Webinar | IMI2 - Call 20
Innovations to accelerate vaccine development and manufacture

27.01.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Inmaculada Aguilera, IMI
- The Call topic – Yannick Vanloubbeeck, Philippe Denoel, Landry Cochard, GSK
- Questions & answers

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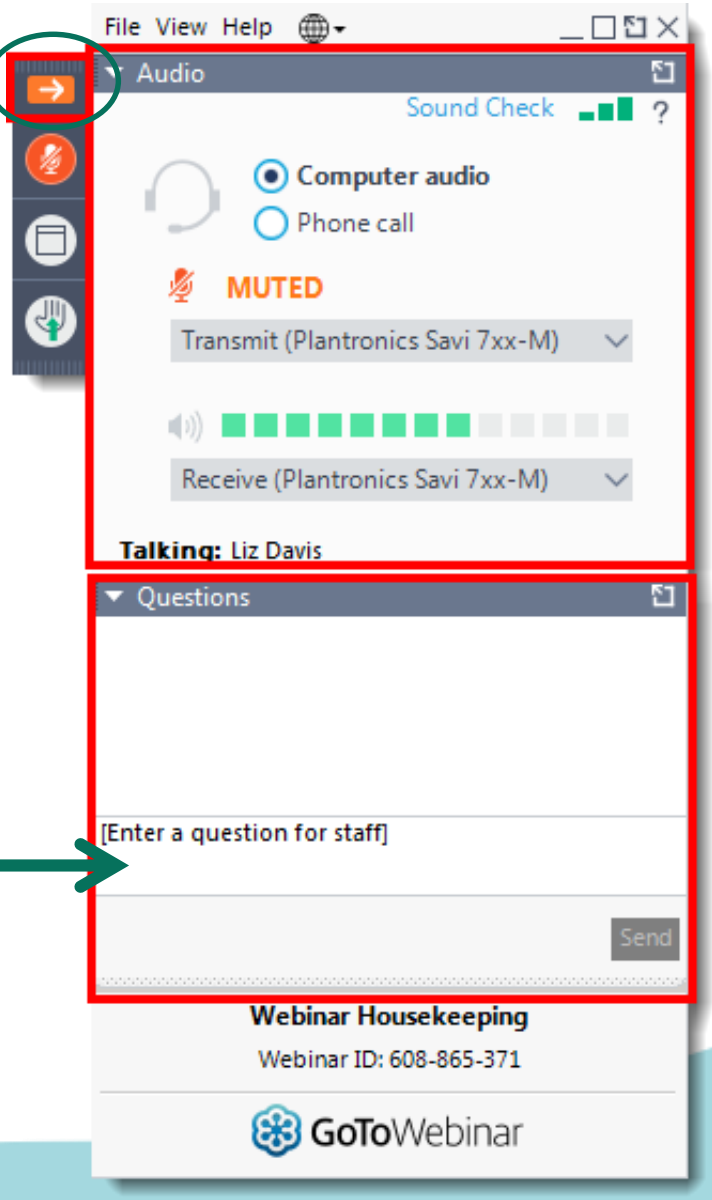

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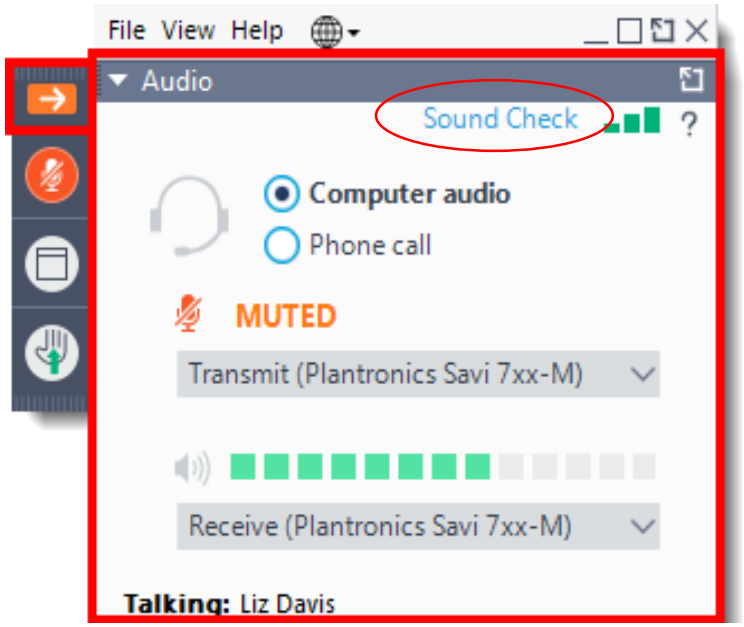

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Before we start…

- This webinar is being recorded and will be published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar web page
- A participant list will be published on the website
- IMI2 – Call 20 has been launched and all Call documents & details of how to apply can be found on the IMI website

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Webinar | IMI2 - Call 20

Innovations to accelerate vaccine development and manufacture

Inmaculada Aguilera, IMI

Today's webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme
- Proposed project
  - Objectives, need for public-private collaborative research
  - Key deliverables
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium

Will not cover rules and procedures

- A webinar on rules and procedures will take place on Thursday 29 January, 11:00 – 12:30

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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 partnership 2008-2020

IMI 1:

- 2008-2013
- €2 bn budget
- 59 projects

IMI 2:

- 2014-2020
- €3.3 bn budget
- More ambitious, more open, greater scope

€2.5 bn

EU contributions from FP7 / H2020

€ 2.5 bn

Pharma contributions in-kind

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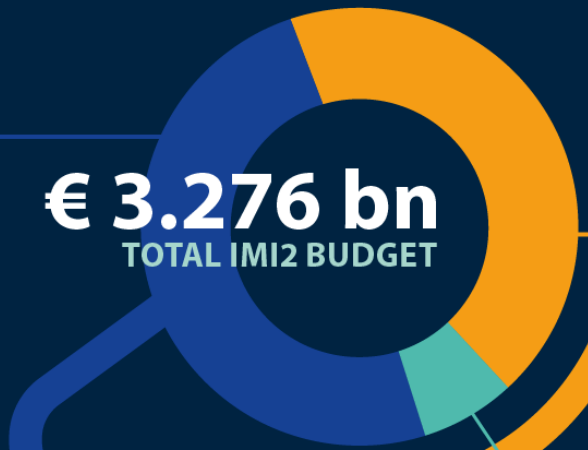
IMI2 funding
(2014-2020)

IMI FUNDING MODEL

efpia

IN-KIND PRIVATE CONTRIBUTION
€1.425 bn
EFPIA companies receive no funding

public contribution
€1.638 bn
funding from Horizon 2020



OTHER CONTRIBUTIONS
€213 MILLION
(Associated Partners, e.g. charities, non-EFPIA companies)

EU funding goes to

SMES
UNIVERSITIES
PATIENTS, REGULATORS...

