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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

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AI-Assisted Workflows for Enhanced Consistency and Auditability of SDTM generation

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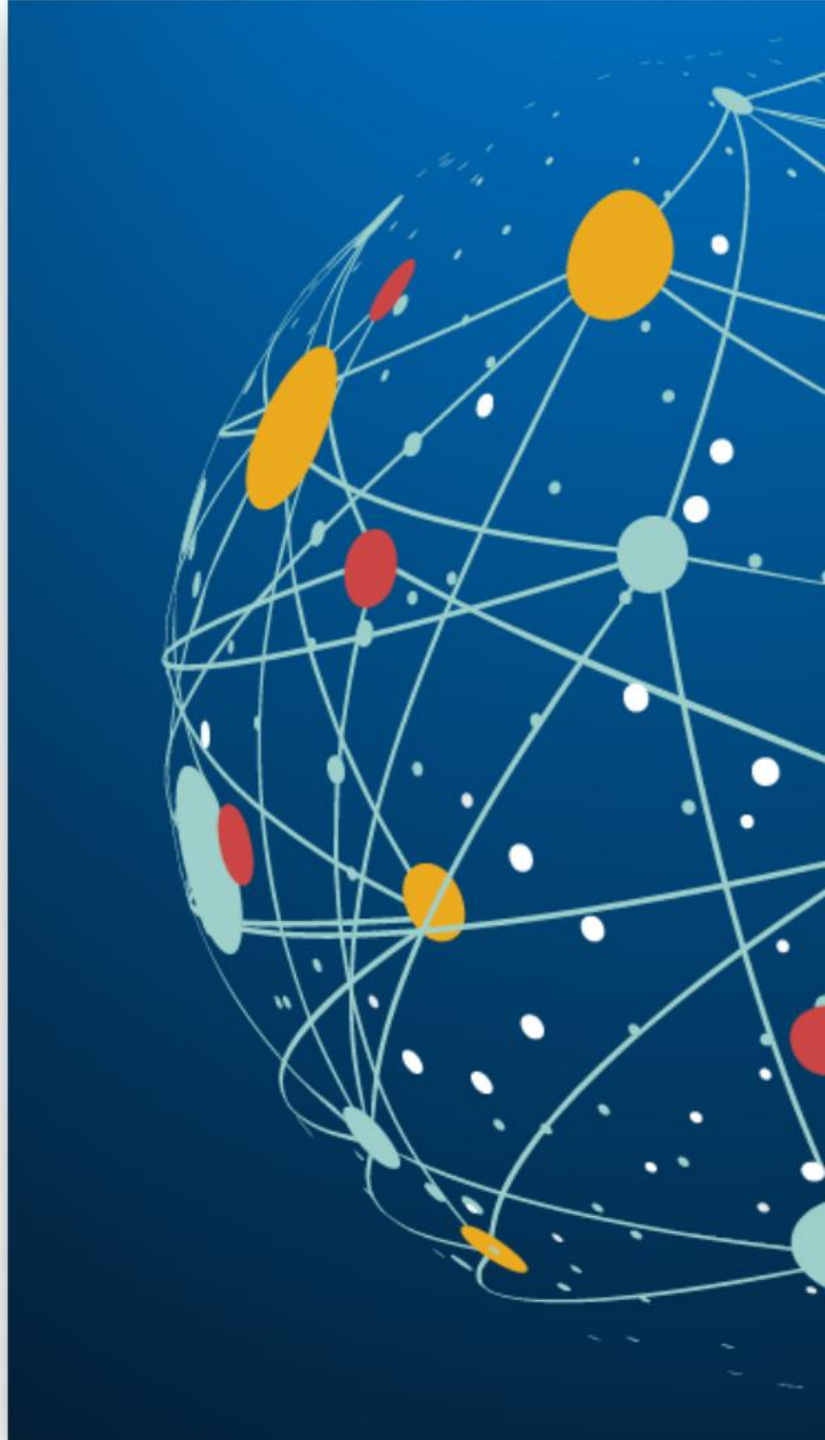
Agenda

1. Using SDTM: from compliance to added value
2. Current State of SDTM Mapping
   - Key Challenges Across Studies
   - Limitation of existing Automation
3. Our Approach – Moving Beyond Automation
4. Adoption insights & Lessons Learned
5. Key Takeaways & Closing

Using SDTM: from compliance to added value

Setting the Context

- SDTM remains a core requirement for regulatory submissions
- It ensures consistent structure for regulatory review
- It has become a central data standardization tool across studies and sponsors
- **Standardization is established, but execution remains nuanced**



Current State of SDTM Mapping

Key Challenges Across Studies

Limitations of Existing Automations

An algorithmic, EDC-agnostic approach to SDTM mapping

"Due to the differences in raw data structures and data collection standards, it may seem impossible to develop a common approach for programming SDTM datasets."

