Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

IHI call 10 – topic 3

John CLIFFORD, Scientific Project Officer, IHI
09/01/25 • 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 Q&A function on the right corner of your screen.

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Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 10 topic 3 presented by lead of the pre-identified industry consortium
  - Proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover**
  - rules and procedures

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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)

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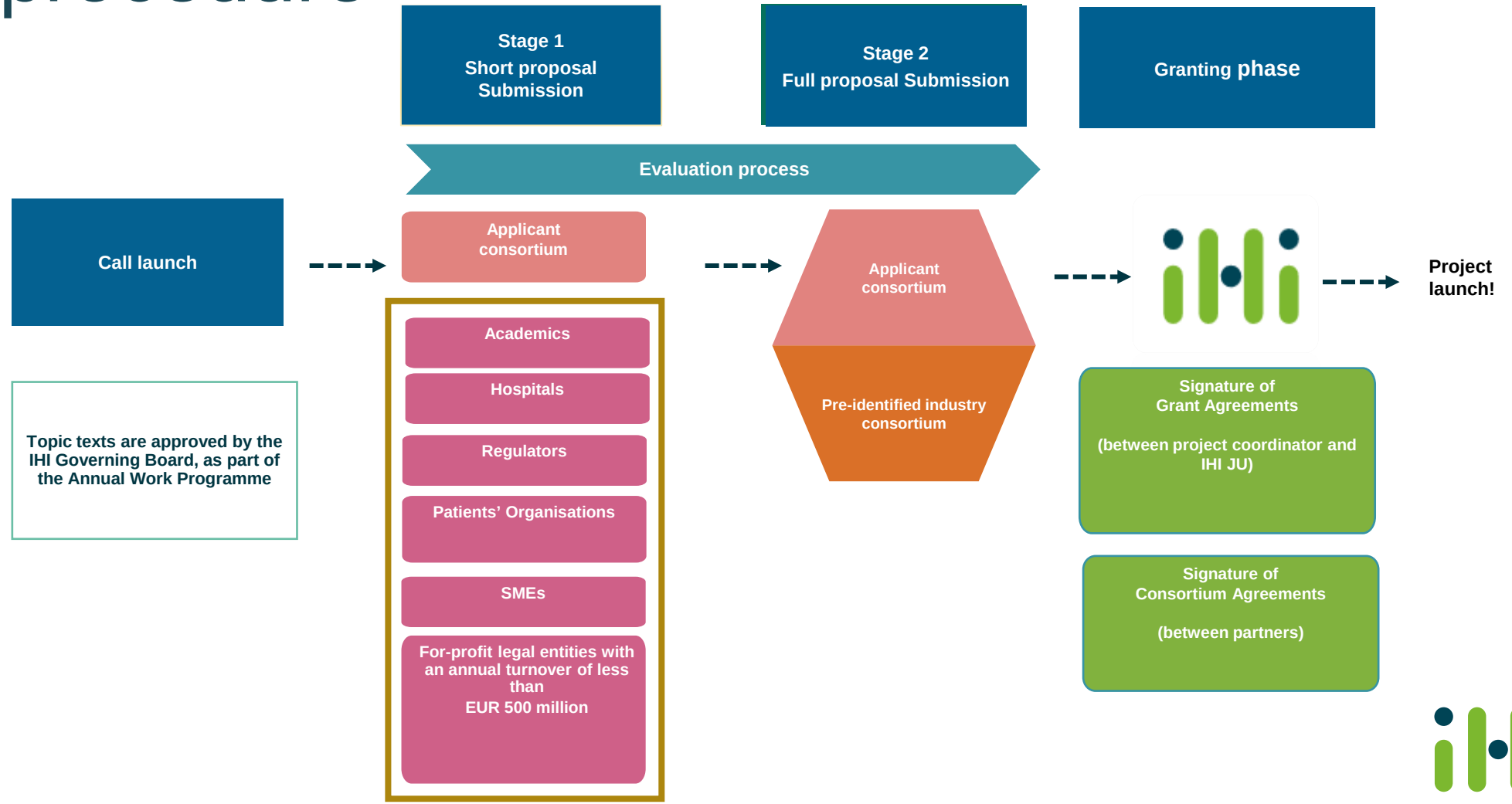
https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

