

# Future of Pharmacovigilance

ADVANCING DRUG SAFETY THROUGH  
INNOVATIVE MONITORING SOLUTIONS

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# Agenda

1. **! "\$** PHARMACOVIGILANCE: WHAT COMES NEXT FOR THE INDUSTRY?
2. TRANSFORMING THE SCIENCE AT THE HEART OF PHARMACOVIGILANCE .
3. BUILDING TRUST AND OPENNESS WITH TECHNOLOGY AUTOMATING TO INNOVATE.  
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4. EMERGING MARKETS AND DRUG SAFETY RISK.
5. TAKE AWAY MESSAGES.



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# Future of Pharmacovigilance – Increasingly Complex World



# Evolving Complexity in Therapeutic Innovation

## **Therapeutic Innovation Complexity**

New therapies like **Advanced Therapy Medicinal Products (ATMPs)** like human cells based products/Modified human cells,.. increase safety monitoring complexity with **diverse patient groups**.

## **Real-World Data Explosion**

Data from health records enhances signal detection but **escalates analytical demands**.

## **Agile Safety Systems**

Global demands push for **agile, predictive safety systems** enabling early risk identification and rapid response.

## **Collaborative Pharmacovigilance**

Effective safety relies on collaboration between **regulators, industry, and healthcare for lifecycle monitoring**.



What Comes Next for the  
Industry?

# Predictive and Globally Harmonized Pharmacovigilance

## **Predictive Safety Monitoring**

Use of real-world data from health records enables early detection of safety risks before escalation.

## **Harmonized AI Governance**

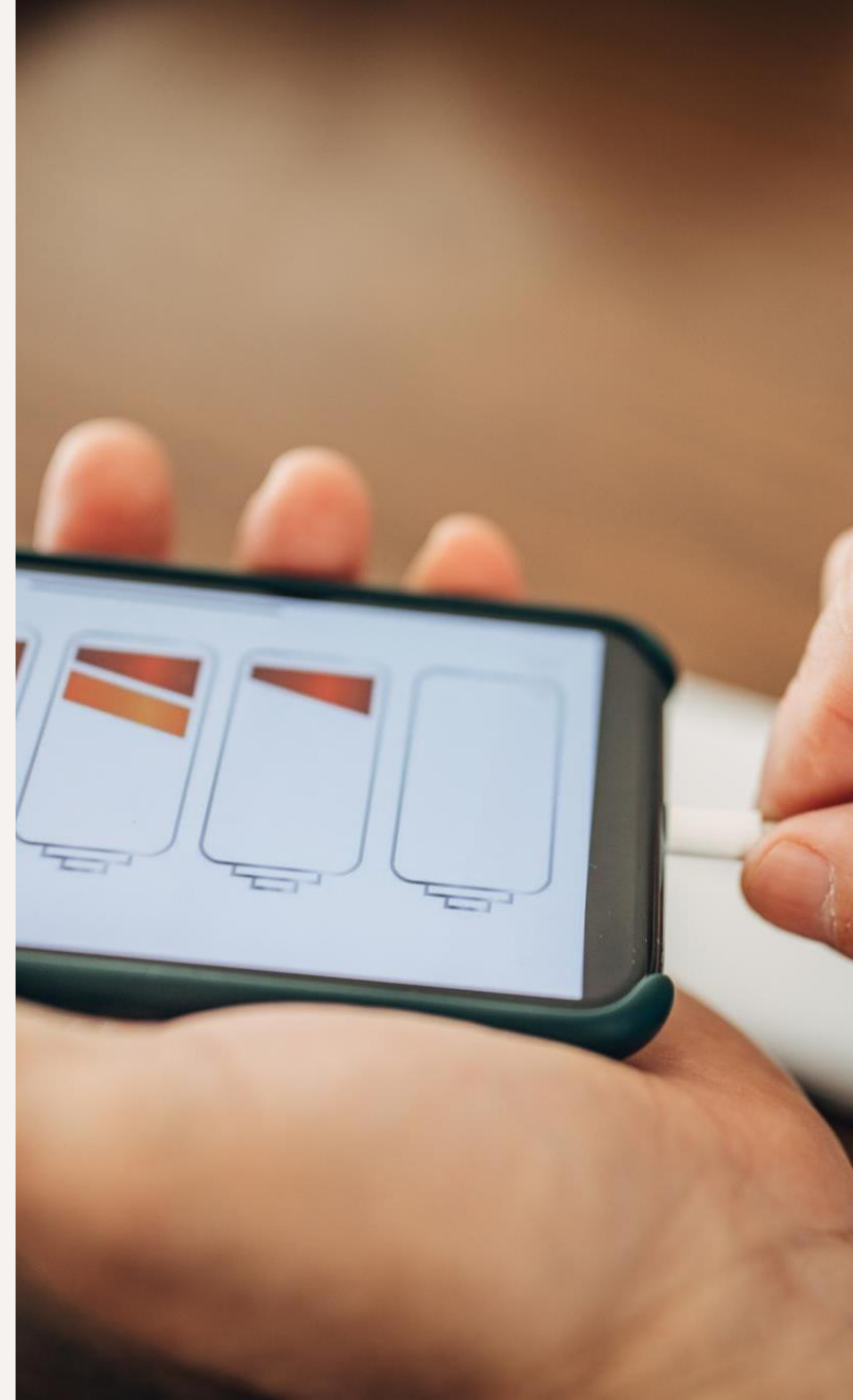
Global frameworks promote transparency and fairness in applying AI and machine learning to safety decisions.

