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

Calls for proposals under this destination are directed towards the Key Strategic Orientation KSO-A *'Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains'* of Horizon Europe's Strategic Plan 2021-2024. Research and innovation supported under this destination should contribute to the impact area *'High quality digital services for all'* and in particular to the following expected impact, set out in the Strategic Plan for the health cluster: '*Health technologies, new tools and digital solutions are applied effectively thanks to their inclusive, secure and ethical development, delivery, integration and deployment in health policies and health and care systems'*. In addition, research and innovation supported under this destination could also contribute to the following impact areas: *'A competitive and secure data-economy'*, *'Industrial leadership in key and emerging technologies that work for people'*, and *'Good health and high-quality accessible health care'*.

Technology is a key driver for innovation in the health care sector. It can provide better and more cost-efficient solutions with high societal impact, tailored to the specific health care needs of the individual. However, novel tools, therapies, technologies and digital approaches face specific barriers and hurdles in piloting, implementing and scaling-up before reaching the patient, encountering additional challenges such as public acceptance and trust. Emerging and disruptive technologies offer big opportunities for transforming health care, thereby promoting the health and well-being of citizens. Unlocking this potential and harnessing the opportunities depends on the capacity to collect, integrate and interpret large amounts of data, as well as ensure compatibility with appropriate regulatory frameworks and infrastructures that will both safeguard the rights of the individual and of society and stimulate innovation to develop impactful solutions. In addition to existing European Research Infrastructures, the European Health Data Space will promote health-data exchange and facilitate cross-border research activities. Moreover, the European Health Emergency Preparedness and Response Authority (HERA) aims to improve to improve the EU's readiness for health emergencies by supporting research, innovation and development of technologies and medical countermeasures needed against potential cross-border health threats. This destination aims to promote the development of tools, technologies and digital solutions for treatments, medicines, medical devices and improved health outcomes, taking into consideration safety, effectiveness, appropriateness, accessibility, comparative value-added and fiscal sustainability as well as issues of ethical, legal and regulatory nature.

In this work programme destination 5 has a strong focus on the personalisation of health technologies and will address the following issues:

Developing computational systems for point-of-care applications, developing and validating computational models of physiological systems and integrating health data from different sources, for better patient management and improved clinical outcomes;

Fostering translational biomedical research and advancing regenerative medicine approaches into clinical settings and manufacturing;

Preparing for potential cross-border health threats through the development of innovative in-vitro-diagnostics;

Supporting the establishment of the European Health Data Space by designing a data quality label.

In view of increasing the impact of EU investments under Horizon Europe, the European Commission welcomes and supports cooperation between EU-funded projects to enable cross-fertilisation and other synergies. This could range from networking to joint activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Opportunities for potential synergies exist between projects funded under the same topic but also between other projects funded under another topic, cluster or pillar of Horizon Europe (but also with ongoing projects funded under Horizon 2020). In particular, this could involve projects related to European health research infrastructures (under pillar I of Horizon Europe), the EIC strategic challenges on health, the European Innovation Ecosystems (EIE) interregional networks on health and EIT-KIC Health (under pillar III of Horizon Europe) or in areas cutting across the health and other clusters (under pillar II of Horizon Europe), like, for instance, with cluster 4 *"Digital, Industry and Space"* on digitalisation of the health sector or key enabling technologies.

Expected Impacts

Proposals for topics under this destination should set out a credible pathway towards unlocking the full potential of new tools, technologies and digital solutions for a healthy society, and more specifically to several of the following expected impacts:

- Europe's scientific and technological expertise and know-how, its capabilities for innovation in new tools, technologies and digital solutions, and its ability to take-up, scale-up and integrate innovation in health care is world-class.
- Citizens benefit from targeted and faster research resulting in safer, more sustainable, efficient, cost-effective and affordable tools, technologies and digital solutions for improved (personalised) disease prevention, diagnosis, treatment and monitoring for better patient outcome and well-being, in particular through increasingly shared health resources (interoperable data, infrastructure, expertise, citizen/patient driven co-creation)[233].
- The EU gains high visibility and leadership in terms of health technology development, including through international cooperation.

[233] Commission Communication on the digital transformation of health and care; COM(2018) 233 final.

- The burden of diseases in the EU and worldwide is reduced through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health care.
- Both the productivity of health research and innovation, and the quality and outcome of health care is improved thanks to the use of health data and innovative analytical tools, such as artificial intelligence (AI) supported decision-making, in a secure and ethical manner, respecting individual integrity and underpinned with public acceptance and trust.
- Citizens trust and support the opportunities offered by innovative technologies for health care, based on expected health outcomes and potential risks involved.

Legal entities established in China are not eligible to participate in Innovation Actions in any capacity. Please refer to the Annex B of the General Annexes of this Work Programme for further details.

