

**Webinar | IMI2 - Call 8
'Ebola and other filoviral
haemorrhagic fevers (Ebola+)
programme: future outbreaks'**

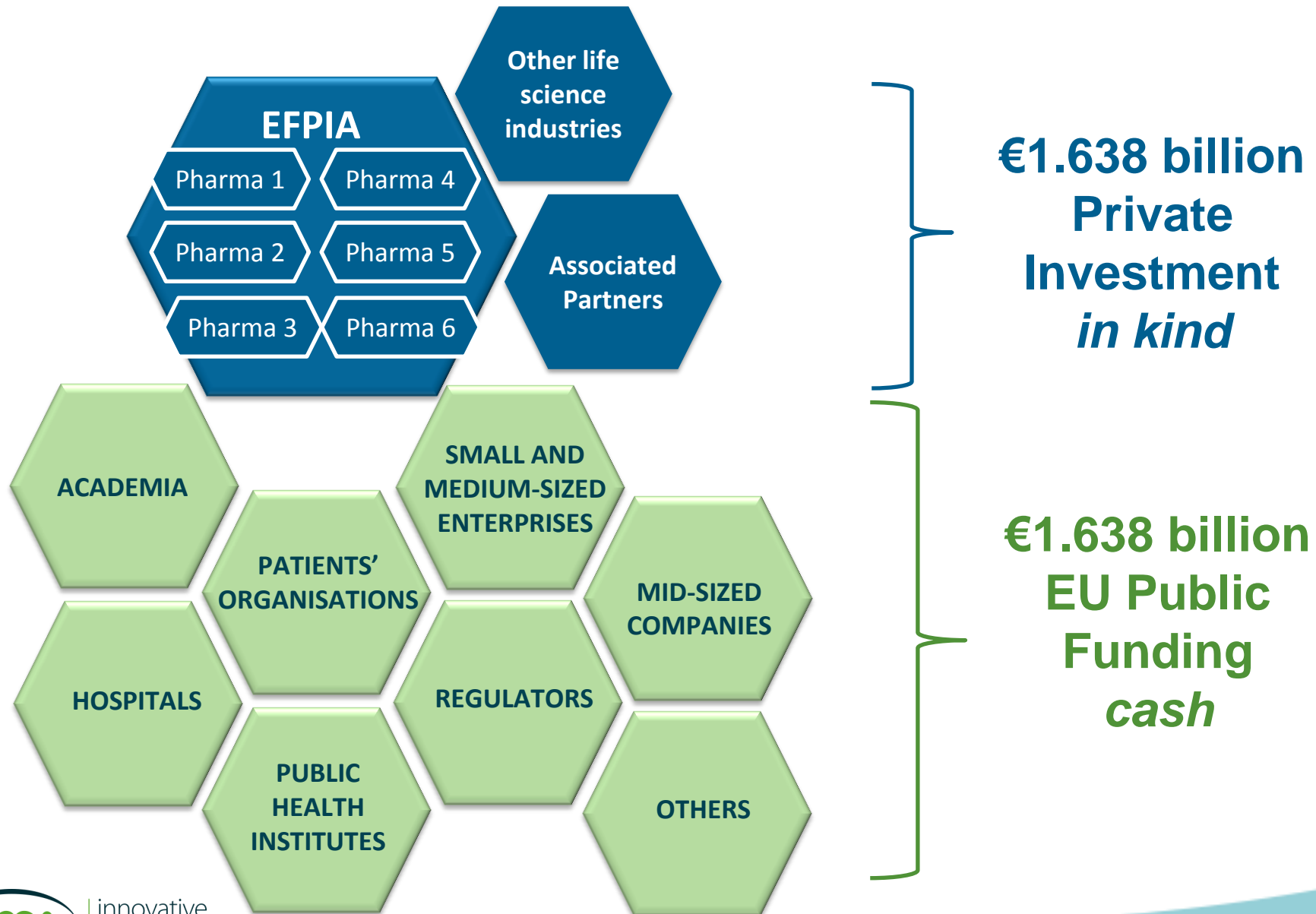
Dr. Angela Wittelsberger
IMI Scientific Officer
15.01.2016

Today's webinar

Will cover :

