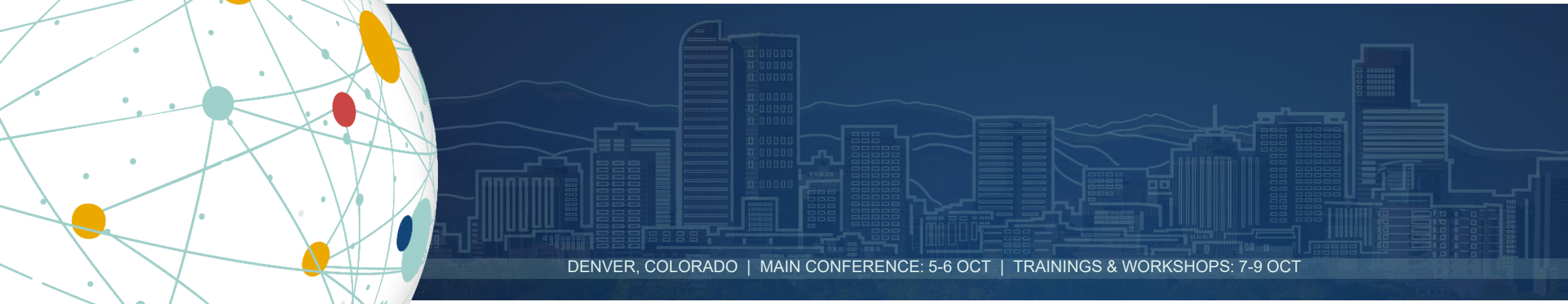
SAP-GENIE · USE CASE 02



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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



AI-Driven Generation of Statistical Analysis Plans

Accurate · Consistent · Traceable to study design

Raj Chennamaneni · Kumud Kanneganti · Sachin Tiwari · Dilip Nalla · Sudhir Kedhare

PART 1

The design

How it's built — and why the output can be trusted.

What it delivers

- **Faster first drafts** — SAP and metadata generated in one governed step
- **Eliminate manual reconciliation** — artifacts stay aligned by construction, not by cross-checking
- **Traceable by design** — every analysis links back to its protocol source
- **Consistent standards** — study-level conventions applied uniformly across artifacts

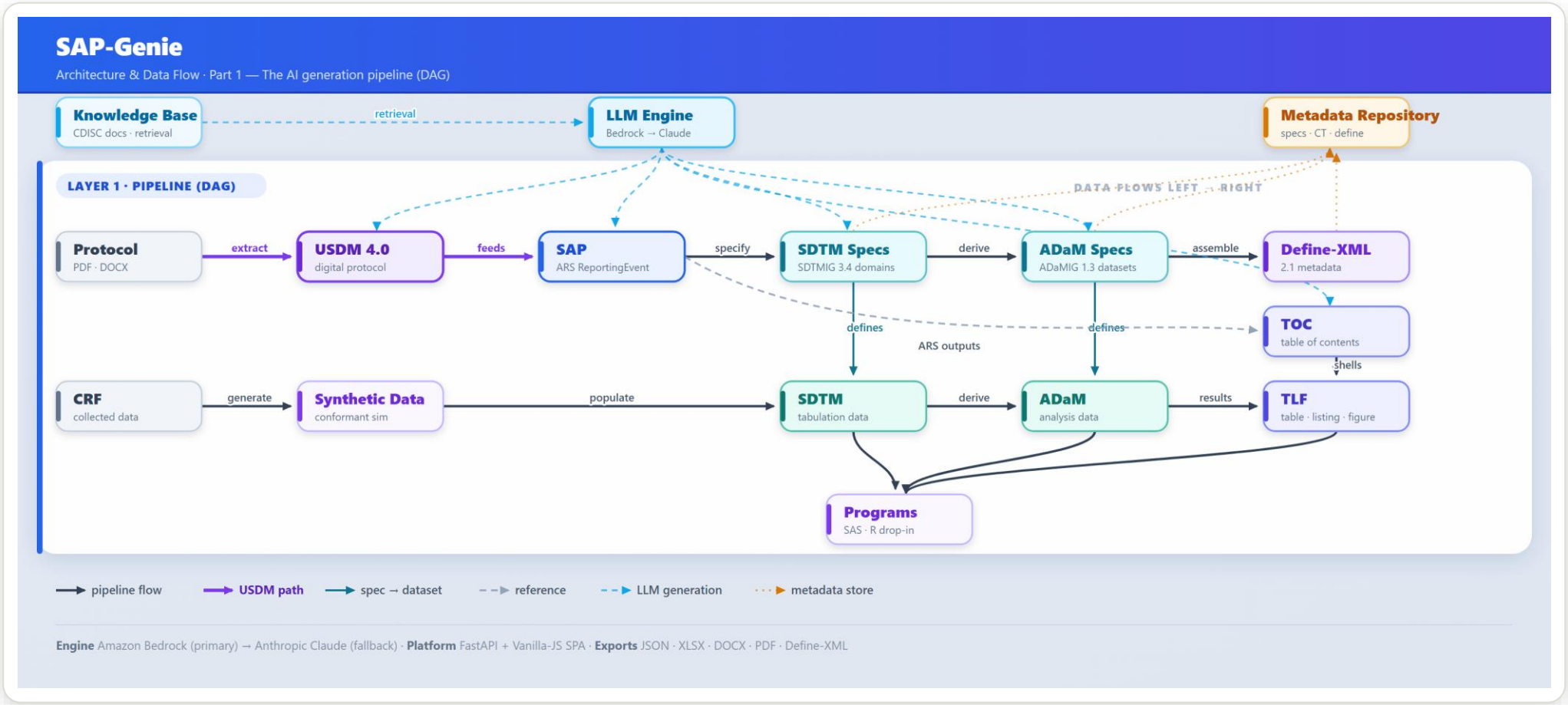
One app, all deliverables

- **One app, not many** — a single workspace produces every deliverable instead of stitching together separate tools
- **No hand-offs between apps** — one governed pipeline end to end, so nothing drifts between systems

