



Webinar | IMI2 – Call 17

Optimising future obesity treatment

29.01.2019

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Nathalie Seigneuret, IMI
- The Call topic – Martin Ridderstråle, Novo Nordisk
- Involvement of SMEs, patient groups, regulators – Nathalie Seigneuret, IMI
- Questions & answers

How to use GoToWebinar

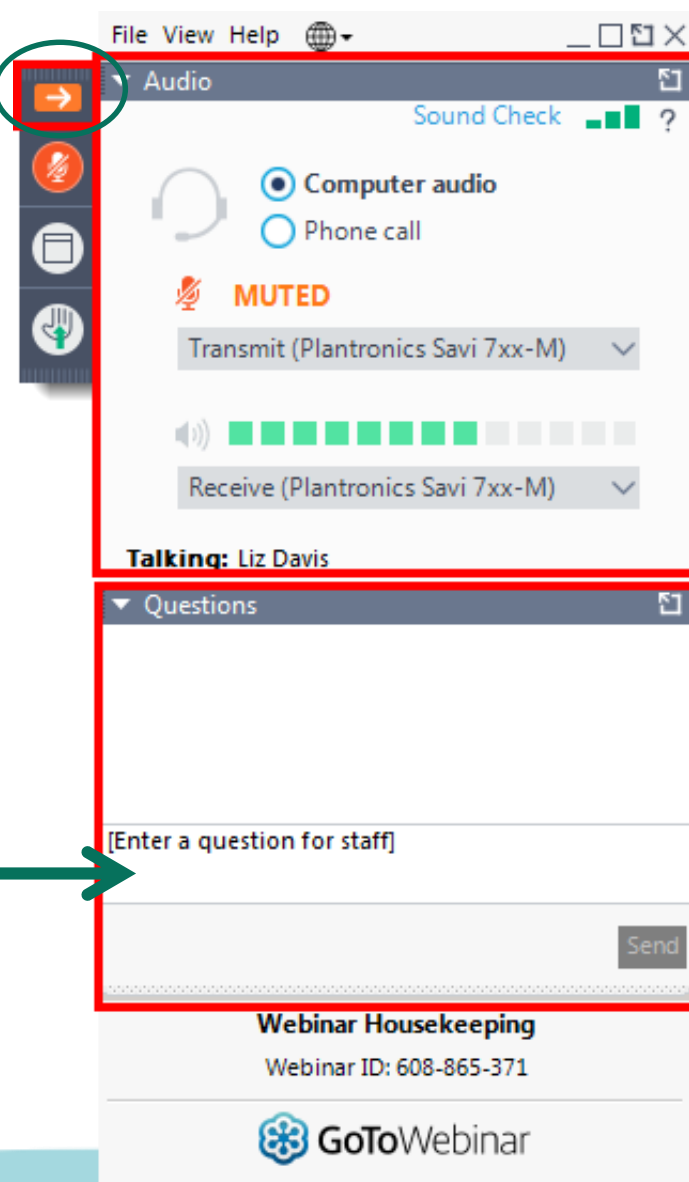
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question orally

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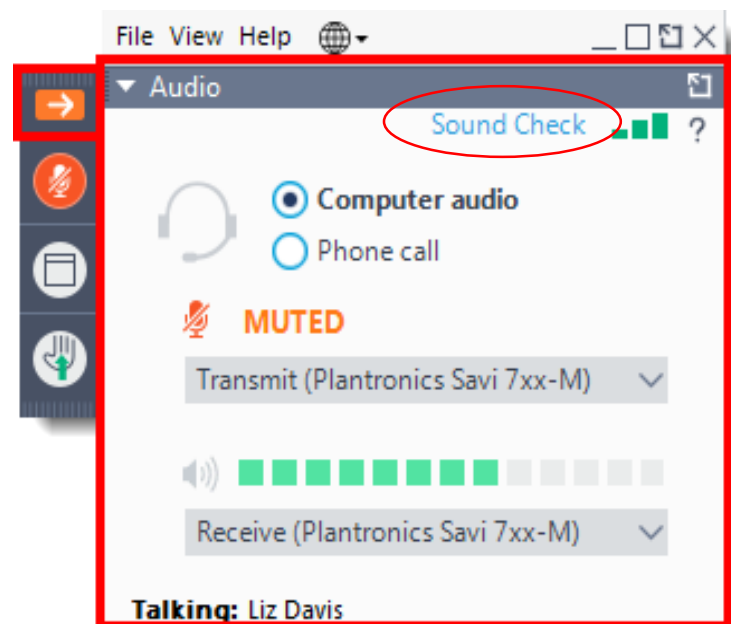
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Before we start...

