

Welcome to the webinar

Essential strategies for pharmacovigilance and post-market surveillance

With Dr. Manolo Beelke



What is Qualio?

The #1 cloud-based quality management system for life science companies



Easy to use



Scales as you grow



Trusted globally

Today's speaker

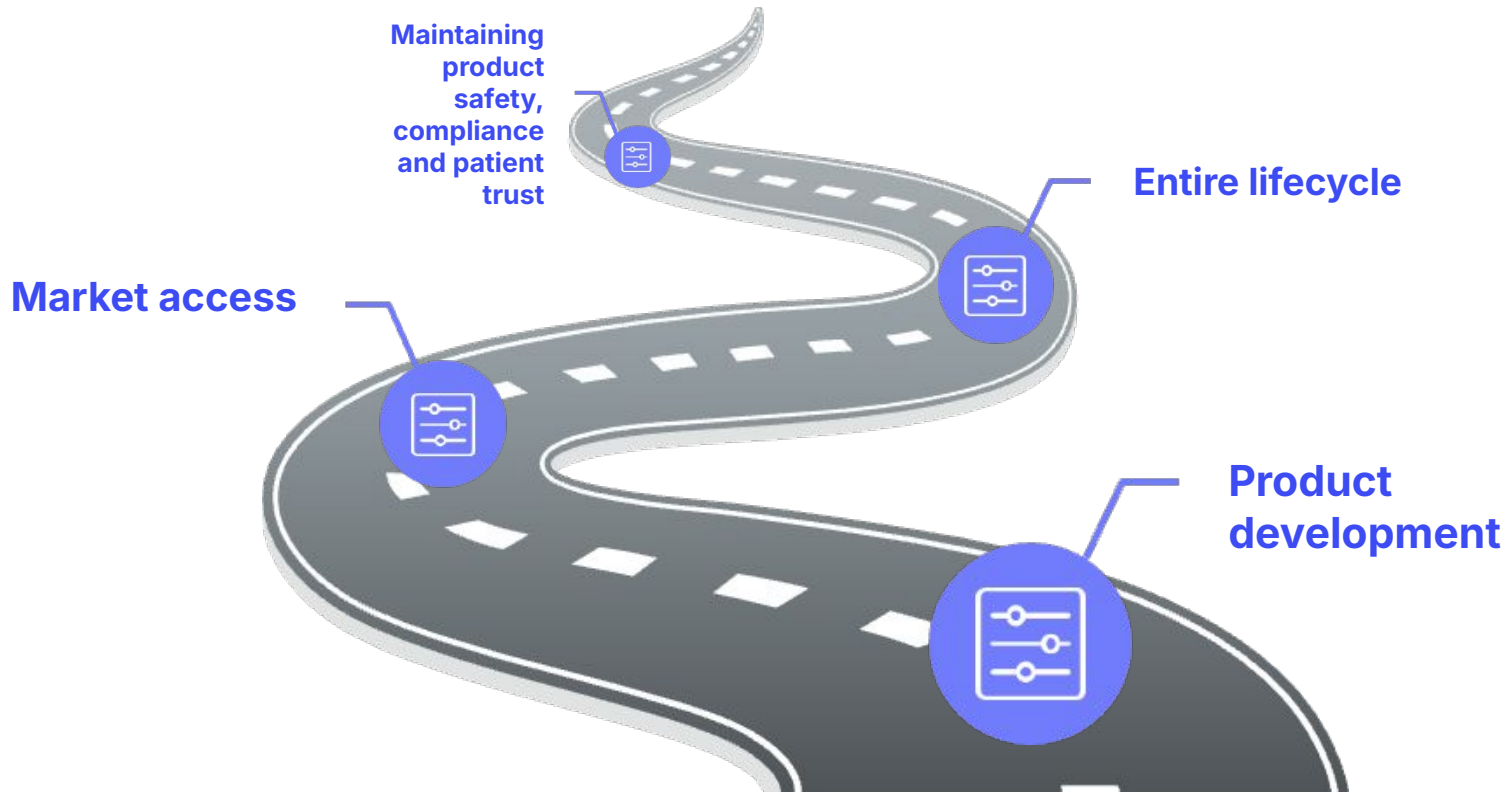


Dr. Manolo Beelke

Chief Medical Officer, Founder &
Managing Director

Manolo Beelke & Partners

Pharmacovigilance: a continuous journey



Today's agenda

01

Intro to pharmacovigilance

02

Regulatory framework & compliance

03

Building and strengthening your PV program

04

Detecting and prioritizing signals



Today's agenda

05 Case studies & practical examples

06 Post-market surveillance

07 Leveraging technology in PV

08 Conclusion, takeaways & Q&A



What is pharmacovigilance, really?



