

# The Alliance of Health Research Institutes in Spain: A vision for the next Framework Programme



The Alliance of **Health Research  
Institutes** in Spain: A vision for the  
next **Framework Programme**






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This report has been prepared by the **Deputy Directorate General for International Programmes and Strategic Partnerships** of the Carlos III Health Institute (ISCIII), in collaboration with the **European Office** of the Spanish Foundation for Science and Technology (FECYT)





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# Presentation of the report's conclusions and position for the next Framework Programme

This document provides an analysis of the participation of Health Research Institutes (HRIs) in European research and innovation programmes, identifying key opportunities and challenges for their future engagement. The report has been developed based on input from the Alliance of HRIs and a review of available participation data. This work was undertaken by the Office for International Health Research Programmes and Strategic Partnerships of the Carlos III Institute of Health (ISCIII, hereinafter), in collaboration with the European Office of the Spanish Foundation for Science and Technology (FECYT, hereinafter).

In summary, the following **key messages and recommendations** for the forthcoming Research and Innovation Framework Programme (FP10) have emerged from this consultation process:

## Ambition and Vision

- ▶ Europe requires a forward-looking, strategically ambitious and adequately resourced Framework Programme that is strongly committed to research, development and innovation (R&D&I) and capable of delivering measurable societal impact in the medium and long term.

## Support for Clinical and Health Research

- ▶ The European Research Council (ERC) and Marie Skłodowska-Curie Actions (MSCA) are recognised as valuable mechanisms for talent attraction. However, additional opportunities should be tailored to the specific needs of **clinician scientists**, who face systemic disadvantages compared to laboratory-based researchers due to their dual roles in clinical care and research.
- ▶ Participation criteria under MSCA should be made more flexible to enable better **compatibility between research activity and clinical duties**. Similarly, for ERC Starting and Consolidator Grants (ERC-StG, ERC-CoG), consideration should be given to clinical workload as a justification for extending the eligibility window.
- ▶ The **inclusion of multicentre and multinational clinical trials** in the Framework Programme is welcomed. Nevertheless, implementation would be significantly enhanced by greater harmonisation of administrative procedures across different countries and by **streamlining justification and reporting requirements**.



- ▶ To promote **meaningful synergies**, it is essential to align participation rules across programmes that focus on health research.

## Frontier Science, the Basis for Research

- ▶ There is a critical need to provide **dedicated funding for fundamental research at lower Technology Readiness Levels (TRLs)**, which remains the cornerstone of scientific discovery and a driver of **breakthrough innovations that can reshape society**.
- ▶ Incorporating **bottom-up approaches and topics aligned with European Commission strategic priorities** is instrumental in fostering innovative, high-risk yet feasible ideas that can advance health outcomes and strengthen health systems.

## Paving the Way for Innovation

- ▶ There is a recognised need to boost the number of projects focused on the validation or evaluation of health technologies, as well as those related to innovative public procurement or pre-commercial procurement, to help **lower barriers to market entry**.

## Promoting Collaboration and Diversity

- ▶ To enhance the strategic role of **Research Infrastructures**, it is important to provide the research community with **accessible, transparent information regarding access conditions, usage protocols and associated costs**.

- ▶ Drawing from other institutionalised partnership models, there is a clear priority to strengthen **cooperative research efforts with Latin America**.
- ▶ Continued efforts are needed to promote **open science practices, integrate gender perspectives and actively involve citizens and patients** in both research projects and funding calls. Appropriate monitoring mechanisms should be embedded to track progress, and reforms in research assessment should be encouraged and operationalised at the project level. Capacity-building through training and support structures will be key to enabling this cultural shift.

## Reducing Bureaucratic Burden

- ▶ The **Lump Sum funding model is well suited to projects with budgets below EUR 10 million**. For larger-scale initiatives, alternative simplification measures should be explored that preserve milestone-based accountability while reducing administrative complexity.
- ▶ A strong **preference exists for two-stage calls**, as these reduce initial workload and allow applicants to gauge the competitiveness of their proposals before committing full resources. This format has proven effective in increasing the engagement of early-career and emerging researchers, clinician scientists, and those constrained by heavy clinical or administrative responsibilities, who may otherwise be discouraged from submitting full proposals.

# Consultation with the HRI Alliance

## Introduction: The HRI Alliance

This report outlines the priority areas for research and innovation identified by the accredited Health Research Institutes (HRIs). It also highlights the strengths and opportunities present within the Spanish and European health systems, while identifying the critical challenges that must be addressed during the 2028–2034 period through the forthcoming European Framework Programme for Research and Innovation.

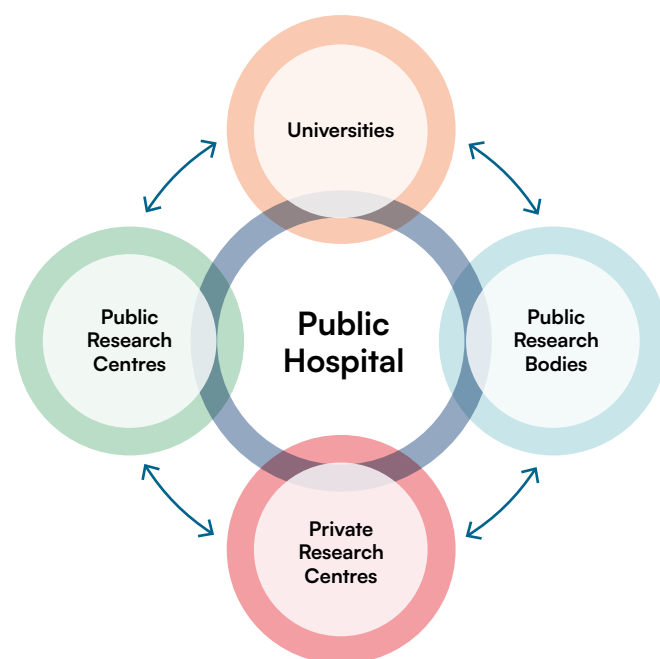
The HRIs are multidisciplinary centres devoted to both basic and applied biomedical research. These institutes are formed through partnerships between Spanish National Health Service hospitals and universities, public research organisations, and other public or private research institutions. Their core objective is to generate new biomedical and health knowledge, promote knowledge transfer and innovation in healthcare, and contribute to tangible improvements in population health.

In essence, the HRI seeks to embed hospitals within an integrated environment where education, healthcare delivery, and research coexist. This model fosters translational research, supporting the effective transition of scientific discoveries into clinical and public health applications.

The accreditation of the HRIs is overseen by the Carlos III Health Institute (ISCIII) and is based on a quality certification process assessing governance structures, research outcomes, and societal impact. The process is underpinned by criteria of efficiency and scientific excellence and includes a mechanism for continuous monitoring to support periodic reaccreditation.

The entire process is conducted in accordance with the provisions of **Royal Decree 279/2016 of 24 June on**

Conceptual map of the centres that can make up an HRI

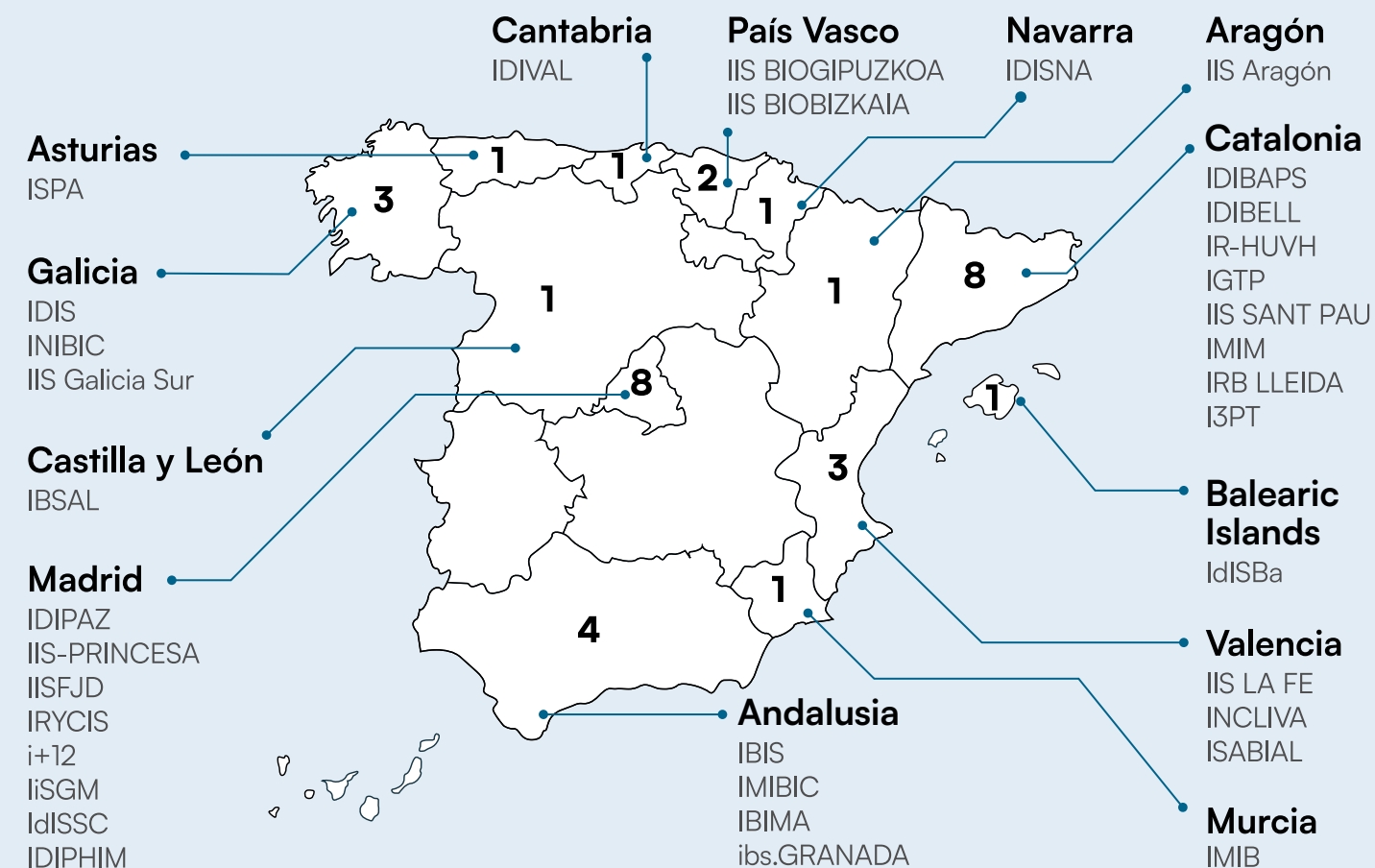


**the Accreditation of Biomedical or Health Research Institutes<sup>1</sup>**, as well as the **Second Technical Guide for Accreditation Assessment<sup>2</sup>**, currently in force and approved by the Ministry of Science, Innovation and Universities (MCIU) on 30 January 2025. Since the accreditation of the first HRI in 2009, the programme has expanded nationwide. As of now, there are 35 accredited HRIs across 13 of Spain's 17 Autonomous Communities, bringing together over 29,000 biomedical and health researchers from 176 institutions.

<sup>1</sup> RD 279/2016, of 24 June, on Accreditation of Biomedical or Health Research Institutes: <https://www.boe.es/boe/dias/2016/07/05/pdfs/BOE-A-2016-6474.pdf>

<sup>2</sup> Technical guide to accreditation assessment: [https://sede.isciii.gob.es/anouncements\\_detail.jsp?pub=51415](https://sede.isciii.gob.es/anouncements_detail.jsp?pub=51415)

Map of accredited HRI as of 31-12-2024



**35**  
HRIs



**+380**  
Centres



**>31.000**  
Research Staff





In 2019, the HRI FORUM was established and was subsequently renamed the **HRI Alliance** in 2020. The Alliance was created as a stable platform for collaboration and joint action. It serves to address common needs, guide the scientific strategy of the HRIs, align institutional priorities with those of the European research and innovation framework, and foster cooperation and synergies. Its goal is to enhance the competitiveness of the Spanish National Health Service as a whole.

## Objectives and methodology

Considering the current context, during the final quarter of 2024, the Deputy Directorate General for International Programmes and Strategic Partnerships of the Carlos III Health Institute (ISCIII), in collaboration with the European Office of the Spanish Foundation for Science and Technology (FECYT), jointly developed and implemented a structured consultation exercise. This consultation was composed of two questionnaires, each featuring a combination of closed, scaled, and multiple-choice questions, complemented by open-ended items designed to collect detailed insights, experiences, and perspectives from members of the HRI Alliance.

The first questionnaire centred on **strategic dimensions of the current and forthcoming EU Framework Programme for Research and Innovation**, with a primary focus on qualitative input. The second questionnaire adopted a more quantitative approach, examining practical aspects related to the implementation of **Horizon Europe rules for participation and key issues in project management**.

The consultation was distributed to all 35 accredited Health Research Institutes (HRIs), which were actively encouraged to contribute their views and reflections on both the present and future landscape of European research and innovation policy.

At the beginning of 2025, the data gathered through this process were analysed and consolidated in this consensus report. The document is structured around **four key sections**: an overview of Horizon Europe, the EU's R&I Framework Programme for 2021–2027; participation of the Spanish National Health Service in health-related calls; policy considerations in view of the upcoming Multiannual Financial Framework (2028–2034); and a synthesis of the consultation's results.





# Framework Programme: Horizon Europe

The primary objective of Horizon Europe is to maximise the scientific, technological, economic and social impact of EU investments in R&I

Horizon Europe (HE) is the European Union's flagship Research and Innovation (R&I) Framework Programme for the period 2021–2027, with a total allocated budget of EUR95.517 billion, marking the most ambitious EU R&I funding programme to date. Horizon Europe is designed to reinforce Europe's leadership in science and technology while advancing strategic objectives aligned with the United Nations Sustainable Development Goals (SDGs) and the Paris Agreement.

Moreover, Horizon Europe fosters international cooperation, recognising that complex global challenges require joint efforts and cross-border collaboration.

A strong emphasis is placed on inclusiveness and gender equality, ensuring that Europe's diverse talent base is fully mobilised and integrated into the research and innovation ecosystem.

The **primary objective** of Horizon Europe is to maximise the scientific, technological, economic and social impact of EU investments in R&I, thereby strengthening its scientific and technological bases and promoting the competitiveness of all Member States (MS).

Horizon Europe is also expected to deliver wide-reaching impacts for the European economy and society, including the creation of high-skill employment, increased Gross Domestic Product (GDP), and measurable progress in addressing climate change and other pressing global issues. Importantly, the programme aims to cement Europe's position as a global leader in science and technology.

The structure of Horizon Europe is organised around three interlinked pillars, each addressing distinct but complementary objectives. These pillars collectively support excellence, innovation, and impact across the R&I landscape.

## PILLAR 1:

### Excellent Science — Advancing the Frontiers of Knowledge

The 'Excellent Science' pillar serves as the cornerstone for high-impact, frontier research in Europe. Its main purpose is to support ambitious, high-risk research that pushes the boundaries of knowledge. At its heart is the **European Research Council (ERC)**, which funds investigator-driven projects that address complex scientific challenges at the cutting edge of their respective fields. This pillar also prioritises the development of human capital in research through the **Marie Skłodowska-Curie Actions (MSCA)**,

which promote the mobility of researchers across borders and sectors, enhancing their skills and broadening their professional experience.

In addition, substantial investments are made in strengthening access to world-class **research infrastructures**, ensuring that European researchers are equipped with the advanced tools and facilities required to conduct breakthrough scientific work.

## PILLAR 2:

### Global Challenges and European Industrial Competitiveness — Tackling Societal Priorities

This pillar focuses on addressing the most pressing challenges facing society today, from climate change to health and safety. This pillar is organised around six thematic clusters: Cluster 1 — Health; Cluster 2 — Culture, Creativity and Inclusive Society; Cluster 3 — Civil Security for Society; Cluster 4 — Digital, Industry and Space; Cluster 5 — Climate, Energy and Mobility; and Cluster 6 — Food, Bioeconomy, Natural Resources, Agriculture and Environment.

In this context, the **EU Missions** play a key role by mobilising resources and fostering collaboration to deliver tangible solutions to major societal challenges, including cancer; climate change adaptation and the associated societal transformation; the restoration of oceans and waters; climate-neutral and smart cities; and a soil deal for Europe. This pillar supports collaborative research and innovation projects aimed at developing innovative, interdisciplinary, and cross-sectoral approaches to these challenges.

**European Partnerships** play a crucial role in this pillar, fostering collaboration between industry, MS and the research community. These partnerships allow for pooling efforts and resources to address complex challenges more effectively. In the field of health, a broad portfolio of

partnerships is supported under this pillar. These include institutionalised partnerships such as the Innovative Health Initiative (IHI) and the European & Developing Countries Clinical Trials Partnership (EDCTP3), alongside co-funded initiatives such as Transforming Health and Care Systems (THCS), the Partnership for the Assessment of Risks from Chemicals (PARC), the European Research Area for Health (ERA4Health), and thematic partnerships in personalised medicine (EP PerMed), rare diseases (ERDERA), antimicrobial resistance and One Health (EUP OHAMR), pandemic preparedness (BE READY), and brain health.