How does IHI work? Two-stage procedure



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Per- and Poly-FluoroAlkyl Substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

IHI Call 10 - Topic 3

John O’Hara
07.01.2025

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The challenge

PFAS make up a large group of persistent anthropogenic chemicals which are difficult to degrade and/or dispose of in an environmentally respectful manner

Understanding PFAS in the medtech sector	Obtaining information on PFAS uses in healthcare due to a complex global supply chain and limited data sharing
Specific use of PFAS chemicals	Many specific use requirements and potential exposure routes due to the ubiquitous nature of PFAS use in the healthcare sector, including in production equipment, consumables, packaging, delivery devices, medical devices, complex machinery and cleaning agents
Identifying alternatives	for high-performing PFAS like polytetrafluoroethylene (PTFE) while ensuring product quality and safety;
Detection and Measurement	Accurately detecting and measuring PFAS in the environment is challenging. Current methods may not always identify all PFAS compounds, leading to potential gaps in monitoring and remediation efforts
End-of-life management	End-of-life management of healthcare products is underdeveloped, with inconsistent approaches to multicomponent waste management
Regulatory Compliance	Governments are increasingly regulating PFAS, which requires industries to adapt quickly. Compliance with these regulations can be complex and costly
Remediation Difficulties	Current wastewater treatment technologies struggle to eliminate complex PFAS

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Need for public-private, cross-sector collaboration

The overall aim of this topic is to provide world leading, fully integrated and globally applicable solutions to address PFAS emission and exposure concerns, for example by substitution

Collaboration among scientists, policymakers, regulators, healthcare providers, chemical manufacturers, patient groups and trade associations and waste managers is vital to address technical, legal, and practical considerations. Proper scientific assessment of alternatives is necessary to maintain safety and quality

Public-private partnership is essential to offer access to necessary funding, research facilities, and data. Engaging diverse stakeholders and cross-sector collaboration ensures comprehensive and accepted solutions can be developed.

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Scope of the topic

The overall aim is to provide world-leading, fully integrated and globally applicable solutions to address PFAS emission and exposure concerns

Objective 1

Cross-sector solutions to develop PFAS alternatives

- Reporting system to label PFAS-containing raw materials or medical device components
- Technology on optimised materials capable of replacing PFAS in specific applications
- Reliable data on alternative materials that could replace PFAS and corresponding design and performance characteristics
- Technology for replacing PFAS chemicals in chemical synthesis or excipients in drug manufacturing
- Replacements for trifluoroacetic acid (TFA) in chromatography and other analytical methods
- Development of PFAS-free process aids (tubing, gaskets, fittings)
- Searchable database of validated PFAS alternatives

Objective 2

Understanding PFAS in the MedTech sector

- Increased knowledge of PFAS types and applications throughout the MedTech and diagnostic process supply chain
- Robust evaluation of PFAS alternatives
- Enhanced stakeholder information sharing between MedTech and the manufacturers of equipment, devices, disposables, PPE manufacturers and other activities identified by this mapping exercise

Objective 3

Sector-specific solutions to reduce and reuse PFAS materials

- End-of-life management guidelines for PFAS components/chemicals, including circularity aspects and waste treatment
- PFAS-specific removal, decontamination or environmentally responsible disposal technologies for TFA from wastewaters

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Expected outcomes

The action under this topic must contribute to all the following outcomes:

- Replace PFAS: New environmentally sustainable materials as alternatives to PFAS that maintain patient safety are developed for the benefit of the healthcare industry and the citizens;
- Reduce / re-use PFAS: Improved usage of PFAS materials and minimized exposure is achieved for the benefit of the environment and therefore citizens and society;
- A mapping of the types and applications of PFAS throughout the supply chain is available for healthcare technologies and products, including collaborating with upstream suppliers;
- An available database of alternatives to PFAS;
- New disposal processes of PFAS are available for the benefit of the environment and therefore citizens and society.

