

JOINT TRANSNATIONAL CALL FOR PROPOSALS (2019) FOR
“PERSONALISED MEDICINE: MULTIDISCIPLINARY RESEARCH
TOWARDS IMPLEMENTATION”



(ERA Net Grant 779282)

CALL TEXT

IMPORTANT DEADLINES

SUBMISSION OF PRE-PROPOSALS: 7 March 2019 at 17:00 (CET)
SUBMISSION OF INVITED FULL-PROPOSALS: 17 June 2019 at 17:00 (CEST)


Link to electronic proposal submission:

<https://ptoutline.eu/app/erapermed2019>

ERA PERMED JOINT CALL SECRETARIAT

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1. INTRODUCTION & MOTIVATION

Personalised Medicine (PM) represents a paradigm shift from a “one size fits all” approach to an optimised strategy for prevention, diagnosis and treatment of disease for each individual person, based on his or her unique characteristics. In this way, PM puts the patient at the very centre of health care, aiming for optimised management of a patient’s disease and/or the predisposition to disease. Recent developments in areas such as diagnostic tests, medical imaging, biosignal monitoring, omics technologies, molecular pathways, lifestyle data, real-time monitoring of conditions and information technology, support this development.

Definition of Personalised Medicine:

ERA PerMed follows the definition stated in the Strategic Research and Innovation Agenda (SRIA) of PerMed, adopted from the Horizon2020 advisory group¹:

“Personalised Medicine refers to a medical model using characterisation of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention.”

Some additional information can be found in the Advice for 2018–2020 of the Horizon 2020 Advisory Group for Societal Challenge 1, “Health, Demographic Change and Well-being”²:

“Different synonymous terms have been used alongside ‘personalised medicine’, most commonly ‘precision medicine’ and ‘stratified medicine’. While there may be subtle differences in the literal meanings of these terms, they usually refer to the same concept when applied in practice. Stratified medicine (mainly used in the UK) is more treatment – dependent, while precision medicine (mostly used in US) has a relatively broad meaning as it refers to 4P (predictive, preventive, personalised and participatory) medicine. We use the term personalised medicine, because the term best reflects the ultimate goal of effectively tailoring treatment based on an individual’s ‘personal profile’, as determined by the individual’s genotype and phenotype data. Based on individuals’ profiles, PM aims to identify the optimal treatment regime by avoiding the treatment-failure approach commonly used in current evidence-based medicine.”

The health systems of the European Union occupy a central part of Europe’s high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. The overarching values of universality, access to good quality care, equity, and solidarity have been widely accepted in the work of the different EU institutions.

Current advances in the field of genomics and other omic disciplines, together with the technological progress (such as High Performance Computing), hold the promise to finally bring PM into practice and enable preventive and predictive care models.

¹ European Commission. Advice for 2016/2017 of the Horizon 2020 Advisory Group for Social Challenge 1, “Health, Demographic Change and Wellbeing”, July 2014: <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailPDF&groupID=2942>

² https://ec.europa.eu/research/health/pdf/ag_advice_report_2018-2020.pdf

Besides the possibility to enhance the lifespan of patients and to increase the quality of clinical practice through more targeted therapies, improvements in PM in the long term may also lead to more efficient use of costs for health systems through early detection, prevention, accurate risk assessment and efficiencies in care delivery.

However, despite recent progress in this field, many challenges remain. The development of PM approaches is complex, interlinked and global in nature and requires truly multidisciplinary, cross-sectoral and transnational collaborations.

ERA PerMed seeks to facilitate these collaborations, and to foster the sharing of ideas, knowledge, data and results between academic researchers from different disciplines (e.g. life sciences, physics, bioinformatics, ethics, economics and health-service research), health care providers, industry/pharma, regulatory authorities as well as health technology assessors.

ERA PerMed³ is an ERA-NET Cofund, supported by 32 partners from 23 countries and cofunded by the European Commission. It aims to align national research strategies and funding activities, promote excellence, reinforce the competitiveness of and at the same time foster cooperation between European players in PM, and enhance European collaboration with non-EU countries.

ERA PerMed is closely linked to the International Consortium for Personalised Medicine (ICPerMed⁴), established in November 2016. The [Action Plan⁵](#) of ICPerMed builds on the Strategic Research and Innovation Agenda (SRIA) “Shaping Europe's Vision for Personalised Medicine”⁶ developed by PerMed in 2015. **ERA PerMed** will foster the implementation of the Action Plan by funding transnational research projects in the field of PM.

The funding organisations listed below have decided to jointly launch the second ERA PerMed Joint Transnational Call (JTC2019) in order to fund international high quality research projects in PM. The **Joint Call Secretariat (JCS)** will centrally coordinate this call for proposals.

The call is opened and supported simultaneously by the following funding organizations in their respective regions/countries:

- **Austrian Science Fund, (FWF), Austria**
- **Fund for Scientific Research – FNRS, (F.R.S.-FNRS), Belgium**
- **The Canadian Institutes of Health Research, (CIHR), Canada**
- **Quebec Health Research Funds (FRQS), Quebec (Canada)**
- **Ministry of Science and Education of the Republic of Croatia, (MSE), Croatia**
- **Innovation Fund Denmark, (InnoFond), Denmark**
- **Academy of Scientific Research and Technology, (ASRT), Egypt**
- **Academy of Finland, (AKA), Finland**
- **The French National Research Agency, (ANR), France**

³ For more information, please visit the ERA PerMed website: www.erapermed.eu

⁴ For more information, see <http://www.icpermed.eu/>

⁵ The ICPerMed Action Plan is published on: http://www.icpermed.eu/media/content/ICPerMed_Actionplan_2017_web.pdf

⁶ The CSA PerMed SRIA is published on <http://www.permed2020.eu>; http://www.permed2020.eu/media/PerMed_SRIA.pdf

- Federal Ministry of Education and Research, (BMBF) / German Aerospace Centre e.V. – Programme Management Agency, (DLR), Germany
- Federal Ministry of Health, (BMG) / Innovation und Technik GmbH, Programme Management Agency, (VDI/VDE), Germany
- Saxon State Ministry for Higher Education, Research and the Arts, (SMWK), Saxony (Germany)
- General Secretariat for Research and Technology, (GSRT), Greece
- National Research, Development and Innovation Office, (NKFIH), Hungary
- Health Research Board, (HRB), Ireland
- Ministry of Health, The Chief Scientist Office, (CSO-MOH), Israel
- Italian Ministry of Health, (IT-MoH), Italy
- Regional Foundation for Biomedical Research, (FRRB), Lombardy (Italy)
- Tuscany Region, (TuscReg), Tuscany (Italy)
- State Education Development Agency, (VIAA), Latvia
- National Research Fund, (FNR), Luxembourg
- Research Council of Norway, (RCN), Norway
- National Centre for Research and Development, (NCBR), Poland
- Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI), Romania
- Centro para el Desarrollo Tecnológico Industrial, (CDTI), Spain
- National Institute of Health Carlos III, (ISCIII), Spain
- The Scientific Foundation of the Spanish Association Against Cancer, (AECC-FC), Spain
- Health Department – Generalitat de Catalunya, (DS-CAT), Catalonia (Spain)
- Government of Navarre, (GN), Navarre (Spain)
- Swedish Research Council, (SRC), Sweden
- The Scientific and Technological Research Council of Turkey, (TUBITAK), Turkey

