Webinar | IMI2 - Call 23
Returning re-usable Clinical Trial Data to Study Participants within a GDPR compliant and approved framework

19.06.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Iwona Jablonska, IMI
- The Call topic – Anne Bahr, Sanofi & Andrew Kopelman, Medidata
- Involvement of SMEs, patient groups, regulators – Iwona Jablonska, IMI
- Questions & answers

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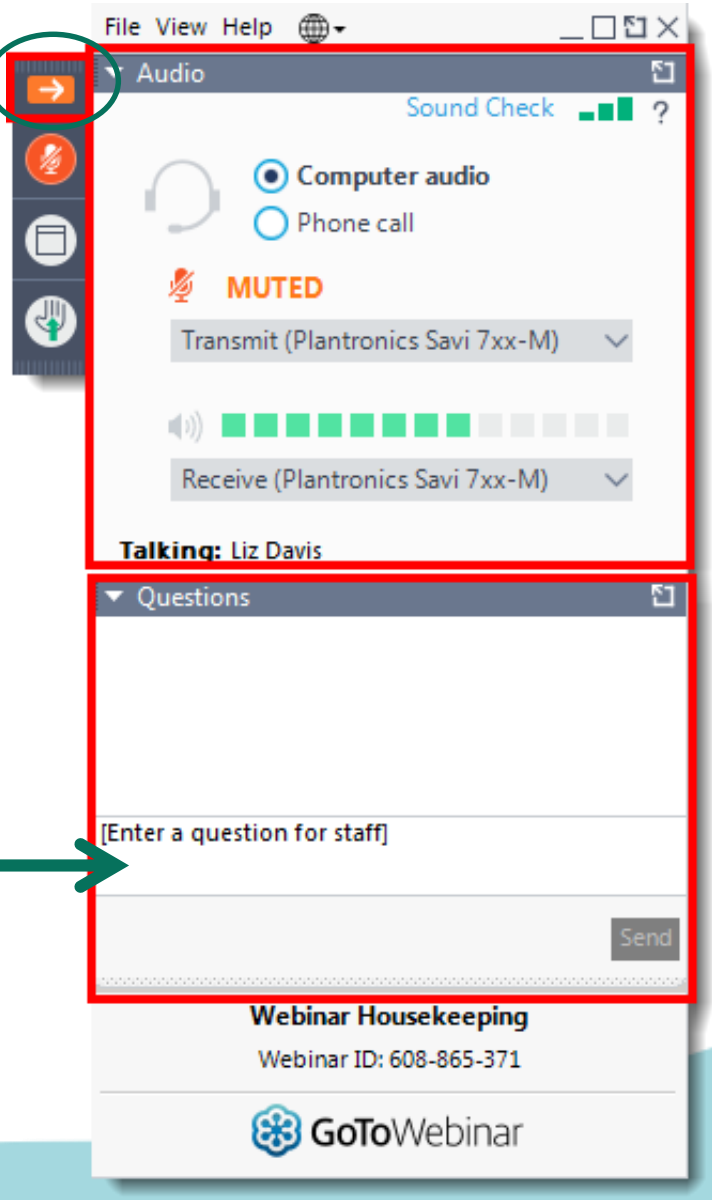

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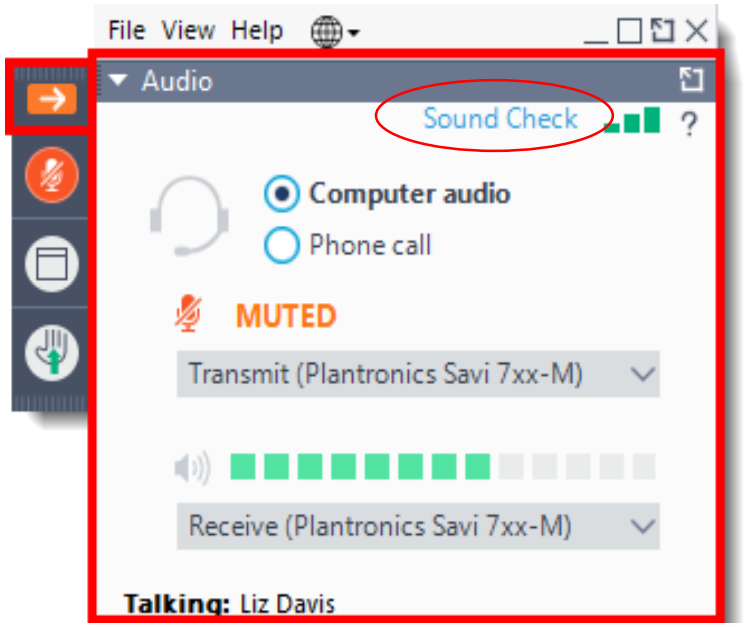

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Before we start…

- 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
- All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

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Webinar | IMI2 - Call 23

Returning Clinical Trial Data to Study Participants within a GDPR compliant and approved ethical framework

Iwona Jablonska

Today's webinar

Will cover all aspects of the call topic

- Introduction to the IMI programme's specificities
- Proposed project:
  - Objectives to be achieved and the need for public-private collaborative research to fulfill them;
  - Key deliverables to be completed;
  - Structure of the project;
  - Expected contributions of the applicants and of the 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

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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.

