

Dr. Martha Cahill PhD, MBA





National Contact Point for Health, State Representative for the Innovative Health Initiative (IHI)

Horizon Europe Health Opportunities

- Health Program Opened 22nd June 21
- Cancer Mission Q3/Q4
- Innovative Health Initiative (IHI) Q3/Q4
- European Innovation Council (EIC) – Health Challenges
- Future Partnerships (co-funds) 2021 2024



Horizon Europe Strategic Planning

- Horizon Europe budget of €95.5 billion for 2021 2027
- Strategic Plan defines the strategic orientation of the research and
- innovation for 2021-2024 focus on a climate neutral and green Europe & Digitalisation
- Defined Plan for Health : Prepared, increasing resilience to threats and disasters, high-quality healthcare, safe trusted, cost effective tools, technologies and digital solutions, health promotion, disease prevention, diagnosis, treatment, monitoring, decision-making, breakthrough health technologies, strategic autonomy in essential medical supplies and digital technologies, SME's and economic growth.....
- **Missions** 5 Missions tackling some of our greatest EU and global challenges

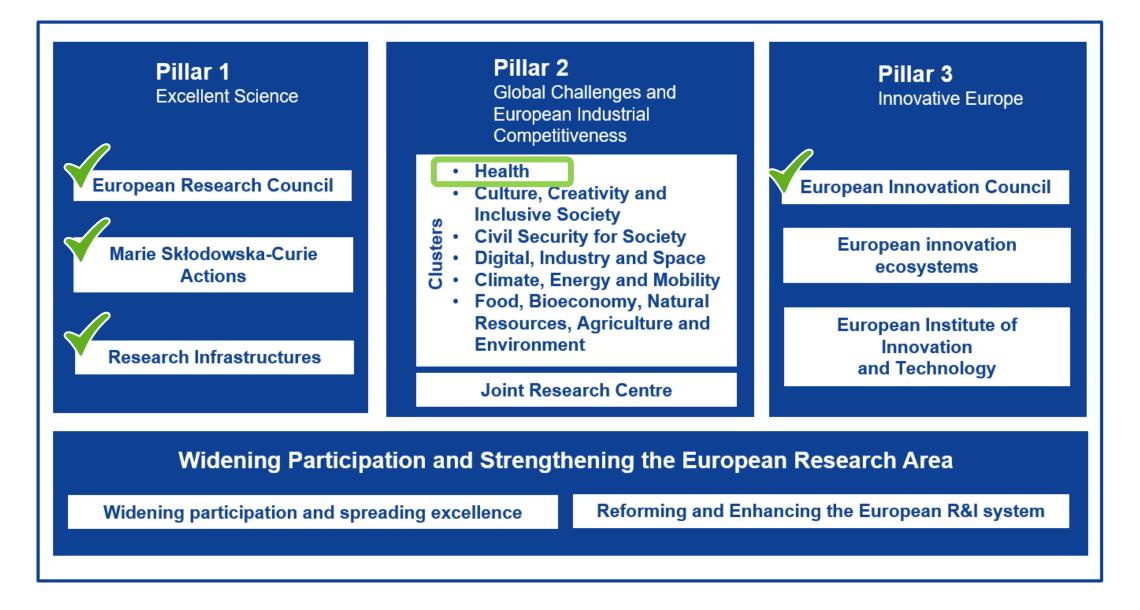
• The Cancer Mission

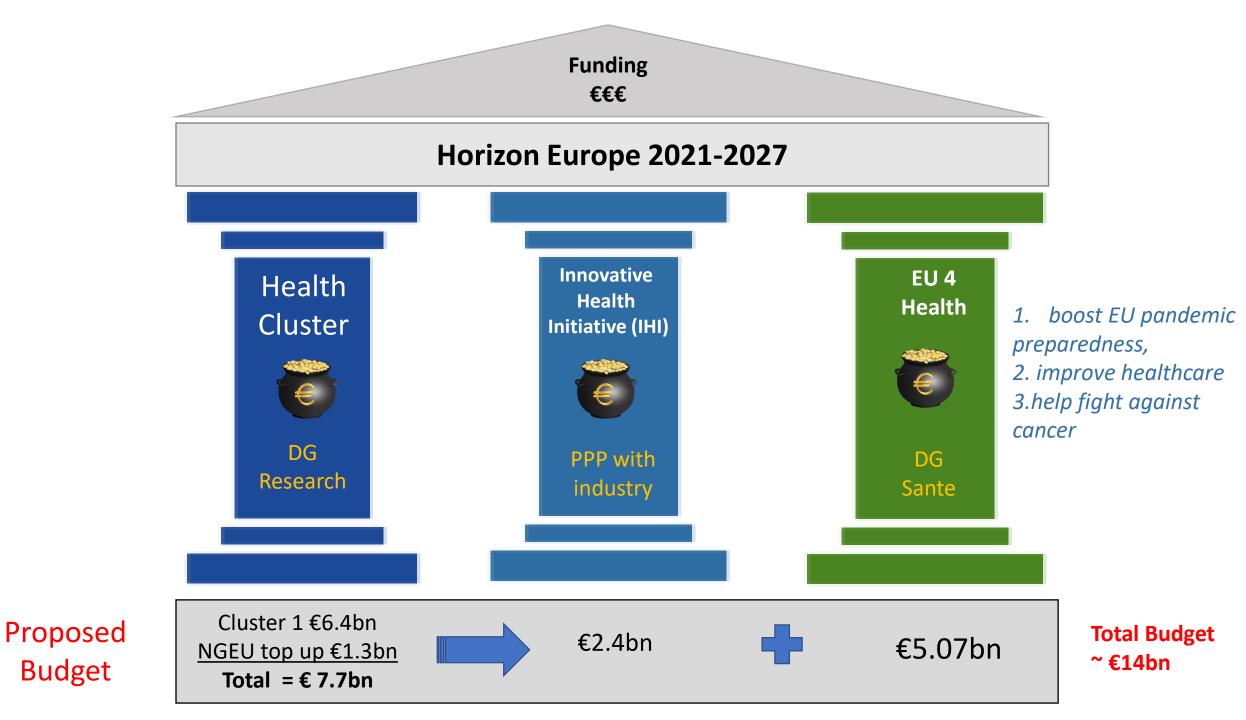
Partnerships – Greater Alignment with Horizon Europe Strategic Plan
PPP– Single Basic Act /Legislation and governance Structure – Innovative Health Initiative (IHI)