- 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 and published on the website
- IMI2 – Call 17 has been launched and all Call documents & details of how to apply can be found on the IMI website

Webinar | IMI2 - Call 17

Optimising future obesity treatment

Nathalie Seigneuret

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 31 January, 10:30 – 12:00

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

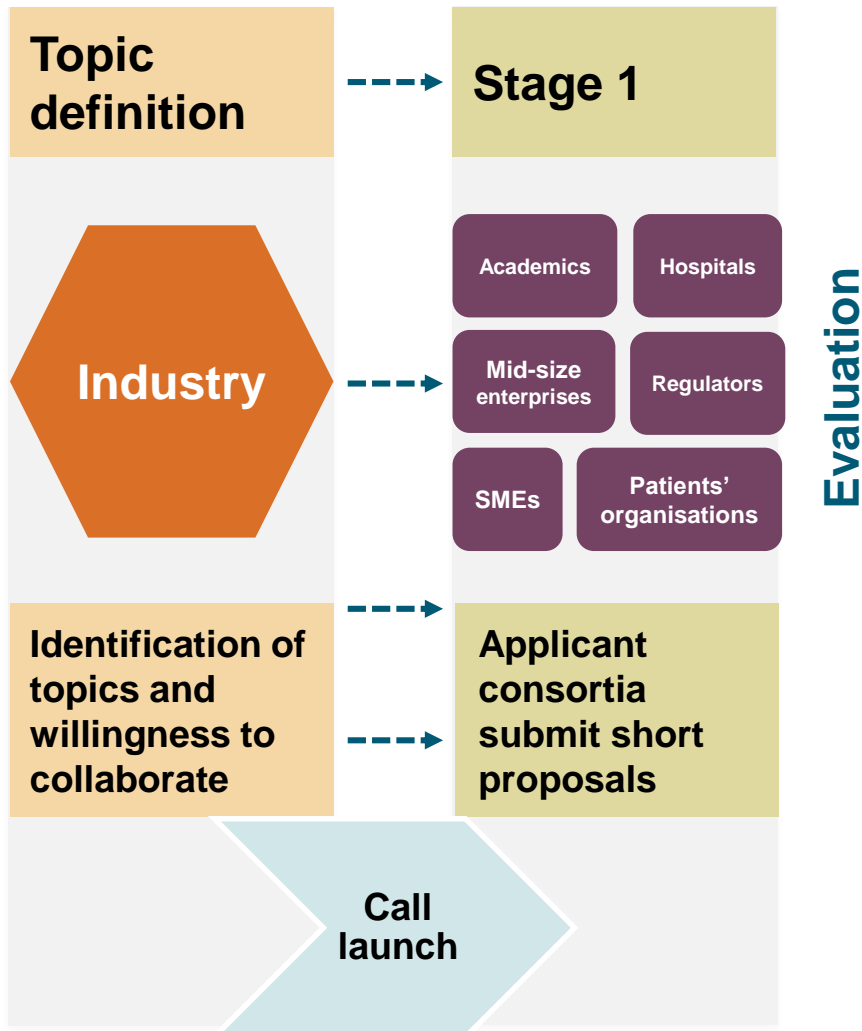
Scale is a key to success and is provided through IMI funding