EFPIA contribute researchers, laboratories, generation of data, curation of compounds, and cash

Public and private partners collaborate in IMI2 projects

Accelerating research and development

Speeding up patient access to innovative treatments

Improving patient outcomes and safety of medicines

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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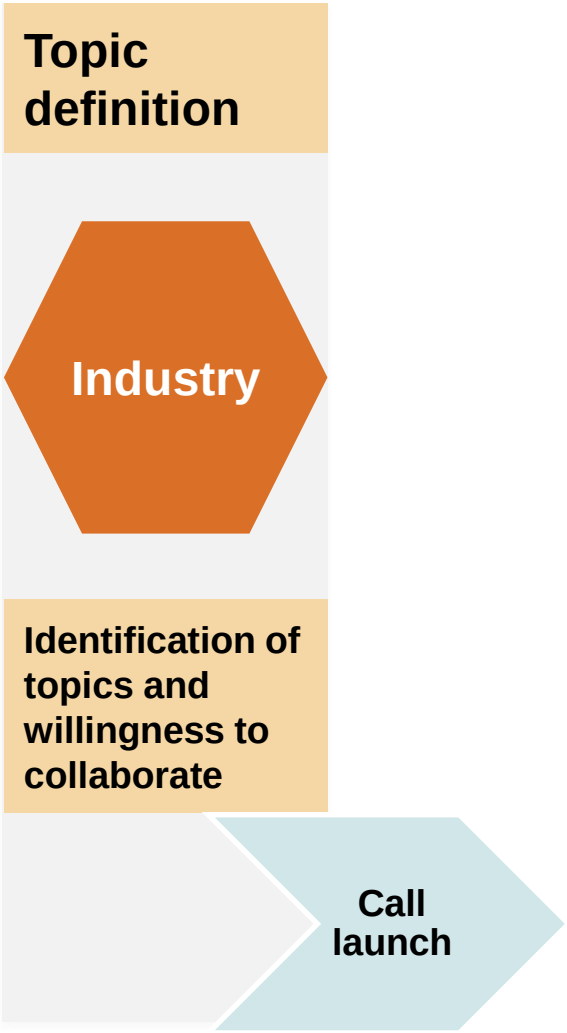
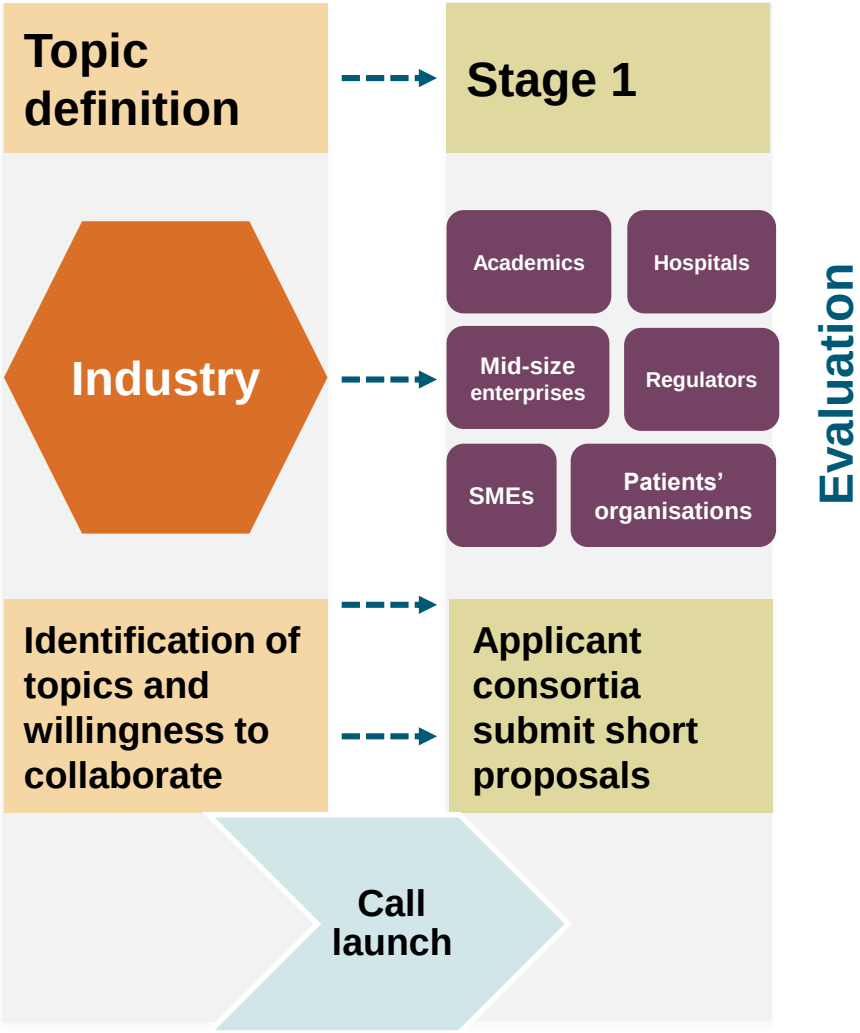
Typical IMI project life cycle



