



European Federation of Pharmaceutical  
Industries and Associations

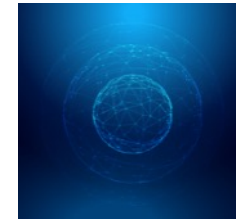
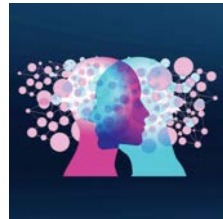


Looking forward.

Pharmacovigilance in the next 5 years →

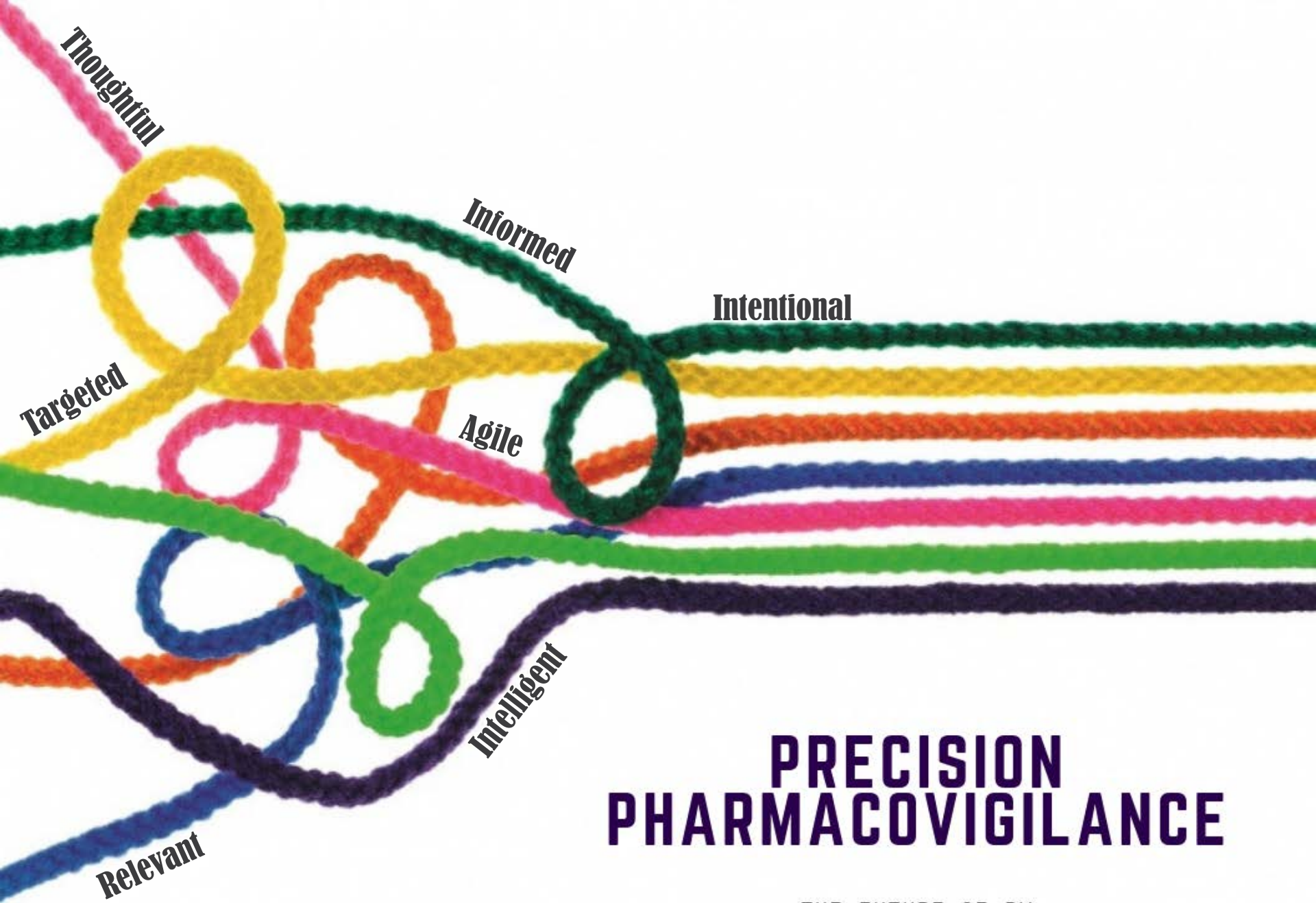
The Industry Vision

Vicki Edwards



24 September, 2018

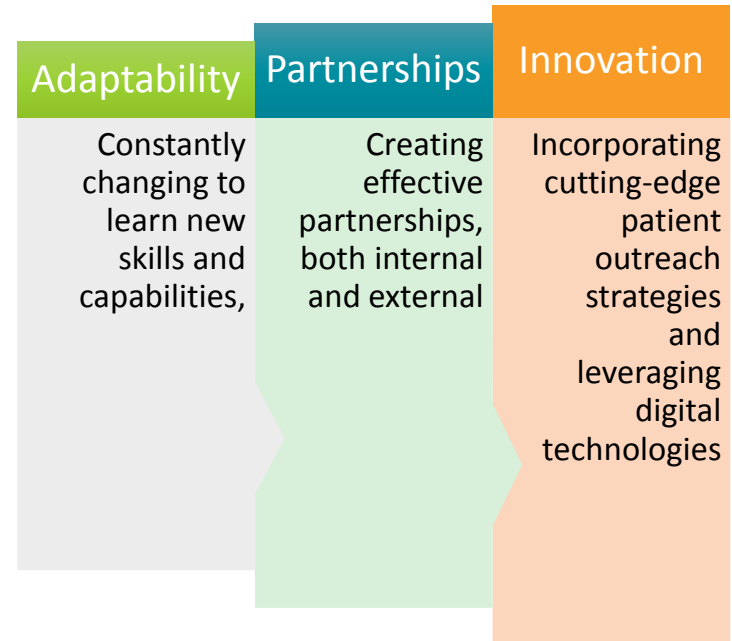
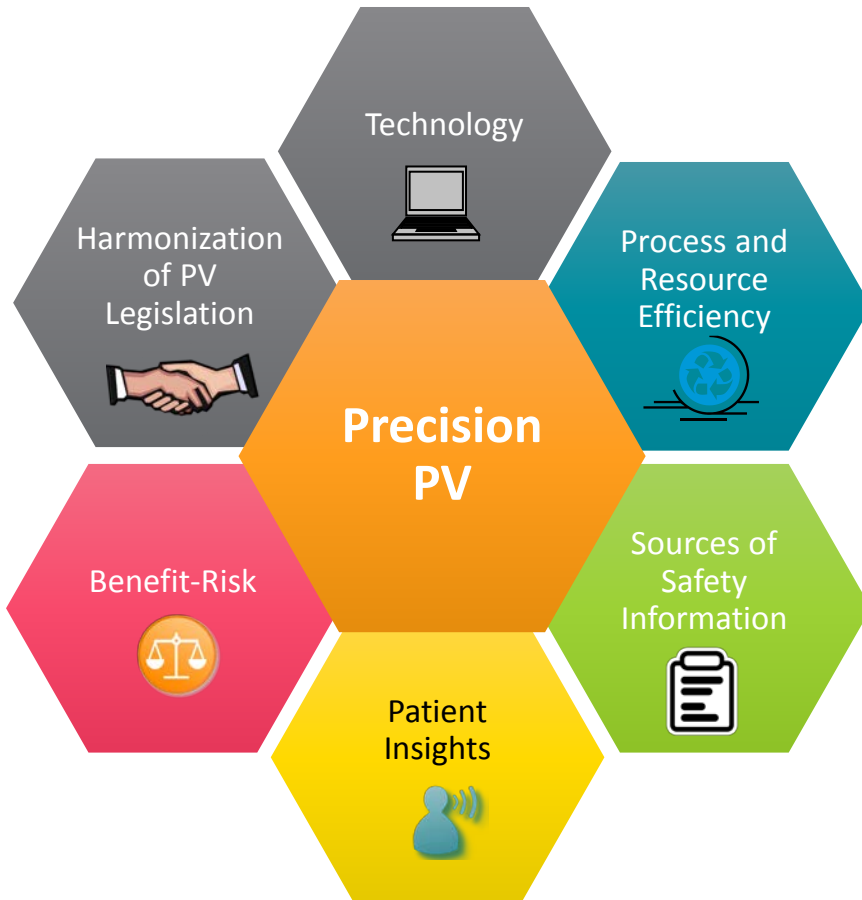