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Expected impact

This topic will enable and directly contribute to the EU health priorities, initiatives, and policies. The proposed IHI JU's topic would strengthen collaboration between healthcare system stakeholders to reduce emissions of, and exposure to PFAS, evaluate alternatives and therefore, contribute to the EU Chemicals Strategy for Sustainability of the EU Green Deal

- Contribute to IHI JU SRIA objectives, driving cross-sectoral health innovation for a competitive European health industry. Contribute to the objectives of the Industrial Strategy for Europe and Pharmaceutical Strategy for Europe;
- Understanding human health and environmental risks from PFAS in healthcare from a life cycle perspective, ie mapping where PFAS is introduced in the healthcare industry and removal, where possible. ;
- Manage PFAS risks with novel mitigation measures, including safe disposal, reuse, and recycling;
- Develop methodologies and solutions for PFAS replacement that meet regulatory requirements without compromising efficacy, quality, safety, or environmental performance;
- Position the EU as a leader in safe, sustainable PFAS alternatives through industry-academia collaboration; Ensure medicine supply in the EU, avoid non-EU dependencies, and keep R&D activities in Europe for active substances to address societal and political needs
- Strengthen stakeholder collaboration to reduce emissions and exposure until alternatives are found;
- Share industry knowledge and best practices to inform future PFAS policy;
- Improve business planning certainty for medical technology manufacturers, ensuring long-term sustainability and patient access

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Expected contributions of the industry consortium

Composition of the industry consortium:

- Pharmaceutical and vaccines development and manufacturing industry
- Medical technologies (medical devices, in vitro diagnostic devices (IVDs), imaging devices, drug-device combination products, etc.) development and manufacturing industry
- Formulators and component manufacturers (to create samples and help test new materials)
- Chemical manufacturers (to inform chemical synthesis and manufacture)

Contribution:

- chemical synthesis and active pharmaceutical ingredient (AP)I/drug product manufacturing;
- medical device manufacturing and assembly, packaging, distribution, medical supply chain management and quality control;
- regulatory affairs topics, occupational safety;
- standardised analytical methods and in process controls;
- use of process aids, their procurement and quality assurance aspects (e.g. qualification);
- management of chemical/biotechnology waste and decontamination of wastewater;
- circular economy expertise;
- safe and sustainable by design methodologies;
- activities, results and insights from existing pilots and studies (these may include historical data generated outside of the project timelines that will not constitute part of the in-kind contribution);
- publication support and data dissemination

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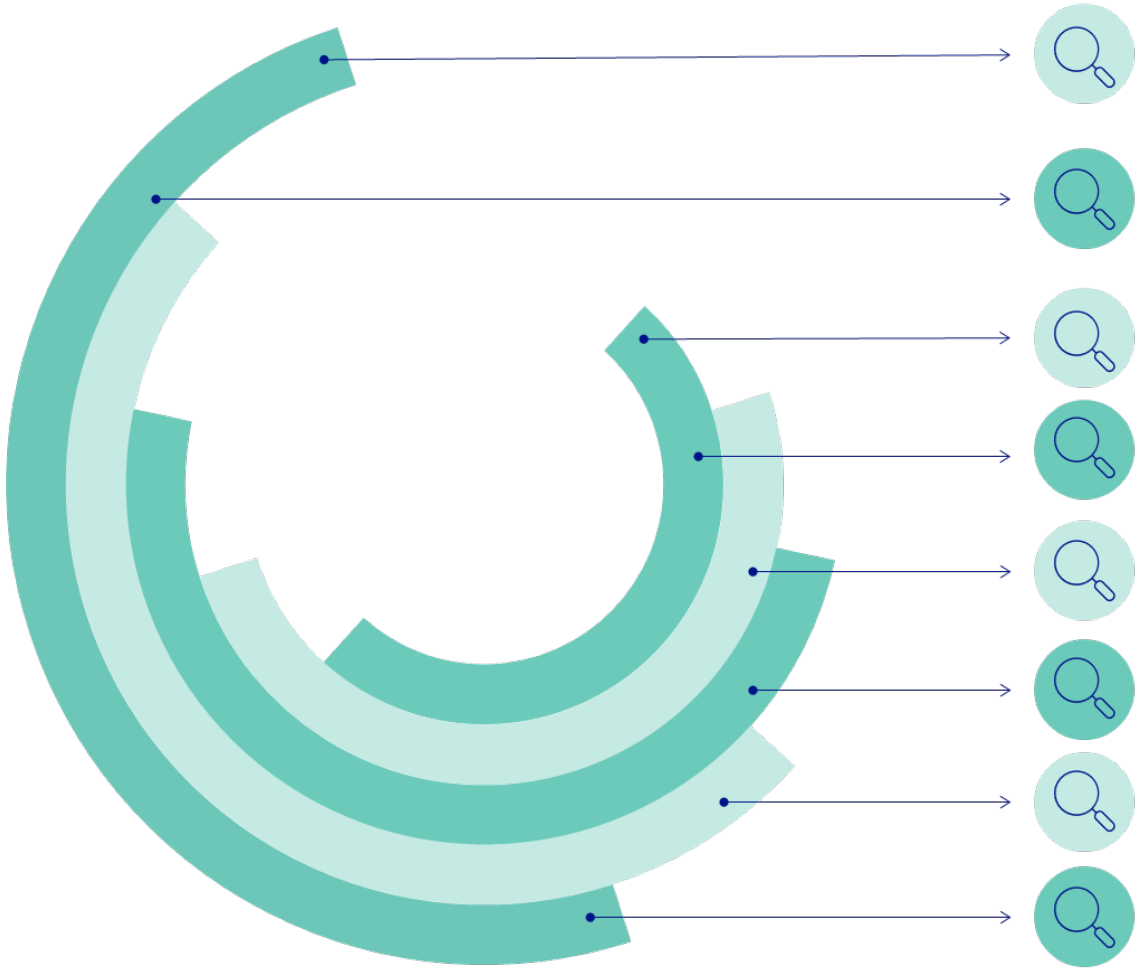
Expected contributions of the applicants



