Patient-centred clinical-study endpoints derived using digital health technologies

IHI call 8 – topic 4

Angelica VALENTE
21/06/2024 • Online

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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.

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Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 8 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- Presentation & Recording

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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)

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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**.

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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)

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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

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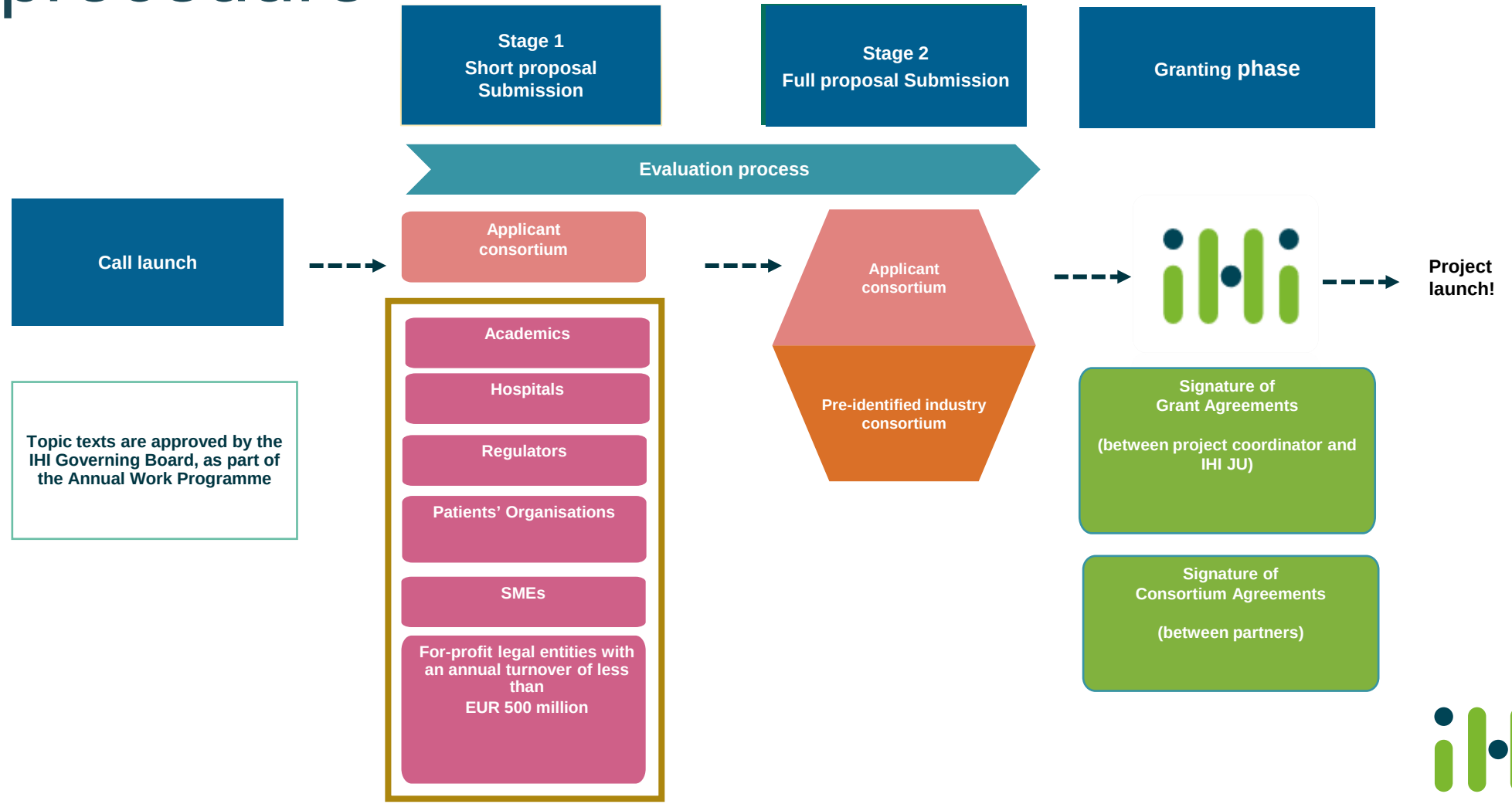
https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

How does IHI work? Two-stage procedure



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Patient-centred clinical-study endpoints derived using digital health technologies

IHI call 8 – topic 4

Brett Hauber, Pfizer
21 Jun 2024 • Online

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The challenge

- The following measures can be used to understand patient-centred benefits of therapies (i.e., meaningful improvements in how a patient feels or functions):
  - Patient preference information (PPI)
  - Clinical outcome assessments (COAs) including patient-reported outcome (PRO) measures
  - Digital health technology-derived (DHT-derived) measures of how a patient feels or functions
- There is no unifying framework for understanding the relationships between these measures, nor how they can be used in combination to demonstrate meaningful, patient-centred benefits of therapies for chronic diseases in clinical studies.

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Need for public-private, cross-sector collaboration

- This topic aims to develop a unified framework and consensus-based recommendations for using multiple types of patient-centred information to support the use of DHT-derived endpoints to demonstrate therapeutic benefit. This requires input from multiple disciplines, each with their own practices and guidelines.
- Stakeholders with an interest in the use of these measures in clinical development are numerous and varied and include:
  - patient groups,
  - regulatory authorities,
  - HTA bodies
  - health technology and therapy developers
  - others
- Consensus from such a wide range of interested parties requires collaboration among multiple research disciplines and stakeholders.

