

Improving Patient Health and Safety through Pharmacovigilance and Medical Information Synergy

Panelists:

Nikkita Evans, BSc, Principal Pharmacovigilance Safety Scientist, ProPharma

Beth Jeffries, PharmD, Medical Information Program Manager, ProPharma

Moderator: Dr. Andrew Warmington, Manufacturing Editor, Citeline

KEY TAKEAWAYS

- Early signal detection is crucial for ensuring patient safety.
- Signal validation and management is where collaboration between MI/PV is critically important.
- MI teams play a key strategic role in identifying and managing safety signals.

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OVERVIEW

Collaboration between life sciences organizations' [pharmacovigilance](#) (PV) and [medical information](#) (MI) departments can enhance patient safety by improving early detection of potentially causal associations between drug interventions and adverse events—and by quickly communicating validated signals.

The role of medical information, in particular, is increasingly important, not only for the initial collection of data, but also for triaging and communicating any safety-related updates resulting from that data.

CONTEXT

The panelists discussed the importance of early detection and communication of safety signals, key steps and tools in signal detection and communication, and MI's contribution to signal detection and safety surveillance. The discussion also highlighted the impact of cross-functional alignment between PV and MI on faster response, more informed regulatory action, and better patient outcomes.

KEY TAKEAWAYS

Early signal detection is crucial for ensuring patient safety.

The [definition of a safety signal](#), as per the Good Pharmacovigilance Practices (GVP), is information arising from observations or experiments which suggests a new potentially causal association (or a new aspect of a known association) between a medicinal product and an event. The association, which in the context of patient safety typically refers to an adverse event, must be judged to be of sufficient likelihood to justify verification.

Biotech and pharma companies' capability to detect safety signals is relevant because clinical trials often provide limited data on the full safety profile of new drugs. This is often due to small sample sizes, the relatively short duration of trials and selective patient populations which may exclude special populations such as geriatric, pediatric or pregnant patients.

Figure 1 shows the relevance of signal detection for rare or extremely rare adverse reactions (ADRs) during post-approval, when a much larger number of patients (>3,000) than those participating in the trial are potentially using the drug.

Figure 1. Why signal detection post-approval is necessary

Frequency of ADR		Detection
1 : 10	Very common ($\geq 10\%$)	Development programme ($\leq 3,000$)
1 : 100	Common ($1\% - <10\%$)	
1 : 1000	Uncommon ($0.1\% - <1\%$)	
1 : 10,000	Rare ($0.01\% - <0.1\%$)	Market Surveillance ($>3,000$)
1 : 100,000	Very rare ($< 0.01\%$)	
1 : 1,000,000	Not known (cannot be estimated from the available data)	
1 : 10,000,000		

“Sometimes rare side effects might not appear until the drug has been used by thousands or even millions of patients,” Nikkita Evans, principal pharmacovigilance safety scientist at ProPharma, said. “Some effects might not be seen until the drug has been used for a long period of time, and therefore might not be identified in the trial period.”

Figure 2. Sources of safety data for signal detection



Signal detection methods include both quantitative (statistical) and qualitative (case-based) methods, with the former typically used for removing noise in large datasets and the latter for building a full picture of causality in small datasets. Quantitative methods typically rely on algorithms, while qualitative methods rely on expert judgment and clinical knowledge.

Signal validation and management is where collaboration between MI/PV is critically important.

Potential signals may be noted by a company’s MI team, but must be assessed and validated by the PV team against four key considerations:

1. **Previous awareness:** Extent to which information is included in the Summary of Product Characteristics (SmPC), potential class effect.
2. **Strength of evidence:** Total number of cases, quality of the data, possible mechanism based on biological and pharmacological plausibility.
3. **Clinical relevance and context:** Seriousness, severity, outcome, and reversibility of the reaction; reactions occurring in vulnerable populations or in different patterns of use (e.g., overdose, abuse, off-label use, medication errors).
4. **Additional data sources:** Data pertaining to the same substance of the same product class, databases with larger datasets, information published by other regulatory agencies worldwide.

