Webinar | IMI2 - Call 15
Blockchain enabled healthcare

17.07.2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Colm Carroll, IMI
- The Call topic – Marco Cuomo and Dan Fritz, Novartis
- Involvement of SMEs, patient groups, regulators – Colm Carroll, IMI
- Questions & answers

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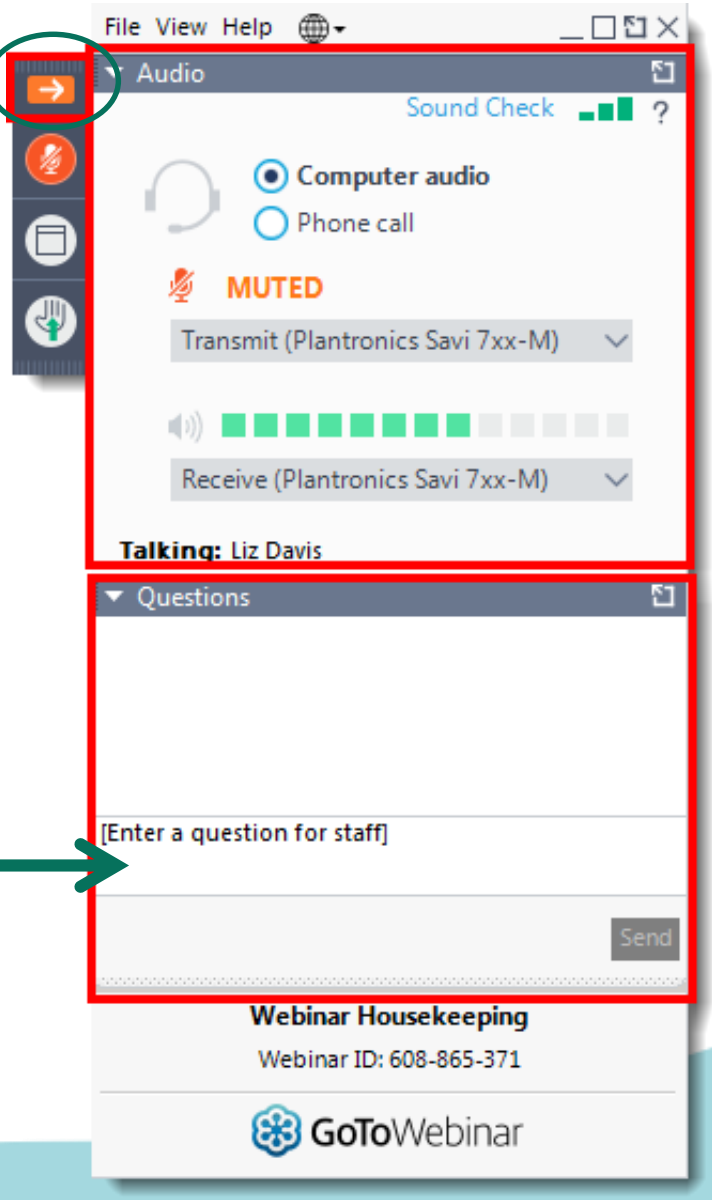

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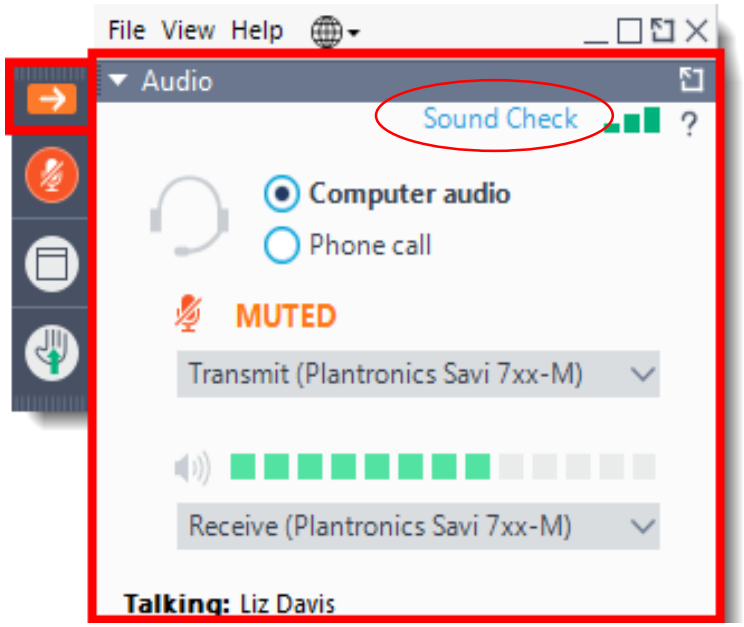

