Webinar | IMI2 - Call 22

Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities

16.06.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Nathalie Seigneuret, IMI
- Call topic – Nathalie Seigneuret, IMI
- From Call to grant award – Fabrizio Federici, IMI
- Questions & answers

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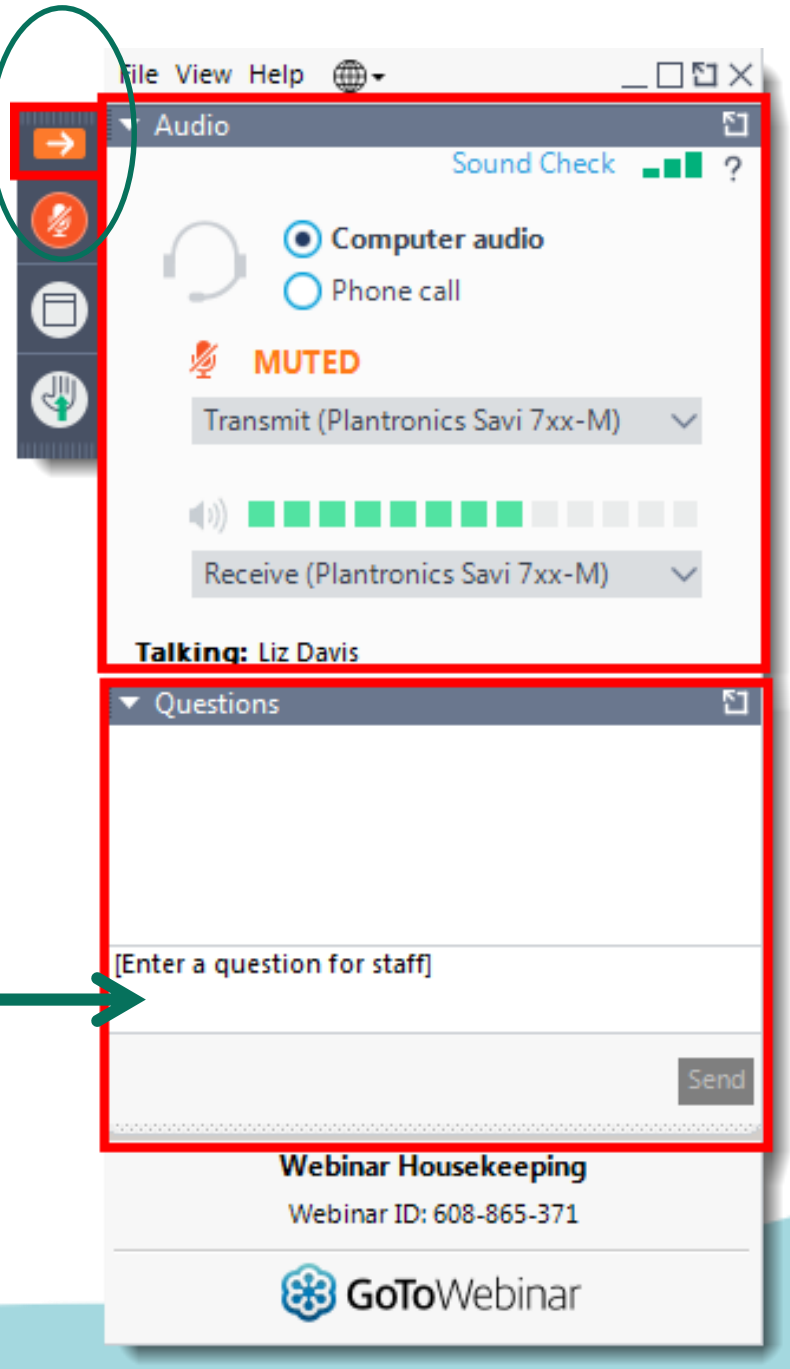

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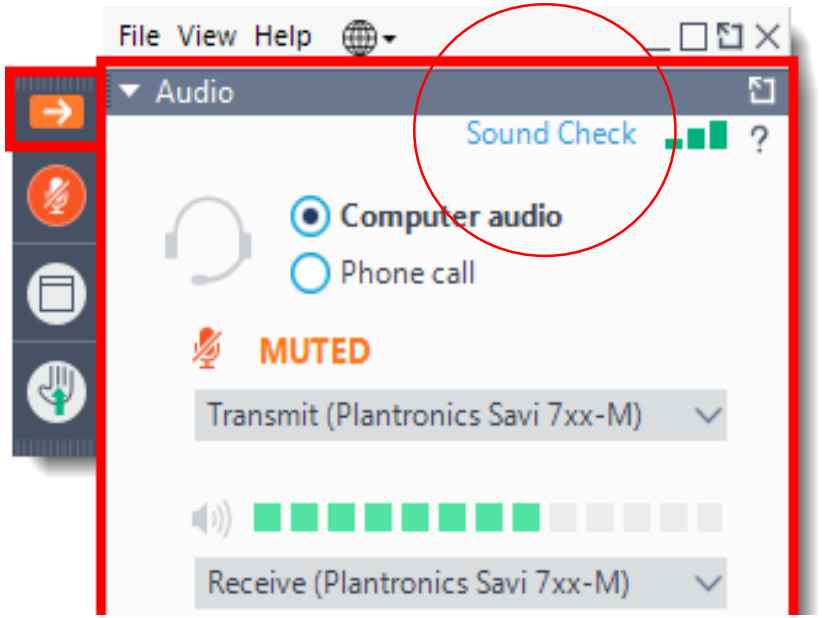

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Before we start…

- 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.

