Webinar | IMI2 – Call 12
Analysing the infectious disease burden and the use of vaccines to improve healthy years in aging populations

12.07.2017 • 16:00 CEST

Today's webinar

- **Will cover all aspects of the Call topic**
  - Objectives of the project
  - Need for public-private collaborative research
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium
  - Key deliverables
- **Will not cover rules and procedures**
  - A webinar on rules and procedures will take place on 17.07.2017 at 14:30
  - Register at http://www.imi.europa.eu/events/2017/06/27/webinars-imi2-%E2%80%93-calls-11-12

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IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

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IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges**.

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IMI 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

€1.425 bn

Other €213 m

IMI 2 total budget €3.276 billion

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Associated Partners e.g. charities, non-EFPIA companies

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How a topic is generated

Industrial partners align themselves around a real challenge for industry and agree to work together **and commit resources**

New ideas from public sector, universities, SMEs etc. are needed to address the challenge

Scale is a key to success and is provided through IMI funding

Outcomes should be transformative for the industry as well as having a clear “public” value

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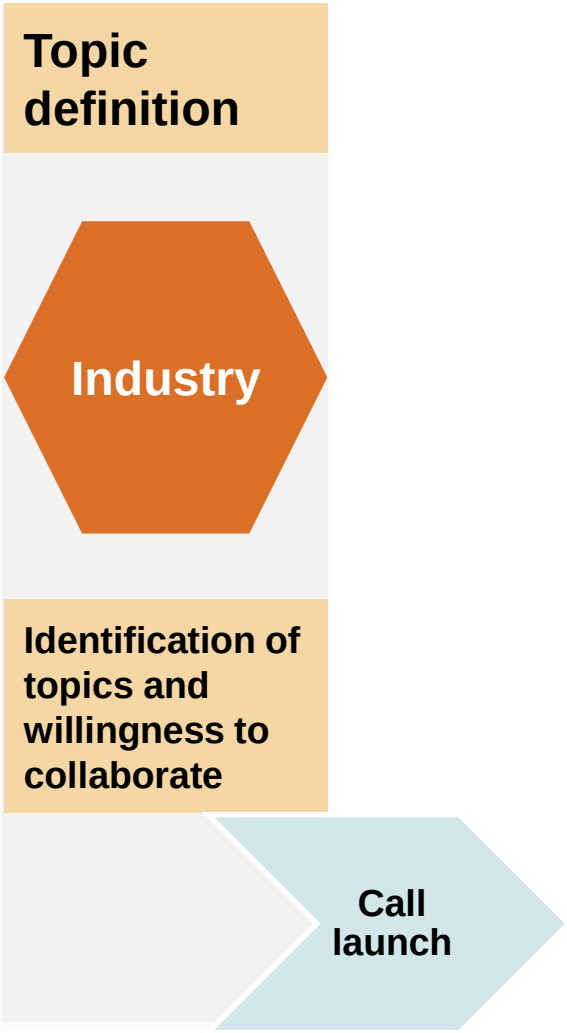
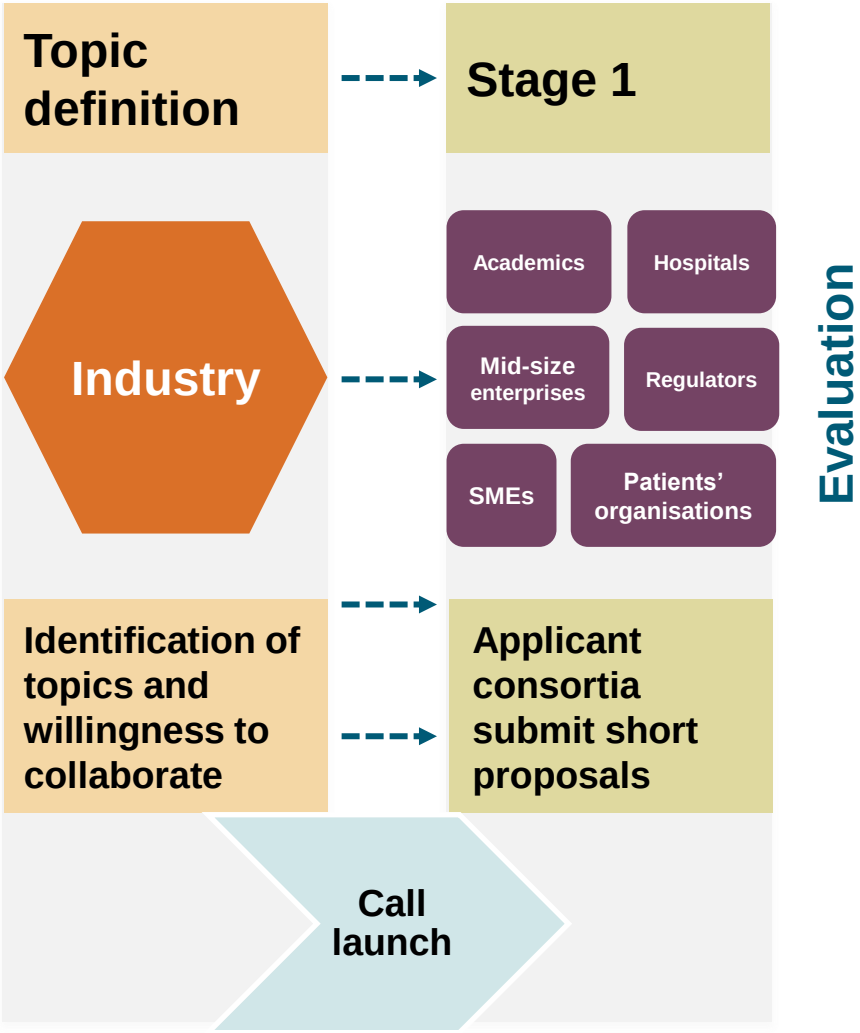
Typical IMI project life cycle



