

- **An AI foundation toxicology model and framework to support waiving a second species in drug safety studies**

IHI call 13 – topic 2

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Before we start...

- We are recording this session and it will be published on the IHI website. We will also publish the presentation slides.
- The call will be launched shortly and all links and details of how to apply will be published on the [IHI website](#) and the Funding and Tenders Portal.
- If you want to ask a question please use the chat function on the right corner of your screen.



Today's webinar

- **Will cover:**

- Introduction to IHI programme
- IHI call 13 topic 2 presented by lead of the pre-identified industry consortium
- Proposal submission & evaluation
- Tips for writing a successful proposal

- **Will not cover**

- Rules and procedures

Innovative Health Initiative

EU partnership in health between:

- the **European Union** represented by the European Commission &
- **Healthcare industry associations:**
 - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
 - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
 - **EuropaBio** (biotechnology industry)
 - **MedTech Europe** (medical technology industry)



IHI's general objectives

- Turn health research and innovation into **real benefits for patients and society**
- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need
- Make Europe's health industries globally **competitive**.

IHI projects are...

Created via open and competitive calls for proposals

Cross sectorial public private partnerships leveraging:

- Contributions from industrial partners from the IHI industry associations (COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTechEurope)
- if relevant, contributions from contributing partners (must be approved by IHI GB)

and

- Public funding via European Commission (Horizon Europe)

Strategic Research & Innovation Agenda

Focus

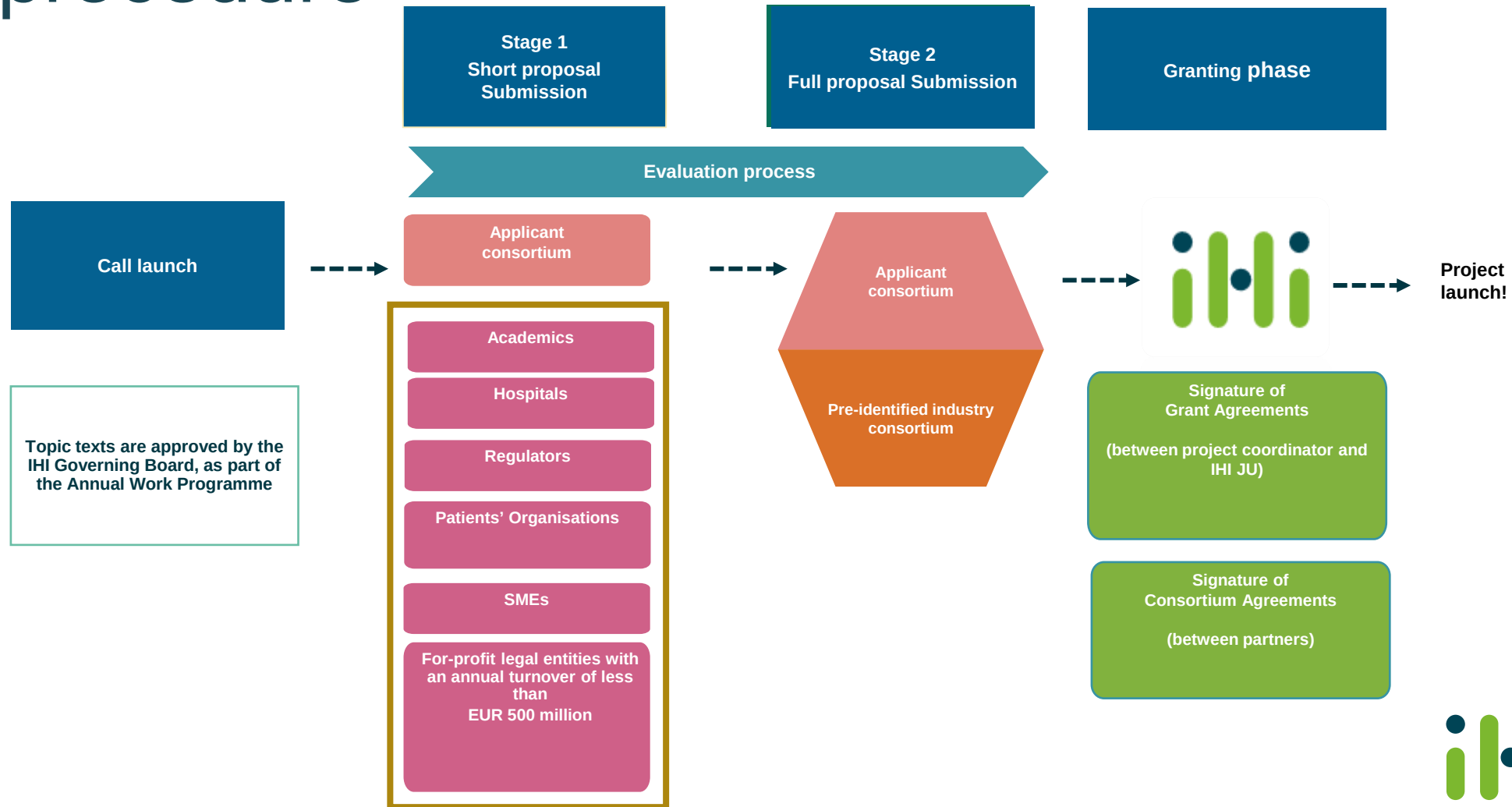
- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

