



Webinar | IMI2 – Call 13

Genome-environment interactions in inflammatory skin disease

15 December 2017 • 15:00 CET

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Iwona Jablonska, IMI
- The Call topic – Paul Bryce & Peter Hecht, Sanofi
- Involvement of SMEs, patients and regulators – Iwona Jablonska, IMI
- Questions & answers

How to use GoToWebinar - audio

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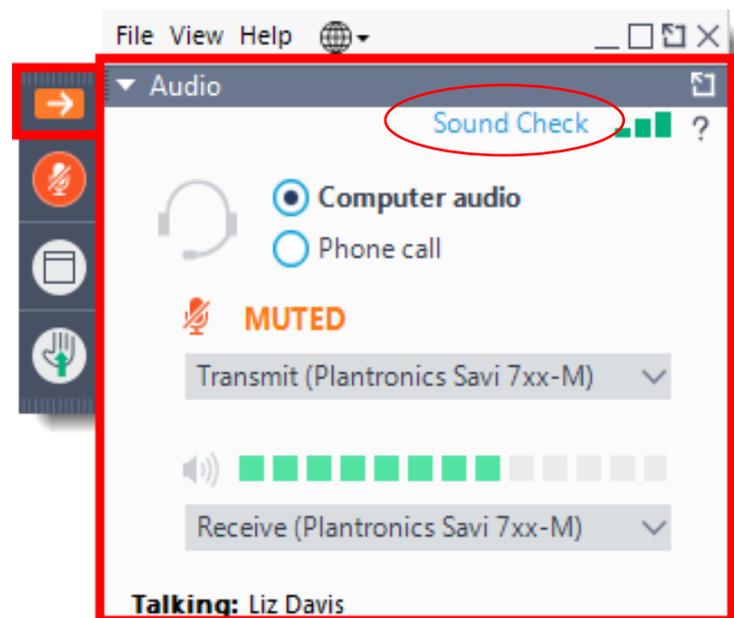
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How to use GoToWebinar

Expand / minimise control panel →

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Raise / lower your hand
e.g. if you want to ask a
question orally

Send a question in writing →

The screenshot shows the GoToWebinar control panel interface. A red border highlights the main control area. On the left, a vertical toolbar contains several icons: a right-pointing arrow (highlighted with a red box), a microphone with a slash (Microphone status), a square with a diagonal line (Full screen), and a hand with a green dot (Raise/Lower hand). The main panel displays the 'Audio' settings, including 'Sound Check', 'Computer audio' (selected), 'Phone call', and a 'MUTED' status. Below this, there are dropdown menus for 'Transmit' and 'Receive' (both set to 'Plantronics Savi 7xx-M'). A 'Talking:' indicator shows 'Liz Davis'. The 'Questions' section is visible below, featuring a text input field with the placeholder '[Enter a question for staff]' and a 'Send' button. At the bottom, the webinar title 'Webinar Housekeeping' and ID '608-865-371' are shown, along with the GoToWebinar logo.

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

Webinar | IMI2 - Call 13

Topic 2: Genome-Environment Interactions in Inflammatory Skin Disease

Iwona Jablonska

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

- **Webinars on IMI's rules and procedures and opportunities for SMEs** took place on Thursday 7 December – recordings are available online
- Both will be repeated in January 2018 – sign up via imi.europa.eu

