Rules and Procedures for IMI Calls for proposals

IMI Webinar • 25 April 2016

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- IMI Rules & Procedures – Magda Gunn & Fabrizio Federici, IMI
- Questions & answers

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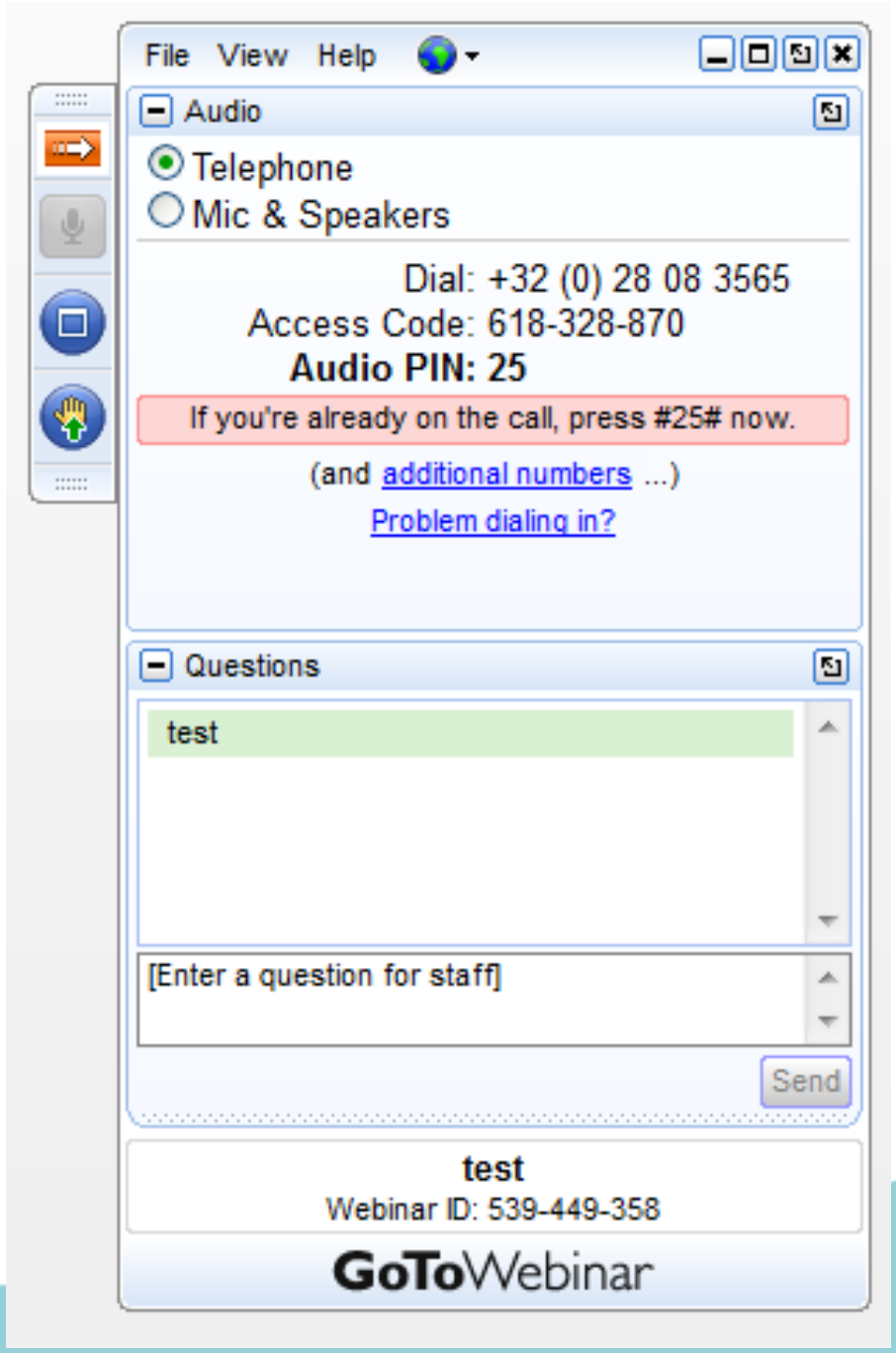
How to use GoToWebinar

Expand / minimise control panel

Microphone

Full screen

Raise / lower your hand



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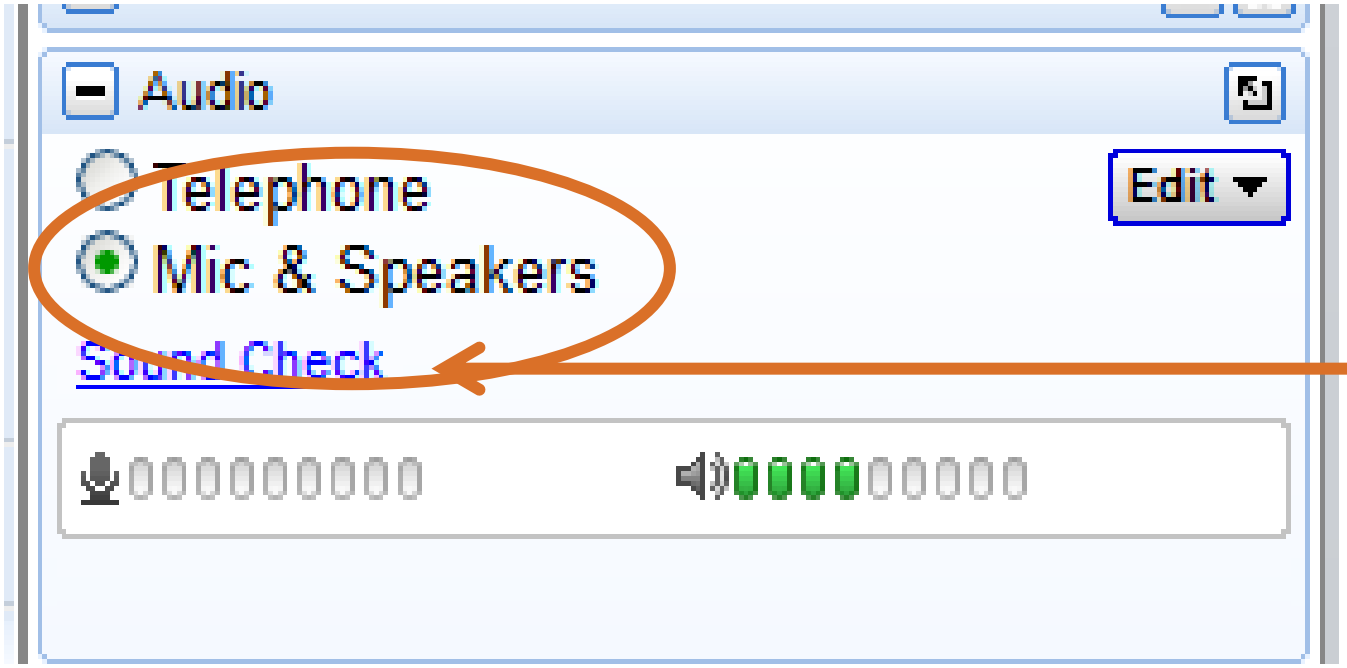
How to use GoToWebinar - audio

