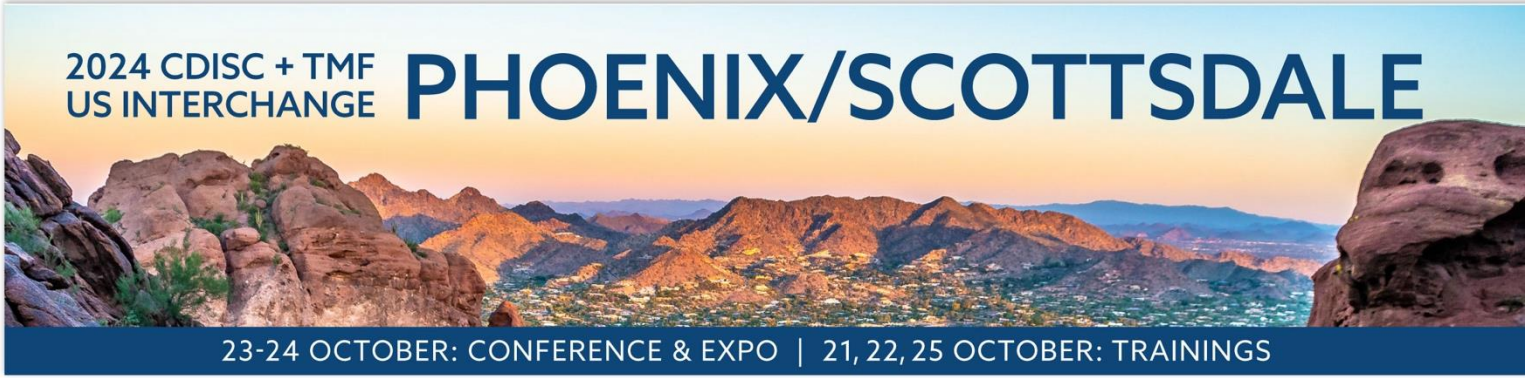


DDF and Breaking Down the Document Barrier

Bob Brindle, VP Product Management, Nurocor
Frederik Malfait, SVP Information Architecture, Nurocor

Meet the Speakers

Bob Brindle

Title: VP Product Management

Organization: Nurocor

Frederik Malfait

Title: SVP Information Architecture

Organization: Nurocor

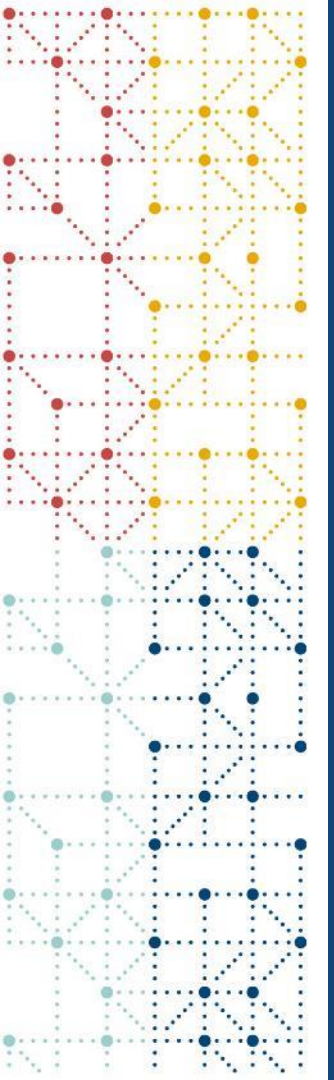
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. The road to digitalization
2. Upstream and downstream
3. Breaking down the document barrier
4. Clinical document authoring



The road to digitalization

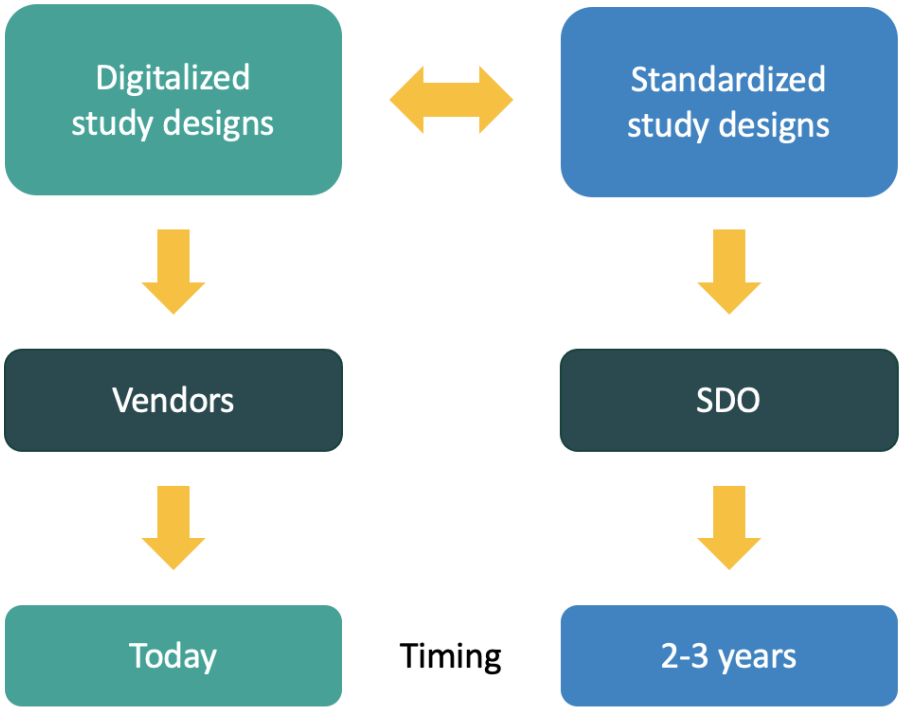
It's a dangerous business, Frodo, going out your door. You step onto the road, and if you don't keep your feet, there's no knowing where you'll be swept off to.

J.R.R. Tolkien

The Journey (so far)

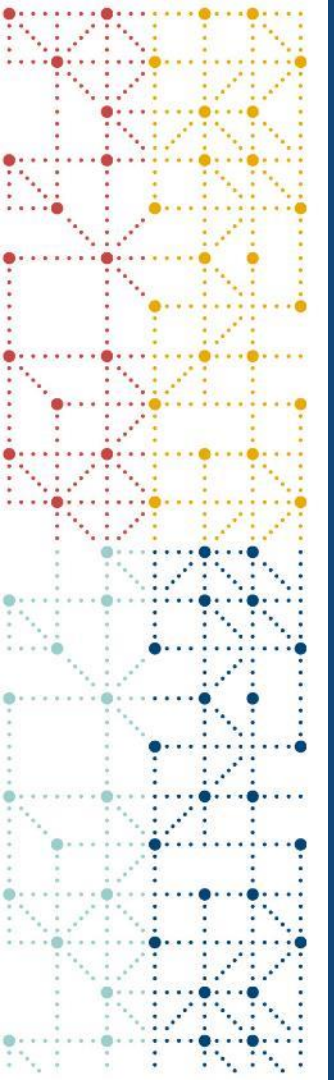
	TransCelerate DDF	Nurocor Clinical Platform
2018		Infrastructure
2019	Nov. white paper	Study Designer and SoA
2020	Feb. hackathon 	Study and Protocol Elements
2021		Lean Protocol
2022	USDM / SDR / hackathon	Specimen Management
2023	USDM / SDR v2 / discovery day	Clinical Document Authoring
2024	USDM / SDR v3	Integrations and Insights / ICH M11
2025	USDM / SDR v4	Design Center

