Leveraging Europe’s expertise to accelerate cell therapy for Type 1 Diabetes

IHI call 11 – topic 4

Klelia Salpea, PhD, IHI Scientific Officer
30/06/2025 • Online

innovative health initiative

Before we start…

- We are recording this webinar and it will be published on the IHI website.
- We will also publish the presentation slides.
- IHI call 11 was launched on 17.06.2025 and the final call texts and details of how to apply can be found at IHI call 11 | IHI Innovative Health Initiative
- Ask questions by using the chat function (bottom right on your screen)

innovative health initiative

Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 11 topic 4 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

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)

COCIR Advancing Healthcare efpia EuropaBio The European Association for Bioindustries MedTech Europe from diagnosis to cure Vaccines Europe

Co-funded by the European Union

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**.

innovative health initiative

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)

innovative health initiative

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

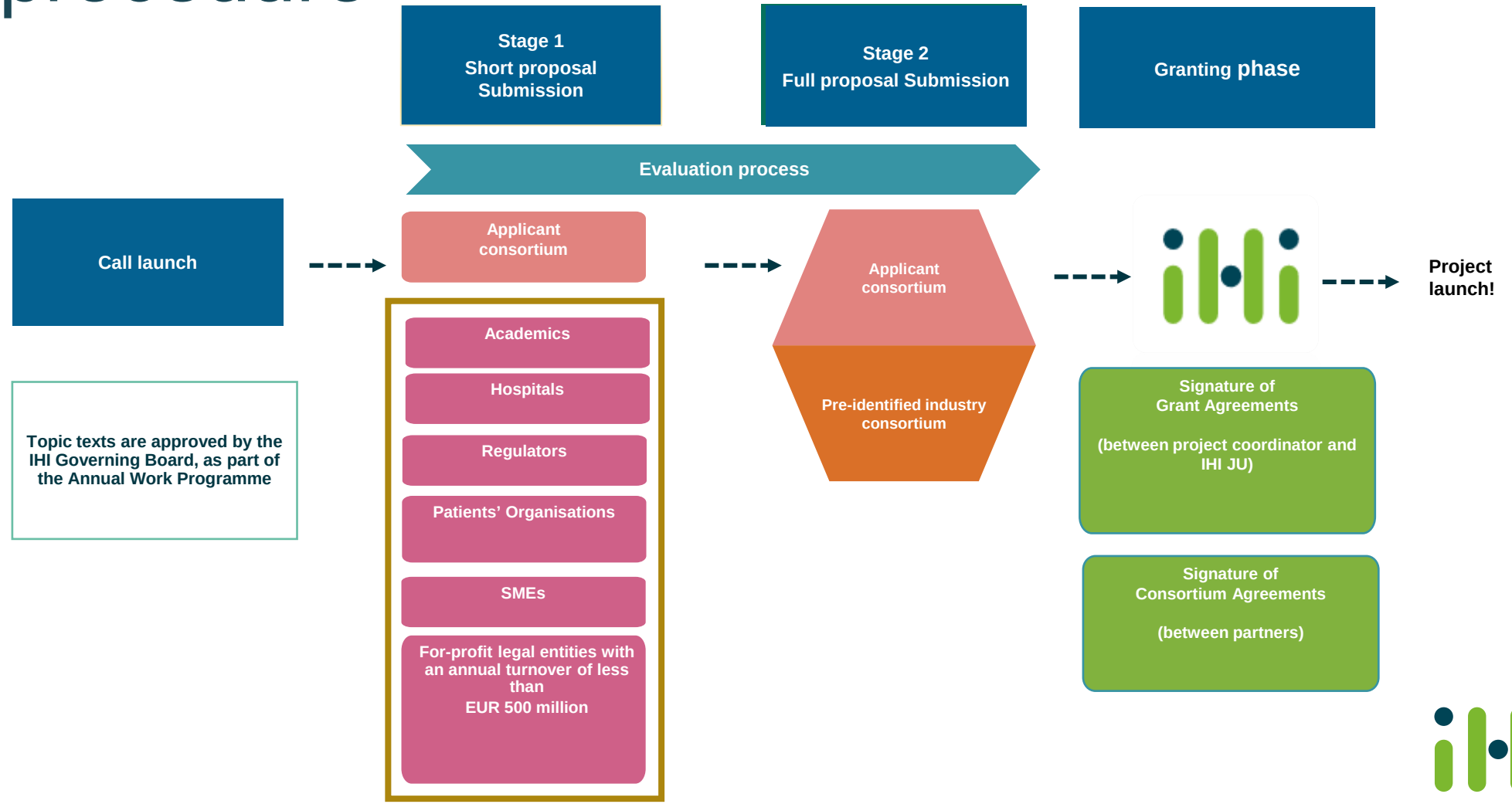
- Lay foundations for development **of safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level