- 1) Science and activities focused on detecting, assessing, understanding and preventing adverse drug effects**
- 2) Ensuring your drug's benefits outweigh its risks**
- 3) Ongoing safety monitoring through the entire lifecycle of the product**





FDA Post-Market Requirements – US standards emphasizing adverse event reporting.

Good Pharmacovigilance Practices (GVP) – EU standards for maintaining consistent drug safety.

International Council for Harmonisation (ICH) – Promotes global pharmacovigilance standards.

Why is PV important?

- 1 Real-time detection and management of adverse events
- 2 Ensures patient safety and regulatory compliance
- 3 Builds public and industry trust
- 4 Supporting long-term product success



Key components

**Identify and
mitigate known
and potential
risks**

Risk management plans (RMPs)

**Systematic
gathering of
real-world safety
data**

Data collection & analysis

**Identifying and
prioritizing
adverse events**

Signal detection & management

Understanding risk management plans

PV plan:

Routine &
additional safety
monitoring



**Safety
specifications:**

Identify
known/potential
risks

**Risk
minimization:**

Steps to reduce
identified risks

A thorough RMP
satisfies regulatory
requirements *and*
enables a proactive
approach to
managing safety

Where do we look?

Adverse event reports: Direct reports from healthcare providers, patients, customers & caregivers

National and international databases:
Such as WHO's VigiBase, EudraVigilance, and the FDA's MedWatch

Social media, forums, customer complaints:
Identification of potential safety concerns in public and from customer base

Health insurance claim data: Data that helps identify patterns in drug usage and related adverse effects

Electronic Health Records (EHRs): Comprehensive data from patient treatment and outcomes

Patient registries: Organized data on specific patient populations or conditions

Pharmacy and prescription data:
Information on medication usage patterns

Clinical and observational studies:
Post-marketing research to gather additional safety data



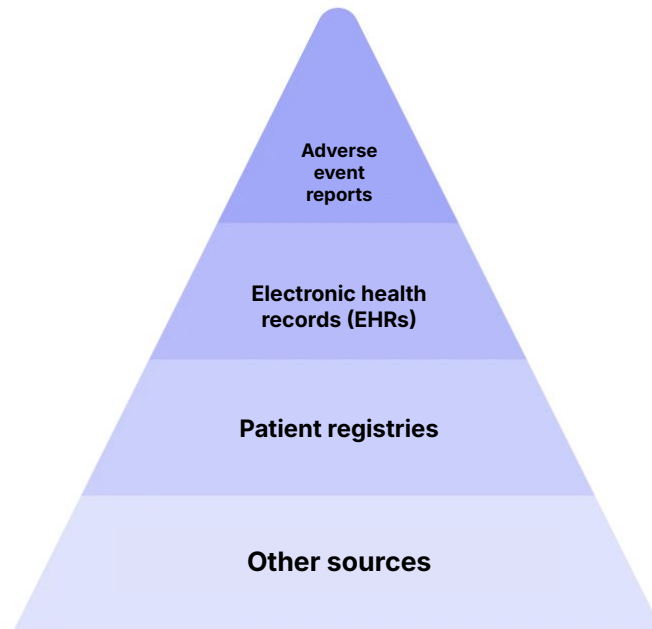
The core sources

Data collection & quality assurance

Effective pharmacovigilance relies on accurate and comprehensive data collection

QA is essential to ensure that data from these sources is accurate, reliable and up-to-date

High-quality data = better decision-making and effective signal detection and management



Adverse Event Reporting: Timelines and Forms

01

What Needs to Be Reported?

- All adverse events, including serious, unexpected, and lack of efficacy.
- Serious events must be expedited

02

Timeline Variations

- **Serious, Unexpected AEs:** Within 15 days (FDA, EMA).
- **Periodic Reporting:** Quarterly for the first 3 years, then annually (FDA); PSURs annually for 3 years, then every 3 years (EMA).

