Denise Myshko

The ERA of Proactive Safety

Process, people, and technology have to align to enable a truly proactive risk-management and pharmacovigilance program that protects patients.

First, do no harm. This is medicine's highest ethical standard, an oath physicians take when they begin to practice. In the last few years, dangerous side effects of blockbuster products and some high-profile product withdrawals have brought this principle to the forefront of drug development.

Drug safety and pharmacovigilance have routinely been top of mind for pharmaceutical companies. But the processes and systems put in place have primarily been reactive rather than proactive. Now, however, consumers, physicians, payers, and regulators are demanding safer products and faster responses from the industry to address safety concerns. Additionally, regulators are requiring surveillance programs throughout a product's life cycle.

Technology and integrated systems now provide the opportunity for biopharmaceutical companies to implement proactive approaches to pharmacovigilance and move away from the traditional silo structure. Experts say there is a fundamental shift in the way companies are reorganizing their approach, they are also reinforcing that there is still a need for cross collaboration within companies and with partners in terms of people, process, and systems to achieve a truly proactive risk management and pharmacovigilance program.

Dan Foltz, director, health informatics, at CSC Life Sciences, says companies need to elevate the management, use, and access of information to an enterprise level.

"Right now information exists in silos across the company from discovery through clinical development and commercialization,, he says," he says. "There needs to be integrated data plans and integrated systems so that companies can access, link, and use all of the information assets that they have, as well as connect into the healthcare community to better understand and improve the impact of products in real-world settings."

"As an industry, companies are starting to get to the root of safety issues, and it's not just throwing more data at the problem," says Roy Devine, VP of Patni Life Sciences. "The increase of proactive safety programs will provide better products that are better tolerated by the patient population. I'm optimistic that companies will be able to do a better job for their end constituents — patients — over time."

Pharmacovigilance — the detection, assessment, and prevention of adverse effects of medicines — has now become a regulatory mandate, with product approval conditions that include some type of postmarketing surveillance component.

Every company wants to and should, at this point, be practicing proactive pharmacovigilance, says Linda Scarazzini, M.D., associate VP, U.S. risk identification, surveillance, and communication (RISC), at Sanofi-Aventis U.S.

"All companies want to have a proactive approach to patient safety," she says. "We want to be able to foresee and understand and predict what the potential safety issues will be related to either inherent toxicity or other risks, including off-label use or misuse. We want to design effective mitigation strategies that will work in the real world."

Dr. Scarazzini says beyond routine pharmacovigilance, more active surveillance mechanisms are being explored and implemented by companies.

"These include the monitoring of claims databases and electronic health records for evidence of new adverse events," she says.

Several trends are behind the increased focus on drug safety, Mr. Foltz says.

"One is the introduction of complex treatments, such as biologics, for which not all of the effects and treatment models may be fully understood," he says. "Another trend is increasing scrutiny of product safety caused in part by high visibility product withdrawals. A third trend is an increasing sophistication of the data and tools that are at our disposal to monitor and manage risk."

Gregory Hess, M.D., chief medical officer of SDI, says there is also a growing awareness of the value of retrospective observational data and effectiveness research.

"In the past, there was a deficit of postapproval studies," he says. "Now companies and the FDA are more aware of the value in studying a drug after it's been approved."

Experts say technology that is fully aligned with business processes is allowing pharma companies to integrate all of their data from various sources across the globe to do real-time analysis of safety information.

"Real-time analysis of safety data allows companies to take immediate and proactive action," says Krishnan Rajagopalan, Ph.D., global head of life sciences BPO, at Cognizant. "This is vitally important from a patient safety, risk, compliance, and brand or competitive positioning perspective, and this is why pharmacovigilance is one of the most critical business process areas."

Dr. Scarazzini says going forward, claims

> "There is a growing awareness of the value of retrospective observational data and effectiveness research."
>
> **DR. GREGORY HESS** / SDI

> "To ensure safety profiling, safety reporting requirements need to be harmonized."
>
> **VIVIAN BROACH** / PPD

data and electronic health records will be used for enhanced active surveillance.