2. TIMELINE OF THE CALL

January 9 th , 2019	Publication of the call
January 9 th , 2019	Opening of the submission system for pre-proposals
March 7 th , 2019 (17:00, CET)	Deadline for pre-proposal submission
(expected around) May 13 th , 2019	Communication of the results of the pre-proposal assessment and invitation for full-proposal stage
June 17 th , 2019 (17:00, CEST)	Deadline for full-proposal submission
Mid/end of August 2019	Rebuttal stage
September 2019	Peer Review Panel meeting and CSC meeting for funding recommendation to national funding agencies
October 2019	Communication of the funding decisions to the applicants
End of 2019, beginning of 2020	Expected project start (also subject to national procedures)

3. AIM OF THE CALL

With its second transnational call (non-cofunded by the EC), ERA PerMed fosters research and innovation activities that build close linkages between basic biomedical research, clinical research, physical sciences and bioengineering, bioinformatics and biostatistics, epidemiology, socio-economic research, as well as research on the integration of PM into clinical practice and on ethical, legal and social implications across the participating countries and beyond. This implies a wide range of multidisciplinary activities brought together by different stakeholders from academia (e.g. universities and research institutions), clinics (e.g. clinical laboratories, medical professionals), industry (e.g. pharmaceutical industry, biotechnology companies, information technology companies including Health Information Technology – HIT), policy makers, regulatory/health technology assessment (HTA) agencies and patients/patient organisations.

The overarching goal is to improve disease management, based on broader and more efficiently elaborated patient stratification, diagnostics and tailored treatment protocols, and disease prevention. The project development should include early involvement of regulatory authorities as well as close interaction with the different key players along the value chain to bridge the gap between first discoveries or inventions until market access. Proposals submitted under this call are expected to demonstrate the applicability of project outcomes to clinical practice. The clinical relevance of the suggested PM approach needs to be convincingly shown. Moreover, proposals are expected to include research on ethical, legal and socio-economic implications, including health economics and regulation, and/or research on optimisation of health care systems.

The overall objectives of the call are:

- To support **translational research projects** in the field of Personalised Medicine;
- To encourage and enable **interdisciplinary collaborations towards implementation of PM**, combining pre-clinical and/or clinical research with bio-informatics components and research on relevant ethical, legal and social aspects and/or research on the optimisation of health care systems;
- To encourage **collaboration between academia** (research teams from universities, higher education institutions, public research institutions), **clinical/public health research** (research teams from hospital/ public health, health care settings and other health care organisations), private partners e.g. **SMEs**⁷ (small and medium-sized enterprises) as well as policy makers, regulatory/HTA agencies and patient organisations.

⁷ https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

The JTC2019 of ERA PerMed comprises three Research Areas:

Research area 1 “Translating Basic to Clinical Research and Beyond”	Research area 2 “Integrating Big Data and ICT Solutions”	Research area 3 “Research towards Responsible Implementation in Health Care”
Module 1A: Pre-clinical Research	Module 2A: Data and ICT – Enabling Technology	Module 3A: Optimising Health Care System
Module 1B: Clinical Research	Module 2B: Data and ICT - Towards Application in Health Care	Module 3B: Ethical, Legal and Social Aspects

ICT: Information and Communications Technology (or Technologies)

Each project proposal **MUST** address **at least one module of Research Area 3** and **at least one module of Research Area 1 or 2**:

Research Areas/Modules combined in proposal	Research Area 1 Module 1A and/or 1B	Research Area 2 Module 2A and/or 2B	Research Area 3 Module 3A and/or 3B (<u>mandatory</u>)
Eligible	X		X
Eligible		X	X
Eligible	X	X	X
Not eligible	X	X	

The coherent integration and combination of the different Research Areas and Modules in the proposals is part of the evaluation process.

Research Area 1: “Translating Basic to Clinical Research and Beyond”.

Research proposals should aim to improve the exchange between basic and clinical research. This is needed to allow the transition from bench to bedside (e.g. by translational science, transferring pre-clinical technologies/predictive models to clinical application) but also vice versa by using e.g. existing databases, repositories and cohorts, and by sharing experiences obtained in classical and innovative clinical studies/trials. The aim is to achieve a better identification and validation of known biomarkers (including omics data and others, e.g. obtained by imaging-based, biosignal monitoring approaches, etc.).

Proposals are expected to thoroughly describe appropriate validation strategies according to the translational gap to be bridged. The inclusion of a strategy to ensure the reproducibility of results is encouraged.

Research projects on diseases other than cancer are also encouraged.

Module 1A: Pre-clinical Research**Scope**

- Development and implementation of high-throughput pre-clinical models for (A) validation of data and hypotheses from human population, clinical and molecular studies and/or (B) prediction of clinical outcome. This may include animal models, cell culture models, organoids, etc.
- Classification of diseases at the molecular level, which can be instrumental for successful implementation of PM, including pre-clinical studies for validation of biomarkers that can be used in diagnosis, prognosis and prediction of response to treatment.
- Validation (in preclinical models, in terms of reproducibility, safety and efficiency) and characterisation of the role of biomarkers in predictive medicine for future prevention, assessment and management of diseases.

Module 1B: Clinical Research**Scope**

- Improvement, validation and combination of different tools (e.g. imaging) as well as omic tools for diagnostics and different integrated analytical methods, allowing the discovery of molecular characteristics involved in disease etio-pathogenesis, development and progression and in patient treatment including pharmacokinetics or pharmacodynamics.
- Development and evaluation of concepts for innovative clinical trial methodologies, suitable for PM approaches, taking into account that more flexible and innovative trial design is needed.
- Development of new concepts and stratification strategies in exploratory clinical studies (for further indications, see also the blue box on page 11).
- Clinical and omics data integration, use of machine learning technology to provide personalised treatment for patients.

Research Area 2: “Integrating Big Data and ICT⁸ Solutions”.

Systematic integration of different bioinformatic resources (databases, algorithms, etc.), Big Data and ICT solutions should be an essential part of the research proposals submitted to this call wherever appropriate. The re-use of data is encouraged. Developed PM approaches should support the easy flow, robust analysis and interpretation of information such as clinical data (including imaging data and physiological monitoring data), omics data, data on biological

⁸ Information and Communications Technology (or Technologies)

samples, as well as patient outcomes among different institutions while ensuring data security and data protection.

Applicants are asked to describe new or existing tools, methodologies, technologies and digital supports used in the project. This includes ICT solutions (e.g. eHealth and mHealth solutions and telehealth) for timely and safe transfer of health information and facilitating the use of data, including electronic medical records (structured and unstructured sources), by respecting on one hand data security, protection and privacy, and on the other hand ensuring interoperability, completeness, sufficient documentation and comparability of data.

The re-use or combination of already existing tools is also welcome. Outlining how developed/used ICT solutions will be maintained after the end of the project is encouraged.

Module 2A: Data and ICT – Enabling Technology

Scope

- Research on data harmonisation strategies and development of specific ICT solutions for research questions addressed in the consortium.
- Strategies for developing common quality standards, semantics and minimal indicators, and metrics for data and metadata.
- Development of biomedical and/or computational (ICT) tools respecting interoperability of the databases as well as data privacy regulations.
- Development of bioinformatic models/methods to integrate, analyse and extract value from databases, allowing e.g. the (automated or manually curated) integration and processing of data from unstructured sources and the combination of multiple data sources by maintaining statistical power.
- Development of new devices/tools for data collection (e.g. mHealth, wearable devices for continuous online physiological monitoring, haptic devices, etc.).

