Webinar │IMI2 - Call 23 Behavioural model of factors affecting patient adherence

17.06.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Inmaculada Aguilera, IMI
- The Call topic – Claire Everitt, Pfizer & Laurent Mercier, Merck
- Involvement of SMEs, patient groups, regulators – Inmaculada Aguilera, 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 →

innovative
medicines
initiative

How to use GoToWebinar - audio

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

Can't hear us?

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

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

Can't hear us?

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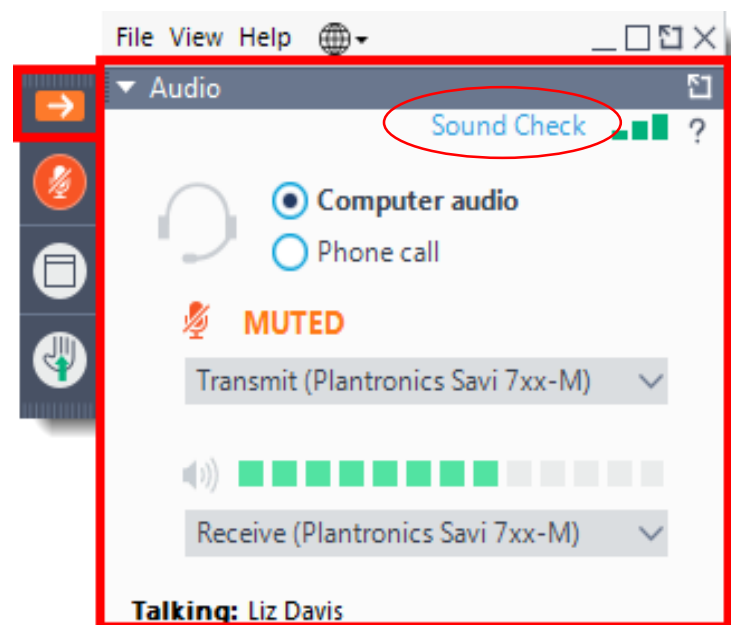
Before we start…

- 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.

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

innovative medicines initiative

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

IMI1:
- 2008-2013
- €2 bn budget
- 59 projects

IMI2:
- 2014-2020
- €3.3 bn budget
- More ambitious, more open, greater scope

€2.5 bn
EU contributions from FP7 / H2020

€2.5 bn
Pharma contributions in-kind

IMI2 funding

IMI FUNDING MODEL

(2014-2020)