"As the technology and the sophistication of the tools available to evaluate safety of marketed products continues to expand we, as well as the FDA and other worldwide agencies, continue to grapple with learning the best, most practical ways to use these enhancements to our advantage to evaluate safety issues and act on them," she says.

Challenges for Proactive Pharmacovigilance

A report from Cutting Edge Information found that drug safety groups' activities vary widely from company to company. On average, about 64% of companies surveyed by Cutting Edge Information outsource some portion of their drug safety budget. The outsourcing of IT solutions is also popular, with 64% of companies choosing this option.

The Cutting Edge Information report also found that overall 17% of companies responded drug safety is a stand-alone entity reporting up to C-level executives; 33% of large and midsize companies report having a stand-alone safety department reporting up to senior executives.

Dr. Rajagopalan says companies are recognizing the need for better governance of safety groups.

"Both the clinical development organization and the pharmacovigilance or safety groups need to report into a single function," he says. "This will allow them to look across the company at the safety information by therapeutic area and by product portfolio and feed the data back to the clinical protocol for the next drug that may be developed."

He says pharmacovigilance and safety issues are not a silo function, but a cross-process function that requires collaboration among many functional groups such as risk management, packaging, labeling, clinical operations, therapeutic teams, biostatistics, regulatory affairs, medical writing, and public relations functions.

Dr. Rajagopalan points out that pharmacovigilance is now a global effort, and this, in itself, creates many challenges for companies.

"For example, even within one organization, the processes may be inconsistent across geographies and business units or functions," he says. "A major issue for companies is coming up with a single pharmacovigilance and safety process."

The EU is about to issue revised regulations and directives on pharmacovigilance, says Carrie Corboy, R.Ph., Pharm.D., executive director, global safety and pharmacovigilance, at PharmaNet.

"The EU proposed changes include greater,

TIPS

Tips for Building an Adaptive Pharmacovigilance Framework

- 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 process and organizational checks and balances are in place to limit bias and manage regulatory risk
- 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 transparency and accessibility of safety information
- Select a vendor that best matches the pharmacovigilance operating model, business process, and vendor/system selection criteria
- 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

Source: PricewaterhouseCoopers.
For more information, visit pwc.com.

> "There is an increasing sophistication of the tools that are at our disposal to monitor and manage risk."
>
> **DAN FOLTZ** / CSC Life Sciences

> "Every company should be practicing proactive pharmacovigilance."
>
> **DR. LINDA SCARAZZINI** / Sanofi-Aventis

> "There is a need for cross collaboration within companies, from a process and systems perspective."
>
> **DR. KRISHNAN RAJAGOPALAN**
> Cognizant

Three Major Phases to REMS Life-Cycle Management

1. Evaluation, Planning, and Design Phase
Companies should be looking to other industries and stakeholders for validated or proven approaches to evaluate risks and design risk-mitigation strategies. There are evidence-based methods and effective tools that have been deployed in other industries that could be readily repurposed for pharmaceutical risk management.

2. Implementation and Management Phase
Companies need to begin to organize themselves internally to be able to actively plan, implement, project manage, and track REMS programs. Many companies are now moving toward a more centralized REMS program-management office approach.

3. Tracking Phase
Companies should begin anticipating the need to modify a REMS program as early as possible during the program design phase. They should be prepared to track and analyze surrogate measures of program implementation effectiveness, as well as to conduct formal program assessments, to better understand how the program could be modified and improved over time to achieve the REMS goal.

Source: Dr. Linda Scarazzini, Sanofi-Aventis U.S.

and more consistent, transparency to the public via the web," she says. "The ICH guideline for a developmental safety update report (DSUR) has reached Step 4, and several countries have indicated they would accept this in place of local documents. Formal notification of DSUR acceptance is imminent."

In the United States, the FDA started to push adverse event reporting requirements into early development. In September 2010, for example, the FDA issued final regulations addressing the safety reporting guidances for investigational new drug applications (INDs). The new rule requires that certain safety information that previously had not been required to be reported to the FDA be reported within 15 days of becoming aware of an occurrence.

Dr. Corboy says regulatory agencies are becoming more focused in all aspects.