Module 2B: Data and ICT – Towards Application in Health Care

Scope

- Research on data integration and interpretation of complex/multifactorial diseases and other diseases, aimed to advance PM. Demonstration of the potential clinical benefit using various datasets (e.g. from large, multimodal and multicentric public data repositories and clinical records from different sources), various data types (e.g. behavioural and molecular data) and different forms of mathematical, statistical and modelling framework for the exploration and validation of data quality and its information content as a basis for future proof-of-concept studies.
- Development of innovative and easy-to-handle clinical decision support tools tailored to health care professionals to provide suitable and consequent interpretation of

complex multifactorial and multimodal data (including e.g. clinically validated data and information on current diagnosis and treatment options).

- Development of telehealth and telemedicine applications to support the implementation of PM, e.g. by using and combining innovatively already validated and novel e- and mHealth options, such as e.g. innovative physiological sensor and patient monitoring technologies combined with mHealth solutions for real-time personalised feedback.

Research Area 3: *"Research towards Responsible Implementation in Health Care"*

Even though promising approaches in PM exist, large-scale implementation in healthcare systems is still to come. Research is needed into how different countries' health care systems could be adapted and how the outcomes of these studies could be taken into account in implementation processes. This comprises research on future optimisation of health care systems including research on regulatory frameworks in health economics (e.g. through to market access, if applicable). Health economics aspects can assess the cost-effectiveness of PM approaches or even develop recommendations and/or new models and tools to enable this kind of assessment.

In addition, there is a broad range of ethical, legal and social aspects (ELSA) to consider, e.g. research on regulations in diagnostics and drugs, fundamental societal challenges, as well as research on citizen/patient involvement.

Both of these cross-cutting topics (research on the optimisation of health care systems and ELSA) should be addressed as early as possible during the development of PM strategies.

Proposals submitted to this call should include research on at least one of these topics (Module 3A or 3B). The research conducted in Research Area 3 should relate directly to the research question(s) addressed in Research Area(s) 1 and/or 2.

Module 3A: Optimising Health Care System

Scope

- Research on the analysis, comparison and optimisation of national and regional health care systems in the context of PM. Suggestions for the optimisation of health care systems can be elaborated in order to support the reasonable implementation of existing best practice and lessons learned in the light of sustainable solutions. Investigation of the social conditions, such as availability of insurance and employment, should form part of this research.
- Research on development, application and adaptation of new models and approaches for health care and their application/adaptation to healthcare systems in different regions/countries. This should lead e.g. to support models and tools (such as pharmaco-economy, clinical risk assessment and management, and others), and

enable better diagnosis and care for the benefit of citizens and patients, based on available data and information on current diagnosis.

- Research on health economic aspects of PM, e.g. on the cost-effectiveness of PM approaches for treatments, taking into account patient outcomes and quality of life. Research investigating whether a patient-centred, PM approach requires refinement of or even new health economic and pharma-economic models; not only for treatment of diseases, but also for prevention.
- Research on the overall economic impact of an optimised health care system based on improved treatment of diseases and prevention within the framework of PM. This includes identification of the different economic actors (market players) and their economic strategies.
- Research on provision of equitable access to PM approaches for all patients regardless of economic, educational or geographic status (including research on the effect of PM on social inequalities).

Module 3B: Ethical, Legal and Social Aspects

Scope

- Research on optimised data security, protection, confidentiality, privacy and ownership within PM approaches; responsible ways to enable the use of personal and patient data for research purposes.
- Research on adequate regulatory structures and pathways in PM; e.g. in the context of development of new clinical trial design methodology for PM. Research on refinement of existing and – where appropriate – development of new guidelines and reflection papers for researchers to facilitate the approval process with regulatory authorities and their communication with reimbursement authorities.
- Research on how to overcome the challenges posed by different regional or national regulatory frameworks, for example in multi-centred clinical trials with study centres in several countries, including e.g. the impact of different cultural codes (affecting the collection of informed consent), educational attainment and/or social/economic status.
- Research on fundamental societal challenges raised by PM, e.g. questions of solidarity, fairness or rationality of allocation of resources and research foci.
- Development of new forms and interplay of stakeholder exchange (including all different key players – from academic researchers from different disciplines, health care providers, industry/pharma and regulatory authorities, as well as citizens and patients).
- Research on responsibility and liability as well as challenges for our view on the nature of humans and humankind, human dignity; heritability and generational responsibility or the interface and tension between the state of health, and illness.

- Research on ethical, legal and social aspects in the context of decision support systems, especially with the use of artificial intelligence: availability and suitability of training data (in machine learning), requirements on transparent decision-making, questions of responsibility and liability, potential changes in the role and self-image of physicians.
- Research on appropriate ways and methods for participatory health research/patient involvement in research projects for PM.
- Research on the different users' perspectives (expectations vs. capacity and willingness to provide requested input) among the various key players (e.g. researchers, health care providers, etc.) and professional dynamics connected to PM approaches. This research might also include reflections on organisational innovation (changes in the organisation of the health service).

Small exploratory clinical studies are within the scope of the call.

ERA PerMed can support exploratory clinical studies, including those with a smaller number of patients/volunteers that aim to demonstrate the feasibility of early diagnosis and/or stratification of, for example, patients for existing drugs. Exploratory clinical studies submitted to this call should be designed to allow further scalability, although their escalation is not part of this joint call.

Clinical trials that include a larger number of patients, for example for the identification or development of novel drugs, **are beyond the scope of the call**.

Proposals must adhere to the requested budget and time frame of the planned studies. Studies should be finalised within the 3-year funding period of the call. ERA PerMed will only fund those parts of the proposed study that address the aim of the call.

ERA PerMed supports exploratory clinical studies assessing the viability of a future study (e.g. clinical trial):

- **Pilot studies** in which the future definitive study, or parts of it, including the randomisation or non-randomisation of participants, is conducted on a smaller scale (piloted) to assess its feasibility. Pilot studies should resemble the main (future) study in many respects including the assessment of the primary outcome.
- **Feasibility studies that are not pilot studies**, such as those in which the investigators attempt to answer a question about whether some element of the future intervention is deemed feasible. In contrast to pilot studies, in this kind of study there is no part of the future study being conducted on a smaller scale. Feasibility studies that are not pilot studies are used to estimate important parameters that are needed to design the main study.

Proposals including an exploratory clinical study must include as an Annex at the full-proposal stage the duly filled out form for "Exploratory Clinical Studies" (template available on the ERA PerMed website).

Please note:

The Technology Readiness Levels (TRL)⁹ funded differ between the funding organisations. Please check the regional/national regulations (“Guidelines for Applicants”).

Regional/national eligibility rules apply to the funding of different research areas and modules as well as to the funding of clinical studies (see also Annex II and “Guidelines for Applicants”). Therefore, applicants are strongly advised to contact their relevant funding organisation contact person (see also Annex I) and to read carefully the regional/national eligibility rules (“Guidelines for Applicants”, Annex 2) prior to submission.