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

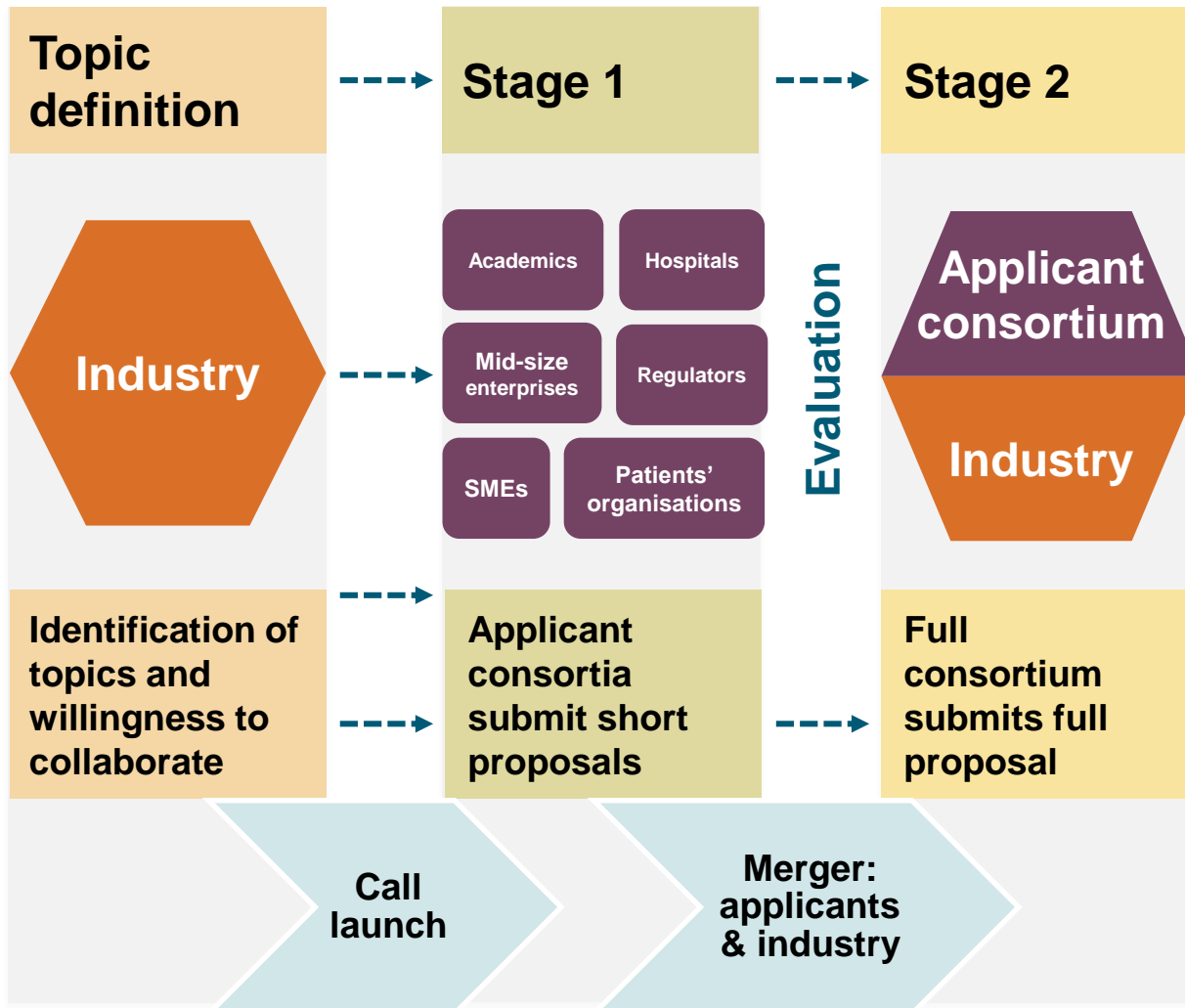
Typical IMI project life cycle



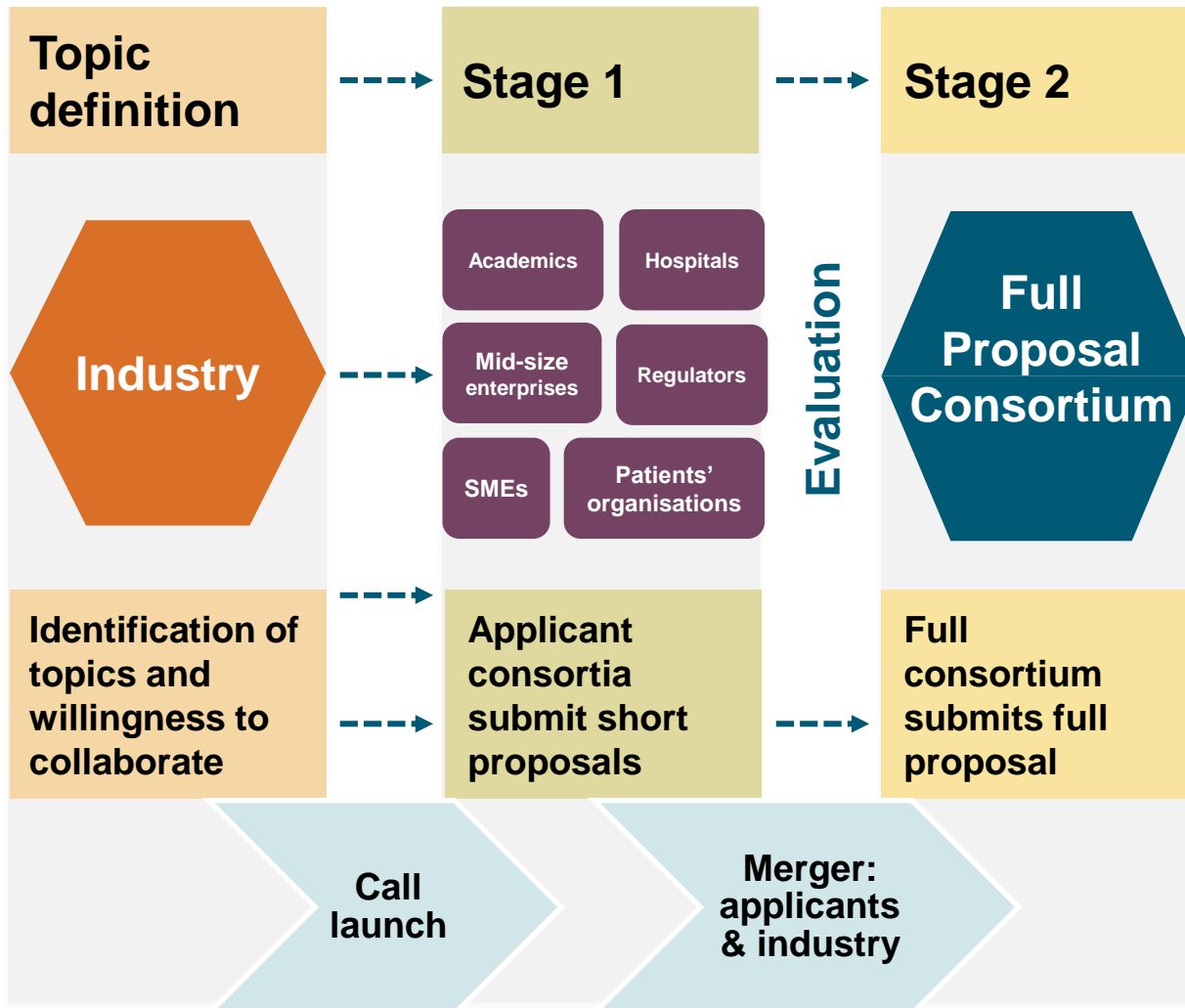
