

Webinar | IMI2 – Call 13 **CONCEPTION – continuum of evidence from pregnancy exposures, reproductive toxicology and breastfeeding to improve outcomes now**

11 December 2017 • 15:00 CET

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Nathalie Seigneuret, IMI
- The Call topic – Ida Niklson, Novartis
- Involvement of SMEs, patients and regulators – Nathalie Seigneuret, IMI
- Questions & answers

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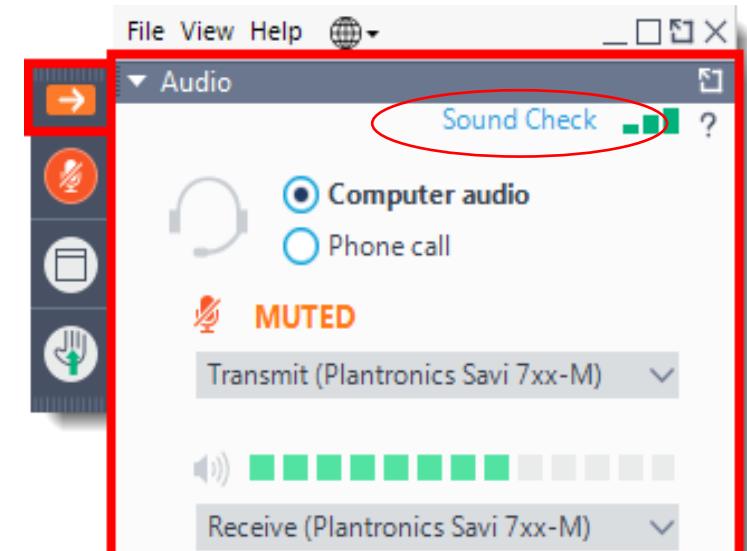
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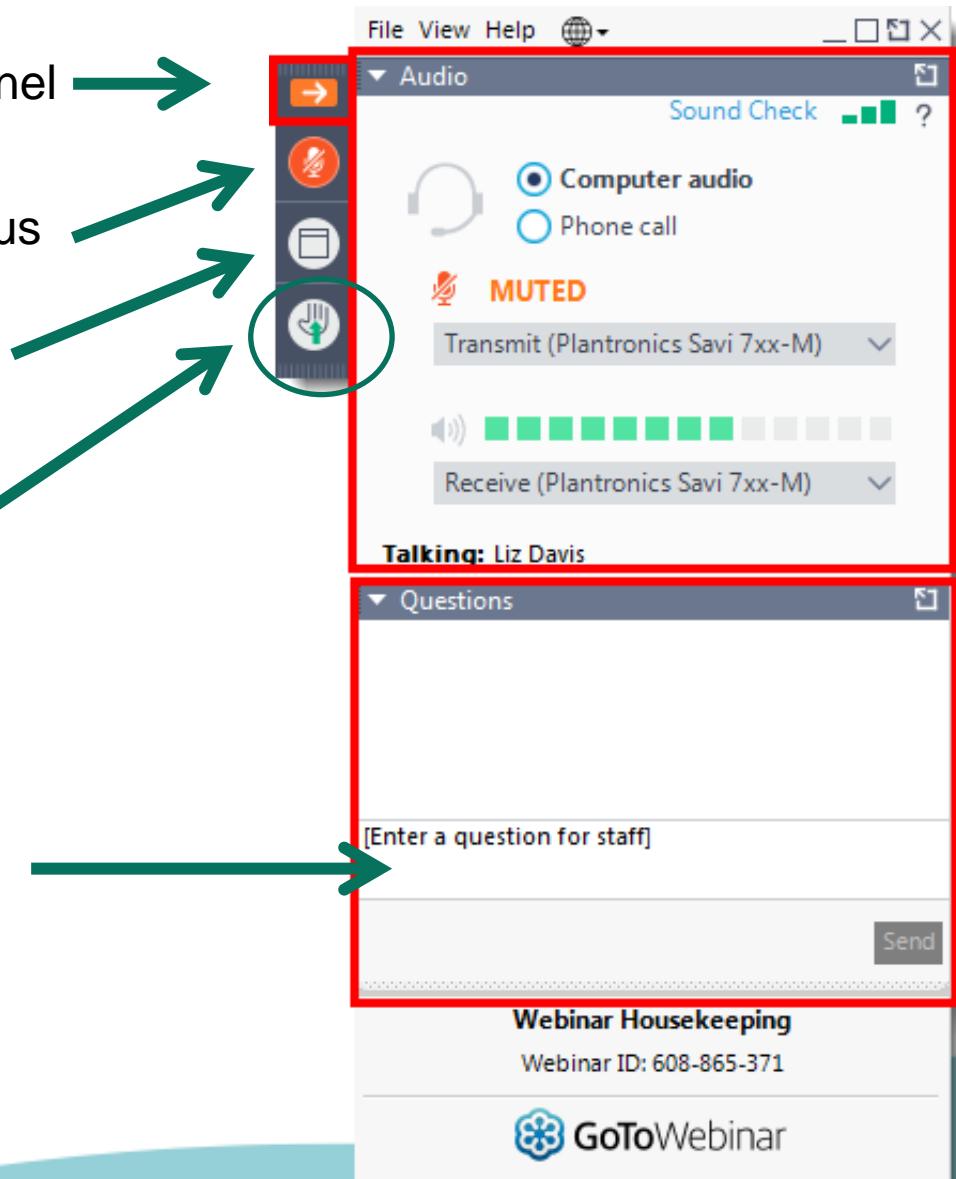
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question orally

