

Webinar | IMI2 – Call 14

Non-invasive molecular imaging of immune cells

9 April 2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Isabella Tamagnini, IMI
- The Call topic – Wouter Driessen, Roche
- Opportunities for patient groups and SMEs – Isabella Tamagnini, IMI
- Questions & answers

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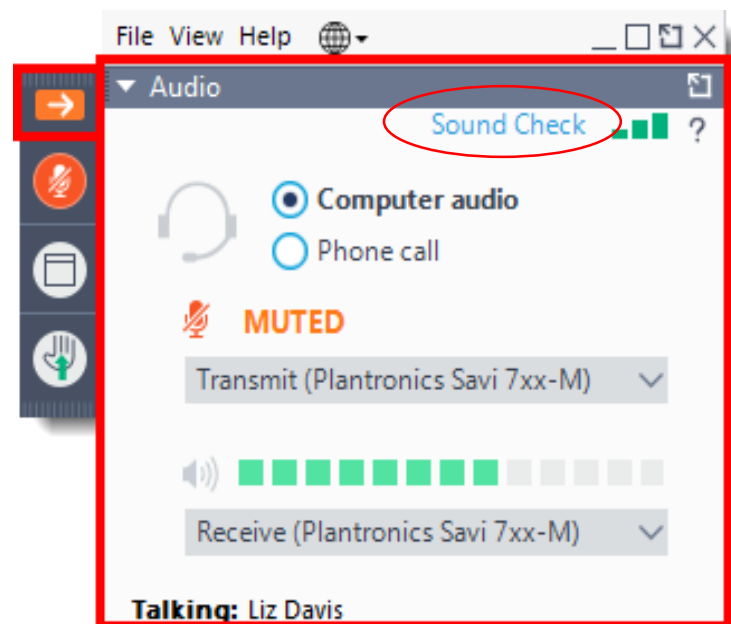
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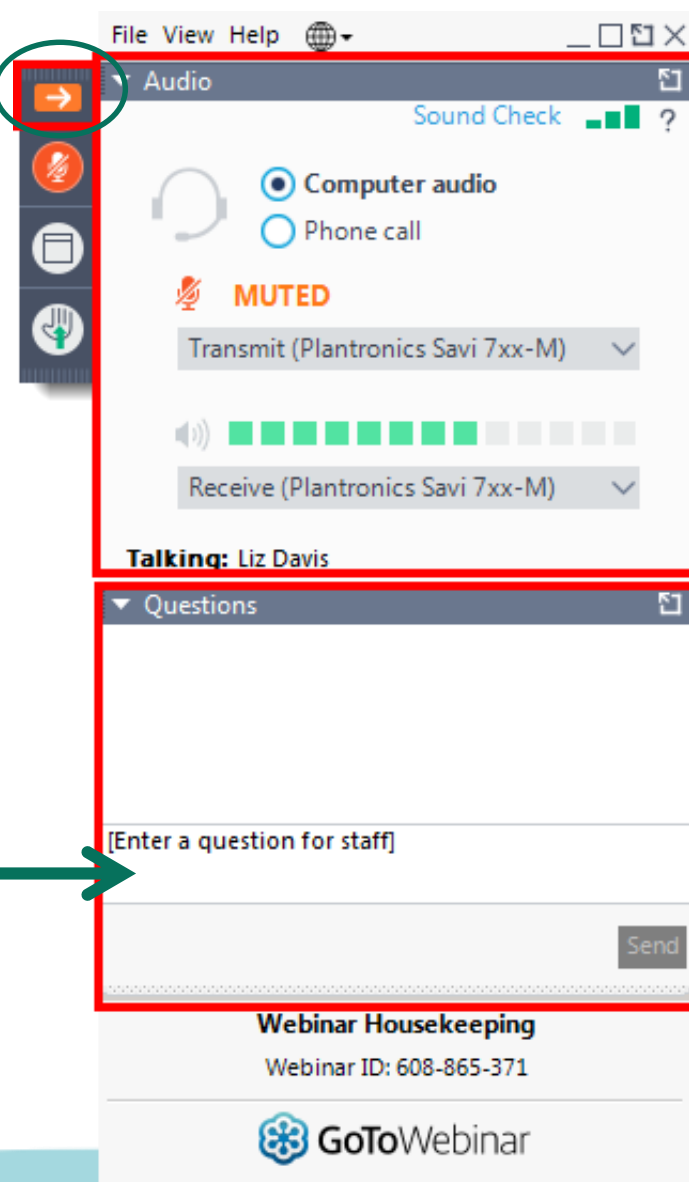
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question orally

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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
- IMI2 – Call 14 has been launched and all Call documents & details of how to apply can be found on the IMI website

Webinar | IMI2 - Call 14

Non-invasive clinical molecular imaging of immune cells

Isabella Tamagnini

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 Wednesday 11 April, 10:30-12:00

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.

