Webinar | IMI2 - Call 20
Handling of protein drug products and stability concerns

31.01.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Kalliopi Christoforidi, IMI
- The Call topic – Reza Nejadnik, Marc Dietrich, Sanofi
- Involvement of SMEs, patient groups, regulators – Kalliopi Christoforidi, IMI
- Questions & answers

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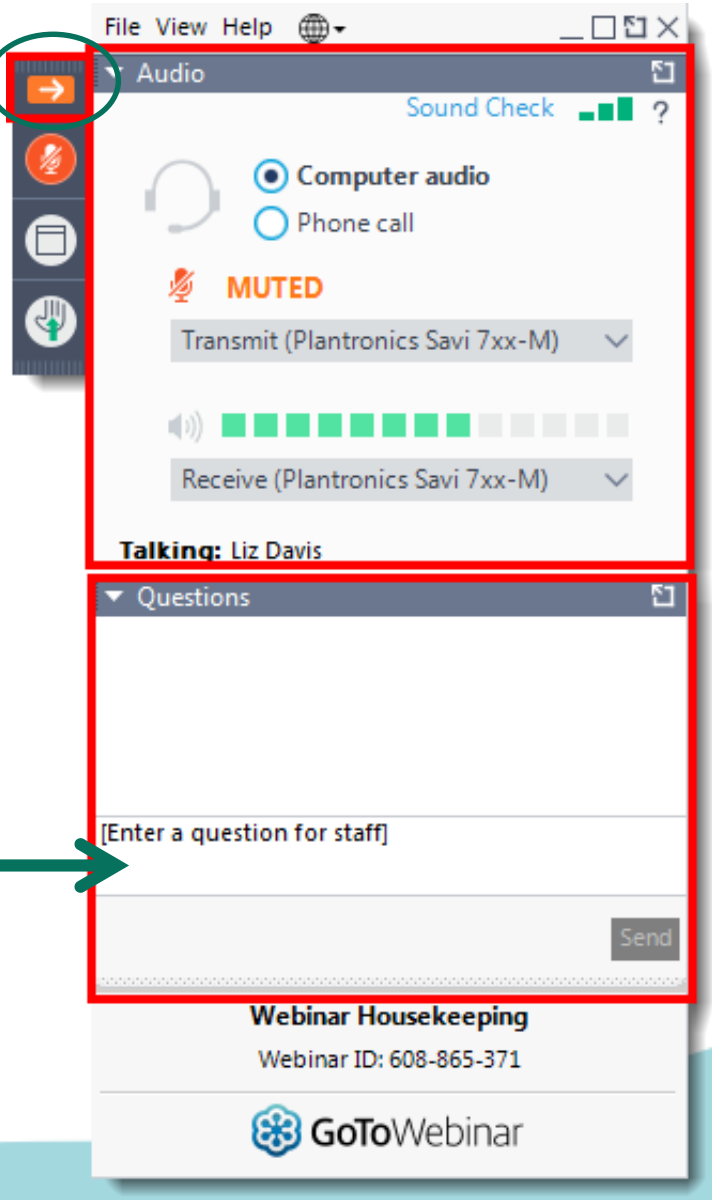

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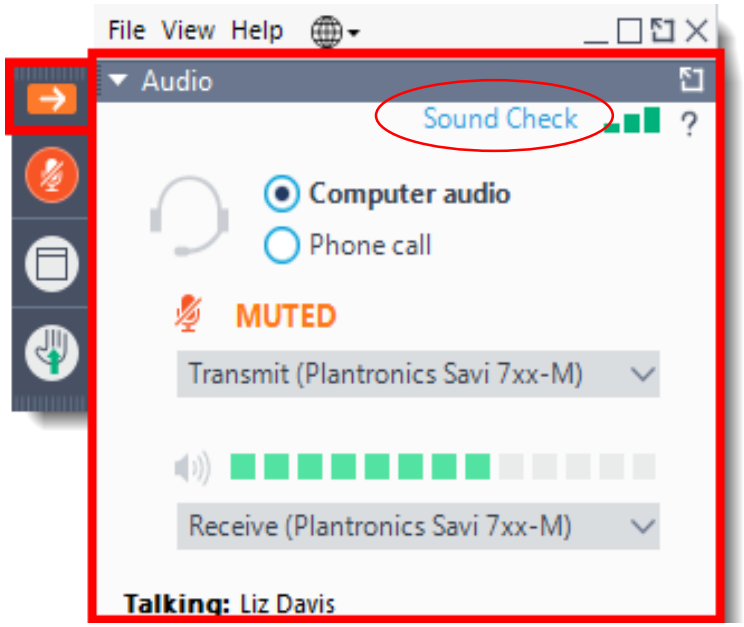

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Before we start…

- 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

Handling of protein drug products and stability concerns

Kalliopi Christoforidi

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 to be completed
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium

Will not cover rules and procedures

- A recording of the webinar on Rules and Procedures is available at: https://www.imi.europa.eu/news-events/events/imi2-call-20-webinars

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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

