



Webinar | IMI2 - Calls 15 & 16 Opportunities for SMEs

23.07.2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Opportunities for SMEs in IMI2 – Calls 15 & 16 – Colm Carroll, IMI
- Questions & answers

How to use GoToWebinar

Expand / minimise control panel →

Microphone status →

Full screen →

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

Send a question in writing →

The screenshot shows the GoToWebinar interface with several key elements highlighted by a red border and green arrows. At the top, a menu bar contains 'File View Help' and a globe icon. Below it, the 'Audio' control panel is visible, featuring a 'Sound Check' indicator with a signal strength bar and a question mark. The audio settings are set to 'Computer audio' (selected) and 'Phone call'. A prominent 'MUTED' status is shown with a microphone icon. Below this, there are dropdown menus for 'Transmit (Plantronics Savi 7xx-M)' and 'Receive (Plantronics Savi 7xx-M)', along with a volume slider. The current speaker is identified as 'Talking: Liz Davis'. Below the audio controls is a 'Questions' section with a text input field containing the placeholder '[Enter a question for staff]' and a 'Send' button. At the bottom of the interface, the text 'Webinar Housekeeping' and 'Webinar ID: 608-865-371' is displayed, followed by the GoToWebinar logo.

How to use GoToWebinar - audio

To listen via your computer, select **Computer audio**

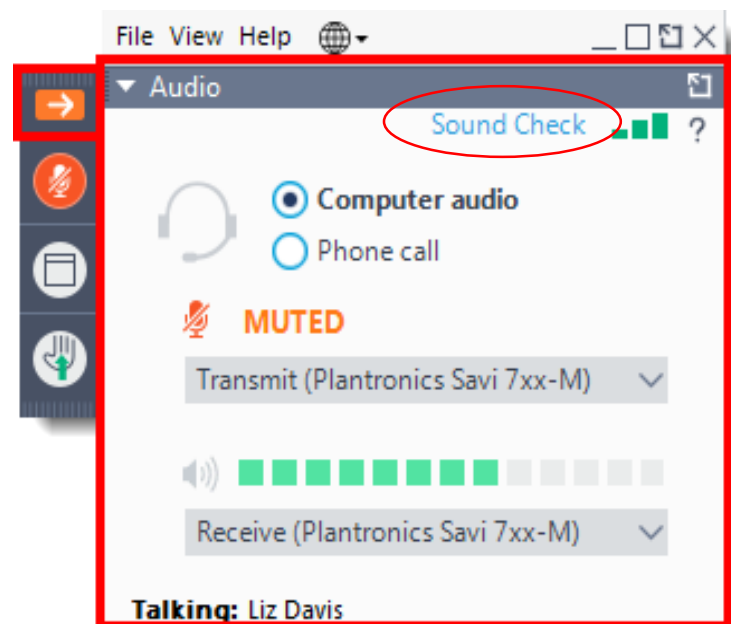
Can't hear us?

- Check your **speakers are switched on and not muted**
- Do a **Sound Check** to make sure GoToWebinar is picking up the right speakers
- Still not working? Select **Phone call** and dial the numbers given on your phone

To listen in via your phone, select **Phone call**, pick your country, and dial the numbers given

Can't hear us?

- Check you have selected **Phone call** in the audio panel
- Try **another country's** phone number
- Still not working? Select **Computer audio** and listen over your computer's speakers



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 – Calls 15 and 16 have been launched and all Call documents & details of how to apply can be found on the IMI website



SMEs in IMI2 Calls 15 & 16

Today's webinar

Will cover the following:

- Introduction to IMI
- Overview on why SMEs should join IMI projects
- Tips for joining applicant consortia
- SME opportunities in Call 15 & 16 topics
- Other SME opportunities in IMI

Will not cover rules and procedures

- A webinar on rules and procedures took place on **Tue 10 July**
View the recording and download the participant list at:

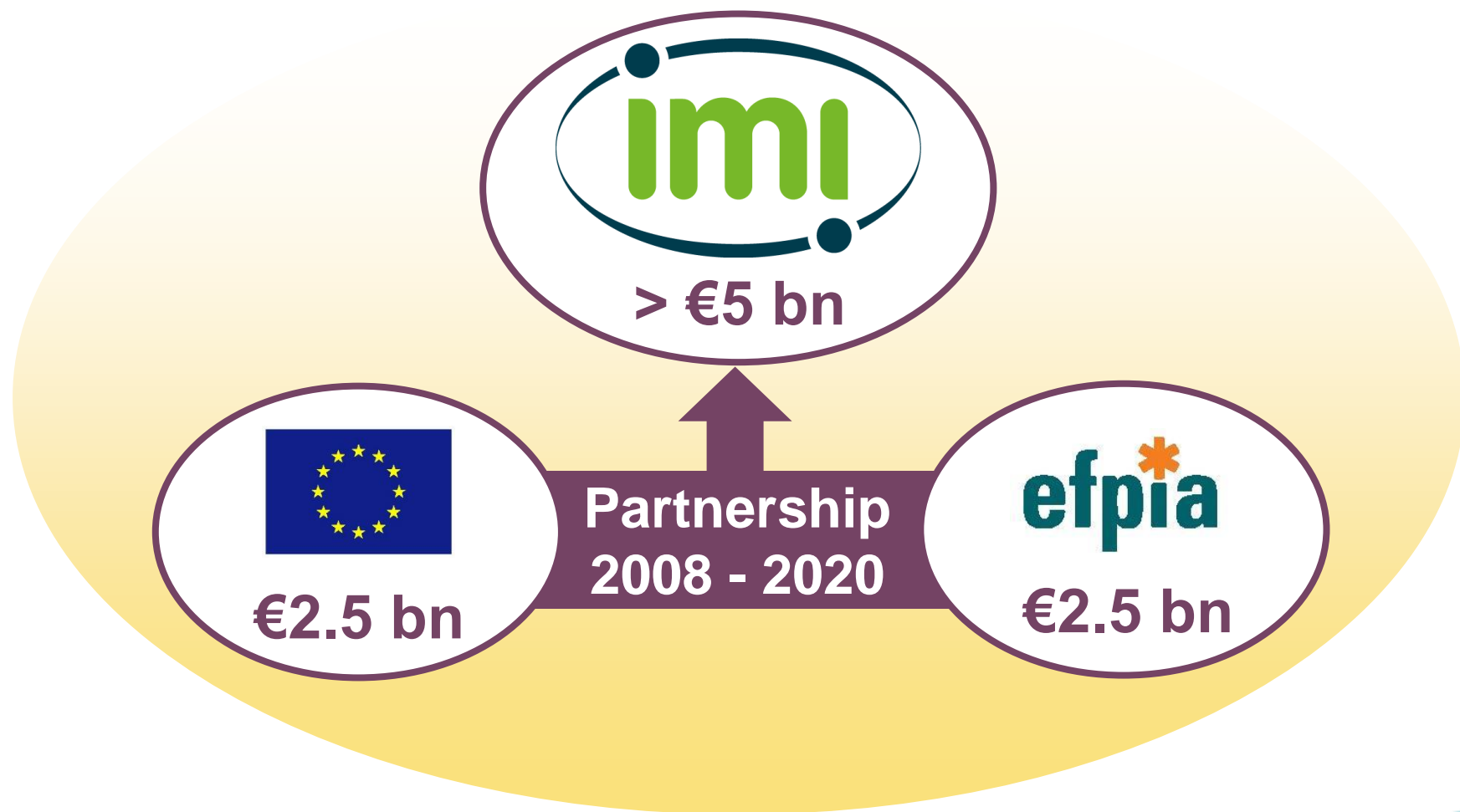
<http://europa.eu/!Yg99yW>

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 – Europe's partnership for health



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**.

Why do we want SMEs in IMI projects?

- SMEs can act as a **key interface** between latest academic discoveries and implementation in industry
- SMEs can bring **industrial grade products/services** to IMI projects
- With a commercial focus, SMEs can **drive projects to achieve** high impact results
- By developing products & services, SMEs can ensure the results of IMI projects are **widely available after the funding ends**
- Help create a **favourable ecosystem for SME innovation and growth.**

Why should an SME participate in an IMI project?

- IMI projects are focused on **translating excellent research** into real world outcomes – an opportunity for SMEs
- SMEs can **fine-tune innovative services and products** with the actual end-user scientists
- Collaboration with large pharmaceutical companies and others allows **access to whole value chain** of drug discovery & the **building of research and business networks**
- **Enhancing reputation and visibility.** IMI project achievements often get recognised and promoted on an international level
- Funding: **100%** of costs **reimbursed**

Examples of SMEs in existing projects

K4DD - Sierra Sensors



Molecular Affinity Screening System developed within the K4DD project using input from pharma partners.

Measures target-ligand binding kinetics in high-throughput format

Acquired by

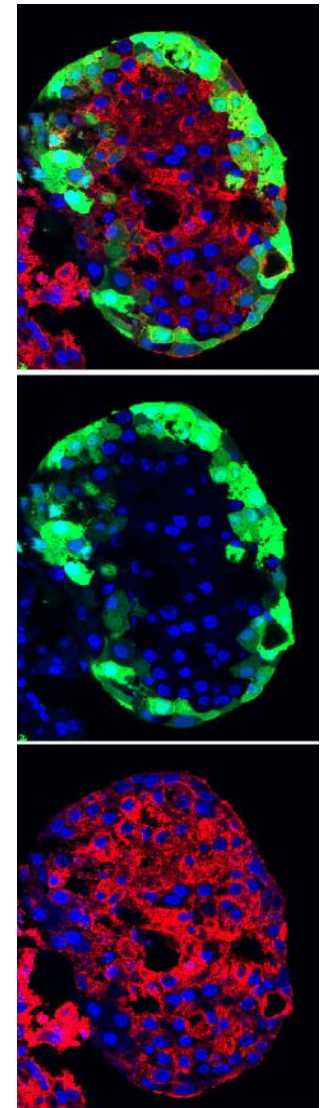


IMIDIA delivers a world first – driven by SME involvement

- IMIDIA generated the first human pancreatic beta cell line
- A French SME was at the heart of the research

‘Thanks to this collaboration, the robustness of our beta cells has been validated by large pharma companies – a major advantage for a biotechnology company like Endocells.’

– Anne-Fabienne Weitsch, CEO of Endocells



SME success stories



- Thanks to IMI the company went from 6 to 50 employees.
- Now they are ready to further expand.



- Developed blood tests for Alzheimer's diagnosis, stratification and companion diagnostics in AD. The Panel was tested on 300 patients in an IMI project.