Proposed structure for Horizon Europe 2021 - 2027





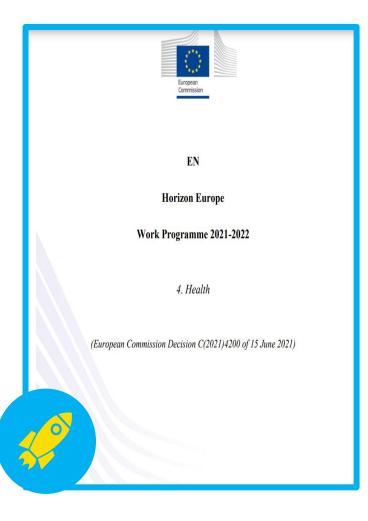
Health Work Programme for 2021 -2022 has now been published

Online link to the work program

~€2bn funding for the first two years.

Horizon Europe First Calls opened on the 22nd June

Apply online EU Funding and Tender Portal



Health Cluster

Research

Health Cluster : Trends and Hot Topics



Health Cluster : Structure of the Work Program

- 2 year work program
- Topics are grouped under each of the six destinations
- They can be single of two stage topics
 - Two stage topics are anticipated to be larger is size, more MS participants but a smaller number of applications.
- The Individual topic budgets now confirmed. i.e., budget/project
- The instrument involved are highlighted : RIA, CSA, PCP, PIP, IA



Health Cluster : Structure of the Work Program

- Research and innovation actions (RIA)
- Collaborated Project
- Consortium of at least 3 independent legal entities
- Established in 3 MS or Associated States
- Focus on research and innovation



- Coordination and Support Action (CSA)
- Activities contributing to the objects of Horizon Europe
- Coordination of co-funding activities
- Widening participation & Spreading excellence

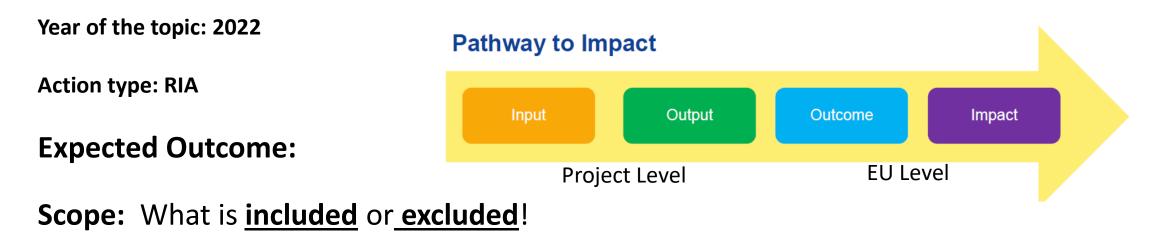


Many Coordination and support actions (CSA's) are Building blocks for future co-funds, partnerships

Topic Structure & Identifiers

HORIZON-HLTH-2022-STAYHLTH--01-05- two-stage: Prevention of obesity through the life course

Conditions related to this topic :Budget details have now been added & include €/Topic, no of projects & € /project



Note:

- Pay particular attention to the expected outcomes and impacts of the destination.
- Take note of referenced documents or policies. These are often in the footnotes.
 - eg., <u>https://www.who.int/cancer/palliative/definition/en/</u>

Cancer Related Topics in the 2021-2022 WP

- The Cancer Mission and Cancer topics will be included in a separate program which is currently under development.
- Some topics included in the Health work program are not restricted to any particular disease area can include Cancer research <u>but you</u> <u>need to read the text carefully</u>.

Topics that specifically exclude Cancer

HORIZON-HLTH-2022- TOOL-11-01: Optimising effectiveness in patients of existing prescription drugs for major diseases (except cancer) with the use of biomarkers,

HORIZON-HLTH-2022-DISEASE-06-two-stage-02: Development of new effective therapies for rare diseases -Rare infectious diseases and rare cancers will not be considered in this call.

HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation immunotherapies for diseases or disorders with unmet medical need -

Footnote: Excluded from the scope are the preventive vaccines, the immunotherapies for rare diseases and the repurposing of drugs as they are covered by other topics in the HE research programme 2021-2022. Research on cancer immunotherapies is excluded as it will be covered by the Mission on Cancer. Therapeutic vaccines are included.

Health Cluster

DG Research

1.Staying healthy in a rapidly changing society

2.Living and working in a health-promoting environment

3. Tackling diseases and reducing disease burden

4. Ensuring access to innovative, sustainable and high-quality healthcare

5.Unlocking the full potential of new tools, technologies and digital solutions for a healthy society

6.Maintaining an innovative, sustainable and globally competitive health industry

