Research at Institute of Health Carlos III: A vision for the next **Framework Programme**

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES
Instituto de Salud Carlos III
Ciencia y Salud 1986-2026
2001-2026 FECYT INNOVACIÓN
oficina europea

Research at Institute of Health Carlos III: A vision for the next **Framework Programme**

NIPO pdf English text: 156250467
NIPO paper: 156250451

Editing, coordination and content development:
Instituto de Salud Carlos III (ISCIII).

Thanks to the Spanish Foundation
for Science and Technology (FECYT) for
collaboration in the preparation of this report.

Thanks to the ISCIII structures and the
intramural centres for their participation and
contribution to the responses.

Follow us at


@HealthISCIII


linkedin.com/company/instituto-de-salud-carlos-iii/


youtube.com/c/InstitutodeSaludCarlosIII


instagram.com/isciiisalud/


bsky.app/profile/isciiisalud.bsky.social

www.isciii.es

This report has been prepared by
the **Subdirectorate General for International Research Programmes and Institutional Relations of the ISCIII and the** of the ISCIII and the **European Office** of the FECYT

Contents

Introduction

The Carlos III Health Institute (ISCIII in Spanish) is a Public Research Body (PRB) created to perform direct scientific and technical research activities, technological service provision activities, and those other activities of a complementary nature attributed to the body, as necessary for the appropriate scientific and technological progress of society. In addition, its core competence, which is reflected in the Spanish Science, Technology and Innovation System (SECTI in Spanish) and in the National Health System (NHS), is to carry out activities to finance scientific and technical research. The ISCIII, in its capacity as a PRB, is configured as a fundamental instrument of the General State Administration for the promotion of biomedical research.

The ISCIII has a dynamic network of institutes, units and national research centres specialising in areas of knowledge that cover a wide range of research areas in biomedicine and health.

The scientific community of the ISCIII, distributed in several of its own centres and in foundations and consortia linked to it, is committed to excellence in biomedical research and innovation. From the study of infectious diseases to epidemiological research and health promotion, our centres play a fundamental role in the advancement of medical research and the improvement of health, and are national and international benchmarks.

The ISCIII has **14 centres and units of its own:**

cne
National Centre for Epidemiology

cnm
National Centre for Microbiology

cnsa
National Centre for Environmental Health

cnmt
National Centre for Tropical Medicine

iier
Rare Disease Research Institute

aets
Health Technology Assessment Agency

bncs
National Library of Health Sciences

enmt
National School of Occupational Medicine

ens
National School of Health

ufiec
Chronic Diseases Functional Research Unit

Telemedicine and

uites
e-Health Research Unit

investén-isciii
Health Care and Services Research Unit

lcd
Anti-Doping Laboratory

uccts
Central Scientific-Technical Units

And **4 linked centres:**

cnio
Spanish National Cancer Research Centre (CNIO)

cien
National Centre for Research in Neurological Diseases (CIEN)

cnic
National Centre for Cardiovascular Research (CNIC)

ciber
Centre for Biomedical Research Network (CIBER)

The aim of this report is to understand the vision and positioning of the ISCIII's scientific community with regard to the changes in the future European Union Framework Programme for Research and Innovation (FP10), as well as the priority research and innovation areas identified. It also seeks to highlight the opportunities and strengths of research at the ISCIII and to point out the challenges it faces. In this way, it aims to provide the ISCIII's vision of the direction the future Framework Programme should take.

This report has benefited from the contribution of the scientific community of the ISCIII, from the directors and researchers of its own and related centres to the staff managing European projects.

Objective and methodology

32 responses to the strategic form and 11 responses to the management form have been received.

During the second and third quarter of 2025, the ISCIII designed a consultation consisting of two questionnaires structured around closed questions, scaled questions and multiple choice questions, also incorporating open questions to gather the comments, experiences and points of view of the centres regarding the next FP10.

Firstly, a **strategic form** was drawn up, addressed to the directors of centres and units, and to the rest of the ISCIII scientific community, to gather their opinion. It included questions aimed at strategic aspects of the current and future Framework Programme for Research and Innovation.

Secondly, a **management form** was drawn up and sent to the European project managers of the ISCIII centres. It incorporated questions from a more practical perspective on the application of the rules of participation in the European Union's Framework Programme for Research and Innovation, as well as aspects of project management itself.

32 responses to the strategic form and 11 responses to the management form have been received.

During September 2025, the data presented in this report were collected and analysed in four sections:

- Participation of the ISCIII and its centres in the Horizon Europe Framework Programme in recent years.
- Analysis of the results of the strategic form.
- Analysis of the results of the management form.
- Conclusions, recommendations and key messages for the future.

Participation of the ISCIII in the Horizon Europe Framework Programme

To date, the ISCIII participates or has participated in 29 Horizon Europe projects, distributed as follows:

PILLAR	NO. OF PROJECTS	DESCRIPTION
I. Excellent Science	8	**Marie Sklodowska-Curie Actions** - 5 MSCA DN projects **Research Infrastructures** - 3 projects
II. Global Challenges and European Industrial Competitiveness	20	**Health Cluster** - 18 projects **Mission Cancer** - 1 project **Climate, Energy and Mobility Cluster** - 1 project
III. Innovative Europe	1	**EIC Pathfinder Open** - 1 project

Participation of the centres linked to the ISCIII in Horizon Europe

In addition to the ISCIII as an actor in Horizon Europe, we wanted to capture the reality of its associated centres as respondents in the current framework programme, as they play a fundamental role in the advancement of biomedical research and the improvement of health at an international level.

CENTRE	No. OF PROJECTS	DESCRIPTION	
CNIO	14	**Pillar I** - 10 projects **Pillar II - Health Cluster** - 4 projects	
CIEN	1	**Pillar II - Health Cluster** - 1 project	
CNIC	11	**Pillar I** - 8 projects **Pillar II - Health Cluster** - 1 project **Pillar III** - 2 projects	
CIBER	15	**CIBERCV**	**Pillar II - Health Cluster - IHI** - 1 project
		CIBER-BBN	**Pillar I** - 3 projects **Pillar II** - 2 projects **Pillar III** - 2 projects
		CIBERONC	**Pillar II** - 1 project
		CIBEROBN	**Pillar II** - 3 projects
		CIBERER	**Pillar II** - 1 project
		CYBERES	**Pillar I** - 1 project
		CIBERESP	**Pillar II** - 1 project

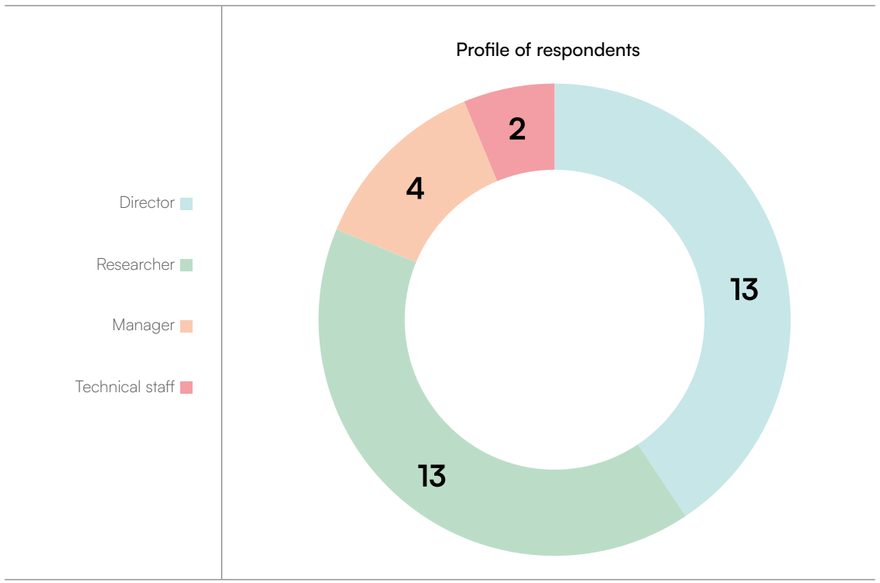
Strategic form.

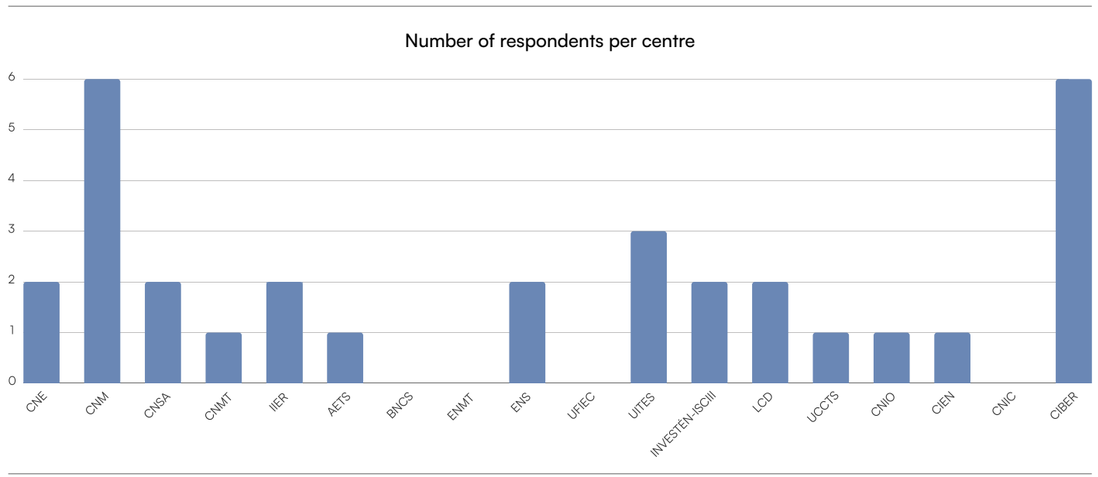
Positioning for Horizon Europe and the future framework programme for research and innovation of the European Union (FP10)

Profile of participants

The participation of ISCIII centres and related units has been extensive. Almost all ISCIII centres or units have participated.

With regard to the profile of the respondents, **41%** of the responses came from heads of centres, **41%** from researchers, **13%** from managers and **6%** from technical staff.





Framework Programme: Horizon Europe

Horizon Europe (HE) is the European Union's (EU) flagship Framework Programme for Research and Innovation (R&I) for the period 2021-2027, with an unprecedented budget of €95.517 billion. This programme not only seeks to consolidate Europe's leadership in science and technology, but also strategically aligns with the UN Sustainable Development Goals (SDGs) and the Paris Agreement, reflecting the EU's commitment to a sustainable and equitable future.

