Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

IHI call 3 – topic 1

14.12.2022

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Before we start…

Recording

- We are recording this session. The **recording & slides will be published** on the IHI website and B2Match platform.

Questions

- Please use the **‘Join the chat’ function** at the top right of the screen to ask questions.

Today’s webinar

Will cover:

- Introduction to IHI programme
- IHI Call Topic:
  - Challenge, need for public-private collaborative research
  - Scope, outcomes & impacts, budget
- Proposal preparation tips, matchmaking & participant pitches

Will not cover rules & procedures or budgets

- These webinars are on the IHI website
  - www.ihi.europa.eu/news-events/events/ihi-call-days-call-3

Innovative Health Initiative

Public private partnership 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

Through **cross sectoral, pre-competitive** collaboration:

- 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.**

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

IHI Funding model

As a **public private partnership,** IHI's projects are co-funded by:

- EU **cash contributions**
  - Primarily supporting universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies.*
- IHI **private members** and **contributing partners**
  - Must **provide at least 45% of total project eligible costs**, usually via researchers participating in the project

* Large companies can also receive EU funds

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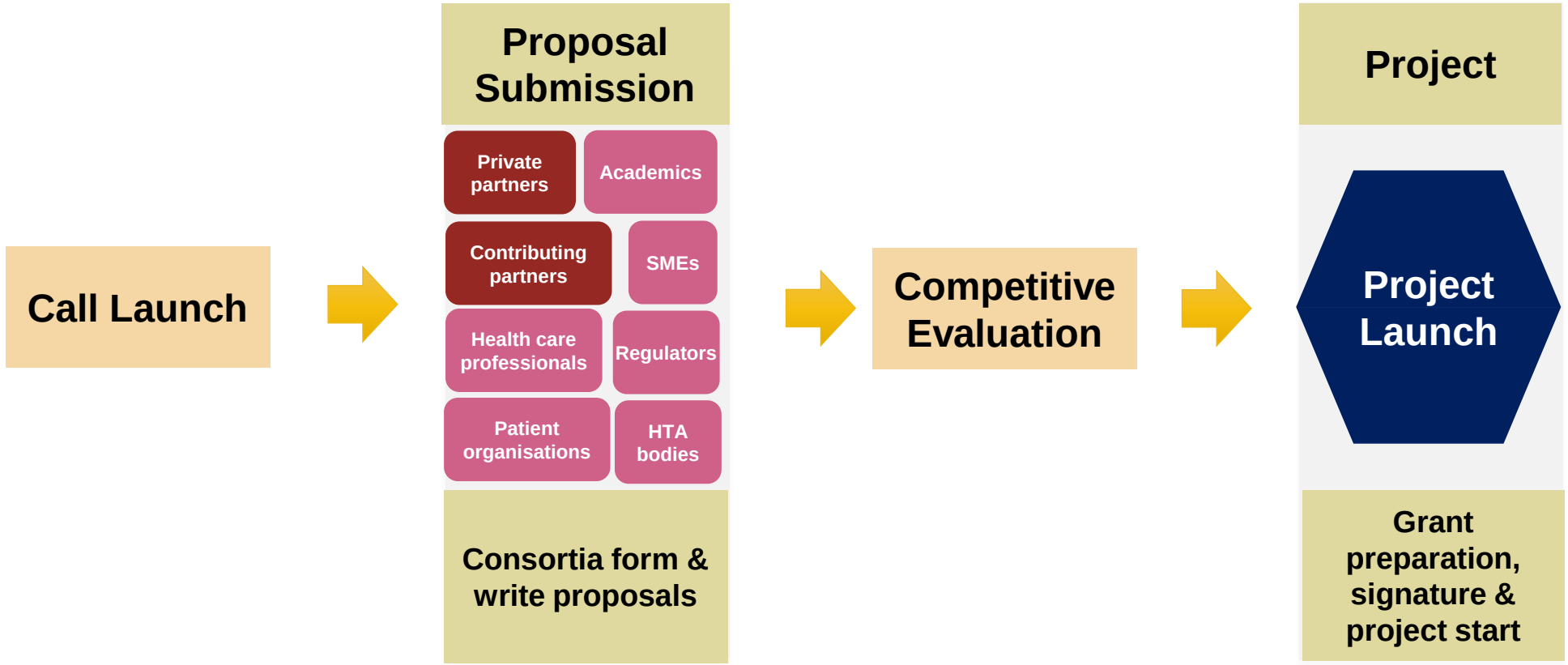
How IHI works: Single-stage procedure



Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

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The challenge

- Rising burden of disease is a major challenge to the sustainability and resilience of healthcare systems in Europe.

