Webinar | IMI2 – Call 13
Human tumour microenvironment immunoprofiling

1 December 2017 • 10:30 CET

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Oussama Karroum, IMI
- The Call topic – Ralph Lindemann, Merck Biopharma
- Questions & answers

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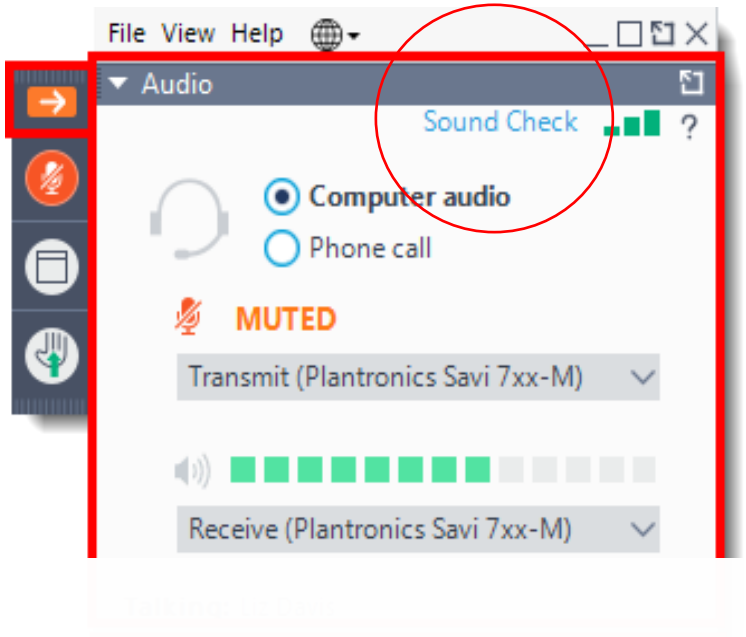

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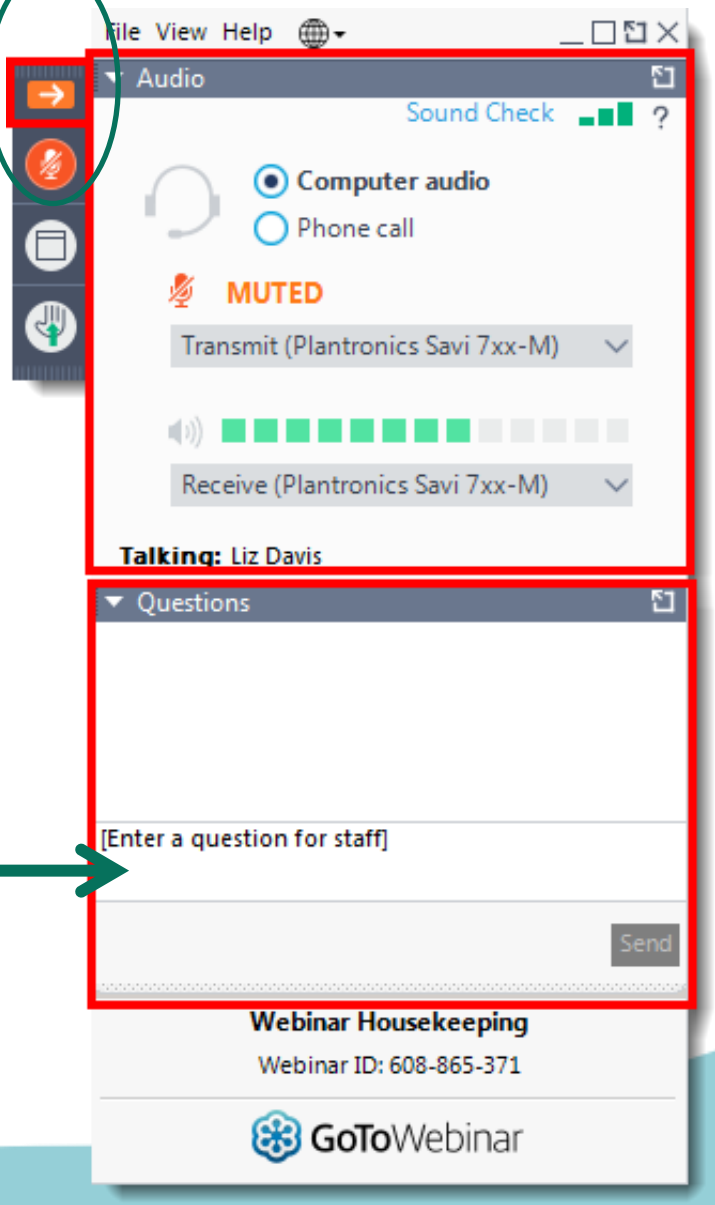