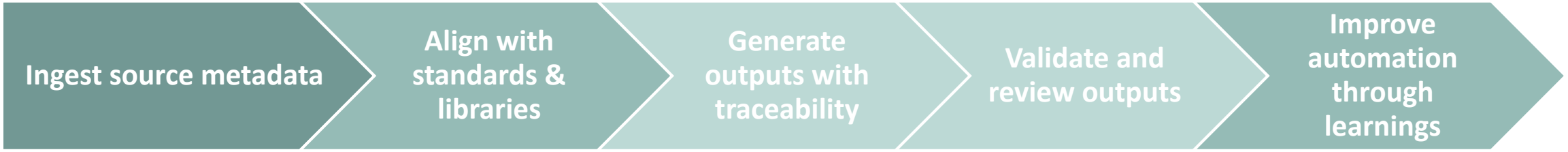
Pharmaverse - sdtm.oak

Automating ~ 80% of SDTM domains

Current State of SDTM Mapping

- SDTM mapping is moving from a **document-heavy, manual translation exercise**

- ...to a **metadata-driven automated** engineering workflow.



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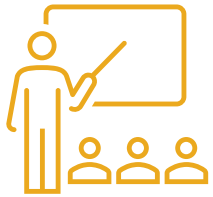
Key Challenges Across Studies

- Heterogenous raw data
- Use of proprietary standards instead of CDASH
- Some domains are harder to standardize (e.g. associated person, SUPP/NSV and RELREC domains)
- Nontrivial validation and CT management