The following call(s) in this work programme contribute to this destination:

Call	Budgets (EUR million)		Deadline(s)
	2023	2024	
HORIZON-HLTH-2023-TOOL-05	214.00		13 Apr 2023
HORIZON-HLTH-2024-TOOL-05-two-stage		25.00	19 Sep 2023 (First Stage) 11 Apr 2024 (Second Stage)
HORIZON-HLTH-2024-TOOL-11		25.00	11 Apr 2024
Overall indicative budget	214.00	50.00	

Call - Tools and technologies for a healthy society (Single stage - 2023)

HORIZON-HLTH-2023-TOOL-05

Conditions for the Call

Indicative budget(s)[234]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[235]	Indicative number of projects expected to be funded
		2023		
Opening: 12 Jan 2023 Deadline(s): 13 Apr 2023				
HORIZON-HLTH-2023-TOOL-05-01	RIA	50.00 [236]	8.00 to 10.00	5
HORIZON-HLTH-2023-TOOL-05-03	RIA	50.00 [237]	8.00 to 10.00	5
HORIZON-HLTH-2023-TOOL-05-04	RIA	35.00 [238]	8.00 to 10.00	4
HORIZON-HLTH-2023-TOOL-05-05	IA	35.00 [239]	8.00 to 10.00	4
HORIZON-HLTH-2023-TOOL-05-08	IA	40.00 [240]	5.00 to 7.00	6
HORIZON-HLTH-2023-TOOL-05-09	CSA	4.00 [241]	Around 4.00	1
Overall indicative budget		214.00		

General conditions relating to this call

234 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.
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 years 2023 and 2024.

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

236 Of which EUR 30.00 million from the 'NGEU' Fund Source.

237 Of which EUR 30.00 million from the 'NGEU' Fund Source.

238 Of which EUR 20.69 million from the 'NGEU' Fund Source.

239 Of which EUR 20.00 million from the 'NGEU' Fund Source.

240 Of which EUR 24.00 million from the 'NGEU' Fund Source.

241 Of which EUR 2.00 million from the 'NGEU' Fund Source.

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.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2023-TOOL-05-01: Clinical trials of combined Advanced Therapy Medicinal Products (ATMPs)

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 8.00 and 10.00 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 50.00 million.
Type of Action	Research and Innovation Actions
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.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following Expected Outcomes:

- Healthcare providers increase their knowledge on the potential of combined ATMPs and get access to innovative treatment options with demonstrated health benefits for unmet medical needs;
- Developers and manufacturers of combined ATMPs obtain scientific evidence on the proposed therapeutic approach;
- Patients benefit from new advanced therapies delivered through the combined ATMPs;
- EU companies get a better market position in the field of combined ATMPs.

Scope: The subjects of this topic are combined ATMPs (Advanced Therapy Medicinal Products) according to the definition of the ATMP-regulation (EU 1394/2007, Article 2d). Such combined ATMPs are composed of an ATMP and one or more medical devices or one or more active implantable medical devices, and their cellular or tissue part must either contain viable cells or tissues, or non-viable cells or tissues liable for exerting the primary action on the human body.

The combined ATMPs should be more effective than current state-of-the-art solutions on the European market owing to improved features like personalisation, accuracy, reliability and usability and contribute to long-term sustainability (faster and affordable) of European health systems.

Research should focus on advanced stages of clinical development with regulatory work on the Medical Device part completed and safety studies of the combination product in an advanced stage.

Proposals should address all of the following activities:

- Phase 2 clinical trials and above of combined ATMPs focussing on:
    - technologies ready to undergo interventional clinical trials in patients/end users assessing the usability and clinical performance, and/or
    - technologies that have demonstrable safety/performance profiles and should undergo clinical validation in view of their inclusion into guidelines for specific clinical pathways.
- Delivery of safe and clinically validated combined ATMPs that are compliant with current European regulatory requirements. The related regulatory work should be considered as an essential component and the proposed work should involve consultation/interaction with competent regulatory agencies such as the European

Medicines Agency (EMA) or national regulatory agency. Applicants are encouraged to seek regulatory and/or Health Technology Assessment (HTA) advice as appropriate.

The topic invites proposals that include innovative treatments for any medical condition excluding rare diseases that are ready to be assessed for clinical efficacy (performance and clinical benefit) in a specific indication on a big number of patient cohorts; already existing market solutions are not in the scope of this topic.

Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and any other non-health related individual attributes should be taken into consideration. SME participation is strongly encouraged.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-03: Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 8.00 and 10.00 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 50.00 million.
Type of Action	Research and Innovation Actions
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).
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following expected outcomes:

- Clinicians and other healthcare professionals have access to and/or use validated multi-scale computational models of individual patients for delivering optimised and cost-effective patient management strategies superior to the current standard of care.
- Healthcare professionals benefit from enhanced knowledge of complex disease onset and progression by recourse to validated, multi-scale and multi-organ models.
- Clinicians and patients benefit from new, improved personalised diagnostics, medicinal products, devices, and therapeutic strategies tailored to the individual patient patho-physiology.
- Citizens and patients have access to validated 'virtual twin' models enabling the integration of citizen-generated data with medical and other longitudinal health data, and benefit from early detection of disease onset, prediction of disease progression and treatment options, and effective disease management.

Scope: This topic will contribute to the consolidation of existing virtual twin models and support research to move towards a more integrated human virtual twin, with the aim to accelerate translational research towards cost-effective development of new health technologies. Furthermore, 'virtual twin' patient models hold the potential of transforming clinical processes and healthcare with longitudinal monitoring, making personalised medicine, disease prevention and individualised patient management a reality.

Proposals are expected to contribute to the virtual human twin roadmap and ecosystem supported under the Digital Europe Programme[242], with models aligned and interoperable with those linked to the repository developed thereunder.

The proposals should address all of the following activities:

- Develop multi-scale and multi-organ, dynamic, interoperable, modular computational models, capable of accurately simulating the individual patient patho-physiology, spanning different anatomical scales, from the molecular to cell, tissue, organ and systems level, as necessary. Proposals should be multidisciplinary and focus on groups of communicable and/or non-communicable diseases with commonalities within the same or across different medical domains, including co-morbidities. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations towards citizen and patient benefit.

[242] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2021-deploy-01-twins-health;callCode=DIGITAL-2021-DEPLOY-01 DIGITAL-2021-DEPLOY-01-TWINS-HEALTH

- Advance the state of the art in multi-scale modelling by employing diverse modelling methodologies, including but not limited to: mechanistic modelling, artificial intelligence, agent-based and network physiology as a means for modelling the healthy state, disease onset, progression, treatment and recovery. Availability of the necessary diverse data types (e.g. data from lab tests, medical imaging, wearables, sensors, medical check-ups, mHealth devices, longitudinal health monitoring etc.) should be demonstrated and the sex/gender dimension should be investigated.

- Integrate standardised spatiotemporal multi-scale models as a basis for developing personalised 'virtual twin' models taking account of patient individual characteristics, medical and health status history for advancing personalised disease management. Proposals should ensure that the development of 'virtual twin' models is driven by the end-users/citizens/healthcare professionals needs and their active involvement throughout the development process. Furthermore, applicants should utilise appropriate IT solutions for model visualisation and demonstrate their accessibility and usability for clinical uptake.

- Validate multi-scale patient-specific models and generate evidence that results can deliver clinically meaningful, real-world observations for the human diseases under study. Applicants should implement proof-of-concept, feasibility studies in relevant end user environments and/or real-world settings, and collect evidence of utility vis-à-vis current clinical practice. Dynamic 'virtual twin' models and simulations as clinical decision support tools will need be shown to improve prognosis, medical diagnosis, treatments and health outcomes across the continuum of diseases evolution, including co-morbidities and long-term care as appropriate. An exploitation strategy and a business plan, including regulatory and industrial input, should be developed for accelerating clinical and/or market uptake.

The proposals should adhere to the FAIR data[243] principles and adopt data quality standards, GDPR-compliant data sharing, access and data integration procedures based on good practices developed by the European research infrastructures. In relation to the use and interpretation of data, special attention should be paid to systematically assess for bias and/or discrimination (sex/gender, ethnic, minority and vulnerable groups aspects). Proposals are invited to consider adopting recommendations for in-silico models construction and validation.[244]

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.

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243 See definition of FAIR data in the introduction to this work programme part.

244 ISO-paper under development "Recommendations and requirements for predictive computational models in personalized medicine research — Part 1: Guidelines for constructing, verifying and validating models".

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes. 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. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-04: Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 8.00 and 10.00 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 35.00 million.
Type of Action	Research and Innovation Actions
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).
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to most of the following expected outcomes:

- Researchers, innovators and healthcare professionals benefit from better linkage of health data from various sources, including genomics, based on harmonised approaches related to data structure, format and quality, applicable across certain disease areas and across national borders.

- Researchers, innovators, healthcare professionals and health policymakers have access to advanced digital tools for the integration, management and analysis of various health data re-used in a secure, cost-effective and clinically meaningful way enabling the improvement of health outcomes.

- By linking and using effectively more data and new methods and tools, including artificial intelligence, researchers, innovators and healthcare professionals are able to advance our understanding of the risk factors, causes, development and optimal treatment in disease areas where genomics integrated with other health data, spanning from clinical to e.g. lifestyle, offer potential for novel and more comprehensive information.