Recommendations

Proposals **must be interdisciplinary and clearly demonstrate the potential impact on PM** as well as **the added value of transnational collaboration**: sharing of resources (registries, diagnosis, biobanks, models, databases, Electronic Health Records, diagnostic and bio-informatics tools, etc.), platforms/infrastructures, interoperability of data harmonisation strategies and sharing of specific know-how. In order to achieve these goals, the necessary expertise and resources should be brought together from academia, clinical/public health sector and private partners. The research teams within a consortium should include investigators from all scientific disciplines, research areas and expertise necessary to achieve the proposed objectives. The individual project partners of the joint applications should be complementary. The proposed work should contain novel, innovative, ambitious ideas and promote innovative PM solutions to move from scientific value to benefit for patients (including analyses of applicability to medical care in terms of e.g. money, time, resources, technical feasibility, etc.).

Consultation with stakeholders relevant for a successful implementation into health care (e.g. regulatory authorities or health insurance providers) beforehand is recommended. The outcome of these discussions and their impact on the project’s concept can be described in the proposal.

Consortia are asked to clearly demonstrate and describe how the selected Research Areas and Modules are integrated in the proposal and addressed in the work plan. The coherent integration and combination of the different Research Areas and Modules in the proposals will be part of the evaluation process (see also page 22: “3. Quality and efficiency of the implementation”). The integration of all three Research Areas (inclusion of at least one Module from each Research Area) in one proposal is encouraged.

Active participation of early-career researchers/scientists in project proposals is encouraged. An early-career researcher/scientist is someone who has been awarded his/her first PhD/MD

⁹ Horizon 2020 scale for TRL: http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf

or equivalent doctoral degree at least 2 and up to 10 years prior to the proposal submission deadline¹⁰ (see further details in Annex III).

Patient involvement

ERA PerMed strongly encourages the active involvement of members of the public in the proposed research projects. This includes patients, citizens/potential patients, carers, people who use health and social care services, as well as patient organisations. The goal is to raise awareness, share knowledge and improve dialogue between researchers, healthcare providers, policy-makers, industry and the public.

Therefore, consortia submitting proposals to this call are asked to describe the level of public involvement in the research throughout the various stages of research design, conduct, analysis and dissemination. The extent of public/patient involvement may vary according to the context of the study proposed and regional/national regulations of participating funding organisations.

Involving members of the public in research projects can improve quality and relevance by:

- Providing a different perspective – to profit from experiences obtained in research and experiences of those who are using the service or living with a health condition;
- Using clear and accessible language and content of information in documents provided to the wider public;
- Helping to ensure that the methods proposed for the study are suited and sensitive to the situations of potential research participants;
- Helping to ensure that the research considers outcomes that are important to the public;
- Helping to increase the participation of potential participants in research by making the research more comprehensive and therefore acceptable.

In addition to improving research relevance and quality, involving members of the public ensures that research considers broader principles of citizenship, accountability and transparency.

Inclusion of sex, gender analysis¹¹ and/or underrepresented populations

Applicants are strongly encouraged to integrate sex and gender considerations in proposals submitted to the ERA PerMed call, as well as underrepresented populations in the proposed research. This includes not only the **sex distribution of research teams**, but also the **inclusion**

¹⁰ PhD equivalence and eligible extensions to this period in case of career breaks are detailed in Annex III.

¹¹ Applicants are encouraged to visit the further link and to complete the modules in order to increase the quality of their applications concerning the integration of sex and gender-based considerations: <http://www.cihr-irsc.gc.ca/e/49347.html>

of sex and/or gender analysis in the research itself. This applies especially in cases where patients are involved in the proposal. A project is considered sex- and gender-relevant when it concerns individuals or groups of people and/or when its findings may affect individuals or groups.

The inclusion of gender and/or sex analysis is part of the evaluation and represents one evaluation sub-criterion in “2. Impact”, “f. Consideration of sex aspects and underrepresented populations in research teams. Inclusion of sex and/or gender analysis and underrepresented populations in the research, if applicable” (page 21).

Scientific Data Open Access Policy

Proposals should explain how the data gathered through the project would be available (findable, accessible, interoperable and re-usable) to the wider research community, even after the end of the project. In addition, ERA PerMed expects proposals to develop data management plans (DMPs) following the **FAIR principles**¹². Consortia of projects selected for funding must submit a detailed DMP (template available on the ERA PerMed website). The project coordinator is responsible for sending the complete DMP to the JCS no later than three months after the official start of the project.

Compliance with the DMP must be reported in each annual scientific project progress report. Publication of scientific outcomes of the project is subject to open access and budget should be allocated for this in the proposal budget plan.

¹² http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

4. APPLICATION

A. FUNDING RECIPIENTS

Eligibility criteria:

- Only transnational projects will be funded.
- **Each consortium submitting a proposal must involve at least three partners eligible for funding coming from three different countries whose funders participate in the call** (see list above). All three legal entities must be independent of each other.
- The **project coordinator must be eligible to be funded** by his/her regional/national participating funding organisation.
- **The maximum number of partners per project at the pre-proposal stage is six. At the full-proposal stage, the consortium may be expanded to up to seven partners in total only by inclusion of a partner from an underrepresented country.** A list of underrepresented countries will be provided to the coordinators invited to submit full-proposals.
- **Within one consortium, no more than two partners from the same country participating in the call will be accepted, including those partners with their own funding.** For some funding agencies the maximum number of eligible partners that can be funded in one project is limited to one (see also “Guidelines for Applicants” for individual funding rules).
- Partners not eligible for funding by one of the organisations participating in this JTC (e.g. from non-funding countries or not fundable according to the regional/national regulations of the participating funding organisations) may participate in projects if they are able to secure their own funding. **No more than one partner with its own funding is allowed** in consortia with at least 3 partners eligible for funding.

Joint research proposals may be submitted by applicants belonging to the following categories (for the regional/national regulations of the funding organisations, please see “Guidelines for Applicants”):

- A. Academia** (research teams working in universities, other higher education institutions) **or research institutes;**
- B. Clinical/public health sector** (research teams working in hospitals/public health and/or other health care settings and health organisations). Participation of clinicians (e.g. medical doctors, nurses) in the research teams is encouraged;
- C. (Industry) Private partners, e.g. SMEs¹³** (small and medium-sized enterprises).

¹³ https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

Consortia submitting applications to this call are strongly encourage to include partners from different categories (A, B and C) in line with the crosscutting/multidisciplinary character of the call, allowing the inclusion of partners from different levels of the value chain. The number of participants, the category of partner organisations and their research contribution should be appropriate for the aims of the transnational research project and should be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass necessary to achieve ambitious scientific goals and should clearly demonstrate added value from the cooperation.

Research groups, SMEs and industry partners (non-SMEs) not eligible for funding by one of the organisations participating in this Joint Transnational Call (e.g. from non-funding countries or not fundable according to regional/national regulations of the participating funding organisations) may participate in transnational projects if they are able to secure their own funding. Such partners must state in advance their source of funding for the project. They are treated as full partners and must be included in the pre- and full-proposal templates as such. Please be aware that **no more than one partner with its own funding** is allowed in consortia with at least 3 partners eligible for funding (i.e. proposals with 4-6 partners in total, including the partner with its own funding, in the pre-proposal stage, and up to 7 for full-proposals). A letter of commitment must be included as an annex to the proposal in the full-proposal step summarising the commitment of this partner to the project and demonstrating the source of funding. The budget of a non-funded partner shall not exceed 30% of the total transnational project budget requested.