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Before we start…

- 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 circulated and published on the website
- All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

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Webinar | IMI2 - Call 15
Blockchain enabled healthcare

Colm Carroll
IMI webinar • 17.07.2018

Today's webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme

- Proposed project

Will not cover rules and procedures

- A webinar on rules and procedures took place on **Tuesday 10 July**

  View the recording and download the participant list at:

  http://europa.eu/!Yg99yW

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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 2 budget (2014 – 2024)

EU funding goes to:

Universities

Hospitals

SMEs

Mid-sized companies

Patient groups

€1.638 bn

efpia

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

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

IMI 2 total budget €3.276 billion

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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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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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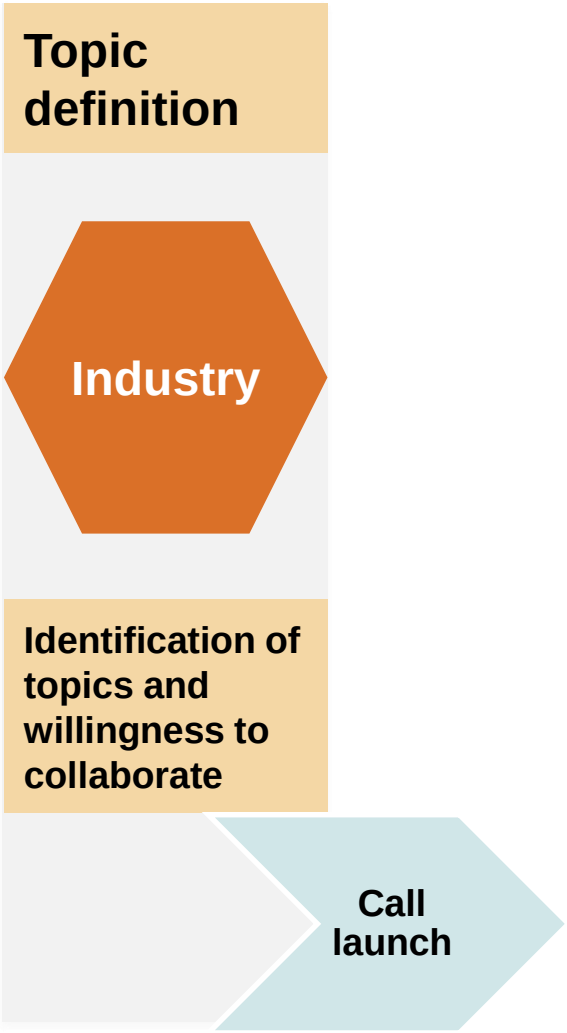
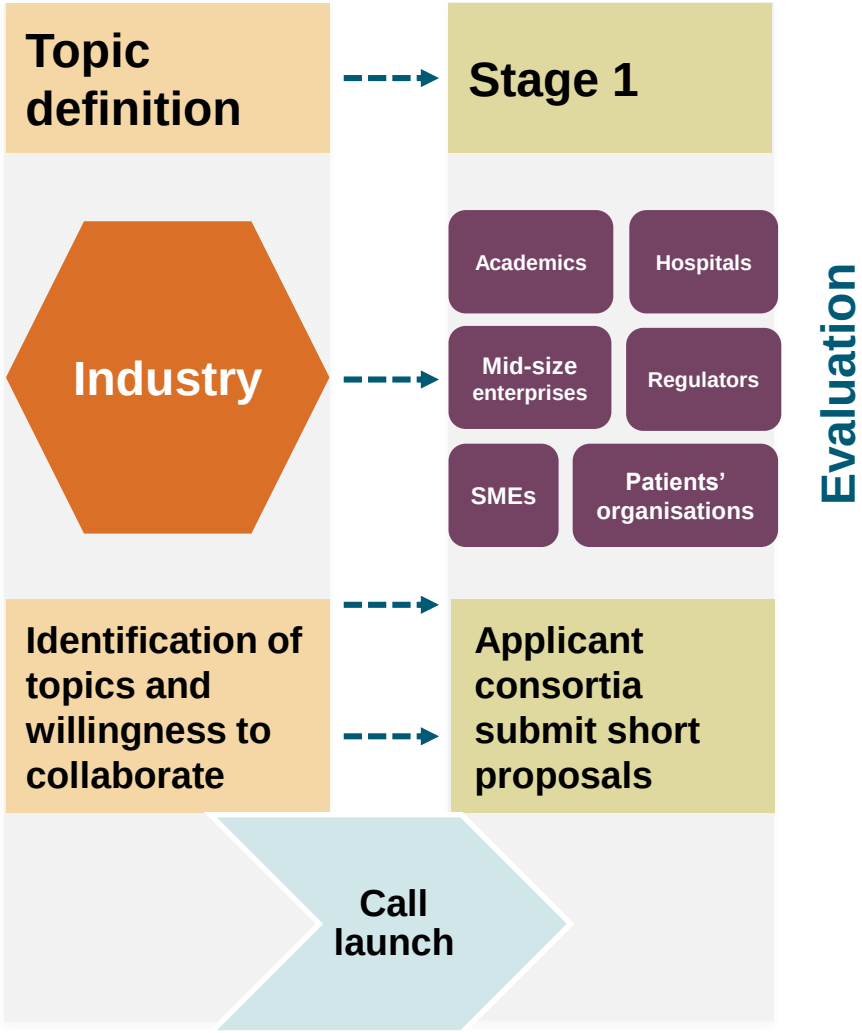
Typical IMI project life cycle