Academic centres and research organisations

- Expertise in PFAS analytics, chemical synthesis, material sciences, coatings, and biodegradation
- Researchers working on PFAS alternatives and optimising existing materials

Manufacturers

- PFAS materials (e.g., films, spare parts, equipment, implants, foils)
- Medical manufacturing, critical technologies, medicinal products, and vaccines
- Drug substance manufacturing/vaccines targeting PFAS excipient replacements/reductions

Standards organisations

Develop and update analytical standards/testing methodologies

Analytical methods experts

Replace TFA in chromatography and other technologies

Process aids development experts

Replace PFAS-containing process aids (tubing, gaskets, fittings) with PFAS-free alternatives

Healthcare waste and urban wastewater management organisations

Experts and consultants

- "Safe and sustainable by design"
- Circular economy experts (establish PFAS-specific collection and recycling systems)
- Providing input and testing solutions

Project management

- Coordinate communication, meetings, and risk management
- Grant administration, financial management, and reporting
- Digital/IT development and implementation of support for data governance and management
- Coordinate internal and external networking and stakeholder engagement

Also aiming for relevant interactions between the consortium and regulatory partners (i.e., notified bodies, policy makers); waste management companies; hospitals and other healthcare settings and providers

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Key Facts

- Consortium
  - Flagship cross-sectorial project involving EFPIA, MedTech Europe and COCIR partners
  - Pre-identified industry consortium: **25 companies** – with **UCB as industry lead**

- Budget: ~48 million EUR in total
    - 23.9 million EUR industry in-kind commitments identified
    - 24 million maximum financial contribution from the IHI JU.

- Duration
  - The indicative duration of the action is 60 months.
  - This duration is indicative only. In the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a 18 different duration when submitting the full proposal.

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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

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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 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/open-calls
  - 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

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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:
  - be.linkedin.com/company/innovative-health-initiative

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Calls 9 & 10

14 Jan	**10:30**	Call 9: General information
15 Jan	**10:30**	Call 9: Rules & procedures
15 Jan	**14:30**	Call 10: Secondary use of data in the European Health Data Space
16 Jan	**10:30**	Call 10: Rules & procedures

Online event

COCIR Advancing HealthCare · efpia · EuropaBio · MedTech Europe from diagnosis to cure · Vaccines Europe · Co-funded by the European Union

Questions time

If you want to ask a question, please use the Q&A function on the right corner of your screen

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