

- Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment

IHI call 4 – topic 6

Important disclaimer

Please be aware that the call topics are still under consultation with the States' Representatives Group and the Science and Innovation Panel (IHI advisory bodies).

All information regarding future IHI call topics is indicative and subject to change until call launch.

You will find the final authorised version of the topic text on the Funding and Tenders Portal at call launch.

Before we start...

- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.

Today's session

- **Will cover:**
 - Introduction to IHI programme
 - IHI Call 4 Topic 2 presented by lead industry pre-identified consortium
 - Information on proposal submission & evaluation
 - Tips for writing a successful proposal
- **Will not cover** rules and procedures
 - The webinar on rules and procedures will be made available on the IHI website.

Innovative Health Initiative

EU's new **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**.

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.

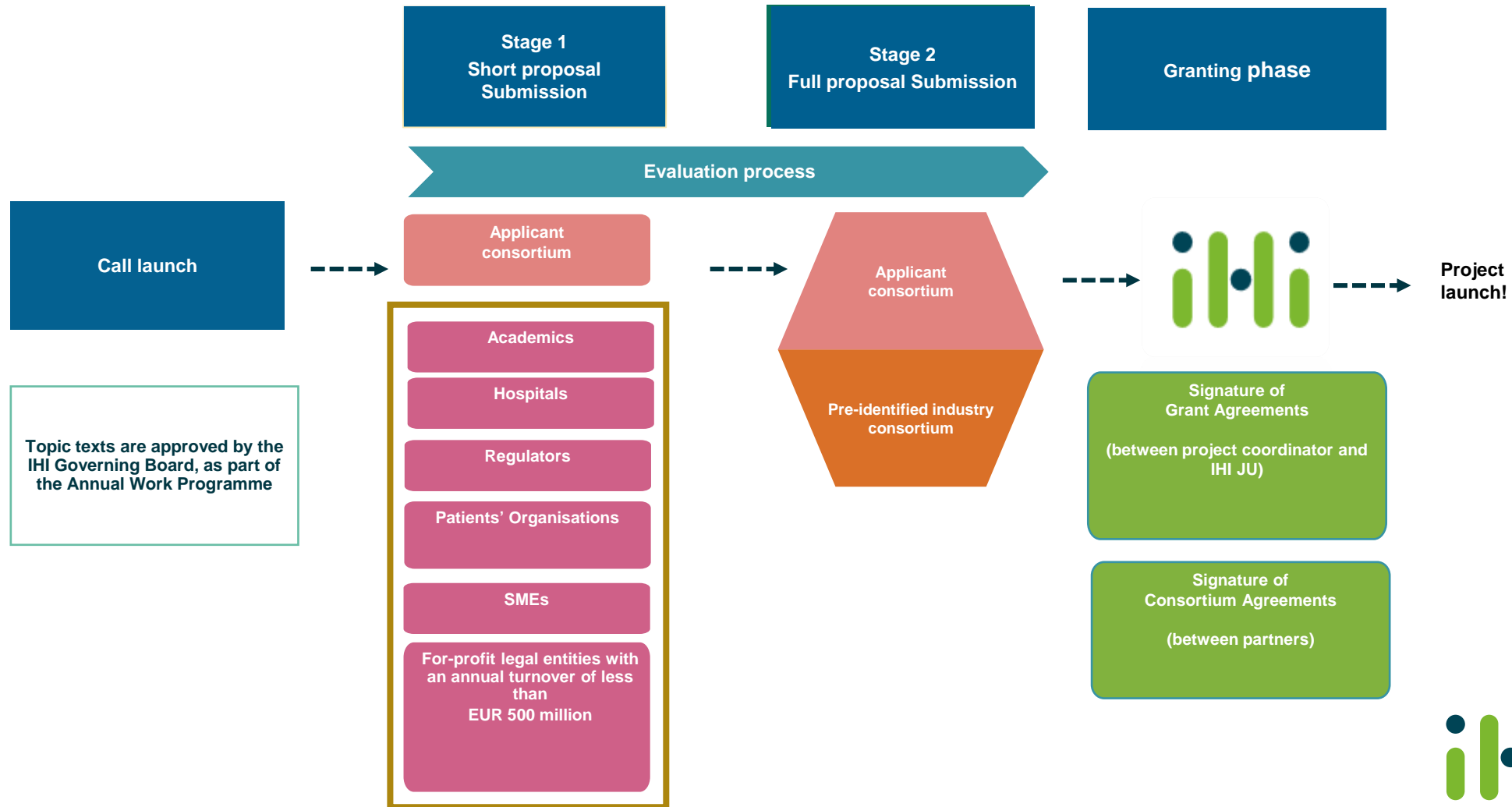
Goal


- 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

<https://www.ihl.europa.eu/about-ihl/research-and-innovation-agenda>

Two –stage calls – How does it work?





- Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment

IHI call 4 – topic 6

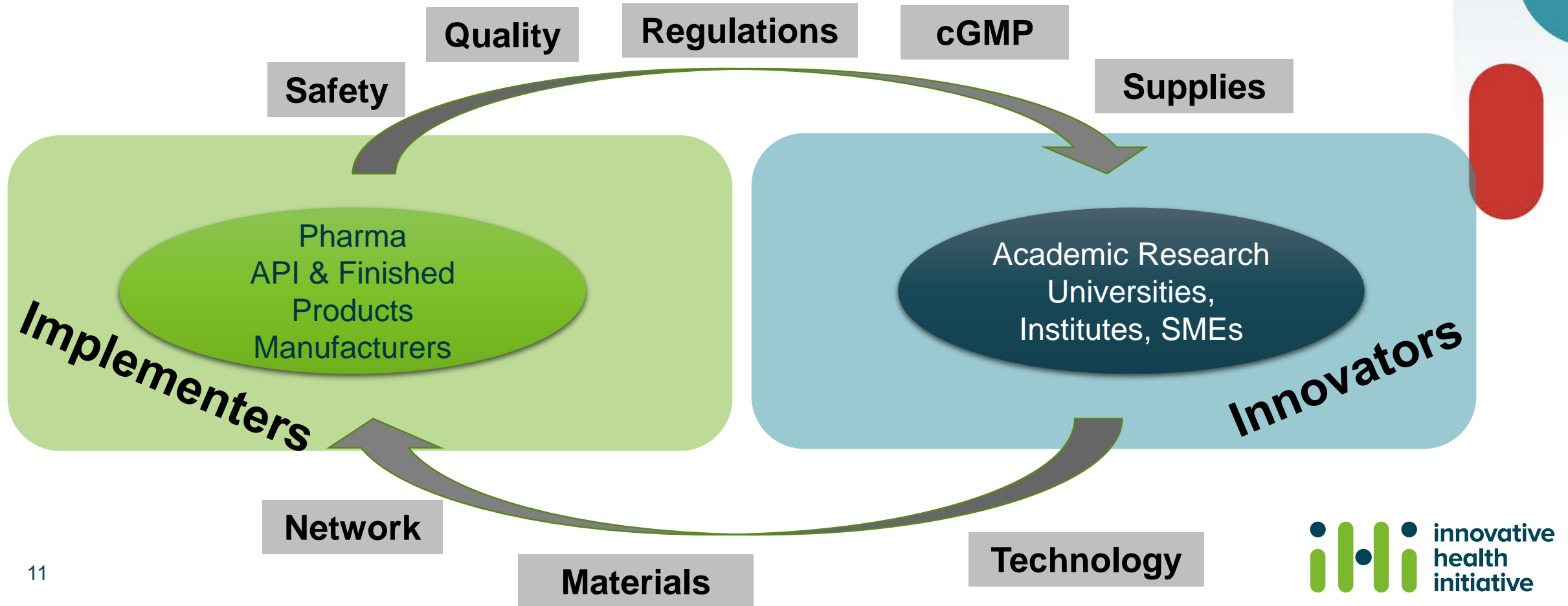
The challenge

Pharma Industries generate 4.4% of global CO₂

- Manufacturing processes not optimized for environmental impact
 - Water/energy consumption
 - “Old” equipment
 - Traditional batch manufacturing
- No harmonized measure in place to assess environmental impact of manufacturing processes across pharma sector
- Long regulatory cycle times to implement process changes

