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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

Kickstarting Your DDF/USDM Journey, Lessons Learned from a Real-World Proof of Concept

Jasmine Kestemont, Managing Partner/Consultant Innovion and Head Data Acquisition, argenx
Stijn Rogiers, Head Data Integration & Standards, Data Acquisition, argenx

Speakers Bio

Jasmine Kestemont

Title: Head of Data Acquisition & Managing Partner

Organization: argenx / Innovion

Jasmine Kestemont is an entrepreneurial business leader with significant experience in both Sponsor and services organizations. After a few years of global work experience, she has returned to the area she is most passionate about, data and project management, with a special interest in data standardization and regulatory submissions. Jasmine is Head of Data Acquisition at argenx.

Jasmine Kestemont | LinkedIn

Stijn Rogiers

Title: Head Data Integration & Standards

Organization: argenx

Stijn joined argenx in June 2022 as Head Data Integrations and Standards (Data Acquisition). Argenx is a fast-moving and growing Biotech company. Stijn has 25+ years of experience both at CRO, Pharma industry and Technology. He worked 5 years at SGS Life Sciences (CRO), 10 years within Janssen (Johnson & Johnson) and 7 years at SAS Institute (analytics leader) before moving to argenx. Stijn is also a member of the European CDISC Coordinating Committee (E3C).

Stijn Rogiers | LinkedIn

Agenda

1. Why it Matters & The Framework
2. The argenx Journey (2023-now)
3. The Participant Journey Use Case
   - ✓ *Intro and PoC in Action*
4. Recap & Lessons Learned
5. Kickstarting your own journey

Why it matters:
From Documents to Data

Clinical trials today are built around static documents. Digital Data Flow changes the starting point.

Document-Centric (Today)

- Protocol is a Word document — the only source of truth
- Downstream systems re-author the same content from scratch
- Each handoff introduces duplication, delays, and risk of error
- Amendments ripple slowly and inconsistently
- No machine-readable representation exists

Data-Centric, Digital and Automated (Tomorrow)

- Protocol is a structured digital object from day one
- Documents are generated outputs, not the source
- Downstream systems consume the same USDM directly
- Amendments propagate automatically and traceably
- Machine-readable — ready for automation and AI

The Framework:
A Harmonized Foundation for Protocol Digitization

1

USDM v4.0

Released June 2025

CDISC **Unified Study Definitions Model** providing the data standard for machine-readable study definitions

2

ICH M11 Guideline

Global harmonized protocol template establishing a common structure for clinical trial protocols

3

Technical Specification

Clinical Implementation Template and Technical Spec **bridging the gap from standard to implementation**

> *Together, these provide a harmonized framework for digitizing protocol content — but **many organizations still struggle with how to begin practical implementation.***

Our Journey:
From Exploration to Real-World Implementation

DDF Workshop

at PHUSE EU Connect

NLP / LLM Probe

Exploratory Extraction from Protocols

(PHUSE Paper)

Framework Ready

USDM v4.0 & PoC Partner Selection

PoC Build

SoA Digitization & Participant Journey rendering

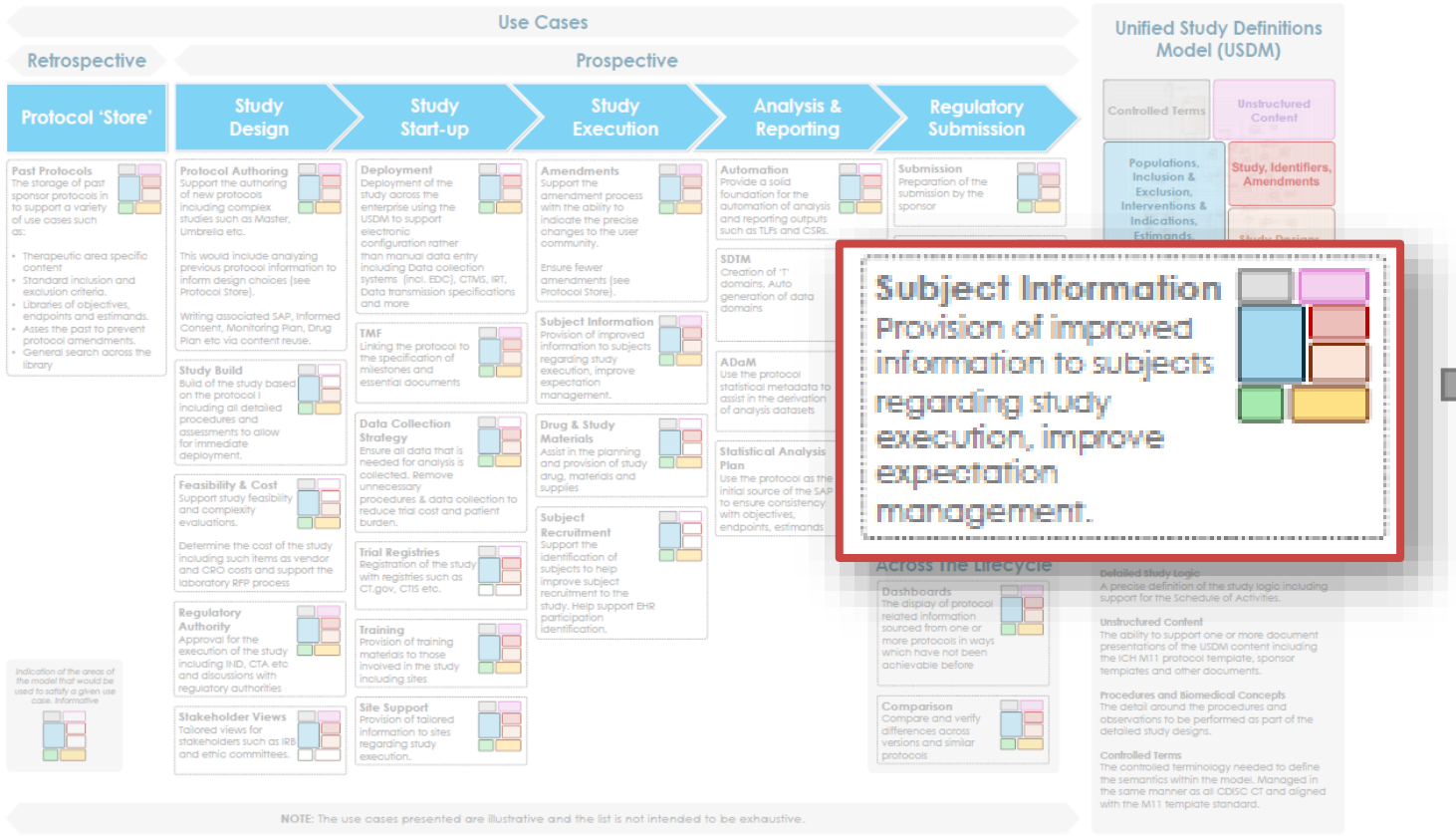
Exec. Management Approval

Presentation + Approval Next Steps + Knowledge Sharing (start change management)

Conference Sharing and Preparing for Next Steps

Key Insight: *Starting small with exploratory phases built organizational knowledge and stakeholder buy-in before committing to a full PoC.*

Use Case selected for this PoC



Automation of Patient Journey based on the CTP SoA

Proof of Concept:
What We Set Out to Build

> *Scope: Convert existing protocols Schedule of Activities into a **USDM-compliant digital model**, then generate a **Trial Participant Journey view** — a tangible output both **sites, patients and argenx** can use.*

1

Parse

Extract the SoA table, footnotes, and timing from Word protocol(s)

2

Map

Translate protocol concepts into USDM classes and attributes

3

Enrich & Refine

Make SoA machine-readable: Resolve footnote semantics, ordering, and missing structure

4

Generate

Produce the Participant Journey views and downstream outputs

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Deep Dive:
Making the SoA truly Machine-Readable

A standard SoA table in a protocol document contains implicit knowledge that must be made explicit for digital processing.

Non-Visit Activities

Daily diaries, weekly injections, and home-based activities are described across visits or/and in footnotes rather than as structured visit data.

These need to be extracted and modeled as distinct encounters in the USDM.

Assessment Ordering

The **order of questionnaires and assessments** is buried in footnote text (e.g., 'administer in the following order: A, B, C...').

This must become explicit sequencing metadata and conditional rules..

Composite Measures

Some listed assessments are actually **composite scores calculated from other assessments,** not site/patient activities.

These require different modeling to avoid confusing site staff, participants and Clinical Trial Team members /Extended team.

