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DFG BBSRC-UKRI-DFG Lead Agency Agreement: Pilot Call on the “Integrative Microbiome”, deadline: 10. October 2023, 1. Stage

This joint DFG-BBSRC funding opportunity invites collaborative research proposals which aim to answer fundamental functional questions related to how phenomena mediated by microbiomes operate. The integrative microbiome is a research area that resolves to combine the investigation of complex communities of microorganisms (bacteria, fungi, archaea, protists and viruses) with their relationship and influence on environments which they are associated with. It examines the microbiome as a whole and considers the functional interconnections between microbial, host and wider environmental factors.

One of the biggest challenges in the integrative microbiome field is to move beyond correlative or associative studies to investigate the functional mechanisms underpinning these interactions. This includes how the constituents of microbial communities interact with each other, how the environment affects microbial population dynamics and how the microbiome influences its host and vice versa.

Proposals which are only associative or correlative in nature and do not have a clearly articulated plan to dissect the functional underpinnings of any microbiome-associated effects will be excluded.

Applications might be expected to take a range of complementary approaches, and multidisciplinary proposals are encouraged. This includes proposals that are integrated across scales ranging from community ecology, organismal physiology, tissue, single-cell and molecular level interactions. In addition to fundamental research in laboratory model systems, applications in areas involving microbiomes associated with non-human animals including livestock and companion animals, plants including crops, soil or other human-managed ecosystems (greenhouses, aquaculture facilities etc.) are encouraged to apply. New tools and technologies are enabling the functional dissection of integrative microbiome interactions at an unprecedented level of detail and generating vast amounts of quantitative data. Correspondingly, the development or adaptation of existing technologies or analysis approaches including bioinformatics and mathematical modelling will be supported, provided this will lead to the underpinnings that answer the fundamental bioscience questions posed within the project.

The principal aim of proposals submitted under this opportunity should be the generation of new fundamental knowledge relating to the function of the integrated microbiome. Through building joint UK-German capability and capacity in integrative microbiome research, the BBSRC and the DFG ultimately expect to establish the fundamental knowledge and evidence needed to enable scientifically robust management and utilisation of these complex microbial communities in a range of contexts in the longer term.

Examples of key challenges

- Probing the role of variation and heterogeneity in microbiomes, within and between individuals (single-cell, microfluidics etc.).
- Establishing artificial minimal microbiomes as experimental models in the laboratory to test the effects of perturbations in a controlled context such as gnotobiotic systems, organoids, rhizoboxes and hydroponics.
- Developing an understanding of the integrative microbiome in a dynamic context across a time series including longitudinally and/or intergenerationally.
- Understanding the physical structure of microbiomes and how this influences functional relationships.

Proposals must address the priorities of the call. Each joint research project must consist of a German and a UK team. Each national team must be led by one principal investigator eligible to apply to the respective funding agency. Applicants in the UK must meet the BBSRC eligibility requirements.

The call will be managed in a two-stage application process.

Further Information:

https://www.dfg.de/foerderung/info_wissenschaft/ausschreibungen/info_wissenschaft_23_65/index.html

DFG AEI-DFG Call for Joint Spanish-German Research Projects in the Fields of Psychology, Mathematics, Atmospheric Science, Oceanography and Climate Research, deadline: 25. October 2023

The Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) together with the Agencia Estatal de Investigación (AEI, State Research Agency) is pleased to announce the launch of a pilot for a joint Lead Agency Procedure. The pilot is intended to encompass two calls. In this first pilot call, the DFG will act as the lead agency and will be responsible

for the review and evaluation process. After successful completion of this first pilot call, a second call with the AEI as the lead agency is envisaged.

In the current pilot call, Spanish-German research teams are invited to submit joint research proposals in the fields of:

- Psychology (DFG Review Board 110, AEI Area 8. PSI)
- Mathematics (DFG Review Board 312, AEI Area 9. MTM)
- Atmospheric Science, Oceanography and Climate Research (DFG Review Board 313, AEI subareas CYA and MAR of the Area 16, CTM)

Applicants should ensure that their project falls within one of these fields, i.e. is covered by both the above-mentioned DFG review boards ("Fachkollegien") and the AEI areas and subareas (see links below).

Applicants should demonstrate how bringing together researchers based in Spain and Germany will add value and advance their research. It is expected that each partner substantially contributes to the common project. Projects should be integrated but do not have to be symmetrical. However, work packages are expected to be delivered with a reasonably equal distribution between the partners and schedules should be well-coordinated. The team of applicants should ensure there is a plan for effective delivery and coordination of research across the partners.

Please note that there are no separate funds available for this joint initiative. These opportunities follow the general funding lines and budget of the AEI and the DFG. Proposals must succeed on the strengths of their intellectual merit and teams in comparison with other proposals.

Proposals must address the above-mentioned research fields of the call. Each research project must be jointly conducted by a team of Spanish and German applicants.

Proposals must be submitted by 25 October 2023 to the DFG by the German principal investigator.

Further Information:

https://www.dfg.de/foerderung/info_wissenschaft/ausschreibungen/info_wissenschaft_23_66/index.html

BMEL Innovations- und Transformationsdialog im Bilateralen Kooperationsprogramm, Frist: 20. August 2023, 1. Stufe

Der Innovations- und Transformationsdialog (ITD) ist eine Initiative des Bundesministeriums für Ernährung und Landwirtschaft (BMEL), um die Transformation der Ernährungssysteme und die Verbreitung nachhaltiger Innovationen voranzutreiben. Dabei ist das Ziel, herausragende, innovative Ideen für die Beschleunigung des Wandels im landwirtschaftlichen Bereich zu unterstützen. Die geförderten Projekte sollen innovative Ansätze beinhalten, die Diskussionen voranbringen und partnerschaftliche Wege in der internationalen Zusammenarbeit ausloten, um krisenfeste und klimafreundliche Ernährungssysteme zu schaffen und die biologische Vielfalt zu erhalten und zu stärken.

Antragsberechtigt sind Organisationen aus Praxis, Wissenschaft und Zivilgesellschaft mit Sitz in Deutschland, deren Geschäftstätigkeit in den Bereich der Transformation der Ernährungssysteme und/oder der Förderung nachhaltiger Innovationen im bilateralen Kontext fällt.

Für die Bewilligung der Projekte ist ein zweistufiges Verfahren vorgesehen.

- Dabei sind in einem ersten Schritt zunächst Ideenskizzen einzureichen, die wettbewerblich begutachtet werden.
- Die Erstellerinnen und Ersteller der vielversprechendsten Ideenskizzen werden anschließend aufgefordert, einen Förderantrag zu stellen.

Die Projektskizzen sind bis einschließlich zum 20. August 2023 einzureichen.

Weitere Informationen:

https://www.bmel-kooperationsprogramm.de/nachrichten/nachrichten-detailansicht/?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bmodule%5D=News

HORIZON EUROPE Accelerating the implementation of New Approach Methodologies and other innovative non-animal approaches for the development, testing and production of health technologies, deadline: 16. January 2024 17:00 Brussels time

Animals and animal-derived materials are widely used in biomedical research and in the production and development of health technologies. This raises serious ethical concerns, and there is growing societal pressure to move towards alternative approaches and methods. Besides major ethical concerns, there is also scientific evidence that supports moving away from

animal-based approaches and finding more human relevant methods and strategies for both the assessment of safety and efficacy of new health technologies and for manufacturing. Animal testing requires time-consuming protocols, high costs for animal supply, and the results are not always reproducible and applicable to humans. In addition, for the development and production of health technologies (e.g. in vitro diagnostics) as well as in biomedical research in general, materials of animal origin are required (e.g. biomolecules, sera). These animal-derived products require large amounts of animals for their production. Therefore, also in this context, there is a need to foster progress towards new alternatives (e.g. synthetic matrix, recombinant proteins, optimisation of production processes via artificial intelligence) to reduce the overall number of animals that are bred for these purposes.

NAMs and other innovative non-animal approaches have high potential to improve the development and/or production of health technologies, while contributing to the reduction and replacement of the use of animals. Recent improved biological knowledge, technological advances, computer simulations and innovative non animal approaches and methods (e.g. organoids, complex 3D cell models, microphysiological systems¹, in silico models, non-animal derived antibodies and other biomolecules² provide the opportunity to move forward with safer and more effective tools for protecting human health and preventing/treating diseases that would in parallel entail an improvement of animal to human translation or better production processes, as well as helping progress towards the replacement of animals used in biomedical research in general. While the potential for using non-animal approaches for the production, development and testing of new health technologies is enormous, more evidence and high-quality data for their performance evaluation in comparison with established animal-based approaches for a specific application (such as a production process, primary pharmacology, or next-generation-risk-assessment – NGRA) and for their validation are required by the industry and regulators to implement these alternative approaches in R&D and decision making processes. In addition, policy makers require a large body of up-to-date, high-quality knowledge to inform relevant health policies and ensure the long-term goal of full transition to non-animal approaches.

The current topic seeks to address these challenges by exploiting the latest relevant scientific advancements to develop NAMs and other non-animal approaches, which could be more readily available and more efficient than those involving animals, and which should improve either the development, including efficacy and safety assessment, of new health technologies for infectious/non-communicable diseases or the production processes of such technologies.

The projects funded under this topic should aim to do the following.

- Develop new NAM/s or other non-animal approach/es (or a combination of those) or use existing ones in an innovative way to improve (early-stage) assessment of new health technologies (and animal to human translation where relevant), or to improve the production processes of health technologies (such as bio/pharmaceuticals, vaccines, medical devices including in vitro diagnostics, and radio-chemicals).
 - Specify the context of use (e.g. primary pharmacology, toxicology, safety, quality control, production processes) of the novel approach/es, how it/they can be integrated efficiently in the relevant workflows and propose and implement a plan to carry out their performance evaluation and validation, as well as demonstrate their added value in comparison to relevant established animal-based approaches.
 - Make a comparative evaluation of the different approaches to replace, reduce and refine animal use, including the identification and assessment of parameters that influence their usefulness such as their reliability, reproducibility, robustness and fitness for purpose.
 - Generate evidence on the robustness, reliability, and applicability of these novel approaches in an industrial research and development (R&D) context and to support regulatory decision making in testing, development or production of health technologies, as relevant. Accordingly, applicants should develop a strategy/plan for generating appropriate evidence to support regulatory acceptance and engage with regulators in a timely manner (e.g. through the European Medicines Agency [EMA] Innovation Task Force or qualification advice).
 - Gather and produce high quality datasets to generate a solid knowledge base for supporting the use of NAMs and other non-animal approaches in the field of health technology and drive 3Rs implementation. To ensure the sustainability of the results and foster future development and validation of innovative non animal approaches, applicants should develop a fit-for-purpose scalable digital data repository. Applicants should consider and leverage as much as possible existing infrastructures.
 - Establish a collaboration platform between all relevant stakeholders from public and private sides, including regulatory agencies and policy makers, to exchange information, prepare white papers and guidelines to foster uptake or translation into health policies, supporting an adequately reflected transition to full implementation of non-animal approaches in health technology development and manufacturing. Patients and/or patient organisations may be included and actively contribute to such activities by providing, for example, their insight on the use of human-derived samples, as relevant.
 - Accelerate the broad implementation of the NAMs and other non-animal approaches in research through a strong communication and dissemination plan, fostering also exchanges and cross fertilisation with other projects funded in this area.
- Projects funded under this topic are expected to contribute to relevant EU health policy initiatives such as the new Indus-

trial Strategy for Europe, the European Health Emergency and Response Authority (HERA) and the EC proposal on the European Health Data Space (EHDS).

Furthermore, applicants are expected to explore and/or implement synergies³ and complementarities with relevant initiatives/projects, at national, European and international level. They should also consider, as relevant, the activities of the 3Rs Working Party of EMA.

