



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Accelerated **D**evelopment of **V**Accine be**N**efit-risk **C**ollaboration in **E**urope

ADVANCE

Presented by: Malgorzata Leszczynska on behalf of Xavier Kurz
Best Evidence Development

An agency of the European Union





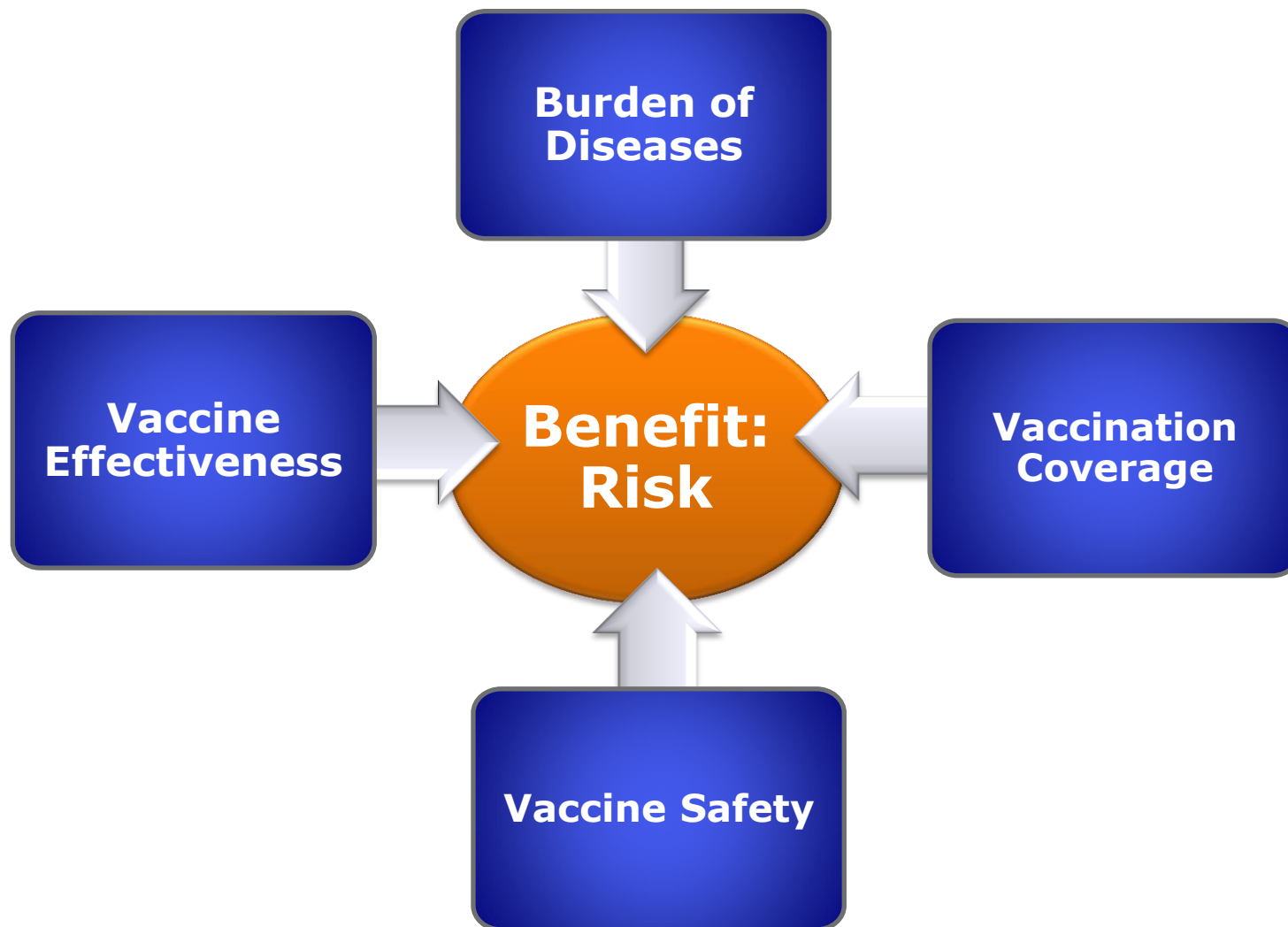
Aim

Long-term vision:

- The ADVANCE vision is focused on “timely and best evidence on vaccine benefits and risks”.
- The mission is to establish a Blueprint for a validated and tested best practice framework that could rapidly provide robust data on vaccine benefits and risks to support accelerated decision making.



