Webinar | IMI2 – Call 13
The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use

15 December 2017 • 10:30 CET

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Angela Wittelsberger, IMI
- The Call topic – Mark Miller & Philippe Cleuziat, bioMérieux; Jorge Villacian, Janssen Diagnostics
- Involvement of SMEs, patients and regulators – Angela Wittelsberger, IMI
- Questions & answers

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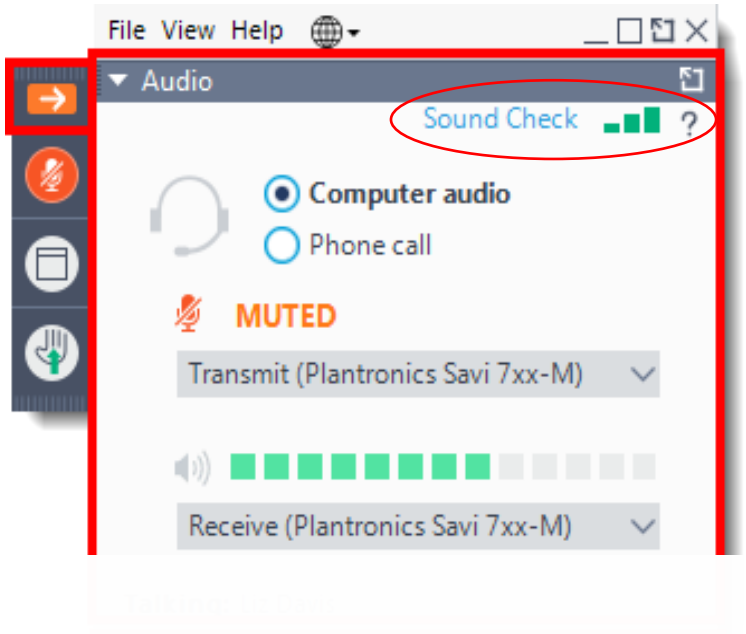

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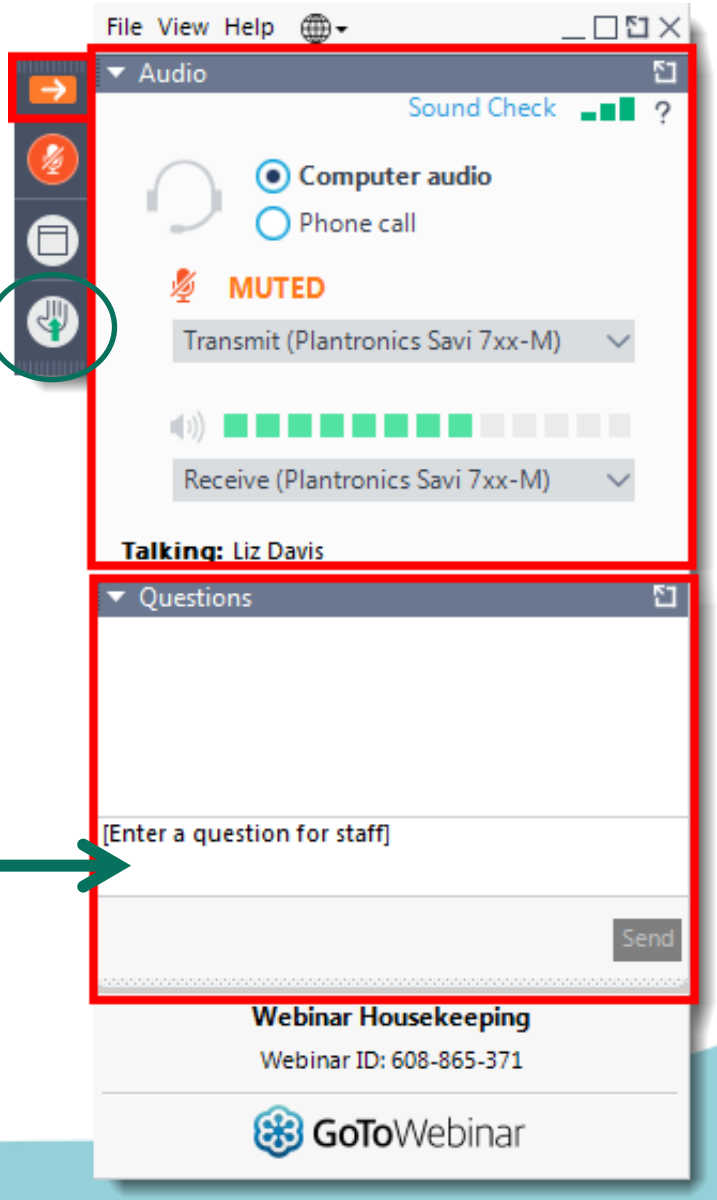

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Before we start…

- 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
- IMI2 – Call 13 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 13

The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use

Angela Wittelsberger, 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 took place on Thursday 7 December – the recording is online. It will be repeated on Tuesday 16 January 2018 – sign up via the IMI website