Expected Outcome:

- Research and innovation (R&I) actions (projects) to be supported under this topic must contribute to all the following outcomes.
- Researchers will benefit from the implementation of NAMs and other innovative non-animal approaches which have been assessed and validated for their performance and found to be relevant, reproducible, predictive, and standardised, ultimately leading, as relevant, to their regulatory acceptance for use in infectious and/or non-communicable disease applications. The new approaches should lead to an improvement in the assessment of health technologies (and animal to human translation where relevant) and/or production processes, and to a significant reduction in the number of animals used. In addition, these approaches may answer questions that current methods cannot, and improve the predictability and robustness of evidence generated for regulatory decision-making.
- European industry will benefit from the establishment and availability of NAMs and other innovative non animal approaches for the testing, development and/or production of health technologies that are fit-for-purpose to support regulatory decision making.
- Researchers and developers of innovative healthcare solutions will have access to high-quality data, new recommendations and best practices to incentivise the use of NAMs and other non-animal approaches and their integration in industrial processes. This should be supported by an appropriate digital repository to ensure both the sustainability and scalability of the knowledge base.
- Regulators and policy makers will gain knowledge and have access to high-quality data on the characteristics and use of NAMs and other innovative non-animal approaches in the production and development of health technologies to foster the development of harmonised guidance and requirements, as well as uptake or translation into health policies.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-05-01;callCode=H202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Inclusive clinical studies for equitable access to clinical research in Europe, deadline: 08. November 2023 17:00 Brussels time, 1. Stage

The research and innovation (R&I) action (project) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes.

- Researchers, including industry stakeholders, clinical investigators and healthcare providers, strengthen the understanding, through use cases, of the impact of study design/protocols and study conduct on patient recruitment/retention that will help future clinical studies. These stakeholders will also benefit from gaining clarity on what clinical study diversity means in Europe, especially considering the emerging guidance from the US Food and Drug Administration (FDA) on clinical trial diversity in the US.
- Patients will benefit from a sustainable, easy-to-use digital platform, built with input from patients and/or patient support organisations, enabling more underserved patients to identify clinical studies that they are eligible for. Investigators/sites would be able to locate patients for ongoing clinical studies. This will benefit both recruitment and retention of underserved patients as it will act as a match-making portal that will be accessible to all sponsors (including academics/investigator-initiated trials, industry, etc.), and provide patient support to enable patients to allay their concerns in a timely manner, increasing their knowledge/education and building trust toward clinical research
- Researchers, including industry stakeholders, sponsors, clinical investigators, clinical research organisations, healthcare providers and patients/caregivers benefit from a toolbox of new approaches, tools, solutions and best practice approaches to facilitate and increase patient recruitment and retention, to better design and conduct clinical studies including adaptive designs, registry studies and decentralised studies with a particular focus on under-represented and underserved patient populations in Europe. Taking account of regulatory requirements, this will lead to more effective clinical studies with an increased recruitment/retention of diverse patient populations that is supported by a community-informed approach.
- Increasing population representativeness also better reflects real-world patients and helps the generalisability of the study

findings, leading to better innovations. This is a positive outcome for all patients (not just underserved patients). Targeted under-represented and underserved patient populations have increased trust in clinical studies, which helps to overcome recruitment, participation, and retention challenges through educational programmes, public outreach, and community outreach/engagement.

- Clinical investigators, clinical sites and existing clinical networks benefit from cultural competency and educational training to better engage with diverse populations. New investigators from underserved communities will benefit from inclusion in clinical studies.
- The pool of clinical sites with access to diverse clinical research staff that can facilitate the education, recruitment, and retention of diverse populations in clinical studies is broadened.
- Community-based sites and organisations are better engaged to provide input on the conduct of clinical studies and to promote diversity in patient populations through inclusive enrolment practices.
- Regulators, health technology assessment bodies and payers benefit from better information on health technologies including medicinal products, medical devices benefit-risk profile across the patient populations for use in clinical practices.
- Data standards established in agreement with regulators. Standardisation of data standards for demographic descriptors across sponsors such as race, ethnicity, gender, sex, and other selected diverse factors for the defined underserved and under-represented populations are essential for consistent reporting and valid demographic measurement.

Patient recruitment and retention remains a leading challenge in the efficient completion of clinical studies, including studies on medicinal products, medical devices, or IVDs. Furthermore, despite advancement of enrolment practices designed to better reflect the population most likely to use the health technologies in clinical practice, there is still only limited diversity within recruited patient populations. The under-representation of diverse populations (due for instance to their race and ethnicity, gender, age, socio-economic status, geographical location) creates knowledge gaps about the risks and benefits of health technologies for these specific populations.

This topic aims to develop a multi-faceted, intersectional approach to overcome the multifactorial barriers associated with the recruitment and retention of underserved patient populations in clinical studies and to contribute to transforming the way clinical studies are conducted in Europe.

To fulfil this aim, the following activities around the defined themes should be addressed.

Landscape

- Agree a definition of “underserved” populations in Europe with regulators, that includes populations facing socio-economic, systemic, or cultural barriers that prevent equitable access to clinical studies. This may be broader than populations currently defined in the demographics that sponsors collect, such as age, sex, gender, race, and ethnicity. This could include rural populations, refugees, homeless, illiterate, disabled people, and those belonging to minority populations.
- Estimate the current participation of diverse study populations in clinical studies differentiated by success in recruitment and retention; identify and evaluate the factors that contribute to and limit existing initiatives to increase diversity of recruitment and retention in clinical studies.
- Define and develop country-, social- and culture- specific understanding of factors driving under-representation and underserved populations in Europe. Shape the development of guidance on how to reach and retain underserved populations in clinical studies in different settings and countries, and how to collect data in a GDPR-compliant fashion across Europe.
- Establish a sustainable patient-centric digital platform (open to all sponsors) connecting the patients, patient support organisations, sponsors, and investigators at different sites (including in community settings, hospitals, primary physicians, etc). To ensure patient engagement, the platform should use lay language and make use of existing resources such as ClinicalTrials.gov information; patient support information developed by patient organisations, or Clinical Trials Information System (CTIS). This is important to ensure that the patient/community engagement activities undertaken lead to patients being directed to use the platform, leading to an improvement in participation of diverse patients. The needs of underserved populations with access barriers to digital platforms or language barriers should be considered.
- Define the governance structure and maintenance/ownership of the platform. The active involvement of underserved patients / patient representatives is expected in the planning and development of the platform, as well as governance activities.
- Understand the interface between international, regional, and local approaches from a patient-centricity perspective (while the strategies may need to be developed and implemented locally, they will be part of multi-regional/multi-country clinical studies conducted by sponsors)

Protocol design and clinical operations

- Establish criteria for measuring ‘representativeness’, i.e. patients enrolled in the trial represent the prevalence of the disease in different sub-populations. For example:
 - Representation: age, sex, gender, race, ethnicity (measured against prevalence).
 - Inclusion: socioeconomic status, rural vs. urban access, sexual orientation, disability, payer status (private vs public), pregnancy/lactation status, etc.

- Identify and assess existing tools and solutions for patient recruitment and retention that could be used for recruitment and retention of a diverse population from a European perspective. Develop a set of suitable tools, solutions, and strategies applicable for different types of clinical studies, including studies with medicinal products, medical devices, or IVDs.
- Identify and review aspects of study design such as narrow eligibility criteria, methodological approaches, logistical and other patient-related factors that could limit broader patient and communities' engagement, taking account of regulatory requirements; define recommendations for best practices.
- Explore and validate approaches that improve access, participation, recruitment, and retention of diverse patient populations, including innovative technology solutions, clinical research methodologies (e.g., adaptive, home based/hybrid), leveraging real world data sources etc.

Community engagement

- Raise awareness, develop educational activities and inclusive toolkits to increase knowledge and trust of target populations towards clinical studies to overcome recruitment, participation, retention challenges and to enable early patient engagement.
- Develop targeted activities to foster community engagement and build trust with patients.
- Establish connections between different stakeholders in the community e.g. researchers, industry stakeholders, patients, caregivers, investigators, and healthcare providers.

Investigators / clinical sites

- Build new site capabilities and develop training activities to increase the number of community-based sites and expand the pool of investigators, including investigators from under-represented communities and naïve investigators, to set them up in geographies where the infrastructure is missing.
- Create the necessary support mechanisms and define specialised training e.g. cultural competency training, naïve investigator training, etc. through existing clinical networks, medical institutions, patient organisations and community-based organisations. Existing resources such as Clinical Trials Transformation Initiative (CTTI), or other projects such as IMI (Innovative Medicines Initiative) projects conect4children (c4c) and EUPATI can be leveraged.

To ensure the applicability of the solutions/tools/recommendations, the applicants should test them in pilot use cases, which will be determined during the project based on the availability of cases from sponsor companies and in discussion with the consortium, in one or more disease areas of choice. The proposed disease areas should constitute an unmet public health need and a significant burden to patients, healthcare systems and society (e.g. breast cancer, prostate cancer, hypertension, lupus etc). Furthermore, the proposed areas should be representative to allow broad implementation across diverse disease areas, different cultural and geographical distributions, types of clinical research such as clinical studies on medical products, clinical investigations for medical devices, performance studies for IVDs, and studies testing non-pharmacological and rehabilitation interventions.

The purpose of the pilot use cases is to test tools and solutions for patient recruitment and retention, assess the functionality of the digital platform, and test the improvements brought by the digital platform on patient recruitment and retention. The focus will be on testing the robustness of the infrastructure to ensure the solutions put in place are "fit for purpose". The testing could establish the viability of the solutions, for example:

- number of new sites added to the platform;
- number of under-represented investigators trained through this initiative;
- number of investigators that serve underserved patient populations;
- effectiveness of community engagement activities as judged by patient support organisations;
- effectiveness of recruitment and retention activities via the platform, as experienced by investigators and patients;
- analysis of number of users of the platform and the type of content accessed by users.

Applicants are expected to consider the potential regulatory impact of the results and as relevant develop a strategy/plan for generating appropriate evidence, and to engage with regulators in a timely manner (e.g., through the EMA Innovation Task Force, qualification advice).

In their proposals, applicants should leverage and build on existing tools & solutions and best practice experiences that have already been developed at national European and/or international level, including tools developed in IMI/IHI projects.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-04-03-two-stage;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Safe & Sustainable by Design (SSbD) packaging and single use device solutions for health-care products, deadline: 08. November 2023 17:00 Brussels time, 1. Stage

The project should contribute to the following outcomes:

- Paradigm shifts in standard materials to shape products of the future (e.g. reduced material usage by pushing the boundaries on material specifications such as down gauging foils/films, blending virgin and recycled polymers, inclusion of more sustainable materials as newly proposed from material suppliers, etc.).
 - Development of new and effective technologies, products and innovations that generate minimal waste from packaging and enable the recycling of used devices (including devices which have been in contact with human tissues, i.e. infectious waste¹) throughout their lifetime of use in healthcare systems, by applying the principles of the safe & sustainable by design (SSbD) framework.
 - Alignment with the European Packaging and Packaging Waste² and Ecodesign of Sustainable Products³ Directive proposals.
 - Such innovations – i.e. packaging materials & single-use medical devices (e.g., pens used for insulin injection, surgical trocars) are easily accessible in sufficient quantities to healthcare providers (e.g., hospitals, medical analysis laboratories, caregivers, and patient associations/organisations).
 - Environmentally-friendly packaging and device materials are designed from sustainable raw components and manufacturing processes with minimal carbon footprint.
 - Selective sorting procedures, implementable by healthcare providers.
 - The creation of short circuits for recycling packaging and device waste from healthcare providers' locations.
- Healthcare systems more widely adopt a lifecycle assessment approach, enabling healthcare to become a more sustainable industry with closer and more circular recycling loops for packaging as well as single-use devices, including those which may have been contaminated (i.e. infectious waste).

