

**Webinar | IMI2 - Call 23**  
**A platform for accelerating  
biomarker discovery and validation  
to support therapeutics  
development for neurodegenerative  
diseases**

26.06.2020

# Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Elisabetta Vaudano, IMI
- The Call topic – Bose Niranjana, Gates Ventures & Johannes Streffer, UCB
- Involvement of SMEs, patient groups, regulators – Elisabetta Vaudano, 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 →

The screenshot shows the GoToWebinar interface with several key elements highlighted by a red border and green arrows:

- Expand / minimise control panel:** A red circle highlights the right-pointing arrow icon in the top-left corner of the control panel.
- Microphone status:** A red circle highlights the microphone icon in the top-left corner of the control panel.
- Full screen:** A red circle highlights the full-screen icon in the top-left corner of the control panel.
- Raise / lower your hand:** A red circle highlights the hand icon in the top-left corner of the control panel.
- Send a question in writing:** A red circle highlights the text input field and the "Send" button in the "Questions" section.

The interface includes the following components:

- Audio Control Panel:** Features a "Sound Check" indicator, "Computer audio" (selected) and "Phone call" options, a "MUTED" status, and dropdown menus for "Transmit (Plantronics Savi 7xx-M)" and "Receive (Plantronics Savi 7xx-M)".
- Questions Section:** A text input field with the placeholder "[Enter a question for staff]" and a "Send" button.
- Webinar Housekeeping:** Displays "Webinar ID: 608-865-371" and the "GoToWebinar" logo.

# How to use GoToWebinar - audio

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

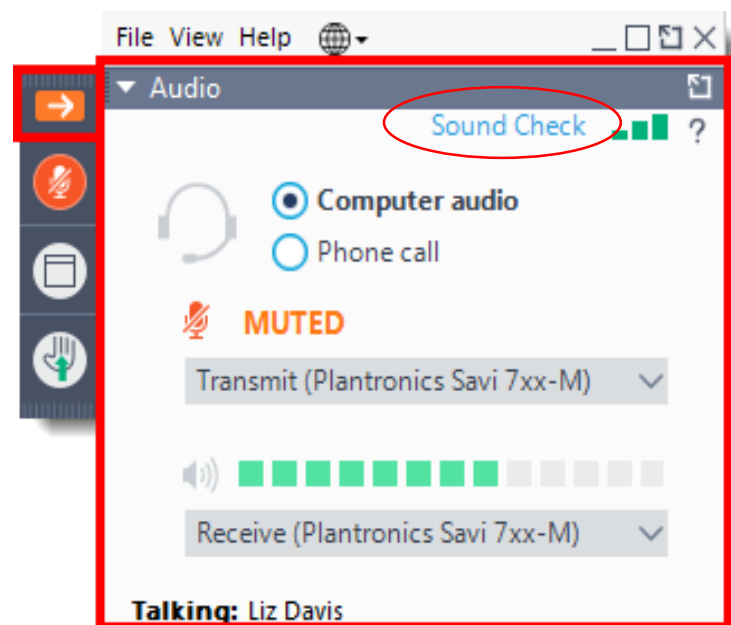
## Can't hear us?

- 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
- IMI2 – Call 23 has been launched and all Call documents & details of how to apply can be found on the IMI website

## **Webinar | IMI2 - Call 23**

**A platform for accelerating  
biomarker discovery and validation  
to support therapeutics  
development for neurodegenerative  
diseases**

# 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

# 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

(2014-2020)

IMI FUNDING MODEL

efpia

## IN-KIND PRIVATE CONTRIBUTION

€1.425 bn

EFPIA companies receive no funding

€ 3.276 bn  
TOTAL IMI2 BUDGET



## public contribution

€1.638 bn

funding from Horizon 2020

## OTHER CONTRIBUTIONS

€213 MILLION

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

EU funding goes to ▶

SMES

UNIVERSITIES

PATIENTS, REGULATORS...

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

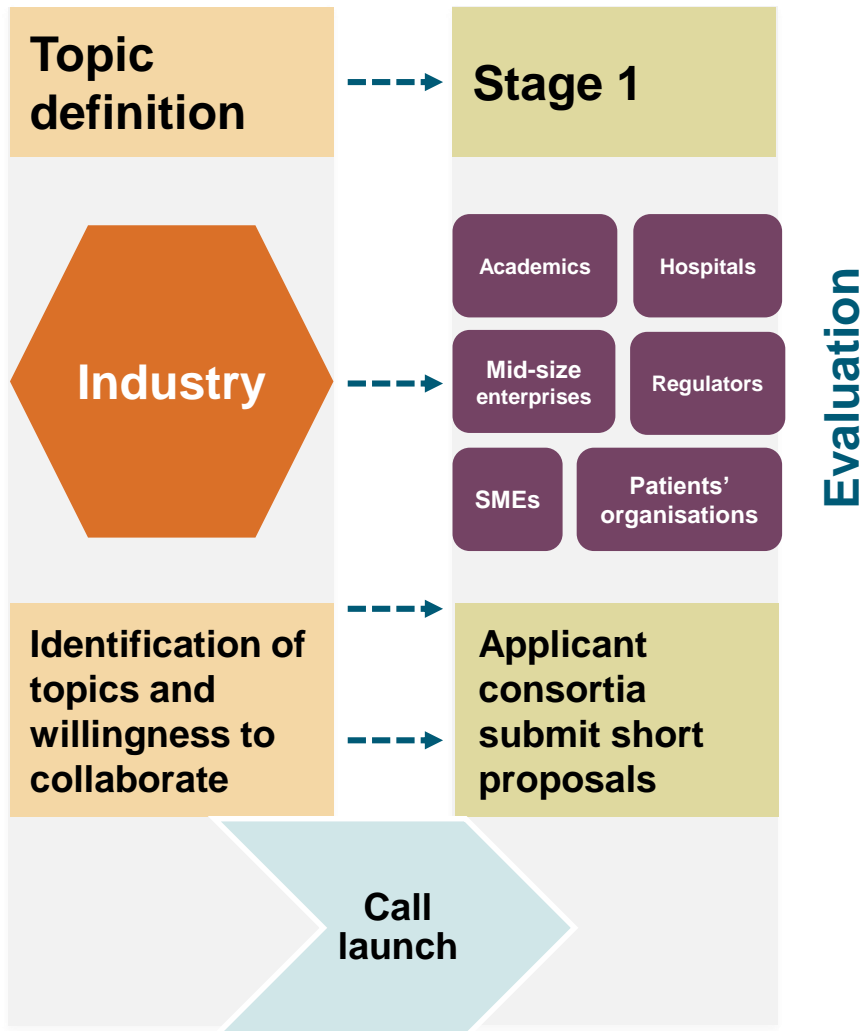
Scale is a key to success and is provided through IMI funding