In addition, HE actively promotes international collaboration, recognising the importance of tackling global challenges together.

Specific attention is given to inclusion and gender equality in research and innovation, ensuring that Europe's diverse talent contributes fully to scientific and technological progress.

The **primary objective** of HE is to maximise the scientific, technological, economic and societal impact of EU investments in R&I, thereby strengthening its scientific and technological bases and fostering the competitiveness of all Member States (MSs).

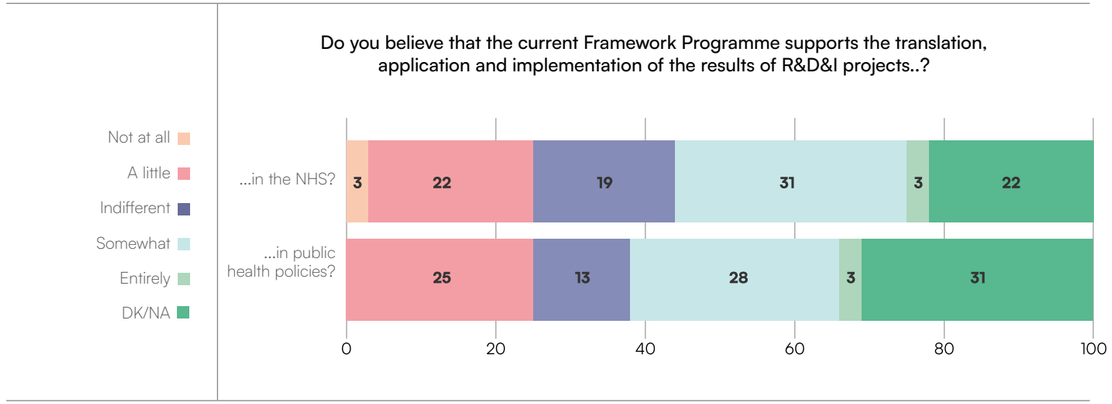
HE is expected to generate a significant **impact** on the European economy and society, including the creation of highly skilled jobs, increasing Gross Domestic Product (GDP), making progress in the fight against climate change and other global challenges. And finally, strengthening Europe's leadership in science and technology.

Horizon Europe **is structured in three interconnected pillars** , each with specific objectives and focus areas, designed to drive excellence in all aspects of research and innovation.

Horizon Europe and Translational and Clinical Research

According to the results obtained in relation to whether the **current Framework Programme, HE, supports the translation, application and implementation of the results of R&D&I projects** in the NHS, opinion is divided. **25%** of respondents consider the Framework Programme provides this support **poorly or not at all**, arguing that implementation in clinical practice remains limited and that there are regulatory barriers, a lack of coordination with national health systems, and little connection between research and care innovation. Although **34%** consider that it supports these tasks to a **large extent** and that the Framework Programme has promoted projects with an impact on the NHS, they continue to identify as **barriers** that this transfer of results requires greater specific support, especially in areas of healthcare organisation, quality and patient safety, and that there should be complementary national financial support.

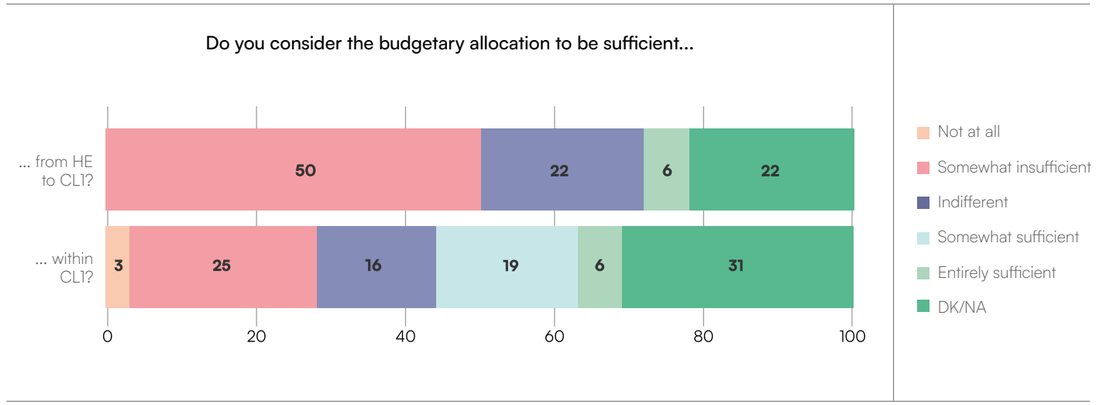
Regarding the support provided by the **current Framework Programme for the translation, application and implementation of the results of R&D&I projects into public policy,** opinion is once again divided. **25%** of respondents give **little or no** support, considering R&D and innovation and public policy to be generally very different fields, resulting in a large time lag in terms of applying the results and putting them into practice, and that the Framework Programme is very restricted to public health policies rather than other types of policies. However, **31%** of respondents **largely** support this, as many of the European projects include political representatives in their governing bodies who help define priorities and their results are used to define regulations. In Spain, this policy impact is also considered to be more limited due to the lack of coordination and the internal bureaucracy of the health system.



HE Health Cluster

Currently, the **HE Health Cluster (Pillar II) encompasses the Partnerships, the Cancer Mission and the Work Programme, representing 8.6% of the total budget of the Framework Programme** (€8.246 billion of the total €95.517 billion). **50%** of those surveyed considered the budgetary contribution for all the programmes encompassed by the Health Cluster to be **inadequate**, considering it insufficient in the face of the challenges facing Health in Europe and those coming in the future and the fundamental role of biomedicine. In general terms, respondents considered **appropriate percentage** of the total Framework Programme budget devoted to health **should be in the range of 10-15%**.

The €8.246 billion euros of the Health Cluster (CL1) are distributed as follows: 50% for partnerships, 10% for the Cancer Mission and 40% for the Work Programme calls for proposals. Opinion is divided on this distribution. 28% **do not** consider it **adequate** and, in general, propose to lower the percentage dedicated to Partnerships by 10-15% and to increase it for the calls for proposals of the Work Programme, while keeping the percentage dedicated to the Cancer Mission more or less the same. They argue that the partnerships focus on very specific topics and limit the funding of the Work Programme to accommodate other health-focused subjects that are not covered by Mission Cancer or the partnerships. **25%** consider this distribution **appropriate**.



Principal challenges facing the ISCIII in the next 7 years

The principal challenge, identified by 44% of respondents, lies in the management of **human resources**. A need for more qualified and stable staff is identified. This challenge is compounded by forthcoming retirements, difficulties in retaining talent and limited availability of staff in both research and management. According to the ISCIII centres, this situation poses challenges for maintaining the sustainability of current activities and, at the same time, reinforces the importance of strengthening capacity for the development and promotion of the institute.

Secondly, 31% of the respondents consider that the other challenge facing the ISCIII is to drive translational and clinical research, and for this to have a real impact on public health actions and policies. It is considered that the ISCIII should preferably promote translational and clinical research in support of the NHS, doing so with a strategic vision, exercising leadership and focusing its efforts on effective **innovation-oriented** translation.

It also identifies a number of other challenges that the ISCIII could potentially face in the coming years, such as **data use, sharing and interoperability**.

Scientific and health research

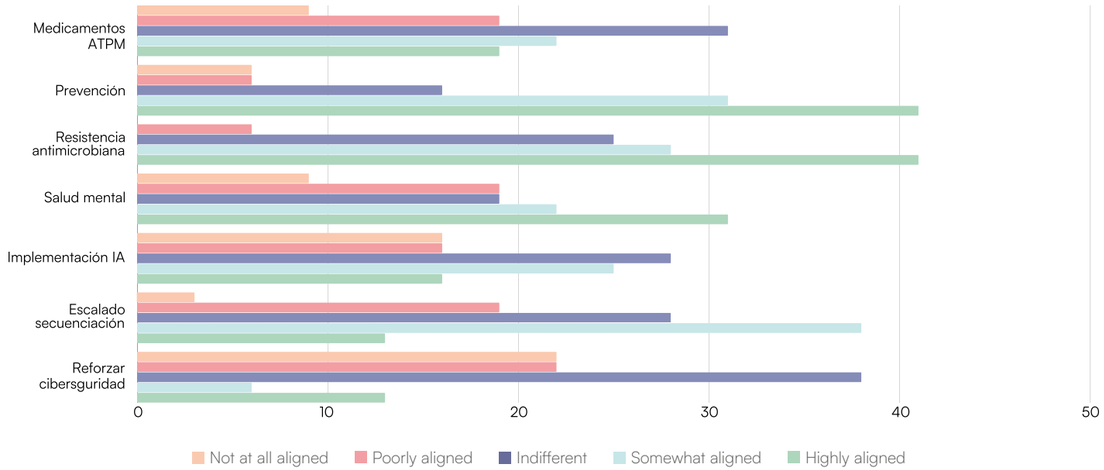
Indications from the new College of Commissioners indicate that some of the **health priorities for the next Framework Programme** will be the development of new advanced and orphan therapy drugs, health prevention, antimicrobial resistance, mental health, implementation of artificial intelligence, scaling up sequencing, and strengthening cybersecurity in hospitals.

For **almost half** of the respondents, the two priorities of the Framework Programme most aligned with national and ISCIII priorities are health prevention and antimicrobial resistance. Whereas **the least aligned** are the implementation of artificial intelligence and the reinforcement of cybersecurity in hospitals, although the importance of cybersecurity is recognised, it is not seen as an issue directly related to health.

Among the respondents, the following are considered necessary to be included among the European priorities:

- Frailty and healthy ageing and lifelong health prevention.
- Infectious and non-communicable diseases.
- Drug resistance.
- Improved digitisation and data sharing*.
- Alignment of research activities with the priorities set out in health policies.

Do you consider these priorities to be aligned with national priorities and those of the ISCIII?

