Clinical Intelligence Platform - Use Cases

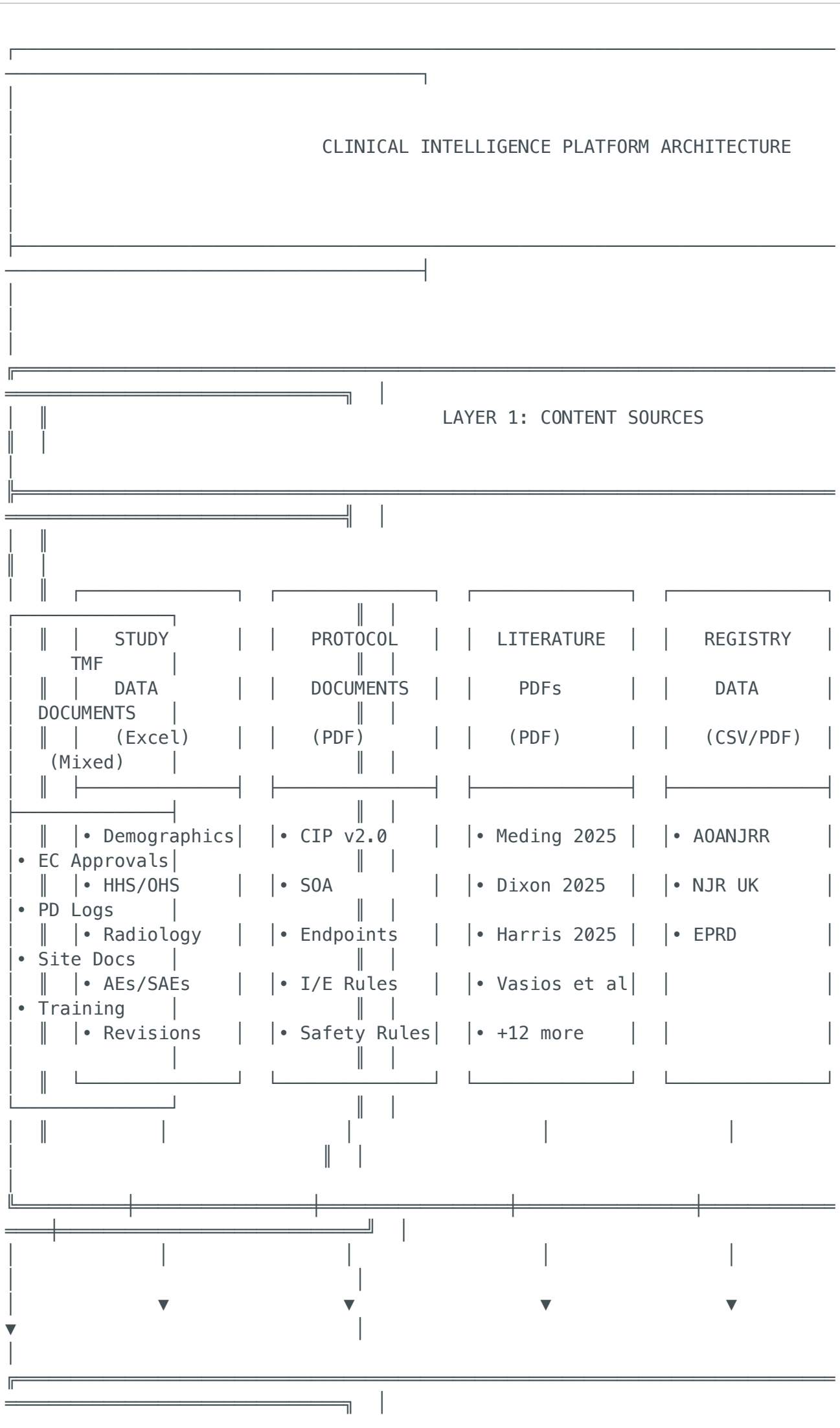
H-34 DELTA Revision Cup Study - POC Use Case Specifications

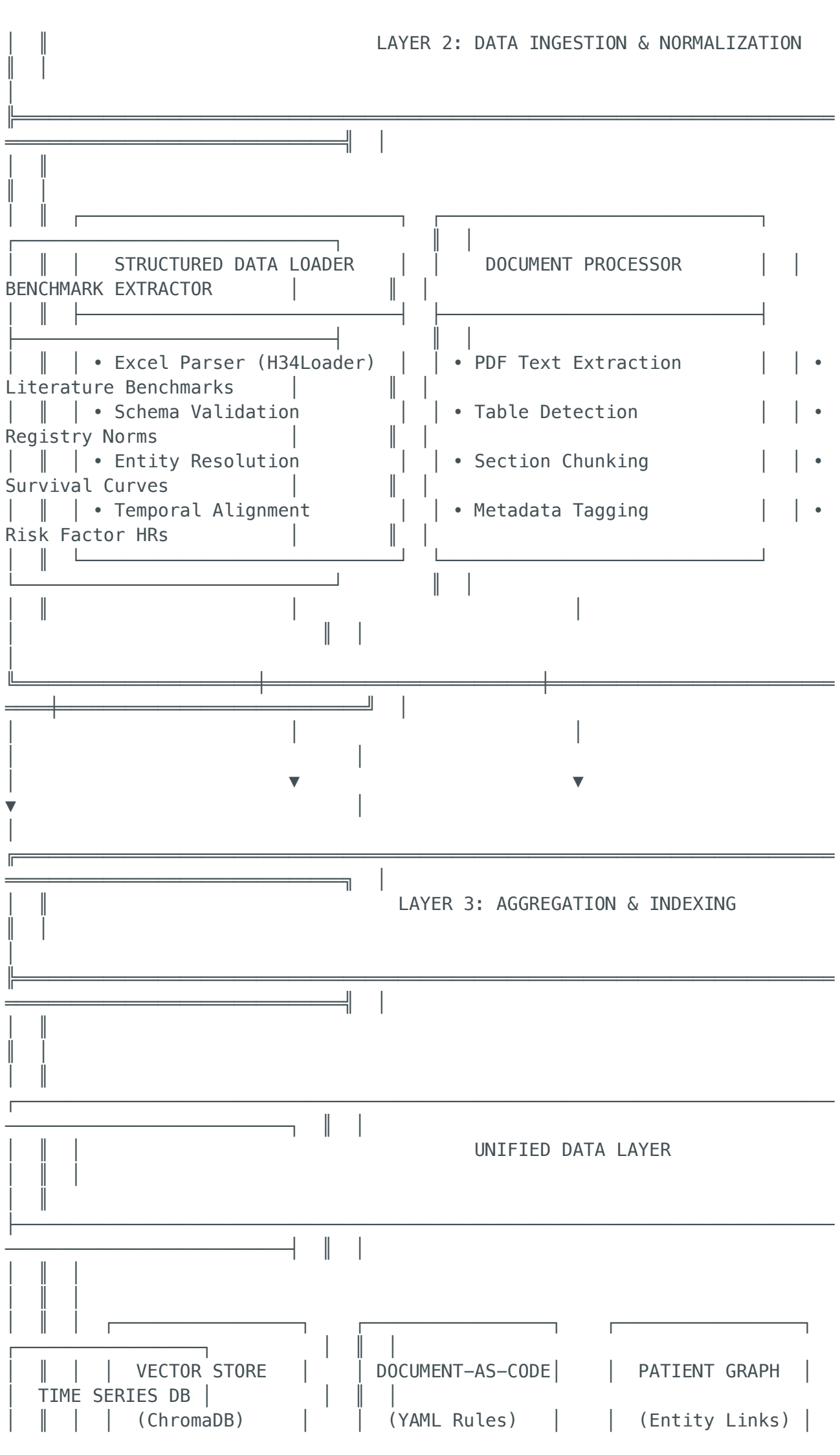
Version: 1.0 | **Date:** January 11, 2026

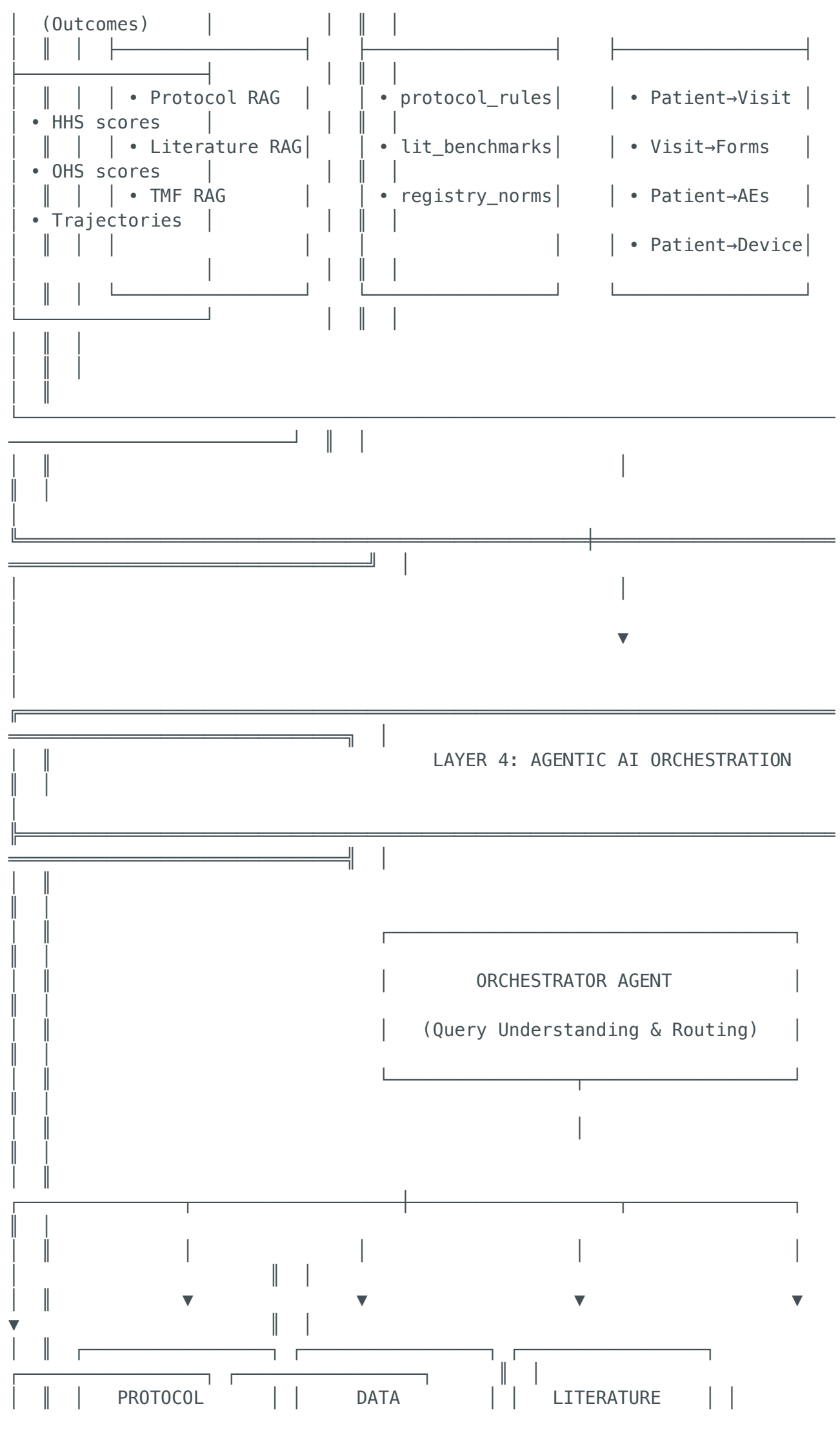
Multi-Source Architecture Overview

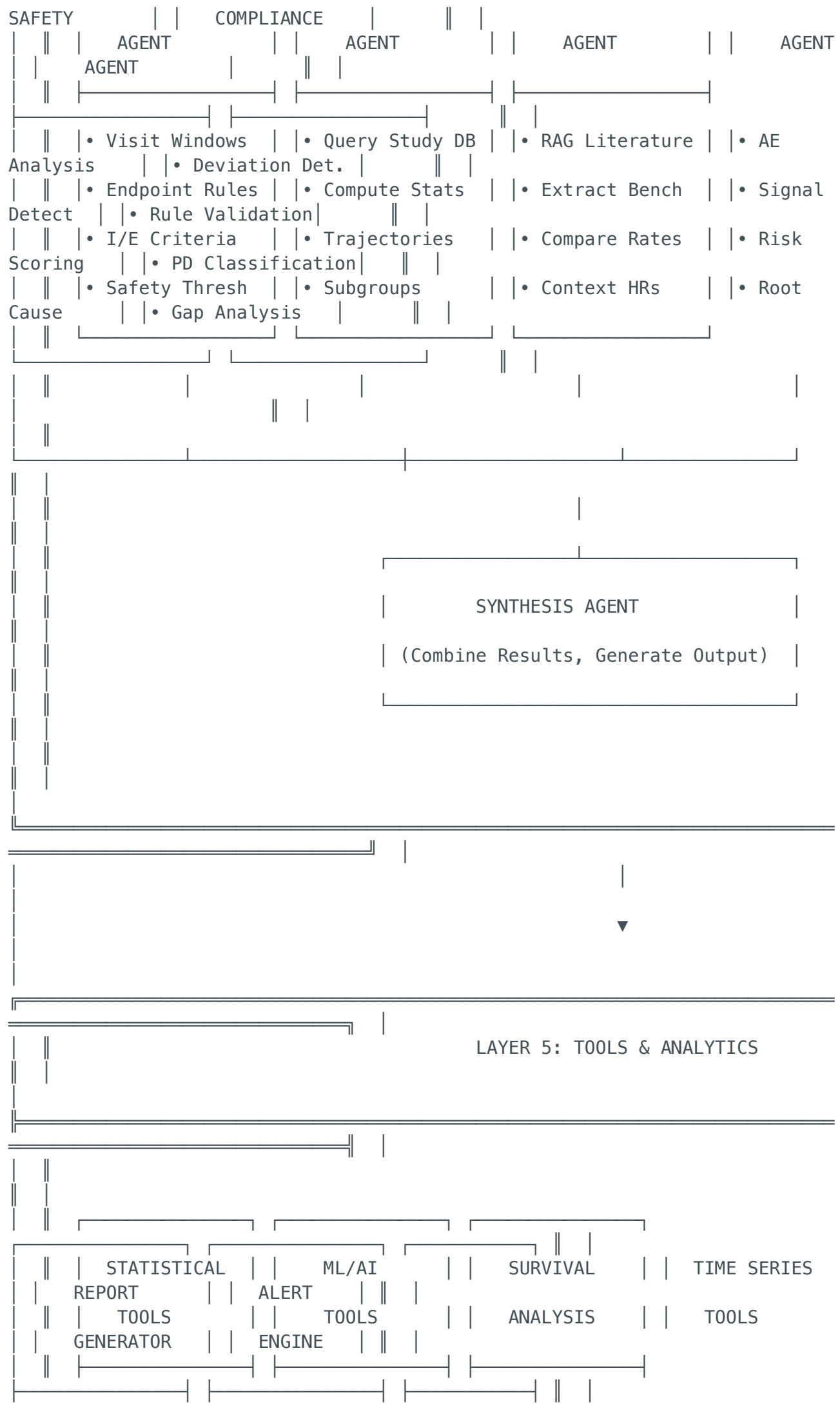
> **Core Principle:** Each use case leverages multiple data sources orchestrated through specialized AI agents. The architecture below shows how content flows from raw sources through aggregation, agent processing, and finally to user experience.