€ 3.276 bn
TOTAL IMI2 BUDGET

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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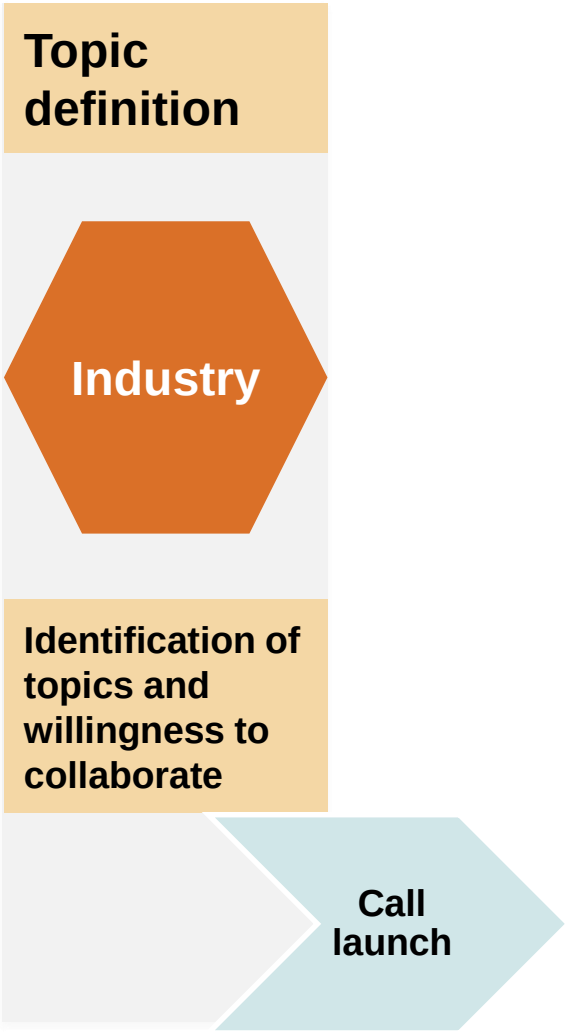
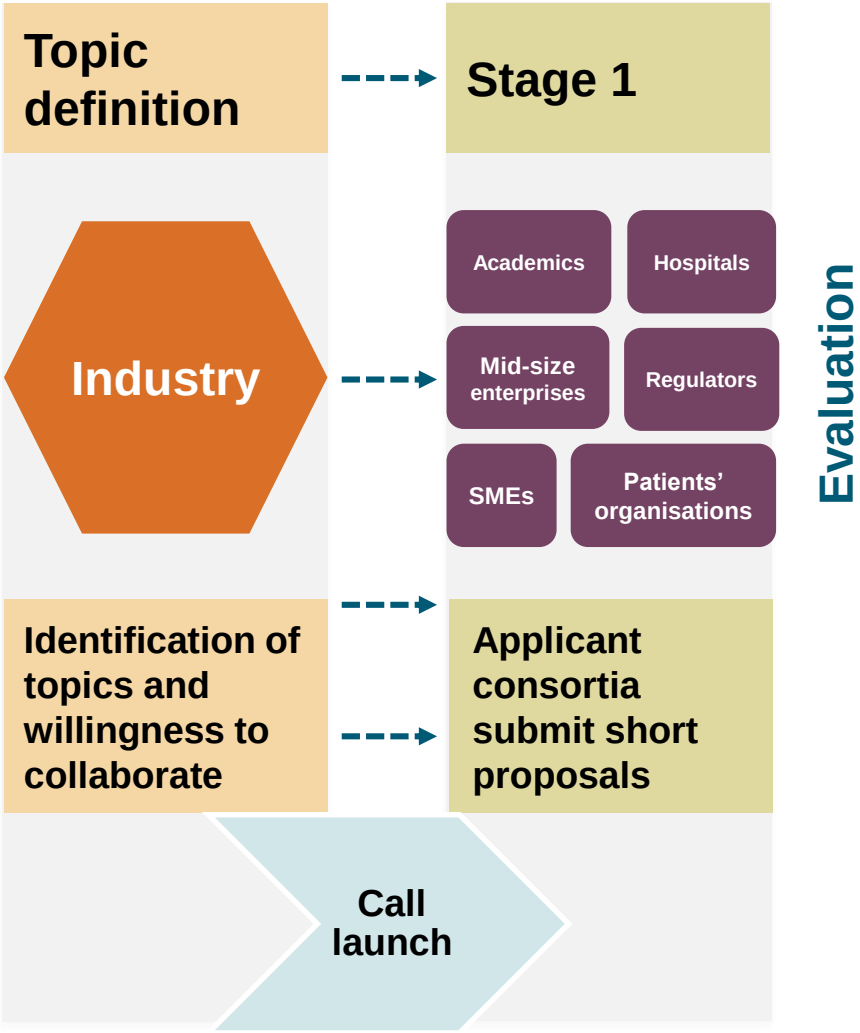
Typical IMI project life cycle



