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AI Strea

AI-Driven Metadata Integration

Transforming TLF Development Through Unified Metadata Management

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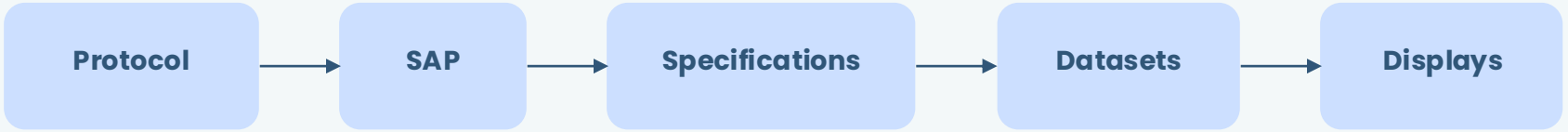
The Challenge: Traditional Approach

Fragmented process:



- Each artifact **built manually** or semi-manually in isolation
- **Constant revisions** lead to inconsistencies and discontinuities
- Information **siloed** across documents—difficult to trace connections
- **Inefficient reuse** and validation of study artifacts

The Business Impact of Fragmentation

Inefficiency	Sequential, manual processes waste time and resources
Inconsistency	Data conflicts arise from isolated artifact development
Discontinuity	Revisions break traceability between artifacts
Scalability	Growing study complexity strains existing workflows
Regulatory Risk	Audit trails fragmented across multiple systems

Why Now?
Why This Approach?

1. **GenAI Maturity:** enable reliable metadata extraction (not available 1-2 years ago)
2. **Regulatory Acceptance**
3. **Study Complexity Explosion:** Protocols are getting larger; manual workflows breaking
4. **Industry Timing:** Major pharma piloting AI solutions internally (competitors moving now)

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The Paradigm Shift

Today

Document-Centric Model

- × Separate artifacts
- × Manual linkage
- × Limited traceability
- × Revision bottlenecks
- × Data silos
- × Auditor friction

AI-Enabled

Metadata-Driven Model

- ✓ Unified repository
- ✓ Automated integration
- ✓ Full traceability
- ✓ Real-time updates
- ✓ Seamless reuse
- ✓ Audit-ready