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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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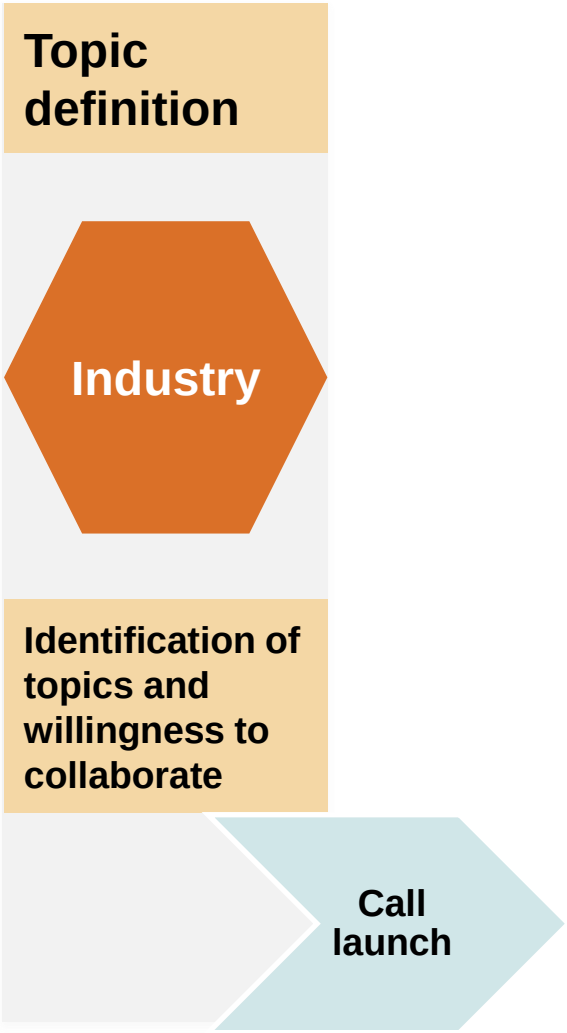
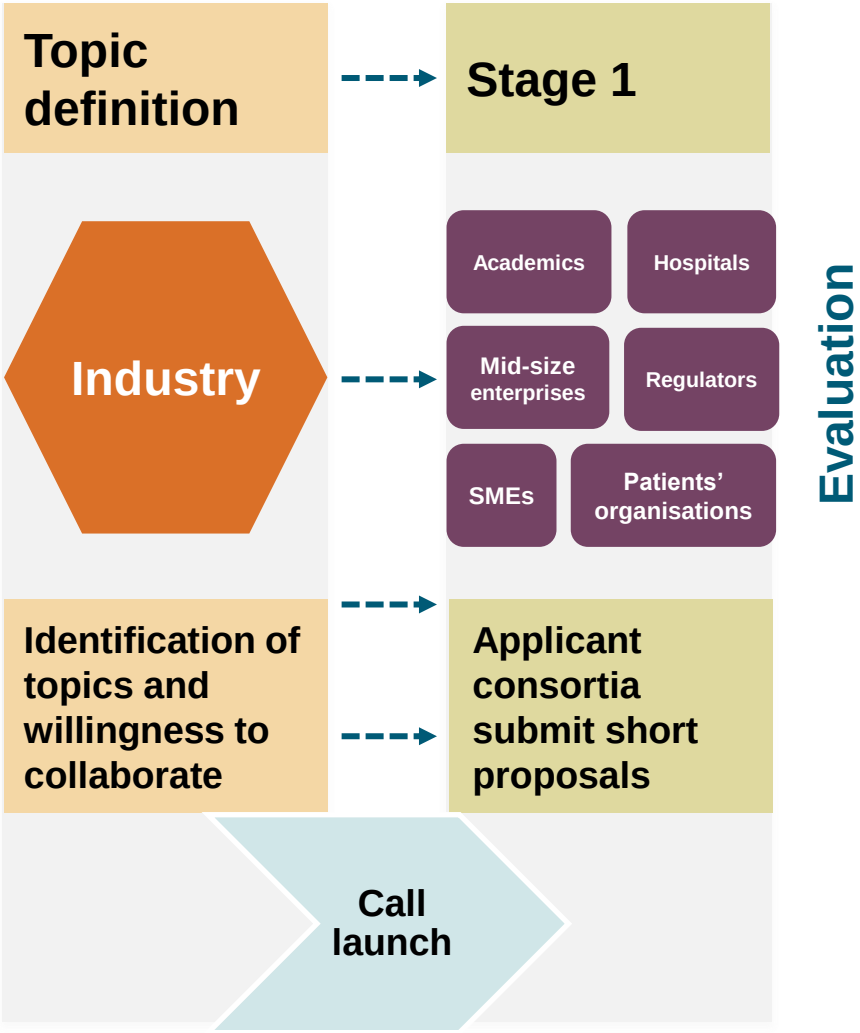
Typical IMI project life cycle