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

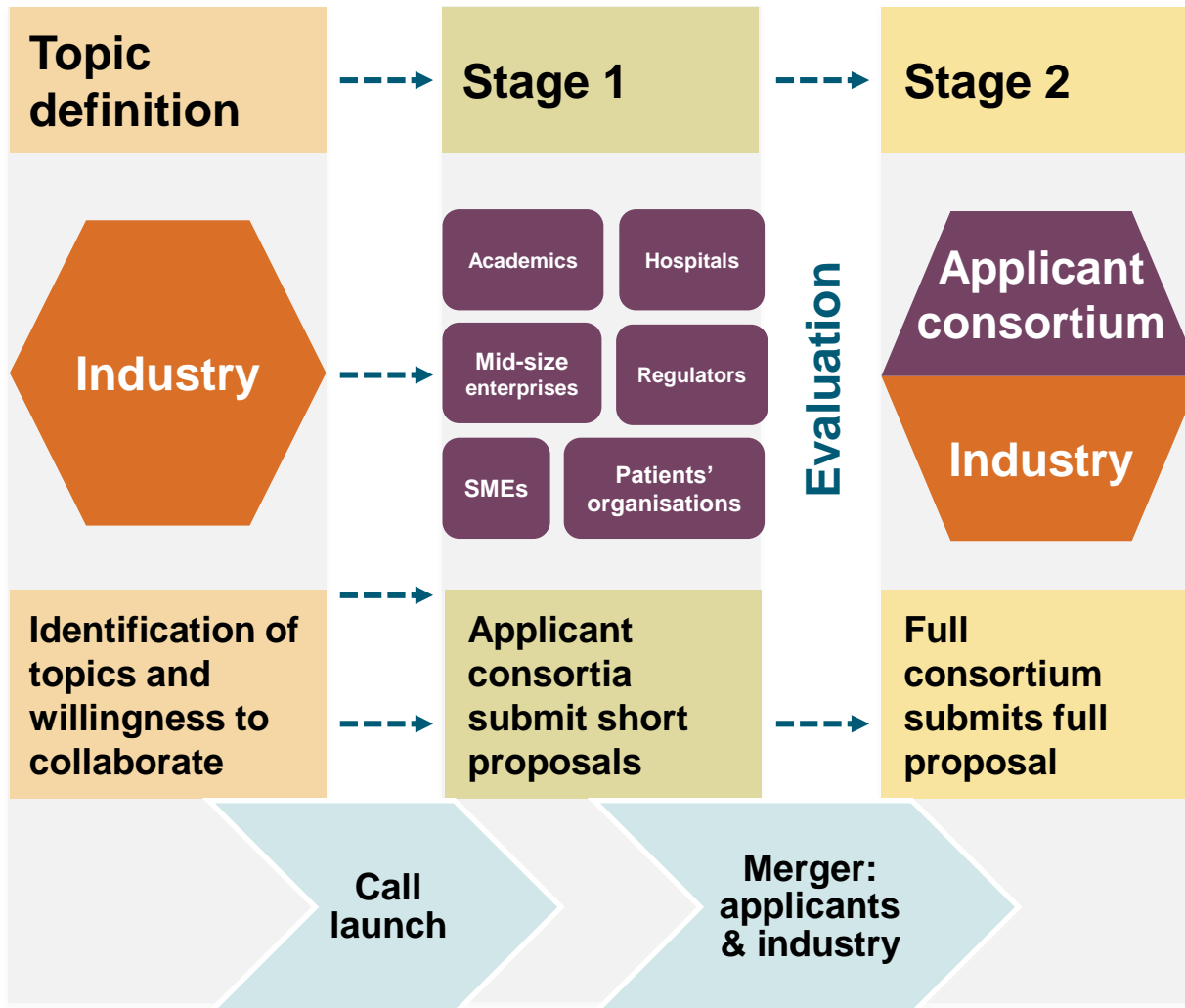
# Typical IMI project life cycle



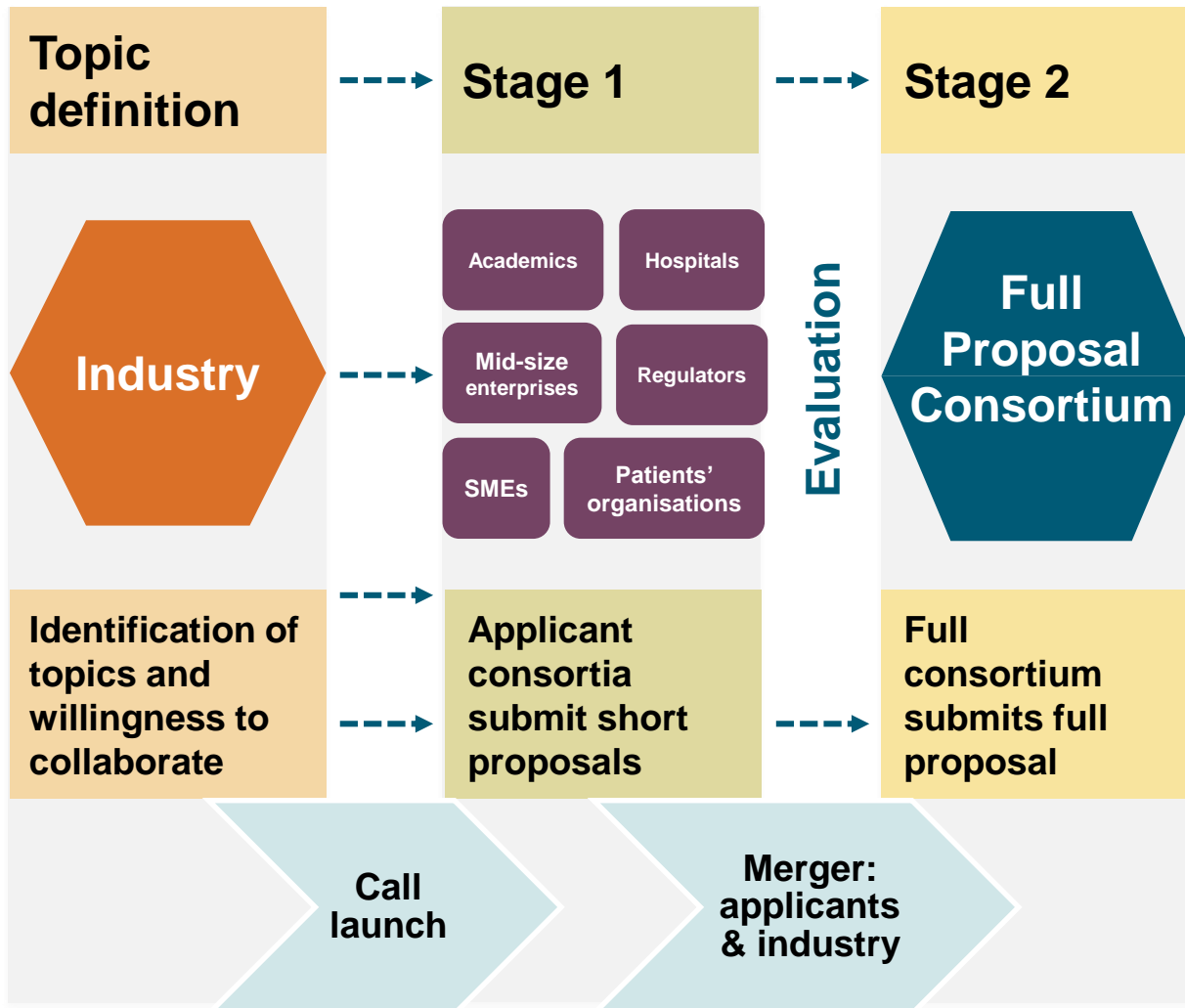
# Typical IMI project life cycle



# Typical IMI project life cycle

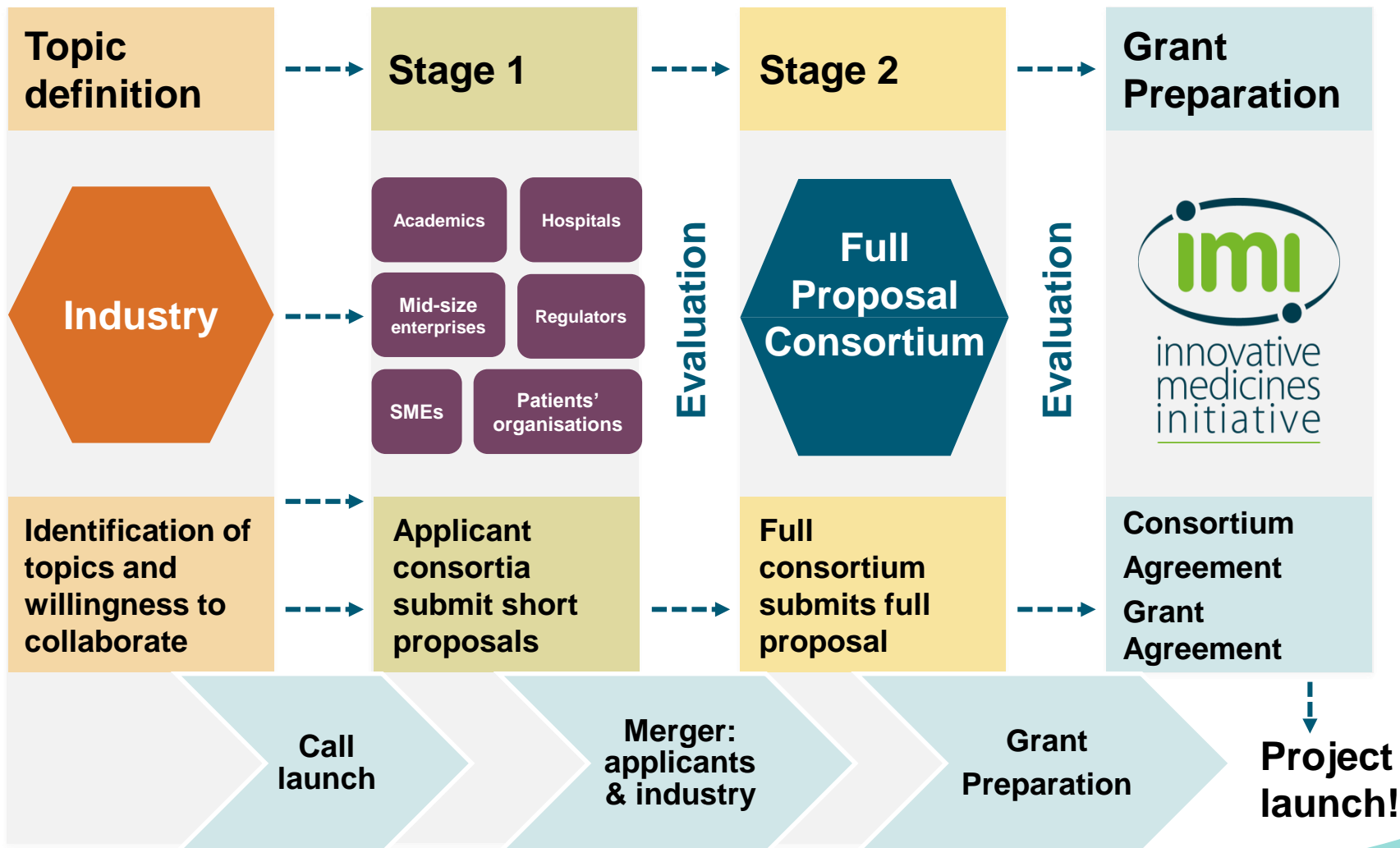


# Typical IMI project life cycle





# Typical IMI project life cycle



# Submitting a proposal

Via the **new** Funding and Tenders Portal

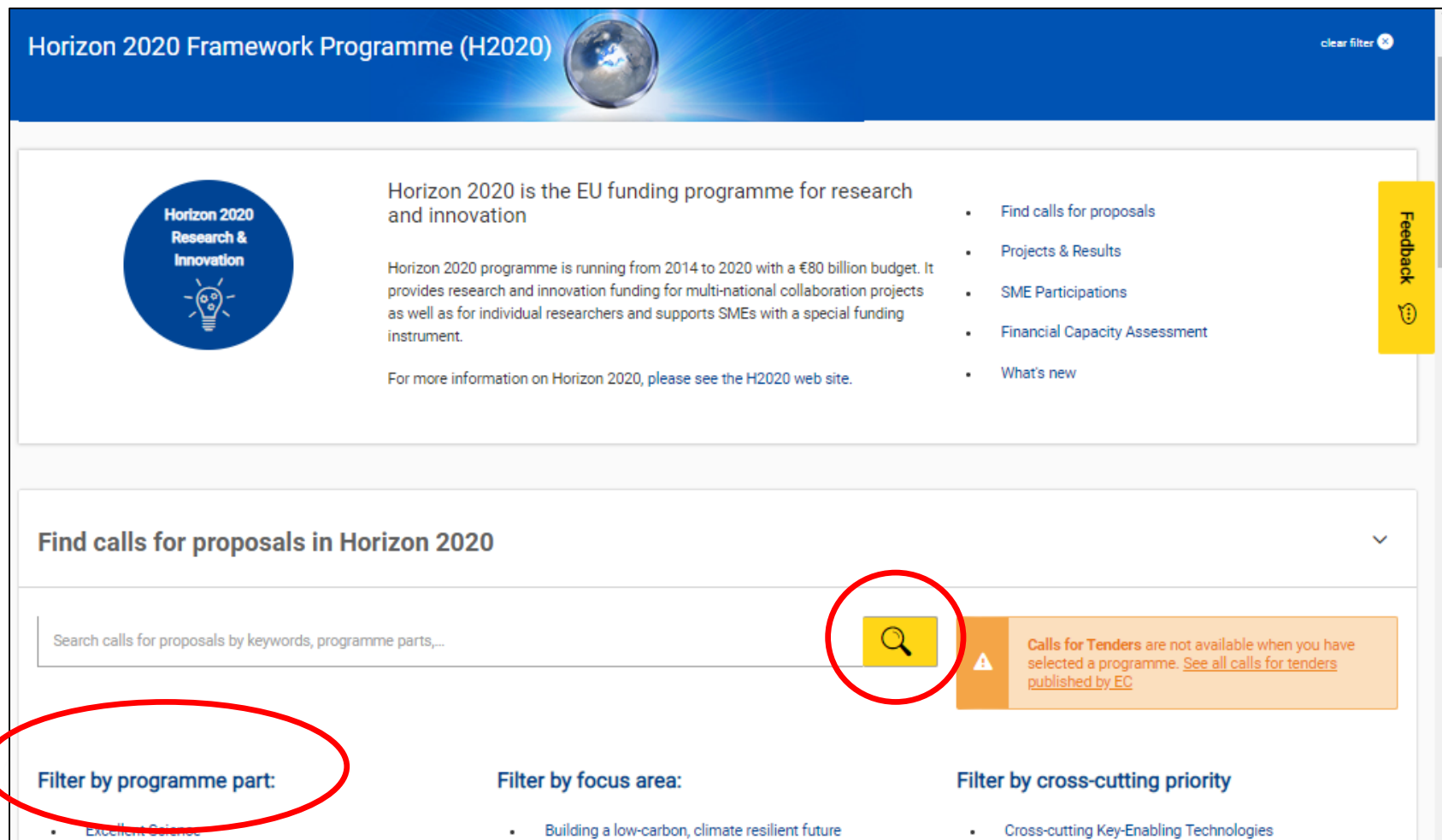
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

The screenshot shows the 'Funding & tender opportunities' portal. At the top, there is a header with the European Commission logo and the text 'Funding & tender opportunities Single Electronic Data Interchange Area (SEDIA)'. On the right, there are links for 'English EN', 'Register', and 'Login'. Below the header is a navigation bar with a home icon and menu items: 'SEARCH FUNDING & TENDERS', 'HOW TO PARTICIPATE', 'PROJECTS & RESULTS', 'WORK AS AN EXPERT', and 'SUPPORT'. A 'select programme' button is also present. A large blue banner contains the text: 'The Funding & Tenders Portal is the entry point (the Single Electronic Data Interchange Area) for participants and experts in funding programmes and tenders managed by the European Commission and other EU bodies.' Below this is a section titled 'Find calls for proposals and tenders' with a search bar and a yellow 'Search' button. The main content area is titled 'Calls for proposals by EU Programme' and displays a grid of programmes. The 'Horizon 2020 Framework Programme (H2020)' is circled in red.