- Identifying individuals at risk of developing an illness so that they can receive an appropriate intervention before the disease develops could help address this problem.

- However, for many health conditions, we lack full understanding of the underlying mechanisms, including the predisposition to disease and how environmental and genetic factors affect the occurrence of the disease

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Need for public-private, cross-sector collaboration

- Significant cross-sectoral expertise needed:
  - Patients
  - Healthcare professionals
  - Biomarker specialists
  - Machine learning experts
  - Academic researchers
  - SMEs
  - Pharmaceutical companies
  - Medical technology companies

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Scope of the topic (1/2)

- Develop a **screening platform** and generate the evidence base for general population screening for **a clearly identified disease(s)** of unmet public health need

- Specify the initial **biomarkers** to identify people at risk

- Clinically **validate** and assess the utility of the **screening platform** and **biomarkers** to identify people at risk.

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Scope of the topic (2/2)

- Deliver **digital tools & innovative assay technologies** for efficient management and execution of screening programmes.
- Develop/ optimise **clinical practice guidelines**
- Provide **training /education** to:
  - Relevant healthcare professionals
  - Patients and family members

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Expected outcomes

- Patients will receive more **timely, personalised interventions**
- Doctors will have a **screening platform & biomarkers** to identify people at risk & help **select the best preventative action**.
- Researchers will have **new biomarkers** to develop personalised interventions
- Healthcare systems will have **reliable evidence** to target interventions to those who will benefit most.

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Expected impacts

- Facilitate **development of cost-effective interventions** and strategies for the prevention and early diagnosis of disease.
- Patients benefit from new **preventive interventions** before onset of symptoms.
- Availability of **biomarkers** for disease interception and diagnosis.
- New advanced AI analytics to increase the availability of **personalised health interventions** to end-users.

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Other considerations

- Seek **engagement with regulators** where relevant.
- Demonstrate that the outputs can be **taken up by healthcare systems**.
- **Allocate resources** to explore synergies with other relevant initiatives.

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Dissemination, exploitation & communication

- **Reserve budget** for effective communication
- Consider an early **business plan**

- In particular:
  - **Publish & promote** the methods, standard operating procedures, algorithms, standards and guidelines etc.
  - The **‘3As’ criteria apply**: products and services developed based on clinical studies are *affordable, available and accessible*

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Budget & Duration

BUDGET

- Total of **EUR 30 million public funding available**
  - Expect to fund projects requesting EUR 10-15 million public funding each.
- At least **45% of the total budget** of each project must be covered by **contributions provided by IHI private members & contributing partners**

DURATION

- Applicants should **propose a project duration** such that it matches project activities and expected outcomes and impacts

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Simplified example budget

Participant type	Total costs	Requested IHI funding	In-kind contributions (IKOP, IKAA, FCs)
'Public' partners (Universities, hospitals, SMEs, patient orgs, regulators…..)	10 million	10 million	0
Private members & Contributing partners	10 million	0	10 million
Total	**20 million**	**10 million** (50%)	**10 million** (50%)

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Proposal Submission & Evaluation

Proposal Template: Parts A, B & Annexes

- **Part A** is **administrative & researcher data** that is entered in webforms.

- **Part B** is the **narrative part** that includes three sections:
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**

- **Annexes:**
  - Participant type
  - Budget details
  - Clinical studies template
  - Coordinator declaration

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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, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.
- **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.
  - Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

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Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
  - 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

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - www.ihi.europa.eu/apply-funding/open-calls
- Form your consortium **early**
  - Always think “public-private partnership“
  - Include partners bringing **in-kind contributions**
- Ensure you provide **all information requested in the call text and proposal template**
- Consider & plan for the potential **regulatory impact** of results

Finding project partners

You'll need to **build or join a consortium**!

- Arrange a meeting with **IHI Call Days participants**
- 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 **IHI social media**

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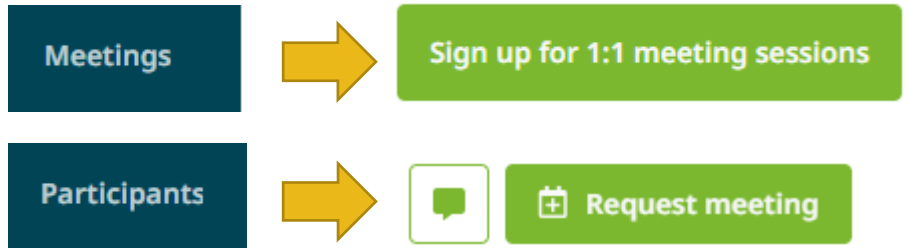
Matchmaking: Meet via B2Match

Book your meetings

1. Make yourself available using **meetings tab**
2. Find/meet partners on the **participants tab**
3. Enter meeting details, add a message.
4. **Send the request**