WHAT WE BUILT

The Participant Journey in Action

From digital SoA to visual, actionable outputs

Parse and Map - CPT Document

1

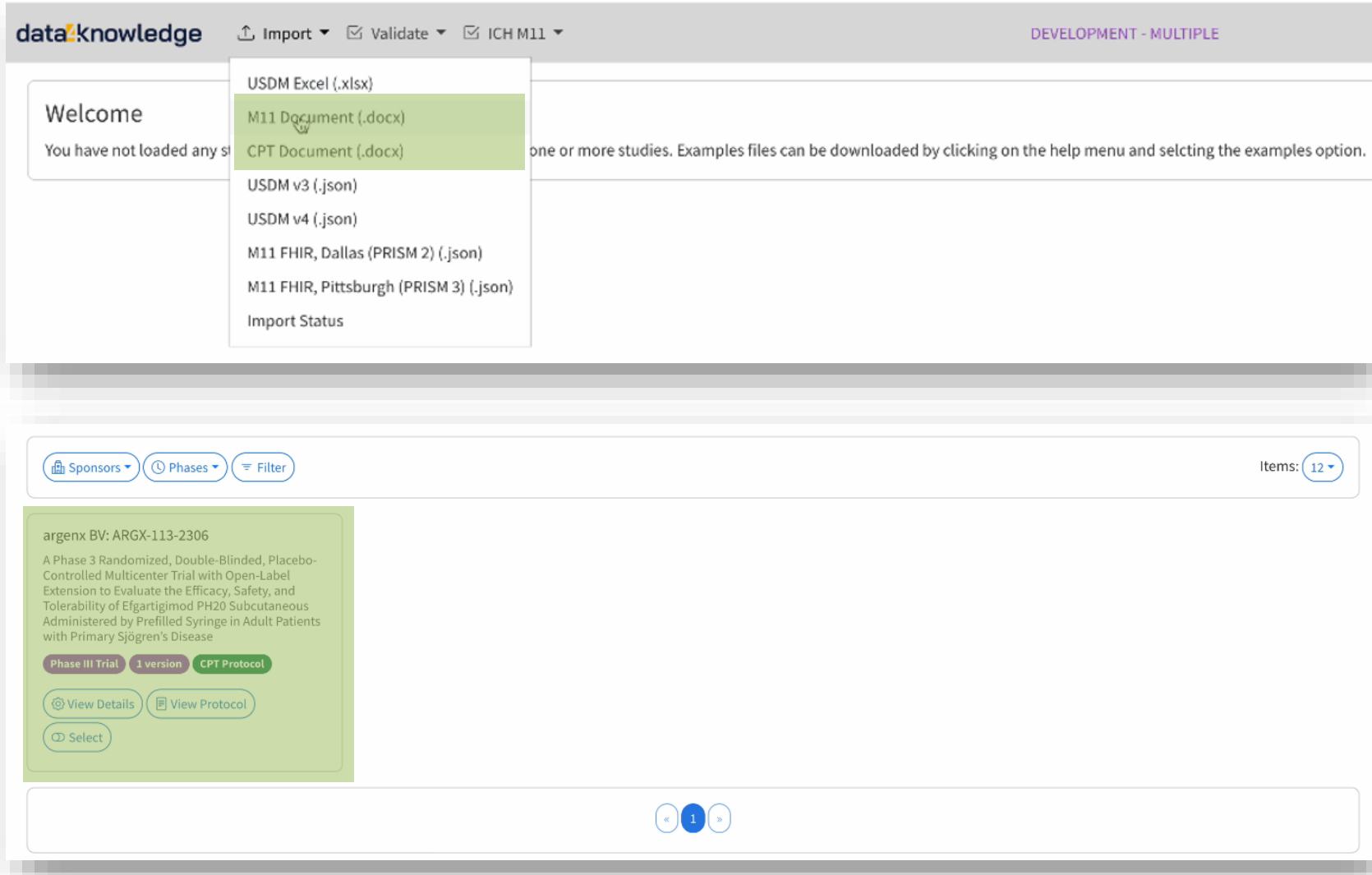
Parse

Extract the SoA table, footnotes, and timing from Word protocol(s)

2

Map

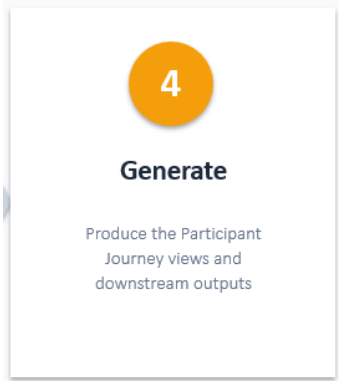
Translate protocol concepts into USDM classes and attributes