To collect the necessary patient data and/or samples for the proposed study, a consortium may need to collaborate with other centres. If the only role of those centres is to provide patients' data and/or samples for the study, they will not be treated as partners of the consortium but can be included otherwise, e.g. via cooperation agreements or subcontracting.

Number of partners in the proposal*	Pre-proposal				Full-proposal (only by inclusion of one underrepresented country)
	3	4	5	6	7
Maximum number of partners with own funding	0	1	1	1	1
Maximum number of partners per country	1	2	2	2	2

* minimum 3 partners eligible for funding from three different countries participating in the call.

Each consortium must nominate only one **project coordinator** from among the project's principal investigators. The inclusion of a co-coordinator is not allowed. The coordinator must be eligible to be funded by his/her regional/national participating funding organisation. The project coordinator will represent the consortium externally and in its dealings with the JCS

and the **Call Steering Committee¹⁴ (CSC)**, and will be responsible for its internal scientific management such as project monitoring, reporting, intellectual property rights (IPR) management and contact with the JCS.

Only one principal investigator will represent each project partner. Within a joint proposal, each project partner's principal investigator will be the contact person for the JCS and the relevant regional/national funding organisation.

Although proposals will be submitted jointly by research groups from several regions/countries, research groups will be funded by the individual funding organisation of the respective region/country from which applicants have applied. Applicants are therefore subject to the eligibility criteria of the relevant funding organisations of the respective region/country (see also Annex II and "Guidelines for Applicants"). Applicants should therefore carefully read the funding rules and eligibility criteria of the relevant funding organisations. **Applicants are strongly advised to contact their relevant funding organisation (see also Annex I) prior to submission; please note that this step might be mandatory for some regions/countries.**

Please note that if a **partner** is found to be ineligible by one of the funding organisations after the formal check, the entire proposal may be rejected without further review. For a definition of eligible partners see "Guidelines for Applicants", the regional/national regulations, and contact your regional/national funding organisation (see also Annex I).

Nevertheless, the applicant will be informed that a redress procedure is available. The redress procedure pertains to the eligibility-checking process only; it is not an automatic re-evaluation, and the judgement of appropriately qualified experts is not called into question.

For regional/national eligibility reasons, applicants must indicate in the pre-proposal form if the study submitted is subject to other evaluation processes, such as other joint transnational calls (e.g. NEURON, E-RARE, EJP-RD, ERA-CVD, JPND, HDHL, EuroNanoMed, ERA-Co-SysMed, Transcan and others) and national calls. Applicants shall avoid applying to different calls for same research activities. Double funding is not allowed.

Double submission of the same proposal on neurodegenerative diseases focusing on medical imaging in the light of PM within the cofunded JPND JTC2019 and the ERA PerMed JTC2019 is not eligible. Double submission of the same proposal within the cofunded EJP Rare Diseases JTC2019 and the ERA PerMed JTC2019 is not eligible.

¹⁴ Call Steering Committee: composed of a single representative from each country's/region's funding organisation.

B. FINANCIAL AND LEGAL ASPECTS

The maximum duration of the projects must be three years in accordance with ERA PerMed funding organisation regulations. The performed studies should be finalised at the latest within the third year of the funding period. **Eligible costs and funding provisions may vary according to the respective funding organisation's regulations.** Project partners must refer and adhere to their own regional/national regulations and scientific remits as detailed in the relevant regional/national announcements (see Annex II).

C. SUBMISSION OF JOINT PROPOSALS

A **two-step submission and evaluation procedure** for joint applications has been established: pre-proposals and full-proposals. In both phases, one joint proposal document shall be prepared by the partners of a joint transnational project proposal, and must be submitted to the JCS by the project coordinator by uploading it on the electronic submission system (<https://ptoutline.eu/app/erapermed2019>). The proposals must be written in English, must respect the template form in terms of overall size and section pages and characters limits, and must strictly adhere to the "Guidelines for Applicants". The pre-proposal form can be downloaded from the ERA PerMed website (www.erapermed.eu).

Submitted pre-proposals that do not use the respective template will be declared ineligible.

Joint **pre-proposals** must be received by the JCS in electronic format no later than **7 March 2019 at 17:00 CET**.

The decision regarding applicants selected to submit a full-proposal will be communicated to applicants as soon as possible around 13 May 2019. At the same time, the JCS will send the coordinator a full-proposal application template if the respective proposal is recommended for the full-proposal stage.

Full-proposals (in English) must be received by the JCS in electronic format no later than **17 June 2019 at 17:00 CEST**. Please note that **joint full-proposals will be accepted only from those applicants explicitly invited to submit by the JCS**. Submitted full-proposals that do not use the respective template will be declared ineligible.

In general, no fundamental changes between the pre- and full-proposals concerning the composition of the consortia, objectives of the project or requested budget will be accepted. The CSC may, however, allow such changes only in exceptional cases, duly justified to the JCS. Further information on electronic submission of pre- and full-proposals is available on the ERA PerMed website (www.erapermed.eu) and in the "Guidelines for Applicants". Applicants should take note of individual regional/national rules, and should contact their regional/national contact person if they have any questions.

Applicants from some regions/countries might be required to submit the additional regional/national proposal and/or other information, in some cases before the deadline of this call, directly to the regional/national funding organisations in question. Applicants are

therefore **strongly advised** to check their funding organisation's specific regulations. See "Guidelines for Applicants" for more details.

Ethical and legal issues must be addressed in each application, according to the relevant region's/country's regulations, as well as **patient participation (which is encouraged)**.

The ERA PerMed Call Steering Committee (CSC) will take all lawful steps to ensure the confidentiality of the information and documents obtained during the joint call evaluation and selection procedure.

D. FURTHER INFORMATION

Applicants should contact their corresponding regional/national representative to enquire about eligibility with their respective funding organisations in advance of submitting an application (see regional/national contact details, Annex I). For additional information, please contact the JCS (ERAPerMed@agencerecherche.fr). Adherence to the regional/national funding regulations in the "Guidelines for Applicants" document is mandatory (www.erapermed.eu).

5. FORMAL CHECK AND EVALUATION OF PROPOSALS

A. FORMAL CHECK AND EVALUATION OF PRE-PROPOSALS

The JCS will check all proposals to ensure that they meet the call's formal criteria (see also "4. Applications, A. Funding recipients"). In parallel, the JCS will forward the proposals to the regional/national funding organisations, which will perform a check for compliance according to their regional/national rules.

Please note that if a proposal includes one ineligible partner, the whole proposal may be rejected (for the definition of eligible partners see "Guidelines for Applicants" and regional/national funding regulations and contact your regional/national contact person, see also Annex I).

Each pre-proposal passing the eligibility check (performed by the JCS and the participating funding agencies) will be sent to at least three reviewers for a first evaluation (see evaluation criteria below, "5. Formal check and evaluation of proposals, C. Evaluation criteria"). The reviewers will assess the pre-proposal and complete a written evaluation form with scores and comments for each criterion. The CSC members will meet to decide which proposals will be invited for full-proposal submission based on the reviewers' recommendations and to ensure a reasonable balance of requested and available regional/national budgets.

