

KERC Horizon Europe Pillar 2 Webinar

# Work Programme 2025 Introduction





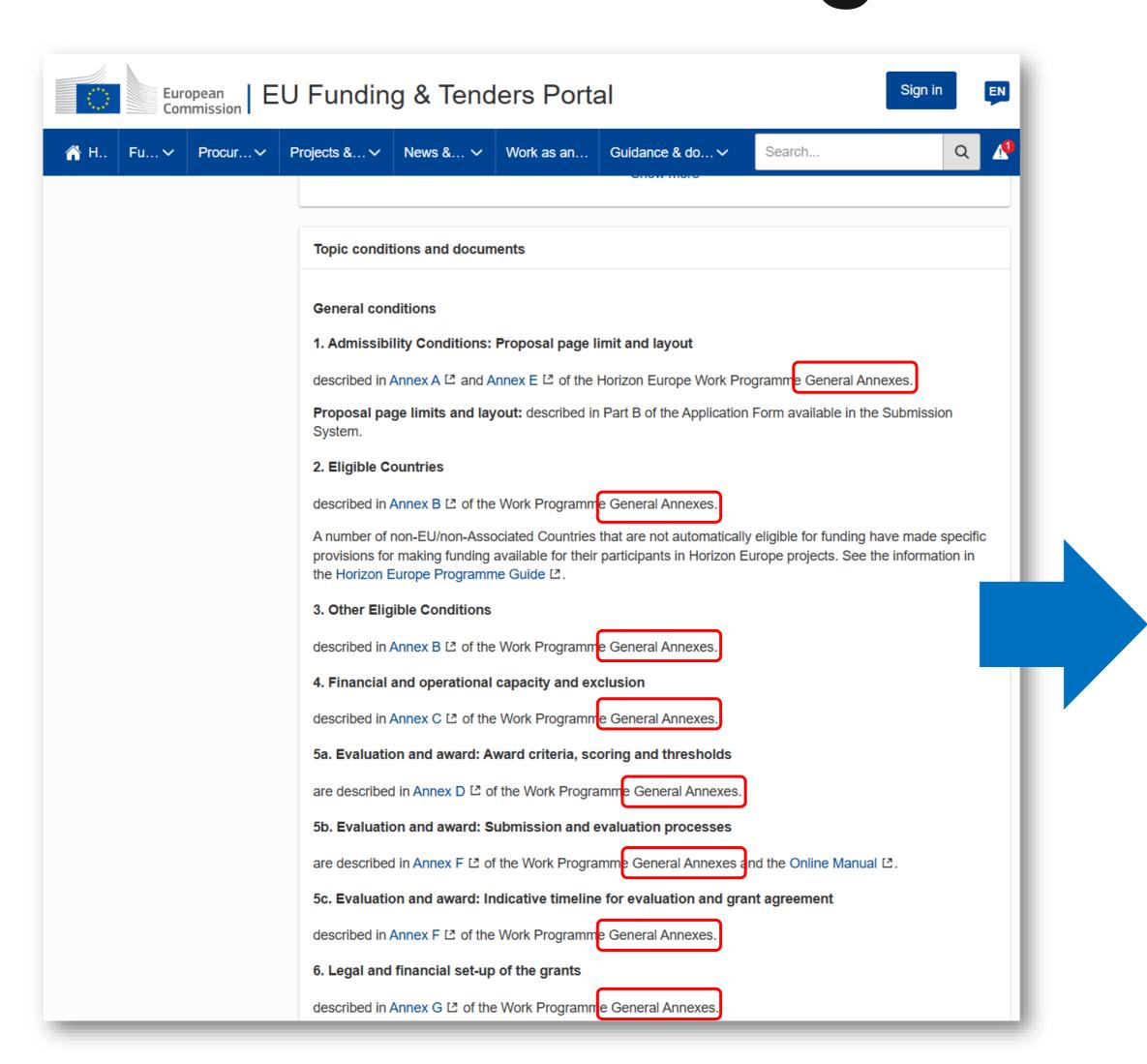
# Pre-publication announced at the end of April

Pre-published work programme 2025 parts:

- General introduction
- Research infrastructures
- Cluster 1 'Health'
- Cluster 2 'Culture, creativity and inclusive society'
- Cluster 3 'Civil Security for Society'
- Cluster 4 'Digital, Industry and Space'
- Cluster 5 'Climate, Energy and Mobility'
- Cluster 6 'Food, Bioeconomy Natural Resources, Agriculture and Environment'
- European innovation ecosystems
- <u>Widening participation and strengthening the European Research Area</u>
- <u>EU Missions</u>
- New European Bauhaus Facility
- General Annexes for 2025