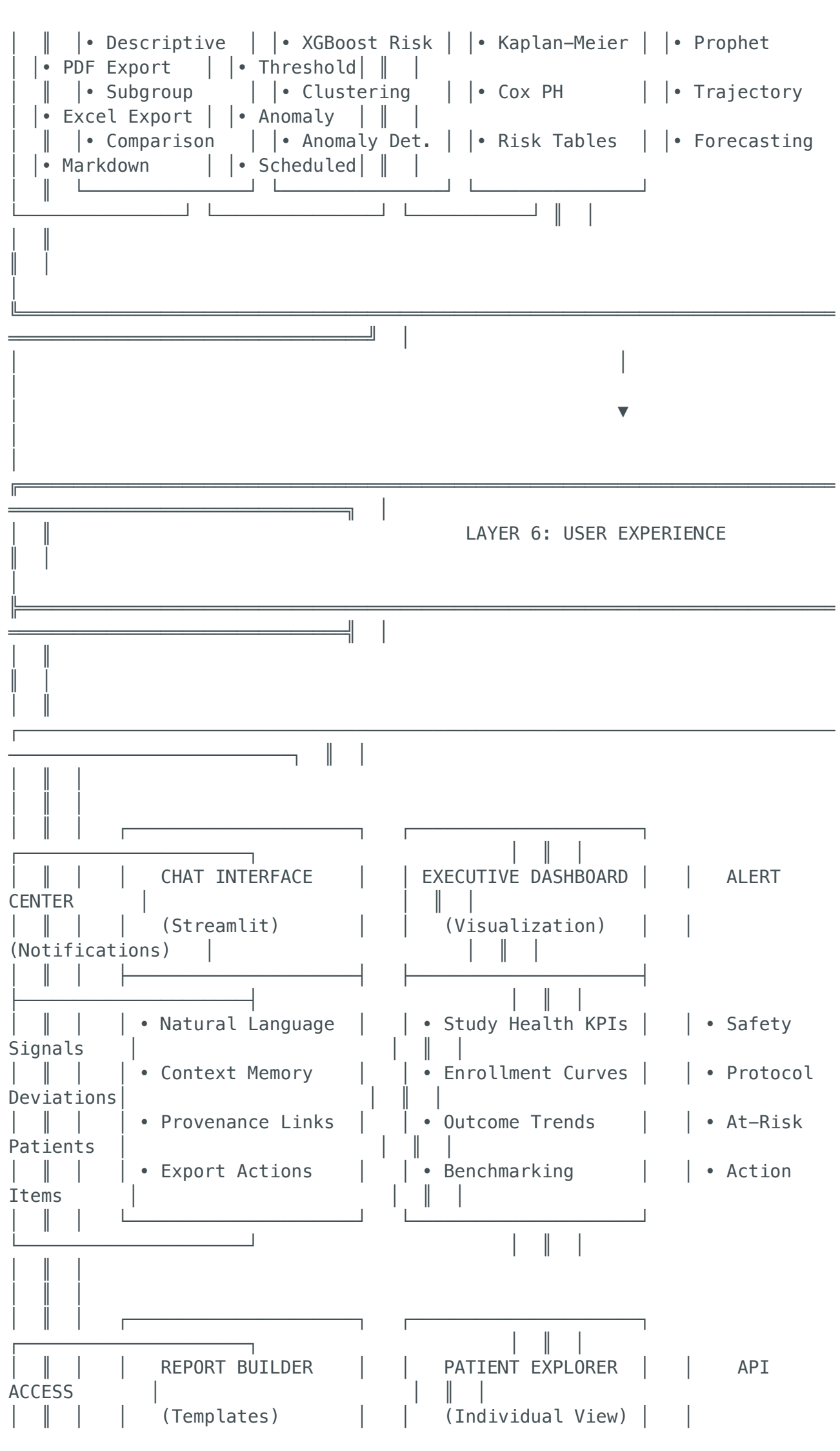
System Architecture Visualization

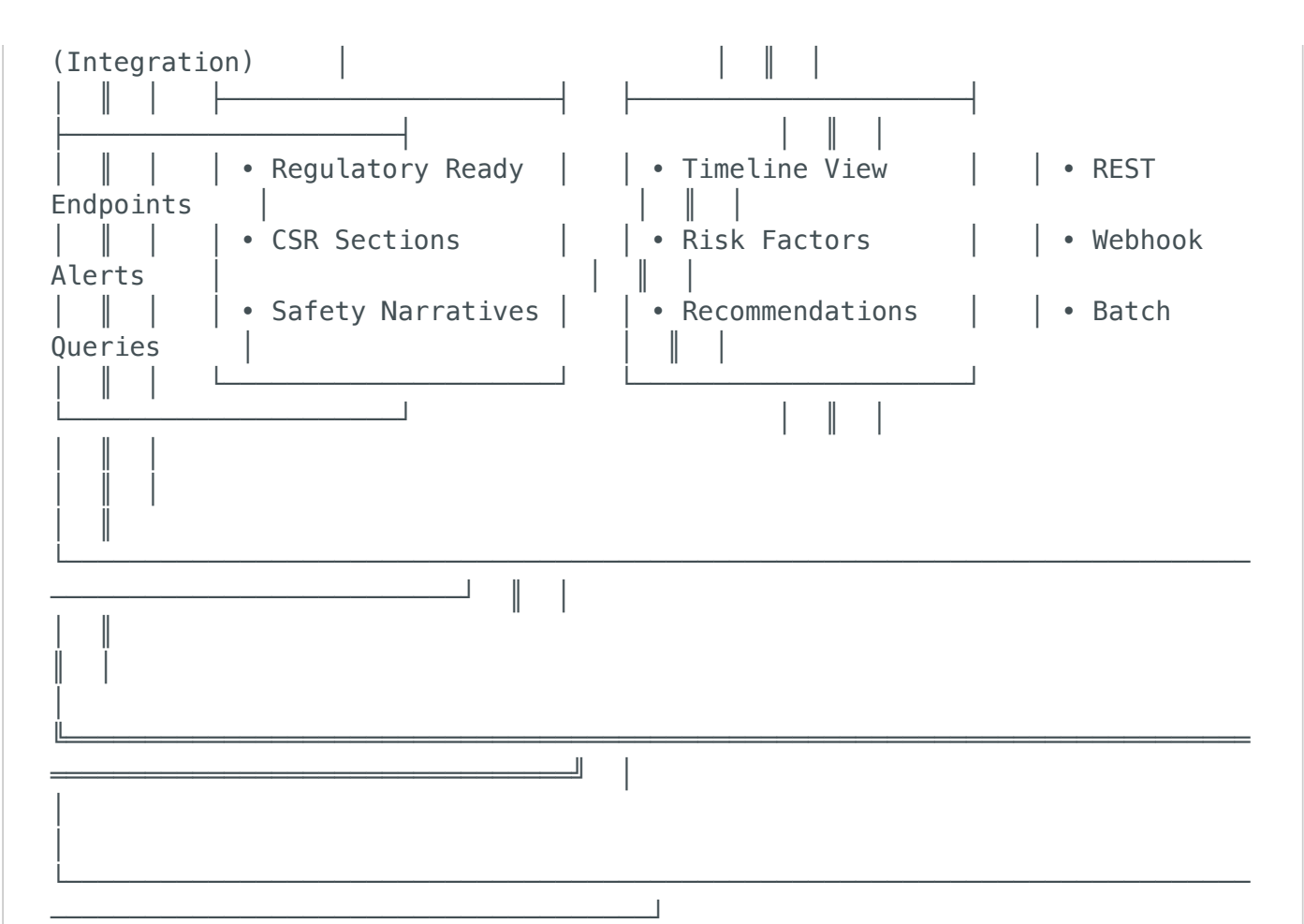

CLINICAL INTELLIGENCE PLATFORM ARCHITECTURE
LAYER 1: CONTENT SOURCES
STUDY DATA (Excel) (Mixed)
• Demographics
• HHS/OHS
• Radiology
• AEs/SAEs
• Revisions
TMF DOCUMENTS
• EC Approvals
• PD Logs
• Site Docs
• Training
PROTOCOL DOCUMENTS (PDF)
• CIP v2.0
• SOA
• Endpoints
• I/E Rules
• Safety Rules
LITERATURE PDFs (PDF)
• Meding 2025
• Dixon 2025
• Harris 2025
• Vasios et al
• +12 more
REGISTRY DATA (CSV/PDF)
• AOANJRR
• NJR UK
• EPRD


LAYER 2: DATA INGESTION & NORMALIZATION
STRUCTURED DATA LOADER
• Excel Parser (H34Loader)
• Schema Validation
• Entity Resolution
• Temporal Alignment
DOCUMENT PROCESSOR
• PDF Text Extraction
• Table Detection
• Section Chunking
• Metadata Tagging
BENCHMARK EXTRACTOR
• Literature Benchmarks
• Registry Norms
• Survival Curves
• Risk Factor HRs
LAYER 3: AGGREGATION & INDEXING
UNIFIED DATA LAYER
VECTOR STORE
(ChromaDB)
DOCUMENT-AS-CODE
(YAML Rules)
PATIENT GRAPH
(Entity Links)
TIME SERIES DB

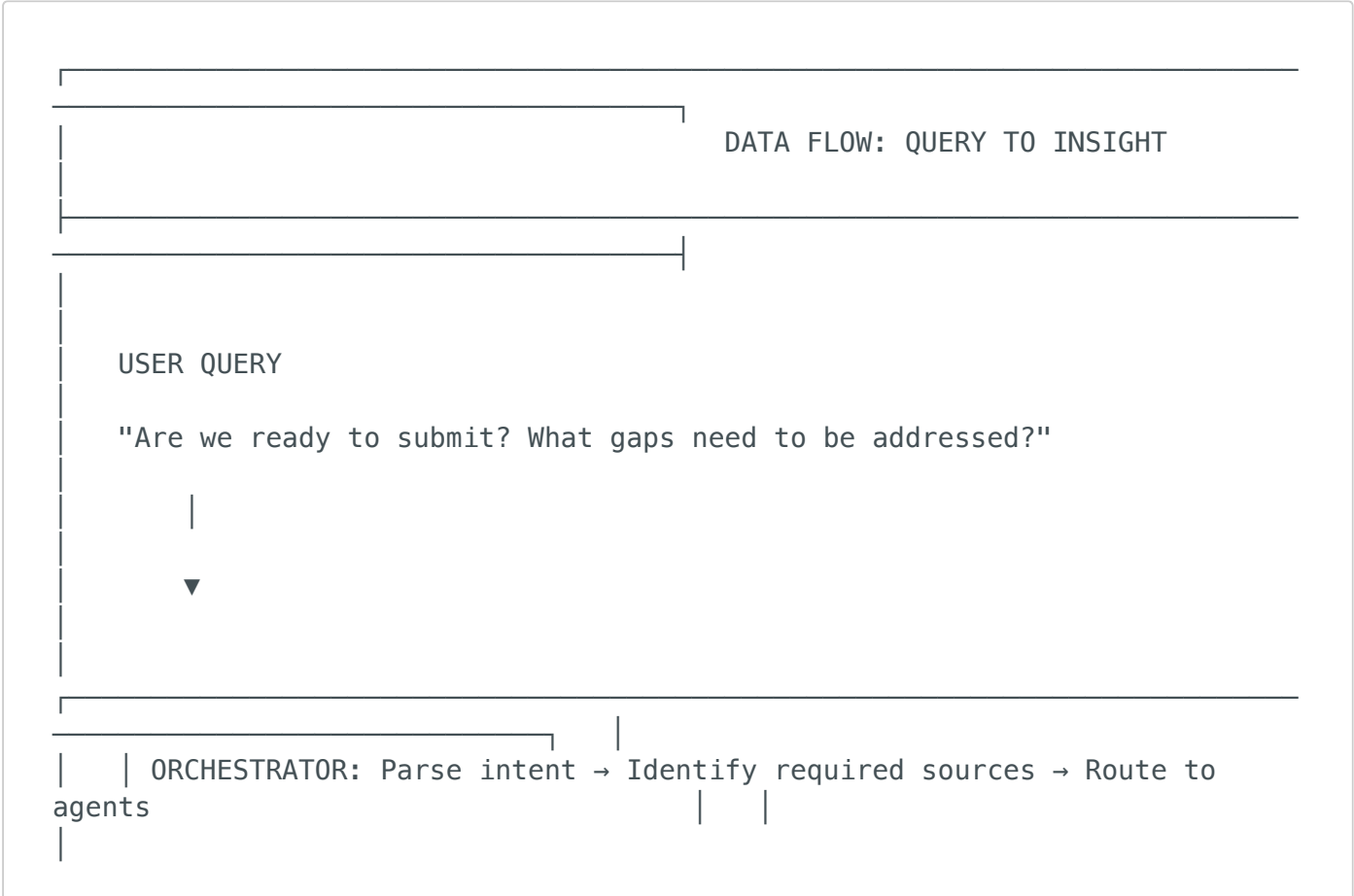

(Outcomes)
• Protocol RAG
• Literature RAG
• TMF RAG
• HHS scores
• OHS scores
• Trajectories
• protocol_rules
• lit_benchmarks
• registry_norms
• Patient→Visit
• Visit→Forms
• Patient→AEs
• Patient→Device
LAYER 4: AGENTIC AI ORCHESTRATION
ORCHESTRATOR AGENT
(Query Understanding & Routing)
PROTOCOL
DATA
LITERATURE

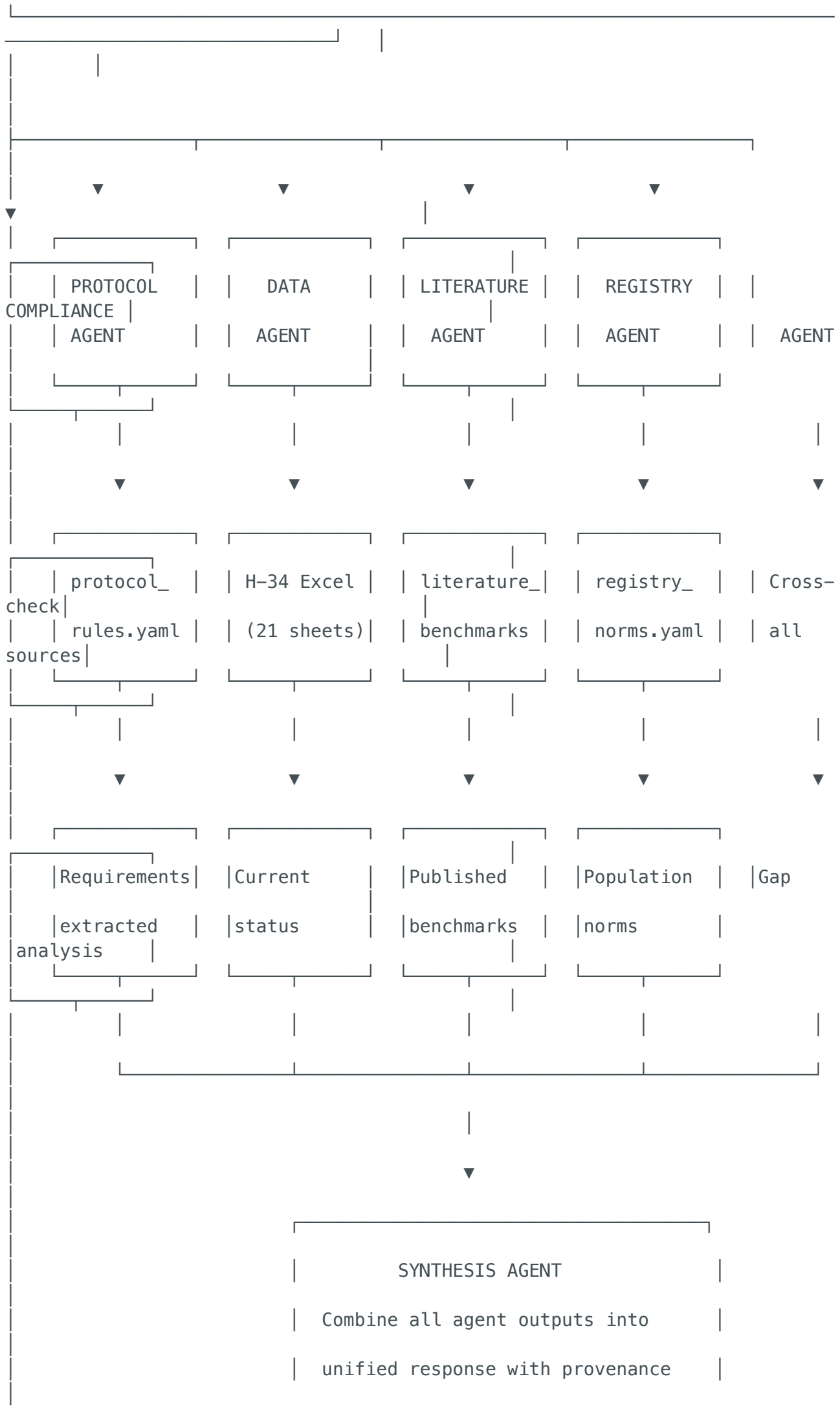

SAFETY
COMPLIANCE
AGENT
AGENT
AGENT
AGENT
AGENT
• Visit Windows
• Query Study DB
• RAG Literature
• AE Analysis
• Deviation Det.
• Endpoint Rules
• Compute Stats
• Extract Bench
• Signal Detect
• Rule Validation
• I/E Criteria
• Trajectories
• Compare Rates
• Risk Scoring
• PD Classification
• Safety Thresh
• Subgroups
• Context HRs
• Root Cause
• Gap Analysis
SYNTHESIS AGENT
(Combine Results, Generate Output)
LAYER 5: TOOLS & ANALYTICS
STATISTICAL REPORT TOOLS GENERATOR
ML/AI ALERT TOOLS ENGINE
SURVIVAL ANALYSIS
TIME SERIES TOOLS

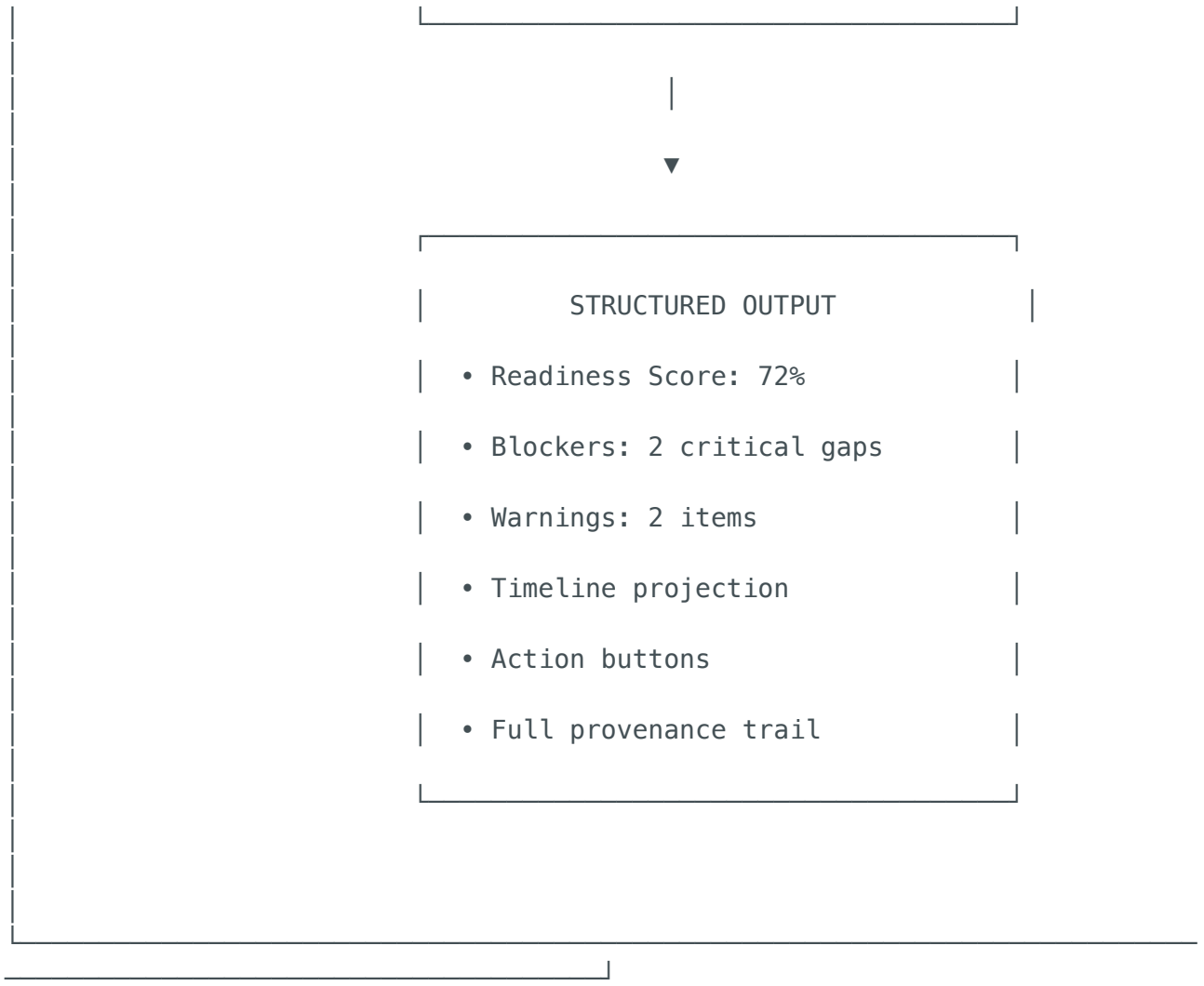

• Descriptive
• PDF Export
• Subgroup
• Excel Export
• Comparison
• Markdown
• XGBoost Risk
• Threshold
• Clustering
• Anomaly
• Anomaly Det.
• Scheduled
• Kaplan-Meier
• Cox PH
• Risk Tables
• Prophet
• Trajectory
• Forecasting
LAYER 6: USER EXPERIENCE
CHAT INTERFACE
(Streamlit)
• Natural Language
• Context Memory
• Provenance Links
• Export Actions
EXECUTIVE DASHBOARD
(Visualization)
• Study Health KPIs
• Enrollment Curves
• Outcome Trends
• Benchmarking
ALERT CENTER
(Notifications)
• Safety Signals
• Protocol Deviations
• At-Risk Patients
• Action Items
REPORT BUILDER
(Templates)
PATIENT EXPLORER
(Individual View)
API ACCESS



Data Flow Diagram




PROTOCOL COMPLIANCE AGENT
DATA AGENT
LITERATURE AGENT
REGISTRY AGENT
AGENT
protocol_rules.yaml
H-34 Excel (21 sheets)
literature_benchmarks
registry_norms.yaml
Cross-check all sources
Requirements extracted
Current status
Published benchmarks
Population norms
Gap analysis
SYNTHESIS AGENT
Combine all agent outputs into unified response with provenance



Use Case Specifications

UC1: Regulatory Submission Readiness Assessment

Overview

Attribute	Value
UC ID	UC1
Name	Regulatory Submission Readiness Assessment
Category	Compliance & Regulatory

Attribute	Value
Trigger	User query or scheduled assessment
Complexity	High (5 agents, 4+ data sources)

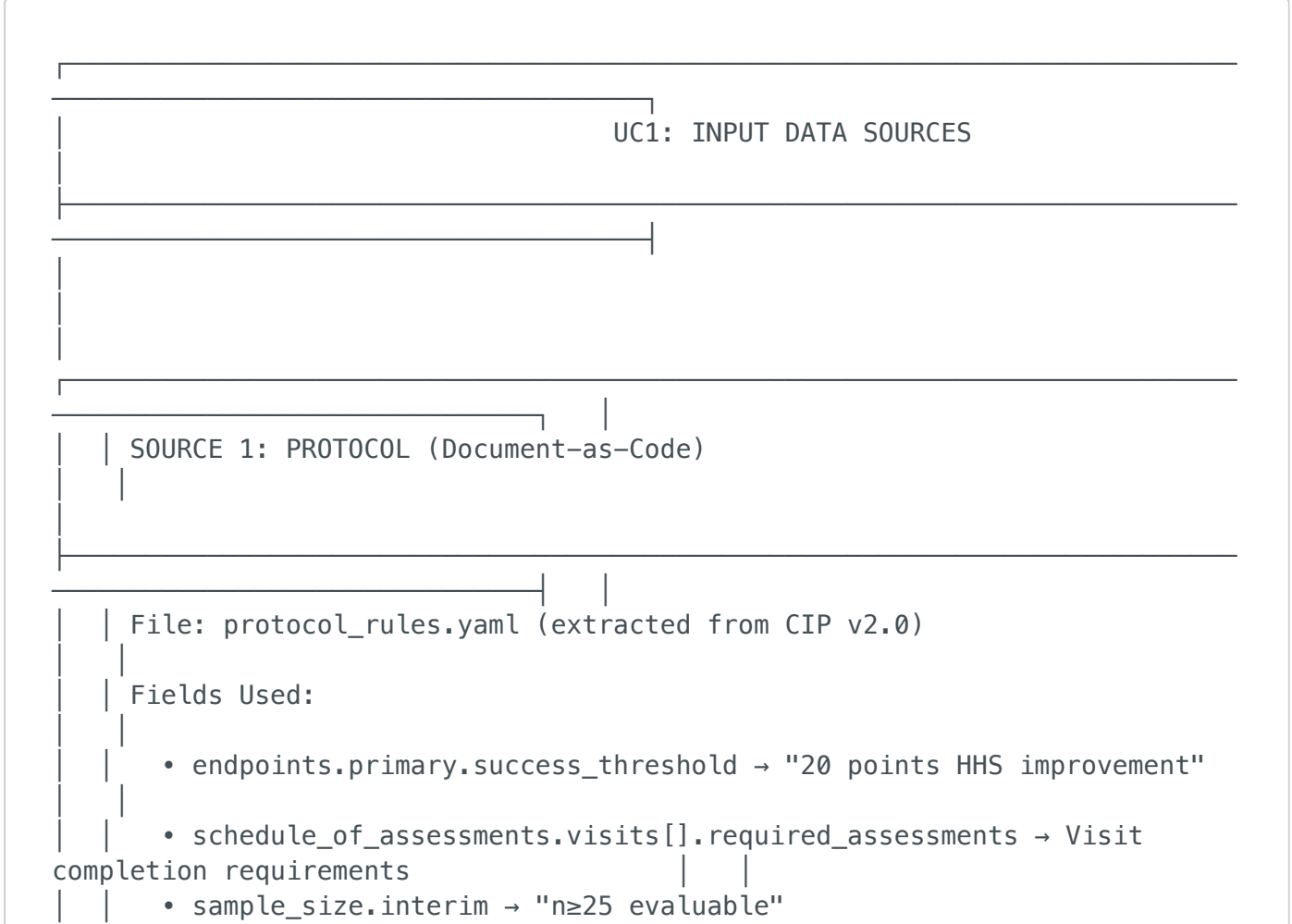
Business Problem

Clinical teams spend **3-5 days** manually cross-referencing protocol requirements, study data, literature benchmarks, and regulatory expectations to assess submission readiness. Gaps are discovered late, causing delays and rework.

