The Future of Pharmacovigilance: Five Imperatives that Will Drive Improved Business Outcomes

In the face of growing challenges, PV leaders must focus on collaboration, globalization, capacity management, transparency and integrating and analyzing information.

Executive Summary

It is said that small ripples can cause large waves on the opposite side of a pond. Well, it may be time for pharmacovigilance (PV) executives to break out their surf boards and help their organizations develop new PV skills to ride out the current tide.

Several high-profile safety issues, regulatory warnings and negative media coverage have sent ripples through the PV pond that will forever change pharmacovigilance as we know it today. This white paper offers a strategic framework for PV decision makers to more effectively navigate the industry’s choppy waters over the long term.

A Reflection of the Past

Five to 10 years ago, the PV environment was in its early stages of maturity. Yet the landscape is not much different today: expensive and outdated systems; limited integration of data; inconsistent standards; unpredictable and highly variable processes; complex, non-harmonized global regulations; and public and media scrutiny. At best, PV today has doubled in complexity due to the increased influence of emerging markets, higher data volumes, radically changing regulations and the emergence of social media and innovative technological advances.

So, what is a PV executive to do? As one senior executive once said, “Industry leaders solve industry problems.” While this can be true, meaningful and sustainable change requires industry executives to look beyond the day-to-day challenges and redefine what will be important in the long term. The question to ask is, “How can we drive consequential and valuable change?” The time is now to elevate the PV organization’s role to a more strategic level by focusing on five imperatives that will drive better outcomes (see Figure 1, next page).

1. Collaboration: How will PV teams collaborate more effectively with key external stakeholders to drive better outcomes? How will they embed themselves as an integral part of internal teams to deliver more significant insights on products, disease states, trial design and recruitment?

2. Globalization: How will organizations not only operate more effectively across multiple regions and health authorities but actually capitalize on expansion into these markets, as well?
3. **Capacity management**: How will PV executives plan, understand and drive higher capacity as the need increases for improved timeliness, productivity and expectations from multiple regulatory agencies?

4. **Information and analytics**: What role will technology play, as organizations look to leverage the right information and analytics approaches to deliver significant value across the R&D value chain?

5. **Transparency and trust**: What will be the strategy and approach for driving higher levels of internal and external transparency by ensuring that safety information reaches the right audience at the right time to build confidence across the value chain?

**Collaborate Beyond the Four Walls, With Impact**

Times have changed. The world is demanding better, more targeted medicines that deliver better patient outcomes. Justifiably, this demand encapsulates the core ingredients for more successful industry collaboration: increased focus on outcomes and tapping into the best science, regardless of its origin. But while regulators, biopharma, patients, payers, healthcare professionals and other stakeholders are uniting around outcomes, individual PV organizations have yet to fully embrace these ingredients.

While regulators, biopharma, patients, payers, healthcare professionals and other stakeholders are uniting around outcomes, individual PV organizations have yet to fully embrace these ingredients.

Pressure from local regulatory agencies has increased the need for specialized skills and resulted in escalating costs. The emergence of successful “coopetition” models holds the promise that PV organizations will soon develop more networked external collaboration models, as exemplified by companies like Pfizer (Centers for Therapeutic Innovation, CTI) and Astra Zeneca (A5 Alliance). These existing models recognize the value of open innovation, and despite challenges with optimal sharing of information, there is a strong recognition of the value of aligning complementary skills, information, assets and cultures collaboratively toward a joint outcome.

Several characteristics of this new model will enable more effective external collaboration. They include:

- **Redefining competitive boundaries**: Critical evaluation of competitive aspects that will enable increased sharing of information.
- **Deploying secure collaboration platforms**: Secure collaboration platforms that serve as an extension of stakeholder tools, systems and data sources while protecting identified and potential intellectual property.
- **Delivering to industry-defined outcomes**: Commitment to deliver to unbiased, externally defined, scientific-driven outcomes rather than traditional benchmarks informed by the best internal performance.
- **Rewarding joint success**: The development of tangible commercial arrangements that capitalize on meaningful outcomes rather than a pre-defined scope.

