



Pharmacovigilance of the Future

Transformation Roadmap for
Pharmacovigilance in the Digital Era

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Executive summary

Pharmaceutical firms stand at an important crossroads in their R&D and clinical trials journey. The end of the blockbuster model has meant that pharma firms need to participate in a number of therapy areas, while still streamlining costs and improving time-to-value for new drugs. To ensure drug safety in a patient-centric digital era, firms now need a more efficient and innovative mechanism to handle adverse events following drug launch. They also need to engage patients who are increasingly taking ownership of health outcomes in their own hands. Across the healthcare ecosystem, we see pharma firms collaborating more closely with different participants through a variety of new models including outcomes-based pricing arrangements with payers.

The volume of data (signals) a pharma firm receives in the age of social media, artificial intelligence, and ubiquitous mobility is unparalleled. Combined with a significant shift in the underlying technology stack, increasing regulatory reporting requirements, and shorter turnaround times, there is a perfect storm occurring in the world of pharmacovigilance (PV).

While spending on PV has increased, the result has not been a commensurate improvement in drug safety, nor has negative impact on the pharma industry (in terms of financial and reputational loss due to recalls) been mitigated. The industry recognizes that PV needs to change from a regulatory-driven exercise to a more proactive and intelligent function. But this shift requires a fundamental reimagining in the way the industry approaches PV.

The PV function needs to transform from transactional in nature to an interconnected part of the clinical and R&D lifecycle, through the following approach:

- Reimagining platforms: Revise platforms to shift from the present approaches, which are rooted in legacy and do not speak to a modern enterprise's connected ecosystem
- Introducing intelligence: Re-examine reactive interventions by introducing intelligence based on pattern recognition and 360-degree patient view
- Reengineering processes: Empower underlying processes through the leverage of data, machine learning, RPA, and proactive compliance

Our research establishes how these changes not only help reimagine PV but also unlock meaningful value through a 20-30% cost reduction in PV spend for a large pharma firm.

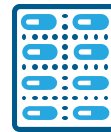
This transformation needs to be accompanied through a philosophical shift in the perceived impact of PV, which stretches beyond stemming rising case volumes and cost impact into improving overall patient safety, reinstating trust between patients and pharma firms, and introducing reverse feedback loops to ultimately improve clinical and R&D processes.

Examining the dichotomy in pharmacovigilance

The drug safety ecosystem is becoming increasingly complex and difficult to navigate with more information channels, greater reporting, and different therapies. To manage this complexity, firms have tripled their annual pharmacovigilance (PV) spend as a percentage of total sales – from 0.3% in 2003 to over 1% in 2017. In fact, if drug recalls are any indication of drug safety, performance has deteriorated (see Exhibit 2). Worse still, financial loss is only one problem; loss of life due to Adverse Drug Reactions (ADRs) is a bigger concern, with thousands of lives (over 100,000 in the United States alone) lost every year due to undisclosed/undiscovered side effects of drugs.



↑ PV spend as a percentage of sales



↑ Total number of annual drug recalls



↓ Impression of the pharma industry

EXHIBIT 1

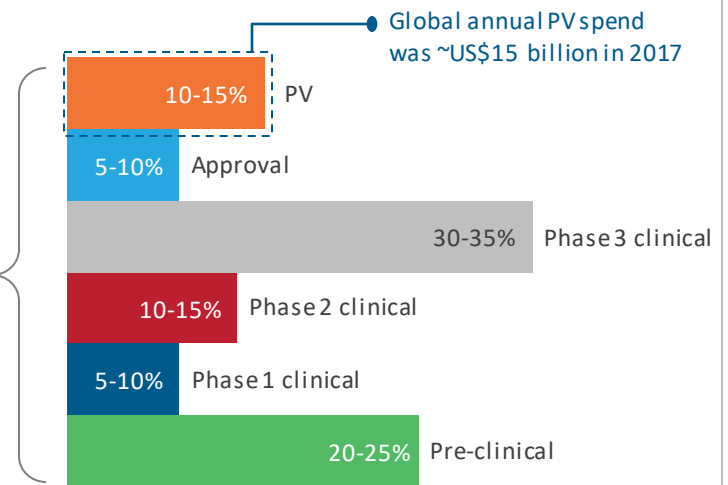
Expenditure on pharmaceutical market processes

Source: Everest Group (2018)