- Healthcare professionals and health policymakers benefit from data-driven solutions and reinforced evidence base for decisions addressing health and care challenges.

- Citizens can be offered data-driven patient-focused health interventions, resulting in improved disease prevention, diagnosis, treatment and monitoring towards better patient outcomes and well-being.

- Citizens' trust in the sharing and re-use of health data for research and healthcare increases due to the application of advanced technologies and data governance preserving data privacy and security.

Scope: Health data bear vast information potential in many disease areas, to significantly improve the outcomes and efficiency of healthcare delivery, unlock new research and innovation avenues, and inform public health policy across Europe. There is a huge need of integration, use and deployment of health data from multiple sources for effectively addressing the challenges of medical research underpinning diagnostics, therapy guidance and implementation decisions on new therapies. Such integration requires linking data of different types, disease areas and provenance which are scattered in repositories and databases across Europe.

This topic aims to support proposals focusing on the integration of health data from multiple sources (e.g. electronic health records, genomics, medical imaging, laboratory and diagnostic results, pathogen data, public health registries and other clinical research data) by linking real-

world and clinical research data. The data integration should be exemplified in several use-cases, i.e. well-justified groups of diseases (excluding cancer), within and/or across medical domains, and pave the way towards improved health outcomes. At least one of those use cases should build on the use of whole genome sequence data.

The consortium should ensure wide coverage of EU and associated countries, contributing significantly to health data standardisation, while catering for the diversity of health data sources.

To enhance synergies and avoid overlaps of activities, the proposals are expected to align with and complement the relevant European initiatives, in particular the European Health Data Space (EHDS), the 1+Million Genomes initiative (1+MG) and the European Open Science Cloud.

The applicants have to demonstrate that the necessary data sources are, or will be, effectively, timely and legally available for the proposed research activities.

The proposals should address all of the following activities:

- Identification of the barriers to health data integration and access as needed for the selected use cases, and of specific existing tools, technological solutions and coordination and standardisation agreements addressing those barriers. Issues to be covered include semantic ontologies, data standards and formats, data quality, data storage, management and access modalities, as well as enhanced findability of relevant datasets through improved metadata standards and data catalogues.

- New approaches to assemble large, easily findable and lawfully accessible high-quality datasets integrating multiple types of health data leading to improved clinical outcomes (e.g. new care solutions, personalised disease management, advanced diagnostic tools), taking into account data FAIRification[245] and inter-operability needs.

- New techniques, support tools, mechanisms and modalities to enable GDPR compliant access to sensitive personal data, including genomics, allowing for their re-use across borders and integration of different types of data relevant to human health. Legal and ethical frameworks should duly consider the heterogeneity in national and sectorial rules and procedures for data access and re-use.

- Data management approaches for cross-border distributed data storage and processing, enabling remote collaboration, electronic consent management, data provenance tracking, and scalability of data management resources, ensuring data privacy and security, and resulting in robust support to advanced, innovative clinical workflows. Joint data governance is expected to be piloted among several clinical centres across Europe.

[245] See definition of FAIR data in the introduction to this work programme part.

- Development of a data analytics platform applying distributed learning and artificial intelligence approaches to query and aggregate efficiently, effectively and securely data from multiple sources for multiple use cases (groups of diseases), to monitor patients' health status, analyse causal inference, support diagnosis and health policymakers, and establish recommendations for patients and other stakeholders.

The proposals should adhere to the FAIR data[246] principles and build on existing and justified tools and harmonisation efforts, such as widely used standards for encoding the different types of health data and inter-operability for cross-sector collaborations. Also the data collection, management and/or modelling should build on ongoing EU and international efforts to avoid possible duplication of efforts and fragmentation. In particular, projects are expected to take into account the legislation, if available, on the EHDS, so as to align project activities with pertinent EHDS infrastructure efforts that provide for the secondary use of health data as regards e.g. cross-border access to data, cross-border infrastructures, data quality and utility labelling. The achievements of the relevant past and ongoing EU-funded projects and initiatives, and good practices developed by the European research infrastructures, should be duly considered and used. Close involvement of patients and end-users is crucial to ensure that the project outcomes are relevant, widely accepted and feasible in real-world settings.

The tools developed by the projects are expected to be widely accessible and amenable to necessary updates after the project's end for further use by interested parties. Datasets generated during the project should be accessible to researchers and innovators. For example, genomic data and linked patient level data are expected to be made accessible for secondary use through the 1+MG data infrastructure.

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

All projects funded under this topic are strongly encouraged to participate in networking and joint activities. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes. 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. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders.