<u>https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/horizon-europe-work-programmes\_en</u>





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- B Eligibility
- C Financial and operational capacity and exclusion
- D Award criteria
- E Documents
- □ F Procedure
- G Legal and financial set-up of the grant agreements
- H Specific conditions



### A-Admissibility

- Call deadline
- Electronic submission
- Forms
- Complete
- Readable, accessible and printable
- Plan for the D&E
- Blind evaluation
- Page limits (45 pages)
  - 45 pages for RIA and IA
  - 30 pages for CSA
  - 50 pages for lump sum funding (RIA & IA)
  - 33 pages for lump sum funding (CSA)



**B-Eligibility** 

- Any legal entity is eligible to participate
- Must be registered in the <u>Participant Register</u>
  - Participant Identification Code (PIC)
  - For the validation, necessary documents will be requested
- Restrictions may apply (check specific call/topic conditions)
- Entities eligible for funding (MS, associated countries...)
- Consortium composition
  - At least one MS entity, and at least two other MS/AC entity
- Eligible activities
- Ethical principles
- Security
- GEP



C – Financial and operational capacity and exclusion

D-Award Criteria

E-Documents

F-Procedure

Funding rate: 100% (RIA) or 70% (IA)

Budget categories and Cost eligibility rules

G-Legal and financial set-up of the grant agreements

### Other documents



- Topic page of the Funding & Tenders Portal
- General Annexes
- Horizon Europe Programme Guide
- EU Funding & Tenders Portal Online Manual
- <u>EU Grants AGA Annotated Grant Agreement</u>

### What's new in 2025?





### EU 연구혁신 주간 동향 보고

<'25.4.30, 한-EU연구협력센터>

- HE 워크프로그램 2025, 자금 지원 방식 간소화 도입 주요 내용(4.28)
- (1) 올해 워크프로그램은 이전보다 더 짧고 덜 규범적(prescriptive) -> 체크 항목을 줄이고, 신청자에게 더 많은 자율성을 제공하여 행정 부담 감소
- (2) **단일 과제 지원 공고 감소** -> 단일 보조금을 놓고 경쟁할 필요 감소, 각 프로젝트가 연구 주제의 모든 측면을 다룰 필요 無
- (3) 2단계 신청 절차 공고 증대 -> 신청 절차 간소화
- ※ 2단계(two stage) 신청절차는 전체 제안서 제출 전에 간략한 요약 제안서를 제출하도록 하여 1단계를 통과하지 못한 신청자의 시간을 절약, 2025년 워크 프로그램에는 2단계로 진행되는 공고가 총 29개 있음
- (4) 럼섬 펀딩 확대 -> 수혜자의 연구비 사용집행실적 보고 요건 완화
- ※ 올해 예산의 35%가 럼섬 펀딩으로 지원, 집행위는 2027년까지 최소 50%의 연구비를 럼섬으로 지급하는 것을 목표로 함
- (5) 'Do No Significant Harm' 원칙 및 AI 도구의 견고성 검증 등 추가 요건에 대한 규칙 개정
- ※ 집행위는 성평등계획(GEP) 요건 간소화도 제안하였으나 회원국들의 반대로 인해 2026년도에 추가적 합의가 이어질 예정
- (6) 블라인드 평가 시범 운영 지속 -> 지난 몇 년 동안 집행위는 2단계 평가의 첫 단계에서 지원자들에게 신원을 공개하지 않도록 요청하여 편향을 방지하는 방안을 검토해 옴
- ※ 예) 루벤대와 같은 호라이즌 선도 기관의 지원서를 평가자가 볼 경우, 단순히 해당 기관의 평판 때문에 지원서를 '훌륭함'으로 평가하는 편향이 있을 수 있음
- (기타) ▲집행위, '유럽 생명과학 전략'에 대한 공공 의견수렴 성황리 종료(4.28)
- ▲집행위, '유럽 연구 및 기술 인프라 전략'에 대한 의견수렴 개시(4.25)
- ▲유럽혁신위원회(EIC) 포럼, EU 스타트업 및 스케일업 전략에 대한 의견 제시(4.25) ▲유럽통계청(Eurostat), '유럽 디지털화 현황 2025' 출간(4.29)

