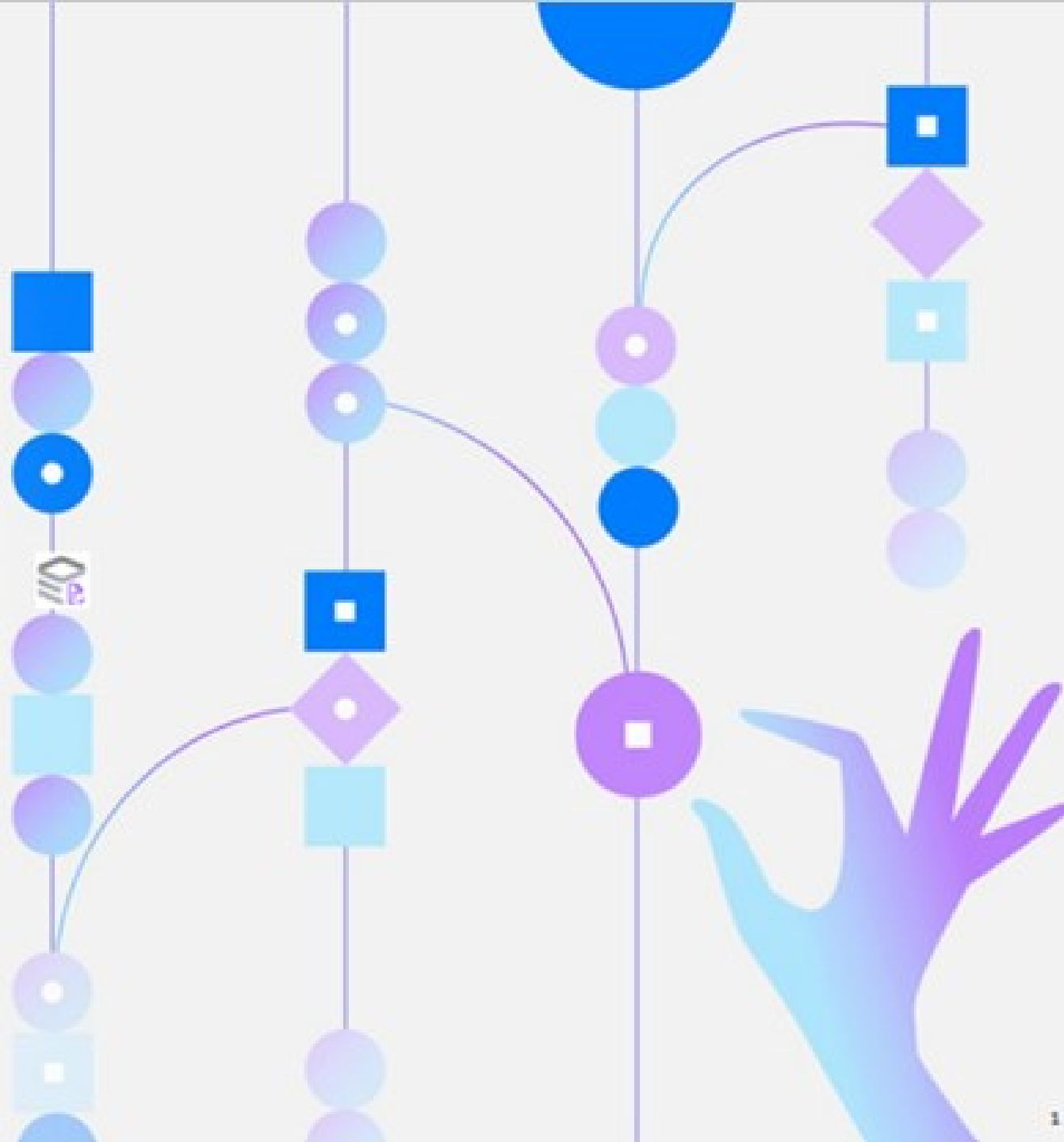
STAR Agentic AI
For HLS

# 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.

# STAR Agentic AI For HLS

## 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 Insight Generation
- Data Quality & Insight Management

### Capabilities

**Agentic AI Orchestration**
Coordinates multiple domain-specific agents for PV, PQC, and MDM to automate safety and quality workflows at scale.

