Webinar | IMI2 - Call 16
AMR Accelerator programme
Pillar C: Portfolio Building Networks to advance the R&D pipeline of new and innovative agents to address AMR

06.07.2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- The IMI Call process – Angela Wittelsberger, IMI
- IMI2 – Call 16 – Angela Wittelsberger, IMI
- Questions & answers

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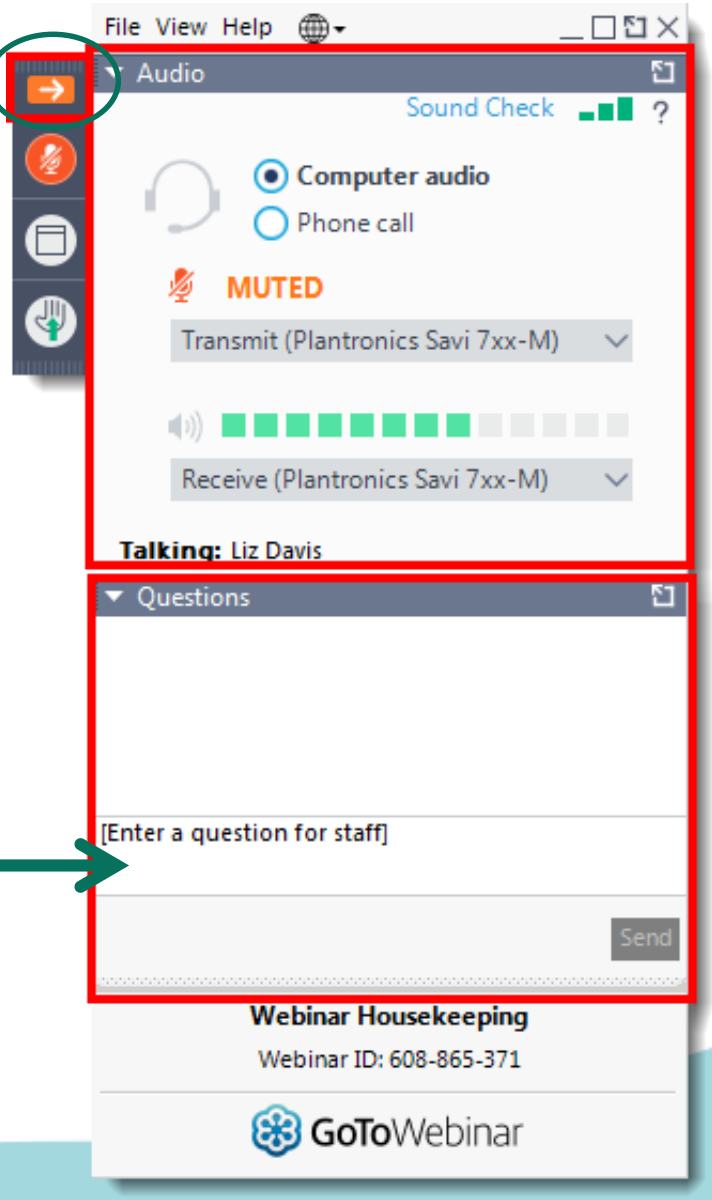

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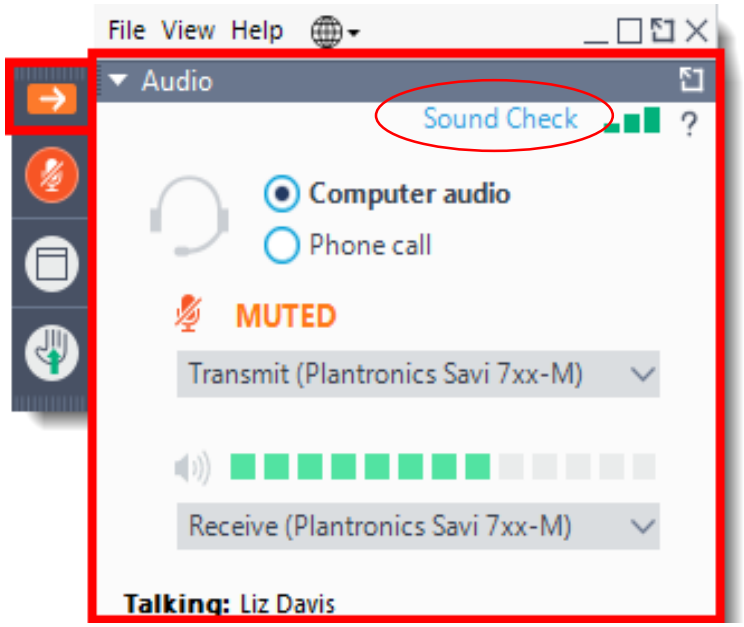