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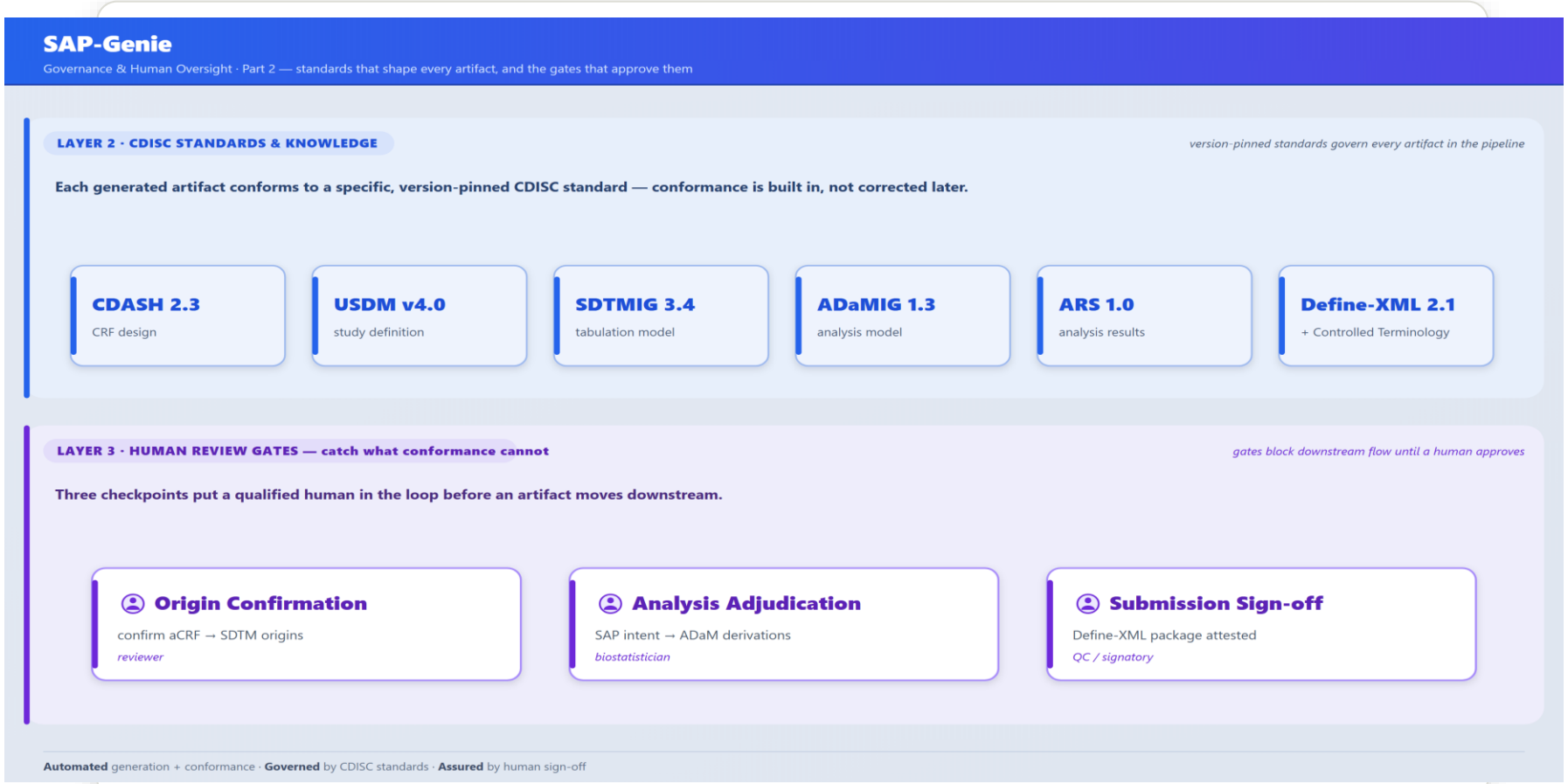
HOW IT WORKS

Architecture-1 — The generation pipeline



HOW IT WORKS

Architecture, part 2 — standards and review gates



AI generates; study experts review, refine, and approve at controlled decision points.

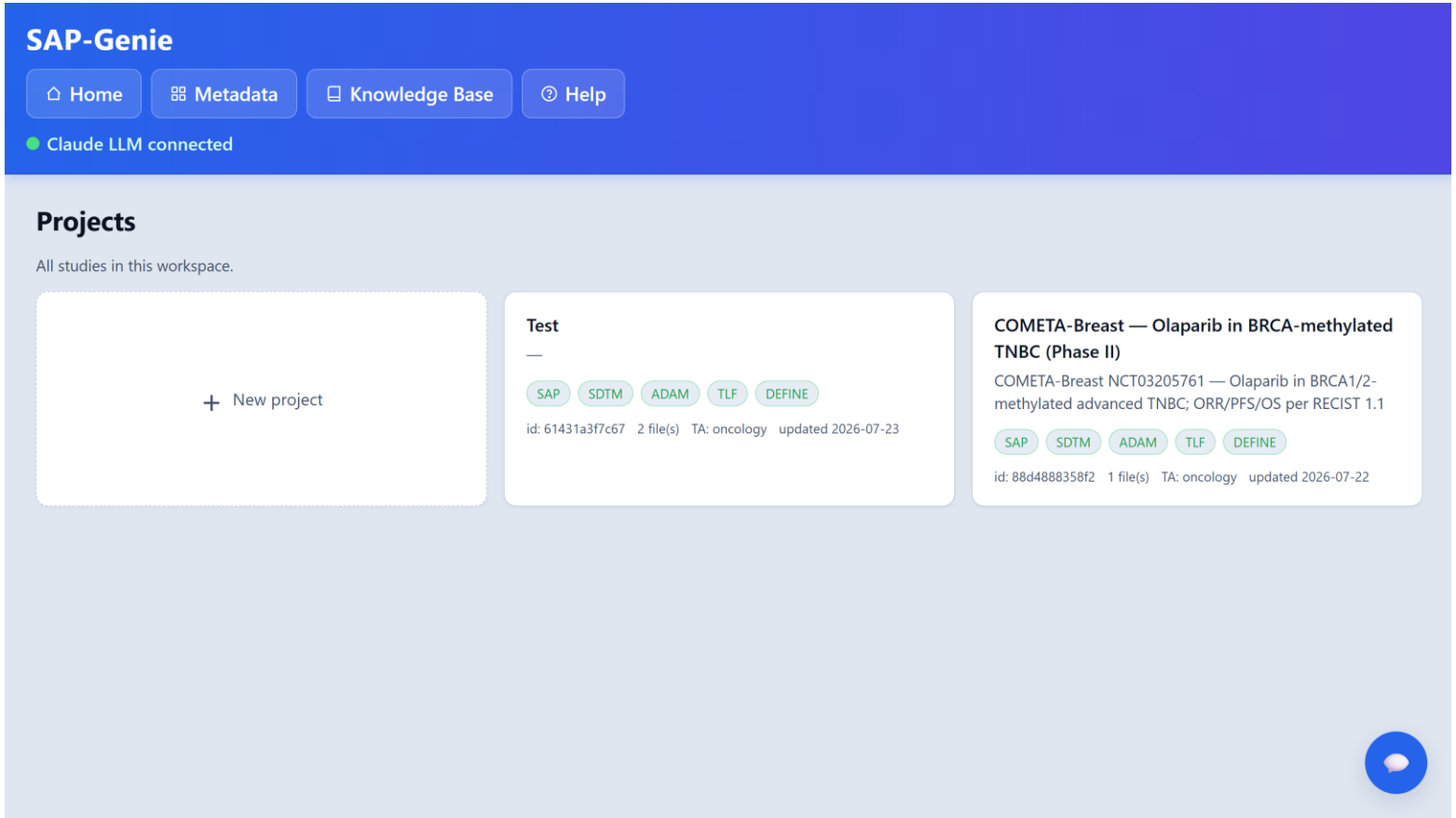
PART 2

The app

From protocol to package — a single governed workflow.