Typical IMI project life cycle



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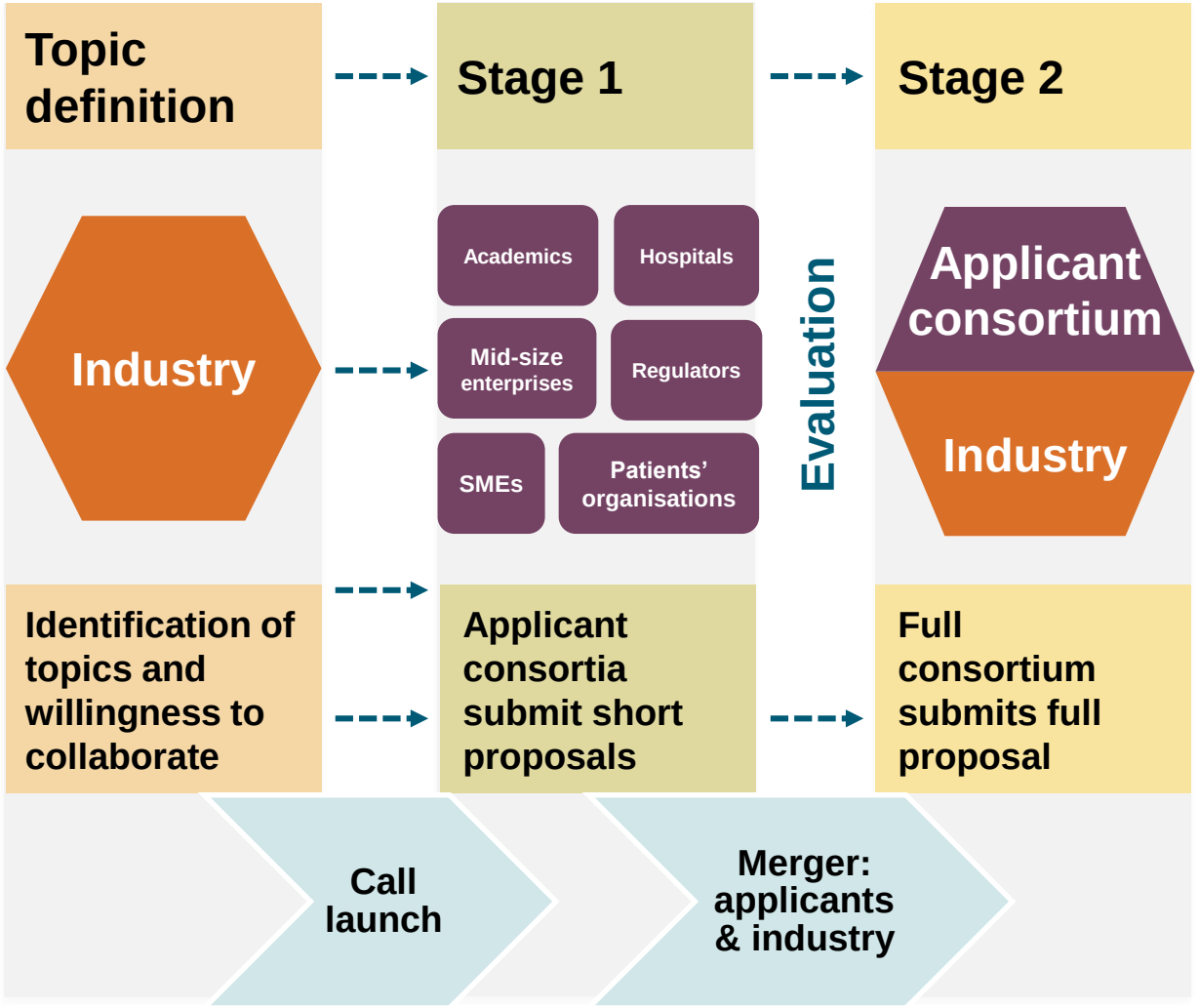
Typical IMI project life cycle



