Webinar | IMI2 – Call 17
Intelligent prediction and identification of environmental risks posed by human medicinal products

23.01.2019

Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- Introduction – Tek-Ang Lim, IMI
- The Call topic – Jason Snape, AstraZeneca
- Involvement of SMEs, patient groups, regulators – Tek-Ang Lim, IMI
- Questions & answers

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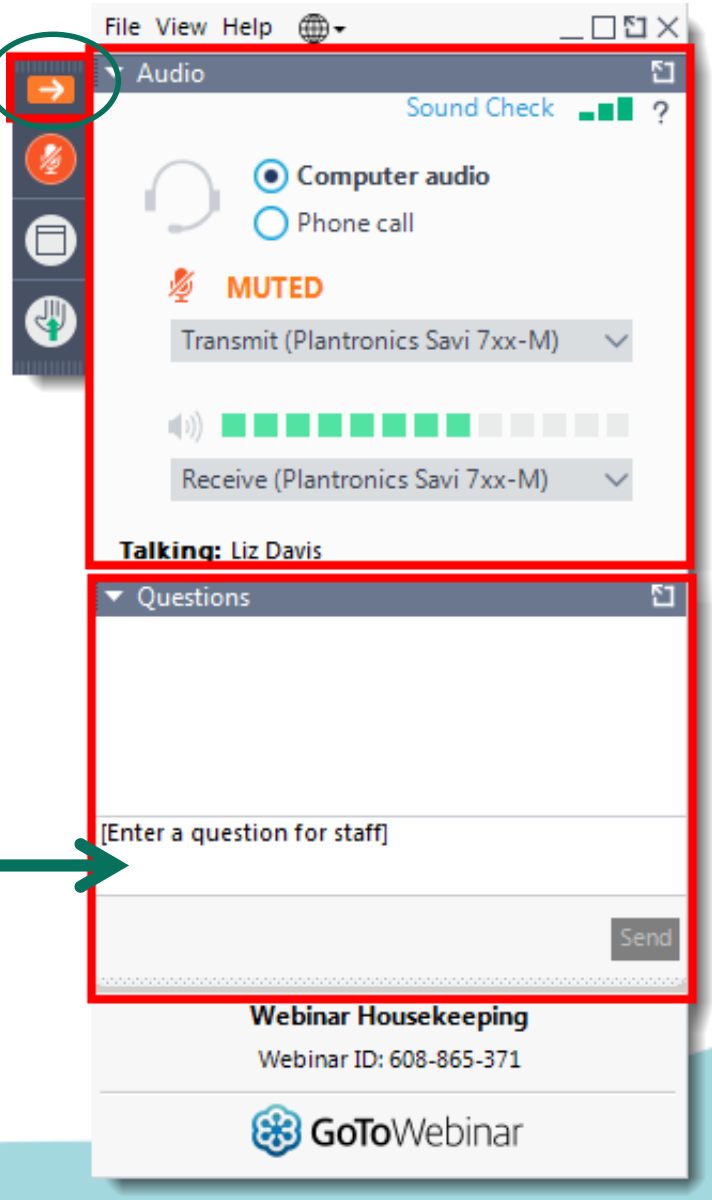

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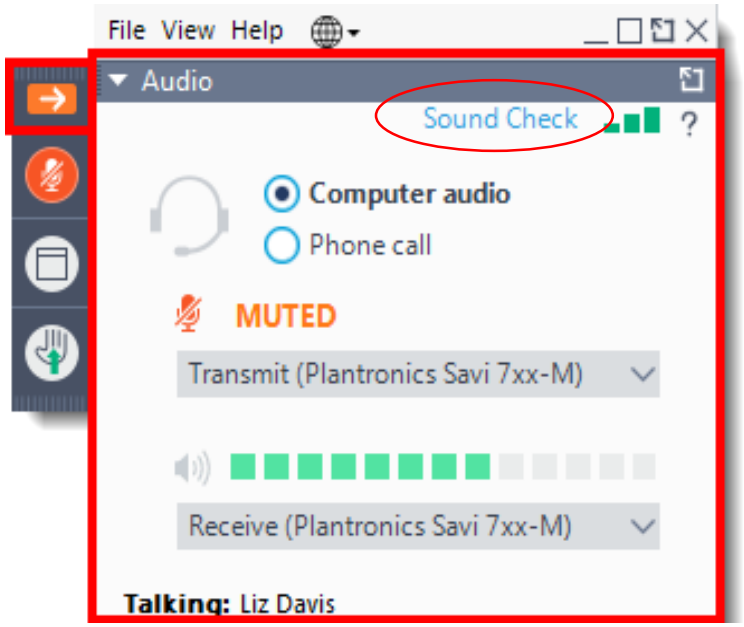

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Before we start…

- 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
- IMI2 – Call 17 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 17 Topic 3

Intelligent prediction and identification of environmental risks posed by human medicinal products