Solutions should include a holistic approach such as:

- adoption of biomass balanced materials that reduce environmental impacts, and
 - inclusion of advanced recycling technologies such as various chemical recycling technologies (hydrolysis, pyrolysis, solvolysis, etc.) if improvements to environmental impacts can be properly documented.
- Patient outcomes and the safety/performance of medical products should not be compromised by the environmentally-friendly packaging and device solutions to be developed by the project.
- Notably, these packaging solutions should be compliant with existing standards (e.g. primary packaging with sterile barrier: ISO 11607) to guarantee the safe use of medical products, i.e. maintenance of the safety and performance levels that are claimed throughout their intended shelf life.
- Depending on the use cases selected by the project, they must provide a sterile barrier, maintain controlled humidity, protect against light, etc. throughout their shelf life, including shipment from manufacturing site to end users.
 - When used as a sterile barrier, they should be compatible with common sterilisation processes (e.g. steam, gas sterilisation such as hydrogen peroxide; radiation treatments such as e-beam, gamma irradiation, X-rays, etc.).
 - When used as medical products for use in humans, existing safety & biocompatibility standards are met such as European Pharmacopeia (EP) compendia, ISO 10993, etc. (e.g. not generating extractible and leachable harmful products during the full shelf life of the products).
 - The chemical and physical properties of the new material formulations should also guarantee the intended shelf life of the medical products (e.g. up to 5 years).
 - Work with regulators (e.g. European Chemicals Agency (ECHA), European Directorate for the Quality of Medicines & HealthCare (EDQM), European Pharmacopeia (EP), US Pharmacopeia (USP), American Chemical Society (ACS), etc.) to create new or revised standards/monographs for new materials that are used in health products. By extension, this engagement should contribute to the generation of future product eco-design labels / green claims.
 - For example, the use of packaging composed of biodegradable, recyclable and/or environmentally benign ingredients is favoured if the claimed performance and safety of the medical products are maintained.
 - Improved and simplified protocols for the management, collection, and recycling of medical device waste (packaging and devices) to reduce waste management costs for healthcare providers and minimise the environmental impact of the medical waste generated by medical devices.
 - Protocols for the collection of single-use devices and their packaging to drive circularity should be easily implementable by healthcare providers. Their adoption must be possible for the greatest number of healthcare providers, regardless of their

location. They may potentially include the decontamination of products if they have been in contact with human tissues to allow their sorting and recycling under the safest conditions.

- Improved and simplified protocols for supply chains and logistics for sorting of packaging waste of health products for healthcare providers with a minimised carbon footprint.

The outcomes must be as cost-effective as possible so as not to burden health systems with prohibitive additional costs.

Overall, the project is expected to yield strong results from the use cases. The results should be taken as evidence to collaboratively shape European legislation on packaging and packaging waste and the eco design of sustainable products for health technology industries.

Product development

The project should accelerate the implementation of alternative eco-packaging and device materials through collaborative work by including policy makers, regulators, and standards bodies. It should identify, characterise, and test new replacement materials according to specifications and in compliance with existing standards (e.g. primary packaging with sterile barrier: ISO 11607).

The project should examine the European landscape of materials, whether commercially available or under development, which may be acceptable as components of sustainable packaging and appliance solutions, from different perspectives, regulations, possibility to recycle with current and future waste management processes, and sustainability of industrial supply. Such a review can benefit from and partner with the European Partnership for the Assessment of Risks from Chemicals (PARC) and with the successor partnership of the M.ERA-NET III and the AMI2030 initiative. In addition, synergies with projects funded in the HORIZON EUROPE* Cluster 4 addressing SSbD could be envisaged (HORIZON-CL4-2023-RESILIENCE-01-21: Innovative methods for safety and sustainability assessments of chemicals and materials (RIA); HORIZON-CL4-2023-RESILIENCE-01-22: Integrated approach for impact assessment of safe and sustainable chemicals and materials (RIA); HORIZON-CL4-2023-RESILIENCE-01-23: Computational models for the development of safe and sustainable by design chemicals and materials (RIA)).

Health tech companies are expected to design and develop new packaging and devices (e.g. insulin pens, staplers) by starting from solutions that already exist or are at an advanced stage of development (e.g. available paper-based covers / packaging seals reinforced with polyolefins, or mixtures of virgin and chemically recycled polymers for the manufacture of blisters), and/or by selecting fully compostable or recyclable materials (for example, biomass balanced polymers as currently proposed and under development by chemical companies) to generate innovative packaging and device solutions. The polymers or materials to be selected must not only be recyclable/compostable, but also manufactured with a minimal environmental footprint.

The design and development of the new packaging and devices should apply and adapt circular economy principles and be guided by the SSbD framework. It should be done in close partnership with all players of the value chain from the manufacturers of the raw materials to the end users, the healthcare providers. The packaging and device use cases of the project are highly expected to improve and enrich the current SSbD framework, through concrete feedback to the European Commission and lessons learned. It is envisioned that this will necessitate regular interactions between the project and the developers of the SSbD framework at the European Commission.

Recycling

The project should promote the management of waste from packaging and single-use devices (including complex devices) by end users, the healthcare providers, considered as key partners of the project. This should lead to the effective implementation of the sorting and recycling of waste through collaborative work, including technical, organisational, and regulatory aspects (e.g. allowing the reuse of plastics etc. after industrial disinfection and/or decontamination of infectious waste, development of new recycling processes, setting up composting units etc.). Preferably, healthcare providers should include not only hospitals, but also other end users such as nursing homes. Healthcare providers should preferably be from several EU Member States or associated countries (e.g. minimum 3 EU Member States or associated countries), given the great disparity of practices from one country to another, in terms of legislation and implementation of waste sorting and recycling. Importantly, the project should extend existing life cycle assessment (LCA) based metrics systems to packaging and devices, by considering the life cycle of the packaging materials, from their manufacturing to their recycling / composting. The LCA study must be carried out by an independent institution. Key performance indicators are expected to come from comparing LCA metrics with the implementation of the SSbD framework, which should lead to better packaging and device recyclability and more favourable life cycle outcomes.

Another key element of the project is expected to come from an active partnership with European non-profit packaging associations, single-use plastic, and waste management associations and, possibly, standards bodies and approval bodies responsible for marketing authorisations. These institutions should work with European policy makers to support evidence-based policy making based on the findings of the different use cases of the project. The development and implementation of recyclable packaging and device solutions should also be articulated by the health tech trade associations, at the European

(i.e. EFPIA, COCIR, MedTech Europe, EuropaBio and Vaccines Europe) or national levels, in particular with their working groups on sustainability and the circular economy.

General lessons / best practices and results will be shared as far as possible (e.g. peer-reviewed articles, white papers, press releases, web media, report deliverables, etc.). Communicating project results is essential to collaboratively shaping the acceptability, adoptability, and implementation of European legislation on packaging and packaging waste and the eco-design of sustainable products for health technology industries.

Besides this topic, another topic in this IHI call entitled "Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment" will aim to improve the manufacturing efficiency of drug substances of chemical/biological origin (covering all chemical drug substances, proteins, oligonucleotides, vaccines or polypeptides etc.) by developing new manufacturing technologies, saving natural resources like water and fossil or fossil-based raw materials, and reducing waste in accordance with circularity principles (reduce, reuse, refine, recycle).

To jointly develop new strategies to ensure a greener healthcare industry along the whole value chain, and to avoid overlaps, a close collaboration between the two topics is essential and should be reflected by providing dedicated resources in both projects to align on common life cycle assessment (LCA) methodologies and LCA data.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-04-05-two-stage;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Patient-centric blood sample collection to enable decentralised clinical trials and improve access to healthcare, deadline: 08. November 2023 17:00 brussels time, 1. Stage

The results of the project generated by this topic will enable innovations in healthcare delivery and research by generating the infrastructure and logistics for blood collection at home, that is simple, minimally invasive, less painful, convenient, and feasible.

Importantly, the project will also provide new insights and enrich information related to the research questions by creating an unprecedented data set that will enable multiple secondary research options for years to come. Notably:

- It will create insights into the public acceptability for microsampling home: are patients comfortable with a new kind of medical technology? What training is necessary?
- Are we able to advance the transition of care from the hospital to the home? Does the care quality improve?
- How do we utilise the higher frequency of data, including its integration with electronic medical records and using advanced analytics methodology?
- Do doctors' practices and decisions change with the increased frequency of biomarker data, and does it lead to better outcomes for the patient?

While integrating existing components for microsample collection and central lab analysis, quality standards for the new infrastructure and logistics will be rigorously and transparently validated and established in Europe and harmonised with parallel ongoing efforts in the USA. The harmonisation will critically enhance the implementation of microsampling in global clinical trials of new therapeutics. The validation and establishment of microsampling at home by patients and/or their caregivers will be undertaken in ways that are acceptable for patients and their caregivers, health care professionals, regulatory agencies, policy makers, Health Technology Assessment (HTA) experts, payers, and advocacy groups.

The overall aim of the project generated from this topic is to create and validate the infrastructure and logistics for blood collection by the patient and/or caregiver at home as a healthcare tool and an alternative to the current gold standard venous blood for routine clinical assays. This project will employ only commercially available CE-marked microsampling devices, according to their intended use. The development of new devices for blood sampling or of new clinical assays / analytes is not the focus of this project, and no new clinical assays will be evaluated. Similarly, given their current maturity, home sample analysis is out of scope.

Training materials, customised for patients and caregivers as well as for medical personnel will be developed, ensuring the acceptability of the new approach to these groups. Interactions with regulatory authorities, the European Medicines Agency (EMA), local European agencies as well as regulatory agencies from non-EU European countries and the US Food and Drug Administration (FDA) will be sought to advance the regulatory acceptability of the logistics model and harmonisation across the EU, other non-EU European countries and the US. Further, key stakeholders (e.g. policy makers, HTA experts, payers, patient advocacy groups) will be encouraged to implement the infrastructure and logistics throughout Europe. Lastly, the

best ways to integrate, transmit, and analyse (including AI) the data generated will be explored. Results will be shared broadly through peer-reviewed publications or other mechanisms.

To be noted – home blood microsampling has been used in geographically restricted pilot projects¹. With the project generated from this topic, it is expected to generalise them, and leverage the learnings from the pilot projects, to enable broad adoption. Importantly, it is known that patients greatly appreciated this experience compared to the traditional blood sampling methods currently in use.

Applicants should in their proposal address the following:

1. Demonstration of concordance between patient-centric microsampling techniques and venipuncture

This requires delivery of a framework across Europe for establishing concordance between capillary blood as collected by microsampling devices outside of traditional collection setting by the patient and/or caregiver, versus the gold standard venous blood, for routine clinical assays.

- To generate an umbrella / master protocol that is acceptable for regulatory authorities in EU and non EU-European countries, and can be easily adopted for future applications (e.g. in additional patient populations, countries, by any vendor or organisation). To assure patient-centricity, feedback on the umbrella protocol by patient representatives and caregivers will be sought.

The umbrella / master protocol must include:

- sites in at least 3 EU member states, and may include additional sites in third countries associated to HORIZON EUROPE* or other European countries; at least one of the countries must be in Eastern Europe¹;

- at least two different types (e.g., finger stick, upper arm capillary) of commercially available CE-marked microsampling devices; for clarity, at least one device should perform liquid blood sampling, the additional devices may collect dried blood.

