Webinar | IMI2 - Call 20

Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in psoriatic arthritis

22.01.2020 • 11:00 CET

Agenda

- How to use GoToWebinar – Alessandra Paccamiccio, IMI
- Introduction – Isabella Tamagnini, IMI
- The Call topic – Bruno Boutouyrie-Dumont, Novartis
- Involvement of SMEs, patient groups, regulators – Isabella Tamagnini, IMI
- Questions & answers

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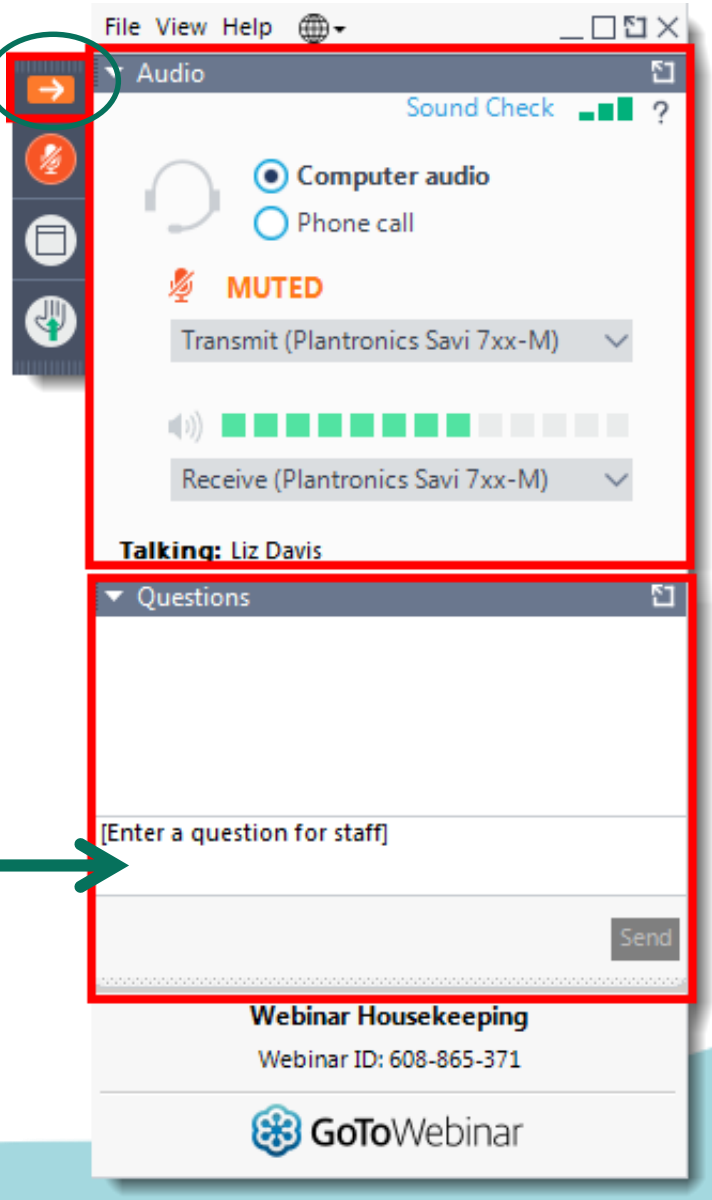

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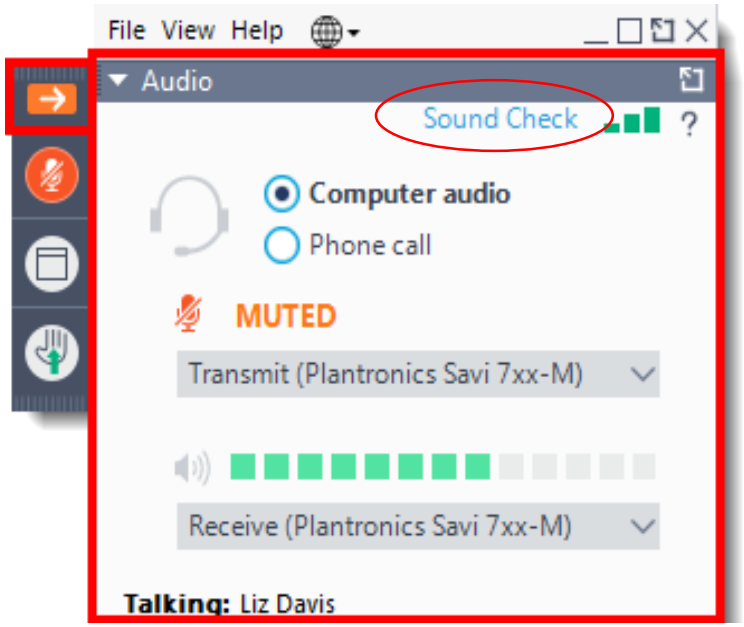

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Before we start…

- 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 published on the website
- IMI2 – Call 20 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 20

Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in psoriatic arthritis

Tamagnini Isabella

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 29 January, 11:00 – 12:30

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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

IMI 1:

- 2008-2013
- €2 bn budget
- 59 projects

IMI 2:

- 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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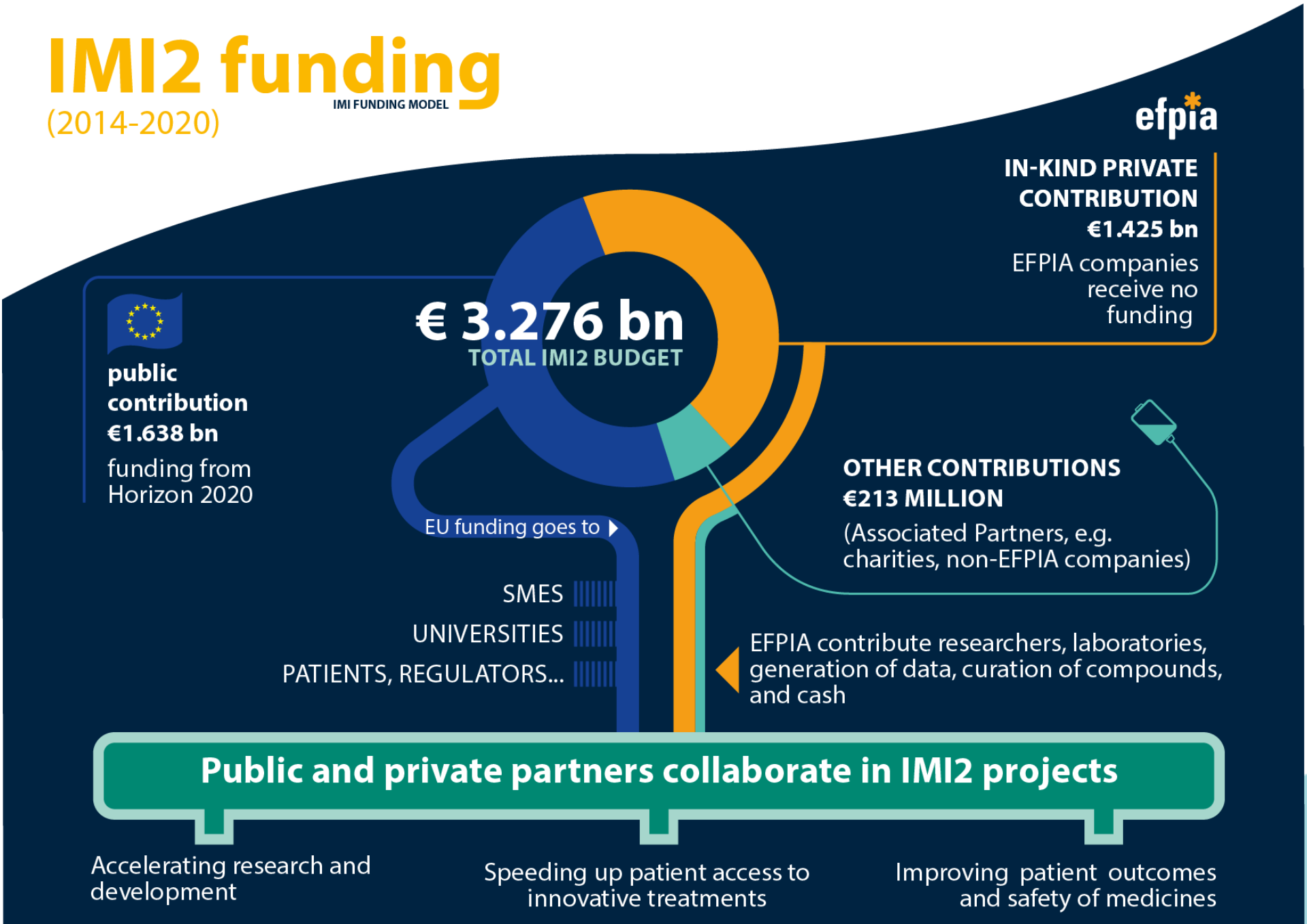
IMI2 funding
(2014-2020)