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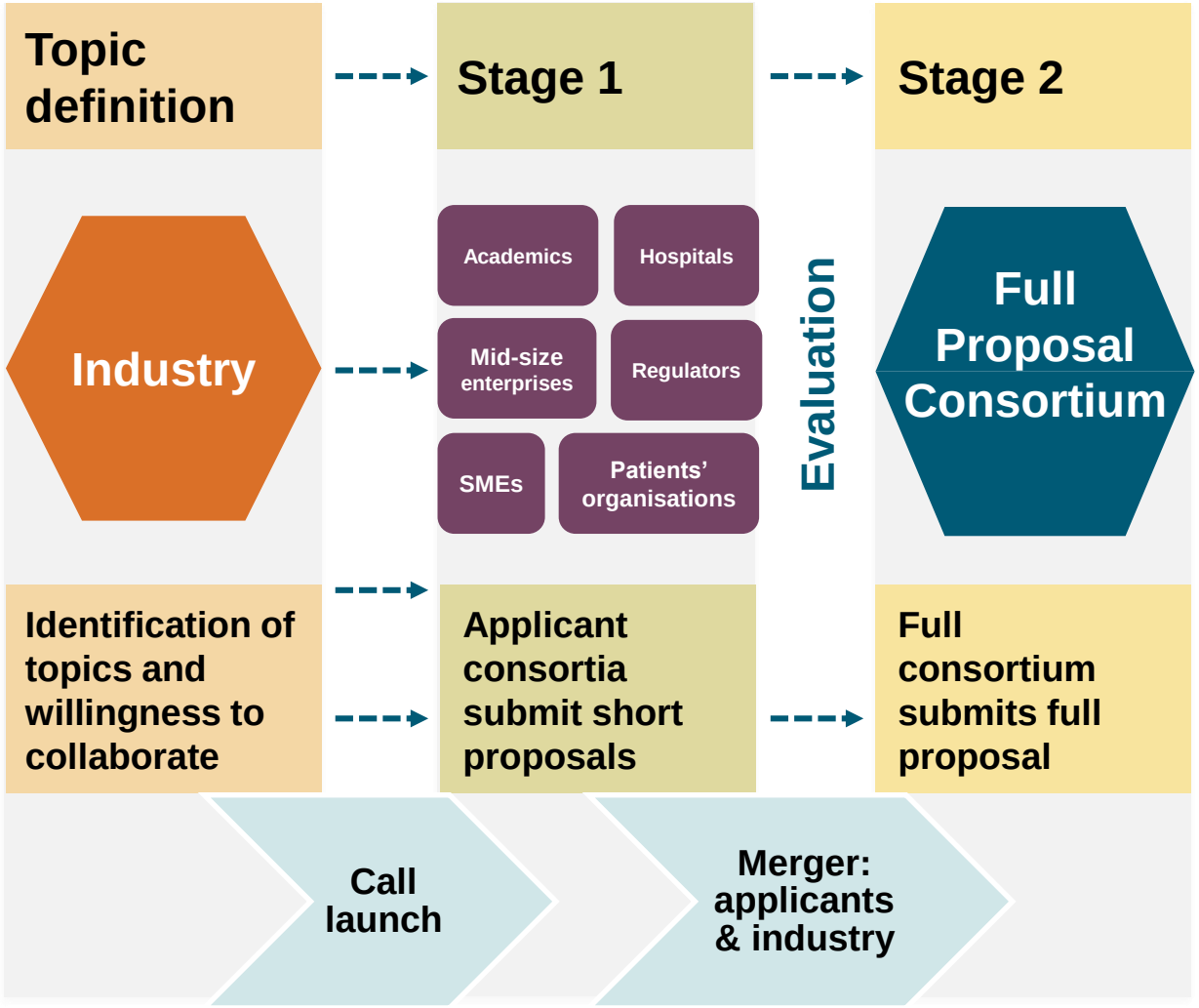
Typical IMI project life cycle