Calls for proposals by EU Programme							
3rd Health Programme (3HP)	Asylum, Migration and Integration Fund (AMIF)	Consumer Programme (CP)	Creative Europe (CREA)	Erasmus+ Programme (EPLUS)	European Maritime and Fisheries Fund (EMFF)	HERCULE III (HERC)	<b>Horizon 2020 Framework Programme (H2020)</b>
Internal Security Fund Borders and Visa (ISFB)	Internal Security Fund Police (ISFP)	Justice Programme (JUST)	Pilot Projects and Preparatory Actions (PPPA)	Programme for the Competitiveness of	Promotion of Agricultural Products (AGRIP)	Research Fund for Coal & Steel (RFCS)	Rights, Equality and Citizenship Programme

# New Funding and Tenders Portal Horizon 2020 section

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/programmes/h2020>



Horizon 2020 Framework Programme (H2020) clear filter

**Horizon 2020 Research & Innovation**

Horizon 2020 is the EU funding programme for research and innovation

Horizon 2020 programme is running from 2014 to 2020 with a €80 billion budget. It provides research and innovation funding for multi-national collaboration projects as well as for individual researchers and supports SMEs with a special funding instrument.

For more information on Horizon 2020, please see the H2020 web site.

- Find calls for proposals
- Projects & Results
- SME Participations
- Financial Capacity Assessment
- What's new

**Feedback**

**Find calls for proposals in Horizon 2020**

Search calls for proposals by keywords, programme parts,...

**Filter by programme part:**

- Excellent Science

**Filter by focus area:**

- Building a low-carbon, climate resilient future

**Filter by cross-cutting priority:**

- Cross-cutting Key-Enabling Technologies

**Warning:** Calls for Tenders are not available when you have selected a programme. [See all calls for tenders published by EC](#)

# 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)**

# 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.
- 
- 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](http://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](mailto: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](http://www.imi-partnering.eu)
- Get in touch with your **local IMI contact point**:  
[www.imi.europa.eu/about-imi/governance/states-representatives-group](http://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
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)

**A platform for accelerating  
biomarker discovery and validation  
to support therapeutics  
development for neurodegenerative  
diseases**

**Bose Niranjana, Gates Ventures & Johannes Streffer, UCB**  
26.06.2020 • IMI webinar

# Neurodegenerative diseases, and in particular Alzheimer's disease (AD) and Parkinson's disease (PD), represent a huge economic and societal burden

- Chronic progressive disease with late/difficult clinical diagnosis:
  - **Insufficient toolbox of biomarkers** and associated clinical progression data to easily screen populations, diagnose patients, monitor progression and response to treatment
- **Significant amounts of data and samples are available** and could accelerate biomarker discovery and development in a major way
- However, these **valuable resources remain in silos**, and cannot easily be shared and accessed by the research community

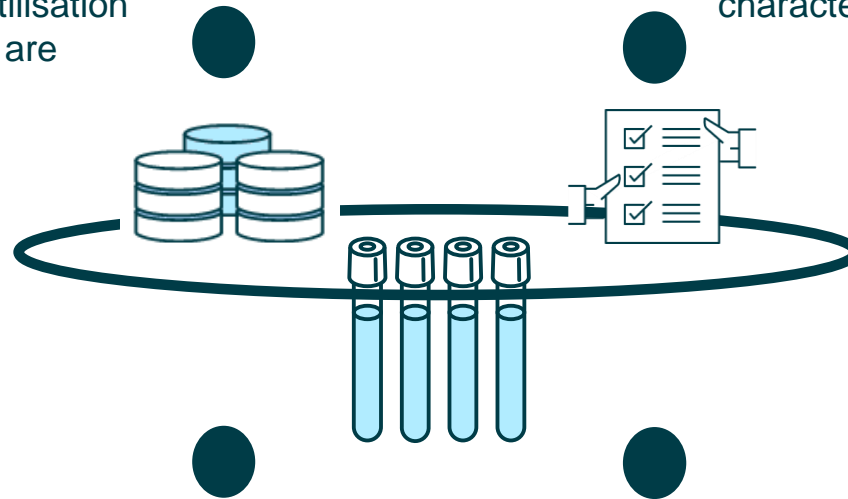
# Key challenges that need to be addressed

## DATA SHARING

Platforms / processes to share clinical data and enable reutilisation of derived data are lacking

## SAMPLE & DATA ACCESS FOR RESEARCH USE

Insufficient access to high-quality, longitudinal, and well-characterised samples and data



## TRANSPARENCY

No centralized resource documenting available sample types and datasets

## SAMPLE QUALITY

Lack of standardisation in collecting and processing samples and linked datasets

# Need to join forces with ALL stakeholders

- Bio-banking, data sharing, and biomarker analysis are in constant and rapid evolution:
  - Technological, legal and ethical perspectives
- Different stakeholder groups with diverse experience, know-how and resources --- need to leverage-at-scale
- Synergistic, public-private partnership effort is needed to successfully tackle these challenges to solve fragmentation, dispersion and lack of sustainability
- IMI framework offers an ideal model to create such an initiative at scale in terms of resourcing and the integration of all necessary stakeholder groups