The **Joint Research Centre (JRC)** plays an integral role within this pillar by providing independent scientific advice and technical support to EU institutions and national authorities. Its contributions ensure that EU policies are underpinned by robust, evidence-based knowledge.

Moreover, Pillar II actively contributes to reinforcing the **competitiveness of European industry**. It fosters the development and uptake of advanced technologies, enhances the innovation capacity of businesses, and supports the creation of high-quality jobs, thereby ensuring Europe's global leadership in strategic sectors.



### PILLAR 3:

#### Innovative Europe

— Transforming Ideas into Market Uptake

Pillar III is dedicated to fostering breakthrough innovations and accelerating their journey from concept to market-ready solutions. At the heart of this pillar is the **European Innovation Council (EIC)**, which plays a pivotal role by providing targeted support for the development of disruptive technologies and by empowering innovators, entrepreneurs and small and medium-sized enterprises (SMEs) with strong growth potential.

Complementing this, the **European Institute of Innovation and Technology (EIT)** contributes to this objective by promoting the integration of research, higher education and entrepreneurship through its Knowledge and Innovation Communities (KICs). These communities act as innovation hubs, fostering ecosystems where talent, ideas and investment converge to bring forward real-world impact.

### HORIZONTAL PROGRAMME:

#### Widening Participation and Strengthening the European Research Area (ERA)

This horizontal programme supports Member States in developing their R&I capacities. It focuses on reducing disparities in R&I performance between Member States and addressing cross-cutting priorities that need to

be developed to achieve the full deployment of the European Research Area. It promotes collaboration and exchange of good practice across the EU.



# Participation of the National Health System in the Framework Programme

This section outlines the key outcomes of the Spanish National Health Service’s (SNHS) participation in the Horizon 2020 (2014-2020) and Horizon Europe (2021-2027) Framework Programmes. For the purposes of this analysis, only competitive calls have been considered. Regarding Horizon Europe, only calls from 2021-2023 have been included, as the information for 2024 was incomplete at the time of preparing this report.

The two variables considered in this analysis are the total funds obtained by the Spanish National Health Service as a whole and the number of projects involving SNHS entities. The annual evolution of both metrics from 2014 to 2023 is shown.

A total of five graphs are shown:

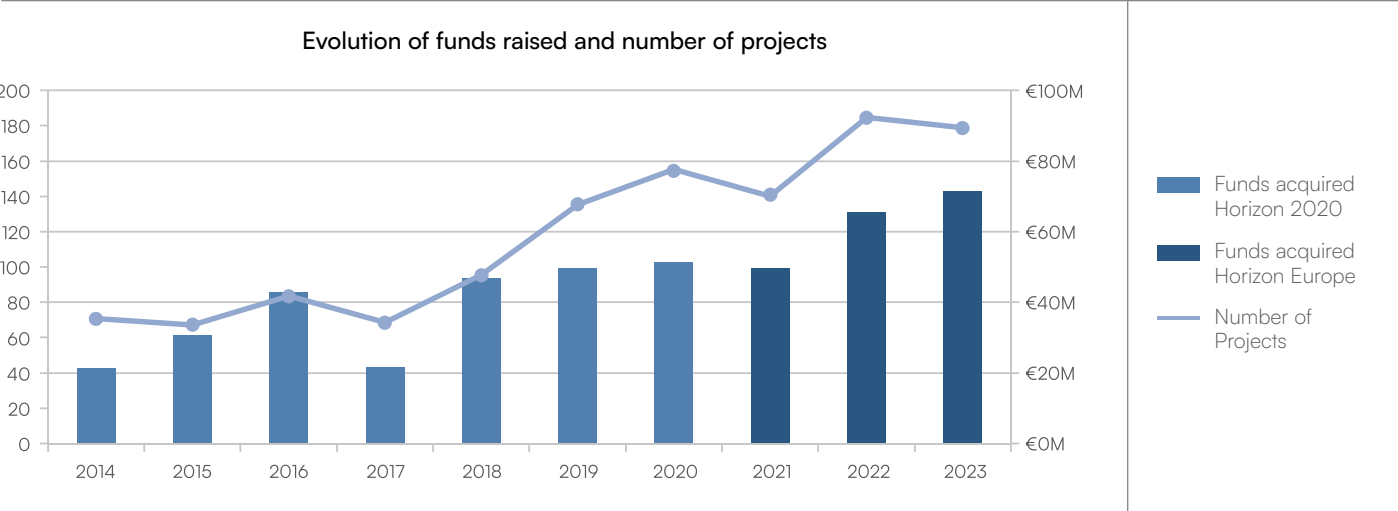
- ▶ General participation
- ▶ European Research Council (ERC)
- ▶ Marie Skłodowska-Curie Actions (MSCA)
- ▶ Health (Societal Challenge 1, Horizon 2020; Health Cluster and Cancer Mission, Horizon Europe)
- ▶ European Innovation Council (EIC, Horizon Europe) and Future Emerging Technologies (FET, Horizon 2020)

Additionally, this section provides a summary table detailing the key thematic areas to which the funded projects contribute.

<sup>3</sup>The analysis includes all Health Innovation Entities (HIEs), whether accredited or not, as well as other entities from the Spanish National Health Service.  
<sup>4</sup>For an analysis of Spanish participation in Horizon Europe, please consult the CDTI analysis and the [report of the Europea Office of FECYT](https://www.horizonteeuropa.es/informe-de-la-oficina-europea-sobre-horizonte-europa) published at the end of 2024, available at <https://www.horizonteeuropa.es/informe-de-la-oficina-europea-sobre-horizonte-europa> and at <https://www.cdti.es/noticias/espana-logra-un-record-de-retorno-de-3416-millones-de-euros-con-el-programa-horizonte-O>

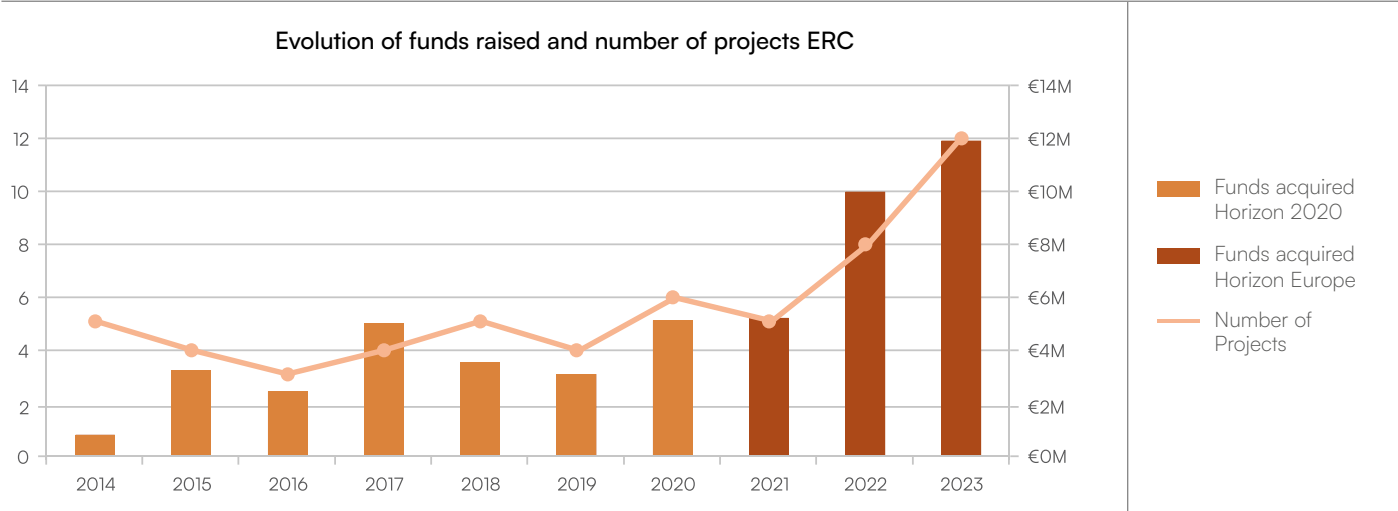
## General Participation

The general participation graph encompasses figures for the four areas shown in the other graphs. As illustrated in Graph 1, there is a clear upward trend in both funds raised and the number of projects involved, except for 2017. In 2014 (the first year of the series), approximately €20 million was raised, involving 72 projects. By 2023, this had risen to over €70 million, involving 179 projects.



## European Research Council (ERC)

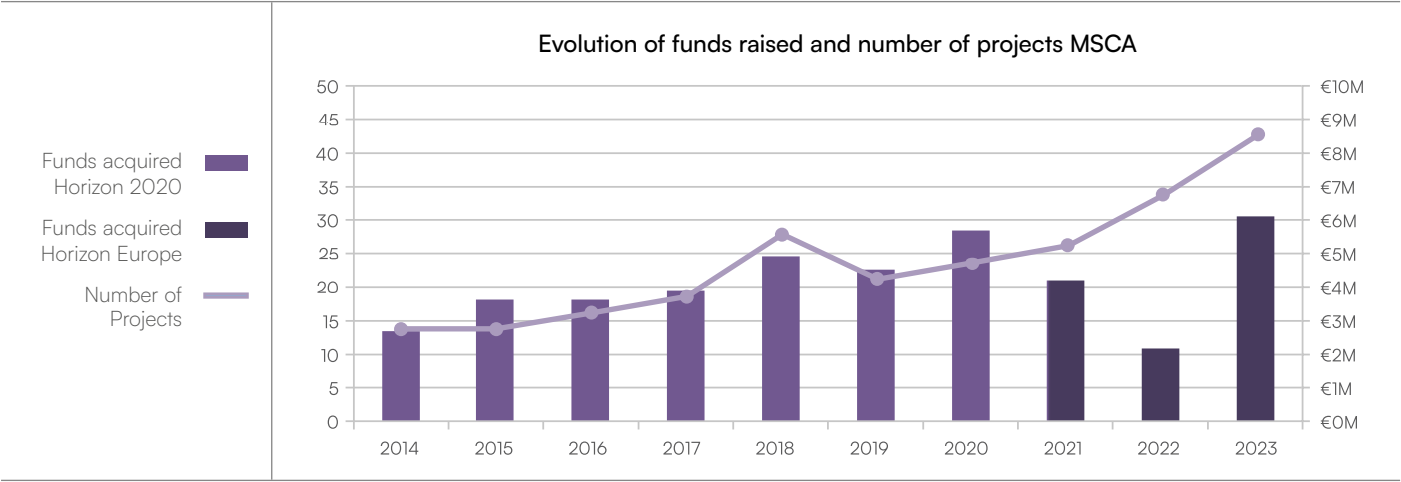
For participation in ERC projects, from 2015 to 2021, participation figures remained stable at around 3-4 projects annually, with annual funding between €2 million and €5 million. However, from 2022 onwards, a significant increase was observed, with 2023 figures more than doubling compared to 2021, both in terms of funds and the number of projects.





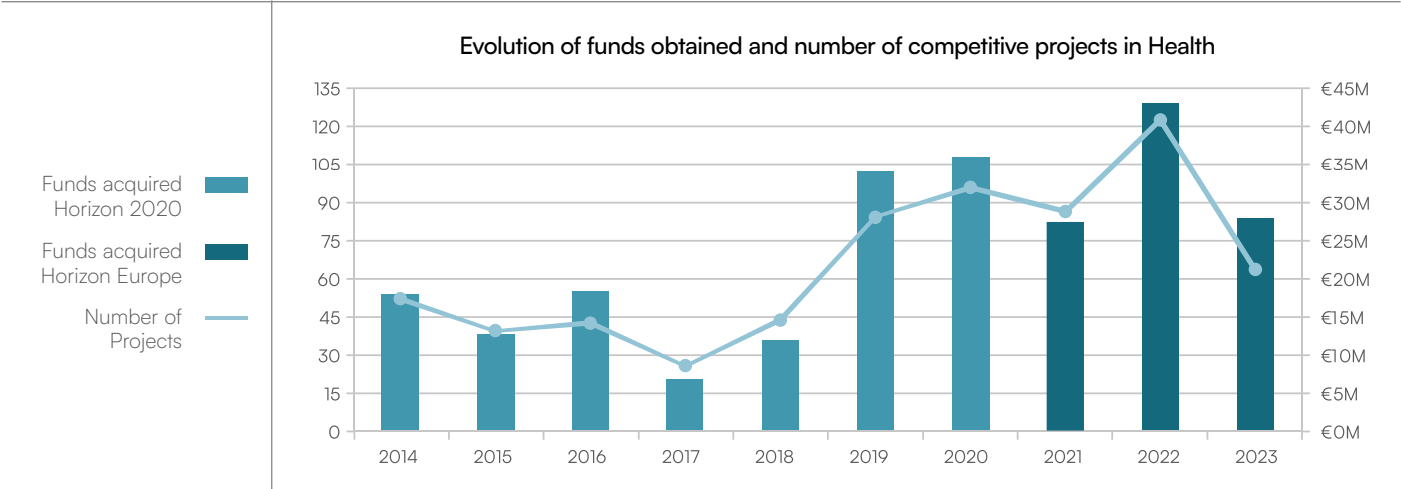
### Marie Skłodowska Curie Actions (MSCA)

In terms of funds raised through MSCA actions, there is a slight upward trend over the period analysed, although 2021 and particularly 2022 saw a significant decrease. However, this funding trend is not mirrored by the number of projects, which has shown a more stable and consistent upward trajectory since 2014. This divergence suggests that while Spanish National Health Service entities have increased their participation in MSCA projects, they have often requested smaller amounts of funding or participated in initiatives with lower financial envelopes per project. In the Horizon Europe period, 2023 saw a notable upturn, largely driven by the coordination of a COFUND project, which brought in nearly €1.7 million for the Spanish National Health Service.



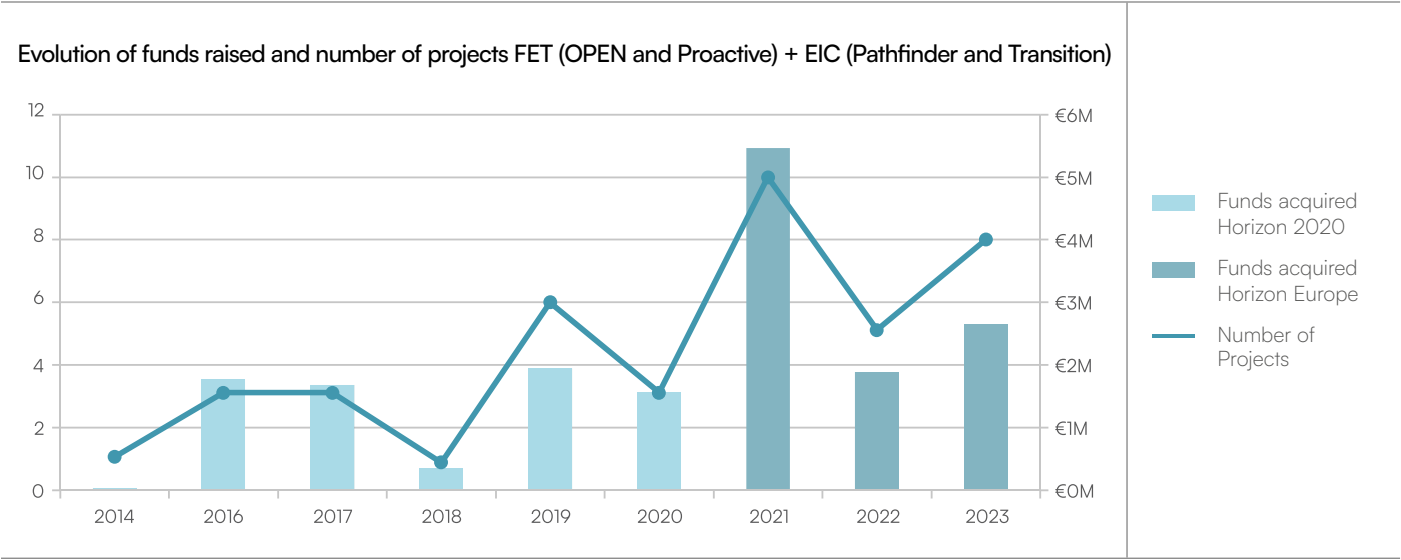
### Health

Data on fundraising and participation in competitive health-related projects (i.e., Horizon 2020’s Social Health Challenge, the Health Cluster, and the Cancer Mission in Horizon Europe) can be divided into two phases. Between 2014 and 2018, results remained relatively stable, at a modest level. However, from 2019 onwards, for the final Horizon 2020 calls, a notable increase was observed in both variables analysed, with results in Horizon Europe maintaining similar growth patterns.






### European Innovation Council (EIC) and Horizon 2020 Future Emerging Technologies (FET)

The final graph displays combined participation data for Future Emerging Technologies (FET) under Horizon 2020 and the EIC’s Pathfinder and Transition instruments for Horizon Europe. Notably, there was significant growth in 2021, marking the first year of Horizon Europe.



