Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare

IHI call 4 – topic 2

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

Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare

IHI call 4 – topic 2

John Clifford, Scientific Project Officer, IHI
18.01.23 • Online

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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 take place at a later stage

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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)

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

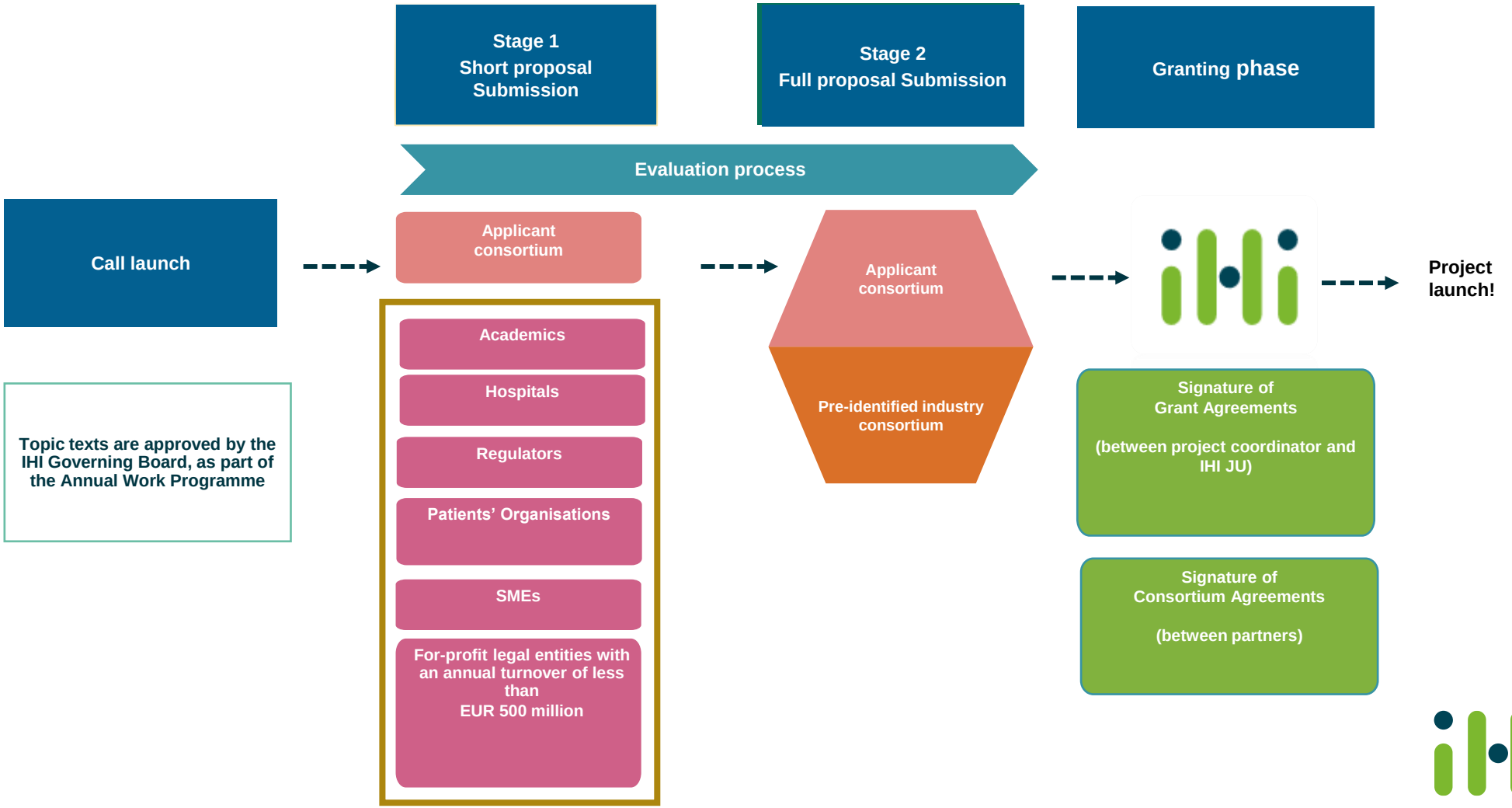
Goal

- 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.ihi.europa.eu/about-ihi/research-and-innovation-agenda

Two –stage calls – How does it work?