Typical IMI project life cycle



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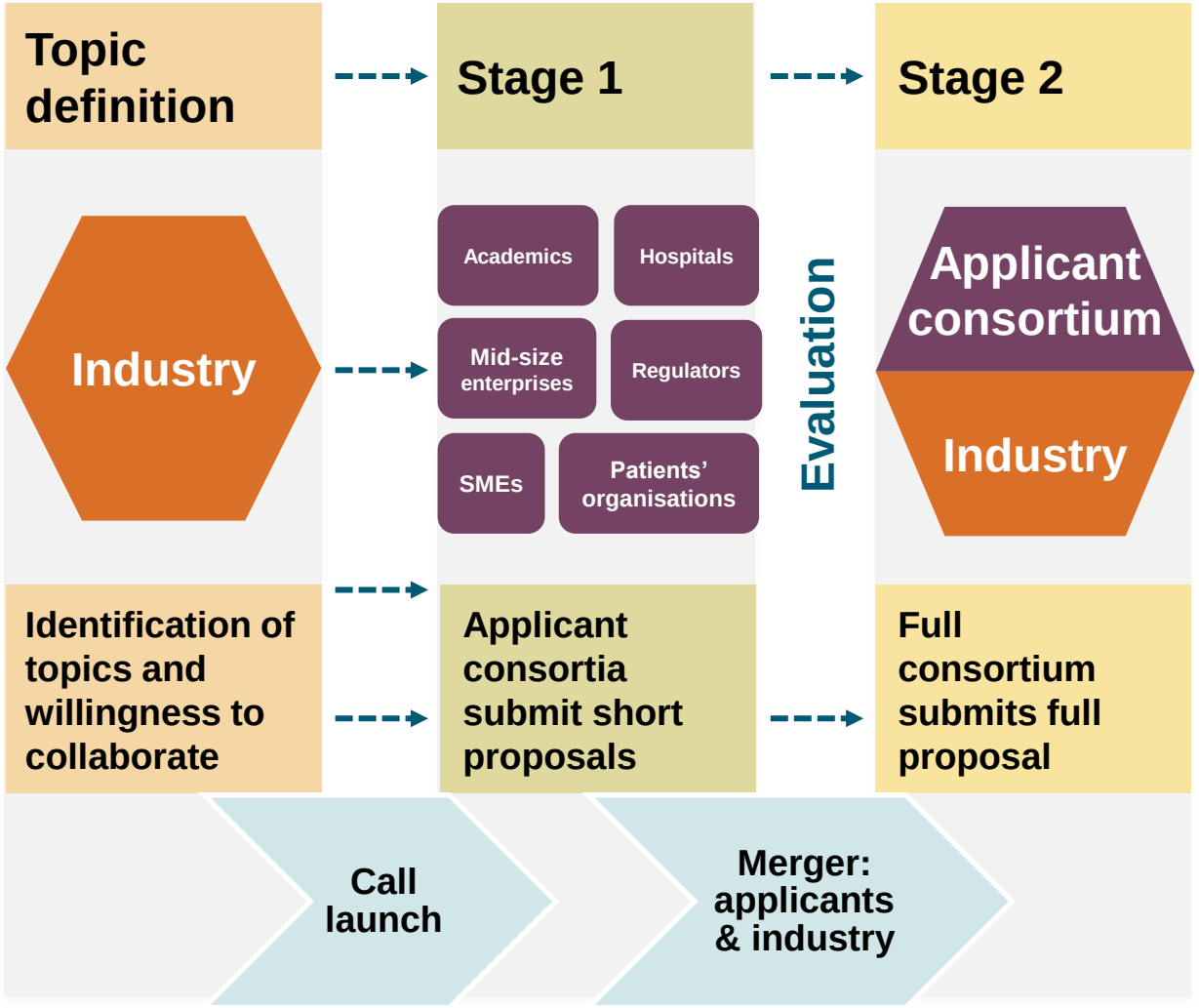
Typical IMI project life cycle