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

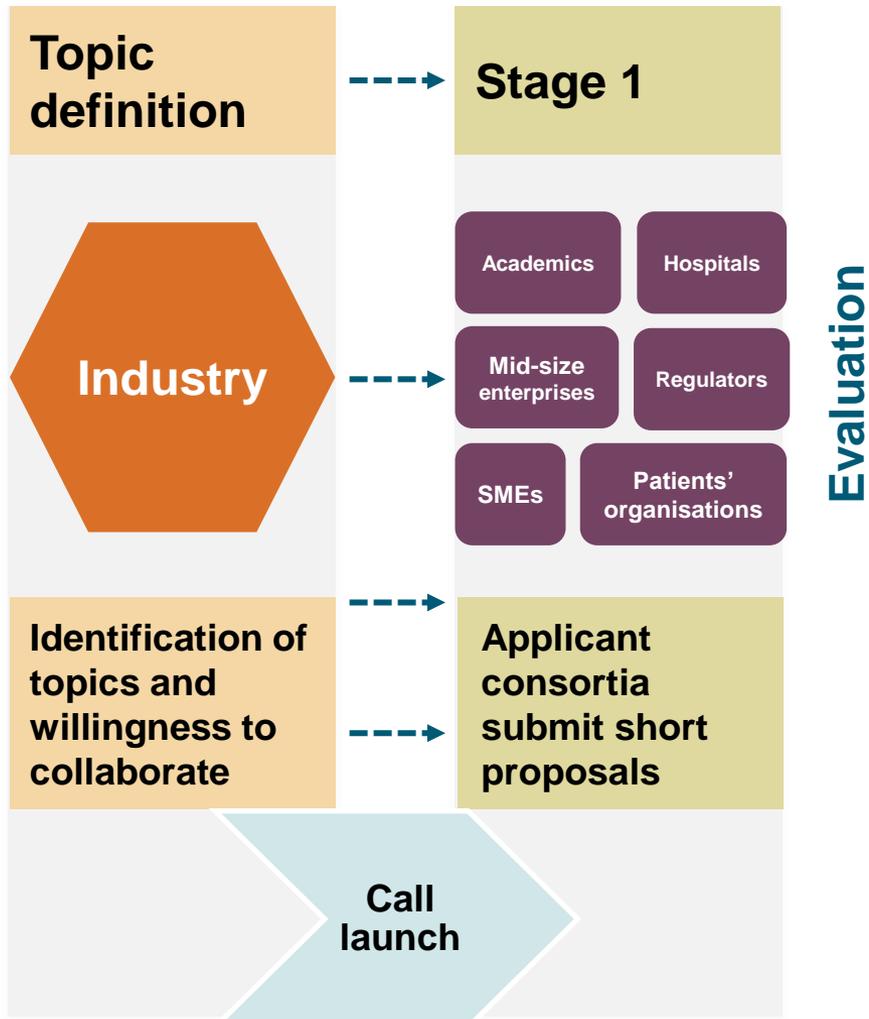
Scale is a key to success and is provided through IMI funding

