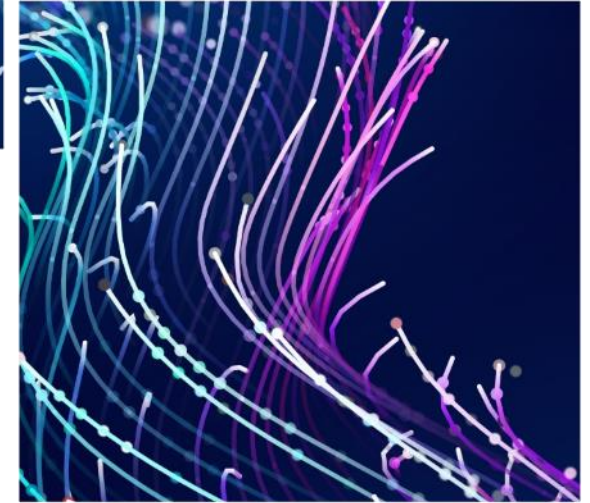


Reimagining SDTM Mapping with Agentic AI and Automation

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24 March 2026



A year of implementation taught us this:

We automated the code.

... but mapping churn and revision
still showed up in review.

Agenda

1. What automation solved — and where it plateaued
2. Reframing SDTM mapping as a reasoning problem
3. Agentic, human-in-the-loop specification creation
4. End-to-end workflow & architectural considerations
5. Outcomes, limitations, and what's next

1. What automation solved — and where it plateaued

Execution automation works.

Reasoning is where the work remains.



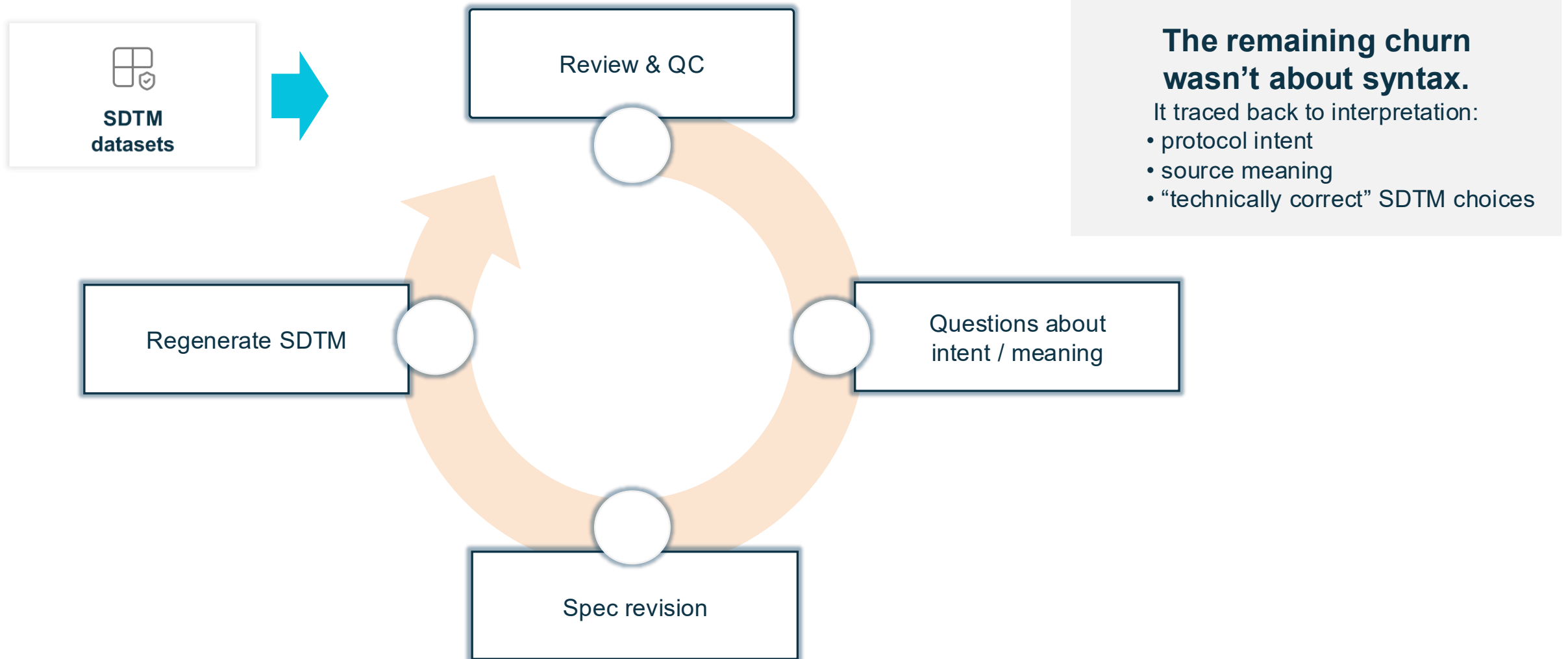
A year of automation



Shorter programming time; consistent code output

Review shifts from “did we program it correctly?” to “is the logic right?”

