Looking forward.
Pharmacovigilance in the next 5 years →
The Industry Vision

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Precision Pharmacovigilance

The Future of PV
Precision Pharmacovigilance

- Harmonization of PV Legislation
- Process and Resource Efficiency
- Sources of Safety Information
- Patient Insights
- Technology

**Precision PV**

**Adaptability**
- Constantly changing to learn new skills and capabilities,

**Partnerships**
- Creating effective partnerships, both internal and external

**Innovation**
- Incorporating cutting-edge patient outreach strategies and leveraging digital technologies

- Benefit-Risk
- Innovation

Creating effective partnerships, both internal and external

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Precision Pharmacovigilance

Technology

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Precision PV

- NLP
- AI
- Bots
- Wearables
- Digital Health
- ePIL
- eRisk Minimization

efpia
Opportunity for PV Technology

**OPPORTUNITY**
- Simplified Compliance
- Better quality of data and analysis
- Reduced cost/increased efficiency

**TECHNOLOGIES**
- Machine Learning
- Natural Language Processing
- Robotic Process Automation
  - API

**EXPERIMENTATION**
- Case Assignment
- Email Management
- MeDRA Adverse Event Coding
- Non-Qualifiable Case Identification and Handling
Artificial Intelligence (AI)

Larger and more interconnected data enable analyses previously not thought possible

AI systems require thorough preparation of data, intensive monitoring of algorithms, and customization to be useful

The same system that recommends a shirt you may like on Amazon may be used to identify ADRs from text
Wearables
Regulators are developing and adopting new technology to optimise reporting of Adverse Events
"From Volume to Value"
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- Outsourcing – strategic partnerships
- More efficient processes
- Different ways of working
- Stronger internal partnerships with stakeholder
- Do more with less
- Challenge status quo
- Increased cross industry collaboration
- Global databases

EFPIA
Realize a disruptive and dramatic industry-wide optimization by establishing a multi-tenant pharmacovigilance database platform with true cost-sharing.
Precision Pharmacovigilance

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Sources of Safety Information

- Real World Data
- Patient Support Programs
- ICH E19
- Registries
- PASS
- Sentinel
- Risk minimization effectiveness studies

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efpia
Epidemiologists can effectively use Real World Data across the product life-cycle

**EARLY STAGE PLANNING**
- Identify Unmet Need
- Explore Cause of Disease
- R&D Prioritization

**LATE PHASE EXECUTION**
- Portfolio Expansion
- Post-Marketing Safety Studies
- Optimize Target Patient Population
- Clinical Trial Design

**DRUG DEVELOPMENT PROGRESSION**
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- Preference Studies
- CIOMS XI
- Health Literacy
- Patient-Centricity
- Risk Minimization Tools
- Patient Organizations
- Effective Risk Communication
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- Structured B-R Assessment
- Thoughtful Risk Management Planning
- Prioritizing Public Health
- Targeted Education (Med, Nursing, Pharm Schools)
- Risk Minimization Tools
- Public-Private Partnerships

Benefit-Risk
Structured B/R Assessment – The New Normal

Having a robust, structured approach for B/R assessment is a new and high priority for industry.

Evolving ‘best’ practice
Past decade of B/R initiatives established new approaches to perform assessments

Regulatory Requirements
Recent ICH guideline introduced structured B/R into Clinical Overview (CTD)

Lifecycle approach
Flexibility to address development and on-market products (i.e. use in PBRER, PSUR)
Precision Pharmacovigilance

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- ICH
- Right Sized PV
- WHO partnerships
- Gates Foundation
- Proliferation of nat’l QPPVs
- Frenetic pace of regulatory change
The Global PV landscape is rapidly changing in emerging markets.
Imagination is as vital to any advance in science as learning and precision are essential for starting points.

— Percival Lowell —