

HILL RESEARCH · CLINICAL BIOMETRICS, AI-NATIVE

# From raw clinical data to FDA-ready submission.

*One platform across the trial lifecycle. TriClick Evidence and Recruitment start with defensible source context and cohort logic; Stats, Annotation, Compliance, Data Management, and Medical Writing carry the work through submission.*

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**90 min**

Phase III oncology TFL package, submission-ready.

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**15,000+**

Reusable TFL library entries annotated by domain experts.

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**60+**

Clinical studies delivered across oncology, CNS, and immunology.

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**INSIDE THIS ISSUE · 16 PAGES**

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**01 – 02****Guide intro & product fit**

Client-facing context and where TriClick plugs into clinical workflows.

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**03 – 11****Seven products · one platform**

Evidence · Recruitment · Stats · Annotation · Compliance · Data Management · Medical Writing.

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**12 – 14****Architecture & proof**

Five-layer reuse · seven-layer audit stack · Phase III case study.

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**15 – 16****Services & engagement**

SAS · Biostatistics · FSP — software-only to full project outsourcing.

PRODUCT FIT

# Where TriClick helps your clinical teams.

*TriClick is built for the operational points where clinical data work slows down: data management, PHI handling, patient screening, evidence retrieval, SDTM/ADaM/TFL generation, medical writing, and audit review.*

# 90

Minutes to a submission-ready TFL package in a Phase III oncology case study

Hill Research case study · 2025

# 99%+

PHI de-identification accuracy for compliance workflows

TriClick Compliance product overview

# 94%

Eligibility matching accuracy across 30+ disease areas

TriClick Recruitment product overview

## WHAT YOUR TEAM CAN USE

### DATA OPERATIONS

#### Build the study data backbone

TriClick Data Management turns protocol requirements into database structure, edit checks, validation plans, and audit-trailed outputs.

CLIENT RECEIVES: AUDIT-READY DATA-MANAGEMENT PLAN

### CLINICAL OPERATIONS

#### Screen and protect patient data

Recruitment and Compliance support eligibility matching, cohort review, PHI de-identification, and sponsor review workflows.

CLIENT RECEIVES: CLEANER COHORTS AND REVIEW TRAIL

### BIOMETRICS

#### Move faster from SDTM to TFL

TriClick Stats keeps code, review verdicts, and submission package exports attached to every generated output.

CLIENT RECEIVES: SUBMISSION PACKAGE OUTPUTS

### REGULATORY WRITING

#### Draft from traceable evidence

Evidence and Medical Writing connect cited sources, reviewer materials, CSR sections, and response narratives.

CLIENT RECEIVES: NARRATIVES TIED TO EVIDENCE

WHAT WE BUILD

# One platform, raw data to submission.

Seven TriClick products cover the trial lifecycle: evidence, recruitment, statistics, annotation, compliance, data management, and medical writing.



**TRICLICK DATA MANAGEMENT**

Evidence and Recruitment start with defensible source context and cohort logic before downstream data work begins.

**STATS THROUGH DATA MANAGEMENT**

Stats, Annotation, Compliance, and Data Management turn study inputs into auditable datasets, TFLs, and regulatory handoffs.

**SERVICES – HUMANS IN THE LOOP**

Software-only, software + FSP, or full project outsourcing. Hill Research operators sit alongside your team at the engagement depth you need.

HOW YOU PLUG IN

# Plug in at any step of your process.

You don't replace your stack. You attach Hill Research's products to the milestones you already run — protocol, EDC setup, data collection, lock, submission.

SPONSOR PROCESS

<p><b>Stage 01</b> <b>PROTOCOL DESIGN</b></p> <p>Endpoints, sample size, study schema, statistical hypotheses.</p> <p><i>Owned by sponsor biostat &amp; clinical leads</i></p>	<p><b>Stage 02</b> <b>EDC SETUP</b></p> <p>CRFs, edit checks, study build, EDC vendor configuration.</p> <p><i>Owned by sponsor data management</i></p>	<p><b>Stage 03</b> <b>DATA COLLECTION</b></p> <p>Site visits, data entry, queries, source data verification.</p> <p><i>Owned by sites + sponsor monitors</i></p>
<p><b>Stage 04</b> <b>DATABASE LOCK</b></p> <p>Cleaning, reconciliation, medical coding, freeze-and-lock.</p> <p><i>Owned by sponsor DM + medical review</i></p>	<p><b>Stage 05</b> <b>CSR &amp; SUBMISSION</b></p> <p>SDTM/ADaM datasets, TFL, Reviewer's Guide, CSR writing, FDA review.</p> <p><i>Owned by sponsor biostat + regulatory</i></p>	

HILL RESEARCH TOUCHPOINTS

<p>TRICLICK DATA MANAGEMENT · BUILD</p> <p><b>Protocol → CRF data model</b></p> <p>Parses the protocol; emits canonical CRF, Data Validation Plan, and Data Management Plan.</p> <p><b>Output · Canonical CRF · DVP · DMP</b></p>	<p>TRICLICK DATA MANAGEMENT + ANNOTATION</p> <p><b>Edit checks · CRF metadata</b></p> <p>DM builds the database; Annotation maps every CRF field to the SDTM Implementation Guide.</p> <p><b>Output · Edit checks · aCRF</b></p>	<p>DM · COMPLIANCE · RECRUITMENT</p> <p><b>Live ingestion · queries · PHI · eligibility</b></p> <p>DM ingests + queries; Compliance handles PHI; Recruitment screens cohorts.</p> <p><b>Output · Clean data · matched cohorts</b></p>
<p>TRICLICK DATA MANAGEMENT · CODE</p> <p><b>Reconcile · code · medical review</b></p> <p>Cross-source reconciliation, MedDRA / WHO Drug coding, medical review workflow before lock.</p> <p><b>Output · Coded, locked datasets</b></p>	<p>TRICLICK STATS · EVIDENCE · WRITING</p> <p><b>TFL · evidence · CSR narrative</b></p> <p>Submission package generation, literature alignment, and source-linked medical writing.</p> <p><b>Output · Submission-ready TFL · CSR draft</b></p>	

