

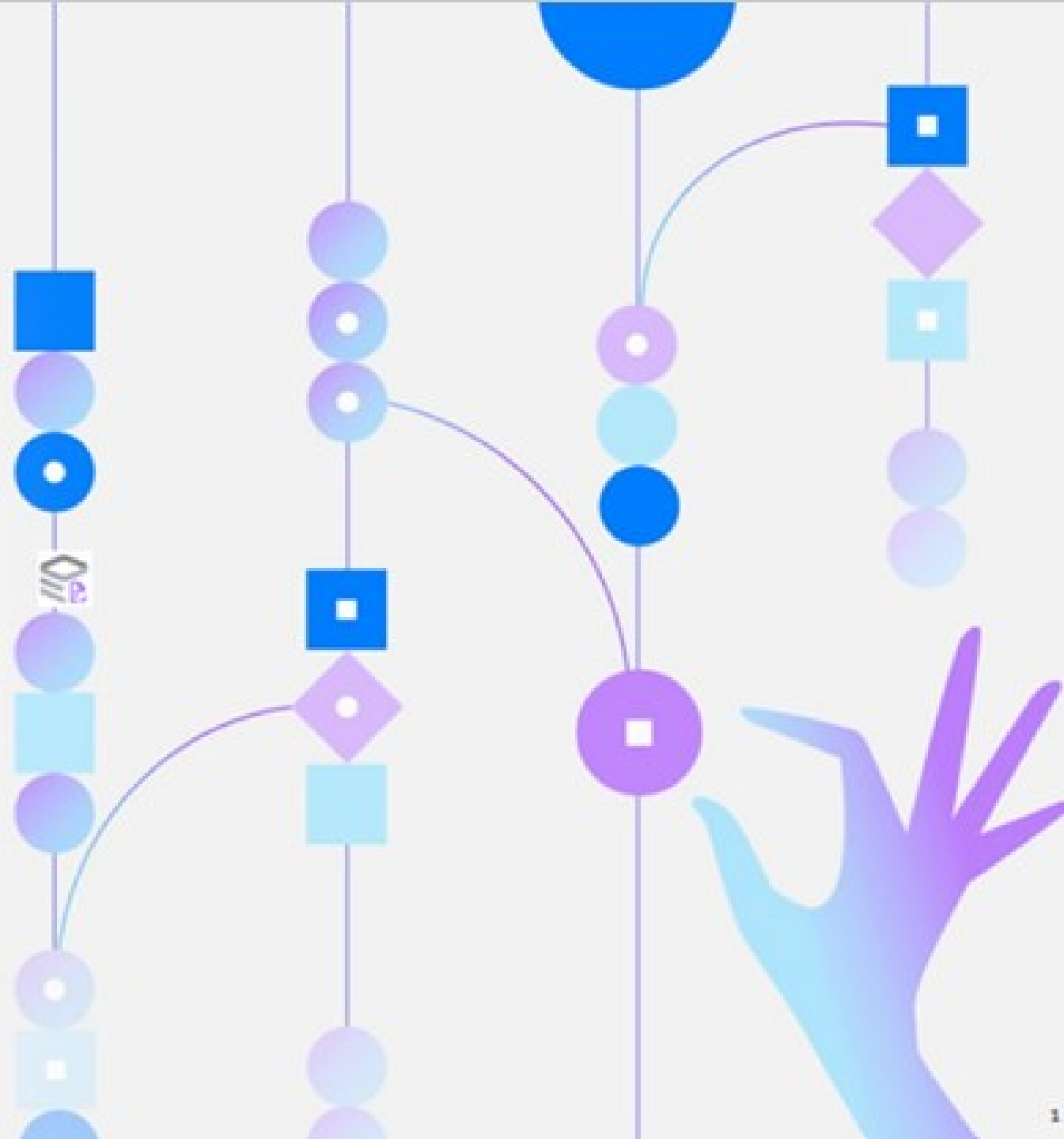


STAR Agentic AI  
For HLS

## STAR AI for Azure:

Modular Agentic Orchestration for  
Healthcare & Life Sciences, Natively  
Deployed on Azure

2025



# AI led Transformation in Healthcare & Life Sciences

## The Challenges | Bottlenecks & Risks in HLS Operations

### Fragmented Data & Manual Reconciliation



HLS teams grapple with disparate data sources, leading to time-consuming manual processes for data quality, Golden Record generation, and lineage tracking.