IMI FUNDING MODEL



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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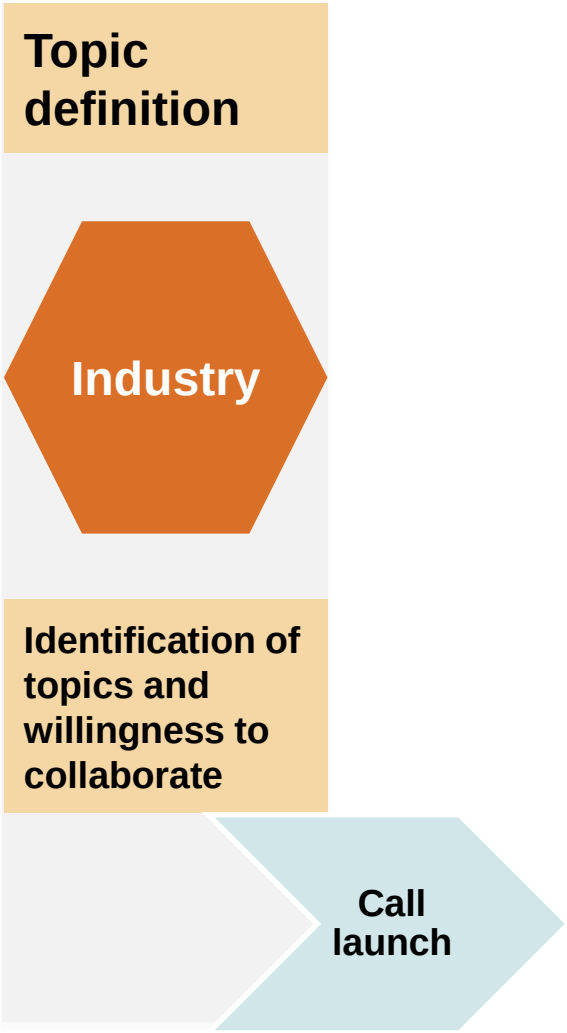
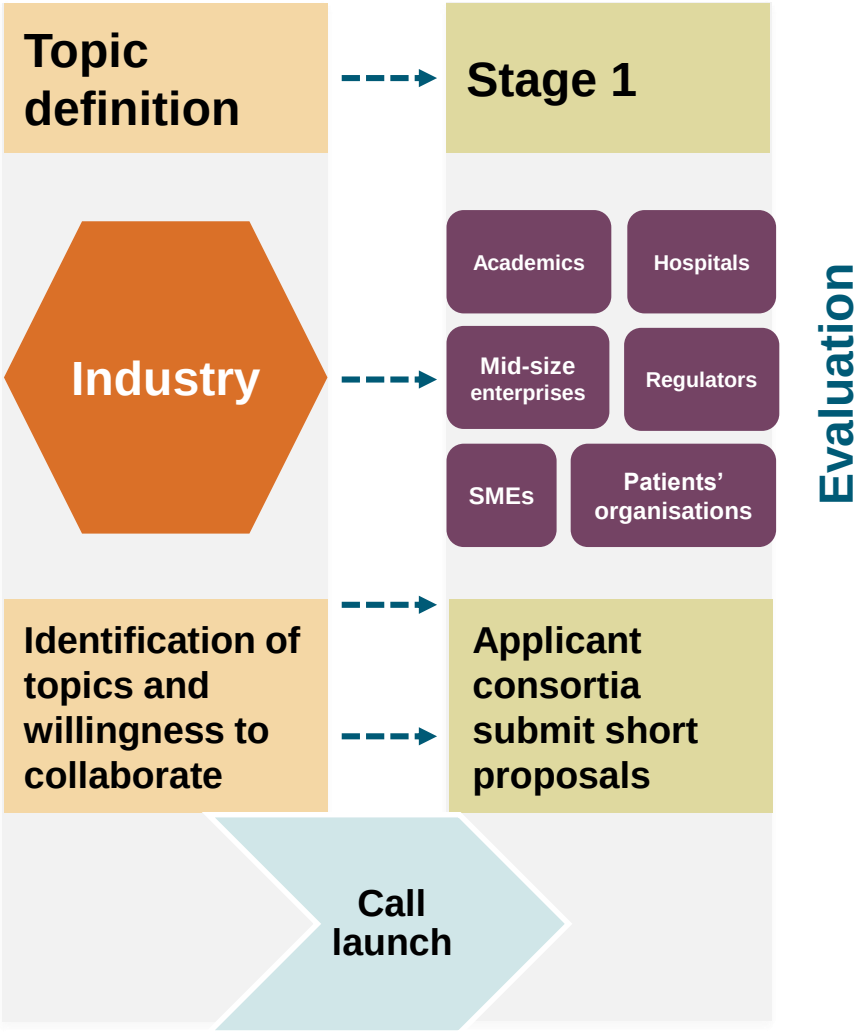
Typical IMI project life cycle



Typical IMI project life cycle



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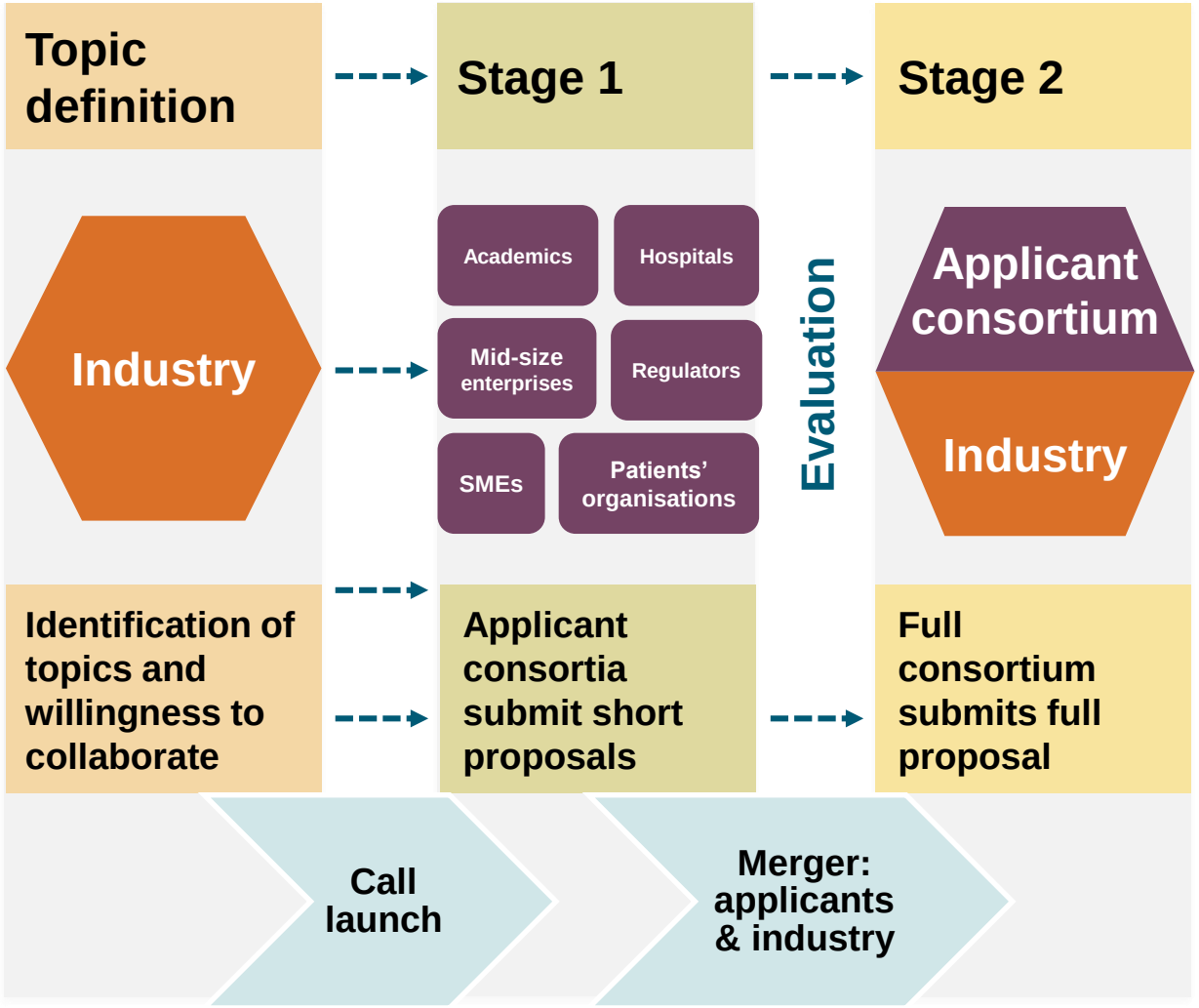
Typical IMI project life cycle



