

2024 EU4Health Stakeholders' Consultation

Summary report

1. Background Information

Article 16 of the EU4Health Programme Regulation (EU) 2021/522 stipulates that the European Commission shall consult with relevant stakeholders, including representatives of civil society and patient organisations, to gather their perspectives on: (a) the priorities and strategic orientations of the annual work programme; and (b) the needs to be addressed through the annual work programme and the results achieved. The Commission conducts the consultation and provide stakeholders with information at least once a year, within the six months preceding the presentation of the draft work programme to the EU4Health Programme Committee. Prior to the final meeting of the EU4Health Steering Group each year, the Commission presents the outcomes of the EU4Health Steering Group proceedings and the consultation of stakeholders to the European Parliament. Additionally, recital (43) emphasizes the importance of extensive outreach activities to ensure that the views and needs of civil society are adequately represented and considered during the Programme's implementation.

Objectives of the targeted consultation

The targeted stakeholder's consultation was conducted between 22 April to 10 June 2024. The questionnaire was distributed to the public through the EUSurvey tool. To specifically engage the public health community, it was disseminated via the Health and Digital Executive Agency website and the DG SANTE's Health Policy Platform (HPP), via DG SANTE's newsletter and social media. The consultation was also announced to the members of the EU4Health Steering Group, the EU4Health National Focal Points, and a number of expert groups and the ERNs. This targeted consultation aimed to gather feedback from stakeholders on the priorities and strategic orientations, as well as the needs to be addressed through the EU4Health annual work programme. It focused particularly on input that could inform the 2025 EU4Health work programme and beyond. Responses were collected for all proposed questions, and contributions were sought to describe needs, challenges, and potential solutions. The preliminary outcomes of the targeted consultation were presented and discussed during the Stakeholders' Conference held on 19 June 2024 and will contribute to the further development of the EU4Health 2025 work programme. The targeted stakeholders' consultation was complemented by stakeholders' outreach activities in various policy events and Commission health policies expert groups in light of the 'Political guidelines for the next European Commission 2024-2029' and the Mission letter for the Commissioner-designate for Health and Animal Welfare including its final format.

2. Stakeholders' analysis

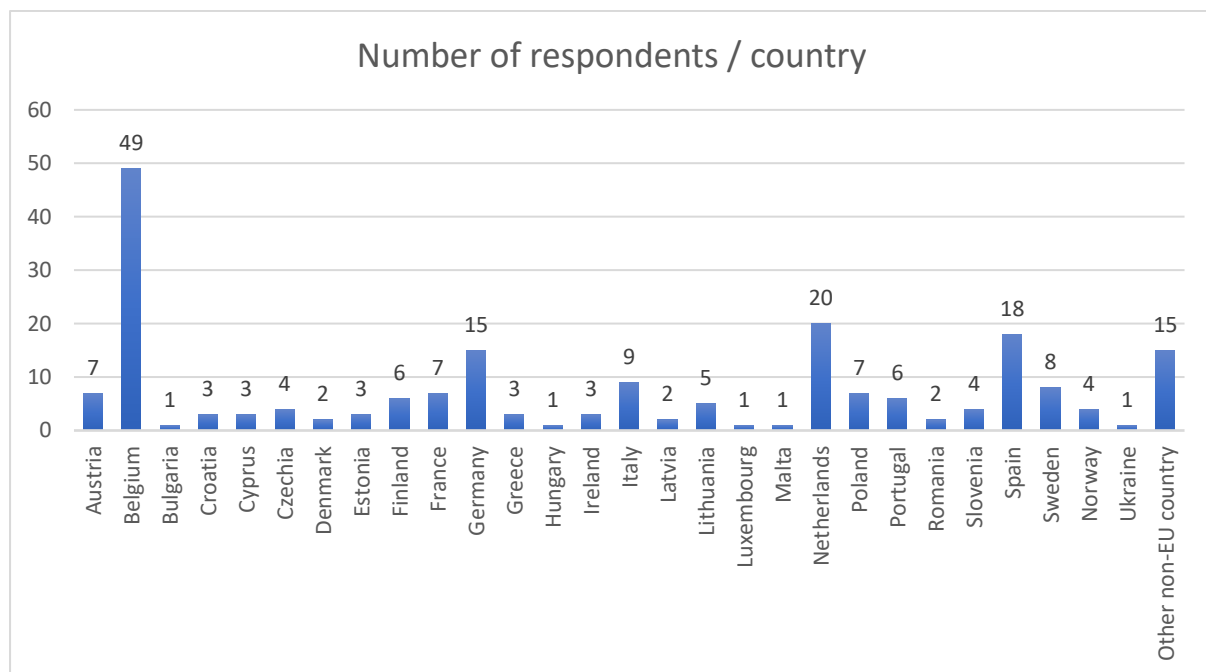
The survey was composed of eighteen questions. The first three asked about the type of organisation that the respondents represented. The next six questions were about the content and priorities of the EU4Health Programme. The following five questions were enquiring about the synergies, added value,

collaboration and innovation fostered by the EU4Health programme. The last four questions were about the implementation tools and the fate of the projects without EU4Health financing. The questionnaire followed the format of a public consultation with open and closed questions by using the EUSurvey tool.