Using your computer's microphone / speakers



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

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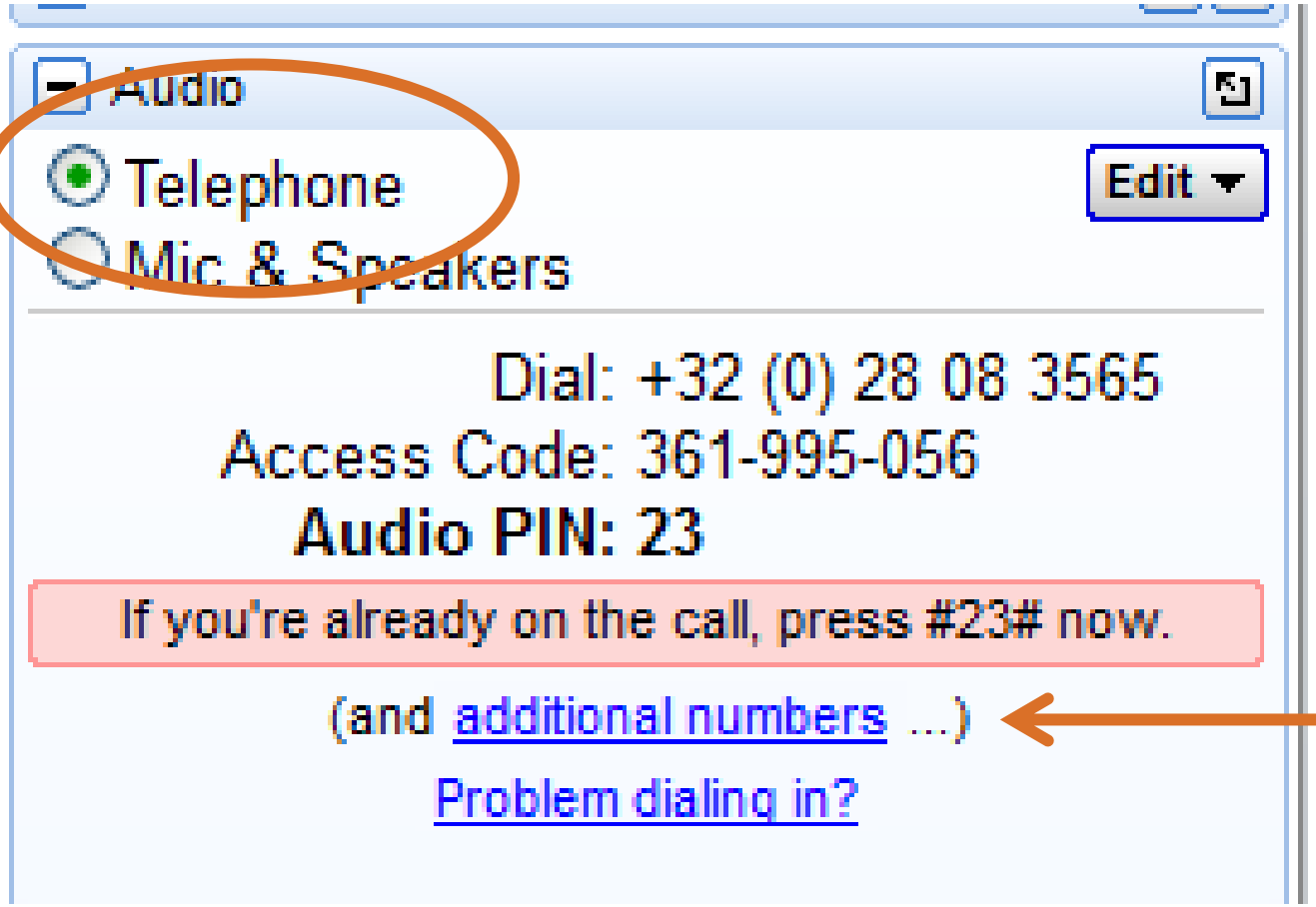
How to use GoToWebinar - audio

Using a telephone



Problems?