Cost of goods sold 30-35%	SG&A 25-30%	Operating income 15-20%	R&D 15-20%
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100% = ~US\$1 trillion

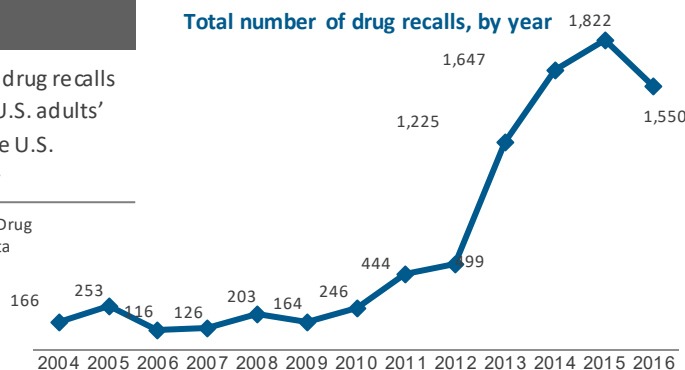


As Exhibit 2 demonstrates, in spite of increased spending on PV, drug recalls have seen a precipitous rise and the view of the pharma industry among adults in the U.S. is not particularly positive.

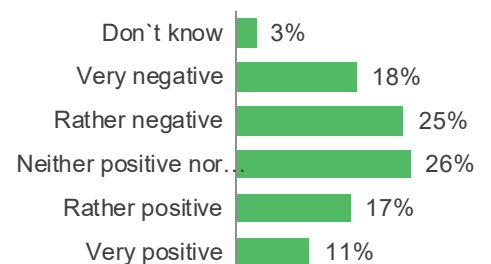
EXHIBIT 2

Total number of drug recalls by the FDA and U.S. adults' impression of the U.S. pharma industry

Source: US Food and Drug Administration, Statista



U.S. adults' impression of the U.S. pharma industry 2017, Percentage of respondents



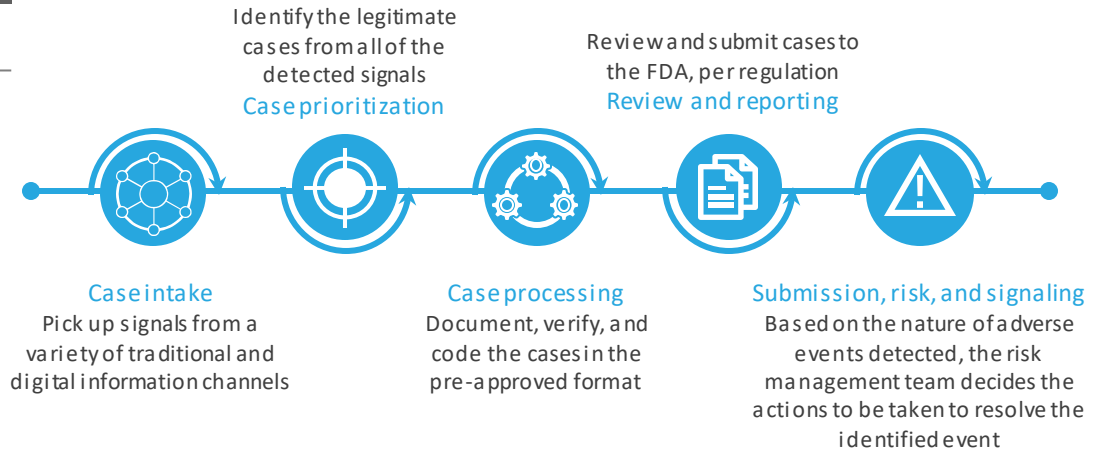
Evaluating the state of PV

The PV value chain for a pharmaceutical firm is comprised of five distinct steps as shown in Exhibit 3.

EXHIBIT 3

PV value chain

Source: Everest Group (2018)