efpia*

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

public contribution
€1.638 bn
funding from Horizon 2020

€ 3.276 bn
TOTAL IMI2 BUDGET

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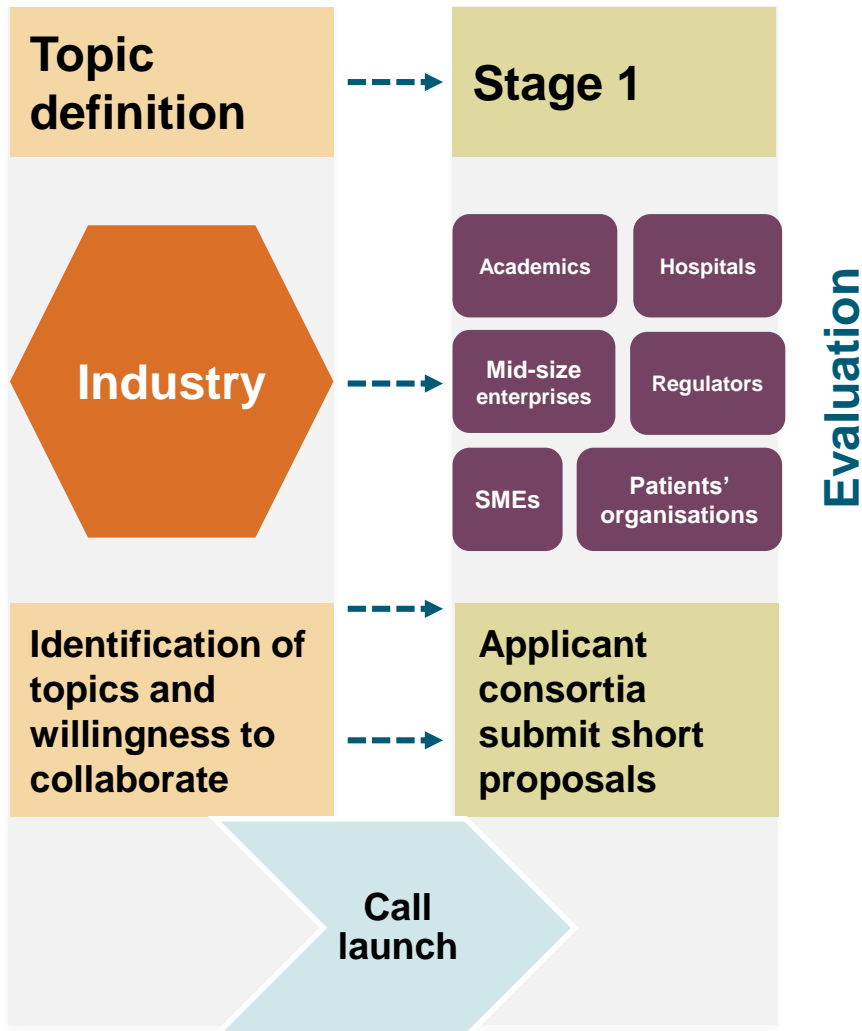
Scale is a key to success and is provided through IMI funding