Typical IMI project life cycle



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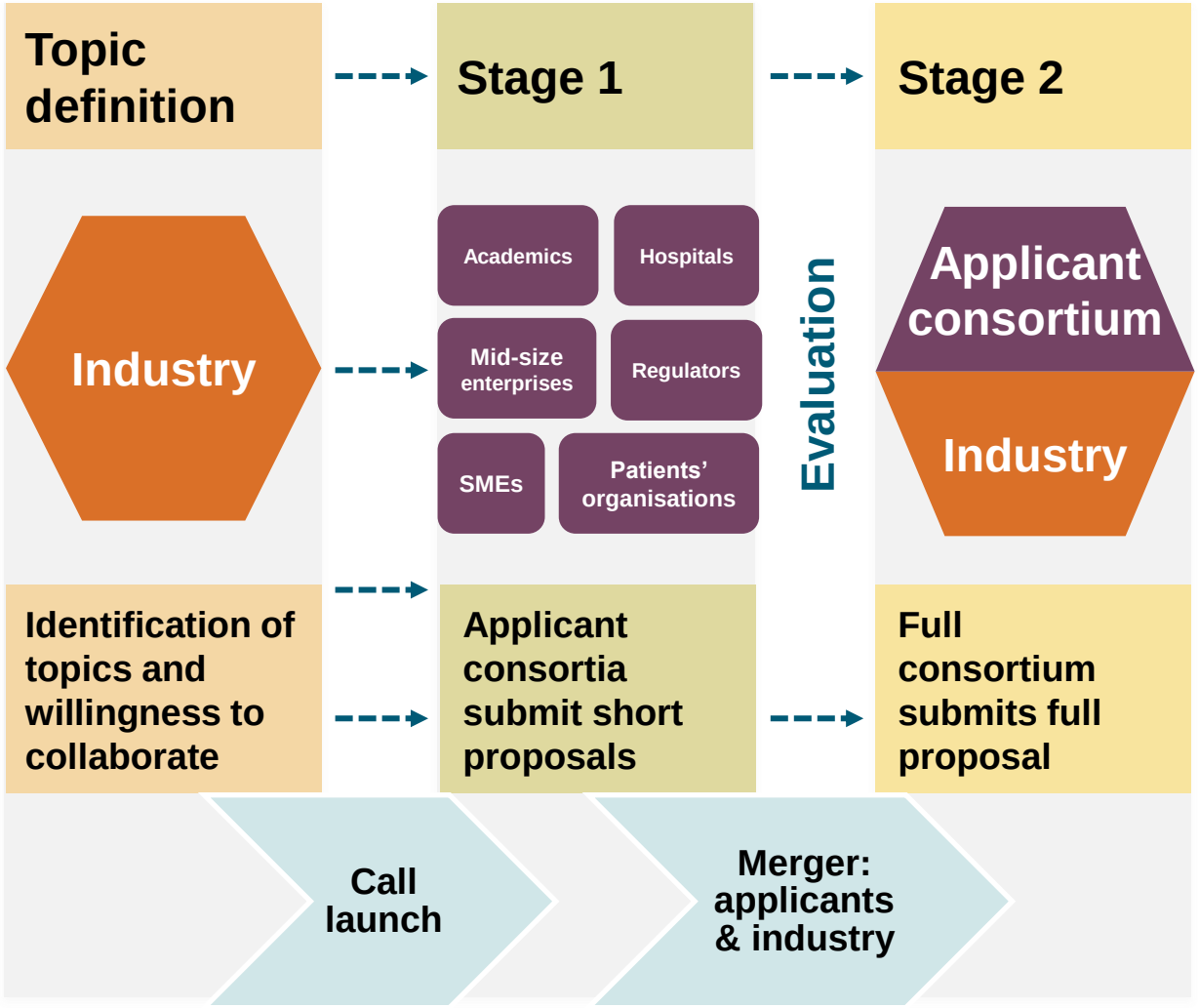
Typical IMI project life cycle