ENGAGEMENT MODEL

<p><b>LIGHTEST</b> <b>Software-only</b></p> <p>Self-serve TriClick + Data Management via API. Your team operates everything; we ship updates.</p>	<p><b>HYBRID</b> <b>Software + FSP staffing</b></p> <p>Hill Research operators run the platform. Your team owns scientific decisions.</p>	<p><b>FULL</b> <b>Project outsourcing</b></p> <p>Hill Research delivers protocol → submission. You provide inputs and approvals.</p>
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PRODUCT 01 · EVIDENCE RETRIEVAL

# TriClick Evidence

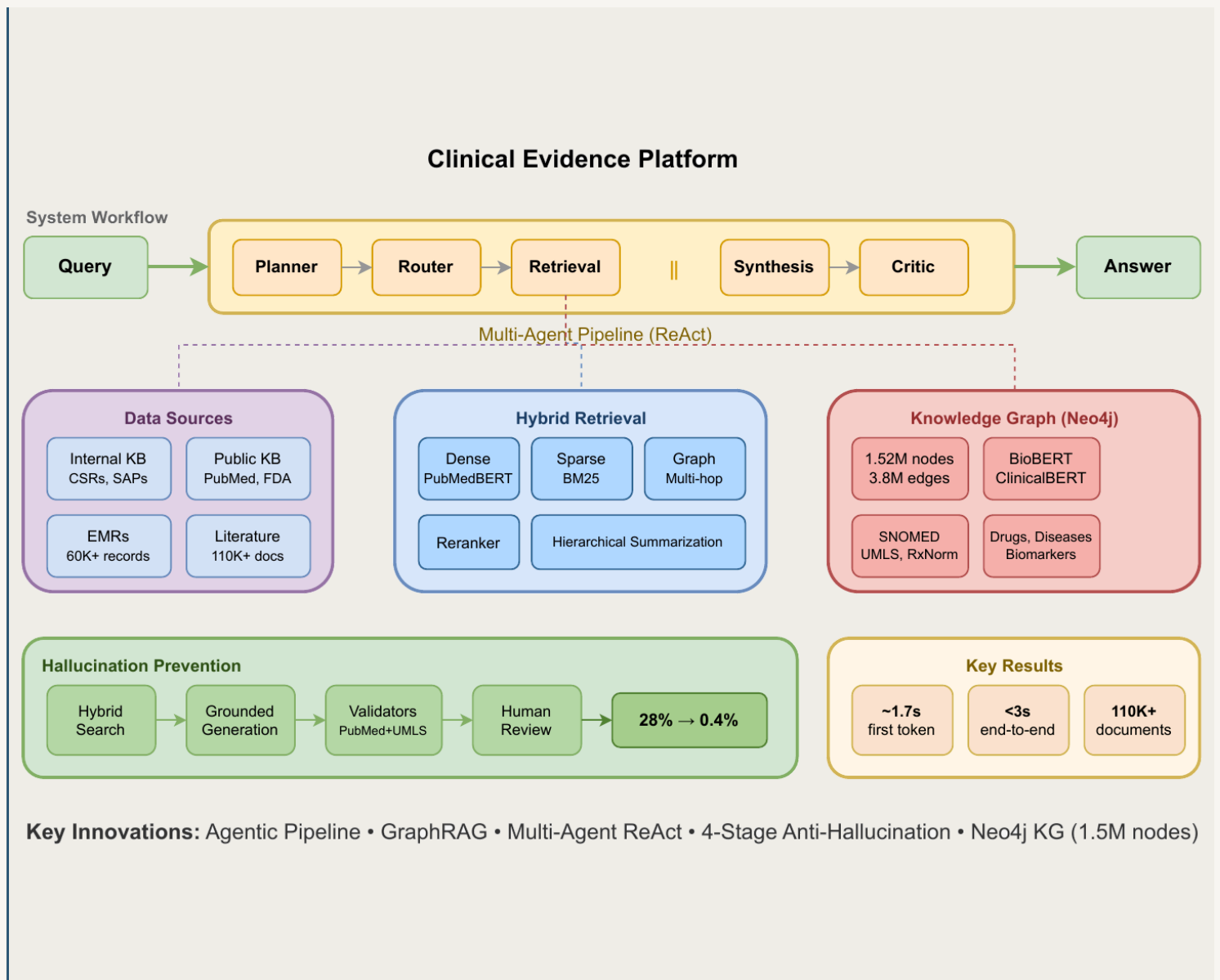
Literature, registries, and regulatory filings available on demand, with source-grounded retrieval and critic checks before content reaches a reviewer.

<p><b>110K+ DOCUMENTS</b></p> <p>Clinical documents indexed and queryable across the evidence workspace.</p>	<p><b>1.7S FIRST TOKEN</b></p> <p>Fast response start while preserving source traceability.</p>	<p><b>HALLUCINATION CHECK</b></p> <p>4-stage anti-hallucination flow reduces unsupported claims.</p>	<p><b>TIME-AWARE RETRIEVAL</b></p> <p>Prevents stale and fresh evidence from being mixed.</p>
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**CLINICAL EVIDENCE PLATFORM**

Literature and regulatory evidence tied to the workflow.