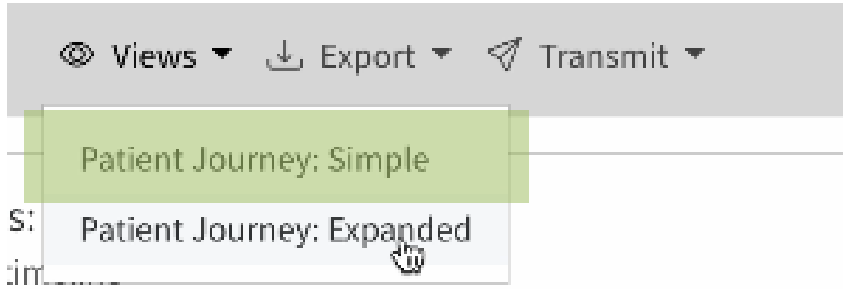


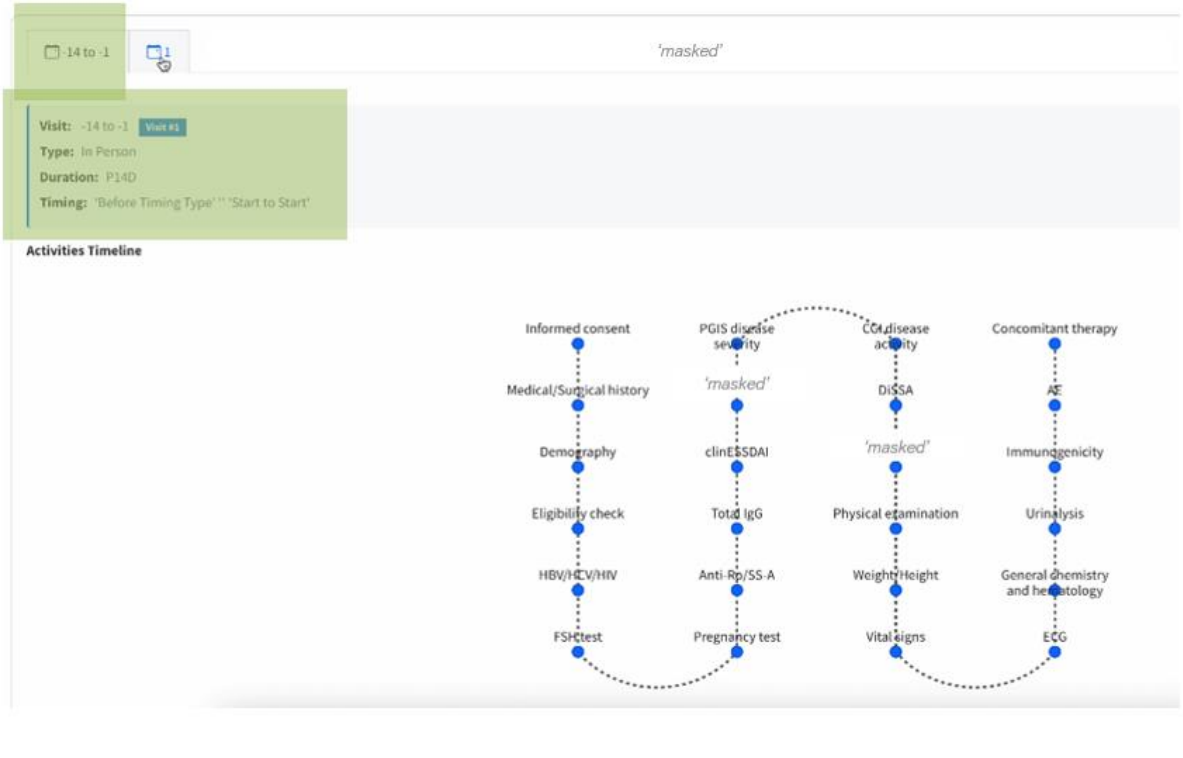
SoA – Main Timeline

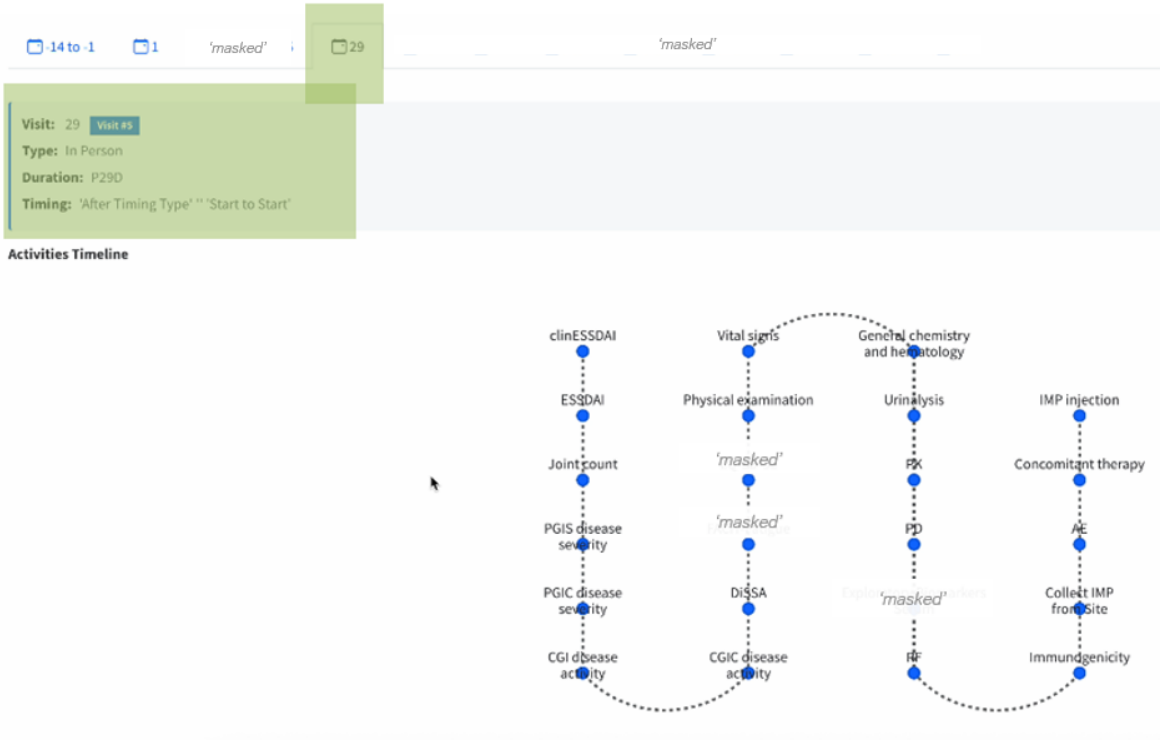
	SCR	BL	Double-blinded treatment period										
	SCR	BL	W1	'masked'									
	-14 to -1	1	8	'masked'									
			-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day	-2..+2 day
IMP will need to be collected from sites at least once every 8 weeks, even if an on-site visit is not mandated at this time. All activities (safety and efficacy assessments, predose blood sampling) will be completed before administering the IMP injection.													
Eligibility/BL only													
Informed consent	X												
Medical/Surgical history	X												
Demography	X												
Eligibility check	X	X											
Randomization		X											
HBV/HCV/HIV	X												
FSH test	X												
Pregnancy test	X	X											X
Anti-Ro/SS-A	X												
Total IgG	X												
Efficacy													
clinESSDAI	X	X			X		X		X		X		X
ESSDAI		X			X		X		X		X		X
STAR							X		X		X		X
CRESS							X		X		X		X

Participant Journey

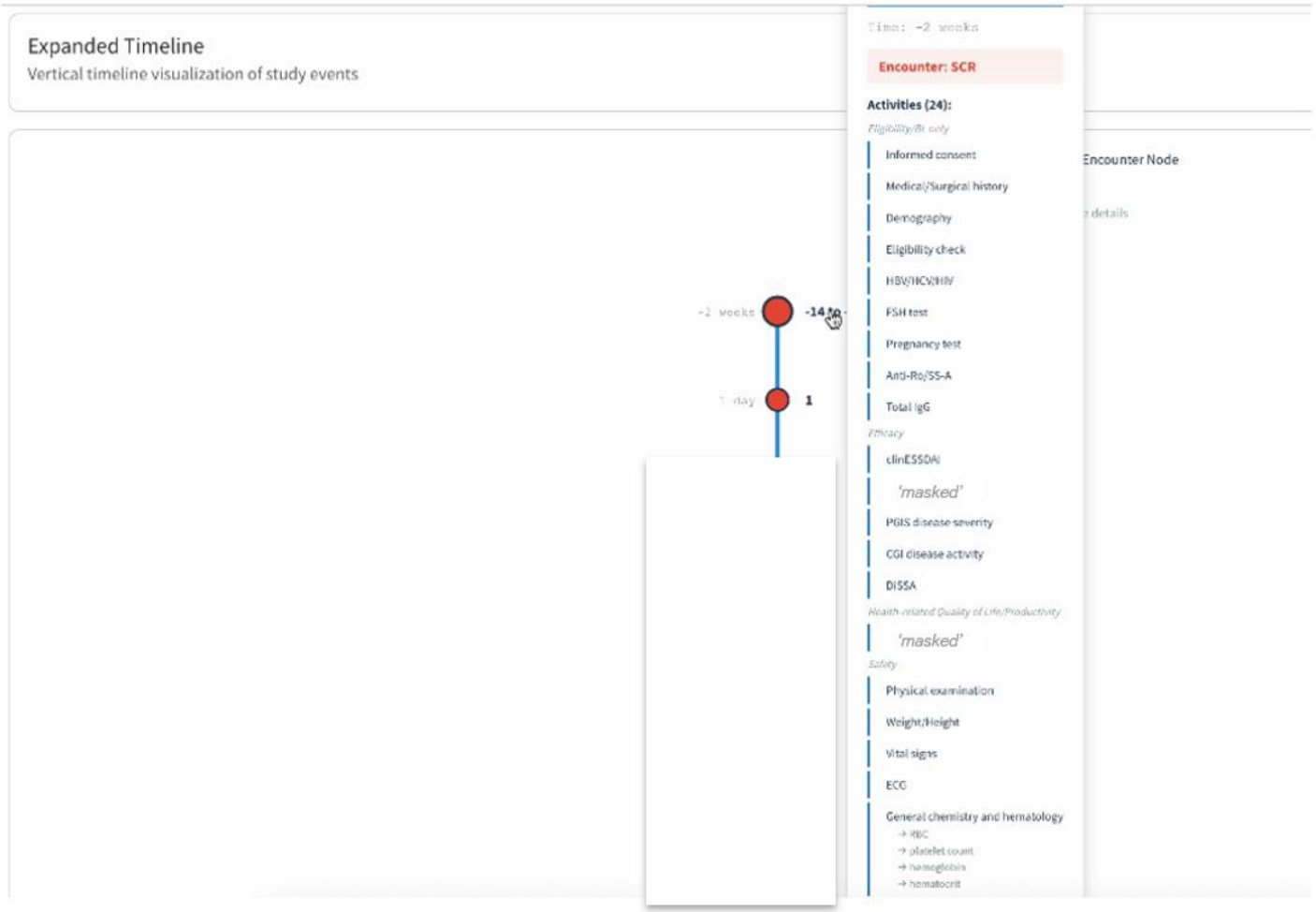


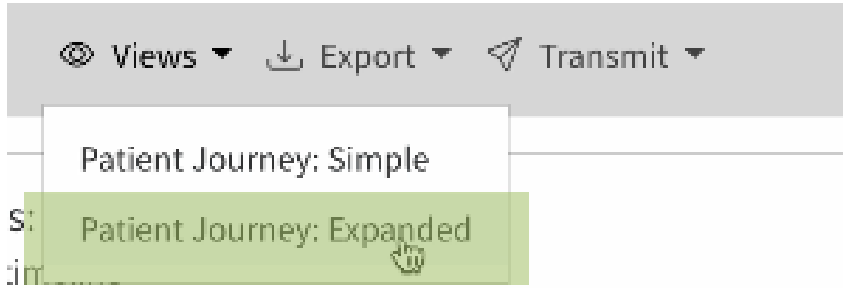




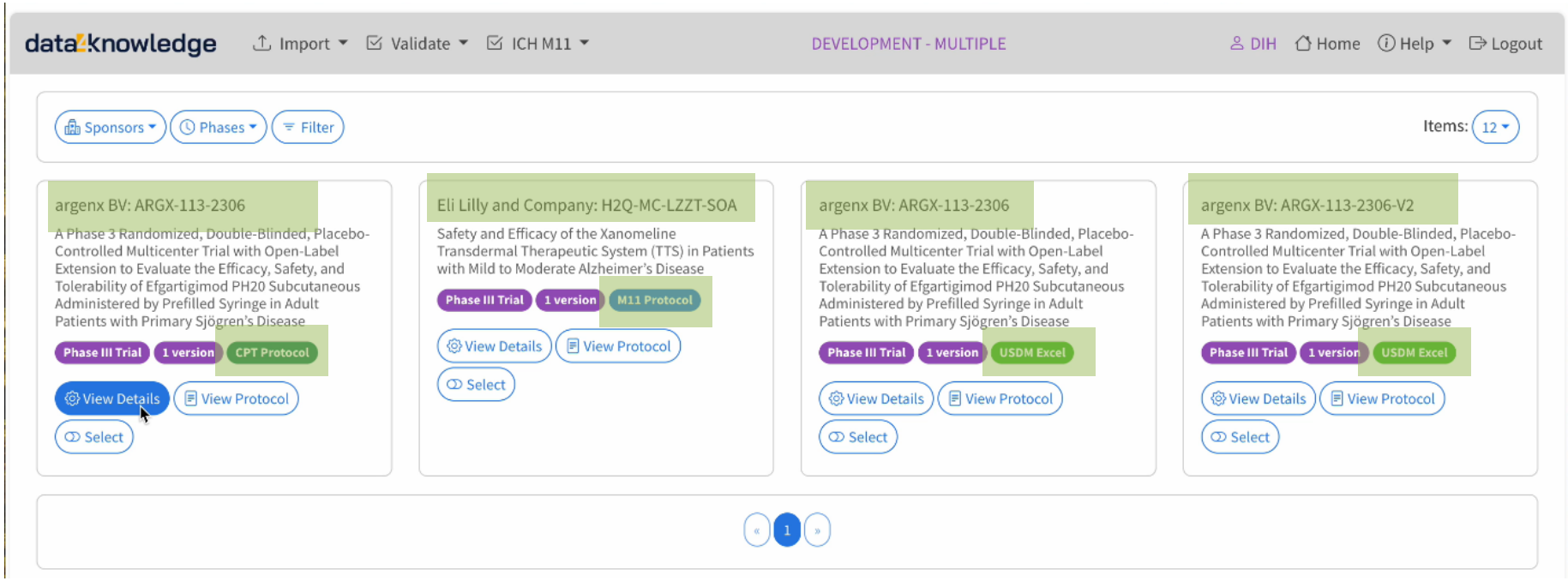


Participant Journey





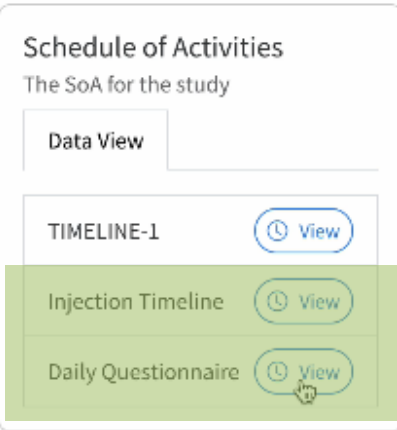
Enrich & Refine - USDM



3

Enrich & Refine

Make SoA machine-readable: Resolve footnote semantics, ordering, and missing structure