Goal

- Lay foundations for development of **safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level

How does IHI work? Two-stage procedure



- **An AI foundation toxicology model and framework to support waiving a second species in drug safety studies**

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The challenge

Why move beyond two-species testing

- Regulatory guidelines (e.g. ICH M3(R2)) have historically required toxicity testing in two species, typically one rodent and one non-rodent
- This two-species approach is increasingly challenged by:
 - ethical considerations and the 3Rs principles
 - long, costly study durations and limited reproducibility
 - uncertainty over human relevance
- Absence of standardised, data-driven methods means waiver decisions vary across reviewers and jurisdictions, discouraging change
- The global policy landscape is shifting: EC roadmap to phase out animal testing (adopted on June 1st 2026), EMA NAM focus, UK Replacing Animals in Science strategy, and the FDA preclinical roadmap
- Advances in mechanistic toxicology, advanced in vitro systems, multi-omics and AI now enable New Approach Methodologies (NAMs)



Need for public-private, cross-sector collaboration

Why this can only be achieved through an IHI JU action

- Regulator-trusted, NAM-enabled second species waivers require assets no single organisation holds alone:
 - large, heterogeneous datasets pooled from many companies
 - federated collaboration across pharmaceutical companies and stakeholders
 - cross-disciplinary expertise in toxicology, data science, regulatory science and ethics
 - early, coordinated engagement with regulatory authorities
- IHI JU public-private partnerships provide the framework, scale and infrastructure to deliver impact, ensure sustainability and build broad stakeholder confidence
- Collaboration spans pharmaceutical and biotech companies, regulators, academia, SMEs and patient advocacy groups



Scope of the topic

An AI Foundation Toxicology Model to standardise waivers

- Develop a transparent, AI-driven Foundation Toxicology Model to standardise second-species waivers for chronic and sub-chronic small molecule general toxicology studies
- Underpinned by diverse, standardised, high-quality in vivo datasets and a robust weight-of-evidence framework
- Main context of use: predict whether a second species will provide additional safety-relevant information (missed toxicity, organ-specific findings, NOAEL divergence)
- Five workstreams the proposal should deliver:
 - consolidate and evaluate data sources
 - select and optimise AI methods
 - develop and validate the AI Foundation Toxicology Model
 - establish a standardised weight-of-evidence framework
 - prepare for regulatory uptake and long-term sustainability
- Builds on IMI/IHI projects (BigPicture, eTRANSAFE, eTOX, imSAVAR, VICT3R) and NC3Rs / ASPIS initiatives; longer-term goal to extend to single-species waivers beyond small molecules (e.g. oligonucleotides)