- routine clinical assays: i.e. blood chemistry, liver and lipid panels;

- collection of at least 50 % of microsamples by the patient and/or the caretaker; the other 50 % may be taken by hospital or nursing personnel (including remote or traveling nurses);

- collection of least 50 % of microsamples at home; the project may include collections in other locations (e.g. hospitals, general practitioners, specialists' offices) for concordance testing and establishing microsampling of capillary blood versus venous blood for routine assays

- To design, adapt, and translate patient-facing materials, obtain ethics board approvals, obtain competent/regulatory authority approvals, recruit healthy human volunteers and expand to a patient population which should be agreed upon in a project committee, collect biological samples and conduct bioanalysis according to the study protocol.

- To investigate potential errors related to the mishandling of samples and design ways to mitigate them, as well as the potentially harmful downstream effects for the individual.

- To conduct concordance analyses according to existing regulatory guidance for routine clinical assays², and define sample quality criteria (if applicable).

2. Validation of the logistics of sample collection and shipping, standardising central lab analysis.

This requires identification of an optimum workflow for device ordering, fulfilment, shipping, at-home collection and return to central labs and a seamless integration of microsampling into current central lab processes, accessioning, analysis and reporting.

- To select at least two different types of CE-marked microsampling devices, and identify and audit device vendors with ordering (portal) and fulfilment capabilities; to work with device vendors on ordering devices.

- To define appropriate shippers/processing/temperature based on the devices and assay requirements, and confirm requisition requirements.

- To identify strategic partners in terms of logistical expertise, e.g. global couriers.

- To identify countries to test devices in and confirm regulatory requirements for self-collections or collections by caretaker and shipping of devices.

- To define the support need for the use of devices and training participants on devices; to identify telehealth partners e.g. for identification verification.

- To identify the best ways to integrate the new data with existing electronic medical records and medical decision frameworks.

- To investigate the 'green dimension' of logistics: microsampling has the potential to reduce the green footprint of office visits and transportation required (fuel, costs, carbon emissions).

- To confirm the accessioning process needed, reporting requirements, and data management model.

If possible, to assess the cost savings obtained with microsampling methods as compared to gathering blood in the hospital.

3. Education and medical & patient acceptability

- To deliver training materials for patients, caregivers and clinical trial sites, taking into account the variety of patients' and caregivers' ages, abilities, etc., and ensuring smooth behind-the-scenes shipment logistics and support.

- To develop guidelines for compiling training materials to meet expectations from different training recipients, such as clinical sites, patients, caregivers, telehealth and home health providers, leveraging previous feedback collected from users (patients, caregivers, principal investigators (PIs) and medical personnel), including to develop training by telehealth.
 - To develop a plan to collect patient, caregiver and medical personnel (site staff, PIs, trial coordinator) experience and feedback:
 - to develop a well-designed questionnaire that will be used either electronically or in paper format, develop tool(s) to collect feedback and store the information, pilot the use, refine the questionnaire and data base as needed;
 - to implement the questionnaire to collect feedback from different groups (patients and caregivers, medical personnel, regulators, device manufactures);
 - to maintain a database of information collected and perform data analysis to obtain patient acceptability scores;
 - to get insights into research questions related to the implementation of microsampling which are described in 'Expected outcomes' (see above).
 - To publish survey results to validate the training and feedback with other patient advocacy groups.
4. Regulatory acceptability and implementation in clinical practice in the EU, other non-EU European countries and the US
- To prepare an overview of the regulatory landscape of microsampling at home per country in the EU, third countries associated to HORIZON EUROPE*, and other European countries, and to conduct an in-depth exploration in those countries that might be suitable for the microsampling logistics modelling.
 - To establish an early and continuous dialogue with the European Medicine Agency (EMA) Innovation Task Force, in addition to local regulatory agencies of the EU, and relevant authorities of other non-EU European countries and the FDA:
 - to assess acceptability with regulators and seek prospective input on the umbrella / master protocol, choice of countries and approach to validating the logistics;
 - to discuss the best strategy/timing for qualification and/or integration of project outputs into regulatory practices, prepare relevant documents (e.g. briefing books, EMA guidance document) to share project results, request scientific and qualification advice, and seek a harmonisation with the regulatory agencies from other non-EU European countries and the FDA, which is key to global clinical trials of new therapeutics.
 - To interact with policy makers, HTA experts, payers, and advocacy groups to facilitate the implementation of project results in clinical practice throughout the EU, and other non-EU European countries and the US.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-04-02-two-stage;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Establishing novel approaches to improve clinical trials for rare and ultra-rare diseases, deadline: 08. November 2023 17:00 Brussels time, 1. Stage

The project generated from the topic should not only develop capacities and capabilities to execute innovative trial designs, but also plan to identify solutions to address scientific gaps as well as technical and operational challenges, and to collaborate / find synergies with relevant existing initiatives to establish a new, dedicated, rare disease specific and sustainable infrastructure. The project is expected to support innovation and optimise drug development for rare diseases with high unmet medical needs by focusing on clinical trials conducted for small populations and clusters of diseases with commonalities. With a focus on addressing 'white spots¹' in a subset of the 95% of underserved rare diseases, the R&I action to be supported under this topic should:

- Deliver novel rare/ultra-rare disease-specific methodological approaches² to transform the way treatments are developed with a view towards accelerating approval and access.
- Pressure-test new clinical trial designs by using the playbooks co-created with stakeholders through case studies and modelling, addressing up to four selected paediatric / rare disease (or clusters of ultra rare diseases with commonalities) case studies, and different types of interventions (at least one for advanced therapy medicinal products (ATMP)).

In more detail, all the following outcomes are expected to be delivered:

- Playbooks for designing novel clinical trials (CT) for rare diseases / clusters of diseases that can also be used for education and training. Jointly created with and validated by regulators, health technology assessment (HTA) bodies, these playbooks should include:
 - good practice recommendations for multinational innovative studies, electronic health records (EHRs) driven registries and

longitudinal natural history studies;

- standardised processes across all disease areas, countries and sites for fast and reliable feasibility processes, allowing – for example – for early feasibility assessment to support the design of feasible development programmes. Effectiveness assessment of optimised CT designs as compared to the ‘gold-standard’ CT design for rare diseases;
- study protocols co-created by expert network(s) with regulators, HTA bodies, patients, and industry;
- agreement on a minimum set of data variables to be included in every registry / newly designed real world data (RWD) source (baseline patient characteristics, disease-related information, etc.) to ensure usability for regulatory decision-making and study planning;
- information to support clinical research network set-up for conducting innovative trials including, for example, real world evidence (RWE), remote elements etc;
- guidance from expert advice to developers on specific aspects when designing CTs.
- Alignment and complementarity with the European Partnership on Rare Diseases (in particular the ‘Clinical Research Network’) co-funded by HORIZON EUROPE* and Member States and Associated countries, to create synergies and avoid overlaps.
- Certified/qualified clinical trial sites scientifically and operationally (especially in the areas of ATMPs) with readily available pools of patients ready to be recruited into CTs where appropriate; working to agreed site standards along comparable process and quality standards.
- Structured and predictable system for referral of patient (physically and virtually) to expert centres, facilitated through incentives and avoiding patient disadvantages (travel etc.) and incongruity amongst healthcare providers.

Developing medicines for rare diseases involves complexities and challenges beyond those typically seen for common conditions, in particular:

- for most rare diseases, disease aetiology, biology and natural history are insufficiently understood, while there are often no established endpoints for use in clinical trials;
- enrolling, engaging and retaining patients, including patients who may be far apart geographically;
- designing and evaluating clinical trials, including using/identifying relevant outcome measures;
- ensuring the quality of patient data, and enabling re-use of data (e.g. registries);
- underdeveloped and fragmented clinical trial infrastructure for the conduct of clinical studies, including those using ATMPs and for cell and gene therapies;
- an evolving and internationally fragmented global regulatory and landscape.

The evaluation of the regulations on Orphan Medicinal Products and Paediatric Medicines by the European Commission has concluded that those regulations have boosted the development of new therapies for rare diseases but have not yet adequately managed to direct research and innovation towards the areas of greatest unmet medical need. There is clearly a need for holistic and inclusive solutions to address the persisting root causes of these unmet medical needs and to deliver more medicines for patients with rare diseases. This topic, which contributes to the Rare Disease MOONSHOT Initiative¹ is expected to be an important catalyst for innovation for patients affected by some of the 95% of rare diseases without treatment options. Importantly, the project selected under this call would also align with the identified strategic priorities of the HORIZON EUROPE* co-funded Partnership on Rare Diseases that is expected to start in mid-2024 and to consolidate the Rare Disease (RD) research and innovation ecosystem.

The topic aims to unravel roadblocks on the current clinical development pathways and deliver methodological solutions for innovative clinical trial designs and analyses, including regulatory considerations.

To fulfil this aim, the proposal should:

- identify good practices for the design, use and implementation of innovative clinical trial (e.g., basket trials, platform trials, in silico trials) and of tools/methods (e.g., RWD, digital health technologies, quantitative approaches, trial with remote elements) developed for small populations and clusters of diseases, while also addressing scientific and statistical challenges with the generation and interpretation of small, incomplete and/or heterogenous data sets to help support CT and product approval;
- identify good practices to address knowledge gaps including the collection of natural history data, the development of relevant new endpoints and patient reported outcomes (PROs) which should be incorporated into the CT design;
- benchmark new clinical trial designs (i.e. basket, platform CTs, shared control arm trials between different sponsors...) that should be assessed and compared to the existing ‘gold standard’ CT model for rare diseases (i.e. single arm);
- focus on paediatric and adult rare diseases (‘white spots’);
- develop appropriate capacity and capability for innovative clinical trials as well as education and training programmes based on lessons learnt from existing initiatives and developers’ experience so that best practices to optimise drug development in rare diseases can be shared and disseminated, and playbooks deployed;
- develop a virtual platform for knowledge and tool sharing, which could be also used for playbook deployment;

- identify clinical trial sites which are certified/qualified scientifically and operationally (especially in the areas of ATMPs) with readily available pools of patients ready to be recruited into CTs where appropriate. Taking into account the cohort size of such clinical trials it will be quite important to ensure the cultural and geographical distribution of the CT at EU level;

To be successful and deliver according to the objectives, it is important:

- to capitalise on past public investments and collaborate with relevant stakeholders, e.g. with the European Reference Networks (ERNs) and their registries, the European Joint Programme on Rare Diseases (EJP RD2) and the future European partnership on rare diseases (RDP) to foster a more cost-effective pathway for the development of treatments for patients with rare diseases in Europe. The ERNs³ are being established under the Directive on patients' rights in cross-border healthcare, with their registries under the supervision of the Member States⁴ and therefore any plan for collaboration between ERNs and industry should be compatible with the principles⁵ set up by the ERN Board of Member States and the Commission services. Hence the need to identify solutions to unlock industry collaboration with ERNs (e.g., leveraging on ERNs' clinical expertise, ERN registries, etc.) should be in line with these principles;
- to utilise the European Commission's infrastructure for the RD registry data and clinical cohorts ecosystem, namely the European Platform on Rare Disease Registration (EU RD Platform) for clinical data management;
- to leverage key learnings from existing ongoing initiatives, e.g., the Bespoke Gene Therapy Consortium⁶ IMI EU-PEARL7 EUnetHTA²¹⁸ or of the IRDIRC "Orphan Drug Development Guidebook" project⁹ which aims at creating a simple guidebook for academic and industrial drug developers describing the available tools and initiatives specific for rare disease development and how best to use them;
- to build upon the results of Horizon 2020 (H2020) research projects such as the European Rare disease research Coordination and support Action (ERICA) and FP7 projects developing methodologies for clinical trials for small populations¹⁰ namely IDEAL¹¹, InSPiRe¹² or ASTERIX¹³. It will be crucial to optimise their findings (if necessary) based on new scientific/technological progress and find synergies with other existing projects, whether completed or ongoing;
- to build synergies with the new cluster of HORIZON EUROPE* projects on developing new effective therapies for RD with no approved options (expected to start in Q3 2023) and to partner with existing projects/initiatives, e.g., IMI (Innovative Medicines Initiative) Screen4Care¹⁴, IMI conect4children (c4c)¹⁵, Remedi4All¹⁶, C-Path RDCA-DAP¹⁷;
- to help overcome the fragmentation of the clinical trial environment across Europe;
- to identify solutions to overcome hurdles in the implementation of cross-border patient participation in clinical trials;
- to develop best practices to support the development of innovative and 'regulatory-grade' clinical trials and generate the appropriate evidence for regulatory and HTA decision-making.