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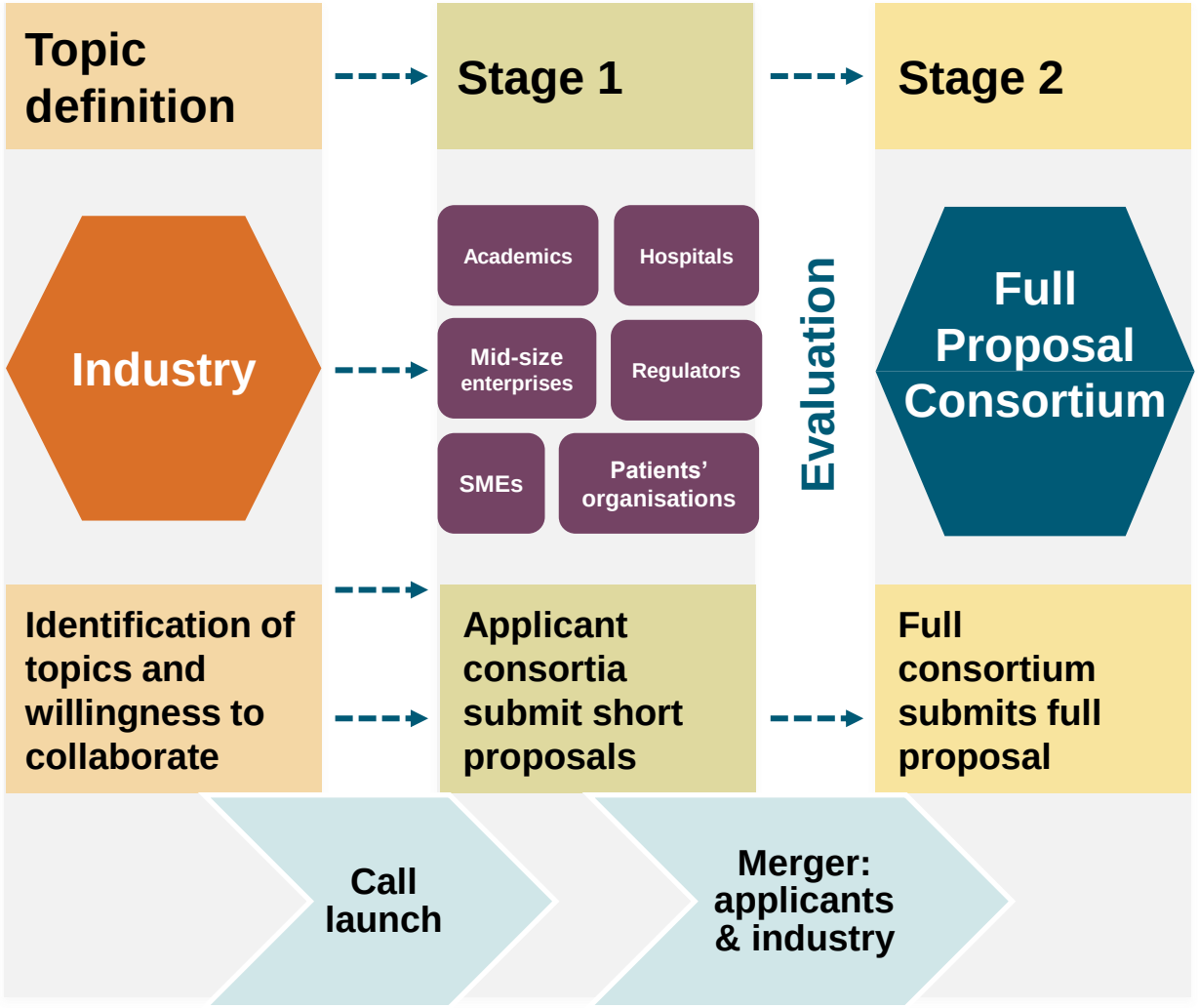
Typical IMI project life cycle



