Webinar | IMI2 - Call 23
Modelling the impact of monoclonal antibodies and vaccines on the reduction of antimicrobial resistance

22.06.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Tek-Ang Lim, IMI
- The Call topic – Venanzio Vella and Landry Cochard, GSK
- Involvement of SMEs, public health institutes, regulatory authorities – Tek-Ang Lim, IMI
- Questions & answers

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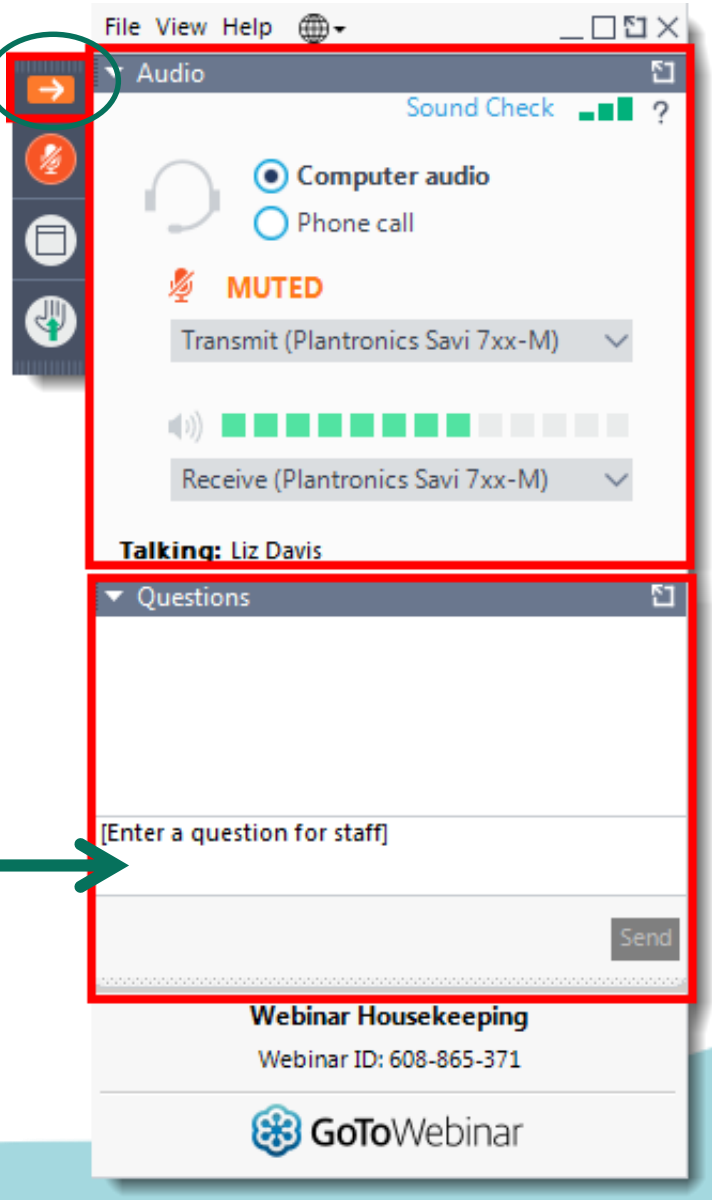

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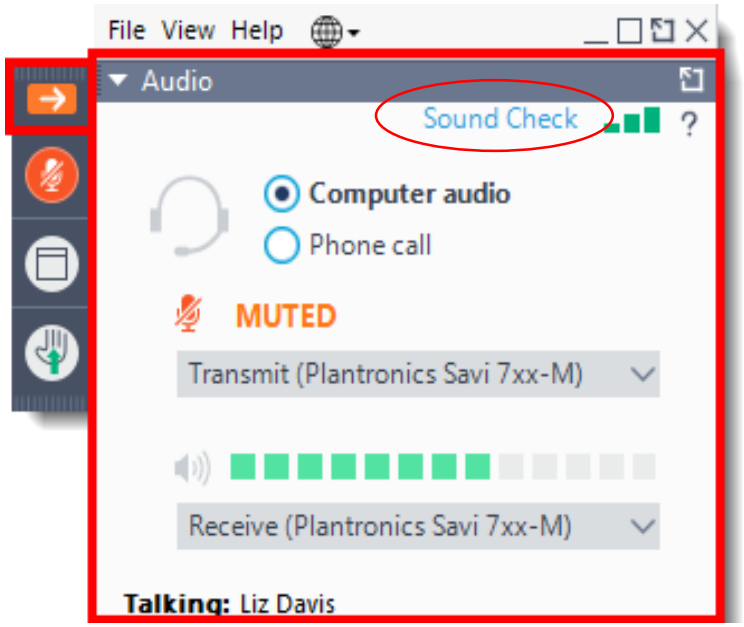

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Before we start…

- We are recording this webinar and it will be published on the IMI website and / or IMI YouTube channel
- We will also publish the presentation slides and the participant list on the webinar web page
- 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 23 Topic 2

Modelling the impact of monoclonal antibodies and vaccines on the reduction of antimicrobial resistance

Pillar A AMR Accelerator

Tek-Ang Lim

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
  30 June 2020, 11:00 am – 12:30 pm CEST

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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.