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

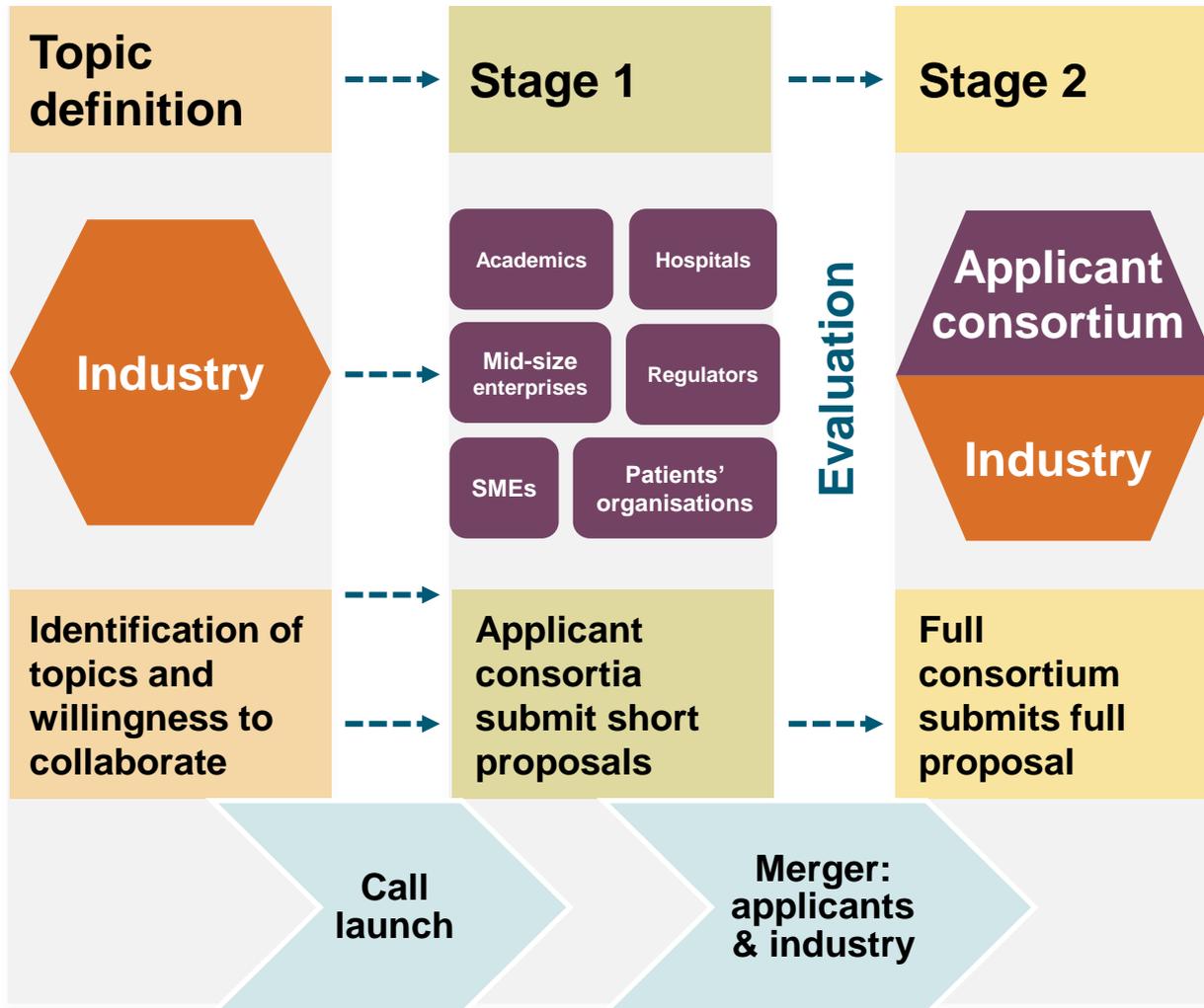
Typical IMI project life cycle



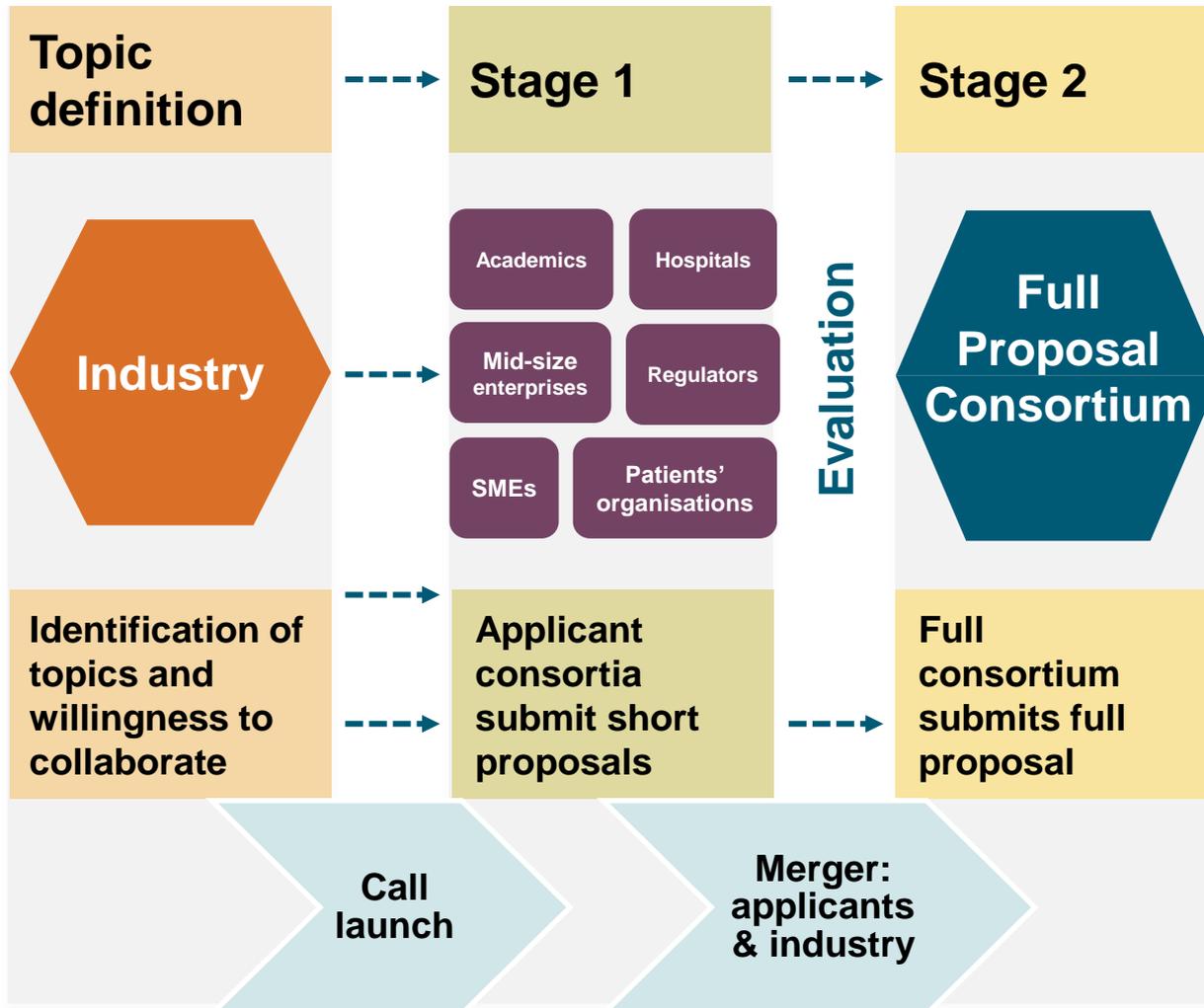
Typical IMI project life cycle



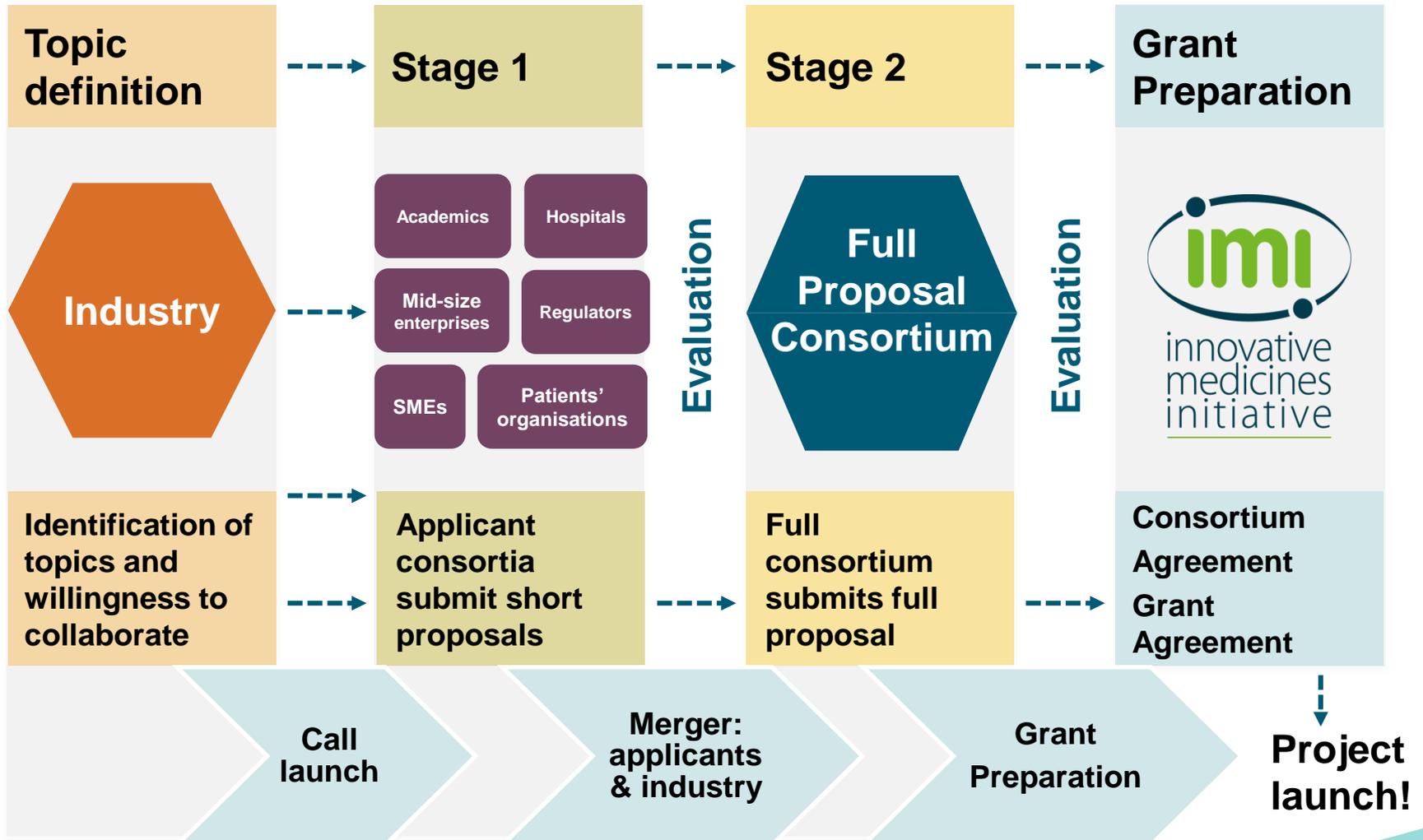
Typical IMI project life cycle



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 'Search Topics', 'Updates', and 'Calls', where 'H2020' is highlighted. The main content area is titled 'Calls for Proposals' and features a 'Horizon 2020' section with a globe icon and a link for 'Advanced search for topics Calls for tenders on TED'. Below this, there are filterable categories: 'Excellent Science' (including ERC, FET, Marie-Sklodowska-Curie Actions, and Research Infrastructures) and 'Industrial Leadership' (including LEIT and ICT). A 'Status' filter is set to 'Calls with forthcoming topics' and 'Calls with open topics'. The 'Sort by' dropdown is set to 'Publication date', and a search filter 'IMI2' is entered in the search box.

