

PEGA PHARMACOVIGILANCE

Reduce adverse event and product complaint management costs and improve visibility for patient safety and regulatory compliance.

A PEGA DATASHEET

Smarter, Reliable Adverse Event Management

Life Sciences companies require complete control and visibility of their adverse event (AE) and product complaints, ranging from intake and analysis to reporting and partner activities. Pega enables Life Sciences organizations to connect all aspects of AE and complaint management, enabling process efficiency improvements, overall cost reduction and reduced risk.

Pega delivers a truly reusable adverse event management application that streamlines submissions, easily accommodates unique requirements by regulatory agency, product line or any other business factor, and delivers the agility needed to rapidly adapt to regulatory, risk management, or labelling changes. Pega PV also supports processes beyond the conventional safety system – such as managing Pharmacovigilance Agreements (PVAs) and the related activities and responsibilities of business partners. Life Sciences companies can benefit from the following advantages:

- **Maximize the return on the investment**
With Pega's flexible Build for Change® technology, business-friendly process modeling tools capture AE case management requirements directly into the system creating reusable components so that new products, compliance rules, operational processes and regulations can be deployed with shorter delivery times, improved product quality and lower development costs. Your solution can be readily changed and adapted to accommodate a dynamic regulatory environment.
- **Scale efficiently and reduce operational expense**
Pega's award-winning enterprise process and business rules engines orchestrate and automate AE case management, eliminating error-prone manual handoffs and rework while scaling efficiently to offer complete front-to-back-office work automation.
- **Leverage existing technology**
Fast, easy and secure integration to multiple enterprise and partner systems extend the use of enterprise data to fully automate AE processes dynamically managed with business activity dashboards, reports, and automated alerts.

Pega's comprehensive platform eliminates duplicative and manual efforts to improve efficiency in pharmacovigilance operations, reducing per-case processing costs through automation and integration, while helping you better manage patient safety through improved visibility and control.

CHALLENGES

Growth in business volume, mergers and acquisitions, new data sources like social media, outsourcing, and changes in regulatory requirements all create significant challenges for the conventional approaches and software used to manage adverse events and product complaints.

SOLUTION

Pega delivers a unique and comprehensive Pharmacovigilance application that combines process and decision-based technology to create a flexible, reusable adverse event case management and product complaint environment. Rapid configurability and flexibility address changing global regulatory requirements. Automated and configurable business rules ensure compliance while simplifying process efficiency. Out-of-the-box processes speed deployment, but unlike conventional PV solutions, the Pega platform enables a high degree of flexibility and extensibility through built-in integration support.

Reducing Costs by 45%

To help a leading Contract Research Organization comply with global regulatory requirements and meet customer demands, Pega delivered a pharmacovigilance management solution supporting multiple customers from various regions with diverse requirements within a single environment. The solution simplified maintaining regulatory compliance and reduced the manual efforts associated with the review, approval and submission of adverse events consequently lowering costs by 45%.

Enhance Efficiency

- Automated guidance provides users assistance throughout the complex AE case process, reducing training time and helping drive work to completion.
- Deploy skill-based routing of cases to manage multiple languages, regulatory, and product specialties automatically, selecting the best resources for the task.
- Simultaneously support multiple product types (e.g. drugs & devices), deadlines, and reports in a single case, and manage higher level tasks like signal detection and risk profile management activities across products.

Increase Business Agility

- Pega's build once and re-use everywhere capabilities allow Life Sciences companies to integrate Pega PV in solutions leveraged by care providers, call centers and other channels – including social media and mobile devices – without customization.
- Responsive data capture and intelligent case assessment with dynamic questionnaires that automatically adapt for a specific product type, region, and risk profile.
- Improve case handling to support processes outside of the core PV system (e.g. CAPA, Partner Agreements) and other activities not managed by typical safety systems.
- Pega automates the application of regulatory reporting rules and product specific factors for deciding what cases need to be reported and to which regulators, in which format and under what deadline.

Pega PV Features

- Inbound** – Automates data capture and triage with dynamic questionnaires that adapt for a specific product type, region, and risk profile. Pega can automatically pass data from Pega to PV systems via E2B or other built-in integration methods.
- Outbound** - Automates the generation of safety reports and distribution of global reports and submissions to affiliates, business partners, regulators and other interested parties. Pega can automatically collect AE case data from other PV systems via E2B or other integration methods to do automated, rules-based (e.g. labeledness/seriousness/locale) report generation, distribution, affiliate review, and submission for E2B (M2/R3), eMDR, MedWatch, and CIOMS.
- Integration** – Pega automates the movement of data between systems. Pega acts as an integrated process orchestration layer by pulling and pushing data to and from systems of record as needed, letting processes, not system boundaries direct the flow of work. These other systems can include not only safety systems, but other data sources, social media, Optical Character Recognition (OCR), and Natural Language Processing (NLP).
- Case Management** – Pega simultaneously support multiple product types (e.g. drugs & devices), deadlines, and reports in a single case, and manage higher level tasks like signal detection and risk profile management activities across products. Pega Case Management collects structured and unstructured data, source document, and related artifacts virtually within each case, leveraging external repositories for content/document management as needed.