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

Typical IMI project life cycle

Topic definition

Industry

Identification of topics and willingness to collaborate

Call launch

Typical IMI project life cycle

Topic definition

Stage 1

Industry

Academics   Hospitals

Mid-size enterprises   Regulators

SMEs   Patients' organisations

Evaluation

Identification of topics and willingness to collaborate

Applicant consortia submit short proposals

Call launch

imi innovative medicines initiative
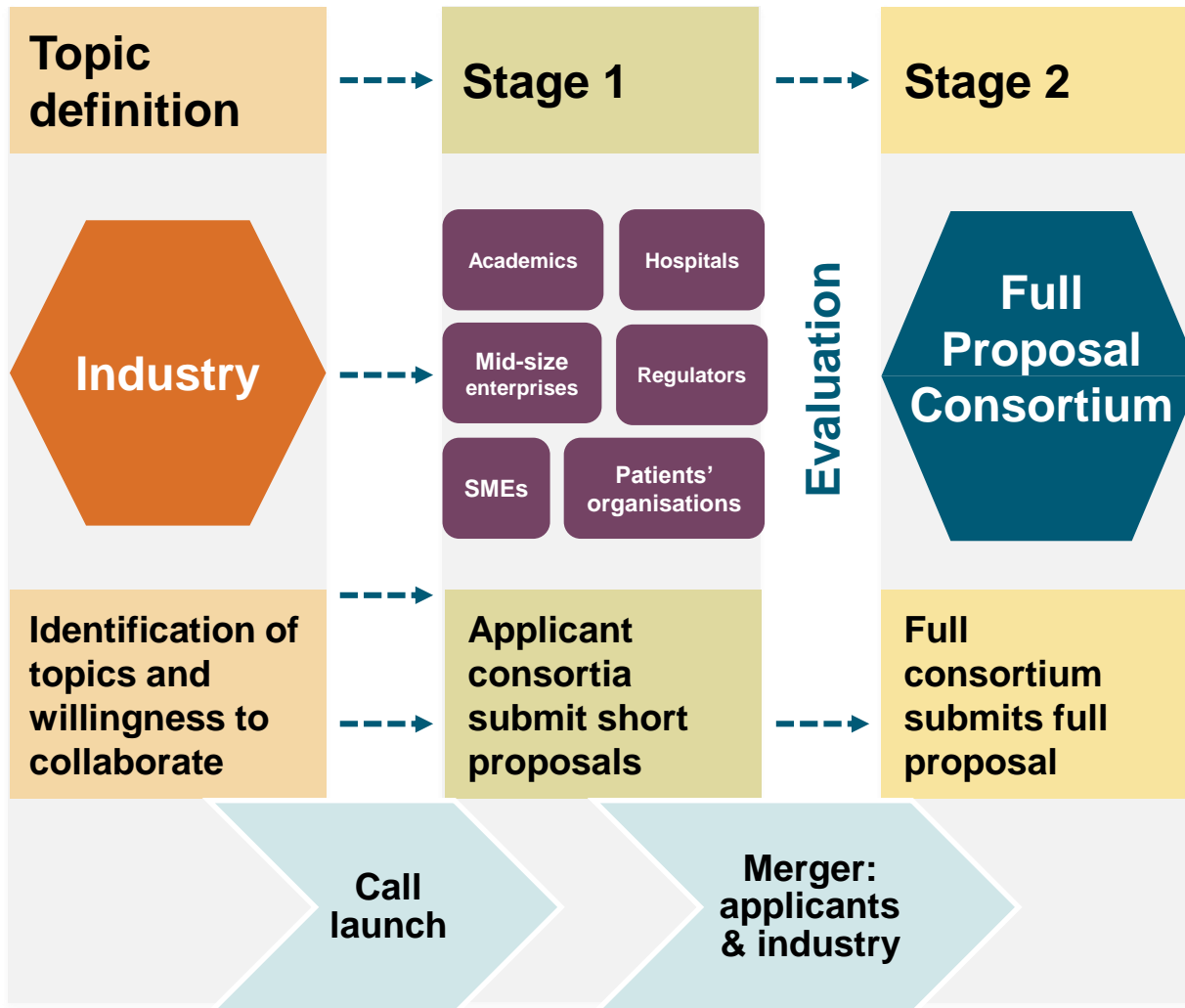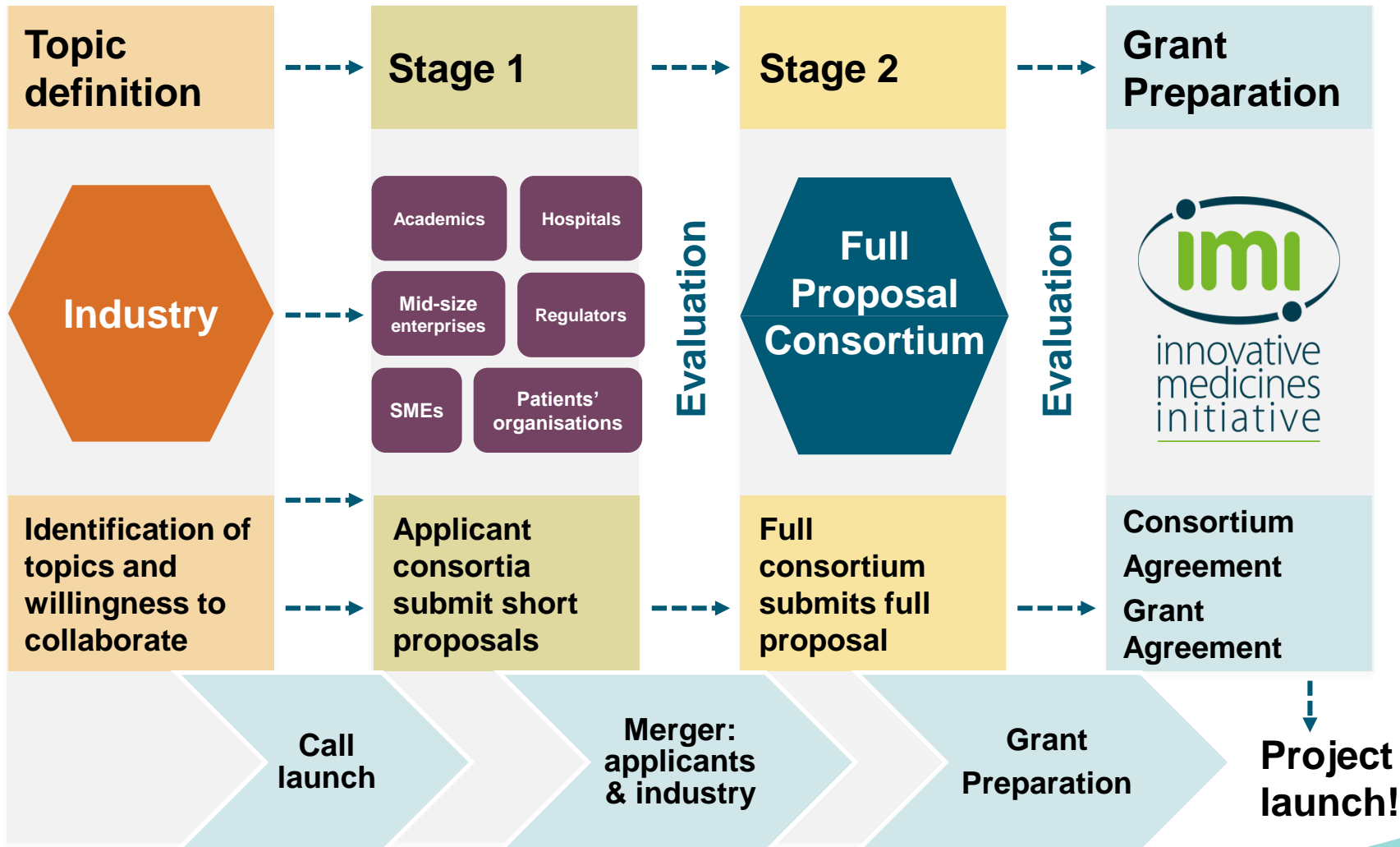
Typical IMI project life cycle
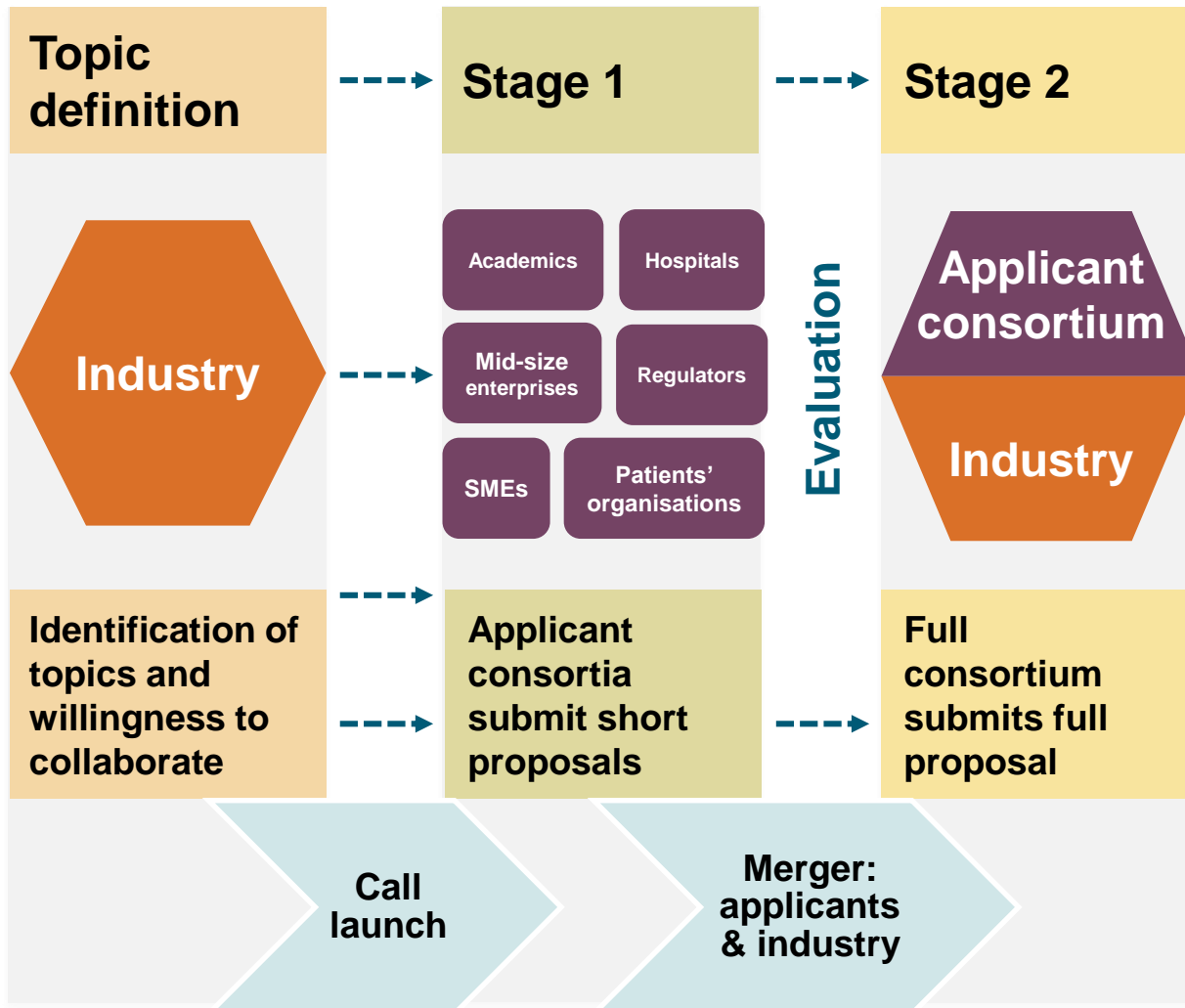
Typical IMI project life cycle