Adoption versus Standardization



ICH M11
HL7 Vulcan UDP
CDISC USDM

Not if but when

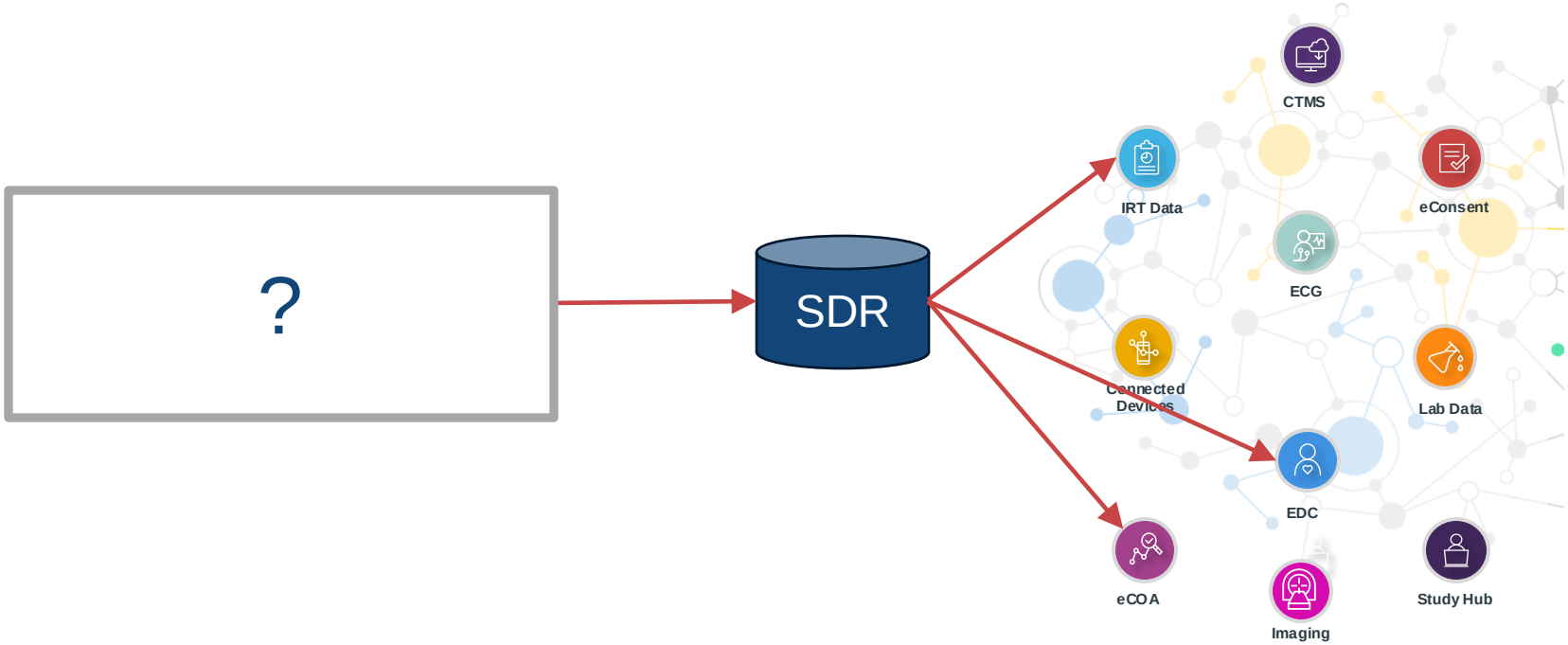


Upstream and downstream

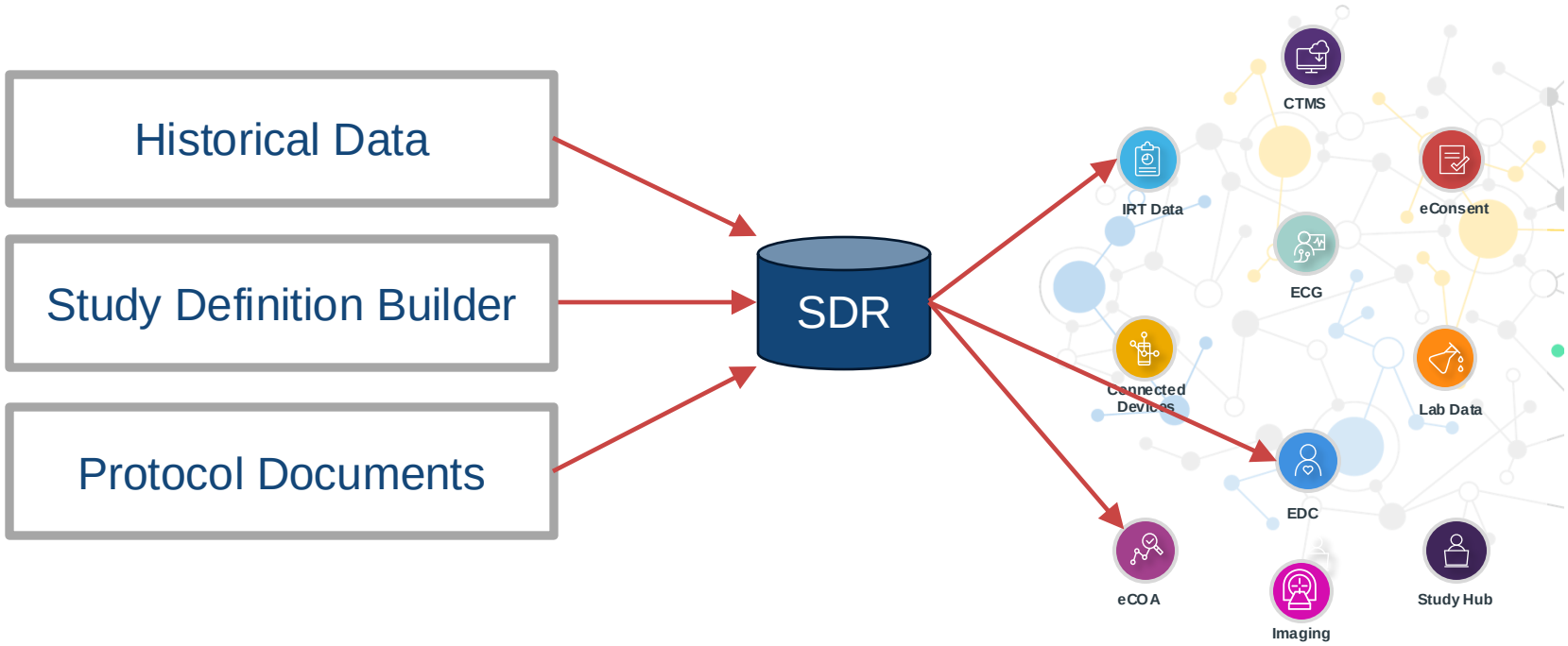
There comes a point where we need to stop just pulling people out of the river. We need to go upstream and find out why they're falling in.

