

XBIOM PLATFORM · SINGLE-TRACK™ PROCESS

Single-Track CRO Process Automates Generation of Study Report & SEND



SOT 2026



What We'll Cover Today

01

The Problem – Sequential Track CRO Process

CRO Study Directors Generate Study Reports Before a Separate Team Generates SEND adding 4-5 weeks to Submission Readiness

02

Xbiom Single-Track™

Merge the two processes into a Single-Track and Generate Both Study Report & SEND together Driven by the Same Data

03

Technology . Process . Automation

Essential Technology Capabilities, Tried and Proven Processes, with Regulatory Complaint Automation Assisted by AI LLM only for Supervised Data to Text Generation

04

Live Demo

Seeing Single-Track in action — from raw data to final report

05

The Results

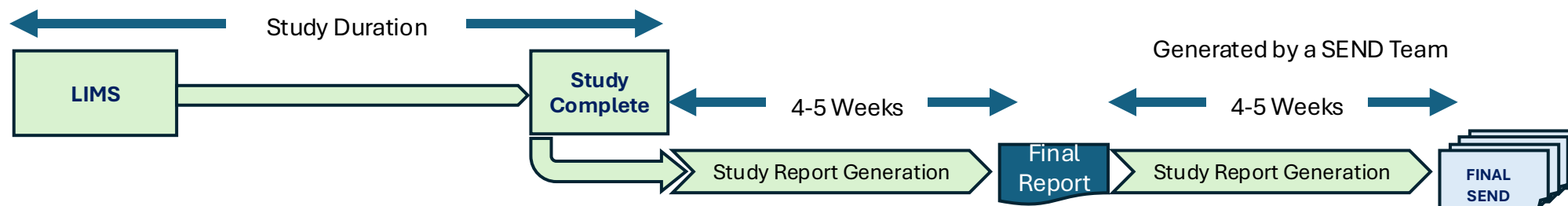
Deliver Study Report & SEND 6 – 8 Weeks Sooner
Save \$12-\$20K per Study in Operating Costs
Assure Quality – One Data Drives both Deliverables

06

Q&A / Next Steps

Getting started with Xbiom

The Sequential-Track Dilemma



STUDY REPORT TRACK

- 1 Collect Study Data Sources – LIMS + Bio-Analytics and Assays
- 2 Data Integration for ALL Study Data, Write Sub-Reports, Analysis of ALL Study Data
- 3 Study Director Drafts, Assembles Study Report Sections for QC and Review
- 4 Sponsor Submission Ready Study Report