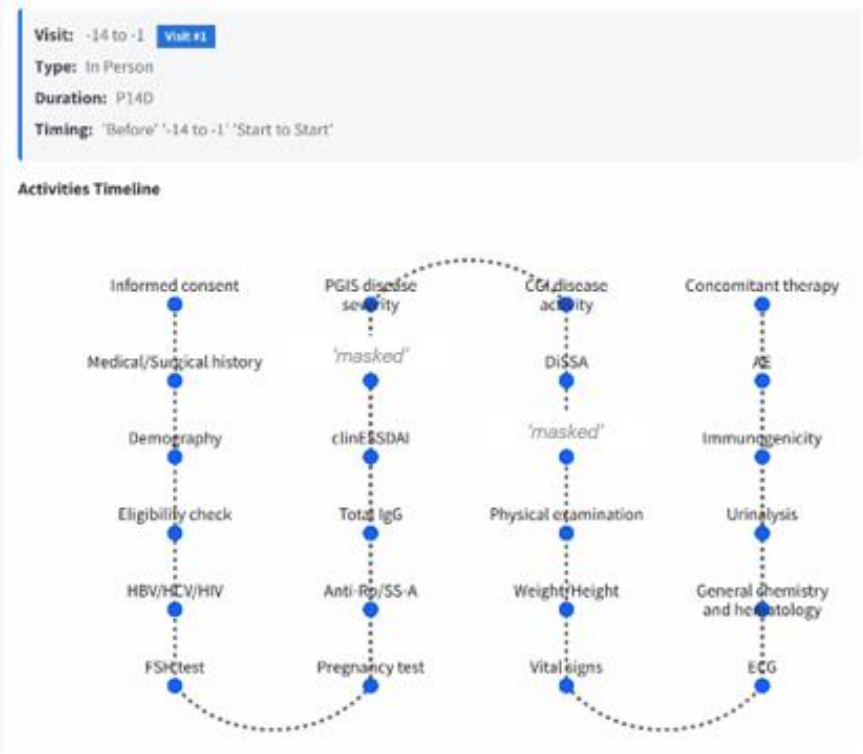
Descriptions in SoA about non-visit activities

1. Patient Diary & IMP → update USDM (make machine readable)

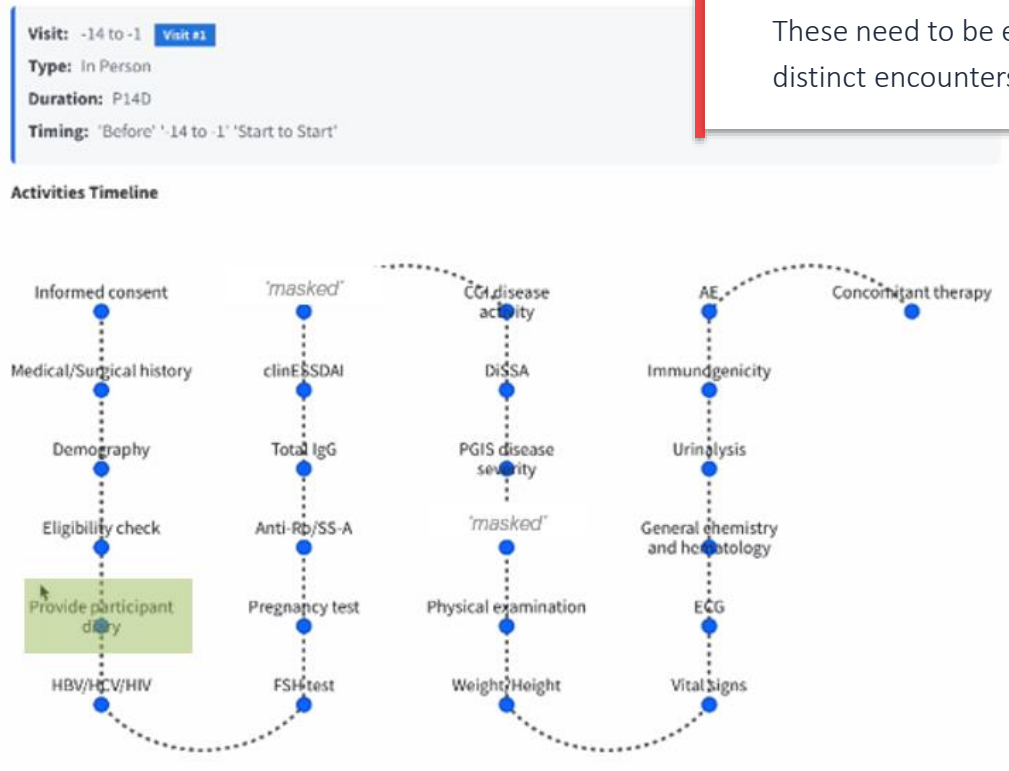
	SCR	BL	Double-blinded treatment period												
			Study Weeks												Other visits
	SCR	BL	W1	"masked"										IMP D/C[a]	SFV[b]
Study Day	-14 to -1[c]	1	8	"masked"										N/A	N/A
Window (days)			±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	N/A	±3
DiSSA[i]	*Daily Patient Diary*													X	
IMP injection		*Weekly Injections (at site and at home)*													

Enrich & Refine - USDM

Before



After



Non-Visit Activities (diary example)

Daily diaries, weekly injections, and home-based activities are described across visits or/and in footnotes rather than as structured visit data.

These need to be extracted and modeled as distinct encounters in the USDM.

Descriptions in SoA about non-visit activities

2. ESSDAI-related lab tests (missing) → update USDM (make machine readable)

	SCR	BL	Double-blinded treatment period											Related sections
			Study Weeks										Other visits	
	SCR	BL	W1	'masked'								IMP D/C[a]	SFV[b]	
Study Day	-14 to -1[c]	1	8	'masked'								N/A	N/A	
Window (days)			±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	±3	Related sections
Efficacy														
clinESSDAI[g,h]	X	X			X		X		X		X		X		Section 8.2.1.1
ESSDAI[g,i]		X			X		X		X		X		X		Section 8.2.1.1
STAR							X		X		X		X		Section 8.2.2.6
CRESS							X		X		X		X		Section 8.2.2.7

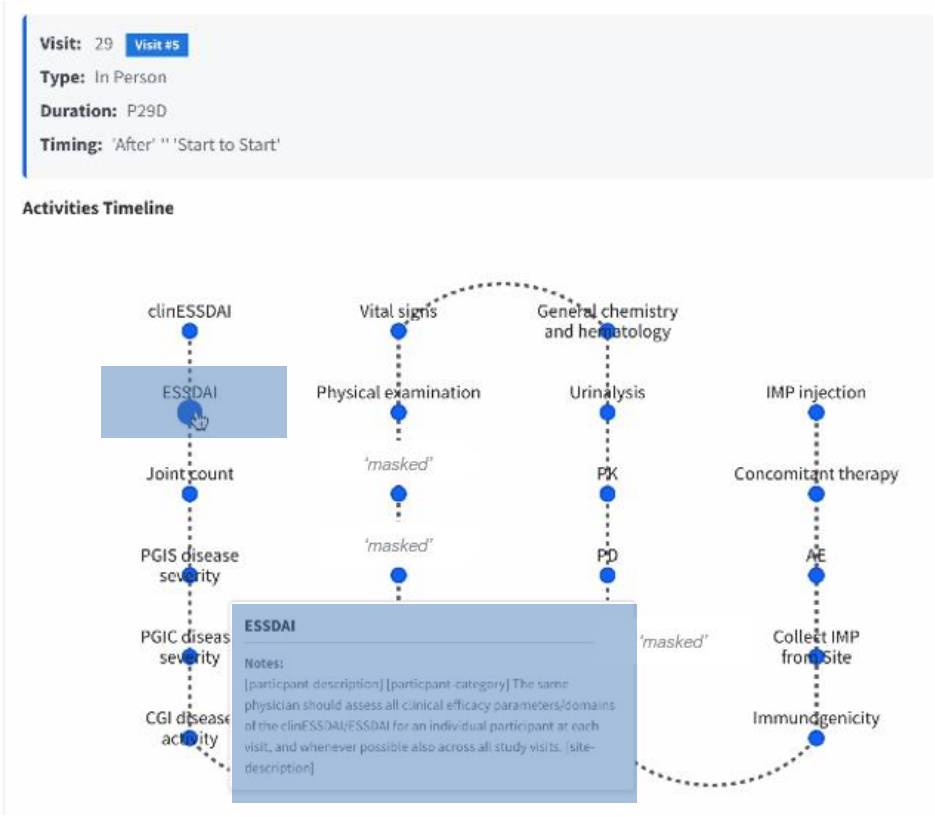
g ESSDAI-related laboratory tests of the biological domain include serum protein electrophoresis (clonal component and gammaglobulins), and serum measurement of cryoglobulins, C3, C4, and CH50. The biological domain will be blinded, and sites will score the ESSDAI without it. Standard hematology assessments for hemoglobin and cell counts (RBC, platelets, lymphocytes, neutrophils) will support the (clin)ESSDAI score calculation.

