Appian

# A Platform Approach to Safety Signal Management

## SOLUTIONS FOR PHARMACOVIGILANCE AND THE LIFE SCIENCES PRODUCT LIFECYCLE

By Evi Cohen

Life sciences companies need to deliver to market safely and securely through a time sensitive, regulatory-intensive environment and across a process-driven product lifecycle. Further, they are required to guarantee continued safe and efficacious supply of their product as long as it is marketed. The governing regulations also require sponsors to maintain a safety and surveillance program in support of safe and efficacious supply.

Monitoring for and identifying safety signals is intricate, data intensive and arduous. Managing the process of adjudicating identified signals is not much simpler. Various specialized technology solutions have been established over the years and leveraging more recent platform technologies can help simplify how life sciences companies meet the challenges.

Appian has experience designing and building pharmacovigilance solutions for some of the the largest multinational pharmaceutical companies, helping them get their products to market faster, while navigating the complex roadmap of government regulations.

The Appian low-code application development platform works across the product lifecycle, from inception through research and clinical trials and finally to the distribution to patients and the follow up that ensues. And that's just a simple look at what it takes to get a product to market, Appian is a vital tool along every step of the way to bring pharmaceuticals safely into the hands of the people who need them.

Appian's single, unified digital platform approach with speed and ease of implementation and rapid application deployment is being selected over packaged point solutions for pharmacovigilance initiatives for the following reasons:

- **Software fits process** – the business has complete flexibility to design a solution that both meets regulatory requirements and accommodates the specific use case of your organization helping your PV group excel over other PV shops

- **Configurable low-code** – development of the solution is performed on a low code platform that relies mostly on configuration of a wider array of objects rather than coding

- **Simple user interface** – clean, unified and intuitive user interface that requires very little training.

- **Unlimited applications** – Appian provides you with a platform, and not just a point solution. This means that you have the flexibility to continue expanding and building out additional connected solutions

- **Cloud based** – minimizes project risk by limiting upfront capital investment and allows your organization to focus on core business

- **Social Enterprise** – Appian's solutions include social enterprise capabilities connecting your organization and floating all current and timely news related to the specific business context

- **Mobile enabled** – with Appian there is no need to invest in mobile development. Our solutions are instantly mobile enabled on any mobile platform leveraging the native mobile UI

## RAPID DEPLOYMENT

Nothing can tell the story of **rapid deployment** of a GVP Module IX compliant Pharmacovigilance solution better than a head to head comparison. Recently, Appian indirectly participated in such a comparison when **two large multinational pharmaceutical companies went head to head in a public DIA Webinar** — GVP Module IX Compliant Signal Management Systems in Pharmacovigilance: A Tale of Two Experiences.

In this webinar, we heard the two firms compare their mutually exclusive, but somewhat parallel, experiences implementing a Module IX Compliant Signal Management System. One was implemented with Appian in 16 weeks, while the other chose another provider and went through an implementation that lasted 16 months, and their next steps were still to add reports, KPIs, and dashboards, while Appian's solution was already complete.

The table below provides a synopsis of the webinar Q&A:

## Recent Webinar Comparing Two Pharmaceutical Companies Sponsored by Drug Information Association (DIA)

| | Pharmaceutical Company A | Pharmaceutical Company B |
|---|---|---|
| Q | When did you go live and was your implementation already inspected by the FDA? | |
| A | We went live Nov. 2014. The solution was developed in 4 months or 16 weeks.<br><br>Not inspected yet. | Went live Apr. 2014. Took 16 months to develop.<br><br>Our affiliate PV sites were inspected, but not the system itself. |
| Q | BPM is not widely used for "Safety" applications yet, do you see other applications for these types of solutions? | |
| A | Risk management system is already in use, and we could see bringing in the labeling process | We are looking ahead to adding extra reports, KPIs, and dashboards.<br><br>We are evaluating bringing in Periodic Reporting as a new application. |
| Q | We heard it took Company B 16 months to develop the system. How long did it take Company A to develop using BPM? Why did you not go with a COTS? Did you use a partner? | |
| A | Vendor evaluation and selection took a few months, but we had the selected vendor, Appian, come in July, 2014, and we went live with the system Nov. 2014.<br><br>We opted for this type of a solution since it is more flexible and can be designed to better fit your purpose and process. COTS limit your options and require you to fit your process to the established software design.<br><br>We partnered with Appian Professional Services and also sent our folks to Appian designer courses. | |
| Q | What is the approximate number of products you currently handle with the system? | |
| A | We included our entire portfolio in the system about 100 products, both marketed and products in development. | About 80 products |
| Q | How many signals and risks are you handling with the system? | |
| A | Can't really disclose, but the system is capable of handling the desired volume | Same. We can't disclose this, but we have no capacity issues. |

## FIT FOR PURPOSE

Appian's low-code platform is uniquely fit for purpose in the pharmacovigilance space because of its solid dynamic case management roots coupled with best of breed Business Process Management (BPM) capabilities.

The unique requirements for meeting Module IX's highly prescriptive process steps are a great fit with Appian's BPM and Case Management solution. This fit stems from Appian's platform providing the system designer the ability to design and build an application that is capable of guiding each and all subject matter professionals along a highly prescriptive path, yet doing so with the feel of an "invisible hand." In other words, the process model built using Appian's unique process model designer results in a simple and comfortable experience for the users. This is an experience where the users are always provided with all the information they require at each step of their work, they are guided to the next step, and any actions available at each step are easily accessible and clear.

