



**Webinar | IMI2 - Call 20
Academia and industry united
innovation and treatment for
tuberculosis (UNITE4TB)**

23.01.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Tek Lim, IMI
- The Call topic – David Barros, GSK; Gavin Koh, GSK; Michael Hoelscher, LMU
- Involvement of SMEs, patient groups, regulators – Tek Lim, 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, there is a menu bar with 'File', 'View', and 'Help'. Below it is the 'Audio' control panel, which includes a 'Sound Check' indicator and two radio buttons for '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)'. A volume slider is also visible. The 'Talking:' section indicates 'Liz Davis' is speaking. 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, along with the GoToWebinar logo.

How to use GoToWebinar - audio

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

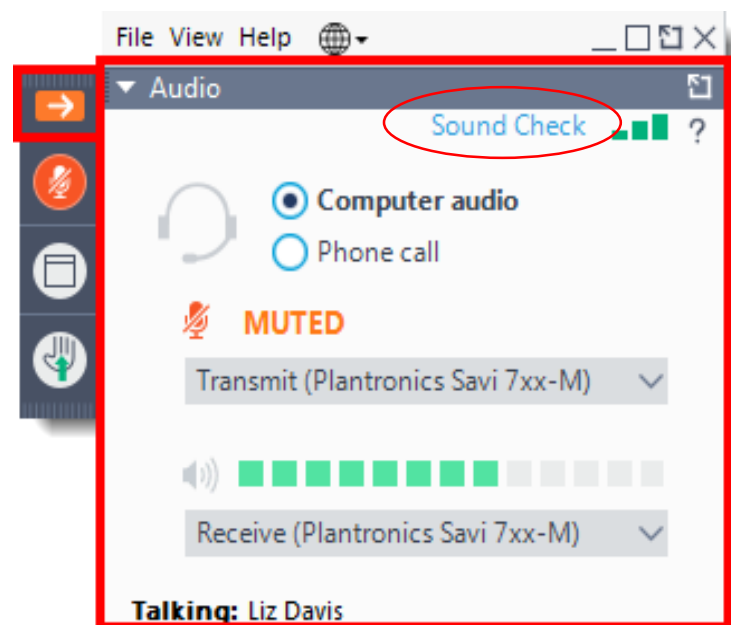
Can't hear us?

- 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

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- 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 published on the website
- IMI2 – Call 20 has been launched and all Call documents & details of how to apply can be found on the IMI website

Webinar | IMI2 - Call 20

**Topic 3: Academia and industry
united innovation and treatment for
tuberculosis**

Pillar B AMR Accelerator

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 will take place on Thursday 29 January, 11:00 – 12:30

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 partnership 2008-2020

IMI 1:

- 2008-2013
- €2 bn budget
- 59 projects



IMI 2:

- 2014-2020
- €3.3 bn budget
- More ambitious, more open, greater scope



€2.5 bn
EU
contributions
from FP7 /
H2020



efpia

€ 2.5 bn
Pharma
contributions
in-kind

IMI2 funding

(2014-2020)

IMI FUNDING MODEL

efpia

IN-KIND PRIVATE CONTRIBUTION

€1.425 bn

EFPIA companies receive no funding

€ 3.276 bn
TOTAL IMI2 BUDGET



public contribution

€1.638 bn

funding from Horizon 2020

EU funding goes to ▶

SMES

UNIVERSITIES

PATIENTS, REGULATORS...

OTHER CONTRIBUTIONS

€213 MILLION

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

EFPIA contribute researchers, laboratories, generation of data, curation of compounds, and cash

Public and private partners collaborate in IMI2 projects

Accelerating research and development

Speeding up patient access to innovative treatments

Improving patient outcomes and safety of medicines

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

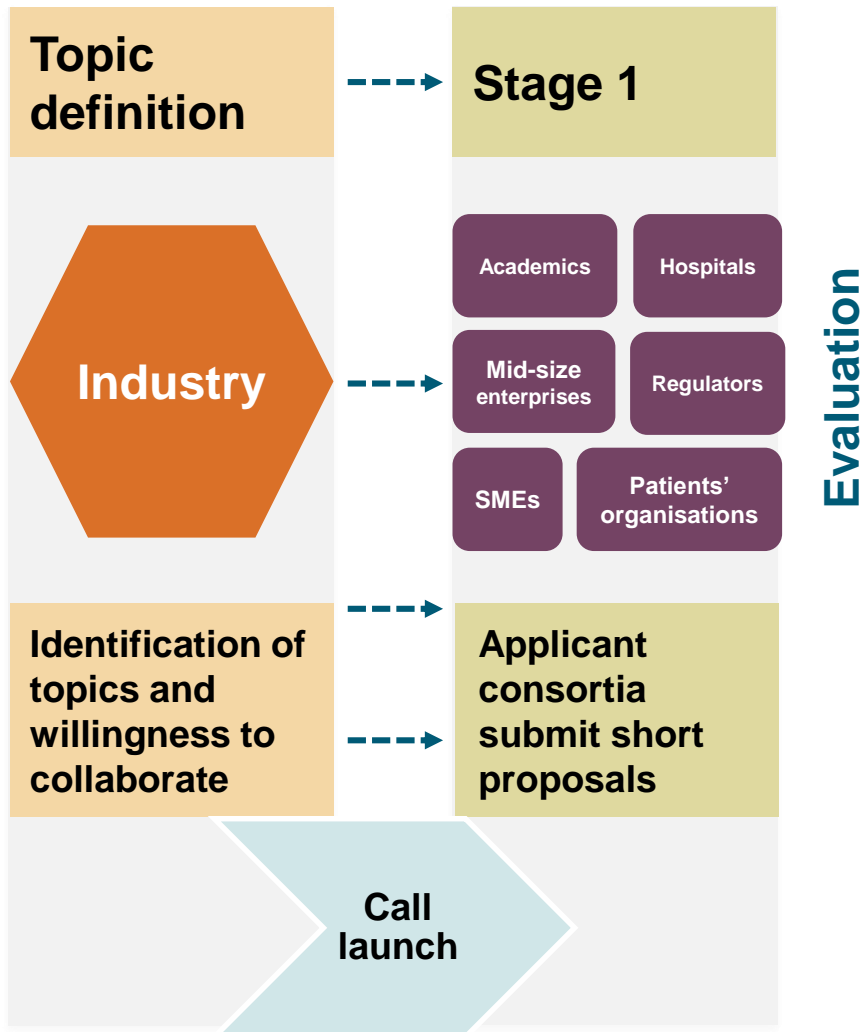
Scale is a key to success and is provided through IMI funding

