Webinar | IMI2 - Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project

21.06.2019

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Colm Carroll, IMI
- The Call topic – Giovanna Ferrari, Pfizer
- Involvement of SMEs, patient groups, regulators – Colm Carroll, IMI
- Questions & answers

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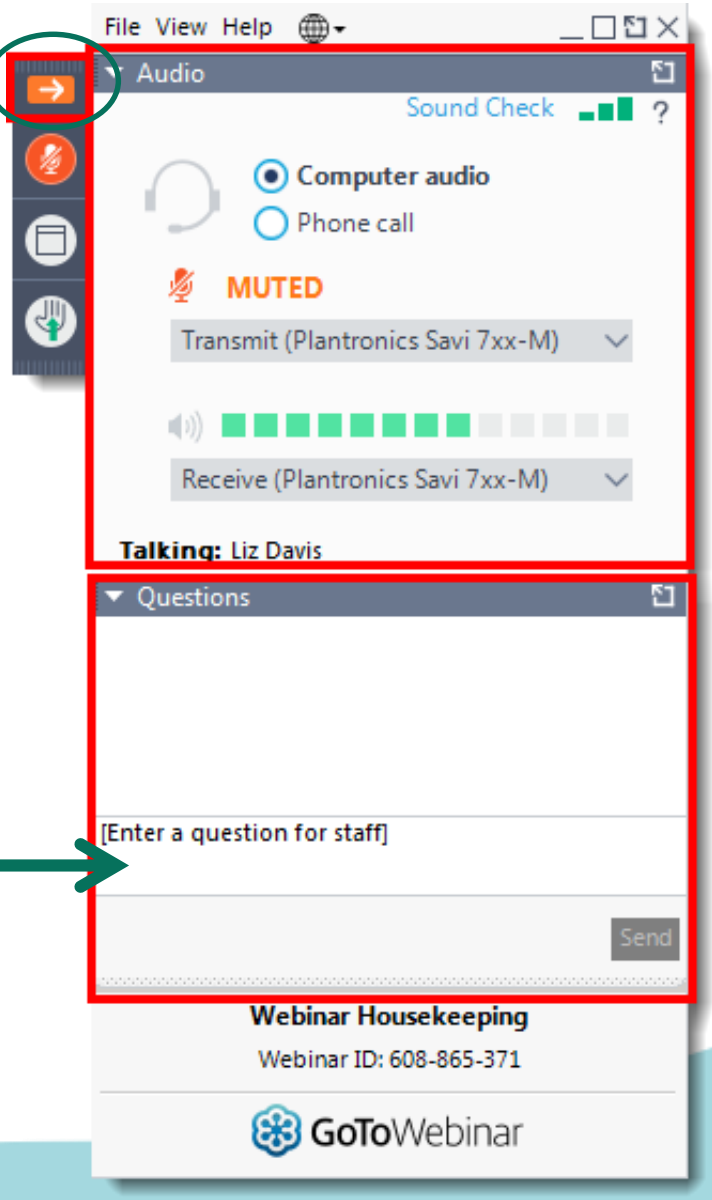

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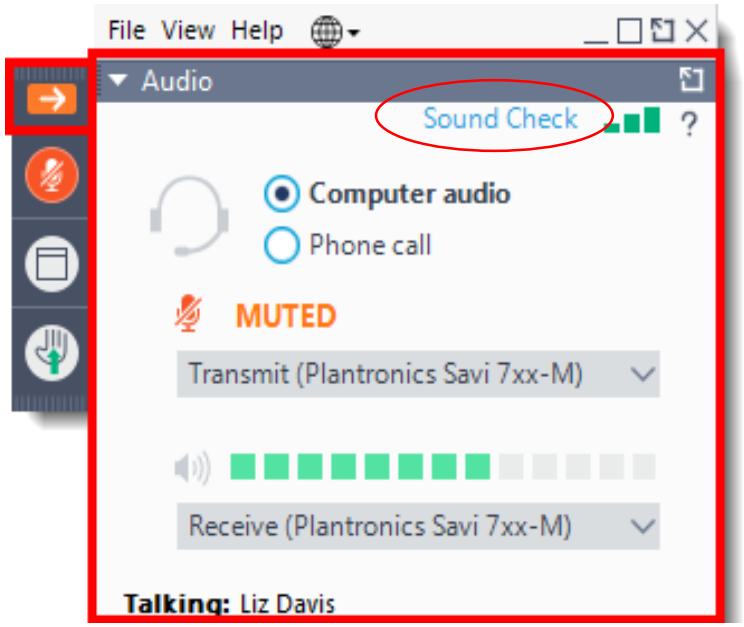

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Before we start…

- 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
- 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 18

Improving patient access, understanding, and adherence to healthcare information: an integrated digital health information project

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 recording of the webinar on rules and procedures is available here: https://europa.eu/!wU49WU