- Try listening in over your computer's speakers
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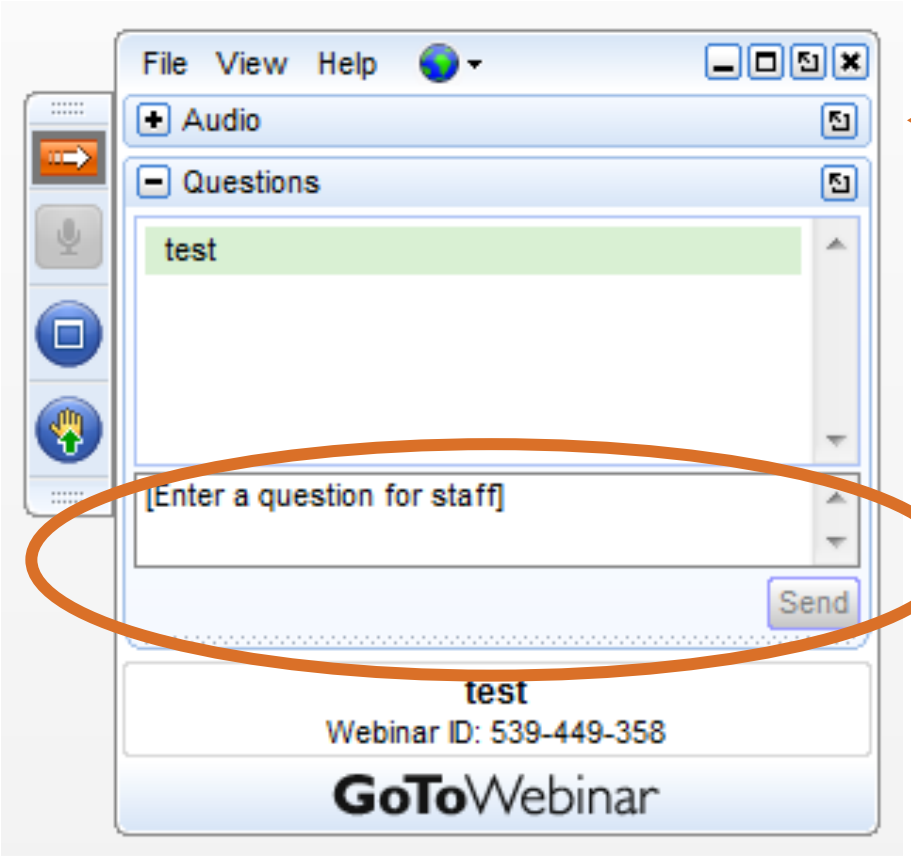
How to use GoToWebinar - questions



In writing

- Type your question
- Click on ‘Send’

By phone

- Click on the ‘raise hand’ icon

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Before we start…

- IMI 2 – Call 9 has not yet been launched. All information is indicative, pending Governing Board approval.
- Please note that this webinar may be recorded and published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar webpage
- No participant list circulated for this webinar

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IMI 2 – Call 9

IMI 2 - Call 9

- Date of Call launch: coming soon!
- Calls text and documents will be published on the IMI website – www.imi.europa.eu
- **Deadline for short proposal submission**: See the final Call documents
- Webinar topic presentations and recordings: http://bit.ly/1RSPiTC

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IMI2 Call 9 - topics

- Data quality in preclinical research and development
- Development of immune tolerance therapies for the treatment of rheumatic diseases
- Next generation of electronic translational safety – NEXGETS
- Identification and validation of non-invasive markers across the spectrum of nonalcoholic fatty liver disease (NAFLD)
- Addressing the clinical burden of Clostridium difficile infection (CDI): evaluation of the burden, current practices and set up of a European research platform
- Joint influenza vaccine effectiveness surveillance - JIVES

IMI Calls for proposals: rules and procedures

Fabrizio Federici, IMI Legal Officer
Magda Gunn, IMI Scientific Project Manager
IMI webinar • 25 April 2016

Outline

1. Introducing IMI
2. Participation rules
3. Funding rules
4. Intellectual property rules
5. From Call to grant award
6. Writing a successful proposal
7. More information

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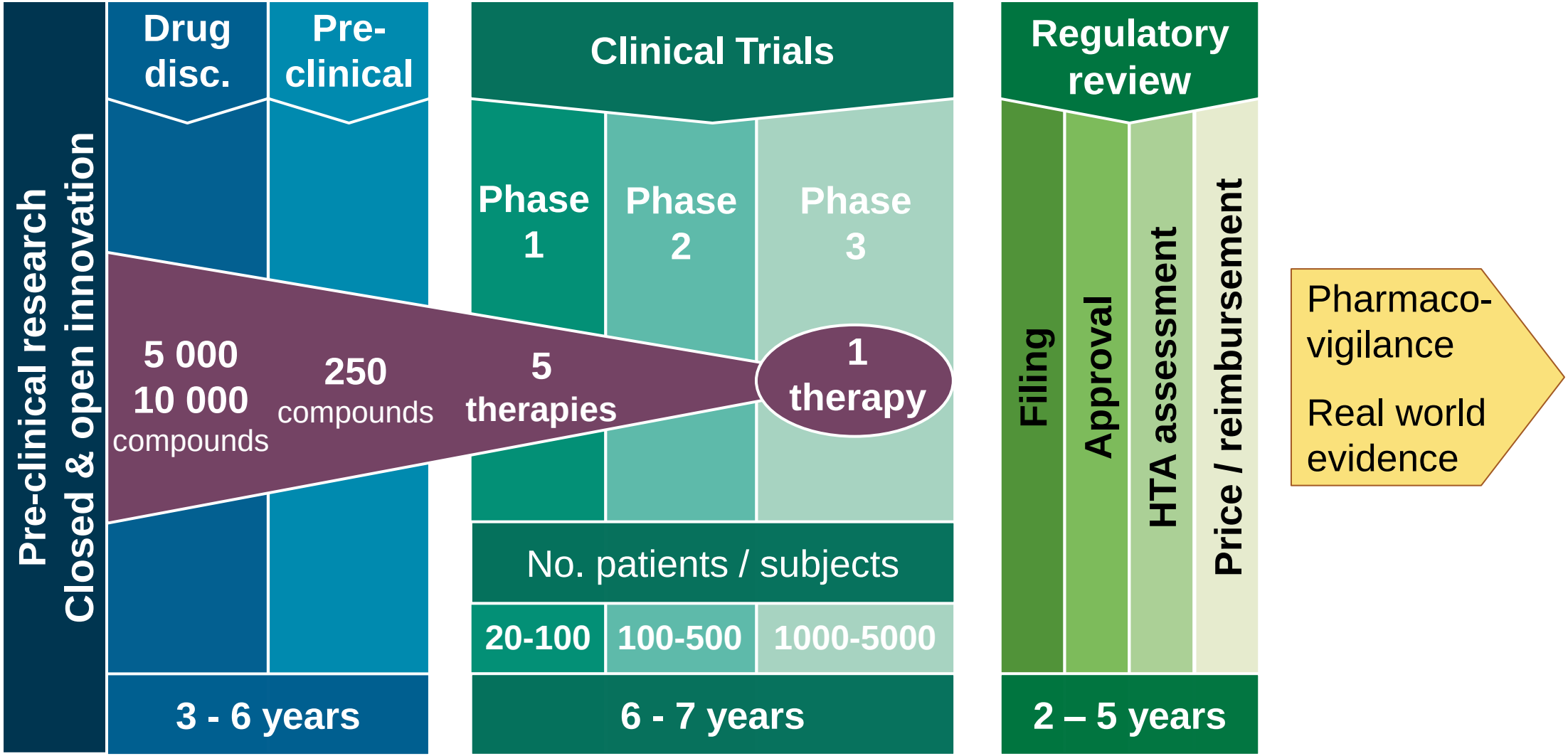
Introducing IMI