Typical IMI project life cycle



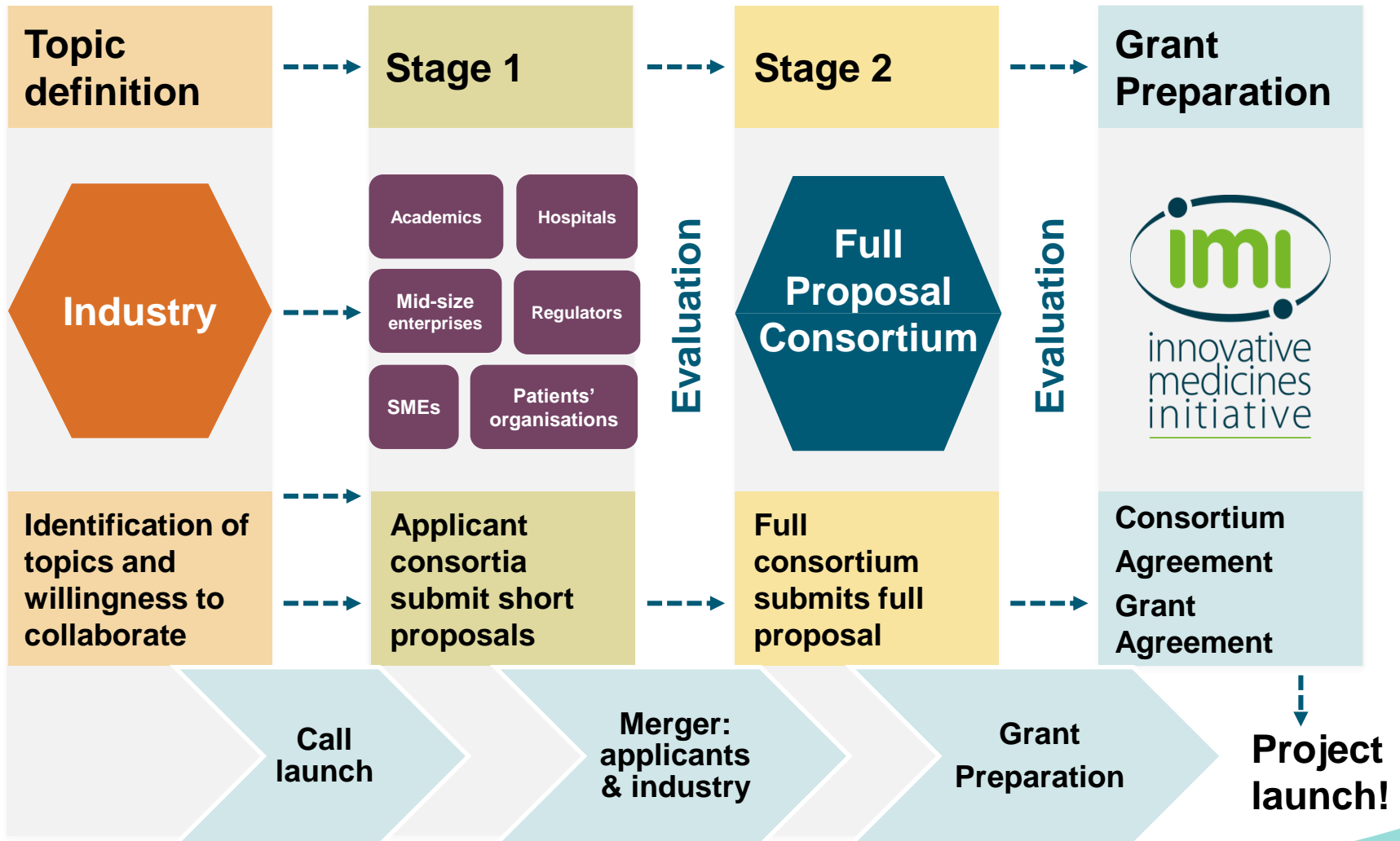
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



