



MANAGING DRUG SAFETY ACROSS GLOBAL PARTNERSHIPS

AUTOMATING PHARMACOVIGILANCE AGREEMENT MANAGEMENT

A PEGA LIFE SCIENCES CASE STUDY



Pfizer Inc., a biopharmaceutical company that discovers, develops, manufactures, and sells healthcare products worldwide.

Business Goals

- Track lifecycles for Pharmacovigilance Agreements (PVAs)
- Capture operational data from PVAs
- Increase efficiency of tracking PVA commitments
- Provide real-time reports and alerts
- Reduce budget and improve timeliness of PVA related activities

Results

- Managing PVAs for 5,800 Products across 500 partners
- Reduced reporting efforts from 5 days to a half-day
- Eliminated manual tracking of Periodic Reviews
- Improved ability to demonstrate compliance and support audits

Reduced 90% of administrative work for report preparation, and eliminated manual tracking for periodic reviews.



Vision: Automated Oversight of Pharmacovigilance Activities

Like all pharmaceutical companies, Pfizer is responsible for constant and comprehensive oversight for the safety of their products. This responsibility extends even to where contractual agreements exist between Pfizer and their global partners. From a practical perspective, this means that Pfizer needs to manage Pharmacovigilance Agreements (PVAs) between them and their hundreds of global partners, as well as any safety monitoring activities defined by those PVAs for thousands of products worldwide. Strict regulatory oversight from health authorities and frequent reporting and audit requirements means that Pfizer also must be able to provide transparency and complete auditability.

Execution: Rapid Delivery of an Integrated Solution

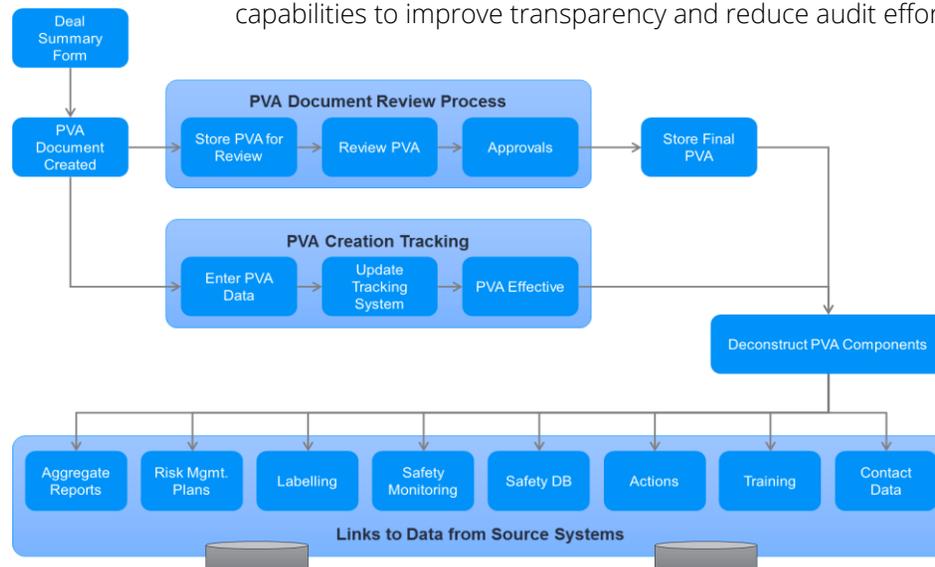
Pfizer leveraged Pega's industry-leading Business Process Management and Dynamic Case Management, along with Pega's Pharmacovigilance application to deliver their Pharmacovigilance Exchange (PVX) solution in less than four months. Pfizer's rapid deployment was facilitated not only by Pega's Direct Capture of Objectives, but also by Pega's patented Situational Layer Cake, which enabled the reuse of many of Pfizer's existing components from other Pega solutions throughout Pfizer, reducing development efforts by an estimated 30%.

Outcome: Pega Improves Efficiency and Supports Compliance

The PVX application has reduced or eliminated a significant amount of manual work for Pfizer. It starts with the creation or import of a PVA. The lifecycle of each PVAs managed within Pega, including creation, review, approval, and updates. PVA milestones are automatically tracked with notifications and alerts for key dates. This alone improves transparency and compliance, but it's actually the second component of the application that delivers the most innovation and value.

Automated Pharmacovigilance Activities Tracking

Once a PVA is active, PVX captures the structured details about each activity – Aggregate Reports, Risk Management, Label Updates, etc. It defines who is responsible for what activity, along with any deadlines or systems involved. Pega then tracks each activity, alerting when activities are due, and accessing on-demand data from Pfizer's other PV systems. Lastly, it includes comprehensive reporting and audit capabilities to improve transparency and reduce audit efforts.



ABOUT PEGASYSTEMS

Pegasystems develops strategic applications for sales, marketing, service and operations. Pega's applications streamline critical business operations, connect enterprises to their customers seamlessly in real-time across channels, and adapt to meet rapidly changing requirements. Pega's Global 500 customers include the world's largest and most sophisticated enterprises. Pega's applications, available in the cloud or on-premises, are built on its unified Pega 7 platform, which uses visual tools to easily extend and change applications to meet clients' strategic business needs. Pega's clients report that Pega gives them the fastest time to value, extremely rapid deployment, efficient re-use and global scale.

