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for translational medicine

Expertise of EATRIS member institutions for Horizon Europe calls

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In this overview, you will find summaries of the relevant expertise of EATRIS member institutions for the Horizon Europe Health Cluster and European Innovation Council calls with a translational dimension.

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Horizon Europe – European Innovation Council Pathfinder (2021 challenges)

Call	Topic
<u>EIC Pathfinder Challenge</u>	Tools to measure & stimulate activity in brain tissue

Horizon Europe – Health cluster (2021-2022)

Call	Topic	Institutions' expertise
HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage	Prevention of obesity through the life course	<ul style="list-style-type: none"> • Multiomics technologies (Genomics: NGS, deep genome sequencing, Mass spectrometry for multi-omic analysis) • Biomarkers expertise, (metabolic) Imaging capabilities, samples/data cohorts.
HORIZON-HLTH-STAYHLTH-2021-01-02	Towards a molecular and neurobiological understanding of mental health and mental illness for the benefit of citizens and patient	<ul style="list-style-type: none"> • Multiomics technologies (Genomics: NGS, deep genome sequencing, Mass spectrometry for multi-omic analysis) • Biomarkers expertise, Imaging capabilities, samples/data cohorts • Disease experts • In silico platforms to predict novel drug targets (systems biology approaches) • Study mode of action of (potential) drug targets correlated to mental disease • Neuroimaging (MRI, PET/CT) and data analysis • (Early) clinical trial capacity with support of appropriate biomarker tools.
HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage	Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression	<ul style="list-style-type: none"> • Regulatory expertise • Network of over 50 academic medical research centres with translational capacities to support validation of novel AI tools • Translational imaging data to support radiomics approaches
HORIZON-HLTH-2021-DISEASE-04-02	Building a European innovation platform for the repurposing of medicinal products	<ul style="list-style-type: none"> • Chemosensitivity screening in using existing drugs and patient materials • In silico/ systems biology approaches to support repurposing campaigns • Drug (re-)formulation expertise • Clinical expertise with experience in drug repurposing programs for oncology, rare disease, and infectious disease

		<ul style="list-style-type: none"> • Covid-19 research forum with listed translational research capabilities to support repurposing activities. • Upscaling of small molecule drugs production, incl. GXP compliant preclinical development activities.
HORIZON-HLTH-2021-DISEASE-04-07	Personalised medicine and infectious diseases: understanding the individual host response to viruses (e.g., SARS-CoV-2)	<ul style="list-style-type: none"> • Multiomics technologies (Genomics: NGS, deep genome sequencing, Mass spectrometry for multi-omic analysis) • Expertise in Biomarkers (Discovery, validation, assays), Samples/data cohorts, Preclinical models, Quality initiative, Innovation Management, • Covid-19 research forum with listed translational research capabilities to support development of personalised therapeutic treatment activities.
HORIZON-HLTH-2022-DISEASE-06-02-two-stage	Pre-clinical development of the next generation immunotherapies for diseases or disorders with unmet medical need	<ul style="list-style-type: none"> • Preclinical development and study of new immunotherapeutic agents in vitro and in relevant animal disease models • Preclinical and clinical Immune profiling, immune monitoring • Study of immune toxicity • Regulatory compliant development of next generation CAR-T cell therapies • Immune imaging (PET, PET/CT, MR) with over 70 validated tracers (GMP grade) available in translational imaging centres • HTA analysis capacity • Support in first in man clinical study design • Systems level characterization of immune cells in human tissues (multi-parametric flow cytometry, mass cytometry [CyTOF], Helios) and Immune assays (in vitro functional immune assays, high-throughput multiplex immunoassay) • Identification and isolation of tissue immunological subsets for deep profiling (RNAseq, Spectral Flow, single cell RNA-seq), SNP Array, TCR-sequencing (immunochip, immunoseq) of immune cell subsets • Large/Medium-scale analysis of the immune proteins (Mass spectrometry; Multiplex immuno-assays)