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**.

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

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

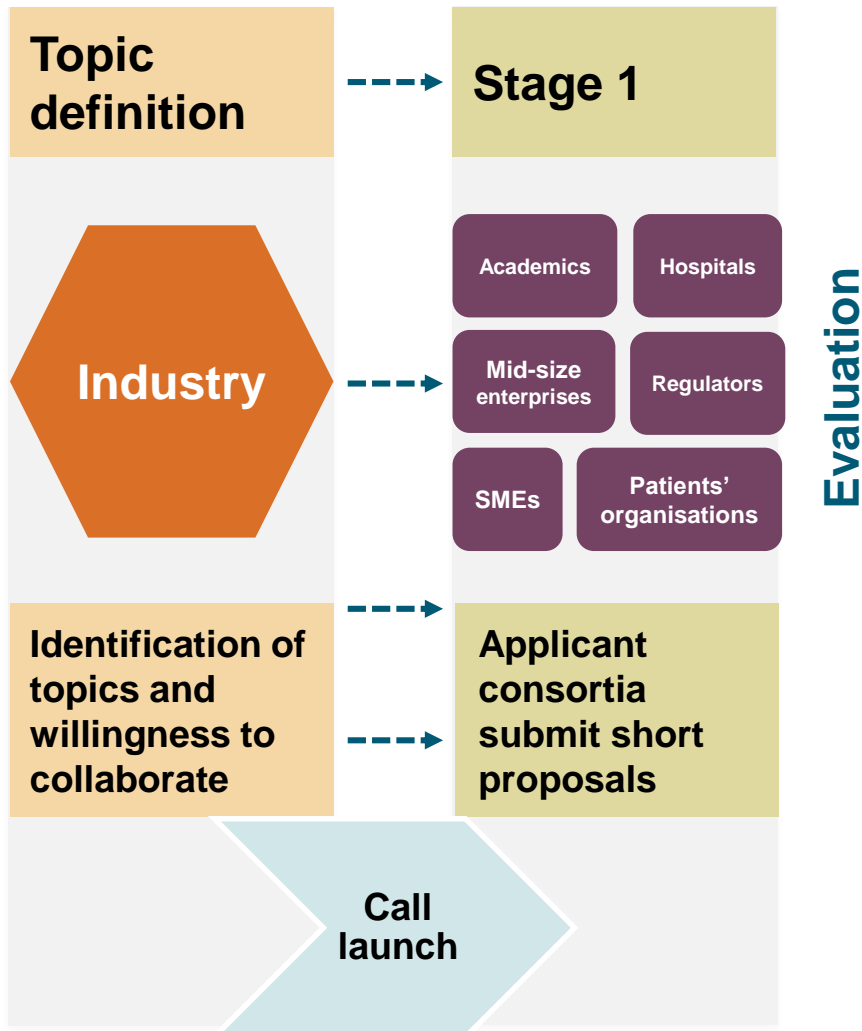
Scale is a key to success and is provided through IMI funding