# Objectives of the full project



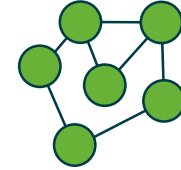
## SHARING & ACCESS

Create a set of agreed principles to enable sharing & access to data and samples



## NETWORKING

Establish a network that can house high quality data & samples, which could have federated & centralised elements



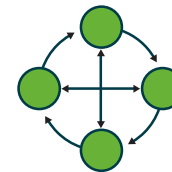
## GOVERNANCE & SOPS

Establish fair & transparent governance & processes specifically to enable sharing & access to data & samples



## CASE STUDIES

Test the above with defined case studies, apply the learnings to fine-tune processes & use the outcomes to grow the platform



## SELF-SUSTAINABLE

Platform must be a self-sustainable entity by the end of the project

# Expected and described impact

- The self-sustainable network platform composed of a European biobank operation, and accompanying data platform, will **positively fuel and impact basic research and development** and drug development campaigns
- The public-private partnership providing infrastructure to enable worldwide sample and data sharing will have a substantial impact on the **development and regulatory validation of biomarkers/diagnostics**, and how in turn this would likely have a cascading effect on **accelerating therapeutic development**



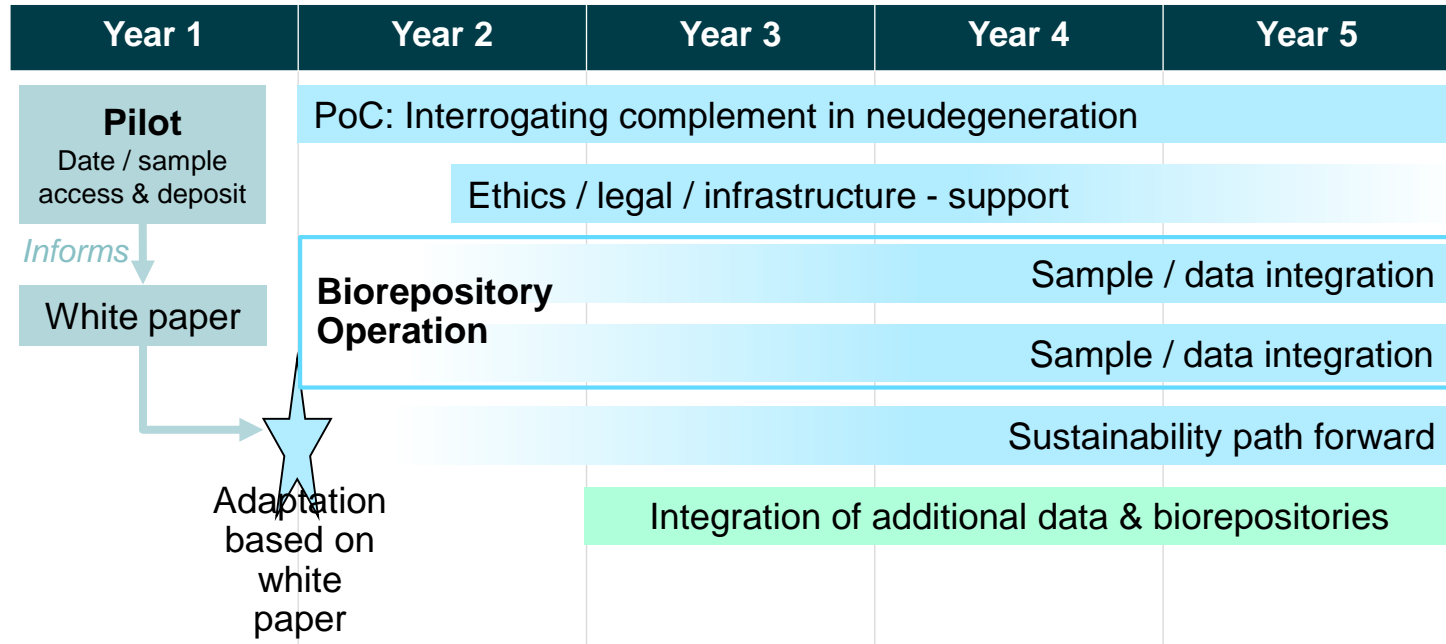
# Expected and described impact

- Leverage public-private partnership model to maximise impact on:
  - Innovation
  - Research and development
  - Regulatory, clinical and healthcare practices
- Outline the strategy for engagement with stakeholder groups (patients, healthcare professional associations, providers, regulators, HTA agencies, payers, etc.)

## *Dissemination must include:*

- 1. Publication and actively engaging stakeholders to implement the agreed principles for data/sample sharing and access*
- 2. Demonstrating the value of the platform and impact of the enabled data/sample usage*

# Potential project architecture



- Pilot A/T/N
- Potential Applications
- New Biosample

# The industry consortium is composed of the following EFPIA partners

CO-LEAD



CO-LEAD



# Expected contributions of industry consortium – assets and in-kind

- ✓ Existing samples including accompanying data and information
- ✓ Assays, SOPs, and needed diagnostics material (e.g., antibodies)
- ✓ Research assays with CSF and plasma markers or neurodegeneration and neuroinflammation (via contract research organization)
- ✓ Complement system diagnostic assays
- ✓ Datasets from retrospective and ongoing interventional and/or observational studies to the data platform
- ✓ AD Workbench data platform to provide both storage and computational needs, tools and a virtual analytics environment
- ✓ Points of contact with other related initiatives (i.e., Diagnostics Accelerator, Dementia Discovery Fund, EDoN)

# Expected contributions of industry consortium – relevant expertise

- ✔ Identification and transfer of samples and accompanying data into the biorepository
- ✔ Legal, technical and other resources (FTEs) to enable successful transfer of samples and utility of platform
- ✔ Testing of the consistency and quality of sample handling, storage and distribution
- ✔ Interaction to ensure banking of samples will aid in disease understanding and modelling
- ✔ Support for research activities and development of protocols
- ✔ Facilitation of transfer of capabilities and knowledge to reach the goal of self-sustainability