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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
- 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

ConcePTION – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now

Nathalie Seigneuret

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

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

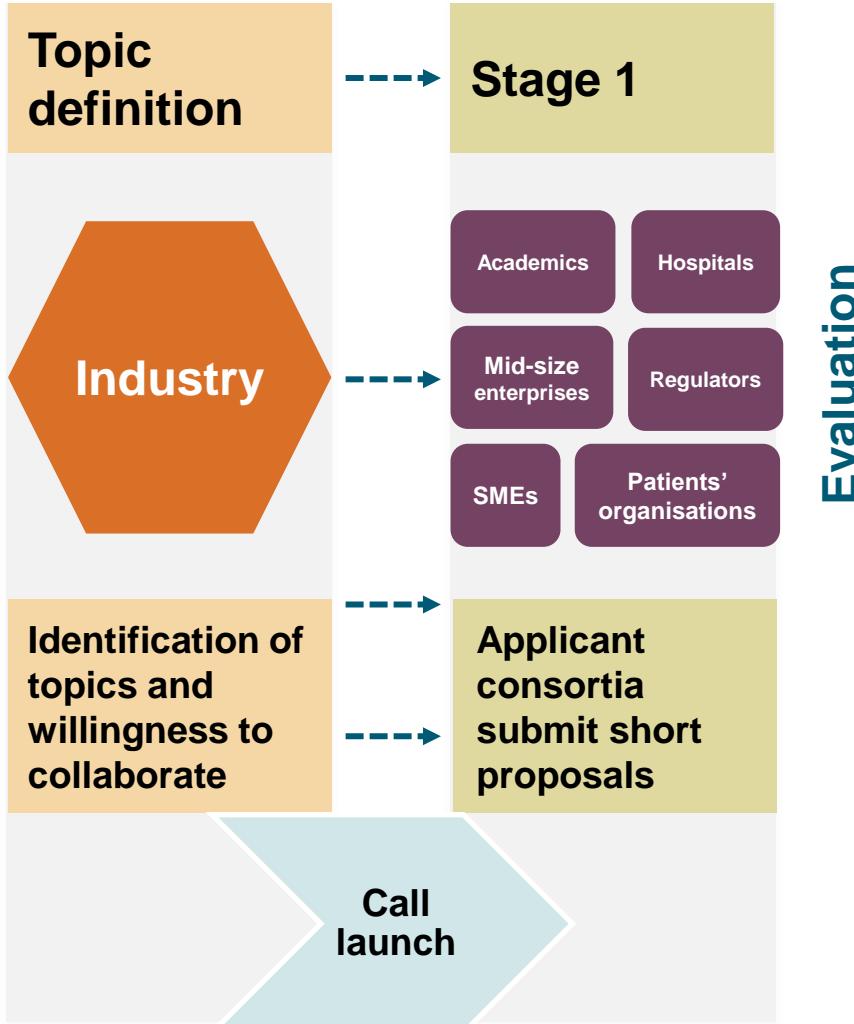
Scale is a key to success and is provided through IMI funding