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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 partnership 2008-2020

IMI1:

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

IMI2:

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

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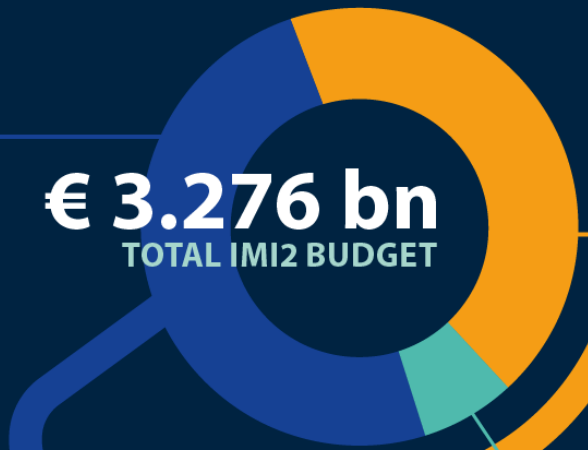
IMI2 funding
(2014-2020)

IMI FUNDING MODEL

efpia

IN-KIND PRIVATE CONTRIBUTION
€1.425 bn
EFPIA companies receive no funding

public contribution
€1.638 bn
funding from Horizon 2020



OTHER CONTRIBUTIONS
€213 MILLION
(Associated Partners, e.g. charities, non-EFPIA companies)

EU funding goes to

SMES
UNIVERSITIES
PATIENTS, REGULATORS...

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

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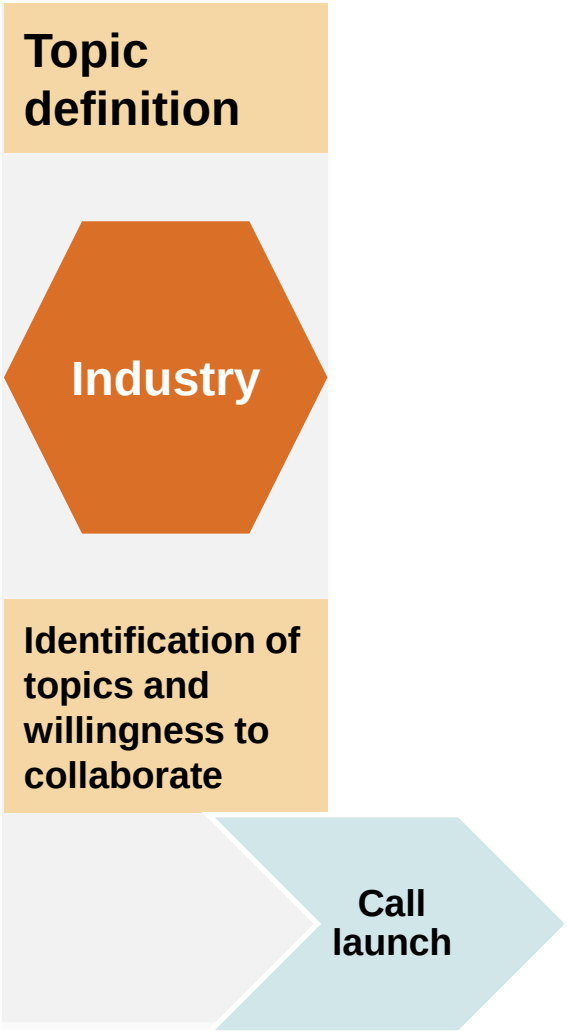
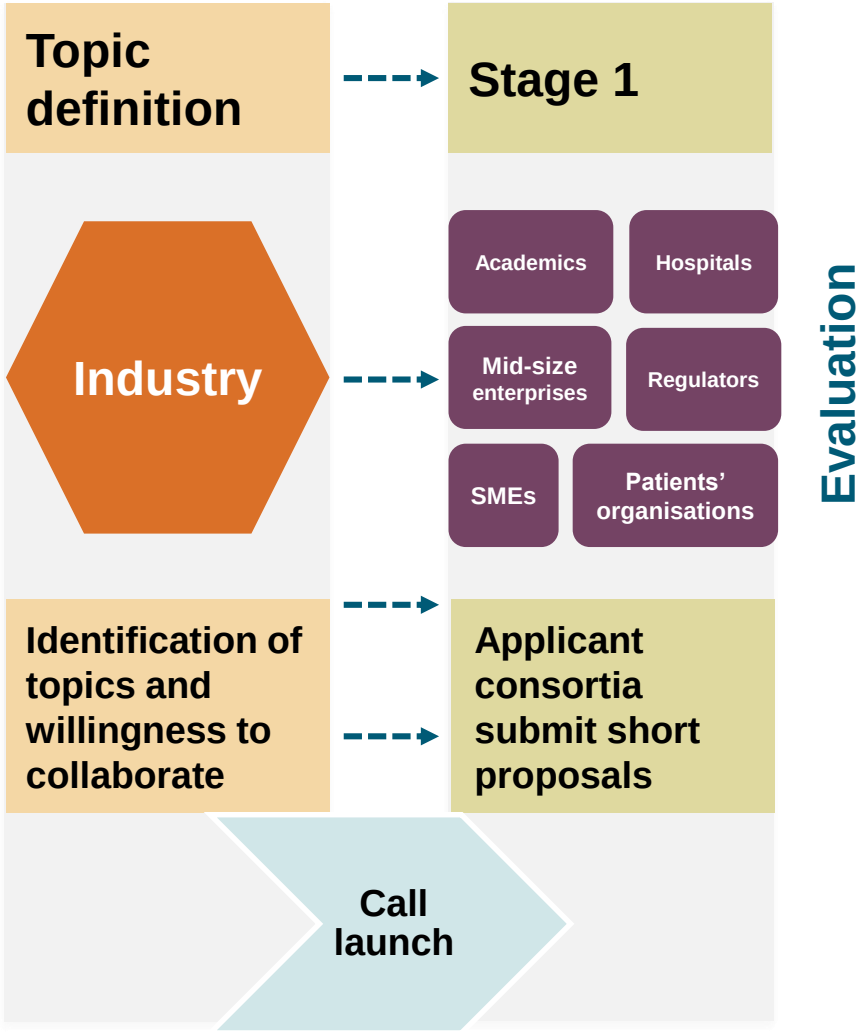
Typical IMI project life cycle