Enrich & Refine - USDM

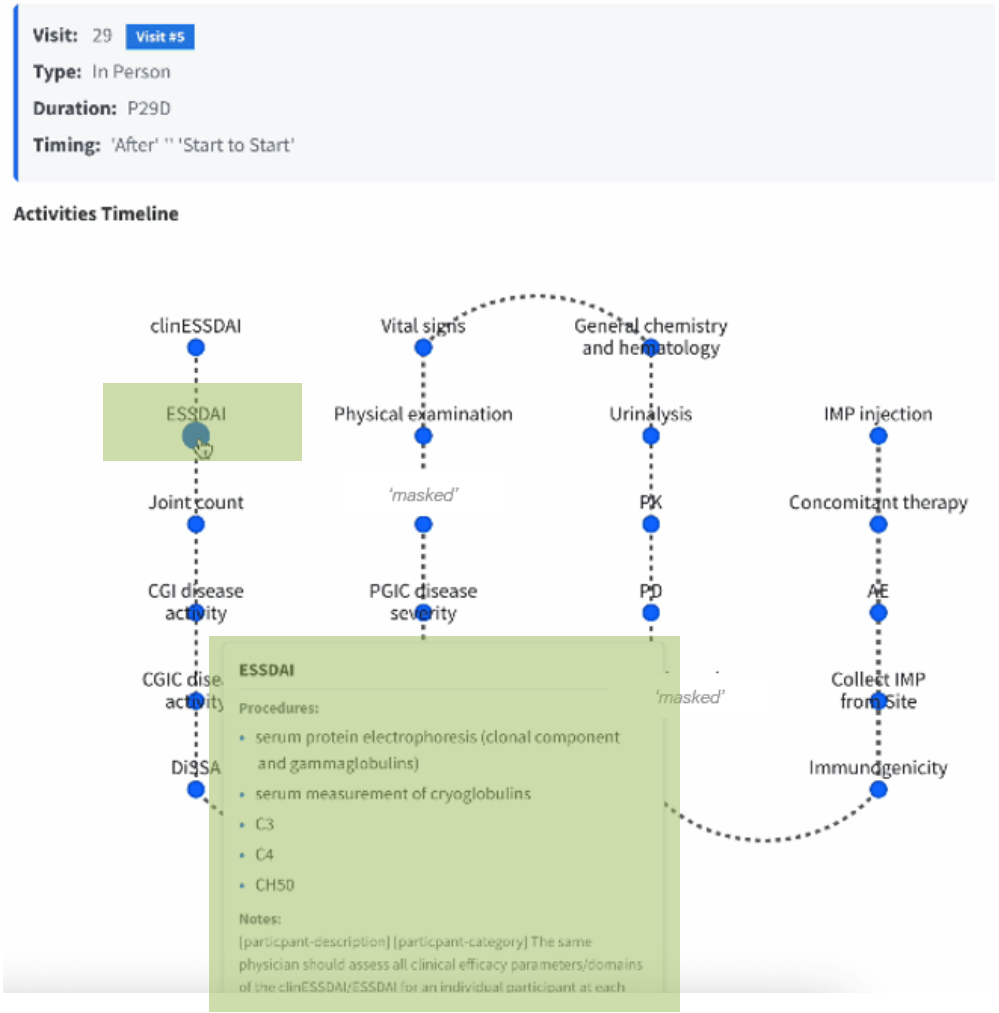
ESSDAI example

Structured visit data (procedures) iso footnotes.

Before



After



Descriptions in SoA about non-visit activities

3. Order of (assessments) Questionnaires → update USDM (make machine readable)

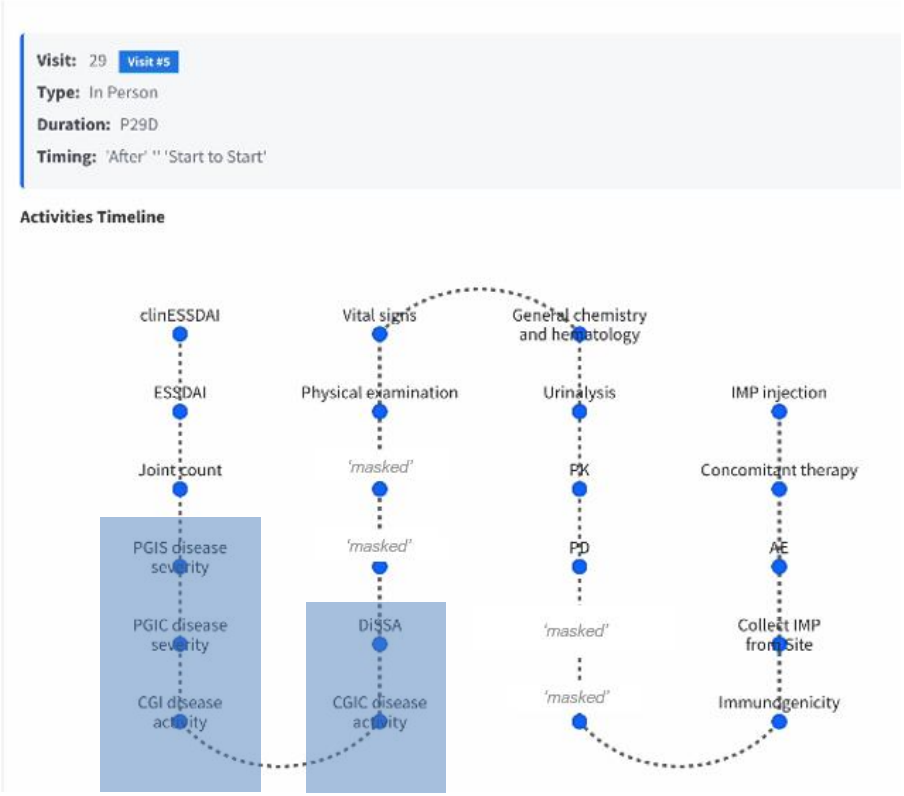
	SCR	BL	Double-blinded treatment period													Related sections
			Study Weeks												Other visits	
	SCR	BL	W1	'masked'										IMP D/C[a]	SFV[b]	
Study Day	-14 to -1[c]	1	8	'masked'										N/A	N/A	
Window (days)			±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	N/A	±3	Related sections
Efficacy																
'masked'		X					X		X		X		X	X		Section 8.2.3.3
PGIS disease severity	X	X			X		X		X		X		X	X		Section 8.2.3.4
PGIC disease severity					X		X		X		X		X	X		Section 8.2.3.5
DiSSA[i]	'masked'													X		Section 8.2.3.1
'masked'		X			X		X		X		X		X	X		Section 8.2.3.2
Health-related Quality of Life/Productivity[i]																
		X					X		X		X		X	X		Section 8.10.3
'masked'	X	X			X		X		X		X		X	X		Section 8.10.1
		X							X				X	X		Section 8.10.2

i These assessments may be completed up to 1 day before the study visit. Patient-reported outcome questionnaires will be administered in a quiet place before any other study visit procedure (with the exception 'masked' if performed prior to the visit day), and before discussions with staff about disease/treatment during on-site visit days. All activities (safety and efficacy assessments, predose blood sampling) will be completed before administering the IMP injection. As much as possible, the questionnaires will be administered in the following order: 'masked'

'masked'

Enrich & Refine - USDM

Before



After

Assessment Ordering

The **order of questionnaires and assessments** is buried in footnote text (e.g., 'administer in the following order: A, B, C...').

This must become explicit sequencing metadata and conditional rules..