Submitting a proposal

Via the **new** Funding and Tenders Portal

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

The screenshot shows the top of the European Commission's Funding & tender opportunities portal. The header includes the European Commission logo, the text 'Funding & tender opportunities' and 'Single Electronic Data Interchange Area (SEDIA)', and language options for English (EN). There are 'Register' and 'Login' buttons. A navigation bar contains links for 'SEARCH FUNDING & TENDERS', 'HOW TO PARTICIPATE', 'PROJECTS & RESULTS', 'WORK AS AN EXPERT', and 'SUPPORT'. A search bar is present with the placeholder text 'Search calls for proposals and tenders by keywords, programmes...' and a yellow 'Search' button. Below the search bar, a section titled 'Calls for proposals by EU Programme' displays a grid of various EU programmes. The 'Horizon 2020 Framework Programme (H2020)' is circled in red.

European Commission | Funding & tender opportunities
Single Electronic Data Interchange Area (SEDIA)

English EN
Register Login

SEARCH FUNDING & TENDERS HOW TO PARTICIPATE PROJECTS & RESULTS WORK AS AN EXPERT SUPPORT

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.

Find calls for proposals and tenders

Search calls for proposals and tenders by keywords, programmes... Search

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)	Horizon 2020 Framework Programme (H2020)
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	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;
- 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.

■ 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 **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
- 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.

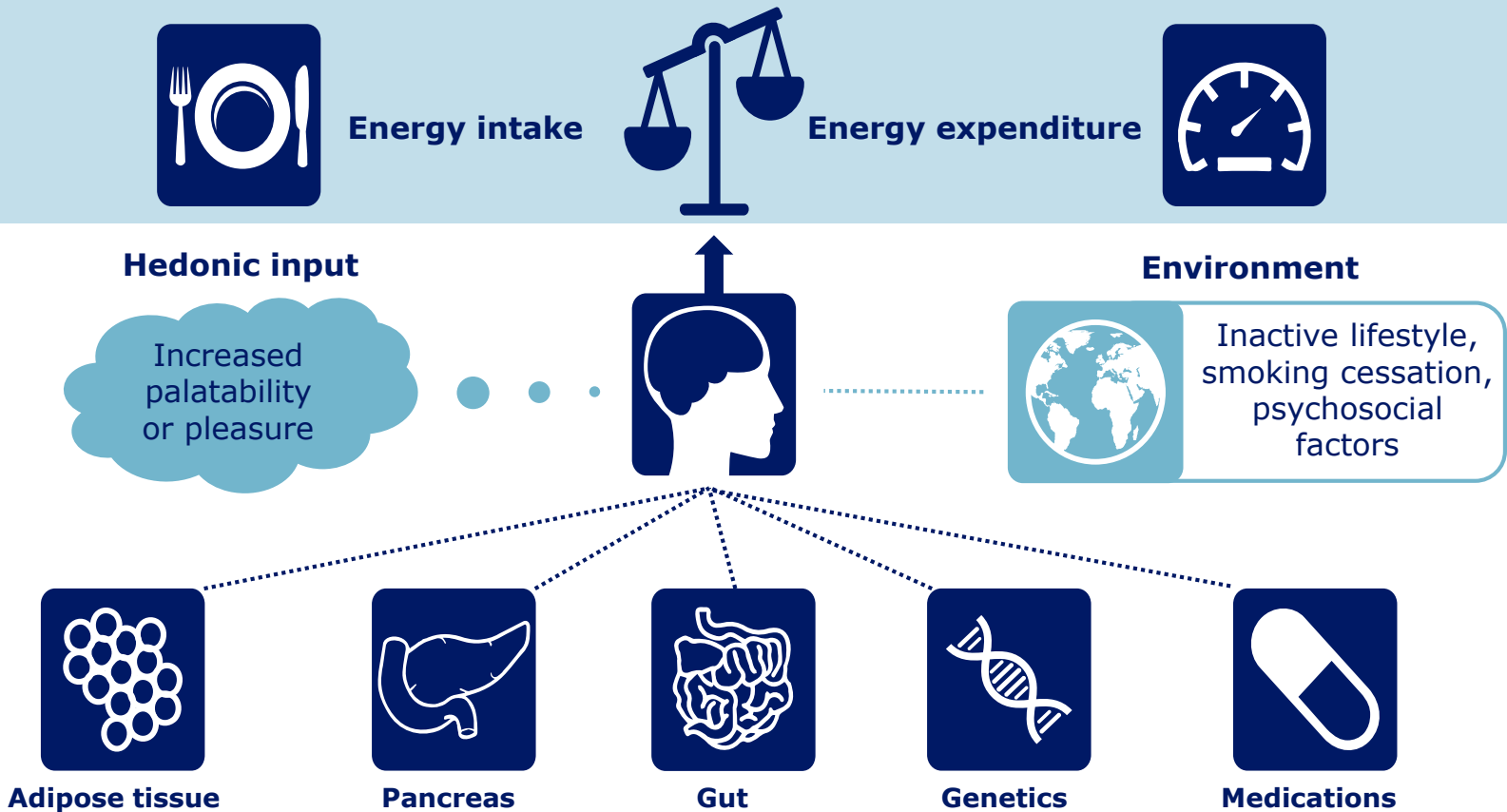
- SMEs and mid-sized companies
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)