Webinar | IMI2 - Call 22
Introduction

Nathalie Seigneuret 16.06.2020

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

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges in areas of unmet medical needs**.

All partners needed to find transformative solutions to **reduce late stage attrition, speed patient access** and **improve health outcomes** and find solutions for a sustainable healthcare system

Academia

Charities

Regulators

SMEs

HTA bodies

Pharma companies

Payers

Diagnostic companies

Healthcare practitioners

Other sectors (e.g imaging, nutrition…)

Public health bodies

Patients

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IMI2 overall objectives

- **improve the current drug development process** through development of tools, standards &approaches to assess **efficacy**, **safety** & **quality** of health products.
- **develop diagnostic & treatment biomarkers** for diseases clearly linked to clinical relevance & approved by regulators
- **reduce time to clinical proof of concept** (e.g. for cancer, immunological, respiratory, neurological/neurodegen. diseases)
- **increase success rate in clinical trials** of priority meds (WHO)
- **develop new therapies** for diseases with **high unmet need**, (e.g. Alzheimer's) & **limited market incentives** (e.g. AMR)
- **reduce failure rate of vaccine candidates** in phase III trials through new biomarkers for efficacy & safety checks

- IMI2 legislation -

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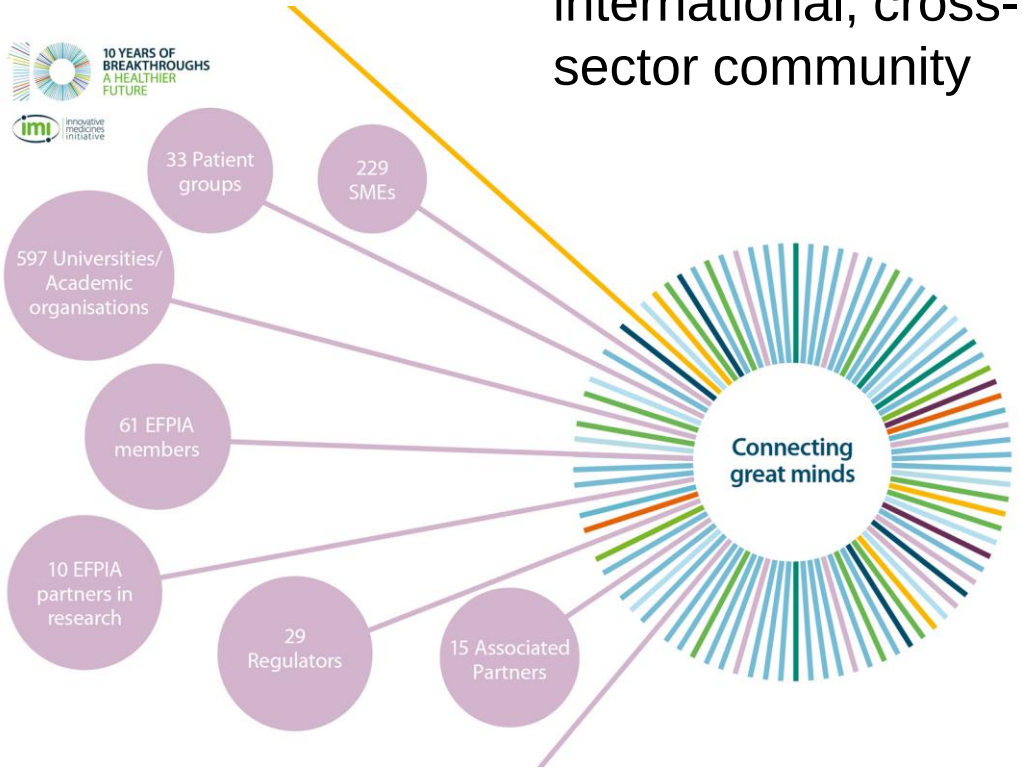
IMI – Europe's partnership for health

IMI2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegene-rative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines

- Aligned with WHO priorities

- Over 11 500 researchers from an international, cross-sector community



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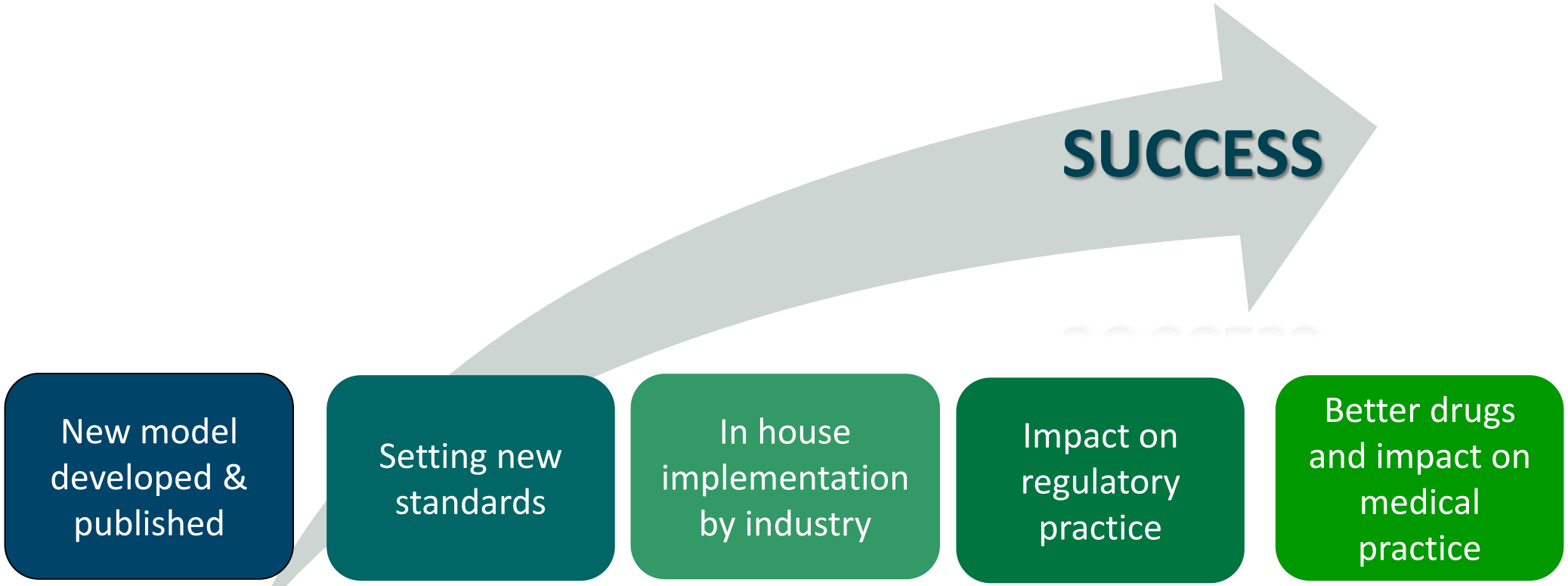
Measures of success



TRANSLATE SCIENCE INTO REGULATORY PATHWAYS AND REAL WORLD PRACTICE

PATIENTS ACCESS TO INNOVATIVE PREVENTIVE & THERAPEUTIC OPTIONS

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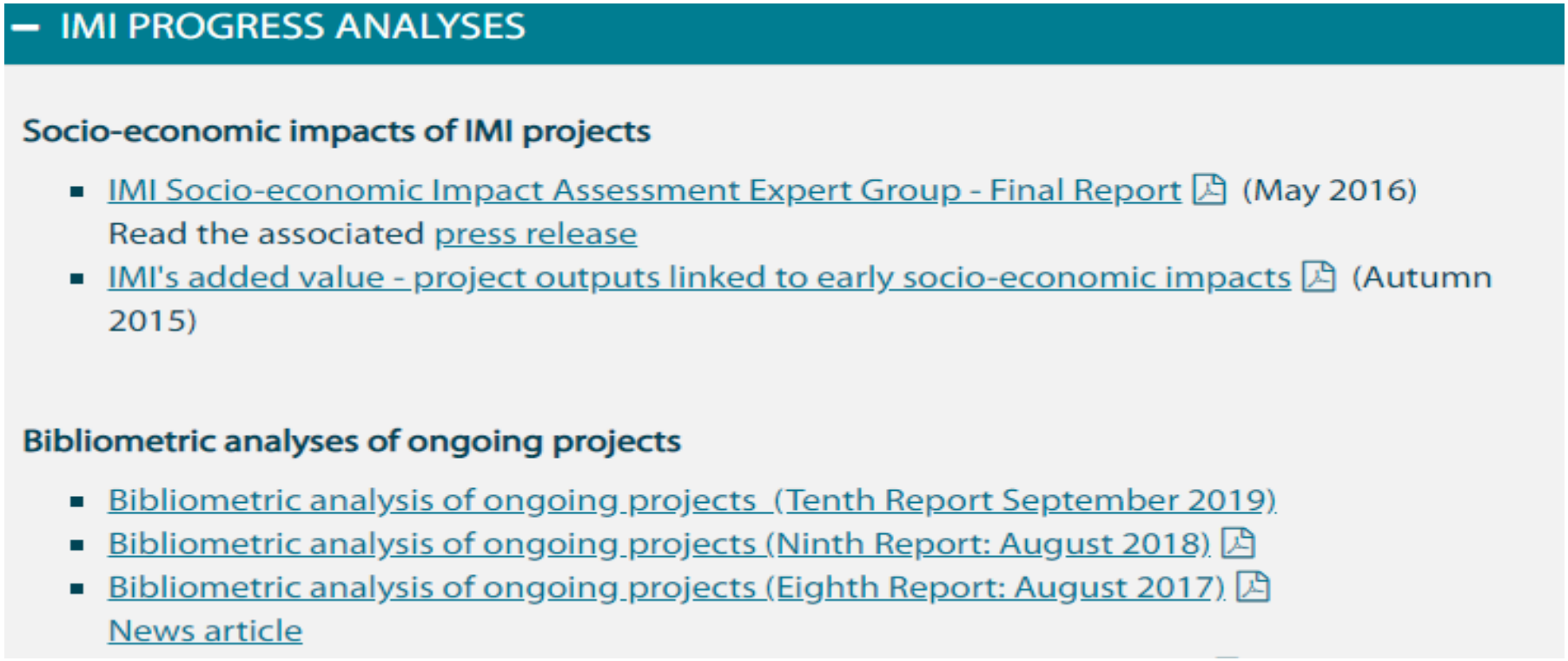
Measuring Impact of IMI (projects)