- Developed computer models for predicting toxicity, which were validated by pharmas in eTOX. Now they have signed a contract with one of the companies to use their models in house.



IMI IP rules consider SME's needs

- Opportunity for **further development & validation of assets**
- Background and sideground **assets protected**
- New results **owned by the generator**
- **Result owner decides** best protection modalities & exploitation strategy
- **Access to expertise** from the other partners on equal basis
- Publication/dissemination **subject to conditions**, such as respect of the legitimate interests

“We are a start-up company and our patents are the most valuable asset that we have. We jumped into the project and we are glad that we did, because our IP rights are protected – participating in this project didn't harm us at all.”



Topic development & Proposal submission

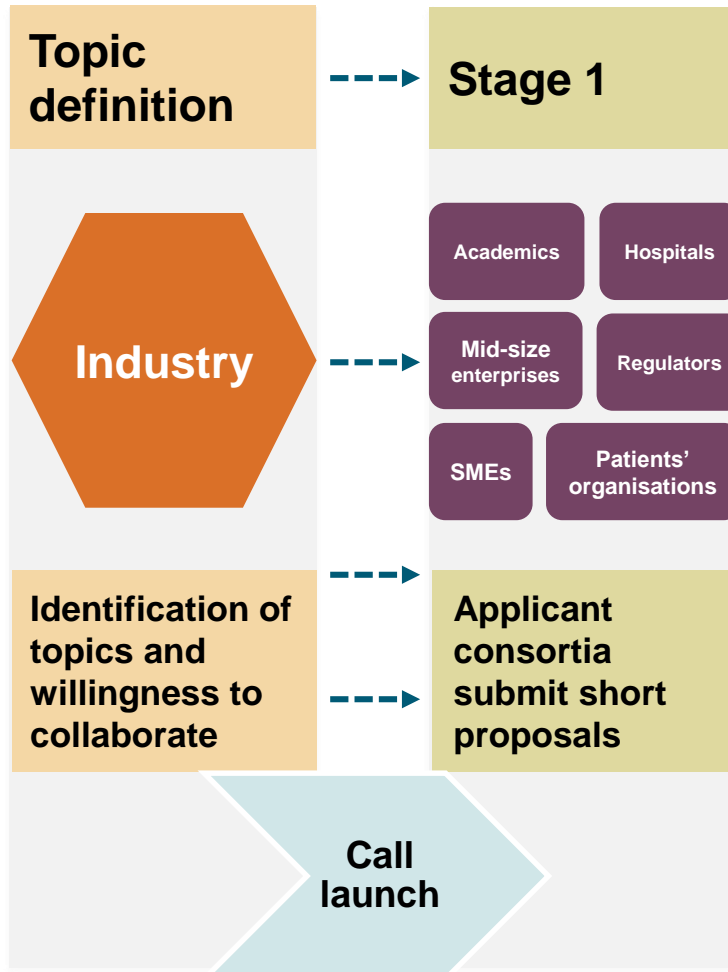
IMI Topic Definition



Topic Definition

- 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**
- **Consultation** with H2020 countries, IMI2 SC, EC