246 See definition of FAIR data in the introduction to this work programme part.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-05: Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 8.00 and 10.00 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 35.00 million.
Type of Action	Innovation Actions
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).
Technology Readiness Level	Activities are expected to achieve TRL 7 by the end of the project – see General Annex B.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to all of the following expected outcomes:

- Healthcare professionals benefit from secure, highly performant Point-of-Care computing technologies and devices able to process and analyse vast amounts of real-time data at the point of care, combined with extended reality and visualisation

techniques, to enable continuous monitoring and/or fast real-time health status checks in clinical settings and workflows.

- Patients and clinicians benefit from wider access to real-time diagnosis, screening, monitoring and treatments using novel imaging and/or robotics systems and/or Point-of-Care devices that are seamlessly integrated in care environments and workflows.

- Quicker reaction times and improved patient safety in care settings.

- Researchers and healthcare professionals have more opportunities to use, extract value from and contribute to the uptake of real-time health data and/or Point-of-Care computing; existing technologies and methods are expected to progress from their current technology readiness levels (TRL), from TRL 3-4 to at least TRL 7[247].

- Health and care settings benefit from reduced energy consumption of Point-of-Care tools, devices and systems, and/or data analysis.

Scope: The proposals are expected to develop and test innovative tools, devices and systems for point-of-care applications, including but not limited to robotics, photonics, bio-sensing, artificial intelligence etc. These would provide clinicians with real-time imaging, data analysis and interactive visual presentation for understanding and diagnosing diseases, facilitating risk-assessment, prevention, and carrying out medical interventions with improved patient safety. The proposals should demonstrate advancement and integration of technologies from proof-of-concept to prototype demonstration in operational environment. Devices and systems should be designed, developed and tested vis-à-vis defined use cases, based on the appropriate involvement of clinicians and other stakeholders, ensuring they can be seamlessly integrated into existing digital infrastructures and clinical workflows. The use cases in care settings could include but are not limited to surgery workflows, Intensive Care Unit workflows and integration of remote patient monitoring into clinical workflows. Data quality, integration and interoperability, as well as issues of cybersecurity and data protection have to be addressed. Design should take gender specificities into account. Clinical studies should be an integral part of the work proposed, with developmental iteration steps and consultation of regulators included as appropriate. Establishing synergies with AI Testing and Experimentation Facilities, European Digital Innovation Hubs and other similar initiatives is encouraged. Proposals must include a short description of initial business plan as part of the exploitation activities.

The proposals should address all of the following activities:

- Development and clinical validation of compact, cost- and energy-efficient, extended reality-enabled and other Point-of-Care devices and systems, with fast/real-time response

[247] From proof-of-concept/technology validated in lab to at least prototype demonstration in operational environment; the definitions used in H2020 for TRLs apply under this topic: https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf

times as required, reliable and capable of integration into clinical settings and workflows.

- Development and validation of instruments, continuous monitoring systems and/or analysis algorithms, including artificial intelligence approaches, for the analysis of biological samples, enabling detection of biomarkers in body fluids and tissues in clinical settings.

- Development and validation of imaging systems with a high spatial resolution down to the cellular level allowing for immediate clinical interventions. Single imaging modalities or the combination of different imaging modalities should be made compatible with other imaging tools and with state-of-the-art and/or novel medical technologies and devices, for example those used to remove tissues in precision surgery (e.g. robotic surgery).

- Advancements in the use of Point-of-Care computing, data modelling, extended reality and/or machine learning/AI technologies applied to diagnosis and risk assessment in cases requiring very fast, near to real-time response times in clinical settings and workflows. In addition, projects should showcase how distributed systems bringing computation and storage physically close to where data is generated and used can most effectively deliver actionable outputs for person-centred health care, contributing to improved patient safety, in the areas of for example healthy living support, remote patient monitoring, surgery workflows or acute care.

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.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-08: Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats

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 40.00 million.
Type of Action	Innovation Actions

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. The Joint Research Centre (JRC) may participate as member of the consortium selected for 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).
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "*Unlocking the full potential of new tools, technologies and digital solutions for a healthy society*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities, including health care providers and payers, as well as regulators, health systems and patients benefit from innovative diagnostic solutions that are better suited to tackle cross-border health threats.
- The scientific and clinical communities have access to novel and improved methodologies for detection of pathogens with pandemic potential in humans and for timely discovery of other health threats, such as chemical, radiological and nuclear threats, including considerations on detection in animals and environmental conditions (One Health approach).
- A diverse and robust pipeline of in vitro diagnostics[248] is available, increasing options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally, this is also the case for other health threats that can be linked for instance to terror attacks. New cross-border health threats are expected to emerge in the coming years and therefore it is essential to promote advanced research of medical countermeasures that can be used to detect, prevent and treat in case of a new health

[248] As defined in Guidance on Classification Rules for in-vitro Diagnostic Medical Devices for Regulation (EU) 2017/746 MDCG 2020-16 rev.1: https://ec.europa.eu/health/system/files/2022-01/md_mdcg_2020_guidance_classification_ivd-md_en.pdf

emergency. One of the most important aspects in crisis preparedness times is to ensure the availability of diagnostics that can contribute to detecting and characterising health threats.