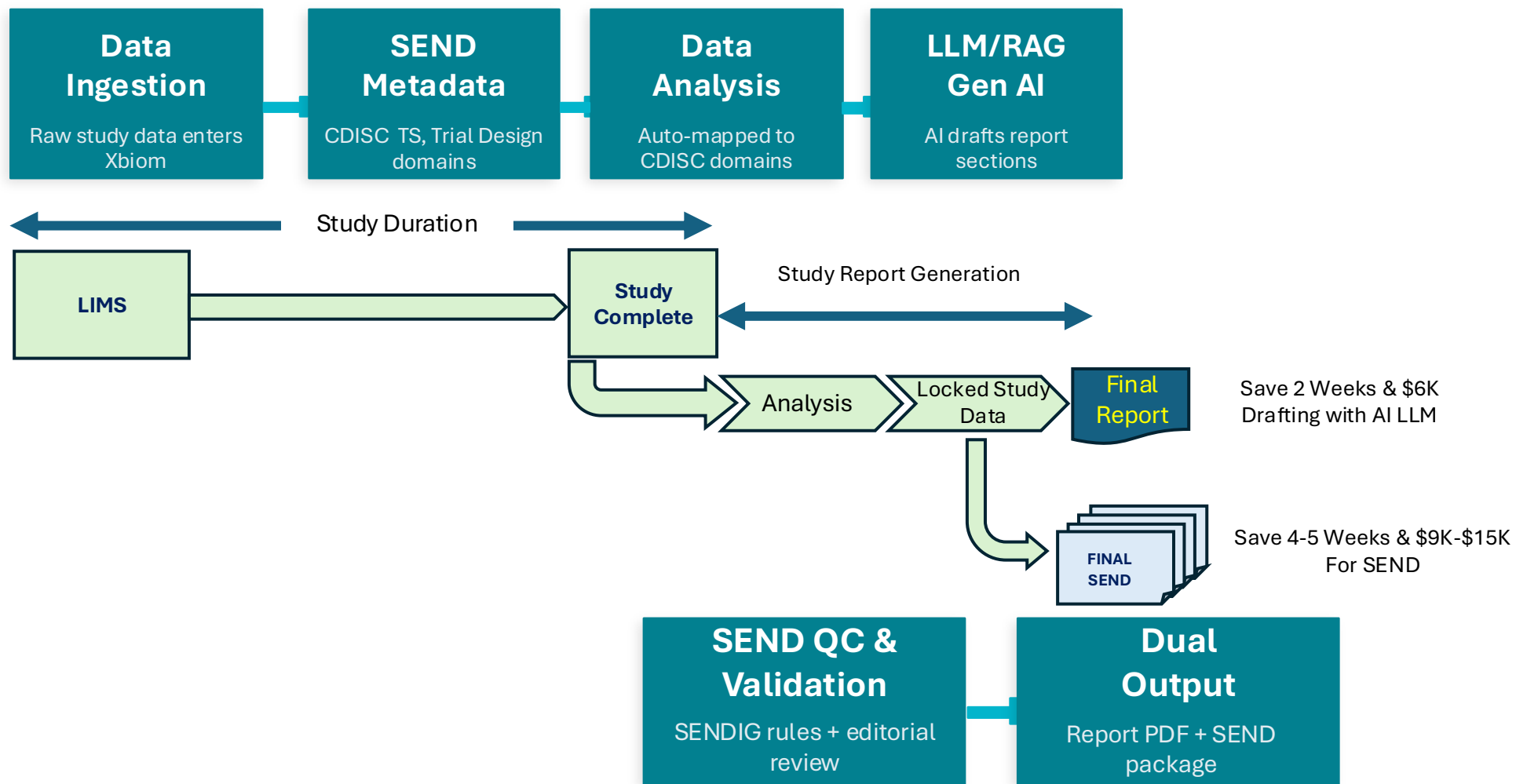
 **4–6 weeks After Histopathology & Sub-Reports**

SEND SUBMISSION TRACK

- 1 Start with Final Study Report & All Study Data Sources including LIMS
- 2 Extract TS, Trial Design, Methods & Practices from Study Report & Protocol
- 3 Map & Harmonize Integrated Study Data to SEND IG & CT
- 4 Spot-Check OR Reconcile Against Study Report, Conformance Validation

 **+4–5 additional weeks**

Single-Track Merges Both Processes into One



Data Interlock Assures Consistency

'Interlocking' means the SEND dataset and the Study Report are derived from one Integrated, Analyzed Study Dataset

1

STUDY DATA MODEL

A single canonical record for every measurement, timepoint, and finding – derived from ALL study sources, plus SEND metadata

- Integrated once,
- Analyzed once for reporting,
- Referenced by both the study report and SEND Generators

2

BIDIRECTIONAL TRACEABILITY

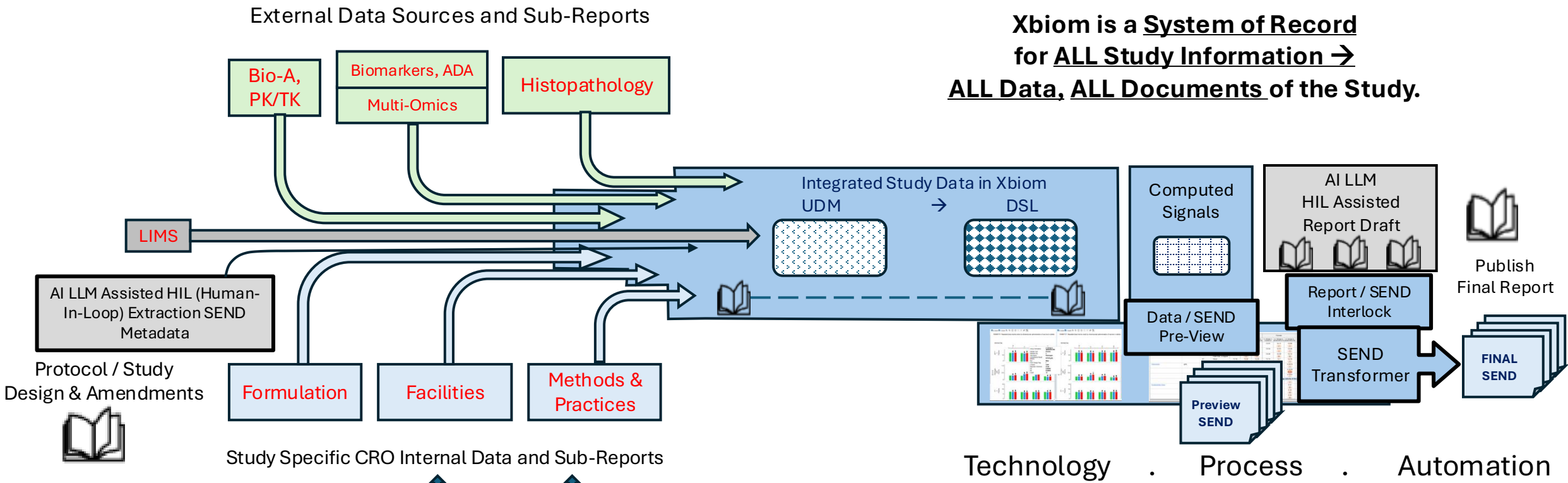
Every value in the SEND dataset traces to its source observation, and every report statement traces to the same source observation.