Call 15 submission/evaluation life cycle

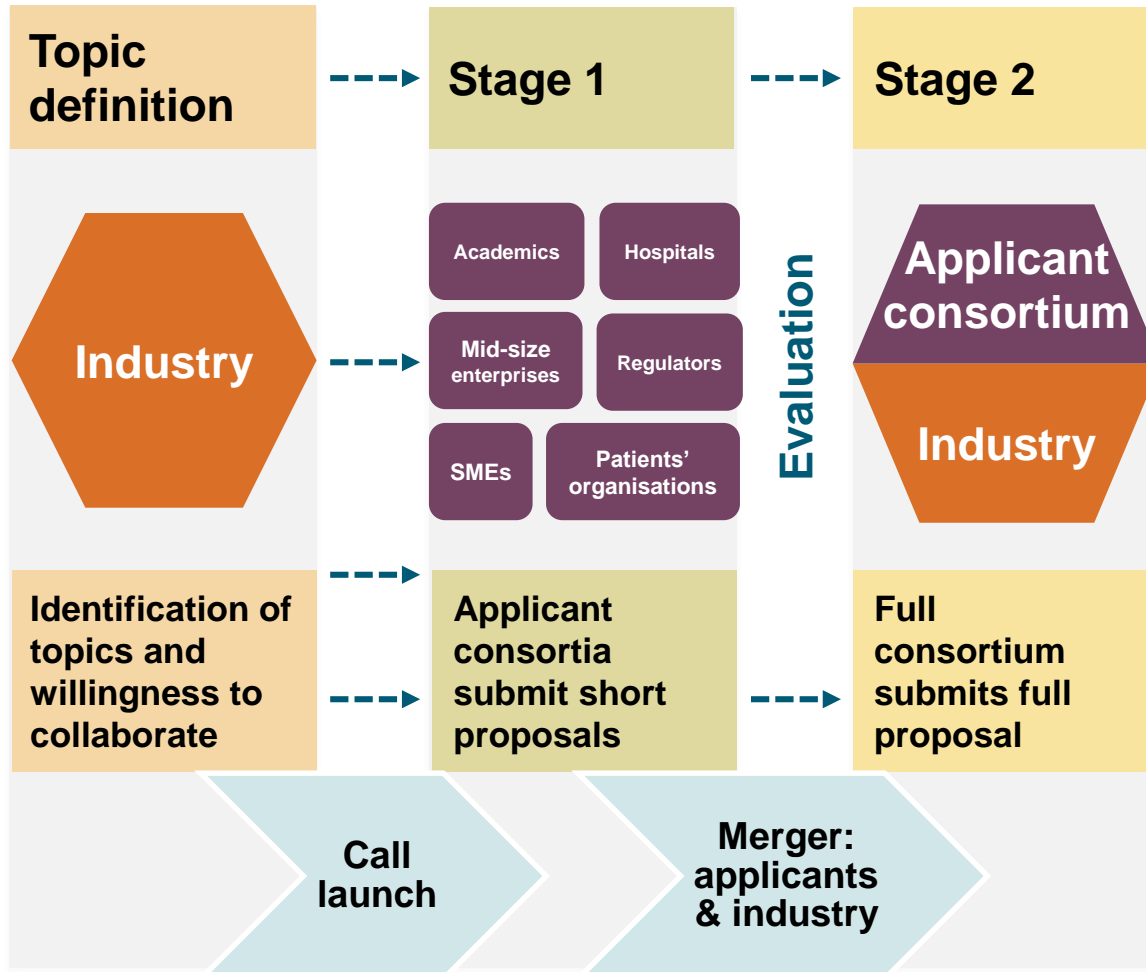


Evaluation

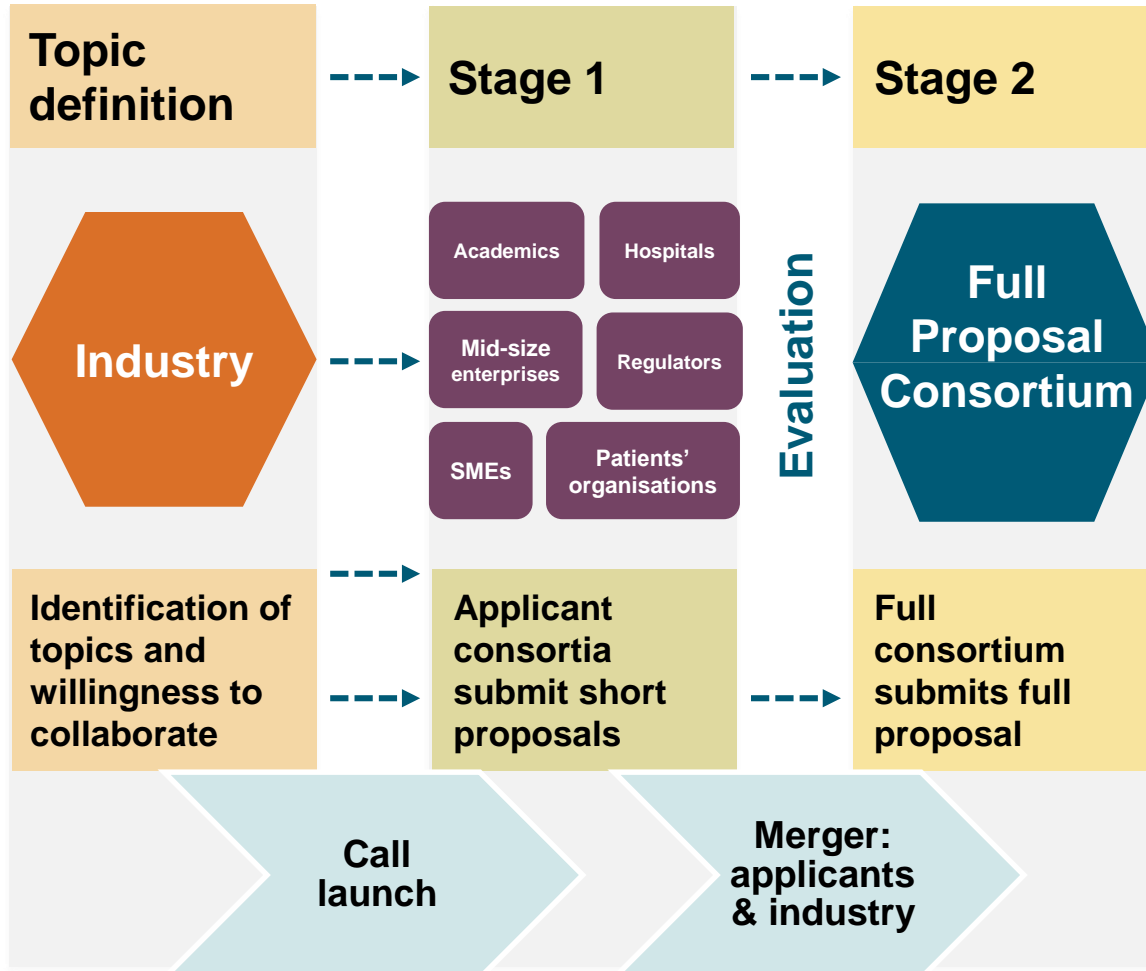
Proposal Submission & Evaluation

- **Consortia** applying for the public funding **form** and submit a Short Proposal meeting the requirements of the topic text
- All proposals evaluated by an **independent panel**
- **Only top ranked proposal** goes through to the next stage