Limitation of existing Automation



Training data

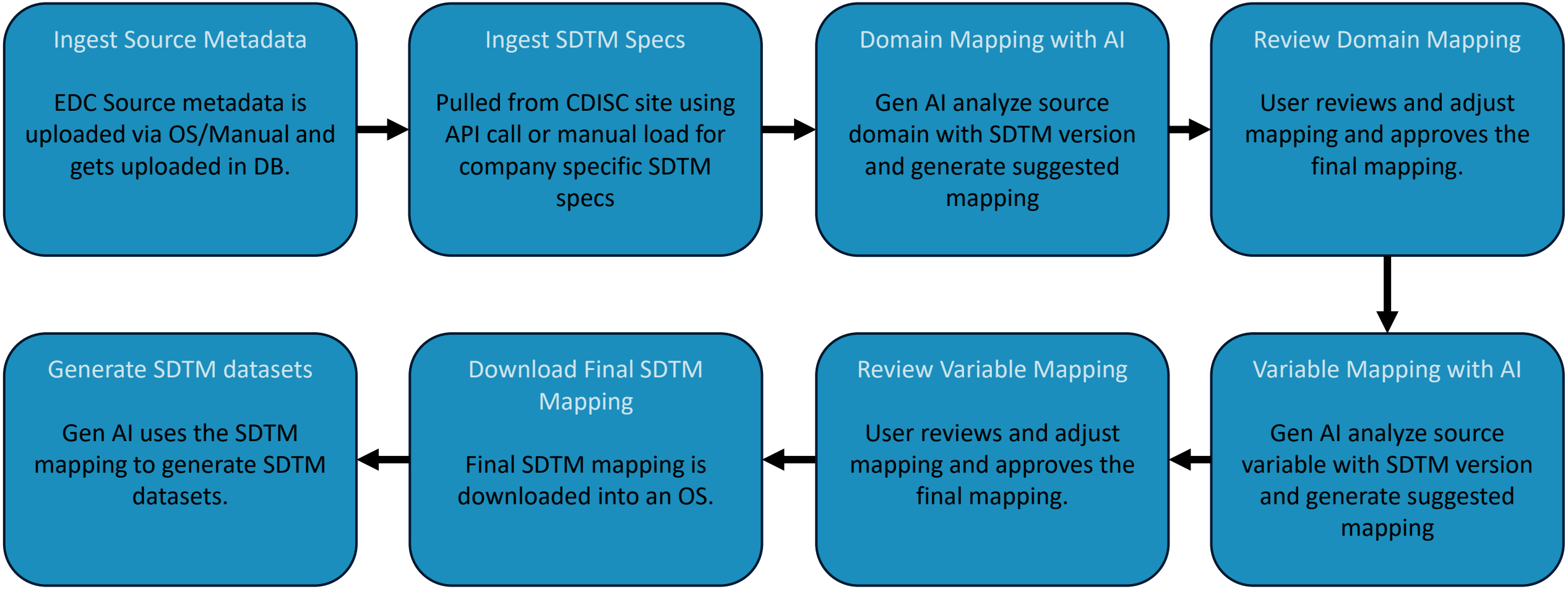
Sponsor context

Limited domain coverage

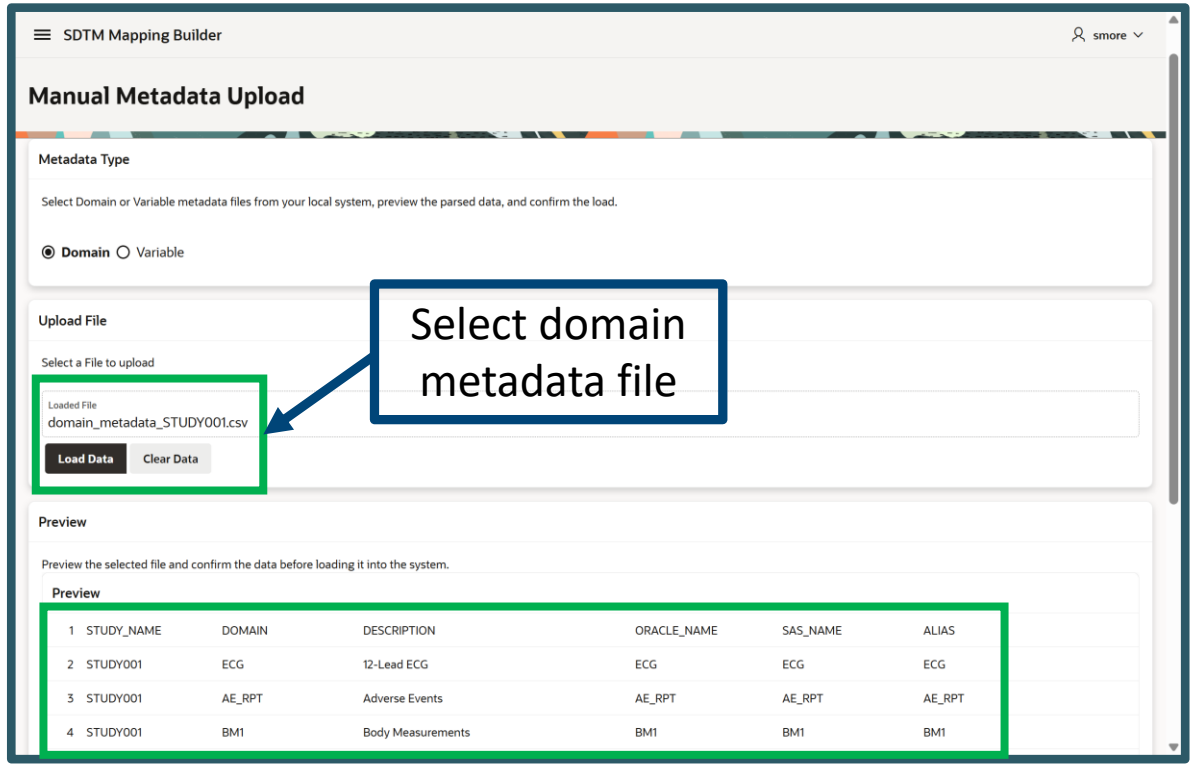
Semantic interpretation

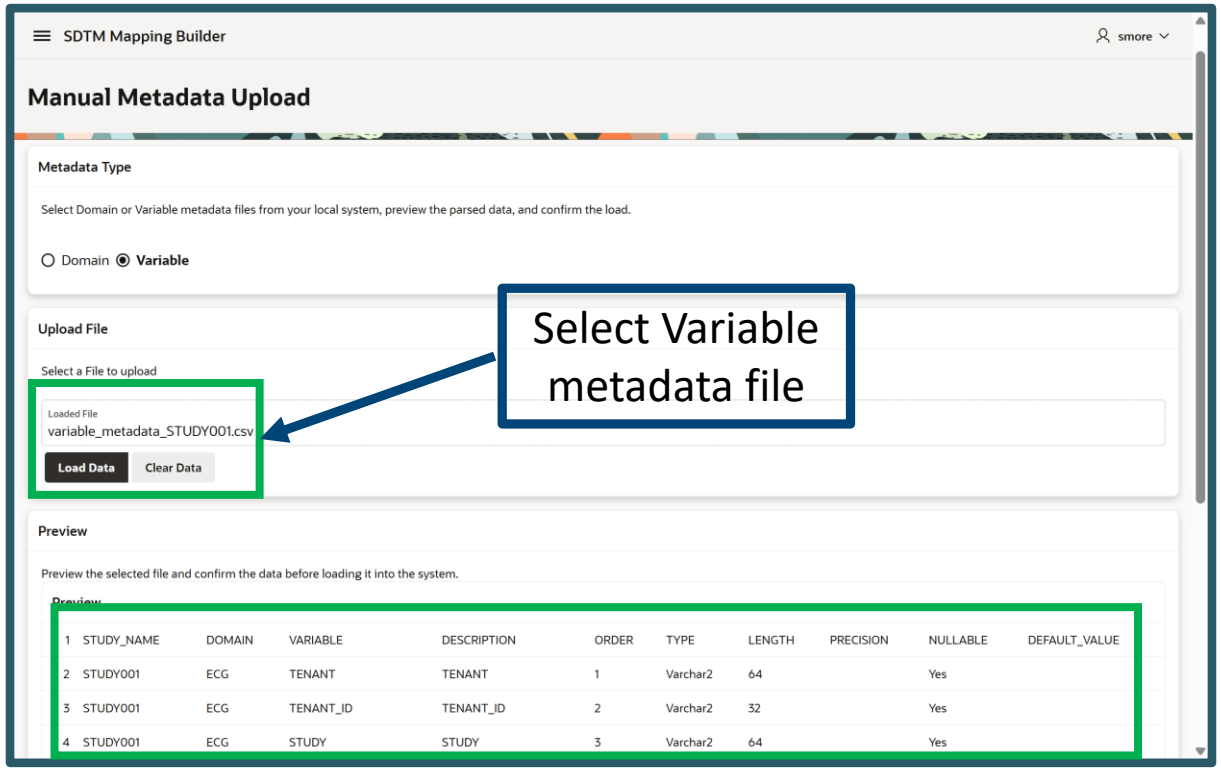
Relational, contextual, and study-specific constructs