Descriptions in SoA about non-visit activities

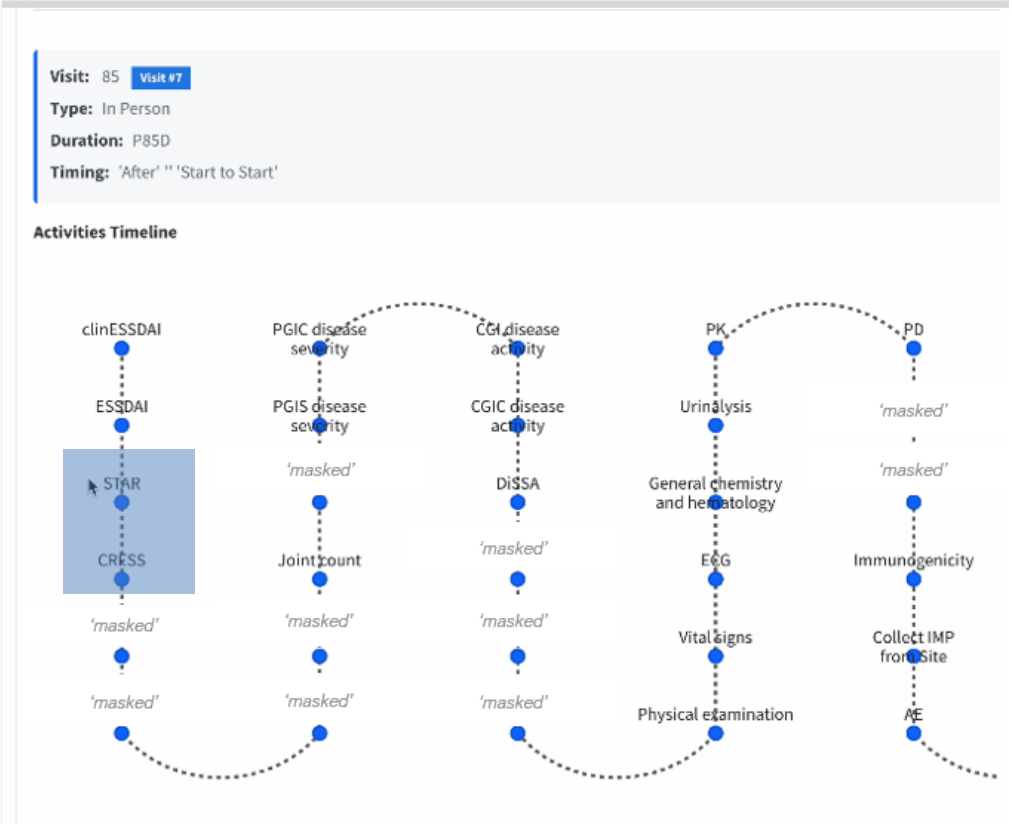
4. STAR & CRESS (composite measures; no site activities/calculations) → update USDM

	SCR	BL	Double-blinded treatment period												Related sections
			Study Weeks											Other visits	
	SCR	BL	W1	'masked'									IMP D/C[a]	SFV[b]	
Study Day	-14 to -1[c]	1	8	'masked'									N/A	N/A	
Window (days)			±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	±2	N/A	±3	Related sections
Efficacy															
clinESSDAI[g,h]	X	X			X		X		X		X		X	X		Section 8.2.1.1
ESSDAI[g,i]		X			X		X		X		X		X	X		Section 8.2.1.1
STAR							X		X		X		X	X		Section 8.2.2.6
CRESS							X		X		X		X	X		Section 8.2.2.7

- STAR and CRESS are composite measures that are a score calculated based on results from other assessments
- No extra assessment to be done by site/patient (calculation done by stats)

Enrich & Refine - USDM

Before



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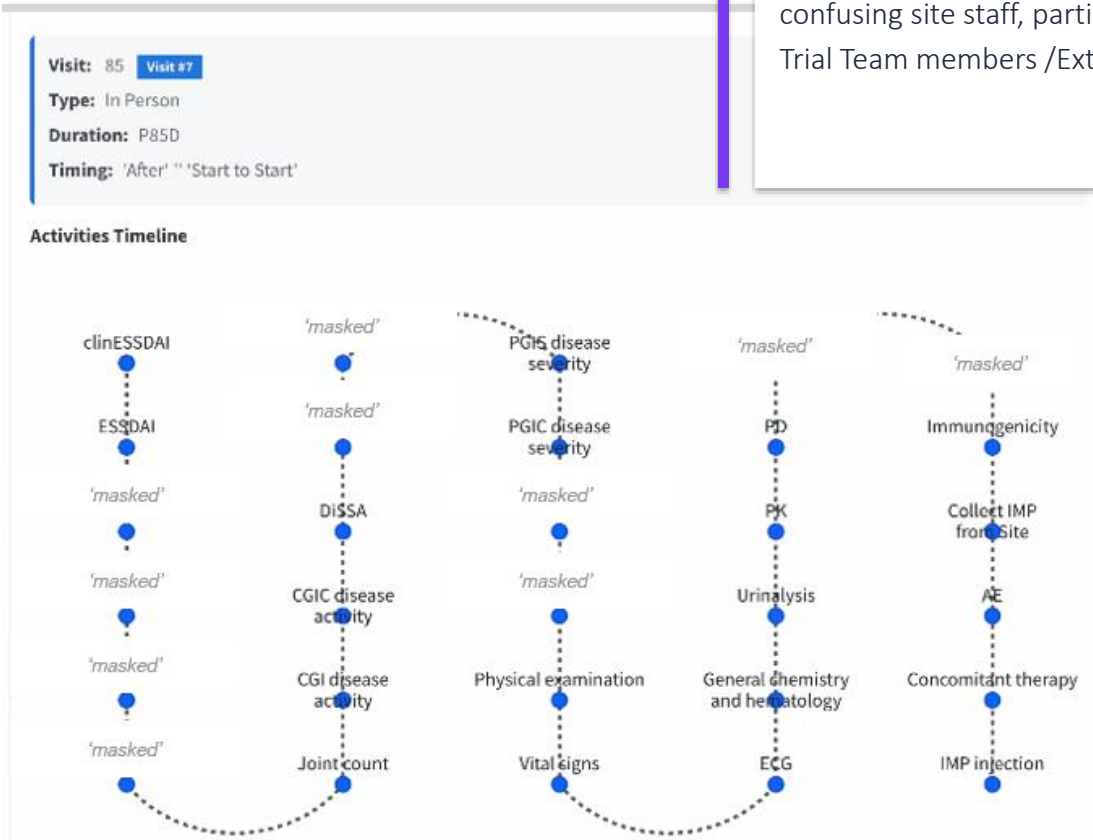


Composite Measures

Some listed assessments are actually **composite scores calculated from other assessments,** not site/patient activities.

These require different modeling to avoid confusing site staff, participants and Clinical Trial Team members /Extended team.

Outputs:
Three Views, One Source of Truth

Site-Facing View

Detailed visit-by-visit breakdown of all assessments, their required order, and timing **— giving site teams a clear visual guide for conducting each encounter.**

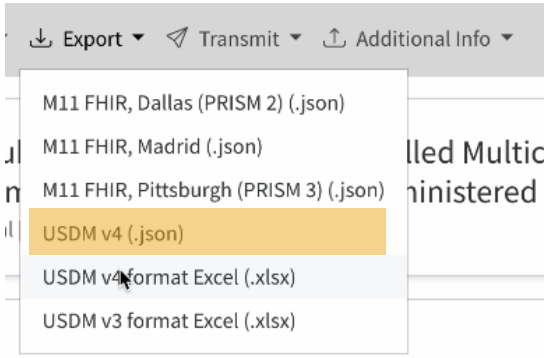
Patient-Facing View

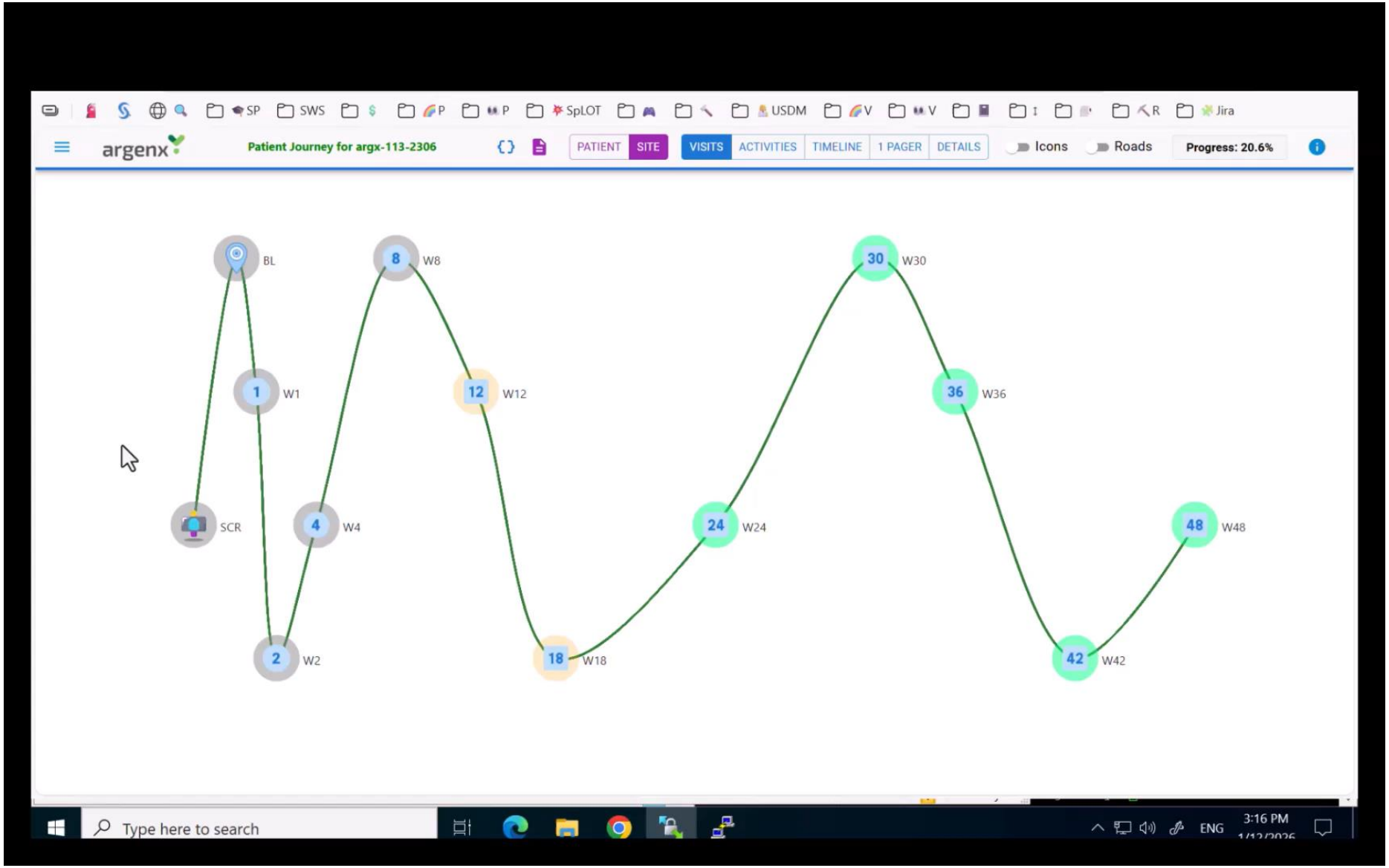
Simplified, participant-friendly overview of the study journey, showing what to expect at each visit and between visits **to improve engagement and retention.**