- Background of the Innovative Medicines Initiative's Ebola+ programme
- IMI2 Call 8: Scope, objectives & expected impact
- Call process
- Tips and recommendations for a successful proposal
- Rules and procedures

The Innovative Medicines Initiative: a public-private partnership between EFPIA and the EU



October/November 2014

European
Commission &
EFPIA

- Other funders
- Situation of current epidemic
- Short term goals
- Long term strategy
- Need for collaboration

A programmatic
approach in IMI

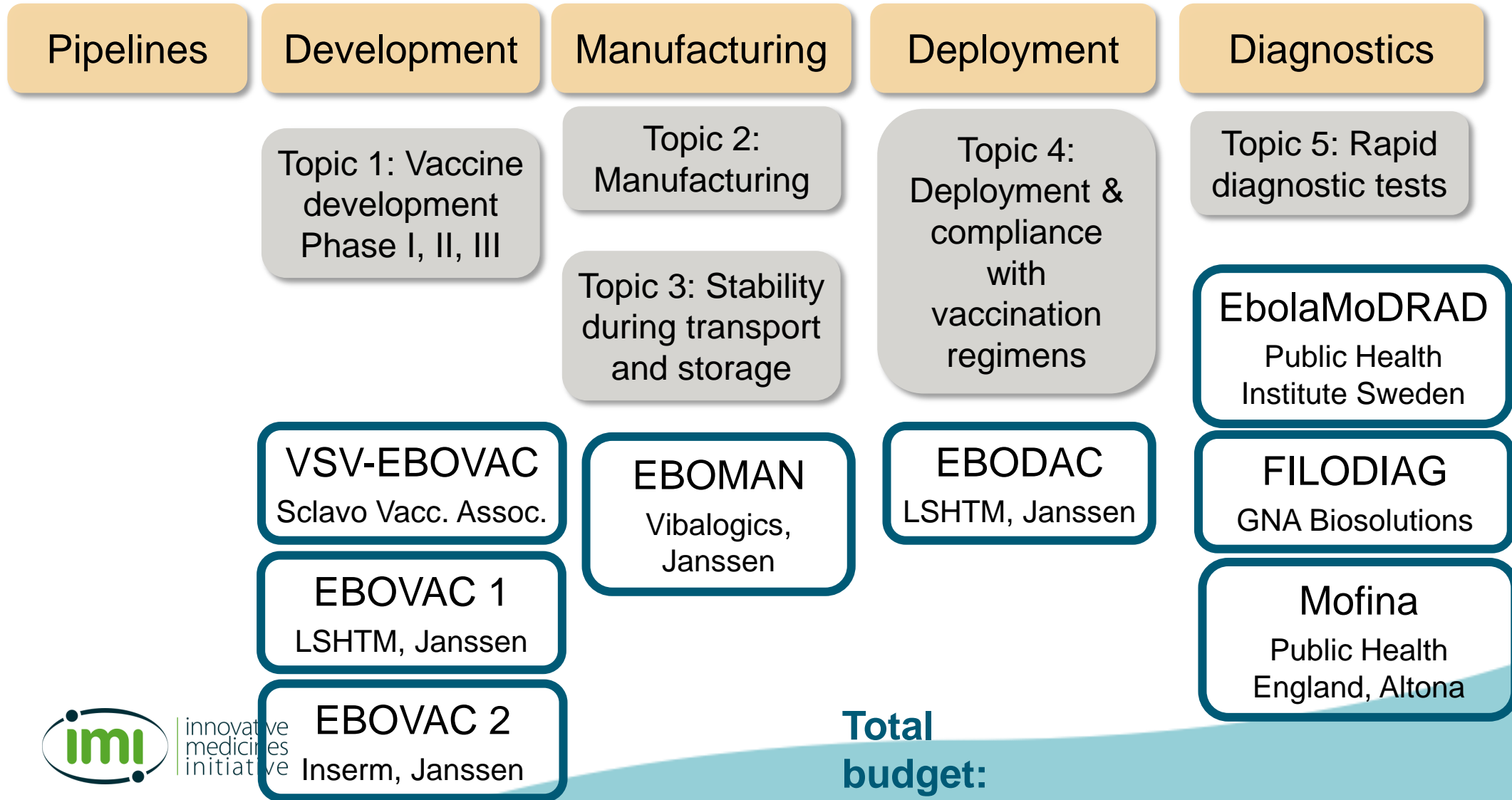
- Filoviral haemorrhagic fevers
- Fast impact and longer term
- Broad scope from early discovery to compliance, diagnostics