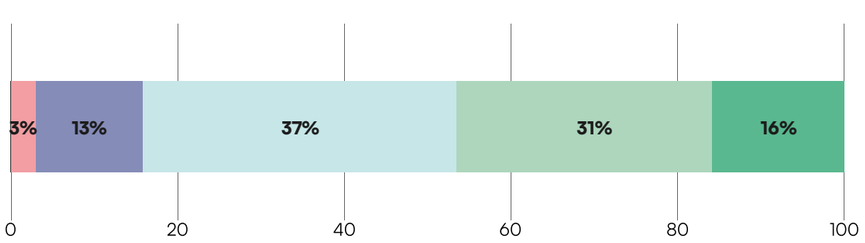


Clinical Trials

Recent reports on the future Framework Program indicate that **clinical research in Europe should be strengthened**. As a result, the European Commission is including more clinical trials (CTs) in the work programme and partnerships. **69%** of respondents consider **the inclusion of independent,** researcher-led **CTs** in European projects to be **positive to very positive**, as they strengthen clinical research in Europe, provide valuable evidence for medical practice, and respond to needs of the healthcare system that are often not funded by the pharmaceutical industry. Moreover, the evidence obtained from the CTs is of the highest quality, so it is in the interest of public institutions to increase activity in this area.

* In healthcare, digitisation plays a key role in improving the efficiency of services and access to information. Interoperability and secure data sharing between health professionals and research centres facilitates a more integrated and evidence-based approach. The adoption of digital technologies can improve disease monitoring, treatment management and informed decision-making.

What is your assessment of the inclusion of independent researcher-led CTs in European projects, both in the work programme and in partnerships?

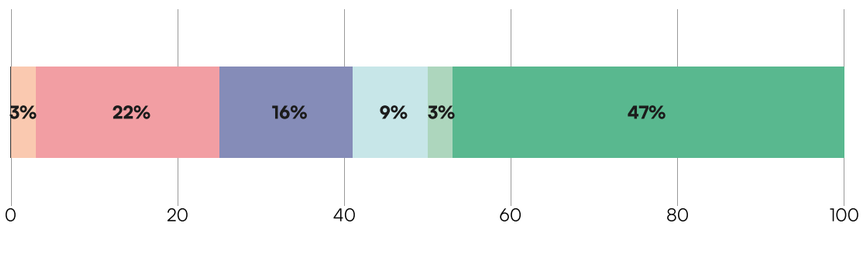


CTs

International multicentre CTs are more complex, costly and involve more demanding challenges in study planning, execution, analysis and follow-up. For **25%** of respondents, the Framework Programme, as designed, will have **little or no capability to offer solutions to the challenges of multi-centre, multinational CTs.** They point out that multinational CTs have complex **barriers** , such as regulatory differences between Member States, high costs, administrative bureaucracy, heterogeneity in ethical procedures, and complexity in data management and logistical coordination. It is considered that the Framework Programme does not always sufficiently cover the real costs of implementation, especially in multi-country trials and multi-centre trials with different implementation capacities.

It is worth noting that **almost half** of the respondents (47%) do not have the necessary knowledge of this issue.

Do you consider the Framework Programme, as it is designed, capable of tackling to the challenges of multi-centre, multinational CTs?



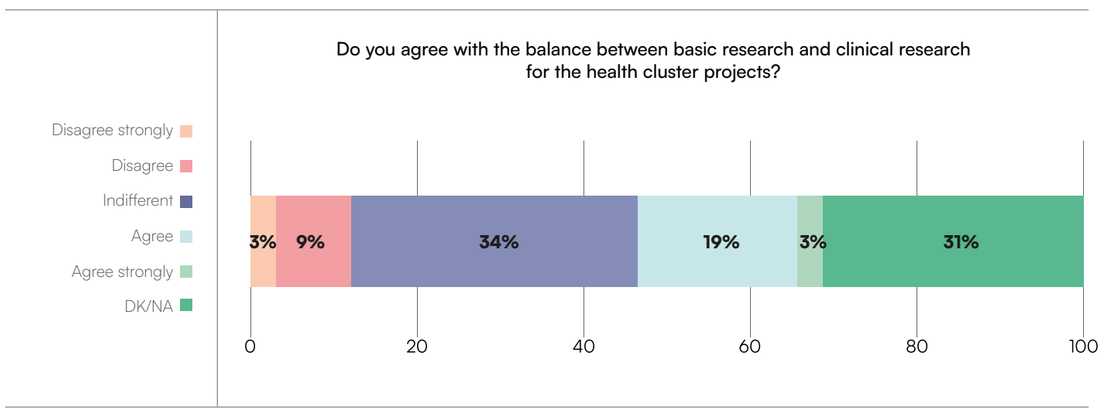
Participants propose the following measures **as possible solutions to the challenges of multi-country multi-centre** CTs:

- A specific and adapted framework, through European regulatory harmonisation, to facilitate the implementation of large-scale CTs, to simplify transnational regulatory procedures, and to provide centralised operational and technical support.
- Upskilling with specific training for clinical managers in this field.
- Use of shared platforms with compatibility of data systems and specific funding mechanisms.
- Creation of a strong multi-country institution, through a new EU agency, to develop and implement these trials.
- Independent clinical trials, not so closely aligned with the priorities of the pharmaceutical industry.
- Increased number of clinical trials at more advanced stages and with more diverse populations.
- Increased implementation times for CTs.
- Longer project implementation time.

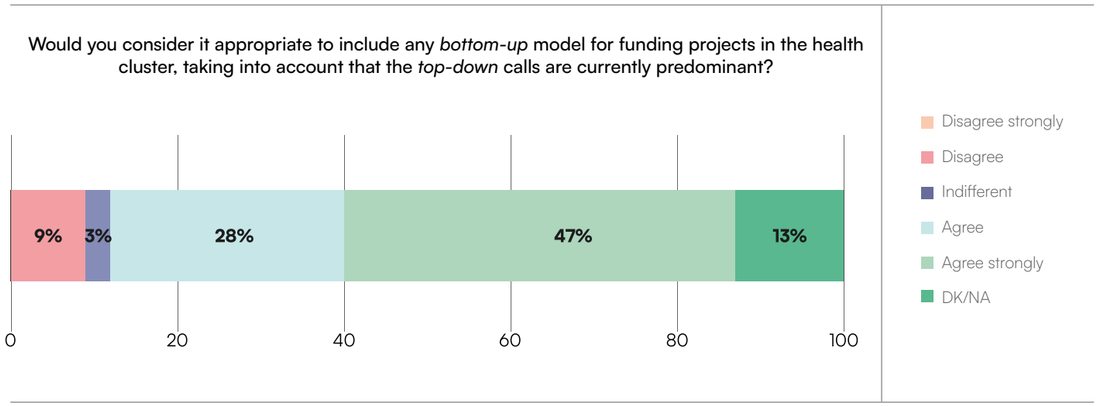
Balance between basic and clinical research in health cluster projects

In relation to the **balance between basic and clinical research in the health cluster projects**, **22%** of the respondents consider it **adequate or very adequate**, driving both fundamental knowledge and its translation into medical practice. However, it would be desirable to strengthen independent clinical research.

It is striking that **over half** of the respondents are either unaware of this topic or it does not directly apply to their field of research.



The results of the **Horizon 2020 final evaluation** and the **HE interim evaluation** point to advantages of the ***bottom-up* approach**[1] leading to creative and innovative proposals in different fields of science. For **75%** of the respondents, it would be **highly desirable to include this *bottom-up* approach** to finance projects in the health cluster, where the *top-down* calls currently predominate[2]. Respondents see this *bottom-up* approach as positive because it would leave room for exploring innovative ideas in health, which do not easily fit into established thematic frameworks, but have high scientific or social potential, and which may respond to emerging needs not covered by current calls.

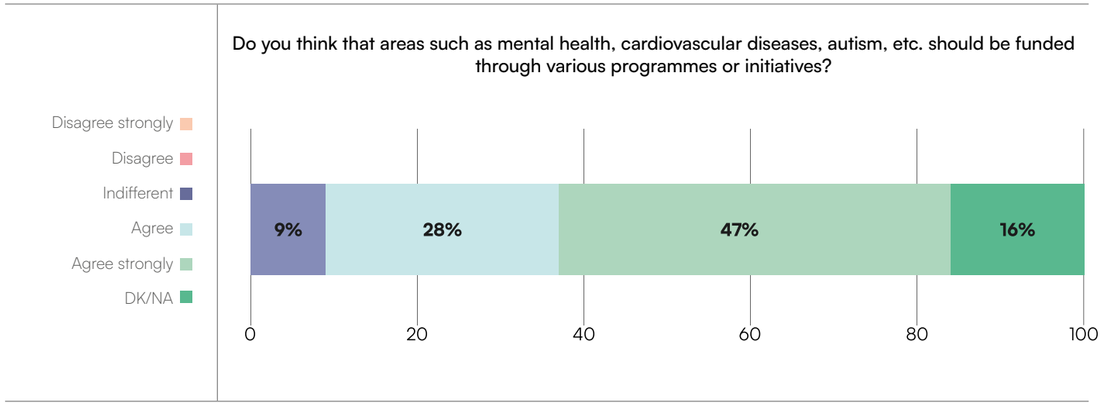


[1] Bottom-up approach: calls with an unrestricted thematic and scope approach, where research and innovation proposals come from researchers themselves according to their own interests and ideas, rather than being dictated by pre-defined priorities of the European Commission.

[2] Top-down approach: calls funded by the European Commission that focus on specific, pre-determined topics defined in the work programme, guiding researchers towards strategic EU challenges rather than leaving the subject matter entirely open to applicants.

Synergies between programmes

Europe's Beating Cancer Plan is currently implemented through, among other initiatives, the Cancer Mission, the EU4Health Programme and new legislation. 75% of respondents consider it **desirable or very desirable** that this same approach of promoting and funding the same issue through various programmes and initiatives should be applied to other areas such as mental health, cardiovascular diseases, autism, among others. This approach would allow for a more holistic approach to complex health problems, combining research, implementation, policy and technology, and addressing different facets of the same challenge, from basic research to practical application. In addition, the more focused thematic approach increases the chances of obtaining funding compared to more general European calls.



Respondents point to the need for **additional funding programmes in the following key areas:**

- Neurodegenerative diseases.
- Mental health.
- Emerging infectious diseases.
- Healthy ageing.
- Chronic diseases.

The Horizon Europe framework programme is actively promoting the **search for synergies between different health funding programmes**, especially with EU4Health and the Digital Europe programme. **66%** of the respondents value the establishment of these synergies **positively**.

