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**Transforming
pharmacovigilance**
Using technology and
analytics to enable next-
generation patient safety

Automation, cognitive technologies, and advanced analytics are providing opportunities to transform pharmacovigilance from the process of compiling data and preparing information for regulators to creating a learning system to improve a drug's risk-benefit profile, help providers select the optimal treatment, and increase product quality and patient safety.

The evolving pharmacovigilance landscape

For the past several decades, the pharmacovigilance (PV) function has been responsible for collecting, processing, and reporting adverse events (AEs) and other product safety information to regulators. PV's process-heavy nature often drove companies to select associated safety systems based on their ability to organize data and optimize efficiency, typically leaving limited system options.¹

Today's PV function is being reshaped by numerous global health care trends (figure 1). While many of these trends are delivering considerable benefits, they also are exerting pressure on biopharmaceutical companies' existing safety systems.²

As a result, many organizations are facing significant cost burdens to maintain and upgrade these systems, even though—under the current safety system paradigm—the same trends may cause the costs of traditional upgrade approaches to grow disproportionately versus benefits.³ This, in turn, is prompting many biopharma companies to consider how automation, cognitive technologies, and advanced analytics may help them get more from their PV systems—to progress from merely analyzing, formatting, and submitting reports on patient- and provider-supplied case processing and signaling data to creating a next-generation digital learning system that efficiently and cost-effectively increases product quality and patient safety.

Figure 1. Industry drivers impacting the PV landscape

Today's PV function is being reshaped by numerous global health care trends.



AE volumes growing with disease complexity

The volume of AE cases is growing with disease complexity and as additional sources of AE information are explored



Global regulations becoming more complex

Increased regulatory scrutiny will continue driving the need for new PV capabilities; regulations will evolve and formalize in countries with nascent regulatory environments



Product portfolios and TAs increasing complexity

Product portfolios and TAs are increasing in complexity; PV organizations must be prepared to handle this



Rising organizational pressure to minimize costs

Top-down organizational pressure to reduce PV costs has increased in recent years



Wearables, social media driving real-time data

New sources of information and potentially new PV obligations are necessitating the building of advanced analytics capabilities which can be used to drive value



Regulators evaluating RWE sources

Regulators ahead of industry in evaluating and implementing processes and standards to explore RWE sources for signals and safety information



Data science and automation evolving for signal detection, case management

Focus on risk/benefit analysis and signal management; need for advanced safety data analytics tools



Consumerism is demanding increased focus on patient centricity

Patient focused strategies and involvement throughout the healthcare continuum

Survey examines state of biopharma's PV practices

In October 2018, Deloitte interviewed senior executives from global mid- and large-cap biopharmaceutical companies—whose therapies represent almost one million of the 2.2 million cases filed with the FDA each year—to determine the current state of pharmacovigilance practices from a cost (people and technology) perspective and to learn about their PV plans for the next three to five years. Among the survey's findings:

- Distribution of the PV budget to labor versus technology was not substantially different among firms of any size.
- Allocation of labor cost to outsourcing was higher for smaller firms.
- More of the larger firms' budget was allocated to case processing than smaller firms.
- Larger firms lag smaller firms in allocating limited safety budget to higher value-added activities.
- The majority of surveyed firms are investing in automation. Case processing is overwhelmingly the target, with focus areas in intake, triage, and follow-up. This is congruent with a focus on improved tooling to support true patient safety.
- Currently, the focus for future signaling capabilities appears to be drug benefit and risk management, as opposed to developing evidence for potential discovery feedback.

With the potential for continued technological innovation, PV organizations are on the leading edge of making a consistent, sustained set of bold moves to take advantage of safety capabilities like those in other industries⁶.