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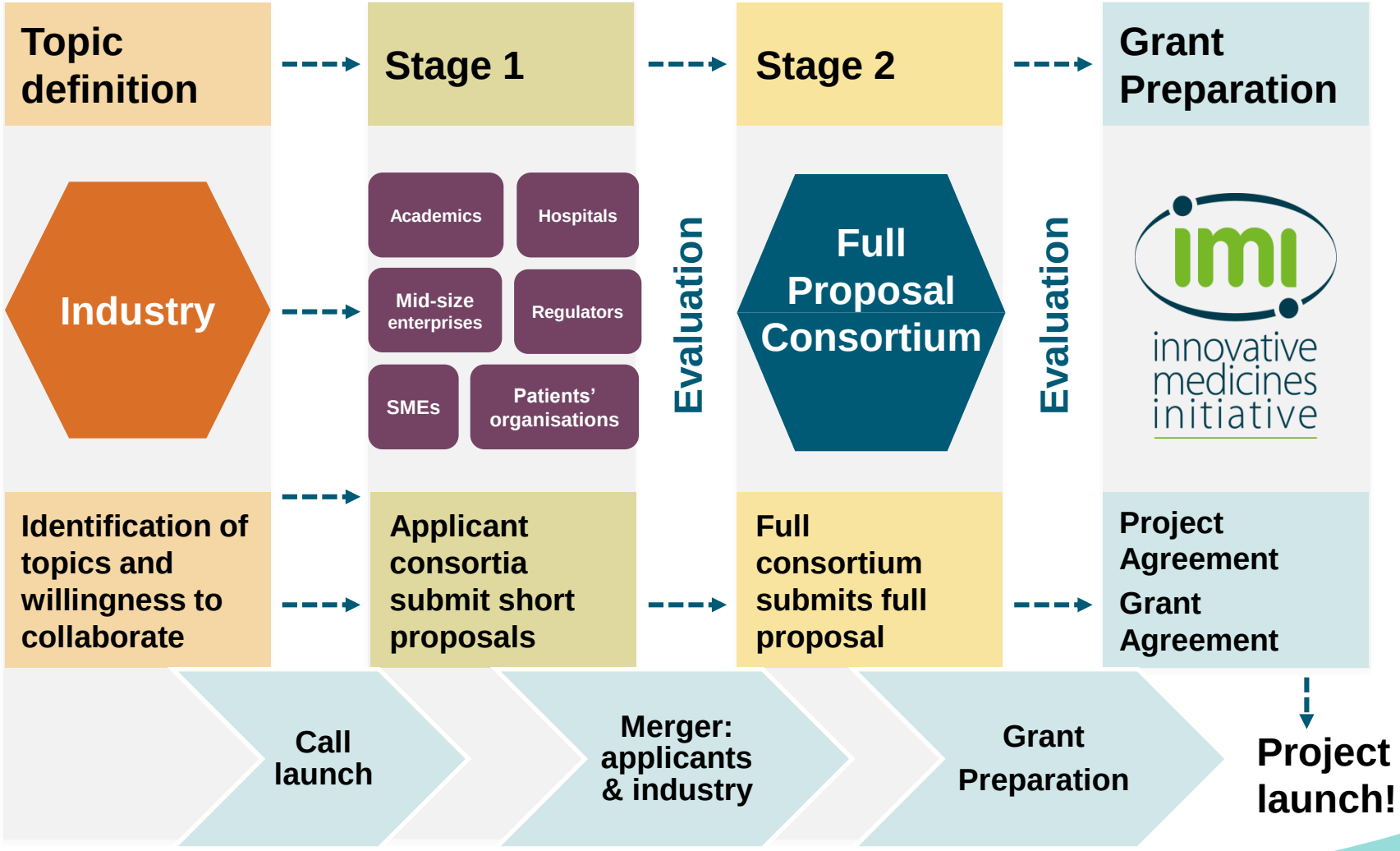
Typical IMI project life cycle



