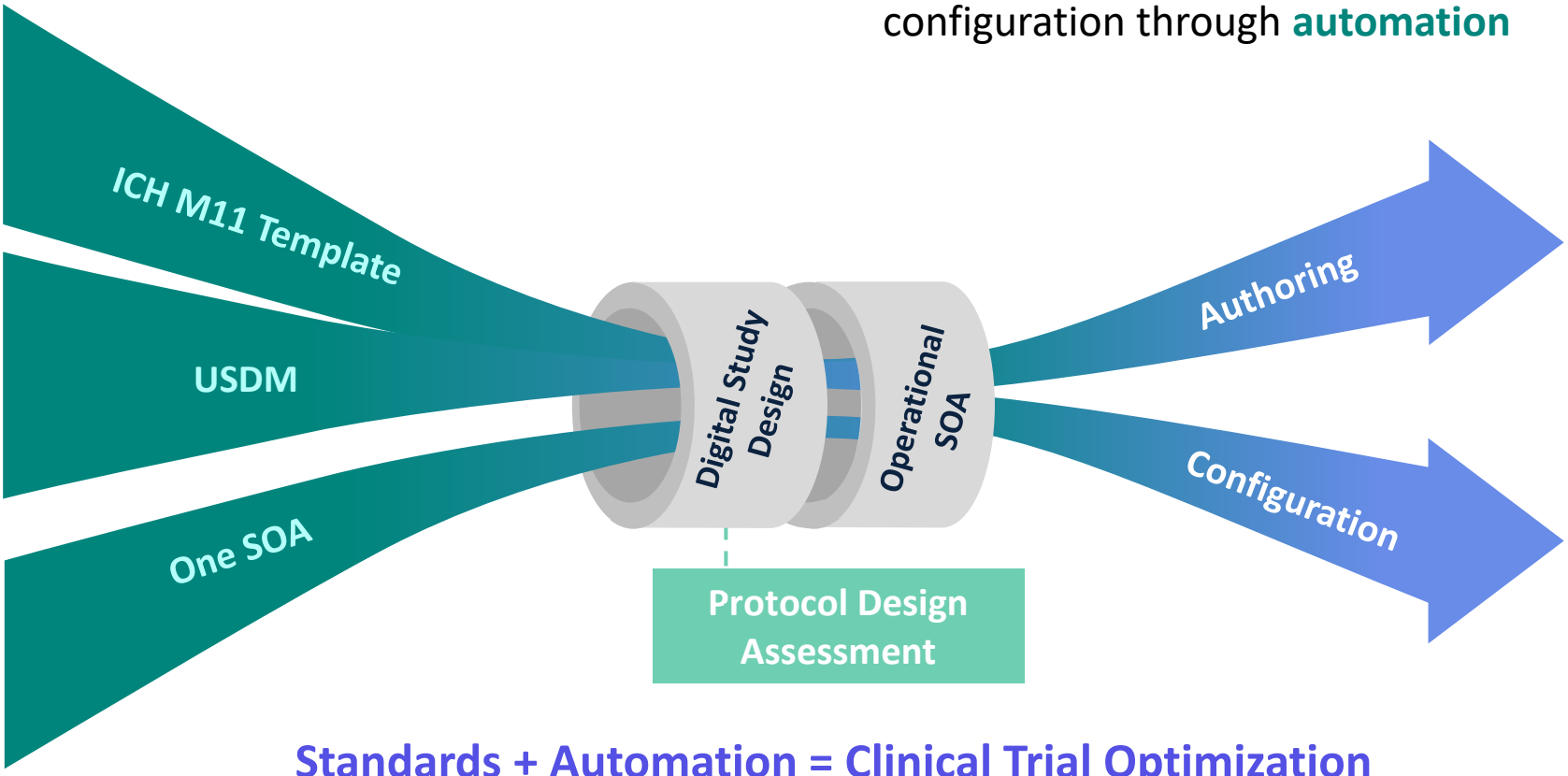
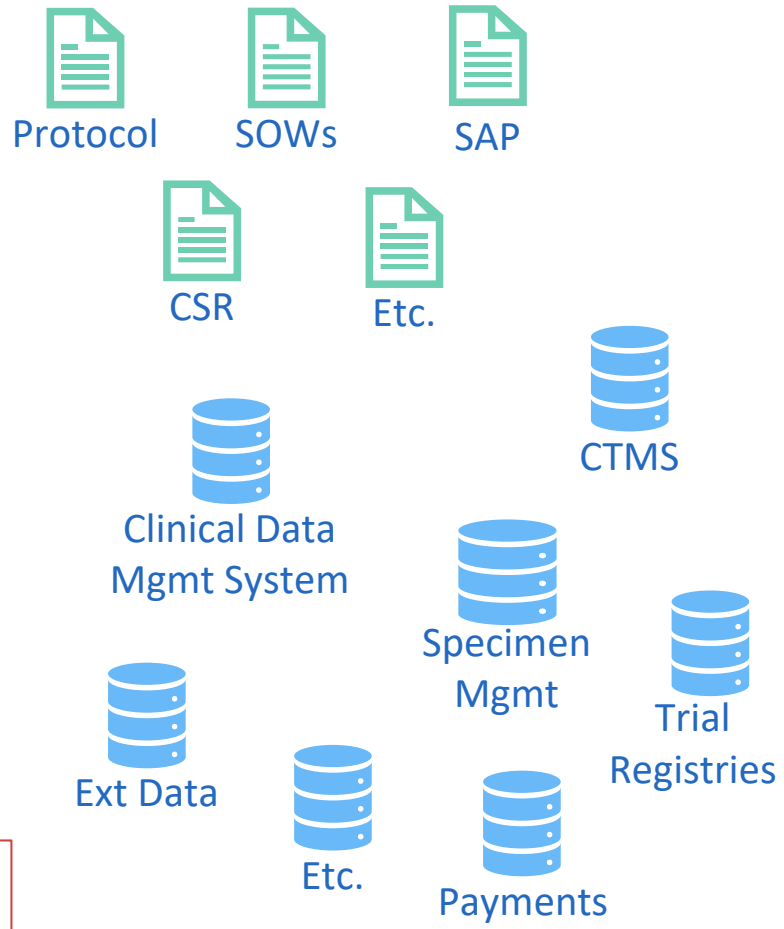
One standard. One model. One connected ecosystem.