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Before we start…

- 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

Human tumour microenvironment immunoprofiling

Karroum Oussama

01.12.2017

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 7 December, 15:00-16:30

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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 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

€1.425 bn

Other €213 m

IMI 2 total budget €3.276 billion

EFPIA companies

receive no funding

contribute to projects ‘in kind’

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

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How a topic is generated

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

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

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

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

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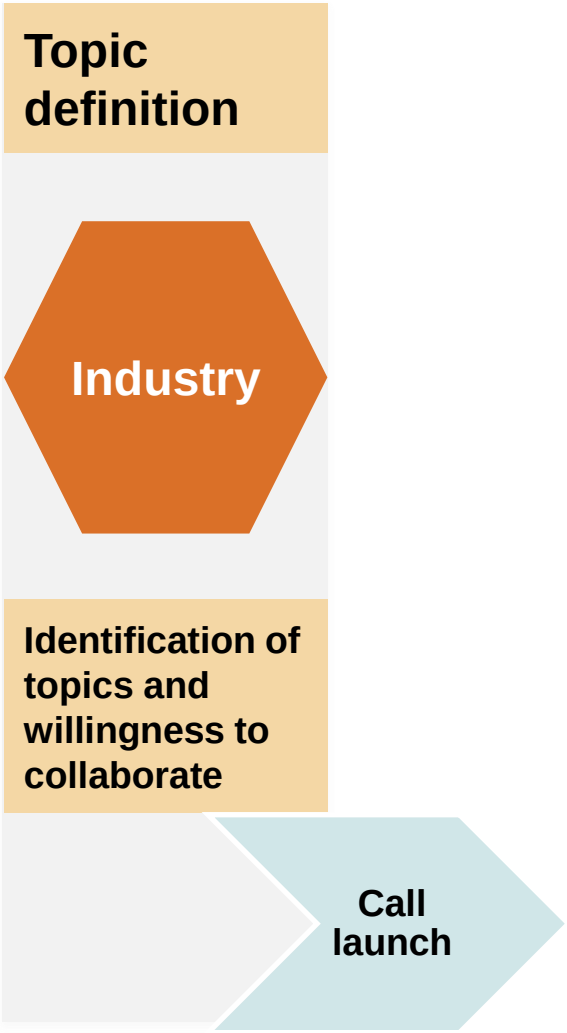
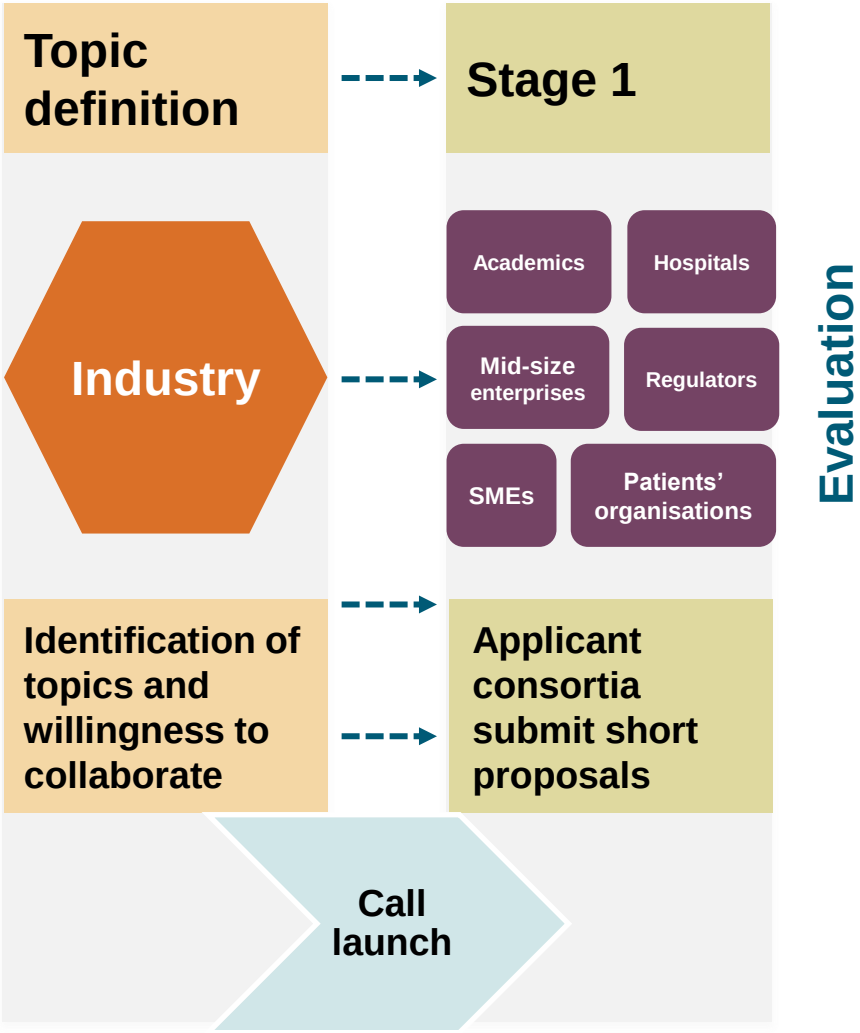
Typical IMI project life cycle