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

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)** |

innovative medicines initiative

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.

  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)

innovative medicines initiative

Behavioural Model of Factors Affecting Patient Adherence

Claire Everitt
Laurent Mercier
17.06.2020 • IMI webinar

Background

- Patient non-adherence is a significant issue across therapeutic areas (200,000 annual EU premature deaths[1], EUR 125 billion annual costs in Europe[2])

- Adherence rates average 50%

- Existing research limited to specific sub-topics due to breadth of field

- Effectiveness of solutions (e.g. app-based) has been highly variable[3]

- Good understanding of problem needed to deliver effective solutions

- Target:

  ✓ Assess adherence factors, including patient behaviour;

  ✓ Develop a disease-agnostic baseline model.

  ✓ Enable broad, cost-effective implementation with significant positive impact on patient adherence.

[1]   https://www.oecd-ilibrary.org/docserver/health_glance_eur-2018-en.pdf
[2]   A.O. Iuga, M.J. McGuire. Adherence and Healthcare Costs. Risk Management
       Healthcare Policy 2014; 7: 35–44. doi: 10.2147/RMHP.S19801
[3]   T.Forissier, K.Firlik. Estimated Annual Pharmaceutical Revenue Loss Due to
       Medication Non-Adherence.Capgemini Consulting. 2012

innovative
medicines
initiative

Need for public-private collaboration

- Public-private partnership is a unique mechanism to bring together diverse stakeholders inputs needed **to achieve transformational aims of the project and deliver sustainability**.