innovative health initiative

https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

How does IHI work? Two-stage procedure



innovative health initiative

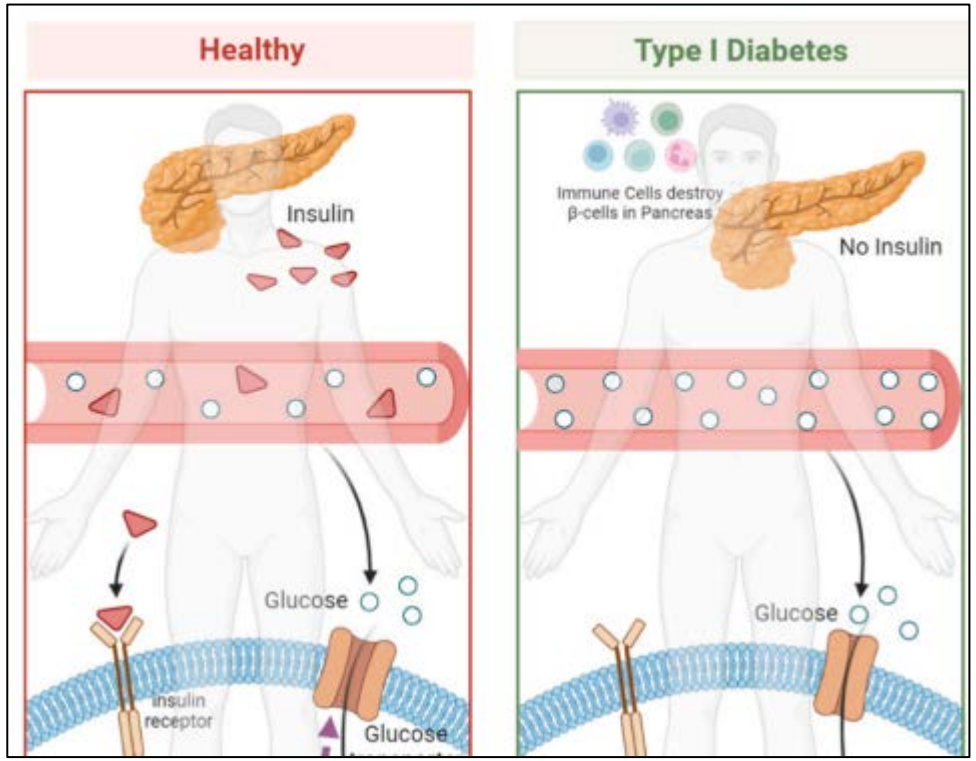
Leveraging Europe's expertise to accelerate cell therapy for type 1 diabetes