Desmond Tutu

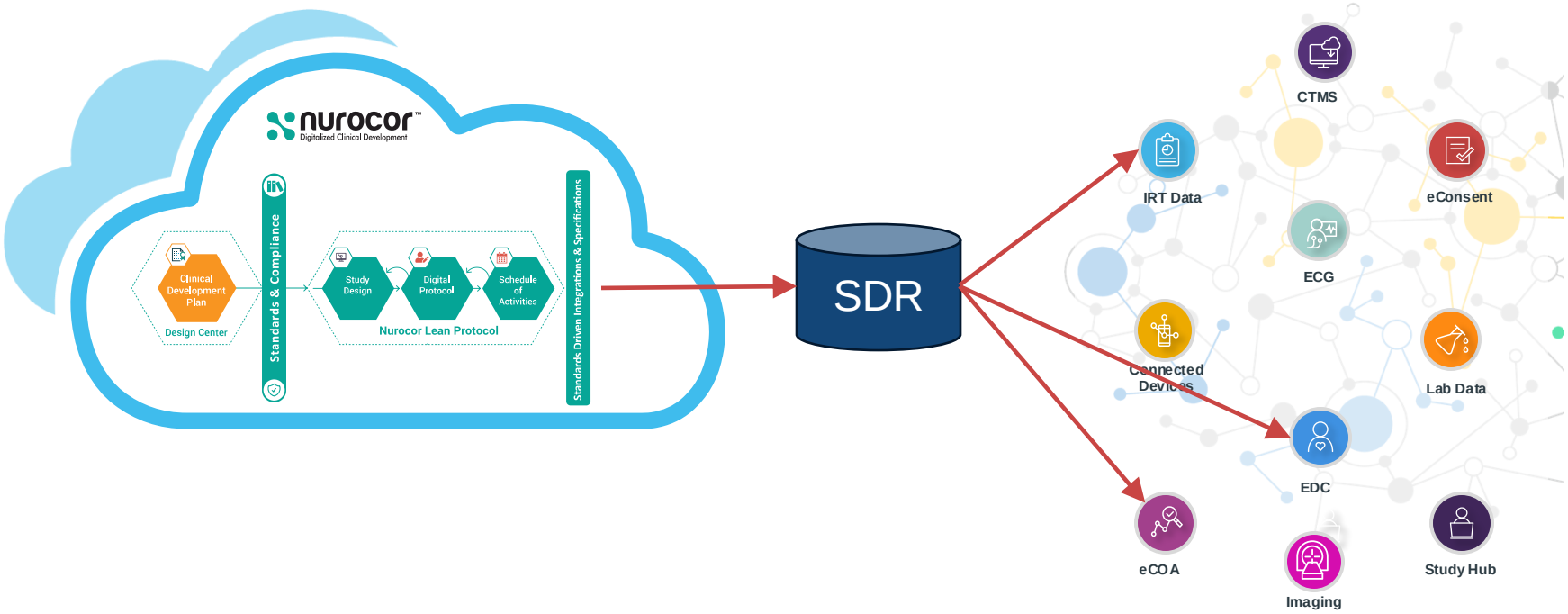
Driving digitalization – Hub Architecture

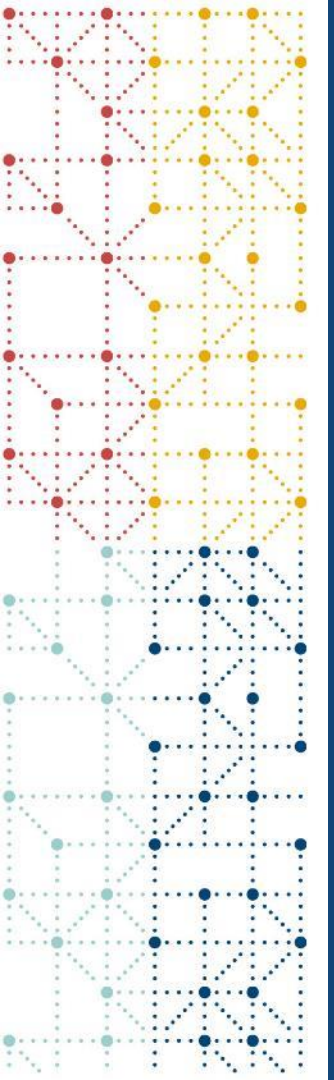


Upstream possibilities



Upstream study definition builder





Breaking down the document barrier

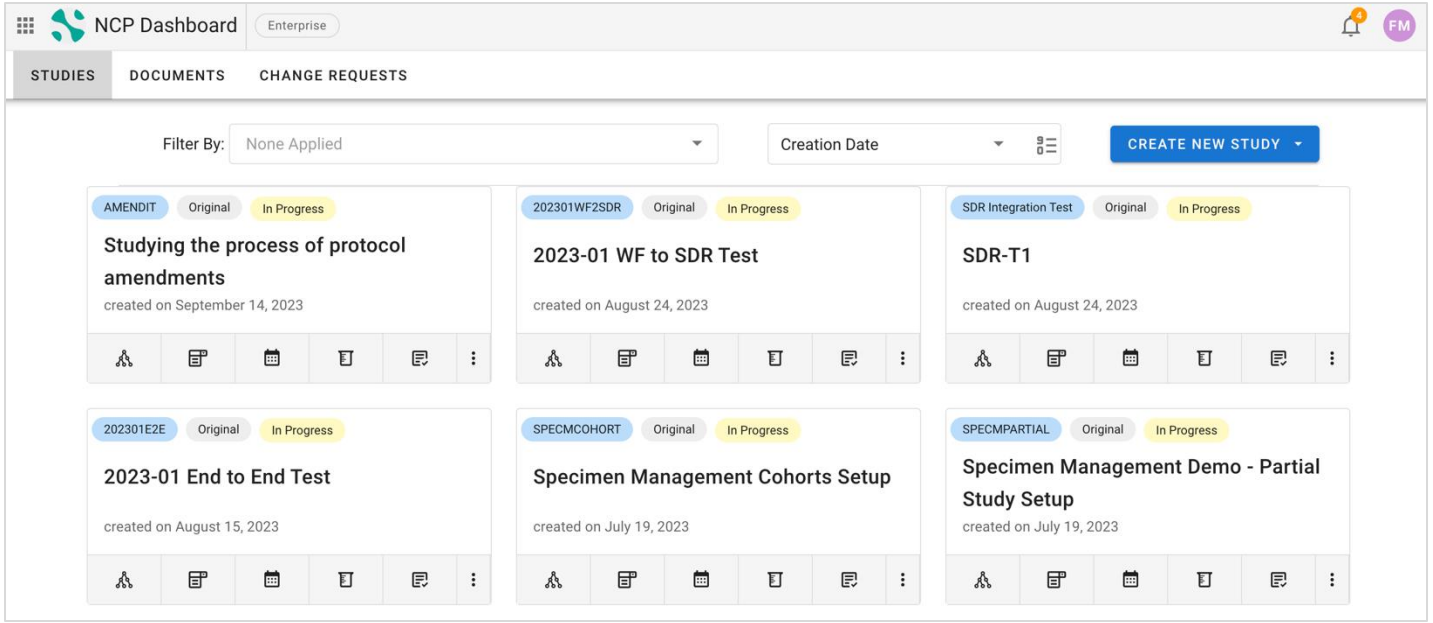
Disrupt yourself before someone else does.