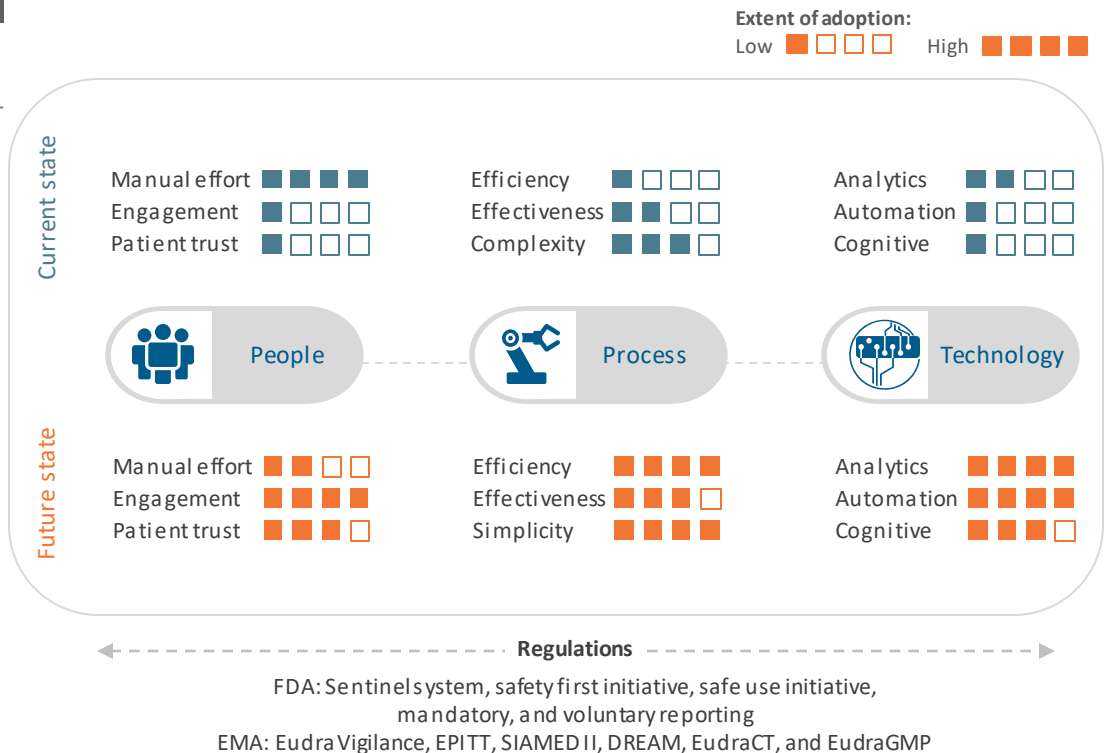


Using three organizational levers – people, process, and technology – we have completed a comprehensive evaluation of the current and future states of the PV landscape. PV regulations will influence the transition of these parameters from their current state to the future state.

EXHIBIT 4

Framework for evaluating the state of PV

Source: Everest Group (2018)



