Webinar | IMI2 - Call 15 Microenvironment imposed signatures in tissue and liquid biopsies in immune mediated disease

09.07.2018

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Iwona Jablonska, IMI
- The Call topic – Gillian Tannahill and Gerben Bouma, GSK
- Involvement of SMEs, patient groups, regulators – Iwona Jablonska, IMI
- Questions & answers

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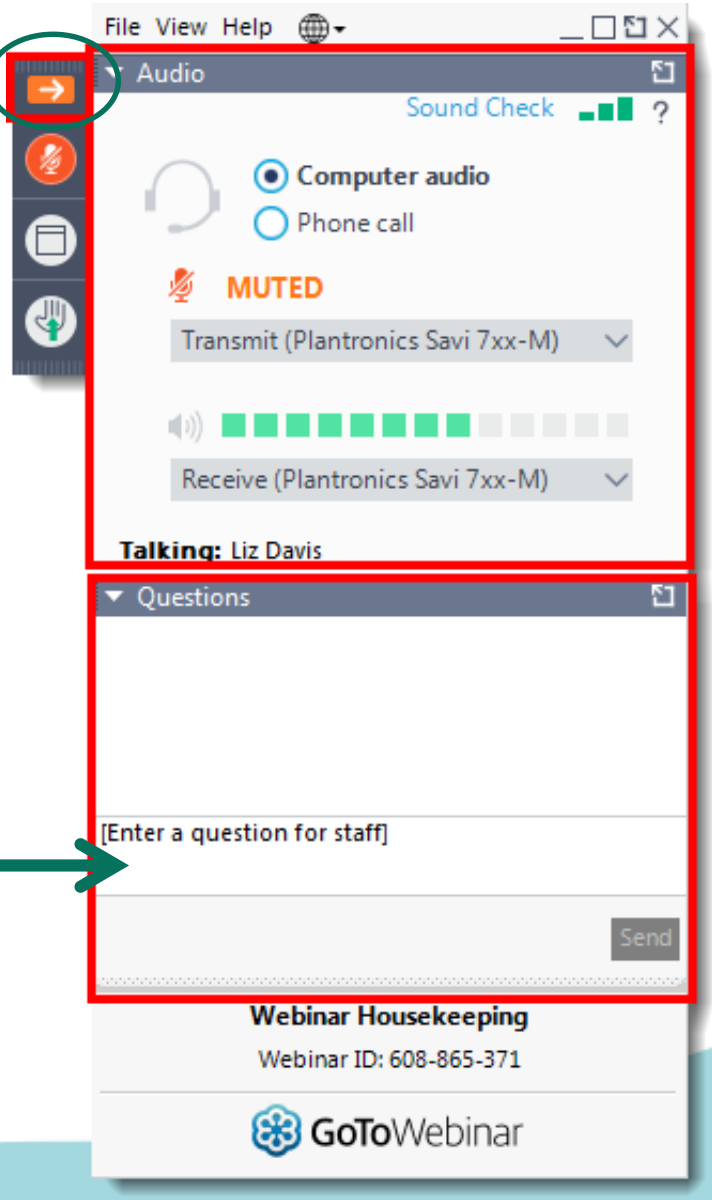

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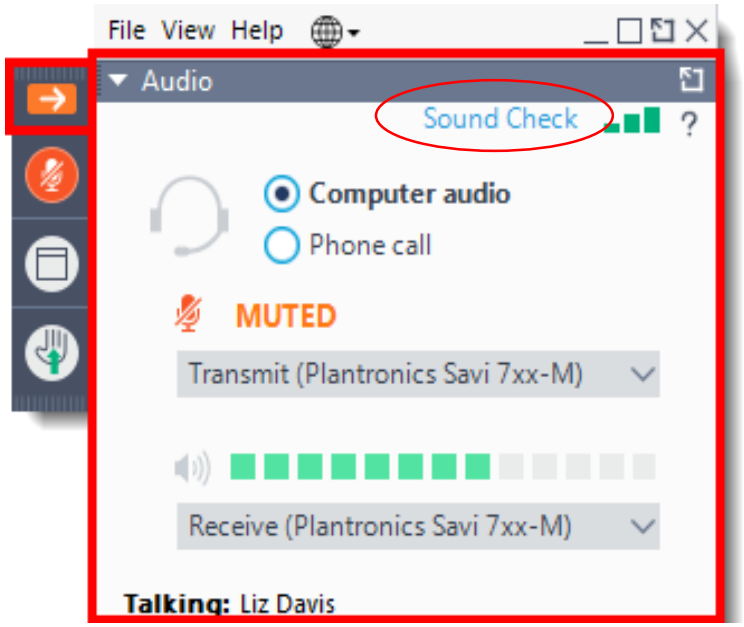

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Before we start…

- 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 15

Microenvironment imposed signatures in tissue and liquid biopsies in immune-mediated diseases

Iwona Jablonska

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 **Tuesday 10 July at 10:30**

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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 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

€1.425 bn

Other €213 m

IMI 2 total budget €3.276 billion

EFPIA companies

receive no funding

contribute to projects ‘in kind’

