



Innovative Medicines Initiative

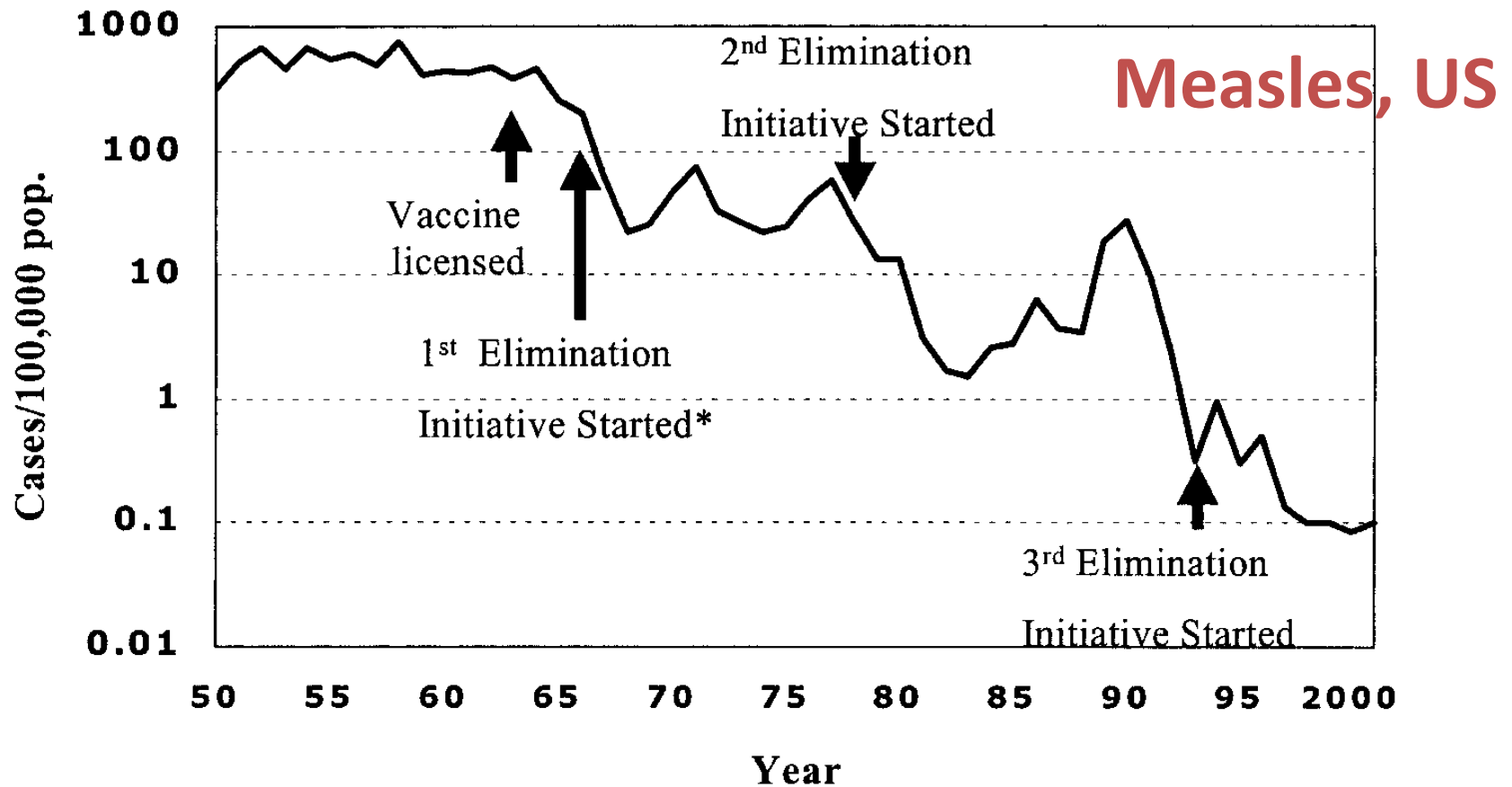
# Developing a framework for rapid assessment of vaccination benefit/risk in Europe