3

AUTOMATED TRANSFORMATION

- Study Data Model is source of all data and analysis results
- Study Report Generation by Director with AI LLM Assistance for drafting text
- SEND package Generation with same data and metadata

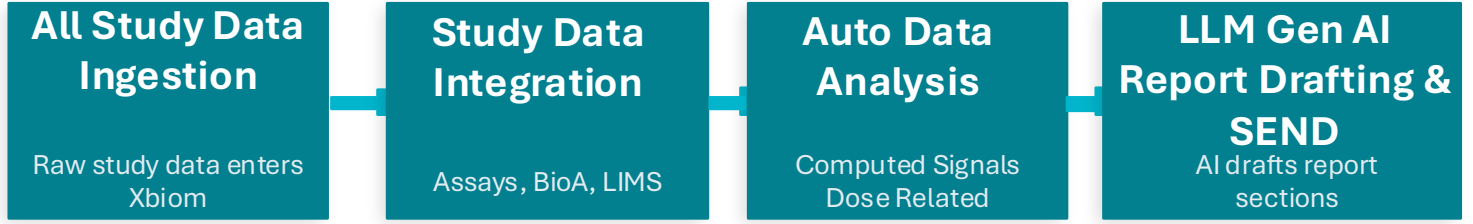
Single-Track Enabled Xbiom™ Study Information Management System (SIMS)