B. FORMAL CHECK AND EVALUATION OF FULL-PROPOSALS. REBUTTAL STAGE

The JCS will review the full-proposals to ensure that they meet the call's formal criteria and have not changed substantially from the respective pre-proposals prior to sending them to the reviewers. Any fundamental changes between the pre- and full-proposal concerning the composition of the consortium, objectives of the project or requested budget must be communicated to the JCS and to the regional/national funding organisations. In exceptional cases, these changes may be admitted if detailed justification is provided and if they are accepted by the CSC.

Each full-proposal will be allocated to three reviewers who provide expertise within the profile of the application. The reviewers will assess the full-proposal and complete a written evaluation form with scores and comments for each criterion (see evaluation criteria below). The reviewers will meet in a Peer Review Panel (PRP) to discuss all proposals, to produce an assessment report for each full-proposal and a ranking list of proposals recommended for funding. The composition of the PRP will be communicated through the ERA PerMed website at the end of the entire review process.

Rebuttal stage: Before the PRP plenary meeting to discuss the **full-proposals**, each project coordinator will have the opportunity to study the assessments and to provide comments on the arguments and evaluations of the reviewers, who remain anonymous. This stage allows applicants to comment on factual errors or misunderstandings that may have been committed by the reviewers while assessing their proposal and to reply to reviewers' questions. However, issues that are not related with reviewers' comments or questions, cannot be addressed and the work plan cannot be modified at this stage. Answers sent after the notified deadline, or not related with reviewers' comments or questions, will be disregarded.

C. EVALUATION CRITERIA

Pre-proposals and full-proposals will be assessed according to specific evaluation criteria using a common evaluation form (proposals not falling within the scope of the call will not be evaluated further). A scoring system from 0 to 5 will be used to evaluate the proposal's performance with respect to the different evaluation criteria.

Scoring system:

0: Failure. The proposal fails to address the criterion in question, or cannot be judged because of missing or incomplete information.

1: Poor. The proposal shows serious weaknesses in relation to the criterion in question.

2: Fair. The proposal generally addresses the criterion, but there are significant weaknesses that need corrections.

3: Good. The proposal addresses the criterion in question well, but certain improvements are necessary.

4: Very good. The proposal addresses the criterion very well, but small improvements are possible.

5: Excellent. The proposal successfully addresses all aspects of the criterion in question.

Evaluation scores will be awarded for the three main criteria, and not singularly for the different aspects listed below the criteria. The three criteria are weighted equally and the maximum total score for the three evaluation criteria that can be reached in the remote evaluation is 15 points. The threshold for every individual criterion based on the evaluation of the three reviewers will be 3.

Evaluation criteria:

1. Excellence:

- a. Clarity and pertinence of the objectives;
- b. Scientific quality of the proposed approach and methodology;
- c. Soundness of the concept;
- d. Novelty of the concept;
- e. Feasibility of the project (adequate requested resources, time schedule);
- f. Quality of the project consortium: international competitiveness of participants in the field(s), previous work and expertise of the participants, added value of the transnational collaboration.

2. Impact:

- a. Added value of the transnational collaboration; sharing of resources (registries, diagnosis, biobanks, models, databases, diagnostic and informatics tools, etc.), platforms/infrastructures, harmonisation of data and sharing of specific know-how;
- b. Potential impact of the expected results on clinical and other health related applications;
- c. Involvement of pertinent patient organisations, patient representatives (if available/applicable);
- d. Involvement of private partners (SME and/or industry, if available/applicable);
- e. Innovative potential;
- f. Consideration of sex aspects and underrepresented populations in research teams. Inclusion of sex and/or gender analysis and underrepresented populations in the research, if applicable.

3. Quality and efficiency of the implementation:

- a. Quality of the project plan;
- b. Adequateness of the work package structure and work plan (tasks, matching events, time schedule);

- c. Balanced participation of project partners and integration of workload in the different work packages, quality and efficiency of the coordination and scientific management;
- d. Scientific justification and adequateness of the requested budget (rational distribution of resources in relation to the project's activities, partner responsibilities and time frame);
- e. Risk assessment, regulatory and ethics issues properly addressed (when necessary);
- f. Coherent integration and combination of Research Areas and Modules in the proposal.

D. CONFLICTS OF INTEREST (EVALUATION PANEL)

All necessary steps will be taken by the JCS and the CSC to ensure no conflict of interest by PRP members for those proposals assigned to them for review. The PRP members will be required to formally declare that no conflict of interest exists at any point in the evaluation process and will sign a confidentiality agreement concerning all documents and the entire process. Any PRP member who breaches the conflict-of-interest rule will be discharged from participating in the panel. Projects assigned to that reviewer will be assigned to another reviewer.

A first review for conflicts of interest will be performed by the JCS when analysing the reviewers' publications. Reviewers are bound to indicate after receiving the proposals whether there is a conflict of interest with any of the researchers or research groups in the proposals for review. Reviewers will sign a formal declaration that they will not participate in the call nor have any conflicting interests regarding the researchers or research groups participating in the projects that are reviewed.

6. FINAL DECISION ON FUNDING

Based on the ranking list established by the PRP and on available funding, the CSC will recommend those projects to be funded to the regional/national funding organisations. Based on these recommendations, final decisions will be made by the regional/national funding organisations, subject to budgetary considerations. The regional/national funding organisations will follow the ranking list established by the PRP members.

The funding decision will be final and no complaint will be accepted or processed by the ERA PerMed consortium.

The project coordinator will be informed by the JCS about the final decision. The project partners should be informed by their project coordinator.

7. PROJECT START AND CONSORTIUM AGREEMENT

Consortium members of projects selected for funding must fix a common project start date, which will be the reference date for the annual progress reports and final reporting. This common project start date must be stated in the Project Consortium Agreement (CA).

Project coordinators will be responsible for drafting a Project Consortium Agreement suited to their consortium in order to manage the delivery of the project activities, intellectual property rights (IPR) and decision-making, and to avoid disputes, that could compromise the completion of the project. The coordinator is responsible for sending the CA signed by all partners to the JCS. This consortium agreement must state that funding and administrative matters are not regulated by the CA and are issues addressed bilaterally between each project partner and its funder in the relevant Grant Agreement (GA). The CA will be made available to the relevant funding organisations. The project consortium is strongly encouraged to sign this CA before the official project start date and, in any case, the CA should be signed **no later than six months after the official project start date**. Please note that regional and national funding agencies' regulations concerning the requirement for a CA may apply. Further instructions will be provided by the JCS to the coordinators of the projects selected for funding.

8. REPORTING REQUIREMENTS

Each project coordinator, on behalf of all participating project partners, shall submit to the JCS an annual and final scientific progress report the first year, second year and a final report of the transnational project in English. A report template will be provided by JCS stating the scientific progress, the goals that have been met, and corrective measures in the event that the annual project plan has not been fulfilled. It may also be necessary for project partners' principal investigators to submit reports individually to their national funding agency/body in accordance with the respective regional/national regulations. In addition, project coordinators may be asked to present the project results at ERA PerMed meetings and be invited to attend at least one midterm seminar and one final symposium. Accordingly, travel expenses to attend these mandatory meetings should be included in the proposal budget plans.

In case of ANY significant changes in the work programme or the consortium's composition, the coordinator must promptly inform the JCS. The JCS will inform the relevant funding organisations, who will decide upon the proper action to be taken.