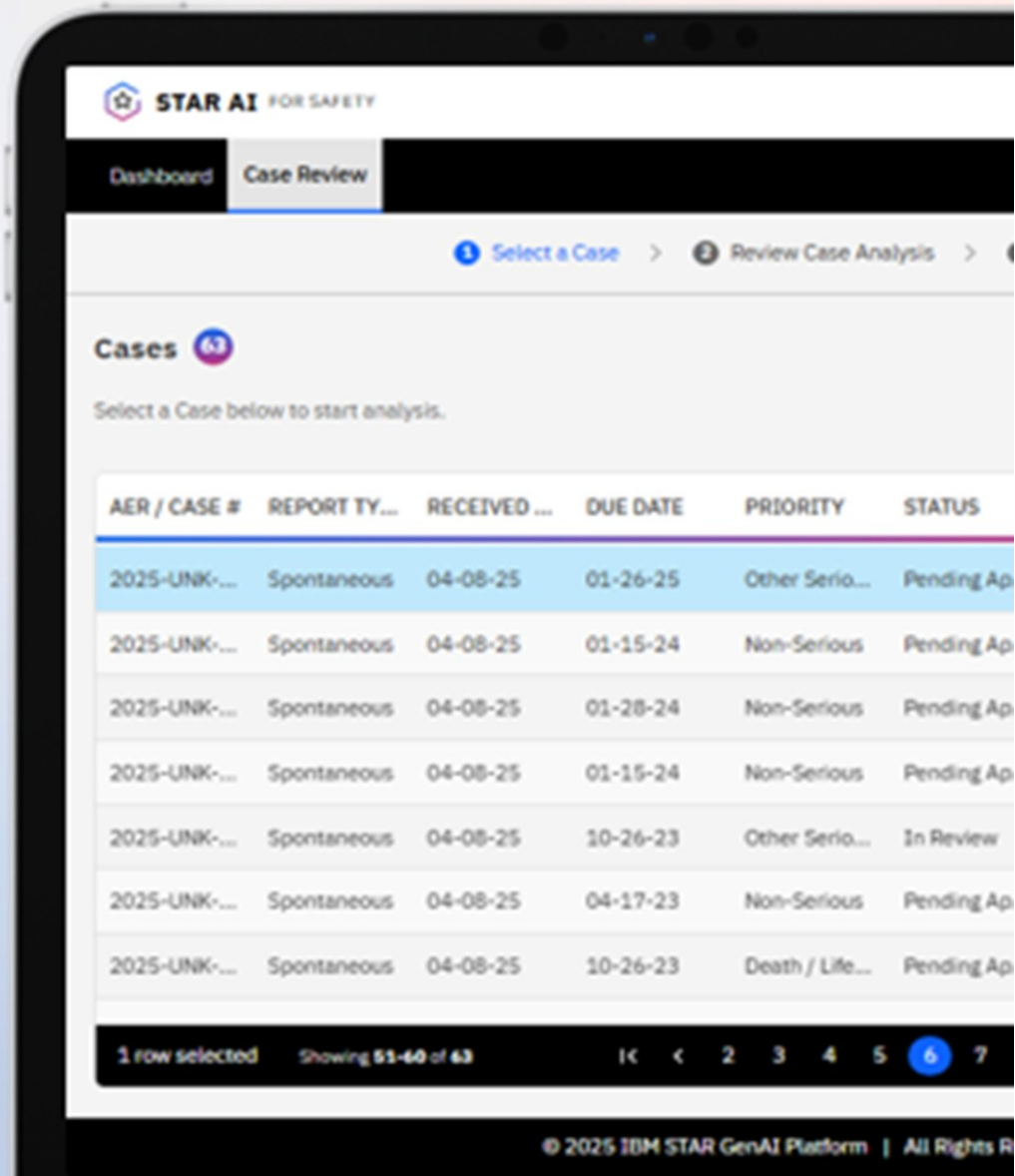
**Contextual Automation**
Processes unstructured inputs with regulatory, medical, and operational awareness for precise, auditable outputs.

**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.



STAR Agentic AI
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# 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