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

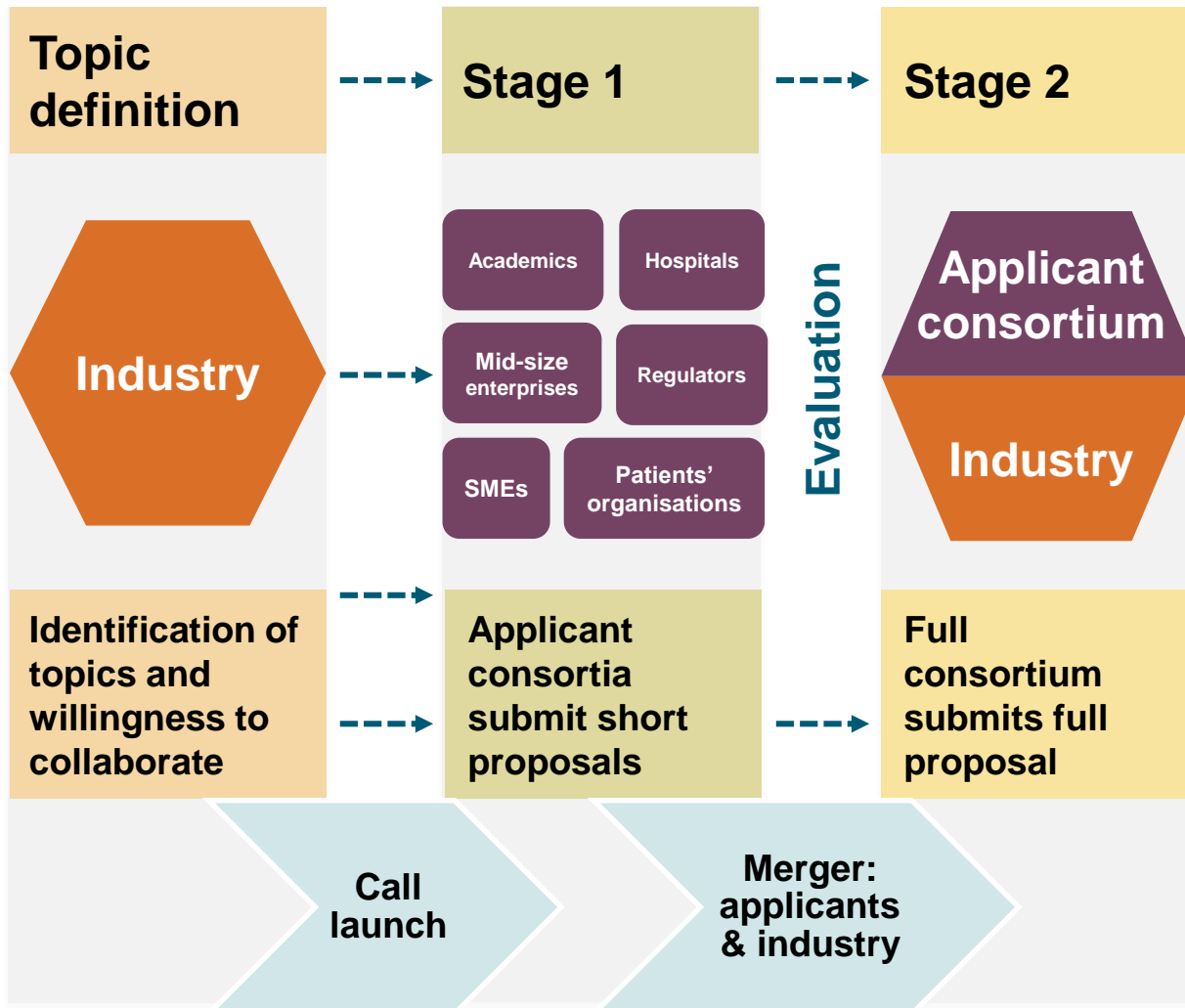
Typical IMI project life cycle



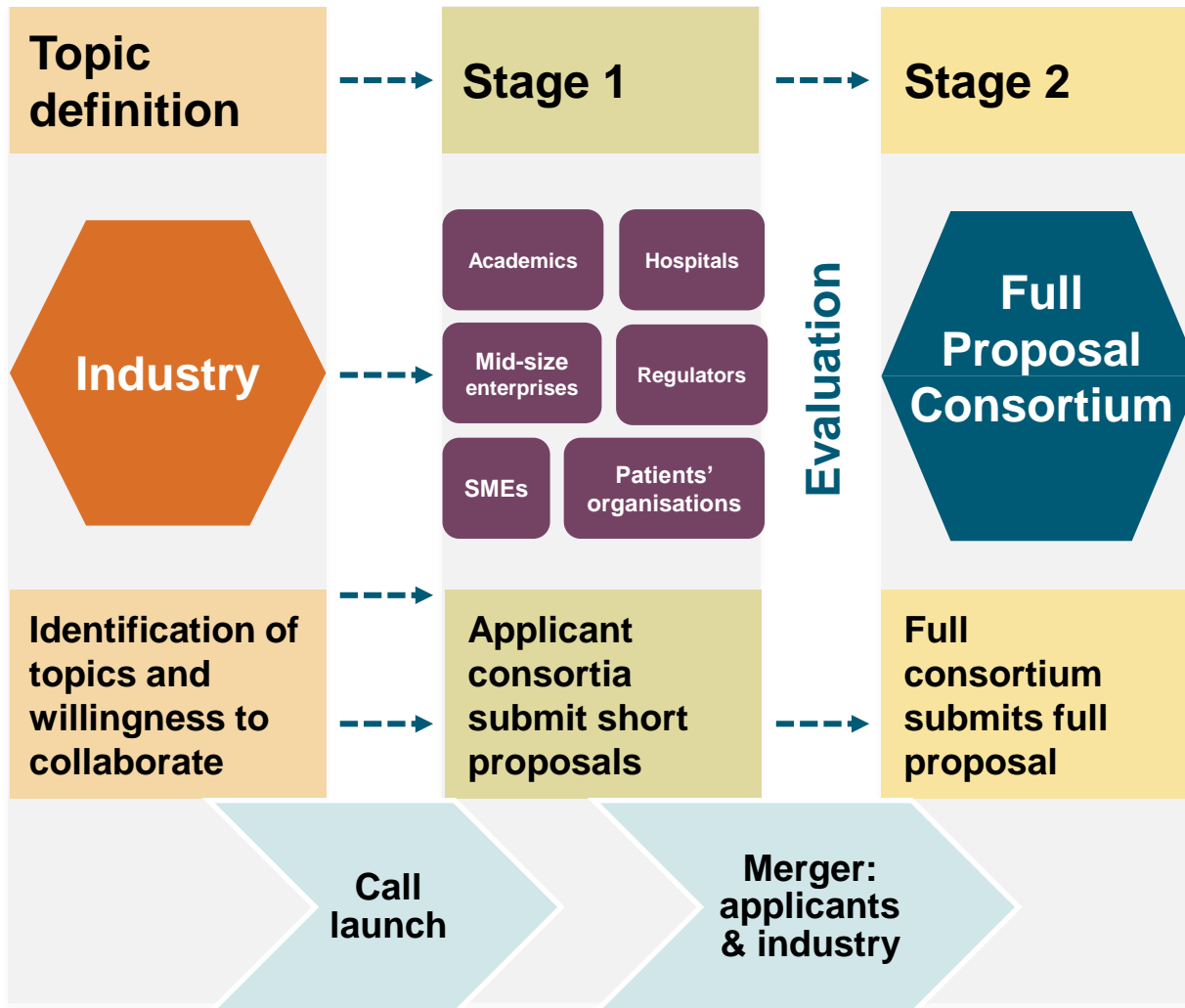