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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**.

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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

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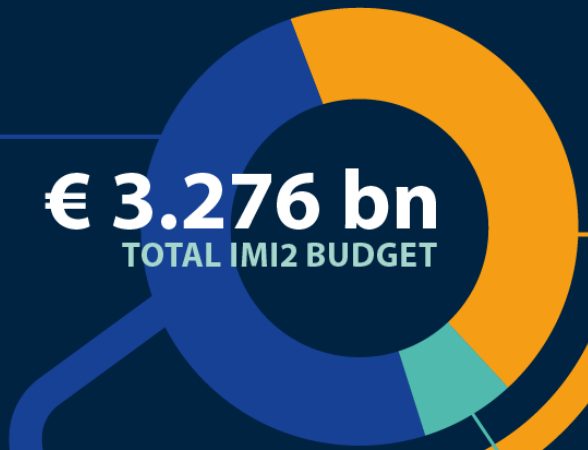
IMI2 funding
(2014-2020)

IMI FUNDING MODEL

efpia

IN-KIND PRIVATE CONTRIBUTION
€1.425 bn
EFPIA companies receive no funding

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

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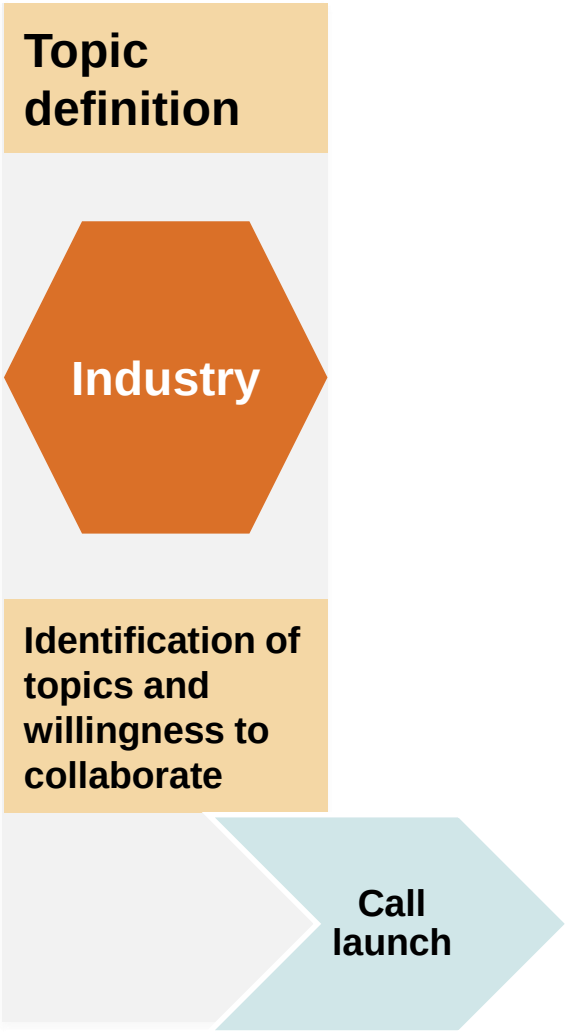
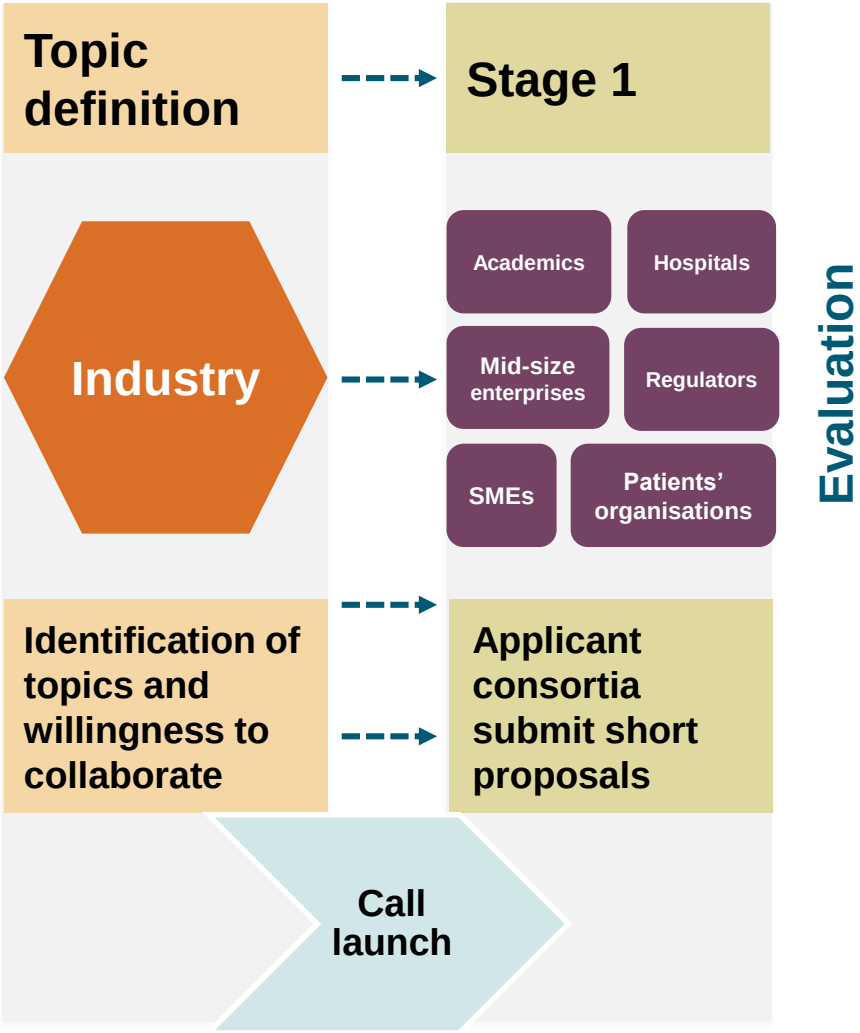
Typical IMI project life cycle