- Access to 3D culture systems; patient-derived organoids; patient-derived xenografts, Spheroids and Multifluidic Devices for Immune surveillance in TME
- Ex vivo and in vivo preclinical disease models
- In vivo Imaging Technologies to Monitor the Immune System - Mass Cytometry Imaging (MCI), PET-CT, PET-MRI, US modalities for studies of the immune system response
- Multimodal Imaging approaches to track cells to measure biodistribution and efficacy of immunotherapies including nanoparticle approaches, PET-CT, PET-MRI
- Epigenetics of immune cells to study genome-wide epigenetic changes including DNA methylation, histone modifications and non-coding RNAs expression
- Multiomics (epigenomic, transcriptomic, proteomic, metabolomics, study of the microbiome and virome, etc.) to assess functional characteristics of TME-tumour cell interplay within the primary tumour and/or metastases (e.g the underlying signaling, the transcriptional landscape, the cell-cell communication, the network regulation of immune cells, etc.), to identify candidate TME targets and to assess the activity of pathway-targeting agents.
- Pre-clinical evaluation of immunogenicity, efficacy and toxicology
- Preclinical Validation- Development of in vitro and in vivo validated assays for pre-clinical studies.
- Expertise in cell therapy and genome editing products in targeted cells and tissues (e.g., base editing, prime editing, talens, zinc-finger nucleases, CRISPR).
- Expertise in novel RNA-based therapeutics
- Expertise in Regulatory Expertise for Advanced Therapies
- Expertise in upscaling and product development of advanced therapies
- Health Technology Assessment

**HORIZON-HLTH-
2022-DISEASE-06-
03-two-stage**

Vaccines 2.0 - developing the next generation of vaccines

- Immunomonitoring - Systems level characterization of immune cells in human tissues (multi-parametric flow cytometry, mass cytometry [CyTOF], Helios) and Immune assays (in vitro functional immune assays, high-throughput multiplex immunoassay)
 - Identification and isolation of tissue immunological subsets for deep profiling (RNAseq, Spectral Flow, single cell RNA-seq), SNP Array, TCR- sequencing (immunochip, immunoseq) of immune cell subsets
 - Large/Medium-scale analysis of the immune proteins (Mass spectrometry; Multiplex immuno-assays)
 - Access to 3D culture systems; patient-derived organoids; patient-derived xenografts, Spheroids and Multifluidic Devices for Immune surveillance in TME
 - In vivo Imaging Technologies to Monitor the Immune System - Mass Cytometry Imaging (MCI), PET-CT, PET-MRI, US modalities for studies of the immune system response
 - Multimodal Imaging approaches to track cells to measure biodistribution and efficacy of immunotherapies including nanoparticle approaches, PET-CT, PET-MRI
 - Epigenetics of immune cells to study genome-wide epigenetic changes including DNA methylation, histone modifications and non-coding RNAs expression PET-CT, PET-MRI
- Bioinformatics and Data Center
- In vivo models:
- Humanized mouse models (e.g., patient-derived xenograft; immuno-Avatar)
- Immunocompetent and genetically engineered mouse models
- Non-human primates and other species
- High Throughput Genome Engineering – CRISPR
- Vaccine Formulation-Optimisation of vaccine formulation in preparation for scale-up under GMP conditions.

- Appropriate strategy for a delivery system and adjuvantage.
- Preclinical Validation- Development of in vitro and in vivo validated assays for pre-clinical studies.
- Development of validated measures for the evaluation of humoral and cellular immune responses at systemic, mucosal and in situ levels.
- Development of adequate potency tests.
- Pre-clinical in vivo validation in disease specific animal models including primates up to BSL3 containment.
- Pre-clinical evaluation of vaccine immunogenicity, efficacy and toxicology.
- Exploration of upstream processing; evaluation of expression system.
- Exploration of downstream processing (incl. possible inactivation).
- Confirmation of a feasible small-scale process (scalability, reproducibility).
- Scalability, reproducibility and initial process validation as required for phase I.
- GMP pharmaceutical production centres with vaccine authorisations. Preparation of GMP batches of vaccines for toxicology and clinical studies.
- Clinical trial centres for phase I and II studies in conjunction with a university medical centre to foster interaction between clinicians and specialist scientists.
- Support for trial design and GCP execution.
- Clinical imaging for analysis, integration and interpretation in various patient cohorts.
- Data analysis centres manage the processing and integration of multi- modality data.
- Regulatory Services- Scientific Advice, TPP and IMPD development

