Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

IHI call 7 – topic 3

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11/01/2024 • Online

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Before we start…

- We are recording this webinar and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides
- The call will be officially launched next week and all links and details of how to apply will be published on the IHI website and the Funding and Tenders Portal.

Today’s session

- **Will cover**:
  - Introduction to IHI programme
  - IHI call topic
    - Challenge, need for public-private collaborative research
    - Scope, outcomes & impacts, budget
  - Proposal submission, evaluation & preparation tips

- **Will not cover**
  - rules and procedures
  - how to prepare the financial proposal

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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**.

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

IHI projects are…

Created via open and competitive calls for proposals

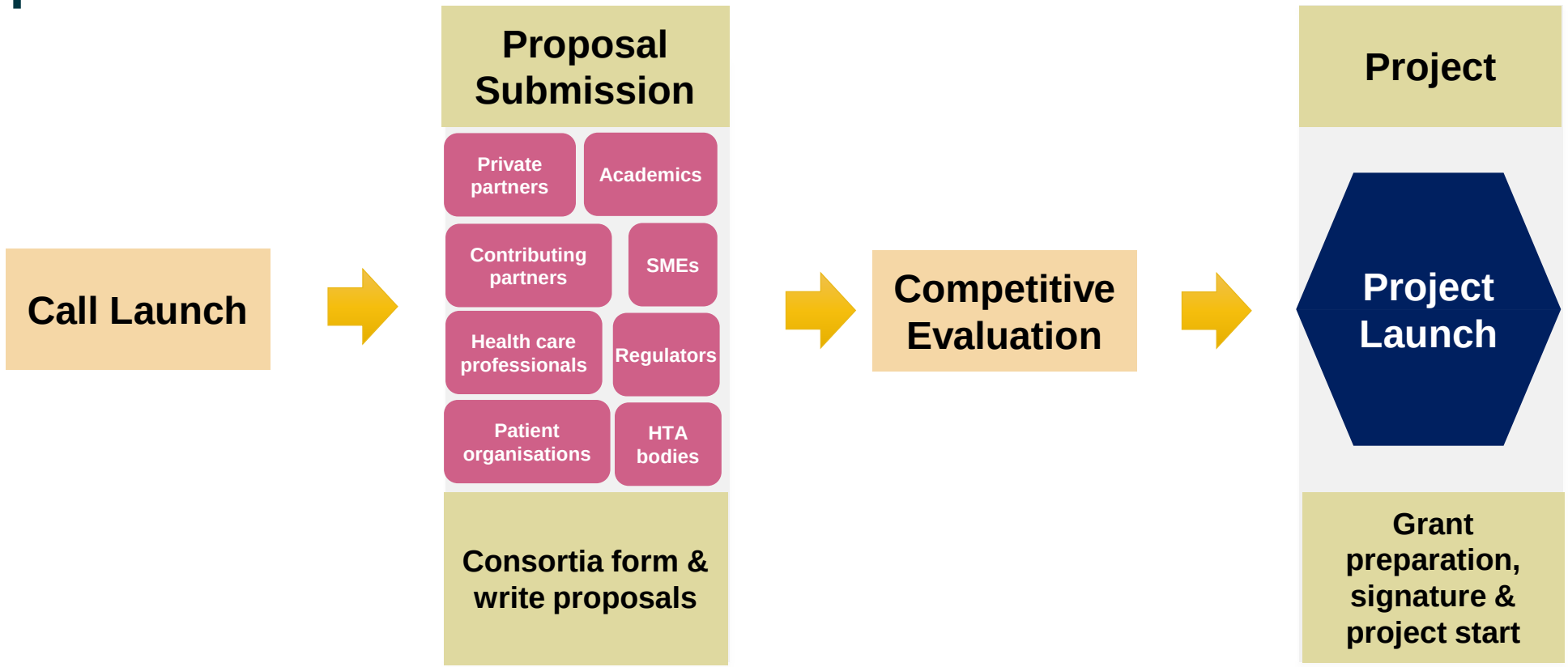
Cross sectorial public private partnerships leveraging:

- 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)

How does IHI work? Single-stage procedure



Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

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The challenge

- Biomarker-driven approaches for diagnosis, monitoring disease progression and assessing treatment response have immense potential to progress precision medicine.
- few biomarkers are subject to rigorous testing in clinical settings and shown to be fit for purpose (clinically validated).
- several novel biomarkers are promising, but the technology to make them accessible for clinical use may not be mature enough, which hampers their validation for use.
- Technology development or improvements to existing technologies may enable to progress these biomarkers to clinical validation.
- For scaling up the clinical validation of candidate biomarkers there is a need for a methodological framework that aligns definitions and expectations on biomarkers' utilities of different healthcare actors.