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

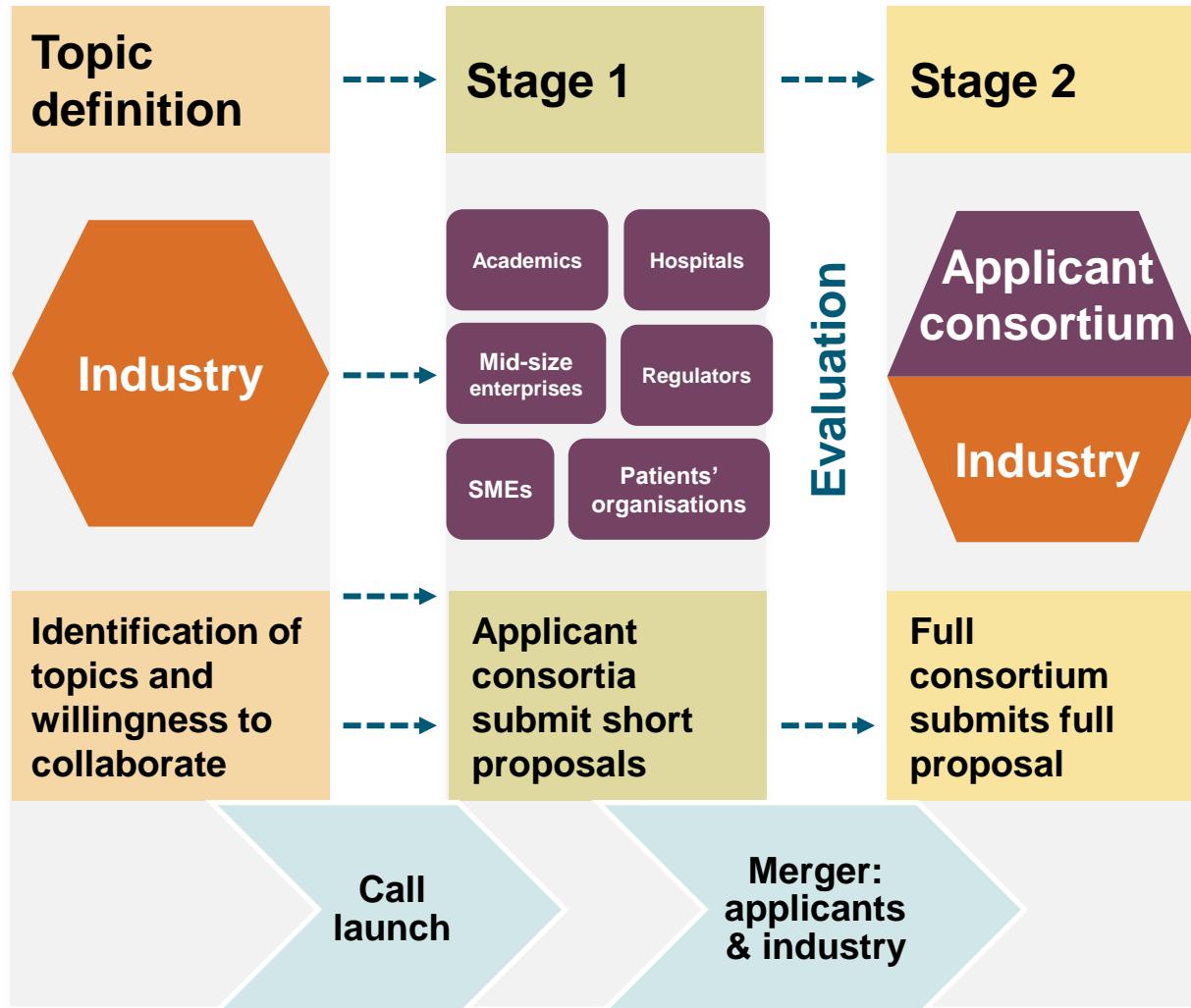
Typical IMI project life cycle



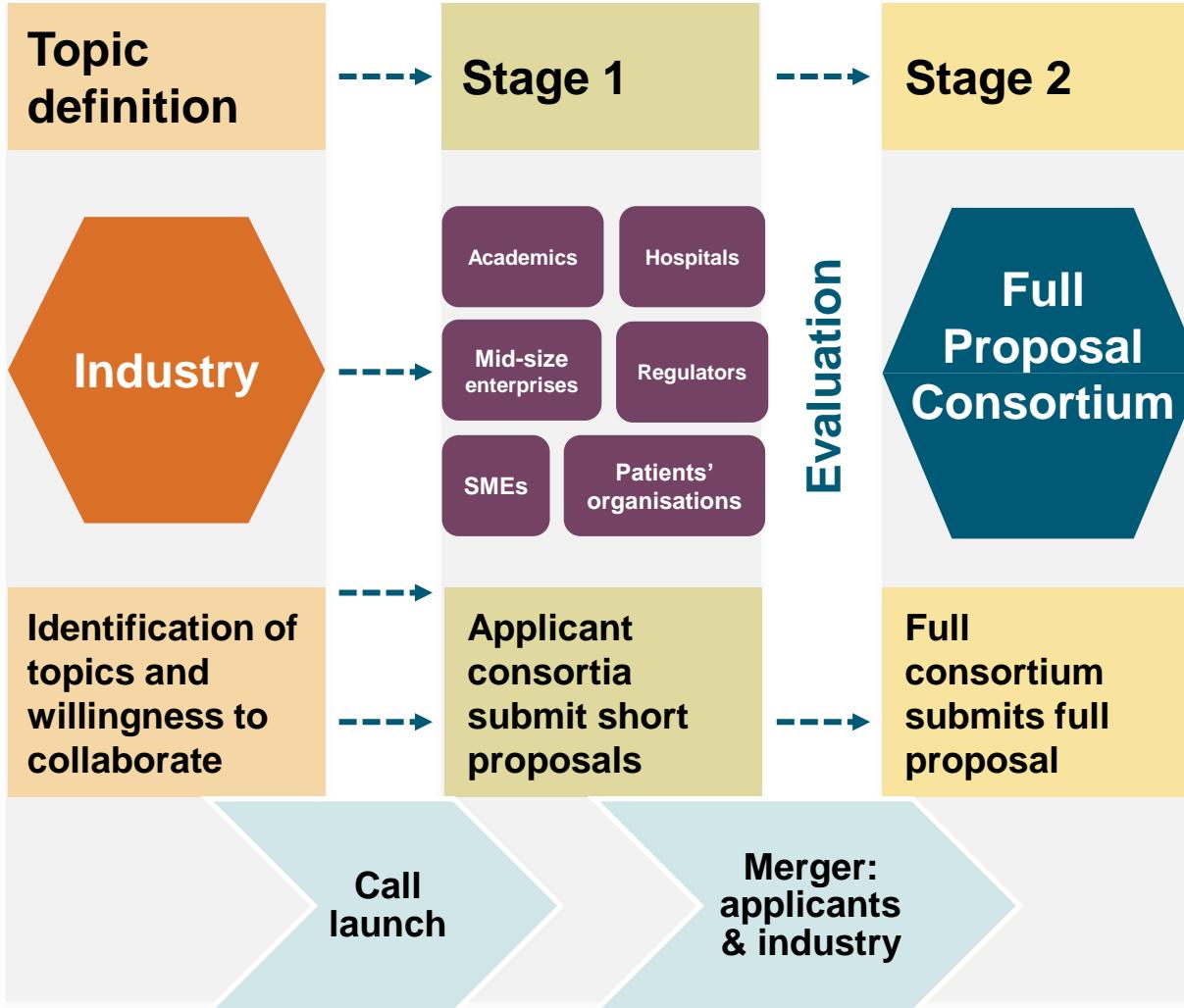
Typical IMI project life cycle



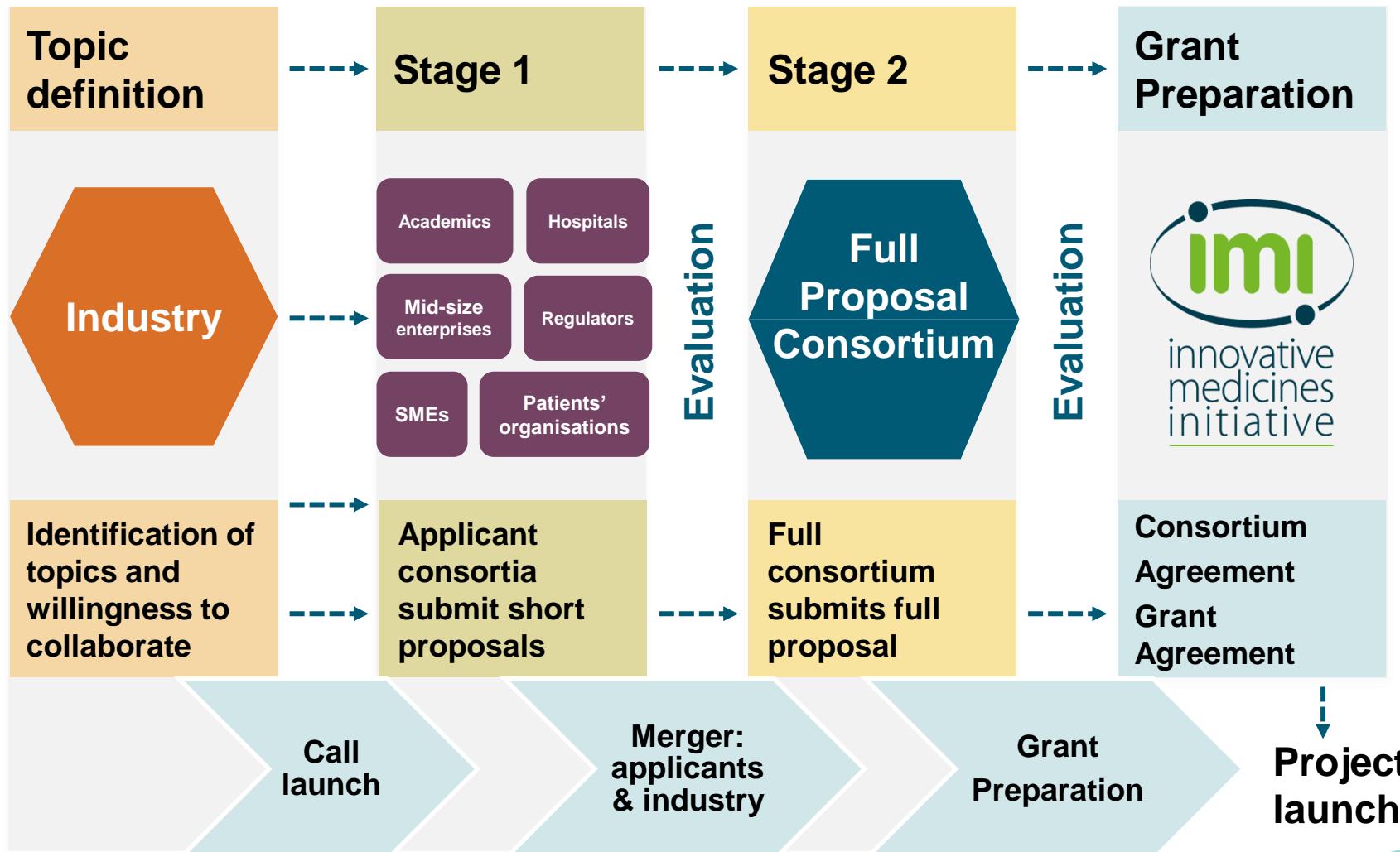
Typical IMI project life cycle



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 shows the European Commission's Research & Innovation Participant Portal. At the top, there are logos for the European Commission and the Research & Innovation program. The main navigation bar includes links for HOME, FUNDING OPPORTUNITIES, HOW TO PARTICIPATE, EXPERTS, SUPPORT, a search bar, and options to LOGIN or REGISTER.

The page title is "Calls for Proposals". On the left, a sidebar lists various EU Programmes from 2014-2020, with "H2020" highlighted. The main content area displays a list of calls under the "Horizon 2020" heading. The first call listed is "Excellent Science", which includes sub-topics like European Research Council (ERC), Future and Emerging Technologies (FET), Marie-Sklodowska-Curie Actions, and Research Infrastructures. Another call listed is "Industrial Leadership", which includes sub-topics like Leadership in enabling and industrial technologies (LEIT) and Information and Communication Technologies.

On the right side of the main content area, there are links for "Advanced search for topics" and "Calls for tenders on TED". Below the main content area, there are filters for "Status" (with checkboxes for "Calls with forthcoming topics", "Calls with open topics", and "Calls with only closed topics"), "Sort by" (with radio buttons for "Call title", "Call identifier", and "Publication date"), and a search bar with the text "IMI2" and a "FILTER" button.

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-imি/governance/states-representatives-group](http://www.imi.europa.eu/about-imि/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...)