# Expected resources and expertise of the applicants

- ✓ Technology and technical architecture for biobanks and biorepository know-how for long-term collaboration, storage and distribution
- ✓ Expertise regarding establishing and managing a data platform
- ✓ Knowledge in establishing and maintaining a harmonized online data portal / interface
- ✓ Experience relevant to biomarker discovery and validation
- ✓ EU and worldwide legal, ethical and regulatory expertise
- ✓ Business, financial and economics experience to transform the bio-sample repository into a self-sustainable business
- ✓ Applicants are encouraged to have patient group involvement with the consortium

# Expected resources and expertise of the applicants

- ✔ A pre-existing and functional sample repository, preferentially with a background in the neurodegenerative disease therapeutic area (Alzheimer's disease and related tauopathies, Parkinson's disease), that could be made available for distribution at the beginning of the action
- ✔ Active cohorts with early stage neurodegenerative disease (e.g. Alzheimer's disease and Parkinson's disease)
- ✔ An established distribution pipeline to deliver samples to customers and be operational at within first year of the action
- ✔ Existing sample and data sets that will be contributed to this network

# Key facts

## Indicative duration of the action: 60 months

- This duration is indicative only
- At stage 2, the consortium selected at stage 1 and the predefined industry consortium may jointly agree on a different duration when submitting the stage 2 proposal

## Indicative budget:

- Max financial contribution from IMI2 JU: **EUR 9 680 000**
- Indicative total contribution from EFPIA partners: **EUR 9 720 000**
- This includes financial contribution from the EFPIA partners of EUR 3 000 000
- Allocation of the EUR 3 000 000 contribution will be decided when preparing the stage 2 proposal
- **At stage 1 only budget for activities funded by IMI2 JU contribution**



# What's in it for you?

- Expected access to select high-quality samples and datasets from industry partners
- Use of the AD Workbench data platform for the project
- Access to industry consortium expertise and resources to support project execution
- The ability and resources to investigate specific case studies using data and samples of the platform towards biomarker discovery and validation

# Key deliverables of the full project

## *Associated with Objective 1*

**Create a set of agreed principles to enable sharing and access to data and samples, taking into consideration the established legal and ethical research standards and principles (e.g., IT, GDPR, legal, ethical, regulatory, societal) and their practical application:**

- Establish an advisory body representing the diverse experts within and outside the consortium
- Delivery of an initial white paper addressing the gaps and requirements to establish a network to house data and samples, and enable sharing / access to support biomarker discovery and validation
- Delivery of final white paper with agreed principles and identification of the cohorts participating. Must incorporate all learnings generated by project activities

# Key deliverables of the full project

## *Associated with Objective 2*

**Establish a network that can house high quality data and samples, which could have federated and centralised elements:**

- Establish a framework to leverage (or integrate with) existing/proposed data platforms, which must be scalable to accommodate retrospective and prospective data, and a strategy for its dynamic fine-tuning as the initiative grows
- An established interoperable scalable network of biobanks to accommodate retrospective and prospective samples and a strategy for its dynamic fine-tuning as the initiative grows

# Key deliverables of the full project

## *Associated with Objective 3*

### **Establish governance and processes to enable sharing and access:**

- Establish a credible sample and data access committee
  - with clear and transparent rules of appointment
  - including relevant stakeholder representation (including patients)
  - with an agreed charter (from the overall consortium) to enable consistent access to samples and data
- Establish a process for efficiently linking to regulatory procedures (e.g., Innovation Task Force and/or Scientific Advice by European Medicines Agency (EMA)) for maximum impact on drug development and/or biomarker validation. Include the consideration of regulators or, at a minimum, a regulatory expert in the advisory committee.

# Key deliverables of the full project

## *Associated with Objective 4*

### **Test the above with case studies:**

- Produce reports on the performed case studies, and demonstrating the utility of the data, biomarkers and biorepository
- Case studies
  - The ATN (amyloid-tau-neurodegeneration) system in early AD cohorts, compared to complex and expensive markers
  - The complement pathway biomarkers across a panel of neurodegenerative diseases
  - At least one cohort with longitudinally collected digital biomarkers
- Generation of harmonised sample and datasets and incorporation in the platform

# Key deliverables of the full project

## *Associated with Objective 5*

**This network must be a self-sustainable entity by the end of the project:**

- Draft sustainability plan: A first draft of a detailed sustainability plan (financial and business) must be developed to demonstrate sustained operation after funding period
- Finalised and implemented sustainability plan: Self-sustainability of the entity must be demonstrated via a finalised and implemented sustainability plan

# Key deliverables of the full project

## *Suggested allocation to Phase 1 of activities (thus to be achieved by end of 1st year of activities)*

**Associated with objective 1) Create a set of agreed principles to enable sharing and access to data and samples:**

- Establish an advisory body
- Deliver a white paper that addresses gaps and requirements to establish the network

**Associated with objective 4) Test the above with case studies:**

- Gauge the ATN (amyloid-tau-neurodegeneration) system in cohorts with early Alzheimer's disease, to allow comparison of the more complex and expensive markers like CSF A $\beta$  and tau, Amyloid-PET and MRI with potential liquid-biopsy (blood, saliva...) markers as alternate biomarkers



**Thank you**

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@IMI\_JU





# Appendix

# Need for public-private collaboration

- Many different stakeholder groups have the relevant experience, know-how and resources but they are not currently shared or leveraged at scale
- A public-private partnership synergistic effort is needed solve the current fragmentation, dispersion and lack of sustainability
- A concerted initiative to create a scalable and self-sustaining public-private federated bio-banking infrastructure has never been tried before nor have all the elements necessary for its success, such as upscaling and sustainability, been previously identified
- The Innovative Medicines Initiative (IMI) framework offers an ideal model to create such an initiative at the necessary scale

# Pre-competitive nature

- Enabling **pre-competitive sharing and access** to high quality samples and data for biomarker discovery / validation has a twofold public health benefit:
  1. More efficient and effective **translation of research** into relevant outputs by boosting cooperation, reproducibility of research, and cost-efficiency
  2. Availability of validated biomarkers would speed up the **development of novel therapies** and their **effective deployment** at scale

# Objectives of the full project – full text

- Create a set of agreed principles to enable sharing and access to data and samples, taking into consideration all the established legal and ethical research standards and principles (e.g. General Data Protection Regulation (GDPR), legal, intellectual property (IP), ethical, regulatory, societal issues) and their practical implementation.