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

Genome-Environment Interactions in Inflammatory Skin Disease

P. Bryce – Sanofi: Scientific Lead

P. Hecht – Sanofi: IMI Alliance Mgmt

Background & Objective

- Inflammatory skin diseases affect a significant percentage of our global population. Atopic Dermatitis (AD) affects approximately 10% of children and 3% of adults worldwide. Psoriasis (Pso) affects approximately 2% of our population.
- Poor understanding of their mechanism, endotypes, ontology and co-morbidities, affecting the quality of effective treatments.
- While there may be aspects of these diseases that overlap, others show little or no similarities e.g. their associated co-morbidities are generally quite distinct with Pso being linked with arthritis, psychiatric disorders, metabolic syndrome and cardiovascular sequelae while AD is associated with rhinitis, asthma, food allergy as well as cardiovascular complications.
- Need for sophisticated, in-depth investigations of these diseases that address transformative topics. These studies include, but are not limited to, the impact of environmental factors (e.g. via the microbiome) interacting with genomic factors and studies that help elucidate molecular pathways of disease in a comprehensive, patient-driven manner.
- To define the key heterogeneous and homogeneous aspects of AD and Pso, both within each disease and across their shared biology.
- Such characterization can include clinical hallmarks, patient epidemiology and reported outcomes, and assessment of molecular signatures.
- Expanding our current knowledge to understand unique endotypes of inflammatory skin diseases will help give rise to more precise, targeted treatments that can yield long lasting reductions in disease burden and improved patient quality of life, fulfilling unmet medical needs in patient care.