Typical IMI project life cycle



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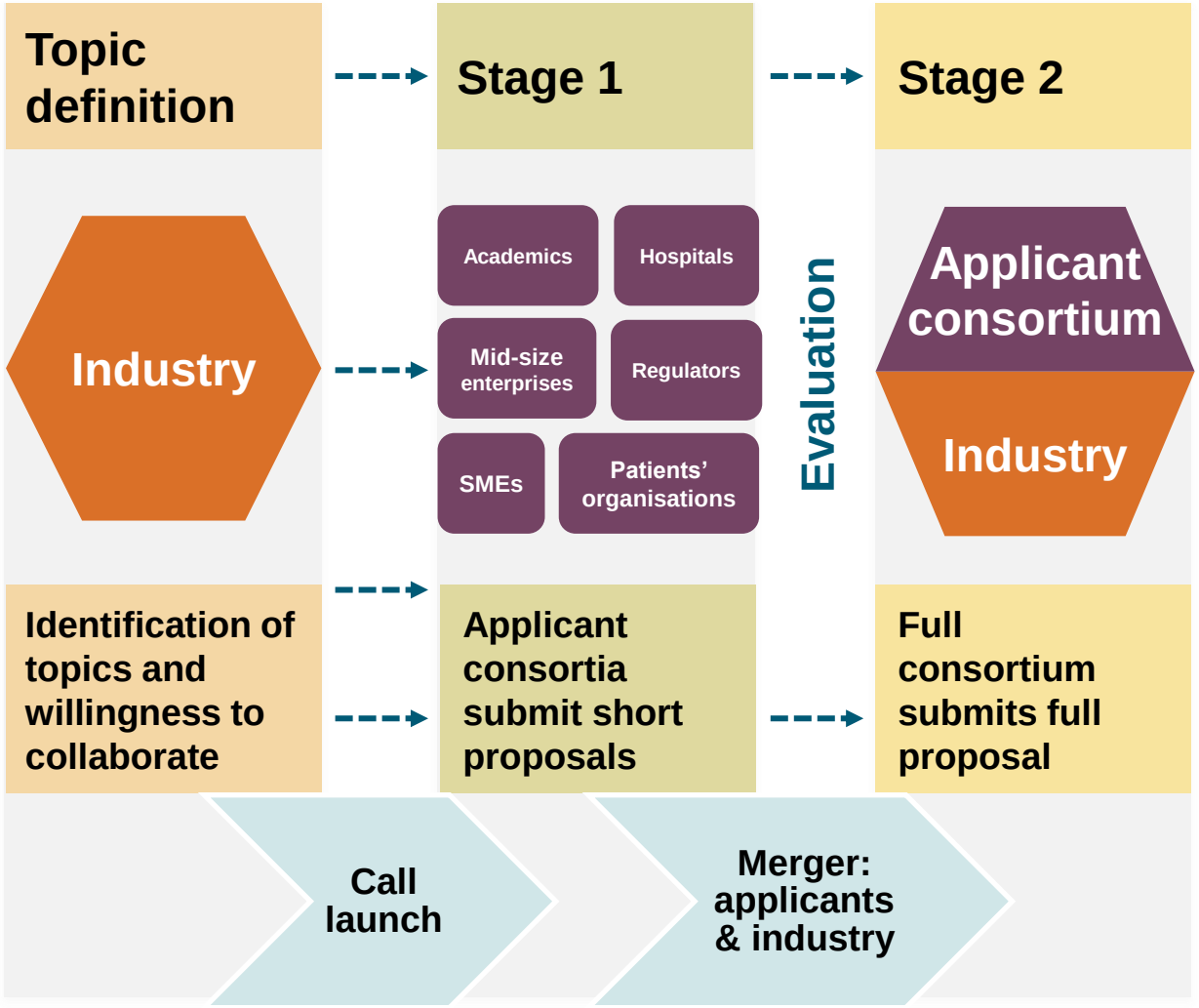
Typical IMI project life cycle



