

CASE STUDY:

# Accelerating End-to-End Safety Assessment across Fragmented Data with Signals Agents

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The signal and risk management landscape is rapidly evolving as artificial intelligence (AI) reshapes how organizations identify, evaluate, and respond to potential safety risks. Traditional approaches have relied heavily on manual evidence gathering, extensive expert reviews, and sequential workflows, often resulting in lengthy assessment timelines.

This case study compares these conventional methods with an AI-enabled approach, illustrating how intelligent agents can transform signal evaluation by accelerating insight generation while supporting rigorous, evidence-based decision-making.

Specifically, this case study demonstrates how **Signals Agents**, powered by **NavaX™**, accelerates time-to-insight when evaluating potential associations between medicinal products and adverse events, serving as an active intelligent partner for signaling with orchestrated end-to-end evidence gathering, case assessment, signal evaluation, and regulatory response preparation.

## 1. Executive Summary & Cross-Case Propositions

- **The Baseline Hypothesis:** Transitioning from fragmented, manually driven signal evaluation workflows to autonomous, agent-based orchestrated intelligence dramatically collapses cycle times, enforces analytical reproducibility, and improves the speed of regulatory compliance – all without sacrificing scientific rigor.
- **Core Research/Business Question:** How does embedding an autonomous agent network alter the speed, quality, and consistency of complex Health Authority signal evaluations across multiple systems, compared to traditional, manual data aggregation methods?

## 3. Methodology Profiles

To evaluate the true impact of automation, this study establishes two distinct methodologies deployed to handle a complex regulatory inquiry:

### Methodology A The Traditional Approach

The traditional methodology is siloed and highly manual. The safety scientist acts as a data collector that must manually navigate separate access mechanisms, distinct user interfaces, and varied data schema across multiple internal and external databases.

## 2. Time Context & Point of View

- **Time Context:** The duration required to evaluate an urgent, time-sensitive Health Authority request concerning emerging safety signals.
- **Point of View:** Safety Scientist, Safety Scientist Lead, Drug Safety Physician, Therapeutic Area Head, and Head of Risk Management.



### Methodology B The Agentic Approach

The second methodology establishes a single, integrated workspace powered by Signals Agents. The system serves as an active, intelligent orchestration partner that autonomously gathers, harmonizes, and summarizes end-to-end evidence under the oversight of the safety scientist.

## 4. Case Example

### Cross-Case Analysis Matrix: GLP-1 Receptor Agonists vs. Suicidal Ideation

In this case, we consider the evaluation of the following complex safety concept:

**"Conduct a comprehensive signal evaluation for GLP-1 receptor agonists and the potential association with suicidal ideation and self-injurious behavior."**

- 1 The investigation begins by **defining a robust case identification strategy**. This includes establishing the scope of the review by identifying the GLP-1 receptor agonists of interest and developing a comprehensive MedDRA search strategy. Relevant Preferred Terms (PTs), High-Level Terms (HLTs), and Standardized MedDRA Queries (SMQs) related to suicidal ideation, self-injurious behavior, suicide attempts, and completed suicide are selected to ensure consistent and reproducible case retrieval across all data sources.
- 2 Once the search strategy is finalized, the investigation moves to **internal safety case review**, where data is systematically retrieved and reviewed from internal sources. Internal safety databases are queried to identify relevant individual case safety reports (ICSRs), followed by detailed medical assessment of case narratives, temporal relationships, de-challenge/rechallenge information, alternative etiologies, psychiatric history, concomitant medications, and potential confounding factors.
- 3 From there, the next step is **external databases review**, where external regulatory and PV databases – including FAERS, VigiBase, and PMDA – are evaluated to assess reporting patterns, disproportionality measures where applicable, geographic distribution, demographic characteristics, seriousness, outcomes, and consistency of reported events, in addition to trends over time and potential product- or class-specific reporting patterns.
- 4 Targeted **literature and clinical reviews** are then conducted to identify published case reports, observational studies, epidemiologic analyses, mechanistic evidence, and systematic reviews, and clinical trial evidence relevant to the potential association.
- 5 The findings from all sources then undergo **assembly, cross-validation, and synthesis**. Evidence is assessed for consistency, strength of association, temporality, dose-response relationships, biological plausibility, and alternative explanations.
- 6 Finally, a **comprehensive causality assessment** is performed using established signal evaluation principles. The totality of evidence is weighed to determine whether the findings support a potential safety signal, represent an observed association requiring continued monitoring, or are more likely explained by confounding factors, underlying disease characteristics.