### Inefficient & Inconsistent Compliance Workflows



Complex regulatory requirements across Pharmacovigilance and Product Quality often result in manual, error-prone processes and varied application of compliance rules.

### Slow & Costly Insight Generation



Extracting, summarizing, and synthesizing critical medical and commercial insights from vast amounts of literature and clinical content is a laborious, time-intensive, and expensive endeavor.

## The Impact | The cost of Inaction

### Ballooning Operational Costs

Manual processes across safety, quality, and data workflows will perpetuate inefficiencies and escalate expenditures.

### Heightened Regulatory & Audit Risk

Poor data quality, lack of explainability, and manual errors will increase regulatory scrutiny, fines, and reputational damage.

### Stalled Strategic Agility & Market Responsiveness

Inability to rapidly synthesize medical and market intelligence will hinder strategic decisions and lead to missed opportunities.

**The Opportunity** | Utilize AI agents to accelerate compliance checks, generate real-time insights, and significantly reduce operational costs, driving unparalleled efficiency and audit readiness.

### Accelerate Compliance & Case Processing

1

Automate Adverse Event case intake, PQC classification, narrative generation, and regulatory form population from diverse sources, ensuring consistent, high-speed compliance.

**Value:** 50-70% faster cycle time for case and complaint handling, reducing compliance backlogs.

### Drive High-Confidence Data Quality

2

Leverage AI for high-confidence Golden Record generation, match resolution, and discrepancy explanations, providing co-pilot guidance for data stewards.

**Value:** 40% fewer manual match errors, achieving >95% auto-merge accuracy for critical data.

### Unlock Real-Time Medical Insights

3

Automate insight extraction, AI summarization at scale, and strategic alignment for stakeholders, creating a scalable, traceable knowledge engine.

**Value:** Reduced narrative drafting from 6 weeks to 8 minutes, enabling real-time, personalized insight delivery.



## An advanced Agentic AI accelerator to scale your compliance

IBM's Agentic AI solution for customer + supplier compliance is an advanced solution that simplifies the due diligence in a more intelligent, transparent, and user-centric way.

### App Overview

STAR AI is a multi-agent orchestration platform designed to accelerate compliance, insight generation, and operational excellence across pharmacovigilance, product quality, data stewardship, and medical intelligence in Life Sciences and Healthcare.

Azure-native and containerized for deployment across any cloud (AWS, GCP, IBM Cloud), STAR integrates GenAI-driven agents with domain-tuned workflows and real-time AI governance.

### Use Cases

Pharmacovigilance Automation

Product Quality Complaint Automation

Medical Insights Generation

Data Quality & Insight Management

### Capabilities



#### Agentic AI Orchestration

Coordinates multiple domain-specific agents for PV, PQ, and MDM to automate safety and quality workflows at scale.



#### Contextual Automation

Processes unstructured inputs with regulatory, medical, and operational awareness for precise, auditable outputs.



#### Confidence Driven Decisions

Outputs include AI-generated rationale and confidence scores to support human-in-the-loop validation and compliance.



#### Real-Time Insights Generation

Extracts and synthesizes findings from literature, trials, and social data to enable dynamic decision-making.



#### Enterprise Integration Ready

Integration ready to Industry solutions such as, Argus, ArisG, Veeva, Dynamics, and MDM platforms with API-first, container-based deployment.



#### Built-in AI Governance

Compliance-first HIPAA, 21 CFR Part 11, and GxP compliance through audit trails, lineage tracking, and explainability.

The screenshot shows the 'Case Review' tab in the STAR AI FOR SAFETY application. It features a breadcrumb trail: 'Dashboard > Case Review > 1 Select a Case > 2 Review Case Analysis'. Below this, there's a 'Cases' section with a count of 63. A message says 'Select a Case below to start analysis.' Below that is a table with columns: AER / CASE #, REPORT TY..., RECEIVED ..., DUE DATE, PRIORITY, and STATUS. The table contains 8 rows of data. At the bottom, there's a pagination bar showing '1 row selected', 'Showing 51-60 of 63', and a set of navigation buttons including '<', '>', and numbered buttons 2 through 7, with 6 being the active page.

| AER / CASE # | REPORT TY... | RECEIVED ... | DUE DATE | PRIORITY        | STATUS     |
|--------------|--------------|--------------|----------|-----------------|------------|
| 2025-UNK-... | Spontaneous  | 04-08-25     | 01-26-25 | Other Serio...  | Pending Ap |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 01-15-24 | Non-Serious     | Pending Ap |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 01-28-24 | Non-Serious     | Pending Ap |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 01-15-24 | Non-Serious     | Pending Ap |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 10-26-23 | Other Serio...  | In Review  |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 04-17-23 | Non-Serious     | Pending Ap |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 10-26-23 | Death / Life... | Pending Ap |