Tek-Ang Lim

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

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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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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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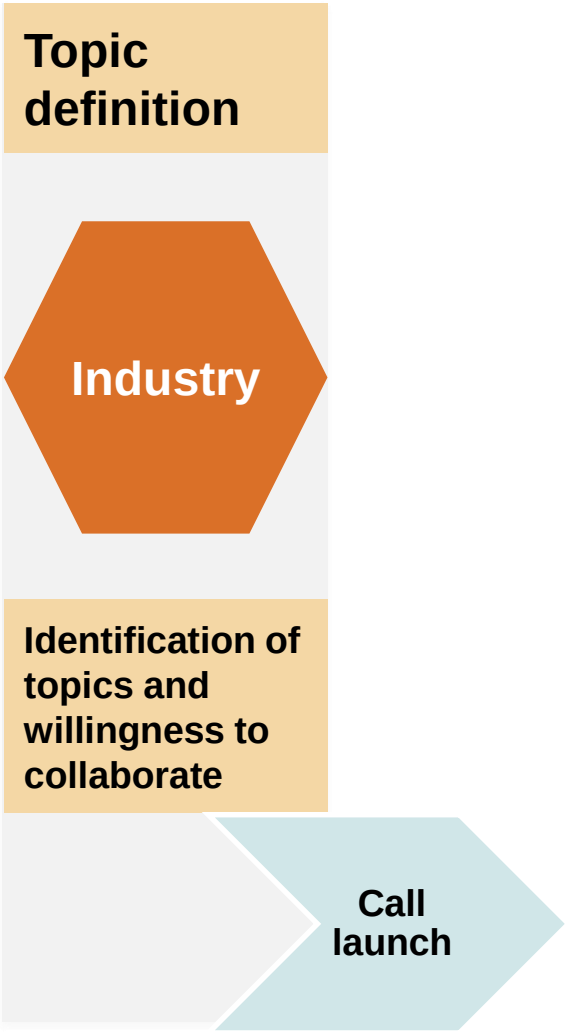
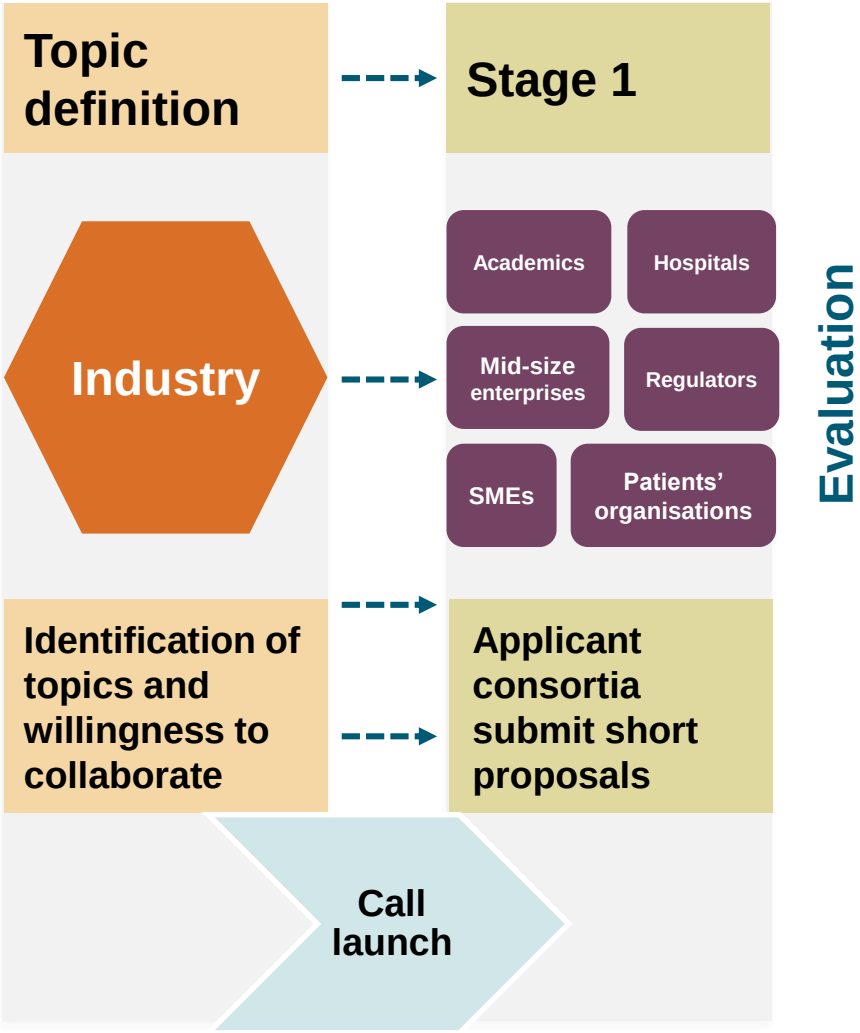
Typical IMI project life cycle



Typical IMI project life cycle



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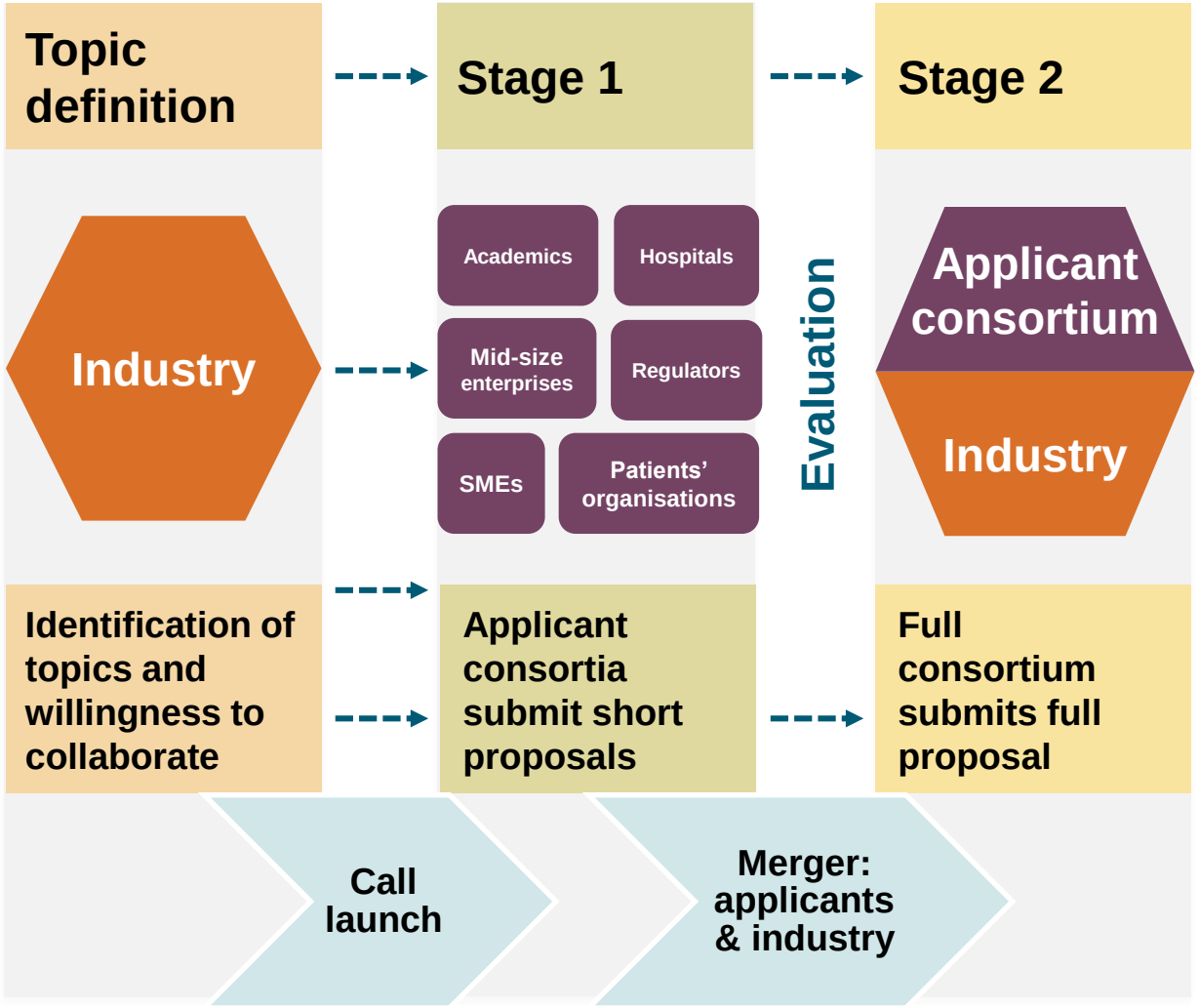
Typical IMI project life cycle