User Query Examples

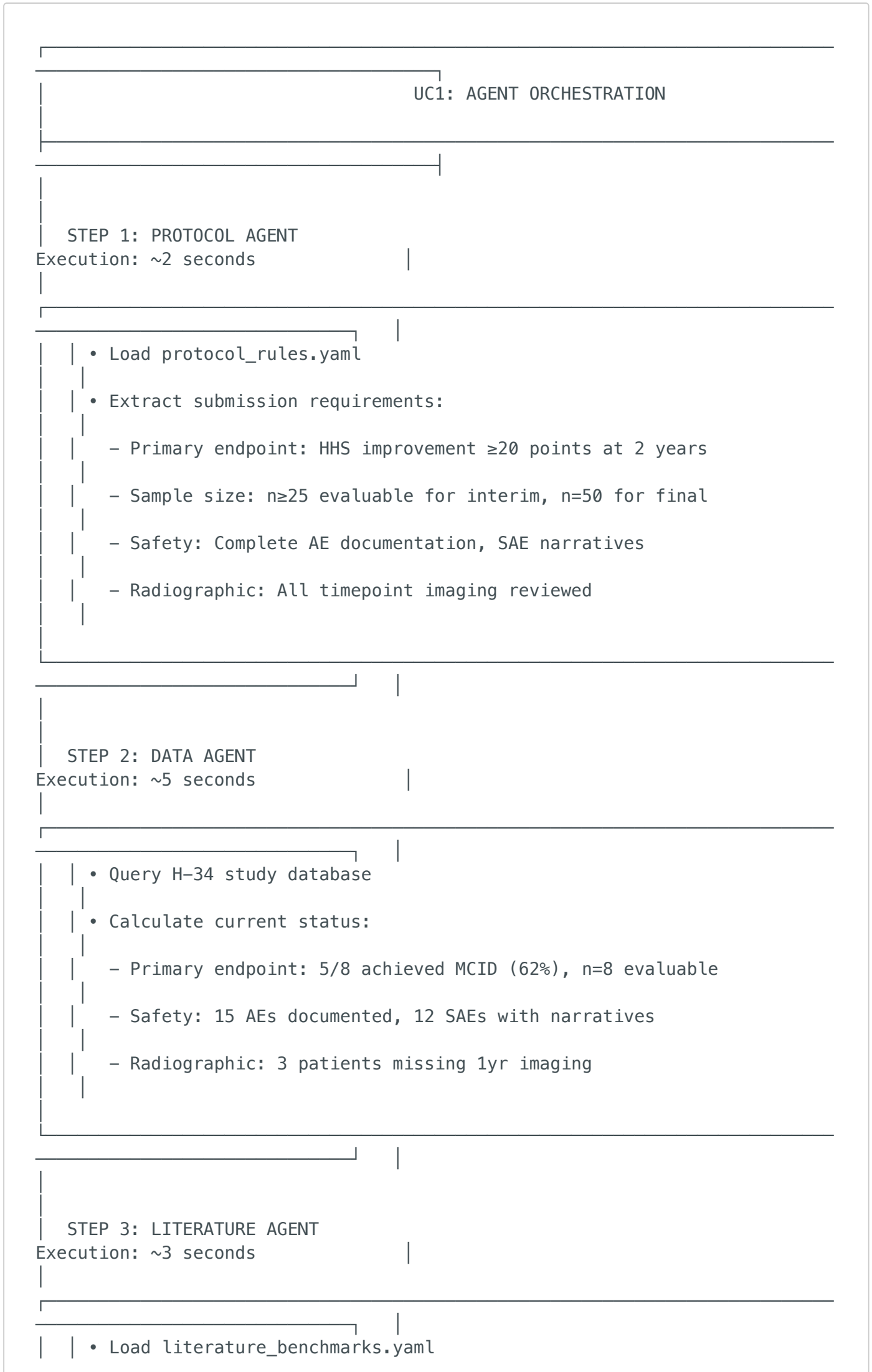
- "Are we ready to submit? What gaps need to be addressed?"
- "What's our submission readiness status?"
- "Generate regulatory readiness report"

Input Data Sources

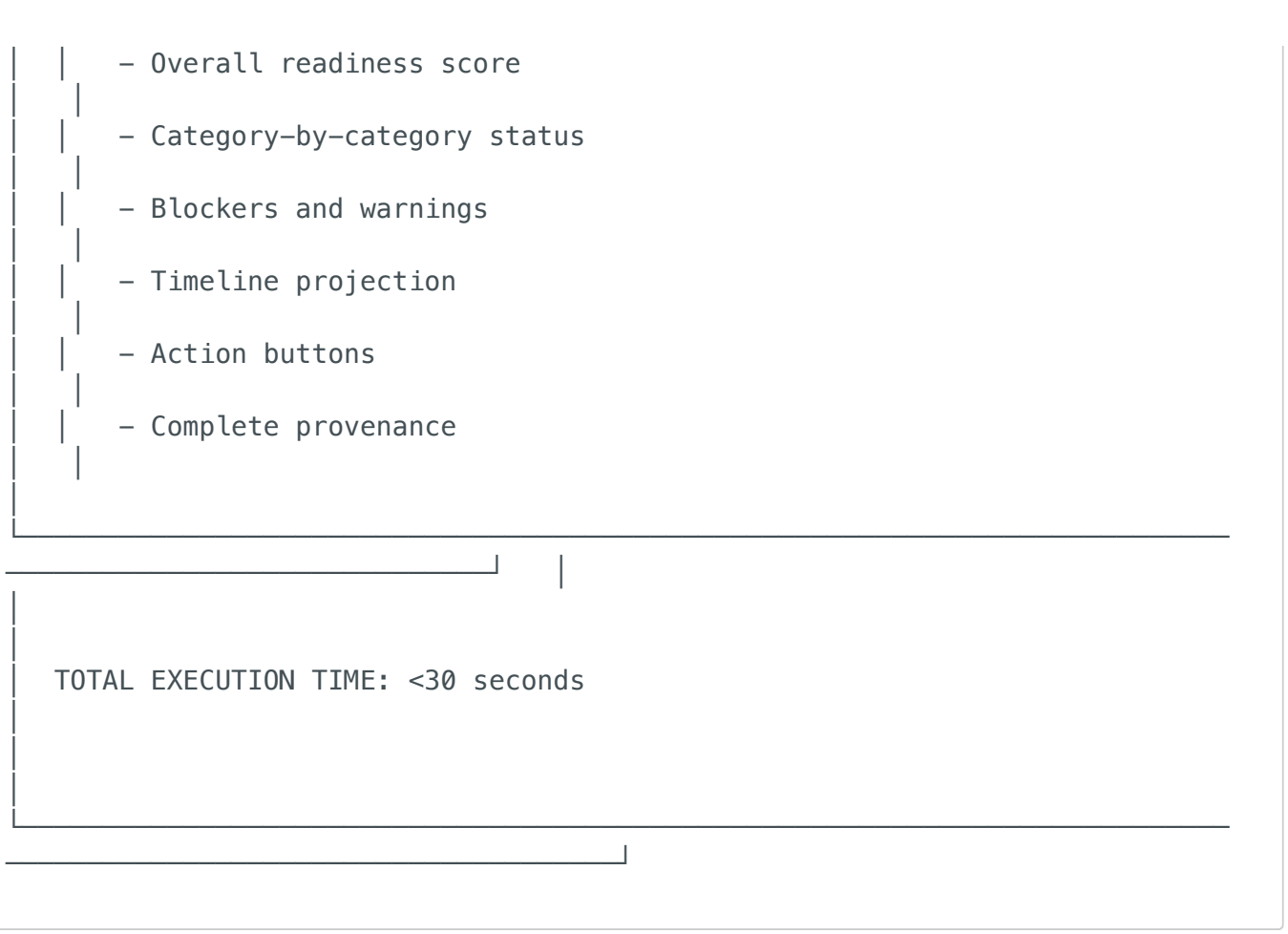



• safety_requirements.sae_narrative → "All SAEs require narratives"
• radiographic_requirements → "All timepoints must have imaging review"
SOURCE 2: STUDY DATA (Structured)
File: H-34DELTARevisionstudy_export_20250912.xlsx
Sheets Used:
• Sheet 1 (Patients) → Enrollment count, patient status
• Sheet 18 (Score HHS) → Primary endpoint data, MCID calculation
• Sheet 17 (Adverse Events) → Safety completeness, SAE narratives
• Sheets 7-16 (Follow-ups) → Visit completion, radiographic data availability
• Sheet 20 (Explants) → Revision event counts
Key Calculations:
• Patients with 2-year HHS: 8/37
• MCID achieved: 5/8 (62%)
• SAEs with narratives: 12/12
• Missing radiographic: 3 patients at 1-year
SOURCE 3: LITERATURE BENCHMARKS (Document-as-Code)
File: literature_benchmarks.yaml

Agent Orchestration


UC1: AGENT ORCHESTRATION
STEP 1: PROTOCOL AGENT
Execution: ~2 seconds
• Load protocol_rules.yaml
• Extract submission requirements:
- Primary endpoint: HHS improvement ≥20 points at 2 years
- Sample size: n≥25 evaluable for interim, n=50 for final
- Safety: Complete AE documentation, SAE narratives
- Radiographic: All timepoint imaging reviewed
STEP 2: DATA AGENT
Execution: ~5 seconds
• Query H-34 study database
• Calculate current status:
- Primary endpoint: 5/8 achieved MCID (62%), n=8 evaluable
- Safety: 15 AEs documented, 12 SAEs with narratives
- Radiographic: 3 patients missing 1yr imaging
STEP 3: LITERATURE AGENT
Execution: ~3 seconds
• Load literature_benchmarks.yaml

```
│    │
│   │ • Retrieve comparators:
│    │
│   │   - Meding et al: 72% MCID (our 62% within range)
│    │
│   │   - Revision rate benchmark: 6.2% (our 8.1% at upper boundary)
│    │
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────────┘    │
│
│
│  STEP 4: REGISTRY AGENT
Execution: ~2 seconds              │
│
┌──────────────────────────────────────────────────────────────────────────────
──────────────────────────────┐    │
│   │ • Load registry_norms.yaml
│    │
│   │ • External validation:
│    │
│   │   - AOANJRR 2yr survival: 94% (our ~92% within CI)
│    │
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────────┘    │
│
│
│  STEP 5: COMPLIANCE AGENT
Execution: ~8 seconds              │
│
┌──────────────────────────────────────────────────────────────────────────────
──────────────────────────────┐    │
│   │ • Cross-reference all sources
│    │
│   │ • Generate gap analysis:
│    │
│   │   - Protocol vs Data: Sample size gap, radiographic gaps
│    │
│   │   - Literature comparison: Performance validation
│    │
│   │   - Registry validation: External benchmarking
│    │
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────────┘    │
│
│
│  STEP 6: SYNTHESIS AGENT
Execution: ~10 seconds             │
│
┌──────────────────────────────────────────────────────────────────────────────
──────────────────────────────┐    │
│   │ • Combine all agent outputs
│    │
│   │ • Generate structured report with:
│    │
```



Output Specification

Output Element	Description	Format
Readiness Score	Overall percentage (0-100%)	Progress bar + number
Category Status	Pass/Gap/Watch per requirement	Table with icons
Blockers	Critical items preventing submission	Numbered list
Warnings	Items needing attention	Numbered list
Timeline	Projected path to readiness	Timeline visualization
Actions	One-click action buttons	Button array
Provenance	Source citations for every finding	Footer text

Value Delivered

Metric	Traditional	With Platform
Time to assess	3-5 days	30 seconds

Metric	Traditional	With Platform
Sources consulted	Manual cross-reference	4 sources automated
Gap detection	Often late discovery	Real-time identification
Actionability	Data only	Specific remediation steps

UC2: Safety Signal Detection & Contextualization

Overview

Attribute	Value
UC ID	UC2
Name	Safety Signal Detection & Contextualization
Category	Safety & Vigilance
Trigger	Proactive (data refresh) or user query
Complexity	High (5 agents, 5+ data sources)

Business Problem

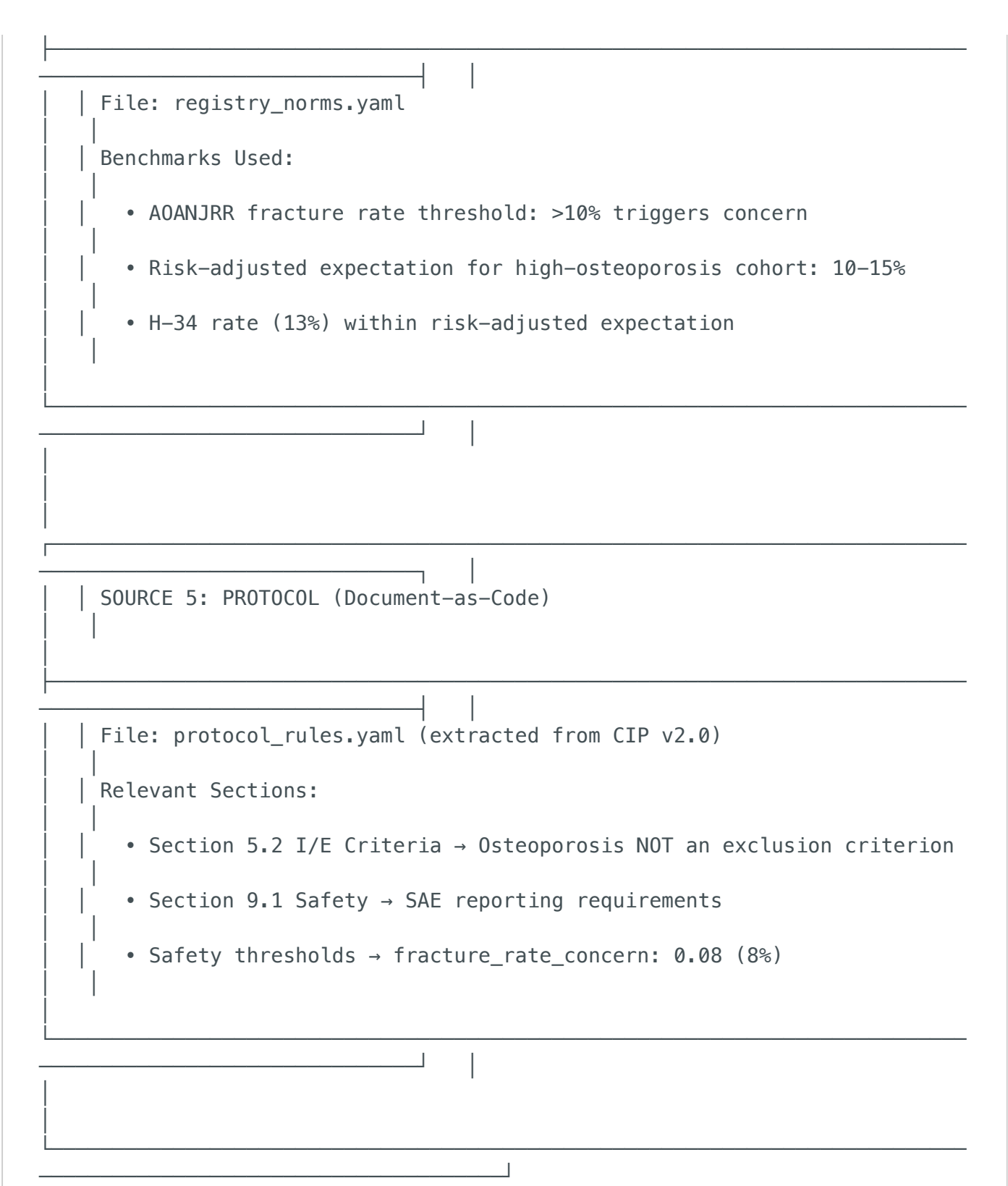
Safety signals in small studies are hard to interpret without external context. A 13% fracture rate looks concerning in isolation, but teams must manually search literature and registries to determine if it's actually elevated or expected for the patient population.