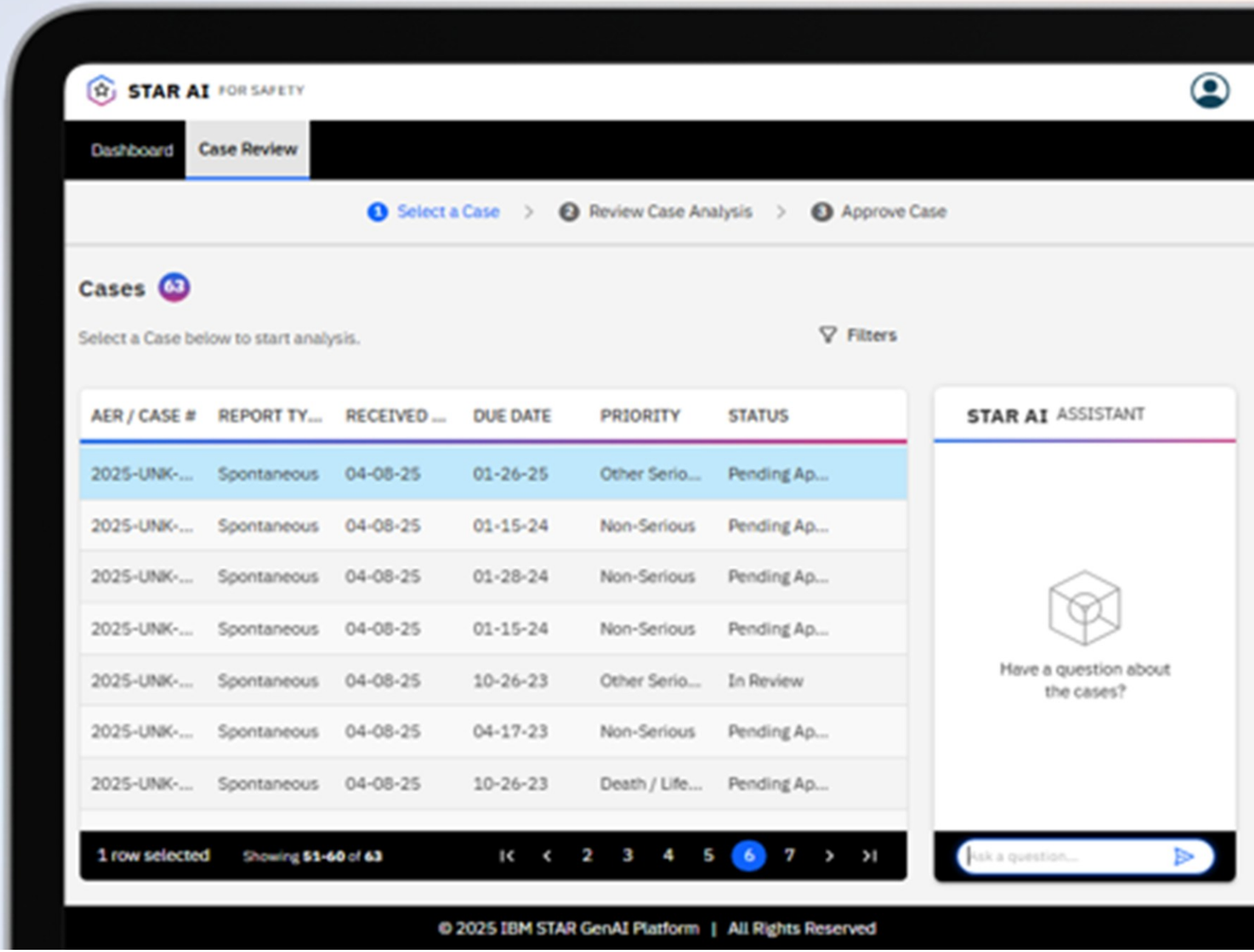
# STAR Agentic AI For HLS

Related Use Cases: AI for Safety Adverse Events

Product Quality Complaint Automation

## 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)



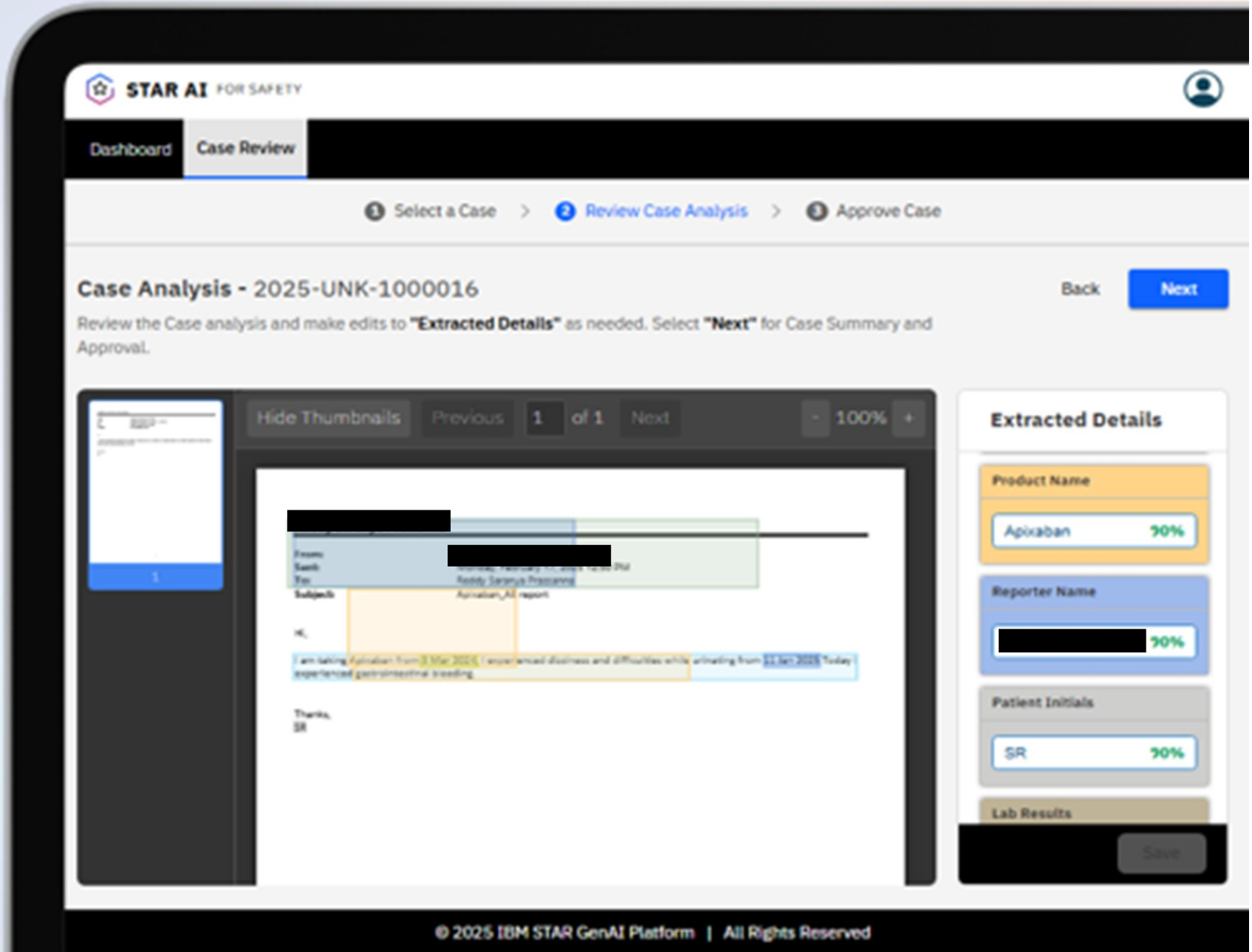
# STAR Agentic AI For HLS

Related Use Cases: AI for Safety Adverse Events