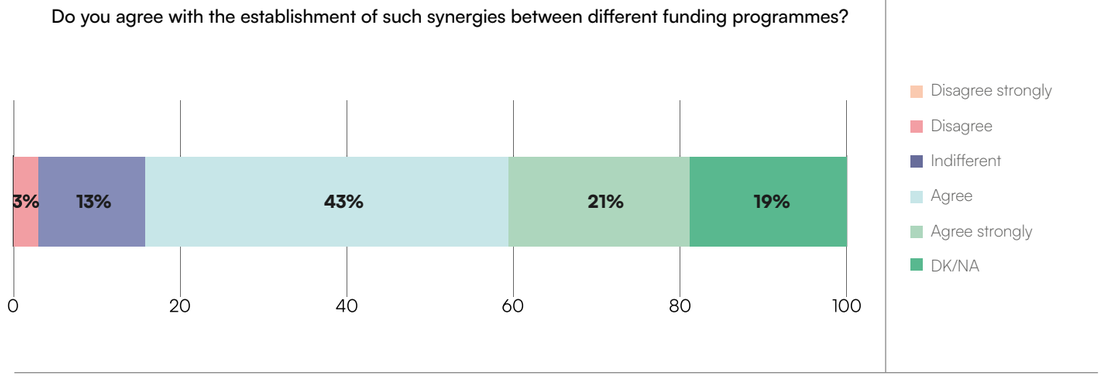
SYNERGIES BETWEEN DIFFERENT HEALTH FUNDING PROGRAMMES

Positive aspects

- Impact amplification
- Fosters complementarity and optimisation of resources
- Avoids duplication
- Strengthens the coordination of health policies with more integrated projects
- Encourages multidisciplinary collaboration
- For certain subjects (e.g. rare diseases) these synergies are essential

Negative aspects

- Increases administrative and coordination complexity
- Need for greater inter-agency coordination



In order to **maximise the impact** of research results, respondents believe the **health cluster should establish priority synergies mainly with cluster 6** (Diet, bioeconomy, natural resources, agriculture and environment). Establish synergies with this cluster is considered essential for the following reasons:

- To address the root causes of certain diseases such as tropical diseases.
- Because the interaction between environment, agriculture and zoonoses directly influences the emergence and transmission of pathogens.
- Because pollution has a more direct impact on health than other aspects.
- Because there are direct synergies between climate and health studies, and the climate emergency is also a priority in the health field.

Secondly, synergies with **Cluster 4** (Digital World, Industry and Space) are also considered a priority. The development of digital tools and interaction with civil society are fundamental to the success of biomedical research. The development of digital tools and the integration of data technologies are also key to advancing personalised medicine and public health.

Most respondents highlight the ***"One Health"***[3] approach as one of the key aspects to establishing synergies and maximising the impact of funded projects in health.

With which other clusters should the Health Cluster establish priority synergies?

Partnerships

Within Pillar II, European associations and partnerships play a crucial role in fostering collaboration between industry, Member States and the research community. These partnerships allow for pooling efforts and resources to address complex challenges more effectively.

In the area of health, there are a number of partnerships, including:

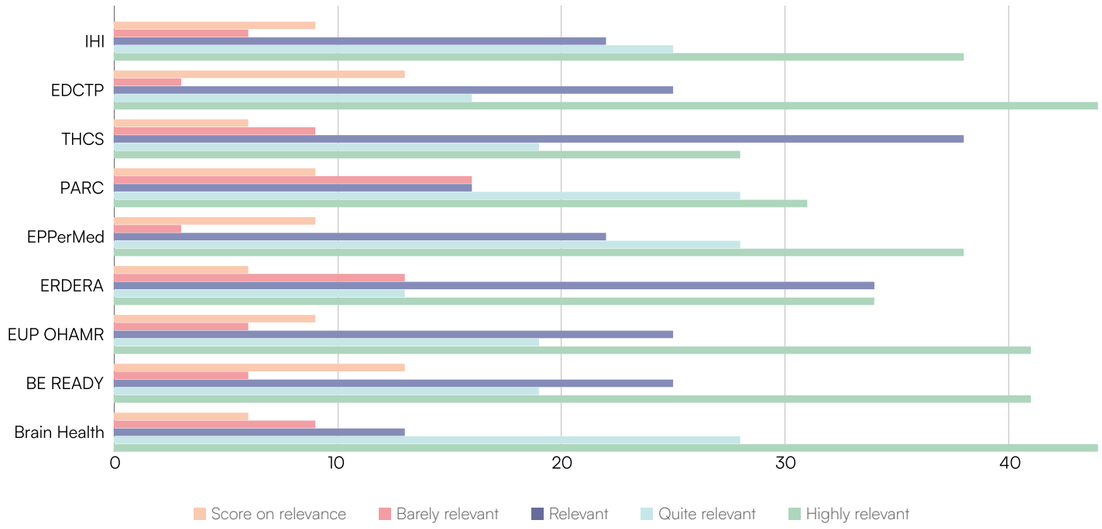
Institutionalised:

- *Innovative Health Initiatives* (IHI).
- *Global Health EDCTP3* (EDCTP).

Co-financed:

- *European Partnership on transforming health and care systems* (THCS).
- *Partnership for the Assessment of Risks from Chemicals* (PARC).
- *European Partnership for Personalised Medicine* (EPPerMed).
- *European Rare Disease Research Alliance* (ERDERA).
- *European Partnership on One Health Antimicrobial Resistance* (EUP OHAMR).
- *European partnership for pandemic preparedness* (BE READY).
- *European Partnership for Brain Health*.

Rate the relevance of the different topics

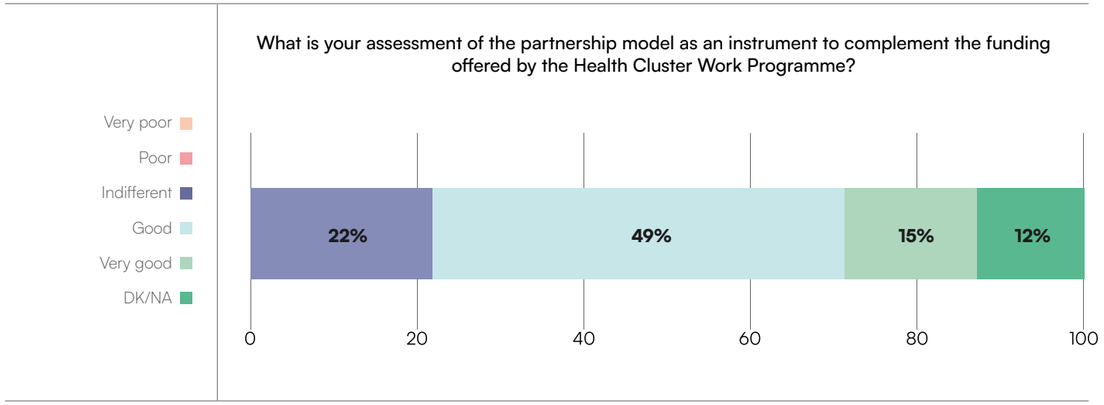


Among the respondents, 31% would propose additional partnerships in the following areas:

- Neurodegeneration.
- Direct impact of climate change on health.
- Global Health: cooperative research between Europe, Latin America, Africa and Asia.
- Sustainability of health systems.
- Work climate.
- Ageing and health.
- Preventive medicine.

3 ***"One Health"*** is a holistic and unifying approach that aims to balance and optimise the health of people, animals and ecosystems. It uses the close and interdependent links between these fields to establish new methods for disease surveillance and control. (https://www.who.int/es/news-room/fact-sheets/detail/one-health)

72% of the respondents consider that partnerships are a **good instrument** to complement the funding offered by the health cluster work programme. Partnerships are seen as enabling complex challenges to be addressed in a structured and collaborative way, increasing the visibility of strategic priorities, promoting stable international networks and bringing additional resources to projects with high potential impact. They also increase the chances of success in terms of obtaining funding. However, the difference in funding and regulations between countries is highlighted as a **limiting factor**, and it is considered that Spain should offer higher funding. There is a general consensus that the instrument is very useful.



47% of the respondents have **experience** of participating in partnerships, with **100%** of them having participated as **partners**.

More than half of the respondents with previous experience in partnerships consider that the **evolution of the instrument has been good or very good** as they have improved in their capacity for thematic structuring and visibility, although there are still significant differences in the co-funding rules between countries, and certain bureaucratic barriers that may discourage the participation of smaller centres or those from countries with lower national funding.

For **two thirds** of the respondents (66%) it is considered relevant to start working in a partnership similar to EDCTP3[4] that would facilitate cooperative research with Latin America, given that it shares with Europe multiple health challenges such as tropical diseases, antimicrobial resistance, maternal and child health, and the effects of climate change on health, which is why it is considered necessary to strengthen collaborative research capacities. Such a partnership would facilitate the sharing of knowledge, resources and technologies, improving genomic surveillance, the development of therapies and rapid response to outbreaks or other emergencies. In addition to fostering scientific integration between Europe and Latin America to address common challenges in public health.

The respondents consider that the ISCIII, and other Spanish institutions, would have an important role to play in this partnership with Latin America.

[4] EDCTP3. The EDCTP3 institutionalised partnership aims to bring new solutions to reduce the burden of infectious diseases in sub-Saharan Africa and strengthen research capacities to prepare for and respond to re-emerging infectious diseases.

Cross-cutting issues

Social Sciences in Health Projects

The **integration of social sciences into the health cluster projects** is rated positively by the survey respondents **(63%).**

INTEGRATION OF THE SOCIAL SCIENCES INTO HEALTH CLUSTER PROJECTS

Positive aspects

Necessary in a holistic approach and contextualisation of results for patient-centred research

Provides understanding of the social and cultural context of health problems

Improves the applicability of solutions and fosters the adoption of innovations through behavioural analysis, risk perception, equity and access

Patient-Reported Outcomes (PROs)[5] are becoming increasingly important for assessing people's health status and to do that, the integration of social sciences in health-focused projects is necessary

Negative aspects

Lack of clear methodologies for integrating qualitative results

Lack of general knowledge in theoretical models

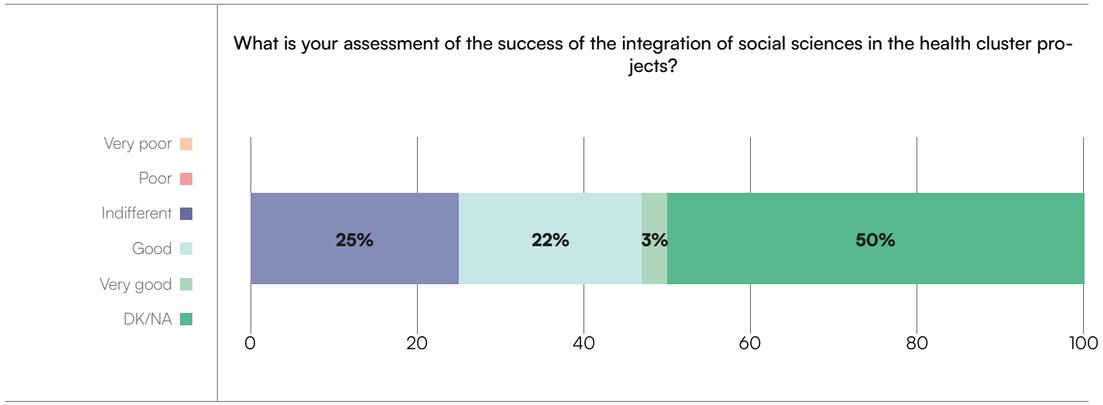
Lack of expertise in the area

Limited and uneven participation between projects

Incorporated, in some cases, in a superficial way

As to whether this **integration of social sciences in health projects** has been successful, **22%** consider that it has been **somewhat successful**. Although the integration of social sciences in the projects is mostly viewed in positive terms, more than two thirds of the respondents see it as still too early to assess whether this integration has been successful or not because, although its usefulness is acknowledged, the practical implementation has varied. It is necessary to promote mechanisms that ensure real and meaningful participation from the early stages of project design, including co-creation with social stakeholders.