Typical IMI project life cycle



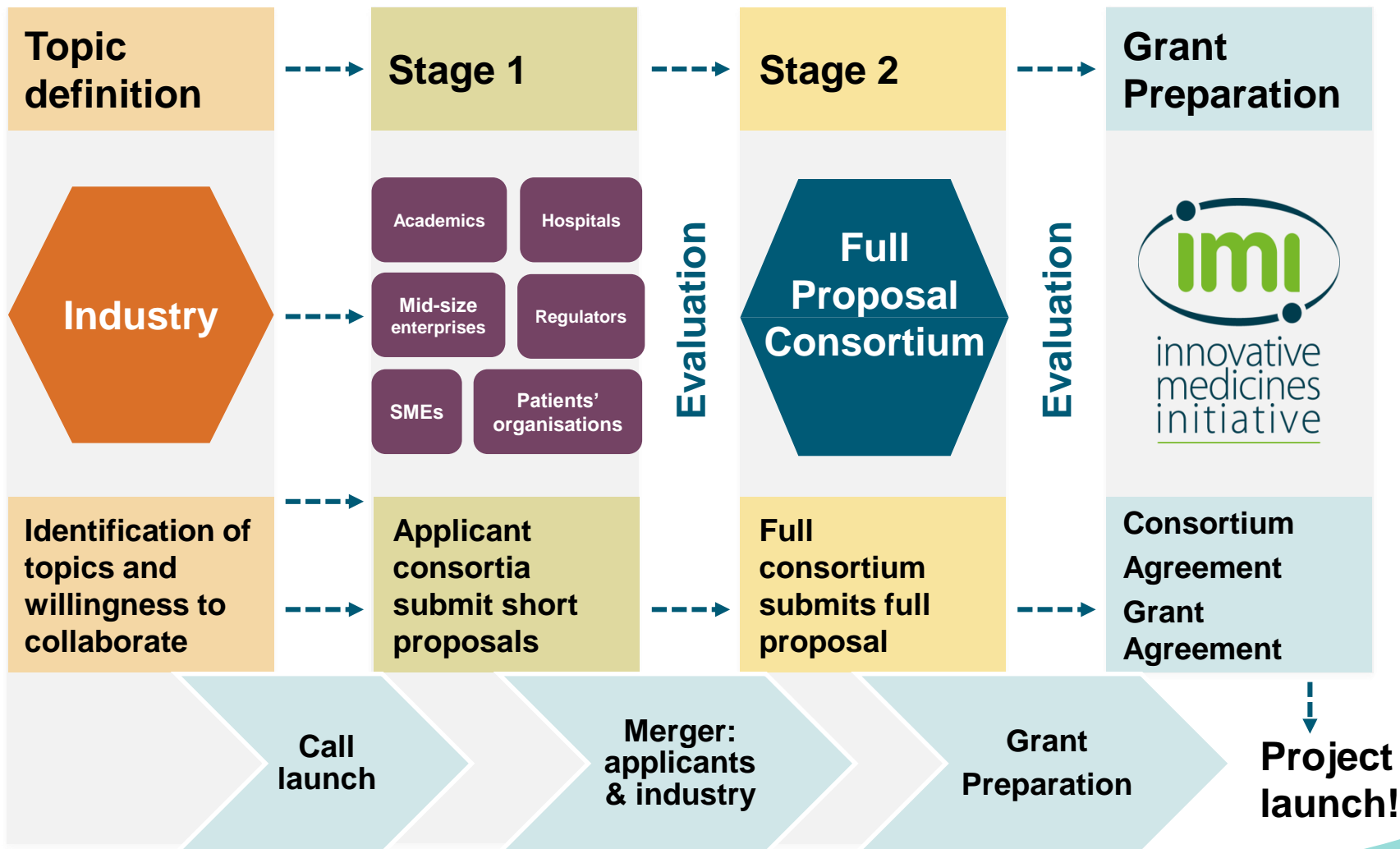
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