Selected project coordinators, upon notification, are required to deliver an abstract of their project suitable for communication and dissemination purposes.

In addition, the funding recipients are expected to participate in and contribute to any communication activity initiated by ERA PerMed during the funding period (mandatory) and beyond.

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA PerMed-funded projects include a proper acknowledgement of the ERA PerMed ERA-NET and the respective funding partner organisations. Publication with Open Access is mandatory.

ANNEX I. REGIONAL/NATIONAL CONTACT DETAILS

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
<i>Austrian Science Fund, (FWF)</i>	AUSTRIA	Stephanie Resch Tel: (+43) (0) 1 505 67 40-8201 Stephanie.Resch@fwf.ac.at Iris Fortmann Tel: (+43) (0) 1 505 67 40-8211 Iris.Fortmann@fwf.ac.at
<i>Fund for Scientific Research – FNRS, (F.R.S.-FNRS)</i>	BELGIUM	Joël Groeneveld Tel: (+32)2 504 9270 joel.groeneveld@frs-fnrs.be Florence Quist Tel: (+32)2 504 9351 florence.quist@frs-fnrs.be
<i>Canadian Institutes of Health Research, (CIHR)</i>	CANADA	Ilana Gombos Tel: +1 613-952-0819 Ilana.Gombos@cihr-irsc.gc.ca
<i>Fonds de recherche du Québec - Santé, (FRQS)</i>	CANADA QUEBEC	Maxime Beaudoin Tel: 514-873-2114 ext.1369 Maxime.beaudoin@frq.gouv.qc.ca
<i>Ministry of Science and Education of the Republic of Croatia, (MSE)</i>	CROATIA	Staša Skenžić Stasa.Skenzic@mzo.hr
<i>Innovation Fund Denmark, (InnoFond)</i>	DENMARK	Ejner Moltzen Tel: (+45) 31330306 Ejner.moltzen@innofond.dk Jens Peter Vittrup Tel: (+45) 61905023 Jens.peter.vittrup@innofond.dk
<i>Academy of Scientific Research and Technology, (ASRT)</i>	EGYPT	Amr Radwan +201225643263 Radwan.Amro@gmail.com Salma Essawi Sme@sti.sci.eg , innov@sti.sci.eg
<i>Academy of Finland, (AKA)</i>	FINLAND	Heikki Vilen Tel: +358 (0) 295 335135 heikki.vilen@aka.fi
<i>Agence Nationale de la Recherche, (ANR)</i>	FRANCE	Monika Frenzel Tel: (+33) (0) 1 73 54 83 32 ERAPerMed@agencerecherche.fr

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
Federal Ministry of Education and Research, (BMBF) German Aerospace Centre e.V. – Programme Management Agency, (DLR)	GERMANY	Dr. Katja Kuhlmann katja.kuhlmann@dlr.de Tel: (+49) 228 3821 2211 Dr. Petra Lüers Petra.Lueers@dlr.de
Federal Ministry of Health, (BMG) VDI/VDE Innovation und Technik GmbH, Programme Management Agency	GERMANY	Dr. Anne Dwertmann Tel: (+49) 30 310078 427 Anne.Dwertmann@vdivde-it.de Dr. Andrea Repen Tel: (+49) 30 310078 424 Andrea.Repen@vdivde-it.de
Saxon State Ministry for Higher Education, Research and the Arts, (SMWK)	GERMANY (SACHSEN)	Eva Damm Tel: (+49) 351 564 6425 permed@smwk.sachsen.de Gabriele Süptitz Tel: (+49) 351 564 6422 permed@smwk.sachsen.de
General Secretariat for Research and Technology, (GSRT)	GREECE	Georgia Kostopoulou Tel: (+30) 210 2131300 100 g.kostopoulou@gsrt.gr
National Research, Development and Innovation Office, (NKFIH)	HUNGARY	Dr. Klára Horváth Tel: +36 1 896 37 48 klara.horvath@nkfi.gov.hu
Health Research Board, (HRB)	IRELAND	Dr Caitriona Creely Tel: (+353) 1234 5204 ccreely@hrb.ie
Chief Scientist Office, Ministry Of Health, (CSO-MOH)	ISRAEL	Yahaloma Gat Tel: (+972) (0) 56 242 476 y.gat@moh.gov.il
Italian Ministry of Health, (IT-MoH)	ITALY	Dr. Gaetano Guglielmi Directorate General for Health Research and Innovation Tel: (+39) 065994.3528 g.guglielmi@sanita.it Dr. Maria Josè Ruiz Alvarez Tel: (+39) 065994.3214 mj.ruizalvarez-esterno@sanita.it

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
<i>Regional Foundation for Biomedical Research, (FRRB)</i>	ITALY (LOMBARDY)	Carmen De Francesco Tel: +39 02 6765 0170 Paola Larghi Tel: +39 02 6765 0173 Paola Bello Tel: +39 02 6765 0174 bandi@frrb.it
<i>Tuscany Region, (TuscReg)</i>	ITALY (TUSCANY)	Donatella Tanini Tel: +39 (0) 55 43 83 256 erapermed@regione.toscana.it
<i>State Education Development Agency (VIAA)</i>	LATVIA	Maija Bundule Tel: +371- 67785423 Maija.Bundule@viaa.gov.lv Uldis Berkis Tel: +371 29472349 Uldis.Berkis@viaa.gov.lv
<i>National Research Fund, (FNR)</i>	LUXEMBOURG	Marie-Claude Marx Tel: +352 261925 – 21 marie-claude.marx@fnr.lu
<i>The Research Council of Norway, (RCN)</i>	NORWAY	Karianne Solaas Tel: (+47) 945 35 380 kso@rcn.no
<i>National Centre for Research and Development, (NCBR)</i>	POLAND	Marcin Chmielewski Tel: +48 22 39 07 109 marcin.chmielewski@ncbr.gov.pl
<i>Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI)</i>	ROMANIA	Cristina Cotet Tel: 021/302.38.84 cristina.cotet@uefiscdi.ro
<i>National Institute of Health Carlos III, (ISCIII)</i>	SPAIN	Mauricio García-Franco Eduard Güell Tel: +34 91 822 2885 mauriciog@isciii.es eranetpm@isciii.es
<i>Centro para el Desarrollo Tecnológico Industrial, (CDTI)</i>	SPAIN	Sara Alfonso Tel: +34 915810489 sara.alfonso@cdti.es

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
<i>The Scientific Foundation of the Spanish Association Against Cancer, (AECC-FC)</i>	SPAIN	Marta Puyol Tel: (+34) 913108207 marta.puyol@aecc.es
<i>Health Department – Generalitat de Catalunya, (DS-CAT)</i>	SPAIN (CATALONIA)	Montserrat Llavayol Tel: +34935566172 peris@gencat.cat
<i>Government of Navarre, (GN)</i>	SPAIN (NAVARRA)	Sara Torres Tel: +34848427873 storresl@navarra.es
<i>Swedish Research Council, (SRC)</i>	SWEDEN	Malin Eklund Tel: +46 (0)76 526 72 56 Malin.Eklund@vr.se
<i>The Scientific and Technological Research Council of Turkey, (TUBITAK)</i>	TURKEY	Dr. Banu Gökçay Tel: +90 312 298 1211 banu.buruk@tubitak.gov.tr

ANNEX II. INDICATIVE FUNDING COMMITMENTS OF THE PARTICIPATING ORGANISATIONS OF THE ERA PERMED JTC 2019 (THIS TABLE IS MEANT FOR A FIRST OVERVIEW ONLY. PLEASE REFER TO THE REGIONAL/NATIONAL GUIDELINES FOR DETAILS.)