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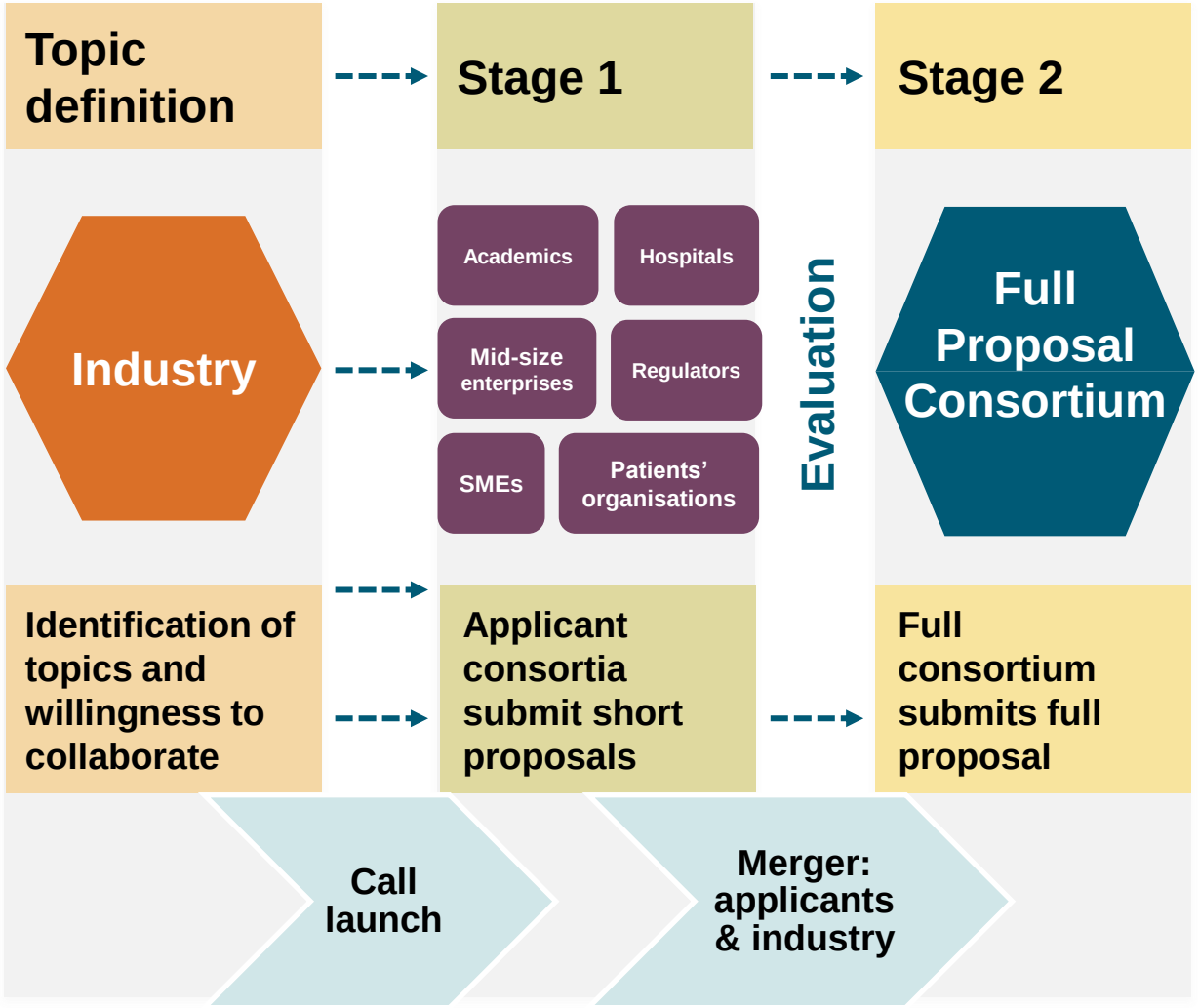
Typical IMI project life cycle