Typical IMI project life cycle



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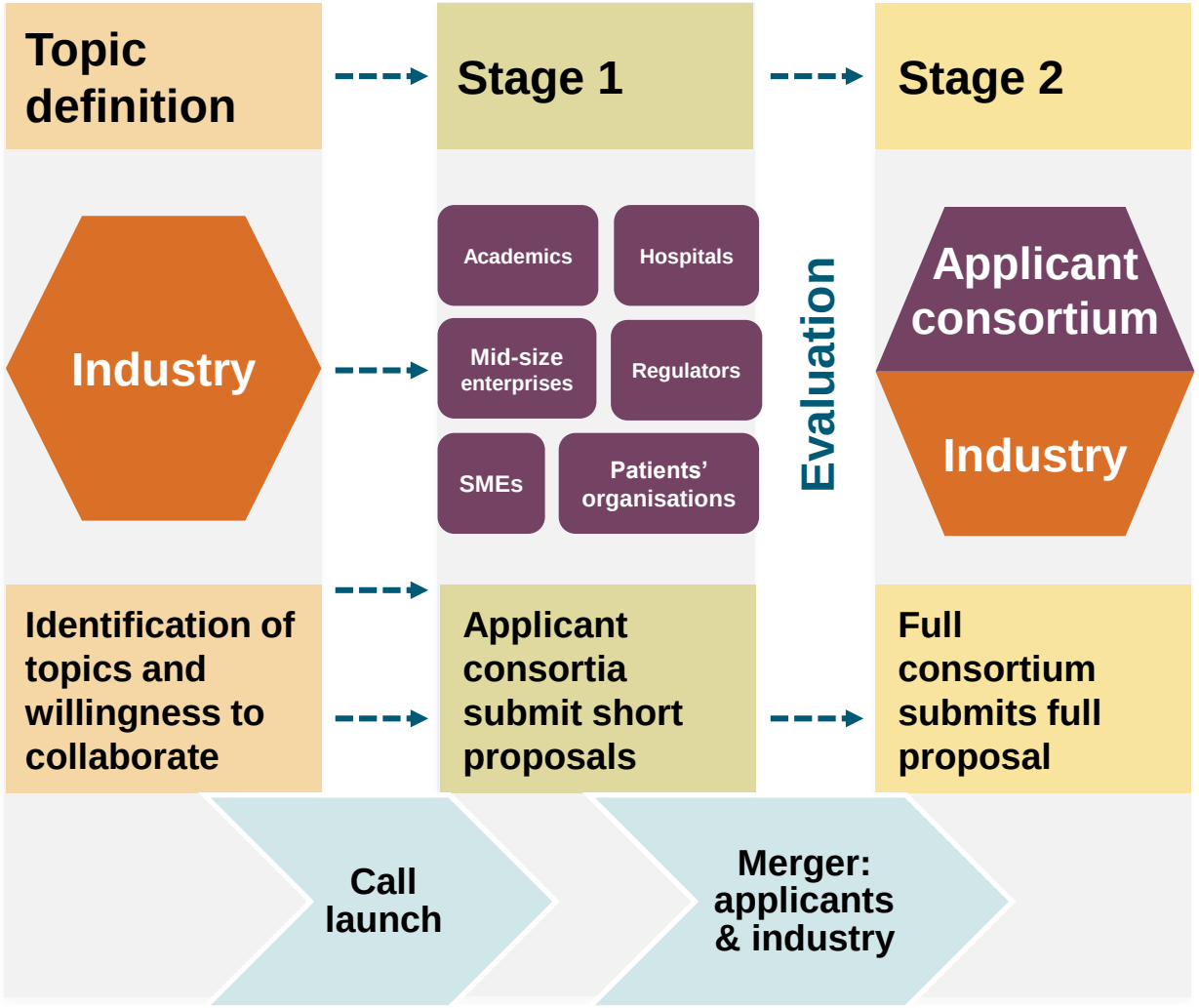
Typical IMI project life cycle