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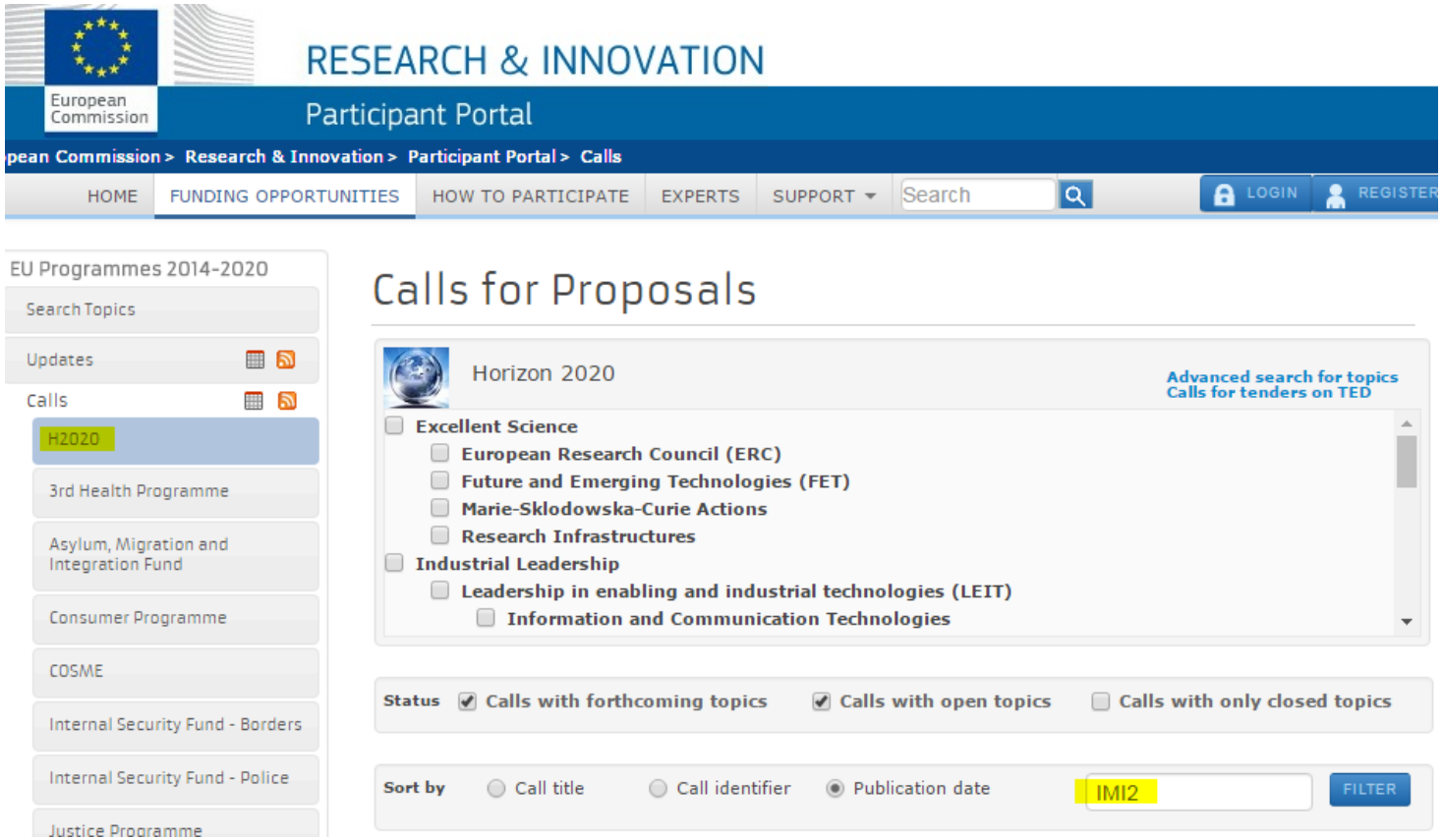
Submitting a proposal

- http://europa.eu/!Mg84kq



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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

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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:** https://www.imi.europa.eu/apply-funding
- 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 **Programme Office** (**NOT** 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 H2020 member & associated states** 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:**
  - H2020 portal: http://europa.eu/!Mg84kq
  - German NCP version: http://www.imi-partnering.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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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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Blockchain Enabled Healthcare

Marco Cuomo and Dan Fritz

17.07.2018 • IMI webinar

Need for public-private collaboration

The pharmaceutical ecosystem have many areas that suffer from complexity, a lack of transparency, coordination and trust:

- Counterfeit medicines market estimated at EUR 160 billion
- Lack of access to medicines, especially in developing countries
- Data accessibility leading to lost opportunities for improved research and new innovative medicines
- Patient privacy considerations hindering clinical trial recruitment
- Lack of visibility and shared “source of truth” leading to friction and cost in development and distribution
- Increasing risk of cyber threats, especially with central data storage and sharing

Objectives of the full project & deliverables

Objectives	Deliverables
Governance, Operating model	Formalization of an independent **governance model** with equitable representation **by all industry participants** for oversight accountability to enable sustainability, continuous improvement of the healthcare blockchain framework. This deliverable is framework (not project) governance.
Business use cases	Definition of **common requirements** and evaluation of blockchain technology benefits for **pharmaceutical value chain** and healthcare ecosystem processes. Design of process, system, data and organizational model for each use case.
Healthcare Blockchain Standards & Solutions	Leveraging **existing standards** and development of complementary standards if required. The analysis and requirements for new standards will be a major deliverable of the first year of the project.
Framework and Reference Implementation	Definition and **implementation** of an **open-source reference** architecture for an industry-wide blockchain network or networks as the basis for application specific solutions such as anti-counterfeiting or clinical trials as specified in the business use cases.
Regulatory, Legal & Data privacy framework	**Identification** of and compliance with existing and anticipated drug development, manufacturing and distribution **regulations**, which could be harmonized to benefit patients and **strengthen** overall security and data integrity.
Change Management	Includes a methodology adoption **or how-to "handbook"** tailored to small, medium or large industry partners. Addresses both **technical** and **organizational** components.