Future focus: Automating case processing and signaling

Results of a 2018 Deloitte survey⁴ of mid- and large-cap global biopharma companies' PV practices, costs, and plans (see sidebar) show that a majority are investing in PV-related automation (or evaluating the business case) to gain process efficiencies, free up resources to perform value-added tasks (e.g., benefits-risk evaluation and management, signal investigation, and real-world evidence analysis); improve quality assurance consistency, accuracy, and reliability; and reduce their PV cost burden.

Companies' plans for the next three to five years focus heavily on leveraging cognitive automation with current safety databases. **Driving cost out of case processing is the primary goal for 90 percent of respondents; capturing data to improve signaling is also important** (figure 2).⁵

Case processing: With PV budgets allocating 40 percent to 85 percent of spend on case processing, and case volumes growing at a rate of 10–15 percent per year,⁷ driving cost out of case processing is the primary goal for 90 percent of survey respondents. Low-cost leaders are outsourcing, taking advantage of scale, and moving aggressively to automate case processing. Survey respondents expect automation to produce an average annual cost savings of 30 percent per Individual Case Safety Report (ICSR).

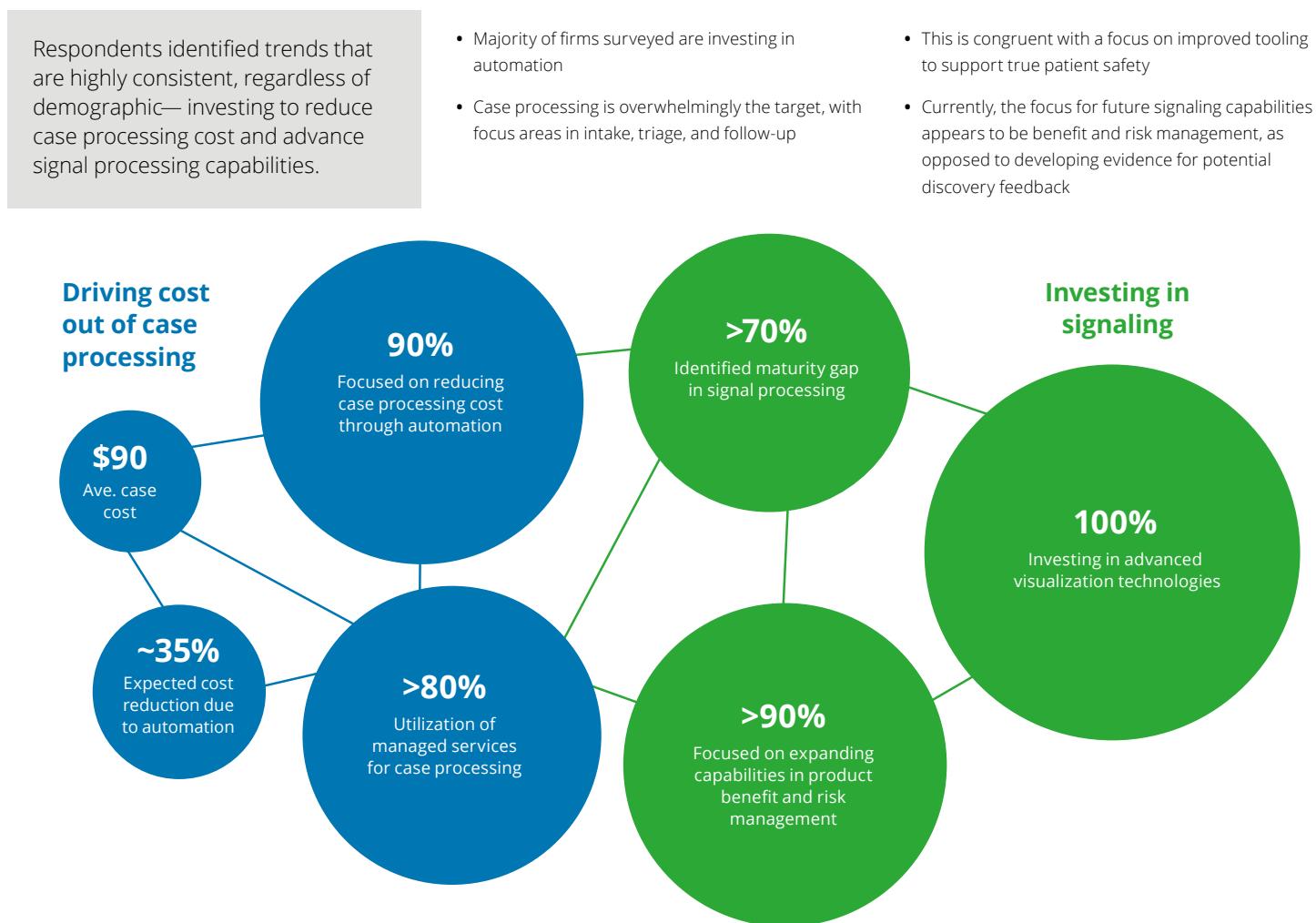
The productivity differential between case processing teams can be significant: at scale, the range is as much as 300 or 400 annual ICSRs per full-time equivalent (FTE) to 1,000 or 2,000 ICSRs per FTE. Among productivity drivers are native automation and "bolt-on" tools to reduce the effort required to perform duplicate checks, speed up coding activities, and streamline narrative writing. However, there is limited capability to "automate out" entire steps within the case processing value chain and generate only proofs of concept targeted at end-to-end case automation. Gaining cost control over this process while maintaining compliance and enhancing patient safety is entirely dependent on companies' ability to automate more and more of these activities.