Jay Samit

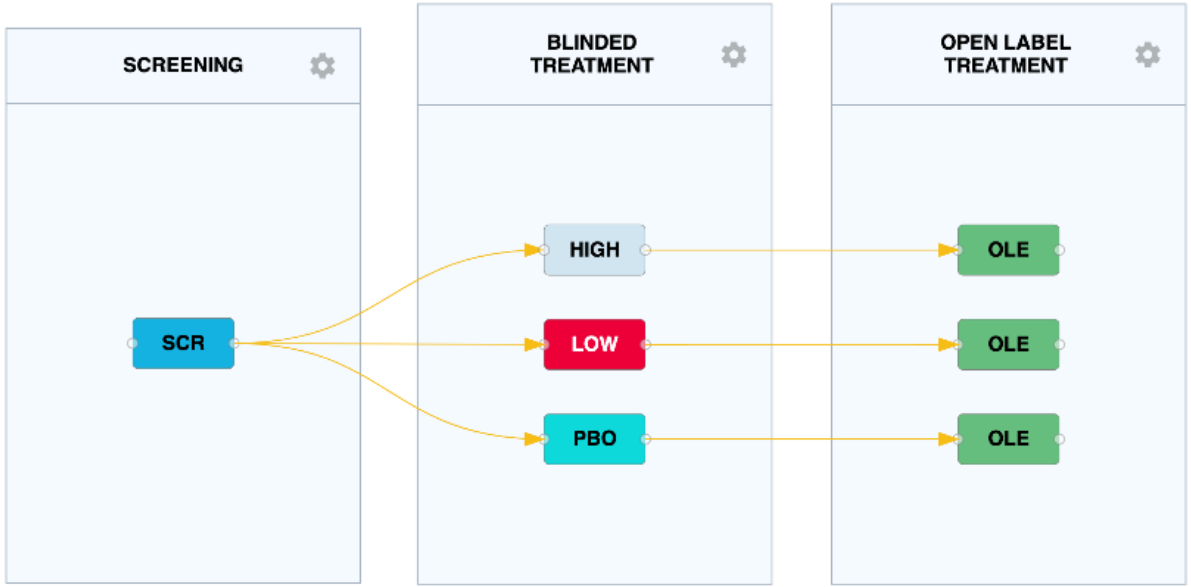
Codify the study design into components

- Components are well defined entities
- Components have well defined relationships
- Components can be templated
- Components can receive, carry, and send information
- Components can have many representations
- Components can be tracked
- Components can be reused (write once, read many)
- Components are actionable
- Components can be assembled