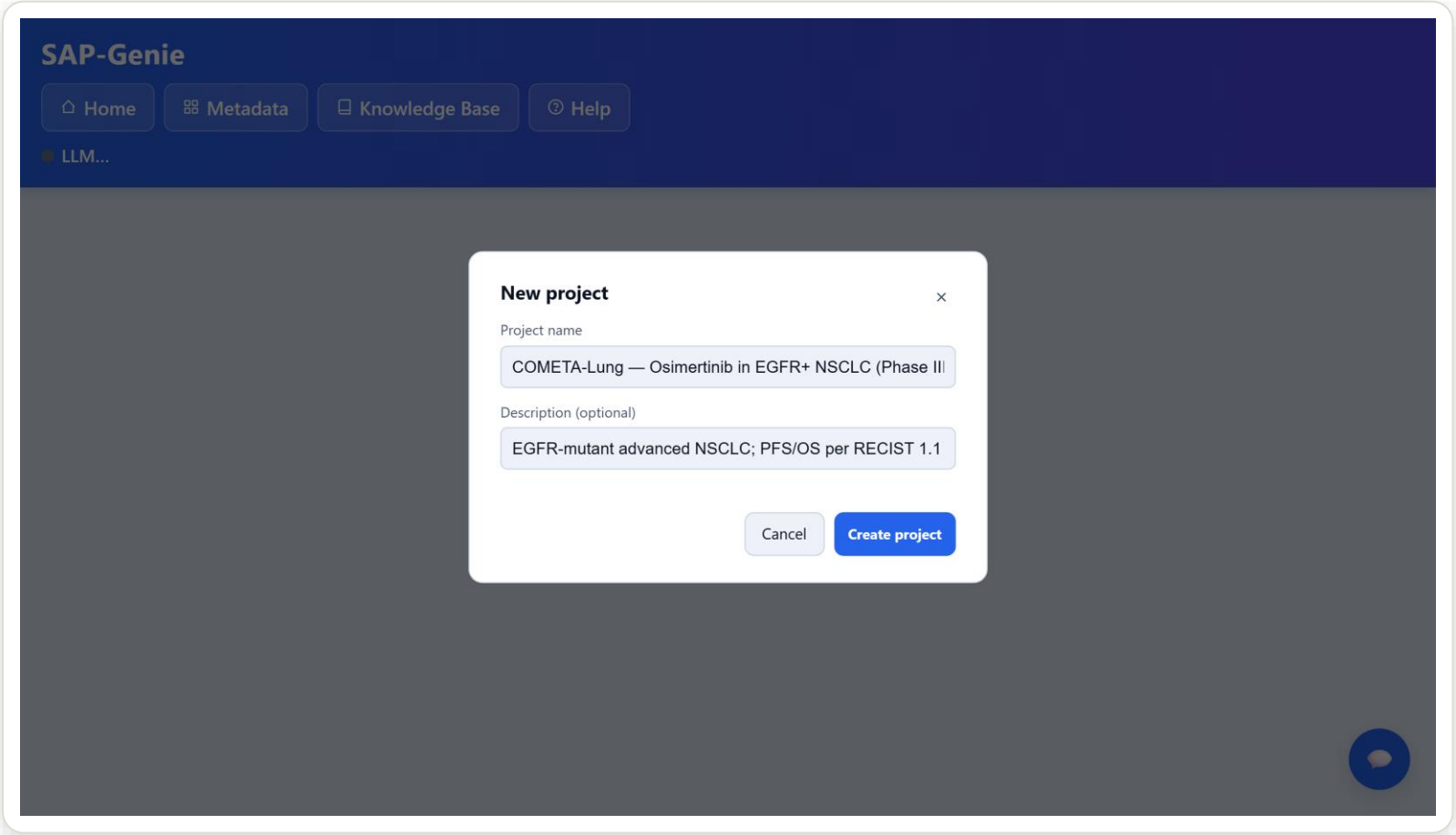
THE APP

One workspace. One study. One governed generation workflow.