[5] ***Patient-reported outcomes (PROs).*** This is health-related information that comes directly from the patients themselves, without the interpretation of a clinical professional. They capture the patient's perspective on their own health, such as their symptoms, daily functioning, quality of life, mental and emotional well-being, and satisfaction with care. PROs are standardised tools, often questionnaires, used to collect this data. PROs are valuable for understanding the effects of treatment from the patient's perspective, improving treatment plans and optimising the overall quality of care.



Open Science

One of the requirements and obligations for proposals submitted under the current Framework Programme is quality and relevance to **open science practices**[6]**. 84%** of respondents consider it **positive or very positive** that open science is an evaluation criterion in proposals.

OPEN SCIENCE AS AN EVALUATION CRITERION IN PROPOSALS

Positive aspects	Negative aspects
Improves transparency, reproducibility, international co-operation	Open science must be accompanied by funding, as open publishing comes at an additional cost. Without sufficient dedicated funds, it is difficult to implement it 100%
Enables higher return on public investment	Another important challenge of open science is the protection of sensitive data, especially in clinical trials or vulnerable populations, which can impact on the administrative burden and lead to increased workload for research groups
Allows for greater and faster impact	
Facilitates rapid access to data and results which, for example in the case of infectious diseases, are key to accelerating detection and response to outbreaks of infectious diseases	

6 Open Science. Research approach that prioritises transparency, collaboration and open access to research results. Involves opening up publications, data, methodologies and other aspects of the research process to encourage greater participation, reproducibility and exploitation of knowledge.

The **involvement of patients and patient representatives in health research and innovation** can be of great benefit to projects and their outcomes. Participants with **previous experience (63%)** identify the following **limitations** to this involvement:

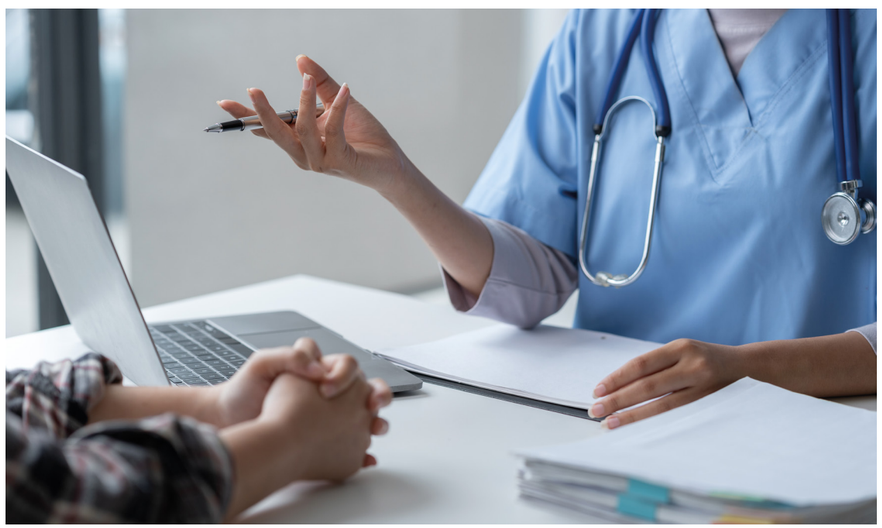
- Difficulty in identifying trained and committed patients.
- Approaches are either not very inclusive or focus solely on the biomedical perspective.
- The representation of groups from low and middle income countries is limited.
- Very recent experience and, at the Spanish level, it is still far from the maturity of some patient organisations in other countries.

To **encourage patient participation**, respondents recommend:

- Strengthening specific training programmes for patients and representatives.
- Establishment of mediation platforms between researchers and patient associations.
- Funding for real and structured citizen participation, beyond formal compliance.
- Possibility of rewarding respondents, financially or otherwise.
- Participation should be formally recognised to facilitate, for example, work permits.

In terms of how the **Framework Programme could incentivise this participation**, the following measures are highlighted:

- Specific funding for training and involvement.
- Evaluation criteria that reward co-creation and co-development of projects with society (by including citizen/patient evaluators in evaluation panels).
- Visibility for best practices and success stories where citizen participation has generated real impact.



Gender dimension

The **integration of the gender dimension** in research proposals is provided for by default throughout the entire Horizon Europe Framework Programme. **72%** of respondents consider that integration to be **positive or very positive** .

INTEGRATING THE GENDER DIMENSION IN HE PROPOSALS

Positive aspects	Negative aspects
Improves the quality of science and results by incorporating diversity in design, analysis and implementation	Lack of disaggregated data and specific analysis in some studies
Helps reduce structural health inequalities	Formal compliance may result in including this perspective in a superficial way
Stimulates research with an intersectional approach	It is still treated as a documentary requirement rather than a strategic dimension
It allows for the identification of relevant differences in prevention, diagnosis and treatment	

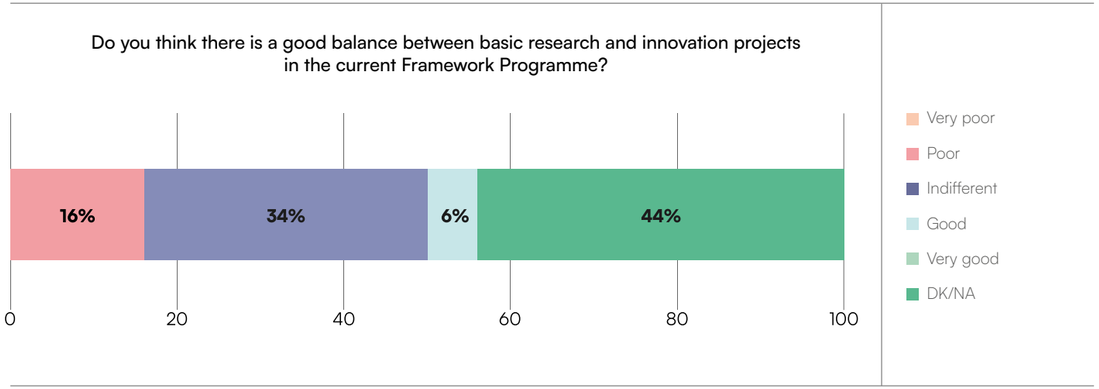
It is considered that this **integration should be strengthened by** mainstreaming it throughout the project cycle, from hypothesis formulation to dissemination of results, by promoting specific research on sexual and reproductive health, women's health and gender inequalities in health systems, and by promoting measures for women's leadership in science.

Transfer and innovation

Within the Framework Programme, **Innovation Actions** (IAs) and **Research and Innovation Actions** (RIAs) are the funding vehicles for the health cluster.

IAs are geared towards advancing innovative solutions towards market readiness. They involve rigorous testing, validation and demonstration activities, often in collaboration with industrial partners, with the aim of accelerating the commercialisation of breakthrough technologies or services. **RIAs,** meanwhile, focus on pushing the boundaries of knowledge through pioneering research efforts. These actions support collaborative research efforts aimed at addressing specific scientific or technological challenges, with the objective of generating advances in understanding or technological development.

The balance between RIAs and IAs in the health programme is much higher for RIAs (15 topics out of 17 for RIAs and 1 topic out of 17 for IAs in the last call). For **50%** of the respondents, the **balance between basic research (BRI) and innovation (IA) projects is not adequate,** there is considered to be a notable imbalance, and the intermediate phases of translational research and pre-clinical/ early clinical development are under-represented or difficult to fit into current funding formats. Greater connection with industry and the care environment is also necessary.



The transfer and valuation of research results, as well as technological innovation, are important aspects of R&D&I in the Spanish NHS. For **38%** of respondents, **the Framework Programme deals unsatisfactorily with the validation of proofs of concept or technology demonstration projects.** Despite some opportunities, there is no clear strategy or sufficient funding to take proof of concept to the next level. RIAs often end too early in the development chain, and IAs often require a level of technological maturity that many projects do not yet reach, especially those developed in academia. This limits the effective transfer of results, especially in technologies aimed at resource-poor environments. It is noted that it would be positive if there were more calls focused on concept testing.

Opinion on whether **to improve the translation and transfer of research results the number of IAs should be increased is divided,** 28% would increase this balance and 22% would keep it the same, while 44% have no opinion. Some respondents think that increasing IAs could improve the translation into the health system. However, a balance should be maintained so as not to penalise fundamental research. To this end, IAs are essential to validate technologies and intervention models, but they must also be adapted to the context of health research. Other respondents, for their part, believe that a general increase in IAs is not necessarily the solution. What would be needed is more flexibility and funding for the intermediate stages of development (proofs of concept, prototypes, etc.) that lie between RIAs and IAs. An instrument that effectively covers the translation *gap* is needed.

It should be noted that only **3%** of the respondents have **experience** as a partner or coordinator in **projects funded under the Innovation Actions format.**

Other instruments for financing innovation

The **Innovative Health Initiative partnership** (IHI) is a public-private partnership between the European Commission and the European life sciences industry. This partnership is part of the European Union's Horizon Europe programme and aims to accelerate the development and implementation of innovations in the field of health. For the respondents, the IHI partnership is largely unknown (only 3% of them have participated in IHI-funded projects).