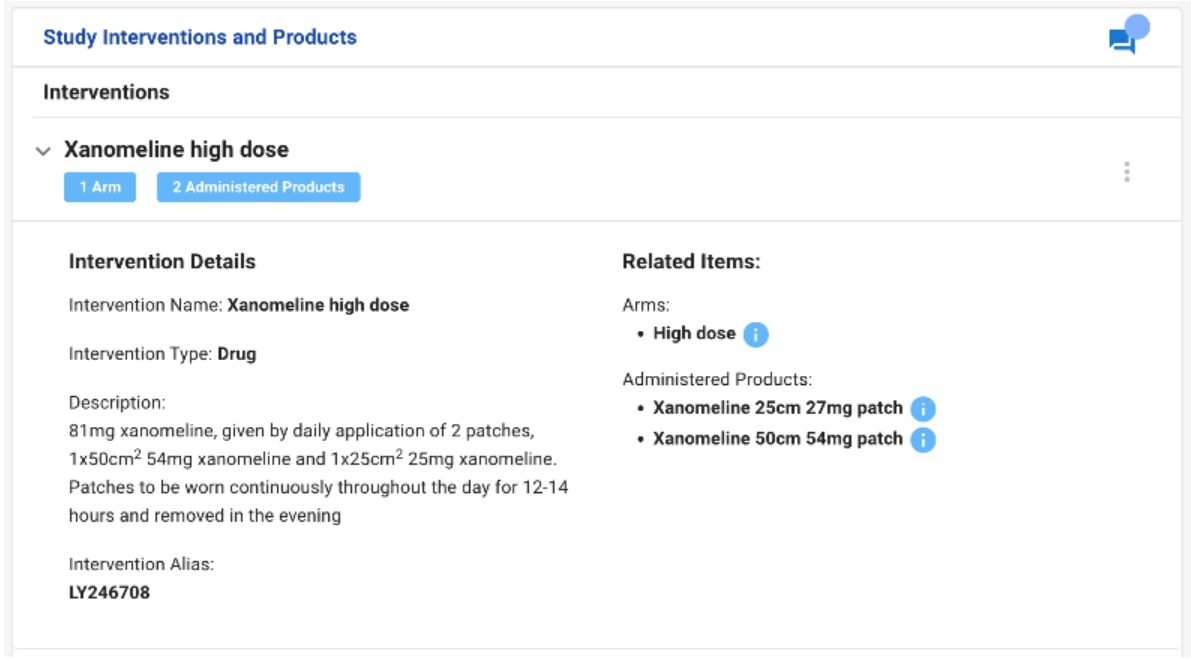
Study dashboards



Trial design schematic



Interventions and products



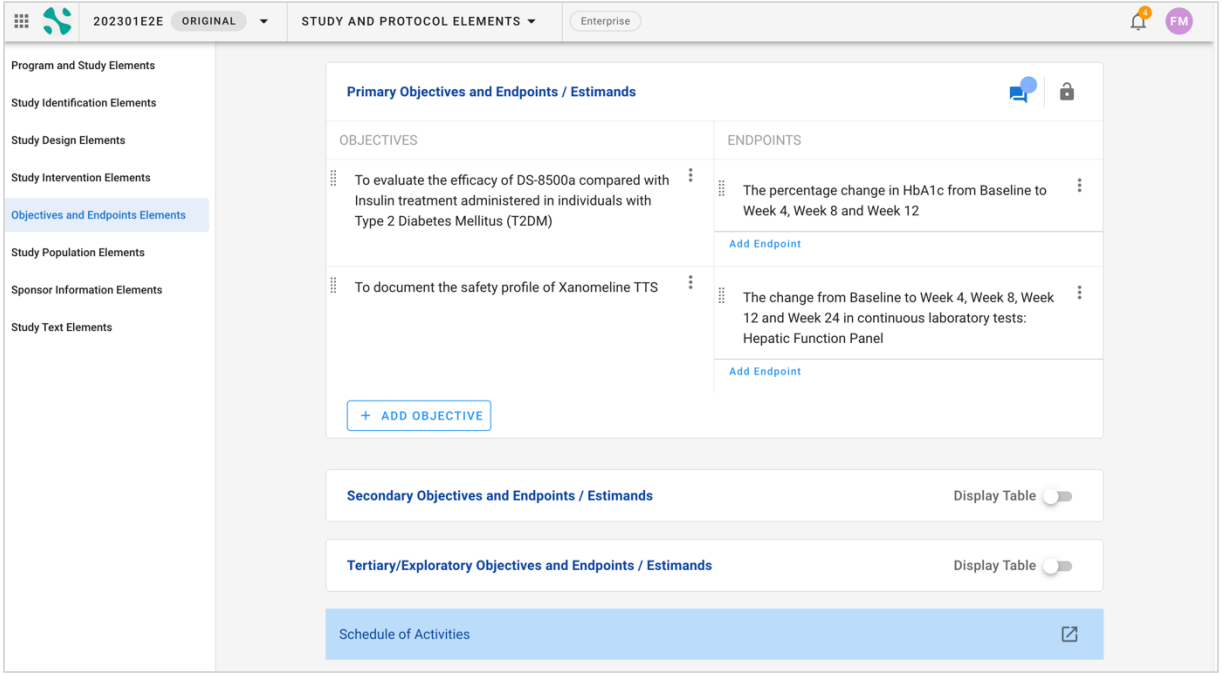
Eligibility criteria

Eligibility Criteria

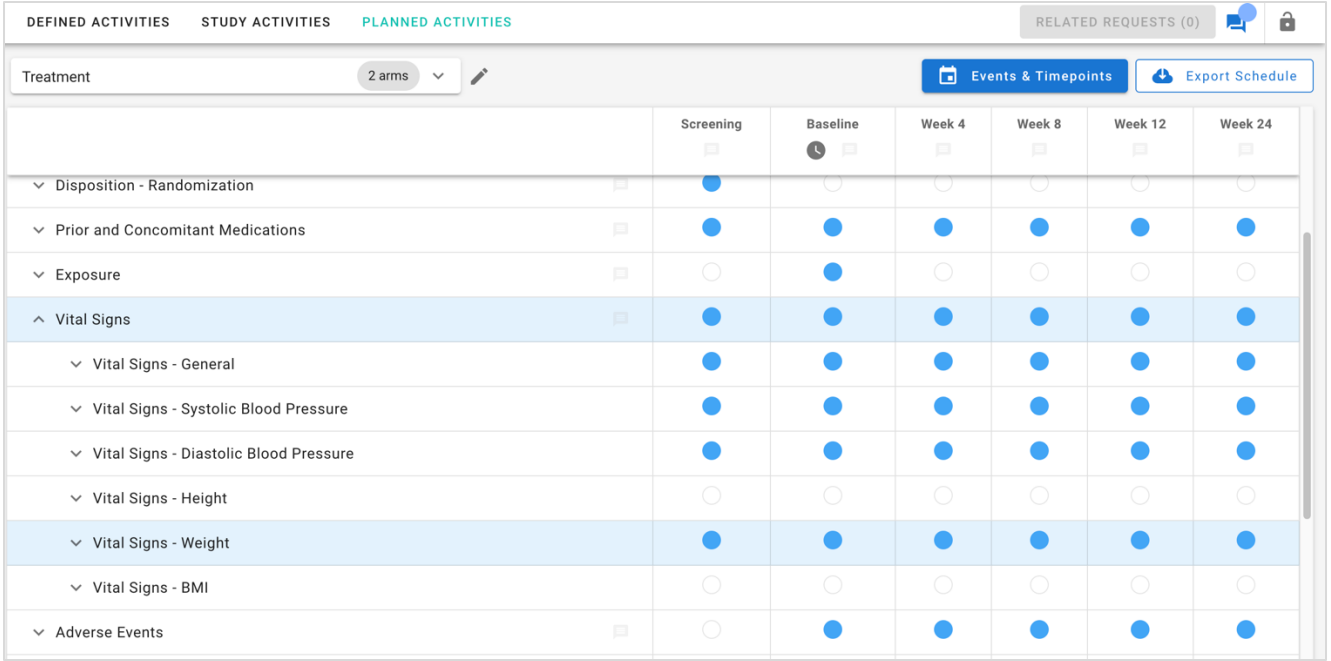
Inclusion Criteria

Protocol Text	Submission Text
Participant must be male or a postmenopausal female	Males and postmenopausal females
Aged >= 50 year(s), at the time of signing the informed consent	At least 50 years of age
Meets the Diagnostic and Statistical Manual of Mental Disorders Version 5 (DSM-5) criteria and/or National Institute of Neurological and Communicative Disorders and Stroke-Alzheimer's Disease and Related Disorder Association's (NINCDS-ADRDA) criteria for probable AD	Diagnosis of probable Alzheimer's Disease

