

# Unlocking the power of pharmacovigilance\*

## An adaptive approach to an evolving drug safety environment

PricewaterhouseCoopers' Health Research Institute

The idea that controlled clinical trials can establish product safety and effectiveness is a core principle of the pharmaceutical industry. Neither the clinical trials process nor the approval procedures of the U.S. Food and Drug Administration (FDA), however, can provide a perfect guarantee of safety for all potential consumers under all circumstances. Despite this fact, there are viable solutions that pharmaceutical companies can implement to support pharmacovigilance—the systematic detection, assessment, understanding and prevention of adverse drug reactions. When built into existing research and development practices, pharmacovigilance activities can enhance patient safety while reducing or even preventing costly safety-related withdrawals.

Currently, however, pharmaceutical executives face a number of challenges in the area of pharmacovigilance. In the four decades from the thalidomide tragedy to the recent drug recalls, companies have used pharmacovigilance methods designed to identify rare, easily identified safety problems. During the same four decades, we have seen the growth of a fragmented healthcare system that lacks a unifying infrastructure. As a result, this system operates primarily in reaction to rather than in anticipation of major pharmaceutical safety events. As drug consumption has increased and the public has grown to expect greater drug safety, the traditional reactive approach has proven largely incapable of addressing both shifts in public expectations and regulatory and media scrutiny. This reality has revealed issues in the four areas involved in patient safety operations: organizational alignment, operations management, data management, and risk management.

When appropriately aligned and supported, these areas can work together to enable a flexible, adaptable, and proactive system for addressing patient safety issues. Companies can unlock the power of their pharmacovigilance activities by creating an operational framework that supports the key patient safety infrastructures. In *Unlocking the Power*, we recommend that companies consider the following actions as they build an adaptive pharmacovigilance framework:

### 1. Align and clarify roles, responsibilities, and communications

- Develop an objective, data-driven, team-based approach to risk monitoring and evaluation
- Implement well-defined decision-making models, escalation processes, and communication channels
- Determine the pharmacovigilance workload and sufficiently resource the required effort
- Designate a pharmacovigilance operating model and business process owner
- Ensure that appropriate process and organizational checks and balances are in place to limit bias and manage regulatory risk

### 2. Standardize pharmacovigilance processes and data management

- Align operational activities across departments and across sites
- Implement process-driven standard operating procedures, work instructions, and training materials
- Integrate safety data through data and system interoperability standards
- Implement workflow management technology to ensure appropriate transparency and accessibility of safety information
- Select a vendor that best matches the pharmacovigilance operating model, business process and vendor/system selection criteria

### 3. Implement proactive risk minimization

- Develop risk management action plans based on pre-established risk scoring mitigation processes
- Implement data mining techniques to bolster safety analytics, reporting, and investigation
- Incorporate continuous improvement activities and standardized risk communication plans
- Create a dashboard that summarizes and promotes timely awareness of safety risks across the portfolio and timely execution of safety risk minimization activities

The time for companies to reexamine their pharmacovigilance practices and to develop and implement effective, best-in-class solutions is now. Many organizations

have already begun to evaluate and enhance their pharmacovigilance practices for efficacy and efficiency, and through that experience many have encountered significant obstacles.

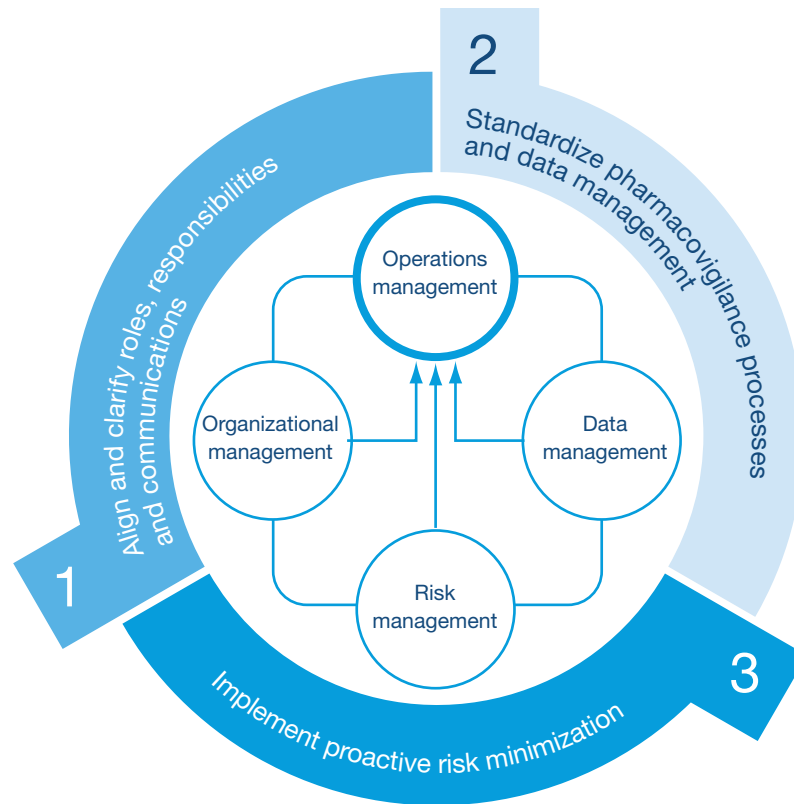
We believe that the practical approach that we present in *Unlocking the Power* provides a fresh perspective, both to those companies that have just begun the journey and to those that have encountered obstacles along the way. We have developed a framework that will enable companies to find success by concentrating on the integration of operations, risk management and the supporting organization. The power of this approach lies in the alignment of strategy with accountability and in the linkage of diverse functional areas within an adaptable, integrated operating framework—a framework that enables companies to navigate more easily both the challenging pharmacovigilance environment and the ever-changing expectations of the industry, regulators, and the public.

In the full version of this report, we provide insights that can guide companies as they contemplate the actions they will take to create this framework and foster the culture necessary to support it. We developed these insights based on conversations with several top industry executives in the R&D and drug safety areas, as well as our own experience in the drug safety space. We believe that those companies that examine their existing operations within the context of our recommendations can provide a better, safer post-market pharmaceutical environment. By so doing, companies will in turn find that they have greatly reduced both the costs and the risks relevant to drug safety, while simultaneously achieving significantly-improved outcomes for all patients.

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# The three strategies of effective pharmacovigilance

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“For a pharmaceutical company to be successful, drug safety has to be at the core of all discussions across the organization. Pharmacovigilance has to be embedded into the day-to-day operations of the company. Similar to other systems, most of the issues around pharmacovigilance systems are not IT [information technology] issues but mainly process and people and organization issues. Tools, including IT solutions, must be implemented in the context of addressing process improvements and organizational needs.”

Jean-Louis Saillot, M.D.  
Vice president and head  
of global pharmacovigilance  
at Schering-Plough

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