## AI-Led Business Value

The Tangible Benefits and Value of STAR Agentic AI. Discover how our platform delivers significant improvements in efficiency, compliance, and cost savings across HLS operations

### Personas



Adverse Event Processor



Quality Investigator



Medical Reviewer



Data Steward

### Use Case Portfolio

#### 1. Pharmacovigilance (PV) Automation

- AE case intake and triage from multiple sources (emails, portals, EHR)
- Narrative generation and regulatory form population
- MedDRA/WHO Drug coding, seriousness assessment, and causality review

#### 2. Product Quality Complaint (PQC) Automation

- Complaint intake and classification
- Root cause analysis, CAPA generation, and audit trail maintenance
- Guided UI for investigation workflows

#### 3. Medical Insights Generation

- Automated Insight Extraction from literature, social signals, and clinical content
- AI Summarization at scale for stakeholders (e.g., medical directors, MSLs)
- Strategic Alignment with regulatory-aware narratives and business themes
- Medical & Commercial Synthesis with human-in-the-loop curation and scoring
- Scalable Knowledge Engine with embedded traceability and scoring

#### 4. Data Quality & Insight Management (DQIM)

- High-confidence Golden Record generation (>95% auto-merge accuracy)
- Match resolution, lineage tracking, discrepancy explanations
- Co-pilot guidance for data stewards using contextual insights
- Modular rule integration and MDM system plug-ins

### Benefits & Value

**50-70%**

Faster cycle time in case and compliance handling

**↓40%**

Fewer manual match errors

**95%+**

Merge confidence

Data  
Steward  
Efficiency

**30-50%**

Reduction in operational costs across safety, quality, and data workflows



#### Narrative Drafting Speed

Reduced from 6 weeks → 8 minutes

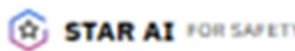


#### Audit & Regulatory Readiness

Embedded explainability, lineage, and quality scoring

## Key Features | Intelligent Case Intake and Review

- AI-augmented case queue enables rapid review and prioritization
- Automatically extracts and classifies adverse events from multiple intake sources
- STAR AI Assistant available for real-time guidance and status queries
- Structured data view with severity, due date, and status for each case
- Enables high-throughput operations with human-in-the-loop assurance
- Designed for regulatory workflows (e.g., ICH E2B, FDA 21 CFR Part 11)
- Integration-ready with safety systems (e.g., Argus, ArisG)



Dashboard

Case Review

1 Select a Case

2 Review Case Analysis

3 Approve Case

Cases 63

Select a Case below to start analysis.

Filters

| AER / CASE # | REPORT TY... | RECEIVED ... | DUE DATE | PRIORITY        | STATUS        |
|--------------|--------------|--------------|----------|-----------------|---------------|
| 2025-UNK-... | Spontaneous  | 04-08-25     | 01-26-25 | Other Serio...  | Pending Ap... |
| 2025-UNK-... | Spontaneous  | 04-08-25     | 01-15-24 | Non-Serious     | Pending Ap... |
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| 2025-UNK-... | Spontaneous  | 04-08-25     | 10-26-23 | Death / Life... | Pending Ap... |