Health funding opportunities for public institutions such as the European Innovation Council (EIC) and European Institute of Innovation and Technology (EIT) calls can also be found in **HE Pillar III**. In terms of participation in these two programmes, only 6% have participated in either of them.

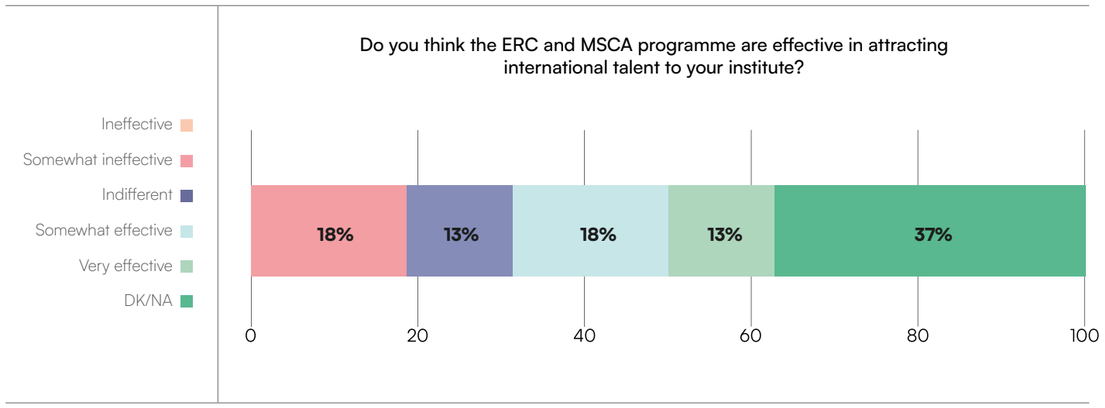
Those who consider **the calls promoted by the EIC** (Pathfinder, Transition and Accelerator) to foster public-private collaboration and the transfer of research results to be a good or very good instrument (28%) **highlight that these instruments promote scalability, public-private collaboration, technological maturity, support the creation of** innovative start-ups and bring research closer to the market. **72% of the respondents consider that they do not have a sufficient opinion on this issue.**

The results of the **interim evaluation of HE** indicate that **innovative public procurement** actions are a driver of innovation in public health systems. **41%** of respondents **consider it beneficial** for health systems that innovative public procurement or pre-commercial public procurement projects should be promoted in the next Framework Programme. They are identified as instruments that accelerate the adoption of innovations and benefit health systems. They have mobilised great professionals in hospitals who have seen a new opportunity to channel their expertise and initiatives. Innovative public procurement or pre-commercial procurement are instruments that help implement innovation in public health systems and therefore seem positive.

Human resources in health research

Excellent Science Pillar I is presented as the driving force for cutting-edge research in Europe. Its main objective is to push the boundaries of knowledge by supporting ambitious, high-risk research projects. The **European Research** Council (ERC) plays a key role in this pillar, funding projects led by a principal investigator to address complex problems at the frontier of knowledge. This pillar also invests in the development of scientific talent through the **Marie Skłodowska-Curie Actions** (MSCAs).

On the question of whether the **ERC and MSCA programmes are effective in attracting international talent to the centres,** opinion is divided. 31% consider it effective, while 19% believe it is not effective at all. Opinion is also divided as to which of the two programmes is more effective.



The **main barriers** encountered when trying to attract and retain international talent through ERC and MSCA projects are:

- Lack of complementary funding.
- Bureaucratic processes.
- Lack of job stability.
- The lack of international visibility of the ISCIII.
- The inability of the ISCIII to hire demonstrably qualified staff other than through a competitive examination system.
- The lack of competitive salaries compared to other European countries and other centres in Spain.

Because respondents have no direct experience in obtaining funding for the ERC and MSCA PF programmes, the views expressed can only be based on indirect experience or information shared by third parties. **59%** of respondents do not have enough information to give an opinion on whether the **ERC and MSCA calls help develop talent retention strategies at their institution. The remaining 40% have divided opinions** tending to consider that they do not contribute to talent retention. There is an idea that these programmes serve primarily for the development of a specific project and that their effect is limited without job stability and national support to ensure continuity after the project.

47% of respondents believe **the current Framework Programme does not sufficiently support the development of a clinical research career at their institution,** while **31% say that it partly supports it**. For them, the Framework Programme offers some opportunities for clinical research, but there is no structured scheme for a comprehensive clinical research career, and those that do exist lack calls for training, mobility or stability of staff, and then there is the fact that they are highly competitive and administratively complex, leading to great difficulty in access and consolidation of researchers.

European infrastructures

The objective of the Framework Programme's Research Infrastructures (RIs) programme is to facilitate access to research infrastructures and their state-of-the-art facilities to foster research excellence. **41%** of respondents believe the current RIs **contribute between somewhat to a lot to this objective.** Access to these infrastructures is seen as positive as they clearly contribute to access to cutting-edge technologies and services that foster research excellence. However, **barriers** are identified such as the high competitiveness of accessing them, the high costs associated with them and the lack of national mechanisms to facilitate their full use. Furthermore, it is felt that the ISCIII's research infrastructures should be more connected or linked to these large infrastructures.

Only **25%** of the respondents have **experience participating in European research infrastructure programme projects** or have participated in a project with a European research infrastructure.

The European Research Infrastructures or Infrastructure Projects in which ISCIII researchers are currently participating are the following:

European Research Infrastructures:

- BBMRI-ERIC (*Biobanking and BioMolecular Resources Research Infrastructure*).
- ELIXIR (*European Life Sciences Infrastructure*).
- ERINHA (*European Research Infrastructure on Highly Pathogenic Agents*).
- MIRRI (*Microbial Resource Research Infrastructure*).

Projects:

- ERDRI (*European Rare Disease Registry Infrastructure*).
- EIRENE (*Research Infrastructure for EnvIRonmental Exposure assessmeNt in Europe*).

The main **advantages of** participating in projects with European research infrastructures are the possibility of collaborating to improve access to existing resources (for example, being able to find samples for research in different biobanks in different European centres), being able to learn more about the experiences of other countries and for others to learn about the quality work carried out at the ISCIII, as well as access to protocols, training and funding, which would otherwise not be possible.

The main **barriers** identified for establishing these collaborations are that the system is very closed and difficult to access, and that there is little information.

59% of respondents **are aware** (47% "partly so") of the **services** offered by major European research **infrastructures** . The main **barriers** to learning about their services are that information on how to take advantage of these resources is limited, scattered and difficult to locate, and that if you are not very involved it is not easy to learn about them.

78% of respondents **do not know how accessible** research infrastructures are. **13%** consider them **accessible** and **9% do not**. The main **constraints** identified for accessing research infrastructures are that access is often limited by high competition, bureaucracy, related costs (some infrastructures are accessed on a fee-paying basis which is not always feasible) and lack of national support.

The infrastructures identified as having the greatest impact on ISCIII centres are **EATRIS, ECRIN, ELIXIR and BBMRI**. They are identified as such either because they are the most closely related to the respondents' fields of work or because they are participating in them.

Research Infrastructures are presented as a major asset of the European Research Area capable of boosting the R&D&I ecosystem and attracting and retaining researchers. However, reports suggest that it is becoming increasingly difficult to ensure the sustainability of different infrastructures, while at the same time developing new technological and digital infrastructures. **59% of the respondents agree that prioritisation or restructuring of the different infrastructures is necessary**. It is recognised that, given the current situation, it is difficult to sustain everything and therefore prioritisation or restructuring is required. It is also suggested that, if infrastructure is created, its sustainability should be considered from the outset and its creation should be conditioned by it. Furthermore, the main objective of this restructuring would be to optimise resources, avoid duplication and guarantee the most critical infrastructures for research, as well as to merge infrastructures that could be one and the same in terms of subject matter.

Health data

The European Union is making a major commitment to the **European Open Science Cloud** (EOSC) initiative, which aims to promote open science through the creation of an open, collaborative and sustainable digital research infrastructure. The EOSC advocates the management and application of research data to ensure scientists' access to data-driven science.

The **actions** proposed for implementation in the **next Framework Programme** to further develop this initiative are the following:

- Fund tools and services compatible with FAIR principles.
- Strengthen open science training.
- Require active and open data management plans.
- Connect EOSC with large research infrastructures (RIs), consolidating their governance and sustainability.
- Long-term financing for start-up and maintenance.
- Recognise data sharing as a scientific merit in project evaluations.
- Create a European public agency for the dissemination of scientific results.
- Specific calls to address technological/cybersecurity/legal aspects and clinical projects themselves.
- Establishment of a network national nodes that could connect to the European Cloud.
- Fund training programmes for researchers to acquire the necessary skills in data management and open science.
- Create a network of data science experts to advise projects during implementation.

44% of the respondents **state that initiatives are underway in their centres to advance in terms of access to, and sharing of, research data** generated by their researchers. These initiatives range from the creation of repositories, dissemination of activities, alignment with FAIR principles and policies, to the coordination by the ISCIII of all repositories and databases with personal patient data.

In the **European Data Strategy**, the creation of common European data spaces, including health, is envisaged. The EC is funding projects for the development and implementation of health data spaces such as the European Health Data Space, the Joint Action towards the European Health Data Space (TEHDAS), the Pan-European Federated Cancer Imaging Infrastructure (EUCAIM), or the European Genomic Data Infrastructure (GDI). **78%** of respondents consider **the sharing of health data and its reuse to be positive or very positive**, as it is essential to advance personalised medicine, early diagnosis and evidence-based public health, to accelerate knowledge and is necessary to avoid the duplication of studies.

Challenges identified include the difficulty of ensuring data anonymisation, related ethical issues, structural limitations and accessibility. It is also stressed that these initiatives are progressing very slowly.

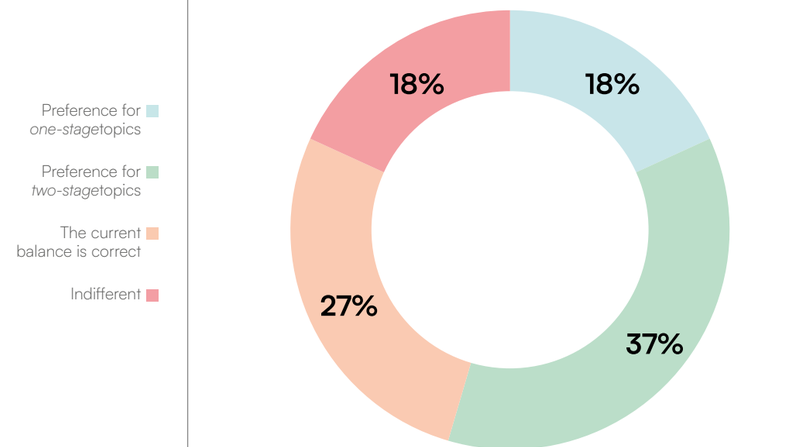
Management form

Preparation of proposals

There is a **slight preference for two-stage calls** (37%), with a significant percentage of managers considering the current balance between one and two-stage proposals to be correct (27%).