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Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare

IHI call 4 – topic 2

Dr. Tony Fantana
18.01.2023 • Online

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The challenge

Blood based diagnostics are ubiquitous – but remain burdensome

- Collecting venous blood samples for diagnostic purposes has been the cornerstone for informing patient care and a key element of clinical trials.
- Ordering a blood draw has become almost a reflex for clinicians and drug developers, however **venipuncture is still the traditional way to collect blood**.
- Venipuncture can be **painful** and **requires individuals to travel** to their healthcare provider or clinic:
  - This results in a **burden** on patients, doctors, healthcare systems, payers, and the pharmaceutical industry
  - A particularly high burden may be imposed on **vulnerable populations** such as children and elderly individuals, as it may lead to increased exposure to disease during a pandemic, or to anaemia (e.g., in oncology).
- The **current blood collection procedures are too inflexible to allow for ongoing monitoring** for treatment, progression, or intervention in clinical decentralised trials and clinical practice
- There is a great need for acceptance and implementation of **patient-centric** (as opposed to clinic-centric) **blood sampling approaches**

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Need for public-private, cross-sector collaboration

Crucial importance of a harmonized approach across all stakeholders in the EU

- A **joint concerted initiative is required to create a practical implementation path** in Europe for patient-centric blood samples in decentralised clinical trials, trials at home, and inclusion trials
- Essential to **include industry partners from different sectors**, e.g. the pharmaceutical industry, medical device manufactures, *in vitro* diagnostic companies
  - exchange knowledge and experience and contribute complementary infrastructures
- Collaboration required with **clinical centres** that are experienced in conducting decentralised trials, and with **academia and SMEs** that are experienced in methods and devices for microsampling and data collection and analysis
- The engagement of **patients, caregivers, and health care professionals** is required to ensure the incorporation of the user experience into the novel infrastructure and logistics for patient-centric blood microsample collection at home.
- The involvement of **regulators, policy makers, payers, and HTA experts** will facilitate the acceptance of the microsampling logistics model

Crucially important to develop a harmonised approach that is acceptable and accessible to all stakeholders in the healthcare systems to ensure implementation across Europe. This can be best assured under a public-private partnership.

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Scope of the topic

Create and validate infrastructure and logistics for patient centric blood collection

1. Demonstration of **concordance** between patient-centric microsampling techniques and venipuncture
2. **Validation of the logistics** of sample collection and shipping, standardising central lab analysis
3. **Education** and medical & patient acceptability
4. **Regulatory** acceptability and implementation in clinical practice in the EU, other non-EU European countries and USA

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Expected outcomes

Enable innovations in healthcare delivery and research

1. Create **insights** into the public acceptability for microsampling home
2. **Advance** the transition of care from the hospital to the home. Measure change in **care quality**
3. Integrate with electronic medical records, use advanced analytics methodology, **utilize the higher frequency** of data
4. Lay the groundwork to measure how **doctor's practices and decisions** change with the increased frequency of biomarker data, as well as patient outcomes

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Expected impact

Improved patient experience, enabling decentralized trials and care

The generation of an infrastructure and logistics for at-home collection of small-volume (less than 500 µl) blood samples (‘microsampling’) as an alternative to venipuncture for routine central lab analysis will contribute to the following impacts:

- Deliver a much-improved experience to our patients by decreasing the burden on patients (in particular vulnerable populations) and optimising patient care in Europe.
- Improve decentralised clinical trials, trials at home, and inclusion trials.
- Facilitate monitoring for prevention, treatment, and surveillance.