The H2020 and Horizon Europe projects involving entities from the Spanish National Health Service span a broad spectrum of thematic areas. Based on an analysis of the titles of funded projects, these can be categorised into the following overarching domains:

 <div>Research on COVID-19 and SARS-CoV.2</div>	 <div>Innovations in cancer and personalised therapies</div>	 <div>Focus on chronic diseases and co-morbidities</div>	 <div>Mental health and well-being in society</div>
 <div>Development of health and data technologies</div>	 <div>Infectious diseases</div>	 <div>Ageing</div>	

# Political context

Before examining the results of the consultation to the HRIs, it is helpful to briefly consider the current European policy context surrounding the design and structuring of future EU programmes. Over the past eighteen months, several high-level reports have set out policy recommendations aimed at shaping the future of the European Union, each focusing on different dimensions in anticipation of the next Multiannual Financial Framework (2028–2034). These include:

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## Much more than a market. Speed, security and solidarity

*Enrico Letta. April 2024*

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## The future of European Competitiveness

*Mario Draghi. September 2024*

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## Align, Act, Accelerate. Research, Technology and Innovation to boost European Competitiveness

*Commission Expert Group on the Interim Evaluation of Horizon Europe*

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## A Competitiveness Compass for the EU

*European Commission*

While each of these reports addresses broader thematic areas, such as the Single Market, competitiveness, and the evaluation of Framework Programmes, they also include specific recommendations related to health, which are summarised below.

### Letta Report. *Much more than a market.*

This report, authored by former Italian Prime Minister Enrico Letta at the request of the then President of the European Council, Charles Michel, presents an assessment of the current state of the EU Single Market and proposes actions to deepen integration to boost competitiveness.

In the area of health, the Letta report calls for progress toward a single pharmaceutical market and highlights the need to **address inequalities** between Member States in terms of healthcare expenditure and access to treatment. The report advocates increased production of medicines and a move towards strategic **autonomy in critical areas such as raw materials, vaccines, and antibiotics**. It identifies three major public health challenges: **mental health, neurodegenerative diseases, and antimicrobial resistance (AMR)**. To tackle AMR, the report proposes intensified R&D efforts on antibiotics, reinforced vaccination strategies, and the introduction of a European vaccination passport.

In response to **population ageing**, it recommends adapting the skills and infrastructure of health systems, combining national and European initiatives, and leveraging technologies such as AI, telemedicine, and advanced genomics. It also suggests using European Cohesion Funds to develop community-based healthcare networks.

Despite the European Commission's centralised authorisation process for medicines, the report

notes persistent **disparities among Member States in access to treatment**.

On **clinical trials**, the report stresses the importance of leveraging the Single Market to enhance efficiency and competitiveness by removing regulatory obstacles and **fostering transnational clinical trial networks**. At present, variations in national regulations and the inconsistent criteria applied by ethics committees act as barriers to greater alignment.

**Interoperability of health data** is identified as essential for both the functioning of a single health market and for the competitiveness of European research and innovation. The report welcomes progress made through the European Health Data Space (EHDS) and calls for the swift implementation of the proposed legislation.

It also recommends building on the **joint vaccine procurement** experience during the COVID-19 pandemic by extending the model to other medicines. This would enhance the EU's collective negotiating power, particularly benefiting smaller Member States, and could be supported through the establishment of a European Guarantee Fund. Finally, the report underlines the value of the "One Health" approach as a framework for integrated, cross-sectoral health policy. It also welcomes ongoing legislative work by European institutions on voluntary unpaid donations (VUD) of substances of human origin (SoHO), aimed at harmonising rules across the EU.

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The Letta report calls for progress toward a single pharmaceutical market and highlights the need to address inequalities between Member States in terms of healthcare expenditure and access to treatment

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## Draghi Report. *The Future of European Competitiveness*

It further underscores the importance of maintaining and expanding research and innovation activities within the EU, with a specific focus on the pharmaceutical sector

Commissioned by European Commission President Ursula von der Leyen and led by Mario Draghi, former President of the European Central Bank and former Prime Minister of Italy, this report sets out a **strategic vision for enhancing Europe’s competitiveness**. It identifies three key transformational pillars: innovation, decarbonisation, and economic security, as essential to securing the EU’s long-term position in the global economy.

In the area of health, the report outlines a series of proposals aimed at improving **coordination of health data**, strengthening research capacities, **streamlining regulatory processes**, and **fostering innovation within the pharmaceutical sector**. These recommendations are framed within the broader goal of boosting European competitiveness in health and life sciences.

The Draghi report shares **considerable alignment with the Letta report**, particularly in its emphasis on **reducing the EU’s external dependencies** in pharmaceutical manufacturing, capitalising on the potential of **multi-centre clinical trials**, and accelerating

the digital transformation of national health systems through the full implementation of the **European Health Data Space (EHDS)**.

It further underscores the importance of maintaining and expanding research and innovation activities within the EU, with a specific focus on the pharmaceutical sector. In this context, the report advocates for the **secondary use of health data** as a critical enabler of these activities.

Regarding artificial intelligence (AI), the report recommends providing clear and consistent guidance on its application throughout the medicinal product lifecycle, especially in clinical trials and pharmacovigilance. It stresses the importance of regulatory simplification through the revision and streamlining of existing rules and guidelines.

To address the funding gap facing the pharmaceutical industry, the report proposes reorienting EU funding towards the development of **world-class innovation centres**, with the aim of strengthening R&D capacity across the sector.

## Align, Act, Accelerate. Commission Expert Group on the Interim Evaluation of Horizon Europe<sup>5</sup>

The primary aim of this report is to set out a series of recommendations for shaping the next EU Framework Programme. It was drafted by a group of independent experts chaired by Manuel Heitor, former Portuguese Minister for Science, Technology and Higher Education.

The report is organised around **three guiding principles** (align, act, accelerate) and presents **twelve recommendations** designed to support the development of a Framework

Programme that strengthens Europe’s global competitiveness.

Throughout the report, several health-related considerations are highlighted and summarised below. The document aligns closely with the strategic vision laid out in the Letta and Draghi reports, particularly in its emphasis on improving public well-being through innovative and responsive health policies.

One of the central proposals is a revision of the governance structure of the future Framework Programme, including the creation of a **Social Challenges Council**, with health positioned as a key focus area. This body would enable a more autonomous and focused approach to addressing Europe’s major societal challenges. Under this new governance model, the Council would prioritise issues such as mental health, antimicrobial resistance, and neurodegenerative diseases.

The report also calls for broadening the scope of health policy to better incorporate areas that have historically been under-addressed,

including mental health, stress, and the health impacts of climate change.

In terms of research policy, the report underscores the importance of increasing the scale and depth of transnational collaboration. **Looking ahead to the next Framework Programme (FP10)**, the report places strong emphasis on the need to ensure that **health research strategies are fully aligned with the overarching objectives** of the programme. Accordingly, the recommendations focus on enhancing **strategic alignment, increasing investment, and improving resource allocation** in research and innovation.

The report also calls for broadening the scope of health policy to better incorporate areas that have historically been under-addressed

## A Competitiveness Compass for the EU

The European Commission’s Competitiveness Compass is the most recent strategic document<sup>6</sup> setting out the EU’s priorities for the coming years. It draws extensively on the recommendations of the Draghi Report to outline a forward-looking agenda. The strategy is built around three core transformative imperatives: closing the innovation gap, delivering a joint roadmap for decarbonisation and competitiveness, and reducing strategic dependencies while enhancing security.

It identifies five horizontal enablers to underpin these transformations: streamlining regulation, unlocking the full potential of the Single Market, mobilising financing through a Savings and Investment Union, promoting skills and quality employment, and ensuring more effective coordination between national and European policies. Several of these cross-cutting enablers translate into concrete health-related initiatives. For example, the European Health Data Space (EHDS) aims to capitalise on the Single Market’s potential in health, while near-term actions include

proposals to simplify the regulatory approval processes for medical devices. Moreover, technologies such as artificial intelligence (AI), highlighted as key drivers of competitiveness, are recognised for their transformative potential across all sectors - including health.

The strategy also outlines some legislative initiatives expected to be adopted during the 2024—2029 European legislative cycle:

- **The European Biotechnology Act and Bioeconomy Strategy** (2025—2026), which will provide a renewed innovation framework across sectors such as health technologies and clinical trials, with the aim of unlocking the full economic potential of biotechnology in Europe.
- **Critical Medicines Act** (2025). The paper underscores the importance of reducing Europe’s reliance on single or highly concentrated suppliers for critical active pharmaceutical ingredients that are vital to safeguarding public health.

The strategy is built around three core transformative imperatives: closing the innovation gap, delivering a joint roadmap for decarbonisation and competitiveness, and reducing strategic dependencies while enhancing security

<sup>5</sup>Drawn up by the group of experts led by Manuel Heitor.

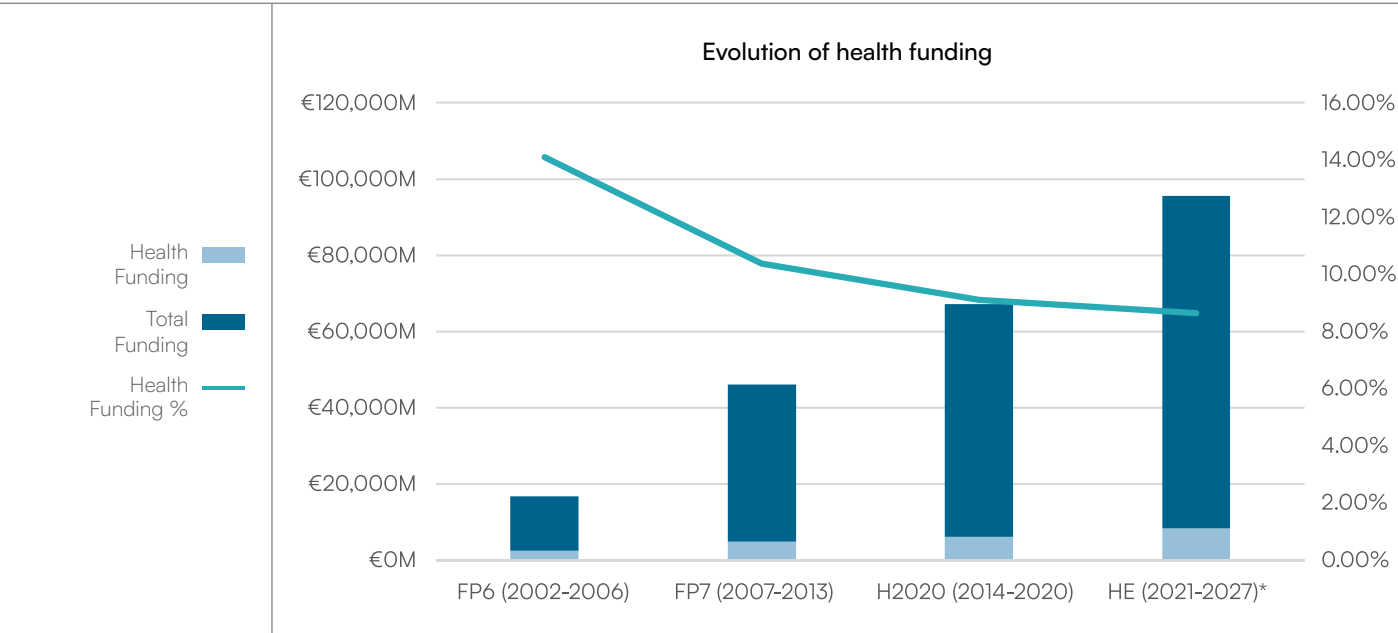
<sup>6</sup>COM (2025) 30 final. 29/01/2025.

# Strategic Form Analysis

## General Issues

Overall, the HRIs acknowledge that Horizon Europe **offers substantial funding, fosters interdisciplinary collaboration, and prioritises the enhancement of public health**. However, there is a need for greater support in translation to ensure that once solutions are developed, they can be scaled and implemented in clinical practice. This is especially important when considering the varying regulatory frameworks across National Health Systems in different countries.

At present, the Health Cluster, comprising partnerships, the cancer mission, and work programme calls, accounts for 8.6% of the total budget of the Framework Programme (EUR 8.246 million out of a total of EUR 95.517 million). Despite an increase in the overall budget for previous Framework Programmes, the proportion allocated to health has been on the decline. The HRIs argue that to address the emerging challenges facing the Spanish National Health Service in the coming years, the funding dedicated to the Health Cluster should reverse this trend and, ideally, be increased to 15% of the next Framework Programme's total envelope.



\*Data obtained from Horizon Dashboard.

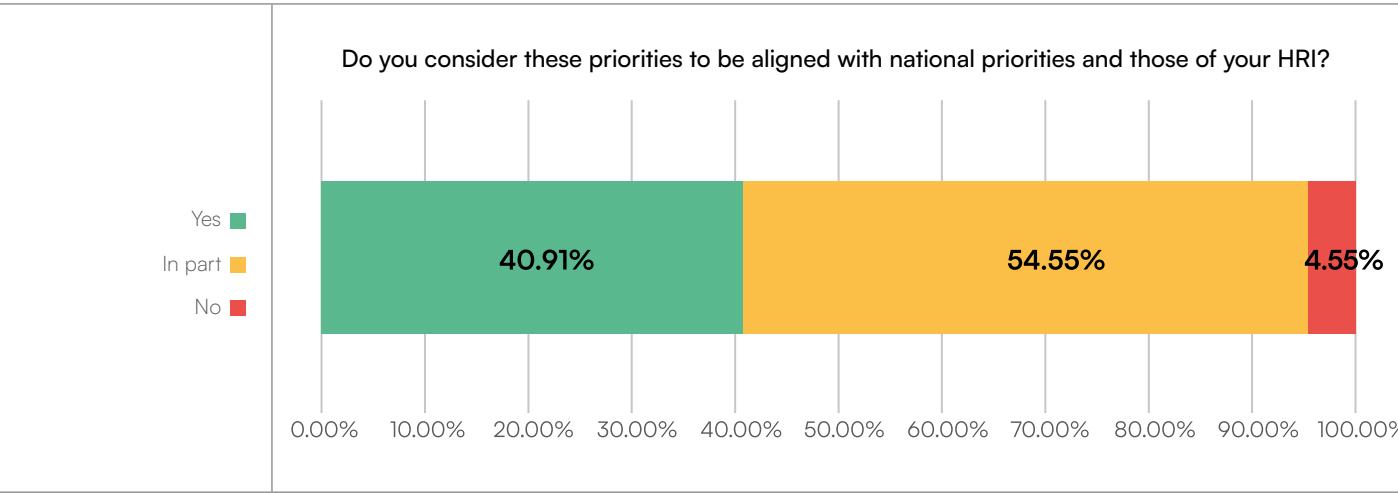
The HRIs agree that the main challenges facing the Spanish National Health Service in the next Framework Programme, across the various areas, will be as follows:

ÁREAS	CHALLENGES	SCIENTIFIC AREAS TO BE DEVELOPED
Basic research	<ul style="list-style-type: none"><li>▶ Insufficient funding to explore emerging scientific fields</li><li>▶ Challenges in talent retention and generational renewal</li><li>▶ Limited support for interdisciplinary research</li></ul>	One Health, nutrition, allergens, antimicrobial resistance, complex diseases and their underlying mechanisms, non-communicable diseases, rare diseases, early biomarkers in cancer, central nervous system, mechanisms of cell regulation and host—host interactions, mechanisms of response and resistance to immunotherapies, and the role of the microbiome in cancer.
Translational research	<ul style="list-style-type: none"><li>▶ Need to better integrate research with clinical practice and strengthen the scientific career of clinician researchers</li><li>▶ Complex administrative and regulatory frameworks</li></ul>	Frailty and healthy ageing, development of advanced therapies, personalised treatment approaches, drug repositioning, emerging epidemics and infections, cancer treatment, integrated care for patients with chronic conditions, diseases with higher prevalence in women, and treatment of neurodegenerative and neuropsychiatric disorders.
Innovation	<ul style="list-style-type: none"><li>▶ Barriers to the implementation of innovations in the market or clinical practice</li></ul>	New diagnostic approaches, 3D-printed pharmaceuticals, and novel advanced therapies.
RH	<ul style="list-style-type: none"><li>▶ Retention and stabilisation of talent</li><li>▶ Promotion of the clinician researcher career path and broader encouragement of research in clinical care settings.</li></ul>	
Infrastructure	<ul style="list-style-type: none"><li>▶ Outdated infrastructures requiring renovation and modernisation</li><li>▶ Limited access to cost-efficient European infrastructures</li><li>▶ Need for improved coordination and optimisation of national infrastructures to enhance research capacities</li></ul>	
Health data	<ul style="list-style-type: none"><li>▶ Data interoperability</li><li>▶ Guarantee access to infrastructure for data storage and sharing</li><li>▶ Facilitating research with data by adapting procedures</li><li>▶ Maintaining data security and privacy</li></ul>	



Health Research

According to the feedback received, a significant proportion (55%) believe that the priorities set by the new College of Commissioners for the next Framework Programme, including the development of new advanced therapy medicinal products (ATMPs) and orphan drugs, health prevention, antimicrobial resistance, mental health, rare diseases, medical conditions with high burden and low research activity, AI deployment, sequencing scale-up, and strengthening hospital cybersecurity, are only partially aligned with the priorities of the Spanish National Health Service. Healthy ageing, prevention of frailty, rare diseases and non-communicable diseases, especially those of a chronic nature, should be incorporated among the priorities at European level.