Typical IMI project life cycle



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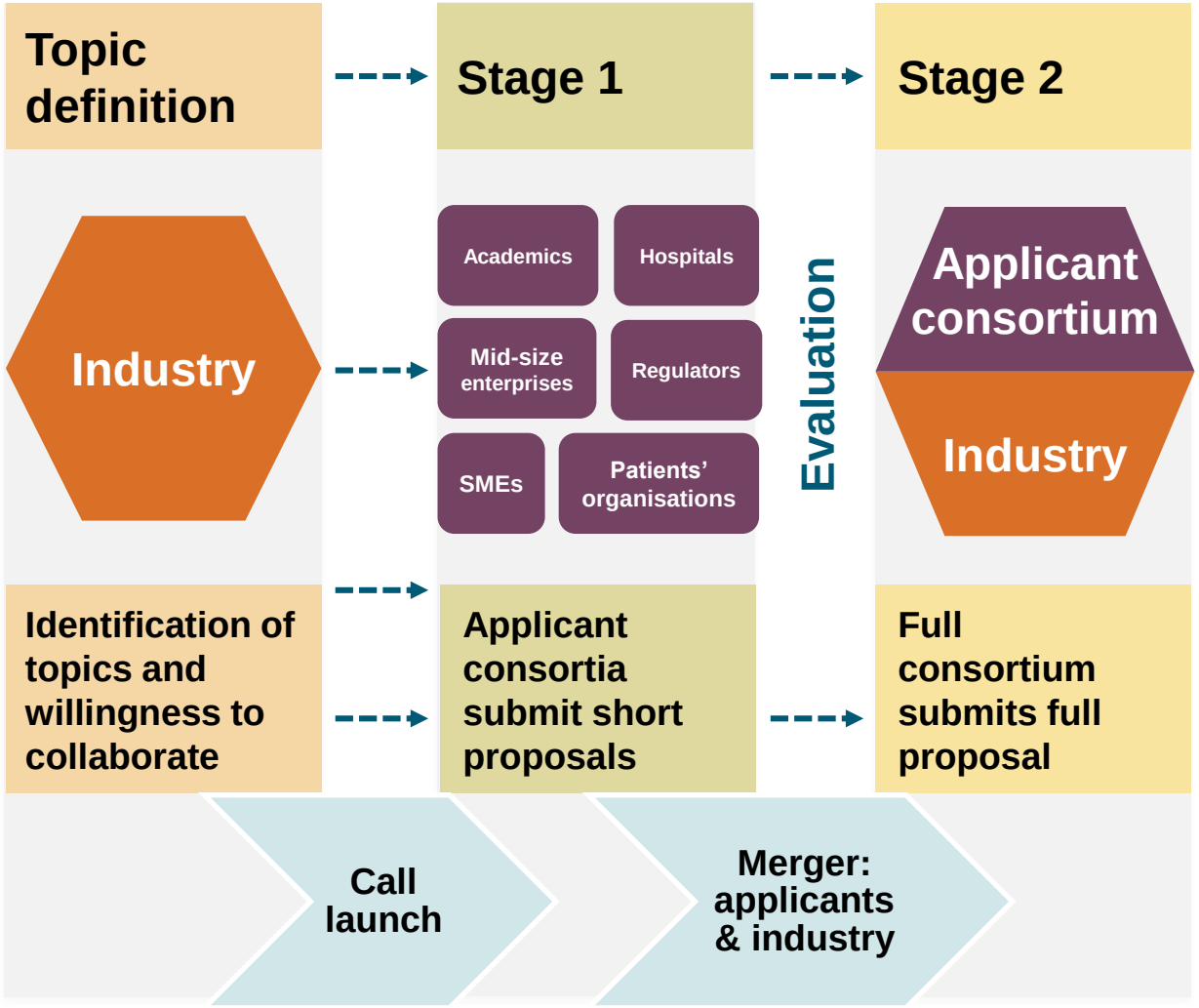
Typical IMI project life cycle