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Before we start…

- 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 and published on the website
- All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

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Webinar | IMI2 - Call 16

AMR Accelerator Programme – Pillar C: Portfolio Building Networks to advance the R&D pipeline of new and innovative agents to address AMR topics

Angela Wittelsberger, Ph.D.
IMI Scientific Officer
6th July 2018

Today's webinar

Will cover all aspects of Call 16

- Some background on the Innovative Medicines Initiative
- Proposed actions under Pillar C of the AMR Accelerator Programme
  - Objectives, need for public-private collaborative research
  - Key deliverables
  - Expected contribution of the applicants

Will not cover in great deal introduction to AMR Accelerator

- For a better picture of the AMR Accelerator as a whole, applicants to Call 16 topics are invited to also participate to a dedicated webinar on **Monday July 16 at 14:30**

Will not cover rules and procedures

- A webinar on rules and procedures will take place on

Tuesday 10 July at 10:30

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The Innovative Medicines Initiative – 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

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

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

IMI 2 total budget €3.276 billion

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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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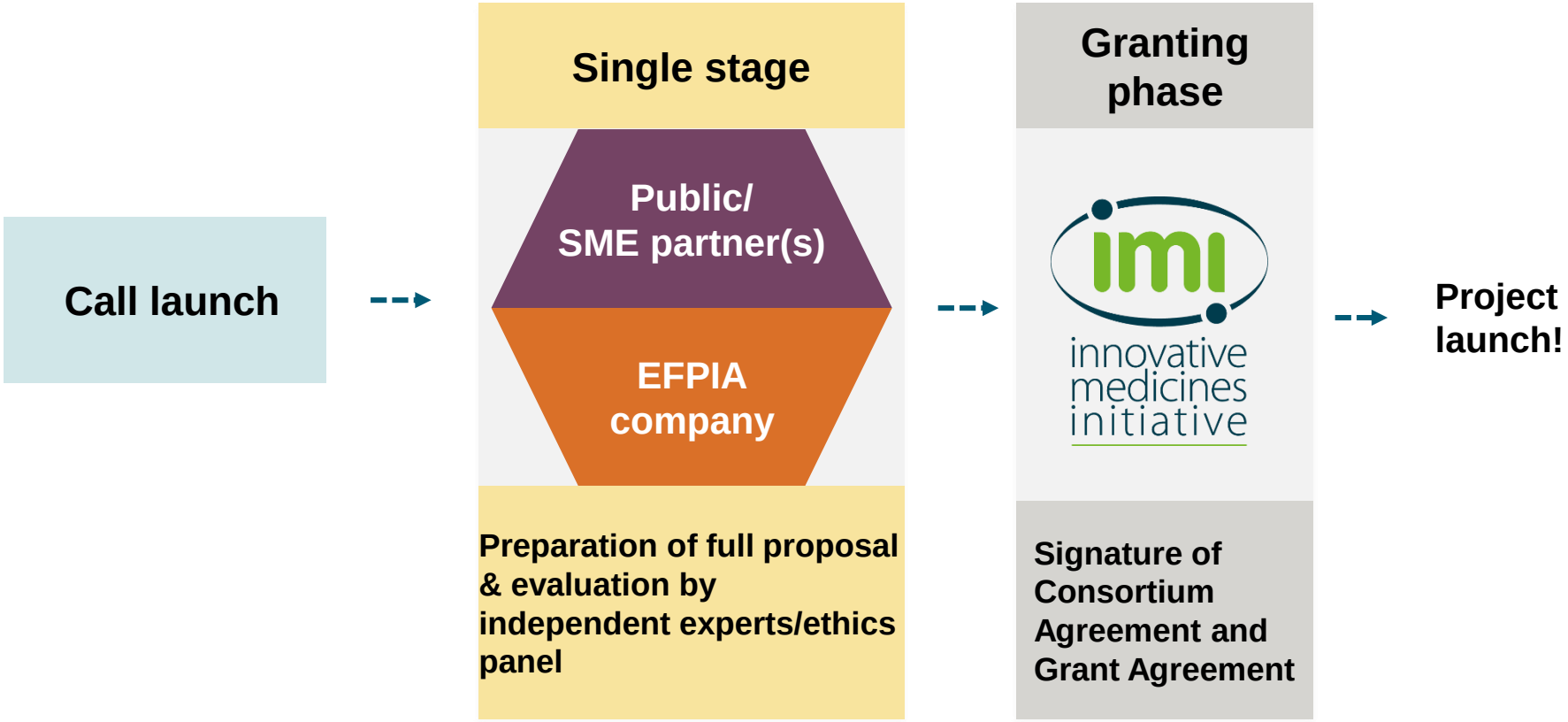
IMI2 Call 16: a single-stage Call process