The inclusion of **multicentre and multinational clinical trials (CTs)** is highly regarded by the Health Research Institutes (100% of responses were in favour), though several significant challenges and limitations have been identified, including:

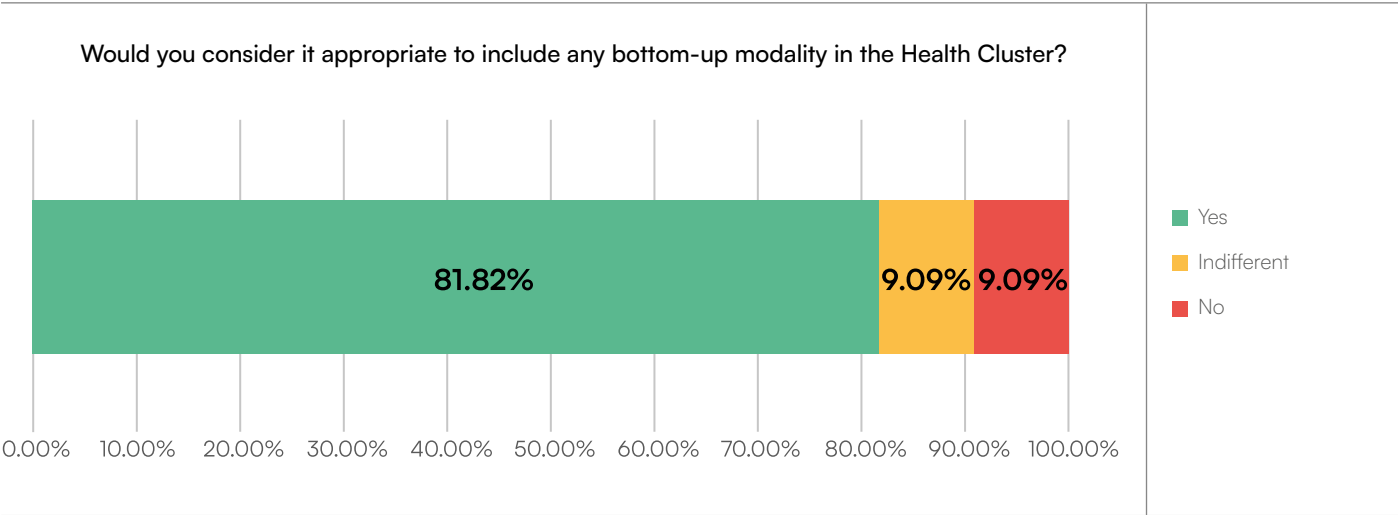
- ▶ The sharing of clinical data across Europe, which will be supported by the implementation of the European Health Data Space (EHDS).
- ▶ Country-specific regulations and the uneven application of European legislation on clinical trials (CTs).
- ▶ Administrative barriers that impede the planning and execution of the CTs.

To address these challenges, the following solutions are proposed:

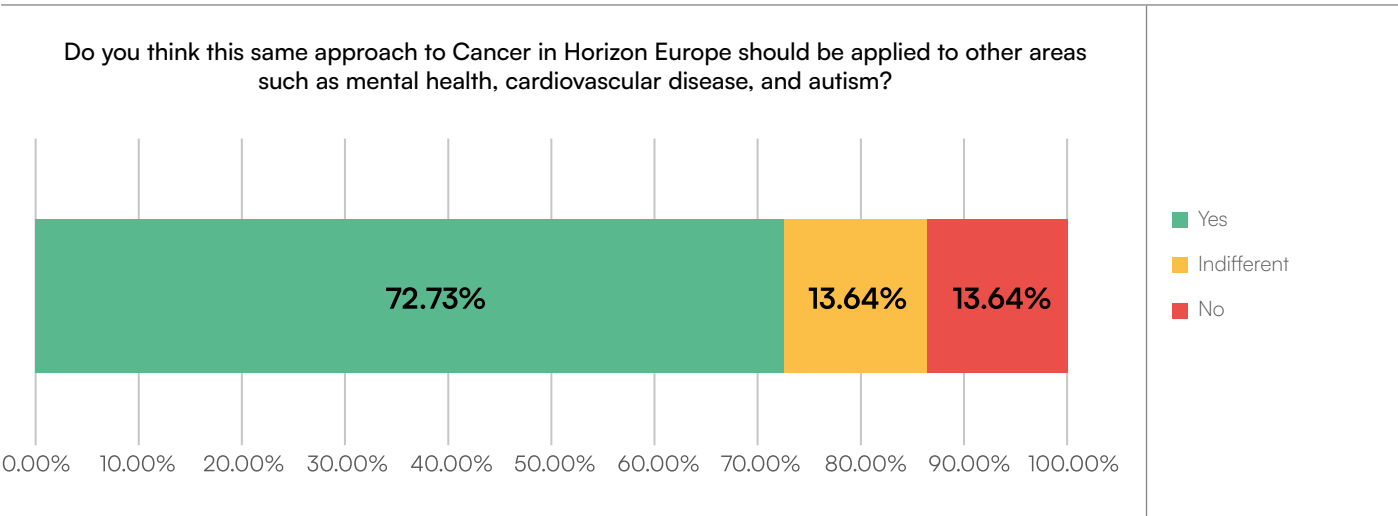
- ▶ Ongoing training in international regulations, trial design, data management, and negotiation.
- ▶ Harmonisation and simplification of processes and formalities, ranging from model contracts to protocol translations.
- ▶ Strengthening the support capacities of the SCREN/ECRIN network and establishing national collaborative structures.

<sup>a</sup>Priorities set by the new College of Commissioners for the next Framework Programme: <https://elections.europa.eu/european-commission/en/>  
<sup>b</sup>European Health Data Space (EHDS): [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds\\_es](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_es)

Regarding the **Health Cluster**, over 80% of responses indicated that it is essential to include a bottom-up modality, i.e., calls without predefined topics. The introduction of this bottom-up approach should not replace, but rather complement, the predefined topics that address the challenges identified at the European level and incorporated within the Framework Programme. Through bottom-up calls, an opportunity would be created to accommodate innovative ideas with controlled risks, which could represent significant advances in health or improve the functioning of health systems.



On the other hand, a significant majority (over 70%) consider it appropriate to apply the **mission** approach to other diseases, not just cancer, without increasing the complexity of the funding ecosystem. The fragmentation of a theme across multiple programmes complicates the research community’s understanding of where their proposals fit, so the mission approach could help address this issue.



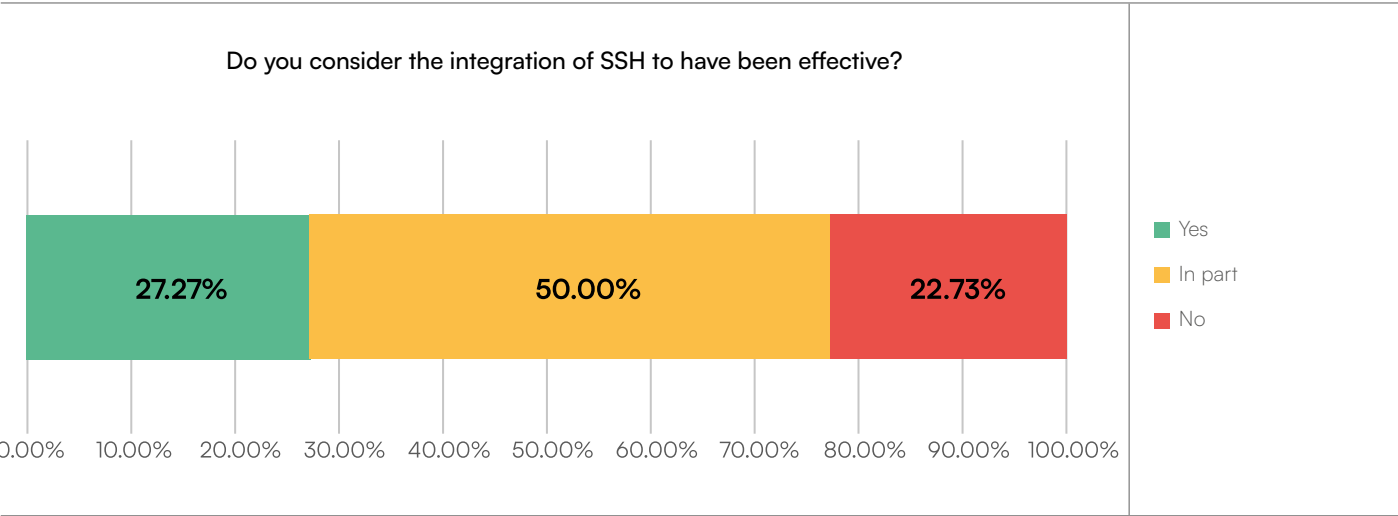


In the same context, there is support for **fostering synergies between programmes**, if this does not add complexity to the participation rules and is planned in such a way as to avoid funding overlaps in some areas while leaving others underfunded. Furthermore, the HRIs highlight the need for harmonisation across the different programmes addressing health research, with clear and straightforward participation and justification rules, focused on achieving project milestones.

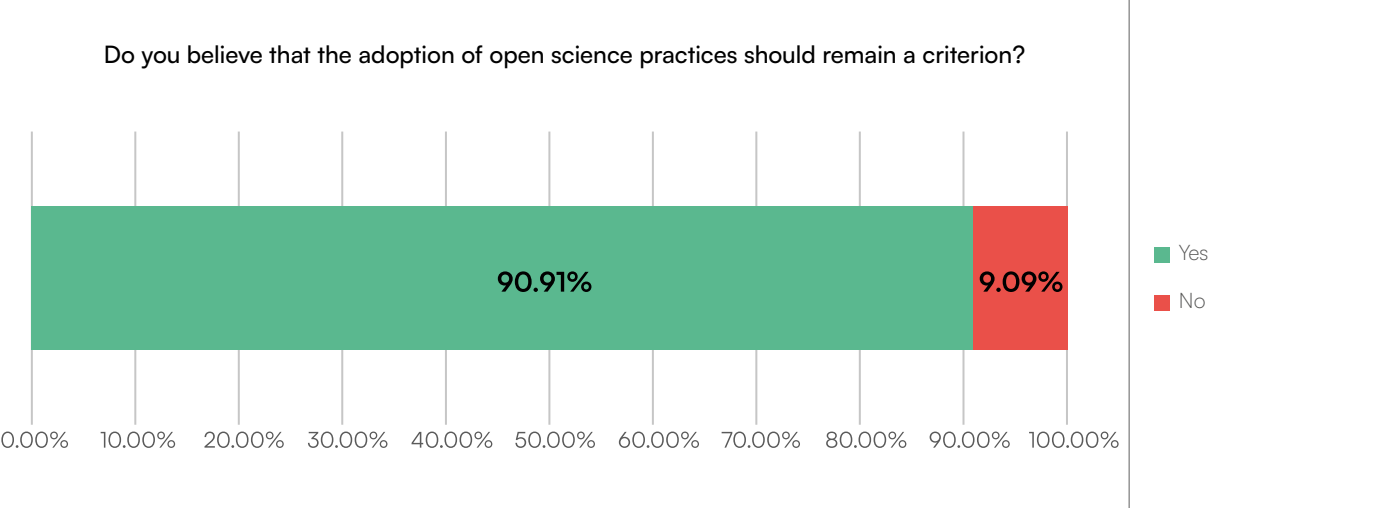
Similarly, in terms of potential **synergies with other clusters within the Framework Programme**, it is considered that the Health Cluster should prioritise synergies with the clusters CL5: Climate, energy, and mobility (3.95/5) and CL6: Food, bioeconomy, natural resources, agriculture, and environment (3.9/5).

### Cross-Cutting Issues

Survey participants note that the **inclusion of social sciences and humanities (SSH)** has had partial success, with over 70% of respondents indicating that such integration has been either unsuccessful or only partially successful. The feedback received highlights the challenges that HRIs face in integrating SSH into projects, pointing to the need for clearer information, and dedicated training, on what is expected by the EU, as well as mechanisms to support the identification of partners with the necessary expertise and capacity in these areas. At the same time, responses indicate that ISIs view social and ethical dimensions as highly relevant, with several suggesting these could even be the focus of dedicated funding.



A strong majority (90% of responses) consider the adoption of **open science practices** to be highly relevant. However, according to the comments, fostering a shift in research culture and embedding these practices in researchers' day-to-day activities will require more targeted training and stronger support throughout implementation.



The integration of **the gender dimension in research** is generally viewed very positively, with emphasis also placed on the need to address other aspects of human diversity, including geographical and ethnic representation. Respondents stress that these elements should be internalised in project design to mitigate potential biases. Nonetheless, it is acknowledged that integration must be tailored to each project’s specific context.

In this regard, HRIs recommend the establishment of monitoring mechanisms to evaluate how gender perspectives are applied within projects and their impact on outcomes. They also call for more dedicated projects that explore gender-based differences in health to broaden the scientific evidence base.

**Patient and representative involvement in projects** is perceived as highly beneficial. To enhance their participation—particularly in the context of European-funded research, it is recommended to:

- ▶ Provide training and capacity-building opportunities for both research staff and patient representatives.
- ▶ Recognise the contribution of both groups, thereby incentivising continued involvement.

### Partnerships

The topics covered by existing partnerships are broadly relevant to the Spanish National Health Service. Among these, PARC (2.65/5) and EDCTP3 (3.3/5) receive the **lowest** ratings, while EP PerMed (4.47/5) and IHI (4.25/5) are rated **most** positively.

As for future thematic priorities, respondents identify the creation of a partnership for cooperative research with Latin America as a key objective. They also support the establishment of a broader global health partnership that includes regions such as Africa and Latin America.

Generally, HRIs regard co-funded partnerships as an effective gateway into European-level research. Recurring calls on specific topics are

- ▶ Streamline administrative procedures to facilitate the inclusion of small or local patient associations, which often face difficulties in managing participation in European projects.
- ▶ Clarify the role of patients within projects, including the stage at which they should be involved. If involvement occurs too late, they cannot contribute meaningfully to study design or priority-setting.
- ▶ Make the participation of patients and civil society a clearly defined evaluation criterion within Health Cluster calls.
- ▶ Create online platforms and organise in-person events to foster direct interaction between researchers and patient communities.

In addition, the European Commission expects Health Cluster projects to **support policy development**. However, current mechanisms for policy impact are perceived as insufficiently clear or accessible. According to feedback from HRIs, it would be advisable to create a one-stop shop and simplify procedures to facilitate policy engagement, thereby fostering closer cooperation among different stakeholders.

particularly appreciated. However, the current landscape of health partnerships is seen as overly fragmented, and there is a recognised need to harmonise procedures to reduce the administrative burden associated with participating in transnational calls. The main obstacles identified include unequal funding contributions across countries and limited funding available through some partnerships, which can hinder participation.

Autonomous Communities in Spain, whose regional agencies act as funding bodies in co-funded partnerships, view this participation positively. Their deeper understanding of partnership dynamics enables more targeted promotion, resulting in greater engagement and leadership within relevant scientific domains.

### Innovation

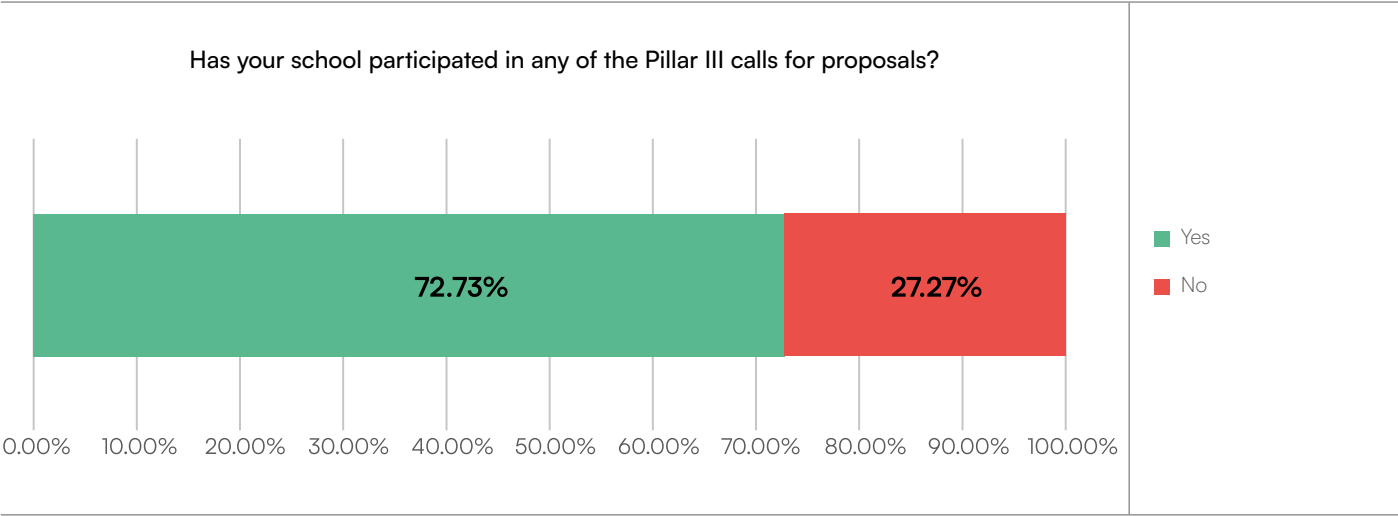
Regarding the research-innovation balance, the responses received indicate that there is generally a good equilibrium. However:

- ▶ There is a noticeable trend towards increasing Technology Readiness Levels (TRLs), and it is necessary to ensure sufficient funding for low TRL basic research to develop new paradigms and explore lines of inquiry with future impact potential.
- ▶ While innovation is envisaged, its effective implementation in clinical practice remains limited.
- ▶ There is a lack of information and training to promote innovation within HRIs.