Step by Step guide

https://europa.eu/!fnJFFM

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Pitching Session

Today 14th December 2022, **11:30 – 13:00 CET**

Join via the B2Match platform: https://ihi-call-days.ihi.b2match.io/

Presentation title	Organisation
Global Research Initiative for Patient screening on NASH - (GRIP on NASH)	University Medical Center Utrecht - Julius Center for Health Sciences and Primary Care
Molecular biomarkers and clinical assessment of rare and common disorders	University of Siena
Privacy-preserving AI for medical mechanotyping	University of Hamburg
Distributed data valuation technology and decision support system	Skein
ENGAGE - The challenge of liver cancer screening and outcome prediction	Siemens Healthineers
PREDICTOM - Prediction of Neurodegenerative Disease using an AI driven Screening Platform	GE Healthcare
Biomarkers for diseases of public health interest - EPTRI Thematic Research Platform on Paediatric Biomarkers & Biosamples	CVBF-EPTRI
Highspeed RACE - Analytical platform for Highspeed cohort screening using Raman enhaced cell analysis	Fraunhofer ILT
NAKO - German National Cohort - a resource for health data and biosamples	Helmholtz Munich
European Bank for iPSCs	European Bank for induced Pluripotent Stem Cells
Health, Clinical and Multi-omics Data Integration & Interpretation for precision health - prevention and management of chronic diseases	Collaborate Healthcare IKE
High Sensitivity in Early Cancer Screening	4D Lifetec AG
Mind the Gap - Manufacturing of Immunoassay & Development of The Glycan Analysis Protocol	GLYCANOSTICS, s.r.o.
Last resort for hard to treat lung tumors	Vivomicx
Novel "targeted RNA sequencing technology" - ciRNAseq	Predica Diagnostics BV
Early Lung Cancer Screening	Hygiaso Ltd
Eforto - physical reserve monitoring a digital biomarker of frailty	UniWeb BV
Quibim: Transforming imaging data into actionable predictions	Quibim SL
Privacy-Preserving Data - Collaborations across Life Sciences	Rhino Health, LTD

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Key points

Finding consortium partners

- Be proactive
- **Start working now!**

Proposals

- **Read the call text** very carefully
- Follow all the guidance in the **proposal template**
- Reserve dedicated **funding for communication & sustainability**

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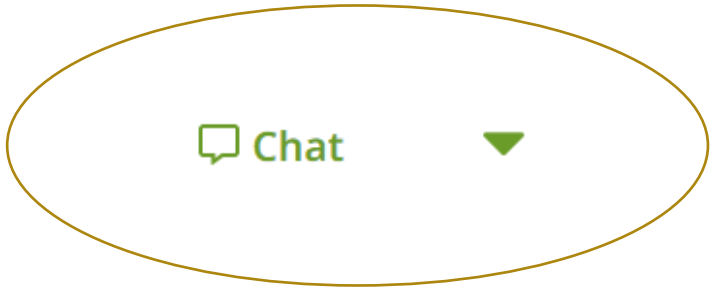
Questions time