Our Approach – Moving Beyond Automation

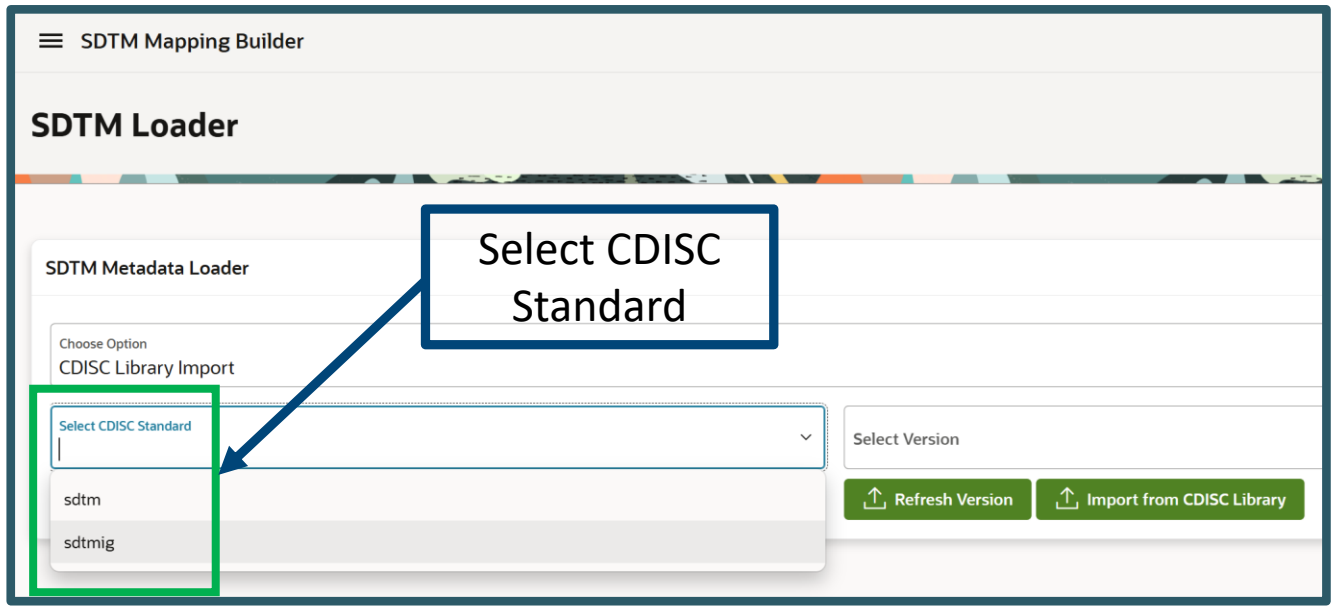


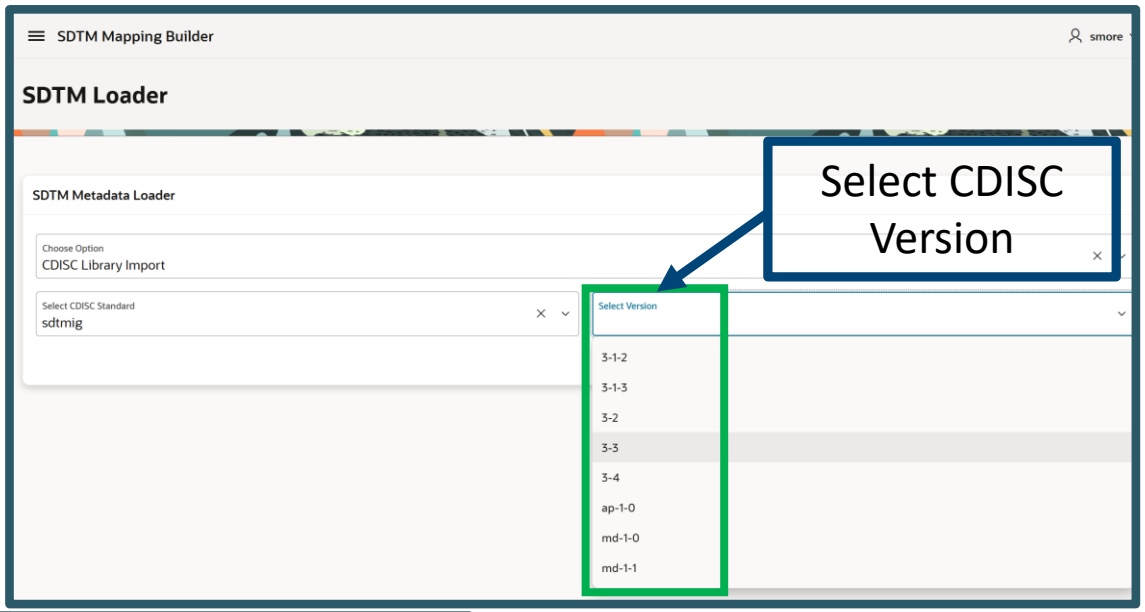