Typical IMI project life cycle



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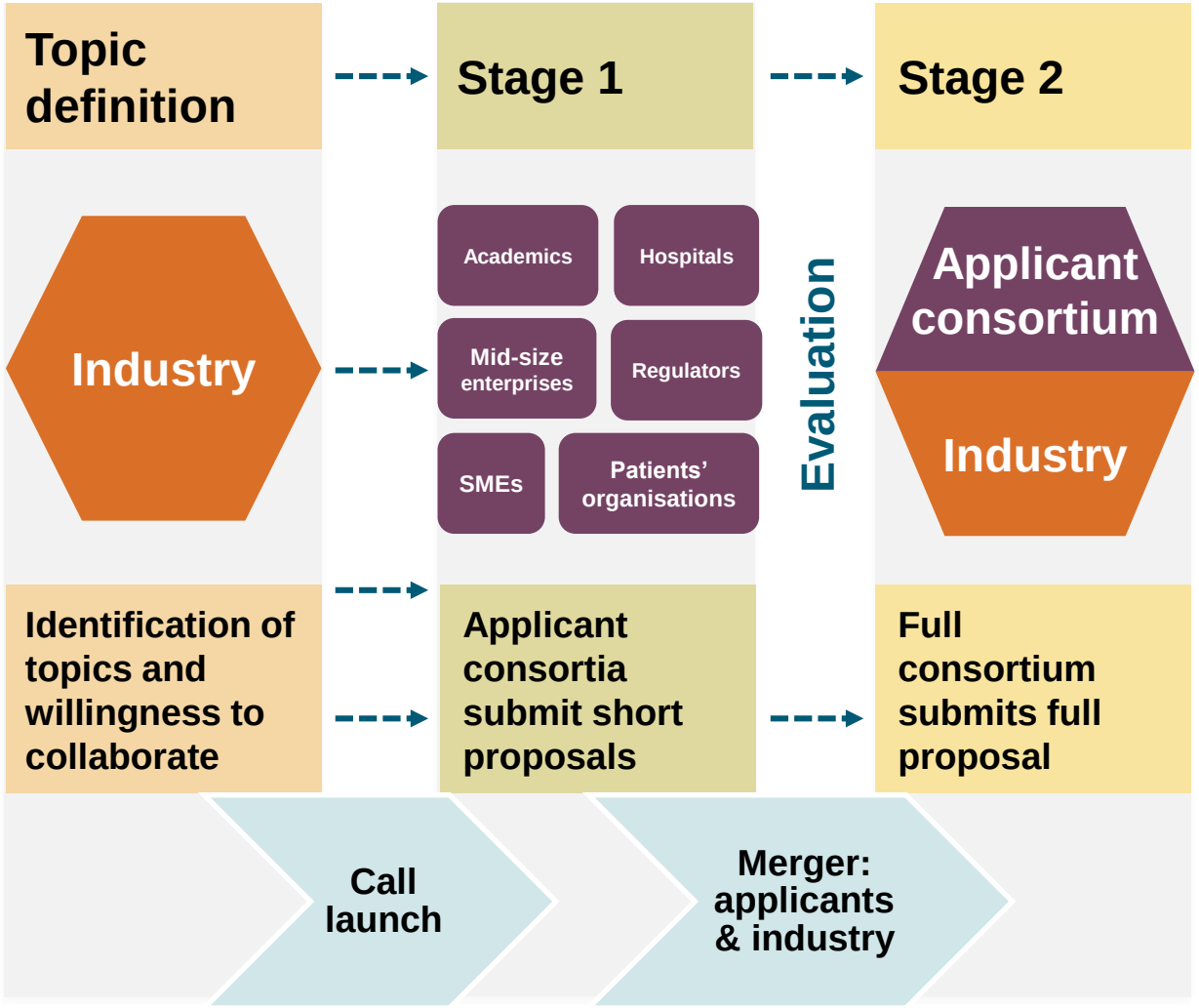
Typical IMI project life cycle



