

**Webinar | IMI2 – Call 13
Support and coordination action for
the projects of the
neurodegeneration area of the
Innovative Medicines Initiative**

27.11.2017 • 15:00 CET

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Elisabetta Vaudano, IMI
- The Call topic – Michael Hutton, Eli Lilly
- Questions & answers

How to use GoToWebinar - audio

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

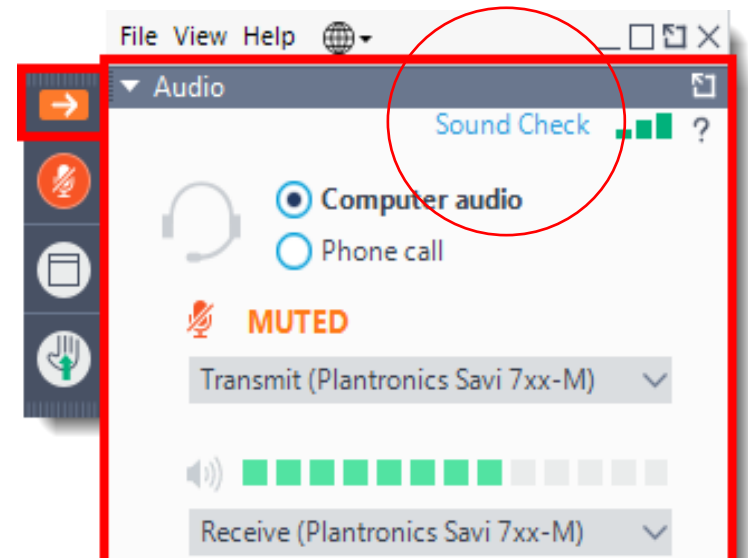
Can't hear us?

- 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 dial the numbers given on your phone