Challenges in medicines development



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IMI – key concepts

- Non-competitive collaborative research
- Competitive Calls for proposals
- Open collaboration in public-private consortia
  - Data sharing, dissemination of results…
- Industry contribution is in kind

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IMI 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

efpia

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

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

IMI 2 total budget €3.276 billion

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IMI 2 Strategic Research Agenda

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

The right prevention and treatment for the right patient at the right time

Strategic Research Agenda for Innovative Medicines Initiative 2

Aligned with WHO priorities

efpia European Federation of Pharmaceutical Industries and Associations

Vaccines Europe An industry for healthy lives

ebe european biopharmaceutical enterprises

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IMI 2 Strategic Research Agenda

Priority Themes

1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Support Technologies

1. Imaging
2. ICT
3. Medical devices….

Enablers

Patient access to innovative solutions (MAPPs)

- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation & interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

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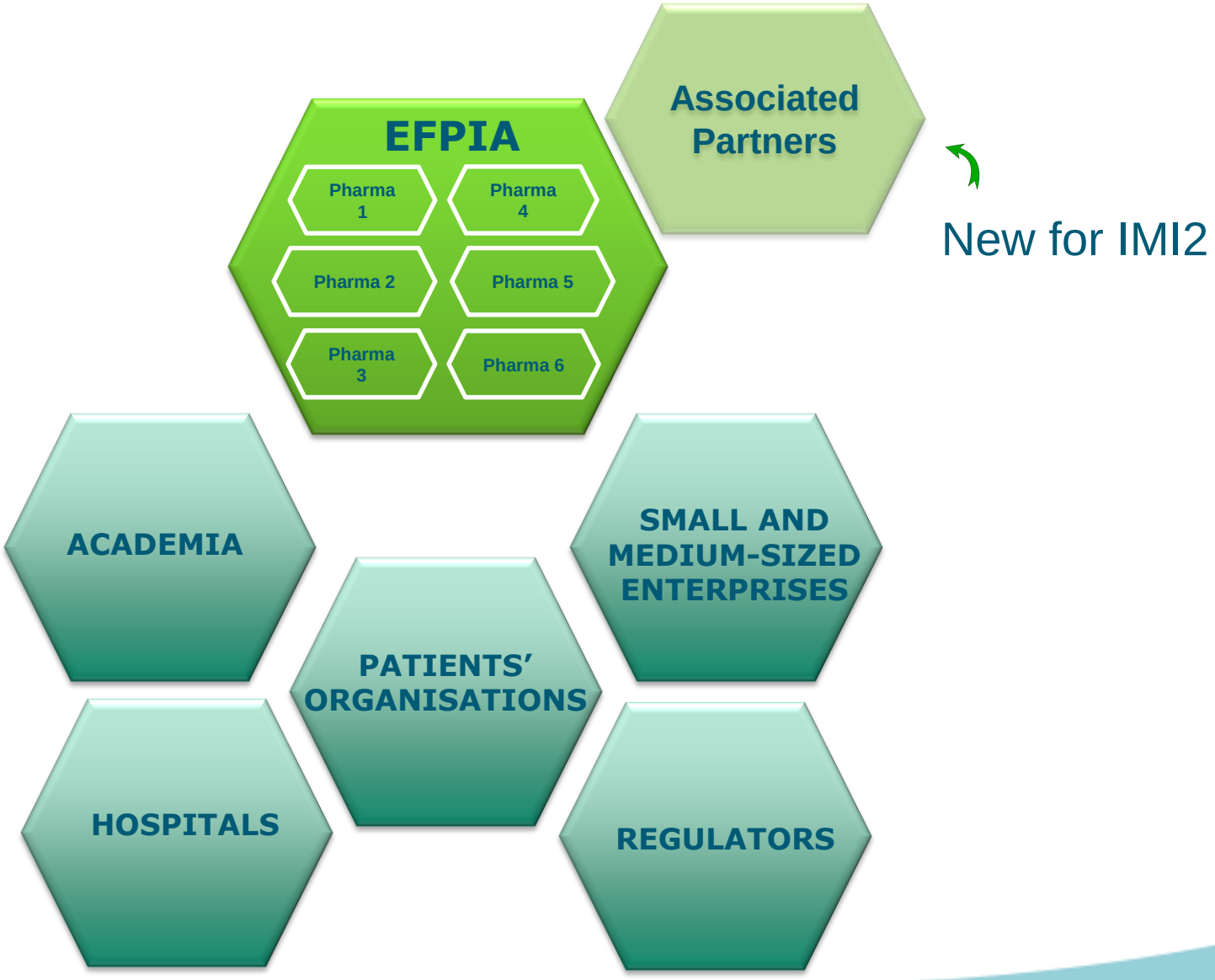
A typical IMI consortium



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An international, cross-sector community

Over 7 000 researchers working for:

- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

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Participation rules

A single set of rules

- **Covering all H2020 research and innovation actions**
- **Adaptability where needed:**
  - Entities eligible for funding
  - IP

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Conditions for this Call for proposals

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

- **Minimum conditions for Research and Innovation Actions**

  At least three independent legal entities, each established in a different EU Member State or H2020 associated country

- **Two-stages**

  Stage 1 SPs from applicants requesting JU funding

  Stage 2 merging 1st ranked SPs with industry consortia

- **Evaluation criteria**

  At stage 1, all 3 criteria are evaluated ***NEW!***

- **Page-limits** ***NEW!***

  SP 30 pp, FP 70 pp

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Conditions for this Call for proposals