HORIZON-HLTH-2022-DISEASE-06-04-two-stage	Development of new effective therapies for rare diseases	<ul style="list-style-type: none"> • Preclinical and translational disease models • Clinical trial capacity with experience in evaluation of novel therapeutic treatments for rare diseases • Biomarker development expertise • Regulatory support for submission of Orphan Drug Designation requests • Drug repurposing expertise • Well connected to European Reference Network of rare diseases
HORIZON-HLTH-2021-DISEASE-04-04	Clinical validation of artificial intelligence (AI) solutions for treatment and care	<ul style="list-style-type: none"> • Regulatory expertise • Network of over 50 academic medical research centres with translational capacities to support validation of novel AI tools. • Broad experience in Personalised Medicine with potential research data to be shared • HTA analysis • Translational imaging data to support radiomics approaches
HORIZON-HLTH-2021-TOOL-06-01	Smart medical devices and their surgical implantation for use in resource-constrained settings	<ul style="list-style-type: none"> • Regulatory expertise • Clinical experts in various indications (oncology, neurology, rare diseases, infection, metabolic disorders, cardiology, endocrinology, etc) • HTA analysis
HORIZON-HLTH-TOOL-2021-06-02	Next generation advanced therapies to treat highly prevalent and high burden diseases with unmet needs	<ul style="list-style-type: none"> • Expertise in cell therapy and genome editing products in targeted cells and tissues (e.g., base editing, prime editing, talens, zinc-finger nucleases, CRISPR). • Expertise in novel RNA-based therapeutics • Expertise in upscaling and product development of advanced therapies • Clinical trial centres for phase I studies in conjunction with a university medical centre to foster interaction between clinicians and specialist scientists. • Support for trial design and GCP execution.

- Multimodal Imaging approaches to track cells to measure biodistribution and efficacy of immunotherapies including nanoparticle approaches, PET-CT, PET-MRI
- In vivo Imaging Technologies to Monitor the Immune System - Mass Cytometry Imaging (MCI), PET-CT, PET-MRI, US modalities for studies of the immune system response
- Data analysis centres manage the processing and integration of multi- modality data.
- Regulatory Services- Scientific Advice, TPP and IMPD development
- Access to 3D culture systems; patient-derived organoids; patient-derived xenografts, Spheroids and Multifluidic Devices for Immune surveillance in TME for ATMP products
- Epigenetics of immune cells to study genome-wide epigenetic changes including DNA methylation, histone modifications and non-coding RNAs expression
- Multiomics (epigenomic, transcriptomic, proteomic, metabolomics, study of the microbiome and virome, etc.) to assess functional characteristics of TME-tumour cell interplay within the primary tumour and/or metastases (e.g the underlying signaling, the transcriptional landscape, the cell-cell communication, the network regulation of immune cells, etc.), to identify candidate TME targets and to assess the activity of pathway-targeting agents
- Immune profiling – Systems level characterization of immune cells in human tissues (multi-parametric flow cytometry, mass cytometry [CyTOF], Helios) and Immune assays (in vitro functional immune assays, high-throughput multiplex immunoassay)
- Bioinformatics and Data Center
- In vivo models:
- Humanized mouse models (e.g., patient-derived xenograft; immuno-Avatar)
- Immunocompetent and genetically engineered mouse models

