Webinar | IMI2 - Call 23
Optimal treatment for patients with solid tumours in Europe through artificial intelligence

25.06.2020

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Oussama Karroum, IMI
- The Call topic – Hagen Krüger, Pfizer
- Involvement of SMEs, patient groups, regulators – Oussama Karroum, IMI
- Questions & answers

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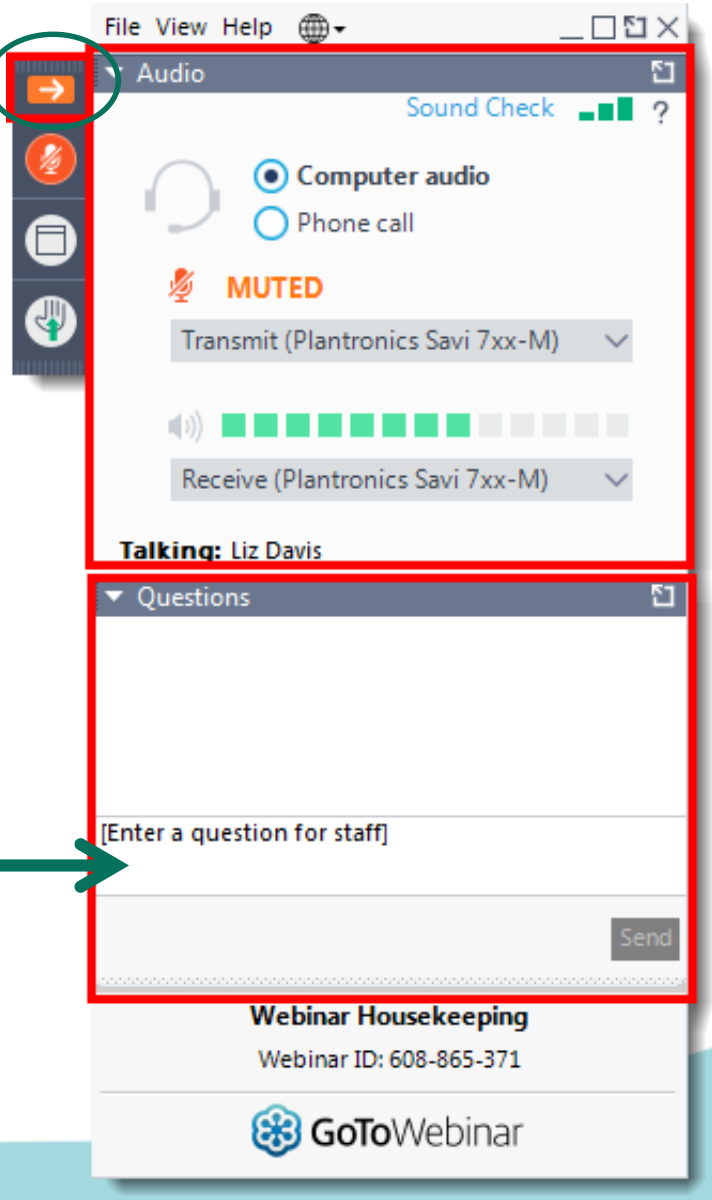

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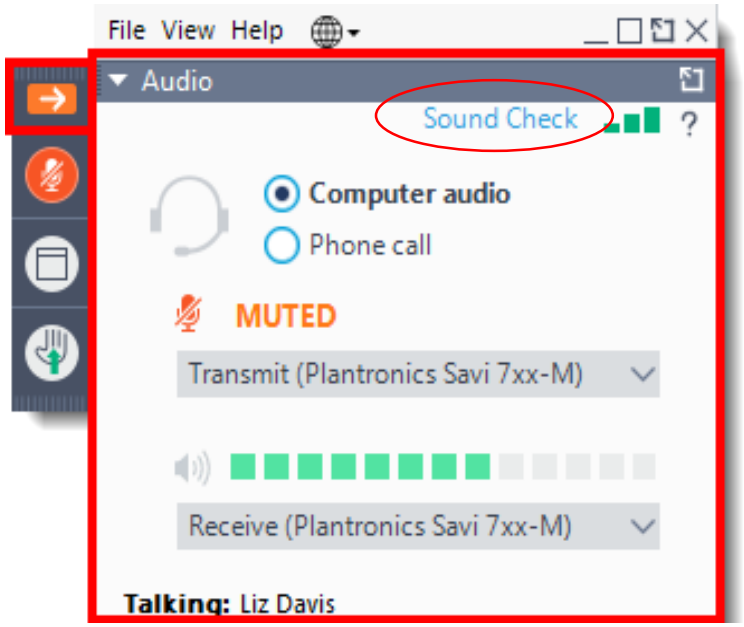

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Before we start…

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

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Webinar | IMI2 - Call 23

Optimal treatment for patients with solid tumours in Europe through Artificial Intelligence

Oussama Karroum, PhD
IMI Scientific project officer
25 June 2020

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

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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

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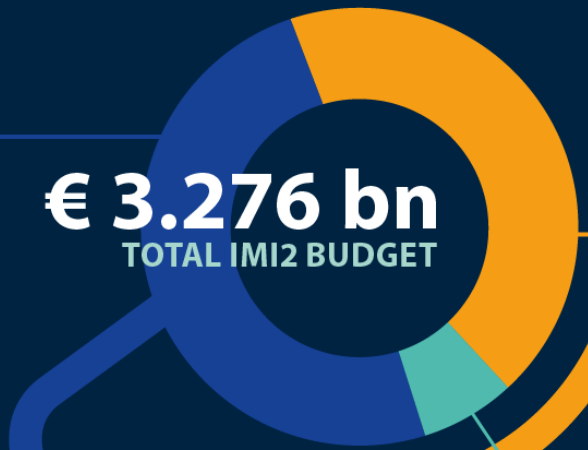
IMI2 funding
(2014-2020)