6 Nov: IMI2 Call 2 launching
the Ebola+ programme with
first five topics

Other calls in the future

Ebola+ programme: current overview

IMI2 Ebola and other filoviral haemorrhagic fevers programme
Joint Information repository, Scientific Advisory Board, Ethics Board



Total budget:
€ 215 million

IMI2 Call 8: Projects will join the Ebola+ family

- Projects funded under this Call for proposals will be part of the IMI2 Ebola+ programme
- It is expected that projects will interact with other Ebola+ projects, e.g. joint Scientific Advisory Board, joint Ethics Board, joint Information Repository

IMI2 Call 8: second Call for Proposals under the Ebola+ programme

- Same **broad scope**
- to capture emerging scientific advances and to progress rapidly into health care interventions
- Fast development, uptake and/or deployment should be ensured
- must result in increased readiness to respond to future outbreaks
- Attention should be paid to exploiting support from different stakeholders, **including mobilisation of funds through the inclusion of contributing partners**
- Partners in consortiums must have the **capability and capacity to broaden and fast-forward results into validated treatments**
- Encouraged to build on outcomes of research stemming from current research programmes national or international

Broad scope

- Proposals may address aspects of **pre-clinical development and/or Phase 1, 2, and 3 clinical developments of vaccines (in particular multivalent), treatments and diagnosis** of Ebola and other filovirus infections
- **Manufacturing strategies, vaccine stability during transport and storage, and/or deployment of vaccines and treatments** also in scope
- Adaptable platforms addressing multiple other priority pathogens in addition to filoviruses also in scope

IMI2 Call 8: Expected key deliverables

Must be outputs that will increase our preparedness to react to future outbreaks of Ebola and other filoviral haemorrhagic fevers.

Might include, but not limited to:

- a novel vaccine candidate, diagnostic or treatment ready for testing in an outbreak setting
- tools to help with pre-clinical and clinical development
- a novel diagnostic test
- Novel strategies to improve the stability of vaccines at 8°C or ambient temperatures
- Novel manufacturing or delivery strategies
- Strategies for optimal deployment/adherence to vaccination programmes
- Exploitation of recent advances in our understanding of Ebola/filoviral infections & accelerated health care intervention