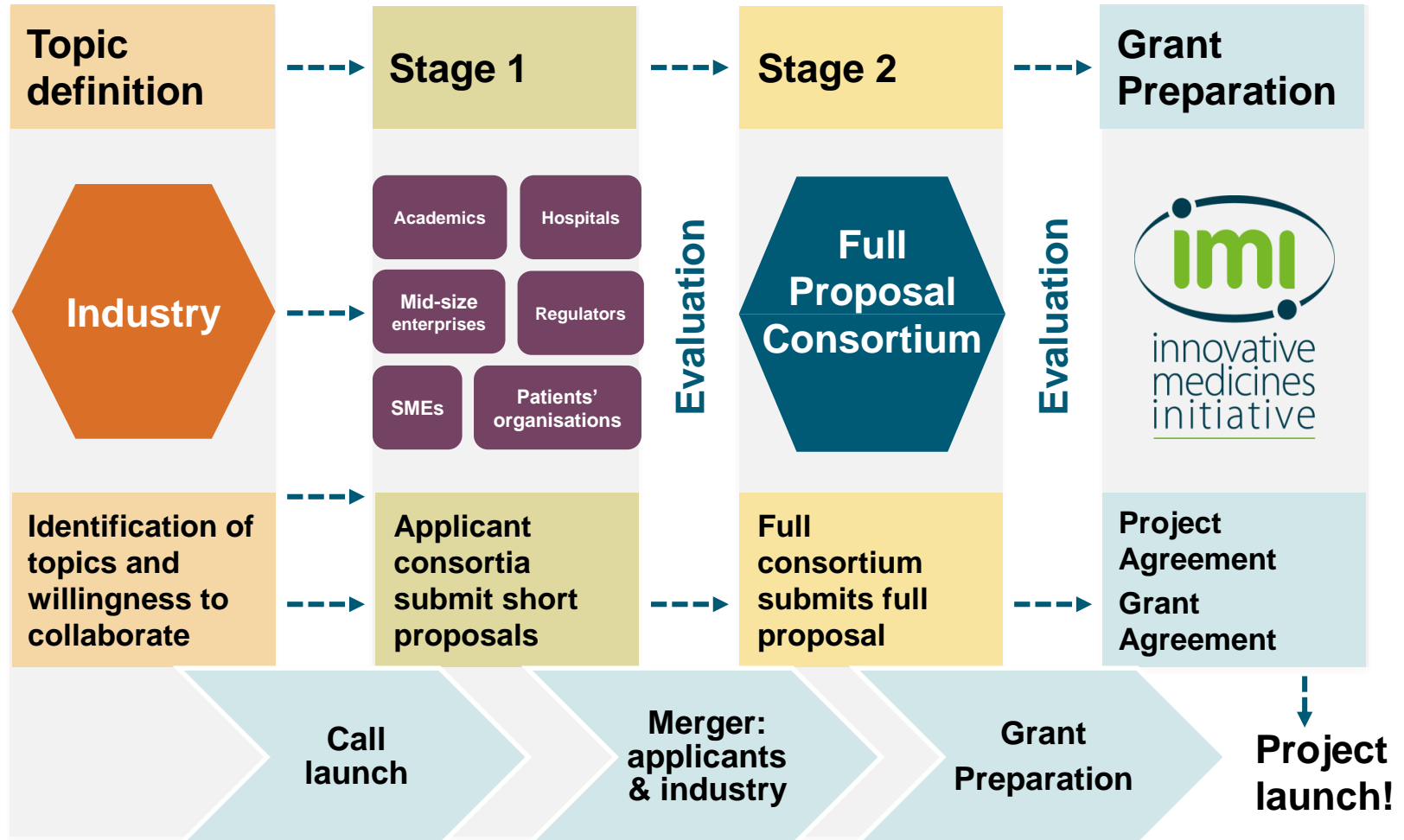
Call 15 submission/evaluation life cycle