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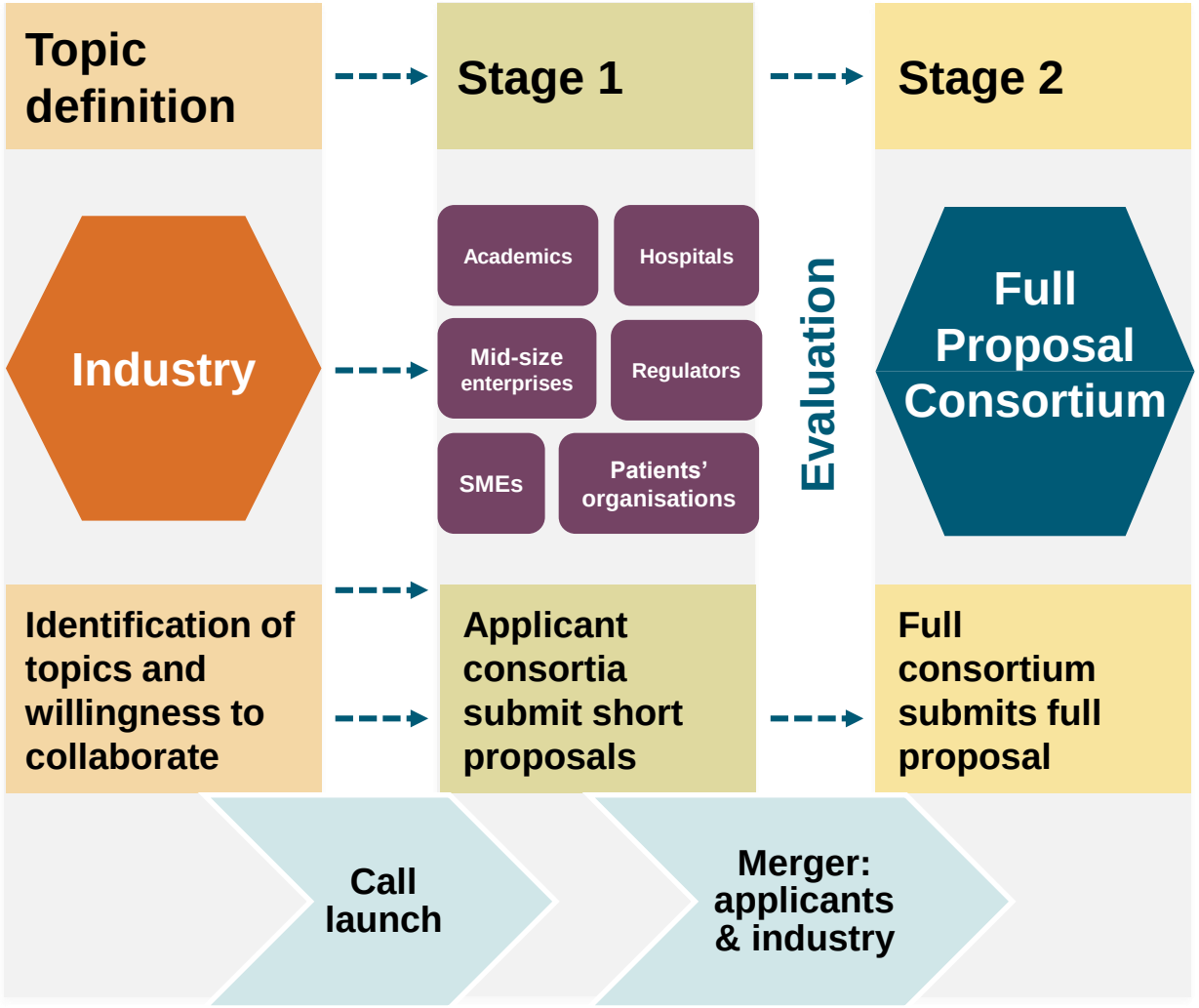
Typical IMI project life cycle