If a safety signal has been validated, pharma companies need to update product labeling and ensure the new information has been communicated to regulatory authorities, healthcare professionals, and patients. They also need to reflect this information in internal risk management plans, implement risk minimization measures, document actions, and update internal trackers.

“Signal management is a critical part of the PV process because it supports patient safety through early identification of potential risks before they become widespread. It also supports regulatory decision making by enabling timely updates of product labeling; risk minimization through targeted safety communication; and healthcare professionals in making informed treatment decisions.”

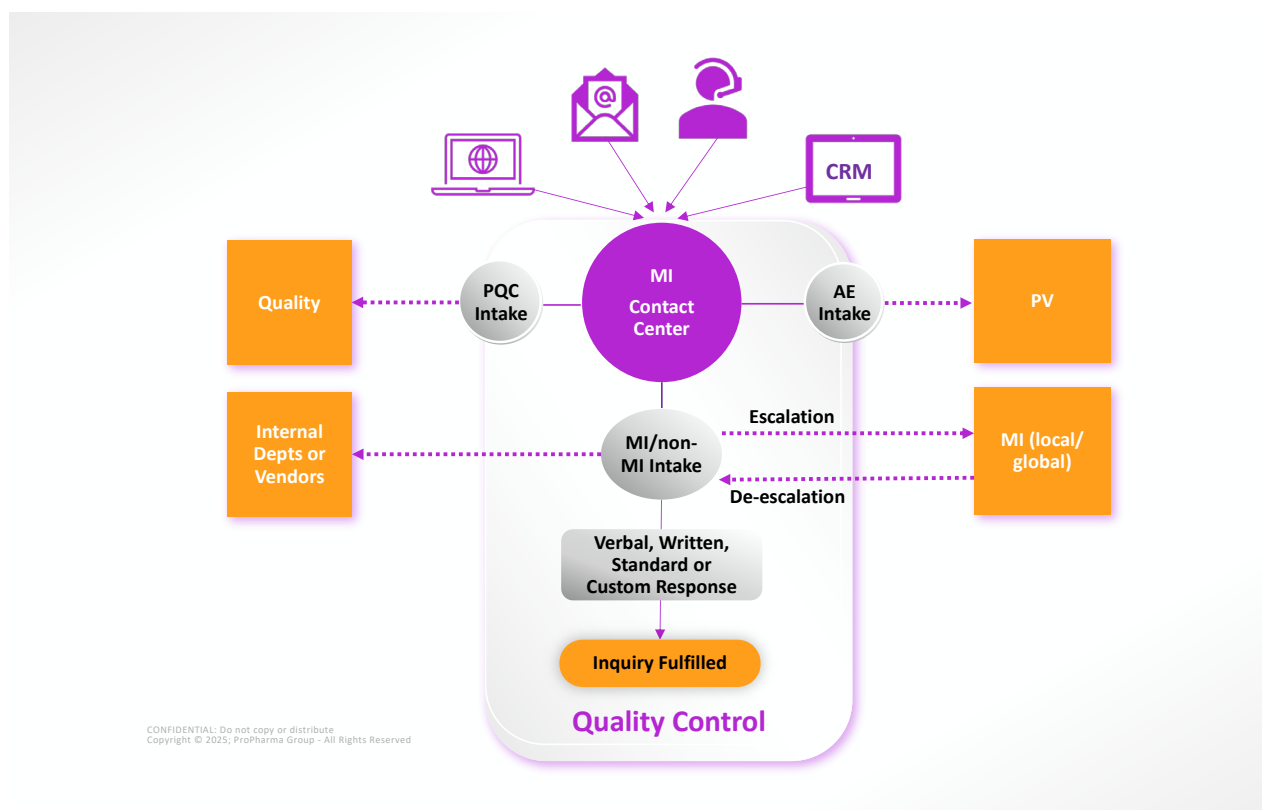
– Nikkita Evans, ProPharma

MI teams play a key strategic role in identifying and managing safety signals.

MI teams are responsible for answering questions from healthcare professionals and members of the public regarding a company’s products, with the aim of helping physicians make clinically informed decisions and improving patient health and safety.

The questions MI professionals receive are essential to detecting signals because they come from the front line of healthcare and can reveal emerging safety concerns before they appear in traditional safety databases. To support these activities, MI systems track common topics, keywords, and trends from incoming queries, categorize and document the information, and share it with the companies’ PV teams.