Standardized SOA → Digital Study Design → Faster Startup → Higher Quality Trials & Less Burden for All

Changing the Authoring Paradigm

Standards compliant data-driven **study design enables clinical trial optimization** by accelerating authoring and tool configuration through **automation**





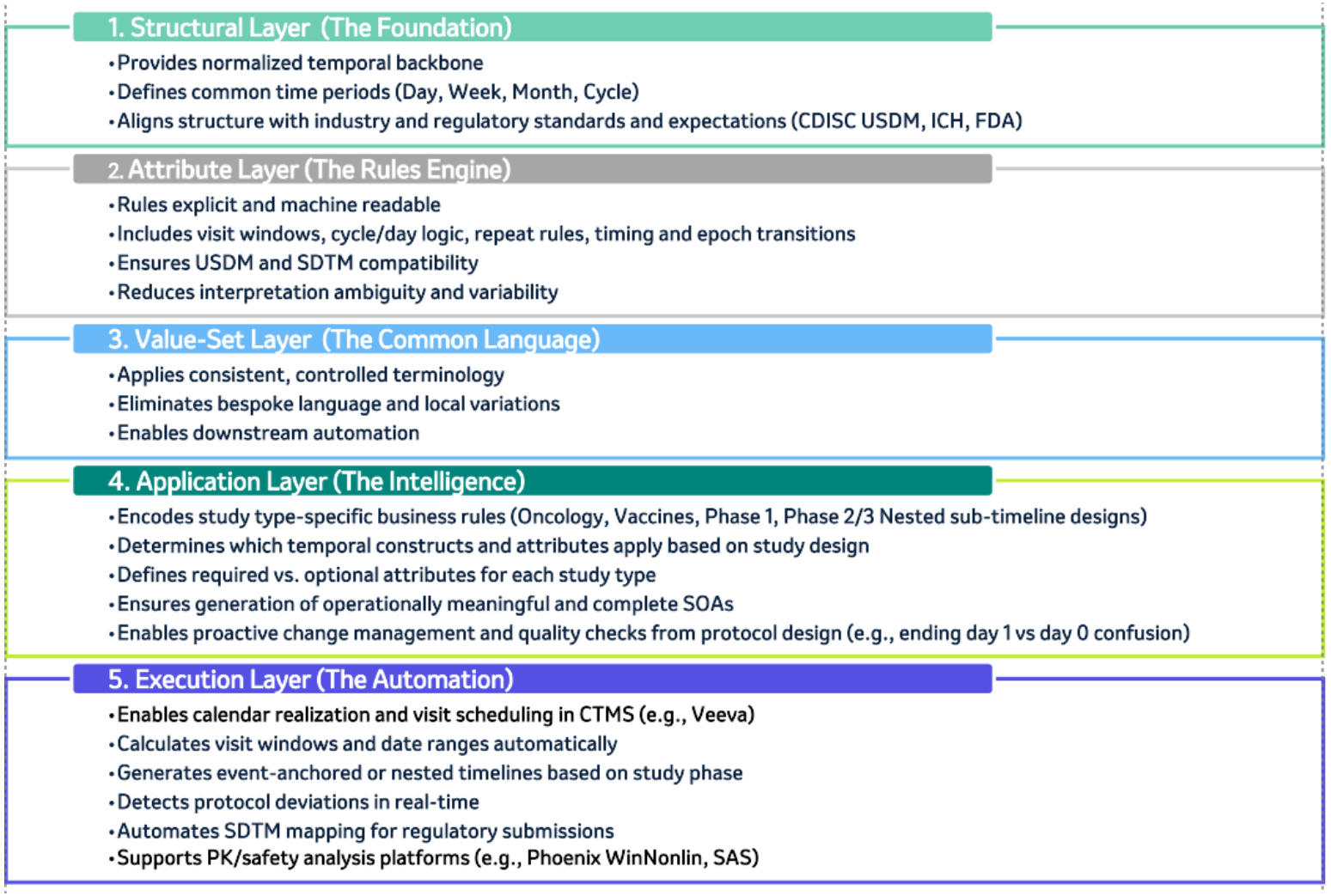
Standards + Automation = Clinical Trial Optimization

Thank You! Questions?

Backup Slides

Development Approach Overview – The SOA Ontology and Metadata Model

Five-layer architecture that transforms protocol content from static documents into computable, standards-based metadata.
Normalized time backbone (days, weeks, months, cycles) aligned with CDISC and regulatory expectations.
Machine-readable rules and controlled terminology to remove ambiguity and local variation.
Study-specific intelligence layer that encodes business rules and best practices across phases and therapeutic areas.
Execution and automation that turns metadata into real study calendars, quality checks, SDTM outputs, and analysis-ready data.



SOA Model Controlled Terminology

SOA Common Attributes	Synonym	Definition
STUDY DAY	SD	A numeric identifier indicating the planned day number in the study timeline on which a protocol-scheduled visit or activity is intended to occur.
STUDY WEEK		A protocol-scheduled and defined seven-day period during which study activities occur, numbered sequentially throughout the trial.
STUDY MONTH		A protocol-scheduled and defined month-based interval during which study activities occur, numbered sequentially throughout the trial. Month duration and boundaries are determined by the protocol's Month Interval Convention, which specifies either fixed-length nominal months or variable-length calendar months.
MONTH INTERVAL CONVENTION		The protocol-defined rule specifying how study days are grouped into month-based intervals, either as fixed-length nominal months (e.g., 28, 29, or 30 days) or variable-length calendar months aligned to actual dates.
MONTH INTERVAL RANGE		The range of study days encompassed by a specific month interval, expressed as the first and last Study Day of that interval (e.g., Month 1 = SD1-SD30, Month 2 = SD31-SD60).
STUDY CYCLE		A protocol-scheduled and defined repeating period of specified duration during which a predetermined sequence of interventions and assessments occurs, numbered sequentially throughout the study.
CYCLE DURATION		The protocol-scheduled and specified time interval that defines the standard length of a repeating study cycle, determining when one cycle ends and the next begins.
CYCLE DAY	CD	A relative day within a protocol-scheduled and defined Study Cycle, numbered sequentially from the start of each cycle, on which study activities occur.
CONTACT MODE		The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device) associated with the study.
ENVIRONMENTAL SETTING		The environment/setting where the event, intervention, or finding occurred.