The GoToWebinar control panel

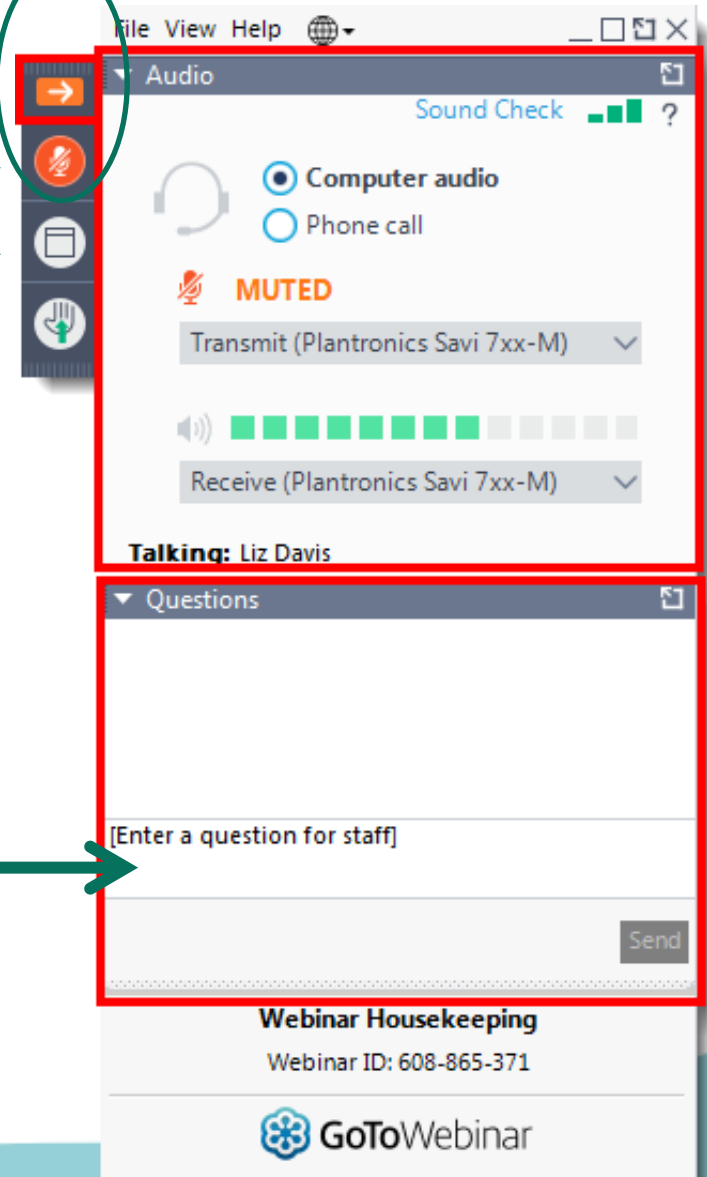
Expand / minimise control panel →

Microphone status →

Full screen →

Raise / lower your hand
e.g. if you want to ask a
question orally

Send a question in writing →



Before we start...

- This webinar is being recorded and will be published on the IMI website and / or IMI YouTube channel
- Presentation slides will be published on the webinar web page
- A participant list will be circulated
- The Call has not yet been launched – all information on the Call is indicative pending Governing Board approval

Webinar | IMI2 - Call 13

Support and coordination action for the projects of the Neurodegeneration area of the Innovative Medicines Initiative

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 Thursday 7 December, 15:00-16:30

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 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc...



€1.638 bn



€1.425 bn

Other

€213 m

IMI 2 total budget

€3.276 billion

EFPIA companies

receive no funding

contribute to projects 'in kind'

Associated Partners

e.g. charities, non-EFPIA companies

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

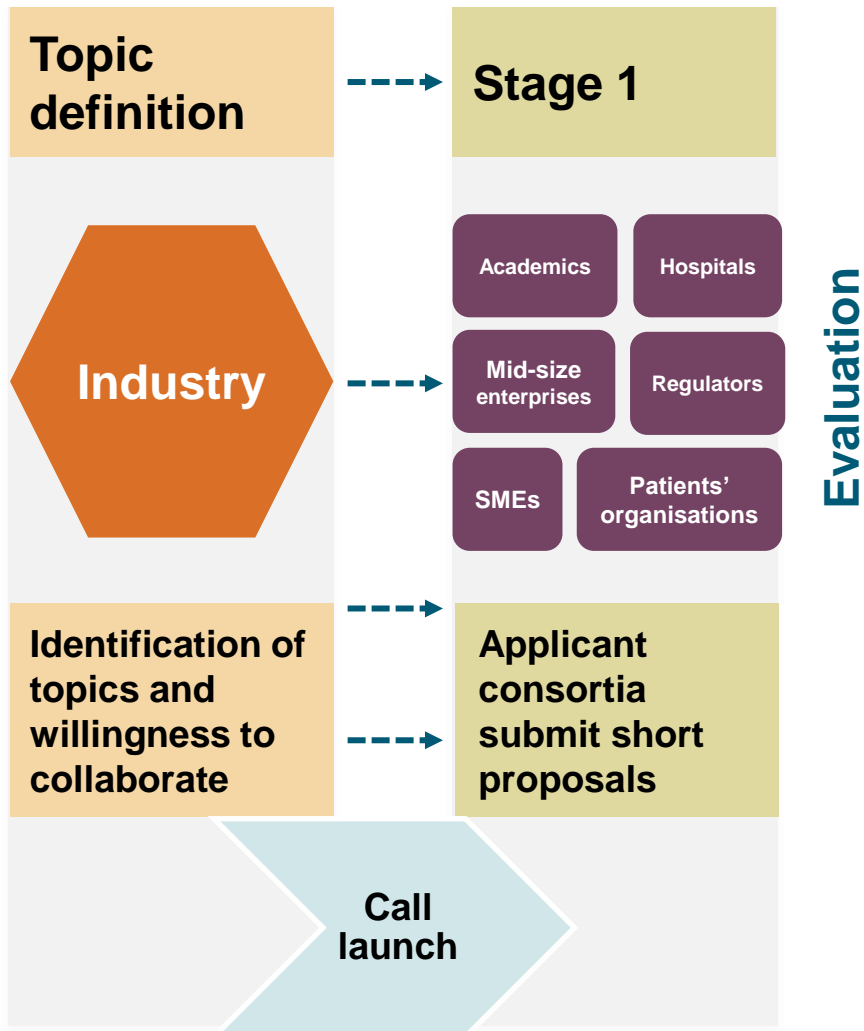
Scale is a key to success and is provided through IMI funding