Signaling: Most pharmaceutical companies continue to use traditional signal detection and investigation methods (e.g., medical assessment of individual spontaneous reports of adverse events, interventional clinical trials, database mining); a few are leveraging real-world evidence (RWE); almost none are progressing social media channels. This is consistent with current PV system capabilities.

Survey respondents see broad opportunities to improve their signal processing and investigation maturity; half say they plan to expand these capabilities. As pharma companies continue to drive toward true safety management, short-term signaling investments are likely to focus on visualization and longer-term efforts on data integration and tool and

process investments. Using safety information to tie back into the discovery process remains a gap due to limitations with existing signal detection and management systems. The better the data quality and consistency, the better the signal detection. The ultimate goal is predictive signaling.

Figure 2. Pharmacovigilance automation focus areas



Creating a next-gen PV system for improved patient safety

Lowering case processing costs, expanding signal processing capabilities, and expediting product safety reports are compelling reasons for biopharma companies to include automation, cognitive technologies, and advanced analytics in their PV budgets. Yet we anticipate even greater gains if biopharmas leverage digital technology to create a next-generation PV learning system for improved patient safety. Moving to a proactive and patient-centric approach can help enable a detailed understanding of product benefit risk profiles and a true, evidence-based center for safety intelligence across the entire product life cycle. However, pharma companies' current use of multiple, siloed information systems to process safety data may prevent many of them from reaching this desired future state. For example, various internal PV groups examine safety data coming from external sources in different ways and for different purposes; each group may pull and analyze data from as many as a dozen disparate systems and—unsurprisingly—draw multiple versions of the truth.

One approach to breaking the case processing cost curve while also enhancing the role of signaling is to institute an end-to-end, modular, “learning loop” system that uses a unified data platform and automation to cognitively process

upstream and downstream safety information (figure 3)⁸ and leverage continual learning to help mitigate risk, strengthen compliance, and improve patient outcomes.

System capabilities should include:

- **Cognitive case processing** to automate data intake and processing to help significantly improve the efficiency and quality of the AE life cycle.
- **Aggregate and operational reporting** that is scalable, user-friendly, and designed to accommodate high case volumes and large data sets.
- **Signal detection, evaluation, and management** that consolidate and streamline processes and systems so analysts can perform validation and assessment activities and capture results and annotations without leaving the system, leading to more efficient, accurate signal management.
- **Safety metrics** that leverage existing safety data, new real-world sources, and supervised and unsupervised machine learning to detect, assess, understand, and help prevent safety-related issues while uncovering benefits that can improve patient outcomes.