Typical IMI project life cycle



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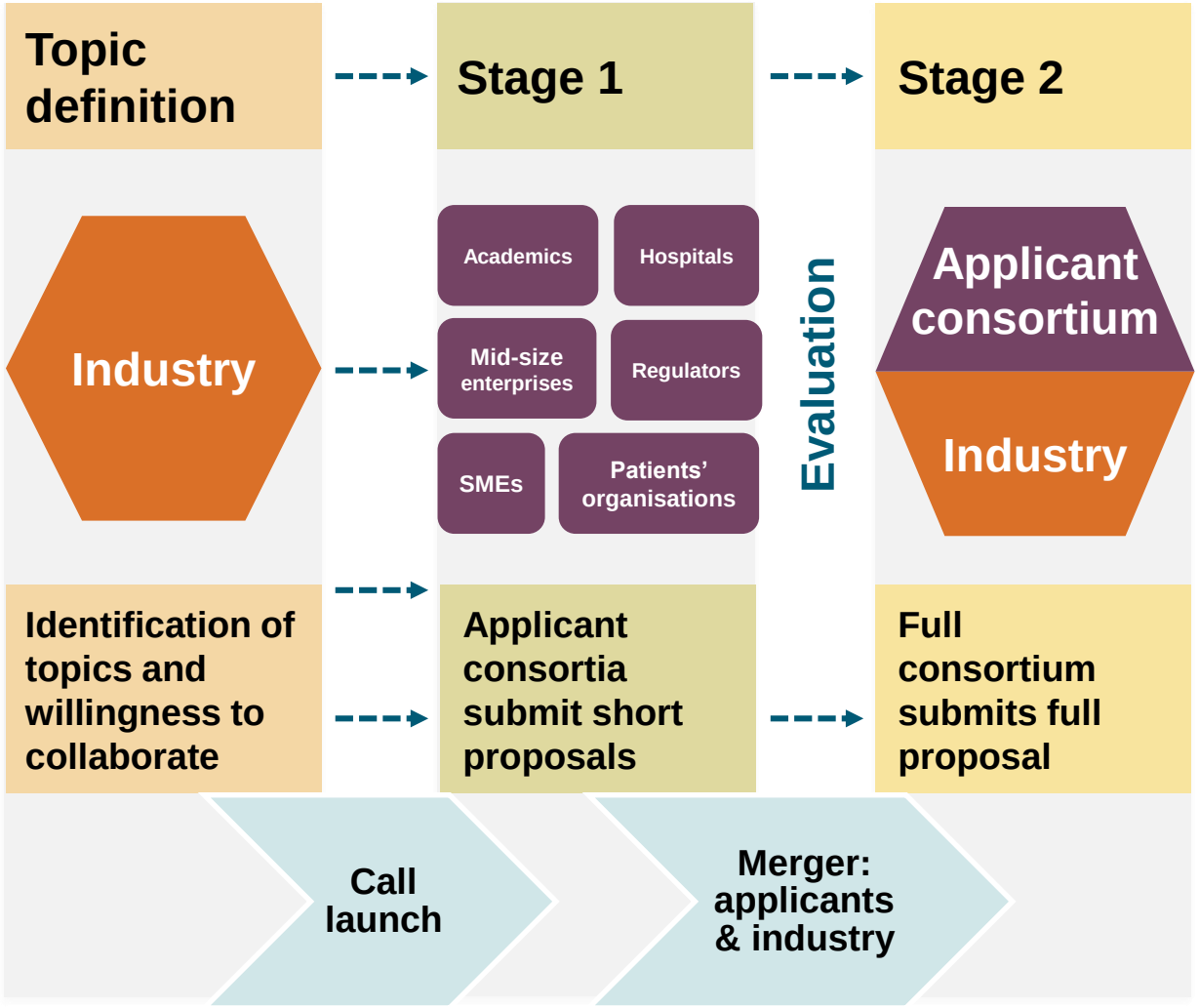
Typical IMI project life cycle



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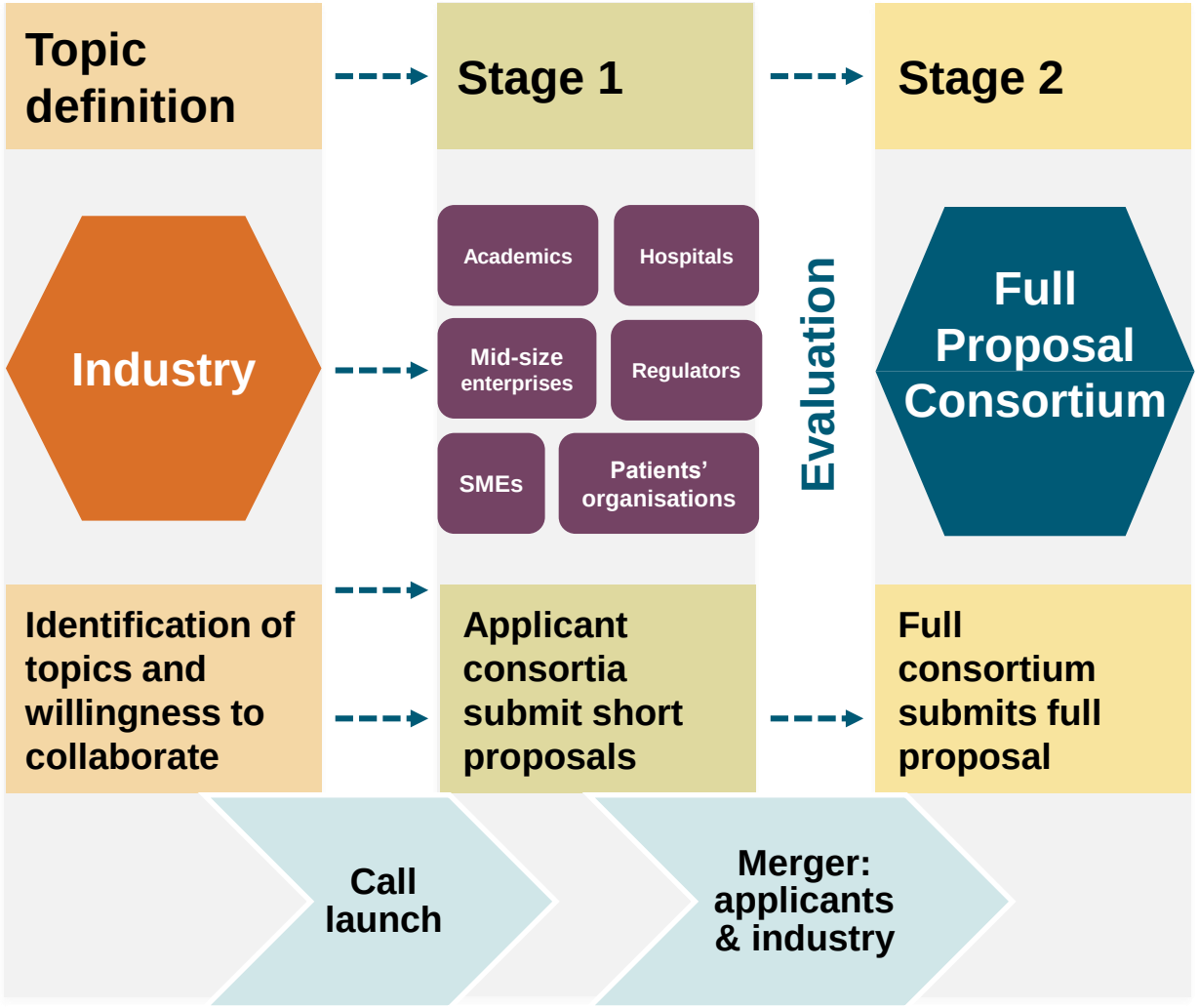
Typical IMI project life cycle