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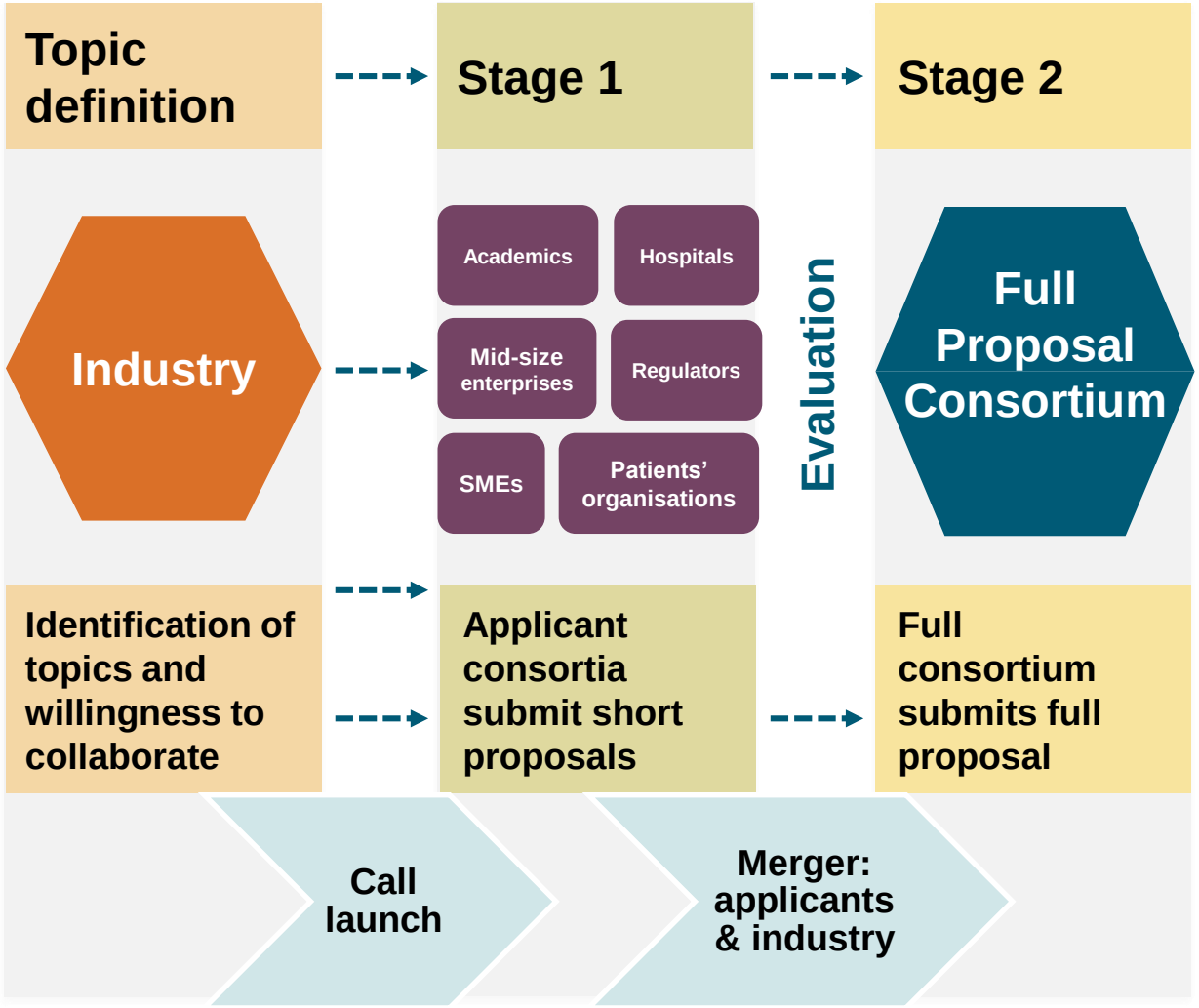
Typical IMI project life cycle