Eligibility criteria: different from what we normally have for IMI calls !

- Applicant consortium must include at least one EFPIA constituent or affiliated entity, i.e. EFPIA company.
- Applicant consortium must involve at least two independent legal entities established in different EU Member States, or countries associated to Horizon 2020

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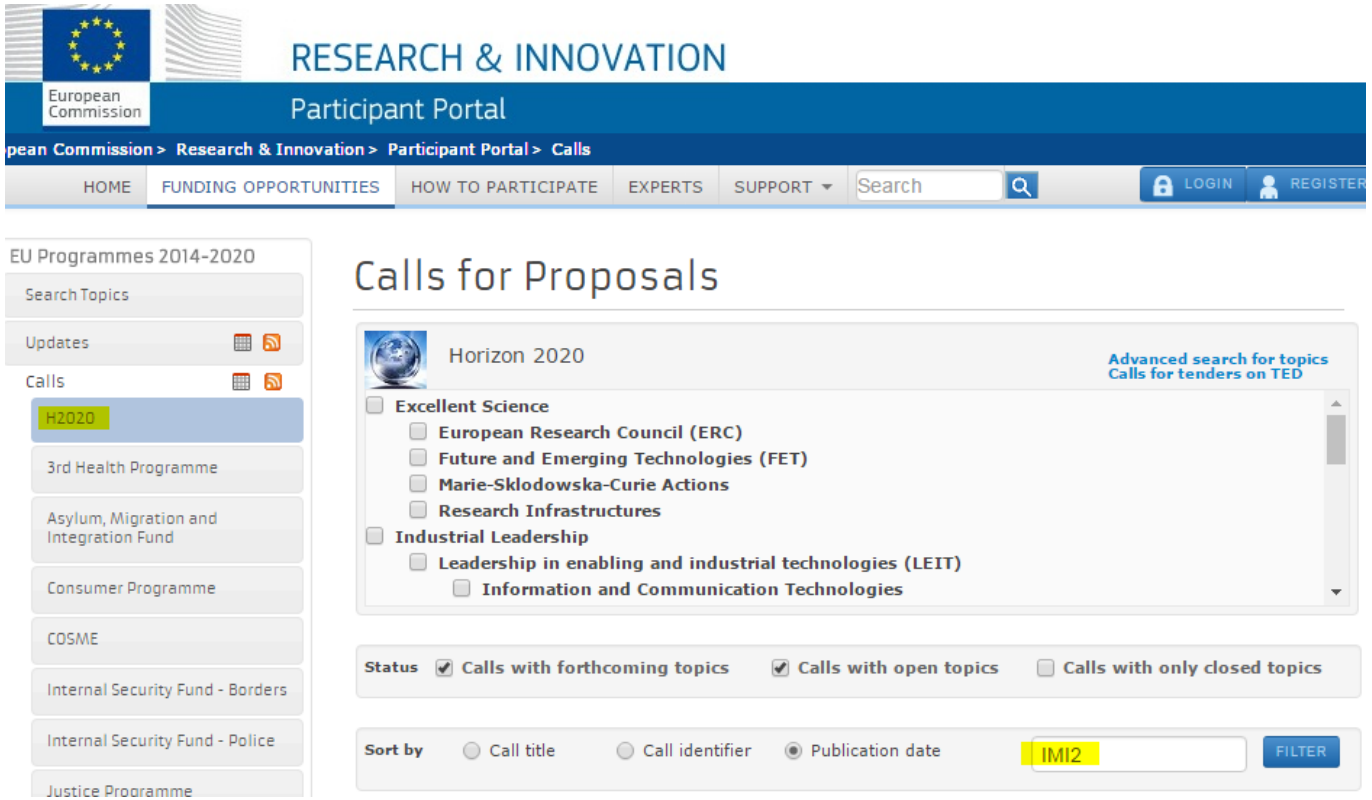
Submitting a proposal