Need and opportunity for public-private collaborative research

This complex issue can only be adequately addressed by a **combination of collaboration and specialised expertise**. Specific contributions to a collaborative effort would likely be:

- Pharmaceutical companies possess access to clinical trial samples related to Psoriasis and AD, and the expertise in specialised technologies that can be applied;
- Academia has the clinical expertise and patient access (both retrospective and prospective) needed, as well as unique, state-of-the-art technologies;
- Patients and caregivers, as well as advocacy groups related to these diseases, provide important inputs into the real-world issues related to inflammatory skin diseases;
- Small- and Medium-sized Enterprises (SMEs), businesses with appropriate interests and Contract Research Organisations may contribute to centralised development of key output information and deliverables.

Scope:

- To lead to a step change in our understanding of the molecular mechanism and ontology of the two main inflammatory skin diseases: AD and Pso.
- Elucidating the molecular pathways of these inflammatory skin conditions over time will give rise to novel and meaningful therapeutic targets for specific patient populations and help address the complex patterns of co-morbidities.
- Identify biomarkers that will enable robust, efficient and meaningful patient management.

These objectives should be achieved both via a retrospective assessment of Pso and AD patients that can aid in defining key endotypes of disease and the disease commonalities and uniqueness, as well as via access to ongoing prospective studies that will embrace novel approaches and hypotheses relating to defining these. It is expected that reliable access to robustly defined clinical information and specimens will be vital to the overall scope.

Expected key deliverables

- Identify shared and distinct disease mechanisms of AD and Pso
- Establish a new disease ontology by defining distinct and overlapping inflammatory skin disease endotypes and co-morbidities
- Identify molecular, immunological and microbial biomarkers that inform prognosis and response to therapy of patients suffering from inflammatory skin disease – these deliverables should be capable of improving diagnosis and directed care decisions

Participation and budgets

- Participating companies:
 - Sanofi (Lead)
 - Boehringer Ingelheim
 - Pfizer
 - UCB
- The indicative industry in-kind contribution is EUR 8 300 000
- The financial contribution from IMI2 JU is a maximum of EUR 10 500 000 (tbc)
- The indicative duration of the action is 60 months

Expected in-kind industry contribution

- Pharma companies have contributions are framed across the needs of the work-flow and include management support, methodological expertise and training, access to specimens and samples and data-management and data control. The specifics of each partner are listed in the call topic text
 - **Sanofi (Project Leader)**
 - Scientific leadership and alliance management
 - Access to precision based technologies and bioinformatic capabilities. clinical and translational expertise and access to resources that are necessary for regulatory oversight and ethics.
 - **Boehringer Ingelheim**
 - postdoctoral scientists embedded within members of the consortium.
 - Support for activities immune cell assays, (prospective & retrospective cohorts)
 - **Pfizer:**
 - samples from ongoing prospective clinical trials
 - advanced technologies (e.g. single cell analysis from skin, lipidomics, epigenetics) that cannot be performed on retrospective samples.
 - contributions to the clinical and molecular profiling needs important to assessing endotypes of AD and Pso.
 - **UCB:**
 - Internal FTEs for clinical and molecular profiling
 - Support Data management and capture needs

Applicant consortium

- Access to existing samples relevant to the skin disease topic (especially AD and/or Pso), as well as access to *de novo* samples from ongoing collection.
- Access to clinical epidemiology information related to skin diseases through comprehensive medical records.
- Highly specialized techniques of relevance to the overall topic and science of skin and inflammation, including microbiome assessment, and bulk and/or single-cell analysis of transcriptomics, lipidomics, metabolomics; inclusion of precision-based approaches to this is considered a strength.
- Provide state-of-the-art approaches to studying skin biology, including 3D organotypic cultures.
- advanced modelling of human diseases based on multi-parameter data streams