Beyond emerging external collaboration models, PV organizations must find a way to drive more meaningful internal collaboration. Historically, PV has operated in a silo, outside the rest of the R&D organization. Companies have differed on where safety fits into the organization - a view that is perhaps a remnant of the more traditional post-marketing support function that polices and diminishes the product label.

However, we have reached a tipping point where external pressures and innovative leadership are driving PV organizations to transform, seeking more influence and striving to become an integrated part of end-to-end product decisions.

**PV’s Business Imperatives**

![Figure 1](image-url)
The imperative for internal collaboration will translate into three key changes for PV:

1. **A more strategic role in providing insight across the R&D value chain.** This includes leveraging disease state and cohort understanding to help shape product direction, defining early risk management strategies, and providing input on clinical endpoints, recruiting and trial design. The PV function’s ability to demonstrate value in terms of differentiating products, expediting portfolio decisions and increasing the likelihood of product approval will be transformative, to say the least.

2. **Safety’s role in business development.** PV executives voice a desire to be engaged earlier in the process and become more influential in alliance decisions and commercial arrangements through their input on product safety profiles. They aspire to move from a post-deal support role to having a seat at the “pre-deal” table.

3. **End-to-end product accountability,** primarily driven by external pressures. As regulators and other external stakeholders look for improved outcomes, they have increased their demand for tighter controls across the product lifecycle. As evidenced by recent high-profile issues related to manufacturing, local transparency/control, promotions/marketing and other findings, biopharma companies are beginning to look to the PV organization to help manage end-to-end risks that will impact patient outcomes. PV leaders must rethink their operating models to build better relationships and be more integrated with groups like manufacturing, clinical, regulatory and commercial operations.

Globalize: Beyond Cost Takeout

The word globalization is viewed as a euphemism that conjures images of low-cost outsourcing models. However, the globalization imperative is much more than labor arbitrage; it is a strategy that addresses current challenges while taking advantage of growth and innovation opportunities in emerging markets such as China, India, Argentina, Brazil and the Philippines. Additionally, a globalization strategy is responsive to regulatory authorities’ tendency to collaborate globally on inspections, policy and forums, and paves the way to leverage the increasing regulatory influence of emerging markets.

The PV globalization imperative will be enabled by a new operating model with regionally-based centers of excellence, harmonized processes and tools, organizational alignment and integration, virtual collaboration platforms, elevated strategic affiliate roles, and global operational transparency.

Effective globalization will deliver tangible results in three areas:

- It will help increase visibility and governance of local activities in terms of study execution, access to collected data and governance of regulatory commitments and completion.
- Establishing a more strategic presence in local markets will help drive transparency to market needs and influence on commitments that can result in harmonization.
- Tapping into a global talent pool will provide access to emerging needs for specialized skills as part of a regional competency model, leveraged globally.

In the end, a globalization strategy addresses increasing competition, develops market-differentiated products targeted at specific populations and deals with a shortage of talent in key markets that is essential for driving innovation. Globalization is all about making a PV organization agile, nimble and compliant while keeping an eye on cost.

Capacity Management: Simplification is the Key to Success

One of the longest standing challenges within pharmacovigilance, and more broadly across R&D, has been “do more with less.” PV operations have always faced the challenge of having to process a highly variable volume of cases within a fixed period of time. To make matters even worse, additional complexities such as the proliferation of licensing agreements, commitment to local exceptions and geographically dispersed teams and partners can reduce actual reporting windows to five days or less.

Historically, organizations have responded in two ways. Some have embedded excess capacity to handle peaks in case volume, increasing operational costs for primarily under-utilized resources. Other more cost-conscious organizations have optimized team utilization at the expense of PV leaders must rethink their operating models to build better relationships and be more integrated with groups like manufacturing, clinical, regulatory and commercial operations.
introducing a backlog of cases, ultimately leading to compliance issues, as well as compromised quality and timeliness of signal detection. Recent years have demonstrated the impact of these choices, namely, escalating operational costs and high-profile regulatory warning letters.

The answer to these capacity management challenges lies in making three changes:

• Flexible, specialized sourcing models.
• Metrics-driven forecasting and resource management.
• Global simplification and standardization.

