DrugTrial — AI-Powered Clinical Trial Automation Platform

Agentic, on-premise protocol → recruitment automation with cryptographic audit trails

"Protocol PDFs → FDA forms, safety models, targets, and patient matches — minutes, on-premise, zero data exfiltration."

Why clinical trials are broken

- Manual protocol review and FDA form filling (weeks; high error rates).
- Disconnected toolchain: EDC/CTMS, literature, and safety are siloed.
- Recruitment bottleneck: ~80% of trials miss enrollment timelines.
- Privacy & compliance block cloud AI for patient data.

IMPACT METRICS

$2.6B

Average drug development cost

10–15 years

Time to market

48,000+

Active clinical trials

One platform. Thirteen agents. Zero data leakage.

DrugTrial converts protocol PDFs into structured FDA forms (1571/1572), normalizes eligibility criteria with UMLS codes, mines PubMed to validate HGNC/UniProt biological targets, and runs in-silico safety models via RDKit (toxicity, DDI, PK/PD). Batch patient screening aligns to structured criteria with per-criterion confidence. All agents are orchestrated by an event-driven Trial Orchestrator, run locally via Ollama with Llama 3.1, persist to PostgreSQL and Neo4j, and maintain SHA-256 hash-chained audit trails aligned with 21 CFR Part 11.

Trial Orchestrator
Rule-based planner; parallel dispatch

FDA Processor
PDF → 1571/1572 + validation

Protocol Rule Agent
Nested criteria; negation detect

Eligibility Matcher
Batch screening + confidence

LTAA
PubMed → Neo4j → targets

InSilico Suite
RDKit descriptors → DDI → PK/PD

De-ID Agent
SHA-256 pseudonymization

PDF Parse/OCR
Table/figure-aware parsing

Form Validator
Part 11-compliant eSign

Audit Logger
Hash-chained event log

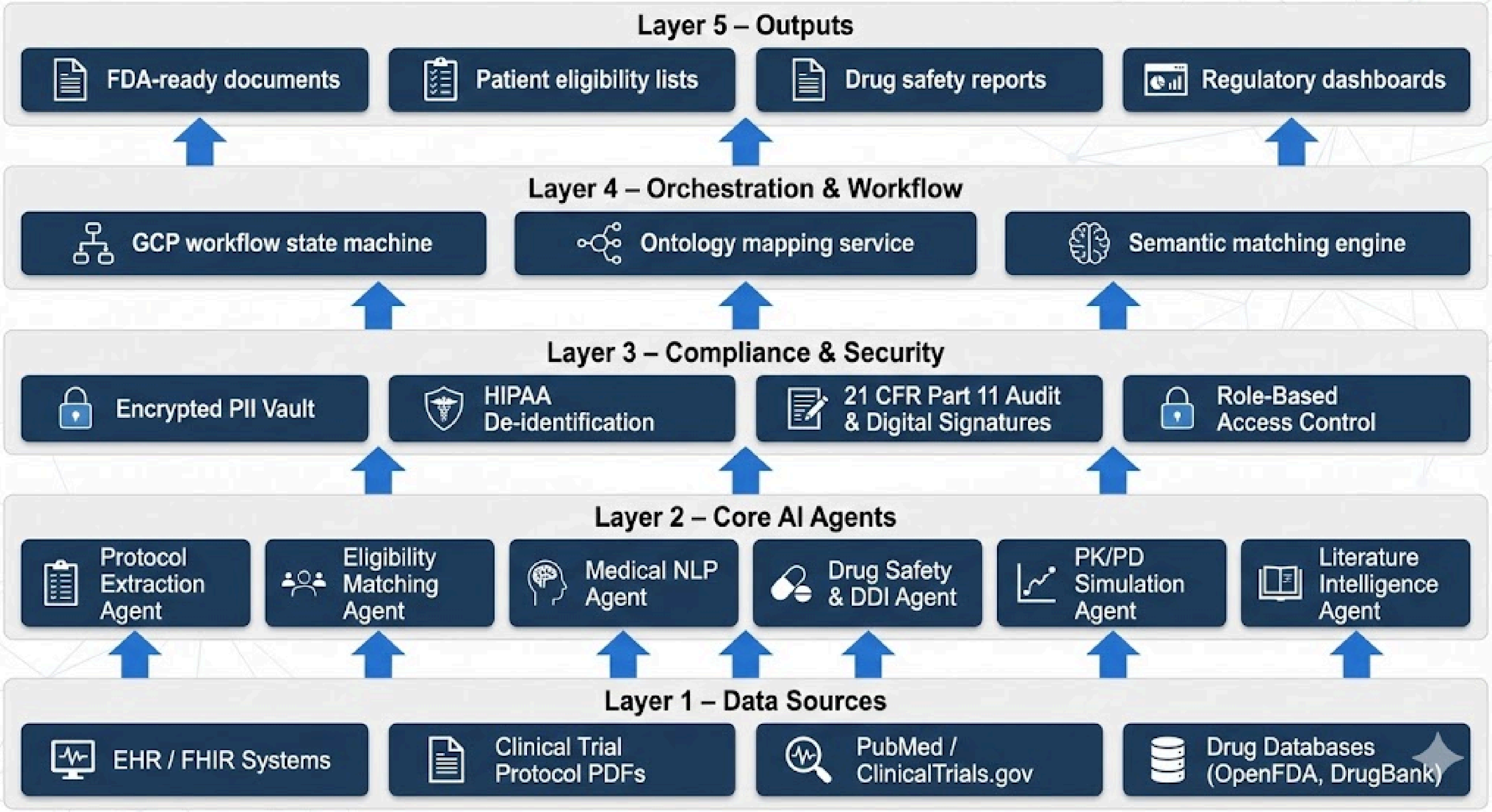
EHR/FHIR Adapter
ICD-10/LOINC/RxNorm map

