

Webinar | IMI2 AMR Accelerator
Pillar B: Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic

24.09.2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction to IMI & the Call process – Tek-Ang Lim, IMI
- Introduction to the IMI2 Antimicrobial Resistance (AMR) Accelerator programme – Tek-Ang Lim, IMI
- AMR Accelerator programme Pillar B: TB drug development Network (TBDDN) – Joel Lelievre, on behalf of the industry consortium, GlaxoSmithKline
- 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:

- Expand / minimise control panel:** A red circle highlights the right-pointing arrow icon at the top of the control panel.
- Microphone status:** An arrow points to the microphone icon, which is currently muted (indicated by a red slash).
- Full screen:** An arrow points to the full-screen icon (a square with a smaller square inside).
- Raise / lower your hand:** An arrow points to the hand icon, which is currently raised (indicated by a green hand).
- Send a question in writing:** An arrow points to the text input field labeled "[Enter a question for staff]" and the "Send" button.

The interface also displays the following information:

- File View Help
- Audio
- Sound Check
- Computer audio (selected) / Phone call
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- Talking: Liz Davis
- Questions
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- GoToWebinar logo

How to use GoToWebinar - audio

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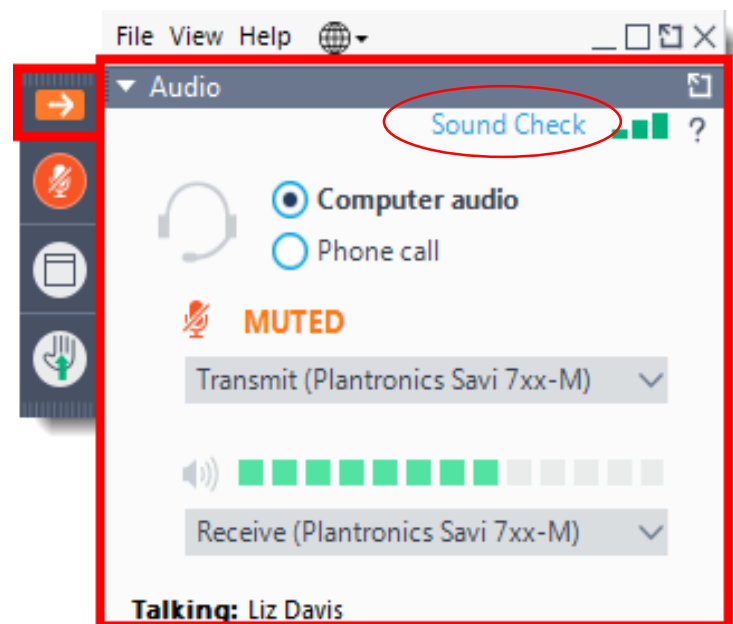
Can't hear us?

- Check your **speakers are switched on and not muted**
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- Check you have selected **Phone call** in the audio panel
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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
- The presentation slides will be published on the IMI website
- A participant list will be circulated and published on the website
- Details of the topic and information on how to apply can be found online at bit.ly/IMI2Call15



Introduction to IMI and the Call process

Tek-Ang Lim

Today's webinar

Will cover all aspects of the Call topic

- Introduction to IMI programme
- Introduction to the AMR Accelerator
- Proposed projects for AMR Accelerator Pillar B
 - 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 (webinar held on 10 July)
- AMR Accelerator Pillars A and C (webinars held in July)