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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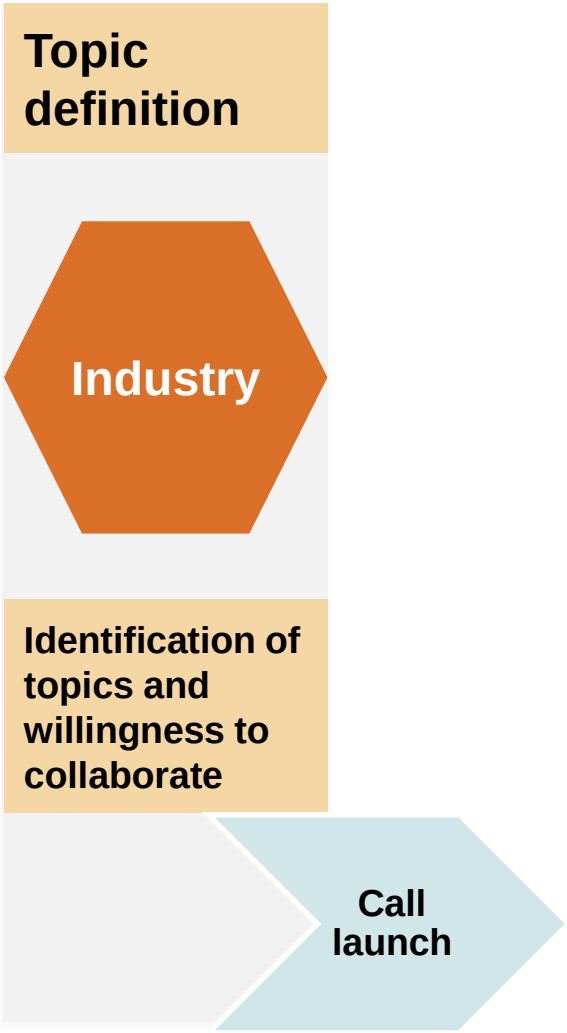
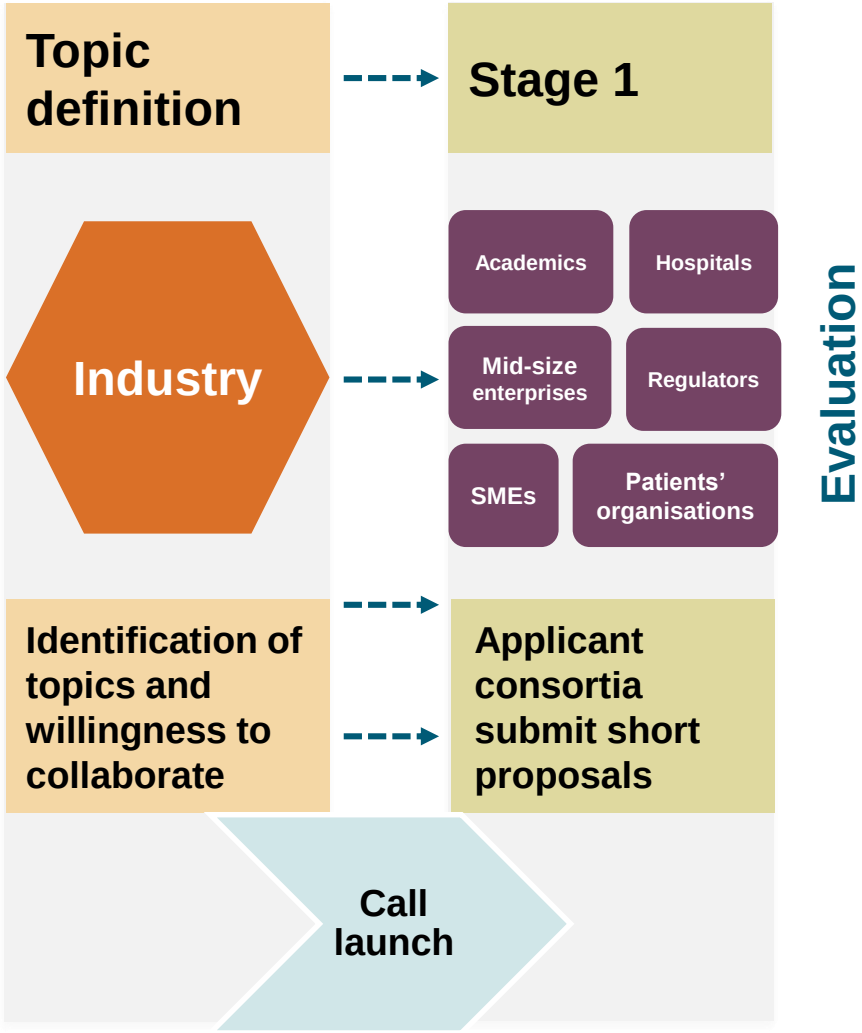
Typical IMI project life cycle