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

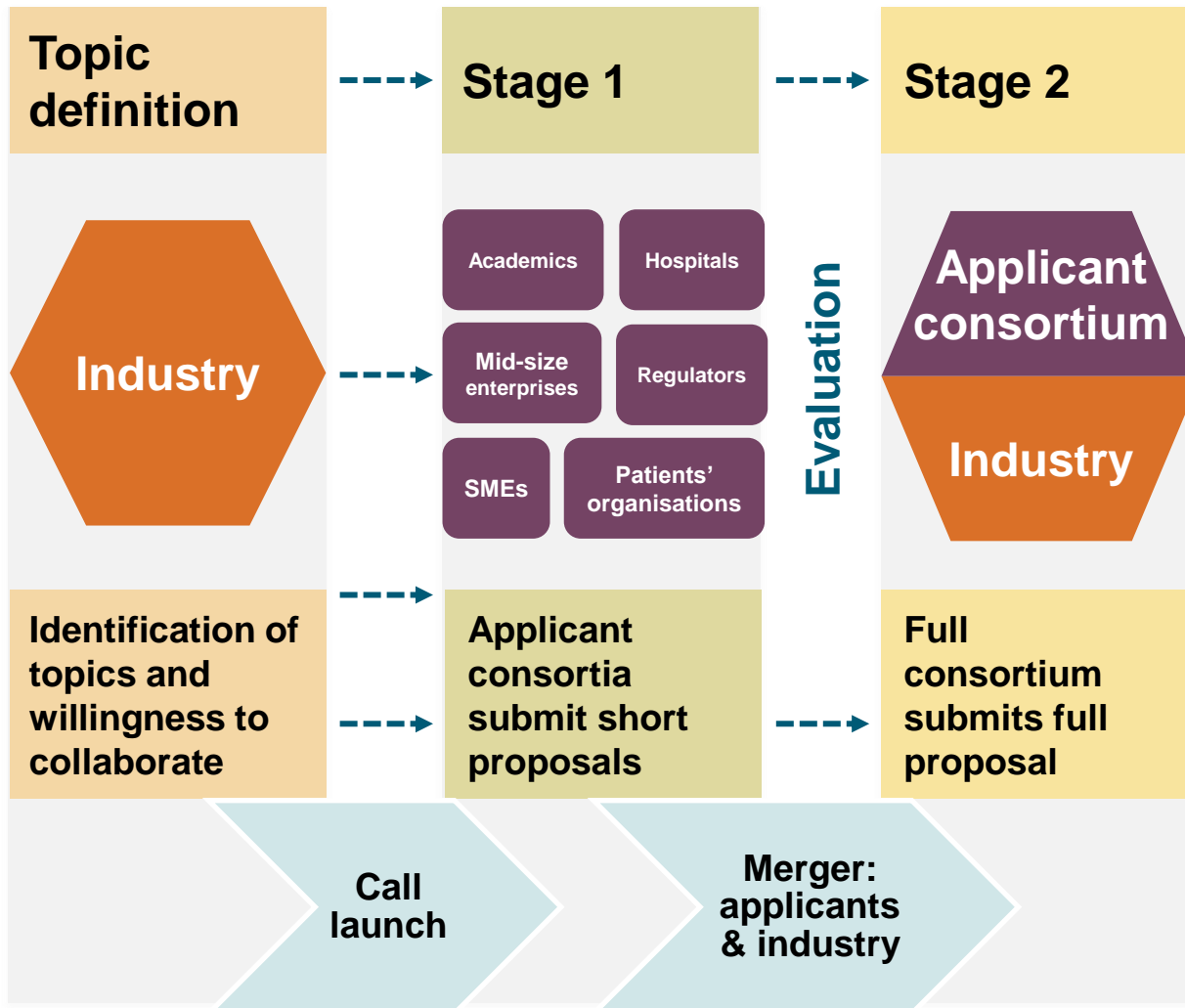