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Expected contributions of the applicants

Focus: integration of existing innovative technologies establishing infrastructure

- Grant administration: financial administration, submission of deliverables, periodic reports, etc
- Project management:
  - Coordinate internal communication and meetings, general oversight, risk management
  - Provide and maintain IT infrastructure and data management plan
  - Coordinate and synergize with other European initiatives or relevant groups (e.g. patient advocacy)
- Umbrella/master study: obtain the necessary authority approvals, develop participant / patient facing materials, provide recruitment of participants / patients and conduct the umbrella / master study including the collection of biological samples
- To provide microsampling techniques and at least 1 device for the collection of capillary blood of the upper arm
- To develop logistical capability around implementing new technologies for microsampling, work with device vendors on ordering devices, develop protocols for the testing of microsampling devices, act as investigative sites to test devices including Institutional Review Boards (IRB), consents etc., and train participants on devices
- To engage and activate patients, caregivers, clinicians, and hospitals and obtain feedback on the support needed, develop questionnaires to collect their experience, perform data analysis, assess acceptability and concerns, and develop and refine training materials for different recipients
- To interact with regulatory authorities, HTA bodies, payers, policy makers, and advocacy groups

Focus: integration of existing innovative technologies to establish the infrastructure and logistics for patient-centric blood microsample collection at home in Europe (**not development of novel devices or assays**)

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Expected (in-kind) contributions of the industry consortium

Expertise and assets

- Clinical trial and medical expertise
- Analytical techniques, sample analysis, provision of 1 device for capillary sampling (finger stick)
- Logistics – including sample quality, collection compliance, data
- Guidance in feedback collection and development of training materials (patients, HCPs, etc)
- Integration of requirements and interaction with regulatory authorities, HTA, payers, policy makers, advocacy groups

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Budget

Indicative Budget: ~8 Mio Eur

- The maximum financial contribution from IHI is up to EUR 4 412 556
- The indicative in-kind and financial contribution from industry partners is EUR 3 493 000
- The indicative in-kind contribution from IHI JU (Joint Undertaking) contributing partners is EUR 300 000

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Duration

Indicative Duration: 42 Months

This duration is indicative only. At stage 2, the consortium selected at stage 1 and the predefined industry consortium and contributing partners may jointly agree on a different duration when submitting the full proposal

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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 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.ihi.europa.eu/apply-funding/open-calls
  - www.ihi.europa.eu/apply-funding/future-opportunities
- 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

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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

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/!fnJFFM

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Thank you for your attention

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Microsampling: **Patient-centric blood sample collection will enable decentralised clinical trials and improve access to healthcare**

Scope

- **Validate the science:** Umbrella/master protocol to prove concordance between the new commercially available patient-centric microsampling techniques and venipuncture, analysing routine clinical assay panels.
- **Validate the logistics of sample collection and shipping**, standardizing central lab analysis
- **Education:** training materials for both patients and clinical trial sites.
- **Patient acceptability and experience:** collect data on experience, ensure acceptability
- **Regulatory acceptability** and **implementation into clinical practice in the EU, the UK and USA.**

Outcome

- Enabling implementation of small volume blood sample collection (<500µl) that is **simple, minimally invasive, less painful, convenient**, and **feasible at home.**
- **Validation** and **standardization** of technologies and logistics, in ways that are **acceptable for patients** and their **caregivers**, **health care professionals,** and **regulatory agencies.**

❖ To ensure implementation across Europe, a **harmonized approach accessible to all stakeholders** in the healthcare systems **is crucial**, and thus a **two-stage process** is needed**.**

Impact

Accelerate patients' access to improved treatment options across Europe

Patients: improve the monitoring of disease and treatment intervention, increase convenience, and reduces the burden and pain

Health care professionals: trustworthy validated tools

Health care systems and payers: enable better care in the "real world"

Pharma companies: enhance science and discovery; allow for early detection of signals; decentralized clinical trials

Medical technology companies: validated standards and assays, established logistics

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