Vincent Bauchau (GSK Biologicals)



efpia\*

# Need for public-private collaboration

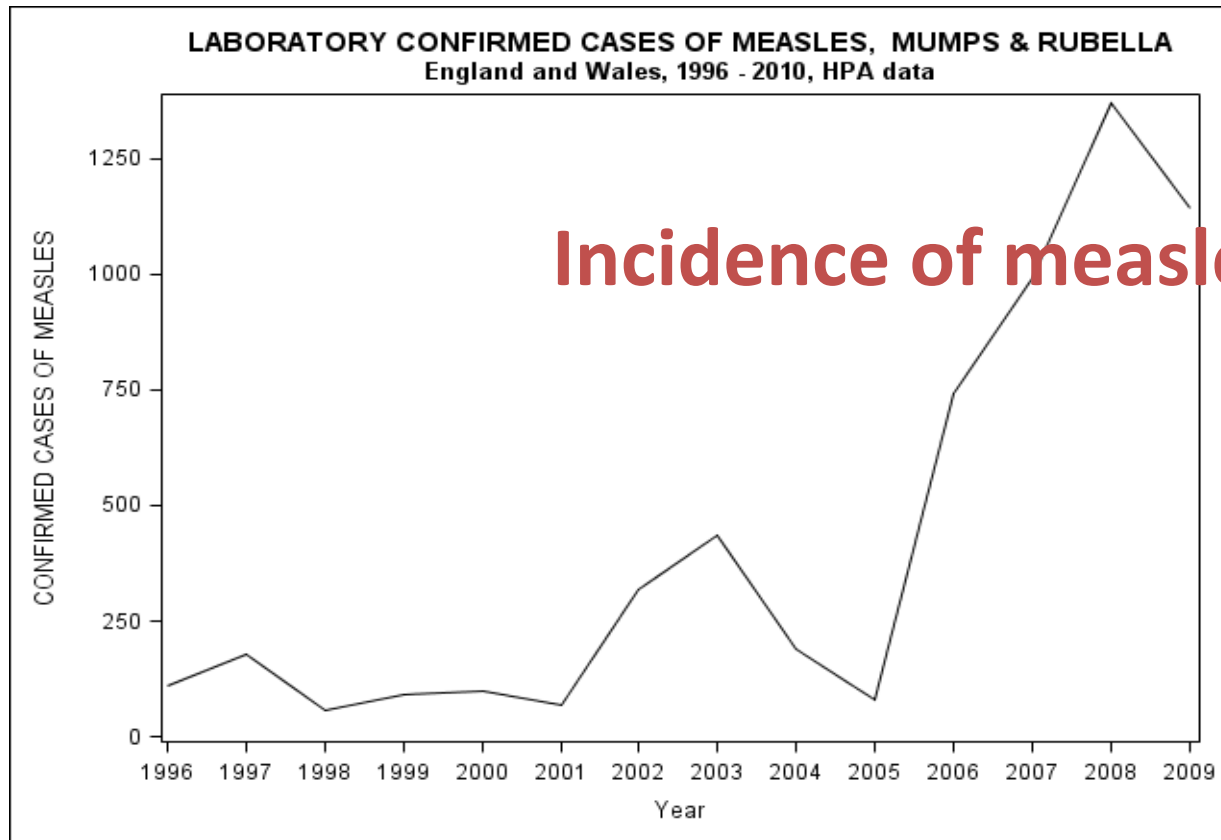


Please note the log scale

Orenstein et al. 2004, *Journal of Infectious Diseases* 189:S1-3



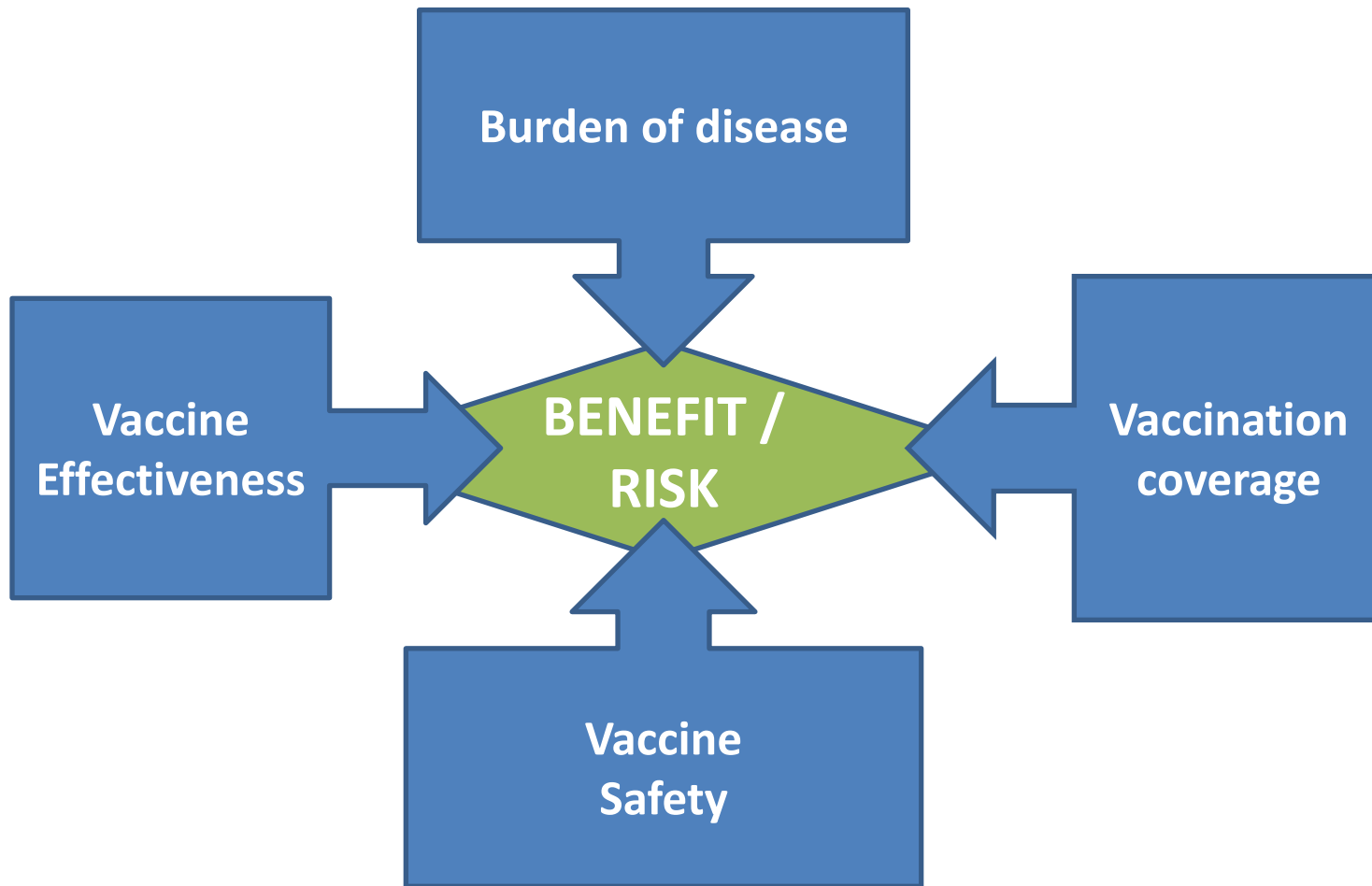
# Need for public-private collaboration



Data source: HPA, <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Measles/EpidemiologicalData/measDataMMRConfirmed/>



# Need for public-private collaboration



# Need for public-private collaboration

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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
- Not enough coordination, overlap
- Transparent governance rules



# Objectives of the full project



2012

2013

2014

2015

2016

2017

2018

2019

...

...



IMI project (5 years)

Proof-of-concept studies

PRODUCTION

Sustainable infrastructure  
(Governance, funding)



# Objectives of the full project

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- **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

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## 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

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- Current needs and challenges are similar across all vaccine manufacturers
- Governance and tools will be similarly useful to all



# Suggested architecture of the project

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- 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

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- 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



# Expected (in kind) contributions of EFPIA members

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- 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?

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- Unique opportunity for all stakeholders to sit around the table
- Exciting and challenging project
- Long term vision



# Key deliverables of the full project

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- 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 stakeholders
- 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?

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- 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)