Submitting a proposal

Via the **new** Funding and Tenders Portal

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

The screenshot shows the 'Funding & tender opportunities' portal. At the top, there is a header with the European Commission logo and the text 'Funding & tender opportunities Single Electronic Data Interchange Area (SEDIA)'. On the right, there are links for 'English EN', 'Register', and 'Login'. Below the header is a navigation bar with a home icon and menu items: 'SEARCH FUNDING & TENDERS', 'HOW TO PARTICIPATE', 'PROJECTS & RESULTS', 'WORK AS AN EXPERT', and 'SUPPORT'. A 'select programme' button is also present.

The main content area features a blue banner with the text: 'The Funding & Tenders Portal is the entry point (the Single Electronic Data Interchange Area) for participants and experts in funding programmes and tenders managed by the European Commission and other EU bodies.' A 'Feedback' button is located on the right side of this banner.

Below the banner is a section titled 'Find calls for proposals and tenders' with a search bar containing the placeholder text 'Search calls for proposals and tenders by keywords, programmes...' and a yellow 'Search' button.

The bottom section is titled 'Calls for proposals by EU Programme' and contains a grid of 14 programmes. The 'Horizon 2020 Framework Programme (H2020)' is circled in red.

3rd Health Programme (3HP)	Asylum, Migration and Integration Fund (AMIF)	Consumer Programme (CP)	Creative Europe (CREA)	Erasmus+ Programme (EPLUS)	European Maritime and Fisheries Fund (EMFF)	HERCULE III (HERC)	Horizon 2020 Framework Programme (H2020)
Internal Security Fund Borders and Visa (ISFB)	Internal Security Fund Police (ISFP)	Justice Programme (JUST)	Pilot Projects and Preparatory Actions (PPPA)	Programme for the Competitiveness of	Promotion of Agricultural Products (AGRIP)	Research Fund for Coal & Steel (RFCS)	Rights, Equality and Citizenship Programme

New Funding and Tenders Portal Horizon 2020 section

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/programmes/h2020>

Horizon 2020 Framework Programme (H2020) clear filter

Horizon 2020 Research & Innovation

Horizon 2020 is the EU funding programme for research and innovation

Horizon 2020 programme is running from 2014 to 2020 with a €80 billion budget. It provides research and innovation funding for multi-national collaboration projects as well as for individual researchers and supports SMEs with a special funding instrument.

For more information on Horizon 2020, please see the H2020 web site.

- Find calls for proposals
- Projects & Results
- SME Participations
- Financial Capacity Assessment
- What's new

Feedback

Find calls for proposals in Horizon 2020

Search calls for proposals by keywords, programme parts,...

Filter by programme part:

- Excellent Science

Filter by focus area:

- Building a low-carbon, climate resilient future

Filter by cross-cutting priority:

- Cross-cutting Key-Enabling Technologies

Warning: Calls for Tenders are not available when you have selected a programme. [See all calls for tenders published by EC](#)

Proposal Template – Newly updated

- 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

1.1 Objectives

1.2 Concept and methodology

1.3 Ambition

2. IMPACT

2.1 Expected impacts

2.2 Outline Measures to maximise impact

3. IMPLEMENTATION

3.1 Outline of project work plan — Work packages, and major deliverables

3.2 Management structure and procedures

3.3 Consortium as a whole

3.4 List of work packages

4. PARTICIPANTS

4.1. Participants (applicants)

Evaluation Criteria (1/2) – Newly updated

■ Excellence

- Level to which all the objectives of the Call topic text are addressed;
- Soundness of the concept and credibility of the proposed methodology;
- Extent that the proposed work is beyond the state of the art and demonstrates innovation potential;
- Appropriate consideration of interdisciplinary approaches and use of stakeholder knowledge.

■ Impact

- Demonstration of how the outputs of the project will contribute to each of the expected impacts mentioned in the relevant Call topic text;
- Outline of how the project plans to leverage the public-private partnership model to achieve greater impact on innovation within research and development, regulatory, clinical and healthcare practices, as relevant ;
- Impacts on competitiveness and growth of companies including SMEs;
- Quality of the proposed outline to:
 - Disseminate, exploit and sustain the project results;
 - Manage research data;
 - Communicate the project activities to relevant target audiences.

