MarkLogic®

SOLUTIONS

The Operational Data Hub for Pharmacovigilance

A Faster Way to Detect and Evaluate Safety Signals for Adverse Events

In the pharmaceutical industry, adverse events can arise at anytime in a drug's lifecycle with consequences ranging from damaging to devastating. Once an adverse event is detected, immediate action is required to protect patient safety and meet regulatory mandates for timely reporting. But, with disconnected data silos, separate warehouses for analytics and operations and the use of inflexible data technologies that require extensive data-modeling processes, it can take months to draw critical insights from the massive volume and variety of available safety information. With 328,000 deaths per year being attributed to adverse drug reactions in the United States and Europe alone,[1] it's clear that the pharmaceutical industry needs a faster approach to data integration and analysis to advance drug safety, ensure patient outcomes and maintain regulatory compliance.

How Data Silos Undermine Drug Safety Surveillance

Slow Signal Detection

Multi-structured drug-safety data is stored in disconnected repositories across the enterprise—making it difficult to efficiently integrate and analyze it for insights.

Cumbersome Compliance Processes

Post market, drug manufacturers have a maximum of 15 days to report unexpected adverse events to the FDA. But, with the high volume and wide variety of published safety literature, it's difficult to detect and report adverse events within the regulatory timeline.

Lack of Data Governance

Pharmacovigilance requires that drug manufacturers have the capability to confidently address issues with data governance, including provenance, lineage, traceability, timeliness, completeness and accuracy.

> "We determined that NoSQL would be best to address our agility and metadata needs, and MarkLogic's search, semantics and security features made it optimal to serve as the foundation for the next generation of our catalog."
>
> — Senior IT Manager, Fortune 50 Pharma

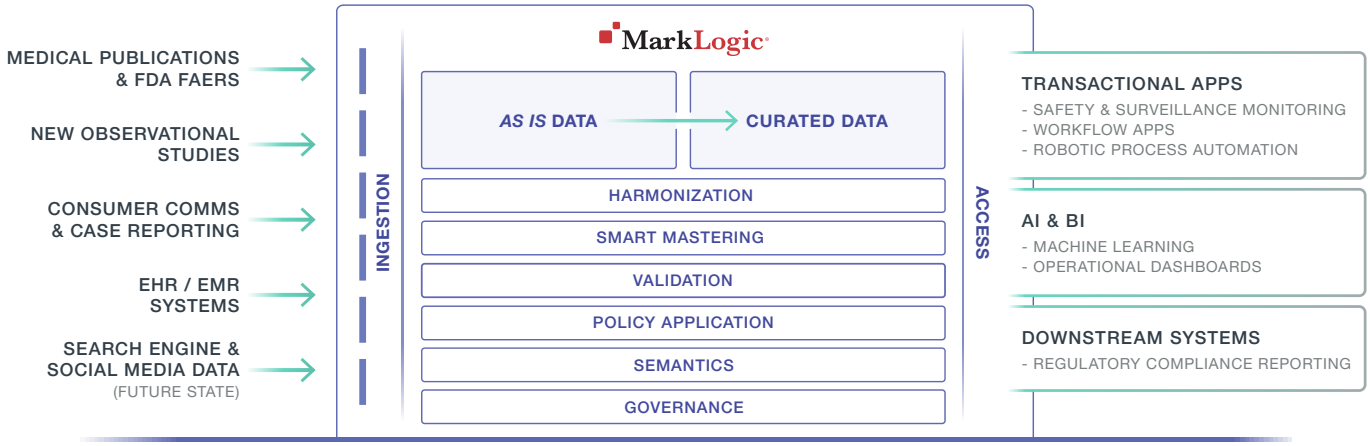
Achieve a Complete View of Drug Safety Data in Less Time

To support objectives around signal detection, safety risk management, labeling accuracy and regulatory compliance, pharmas need more than analytics tools and data lakes that lack in governance—they need secure access to high-quality data and the ability to accelerate development of actionable information.

MarkLogic® responds to these requirements by deploying an Operational Data Hub (ODH) that enables pharmas to leverage all of their data on an enterprise-ready platform that accelerates signal detection for adverse events and across the pharmacovigilance practice. The ODH provides a single source of truth across all sources of drug data and metadata, serving as a trusted record of critical information.

1 Harvard University, Edmond J. Safra Center for Ethics, New Prescription Drugs: A Major Health Risk With Few Offsetting Advantages, https://ethics.harvard.edu/blog/new-prescription-drugs-major-health-risk-few-offsetting-advantages

MarkLogic®



The operational data hub for drug safety surveillance

By enabling up to10X faster data integration, from both traditional and emerging sources of data, MarkLogic's operational data hub technology enhances detection of adverse events at every point in the drug lifecycle—from clinical trial through post-market—empowering pharmas to avoid regulatory roadblocks, costly fines or worse, while protecting their reputations with both patients and regulators.

MarkLogic is a database platform built with a flexible data model to quickly ingest, manage and search multi-structured information generated from a variety of data sources without sacrificing the data resiliency and consistency features of relational databases. With these core enterprise capabilities and advanced features such as semantics and smart mastering, MarkLogic enables pharmaceutical organizations to accelerate time-to-insight and quickly report safety-related events to regulatory authorities.

Pharmaceutical Companies Succeed With MarkLogic

- AbbVie stores, integrates and links R&D drug information from across five data repositories onto one searchable platform.
- A Fortune 50 pharma built a metadata catalog on MarkLogic in just six months to accelerate development of RWE.
- Amgen is efficiently connecting data from across the supply chain, unlocking knowledge to improve lane carrier operations and ensure compliance.

Experience the MarkLogic Difference

MarkLogic gives pharmaceutical organizations the ability to streamline operations and speed up the time-to-insight in pharmacovigilance practice. As the world's best database for integrating data from silos, MarkLogic's platform solutions empower our pharmaceutical customers to achieve a complete and actionable view of data at less time and cost.

Visit www.marklogic.com to find out how leading pharmas across the globe are driving better performance with MarkLogic.

MARKLOGIC CORPORATION
999 Skyway Road, Suite 200 San Carlos, CA 94070
+1 650 655 2300 | +1 877 992 8885 | www.marklogic.com | sales@marklogic.com