Pre-competitive nature

- Blockchain is a technology that requires collaboration to be effective
- Blockchain is about the ecosystem
- Network effect for a distributed ledger : The greater the number of users, the more valuable the technology is to all of them.
- Consortia allow companies to take advantage of blockchain network effects from day one, by providing a vehicle to create a governance structure around this collaboration, often among players that compete against one other

Expected impact (visionary)

- Patients will have earlier access to both the medicines they need and information of drug provenance
- Permissioned and secure healthcare data sharing will be enabled between patients, healthcare providers, researchers and other stakeholders.
- Healthcare providers will use limited resources more efficiently by streamlining clinical trials and eliminating expenses for counterfeit and substandard medicines
- The pharmaceutical industry will benefit from widely accepted standards and demonstrated actions to ensure the integrity of drug development and distribution to the patient
- The applicant consortium will benefit from investments in research programmes and early adoption of innovative solutions

Suggested architecture of the project

- **#1** Define use case strategy and build up use case with benefit realization. Potential to have one workpackage per group of use cases (e.g: supply chain)
- **#2** Healthcare Blockchain Standards & Solutions
- **#3** Provide architecture Framework, design and develop the Blockchain healthcare fuondations
- **#4** Formalization of an independent governance model enabling sustainability, continuous improvement and equitable representation by all industry participants
- **#5** Define the regulation, legal and data Privacy framework for healthcare blockchain
- **#6** Drive shift in mindset (e.g. “distributed ledger”) and ensure fast adoption

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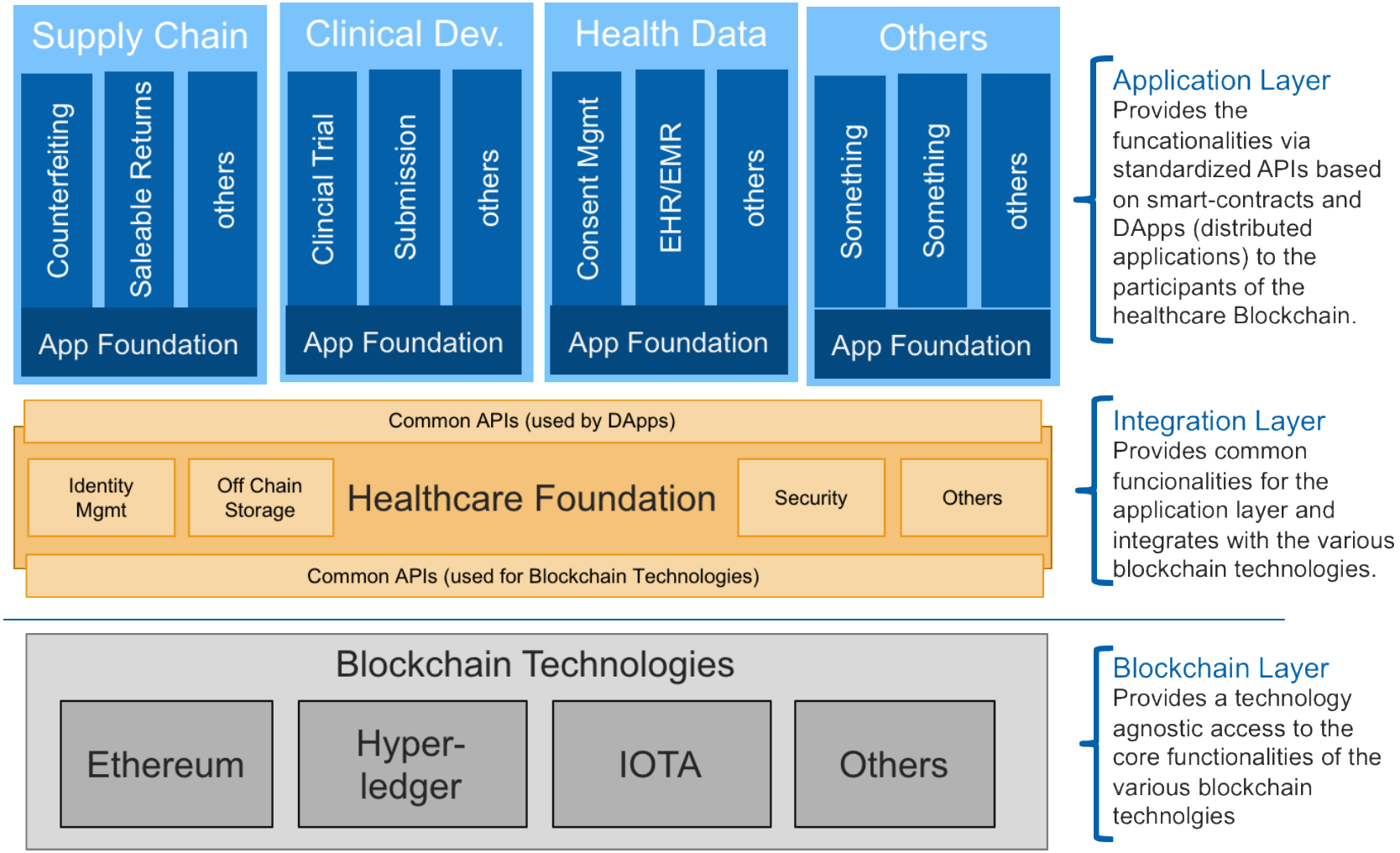
High Level Architecture Framework



