

GENERATION GOT CHEAP. TRUST HASN'T.



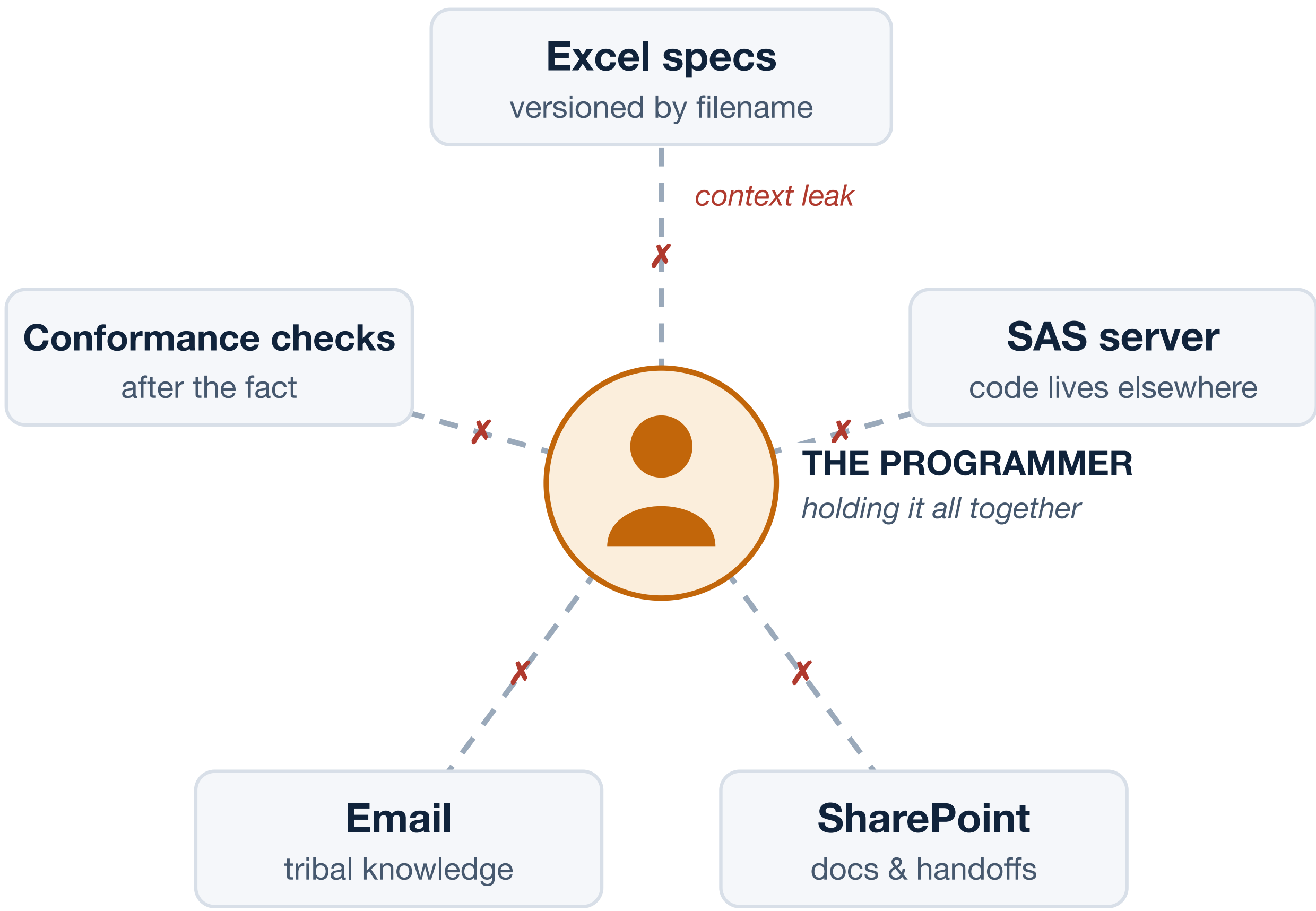
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A **platform-based, grounded vision** for CDISC workflows.

STATUS QUO

The programmer is the glue

CDISC today is organized around **the programmer as glue**. The tools work individually, but nothing carries context between them. **A person does**.



The glue is where **context, effort, and traceability leak**.

WORKAROUNDS FOR OPTIMIZATION

- 1 Fragmentation of work**
split across owners and vendors, to parallelize
- 2 Expensive QC & double programming**
duplicate builds as the default proof of correctness
- 3 Large investments in rules-based automation & standards**
macro frameworks that decay without constant upkeep

Each addresses **symptoms** of context and information loss — instead of the core problem.