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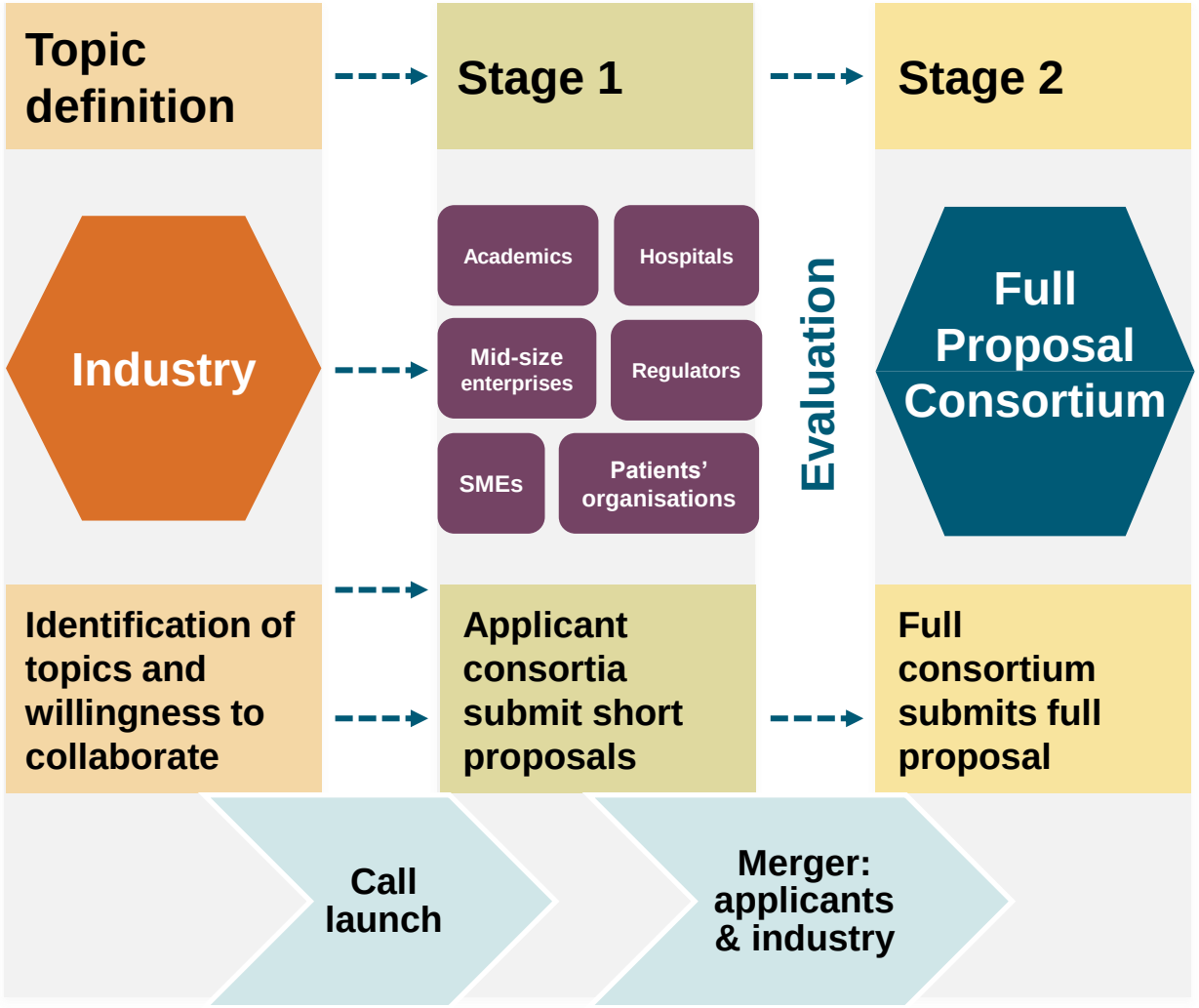
Typical IMI project life cycle



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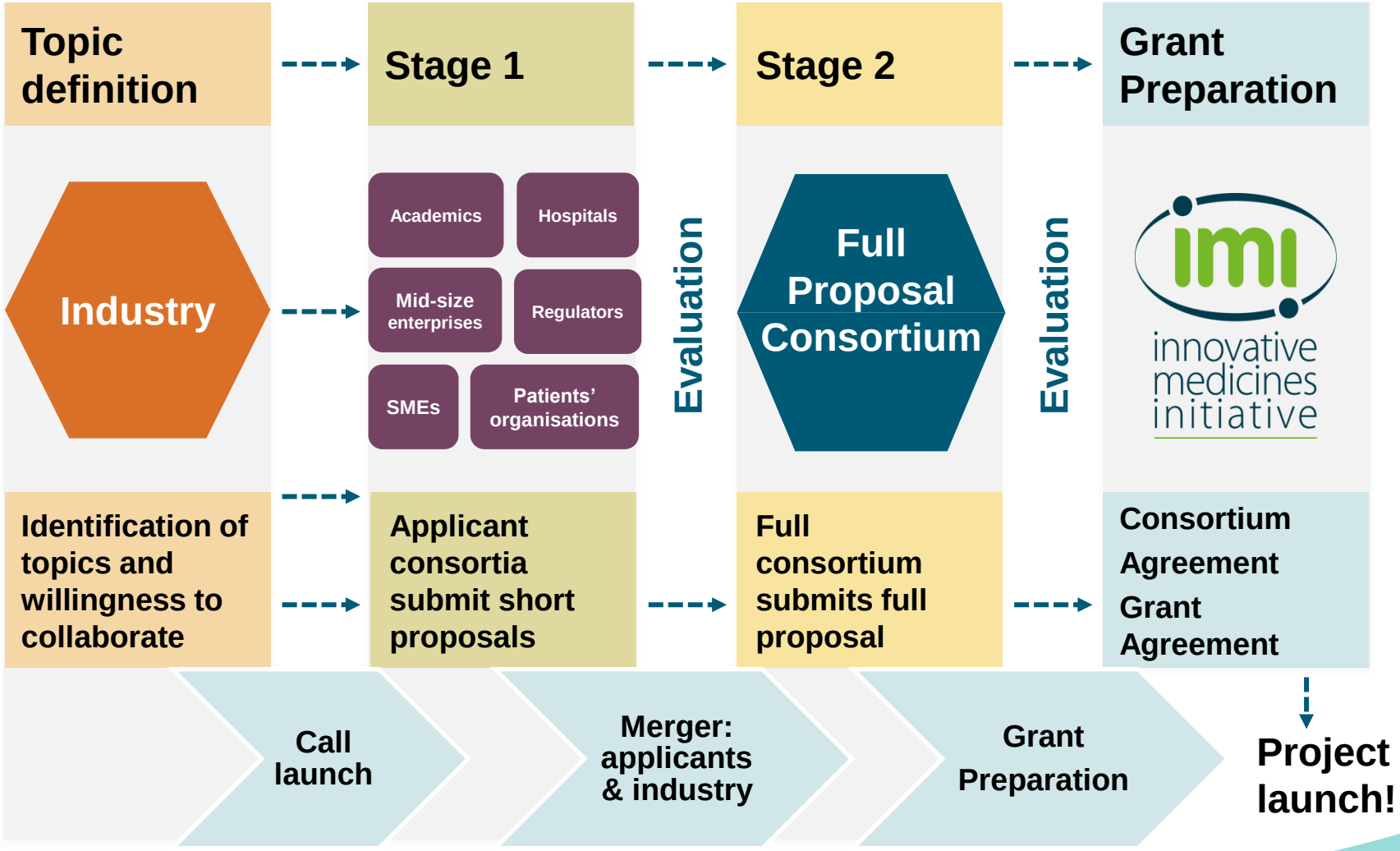
Typical IMI project life cycle