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

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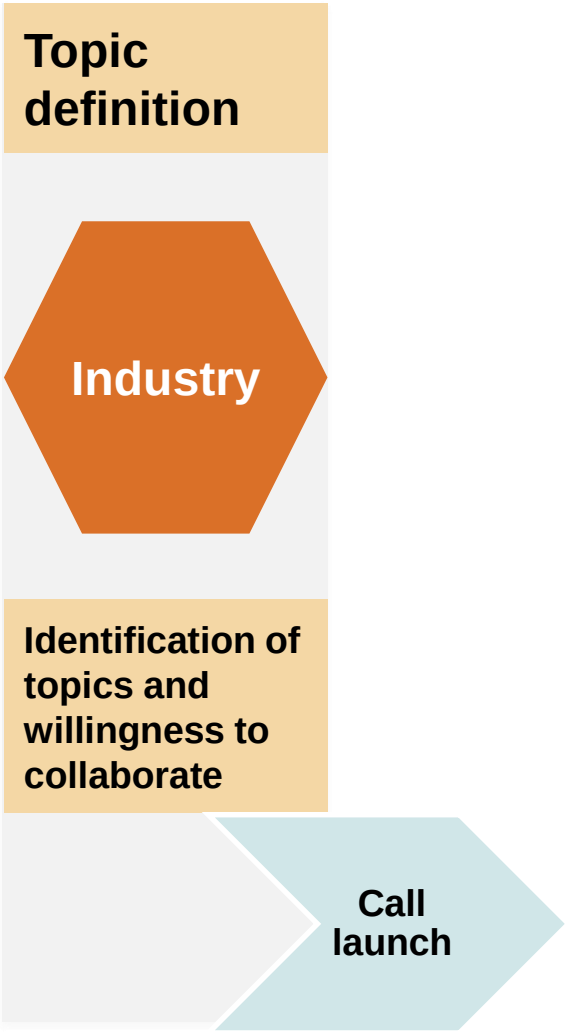
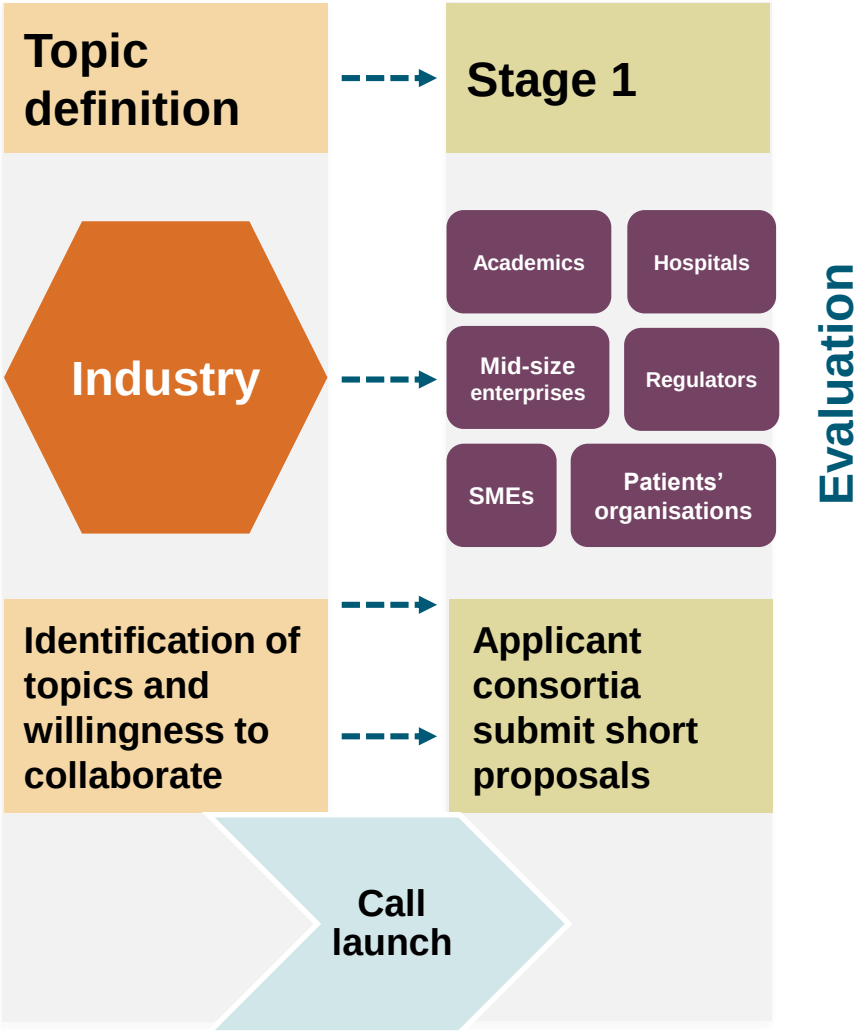
Typical IMI project life cycle