IMI2 Call 8: Expected key deliverables

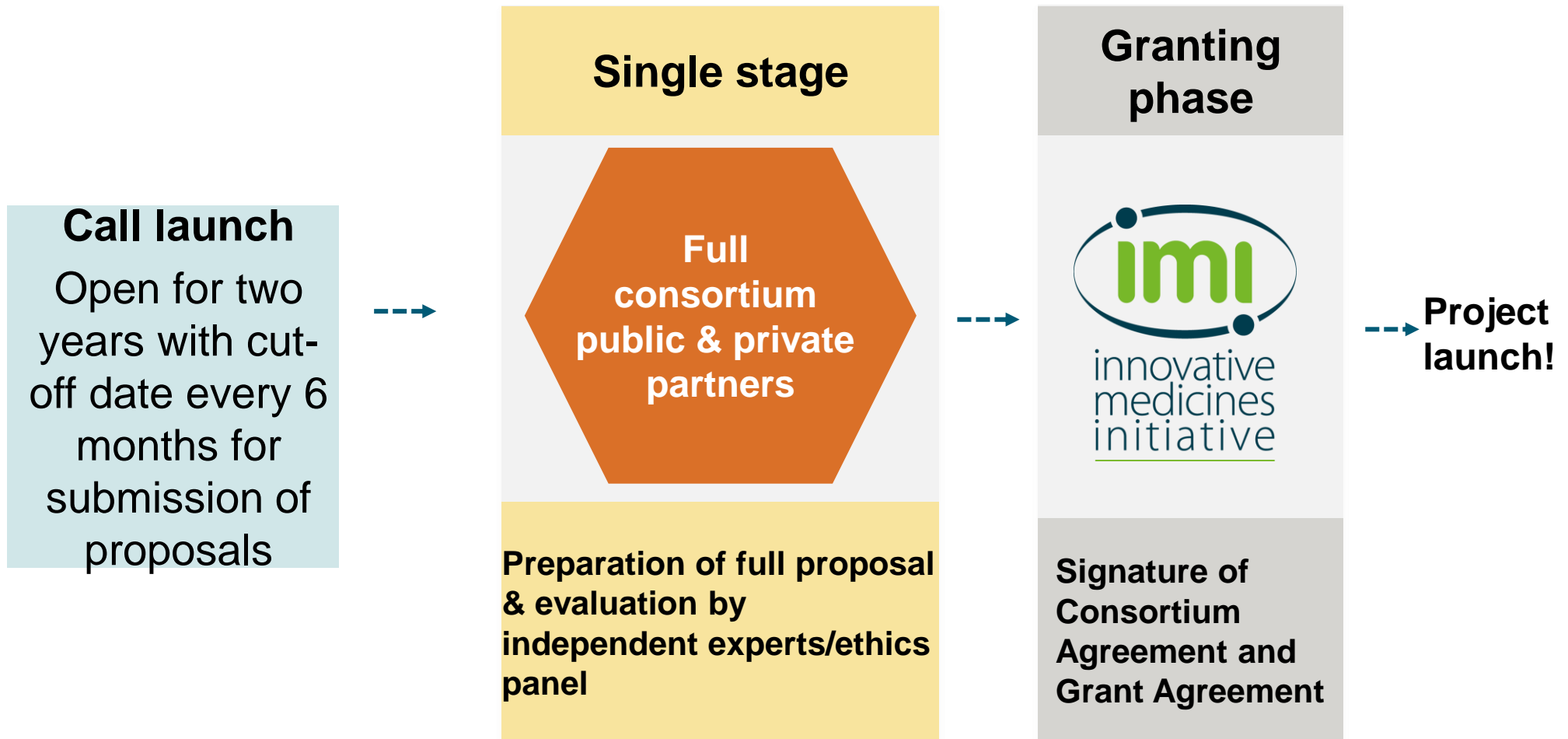
Every proposal should include:

- A plan for a clearly defined strategy on how to ensure translation of the relevant project outputs into regulatory, clinical and healthcare practices, into value for people in countries at risk of future outbreaks of filoviral haemorrhagic fevers
- A plan for interactions with regulatory agencies/health technology assessment bodies (where relevant) including milestones and allocated resources
- A plan for sustaining project result and outputs

IMI2 Call 8: Expected impact

- Work proposed must contribute to the objectives of IMI2 and Ebola+ aiming at leveraging input and multi-disciplinary expertise across stakeholders
- Work must increase the readiness to respond to future outbreaks
- Must maximise benefit to people in the countries at risk; Therefore, applicant consortia should have the **capability to accelerate project results into health care interventions**
- Expectation to exploit support from different stakeholders, including the **mobilisation of funds through the inclusion of contributing partners under the IMI scheme of public-private consortia (at least 40% of total project costs)**
- Expectation that funded projects will have a significant impact on global health, both at individual and public health level

IMI2 Call 8: a single-stage Call process



IMI2 Call 8: an Open Call with cut-off dates

- **Open call with cut-off dates**

The call will be open for 2 years with several cut-off dates until March 2018:

First submission deadline: 16 March 2016

Subsequent cut-off dates: 15 September 2016, 16 March 2017, 15 September 2017, 15 March 2018

- **Indicative IMI Joint Undertaking contribution**

Up to EUR 70 million available as of first cut-off date

At a given cut-off date, submitted Full Proposals are evaluated by a panel of independent experts and ranked in one single ranking list

- **Project duration**

Aligned with activities proposed and work plan

IMI2 Evaluation criteria

- **Excellence – threshold of 4**

Please note sub-criteria listed in evaluation form, e.g. clarity and pertinence of the objectives; credibility of the proposed approach; soundness of the concept, ambition, innovation; mobilisation of necessary expertise

- **Impact – threshold of 4**

Please note sub-criteria listed in evaluation form, e.g. referring to Expected impacts' section of Call text; enhancing innovation capacity; impact on health; contributing to IMI2 objectives; exploitation and dissemination of results; communication about project