All the survey questions were answered, along with additional detailed contributions from the respondents. Respondents provided their views on needs and objectives and shared their experiences regarding possible actions to be prioritised in the forthcoming work programmes.

During the seven weeks of consultation, 210 replies were received. The geographical coverage was extensive, with at least one participant recorded from 26 Member States. There was no reply by any stakeholder from Slovak Republic. Eight non-EU countries, of which two are associated to the Programme, were also represented by at least one respondent to the survey. The highest number of respondents were from Belgium, which reflects the concentration of stakeholder organisations in Brussels. The Netherlands, Spain and Germany followed in terms of number of respondents.

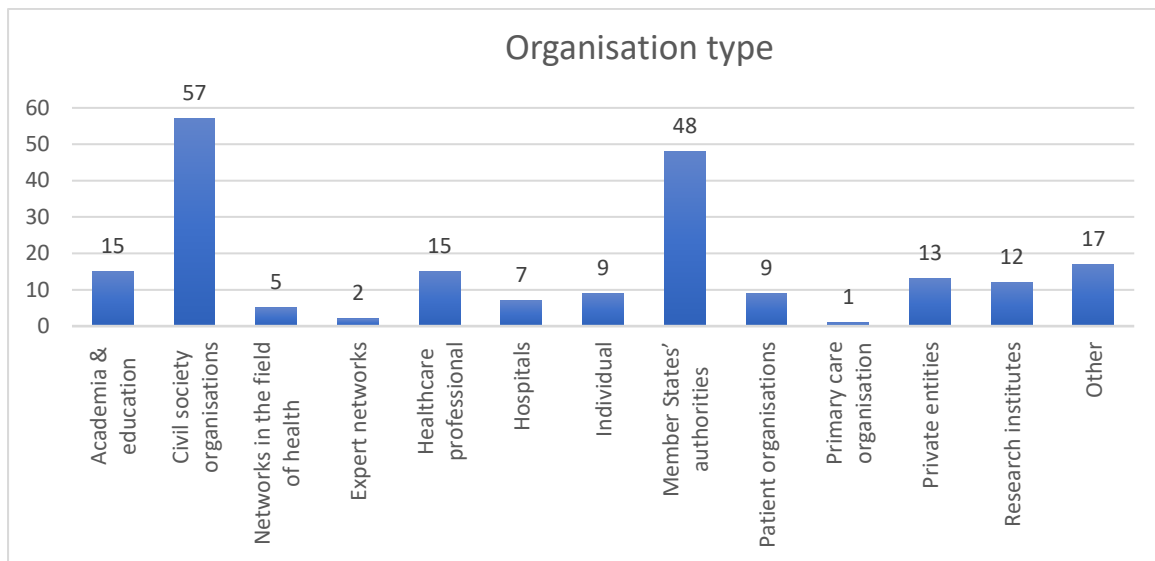
Figure 1: Participation to the consultation by country (number of participants; n=210)



The consultation engaged a broad range of relevant stakeholders, with responses received from all targeted categories, including academia or education establishments, civil society organisations, networks in the health field, expert networks, healthcare professionals, hospitals, primary care organisations, patient organisation, individuals, Member States' authorities, private entities, and research institutes. Civil society organisations and Member States' authorities were the most represented respondents.

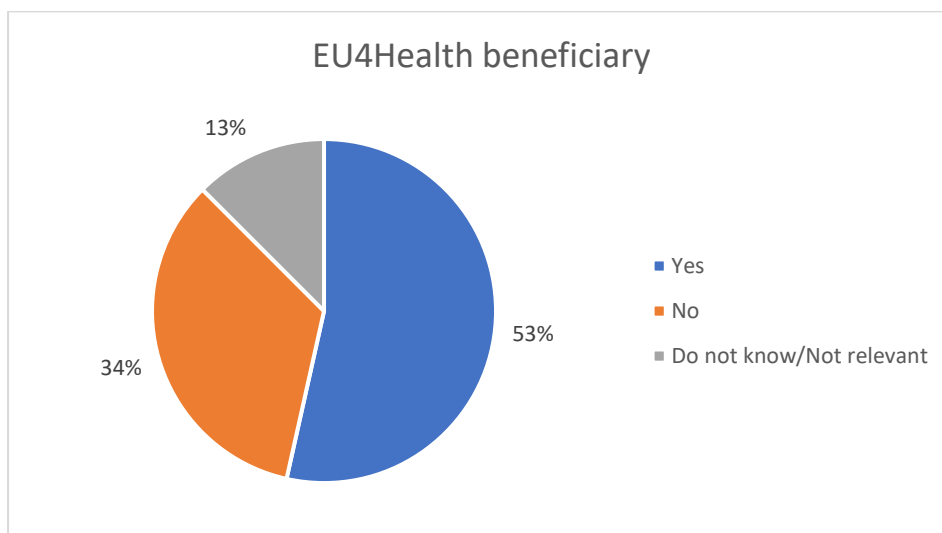
Civil society organisations actively participated in the survey, representing 27% of total replies. The Member States' authorities made up 23% of the responses.

Figure 2: Participation in the consultation by category of respondent (number of respondents per category; n=210)



The majority of survey respondents (53%) indicated that they are or have been beneficiaries of the EU4Health Programme. 34% were not beneficiaries, while 13% indicated they do not know or that the question was not relevant for them. This indicates that interest in the Programme goes beyond the group of those who are already involved directly or via their organisations and institutions in its implementation.