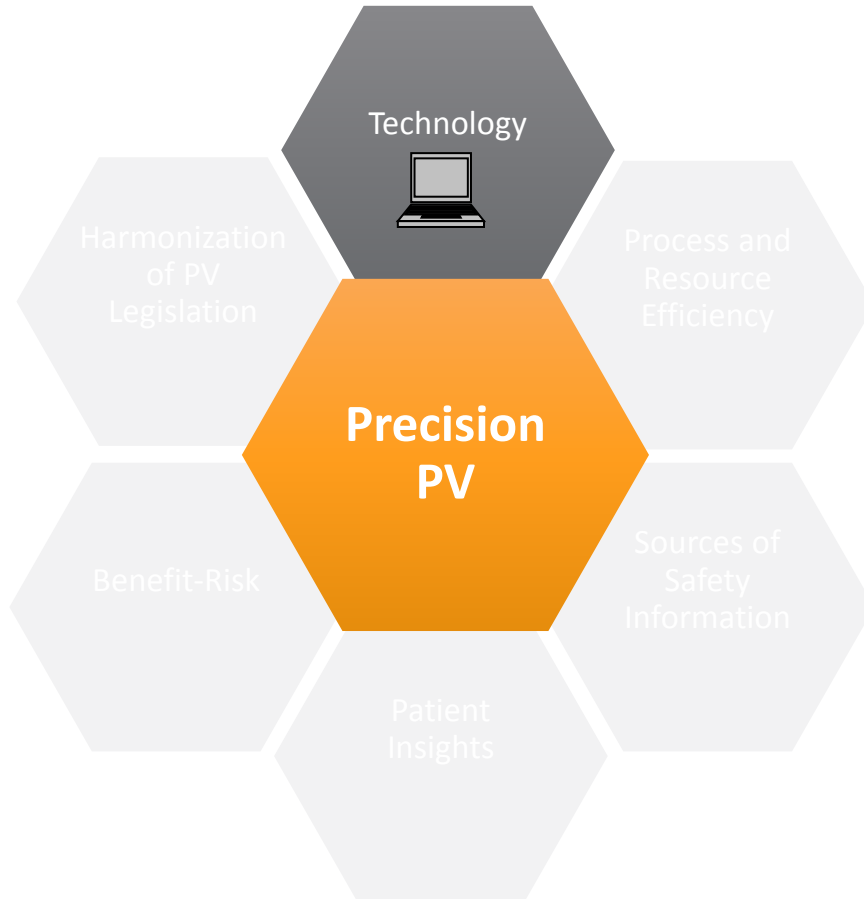
# PRECISION PHARMACOVIGILANCE

THE FUTURE OF PV

# Precision Pharmacovigilance



# Precision Pharmacovigilance



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

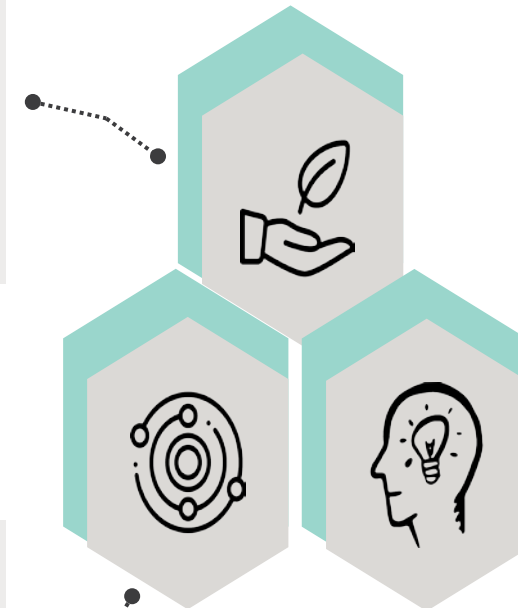
# Opportunity for PV Technology

## *OPPORTUNITY*

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

## *TECHNOLOGIES*

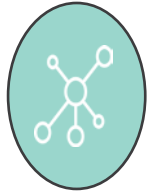
- *Machine Learning*
- *Natural Language Processing*
- *Robotic Process Automation*
  - *API*



## *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

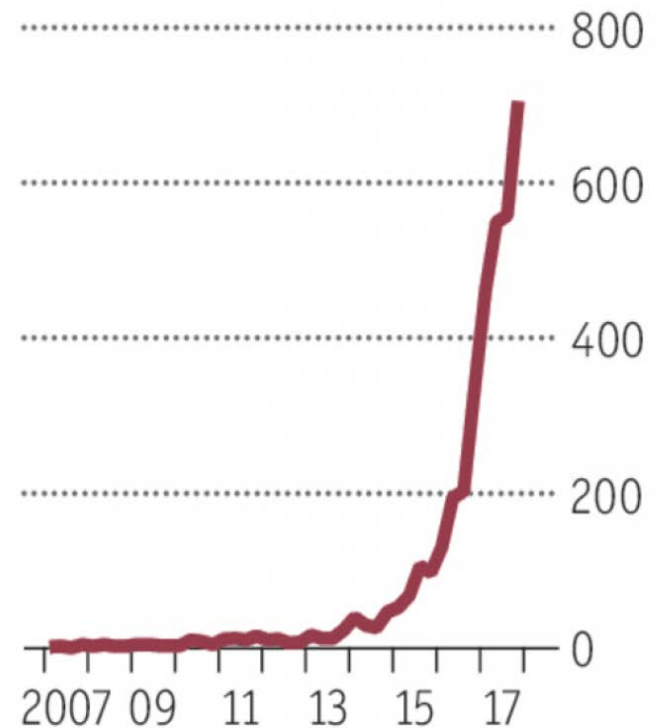


AI systems require thorough preparation of data, intensive monitoring of algorithms, and customization to be useful

*The same system that recommends a shirt you may like on Amazon may be used to identify ADRs from text*

# Machine Learning

Mentions of AI and machine learning on earnings calls of public companies



Source: Bloomberg

# Wearables

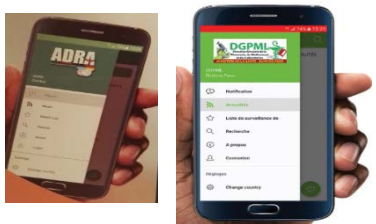






# AE Reporting & Digital Portals

Regulators are developing and adopting new technology to optimise reporting of Adverse Events



**A social media project to raise drug safety awareness in Kuwait**  
 Although there is yet to be a national pharmacovigilance centre in Kuwait, Rose Al-Dias launched a social media campaign to inform the public in her

**Report Me Kuwait**  
 @Report\_Me\_Kwt  
 Uppsala Monitoring, الأخطاء الدوائية, and 20 others follow  
 نتمتع باليقظة الدوائية. لا نشغل أي جهة حكومية أو خاصة ونهدف للتوعية باستخدام الأمن للدواء.  
 Snap:@reportme\_kwt, Twitter: @Report\_Me\_Kwt