Typical IMI project life cycle



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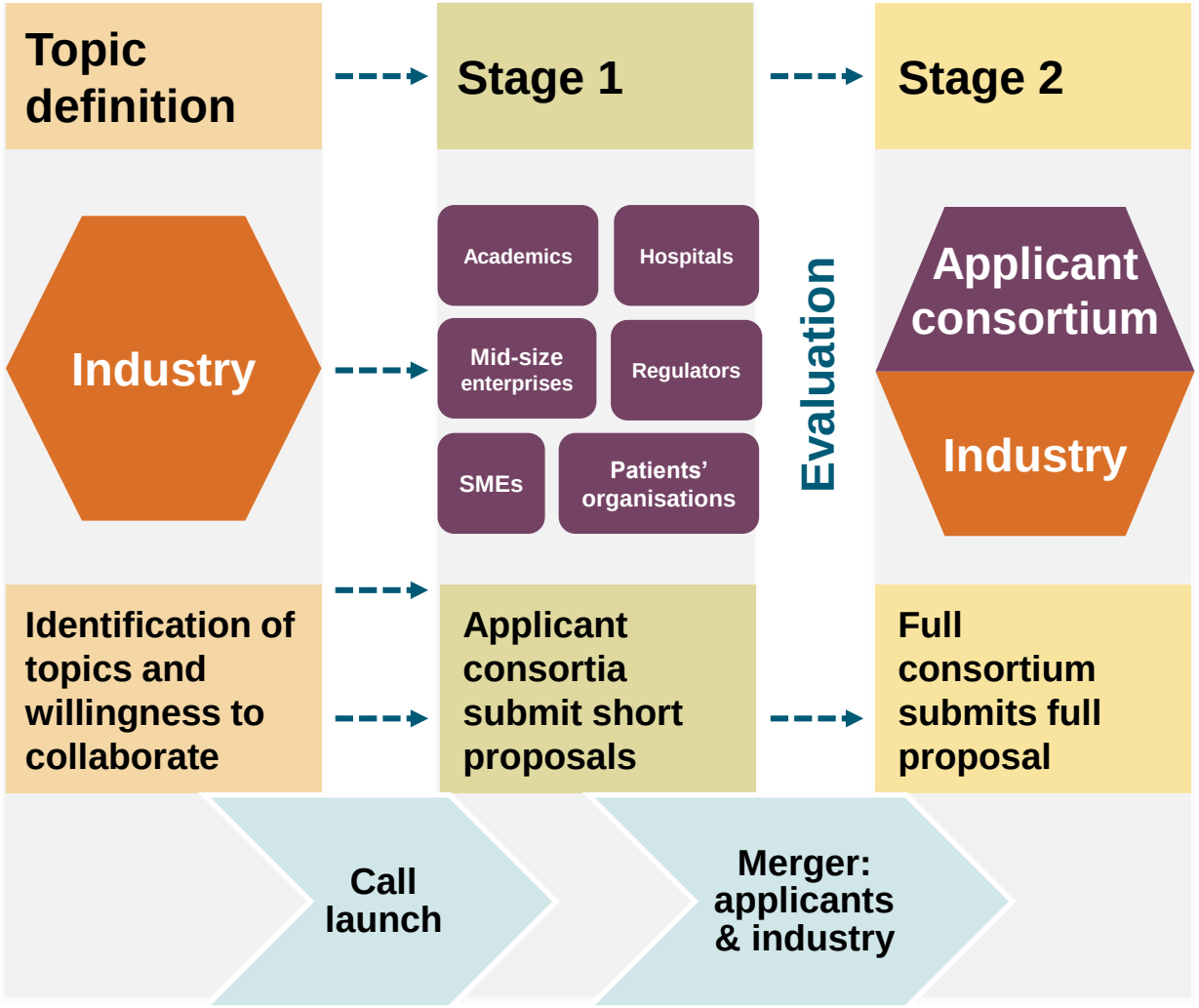
Typical IMI project life cycle



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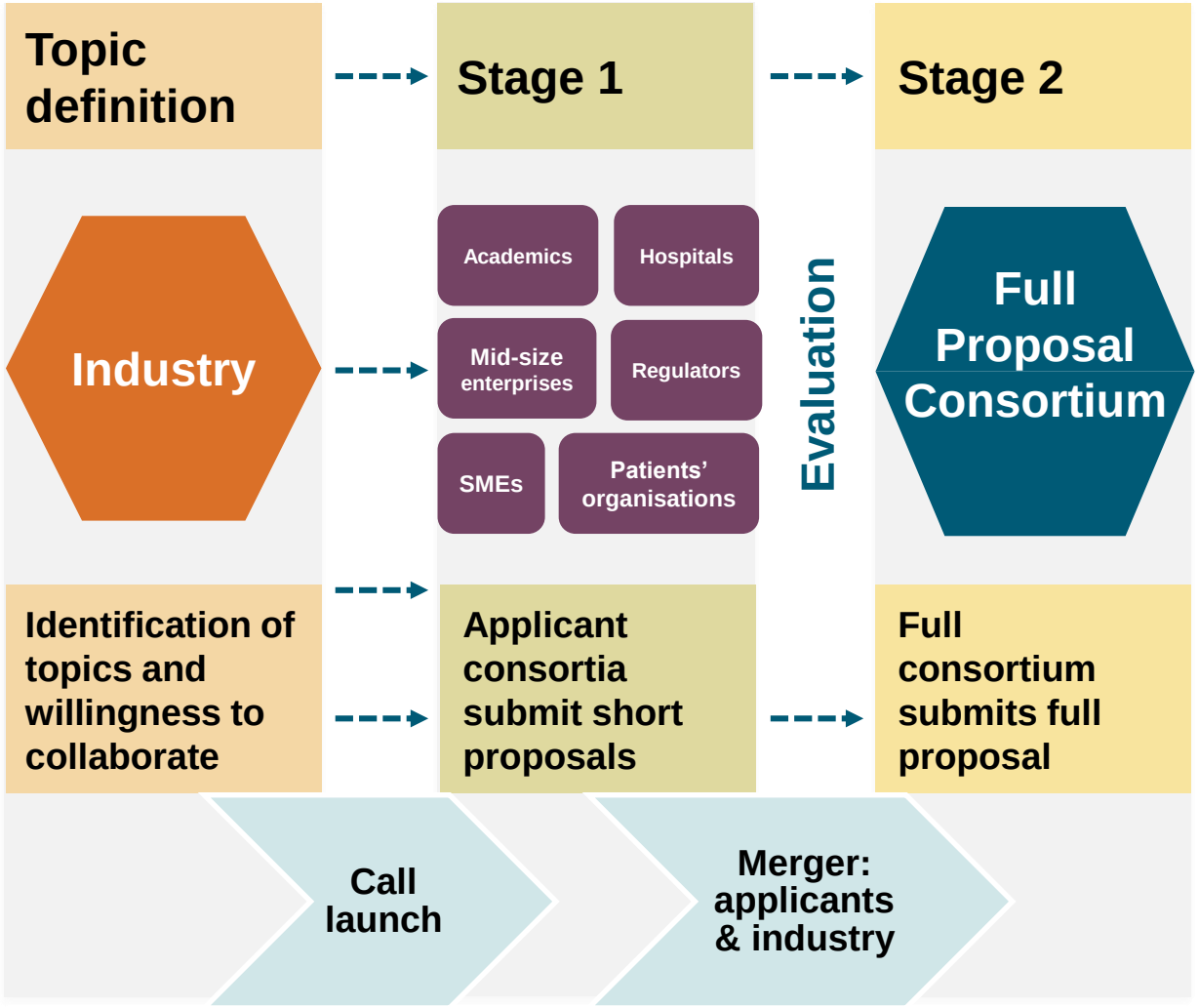
Typical IMI project life cycle