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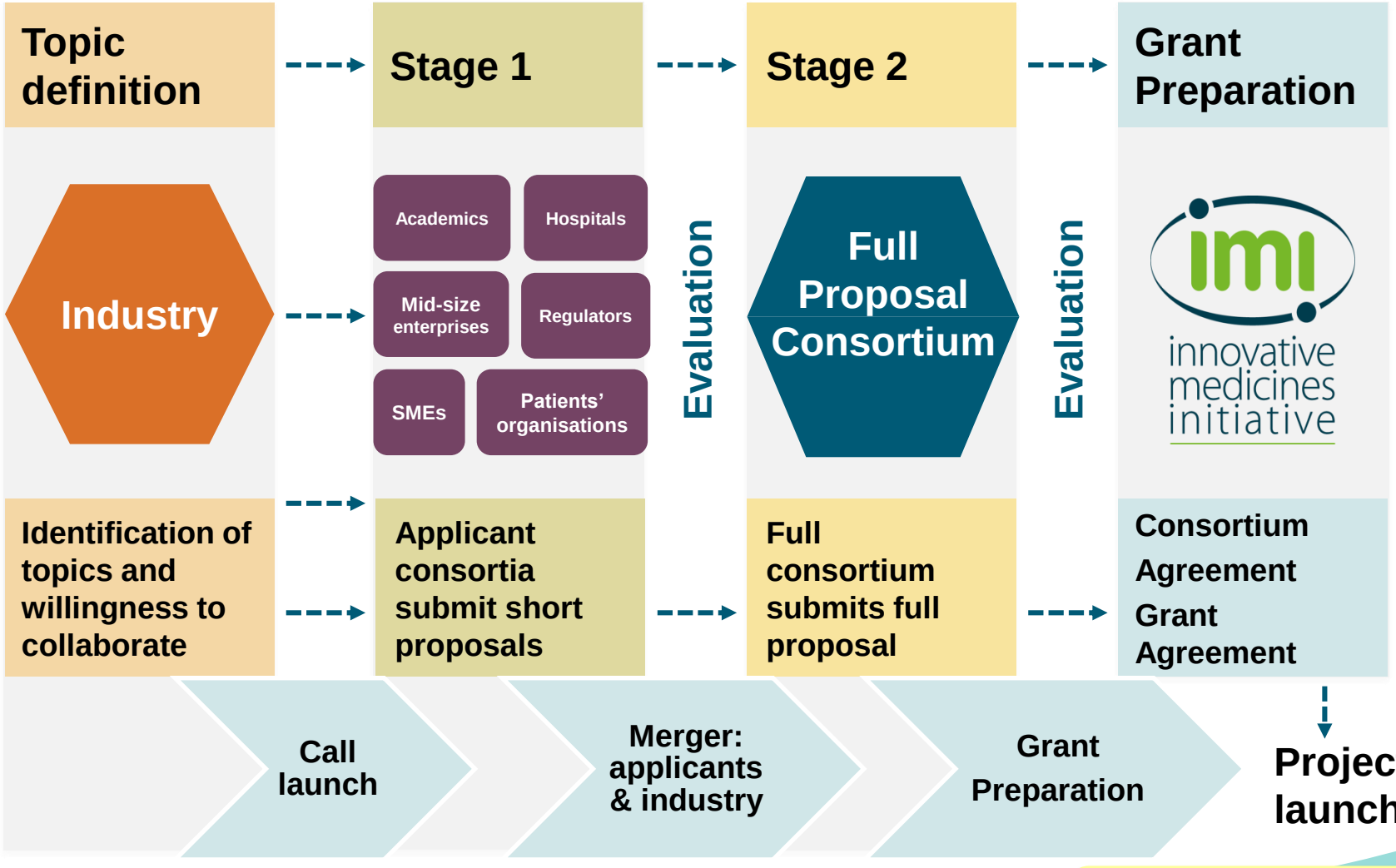
Typical IMI project life cycle



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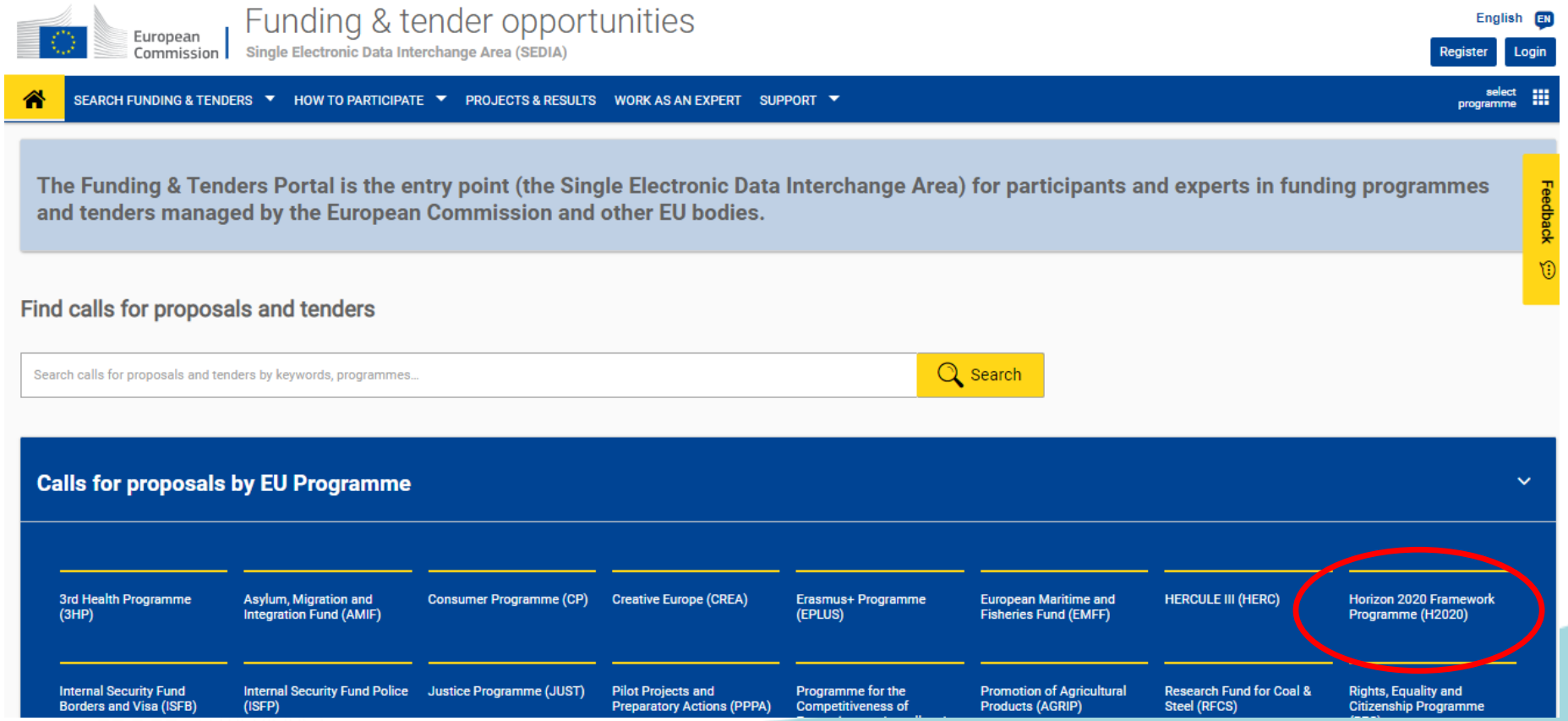
Expected GA signature – Summer 2021