Appian's Safety Information Management System provides:

- A collaborative, cross-functional, centralized BPM solution
- Efficient and standardized signal management activities
- Easier access to information for decision makers, stakeholders and regulators
- Documenting signal detection, assessment, decision making and risk minimization actions
- Generates system alerts of assigned tasks, actions and decisions in real time

## SUITABILITY FACTORS

### Signal Detection & Identification

The activity of identifying new possible side effects, or an adverse event with a drug or medical device, relies heavily on big data capabilities and statistics.There are a set of industry standard tools and databases designed to meet the challenges of signal detection, mining for and collecting big data related to adverse drug events.

Appian is an excellent platform for handling the signals that are detected or identified. With a wide range of integration interfaces, Appian provides the flexibility to work in tandem with any software selected for signal detection and identification. Appian's software can initiate processes from events discovered in external systems. Using a database, web service interface (SOAP or REST), or, if necessary, a custom-built Java plug-in, Appian can listen for the event and initiate process based on the contents of the event. These connections can be designed to be bidirectional providing for strong feedback loops to existing systems.

### Signal Refinement

The process to refine a detected or identified Drug Safety Signal is where Appian's solution truly begins to show its power in comparison to other vendors on the market. Sifting through all signals and evidence available where possible, in the context of additional or different patient populations, additional or different sources of data and information, requires a meticulous and diligent process.

The process of Signal Refinement is strongly supported by solutions designed and implemented on the Appian platform. Signal Validation and Signal Analysis and Prioritization depend on close collaboration of subject matter experts, with a complete set of information at their disposal to facilitate rapid decisions that limit risk to the patient population.

Appian's simple interface, with a unique approach to marrying human and automated processes with the relevant data, facilitates solid and speedy decision making, while minimizing the risk of information getting missed or lost in the process.

Appian includes a sophisticated rules definition language that provides the mechanisms for automation of critical process steps reducing the risk of human errors.

**Automation**

Signal refinement involves various types of automated and human driven decision making. With Appian's fit-to-purpose applications, data associated with signals can be drawn from related systems as necessary. The gathered data can then be used in the evaluation. Automated rules implementing best practices and industry standards are used to guide processing of the most clear and basic cases. In the more challenging cases where human decisions are required, Appian presents all the relevant data to the decision maker permitting them to gather additional related knowledge all in the same place, without having to jump to other systems, and allowing them to focus on the most important part of their work and facilitating rapid, yet solid, decision making.

**Signal Evaluation**

This is the formal protocol driven approach using well-established data sources (Administrative data, EMR, Claims, etc.) to assess the biological and clinical significance of a detected Drug Safety Signal, with the goal of verifying sufficient evidence demonstrating the existence of a new potential causal association or a new aspect of a known association.

Signal Evaluation comprises Signal Assessment, the Recommendation of Actions, and possible further Exchange of Information. A strict formal protocol driven approach is applicable here, and similar with Signal Refinement, it can benefit from a strong process and rules based approach supported by the Appian Platform. The processes designed using the platform guide the knowledge workers through the desired prescribed steps. This is achieved in a way that is transparent to the user, yet provides strong adherence to the prescribed protocols.

Using Appian's approach, you will benefit from efficiency and standardization:

- Source and product agnostic
- Leverage content for push button reports:
  - PSUR/PBRER Sections 15, 16.2
  - Bi-weekly QPPV reports
  - Signal Summary Report (SSR)
  - Full Signal Assessment Report (SAR)
  - PvNet Benchmarking
  - Process Metric Dashboards

The Appian Pharmacovigilance approach includes:

- Flexible workflow tool to fit process
- User group specific permissions
- Configurable reports: Excel, MS Word
- Process data metrics: Dashboards
- Robust audit trail and data archive: Full audit trail, document archive, disaster recovery

## REDESIGN

The benefits of utilizing the Appian platform for building your Signal Management Process include:

- End to End Review
- Gap Analysis against World Wide Signal Management guidance
- Industry best practices considered
- Signal Management process linkages to other processes identified e.g. Risk Management, Periodic Reporting, Labeling Modifications
- Creation of comprehensive Signal Management Process Map
- Review of Requirements for implementation of new process
  - Impact of Quality Documents
  - Training
  - Role Descriptions
  - Documentation in PSMF (Pharmacovigilance Safety Master File)
  - IT system requirements qualified and implemented

## TAKE THE NEXT STEP WITH APPIAN

Appian can orchestrate the controls needed across specialized tool suites to ensure improvements are being made in a managed and auditable fashion.

Appian also provides the necessary platform for continuous process improvement and changes to a process, collecting metrics about process performance, collaboratively assessing the outcomes and making decisions about possible process improvements, while providing the insightful dashboards into the state of your business processes overall.

All in all, Appian provides a top notch pharmacovigilance solution, that guides life science products through the detailed and complicated steps of the product lifecycle as well. With Appian, the stress of bringing a product to market and assuring continuing quality can be lessened, and the person who needs that product the most, the patient, ultimately reaps these benefits.

## ABOUT THE AUTHOR

**Evjatar (Evi) Cohen** is an experienced pharmaceutical executive with an extensive background in developing global business portfolios with emphasis on new products, technologies, and IP. As Global Practice Leader for Life Sciences at Appian, Mr. Cohen is responsible for client success and continued growth. Formerly, Mr. Cohen served as Vice President of Global Innovation at Catalent. Mr. Cohen holds an M.B.A. in Pharmaceutical Management, M.S. in Biotechnology, and a B.S. in Chemistry.

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