Unified Clinical Intelligence

An AI Platform for End-to-End Clinical Development

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THE PROBLEM

Intelligence Gets Lost in the Handoff

The consequences:

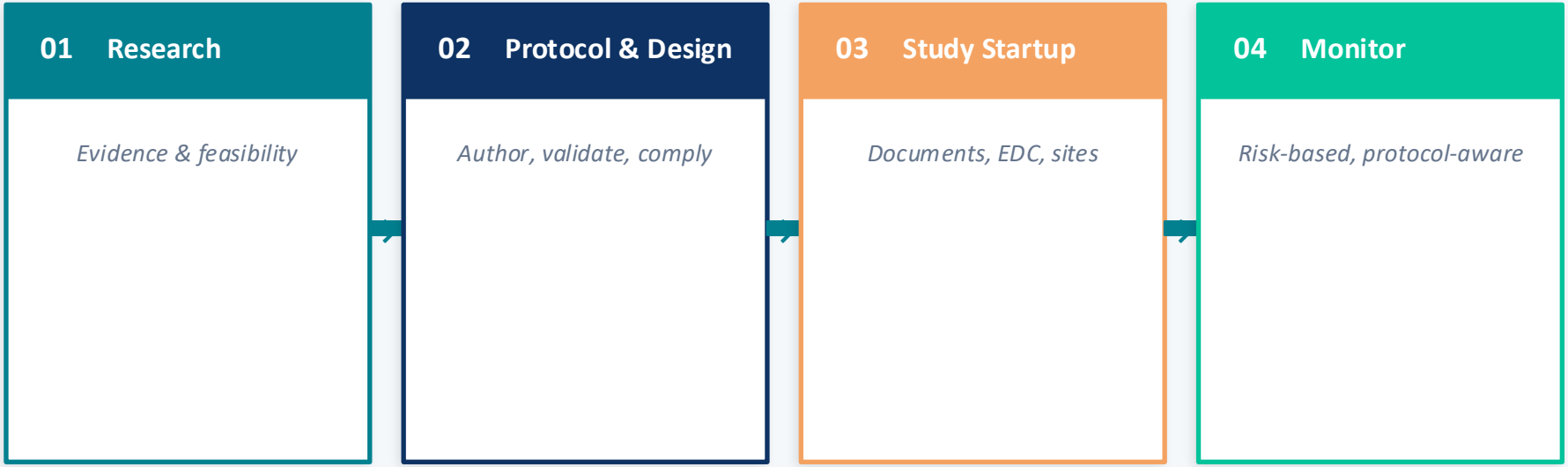
- Protocol amendments from decisions made before the protocol was written
- Study startup delays from manual transcription and rework
- Monitoring gaps when site data isn't connected to protocol context
- 30–40% of trial timeline delays accumulate before a single patient is enrolled

The clinical trial lifecycle has never been designed as a system.
It has been designed as a sequence of handoffs —
and every handoff is where intelligence gets lost.

The answer: replace the handoff with a connected intelligence platform.
One source of truth. End to end.

THE PLATFORM

A Connected Loop Across the Full Trial Lifecycle



Protocol Ingestion & Digitization · Single Source of Truth · Cascade Intelligence

Every phase feeds the next — intelligence never gets lost in translation.

Know Before You Design

Data Sources

PubMed & Literature
Disease landscape, mechanistic evidence

AACT / CT.gov
Prior trials, competitive design benchmarks

TRINETX (300M+ records)
Real-world patient feasibility validation

ORPHA & Rare Disease DBs
Orphan indication population sizing

Sponsor Knowledgebase
Organizational context & prior learnings

Output: Structured Synopsis

- Study objectives & design rationale
- Primary & secondary endpoints
- Validated I/E criteria (patient-grounded)
- Enrollment assumptions & timeline benchmarks
- Competitive landscape summary

Most protocol amendments trace back to decisions made before the protocol was written.