Typical IMI project life cycle



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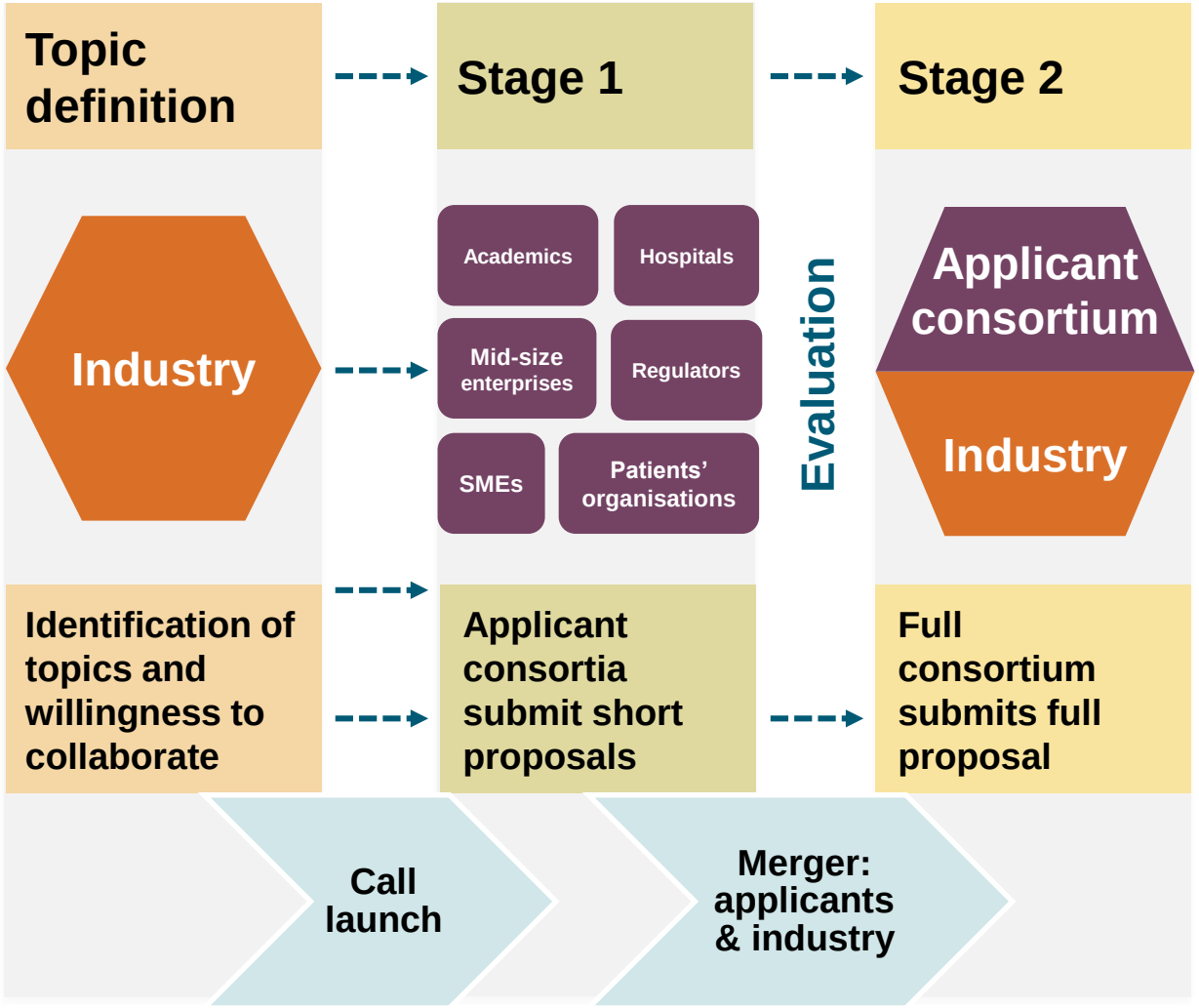
Typical IMI project life cycle



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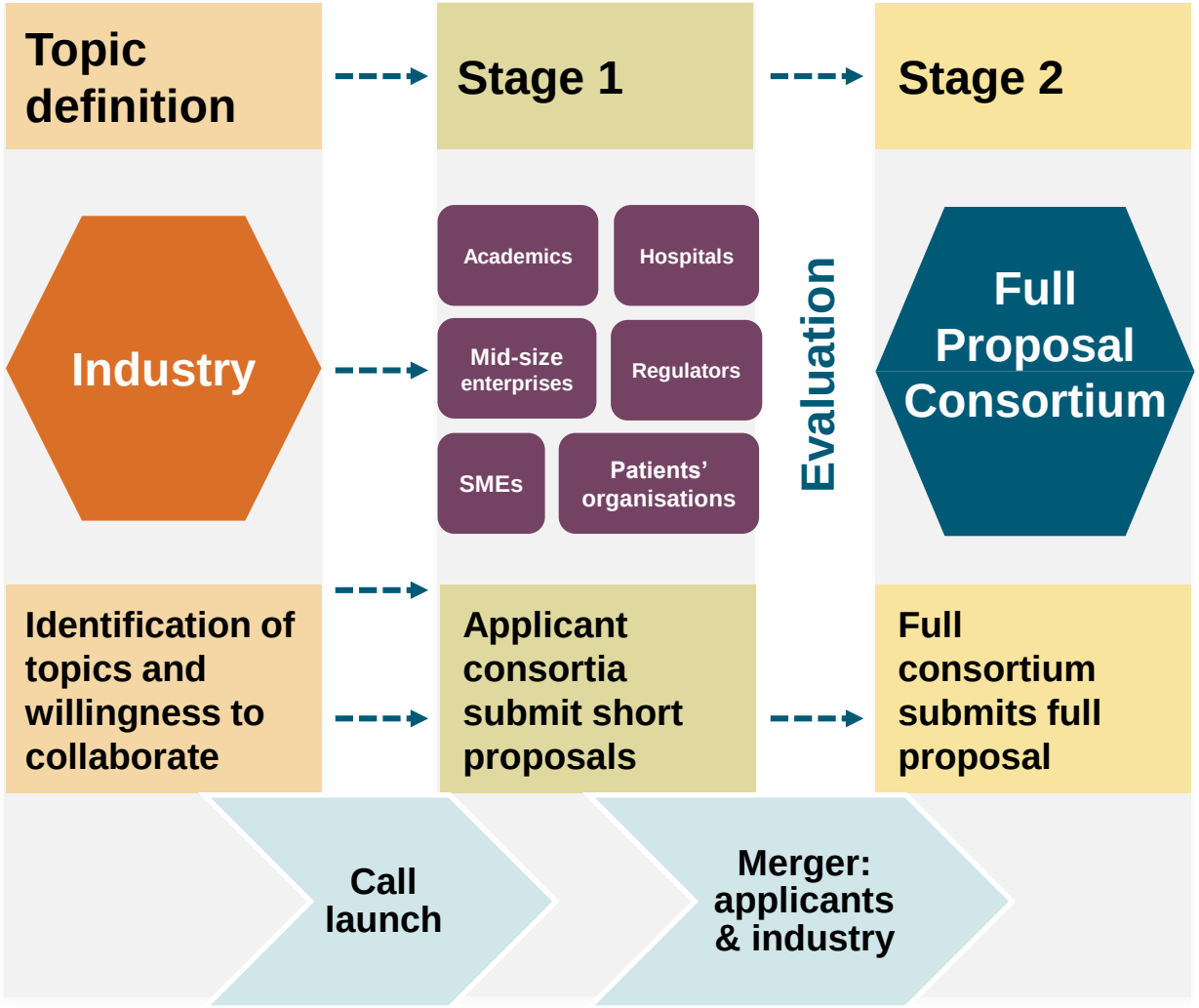
Typical IMI project life cycle