Key performance indicators (KPIs)

Reporting on measuring and outcomes on the ten Key Performance Indicators provided yearly as part of the IMI2 JU Annual Activity Reports for year 2018 and beyond.
https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2_KPIs_approved_14_DEC_2017.pdf

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Example of IMI2 Key performance indicators

KPI	Definition	Comment	Relates to	Baseline	Target
1	Number of relevant priority areas in the WHO "Priority Medicines for Europe and the World 2013 Update" reflected in the IMI2 Strategic Research Agenda (SRA) and addressed by IMI2 projects.	Based on the SRA and including the WHO priority medicines therapeutic areas: - Expressed as a number of areas reflected in the IMI2 portfolio. - Complemented by the number and budget of grant agreements that delivered them.	IMI2 Regulation objective b1: b1: "increase the success rate in clinical trials of priority medicines identified by the WHO"	0	12
2	The number of project developed assets which complete a significant milestone during the course of an IMI2 project.	Assets are defined as new drug or diagnostic candidates, targets, biomarkers or other tools that can be shown to have reached a significant milestone or pass a significant stage gate.	IMI2 Regulation objective b1, b2, b4, b5 and b6: b1: "increase the success rate in clinical trials of priority medicines identified by the WHO" b2: "reduce the time to reach clinical proof of concept in medicine development…" b4: "develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators" b5: "reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks" b6: "improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products"	0	50

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Example of IMI2 Key performance indicators

KPI	Definition	Comment	Relates to	Baseline	Target
3	New or improved guidelines, methodologies, tools, technologies or solutions accepted by regulatory authorities for use in the context of R&D, specifically for: - new tools for preclinical drug development, - biomarkers and tools developed to predict clinical outcomes, - improved protocols to design and process of clinical trials, - new biomarkers developed for the efficacy and safety of vaccine candidates.	- Measured by the number of the formal qualification procedures completed (letters of support, qualification opinions received). - Complemented by number of qualification procedures launched. - Expressed as net figure. - Complemented by the number and budget of grant agreements that delivered them.	IMI2 Regulation objective b1, b2, b4, b5 and b6: b1: "increase the success rate in clinical trials of priority medicines identified by the WHO" b2: "reduce the time to reach clinical proof of concept in medicine development…" b4: "develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators" b5: "reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks" b6: "improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products"	0	10 (for completed procedures)

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Examples from a decade of successes

- Ebola vaccines and diagnostics
- new candidate antibiotics,
- Tools to predict toxicity approved by regulators
- Technology platforms like ELF, EHR4CR, EMIF
- 70 novel drug targets, 35 validated drug targets
- New path for complex but highly relevant public health burdens like dementia or other neurological conditions (pain, autism)
- Gaps in the ecosystem like several clinical trials networks (1800 sites across Europe) including for paediatrics
- 39 cohorts and registries to optimise clinical trials
- Manufacturing method of flucytosine that dramatically cuts production cost
- Outcomes (real world data) data infrastructure and governance
- First ever human beta cell line culture which changed the way diabetes research is done

€5.3bn	148	3 606	>7 000	>3 800
BUDGET	PROJECTS	PARTICIPANTS	PROJECT OUTPUTS	PUBLICATIONS

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Example of success story

Support for patients with respiratory diseases

13/03/2019

IMI's PRO-active project has developed new patient-centred tools and approaches to help people with chronic obstructive respiratory disease (COPD) get more personalised treatments - a means to boost their activity levels, health and well-being.

COPD affects 1 in 10 of all people aged 50 and over and is a leading cause of death. The disease is characterised by breathlessness, coughing and often excessive mucus production, all of which make any physical activity uncomfortable and difficult for sufferers. In Europe alone, some 300 000 Europeans die each year from COPD.

Physical inactivity is a key predictor of death in patients with COPD. The IMI project PRO-active has developed new tools to help researchers and clinicians measure the impact of the disease on patients experience with physical activity and the physical difficulties patients encounter. This information can now be used to assess the impact of effective treatments on an outcome that is directly relevant to patients.

'Lack of physical activity is an indicator of mortality,' says project coordinator Thierry Troosters of the Katholieke Universiteit Leuven in Belgium. 'Patients with COPD who drop their physical activity levels are more likely to die than people who maintain those levels. We could already measure physical activity, but now we have a tool that captures how patients experience it.'

The new tools are providing doctors, nurses and other healthcare workers and researchers with unique information on the effect of treatment on their patients, he adds. They will also feed into the way new medicines and other interventions are assessed and benchmarked, based on patients' experiences.

A focus on patient experience

By combining wearable physical activity monitors with short daily surveys, researchers found an effective way to gauge symptom-related stress experienced when patients were active. Three different kinds of activity monitors were trialled to find the most sensitive ones, which are best suited for people with chronic diseases.

