Developing a framework for rapid assessment of vaccination benefit/risk in Europe

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Need for public-private collaboration

Please note the log scale
Orenstein et al. 2004, Journal of Infectious Diseases 189:S1–3

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Need for public-private collaboration

**LABORATORY CONFIRMED CASES OF MEASLES, MUMPS & RUBELLA**

England and Wales, 1996 - 2010, HPA data

Data source: HPA, [http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Measles/EpidemiologicalData/measDataMMRConfirmed/](http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Measles/EpidemiologicalData/measDataMMRConfirmed/)

Incidence of measles, UK
Need for public-private collaboration

- Burden of disease
- Vaccine Effectiveness
- Vaccination coverage
- Vaccine Safety

BENEFIT / RISK
Need for public-private collaboration

Diversity of stakeholders: regulatory agencies, public health institutes, vaccine manufacturers, ...

Integrated, rapid system to maintain or restore public trust as fast as possible

Challenges on both a technical and governance level
- Data sources
- Analytical methods for integrated B/R
- No enough coordination, overlap
- Transparent governance rules

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Objectives of the full project

IMI project (5 years)

Proof-of-concept studies

PRODUCTION

Sustainable infrastructure (Governance, funding)

2012  2013  2014  2015  2016  2017  2018  2019  ...  ...

IMI project (5 years)
Objectives of the full project

• **Long-term vision**: an efficient and sustainable infrastructure for rapid and integrated post-licensure monitoring of vaccines under clear governance rules meeting the common interest of all main stakeholders

• **Aim of this call**: deliver the necessary steps to prepare the implementation of a sustainable system
Objectives of the full project

Objectives of this call

• Identify/develop governance principles and rules that recognise all main stakeholders
• Map the current synergies in existing relevant ongoing projects that provide relevant data, information and methodological tools
• Proof of concept studies
• Deliver an action plan for long-term expandability and sustainability to allow transition to production
Pre-competitive nature

• Current needs and challenges are similar across all vaccine manufacturers
• Governance and tools will be similarly usefull to all
Suggested architecture of the project

- WP1: Governance and code of conduct for public/private partnership in studies of benefit/risk of vaccines
- WP2: Mapping of project synergies
- WP3: Data sources for rapid and integrated benefit/risk analyses
Suggested architecture of the project

• W4: Identification and/or development of methods for integrated analysis of burden of diseases, vaccination coverage and vaccine safety and effectiveness

• WP5: Proof-of-concept studies of a framework to perform vaccine benefit/risk

• WP6: Project Management

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Expected (in kind) contributions of EFPIA members

• Expertise in vaccines
• Experience in the challenges to implement studies defined by Risk Management Plans
• Research capacity in disease epidemiology, pharmacoepidemiology, pharmacovigilance
What’s in it for you?

• Unique opportunity for all stakeholders to sit around the table
• Exciting and challenging project
• Long term vision
Key deliverables of the full project

• Annual review to map the needs, gaps, resources, methods and processes for rapid, integrated post-approval monitoring of vaccines in Europe, reflecting the views of all main stake-holders

• Proof-of-concept studies to assess selected data sources, analytical methods and governance rules

• A recognised central forum to build trust between all the main stakeholders and facilitate timely agreement on governance

• Guidance for best practices and governance for the conduct of pharmacoepidemiological studies to monitor benefit/risk of vaccines under private/public partnership

• An action plan for a sustainable framework for assessing vaccine impact, including plan for governance, funding mechanism, integration of/with other initiatives (as mapped) and supporting organisation.
Questions?

• Contact the **IMI Executive Office**

  E-mail: [infodesk@imi.europa.eu](mailto:infodesk@imi.europa.eu)
  Website: [www.imi.europa.eu](http://www.imi.europa.eu)
Questions and Answers

Type your question into the box in the Questions panel and click on ‘Send’

Raise your hand