Once developed and established, the playbooks and related infrastructures will be pressure-tested through case studies and modelling, using up to four selected paediatric/rare diseases (with at least one ultra-rare disease or clusters of diseases) and different types of interventions (at least one being an ATMP).

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-04-04-two-stage;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Expanding translational knowledge in minipigs: a path to reduce and replace non-human primates in non-clinical safety assessment, deadline: 08. November 2023 17:00 Brussels time, 1. Stage

Expected Outcome:

- Obtain and share biological knowledge of minipigs, thereby facilitating the development of innovative solutions by improving the translational understanding between minipigs versus NHPs and humans, including further understanding of the minipig immune system, with the overall aim to replace, reduce and refine the use of animals in non-clinical safety assessment.
- A regulatory pathway for nonclinical safety assessment of biologicals and other new therapeutic modalities in minipigs with the potential to impact regulatory strategies.
- Publicly available databases and software for physiological, genomic, transcriptomic, metabolomic, proteomic and epigenetic minipig data to understand underlying mechanisms of disease/toxicities and find new mode of actions for pharmaceutical interventions.
- Characterised and validated genetically modified minipig models:
- genetically modified minipig models based on the CRISPR/Cas9 gene-editing technology.

- minipigs with 'humanised' immune system components and effectors for testing biologicals.
- small-sized micropig for efficacy/safety assessment to facilitate compound availability in pharmaceutical R&D.
- Assessment of the utility of the minipig as a relevant toxicology species for immuno-safety testing using therapeutics which have been tested preclinically and clinically. Assisting and synergising the already existing translational and regulatory efforts related to immunological safety evaluation. Developing validated antibodies and in vitro immunoassays to characterise the immune system and assess the immuno-safety of therapeutics in minipigs.
- Minipig-specific technology for automated study data: validated medical devices, biosensors, algorithms, software, and digital animal housing. Machine learning and artificial intelligence (AI)-based tools to monitor abnormalities in behaviour and physiological systems in undisturbed animals.

To ensure long-term sustainability, all the interdisciplinary science-based knowledge obtained and generated in the project arising from this topic will be shared, integrated, digitalised, and published in peer-reviewed journals, encouraging industry and academia to develop innovative medical science solutions and technologies, such as scientifically and ethically sound animal models, assays, biomarkers, monitoring devices, biosensors for normal physiological behaviour, and algorithms. Based on the close collaboration with regulatory bodies, the knowledge generated in the project is further expected to impact regulatory guideline strategies. All outputs will require long-term sustainability and maintenance to fulfil the scope of the project.

Challenges:

- Increasing need to find alternatives to testing in NHPs in line with EU legislation.
- Almost no precedence in minipig use for safety testing of biologicals and new therapeutic modalities [e.g., oligonucleotides, small interfering RNAs (siRNAs), crystallisable fragments (Fcs), antigen-binding fragments (Fabs), single-chain variable fragments (scFvs), monoclonal antibodies (mAbs), vaccines, gene-editing and cell-based therapies].
- Lack of scientific knowledge to scientifically justify a de-selection of NHPs in the non-clinical safety assessment of new therapeutics. Lack of public minipig reference 'omics' with good quality annotation: Full genome sequencing, in parallel with baseline transcriptomics, proteomics, metabolomics and epigenetic information.
- Lack of 'humanised' and genetically modified models available for efficacy/safety testing, including genetically modified smaller micropigs to address cases of limited substance supply.
- Significant knowledge gap on the minipig immune system and reduced number of laboratory tools and reagents when compared to other toxicology species (rodent and non-rodent).
- Lack of widespread use of biosensors, medical devices, 'intelligent' animal housing for automated data collection and analysis in minipig studies.

Objectives:

The overall objective of this topic is to characterise the minipig for use in R&D of new therapeutics and innovative medical technologies. The knowledge generated in this proposal may facilitate innovative health solutions and improve disease understanding and human predictions. The goal is to advance biomedical R&D by generating background scientific data to evaluate if the minipigs could be a viable and feasible alternative to NHPs in key therapeutic areas, with a special focus on translatability from minipigs to humans.

Key activities:

- Compile and publish existing historical safety data in minipig biomedical R&D and discuss data with regulators.
- Evaluate the translatability of minipigs in human risk assessment following treatment with biologicals and new therapeutic modalities, and discuss future perspectives of the minipigs with regulatory agencies, e.g., by requesting regulatory interactions with European Medicines Agency (EMA) such as scientific advice and/or novel methodology qualification advice to understand possible regulatory hurdles in using minipigs for safety assessment.
- Minipigs multi-omics and imaging: Generate omics reference data (genomics, transcriptomics, proteomics, metabolomics, and epigenetic information) to enable translational research in minipigs. To further characterise the minipig, imaging technologies such as magnetic resonance imaging (MRI), computed tomography (CT) scans and positron emission tomography (PET) scans are also of interest.
- Genetically modified pig models including the micro-pig: Characterise and validate humanised and genetically modified minipig models, including the micropig to generate translatable animal models in non-clinical safety assessment.
- iPig: Digital technologies, clinical data collection and AI: Create, validate, qualify, and benchmark digital solutions that can objectively measure clinically relevant and functional biomarkers in minipigs for use in preclinical toxicity studies in line with the regulatory agencies' requirements.
- Minipig immune system: validate reagents, assays, and biomarkers for immunological investigations: Conduct investigative studies in minipigs to support their translational significance in immuno-safety assessments and validate reagents/assays.
- Project management: Compile, digitalise, and publish existing and newly-produced data.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-04-01-two-stage;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment, deadline: 08. November 2023 17:00 Brussels time, 1. Stage

We expect all of the following outcomes to be generated from the topic:

- Generation of novel, process-intensified manufacturing methods and unit operations according to safe and sustainable by design (SSbD) principles with the following goals.
- Reducing solvent volumes in chemical synthesis and cleaning operations: Large volumes of pure and high-quality organic solvents are required for pharmaceutical manufacturing without ever being reused or recovered. The goal is to identify ways to either eliminate solvents, by increasing the usage of water-based reactions; reuse solvents; or more preferably avoid entirely the use of high solvent volumes. Innovative methods (e.g. surface functionalisation) of cleaning and rinsing techniques (equipment, medical devices) need to be developed to minimise solvent waste.
- Replacement of substances of concern:
 - by either replacing reagents with less toxic chemicals, e.g. replacements of chlorinated solvents, toxic reagents, heavy metal based homogeneous catalysts;
 - by identifying alternative routes to target the chemical transformation, e.g. through catalytic or biocatalytic rather than stoichiometric chemical transformations, or by reducing the overall number of steps (e.g. through cascade reactions) with a significant impact on the use of solvents and chemicals.
- Reducing total water volumes in fermentation processes (both upstream and downstream) by innovative fermentation designs, e.g. continuous manufacturing, perfusion technology and reusable downstream processing aids, or preferably by reducing or recycling the purified water (PW), and particularly high quality water (e.g. sterile water for injection (WFI)) volumes.
- New fermentation/cultivation and purification technologies (e.g. alternatives to chromatography or innovative chromatography technologies, buffers and resins) with reduced water and energy demands.
- Reducing energy consumption in chemical or biotechnological processes: Heating, cooling and sterilisation / cleaning in place (CIP/SIP) operations are energy intensive. Use of alternative chemical transformation steps or sterilisation techniques should help to reduce energy consumption.
- Harvesting new sources of raw materials other than fossil sources to have reliable access to readily available starting materials, solvents, reagents, homogeneous catalysts (where possible transition metal based or, if necessary, rare earth metal based) or biocatalysts (enzymes for catalytic chemical transformations).
- Changing biomanufacturing¹: Many biotechnological manufacturing processes rely on single-use equipment, consumables and materials, and this contributes to an increase in solid waste generation, especially plastics. Novel single-use materials will be developed from renewable sources with the possibility of recovering valuable materials like transition metals/rare earth metals from electronic components of single-use equipment (single-use reactors, electrodes, probes etc.) or using single-use equipment manufactured from renewable resources.
- According to the World Economic Forum 2022 report, the pharmaceutical industry is fuelling the climate crisis where the sector is responsible for 4.4% of global emissions and its CO₂ footprint is forecast to triple by 2050. Reducing the generation of greenhouse gases (mainly CO₂, methane, nitrous oxide) is a key element to preventing climate change. Any attempt to improve the efficiency and environmental compatibility of a manufacturing process under development is expected to reduce the generation of GHGs everywhere on the planet. A thorough assessment of the origins and the life cycles of all chemicals, reagents, solvents and API (active pharmaceutical ingredient) drug substances procured must be performed to have a complete cradle-to-gate analysis of the GHG generation to be measured as GHG footprint per mass/dose/treatment. All changes in manufacturing processes should include considerations of the economic impacts. This includes the development of thresholds for the recovery and reuse of solvents.
- All aspects of process designs should be quantified in standardised assessment systems comprising as many influence factors as possible to describe the full environmental impact of a single drug product on everybody's environment. Artificial intelligence (AI) / machine learning (ML) driven technology should help to sharpen the full picture of the environmental impacts from material supplies via manufacturing to the consumer and waste (= cradle-to-gate analysis). A publicly accessible digital toolbox will be developed that guides development chemists, biotechnologists and engineers to create the

best possible manufacturing processes that produce safe and high-quality products with the minimum environmental impact possible.

- The harmonisation of assessment systems³ across the healthcare industry is expected to be incorporated into European environmental guidelines, and standards aligned with existing standards outside the scope of the EC.

Many programmes launched on green chemistry and green pharmaceuticals (e.g. Innovative Medicines Initiative [IMI] projects like CHEM21 and iCONSENSUS, or HORIZON-HLTH-2021-IND-07-01 projects) aim to demonstrate the technical feasibility of applying new methods to improve the overall efficiency and robustness of single manufacturing steps and how to assess their impact on the environment.

The scope of this topic is as follows.

- To transfer approaches from green chemistry and technology into biomanufacturing by developing new types of upstream and downstream processing methods with increased efficiency, more balanced energy consumption and less waste (stainless steel vs. single-use equipment), continuous manufacturing (perfusion cell cultures vs. fed-batch), and the production of enzymes as process reagents in the manufacture of pharmaceutical products.

- To apply innovative technology to the chemical synthesis of e.g. small molecules, oligonucleotides, peptides and vaccines, by removal of hazardous chemicals, and streamline manufacturing processes and energy consumption, mainly by introducing new production and analytical technologies using "greener" solvents, smaller solvent volumes (e.g. mechanochemistry, alternatives to chromatography), continuous manufacturing processes (e.g. flow-chemistry) and emphasising catalysis and enzymatic chemistry. More sustainable sterilisation processes as alternative to ethylene oxide sterilisation for devices.

- To identify, characterise and test novel replacement materials for single-use equipment and process aids (tubing, bags, PVCs (polyvinyl chlorides)) based on materials from renewable sources, e.g. BioPET (biorenewable polyethylene terephthalate).