"We've seen exponential increases in both food and device recalls this year," she says. "The agency has made it clear, with its revised final rule on IND Safety Reporting requirements, that it is interested in meaningful information, right from the start of drug development. The release of a final rule on postmarketing safety reporting is expected shortly and will complement the IND Safety Reporting final rule released in September. And we expect a postmarketing final rule will be released with the same understanding and the expectation that compliance with the new rule should be quick and relatively easy. Therefore, I expect the agency will strongly enforce compliance with existing and any new regulation."

Strategies and Best Practices

Our experts say key components for a successful pharmacovigilance program include an integrated infrastructure, a compliance plan, well-trained and dedicated pharmacovigilance staff, and the technology to support the ever-changing environment.

Dr. Corboy says pharmacovigilance programs must integrate certain basic components with an emphasis on continuity throughout drug development, from preclinical through postmarketing.

"These components include signal detection based on individual reports of adverse events, routine review of aggregate data, both on a given product and with the context of similar products — either by class or indication, review and assessment of data from company sources — safety databases, clinical databases, as well as the global literature," she says. "Finally, the program must include both clinical and nonclinical data. Pharmacovigilance brings meaning to the various data, through context and evaluation."

Experts say early planning for pharmacovigilance activities is critical. Mark Nelson Tyrrell, director of risk management services for the Americas, at PRA International, agrees, saying the best risk management program begins with proof of concept in early development.

"Any product falls into one of two categories; it's either part of an existing therapeutic class or it is a new molecular entity for a first-in-class product," he says. "If it's part of an existing therapeutic class, there are data on classwide effects, but comparative rates still need to be determined. If the product is first in class, the safety profile is probably unknown, and signal detection programs will need to be set up."

David Selkirk, VP, clinical development, late phase, at Omnicare Clinical Research, says it's critical that the proper infrastructure is in place so that ADRs are optimally collected.

"There is a large array of technology options, including the Internet, available for this purpose," he says. "The idea of signal detection is paramount in that the sponsor needs to find the pharmacodynamic effects that have a causal relationship to the medication. These outcomes are then reported to the regulators for assessment, who in turn will work with sponsors to maximize public safety."

Mr. Devine points out that not all risk mitigation strategies are created equal.

"The long-term economic impact of the one selected needs to be evaluated," he says. "Patient registries are not expensive to set up, but managing them for the next 20 years can be significant, and this aspect needs to be addressed. Restricting the potential prescribing population down to a certain number can have long-term operational cost impact, since making the target patient population too restrictive can reduce overall sales. Companies need to consider the actual financial impact and the return on the investment for the different solutions and not just pick a mitigation strategy that they think will get approved."

For the foreseeable future, sponsor organizations will need to budget more time and money into postmarketing surveillance programs, Mr. Selkirk says.

"They need to show that they are investing in protecting public safety," he says. "Specifically, if a manufacturer is launching a product within a class of drugs with known safety concerns, it must demonstrate the effectiveness of the product in the real-world setting. HTA, or health technology assessments, groups will also be evaluating the value these products bring to society. In general, manufacturers need to assume that significant resources will continue to be involved postlaunch, and this will likely affect product pricing for the future."

Mr. Selkirk says there is a significant need for more humanistic data from contemporary medical practices.

"Manufacturers, physicians, and patients alike will all be under increased pressure to participate in observational research," he says. "The purpose of this research is not to influence the treatment methodology in any way, but rather to document and analyze how the therapy is being administered in practical use. The requirement for more observational data will place a significant financial burden on manufacturers. Everyone needs to contribute to making this process less labor-intensive."

Upcoming Conferences

Pharmacovigilance Summit
March 14 - 15, 2011
Copthorne Tara Hotel, London

Continuous evaluation and assessment are best practices and help to ensure procedures are compliant and up to date with regulatory requirements across all aspects of pharmacovigilance, says Vivian Broach, VP of operations, postapproval pharmacovigilance, at PPD.