# 2025 pillar 2 open call funding overview (KER®



Cluster	Number of topics	Number of funded projects	Total budget (€M)
1	21	83	923.00
2	32	84	357.30
3	24	61	246.55
4	82	173	1,208.60
5	86	177	1,142.60
6	82	143	948.90
Total	327	721	4,826.95

<sup>※</sup> https://k-erc.eu/wp-content/uploads/2025/05/KERC-Horizon-Europe-Work-Programme-2025-필라2-<u>초안-주요-내용-분석-20250512.pdf</u>

# 2025 pillar 2 open call funding overview (KER®



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#### 클러스터 1 - Health Cluster

#### ① 도달목표(Destinations)별 연구주제수/과제수/예산

구분	도달목표	주제 수 (개)	과제 수 (건)	예산 (백만€)
1	Staying Healthy in a rapidly changing society (STAYHLTH) 건강 유지	1	5	40
2	Living and working in a health-promoting environment (ENVHLTH) 건강에 대한 환경 영향	2	11	80
3	Tackling diseases and reducing disease burden (DISEASE) 질병 퇴치	10	33	459
4	Ensuring equal access to innovative, sustainable, and high-quality healthcare (CARE) 헬스케어	1	2	40
5	Devloping and using new tools, technologies and digital solutions for a healthy society (TOOL) 의료도구/기술/솔루션	4	21	220
6	Maintaining an innovative, sustainable, and competitive EU health Industry (IND) EU보건산업	3	11	84
	총계	21	83	923.00

#### ② 2025년도 공고(Call) 예산 및 예정일

공고번호	도달목표	신청 기간	예산(백만€)
Horizon-HLTH-2025-01	<ul><li>DISEASE</li><li>CARE</li><li>TOOL</li><li>IND</li></ul>	5.22~9.16	486.00
Horizon-HLTH-2025-02	DISEASE(COFUND)	5.13~6.3	133.50
Horizon-HLTH-2025-03 -two-stage	<ul><li>STAYHLTH</li><li>ENVHLTH</li><li>DISEASE</li><li>IND</li></ul>	5.22~9.16	210.00
	총 계		829.50

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#### 클러스터 2 - Culture, Creativity and Inclusive Society

#### ① 도달목표(Destinations)별 연구주제수/과제수/예산

구분	도달목표 (관련 분야)	주제 수 (개)	과제 수 (건)	예산 (백만€)
1	Innovative Research on Democracy and Governance (DEMOCRACY) 민주주의 및 거버넌스	12	27	94.00
2	Innovative Research on European Cultural Heritage and Cultural and Creative Industires (HERITAGE) 유럽문화유산 및 문화창작산업	9	26	154.50
3	Innovative Research on Social and Economic Transformations (TRANSFO) 사회·경제 변혁	11	31	108.80
	총계	32	84	357.30

#### ② 2025년도 공고(Call) 예산 및 예정일

공고번호	도달목표	신청 기간	예산(백만€)
HORIZON-CL2-2025-01	<ul><li>DEMOCRACY</li><li>HERITAGE</li><li>TRANSFO</li></ul>	5.15~9.16	275.10
HORIZON-CL2-2025-02 -two-stage	HERITAGE     TRANSFO	5.15-9.16	22.20
HORIZON-CL2-2025-03	• HERITAGE	5.15-9.16	60.00
	총 계		357.30

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#### 클러스터 3 - Civil security for Society

#### ① 도달목표(Destinations)별 연구주제수/과제수/예산

구분	도달목표 (관련 분야)	주제 수 (개)	과제 수 (건)	예산 (백만€)
1	Better Protect the EU and its citizens against Crime and Terrorism (FCT) 범죄 및 테러 예방	3	13	43.50
2	Effective management of EU external borders (BM) EU 국경 관리	3	9	28.00
3	Resilient Infrastructure (INFRA) 인프라 회복탄력성	2	5	22.00
4	Increased Cybersecurity (CS) 사이버보안	6	16	90.55
5	Disaster-Resilient Society for Europe (DRS) 재난 회복탄력적인 사회	4	10	41.00
6	Strengthened Security Research and Innovation (SSRI) 강화된 안보 연구혁신	6	8	21.50
	총계	24	61	246.55