Ingest Source Metadata

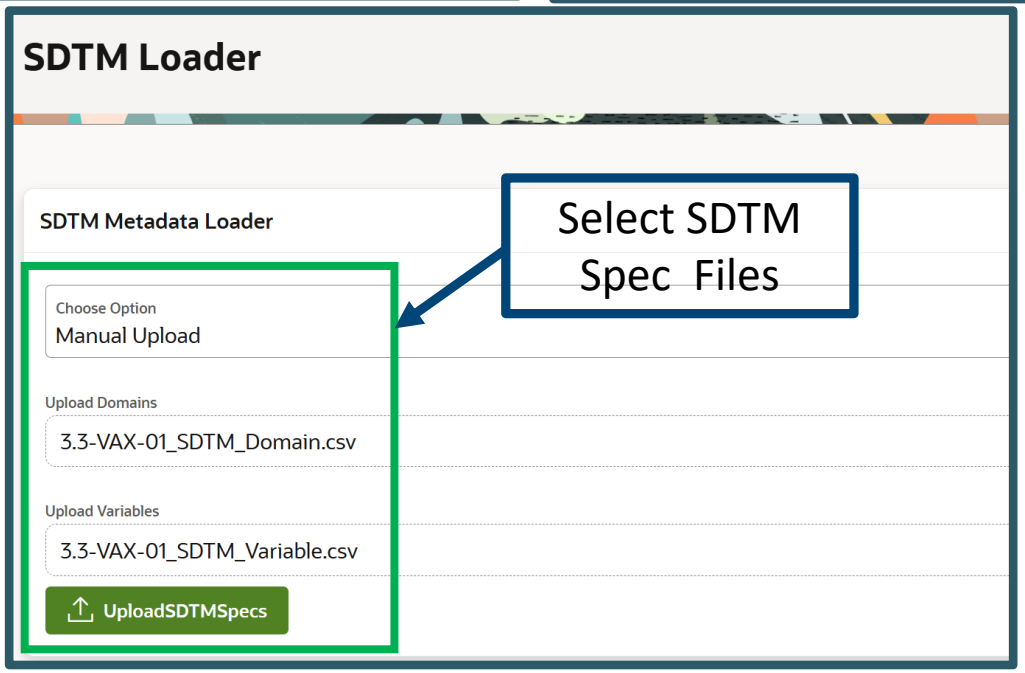




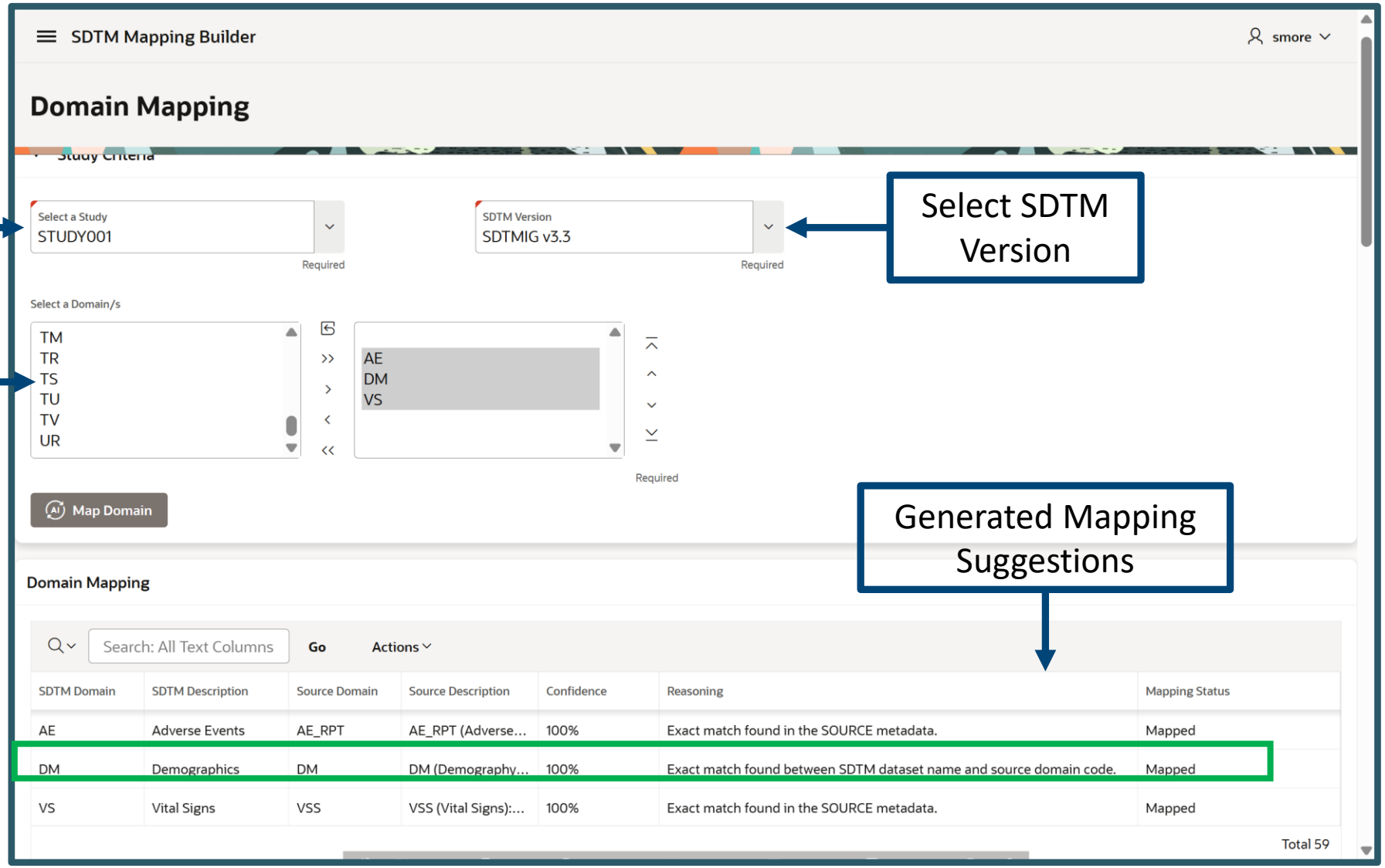