Figure 3: EU4Health beneficiary status of respondent (number of respondents per category; n=200)



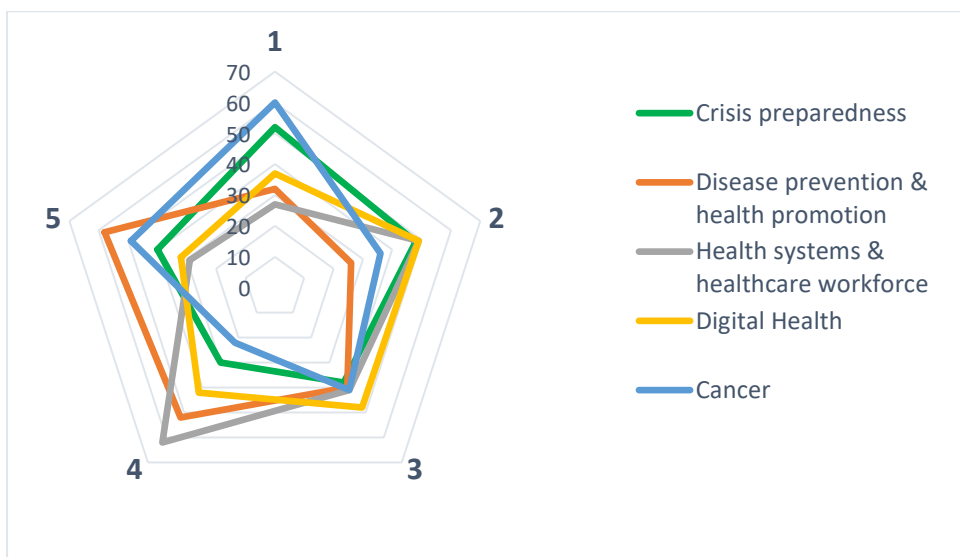
3. Strand priorities

Stakeholders were invited to express their opinion on the key priorities to be taken up by the work programme 2025 and beyond. The open questions were related to the fields covered by EU4Health and are summarised below.

a) Resource allocation

The EU4health work programmes' strategic orientations are structured into four strands of action: Crisis preparedness, Disease prevention & health promotion, Health systems & healthcare workforce, and Digital health and one cross-cutting priority – Cancer. Participants were asked to indicate the strand, that effectively allocates resources to address both current and future health needs without neglecting any aspect. All strands received a very similar average scores ranging from 2.8 for Crisis preparedness to 3.4 for Disease prevention & Health promotion (scale 1-5 with 1 being least effective and 5 most effective). This demonstrates that overall stakeholders perceive all strands of the EU4Health Programme as allocating resources rather effectively.

Figure 4: EU4Health strands effectively allocating resources (1 = Least effective to 5 = Most effective)



b) Priorities in prevention, preparedness & response to cross-border health threats

Part of the stakeholders identified disease surveillance activities and cooperation as key areas, emphasising the need for increased early detection efforts and real-time data sharing among Member states.

Continuity of care for non-communicable diseases (NCDs), including childhood cancer, during crises is a concern and it should be integrating into national crisis preparedness plans to avoid disruption. The training of healthcare professionals for cross border health crisis is a priority for the survey respondents which should include the development of protocols and guidance for decision-making on resource allocation and prioritisation.

The importance of public health information is stressed, with a need for trusted and accessible information to guide the public during health crises. Due to the raising rates of sexually transmitted infections (including HIV), some stakeholders call for greater emphasis of this topic. Prevention, preparedness and response plans should be inclusive by taking into account the needs of vulnerable populations such as persons with disabilities or migrants.

Climate change is a pressing concern, with an increase of vector borne and emerging diseases. The stakeholders suggest an increased cooperation with global health actors and the development of integrated surveillance networks that combine human, animal, and environmental health data. The emergency preparedness and response plans should integrate behavioural & cultural insights and have mental health and psychosocial support as key components.

AMR is seen by part of the stakeholders as an important cross boarder health threat that necessitates investments covering all aspects from research in new antimicrobials to stewardship programme.

Other topic prioritised by stakeholders are the development of medical countermeasures and the coordinated procurement of those, the enhanced surveillance tools (including AI tools), medical equipment traceability at EU level, common pandemic exercises and the better radiological emergency preparedness.

Overall, stakeholders emphasised the need for improved cross-border cooperation, workforce training, enhanced surveillance and public health information to effectively prevent, prepare for, and respond to cross boarder health threats in the EU.

c) Priorities in health promotion and disease prevention

Some of the stakeholders suggest prioritising various approaches to health promotion and disease prevention to address the current and future needs of the European population. There is a strong support for continued cancer prevention and screening programmes in particular for lung and prostate cancers. In addition, the stakeholders stress the importance of informing the citizens about lifestyle related cancer risk factors such as tobacco, alcohol, unhealthy diets, and endocrine disrupting chemicals. There is a call for enhancing access to genetic counselling for hereditary cancers and improving standardisation and monitoring of vaccination for preventable cancers.