- To create new life cycle assessments (LCA) of drug substances and drug products of all (including new) modalities¹ to gain a holistic view of the end-to-end environmental impact of all materials, energies, chemicals and wastes involved in the production of medicines, with the ultimate goal of achieving comparability of diverse manufacturing processes, technologies and products, e.g. chemical entities (tablets / liquid formulations) or biologics (lyophilised / liquid formulations).

- To promote diversified value/supply chains resulting in a shift away from dependencies on specific suppliers and ingredients, thereby promoting the security and resilience of the European pharmaceutical and healthcare industry and the health of European citizens.

- To harmonise and standardise the definitions, manufacturing ontologies, methodologies and frameworks for environmental impact assessment (e.g. LCA standards) of healthcare, including pharmaceutical products, across the European healthcare sector, and align with industries outside the EU (north America, Asia, UK etc.).

- To evaluate the applicability and relevance of the proposed solutions, existing impact assessments (e.g. life cycle assessments, based on existing industry standards, e.g. the standard developed by the Sustainable Markets Initiative, SMI) should be performed to show superiority in comparison to existing approaches.

Previous and current projects (cf. HORIZON-HLTH-2021-IND-07-01 projects IMPACTIVE, ENVIROMED, ETERNAL, SusPHARMA and TransPharm) have a strong focus on the environmental impact of current and new manufacturing technologies at low technology readiness level (TRL) using life cycle assessments. In this project, the industrialisation of new technology is pursued more intensively and on a larger scale at higher TRL by all partners. In this project, the standardisation of environmental impact assessment methodologies (e.g. LCA) of industrial processes is prioritised rather than the individual assessment of new technologies.

Continuous alignment and exchange with the relevant projects from the existing HORIZON EUROPE* and IMI programmes will avoid duplication of the work and allow for the harmonisation of scientific efforts.

Resources and learnings from previous and ongoing initiatives (e.g. projects funded under IMI1 / IMI22 or other Horizon 2020, HORIZON EUROPE*, NextGenEU and EU4Health projects) should also be taken into consideration.

Current projects like IMI project PREMIER³ demonstrate the impact of drug substances, by bioaccumulation, in living organisms and mobility across the environment. In contrast, the aim of this project is to avoid the accumulation or distribution of any substances of concern in nature and therefore identify new transformations that can replace stoichiometric or catalytic use of toxic reagents or catalysts, respectively.

Most fine chemicals originate from fossil sources. Creative utilisation of new sources is the key to directing our future manufacturing efforts into a more sustainable production of second-generation fine chemicals and drugs. Developing new skills and technologies by exploring renewable sources for the bulk production of chemical starting materials of high quality based on European research networks promotes and facilitates Europe's independence from raw material sources outside Europe and diversifies global supply chains. This will make sensitive supply chains more stable and guarantee reliable patient care in Europe.

The compilation of life cycle assessment data is a time-consuming and cost intensive process, requiring the collection of a large amount of data on raw materials, consumables, transport, manufacturing utilities, devices and other materials needed

during the use phase and waste treatment of pharmaceutical products. Therefore, LCAs are created when the asset has already reached a mature development state. Early involvement of product environmental data can help guide development scientists in a more sustainable and overall impactful direction of manufacturing processes and technologies. While ongoing projects such as TransPharm4focus on developing new impact assessment methodologies for assessing the sustainability of pharmaceuticals, the project in this call will be complementary by applying harmonised standards for LCA. A harmonised set of standard data will be applied in close collaboration with SMI (Sustainable Markets Initiative) in this project based on a common set of product category rules (PCR), which will be fed into a shared database and digital planning tool that enables a non-expert user to investigate the environmental impact of new process designs, or later process or product changes. EU PEF / PEFCR (= product environmental footprint / product environmental footprint category rules) will be a key reference and over-arching starting point for a medicine-specific Product Environmental Footprint standard.

This project will therefore focus on the standardisation and harmonisation of assessing and scoring the environmental performance of systems across industry: healthcare and API manufacturing by chemical and biotech companies. They have developed a strong commitment to sustainability by design approaches over the past years with individually developed life cycle assessment methodologies to evaluate the environmental impact of their respective process developments and improvements. All methodologies lack a common framework of metrics and quantitative sets of descriptors to allow comparability of identical unit operations with different assessment systems.

The Chemicals Strategy for Sustainability has as its objective the transition towards safer and more sustainable chemicals in line with the SSbD principles. It will require that industry minimises, substitutes as far as possible, and phases out the most harmful chemicals in healthcare products whilst at the same time ensuring the sustainability / availability, safety, quality and efficacy of these products.

The early involvement of European regulatory authorities, both related to environmental footprinting requirements and from a medicine manufacturing perspective, are essential for the harmonisation of standards with existing European directives.

Besides this topic, another topic in this IHI call entitled "Safe & sustainable by design (SSbD) packaging and single use device solutions for healthcare products" will cover the reduction of waste, the recyclability and circularity as well as renewable feedstock of packaging materials. The impact of innovative packaging and device materials on the life cycle assessment (LCA) of the healthcare products will be investigated in this SSbD project. In order to jointly develop new strategies to ensure a greener healthcare industry along the whole value chain, and to avoid overlaps, a close collaboration between the two topics is essential and should be reflected by providing dedicated resources in both projects to align on common LCA methodologies and LCA data.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-04-06-two-stage;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Innovation Action in Low Latency and High Bandwidth Interconnects, deadline: 31. January 2024 17:00 Brussels time

Expected Outcome:

- Contribution towards European technological sovereignty, by establishing, maintaining and implementing a strategic R&I roadmap that fosters the European capabilities to design, develop and produce inter-node interconnects.
- Delivering scalable energy efficient inter-node interconnect for exascale and post exascale supercomputers. The development of European interconnect should prepare the technology for its future uptake and integration in post-exascale supercomputers to be acquired at a later stage by the EuroHPC JU targeting systems incorporating European technologies.
- A suitable software stack, including configuration, installation and management tools.

The aim is to support the R&I technology development of innovative and competitive European HPC inter-node interconnect technology.

- Develop a roadmap for European scalable inter-node interconnects targeting HPC exascale and post-exascale systems. The roadmap should take into account the EuroHPC supported work in this area such as the components being developed in the EUROHPC RED-SEA project as well as in the area of processors and accelerators.
- Develop the inter-node interconnect hardware addressing design, development, testing and tape-out as well as integration in test-beds. The work should foster synergies with the EuroHPC supported work in the area of processors and accelerators.
- Develop the software, installation, configuration and management tools for the developed interconnect, driven by the needs

of relevant HPC workflows and application requirements.

- Address issues like high bandwidth, low latency, power efficiency, virtualisation, scalability, reliability, security, etc.

Proposals should clearly demonstrate that all partners in the consortium have a significant and justified role, including appropriate deliverables under their responsibility which cover the specific contributions of each partner. Due to the specific focus of the action, the consortium is expected to include not more than five partners to ensure an efficient and effective implementation and delivery of the objectives.

The JU considers that a contribution from the JU of up to EUR 30 million, matched by the Participating States with a similar amount, and a duration of 3 years would allow this specific challenge to be addressed appropriately. Nevertheless this does not preclude submission and selection of proposals with another duration or requesting other amounts.

Specific Topic Conditions:

Activities are expected to achieve TRL 8 by the end of the project – see General Annex B. Activities may start at any TRL.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-eurohpc-ju-2023-inter-02-01;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod%202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Next Generation Innovation Talents, deadline: 04. October 2023 17:00 Brussels time

The objective of the 'Next Generation Innovation Talents' scheme is to enable researchers and aspiring innovators to better understand and gain direct experience of the complex process of taking innovation beyond invention and help them develop their entrepreneurial mindset. At the same time, this scheme aims to provide innovative start-ups with access to new ideas and insights from the cutting edge of research, thus accelerating the development of their breakthrough products and services.

The scheme will allow eligible researchers to carry out an innovation internship in a hosting company, and will be open to:

- As hosting companies: start-ups and SMEs supported by the EIC Accelerator (including H2020 SME instrument), EIC awarded Seal of Excellence companies, SMEs/ start-ups in EIC Transition; as well as start-ups/SMEs supported by EIT-KIC innovation and business creation services, including those created as a result of receiving support from KICs; the startups / scaleups that have been created out of KICs Innovation activities; the startups / scaleups / SMEs that have been partners of KICs for Innovation activities; the startups / scaleups that have at least one co-founder who is an EIT Alumni member

- As researchers eligible for internships: PhD candidates and postdoctoral researchers participating in: projects funded by the European Research Council (ERC); the EIC Pathfinder; the Marie Skłodowska Skłodowska-Curie Actions (MSCA) postdoctoral fellowships, doctoral networks and COFUND programmes; the Research Infrastructures part of HORIZON EUROPE*, and relevant students in (and graduates from) EIT Label Masters and Doctoral programmes, EIT Alumni and EIT Jumpstarter beneficiaries and participants from other postdoctoral training programmes supported by the EIT KICs.

Additional partner programmes, including international partner programmes, may be included in eligibility for the internship in agreement between the Commission, the beneficiary of this call and the partner programme.

The winner of this call (hereafter 'Beneficiary') can be a single legal entity or a consortium of legal entities. The scheme will be implemented by the beneficiary in close cooperation with each of the original funding schemes (partner programmes) of the researchers (MSCA, EIT, ERC, EIC Pathfinder, the Research Infrastructure part of HORIZON EUROPE*). The costs of the internships will be covered by the partner programmes (with exception of ERC), in line with their work programmes. The hosting companies will not provide any direct payment to the interns. It is expected that approximately 600 innovation internships will be supported under this action, of approximately three to six months each, over a two-year period.

The Scheme has two main streams:

- Deep tech talents: Internship duration of 3 to 6 months open to PhD candidates and postdoctoral researchers currently working for ERC, EIC Pathfinder, MSCA, EIT and Research Infrastructure actions. These internships will be dedicated to highly specialised work on specific project or assistance to a senior executive (CEO, CTO, CSO) as requested by the hosting company.

- Aspiring innovators: Internship duration of up to 6 months open to relevant students in (and graduates from) EIT Label Masters and Doctoral programmes, EIT Alumni, EIT Jumpstarter beneficiaries. These internships are for less specialist work experience in the host organisation.

The actions under this call should include as minimum the following key tasks:

- Support to the preparation and implementation of call(s) for expression(s) of interest to eligible researchers/ research

- organisations and eligible companies in coordination with the EU partner programmes;
- Creation of a matchmaking IT platform between interested researchers (candidate interns) and companies;
 - Provision of guidance and support for candidate interns and companies;
 - Handling of agreements with the research institutes and the companies, including standard agreements on intellectual property, conditions of work etc.;
 - Follow up on any practical issues related to the internships;
 - Organisation of information and dissemination campaigns;
 - When relevant, organisation of financial support to internships to cover additional costs of interns (financial support to third parties, see below);
 - Regular reporting back to each respective EU funding programme, companies and interns;
 - Provision of feedback on the effectiveness and impact of scheme (e.g. through surveys, focus groups);

The selection of internships to benefit from this action should include the following procedure:

Step 1: call for expression of interest to eligible companies to host internships. The proposed internships must be assessed for their suitability and relevance to the objectives of this scheme

Step 2: call for expression of interest to eligible researchers to participate in the proposed internships.

Step 3: matchmaking between the researchers and the internship positions in the host companies. Applicants must specify in their proposals how they intend to undertake this matchmaking (which criteria, how to ensure a geographical and gender balance, etc). The application and matchmaking process must be lean and agile, creating as less as possible administrative burden for the applicants and the companies.

The interns selected for the internships must have the necessary approvals from their institutions and project leaders/ Principal Investigators to participate in the scheme (when relevant).