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Expected contributions of the applicants

- Experience in blockchain technology and can demonstrate thought leadership with evidence
- Knowledge of the healthcare industry and processes and related to pharmaceutical drug development and operations
- There are numerous working groups, projects and standards that must be leveraged to the maximum extent possible (from Healthcare industry and other industries)
- Patient, Patient representatives, and Public health institutes and non-governmental agencies must be represented

Expected (in kind) contributions of industry consortium

- Experts in various pharmaceutical areas such as Clinical trial and drug submission, regulatory affairs, supplier qualification, packaging, anti-counterfeiting, manufacturing and distribution, supply chain, etc.
- IT Enterprise, technology and integration architects, blockchain application developers, business analysts, project managers
- Product security, information security, cyber security, compliance, data privacy, legal, risk, integrity, environmental, and financial experts

What's in it for you?

- Helping patients by building the foundation
- Be at the forefront of new technology
- Defining standards for the whole healthcare industry
- Engagement with subject matter experts from the industry
- Put the power in the hand of the patient

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Thank you

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@IMI_JU

Involvement of SMEs, patient groups & regulators

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 by bringing expertise in:

- researchers related to pharmaceutical drug development and operations and blockchain and distributed ledger technology;
- solution providers of IT technology and system integrators, blockchain developers, project managers, software and technology experts.

Patient Participation

There are many ways you can improve project performance by working with patients as partners:

- Ensure patient needs are prioritised
- Inclusion of patient privacy considerations (eg patient consent)
- Community outreach, dissemination and adoption

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

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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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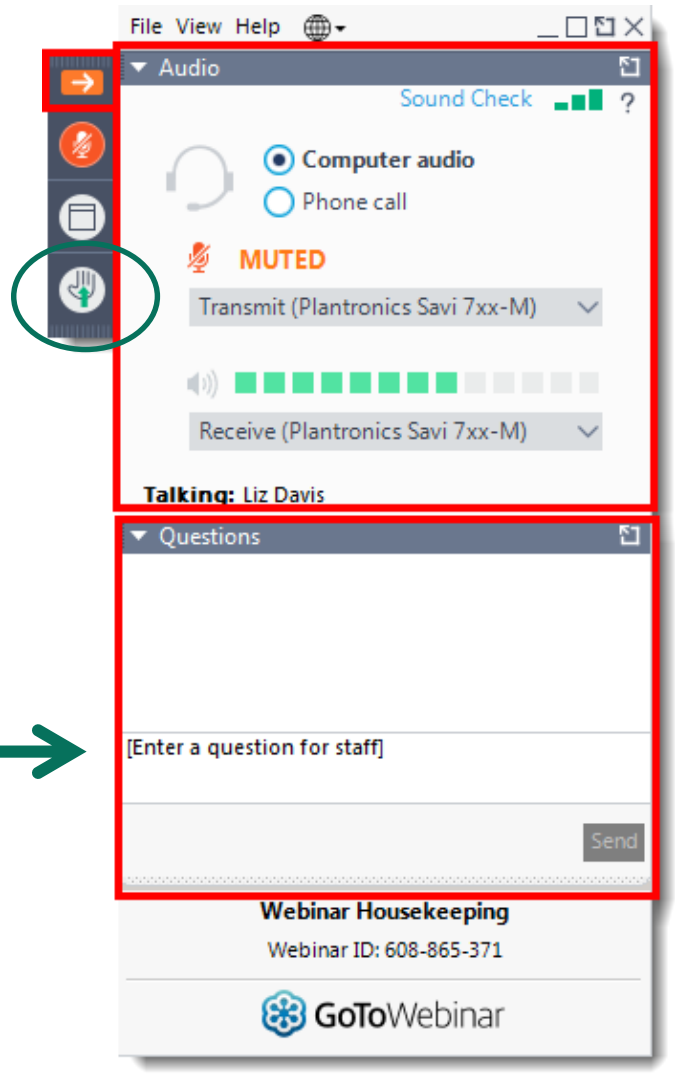
Questions & answers

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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Thank you!