HORIZON-HLTH-2027-02-IND-02-two-stage: Portable and versatile Point-of-care diagnostics

Call: Cluster 1 - Health (Two stage - 2027)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 5.00 and 7.00 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 39.30 million.
Type of Action	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). In line with the "restriction on control in innovation actions in critical technology areas" delineated in General Annex B of the General Annexes, entities established in an eligible country but which are directly or indirectly controlled by China or by a legal entity established in China are not eligible to participate in the action.
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 four times the available budget, and not less than three 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) [449].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Maintaining an innovative, sustainable, and competitive EU health industry". 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:

- Healthcare professionals dispose of diagnostic tools at the point of care that accelerate therapeutic decision making.
- Patients benefit from fast and accurate diagnosis leading to improved health outcomes.
- Thanks to more efficient diagnosis, health systems will get better evidence for disease control and prevention strategies.

Scope: Point-of-Care (PoC) medical testing has made great technical progress (e.g. improved extraction, microfluidics, miniaturisation, and data processing techniques) with PoC test accuracies nearly matching those of lab-based tests. PoC tests may thus be an alternative to laboratory testing methods, enabling faster diagnostic results and therapeutic decision making.

[449] 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

However, PoC testing is not always achieving a completely accurate diagnosis and one of the major issues with PoC diagnostics is the occurrence of false results during testing, another one is the often-cumbersome sample preparation. Hence there is a need for PoC diagnostics that are more sensitive, selective and easy-to-use allowing for improved clinical practice.

The World Health Organization (WHO) has defined a set of criteria for PoC diagnostics in primary care which, in the advent of digital technologies, has been completed with two additional features and is represented by the acronym REASSURED: Real-time connectivity, Ease of specimen collection and environmental friendliness, Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free (or equipment-modest) and Deliverable to end users. To these criteria adds the feature of "sample-to-answer" (sometimes also called "sample-to-result") and more challenges like: Miniaturisation, power supply, versatility (nature and origin of the human sample), biocompatibility of the used materials and their suitability for mass production, readiness for high-throughput testing, quality control, regulatory compliance, environmental footprint and, last but not least, cost, which is of particular concern in resource-limited settings. All these challenges are not only valid for PoC diagnostics developed for infectious diseases, they equally apply to those that are designed to detect non-communicable diseases as well as their continuous monitoring on patients. Mobile technologies are playing an important role, especially since around 70% of the globally 7.4 billion cell phone users live in developing countries, which are the areas in direct need of advanced and more accessible PoC diagnostics (lower density of relevant health infrastructure, e.g. hospitals and laboratory medicine testing facilities). Mobile phones have not only been proposed and tested for data acquisition and readout of assays, images and other results but also for sample processing (e.g. for heating step), as have been Machine-Learning/Artificial Intelligence (ML/AI) powered algorithms that are integrated in the diagnostic devices to analyse complex biological data and detect patterns that might be missed by human analysis.

The selection of the PoC device to be developed or optimised should be based on an objectively conducted clinical needs assessment, which includes -next to clinicians' perspectives- the complete care pathway and system-level needs. Moreover, a value-based concept should be applied in the choice and development of the PoC device, taking into account its Health Technology Assessment (HTA) by the relevant HTA bodies, in order to facilitate their decisions for adoption.

Proposals should be driven by a clear clinical need, integrate a value-based concept and include all the following activities:

- The optimisation of (the) targeted PoC diagnostic device(s) that take(s) the above-mentioned criteria, challenges and aspects into consideration.

- The elaboration of a comparative study clearly demonstrating the added value and improved performance of the optimised PoC diagnostic device(s) as compared to the current state of the art for the targeted diagnostic application.

- The conduct of clinical studies of (the) optimised PoC diagnostic medical device(s) as a preferred information source for their clinical validation; subsequent conformity

assessment in agreement with requisite EU's In-Vitro Medical Device (IVDR) or Medical Device (MDR) regulatory requirements.

In general, priority should be given to approaches that are suitable for resource-limited settings. In case of targeting infectious diseases, priority should be given to approaches enabling the distinction between viral, bacterial or fungal infections. In case of targeting non-communicable diseases, priority should be given to approaches that are used in emergency cases where decisions can have life-saving character.

Applicants invited to the second stage and envisaging to include clinical studies[450] should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

[450] Please note that the definition of clinical studies (see introduction to this Work Programme part) is broad and it is recommended that you review it thoroughly before submitting your application.