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Scope of the topic*

Development of:

- A **framework** for using PPI, COAs, and DHT-derived measures in combination in the development, acceptance and implementation of patient-centred DHT-derived clinical-study endpoints in clinical studies of treatments for chronic diseases.

- Consensus **recommendations** for:
  - using quantitative PPI to better understand COA data
  - understanding the relationships between COA data and patient-centred DHT-derived endpoints in diverse therapeutic areas.
  - using DHTs to collect PPI and COA data
  - using quantitative PPI, COAs, and patient-centred DHT-derived measures in combination.

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* Additional details on the scope of the topic are provided in the topic text.

Scope of the Topic*

- **Conduct at least 4 use cases** which should:
  - include a range of digital measurement domains
  - address differences between passive and interactive DHTs
  - include a range of patient ages
  - address issues related to diversity in patient populations
  - address issues related to combining and/or jointly analysing PPI, COA, and/or DHT-derived data using new techniques

- **Disease Areas** for case studies:
  - paediatric radiation oncology
  - lung cancer
  - non-motor and motor symptoms in Parkinson's disease
  - obesity

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* Additional details on the scope of the topic are provided in the topic text.

Expected outcomes*

- **Unifying framework** and consensus-based recommendations
- **New methods** for analysing PPI and COA data collected using DHT and for combining data from PPI, COA, and DHT-derived measures
- **Consistent framework for engagement** regarding the development and use of patient-centred, DHT-derived clinical-study endpoints is available to industry and stakeholders
- **Acceptance among stakeholders** indicated by a qualification opinion, endorsement, adoption or other approval by each relevant stakeholder group
- **Implementation** in regulatory and reimbursement decisions

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* Additional details on the expected outcomes are provided in the topic text.

Expected impact

- Greater understanding of the relationship between multiple patient-centred measurements to provide greater insight into the patient perspective
- Reduced uncertainty regarding the PPI and COA data required to demonstrate the patient-relevance of DHT-derived clinical-study endpoints
- Improved and more efficient engagement between industry and stakeholders in the evaluation of technologies developed using patient-centred DHT-derived endpoints in clinical studies
- Increased speed and efficiency in the development and evaluation of innovative therapeutic technologies
- Greater benefit to patients from improved health care
- Patients having improved access to innovations that meet their needs
- Better informed decision-making at all levels of the health care system.

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Industry Consortium

Lead:

Pfizer

Contributing Partners:

GENAIZ

John Snow LABS

Industry Consortium:

Mölnlycke®

abbvie

Roche

AstraZeneca

ucb

novo nordisk®

varian
A Siemens Healthineers Company

NOVARTIS

Johnson&Johnson

IQVIA

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Expected contributions of the industry consortium

- Results and insights from existing pilots and studies*
- Real-world evidence (RWE) and clinical trial data*
- Expertise in medicine; clinical development of therapies; digital measurement technologies; patient reported outcome measures and clinical outcome assessments; patient preference information; clinical and real-world data collection and analysis
- Expertise in regulatory strategy, policy, and decision making; health technology assessment and reimbursement; and publication support
- Data platforms, digital tools, apps, remote monitoring technology, healthcare-specific Natural Language Processing (NLP), Artificial Intelligence (AI)

* Contributions to this project may include historical data generated outside of the project timelines. In this case, it will be considered as background provided to the project but with no value assigned and will therefore not constitute part of the in-kind contribution from the pre-defined industry consortium.

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Expected contributions of the applicants

Expertise and resources expected to be brought into the project

- Demonstrated experience in:
  - managing multi-stakeholder, cross-sectoral projects
  - interacting with regulatory authorities, HTA bodies, citizens and/or patient representatives
- Expertise in:
  - PPI, COAs, and DHT-derived measures
  - clinical study design
  - health technology assessment and economic evaluation of therapies
  - public health impacts of therapeutic technologies
  - advanced data management and data analytic techniques including, but not limited to, large-language models and artificial intelligence
- Academic medical centres that can manage clinical case studies
- DHT partners that can contribute to the clinical case studies within the disease areas

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Key Facts

- Budget:
  - Financial contribution from the IHI JU: up to **EUR 12 600 000**
  - Indicative in-kind contribution from industry: EUR 9 434 420
  - Indicative in-kind contribution from contributing partners: EUR 3 867 000.

- Duration: 60 months
  - Expected Sept 2025 – August 2030

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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

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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

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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.

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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.

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Tips for applicants

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Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - www.ihi.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 our **guide for applicants and project consortia on regulatory considerations for IMI and IHI projects** for useful advice on regulatory issues to consider when preparing your proposal

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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

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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/!fnJFFM

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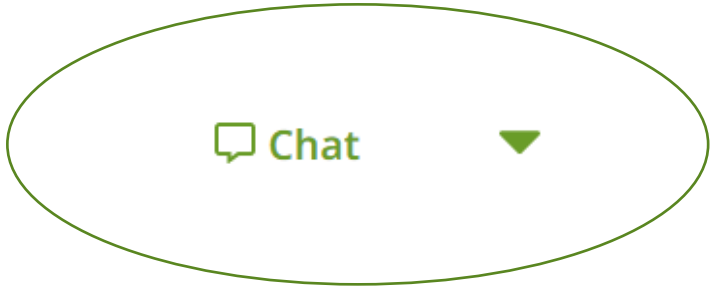
Questions time

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



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