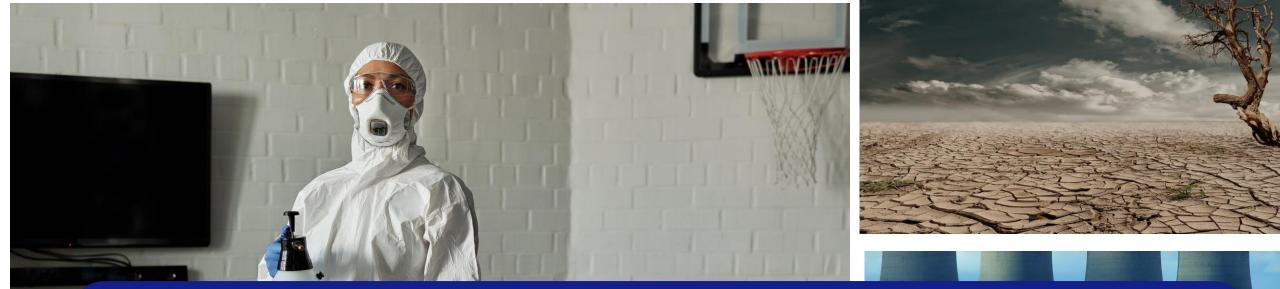


Destination 1

Staying healthy in a rapidly changing society



Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument	Single Stage or 2- Stage?
Destination 1. Staying healthy in a rapidly changing society	69	220		
> Call HORIZON-HLTH-2021-STAYHLTH-01 – Staying healthy (2021)				
HORIZON-HLTH-2021-STAYHLTH-01-02 Towards a molecular and neurobiological understanding of mental health and mental illness for the benefit of citizens and patients	60 🔶	~6 projects x €10m each	RIA	Single Stage
HORIZON-HLTH-2021-STAYHLTH-01-03 Healthy citizens 2.0: Supporting digital empowerment and health literacy	3		CSA	Single Stage
HORIZON-HLTH-2021-STAYHLTH-01-04 A roadmap for personalised prevention	3		CSA	Single Stage
HORIZON-HLTH-2021-STAYHLTH-01-05 Mobilising the network of National Contact Points (NCPs) in the Health Cluster	3		CSA	Single Stage
> Call HORIZON-HLTH-2022-STAYHLTH-01-two-stage – Staying healt	hy (Two stage	e - 2022)		
HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage Boosting mental Health in Europe in times of change		50	RIA	Two Stage
HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non- communicable diseases and/or their progression	~10 projects x €6m each	60	RIA	Two Stage
HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage Prevention of obesity through the life course		60	RIA	Two Stage
> Call HORIZON-HLTH-2022-STAYHLTH-02 Staying healthy (Single sta	ge, 2022)			
HORIZON-HLTH-2022-STAYHLTH-02-01 Personalised blue print of chronic inflammation in health-to-disease transition		50	RIA	Single Stage



Destination 2

Living and working in a health-promoting environment



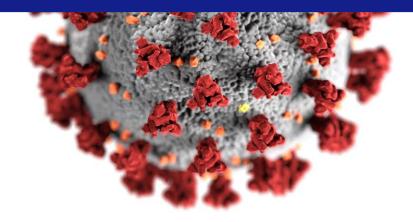
Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument	Single Stage or 2- Stage?
Destination 2. Living and working in a health-promoting environment	130	20		
> Call HORIZON-HLTH-2021-ENVHLTH-02 - Environment and health (2021)			
HORIZON-HLTH-2021-ENVHLTH-02-01 Exposure to electromagnetic fields (EMF) and health	30		RIA	Single Stage
HORIZON-HLTH-2021-ENVHLTH-02-02 Indoor air quality and health	40		RIA	Single Stage
HORIZON-HLTH-2021-ENVHLTH-02-03 Health impacts of climate change, costs and benefits of action and inaction	60		RIA	Single Stage
> Call HORIZON-HLTH-2022-ENVHLTH-04 – Environment and health	(Single Stage	- 2022)		
HORIZON-HLTH-2022-ENVHLTH-04-01 Methods for assessing health-related costs to environmental stressors		20	RIA	Single Stage



Destination 3

Tackling diseases and reducing disease burden





Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument
Destination 3. Tackling diseases and reducing disease burden	4444.5	4738	
> Call HORIZON-HLTH-2021-DISEASE-04 – Tackling diseases (2021)			
HORIZON-HLTH-2021-DISEASE-04-01 Improved supportive, palliative, survivorship and end-of-life care of cancer patients	50		RIA
HORIZON-HLTH-2021-DISEASE-04-02 Building a European innovation platform for the repurposing of medicinal products	50		RIA
HORIZON-HLTH-2021-DISEASE-04-03 Innovative approaches to enhance poverty-related diseases research in sub- Saharan Africa	40		RIA
HORIZON-HLTH-2021-DISEASE-04-04 Clinical validation of artificial intelligence (AI) solutions for treatment and care	60	~10 projects x €6m each	RIA
HORIZON-HLTH-2021-DISEASE-04-07 Personalised medicine and infectious diseases: understanding the individual host response to viruses (e.g., SARS-CoV-2)	60		RIA
HORIZON-HLTH-2021-DISEASE-04-05 A roadmap towards the creation of the European One Health antimicrobial resistance partnership (OH AMR)	0.5	8	CSA
HORIZON-HLTH-2021-DISEASE-04-06: Building a European Research and Innovation Partnership for Pandemic Preparedness	2		CSA CSA

Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument	Single Stage or 2- Stage?
Destination 3. Tackling diseases and reducing disease burden		2359		
> Call HORIZON-HLTH-2022-DISEASE-06-two-stage – Tackling disease	es (Two Stage	- 2022)		
HORIZON-HLTH-2022-DISEASE-06-02-two-stage Pre-clinical development of the next generation immunotherapies for diseases or disorders with unmet medical need		60	RIA	Two Stage
HORIZON-HLTH-2022-DISEASE-06-03-two-stage Vaccines 2.0 - developing the next generation of vaccines		40	RIA	Two Stage
HORIZON-HLTH-2022-DISEASE-06-04-two-stage Development of new effective therapies for rare diseases		60	RIA	Two Stage
> Call HORIZON-HLTH-2022-DISEASE-07 – Tackling diseases (Single St				
HORIZON-HLTH-2022-DISEASE-07-02 Pandemic Preparedness		10	RIA	Single Stage
HORIZON-HLTH-2022-DISEASE-07-03 Non-communicable diseases risk reduction in adolescence and youth (Global Alliance for Chronic Disease -GACD)		25	RIA	Single Stage
HORIZON-HLTH-2022-DISEASE-07-01 Support for the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)		2	CSA	Single Stage



Destination 4

Ensuring access to innovative, sustainable and high-quality healthcare





Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument	Single Stage or 2- Stage?
Destination 4. Ensuring access to innovative, sustainable and high-quality health care	70	70		
> Call HORIZON-HLTH-2021-CARE-05 – Ensuring access to innovative,	, sustainable	and high-qu	ality health care (2	021)
HORIZON-HLTH-2021-CARE-05-01 Enhancing quality of care and patient safety	25		RIA	Single Stage
HORIZON-HLTH-2021-CARE-05-02 Data-driven decision-support tools for better health and care delivery and policy- making with a focus on cancer	40		RIA	Single Stage
HORIZON-HLTH-2021-CARE-05-04 Health and care innovation procurement network	5		CSA	Single Stage
> Call HORIZON-HLTH-2022-CARE-08 – Ensuring access to innovativ 2022)	e, sustainab	le and high-o	quality health care	Single Stage -
HORIZON-HLTH-2022-CARE-08-02 Pre-commercial research and innovation procurement (PCP) for building the resilience of health and care systems in the context of recovery	•	25	РСР	Single Stage
HORIZON-HLTH-2022-CARE-08-03 Public procurement for innovative solutions (PPI) for building the resilience c health and care systems in the context of recovery		15	PPI	Single Stage
HORIZON-HLTH-2022-CARE-08-04 Better financial models for health systems		30	RIA	Single Stage