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



- **Call launch**: 18th July 2018
- **Full proposal submission deadline**: 24th October 2018

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Proposal Template

- Available on IMI website & H2020 submission tool
- For full proposals, the page limit is **70 pages** (for sections 1-3)

Please do not consider the page limit as a target. It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long proposals in a positive light.

Title of proposal

List of participants

Table of contents

1. EXCELLENCE

- *1.1 Objectives*
- *1.2 Relation to the call topic text*
- *1.3 Concept and approach*
- *1.4 Ambition*

2. IMPACT

- *2.1 Expected impacts*
- *2.2 Measures to maximise impact*

3. IMPLEMENTATION

- *3.1 Project plan – work packages, deliverables and milestones*
- *3.2 Management structures and procedures*
- *3.3 Consortium as a whole*
- *3.4 Resources to be committed*

4. MEMBERS OF THE CONSORTIUM

- *4.1 Participants*
- *4.2 Third parties involved in the project*

5. ETHICS

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Evaluation Criteria (1/3)

- **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.

Evaluation Criteria (2/3)

- **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;
  - Enhancing innovation capacity and integration of new knowledge;
  - Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
  - Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.
  - Any other environmental and socially important impacts
  - Effectiveness of the proposed measures to exploit and disseminate the project's results (including management of IPR), to communicate the project, and to manage research data where relevant.

Evaluation Criteria (3/3)

- **Quality and efficiency of the implementation**
  - Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget;
  - Complementarity of the participants within the consortium (where relevant);
  - Clearly defined contribution to the project plan of the industrial partners (where relevant);
  - Appropriateness of the management structures and procedures, including manageability of the consortium, risk and innovation management and sustainability plan

Tips for writing a successful proposal

- Read all the call-relevant material, including **Call text** and **evaluation criteria:**
  www.imi.europa.eu
- Begin forming your consortium **early**
  Partner search tools & networking
- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **IMI Office** should you have questions:
  infodesk@imi.europa.eu

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Common mistakes

- Admissibility/Eligibility criteria not met**:**
  - submission **deadline** missed
  - minimum of **2 legal entities** from **2 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**

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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
- Network on **social media** (e.g. IMI LinkedIn group)
- Companies that expressed particular interest in the Portfolio Building Network are Janssen (RnDG3O@its.jnj.com), GSK (AMR_Accelerator@gsk.com), and Evotec (michael.mourez@evotec.com). Other EFPIA companies can also participate.

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

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AMR Accelerator Programme –

Pillar C: Portfolio Building Networks to advance the R&D pipeline of new and innovative agents to address AMR topics

The IMI2 AMR Accelerator programme

- **AN AMBITIOUS AIM:** to progress a pipeline of new potential medicines to treat patients with resistant bacterial infections or to prevent them; up to >10 new preclinical candidates and >5 ‘phase 2-ready’ assets over six-year period
- **A BROAD SCOPE:** prevention (vaccines, mAbs, immunoprophylaxis, other) and treatment (new antibiotics, non-antibiotic alternatives, and combinations), Gram+ and Gram- bacteria, tuberculosis (TB) and non-tubercular mycobacteria (NTM)
- **A SIGNIFICANT BUDGET:** ~ € 300 000 000

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Need for public-private collaboration