ConcePTION – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now

Dr. Ida Niklson, MD, PhD.
11.12.2017 • IMI webinar

Need for public-private collaboration

- The lack of systematic research to understand medication effects during pregnancy and lactation is a growing public health concern
 - Challenge is too broad, too sensitive for a single stakeholder
 - Spans entire drug R&D cycle, e.g. bench to postmarket
 - Wide array of stakeholders across many sectors
- IMI2 JU - ideal neutral framework
 - Transparency across stakeholders
 - Enable sharing data in a secure environment
 - Health authorities & patient groups key partners in creating value

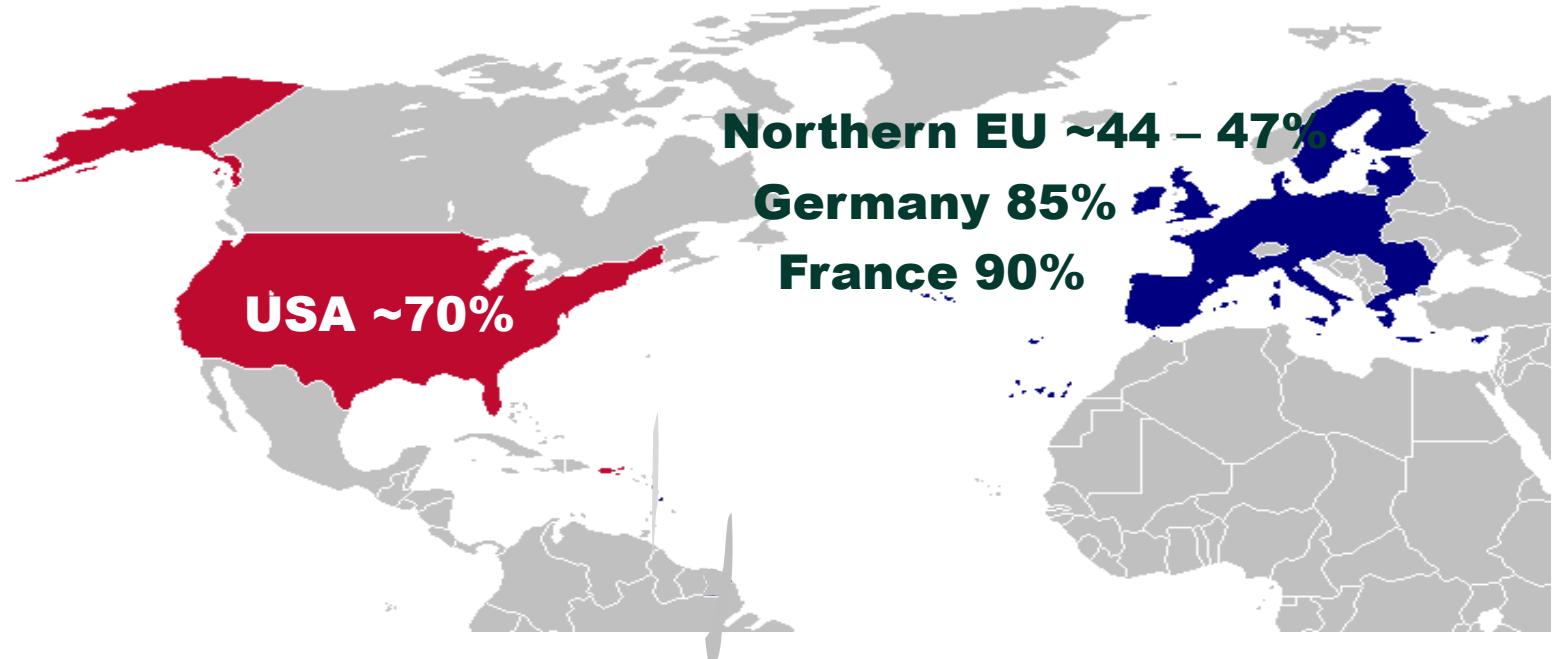
Objectives of the full project

- **WP 1** – Alternatives to pregnancy registries - high quality, & timely data, including long-term outcomes in children
- **WP 2** – Harmonize & enhance pregnancy data collection
- **WP 3** – Preclinical lactation models & standards for human lactation studies
- **WP 4** – Sustainable Europe-wide human milk biobank & analytical center
- **WP 5** – Information & education to HCPs, patients, & public

Pre-competitive nature

- Patient and societal benefits
- Successes are of equal importance across industry and public
- Aims are not focused on any pharmaceutic product
- Objectives aligned to develop platforms that enable drug research

Expected impact



- 230 million pregnancies worldwide in 2012³
- 5.1 million children born - EU-28 in 2014⁴
- 6 million children born - US
- Medication use in pregnancy is common⁵
 - Estimation in the EU: 2 million pregnancies each year

Expected impact

- Better & faster understanding of benefits & risks of medications used during pregnancy and lactation
- Advance & enable science related to understanding drug concentrations in breast milk
 - First EU sustainable breast milk biobank and an analysis centre(s)
- Trusted source of high-quality, science-based information & education for HCPs, patients, & public