		<ul style="list-style-type: none"> • Non-human primates and other species • Development of adequate potency tests. • Pre-clinical in vivo validation in disease specific animal models including primates • Pre-clinical evaluation of ATMP immunogenicity, efficacy and toxicology. • Access to collaborative network to provide a framework for hiPSC generation of hiPSC homozygous for frequent HLA haplotypes
HORIZON-HLTH-2022-TOOL-11-01	Optimising effectiveness in patients of existing prescription drugs for major diseases (except cancer) with the use of biomarkers	<ul style="list-style-type: none"> • Multiomics technologies (Genomics: NGS, deep genome sequencing, Mass spectrometry for multi-omic analysis) • Expertise in Biomarkers (Discovery, validation, assays)
HORIZON-HLTH-2022-TOOL-12-01-two-stage	Computational models for new patient stratification strategies	<ul style="list-style-type: none"> • AI capacities (novel machine learning methods and models to answer key questions in biomedicine, digital diagnostics and medical AI to support patient care) • Biomarkers expertise • Bioimage informatics capabilities • Radiomics, • samples/data cohorts • Digital biomarkers • Data Integration ("System Biology") expertise • Development of new algorithms, e.g. new decision algorithms, new sequence aligners for NGS data, etc. • Multiomics technologies and data integration • Experience in health informatics standards, clinical information modelling, interoperability, telemedicine, decision support, application of Natural Language Processing techniques, in Electronic Health Records and application of predictive modelling, development and application of software tools for the analysis of molecular, clinical and neuroimaging data for complex diseases.

Horizon Europe – European Innovation Council Pathfinder (2021 challenges)

EIC Pathfinder Challenge	Tools to measure & stimulate activity in brain tissue	<ul style="list-style-type: none">• Expertise in cell therapy and genome editing products in targeted cells and tissues (e.g., base editing, prime editing, talens, zinc-finger nucleases, CRISPR).• Expertise in novel RNA-based therapeutics• Expertise in in gene delivery vehicles using next generation AAV or other recombinant vectors• Expertise in upscaling and GMP product development of advanced therapies in cell and gene therapies and vector production• Clinical trial centres for phase I/II studies in conjunction with a university medical centre to foster interaction between clinicians and specialist scientists.• Support for trial design and GCP execution.• Advanced technologies for disease specific research including cancer organoids, organ on a chip to test responses to different ATMPs• Multimodal Imaging approaches to track cells to measure biodistribution and efficacy of immunotherapies including nanoparticle approaches, PET-CT, PET-MRI• In vivo Imaging Technologies to Monitor the Immune System• Mass Cytometry Imaging (MCI), PET-CT, PET-MRI, US modalities for studies of the immune system response• Data analysis centres manage the processing and integration of multi- modality data.• Regulatory Services- Scientific Advice, TPP and IMPD development• Access to 3D culture systems; patient-derived organoids; patient-derived xenografts, Spheroids and Multifluidic Devices for Immune surveillance in TME for ATMP products• Epigenetics of immune cells to study genome-wide epigenetic changes including DNA methylation, histone modifications and non-coding RNAs expression• Multiomics (epigenomic, transcriptomic, proteomic, metabolomics, study of the microbiome and virome, etc.) to assess functional
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		<p>characteristics of TME-tumour cell interplay within the primary tumour and/or metastases (e.g the underlying signaling, the transcriptional landscape, the cell-cell communication, the network regulation of immune cells, etc.), to identify candidate TME targets and to assess the activity of pathway-targeting agents</p> <ul style="list-style-type: none"> • Immune profiling • Systems level characterization of immune cells in human tissues (multi-parametric flow cytometry, mass cytometry [CyTOF], Helios) and Immune assays (in vitro functional immune assays, high-throughput multiplex immunoassay) • Bioinformatics and Data Center - In vivo models: <ul style="list-style-type: none"> o Humanized mouse models (e.g., patient-derived xenograft; immuno-Avatar) o Immunocompetent and genetically engineered mouse models o Non-human primates and other species • Development of adequate potency tests. • Pre-clinical in vivo validation in disease specific animal models including primates • Pre-clinical evaluation of ATMP immunogenicity, efficacy and toxicology. <p>Access to collaborative network to provide a framework for hiPSC generation of hiPSC homozygous for frequent HLA haplotypes.</p>
<p>EIC Pathfinder Challenge</p>	<p>Emerging Technologies in Cell & Gene Therapy</p>	<ul style="list-style-type: none"> • Animal models for brain diseases • Radiomics • Optogenetics • Neuroimaging (MRI/PET/CT) • Ultrasound methods • Optical methods • Electrophysiology (patch recording, MEG and EEG, recordings from cell cultures, brain slices) • Brain sensing and/or stimulation technologies (deep brain stimulation)

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- AI methods (machine learning/deep learning)
 - Data analysis centres manage the processing and integration of multi- modality data.
 - Regulatory services