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Need for public-private, cross-sector collaboration

The clinical validation of biomarkers and the development of their linked technologies is a challenging process which require collaboration of many stakeholders in the healthcare ecosystem, among which:

- patients,
- clinicians, statisticians, biomarker specialists, machine learning experts, other scientists,
- healthcare professionals,
- experts in regulatory affairs,
- small and medium-sized enterprises (SMEs),
- pharmaceutical and medical technology industries

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Scope of the topic -1

- to progress candidate biomarkers towards clinical validation and, when relevant, to regulatory acceptance;

and/or

- to progress towards clinical validation innovative technologies necessary for making biomarker(s) accessible for clinical use. *In proposals focusing uniquely on these technologies, applicants should justify how such progress will enable the validation of the biomarker(s) for use in a clinical context.*

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Scope of the topic -2

- Assemble a cross-sectoral public-private partnership to align and develop a methodological framework and roadmap for progressing selected candidate biomarker(s) and/or linked technologies enabling the clinical use of the biomarker(s) (or a combination thereof) to rigorous clinical validation.

- Provide a justification and clearly demonstrate why the proposal area responds to an unmet public health need.

- Progress biomarker(s) and/or technologies towards clinical and analytical validation in one or more of these areas: diagnosing disease, early treatment path selection, monitoring disease progression, or treatment response assessment:

Applicants should provide in their proposal sufficient preliminary evidence, including relevant methodology(ies) and high-quality data to demonstrate that the biomarker(s) and/or technology(ies) can be progressed towards clinical validation and, when relevant, to regulatory acceptance.

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Scope of the topic -3

- Build on existing solutions to develop a collaborative platform to integrate, analyse and share data for the validation of biomarker(s) and/or linked technologies during the project, as well as to support future biomarker validation beyond the project duration.
- Develop a regulatory strategy and interaction plan for evidence generation to support the regulatory qualification of the biomarker/s and/or technologies and engage with regulators in a timely manner.
- Elaborate a plan for interacting with all the relevant actors in the learning healthcare system to align on utilities of the candidate biomarker(s) and/or technologies for clinical use and guide the roadmap
- Disseminate the results of the project to ensure uptake by relevant stakeholders, including healthcare systems and technology developers.
- Synergise with other relevant initiatives, including other projects funded under this topic and those funded under IHI Call 3 topic 1 as relevant.

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Expected outcomes

- Healthcare professionals and Researchers: Novel, robust and fit for purpose biomarkers with linked technologies enabling their use in clinical setting and progress towards validation.

- Researchers: Robust and fit for purpose biomarkers with linked technology for development of safer and more effective personalised treatments and/or key technologies for the safe and appropriate use and selection of a corresponding drug or biological product or its development.

- Regulators: Robust evidence on the suitability of selected biomarkers and their linked technologies to enable regulatory acceptance for a specific use.

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Expected impacts

- New clinically-validated biomarker-driven approaches are available for more precise and effective diagnosis, leaner diagnosis-to-treatment pathways, better treatment path selection, or improved follow-up and treatment response assessment and monitoring.
- A significant reduction in the diagnostic or therapeutic burden for patients (and caregivers) for example by favouring non- or minimally-invasive approaches.
- Validated tools and approaches supporting evidence-based health and care decisions addressing both the needs of patients and of healthcare systems.
- An increase in the competitiveness of European health industries.

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Dissemination, exploitation & communication

- **Reserve budget** for effective dissemination, exploitation & communication
- **Describe the dissemination, exploitation and communication measures** that are planned, and the target group(s) addressed, in particular:
    - Encourage the uptake of the results of the project through a strong communication and outreach plan
    - Allocating appropriate resources to explore synergies with other relevant initiatives and projects
    - Consider that the Availability, Accessibility and Affordability (3A) provisions (3As) are applicable.