<p><b>AGENTIC PIPELINE</b></p> <p>Planner → Router → Retrieval → Synthesis → Critic.</p>	<p><b>KNOWLEDGE GRAPH</b></p> <p>Hybrid retrieval over a 1.5M-node clinical knowledge graph.</p>	<p><b>CLAIM CONTROL</b></p> <p>Hallucination rate 28% → 0.4% through retrieval and critic checks.</p>
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EVIDENCE SOURCES: PUBMED CLINICALTRIALS.GOV FDA REVIEWS EMA ASSESSMENTS SNOMED · UMLS · RXNORM

SPONSOR LITERATURE

PRODUCT 02 · PATIENT SCREENING

# TriClick Recruitment

*Patient eligibility automated against the protocol, with edge cases surfaced for human review instead of hidden inside a black-box match score.*

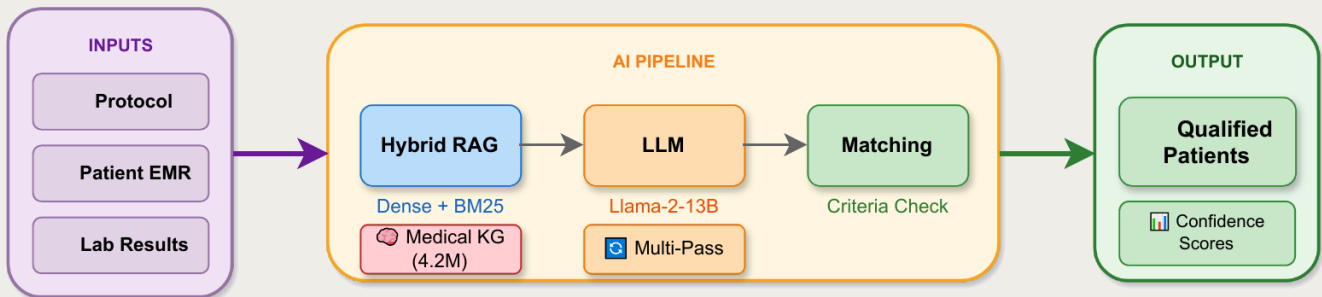
<p><b>94% ACCURACY</b></p> <p>Eligibility matching accuracy across 30+ disease areas.</p>	<p><b>20× FASTER</b></p> <p>Protocol-to-chart review compared with manual screening.</p>	<p><b>5× MORE QUALIFIED</b></p> <p>More qualified patients identified from existing clinical records.</p>	<p><b>RARE DISEASE</b></p> <p>Zero-shot rare-disease matching at 87%.</p>
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**PATIENT SCREENING AGENT**

**Eligibility reasoning over EHR and protocol criteria.**

Hybrid RAG (Dense + BM25) plus Llama-2-13B reasoning over EHR.	Medical Knowledge Graph: 4.2M entities across UMLS and SNOMED.	Multi-pass recall optimization surfaces edge cases for human review.
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## Patient Screening Agent: AI-Powered Clinical Trial Matching



**KEY RESULTS**

<b>94% Accuracy</b>	<b>20X Faster</b>	<b>5X More Patients</b>	<b>30+ Diseases</b>	<b>87% Zero-Shot</b>	<b>93% Few-Shot</b>	<b>8-bit Quantized</b>
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Key Innovations: Hybrid RAG (Dense+BM25) • Medical KG (UMLS/SNOMED) • Zero-Shot Rare Disease • Multi-Pass Recall Optimization

PRODUCT 03 · STATISTICAL PROGRAMMING

# TriClick Stats

SDTM → ADaM → TFL generation with a visible 3-agent execution timeline, Review Agent verdicts, code commentary, and export-ready submission package outputs.

**PURE LLM INTELLIGENCE**

No fixed templates. Context-aware reasoning over study specs.

**SELF-HEALING**

Errors fixed in-loop. 99%+ retry success.

**END-TO-END API**

Streaming, multi-format I/O. Drops into existing biostat stacks.

**HUMAN-IN-THE-LOOP**

Every output traced to spec, code, and Review Agent verdict.

STEP 01 · PROJECT SETUP

STEP 02 · TFL RUN DETAIL

Population	Placebo (N=27) n(%)	Drug (N=21) n(%)	Total (N=48) n(%)
Intent-to-Treat	27 (100.0)	21 (100.0)	48 (100.0)
Safety	25 (92.6)	21 (100.0)	46 (95.8)
Immunogenicity	10 (37.0)	13 (61.9)	23 (47.9)