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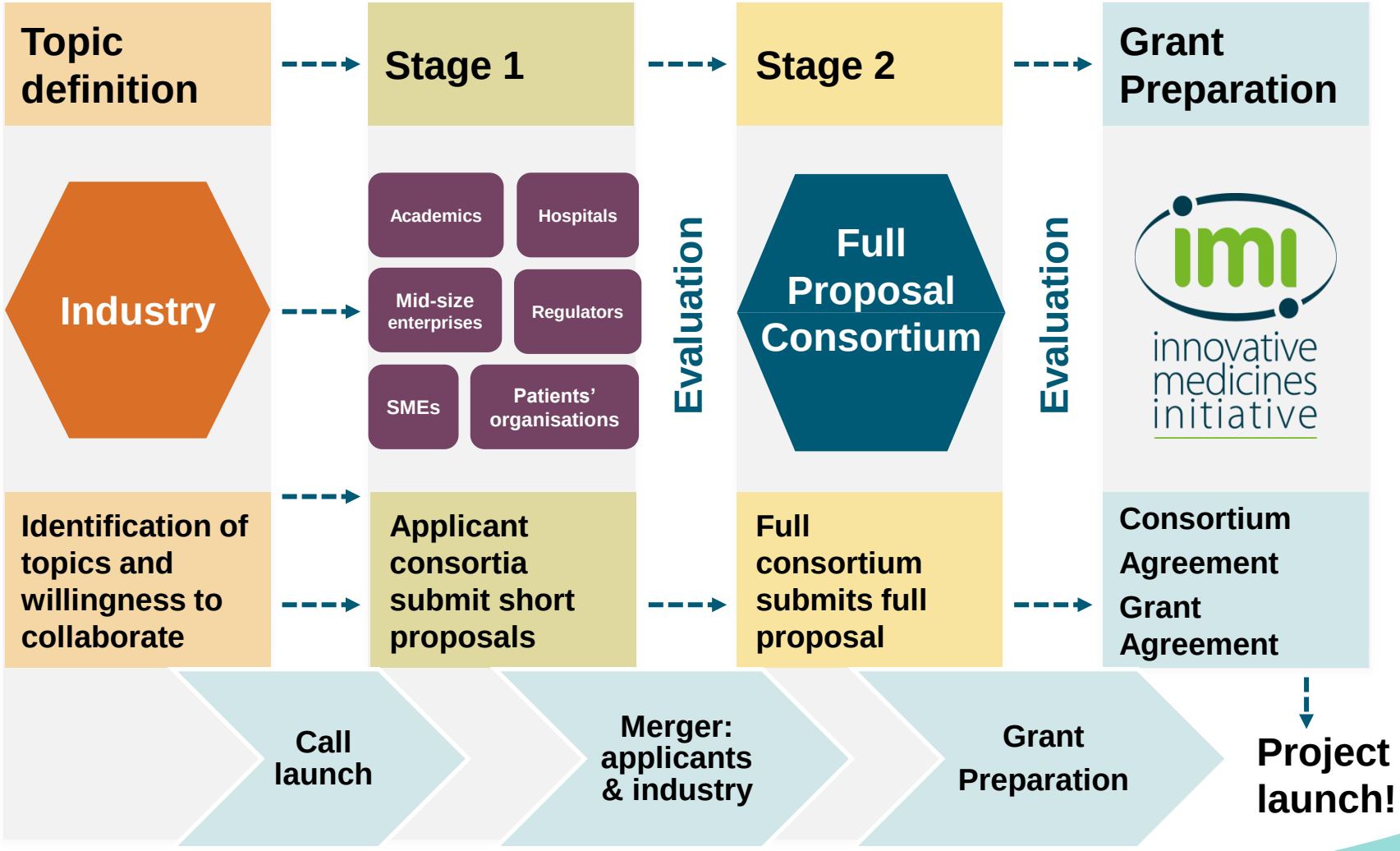
Typical IMI project life cycle