Input from patients was key to the development of the PRO-active tool. COPD sufferers themselves designed the user-friendly questions for the surveys and patient organisations were also given important managerial roles on the ethics committee board of the project.

'We want to get insights from the patients' perspective on how an intervention benefits them directly,' says Troosters, explaining how normally treatment testing focuses on physiological results, but not patient experiences.

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Webinar | IMI2 - Call 22
Restricted Call

Nathalie Seigneuret 16.06.2020

Background

- Major challenges within the medicines development process (scale of the investment required, the stepwise approach, long development timelines and successful involvement of relevant stakeholders)

- Potential for collaborative public private partnerships like IMI2 JU to deliver well beyond the initially expected outputs

- Certain IMI2 JU topics included pre -information to potential applicants that at a later stage a subsequent Call for proposals, restricted to consortia selected under initial topics could be published

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Scope

- To support further research activities in those exceptional cases where it is necessary

- To enable successful consortia to build on the achievements of their initial action and move onto the next step of the challenge

Scope

Specific points of focus:

- scientific relevance for successfully addressing **IMI2 JU objectives**;
- relevance of the proposed activities to an area with a **high unmet need** from the public health perspective and having industrial challenges (where relevant). Inclusion of a landscaping exercise to demonstrate that no similar initiative of the same extent is already ongoing at national, European or global level;
- need for the proposed activities to (in a timely fashion) seamlessly **build on and add value to the already remarkable results** achieved in the initial action as demonstrated and documented by the applicant consortium;

Scope

- **scope** of proposed activities that goes **beyond the scope of the initial action** (e.g. initial objectives and its financial and temporal framework)
  - *If new action and the initial one will run in parallel, proposed measures to ensure the achievement of the respective objectives and no double funding*

- **specific circumstances** justifying that only the initial consortium can carry out the follow-up activities successfully (e.g unique expertise, equipment, methodologies, access to unique resources and IP rights)
  - *some justified modifications of the partners list may be accepted to cover the expertise needed for newly proposed activities*

- proposed activities build on and benefit from the **strong foundations established** as public-private partnership **in the initial action** (e.g. governance, workflows, procedures)

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Scope

The applicants will also need to justify why the proposed research activities can only be carried out in public private collaboration, including substantial contributions in the project activities i.e. EFPIA constituents and affiliated entities and, where relevant, by IMI2 JU Associated Partners

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Additional condition for participation

This Call is restricted to the initial consortia of actions funded under topics published in the **IMI2 JU Annual Work Plans of 2014, 2015 and of 2016**

- These actions are sufficiently advanced to be considered for follow-up activities;

  and

- The specific topic in the relevant Work Plan already informed potential applicants about the possibility of a later restricted Call

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Additional condition for participation

- Consortia that meet these conditions under AWP 2014, 2015 and 2016 are:
  - ADAPT-SMART
  - BEAt-DKD
  - C4c
  - COMBACTE-CDI
  - DO-IT
  - HARMONY
  - Hypo-RESOLVE
  - INNODIA
  - ITCC-P4
  - LITMUS
  - MOPEAD
  - NGN-PET
  - PARADIGM
  - PIONEER
  - PRISM
  - RADAR-CNS
  - RESCEU
  - RESOLUTE
  - RHAPSODY
  - TransQST

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Deliverables

- To be defined by applicants consortia in their proposal

- Highlight:
  - which deliverables would be sustained beyond the duration of the funded action; and
  - how this would be achieved along with any key results that would be expected to be made openly accessible

Expected impact

Describe how the proposal will uniquely contribute to the following impacts and include baseline, targets and metrics to measure impact.

- Improve current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health product;
- Benefit public health & improve health and well-being of European citizens;
- Contribute to the EU's industrial leadership, including in relation to SMEs;
- Impact on regulatory/health technology assessment, and healthcare practices, if relevant;
- Further maximise IMI2 JU PPP value by harnessing support from different stakeholders, including mobilisation of contributing partners (i.e. EFPIA constituents and affiliated entities and, where relevant, by IMI2 JU Associated Partners) – not necessarily involved in the initial project.

  ✋These contributions must be on top to those already committed in the initial project.

Key points

Indicative duration of the action

24 months

Applicants may propose a different duration if properly justified

Indicative budget

Maximum total financial contribution from IMI2 JU **of EUR 11 427 098**

Within this budgetary envelope, each proposal must include a sound justification of the budget requested, taking into account the proposed in-kind contributions from contributing partners, i.e. EFPIA constituents or affiliated entities and/or, when relevant, IMI2 JU Associated Partners.