Recording and presentations available online

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

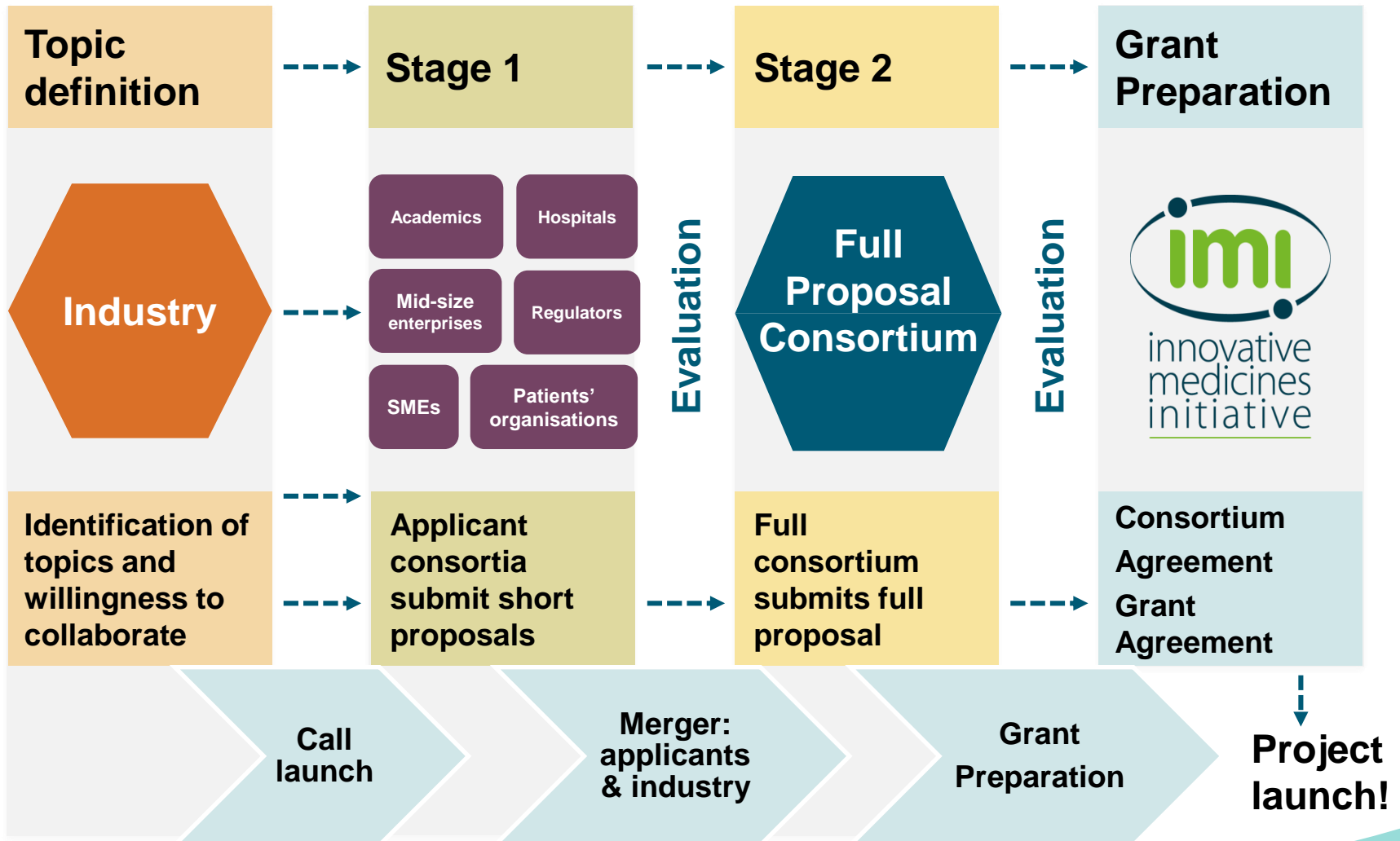
Industrial partners align themselves around a real challenge for industry and agree to work together **and commit resources**

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



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', 'Asylum, Migration and Integration Fund', 'Consumer Programme', 'COSME', 'Internal Security Fund - Borders', 'Internal Security Fund - Police', and 'Justice Programme'. The main content area is titled 'Calls for Proposals' and features a 'Horizon 2020' section with a globe icon. Below this, there are filter options for 'Excellent Science' (ERC, FET, Marie-Sklodowska-Curie Actions, Research Infrastructures) and 'Industrial Leadership' (LEIT, 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
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)



Introduction to the IMI2 Antimicrobial Resistance (AMR) Accelerator programme

Tek-Ang Lim

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

The three pillars of the AMR Accelerator

AMR Accelerator

PILLAR A:

Capability Network
Basic science to build knowledge

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

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 discover, study, and advance potential new treatments for AMR infection

Some specific aspects of the AMR Accelerator programme

- Consists of 3 pillars under which multiple actions are expected
- Applicants may submit a proposal to any of the topics under the different pillars and are not obliged to apply for all. If applicants wish to submit for more than one topic, separate proposals should be submitted.
- Collaboration agreements foreseen to ensure smooth operation of the projects in the AMR Accelerator.
Consortia selected under Pillars A, B, and C will conclude collaboration agreements with the CBN consortium selected under topic 7.