Timeline & One-Pager

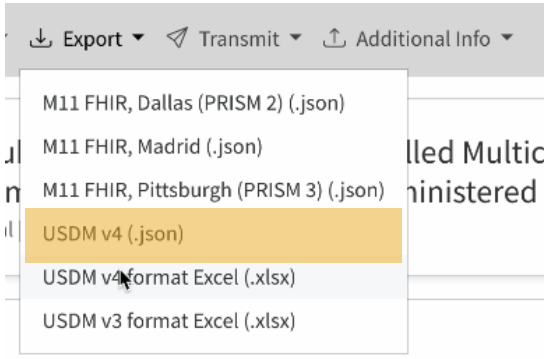
Comprehensive visual timeline consolidating the entire study schedule into a single view, ideal for IRB/EC submissions and stakeholder briefings.

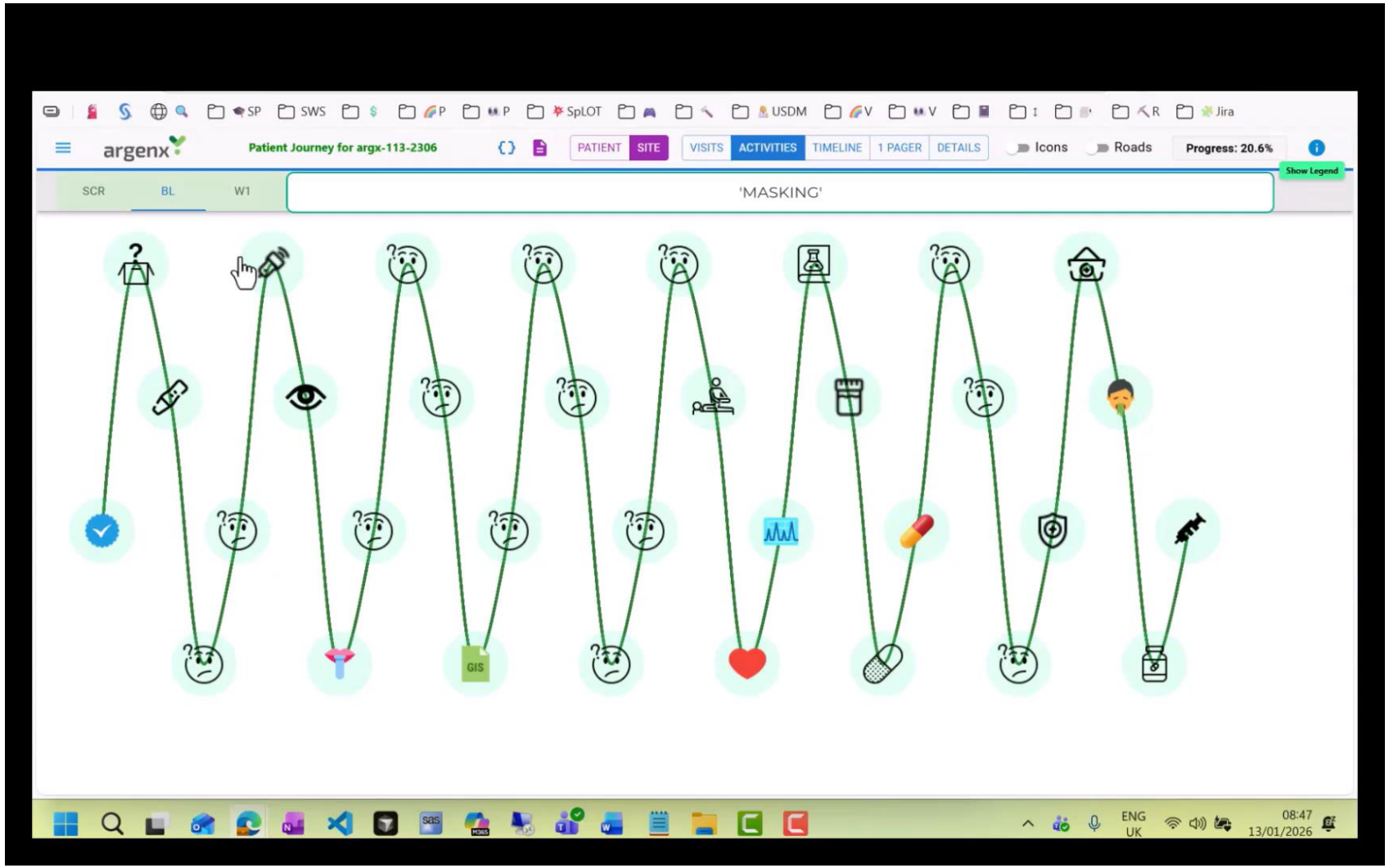
Participants Journey - Site & Patient view of "Visits"



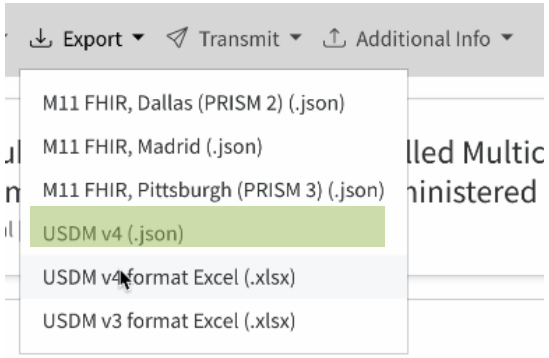


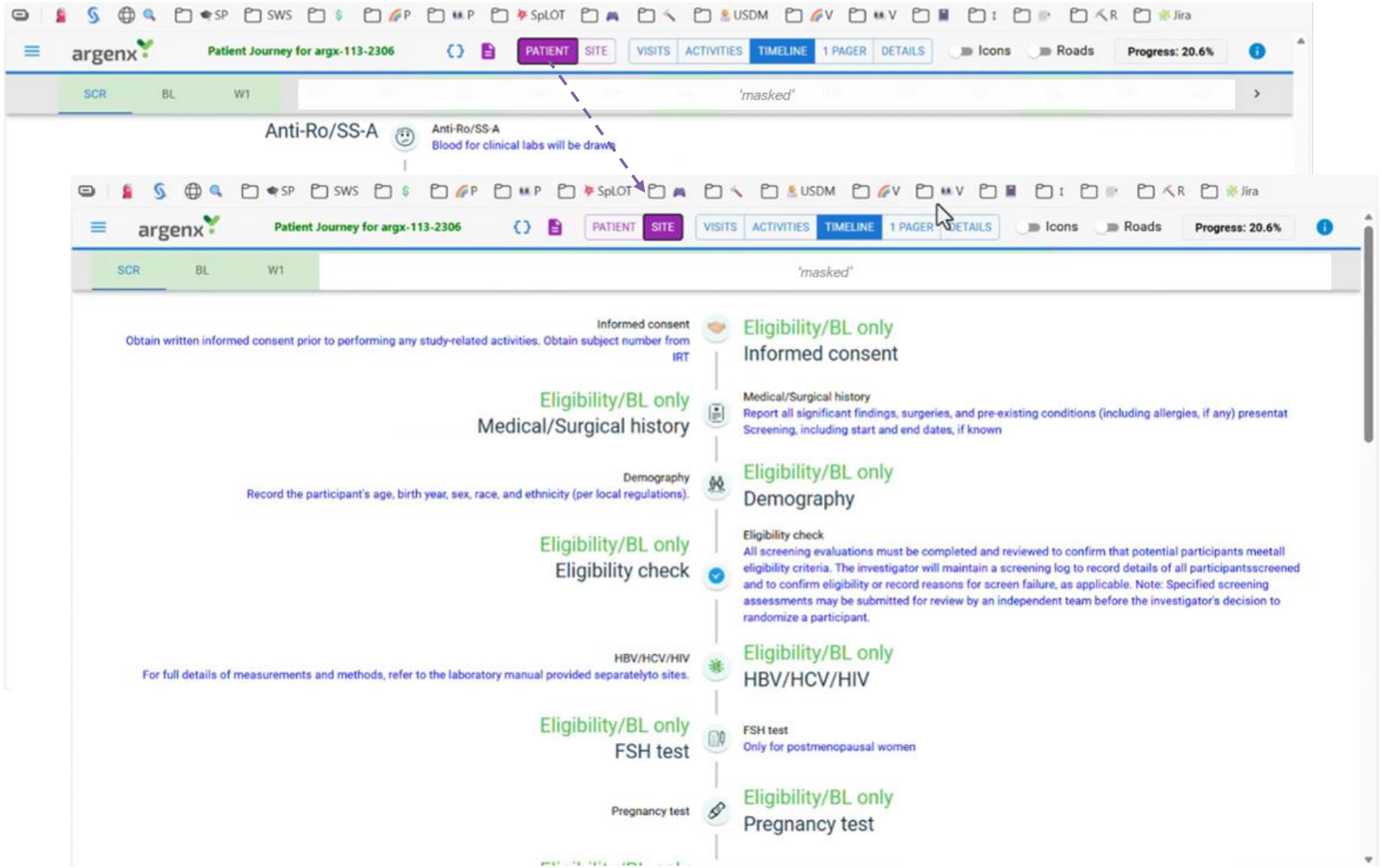
Participants Journey - Site & Patient view of “Activities”