PRODUCT 04 · CRF ANNOTATION

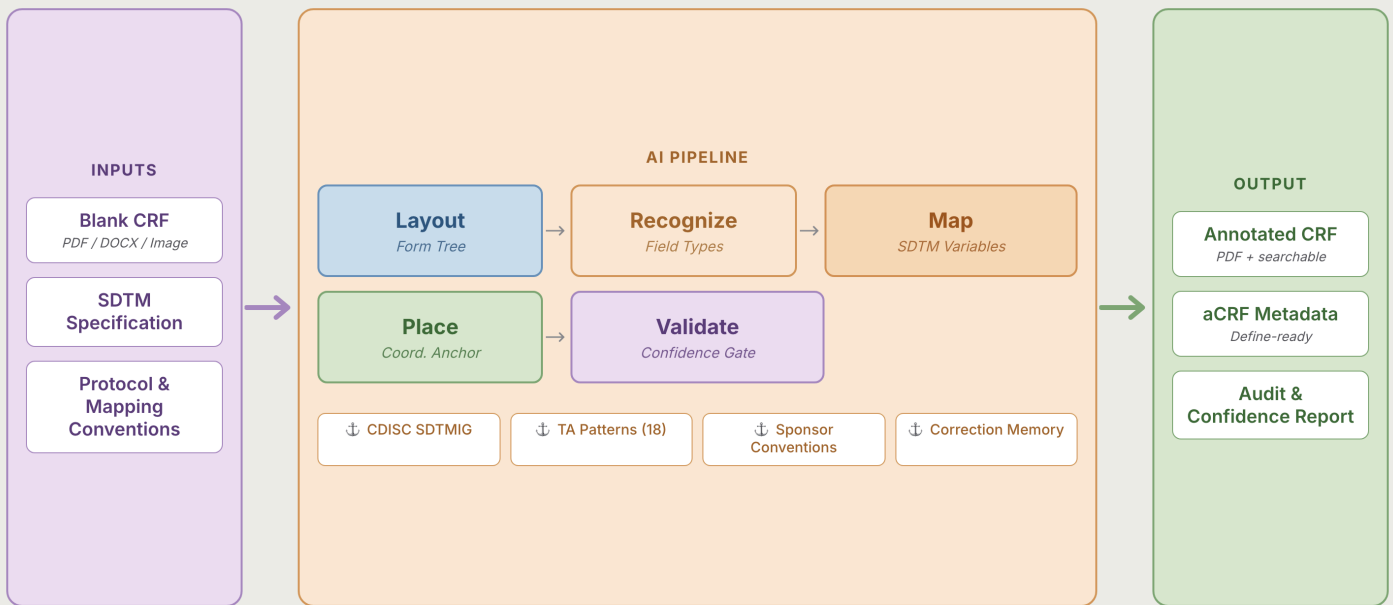
# TriClick Annotation

CRF-to-metadata mapping that turns sponsor forms into SDTM-aligned annotated CRFs and metadata handoffs for downstream programming.

<p><b>CRF PARSING</b></p> <p>Reads sponsor CRF layouts and field structure.</p>	<p><b>SDTM ALIGNED</b></p> <p>Maps each field against SDTM Implementation Guide expectations.</p>	<p><b>ACRF OUTPUT</b></p> <p>Annotated CRF artifacts ready for submission workflow.</p>	<p><b>REVIEW AGENT</b></p> <p>Checks domains and consistency before handoff.</p>
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<p><b>CRF - TO - METADATA MAPPING</b></p>	<p><b>Audit-ready aCRFs without manual mapping loops.</b></p>		
<p>Parses CRF layouts and reconciles them against SDTM Implementation Guide.</p>	<p>Outputs aCRF artifacts and meta-data mappings consumed by the SDTM Agent.</p>	<p>Domain validation and consistency check via the Review Agent.</p>	

## TriClick Annotation: Automatic CRF Annotation Agent



KEY RESULTS						
<p><b>99.5%</b> Accuracy</p>	<p><b>~1 hr</b> per CRF</p>	<p><b>18</b> TA Areas</p>	<p><b>4-Layer</b> Validation</p>	<p><b>&lt;95%</b> Flagged</p>	<p><b>Spec</b> Grounded</p>	<p><b>Zero</b> Patient Data</p>

**Key Innovations:** Hierarchical Form Understanding · Spec-Grounded SDTM Mapping · Confidence-Gated Review · Cross-Study Correction Memory

<p><b>CLIENT RECEIVES</b></p>	<p>Annotated CRFs, field metadata, and validation notes for the SDTM programming path.</p>
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PRODUCT 05 · PHI PROTECTION

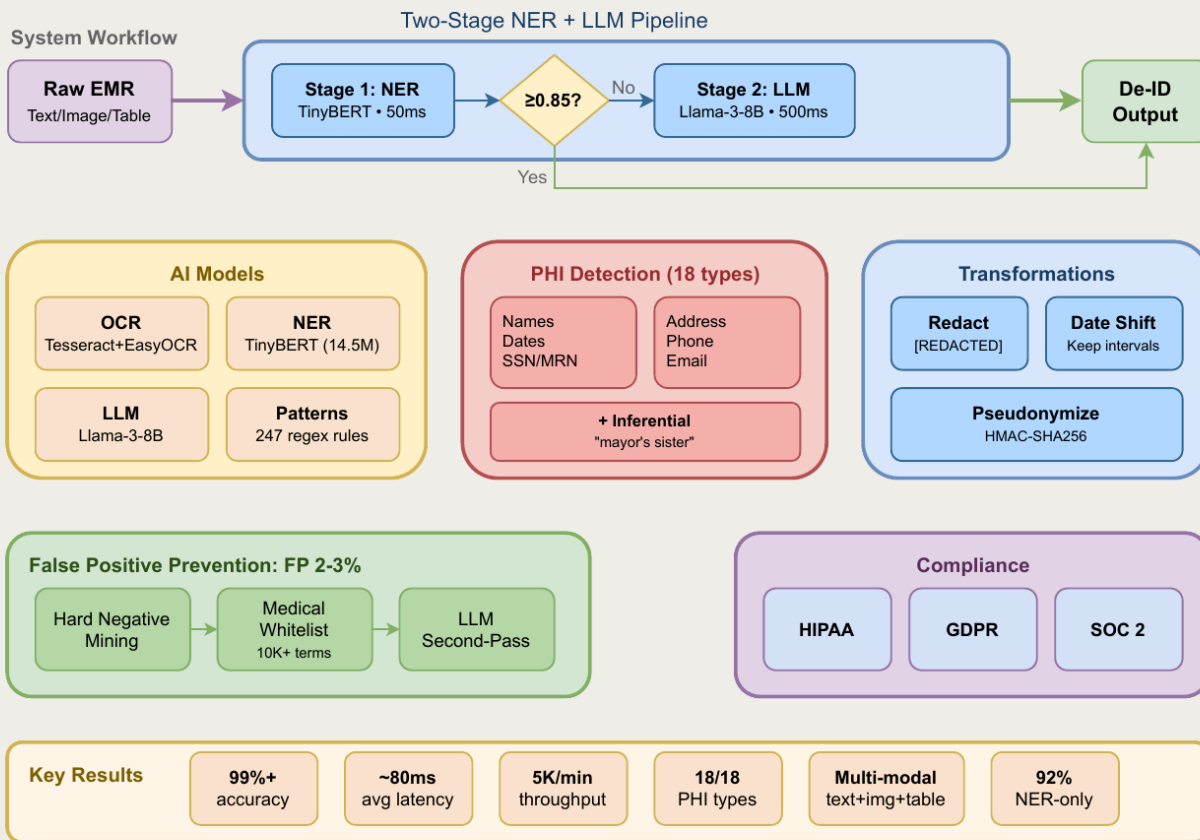
# TriClick Compliance

PHI de-identification and provenance checks across the clinical data path, built for sponsor review and regulated handoff.