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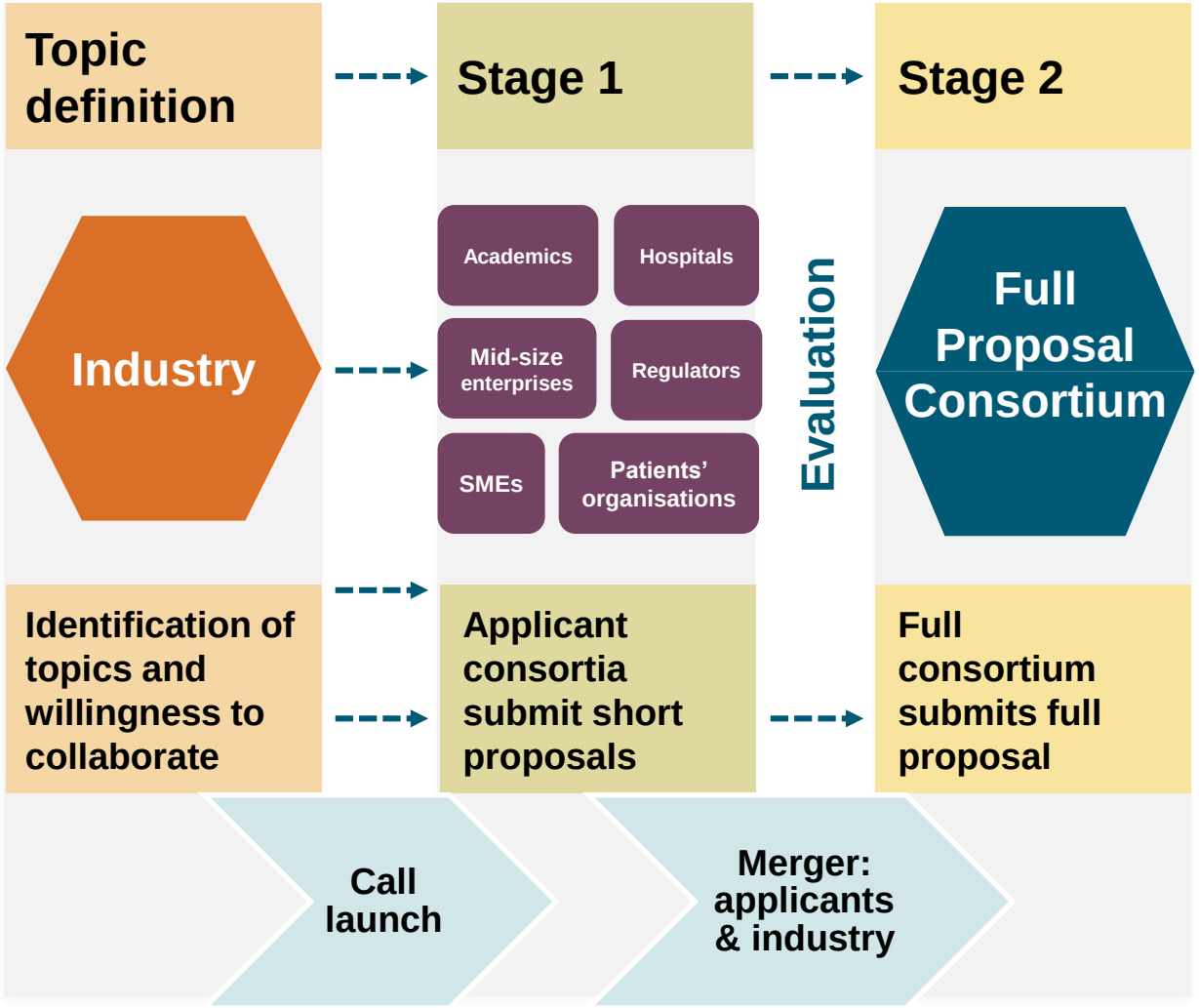
Typical IMI project life cycle



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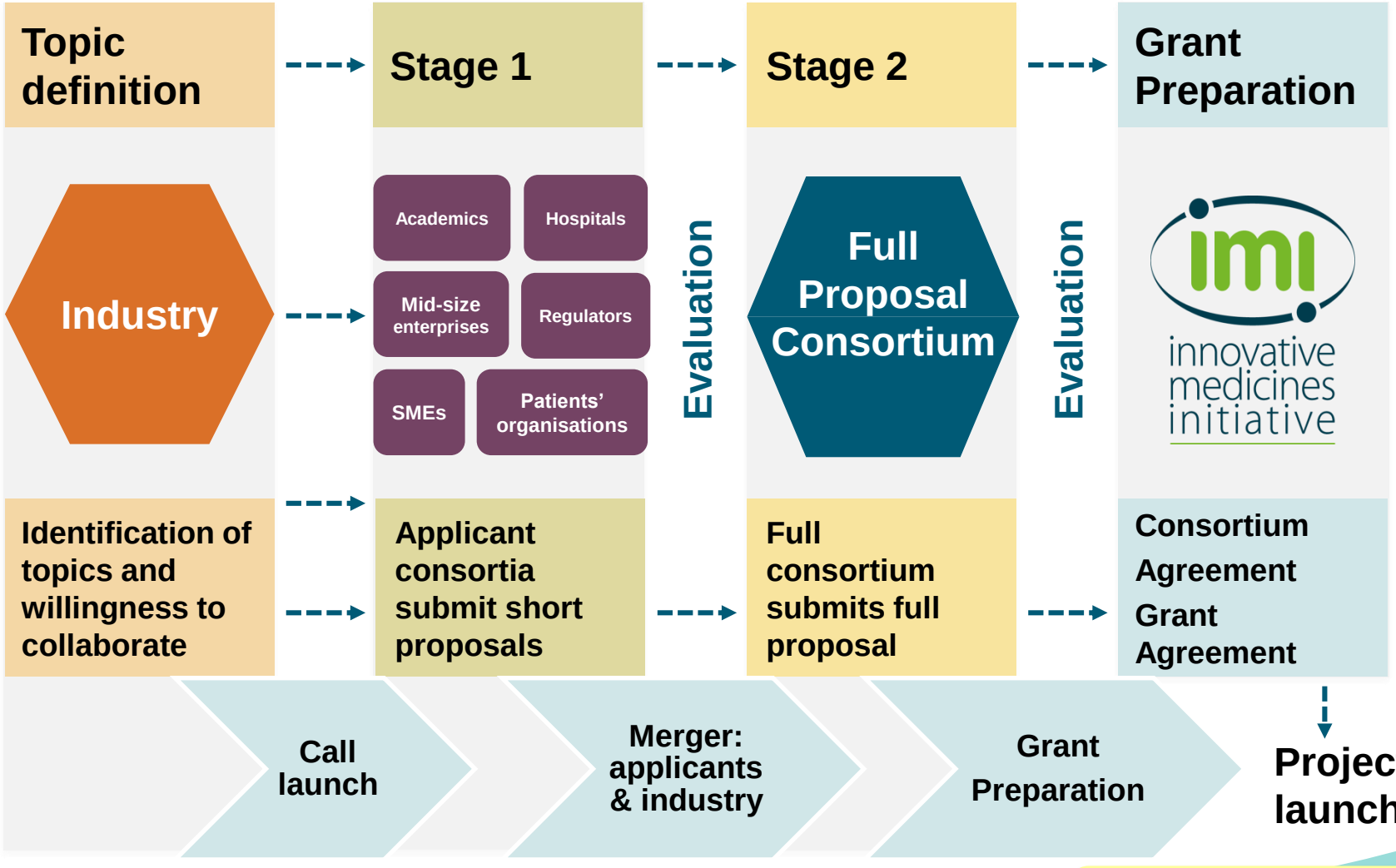
Typical IMI project life cycle