Shared Naming Convention

SY helps with mapping

DEF locks in meaning and ensures cross-study consistency

- ✓ Visit Label Values
- Visit Number Values
- Disposition_Milestone Event
- Event-Triggered Visit Logic
- Anchor Event Values
- Event-Anchor Rel Position Value
- Event-Rel Time Offset Values
- Event-Anchor Subtime Flag Value
- Study Month Values
- Month Interval Convention
- Study Week Valus

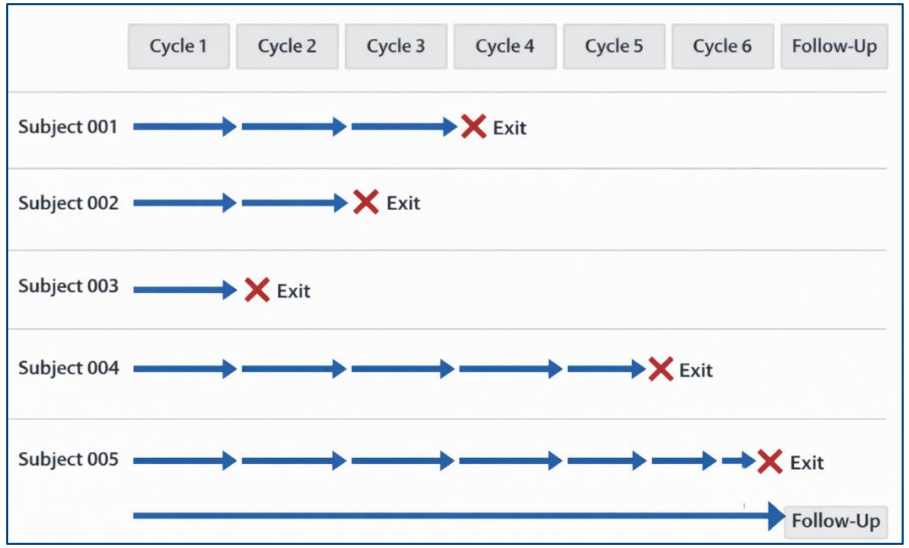
SOA Facing Term (Preferred Term)	Synonym	Draft Definition
SCR VST	Screen Visit	A protocol-scheduled study visit conducted prior to treatment initiation to assess eligi and collect pre-treatment data.
BL VST	Baseline Visit	A protocol-scheduled study visit during which pre-treatment reference values are established for efficacy and safety parameters, serving as the comparative benchmark all subsequent treatment-period assessments.
RIN VST	Run-In Visit	A protocol-scheduled study visit conducted during a pre-randomization run-in period, during which participants may receive placebo, active comparator, or standard therap assess tolerability, verify eligibility criteria, ensure protocol adherence, or establish sta baseline values before randomization to study treatment arms.
TRT VST	Treatment Visit	A protocol-scheduled study visit conducted during active study treatment for intervent administration and participant assessment.
SAFETY VST	Safety Evaluation Visit; Safety Monitoring Visit; Safety Assessment Visit	A protocol-scheduled study visit specifically designated for comprehensive safety evaluations, including adverse event assessment, laboratory tests, vital signs, and oth safety-related procedures, typically occurring at regular intervals during treatment or a dose modifications.
EFFICACY VST	Efficacy Assessment Visit; Efficacy Evaluation Visit	A protocol-scheduled study visit specifically designated for measuring treatment effectiveness through efficacy endpoints and response assessments, typically occurri regular intervals during and after treatment.