Evolving priorities and technology advances

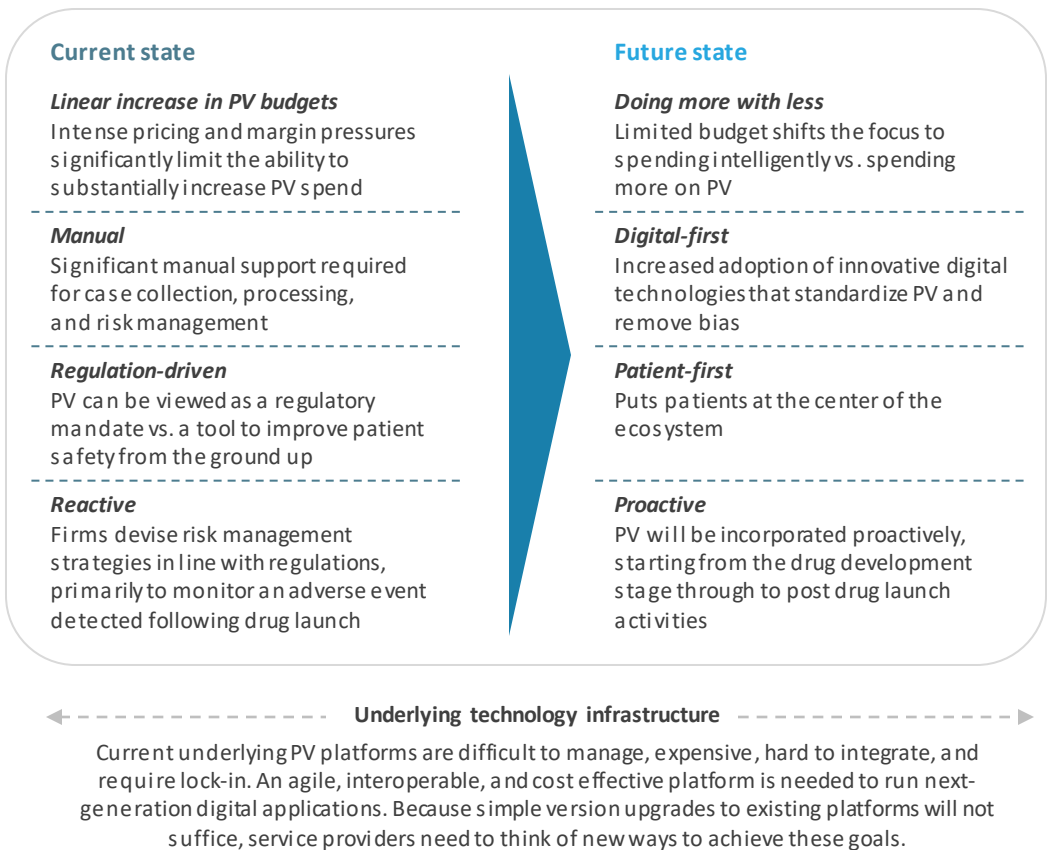
Evolution of priorities

Increasingly stringent regulations and intense margin pressures are driving changes in priorities for pharmaceuticals, as illustrated in Exhibit 5. Emphasis on patient experience and safety is also impacting the way pharma firms approach PV.

EXHIBIT 5

Evolution of PV

Source: Everest Group (2018)



Technology advances in PV

As pharma firms' priorities continue to evolve, digital technology can enable them to achieve their future state. PV market disruption is happening so quickly that solutions involving basic automation and analytics have become table stakes, forcing exploration of more advanced alternatives, such as those discussed in Exhibit 6.

Pharma firms have already adopted technologies such as automation, AI, and cloud computing for different functions. Some examples of pharma firms and regulatory bodies adopting these technologies for various functions are noted in Exhibit 6.

EXHIBIT 6

Technology innovations in life sciences

Source: Everest Group (2018)

Merck has entered into a collaboration with Project Data Sphere to jointly lead the Global Oncology Big Data Alliance

Pfizer has partnered to automate the clinical trials process and manage risk proactively

GSK leveraging AI-enabled platforms for drug discovery

Celgene is developing a cloud-based patient safety monitoring tool

The FDA developed and launched a mobile app—MedWatcher—to record ADR-submitted by healthcare providers, patients, and caregivers

In November 2017, the FDA approved the first digital pill called Abilify MyCite, which tracks if patients have taken their medication

Proactive PV



Pharma firms are transforming the PV process from a reactive model to a more proactive one. Firms are now trying to identify all possible adverse event scenarios during every stage of the drug discovery and development process, thus increasing their chances of solving a problem before the drug is released in the market. To a large extent, this process brings more proactive intelligence upstream, eliminating the risk of safety breaches that might occur after the drug is released.

Big data analytics



Often, data analytics capabilities and features are part of a larger end-to-end PV platform. Analytics capabilities include master data management, consolidated 360-degree assessment, and provider data, text/voice analytics for ADR classification and signal analysis.

RPA



Firms are adopting automation tools for signal detection and case processing, including case intake and triage, medical coding, and narrative writing. Automation also helps with information integration and exchange and regulatory compliance. RPA-based automation platforms are gaining traction, especially for case processing.

AI



Data is becoming increasingly important as more pharma companies invest in technologies to use the vast amount of available digital data to complement AE signal detection from primary sources. However, the amount of data available is so vast that it requires AI to detect patterns and generate insights.

Cloud solutions



Cloud-based solutions enable a massive quantity of data to be stored with minimal investment. They also support data collection from multiple stakeholders – healthcare providers, physicians, pharmaceutical companies, and users – to build an integrated database that can be used to understand ADR patterns and symptom occurrences across multiple countries.

Mobile apps



Mobile capability presents a huge opportunity for pharma companies to reduce signal detection time from months to days. AE reporting through a mobile app is much easier for a patient than is a phone call to a doctor, giving patients an additional impetus to report even minor side effects, which can significantly reduce the chances of side effects remaining undisclosed for long periods after the drug has been launched.

Amplified data sources



Digitized medicine generates real-time data about every effect a patient experiences from a drug. Unlike digital data from the internet, which has 95-98% noise, AE signal detection in this case does not require much filtration. Additionally, real-time data tracking makes the PV process much faster than the traditional approach, which typically took years.