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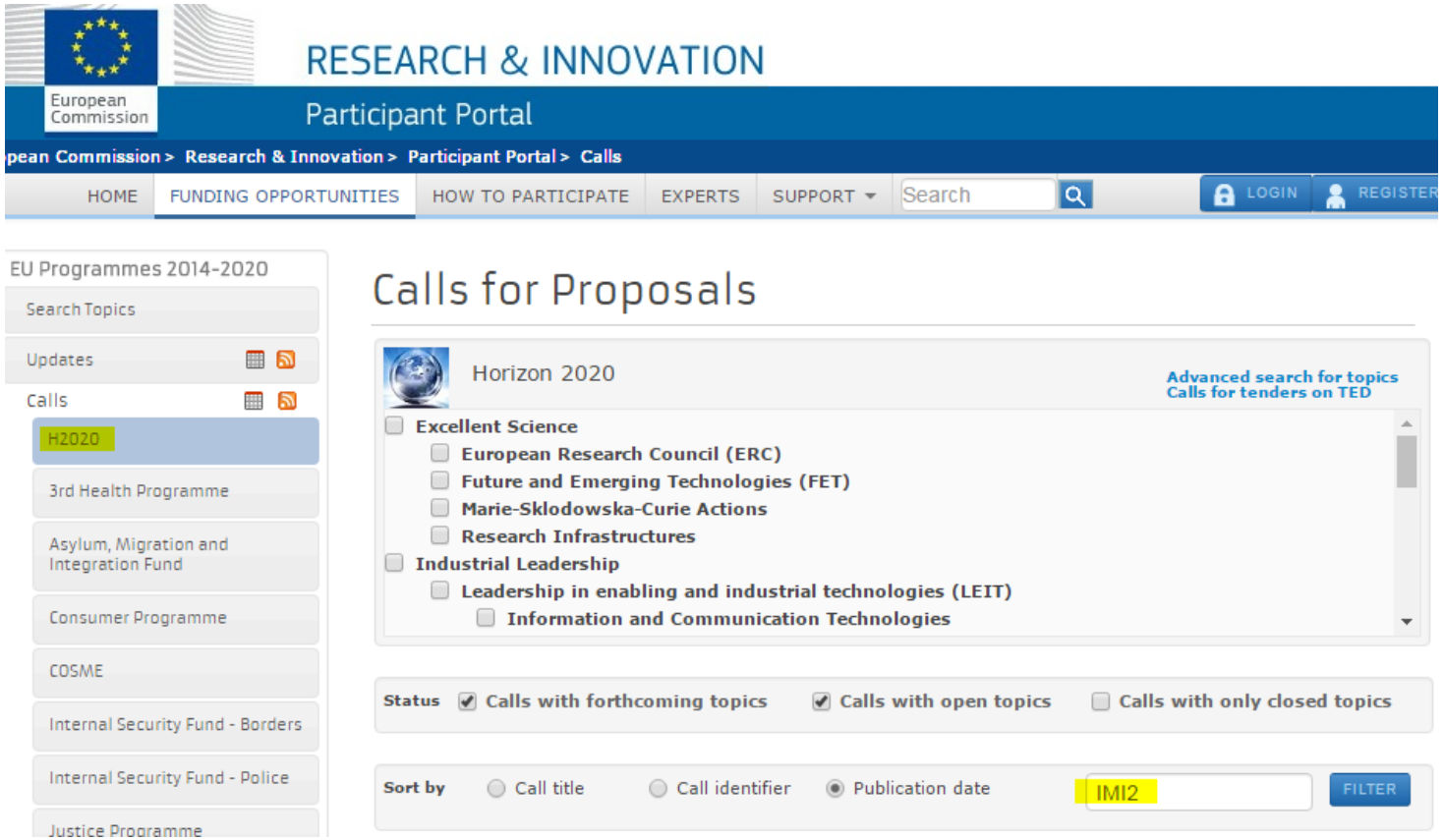
Submitting a proposal