# Objectives of the full project – full text

- Establish a network that can house high quality data and samples, which could have federated and centralised elements. This must build on existing ongoing and relevant cohorts (see below). The overall solution has to be interoperable (e.g. with other global data platforms), scalable and suitable for a broad variety of both data types (including digital), and samples, from public and private (e.g. proprietary clinical trials) sources, whether they be part of the consortium or provided from external donors. The overall solution has to be interoperable (e.g. with other global data platforms), scalable and suitable for a broad variety of both data types (including digital), and samples, from public and private (e.g. proprietary clinical trials) sources, whether they be part of the consortium or provided from external donors.

# Objectives of the full project – full text

- Establish fair and transparent governance and processes specifically to enable sharing and access to data and samples.

# Objectives of the full project – full text

- Test the above with the defined case studies and apply the learnings to fine-tune processes and use the outcomes to grow the platform.

# Objectives of the full project – full text

- This platform must be a self-sustainable entity by the end of the project.



# Involvement of SMEs, patient groups, regulators

# 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 :

- data / information technology infrastructure expertise
- experience with federated and/or centralised laboratory information management system (LIMS) architecture, security and standards to monitor the status of the repository and maintain and amend information available to each specimen.
- Business, financial, and economics experience to transform the bio-sample repository into a self-sustainable business
- Project management
- Assays and tools relevant to implementation of the case studies

# Patient participation

- Involvement of patient organisations imperative for this topic to ensure patient centricity;
- A clear plan on how to involve the public and patients in the project from the beginning until the end of the project, as well as a demonstration of their involvement in the formulation of the proposal is a requirement and has to be included in the proposal. This is especially important given the need to engage ongoing cohorts for this project to be successful.
- Consent and other aspects key for the biorepository success e.g. ‘Henrietta Lacks’ representation.
- Community outreach and dissemination

# Interactions with regulators

- **Have a plan for interaction** with relevant **milestones** and **resources** allocated, as needed
- Consider the **formal regulatory process** to ensure **regulatory acceptance of project results**, specifically for progressing the biomarkers towards validation.
- Get familiar with **services offered for dialogue** (e.g. at EMA through qualification advice, Innovation Task Force, briefing meetings)
- Consider involving regulators as project participants or in the **advisory board**
- Have a plan for dialogue with **HTA bodies / payers**, to ensure full impact of the project

**To maximise impact of science generated by projects**



**Engage in dialogue with regulatory authorities**

More info:

- [Webinar & presentations](#) 'How to engage with regulators EMA / FDA'
- 'Raising awareness of regulatory requirements: [A guidance tool for researchers](#)'



**Thank you**

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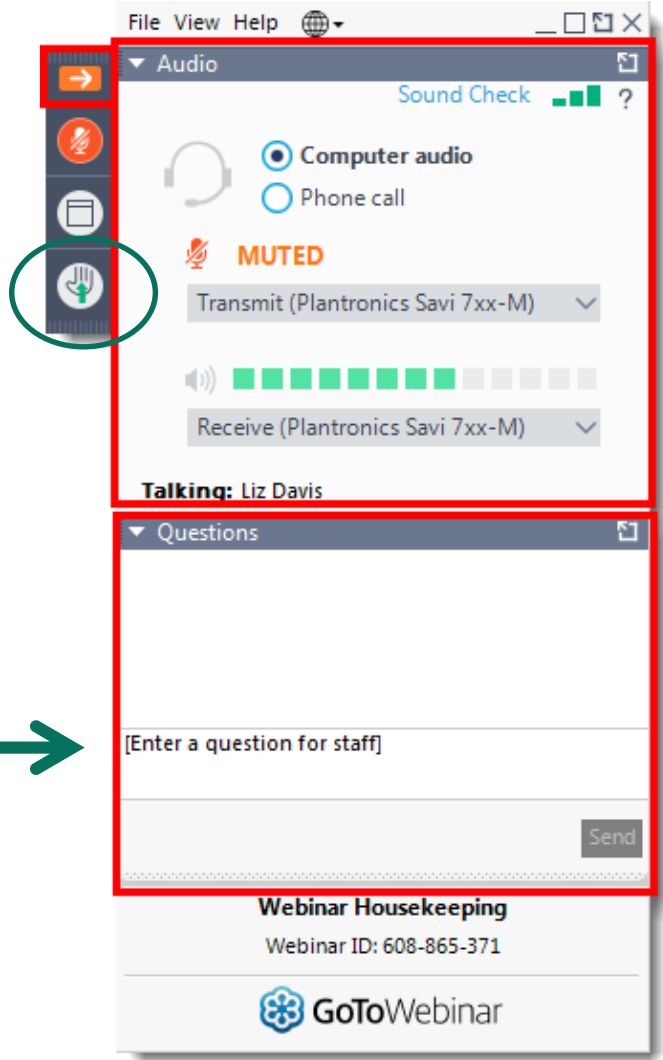
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# Questions & answers

# 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](mailto:applicants@imi.europa.eu)



**Thank you!**