A year of automation



2. Reframing SDTM mapping as a reasoning problem

SDTM mapping is not primarily a coding problem; it's a reasoning problem supported by coding.



Execution vs. Reasoning

Mapping is not primarily a coding problem. It is a reasoning problem supported by coding.

EXECUTION (mostly solved)

- Deterministic code generation
- Repeatable transformations
- Scaling & optimization
- Great for speed... once the spec is correct

REASONING (where churn lives)

- Interpret protocol intent
- Understand source meaning in practice
- Choose among valid SDTM options
- Make tradeoffs explicit and reviewable

If reasoning stays implicit, decisions get revisited late — when change is expensive.

What mapping reasoning looks like in practice



PROTOCOL INTENT

What question is the study trying to answer?

How are endpoints defined in the SAP?

Are we reflecting analysis intent or raw collection?



SOURCE MEANING

What does this field really represent?

Is missingness meaningful or just uncollected?



STANDARDS CHOICES

Multiple valid interpretations of IG direction: which is the most defensible?

Are we emphasizing strict conformance or clinical clarity?



PRECEDENT & TRADEOFFS

Consistency across studies, application of organizational standards.

How was this handled in prior submissions?

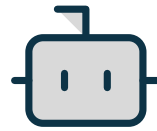
Is consistency more valuable than purist compliance?

None of these are coding questions!

3. Agentic, human-in-the-loop specification creation



Agentic reasoning for mapping



Agentic reasoning includes:
evaluating alternatives,
applying constraints,
and producing justified recommendations.