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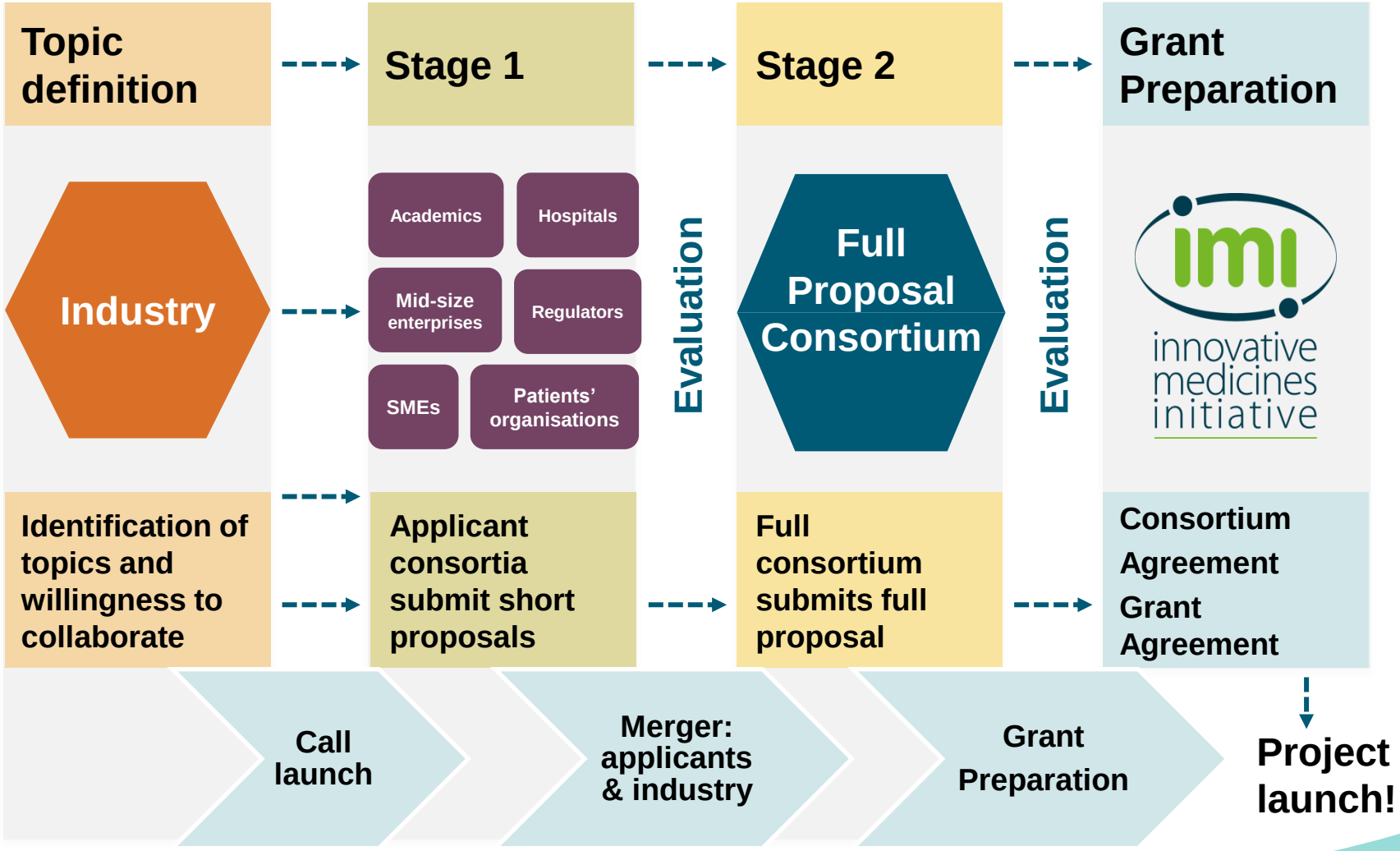
Typical IMI project life cycle