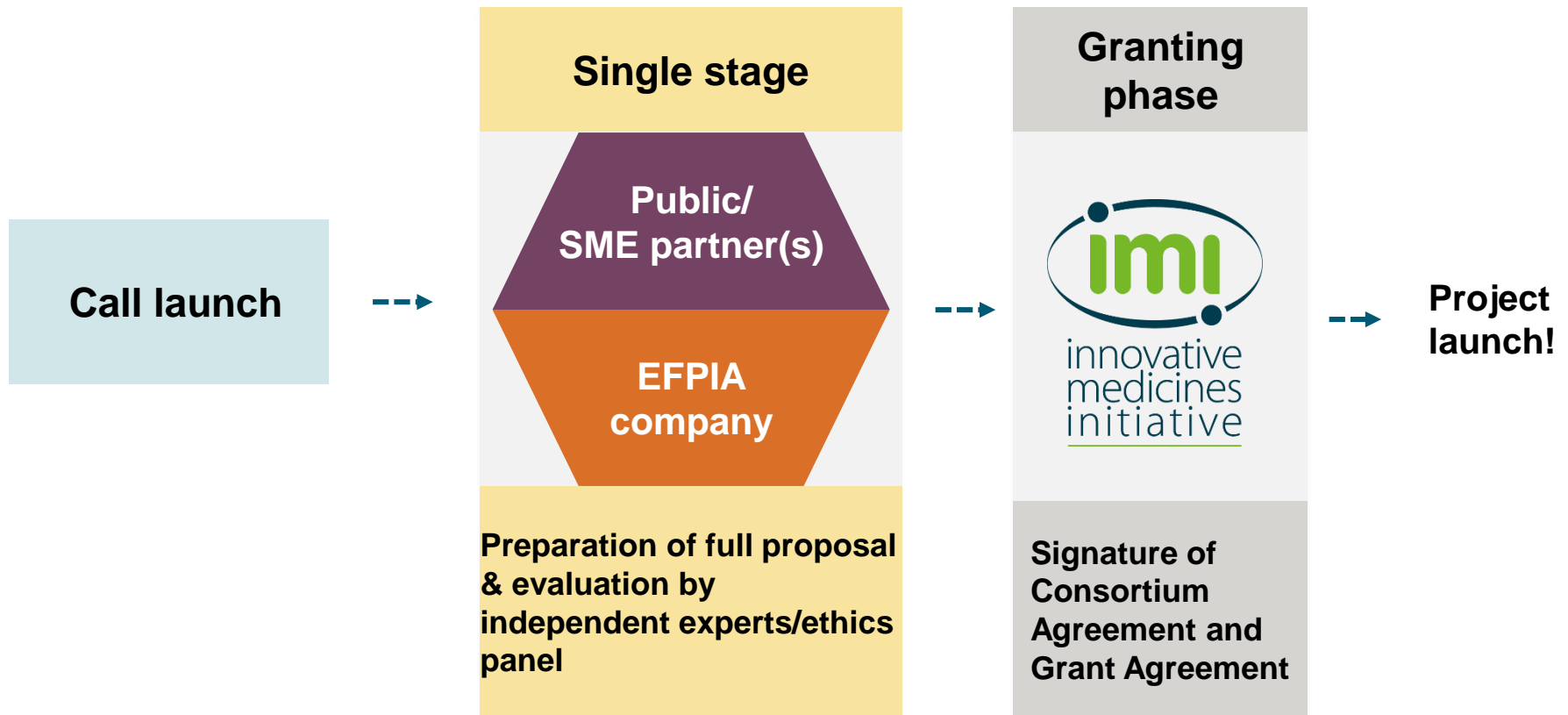
Call 15 submission/evaluation life cycle



Call 15 submission/evaluation life cycle



Call 16: a single-stage Call process



Joining an applicant consortium

- **Be proactive**
 - Develop your network
 - Reach out to potential coordinators, make their life easy
- **Be prepared**
 - Summarise your skills and proposed topic activities
 - Estimate the budget required
- **Be flexible**

Finding consortia / partners

- **Network with your contacts**
- Network with **SME & topic webinar participants**
- Use **Partner Search Tools**:
 - Horizon2020 participant portal: <http://europa.eu/!Mg84kq>
 - German NCP version: <http://www.imi-partnering.eu>
- Get in touch with your **local IMI contact point**:
www.imi.europa.eu/content/states-representatives-groups
- Talk to your Health National Contact Point (NCP)
- **Network on social media** (e.g. IMI LinkedIn group)

Tips for writing a successful proposal

- Read **all** the call-relevant material
- Begin **forming your consortium early**:
 - Partner search tools & networking events
- Provide reviewers with **all the information requested** to allow them to evaluate your proposal
- **Submit your proposal early**
- Contact the SME helpdesk: SME@imi.europa.eu

Common Mistakes

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



SME participation in IMI2 Calls 15 & 16

Topic texts & webinars

A summary of all topics is presented below

If interested in a particular topic, please:

- Read the topic texts
 - Call 15: <http://europa.eu/!mw46tf>
 - Call 16: <http://europa.eu/!nf48kC>
- View the topic specific webinars at:
 - <http://europa.eu/!Yg99yW>

Topic 1: Integrated research platforms enabling patient-centric drug development

The topic aims to:

- Transform new experimental clinical development concepts into a reusable and endorsed methodology that is broadly accepted for application in new drug development

Key Deliverables

- Toolbox of guidance/best practices for running IRPs
- Disease-specific IRPs (MDD, TB, NASH, NF)
- Communication strategy
- KPIs for performance and execution of IRPs and platform trials

Topic 1: Expected contributions from SMEs

- Statistics and modelling & simulation;
- Technology for querying EHRs, registries and RWD;
- Medical & scientific writing supporting regulatory interactions;
- Business process design;
- Clinical operations, patient engagement
- Legal and IP, project management and communication;

Topic 1: Details

Duration

- The indicative duration of the action is 42 months.

Indicative budget

- In-kind contribution: EUR 12 365 000
- IMI2 JU contribution: up to EUR 12 005 000

Topic 2: Blockchain enabled healthcare

The topic aims to:

- Establish an agreed blockchain implementation that can be used to facilitate transactions in healthcare. Example use cases: medicines verification, patient consent etc....

Key Deliverables

- Healthcare blockchain standards & governance
- Framework and reference implementation.
- Business use cases.
- Regulatory, legal & data privacy

Topic 2: Expected contributions from SMEs

- Solution providers of IT technology and system integrators, blockchain developers, project managers, software and technology experts
- Expertise and capability to realise blockchain technology solutions
- Researchers related to pharmaceutical drug development and operations and blockchain and distributed ledger technology

Topic 2: Details

Duration

- The indicative duration of the action is 36 months.