- 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

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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:**
  - EU participant portal: https://ec.europa.eu/research/participants/portal/desktop/en/organisations/partner_search.html
  - 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
  – *check the list of interested SMEs on the Call 13 web page*
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc…)

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Topic 3: The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use

Mark Miller / Philippe Cleuziat / Jorge Villacian

15.12.2017 • IMI webinar

Call context / Challenges to be addressed

- Antimicrobial-resistant (AMR) bacterial strains killed 25 000 people in the EU in 2007 and cost the economy €1.5 billion a year.
- Many antibiotics that were once thought to put an end to infectious diseases are no longer working.
- Huge amounts of antibiotics are prescribed and consumed unnecessarily in almost all healthcare systems, creating a huge global health crisis. **Prudent use of antibiotics is urgently required protect the efficacy of our currently available antibiotics**.
  - → **Diagnostics** have the potential to provide more targeted, accurate use of antibiotics.
  - → **A pan-European approach is required to demonstrate the medial, economical and public health value of diagnostics for combatting AMR.**

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Need for public-private collaboration

- **Cooperation** amongst industry, academia, patients/patient groups, policy-makers, public health experts and healthcare decision-makers **is urgent to**:
  - **implement critical solutions**, including **impactful diagnostics** to **preserve the efficacy of antibiotics** currently available or in development;
  - **Address the barriers which prevent the uptake and development of diagnostics for antimicrobial stewardship** which includes studies, policy development, funding/reimbursement formulae and schemes, physician education and patient awareness, psychosocial factors, appropriate and innovative assessment and disparate regulatory requirements.

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Objectives of the full project (1/2)

The main objective of this action is to understand, demonstrate, and quantify the value of diagnostics and obstacles to their adoption and use in the framework of a Standardised Care Network to combat antimicrobial resistance (AMR) by optimising antibiotic use in Europe.

- **Objective 1:**

  Establish a **health-economic framework** to assess and demonstrate the impact – for individual patients and public health in general – of increasing the use of diagnostics to reduce or optimize antibiotic prescription and ultimately combat the development of antibiotic resistance.

- **Objective 2:**

  Establish a **Standardised Care Network** (pre-existing or new) in order to conduct clinical trials evaluating the value of diagnostics.

Objectives of the full project (2/2)

- **Objective 3:**

  Design and implement **clinical studies to demonstrate the value of diagnostics** in the optimal management of **Community-Acquired Acute Respiratory Tract Infections (CA-ARTIs)**, by using the outputs, measures and deliverables defined in the health-economic framework (Objective 1).

- **Objective 4:**

  Explore, define and attempt to resolve the many aspects which prevent the more widespread adoption of diagnostics when delivering healthcare to the population. Focus will be necessary on **patient and healthcare provider education**, psychological, ethical, organisational and social barriers.

Pre-competitive nature

- Public/Private efforts will be combined to demonstrate the medical value, healthcare benefit and economic viability of diagnostic tests, and educate health professionals, prescribers, payers and patients for combatting antibiotic resistance and improving patient outcome;
- The industry consortium has agreed and experienced that novel guidelines are required to allow changes in medical practice and behavior to reduce AMR;
- Project-generated experience and expertise will be openly shared and should lead to new recommendations and incentives for development of innovative diagnostic tests;
- Tools and results will be made available to the public, scientific community, healthcare providers, decision-makers, payers, etc.
- Interactions with other relevant global initiatives and consortia will be built to optimise efforts and funding.

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Expected impact (1/2)

- Optimum use of diagnostic tests in CA-ARTIs for achieving improved patient outcomes, reduction in the inappropriate use of antibiotics, and decrease in the incidence of key antibiotic-resistant pathogens;
- Wide dissemination of evidence-based conclusions that will sensitize the medical and patient communities, as well as decision-makers, to the clinical and economic value of diagnostics;
- Incorporation of guidance using diagnostic tests and testing algorithms in national and international guidelines;
- Assistance to regulatory bodies to facilitate adoption of diagnostic tests into wider routine practice;

Expected impact (2/2)

- Assistance to Health Technology Assessment (HTA) bodies to enable appropriate, fit-for-purpose assessment of the clinical value of diagnostics;
- Reform of pricing policies (including reimbursement) related to diagnostic tests, according to the demonstrated or anticipated medical value and health outcomes.
- Strengthened competitiveness and industrial leadership of Europe, through the active participation of SMEs.