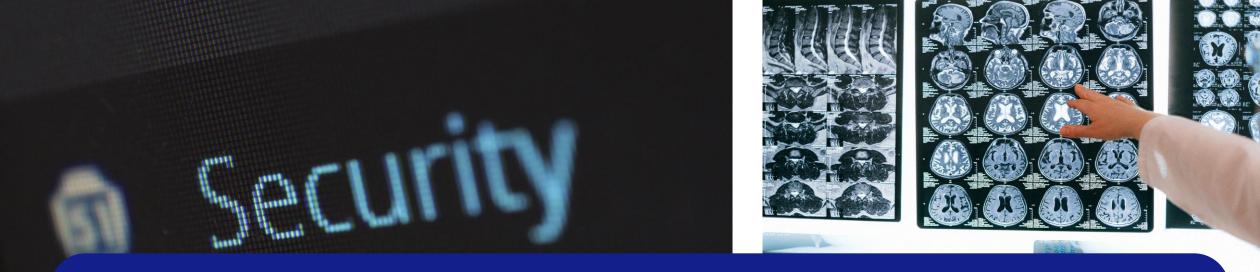


Destination 5

Unlocking the full potential of new tools, technologies and digital solutions for a healthy society



Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument	Single Stage or 2- Stage?
Destination 5. Unlocking the full potential of new tools, technologies & digital solutions for a healthy society	115	155		
> Call HORIZON-HLTH-2021-TOOL-06 – Tools and technologies for a l	healthy socie	ty (2021)		
HORIZON-HLTH-2021-TOOL-06-01 Smart medical devices and their surgical implantation for use in resource- constrained settings TRL 7	25		IA	Single Stage
HORIZON-HLTH-2021-TOOL-06-02 Next generation advanced therapies to treat highly prevalent and high burden diseases with unmet needs	60		RIA	Single Stage
HORIZON-HLTH-2021-TOOL-06-03 Innovative tools for use and re-use of health data (in particular electronic health records and/or patient registries)	30		RIA	Single Stage
> Call HORIZON-HLTH-2022-TOOL-11 – Tools and technologies for a l	healthy socie	ty (Single Sta	age - 2022)	
HORIZON-HLTH-2022-TOOL-11-01 Optimising effectiveness in patients of existing prescription drugs for major diseases <mark>(except cancer)</mark> with the use of biomarkers		60	RIA	Single Stage
HORIZON-HLTH-2022-TOOL-11-02 New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment		35	RIA	Single Stage
> Call HORIZON-HLTH-2022-TOOL-12-two-stage – Tools and technology	ogies for a he	althy societ	y (Two Stages - 202	2)
HORIZON-HLTH-2022-TOOL-12-01-two-stage Computational models for new patient stratification strategies		60	RIA	Two Stages



Destination 6

Maintaining an innovative, sustainable and globally competitive health industry





Topics by 'Destination' or 'Expected Impact'	2021	2022	Instrument	Single Stage or 2 Stage?
Destination 6. Maintaining an innovative, sustainable and globally competitive health industry	44	69		
> Call HORIZON-HLTH-2021-IND-07 – A competitive health-related in	ndustry (2021)		
HORIZON-HLTH-2021-IND-07-01 Green pharmaceuticals	40		RIA	Single Stage
HORIZON-HLTH-2021-IND-07-02 Development procurement and responsible management of new antimicrobials	2		CSA	Single Stage
HORIZON-HLTH-2021-IND-07-03 Promoting a trusted mHealth label in Europe: uptake of technical specifications for quality and reliability of health and wellness apps	2		CSA	Single Stage
> Call HORIZON-HLTH-2022-IND-13 – A competitive health-related in	ndustry (2022)		
HORIZON-HLTH-2022-IND-13-01 Enhancing cybersecurity of connected medical devices		20	RIA	Single Stage
HORIZON-HLTH-2022-IND-13-02 Scaling up multi-party computation, data anonymisation techniques and synthetic data generation		30	RIA	Single Stage
HORIZON-HLTH-2022-IND-13-03 New pricing and payment models for cost-effective and affordable health innovations		15	RIA	Single Stage
HORIZON-HLTH-2022-IND-13-04 Setting up a European Smart Health Innovation Hub		2	CSA	Single Stage
HORIZON-HLTH-2022-IND-13-05 Setting up a European Electronic Health Record Exchange Format (EEHRxF) Ecosystem#		2	CSA	Single Stage

Health Cluster : Proposed Call Opening Dates

Calls	Dates
2021 Calls Open	Opening: 22 nd June 2021– Closing: 21 st Sept 2021
2022 Single Stage Calls	Opening: 6 th Oct 2021 - Closing: 21 st April 2022
Two Stage Calls for 2022	First Stage: Opening: 6 th Oct 2021 - Closing: 1 st Feb 2022
	Evaluation Second Stage – ~March - Closing : 6 th Sept 2022

Take Note of the Conditions in the Annexes

Details in the General Annex – Call Conditions -DRAFT

Pages numbers are limited

- RIA applications the limit for a full application is 45 pages
- Coordination and support actions limited to 30 pages
- Programme co-fund actions limited is 70 pages
- The limit for a first-stage application is limited to 10 pages.



There will be an automatic warning and invitation to re-submit if you exceed your limit.

After the call deadline, excess pages will be automatically made invisible, and will not be taken into consideration by the evaluators.

Associated Countries

- The negotiations formally start in February with discussions on specific terms and conditions. They aim to complete the process with signed agreements before the summer.
- There are 16 non-EU countries, including Switzerland, Norway, Israel and Iceland who are associate members of the EU research programme.
- Depending on the terms of the deal, it may take many months before it could be cleared.