Need for partnership





Participating Public Health Institutes

- **Full partners:** ECDC (SE) / WIV-ISP (BE) / RVH (NL) / SSI (DK) / ASLPCR (IT)
- **Associate partners:** UK / SMI (SE) / THL (FI) / KEELPNO & ESDY (EL) as well as Slovenia / Bulgaria / Hungary

Participating Regulatory Agencies

- **Full partners:** EMA / MHRA (UK) / AEMPS (ES)
- **Associate partners:** AIFA (IT) / ANSM (FR) / EOF (EL) / VVKT (LT) / JAZMP(SI) / WUM (PL) / IMB (IE)



Challenges

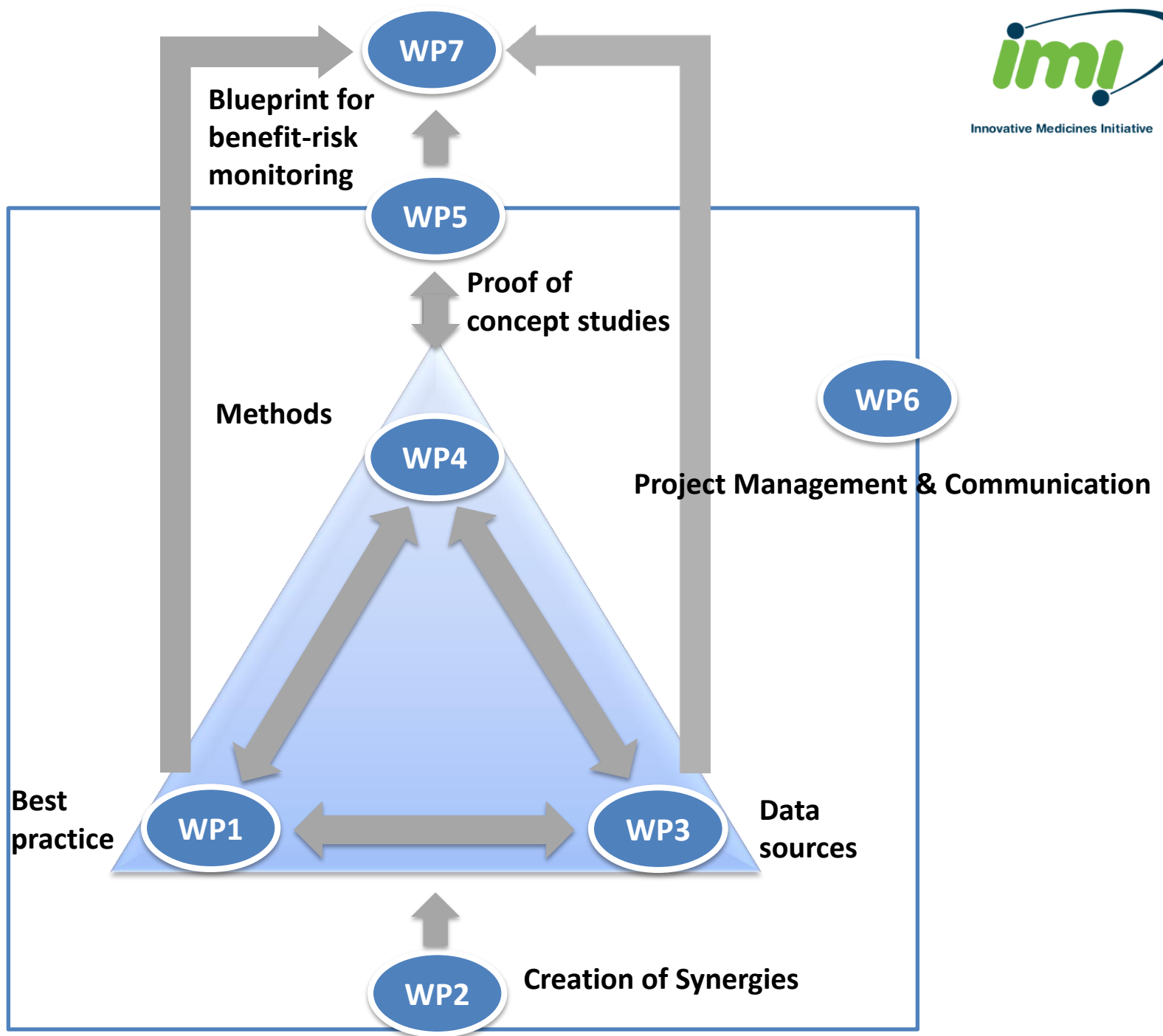
Diversity of stakeholders:

- Regulatory agencies, public health institutes, vaccine manufacturers, ...

Challenges on technical, governance and legal level

- Data sources
- Analytical methods for integrated B/R
- Coordination, overlap
- Transparent governance rules
- Increasing (complexity of) obligations

ADVANCE PROJECT WORKPLAN





Role of European Medicines Agency

Development of best practice and code of conduct for benefit-risk monitoring of vaccines (WP 1)

- Stakeholder needs and challenges (several workshops)
- Landscape analysis and models for public-public and public-private interactions
- Best practice guidance & code of conduct
- Communication strategy around vaccine benefit-risk and public private collaboration



Leading to code of conduct/guidance, proposal for proof of concept studies and white paper



Led by European Medicines Agency & SP MSD



Thank you for your attention.