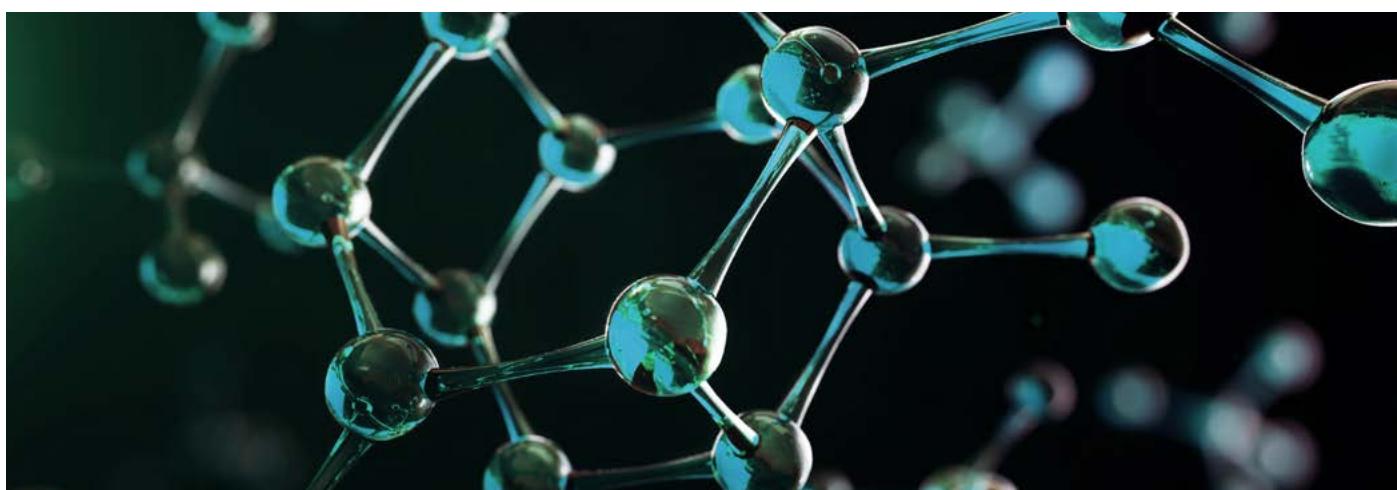
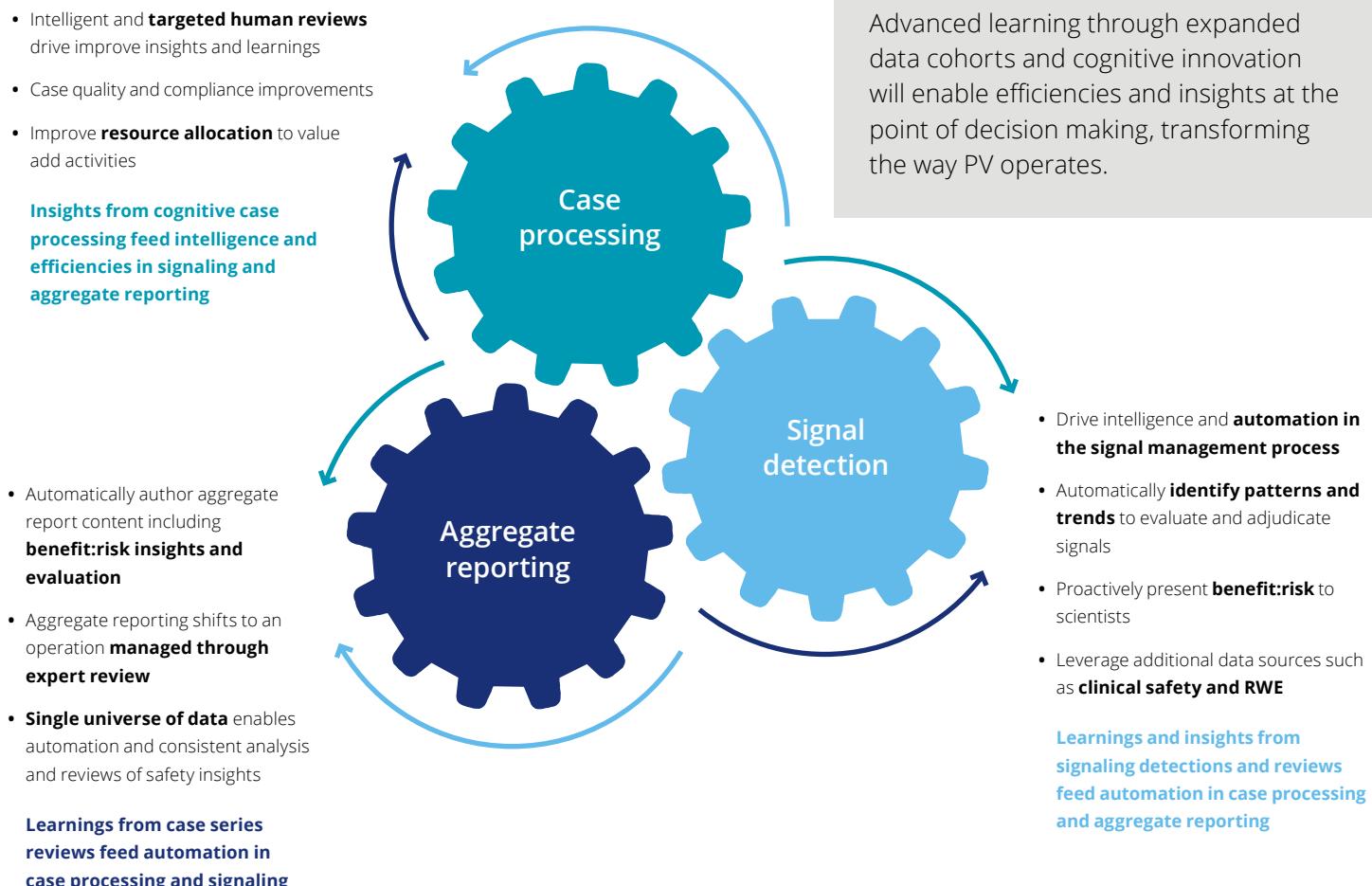