Eliminate the Gap Between Synopsis and Submission-Ready Protocol

Traditional Approach

- Manual copy-paste from synopsis
- Version drift before governance review
- Compliance gaps discovered late
- Amendment impact unknown until triggered
- Each document updated independently

AI-Powered Authoring

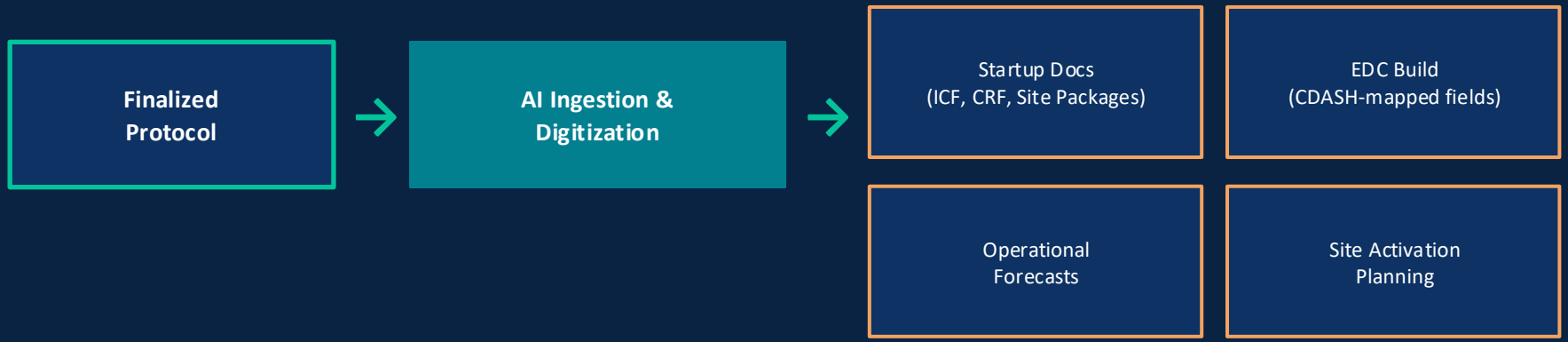
- First drafts from synopsis + org templates
- Real-time ICH-GCP compliance validation
- Inconsistencies flagged during authoring
- Design benchmarked vs. comparable trials
- Approved amendments cascade automatically

Cascade Update Architecture: An approved change propagates automatically — protocol → IB → ICF → CSR — version-controlled, audit trail intact.

THE BRIDGE

The Protocol Is No Longer a Document.

It's a Data Asset.



Every downstream team works from the same structured source — automatically.

Most operational problems in clinical trials are protocol problems that weren't caught early enough.

From Locked Protocol to Site-Ready — Faster, Smarter

Study Startup Documents

ICF, CRF, site packages auto-generated from protocol language
80%+ faster creation
Version consistency maintained

EDC Build

Protocol endpoints → CDASH-compliant fields
No manual re-transcription
No mapping errors post-study start

30–40%

of trial timeline delays occur during startup

Operational Forecasting

Visit windows & subject burden modeled from protocol
Benchmarked vs. AACT/CT.gov prior trials
Proactive planning before site activation

Site Activation Planning

Sites ranked by ability to execute this study
Feasibility scoring driven by protocol requirements
Not generic readiness — specific fit

System Integrations: CTMS · EDC · eTMF · Site Feasibility Databases

Every Visit. Every Data Point. Grounded in the Protocol.

1. Visit Prep

AI generates visit-specific briefs from protocol, prior reports, and live EDC/CTMS data

→

2. SDR Review

Source-to-EDC reconciliation with discrepancies flagged automatically before they compound

→

3. Deviation Analysis

Deviations cross-referenced to exact protocol section & regulatory language in real time

→

4. SIV Preparation

Protocol requirements, site readiness, and GCP documentation — all in one workspace

Risk-Based Monitoring Intelligence

Patient Recruitment · Screen Failure Rates · Protocol Deviations · AE/SAE Volume

SAE Reporting Timeliness · EDC Data Entry Lag · GCP & Training Compliance · Query Resolution

Each domain tracked, scored, and traced back to the protocol section — giving monitors defensible, audit-ready answers.