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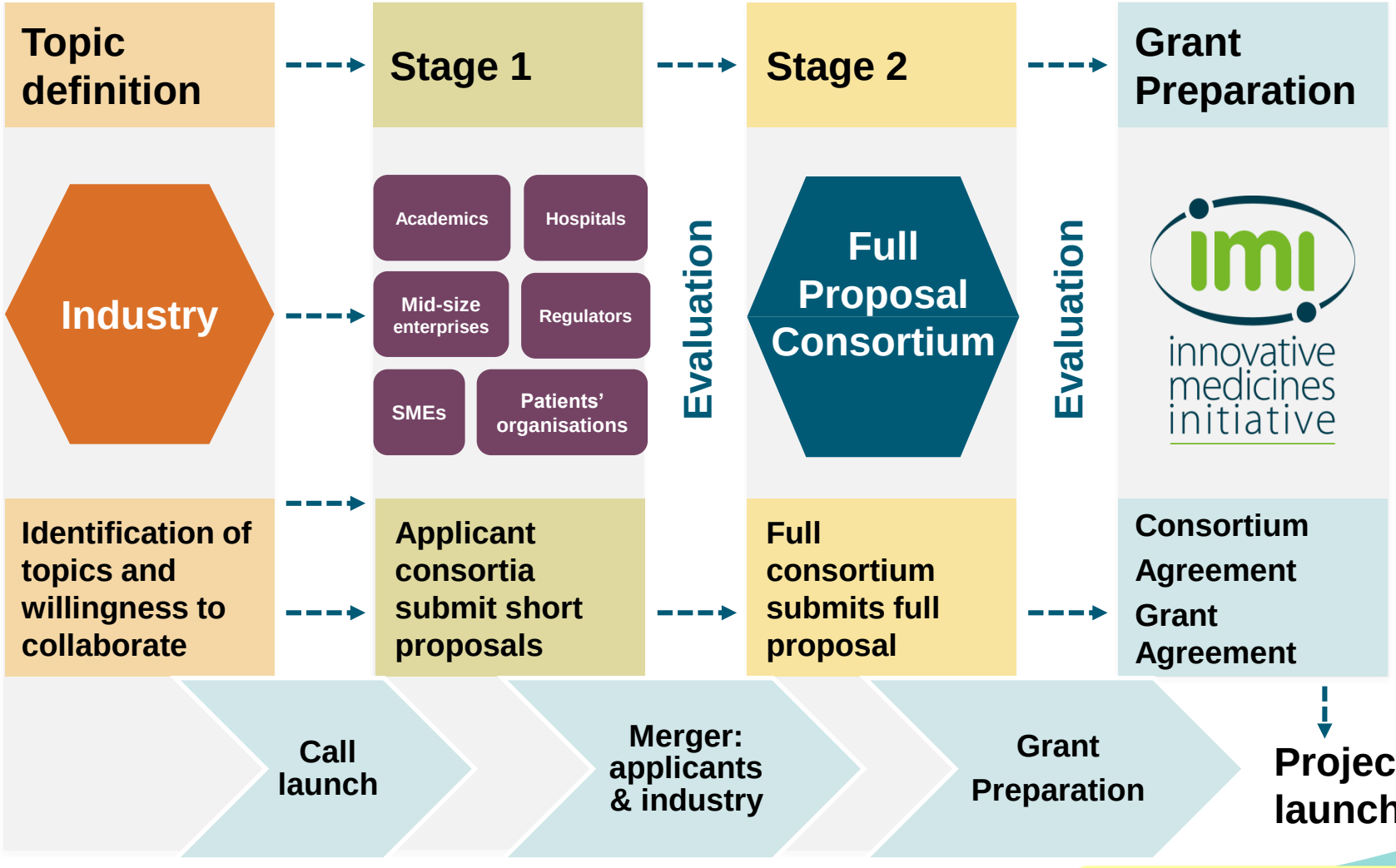
Typical IMI project life cycle



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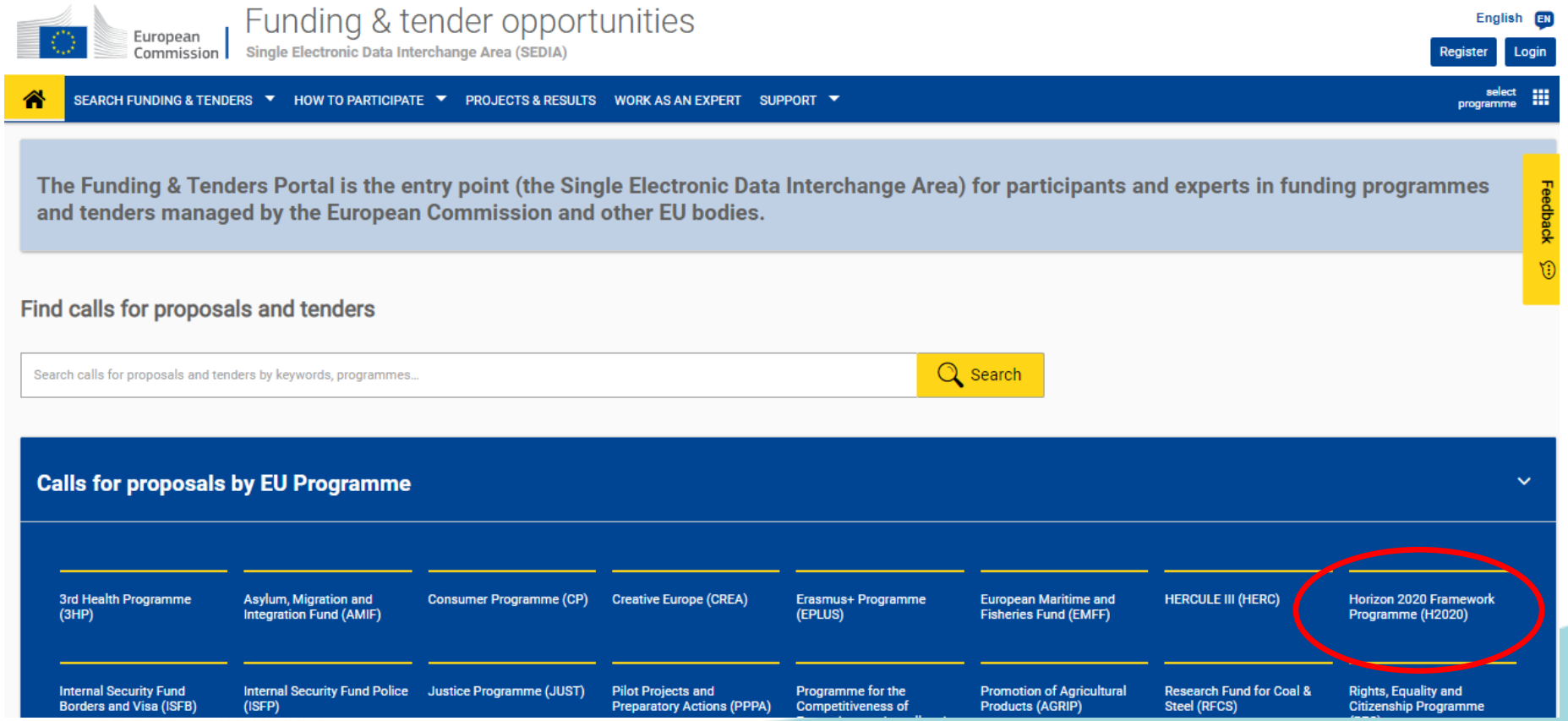
Expected GA signature – Spring 2021