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

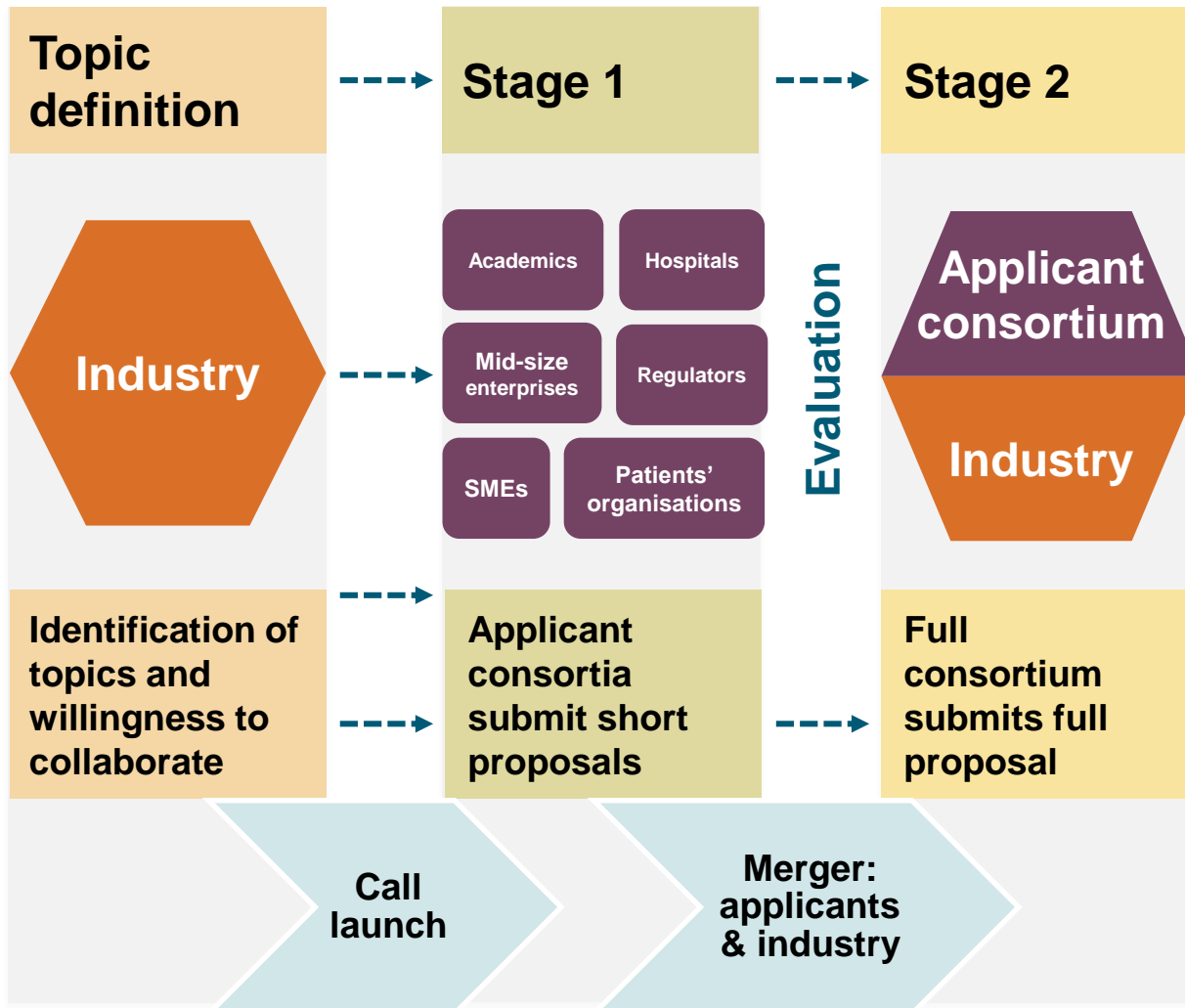
Typical IMI project life cycle



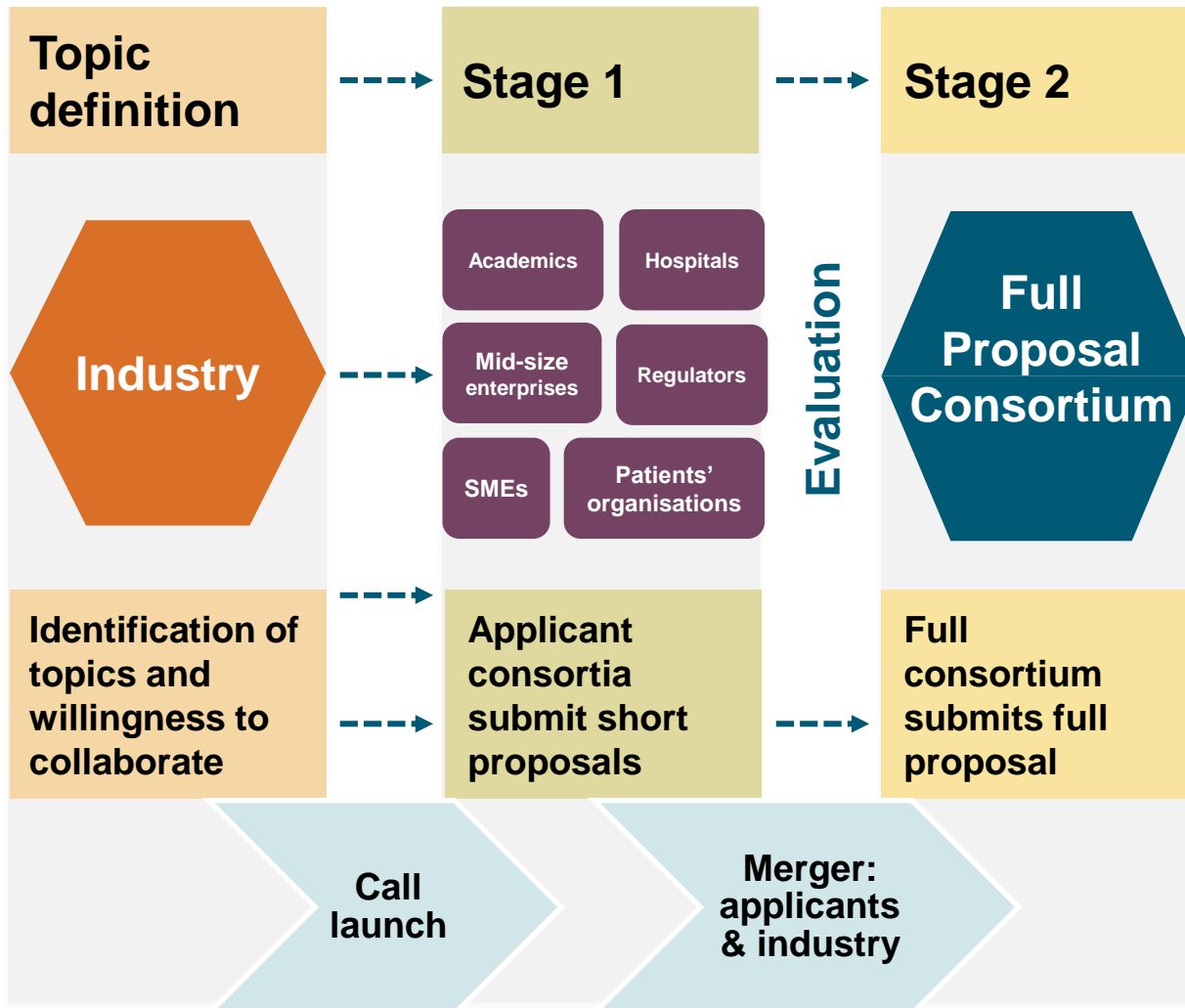
Typical IMI project life cycle



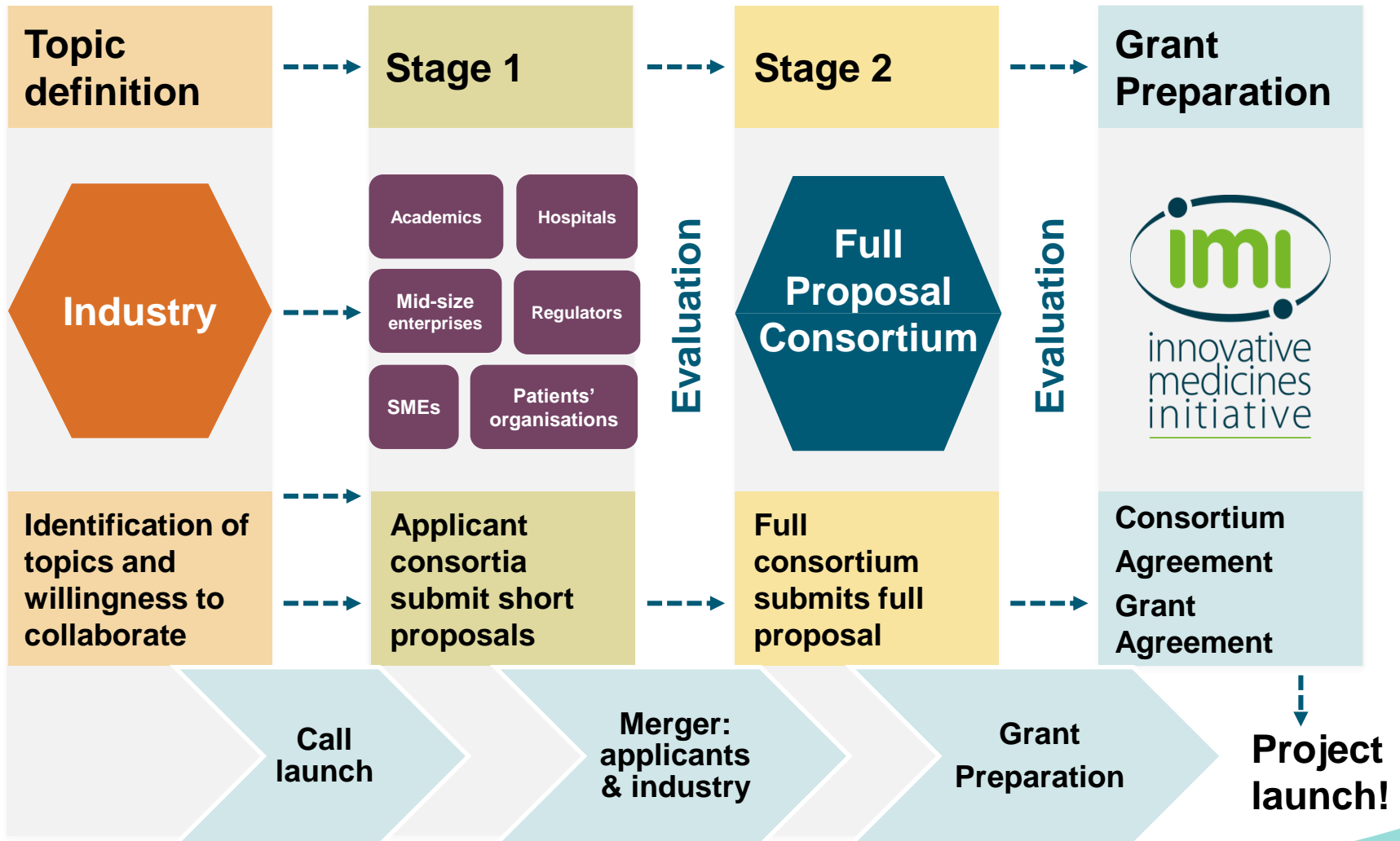
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



Submitting a proposal

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

The screenshot displays the 'Participant Portal' for 'RESEARCH & INNOVATION' by the European Commission. The main navigation bar includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A search bar and 'LOGIN'/'REGISTER' buttons are also present. The left sidebar lists 'EU Programmes 2014-2020' with categories like 'H2020', '3rd Health Programme', and 'Asylum, Migration and Integration Fund'. The main content area is titled 'Calls for Proposals' and features a 'Horizon 2020' section with a list of topics: 'Excellent Science' (including ERC, FET, Marie-Sklodowska-Curie