Cyclic SOA Requirements

Cyclic SOA - What We Saw in Cycle-based SOAs

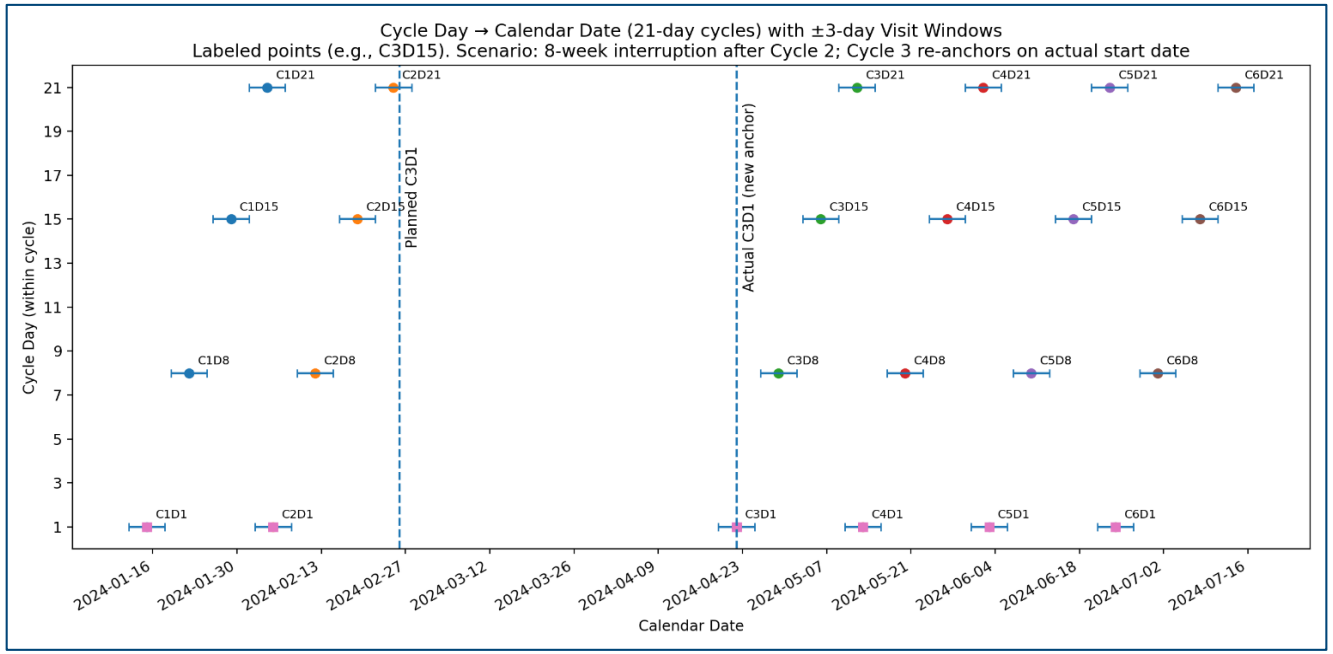
Cyclic SOAs and Oncology-Type Study Designs

- Many oncology and other treatment trials organize SOAs by **Study Cycle and Cycle Day** (e.g., C1D1, C1D8, C2D1).
- Progression through cycles is **conditional**, not fixed—each new cycle depends on toxicity, labs, and ongoing benefit.
- Follow-up often depends on **emergent events** like "last dose," which can occur in any cycle.
- We reviewed real oncology SOAs and spoke with our Oncology Group to understand how cycles and event-anchored timelines are currently represented.



Conditional timelines (typical in oncology):

- Progression to the next cycle is **not guaranteed**; each cycle is **earned** based on predefined criteria (toxicity, labs, clinical benefit).
- The timeline **unfolds dynamically** for each patient (e.g., one patient completes 6 cycles, another stops after Cycle 1 due to toxicity).



Treatment Interruption Occurs Often:

- Y-axis: Cycle Day (1–21)
- X-axis: Calendar Date
- Dots: Target visit dates (**CD 1, 8, 15, 21** are plotted for each cycle)
- Horizontal whiskers: **±3 days** allowable window
- Dashed lines: **Planned C3D1** vs **Actual C3D1 (new anchor)** after the interruption

Cyclic SOA– Examples (Oncology)

Scroll down to see the example description.