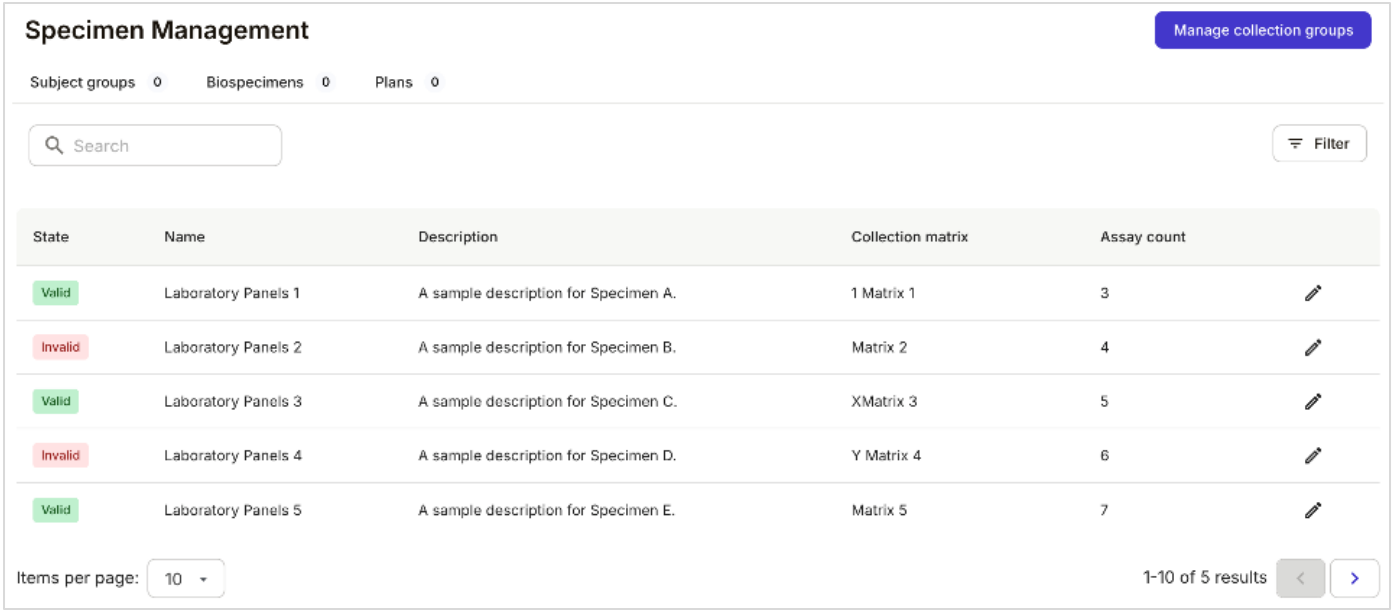
Objectives and endpoints



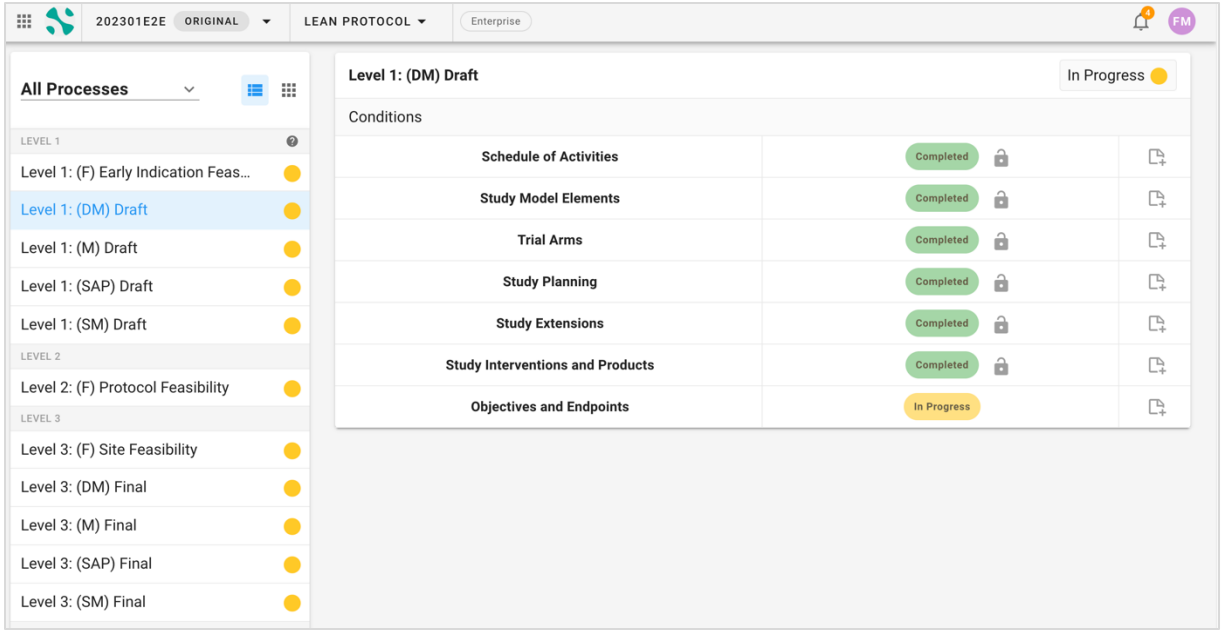
Schedule of Activities



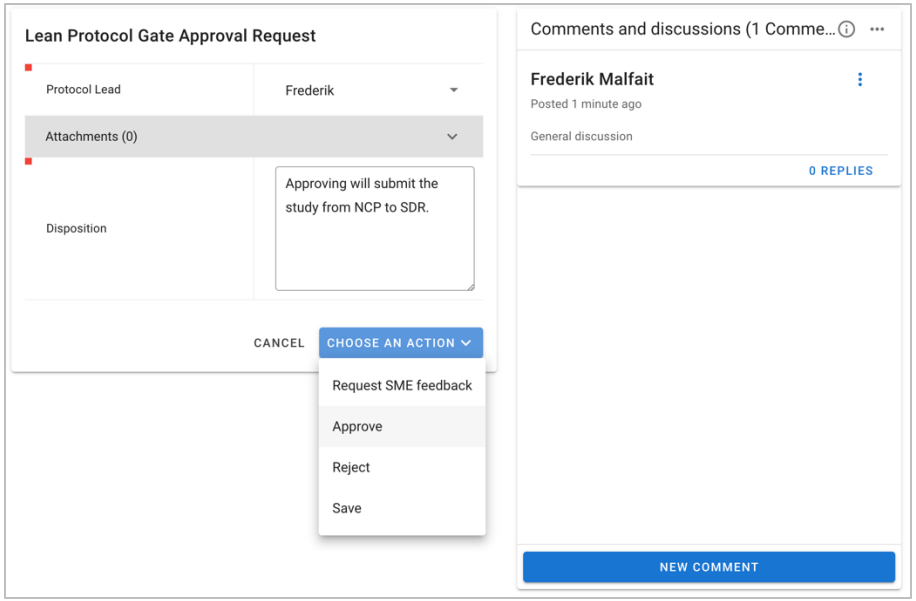
Specimen Management Plans

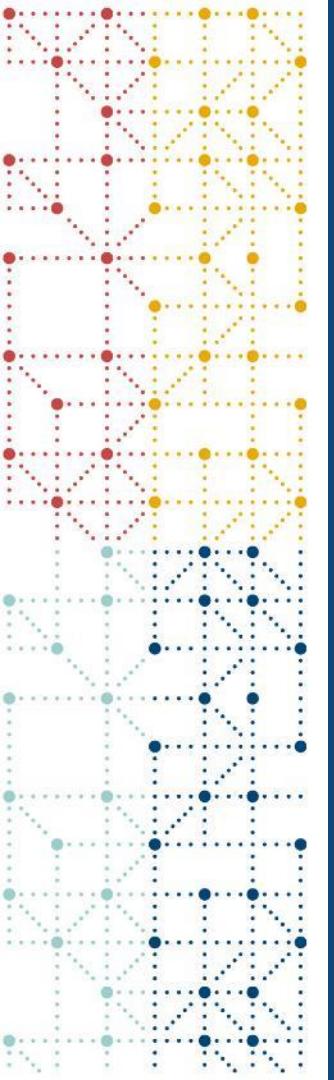


Lean Protocol™



Workflow driven system integrations (SDR)