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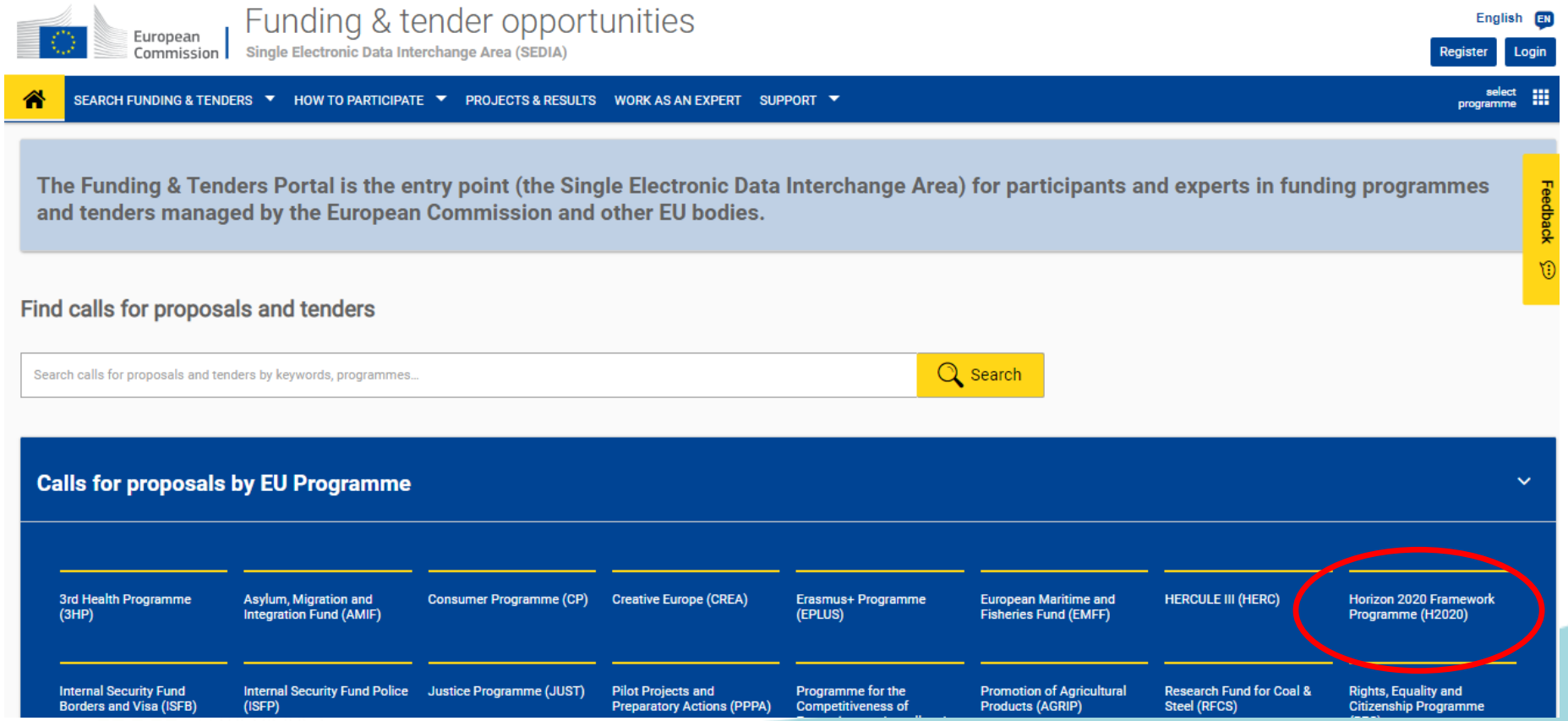
Expected GA signature – Spring 2021