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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 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

efpia

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other €213 m

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

IMI 2 total budget €3.276 billion

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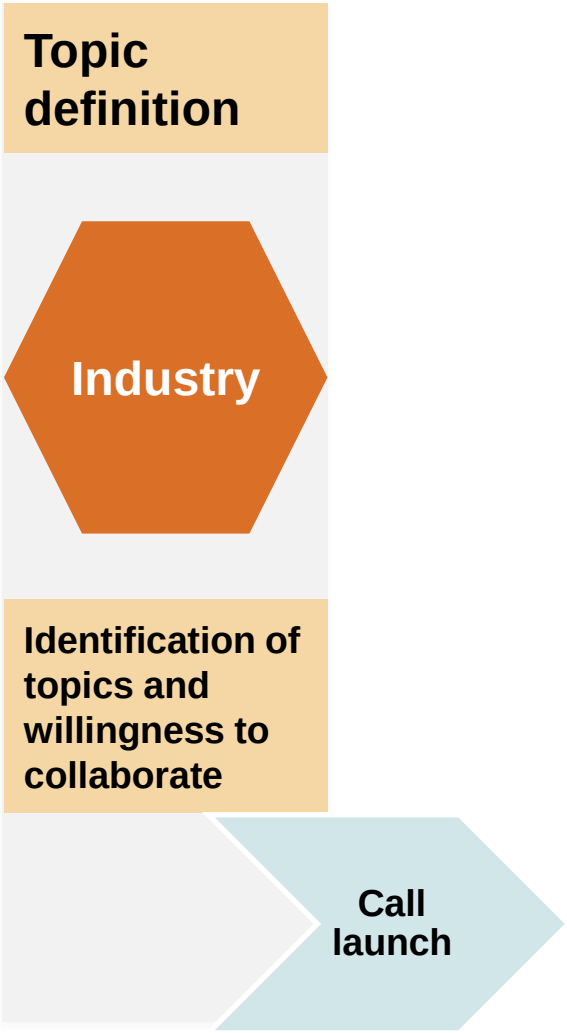
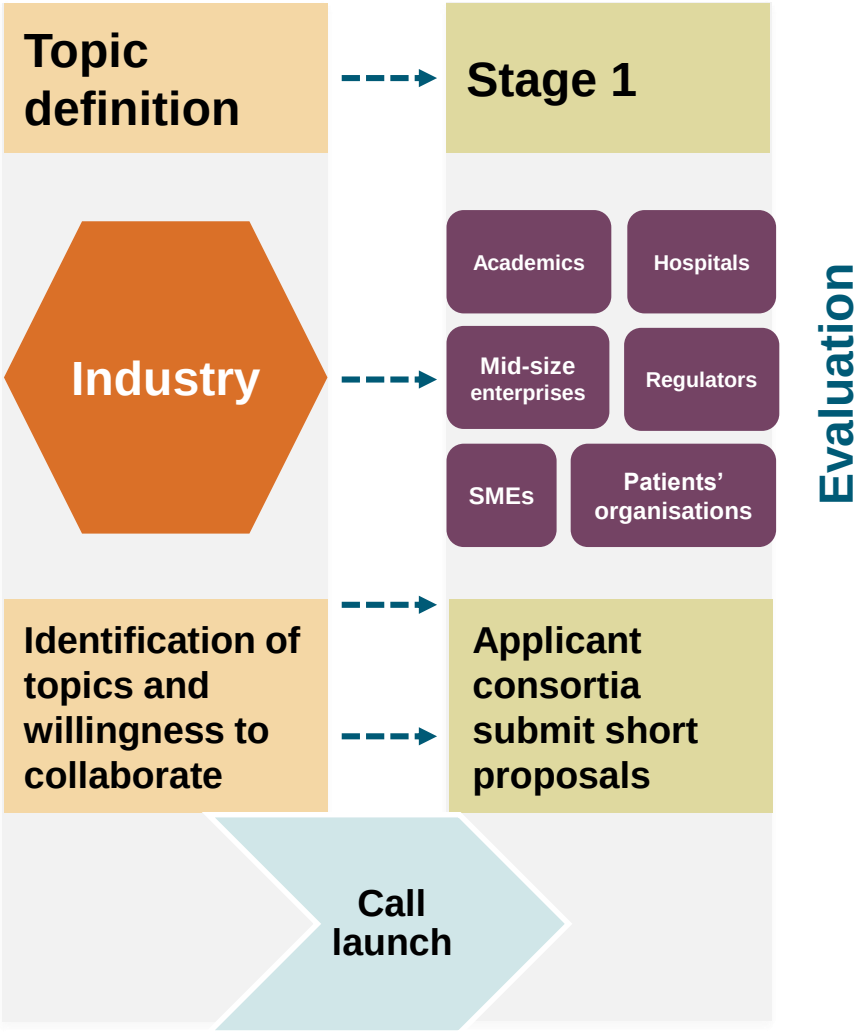
Typical IMI project life cycle