03

Formats

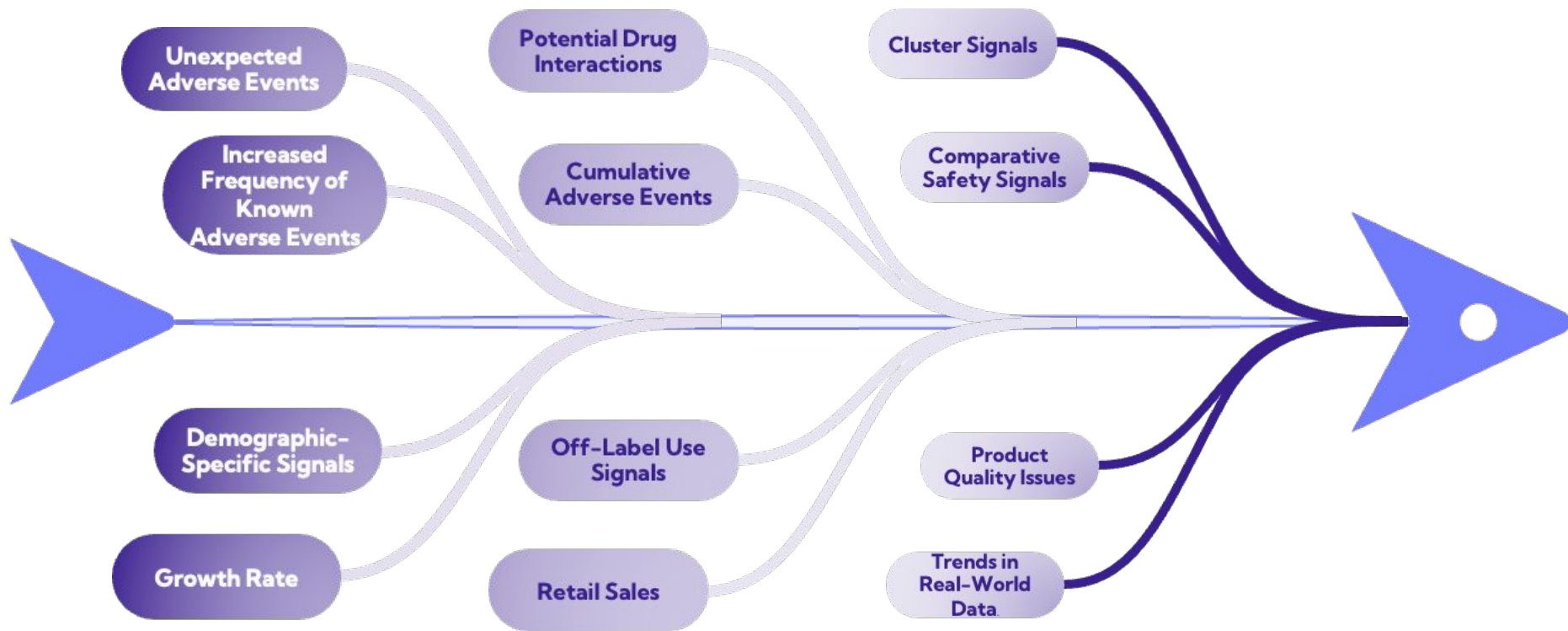
- ICSRs for individual cases (using E2B standards).
- Periodic Safety Reports: PSUR (EU), Annual Reports (US).

04

System

- Reports submitted via **EudraVigilance (EU)** and **FAERS (US)**.