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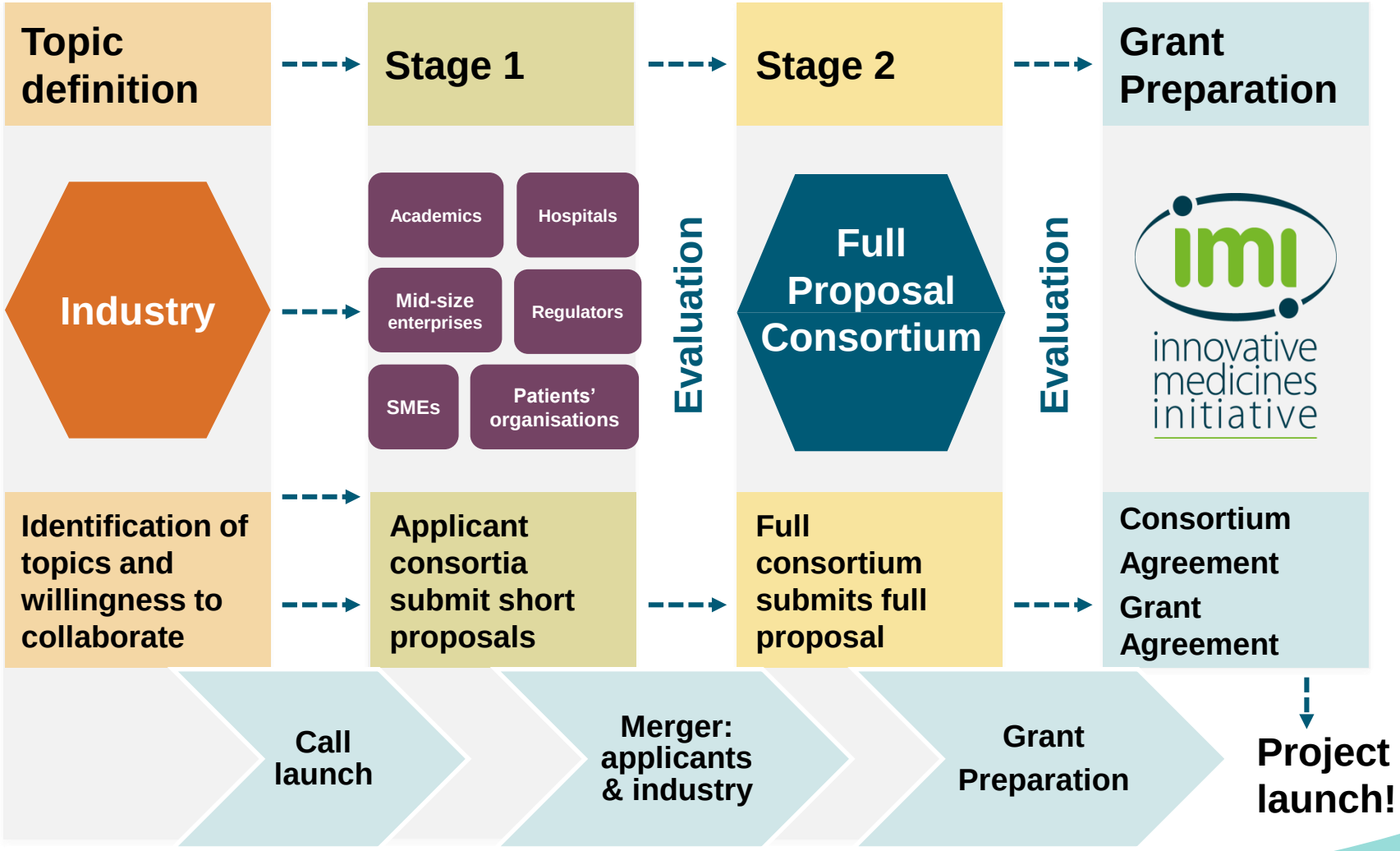
Typical IMI project life cycle