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



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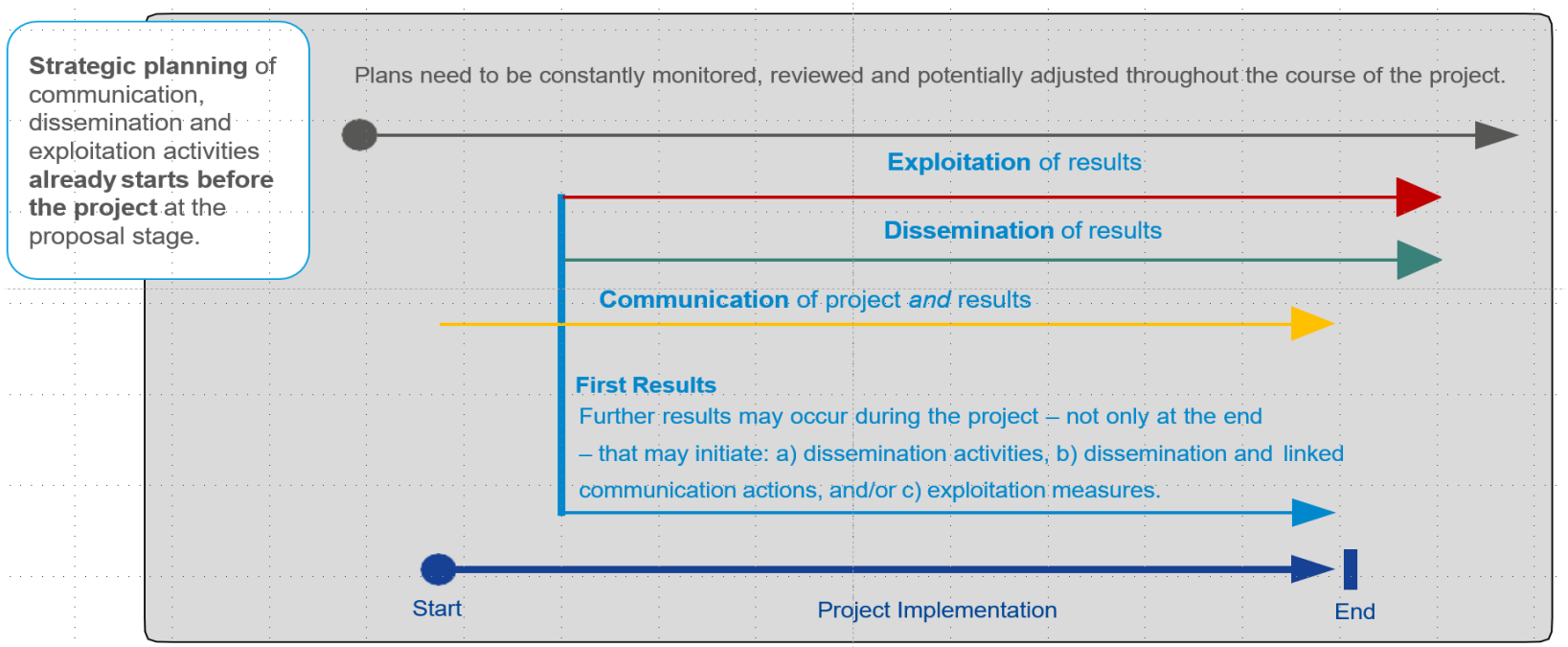
Additional Slides

Simplified example budget

Participant type	Total costs	Requested IHI funding	In-kind contributions (IKOP, IKAA, FCs)
'Public' partners (Universities, hospitals, SMEs, patient orgs, regulators…..)	7.5 million	7.5 million	0
Private member 1	7.5 million	0	7.5 million
Private member 2 'hybrid'	5 million	2.5 million	2.5 million
Total	**20 million**	**10 million** (50%)	**10 million** (50%)

Dissemination, exploitation & communication

- Importance to communicate and disseminate results throughout the full lifespan of the project
- Plan Dissemination & Exploitation measures to maximise the impact
- Plan communication measures for promoting the project and its findings
- Short description of the Dissemination, Exploitation & Communication (D, E & C) activities, together with the impact pathways in the proposal. This is an admissibility condition.
- Full-fledged D, E & C plan to be submitted as a deliverable after the first 6 months of the project.



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Dissemination, exploitation & communication

SPECIFIC NEEDS
What are the specific needs that triggered this project? **Example 1** **Health solutions need to be better tailored to patients' needs. Novel approaches are needed to capture patients' needs and to involve them in the development a novel health technology.**

EXPECTED RESULTS
What do you expect to generate by the end of the project? **Example 1** **Patient-centric clinical development: Patients perspectives included in design of studies.** **Patients' perspective incorporated into the evidence generated for decision making.**

D & E & C MEASURES
What dissemination, exploitation and communication measures will you apply to the results? **Example 1** **Exploitation: Approach to include patients' perspectives is adopted by industry in their novel health technologies development programmes.** **Dissemination towards the scientific community and industry: Scientific publication of the results of the demonstration pilot** **Communication towards citizens: An event in a shopping mall to show how the outcomes of the action are relevant to our everyday lives.**

TARGET GROUPS
Who will use or further up-take the results of the project? Who will benefit from the results of the project? **Example 1** **Healthcare industry companies: pharmaceutical (including vaccine), biopharmaceutical, medical (and digital) technologies, etc.** **Scientific community (clinical research investigations, and testing activities of health solutions)** **End-user of the novel health technology: patients and citizens**

OUTCOMES
What change do you expect to see after successful dissemination and exploitation of project results to the target group(s)? **Example 1** **Healthcare industry partners: novel health technologies adapted to patients' needs.** **Use of the scientific results published (measured through the bibliometric indicators of the project publication).**

IMPACTS
What are the expected wider scientific, economic and societal effects of the project contributing to the expected impacts outlined in the topic text? **Example 1** **Scientific: New approach to patient engagement in the development of novel health technologies tailored to the patients needs.** **Economic/Technological: Health solutions designed with the patients in mind will facilitate the adoption of the health technology by the market / healthcare system** **Societal: Patients will benefit from truly patient-centric health technologies (designed from the start based on their needs)**

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Thank you for your attention

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EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union