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The Next Phase of Pharmacovigilance

Why Post-Market Safety Monitoring Needs a Broader, More Real-Time Approach

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Post-market safety monitoring matters more than ever

Pharmacovigilance plays a critical role in ensuring the long-term safety of drugs, biologics, and medical devices by detecting rare, delayed, or population-specific adverse events that often do not appear during clinical trials. As pressure grows to bring life-saving treatments to patients faster, post-market surveillance is becoming even more important.

The FDA has taken steps to accelerate approvals by streamlining certain regulatory processes and reducing some pre-market requirements. These efforts are designed to shorten development and review timelines, but they also shift more responsibility to real-world monitoring after products enter the market. That raises an important question: Are today's pharmacovigilance systems equipped to detect safety signals early enough?

Traditional reporting still matters but it is not enough

For decades, safety monitoring has relied heavily on passive adverse event reporting from patients receiving drugs, biologics including vaccines, and treatments involving medical devices. More recently, organizations have also looked to other established data sources such as claims data, electronic health records, clinical notes, and registry data.

These traditional sources remain necessary. They help identify low-frequency safety events and support informed action on recalls, warnings, and other safety decisions. But they are also often lagging, incomplete, and reactive. Many pharmacovigilance frameworks still depend on spontaneous reporting systems, manual case processing, and rule-based statistical methods that can struggle to keep pace with the volume, speed, and variety of safety-related data generated across today's healthcare landscape.

The result is a system that can be slow to detect weak or emerging signals and limited in its ability to draw insight from less structured data.

Broader signals can strengthen early detection

If the goal is earlier detection, more informed action, and better injury prevention, incremental improvements to traditional data sources alone may not be enough. Pharmacovigilance may need to expand its field of view.

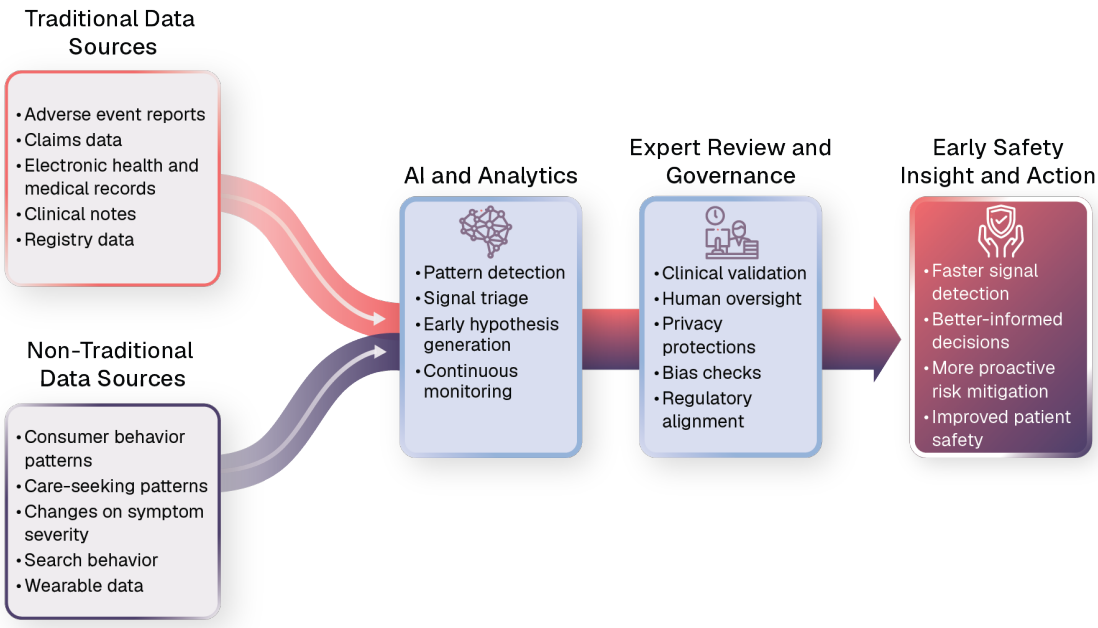
One approach is to incorporate non-traditional proxies of adverse events — signals that may emerge before a formal report is filed or a pattern is visible in traditional systems. These sources could include:

- Consumer behavior patterns, such as sudden discontinuation, switching, or substitution of over-the-counter products
- Care-seeking signals, such as urgent care visits, telehealth spikes, or pharmacy consultations

- Acuity indicators, such as changes in utilization intensity, diagnostic escalation, or symptom clustering
- Digital signals from patient journeys, such as search behavior, wearable data, and engagement patterns

Individually, these inputs may seem noisy. Collectively, they may offer earlier directional insight into emerging safety issues.