Submitting a proposal

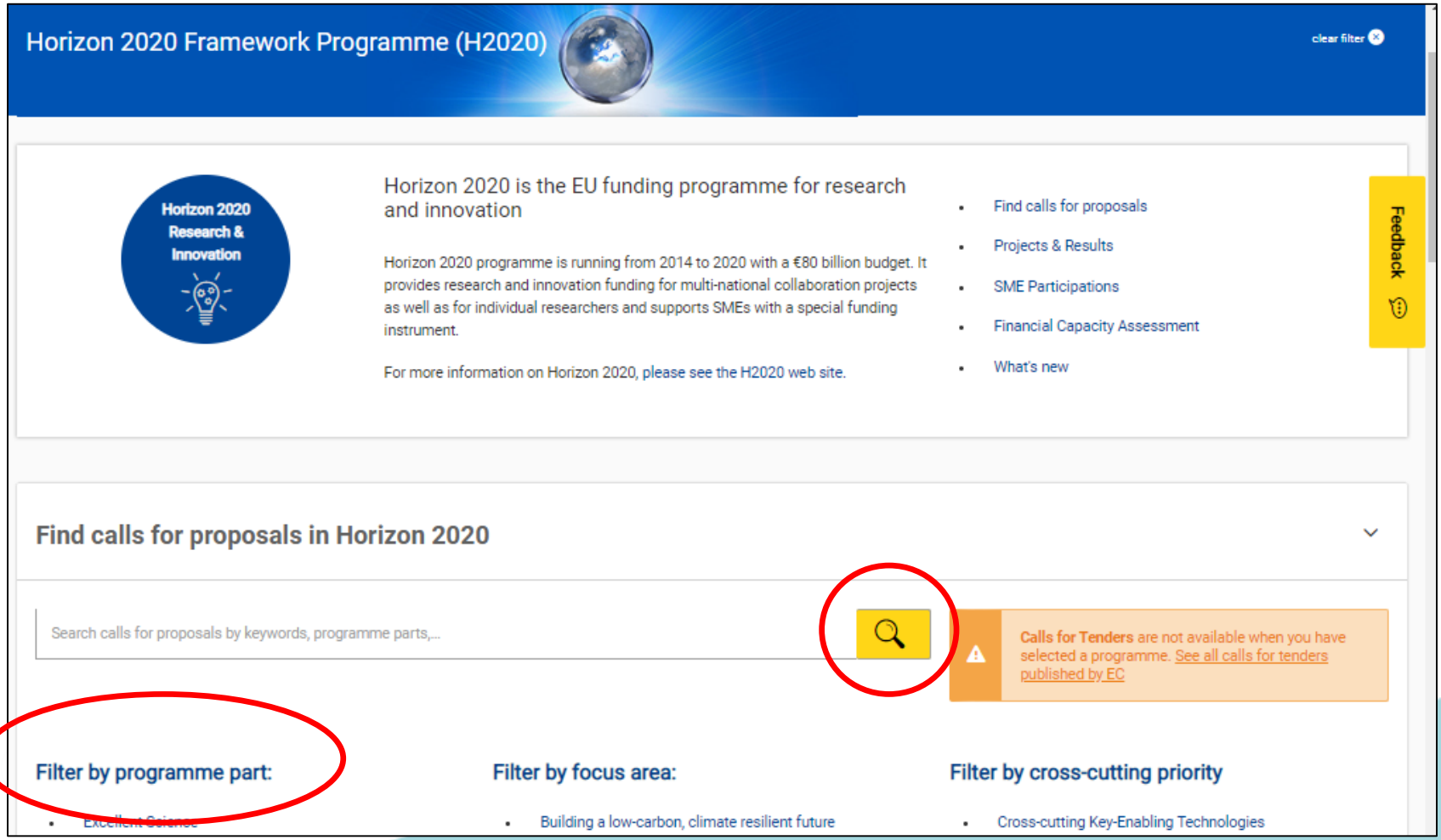
Via the **new** Funding and Tenders Portal

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home



New Funding and Tenders Portal Horizon 2020 section

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/programmes/h2020



Proposal Template – Newly updated

- 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

1. EXCELLENCE

- **1.1 Objectives**
- **1.2 Concept and methodology**
- **1.3 Ambition**

2. IMPACT

- **2.1 Expected impacts**
- **2.2 Outline Measures to maximise impact**

3. IMPLEMENTATION

- **3.1 Outline of project work plan — Work packages, and major deliverables**
- **3.2 Management structure and procedures**
- **3.3 Consortium as a whole**
- **3.4 List of work packages**

4. PARTICIPANTS

- **4.1. Participants (applicants)**

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Evaluation Criteria (1/2) – Newly updated

- **Excellence**
  - Level to which all the objectives of the Call topic text are addressed;
  - Soundness of the concept and credibility of the proposed methodology;
  - Extent that the proposed work is beyond the state of the art and demonstrates innovation potential;
  - Appropriate consideration of interdisciplinary approaches and use of stakeholder knowledge.
- **Impact**
  - Demonstration of how the outputs of the project will contribute to each of the expected impacts mentioned in the relevant Call topic text;
  - Outline of how the project plans to leverage the public-private partnership model to achieve greater impact on innovation within research and development, regulatory, clinical and healthcare practices, as relevant ;
  - Impacts on competitiveness and growth of companies including SMEs;
  - Quality of the proposed outline to:
    - Disseminate, exploit and sustain the project results;
    - Manage research data;
    - Communicate the project activities to relevant target audiences.

Evaluation Criteria (2/2) – Newly updated

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan outline, including extent to which the resources assigned to work packages are in line with their objectives and deliverables;
  - Appropriateness of the outline management structures and procedures;
  - Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role;
  - Complementarity of the participants and extent to which the consortium as whole brings together the necessary expertise;
  - Strategy to create a successful partnership with the industry consortium as mentioned in the Call topic text.

New thresholds:

- 3 for each of the evaluation criteria ‘excellence’, ‘impact’ and ‘quality and efficiency of the implementation’
- the overall threshold is 10

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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:**
  - EU Funding & Tenders portal: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/partner-search
  - German NCP partner search tool: www.imi-partnering.eu
- Get in touch with your **local IMI contact point**: www.imi.europa.eu/about-imi/governance/states-representatives-group
- Talk to your **Health National Contact Point** (NCP)
- Network on **social media** (e.g. IMI LinkedIn group)

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Participation of SMEs, patient groups, regulators

We encourage the participation of a wide range of health research and drug development stakeholders in our projects.