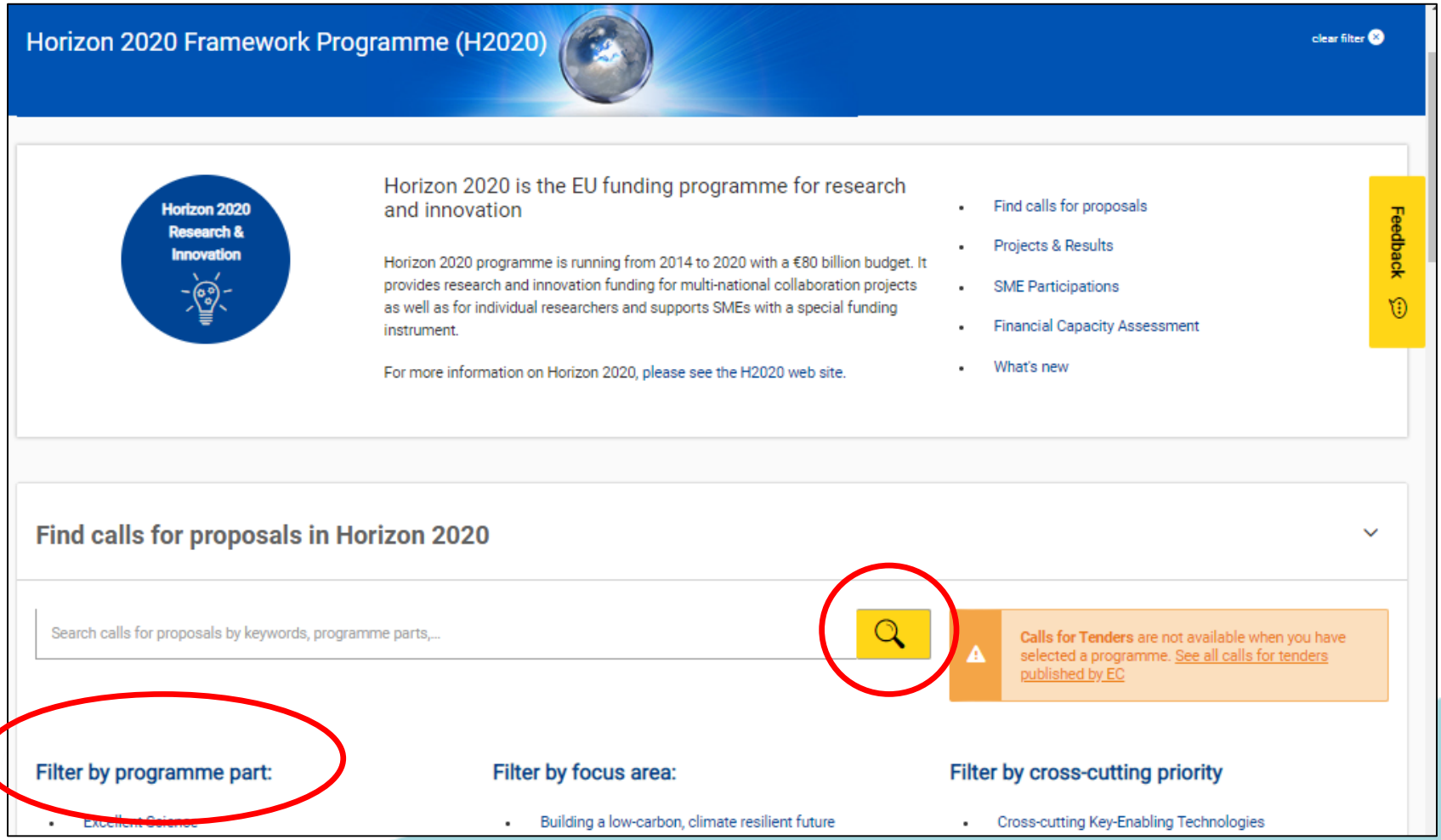
Submitting a proposal

Via the **new** Funding and Tenders Portal



New Funding and Tenders Portal Horizon 2020 section

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



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)

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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.