Suggested Project Architecture

WP6
Engagement with health & regulatory authorities

WP1

Alternatives to pregnancy registries

WP2

Optimize & enhance pharmacovigilance

WP3

Lactation drug transfer data generation
using animal models

WP4

Human milk biobank & analytical center

WP5

Dissemination & Education

WP7
Project Management

Scientific &
Regulatory
Advisory
Board

Stakeholder
Advisory
Board

Expected contributions of the applicants

- Real world evidence (RWE) study design & analysis
- Pharmacoepidemiology & pharmacovigilance
- Teratology, paediatrics, obstetrics and neonatology
- Animal model development
- Reproductive toxicology
- Bioanalytical science
- Breast milk biobank & bioanalytical centre
- Professional project management

Expected contributions of the applicants (2)

- Professional associations
- Patient perspective & advocacy
- Legal & ethics & privacy law
- Finance & sustainability models
- Communication & education for experts & non-experts
- Web design & site maintenance
- Regulatory expertise & Health Authority interactions

Expected (in kind) contributions of industry consortium

- Pharmacoepidemiology & pharmacovigilance
- Preclinical safety, modeling & simulation
- Bioanalytical science, human bio-specimen collection, storage & protocols
- Human lactation studies
- Patient affairs
- Communication experts
- Regulatory affairs science & drug product labelling

What's in it for you?

- Academic researchers
 - Contribute to important public health issue
 - Collaboration in multidisciplinary framework
 - Publications with high & broad impact in science and medicine
 - Jobs - newly created research platforms
- SMEs
 - Specialized expertise in relatively untapped area of research
 - Project management
 - Jobs - newly created research platforms
- Patients & Professional Organizations – help shape research agenda
- Health authorities – can better serve public health

Objectives of the full project (1)

Work Package 1 – Alternatives to pregnancy registries

- Define data collection & analytics alternatives to pregnancy registries
 - Rapidly & robustly estimate rates of adverse pregnancy outcomes & association to maternal drug exposure
 - Long term effects in children
 - Medication exposed
 - Disease controls
 - Non-disease controls

Objectives of the full project (2)

Work Package 2 – Harmonized Pharmacovigilance

- Harmonise data elements collected during routine pharmacovigilance
- Enhance the rate & quality of pregnancy case reports from
 - clinical studies
 - clinical practice

Objectives of the full project (3)

Work Package 3 – Lactation data generation

- Develop & validate
 - Animal lactation model - improve translatability to humans
 - Pharmacodynamic model to translate between species for more reliable information for the initial product label
- Develop standards for conducting human lactation studies

Objectives of the full project (4)

Work Package 4 – Human Milk Biobank and Analytical Center

- Establish a Europe-wide human milk biobank
 - Patients taking prescription medications
 - Healthy volunteers for basic milk research
 - Bioanalytical centre for assay development
- Add-on to existing biobank with government support

Objectives of the full project (5)

Work Package 5 – Dissemination & Education

- Educate HCPs
 - importance of reporting pregnancy cases
- Educate patients
 - understanding prescription drug labels
 - obtaining information on medication effects when used during pregnancy and breastfeeding
- Educate the public
 - why research in this field is necessary

Key deliverables of the full project (WP1)

Moving beyond pregnancy registries to enhance understanding of disease related pregnancy outcomes, medication use and safety in pregnancy

- Catalogue data sources & methods
 - medication exposure
 - pregnancy outcomes, including long-term
- Create & publish consensus-driven common data elements & model
 - industry-wide standardization
 - meets regulatory standard for inclusion in product labeling

Key deliverables of the full project (WP1)

- Governance structure for de-identified data sharing
- Publish recommendations for data collection & analytical standards for drug utilisation & medication safety studies
 - using secondary data approaches
 - demonstration projects with established & newly marketed products;
- Publish recommendations to understand disease impact on pregnancy outcomes
- Publish aligned recommendations on how to prepare for pregnancy & medication use during pregnancy for HCPs, patients & general public

Key deliverables of the full project (WP2)

Enhance safety data collection in pregnancy and the analysis of case reports

- Publish standard core data elements for pregnancy exposure & follow-up case reports
- Publish standard method for aggregate reviews

Key deliverables of the full project (WP3)

Enhance data generation during lactation while taking medicine & standardise approaches to human lactation studies