<p><b>99%+ ACCURACY</b> PHI identification accuracy for compliance workflows.</p>	<p><b>18 PHI TYPES</b> Named and inferential identifiers detected before handoff.</p>	<p><b>~80MS LATENCY</b> Fast pass over records before LLM triage.</p>	<p><b>5K RECORDS/MIN</b> Throughput for batch de-identification workflows.</p>
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<p><b>DATA COMPLIANCE AGENT</b></p>	<p><b>PHI de-identification with audit trail attached.</b></p>		
	<p>TinyBERT NER fast pass followed by Llama-3-8B low-confidence triage.</p>	<p>Inferential PHI detection catches indirect identifiers.</p>	<p>Cryptographic provenance keeps every redaction auditable.</p>

## Data Compliance Agent — AI-Powered De-Identification



**Key Innovations:** Two-Stage NER+LLM • Hard Negative Mining • Medical Whitelist • Inferential PHI Detection • Multi-Modal Support

### REGULATORY & STANDARDS COVERAGE

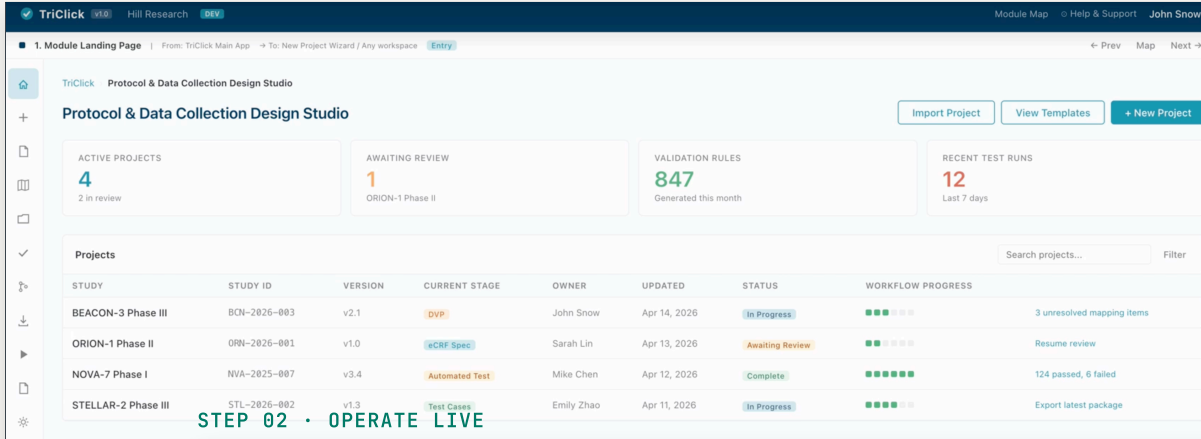


PRODUCT 06 · CLINICAL DATA WORKSPACE

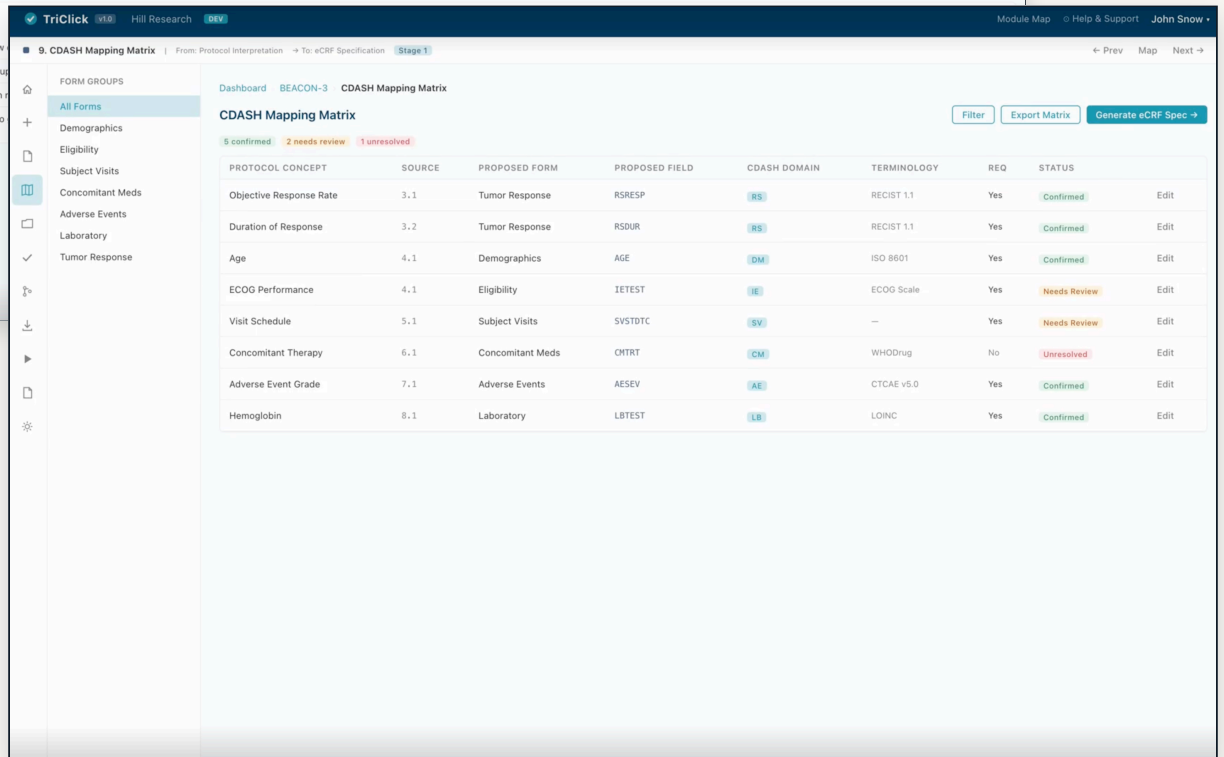
# TriClick Data Management

One workspace for protocol parsing, study database build, live data ingestion, reconciliation, medical coding, and review. Every action is audit-trailed and connector-ready for the major EDCs.

