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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

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Building USDM and ICH M11 Protocols from Scratch

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Agenda

1. Challenges of Converting MS /PDF Protocols to USDM
2. ICH M11: Progress on standardization and gaps
3. Build USDM-native from the start
4. Challenges of building USDM-native protocols
5. Our approach
6. Conclusion

Speakers

- Veterinarian with a PhD in Immunology
- 10+ years of experience in clinical trial management
- Focused on digital transformation & standardization of clinical trial protocols

Dr.Poorya Amini

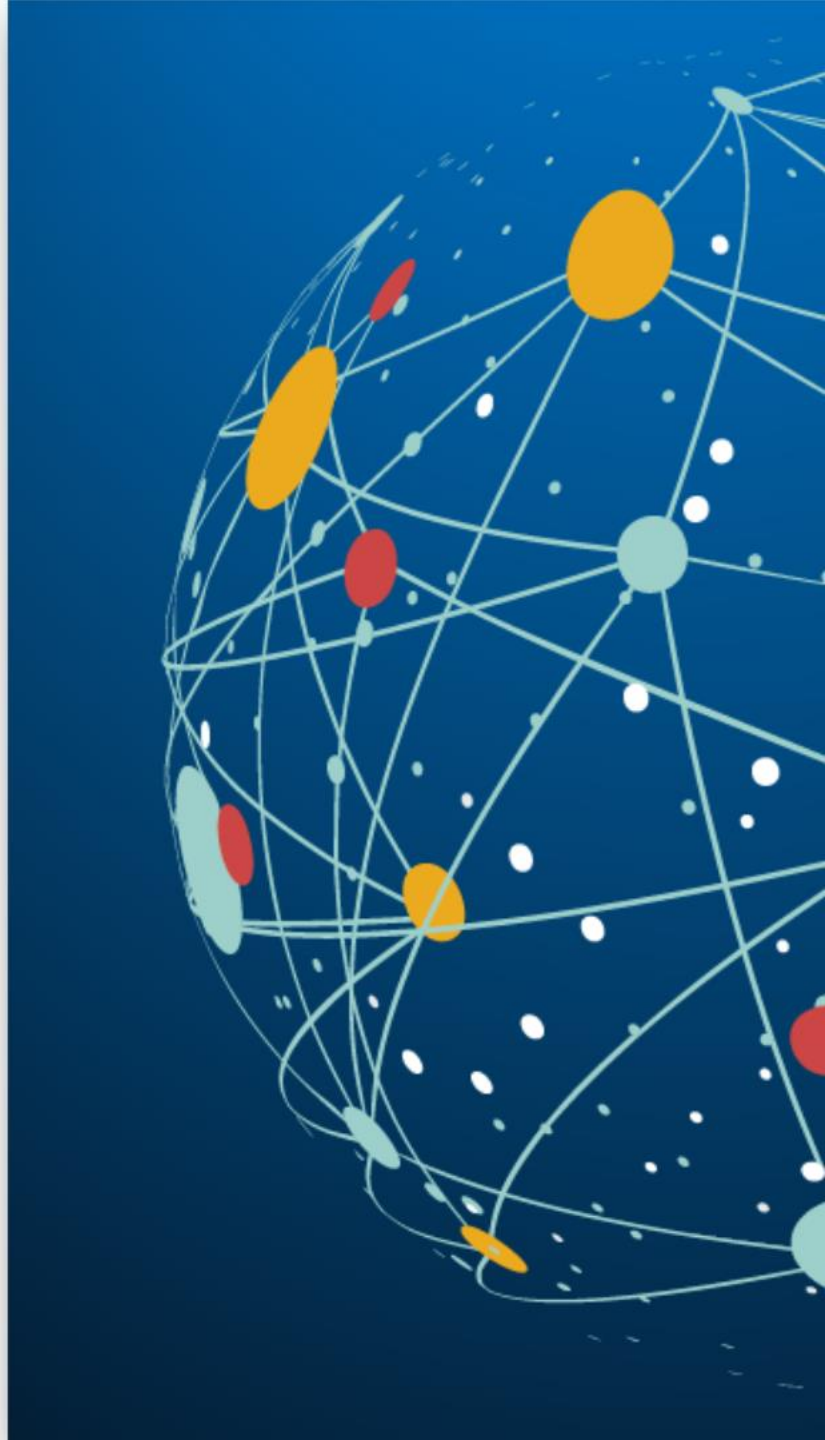
Founder & CEO

Risklick

1. Challenges of Converting MS /PDF Protocols to USDM

Converting Word/PDF protocols to USDM is harder than it looks

1. Structural / parsing challenges
2. USDM-specific mapping challenges
3. Maintenance challenge



1. Structural / Parsing Challenges

- Huge variation in protocol templates across sponsors

- Intra-protocol inconsistencies:

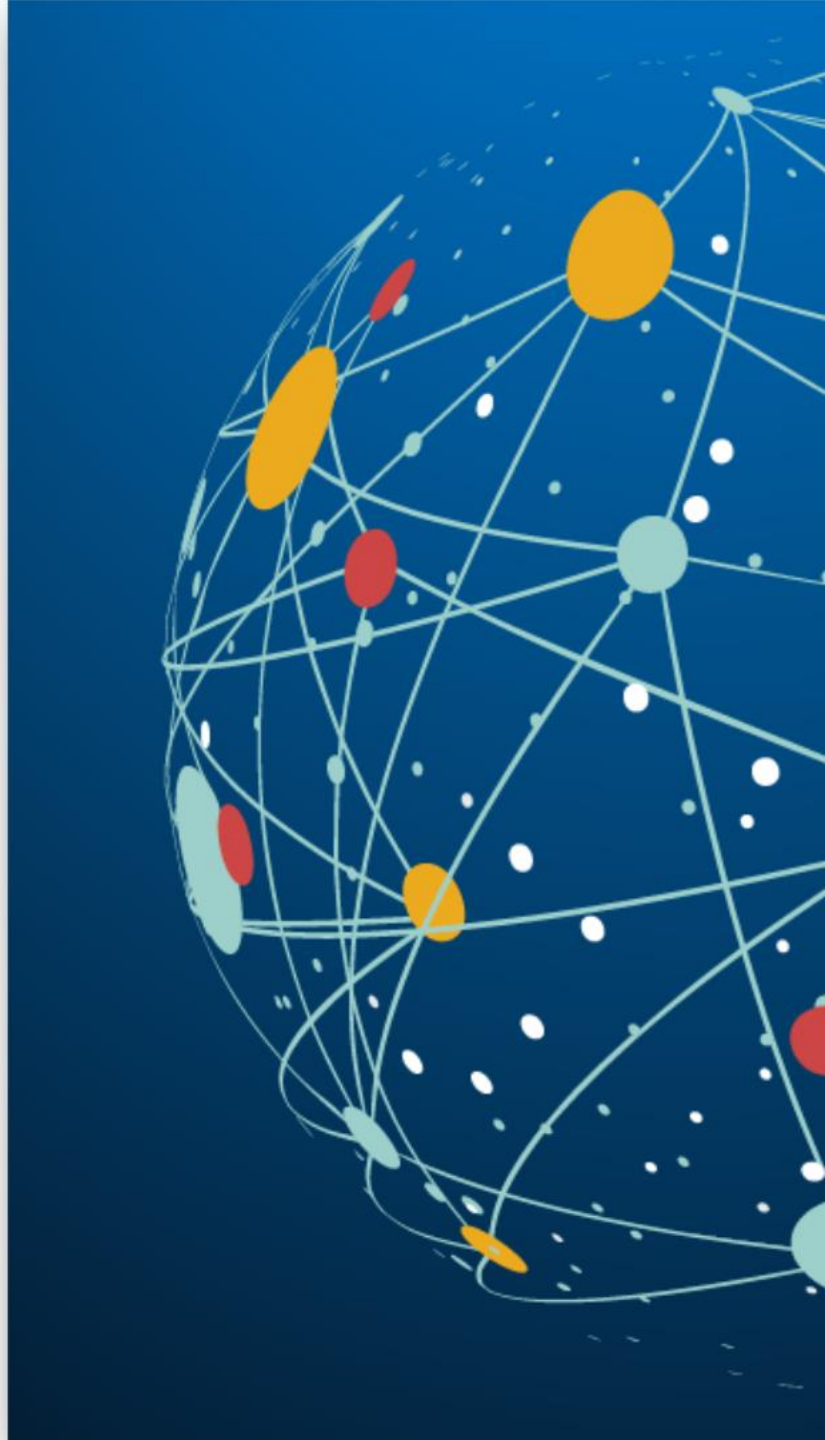
  Conflicts between synopsis, body, SoA, and narrative within the same document

- Mixed content types:

  Same concept expressed in both prose and tables, causing duplication or conflicts

- Implicit relationships:

  Activities, visits, arms, and epochs are implied through layout/indentation, never formally declared



The Schedule of Activities:
The hardest section to parse

Structural variation:

- Single master table vs. multiple split tables
- Row/column orientation is not standardized
- Nested row groupings vs. flat activity lists

Content granularity variation:

- Activity granularity is entirely sponsor-defined
- Vital signs, ECG, PK sampling, split or merged depending on sponsor preference
- Screening, unscheduled, and early termination visits included inline or in separate tables

Footnote & conditionality variation:

- Symbols vary widely — ✓, X, bullets, numbers, letters, shading, merged cells
- Window periods expressed in table headers, footnotes, or a separate narrative section
- Conditional logic ("only if fasting", "omit if prior dose < 48h") buried in free-text footnotes with no standard structure