- Significiant scientific challenges to the discovery of new treatments and prevention of AMR infections, including TB
  - Collaborative approaches needed to address these challenges
  - Shared experience, learnings and resources
- Current ‘broken’ economic models for Return on Investment for antibacterials
  - External funding of antibacterial R&D in companies (e.g. ‘push-incentives’) are complementing internal resources
- IMI’s New Drugs for Bad Bugs (ND4BB) programme successfully implements PPPs in the field of AMR: The AMR Accelerator will complement and build upon ND4BB

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The three pillars of the AMR Accelerator

AMR Accelerator

PILLAR A:
Capability Network
Basic science to build knowledge

1. Projects focused on improving success of AMR R&D
2. Coordination & support of project across Accelerator

PILLAR B:
TB Drug Discovery
Progress novel TB programs to end Ph 1

Build preclinical capabilities, explore basic science to support TB drug discovery and progress TB assets through end of Ph1

PILLAR C:
Portfolio Network
Incubate early drug discovery programs

Novel framework to discovery, study, and advance potential new treatments for AMR infection

- Capability Building Network (Pillar A) and TB Drug Development Network (Pillar B) are part of IMI2 Call 15
  - Informational webinar scheduled for 16 July

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IMI2 Call 16 launches the Portfolio Building Network (Pillar C) of the Accelerator

- The call includes 7 independent topics: applicants can apply to one or several topics (separate applications)
- The call follows a single-stage process (different from the Pillar A and Pillar B topics of the AMR Accelerator in IMI2 Call 15)
- There is no pre-defined industry consortium; companies that have expressed interest in the Portfolio Building Network are GSK, Janssen, and Evotec; all EFPIA companies can in principle participate under this call
- Requirement for one EFPIA company in each proposal
- The applicant consortium may be limited in size but must involve at least two independent legal entities established in two different EU Member States, or countries associated to H2020
- In the future, additional single-stage calls for proposals might be launched under Pillar C of the Accelerator

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IMI2 Call 16 : 7 topics

- Topic 1: Tuberculosis assets that synergize with bedaquiline, cytochrome bc or bd inhibitors
- Topic 2: Non-tubercular mycobacteria (NTM) assets that may act synergistically with bedaquiline and cytochrome bc drugs
- Topic 3: Novel assets for TB and NTM & biomarkers for TB and NTM infection
- Topic 4: Determination of gepotidacin levels in tonsils and prostatic tissue
- Topic 5: Infection site targeting, antibiotic encapsulated nanoparticles
- Topic 6: Functional Ethionamide Boosters. A novel combination for TB therapy
- Topic 7: Intravenous treatments of serious Gram-negative infections

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Objectives of Call 16, all topics

- Discover and progress novel assets for treatment or prevention of AMR infections
- Create flexible, nimble partnerships between EFPIA companies & SMEs / academics that can react to unfolding data
- Overall deliver multiple preclinical drug candidates, First-Time-in-Human (FTIH) starts, and phase 2-ready assets

Topics 1-3: Applicant consortia

- Discovery capabilities including but not limited to:
  - animal infection, dormancy, and *in vitro* models to characterise the response to antibiotics; infected macrophage models; exploration of MoA, and targets; profiling new inhibitors & combos.
- PK/PD studies/models, non-GLP and GLP toxicology profiling;
- GMP manufacturing and formulation development
- Access to compound in the field of TB/NTM. Bedaquiline and cytochrome bc/bd inhibitors could be brought to the combination

Additional capabilities needed for Topics 1-2:

- access to network of patients of different socio-economic backgrounds on mycobacterial therapy and/or paediatric patients with underlying lung disease and carrying a mycobacterial infection.
- In-depth TB & NTM expertise, including ability to conduct Ph1 clinical studies in healthy volunteers, TB and/or NTM patients is mandatory

Key Deliverables for Topics 1-3

- Topic 1: TB assets that synergize with bedaquiline, cytochrome bc or bd inhibitors
  - one preNME candidate for TB
  - profiling and phase 1 studies of a novel TB preclinical candidate to deliver a phase 2 ready TB asset

- Topic 2: Non-tubercular mycobacteria (NTM) assets that may act synergistically with bedaquiline and cytochrome bc drugs
  - profiling and phase 1 studies of a novel NTM preclinical candidate to deliver a phase 2a ready NTM asset