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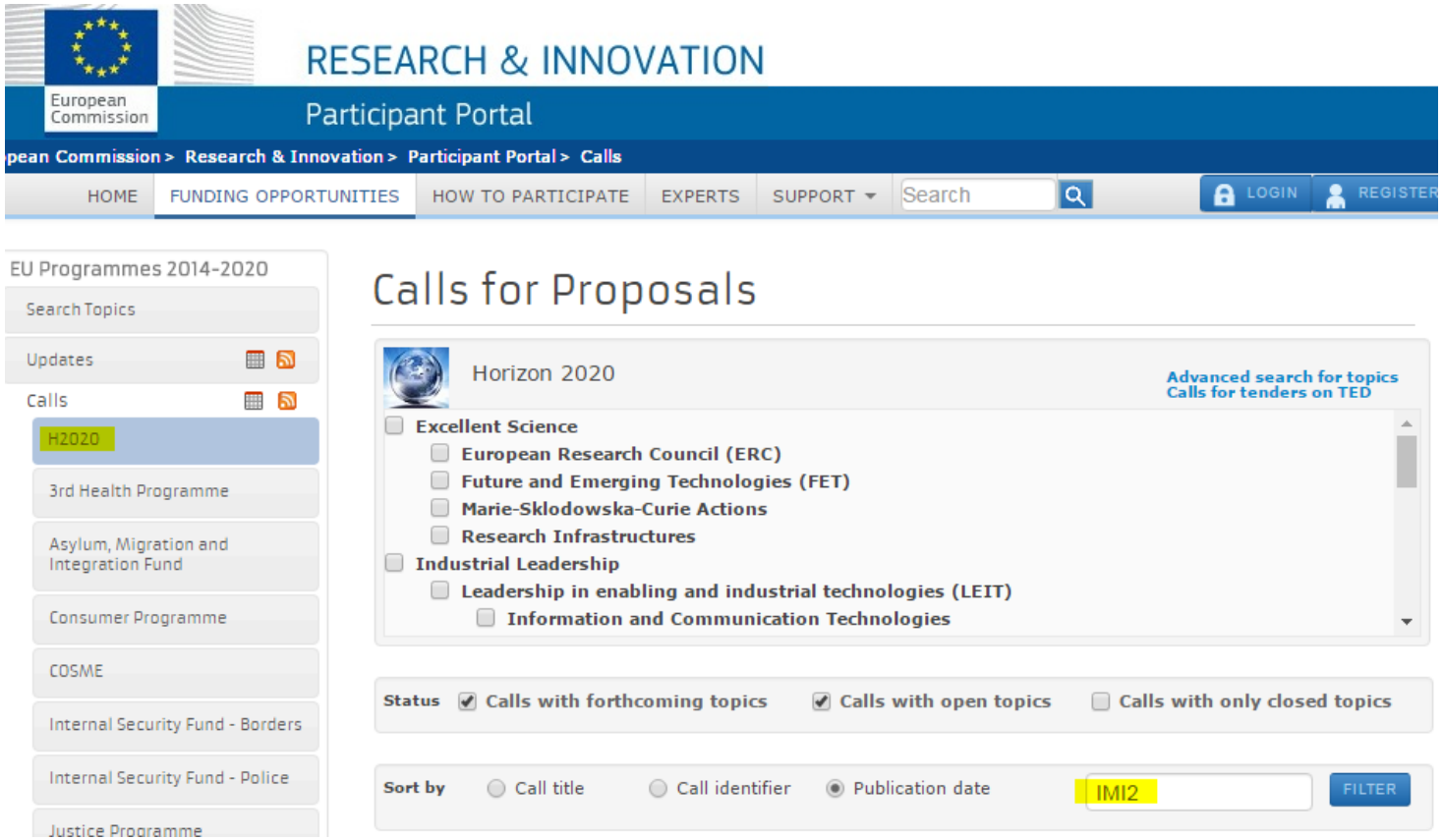
Submitting a proposal

- https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/index.html



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Proposal Template

- Available on IMI website & H2020 submission tool
- For first stage proposals, the page limit is **30 pages**.

