SYSTEMS ARCHITECTURE • HIGH-THROUGHPUT COMPILATION

AUTOMATING THE CLINICAL PIER

How sovereign protocol compilation expands CRO study intake by 10x without adding clerical headcount or sacrificing GxP rigor.

THE INDUSTRIAL ARCHITECTURE:

Collapsing 16 Weeks Into 24 Hours

- Manual EDC setup is a deterministic compilation problem, not typing.
- Translating 150-page protocol PDFs into production Medidata Rave ALS.
- Every variable mapped to exact source character coordinates (charInterval).
- Local Gemma 4 adversarial consensus verification before schema locking.
- 100% air-gapped on dedicated Dell Blackwell appliances. Zero cloud leaks.

SWIPE TO EXAMINE THE COMPILATION TIMELINE →

EXHIBIT 01: THROUGHPUT BENCHMARK

THE 24-HOUR PIPELINE

Cycle Time Comparison:

LEGACY MANUAL BUILD: **12 to 16 WEEKS**

Sequential human typing, email attachments, disconnected Excel sheets.

G-FLOW COMPILER: **< 24 HOURS**

13-phase deterministic compilation directly into production Rave ALS & ODM-XML.

Empirical Subphase Breakdown (NCT04586231 Oncology Trial):

Phase 1: SoA Table Extraction	18.4s	Visual grid decomposition via vision models.
Phase 2: CDASH Mapping	42.1s	CDASH domain mapping with bounding boxes.
Phase 3: Rave ALS Generation	28.6s	Direct ALS spreadsheet & edit check synthesis.
Phase 4: Consensus Validation	14.2s	Adversarial evaluation by local Gemma 4 peer.

SWIPE TO EXAMINE CHARACTER-LEVEL GROUNDING →

Empirical Benchmark: NCT04586231 (120-page Phase III RCC Oncology Protocol) | G-Flow Tiger Tier

EXHIBIT 02: REGULATORY AUDIT DEFENSE

CHARACTER-LEVEL PROOF

DETERMINISTIC GXP PROOF STANDARD: FDA 21 CFR PART 11

100% GROUNDED

Every extracted variable links directly to exact bounding-box coordinates (charInterval spans) in the source clinical protocol PDF with zero hallucination risk or synthetic overrides. Complete 21 CFR Part 11 audit defensibility across all extracted CDISC and EDC domains.

How G-Flow Defends GxP Audits:

ZERO-HALLUCINATION GATES

1. 1-Click Coordinate Grounding Proof:

Auditors click any variable in the study canvas and immediately view the exact sentence highlighted on the original protocol PDF page with character-level charInterval bounding boxes.

2. Local Gemma 4 Adversarial Consensus:

An on-premise Gemma 4 peer reviewer independently validates extracted CDASH domains and multi-variable edit checks against protocol logic before schema lock and study export.

3. Cryptographic Regulatory Sign-Off:

Study definitions remain strictly immutable behind private firewalls until multi-role digital signatures are logged and timestamped according to 21 CFR Part 11 audit trail requirements.

SWIPE TO EXAMINE NATIVE EDC OUTPUTS →

Statutory Grounding: FDA 21 CFR Part 11.10 (Audit Trails & Data Verification)

EXHIBIT 03: INTEROPERABILITY

NATIVE EDC TARGETS

Medidata Rave ALS

Direct synthesis of production Architect Loader Sheets (Draft, Forms, Fields, DataDictionaries, UnitDictionaries, Edit
Ready for direct Rave import.

CDISC ODM-XML & SDM-XML

Complete CDISC Operational Data Model (ODM) and Study Design Model (SDM) structural representations conforming to CDASH standards.

Veeva Vault CDMS

Automated export of validated study definitions for direct ingestion into modern Veeva clinical data environments without manual mapping.

SWIPE TO EXAMINE FIXED-BID UNIT ECONOMICS →

Target Interoperability: Medidata Solutions (Rave ALS); CDISC Consortium (ODM-XML v1.3.2); Veeva Systems

UNIT ECONOMICS & COMMERCIAL LEVERAGE

MARGIN EXPANSION

CLERICAL TRANSCRIPTION RECLAIMED PER BUILD:

500+ HOURS

Reclaiming 70% of billable data management hours from manual busywork.

- Fixed-Bid Protection: Deliver builds in days, locking in maximum milestone profitability.
- Zero Subcontractor Leaks: Keep 100% of study setup margin in-house.
- Senior Retention: Senior CDMs review 10 to 15 studies/year with higher job satisfaction.
- Bid Defense Scarcity: Win competitive sponsor bids with guaranteed 24-hour turnaround.
- Strict On-Premise Air-Gap: Dedicated Dell hardware appliances behind your firewall.

SWIPE FOR CITATIONS & ACTION PLAN →

Economic Modeling: Tufts CSDD Clinical Benchmark Study; SCDM Talent Report; VonCasper Solutions

STATUTORY GROUNDING & ACTION PLAN

CITATIONS & ACTION PLAN

PEER-REVIEWED & INDUSTRY BIBLIOGRAPHY:

1. IQVIA Institute for Human Data Science
Global Trends in R&D: Overview through 2025/2026 (Surge of 6,000+ active clinical investigational assets, multi-specific antibodies, and ADC pipelines) • iqvia.com

2. Tufts Center for the Study of Drug Development (CSDD)
Rising Protocol Complexity Impact Report (Average clinical investigative procedures surged +44%, endpoints grew +27%, expanding visual SoA matrices) • csdd.tufts.edu

3. Society for Clinical Data Management (SCDM)
Reflections on the Evolution from CDM to Clinical Data Science (>70% of study build timeline consumed by repetitive manual transcription and eCRF typing) • scdm.org

4. U.S. FDA 21 CFR Part 11.10
Controls for Closed Systems: Statutory Data Lineage, Complete Character-Level Audit Trails, and System Validation Requirements for Clinical Records • fda.gov

Benchmark Your CRO Study Setup Friction

Calculate setup cycle latency, capacity limits, and intake expansion in 60 seconds.

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