System Integrations: EDC · CTMS · IP Accounting · eTMF · 160+ Trial Document Types (RAG)

Risk-Based Monitoring · Domain Coverage Matrix

Risk Domain	Threshold	Rating	Intelligence Driver
Patient Recruitment	≤10% below target @ 6mo	★★★★★	*CTMS adds CRA narrative & intervention history*
Screen Failure Rate	≤20%	★★★★★	*Root cause narrative layer added*
Protocol Deviation	≤10% of subjects	★★★★★	*Full CAPA lifecycle incl. effectiveness checks*
AE/SAE Volume	≤10% of enrolled	★★★★★	*DSMB escalation chain tracked*
SAE Reporting Timeliness	≤24hr/≤5 days/≤7 days PI	★★★★★	*5 compliance timelines per event — major uplift*
EDC Data Entry	≤3 business days	★★★★★	*Monitoring response to systemic lag tracked*
GCP & Training	No expired/incomplete	★★★★★	*Training & delegation table closes this risk*
IRT Drug Accountability	≤20% error rate	★★★☆☆	*Context improved; kit-level reconciliation pending*
Lab Sample Tracking	Retest ≤4 weeks	★★★☆☆	*Visit narratives reference lab kit management*
SUSAR Acknowledgement	Per sponsor SLA	★☆☆☆☆	*Requires eTMF/safety distribution data*

COMPOUNDING VALUE

The Impact Compounds — It Doesn't Just Add Up

Efficiency

80%+

Faster startup document creation

30-40%

Timeline delay reduction potential

Hours → Seconds

Information retrieval at site visits

Accuracy

↓ Amendments

Evidence-grounded protocol design

Zero Drift

Single source of truth across documents

Traced Answers

Every output cited to source material

Compliance

Real-Time

ICH-GCP validation during authoring

Audit-Ready

Complete version history from day one

12 Risk Domains

Continuously monitored, scored, and tracked

Better protocols improve enrollment. Fewer amendments reduce delays. Embedded compliance lowers inspection risk.

THE SHIFT

From AI as a Productivity Tool…

…to AI as Institutional Intelligence.

Point Tool Approach

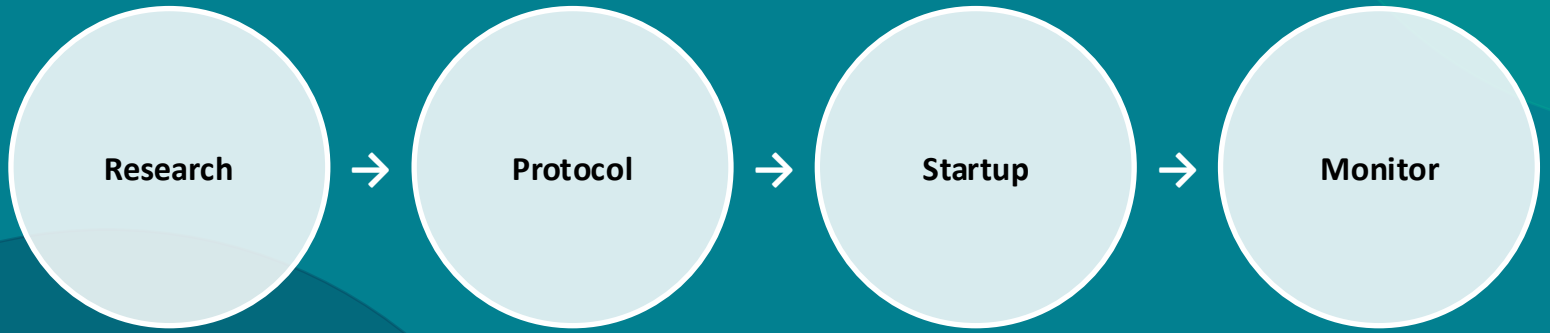
- Generates a document — fast
- Isolated from downstream systems
- No organizational memory
- Requires manual hand-off at every phase
- AI knows nothing about your trial history

Unified Intelligence Layer

- Generates a document system — connected
- Protocol-aware across every phase
- Learns from your organization's data
- Insight flows automatically downstream
- Every answer is traceable and audit-ready

THE CONNECTED TRIAL

One Platform. One Source of Truth. End to End.



The insight that grounds your protocol is the same insight that builds your EDC, activates your sites, and prepares your monitors.

Questions & Discussion

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