Since access to clinical information and specimens is critical to the overall success of defining endotypes and the consortium goals, applicants should demonstrate their capacity (e.g. patient consent or waiver to consent) and quality to provide access to these

Involvement of SMEs, patient groups, regulators

Iwona Jablonska

SME participation

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

- The applicant consortium must demonstrate significant experience, possibly through the participation of an experienced SME, in both Advanced Analytical approaches and strong Data Management practices.
- The contribution of SMEs would be considered especially beneficial in the context of professional data management and orchestrating data collection, analysis and availability to the rest of the consortium in a centralised, scalable and sustainable manner.

Patient participation

Expected impact on clinical, healthcare practices and ultimately on patients' lives:

Understanding of early life events and environmental influences over disease progression and severity will support improvement in physician recommendations and management of patients.

Need for patients participation

Patients and caregivers, as well as advocacy groups related to these diseases, provide important inputs into the real-world issues related to inflammatory skin diseases

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

Regulators

Expected impact on regulatory aspects:

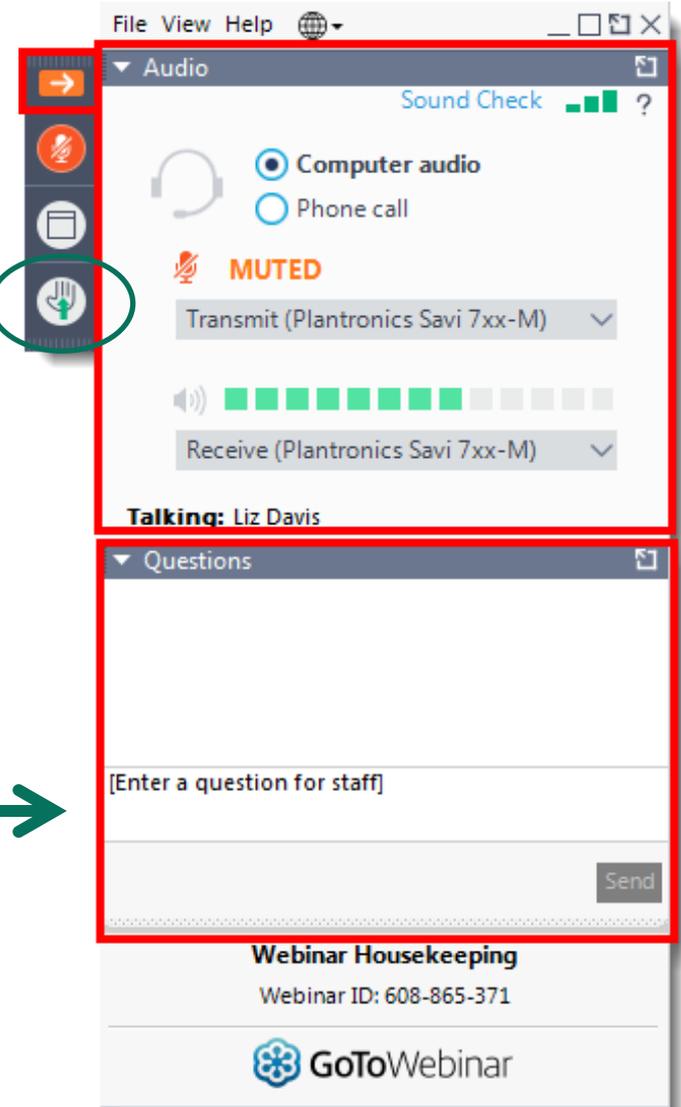
Regulatory Pathways and Health Technology Assessment: establishment of comprehensive disease endophenotyping will improve directed care decisions and future clinical trial design, including biomarkers, quality of life considerations, and patient enrolment suitability.



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