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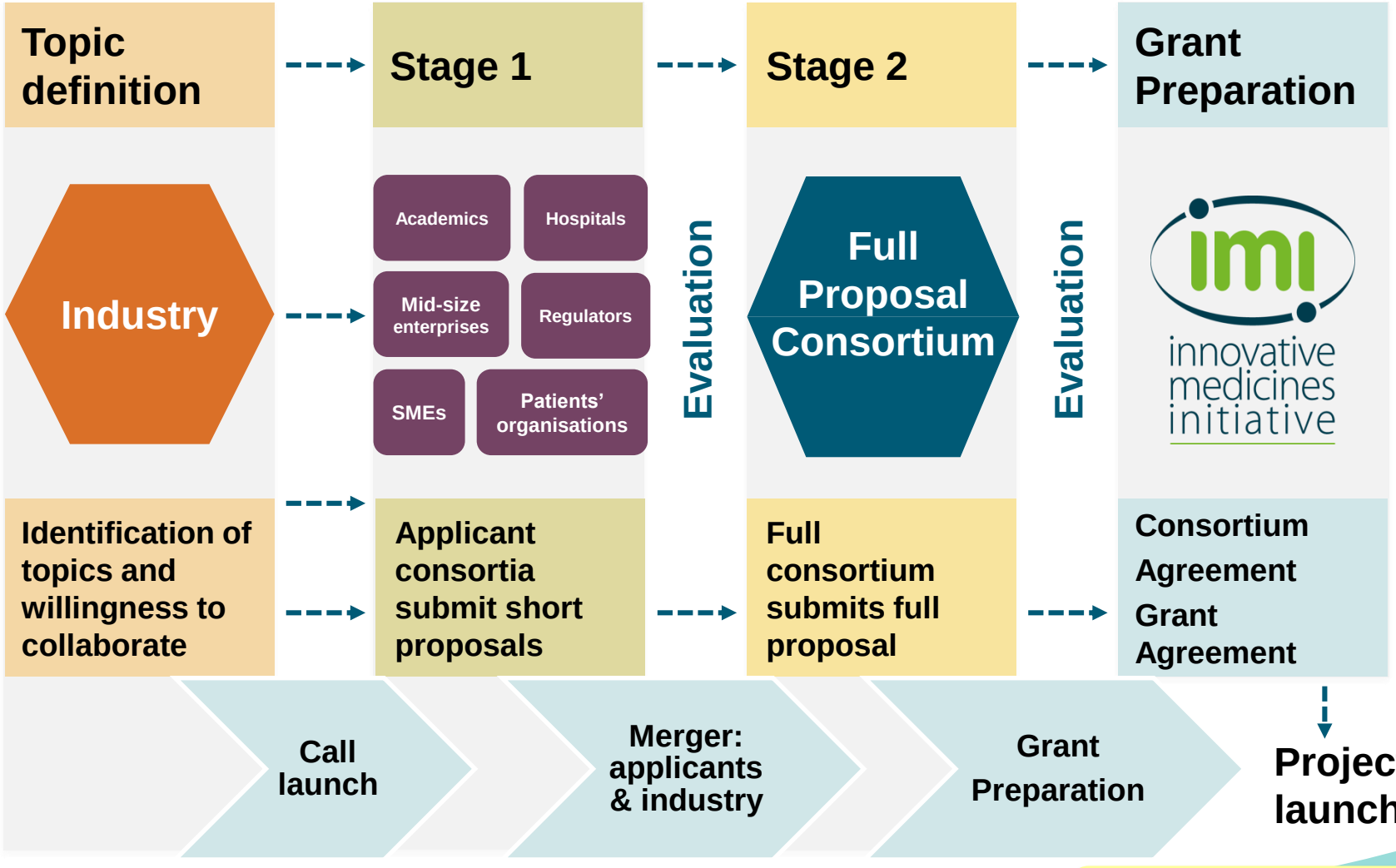
Typical IMI project life cycle