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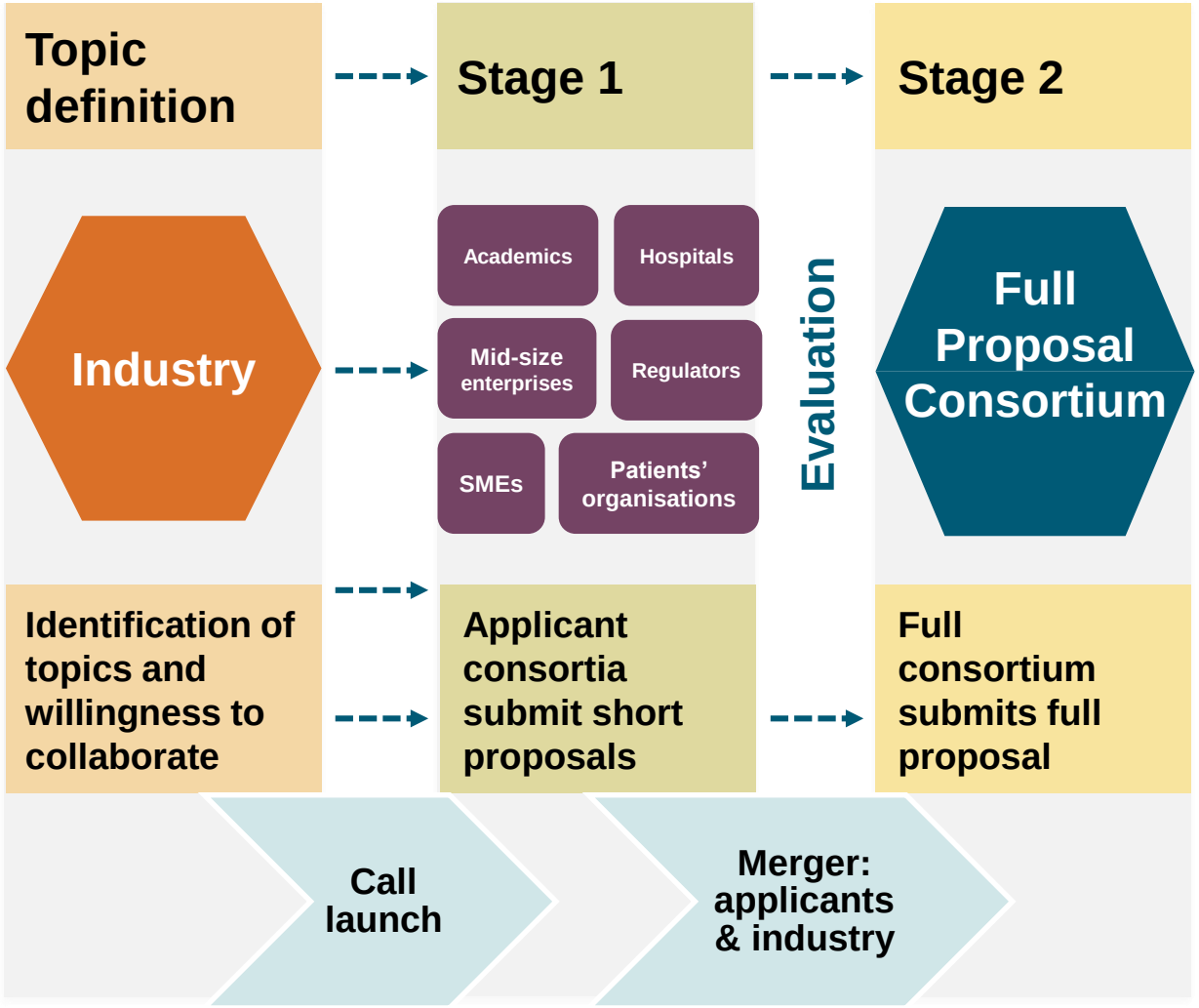
Typical IMI project life cycle



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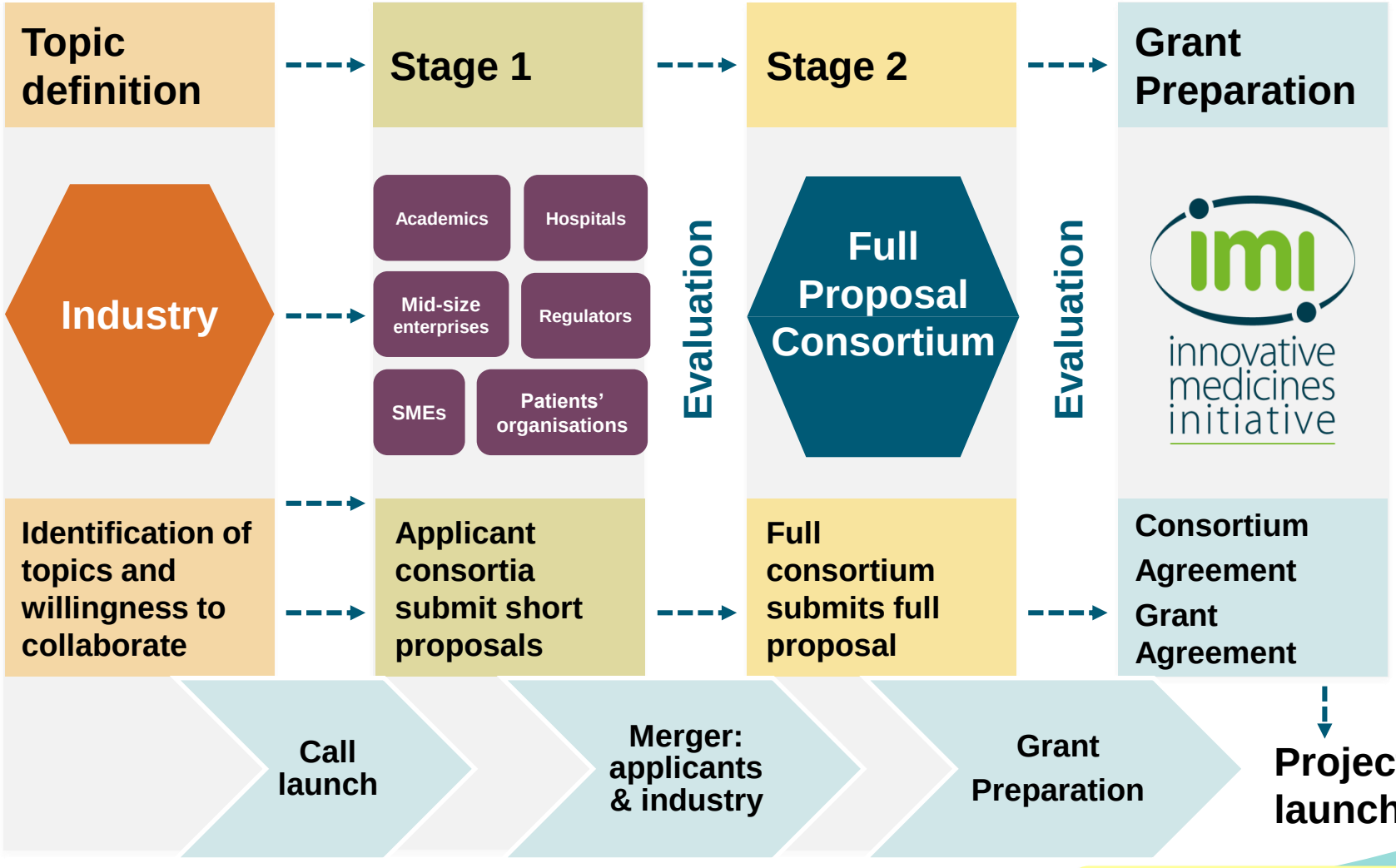
Typical IMI project life cycle