## **Dynamic Benefit-Risk Models**

Next-generation models adjust benefit-risk evaluations dynamically with new data streams during drug lifecycle.

## **Patient Co-Creation**

Patients actively contribute to safety system design, reporting, and communication strategies improving pharmacovigilance.



# Regulatory Shifts and Industry Evolution

## Evolving Regulatory Expectations

Global authorities are updating regulations to integrate real-world evidence and advanced analytics in safety evaluations.

## Updated Safety Systems

MAHs must adopt **AI-driven case processing** and **automated reporting** to reduce operational burdens in pharmacovigilance.

## Strategic Role Expansion

Pharmacovigilance is evolving into a **strategic partner** for product lifecycle and development management.

## Future Industry Adaptations

PV talents upskilling and digital investments are essential for building **adaptive safety ecosystems** aligned with innovation.



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# Transforming the Science at the Heart of Pharmacovigilance

# Scientific Modernization and Precision Pharmacovigilance

## Deep Phenotyping for Targeted Detection

Deep phenotyping captures **patient-specific traits** enabling precise detection and classification of adverse events.

## Multi-Omics Data Integration

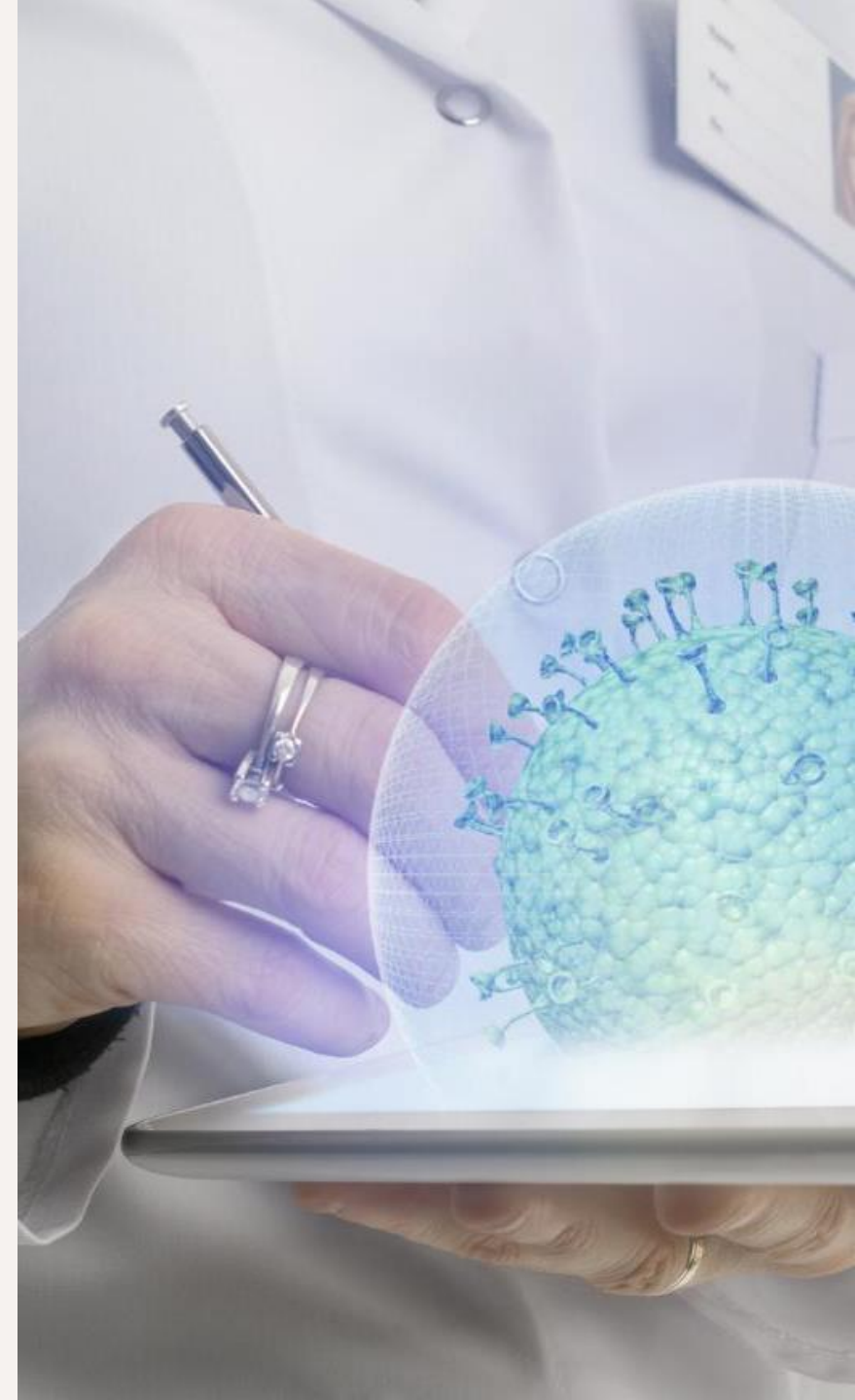
Combining genomics, proteomics, and metabolomics helps track biological markers predicting treatment risks.