EVALUATE CONTEXT

Protocol + source metadata
+ standard IG



GENERATE OPTIONS

Evaluate candidates:
mapping + logic



EXPLAIN & RANK

Rationale,
confidence

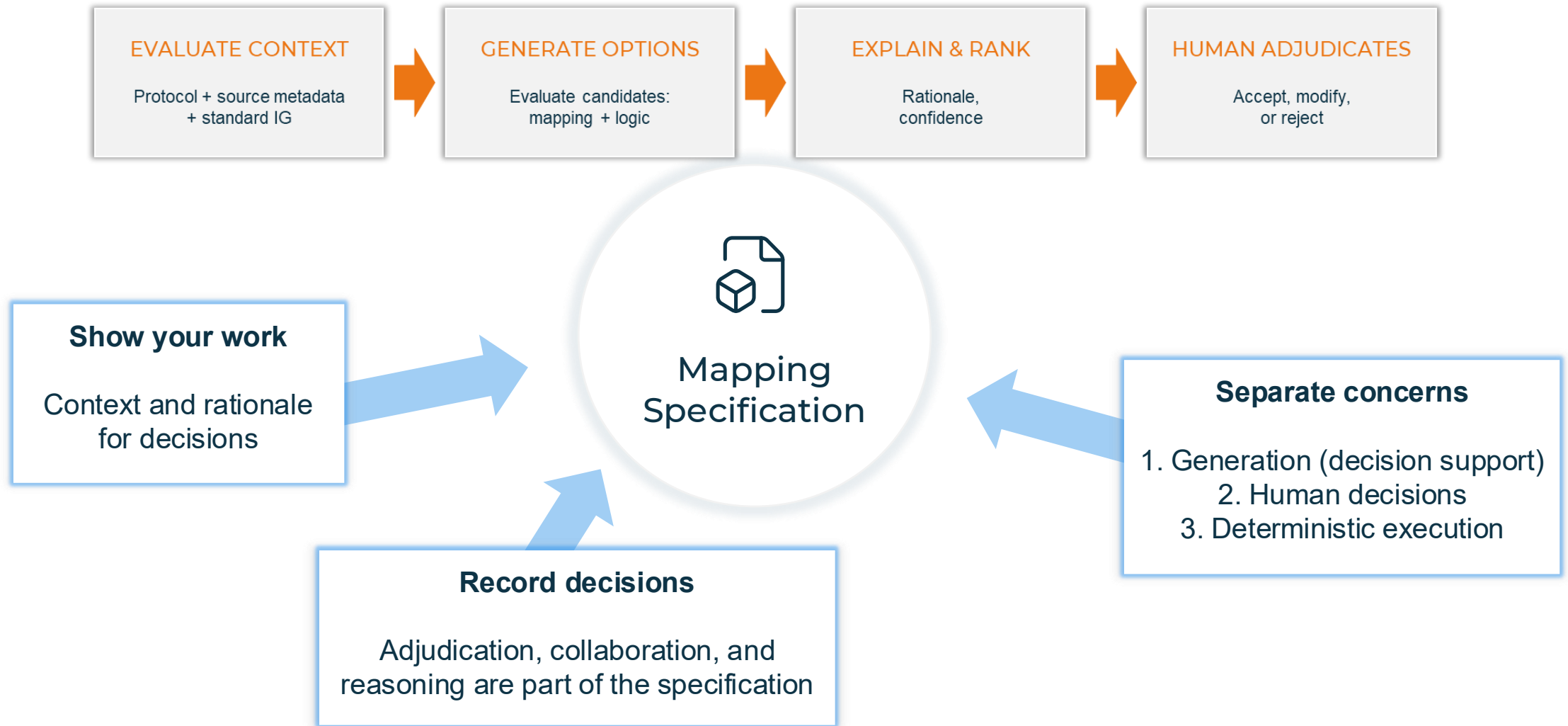


HUMAN ADJUDICATES

Accept, modify,
or reject

Transparency as a design principle

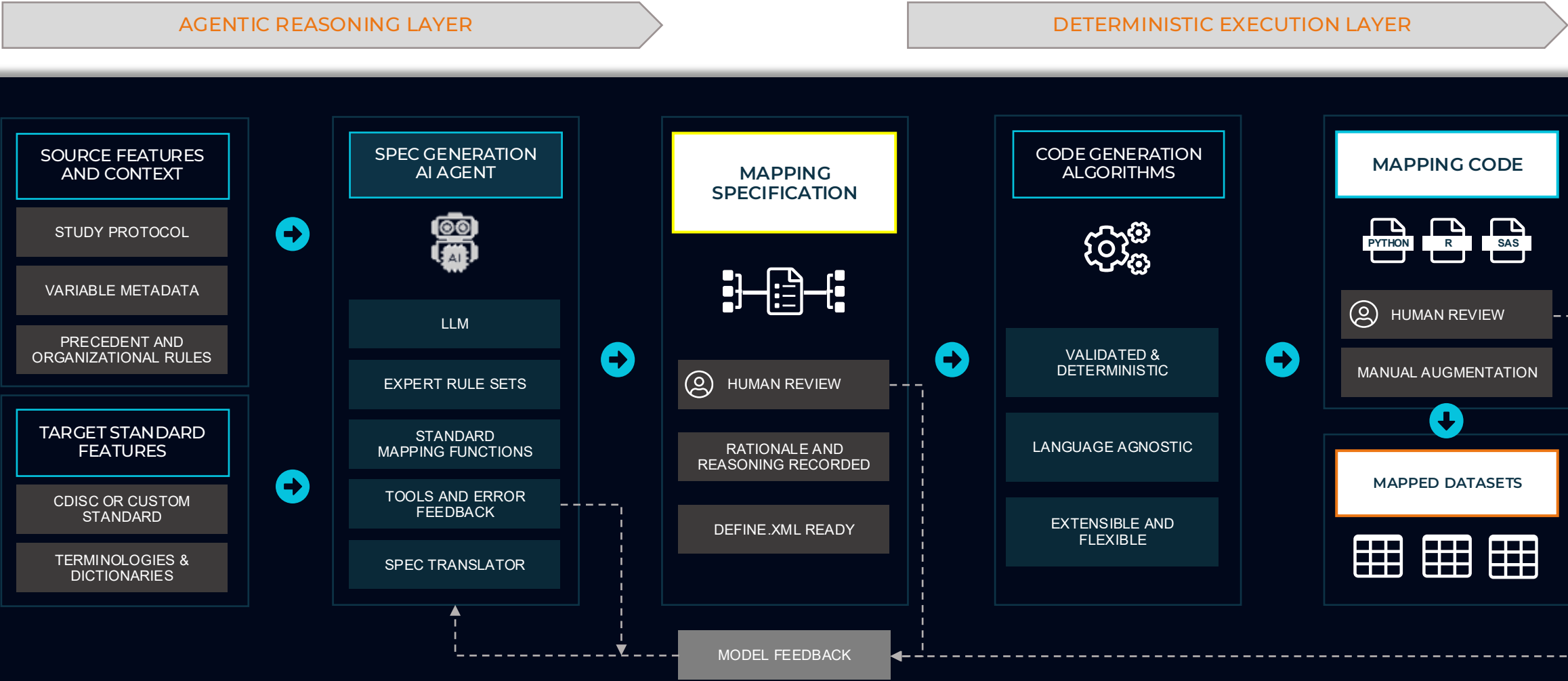
The specification becomes not just a record of final mapping decisions, but a record of reasoning and justification



4. End-to-end workflow & architectural considerations



A practical end-to-end workflow (reasoning + execution)



5. Outcomes, limitations, and what's next



Outcomes, limitations, and what's next

EARLY OUTCOMES

- Execution effort reduced and more consistent
- Review attention concentrates on fewer, higher-impact decisions
- Ambiguity is surfaced earlier when it's cheapest to resolve

LIMITATIONS / FUTURE WORK

- Evidence is limited; not controlled or large-scale
- Variability + evolving guidance will always require experts
- Next: broaden patterns; stronger models; governance playbook

Takeaway: move decisions upstream, make decisions explicit, keep execution deterministic.



The Clinical Data
Science Conference

US 2026

22-26 March
Renaissance Austin Hotel

Thank you!



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