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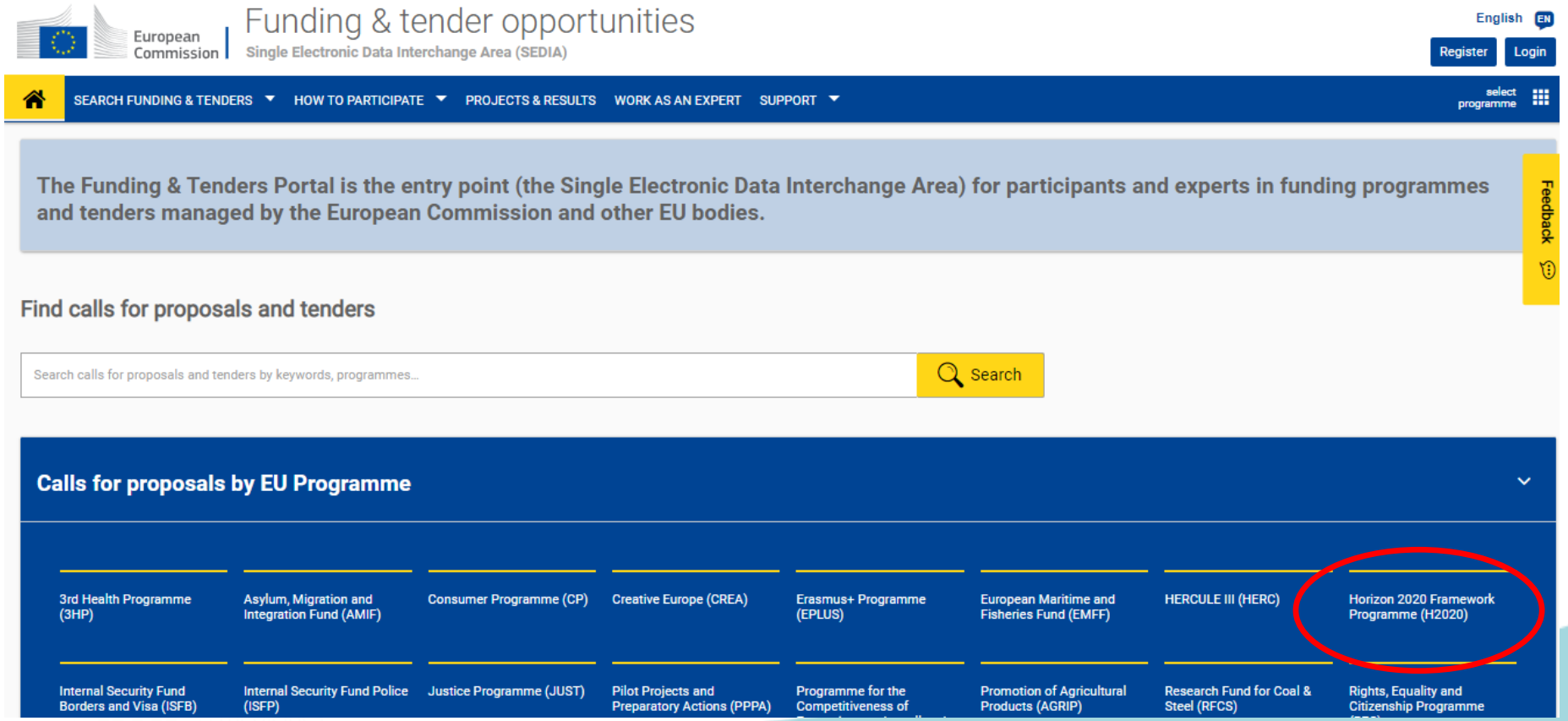
Expected GA signature – Summer 2021