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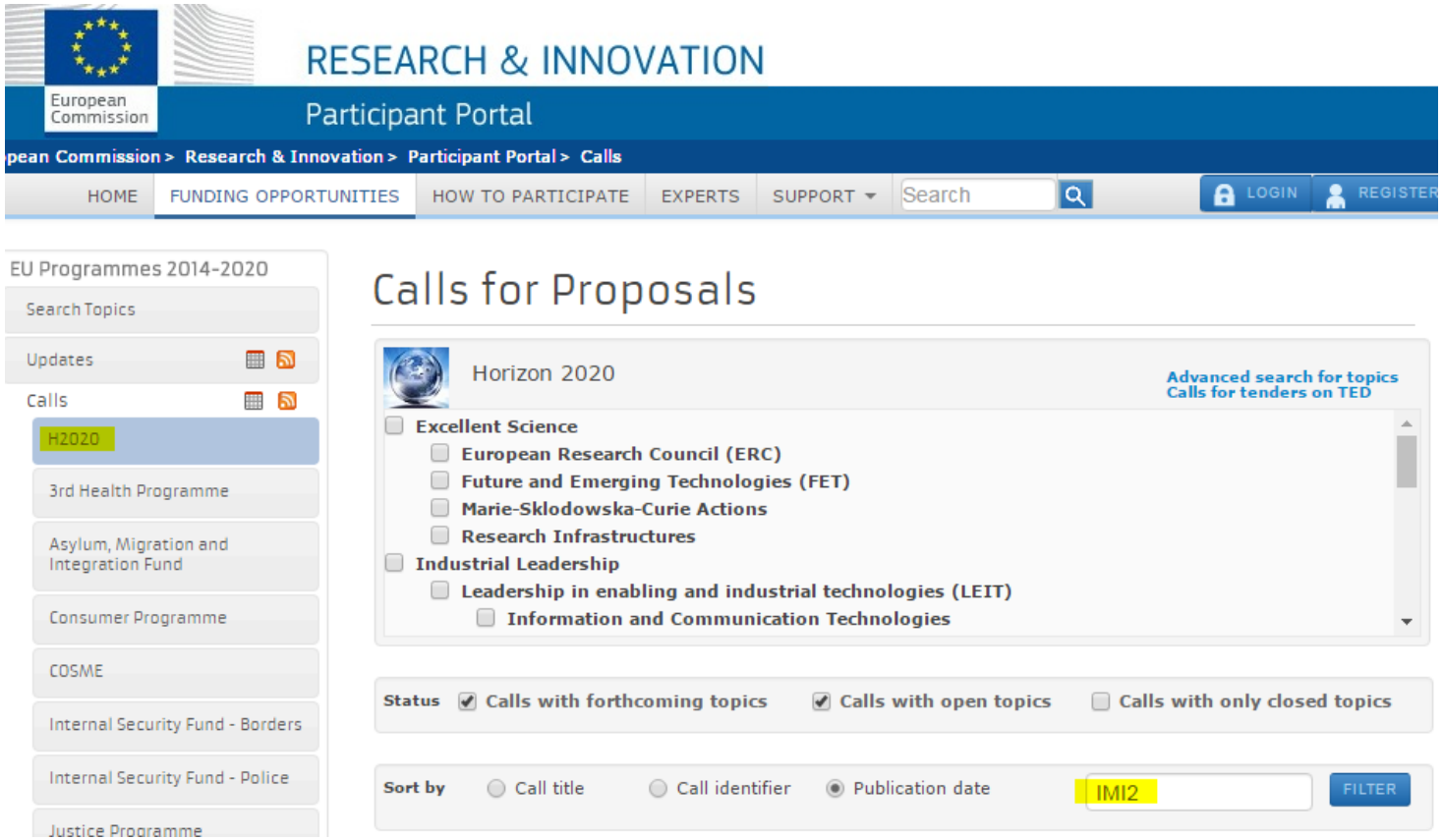
Submitting a proposal

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



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Proposal Template

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

Title of Proposal

List of participants

Table of Contents

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Evaluation Criteria (1/2)

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

Evaluation Criteria (2/2)

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

Tips for writing a successful proposal

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

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Common mistakes

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

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Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools:**
  - 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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Human Tumour Microenvironment Immunoprofiling

Ralph Lindemann, Merck Biopharma

01.12.2017 • IMI Webinar

Objectives of the full project

- Create a **database** containing
  - integrated cellular and molecular data from the **tumour microenvironment of patients** treated with (non-)targeted therapy, in particular **immunotherapy**
  - as well as key information from patient history and clinical progression that will **enable development** of **novel predictive biomarkers** and **rational combination treatments** in oncology.

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Need for public-private collaboration

- The project requires **access to large numbers of patient samples** from numerous clinical centres as well as collaboration of different partners to **analyse them for their molecular and cellular composition**.
- A collaborative effort is needed to **store and integrate patient and sample data according to agreed standards** to allow for comparability of data and further analyses. Bioinformatics expertise as well as IT and legal support will be needed.