"Greater emphasis on frequent aggregate safety data reviews vs. individual case reviews is critical," she says. "There needs to be frequent and open communications between partners, agencies, and vendors. Additionally, global harmonization of safety reporting requirements needs to be considered to decrease the price of research and development and to ensure continued safety profiling." PV

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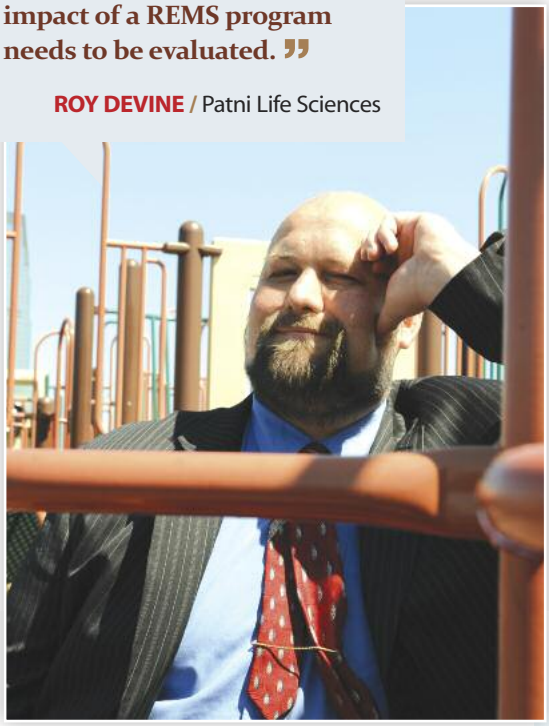
> **"The long-term economic impact of a REMS program needs to be evaluated."**
>
> **ROY DEVINE** / Patni Life Sciences



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Safety by the CLASS

An FDA panel has voted against a controversial plan to include classwide REMS programs on opioid products. Industry experts talk about the implications and what's likely to happen next.

In July 2010, an FDA panel voted against the controversial opioid risk evaluation and mitigation strategies. Most committee members said safety measures for opioids are urgently needed, but voiced concern that the current approach does not go far enough to protect the public.

The committee unanimously agreed that the goals of REMS are appropriate, however, the individual components of the REMS are insufficient to address the misuse and abuse of opioid analgesics. Committee members strongly stressed the need for appropriate and adequate legislation to further the collaboration with other federal agencies since voluntary training and education efforts have not worked. Many members suggested that mandatory prescriber education and mandatory patient counseling are needed.

FDA officials say the agency continues to review input received from the July 2010 advisory committee meeting and the public. The agency has not yet made any final decisions on the REMS program. Once final decisions are made, regulators will communicate these requirements to the manufacturers, and they will have up to 120 days to submit a program for the FDA's review and approval. The FDA hopes to approve the program sometime in 2011 with the roll out and implementation to follow.

"There were strong arguments from opponents and proponents for a classwide REMS," says Mark Nelson Tyrrell, director of risk management services for the Americas, at PRA International. "The issue becomes how to provide access of these proven therapies to the patients who really need them while trying to meet the public goal of ensuring they are being used appropriately and as part of a necessary regimen."

Postmarketing on Track

A recent FDA study of 1,551 postmarketing studies/clinical trials showed that 40% of the postmarketing studies/clinical trials had been closed (either fulfilled or released) by the FDA. Of the remaining 60%, most were in progress and on schedule or the final report had been submitted for FDA review. Other findings: the status of 591 requirements changed; almost half (46%) were updated to fulfilled status; and 17% of the backlog of requirements were delayed.

Source: FDA. For more information, visit fda.gov.

Mr. Tyrrell says it remains to be seen whether a consolidated effort by all manufacturers to develop one focused education and outreach program will succeed where multiple various programs have failed.

Developing a REMS for an entire class of drugs with a highly variable patient population is very challenging, says Carrie Corboy, R.Ph., Pharm.D., executive director, global safety and pharmacovigilance, at PharmaNet.

"Many companies have little experience with REMS development and even fewer have developed a REMS containing anything more than a medication guide," she says. "There has not been enough time to evaluate the effectiveness of these REMS with elements for safe use."

There are still questions as to how to handle differences in the products, says Roy Devine, VP of Patni Life Sciences.