Typical IMI project life cycle



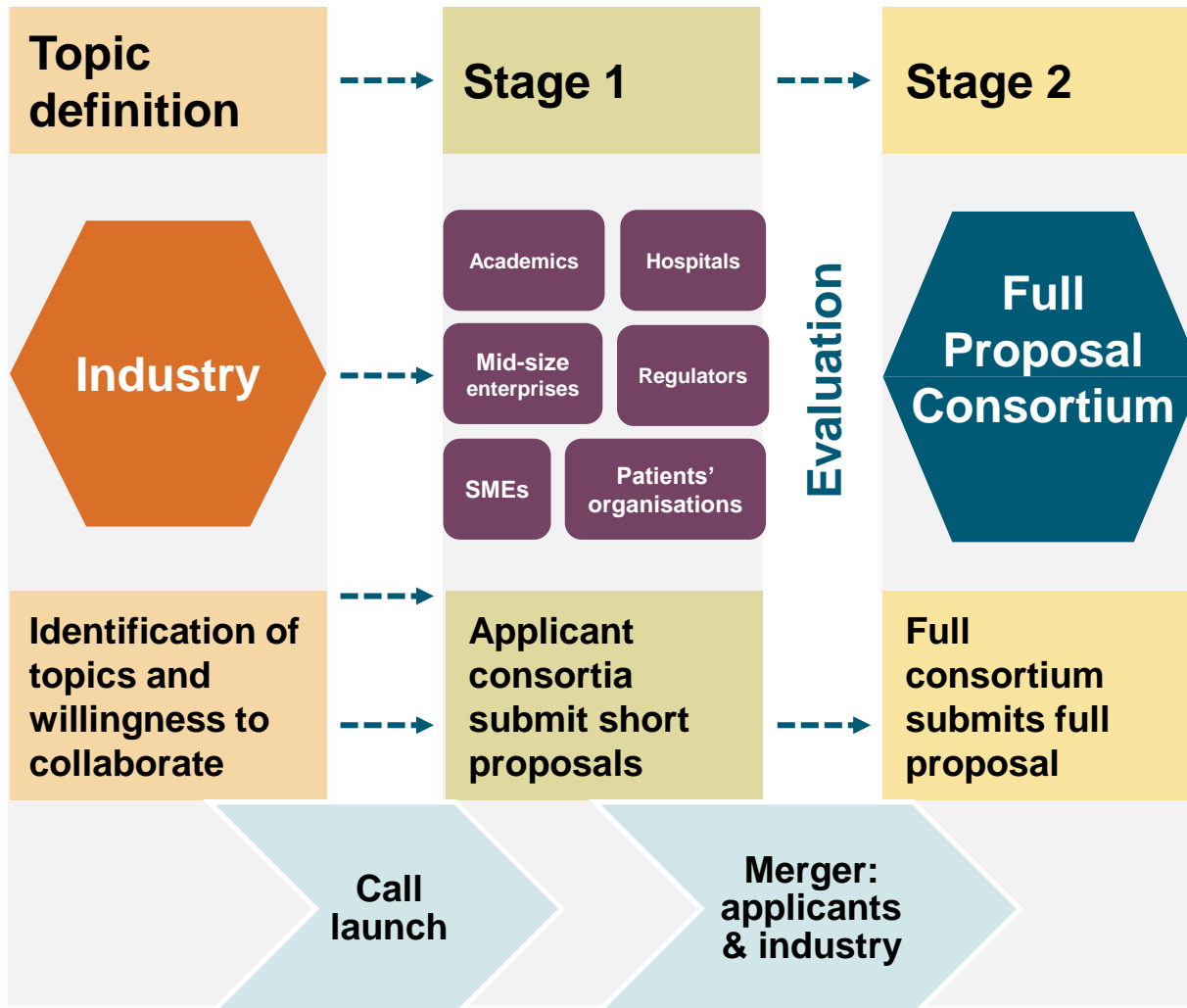
Typical IMI project life cycle