**Pharmacy and Poisons**  
 @ppbkenya  
 Ministry of Health, Kofi Nyame, and 1 other follow  
 The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya.  
 Nairobi pharmacyboardkenya.org

**ANVISA**  
 @brasil\_ANVISA  
 Marilena and Pflarma follow  
 ANVISA - Agência Nacional de Vigilância Sanitária. [Sistema Automático]  
 Brasilia - DF, Brasil anvisa.gov.br

**Drug Regulatory Authority of Pakistan**  
 @DRA\_Pakistan

**FDAGhana**  
 @FDAGhana  
 News and information on Ghana's Food and Drugs Authority  
 Accra, Ghana fdaghana.gov.gh

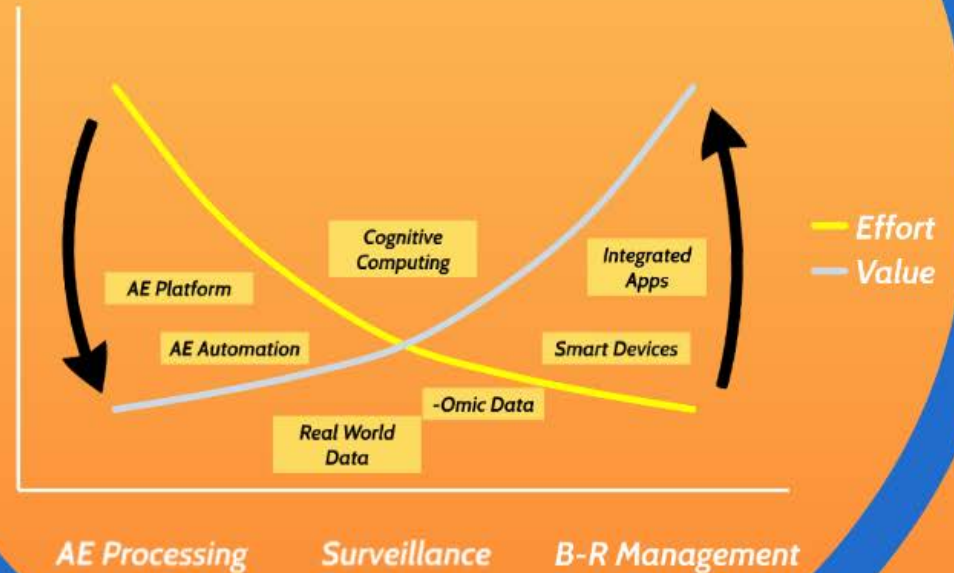
**Uganda National Drug Authority**  
 @UNDAuthority  
 Jeff Emmerson, Penn CPeRT, and 7 others follow  
 Official Twitter Handle for NDA. MISSION: Promoting and protecting public health through the effective regulation of human, animal medicines and health care.  
 Uganda nda.or.ug

**هيئة الغذاء والدواء**  
 @Saudi\_FDA  
 Tariq Alhawassi, Nelson Quiroga, and 15 others follow  
 الحساب الرسمي للهيئة العامة للغذاء والدواء (بالأمم المتحدة)  
 Riyadh-Saudi Arabia SFDA.GOV.SA