STEP 01 · BUILD STUDIO



STEP 02 · OPERATE LIVE



TriClick DM Studio. Product mockups from the clinical data workspace: study build on the left, live ingestion and reconciliation on the right.

EDC CONNECTORS

Medidata Rave

Veeva Vault

Oracle Clinical One

Viedoc

Castor

TRICLICK DATA MANAGEMENT

Clean, coded clinical datasets  
Outputs travel with a contract: schema, quality, coding decisions, audit trail.



TRICLICK STATS

SDTM Agent reads the contract  
Bad data never propagates silently. Clean inputs go in; submission-ready TFLs come out.

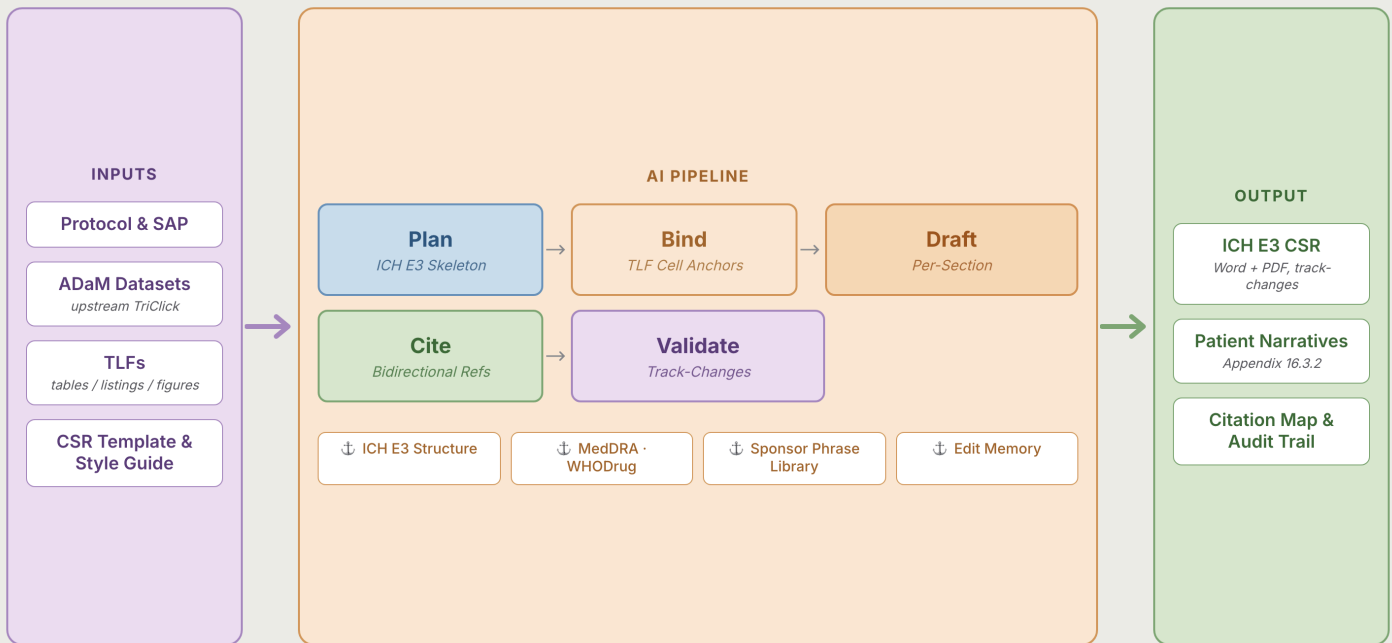
PRODUCT 07 · FDA SUBMISSION WRITING

# TriClick Medical Writing

Draft and review submission narratives from the same evidence ledger that produced the datasets, tables, listings, figures, and reviewer materials.

<p><b>CSR DRAFTING</b></p> <p>Clinical Study Report sections assembled from protocol, SAP, outputs, and evidence.</p>	<p><b>TRACEABLE CLAIMS</b></p> <p>Each narrative statement links back to source tables, datasets, or cited evidence.</p>	<p><b>REVIEW WORKFLOW</b></p> <p>Medical writer, biostatistician, and sponsor comments stay attached to the section.</p>	<p><b>SUBMISSION PACKAGE</b></p> <p>CSR, Reviewer's Guide, response drafts, and appendix-ready exports move together.</p>
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## TriClick Medical Writing: CSR Authoring Agent



**KEY RESULTS**

<b>100%</b> ICH E3 Coverage	<b>0</b> LLM Math	<b>Hard</b> TLF Binding	<b>Bi-Dir</b> Traceability	<b>Redline</b> not Publish	<b>Δ-Only</b> Re-Bind	<b>Edit</b> Memory Loop
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Key Innovations: Hard TLF Binding · Spec-Grounded Outline · Bidirectional Traceability · Track-Changes Redline · Cross-Study Edit Memory