Typical IMI project life cycle



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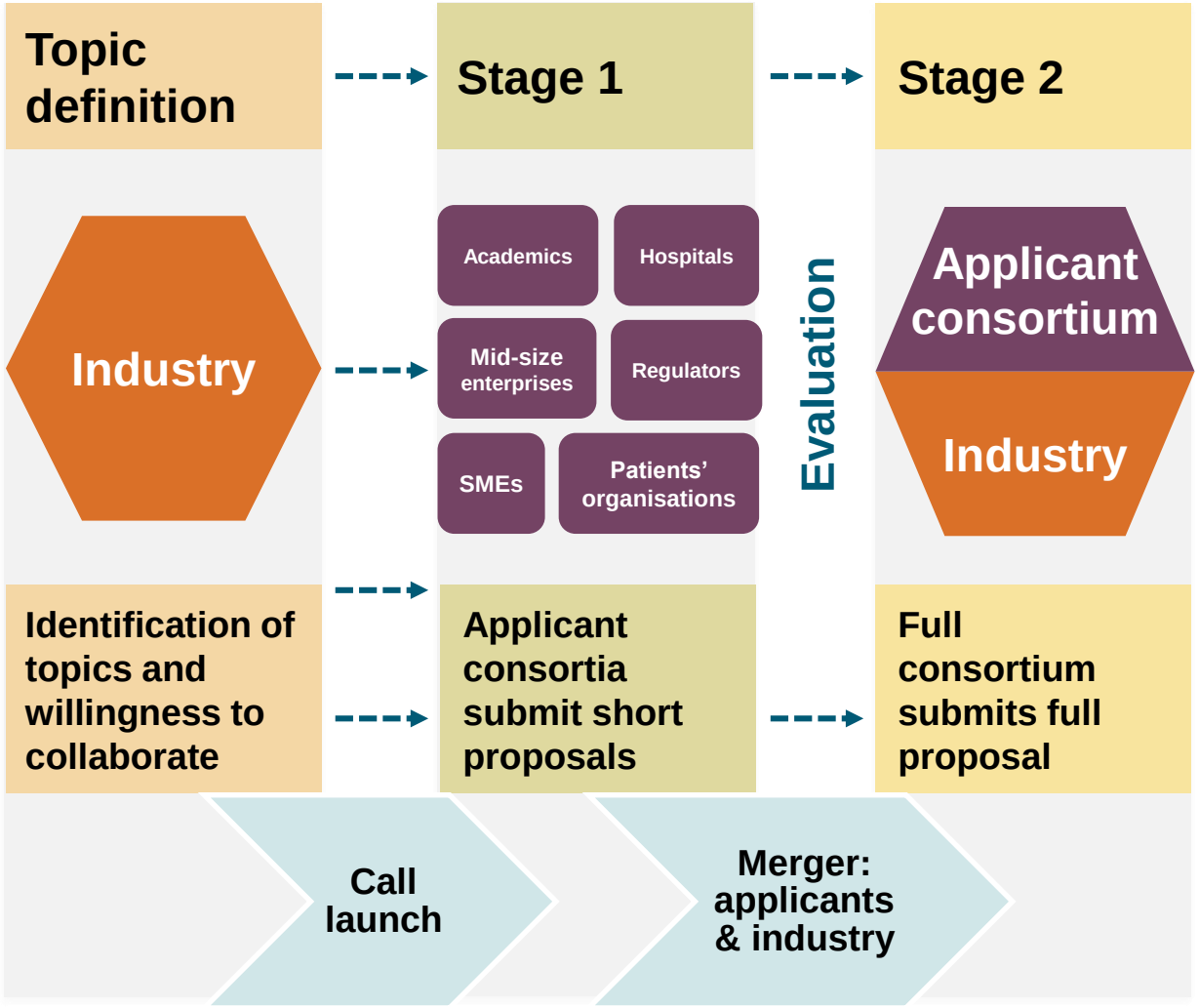
Typical IMI project life cycle



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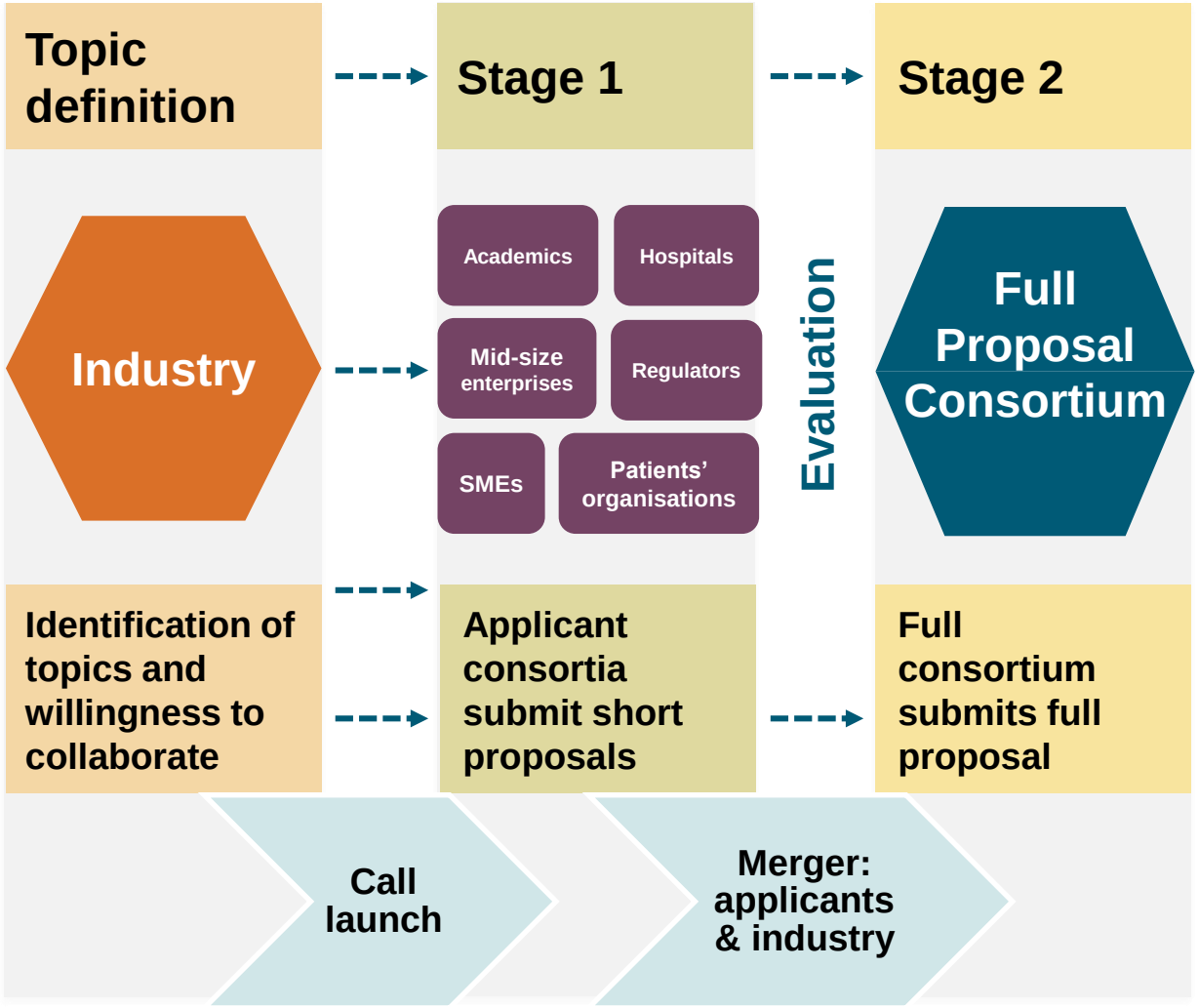
Typical IMI project life cycle