Submitting a proposal

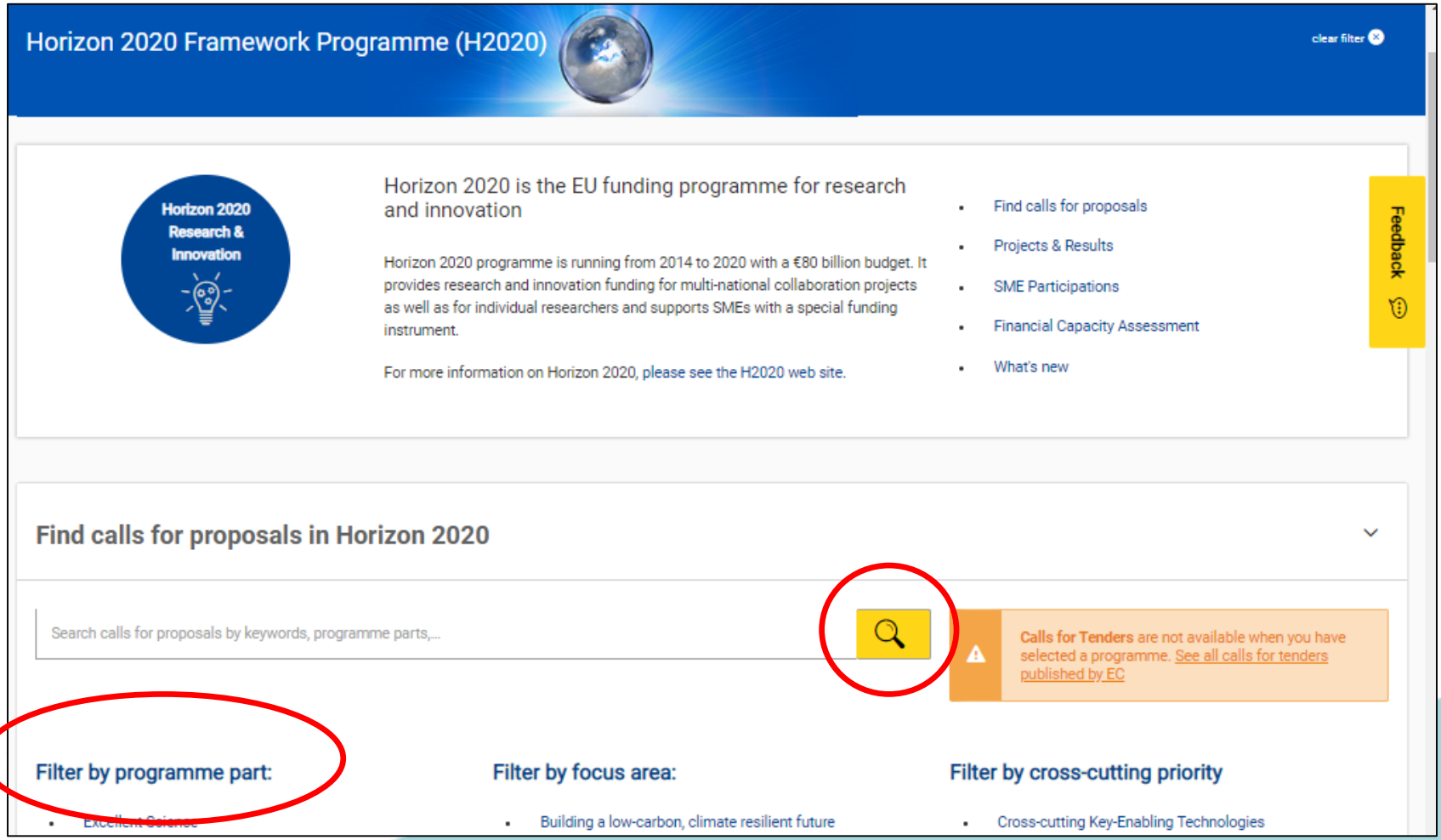
Via the **new** Funding and Tenders Portal

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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Handling of protein drug products and stability concerns

Dr. Reza Nejadnik, Dr. Marc D. Voss
Sanofi
31.01.2020 • IMI webinar

Need for public-private collaboration

- Protein pharmaceuticals became the fastest growing class of therapeutics
- Protein pharmaceuticals are sensitive towards physical aggregation and chemical degradation
- Protein drug product handling in hospitals, pharmacies and by patients impacts safety and efficacy
- The challenge is a multi-faceted one and tackling it requires participation of public and private sides

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Objectives of the full project

- Improve the understanding of real-world stressful drug product handling steps and their effects
- Develop guidelines and operating processes to improve drug product robustness and pharma processes
- Develop more efficient training

Pre-competitive nature

- Collaboration of industry, public partners and SMEs to allocate the skills and capabilities to analyse the impact of DP handling and identifying solutions for improvment

- Pharma assets will be brought in, the scope will be defined in collaboration with the public partners

- Deep knowledge on drug product handling will enable industry to improve manufacturing and developement, hospitals to improve training and processes and patients to better informed applications.

