

Pharmacovigilance Pressures Demand Transformative Technology

The demands on Pharmacovigilance (PV) organizations are increasing as health authorities seek to reduce exposure to medications where risk outweighs benefit. Commercial life science companies are confronted daily with multiple inputs that require analysis and response to minimize risks associated with approved medical products. Clear information and rapid, collaborative input is required to make appropriate decisions, but most PV organizations cannot quickly get the necessary information and input, putting companies at undue risk. Why does this happen? Heavily siloed data, limited integrations, inconsistent standards across geographic boundaries and therapeutic categories, unreliable and highly variable processes, and complex, non-harmonized global regulations.

The net result is PV professionals forced to work in inefficient and disjointed ways. There exists too much manual effort and re-entry of data in places where automation should reign. For example, in most organizations, e-mail becomes the default collaboration tool, but rarely are all the right people included in a given discussion. Data required for regulatory reporting purposes is generally maintained in complicated excel spreadsheets, making it difficult to control versions and quickly produce regulatory submission forms. These approaches have several things in common, and none of them good: increased risk of errors, lack of transparency and insight into the process, and limited analytic capabilities. Not surprisingly, PV professionals waste hundreds of hours just trying to complete basic tasks.

HOW PV ORGANIZATIONS SHOULD FUNCTION – IF THEY HAD THE RIGHT TECHNOLOGY

Pharmacovigilance requires reaction, clear oversight, and rapid action. New signals continuously emerge and must be adjudicated quickly. Managers need visibility to the full volume of activity to quickly spot trends and raise alerts. People who can provide relevant information should be automatically made aware of situations where they can contribute, whether or not others think to include them in e-mail communications (or even know who they are). Issues that require reporting to the various regulatory bodies must be completed in the format each regulator

requires without a huge manual effort. Necessary labeling changes must be moved through the system with great speed. The costs of not having ideal collaboration and fast-moving information are great. PV staff inefficiency is extremely costly; most are highly trained doctors and other professionals with advanced degrees. Safety signal information not handled appropriately and not reported in a timely manner exposes the organization to regulatory fines. Information received but not properly researched or used exposes the company to potential litigation. Effective technology that ensures proper movement of information while maximizing collaboration can make an enormous difference.



THE APPIAN PLATFORM: THE NEW BACKBONE FOR PHARMACOVIGILANCE

Appian is an application platform that allows organizations to create their own process- and data- based apps and integrate them with existing IT systems. Appian has roots in business process management (BPM) and has greatly expanded those concepts to include native mobile access, process-based collaboration, and unified records. Life sciences companies are using Appian technology to automate their unique processes and streamline everything from knowledge management in clinical research, to FCPA and Sunshine Act compliance, to clinical trials. The most advanced life sciences companies are using Appian as an interface to a variety of existing apps, as well as a platform for developing new apps that eliminate the gaps that cause manual work.

Here are some of the specific ways using Appian can positively impact operations in your pharmacovigilance organization:

Rapid Signal Adjudication and Reporting

Dramatically reduce the time from signal detection to characterization to adjudication. Minimize manual activities, duplicate entries and reduce risk of errors or inaccurate data through process automation. Automate the import of safety information coming from multiple sources suitable for regulatory reporting purposes (PSUR, DSUR, etc).

Automate PV Task Management

Appian apps can be created to eliminate “white spaces” between existing IT systems that PV teams use. These white spaces result in manual work processes which are difficult to track and impossible for managers to see clearly. Appian provides complete audit trails and automatic software documentation to mitigate organizational risk.

Increase PV Activity Visibility

With all work processes tracked and managed, providing a 360-degree view of all PV activity requires just a simple report, viewable from any mobile device just as easily as from a computer screen. This provides executives any-time insight to identify process inefficiencies and bottlenecks. Users can drill down through reports to see more detail and be better informed on the spot.

Standardized PV Processes with Local Variations

Our flexible modern Work Platform allows organizations to have a single interface to enforce efficient processes and SOPs across multiple geographies and therapeutic areas, with the ability to customize for unique local situations. Business rules are enforced and exceptions are documented.

Enhance Collaboration

Enable process steps to trigger notices to Appian’s News feed so PV event and/or notice information is automatically pushed to those who need it, all in an intuitive, collaborative interface with no need for email. The same interface can be used to gather knowledge and take direct action, speeding up cycle times.

Unified Records of any PV Element

Information from multiple systems is converged into a single unified record in the Appian interface, greatly reducing time and effort for users need to find valid, useful information.

Appian is uniquely positioned to provide the technology solutions PV organizations need to stay ahead of increasing demands and changing requirements.

Appian

Appian provides a leading low-code software development platform that enables organizations to rapidly develop powerful and unique applications. The applications created on Appian’s platform help companies drive digital transformation and competitive differentiation.

For more information, visit www.appian.com