Expected outcomes

Four outcomes the action must deliver

- A validated AI Foundation Toxicology Model giving transparent probabilistic predictions on when a second species is unlikely to add safety-relevant information
- A standardised, transparent weight-of-evidence framework for reproducible assessment of evidence quality, consistency, relevance and uncertainty
- Functional tools, templates and training materials supporting real-world implementation, including explainability, provenance, governance and ethical use
- Enhanced industry and regulator confidence in second-species waiver applications, enabling consistent global decision-making without compromising patient safety

Expected impact

Benefits for science, industry, regulators and patients

- Faster, more informed decision-making through an AI-driven NAM and rapid processing of large data volumes
- Increased consistency and standardisation in NAM-based approaches, improving industrial competitiveness
- Regulatory adoption of a NAM-enabled second-species waiver model and weight-of-evidence framework
- Reduction in animal use, accelerated timelines and lower costs, supporting the 3Rs and EU Directive 2010/63/EU
- Improved public health, with patients benefiting from safe, effective medicines developed faster



Expected contributions of the industry consortium



- Pre-identified industry consortium: AbbVie, Bayer, Bristol Myers Squibb, Eli Lilly, Gilead, Novartis, Pfizer (Lead) and Servier
- Contributing partner: UKRI NC3Rs (National Centre for the Replacement, Refinement and Reduction of Animals in Research)
- Expected contributions:
 - proprietary toxicology and mechanistic datasets
 - expertise in CDISC SEND, AI/ML, mechanistic toxicology, pharmaceutical and regulatory sciences, and federated analytics
 - infrastructure for federated learning
 - leadership in model development, validation and regulatory engagement

Expected contributions of the applicants

Expertise and resources expected to be brought into the project

- Pharmaceutical and toxicology data management, engineering and integration: SEND-formatted and unstructured study data, in vitro and omics; ontology mapping; value and text extraction; federated platforms
- AI/ML model development: core ML, AI and data science, large-scale models (multi-billion parameters) and multi-modal development
- Experience with complex probabilistic predictions from foundation or fine-tuned models
- Regulatory and compliance SOPs for AI model validation and monitoring; weight-of-evidence decision-making
- Project management for large multi-stakeholder European public-private partnerships
- Technological infrastructure: high-performance computing, secure data storage and a federated data platform for blinded sharing and analysis
- Provision of proprietary toxicology and mechanistic datasets, where available



Key Facts

- **Budget**

- IHI JU financial contribution: up to EUR 9 000 000
- Industry beneficiaries in-kind contribution: EUR 7 300 000
- Contributing partner (UKRI NC3Rs) in-kind contribution: EUR 100 000

- **Duration**

- 60 months (indicative)





Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu





Proposal submission & evaluation

Proposal Template - Parts A, B & Annexes

- **Part A** of the proposal is **administrative data** that is entered in webforms through the Funding & Tenders Portal.
- **Part B** of the proposal is the **narrative part** that includes three sections:
 - Excellence
 - Impact
 - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**
- **Annex:**
 - Participant type



Evaluation Criteria (1/2)

- **Excellence**

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology

- **Impact**

- Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.





Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
 - Quality and effectiveness of the outline of the work plan
 - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.





● Tips for applicants



Tips for applicants

- Read all the call-relevant material, especially the **topic text**
 - www.ih.europa.eu/apply-funding/open-calls
 - www.ih.europa.eu/apply-funding/future-opportunities
- Form your consortium **early**
 - Already think “public-private partnership”
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results (see also our [guide](#))



Finding project partners

You'll need to build or join a consortium!

- Use EU Funding & Tenders portal **partner search tool**:
 - <https://europa.eu/!QU87Nx>
- Get in touch with your **IHI national contact point**:
 - <https://europa.eu/!D7jyMy>
- Network on social media:
 - <https://bsky.app/profile/ihieurope.bsky.social>
 - be.linkedin.com/company/innovative-health-initiative



Thank you for your attention

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