Actions, and Research Infrastructures) and 'Industrial Leadership' (including LEIT and ICT). Below this, there are filters for 'Status' (Calls with forthcoming topics, open topics, or only closed topics) and 'Sort by' (Call title, Call identifier, or Publication date). A search filter 'IMI2' is entered in the search bar, and a 'FILTER' button is visible.

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

1. EXCELLENCE	3. IMPLEMENTATION
1.1 Objectives	3.1 Outline of project plan — Work packages, and major deliverables
1.2 Relation to the call topic text.	3.2 Management structure and procedures
1.3 Concept and approach	3.3 Consortium as a whole
1.4 Ambition	3.4 Table 3.1a: List of work packages
2. IMPACT	4. PARTICIPANTS
1 Expected impacts	4.1. Participants (applicants)

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

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.

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)

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 14 web page*
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)

Non-invasive clinical molecular imaging of immune cells

Need for public-private collaboration

- Ambitious proposal with the aim to develop a set of **transformational clinical imaging agents and protocols**
- Topic focuses on the cell phenotype and function of various immune cells, in **various disease areas** involving widely **differing organ/tissue systems**
- Successful implementation requires a very **broad spectrum of diverse technical and biological expertise**; a combination unlikely to be within the scope a single company or organisation.
- The topic provides opportunity for a unique public-private partnership platform of leading experts from industry, academia and regulators with expertise in immunology, imaging technologies, data management, analytics and regulatory sciences.