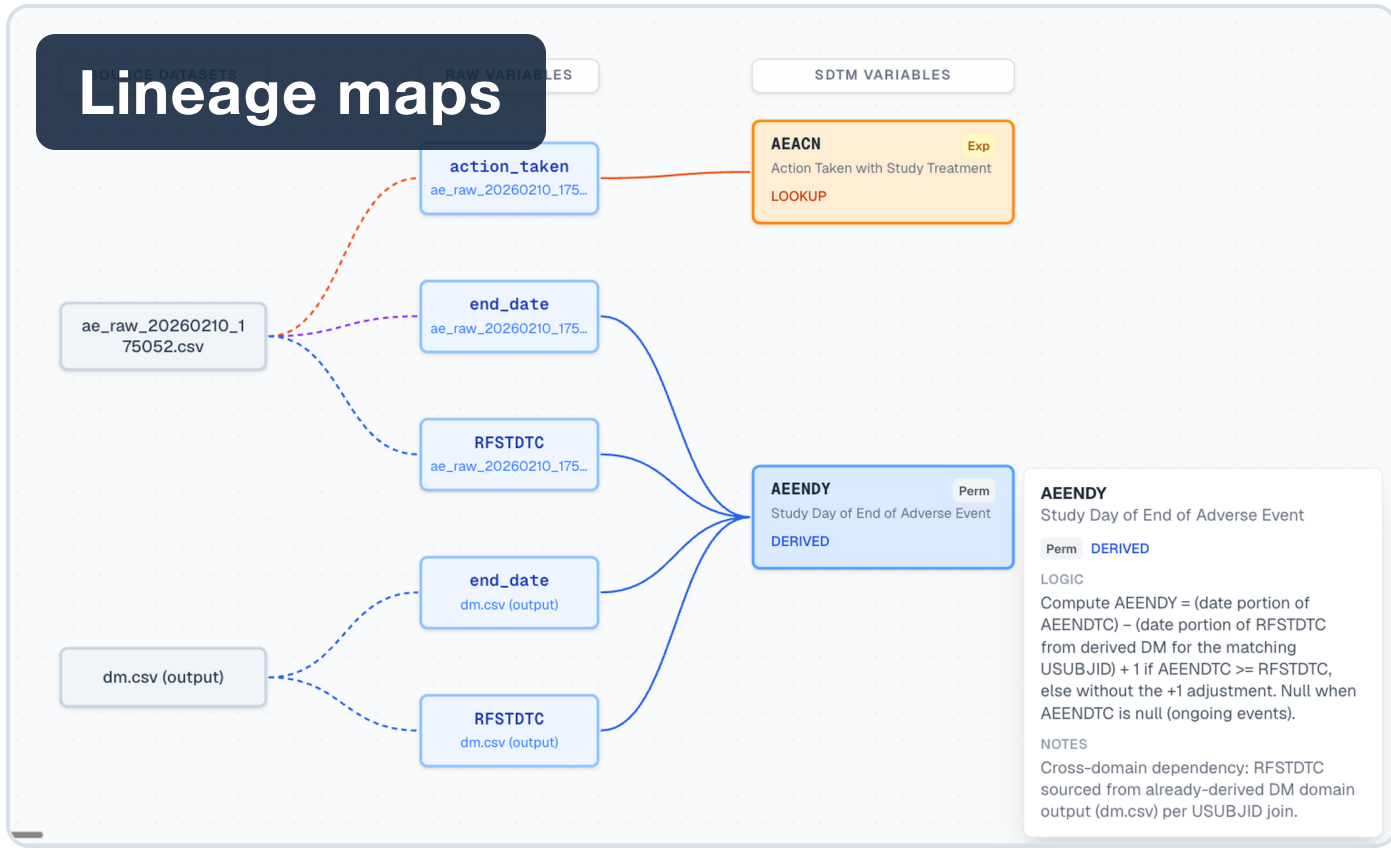
IN PRACTICE

What Platforms Can Aspire to Deliver

HARNESS-BASED AI

- ✓ **Agentic, with boundaries**
- ✓ **Built-in self-verification**
- ✓ **Balanced AI use**
generation and validation