Ingest SDTM Specifications







Domain Mapping with Gen AI



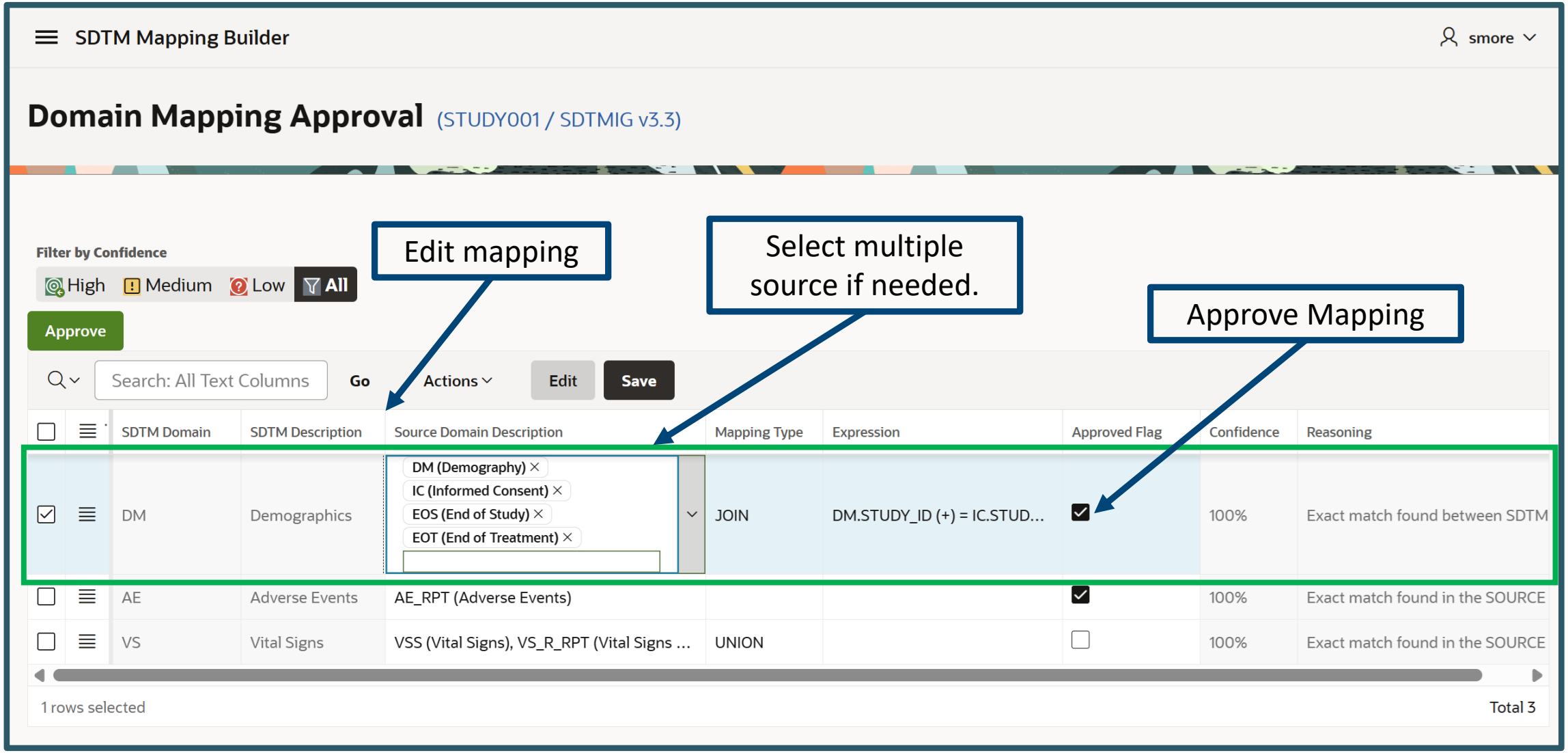
Select Study

Select Domain(s)