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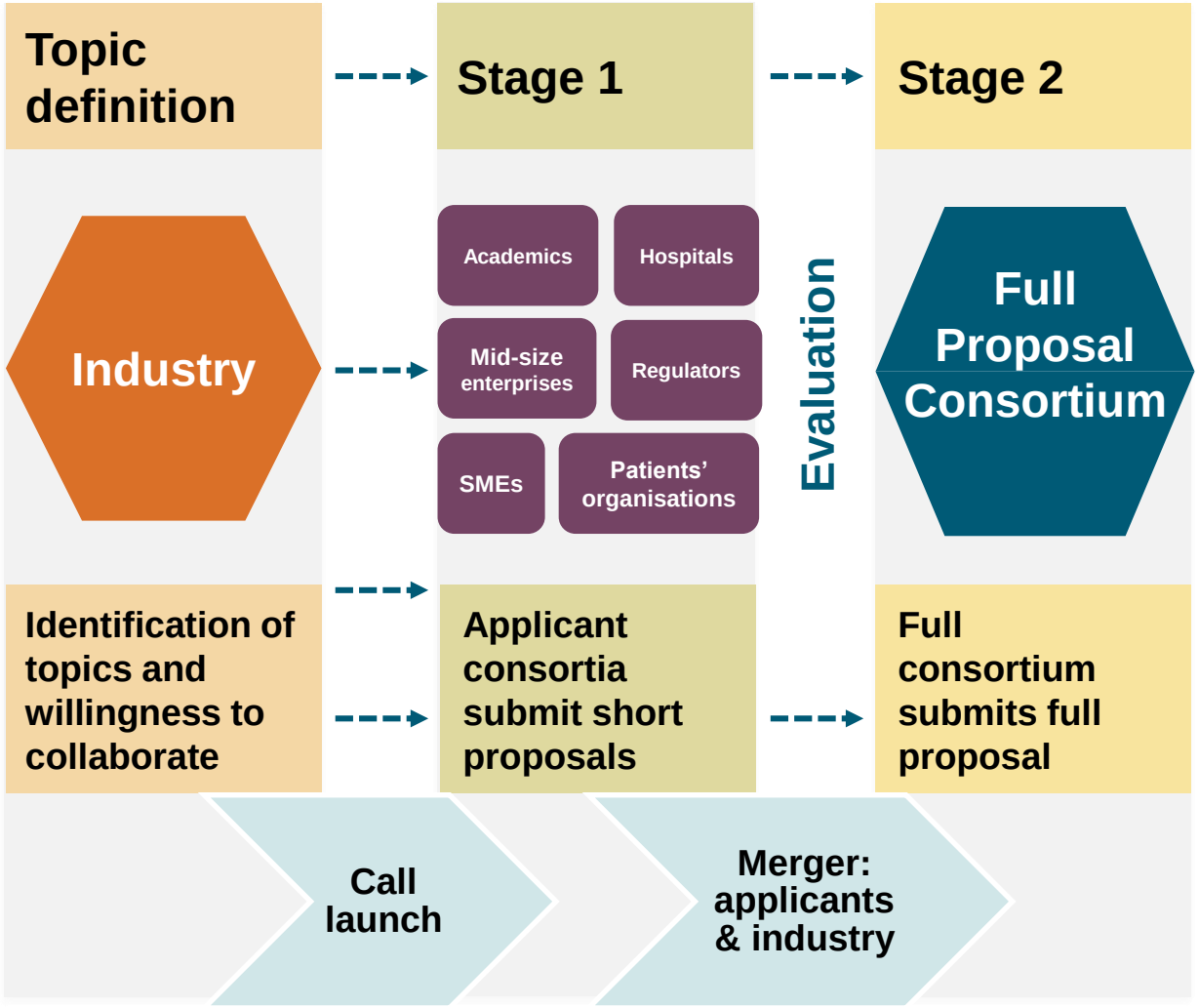
Typical IMI project life cycle