1 row selected

Showing 51-60 of 63

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6

7

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STAR AI ASSISTANT

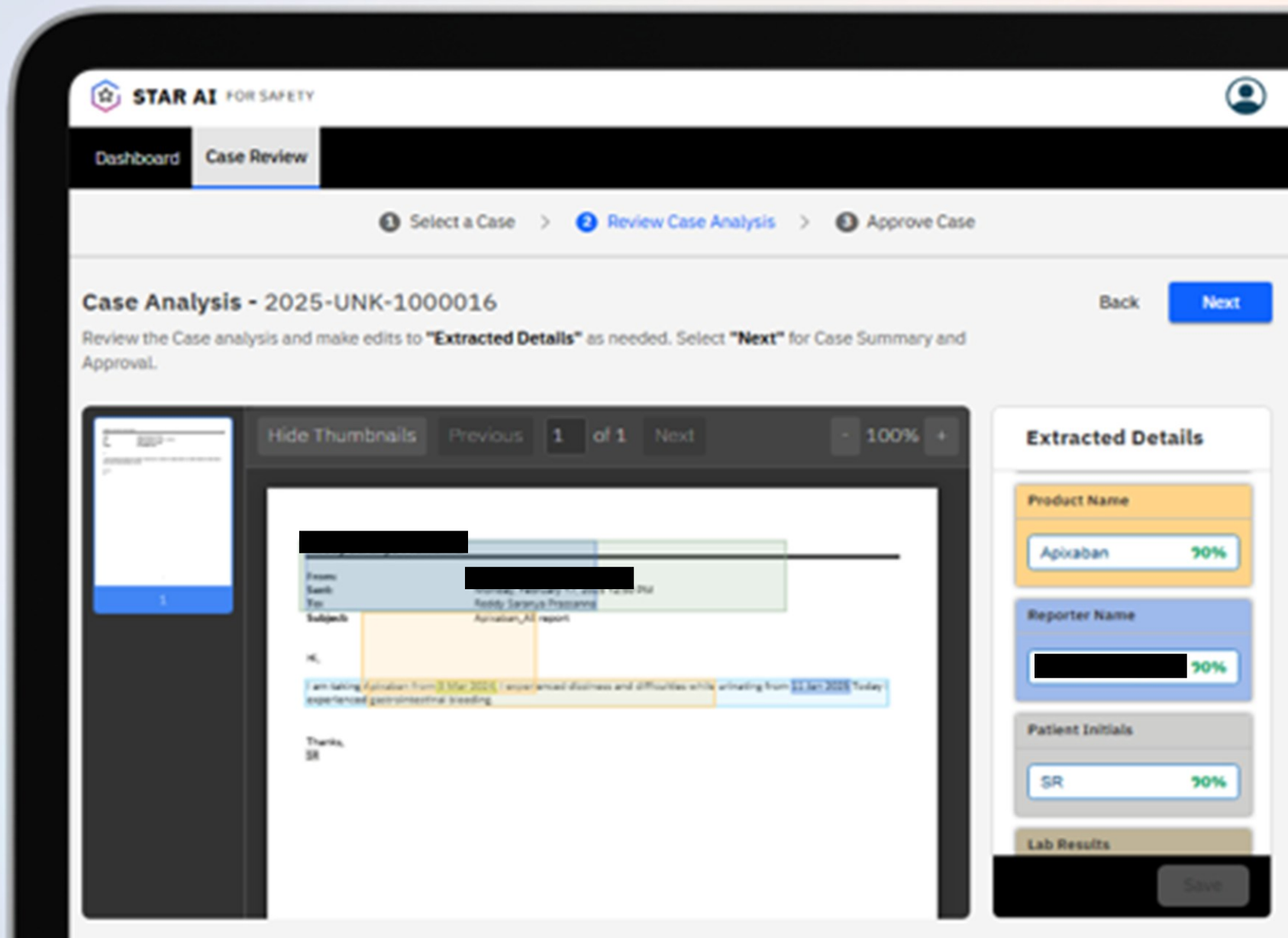


Have a question about the cases?

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## Key Features | Case Analysis with Auto-Extraction