Knowledge Graph
Entity normalization → Neo4j

Chat Agent
NL Q&A over trial artifacts

ORCHESTRATION FLOW

Multi-agent system automates FDA extraction, literature validation, in-silico safety, and patient matching.


Layer 5 – Outputs
FDA-ready documents
Patient eligibility lists
Drug safety reports
Regulatory dashboards
Layer 4 – Orchestration & Workflow
GCP workflow state machine
Ontology mapping service
Semantic matching engine
Layer 3 – Compliance & Security
Encrypted PII Vault
HIPAA De-identification
21 CFR Part 11 Audit & Digital Signatures
Role-Based Access Control
Layer 2 – Core AI Agents
Protocol Extraction Agent
Eligibility Matching Agent
Medical NLP Agent
Drug Safety & DDI Agent
PK/PD Simulation Agent
Literature Intelligence Agent
Layer 1 – Data Sources
EHR / FHIR Systems
Clinical Trial Protocol PDFs
PubMed / ClinicalTrials.gov
Drug Databases (OpenFDA, DrugBank)

DrugTrial AI: Development Roadmap & Critical Milestones

Phase 1
(0–3 Months | P0 Critical)

- HIPAA de-identification fixes
- Encrypted PII vault
- Medical ontology mapping (ICD-10, SNOMED, LOINC, RxNorm)
- 21 CFR Part 11 digital signatures and audit compliance
- EHR/FHIR integration

Phase 2
(3–6 Months | P1 High Value)

- Semantic eligibility matching
- Temporal reasoning for conditions and medications
- ML-based toxicity prediction
- Expanded drug–drug interaction database
- GCP workflow state machine
- Re-identification risk analysis

Phase 3
(6–12 Months | P2 Advanced)

- ClinicalTrials.gov integration
- Full-text research ingestion
- Advanced PK/PD modeling
- eCTD FDA submission automation