- ▶ It is therefore necessary to increase investment and launch specific calls for projects aimed at validating or assessing health technologies (TRL 4—6), particularly those that have proven feasible in laboratory settings but still require real-world validation to overcome barriers to market uptake.

The IHI partnership is regarded as a key mechanism for knowledge transfer and public—private collaboration. However, HRIs highlight the complexity of the participation rules, which require further simplification to ensure equitable access to these opportunities.

Regarding Horizon Europe Pillar III (EIC, EIE, EIT), 70% of respondents report having participated in one of its calls.



In relation to each of the components of Pillar III, feedback reveals that **EIT Health** is perceived as variable and confusing, marked by regulatory uncertainty and a notable decrease in available funding. Furthermore, HRIs note that EIT Health offers limited opportunities for leadership and collaboration with the private sector due to the restrictive nature of its calls.

In contrast, the **EIC Pathfinder** is viewed as an attractive programme, but HRIs report limited success in accessing it due to low funding volumes, low success rates, and the requirement to establish interdisciplinary consortia. The **EIC Transition** scheme presents eligibility constraints, as it requires the proposal to build upon previous funding obtained under the EIC Pathfinder, ERC Proof of Concept, or Horizon Europe clusters and H2020 Societal Challenges.

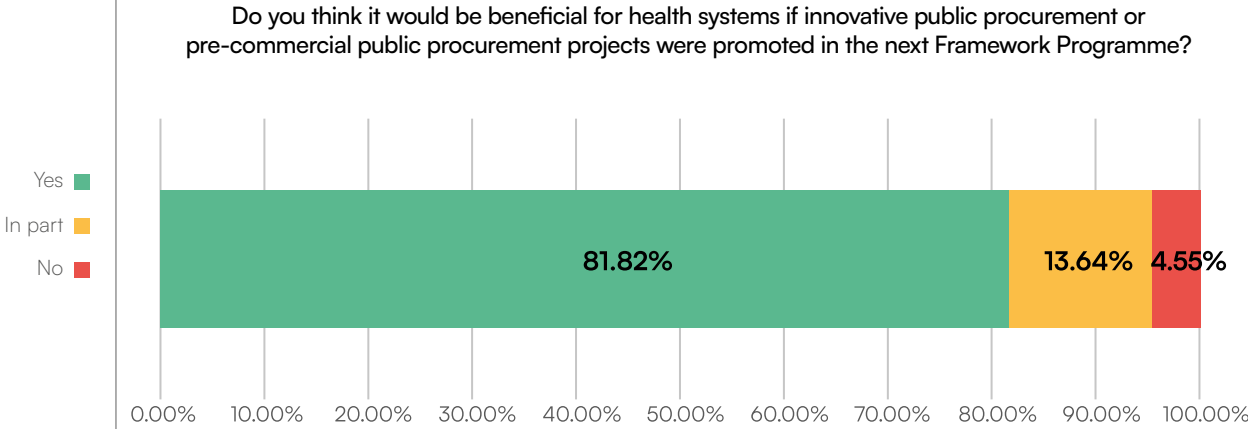


Over 80% of HRIs believe that the next Framework Programme should increase support for IP and PCP projects within the Health Cluster



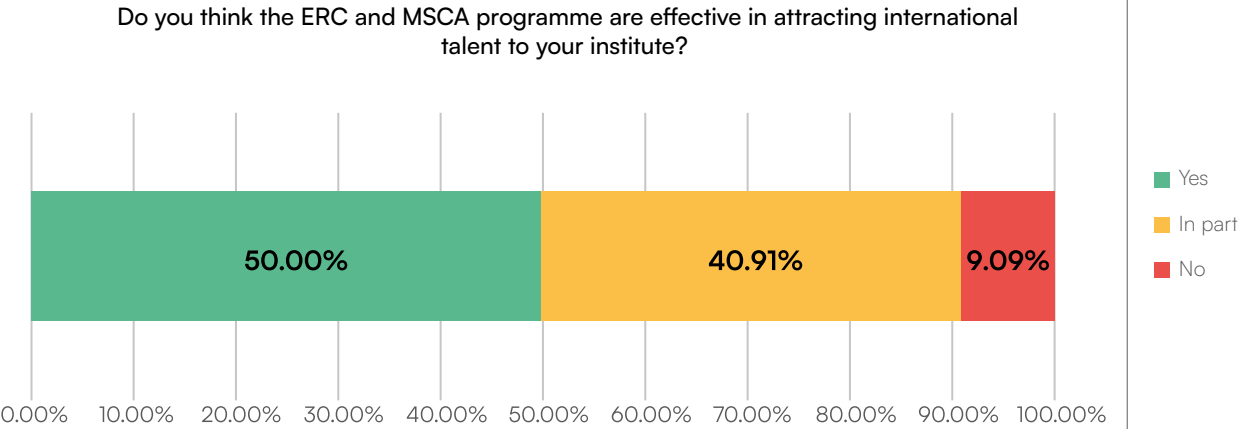
According to respondents, these restrictions limit the potential for innovation projects previously financed at the national or regional level to secure European funding for further development towards the market, with the validation of health technologies representing a particularly relevant area for HRIs.

Finally, a large majority of HRIs (over 80%) believe that the next Framework Programme should increase support for Innovation Procurement (IP) and Pre-Commercial Procurement (PCP) projects within the Health Cluster. For these actions to be effective, it is essential to harmonise procurement procedures across Member States.



### Human Resources

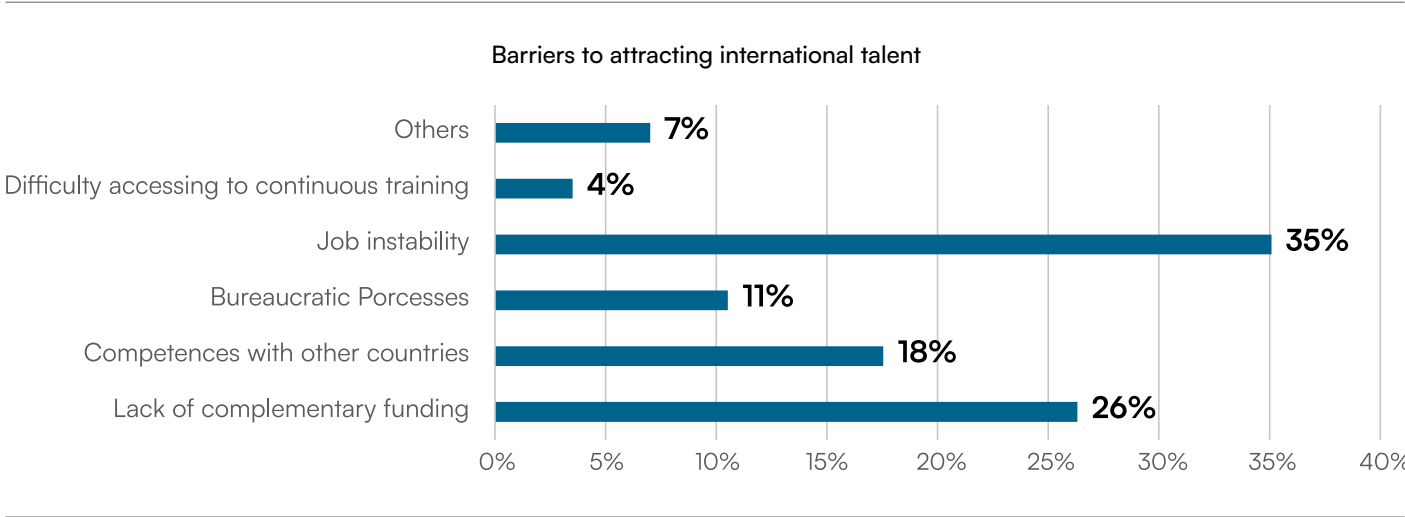
Overall, the **European Research Council (ERC)** and **Marie Skłodowska-Curie Actions (MSCA)** programmes are viewed as valuable tools to attract **international talent** and enhance the research capacity of HRIs.



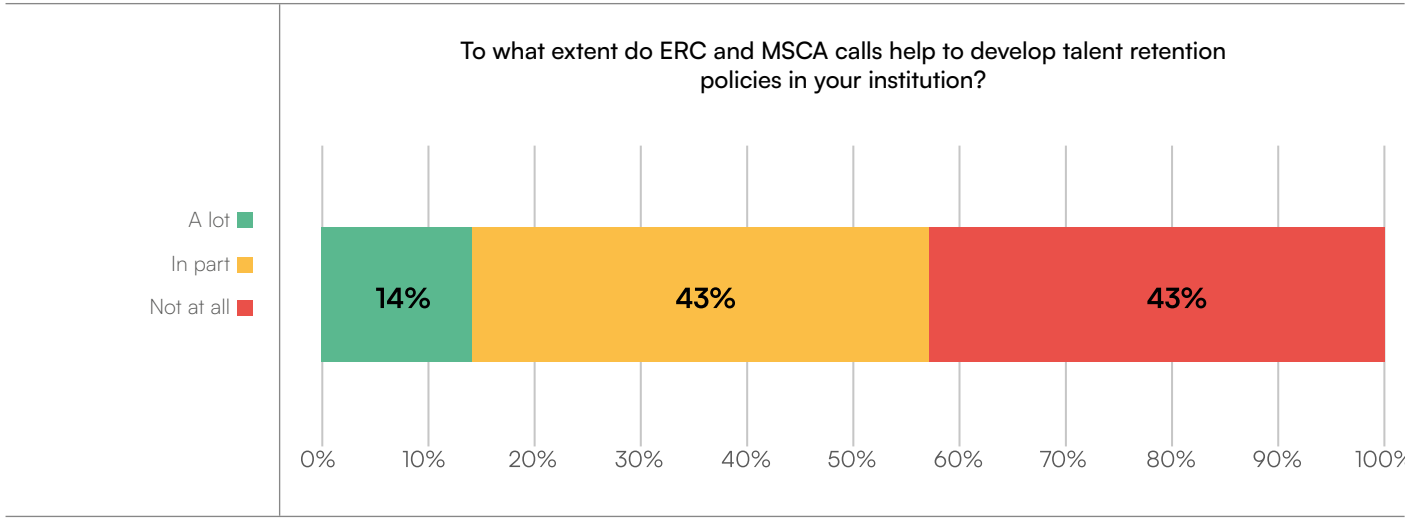
However, their highly competitive nature makes them less accessible to smaller institutions or those with limited critical mass. While the visibility and prestige of these instruments are acknowledged, they are not sufficient to ensure retention without additional support measures. In this context, respondents recommend greater promotion, administrative support, and incentives, such as job stability and integration packages.

The main **barriers to attracting and retaining talent** include:

- ▶ **Structural Limitations:** Lack of physical space in institutions; difficulty competing with universities offering more stable teaching careers; and less capacity to attract international talent compared to well-established centres.
- ▶ **Care Burden:** In clinical environments, research is often deprioritised due to heavy care responsibilities.
- ▶ **Difficulty in Researcher Stabilisation:** The absence of career continuity plans within the Spanish National Health System and limited co-financing mechanisms increases the risk of researchers migrating to industry or more structured institutions.
- ▶ **Bureaucratic and Regulatory Hurdles:** Particularly in clinical research, where administrative complexity hinders participation.



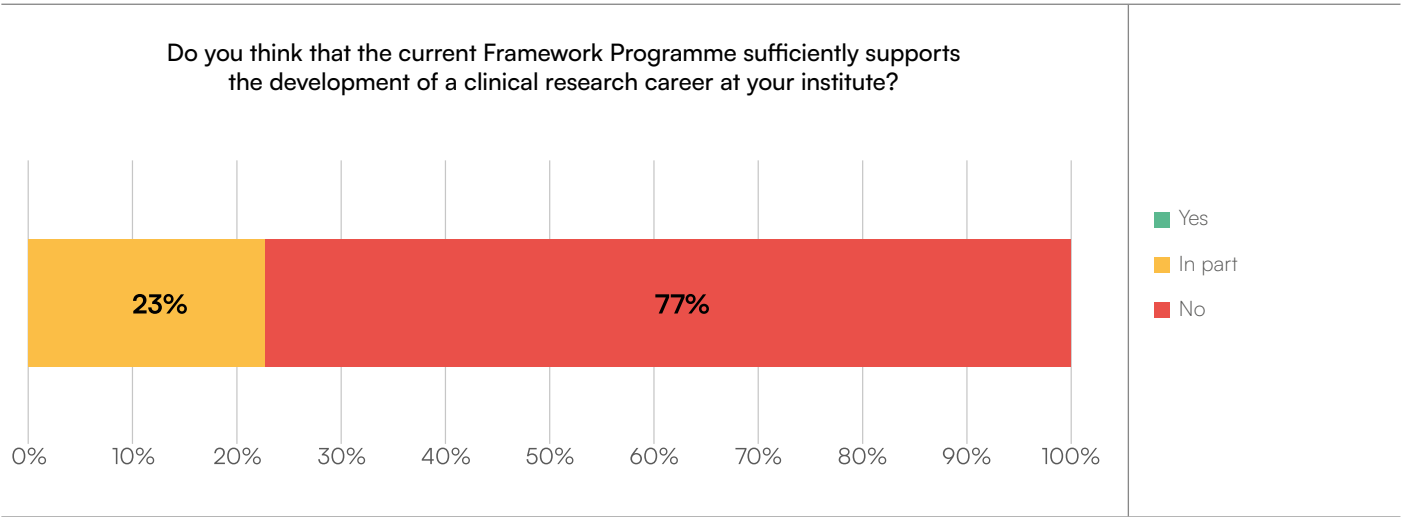
Regarding the impact of **talent retention policies**, institutions acknowledge that ERC and MSCA improve the employability and profile of researchers, but do not guarantee their long-term retention.



In this regard, it is worth highlighting the following:

- ▶ Difficulties in consolidating research careers within HRIs due to dependency on external funding, without corresponding continuity mechanisms in place.
- ▶ Job instability remains a major obstacle to retention, even when researchers obtain external funding.

Notably, 77% of respondents believe that the current Framework Programme does not provide sufficient support for the development of **clinical research careers** within their institutions, while 23% feel it offers only partial support.



Several challenges have been identified in this regard:

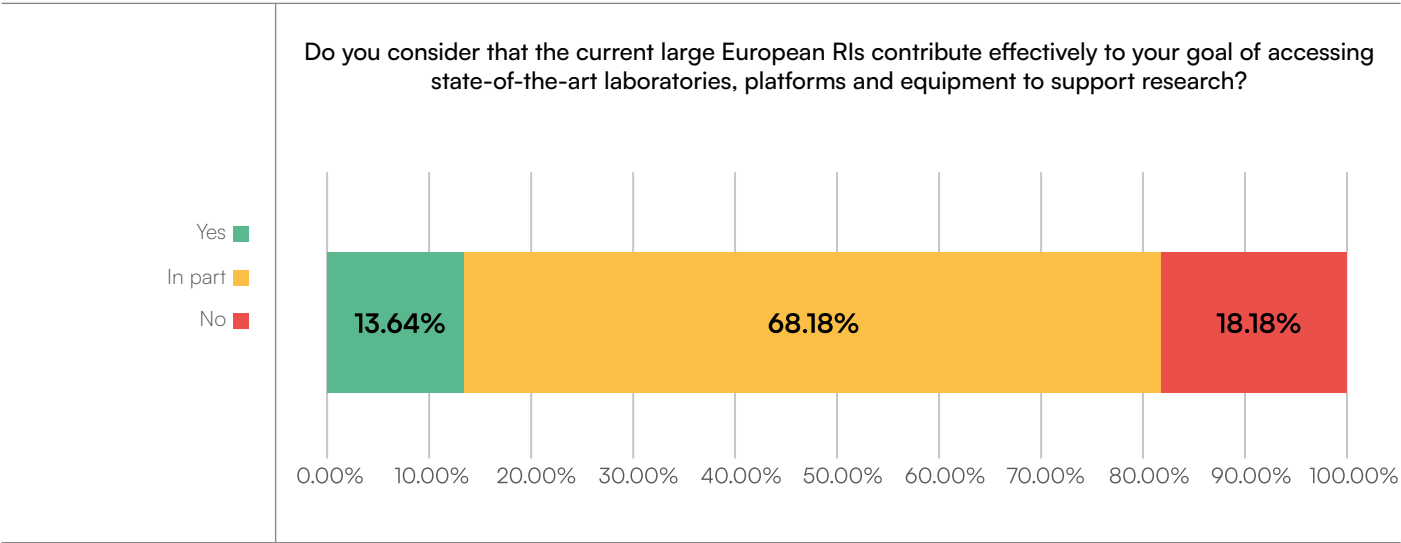
- ▶ Lack of alignment with clinical profiles. Programmes such as the ERC and MSCA do not explicitly address the needs of clinician scientists, which creates barriers to their participation in funding opportunities.
- ▶ Incompatibility between research and clinical duties. The high burden of care, combined with increasingly stringent regulatory requirements, limits the time that clinicians can dedicate to research. In addition, full-time contracts linked to European research projects often prevent the possibility of combining research and clinical practice.
- ▶ Dependence on national and regional policy frameworks. The stabilisation of clinical research staff is subject to institutional and regional regulations, which complicates long-term retention.
- ▶ Need for targeted programmes. There is a clear demand for intensification measures to reduce clinical workloads, as well as support for early-stage researchers and more flexible arrangements within European programmes.