Figure 3. PV learning system for improved patient safety

Among the potential benefits of a transformed PV function are improved efficiency and accuracy, reduced cost per case, improved case quality, prioritized resource allocation, and simplified and accelerated compliance. As the market becomes crowded with safety automation vendors and options, it is important to recognize and consider differences in the various approaches and their potential benefits.

As a cognitive use case example, we recently ran a pilot for a large global pharmaceutical company. The objective was to automatically process structured (E2B, forms) and unstructured (emails, other unstructured) cases into the global safety database and automatically determine case validity. Using its structured and unstructured data and our ConvergeHEALTH Safety cognitive algorithms and predictive modeling, we processed 5,100 cases with greater than

83 percent accuracy. Return on investment (ROI) on this case study demonstrated a 60 percent projected efficiency in case processing productivity based on initial results. For instance, based on initial results, only 17 percent of cases require manual intervention for Patient Details. With continued use, the system gets smarter with each self-learning loop and results continue to improve.

Is it time for a Global Drug Safety Data Bank?

Increasing complexities arising from recent industry globalization have created challenges in reporting and monitoring serious adverse events. A consolidated and centralized Global Drug Safety Data Bank (GDSDB) for use by regulators, industry, investigators, and patients could streamline case processing costs, increase focus on signal detection and management, and unleash the power of big data analytics to more rapidly and efficiently generate key health care insights and safeguard patient safety.