How AI Transforms the Workflow

Extract

GenAI processes Protocol, SAP, Specs, Datasets, Displays

Integrate

Link metadata facets into unified repository

Validate

Ensure consistency automatically

Trace

Maintain bidirectional links to original artifacts

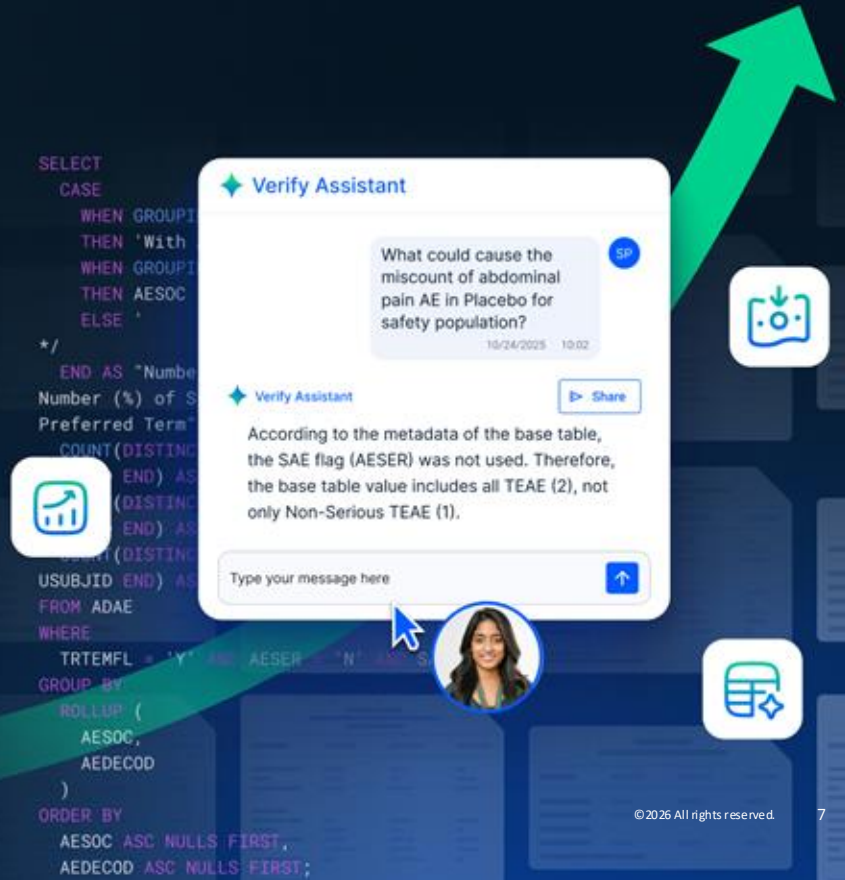
Enable

Support agile updates with instant propagation

Draft

Demo Video

Behind the scene



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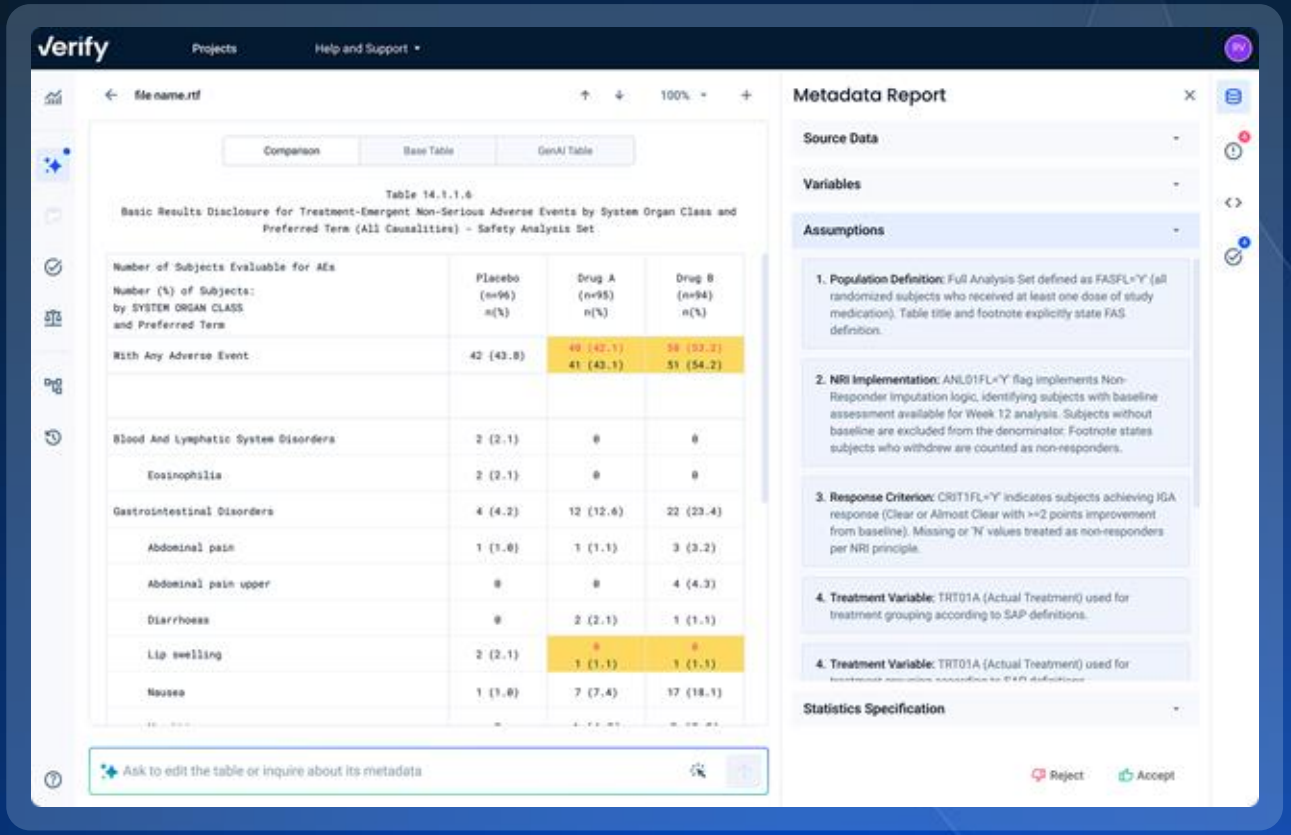
Draft

Generative Metadata Review in Verify



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Validation & Regulatory Compliance

AI Extraction Layer

- **Automated Validation Engine**
  (99%+ accuracy gates)
- **Manual Review Gates**
  (Critical metadata only)
- **Audit Trail Generation**
  (FDA-compliant logging)

Compliance Assurance

- ✓ 21 CFR Part 11 Ready
- ✓ Traceability to Source
- ✓ AI Validation Records
- ✓ Change Management
- ✓ Regulatory Submission Ready

Fast-Track Implementation: From Days to Value

Week 1

Setup & Pilot

Days 1-3: Environment setup

Day 4-5: First study loaded

Day 6-7: Live testing

Week 2-3

Feedback Loop

Day 8-10: User feedback

Day 11-14: Refinements

Execution: iterate continuously

Week 4+

Scale & Optimize

Day 15+: Production rollout
Continuous improvement

New studies: 30-40% faster

Q&A

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Thank You

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