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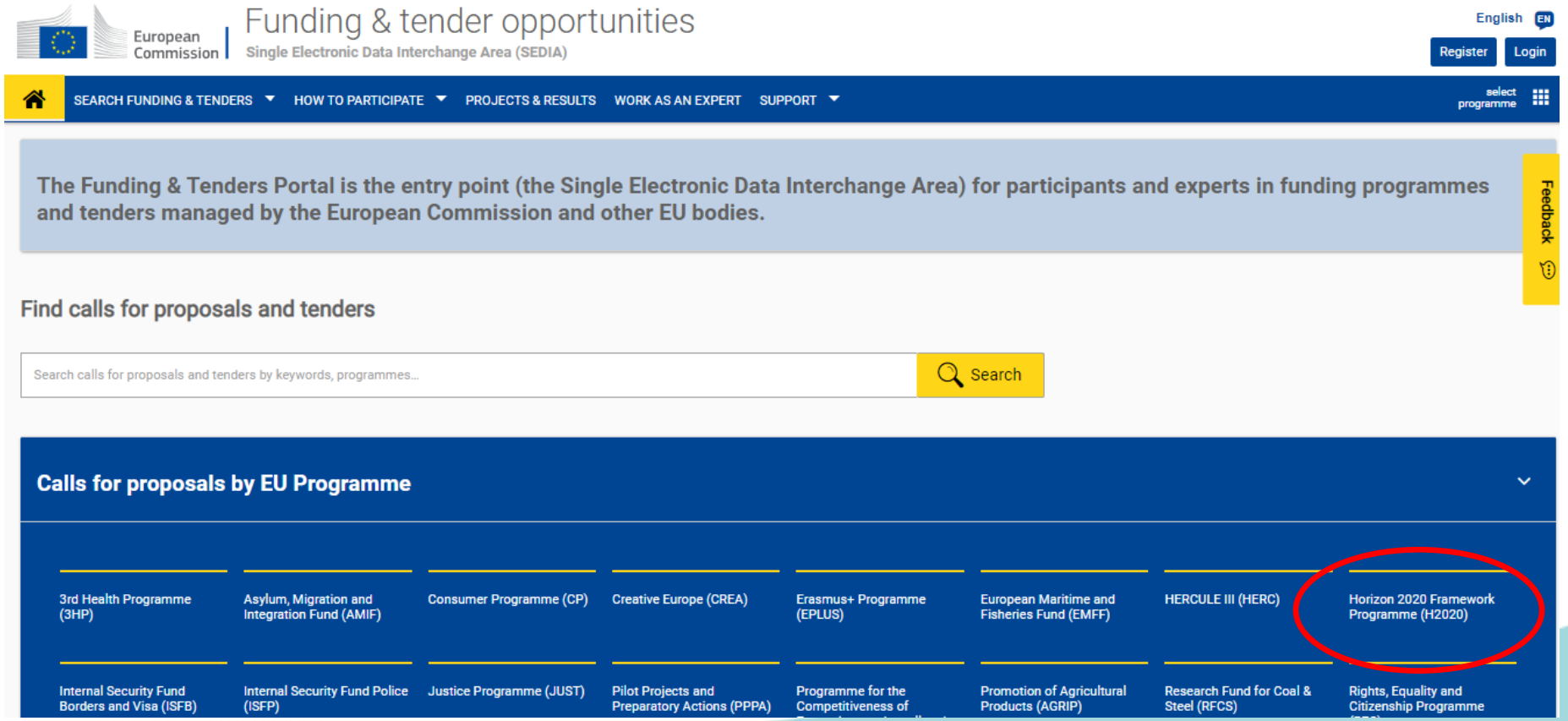
Expected GA signature – Mars/April 2021

Submitting a proposal

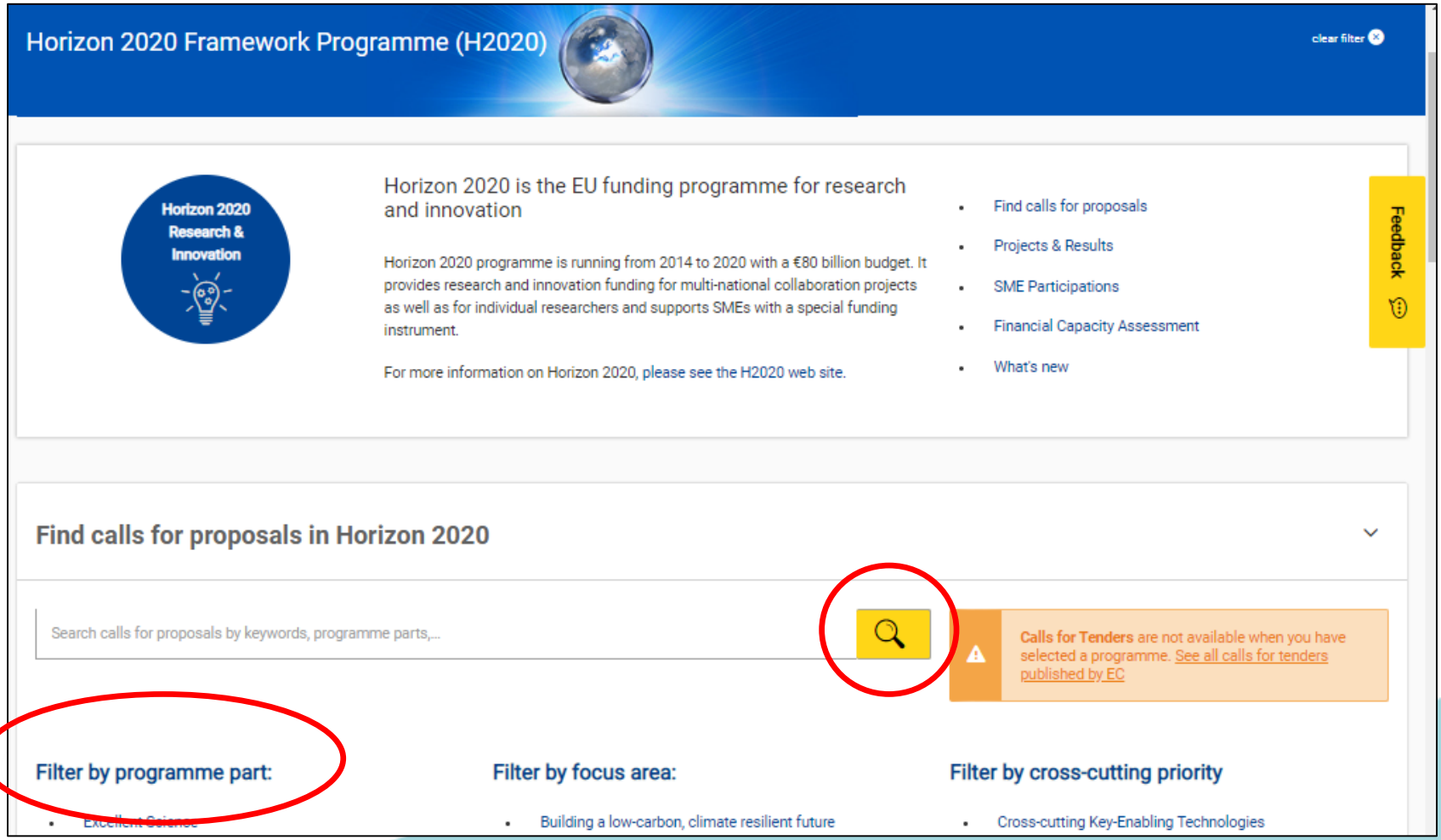
Via the **new** Funding and Tenders Portal