- SMEs and mid-sized companies
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc…)

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Interactions with regulators

- **Have a plan for interaction** with relevant **milestones** and **resources** allocated, as needed
- Consider the **formal regulatory process** to ensure **regulatory acceptance of project results** (e.g. qualification procedure for biomarkers)
- Get familiar with **services offered for dialogue** (e.g. at EMA through qualification advice, Innovation Task Force, briefing meetings)
- Consider involving regulators as project participants or in the **advisory board**
- Have a plan for dialogue with **HTA bodies / payers**, if relevant

To maximise impact of science generated by projects

Engage in dialogue with regulatory authorities

More info:

- Webinar & presentations 'How to engage with regulators EMA / FDA'
- 'Raising awareness of regulatory requirements: A guidance tool for researchers'

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Thank you

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Innovations to accelerate vaccine development and manufacture

Yannick Vanloubbeeck, Philippe Denoel, Landry Cochard

27.01.2020 • IMI webinar

Need for public-private collaboration

- Advances in immunology, disease modelling, in silico modelling, including the analysis of big data and the application of machine learning, artificial intelligence, provide opportunities to innovate, de-risk and accelerate the vaccine-development process. Many of these advances have occurred in the academic sector.
- These advances can be harnessed to tackle scientific bottlenecks in vaccine development and to nurture and expand a vaccines innovation ecosystem by bringing together academics, small and medium-sized enterprises (SMEs) and industry to collaborate in four areas:
    - Systems-immunology platform for model development;
    - Novel controlled human infection models (CHIMs);
    - Innovations in human in vitro mucosa models and assays; and
    - Biomanufacturing platforms using mathematical modelling.

Objectives of the project

- Accelerate and de-risk the development of new vaccines by incorporating scientific and technological advances from the academic and biotech sectors into industry.

- Develop more predictive biological and mathematical models of vaccine performance.

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Pre-competitive nature

- A consortium of academics, SMEs and industry will provide the opportunity to gather the best experts to address these challenges.
  - Academia is at the forefront of scientific and technological advances;
  - SMEs are adept at providing services and innovating those services;
  - Industry has broad overlapping expertise in vaccine development and manufacture.
- Although the topic covers distinct scientific domains, there are numerous synergies among them. Hence, to address the challenges and to maximise these synergies, collaborations within the sector and with other sectors are needed, and therefore investment in a public-private partnership can provide the impetus to bring academics and SMEs into an alliance with industry partners.

Expected impact

- A greater success rate in bringing vaccine candidates through clinical development.
- Increased efficiencies in the transitioning of biomanufacturing processes during vaccine development.
- A more vibrant ecosystem of vaccine innovation in Europe.

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Suggested architecture of the project

WP1 Coordination and project management
WP1.1 Overall project management
WP1.2 Coordination and interactions among Subtopics
WP1.3 Reporting
WP1.4 Calls for proposals

WP2 Subtopic 1: Systems-immunology platform

WP2.1 Definition of platform and data requirements
WP2.2 Backend development
WP2.3 Frontend development
WP2.4 Scientific validation
WP2.5 Case studies

WP3 Subtopic 2: CHIMs

For each pathogen (influenza, RSV and *C. difficile*):
WP3.1 Road map for CHIM development and standardisation, including the consideration of ethical and environmental issues.
WP3.2 Identification, manufacture and clinical evaluation of challenge strains
WP3.3 Positioning the newly developed CHIMs in the regulatory framework – potential & limitations.

WP4 Subtopic 3: Human in vitro mucosa models and assays

WP4.1 Road map for model and assay development and standardisation
WP4.2 Development of model and assay prototypes
WP4.3 Case studies and validation of models and assays
WP4.4 Standardisation and guidelines on the use of models and assays

WP5 Subtopic 4: Mathematical modelling for Biomanufacturing

WP5.1 Stability prediction models
WP5.2 Bioprocess scale-up/scale-down models
WP5.3 Empirical POC - prospective studies with real-life products to validate both models
WP5.4 Regulatory dialogue for road maps of implementation of new tools in CMC dossiers

WP6 Communication and dissemination
WP6.1 Communication and dissemination
WP6.2 Databases and data management (set-up and sustainability)
WP6.3 Exploitation of results

Key deliverables of the project

- **All subtopics (under the direction of the coordinator)**
  - Data-management and data-sharing procedures, tools and infrastructures to support collaborations between subtopics;
  - Sustainability plan for datasets and data management;
  - Joint subtopic workshops to identify/develop/ratify collaborations between subtopics;
  - Scientific publications.

Expected contributions of the applicants

Public and private partners: see specific contributions expected in each subtopic.

Suitable SMEs could be considered in the four subtopics for the following activities:

- Back-end and front-end IT infrastructure construction for in silico platforms.
- Manufacture (and associated optimisation) of challenge pathogens for CHIMs.
- Design/production of monitoring devices for biomanufacturing.
- Project management activities.

Expected (in kind) contributions of industry consortium

- **All subtopics**:
  - Expertise in vaccine development, manufacturing processes and global regulatory affairs;
  - Industry leadership in IMI projects;
  - Establishing links with other major existing initiatives, and where possible, obtaining access to relevant databases or datasets.

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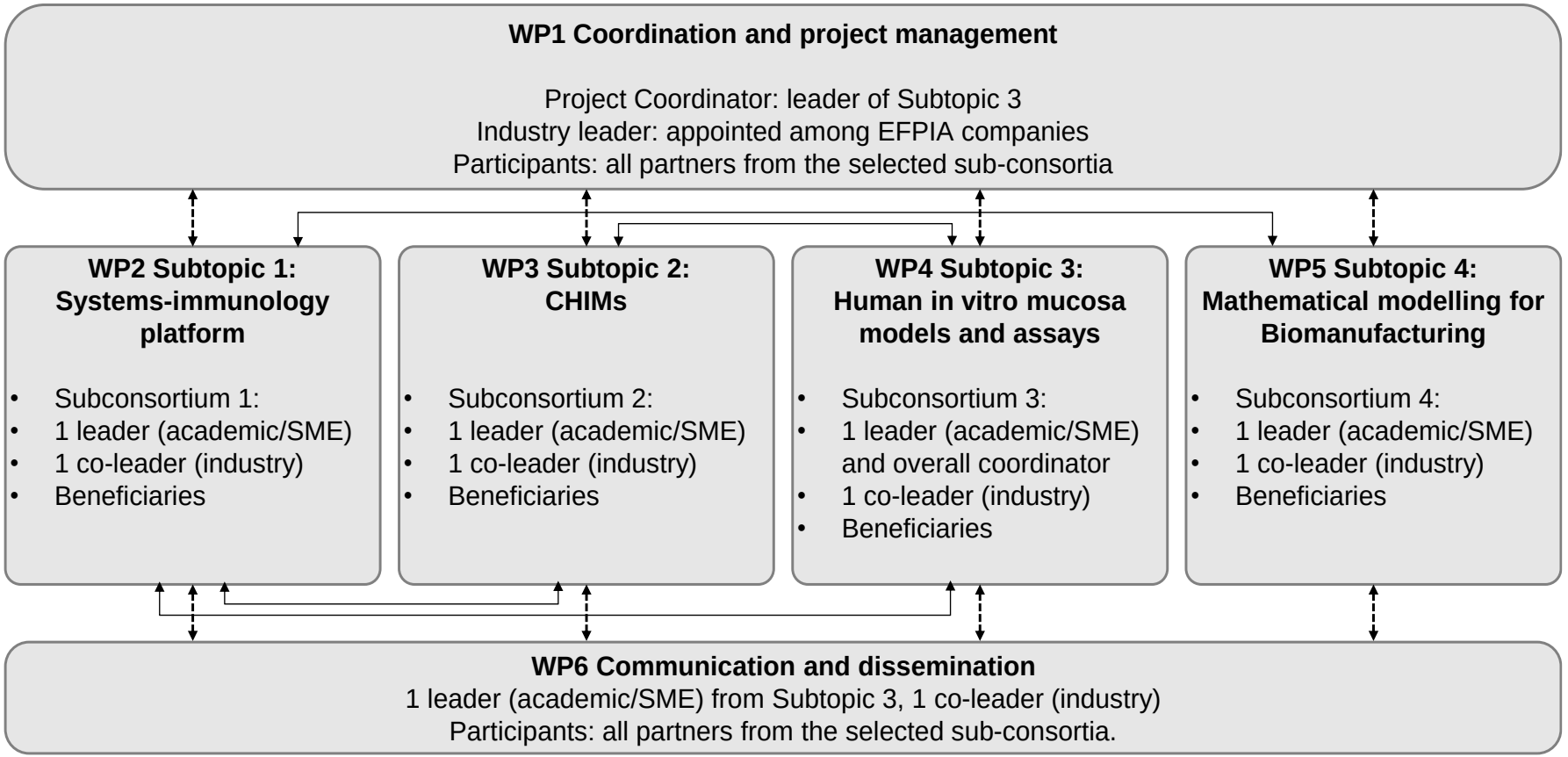
4 subtopics, 1 project