Need for public-private collaboration

- Significant 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

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 a large and vibrant AMR network
- Further validation of your asset, model, or tool
- Opportunity to facilitate interactions with the global AMR community
- IMI in particular encourages the participation of SME's
- Patients and patient organisations are encouraged to participate and provide their views

Additional points of note

- A Q&A document was posted on the IMI website that covers specific questions around IP and data sharing

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/future-topics/AMRaccelerator_QandA_vJune2018.pdf

- Suggest all applicants read and understand this documents in parallel with the Topic texts

AMR Accelerator programme Pillar B: TB drug development Network (TBDDN)

Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic

The three pillars of the AMR Accelerator

PILLAR A:
Capability Network
Basic science to build knowledge

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

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 discover, study, and advance potential new treatments for AMR infection

AMR Accelerator

TBDDN Scope

A platform to:

- Profile and progress a portfolio of anti-TB compounds (EFPIA & APs) from advanced lead stage through Phase 1 (ready to enter Ph-2)
- Pan-TB regimen - facilitate the design of combination regimens for the treatment of any form of TB including MDR
- Create tools and technologies to progress anti-TB compounds
- Provide learnings from the analysis of shared anti-TB clinical trial data
- Develop new alternative anti-TB drugs (host or virulence approaches)
- Interact with TB stakeholders and explore synergies

Expected contributions of the applicants

PROFILING

- Analysis of preclinical and clinical TB trial data including collection, collation and curation of TB-specific data sets
- *In vitro* and *in vivo* tools to identify, characterise and progress single drugs and combinations. Including imaging platforms to measure pharmacodynamic responses at the sites of action
- Translation of PK/PD and regulatory knowledge to support the development of limited use/accelerated pathways for TB drugs
- Translational PBPK-PD models fed with preclinical data in the TB space (PBPK, PD and disease progression integrative models), expertise in preclinical and clinical TB biomarkers
- Drug discovery optimisation activities, e.g. medicinal chemistry, microbiology, scale up, formulation, DMPK, toxicology, etc

Expected contributions of the applicants

PORTOFLIO

- Scale up synthesis of non-GMP grade of selected pre-candidates to assess therapeutic index of preclinical pre-candidates (non GLP toxicity and *in vivo* profiling into advanced TB models)
- Pharmaceutical development techniques to maximise the evaluation of the therapeutic index of novel compound
- Scale up synthesis of selected candidate compounds of GMP grade (1-5 kg) of active product ingredients of GMP grade to perform GLP toxicity studies
- First into human studies (FTIH): ability to conduct in parallel several first into human studies (FTIH)

Expected (in kind) contributions of industry consortium

- Bring novel advanced TB molecules for progression to FTIH
- Perform preclinical development studies
- Share historical TB drug discovery and development data
- Pre-candidate studies: discovery activities from Lead optimisation to selection of a molecule as preclinical candidate
- Preclinical development: studies performed between preclinical candidate and first time in human
- Early pharmaceutical development including process chemistry development, pre-formulation, formulation and drug delivery techniques to maximise the evaluation of the therapeutic index of novel compound
- Conduct standard medicinal chemistry, microbiology, pharmacology and early ADMET optimisation programmes for novel anti-TB compounds.

Expected (in kind) contributions of industry consortium

- Conduct and share results and information of enabling studies such as synthesis (up-scales, fermentation), optimisation of lead molecules, computational chemistry, profiling in *in vitro* and *in vivo* models (marmoset and murine models, cell & lesion penetration, PKPD profiling and modelling, metabolomics), access to enzymology platforms (biochemical and biophysical assays and crystallography) and toxicology of novel pre-candidates from TB portfolios from EFPIA and Associated Partners for further analysis
- Generate and share data, samples, and information from industry-sponsored clinical trials (Phase 1-3) in the field of TB including drug sensitive, drug resistant, and multidrug resistant tuberculosis, of compounds including enabling studies of novel precandidates from TB portfolios from EFPIA and associated partners for further analysis
- Assist in the analysis of the output of clinical trials in the TB space, e.g. efficacy, safety, translation of preclinical data with respect to safety, tolerability, dose prediction, animal models of infection and efficacy

Suggested architecture of the projects

Applicants should:

- Suggest complete architectures in the submitted proposals (e.g. number of work packages).
- Integrate contributions from EFPIA companies and Associated Partners to set up Profiling and Portfolio platforms that are fit for purpose.
- Propose a structure capable of progressing several molecules from Candidate stage up to Phase II ready.
- Present a flexible structure that takes into account decision making and attrition when planning distribution of resources per WPs over the lifetime of the project.

Key deliverables of the full project

Deliverable 1: Development and implementation of new assays and tools to study anti-TB compounds

- In vitro and in vivo assays that enable the rational design of novel, pan-active anti-TB drug candidates
- Development of imaging platform (*in vitro/in vivo*)
- PK/PD studies/models required to support approval for novel TB investigational new drug (INDs) and combinations of INDs & acceptance with EMA & FDA
- Translational PBPK-PD models
- Novel biomarkers to assess treatment efficacy, disease evolution and cure at preclinical and clinical stages
- New host-defence and virulence approaches

Deliverable 2: An advanced portfolio of anti-TB compounds:

- new or repurposed clinical candidates ready to enter into Phase 2 proof of concept studies in TB patients (note that Phase 2 studies are outside the scope of the TBDDN)
- novel combination regimens that will be formed by combining the clinical candidates

Key deliverables of the full project

Deliverable 3: Learnings derived from shared TB clinical trial data (e.g. Phase 1-3 clinical trials related to TB) and associated enabling studies:

- generation and collation of clinical trial data to allow for analysis and translation of preclinical to clinical data with respect to, for example, safety, tolerability, dose prediction, animal models of infection and efficacy, and greater disease understanding.