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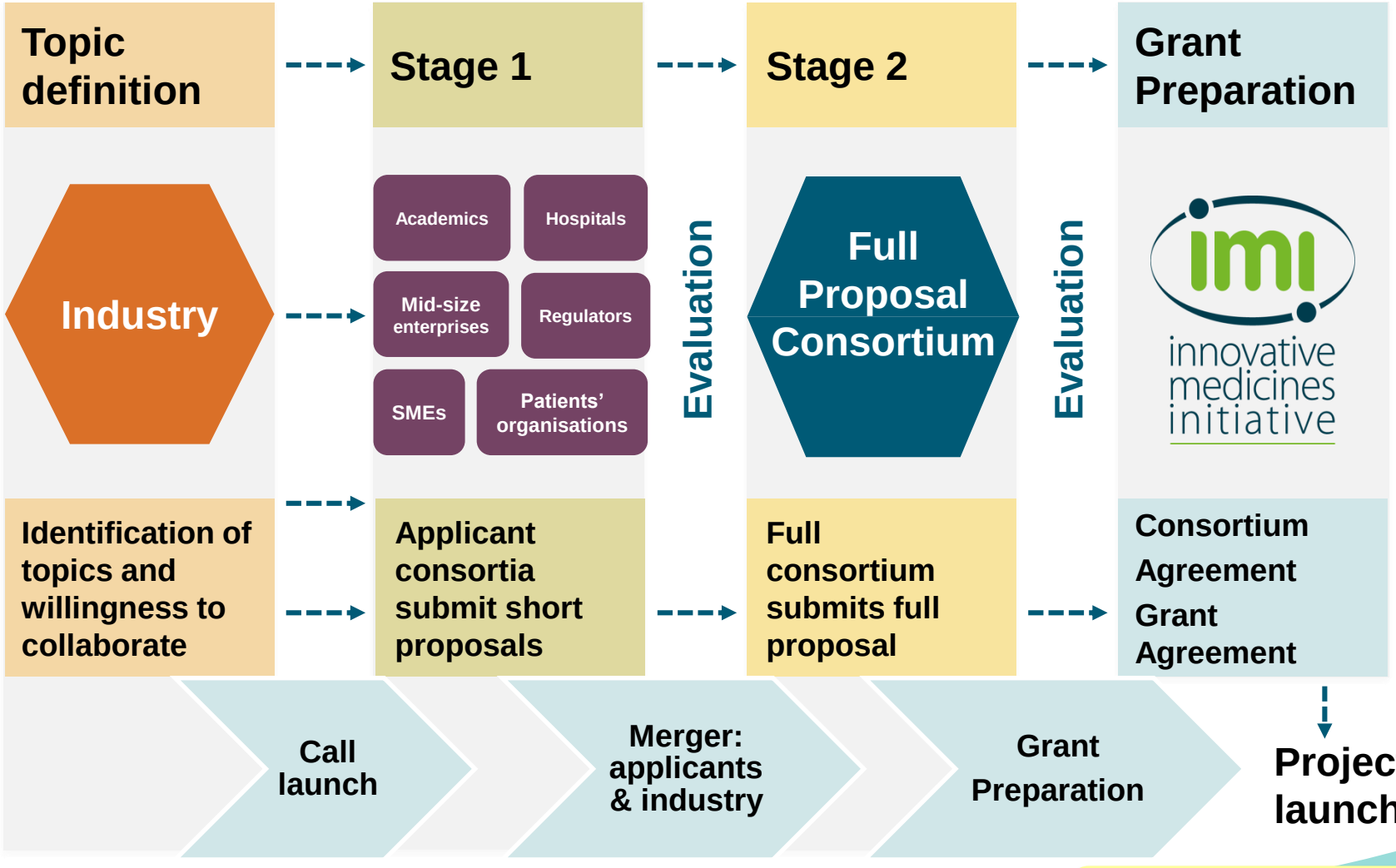
Typical IMI project life cycle