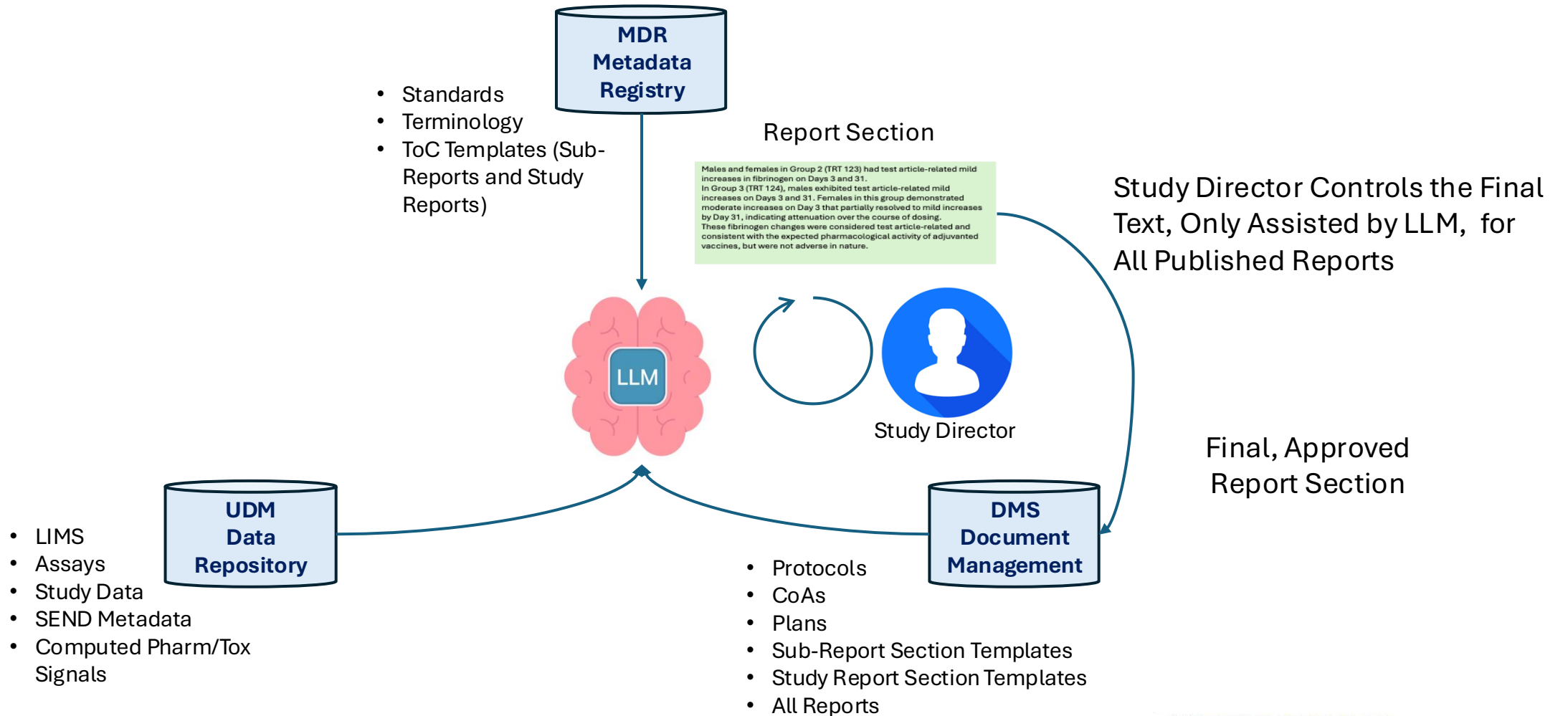
Xbiom is a System of Record for ALL Study Information → ALL Data, ALL Documents of the Study.

Study Specific CRO Internal Data and Sub-Reports

Facilities & Lab Instruments Operations Data



Human-in-Loop Control of LLM for Authoring



AI LLM USAGE & GOVERNANCE PRINCIPLES

*Precise compartmentalization of AI LLM and Regulatory Compliant Study Information Management Systems**

1

Human In Loop

- AI LLM work in a narrow context window controlled by the Human User (e.g. Study Director)
- Generative Text for Report Drafts are managed with supervisory control with clear view of the source, reference, and context
- PDF or Document to Data extraction is done on chunked content under supervision and validated before ingestion

2

COMPARTMENTALIZATION

- Study Data and Content are maintained in a sterile CFR Part 11 controlled data space that is impenetrable by AI LLM or its agents
- Text → Data and Data → Text conversions by AI LLM are done outside of this sterile perimeter