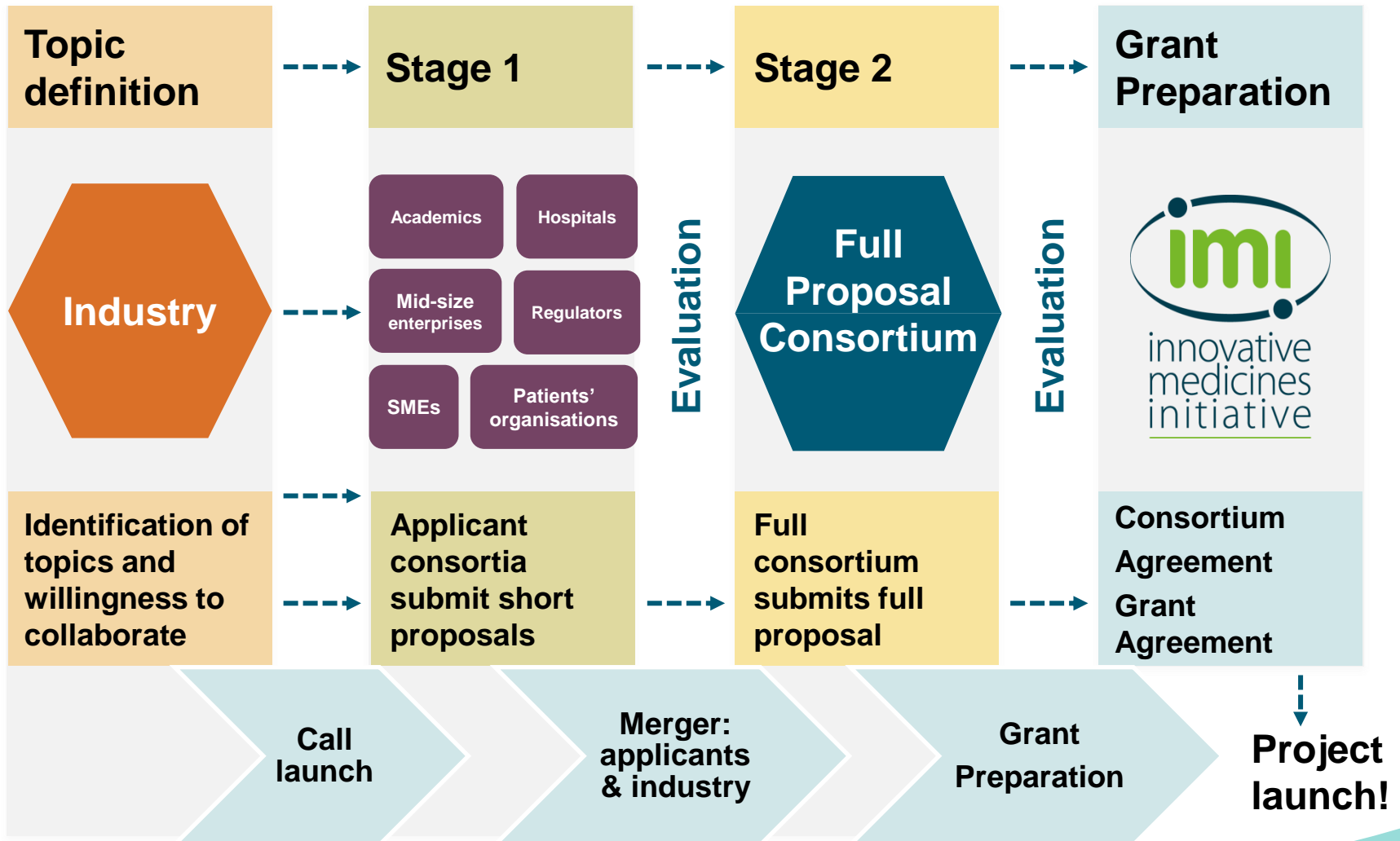
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



