

IHI Call Days | Call 9

PV SQUARED: Patient Voice for Pharmacovigilance

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Link to the IHI brokerage platform:

- Proposal sharing: [PV SQUARED](#)
- Participant profile: [Irina Efimenko](#)

Challenges and objectives

SO3: demonstrate the feasibility of people-centred, integrated healthcare solutions

- To meet unmet public need for **regular, proactive detection & interpretation of safety signals** in post-marketing surveillance - with the ambition to integrate **people-centered approaches, patient perspective, PROMs and PREMs** to assess clinical benefits
- To leverage millions of voices (incl. patient experts with a high level of awareness)
- To bring in perspective of underrepresented groups, vulnerable populations, those having poorer access to healthcare

The approach to solve the problem

To develop and pilot models and tools to detect and interpret safety signals in patient-generated data in **5+ disease areas** and **10+ EU languages**

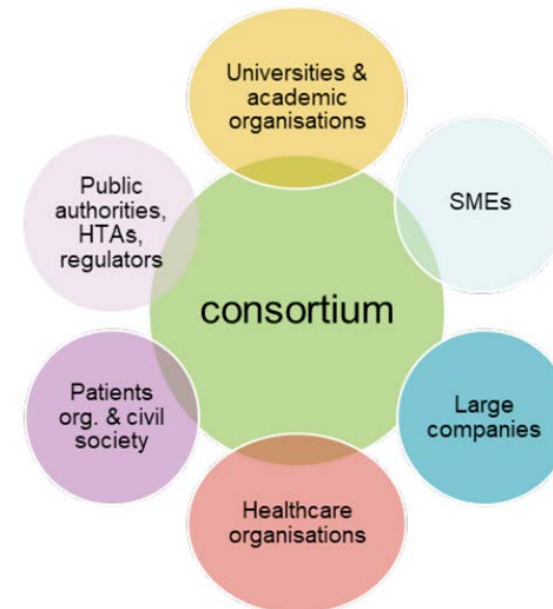
- How to distinguish between **noise** and **“real” signal**?
- What is the model for harmonising data from **heterogeneous sources**?
- What is the right balance between HCP and **patient perspective** when assessing treatment safety and effectiveness?
- How should patient / caregiver perspective be included in the HTA (**success criteria of treatment**, safety / effectiveness tradeoff)?
- What should be the right way to assess treatment value proposition and to communicate it to various stakeholders considering **PROMs & PREMs**?



better allocation of resources, improved adherence, cost effectiveness, societal impact of healthcare innovations

Why is the project suitable for IHI?

- Early detection of safety signals from RWD to improve the adoption of safe and effective therapies and vaccines with ensuing societal benefits
- Ambitious goal to integrate people-generated information, introduce patient preferences in HTA that no company or institution can address alone
- Better resource allocation, improved adherence, cost effectiveness, higher societal impact of healthcare innovations
- Standardization of PV signal interpretation (pre-competitive methodology)



Outcomes and Impact

- Methods, tools, **PROMs and PREMs** for safety signal detection and interpretation from patient-generated data piloted in 5+ high-burden disease areas and 10+ EU languages



SO3 + SO2 (novel methods and tools for post-marketing surveillance) +
SO4 (multiple sources of RWE) +
SO5 (integration of patient perspective to assess value)

Expertise and resources

- We have:
 - AI and NLP platform validated by 20+ industry leaders, in 60+ countries, 40+ languages and ~100 disease areas
 - Preliminary interest from 3 industry leaders, 3 PAGs, universities
- We are looking for:
 - Methodological support from experts in Regulatory Affairs
 - Engagement of relevant associations (EFPIA, Vaccines Europe, Medtech Europe)
- We are ready for:
 - IKOP
 - IKAA

Additional information: About us



- HQ-d in Lausanne, Switzerland, R&D HQ in Helsinki, Finland
- Customers in 60+ countries; 40+ languages
- 90+ medical conditions ($\frac{1}{3}$ oncology, $\frac{1}{3}$ rare diseases, $\frac{1}{3}$ other conditions)
- Trusted by 20+ global industry leaders; Google AI First Program
- 300+ years of experience in AI, unique proprietary platform