User Query Examples

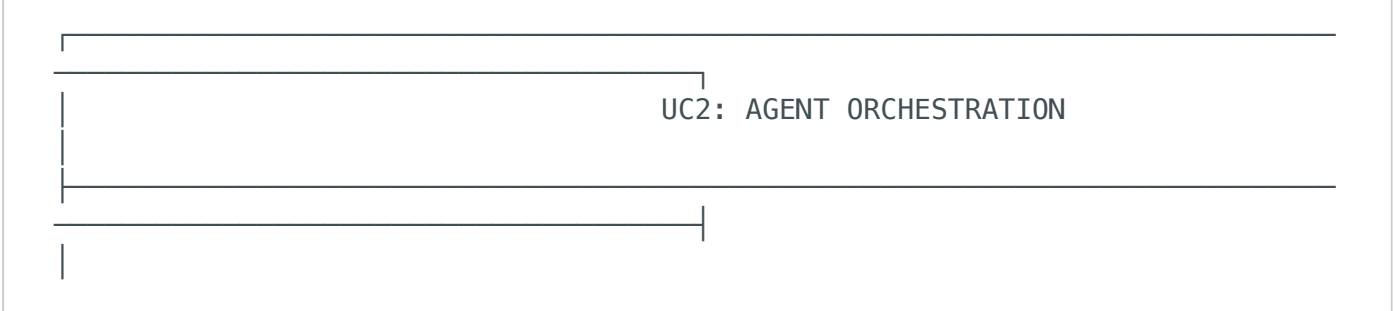
- "Are there any safety concerns I should know about?"
- "Analyze our AE rates compared to published data"
- "Is our fracture rate concerning?"
- **PROACTIVE:** System alerts without user query

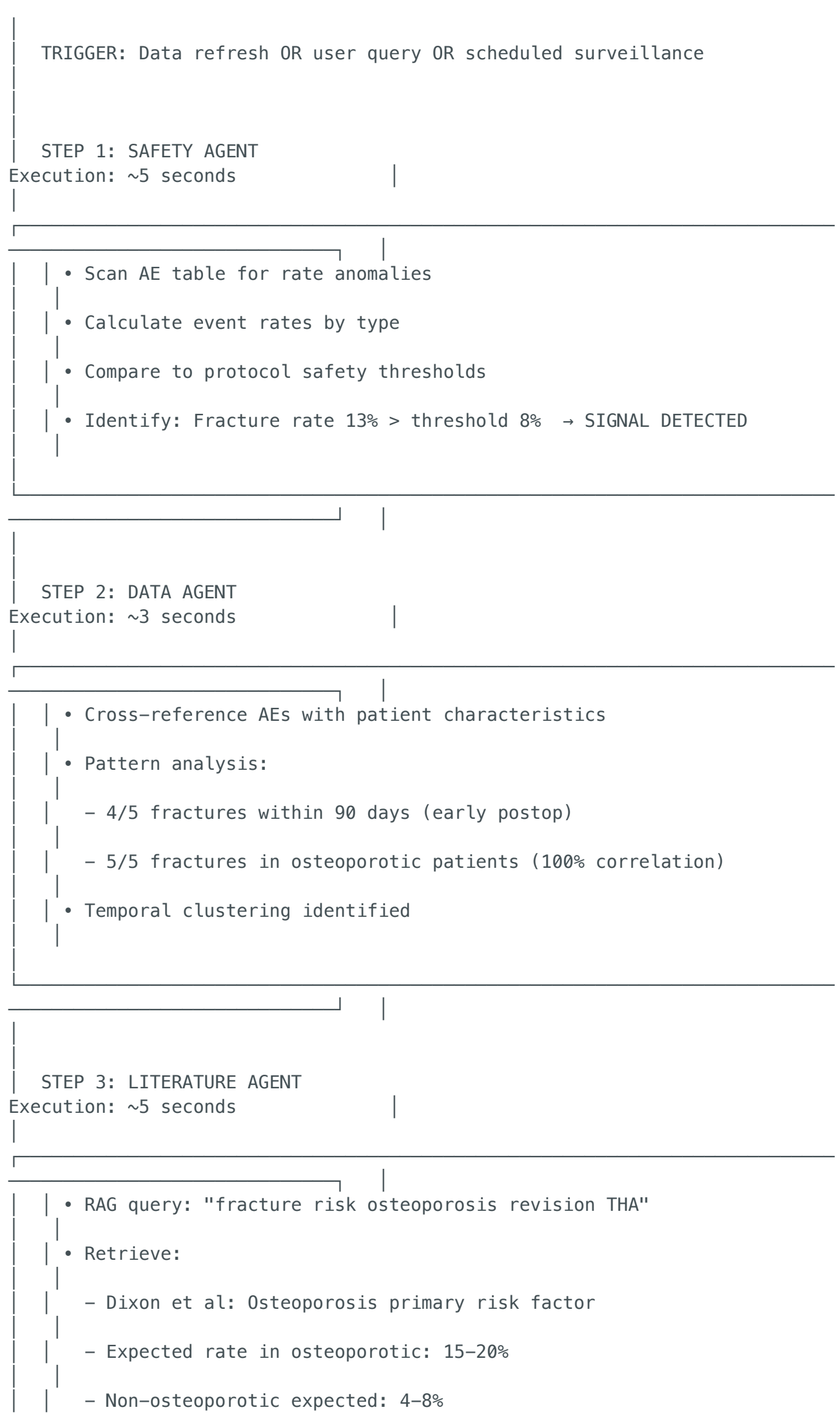
Input Data Sources

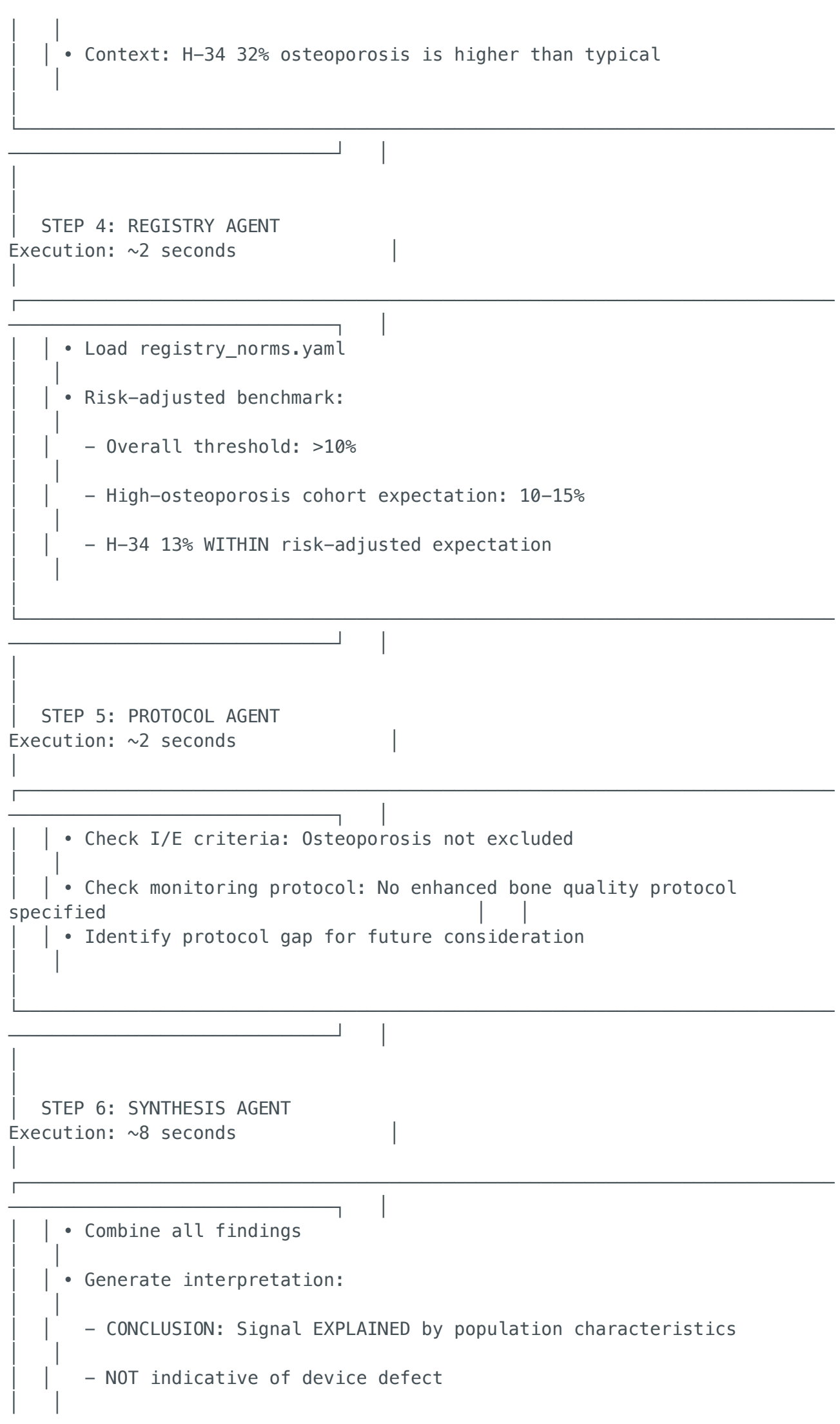
```
──────────────────────────────────┤   │
│   │ File: H-34DELTARevisionstudy_export_20250912.xlsx → Sheet 1 (Patients),
Sheet 2 (Preoperatives)          │   │
│   │ Fields Used:
│   │
│   │   • Age, Gender, BMI → Risk factor analysis
│   │
│   │   • Primary Diagnosis → Underlying condition
│   │
│   │   • Comorbidities → Osteoporosis, diabetes, etc.
│   │
│   │ Key Findings:
│   │
│   │   • Osteoporosis prevalence: 12/37 (32%)
│   │
│   │   • Fractures in osteoporotic patients: 5/5 (100%)
│   │
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────────────┘   │
│
│
│
┌──────────────────────────────────────────────────────────────────────────────
──────────────────────────────────┐   │
│   │ SOURCE 3: LITERATURE (RAG + Document-as-Code)
│   │
│
├──────────────────────────────────────────────────────────────────────────────
──────────────────────────────────┤   │
│   │ Files: 15 indexed PDFs + literature_benchmarks.yaml
│   │
│   │ Key Publications:
│   │
│   │   • Dixon et al 2025 → Osteoporosis as primary fracture risk factor,
expected rate 15-20% in osteoporotic│   │
│   │   • Harris et al 2025 → AE rate benchmarks 28-40%
│   │
│   │   • Meding et al 2025 → Overall fracture rate in non-osteoporotic: 4-8%
│   │
│   │ Risk Factor Extraction:
│   │
│   │   • Osteoporosis HR for fracture: 2.4 (Dixon)
│   │
│   │   • Expected fracture rate with 32% osteoporosis prevalence: 10-15%
│   │
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────────────┘   │
│
│
│
┌──────────────────────────────────────────────────────────────────────────────
──────────────────────────────────┐   │
│   │ SOURCE 4: REGISTRY NORMS (Document-as-Code)
│   │
│
```



Agent Orchestration




TRIGGER: Data refresh OR user query OR scheduled surveillance
STEP 1: SAFETY AGENT
Execution: ~5 seconds
• Scan AE table for rate anomalies
• Calculate event rates by type
• Compare to protocol safety thresholds
• Identify: Fracture rate 13% > threshold 8% → SIGNAL DETECTED
STEP 2: DATA AGENT
Execution: ~3 seconds
• Cross-reference AEs with patient characteristics
• Pattern analysis:
- 4/5 fractures within 90 days (early postop)
- 5/5 fractures in osteoporotic patients (100% correlation)
• Temporal clustering identified
STEP 3: LITERATURE AGENT
Execution: ~5 seconds
• RAG query: "fracture risk osteoporosis revision THA"
• Retrieve:
- Dixon et al: Osteoporosis primary risk factor
- Expected rate in osteoporotic: 15–20%
- Non-osteoporotic expected: 4–8%


• Context: H-34 32% osteoporosis is higher than typical
STEP 4: REGISTRY AGENT
Execution: ~2 seconds
• Load registry_norms.yaml
• Risk-adjusted benchmark:
- Overall threshold: >10%
- High-osteoporosis cohort expectation: 10-15%
- H-34 13% WITHIN risk-adjusted expectation
STEP 5: PROTOCOL AGENT
Execution: ~2 seconds
• Check I/E criteria: Osteoporosis not excluded
• Check monitoring protocol: No enhanced bone quality protocol specified
• Identify protocol gap for future consideration
STEP 6: SYNTHESIS AGENT
Execution: ~8 seconds
• Combine all findings
• Generate interpretation:
- CONCLUSION: Signal EXPLAINED by population characteristics
- NOT indicative of device defect

```
│  │   - Rate within literature-predicted range for risk profile
│   │
│  │ • Generate actionable recommendations
│   │
│  │ • Complete provenance trail
│   │
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────┘   │
│
│
│  TOTAL EXECUTION TIME: <25 seconds
│
│
│
└──────────────────────────────────────────────────────────────────────────────
──────────────────────────────────────┘
```

Output Specification

Output Element	Description	Format
Signal Identification	Rate comparison table	Table with status icons
Cross-Source Context	Evidence from each source	Bulleted sections
Interpretation	High-confidence conclusion	Boxed summary
Regulatory Implication	Documentation requirements	Text paragraph
Recommended Actions	Specific next steps with buttons	Action button array
Provenance	All sources cited	Footer citations

Value Delivered

Metric	Traditional	With Platform
Signal detection	Manual monitoring	Automated on data refresh
Context gathering	Weeks of research	25 seconds
Interpretation	Subjective clinical judgment	Evidence-based, multi-source
Recommendations	Generic	Specific, actionable

UC3: Automated Protocol Deviation Detection & Classification

Overview

Attribute	Value
UC ID	UC3
Name	Automated Protocol Deviation Detection & Classification
Category	Compliance & Quality
Trigger	Automatic on data refresh
Complexity	Medium (3 agents, 2+ data sources)

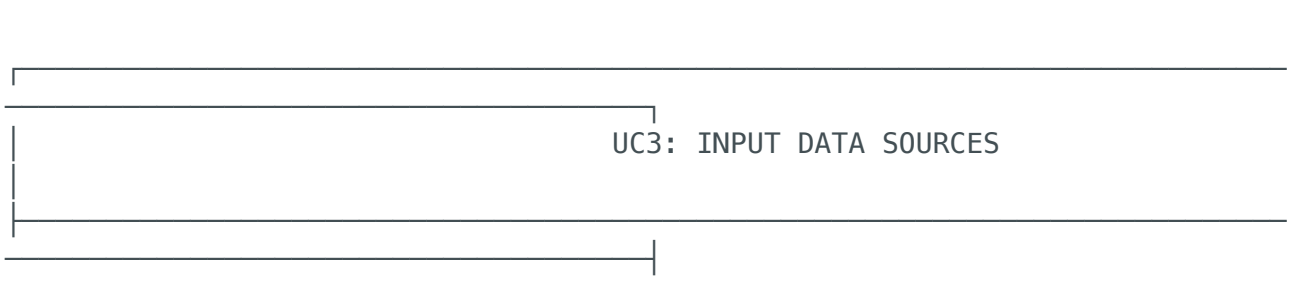
Business Problem

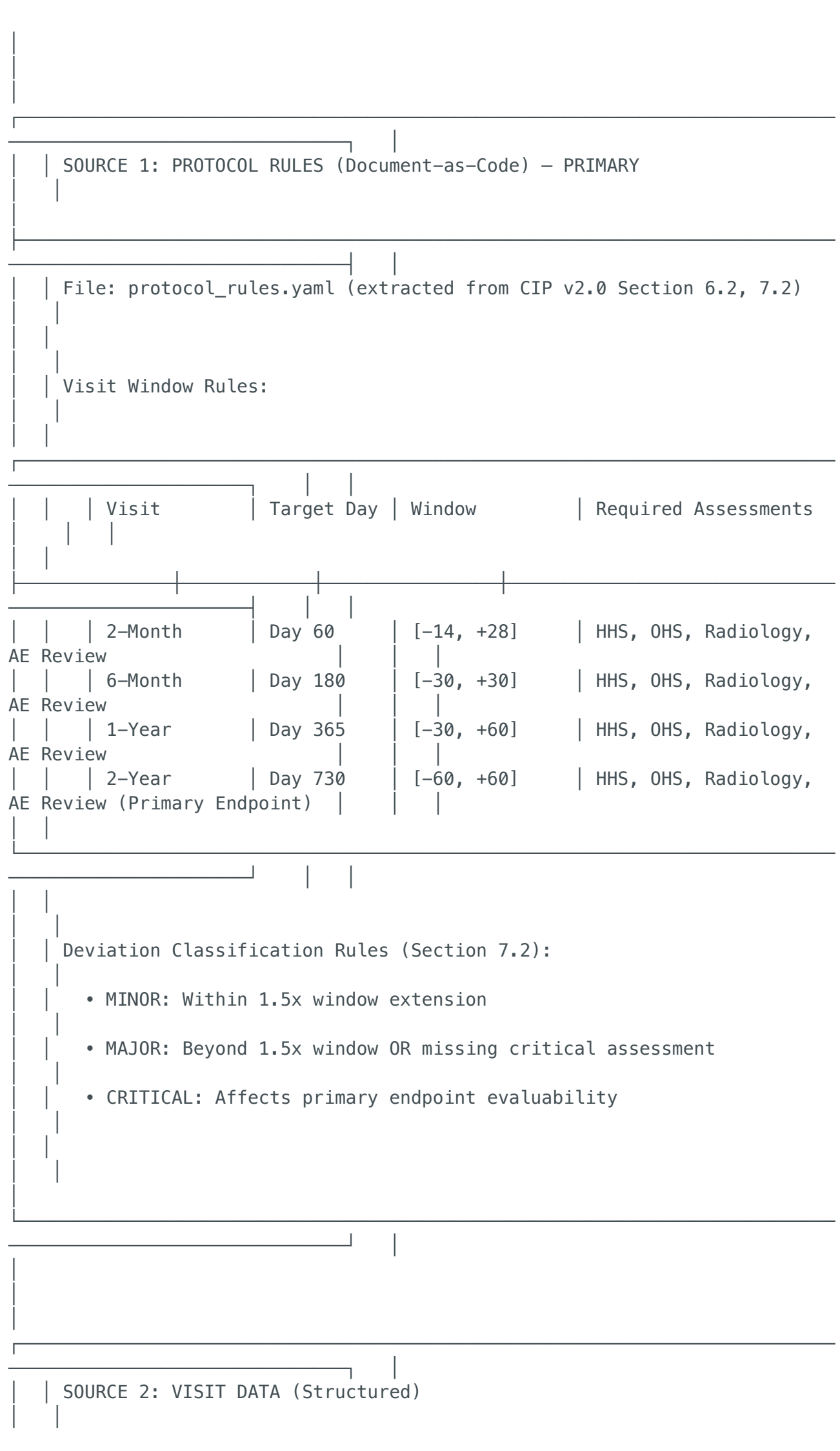
Protocol deviations are identified manually by comparing visit dates to protocol windows—a tedious, error-prone process often discovered late during monitoring visits. This delays corrective action and increases regulatory risk.

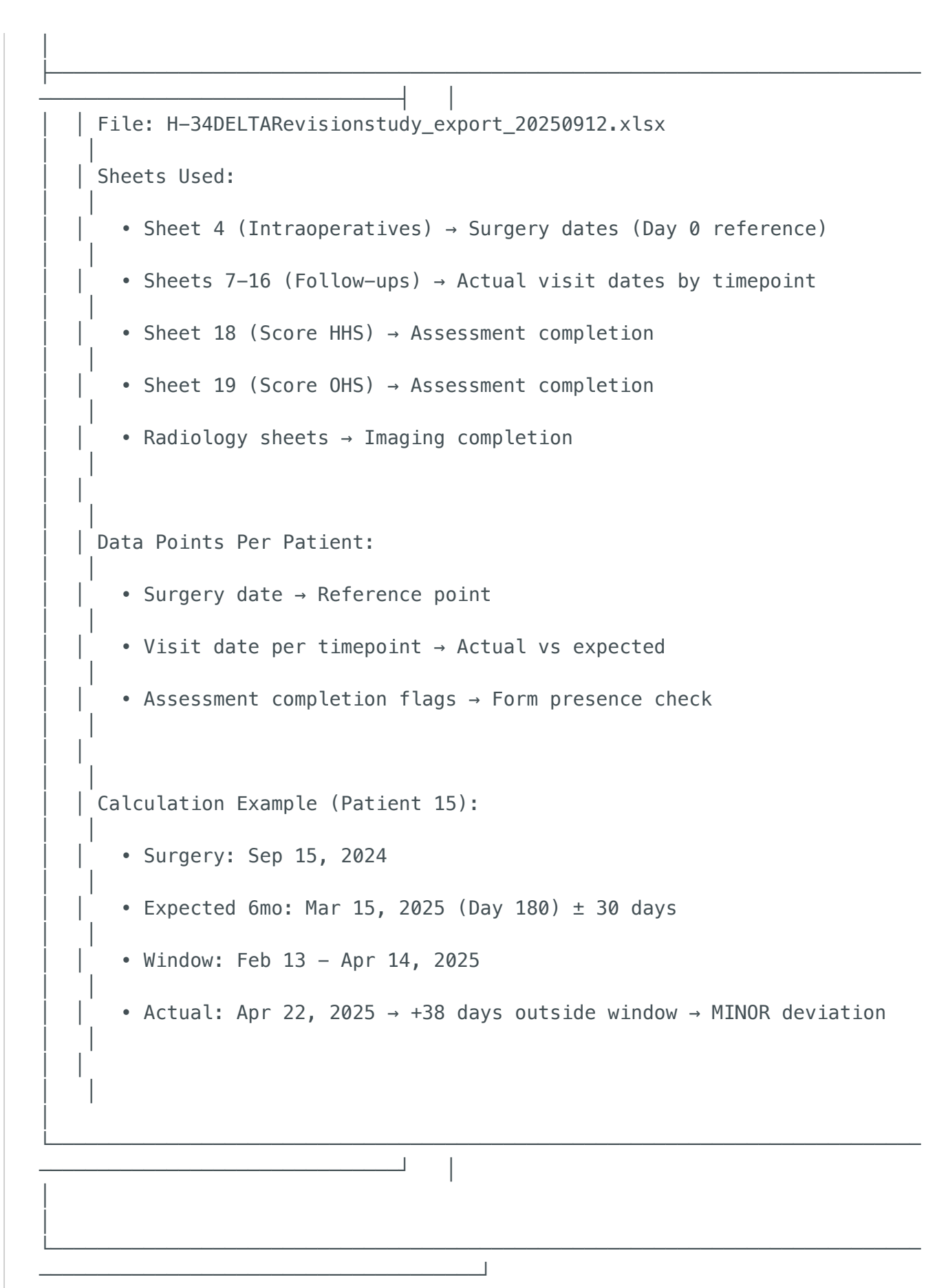
User Query Examples

- "What protocol deviations exist in our data?"
- "Show me patients outside their visit windows"
- "Generate protocol deviation report"
- **AUTOMATIC:** Runs on every data refresh