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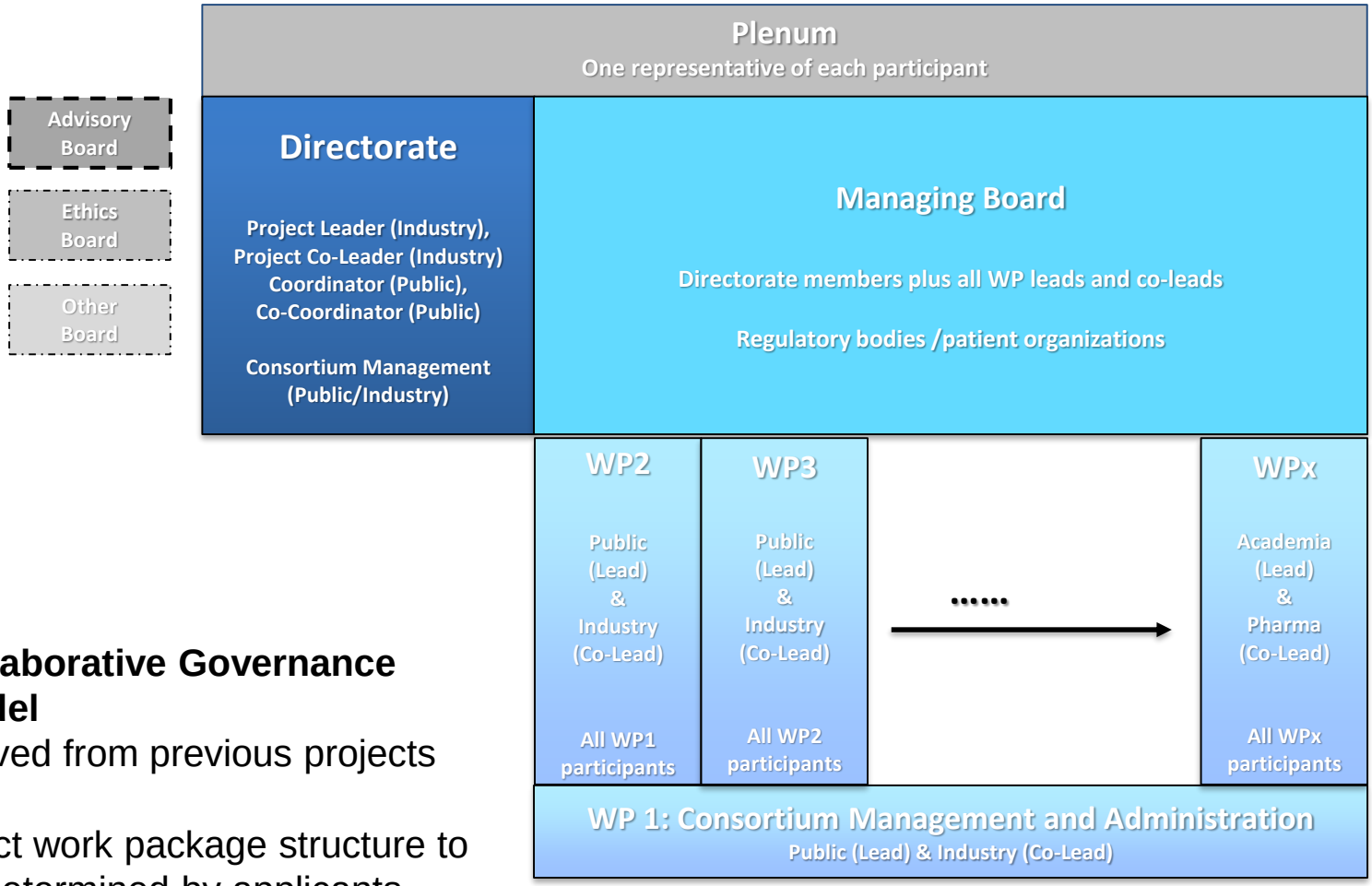
Expected impact

- Better understanding of the handling procedures and associated stresses in hospitals and in the hands of patients
- Assessment of the risks associated with handling steps
- Solutions to ensure high-quality DP delivery and administration
- Improve processes at pharmaceutical industries towards development of more robust DPs
- Improved training for professionals and patient/caregivers to ensure the stability of protein DP benefitting all stakeholders
- Enhanced design of processes and addressing of important but challenging issues around the development of therapeutics and delivery to patients;
- Improvements in the safety and efficacy of protein drug therapies.

Suggested architecture of the project



Collaborative Governance model
derived from previous projects

Exact work package structure to be determined by applicants

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Expected contributions of the applicants

- Global understanding of the protein drug product handling providing first-hand knowledge
- The capability to investigate the real-world handling procedures in hospitals, pharmacies and at homes
- Technical expertise to assess the impact on the stability of protein pharmaceuticals
- Ability to implement new technologies to achieve relevant data for handling conditions
- Expertise in the available methods of communication and training for handling of protein drug products
- Capability to produce novel and efficient training concepts, materials and methods
- Participation of SMEs adding value in the field by novel monitoring concepts or training tools is encouraged
- Ability to successfully work in a multi-disciplinary body (academic, institutes, SMEs, public bodies)

Expected (in kind) contributions of industry consortium

- Budget: 7.1 Mio. Euro (3.96 Mio Euro EFPIA in-kind contributions)
- Duration: 4 years
- Sanofi (lead), AbbVie, AstraZeneca, Boehringer Ingelheim, Lonza, Merck, Pfizer, Roche, Teva

- Development and manufacturing of biologics
- Formulation and process development
- Clinical processes
- Protein and biologics analytics
- Interaction with public health stakeholders and authorities

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What's in it for you?