- Topic 3: Novel assets for TB and NTM & biomarkers for TB and NTM infection
  - Two preNME candidates, one for TB and one for NTM

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Topic 4: Determination of gepotidacin levels in tonsils and prostatic tissue

- **Applicant consortia:**
  - access to patients undergoing tonsillectomy, TURP or prostate biopsy,
  - experience with clinical trials,
  - training in International Council of Harmonisation (ICH) guidelines and good clinical practice (GCP);
  - expertise and capacity to perform PK analysis.
- **Key deliverables of the project**:
  - pharmacokinetic analysis of plasma samples and tissue homogenates to evaluate penetration and exposure in the tonsils & prostate

Topic 5: Infection site targeting, antibiotic encapsulated nanoparticles

- **Applicant consortia:** experience with:
  - bacterial or infection site targeting
  - nanoparticles with clear regulatory path, including production, characterisation, and scale-up, preferably GMP-production
  - incorporation of surface modifications of nanoparticles
  - and capacity to run *in vivo* animal models of infection; rodent toxicology studies, including immunotoxicology, with nanoparticle agents; experience with preclinical PET imaging
- **Key deliverables of the project:**
  - one candidate-selection of an infection site targeting, antibiotic encapsulated nanoparticle for treatment of bacterial infections

Topic 6: Functional Ethionamide Boosters. A novel combination for TB therapy

- **Applicant consortia**, experience with:
  - use of bacterial transcriptional regulators
  - setting up, validating, and running In vitro biochemistry assays; using HPLC/mass spectrometry for the identification of metabolites;
  - capacity to run *Mycobacterium tuberculosis* animal models of infection including PK/PD; toxicology, pharmacokinetics and pharmaceutical development studies, including human dose projection; preclinical PET imaging; API production (incl. GMP manufacturing / CMC / clinical experience), medicinal chemistry
- **Key deliverables of the project**:
  - clinical candidate ready to enter into phase 2 for the treatment of tuberculosis;
  - preclinical candidate backup on a different chemical series

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Topic 7: Intravenous treatments of serious Gram-negative infections

- **Applicant consortia**:
  - compounds and expertise in novel phenotypic screening, including natural products; and technologies to de-orphan hits;
  - approaches to translationally validate novel mode of action to the clinical situation;
  - capacity in med chem, microbiology, pharmacology, early ADMET, PK/PD approaches, etc and perform preclinical development studies (e. g. GLP synthesis & toxicity studies, formulation, etc)
  - expertise in development of companion diagnostics & biomarkers,
  - undertake first into human studies (FTIH) on heathy
- **Key deliverables of the project**:
  - up to two NMEs ready to enter into phase 1 studies;
  - up to four NMEs having completed lead optimisation process so as to be ready to enter phase 1 enabling studies

Budget and project durations

IMI2 Call 16 topic	max. IMI2 JU funding [Euro]	Indicative project duration [months]
Topic 1: Synergistic TB assets	6 840 000	72
Topic 2: Synergistic NTM assets	5 690 000	72
Topic 3: TB and NTM novel MOA and biomarkers	1 770 000	72
Topic 4: Gepotidacin levels	7 300 000	18
Topic 5: Nanoparticle-encapsulated antibiotic	6 000 000	36
Topic 6: Ethionamide boosters	7 000 000	48
Topic 7: Intravenous treatments	12 300 000	72

The total budget of each proposal will consist of the requested IMI2 JU contribution plus the relevant in-kind contribution by the participating EFPIA company (see requirement for participation of EFPIA company or affiliated entity)

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Suggested architecture of the projects

- Applicants to each topic should suggest complete architectures in the submitted proposals (e.g. number of work packages)

Coordination and support

- Applicants should note that for all topics, significant project management support will be provided through the **Coordination and Support group** established by the Capability Building Network (Pillar A of the AMR Accelerator), this includes:
  - Supporting the coordinator in the management of scientific and financial reporting
  - Prosecution of legal agreements such as CDAs, MTAs
  - Meeting facilitation and secretariat

Therefore, only limited project and financial management capabilities will be required from the applicant consortia in this call