- Stage 1, applicant consortia should submit short proposals to one of the four subtopics (1–4).
  - Systems-immunology platform for model development.
  - Novel controlled human infection models (CHIMs).
  - Innovations in human in vitro mucosa models and assays.
  - Biomanufacturing platforms using mathematical modelling.

- Stage 2: a single full proposal should be submitted, involving applicant subconsortia of all four subtopics and the industry consortium.

4 subtopics, 1 project



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ST1 - Systems-immunology platform for model development

- **Objectives**: *d*evelop an open-data/open-source in silico platform focussed on immunobiological processes, for the prediction of:
  - (1) immune responses to vaccines and pathogens,
  - (2) antigen and pathogen features most likely to induce protective immunity, and the anticipated immune responses to those features and
  - (3) emerging medical needs (via AI systems).

- **Expected impact:** better understanding of the immune response to disease, host-pathogen interactions, vaccine mechanisms of action and the associated contribution of genetic / epigenetic / environmental factors on immunobiology.

ST1 - Systems-immunology platform for model development

- **Expected contributions from applicants**:
  - Expertise in computational and mathematical modelling, and immunology;
  - Front-end and back-end in silico platform development;
  - Knowledge-management systems for data integration;
  - Evaluation/curation of open-source data and knowledge that can be utilised for mathematical modelling;
  - Project management skills (subtopic coordination);
  - Communication and dissemination skills;
  - Business sustainability plans.

ST1 - Systems-immunology platform for model development

- **Expected (in kind) contributions of industry consortium**:
  - Expertise:
    - Mathematical modelling, knowledge-management system for data integration;
    - Immunology.
  - Assets:
    - Data from non-clinical and clinical studies. This may include suitable datasets, adapted experiments or analytical experiments (e.g. in vitro data from ongoing or past research projects) to support the project. The specific nature of contribution may be refined at stage 2 to be more appropriately aligned with the project proposed by the applicant consortium.

ST1 - Systems-immunology platform for model development

- **Key deliverable**:

Sustainable open-access and cloud-based in silico platform incorporating knowledge management tools with links to databases of existing knowledge, omics data and validated computational knowledge-driven models and data-driven models, including data from related disease fields.

ST2 - Novel controlled human infection models (CHIMs)

- **Objectives**: develop improved or novel CHIMs for influenza, RSV and *C. difficile*, in order to facilitate the generation of early efficacy data for vaccine candidates.

- **Expected impact:** CHIMs being incorporated into vaccine-development programmes on a wider scale, and validation of their associated guidelines for use to support this incorporation.

ST2 - Novel controlled human infection models (CHIMs)

- **Expected contributions from applicants**:
  - Expertise in microbiology, virology, microbial genetics;
  - Clinical expertise in ethics, immunology, big data analyses and establishment of large databases, regulatory science;
  - Project management skills (subtopic coordination);
  - Communication and dissemination skills.
  - It may also require mobilising the following resources: clinical infrastructures for inpatients, data on previous CHIM activities with specific pathogens, and existing ethical and regulatory frameworks (ethical aspects and guidance will have to be considered).

ST2 - Novel controlled human infection models (CHIMs)

- **Expected (in kind) contributions of industry consortium**:
  - Expertise:
    - Clinical and translational research, virology, immunology, biostatistics, bioinformatics, quantitative mathematics;
    - Good-manufacturing-practice (GMP) production of material and/or viral and bacterial strains for CHIM development;
    - Phenotypic and genetic characterisation of microbial strains.
  - Contributions to clinical studies:
    - Cost of characterisation and GMP manufacturing of relevant challenge strains;
    - Production of GMP RSV stocks;
    - Data on experimental human infection with RSV to be conducted within 24 months of the start of the project.

ST2 - Novel controlled human infection models (CHIMs)

- **Key deliverables**: new CHIMs that can accelerate the development of vaccines against, influenza, RSV and *C. difficile:*
  - Definition of clinical and laboratory (molecular, immunological and microbiological) endpoints for efficacy and/or safety, for use in larger field trials.
  - Improved or new comprehensive pre-screening methodologies that capture relevant pre-disposing factors, e.g. deep immunophenotyping and multi-layer omics.
  - Clear definitions of rescue therapy including appropriate infection control and contingency plans
  - Identification of key parameters for CHIM standardisation, generalised adoption, and ultimately, regulatory acceptance.
  - Data-management and data-sharing procedures, tools and infrastructures to support collaborations between subtopics.

ST3 - Innovations in human in vitro mucosa models and assays

- **Objectives**:
  - develop prototype next-generation in vitro systems for antigen identification/validation and drug substance and drug product characterisation/validation.
  - develop associated functional immune assays (e.g. miniaturised, medium to high throughput) for clinically-relevant (surrogate) endpoints.

- **Expected impact:**
  - Next-generation in vitro models and assays being incorporated into vaccine-development programmes on a wider scale;
  - Potential for the next-generation in vitro models and assays to replace the use of animal testing in research, licensure and release of vaccines (with regulatory agency approval) in the future.