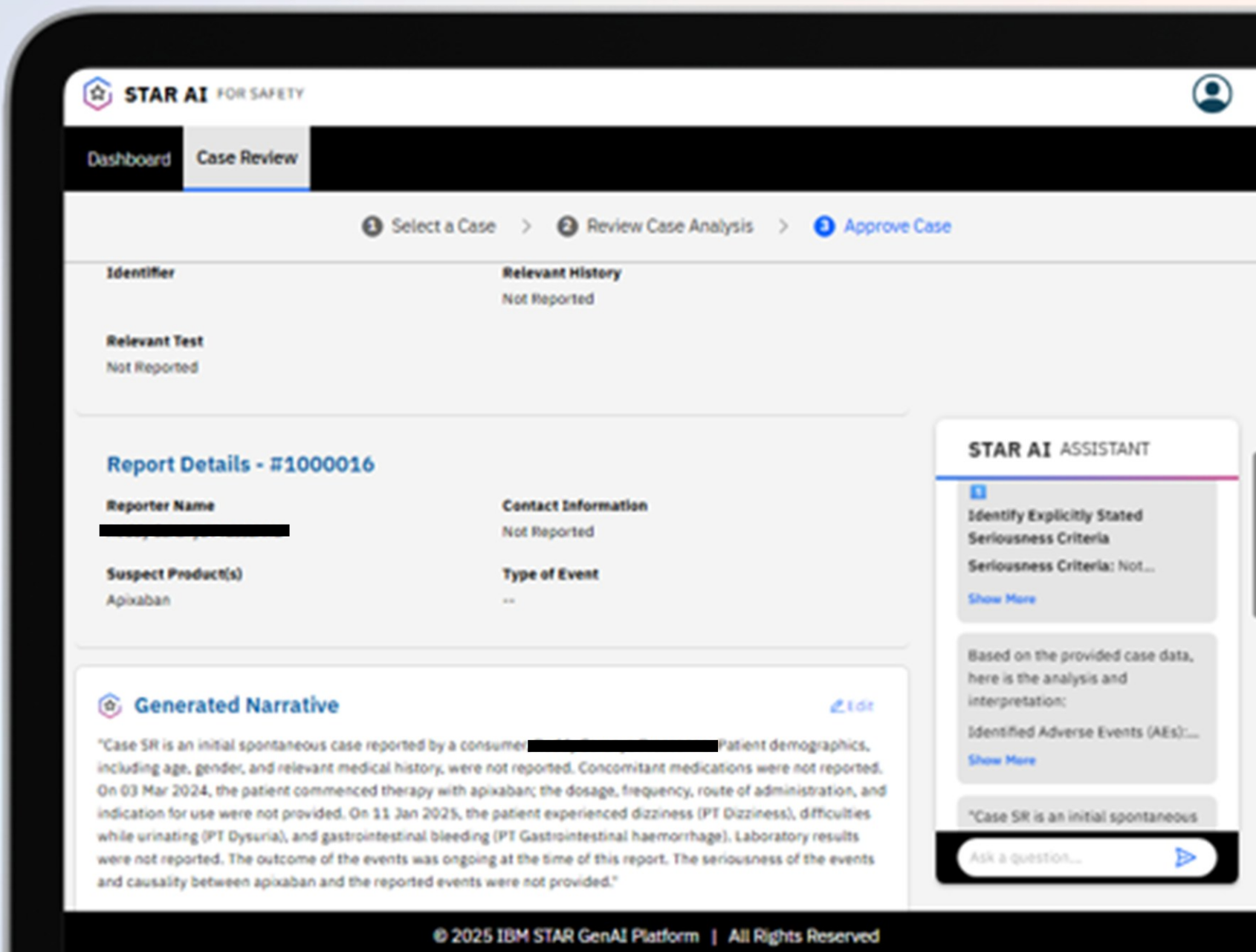
- STAR AI agents extract critical data (e.g., product, reporter, patient) from unstructured sources
- Confidence scores displayed for all extracted entities to guide reviewer decisions
- Multi-lingual translation and normalization built into intake process
- Enables faster triage of high-priority and serious event cases
- Designed to reduce manual data entry by over 60%
- Prepares structured safety case data for downstream processing
- Built-in audit trail for traceability and regulatory compliance



The screenshot displays the 'STAR AI FOR SAFETY' Case Review interface. The top navigation bar includes 'Dashboard' and 'Case Review' tabs. A progress indicator shows three steps: '1 Select a Case', '2 Review Case Analysis' (current step), and '3 Approve Case'. The main heading is 'Case Analysis - 2025-UNK-1000016'. Below this, instructions state: 'Review the Case analysis and make edits to "Extracted Details" as needed. Select "Next" for Case Summary and Approval.' The interface features a central document viewer showing an email from 'Rudolf Sanyal' with subject 'Apixaban AI report'. The email body mentions 'I am taking Apixaban from 3 Mar 2025' and 'I experienced dizziness and difficulties while urinating from 11 Jan 2025'. To the right, the 'Extracted Details' panel shows fields for 'Product Name' (Apixaban, 90% confidence), 'Reporter Name' (redacted, 90% confidence), 'Patient Initials' (SR, 90% confidence), and 'Lab Results'. A 'Save' button is at the bottom right.

## Key Features | Generated Narratives & Assistant Collaboration

- Continuously scans diverse medical literature, trial reports, and real-world data for new insights
- Surfaces sentiment-tagged findings to support clinician decision-making and protocol optimization
- Highlights emerging clinical themes across immunotherapy, adherence, resistance, and diagnostics
- STAR AI Assistant generates evidence-based recommendation
- scoring system ranks relevance, strength, and novelty of each clinical finding
- Promotes earlier detection of risks and opportunities through automated pattern recognition
- Enables contextualized, queriable insight flow for research teams and medical affair



The screenshot displays the STAR AI FOR SAFETY interface, specifically the Case Review section. The interface includes a navigation bar with 'Dashboard' and 'Case Review' tabs. A progress indicator shows three steps: '1 Select a Case', '2 Review Case Analysis', and '3 Approve Case', with the second step being the current active state.