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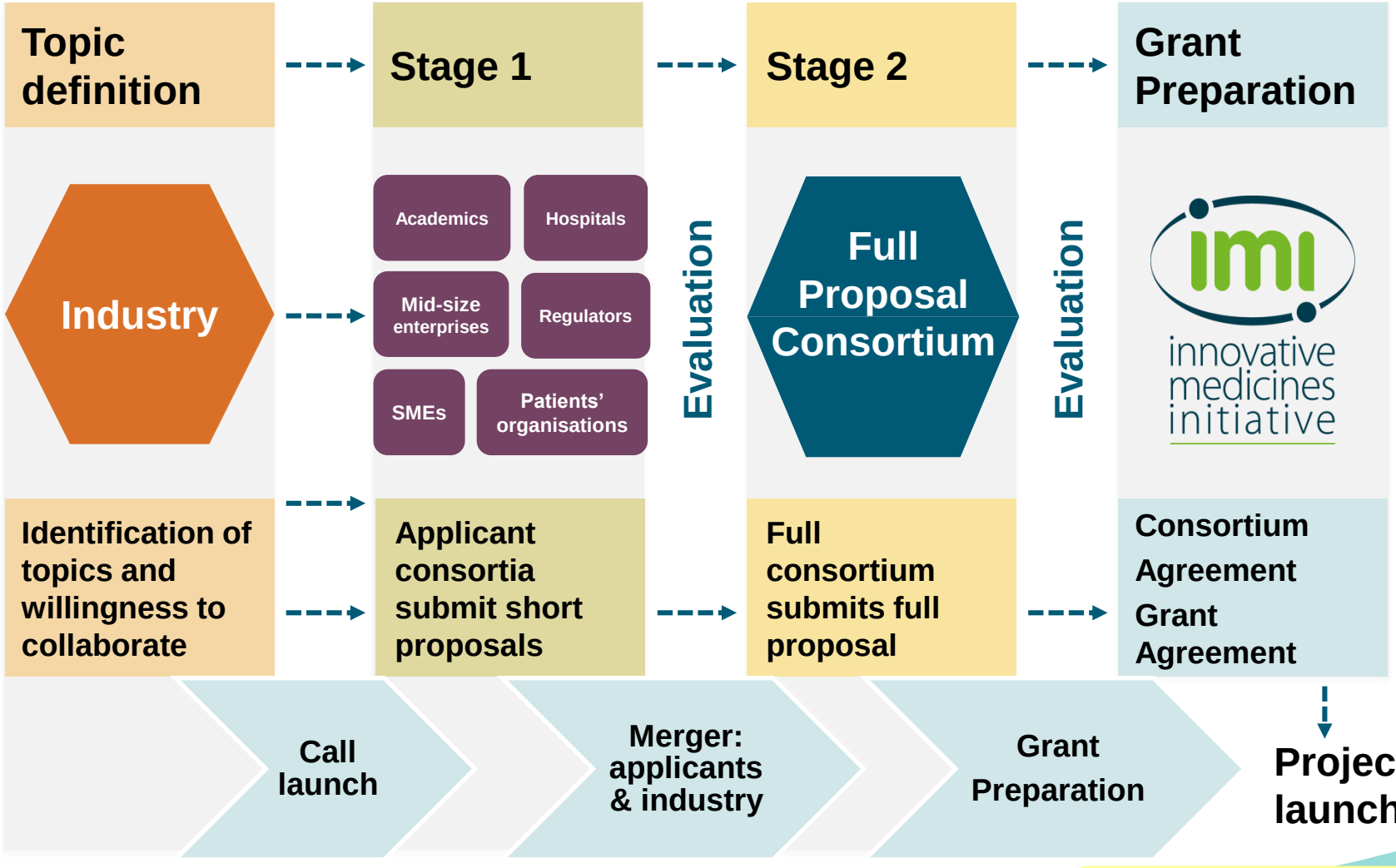
Typical IMI project life cycle