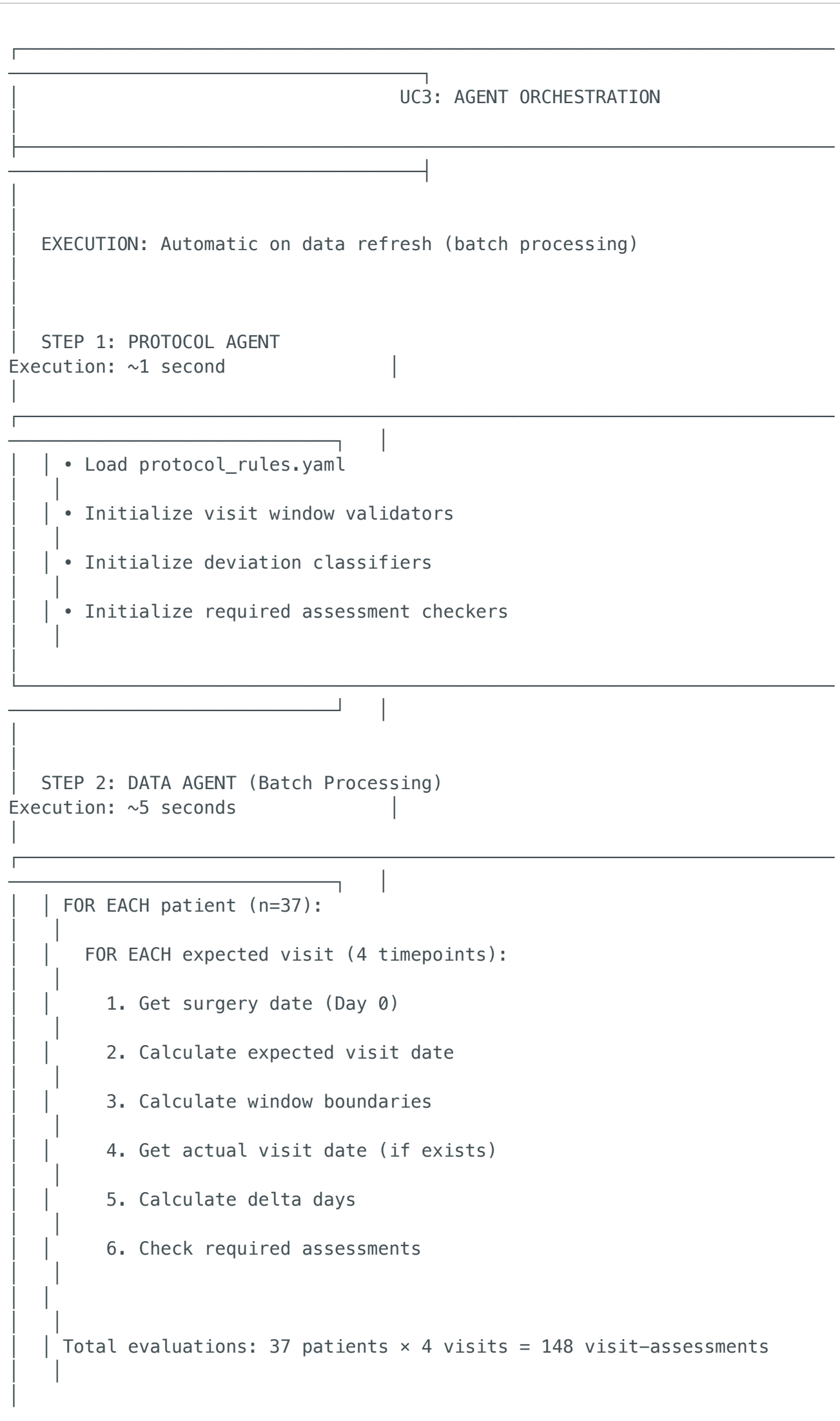
Input Data Sources




SOURCE 1: PROTOCOL RULES (Document-as-Code) — PRIMARY
File: protocol_rules.yaml (extracted from CIP v2.0 Section 6.2, 7.2)
Visit Window Rules:
Visit | Target Day | Window | Required Assessments
2-Month | Day 60 | [-14, +28] | HHS, OHS, Radiology, AE Review
6-Month | Day 180 | [-30, +30] | HHS, OHS, Radiology, AE Review
1-Year | Day 365 | [-30, +60] | HHS, OHS, Radiology, AE Review
2-Year | Day 730 | [-60, +60] | HHS, OHS, Radiology, AE Review (Primary Endpoint)
Deviation Classification Rules (Section 7.2):
• MINOR: Within 1.5x window extension
• MAJOR: Beyond 1.5x window OR missing critical assessment
• CRITICAL: Affects primary endpoint evaluability
SOURCE 2: VISIT DATA (Structured)



Agent Orchestration


UC3: AGENT ORCHESTRATION
EXECUTION: Automatic on data refresh (batch processing)
STEP 1: PROTOCOL AGENT
Execution: ~1 second
• Load protocol_rules.yaml
• Initialize visit window validators
• Initialize deviation classifiers
• Initialize required assessment checkers
STEP 2: DATA AGENT (Batch Processing)
Execution: ~5 seconds
FOR EACH patient (n=37):
FOR EACH expected visit (4 timepoints):
1. Get surgery date (Day 0)
2. Calculate expected visit date
3. Calculate window boundaries
4. Get actual visit date (if exists)
5. Calculate delta days
6. Check required assessments
Total evaluations: 37 patients × 4 visits = 148 visit-assessments


STEP 3: COMPLIANCE AGENT
Execution: ~3 seconds
FOR EACH visit-assessment:
1. Apply deviation classification rules
2. Determine severity: MINOR / MAJOR / CRITICAL
3. Assess impact on endpoint evaluability
4. Generate PD log entry (pre-populated)
Results:
• 142 compliant visit-assessments
• 6 deviations detected (4.1% rate)
- 3 MINOR (timing within extended window)
- 2 MAJOR (outside window or missing visit)
- 1 CRITICAL (affects primary endpoint)
STEP 4: OUTPUT GENERATION
Execution: ~2 seconds
Generate automated outputs:
✅ PD Log entries pre-populated (requires PI signature)
✅ Site query forms generated for MAJOR/CRITICAL
✅ CSR deviation table updated
✅ Monitoring visit agenda updated

```
│
│  TOTAL EXECUTION TIME: ~11 seconds (batch for all 37 patients)
│
│
│
└──────────────────────────────────────────────────────────────────────────────
```

Output Specification

Output Element	Description	Format
Summary Statistics	Total evaluations, deviation count, rate	Header text
Deviation Detail Table	Patient, visit, expected, actual, delta, class, impact	Sortable table
Deviation Breakdown	Count by severity category	Summary list
Auto-Generated Outputs	PD log, queries, CSR table	Status checklist
Action Buttons	Download, send queries, update CSR, trends	Button array
Provenance	Protocol sections, data sheets	Footer citations

Value Delivered

Metric	Traditional	With Platform
Detection timing	Monitoring visits (months)	Real-time (seconds)
Time per patient	15-30 minutes	<1 second
Classification accuracy	Human interpretation	Protocol-defined rules
Documentation	Manual transcription	Auto-generated

UC4: Patient Risk Stratification with Actionable Monitoring Lists

Overview

Attribute	Value
UC ID	UC4
Name	Patient Risk Stratification with Actionable Monitoring Lists
Category	Clinical Decision Support
Trigger	User query or scheduled refresh
Complexity	High (4 models, 4+ data sources)

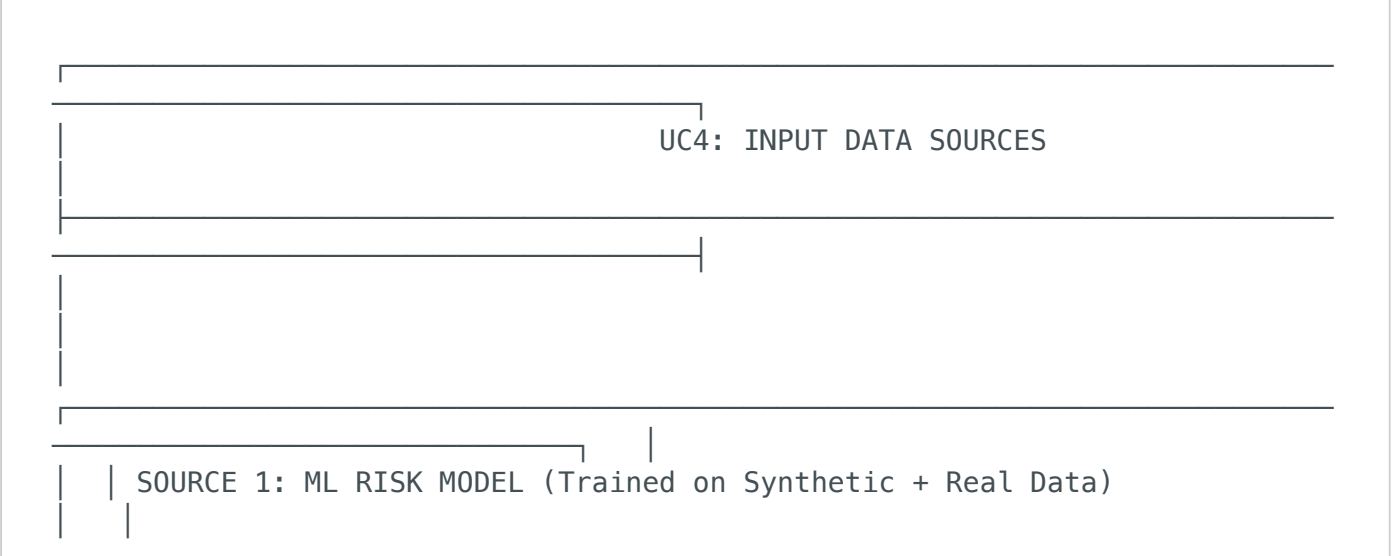
Business Problem

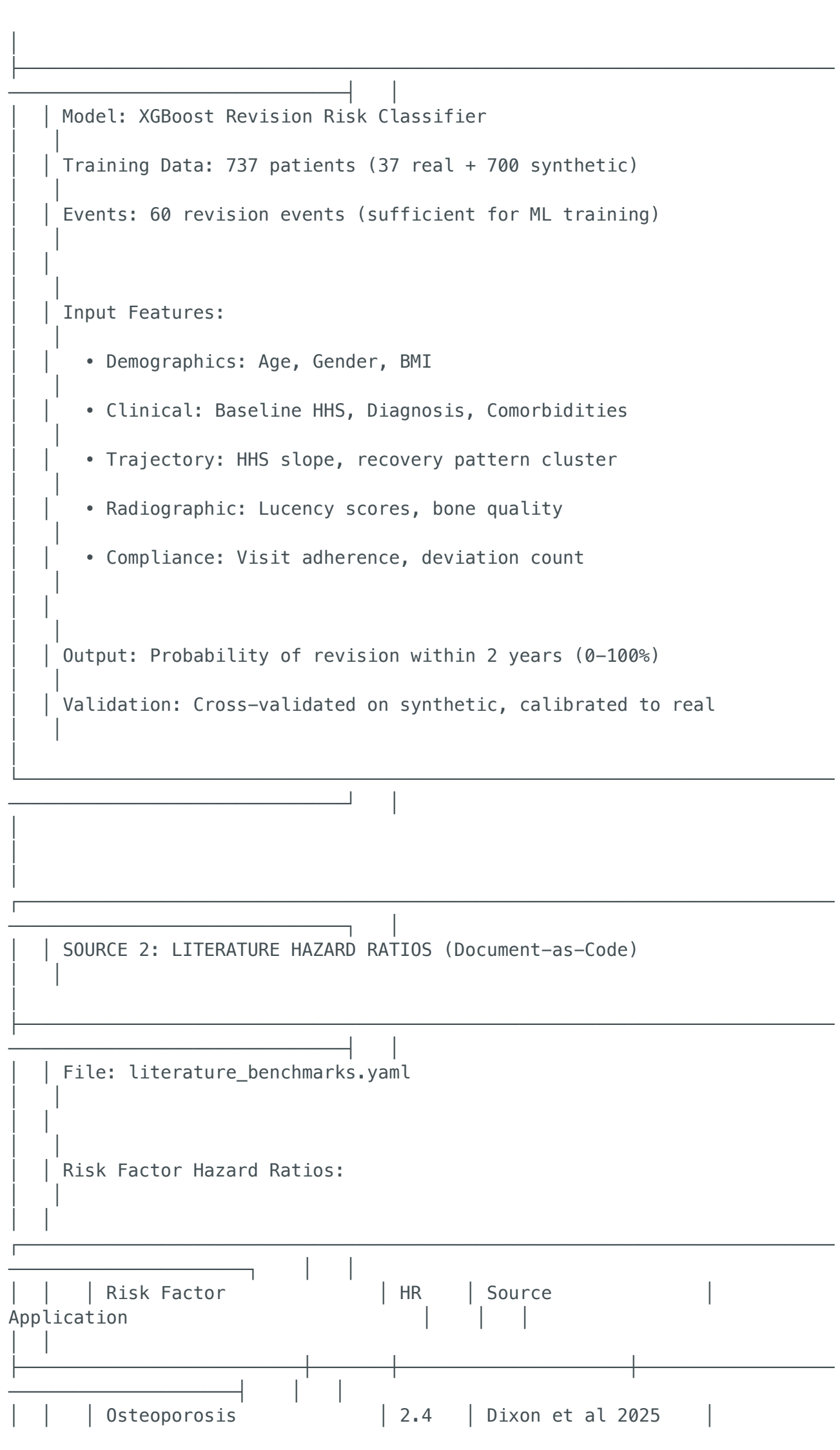
Without predictive tools, all patients receive the same monitoring attention. This wastes resources on low-risk patients while potentially missing early warning signs in high-risk patients who need enhanced surveillance.

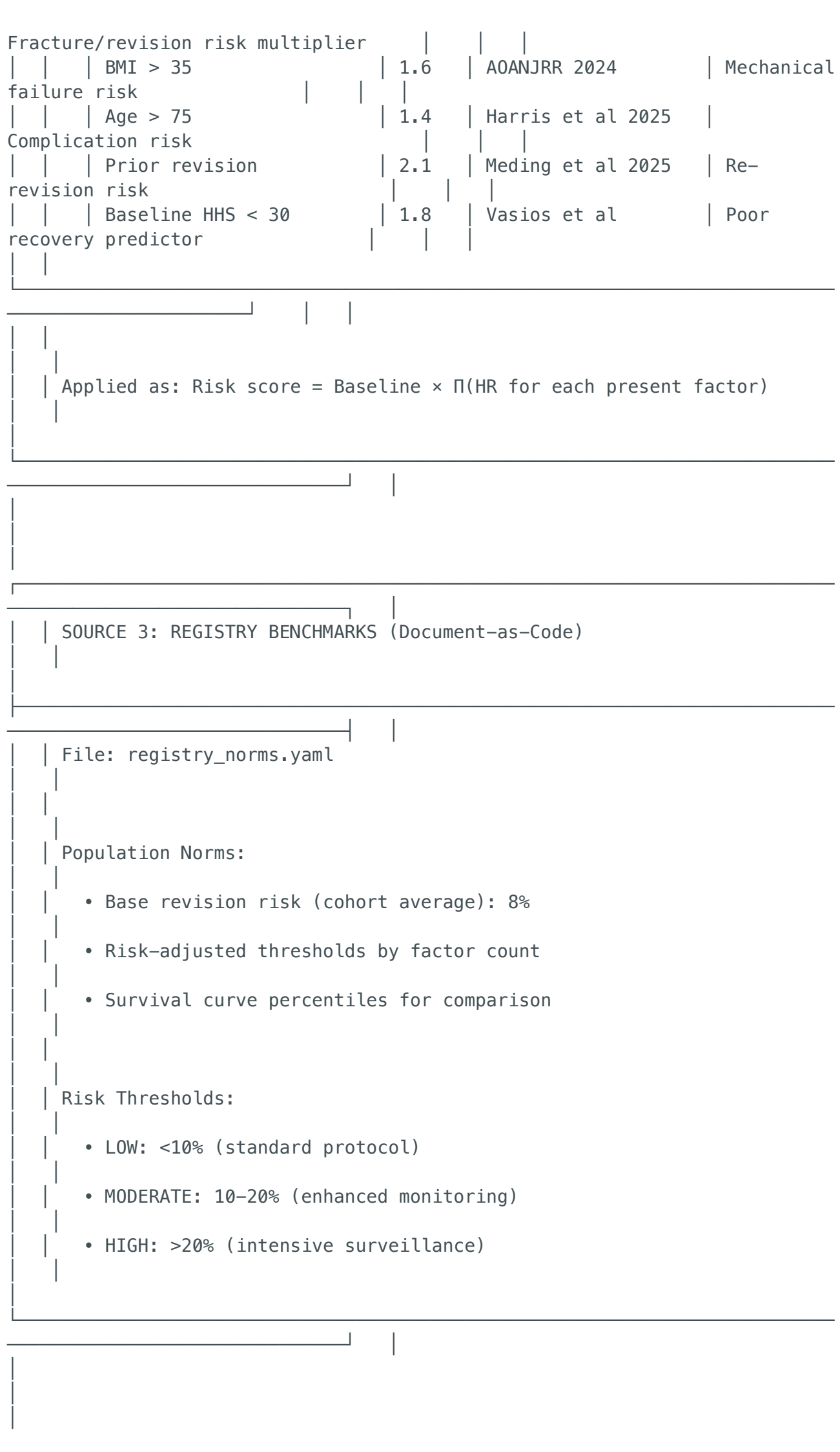
User Query Examples

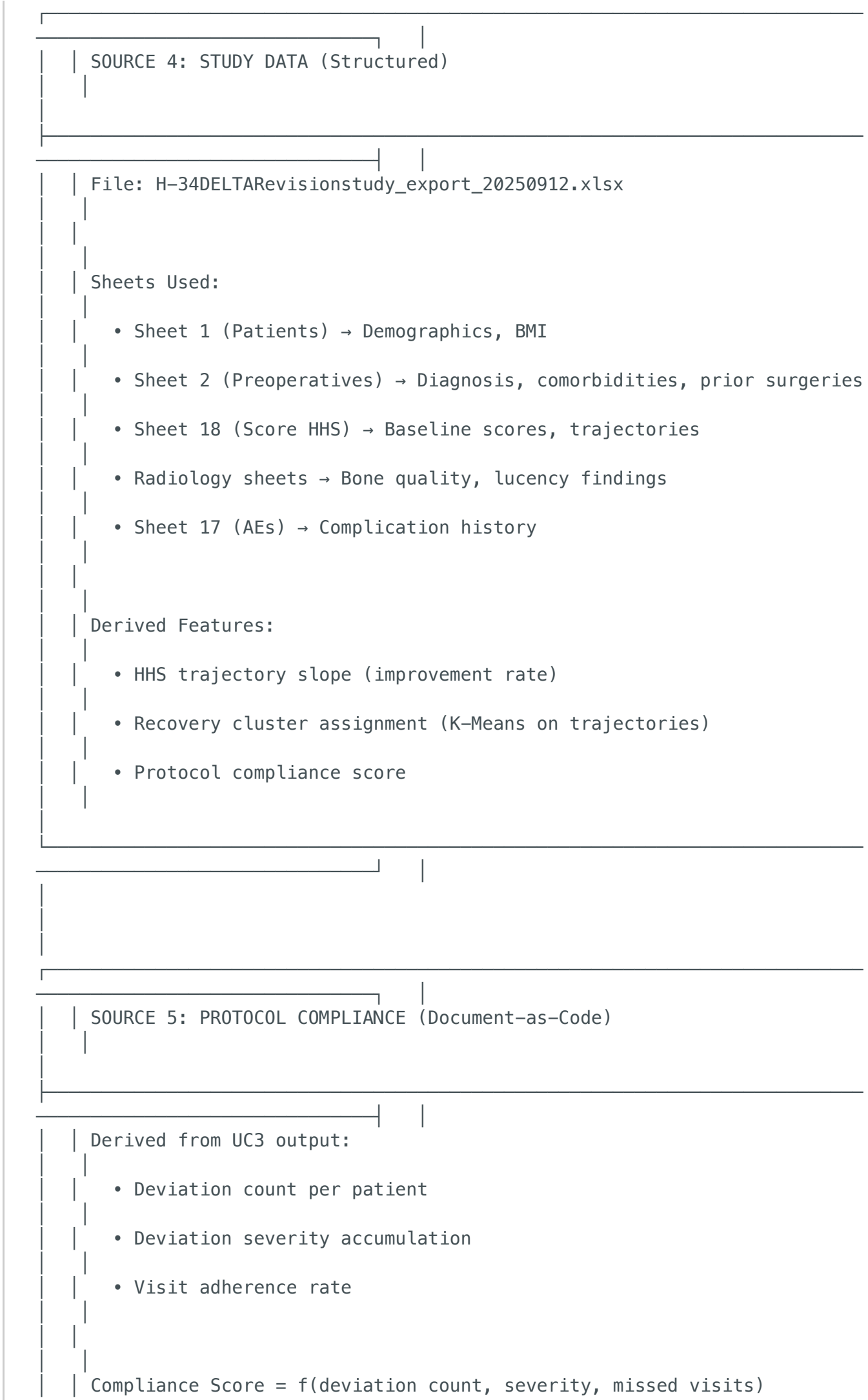
- "Which patients should I be most concerned about?"
- "Who needs enhanced monitoring?"
- "Generate prioritized patient list"
- "What are the highest risk patients?"