Title of Proposal

List of participants

Table of Contents

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Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the proposal to meet all key objectives of the topic;
  - Credibility of the proposed approach;
  - Soundness of the concept, including trans-disciplinary considerations, where relevant;
  - Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;
  - Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.
- **Impact**
  - The expected impacts of the proposed approach as mentioned in the Call for proposals;
  - Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
  - Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
  - Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
  - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
  - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

Tips for writing a successful proposal

- Read **all the call-relevant material:**
  www.imi.europa.eu
- Begin forming your consortium **early**
  Partner search tools & networking events
- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **IMI Office** (**NOT** industry topic writers):
  infodesk@imi.europa.eu

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Common mistakes

- Admissibility/Eligibility criteria not met**:**
  - submission **deadline** missed
  - minimum of **3 legal entities** from **3 member states & H2020 associated countries** not met
- The proposal does **not address all the objectives** of the topic
- A proposal is **scientifically excellent** but will have **limited impact**
- **Complementarity** with Industry consortium not well described.

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Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools:**
  - IMI http://www.imi.europa.eu/content/partner-search
  - German NCP version: http://www.imi-partnering.eu
  - Fit for health: http://www.fitforhealth.eu/
- Get in touch with your **local IMI contact point**: 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)

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SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

For example, being closer to the market, SMEs can drive the tangible outputs of the project, and help ensure these outputs are sustained beyond the project lifetime and therefore help lead to faster impact on healthcare.

Therefore, where possible, include SMEs in your Short Proposal

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Analysing the infectious disease burden and the use of vaccines to improve healthy years in aging populations

Del Giudice Giuseppe, MD, PhD & Standaert Baudouin, MD, PhD, GSK Vaccines

12.07.2017 • IMI webinar

Problem Statement

- The older population augments in size every year because of increased life expectancy
- In addition, older people are more vulnerable to infectious diseases because their immune system becomes weaker with age
- Avoiding infections, therefore, impacts the ambition of supporting healthy aging, a condition that helps optimise the opportunities of good health so that aged individuals maintain their activities of social life and enjoy an independent high quality of life
- A solution to avoid those infections is to develop a well-conceived vaccination programme for the elderly as we did for children years ago

Existing challenges

To get the full picture, we face various challenges:

- getting access and demonstrating how to evaluate and report epidemiologic data for obtaining a clear picture on the infectious disease burden in the aged people
- better understanding the immune response in elderly (65 years +) by deciphering the changes taking place due to age and to other factors
- having disease and economic models available that predict how the current situation may further evolve without any specific intervention or after implementation of an extended vaccination programme
- being able to communicate an integrated view of the problem through training and education of health care professionals

Overall scope of the project

To fill the gap of the current knowledge related to vaccines and vaccination for the elderly, namely in the areas related:

- to the burden of infectious diseases (and their consequences),
- to the waning of the immune responsiveness associated with age and other intervening factors,
- to the value of vaccination in older adults, and
- to the education/training of key stakeholders on vaccination of older adults

Objectives of the full project

The overall scope will be approached by:

- Obtaining a clear picture on the infectious disease burden in an aging population (50 years +);
- Quantifying the problem such as number and type of hospitalisations and medical visits when the 50 years + group is exposed to the health care system;
- Understanding this evolution over the coming years;
- Obtaining a better insight in the immune responsiveness in the age-group >65 years and of the factors (Intrinsic & extrinsic) contributing to it;
- Developing cost-benefit predictions based on an extended vaccination programme;
- Developing strategies to educate all stakeholders working with the elderly.