The main content area is divided into several sections:

- Identifier:** Not Reported
- Relevant History:** Not Reported
- Relevant Test:** Not Reported
- Report Details - #1000016**
  - Reporter Name:** [Redacted]
  - Contact Information:** Not Reported
  - Suspect Product(s):** Apixaban
  - Type of Event:** --
- Generated Narrative** (with an 'Edit' link)
 

"Case SR is an initial spontaneous case reported by a consumer [Redacted] Patient demographics, including age, gender, and relevant medical history, were not reported. Concomitant medications were not reported. On 03 Mar 2024, the patient commenced therapy with apixaban; the dosage, frequency, route of administration, and indication for use were not provided. On 11 Jan 2025, the patient experienced dizziness (PT Dizziness), difficulties while urinating (PT Dysuria), and gastrointestinal bleeding (PT Gastrointestinal haemorrhage). Laboratory results were not reported. The outcome of the events was ongoing at the time of this report. The seriousness of the events and causality between apixaban and the reported events were not provided."

On the right side, there is a **STAR AI ASSISTANT** panel:

- Step 1: Identify Explicitly Stated Seriousness Criteria. Seriousness Criteria: Not... [Show More](#)
- Based on the provided case data, here is the analysis and interpretation: Identified Adverse Events (AEs):... [Show More](#)
- "Case SR is an initial spontaneous"
- Input field: Ask a question... [▶](#)

At the bottom, the footer reads: © 2025 IBM STAR GenAI Platform | All Rights Reserved



- STAR AI agents extract critical data (e.g., product, reporter, patient) from unstructured sources
- Confidence scores displayed for all extracted entities to guide reviewer decisions
- Multi-lingual translation and normalization built into intake process
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Ask a question...

## Key Features | Auto-merged Matches

- Automated Golden Record creation power by STAR AI's agentic flow logic.
- High-confidence auto-merge decisions ( $\Rightarrow$  95%) based on configurable match rules
- Profile comparisons and lineage tracking ensure traceability and auditability.
- Data Stewardship minimized through intelligent match resolution and justification.
- Integration-ready golden records for downstream MDM systems
- Supports modular plug-in architecture for custom rules, scoring models, and source systems.

## STAR AI FOR DATA QUALITY & INSIGHT MANAGEMENT

Dashboard Match Review Match Log

### Match Log

| Outcome     | Date Merged            | Notes | Confidence Score |
|-------------|------------------------|-------|------------------|
| auto_merged | Jul 02, 2025, 14:12:00 |       | 95%              |
| auto_merged | Jul 02, 2025, 14:12:00 |       | 95%              |
| auto_merged | Jul 02, 2025, 14:12:00 |       | 95%              |