Product Quality Complaint Automation

## 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



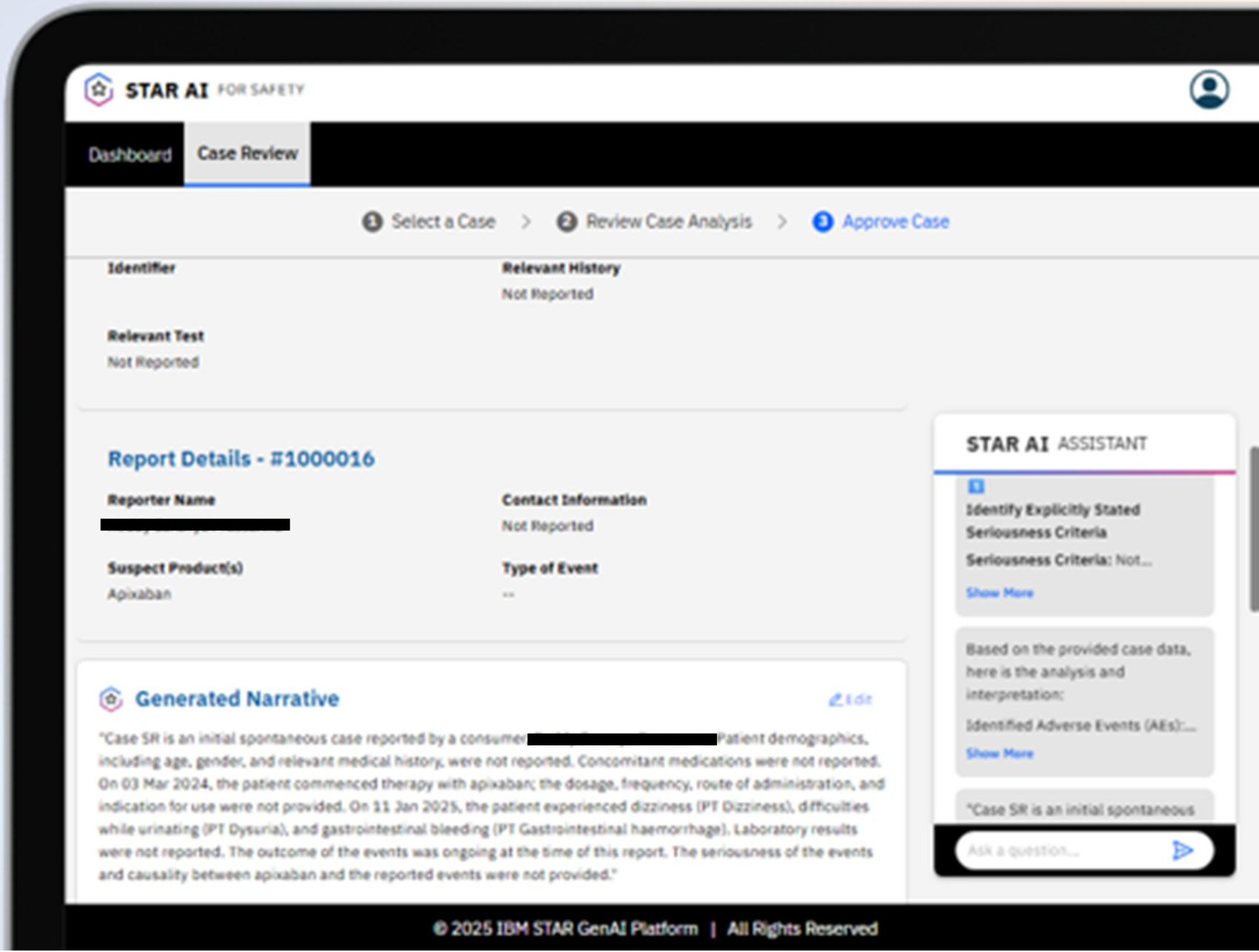
# STAR Agentic AI For HLS

Related Use Cases: AI for Safety Adverse Events

Product Quality Complaint Automation

## 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, queryable insight flow for