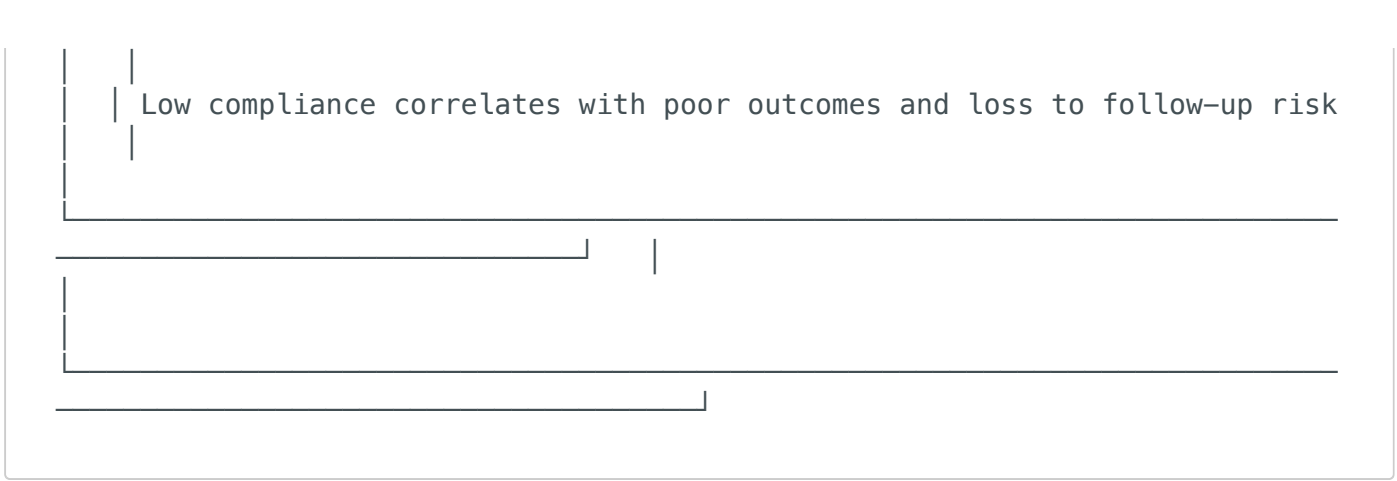
Input Data Sources



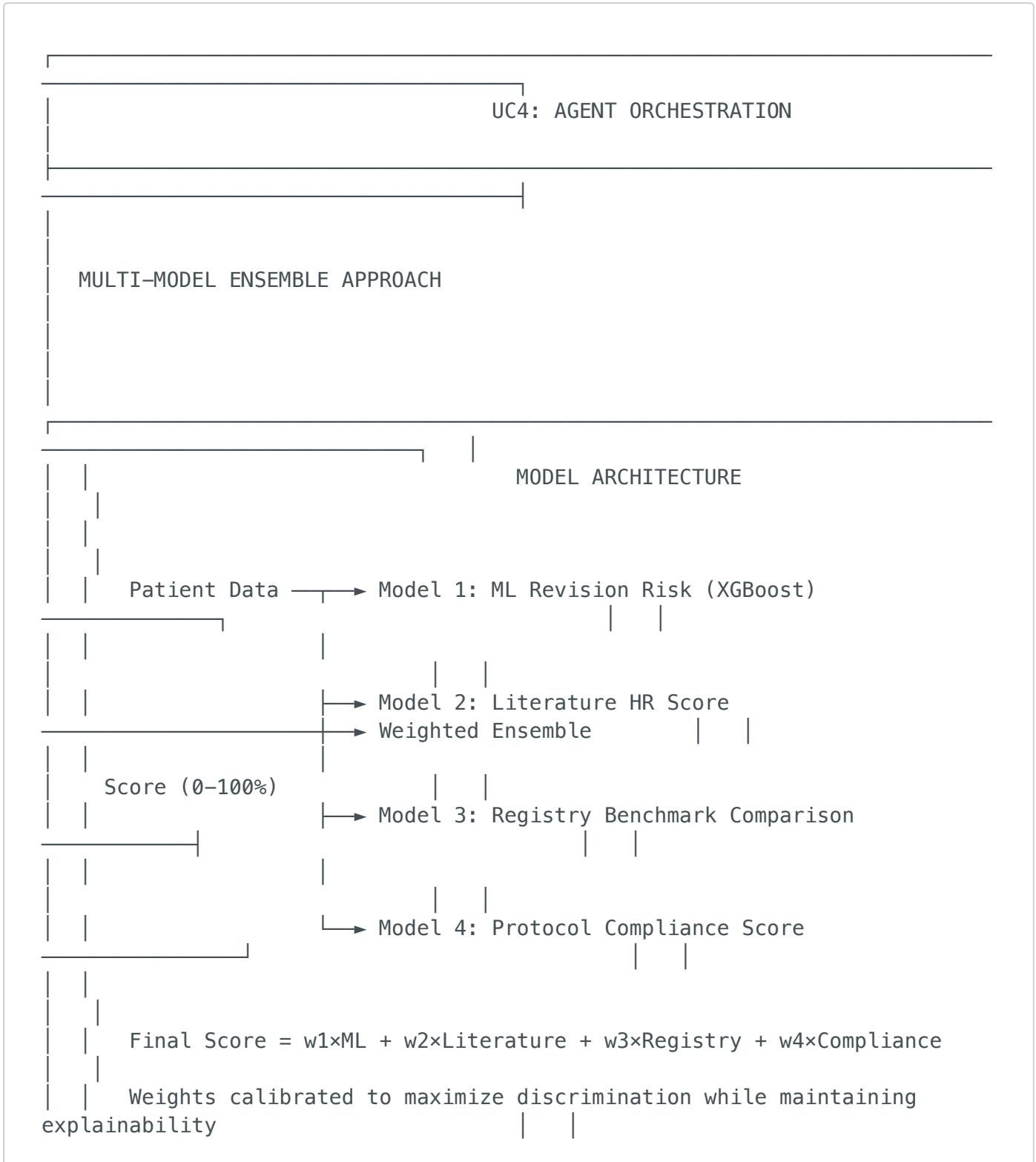

Model: XGBoost Revision Risk Classifier
Training Data: 737 patients (37 real + 700 synthetic)
Events: 60 revision events (sufficient for ML training)
Input Features:
• Demographics: Age, Gender, BMI
• Clinical: Baseline HHS, Diagnosis, Comorbidities
• Trajectory: HHS slope, recovery pattern cluster
• Radiographic: Lucency scores, bone quality
• Compliance: Visit adherence, deviation count
Output: Probability of revision within 2 years (0–100%)
Validation: Cross-validated on synthetic, calibrated to real
SOURCE 2: LITERATURE HAZARD RATIOS (Document-as-Code)
File: literature_benchmarks.yaml
Risk Factor Hazard Ratios:
Risk Factor
HR
Source
Application
Osteoporosis
2.4
Dixon et al 2025

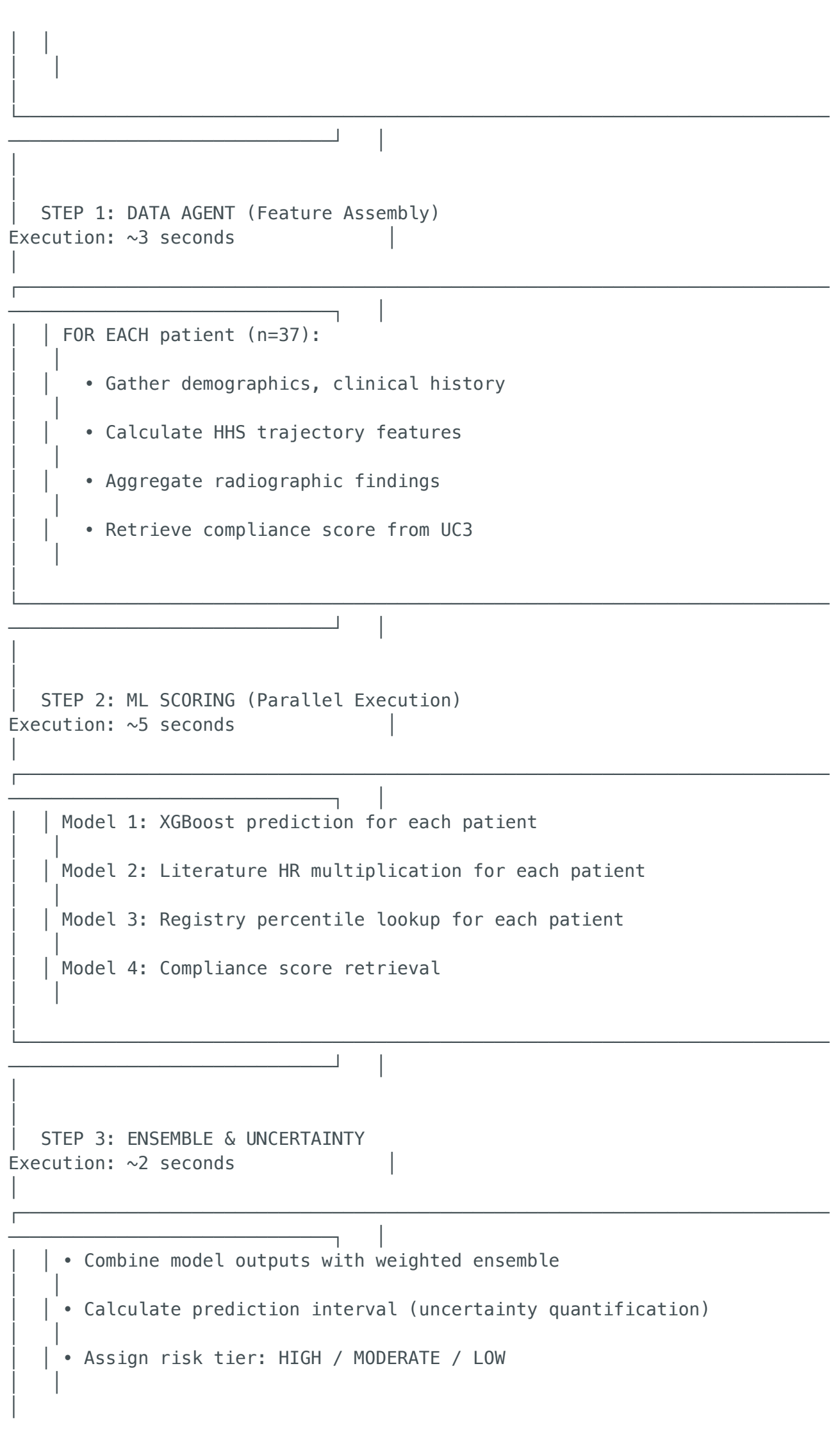

Fracture/revision risk multiplier
| | | BMI > 35 | 1.6 | AOANJRR 2024 | Mechanical failure risk
| | | Age > 75 | 1.4 | Harris et al 2025 | Complication risk
| | | Prior revision | 2.1 | Meding et al 2025 | Re-revision risk
| | | Baseline HHS < 30 | 1.8 | Vasios et al | Poor recovery predictor
Applied as: Risk score = Baseline × Π(HR for each present factor)
SOURCE 3: REGISTRY BENCHMARKS (Document-as-Code)
File: registry_norms.yaml
Population Norms:
• Base revision risk (cohort average): 8%
• Risk-adjusted thresholds by factor count
• Survival curve percentiles for comparison
Risk Thresholds:
• LOW: <10% (standard protocol)
• MODERATE: 10–20% (enhanced monitoring)
• HIGH: >20% (intensive surveillance)

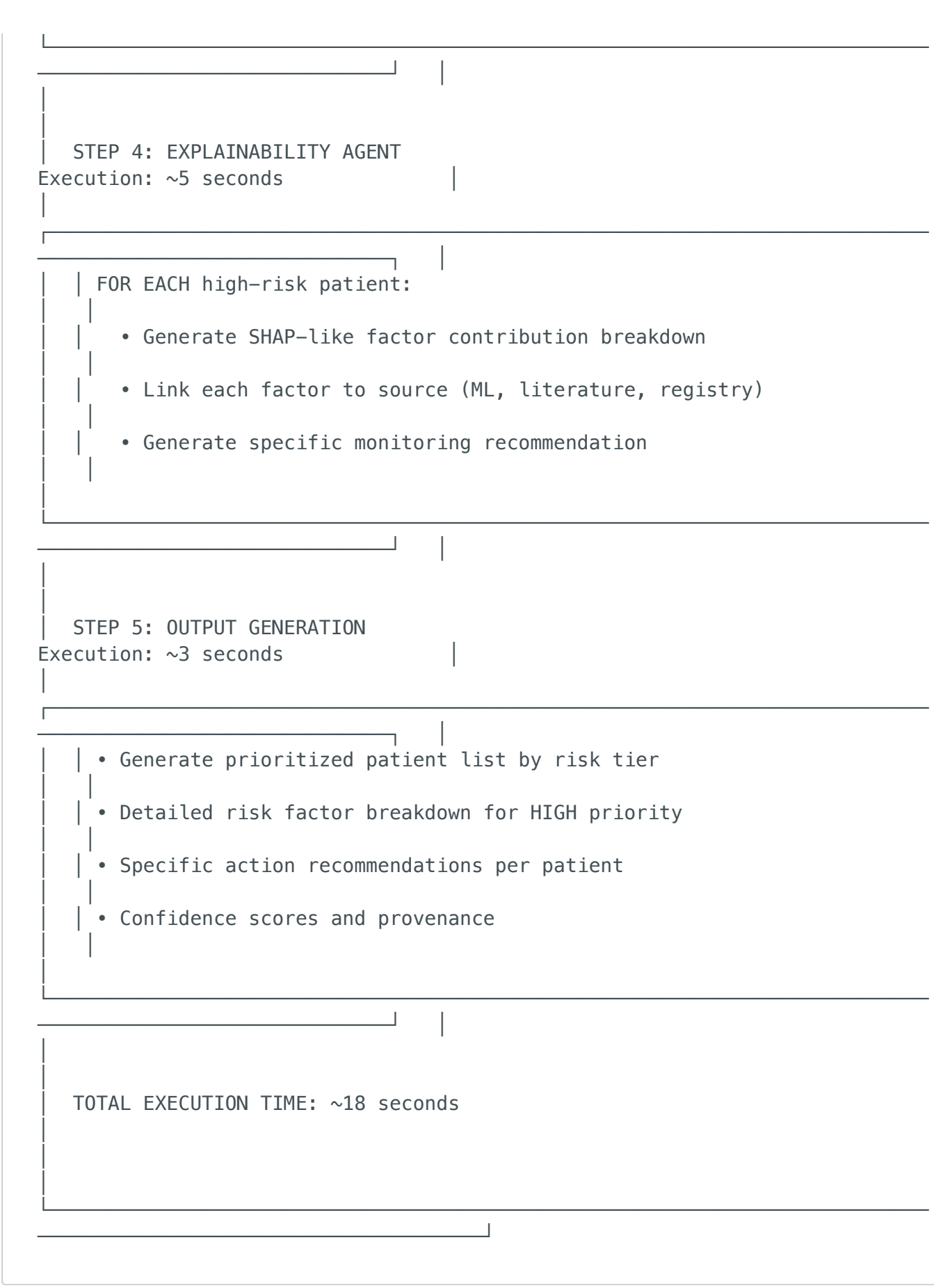

SOURCE 4: STUDY DATA (Structured)
File: H-34DELTARevisionstudy_export_20250912.xlsx
Sheets Used:
• Sheet 1 (Patients) → Demographics, BMI
• Sheet 2 (Preoperatives) → Diagnosis, comorbidities, prior surgeries
• Sheet 18 (Score HHS) → Baseline scores, trajectories
• Radiology sheets → Bone quality, lucency findings
• Sheet 17 (AEs) → Complication history
Derived Features:
• HHS trajectory slope (improvement rate)
• Recovery cluster assignment (K-Means on trajectories)
• Protocol compliance score
SOURCE 5: PROTOCOL COMPLIANCE (Document-as-Code)
Derived from UC3 output:
• Deviation count per patient
• Deviation severity accumulation
• Visit adherence rate
Compliance Score = f(deviation count, severity, missed visits)



Agent Orchestration




STEP 1: DATA AGENT (Feature Assembly)
Execution: ~3 seconds
FOR EACH patient (n=37):
• Gather demographics, clinical history
• Calculate HHS trajectory features
• Aggregate radiographic findings
• Retrieve compliance score from UC3
STEP 2: ML SCORING (Parallel Execution)
Execution: ~5 seconds
Model 1: XGBoost prediction for each patient
Model 2: Literature HR multiplication for each patient
Model 3: Registry percentile lookup for each patient
Model 4: Compliance score retrieval
STEP 3: ENSEMBLE & UNCERTAINTY
Execution: ~2 seconds
• Combine model outputs with weighted ensemble
• Calculate prediction interval (uncertainty quantification)
• Assign risk tier: HIGH / MODERATE / LOW



Output Specification

Output Element	Description	Format
High Priority List	Patients >20% risk with details	Detailed table

Output Element	Description	Format
Moderate Priority List	Patients 10-20% risk	Collapsible list
Low Priority List	Patients <10% risk	Summary count
Factor Contribution	Visual breakdown per patient	Waterfall chart
Confidence Score	Model reliability indicator	Percentage
Recommendations	Specific actions per patient	Action text
Action Buttons	Generate protocol, email site, schedule	Button array

Value Delivered

Metric	Traditional	With Platform
Prioritization method	Subjective judgment	Multi-model ensemble
Explainability	"Clinical intuition"	Factor-by-factor breakdown
Resource allocation	Uniform attention	Risk-stratified focus
Early intervention	Often too late	Proactive identification

UC5: Intelligent Study Health Executive Dashboard

Overview

Attribute	Value
UC ID	UC5
Name	Intelligent Study Health Executive Dashboard
Category	Executive Decision Support
Trigger	Real-time (auto-refresh) or on-demand
Complexity	High (aggregates all agents, 6+ data sources)