- General: Collaborative work on topic of unmet needs and implications on patients' treatments together with key industry companies, universities, hospitals and SMEs.

- Academic researchers: Broad range of stakeholders and collaborators, opportunity to tackle an important challenge together with the various stakeholders, advancing knowledge on much-needed protein product stability topics
- Pharmacists and pharma educators: Ensuring a better training for pharmacists and moving towards safe delivery of protein pharmaceuticals
- SMEs: Potential clients and beta testers
- Patients' organisations: Stronger voice in drug development and patients' needs

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Key deliverables of the full project (i)

- Clear insight into the drug product handling procedures and their impact
  - Detailed outlining of the **handling procedures**
  - Evaluation of the real **impact of handling steps on stability** of protein drug products
  - Outlining of the protein drug **preparation** and **administration supplies** available to pharmacies
  - Assessment of the potential **impacts** on **delivered dose**
  - Estimation of the potential **impacts** on **clinical safety** and **efficacy**

Key deliverables of the full project (ii)

- **Improved protein drug product development processes**
  - Tools and methods to **improve protein drug product robustness** (rational and realistic in-use studies)
  - Determination of **critical parameters, process improvements** and drug product **handling requirements**

- **Improved training on drug product handling**
  - Improved **professional user training** including development of training materials
  - Improved **patient / caregiver training**

Thank you

Questions?

Contact the IMI Executive Office

E-mail: applicants@imi.europa.eu

www.imi.europa.eu

@IMI_JU

Involvement of SMEs, patient groups, regulators

Kalliopi Christoforidi

SME participation

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

Contribution of SMEs would be considered especially beneficial in providing as example the following expertise and activities :

- Technologies that have been developed for other purposes but can be of use for this project
- communication and dissemination
- project management

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Patient participation

- Involvement of patient organisations is vital to ensure the patient-centricity of the research recommendations, dissemination strategies and patients' understanding of educational programmes.

- Many ways to include your patient partners in the project e.g;
  - patient feedback on training needs
  - community outreach and dissemination
  - real-world handling procedures at home

More info: https://www.imi.europa.eu/get-involved/patients

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

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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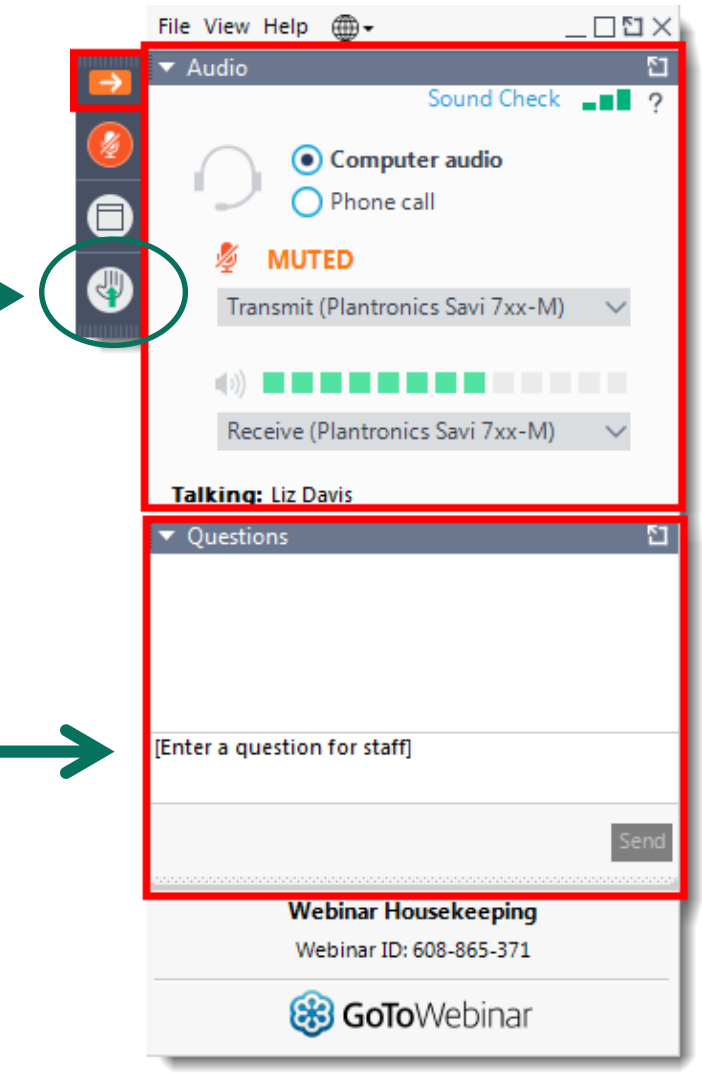
Questions & answers

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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