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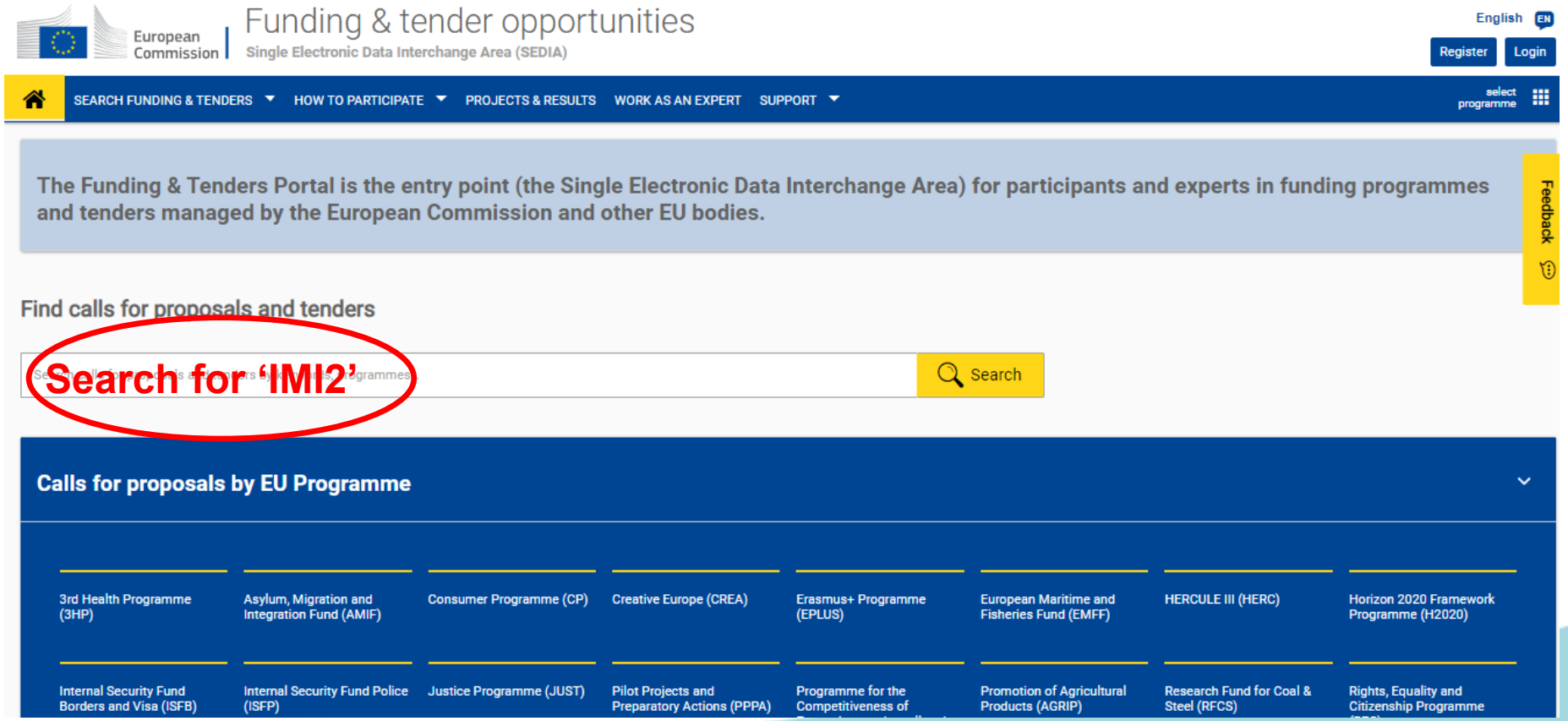
Expected GA signature – Sep/Oct 2020

Submitting a proposal

Via the **new** Funding and Tenders Portal

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



Proposal Template – Newly updated

- 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) – Newly updated

- **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) – Newly updated

- **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.

New 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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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

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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 topic
- 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://europa.eu/!QU87Nx
  - German NCP partner search tool: www.imi-partnering.eu
- Get in touch with your **local IMI contact point**:

  https://europa.eu/!xb69Gg
- 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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Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project

Giovanna Ferrari

21.06.2019 • IMI webinar

Health information in the digital age

Accessing and understanding of health information are components of health literacy, which in turn affects the **day-to-day decisions citizens make in the management of their health and care**, e.g. in relation to adherence.

ACCESSING

- High volumes of information, not always reliable/up to date
- Multiple, fragmented sources (combination of paper/electronic)
- Existing best-practice electronic tools not available in all markets, may not meet full breadth of patient needs

UNDERSTANDING

- Health-related resources generally not personalised to an individual's needs or health literacy level
- The patient leaflet is a key resource however no feedback on how content is being understood/applied in a real-life setting

How can we apply digital technologies to transform the way in which patients access and understand health information, and apply this in managing their health and care?

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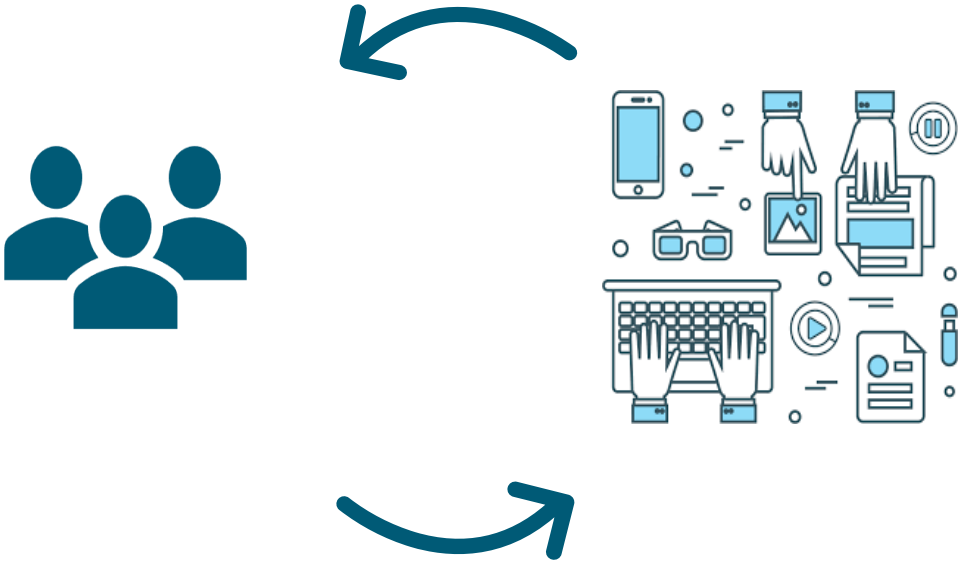
Digital health information: taking an integrated patient-centric approach