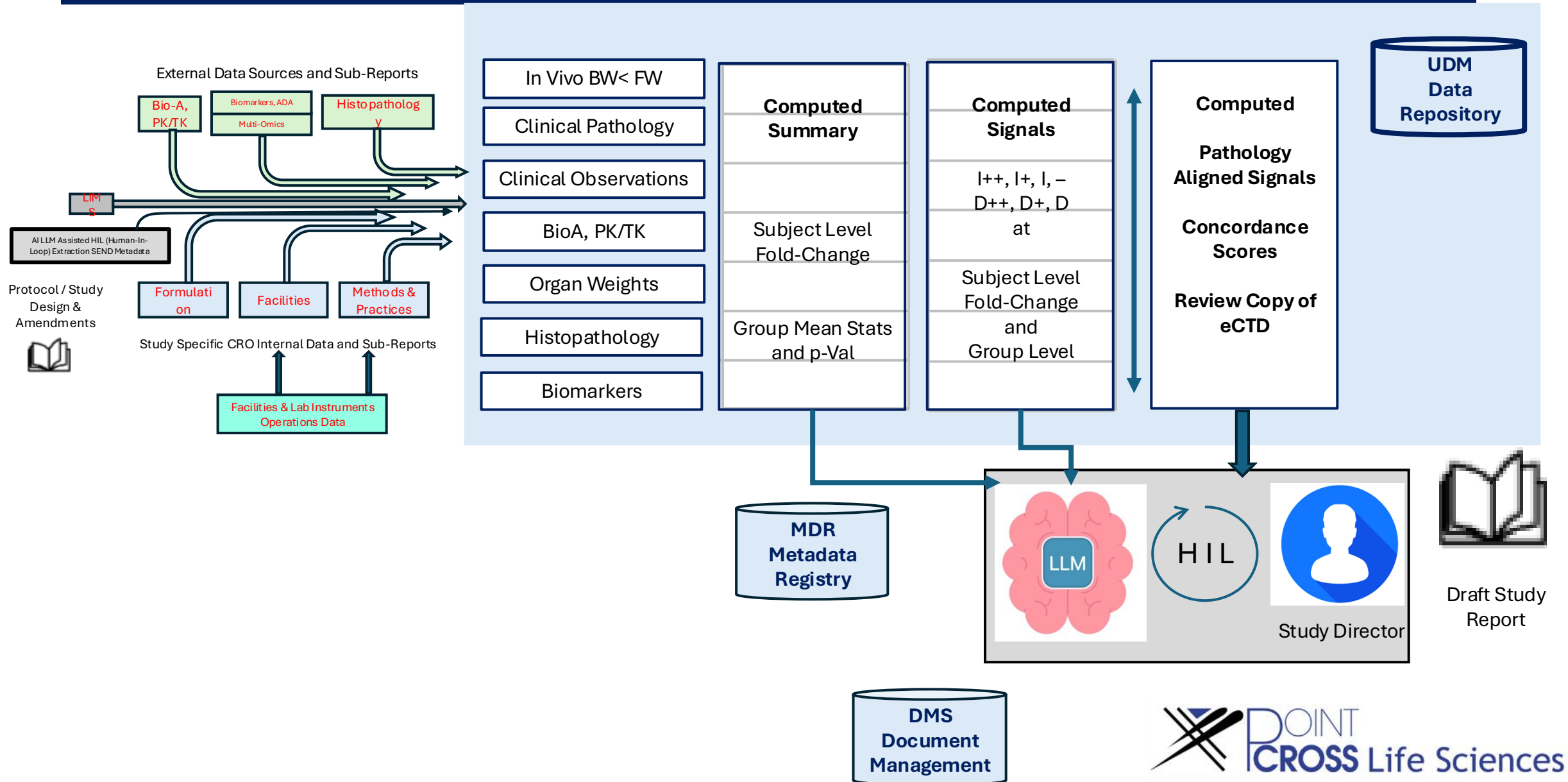
3

RAG ENABLEMENT

- AI LLM interacts with the SIMS Study Information Management System only through a RAG enabled API interface
- All search and retrieval is done by the SIMS data access, indexed search, and retrieval. LLM only repurposes retrieved information for the Human User; or interprets Human Queries for the Rag interface,

* Guiding Principles of Good AI Practice in Drug Development, Jan 2026, FDA and EPA

Computed Concordance and eCTD for LLM Prompts



Short Demo Sequences

D1

Study Setup - SEND TS and Trial Design Domain Mapping

Protocol and Amendments. (0-1:55)

D2

Study Data Ingestion & Integration

Document Management and Integration of LIMS and EX-LIMS data (1:56 – 2:46)

D3

Study Data Visualization

Generate results and computed signals, Study Director annotations and prompted text generation for Report Sections. 2:47 – 4:22

D4

AI Text Section Generation

LLM Assisted Human-In-Loop (HIL) Drafting with Reference Validation - Example: Environmental Conditions section - using Protocol sections, Test facility records, Templates for formatting) 10:30 – 11:25

D5

SEND Preview, Download and Generation of Package

ORRES Splits, nSDRG, Validation & SEND package in one click. 14:46 - 16:03

Before vs. After Single-Track™

	BEFORE	AFTER (SINGLE-TRACK™)
Study report timeline	4-6 weeks after Pathology & All Sub-Reports	2-3 weeks after Pathology & All Sub-Reports
SEND submission time	+4-5 weeks additional	Same Time as Study Report
Reconciliation errors	Spot Checks Leave 10%-34% discrepancies	Study Data Model → Study Report & SEND
Study Director report effort	90% Manual compilation	< 20% (tune, review & approval)
Cost per study	High — dual team effort	40-60% reduction
Audit traceability	Partial — separate trails	Complete — single lineage

Q & A

Questions? Let's discuss how Single-Track™ can transform your reporting workflow.

NEXT STEPS

- Visit us at Booth 2107 at SOT 2026
- Schedule a live interactive demo
- Contact us: ask@pointcross.com or andrew@pointcross.com

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