- Standards & best practice for animal lactation studies
- Predictive animal lactation models
- Publish well-characterised *in silico* and/or physiology-based pharmacokinetic model for human lactation input
- Best practice documents
 - how to implement information from nonclinical studies to inform human breastfeeding studies & define when human lactation studies are indicated
 - standards for conducting human lactation studies
- Aligned principles on when medications can be used during breastfeeding for HCPs, patients & general public

Key deliverables of the full project (WP4)

Establish a non-commercial, Europe-wide breast milk biobank building on an existing biobank, set up with existing government support & an analytical centre for measuring drug concentration values in milk

- Sustainable Europe-wide human milk biobank for voluntary donor & study collected samples;
- Europe-wide human milk sample analytical centre to develop validated methods

Key deliverables of the full project (WP5)

Dissemination and education for HCPs, pregnant and breastfeeding patients and general public

- Centralized, verified & accessible information on medicines use
 - pregnancy
 - breastfeeding
 - impact of untreated disease
- Network to deliver and maintain accurate, current information on good scientific & registry practices
- Guidelines for data privacy, use of electronic tools, & ethics of cross-border communication on pregnancy & breastfeeding

Key deliverables of the full project (WP5)

- HCPs, patients & general public
 - education & training for understanding prescription label on medication use in pregnancy & breastfeeding
- Aligned recommendations for medication use during pregnancy & breastfeeding for HCPs, patients & general public

Involvement of SMEs, patient groups, regulators

Nathalie Seigneuret

SME participation

- IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.
- For example, solutions that are co-created with SMEs can provide an economic stimulus that can be enduring. Their involvement in the action might offer a complementary perspective to industry and the academia, and help deliver the long-term impact of the project.
- For instance, in this topic, SMEs can participate providing expertise and experience in design and analysis of existing data sets, epidemiological design and analytics; animal lactation studies but also, data and knowledge management, project management and professional communication among others.

Patient participation

There are many ways you can improve project performance by working with your patient partners e.g:

- input in data collection in pregnancy
- community outreach and dissemination

“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

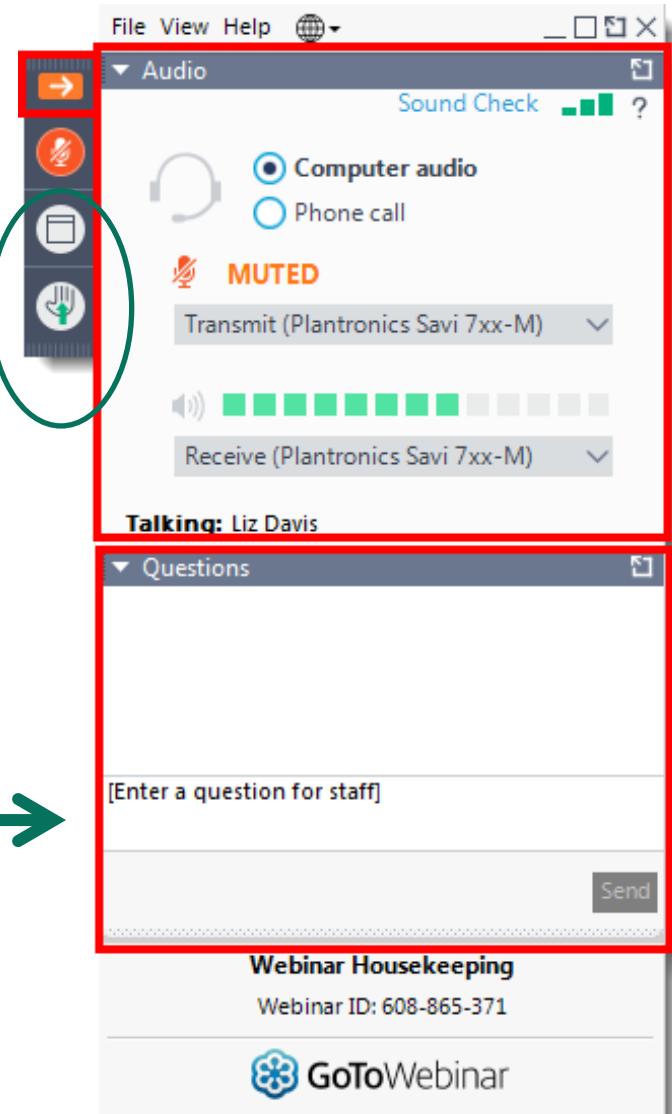
More info: 'Raising awareness of regulatory requirements: A guidance tool for researchers'

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



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