Submitting a proposal

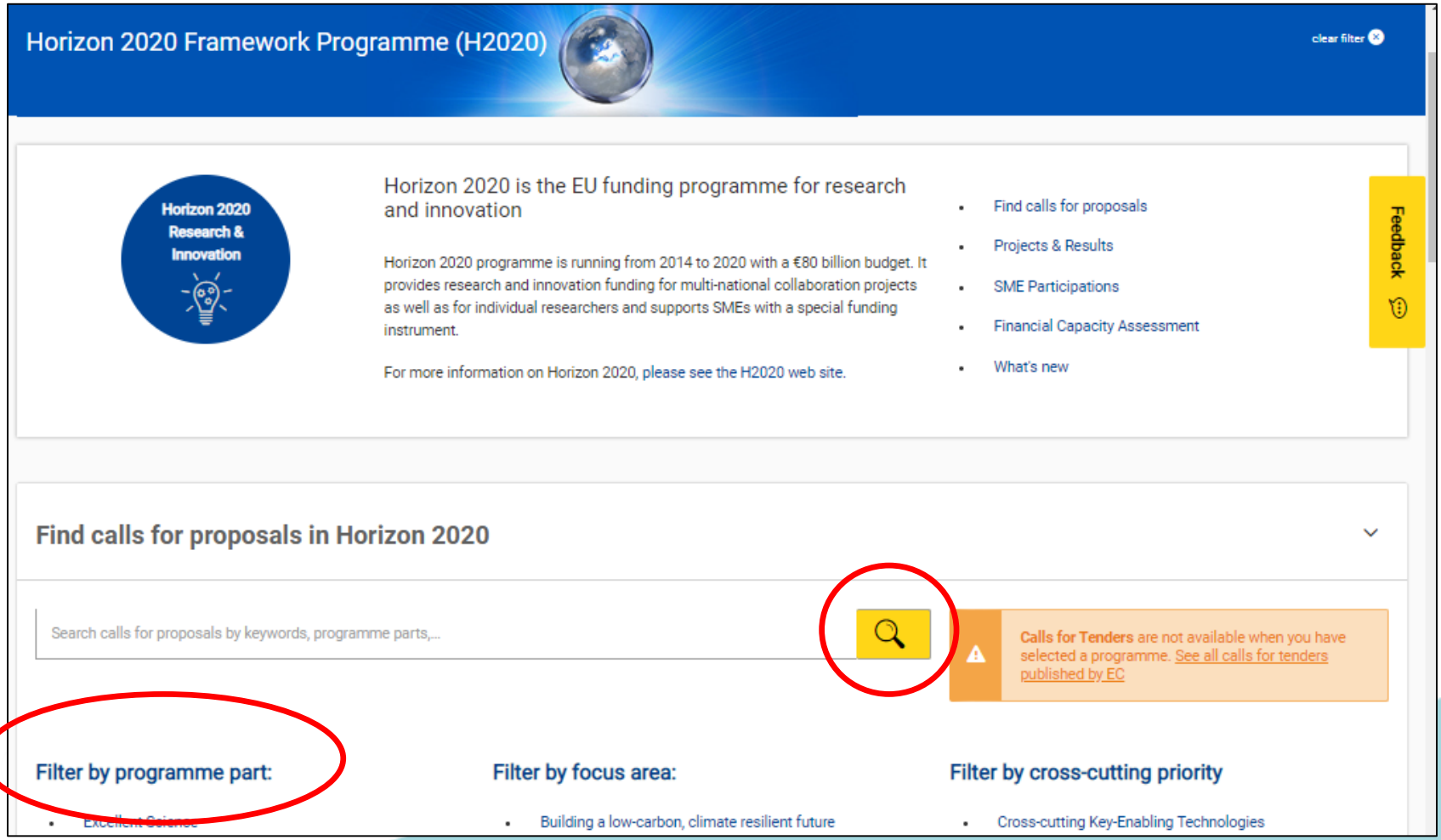
Via the **new** Funding and Tenders Portal

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



New Funding and Tenders Portal Horizon 2020 section

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



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

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)

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Evaluation Criteria (1/2)

- **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)

- **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.

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

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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

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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.

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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)

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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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Modelling the impact of monoclonal antibodies and vaccines on the reduction of antimicrobial resistance

Venanzio Vella and Landry Cochard

22.06.2020 • IMI webinar

Need for public-private collaboration

- Discovery and development of new antibiotics and alternative treatment and prevention options for multi-drug resistant infections is a high medical and societal need.

- In addition to existing initiatives and projects, more work is critical to continue to address the constantly emerging global challenge of AMR.

- IMI has contributed to the development of an **AMR Accelerator** to build a vibrant AMR community in Europe with three pillars:
  - Capability Building Network
  - Tuberculosis Drug Development Network
  - Portfolio Building Network

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Need for public-private collaboration

The AMR Accelerator

Pillar A
Capability Building Network

COMBINE

mAbs and vaccines mathematical modelling

To coordinate and support projects across the Accelerator and deliver pre-competitive science to accelerate scientific discoveries in AMR

Pillar B
TB Drug Development Networks

ERA4TB

UNITED4TB

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

Pillar C
Portfolio Building Networks

Respiri-NTM<

GNA-NOW

Respiri-TB

TRIC-TB

AB-DIRECT

To advance the R&D pipeline of new and innovative agents to address AMR topics

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Need for public-private collaboration

- **Accelerator Pillar A** - **Capability Building Network**:
  - Play key role in a EU AMR programme with connectivity into the broader global agenda on AMR;
  - Enable SME, and/or academic groups to progress pre-competitive basic science project in the AMR field;
  - Opportunity to work within a broad network of researchers focused on AMR science and gain additional experience in AMR science and drug discovery.

- **mAbs and vaccines mathematical modelling:**

Develop a framework for setting up antimicrobial resistance (AMR)-focused economic evaluations of vaccines and mAbs to measure the present rate of growth of AMR, its main drivers, its health and economic consequences, and which vaccines and mAbs might have the best chance of reducing the rate of AMR growth and the related health and economic consequences.

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Need for public-private collaboration

Interactions with other projects from the Accelerator

- A **collaboration agreement** will be signed **with the COMBINE**-853967 consortium selected from IMI2 JU Call 15 topic 7.
- Specific provisions from the Grant Agreement to be applied:
  - Article 2.

    The grant is a 'complementary grant' to grant agreement 853967.

  - Article 31.6.

    The beneficiaries must give — under the conditions set out in Article 31.2 and 31.3 — access to their results to complementary beneficiaries , for the purposes of the complementary grant agreement(s)

  - Article 41.4

    (See next slide for details)

Need for public-private collaboration

Interactions with other projects from the Accelerator

- Article 41.4

The beneficiaries must conclude a written ‘collaboration agreement’ with the complementary beneficiaries to coordinate the work under the Agreement and the complementary grant agreement(s) (see Article 2), covering for instance:

- efficient decision making processes and
- settlement of disputes.

The collaboration agreement must not contain any provision contrary to the Agreement.