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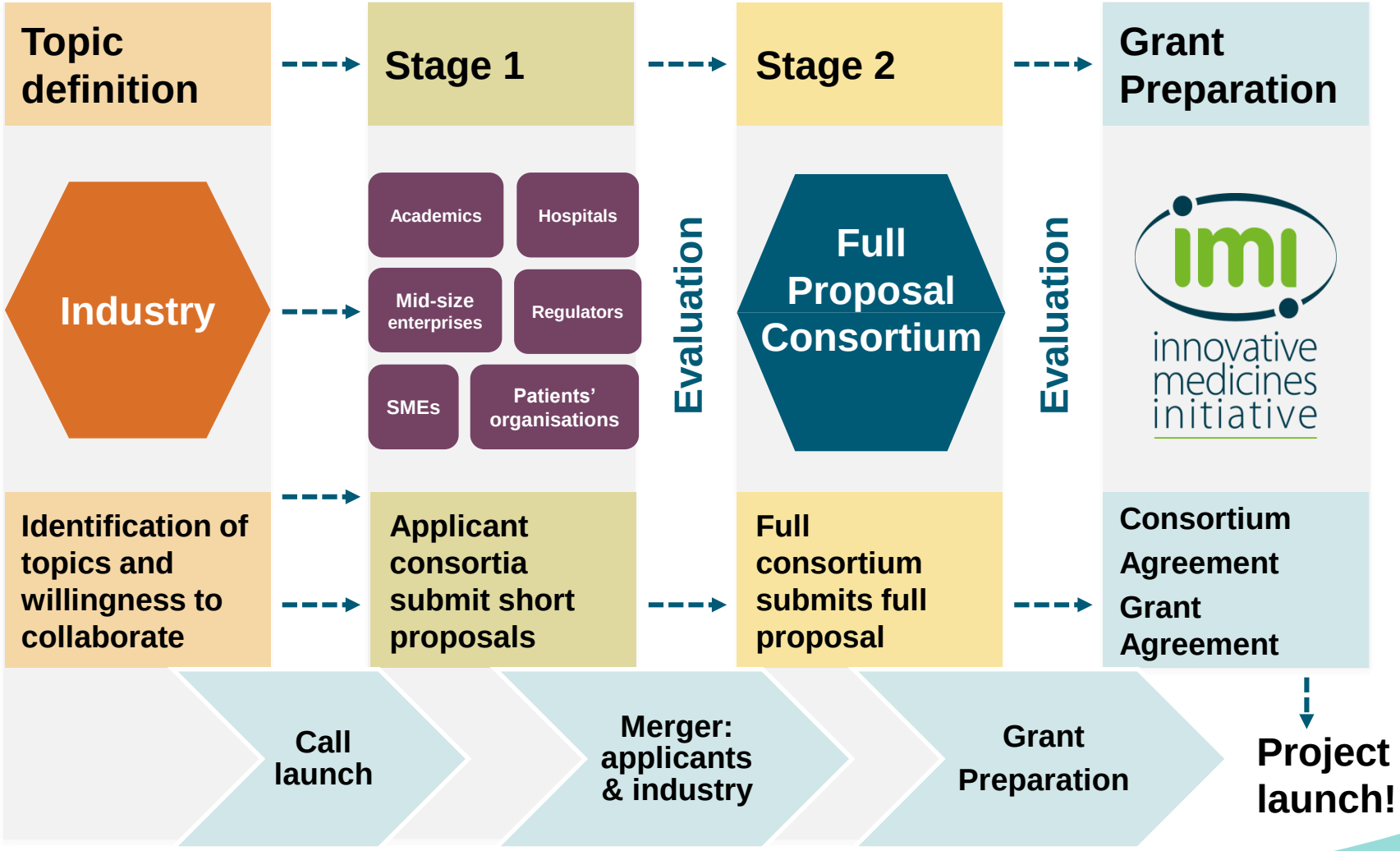
Typical IMI project life cycle



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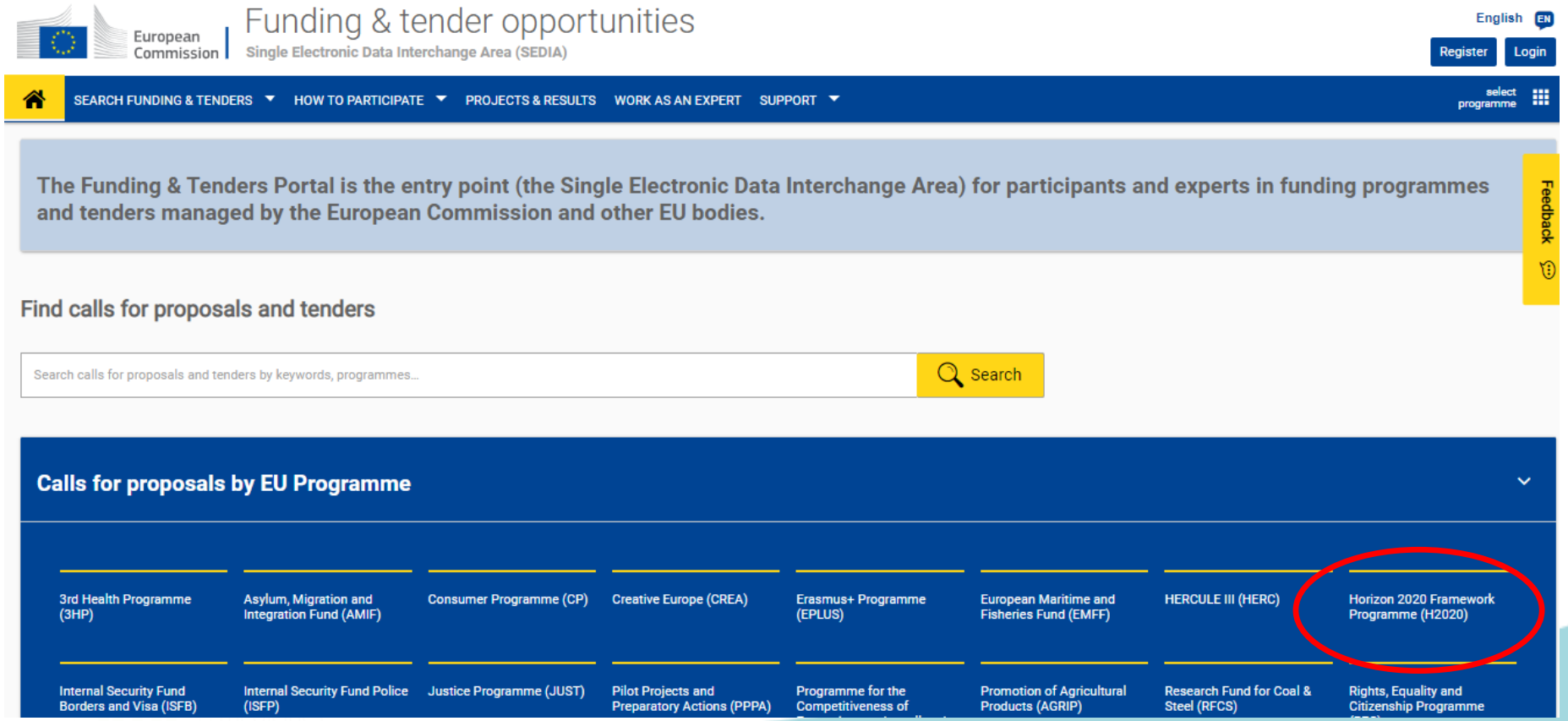
Submitting a proposal