- **Quality and efficiency of the implementation**

Please note sub-criteria listed in evaluation form, e.g. coherence and effectiveness of the project work plan (incl allocation of tasks and resources); complementarity of partners; management structures, incl risk management; sustainability plan

Submitting a proposal – tips

- **Read** all the relevant material on the IMI website **evaluation criteria + Call text !**
- **Understand** the **IMI 2 rules** and respect them
- **Provide all information** the reviewers will need to evaluate your proposal
- **Start working early** (pre-materials available before Call launch)
- **Finalise your submission on time:** Deadline (1st cut-off date) 16 March 2016, 17:00:00 CET / Brussels time
- **Contact** the IMI Programme Office if you have any questions
- **More tips:** www.imi.europa.eu/content/tips-applicants

Submitting a proposal – common mistakes

Admissibility / Eligibility criteria not met:

- Missed deadline
- Proposal out of scope
- Submitted text does not respect the proposal template
- Minimum number of legal entities
- All objectives not addressed
- Redundancy between partners
- Limited impact of the proposal, despite scientific excellence
- Ethical issues not addressed

Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools**:
 - IMI <http://www.imi.europa.eu/content/partner-search>
 - German NCP version: <http://www.imi-partnering.eu>
 - Fit for health: <http://www.fitforhealth.eu/>
- Get in touch with your **local IMI contact point**:
www.imi.europa.eu/content/states-representatives-groups
- Talk to your **Health National Contact Point (NCP)**
- Network on **social media** (e.g. IMI LinkedIn group)

! EFPIA companies/contributing partners have been requested to post their intention to submit a proposal on the IMI Partner Search Tool and the IMI LinkedIn group



Contact IMI

infodesk@imi.europa.eu

www.imi.europa.eu

 [@IMI_JU](https://twitter.com/IMI_JU)

Rules and Procedures for the IMI2 Call 8 for proposals

Fabrizio Federici, IMI Legal Officer
IMI webinar • 15.01.2016

A single set of rules



EU Financial
Regulation
Specific rules for
participation

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

Participation rules

Conditions for this Call for proposals

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

- **Single-stage**

Full proposals combining the public (JU funded) and private partners

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

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

Conditions for this Call for proposals

- **Open call with cut-off dates**

The call will be open for 2 years with several cut-off dates until March 2018

- **Indicative JU contribution**

Up to EUR 70M available as of first cut-off date

At a given cut-off date, submitted FPs are ranked in one single ranking list

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**

Who is eligible for funding?

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

Established in:

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

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

Applicant consortia

Single stage – Full Proposals

- **One Full Consortium consisting of:**
 - IMI fundable legal entities carrying out activities relevant for achieving the project objectives

and/or
 - legal entities carrying out activities relevant for achieving the project objectives not requesting JU funding which are
 - EFPIA companies
 - IMI2 Associated Partners
 - or any contributing organization

Expected Impact

- **Applicant consortia must pay specific attention to the expected impact as described in the Call for proposals:**

FPs are expected to leverage JU funds by mobilising additional resources through the involvement at least one contributing partner (i.e. not requesting JU funding), such as EFPIA company, IMI2 Associated Partners or any other organisation.

The budgeted cost for the participation of a contributing partner is expected to account for $\geq 40\%$ of total project cost.

This is one of the elements which will be assessed and scored under the evaluation criterion 'impact' during the proposal evaluation.

Funding rules

IMI2 Funding model

- **IMI2 is a PPP, actions are normally co-funded by:**
 - JU funding to BRFs (**b**eneficiaries receiving funding = legal entities eligible for funding)
 - In-kind/cash contribution from BNRFs (**b**eneficiaries **not receiving funding**):
 - EFPIA constituents and affiliates
 - IMI2 Associated Partner
 - (future other IMI2 members)

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

One single funding rate per project - BRFs

One project = One rate

For all beneficiaries receiving funding (BRFs) and all activities

Defined in the Annual Work Plan/Call for Proposals:

- 100% of the eligible costs
- Indirect costs: **25% Flat Rate**

EFPIA and Associated Partners contribution - BNRFs

- EFPIA companies
- Other industries and partners (e.g. 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