PV of the future

As the PV landscape continues to evolve rapidly, we expect the future state of PV to look strikingly different from its current state.

- **Case intake:** Pharma firms receive the bulk of their reporting from traditional phone channels or from the FDA. But with consumerization and patient experience on the rise in healthcare, digital information channels – including social media, patient blogs, and mobile apps – will dominate the reporting landscape. This fundamental change in the mix of data sources will dictate the development and adoption of new capabilities. Secondary data sources – EHR, clinical data, claims data, medical literature, and social media – are going to become crucial in shrinking PV timelines
- **Case prioritization:** As the amount of data coming from digital channels explodes, basic data analytics is no longer sufficient to handle the load. The challenge is, first, to define and track better signals and, second, to filter the noise in the massive incoming signal datasets that subsequently identifies possibilities of adverse drug events. To effectively thrive in this new reality, firms must deploy advanced cognitive- and AI-driven platforms with machine learning, pattern recognition, and natural language processing capabilities
- **Case processing:** To date, the majority of case processing is handled manually. But service providers have started to deploy platforms to automate actions such as case intake, triage, medical coding, identification of duplicates, and narrative writing. RPA-driven systems also assist with transferring information to safety databases and generating notifications and follow-ups. This automation-based approach to care processing is making the entire PV value chain more efficient, accurate, and cost effective
- **Review and reporting:** For most firms, the compilation, review and publication of Periodic Safety Update Reports (PSUR) and Development Safety Update Reports (DSUR) is mostly a paper-based task that is manually managed over a span of several months in each cycle. But companies have started to deploy electronic document management technologies to digitally manage each report using a pre-defined template and track tasks and resource assignments via web interfaces
- **Submission, risk, and signaling:** Some critical steps in the PV value chain require extensive knowledge and domain expertise; risk mitigation and management is one, as it requires specialist resources to have complete understanding of the drug and disease under consideration. Traditionally, pharma firms kept such functions in-house, but rising costs and scarcity of required skills have created opportunities for outsourcing service providers that have developed capabilities to take up domain-/knowledge-intensive activities

Sourcing for PV in the new normal

For strategic partners to exhibit skin in the game and pharma firms to meaningfully move the needle on PV transformation, an outcome-based model needs to be considered. This model also ensures service providers share part of the risk and outcome-based metrics based on drug safety breaches help in continuous monitoring and management. To ensure the desired business-led outcomes, PV team needs to be in sync with other divisions such as drug development and quality management






Intelligent and proactive PV: A case study

Automation and cognitive intelligence coupled with a proactive approach to PV can improve patient safety and experience, generate direct cost savings, and prevent negative impact to brand reputation. Exhibit 7 demonstrates the average time/cost contribution corresponding to each component of the PV value chain, as well as the developments that will impact each of these elements in the near future.

EXHIBIT 7

Creating impact across the value chain

Source: Everest Group (2019)

Value chain element	Current average time invested per case (mins)	Updated average time invested per case (mins)	Changes	Level of impact	
				Low	High
 Case intake	90	40-45	<ul style="list-style-type: none"> Automation-driven Proliferation of digital information channels Proactive approach for early detection 	■ ■ ■ ■	
 Case prioritization	25	15-17	<ul style="list-style-type: none"> Eliminate noise from massive signal data AI/cognitive to identify cases from signals 	■ ■ ■ □	□ □
 Case processing	31	17-18	RPA can be deployed for rule based processes	■ ■ ■ ■	□
 Review and reporting	15	10	Reporting process can be standardized and automated	■ ■ ■ □	□ □
 Submission, risk, and signaling	50	35	<ul style="list-style-type: none"> AI can accelerate parts of the process through intelligent decision making Reporting can be standardized and automated Benefits will go beyond time savings to include improved accuracy 	■ □ □ □	

The sample scenario below is based on a typical Big Pharma firm.