The use of digital data and AI is recommended to better coordinate expert communication and assist in symptom surveys, treatment, and clinical trials.

Health literacy promotion is highlighted as a means to empower individuals to make informed health choices. The obesity epidemic's challenges are underscored, necessitating a focus on NCDs risk factors and their broader socio-economic impact.

The survey participants suggest updating the Union legislation for modifiable risk factors, such as alcohol, tobacco, and environmental risks, and to assess the impact of sugar tax, healthy eating policies, and nutritional labelling on population health.

The stakeholders suggest focussing on preventive actions to combat antimicrobial resistance and reinforce basic hygiene standards and protocols.

Targeted screening programmes for diseases, particularly cardiovascular, are recommended, along with addressing social determinants of health and supporting marginalised groups.

Other priority areas proposed by the stakeholders are healthy aging, communicable disease responses, reducing health inequalities, addressing unmet medical needs for degenerative neurological conditions, improve cross-border collaboration for gene and cell therapies and promoting mental health of young people.

Lastly, promoting health as a right, addressing inequalities, and access to sexual and reproductive health services is seen as paramount.

Overall, the stakeholders emphasise a multifaceted approach to health promotion and disease prevention, encompassing awareness campaigns, improved health literacy, digital tools, continued work on cancer prevention and screening, addressing social and lifestyle determinants of health, and legislative updates to mitigate risk factors.

d) Priorities in strengthening of healthcare systems

Stakeholders suggest that the EU4Health Programme should prioritise investment in initiatives that address the critical shortage of health professionals. Efforts should include recruiting and retaining talent and enhancing skills development, especially in digital and green competencies. Special attention is needed for particular areas such as cancer, cardiovascular diseases, and AMR.

The value of networking opportunities for projects and professionals is highlighted, as they lead to improved efficiency and knowledge transfer among Member States. There is a call for the establishment of networks of expertise and promotion of multidisciplinary care for complex diseases, which can result in better coordinated healthcare services. Stakeholders advocate for the enhancement of knowledge exchange, research support, and the creation of collaborative platforms to foster innovation and unify efforts. Continuous education for healthcare professionals should be supported to ensure their preparedness for emerging health threats.

Strategic workforce planning, including understanding workforce needs and developing future projections, is considered necessary to ensure healthcare systems' capacity to respond to threats. Support for infrastructure development and resource sharing is recommended to ensure equitable access to services, especially in countries with less developed healthcare systems.

Stakeholders emphasise the importance of driving forward the digitalisation of health systems, including the adoption of technologies such as AI.

In conclusion, stakeholders emphasised that addressing workforce shortages is still a key priority, followed by the challenge of the digitalisation of health systems and the collaboration as key for bringing optimal care to the patients.

e) Priorities in digital health solutions including utilisation of health data and emerging technologies

Many respondents emphasise the need to support the implementation of the European Health Data Space (EHDS). This includes the development of use cases for the EHDS, particularly in cancer care, and ensuring public awareness and support. Stakeholders advocate for adequate funding for the EHDS and suggest building synergies with other EU funded initiatives.

The survey participants suggest enhancing interoperability of health data systems and utilising AI, machine learning, and telemedicine to predict and manage health conditions, personalise treatments, and improve outcomes while maintaining robust data privacy and security measures.

EU4Health should address health misinformation and support evidence-based decision-making within Europe, given the challenges presented by advanced information platforms. The program should focus on the implementation of the EHDS and AI in healthcare, investing resources to facilitate dialogue and the exchange of practices between authorities and other actors.

Telemedicine should be a priority to support vulnerable populations and people in remote areas, facilitating specialist diagnosis and care.

Establishing cross-border digital health infrastructure, promoting digital health literacy and training, and facilitating interoperability and harmonisation of the digital health ecosystem are considered by the stakeholders as key actions. A tailored approach to the General Data Protection Regulation for health data is supported, along with multistakeholder exchanges on digital health legislation implementation.

Engaging with civil society organisations representing different populations is critical to improving health data collection and monitoring.

A patient-centric approach is advocated, continuing the implementation of pilot projects like Electronic Health Records and e-Prescriptions, while focusing on patient ownership, privacy, and consent.

The importance of patient safety and fostering trust in AI is highlighted, ensuring infrastructure is reliable and cybersecure, and promoting digital literacy for patients and healthcare professionals.

Finally, investment in the training of the healthcare workforce in digital skills and the promotion of the uptake of digital tools and services are seen as crucial for the digital transformation of healthcare systems.

The stakeholders' responses collectively highlight the importance of integrating digital health solutions into the broader healthcare ecosystem, with a focus on enhancing patient outcomes through improved data sharing, interoperability, and the use of emerging technologies, while ensuring data security and addressing misinformation.

f) Priorities in access to affordable and innovative medicines, medical devices and other crisis-relevant products

Stakeholders suggest that EU4Health could enhance transparency in medicine supply chains and address shortages through formal reporting, especially in critical therapeutic areas like cancer.

To enhance access and affordability, the stakeholders suggest establishing mechanisms for joint procurement and promote joint actions. This would tackle discrepancies in access to innovative treatments. A key suggestion is also improving access to preventive and therapeutic options for HIV and other diseases, particularly for vulnerable populations.