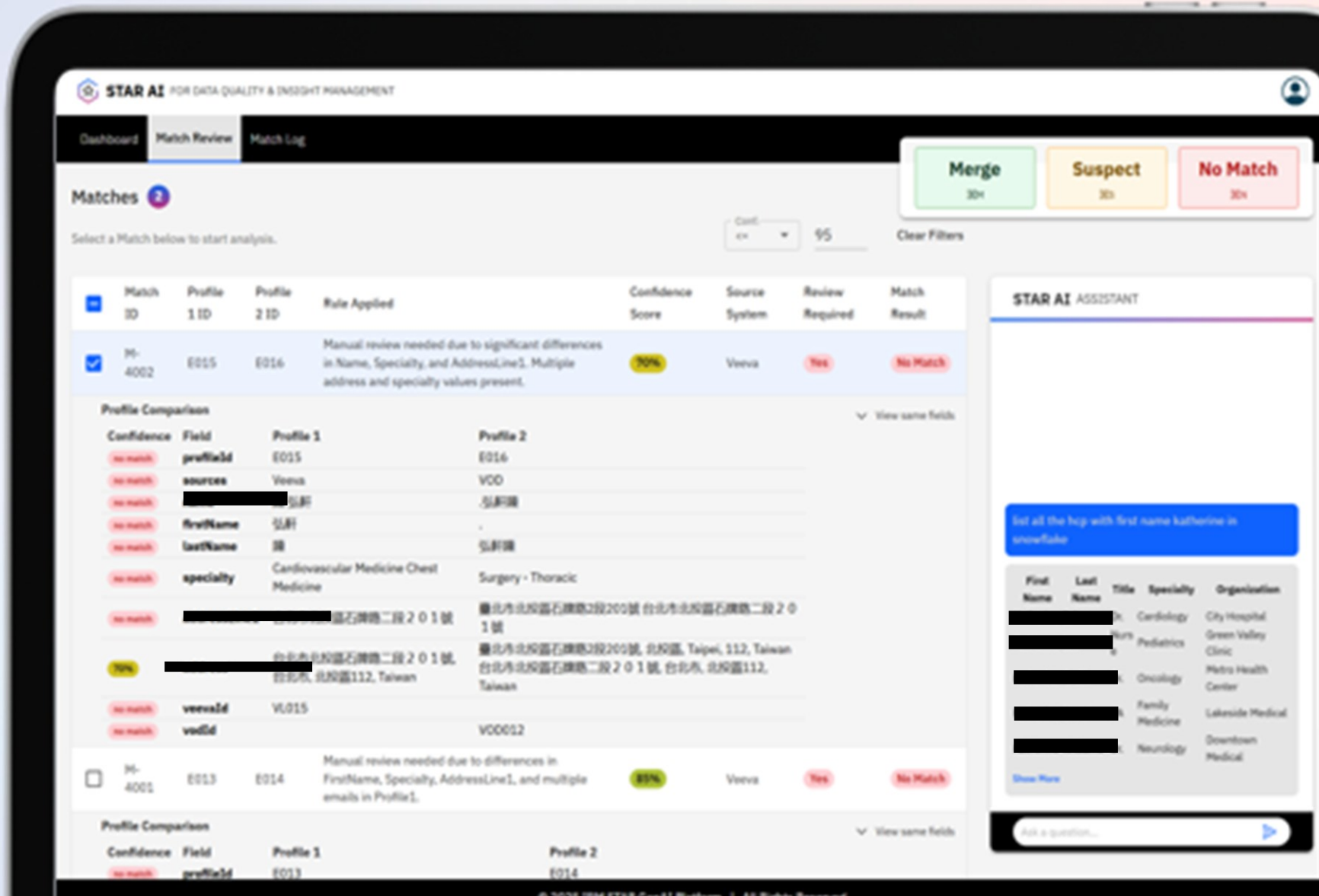
| Profile Comparison |               |                                |                                |                                        |
|--------------------|---------------|--------------------------------|--------------------------------|----------------------------------------|
| Conf               | Field         | Profile 1                      | Profile 2                      | Relationship                           |
| 75%                | profileId     | 5-38715                        | 5-40001                        | Selected '5-40001' from MDM as...      |
| 95%                | name          | [REDACTED]                     | [REDACTED]                     | Selected 'Judy Henderson' from M...    |
| 75%                | firstName     | Judy                           | Judy                           | Selected 'Judy' from MDM as only...    |
| match              | middleName    | B                              | B                              | Both records matched on 'B'.           |
| match              | lastName      | Henderson                      | Henderson                      | Both records matched on 'Henderson'.   |
| match              | suffix        | Dr.                            | Dr.                            | Both records matched on 'Dr'.          |
| match              | gender        | Female                         | Female                         | Both records matched on 'Female'.      |
| 95%                | specialty     | Gastroenterology               | Stomach                        | Selected 'Stomach' from MDM as on...   |
| match              | addressLine1  | 812 Main St                    | 812 Main St                    | Both records matched on '812 Main St'. |
| match              | address       | [REDACTED]                     | [REDACTED]                     | Both records matched on '812 Main St'. |
| match              | email         | Judy.Henderson@johnhoptons.com | Judy.Henderson@johnhoptons.com | Both records matched on 'Judy.Hen...   |
| match              | versionId     | VL-01009                       | VL-01009                       | Both records matched on 'VL-01009'.    |
| match              | social        | [REDACTED]                     | [REDACTED]                     | Selected '1' from MDM as only rec...   |
| match              | licenseNumber | LN-34234                       | LN-34234                       | Both records matched on 'LN-34234'.    |
| match              | country       | US                             | US                             | Both records matched on 'US'.          |
| match              | version       | Version                        | Version                        | Both records matched on 'Version'.     |

|                  |                        |  |     |
|------------------|------------------------|--|-----|
| 95% Global Merge |                        |  |     |
| auto_merged      | Jul 02, 2025, 14:07:34 |  | 95% |
| auto_merged      | Jul 02, 2025, 14:07:34 |  | 95% |
| auto_merged      | Jul 02, 2025, 14:02:06 |  | 95% |
| auto_merged      | Jul 02, 2025, 14:02:06 |  | 95% |