Evaluation Criteria (2/2) – Newly updated

■ Quality and efficiency of the implementation

- Quality and effectiveness of the work plan outline, including extent to which the resources assigned to work packages are in line with their objectives and deliverables;
- Appropriateness of the outline management structures and procedures;
- Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role;
- Complementarity of the participants and extent to which the consortium as whole brings together the necessary expertise;
- Strategy to create a successful partnership with the industry consortium as mentioned in the Call topic text.

New thresholds:

- 3 for each of the evaluation criteria 'excellence', 'impact' and 'quality and efficiency of the implementation'
- the overall threshold is 10

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 Funding & Tenders portal: <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/partner-search>
 - 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...)

Webinar | IMI2 - Call 20 Academia and industry united innovation and treatment for tuberculosis (Unite4TB)

Part of the AMR Accelerator Pillar B

David Barros/Gavin Koh/Michael Hoelscher
23.01.2020 IMI Webinar

Today's webinar

- Some background on the **AMR Accelerator programme**
- Action's funded under **Pillar A and B (IMI 2 Call 15 – Topic 7 and 8) and Pillar C (IMI2 call 16)**
- Proposed action under **Pillar B (IMI 2 Call 20)**
 - Objectives, need for public-private collaborative research
 - Expected contribution of the applicants
 - Key deliverables

The IMI2 AMR Accelerator programme (Call 15 and 16)

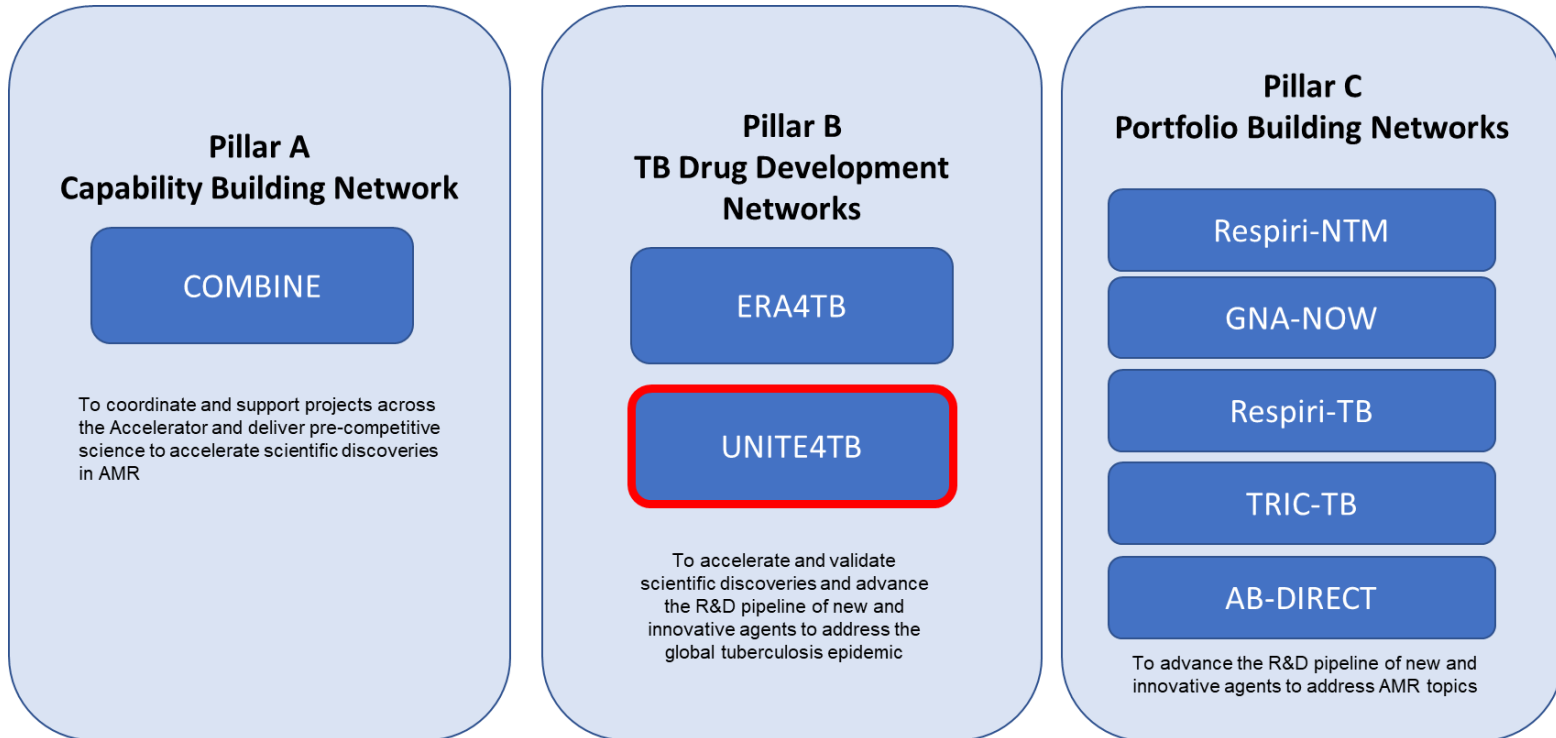
- **AN AMBITIOUS AIM:** to progress a pipeline of new potential medicines to treat patients with resistant bacterial infections or to prevent them; up to >10 new preclinical candidates and >5 'phase 2-ready' assets over six-year period
- **A BROAD SCOPE:** prevention (vaccines, mAbs, immunoprophylaxis, 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