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Suggested architecture of the project (1/3)

- **Work Package 1 - Implementation of diagnostics**

Design and test a framework for establishing a sustainable infrastructure for the evidence-based translation of innovative diagnostics into standard-of-care. The framework should (i) assess and demonstrate the value of diagnostics both for individual patients and for public health; (ii) build on the available evidence and utilise an extensive consultation with key stakeholders.

- **Work Package 2 – Establishment of a Standardised Care Network**

Establish a Standardised Care Network, comprising high-, medium- and low-antibiotic use countries in Europe. The network should include at least five high-income EU countries that represent a large population base and five upper or lower middle-income countries from the EU Member States and H2020 Associated Countries.

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Suggested architecture of the project (2/3)

- **Work Package 3 – Data analysis**

Provide tools and organisation suitable for the analysis of the data from the clinical study undertaken in the Standardised Care Network, including surveillance data, 'best practices' which are based on optimal patient outcomes, and all of the outcomes, measures and deliverables outlined in WP1.

- **Work Package 4 – Clinical study on the value of diagnostics in Community-Acquired Acute Respiratory Tract Infections**

Design and implement clinical studies to demonstrate the value of diagnostics in the optimal management of CA-ARTIs, by using the outcomes, measures and deliverables outlined in WP1 within the Standardised Care Network of WP2.

Suggested architecture of the project (3/3)

- **Work Package 5 – Education & Advocacy**

Address barriers for acceptance of diagnostic tests and help understand motivational factors which may help overcoming hurdles to effectively use these tests in patient management.
Study how patients and populations can be empowered to become value-conscious beneficiaries of diagnostic tests.
Provide a coordinated advocacy effort to help all stakeholders define a new framework that incentivizes the use of diagnostics.

- **Work Package 6 – Project Management**

Establish a framework to optimise resources and ensure delivery of results in due time and/or mitigate the risks associated to the project, maximising interaction and cross-fertilisation across the various WPs. Ensure the strategic alignment of efforts to key deliverables. Oversee, coordinate, manage and facilitate the project and its WPs among the consortia members and with IMI2 JU.

Expected contributions of the applicants (1/2)

EXPERTISE & CAPABLITIES IN:

- Setting up a structured network gathering scientific, clinical, regulatory and health economics expertise applied to diagnostic studies;
- Accessing to a large population suffering from CA-ARTIs across all age groups and differing healthcare environments (i.e. community, acute-care, rehabilitation, long-term care, home care);
- Conducting clinical trials including clinical operations and clinical programme management;
- Working in/establishing standardised procedures and processes in all clinical trials, uniform training of all research personnel, assistance in the design of clinical trials, inclusion of the patient/parent perspective in clinical trials, and the sharing of information related to clinical trials;

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Expected contributions of the applicants (2/2)

EXPERTISE & CAPABLITIES IN:

- Information technologies for Data storage, sharing, analysis and Management;
- Social sciences for analysing barriers to implementation of new health interventions;
- Legal and clinical compliance/ICH GCP (International Council for Harmonisation – Good Clinical Practice) aspects;
- Project management and communication/dissemination, office administration and website management (with previous successful experience).

Expected (in kind and/or financial) contributions of industry consortium

- Supply of pathogen and host-based assays and equipment;
- Expertise in Clinical design and medical affairs;
- Help with Point-of-care data connectivity solutions, software and expertise;
- Contribution to Data analytics (e.g. diagnostic biostatistics and bioinformatics);
- Support for Market access / Pricing / Reimbursement expertise;
- Support for Legal expertise / Health economics;
- Assistance with Bio-banking and pathogen characterisation (e.g. antibiotic susceptibility testing, clinical annotations);
- Support for Training tools and modules (assays, data privacy);
- Assistance with Project Management to contribute to consortium governance structure and meetings.

What's in it for you?

- **Academic researchers**: High profile research, new collaborative networks/partnerships with top teams from industry, academia, patients' organisations. Access to infrastructure technology and resources.
- **SMEs**: easier/quicker access to (i) laboratories, clinical samples and data across Europe, (ii) market (selection of their diagnostic for the trial, expanded pool of customers); exploitation/expansion opportunities (new business, increased visibility).
- **Patients' organisations and patients**: optimised care/treatment through better use of diagnostics/personalised antibiotic therapy.
- **Governments, payers, healthcare systems**: reductions in AMR and healthcare costs due to higher diagnostics use.
- **Industry**: increased use of diagnostics tools; boosted innovation for new diagnostic development; increased reputation and visibility.