Scheduled Planning = used for protocol-defined, prospectively planned visits and milestones that form the standard schedule of activities applicable across participants.

Participant Event-Driven Planning = used for participant-specific visits that are not part of the fixed protocol schedule, but are instead triggered by a participant-level emergent event or condition (e.g., adverse event, withdrawal, pregnancy, actual last dose) that varies in timing across participants.

Trial Completion Planning = used for trial-level milestones or rules that define the scheduled conclusion of the entire clinical trial. These are study design decisions made at protocol authoring and are not tied to individual participant schedules or emergent events.

*STUDY PERIOD:	SCREENING		INTERVENTION																			FOLLOW-UP	
STUDY PERIOD RANGE	SD-35 to SD-1																						
*STUDY PLANNING SCOPE	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Scheduled Planning	Participant Event-Driven Planning	Participant Event-Driven Planning	Trial Completion Planning
VISIT LABEL	SCR VST	SCR VST																			ETD VST	SFU VST	
VISIT NUMBER	V1	V2																					
*DISPOSITION AND MILESTONE EVENT			FIRST DOSE																	PLANNED END OF TREATMENT	EARLY PERMANENT DISCONTINUATION OF TREATMENT		PLANNED END OF TRIAL, LAST PARTICIPANT LAST VISIT
*STUDY CYCLE	N/A		CYCLE1			CYCLE2			CYCLE3			CYCLE4			CYCLE5			CYCLE6						
*CYCLE DURATION	N/A		4 WEEK			4 WEEK			4 WEEK			4 WEEK			4 WEEK			4 WEEK						
*CYCLE DAY	N/A		CD1	CD8	CD22	CD1	CD8	CD22	CD1	CD8	CD22	CD1	CD8	CD22	CD1	CD8	CD22	CD1	CD8	CD22	CD28				
*WINDOW				-2/+2 DAY	-2/+2 DAY		-2/+2 DAY	-2/+2 DAY		-2/+2 DAY	-2/+2 DAY		-2/+2 DAY	-2/+2 DAY		-2/+2 DAY	-2/+2 DAY		-2/+2 DAY	-2/+2 DAY				
*WINDOW ANCHOR TYPE				CD	CD		CD	CD		CD	CD		CD	CD		CD	CD		CD	CD				
*STUDY DAY			*SD1																					
*ANCHOR EVENT			FIRST DOSE			SECOND DOSE			THIRD DOSE			FOURTH DOSE			FIFTH DOSE			SIXTH DOSE				LAST DOSE	LAST DOSE	
*EVENT-ANCHORED RELATIVE POSITION																						POST-DOSE	POST-DOSE	
*EVENT-RELATIVE TIME OFFSET																						7 DAY	30 DAY	
*EVENT-ANCHORED SUB-TIMELINE FLAG			YES			YES			YES			YES			YES			YES				NO	NO	
SCHEDULED ACTIVITIES																								
Height	x	x																x						This is NOT a visit, do not populate activities here.
Weight	x	x	x			x			x			x			x			x						
12-Lead ECG	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	
Hematology	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	
Physical Exam	x	x	x			x			x			x			x			x						

Cyclic SOA– Examples

Event-Anchored Sub-Timeline for Oncology Study

*Event-Anchored Subtimeline for Sparse PK Sampling Example (Note: This is a truncated example for illustrative purposes and does not include all study infusions.)															
*STUDY PERIOD:	INTERVENTION														
*STUDY CYCLE	CYCLE1					CYCLE1					CYCLE2				
*CYCLE DAY	CD1					CD8					CD1				
*ANCHOR EVENT	FIRST DOSE, SOI			FIRST DOSE, EOI		SECOND DOSE, SOI			SECOND DOSE, EOI		FOURTH DOSE, SOI			FOURTH DOSE, EOI	
*EVENT-ANCHORED RELATIVE POSITION	PRE-INFUSION	AT-SOI	POST-INFUSION	AT-EOI	POST-INFUSION	PRE-INFUSION	AT-SOI	POST-INFUSION	AT-EOI	POST-INFUSION	PRE-INFUSION	AT-SOI	POST-INFUSION	AT-EOI	POST-INFUSION
*EVENT-RELATIVE TIME OFFSET	1HOUR	0 HOUR	2 HOUR	0 HOUR	2 Hour	1HOUR	0 HOUR	2 HOUR	0 HOUR	2 Hour	1HOUR	0 HOUR	2 HOUR	0 HOUR	2 Hour
*WINDOW			+0.5 HOUR		+3 Hour			+0.5 HOUR		+3 Hour			+0.5 HOUR		+3 Hour
*WINDOW ANCHOR TYPE			ERTO		ERTO			ERTO		ERTO			ERTO		ERTO
Scheduled Activities															
PK Blood Sampling	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	*This is 1-hour pre SOI	*This is SOI	*This is 2-hour post-SOI (during infusion)	*This is EOI	*This is 2-hour post EOI										