Submitting a proposal

- <https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/index.html>

The screenshot displays the 'Participant Portal' for 'RESEARCH & INNOVATION' by the European Commission. The main navigation bar includes 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A search bar and 'LOGIN'/'REGISTER' buttons are also present. The left sidebar lists 'EU Programmes 2014-2020' with categories like 'Search Topics', 'Updates', and 'Calls', where 'H2020' is highlighted. The main content area is titled 'Calls for Proposals' and features a 'Horizon 2020' section with a list of topics: 'Excellent Science' (including ERC, FET, Marie-Sklodowska-Curie Actions, and Research Infrastructures) and 'Industrial Leadership' (including LEIT and ICT). Below this, there are filters for 'Status' (Calls with forthcoming topics, open topics, or only closed topics) and 'Sort by' (Call title, Call identifier, or Publication date). A search filter 'IMI2' is entered in the search bar, and a 'FILTER' button is visible.

Proposal Template

- Available on IMI website & H2020 submission tool
- For first stage proposals, the page limit is **20 pages**.

Title of Proposal

List of participants

Table of Contents

| | |
|--------------------------------------|---|
| 1. EXCELLENCE | 3. IMPLEMENTATION |
| 1.1 Objectives | 3.1 Outline of project plan — Work packages, and major deliverables |
| 1.2 Relation to the call topic text. | 3.2 Management structure and procedures |
| 1.3 Concept and approach | 3.3 Consortium as a whole |
| 1.4 Ambition | 3.4 Table 3.1a: List of work packages |
| 2. IMPACT | 4. PARTICIPANTS |
| 1 Expected impacts | 4.1. Participants (applicants) |

Evaluation Criteria (1/2)

■ Excellence

- 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;
- Quality of the proposed coordination and/or support measures.
- Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.

■ Impact

- 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;
- Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
- Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
 - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
 - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
 - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

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 at least **one legal entity** established in an **EU Member State or Horizon 2020 associated country** 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 participant portal:
https://ec.europa.eu/research/participants/portal/desktop/en/organisations/partner_search.html
 - 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)

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
 - *check the list of interested SMEs on the Call 13 web page*
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)

Coordination and support action (CSA) for the projects of the Neurodegeneration area of the Innovative Medicines Initiative 2

Michael Hutton and Luc Truyen
27.11.2017 • IMI webinar

Need for a CSA for the IMI projects in the area of Neurodegeneration

- IMI has launched a broad portfolio of projects in Neurodegeneration, mostly focussed on Alzheimer's Disease.
- Globally there has been a major effort in this area with many public-private and large collaborative public efforts initiated.
- There is a constant need for **strengthening the information flow, and enhancing the exchange of experience** between all stakeholder groups, public and private, to allow maximum return on the investment and impact in this area.