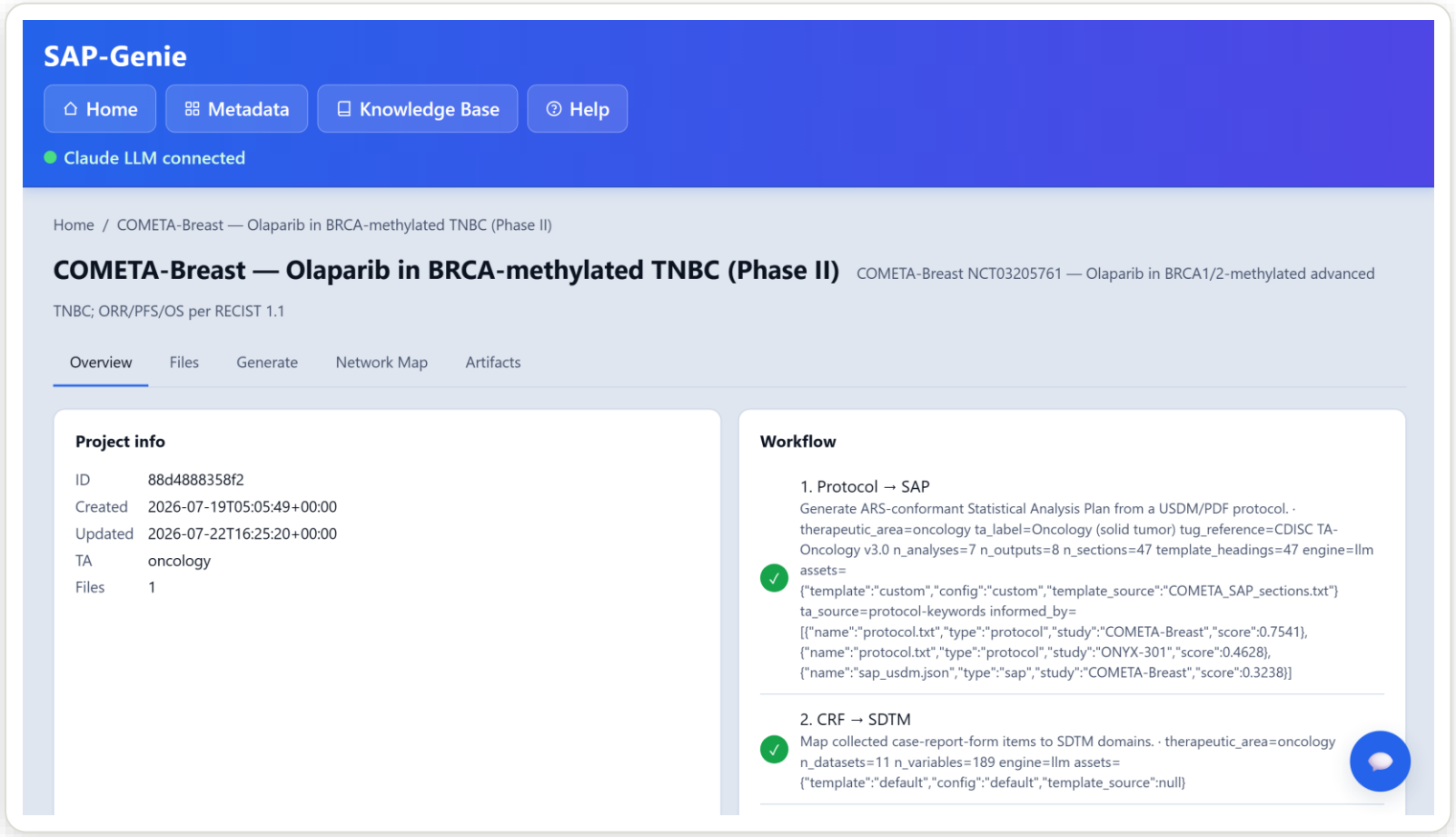
START

Create a project — one container per study



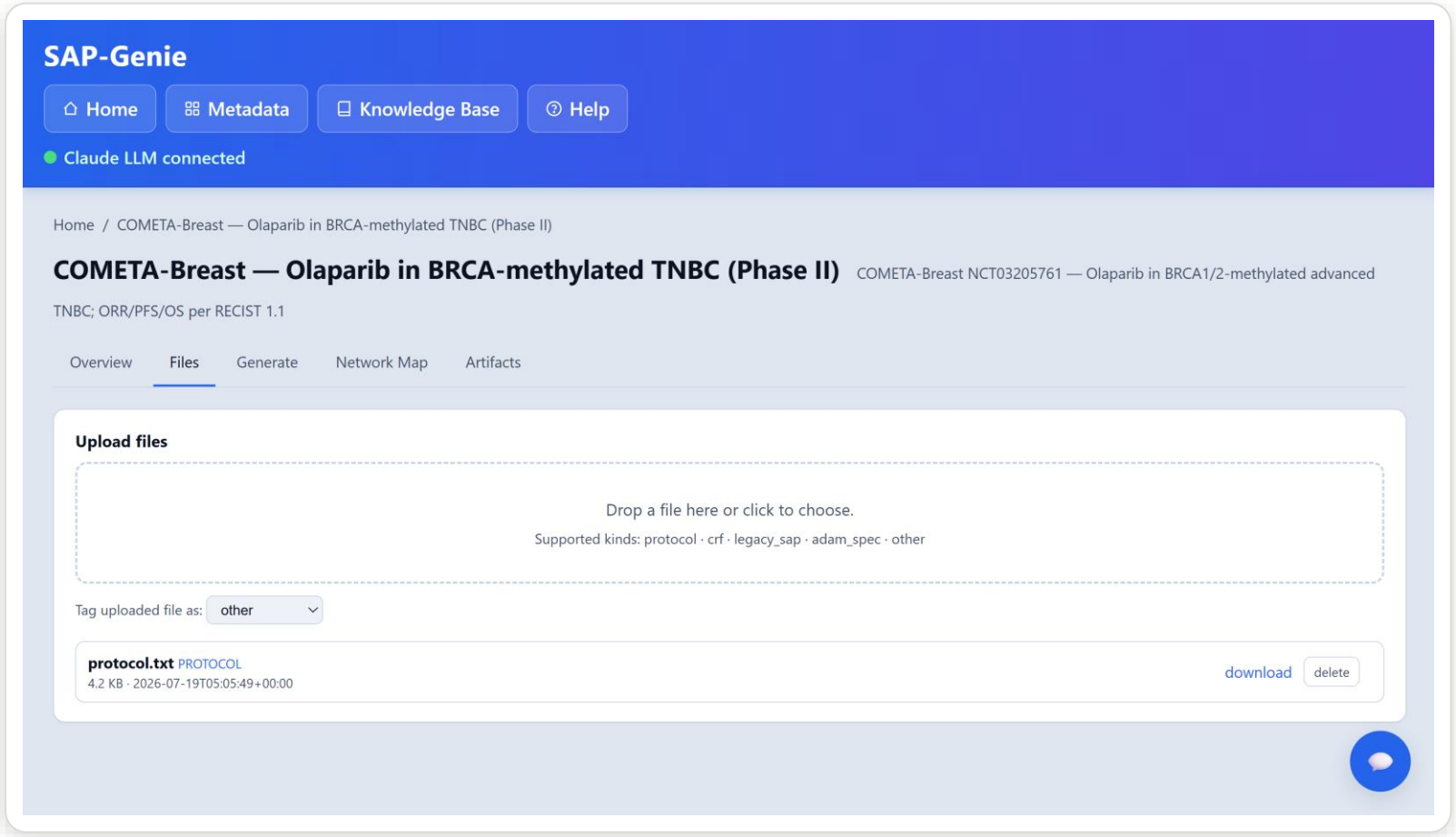
THE PROJECT

Overview: files, generation, lineage and artifacts



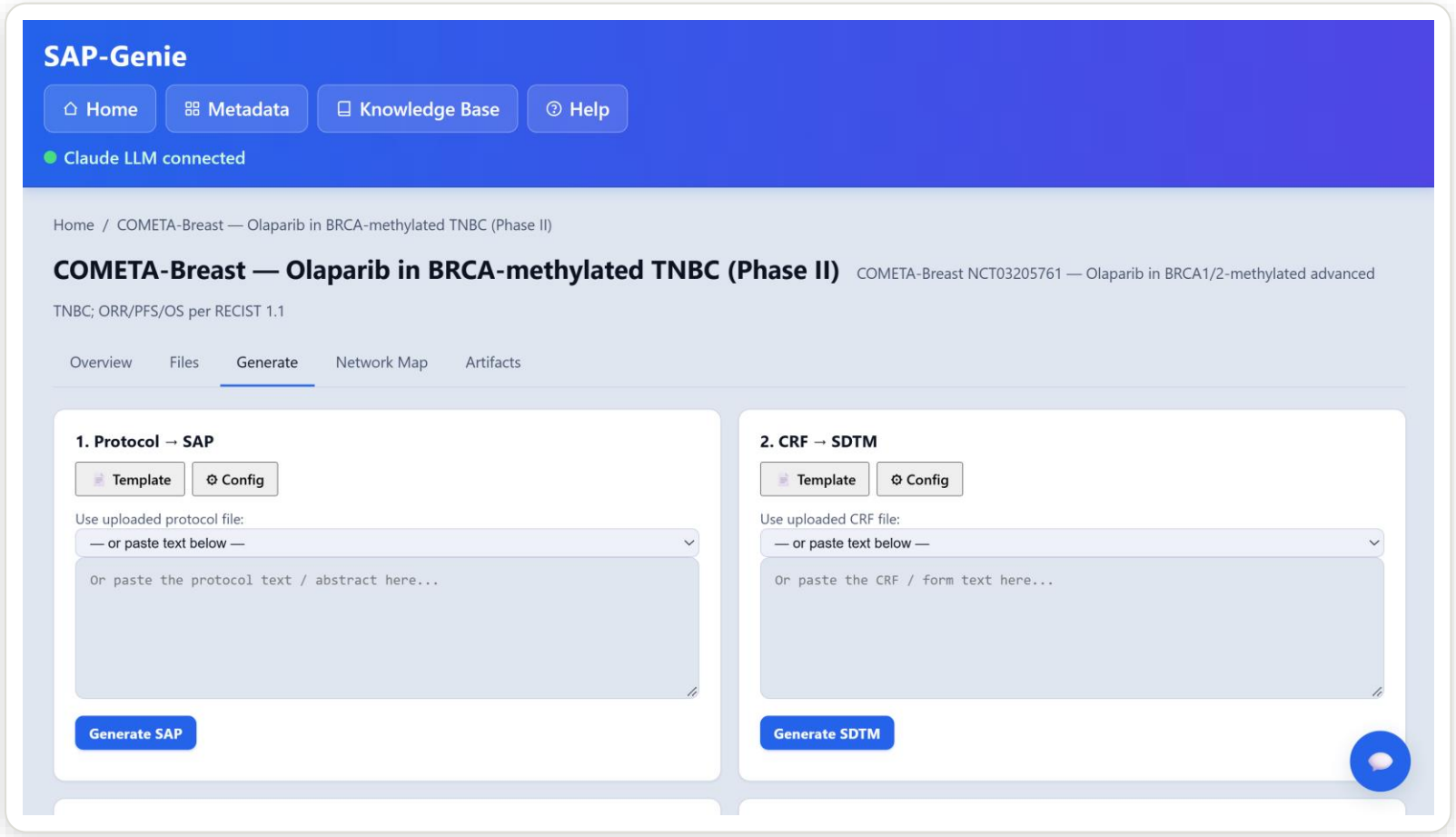
INPUT

It starts with the protocol



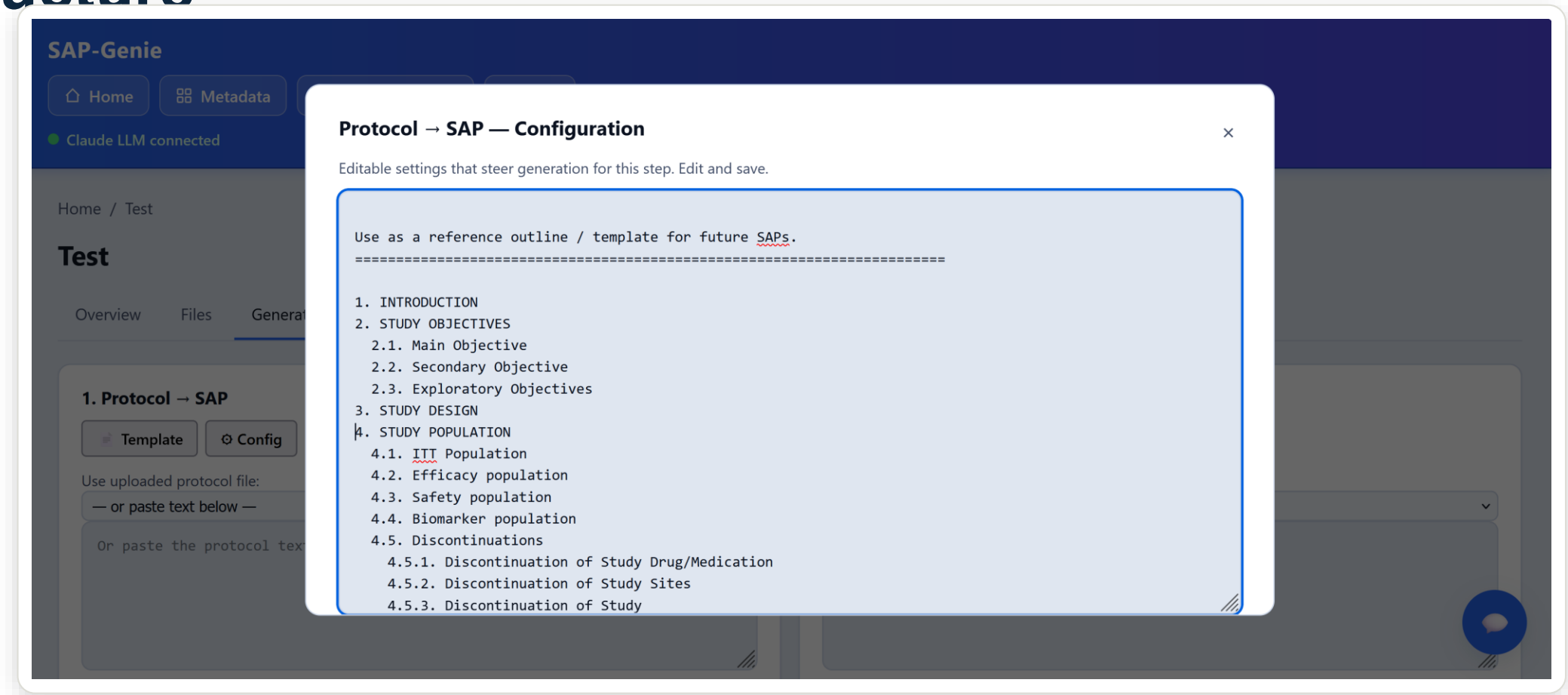
GENERATE

Protocol → SAP in a single step



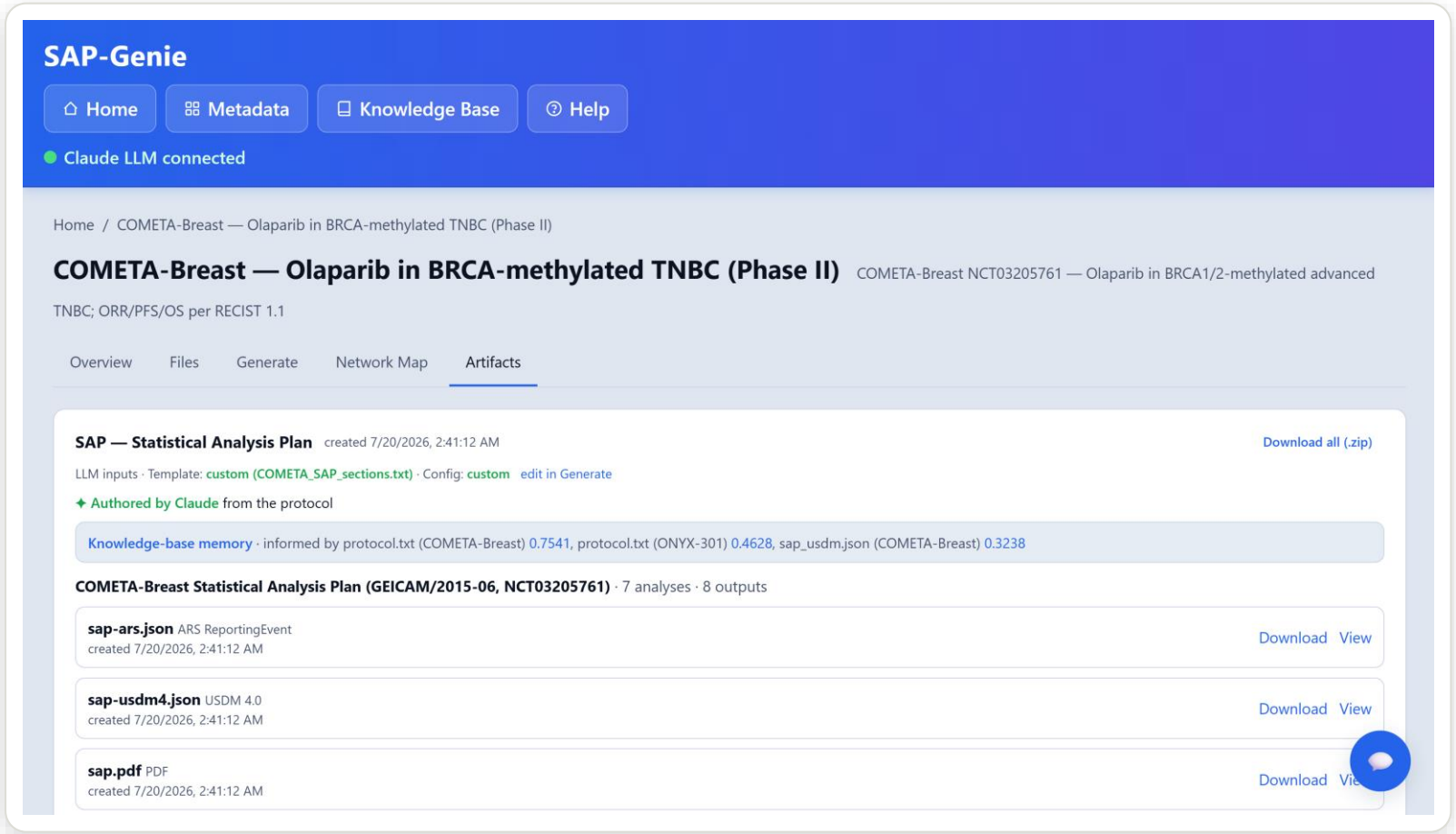
GENERATE

Configuration: forcing a deterministic structure



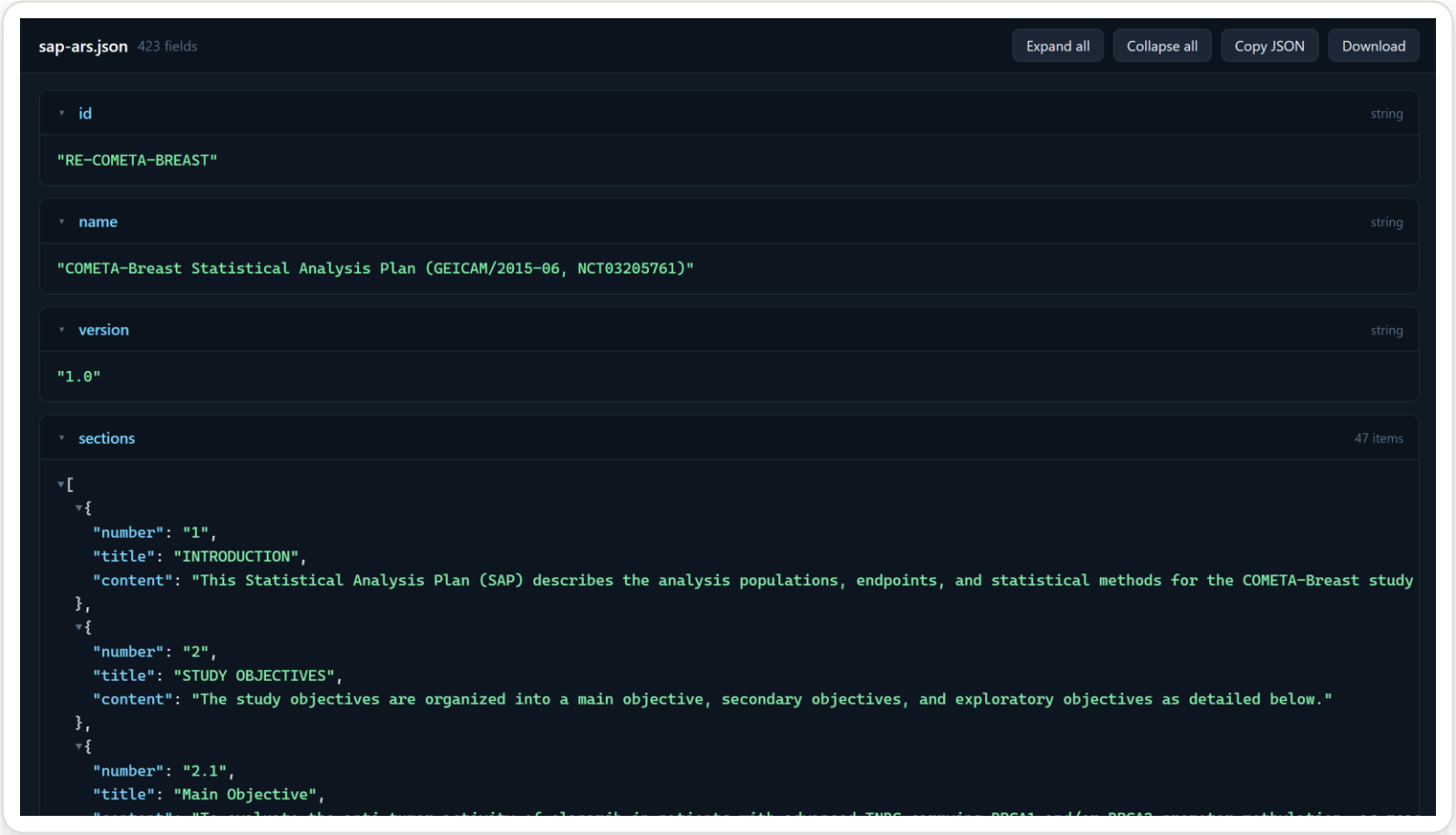