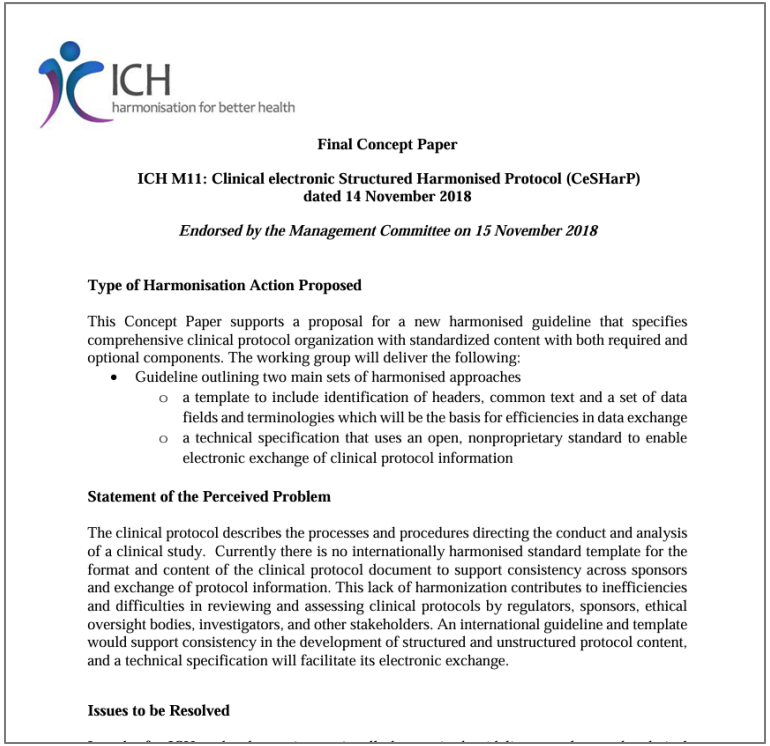
Clinical document authoring

Every writer I know has trouble writing.

Joseph Heller

Documents in a Digital Data Flow

- Documents in traditional published formats (pdf, docx) are still required as part of many regulatory processes
- Content of documents MUST be consistent with the digital study definition
- Current document authoring processes and tools will need to adapt
- ICH M11 is leading us in the right direction



ICH
harmonisation for better health

Final Concept Paper

ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)
dated 14 November 2018

Endorsed by the Management Committee on 15 November 2018

Type of Harmonisation Action Proposed

This Concept Paper supports a proposal for a new harmonised guideline that specifies comprehensive clinical protocol organization with standardized content with both required and optional components. The working group will deliver the following:

- Guideline outlining two main sets of harmonised approaches
  - a template to include identification of headers, common text and a set of data fields and terminologies which will be the basis for efficiencies in data exchange
  - a technical specification that uses an open, nonproprietary standard to enable electronic exchange of clinical protocol information

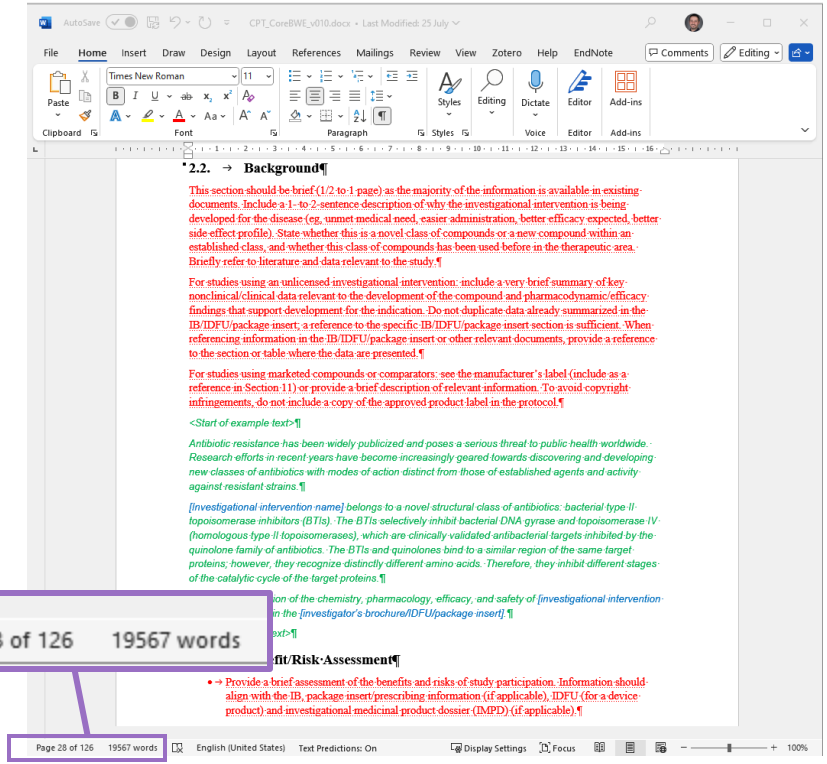
Statement of the Perceived Problem

The clinical protocol describes the processes and procedures directing the conduct and analysis of a clinical study. Currently there is no internationally harmonised standard template for the format and content of the clinical protocol document to support consistency across sponsors and exchange of protocol information. This lack of harmonization contributes to inefficiencies and difficulties in reviewing and assessing clinical protocols by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders. An international guideline and template would support consistency in the development of structured and unstructured protocol content, and a technical specification will facilitate its electronic exchange.

Issues to be Resolved

cdisc

Templates in a document-based process



- Pushing content into a traditional Word-based document template risks breaking the digital data flow
  - Hard to maintain template structure
  - Hard to control access
  - Hard to control edits
  - Copy/paste culture
  - Versions can proliferate and diverge
- Document preparation overheads
  - Review cycles and comment resolution
  - Formatting and styling
  - Links and cross-references
  - Consistency checking
  - Bibliography