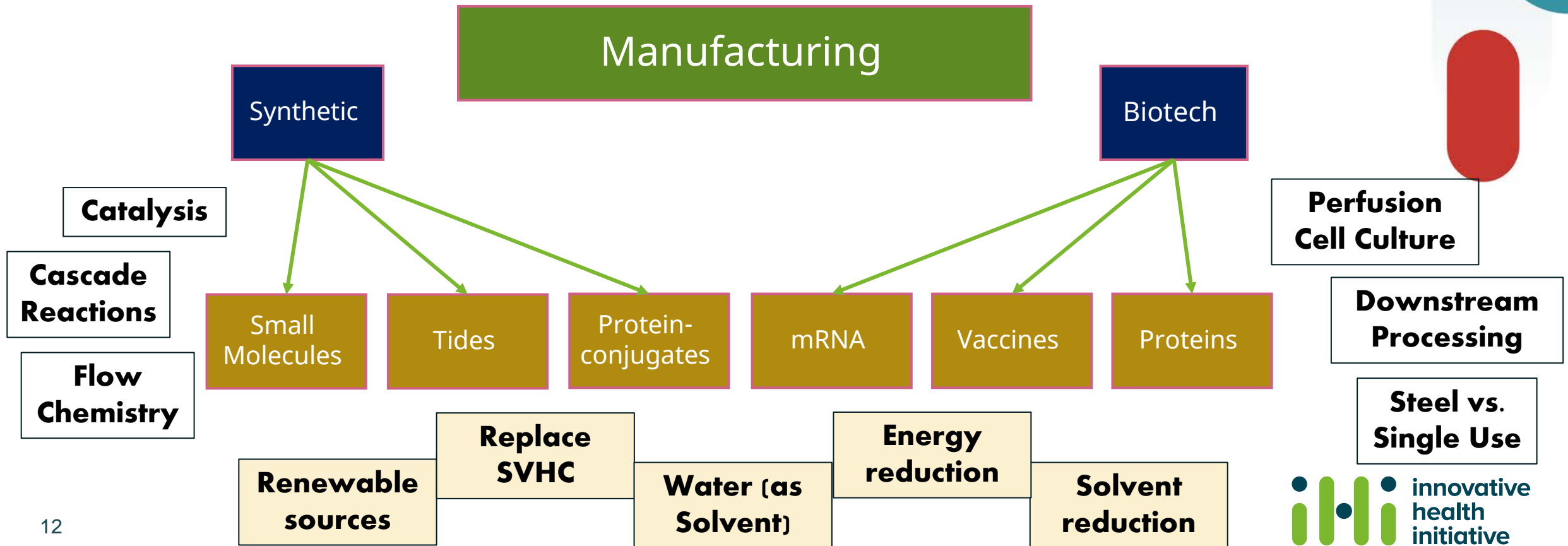
Need for public-private, cross-sector collaboration