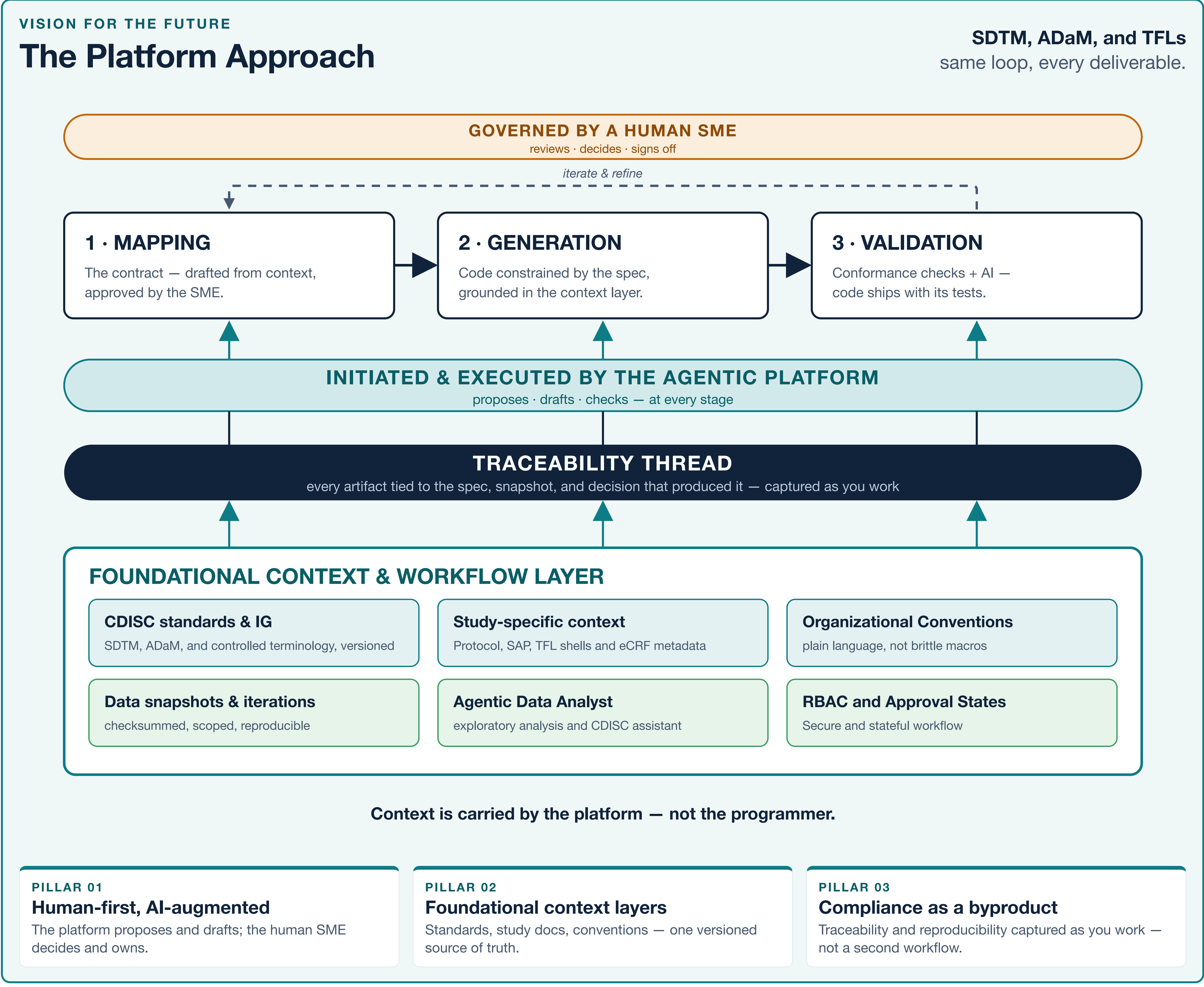
TRUST AND COMPLIANCE



BUSINESS OUTCOMES

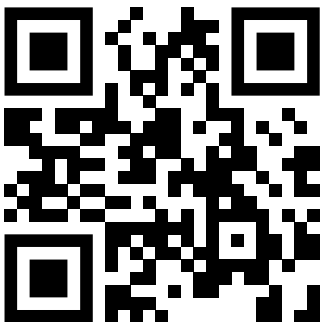
85–90%
Realistic target for work completed by AI, based on early testing

8 weeks → 4 days
For SDTM generation — opportunity to radically compress the timeline, and enable **end-to-end ownership**



“Why not just use ChatGPT or Claude?”
LLMs without versioned context and conventions are just token generators. For regulatory-grade outputs, the platform approach is what provides the **traceability**, the **AI reasoning chain**, and a **controlled harness** for robust, defensible outputs.

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