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Further points to be addressed (1/2)

Points that applicants should pay due attention to when preparing their proposal

- **Data management**
  - due visibility to data management including use of the data standards
  - full 'data management plan' (DMP) as a distinct deliverable due within the first 6 months of the action. DMP needed to be updated during the lifetime of the action
- **Dissemination, exploitation and communication**
  - draft plan for the exploitation and dissemination of results
  - full plan as a distinct deliverable due within the first 6 months of the project
- **Sustainability**
  - sustainability plan beyond the end of the GA (may be updated during the action lifetime)
  - Allocate sufficient resources to the sustainability plan.
  - This may involve engaging with suitable biological and medical sciences research infrastructures

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Further points to be addressed (2/2)

- **Patient and healthcare provider engagement**
  - strategy to engage with patients, learned societies and healthcare providers as relevant encouraged to ensure the project results impact on healthcare practices.
- **Synergies**
  - brief presentation of an environment scan of relevant existing initiatives to ensure synergies and complementarities, and avoid unnecessary overlap and duplication of efforts and include a plan on how they propose to synergise with these initiatives.
- **Regulatory strategy**
  - strategy for the translation of the relevant outputs into the regulatory practice to promote the uptake of the results e.g. qualification advice, qualification opinion when relevant expected (plan for interactions with regulatory agencies/health technology assessment bodies /payers, with relevant milestones and sufficient resources).

Proposal template

- Single stage proposal template to be used
- Template available on IMI website & H2020 submission tool

✋ In addition to all the information to be provided as standard in the relevant sections, there are points specific to this restricted Call for proposals to be addressed

- These are specified in the topic text.

- Please read carefully the topic text.

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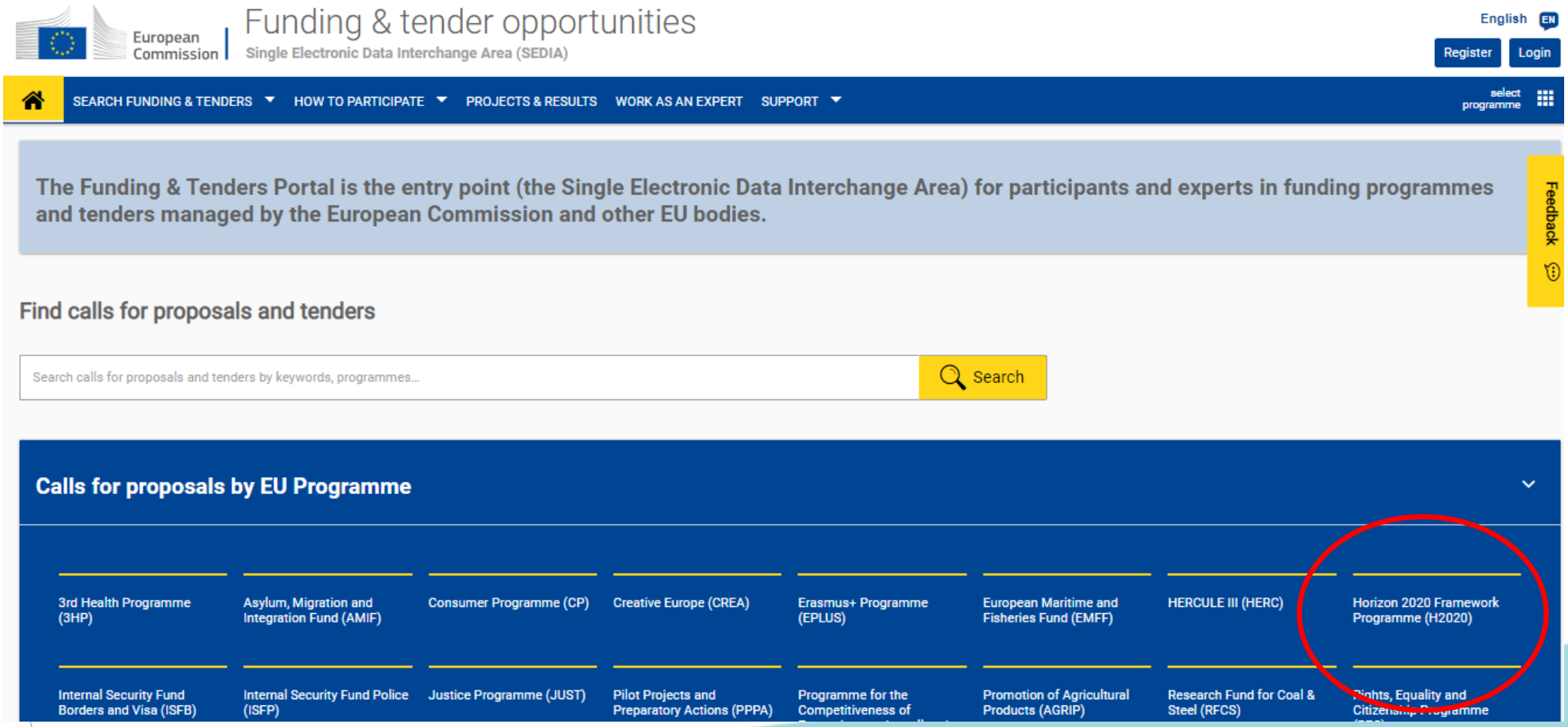
Submitting a proposal

Via the Funding and Tenders Portal

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



From Call to grant award

IMI2 Call 22: a single-stage Call process

Call launch

Single stage

Full consortium public & private partners

Preparation of proposal & evaluation by independent experts/ethics panel

Granting phase

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Signature of Consortium Agreement and Grant Agreement

Project launch!