Combination of scientific innovation and scale-up capabilities



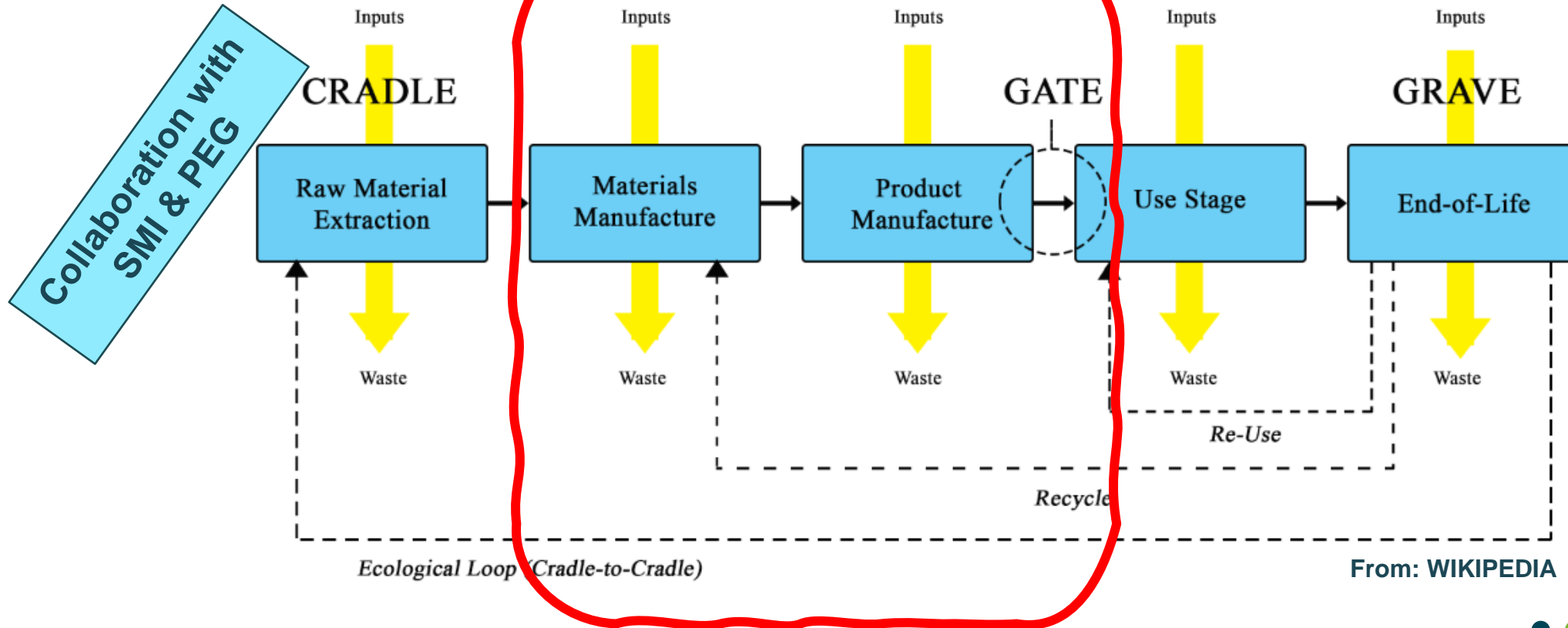
Scope of the topic

Technical Scope



Scope of the topic

LCA Scope



Sector-wide harmonization of LCA Methodologies

Expected outcomes

Cross sectorial collaboration to improve healthcare product manufacturing

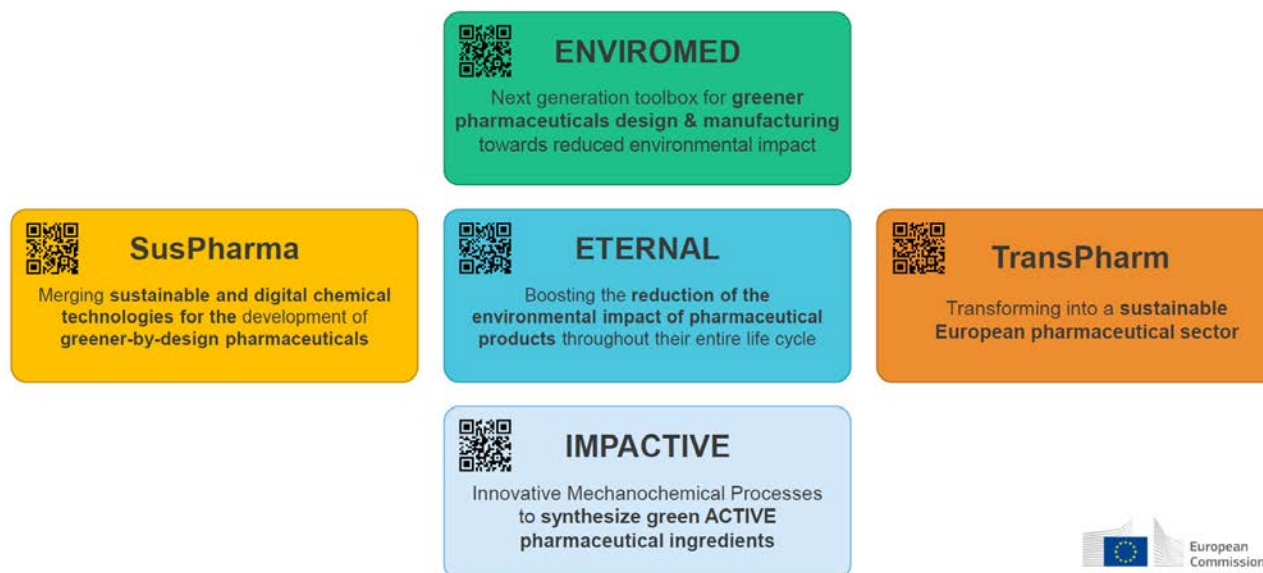
- Innovations in
 - Chemical synthesis (batch vs. continuous)
 - Biologic APIs (fermentation, downstream processing, purification)
 - Manufacturing equipment
 - Use of “substances of concern”
 - Material supplies (from renewable resources)
 - Utilities generation (water, steam)
- Harmonization of LCA methodology
- Guidance how to create “greener factories”