#### ② 2025년도 공고(Call) 예산 및 예정일

공고번호	도달목표	신청 기간	예산(백만€)
Horizon-CL3-2025-01	<ul><li>FCT</li><li>BM</li><li>INFRA</li><li>DRS</li><li>SSRI</li></ul>	6.12~11.12	156.00
Horizon-CL3-2025-02	• cs	6-12~11.12	90.55
	총 계		246.55

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# 2025 pillar 2 open call funding overview (KER®



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### 클러스터 4 - Digital, Space, and Industry

#### ① 도달목표(Destinations)별 연구주제수/과제수/예산

구분	도달목표 (관련 분야)	주제 수 (개)	과제 수 (건)	예산 (백만€)
1	Achieving global leadership in climate-neutral, circular and digitised industrial and digital value chains (TWIN-TRANSITION) 첨단 제조, 청정 가공 등	14	48	338.00
2	Achieving technological leadership for Europe's open strategic autonomy in raw materials, chemicals and innovative materials (MATERIALS) 원자재, 첨단소재 등	13	36	293.00
3	Developing an agile and secure single market and infrastructure for data-services and trustworthy artificial intelligence services (DATA) 데이터, 인공지능 등	8	18	182.10
4	Achieving open strategic autonomy in digital and emerging enabling technologies (DIGITAL-EMERGING) 양자 기술, HPC, AI 등	13	29	271.00
5	Open Strategic Autonomy in Developing, Deploying and Using Global Space-Based Infrastructure, Services, Applications and Data (SPACE) 우주, 지구관측, 위성 등	20	30	139.00
6	Digital and industrial technologies driving human-centric innovation (HUMAN) 가상세계 등	14	37	107.00
	총계	82	198	1,330.10

### ② 2025년도 공고(Call) 예산 및 예정일

공고번호	도달목표	신청 기간	예산(백만€)
Horizon-CL4-2025-01	1, 2, 4, 6	5.22~9.23	494.00
Horizon-CL4-2025-02	5	5.22~9.25	139.00
Horizon-CL4-2025-03	2, 3, 4, 6	6.10~10.2	404.10
Horizon-CL4-2025-04	3, 4, 6	6.10~10.2	132.00
Horizon-CL4-2025-05-two stage	1, 2	5.22~9.23	161.00
총 2	1,330.10		

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#### 클러스터 5 - Climate, Energy and Mobility

#### ① 도달목표(Destinations)별 연구주제수/과제수/예산

구분	도달목표 (관련 분야)	주제 수 (개)	과제 수 (건)	예산 (백만€)
1	Climate sciences and responses for the transformation towards climate neutrality 기후과학, 기후대응, 기후중립	7	15	101.50
2	Cross-sectoral solutions for the climate transition 기후전환 솔루션	12	35	251.50
3	Sustainable, secure and competitive energy supply 에너지 공급	27	61	407.00
4	Efficient, sustainable and inclusive energy use 에너지 사용	6	17	84.00
5	Clean and competitive solutions for all transport modes 운송 솔루션	19	25	162.60
6	Safe, resilient transport and smart mobility services for passengers and goods 운송 및 스마트 모빌리티 서비스	15	24	136.00
	총계	86	177	1,142.60

#### ② 2025년도 공고(Call) 예산 및 예정일

공고번호	신청 기간(1단계)	예산(백만€)
HORIZON-CL5-2025-01-Two-Stage	5.6~9.2	24.00
HORIZON-CL5-2025-02	5.6~9.2	274.00
HORIZON-CL5-2025-03-Two-Stage	5.6~9.4	7.00
HORIZON-CL5-2025-04	5.6~9.4	174.10
HORIZON-CL5-2025-05-Two-Stage	5.6~9.4	18.00
HORIZON-CL5-2025-06	5.6~9.24	139.50
HORIZON-CL5-2026-01	9.16~1.20	188.00
HORIZON-CL5-2026-02	9.16~2.17	318.00
총계		1,142.60

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#### 클러스터 6 - Food, Bioeconomy, Natural Resources, Agriculture and Environment