Proposals received to improve clinical research career development focus on the following areas:

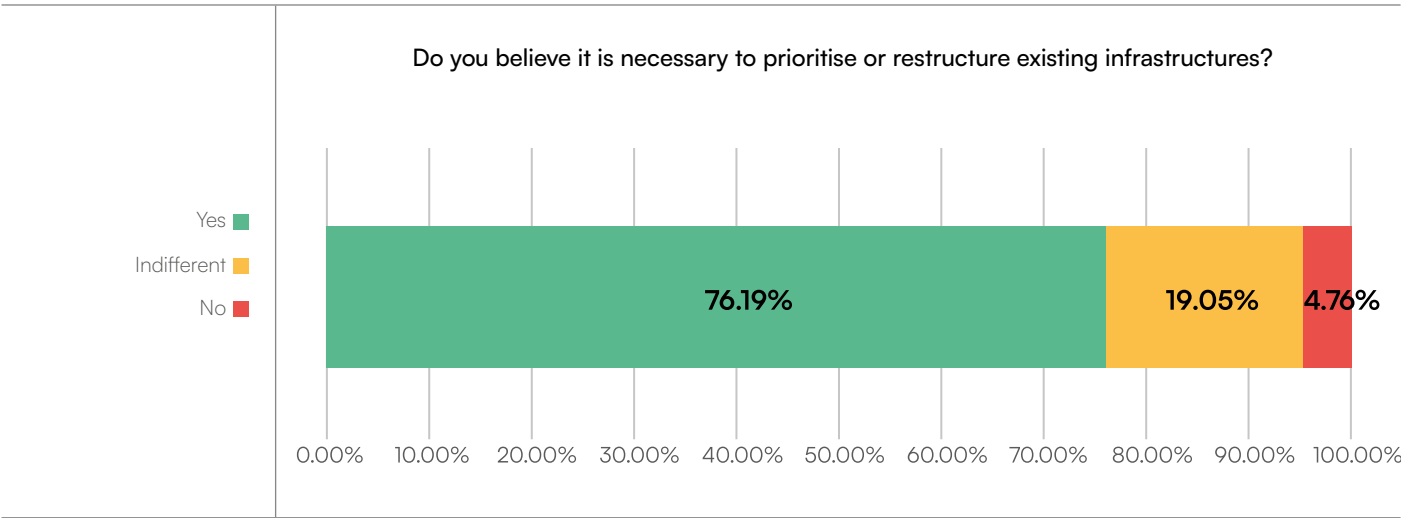
- ▶ Introducing greater flexibility into the ERC and MSCA schemes to ensure they are accessible to clinical profiles, facilitating the balance between care provision and research.
- ▶ Implementing intensification initiatives within the Spanish National Health Service to reduce the clinical burden and enable increased research engagement.
- ▶ Enhancing funding levels and job stability through European projects, by offering longer-term contracts and mechanisms for career consolidation.

Research Infrastructures

Overall, the responses from the HRIs suggest that European research infrastructures (RIs) are only partially fulfilling their objective of providing access to cutting-edge laboratories, platforms and equipment to strengthen research capacity.



Consistent with earlier findings, more than 75% of HRIs highlight the need to reorganise existing infrastructures to improve awareness, accessibility and usability among the research community. Only through such restructuring could the full potential of shared European and international resources be realised, including access to existing technical support for the use of specialised equipment, thereby maximising the impact of these infrastructures.

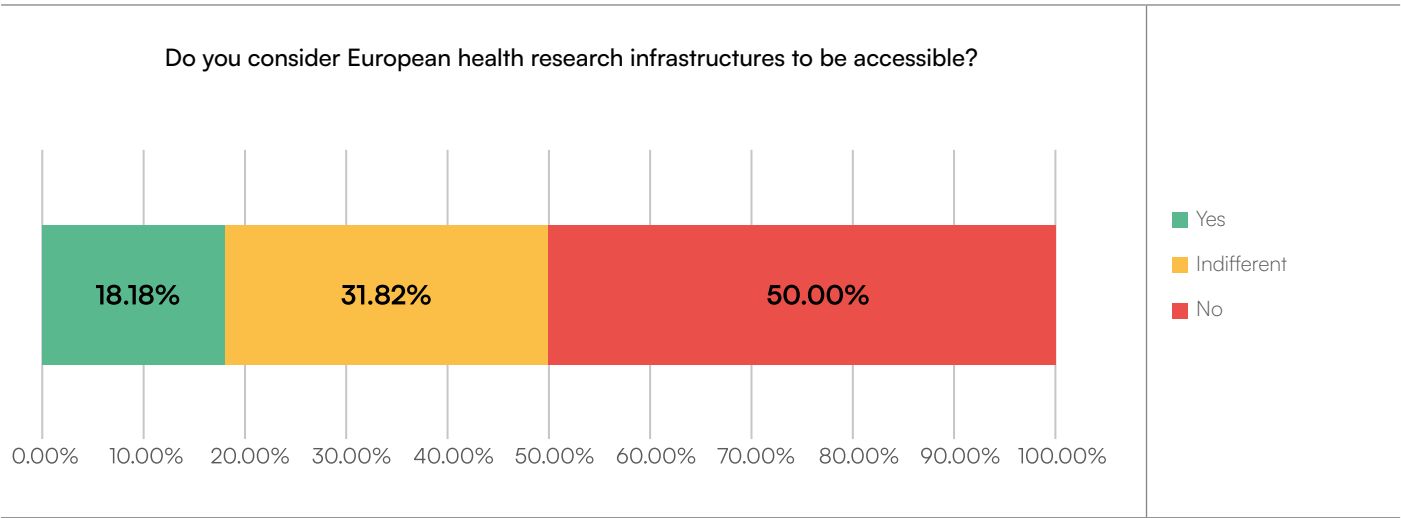


More than 75% of HRIs highlight the need to reorganise existing infrastructures

The input received underscores that the current landscape of infrastructures is fragmented and that clearer prioritisation or streamlining would be beneficial. In this regard, the following actions are proposed:

- ▶ Position infrastructures as service providers, while improving visibility around access routes and pricing structures.
- ▶ Evaluate their impact and relevance within the current R&D&I landscape.
- ▶ Implement sustainable funding models that combine public and private sources, including strategies to generate income.
- ▶ Ensure that infrastructures are interoperable and aligned with international standards to facilitate collaboration and data exchange.

In general, health-related RIs are not perceived as accessible to the broader research community. Feedback indicates that a key challenge lies in the lack of awareness of their existence and limited visibility of the calls through which services can be accessed. In parallel, further comments highlight that the administrative procedures and conditions of use are often complex and overly bureaucratic.



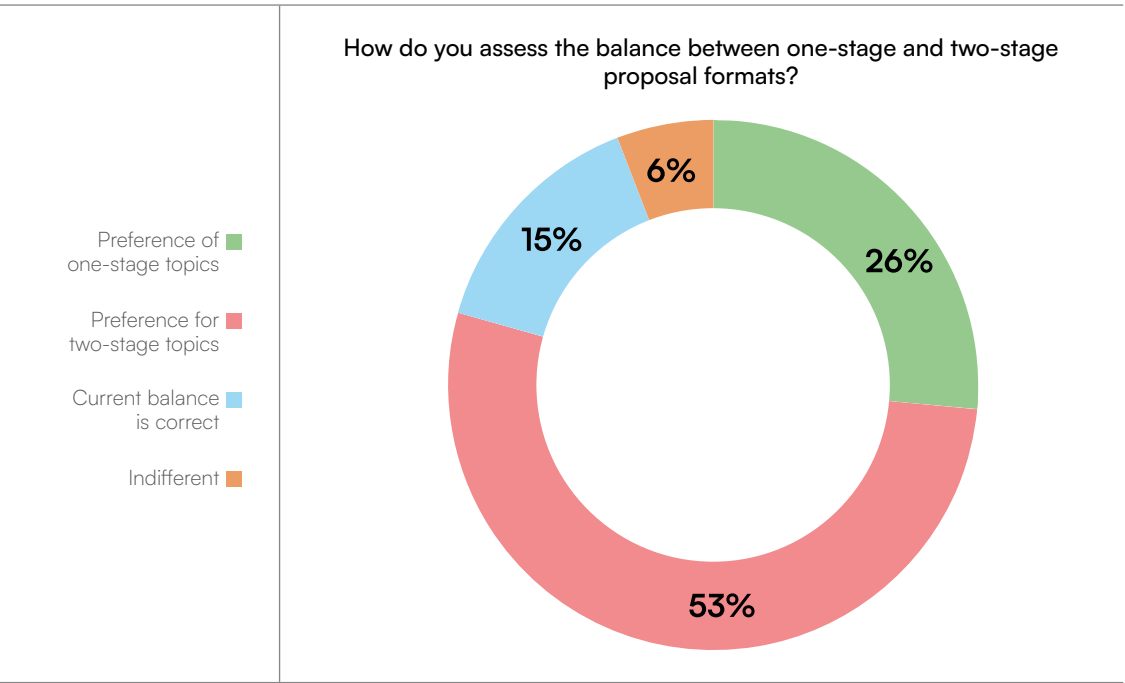


# Management Form Analysis

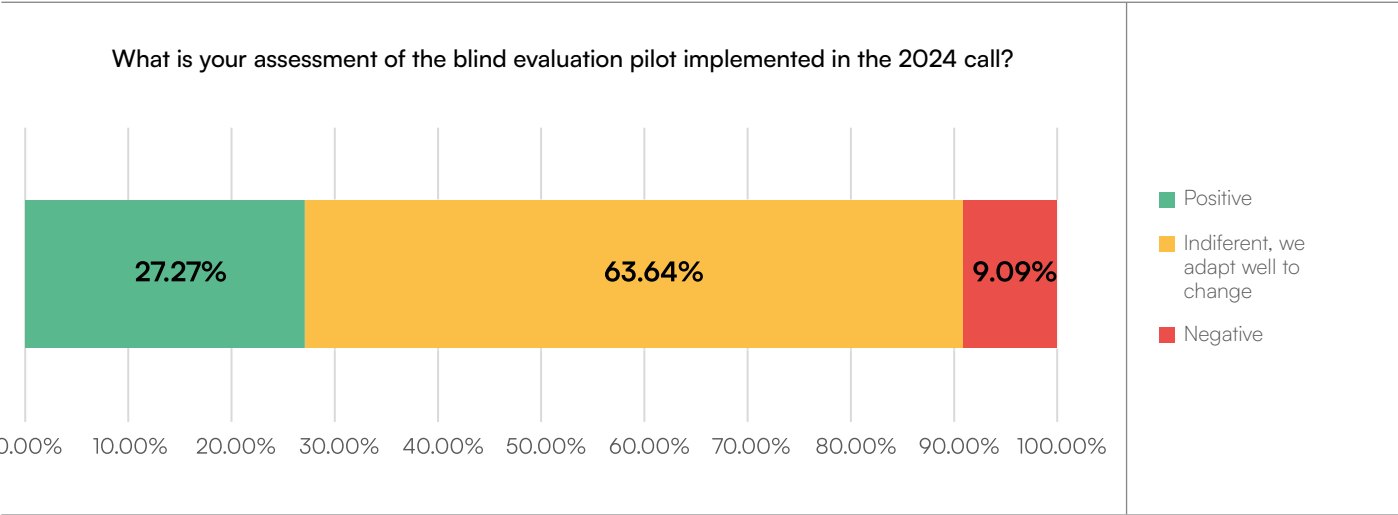
## Proposal Preparation

There is a **clear preference among HRIs for two-stage calls**. Although resolution times may be longer, this format is seen as reducing the initial workload and offering a useful checkpoint to assess whether a proposal is competitive enough to warrant further investment of time and resources.

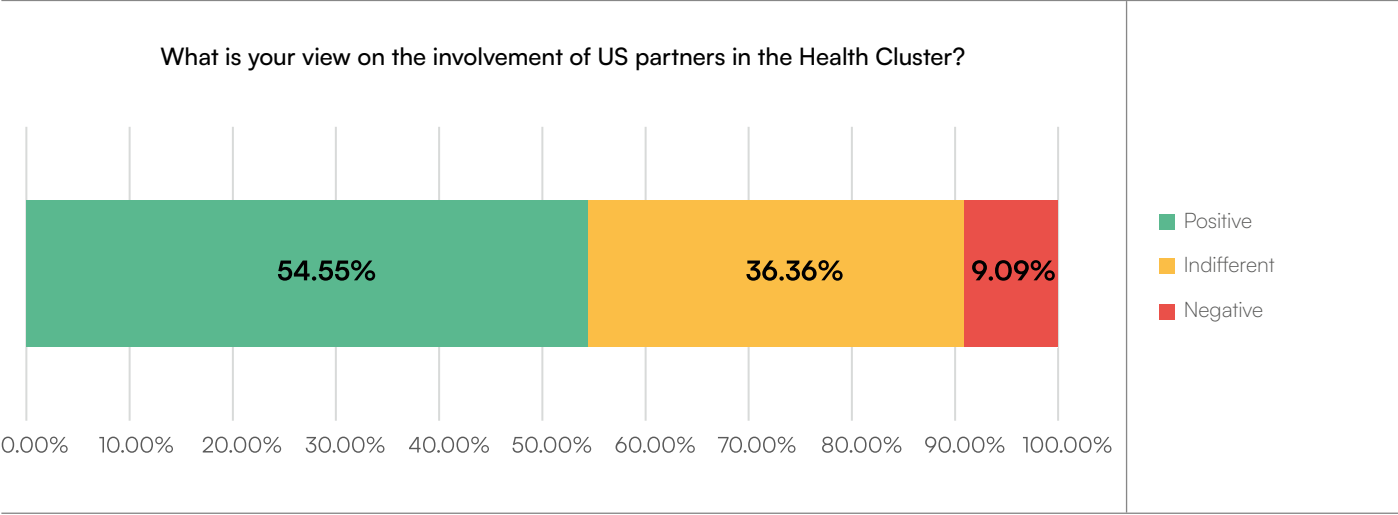
As such, two-stage calls tend to encourage greater participation from early-career researchers, clinician scientists, and others whose workloads might otherwise deter them from preparing a full proposal.



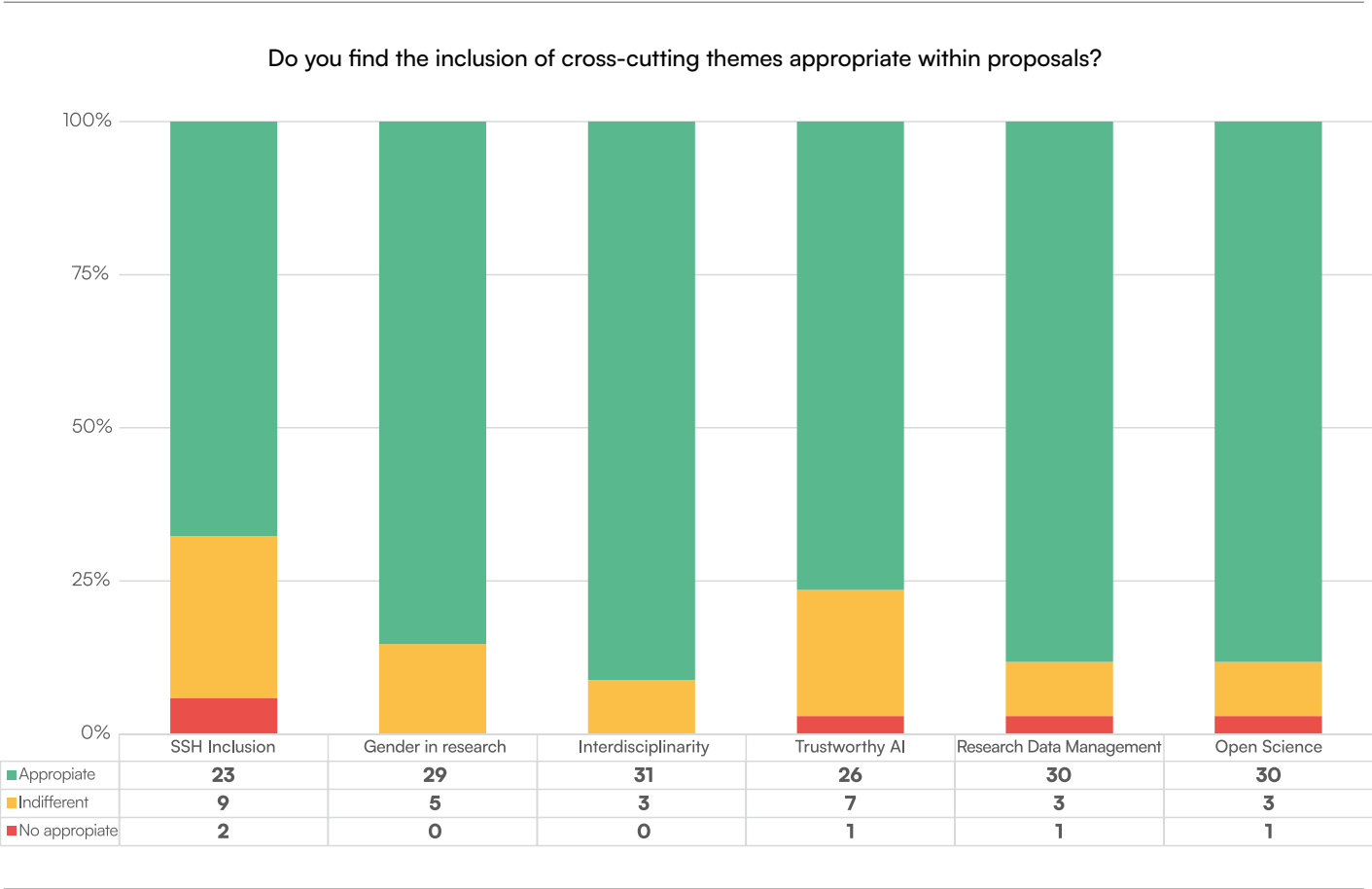
In relation to the blind evaluation pilot introduced in the 2024 call, the majority of HRIs reported a smooth adaptation to this shift in evaluation rules. Nevertheless, a common view is that this format limits the ability to highlight the consortium’s track record, which in turn may affect how excellence is perceived in the evaluation process.