Further funding should be dedicated to the research, development and innovation through public private partnerships, value-based procurement, and fast reimbursement models for digital solutions. The survey respondents identified cardiovascular health as a priority research and development area. The creation of pre-competitive research spaces is seen as a way to help novel therapies overcome non-clinical obstacles to reach patients.

Innovation can be supported by transnational education initiatives, including curriculum development for digital health and therapeutic areas like personalised medicine and cell therapy.

In addition, the unique challenges of rare diseases should be addressed by supporting research, regulatory harmonisation, and collaborations to overcome economic and structural hurdles.

To expedite the availability of new products, the regulatory process across Member States should be streamlined in particular for innovative therapies, drug-device combinations and radioligand therapies.

The stakeholders suggest reinforcing the collaboration with stakeholders, including patients, healthcare professionals, and industry, to define unmet medical needs and propose solutions. In addition, patients should be involved in regulatory decisions and gain better access to clinical trials.

In the opinion of the survey participants, EU4Health should invest in domestic capacities and community engagement programmes to improve the uptake of crisis response products and offer incentives for private entities to maintain or adapt production lines for crisis-relevant products.

The stakeholders emphasise the need for a multi-faceted approach that includes transparency, education, joint procurement, innovation support, and regulatory reform to ensure that patients across the EU have access to affordable and innovative health products.

4. EU4Health and innovation

This section discusses how the EU4Health Programme can support the innovation in the field of health. During the stakeholder consultation participants were asked which are the areas of innovation in health where the Programme can provide the most added value and what are the tools that we could use to achieve it.

The fields highlighted by the stakeholders include digital health, patient integration, innovative financing, and innovation sandboxes.

Digital health

The survey participants have identified digital health as one of the pillars where EU4Health can support innovation. The areas identified include the unified digital health and the single health data market which are based on the adoption and implementation of the EHDS. Key aspects that should be taken into account are the interoperability of the systems and the progressive implementation of the primary and secondary use of data.

Other aspects related to digital health where EU4Health can foster innovation are the novel tools such as the use of AI in the field of health, in particular in combination with a device or a drug.

The digital health innovations are tightly connected to the increased use of wearable devices, the uptake of telemedicine (in particular in remote areas) and the roll-out of e-health throughout Europe.

Patient involvement

Another area where EU4Health can contribute to the innovation is the better/ more frequent involvement of patients in different aspects of healthcare.

The survey participants mentioned that a patient-centric approach would improve the quality of life and the adherence to care. It would also help with the patient's uptake of digital health solutions.

The stakeholders found important the patient integration in early clinical trials and in the research and development phase of new medicines. There is also a need to have an easier access for patients to clinical trials and a favourable environment that would foster clinical trials.

Innovation in the field of radionuclides and nuclear medicine is key to treat serious diseases. A way to promote innovation in this field is to facilitate the organisation of cross border clinical trials in the domain.

Innovative financing

Timely and easy access to financing is a possible obstacle in the path from idea to the widespread solution in the field of health. For this reason, the survey participants have suggested that innovative financing options would promote innovation in health. The tools that can facilitate the innovation are for example calls for proposals for disease specific innovations, efficient reimbursement principles for innovative solutions and, internationally harmonised approaches to joint procurement of medicines. The harmonisation of payment models and reimbursement across different Member States would promote a similar level of access to new medicines in all Member States. The survey participants suggested a better coordination between EU funding instruments when publishing calls for the same or similar topics. Other proposed solutions were the access to finance dedicated for SMEs and public private partnerships in the field of health.

Innovation sandboxes

The survey participants responded that innovation sandboxes to foster experimentation and innovation in the fields of NCDs, including cardiovascular diseases, cancer and diabetes, could provide a conducive environment for testing and scaling new solutions which are dearly needed in this field.

Tools for innovation

The stakeholders responded to the questions on which tools can foster innovation and collaboration within the European Health Union (EHU) to improve prevention and healthcare delivery. Some examples of the suggested tools are:

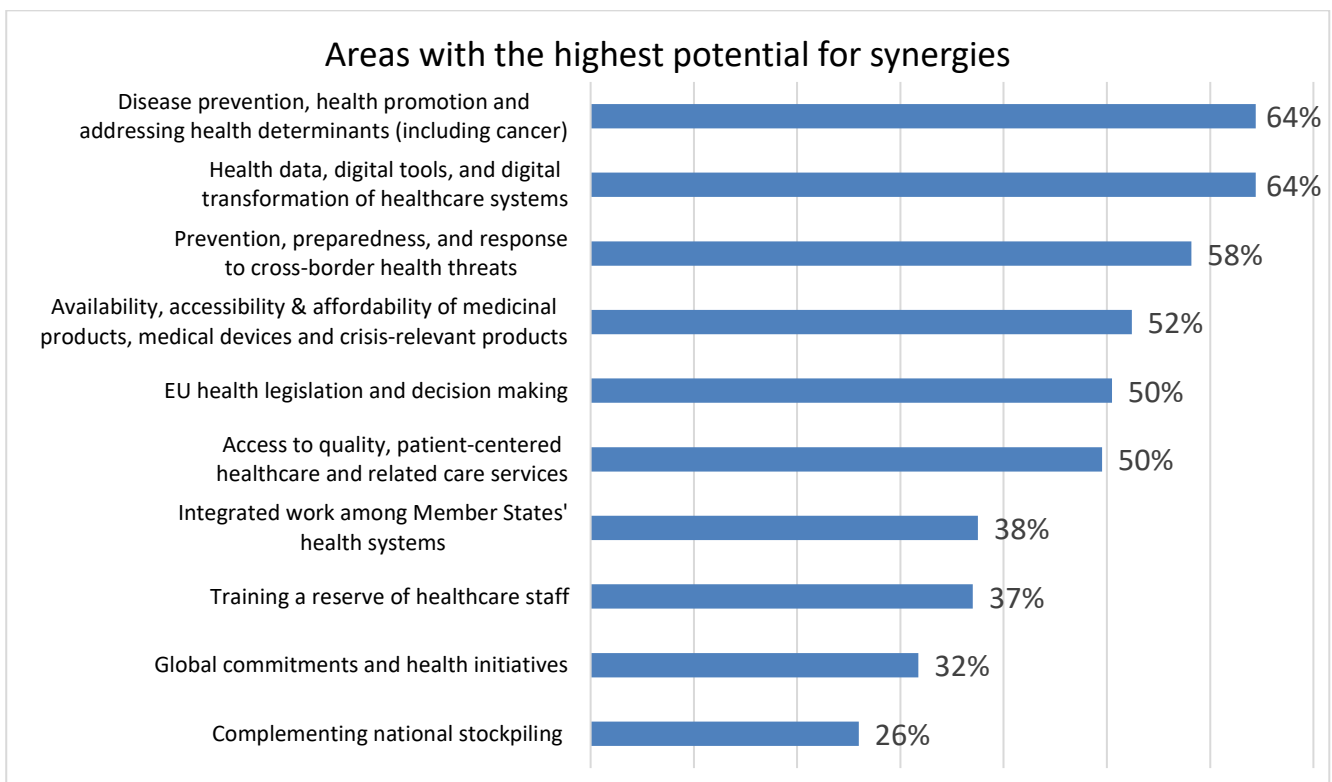
1. **(Regulatory) Sandboxes:** these provide environments to test new medical technologies and regulatory approaches, fostering innovation by allowing controlled experimentation. Sandboxes and accelerated regulatory pathways, closely coordinated with the European Medicines Agency, can facilitate faster patient access to new products. They could be used to test task shifting among healthcare professionals and maximise the current workforce's capacity while maintaining a safe environment for the patients.
2. **EU Missions:** An approach combining research and innovation with new forms of governance, like a missions dedicated to cardiovascular health can spearhead research and innovation in specific health areas.
3. **Common Training Programs:** EU supported health workforce training programs, like those for digital skills and inter-specialty cancer training, are effective for supporting innovation adoption. Training programmes could be used also for developing integrated mental health services and co-creation in healthcare.
4. **Digital Health tools:** These include digital health accelerators, health technology assessments, crowdsourcing, and investment in smartphone-accessible tools that can yield strong returns. Harmonising approaches to digital health technologies among EU countries can foster innovation.
5. **Living Labs:** Living labs involve end users in real world testing, driving practical, patient-centred innovations.
6. **Incentives:** Prolongation of market exclusivity and obligations to develop medicines for diseases in children can boost innovation, especially in case of rare diseases.

Stakeholders emphasise that while sandboxes and living labs are important for innovation, traditional activities such as expert training should not be overlooked.

5. Synergies and collaboration

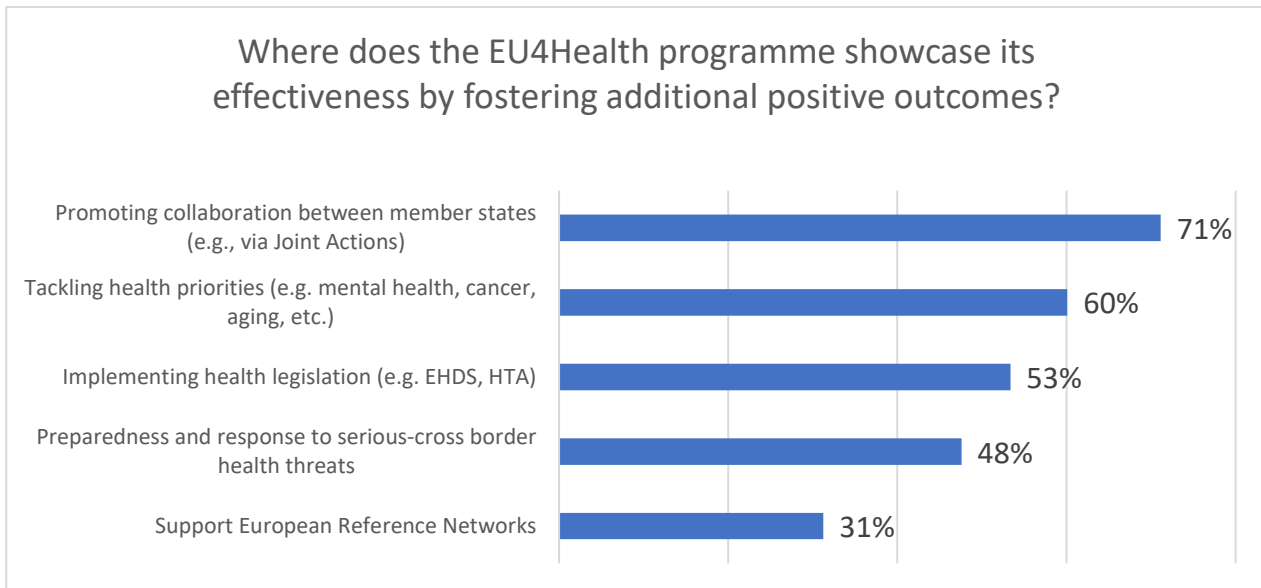
The EU4Health Programme promotes the collaboration between Member States and other stakeholders and is looking to maximise synergies between the national activities and the activities at the European level. For this reason, the Commission has asked the stakeholder “in which areas there is the highest potential for synergies in the scope of actions between the European level and the national level?” Most respondents (64%) marked as most prone to synergies the fields of disease prevention, health promotion and addressing health determinants (including cancer), and the actions on health data and uptake of digital tools and services and the digital transformation of healthcare systems (64%). More than half of respondents (58% and 52% respectively) answered that strengthening the capability for prevention, preparedness, and response to cross-border health threats, and improving the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products have a high potential for synergies.