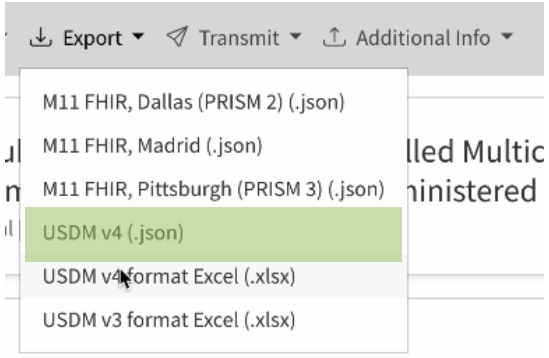


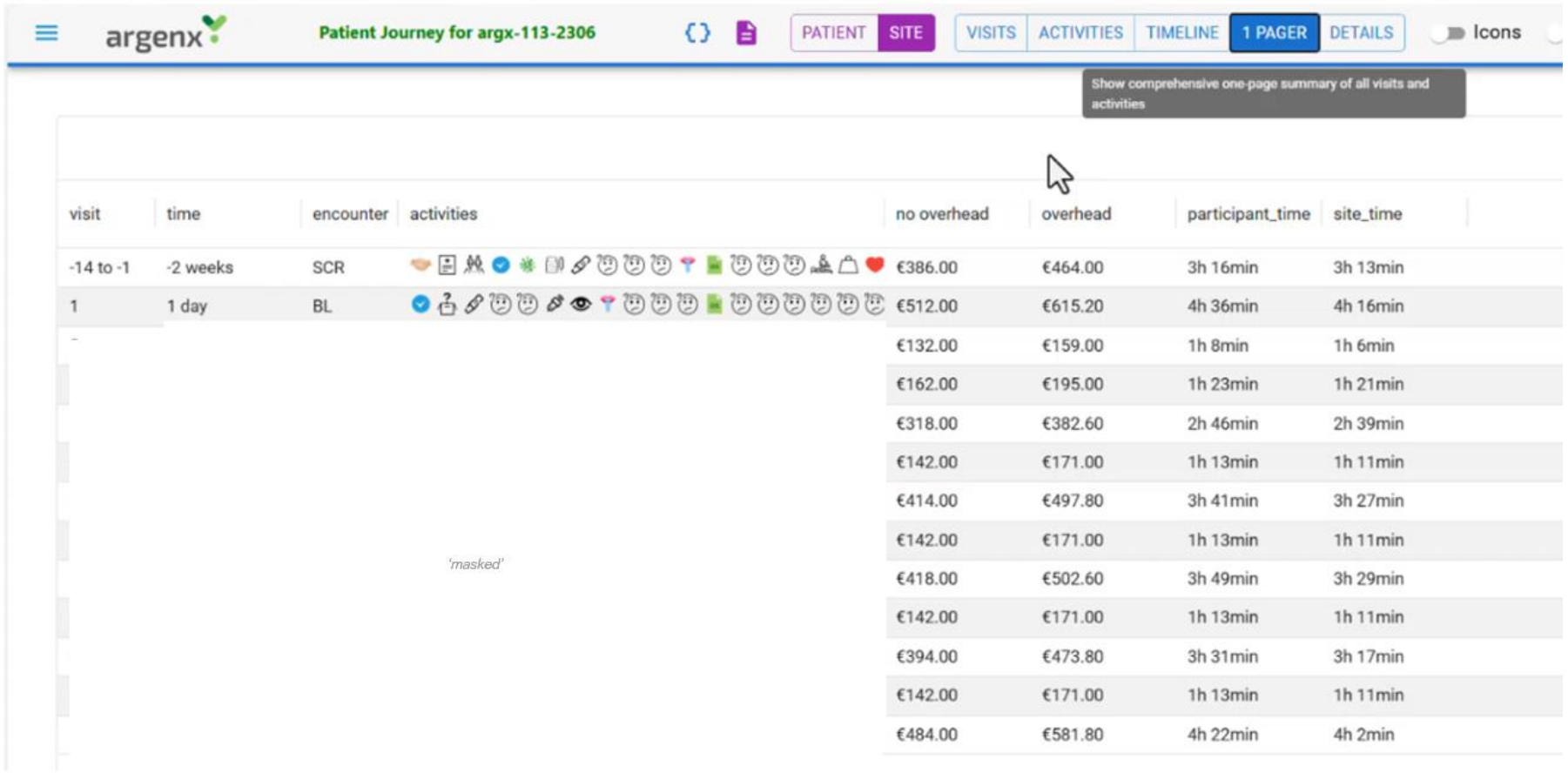
Participants Journey – Timeline & One Pager





Participants Journey – Timeline & One Pager





visit	time	encounter	activities	no overhead	overhead	participant_time	site_time
-14 to -1	-2 weeks	SCR		€386.00	€464.00	3h 16min	3h 13min
1	1 day	BL		€512.00	€615.20	4h 36min	4h 16min
				€132.00	€159.00	1h 8min	1h 6min
				€162.00	€195.00	1h 23min	1h 21min
				€318.00	€382.60	2h 46min	2h 39min
				€142.00	€171.00	1h 13min	1h 11min
				€414.00	€497.80	3h 41min	3h 27min
				€142.00	€171.00	1h 13min	1h 11min
				€418.00	€502.60	3h 49min	3h 29min
				€142.00	€171.00	1h 13min	1h 11min
				€394.00	€473.80	3h 31min	3h 17min
				€142.00	€171.00	1h 13min	1h 11min
				€484.00	€581.80	4h 22min	4h 2min

Proof Of Concept:
What we demonstrated.

USDM v4.0 Compliance

Successfully mapped a real-world protocol (SoA) to the latest USDM standard, validating the model's applicability

End-to-End Digital Flow

From Word protocol to structured USDM to generated outputs — a complete digital pipeline demonstrated

Actionable Outputs

Three distinct participant journey views generated automatically from a single digital source of truth

Reusable Approach

Methodology designed to be protocol-agnostic: applicable to any therapeutic area or study design

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Lessons Learned: **Strategic & Technical.**

Start with one use case

Don't try to digitize the entire protocol at once. A focused SoA digitization proved more valuable than attempting full protocol conversion.

Secure Exec air cover

Cross-functional work stalls without senior sponsorship and a clear mandate.

Enrichment & Validation at each step

Protocols contain extensive implicit knowledge in SoA, footnotes and free text that must be explicitly modeled. Budget time for enrichment and validation.

Show tangible outputs early

The participant journey visualization was the "aha moment" for stakeholders. Abstract data models need concrete demonstrations.

Partner wisely to accelerate & increase success

Collaborating with a USDM specialist accelerated learning and avoided common pitfalls. Domain expertise in USDM standard is essential.

Engage standards community

Active participation in CDISC, PHUSE, and TransCelerate kept our approach aligned and opened collaboration opportunities.

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Your Roadmap:
Kickstarting Your Own Journey

1

Assess Readiness

Evaluate your current protocol authoring workflows, available expertise, and technology stack. Identify quick wins.

2

Pick Your Use Case

Choose a high-impact, bounded use case like SoA digitization. Avoid boiling the ocean with full protocol conversion.

3

Build Your Coalition

Secure executive sponsorship and assemble a cross-functional team: clinical operations, data management, IT, and standards.

4

Partner & Prototype

Engage USDM specialists or technology partners. Build a time-boxed PoC with clear success criteria and deliverables.

5

Scale & Share

Document lessons learned, refine the approach, and expand to additional protocols and use cases. Share with the community.

Eventually… Move from PoC(s) to RFI/RFP (off the shelf platforms)

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Call to Action:
The time to start is now !

You don't need a perfect plan

Start with a small, focused PoC. The learning from doing outweighs months of planning.

The standards are ready

USDM v4.0 and M11 provide a mature, harmonized framework. The tools and community support exist today.

Collaborate and share

The DDF community grows stronger when organizations share their experiences. Your journey helps accelerate the industry.

"The journey of a thousand miles begins with a single step
— ours began with a Schedule of Activities."

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