- **Submission deadlines**

  Established in the Call topic text both for stage 1 and 2

- **Indicative contribution**

  For each topic, the maximum JU contribution and the estimated industry contributions are set in the call text

- **Hearings**

  Panels may decide to held hearings during panel meetings, if so applicant coordinators will be contacted (**SP details!**)

- **Plan for exploitation and dissemination**

  It must be included in FPs

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Conditions for this Call for proposals

- **Additional eligibility conditions, art.9(5) H2020 RfP:**

  - **For all topics of a two stage evaluation**

    At stage 2, pre-defined industry consortia merge with consortia 1st ranked at stage 1

  - **Topic 6 (JIVES)**

    At stage 2, ECDC – NPHI – NRA may join the1st ranked consortium together with pre-defined industry consortium

- **Information on the outcome of the evaluation:**

  ESR max 5 months from submission deadline

Attracting stakeholders

Any legal entity
regardless its place of establishment
carrying out work relevant to the Call objectives
may be part of applicant consortia

But… not all participating entities are eligible for funding

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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**
- **Associated Country**

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

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Expected consortia

Stage 1 of two stage - Short Proposals

- **Consortia consisting of:**
  - IMI fundable legal entities carrying out activities relevant for achieving the project objectives
  - additional legal entities carrying out activities relevant for achieving the project objectives.

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Expected consortia

Stage 2 of two stage – Full Proposals

- **One Full Consortium per topic consisting of:**
  - 1st ranked SP consortium - IMI fundable legal entities/additional legal entities
  - Industry consortium (EFPIA companies and IMI2 Associated Partners) associated to the relevant topics
  - ECDC/NPHI/NRA, *under topic 6 only*

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Funding rules

IMI2 Funding model

- **IMI2 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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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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JU contribution to BRFs covers:

- **Personnel**
  - Wider acceptance of average personnel costs
  - Acceptance of supplementary payments

    For non-profit organisations of up to 8000 euros/year/person
  - Less requirements for time records
- **Equipment, consumables, travels…**
- **Subcontracting**

Considering BRFs accounting and management principles

- **BRFs may also receive Financial contribution from EFPIA/APs**
  - to be reported as receipts

EFPIA and Associated Partners contribution - BNRFs

- EFPIA companies
- Other industries and partners (= Associated Partners to IMI2)
  - In-kind (actual direct and indirect costs or average FTE) and/or cash contributions
  - Based on the usual management principles and accounting practices
  - Contributions from affiliated entities as part of in-kind

When relevant to IMI2 objectives: up to 30% non-EU in-kind contribution

Annual financial reporting is disconnected from GA periodic reports

Deadlines for reporting

- Scientific reporting (full consortium) due at project deadlines (i.e.GA), duration reporting period: 12 months

- Financial reporting for:
  - Beneficiaries receiving JU funding, due at project deadlines (i.e.GA)
    CFS: >EUR 325k at project end

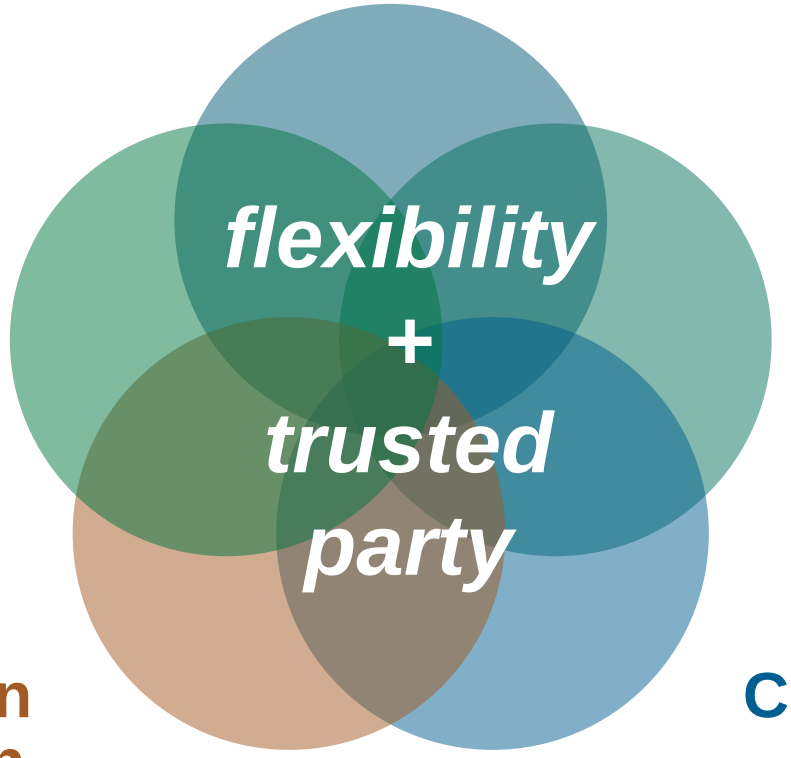
  - Beneficiaries Not receiving funding (e.g. EFPIA companies and APs), due by 31 Jan - certification by 30 April- covering previous calendar year