#### ① 도달목표(Destinations)별 연구주제수/과제수/예산

구분	도달목표 (관련 분야)	주제 수 (개)	과제 수 (건)	예산 (백만€)
1	Biodiversity and ecosystem services (BIODIV) 생물다양성	12	24	175.00
2	Fair, healthy and environment-friendly food systems from primary production to consumption (FARM2FORK) 식품 시스템	22	37	295.00
3	Circular economy and bioeconomy sectors (CIRCBIO) 순환경제 및 바이오경제	16	29	150.00
4	Clean environment and zero pollution (ZEROPOLLUTION) 청정 환경 및 무공해	8	12	68.00
5	Land, ocean and water for climate action (CLIMATE) 기후 - 육지, 해양, 수질	6	13	94.50
6	Resilient, inclusive, healthy and green rural, coastal and urban communities (COMMUNITIES) 지역 커뮤니티	4	6	37.00
7	Innovative governance, environmental observations and digital solutions in support of the Green Deal (GOVERNANCE) 거버넌스, 환경 관측 및 디지털 솔루션	14	22	129.40
	총계	82	143	948.90

#### ② 2025년도 공고(Call) 예산 및 예정일

공고번호	도달목표	신청 기간	예산(백만€)
Horizon-CL6-2025-01	<ul><li>BIODIV</li><li>CIRCBIO</li><li>ZEROPOLLUTION</li></ul>	5.6~9.17	345.00
Horizon-CL6-2025-02	<ul><li>FARM2FORK</li><li>CLIMATE</li><li>COMMUNITIES</li></ul>	5.6~9.16	352.50
Horizon-CL6-2025-03	GOVERNANCE	5.6~9.24	129.40
Horizon-CL6-2025-01 (two-stage)	<ul><li>BIODIV</li><li>CIRCBIO</li><li>ZEROPOLLUTION</li></ul>	5.6~9.4	48.00
Horizon-CL6-2025-02 (two-stage)	<ul><li>FARM2FORK</li><li>CLIMATE</li></ul>	5.6-9.4	74.00
	총 계		948.90



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**Horizon Europe** 

Work Programme 2025

2. Call information

4. Health

This draft has not been adopted or endo the views of the Commission services and official position of the Commission.

3. Expected impact This draft is made public before the adoption of the work programme to provide prential participants with the currently expected main lines of this work programme Desired Common will have legal value. This draft is made public before the adopt

The adoption of the work programme will be announced on the Horizon Europe website and on the Funding and Tenders Portal.

Information and topic descriptions indicated in this draft may not appear in the final work programme; and likewise, new elements may be introduced at a later stage. Any information disclosed by any other party shall not be construed as having been endorsed by or affiliated to the Commission.

The Commission expressly disclaims liability for any future changes of the content of this document.

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Desiration Tablication and advisation bands
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derived proteins for the prevention and treatment of infectious diseases with epidemic
potential
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HORIZON-HLTH-2025-01-DISEASE-05: Support for the functioning of the Global
Research Collaboration for Infectious Disease Preparedness (GloPID-R)
HORIZON-HLTH-2025-01-DISEASE-06: Implementation research addressing strategies
to strengthen health systems for equitable high-quality care and health outcomes in the
context of non-communicable diseases (GACD)
HORIZON-HLTH-2025-01-DISEASE-07: Tackling high-burden for patients and under-
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#### Horizon Europe - Work Programme 2025

Calls

Call - Cluster 1 - Health (Single stage - 2025)

HORIZON-HLTH-2025-01

Overview of this call2

Proposals are invited against the following De

	Topics
<b>1. Ca</b>	Inumber

	Туре	Budgets	Expected	Indicative
	of	(EUR	EU	number
	Action	million)	contribution	of
		2025	per project	projects
4		2025	(EUR	expected
			million)22	to be
ì				funded

Opening: 22 May 2025 Deadline(s): 16 Sep 2025

Destination - Tackling diseases and reducing dis	ease burd	en		
HORIZON-HLTH-2025-01-DISEASE-01: Testing safety and efficacy of phage therapy for the treatment of antibiotic-resistant bacterial infections	RIA	45.00	Around 15.00	3
HORIZON-HLTH-2025-01-DISEASE-03: Development of antibodies and antibody- derived proteins for the prevention and treatment of infectious diseases with epidemic potential	RIA	50.00	Around 10.00	5
HORIZON-HLTH-2025-01-DISEASE-04: Leveraging artificial intelligence for pandemic preparedness and response	RIA	35.00	6.00 to 8.00	5
HORIZON-HLTH-2025-01-DISEASE-05:	CSA	2.00	Around	1

The Director-General responsible for the call may decide to open the call up to one month prior to or