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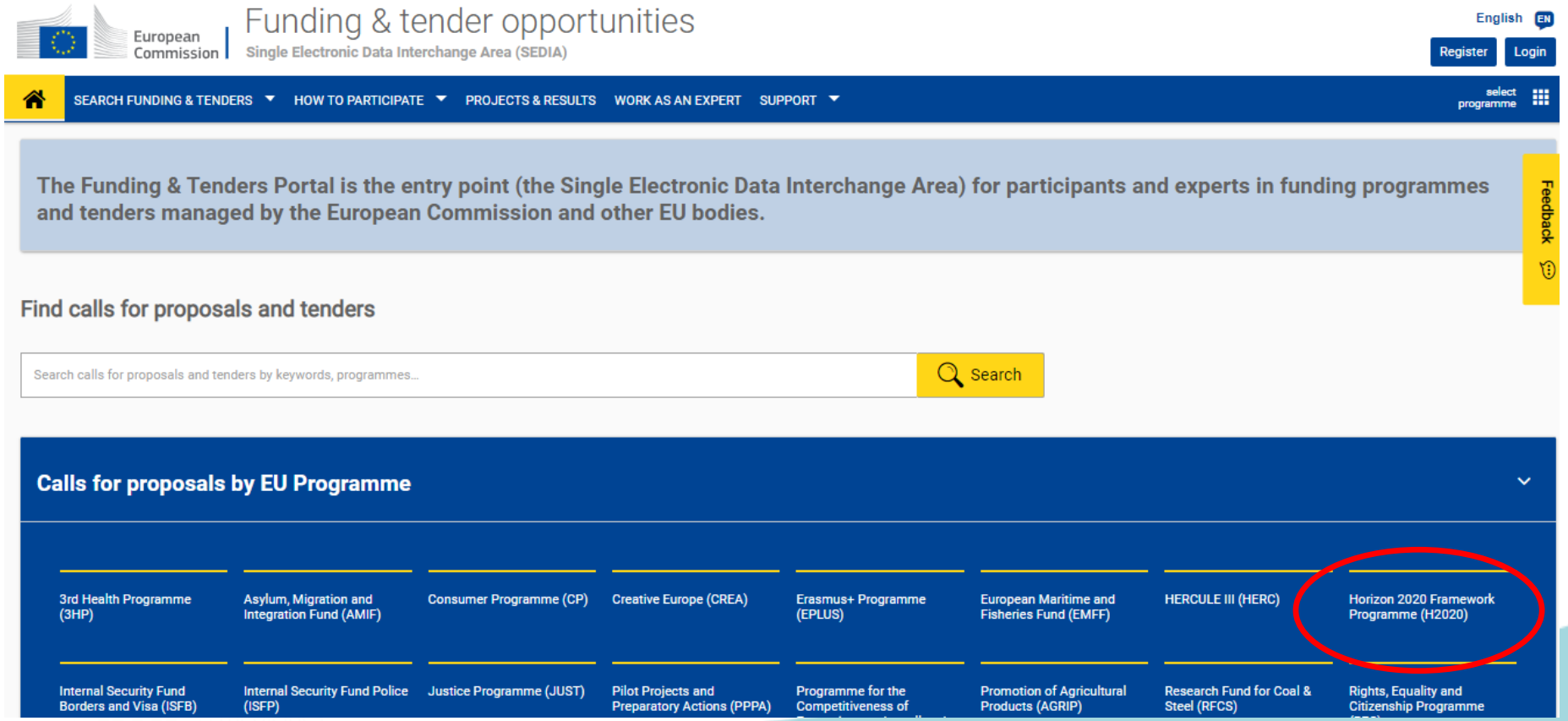
Expected GA signature – Summer 2021

Submitting a proposal

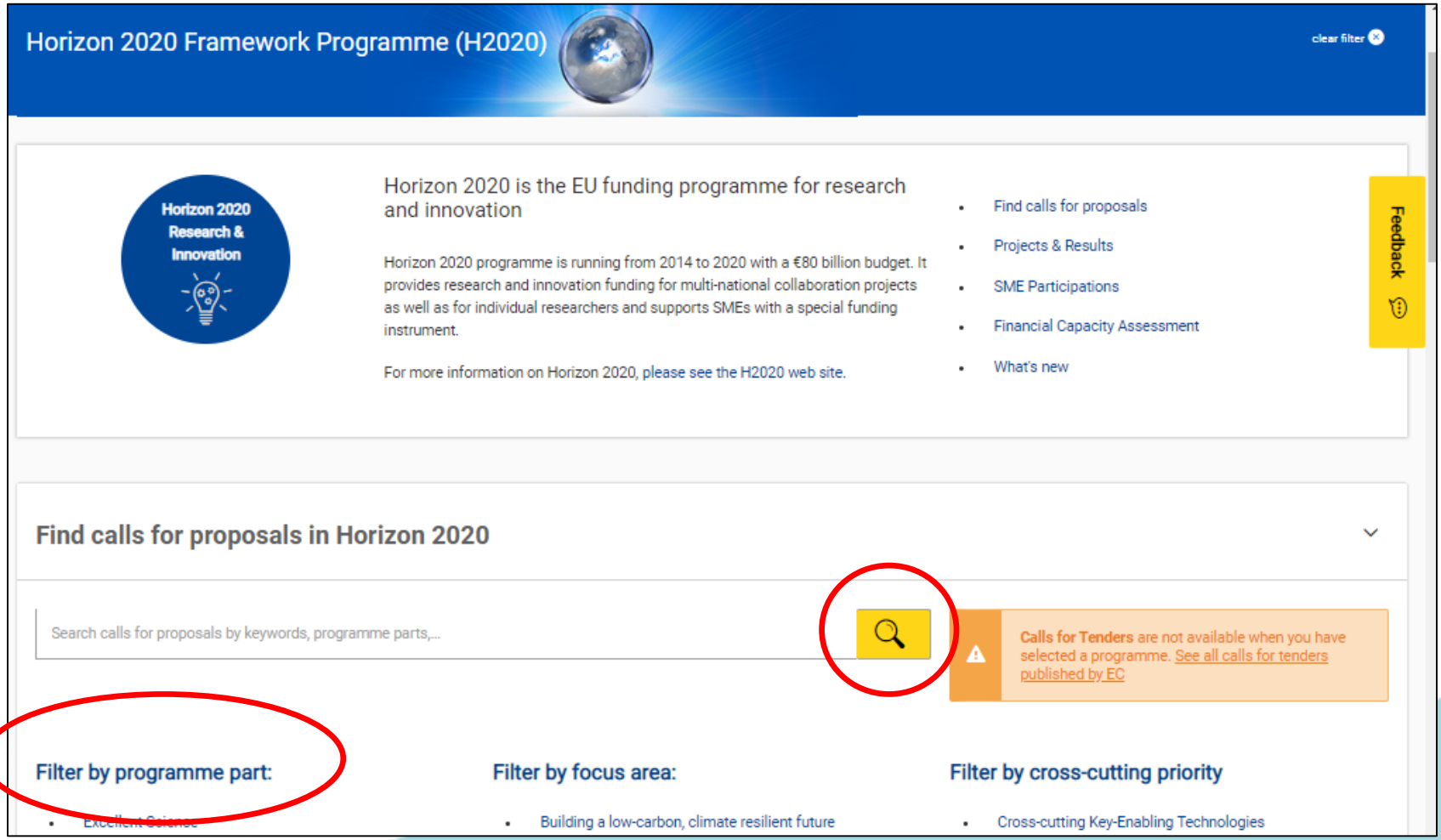
Via the **new** Funding and Tenders Portal

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



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.