research teams and medical affair



# STAR Agentic AI For HLS

Related Use Case:
AI Medical Insight Generation

## Key Features | **Real-Time Medical Insight Curation & Decision Support**

- 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
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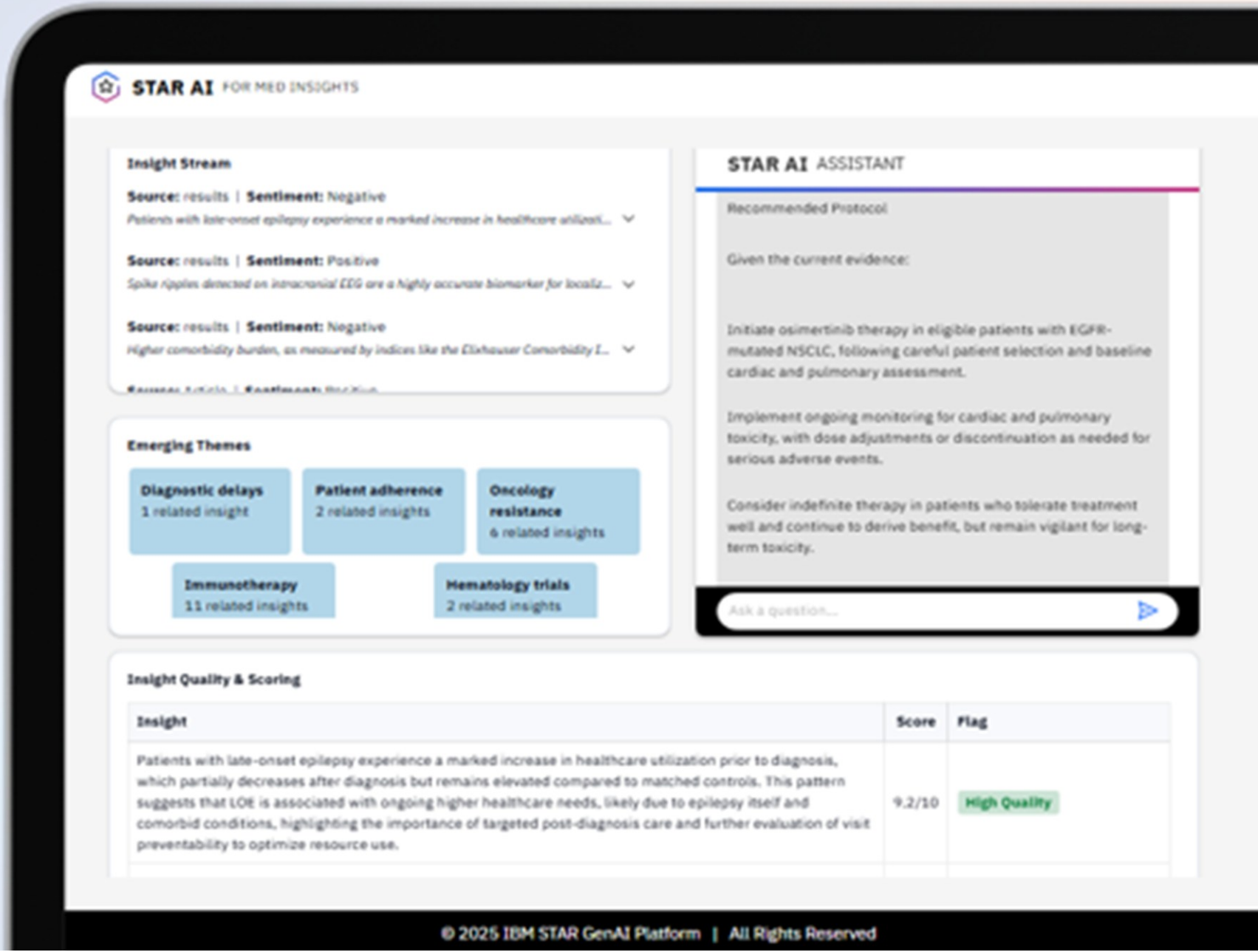