The UK is now an Associated Country

- Top level agreement reached that they would participate in the Horizon Europe
- Need to be considered at least for this year.
- <u>https://ec.europa.eu/info/sites/info/files/research_and_innovation/strate</u> <u>gy_on_research_and_innovation/documents/ec_rtd_uk-participation-in-</u> <u>horizon-europe.pdf</u>



EU Science & Innovation – YouTube Channel



Webinar: How to prepare a successful proposal in Horizon Europe

Standard Proposal Template for RIA /IA

General Model Grant Agreement







European INNOVATION Council

EMPOWERING EUROPEAN INNOVATORS

EU funding for innovation

European Innovation Council (EIC)

- The EIC has a mission to identify, develop and scale-up breakthrough technologies and disruptive innovations.
- The EIC will support start-ups, SMEs and research teams developing highrisk, high-impact breakthrough innovation, with a particular focus on scaling up game-changing solutions.
- €10bn budget form 2021-2027
- Funding options : Grant, Equity or Blend of Grant & Equity
- Grants = 100% funding

EIC Challenges related to Health 2021

Pathfinder	Transition	Accelerate
Open Call for applications April 2021	PILOT PROGRAM	Any time (short applications) stage 1 4 weeks for evaluation – go to stage 2
Closed 19 th May	Closed 22/9/2021	Full applications by 9/6/2021; 6/10/2021
Pathfinder Challenges	Transition Challenges	Accelerate Challenges
1. Awareness Inside		1. Strategic Digital and Health
2. Tools to measure and stimulate activity in brain tissue	PILOT PROGRAM	Technologies
3. Emerging Technologies in Cell and Gene therapy	1. Medical Technology and Devices: from Lab to Patient	
4. Engineered Living Materials		
Closed 27/10/2021	Closed 22/09/2021	Any time (short applications) stage 1 4 weeks for evaluation – go to stage 2 Full applications by 9/6/2021;
		6/10/2021

Dates for Your Diary

EU Commission

Health Information Day

2nd July <u>Cluster 1 - Health | Horizon Europe Info Days</u> 2021 (horizon-europe-infodays2021.eu)

5th July Health Brokerage Days

<u>CLUSTER Health - Horizon Europe Brokerage Event -</u> <u>Home (b2match.io)</u>

	2021	
JANUARY	FEBRUARY	MARCH
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JULY	AUGUST	SEPTEMBER
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OCTOBER	NOVEMBER	DECEMBER
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Mission Areas



EU missions: bold goals to be achieved within a set timeframe aimed at tackling some of our greatest global challenges.

Mission Documents

https://ec.europa.eu/info/news/top-experts-propose-potential-eu-missions-further-consultation-europeans-

2020-jun-25_en&pk_campaign=rtd_news

Why - The Cancer Mission

2.6 million diagnosed with Cancer each year in EU27

Cancer kills 1.2 million people in EU27 each year

Future risks due to

- Aging populations
- Unhealthy lifestyles
- Unfavourable environment conditions
- Current COVID 19 pandemic

Other issues

- Large variation in cancer treatment across Europe
- Inequality in access to treatment and care.





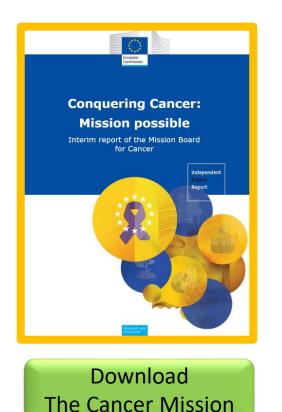


- Prevention Tobacco, Environment
- Early Diagnosis
- Screen programs
- Guidelines/best practice
- Rare forms of Cancer
- Centres of excellence

- Networks
- Registries
- Social issues low income/ patient access
- Quality of life for Survivors jobs, bank, Insurance issues & stigma

Alignment between <u>Cancer Mission</u> and <u>Europe Beating Cancer Plan</u> Alignment between DG Research and DG SANTE

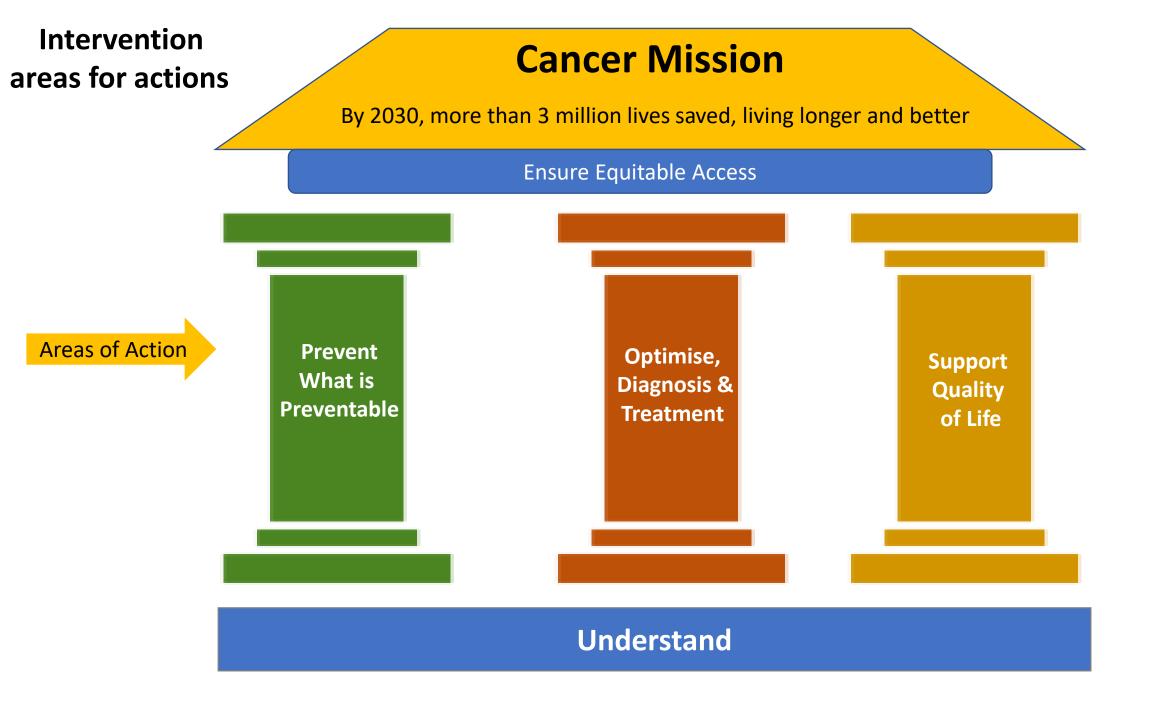
Conquering Cancer: Mission possible



All Missions will details in a separate work program which is under development.