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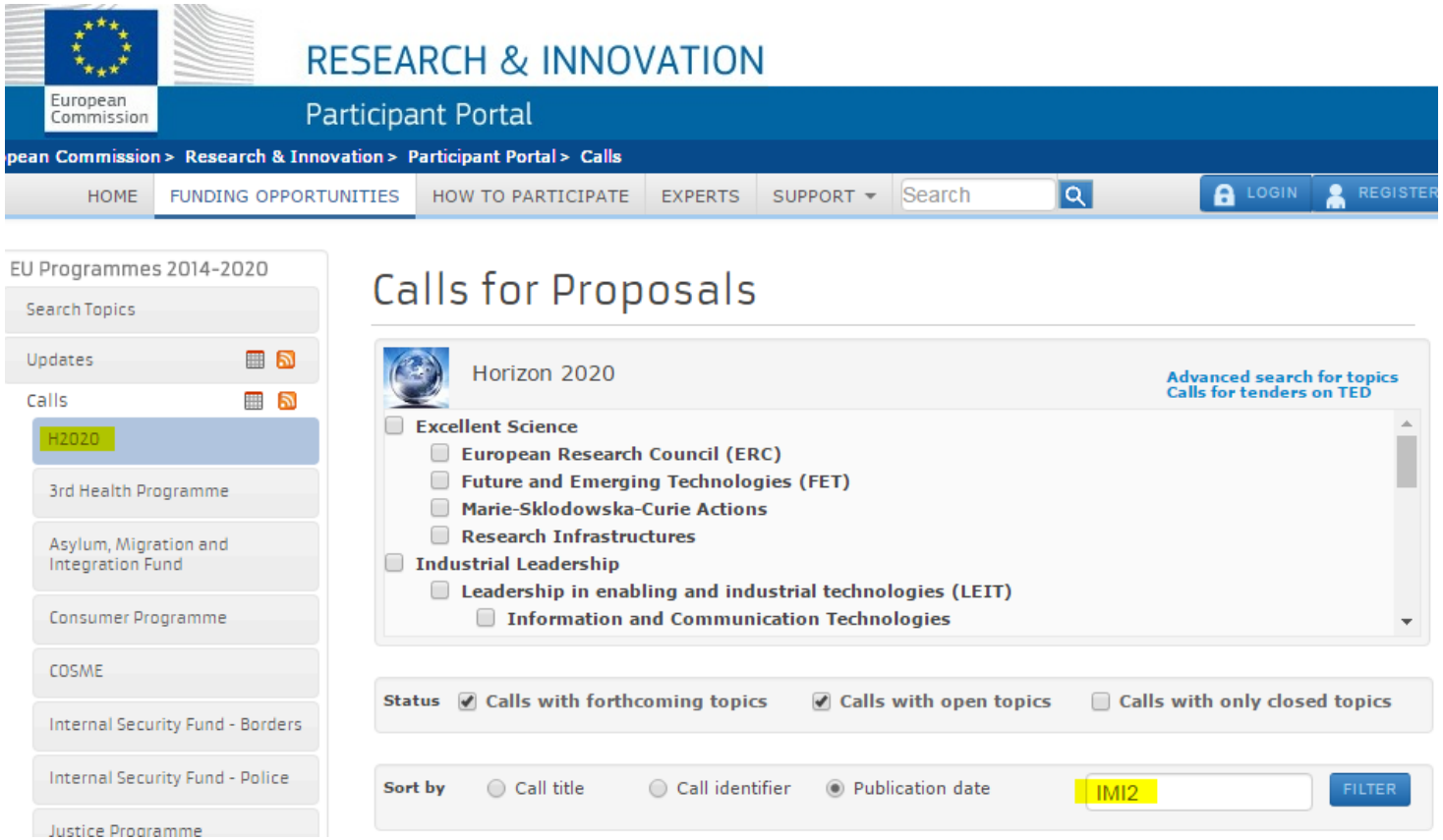
Submitting a proposal

- https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/index.html



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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

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Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the proposal to meet all key objectives of the topic;
  - Credibility of the proposed approach;
  - Soundness of the concept, including trans-disciplinary considerations, where relevant;
  - Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;
  - Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.
- **Impact**
  - The expected impacts of the proposed approach as mentioned in the Call for proposals;
  - Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
  - Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
  - Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
  - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
  - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

Tips for writing a successful proposal

- Read **all the call-relevant material:**
  www.imi.europa.eu
- Begin forming your consortium **early**
  Partner search tools & networking events
- Provide **reviewers** with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **IMI Office** (**NOT** industry topic writers):
  infodesk@imi.europa.eu

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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 is not well described.

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Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools:**
  - EU participant portal: https://ec.europa.eu/research/participants/portal/desktop/en/organisations/partner_search.html
  - 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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Microenvironment imposed signatures in tissue and liquid biopsies in immune-mediated diseases

09 July 2018 • IMI webinar

Gillian Tannahill and Gerben Bouma

Objectives of the full project

Identify disease specific signatures in key organs with correlates in body fluids, which will improve knowledge of pathophysiology of immune-mediated diseases, predict disease progression and monitor treatment ultimately providing superior therapeutic benefit for patients

1. Identification of state-of-the-art technologies (need to be adaptable for use in clinical trials) to interrogate cells in target tissue at **single cell level**
2. Define tissue/**disease-specific signatures**
3. Correlate tissue-specific signatures with '**circulating' signatures**
4. Evaluate robustness of signatures with existing clinical samples
5. Perform bespoke, **non-interventional clinical study** to validate signatures