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Conditions for Call 22 single-stage

H2020 Rules for participation apply to IMI2 JU Call for Proposals and Actions except where specifically derogated

- **Submission deadlines**

  Deadline Proposal submission: **29 September 2020**

- **Minimum conditions**

  Only RIA: at least three independent legal entities, each established in a different EU Member State or H2020 associated country

- **Single-stage - C22**

  Proposals submitted by the initial consortium combining applicants requesting JU funding and contributing in kind.

  All evaluated proposals will be ranked in one single list.

  Proposals above the threshold will be invited in order of ranking to prepare a Grant Agreement within the limits of the available overall budget.

- **No hearing**

  For this call, hearings with applicants consortia will not be organised

A single set of evaluation criteria

- Thresholds and weighting in the **Call documents**
- Minimum of **3 independent experts**

Each proposal **evaluated 'as it is'**, not as 'what could be'

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IMI2 JU Evaluation criteria

Single stage call

- **Excellence – threshold of 4**

  Please note sub-criteria listed in evaluation form,
- **Impact – threshold of 4**

  Please note sub-criteria listed in evaluation form,
- **Quality and efficiency of the implementation – threshold of 4**

  Please note sub-criteria listed in evaluation form

Overall threshold is 12

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Keeping the momentum

Maximum Time To Grant: 8 months from submission of full proposal:

N.B. Call 22 GAs expected to be signed by Q1/2021

5 months
for informing applicants of scientific evaluation

3 months
for signature of grant agreement

NEW Legal entity validated in parallel

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IMI2 Grant Agreement

- The IMI2 JU MGA (v.5) will apply to Call 22
- It follows H2020 Model Grant Agreement (v.5) with IMI2 specificities.
- IMI2 JU Annotated Model Grant Agreement v.2.2 (based upon H2020 AGA v.5.2)
- It is e-signed between IMI2 JU and Coordinator only. Other beneficiaries e-sign Accession Forms
- EFPIA and Associated Partners are beneficiaries not receiving funding (BNRFs, Art.9) - their financial report occurs outside the GA, for more info please consult '*IMI2 JU guidelines for reporting in kind and financial contributions by Members other than the Union and Associated Partners*'

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Consortium agreement

- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the **IMI2 JU Model Grant Agreement**
- To be agreed before the signature of the GA, IMI2 JU is not a party
- **To be adapted to the specific needs of each IMI action!**
- A template prepared by EFPIA shows what a consortium agreement might look like:

  http://efpia.eu/documents/229/141/EFPIA-Consortium-Agreement-Template-for-IMI2-actions

  Consortia may also use alternative templates if they wish.

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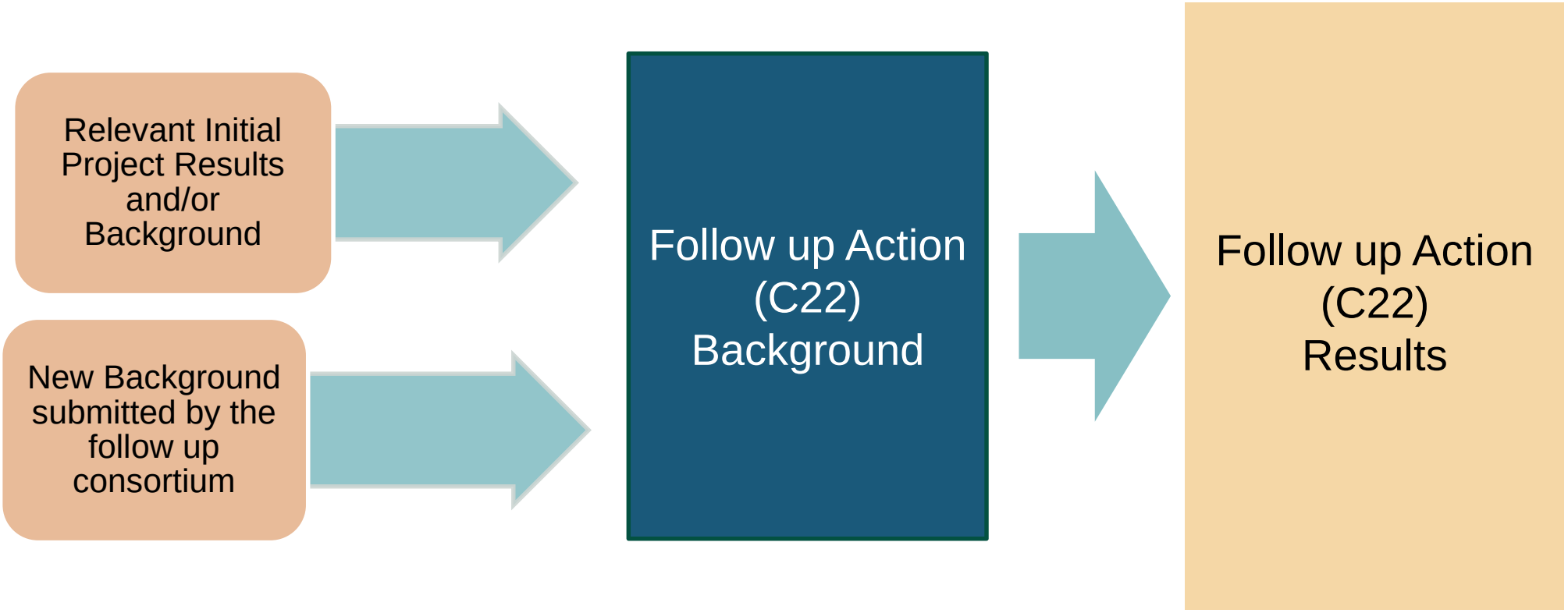
How relevant results of initial project will be used in the follow up action under IMI2 JU Call 22



The consortium of the follow up action should ensure that they have necessary access to the results of the initial project.