Figure 5: Percentage of respondents marking a topic as having high potential for synergies (multiple answers allowed; n=208).



To the question “Where does the EU4Health Programme showcase its effectiveness by fostering additional positive outcomes?”, the majority of respondents (71%) replied that it is in promoting collaboration between Member States (e.g. via joint actions). A large share of stakeholders (60%) replied that tackling current and future health priorities and for 53% implementing actions on health legislation contribute to fostering additional positive outcomes.

Figure 6: Percentage of respondents marking a topic as fostering additional positive outcome (multiple answers allowed; n=208).

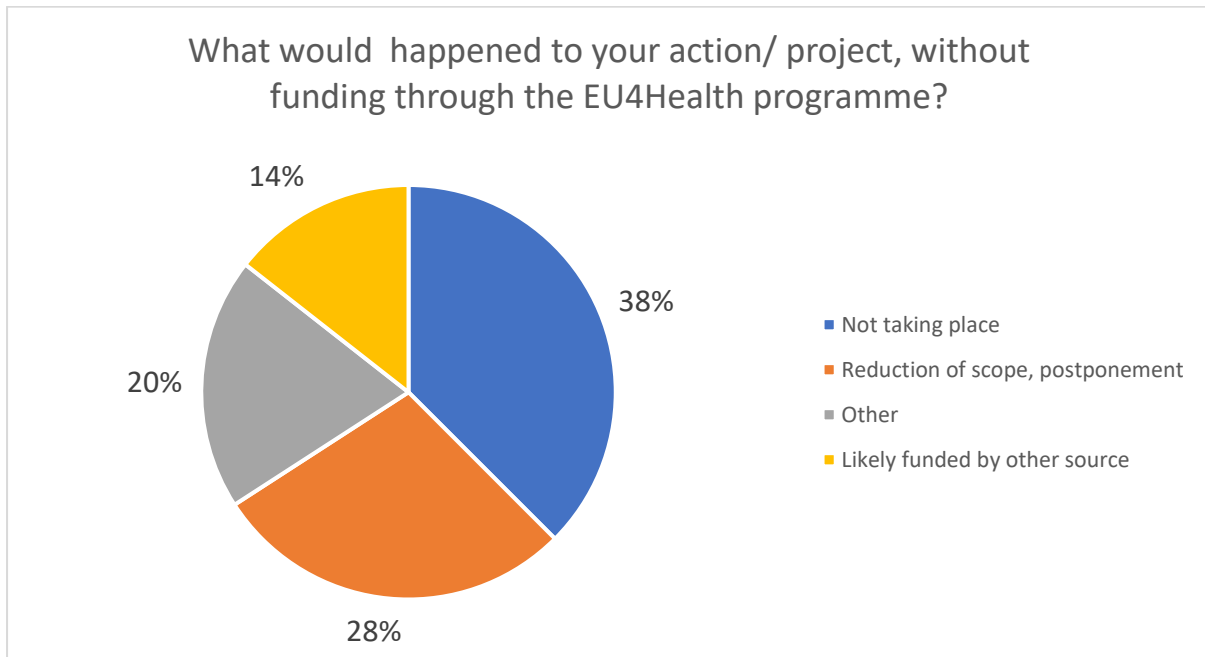


6. Cost of “non- Europe”

The survey participants were asked what (would have) happened to your action/ project, without European level funding through the EU4Health Programme. 38% responded that the action would not have taken place and for 28% the action would have been substantially reduced in scope or postponed. Another 14% of respondents said the action would have likely been funded from other national or European funds. 20% of respondents chose the option “other” as they do not receive EU4Health funding, or the question is not relevant for them.

The responses indicate that EU4Health finances actions that are not covered by other EU or national financing programmes showing the EU added value.

Figure 7: Percentage of respondents per category (n=208).



7. Financing tools

The actions of the EU4Health annual work programme can be implemented in via direct grants (e.g., joint actions or other direct grants), open calls (e.g., action grants, procurement initiatives, and operating grants) or via contribution agreements (indirect management).