- Industry consortium: Merck (lead), AbbVie, Bayer, Eli Lilly, GSK, Janssen/J&J, Sanofi, Servier, Pierre-Fabre

Pre-competitive nature

- Comprehensive database on human tumour microenvironment will benefit multiple public and private partners
- Ultimate aim is to open database to the general public
- Dataset can be the basis for own future analyses and research

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Expected impact

Key examples (*Please review carefully the respective section in the call topic text where detailed information can be found.)*

- Understand human tumour microenvironment and the immune cell infiltrate on a cellular and molecular level in unprecedented detail
- Identify potential predictive biomarkers to enrich for patients responding to immuno-oncology agents
- Identify mechanisms of inherent and acquired resistance towards immuno-oncology agents
- Understand how the tumour microenvironment modulates response to (non-)immuno-oncology therapy
- Inform rational combination treatment approaches to enhance immuno-oncology therapy
- Gain mechanistic understanding of disease progression

Suggested architecture of the project

Proposal for work packages (Please review carefully the respective section in the call topic text, pay attention to what are core versus supplemental activities and suggest matching allocation of resources)

WP	Description
1	Management & steering, coordination, sustainability planning; project management office
2	Communication, Public Relations, and involvement of Patient Advocacy Groups
3	Legal aspects
4.1	**Broad profiling:** immune cell detection and RNAseq **(Core activity)**
4.2	Deep profiling
5	Patients/indications: oversight sample banking and management, QC and ethics
6	Biomarker validation
7	Data integration and bioinformatics
8	Database and IT infrastructure

Key deliverables of the full project (1)

	Description
1	• A data set on presence and spatial distribution of immune cell subtypes in surgical specimen (wherever possible) and biopsies from specific tumour indications (see 3) • Centralized IHC or IF platform with harmonized workflow
2	• RNA seq analysis of all samples as profiled under 1
3	Criteria for sample selection • Lung adenocarcinoma, Head & Neck Cancer, Colorectal Cancer are fix • ICI failures from different indications • Indication as proposed by academic applicant (not: melanoma) • Min. 600 patients per indications envisaged • Emphasis on prospective studies and immune checkpoint therapy
4	Established and validated workflow for sample quality control, tracking and storage.
5	'Deep profiling' data set for a subset of tumour samples (~50-100 per indication) using advanced technologies, e. g. single cell RNA seq
6	Collection and banking of peripheral samples (blood, faeces) for all patients to enable future validation of potential biomarkers

Key deliverables of the full project (2)

	Description
7	Raw data repository with access for all consortium partners
8	Software and bioinformatics packages for full data integration and analysis as well as latest-generation image processing software
9	Database and IT infrastructure
10	Experimental validation packages and classifier signals for potential predictive biomarkers

Total financial contribution: 27.88 mEUR

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Suggested architecture of the project

Key guiding principles

- Public partners are asked to carry out the vast **majority** of the **hands-on work** whereas EFPIA partners contribute in-kind and financially
- **Steering** of the individual work packages and content decisions will be done **jointly** by the public and private partners.
- All **work packages** will be **co-led** by EFPIA and public partners and are expected to have adequate autonomy.

Expected contributions of the applicants

WP	Description
1	• Project coordinator • Professional project management expertise (daily operational support with project meetings, reporting and internal communication), e. g. through a project management office
2	• Carry out communication on project overall • Involve patient advocacy and other groups of interest, e.g. to support patient consent
3	• Ensure legal frame is compatible with deliverable • Implementation of legal frame to allow execution of all the deliverables, e.g. clearance by institutional or pan-consortium ethics committees, availability of IPCFs, data privacy, data repository and access, etc
4.1	• Input and expertise to selection of profiling technologies, antibodies, and immune cell subtypes to be analysed • Applicants are expected to carry out all broad profiling activities, including sample taking, staining, slide scanning, RNAseq, and analysis
4.2	• Input and expertise to selection of deep profiling technologies • Applicants are expected to carry out all deep profiling activities
5	• Possess or deliver workflows for sample collection, quality control, tracking, storage, banking and maintenance, also linked to legal frame, and implement and carry them out for the project

Expected contributions of the applicants

WP	Description
6	• Input to idea generation and execution of biomarker validation
7	• Input to and implementation of software and bioinformatics packages for full data integration and analysis • Carry out data analysis
8	• Implement a raw data repository, upload and maintain data, make data accessible to different consortium members • Develop and implement a sustainable database/IT infrastructure

Expected consortium frame (key items)