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Budget

IHI financial contribution:
EUR 15 million

Industry / CP contribution:
EUR ~15 million *

Project budget:
EUR 30 million

* **At least 45%** of the project budget must be covered by contributions from project participants

Total available IHI funding for this topic: EUR 45 million

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Simplified budget example

Single-stage calls for proposals

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP, FC, IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..) (full costs reimbursed, cannot contribute IKOP/IKAA/FC)	15 million	100%	15 million	0
Private members & contributing partners (contribute IKOP/IKAA/FC, no costs reimbursed)	15 million	100%	0	15 million
Private members & contributing partners ('Hybrid') (costs reimbursed and contribute IKOP/IKAA/FC)	10 million	100%	5 million	5 million
Total	**40 million**	**100%**	**20 million (50%)** Public funds	**20 million (50%)** Private funds

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**

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

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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.
  - Clearly defined and effective integration of in-kind and financial contributions, including those of IHI JU private members, their constituent or affiliated entities to enable a successful public-private partnership.

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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/future-opportunities
- Form your consortium **early**
  - Always think “public-private partnership“
  - Include partners bringing **in-kind contributions**
- 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

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Call 6

- **15 Jan** **14:30** Rules & procedures: two-stage calls
- **16 Jan** **10:30** RWD / RWE in decision-making
- **16 Jan** **14:30** Treatment persistency

Pitches Info sesions

Call 7

- **10 Jan** **10:30** Management of heart disease
- **10 Jan** **14:30** Optimised hospital workflows
- **11 Jan** **10:30** Rules & procedures: single-stage calls
- **11 Jan** **14:30** Clinical validation of biomarkers
- **12 Jan** **14:30** Single-stage calls: financial aspects
- **23 Jan** **14:30** Management of heart disease
- **24 Jan** **14:30** Optimised hospital workflows
- **25 Jan** **14:30** Clinical validation of biomarkers

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Join the call 7 pitching sessions

23 Jan **14:30** Management of heart disease

24 Jan **14:30** Optimised hospital workflows

25 Jan **14:30** Clinical validation of biomarkers

Want to pitch?

- ✓ Indicate this in your profile **by 12 January**
- ✓ Register for the pitching session for your topic
- ✓ Create a participant profile and marketplace
- ✓ Download the slide template from the IHI Call Days portal and send us your presentation **by 19 January**

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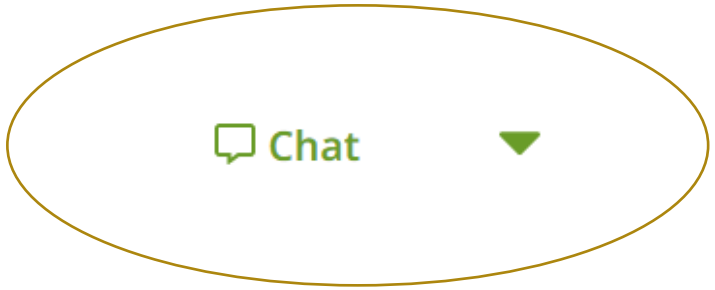
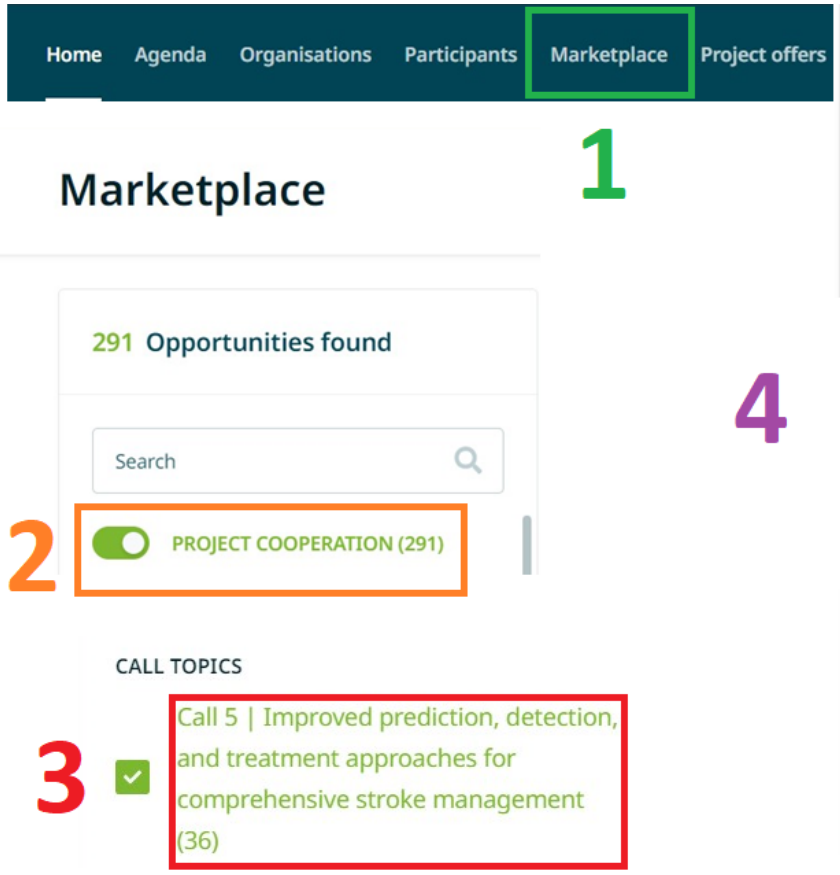
Questions