Signal detection basics

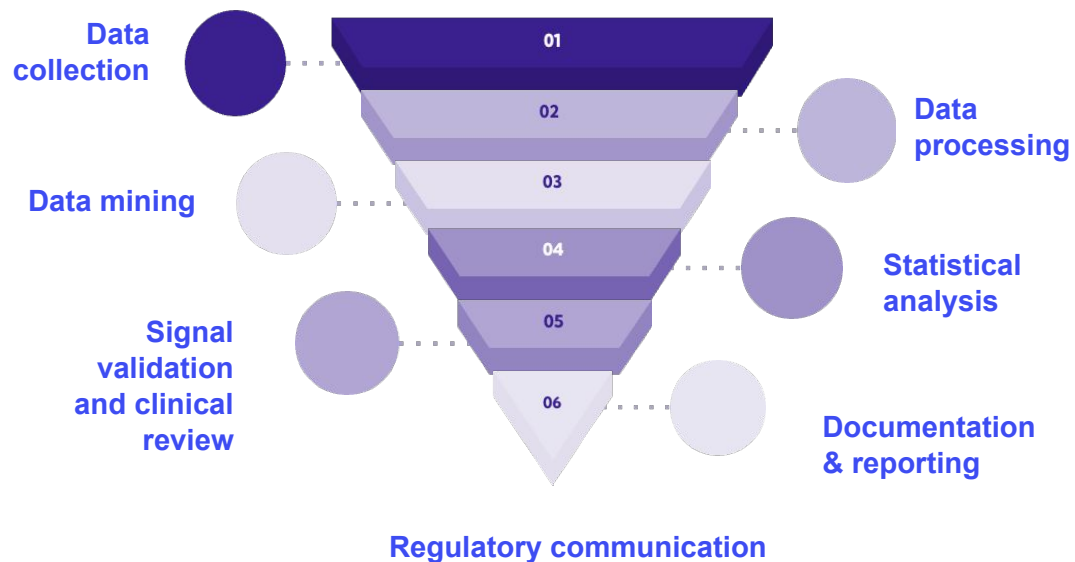


Techniques for signal detection

Data Mining Identifies patterns using algorithms on large datasets

Statistical Analysis Detects deviations from expected trends

Clinical Review Expert analysis adds clinical relevance to findings



Signal prioritization and action: the key steps



Severity

Assess potential impact on patient safety



Frequency

Identify whether it's an isolated event or a recurring issue



Preventability

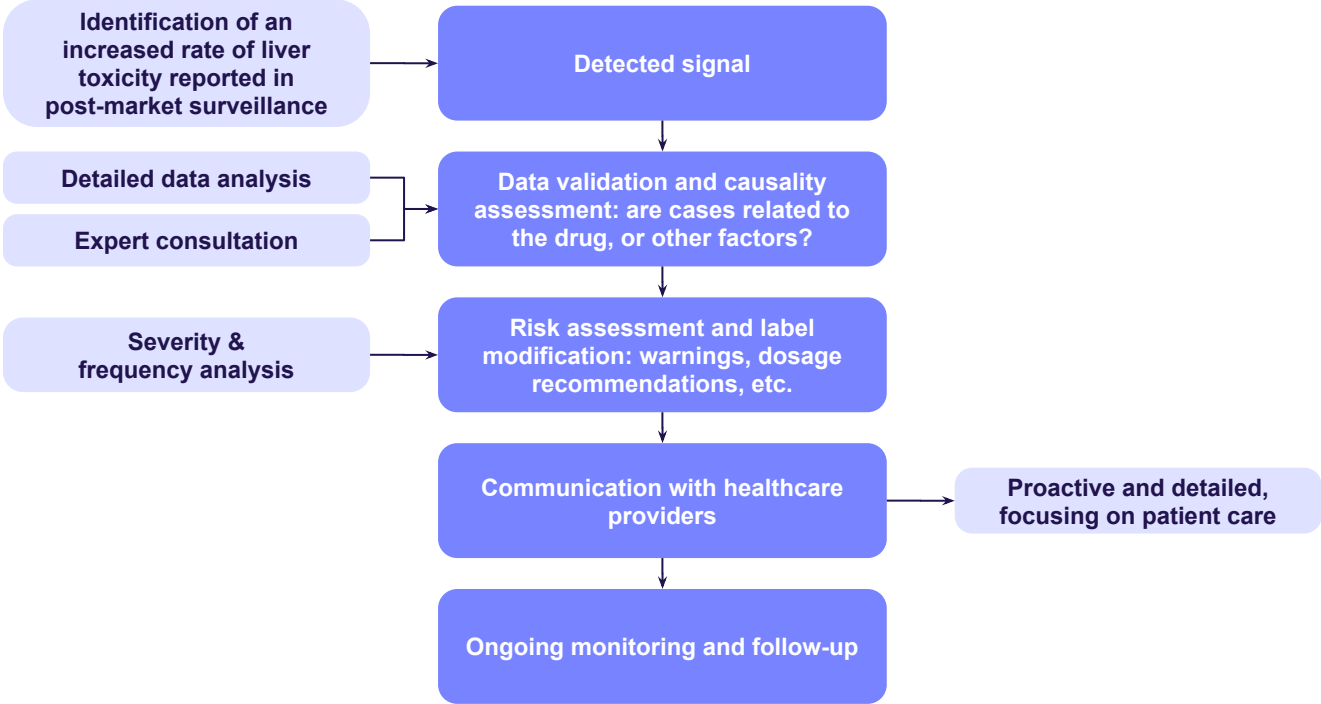
Determine if risks can be managed effectively



Reversibility

Assess whether the adverse effects are reversible or lead to long-term harm

Signal management example



4 ways to minimize post-market risks

1 Frequent internal audits

2 Training programs

3 Rapid response plans

4 Stakeholder engagement

What if we get it wrong?