## Key Features | Multi-Agent Collaboration for Data Match Review

- STAR AI Match Review interface highlights records requiring human in the loop validation
- Clearly explains why auto-merge was not executed, citing specific rule violations or field discrepancies
- Empowers data stewards with contextual insights and comparison between conflicting policies
- Leverages STAR AI Assistant to suggest next-best actions or reference similar historical decisions
- Ensures transparency, traceability, and auditability in complex entity resolution workflows
- Supports threshold-based routing logic, auto-triaging matches into Merge, Suspect, or No Match



**STAR AI FOR DATA QUALITY & INSIGHT MANAGEMENT**

Dashboard | **Match Review** | Match Log

**Matches 2**

Select a Match below to start analysis. Conf: 95 Clear Filters

| Match ID                                   | Profile 1 ID | Profile 2 ID | Rule Applied                                                                                                                             | Confidence Score | Source System | Review Required | Match Result |
|--------------------------------------------|--------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------|-----------------|--------------|
| <input checked="" type="checkbox"/> M-4002 | E015         | E016         | Manual review needed due to significant differences in Name, Specialty, and AddressLine1. Multiple address and specialty values present. | 70%              | Veeva         | Yes             | No Match     |
| <input type="checkbox"/> M-4001            | E013         | E014         | Manual review needed due to differences in FirstName, Specialty, AddressLine1, and multiple emails in Profile1.                          | 85%              | Veeva         | Yes             | No Match     |

**Profile Comparison**

| Confidence | Field        | Profile 1                              | Profile 2                            |
|------------|--------------|----------------------------------------|--------------------------------------|
| No match   | profileId    | E015                                   | E016                                 |
| No match   | sources      | Veeva                                  | VCO                                  |
| No match   | firstName    | 张新                                     | 张新                                   |
| No match   | lastName     | 张                                      | 张新                                   |
| No match   | specialty    | Cardiovascular Medicine Chest Medicine | Surgery - Thoracic                   |
| No match   | addressLine1 | 台北市北投区石牌路二段201号                        | 台北市北投区石牌路二段200号 台北市北投区石牌路二段201号      |
| 70%        | addressLine2 | 台北市北投区石牌路二段201号, 台北市, 北投区112, Taiwan   | 台北市北投区石牌路二段201号, 台北市, 北投区112, Taiwan |
| No match   | veevaId      | V015                                   | V00012                               |
| No match   | veeId        |                                        | V00012                               |

**STAR AI ASSISTANT**

Get all the top with first name Katherine in snowflake

| First Name | Last Name | Title | Specialty       | Organization        |
|------------|-----------|-------|-----------------|---------------------|
| Katherine  | Wang      | Dr.   | Cardiology      | City Hospital       |
| Katherine  | Wang      | Nurse | Pediatrics      | Green Valley Clinic |
| Katherine  | Wang      | Dr.   | Oncology        | Metro Health Center |
| Katherine  | Wang      | Dr.   | Family Medicine | Lakeside Medical    |
| Katherine  | Wang      | Dr.   | Neurology       | Downtown Medical    |

Ask a question...

## Typical Deployment Timeline (8-10 Weeks)\*



### Cross-functional team including:

- AI Solution Architect
- Data Integration Specialist
- Compliance Advisor
- UX Designer
- DevOps Engineer

### Assumptions and Dependencies

#### 1 Setup and onboarding: Environment access prior to project kickoff

- Asset will be deployed in one development environment and availability zone
- Azure resources provisioned
- Required knowledge store finalized

IBM development team onboarded to environment within first week of project

#### 2 SME time commitment: SME input needed:

- Data set knowledge
- As is process and expected results
- UI validation

SME feedback within three (3) business days

#### 3 Base deployment:

- Will cover core base features of the app within 8-10 week MVP
- Following query types will need additional development effort
  - Tool integration like raising ticket in workflow tool like service or any other type of integration with external API
  - Hyper personalization by connecting to user data
  - Queries based structured data sources like data base
  - Complex queries which require custom calculation before responding to user question

\*Azure landing zone services provisioned or readily available