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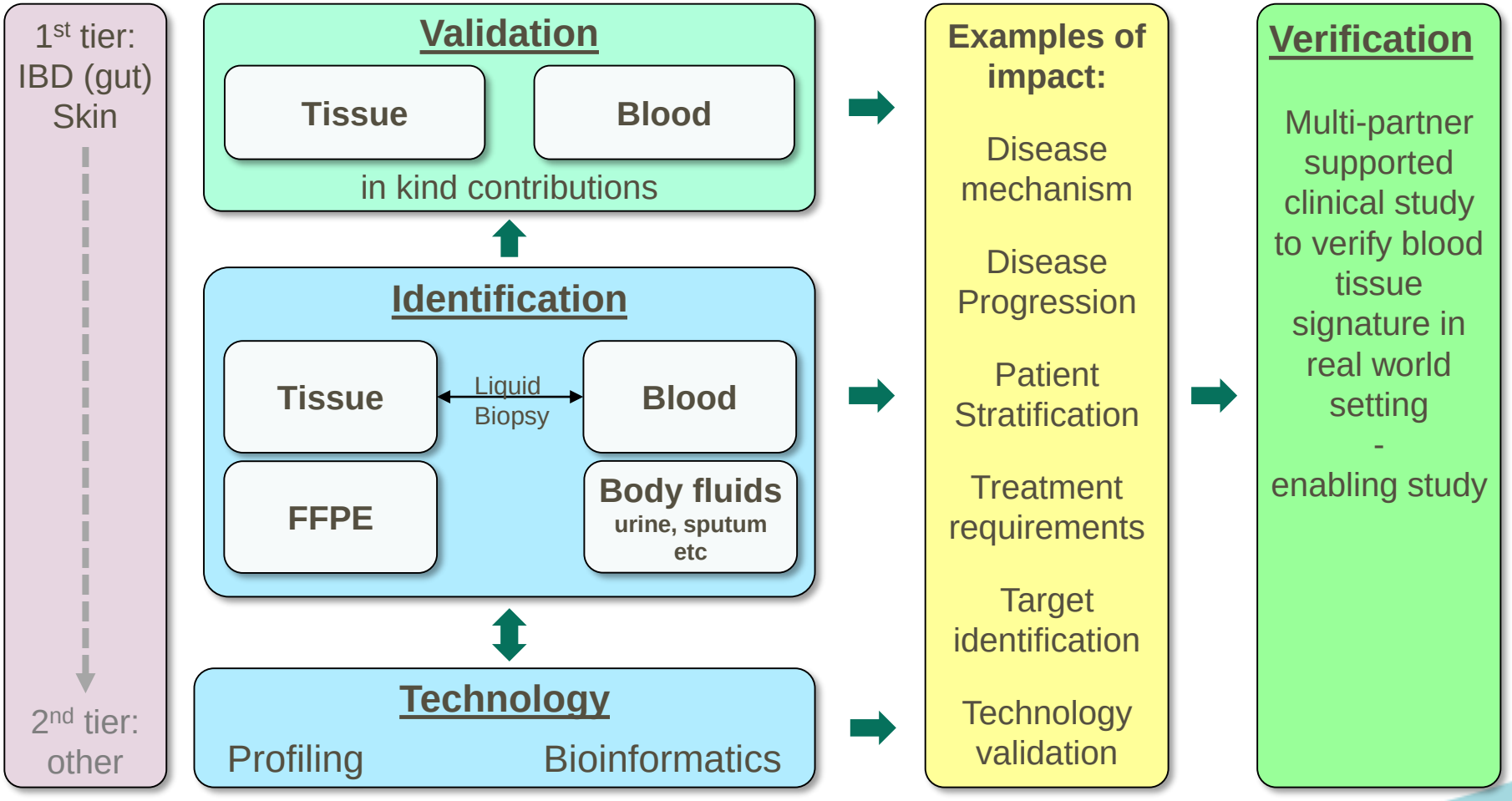
Identification, validation and verification of microenvironment imposed signatures



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Diseases of Interest

Inflammatory bowel disease
(Crohn's disease, ulcerative colitis)

Skin diseases
(atopic dermatitis, cutaneous lupus, psoriasis)

Need for public-private collaboration

- Immune mediated diseases are scientifically complex

- A large interational scientific collaborative project which includes:
  - Clinical and technological excellence from academic partners
  - Clinical development expertise of EFPIA partners
  - Technological expertise of SME partners
  - Advice on validation and adoption for clinicl trial use from regulatory authorities

- Industry consortium: GSK (EFPIA lead), Sanofi (EFPIA co-lead), Eli Lilly, Novartis and Pfizer

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Pre-competitive nature

- Public/Private efforts will be combined to **improve understanding** of disease, enable human **target validation and patient stratification** and develop more **effective and safer therapies**.

- **Project-generated experience, expertise and data will be openly shared** and should advance clinical monitoring in both clinical trials and standard patient care

- **Validated signatures** of tissue microenvironment will be **made available** to the public, scientific community, healthcare providers, regulatory authorities, patient interest groups, payers, etc.

- Interactions with other relevant global initiatives and consortia will be built to optimise efforts and funding.