Financial support to third parties

The reimbursements of the internship expenses for the researchers funded by MSCA, HE Research Infrastructure, EIT/EIT KICs will be borne by the respective partner programmes.

The beneficiary may provide financial support to third parties (ERC and EIC Pathfinder researchers).

At least 50 percent of the total budget for this action must be allocated through financial support to third parties in form of grants (lump sums). The maximum amount to be granted to a third party is EUR [15 900].

For researchers working on ERC actions, the expenses incurred for the internship will not be eligible under the ERC grant, and all costs will be reimbursed as financial support to third parties under this action. The amount will be a flat monthly reimbursement of EUR 4300 for PhD students and EUR 5300 for Postdoctoral researcher for a maximum period 3 months (the internships may be of a longer period but without additional reimbursements through this action).

For researchers working on EIC Pathfinder actions, the personal costs are eligible under the Pathfinder grant (as specified in Section II). An additional mobility allowance will be reimbursed as financial support to third parties under this action. To be eligible for this mobility allowance, the location of the internship must be more than [150km] from the location of the normal place of work of the researcher. The amount will be a flat monthly allowance of EUR 2300 per month for a maximum period of 3 months (the internships may be of a longer period but without additional reimbursements through this action).

The beneficiary must ensure sound financial management and applicants must specify in their proposals how the management and control of this financial support will be organised in an effective and efficient way, including avoidance of any abuse.

Expected Impact:

- Support to at least 600 internships (deep tech talents and aspiring innovators) over the duration of the action. The final number of participants per programme may vary based on demand but assuming high demand from all partner programmes, there should be a minimum of 150 researchers from EIC Pathfinder actions
- Increased awareness and knowledge of researchers about potential career paths in startup companies or for creating their own companies;
- Improved access to research talent by EIC and EIT supported startups and SMEs.
- Increased visibility of the scheme, highlighting the role, funding instruments and opportunities provided by EIC and other EU partner programmes;
- High quality assessment of the impact of the scheme, including feedback from internees and host companies, and recommendations for further development of the scheme

The applicant must provide in its proposal SMART key performance indicators (KPI) to measure the expected impact. These KPIs must measure as minimum: number of matches and internships, impact and satisfaction rates (companies and interns).

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-eic-2023-talents-01-01;callCode=null;freeTextSearchKeyword=;matchWholeText=true;typeCodes=1,0;statusCodes=31094502;programmePeriod=2021-2027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geog>

HORIZON EUROPE Improved prediction, detection, and treatment approaches for comprehensive stroke management, deadline: 16. January 2024 17:00 Brussels time

Research and innovation (R&I) actions (projects) to be supported under this topic must aim to deliver results that contribute to all the following expected outcomes.

- Patients will benefit from superior healthcare compared to the current standard of care through the availability of a clear pathway for prevention, diagnosis, and treatment of their stroke. This should be achieved by early and rapid diagnosis of stroke, more integrated and precise interventions, and treatment strategies with the patient in the centre.
- Healthcare professionals will have access to integrated patients' health data, improved visualisation, predictive computational models and clinical support decision systems for stroke, and benefit from efficient coordination among and within stages of care and clinical specialities.
- Healthcare systems will benefit from more effective organisation of stroke management and personalisation of care delivery. This will increase treatment and care effectiveness and efficiency.
- Researchers will benefit from access to integrated data, innovative modelling-based tools, and a more patient-centred definition of clinical outcomes after stroke (including patient reported outcome measurement and patient reported experience measurement), which will facilitate the continued improvement and development of future intervention strategies.
- Health care systems, researchers, and industry will benefit from new innovative modelling tools enabling integration and analysis of a wider, actionable range of patient-specific data, including federated analysis of data.

Globally, stroke is the second leading cause of death and the third leading cause of disability. One in four people are in danger of stroke in their lifetime¹.

In Europe in 2017, nearly 1.5 million people suffered a stroke, nine million Europeans lived with a stroke, and more than 430,000 people died due to a stroke. The total cost of stroke in that year was €60 billion. The number of new strokes and the number of people living with stroke is set to rise due to the ageing population of Europe, as age is the greatest, non-modifiable risk factor for stroke².

Stroke is a heterogeneous, multifactorial disease regulated by non-modifiable (e.g., age, sex, family history) and modifiable risk factors (e.g., high density lipid-cholesterol, low density lipid-cholesterol, cigarette smoking) and underlying pathologies (such as diabetes, hypertension, atrial fibrillation) and as such, it requires a multi-factorial approach³. However, stroke is a preventable, treatable, and manageable disease and thus the potential to reduce its burden and its long-term consequences exists⁴.

The challenge in stroke management is the lack of efficient and comprehensive pathways along the whole continuum of the disease – including the variation of structural settings depending on the location of the patient (rural vs. central) and between countries. While several effective treatment approaches are available, there are still silos existing between the different stages of care (e.g., primary, acute care, intensive care, chronic hospitalisation, rehabilitation). The implementation of connected healthcare pathways will lead to an improvement in the outcome for the patients and thereby drive efficiency and effectiveness from a clinical and health resource perspective.

Better communication, sharing and integration of data along the whole stroke care pathway has the potential to be a game changer for stroke patients and for the healthcare professionals as well as payers.

Integrating data is key to allow for modelling, artificial intelligence (AI) and machine learning (ML)-based evaluation to identify groups and individual persons at risk and assure early recognition of stroke, thereby providing faster diagnosis and optimal, patient-specific treatment, resulting in better outcomes for patients. Effective, personalised and rapid care is critical and can make a substantial difference between full recovery and possible permanent impairment or death.

Moreover, comprehensive stroke management continues in the post-acute treatment setting and includes long-term follow-up for secondary prevention and rehabilitation. This is important, as a high percentage of patients are readmitted to the hospital or suffer a second stroke. More than a quarter of patients do not adhere to medication and/or have their blood pressure controlled. Patients frequently report that post-stroke follow up is impaired by siloed data between their generalist and specialist care.

Innovative solutions for faster acquisition, integration, and better retention of multiple types of data and better organisation among the various actors across the entire stroke pathway are crucial to achieve optimal prevention and treatment focused

on the needs of patients. Use of novel technologies for federated data analytics and interpretation could help in this direction and assist in providing the right treatment to patients in a timely manner, improving their outcomes.

Applicants to this topic should address all the aims below in their proposals.

- Develop approaches to integrate patient-relevant health data, from primary care / outpatient clinic, hospital, and rehabilitation settings, as relevant, improving data retention along the care pathway. Applicants could consider starting with a focus on patients at higher risk with the possibility to expand to other patients.
- Develop a next generation of systems that promote interoperability of data from different settings (including intensive and acute care units) and support better clinical decision making. Strategic approaches for integration with the EHDS and community-based, collaborative integrated care should be considered.
- Create solutions to foster better access to data for all involved healthcare professionals (primary care, hospital care and after hospital release e.g., rehabilitation) and support exchange of knowledge and information between the different actors – including at the level of algorithms and datasets that can be exchanged under ethically and legally sound conditions.
- Develop innovative tools and approaches, for example ‘virtual human twin’ model approaches and AI/ML for enhanced computational modelling, optimised for transparency to users and non-users, federated data analytics, and visualisation for enhanced output/results view and interpretation. These tools aim at appropriate risk stratification, timely prediction of stroke and stroke recurrence, faster diagnosis, and treatment.
- Propose innovative approaches to improve and expedite diagnostic and treatment decisions for streamlining operations and guiding patients in the continuum of stroke care in a patient-centric way. This should include consideration of the complexity of the organisational dimension.
- Propose approaches to improve implementation and scale-up of treatment in Europe relying on multimodal clinical data capture and their better interpretation and use in patient management and clinical decision-making. This should include consideration of the regional differences in stroke management and access to treatment options across Europe.
- Propose approaches to enhance precision of care delivery as well as improving patient experience and quality of life using new technologies, tools, and educational means (e.g., education on identification of risk factors, signs of stroke, treatment adherence).

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-05-03;callCode=H20202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geographicAreaCode=null>

HORIZON EUROPE Development and proof of principle of new clinical applications of theranostics solutions, deadline: 16. January 2024 17:00 Brussels time

Research and innovation (R&I) actions to be supported under this topic must contribute to at least three of the following outcomes:

- Patients will benefit from increased treatment efficacy, reduction of time-to-treat, fewer side effects, and reduced duration of hospitalisation.
- Healthcare professionals benefit from education, training on theranostic treatment approaches, recommendations, and clinical guidelines on the most appropriate use of theranostic solutions.
- European healthcare systems benefit from a broader spectrum of theranostic treatments and improved cost-effectiveness and affordability of theranostic solutions due to scale effects and more robust European supply chains.
- Technology developers, healthcare professionals and patients benefit from increased information on the sensitivity, quantification, stratification and staging of diseases.

Multi-modal theranostic solutions, currently dominated by radionuclide-based therapy and companion diagnostics, are emerging as safe, personalised, and effective approaches for the treatment of several diseases. However, the use of such therapies is limited to a few specialised centres with the need to increase clinical treatment capacities, and to widen the arsenal of theranostics, possibly including novel non nuclear approaches, e.g. enabled by nanotechnologies.

To address this challenge, project(s) funded under this topic should aim at developing new, or innovative combinations of existing multi-modal theranostic solutions including radiopharmaceuticals and/or non-radioactive theranostic solutions. Applicants should clearly identify a disease(s) of unmet public health need, (e.g., oncology, neurology and/or advanced multi-disease conditions) and explain their choice with relevant evidence where possible.

In particular, for the selected disease(s), the project(s) funded under this topic are expected to address all the following objectives:

- develop innovative theranostic solutions and consider conducting early phase clinical trial(s) as proof of concept(s) to demonstrate the added value of the proposed theranostic solutions for patients;
- develop tools for the quantification of the chosen disease(s) through the development of novel modalities to ensure proper planning and monitoring of patient care, which may include imaging, artificial intelligence and pathology models;
- facilitate the development of tools to increase European theranostic manufacturing capabilities and treatment capacities, including guidance on quality assurance and improving logistics of supply at the EU level;
- develop education and training materials on the deployment of multi-modal theranostic solutions and their integration in clinical settings including recommendations for the organisation and composition of disease-specific medical expert boards. In addition, applicants are expected to consider the potential regulatory impact of the results and if relevant develop a strategy/plan for generating appropriate evidence as well as engaging with regulators in a timely manner (e.g., through the EMA Innovation Task Force, qualification/scientific advice).

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-05-02;callCode=H20202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geographicAreaCode=null>

HORIZON EUROPE Maximising the potential of synthetic data generation in healthcare applications, deadline: 16. January 2024 17:00 Brussels time

The proposals should contribute to all of the following expected outcomes:

- academic and industrial researchers should have access to relevant, robust, and generalisable synthetic data generation methodologies, including open source when relevant, to create and share pools of synthetic patient data in specific use cases;
- academic and industrial researchers should have access to relevant, high quality synthetic datasets;
- thanks to better availability of robust synthetic datasets for training data models, healthcare providers and industry should have a wider range of performant AI-based and other data-driven tools to support diagnostics, personalised treatment decision-making and prediction of health outcomes.

Healthcare research using individual patient data is often constrained due to restrictions in data access because of privacy, security, intellectual property (IP) and other concerns. Synthetic health data, i.e., data that is artificially created to mimic individual patient data, can reduce these concerns, leading to more rapid development of reliable data-driven methods including diagnostic, precision medicine, decision support and patient monitoring tools. However, while many synthetic data generation (SDG) methods are currently available, it is not always clear which method is best for which use case, and SDG methods for some types of data are still immature. Furthermore, it is still unclear whether highly detailed synthetic data, which are often needed for research, can be categorised as anonymous.