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Reference legal documents

- **H2020 Rules for Participation**
- **IMI2 Delegated Regulation**
- **IMI2 model Grant Agreement**
- **IMI2 annotated Grant Agreement**

www.imi.europa.eu/apply-funding/call-documents/imi2-call-documents

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Funding rules

IMI2 JU Funding model

- **IMI2 JU is a PPP, actions are normally co-funded by:**
  - JU funding to BRFs (**b**eneficiaries **r**eceiving **f**unding = legal entities eligible for funding)
  - In-kind/cash contribution from BNRFs (**b**eneficiaries **n**ot **r**eceiving **f**unding):
    - EFPIA constituents and affiliates
    - IMI2 Associated Partner
    - (future other IMI2 members)

Other legal entities may also participate as BNRFs at their own cost

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Who is eligible for funding?

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (≤ €500m)
- Non-profit organisations e.g. research organisations, patient organisations, NGOs, public bodies, intergovernmental organisations etc.

Established in:

- **EU Member State**, or
- **H2020 Associated Country**

Other countries:
No funding ***unless participation deemed essential*** *by IMI2 JU for carrying out the action*

Art.1 Commission Delegated Regulation (EU) No 622/2014

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One single funding rate per project - BRFs

One project = One rate

For all beneficiaries and all activities

- 100% of the eligible costs
- Indirect costs: **25% flat rate**

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Contributing partners

- EFPIA companies/organisations associated to EFPIA, and/or
- Associated Partners (AP) to IMI2 JU

Contribution as **in-kind contribution** or **financial contribution** to BRFs

If the contributing entity is **not** yet an EFPIA member (or affiliate) or an AP at the time of the proposal submission, and the proposal is selected for funding, such a legal entity is invited to become an EFPIA member (or affiliate) or an AP

<u>prior to the signature of the relevant Grant Agreement</u>

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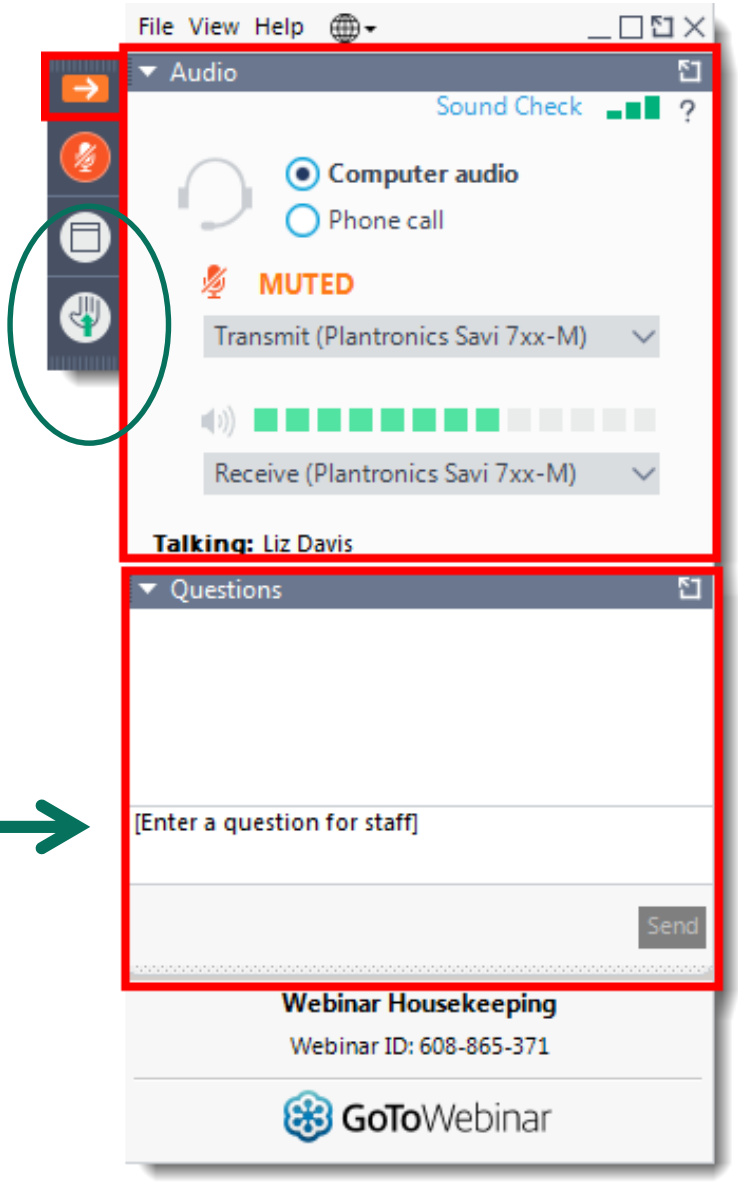
Questions & answers

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!