



PARZIVALPRIME

Team: Riyaz, Dhruv, Preetam

# TrialPlus NEXUS

AI-Powered Clinical Trial Intelligence Platform

58,085

Patients

3,401

Sites

23

Studies

4

AI Agents

5

ML Models



## THE PROBLEM

The multi-source, heterogeneous data from clinical trials remains inconsistent and siloed leading to a delay in identification of operational bottlenecks, inconsistent data quality and limited visibility for scientific decision making. Currently this is being done manually by different teams leading to fragmented communication and increase in cycle times.

# SOLUTION: Layer Architecture and Data Flow

## LAYER 6 Presentation

Role Based Dashboards | AI Assistant | Patient/Study/Site Level Views | Visualization (Forms, Patient Status, DQI, Lab Issues, Open Queries, etc) | React + Vite + NodeJS

## LAYER 5 Collaboration

Investigation Rooms | @Tagging & Mentions | SLA-Monitored Escalation Pipeline | Team Presence Tracking | Evidence Voting | Resolution Workflow

## LAYER 4 Agentic & Generative AI

4 Agents (ReAct + 20+ Tools) | LangGraph Orchestration | ChromaDB for RAG | 12 Types Context-Aware Report Generation | Groq & Ollama Models | Unsloth Fine-tuning

## LAYER 3 ML Models

Patient Risk Classifier | Issue Type Detector | Resolution Time Predictor | Site Risk Ranker | Anomaly Detector | 5 Models | SHAP Explainability | XGBoost | LightGBM | Governance

## LAYER 2 Metrics/Analytics

8-Component DQI | Clean Patient | DB Lock Ready | Cascade Intelligence | Resolution Genome | Causal Hypothesis Engine | Monte-Carlo Simulation | What-If Simulation

## LAYER 1 Data Foundation

9 Sources → 264 Features → Unified Patient Record (57,974 patients) | Neo4j



### Cascade Intelligence

Creates a **NetworkX/Neo4j** Dependency Graph of issues. And understands how fixing 1 issue → unblocks 10+ downstream issues.

E.g. "Fix 12 queries at JP-101

- Unlocks 8 blocked PI signatures
- Clears 3 SAE reviews waiting on data
- NET IMPACT: +14 DQI points for the site"



### Resolution Genome

Every issue resolution becomes knowledge for similar future issues. This module captures and matches patterns.

E.g. "This issue type resolved 847 times. Top solution: 94% success rate"



### Causal Hypothesis Engine & What-If Scenario Simulator

E.g.

> Hypothesis: PI Absence Cascade at Site JP-101: Confidence: 82% | Evidence: Overdue signatures +14, No PI login 10 days

> What-If: Add 2 CRAs → 73% chance of DB Lock by March 15

# ML MODELS: TRAINING & EVALUATION

📄 Methodology: 58,095 patients × 264 features | 70/15/15 Split (Stratified) | 5-Fold CV | Optuna Tuning | SHAP Explainability

## 📊 Site Risk Ranker

Type: Learning-to-Rank (Pairwise)

**NDCG@10: 0.84 | MAP: 0.85**

Model: XGBoost Ranker

Top Features: 141 aggregated from 27 raw features

## 🎯 Patient Risk Classifier

Type: 4-Class Classification

**ROC-AUC: 0.91 | F1: 0.78 | Recall: 84%**

Model: XGBoost + LightGBM Ensemble

Top Features: Query density, SDV rate, Signature delays

## 🕒 Resolution Time Predictor

Type: Quantile Regression

**MAE: 3.2 days | Coverage: 82%**

Model: XGBoost Quantile [0.1-0.9]

Top Features: Issue type, Site history, Complexity

## 🔍 Multi-Label Issue Detector

Type: 14 Binary Classifiers

**Avg AUC: 0.90 | Avg F1: 0.77**

Model: XGBoost (Binary Relevance)

Top Features: Per-issue optimized thresholds

## 🕵️ Anomaly Detector

Type: 4-Class Unsupervised Classification

**Anomalies: 5800 (10%) | Critical : 580 (1%)**

Model: Isolation Forest, DBScan, Autoencoder

Top Features: Per-issue optimized thresholds

## 📈 Model Comparison (Risk Classifier)

| Model               | ROC-AUC | F1   |
|---------------------|---------|------|
| Random Baseline     | 0.50    | 0.21 |
| Logistic Regression | 0.72    | 0.48 |
| Decision Tree       | 0.68    | 0.44 |
| Random Forest       | 0.81    | 0.62 |
| XGBoost             | 0.89    | 0.74 |
| Ensemble ✓          | 0.91    | 0.78 |



## EXPLAINABILITY (SHAP)

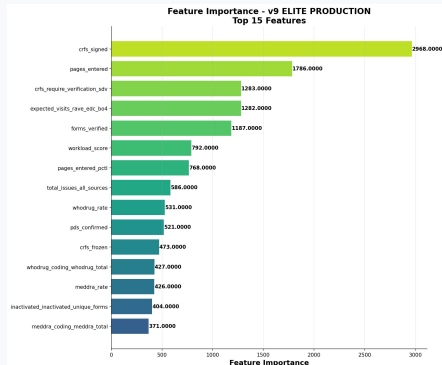
Every prediction includes feature contributions:

*"High Risk (78%) because:*

- 5 open queries (+18% risk)
- 2 missing visits (+12% risk)
- PI signature overdue 45+ days (+8%)"



## SHAP Feature Importance



✓ NO DATA LEAKAGE | ✓ STRICT TRAIN/VAL/TEST SEPARATION | ✓ CONFIDENCE INTERVALS | ✓ CALIBRATED PROBABILITIES

# AGENTIC AI ARCHITECTURE



## SUPERVISOR

Routes, Plans, Orchestrates



## DIAGNOSTIC

NL to SQL, Fetch Data points



## RESOLVER

Action Recommendations



## COMMUNICATOR

Final Response






### ... EXAMPLE: "Why is site JP-101 underperforming?"

- **Supervisor**
  - *Thought:* Complex diagnostic query. Need metrics + root cause
  - *Action:* route\_to\_agent("DIAGNOSTIC", query)
- **Diagnostic**
  - *Thought:* Need current metrics for JP-101
  - *Action:* query\_site\_metrics(site\_id="JP-101")
  - *Observation:* DQI=71, Queries=23, Missing Sigs=12
  - *Thought:* High signatures missing. Check PI activity
  - *Action:* get\_pi\_activity(site\_id="JP-101", days=14)
  - *Observation:* PI signed 0 docs since Nov 1 (conference)
  - *Hypothesis:* PI Absence Pattern, 82% confidence
- **Resolver**
  - *Action:* predict\_recovery(site="JP-101", issue="pi\_absence")
  - *Prediction:* 12 days to recovery, CI: [8, 18] days
- **Communicator**
  - *Action:* search\_resolution\_genome(pattern="pi\_absence")
  - *Recommendation:* [Batch signature session, Delegate to sub-I]

Time taken ~ 6 seconds




## 24 AGENT TOOLS

-  **Data:** get\_patient, get\_site\_summary, get\_high\_priority\_patients
-  **Search:** search\_knowledge (RAG), search\_resolutions, search\_patterns
-  **Analytics:** get\_cascade\_path, get\_cascade\_impact, get\_dblock\_projection
-  **ML:** predict\_risk, detect\_issues, predict\_resolution\_time
-  **Genome:** get\_resolution\_recommendation, get\_patient\_resolution\_plan









## AUTONOMY MATRIX (5×4)

- ≥95% + Low Risk → AUTO-EXECUTE (Immediate)
- 80-94% + Medium → AUTO-DRAFT (72h Human Review)
- 60-79% + High → ESCALATE (24h Manager)
- <60% + Critical → BLOCK (Sponsor Required)
-  NEVER-AUTO (12 Types):
- SAE Causality, Protocol Deviation, Unblinding,
- Regulatory, Site Closure, DB Lock, Consent,
- Medical Judgment, Safety Signal, Locked Data...



## TECHNOLOGY STACK

-  **LLM:** Groq (Llama 3.3 70B) + Ollama (fallback)
-  **Agents:** Custom ReAct Loop + NL-to-SQL Grounding
-  **ML:** XGBoost + LightGBM + Sentence Transformers
-  **Frontend:** React 18 + Vite + TailwindCSS + Recharts
-  **Database:** PostgreSQL + ChromaDB (RAG) + Neo4j (Cascade)
-  **Deploy:** Docker + FastAPI

# RESULTS AND NEW FEATURES

66.7%

Clinical Clean Rate  
38,684 patients

78.0%

Operational Clean  
41,583 patients

73.2%

DB Lock Ready  
10,401 patients

32,287+

Issues Tracked  
Real-time monitoring

## ⚠️ CHALLENGES OVERCOME

- 9 data sources → Unified Patient Record (PostgreSQL)
- Class imbalance (2-45%) → SMOTE + Class Weights (20:15:8:1)
- Multi-class risk → Cascade Prediction (Critical→High→Medium→Low)
- Noisy labels → Percentile thresholds (P50/P80/P95)
- Feature leakage → Outcome features excluded
- Model drift → Low-class recall as stability detector

## 🚀 ROADMAP

- 📺 NEXT: Real-time Streaming (Kafka) | AWS Deployment (SageMaker)
- Expanded Agent Autonomy | Multi-tenant Architecture
- Production SLA Monitoring | Notification Service | Electronic Signatures

97.5

8-point Data Query Index



## DB & Deployment

- PostgreSQL DB
- Dockerized service for DB
- FastAPI Backend



## Monte-Carlo Simulation

- 10,000 runs with uncertainty quantification. What-if scenarios to predict DB lock timeline, site closure impact, transfer success rate, etc.

E.g. Timeline: P50 = 14.2 days | 95% CI: [8.1, 28.7 days] Deadline Probability: 73.2% on-time | Risk Score: 42.5 (MODERATE)



## PSI Drift Detection

- PSI-Based Monitoring with 21 CFR Part 11 Audit. Queries Postgresql for live DQI metrics and logs to audit\_logs.

E.g. "drift\_detection": {"monitor\_class": "Low", "reason": "Low class has 98%+ recall stability", "action": "Alert on >3% week-over-week drop"}



## Frontend Changes

- React18 + Vite + Typescript
- Tailwind CSS + Radix UI
- Tanstack query + table
- Recharts
- Framer Motion
- Zustand