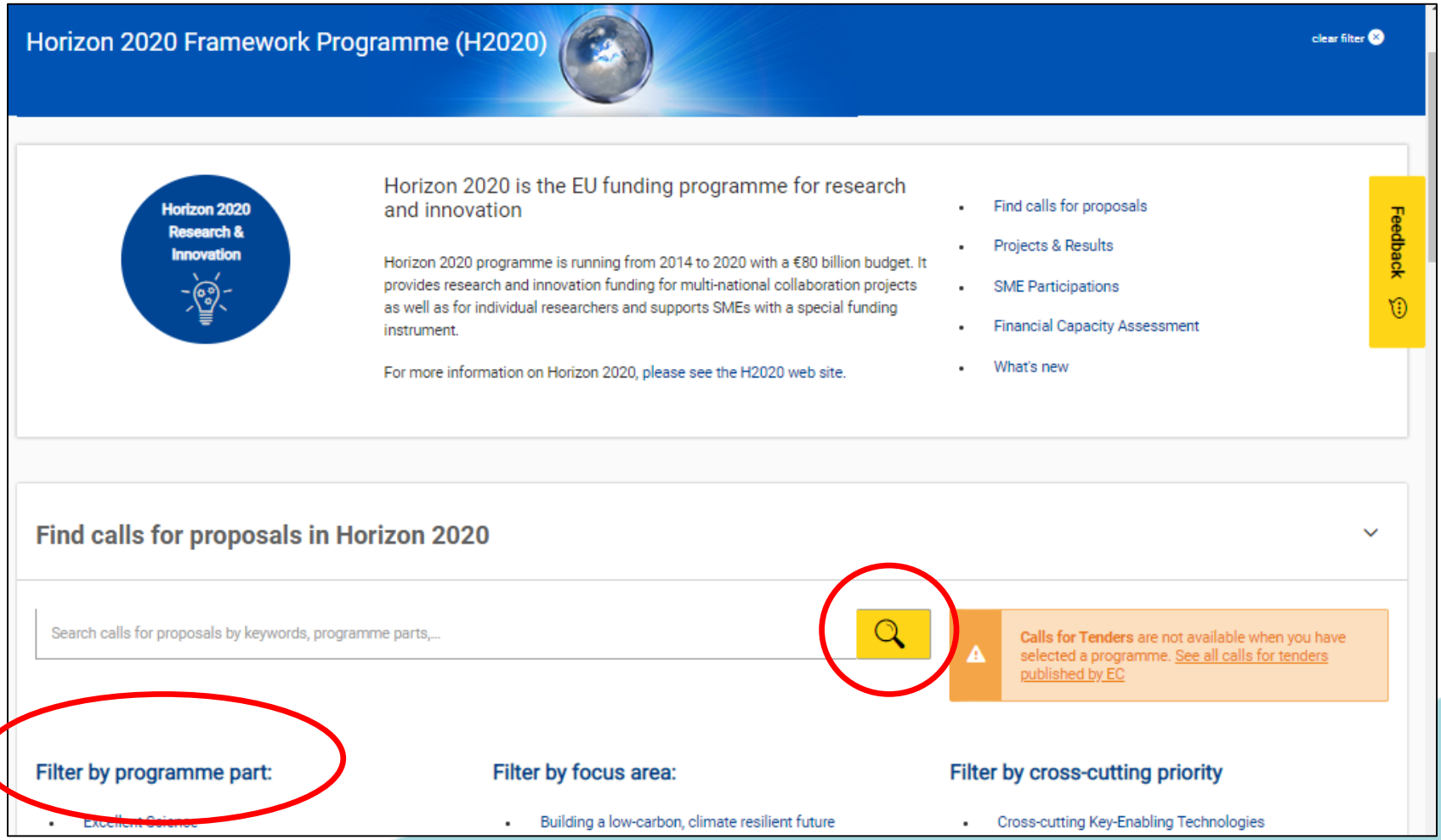
Via the **new** Funding and Tenders Portal

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**	**3.**	**IMPLEMENTATION**
1.1	**Objectives**	**3.1**	**Outline of project plan — Work packages, and major deliverables**
1.2	**Relation to the call topic text.**	**3.2**	**Management structure and procedures**
1.3	**Concept and approach**	**3.3**	**Consortium as a whole**
1.4	**Ambition**	**3.4**	**Table 3.1a: List of work packages**
2.	**IMPACT**	**4.**	**PARTICIPANTS**
1	**Expected impacts**	**4.1.**	**Participants (applicants)**