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ST3 - Innovations in human in vitro mucosa models and assays

- **Expected contributions from applicants**:
  - Expertise in next-generation in vitro systems (organ on chip, 3D tissue models, organoids etc.);
  - Advanced biostatistics and data analysis;
  - Novel immunological assays;
  - Novel reagents for interrogating immune responses to complex epitopes on pathogens;
  - Expertise in association of peripheral immune responses to mucosal pathogens to potentially protective mucosal immune responses;
  - Expertise in prospective clinical cohort studies and in the identification of immune correlates of protection;
  - (…)

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ST3 - Innovations in human in vitro mucosa models and assays

- **Expected contributions from applicants**:
  - (…)
  - Strong expertise and track record in EU coordination and project management of large consortia, including reporting, legal and financial aspects, is required;
  - Communication and dissemination skills: development and implementation of communication, dissemination and use plan.
  - In light of the scope of the project and its four aspects, the applicant consortium for Subtopic 3 should have a global vision and a profound understanding of the challenges and activities to ensure good oversight.

ST3 - Innovations in human in vitro mucosa models and assays

- **Expected (in kind) contributions of industry consortium**:
  - Expertise:
    - Translational preclinical models and in vitro infection models, including organoids;
    - Biomarkers of vaccine safety, reactogenicity, immunogenicity and efficacy, and infectious disease outcomes;
    - Assay miniaturization;
    - Phenotypic and genetic characterization of microbial strains.
  - Assets:
    - Samples / data from non-clinical and clinical studies conducted with the pathogens of choice to help define how findings in the models developed by the consortium relate to natural / controlled infection in humans and how they concord with data from preclinical in vivo studies used historically to predict the behaviour of vaccines in humans.
  - (…)

ST3 - Innovations in human in vitro mucosa models and assays

- (…)
- Contributions to studies for the development of next generation in vitro systems:
  - Pending the final choice of pathogens for the in vitro models and assay development, GSK may contribute by providing relevant materials (antigens, antibodies, preclinical or clinical samples);
  - In-cash contribution for the development and evaluation of in vitro gastro-intestinal models of infection and/or immunity.
- Contributions to services:
  - Contribution for investigating the use of next-generation in vitro systems in evaluating vaccine safety.

ST3 - Innovations in human in vitro mucosa models and assays

- **Key deliverables:** Prototype next-generation in vitro models and assays for clinically-relevant (surrogate) endpoints with guidelines for good laboratory practice (GLP) implementation including robust biostatistical plans.

ST4 - Biomanufacturing platforms using mathematical modelling

- **Objectives**: develop an open data/open source in silico biomanufacturing platform incorporating models for predicting Vaccine-product stability (drug substance/product) and parameters to maintain process robustness for unit-operation scale up or scale down, and for process transfer.

- **Expected impact:**
  - Better understanding of how scale-up and scale-down transitions affect vaccine manufacturing, and can be modulated to ensure vaccine quality and stability/shelf-life;
  - More efficient vaccine-manufacturing processes that could also allow affordable vaccine development for small or restricted target populations, personalised vaccines, or sustainable vaccine development for diseases in low-to-middle income countries.

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ST4 - Biomanufacturing platforms using mathematical modelling

- **Expected contributions from applicants**:
  - Bio pharmaceutical process knowledge;
  - Process Modelling expertise;
  - Front-end and back-end platform development;
  - Knowledge-management system for data integration;
  - Evaluation/curation of open-source data and knowledge that can be utilized for the modelling;
  - Project management skills (subtopic coordination);
  - Communication and dissemination skills;
  - Business sustainability plans.

ST4 - Biomanufacturing platforms using mathematical modelling

- **Expected (in kind) contributions of industry consortium**:
  - Expertise:
    - Process modelling support and revision;
    - Knowledge-management system for data integration.
  - Assets:
    - Help build the in-silico models, provide retrospective data on stability of drug substance and/or process intermediaries and on bioprocess scale-up/scale-down, collected for different classes of vaccines (e.g. native and recombinant proteins, viruses, conjugated protein-polysaccharide, and others);
    - Conduct prospective empirical studies to support qualification/validation of the resulting in-silico models (i.e. proof-of-concept studies) for both stability and process development.

ST4 - Biomanufacturing platforms using mathematical modelling

- **Key deliverables**: sustainable cloud-based in silico platform for:
  - vaccine substance and product stability for different types of vaccines (e.g. subunit, virus, conjugates, etc.);
  - biomanufacturing process robustness (applicable to unit operation scale up or scale down, and process transfer).

Thank you

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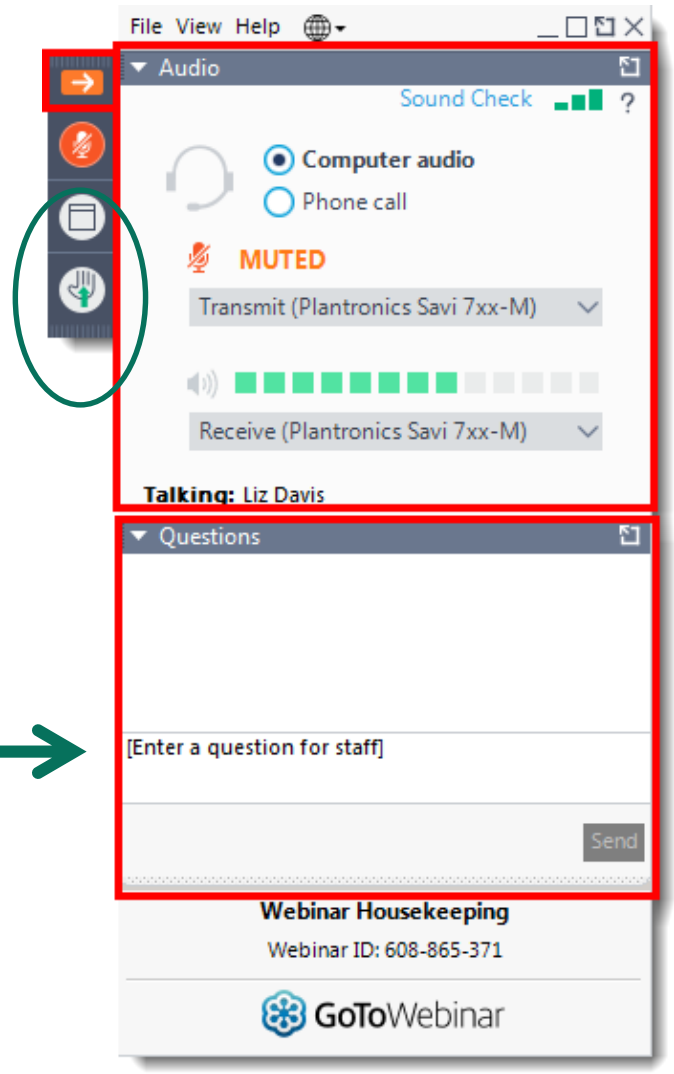
Questions & answers

Questions?

Raise your hand if you want to ask a question orally



Send a question in writing

After the webinar, send any questions to the **IMI Programme Office**

applicants@imi.europa.eu

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