Regarding international collaboration, **the participation of US partners is generally viewed positively**, with only 9% of respondents expressing a negative opinion. Respondents note that US organisations often contribute valuable expertise and resources. However, HRIs acknowledge the challenges involved in involving these partners, which include differences in healthcare system structures, inclusivity approaches, and intellectual property frameworks.

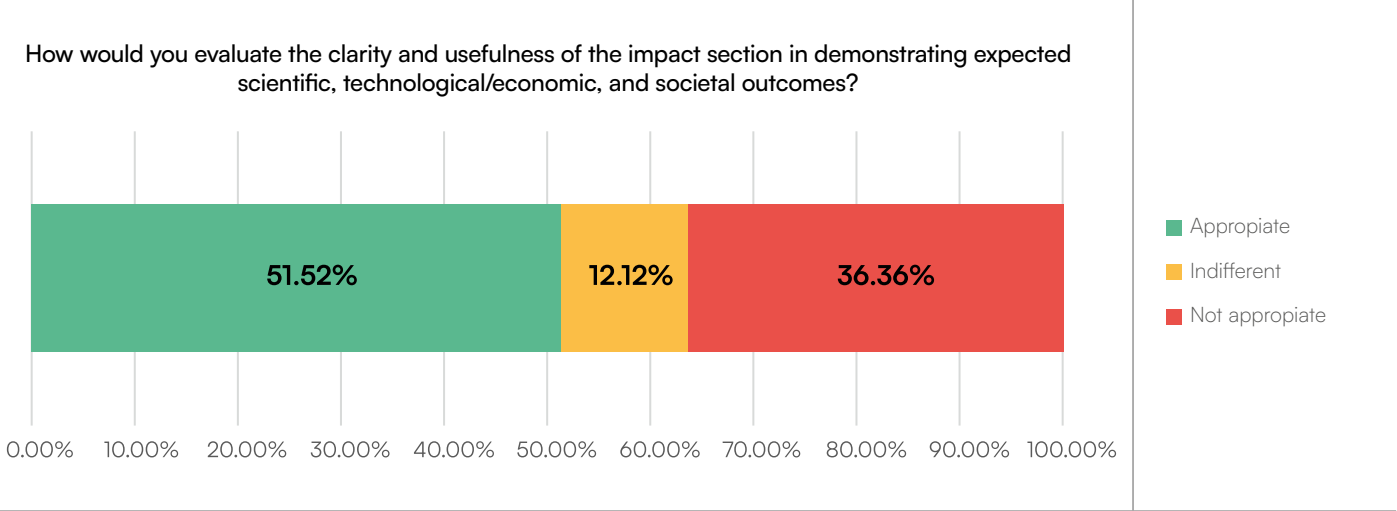


In terms of **cross-cutting issues**, feedback gathered on this aspect complements the insights obtained through the strategic questionnaire. From a project management perspective, there is broad agreement that cross-cutting issues are highly relevant to research and should be integrated into proposals. Nonetheless, respondents also stress that doing so effectively, and in a way that strengthens competitiveness, demands a level of specialisation that many research groups or institutions may currently lack. There is therefore a call for increased guidance and training from the European Commission, more structured support during project implementation, and tools to facilitate the identification of experienced partners in these thematic areas.



The new **“pathway towards impact”** section introduced in the Horizon Europe proposal templates has generally been welcomed by both research and management professionals, with 51% of respondents considering the new format to be clear and appropriate.

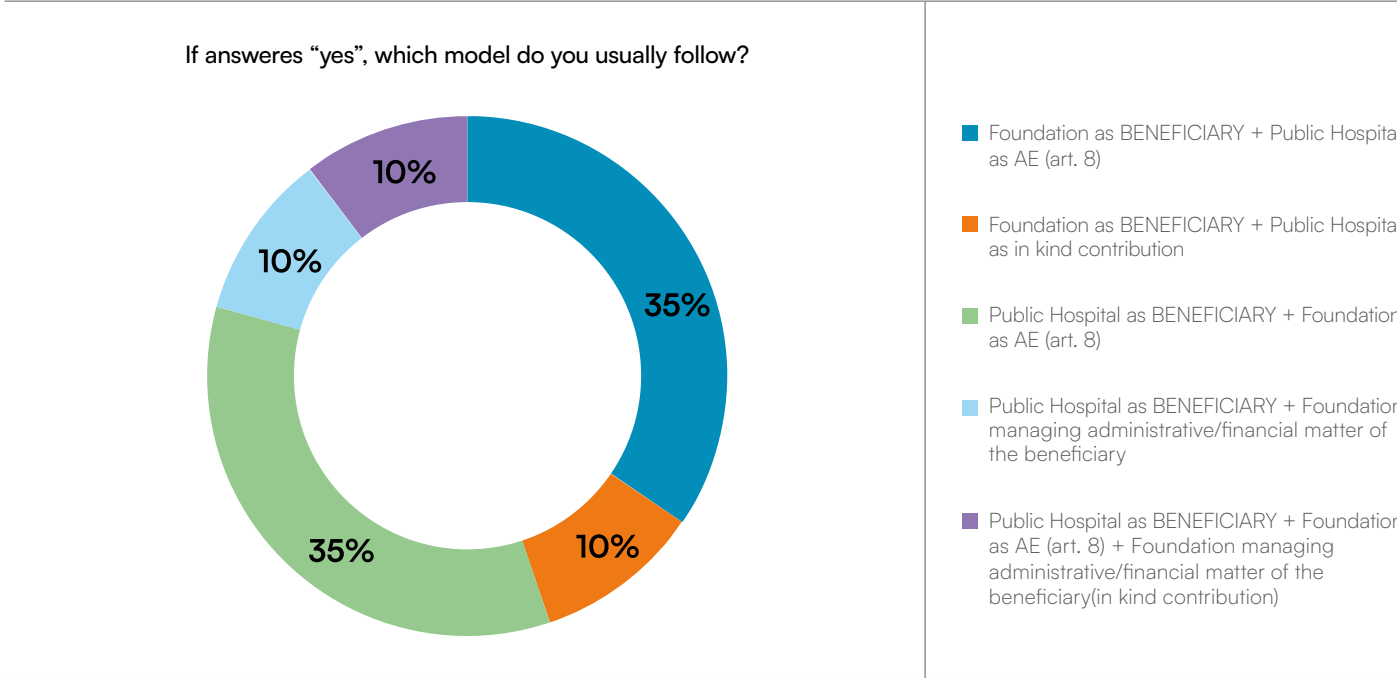
However, there are still difficulties reported in distinguishing between impact, outcomes and outputs, as well as in tailoring and quantifying the concrete effects of the project, especially given the long-term nature of many research initiatives. Respondents also point to the need for additional mechanisms to ensure that project results lead to sustained societal impact.



Third Parties

A large majority of HRIs (94%) make use of the third-party mechanisms provided under Horizon Europe. The most common approach is to designate either the hospital foundation or the regional health service as an Affiliated Entity (35% for each).

Only two HRIs report not using third-party structures, one due to lack of participation in Horizon Europe projects to date, and the other citing limited use so far but anticipating future relevance.

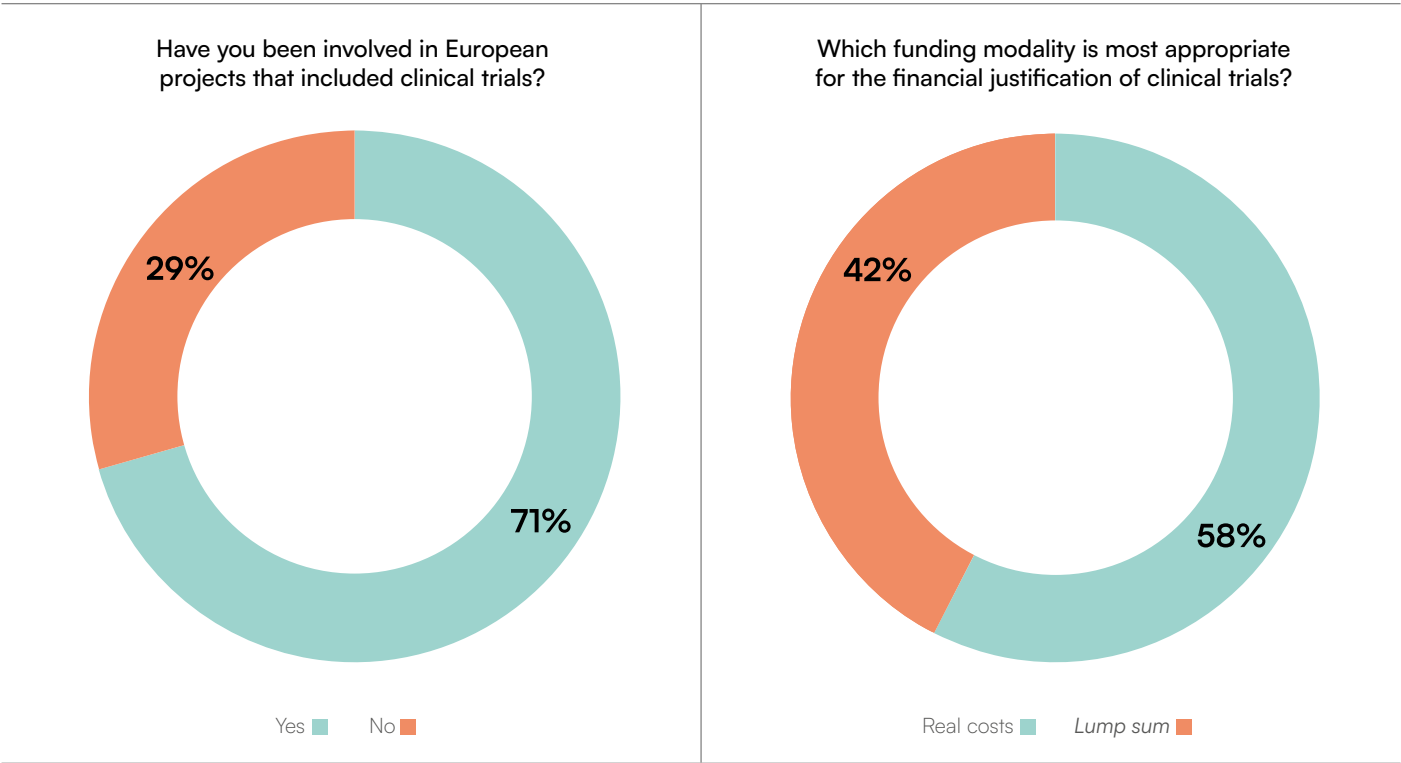


Despite the updates to third-party rules in Horizon Europe compared to previous Framework Programmes, such as H2020, most respondents either report no significant impact (18%) or describe themselves as having adapted well to the changes (40%).

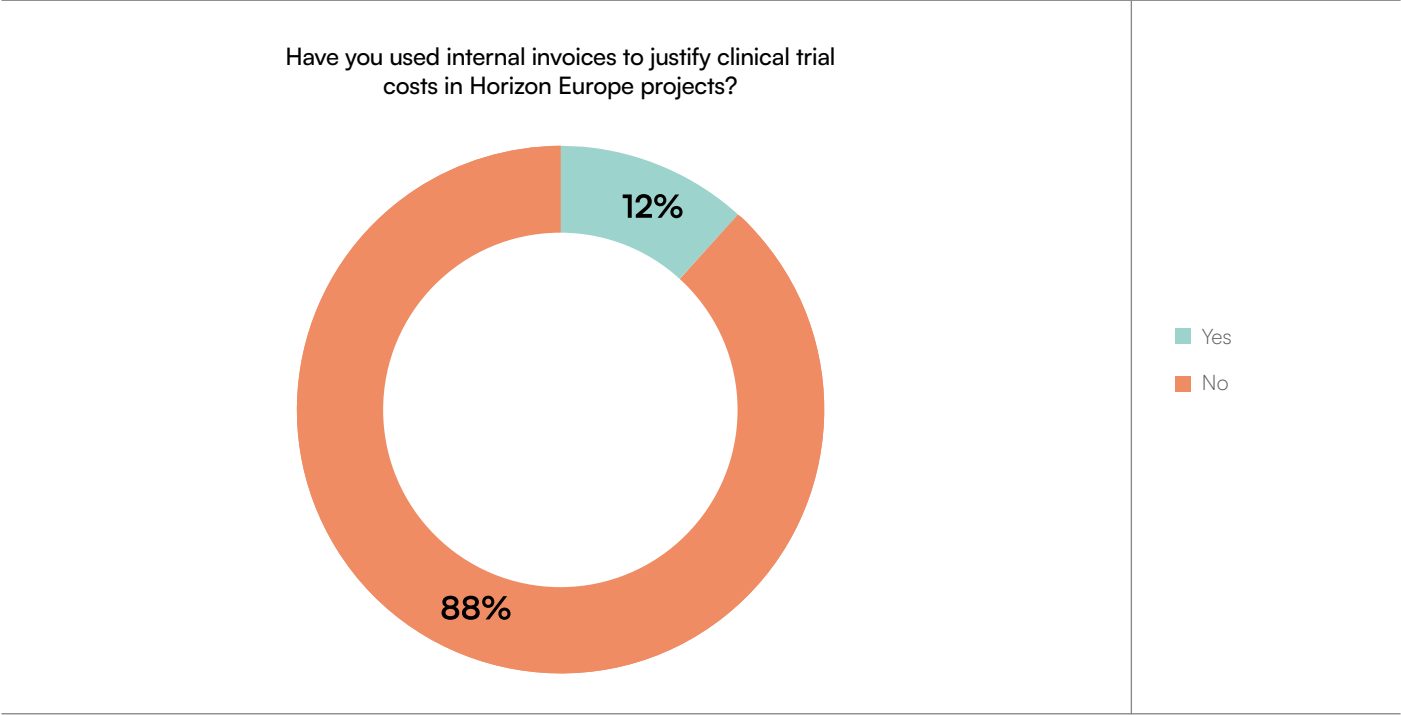
Some HRIs point to variability in implementation across institutions and call for greater national-level alignment or consensus on preferred models of participation. Others suggest that having more standardised national guidelines would facilitate communication with coordinating institutions and Project Officers at the European level.

Clinical Trials

71% of responding HRIs report having participated in European projects involving the conduct of clinical trials (CTs). When asked about the most appropriate method for financial justification of CTs, a slight preference emerges for actual cost reporting (58%) over the Lump Sum model (42%).



Drilling further into this issue, only four entities have made use of the “internal invoices” cost category in their financial reporting for CTs. The majority of HRIs indicate that they have not used this option, primarily due to the absence of an internal cost accounting system.



The “internal invoices” category, introduced as a simplification measure under Horizon 2020, enables entities to report internal prices commonly applied between departments within the same organisation. Many HRIs without analytical accounting systems typically rely on the official public pricing frameworks associated with the Spanish National Health Service. These prices, approved by the Regional Health Ministries of each Autonomous Community, are the standard outside the context of European-funded projects. However, such public prices are not compliant with Horizon Europe eligibility rules, as they are not established at the level of the individual entity and are not auditable. As a result, many HRIs are forced to justify clinical trial costs primarily through reporting of staff hours, a more cumbersome and error-prone approach.

To simplify financial reporting for CTs, some HRIs suggest the introduction of a single model across the Framework Programme based on unit costs. Like the model used in MSCA projects, this would involve defining a unit rate per patient recruited (by country) in the call for proposals. Such a mechanism would allow real costs incurred by the centre to be covered in a more streamlined way, potentially eliminating the need for certification or audit of actual costs.

Other proposals call for greater flexibility in cost certification processes. These include allowing the use of publicly approved price lists and enabling cost certification at regional or national levels, rather than requiring it to be carried out at the level of individual institutions.