## Digital Twins for Safety Simulation

Digital twins simulate **individual patient responses** to therapies, aiding proactive safety planning.

## Predictive and Tailored Risk Mitigation

Precision pharmacovigilance enables **safety strategies tailored to diverse populations and treatments**.





# Building Trust and Openness with Technology

# Technology-Driven Transparency and Engagement

## Real-Time Safety Insights

Digital platforms provide clinicians and regulators with curated, real-time safety information for better decision-making.

## Patient Digital Companions

Mobile apps enhance patient understanding of medication risks and support timely reporting of adverse events.

## Automated Alert Systems

Automated communication channels allow rapid dissemination of emerging safety information to stakeholders.

## AI Explainability Frameworks

Explainable AI ensures stakeholders understand safety signal detection and decision processes in pharmacovigilance.



# Technology-Enabled Transparency and Public Confidence

## Digital Safety Communication

Digital platforms provide real-time safety updates and easy reporting to empower patients and healthcare professionals.

## Patient-Facing Communication Tools

Mobile apps, AI chatbots, and personalized notifications reduce barriers to reporting and promote shared responsibility.

## Global Safety Ecosystems

Collaboration between regulators, pharma, and healthcare enables secure data exchange and builds trust.

## Transparent Risk Communication

Clear communication of uncertainties, benefits, and regulatory decisions strengthens public confidence.





# Automating to Innovate

# Automation and AI for Scalable Pharmacovigilance



## AI-Driven Case Processing

Automated case intake and AI tools reduce cycle times and minimize human error in safety operations.

## Generative AI for Document Preparation

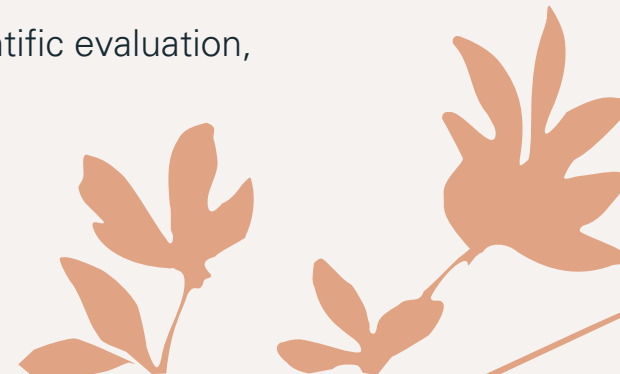
Generative AI accelerates preparation of regulatory documents like PSURs, RMPs, and signal evaluation reports efficiently.

## Workflow and Predictive Automation

Workflow automation prioritizes high-risk cases, while predictive systems forecast workload and resource needs.

## Enhanced Human Expertise

Automation enables PV experts to focus on scientific evaluation, safety planning, and high-value decision-making.



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# Emerging Markets and Drug Safety Risks

# Bias, Underreporting, and Global Equity in Safety Systems

## Challenges of Underreporting

Underreporting due to limited infrastructure, HCP awareness, and cultural barriers impacts the completeness of safety data.