Fines

Regulatory authorities can impose significant financial penalties for missed or inaccurate adverse event reporting or non-compliance with pharmacovigilance standards



Withdrawal

Non-compliance may lead to suspension or revocation of marketing authorization, resulting in halted sales and financial losses



Reputational damage

Failure to meet compliance requirements can damage trust from patients, healthcare professionals and the industry, impacting your reputation and market share



Extra scrutiny

Companies found non-compliant may face more stringent oversight from regulatory bodies, leading to stricter requirements and additional costs for future monitoring

Building a sustainable PV program for new products

Step 01

**Proactive safety
planning**

Step 02

**Collaborative
surveillance**

Step 03

**Continuous
education**

Step 04

**Integration of advanced
technology**



Enhancing PV for existing products



Leveraging technology in pharmacovigilance



AI and machine learning



Big data analytics

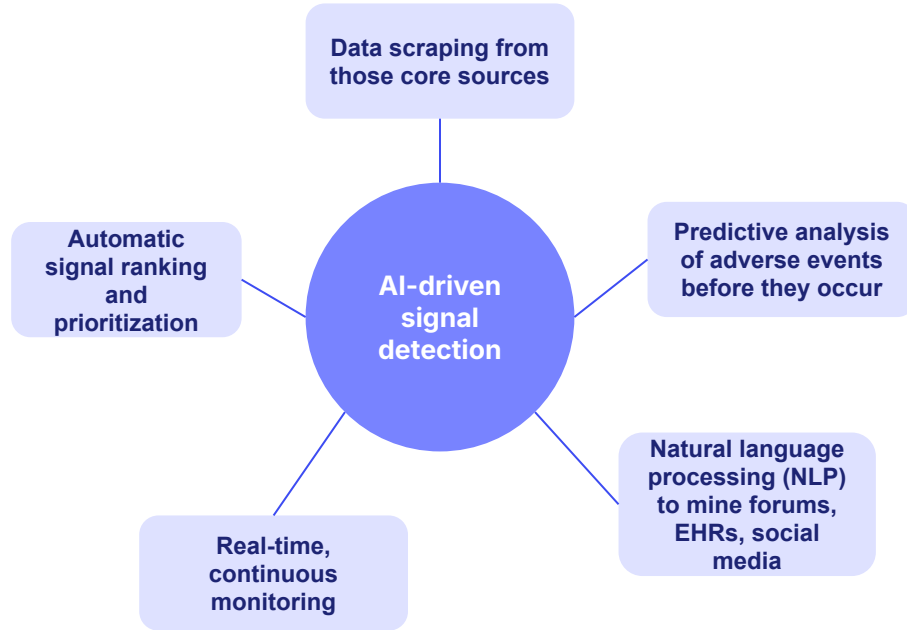


Real-time reporting

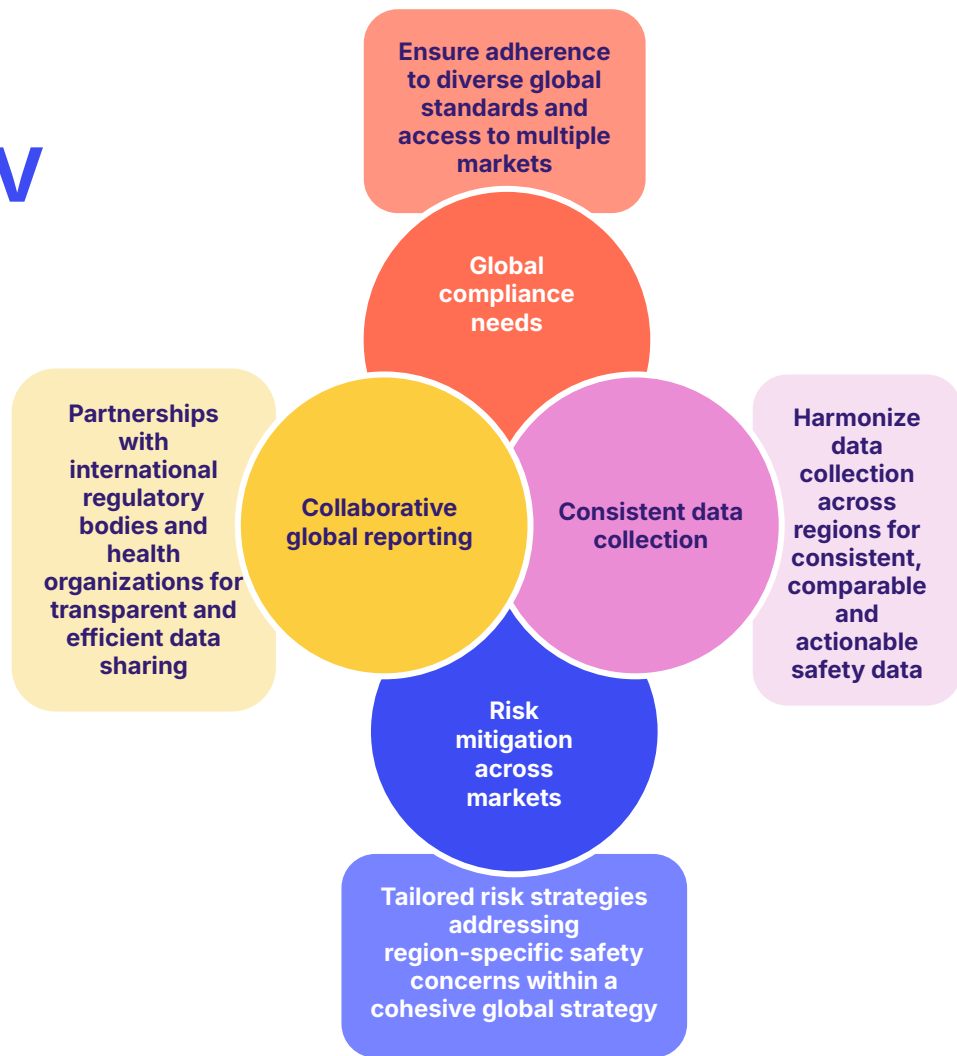
**Automation of
routine tasks**



**Faster, more
cost-efficient,
more reliable PV**



Cross-border PV



Best practices for signal detection



Multiple data sources

Integrate a wide range of data sources to ensure comprehensive monitoring. Diversity helps capture different types of safety signals and enhances overall accuracy of signal detection



Prioritization

Implement a system for prioritizing detected signals based on severity, frequency and impact. High-risk signals should be acted upon first to prevent significant safety issues from escalating