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2. USDM-Specific mapping challenges

- Footnotes and conditions in the SoA
  - Critical conditionality semantically disconnected from the cells they qualify
- Ambiguous terminology
  - "screening visit" vs "baseline visit" vs "Visit 1" across sponsors requires normalization
- Timing & frequency in free text
  - "Day 1 ± 3 days", "every 4 weeks ± 2 days" have no standard extractable pattern
- Epoch and arm structure described narratively or as branching diagrams
- All variations must map to the same USDM structure
- No two SoAs can be parsed with the same ruleset

3. Maintenance challenges

- Amendment documents are often narrative

  ("Section 6.2 is replaced by...”) with no structured diff format

- Keeping the USDM in sync with every amendment cycle is a continuous manual burden

- Versioning and amendments

  Tracked changes & strikethroughs not semantically marked, hard to extract the "current" version

- USDM version updates (e.g., v3 → v4) require re-validation and re-mapping of all previously converted documents

2. ICH M11: Progress on Standardization and Gaps

ICH M11: standardization progress, but gaps remain

What ICH M11 enforces

- Level 1 & 2 section structure is mandatory
- Mandatory SoA content elements
- Standardized USDM digital representation
- Defined required protocol elements across the full document

What remains variable

- Level 3 & 4 sections are sponsor-defined
- SoA visual layout is unconstrained
- Footnote conventions not standardized
- Terminology not controlled
- Legacy protocols remain outside M11

3. Build USDM-native from the start

USDM is the foundation - it must be right

- USDM is the single source of truth for all digital data flow
- Converting Word/PDF to USDM with 100% accuracy demands human intervention & review
- The conversion approach is unsustainable

  It is manual, error-prone, costly, and breaks with every protocol amendment and every USDM version update

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The sustainable and scalable path: build USDM-native from the start

Accuracy & quality:

- No conversion, no transformation errors, USDM is the source, not the output
- 100% structural compliance with ICH M11 guaranteed by design, not by review
- No human reconciliation needed to resolve parsing ambiguities

Efficiency & speed:

- Eliminates the conversion pipeline entirely, no parsing, no validation of extracted output
- Protocol amendments update the USDM directly - no re-mapping or re-validation cycle
- Downstream documents (ICF, SAP, EDC) generated directly from the same USDM source

Scalability & maintainability:

- USDM version updates (e.g., v3 → v4) handled at the template level - all protocols benefit automatically
- One source of truth drives all digital data flow across the full trial lifecycle
- Scales across therapeutic areas, geographies, and regulatory authorities without additional conversion overhead

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4. Challenges of building USDM-native protocols

Challenges of building USDM-native protocols from scratch

1. Disrupting the current way of working
2. Clinical development teams are not USDM experts
3. Extra workload with no immediate benefit
4. Makes the process more rigid and harder to handle study variation

5. Our approach

Protocol AI: USDM-native authoring built for clinical teams

1. One unified digital platform
2. Granular role-based access control
3. Sponsors keep their own templates and workflows
4. Digital Schedule of Activities built for any variation
5. Built-in authoring system with AI agent

What we solve - & what we don't

Challenge	How We Addressed It	Status
Disrupting the current way of working	Sponsors keep their existing MS Word template - familiar structure is preserved. However, the authoring process itself is fundamentally new & will feel different to teams used to working in Word.	Partially addressed
Clinical development teams are not USDM experts	Authors work in natural language and familiar layouts - Protocol AI & the AI agent handle USDM mapping invisibly in the background.	Fully addressed
Extra workload with no immediate benefit	Built-in AI agent drafts protocol text, flags issues, and automates repetitive tasks — reducing authoring effort rather than adding to it.	Fully addressed
Makes the process more rigid and harder to handle study variation	Digital SoA engine handles any study design complexity, adaptive elements, and sponsor-specific variations - structured but not constraining.	Fully addressed
Organizational change management	Requires training, governance, cross-functional alignment, and cultural shift - this is outside the scope of the tool & must be driven by the organization.	Not addressed

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6. Conclusion

The future is USDM - native but it starts with people, not tools

1

Building USDM protocols from scratch is the future of protocol writing

It eliminates transformation errors, enables seamless digital data flow, and future-proofs every clinical trial against regulatory & standards evolution.

2

The technology is ready

Tools like Protocol AI prove that USDM-native authoring can be done today, at scale, without requiring clinical teams to become data standards experts.

3

The hard part is not the tool - it's the transformation

Sustainable adoption requires organizational commitment, cultural shift, leadership buy-in, and a genuine willingness to work in a fundamentally new way.

"The question is no longer can we build USDM-native protocols — it's are we ready to commit to the change?"

Thank You!

Questions?