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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 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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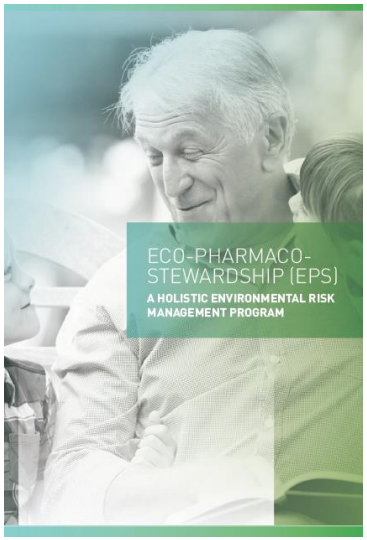
Intelligent prediction and identification of environmental risks posed by human medicinal products

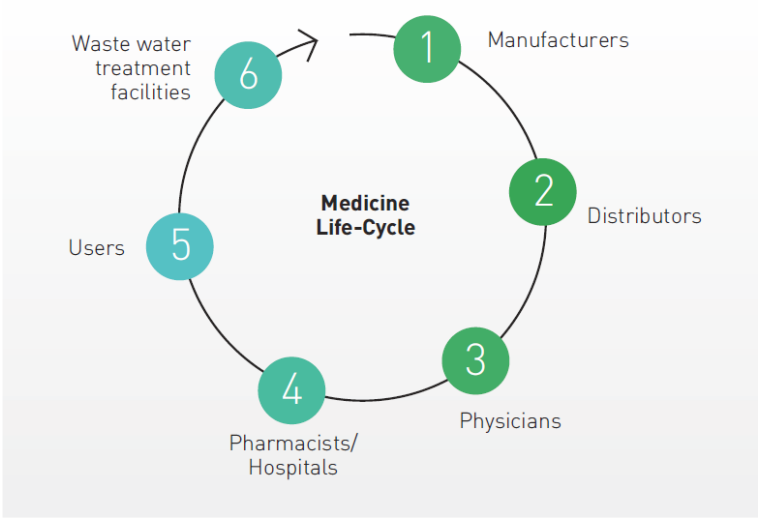
Jason Snape

23.01.2019 • IMI webinar

Need for public-private collaboration

- A public-private collaborative research partnership is required to identify and manage the environmental risks of human medicinal products **across the whole of their product life cycle** as **no single stakeholder** can **proactively manage** and **mitigate** these **risks alone**





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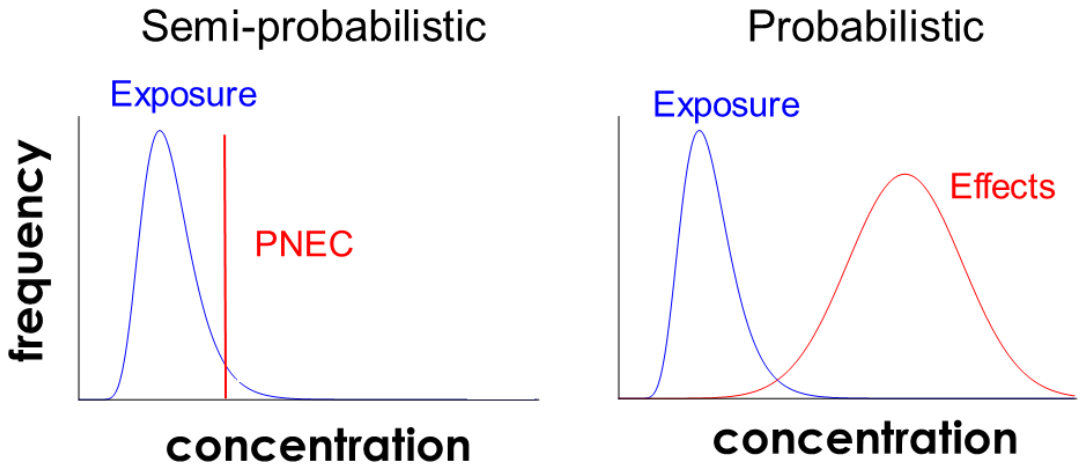
Objectives of the full project (1)

- To develop a database for the collation of ERAs and supporting data with the support of the EMA and national competent authorities
  - act as a single central resource/ reference point
  - maximise transparency of data
  - facilitate accessibility of data
  - minimise duplicate testing, particularly for fish toxicity
  - be active pharmaceutical and not product based

Objectives of the full project (2)

- To enable the ecotoxicology/environmental database to capture
  - spatially refined exposure assessments
  - measured environmental concentrations
  - tools and models to allow probabilistic and/or semi-probabilistic analysis



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Objectives of the full project (3)

- To develop innovative approaches to assess environmental risks. Such innovative approaches should include:
  - providing three-dimensional *in vitro* cell culture approaches to assess API uptake, metabolism, elimination and toxicity in fish
  - improving the predictability and applicability of the fish plasma model
  - applying artificial intelligence and machine learning approaches to improve comparative toxicological predictions between preclinical and environmental safety assessments
  - considering environmental impacts in other environmental taxa and for other environmental compartments

Objectives of the full project (4)

- To apply and validate the tools, models and methodologies developed with an ambition to assess at least 25 legacy APIs, including key metabolites, selected in agreement with key external stakeholders
  - Data may be needed beyond the pharmaceutical industry to support model development and validation
  - it is expected that any ERA data for priority APIs identified, generated and validated in this project will be made publicly available outside the project

Objectives of the full project (5)

- To work across a broad group of stakeholders including the pharmaceutical industry to review and establish the feasibility of developing APIs with a lower environmental impact. The review will need to consider:
  - what the key environmental concerns are
  - trends in drug, discovery, design and delivery
  - the feasibility of integrating these environmental considerations earlier in drug development
  - patient preferences for drug administration
  - The socio-economic impact related with realising the recommendations from the review and associated timescales