Collaboration

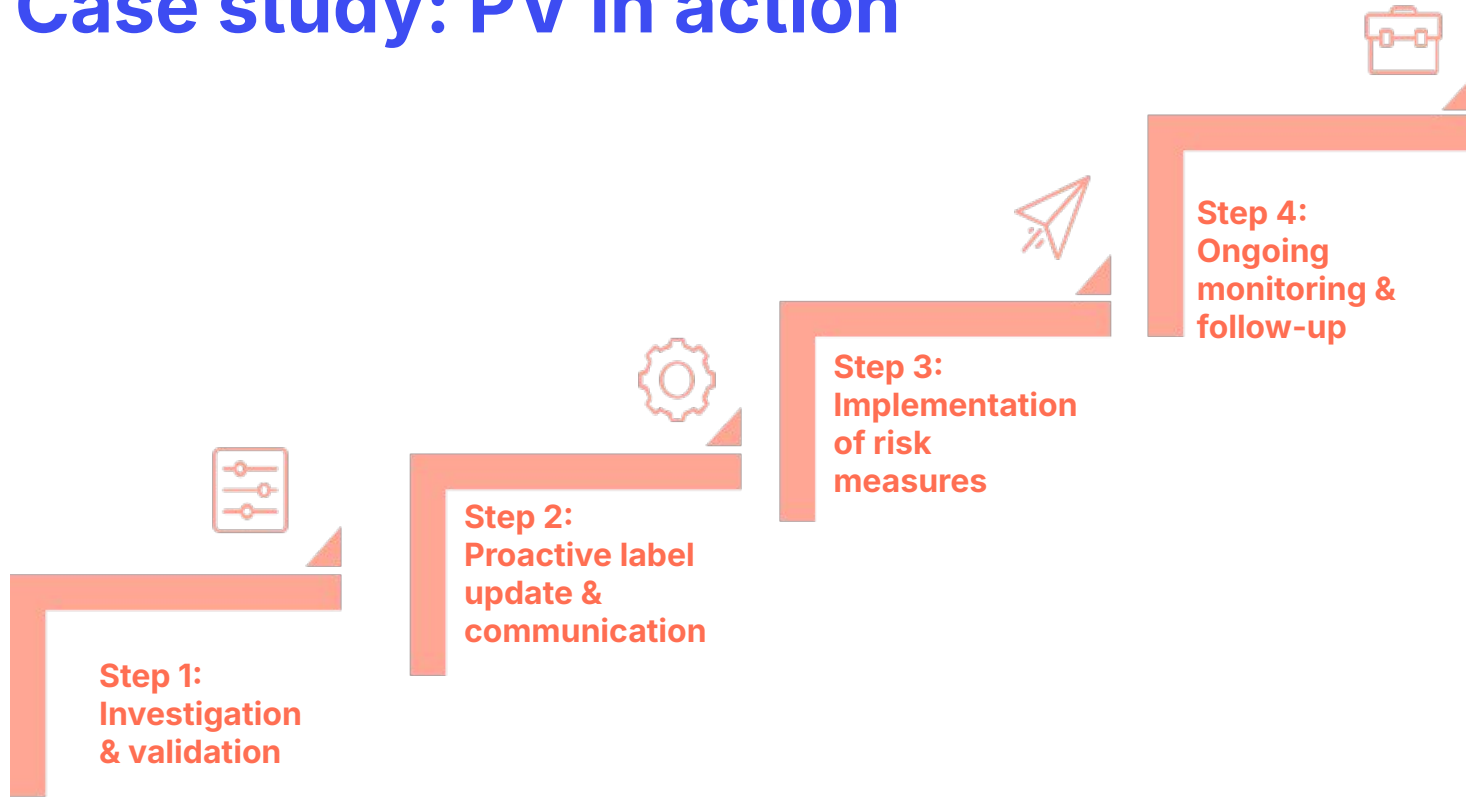
Engage cross-functional teams, including PV specialists, data scientists and clinical experts, to verify/analyze signals and make thorough safety assessments



