

# Webinar | IMI2 - Call 9 'Joint influenza vaccine effectiveness studies'

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# Today's webinar

- **Will cover all aspects of the Call topic**
  - The process (additional eligibility criterion!)
  - The rationale and objectives of the project
  - Need for public-private collaborative research
  - Expected contribution of the applicants
  - Contribution of EFPIA participants, EU and national public health and regulatory bodies
  - Key deliverables
- **Will not cover rules and procedures**
  - A webinar on Rules and Procedures took place on 25 April, presentation and recording are published at [bit.ly/1RSPiTC](http://bit.ly/1RSPiTC)

# Submitting a proposal – tips

- **Read** all the relevant material on the IMI website
- **Understand** the **IMI 2 rules** and respect them
- **Contact** the IMI Programme Office if you have any questions (not the EFPIA topic coordinators)
- **Provide all information** the reviewers will need to evaluate your proposal
- **Start working early**
- **Finalise and submit your proposal**
- **More tips:** [www.imi.europa.eu/content/tips-applicants](http://www.imi.europa.eu/content/tips-applicants)

# Submitting a proposal – common mistakes

## Admissibility / Eligibility criteria not met:

- Missed deadlines
- Proposal out of scope
- Submitted text does not respect the proposal template
- Minimum number of legal entities

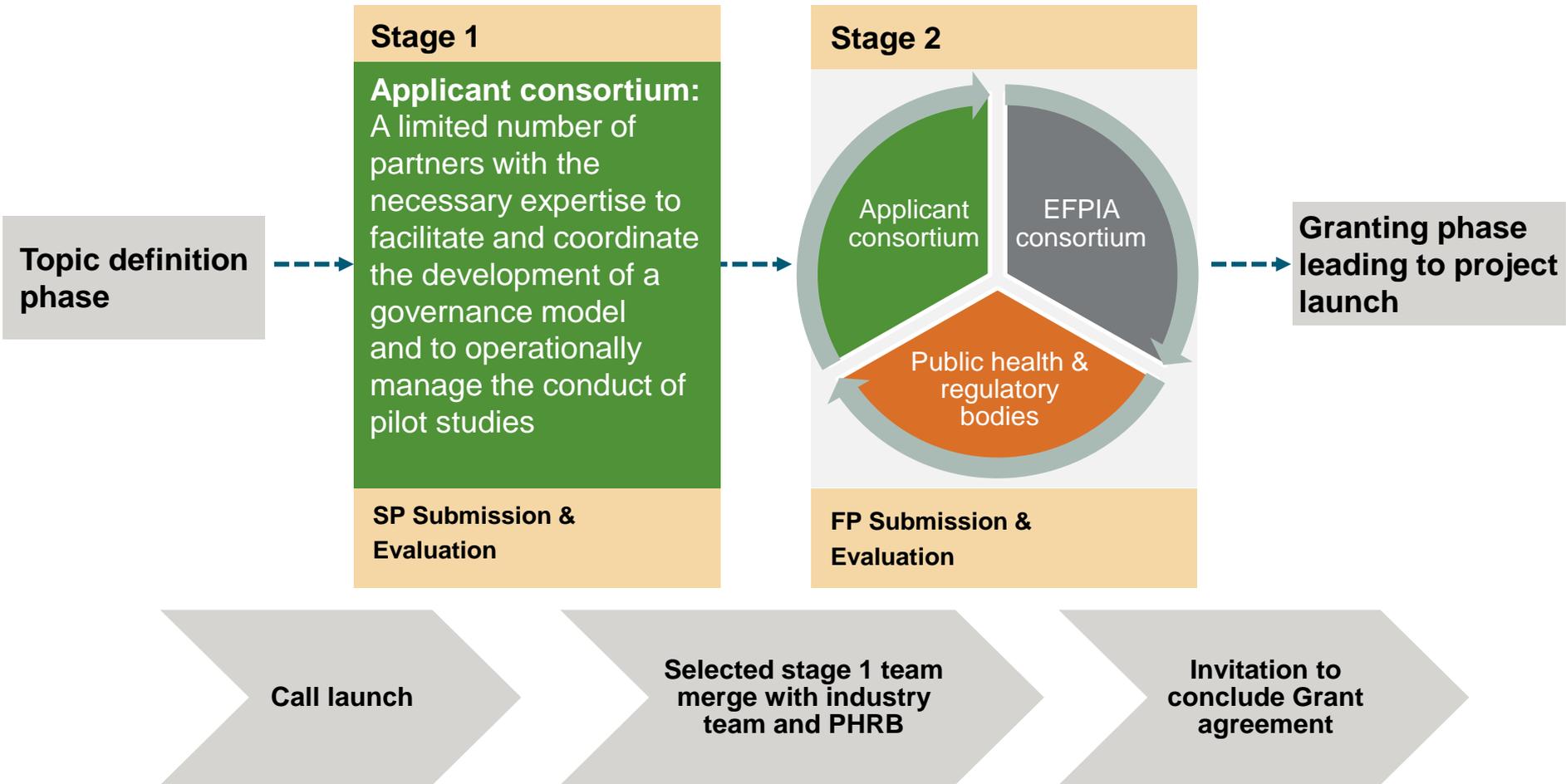
## And to increase your chance of success... beware:

- Redundancy between partners
- All objectives not addressed
- Limited impact of the proposal, despite scientific excellence

# Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use the **IMI Partner Search Tool**  
<http://www.imi.europa.eu/content/partner-search>
- Get in touch with your **local IMI contact point**:  
[www.imi.europa.eu/content/states-representatives-groups](http://www.imi.europa.eu/content/states-representatives-groups)
- Talk to your **Health National Contact Point (NCP)**
- Network on **social media** (e.g. IMI LinkedIn group)

# A two stage process with an additional eligibility criterion



PHRBs: ECDC, national public health institutes & national regulatory agencies

# Timelines & Budget

## Deadline for submission of Short proposals:

- 26 July 2016 (17:00:00 Brussels time)

## Indicative budget:

- Indicative contribution from EFPIA companies: EUR 1 million\*
- IMI2 JU contribution: max. EUR 9 million

In their resource allocation planning, the applicant consortium should set aside an appropriate budget for the public health and regulatory partners that will join during stage 2.

EFPIA companies part of the industry consortium are making a EUR 4 million financial contribution to the IMI2JU in support of this action



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**Dr. Cédric Mahé**  
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# Rationale

- Measurement of influenza vaccine effectiveness is a particularly complex endeavour, both operationally and technically. As a consequence, brand-specific vaccine effectiveness data is missing in the majority of Member States.
- A strengthened capacity in Europe to generate yearly influenza vaccine effectiveness = benefits for the public health sector, vaccine manufacturers and ultimately Europe's citizens
- Discussions on how to best achieve an EU wide vaccine effectiveness platform have been ongoing for several years
- New EU regulatory requirements will ask for brand-specific data and this will necessitate appropriate infrastructure at country level.
- With IMI being an established public-private partnership, it provides a ready mechanism for assembling the key stakeholders for developing the platform

# Need for public-private collaboration

- All stakeholders have a joint interest in improving the availability of vaccine effectiveness data across Member States;
  - Public health institutes to appropriately evaluate the public health benefits accrued by their influenza immunisation programmes
  - Vaccine manufacturers to meet regulatory requirements (report on the benefit/risk of marketed vaccines)
  - EU citizens to improve their level of information about influenza vaccination

This synergy can best be achieved through the development of a transparent collaboration between public and private actors

# Objectives of the full project

- The purpose of this topic is to create a platform under a public-private partnership with the capacity to perform influenza effectiveness assessments.
- More specifically, the key objectives of the action are :
  - To develop and validate a sustainable governance model for the evaluation of type/brand-specific seasonal influenza vaccine effectiveness in Europe,
  - To build an EU/EEA-wide recognised and accepted platform for influenza vaccine effectiveness studies
  - To develop communication tools and guidance for dissemination of the results

# Duration

- The indicative duration of the project is 60 months
- This project will cover four influenza seasons:
  - 2017-2018 to pilot tools
  - 2018-2019, 2019-2020, 2020-2021 to progressively scale up the platform