Electronic Health Records (EHR)

Regulator-approved electronic product information (ePI)

Plus: Health education materials

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Need for public-private collaboration

- A public-private partnership is a unique mechanism to bring together the **diverse stakeholders inputs** needed to **achieve the transformational aims of the project** and **deliver sustainability**.
- For example:
  - Patient and health professional organisation perspectives
  - Academic and research institutions (e.g. research methodology)
  - Contributors with specific expertise (e.g. health literacy, RWD, legal, social sciences)
  - Input from regulators (e.g. for alignment with ongoing initiatives)
  - Technology partners (e.g. ePI providers, EHR experience)
  - Other technology organisations and developers
  - Cross-functional pharmaceutical industry expertise

Objectives of the full project

- **Primary objective:**
  - To demonstrate how the use of an **integrated, digital, user-centric health information solution** could enable a **tangible improvement** in the ability of citizens to **access and understand reliable, relevant health information** from different sources.

- **Secondary objective:**
  - To measure **how improved access to/understanding of health information translates into higher levels of treatment adherence**, safer use of medicines and consequently better health outcomes, with new insights into how health information can be optimised to act as an effective risk minimisation measure.

Pre-competitive nature

- Neutral platform for stakeholder collaboration in the context of project activities
- Project deliverables to be published (research outcomes) and/or made available open-source for future development (technology elements)
- Lay foundations for most effective longer term application of digital technologies to health information
- Sustainability plan to include recommendations for how successful concepts/technology approaches can be implemented into digital healthcare ecosystem
- Aligned to relevant ongoing regional initiatives (e.g. EU Digital Single Market Strategy, EMA draft key principles for ePI)
- Note: any form of promotional materials out of scope

Expected impact

- A **digital transformation** of the way in which patients engage with and manage their health and care throughout their healthcare journey.....
  - **Enable patients to easily access and understand trusted health information, tailored to be relevant** to their needs
  - Further **build patients' (digital) health literacy**
  - Positively impact health care at a societal level by **enhanced adherence**, driving better use of medicines and patient outcomes
  - **Improve the effectiveness of ePI** as a risk minimisation tool
  - **Availability of a technology platform/tool** which can be further developed in line with local healthcare ecosystems