Indicative budget

- In-kind contribution: EUR 9 680 000
- IMI2 JU contribution: up to EUR 8 330 000

Topic 3: Microenvironment imposed signatures in tissue and liquid biopsies in immune-mediated diseases

The topic aims to:

- Identify key organ & disease specific signatures that may predict disease, track progression and therapeutic response

Key Deliverables

- Identification and optimisation of promising technologies to profile cells in a diseasespecific tissue microenvironment.
- Generation of both tissue and body fluid (e.g. blood) profiles
- Mapping of tissue profiles against body fluids and clinical parameters
- Validation of identified signature(s) in both tissue and body fluid in longitudinal patient cohorts

Topic 3: Expected contributions from SMEs

- Provide technology for the identification of disease-specific signatures of the tissue microenvironment and, ultimately, implemented in multi-centre clinical trial settings under GLP conditions.
- SMEs with relevant proven expertise, relevant technology and proven record of delivery of peer-reviewed datasets and data management practices.

Topic 3: Details

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 15 500 000
- IMI2 JU contribution: up to EUR 15 500 000

Topic 4: Emerging translational safety technologies and tools for interrogating human immuno-biology

The topic aims to:

- Enhance translational safety assessment approaches for immunomodulatory therapeutics through the development and validation of innovative non-clinical tools & technologies

Key Deliverables

- Prioritisation of immunomodulatory therapeutic modes of action (MoA)
- Development/evaluation of innovative molecular and cellular immunophenotyping biomarkers
- Development/evaluation of human *in vitro* systems and 'engineered' animal models
- Development of customised non-clinical safety assessment strategies

Topic 4: Expected contributions from SMEs

- Provision of innovative engineered animal models and/or in vitro models that mimic human immuno-biology.

Topic 4: Details

Duration

- The indicative duration of the action is 72 months.

Indicative budget

- EFPIA in-kind contribution: EUR 11 000 000
- IMI2 JU contribution: up to EUR 11 000 000

Topic 5: Development and validation of translational platforms in support of synaptopathy drug discovery

The topic aims to:

- Improve understanding of how synaptic alterations can contribute to CNS disorders
- Develop in-vivo models of synapse function
- Develop clinical platforms & biomarkers to select clinical endpoints

Key Deliverables

- List of robust disease models, preclinical and clinical platforms
- *in vitro* and *vivo* synaptopathy disease models
- Robust clinical assessment battery able to detect synaptic alterations in relevant patient cohorts
- Selected CNS disorder animal models

Topic 5: Expected contributions from SMEs

- PET (Positron Emission Tomography) ligand development.
- Imaging and image analysis technologies.
- Clinical trial operation and execution.
- Targeted mass spectrometry based proteome analysis.
- Data and knowledge management.
- Project management expertise.

Topic 5: Details

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 6 802 000
- IMI2 JU contribution: up to EUR 6 210 862

Topic 6: Digital transformation of clinical trials endpoints

The topic aims to:

- Use latest digital technologies (sensors, mobile apps etc) to convert established clinical trial endpoints to digital endpoints

Key Deliverables

- Identification of the digital data management platform;
- Development of novel methods to probe the ADLs or other endpoints
- Pilot studies to explore acceptability, feasibility and utility of various devices.
- Longitudinal study in digital mobility and clinical outcome assessment over 2.5 years in PD, HD and IMiD populations for assessing clinical endpoints and ADL/ disabilities

Topic 6: Expected contributions from SMEs

- Expertise in device and sensor development: latest remote assessment technologies (wearable, off-body) that could be further developed
- IT/analytics SMEs: data management architecture, hardware/software platform, state-of-the-art algorithms to process and analyse time-series data from sensors/devices, expertise in data privacy and security;

Topic 6: Details

Duration

- The indicative duration of the action is 60 months.

Indicative budget

- EFPIA in-kind contribution: EUR 21 300 000
- IMI2 JU contribution: up to EUR 21 000 000

AMR Accelerator Pillar A: Capability Building Network to accelerate and validate scientific discoveries

The topic aims to:

- Address the innovation gap in the AMR space by enabling pre-competitive research in the treatment and prevention of multidrug resistant infections.

Key Deliverables

- Operationalisation of the entire AMR Accelerator portfolio of projects
- Tools for collection, integration & dissemination of knowledge
- Communication and collaboration across AMR funding landscape
- Learnings derived from shared AMR clinical trial data
- Improved understanding of animal model reproducibility/ translation

AMR Accelerator Pillar A: Expected contributions from SMEs

- Expertise in conducting, and capacity for supporting, grant funded research
- Coordinating multiple discovery AMR projects
- Communications and outreach to the scientific community and public
- Collection, collation and curation of data sets and identifying, implementing, maintaining IT systems across large collaborative projects or PPPs
- Business development as applied to large collaborative projects or PPPs

AMR Accelerator Pillar A: Details

Duration

- The indicative duration of the action is 72 months.

Indicative budget

- EFPIA in-kind contribution: EUR 17 300 000
- IMI2 JU contribution: up to EUR 8 000 000

AMR Accelerator Pillar B: Tuberculosis drug development network

The topic aims to:

- Provide a unique platform where discovery, development, and clinical trial readouts will occur allowing maximal engagement across groups in the TB field

Key Deliverables

- Development and implementation of new assays and tools to study anti-TB compounds
- An advanced portfolio of anti-TB compounds
- Learnings derived from shared TB clinical trial data (e.g. Phase 1-3 clinical trials related to TB) and associated enabling studies

AMR Accelerator Pillar B: Expected contributions from SMEs

- collection, collation and curation of TB-specific data sets and identifying, implementing, maintaining IT systems
- imaging platforms to measure pharmacodynamic responses at the sites of action
- drug discovery optimisation activities, e.g. medicinal chemistry, microbiology, scale up, pharmaceutical formulation, DMPK, toxicology, etc;
- scale up synthesis of selected candidate compounds of GMP grade
- & many additional activities – see topic text

AMR Accelerator Pillar B: Details

Duration

- The indicative duration of the action is 72 months.