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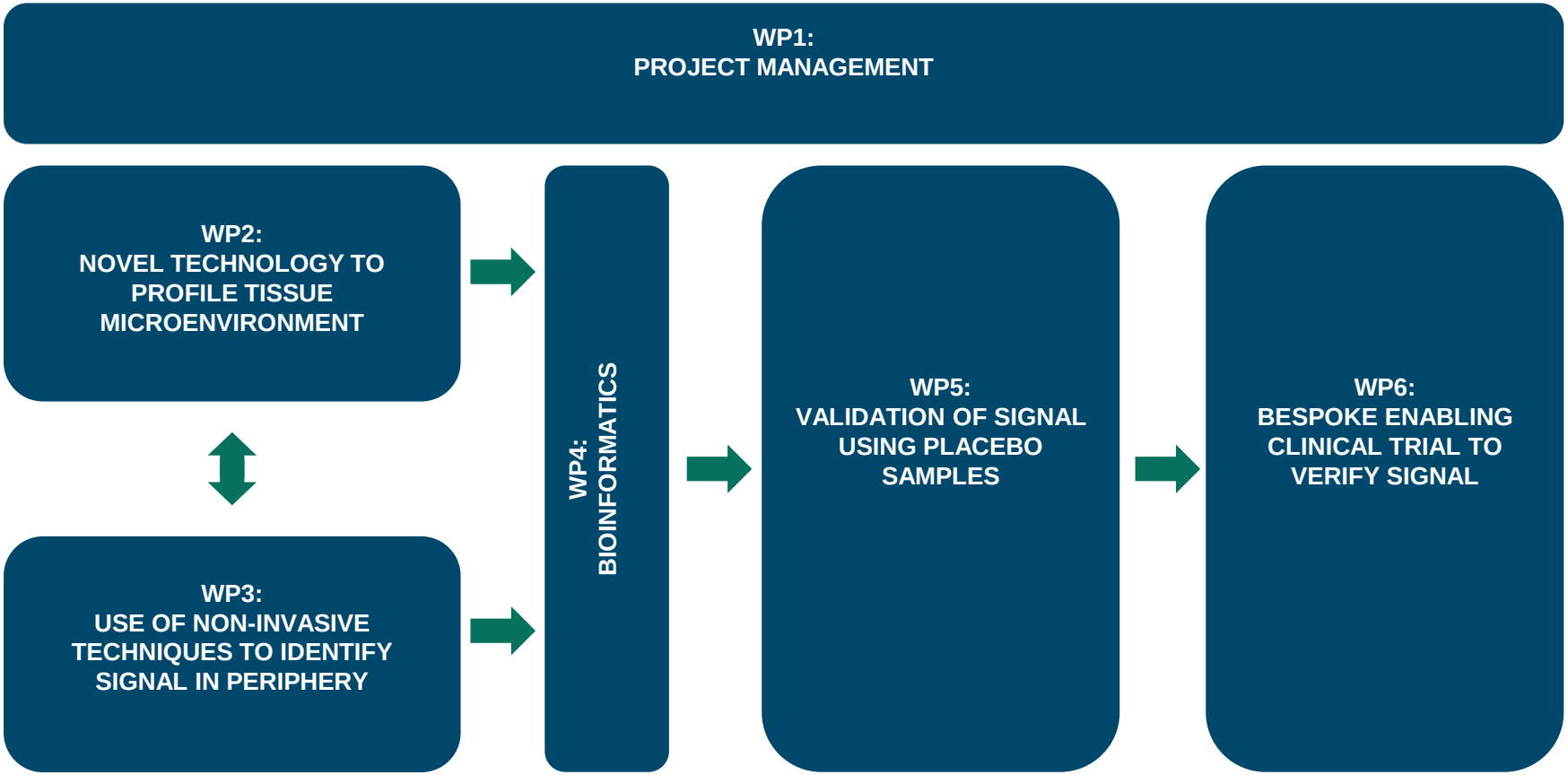
Suggested architecture of the project



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Expected impact

- In-depth characterisation of the tissue micro-environment will provide better disease understanding.
- Circulating signatures of the tissue micro-environment will **advance clinical monitoring** in both clinical trials and standard patient care.
  - Earlier and/or improved detection of disease progression will allow **more tailored treatment**.
  - In clinical trials, earlier and/or improved detection of disease progression may also allow **better patient stratification** and prediction of treatment response.
- The non-interventional trial (WP 6) will allow signature verification and facilitate implementation in future clinical trials and **adoption by regulatory authorities**.

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Expected contributions of the applicants -1

- **Basic/clinical immunology and clinical care expertise** related to inflammatory bowel disease and skin diseases

- Access to **longitudinal clinical samples** that can be made available for identification and evaluation of technologies (WP2,3)

- **Technology and expertise** for identification and correlation of signatures (WP2,3,4). Technology should be readily and feasibly implemented for clinical trial use (e.g. GLP)
  - Single cell profiling technology
  - Multiplex immunohistochemistry
  - Immunophenotyping and immune repertoire characterisation
  - ‘omics’ e.g. metabolomics, profiling autoantibodies, miRNA, epigenetics, transcriptomics etc

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Expected contributions of the applicants -2

- Capability to deliver **analytical platforms** (WP4)
- **Clinical study design and operationalisation** of large multi-centre trials, incl legal and ethical challenges (WP6)
- Resource for **project administration, management** and communication (WP1)
- In particular **SMEs should consider applying** as they are considered key for provision of technologies, advanced analytical approaches and data management (WP2,3,4)

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Expected (in kind) contributions of industry consortium

- Provision of **clinical samples** and clinical data from **prospective clinical trials** in inflammatory bowel disease (Crohn's disease and ulcerative colitis) and skin diseases (including atopic dermatitis, cutaneous lupus and psoriasis) for validation of signatures (WP5)

- **Expertise in clinical development, clinical trial design and operationalisation** (WP6)

- Technology and expertise for identification and correlation of signatures (WP2,3,4) and **implementation of technology in clinical trial use (WP6).**

- Expertise in analytical platforms (WP4)

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What's in it for you?