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



Marketplace



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PROJECT COOPERATION — Updated on June 21, 2023

EEG based Triage of Stroke Patients

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

What kind of expertise are you looking for? (Question for consortium/coordinator seeking partners)

PROJECT COOPERATION — Updated on June 21, 2023

Medical image analysis and segmentation

We would like to join a consortium and can contribute the following expertise:

Medical image data are used in a variety of ways for diagnosis, treatment planning, monitoring of interventions, observation of condition changes and documentation. Common image modalities range from

PROJECT COOPERATION — Updated on June 21, 2023

Remote vital functions monitoring, evaluation and smart interventions

Our research center focuses on the collection, remote monitoring, and evaluation of vital data.

What do we bring to the consortium?

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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 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

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

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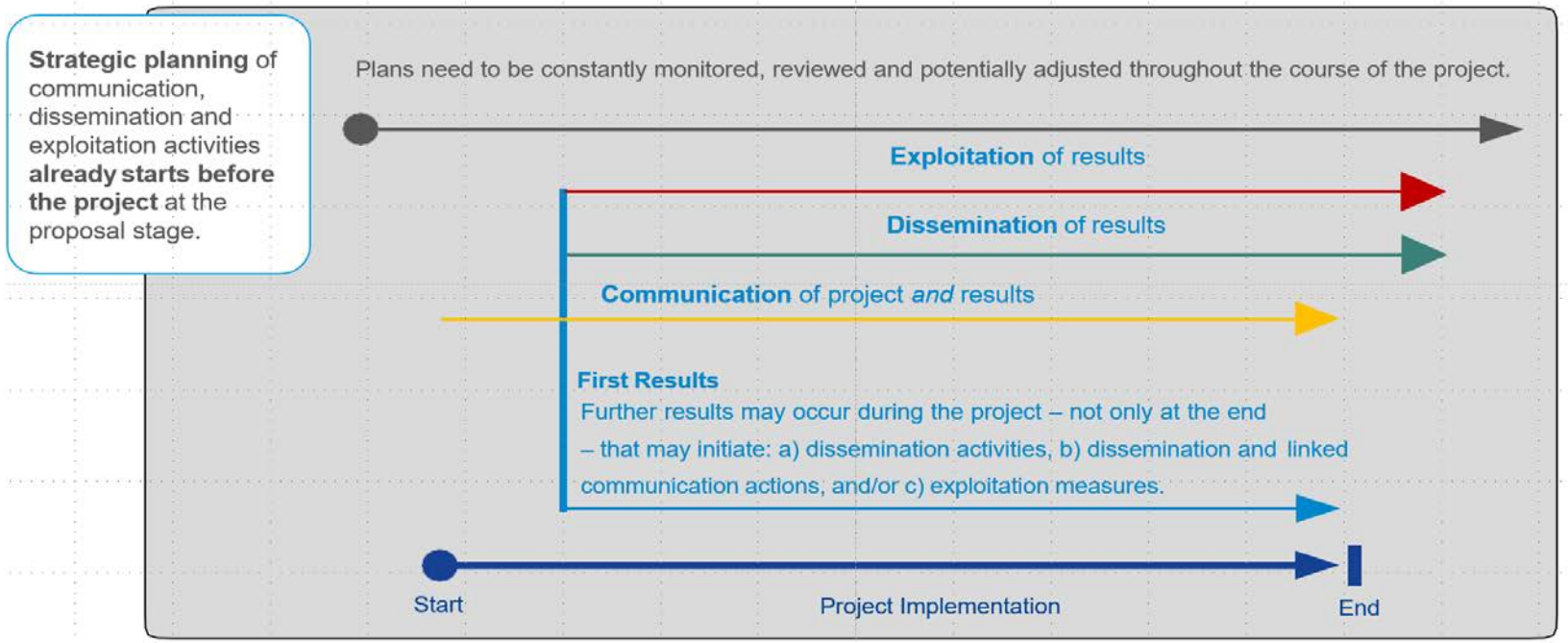
Additional Slides

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.



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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