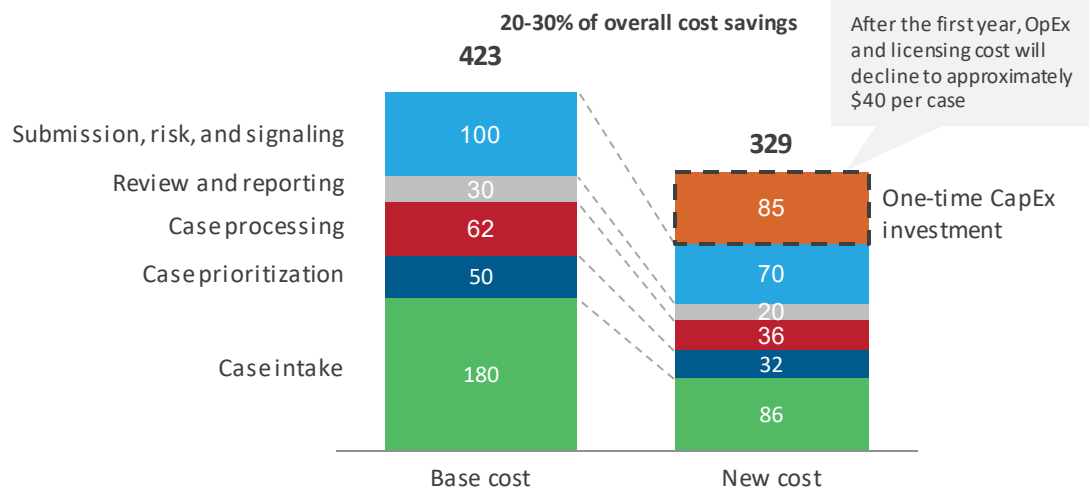
Base case scenario	
Number of cases processed per year	1.25 million
Revenue (2018) (US\$)	~\$53 billion
Annual amount spent on PV (US\$)	~\$530 million
PV amount spent per case (US\$)	\$420-425

Exhibit 8 illustrates cost savings that can be realized from the adoption of automation and cognitive technologies.

EXHIBIT 8

Savings from reimagined PV (US\$)

Source: Everest Group (2018)



As Exhibit 8 shows, a proactive approach coupled with adoption of relevant digital technology can result in 20-30% savings for Pfizer’s overall PV spend, which effectively means Pfizer can directly save 20-30% annually on PV.

Other than saving time (and, hence, money), automation and cognitive will also improve PV process accuracy. These calculations do not include the benefits accrued as a result of increased accuracy:

- Fewer, or the entire elimination of, fines that otherwise might have been levied due to inaccuracies in the traditional PV process
- Managing the rising number of cases (estimated at 20% YoY)
- Improved patient experience given the proactive PV posture
- Case accuracy SLAs can be improved (to ~99%) given that intelligence is embedded in the PV process
- Improved brand reputation due to a decline in drug safety breaches

With maturity, the platform approach offers incremental intangible benefits such as improved patient safety, enhanced regulatory compliance, increased upstream process efficiency, smarter study design, and effective sales and marketing strategies.

Conclusion

PV is in a state of flux – regulators are dynamically adjusting to evolving industry dynamics, patients are taking greater ownership of health decisions, new technologies are being developed; together these events are forcing a business model reinvention. The opportunity is there for the taking.

To truly take advantage of this opportunity, organizations will have to think of new approaches to technology and operations. For instance, can GxP-cloud computing (through Azure, AWS, and Google Cloud Platform) and AI-driven approaches (such as, Cortana and DeepMind) be used to reimagine PV? While these technology companies do not offer PV platforms off-the-shelf, since Silicon Valley is already deploying these technologies at scale, they should provide food for thought for pharma firms looking to reinvigorate PV.

The adoption of digital technologies will have broader business implications beyond the direct gains observed in the PV process. The digital capabilities for PV can also be leveraged for the following:

- **Drug development** – A digitally driven PV process creates a more accurate drug safety profile, and – importantly – in a shorter timeframe as compared to a traditional PV process. R&D teams can effectively leverage these profiles for molecular research related to other drugs in the pipeline
- **Sales tools** – Adoption of digital enables quantification of the improvements made in drug safety and patient outreach. These advances can be leveraged as a sales engine during physician detailing and conferences
- **Outcome-based pricing** – The ability to detect and process signals from various digital information channels can be leveraged to analyze the impact of the drug on patients. This data will help the firms in producing compelling data points that can quantify the drug outcomes
- **Managing consumerization** – Monitoring digital information channels presents pharma firms with an opportunity to establish a personalized two-way interaction medium with ecosystem stakeholders including patients and physicians


Intelligent PV will have broader business implications, ranging from more productive R&D processes to more impactful sales and marketing initiatives. However, apart from a few early movers, most pharma firms have struggled to absorb this approach. As pharma looks at making PV more proactive, reimagining PV from the ground up using data as an orchestrator will be a key imperative.

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