"All opioids are not equal," he says.

> "There will be more programs and requirements for pharmaceutical companies to manage and navigate."
>
> **VIVIAN BROACH** / PPD

> "It remains to be seen if a consolidated effort by all manufacturers focused on education and outreach will succeed when multiple programs have failed."
>
> **MARK NELSON TYRRELL**
> PRA International

Systems for Monitoring Drug Safety

In July 2010, the **FDA** provided an update on its Sentinel Initiative, a long-term program designed to build and implement a national electronic system for monitoring the safety of FDA-approved drugs and other medical products.

This initiative was launched after the passage of the **Food and Drug Administration Amendments Act (FDAAA)** in September 2007. One of the goals set by **FDAAA** was a new **FDA** safety monitoring system. The **FDA** met the July 2010 goal for access to 25 million patients' electronic healthcare data and is already working toward the patient data access goal of 100 million patients by 2012.

The **FDA's Sentinel System** is being developed as a "distributed system," meaning that data remain in their existing secure environments, rather than being consolidated into one database. Collaborators in this public-private partnership include data partners, patient and healthcare professional advocacy groups, academic institutions, and regulated industry.

Within this distributed system, a Coordinating Center will receive and process FDA-generated safety questions.

The Sentinel System will not replace the agency's existing postmarket safety monitoring systems. It will be an "active surveillance" system, because it will enable the agency to initiate its own safety evaluations that use available electronic healthcare data to investigate the safety of medical products.

One pilot program, **Mini-Sentinel,** launched at the end of 2009, will enable the **FDA** to query privately held electronic healthcare data (including administrative claims and clinical data) representing about 60 million patients. Another pilot, The Federal Partners' Collaboration, will enable the **FDA** to query federally held electronic healthcare data, including administrative and claims data, and data from electronic health record systems.

Another initiative is sponsored by **The Foundation for the National Institutes of Health**. **The Observational Medical Outcomes Partnership (OMOP)** is a public-private partnership designed to help improve the monitoring of drugs for safety. The partnership is evaluating research methods that are feasible and useful to analyze existing healthcare databases to identify and evaluate safety and benefit issues of drugs already on the market.

It is composed of representatives from the **FDA**, academia, 17 corporate and nonprofit organizations in the pharmaceutical industry and healthcare providers with large health claim or electronic health record databases. The partnership is focused on the need to advance the science of active medical product safety surveillance by using existing health databases.

In an update in October, the partnership announced it was on track to successfully complete the goals outlined in the original research plan by the first quarter of 2011. **OMOP** is empirically studying the contribution of and synergies among data, technology, methods, and governance required to establish an active surveillance system for pharmaceutical safety using existing observational databases.

In the two years since **OMOP** was launched, it has assembled a central research core of scientists, a program management team responsible for oversight and operations of the research program, technical staff responsible for developing program code for the methods and implementing the research protocols, a research lab with access to five central databases, a funded core of five research partners that represent a distributed network of diverse data sources, types, and populations, a dynamic worldwide community of active surveillance methods collaborators, and a public-private partnership with a governance structure for project oversight.

OMOP was originally launched as a two-year research program that called for the effort to wind down in early 2011. The **OMOP** executive board recommended that **FNIH** continue the partnership. **OMOP** will broaden it stakeholders, to include federal healthcare, insurance, biopharma, IT, and nonprofit partners. **OMOP** will provide grants for promising ideas and will provide data and technical resources to enable research.

Sources: The FDA. For more information, visit fda.gov. The Foundation for the National Institutes of Health. For more information, visit fnih.org.

"Methadone, for example, is a bit different from fentanyl, and having the same requirements for both products doesn't make a lot of sense. There are a lot of differences between products and a single class-level REMS doesn't adequately cover the nuances of the different products."

Mr. Devine says no single solution is going to be a silver bullet.

"There are still going to be compliance issues, abuse in some cases, and reporting issues," he says. "A single, classwide approach doesn't solve the problem. It's a much better idea to take a proactive look at the safety profile of the products than wait until there is a problem."

He says classwide REMS have been used in certain circumstances.