Pre-competitive nature

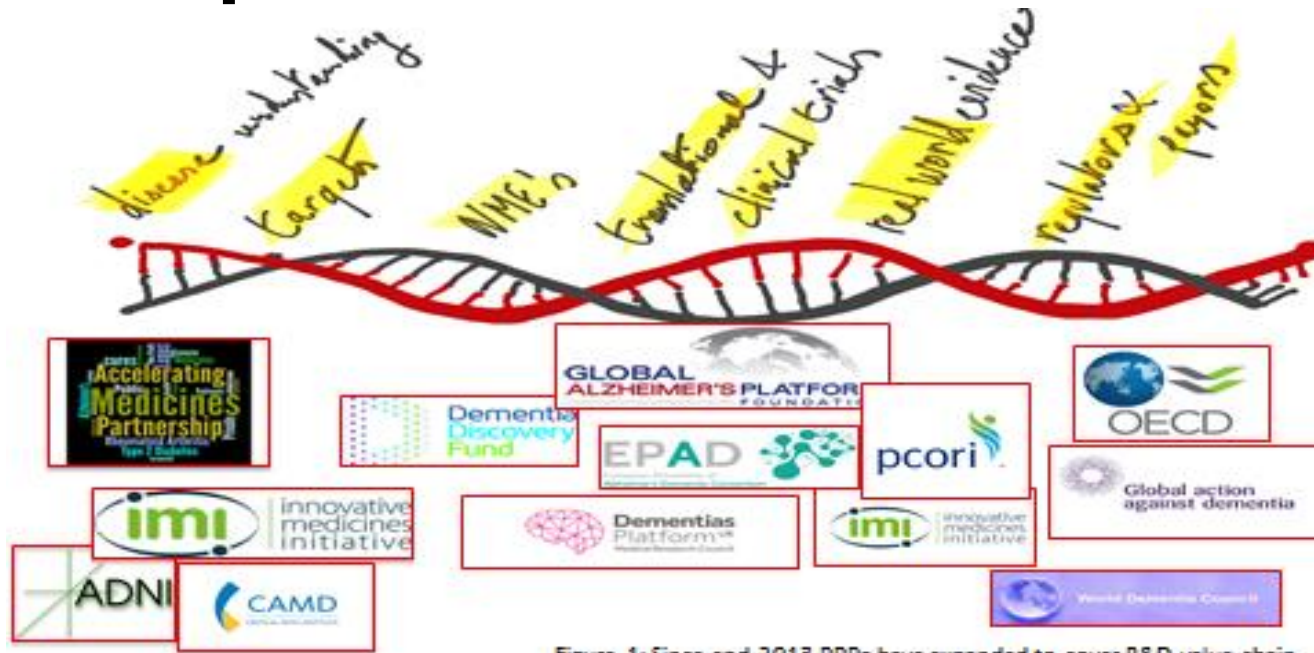


Figure 1: Since end 2013 PPPs have expanded to cover R&D value chain

- The IMI and other initiatives (*) launched in the area of Neurodegeneration cover the **full Research and Development (R&D) value chain** from bench to bedside and are pre-competitive in their nature
- Effective and efficient coordination and support of such a complex landscape of initiatives **can only be achieved as a pre-competitive endeavour**

Challenges to be addressed- 1

- Need for support to ensure that **collaboration and coordination** becomes **intentional and structural** to the IMI portfolio of projects in the area of neurodegeneration
- Effective and efficient collaboration and coordination between **this IMI portfolio and related national, European and global initiatives** is a key success factor to optimize the impact of this important public-private investment.
- **Enabling cross fertilization** of best practices across projects
- Projects would also benefit from support towards the submission of results for regulatory and/or health-technology assessment (HTA) to ensure that **important results can impact regulatory practice and the health care system in a timely manner.**

Challenges to be addressed- 2

- Development of agreements and **good practices for sharing** and re-use of data, biological tools (e.g. cell lines) and other materials, activities that are normally either not or only minimally resourced under individual initiatives
- **Sustainability** - approaches and best practices
- Need to develop some systematic **metrics to show value** in advancing research and remove bottlenecks toward the delivery of innovative treatments to patients.

Scope of the CSA

- Provide the necessary framework and resources to achieve **effective coordination and collaboration among projects in the IMI strategic area of neurodegeneration.**
 - The action will have to build strong links with the portfolio of IMI projects in the area of neurodegeneration to ensure that the activities are in good synergy with those potentially already ongoing within individual initiatives

Objectives of the CSA

- Develop a framework to coordinate and support the **operational alignment** of the IMI Neurodegeneration portfolio
- **Facilitate sharing** and access of data, biological tools and other materials among projects
- Ensure support for **regulatory and/ or HTA interactions**
- Organize and lead **workshops** for sharing best practices across IMI projects and beyond
- Coordinate and support the alignment between IMI and other relevant **partnerships** and initiatives (e.g. DPUK, JPND, GAP, WHO, AMP)
- Perform **mapping** activities of past and ongoing research in Alzheimer's Disease to identify gaps, develop metrics and benchmarks for assessing value and socio-economic impact
- **Engagement with specific stakeholders** (e.g. patient organisations) to promote research collaborations, to disseminate joint activities, to seek alignment on Ethical, Legal and Social Implications of planned research and other issues of common interest