Expected outcomes

Exchange/collaboration with running initiatives

- IHI call 4 – topic 5: Safe & Sustainable by Design (SSbD) packaging and single use device solutions for healthcare products
- HE projects

Selected projects on green pharmaceuticals



Expected impact

Innovation of European Manufacturing Environment

- Europe = Science and Innovation Hub
- Prepare EU pharma industry to significantly reduce environmental impact of drug manufacturing
- Extend the development and manufacturing toolbox by innovative technologies
- Widen the scope of development/manufacturing scientists/engineers

Expected contributions of the applicants

Applicant consortia shall provide ALL of the following

- Grant administration & Project management (meet HE requirements)
- Dissemination
- Demonstrated scientific innovations in the field of
 - NCE/NBE synthesis/fermentation/combinations
 - Innovative process technology
 - Chromatography/Purification
 - Reduction of wastes & energy consumption, reuse of solvent
 - Replacements of stoichiometric reactions (bio-/chemo-catalysis etc.)
- LCA methodology
- AI/ML supported process design technology

Expected (in-kind) contributions of the industry consortium



Manufacturing Technology (70-80% of efforts)

- Drug Development Expertise (drug substance and product manufacturing processes), drug safety, regulatory, environmental/occupational safety, supply chain
- Scale-up
- Chemistry, Manufacturing and Controls (CMC) expertise

LCA Expertise (20-30% of efforts)

- Specifications on product categories and product data to feed the harmonized LCA methodology
- Potentially provide user requirements of a digital LCA tool
- Provide user requirements of new safe and sustainable by design (SSbD) tools
- Collaboration with other initiatives, e.g. SMI (Sustainable Markets Initiative), stakeholders

Budget

Indicative Budget: up to EUR 40 000 000


- Maximum financial contribution from IHI is up to EUR 20 000 000
- Indicative in-kind and financial contribution from industry partners is up to EUR 20 000 000

NB: the above amounts are indicative and subject to change, pending approval by the IHI Governing Board.



Duration

- Indicative duration: **60-72 months.**
- Note: At stage 2, the consortium selected at stage 1 and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.



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 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.ihl.europa.eu/apply-funding/open-calls
- Form your consortium **early**
 - Always 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

Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts & IHI Call Days participants:**
 - <https://ihi-call-days.ihi.b2match.io/>
 - 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:
 - www.twitter.com/IHIEurope
 - be.linkedin.com/company/innovative-health-initiative

www.ihi.europa.eu/apply-funding/find-partners



How to book your meetings via the B2Match platform

Book your meetings in **4** easy steps

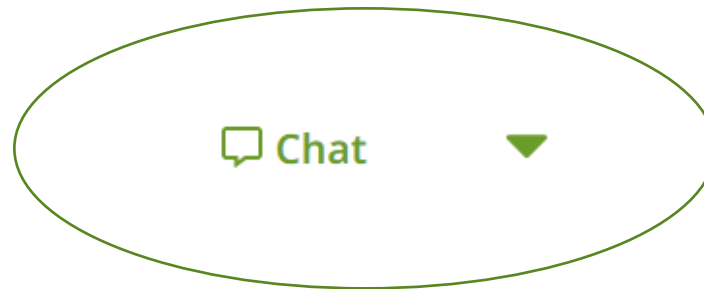
1. Make yourself available
2. Look for partner on the participants or organisation tab
3. Select date, time, attendees (up to eight per meeting), add message
4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: <https://europa.eu/!FkjV9n>



Questions time

If you want to ask a question please use the chat function on the right corner of your screen



#IHICallDays

Call 4



Online event

19 June

16:00-17:30 IHI rules & procedures

20 June

10:00-11:00 Expanding translational knowledge in minipigs

20 June

14:00-15:00 Patient-centric blood sample collection

21 June

10:00-11:00 Inclusive clinical studies

21 June

15:30-16:30 Improving trials for rare diseases

22 June

14:00-15:00 Safe & sustainable by design packaging & devices

22 June

16:00-17:00 Sustainable circular development and manufacture

[Register now](#)



#IHICallDays

Call 5



26 June

15:00-16:30 IHI rules & procedures

27 June

10:00-12:10 Non-animal approaches for health technologies

27 June

14:00-16:10 Theranostics solutions

28 June

14:00-16:10 Stroke management

29 June

10:00-12:10 Synthetic data generation

29 June

14:00-15:30 The financial part of the proposal

Online event

Register now





Thank you for your attention

ihi.europa.eu