Thresholds

- **3** for each of the evaluation criteria ‘excellence’, ‘impact’ and ‘quality and efficiency of the implementation’
- the overall threshold is 10

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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

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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 call topic text
- A proposal is **scientifically excellent** but will have **limited impact**
- **Complementarity** with Industry consortium not well described.

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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)

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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…)

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Returning Clinical Trial Data to Study Participants within a GDPR compliant and approved ethical framework

Anne Bahr & Andrew Kopelman

19.06.2020 • IMI webinar

Need for public-private collaboration

- The data protection framework applicable to clinical studies and secondary use of health data is mainly subject to **local law**: the rules for sharing are puzzling and **require harmonization** across European Member States

- The **sharing** of data collected in a clinical study with its participants is still **uncommon**. The main reasons include:
  - Complexities in setting up the **infrastructure**, **processes** and a common data **format**
  - Concerns around protecting the **integrity** of the study, study participants' **privacy** and confidentiality, maintaining the study **blind**, etc.

- Difficult to integrate clinical study data with EHR in general, and in daily routine practice in particular

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Need for public-private collaboration

- Consequences:
  - **Lost opportunities** to enrich patients' **health care** by improving clinical decision making
  - Hampered clinical **study set up & conduct** and **delayed** scientific health research projects
  - Inability for patients to **contribute** to additional scientific research with their data
  - Decreased patient **willingness to be involved** in studies and increased patient **drop-out**

- Impacts most categories of stakeholders:
  - Industry, Clinical Trial Participants, Advocacy Groups, Patients Groups, Regulators, Academic Institutions, Clinical Trial Sponsors, Tech Companies

- Requires the **alignment** of positions and interpretations across stakeholders
  - To develop standards for collecting, processing and sharing study participants data
  - To propose and negotiate the approval of those standards with ethics committees and personal data protection authorities

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Objectives of the full project

- **Align** local and pan-European implementations and best practice for handling personal data protection regulations in order **to foster the harmonisation** of the legal framework applicable to medical research in the Member States;

- Deliver a successful **prototype process** for **returning clinical trial data to study participants** and to facilitate the **conduct of health research projects**, during and after the study
  - Generate insights and recommendations on **which**, **when and how** this data should be **returned to study participants** through **EHR or other means**
  - Generate insights on how this data is **utilised in health care decision making** and for **future research**
  - Ensure that the whole data process, from collection of data to its destruction or anonymisation, including its sharing and re-use, is **legally compliant** and aligned with the **Study Participants' voice**

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Pre-competitive nature

- The methods and guidance documents developed will be available to all participants during the project and will be made available beyond the life of the project

- The alignment of legal and ethical positions and/ or practices will serve all stakeholders

Expected impact

- ***For patients*:** the project results should **empower patients** by returning their clinical trial data to them to aid better shared medical decision-making
- ***For healthcare professionals*:** enriched healthcare data obtained during clinical care should **aid clinical decision making** and reduce duplication
- ***For EU research*:** giving patients control of their clinical trial data will **open possibilities for ethical data re-use** by enabling patients to donate their data
- ***For regulators*:** exchanging opinions with counterparts from other countries and researchers to propose informed workable aligned positions
- ***For pharma*:** improved **patient retention** as well as access to health data for **future research**
- ***For society*:** increased **transparency** of clinical study and therefore increase the **trust** of patients and **improved oversight** on clinical data re-use.

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Suggested architecture of the project

7 Work Packages

Work Package 1: Legal and Regulatory

- Align IMI DO-IT harmonised consent form and supporting guidance documents with recent regulators updates
- Develop guidance documents necessary for primary and secondary use of clinical data in compliance with GDPR (must include privacy notices, rights management for re-use, clauses for investigators contracts)
- Engage with regulators, patient groups, data protection experts

Work Package 2: Standards

- Review and integrate technical and regulatory standards proposed by WP1 and WP3
- Provide recommendation aligned with patients voice and develop new standards if necessary
- Seek approval of standards by regulators

Work Package 3: Technology Framework

- Develop a technology framework based on existing or new technologies
- Identify potential technical issues
- Set up the process that will be deployed in WP4

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Suggested architecture of the project

7 Work Packages

Work Package 4: Solution implementation – Prototype

- Deploy a working prototype process to establish viability, to suggest overall direction, and to provide feedback (a working prototype demonstrating the feasibility for study participants to get access to their clinical study data)

Work Package 5: Communication, Dissemination

- Establish a website and all appropriate tools for communications purposes
- Establish and implement a communication structure
- Conduct surveys with patients, HCPs, etc.
- Establish and organise dissemination of project results.