ARTIFACTS

Generated artifacts — ARS, USDM and PDF



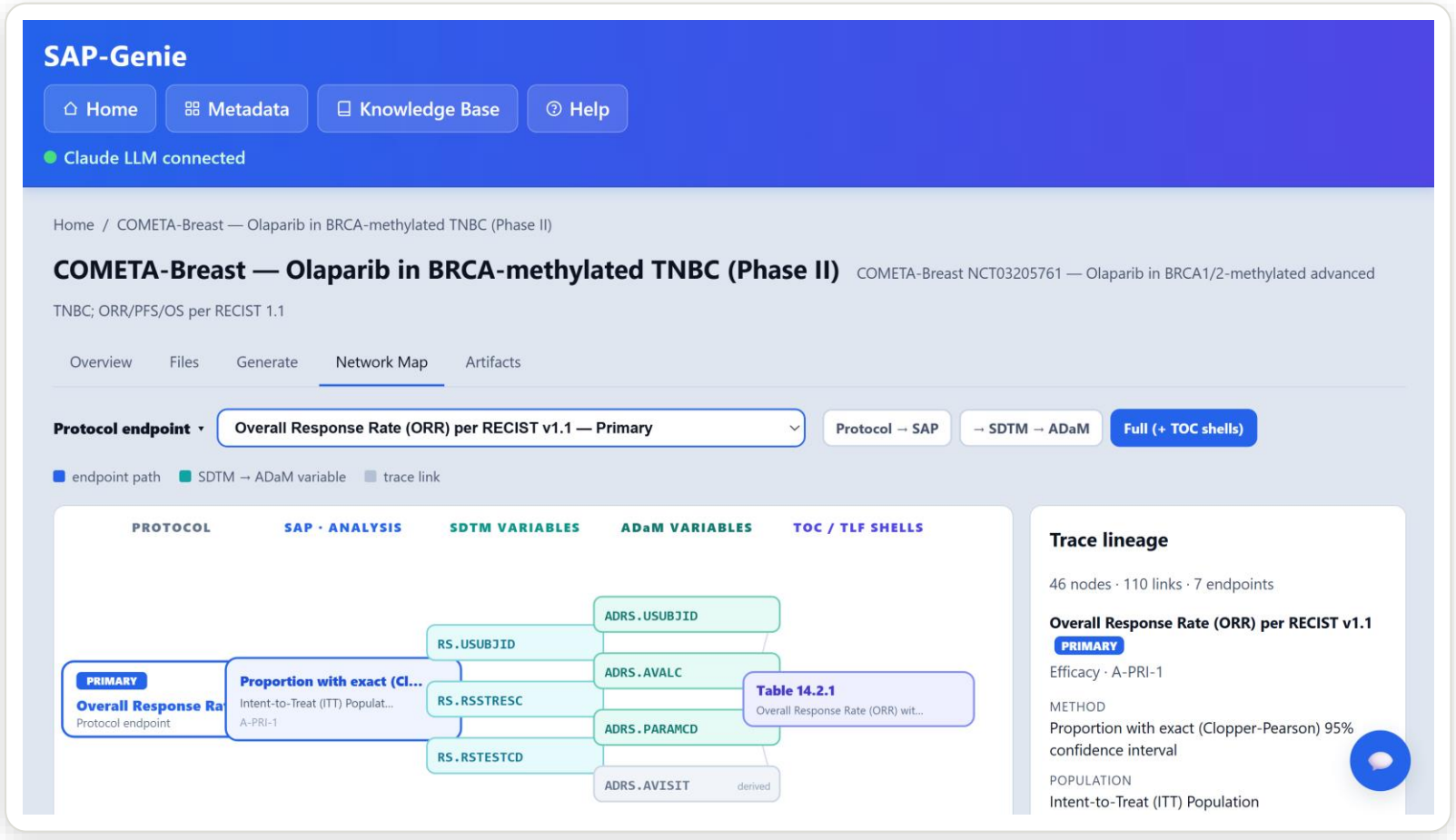
THE SAP

The SAP as a structured object — ARS JSON



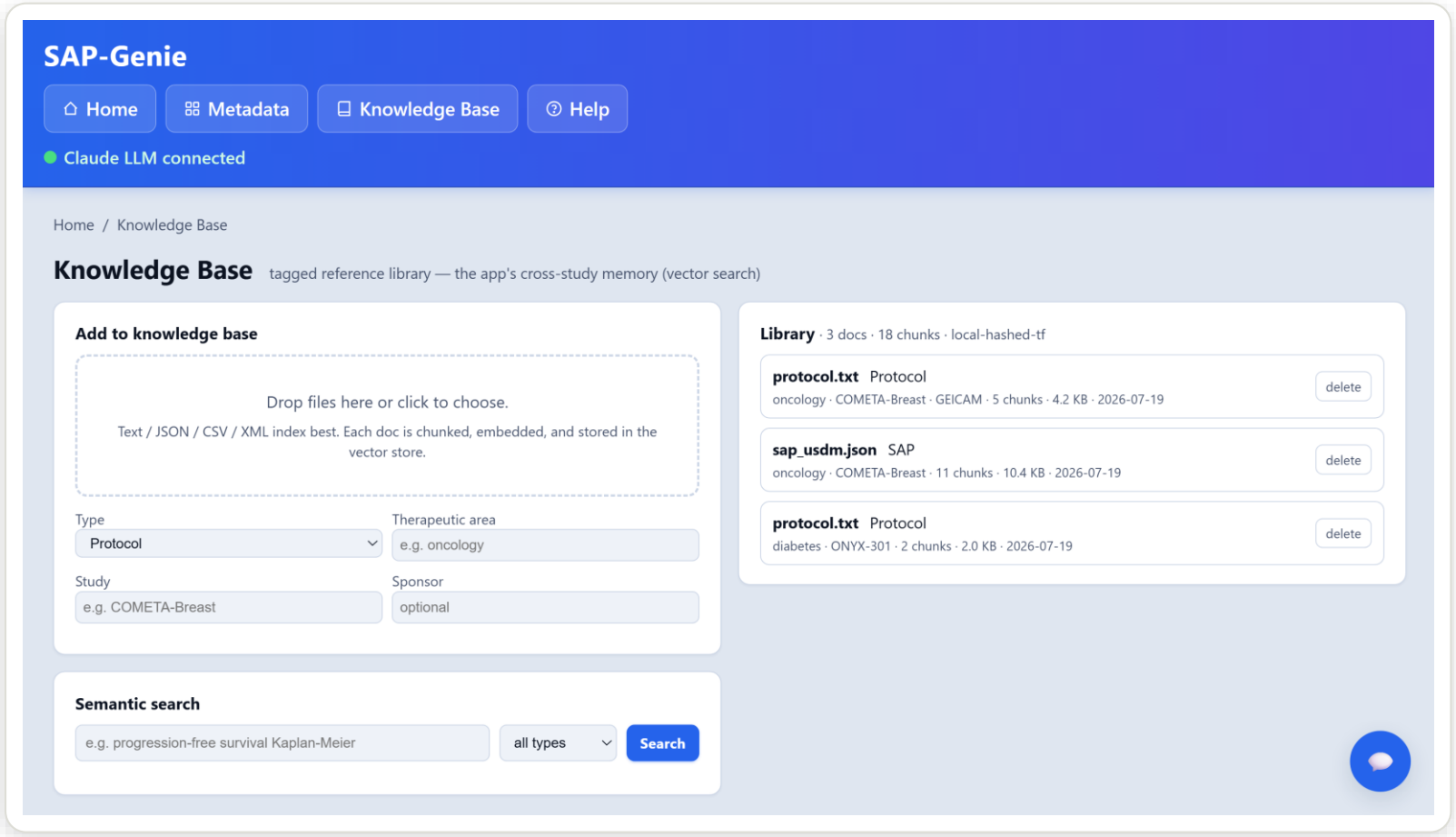
TRACE

Network Map: end-to-end traceability you can click



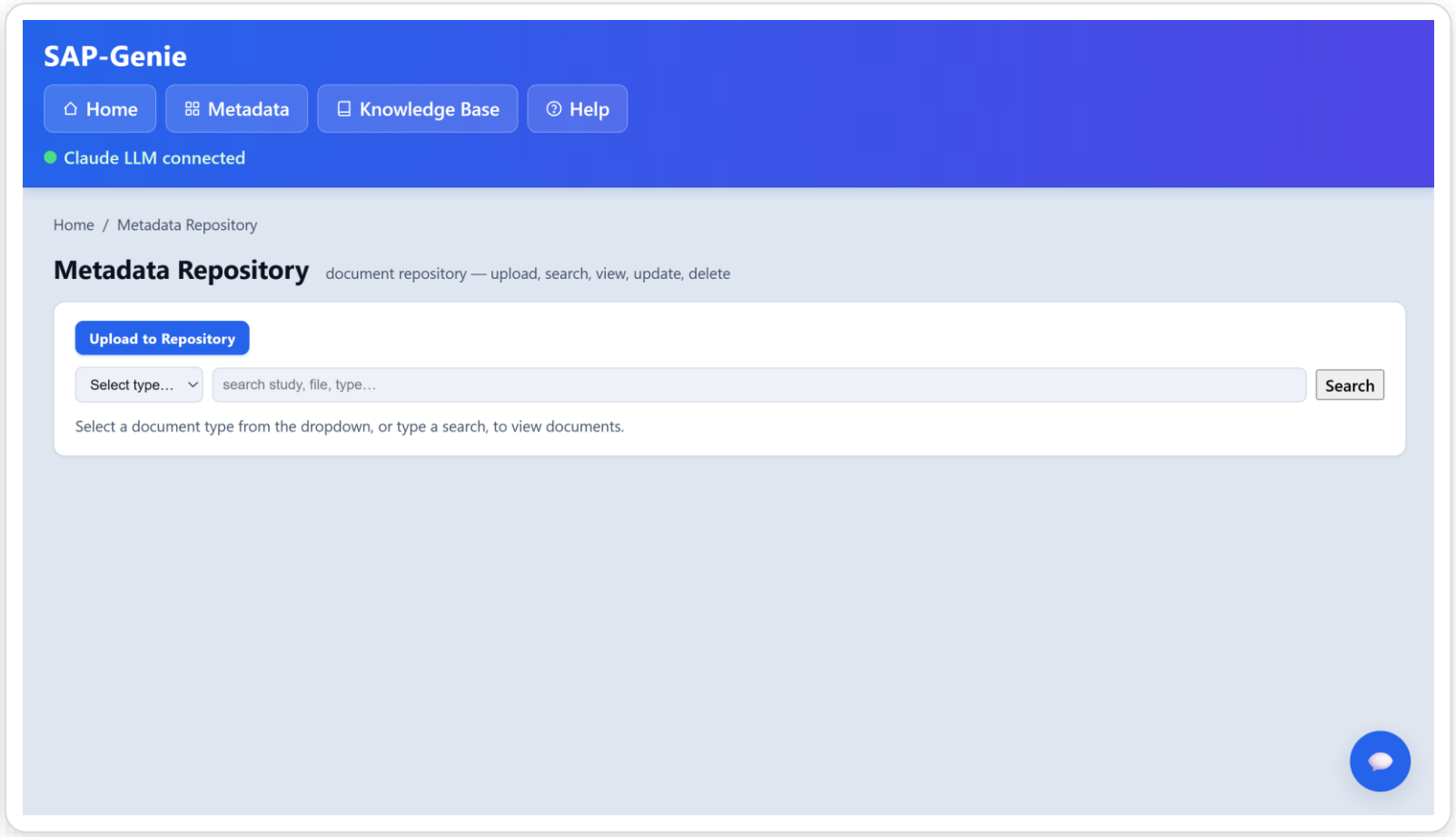
MEMORY

Knowledge Base: cross-study memory



REPOSITORY

Metadata Repository: shared specs, CT and Define



HUMAN IN THE LOOP

Automation accelerates drafting. Humans retain accountability.