- 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://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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Topic 4: Optimal treatment for patients with solid tumours in Europe through Artificial Intelligence

Dr. med. Hagen Krüger

25.06.2020 • IMI webinar

Project background

- **A multitude of new therapeutic agents to treat cancer will be marketed** within the coming years.
- **Choosing the optimal treatment and treatment sequence for the right patient will thus become increasingly complex** and includes genetic analysis, specific tumour biology and biomarkers.
- **To become familiar with the huge volume of available information, physicians need to continuously inform themselves** about guideline changes and marketed treatments and **individual patient data needs to be complete** regarding all reasonably targetable pathways.
- However, **HCPs´ time for continuing education is limited.**
- **Hence, there is a need to provide physicians solutions for real time decision support in oncology** to empower them to choose from the many available treatment options and **ensure that breakthrough medicines reach patients in need.**

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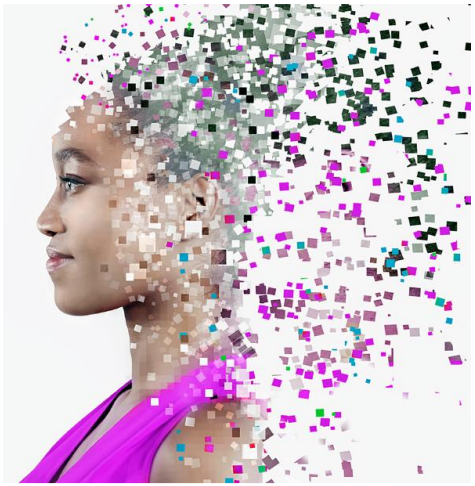
Treatment decision making using AI: Taking patient-centricity to the next level



Digitally assisted guideline based decision support

Data platform: EHRs, real world study data

AI-supported real world knowledge base

Oncologist **Patient** **Project**

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www.accenture.com/healthtechvision,
https://www.accenture.com/_acnmedia/PDF-78/Accenture-digital-health-tech-vision-2018-infographic.pdf , assessed June 4, 2020

Need for public-private collaboration

- A public-private partnership is a unique mechanism to bring together perspectives of public and private stakeholders needed **to achieve the transformational aims** of this project fast and **to achieve long-term sustainability**.

- **Important stakeholders**
  - Medical societies
  - Patient advocacy groups
  - Academic and research institutions
  - Companies with specific technical expertise (e.g. data extraction, data storage, AI algorithms)
  - Technology partners (e.g. for alignment with national initiatives)
  - Cross-functional pharmaceutical industry expertise

Objectives of the full project

This project focuses on the three prioritized indications breast, lung and prostate cancer:

- **Objective 1:**
  - To develop a **decision-support tool** that automatically extracts relevant clinical information from EHRs and **facilitates guideline-compliant treatment** approaches for the solid tumors.
- **Objective 2:**
  - To establish a **structured and interoperable data platform** to unlock real-world-data in an oncology network across in-patient (e.g. academic centres, teaching hospitals) and out-patient (community and private practices) settings.
- **Objective 3:**
  - To establish an **AI-knowledge base to support treatment decisions** and to generate novel research hypotheses.

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Pre-competitive nature

- Neutral platform for public-private partnership in the context of project objectives
- Establish use case for effective AI application to optimize complex decision making process regarding oncology treatments
- Project deliverables to be published (research outcomes)
- Sustainability plan to include recommendations on how to implement the outputs into existing healthcare ecosystem

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Expected impact

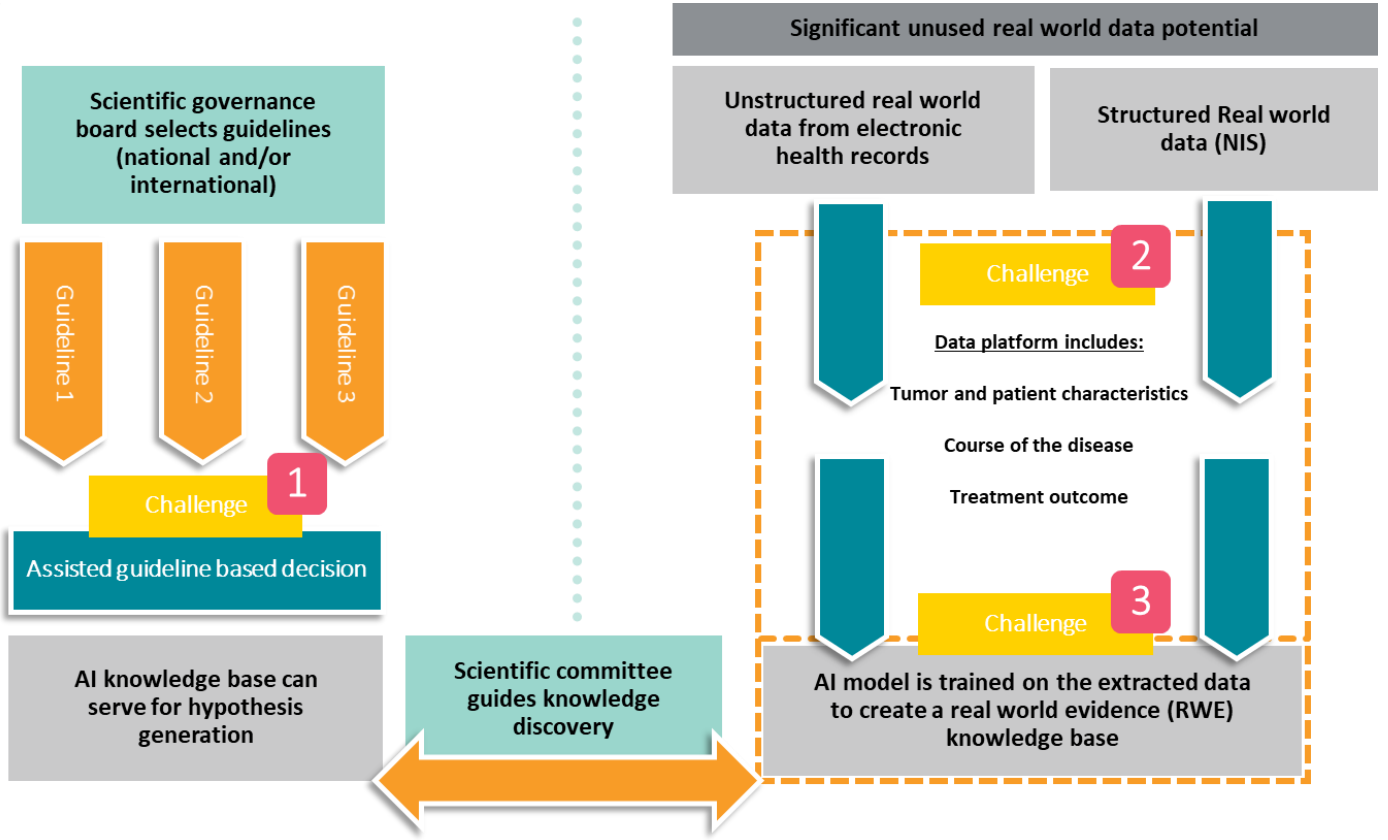
- Patients benefit from optimal guideline-based cancer treatment.
- Future breakthrough medicines reach patients sooner.
- HCPs are given a reproducible and transparent advice to support complex decision-making processes.
- HCPs and cancer patients will be able to compare individual outcomes of different treatment sequences in real-time to allow for truly personalized therapies.
- HCPs will save valuable time due to the automatic assessment, data gathering, and integration of relevant sources of evidence.
- Acts as a much-needed foundation for further research.