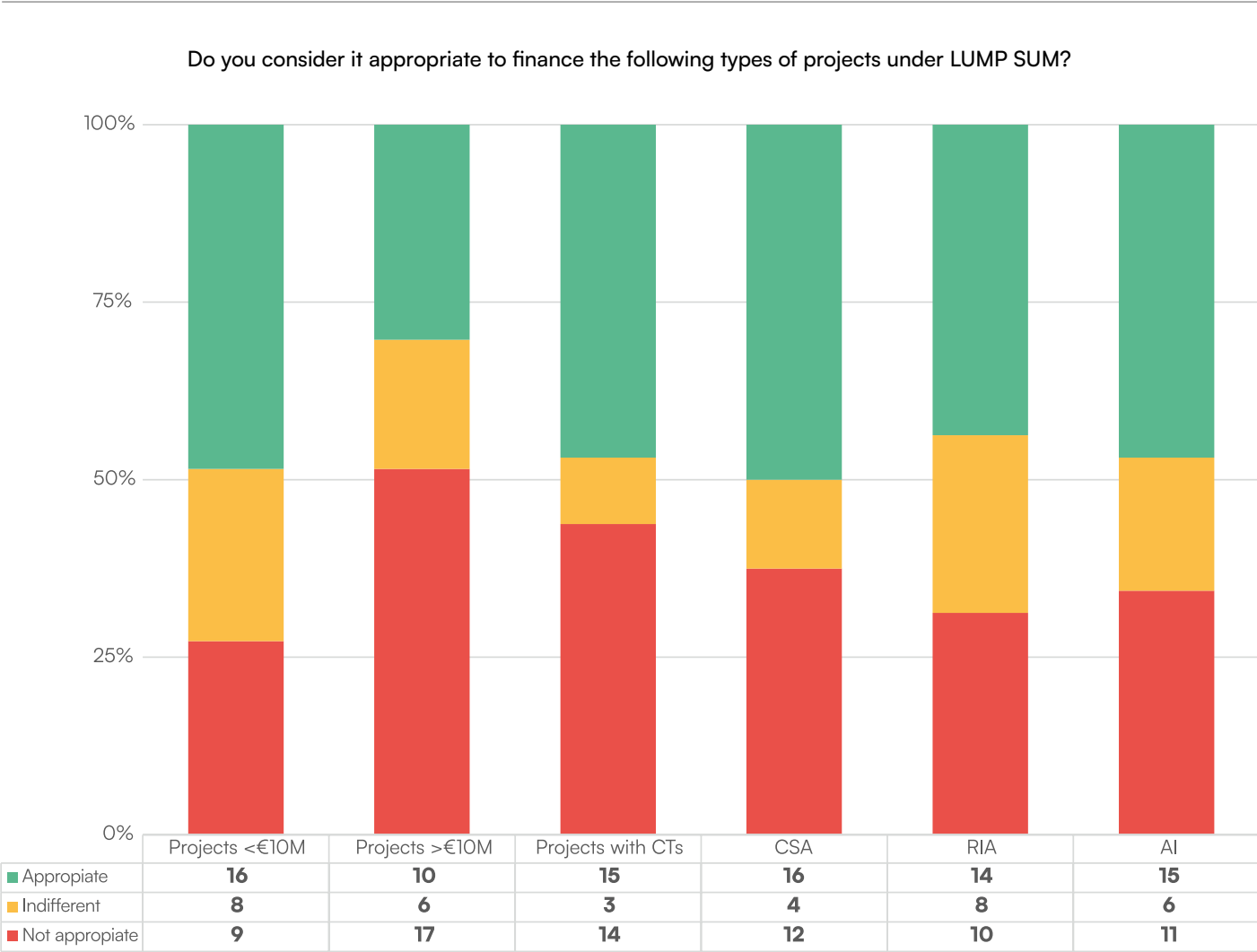




Lump Sum

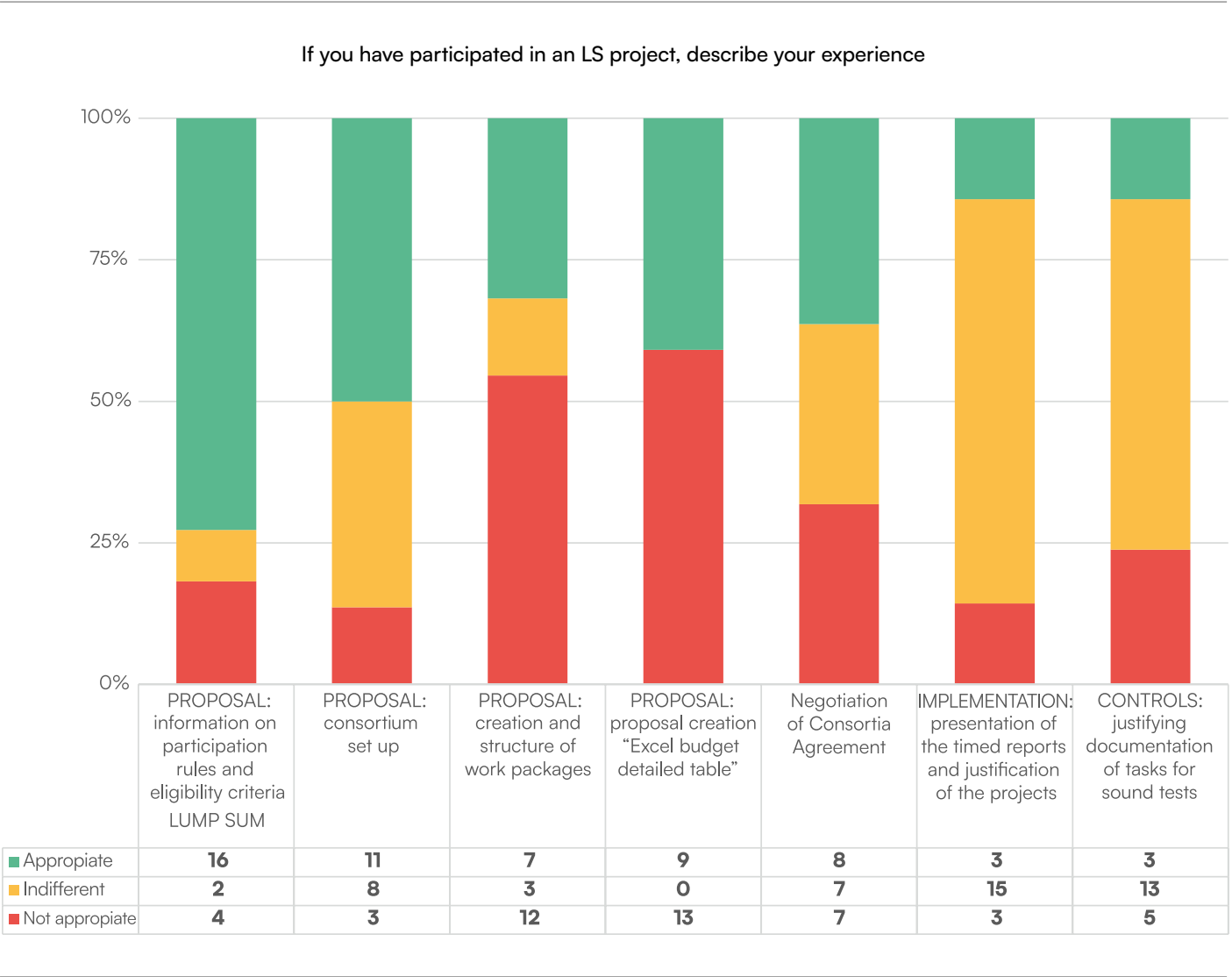
Given the growing adoption of the Lump Sum (LS) funding model under the Framework Programme, HRIs generally consider this approach more appropriate for projects with a total budget of less than €10 million. For larger projects exceeding this threshold, the LS model is viewed as less suitable. When considering the type of projects best suited for LS funding (CSA, RIA, or AI) opinions are divided, with no clear consensus among respondents.

One recurring concern relates to how clinical trials should be integrated into LS-funded projects. HRIs raise questions such as whether CTs should be organised within a single work package or distributed across several. There is also uncertainty about how under-recruitment, i.e. failing to reach 100% of the expected patient enrolment, will impact financial justification under the LS model.



Experience as a Partner

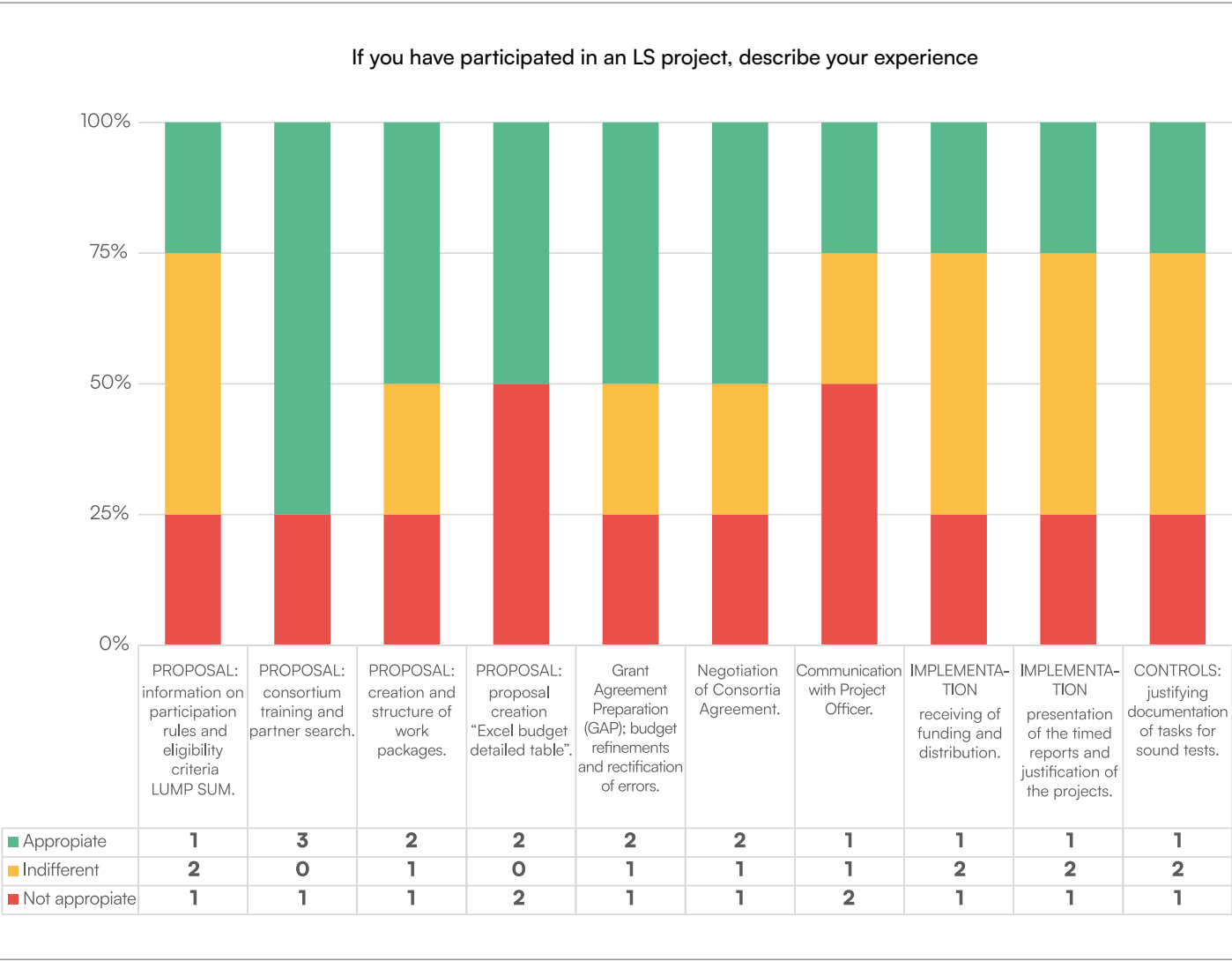
65% of HRIs (22 responses) report having participated as partners in Lump Sum (LS) proposals or projects. Their experience, as reflected in the graph, highlights that the process of structuring the project and preparing the budget was not generally perceived as positive. There remains significant uncertainty regarding project implementation and control mechanisms.



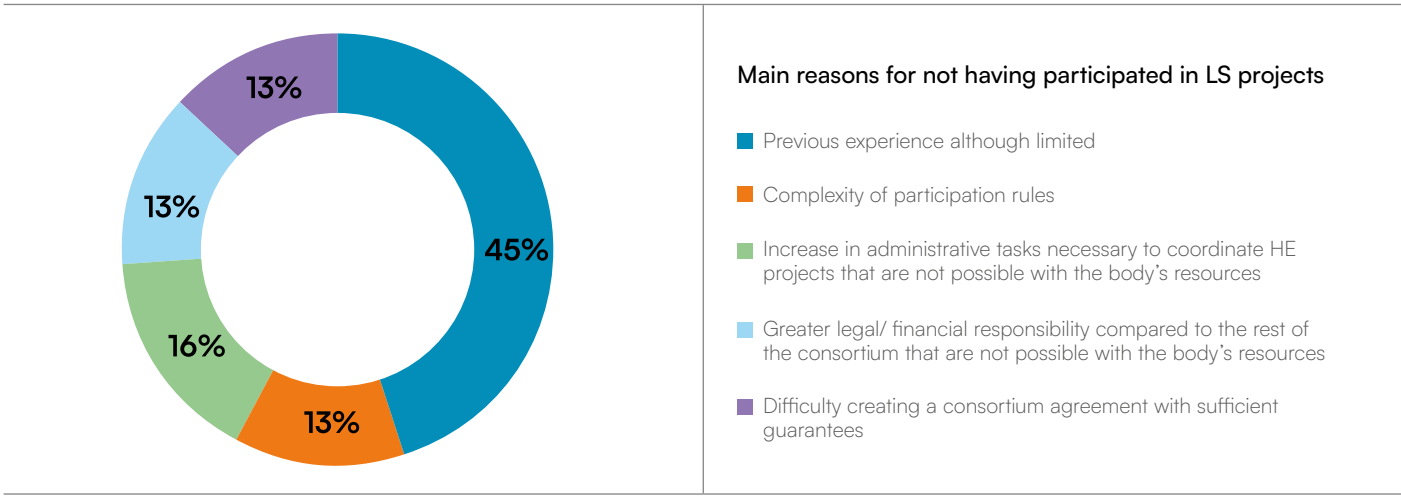
Among organisations that have not yet taken part in LS proposals or projects, the main reason cited is that the topics in which they were involved were not funded under the LS model.

Experience as a Coordinator

Only three HRIs indicate that they have taken on the role of coordinator in an LS project. Their experience is summarised as follows:

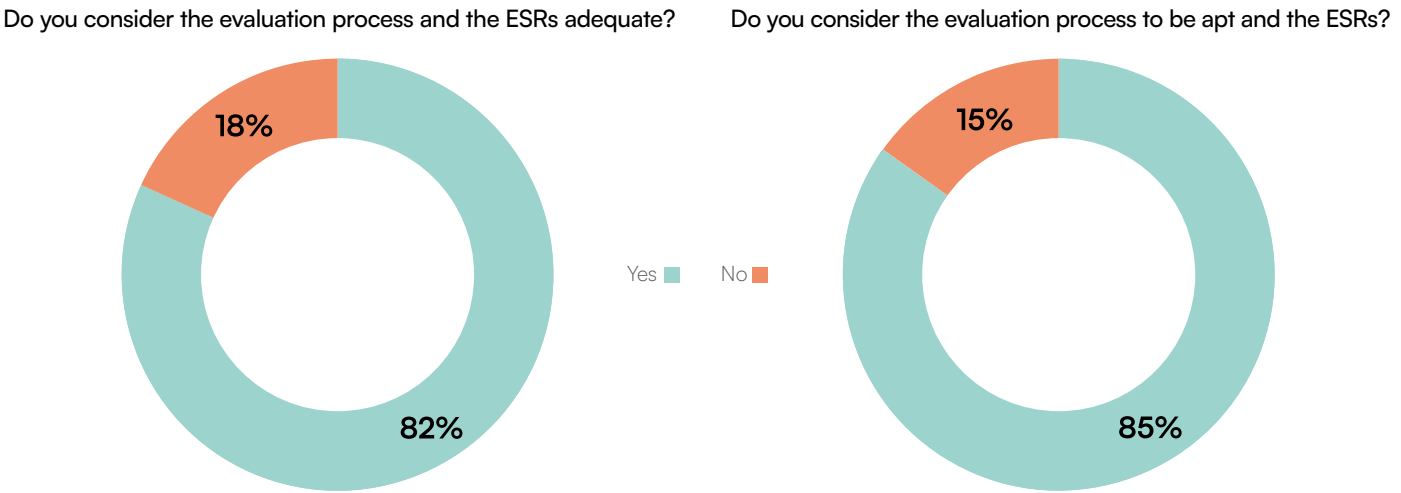


The main reason given for not coordinating LS proposals is the significantly increased workload required to manage these types of projects, which exceeds the institutional capacity of many HRIs.



Evaluation

Overall, HRIs express satisfaction with the evaluation process, including the evaluation reports (ESRs) and the application of tie-breaking criteria.



Among the comments received, several HRIs suggest that ESRs could be made more specific and include constructive feedback from evaluators to help improve future proposals.

Additionally, some respondents propose a more precise application of the “gender balance” criterion, for example, applying it to WP leaders rather than broadly to the researchers’ table.