IMI's Intellectual Property (IP) rules

One set of rules for multiple interests

Support to industry

Incentive to participate



Freedom of access

Dissemination of information

Compensation for IP

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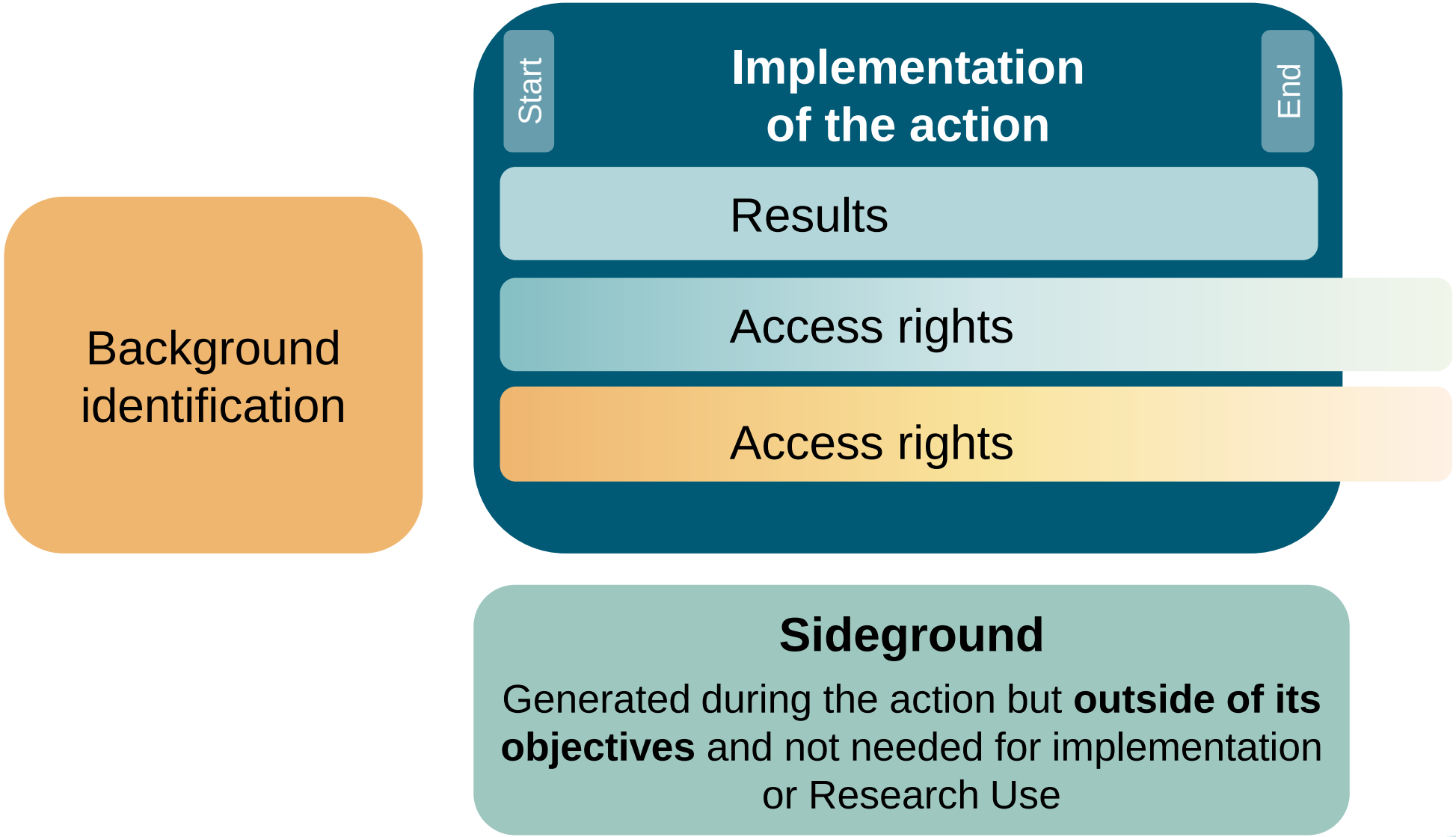
Background vs. Results



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Ownership of results

Results belong to the beneficiary who generated it

Possible transfer of ownership
- within the consortium to affiliates and purchasers without prior notification
- on case-by-case basis

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Joint ownership of results

Individual use of jointly owned results

provided prior notice and fair & reasonable compensation to the other joint owners

Based on previous experience

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Research Use vs. Direct Exploitation

- **Research Use**
  - Use of results or background necessary to use the results for all purposes other than for completing the action or for direct exploitation

Based on previous experience

- **Direct exploitation**
  - to develop for commercialisation or to commercialise the results

Access Rights conditions

Access rights granted by a beneficiary to/on	**Background** (necessary and identified)	**Results**	**Sideground**
Beneficiaries for completion of the action	**Royalty-free**	**Royalty-free**	N.A.
Beneficiaries and affiliates for Research Use	**Fair & reasonable terms** for background needed for using the results	**Fair & reasonable terms**	N.A.
Third Parties for Research Use after the action	**Fair & reasonable terms** for background needed for using the results	**Fair & reasonable terms**	N.A.
Beneficiaries and affiliates or Third Parties for Direct Exploitation	To be negotiated	To be negotiated	N.A.

Based on previous experience

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Access rights to results for third parties

- Only after the end of the action
- Possibility to exclude specific elements of background (only for existing background)

Based on previous experience

- Time-limits to be agreed

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Reference documents

- **H2020 Rules for Participation**
  - IPR section: Article 1.3.c and Articles 41 to 49
- **IMI2 Delegated Regulation**
  - IPR section: Articles 2 to 7
- **IMI2 model Grant Agreement** (revised January 2015)
  - IPR section: Articles 23a to 31
- **IMI2 annotated Grant Agreement** (soon)

www.imi.europa.eu/content/documents

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From Call to grant award

IMI life cycle

- **Call topics definition**
  - Scientific Research Agenda
  - Annual Work Plan
  - Strategic Governing Groups
  - Consultation Member-Associated States/Scientific Committee