- Access to tumour tissue and matched blood samples from patients with informed patient consent forms in place for the full duration of the consortium and beyond
- Experience and technical expertise
  - Tumour microenvironment immunoprofiling and RNAseq
  - Advanced profiling technologies (see topic text for details)
- Experience in handling, analysing and integrating complex data sets including housing a open-access database beyond consortium frame
- Propose plan for aspects related to sustainability
- Ability to coordinate a large research initiative and to create a scientific network, involve patient advocacy groups where needed

Criteria for evaluation of applications
http://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_EvaluationForm_RIA-IA_April2016.pdf

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High-level expected (in kind) contributions of industry consortium

- EFPIA partners contribute in-kind and financially – the public partners are asked to carry out centrally the vast **majority** of the **hands-on work**
- Drive content jointly
- Work package co-leadership
- Hands-on contribution by industry to include
  - Contribution to database / IT solutions and bioinformatic analyses
  - Contribution to biomarker validation studies

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What's in it for you?

Public partner	Potential benefit
Academic partners	• Access to completely novel multi-dimensional data set • Opportunity to publish in leading journals • Improved validation and development of novel procedures and workflows for immune cell detection in clinical samples • Insights to help improve clinical trial design and treatment selection • Insights into industry standards and requirements for biomarker development
SMEs	• Access to completely novel multi-dimensional data set that may be used to test own proprietary platforms, algorithms and IT tools • Insights into key pathology and imaging protocols and their robustness

Thank you

www.imi.europa.eu
@IMI_JU

Involvement of SMEs, patient groups, regulators

Karroum Oussama
01.12.2017

SME participation

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

For example, some ‘deep profiling’ technologies might be established during the course of the project or could be performed by SMEs.

Patient participation

Patient organisations or patient advocacy groups could be consulted, e. g. regarding

- Design of the patient consent form
- Relevant communication about the project and its potential value into the respective cancer patient communities
- Dissemination of the project results

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

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

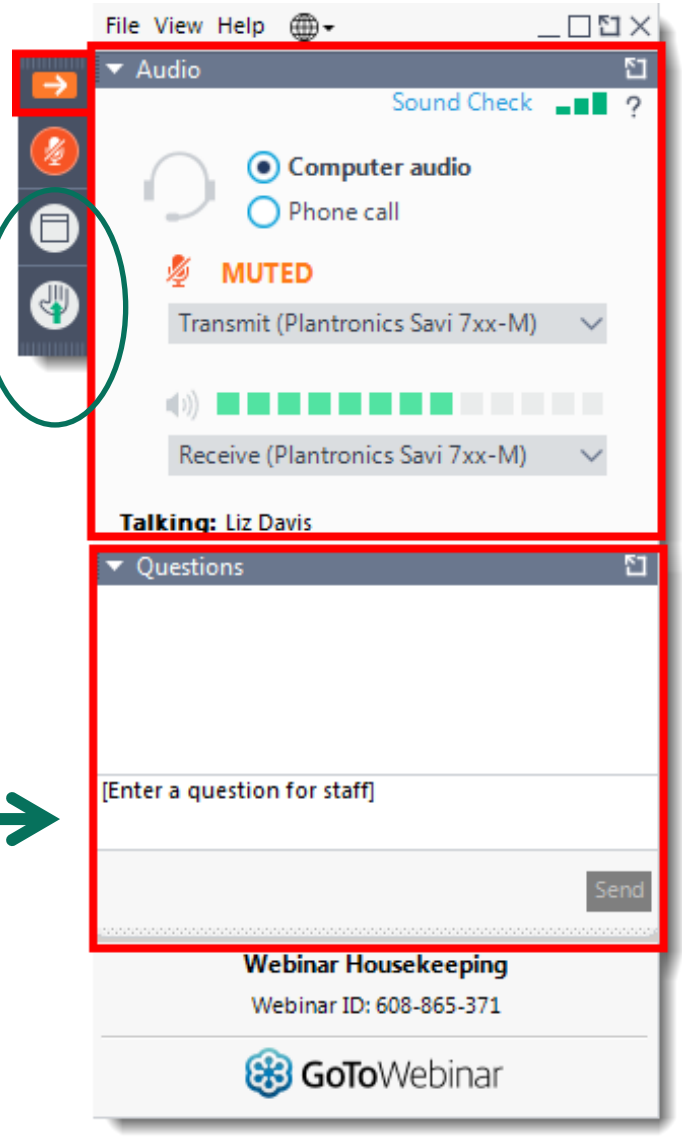
More info: 'Raising awareness of regulatory requirements: A guidance tool for researchers'

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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