To address these challenges and maximise the opportunity offered by synthetic data, projects funded under this topic should address the following objectives:

- assemble a cross-sectoral public-private consortium including synthetic data experts, public and private data owners, and healthcare solution developers;
- using high-quality public and private datasets, develop / further develop and validate reliable SDG methods for relevant healthcare use cases. The use cases to be explored must be described and justified in the proposal, complement work that is already ongoing, and should:
 - ensure the broad applicability of the SDG methods developed and include data types that are not currently adequately addressed, such as device data, image data, genomic data etc;
 - include methods to generate: a) fully synthetic datasets that do not contain any real data; b) hybrid datasets composed of a combination of data derived from both real and synthetic data; and c) synthetically-augmented datasets.
- pay particular attention to bias, both in source data and in the SDG methods.
- validate the synthetic data generation methods applied in the project using source data. This should include assessing the risk of re-identification;
- demonstrate the quality and applicability of the synthetic data generated in the project through the development of relevant models;
- encourage the uptake of the results of the project through a strong communication and outreach plan.

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects, including the EC proposal for an European Health Data Space (EHDS) when it becomes operational.

Further Information:

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ih-2023-05-04;callCode=20202027;programCcm2Id=43108390;programDivisionCode=null;focusAreaCode=null;destinationGroup=null;missionGroup=null;geographicAreaCode=null>

CEDEFOP ReferNet Call for Proposals 2024-2027, deadline: 06. October 2023

With the objective of establishing a European network for VET – ReferNet –, this call aims at selecting one applicant from each eligible country (EU member states, Iceland and Norway) with which Cedefop will conclude a four-year framework partnership agreement (2024-2027) as well as a one-year specific grant agreement for 2024.

An agreement is a legal document signed between Cedefop and the institution beneficiary of the grant.

The establishment of this legal link means:

- that the beneficiary is bound by the obligation to implement the action/work programme under certain conditions and
- that Cedefop is bound by the obligation to pay the grant to exactly the same entity/person provided the action/work programme is implemented according to those conditions.

Therefore, the existence of the legal relationship is a primary condition for the entitlement of the beneficiary to receive the grant and the entitlement of Cedefop to demand the implementation of the specific action/work programme under the conditions specified in the grant agreement.

Refernet is Cedefop's European network of expertise on VET. It was set up in 2002 to meet the growing demand for comparative information about VET systems, developments and policies at the time. The network currently covers EU member states, Iceland and Norway. Each country is represented by a key organisation involved in VET and/or VET-related research and analysis referred to as the national ReferNet partner.

In general terms, a grant is defined as a 'financial contribution' or as 'financial support'; it is a direct payment made by Cedefop to one or more beneficiaries for the purpose of carrying out an action (grant for an action).

The purpose of the transparency principle is to guarantee the effective use of public funds. On the one hand, it enables the target population of potential beneficiaries to obtain accurate and timely information on actions being undertaken by the Union. On the other hand, it is designed to ensure a sufficient level of participation for funds to be allocated to the operators who are best placed to execute actions consistent with the policy.

The purpose of the principle of equal treatment is to guarantee the absence of favouritism in grant award and administration procedures as well as their impartiality. This principle is reflected in the fact that no preferential treatment may be given to any potential beneficiary or beneficiaries; this rule applies not only to the process of identifying and selecting beneficiaries but also during the implementation of the action. Beneficiaries in the same situations or circumstances must be treated in the same way.

The co-financing principle implies that part of the action or of the operational expenditure of a body is to be funded by the beneficiary or covered by contributions other than those made from the Union budget. The purpose of the co-financing principle is to make beneficiaries stakeholders in the implementation of the action and in the proper execution of the work programme. This principle is also intended to ensure that beneficiaries maintain a certain degree of financial independence from Union funding while increasing and diversifying the resources from which the action may benefit.

A grant is by nature a direct payment made by the Commission by way of donation; by definition, this implies that the beneficiary must not derive any profit from the activities funded by the grant. The no-profit principle means that the purpose or effect of grants cannot be to generate profit from the action or work programme implemented by the beneficiary. The principle of non-cumulative award serves to prevent double funding of an action or work programme. This principle is reflected in the rule that prohibits the award of more than one grant funded from the Union budget to the same beneficiary for the same action,

The principle of non-retroactivity: Union funding may not be used to finance actions which have already been completed and which have therefore proved achievable without financial support from the Union. Union funding, in fact, does not add value unless it serves to implement an action in pursuit of objectives formulated in the call for proposals. Financial support, moreover, may apply only to costs pertaining to the implementation of the action that have arisen after the date of signature of the grant agreement. In certain situations, however, grants for actions that have already begun may be awarded if the applicant can demonstrate the need for starting the action prior to signature of the agreement.

The only costs eligible in the context of this call for proposals are those which are:

- directly linked to the project concerned, i.e. generated directly by the project and indispensable for its implementation. These costs have to be necessary and reasonable for the implementation of the project. The project must comply with the

- principles of sound financial management, in particular in terms of value for money and cost-effectiveness;
- generated during the lifetime of the project as defined in the agreement;
 - actually incurred by the partner and co-beneficiaries and recorded in their accounts in conformity with the applicable accounting principles, and which are declared in accordance with the requirements of the applicable tax and social legislation; and
 - identifiable and verifiable with original supporting documents, including pay slips.

Further Information:

<https://www.cedefop.europa.eu/en/about-cedefop/public-procurement/refernet-call-proposals-2024-2027#group-details>

EMBO EMBO Member Keynote Lectures, deadline: 01. October 2023

Organizers of major international scientific meetings can apply for funding for an EMBO Member or EMBO Associate Member to give a keynote lecture. Up to 1,000 euros (within the same continent) and 2,000 euros (intercontinental) to cover travel, accommodation and subsistence costs will be reimbursed to the speaker, who will be requested to submit an expense claim form together with relevant receipts to the ">EMBO Courses & Workshops Office.

The lecture must be given the status of a keynote lecture, featured prominently within the programme and entitled "The EMBO Lecture". Funding will only be provided for one EMBO Member or EMBO Associate Member per meeting. Please note that funding is not available for EMBO Keynote Lectures at EMBO Workshops, EMBO I FEBS Lecture Courses or EMBO | EMBL Symposia.

It is also possible to apply for funding for a virtual keynote lecture. Up to 1,000 euro to cover expenses associated with the virtual meeting platform will be reimbursed to the meeting organizer who will be requested to submit an expense claim form together with relevant receipts to the EMBO Courses & Workshops office.

Applications are handled via the online application system. Please check the eligibility requirements before applying.

Further Information:

<https://www.embo.org/funding/lecture-travel-and-childcare-grants/embo-member-keynote-lectures/>

ESF Fight Kids Cancer 2023-2024 Call for proposals

FIGHT KIDS CANCER is thrilled to announce that its next call opening on September 1st, 2023 will be exclusively dedicated to research on paediatric brain tumours.

In order to substantially support this disease area, which is in dire need for new treatments, FIGHT KIDS CANCER decided to give more flexibility to the applying teams by increasing the possible amount available and duration per grant application:

- For clinical trials:
 - Up to 5 years
 - Up to 5 million euros
- For translation research projects:
 - Up to 4 years
 - Up to 2 million euros

As flexibility is the key motivation for the modification of the grants' duration and amount, the FKC Funders wants to stress the fact that applicants should apply for what they need and not refrain from applying for smaller amounts or shorter projects such as primer/ preliminary studies, projects or programmes grants.

Each project will be evaluated on its merit alone. Shorter, high-risk high gain projects are as welcome as are biology companion projects. Translational projects applying for longer duration or higher amounts will be expected to facilitate collaboration across institutions and borders within Europe to meet the FKC selection criteria.

The FIGHT KIDS CANCER secretariat at European Science Foundation is at the applicant's disposal for their questions.

FIGHT KIDS CANCER aims to catalyse and support pan-European leading-edge research initiatives in paediatric cancer to develop innovative approaches to improve the outcome for all children and adolescents with cancer. This call will cover the following non-exclusive objectives:

- Realise real impact on young patients,
- Improve survival rates and reduce toxicity to restore young patients to full health after treatment,

- Advance fundamental knowledge of paediatric malignancies,
 - Support improved interdisciplinary research, methods and collaborations for tackling the issues of today,
 - Strengthen collaboration and the development of scientific capacity across Europe.
- FIGHT KIDS CANCER aims towards overcoming the structural lack of research dedicated to paediatric cancers by ensuring a recurring endowment that will be granted to the best European research projects every year. An additional ambition is to foster closer working ties between clinical and laboratory researchers.
- Further Information:
<https://www.esf.org/funding-programmes/fight-kids-cancer-2023-2024-call-for-proposals/>

Sonstige EU GREEN - Cluster 1 „Emerging paradigms for health and wellbeing“, Termin: 10. August 2023 um 10:30 Uhr

Am 10.08.2023 führt von 10:30 Uhr - 11:30 Uhr die Stabsstelle Forschungsförderberatung die Veranstaltung „EU GREEN — Die europäische Hochschulallianz als Chance für gemeinsame Forschung“ durch.

Mit dieser Veranstaltung möchten wir Sie für unsere Vision einer europäischen Hochschule begeistern, die vor dem Hintergrund der Sustainable Development Goals der europäischen Union in den Bereichen Forschung, Innovation, Bildung und Gesellschaft gemeinsame europäische Strukturen aufbauen will.

Einen bedeutenden Teil dieser europäischen Hochschulallianz nimmt der Bereich der Forschung ein. Deshalb ist es uns als Forschungsförderberatung/EU-Hochschulnetzwerk besonders wichtig, Sie in diesem Change Prozess als Mitgestaltende im Bereich der Forschung zu gewinnen. Mit acht weiteren europäischen Universitäten verfügt EU GREEN über ein Netzwerk aus Forschenden, die motiviert sind, Ihre Expertise zu teilen und gemeinsam Projektideen zu entwickeln und umzusetzen. Als wissenschaftliche Mitarbeitende und als Professor*in möchten wir Sie deshalb über die unterschiedlichen Forschungsbereiche innerhalb von EU GREEN informieren und Ihnen die Möglichkeit geben, zum Thema „Emerging paradigms for health and wellbeing“ zu erfahren, welche Kooperationsmöglichkeiten bestehen und wie Sie EU GREEN nutzen können.

Die Agenda:

- EU GREEN im Überblick — Chancen und Challenges
- Forschung innerhalb der Allianz
- Mögliche Kooperationen

Die Veranstaltung findet im Tagungsraum der Universitätsbibliothek (Campus Universitätsplatz) in Magdeburg statt. Der Tagungsraum befindet sich im Foyer der Universitätsbibliothek, auf der linken Seite. Es gibt auch die Möglichkeit online an der Veranstaltung teilzunehmen. Der Link wird kurz vor dem Termin per E-Mail zu geschickt.

Kontakt: Lisa Westphal, Telefon: +49 (0) 391 67 57593, E-Mail: lisa.westphal@ovgu.de

Weitere Informationen:

<https://www.ovgu.de/Forschung/Beratung/Forschungsf%C3%B6rderung/News/Veranstaltungen/EU+GREEN+%E2%80%94+Die+p-134340.html>

Sonstige Contact Research Funding Advice of the Otto von Guericke University Magdeburg

For questions about funding opportunities, specific calls for proposals, help with submitting applications and project support, please contact the department for Research Funding Advice/EU-University Network of Otto von Guericke University Magdeburg.

Information on current events, funding structures and contact online at:

<https://www.ovgu.de/en/ContactResearchFundingAdvice>

<https://www.euhoerschulnetz-sachsen-anhalt.de/en/>