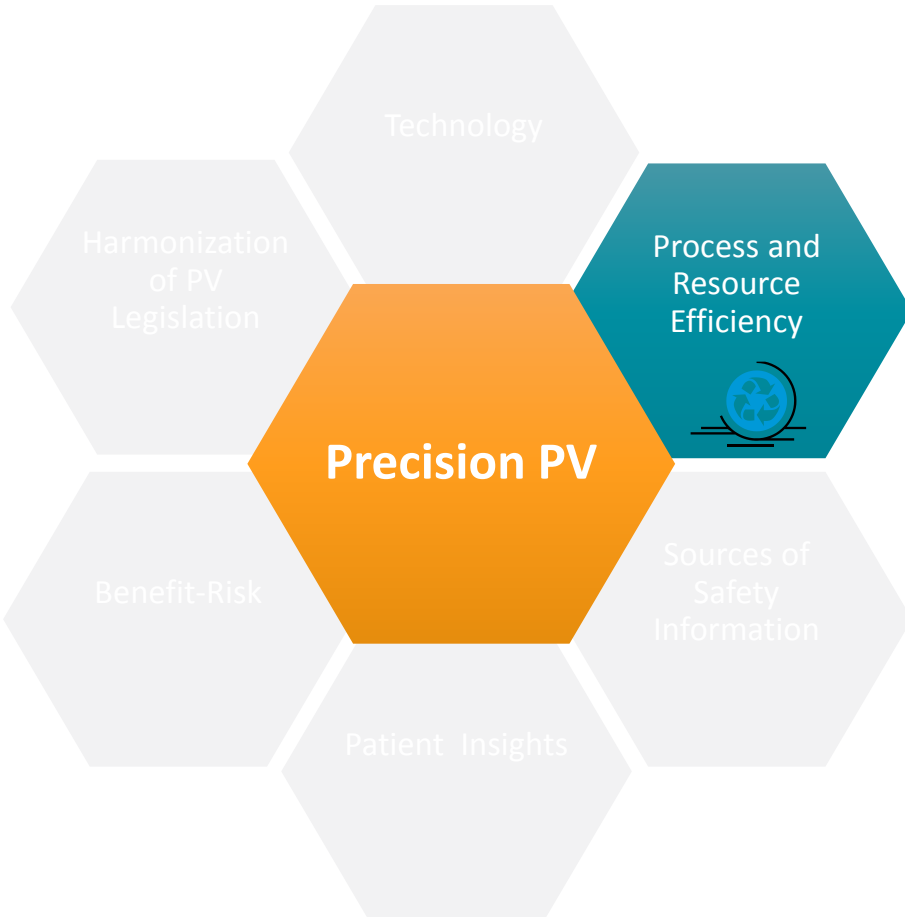


"From  
Volume  
to  
Value"