First, the traditional “stop-and-go” processing model must evolve into a “follow the sun” paradigm, with regional operational centers, strategically distributed across the globe, taking advantage of local talent and language capabilities. These centers must leverage a base set of dedicated resources but offer “shared” excess capacity across clients in a secure model. The result will be an operation that processes cases around the clock, shrinking the timeline to within 24 hours of receipt. By expediting timelines, leveraging multilingual capabilities and tapping into low-cost regions, this model improves upon the cost advantage of traditional outsourcing models by offering reduced risks linked to regulatory reporting and quality.

Building on this flexible sourcing model, the second change will leverage improved metrics reporting and predictive analytics to better understand and manage capacity. Typically, existing case processing operations include multiple handoffs, quality reviews, bidirectional workflows to correct mistakes and numerous exceptions. It is a challenge for traditional systems to measure the actual time spent on a case by role and in aggregate, let alone understand the precise impact of decisions made within the process. The integration of new tools, such as business process management (BPM), will be required to capture the essence of each transaction and translate them into reliable resource algorithms that effectively model current performance.

While this is a good start, it is only half of the story. Organizations must combine these efforts with predictive modeling tools that simulate how key corporate events such as a product launch, label change or clinical study can impact case volume. Integrating these two sides of the equation will provide an agile and optimal resource plan that balances the demand side with an accurate picture of supply.

With an understanding of capacity and demand, as well as a flexible resource delivery model, what remains? The third and possibly most important aspect of capacity management is recognizing that true competitive advantage lies in how smart your signal detection strategies are and not how unique your case processing is. Some organizations have started to realize that the commonality in global regulatory requirements lends itself quite nicely to a shared services model built around a common set of standard operating procedures (SOPs), a robust quality management plan and a shared technology platform. The technology is already here to centralize around one global, multi-tenant database that is highly available. The challenge has been primarily change management, not technology.

Despite posing one of the biggest challenges, a clear roadmap has emerged to address the capacity management imperative going forward. PV organizations will need to simplify and harmonize, optimize global operations and embrace a metrics-driven culture.

Elevate Meaning from Data to Insight
PV organizations place a significant priority on data, both in terms of securing existing data and subscribing to external sources. Not surprisingly, the expected results have not followed. The root of the issue is that the data is not the Holy Grail; derived insight is what really matters. While this may seem obvious, it has been less clear how to drive insight from the increasing amounts of industry data that is available.

Harnessing information and analytics to produce meaningful insight is the next imperative for PV organizations. Going forward, life sciences companies must more effectively integrate internal and external data, experiment with social information in a controlled manner and leverage innovative technologies to process increasing amounts of real-time, unstructured data across disparate and varied sources.
Internally, PV organizations must do a better job of tapping into the value of clinical data by harmonizing processes and technology, as well as standardizing terminology and medical assessments. Additionally, companies must better integrate diverse sets of external data, such as marketing, EMR, genetic, proteomic, social and other outcomes-related information for analysis. More effective integration of both internal and external information will enhance not only product understanding but also disease state and cohort understanding that can add value during early stages of R&D (e.g., defining clinical endpoints) rather than solely support products on the market.

With respect to social information, organizations are starting to listen to conversations about their therapeutic areas and identify Web-based discussions about disease states. Much of this has been in a very controlled, non-product-specific manner that has limited the value of the information. However, with updated guidance from the U.S. Food and Drug Administration (FDA), companies are beginning to re-evaluate their strategies. We will see PV organizations work with their legal teams to define more explicit strategies around building their knowledge of adverse events reported through social media outlets. Companies will begin to access unstructured social information, leveraging “big data” concepts to integrate this data more effectively with the structured information they have already collected.

Overlaying all this newly integrated information will be an enhanced set of analytical tools that will help PV organizations transform the way they detect and manage signals, evaluate trial viability, define trial endpoints and relevant cohorts, analyze literature and social information and capture new types of meaningful patient data related to symptoms, lifestyles and outcomes.