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 – 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://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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Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in Psoriatic Arthritis

Bruno Boutouyrie-Dumont & Owen Davies

22.01.2020 • IMI webinar

Need for public-private collaboration
Background and unmet need

- Psoriatic arthritis (PsA) is a chronic immune-mediated disease involving axial and peripheral joints, nails, skin and enthesis.
- Cutaneous manifestations often precede articular symptoms and it has been estimated that about 20-30% of psoriatic patients develops arthritis or enthesitis over time.
- In fact, this precedence of cutaneous symptoms may give as much as about 7 years to predict, detect and potentially treat PsA.

Need for public-private collaboration

- The focus of this topic is a multifactorial disease represented by its different forms through a wide patient population.
- It goes beyond the more homogeneous ones enrolled in clinical trials for registration of new drugs.
- A broad spectrum of expertise is required for this challenge to be adequately addressed. In this context, collaborative efforts among pharmaceutical industries, academia, small and medium-sized enterprises (SMEs) and patient organisations in a public-private partnership are most likely to harness all the skills and expertise required.

Need for public-private collaboration

- The involvement of representatives of health and regulatory authorities will ensure the necessary regulatory guidance paving the way towards the regulatory acceptance of “early PsA” diagnostic methods and personalised treatments.
- A synergy is expected from industry and other stakeholders joining forces, in this particular area of medicines innovation.

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Objectives of the full project

- To enable rheumatologists, dermatologists and general practitioners to make early diagnosis of PsA in patients with PsO and other rheumatic disorders;
- To early identify patients at risk of progression to PsA in order to enable earlier interventions and possibly prevent PsA development;
- To define the factors that predict disease progression in PsA patients, including early prediction of bone/joint damages, leading to the development of more adapted treatment strategies;
- To develop rational and personalised treatment strategies (e.g. select the optimal first line or second line treatment based on patient characteristics) with optimised outcomes in PsA patients and reduce the disease burden.

Pre-competitive nature

- All data shared between consortia members will be non-competitive by intention.
- The aim is to have free communication on this data.

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Expected impact

- “Early PsA” diagnosis and earlier personalised treatments to patients would impact the disease progression and ultimately prevent PsA development. AI would help identifying endotypes which could take into account the clinical and biological heterogeneities of PsA;
- Development of objective and sensitive functional measures would enable the early diagnosis of PsA in PsO patients and the early prediction of bone/joint damages in PsA patients, yielding long-lived reduction in disease and improvement of patients’ quality of life;
- Improved rates of treatment successes through better understanding of the relation between molecular characteristics of PsA and treatment responses would reduce costs to patients (side effects) and society (economics).

Suggested architecture of the project

- No specific architecture yet discussed between pharma partners
- It can be suggested by the applicants
- Most probably it will be influenced by the different key deliverables

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Expected (in kind) contributions of industry consortium

- **Clinical samples** and **clinical data** from prospective studies placebo arm in the relevant same population
- The industry consortium plans to contribute the following expertise and assets:
    - Translational Medicine Expert
    - Data Manager
    - Biomarker Expert
    - Bioinformatics Expert
    - Statistical Expert
    - Pharmacometric Expert
    - Regulatory Affairs Expert

Expected contributions of the applicants

- Academics, physicians (both rheumatologists and dermatologists) and/or clinical trial centres experienced in PsO/PsA clinical, biological and imaging assessments; capable to justify (1) their expertise to recruit PsO & PsA patients and (2) the number they envisaged to support a valid statistical conclusion; capable to organise prospective longitudinal assessments of PsO patients.
- SMEs & academia / Research and Technology Organisations (RTOs) with past and present experience on genetic, epigenetic, transcriptomic, proteomic, biomarkers, AI/ML techniques and “big data” management techniques; Experience and capacity to manage large volume of various data (clinical, biological, genetic, imaging) to potentially identify endotypes by using AI and ML systems.
- Patient associations and/or patient advocacy groups in PsO/PsA to ensure access to data and information;

Expected contributions of the applicants

- Strong Data Management experience in managing and coordinating a multi-centre multi-node clinical-research data-generation activity of comparable scope.
- Demonstrated ability to deliver analytical platforms for a range of scientific/medical and analytical communities;
- Expertise in a) clinical characterisation and patient access/recruitment (incl. samples and/or data from on-going prospective collections/trials for PsO and/or PsA), b) biological specimen-based profiling, and c) advanced informatics;
- Expertise in access to and use of medical record-based information; Other publicly available data or cohorts could be incorporated in the action generated by this topic.

What's in it for you?

- Academic researchers :
  - Joining a European network toward a common objective to improve treatment of PsA patients
  - Potential funding of innovative clinical research activities
- SMEs
  - Creating new tools or new biomarkers for PsA patients
  - Joining a European network of researchers
- Patients' organisations
  - Having an opportunity to influence new research in psoriatic arthritis

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Key deliverables of the full project

- Early diagnosis of PsA in PsO patients:
  - Identification of predictors of disease progression e.g. genetic, epigenetic, transcriptomic, proteomic and/or clinical biomarkers assessed through longitudinal follow-up until evidence of CASPAR;
  - Identification and characterisation of biomarkers to predict, diagnose and monitor PsA in patients with PsO and to assess treatment response;
  - Biomarkers of tissue damage, predicting disease progression among PsA patients;
  - ML/AI tools to identify novel biomarker signatures;
  - Digital tool(s) developed for use by physicians and/or patients.