**The following matrix outlines the side-by-side operational divergence between the two methodologies:**

| <b>Evaluation Pillars / Workflow Phases</b>            | <b>Methodology A - The Traditional Approach</b>                                                                                                      | <b>Methodology B - The Agentic Approach</b>                                                                                                       | <b>Key Divergence &amp; Impact</b>                                                                                                      |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Strategy &amp; Case Identification</b>           | MedDRA/PT/SMQ search strategies are developed manually, with disconnected queries executed sequentially across safety databases.                     | <b>Automated Strategy Generation:</b> Agents automatically develop inclusion/exclusion criteria and query all repositories instantly.             | <b>Eliminates Setup Friction:</b> Transitions team from syntax building to immediate verification.                                      |
| <b>2. Internal Safety Case Review</b>                  | Manual medical reviews are conducted on thousands of pages of individual case safety reports (ICSRs), timelines, and medical histories.              | <b>Agent-Driven Extraction:</b> AI synthesizes complex narratives, identifies confounding factors, and highlights core timelines.                 | <b>Massive Volume Reduction:</b> Condenses weeks of dense manual text reading into instant contextual insights.                         |
| <b>3. External Databases Review</b>                    | Navigating through fragmented <b>FAERS, VigiBase, and PMDA</b> portals is required to calculate disproportionality metrics and geographic anomalies. | <b>Federated Multi-Database Sync:</b> Automated evidence correlation extracts and maps global data into a single workspace.                       | <b>Global Data Visibility:</b> Provides immediate international reporting context without extensive manual cross-referencing.           |
| <b>4. Literature &amp; Clinical Review</b>             | Manual searching across PubMed and ClinicalTrials.gov leads to high-effort extraction of observational studies and mechanistic data.                 | <b>Intelligent Literature Curation:</b> Semantic search isolates, summarizes, and maps relevant biological plausibility data.                     | <b>Closes Information Gaps:</b> Pinpoints critical mechanism-of-action data without manual search leakage.                              |
| <b>5. Assembly, Cross-Validation, &amp; Synthesis</b>  | Manual data assembly and reconciliation require increased effort to align discrepant findings into a unified, static evidence package.               | <b>Automated Evidence Correlation:</b> Unified workspace matches internal case patterns directly with global registries and literature.           | <b>Zero Manual Reconciliation:</b> Eliminates the risk of missing conflicting data across datasets.                                     |
| <b>6. Causality Evaluation &amp; Regulatory Output</b> | High-effort scientific judgment is applied via manual Bradford Hill frameworks, alongside summaries written from scratch under tight deadlines.      | <b>Structured AI Recommendations:</b> System automatically generates draft causality assessments, signal status reports, and executive summaries. | <b>Scientist as Decision Maker:</b> Shifts the human resource from being a clerical writer to higher-value work as an expert validator. |

## 5. Addressing Alternative Explanations

To help reinforce the scientific validity of this comparative analysis, we have outlined four potential alternative explanations and rival theories.

Challenge

1

**The Disconnected System Variable.** Critics might argue that training teams to use legacy systems faster could yield similar results. However, the data proves that because safety databases, literature repositories, and clinical trials use fundamentally separate analytical models, true efficiency cannot be achieved by human speed alone; it requires architectural interoperability.

Challenge

2

**The Volume Deflation Myth.** It could be posited that smaller case sizes skew the efficiency of AI. In practice, however, as review sizes scale – for example, beyond 100 cases – human cognitive fatigue leads to increased error rates and dramatically lengthens timelines. Signals Agents maintains a flat efficiency curve regardless of data volume.

Challenge

3

**The Subjectivity Variable.** Critics may argue that AI results are subjective. In traditional processes, however, different reviewers interpret the same body of evidence differently when evaluating biological plausibility, while standardized, agentic reasoning models ensure reproducible conclusions and total transparency regarding how a safety signal decision was reached.

Challenge

4

**The Pressure of Compressing Timelines.** Health Authorities continue to shorten regulatory response windows, which could be seen as pressuring organizations to work faster. In practice, however, traditional processes force a compromise between deep scientific investigation and meeting submission deadlines, while agentic-powered intelligence eliminates this compromise by reducing data-gathering latency.

Having addressed the principal objections to this comparison, the remaining question is not conceptual but empirical. Across the workflow phases required to evaluate the GLP-1 receptor agonist and suicidal ideation signal, the two methodologies were tracked side by side to measure a single variable: elapsed time to a defensible conclusion.

The traditional approach requires a safety scientist to manually gather, reconcile, and interpret evidence across disconnected internal databases, external regulatory repositories, and the published literature. The agentic approach, by contrast, consolidates that same evidence into a single orchestrated workspace, shifting the scientist's role from data collector to strategic reviewer.

On the next page, we show the operational benefits achieved by this paradigm shift.

RESEARCH IS TO SEE WHAT EVERYBODY ELSE HAS SEEN,  
AND TO THINK WHAT NOBODY ELSE HAS THOUGHT.

– Albert Szent-Györgyi

## 6. Replicated Outcomes & Strategic Shift

The structural differences between the two methodologies translate into a concrete outcome: how much time each approach demands, phase by phase, on this case.

By deploying replication logic across the end-to-end signaling workflow, the operational shift achieved by the modern, agentic approach is clearly demonstrated:

### With **Traditional Process**

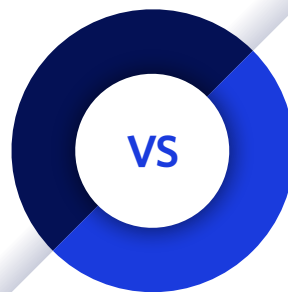
Multiple Disconnected Systems

Manual Evidence Gathering

Extensive Data Reconciliation

Scientist as Data Collector

**WEEKS OF EFFORT**



### With **NavaX Signals Agents**

Single, Integrated Evidence Workspace

Agent-Driven Automated Investigation

Automated Evidence Correlation

Scientist as Strategic Decision Maker

**MINUTES TO INSIGHT**

# ArisGlobal: Your Signals Agents Partner

In an era where timely, evidence-based regulatory decisions are paramount, the ability to seamlessly evaluate data for safety-relevant insights is no longer a competitive advantage — it is a necessity.

Patient safety depends on the timely interpretation of complex and often fragmented evidence, with the future of signaling not defined by the volume of data collected, but by how quickly and confidently that data can be transformed into meaningful safety insights.

Signals Agents reimagines how signal management teams tackle these challenges. By intelligently connecting evidence across internal and external data sources, tedious and labor-intensive workflows are transformed into streamlined, transparent, and scientifically robust assessments. Expert judgment is amplified, rather than replaced, with safety professionals able to focus on conducting critical scientific evaluations, accelerating Health Authority responses, and delivering more confident, audit-ready decisions.

As regulatory expectations continue to evolve, Signals Agents provides a scalable, AI-enabled foundation for organizations to drive faster, higher-quality safety assessments, where every safety insight delivered has the potential to support better patient outcomes.

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