Objectives of the full project (I)

- Develop and validate a quantitative, non-invasive, immune cell imaging platform, which includes novel molecular imaging agents, imaging modalities, and image processing algorithms, ultimately to be used in the clinic
- Clinical validation of existing imaging agents (e.g. agents targeting CD8+ T-cells and immune pathways)
- Development and characterisation of novel molecular imaging agents to be used for imaging immune cells of broad interest:
 - CD4-, CD8-, and regulatory T-cells, B-cells, macrophages and NK-cells
 - Phenotypic imaging agents as well as markers of their activation status are of great interest

Objectives of the full project (II)

- Establishing molecular imaging platforms in disease areas for which biopsies can be obtained
 - Biopsies are for validation purposes, but the objective is to identify tracers that could subsequently be used for other disease areas
 - Examples include cancer, chronic obstructive pulmonary disease (COPD) / asthma, atopic dermatitis, vasculitis, psoriasis, Sjögren's syndrome, inflammatory bowel disease (IBD), rheumatoid arthritis (RA), and transplant tissue, further disease areas may be identified by the consortium
- Optimising the quality of immunotracers to ensure appropriate specificity of binding, as well as pharmacokinetic (incl. characterisation of ADA if applicable) and bio-distribution profiles

Objectives of the full project (III)

- Implementation of non-invasive imaging modalities that can deliver quantitative data
 - Whole-body imaging technologies with the capability to image deep-seated tissue/tumours are preferred (e.g. PET, SPECT, MRI, hybrid modalities, PET/SPECT-CT), but depending on the disease area other non-ionizing methods or pre-targeting approaches can be evaluated (e.g. optical imaging and/or photoacoustic imaging of skin lesions, salivary glands, endoscopic/bronchoscopic examinations for IBD, COPD)
- Pre-clinical studies to evaluate and validate the novel molecular imaging agents/immunotracers and the immune cell imaging platform as required as a proof of concept to enable translation into the clinic.

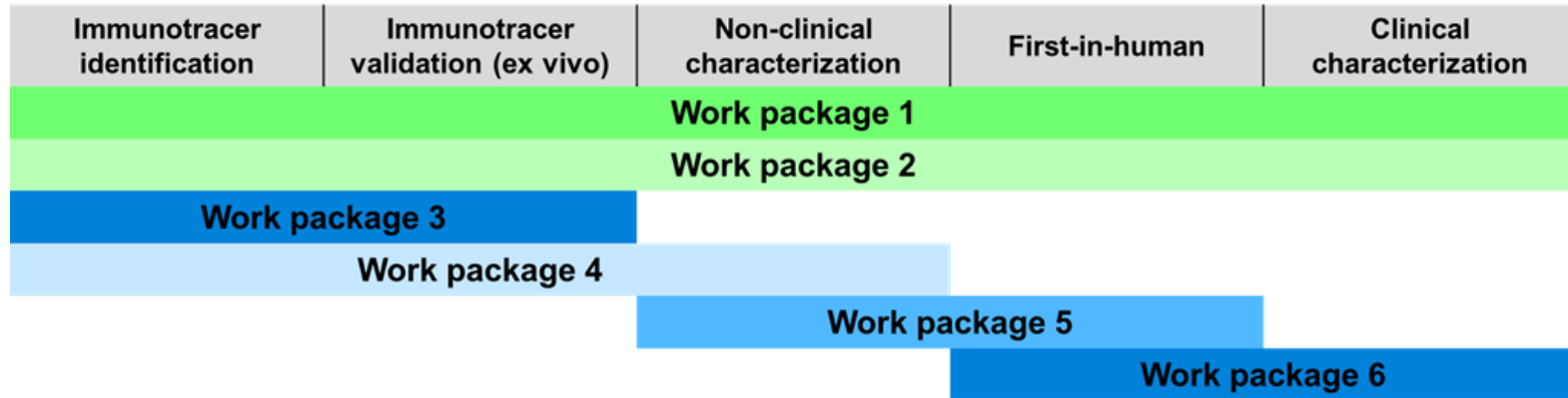
Pre-competitive nature

- Public/Private efforts will be combined to demonstrate the medical value and patient benefit of novel imaging technologies aiming to improving patient outcomes;
- Project-generated experience and expertise will be openly shared and should lead to development of innovative imaging approaches;
- 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.