"One of the options listed as a REMS is to limit the number of doctors who can prescribe certain products," Mr. Devine says. "For example, for class 1 narcotics the doctors who want to prescribe them need to prove to the DEA that they have appropriate security.'"

"Doctors who want to prescribe Thalomid must be registered and comply with very strict reporting requirements as part of S.T.E.P.S. (System for Thalidomide Education and Prescribing Safety)," he says. "It is an overhead for the doctors but it is worth it for the cancer specialist whose patients benefit from a very effective product. This is a very costly program for Celgene but because they are managing the program and they are the only company who makes the product, they will have limited competitive pressure. I

doubt the product will ever go generic, so they should have a very long productive revenue stream from the product line without the price pressure of competition."

Given the complexities surrounding the range of risks and products being addressed, it is possible that the final result will be consistent REMS guidelines specific for this class of product instead of a central program, says Vivian Broach, VP of operations, postapproval pharmacovigilance, at PPD.

"This approach would allow each manufacturer to address both the class risks as well as their product-specific risk," she says. "The challenge of this approach will fall on the prescribers and pharmacies that will need to manage dozens of programs instead of one. We believe the FDA will continue to address REMS in as streamlined approach as possible. But whether this occurs via centralized programs or more consistent programs isn't clear."

Dr. Corboy says if a revision of the classwide REMS is not attained in the early part of 2011, it is likely innovator companies will move forward with developing a REMS to protect their products still under patent.

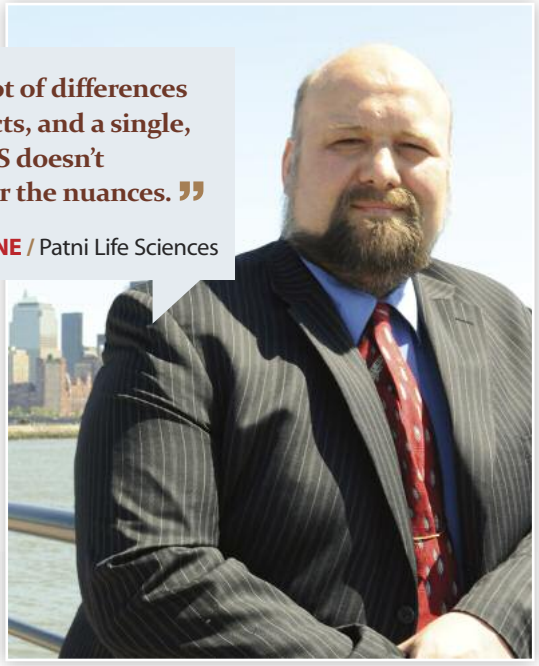
"It is very likely that companies that move more slowly will be forced to adopt what the first companies put in place," she says. "Ultimately, a classwide REMS might come about not by consensus, but by the first-to-finish companies."

Efforts for classwide REMS will continue, says David Selkirk, VP, clinical development, late phase, Omnicare Clinical Research.

"A flaw in one individual plan does not mean that the idea of surveying drug classes will cease," he says. "I would imagine that the FDA and other global regulators will err on the side of caution. If there is a possibility that a type of medication could have an undesirable effect, then a classwide REMS could be put into place. The onus will be on the manufacturer to prove that its individual compound does not demonstrate the risk before it is exempted from the plan. Case in point is the new medication guide for all bisphosphonates prescribed for osteoporosis. There is no confirmed causative relationship of this type of medication to atypical fractures of the thigh and diaphyseal femur fractures, but there is a requirement to communicate the association. This scenario will become increasingly common."

In the near term, Mr. Selkirk says it is doubtful that there will be additional rigor added to what is currently in place.

"In the long-run, though, I think regulatory agencies around the world will incrementally increase the requirements for pharmacovigilance," he says. "The idea of individualized medicine will also drive a lot of population sub-group analysis so that side-effect profiles can be built that are much more specific to different ethnicities, age groups, genders, etc. With the world's population aging, there will also be a demand for safety profiles that are relevant to various co-morbidities and concomitant medications." PV



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- Drug Discovery