- **Call Launch / Evaluation / Grant award**

- **Grant agreement, Consortium agreement, Implementation and Reporting**

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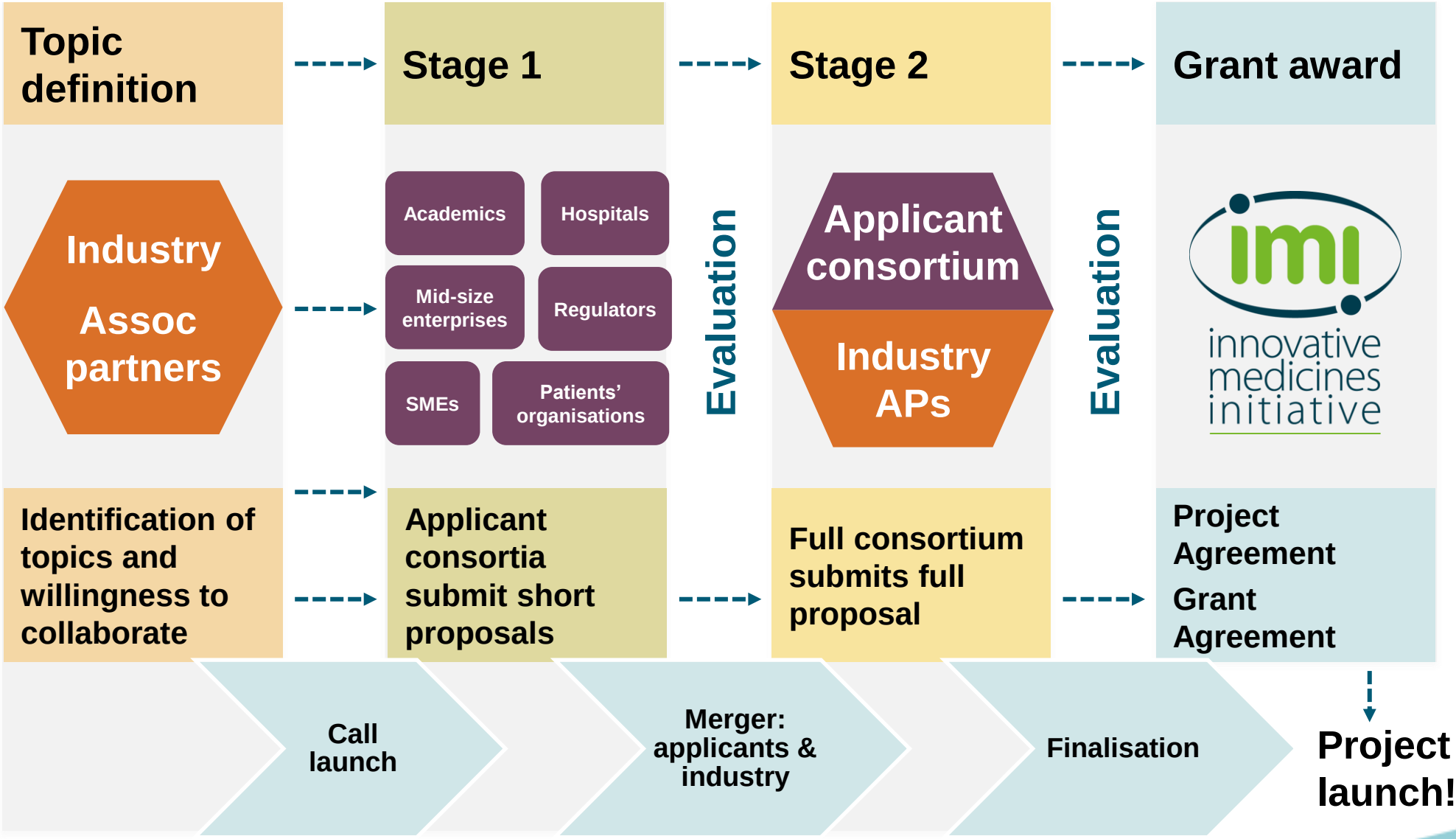
Typical IMI project life cycle



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A single set of evaluation criteria

- Two-stage evaluation:
  all three criteria considered at both stages *NEW!*
- Thresholds and weighting in the **Call documents**
- Minimum of **3 independent experts** (possibility of 2 in a two-stage process)
- New proposal templates for both stages *NEW!*

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

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Evaluation Criteria (RIA)

1. Excellence

The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the call for proposals and referred to in the IMI2 annual work plan :

- Clarity and pertinence of the proposal to meet all key objectives of the topic;
- Credibility of the proposed approach;
- Soundness of the concept, including trans-disciplinary considerations, where relevant;
- Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;
- Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.

Evaluation Criteria (RIA)

2. Impact

The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level:

- The expected impacts of the proposed approach as mentioned in the call for proposals;
- Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
- Enhancing innovation capacity and integration of new knowledge;
- Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
- Improving European citizens' health and wellbeing and contribute to the IMI2 objectives; Any other environmental and socially important impacts;
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.

Evaluation Criteria (RIA)

3. Quality and efficiency of the implementation

The following aspects will be taken into account:

- Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget;
- Complementarity of the participants within the consortium (where relevant);
- Clearly defined contribution to the project plan of the industrial partners (where relevant);
- Appropriateness of the management structures and procedures, including manageability of the consortium, risk and innovation management and sustainability plan.

Keeping the momentum

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

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

- Follows H2020 Model Grant Agreement with IMI2 specificities. An Annotated Model Grant Agreement for IMI2 will soon be available
- Signed between IMI2 JU and Coordinator only. Accession forms for other beneficiaries
- EFPIA and Associated Partners are beneficiaries not receiving funding (BNRFs) (Art.9) - their financial report occurs outside the GA

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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 model Grant Agreement**
- Before the signature of the grant agreement with the IMI Office
- **To be adapted to the specific needs of each IMI action!**

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Tips for success

Common Mistakes

- **Admissibility/Eligibility criteria not met:**
  - submission **deadline** missed
  - proposal **out of scope**
    (if you have doubts on how to respond to the Call contact us)
  - A minimum of **three legal entities** (RIA)