# Pre-competitive nature

- Two stage process
  - Stage 1: Public-private consortium competition
  - Stage 2: ECDC, Public Health and Regulatory Bodies (PHRBs) and EFPIA join the stage 1 winning consortium  
*Partners providing the unique expertise and data from national immunisation programmes*

# Suggested architecture of the project

- **WP1:** Development of a governance model for joint influenza vaccine effectiveness studies in Europe
  - **WP2:** Tools and protocols development
  - **WP3:** Pilot study conduct
  - **WP4:** Generation of result reports
  - **WP5:** Communication and dissemination of results
  - **WP6:** Project coordination
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- The final architecture of the project will be defined in detail together with all partners during stage 2 (i.e. including the industry and PHRBs)

# Expected contributions of the applicants

- Facilitate and coordinate the development of a governance model for joint influenza vaccine effectiveness studies
- Operationally manage and facilitate the conduct of prospective observational studies
- Specifically, expertise in the following areas:
  - Conduct of prospective observational studies
  - Epidemiology
  - Public-private partnership
  - Governance principles, transparency, auditing
  - Large international project coordination
  - Regulatory processes
  - Negotiation and consensus building
  - Pooled data analysis and interpretation
  - Communication of complex notions to professional and lay audiences

The pan-European network, expertise and access to data from national immunisation programmes that is required for the successful implementation of the effectiveness studies should not be part of the applicant consortium, but is expected to be added during stage 2

# The role of ECDC and national public health and regulatory bodies

- ECDC, in cooperation with national Public Health Institutes, will take the lead on the scientific elements of the project, and will have a key role in defining the governance model acceptable by the public sector and in the discussion on the sustainability of the influenza vaccine effectiveness platform.
- In addition of their contribution to the overall project, national Public Health Institutes will also facilitate access to national programme data and infrastructures.
- The EMA scientific advice office will provide informal guidance to the consortium regarding the best route to take at the various stages of the project.

# Expected contributions of EFPIA members

- 0.15 FTE and 200K€ per year per vaccine manufacturers
- Monetary contributions are mainly dedicated at expanding data collection
- Vaccine manufacturers qualified staffs will contribute FTE based on their expertise
  - Conduct of influenza vaccine efficacy and effectiveness studies following rigorous standards and protocols agreed by regulators.
  - Knowledge on their vaccines and expertise in epidemiology, pharmacoepidemiology, data management and regulatory interactions
  - Governance, legal and communication.
  - Synergies with other IMI consortia (ADVANCE, FLUCOP...).

# Key deliverables of the full project (1/3)

## Sustainable platform for influenza vaccine effectiveness studies involving all relevant stakeholders

- A validated governance model for influenza vaccine effectiveness studies in Europe developed with the involvement of all relevant stakeholders.
- A plan for sustaining the results of this action and integrating them into a larger and more generally applicable model for vaccine effectiveness studies in the EU/EEA.

# Key deliverables of the full project (2/3)

## Conduct of pilot studies for determining type/brand-specific effectiveness

- Tools for study site selection
- Protocol for influenza vaccine effectiveness studies.
- Methodology guidelines to identify vaccine status and brands (including vaccination registries consideration)
- Standard operating manual and audit checklist for site oversight
- Recommendation on the how the outcomes could feed other WHO or EU mechanisms
- Evaluation report with a focus on governance, sample size and feasibility.

# Key deliverables of the full project (3/3)

## **Guidelines and recommendations on the production of influenza vaccine effectiveness data, and on the communication and dissemination of results**

- Methodology guidelines for concerted analysis of data and control of confounding factors.
- Analysis plan and guidelines to be endorsed by regulators for interpretation of obtained study data using a multi-stakeholder approach.
- Four timely seasonal reports
- Evaluation of how the vaccine effectiveness results could fulfil the new regulatory requirements.
- Communication guideline and tools including lessons learnt from the actual dissemination of the seasonal study results.
- R&D recommendations based on the identified gaps in the vaccine performance



## Questions?

Contact the IMI Programme Office  
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