Key deliverables of the full project

- **Operational platform** to coordinate and support the activities of the IMI neurodegeneration projects
- **Resource** to enable timely and effective interaction with regulatory authorities and HTAs
- **Guidelines and good practices** for the access and sharing of data, biological tools and other materials among projects
- **Advisory** board and an up-to-date and dynamic catalogue of potential solutions for sustainability of project results
- Workshops and proceedings for **sharing best practices** in IMI projects
- **Metrics** and benchmarks for successful projects
- **Mapping** out of the partnerships and collaborative efforts in neurodegenerative research area and setting up a relevant outreach program

Expected contributions of the applicants

- **Project Management**

- Project management and coordination;
- Organisation and logistics of workshops and international meetings;

- **Expertise:**

- Knowledge and expertise in legal, ethics and data privacy aspects of the management of sensitive personal level data
- Management of biological tools including intellectual property (IP) considerations
- Data hosting and maintenance
- Regulatory science
- Health economics

- **Capabilities:**

- Medical/scientific writing;
- Development of effective communication tools including websites and social media, platforms to disseminate findings

Expected (in kind) contributions of the industry consortium

■ Industry consortium:

- EFPIA partners: Janssen, Eli Lilly, Roche, Takeda, Sanofi
- IMI2 JU Associated partner: Parkinson's UK

■ Will contribute to:

- Project and meeting management
- Measurement and analytical tools
- Regulatory affairs
- Data privacy law and related legal aspects
- Medical affairs and health care communication
- Contribution to website management
- Data/knowledge management, repository of knowledge
- Experts time in relevant scientific areas
- Set up of an overall programme platform (and related IT support to run it)
- Resources for programme management (from strategy to operation)

What's in it for you?

- **Regulatory/HTA/Payers/Policy Makers:** a platform that will facilitate delivery of data needed for the further development of guidelines and policies in the area of Alzheimer's Disease and Neurodegeneration
- **Patient Organizations:** The opportunity to make the patient voice heard and keep the patient at the center of all initiatives in the area
- **Academia:** opportunity to contribute to harmonization and potential standardization of tools, samples and data sharing. Input on matters of education and training, data privacy laws, ethics, regulations and data protection mechanisms, health economics
- **SMEs:** involvement in project management and organization of workshops and international meetings, development of website and tools for information sharing
- **Other non governmental organizations:** Mapping out of the partnerships and collaborative efforts in neurodegenerative research and the development of agreed metrics for impact analysis

Key facts

- **Duration of the action**

The indicative duration of the action is 36 months.

- **Budget figures**

The financial contribution from IMI2 is a maximum of EUR 1.2 MM

The indicative in-kind contribution is EUR 1.2 MM

Total EUR 2.4 MM

Involvement of SMEs, patient groups, regulators

Elisabetta Vaudano

SME participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

There are several potential activities which are suitable for SMEs like:

- project management and coordination;
- organisation and logistics of workshops and international meetings;
- data hosting and maintenance;
- medical/scientific writing;
- development of communication tools and materials (websites, social media, platforms to create awareness of the programme and disseminate findings etc..)

Patient participation

Engagement of patients and patient organizations is key for the success of the CSA:

- In the development of metrics to show the value of the projects towards advancing research and remove bottlenecks toward the delivery of innovative treatments to patients.
- To ensure the results of IMI projects are developed optimally for the benefit of patients;
- Communication tailored to patients
- Development of standards, training and educational guidance on aspects of data privacy laws and regulations, data protection etc. which are suitable and tailored for patients

Interactions with regulators

- Consider having a **plan for interaction** with relevant **milestones**, **resources** allocated
- You may need to go through a **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)
- If regulators are not project participants, consider including them in an **advisory board**
- Consider also a plan for dialogue with **HTA bodies / payers** if relevant

To maximise impact of science generated by projects

Engage in dialogue with regulatory authorities

More info: 'Raising awareness of regulatory requirements: A guidance tool for researchers'

www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/RegulatoryRequirementsGuide.pdf



Questions