- Scale of data to achieve scope of project

- Breadth of skills, expertise, and perspectives required for success:
  - ✓ Patient and health professional organisation
  - ✓ Academic and research institutions (e.g research methodolgy)
  - ✓ Contributors with specific expertise (e.g. Healthcare providers, patients, patient organisations)
  - ✓ Input from regulators (e.g. for alignment with national initiatives)
  - ✓ Technology partners (e.g. Adherence measurement, AI/ML)
  - ✓ Cross-functional pharmaceutical industry expertise

imi | innovative medicines initiative

Objectives of the full project

- Develop comprehensive understanding of factors affecting patient needs and adherence:
  - ✓ independently from the therapeutic area
  - ✓ in a real-world context
  - ✓ balance personalisation with cost-effective and ease of implementation.
- Identify most significant factors
- Evaluate models or create new model
- Collect additional real-world data to refine model
- Provide tools to enable healthcare stakeholders to cost-effectively develop and implement solutions to address patient needs and improve adherence rates

innovative
medicines
initiative

Disease-agnostic model rationale

Some factors which appear to be disease-specific (e.g. stigma of the disease) may exist more generally in the population and merely be weighted more strongly in specific conditions.

Many factors not associated with single disease state (e.g. a patient's health beliefs, need for control, social environment or education level).

✓ Balance between personalisation (complexity) and simplicity of use.

✓ Cost-effective implementation reaching widest possible audience

→ Potential for disease agnostic baseline model

While disease-agnostic, the model should be able to accommodate disease-specific inputs.

Pre-competitive nature

✓ Published open-access model which provides a consistent structure for understanding the patient

✓ Cost-effective application to patient groups

✓ Open-access tools for use by stakeholders

✓ Access for consortium members to wide pool of data

✓ Model can be further developed by each stakeholder as needed

✓ Proof of concept for platform for interaction with patient

innovative
medicines
initiative

Expected impact

A model to understand and predict patient adherence to treatment

- **Positive impact on healthcare at a societal level** through enhanced adherence, targeted use of resources, and improved overall patient outcomes

- **Validated foundation** to compile and understand factors affecting patient non-adherence to treatment regimens and the relative weighting of these factors

- **Identification of sub-groups** of the population with similar causes of non-adherent behaviour to tailor solutions to population needs applied in cost-effective manner to multiple treatment conditions

innovative
medicines
initiative

Expected impact

- Model for the basis of an **industry-wide consistent approach to non-adherence**

- Framework for **future development of patient-centric solutions** with capacity for the model to evolve with future needs of patient populations;

- **Guidance, based on the validated model**, for identifying patient needs and tailoring support tools to address patient adherence needs and improve patient outcomes and quality of life;

- Data collected during the project will provide a **broad and deep resource for future understanding** of adherence.

