

EN

Annex 3

Horizon Europe

Work Programme 2021-2022

4. Health

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Introduction

The European Union and the world are challenged by the first pandemic for just over a century. While it has uncovered vulnerabilities in our social and economic systems, it has also provided new impetus, visibility and recognition of the critical role that health care systems and health professionals play in responding to the needs of people, serving society and underpinning the economy. It also underlined the power of research and innovation in uncovering the knowledge and developing the technologies to respond rapidly and effectively to public health emergencies. In addition to the direct suffering that COVID-19 is causing to symptomatic patients and their families, including long-term COVID-19 symptoms in survivors, the social distancing measures and lockdowns are causing major disruptions in social and economic life aggravating inequalities, loneliness and neglect, but also increasing existential fears, anxieties and distress, with serious negative impact on mental health and well-being. Population groups who are at risk of COVID-19, such as people suffering from co-morbidities and the elderly, are affected by these measures disproportionately but also young people entering and establishing their adult life. There is thus an urgent need for research and innovation to understand the long-term effects of both COVID-19 and the social distancing measures on people's health and well-being, and in turn develop effective responses for a solid recovery of the European Union. Research conducted during the pandemic and following its sequels is pivotal to inform preparedness for potential similar events in the future. The pandemic has also demonstrated the downside of globalisation in which the dependence on global value chains can quickly result in shortages of critical supplies, such as essential medicines or other health technologies.

To help repair the economic and social damage caused by the coronavirus pandemic, the European Commission, the European Parliament and European Union leaders have agreed on a Recovery Plan for Europe that will lead the way out of the crisis and lay the foundations for a modern and more sustainable European Union. The Health cluster will put the focus of this work programme mainly to this endeavour, which will benefit from financial resources from the next Multiannual Financial Framework and from NextGenerationEU (NGEU), the European Union's financing instrument to boost the recovery. It requires research and innovation supporting the recovery of people and communities from COVID-19 but also for making society more resilient and health systems better prepared to any future public health emergency. The Recovery Plan aims the European Union to building back better, which also entails supporting the twin digital and green transitions by unlocking the full potential of data-enabled research and innovation for digitised health systems and a competitive and secure data-economy, including on the basis of European Electronic Health Records as well as the establishment of the European Health Data Space. The digital transformation of health and care will certainly help increase the capacity of health care systems to deliver more personalised and effective health care with less resource wasting. It will contribute but it is not sufficient for making the European Union the first climate-neutral continent by 2050, with zero pollution and zero waste. Additional efforts are needed to make also the delivery of health care, the design of health technologies and their manufacturing more sustainable by

reducing energy consumption, waste, pollution and the release of harmful substances, including pharmaceuticals, into the environment.

Even though research and innovation has the power to uncover the knowledge and developing the technologies to serve societal well-being, economic prosperity and environmental sustainability, it only can succeed through cooperation of the best research teams with the prospective users of such knowledge and technologies. It is thus of the utmost importance to involve those users - like patients and healthy citizens, health care professionals providers and payers, public health authorities and regulators, researchers or innovators from academia and industry - early in the knowledge generation or technology development process, including through patient/citizen engagement, community involvement or other forms of social innovation approaches, such that research and innovation activities are adjusted to the users' particular expectations, needs, constraints and potential.

Nevertheless, the pandemic shows also the importance of effective coordination among European Union countries in the area of health. The European Commission is building a strong European Health Union, in which all European Union countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer. Stronger common preparedness and response will rely on greater input from European Union agencies and bodies, including the newly created EU Health Emergency preparedness and Response Authority (EU-HERA).