Pre-competitive nature

- Environmental management of APIs need to cover the whole product life cycle and not just the point of authorisation
- Few tools and models have developed and validated to predict environmental risk
  - Most existing models predict acute and not chronic toxicity
  - Many pharmaceuticals sit outside the applicability domain of these models
- No EU-wide recognised database exists that collates the environmental data for active pharmaceutical ingredients
- Data transparency and accessibility will foster innovation collaboration and understanding

Expected impact (1)

- The overall aim of this project is to apply innovative approaches to ensure the environmental safety of human medicinal products such that both
  - environmental concerns do not become a barrier to patient access to medicines
  - the intended use of medicines does not pose an unacceptable risk to the environment

Expected impact (2)

- The availability of effective tools to prioritise legacy (pre-2006) APIs for environmental testing will
  - Ensure more effective environmental management of APIs
  - Reduce testing burden without compromising environmental protection
    - Up to 500M Euro saving
    - 3Rs benefits

- The availability of predictive tools and models could allow environmental risks to be integrated earlier within drug development

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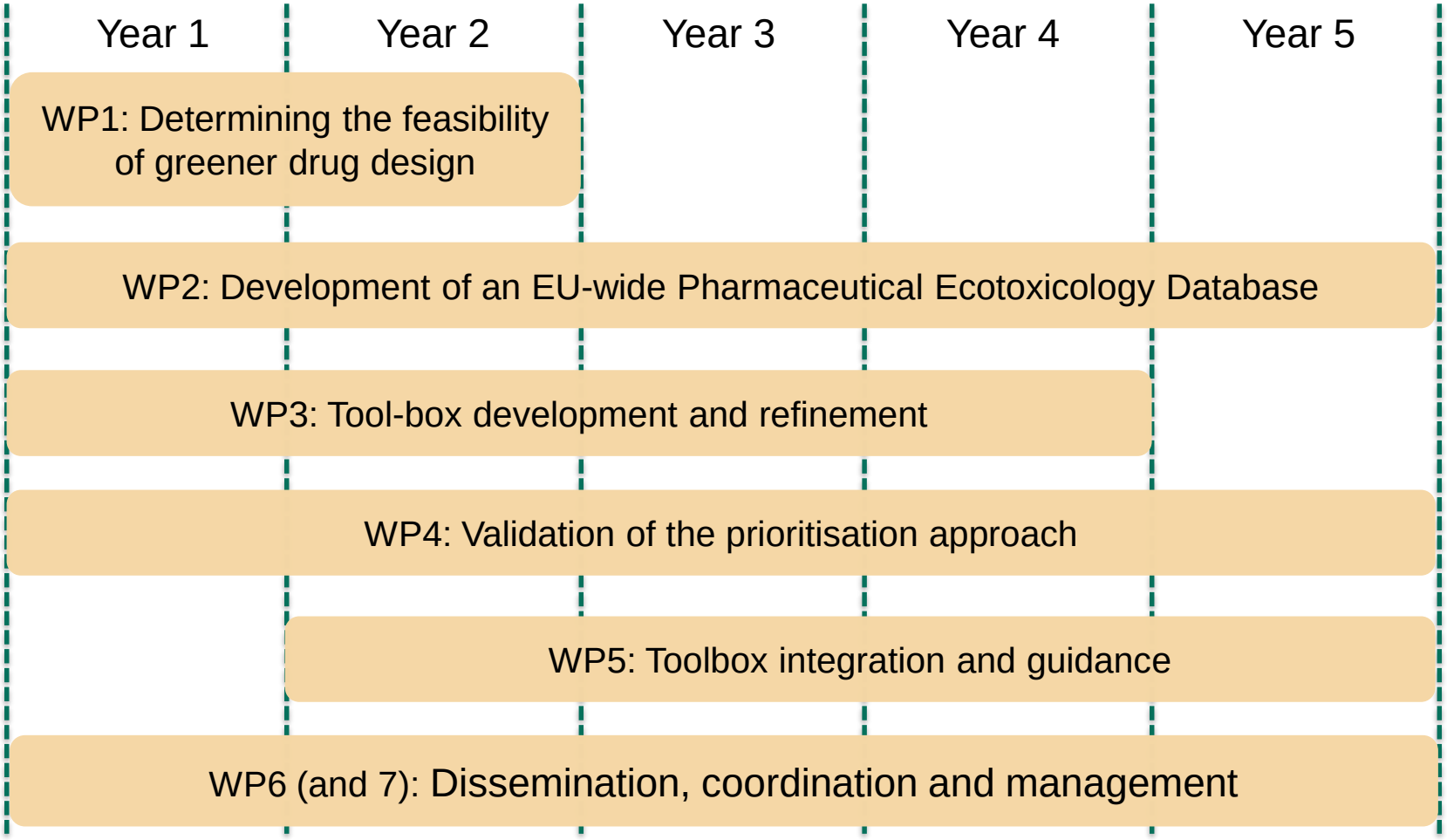
Expected impact (3)

- Increased transparency of data through an EU-wide environmental database for APIs with environmental data (e.g. ecotoxicological endpoints) in the public domain will
  - help all stakeholders understand the risks posed to the environment by human medicinal products
  - allow scientists to present their monitoring work in the context of risk
  - reduce duplication of environmental testing saving costs and animal use

Suggested architecture of the project



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Suggested effort for each work package