Need for public-private collaboration in TB Research

- Tuberculosis (TB) is the leading infectious cause of death worldwide
 - To achieve the target of TB elimination by 2035, the WHO estimates that there is a funding shortfall of over \$1 billion per year in TB research
- Significant scientific challenges to the discovery of new treatments regimens for 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

The IMI2 AMR Accelerator programme

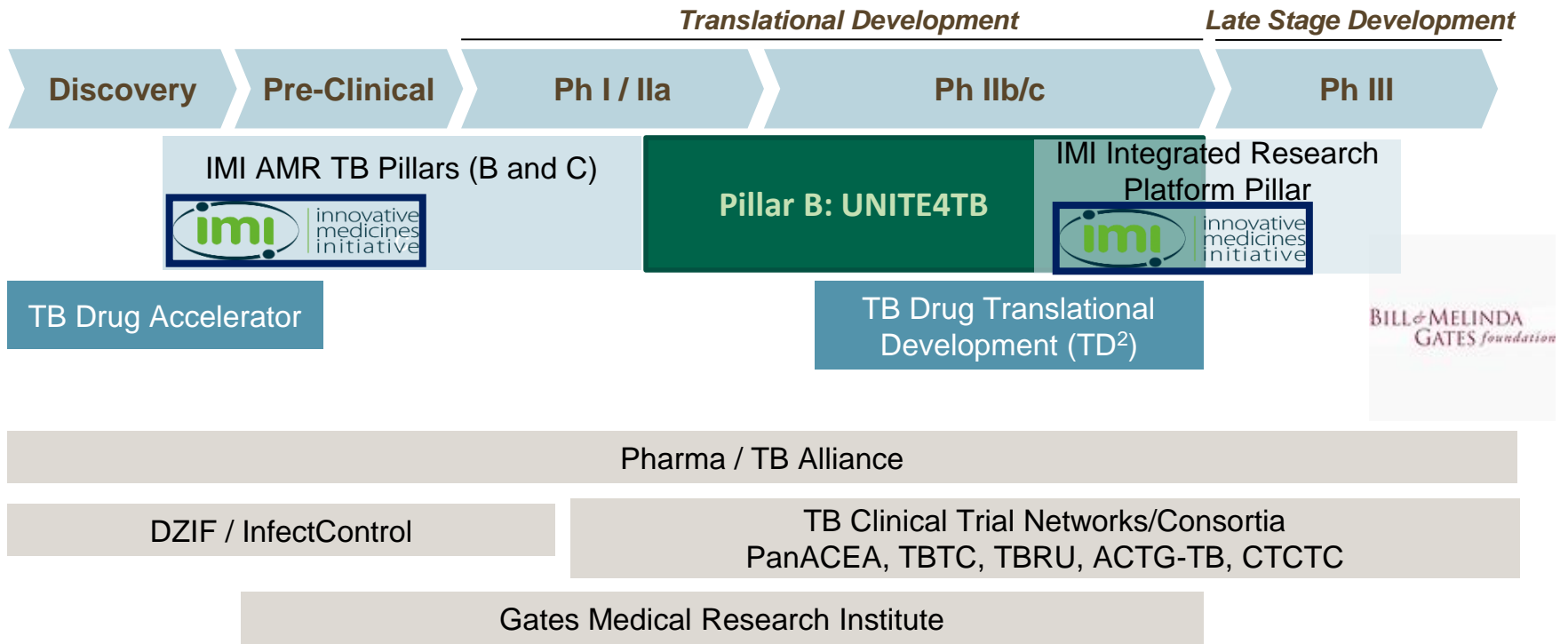
Unite4TB



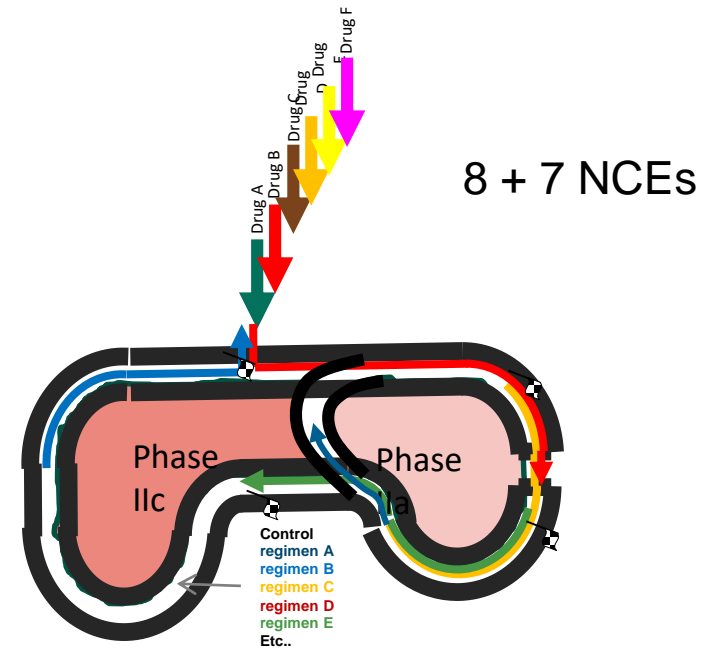
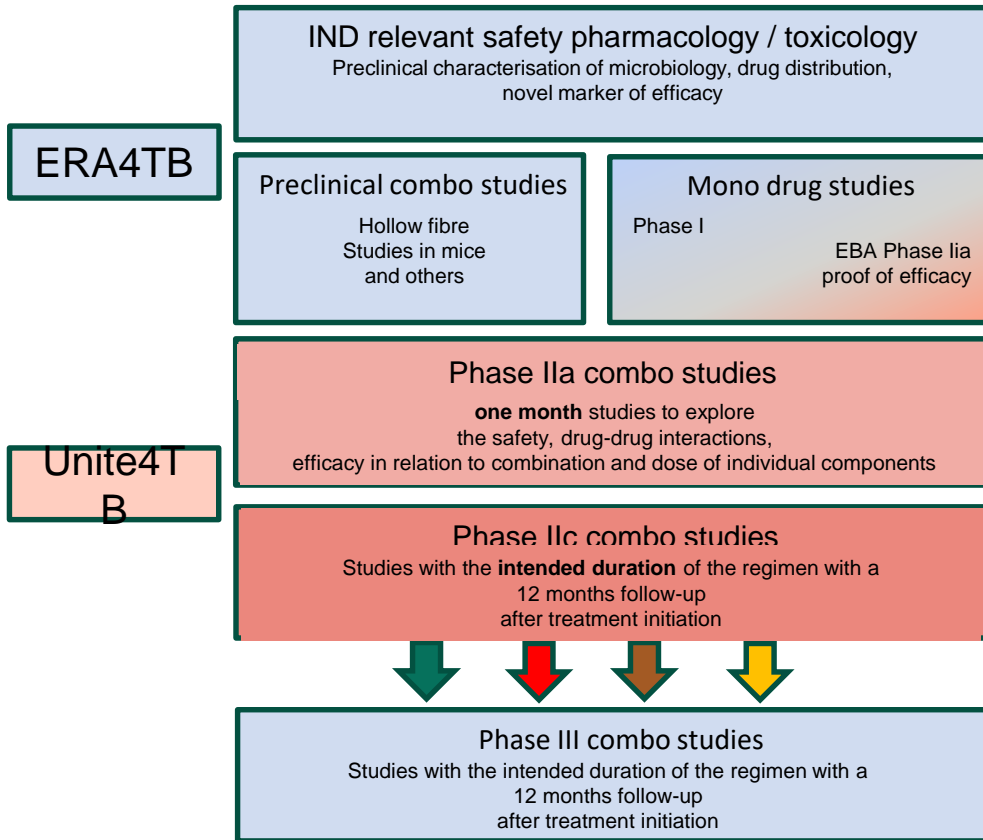