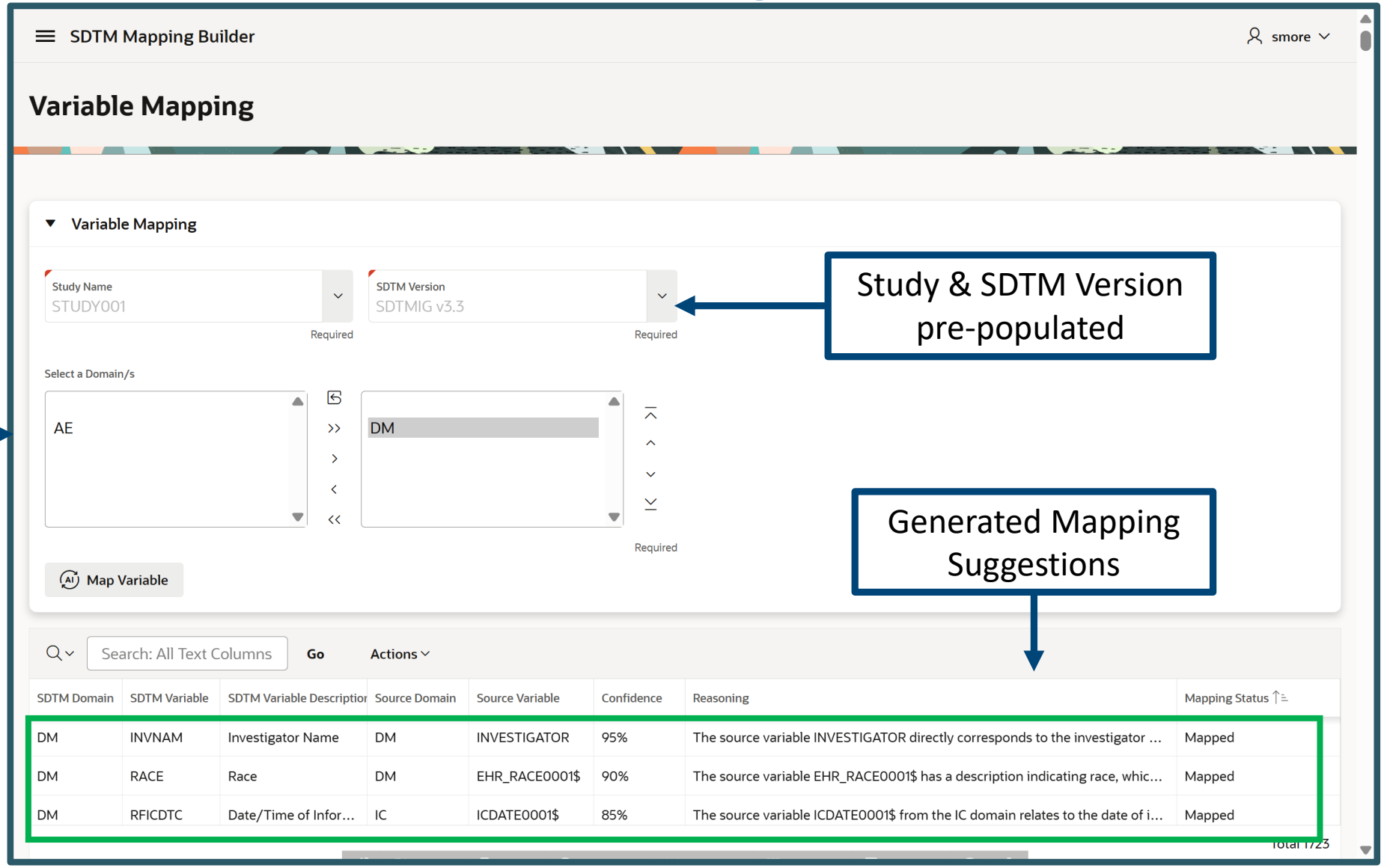
Select SDTM Version

Generated Mapping Suggestions

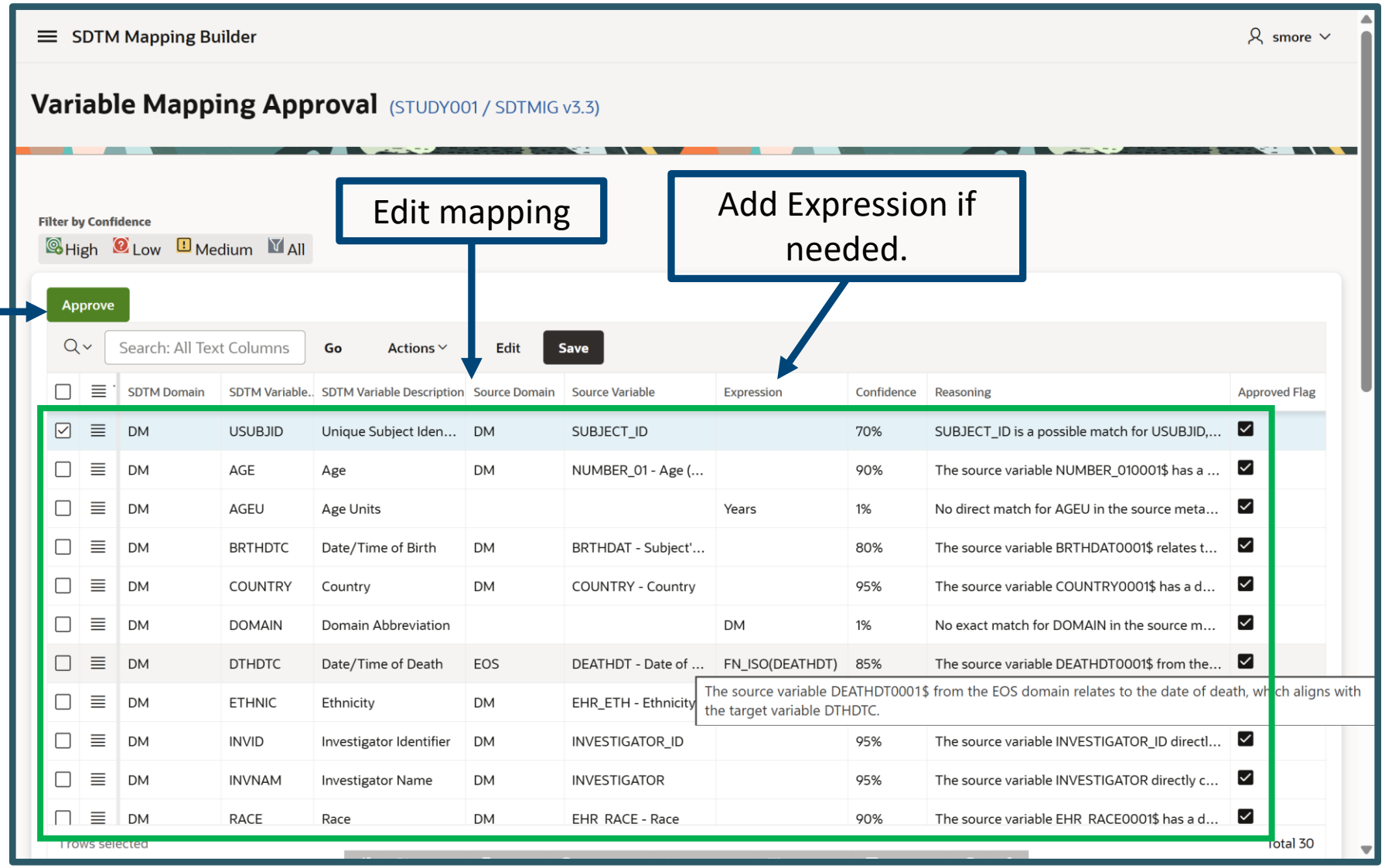
Review Domain Mapping



Variable Mapping with Gen AI

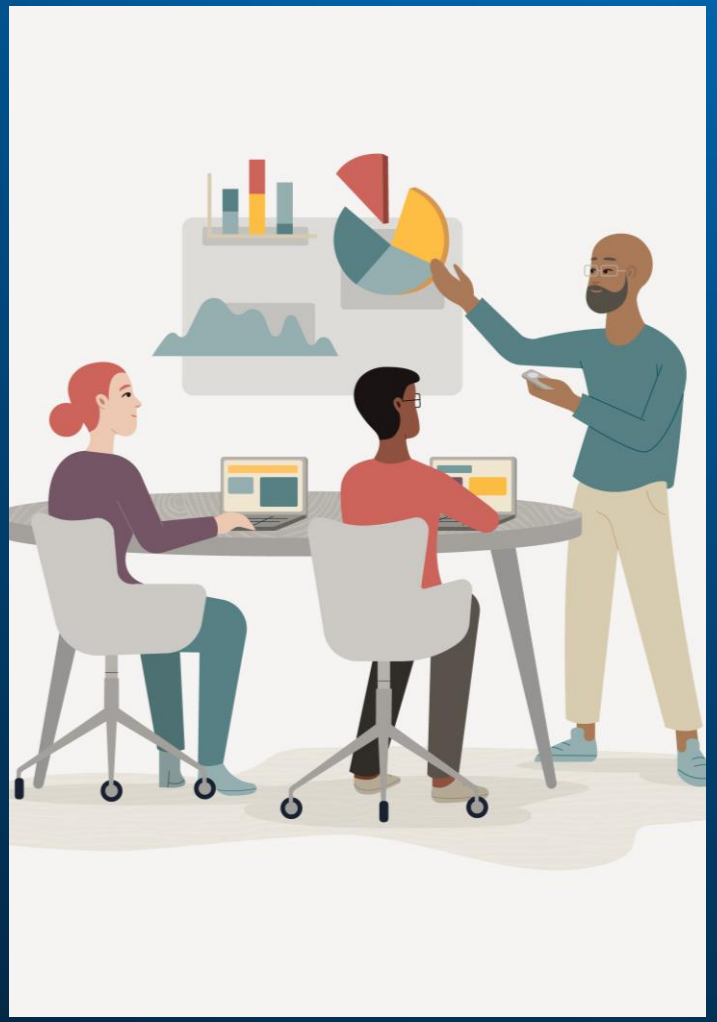


Review Variable Mapping



Adoption insights

- Initial hesitation in trusting AI-generated mappings
- High variability in sponsor standards and study designs
- Integration with existing workflows required careful alignment



Lessons Learned

- Start with AI-assisted mode, not full automation.
- Keep human-in-the-loop for validation and trust building
- Prioritize explainability (rationale + confidence)
- Leverage existing mappings to drive reuse and learning

Key Takeaways & Closing

- SDTM mapping remains manual, complex, and inconsistent
- Traditional automation alone is insufficient.
- AI can enhance mapping, but combining AI + human expertise delivers the best outcomes
- Built-in traceability ensures regulatory readiness

We are not just accelerating SDTM mapping; we are making it smarter, consistent, and inspection-ready.

Thank You!

Questions?