Proposals should develop and advance on new in vitro diagnostics relevant for detecting and characterising cross-border health threats and develop novel approaches to the development of medical countermeasures targeting threats identified by HERA[249].

Proposals should cover pathogens with pandemic potential in humans or other health threats, such as chemical, radiological and nuclear threats for which there are no existing diagnostics or where clinical practice could benefit from innovation. Emphasis should be put on the development of new diagnostics, innovative catch-all methodologies, or on the improvement of existing health technologies advancing diagnostics and characterisation of health threats, applying the One Health approach when relevant.

Proposals should aim to diversify and accelerate the global diagnostic research and development pipeline to tackle cross-border health threats, and to strengthen the current leading role of the EU in research and development, and therefore contributing to the work of the European Health Emergency Preparedness and Response Authority (HERA).

Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.

Proposals should include a clear regulatory path to market in order to ensure future compliance with the legal requirements. Proposals should address several of the following areas:

- Proof-of-concept/early studies linked e.g. to performance evaluation of new diagnostics that facilitate screening, detection of the presence or exposure to a cross-border health threat or determination of infectious/disease status through human samples, included but not limited to the list of high impact health threats identified by HERA, as well chemical, radiological and nuclear threats for which there is a lack of in vitro diagnostics or existing diagnostics have a sub-optimal performance.

- Data-driven diagnostic and prognostic platforms with AI and other advanced data analytics functionalities, adaptable to respond to new and multiple pathogens/threats, e.g. covering prototype viruses.

- Innovative systems linked to high sensitivity/specificity profiles adaptable for broader use should be considered, such as portable, faster, more compact or accurate devices and technologies, including the possibility to develop point of care or self-tests.

- Innovative diagnostics sampling methods or samples bringing a significant improvement, such as less invasive sampling methods.

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

[249] https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf

relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

Proposals should consider the involvement of the European Commission's Joint Research Centre (JRC) in regard to its experience on the performance evaluation of in vitro diagnostic devices, with respect to the value it could bring in providing an effective interface between research activities and regulatory aspects and/or to translating research results into validated test methods and strategies fit for regulatory purpose. In that respect, the JRC will consider collaborating with any successful proposal and this collaboration, when relevant, should be established after the proposal's approval.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

HORIZON-HLTH-2023-TOOL-05-09: Developing a Data Quality and Utility Label for the European Health Data Space

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of around EUR 4.00 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 4.00 million.
Type of Action	Coordination and Support Actions
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, legal entities established in the United States of America may exceptionally participate as a beneficiary or affiliated entity, and are eligible to receive Union funding. Coordinators of projects must be legal entities established in an EU Member State or Associated Country.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this

topic should aim to deliver results that are directed towards and contributing to all of the following expected outcomes:

- Data Users (researchers, innovators, regulators, policymakers, clinicians) are able to identify the most relevant datasets that meet their specific needs through a label describing accurately and in a standard way the quality and utility dimensions of the datasets, as proposed in the legal provisions of the European Health Data Space (EHDS).
- Data holders have clear specifications for dataset quality and utility labelling to comply with the requirements proposed in the EHDS legal provisions. In addition to that, data holders have access to a maturity model with the requirements a dataset needs to fulfil to achieve higher levels of data quality and utility.
- European and National public funders ensure that the datasets, for which they provided funding for the creation and curation of, are more widely available, furthering their reuse for secondary uses as proposed in the EHDS legal provisions (research, innovation, regulatory work, policymaking, personalised medicine).
- The European Commission has access to a set of specifications for the data quality and utility label supporting the implementation of the EHDS legal provisions.

Scope: A vast quantity of health datasets exist across Europe, from multiple sources (individual care, medical registries, social, environmental behavioural, wellbeing, clinical trials, research, administrative, etc.), and of varying quality. This represents a tremendous opportunity for the reuse of this data for purposes other than for the one for which they were originally collected and spur the development of better prevention strategies, diagnoses, treatments and care plans.

The European Health Data Space (EHDS) will provide a common EU framework for secondary use of health data such as research, innovation, regulatory purposes, policymaking and personalised medicine. It will enable data users to have access to large amounts of health data through health data access bodies empowered with the EHDS legal provisions to overcome existing limitations regarding the processing of health data for secondary uses.

To support data users in the discovery and selection of datasets for their purposes, there is a growing need to develop a data quality and utility framework to articulate the characteristics and the potential usefulness of datasets. This framework will also support data holders in identifying and addressing areas of improvement which can, in turn, allow for wider and better use of these datasets.