Expected impact

- Longitudinal, clinical imaging with specific immunotracers opens many opportunities in personalised medicine approaches:
 - Reduction of ambiguity in the evaluation of efficacy by facilitating PoM and PoC studies
 - Target engagement within tissue of interest
 - Early surrogates of response
 - Reduction of the implementation of treatment regimens that are unlikely to be efficacious
 - Patient stratification based on immune status
 - Prediction of response / long-term outcome
 - Dose selection, including personalised dosing

Suggested architecture of the project



- The final architecture of the full proposal will be defined by the participants
 - WP 1&2: More administrative focus (coordination and management, data dissemination, storage, and analysis etc.)
 - WP 3: Generation of imaging agents
 - WP4: Imaging technique (e.g. modality, reconstruction algorithms)
 - WP5: Non-clinical in vivo characterisation
 - WP6: Clinical characterisation

Expected contributions of the applicants (I)

- Coordination and data management of a multi-centre, multi-node clinical-research project
- Identification and evaluation of promising molecular imaging agents
 - generation of immunotracers for at least two of the following key cell types of interest: CD4+, CD8+, regulatory T-cells, B-cells, NK-cells, and macrophages
 - immunotracer optimization in the context of the planned use (e.g. with respect to pharmacokinetic and bio-distribution profile, suitability for repeated use in longitudinal studies)

Expected contributions of the applicants (II)

- Biological validation of specific immunotracers in well-characterised experimental animal models; proof of principle preclinical imaging studies using known therapeutic interventions
- Contribute towards the preparation of regulatory documentation (Investigator Brochure, clinical protocol, Clinical Trial Application dossier etc.)
- Co-coordination of work packages, budget administration, dissemination of scientific results and development of a sustainability plan

Expected (in kind) contributions of industry consortium

- The industry consortium includes expertise in clinical operations, protein engineering, validation of immune cell targeting, and will contribute mainly in the form of:
 - provision and characterisation of antibodies, antibody fragments, and/or small molecule probes
 - prospective clinical trials for selected diseases (immunotracers to be applied in these prospective on-going clinical trials with dedicated imaging activities)
 - samples from prospective clinical trials
 - immuno-histochemical and other appropriate analyses of biopsy material to validate the imaging results
 - historical samples for validation
 - -omics data analysis

What's in it for you?

- Collaborate with enthusiastic partners on the development of a set of **transformational clinical imaging agents and protocols**
- Work on novel ideas, for which we have to make the way while we walk it. We can influence the field of immune cell imaging
- Provide healthcare with novel methods for implementing personalised medicine
- Access to unique reagents and biosamples for validation of imaging tracers
- Access to high quality, clinic-ready compounds and clinical research funding
- Grow your network to develop clinical imaging agents
- Opportunity for high impact publications

Key deliverables of the full project

- Identify and evaluate molecular imaging protocols (*i.e.* tracer, modality, image processing/analysis)
 - For at least 2 of the cell types of broad interest: CD4 T-cells, CD8 T-cells, T-reg, B-cells, NK-cells, macrophages
- Tracer optimisation (e.g. pharmacokinetic properties, biodistribution profile, longitudinal studies)
- Appropriate (semi-)quantitative sensitivity and resolution to allow determination of relative changes
- Clinical proof-of-concept with at least one tracer
- Co-registration and multi-modality approaches



Thank you

www.imi.europa.eu

 @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.

Under this topic, the contribution of SMEs would be considered especially beneficial in areas that include:

- imaging agents and technologies
- advanced analytical approaches
- data management practices
- etc.

Patient participation

IMI encourages applicants to consult patient organisations or patient advocacy groups, e.g. regarding:

- patient consent forms
- relevant communication about the project and its potential value
- dissemination of the project results
- etc.

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](#)



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**

applicants@imi.europa.eu

A screenshot of a webinar interface. The top part shows the 'Audio' control panel with options for 'Computer audio' and 'Phone call'. A 'MUTED' indicator is visible. Below the audio controls is a 'Questions' panel with a text input field containing '[Enter a question for staff]' and a 'Send' button. At the bottom, there is a 'Webinar Housekeeping' section with the 'Webinar ID: 608-865-371' and the 'GoToWebinar' logo. A red border highlights the audio and questions panels. A green circle highlights the 'Raise Hand' icon in the audio panel, and a green arrow points from the text 'Raise your hand if you want to ask a question orally' to this icon. Another green arrow points from the text 'Send a question in writing' to the 'Questions' panel.