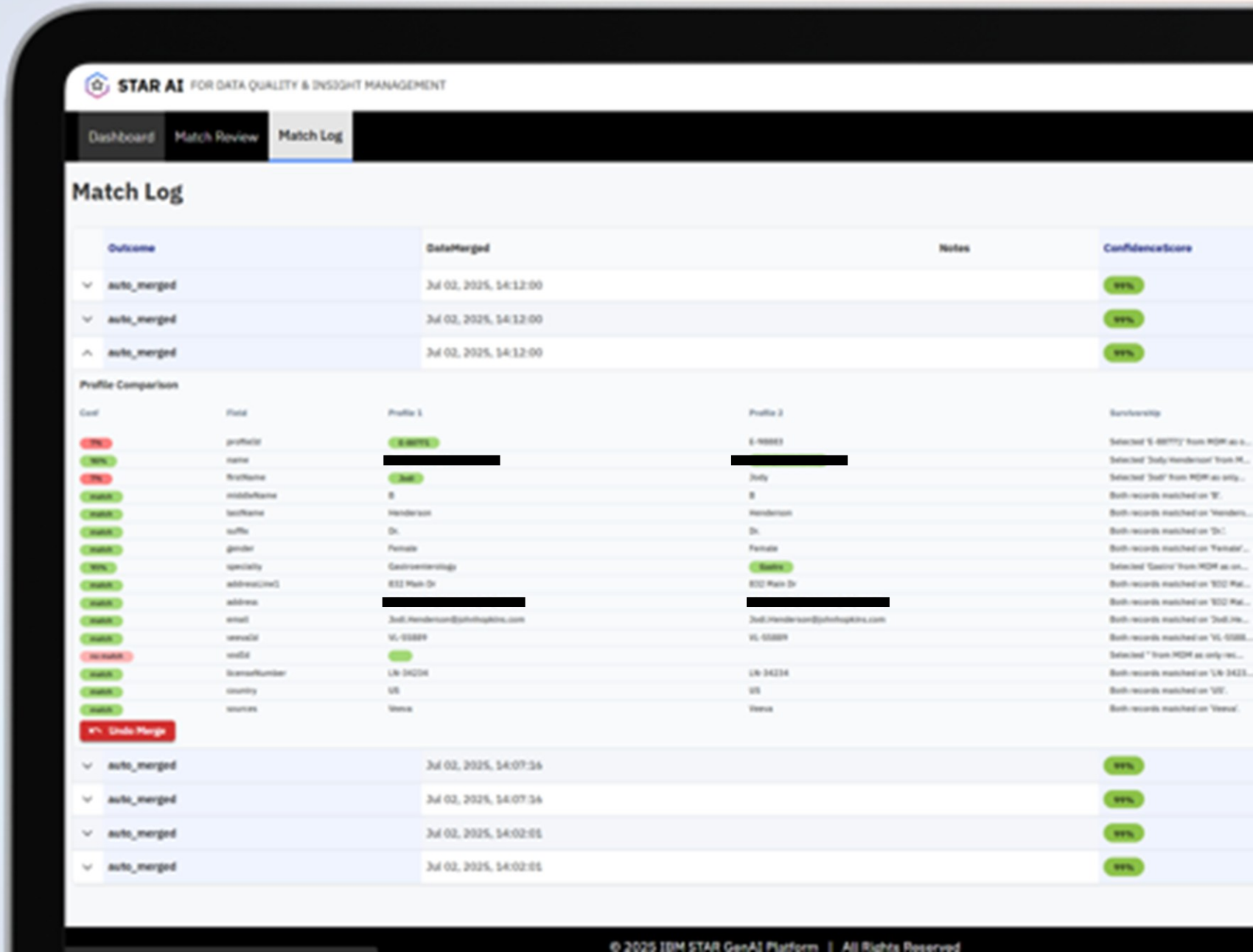
# STAR Agentic AI For HLS

Related Use Case:

Data Quality & Insight Management

## Key Features | **Auto-merged Matches**

- Automated Golden Record creation power by STAR AI's agentic flow logic.
- High-confidence auto-merge decisions (=> 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.