Several initiatives have developed or are developing guidelines and recommendations for health data quality, however, these typically focus on specific data types (i.e. 1+ Million Genome Initiative[250]) or areas of applications (i.e. European Medicines Agency – EMA and Heads of Medicines Agencies' Big Data Steering Group activities to support medicines

250 https://b1mg-project.eu/work-packages/wp3

regulation[251]). Similarly, previous studies and initiatives have addressed specific dimensions of 'data quality' for health data but none are offering a framework suitable for the breadth of data types and encompassing the quality and utility elements proposed in the EHDS legal provisions. The proposed framework should take into account the various needs of data users whilst at the same time avoid becoming an excessive burden on data holders which will need to produce the data quality and utility label.

Proposals should address all of the following activities:

- Perform a mapping of existing data quality and utility principles/initiatives/frameworks (i.e. EMA/HMA Big Data Stakeholders Group Data quality efforts, TEHDAS Data Quality Working Group[252], EOSC-LIFE[253] Health Data Research UK's data quality and utility framework[254], and relevant data principles, resources and tools (FAIR, FAIR Cookbook, etc.)[255];

- Conduct various stakeholder consultations, integrating all relevant data users and data holders of health data, EHDS Health Data Access Bodies (HDABs) and other relevant actors to validate data user needs and adequately take into account relevant initiatives when developing the proposed framework;

- Develop a framework (set of technical specifications) for the data quality and utility label that supports the implementation of the EHDS legal provisions and the roll out of the label by the data holders and EHDS Health Data Access Bodies;

- Pilot and evaluate the use of the proposed framework (as a label and as a maturity model) on a datasets sample representing the wide-ranging data types (such as electronic health records, genomics datasets, medical registries, administrative data, etc.) and taking into account the needs of all data users identified.

- Develop recommendations for the successful implementation and adoption of the data quality and utility label and maturity model across European Member States considering the maturity levels regarding secondary of health data.

The consortium should be composed of representatives from data users, data holders, health data access bodies, and other relevant stakeholders to the scope of secondary use of health data, adequately covering the diversity of heath data types and users' needs across European Member States.

Call - Tools and technologies for a healthy society (Two stage - 2024)

HORIZON-HLTH-2024-TOOL-05-two-stage

251 https://www.ema.europa.eu/en/about-us/how-we-work/big-data
252 https://tehdas.eu/packages/
253 https://www.eosc-life.eu/
254 Development of a data utility framework to support effective health data curation: https://informatics.bmj.com/content/28/1/e100303?utm_source=twitter&utm_medium=social&utm_term=hootsuite&utm_content=sme&utm_campaign=usage
255 See definition of FAIR data in the introduction to this work programme part.

Conditions for the Call

Indicative budget(s)[256]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[257]	Indicative number of projects expected to be funded
		2024		
Opening: 30 Mar 2023 Deadline(s): 19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)				
HORIZON-HLTH-2024-TOOL-05-06-two-stage	RIA	25.00	4.00 to 8.00	4
Overall indicative budget		25.00		

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.

256 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.
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 years 2023 and 2024.

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

Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G.

Proposals are invited against the following topic(s):

HORIZON-HLTH-2024-TOOL-05-06-two-stage: Innovative non-animal human-based tools and strategies for biomedical research

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 budget	The total indicative budget for the topic is EUR 25.00 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 under the blind evaluation pilot (see General Annex F) must not disclose their organisation names, acronyms, logos, nor names of personnel in 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. The Joint Research Centre (JRC) may participate as member of the consortium selected for funding.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: For the second stage, the thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: This topic is part of the blind evaluation pilot under which first stage proposals 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: 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). [258].

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following Expected Outcomes:

- Researchers utilise tools and strategies that are more relevant to the human situation as compared to the currently used animal models.
- Fewer live animals are used in biomedical research.
- Health technology developers will get access to improved human-relevant tools or strategies allowing for a faster pace of innovation.
- Legislators and regulators will benefit from strengthened EU leadership in non-animal based biomedical research that is socially accepted and sustainable.
- Healthcare providers and patients will benefit from innovative tools or strategies opening up novel biomedical concepts enabling improved disease prediction, prevention and treatment.

Scope: The proposal(s) should develop and/or use tools and strategies that address critical areas of biomedical research where animal-models are currently used but are of limited translational value for investigation and development of prevention and treatment. Such advanced tools and strategies should aim at a better understanding of the pathogenesis of disorders that feature a high impact on public health and exhibit a high rate of animal use or severe animal suffering, and enable to develop biomedical concepts with increased translational value, thereby ultimately leading to improved disease prediction, prevention and treatment.