Deliverable 4: Scientific coordination and daily project management

- Scientific, administrative and financial reporting
- Engagement for preclinical and clinical TB data.
- Daily administrative tasks such as the organisation of consortium meetings, intra- and inter-work package meetings, preparation of minutes, progress reports, etc

EFPIA and Associated Partners

The industry consortium is composed of the following EFPIA companies:

- GSK
- Janssen
- Evotec

In addition, includes the following IMI2 Associated Partners:

- Bill & Melinda Gates Foundation
- Global Alliance for TB Drug Development (TB Alliance)
- University of Dundee (Drug Discovery Unit)

Budget and project durations

AMR Accelerator programme Pillar B IMI2 Call 15 topic 8	Planned EFPIA/AP in-kind [Euro]	max. IMI2 JU funding [Euro]	Indicative project duration [months]
Topic 8: Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic	120 000 000	89 830 000	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 companies and Associated Partners

Coordination and support

- Pillar B/Topic 8 will have a management structure which will be supported by the Coordination and Support group established by the Capability Building Network (Pillar A of the AMR Accelerator). The management team of pillar B will perform:
 - Scientific, administrative and financial reporting
 - Engagement for preclinical and clinical TB data
 - Daily administrative tasks such as the organisation of consortium meetings, intra- and inter-work package meetings, preparation of minutes, progress reports, etc
- Representatives from all AMR Accelerator 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)

Expected impact

- Enabling the progression of potential new treatment solutions for TB patients worldwide.
- Strengthen interaction of TB R&D stakeholders from across the EU and globally
- Provide new tools and understandings to progress TB science for the discovery of new preclinical candidates and novel combination regimens
- Contributing to the development of a vibrant TB research environment in the EU and strengthening the competitiveness and industrial leadership of Europe
- Contributing to make the EU's a 'best practice region' for addressing AMR



Thank you

www.imi.europa.eu

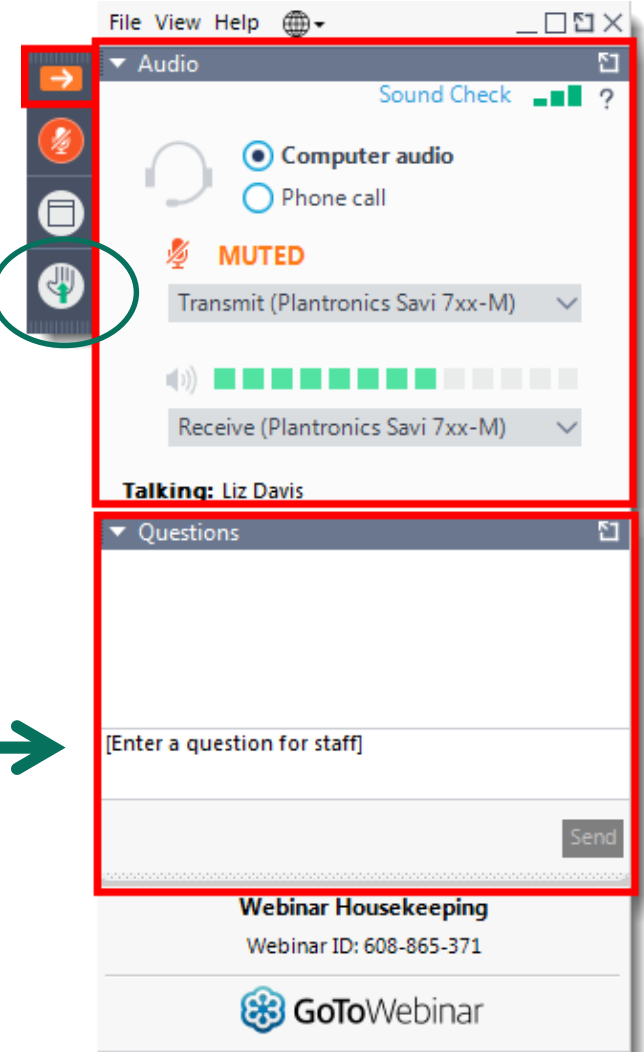
 @IMI_JU



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



Thank you!