- Possibility to be part of an ambitious, collaborative project involving multidisciplinary partners including pharmaceutical industry
- Be part of a project that has the potential to provide superior therapeutic benefit to patients
- Access to **state-of-the-art technologies**
- Collaborate on unprecedented, large scale, n**on-interventional, clinical trial** involving multiple industry partners
- Access to validated technology and tools for clinical use
- Opportunity for **high impact publications**

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Key deliverables of the full project -1

- **Identification and optimisation of promising technologies** and/or platforms suitable to profile cells in a disease-specific tissue microenvironment.
- **Generation of tissue and circulating profiles** using the above technologies
- **Evaluation** of comparability of tissue profiles between fresh and stored samples (e.g. fresh, fresh-frozen vs FFPE)
- Mapping of tissue profiles against circulating profiles to identify specific and **robust signatures**
- **Validation of signatures in both tissue and circulation** in separate cohorts of clinical samples from clinical trials by industry partners
- Correlation of clinical profiles and parameters to signatures to evaluate stability and ability to **track clinically relevant changes**

Key deliverables of the full project -2

- **Generation of raw data repositories** with access to all partners
- **Development of software and bioinformatic packages** for full data integration and analysis
- **Design and development of IT infrastructure** for data query and mid to long-term housing of data within the consortium
- Verification of signatures in a **bespoke, non-interventional clinical trial**
- Expansion of signature evaluation in complementary indications in samples available from industry partners

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Thank you

www.imi.europa.eu

@IMI_JU

Involvement of SMEs, patient groups, regulators

Iwona Jablonska

SME participation

Under this topic:

- SMEs with relevant proven expertise, relevant technology and proven record of delivery of peer-reviewed data sets are encouraged to participate in the applicant consortium.

- The contribution of SMEs would be considered especially beneficial in technologies to characterise the tissue microenvironment or body fluids, advanced analytical approaches and data management practices.

- The inclusion of SMEs into the consortium will maximise the opportunity for suitable technology for the identification of disease-specific signatures of the tissue microenvironment to be identified and, more importantly, ultimately implemented in multi-centre clinical trial settings under good laboratory practice (GLP) conditions

Patient participation

The topic is focused on technology evaluation followed by validation of signatures in a non-interventional trial. The expected impact on patients will be rather long-term (e.g. earlier detection of disease, better patient stratification, more tailored treatment) and therefore going likely beyond the duration of the project.

The engagement with and input from patient groups will be sought later in the process when validated technologies and signatures have been established.

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

Interactions with regulators (1)

- **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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Interactions with regulators (2)

Under this topic:

Advice from regulatory authorities, such as the U.S. Food and Drug Administration (FDA) and/or European Medicines Agency (EMA), will be sought to facilitate regulatory suitability of identified signature(s) for future clinical trials and medicine development.

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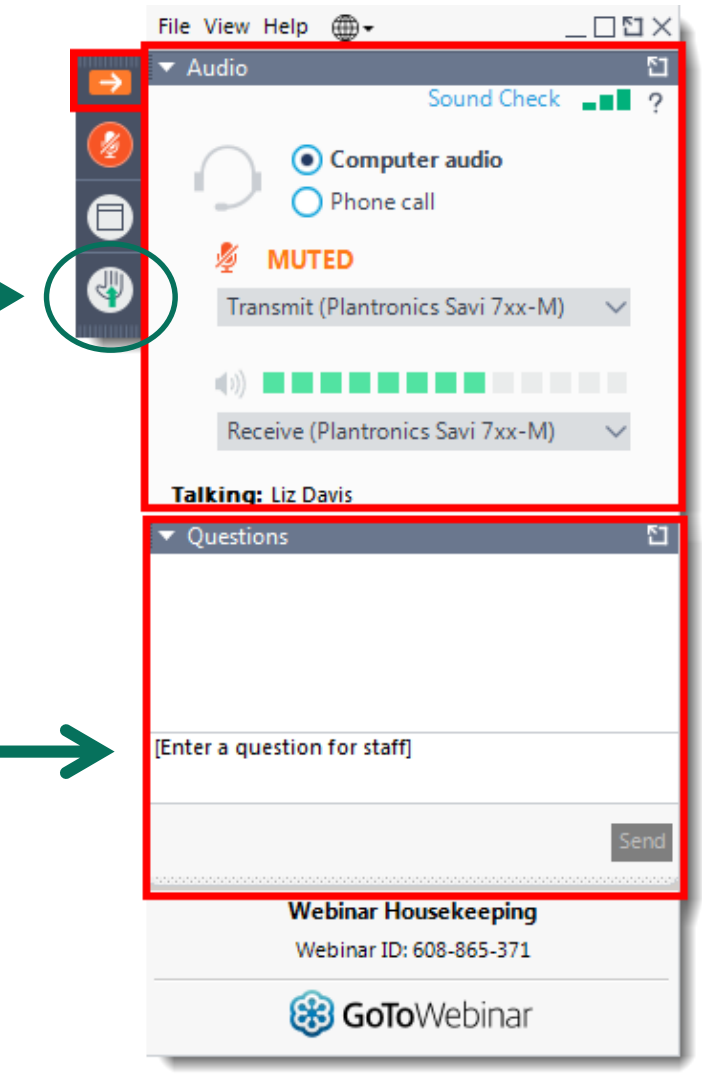
Questions & answers

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!