Suggested architecture of the project

Work Package 1: To determine the burden of infectious diseases in aging adults (50+)

- Obtain a robust protocol of evaluation through review of published data, analysis of existing databases and start filling the gap with epidemiologic studies
- Acquire knowledge on infectious diseases split into 2 categories (existing vaccine-preventable (VP) diseases & upcoming potential vaccine-preventable (PVP) diseases in aging adults)
- Acquire knowledge on the economics of the infectious diseases (cost of illness) split into the 2 categories (VP, PVP)
- Investigate links to diseases/co-morbidities and risks in which infectious diseases could be the trigger for chronic diseases
- Report about volume increase of infectious disease because of the demographic age-change and about the level of heterogeneity related to immune response rates

Suggested architecture of the project

Work Package 2: To better understand the immune response of aging adults (65+) and how it is modulated or affected by internal and external factors after vaccination

- Prospectively designed clinical research study to assess the immune response of aged compared to non-aged adults following vaccination, and, analyses of existing samples from retrospective studies may be considered if allowed by ICF, timing of sampling, volumes available, etc.
- Decipher mechanisms leading to immune waning or reduced immune response and the ability to respond to vaccination with age
- Whenever possible, state-of-the-art dissection of immune responses at the site of the priming of the immune response
- Understanding how the extrinsic factors become important to appreciate heterogeneity of immune-senescence
- Application of new data analysis methods to derive immune profiles associated with aging

Suggested architecture of the project

Work Package 3: To assess with disease models the current management status of infectious diseases in older adults and to simulate the impact of (potentially) vaccine preventable infections

- Set new standards of analysing and reporting health economic results, taking into account indirect effects , e.g., complications, frailty, dependency. It is expected to advance the impact options in a transparent way when analysing and reporting health economic results

- Based on information collected in WP1, develop advanced modelling programmes to demonstrate the impact of vaccination according to various level of immunosenescence and to define best strategies to maximise the overall public health impact of vaccination for aging adults, taking into account potential enablers

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Suggested architecture of the project

Work Package 4: To develop a roadmap about training and education of HCPs

- Vaccination of adults and elderly subjects is not fully perceived as a major need, as compared with the vaccination of the paediatric age-group. Appropriate and innovative communication tools for all stakeholders on the value of vaccines and on vaccination should represent a key need for achieving the scope of healthy aging
- Build a framework of innovative educational and training initiatives
- Develop a network of specialists/experts in the field across Europe to exchange experience and set-up new collaborative projects would be very helpful
- Demonstrate how to secure training of the HCPs in charge of implementing adult vaccination

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Suggested architecture of the project

Work Package 5: project coordination, management, and dissemination activities

- Skilled project management support will be an essential part to ensure project success
- Managing all aspects of project governance, management and coordination. Facilitation and streamlining of cooperation between the different partners of the project and between work packages
- Carrying out all aspects of the dissemination of results, and communication strategy
- Coordinating and communicating with other European initiatives and projects handling complementary activities

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Key deliverables of the full project

- A database on infectious disease burden in aging adults
- Standard methods, definitions, and protocols on how to analyse and report the disease burden in aging adults
- Estimation of the full burden of infectious diseases for VP and PVP
- Identification of intrinsic factors impacting the decline in immune response
- Characterisation of the contribution of extrinsic factors on immune response
- Computational models to conduct simulations in elderly
- Models with scenario-testing of different vaccination strategies
- Recommendation for optimal vaccination strategies
- A roadmap on vaccine confidence targeting HCPs

Expected impact

- Societal gain for healthy aging based on recommendations based on our studies for developing an optimal vaccination strategy
- Health science development on standards for analysing and reporting on epidemiology & economic evaluation
- Basic and applied research in immunology and vaccinology to be applied to the development of better vaccines
- Economic analysis using the right modelling design
- Communication strategies on prevention promotion for elderly
- Strengthening the competitiveness and leadership role on vaccine research and implementation in Europe
- Interaction with regulatory agencies to update the impact of the results on future regulatory approaches

Need for public-private collaboration

- Variety of assessments have been made separately by public & private groups on aging about immuno-senescence, external factors influencing the process, epidemiology & cost burden
- Industry has a long lasting experience in vaccination of elderly (e.g. influenza, pneumococcal, herpes zoster, etc)
- Integrated approach is needed for a holistic evaluation of all the value aspects to reduce cost, avoid duplication of efforts, achieve higher credibility such as
  - Common epidemiology & cost of illness studies
  - New immune response evaluation studies
  - Uniformed economic models
  - Communication & teaching tools for key players in the field