Other Requirements and Recommendations

-Change Management Opportunities

Change Management Opportunities

Other Rules

Ending the Day 0, Week 0, Month 0 debate

- Always anchor on Study Day 1, not Day 0
  - CDISC SDTM (and FDA validation rules) do not support Day 0; timelines go from Day -1 directly to Day 1.
  - Mixing Day 0 and Day 1 across protocols breaks cross-study comparability (e.g., “7 days after first dose” becomes Day 7 vs Day 8) and complicates AE window definitions and reporting.
- Reduce safety, operational, and mapping risk
  - Day 0 creates ambiguity in safety windows (“within 7 days” can mean Day 0–6 or Day 1–7), leading to inconsistent AE counts and potential late-reporting protocol deviations.
  - Supporting both conventions requires extra logic in all timing calculations and BARDS/SDTM mappings, increasing error risk.
- Discourage **Week 0 / Month 0**

Strengthen protocol author training & guardrails

- Embed these conventions into templates, checklists, and authoring guidance -The SOA Ontology and Metadata Model Implememntaion Guide (SOAIG).
- Use SOA validation tools at protocol design time to flag non-compliant timing patterns (Day 0 usage, missing anchors, ambiguous weeks/months) before they propagate downstream.

Schedule of Activities

Ontology and Metadata Model

Design Specifications and Implementation Guideline

Version 1.0, DRAFT (2026-02-06)

4.5 Study Day 1 vs Day 0 Considerations and Concerns

We strongly advise against using Study Day 0 in protocols.

While some protocols label the first dose day as "Day 0," this practice creates significant operational and regulatory challenges:

- **SDTM Compliance:** CDISC SDTM standards explicitly exclude Study Day 0. The SDTM timeline goes from Day -1 (before reference date) directly to Day 1 (reference date), with no Day 0. Using Day 0 in protocols creates mapping conflicts when preparing regulatory submission datasets.
- **FDA validation rules enforce this convention** - Regulatory submissions using Day 0 will trigger validation errors (FDA Study Data Validator Rules v1.6).
- **Cross-Study Comparisons:** If some protocols use Day 0 as the reference point and others use Day 1, the same timepoint (e.g., "7 days after first dose") will have different Study Day values across studies (Day 7 vs. Day 8). This makes it difficult to compare safety data, pool results, or conduct meta-analyses.
- **Safety Window Misclassification and Reporting:** Safety analyses frequently define reporting windows relative to the first administration of the study intervention, such as “AEs occurring within 7, 15, or 30 days of the first dose.” For example, if the requirement is “report AEs within 7 calendar days of dosing,” and Study Day 1 is the anchor, the window is clear: Day 1-Day 7. If a protocol uses Study Day 0, the same window becomes ambiguous and may be interpreted as Day 0-Day 6 (7

calendar days) or Day 1-Day 7 (also 7 calendar days). This means two studies with the same real timeline can produce different AE counts simply because they use different Study Day conventions. This creates avoidable inconsistency in safety summaries, pooled analyses, and cross-study comparisons. If a team miscalculates the reporting window due to Day 0/Day 1 inconsistency, it can result in late reporting (see examples below) - a protocol deviation that must be documented in the SDTM Protocol Deviations (DV) domain using terms such as:

- Reportable Safety Event(s) Reported Late