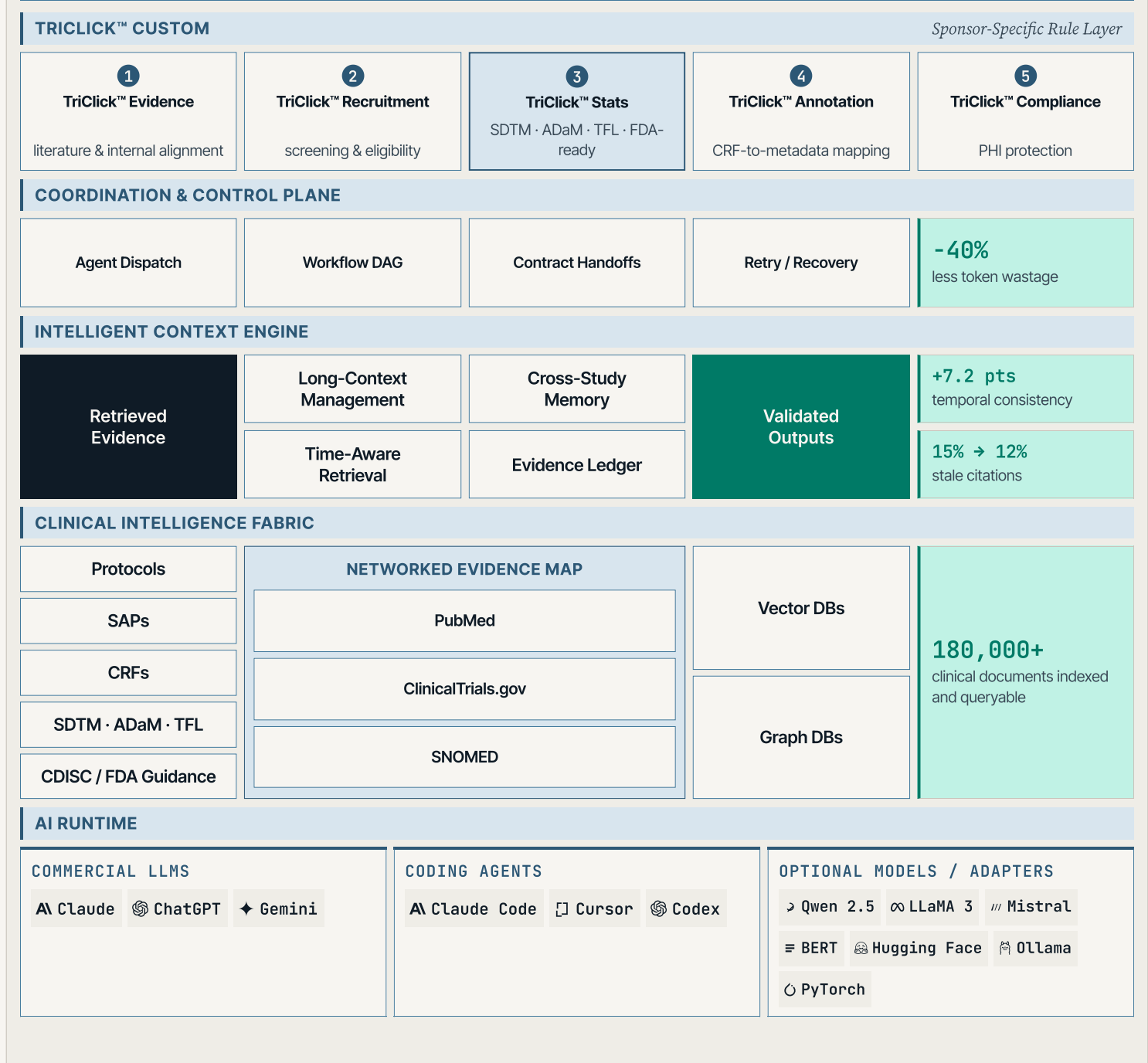
<p><b>01</b></p> <p><b>Read the submission context</b></p> <p>Protocol, SAP, data standards, outputs, and evidence become the writing context.</p>	<p><b>02</b></p> <p><b>Draft by section</b></p> <p>Each section is drafted against its required source materials and review rules.</p>	<p><b>03</b></p> <p><b>Check every claim</b></p> <p>Unsupported statements, missing tables, and stale citations are flagged before export.</p>	<p><b>04</b></p> <p><b>Export for sponsor review</b></p> <p>Medical writers retain control; TriClick keeps the evidence trail attached.</p>
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FIVE-LAYER PLATFORM

# Designed for reuse, not stitched from features.

Every TriClick module reuses the same five layers. Adding a module is a configuration of the rule layer — not a rewrite.

## Platform Architecture Reusable for End-to-End Expansion



<b>L 02 · COORDINATION</b> <b>-40%</b> Token wastage via contract-checked handoffs	<b>L 03 · CONTEXT ENGINE</b> <b>+7.2 pt</b> Temporal consistency across multi-session reasoning	<b>L 04 · INTELLIGENCE FABRIC</b> <b>180k+</b> Clinical documents indexed and queryable
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WHY TRICLICK STATS HOLDS UP TO FDA REVIEW

# Seven layers, thirty-plus papers.

Each layer is backed by peer-reviewed papers, accepted conference work, or preprint evidence. Wrappers cover one or two layers. TriClick Stats covers all seven.

## Audit-Ready Clinical Analytics Stack on Foundation Models

<p><b>TRICLICK Stats</b></p> <p>Covers all 7 layers, backed by 30+ papers.</p> <p>↓ COVERAGE: 7 OF 7</p>	<p><b>7 Audit &amp; Provenance</b></p> <p>Immutable record + crypto provenance ledger · PHI detection F194.2%</p>	<p>14.7% → 1.2% stale citations</p>	<p>PAPERS</p> <ul style="list-style-type: none"> <li>Research Square</li> <li>npj Digital Medicine</li> </ul>
	<p><b>6 Validation, Planning &amp; Repair</b></p> <p>Data-grounded checks · domain-specific gates · multi-critic review</p>	<p>-91% dead-end paths · -78% error cascades</p>	<p>PAPERS</p> <ul style="list-style-type: none"> <li>AAAI 2026</li> <li>Research Square</li> </ul>
	<p><b>5 Memory &amp; Time-Correct Retrieval</b></p> <p>Cross-study memory · knowledge graphs · long-context entity-rich + time-aware retrieval</p>	<p>+21% / -81% recall gain / cost reduction</p>	<p>PAPERS</p> <ul style="list-style-type: none"> <li>MLSys 2026 Oral</li> <li>SIGMETRICS 2026</li> </ul>
	<p><b>4 Workflow Orchestration &amp; Handoffs</b></p> <p>DAG scheduling across 70+ outputs · contract-checked handoffs · incremental regeneration</p>	<p>-29 to -45% token waste via contract handoffs</p>	<p>PAPERS</p> <ul style="list-style-type: none"> <li>ACL 2026 Main</li> <li>ACL 2026 Findings</li> </ul>
	<p><b>3 Clinical Artifact &amp; Data Understanding</b></p> <p>Spec parsing + schema caching · CRF parsing + metadata cleanup · daily profiling (types, nulls, dates)</p>	<p>110K docs · 1.7s · 60K SMRs · query latency</p>	<p>PAPERS</p> <ul style="list-style-type: none"> <li>JAMIA Open 2026</li> </ul>
	<p><b>2 Coding Agent Runtime</b></p> <p>Code gen — R, SAS, Python · execution &amp; debugging · file edits, commands, iterative fixes</p>	<p>Executes edits, debugs code</p>	<p>RUNTIME</p> <ul style="list-style-type: none"> <li>Claude Code · Cursor</li> </ul>
	<p><b>1 Foundation Models (Claude / GPT / Gemini)</b></p> <p>Reasoning &amp; coding · medical text familiarity · long-context generation</p>	<p>Reasoning + text generation</p>	<p>MODELS</p> <ul style="list-style-type: none"> <li>Claude / GPT / Gemini</li> </ul>