Suggested project architecture

1. The scientific governance board selects appropriate guidelines. Based on these guidelines, a transparent decision support tool is delivered.

2. Real world data from electronic health records and non-interventional study data is collected and analyzed.

3. AI is used to develop a knowledge base and generate new hypotheses that can be evaluated in further trials.



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Expected contributions of the applicants

- **Patient organisations and regulatory authorities** to specify the requirements and boundaries of AI-driven data processing, data security and privacy as well as individual data ownership
- **Medical societies** to provide the network of participating in- and out-patient clinics to enable data access
- **Medical experts/institutions** to specify AI approaches, validate the decision support and set the requirements for general acceptance
- **Life-science companies** to contribute study data for the evaluation of therapeutic approaches, as well as expertise in data mining and data-set merging

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Expected contributions of the applicants (2)

- **SMEs** for infrastructure set-up, data management and data security, AI-driven data processing and merging of unstructured information, visualisation and user experience design

- **Network of clinics (in- and/or out-patient)** with ability to provide access to patient level electronic health records

Expected (in kind) contributions of industry consortium

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

- **Personnel with expertise in oncology, AI algorithm implementation, real-world data**
- **Real-world data from (non) interventional studies** supplementing the public partner cohorts.
- Technical support with **statistics, data mining and merging large data sets** from various sources
- **Knowledge and expertise in legal**, ethical and regulatory issues

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What's in it for you?

Patients' advocacy organisations:

Co-creating in the development of new digital healthcare tools ensures that the patient perspective is taken into account fully and addresses patient unmet needs

Medical societies, academic researchers, research institutions, specific experts:

Ensures scientific leadership with the oncologist perspective, validate the decision support and set the requirements for general acceptance

Oncologist networks and hospital chains :

Collaborate in cutting-edge research and state-of-the art data access, to achieve meaningful benefit to the patient and optimize cancer care

Technology partners/SMEs:

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

Regulators:

Contribute to the development of digital tools that can benefit public health, and help shape the future digital health landscape, enhance risk management

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Key deliverables of the full project (1)

- A **decision-making tool based on national /and or international guidelines for the three indications breast, lung and prostate cancer** that automatically extracts and validates relevant clinical information from EHRs while ensuring adherence to existing regulatory and legal requirements

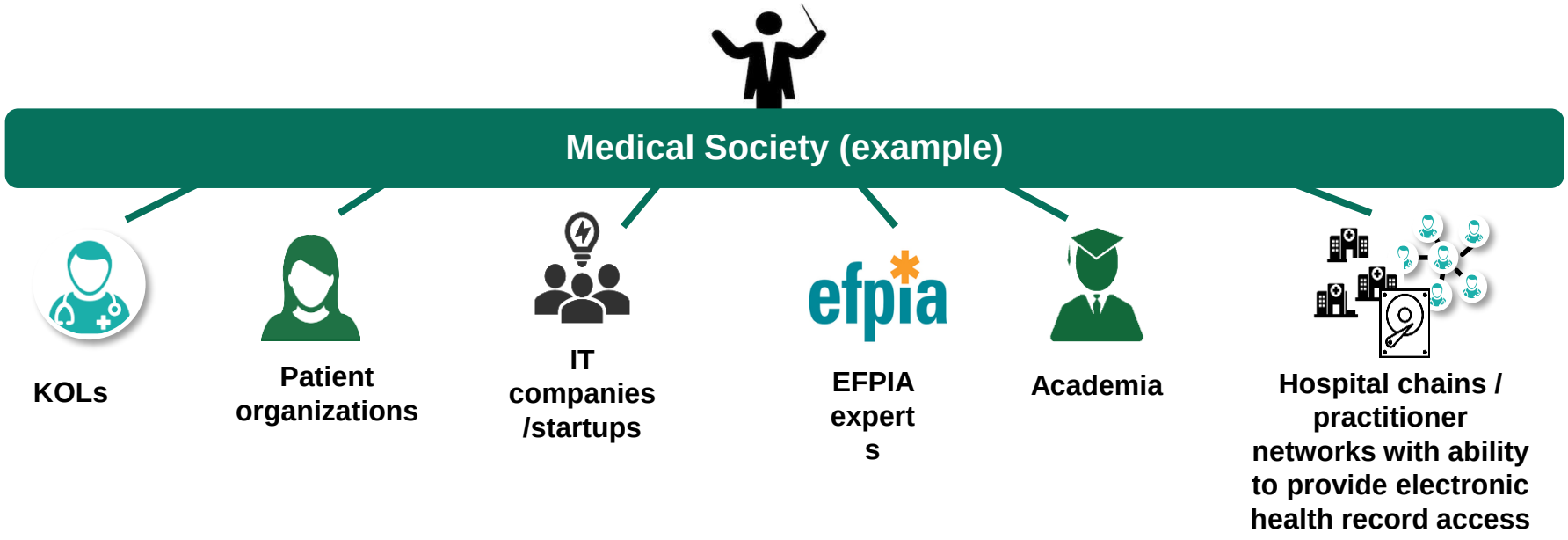
- A **database for real-world treatment outcomes** based on secure and interoperable **cloud-based data storage** and derived from patients in countries that have access to cancer treatments suggested by treatment guidelines. The real world data base needs to be **integrated into existing clinical IT infrastructures** across various geographies and IT infrastructure differences