Suggested architecture of the project
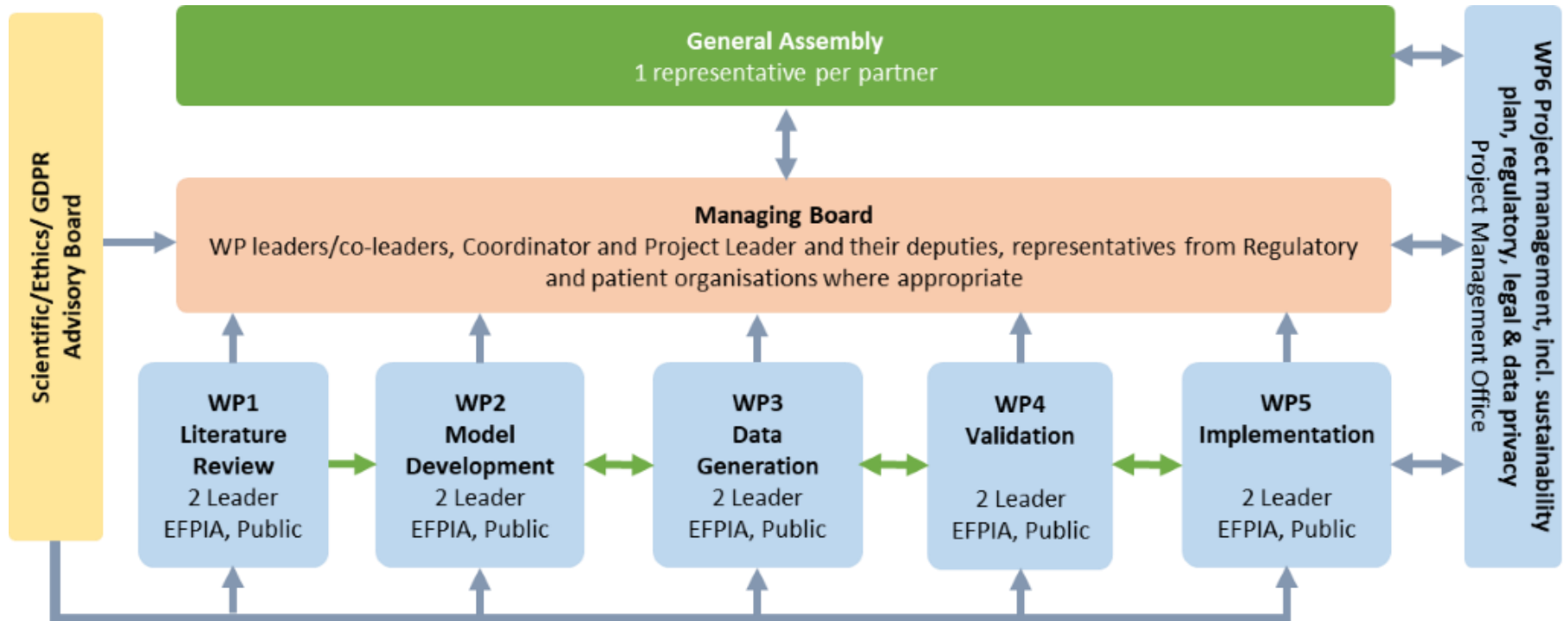
Work packages

- **Work package 1 – Data and Model Review**

- **Work package 2 – Model Development / Refinement**

- **Work package 3 – New Data Generation**

- **Work package 4 – Model validation**

- **Work package 5 – Implementation**

- **Work package 6 – Project Management**

Expected contributions of applicants (1)

- Experience of Patient adherence and contributing factors, from:

  - ✓ across countries and therapeutic areas

  - ✓ different HCPs (e.g. physicians, pharmacists, nurses)

  - ✓ different stakeholders (e.g. patients, healthcare providers, healthcare policy makers, and pharmaceutical researchers);

- Expertise in building and evaluating behavioural models;

- Reporting capabilities;

- Study design and management expertise;

- Model validation using real-world data;

- Expertise in machine learning to identify data patterns and trends;

Expected contributions of applicants (2)

- SMEs with implemented adherence measurement solutions

- Patient communication and interfaces expertise

- Experience in app development

- Legal and data privacy expertise

- Access to health authorities, healthcare professionals, patients, patient advocacy groups and policy makers

- Data management, website management expertise

- Expertise in clinical compliance/ICH GCP aspects

- Project management, project administration/coordination, budget management and communication expertise

Expected (in kind) contributions of industry consortium

- Project leadership and programme oversight

- Curation and re-analysis of adherence data

- Expertise in behavioural science

- Methods development to collect and assess treatment adherence

- Study design, planning and management experience

- Access to planned real-world patient studies for data generation

- Data analyses, including statistical analyses of study results and advanced analytics/machine learning, to identify trends;

- Regulatory, data privacy and medical expertise

What's in it for you?

Patients' and healthcare professional organisations:

Co-creators in development of new healthcare model resulting in tools to provide more focussed support to patients.

Academic researchers, research institutions, specific experts:

Collaborate with different sectors in cutting-edge research to improve the current 'one-size-fits-all' delivery of healthcare (to achieve meaningful benefit to the patient and cross-industry consistency).