The beneficiaries and complementary beneficiaries must create and participate in common boards and advisory structures to decide on collaboration and synchronisation of activities, including on management of outcomes, common approaches towards standardisation, SME involvement, links with regulatory and policy activities, and commonly shared dissemination and awareness raising activities.

The beneficiaries must give access to their results to the complementary beneficiaries, for the purposes of the complementary grant agreement(s) (see Article 31.6).

The beneficiaries must share the technical reports (see Article 20.3 and 20.4). The confidentiality obligations in Article 36 apply.

Need for public-private collaboration

- Need for a broad collaboration involving partners from academia and industry to tackle the following specific challenges:
  - **Measurement of the burden of disease (BOD) and costs of AMR:** there is a need for a disaggregation of the BOD by subpopulation to compare the cost-effectiveness of targeting strategies to go beyond the work performed by Cassini et al
  - **Limitation of models in capturing the complexity of AMR.**
  - **Real data are not easily available to set parameters for the models.**
  - **There is insufficient information on the cost-effectiveness of vaccination and mAb strategies against AMR pathogens**.
  - **Model forecasts need to be validated**. models by filling information gaps and verifying assumptions, on the basis of real data coming from the health care systems.

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Objectives of the full project

- **Evaluate the burden of disease of AMR** by estimating inpatients' (acute care hospitals and long term care facilities) and outpatients' infection rates.
- **Build a comprehensive AMR model** (i.e. model structure, parameters, assumptions) based on an analysis of the strengths and weaknesses of existing models, and a gap analysis.
- **Collecting, gathering, and analysing data** from existing databases to feed the model.
- **Develop and test a cost-effectiveness analysis** (CEA) to estimate the cost and benefits of covering defined target groups (e.g. 18+, 60+, surgeries) with mAbs and vaccines.
- Set up a **study to test, monitor, evaluate and improve the model**.
- Ensure a **public and broad access to the model**.

Pre-competitive nature

A model will have the benefit of predicting the reduction of AMR associated with novel mAb and vaccination strategies against AMR pathogens.

- Allow public health institutes or companies to select the right direction among several priorities.
- Inform policy decisions to prepare acceptance and implementation.
- Joining forces increases the chance that all points of views of the major actors feed into the analysis and produce final results that are agreeable because built through a consensus process.

Combining different perspectives, scientific interests, domains and expertise will create synergies that are not possible if academia or industry operate in isolation.

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Expected impact

- The **epidemiological repository:** access to a publicly available database on the epidemiology of infectious diseases and resource consumption associated with sensitive and resistant pathogens.
- **Mathematical model**: allow policymakers and healthcare managers to make informed decisions on vaccines and mAb strategies.
- **Preserve the efficacy of last resort antimicrobials.**
- Strengthening of the existing AMR surveillance systems.

Analysis of the Burden of Diseases: estimating inpatients' (acute care hospitals and long-term care facilities) and outpatients' infection rates in **8 EU countries for which suitable data is collected and available**.

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Suggested architecture of the project

WP1 Literature review (M1-M12)

T.1.1 - AMR global literature review requirements

T.1.2 - Systematic literature review on BoD to health sector

WP2 Initial model structure (M1-M12)

T.2.1 – Literature review of existing models

T.2.2 – Structure definition and scope

T.2.3 – Theoretical model definition

T.2.4 – Assumptions and scenarios

T.2.5 – Gap analysis

WP3 Data collection (M13-M30)

T.3.1 – Databases mapping

T.3.2 – Data access and use

T.3.3 – Retrospective chart review

T.3.4 – Statistical plan to extract data

WP4 Mathematical modelling (M31-M60)

T.4.1 – Model definition and set-up

T.4.2 – Model testing

T.4.3 – Model calibration

T.4.4 – Scenario analysis

WP5 Monitoring and evaluation of the model (M31-M60)

T.5.1 – Data collection sites

T.5.2 – Refining the model

T.5.3 – Guidance for model use

T.5.4 – Sustainability

WP6 Coordination and project management (M1-M60)

T.6.1 Project coordination

T.6.2 Advisory Board management

T.6.3 Legal, financial, administrative aspects

T.6.4 Project monitoring and reporting

WP7 Communication and dissemination (M1-M60)

T.7.1 Communication and dissemination

T.7.2 Databases and data management (set-up and sustainability)

T.7.3 Exploitation of results

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Suggested architecture of the project

- WP1 - Burden of disease due to AMR

Estimations of the inpatients' and outpatients' infection rates sorted by sensitive and resistant pathogens by population groups, by type of disease, by type of surgery and other specific categorisation of patients.

- WP2 - Model structure development
  - Conducting a systematic review of the models used to predict the influence of mAbs and vaccines for treatment or prevention.
  - Identifying assumptions and information gaps in parameters will involve a review of the disease ecological dynamics.

- WP3 - Data gathering

Databases already identified by industry include the Marketskan and other claims (e.g. Kaiser Permanente) databases in the US, the NHS and GP databases in the UK, the Epidemiologie – France Portal Health Database, the health care database of the German Institute of Medical Documentation and Information, Health for All Italia.

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Suggested architecture of the project

- WP4 - Cost-effectiveness analysis (CEA)

  The WP4 will for instance have to decide :

  - Which vaccines and mAbs should be included in the model.
  - If to limit the perspective to health care costs or to add social costs too.
  - What to include in the existing standard of care (comparator).
  - The patients' pathways by type of health care setting.

- WP5 - Evaluation
  - Set up a long-term monitoring and evaluation strategy to calibrate the model.