- Representatives from all selected projects will contribute to an **advisory and communications board** (containing representatives from all the projects running in the AMR Accelerator in addition to independent experts)

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Decision-making for a dynamic portfolio

- Each applicant consortium must agree on a **fair and robust no/no-go decision making process** to ensure that only the most promising compounds/approaches are pursued
- **Go/no go milestones** need to be clear in each proposal
- A **committee** including at least one project-independent expert tracks progress against milestones and makes recommendations for progression/stop
  - Rapid, streamlined, single-meeting process
  - Cannot force project to continue if all partners suggest termination
  - May result, in case of ‘no go’ decision, in a recommendation to the IMI2 JU to terminate the grant.
  - Final decision about project continuation or termination will be taken by the IMI2 JU in line with provisions of the Grant Agreement

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Expected impact of the Portfolio Building Network

- Contribute to the development of a vibrant AMR research environment in the EU and strengthen the competitiveness and industrial leadership of Europe
- Contribute to the EU's ambition of being a 'best practice region' for addressing AMR;
- Enhance the overall pipeline of medicines for patients with AMR infections and advance new and innovative agents

What's in it for you?

- Direct involvement in discovery and/or development of novel agents to treat AMR infections
- As a partner in any Accelerator project, exposure to large and vibrant AMR network
- Further validation of your asset, model, or tool
- IMI in particular encourages the participation of SME's
- Assets and proposed work can originate from SMEs, academia, or EFPIA companies and will be jointly progressed
- Patients and patient organisations are encouraged to participate and provide their views

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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 needed (project partners or advisors)
- 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'

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Additional points of note

- A Q&A document was posted on the IMI website that covers specific questions around IP and data sharing at: www.imi.europa.eu/apply-funding/future-topics

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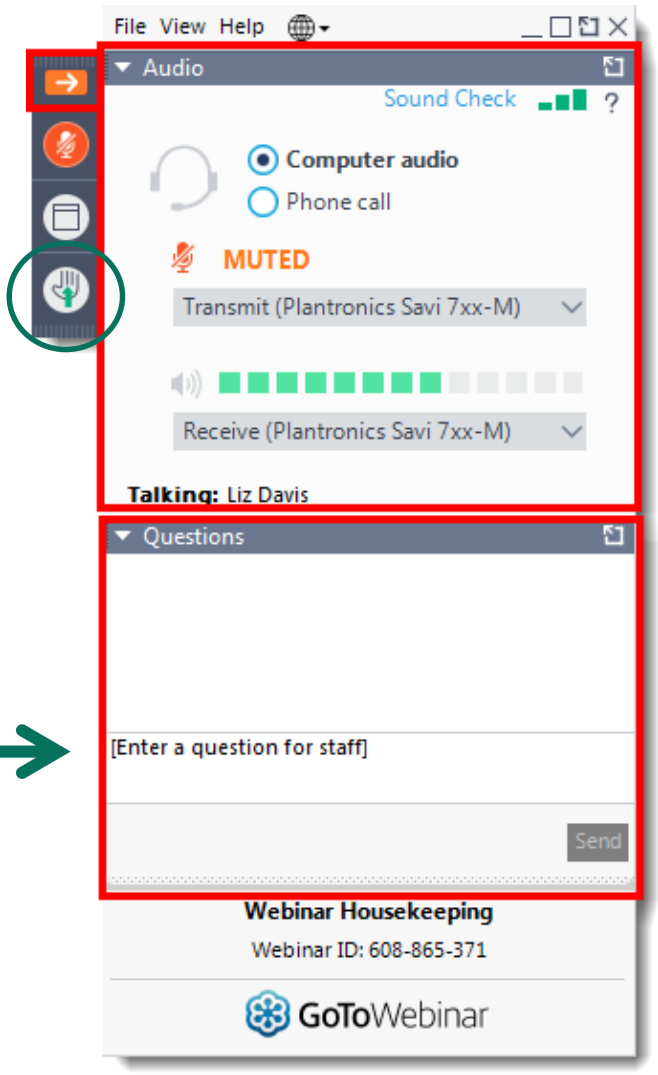
Questions & answers

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

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Thank you!