NB The action selected under call 21 will be a complimentary action to the existing AMR accelerator and expected to sign the AMR accelerator collaborative agreement

TB drug discovery & development

An evolving landscape of complementary and synergistic collaborations

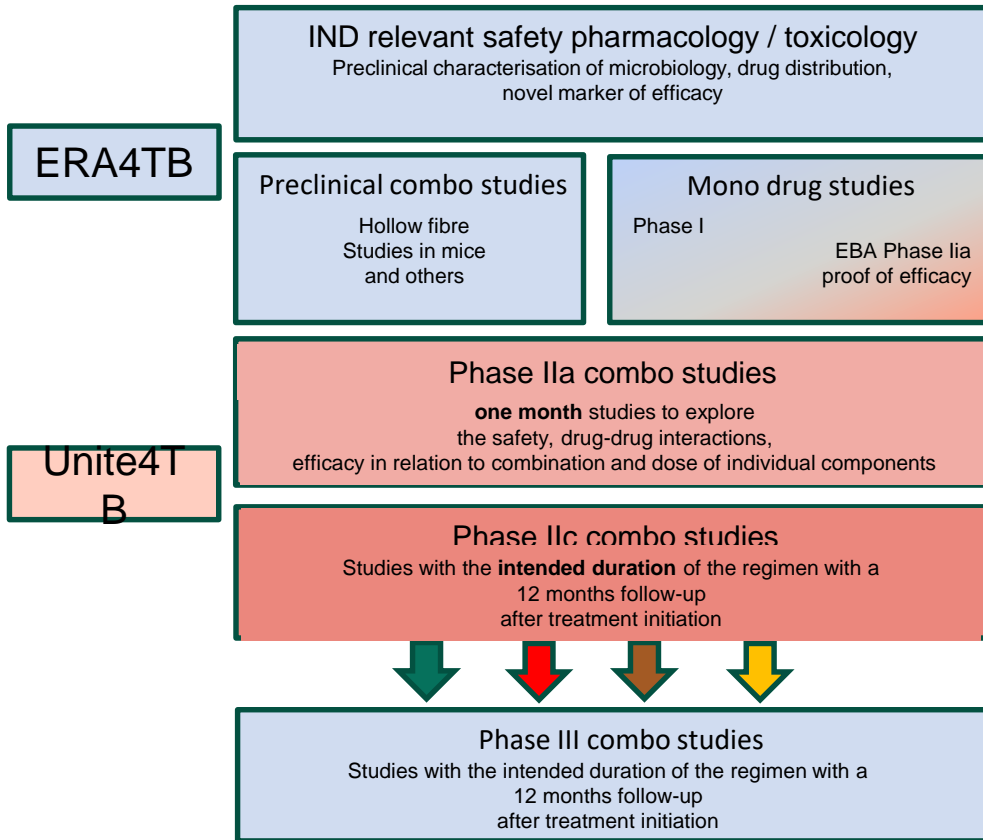


Unite4TB: Accelerating combination



Clinical trials conduct

Clinical trials science



Innovative, adaptive clinical trials

Innovative biomarkers

Pharmacogenomics

Clinical trial simulation tool

Digital health technologies

Artificial Intelligence/Machine Learning

Biobank.