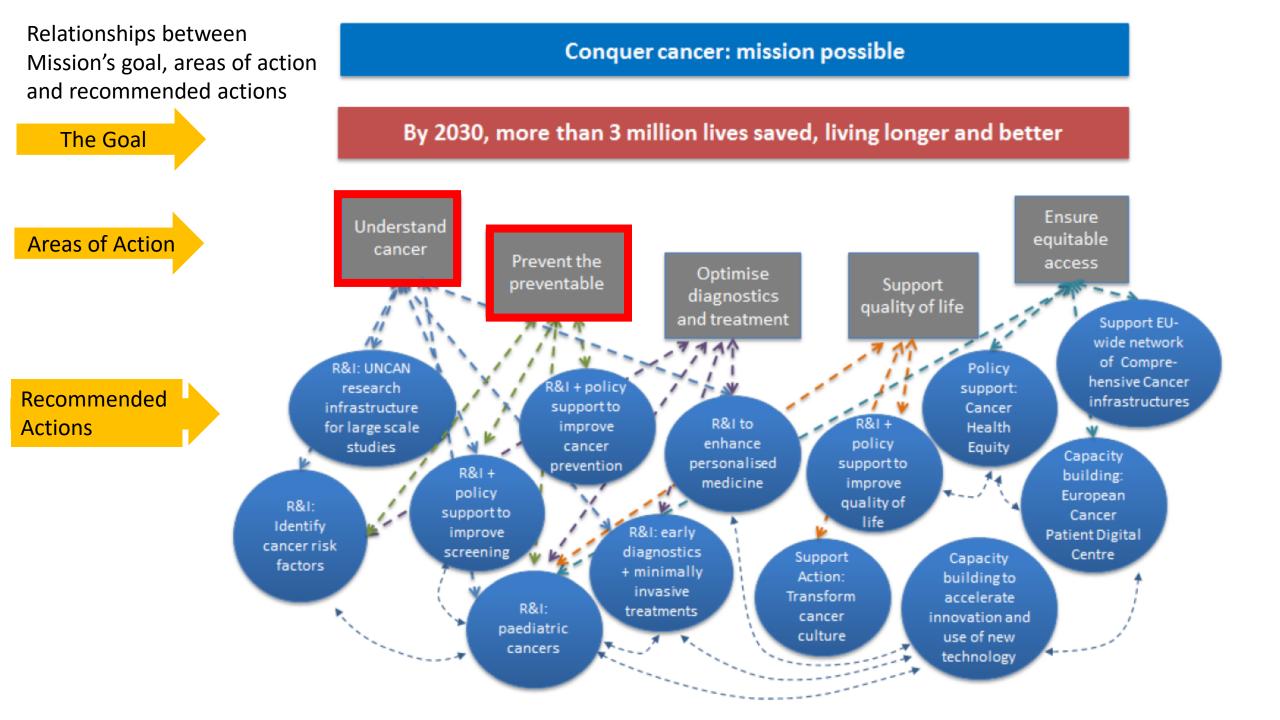
Next Phase will look at the implementation plan, stakeholders, actors and research topics. Policies and Research will have to taken into account

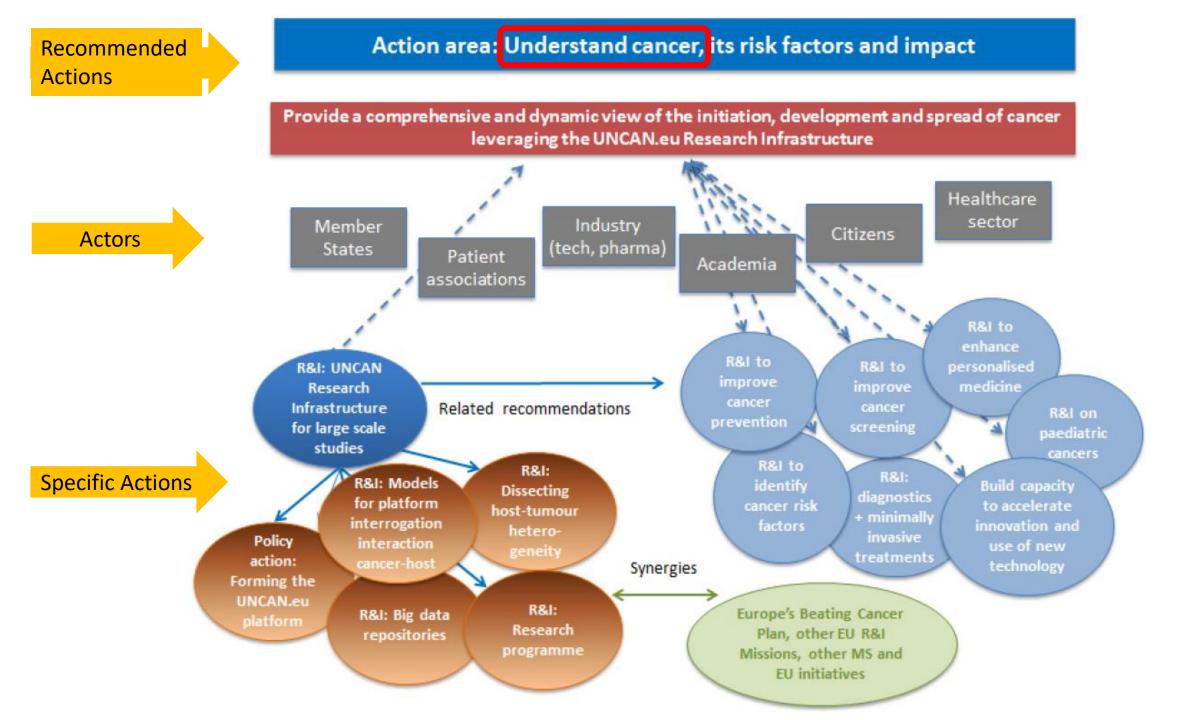
Alignment between <u>Cancer Mission</u> and <u>Europe Beating Cancer Plan</u> Alignment between DG Research and DG SANTE