WP1: Determining the feasibility of greener drug design

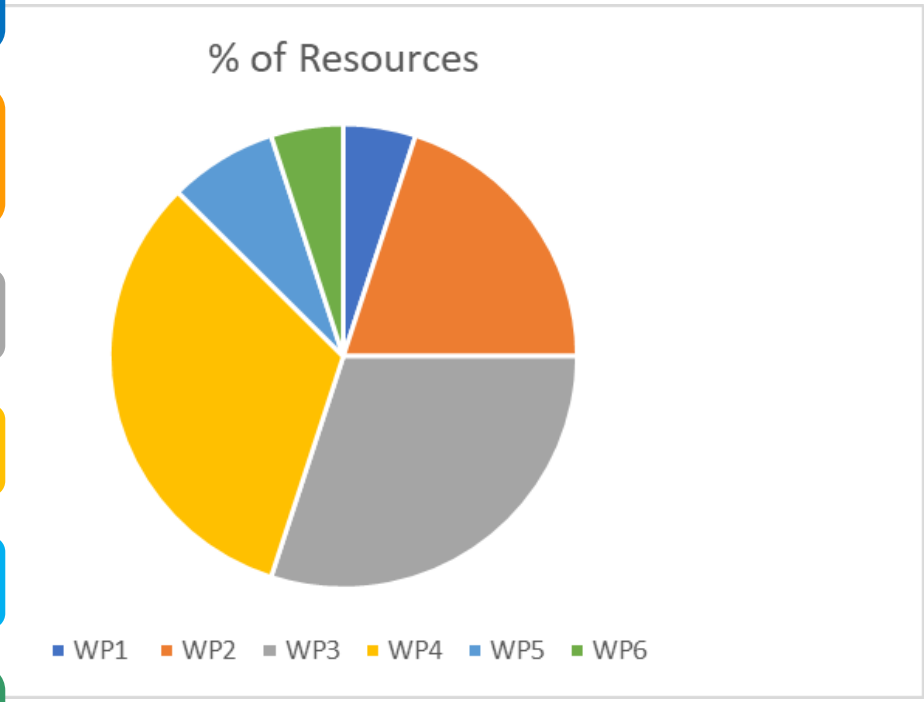
WP2: Development of an EU-wide Pharmaceutical Ecotoxicology Database

WP3: Tool-box development and refinement

WP4: Validation of the prioritisation approach

WP5: Toolbox integration and guidance

WP6 (and 7): Dissemination, coordination and management



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Expected contributions of the applicants (1)

- Experience in leading, managing and measuring impact of public-private partnership consortia
- Expertise in ecotoxicology, environmental exposure assessment and environmental risk assessment
- Expertise in environmental exposure modelling and approaches for semi-probabilistic and probabilistic environmental risk assessment
- Proven ability to generate regulatory compliant environmental risk assessment studies
- Expertise in artificial intelligence and machine learning approaches to big data analysis
- Expertise in drug discovery and drug development

Expected contributions of the applicants (2)

- Expertise in mode-of-action-driven ecotoxicology
- Expertise in data management and curation, database development, data visualisation
- Expertise in the development and implementation of evidence-based decision software
- Expertise in analytical and environmental chemistry to support environmental assessments and environmental monitoring
- Social science experience to support engagement with stakeholders across the product life cycle
- Proven ability to impact environmental policy and regulation

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Expected contributions of industry consortium (1)

- Expertise and experience in leading and managing large scale public-private partnerships
- Provide physico-chemical, ecotoxicology and environmental fate data that are regulatory compliant (provision of existing data by the industry partners does not count as in-kind support)
- Drug discovery and development expertise
- Computational chemistry expertise
- Support for test compound selection and experimental design
- Synthesis of test materials (e.g. 14C API or metabolites) for validation work where existing material is not available
- Design and execution of environmental risk assessments that comply with EMA and FDA regulations

Expected contributions of industry consortium (2)

- Identification of appropriate assays to support tailored environmental assessments
- Techniques and statistical methodology development
- Expertise in regulatory sciences and in strategic approaches to collaborate with environmental authorities to introduce innovative environmental methodologies
- Legal expertise related to intellectual properties management and complex partnership co-development structures

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What's in it for you?

- Helping to ensure that:
  - patient access to medicines does not compromise the natural environment
  - increasingly precautionary approaches to environmental management does not compromise innovation in the pharmaceutical sector and patient access to life changing medicines
- Be at the forefront of new technology and its regulatory and industrial application
- Defining standards for the healthcare industry and environmental regulations
- Building a research partnership with leading academics, industry and regulatory experts

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Key deliverables of the full project (1)

- Agreement on future ERA and risk prioritisation strategy with key stakeholders (i.e. the EC and EMA) together with an associated socioeconomic impact assessment for the implementation of this strategy

- A comprehensive review that establishes the feasibility of developing APIs with a lower environmental impact

Key deliverables of the full project (2)

- Delivery of validated predictive models/tools together that can (i) be integrated earlier within drug development and (ii) prioritise established or legacy APIs for a tailored ERA

- Publicly available tools and models with
  - clearly defined validity domain for each tool and model
  - an impact assessment for false negative and false positive predictions against (i) regulatory decision making and (ii) investment decisions in drug development
  - tailored and definitive ERA data for approximately 25 APIs that have been used to test, validate and refine the prioritisation framework and supporting guidance

Key deliverables of the full project (3)

- An updated knowledge-driven ecotoxicology and ERA database with integrated software to support semi-probabilistic and probabilistic risk assessments

- Recommendations for an EU-wide Pharmaceutical Ecotoxicology Database supported by industry and the European Commission.

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Thank you

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@IMI_JU

Involvement of SMEs, patient groups, regulators

Tek-Ang Lim

SME participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations, and help deliver the long-term impact of the project.

Examples of SMEs contribution that could be considered beneficial in providing the following expertise and activities (list not exhaustive):

- support the development of in vivo, in vitro and in silico tools for ecotox hazard identification, prioritisation and risk assessment;
- expertise in artificial intelligence and machine-learning to support the identification of relationships at a systems-wide level that can act as predictors of environmental hazard and risk;
- medical & scientific writing supporting regulatory interactions;
- Expertise in the waste water industry;
- patient engagement, environmental NGOs.

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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. assess the issue of PiE, strategy of PiE)
- 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!