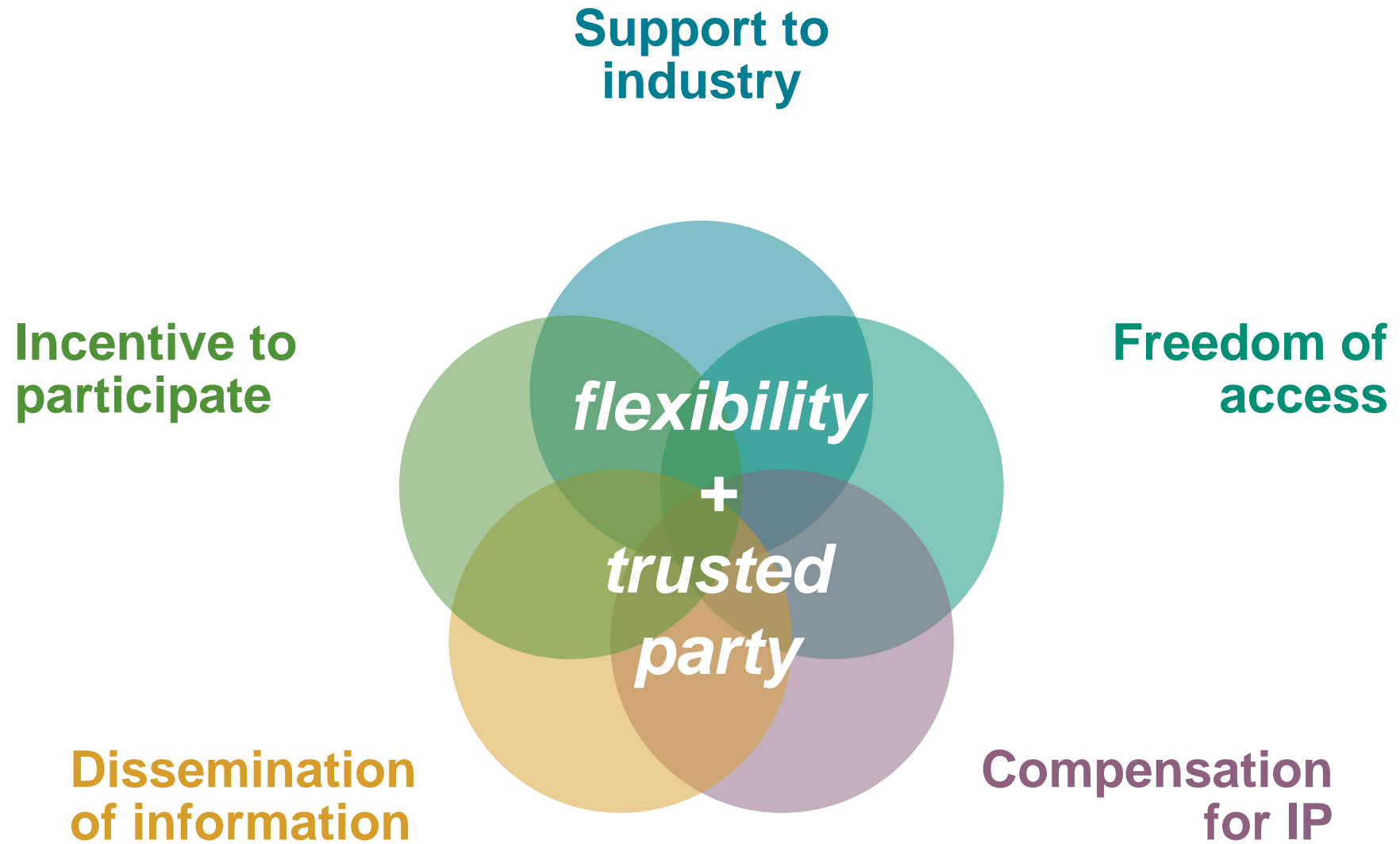
Annual financial reporting is disconnected from GA periodic reports