## Digital Future For PV



# Precision Pharmacovigilance



-  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

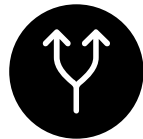
# OBJECTIVE

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

## Industry Challenges



Significant Direct Costs



Opportunity Costs



Inefficient Spending



Redundancy



## Meeting the Challenges



Stop Expensive Upgrades



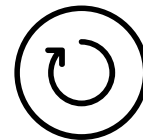
Utility Model



Scalability



Low Cost Solution

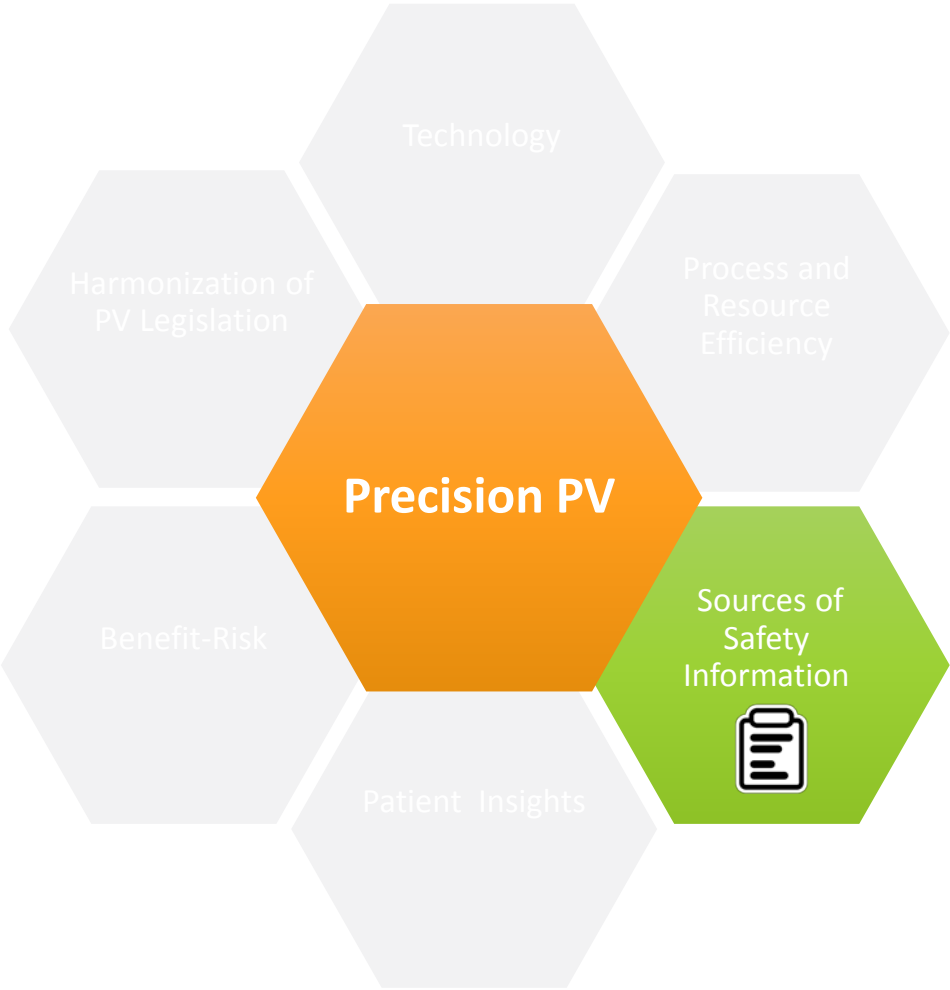


Distinct and Flexible



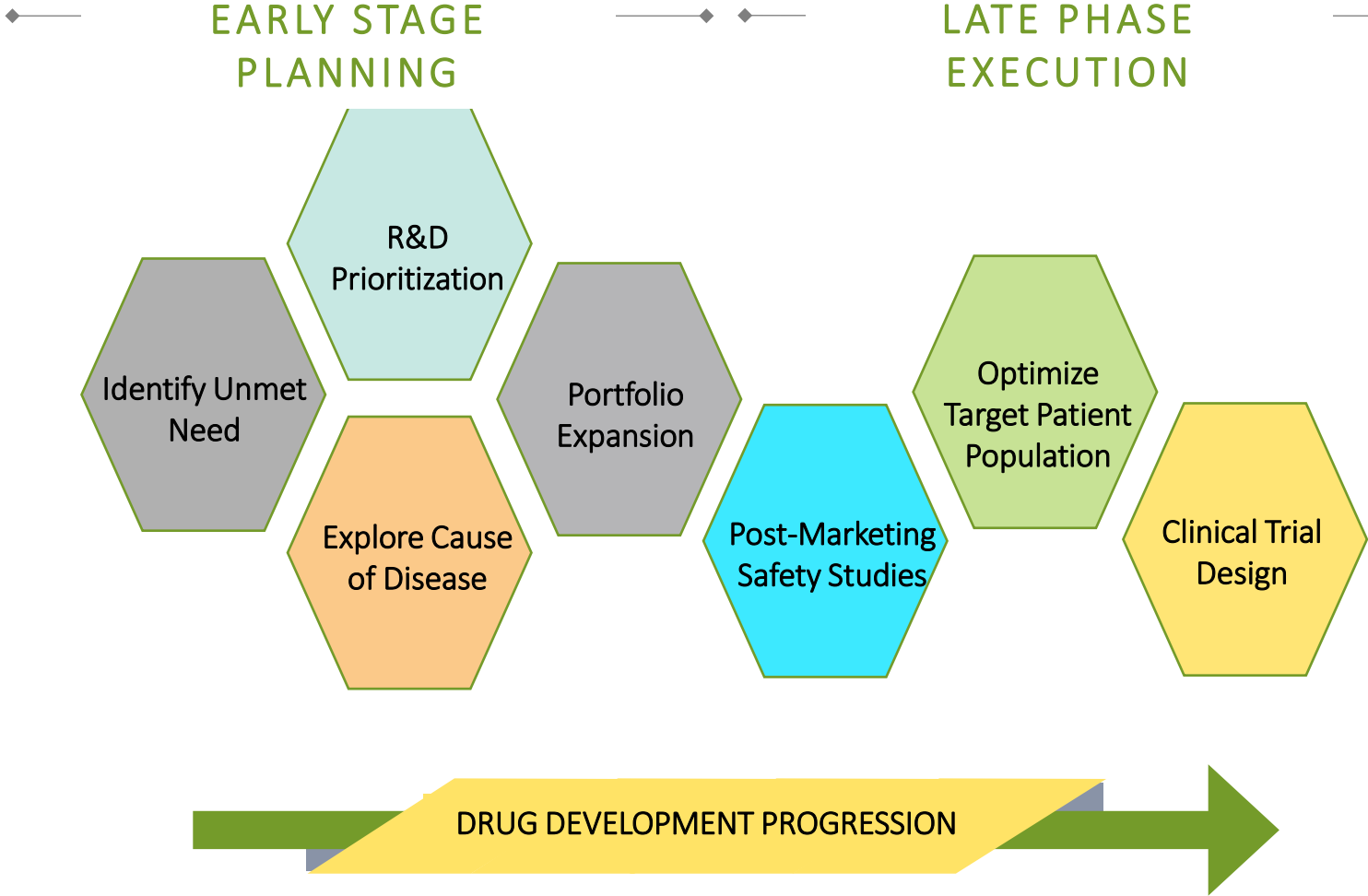
Multi-tenancy

# Precision Pharmacovigilance

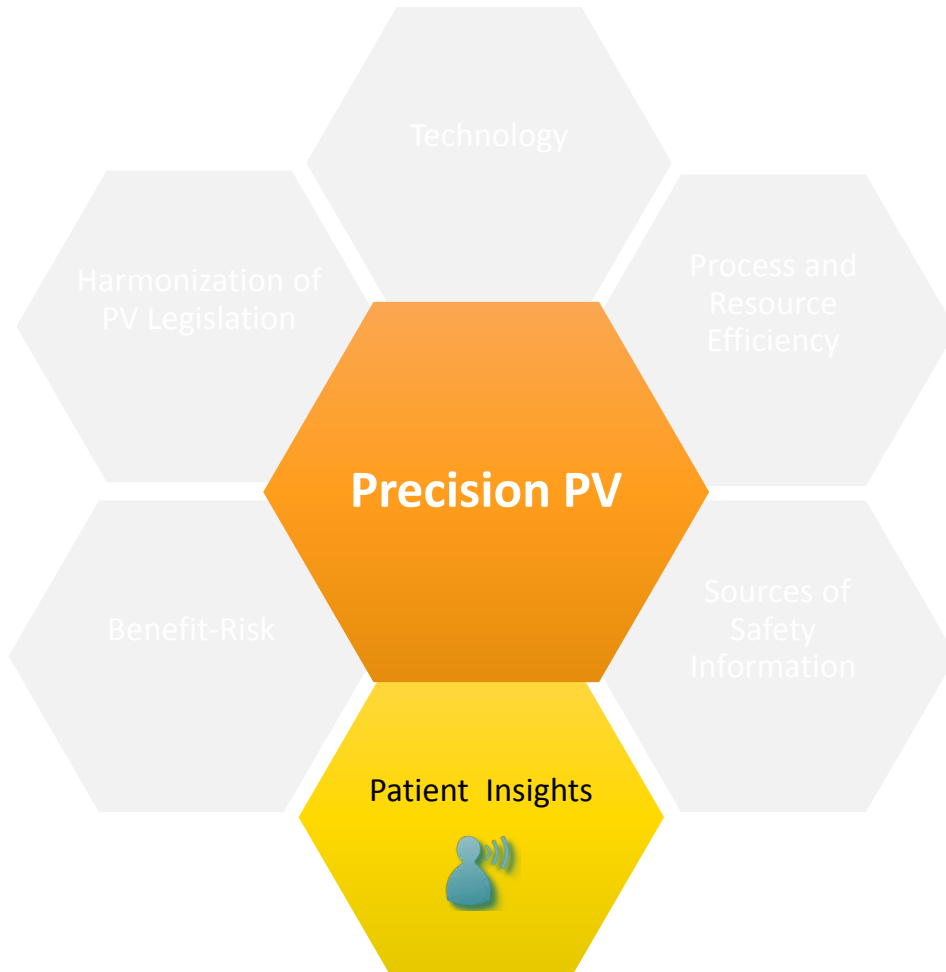


- Real World Data
- Patient Support Programs
- ICH E19
- Registries
- PASS
- Sentinel
- Risk minimization effectiveness studies

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

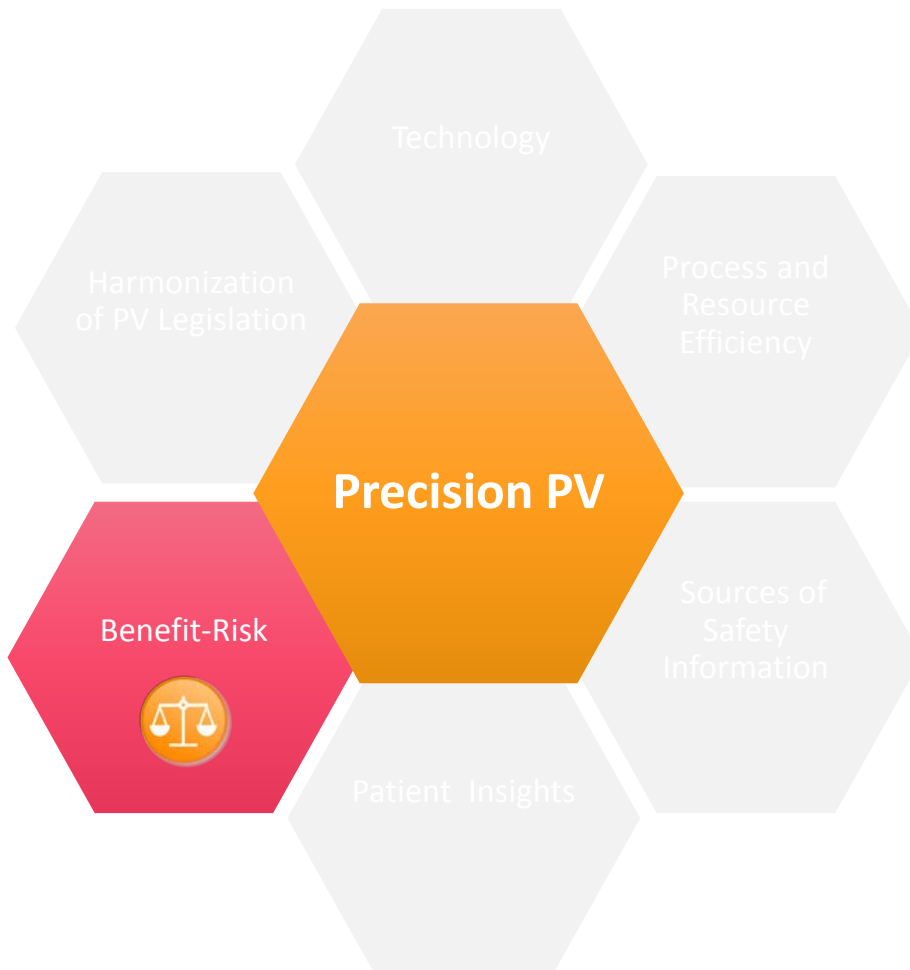


# Precision Pharmacovigilance



- 
- Preference Studies
  - CIOMS XI
  - Health Literacy
  - Patient-Centricity
  - Risk Minimization Tools
  - Patient Organizations
  - Effective Risk Communication

# Precision Pharmacovigilance



- 
-  Structured B-R Assessment
  -  Thoughtful Risk Management Planning
  -  Prioritizing Public Health
  -  Targeted Education (Med, Nursing, Pharm Schools)
  -  Risk Minimization Tools
  -  Public-Private Partnerships