UNITE4TB Objectives of the full project

A platform to:

- Profile and progress a portfolio of anti-TB compounds (EFPIA & APs) through Phase 2 (ready to enter Ph-3)
- 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
 - Biomarkers
 - Diagnostics
 - AI
- Provide learnings from the analysis of shared anti-TB clinical trial data
- Interact with TB stakeholders and explore synergies

Expected impact

- Enabling the progression of potential new treatment solutions for TB patients worldwide.
- 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
- Strengthen interaction of TB R&D stakeholders from across the EU and globally

Suggested architecture of the projects

- Applicants should:
 - Suggest complete architectures in the submitted proposals (e.g. number of work packages).
 - Propose a structure capable of progressing several molecules through Phase II trials.
 - Present a flexible structure that takes into account recruitment rates, decision making and attrition when planning distribution of resources per WPs over the lifetime of the project.

Expected contributions of the applicants

Innovative Clinical Trials

- Experienced TB Investigators and clinical sites with proven ability to recruit the required numbers of patients from within Europe and/or Endemic countries and run the required suite of innovative trials to a regulatory standard (*NB it is not the intent to set up a clinical trial network*)
- Operational Expertise
 - Logistics, Regulatory, ethics
- Scientific Expertise
 - Related to scientific outputs/deliverables

Innovative Biomarkers/Pharmacogenomics

- Expertise in the implementation of previously-identified biomarkers and regulatory buy-in for the proposed biomarker validation framework

Expertise in all innovative digital aspects of the topic proposal

EFPIA and Associated Partners

The industry consortium is composed of the following EFPIA companies:

- GSK
- Janssen
- Otsuka
- bioMérieux

In addition, includes the following IMI2 Associated Partners:

- DZIF
- LMU



Expected (in kind) contributions of industry consortium

- Bring novel advanced TB molecules for progression to Phase 2
 - 8 NCE in Year 1
 - 7 in subsequent years
- Trial Sponsorship and expertise
- 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
- Share historical TB drug discovery and development data

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

Key deliverables of the full project

Deliverables Related to : Innovative Adaptive Clinical Trials

- Established clinical trial capacity with the ability to recruit 1000 patients per year spanning at least two WHO regions
- Developed strategies for adaptive dosing (escalation/de-escalation) and trial-stopping criteria based on in-stream pharmacokinetic, efficacy and safety read-outs while building a pharmacokinetic-pharmacodynamic model, as appropriate
- An established Target Product Profile (TPP), Target Regimen Profile (TRP), aligned with that described by WHO, and due diligence criteria for the progression of assets within the consortium
- Completed clinical trial data: Dose selection criteria for the UNITE4TB portfolio of Innovative NCEs based on completion and results from Phase 2A EBA, and Phase 2B/C combination studies. Identification of at least one viable regimen for Phase 3 clinical trials, or a ranked list of viable treatment regimens (maximum four NCEs each), capable of shortening therapy and/or with a safety/tolerability/accessibility profile better than the current standard-of-care, and which are ready to enter Phase 3;
- Established Biobank

Key deliverables of the full project

Deliverables Related to : Innovative Biomarkers

- A strategy for how published biomarkers will be prioritised and selected for evaluation and validation and subsequently implemented within ongoing trials. For the avoidance of doubt, novel biomarker development is outside the scope of this action
- A strategy for early scientific engagement with the EMA and FDA, prior to clinical study start, to obtain regulatory buy-in for the proposed biomarker validation framework
- A methodological framework to prospectively validate biomarkers to be used in adaptive trial designs to shorten drug development and expand clinical trial capacity, and ideally used as a surrogate marker of sputum culture conversion and sterilising cure
- Data package of prospectively validated model/panel of biomarkers to be used in clinical trials to shorten TB drug/regimen development duration, and ready for submission to the EMA and FDA for regulatory qualification

Key deliverables of the full project

- **Deliverables Related to : Innovations in the field of TB**

Pharmacogenomics

- Exploring how host genetic variation may influence drug absorption, target exposure, clearance, and patient outcomes resulting in pharmacogenomic PKPD models for individual NCEs

Clinical trial simulation

- Developed clinical trial simulation tool(s) incorporating AI/ML to inform trial design, facilitate in-trial adaptation and, possibly, phase 2 trial waiver.

Digital Health technologies

- Evaluation of the impact of these technologies on adherence, and varying treatment durations on adherence in the field
- Technology to evaluate the impact of treatment duration on adherence. Implement and validate digital health technologies to improve adherence to TB regimens within the currently proposed studies.

Artificial Intelligence/Machine Learning

- A strategy for regulatory agency advice and alignment with proposed AI/ML-based models;
- Established models that describe the role of individual biomarkers suitable for regulatory acceptance.

Coordination and support

- Unite4TB 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: COMBINE). The management team of pillar B UNITE4TB 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) (as per collaborative agreement)

Budget and project durations

AMR Accelerator programme Pillar B IMI2 Call 20	Planned EFPIA/AP in-kind [Euro]	max. IMI2 JU funding [Euro]	Indicative project duration [months]
Unite4TB	92 500 000	92 500 000	84

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

Additional points of note

- A Q&A document was posted on the IMI website that covers specific questions around IP and data sharing
www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/Questions_and_answers_on_the_AMR_accelerator_programme.pdf
- Suggest all applicants read and understand this documents in parallel with the Topic texts of the original accelerator, and the proposed updates associated with Call 20



Thank you

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Involvement of SMEs, patient groups, regulators

SME participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations. Contribution of SMEs would be considered especially beneficial in providing as example the following expertise and activities :

- Clinical trials expertise
- data management and harmonisation
- bioinformatics, systems medicine and/or Artificial intelligence

(this list is not exhaustive)

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 project participants or in the **advisory board**
- 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](#)'



Thank you

www.imi.europa.eu

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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