Cancer Mission - 13 Recommendations

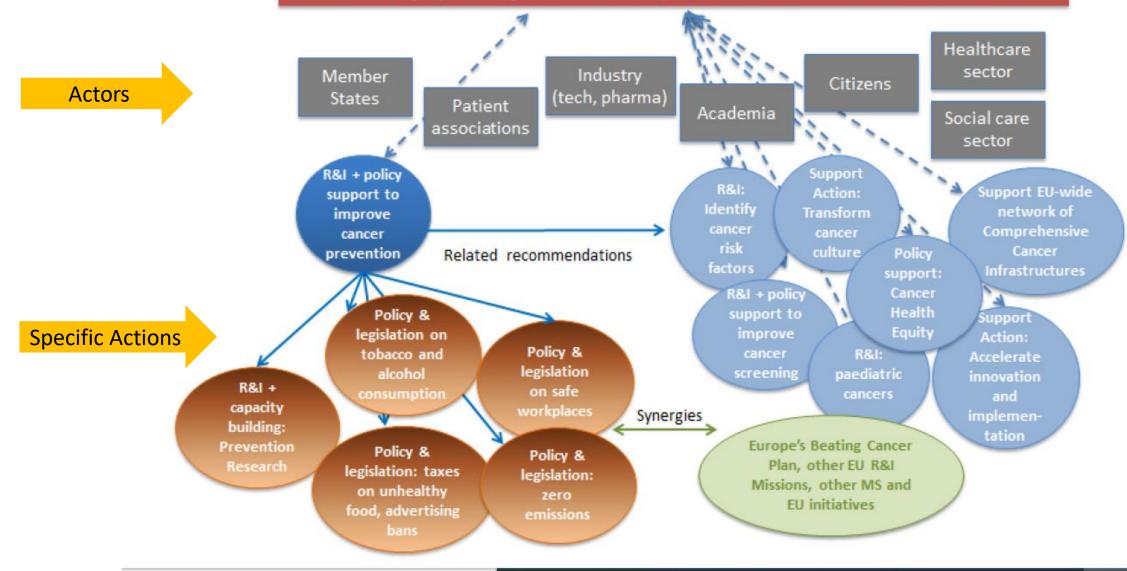
- 1. Launch UNCAN.eu a European Initiative to Understand Cancer
- 2. Develop an EU-wide research programme to identify (poly-) genic risk scores
- 3. Support the development and implementation of effective cancer **prevention strategies** and policies within Member States and the EU
- 4. Optimise existing screening programmes and develop novel approaches for screening and early detection
- 5. Advance and implement **personalised medicine** approaches for all cancer patients in Europe
- 6. Develop an EU-wide research programme on early diagnostic and **minimally invasive treatment technologies**
- 7. Develop an EU-wide research programme and **policy support to improve the quality of life** of cancer patients and survivors, family members and carers, and all persons with an increased risk of cancer
- 8. Create a European Cancer Patient Digital Centre where cancer patients and survivors can deposit and share their data for personalised care.
- 9. Achieve Cancer Health Equity in the EU across the continuum of the disease
- 10. Set up a network of Comprehensive Cancer Infrastructures within and across all EU Member States to increase quality of research and care
- 11. Childhood cancers and cancers in adolescents and young adults: cure more and cure better
- **12.** Accelerate innovation and implementation of new technologies and create Oncology-focused Living Labs to conquer cancer
- **13.** Transform cancer culture, communication and capacity building





Recommended Actions

By 2030, all EU Member States will have implemented comprehensive cancer prevention strategies, resulting in a reduction of preventable cancer cases of at least 25 %