Demo: Upload → Review → Analyze → Screen

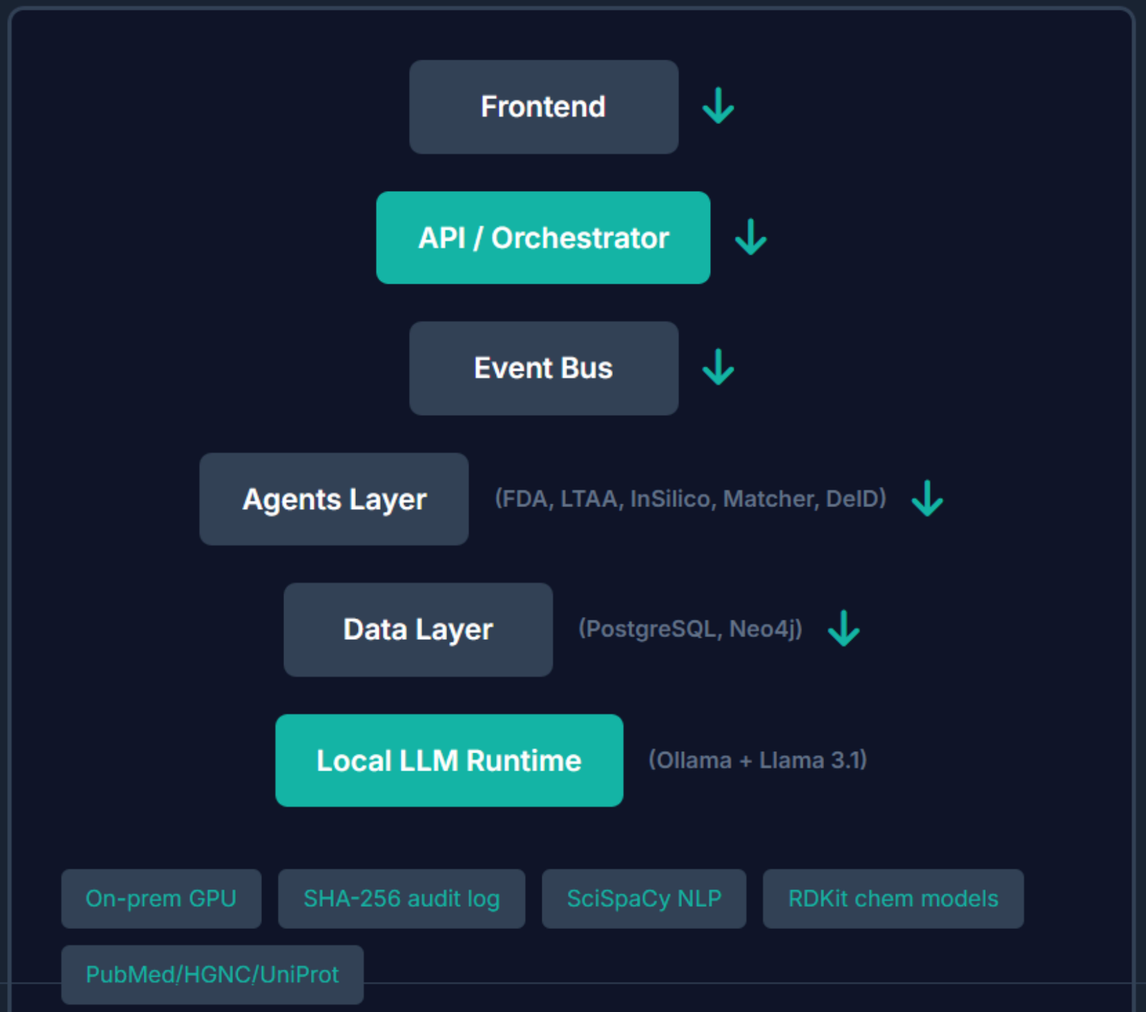
1. **Upload Protocol PDF**
   Compute and display document SHA-256 hash for immutable audit trail

2. **Auto-populate FDA 1571/1572**
   Reviewer edits extracted forms; Part 11-compliant e-signature

3. **Criteria Page with UMLS Links**
   Normalized inclusion/exclusion criteria with provenance and entity links

4. **Screening Dashboard**
   Batch matches with per-criterion reasoning; PI review and override

SYSTEM ARCHITECTURE



Upload a protocol, agents run in parallel, audit logs capture every action — PI reviews and signs.

Market Opportunity & GTM

TOTAL ADDRESSABLE MARKET

- Global clinical development spend: **$100B+**
- CTMS market: **~$2–3B**
- Patient recruitment tech: **~$1–2B**
- Data/AI enablement: **Double-digit CAGR**

TARGET CUSTOMERS

- **Top 20 Pharma**
- **CROs**
- **VC-backed Biotech**
- **Academic Medical Centers**

PRICING TIERS

Tier	Annual Price
Starter	$50K/yr
Professional	$100–200K/yr
Enterprise	$500K+/yr
Academic	Free

ROI HIGHLIGHTS

- Days saved per trial
- Protocol→screening: weeks to <1 hour
- Error rates ↓; faster first-patient-in

Large, growing market; enterprise GTM with attractive unit economics and proof path.

Future Roadmap & Target Market Flowchart

DrugTrial AI clinical trial automation platform