This is not about replacing traditional pharmacovigilance. It is about augmenting existing systems with more forward-looking signals that can support earlier hypothesis generation, faster signal triage, and more proactive risk mitigation.



AI can accelerate insight but expert judgment, trust, and governance still lead

The challenge, of course, is that these data sources are large, messy, fast-moving, and often difficult to interpret. That is where AI and advanced analytics may play an important role.

Machine learning, deep learning, and natural language processing can help automate the ingestion and analysis of large, heterogeneous datasets, improve pattern recognition, and support learning from continuously evolving data streams. Used well, these tools may help surface weak or emerging patterns that warrant closer human review.

But AI does not eliminate the underlying challenges. It introduces its own concerns around data quality, representativeness, bias, transparency, interpretability, and generalizability across populations and therapeutic areas. It also does not eliminate the need for expert

oversight. A more modern pharmacovigilance model still requires subject matter experts to validate signals, assess relevance, and ensure clinical and regulatory rigor.
A more real-time, signal-driven approach to pharmacovigilance cannot succeed on technical capability alone. It also has to be trusted.

That means agencies and their partners need to think carefully about privacy, governance, validation, and responsible use, especially when discussing less traditional indicators such as search behavior, wearable data, or other signals outside formal clinical systems. The goal is not broader surveillance for its own sake. The goal is to identify patterns earlier, validate them responsibly, and improve public health action while maintaining transparency and trust.

Progress will depend on agencies, industry, and health technology partners

A more proactive, signal-driven pharmacovigilance ecosystem will require coordinated action across federal agencies, industry sponsors, and health technology partners, with each bringing a distinct but complementary role.

Federal agencies can lead by establishing clear regulatory frameworks for how non-traditional data sources and AI-driven methodologies may be incorporated into pharmacovigilance. That includes setting standards for data quality, validation, and auditability; issuing guidance on the acceptable use of real-world and proxy data; and investing in modern infrastructure that enables secure, scalable data integration. Agencies will also need to evolve from retrospective signal evaluation toward more continuous, near real-time surveillance while maintaining oversight, transparency, and public trust.

Industry partners, including pharmaceutical, biotech, and device manufacturers, play a critical role in operationalizing these advancements across the product lifecycle. They are well positioned to integrate diverse data streams from development through post-market monitoring, test emerging approaches to early signal detection, and work with regulators to validate new methodologies. Their role is not only to innovate, but to ensure that expanded use of data and analytics remains grounded in scientific rigor, patient safety, and real-world applicability.

Health technology firms can help bridge the gap between fragmented data and actionable insight. With expertise in health, data engineering, AI and machine learning, and scalable analytics platforms, these organizations can support agencies and sponsors by designing systems that ingest complex, high-velocity data, surface weak or emerging signals, and present findings in ways that support clinical, operational, and regulatory decision-making. They can also help build the technical and governance frameworks needed to make these approaches more usable, transparent, and scalable in practice.

Leaders can start with three practical steps

For federal health leaders, the opportunity is not simply to collect more data. It is to build a more practical and responsible framework for identifying, validating, and acting on the signals that matter most.

The most effective way to begin is with three practical steps that strengthen signal detection, oversight, and action.

- Set standards for AI and new data sources by defining clear guidance on data quality, validation, bias, and transparency so organizations can adopt AI and non-traditional signals with confidence and rigor.
- Build real-time, interoperable infrastructure by investing in modern platforms that integrate diverse data streams and enable continuous, near real-time safety monitoring across stakeholders.
- Launch focused pilots and scale what works by testing signal-driven approaches in high-impact areas with industry partners, then expanding proven models with built-in governance and clinical validation.