The proposals should address all of the following aspects:

[258] 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

- The innovative tools and strategies should include a variety of technologies and methodological approaches such as –omics and other high-throughput procedures, human-derived cell-based material, organoids, micro-physiological systems, and in-silico models.
- The newly proposed tools and strategies should demonstrably advance the state-of-the-art in specific areas of biomedical research.
- Prospects and avenues for dissemination, knowledge sharing, uptake or translation into health policies of the proposed tools and strategies within the EU should be provided.
- Aspects such as harm and cost-benefit assessment as well as ease of production with respect to current practices should also be considered.
- Criteria for model qualification and standardisation should be developed in well-justified use-case contexts to demonstrate their translational values.

Proposals could consider the involvement of the European Commission's Joint Research Centre (JRC) to provide added-value regarding such aspects as supporting validation of emerging approaches, promotion of research results, and the interfacing with the regulatory community. In this respect, the JRC is open to collaborate with any successful proposal after the selection process has been completed.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. 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. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders.

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.

Applicants invited to the second stage and envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.

Call - Tools and technologies for a healthy society (Single stage - 2024)

HORIZON-HLTH-2024-TOOL-11

Conditions for the Call

Indicative budget(s)[259]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)[260]	Indicative number of projects expected to be funded
		2024		
Opening: 26 Oct 2023 Deadline(s): 11 Apr 2024				
HORIZON-HLTH-2024-TOOL-11-02	RIA	25.00	6.00 to 8.00	4
Overall indicative budget		25.00		

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	The rules are described in General Annex G.

259 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.
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 years 2023 and 2024.

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

Agreements	

Proposals are invited against the following topic(s):

HORIZON-HLTH-2024-TOOL-11-02: Bio-printing of living cells for regenerative medicine

Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 6.00 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 25.00 million.
Type of Action	Research and Innovation Actions
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.
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 3 (Implementation). The cumulative threshold will be 12.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following expected Outcomes:

- Biomedical scientists will access entire bio-printing units for regenerating human tissue.
- Availability of larger-scale bio-printed tissues for biomedical research purposes to both industry and academia.
- Healthcare professionals acquire information on the safe and effective use of advanced therapies.
- Healthcare providers dispose of tools enabling them to treat conditions of unmet medical need.

- Individual patients will benefit from a personalised approach to their respective medical condition thanks to the bio-printed regenerative medicine solution.

Scope: Regenerative medicine is a branch of translational research in tissue engineering and molecular biology which deals with the "process of replacing, engineering or regenerating human cells, tissues or organs to restore or establish normal function". 3D-printing in general is considered an advanced manufacturing technique and 3D-printing of non-viable biomaterials to serve e.g. as scaffold for cell growth or as structure for medical devices is already broadly used.

However, bio-printing technology involving living cells is still in early stages of development, but has a huge potential for tissue engineering, drug testing and other biomedical applications. Tissue-specific functional 3D bio-printing is a new approach for transplantation applications in regenerative medicine, relying on the fabrication of tissues and organs with respect to the desired shape and function and their delivery and application in vivo. “In-situ bio-printing” known as printing cells and biomaterials directly onto or in a patient, or 4D bio-printing, which introduces a “time” variable that allows 3D printed materials to change shape or function when external stimulus is applied, are recent developments facing multiple additional challenges.

Despite some success of 3D bio-printing with thin tissue, thick tissue and complex organs remain a bottleneck because it is difficult to sufficiently mimic their metabolic needs, and the scientific knowledge about their intimate architecture and interplay with other tissues are not sufficiently elucidated. Next to these limitations are a lack of standardised manufacturing protocols and standardised bio-ink formulations with tuneable properties, unstable cellular behaviour, material biocompatibility and printability, etc. Taken together, 3D bio-printing is confronted with several challenges that currently hamper its large-scale deployment.

To overcome these challenges, researchers should work in multidisciplinary teams with engineers, biomedical scientists, cell biologists and medical doctors and proposals should address most of the following activities:

- Design the best bio-printing strategy for at least one type of tissue thanks to a better understanding of the interconnections of the different cell types inside the chosen tissue or organ

- Develop or improve existing equipment able to print bio-constructs with higher resolution in a shorter time using various biomaterials and different cell types

- Cover all steps of the bio-printing suite, including cell collection, cell differentiation and expansion, imaging, modelling, bio-ink formulation, actual bio-printing, nutrient supply, process monitoring and cell-construct delivery at target site

- Scale-up the chosen bio-printing technology to a GMP-conform manufacturing process

- Combine different bio-printing technologies in order to obtain fully functional synthetic constructs of complex tissues or organs.

Regulatory knowledge of the field is desired and should be documented through contacts with relevant national or international European regulatory authorities.

The chosen medical area (tissue, organ, condition) should be duly justified. Sex differences at the cellular level should be taken into consideration.

Preclinical stage and early clinical development are eligible. The involvement of SMEs is encouraged.

Applicants envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.