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	Horizon Europe - Wor Healt	_	me 2025			
	Support for the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)			2.00		
	HORIZON-HLTH-2025-01-DISEASE-06: Implementation research addressing strategies to strengthen health systems for equitable high- quality care and health outcomes in the context of non-communicable diseases (GACD)	RIA	20.00	3.00 to 4.00	5	
	HORIZON-HLTH-2025-01-DISEASE-07: Tackling high-burden for patients and under- researched medical conditions	RIA	30.00	Around 6.00	5	
	Destination - Ensuring equal access to innovative	e, sustain	able, and h	igh-quality hea	althcare	
2. Openi	HORIZON-HLTH-2025-01-CARE-01: End user-driven application of Generative Artificial models in healthcare (GenAI4EU)		40.00	15.00 to 20.00	2	
Deadl	Designation - Developing and using new tools, to speigty	echnologi	ies and dig	ital solutions f	or a healthy	
Dedai	HORIZON-HLTH-2025-01-TOOL-01: Enhancing cell therapies with genomic techniques	RIA	50.00	8.00 to 10.00	5	
	HORIZON-HLTH-2025-01-TOOL-02: Advancing cell secretome-based therapies	RIA	40.00	9.00 to	<b>uda</b>	et
	HORIZON-HLTH-2025-01-TOOL-03: Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)	RIA	50.00	15.00 to 17.00	3	
	HORIZON-HLTH-2025-01-TOOL-05: Boosting the translation of biotech research into innovative health therapies	RIA	80.00	4.00 to 8.00	10	
	Destination - Maintaining an innovative, sustaina	able, and	competitiv	e EU health in	dustry	
	HODIZON HETH 2025 OF DUD OF	т.	40.00	C 00 4- 0 00	_	

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CSA 4.00

6.00 to 8.00 5

Around

4.00

HORIZON-HLTH-2025-01-IND-01:

Therapy Medicinal Products (ATMPs)

HORIZON-HLTH-2025-01-IND-02:

Optimising the manufacturing of Advanced

Digitalisation of conformity assessment

procedures of medical devices and in vitro

### Horizon Europe - Work Programme 2025

diagnostic medical devices		
Overall indicative budget	486.00	

General conditions relating to this call	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G.

#### Call - Partnerships in Health (2025)

### 4. General conditions

Proposals are invited against the following Destinations and topic(s):

Topics	Type of Action	Budgets (EUR million)		Expected EU	Indicative number	
		2025	2026	2027	contribution per project	of projects

The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.

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The Director-General responsible may delay the deadline(s) by up to two months.

All deadlines are at 17.00.00 Brussels local time.

The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for 2025.

Nonetheless, this does not preclude submission and selection of a proposal requesting different

The Director-General responsible may delay the deadline(s) by up to two months. All deadlines are at 17.00.00 Brussels local time.

The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for 2025.

# Type of Action



Research and Innovation Action (RIA)	Innovation Action (IA)	Coordination and Support Action (CSA)
establishes new knowledge and/or explores a new or improved technology, product, process, service or solution.	produces plans or designs for new or improved products, processes or services including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.	improve cooperation between legal entities from the EU and associated countries to strengthen the European Research Area including, for example, standardisation, dissemination, awareness-raising, communication and networking activities, policy dialogues, mutual learning or studies.
The EU funding covers up to 100% of the project costs.	The EU funding covers up to 70% of the project costs.	The EU funding covers up to 100% of the project costs.
TRL 2~6	TRL 6~8	



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developing, and adopting best practices, as appropriate. Therefore, proposals are expected to 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.

Applicants envisaging to include clinical studies<sup>206</sup> should provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

### HORIZON-HLTH-2025-01-TOOL-05: Boosting the translation of biotech research into innovative health therapies

	Call: Cluster 1 - Health (Single stage - 2025)		
	Specific conditions		
	Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 4.00 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 hudget	The total indicative budget for the topic is EUR 80.00 million.	
	Type of Action	Research and Innovation Actions	
	Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply:  In order to prove that the investigational product is ready for clinical testing, proposals must provide evidence of regulatory approval in the EU already in place for phase I clinical study.  The proposed EU contribution going to small and medium-sized enterprises (SMEs) must be 50% or more of the total EU contribution to the project as a whole.  In addition to the eligibility conditions as described in General Annex B, the consortium must be composed of at most 5 legal entities as beneficiaries.  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).	
•	Award criteria	The criteria are described in General Annex D. The following exceptions apply:	

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.