## Data Quality and Bias

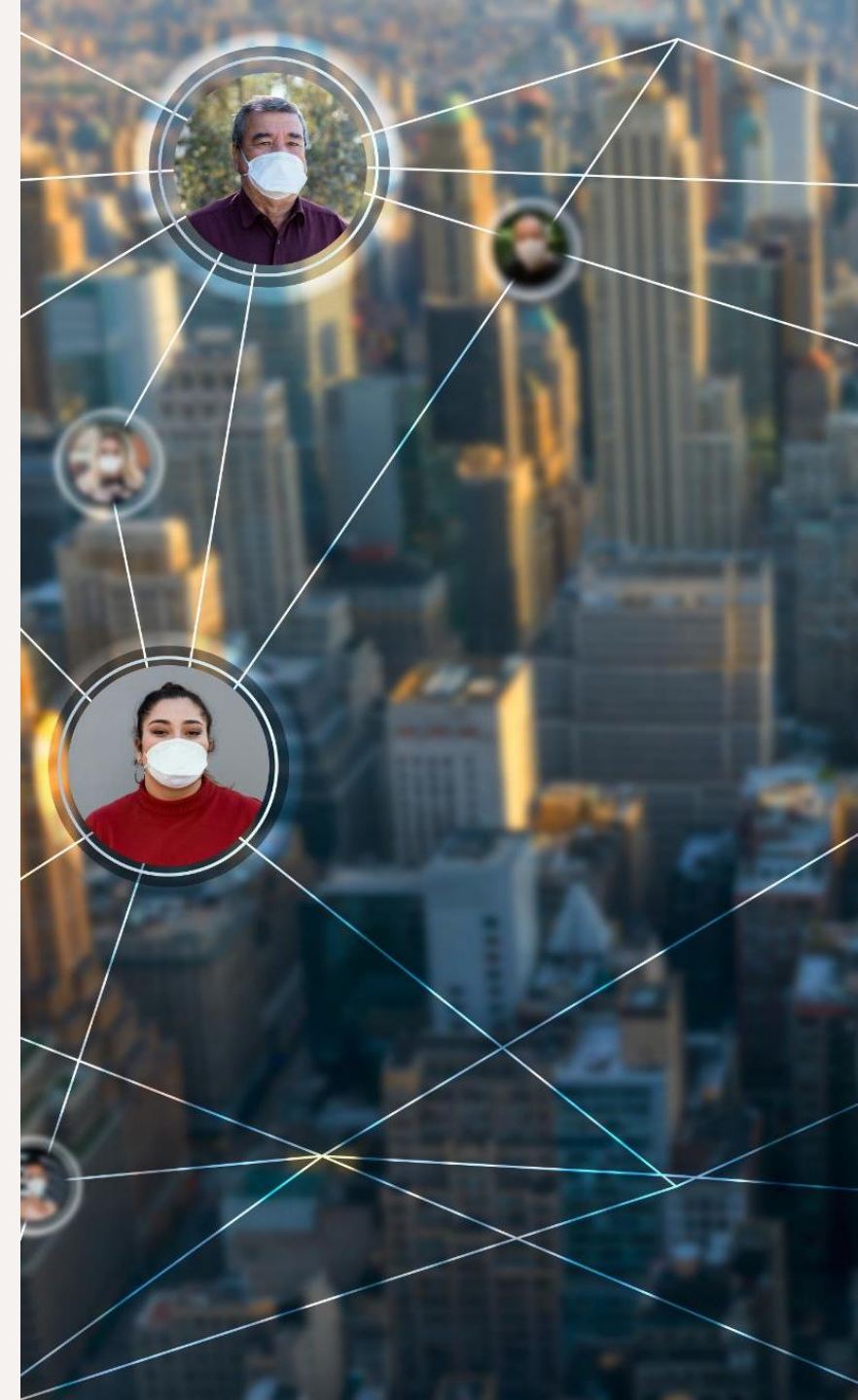
Variable quality and completeness of real-world data create biases in multinational pharmacovigilance analyses.

## Mitigation Strategies

Capacity building, digital tools, and regulatory partnerships help improve reporting and reduce bias in emerging markets.

## Ensuring Global Safety Equity

Creating equitable global safety datasets is essential to ensuring that drugs remain safe for diverse populations and addressing emerging-market challenges is a critical step in achieving globally representative pharmacovigilance insights.



# TAKEAWAY MESSAGES

- The future of pharmacovigilance is no longer defined by incremental improvements—it is being reshaped by transformation.
- scientific innovation, digital acceleration, and global collaboration are converging to redefine what robust, patient-centered safety truly looks like.
- pharmacovigilance becomes increasingly global, we must ensure that every patient, in every region, is represented.
- Automation will streamline our workflows, but it is the strategic insight of pharmacovigilance professionals that guides meaningful safety decisions.
- The future of pharmacovigilance is predictive. It is connected. It is transparent. And it is global. Together—through innovation, collaboration, and a relentless commitment to patients—we will ensure that medicines remain not only effective, but truly safe in an increasingly complex world.





Thank You for Your Attention

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