Optimizing Future Obesity Treatment

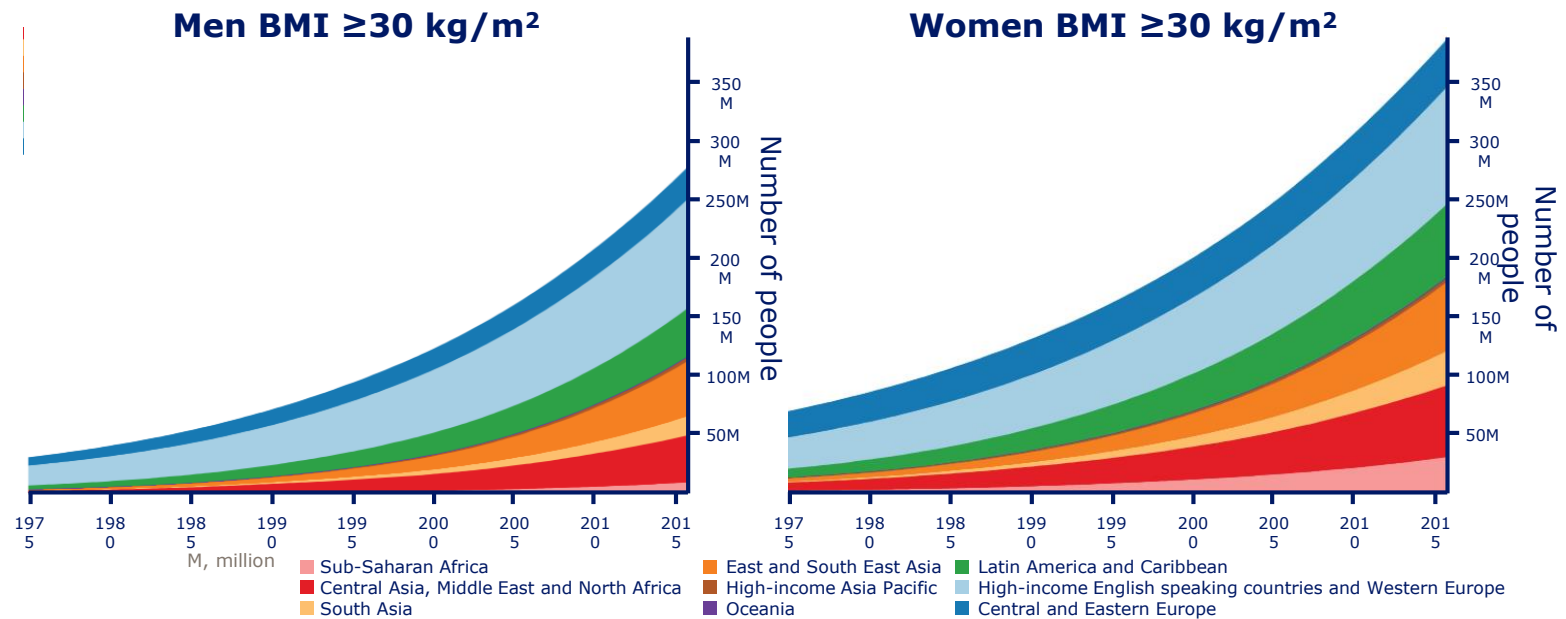
Martin Ridderstråle
29.01.2019 • IMI webinar