With the fourth imperative around analytics and insight, companies will elevate their understanding of real-life data that will allow them to apply insights to translational medicine, comparative effectiveness and precision medicine, including better understanding of populations and the development of biomarkers and diagnostics to help target products to these populations.

**Patient Safety: From Compliance to Brand Differentiation**

Many consumers rely on biologics and pharmaceutical products to extend or improve their quality of life. Yet in the past 10 years, we have seen declining consumer trust in biopharmaceutical companies. In the face of revenue, cost and regulatory pressures, the industry now must deal with unprecedented levels of criticism fueled by several high-profile events that have negated the work conducted by good people looking to serve a noble cause.

The last imperative may prove to be the most challenging: PV organizations need to reinvent themselves around transparency and trust. To do this, PV organizations must understand and proactively publish data, shift their view from “patients” to “real people” and engage more effectively with the public to understand their values.

On the heels of several high-profile safety events, organizations must do a better job of collecting, understanding and proactively publishing their data. They need to preempt potential meta-analysis that leverages local data and methods that may not be immediately transparent to the PV organization. Regardless of intent or fault, we have seen that the resulting and lasting perception of meta-analysis can be that the company was trying to hide information. This damage is difficult, if not impossible, to undo.

Therefore, there must be an evolution in the current mindset to understand patients as people. Human beings are complicated; there are numerous factors that influence how they make decisions, especially with something as significant as medication. No longer should organizations view a missed dose of medication as the fault of a “naïve” or “forgetful” patient, but rather as an explicit choice based on numerous factors. It is atypical for consumers to just accept what their doctors say without question. Instead, they leverage a variety of environmental factors to make healthcare decisions, including:

- Ad hoc online research.
- Advice from family and friends.
- Past history of success, failures and symptoms.
- Convenience.

Organizations must seek to better understand the factors that drive patient choices and incorporate these factors into the very fabric of future PV practices.

Finally, PV organizations must embrace the shift from traditional, conservative approaches that preclude direct patient contact. We have seen
examples where solicitation of patient input has underscored different priorities than was initially expected. Patient surveys have demonstrated increased risk tolerance of side effects when they can experience improved quality of life through better management of uncomfortable or inconvenient symptoms. Additionally, we see patients becoming much more active in sharing their experiences through online sites such as PatientsLikeMe.com.

PV organizations must transform themselves in a way that enhances transparency and trust to ensure future relevance. Much like the approach taken by Volvo decades ago, PV organizations must realize the differentiating value of “safety as a brand.”

**The Path Forward**

We see the sustained ripples in the water. A few small pebbles have been thrown into the pond in the form of regulations, high-profile events, media coverage and ineffectiveness. PV executives must pay close attention to these ripples, as they are sure to result in a slow but predictably mounting wave that will redefine how pharmacovigilance is performed in the future.

PV organizations that address these imperatives will be better positioned over the long term to simultaneously enhance patient safety while reinforcing the R&D value chain with new technologies and processes that drive sustainable revenue growth.

**Footnotes**


**About the Author**

George Botsakos is a Senior Director and Life Sciences R&D Leader within Cognizant Business Consulting. He has nearly two decades of R&D consulting experience for pharma, biotech, CROs and medical device companies. George has worked across all phases of R&D, including more than 12 years within the areas of clinical development and pharmacovigilance. He has delivered against both strategic and operational objectives of his clients, including leading several highly visible initiatives in R&D, such as establishing the first end-to-end PV processing function in Chennai, conducting a strategic industry study focused on PV operating models and leading the transformation of a $500 million-plus medical organization. George is a recognized R&D thought leader, including authoring numerous R&D points of view, a strategic industry PV study and presenting at the R&D Leaders Forum. Prior to joining Cognizant, George was the Americas Life Sciences R&D Leader and PV Practice Leader at IBM, and spent 13 years at Accenture in various leadership roles. He has a BS degree in chemical engineering from Cornell University. George can be reached at George.Botsakos@cognizant.com.

**About Cognizant**

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world's leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 50 delivery centers worldwide and approximately 145,200 employees as of June 30, 2012, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at [www.cognizant.com](http://www.cognizant.com) or follow us on Twitter: Cognizant.