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Procedure	The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 4 (Implementation). The cumulative threshold will be 12.
	The procedure is described in General Annex F. The following exceptions apply:
	Eligible proposals submitted under this topic and exceeding all the evaluation thresholds will be awarded a STEP Seal <sup>207</sup> .

- Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Developing and using new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim to deliver results directed towards and contributing to all the following expected outcomes:
  - · Healthcare providers, researchers and patients get faster access to innovative therapies.
  - The European Union benefits from more clinical trials being conducted with new biotech therapeutic approaches.
  - The competitiveness of small and medium-sized enterprises (SMEs) from the EU and Associated Countries within the health biotech sector is strengthened.

Scope: The Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' 208 has recently identified research and technology transfer to the market as a major challenge for the biotechnology sector. This topic aims to speed up the development of innovative biotechnology-based therapies by supporting the initial phases of clinical research. SMEs play a key role in the EU's potential to innovate, with most biotechnology-derived drugs in development being progressed by SMEs and small biotech companies. However, transitioning from drug discovery and development stages to approved products requires substantial investment and sufficient resources in different areas (e.g., manufacturing, clinical trial management, regulatory affairs, etc.), with the time needed for clinical development often exceeding 10 years 209. This topic targets collaborative multidisciplinary consortia of SMEs, academics, clinicians and research organisations bringing together the necessary expertise to launch the clinical development of novel biotechnology-derived therapeutics. Collaboration with the relevant European research infrastructures is encouraged. This topic does not address the full clinical development needed to bring products to market but aims to support the critical transition phase from preclinical to clinical development by supporting the early clinical phases. A non-exhaustive list of biotechnology-derived therapies in scope include monoclonal antibodies, (therapeutic) vaccines, recombinant biomolecules, Advanced Therapy Medicinal Products (ATMPs), nano-

#### Horizon Europe - Work Programme 2025 Health

based drugs, RNA therapies etc. Whole blood, blood components and other substances of human origin are not within the scope of this topic.

Proposals submitted under this topic should include all the following elements:

- A Clinical study either phase I, II or I/II depending on the appropriate stage of development.
- The proposal should convincingly demonstrate a significant economic potential of the final product(s) for the Single Market.
- A clearly defined exploitation plan, with a detailed proposed route to commercialisation, description of the intellectual property ownership and benefit for the SME(s). The plan should include an anti-shelving strategy, commercial forecasts for the product sales & revenue, and strategies for follow-up financing as well as market authorisation. The exploitation strategy should envisage a first deployment in the EU.
- Justification of the patient populations that will benefit directly from the development of the therapies. Clinical indications where potentially large patient populations could benefit will be favoured.

The maximum project duration should not exceed four years.

Applicants should provide details of their clinical studies<sup>210</sup> in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

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https://strategic-technologies.europa.eu/about/step-seal\_en

https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffe-411b-8ed6-

https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011 2020.pdf

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.

## Thank you!







K-ERC.EU

### Horizon Europe Matchmaking Event

• 1st Korea-EU Horizon Europe Researchers Networking Forum on Artificial Intelligence (1st April)

After-Movie of the 1st Forum: https://www.youtube.com/watch?v=Gz G7RPzvIM











Korea-EU HE & Digital Partnership Researchers Networking Forum on Quantum Technology (9<sup>th</sup> April)
 Organized by KE-QSTCC: <a href="https://k-erc.eu/2025/04/qstcc/24265/">https://k-erc.eu/2025/04/qstcc/24265/</a>







- Korea-EU Horizon Europe Researchers Networking Forum on Advanced Biotechnology (1<sup>th</sup> July)
  - > Call for Applications (deadline 14 May): https://k-erc.eu/2025/05/horizon-europe-category/24560/

### **Next Initiative**

COST (Cooperation in Science & Technology)





and build capacity to address scientific, technological and societal challenges



#### ALL FIELDS OF S&T

(mono- or interdisciplinary, new and emerging fields)



#### ALL PARTNERS

(academia, public organisation, industry, NGO, International Organisations)



CUSCIPEAN COOPERATION

BOTTOM-UP APPROACH



#### LL CAREER STAGES

(young and experienced researchers)



#### ALL COUNTRIES

- 41 COST Full Members
- + 1 Cooperating Member and +1 Partner Member
- 14 Near Neighbour Countries
- Global cooperation

COST Guide book and Webinar for Korea are on its way!