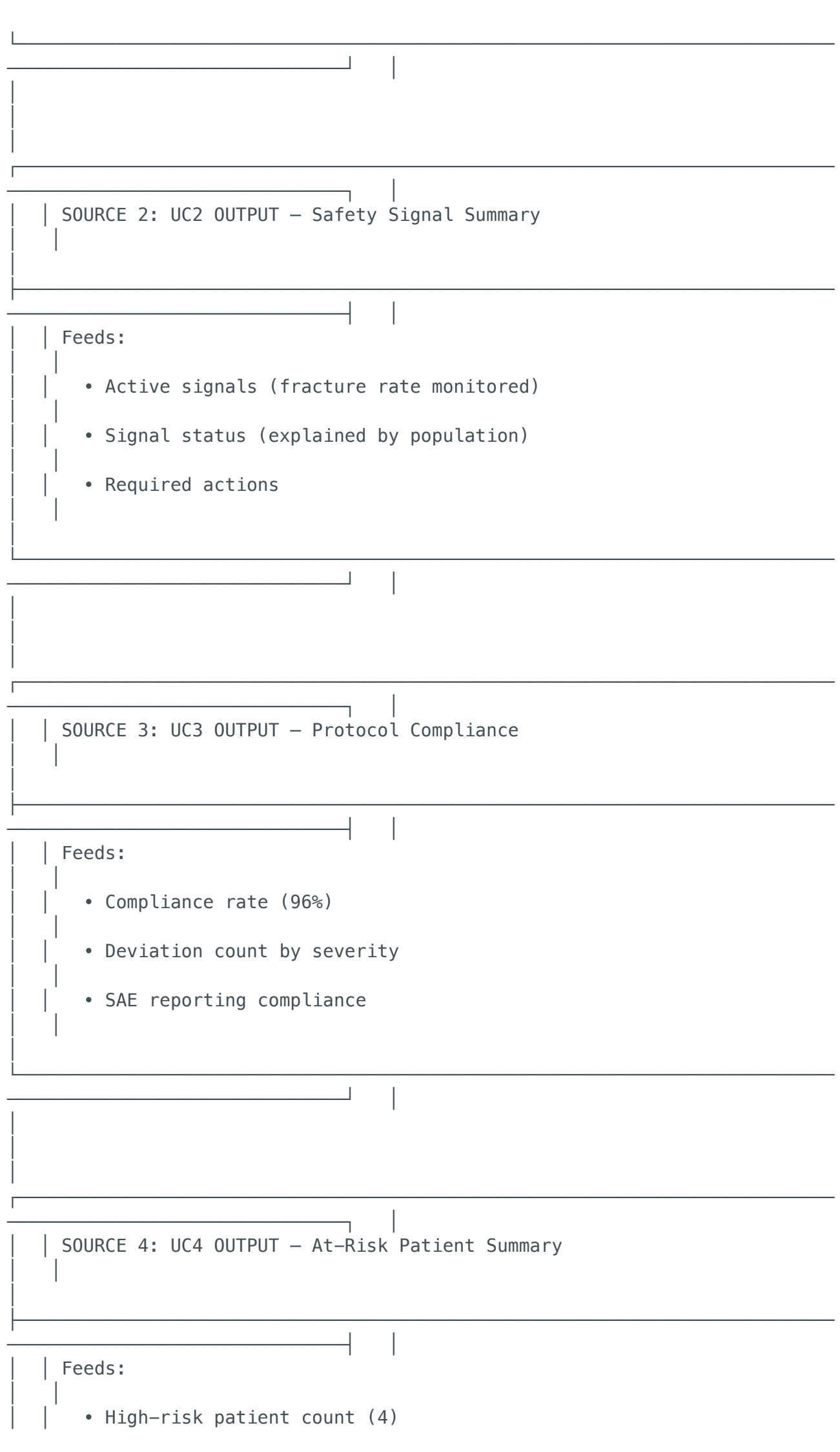
Business Problem

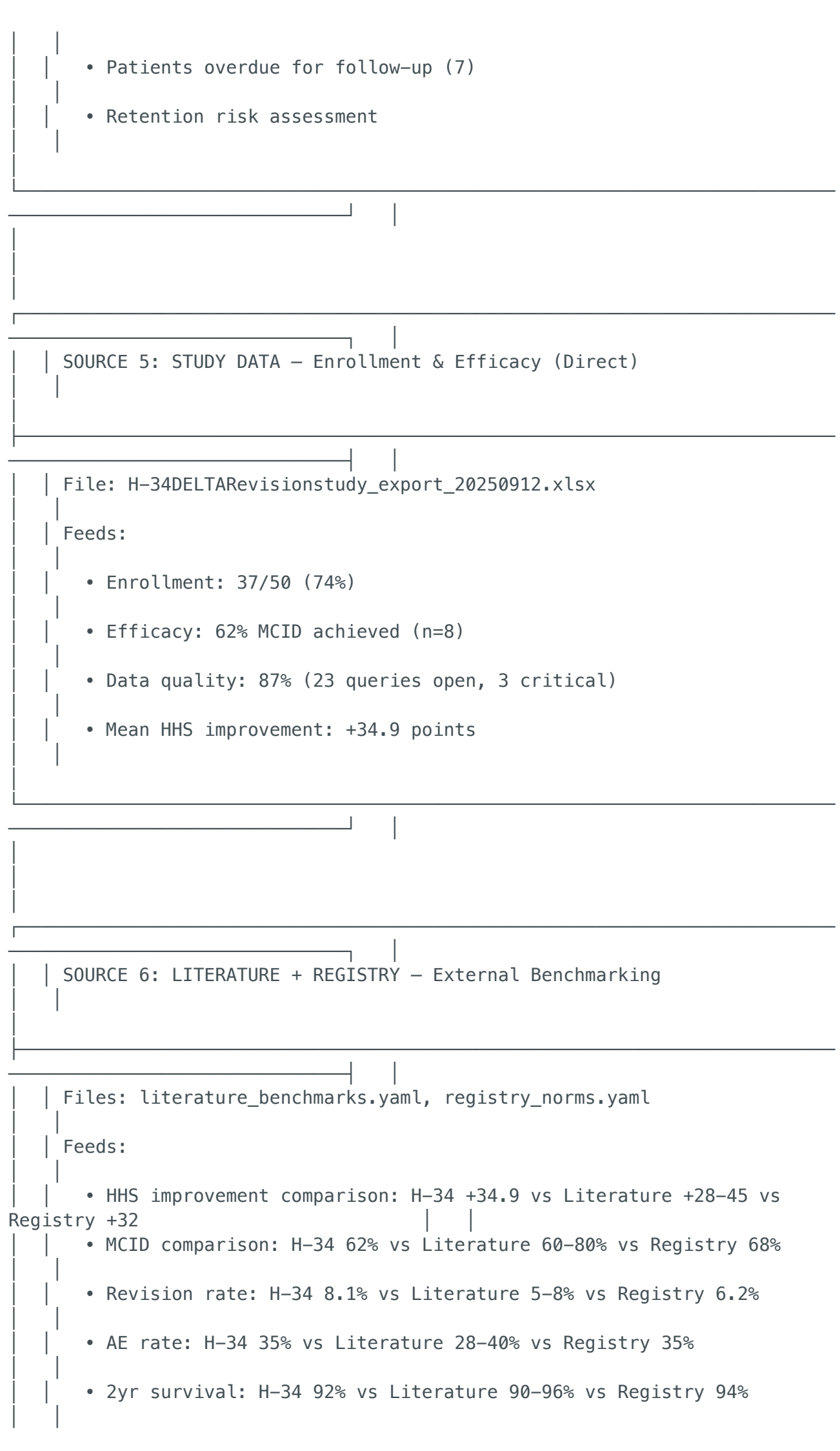
Executives need a single view of study status, but information is scattered across data exports, protocol documents, safety databases, and regulatory trackers. Preparing a status update takes days of manual synthesis.

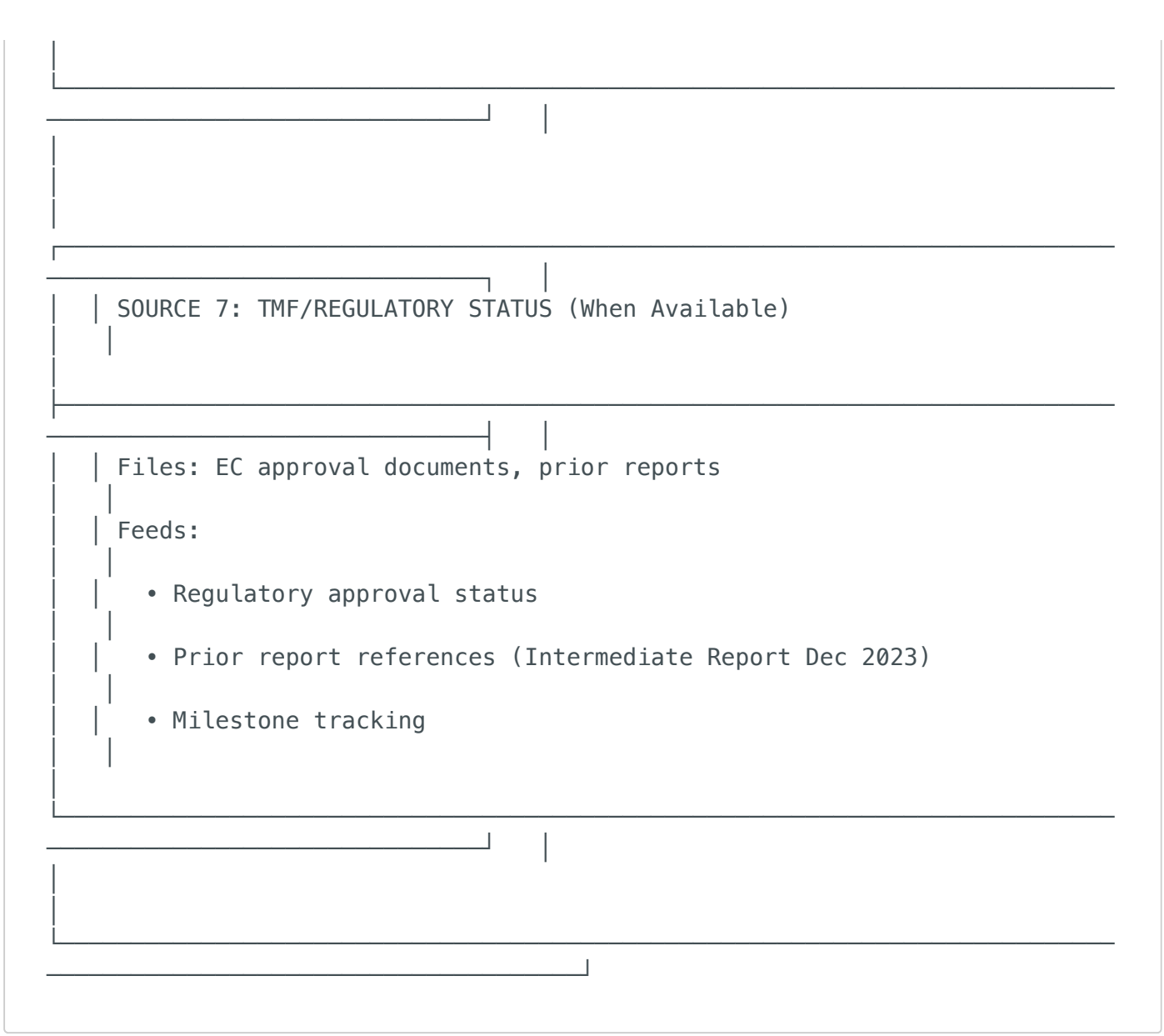
User Query Examples

- "Give me the executive summary"
- "What's the overall study status?"
- "Prepare a board presentation"
- **AUTOMATIC:** Dashboard updates on data refresh

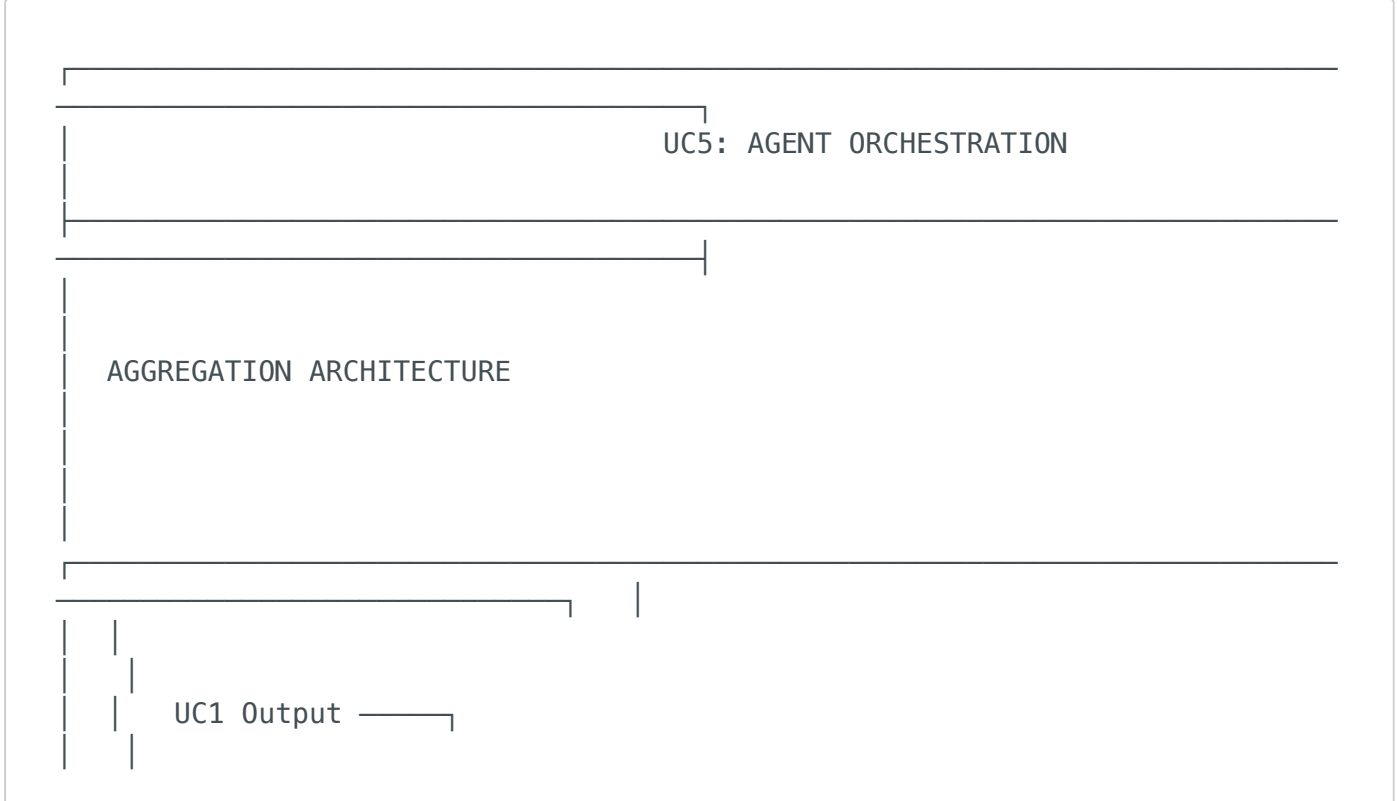
Input Data Sources

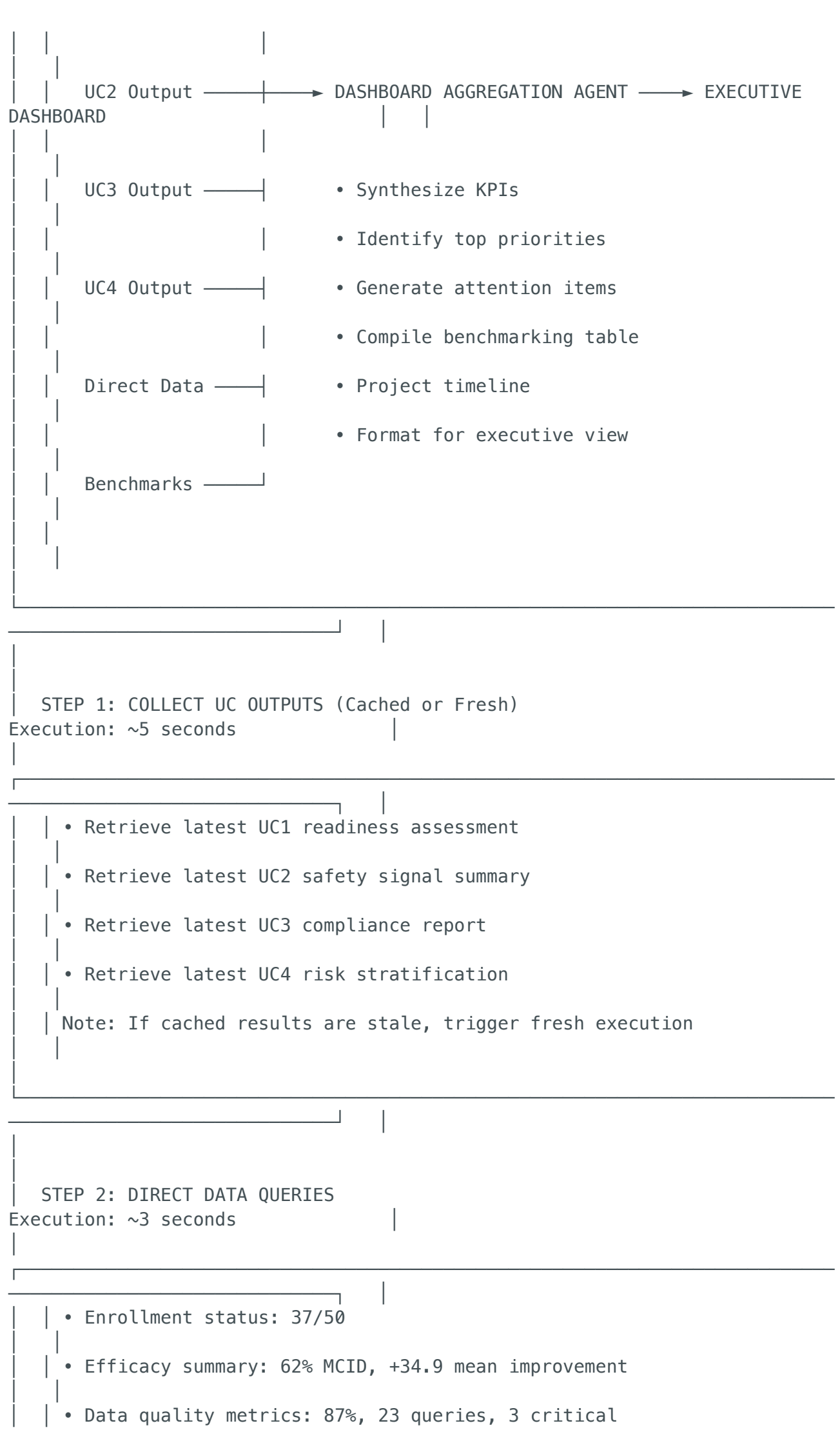

SOURCE 2: UC2 OUTPUT — Safety Signal Summary
Feeds:
• Active signals (fracture rate monitored)
• Signal status (explained by population)
• Required actions
SOURCE 3: UC3 OUTPUT — Protocol Compliance
Feeds:
• Compliance rate (96%)
• Deviation count by severity
• SAE reporting compliance
SOURCE 4: UC4 OUTPUT — At-Risk Patient Summary
Feeds:
• High-risk patient count (4)