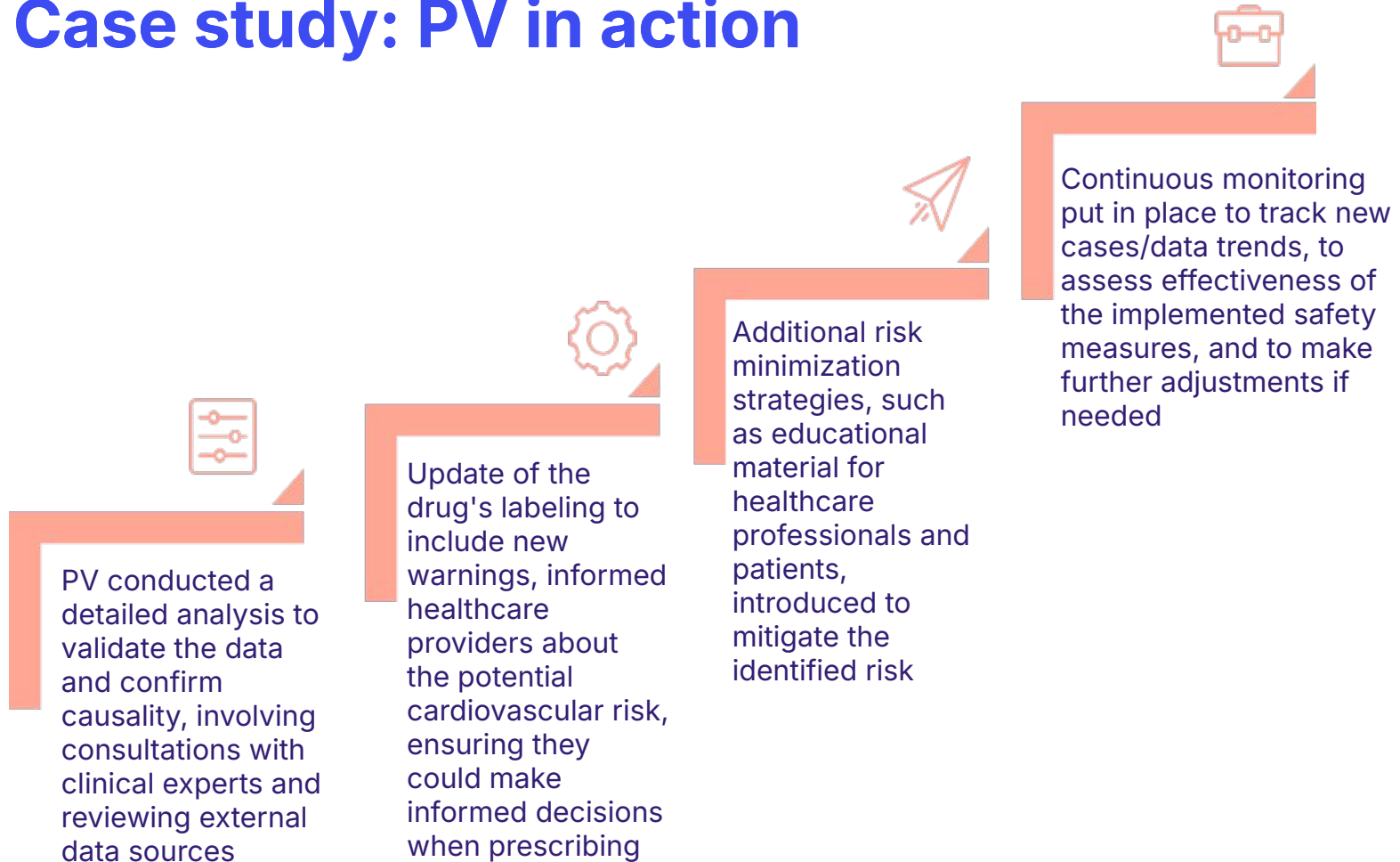
Reassessment

Regularly review and reassess previously detected signals to determine if new data or trends have emerged. Keep safety profiles up to date and continuously improving

Case study: PV in action



Case study: PV in action



Emerging trends in pharmacovigilance



Predictive safety monitoring

The use of AI and machine learning algorithms to predict potential adverse events before they occur.

This trend allows for a more proactive approach, improving the speed and accuracy of risk assessment.



Personalized medicine

The integration of pharmacovigilance with personalized medicine, where safety monitoring is tailored to individual genetic profiles.

This approach helps identify specific patient groups that may be at higher risk for certain adverse events.

Emerging trends in pharmacovigilance



Real-world evidence (RWE)

Increasing reliance on real-world evidence from diverse sources such as EHRs, patient registries, and wearable devices.

Complementing clinical trial data to provide a more comprehensive view of drug safety



Automation and robotic process automation (RPA)

Implementing RPA to automate routine tasks such as case processing, report generation, and data entry.

This trend helps reduce manual workload and minimizes errors, allowing teams to focus on more complex safety analysis.

Challenges and solutions in pharmacovigilance

Challenge	Solution
Integrating data from multiple sources with varying formats	Implementing standardized data formats and using centralized data management platforms to ensure seamless data integration
Navigating different regulatory requirements across regions, which can lead to complexities in maintaining compliance	Building a robust global PV strategy that aligns with major regulatory bodies (e.g., FDA, EMA, ICH) and local regulations, supported by cross-border training programs
Managing a high volume of safety signals and distinguishing high-priority issues from less critical data	Utilizing AI-based tools to automate signal detection and prioritize based on predefined criteria such as severity and frequency
Limited resources	Investing in scalable technologies such as cloud-based PV and eQMS systems, and training staff in efficient workflows to maximize productivity

Takeaways

Establish a robust PV program that aligns with regulatory requirements and includes proactive safety measures throughout your product lifecycle

Use advanced technologies and best practices to detect and prioritize safety signals *early*. This ensures timely action and reduces the risk of adverse events escalating!

Integrate AI, machine learning and big data analytics to enhance efficiency and improve the accuracy of your safety assessments. Real-time analysis can provide significant advantages for signal detection and response

Regularly update risk management strategies and PV practices based on new safety data and evolving regulatory guidelines. Adapting to changes helps maintain compliance and ensures patient safety



Thank you!