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Key deliverables of the full project

- A **defined framework to assess and demonstrate the value of diagnostics** to optimise antibiotic therapy and reduce antibiotic resistance;
- A sustainable **Standardised Care Network** including high-, medium- and low-antibiotic-use countries and encompassing the entire range of healthcare establishment from community clinics to long-term care, able to collect and share thorough information on pathogen, patients status, treatment regimen and outcome;
- **Comprehensive clinical studies on the value of diagnostics in Community-Acquired Acute Respiratory Tract Infections** by using outcomes and measures specified in the framework;
- A **definition** and **better understanding of the barriers and aspects** preventing widespread adoption of diagnostics during healthcare delivery, focusing on education, psychological, organisational, ethical, social, and pragmatic obstacles.

Key facts

Industry consortium:

- **EFPIA partners**: bioMérieux (lead), Janssen Diagnostics, Abbott
- **IMI2 JU Associated Partners**: Accelerate Diagnostics, Bio-Rad, BD, The Wellcome Trust

Duration of the action: 48 months

Budget:

The indicative in-kind/financial contribution from EFPIA partners and IMI2 JU Associated Partners is EUR 6 800 000, of which EUR 3 805 000 financial contribution.

The financial contribution from IMI2 JU is a max. of EUR 6 800 000.

→ **The total financial contribution available to applicants for proposed activities is therefore EUR 10 605 000.**

Involvement of SMEs, patient groups, regulators

Angela Wittelsberger, IMI

SME participation

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

- Definition of the value diagnostics could bring to AMR
- Diagnostic tests, regulatory registered or in the registration process, including novel validated biomarkers
- Services, information systems or software for data sharing, storage and analysis
- Infrastructures, logistics and services for bio-banking and deep characterisation of pathogens or samples
- Project management and dissemination tools including set-up of education programs and training modules on the value of diagnostics to combat AMR

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Patient participation

- Patient expertise to define obstacles to adoption of diagnostics
- Development of pragmatic solutions and evidence-based methods to resolve obstacles

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

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Interactions with regulators

- Consider having a **plan for interaction** with relevant **milestones**, **resources** allocated
- You may need to go through a **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)
- If regulators are not project participants, consider including them in an **advisory board**
- Consider also a plan for dialogue with **HTA bodies / payers** if relevant

To maximise impact of science generated by projects

Engage in dialogue with regulatory authorities

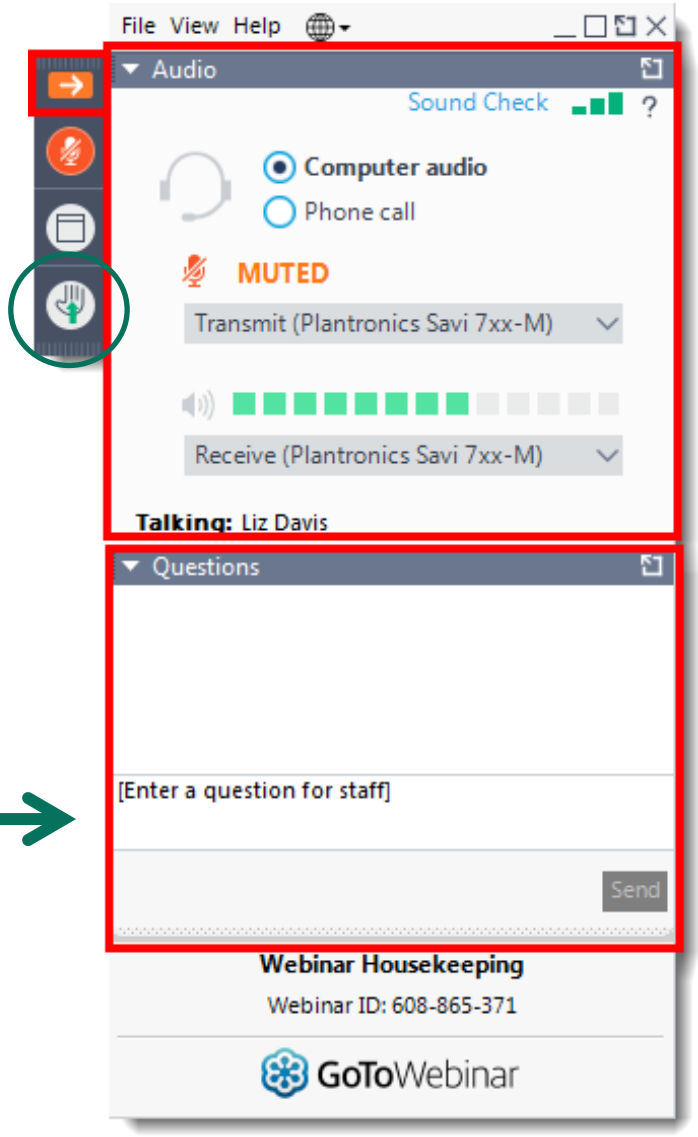
More info: 'Raising awareness of regulatory requirements: A guidance tool for researchers'

www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/RegulatoryRequirementsGuide.pdf

Questions

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**

infodesk@imi.europa.eu

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