Technology partners/SMEs:

Leading role in the development of innovative technology approaches with potential broad longer-term applicability in a healthcare setting

Regulators:

Contribute to the development of a model that can be applied to benefit patient outcomes and help shape the implementation of a cross-industry proof-of-concept for sharing patient information.

imi innovative medicines initiative

Key deliverables of the full project

Initial Research

- Searchable database of published and "grey" sources of data on treatment adherence causes;

- Definition of adherence and methodology for assessing data, including consideration of bias;

- Statistical analysis and prioritisation of relative significance of factors on treatment adherence and persistence;

- Evaluation of available treatment adherence models

- This deliverable will be used by the consortium to choose one model to refine/build a new model for validation;

Key deliverables of the full project

Model Development

- Methods to measure key factors and adherence levels with minimum patient burden;

- Disease-agnostic model of patient behaviour;

- Development of tools:

  - ✓ To collect data from patients

  - ✓ to quantify behavioural factors

  - ✓ for use in validating the model and in future applications

- Evaluation of trends within the data

innovative medicines initiative

Key deliverables of the full project

Validation and Application

- Model validation to demonstrate effective understanding of patient needs and prediction of adherence rates;

- Guidance on applying model to develop solutions which address patient needs and adherence rates;

- Educational tools for patient organisations and support groups, pharmacies and healthcare providers;

- Requirements assessment for data-sharing solutions to minimise patient burden and data entry duplication;

- Potential proof-of-concept solution to demonstrate how a single patient input can be shared with multiple companies.

imi | innovative medicines initiative

Involvement of SMEs and patient groups

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:

- SMEs with implemented solutions (i.e. hardware and software) to measure and manage medication adherence, ideally with own datasets and published evidence.

Patient participation

- Many ways to include your patient partners in the project e.g;

    - Patient input into the implementation of the model, especially patients with multiple conditions and their interaction with adherence solutions.

    - Individualisation of therapies and patient empowerment.

    - Community outreach and dissemination.

"The patient, doctor and researcher – each is a different kind of expert."
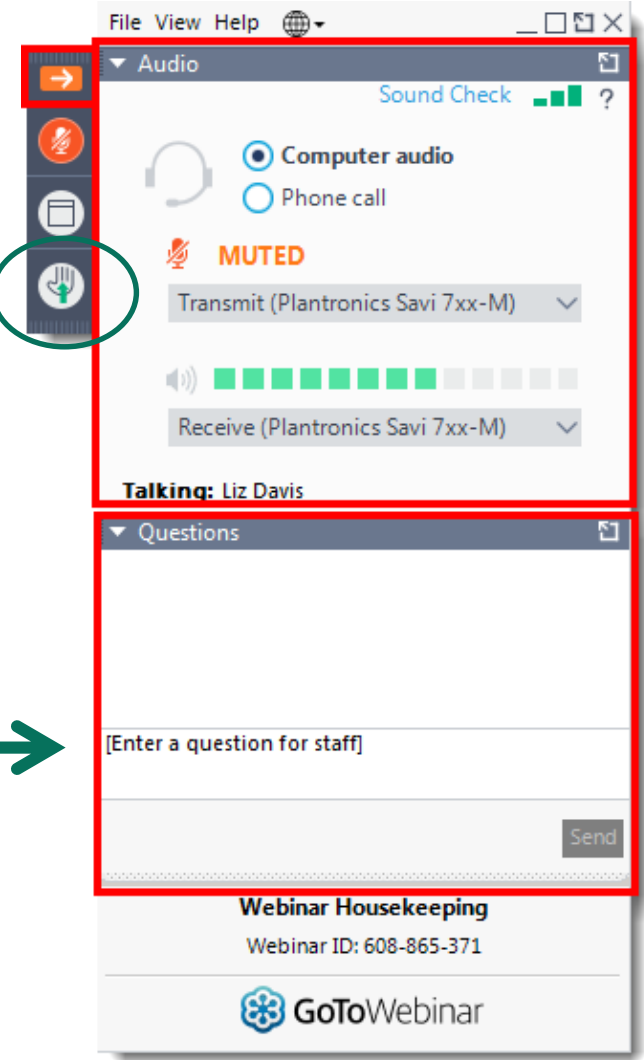
Thank you

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!