Obesity is a complex multifactorial disease



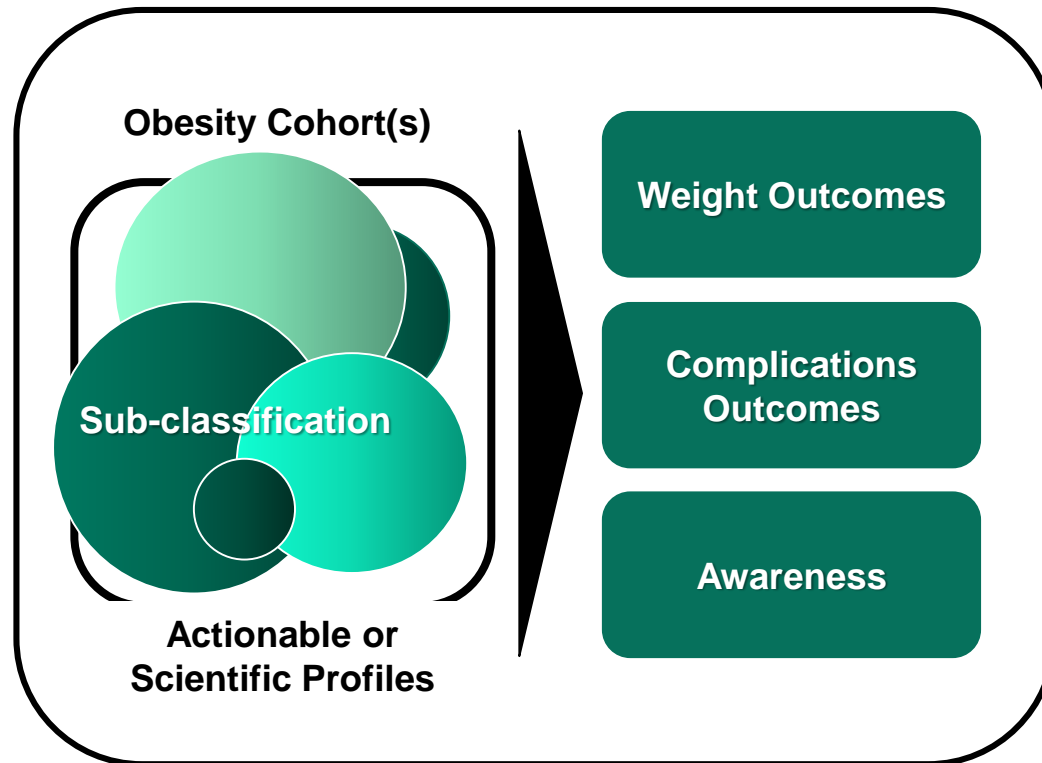
Obesity is an increasing global concern

- Obesity is increasing in all ages all over the world
- Obesity is associated with multiple complications and co-morbidities
- Obesity is a relapsing condition with few treatment options



Deciphering the heterogeneity of Obesity

- The premise for this topic is to decipher the heterogeneity of obesity to optimize future prevention and treatment



Need for public-private collaboration

- Unique scientific opportunity to address the challenges of maximising the efficacy of preventing and treating obesity;
 - Multiple stakeholders with each their own specific expertise that might otherwise not interact such as:
 - Academia/clinical researchers (analysis and interpretation)
 - Patient organisations (relevance)
 - Pharmaceutical industry (fit for innovation purpose)
 - Food industry (context)
 - Diagnostic companies (biomarkers)

Objectives of the full project

- Identify pathophysiologically and clinically meaningful subgroups of obesity to optimise prevention and treatment
- Pool baseline data from pre-existing cohorts to achieve as broad and detailed information on patients with obesity as possible, including sufficient clinical phenotyping and multi-omics data;
- Data-driven analysis, identifying biomarkers for diagnosis, prediction of complications, response to treatment
- Fill gaps of information regarding selected affordable and operational biomarkers by reanalysing pre-existing biobanks;
- Specifically address type 1 diabetes (T1D) and type 2 diabetes (T2D) as examples of conditions in which both clinical phenotype and treatment is influenced by obesity in an intricate manner;

Objectives of the full project

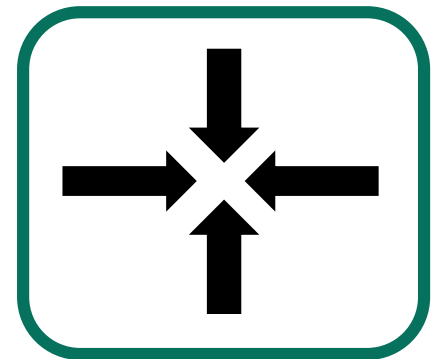
- Form a Patient Advisory Board to ensure that patient-driven research and insights relevant for the project are identified
- Integrate patient perspectives on diagnosis and treatment to understand the need, perceived barriers and value of treatment;
- Conduct a shared value analysis reflecting values and challenges within the obesity landscape to generate educational material supporting a common understanding of obesity;

Pre-competitive nature

- Public-private partnership with shared access to results for research purpose for all partners (IMI concept)
- Neutral ground
- Independent effort to engage with stakeholders

Expected impact

- Novel ways of describing obesity (classification, diagnostics)
- Increased understanding of obesity as a chronic disease
- More targeted treatment and prevention
- Improved trial design
- Evidence-based obesity medicine
- Increased understanding of impact of obesity



Suggested architecture of the project

Work Package structure

- 1 Project management
- 2 Data federation
- 3 Data analysis & biology
- 4 Diabetes & obesity
- 5 Patient perspective
- 6 Shared value analysis