Suggested architecture of the project

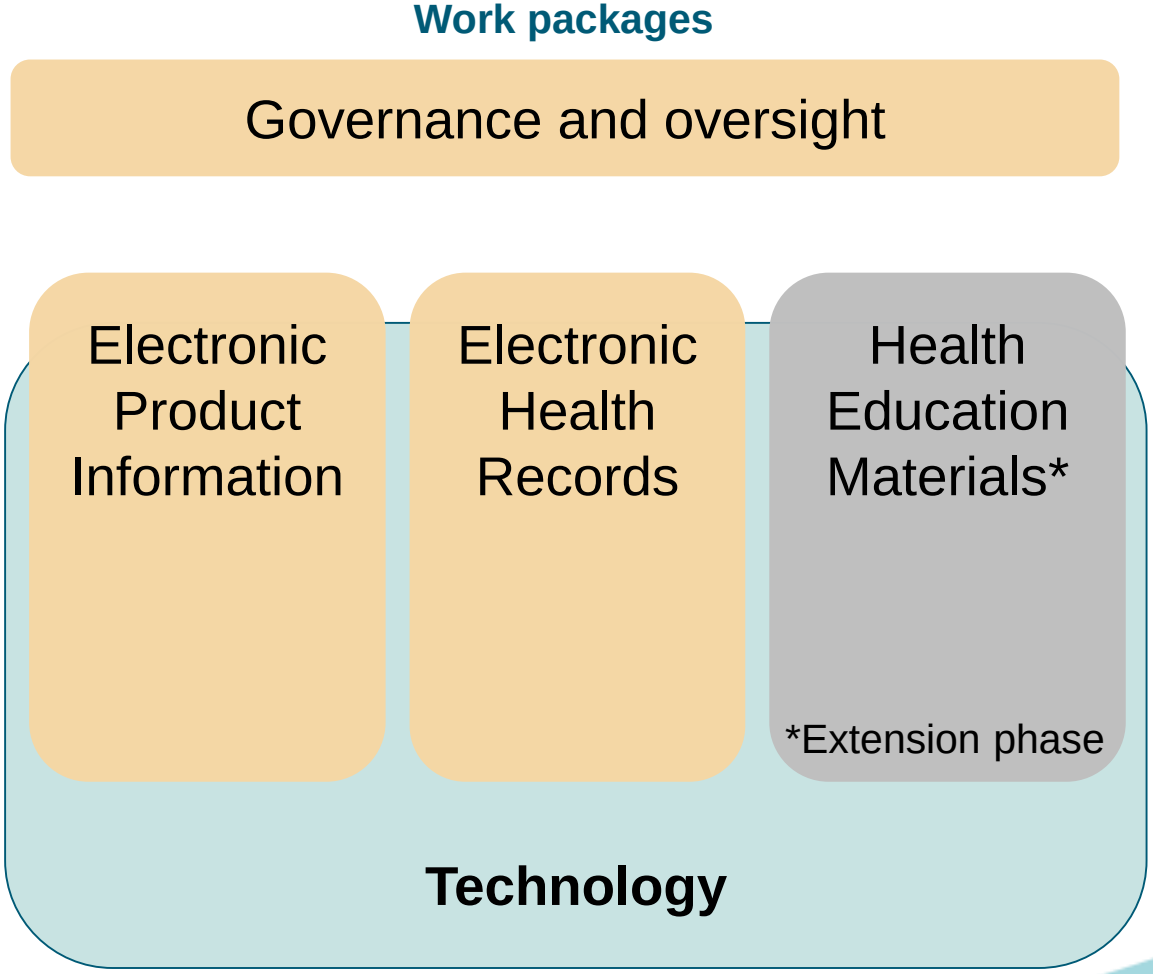
Project phasing

Phase 3:
Source, develop, test across **integrated** information areas

Phase 2:
Source, develop, test across **individua**l information areas

Phase 1:
Establish stakeholder needs, KPI definition, technology planning

Ongoing:
Development and execution of a sustainability plan



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Expected contributions of the applicants (1)

- **Patient groups/healthcare professional groups** to ensure that the **perspective of the end user** is taken into account fully in the research scope
- **Academic and research institutes** specialising in the **provision/use/understanding of health information**, who can support the definition of appropriate KPIs relating to the two key objectives, and development of an appropriate methodology for testing to demonstrate patient understanding and impact
- Expertise in **gathering/use/analysis of real-world data and risk-benefit assessment** to consider impact on risk minimisation

Expected contributions of the applicants (2)

- **Technology partners, including SMEs**, who have experience in **electronic health records, provision of health information** (for example current leaders of national electronic product information initiatives), **platform integration and development of user-centric solutions** within a highly secure environment, and provision of business/regulatory information technology.
- Expertise on the **legal, ethical, social science and GDPR questions** arising from the proposed work
- Ideally, **national competent authorities** would be part of the applicant consortium to ensure wider alignment with relevant initiatives

Expected (in kind) contributions of industry consortium

Functional expertise across a range of disciplines aligned to the project scope and objectives, including:

- Development and maintenance of product information, including electronic product information
- Importance of health literacy and provision of high quality medical information to patients
- Use of real-world data to improve understanding of product safety and effectiveness
- Business technology expertise concerning development of systems, processes, and data standards to support regulatory processes
- Knowledge of development/implementation of EHR systems.

What's in it for you?

Patients' organisations:

Co-creators in the development of digital healthcare approaches that can be demonstrated to truly add value from the patient perspective and address unmet needs

Academic researchers, research institutions, specific experts:

Collaborate with different sectors in cutting-edge research to define how digital tools can be applied in the context of healthcare to achieve meaningful benefit to the patient, and enhance risk management

Technology partners/SMEs:

Play a leading role in the development of innovative technology approaches for health information with potential broad longer-term applicability in a healthcare setting

Regulators:

An opportunity to consider alignment with other relevant initiatives (e.g. ePI) and assess how beneficial concepts/outputs could be embedded into the digital health ecosystem of the future and relevant regulations

Key deliverables of the full project (1)

- An **open-source technology platform** that **integrates content from regulator-approved product information** and **electronic health records** (potentially health education materials)

- A **digital technology solution** that allows **digital health information to be presented to the patient in a tailored, user-friendly manner** to better meet the needs of patients in managing their health and care

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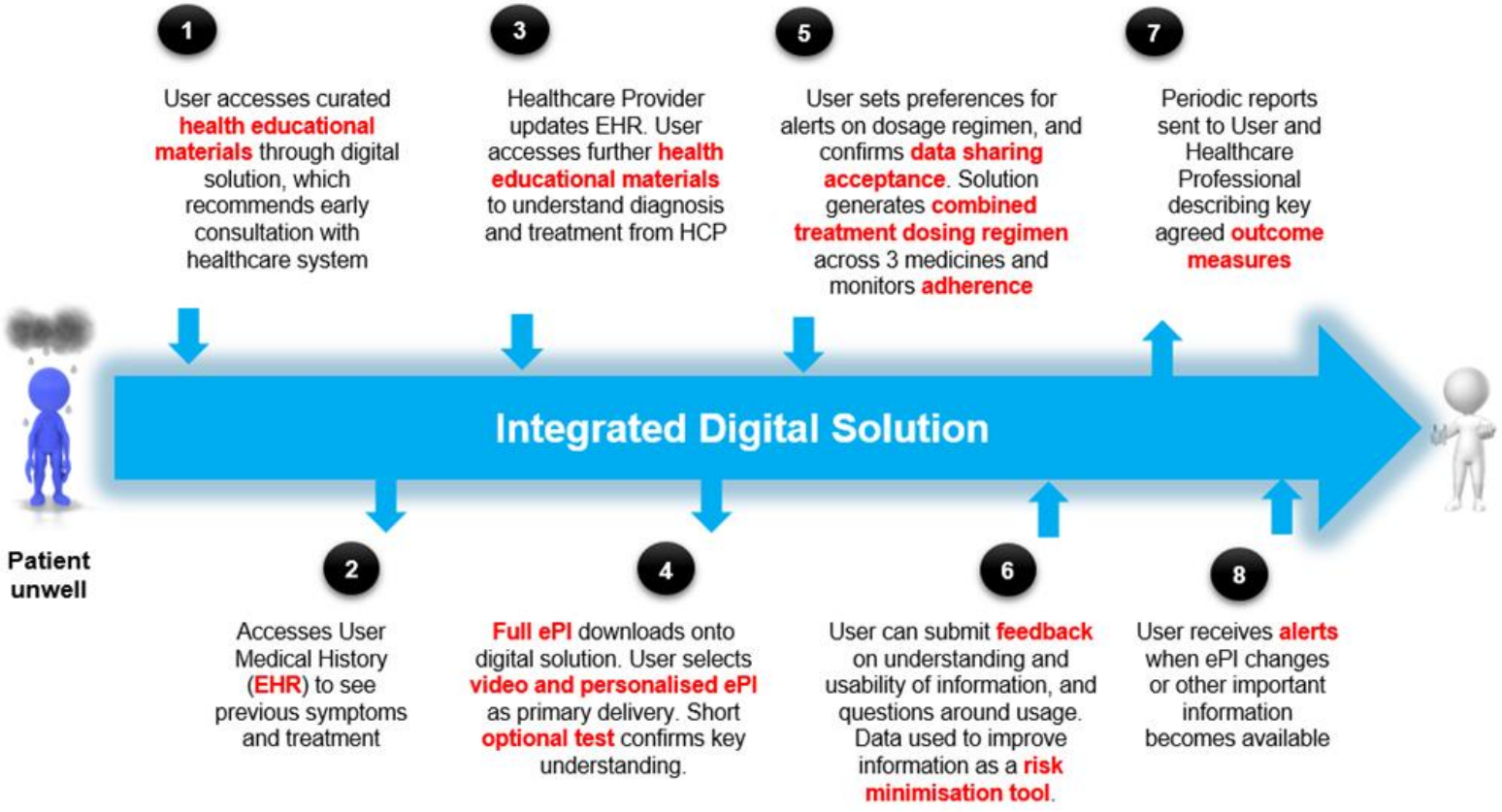
Key deliverables of the full project (2)