Horizon Europe is the research and innovation support programme in a system of European and national funding programmes that share policy objectives. Through the programme, special attention is given to ensuring cooperation between universities, scientific communities and industry, including small and medium-sized enterprises, and citizens and their representatives, in order to bridge gaps between territories, generations and regional cultures, especially caring for the needs of the young in shaping Europe's future. Moreover, accelerating the performance and boosting the use and impact of research and innovation also requires it to make use of complementary capacities, such as European research, innovation and space infrastructures and services, or to develop complementary activities in synergy with other European Union funding programmes. Applicants should consider and actively seek synergies with, and where appropriate possibilities for further funding from, other R&I-relevant EU, national or regional programmes such as: EU4Health, Digital Europe Programme (DEP), European Regional Development Fund (ERDF), European Social Fund (ESF+), Structural Reform Support Programme (SRSP), Just Transition Fund (*JTF*), *European Maritime and Fisheries Fund (EMFF)*, European Agricultural Fund for Rural Development (*EAFRD*) or InvestEU. Additionally, to encourage multi-actors approaches and to be more effective in achieving impact, applicants could consider synergies with relevant initiatives funded at EU level, including the Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT). The innovation ecosystems created and nurtured by the EIT KICs can in particular contribute to building communities or platforms for coordination and support actions, sharing knowledge or disseminating and fostering the exploitation of the project results (the proposals are also encouraged to explore

other forms and means of service provisions distinct to the EIT KICs, in particular EIT KIC Health and EIT KIC Digital).

All could help to support the development of skills and capacities in research or health systems, as well as accelerating the take-up and use of scientific evidences, new technologies and best practices in health care and by health systems, industries and markets, at national or regional level.

As examples, the EU4Health programme can make an important contribution to better implementation of research results. It can provide additional financing to strengthen the piloting of innovative practices developed within the Horizon Europe actions, like for example the partnership on Transforming Health and Care Systems. Piloting and implementation can also be supported for other research results which cannot be translated into marketable products but are rather improvements of health relevant methods and approaches.

The ERDF focuses, amongst others, on the development and strengthening of regional and local research and innovation ecosystems and smart economic transformation, in line with regional/national smart specialisation strategies. It can support building research and innovation capacities and uptake of advanced technologies and roll-out of innovative solutions from the Framework Programmes for research and innovation through the ERDF.

The EU's Recovery and Resilience Facility (RRF), currently available in all Member States, aims at financing projects that directly tackle the economic and social impacts from the Coronavirus crisis and support the green and digital transition. For project ideas that directly contribute to these objectives and that have a strong focus in one Member State it is advisable to check access to the RRF for a fast and targeted support.

Notwithstanding the synergies mentioned above, the work programme 2021-2022 of cluster 1 'Health' captures synergies with other clusters based on the challenges and areas of intervention of each destination. Further synergies are encouraged with regard to complementary funding opportunities provided by topics in other clusters and other pillars of Horizon Europe, notably in the European Research Infrastructure work programme (under pillar I) and the European Innovation Council work programme (under pillar III). Additional synergies could also be explored at project-level, i.e. between the portfolio of projects funded either under the same topic or by establishing a portfolio of projects funded under different topics (of the health cluster, of the other clusters 2-6, or of the pillars I/III of Horizon Europe). In particular, applicants to calls of the health cluster are encouraged to consider, where relevant, the services offered by the current and future EU-funded European Research Infrastructures, including the European Open Science Cloud as well as the European Satellite-based Earth observation, positioning and timing services.^{1,2,3}

¹ 2018 Roadmap of the European Strategy Forum on Research Infrastructures (ESFRI) with the ESFRI research infrastructures list (pp 15-17), https://ec.europa.eu/info/sites/info/files/research_and_innovation/esfri-roadmap-2018.pdf; European Research Infrastructures, Commission website: <https://ec.europa.eu/info/research-and->

The work programme 2021-2022 of cluster 1 'Health' is directed towards two Key Strategic Orientations (KSOs) for research and innovation set by Horizon Europe's strategic plan 2021-2024, notably to creating a more resilient, inclusive and democratic European society (KSO-D) and promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains (KSO-A). It aims to mainly contribute to four impact areas of the strategic plan: Good health and high-quality accessible health care; A resilient EU prepared for emerging threats; High quality digital services for all; and A competitive and secure data-economy.