IHI call 11 – topic 4

Carmen Hurtado
30.06.2015 • Online

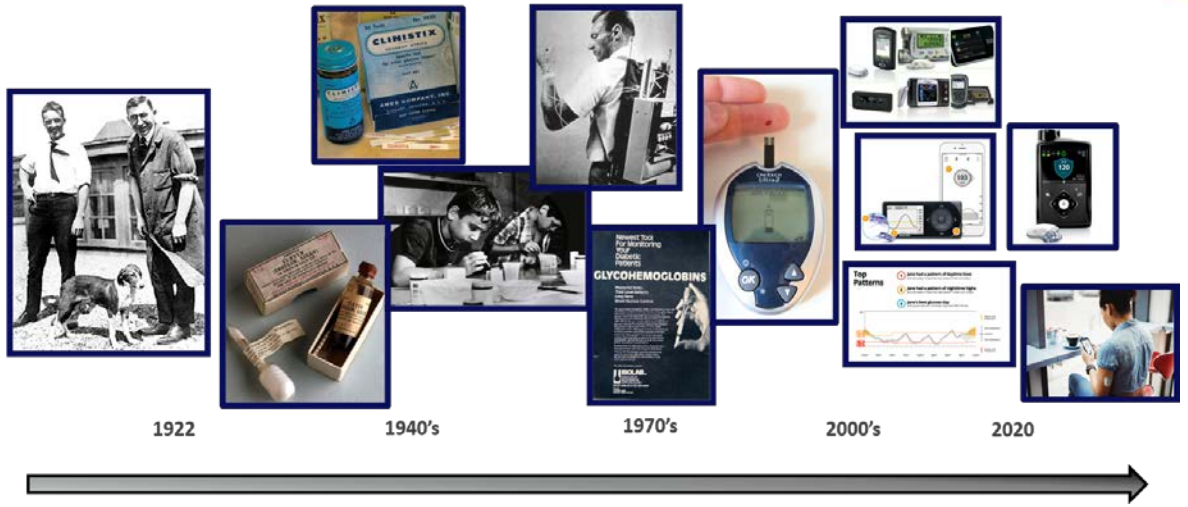
innovative health initiative

The challenge



Eur J Cell Biol. 2023 Jun;102(2):151329. doi: 10.1016/j.ejcb.2023.151329.

Clear Improvement in Diabetes Care 1922-2024



Achieving stable blood glucose levels is challenging

High risk of severe complications

Impacts daily life and mental health, contributing to stress, anxiety, and depression

innovative health initiative

Need for public-private, cross-sector collaboration

Policy Makers

Facilitate timely access

Academia & Research Institutions

- Conduct foundational research
- Lead in islet transplantation science
- Develop advanced preclinical models
- Develop immune-modulating therapies

Clinical Societies & Healthcare Professionals

- Provide clinical expertise
- Ensure practical, real-world implementation. Train healthcare workforce

Pharmaceutical & Biotech Industry

- Support clinical trials and drug development
- Scale manufacturing processes

Payers & HTA Bodies

- Assess cost-effectiveness
- Ensure reimbursement and integration into healthcare systems

Medical Devices Companies

- Enable innovative monitoring tools
- Integrate digital health solutions for patient management

Patient Organisations

- Offer patient-centric insights
- Shape research around real-world needs and quality of life

Regulators

Provide guidance on safety, efficacy, and compliance

innovative health initiative

Scope

This call aims to advance the development and implementation of beta-cell replacement therapies as a functional cure for T1D.

- Establishing standardised criteria and analytical methods
- Enhancing graft survival and immune tolerance
- Advancing manufacturing and quality control
- Streamlining preclinical and clinical development
- Implementing advanced monitoring and artificial intelligence (AI)-driven predictive tools
- Defining clinically meaningful and patient-centred endpoints using real-world evidence
- Exploring reimbursement models for beta-cell therapies
- Integration of cell therapy into diabetes care and collaborative networks

Expected outcomes

🔧 1. Manufacturing & Regulation
•Standardised impurity thresholds & best practices
•Scalable, cost-effective, high-quality production
•Regulatory alignment for clinical translation & reimbursement

🛡️ 2. Immune & Clinical Innovation
•Validated immune-modulating strategies
•Advanced models, biomarkers & success indicators
•Patient-centred clinical endpoints

🤖 3. Technology & Personalisation
•AI-driven predictive tools & real-time monitoring
•Personalised treatment & optimised immunosuppression

4. Research & Clinical Readiness
•Improved preclinical models across patient groups
•Defined criteria for safety & access
•Training programmes for HCPs & clinical pathways

🌍 5. System-wide Integration
•EU innovation hubs for research & regulation harmonisation
•Cost-effectiveness models & reimbursement frameworks
•Broad collaboration across academia, industry, and policymakers

❤️‍🩹 6. Patient Benefit
•Better treatments, access, outcomes, and quality of life

innovative health initiative

Expected impact

1. Widespread Adoption
•Ensure long-term **efficacy**, **accessibility**, and **integration** into healthcare systems

2, Accelerated Innovation
•Advance **stem cell-based therapies** via improved manufacturing, preclinical models, predictive tools & regulatory alignment