Templates in a digital data flow

- Components are well defined entities
- Components have well defined relationships
- Components can be templated
- Components can receive, carry, and send information
- Components can have many representations
- Components can be tracked
- Components can be reused (write once, read many)
- Components are actionable
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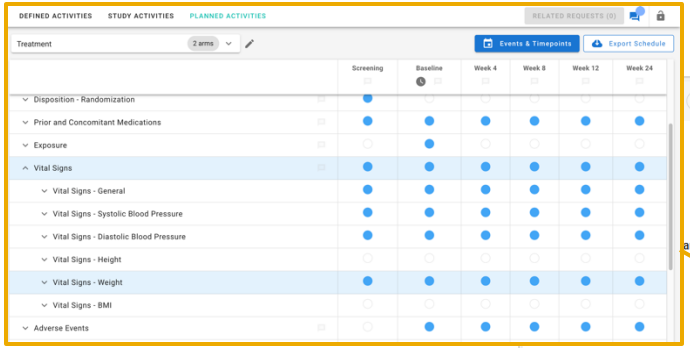
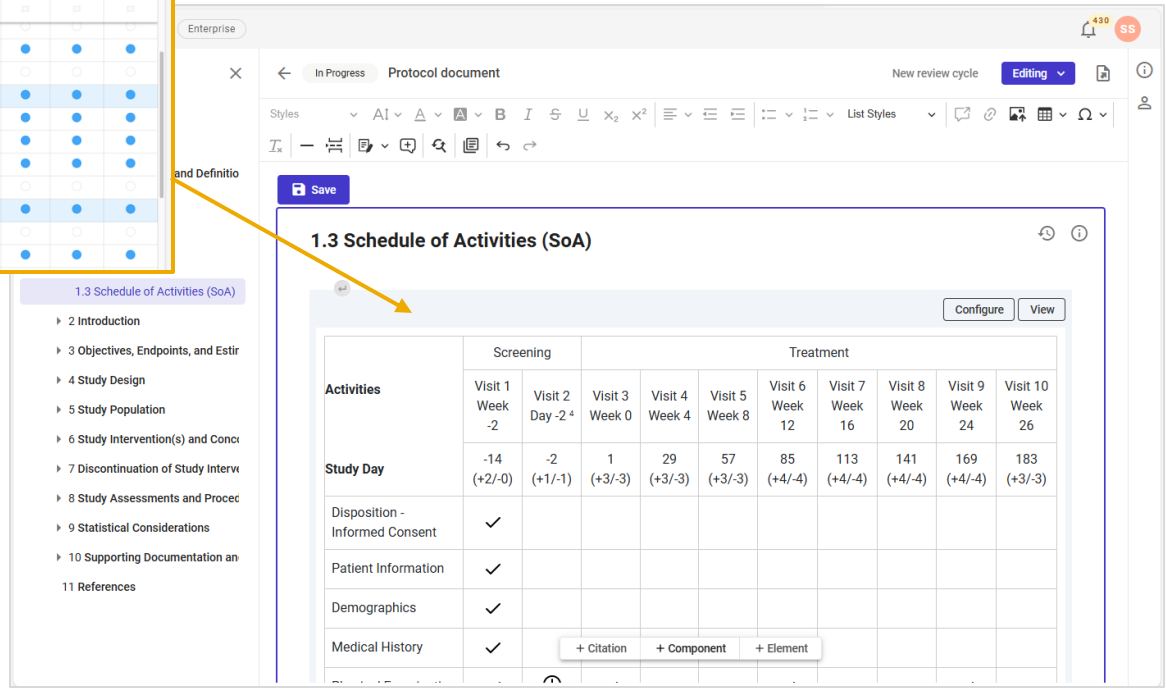
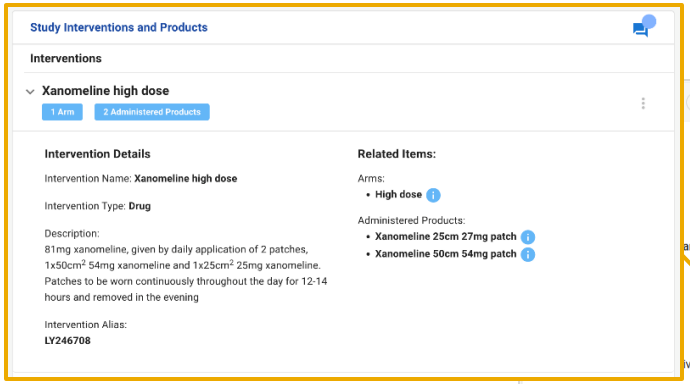
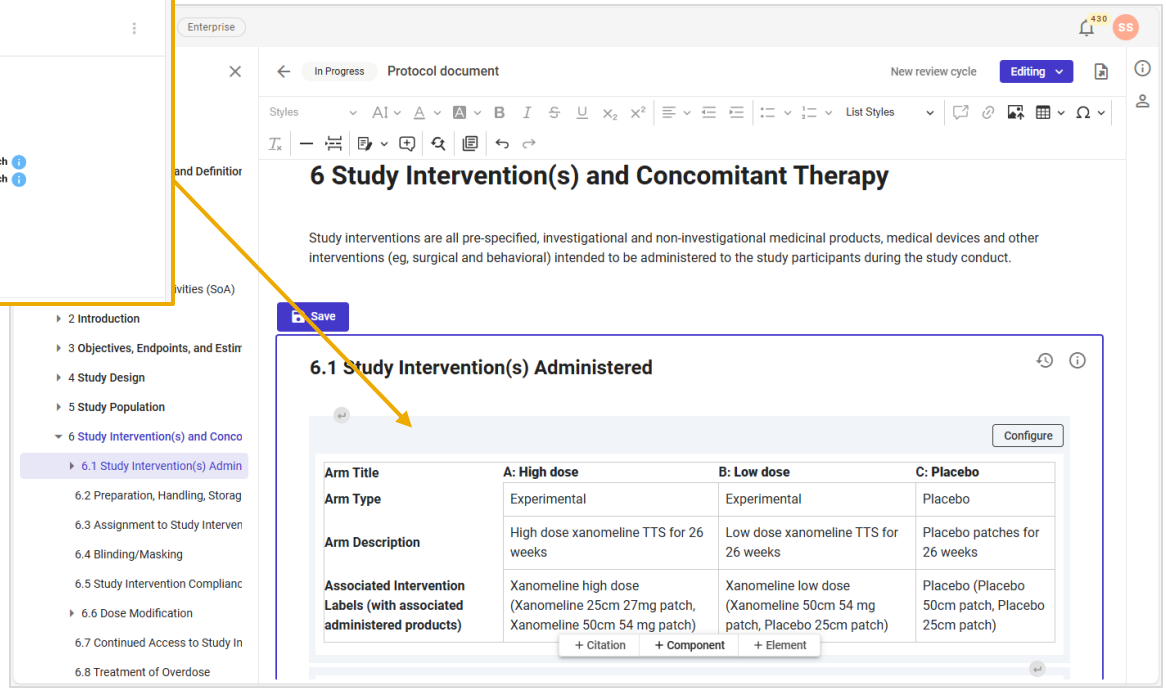
Examples





Examples





Arm Title	A: High dose	B: Low dose	C: Placebo
Arm Type	Experimental	Experimental	Placebo
Arm Description	High dose xanomeline TTS for 26 weeks	Low dose xanomeline TTS for 26 weeks	Placebo patches for 26 weeks
Associated Intervention Labels (with associated administered products)	Xanomeline high dose (Xanomeline 25cm 27mg patch, Xanomeline 50cm 54 mg patch)	Xanomeline low dose (Xanomeline 50cm 54 mg patch, Placebo 25cm patch)	Placebo (Placebo 50cm patch, Placebo 25cm patch)

A complete digital authoring solution

- To achieve success, we need more than templates and standards
- Authors must be supported in developing content that does not flow from components and in producing a polished document as an end product
- A digital authoring solution should focus on improving user experience compared to current processes and tools
  - Collaborative authoring – with guard rails to prevent loss of content
  - Review functionality – structured reviews, traceability of outcome
  - Automatic formatting / styling – use output templates to create final documents
  - Automatic generation of structural items – title page, table of contents, bibliography etc.
  - Opportunities to embed AI for “assisted authoring”
  - Seamless integration into existing approval workflows and document repositories
- Technology is not a problem, change management is key to success

Source: Scientific American

Conclusion

- DDF has been long in the making
- Standards organizations and regulators are embracing the concepts and developing standards, templates and specifications (e.g. USDM and M11)
- Vendors are increasingly developing technology
- Production grade software is available today – it's time to get started
- Change management and willingness to standardize are the remaining challenges
- Adoption of the tools drives further improvement
- An adoption case study is coming up!

Thank You!

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