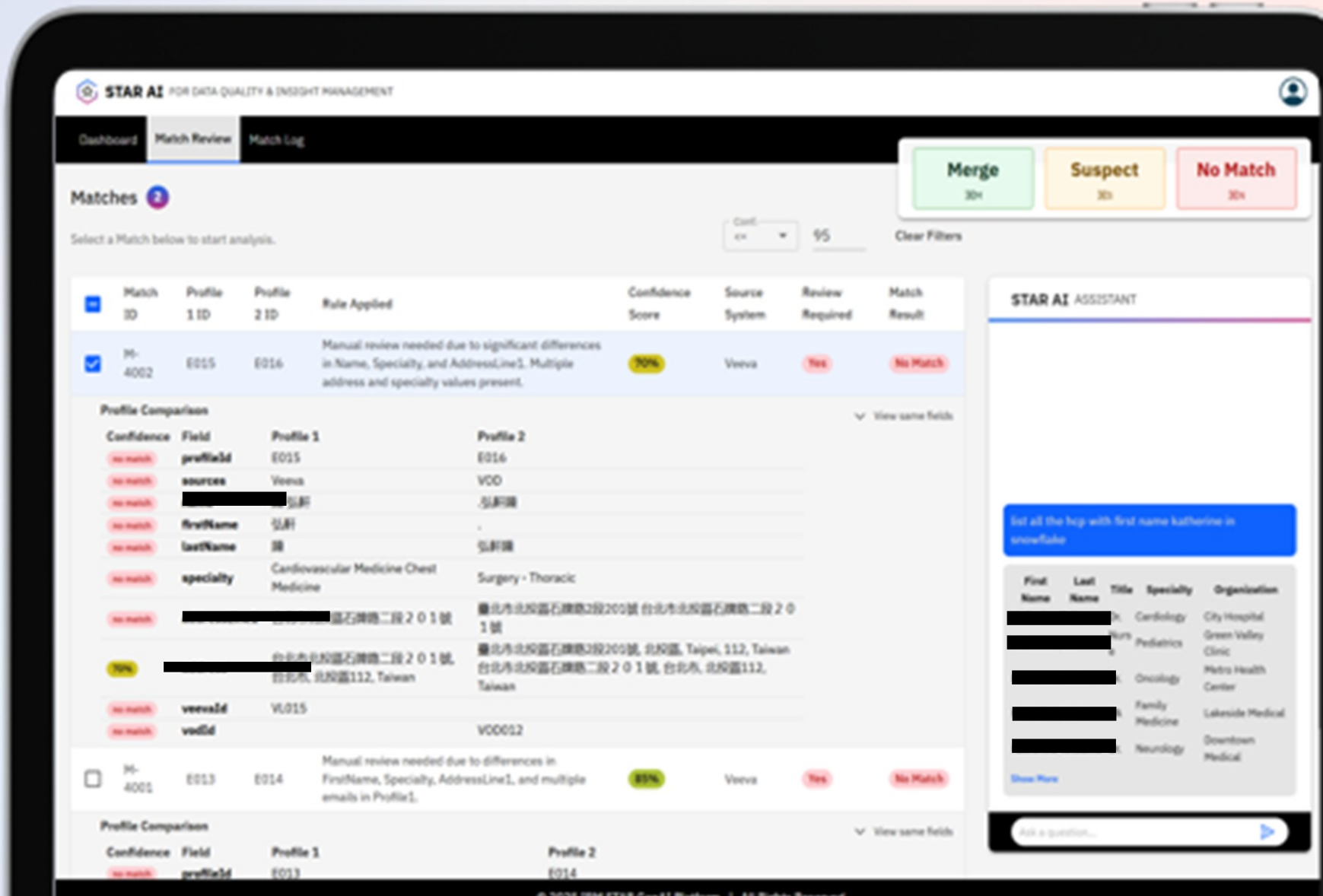


# STAR Agentic AI For HLS

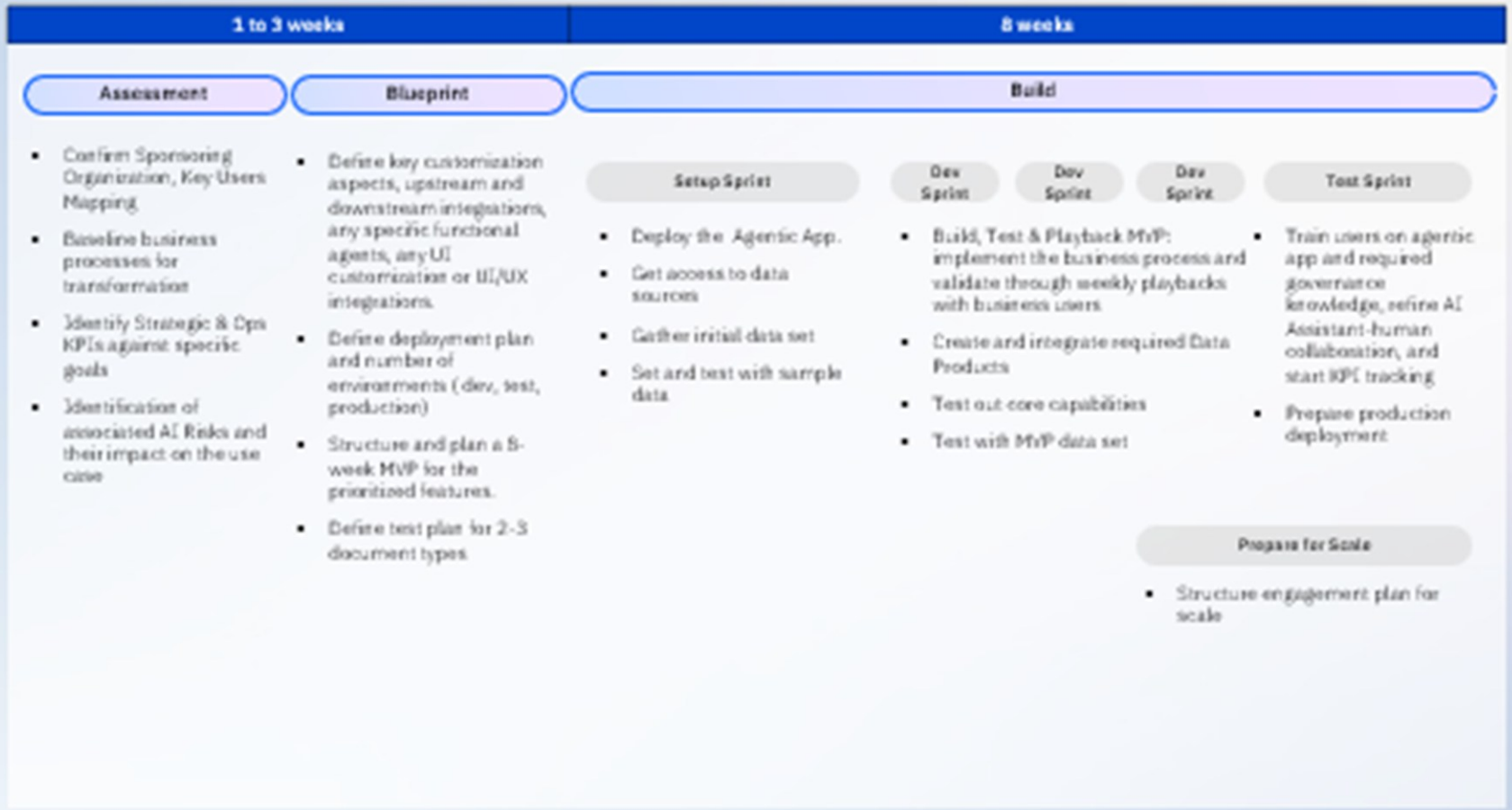
Related Use Case:
Data Quality & Insight Management

## 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



# 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