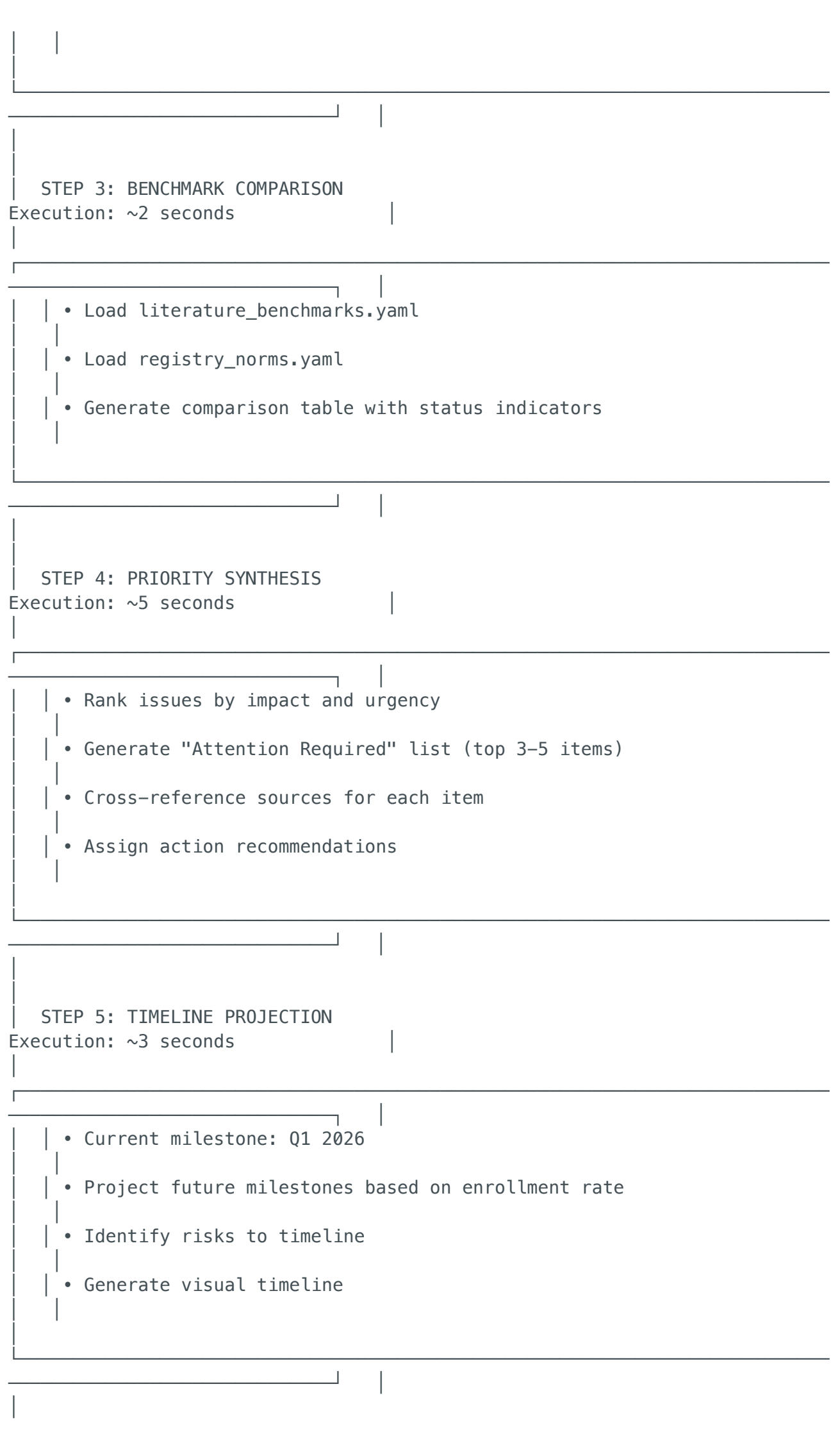

• Patients overdue for follow-up (7)
• Retention risk assessment
SOURCE 5: STUDY DATA — Enrollment & Efficacy (Direct)
File: H-34DELTARevisionstudy_export_20250912.xlsx
Feeds:
• Enrollment: 37/50 (74%)
• Efficacy: 62% MCID achieved (n=8)
• Data quality: 87% (23 queries open, 3 critical)
• Mean HHS improvement: +34.9 points
SOURCE 6: LITERATURE + REGISTRY — External Benchmarking
Files: literature_benchmarks.yaml, registry_norms.yaml
Feeds:
• HHS improvement comparison: H-34 +34.9 vs Literature +28-45 vs Registry +32
• MCID comparison: H-34 62% vs Literature 60-80% vs Registry 68%
• Revision rate: H-34 8.1% vs Literature 5-8% vs Registry 6.2%
• AE rate: H-34 35% vs Literature 28-40% vs Registry 35%
• 2yr survival: H-34 92% vs Literature 90-96% vs Registry 94%

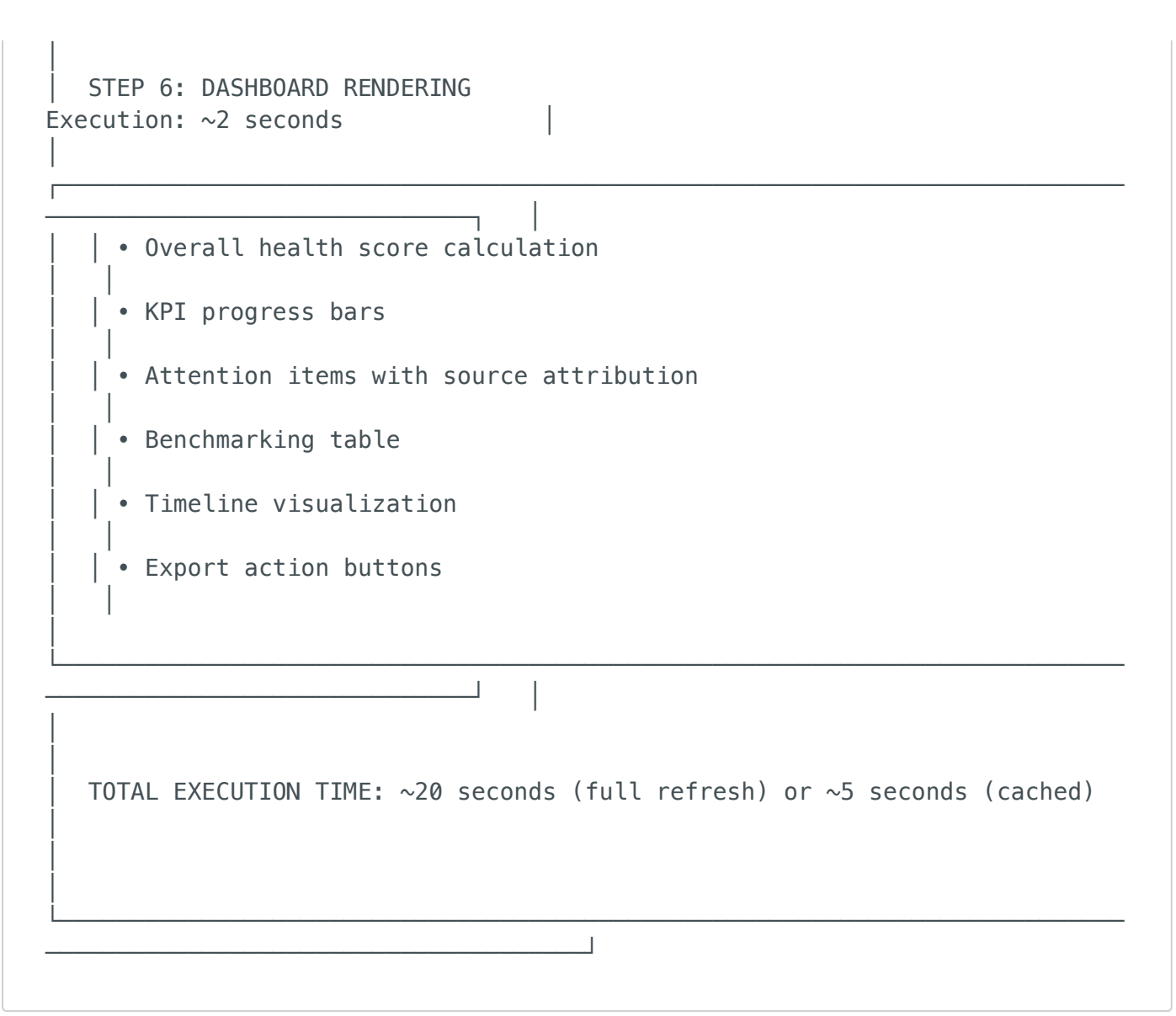


Agent Orchestration




UC2 Output
DASHBOARD AGGREGATION AGENT
EXECUTIVE DASHBOARD
UC3 Output
• Synthesize KPIs
• Identify top priorities
UC4 Output
• Generate attention items
• Compile benchmarking table
Direct Data
• Project timeline
• Format for executive view
Benchmarks
STEP 1: COLLECT UC OUTPUTS (Cached or Fresh)
Execution: ~5 seconds
• Retrieve latest UC1 readiness assessment
• Retrieve latest UC2 safety signal summary
• Retrieve latest UC3 compliance report
• Retrieve latest UC4 risk stratification
Note: If cached results are stale, trigger fresh execution
STEP 2: DIRECT DATA QUERIES
Execution: ~3 seconds
• Enrollment status: 37/50
• Efficacy summary: 62% MCID, +34.9 mean improvement
• Data quality metrics: 87%, 23 queries, 3 critical


STEP 3: BENCHMARK COMPARISON
Execution: ~2 seconds
• Load literature_benchmarks.yaml
• Load registry_norms.yaml
• Generate comparison table with status indicators
STEP 4: PRIORITY SYNTHESIS
Execution: ~5 seconds
• Rank issues by impact and urgency
• Generate "Attention Required" list (top 3–5 items)
• Cross-reference sources for each item
• Assign action recommendations
STEP 5: TIMELINE PROJECTION
Execution: ~3 seconds
• Current milestone: Q1 2026
• Project future milestones based on enrollment rate
• Identify risks to timeline
• Generate visual timeline



Output Specification

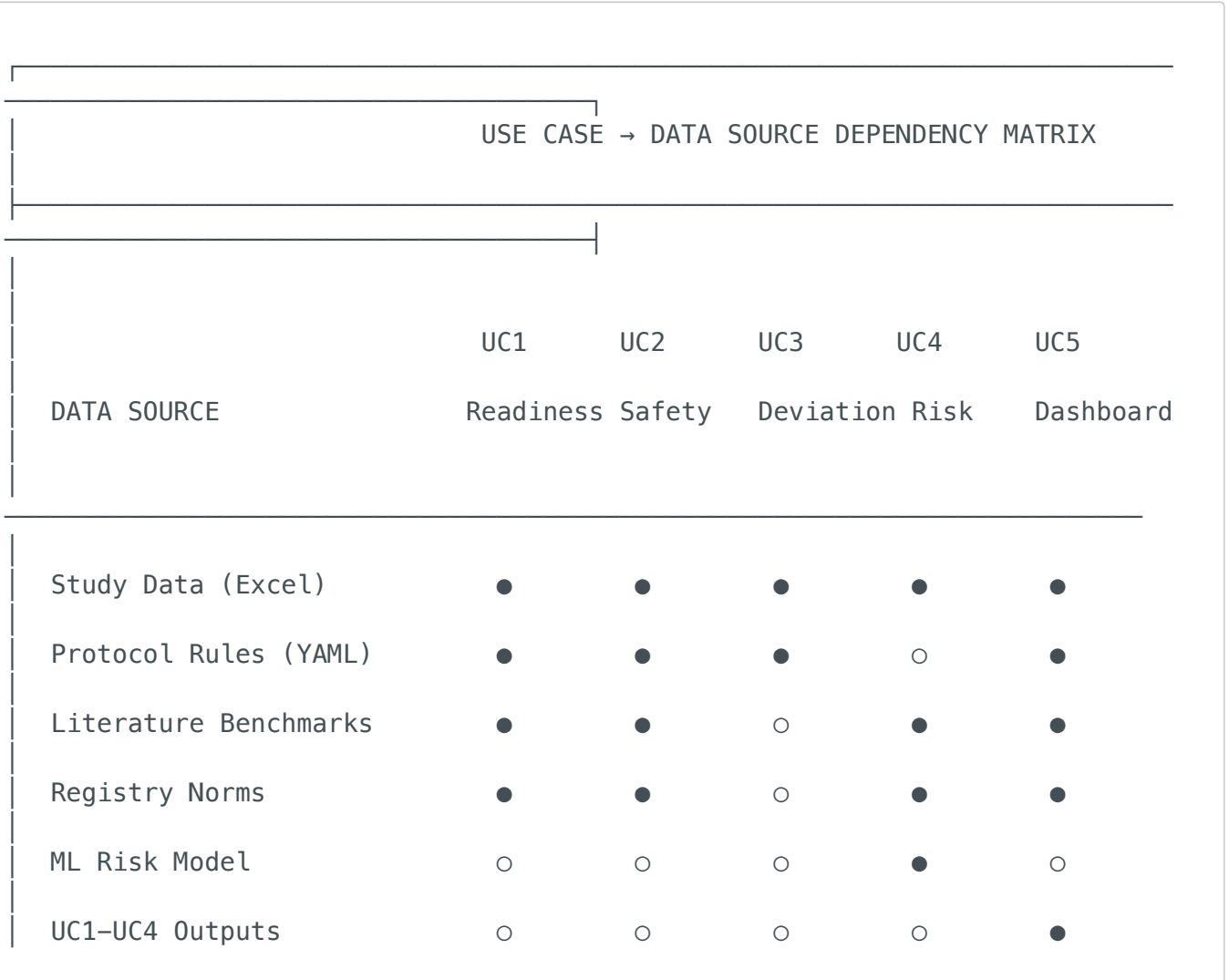
Output Element	Description	Format
Overall Health Score	Composite 0-100 with trend	Score + progress bar
KPI Summary	Enrollment, Efficacy, Safety, Compliance, Quality	Icon + progress bars
Attention Required	Top 3-5 prioritized issues	Numbered list with actions
Benchmarking Table	H-34 vs Literature vs Registry	Comparison table
Regulatory Timeline	Milestone projection	Timeline visual
Export Actions	PDF, presentation, drill-down	Button array

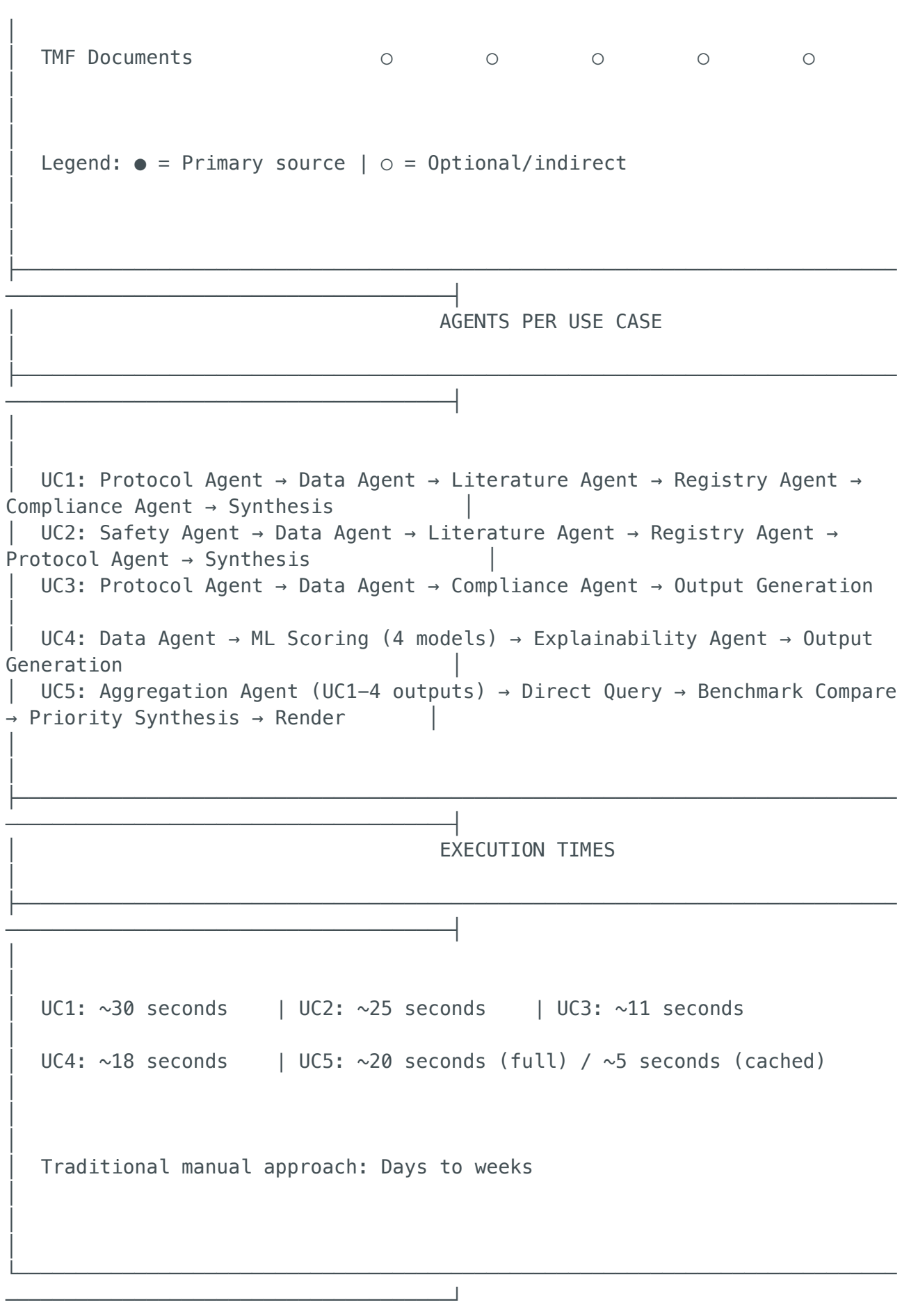
Output Element	Description	Format
Provenance Summary	Data currency timestamp	Footer

Value Delivered

Metric	Traditional	With Platform
Time to prepare	2-3 days	20 seconds
Data sources synthesized	Manual aggregation	6+ automated
Currency	Point-in-time snapshot	Real-time refresh
Benchmarking	Manual literature search	Automated comparison
Actionability	Status report only	Prioritized action items

Summary: Use Case Data Source Matrix





Appendix: Document-as-Code File

Specifications

protocol_rules.yaml

```yaml
# Source: CIP_H-34_v.2.0.pdf
# Extraction Method: LLM-assisted structured extraction
# Last Updated: 2026-01-11

protocol:
  id: "H-34"
  version: "2.0"
  title: "DELTA Revision Cup Clinical Investigation"

schedule_of_assessments:
  visits:
    - id: "fu_2mo"
      day_offset: 60
      window: [-14, +28]
      required_assessments: ["hhs", "ohs", "radiology", "ae_review"]
    - id: "fu_6mo"
      day_offset: 180
      window: [-30, +30]
      required_assessments: ["hhs", "ohs", "radiology", "ae_review"]
    - id: "fu_1yr"
      day_offset: 365
      window: [-30, +60]
      required_assessments: ["hhs", "ohs", "radiology", "ae_review"]
    - id: "fu_2yr"
      day_offset: 730
      window: [-60, +60]
      required_assessments: ["hhs", "ohs", "radiology", "ae_review"]
      critical: true

endpoints:
  primary:
    id: "hhs_improvement"
    calculation: "hhs_2yr - hhs_baseline"
    success_threshold: 20
    success_criterion: "improvement >= 20 points"

safety_thresholds:
  revision_rate_concern: 0.10
  sae_rate_concern: 0.40
  fracture_rate_concern: 0.08

deviation_classification:
  minor: "within_1.5x_window"
  major: "beyond_1.5x_window_or_missing_critical"
  critical: "affects_primary_endpoint"
```

literature_benchmarks.yaml

```yaml
# Source: 15 indexed publications
# Extraction Method: LLM-assisted benchmark extraction
# Last Updated: 2026-01-11

publications:
  - id: "meding_2025"
    title: "Long-term outcomes of cementless revision THA"
    benchmarks:
      hhs_improvement: {mean: 38.2, sd: 14.3, ci_95: [35.7, 40.7]}
      revision_rate: {value: 0.062, ci_95: [0.041, 0.089]}
      mcid_achievement: {value: 0.72}

  - id: "dixon_2025"
    title: "Risk factors for periprosthetic fracture"
    risk_factors:
      osteoporosis: {revision_hr: 1.8, fracture_hr: 2.4}
      fracture_rate_osteoporotic: {min: 0.15, max: 0.20}
      fracture_rate_non_osteoporotic: {min: 0.04, max: 0.08}

  - id: "harris_2025"
    title: "Adverse events in revision THA"
    benchmarks:
      ae_rate: {min: 0.28, max: 0.40}

  - id: "vasios_et_al"
    title: "Functional outcomes following revision"
    benchmarks:
      hhs_improvement_range: {min: 28, max: 42}
```

registry_norms.yaml

```yaml
# Source: AOANJRR 2024, NJR UK
# Extraction Method: Structured data extraction
# Last Updated: 2026-01-11

registries:
  - id: "aoanjrr_2024"
    name: "Australian Orthopaedic Association National Joint Replacement
Registry"
    benchmarks:
      revision_tha:
        cementless_cup:
          survival_2yr: 0.94
          revision_rate_median: 0.062
          revision_rate_p95: 0.12
    risk_factors:
```

```yaml
      osteoporosis: {revision_hr: 1.8, fracture_hr: 2.4}
      bmi_over_35: {revision_hr: 1.6}
    thresholds:
      fracture_rate_concern: 0.10

  - id: "njr_uk"
    name: "National Joint Registry UK"
    benchmarks:
      revision_tha:
        survival_2yr: 0.93
        revision_rate_median: 0.065
```

Version 1.0 — Use Case Specifications with Multi-Source Architecture

Document generated: January 11, 2026