HORIZON-HLTH-2027-02-DISEASE-01-two-stage: Innovative healthcare interventions for non-communicable diseases

Call: Cluster 1 - Health (Two stage - 2027)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 7.00 and 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 63.80 million.
Type of Action	Research and Innovation Actions
Admissibility conditions	The conditions are described in General Annex A. The following exceptions apply: Applicants submitting a proposal for a blind evaluation (see General Annex F) must not disclose their organisation names, acronyms, logos nor names of personnel in the proposal abstract and Part B of their first-stage application (see General Annex E).
Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding. If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used). Subject to restrictions for the protection of European communication networks.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: For the first stage, the thresholds for each criterion will be 4 (Excellence) and 4 (Impact). The overall threshold applying to the sum of the two individual scores will be set at a level that ensures the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget, and not less than two and a half times the available budget.

	For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: The first-stage proposals of this topic will be evaluated blindly.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: The granting authority may, up to 4 years after the end of the action, object to a transfer of ownership or to the exclusive licensing of results, as set out in the specific provision of Annex 5. Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025) [228].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- Researchers, developers and clinical practitioners have access to state-of-the-art knowledge, data, technologies, tools, methods, best practices, and trainings to develop innovative healthcare interventions aimed at reducing burden of the following specific Non-Communicable Diseases (NCDs): cardiovascular diseases, diabetes, chronic respiratory diseases or chronic kidney diseases.

- Scientific and clinical communities can use innovative healthcare interventions to generate meaningful advances in clinical practice and care for patients with NCDs following validation in late-stage clinical trials.

- Scientific and clinical communities make wide use of relevant databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR [229] principles, thereby encouraging further use of the data.

[228] This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ls-decision_he_en.pdf

[229] See definition of FAIR data in the introduction to this Work Programme part.

- Policymakers, scientific and clinical communities, developers, patient organisations, regulators, and other relevant bodies are informed of the research advances made and the requirements for a widespread implementation of the innovative therapeutic interventions and complementary approaches.

- Patients and caregivers are constructively engaged with the research, ensuring that their needs are catered for, with the aim of tangibly benefitting from the interventions.

Scope: NCDs represent over 80% of the disease burden in Europe and the leading cause of avoidable premature deaths. Innovative and effective healthcare interventions are required to provide treatment and disease management solutions and assure best quality of care for patients suffering from NCDs when prevention strategies have failed.

Proposals should address all the following aspects:

- Perform rigorous early stage[230] clinical trial(s) to validate novel or refined healthcare interventions[231] for treatment and/or disease management solutions for patients suffering from the following specific NCDs: cardiovascular diseases, diabetes, chronic respiratory diseases or chronic kidney diseases [232] . Whenever relevant, existing co- and multimorbidities should be addressed in the trial design.

- Clinical trial(s) should be supported by completed proof-of-concept[233] of clinical safety and efficacy.

- Both preclinical research and the draft clinical trial protocol should be completed at the time of submission of the proposal. Proposals should also demonstrate evidence of preliminary consultations with ethics and regulatory authorities at the time of submission.

- A sound feasibility assessment, including an appropriate patient selection and realistic recruitment plans, justified by publications or preliminary results should be provided.

- Take into account sex and gender differences in all relevant aspects throughout the research process, and consider stratification criteria such as age, disability, racial or ethnic origin[234], socio-economic status, genetic and epigenetic variations, etc., where relevant.

- Use and/or develop technologies, including digital ones (e.g. (generative) Artificial Intelligence, wearable technologies) to help implement and monitor the long-term efficacy of the intervention(s), as well as manage the disease and/or monitor their progression (e.g. with unobtrusive technologies suitable for patient monitoring at home and in real-world conditions), whilst also ensuring they are bias-free, inclusive, and ethically sound.

230 For pharmacological interventions: phase 1 and/or phase 2 clinical trials.

231 Applicants may address any mono- or combinatorial pharmacological and/or non-pharmacological interventions.

232 Other diseases are not within the scope of this topic.

233 Comparative effectiveness studies are not within the scope of this topic.

234 The use of the term ‘racial or ethnic origin’ does not imply an acceptance of theories that attempt to determine the existence of separate human races.

Hardware and software should be interoperable in line with internationally accepted standards[235]. The use of virtual human twins[236] could also be considered, where relevant.

- Exploit existing data, health data infrastructures[237], biobanks, registries and/or cohorts, together with the generation of new data that should be managed in line with the FAIR principles and contribute to emerging research infrastructures established in the framework of the European Health Data Space (EHDS)[238], when relevant.

- Advance research by leveraging already existing and emerging state-of-the-art research infrastructures as well as results stemming from EU-supported research projects, where applicable.

- Engage all relevant stakeholders (especially patients and patients' representatives, caregivers, clinicians, counsellors, regulators, etc.) to design end-user optimised interventions.

- Engage with national public health authorities and regulators to ensure a robust development pathway and further uptake of the intervention.

- Present a thorough health-economic assessment and Real-World Data (RWD)[239] analysis to enhance sustainability and scalability of novel interventions.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs) [240] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, institutions as well as the inclusion of relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

All projects funded under this topic are encouraged to participate in networking and joint activities, as appropriate[241] and explore potential synergies with projects funded under the EU4Health Programme (2021-2027)[242] in the area of NCDs.

---

235 For digital technologies concerned, appropriate measures for the security of the communications between the intended parties should be considered, in particular based on the use of post-quantum cryptography.

236 https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins

237 For instance BBMRI, ELIXIR, EU-OPENSCREEN, ECRIN, EATRIS, etc.

238 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

239 EMA definition: "Real-World Data are routinely collected data relating to patient health status or the delivery of healthcare from a variety of sources other than traditional clinical trials (e.g. claims databases, hospital data, electronic health records, registries, mhealth data, etc.)".

240 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361

241 Proposals should include a budget for the attendance to regular joint meetings and may consider covering the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase.

242 https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en