Although the resolution of the call is time-consuming, having two stages facilitates a much better distribution of the efforts of overburdened researchers, as well as allowing for a more efficient initial selection, optimising resources and thus increasing the chances of success with well-focused proposals.

How do you assess the balance between *one-stage and two-stage proposal formats*?

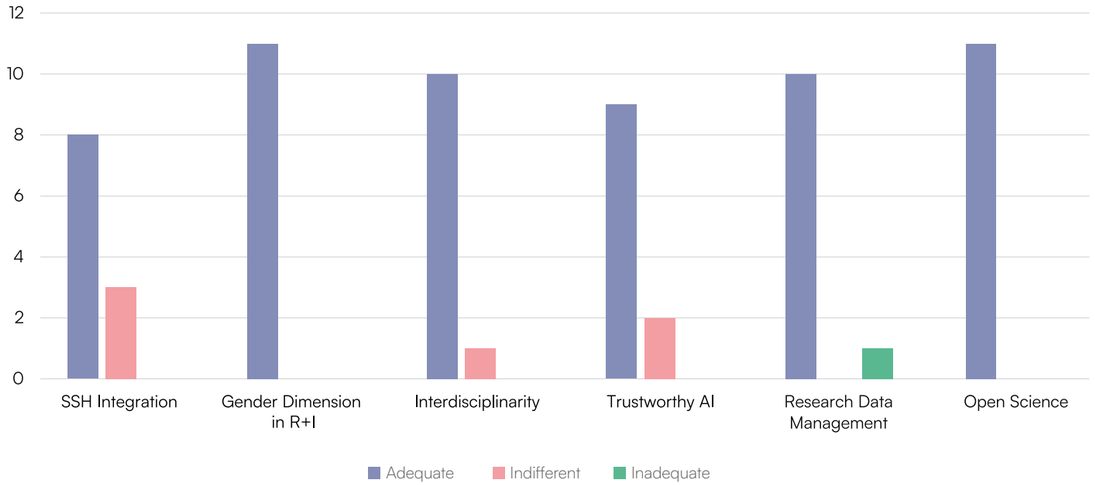


In relation to those calls that have followed a **blind evaluation system**, the **majority of respondents** (67%) have an unfavourable assessment compared to the minority who consider it to be positive or indifferent. Among the main criticisms of this evaluation model is that this system does not allow for the capacities and track record of the participating institutions and teams to be taken into account. However, there are also researchers who consider it a fairer system, reducing possible biases with an assessment solely focused on scientific excellence.

Regarding how they value **United States participation in the health cluster,** it is considered **very positive** that US entities can participate in HE health calls for proposals and receive funding (73%). Among the main positive aspects is that the fact that European entities can participate in NIH calls and American entities can participate in HE calls **favouring European-US collaboration,** as well as increasing the quality of consortia, integrating advanced experiences and technologies. However, some researchers view this participation negatively, considering that it benefits the United States exclusively, to the detriment of European centres.

In relation to the **inclusion of cross-cutting issues in the proposals,** the majority of responses were **positive,** in particular on the inclusion of the gender perspective, the development of open science, and the inclusion of aspects of the social sciences and humanities. In summary, **the cross-cutting sections are considered essential,** to ensure the social relevance of the projects (publicly funded and targeting wider society). However, it is claimed that they should not lead to an increased workload.

Score the relevance of the different topics



The last aspect on which the centres have been consulted is the **impact section,** which has been modified in the proposal templates for Horizon Europe calls, incorporating the *pathway towards impact.* This change is viewed **positively** by the majority (82%). The **main reported benefit** of this change is that impact can be considered as a differentiating criterion in proposals, although there is also a perception that this section has become too complicated.

Third parties

When it comes to participating in Horizon Europe, almost three quarters of respondents (73%) **acknowledge making use of the so-called *Affiliated Entities***.

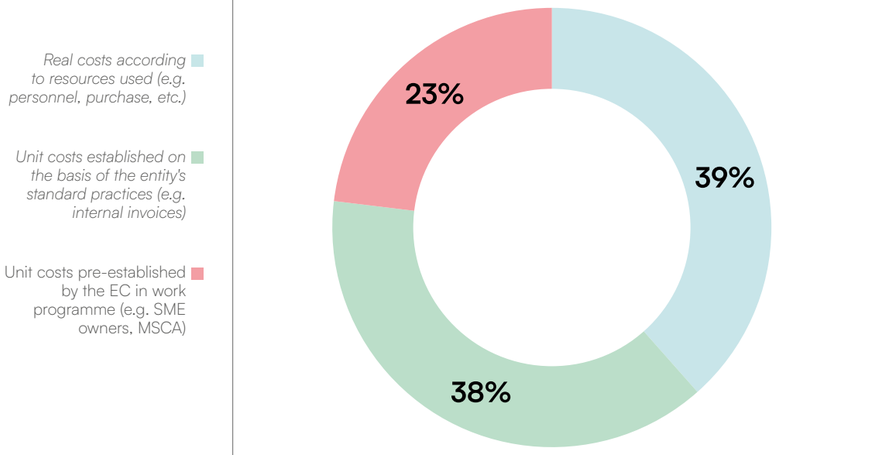
The impact of the **change in the eligibility rules applicable to foundations** on entities has also been assessed. There is a certain indifference in this respect (55%), although a significant percentage (27%) recognise that this change has had an impact, hindering a model in which the figure of hospital foundations is not well understood by the European Union.

Clinical trials

55% of respondents have managed European projects involving clinical trials, compared to 45% who have not managed such projects. Similarly, **respondents are unclear on the most appropriate format for justifying such clinical trials**. While 55% opt for real costs as the ideal measure, the other 45% prefer the *lump sum* model.

The main benefits of using the *lump sum* approach are **the relief from the administrative burden of cost justification**, compared to the difficulty of determining the real cost per patient in clinical trials, as well as the inability most hospitals to justify extraordinary tests using the real cost model. Delving deeper into this question, when asked about **the most appropriate cost category to justify clinical trials, opinion is very divided.**

Under which cost category do you consider it most appropriate to justify the CTs?



The main **benefit of using real costs** is the detailed control over expenditure and the adaptability to variability between centres. On the other hand, the difficulty in multi-centre studies is also noted, as each entity has different accounting and bureaucracy. In this regard, it should be noted that, in European projects, the HE rules establish that, in order to use the category of internal invoices, the costs must be established by the entity itself, based on the real costs recorded through accounting.

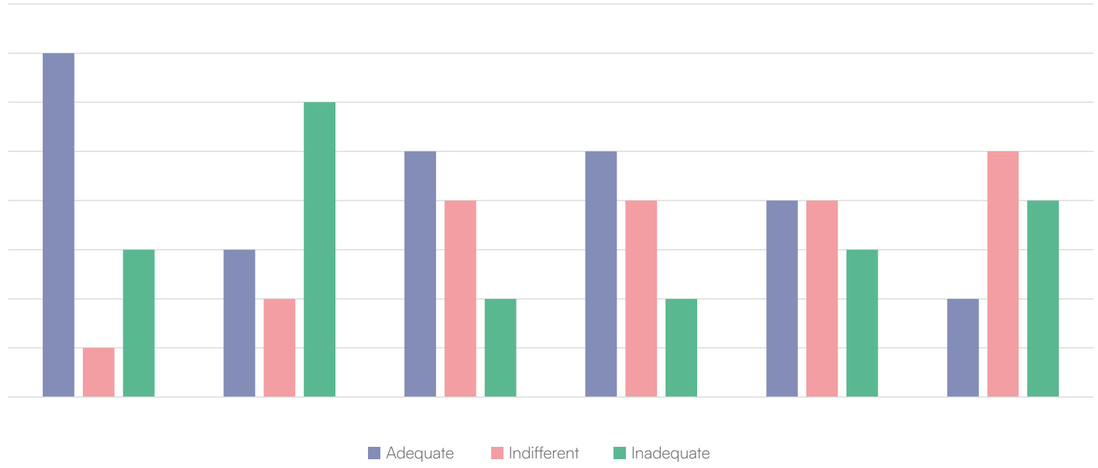
A large majority (73%) have never justified clinical trials through **internal invoices** in HE projects. The main drawbacks encountered include the lack of authorisation in some cases, the difficulty of implementation in multi-centre trials, and the need for very robust financial management to overcome the many administrative hurdles. The bureaucratic difficulty of combining this model with the *lump sum* model is also highlighted.

LUMP SUM

Opinions remain divided on the most suitable model for justifying the different types of **projects funded by HE.** Concerns are generally expressed when using the *lump sum* model because of the risks associated with the non-compliance of any of the partners.

It is considered more appropriate to use the *lump sum* model for projects with a budget of less than €10m, especially clinical trials (CTs) or coordination and support actions (CSAs). In the case of projects funded under the Innovation Actions (IAs) model or projects with a budget of more than €10m, the use of the *lump sum* model is not considered suitable.

Do you consider it appropriate to finance the following types of projects under the *LUMP SUM* model?