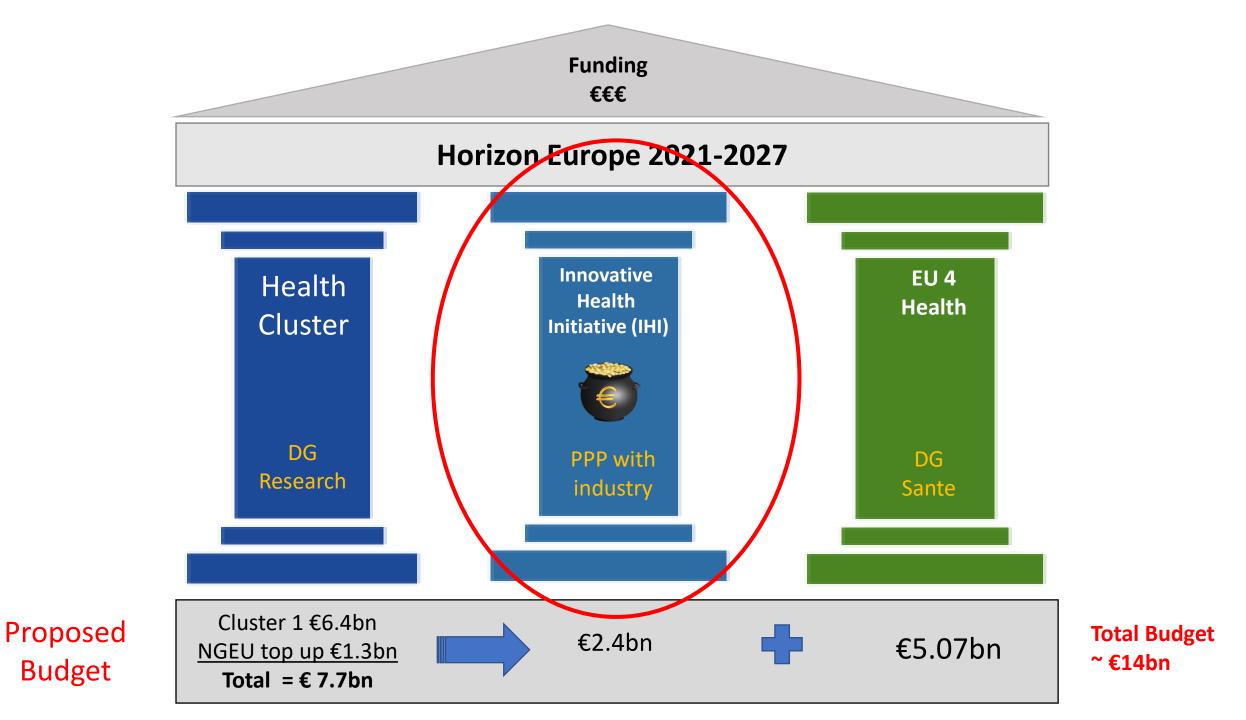


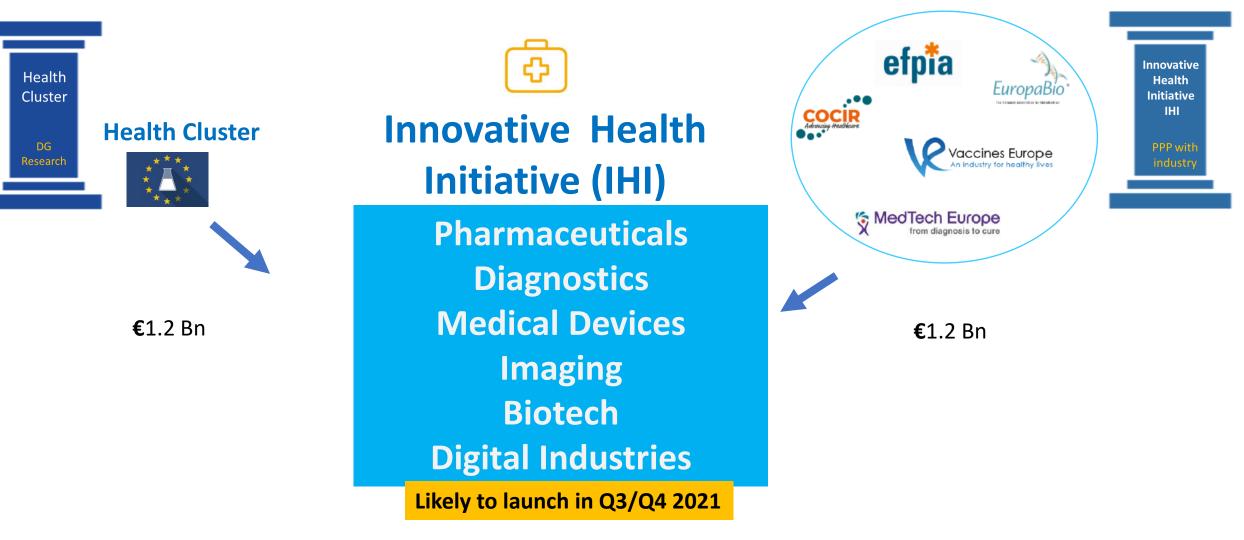
Recommendations to Actions to Specific Actions

- The Recommendations form a coherent Framework of proposed Actions
- These will be developed further in the second half of 2020 into specific actions.

Features of Specific Actions

- Ambitious
- Measurable
- With a tight realistic timeframe
- Actors to carry out the actions will be identified.





Find out more at : <u>https://www.euhealthppp.org/</u>

Review the draft Strategic Research Agenda

Industry Partners for IHI

efpia

Industry Sectors involved

- Pharmaceutical companies (EFPIA)
- Medical Imaging, radiotherapy, health ICT and electro-medical companies (COCIR)

MedTech El

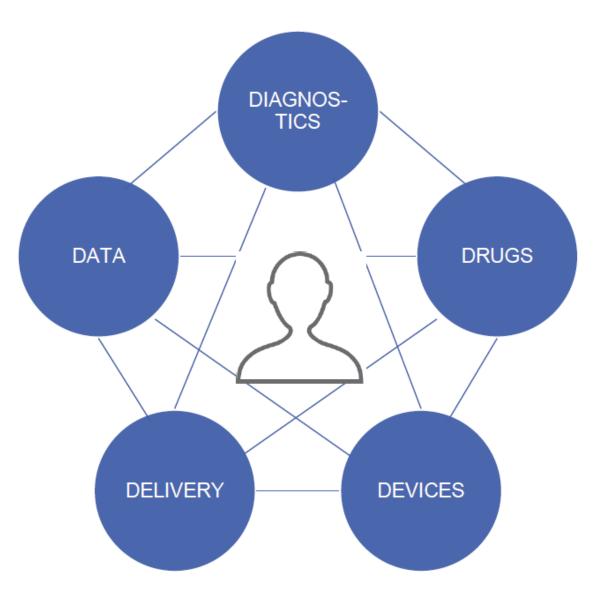
- Medical technology companies (MedTechEurope)
- Biotechnology companies (EuropaBio)
- Vaccine Companies (Vaccine Europe)

Innovative Health Initiative IHI PPP with industry

5D for research and health paradigm shift

Innovative Health Initiative (IHI)





Useful links and resources

- Official Horizon Europe website https://www.horizoneurope.com/
- Orientation towards the First Strategic Plan for Horizon Europe (Oct2019) <u>https://ec.europa.eu/info/files/orientations-towards-first-strategic-plan-horizon-europe_en</u>
- The Missions <u>https://ec.europa.eu/info/horizon-europe_en#missions-in-horizon-europe</u>
- The Cancer Mission <u>https://ec.europa.eu/info/horizon-europe/missions-horizon-europe/cancer_en#documents</u>
- The Innovative Health Initiative (IHI) <u>https://www.euhealthppp.org/</u>

Useful links and resources

Details on proposed European Partnerships in health – Background documents https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-frameworkprogramme/european-partnerships-horizon-europe/candidates-european-partnerships-health en

White Paper on Artificial Intelligence: a European approach to excellence and trust https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approachexcellence-and-trust_en

Proposal for a Regulation laying down harmonised rules on artificial intelligence



Guidelines for Trustworthy AI

Download

Template for essential information for proposals including clinical studies



Thank You



Dr. Martha Cahill PhD, MBA





National Contact Point for Health, State Representative for the Innovative Health Initiative (IHI)