Key deliverables of the full project (2)

- **An explainable AI-based knowledge discovery platform**
  - Monitors the impact of various personalised medical treatments as well as the associated cost and outcome
  - Integrates verified knowledge (e.g. progression-free survival, overall survival, quality of life and adverse events) into the indication-specific knowledge base
  - Integrates simulation features, e.g. to simulate therapy response, side-effects, quality of life or other outcome-related factors based on prediction modelling
  - Is guided by a scientific review committee
  - Allows data analyses by consortium members and third parties after approval of the scientific review committee

A successful consortium needs collaboration of public and private stakeholders across multiple organizations

Possible consortium structure for illustration (example). The consortium structure is proposed by the applying public partners.



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The future of cancer care in the AI age

1 Oncologist is guided through the decision-support platform regarding essential patient data to establish a treatment proposal

2 the decision-support platform recommends 2 further mandatory diagnostic procedures to establish a treatment proposal

3 The treatment proposal is reviewed in a tumor board and agreed on

4 outcomes data like quality of life and adverse events, progression-free survival from routine visits are regularly entered into the real-world database

5 An AI Algorithm discovers a patient subgroup with certain parameters who has a longer overall survival and better QoL with a certain treatment sequence

6 After scientific review committee approval this treatment sequence will be prospectively evaluated and offered to the patient

Patient enters oncologists network/ hospital having the call‘s IT-solution up and running

Optimized cancer care for patients with solid tumours through Artificial Intelligence

Cancer patient has a better quality of life and longer overall survial by optimized treat-ment sequence

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Figures: https://www.accenture.com/_acnmedia/PDF-78/Accenture-digital-health-tech-vision-2018-infographic.pdf , assessed June 4, 2020

Thank you

www.imi.europa.eu

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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.

Contribution of SMEs would be considered especially beneficial in providing as example the following expertise and activities :

- Infrastructure set-up,
- Data management, harmonisation and data security
- AI-driven data processing and merging of unstructured information, visualisation and user experience design

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Patient organisation participation

- Involvement of patient organisations is encouraged for this topic to;
  - Get patient insight
  - Specify the requirements and boundaries of AI-driven data processing, data security and privacy as well as individual data ownership
  - Support 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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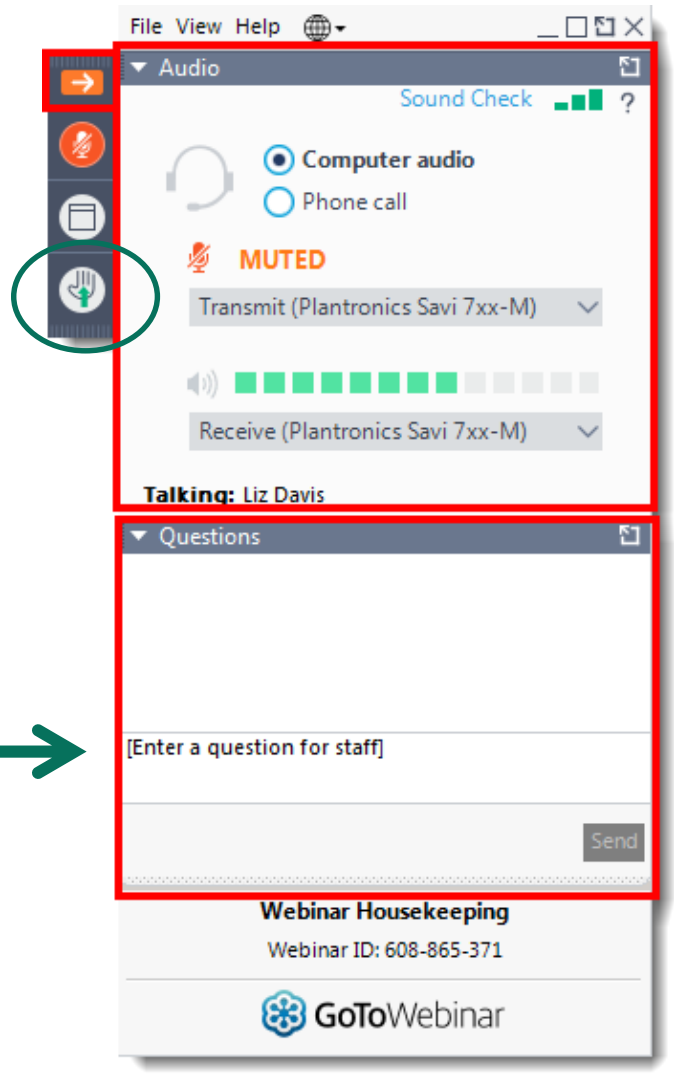
Questions & answers

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!