The Commission asked the survey participants how they perceived the effectiveness of these tools in addressing the key challenges of building the EHU.

Direct grants

Stakeholders recognise the value of direct grants in advancing the EHU, but also identify several areas for improvement to maximise their effectiveness and efficiency, including funding mechanisms, stakeholder involvement, and administrative processes.

Direct grants are praised for enhancing collaboration across the Member States, fostering innovation, and enabling strategic interventions in health priorities. They also facilitate knowledge exchange, promote capacity building, and help achieve a more coordinated approach to complex health challenges.

A perceived challenge is the co-funding model of the EU4Health Programme (with a requirement of up to 40% or 20% co-funding by the beneficiaries), which deters some organisations from applying due to financial constraints. Additionally, there is an administrative burden and a perceived limited transparency of the results, which can exclude smaller organisations and non-governmental stakeholders.

Stakeholders suggest increasing the availability of 100% co-financing and adopting full cost reimbursement models to encourage wider participation. Improvements also involve establishing dedicated webpages for funding opportunities, streamlining administrative processes, and involving a broader range of stakeholders, including industry and non-institutional actors, to enhance the impact of direct grants.

Open calls

The survey participants highlight that open calls encourage innovation and collaboration by inviting diverse stakeholders to propose projects, fostering a competitive environment that ensures that high-quality initiatives receive funding. Open calls also foster knowledge exchange across sectors and stakeholders. These calls as well support transparency and inclusivity in allocating resources to address Europe's pressing health challenges.

A significant administrative burden and the uncertainty of funding outcomes discourage some organisations from applying, leading to limited responses to calls, and the co-funding requirements and capital barriers further restrict accessibility for many organisations. There are calls for more inclusive and accessible funding opportunities, particularly for civil society organisations and groups representing vulnerable communities, to ensure a broad range of participants and avoid duplication of efforts.

To increase efficiency and appeal, there is a suggestion to implement two-stage applications with an initial low-burden phase and to offer 100% grants to relieve the financial constraints on applicants. Some participants suggested that larger grant budgets would lead to a more significant impact. Stakeholders also emphasise the need for better coordination between different EU funding streams to achieve shared goals and objectives.

Contribution agreements

Stakeholders acknowledge that actions implemented by indirect management, such as contribution agreements, can effectively address challenges in the European Health Union, particularly for rare diseases and cross-border healthcare. This approach also enables resource pooling and improves access to necessary treatments regardless of geographic location.

These mechanisms enable tailored responses, leverage specialised expertise, and facilitate collaboration, but disparities in access to specialised treatments for rare diseases remain a concern.

To improve effectiveness, stakeholders suggest streamlining processes, reducing bureaucratic hurdles, and ensuring timely funding. They also emphasise the importance of establishing networks and communication platforms to improve coordination and sharing of best practices across borders.

Some stakeholders have no strong opinion or lack experience with indirect management to comment on its effectiveness or efficiency.

8. Summary

The survey attracted 210 responses from 26 Member States and 8 non-EU countries. The highest number of respondents were based in Belgium, which reflects the concentration of stakeholder organisations in Brussels. Civil society organisations and Member States' authorities were the most represented respondents.

Most stakeholders perceive that all strands of the EU4Health Programme allocate resources rather effectively. The survey participants identified several priorities for each of the main pillars of the EU4Health Programme that could be addressed in the 2025 work programme and beyond. In the field of prevention, preparedness & response to cross-border health threats, stakeholders emphasise the need for improved cross-border cooperation, workforce training, enhanced surveillance and public health information to effectively prevent, prepare for, and respond to cross-border health threats in the EU.

The identified priorities in health promotion and disease prevention include awareness campaigns, improved health literacy, digital tools, continued work on cancer prevention and screening, addressing social and lifestyle determinants of health, and legislative updates to mitigate risk factors.

A key priority for strengthening healthcare systems should address workforce shortages, followed by the challenge of the digitalisation of health systems and the collaboration as key for bringing optimal care to the patients.

Survey respondents collectively highlight the importance of integrating digital health solutions into the broader healthcare ecosystem, with a focus on enhancing patient outcomes through improved data sharing, interoperability, and the use of emerging technologies, while ensuring data security and addressing misinformation as key priorities in digital health solutions including utilisation of health data and emerging technologies.

To improve access to affordable and innovative medicines, medical devices and other crisis-relevant products the stakeholders emphasised the need for a multi-faceted approach that includes transparency, education, joint procurement, innovation support, and regulatory reform to ensure that patients across the EU have access to affordable and innovative health products.

The survey participants responded that the EU4Health Programme can support the innovation in health in the fields of digital health, patient-centric care, innovative financing, and innovation sandboxes.

The respondents are of the opinion that EU4Health promotes synergies mostly in the fields of disease prevention, health promotion and for addressing health determinants (including cancer), and on health data and uptake of digital tools and services and the digital transformation of healthcare systems. A key added value of the Programme is the promotion of collaboration between Member States.

The financing tools used for the implementation of the Programme are well suited to achieve the goals, however, the stakeholders propose to reduce the administrative burden and increase the financing rate.

Most survey participants indicate that without EU4Health funding, their actions would not have taken place or would have been substantially reduced in scope showing the EU-added value of the Programme.