Indicative budget

- EFPIA in-kind contribution: EUR 120 900 000
- IMI2 JU contribution: up to EUR 89 830 000

AMR Accelerator Pillar C: Portfolio Building Networks

These topics aim to:

- Progress a pipeline of potential medicines, including but not limited to new antibiotics, to treat patients with resistant bacterial infections in Europe and across the globe or to prevent them.

Key Deliverables

- The accelerator is expected to deliver up to >10 new preclinical candidates and >5 'phase 2-ready' assets over a roughly six-year period.

AMR Accelerator Pillar C: Topics

- Topic 1: Progress new assets (One pre new molecular entity (preNME) and one first-time-in-human (FTIH)) for **tuberculosis** that act synergistically with bedaquiline, cytochrome bc or cytochrome bd inhibitors
- Topic 2: Progress novel assets (One first-time-in-human (FTIH)) for **non-tubercular mycobacteria** (NTM) that may act synergistically with bedaquiline, and cytochrome bc drugs
- Topic 3: Discover and progress novel assets with new mechanisms of action (1 pre-new molecular entity (NME) for **tuberculosis** (TB) and 1-pre- new molecular entity (NME) for **non-tubercular mycobacteria** (NTM) and **biomarkers for TB and NTM infection**
- Topic 4: Determination of **gepotidacin levels** in tonsils and prostatic tissue
- Topic 5: Infection site targeting, **antibiotic encapsulated in nanoparticles** for treating extracellular bacterial infections
- Topic 6: **Functional ethionamide boosters**. A novel combination for tuberculosis therapy
- Topic 7: **Intravenous treatments of serious infections** (urinary tract infections (UTI), intra-abdominal infections (IAI) & hospital-acquired pneumonia/ventilator associated pneumonia (HAP/VAP)) **caused by Gram(-) bacteria** (Enterobacteriaceae +/- Pseudomonas and/or Acinetobacter

AMR Accelerator Pillar C: Expected contributions from SMEs

- Basic preclinical research capabilities to be able to develop and conduct specific PK/PD studies/models and tolerability studies including toxicology profiling, non-GLP and GLP toxicology profiling.
- experience with clinical trials;
- experience with preclinical PET imaging
- experience with nanoparticles with clear regulatory path,
- GMP manufacturing and formulation development
- & many additional activities – see topic text

AMR Accelerator Pillar C: Details

NB: IMI2 Call 16 is single-stage only

- Submission using Full proposal template & clinical trial annex

Duration

- The indicative duration of the actions is 18 - 72 months.

Indicative budget

- IMI2 JU contribution: EUR 1 770 000 to EUR 12 300 000

Applicant consortia

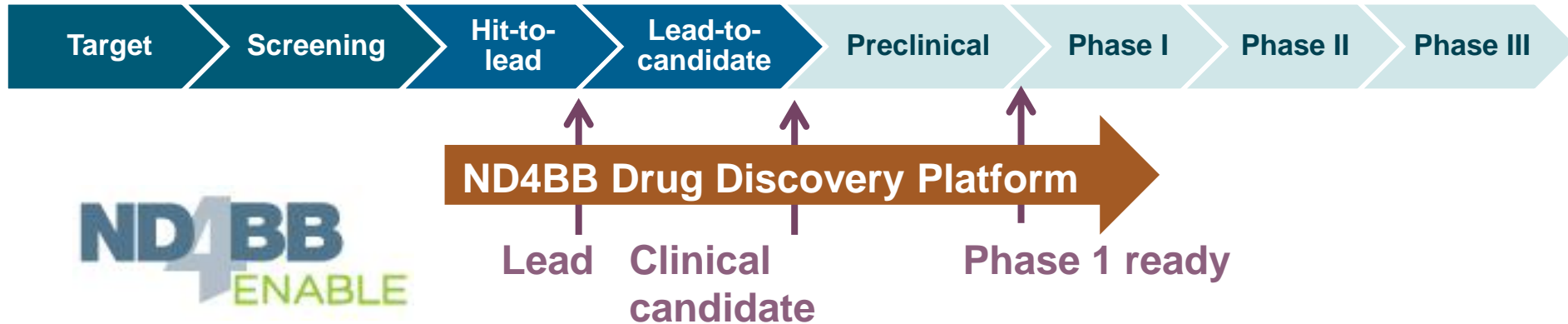
- Each applicant consortium must include at least one EFPIA constituent or affiliated entity, i.e. EFPIA company

FAQ: <http://europa.eu/!Rc99UV>



SME participation in ongoing IMI2 Projects

IMI Drug Discovery Platforms - ENABLE



Drug discovery expertise available to take your **AMR lead project** all the way to **Phase 1 clinical trials**

Apply at <http://nd4bb-enable.eu/>

Support available to submit your proposal

15 programmes already selected



Questions & answers

Questions?

Raise your hand if you want to ask a question orally



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Send a question in writing



After the webinar, send any questions to the **IMI Programme Office**

applicants@imi.europa.eu



Thank you!