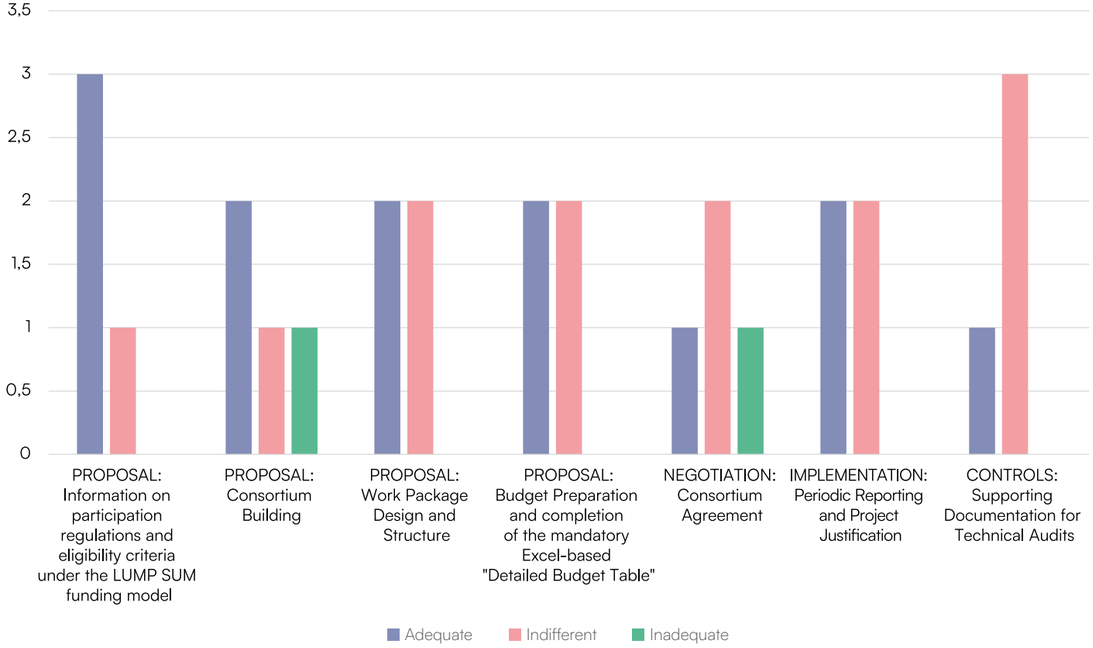


One of the main drawbacks of its adoption is the lack of specific knowledge of this model among both researchers and administrative staff, which is why specific training is required.

Experience as a partner

Among the respondents who stated that they had been involved as partners in a proposal or project, **there was no majority opinion on experience in the various topics surveyed.** Except for information on participation rules and eligibility conditions, which is mostly considered adequate, respondents express indifference at all stages of the project.

Indicate your experience with the *Lump Sum* model

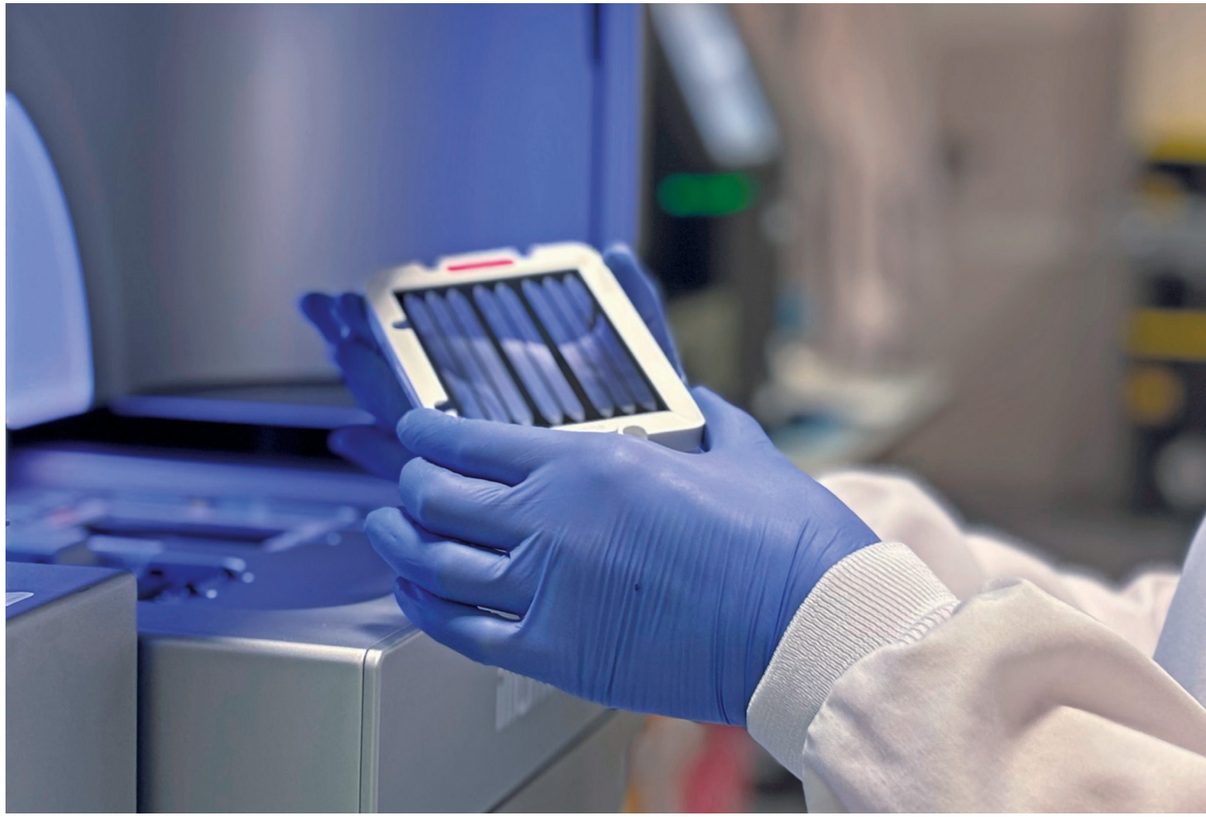


On the other hand, institutions that have not participated as partners in *lump sum* proposals or projects cite complexity, increased administrative burden and limited experience as the main reasons for not having done so. Similarly, none of the respondents has coordinated a proposal or a project under the *lump sum* model, due to the same disadvantages reported for participating as partners.

Evaluation

In general, the centres were **satisfied with the evaluation process, the** evaluation reports received and the criteria for the tie-breakers, with only one respondent expressing dissatisfaction with the process.

Evaluation *Summary Reports*(ESRs) are viewed positively as a means of identifying weaknesses in proposals, although there is a wide disparity between reports, with some being considered too brief or insufficient to provide adequate *feedback* to improve proposals. The tie-breaker criteria are also considered appropriate, with some suggestions for change, such as valuing impact rather than excellence. However, the criteria are generally considered to be arranged in the right order.



Recommendations for the future framework programme

The new Framework Programme should increase the health cluster budget from the current 8.6% to 10-15%.

Following the analysis of the responses received from ISCIII centres to both forms, we highlight the following **key messages and recommendations** for the next Framework Programme:

Vision for the future

The new Framework Programme should increase the health cluster budget from the current 8.6% to 10-15%. The current budgetary contribution for all programmes covered by the Health Cluster is considered insufficient and it is proposed that the appropriate percentage of the total Framework Programme budget dedicated to health should be between 10-15% of the total.

Within the health cluster, the distribution of the budget between partnerships and the Cancer Mission and Work Programme calls should see changes made. It is considered necessary to reduce the percentage dedicated to Partnerships by 10-15% in order to increase the calls of the work programme, while keeping more or less the same percentage dedicated to the Cancer Mission.

The two priorities of the Framework Programme most aligned with national and ISCIII priorities are health prevention and antimicrobial resistance, although there is a need to include new health priorities such as; ageing, digitisation and data sharing, infectious diseases, drug resistance (non-antibiotics) and chronic diseases.

Scientific and health research

The inclusion of independent investigator-led clinical trials in European projects is considered positive to very positive as it strengthens clinical research in Europe, provides evidence of great value for medical practice and facilitates the response to the needs of the health system that are often not funded by the pharmaceutical industry.

Multiple barriers are identified in the implementation of international multi-centre Clinical Trials and the current Framework Programme is not considered able to meet the challenges involved. The following are proposed as solutions to be implemented in the next Framework Programme: the creation of a specific and adapted framework, specific training, the creation of a new agency for its development and implementation, more funding and more run time for projects carrying out clinical trials like these.

It is considered highly desirable to include the *bottom-up* approach for funding projects in the health cluster as it would leave room for exploring innovative ideas in health which do not easily fit into the established thematic frameworks, but which have high scientific or social potential, and which may respond to emerging needs not covered by current calls.

It is considered that the next Framework Programme should extend the approach of promoting and funding the same thematic area through several programmes and initiatives to other areas in addition to the current ones, as well as seeking synergies between different health funding programmes.

Due to their high interconnectedness, priority synergies should be established with the Health cluster and the Food, Bioeconomy, Natural Resources, Agriculture and Environment; and Digital, Industry and Space clusters.

Partnerships

Partnerships are highly valued as a funding instrument and it is considered that this model should be maintained in the next Framework Programme. The creation of new partnerships is also recommended.

Cross-cutting issues

The integration of social sciences, open science and the gender dimension in HE projects, as well as the involvement of patients and patient representatives in HE projects, is highly valued. Furthermore, the integration of all these aspects should be encouraged and strengthened in the next Framework Programme.

Transfer and innovation

The next Framework Programme should improve the translation and transfer of research results by increasing the number of innovation actions (IAs) within the health cluster work programme.

More validation of proof-of-concept or technology demonstration projects is needed, with more funding and greater incorporation of transfer into the academic fabric.

Realistic measures need to be implemented to allow for growth in the transfer network to reach the equivalent of those countries that excel in this area. This would require investment in all types of resources, with special emphasis on human resources.

There is a general lack of knowledge among ISCIII centres about the IHI partnership, EIT Health and the calls promoted by the EIC. There is a need to promote actions aimed at making them better known among the scientific community of the ISCIII.

Human resources

While the ERC and MSCA programmes present themselves as valuable tools for talent attraction, they should include opportunities for talent retention and generational renewal.

It is considered that the current Framework Programme does not sufficiently support clinical research career development and should be promoted for the future programme.

European infrastructures

Research Infrastructures are valued positively as drivers of research, although they need to do more to publicise their functions, services and possibilities for collaboration with the research community. However, it is considered necessary to restructure them in order to optimise resources, avoid duplication and guarantee the most critical infrastructures for research and to merge infrastructures which, due to their subject matter, could be a single one.

Reducing bureaucracy

In order to find real synergies, it is essential to standardise the rules of participation between countries for health research programmes.

The *Lump Sum* model is considered appropriate for projects with a budget of less than €10m. For other types of projects or with larger budgets, simpler alternatives with lower risks for stakeholders should be explored.

There is a preference for two-stage calls due to the lower initial effort. The first screening allows for a more complete dedication in the second phase when the idea has been assessed as sufficiently competitive.


GOBIERNO
DE ESPAÑA
MINISTERIO
DE CIENCIA, INNOVACIÓN
Y UNIVERSIDADES
Instituto
de Salud
Carlos III
Ciencia y Salud
1986-2026
2001-2026
FECYT
INNOVACIÓN
oficina
europea