Pre-competitive nature

- The information that will be collected, analysed and presented through this IMI-project, is a necessary condition for developing new vaccination programs that are of highest value for the target population: the aged adults in Europe

- The type of information (epidemiology, cost, models, immune response) is common knowledge prior to specific development of new vaccines

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Industry Consortium, Duration of the Project, and Indicative Budget

- EFPIA participants
  - GlaxoSmithKline
  - Sanofi Pasteur
  - Janssen
  - Pfizer
  - MSD
  - Vaccines Europe
- Duration of the Project
  - 60 months
- Indicative budget
  - EFPIA contribution:
    EUR 5 500 000
  - IMI-2 contribution:
    EUR 5 500 000

To reflect project priorties, pillars 1 and 2 would have the main allocation of resources, but to reflect their significance, pillars 3 and 4 would still receive a significant allocation of the total indicative budget.

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Expected contributions of the applicants

- Applicants are expected to have experience in working in a multi-disciplinary environment (including epidemiology, modelling, health economics), conducting clinical studies, and knowledge of other IMI projects.
- The partner(s) should have established and well-recognized experience in the field of aging, encompassing aspects related to human vaccination, public health, human immunology, epidemiology, infectious diseases, physiology, medicine, nutrition, economics, advanced disease modelling, training and education capacities and experiences, etc.
- The partner(s) should have experience in assessing vaccination programmes and decision-making processes leading to the implementation of new vaccination programmes, as well as regulatory experience.

Expected (in kind) contributions of industry consortium

- GlaxoSmithKline; Sanofi-Pasteur; Janssen; Pfizer; MSD; Vaccine Europe
  - personnel costs by providing expertise in health economics and outcomes, immunology, epidemiology, statistics, regulatory affairs, patients engagement, project leadership;
  - conduct of a large prospective observational epidemiological study;
  - giving access to a data-base that has already collected some critical information on the subject;
  - disease and economic models already or being developed for elderly;
  - roadmaps for good communication practices

What's in it for you?

- Major attractiveness of the project is the multi-disciplinarity/cross-functionality of the program with necessary interactions between the different work-packages, and between the academic and the industrial environments, along the spirit of IMI
- The area of investigation on epidemiology, immune response, economics in aging adults is new and challenging and will result in novel, ground-breaking results leading to publications and reports to the appropriate stakeholders
- The project is expected to provide new knowledge in various areas, including new methods of analysis & reporting
- The results of the project are expected to influence policy strategy for supporting a better healthy aging program
- The creation of a network of experts in this field in Europe should help enforcing research in that area for a long period of time

Thank you

Contact the IMI Programme Office
infodesk@imi.europa.eu • www.imi.europa.eu

www.imi.europa.eu
@IMI_JU

Participation of SMEs, patients, regulators

Dr. Angela Wittelsberger
IMI webinar • 12.07.2017

SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

In particular, in this topic, SMEs can participate in:

- aspects related to vaccination, public health, immunology, epidemiology, infectious diseases, physiology, medicine, nutrition, economics, advanced disease modelling, training and education capacities and experiences

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Patient Participation

There are many ways you can improve project performance by working with your patient partners:

- input into clinical study protocols
- input into operationalisation & monitoring of subject recruitment for clinical studies
- development of materials to encourage subject recruitment
- input into the wording of informed consents
- Input in design of frailty assessment at start of study
- input into various tools, interpretations of results and recommendation for optimal vaccination strategies in the elderly
- Champions in communication and dissemination

"The patient, doctor and researcher – each is a different kind of expert."

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Interaction with Regulators

To maximise impact of science generated by projects

Engage dialogue with Regulatory Authorities

- Consider having a plan for interaction with relevant milestones, resources allocated
- When relevant need for formal regulatory processes to ensure regulatory acceptance of projects results (e.g qualification procedure for biomarkers)
- Get familiar with various services offered for dialogue (e.g at EMA through qualification advice, Innovation Task Force, briefing meetings)
- If not participant, consider Regulators in the advisory board
- For more info see ‘’Raising Awareness of Regulatory Requirements: A guidance tool for researchers’’ available at http://www.imi.europa.eu/sites/default/files/uploads/documents/RegulatoryRequirementsGuide.pdf
- Consider also plan for dialogue with HTA bodies/payers as relevant

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Questions & answers