Work Package 6 & 7: Business Plan and Sustainability; Project Management & Coordination

- Establish a robust business plan to sustain the project results
- Implement the business plan, including marketing of the project deliverables to relevant end-users
- Manage project costs, tasks and timelines

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Expected contributions of the applicants

- Academic clinical trials **sponsors** from **at least five** different European Member States, including at least one central/eastern European Member State
- **Healthcare professionals**
- Study **participants** and patient **organisations**
- **SMEs** and/or **Public Institutes** with:
  - **Legal, ethics, and data protection** expertise for clinical studies
  - Expertise in collaborating with **ethics committees** and personal data protection **authorities**, as advice from various EU regulators will be essential to the success of this project
  - Expertise in health and clinical data **interoperability** and **frameworks** for secured exchanges as well as in anonymisation of health data
  - Expertise in **EHR** and **clinical trial databases**, including those operating in a commercial environment

Expected (in kind) contributions of industry consortium

- Expertise in conducting studies:
  - Data Management;
  - Study/Trial Operational Managers
  - Biostats
- Expertise in legal in clinical context (GDPR and CTR)
- Experience in networking with EU and local Healthcare and Data Protection Regulators
- Expertise in sensitive Data Exchange and building Digital Infrastructure
- Expertise in Data Security and Data Anonymisation

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Key deliverables of the full project

- Legal standards and guidance documents necessary to comply with **GDPR** and **other applicable laws**
- Harmonized technical **standards** for handling the data
- **Guidance** for returning clinical trial data to patients in Europe
- A **prototype process** demonstrating mechanisms by which clinical trial data can be either **integrated** or **interconnected** with data in a digital solution for patient (EHR or others) and can be re-used in further health research projects

What's in it for you?

- **Influence** the harmonization of **legal framework** for processing clinical data will look like in the near future
- **Contribute** to the **development** of key technical and regulatory **standards** to be used for health research
- Prove being an **innovant actor** in the EU **health data** ecosystem, and beyond
- Ensure that innovative solutions are developed with "**Patient centricity by design**"

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Thank you

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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.

In this specific topic:

*“It would also be crucial to include relevant SMEs. SMEs could, for example, be beneficial in the **legal and data protection areas** as well as **interoperability of data and framework for their secured exchanges.**”*

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Patient participation – in the centre of the topic

- Expertise from study participants and patient organisations is expected
- Substantial, focused input from **study participants, patient organisations and healthcare professionals,** will be necessary, to fully understand what data would be the most important to return to them, what data would be acceptable for being shared with researchers, and how such data may best be returned and/or shared.
- A decision committee in charge of representing patient expectations and involving patient associations (made up of members of the consortium and, if needed, external/invited patient association members).

"The patient, doctor and researcher – each is a different kind of expert."

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'

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Regulators in this topic

- Inputs from various **EU regulators** will be essential to the success of this project and required to develop common, validated usability and privacy standards.

- The proposal could include **a strategy for engagement** with patients, healthcare professional associations, healthcare professionals, **regulators**, ethics committees, HTA agencies, payers etc., where relevant.

- **Expected impact**: the project will **increase the transparency** of clinical study and therefore increase the **trust** of patients in clinical research. At a time where clinical trials are increasingly complex, this may help with recruitment for studies and **improve oversight by patients and regulators** on clinical data re-use.

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Thank you

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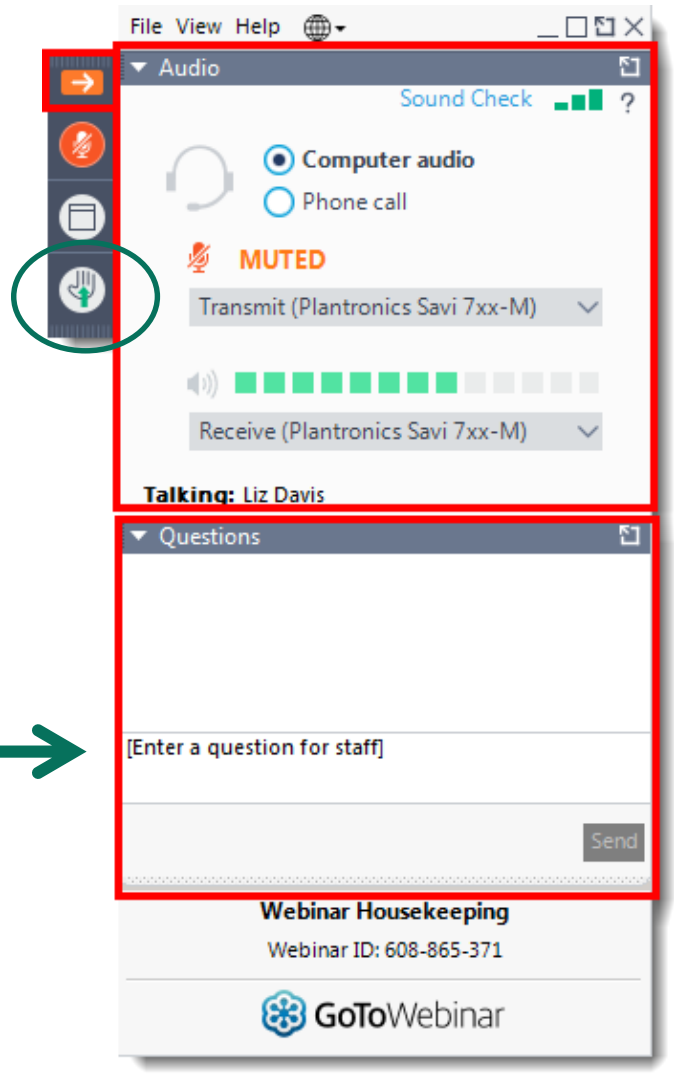
Questions & answers

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

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Thank you!