Expected contributions of the applicants (1/2)

- **Expertise:**
  - Epidemiology
  - Statistics
  - Health Economics
  - Microbiology
  - Laboratory techniques associated with AMR
  - Database management, data scientists
  - Database web programming;
  - Computational and mathematical modelling in infectious diseases;
  - Management Information Systems;
  - General Data Protection Regulation (GDPR) compliance.

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Expected contributions of the applicants (2/2)

- **Other resources:**
  - Access to CDC and ECDC databases;
  - Expertise in dealing with data (retrieve, clean and analyse data), including data coming from US databases;
  - Access to Hospital Information Systems and General Practitioner databases for the retrospective data collection;
  - Access to the Health Information Systems in the countries selected by the applicants.

Expected (in kind) contributions of industry consortium

- GlaxoSmithKline Biologicals
  - ***Expertise***: Epidemiology, Biostatistics, Infectious Disease Modelling, Health Economics, Database Management, Web Design, Vaccine pre-clinical and clinical science, mAb pre-clinical and clinical science, Translational research, Immunology, Phenotypic and genetic characterisation of microbial strains.
  - ***Model development***: allocation of a dedicated modeler to co-develop the model with other partners.
  - ***Databases access***: access to CPRD (Clinical Practice Data Linkage) and IBM Truven Marketscan (including US data).
- Janssen Vaccines & Prevention
  - ***Expertise****:* in clinical development, market access and modelling.
  - ***Model development***: allocation of a dedicated modeler to co-develop the model with other partners.
- Pfizer
  - ***Expertise****:* in clinical development, market access and modelling.

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Budget and projected durations

AMR Accelerator programme Pillar A IMI2 Call 23	Planned EFPIA/AP in-kind [Euro]	max. IMI2 JU funding [Euro]	Indicative project duration [months]
€ 9,250,000	€ 2,750,000	€ 6,500,000	60

The total budget of each proposal consist of the requested IMI2 JU contribution plus the relevant in-kind contribution by the participating EFPIA companies and Associated Partners.

In this specific topic, the lower level of EFPIA/AP in-kind contribution is compensated by additional contributions from EFPIA/AP in other topics from the Accelerator.

Key deliverables of the full project

- Epidemiological repository of incidence, prevalence, disability (e.g. disability-adjusted life years – DALYs, quality-adjusted life year – QALYs), mortality, short- and long-term disability, consumption of antimicrobials, costs and other parameters associated with main pathogens and population groups.
- A systematic review of mathematical models on the effect of vaccines and mAbs on AMR.
- Construction of an open-source mathematical model.
- Economic evaluation of alternative mAbs and vaccines strategies: test of several scenarios, comparing mAb vs vaccines, and different mAb strategies separate from different vaccine strategies.

Thank you

Should you have any question, raise your hand or contact the IMI Executive Office later on.

www.imi.europa.eu

@IMI_JU

Involvement of SMEs, Public Health Institutes, Regulatory Authorities

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 :

- involved in monoclonal antibodies research activities
- mathematical modelling
- data management and harmonisation
- bioinformatics, systems medicine or multi-omics analysis,
- public-health, public relations and communication

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Public health institutes

- public health agencies/authorities because their expertise can substantially contribute to the scientific soundness of the study and because it is important to add their perspective for the success of this project.

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**

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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Thank you

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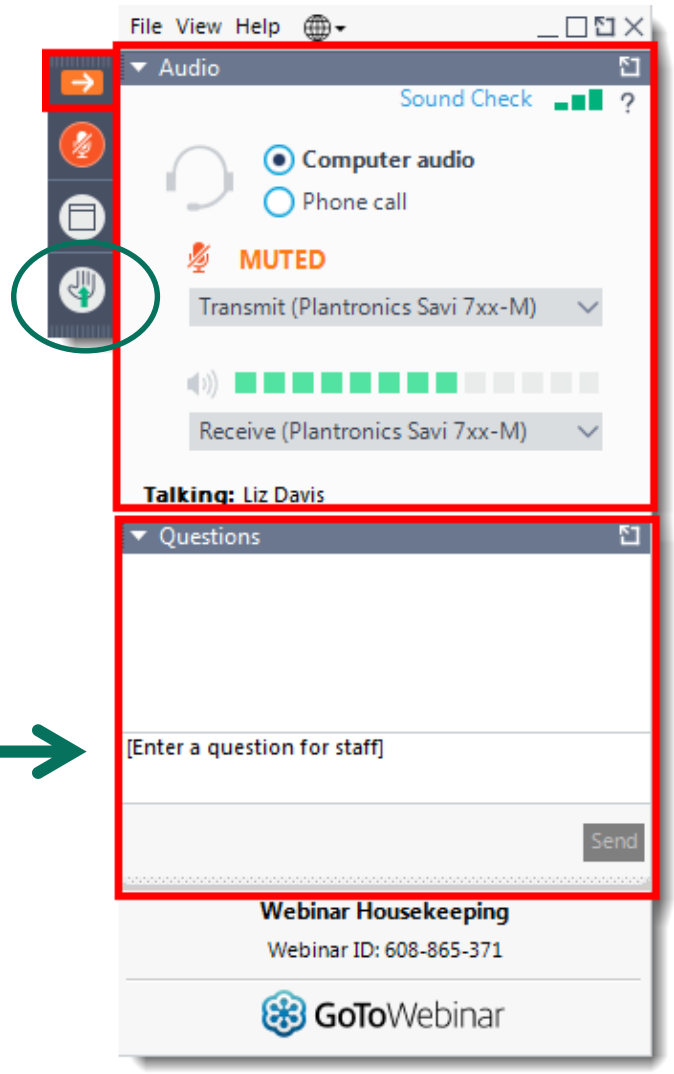
Questions & answers

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!