Regulatory science to support translational development of patient-centred health technologies

HORIZON-HLTH-2026-01-IND-03

Program:	**Horizon Europe Cluster 1**
Típus:	**Research and Innovation Actions**
TRL szint:	**nem releváns**
Támogatás projektenként:	**4 - 6 M EUR**
Támogatott projektek száma:	**4**
Pályázati felület megnyílik:	**2026.02.10.**
Beadási határidő:	**2026.04.16.**
Felhívás linkje:	LINK

Proposals can cover all types of health technologies, aiming to define improved and novel sources of evidence with proven relevance for regulatory decision-making with a focus on safety and performance throughout their lifecycle, i.e. throughout the continuous process of clinical evaluation. To this end, proposals should address either, or a combination of the following: i) the improvement of existing methodologies and their fitness to specific types or classes of health technologies, including methodology for regulatory assessment and ii) explore and examine to which extent novel information sources as indicated above can be considered as evidence that is satisfactory in view of regulatory needs concerning safety and performance.

Proposals should support the update and refinement of regulatory science on health technologies and contribute actionable information that can be used for improved or novel regulatory policies, rules, guidance documents and other tools with a view to ensuring that European patients and healthcare professionals have access to safe and effective innovative health technologies. Proposals should ultimately contribute to a regulatory environment that makes use of the full spectrum of novel biomedical and bio-digital approaches for clinical investigation and evaluation, while promoting a patient-centred approach to health technology innovation, facilitating the timely entry to market of performant and effective innovations and support their uptake in the health systems and clinical workflows without compromising patient safety.

NKFIH Horizont Európa NCP Csapat

ncp@nkfih.gov.hu

Horizont Europa NCP Magyarország

horizonteuropa.nkfih.gov.hu

Development of cell-free protein synthesis platforms for discovery and/or production of biologicals

HORIZON-HLTH-2027-01-IND-01

Program:	**Horizon Europe Cluster 1**
Típus:	**Research and Innovation Actions**
TRL szint:	**nem releváns**
Támogatás projektenként:	**6 - 8 M EUR**
Támogatott projektek száma:	**5**
Pályázati felület megnyílik:	**2027.02.10.**
Beadási határidő:	**2027.04.13.**
Felhívás linkje:	LINK

The application of synthetic biology, potentially also combined with generative AI, and cell-free biosynthesis open up new avenues for the design, discovery and manufacture of therapeutics not only against infectious diseases, but also non-communicable diseases and equally for vaccines.
The proposed work should address at least two of the following elements:

- Address the bottlenecks that currently hamper the large-scale deployment of CFPS, i.e. the lack of a quality-by-design approach, the need to fully characterise the underlying cell lysates and their critical quality attributes and the need for better understanding of the correlations between specific cell lysate properties and CFPS process parameters, specific product quality attributes (such as protein folding), and CFPS platform performance.
- Use synthetic biology techniques for the design of de-novo biomolecules with specific desired properties (antimicrobial, immunogenic, angiogenic, etc.) and develop suitable cell-free systems for the high-throughput screening of the designed biomolecules.
- Develop novel or optimise existing CFPS platforms for the production of the targeted biomolecule to a Good Manufacturing Practices (GMP) conform process, producing clinical-grade material that can be tested in clinical trials.

NKFIH Horizont Európa NCP Csapat

ncp@nkfih.gov.hu

Horizont Europa NCP Magyarország

horizonteuropa.nkfih.gov.hu

Portable and versatile Point-of-care diagnostics

HORIZON-HLTH-2027-02-IND-02-two-stage

Program:	**Horizon Europe Cluster 1**
Típus:	**Innovation Actions**
TRL szint:	**nem releváns**
Támogatás projektenként:	**5 - 7 M EUR**
Támogatott projektek száma:	**6**
Pályázati felület megnyílik:	**2027.02.10.**
Beadási határidő:	**2027.04.13.**
Felhívás linkje:	LINK

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.

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. 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.

NKFIH Horizont Európa NCP Csapat

ncp@nkfih.gov.hu

Horizont Europa NCP Magyarország

horizonteuropa.nkfih.gov.hu