- **Various publications** including the following:
  - A **series of study reports** presenting the outcomes of research studies to demonstrate the benefit that this integrated digital approach offers to patients
  - Details of **key stakeholder needs in terms of information, personalisation and functionality**
  - Evaluation of potential ability of digital solutions to **enhance role of ePI in risk minimisation**
  - **Recommendations** as to how successful concepts can be taken forward for **implementation**
  - Details of **data source specifications,** report on key features for **future standards for ePI**

The future state: an illustrative use-case



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Involvement of SMEs, patient groups, regulators

Colm Carroll, IMI

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 :

- Technical expertise that could support the **platform integration and development of user-centric solutions**
- Expertise in **electronic health records**
- Expertise in the **provision of health information** (for example current leaders of national electronic product information initiatives)

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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;
  - ensure that the **perspective of the patient as an end user** is taken into account fully in the research scope
  - the development of **appropriate KPIs** relating to the two key objectives
  - proof of concept **testing**
  - **community outreach and dissemination**

"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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Questions?

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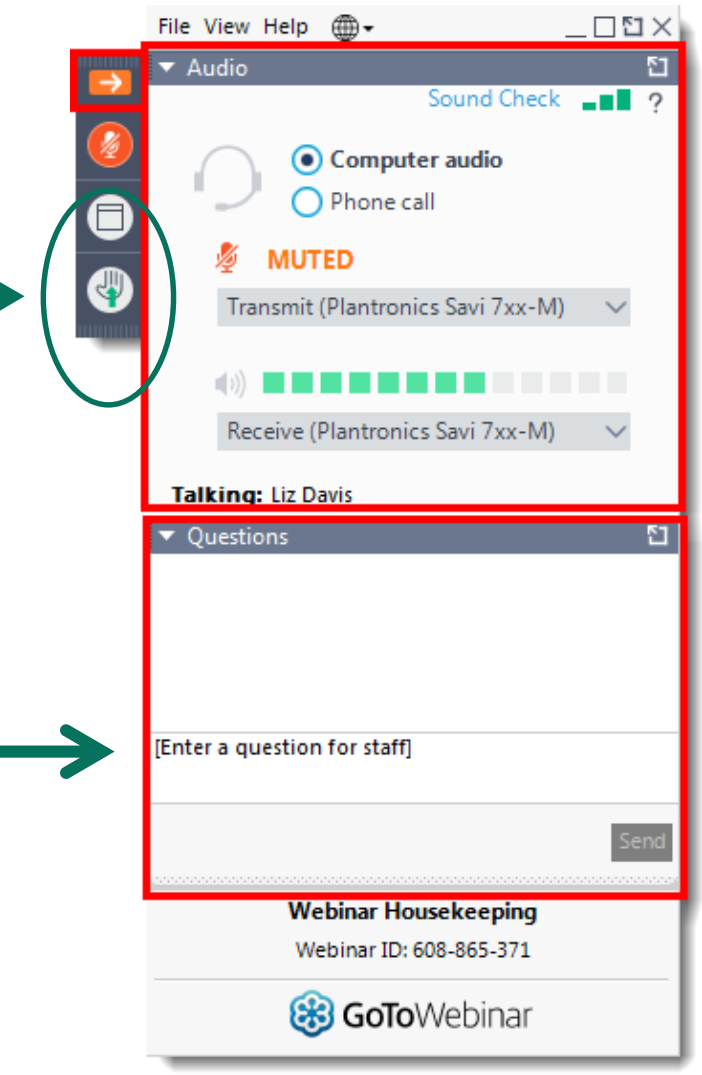

After the webinar, send any questions to the **IMI Programme Office**

applicants@imi.europa.eu

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