3. European Leadership
•Strengthen **innovation hubs** and **clinical networks** in beta-cell therapy

4. Cross-Disease Progress
•Enable scientific and regulatory progress for **other metabolic and autoimmune diseases**

5. **Stakeholder Benefits**
•Deliver improved treatments, clear guidelines & increased investment to **patients, providers, regulators, and industry**

6. Industrial Competitiveness
•Boost European innovation in **cell-based and regenerative therapies**

innovative health initiative

Expected contributions of the industry consortium

- Provision of training materials for healthcare professionals on cell therapy;
- Regulatory, R&D, and clinical expertise;
- Specialised knowledge in clinical protocol design and the development and regulatory alignment of clinically meaningful endpoints;
- Expertise in defining clinically meaningful endpoints;
- Engagement with payers, policymakers, and regulatory agencies to support value-based healthcare adoption;
- Dissemination and communication efforts, including the open sharing of all relevant learnings, tools, and materials to maximise their accessibility and uptake across the healthcare ecosystem.

innovative health initiative

Expected contributions of the applicants

Expertise and resources expected to be brought into the project

🧪 **Scientific & Technical Expertise**
•Beta-cell biology, immune modulation & stem cell technologies
•Gene editing (e.g. CRISPR) & advanced immune-modulating therapies

🏭 **Manufacturing & Quality Control**
•Scalable GMP-compliant cell therapy production
•Cost-effective, consistent process development

📋 **Regulatory & Clinical Design**
•Regulatory engagement (e.g. EMA), trial design across age groups

🧫 **Preclinical & Clinical Development**
•Predictive T1D models & clinical trial networks
•Access to retrospective/prospective islet transplant data
•Use of biomarker & outcome data for engraftment and immune analysis

innovative health initiative

📊 Advanced Monitoring Technologies

•Real-time tools (e.g. CGM, biosensors)

•AI/ML-driven predictive models for personalised therapy

👥 Patient-Centred Research

- Integration of patient input & real-world data
- Protocols for post-transplant care & long-term sustainability

💶 Economic & Policy Expertise

- Cost-effectiveness analysis for beta-cell therapies
- Experience engaging with HTA bodies for reimbursement

🔗 Multidisciplinary Collaboration

- Training programmes for clinicians in cell therapy
- Strong networks: academia, industry, regulators, patients

🏥 Healthcare System Engagement

- Early involvement of regional health authorities
- Alignment with local priorities, regulation & reimbursement

🌐 Knowledge Sharing

- Infrastructure for knowledge sharing
- Capacity to host workshops, webinars & conferences
- Ability to participate in European innovation hubs

📣 Patient Advocacy & Public Engagement

- Collaboration with advocacy groups promoting access, awareness & policy support

innovative health initiative

Key Facts

- Budget

• The maximum financial contribution from the IHI JU is up to EUR 8 825 000.
• The indicative in-kind contribution from industry beneficiaries is EUR 2 300 000.
• The indicative in-kind and financial contribution from IHI JU contributing partners is EUR 7 340 000.

- Duration: 60 months

innovative health initiative

Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

Proposal submission & evaluation

innovative health initiative

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

innovative health initiative

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.

innovative health initiative

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.

innovative health initiative

Tips for applicants

innovative health initiative

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - IHI call 11 | IHI Innovative Health Initiative
- 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)

innovative health initiative

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

innovative health initiative

Eligibility for Funding: UK, Canada, Switzerland, South Korea

In IHI Call 11, legal entities from the following countries are Eligible/Not Eligible to receive funding as follows**:**

Country	Call 11, Topic 01	Call 11, Topics 02 - 05
United Kingdom (‘UK’)	Eligible to receive funding	Not Eligible to receive funding
Canada (‘CA’)	Eligible to receive funding	Not Eligible to receive funding
Switzerland (‘CH’)	Not Eligible to receive funding	
South Korea (‘KR’)	Not Eligible to receive funding	

Alternative Funding: legal entities from UK, CA, CH, and KR may be able to receive funding from their own governments, Potential applicants should contact their National Contact Point (‘NCP’) or relevant representative**.** IHI JU takes no role or responsibility in the application for, or granting of, such funding.

UK applicants: Are requested to contact the UK National Contact Point Ms Jo Frost **(**ncp-health@iuk.ukri.org**)** as soon as possible to register for updates, and for advice and assistance regarding UK participation in IHI Call 11.

innovative health initiative

innovative health initiative

Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union