Figure 3. A high-level overview of the MI query intake process



“The traditional MI flow is a first-line way for members of the public to reach the company with their concerns, but there’s an emerging need to monitor social media sites as well,” Beth Jeffries, MI program manager at ProPharma, said. ProPharma provides social media community monitoring and social response management services.

“Patients are connecting across patient support sites, chat rooms, and blogs. . . These conversations can reveal adverse events. MI contact centers can help monitor these key websites for potential adverse events or product quality complaints.”

– Beth Jeffries, ProPharma

When signals captured by MI teams are deemed valid by PV teams, the information must be shared with relevant stakeholders and the drug’s safety profile must be updated. Some of the tools used to update a medicinal product’s safety information include label updates, “Dear Healthcare Professional” letters, and product recalls (which can be voluntary or mandated by regulators). In the most serious cases, regulatory authorities may issue a product’s full withdrawal from the market.

In all of these scenarios, MI teams play a key role in the actions that lead to issuing safety updates. As the first-line resource for physicians and patients, they can clarify how a drug’s updated safety profile affects them, provide guidance on what to do if the product has already been used, or suggest alternative treatments.

MI professionals are also responsible for outbound communications with providers—for example, to confirm receipt of recall notifications—and for triaging inquiries to other internal departments, such as those tasked with returns/replacements or legal inquiries.

CONCLUSION

The collaborative impact of life sciences organizations’ PV and MI departments goes beyond each function’s individual roles and contributions.

MI contact centers, teams, and professionals are responsible for initial data collection and signal detection through market surveillance, including social media monitoring, and for communicating safety updates to providers, patients, and internal stakeholders.

PV teams, on the other hand, are the experts and key decision makers on validating potential safety signals and ensuring compliance with regulations.

The synergy between these two functions is no longer a “nice to have” but is now an essential must-have for pharma organizations that are committed to patient safety and to maintaining a competitive edge in an industry long dominated by internal silos.

“The collaboration between MI and PV is key to supporting a culture of safety, transparency and trust.”

– Beth Jeffries, ProPharma

BIOGRAPHIES



Nikkita Evans, BSc

Principal Pharmacovigilance Safety Scientist
ProPharma

Nikkita Evans is a Principal Pharmacovigilance Safety Scientist within the Benefit-Risk team at ProPharma, with over 10 years of experience in pharmacovigilance, specializing in signal detection and benefit-risk evaluation. Throughout her career, Nikkita has led critical signal management activities across a broad range of therapeutic areas, applying data-driven methodologies to identify emerging safety concerns and support evidence-based regulatory decision-making.

She has collaborated across diverse cross-functional teams to deliver high-quality, results-oriented outcomes. Nikkita is especially passionate about the effective communication of safety signals—translating complex data into clear, actionable insights that drive patient safety and informed decision-making.



Beth Jeffries, PharmD

Medical Information Program Manager
ProPharma

Beth Jeffries is a Medical Information Program Manager with almost a decade of experience in pharmaceutical sciences and medical communications. She currently leads global medical information programs at ProPharma, where she collaborates with top-tier pharmaceutical clients to ensure the delivery of accurate, compliant, and strategic medical content across international markets.

Beth's expertise spans global medical information strategy, contact center operations, and quality assurance. She has been instrumental in developing training programs, standard response documents, and quality insights that drive continuous improvement and regulatory excellence. Her passion for delivering high-quality medical information and fostering cross-functional collaboration makes her a trusted leader in the field.



Dr. Andrew Warmington (Moderator)

Manufacturing Editor
Citeline

Dr. Andrew Warmington has been writing about pharmaceuticals and related industries since becoming editor of Speciality Chemicals Magazine in 2002. His particular area of expertise is in the C(D)MO drug substance and CRO markets, plus the regulatory side, which was developed during a stint with Chemical Watch. He joined Citeline as Manufacturing Editor in 2022, since when he has authored numerous white papers and articles, and chaired roundtables and other events for clients. He took his BA at the University of York and a DPhil at Oxford University, both in History.