AI assists	Humans decide	Platform records
Extracts protocol content	Confirms interpretation and assumptions	Source-to-output lineage
Drafts SAP sections and artifacts	Reviews methods, populations, and outputs	Comments and requested changes
Identifies gaps or inconsistencies	Approves release-ready content	Versions, approvals, and audit trail

SAP-Genie does not replace statistical judgment. It turns human review into a structured, traceable, and scalable workflow.

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THE PACKAGE

One protocol in — the whole submission package out

1

protocol

PDF · DOCX — one upload

9 deliverables

generated · validated · traced

Validated via completeness, schema, standards & cross-artifact checks + human approval.

SAP
ARS ReportingEvent — analyses, sets, methods

{ json }

SDTM Specs
11 domains · SDTMIG 3.4 · every derivation

{ json }

ADaM Specs
5 datasets · ADaMIG 1.3 · consumed-by links

{ json }

TOC
table of contents — output plan & numbering

{ json }

TLF Shells
mock tables · listings · figures

{ rtf }

TLFs
populated outputs, shell-consistent

{ rtf }

aCRF
annotated CRF — collection → SDTM origins

{ pdf }

SAS Programs
SDTM · ADaM drop-in skeletons

{ sas }

Define-XML
submission metadata · Define 2.1

{ xml }

Every deliverable from the same governed pipeline

Specs, shells, programs and submission metadata are generated together and traced to the same protocol — they stay aligned by construction, not by reconciliation.

Jazz Pharmaceuticals