Deadlines for reporting

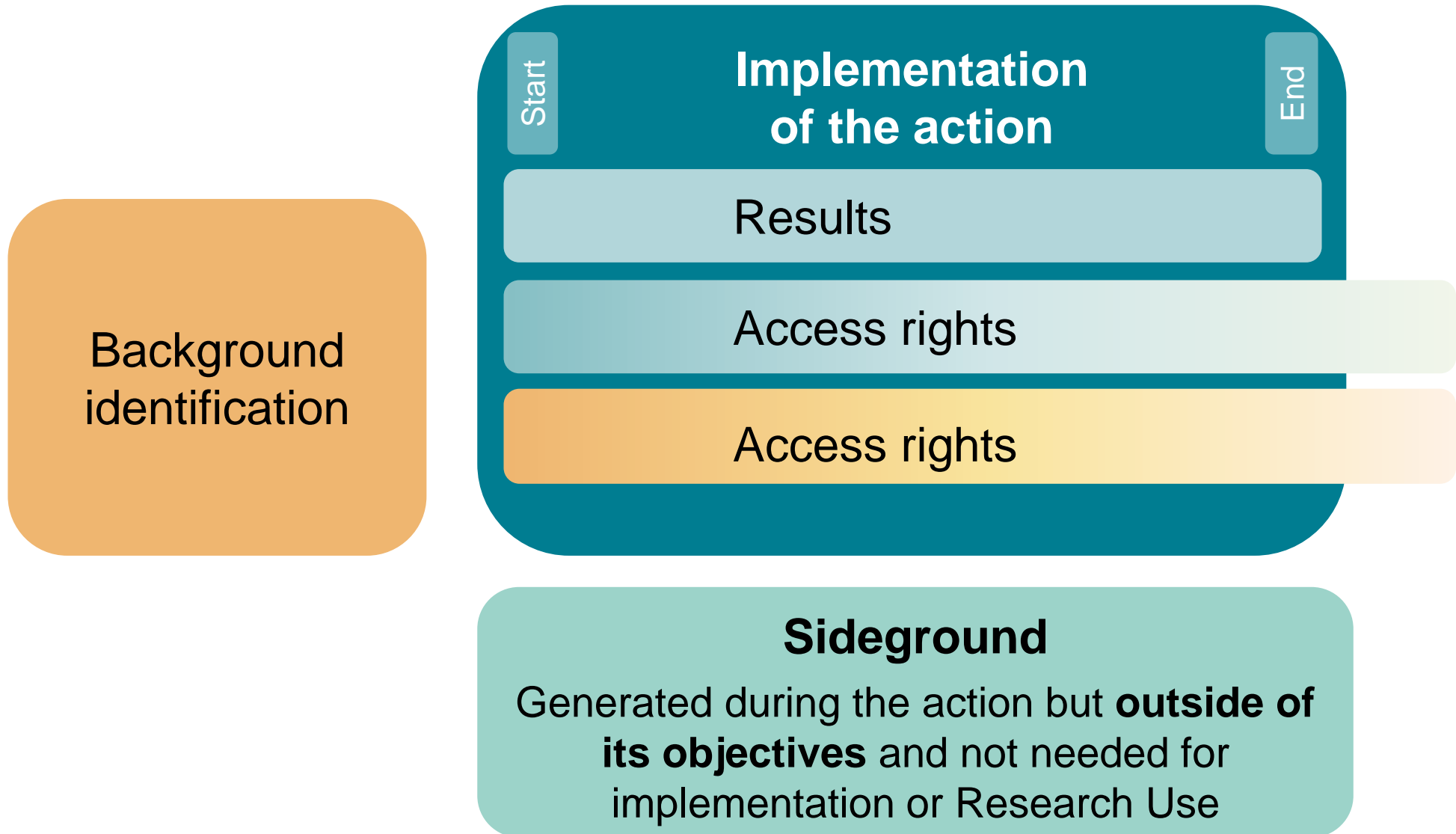
- Scientific reporting (full consortium) due at project deadlines (i.e.GA), duration reporting period: 12 months
- Financial reporting for:
 - Beneficiaries receiving JU funding, due at project deadlines (i.e.GA)
CFS: >EUR 325k at project end
 - Beneficiaries Not receiving funding (e.g. EFPIA companies 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



Background vs. Results



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

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

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

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

Grant award

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

Maximum time to Grant:

8 months from relevant cut-off date (i.e. FP submission)

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!**



Contact IMI

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www.imi.europa.eu

 [@IMI_JU](https://twitter.com/IMI_JU)