# 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)

**Early Development**  
(Proof of Concept)

**Late Development**  
(Registration Program)

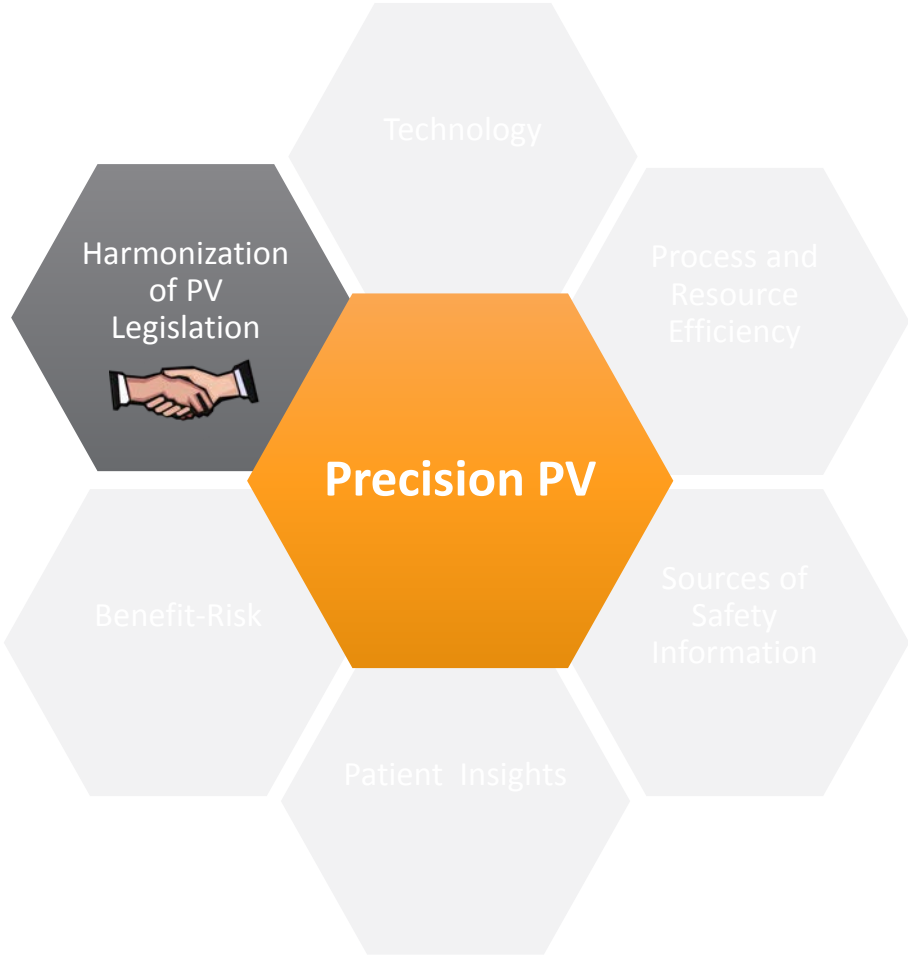
**On Market**  
(RWE Generation)

## Lifecycle approach

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

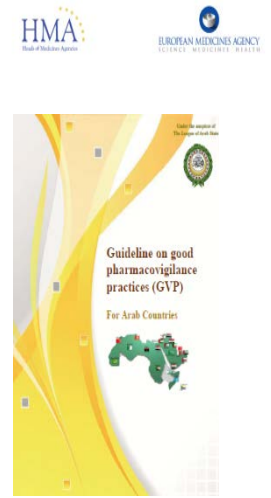


# Precision Pharmacovigilance

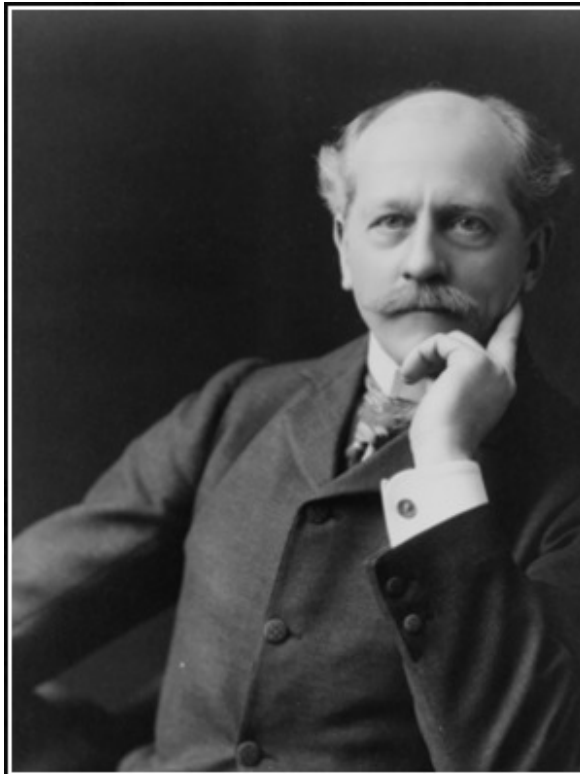


- 
- ICH
  - Right Sized PV
  - WHO partnerships
  - Gates Foundation
  - Proliferation of nat'l QPPVs
  - Frenetic pace of regulatory change

# The Global PV landscape is rapidly changing in emerging markets



**RULES OF GOOD PHARMACOVIGILANCE PRACTICE (GVP) OF EURASIAN ECONOMIC UNION**



Imagination is as vital to any advance in science as learning and precision are essential for starting points.

— *Percival Lowell* —

AZ QUOTES