Deloitte recently convened key stakeholders from the US Food and Drug Administration (FDA) and pharmaceutical drug safety industry leaders to answer the question: How can the FDA and key stakeholders prepare for a successful design and launch of the GDSDB?

Participants in the daylong Deloitte Greenhouse Reimagining Patient Safety session had several important insights:

1. **We are aligned on the problem.** After hearing from a diverse set of stakeholders (including pharma, patient advocate, principal investigator, and regulator) it became evident that all parties are aligned on the overarching problem and the need to solve it. Alignment among this initial group is critical to gaining additional sponsors and advocates who will commit to and contribute to the development of a solution.
2. **Addressing this problem will accelerate our efforts.** While participants noted that some of the largest safety issues happen during the postmarket phase, they agreed that addressing premarket global safety reporting will create operational efficiencies that will allow stakeholders to accelerate efforts and better prioritize their time.
3. **This is just the first step.** Participants agreed that the scope of the pilot will focus on expedited global premarket safety reports and must be capable of managing complex distribution rules. However, participants agreed that the expanded scope of a future-state solution would help to tackle additional phases of clinical trials and incorporate functionality to address broader pain points.
4. **Developing a business case will be critical.** To generate momentum and buy-in, participants expressed the importance of developing and sharing a business case that describes a solution that: 1) creates operational efficiencies, 2) acts as a shared service, 3) improves health outcomes, and 4) can demonstrate both a short- and long-term return on investment (ROI).
5. **Each party plays a unique and important role moving forward.** Participants outlined the unique role each party must play to ensure success moving forward with a focus on securing funding, recruiting additional regulators, and producing the white paper and business case. To continue the momentum, participants committed to rallying additional support and discussing the initiative with leadership in their respective organizations.

Moving forward

All stakeholders in drug development share the responsibility of ensuring patient safety. Automation, cognitive technologies, and advanced analytics are providing opportunities to transform pharmacovigilance from the process of preparing AE reports for regulators to creating a learning system that emphasizes benefit/risk management and proactive surveillance throughout the product life cycle (figure 4).⁹

To begin, PV organizations should look at their vision of the future and decide whether getting there will require incremental or transformational change. Among questions to consider:

- What are the short-term “bare minimums” and our longer-term strategic objectives?
- What are the technology and business trends that may evolve to transform this space?
- What capabilities do we have today? What will we need for the future?
- How can we identify, develop, and implement “quick wins” that may create breathing room to invest in the future of safety?
- Have we looked at both operational transformation and technology solutions to continually improve our safety capabilities and internal efficiencies?

Leading edge PV Organizations will focus on benefit/risk management and proactive surveillance

Figure 4. PV Organizations of the future

Focusing on the business of proactively protecting patient safety



Endnotes

1. Safety system upgrades: Past and future trends driving the decision to upgrade, Deloitte, 2018.
2. Ibid.
3. Ibid.
4. Deloitte's 2019 Next-Generation Safety Survey.
5. Ibid.
6. Ibid.
7. According to Deloitte analysis of the survey responses. The 10–15 percent is based on historical case volumes from FDA, available at the FAERS website: <https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis>.
8. Deloitte observations and analysis of current technology footprint across multiple firms.
9. Ibid.



Contacts

If you are interested in learning how Deloitte is helping our clients to achieve their vision of a transformed pharmacovigilance system, we should talk.

Glenn Carroll

Principal
Deloitte Consulting LLP
gcarroll@deloitte.com

Kevin Sullivan

Principal
Deloitte Consulting LLP
kevsullivan@deloitte.com

Aditya Kudumala

Principal
Deloitte Consulting LLP
akudumala@deloitte.com

Joe Montrosse

Managing Director
Deloitte Consulting LLP
jomontrosse@deloitte.com

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