<p><b>14.7% → 1.2%</b></p> <p>Stale citations after Audit &amp; Provenance layer</p>	<p><b>-91%</b></p> <p>Dead-end reasoning paths via Validation layer</p>	<p><b>-81% / +21%</b></p> <p>Retrieval cost / recall via Memory layer</p>
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RESEARCH VENUES

- JOURNAL JAMIA
- JOURNAL NPJ DIGITAL MEDICINE
- CONF MLSYS 2026
- STATUS ORAL
- CONF SIGMETRICS 2026
- CONF ACL 2026
- CONF AAAI 2026
- PREPRINT RESEARCH SQUARE

## REAL-WORLD CASE STUDY

# Phase III oncology: TFL package in 90 minutes.

**300×***Faster than the prior vendor on the same submission package*HILL RESEARCH  
CASE STUDY · 2025

## PROJECT

Phase III oncology study — submission-grade TFL package

## SPONSOR

Global pharma · TriClick replaced the prior biostat vendor mid-study

## 01 · PROJECT

**Phase III oncology submission package**

Biostatistical programming for a global Phase III study. TFL outputs aligned to ICH and FDA guidance, with sponsor-defined derived endpoints.

## 02 · CHALLENGE

**Vendor delay before submission**

Sponsor replaced its biostatistics vendor mid-study after delivery delays threatened the submission window. TriClick took over from raw EDC outputs.

## 03 · SOLUTION

**TriClick Stats + Hill Research expertise**

SDTM, ADaM, and TFL agents ran the pipeline. Hill Research biostatisticians validated outputs and shaped the Reviewer's Guide for FDA review.

## 04 · OUTCOME

**Submission-ready dry-run TFL in 90 minutes**

First end-to-end TFL package delivered within 90 minutes of project handoff. Traceable outputs, with code, code commentary, and Review-Agent verdicts attached to each table.

FOR TEAMS THAT WANT HUMANS IN THE LOOP

# Services wrap the platform.

Three service lines staffed by Hill Research's biostatisticians, programmers, and clinical operators. Engage at any depth — from software-only to full project outsourcing.

**SERVICE 01**

**SAS Programming with GenAI**

Automated aCRF, patient profiles, TFL generation, and CDISC SDTM/ADaM datasets — programmed once, regenerable on demand.



**RESULT**

Up to -60% manual programming effort

**SERVICE 02**

**Biostatistics & Clinical Development**

Study design optimization, derived efficacy endpoints, custom macros, and ad hoc analysis — backed by Yale-trained biostatisticians.



**TRACK RECORD**

70+ clinical studies delivered

**SERVICE 03**

**FSP — Functional Service Provider**

Flexible insourcing, contract staffing, and full project outsourcing. Hill Research operators sit alongside your biostat team.



**ENGAGEMENT**

Scales with study size

ENGAGEMENT MODEL CONTINUUM

**LIGHTEST**

**Software-only**

Self-serve TriClick + Data Management via API. Your team operates everything.

**HYBRID**

**Software + FSP**

Hill Research operators handle the platform; your team owns scientific decisions.

**FULL**

**Full project outsourcing**

Hill Research delivers protocol → submission. You provide inputs and approvals.



Hill Research's TriClick platform provides strong value for pharma sponsors by enabling more efficient biometrics workflow optimization, improved standardization, and reduced manual effort. From a sourcing perspective, TriClick also supports better supplier management and vendor governance through clearer scope definition, more transparent delivery tracking, and a more cost-efficient operating model. Hill Research is a strong partner for sponsors seeking innovation, quality, and measurable efficiency gains in clinical biometrics delivery.

TOP GLOBAL PHARMA SOURCING LEADERSHIP

TriClick is doing what our best programmers do — minus the constant pings. No hour-long Q&A loops, no repeated misunderstandings. Just clean, usable, submission-ready TFL output.

ASSOCIATE DIRECTOR OF BIOSTATISTICS  
GLOBAL PHARMA SPONSOR

TRICLICK PRODUCT SUITE

**Evidence • Recruitment • Stats**

Source-grounded retrieval, cohort matching, and submission-ready SDTM, ADaM, and TFL generation.

TRICLICK PLATFORM • 7 PRODUCTS

**Annotation • Compliance • Data Management • Medical Writing**

Shared orchestration, context engine, and clinical knowledge fabric. Product modules layer on without rewrites.

SERVICES

**SAS • Biostatistics • FSP**

Engagement scales from software-only API access to full project outsourcing — protocol to submission.

VENTURE & ECOSYSTEM CREDITS



Reference marks are property of their respective owners and are shown only for ecosystem context; their display does not imply endorsement.

From raw clinical data to FDA-ready submission.

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REGULATORY & STANDARDS CONTEXT