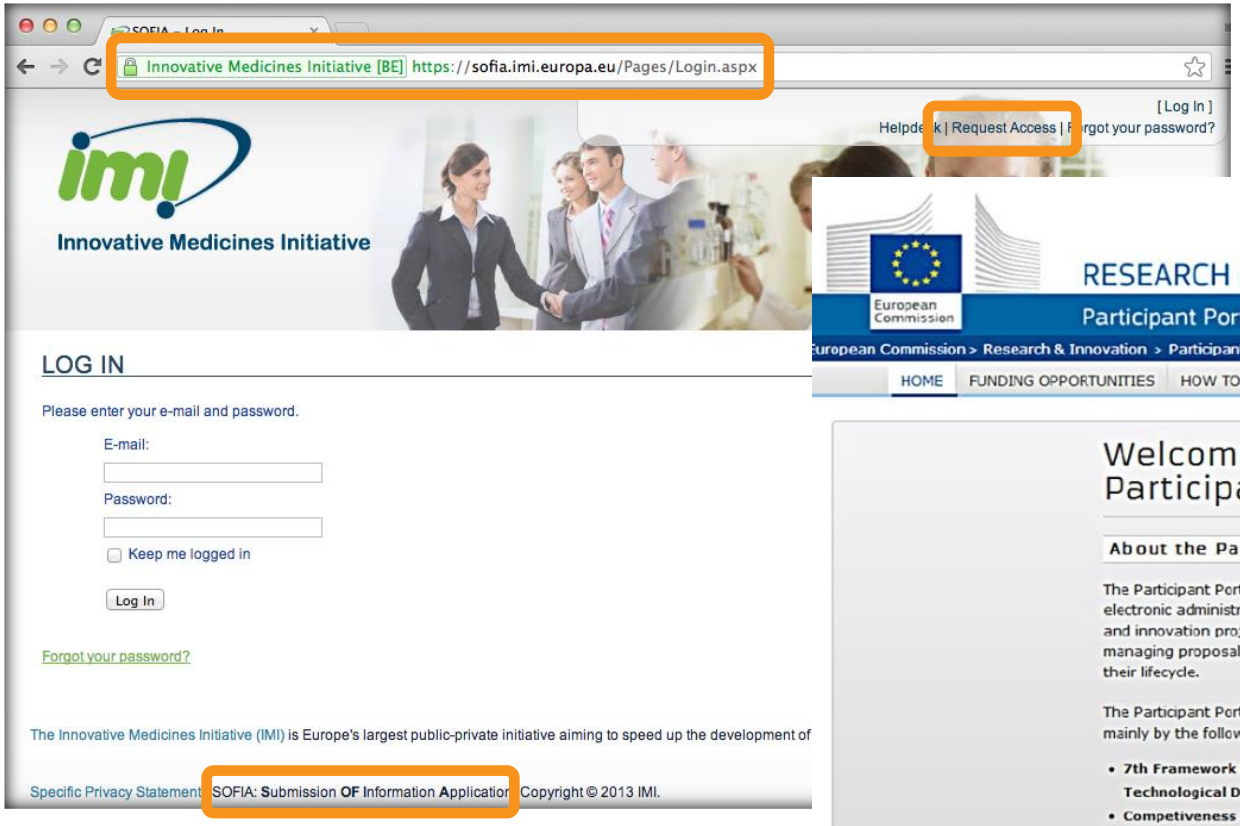
Common Mistakes

- The proposal does not address all the **objectives** (in some cases proposals have nothing to do with the topic!)
- submitted text does not respect the proposal template (sometimes received even slides!)
- Applicants do not have the **capabilities** to address all of the objectives or there is redundancy between partners
- A proposal is scientifically excellent but will have **limited impact**
- **Ethical issues** not addressed

Tips

- **Read all the Call-relevant material that is provided on the IMI website – www.imi.europa.eu**
- **Understand IMI 2 rules** and respect them
- **If in doubt, ask** a member of the Programme Office
- Your proposal should provide **reviewers** with all the information requested to allow them to evaluate it
- Start working early (pre-materials available before)
- **Finalise and submit your submission**
- **More tips:** www.imi.europa.eu/content/tips-applicants

Submitting a proposal



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Partner Search Tool

www.imi.europa.eu/content/partner-search

http://www.fitforhealth.eu/

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More information

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- Follow us on Twitter **@IMI_JU**
- Join our LinkedIn group **bit.ly/LinkedInIMI**
- E-mail us **infodesk@imi.europa.eu**

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Your contact points

At the IMI Programme Office

- General queries: infodesk@imi.europa.eu
- IP queries: IMI-IP-Helpdesk@imi.europa.eu

Local contacts

- IMI States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs

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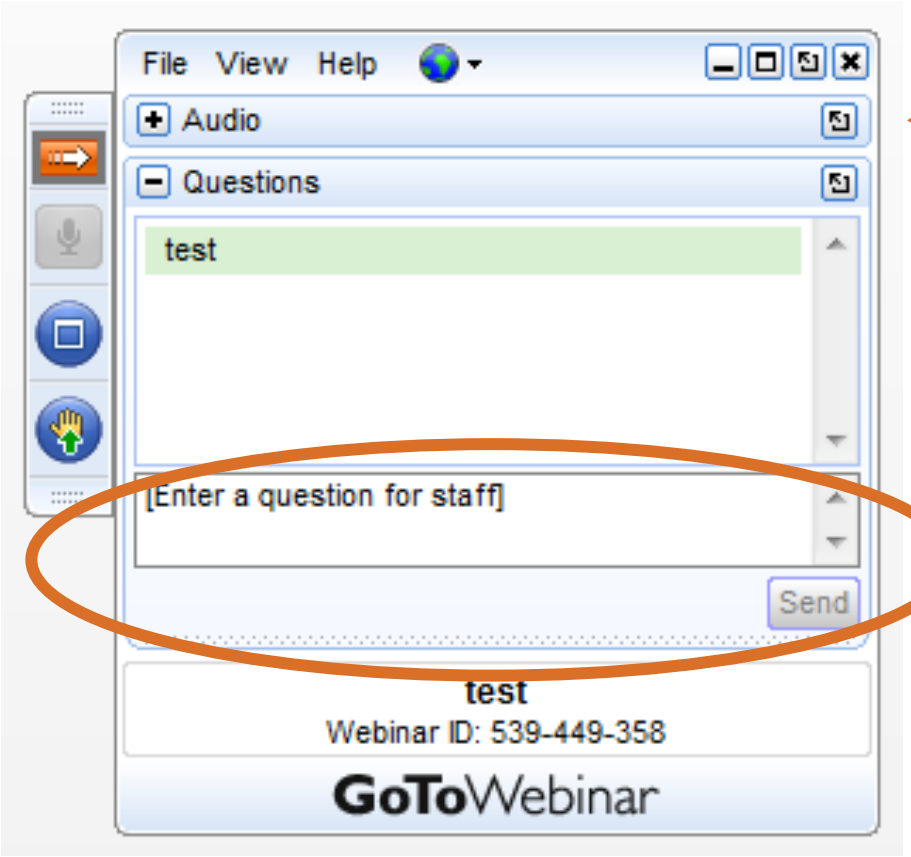
Questions & Answers

How to ask questions



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Thank you!

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