Key deliverables of the full project

- Early prediction of bone/joint damages in PsA patients:
  - Identification of poor radiographic outcomes;
  - Biomarker assay(s) to identify patients that may rapidly develop bone or joint damages, indicating that these patients need strict control of PsA.
- Prediction of best treatment for patients at diagnosis:
  - Biomarker assay(s) to assess response/non-response for various treatments of PsA;
  - Development of a PsA specific algorithm to estimate the expected response to treatments.

Key deliverables of the full project

- Creation of a tissue library, accessible by all involved parties, comprising skin, synovial tissue, synovial fluid and/or peripheral blood cells (including CD4+ and/or CD8+ T cells and/or other lymphocytes, monocytes) for analysis; This tissue library will have to be organised by the consortium with a perspective of sustainability incorporated in its foundation documents. Existing libraries will also be considered and be contacted for possible sustainable collaboration.

Key deliverables of the full project

- Development and implementation of new techniques for diagnostic use e.g. Peptide Immunoaffinity Enrichment with Targeted Mass Spectrometry (Immuno-Multiple Reaction Monitoring, iMRM), Mass Cytometry (e.g. CyTOF), (single cell) investigation of autoantibodies / DNA methylation (e.g. as marks for tissue damage), and other techniques for single cell analysis to support detailed investigation of signalling cross-talk within and between relevant cell populations;
- Novel methods for data mining and AI-driven information extraction;

Key deliverables of the full project

- Letter of support from regulatory bodies (e.g. the European Medicines Agency, EMA and/or Food and Drug Administration FDA) on the potential for qualification/validation of the biomarker(s) and their clinical applications (context of use) in PsA.

Involvement of SMEs, patient groups, regulators

Tamagnini Isabella

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:

- genetic, epigenetic, transcriptomic, proteomic and biomarkers research
- AI/ML techniques
- “big data” management (i.e. clinical, biological, genetic, imaging)
- public-health, public relations and communication
- project management
- etc.

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Patient participation

- Involvement of patient associations and/or patient advocacy groups in PsO/PsA for this topic to ensure patient centricity and access to data and information

- Many ways to include your patient partners in the project e.g;

  - patient insight on the analysis and interpretation;

  - 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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Thank you

www.imi.europa.eu
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Q&A

Q&A: how to ask questions

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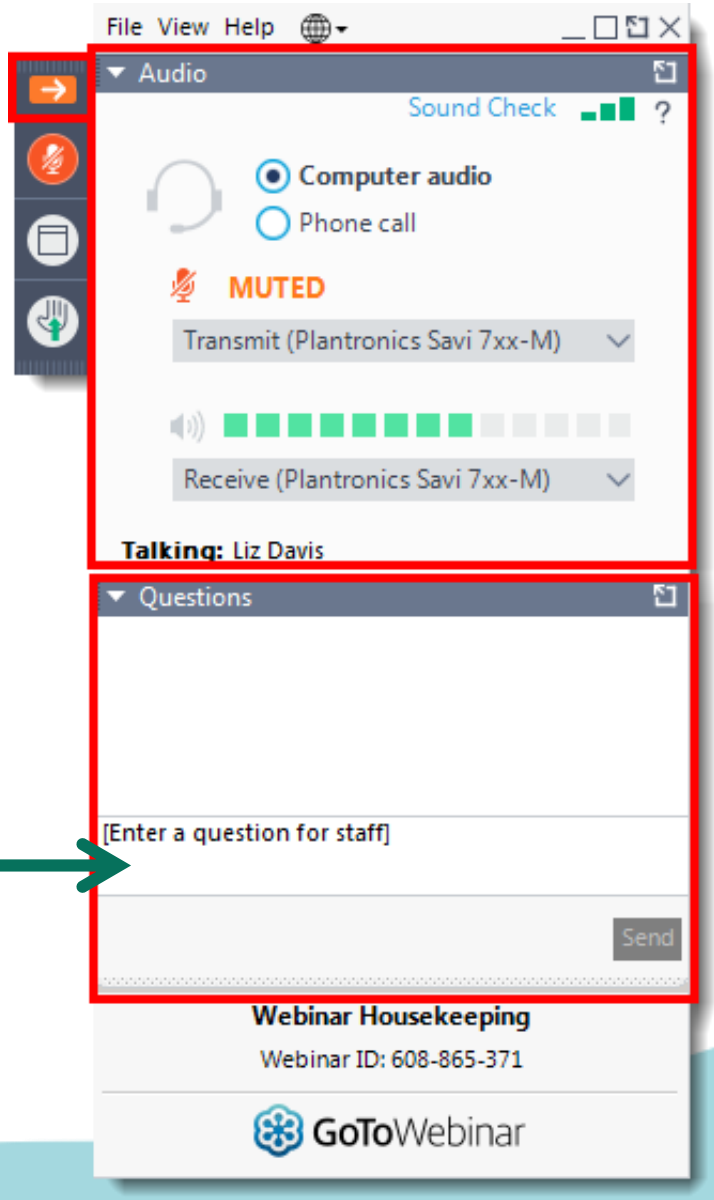

Further questions?

Please contact applicants@imi.europa.eu

Thank you