Expected contributions of the applicants

- Research activities in public health or clinical services within obesity with interest in defining phenotypes for better treatment
- Expertise in anthropology, epidemiology, public health, health economics, data management, harmonisation, bioinformatics, systems medicine, multi-omics, lifestyle treatment, public relations, HCPs, data-driven analysis tools
- Access to obesity databases, pre-existing cohorts and biobanked samples
- Involvement of patients
- SMEs are encouraged to participate

Expected (in kind) contributions of industry consortium

- Anonymised data from clinical trial cohorts from industry partners supplementing the academic cohorts;
- Access (by application) and support for analysis of the Gutenberg Health Study;
- Access to the T1D Exchange data;
- In-depth knowledge in the fields of clinical pharmacology and translational medicine, clinical data management, bioinformatics analysis, and obesity;
- Know-how and means to support establishing the federated database including legal advice, setting up the database, and making analysis feasible, accessible and sustainable over time;
- Limited supplementary funding for supporting further analysis of biobanked samples;
- Limited supplementary funding for developing digital tools to assist physicians in subgrouping of patients based on the outcome of the analysis;
- Management of the consortium including the Patient Advisory Board.



SANOVI



T1D Exchange



Boehringer
Ingelheim

JDRF

OAC

What's in it for you?

- Platform to interact with other players in the field of obesity
- Co-option
 - Development of improved obesity treatment
- Co-learning
 - Shared accelerated competence development
- Co-specialization
 - Better products, services, solutions

Key deliverables of the full project

- Federated database of phenotypic characterisation
- Set of operational variables for stratification of obesity into clinically meaningful patient subgroups
- Description of clinical characteristics and manifestations of the identified patients subgroups, any existing or expected differences in treatment preference, effect, size, and sustainability of the effect and safety
- Algorithm based on operational variables to identify subjects that require and respond differently to prevention and/or treatment
- Description of the impact of obesity on diabetes (patient characteristics, clinical manifestation, treatment and outcomes)
- Documentation of patient preferences regarding diagnosis and treatment
- Shared value analysis among key stakeholders and common understanding and vocabulary about obesity as a disease



Thank you

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Involvement of SMEs, patient groups, regulators

Nathalie Seigneuret

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 :

- research activities in obesity treatment
- data management and harmonisation
- bioinformatics, systems medicine or multi-omics analysis,
- public-health, public relations and communication
- project management

Patient participation

- Involvement of patient organisations imperative for this topic to ensure patient centricity;
- Many ways to include your patient partners in the project e.g;
 - patient insight on the analysis and interpretation;
 - 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** (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)
- Consider involving regulators as project participants or in the **advisory board**
- Have 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:

- [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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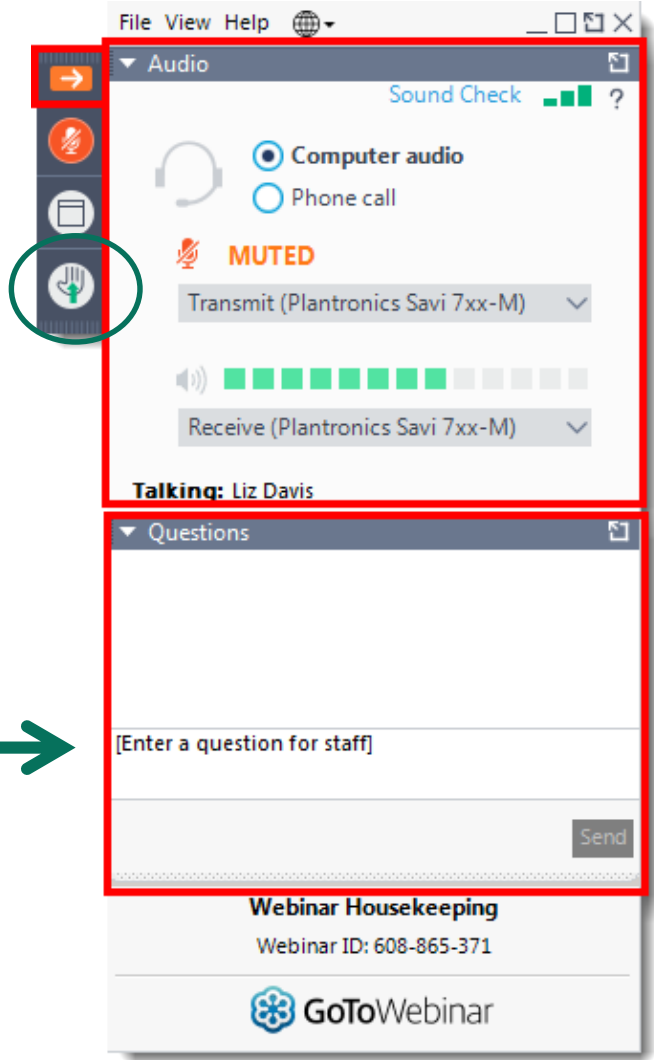
 @IMI_JU



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



Thank you!