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[innovation/strategy/european-research-infrastructures_en](#); List of entities legally established as European Research Infrastructure Consortium (ERIC) <https://www.eric-forum.eu/the-eric-landscape/>.
² European Open Science Cloud (EOSC) <https://www.eosc-portal.eu/>; [European COVID-19 Data Platform](#) / COVID-19 Data Portal <https://www.covid19dataportal.org/>

³ European space technology based earth observation, positioning, navigation and timing services provided by: Copernicus, the European Union's Earth observation programme <https://www.copernicus.eu/en/copernicus-services>; Galileo, the European Global Satellite Navigation System (GNSS) <https://www.gsc-europa.eu/galileo/services/galileo-initial-services>; and the European Geostationary Navigation Overlay Service (EGNOS) <https://www.gsa.europa.eu/egnos/services>.

Other Actions not subject to calls for proposals

1. Mobilisation of research funds in case of Public Health Emergencies

As part of the EU response to the Covid-19 pandemic, and to the raising spread of SARS-CoV-2 variants, grants will be awarded without a call for proposals according to Article 195 (b) of the EU Financial Regulation⁴ and the relevant provisions of the Horizon Europe Framework Programme and Rules for Participation to address this exceptional emergency.

The Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be communicated to the National Contact Points. The invitation to apply for funding may be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances (“extreme urgency” due to the COVID-19 pandemic).

Specific derogations and additional conditions may be announced or directly communicated to the potential applicants. Such conditions will include additional exploitation obligations to ensure that the resulting products will be available and accessible as soon as possible, additional dissemination obligations and additional open science obligations applicable in case of public health emergencies, evaluation ranking based on proposal contribution to the achievement of specific policy objectives and designation that entities from specified third countries are eligible for funding. They may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Expected Impact: Proposals should set out a credible pathway to contributing to one or several of the following expected impacts: Health care providers are able to better tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients effectively thanks to better understanding and treatment of diseases, more effective and innovative health technologies, better ability and preparedness to manage epidemic outbreaks and improved patient safety.

Expected Outcome: Project results are expected to contribute to the following expected outcome: Allow the European Union to respond to Public Health Emergencies.

Scope:

On January 30 2020 WHO declared the COVID 19 outbreak a public health emergency of international concern. One year later, the Pandemic is still not under control.

⁴ Article 195 (b) of the Financial Regulation 2018/1046 "Grants may be awarded without a call for proposals only in the following cases: [...] (b) in other exceptional and duly substantiated emergencies;"

While vaccines are now becoming available and being used, COVID 19 variants are increasingly of concern – because of their potential to affect transmissibility, severity of disease and vaccine effectiveness.

An additional concerted EU effort is needed to further speed up the process of understanding the occurrence and spread of variants and their effect on disease severity and vaccine effectiveness.

For this reason, in 2021, this Cluster will include two different specific actions:

- Support for the development of large scale, COVID19 cohorts and networks beyond Europe's borders, forging links with European initiatives as a global response to the pandemic;
- Conduct of vaccine & therapeutic trials to boost prevention and further inform public health policy and clinical management

It is expected that quality-controlled data are shared in accordance with the FAIR⁵ principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum funding rate and conditions for providing financial support to third parties, are provided in the General Annexes.

The following derogations to the eligibility conditions contained in the General Annexes apply:

Due to the urgency of this action, legal entities established in Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Kosovo⁶, Moldova, Montenegro, Morocco, North Macedonia, Norway, Serbia, Switzerland, Tunisia, Turkey, United Kingdom and Ukraine are eligible for funding from the Union even if the Horizon Europe association agreement with the third country concerned does not apply at the time of signature of the grant agreement.

The consortium must include at least one independent legal entity established in a Member State and at least two other independent legal entities each established in different Member States or countries listed above.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Research and Innovation Actions – Grant awarded without call for proposals according to Financial Regulation Article 195 (b)

Indicative timetable: Second quarter 2021

⁵ FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. <https://www.openaire.eu/how-to-make-your-data-fair>

⁶ This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Indicative budget: EUR 90.00 million from the 2021 budget

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Budget⁷

	Budget line(s)	2021 Budget (EUR million)	2022 Budget (EUR million)
Other actions			
Grant awarded without a call for proposals according to Financial Regulation Article 195 (b)		90.00	00.00
	<i>from 01.020210</i>	<i>90.00</i>	<i>00.00</i>
Estimated total budget		90.00	00.00

⁷ The budget figures given in this table are rounded to two decimal places. The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.