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding private partners*	Funding of call topic research area						Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
				area 1		area 2		area 3			
				1A	1B	2A	2B	3A	3B		
Austrian Science Fund, (FWF)	AUSTRIA	YES	YES	YES	YES	YES	YES	YES	YES	0.9	3
Fund for Scientific Research – FNRS (F.R.S.-FNRS)	BELGIUM	YES	NO	YES	NO	YES	NO	YES	YES	0.2	1
Canadian Institutes of Health Research, (CIHR)	CANADA	YES	NO	NO	YES	YES	YES	YES	YES	0.95	4
Fonds de recherche du Québec - Santé, (FRQS)	CANADA (QUEBEC)	YES	NO	NO	YES	YES	YES	YES	YES	0.36	1-2
Ministry of Science and Education of the Republic of Croatia, (MSE)	CROATIA	YES	YES	YES	YES	YES	YES	YES	YES	0.12	1
Innovation Fund Denmark, (InnoFond)	DENMARK	YES	YES	YES	YES	YES	YES	YES	YES	1.0	3-4
Academy of Scientific Research and Technology, (ASRT)	EGYPT	YES	YES	YES	YES	YES	YES	YES	YES	0.3	3-5

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding private partners*	Funding of call topic research area						Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
				area 1		area 2		area 3			
				1A	1B	2A	2B	3A	3B		
Academy of Finland, (AKA)	FINLAND	YES	NO	YES	YES	YES	YES	YES	YES	1.2	3-4
Agence Nationale de la Recherche, (ANR)	FRANCE	YES	YES	YES	YES	YES	YES	YES	YES	2.5	~10
Federal Ministry of Education and Research, (BMBF) German Aerospace Centre e.V. – Programme Management Agency, (DLR)	GERMANY	YES	YES	YES	YES	YES	YES	NO	YES	7.5	25
Federal Ministry of Health, (BMG) VDI/VDE Innovation und Technik GmbH, Programme Management Agency	GERMANY	YES	NO	NO	NO	YES	YES	YES	YES	1.5	~6
Saxon State Ministry for Higher Education, Research and the Arts, (SMWK)	GERMANY SAXONY (SACHSEN)	YES (Academia)	NO	YES	YES	YES	YES	YES	YES	3.0	Not defined
General Secretariat for Research and Technology, (GSRT)	GREECE	YES	YES	YES	YES	YES	YES	YES	NO	1.2	~5-6
National Research, Development and Innovation Office, (NKFIH)	HUNGARY	YES	YES	YES	YES	YES	YES	YES	YES	0.3	2-3

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding private partners*	Funding of call topic research area						Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
				area 1		area 2		area 3			
				1A	1B	2A	2B	3A	3B		
Health Research Board, (HRB)	IRELAND	YES	NO	YES	YES	NO	YES	YES	YES	0.37	1-2
Chief Scientist Office, Ministry Of Health, (CSO-MOH)	ISRAEL	YES	NO	YES	YES	YES	YES	YES	YES	0.3	2
Italian Ministry of Health, (IT-MoH)	ITALY	YES [Scientific Institutes for Research, Hospitalization and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico pubblici e privati, IRCCS) and National Institute of Health (ISS)]	NO	YES	YES	YES	YES	YES	YES	1.75	7-8
Regional Foundation for Biomedical Research, (FRRB)	ITALY (LOMBARDY)	YES Universities and research centers are eligible ONLY in partnership with IRCCS – public or private - and ASST)	NO	YES	YES	YES	YES	YES	YES	1.5	3-6

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding private partners*	Funding of call topic research area						Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
				area 1		area 2		area 3			
				1A	1B	2A	2B	3A	3B		
Tuscany Region, (TuscReg)	ITALY (TUSCANY)	YES [Tuscany Healthcare Service-SST (Local Health Authorities, University Hospitals, Fondazione Toscana Gabriele Monasterio and ISPRO. Tuscany Universities and other research institutes are eligible ONLY in partnership with the former.	YES (private non for profit research organisations)	YES	YES	YES	YES	YES	YES	0.3	2
State Education Development Agency, (VIAA)	LATVIA	YES (private law clinical organisations like private partners)	Private partners – scientific institutions or enterprises*	YES	YES	YES	YES	YES	YES	0.42	2
National Research Fund, (FNR)	LUXEMBOURG	Yes (under the conditions specified in the FNR eligibility rules)	NO	YES	YES	YES	YES	YES	YES	0.3	1-2
The Research Council of Norway, (RCN)	NORWAY	YES	NO	YES	YES	YES	YES	YES	YES	0.8	2-3

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding private partners*	Funding of call topic research area						Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
				area 1		area 2		area 3			
				1A	1B	2A	2B	3A	3B		
National Centre for Research and Development, (NCBR)	POLAND	YES	YES	YES	YES	YES	YES	NO	NO	0.6	1-3
Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI)	ROMANIA	YES	YES	YES	YES	YES	YES	YES	YES	0.5	1-2
National Institute of Health Carlos III, (ISCIII)	SPAIN	YES	YES, only if it is Non Profit. NO if it is for profit	YES	YES	YES	YES	YES	YES	0.5	3-5
Centro para el Desarrollo Tecnológico Industrial, (CDTI)	SPAIN	NO	YES (FOR PROFIT)	YES	YES	YES	YES	NO	NO	0.5	3-5
The Scientific Foundation of the Spanish Association Against Cancer, (AECC-FC)	SPAIN	YES	YES, only if it is Non Profit. NO if it is for profit	YES	YES	YES	YES	YES	YES	0.35	2-3
Health Department – Generalitat de Catalunya, (DS-CAT)	SPAIN (CATALONIA)	YES	NO	YES	YES	YES	YES	YES	YES	0.5	2
Government of Navarre, (GN)	SPAIN (NAVARRRE)	YES	YES	YES	YES	YES	YES	YES	YES	0.5	1-2

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding private partners*	Funding of call topic research area						Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
				area 1		area 2		area 3			
				1A	1B	2A	2B	3A	3B		
Swedish Research Council, (SRC)	SWEDEN	YES	NO	YES	YES	YES	YES	YES	YES	1.2	3-5
The Scientific and Technological Research Council of Turkey, (TUBITAK)	TURKEY	YES	YES	YES	YES	YES	YES	YES	YES	0.3	1-2

* subject to regional/national eligibility criteria and funding rules. All applicants and partners must comply with the State Aid rules (http://ec.europa.eu/competition/state_aid/overview/index_en.html). Please see more information from each individual funding agency in the “Guidelines for Applicants”.

ANNEX III. DEFINITION OF EARLY-CAREER RESEARCHER/SCIENTIST

Early-career researchers/scientists must have been awarded their first PhD/MD or equivalent doctoral degree at least 2 and up to 10 years' prior the proposal submission deadline for the ERA PerMed JTC2019. Extensions to this period may be allowed in case of eligible career breaks, which must be properly documented. However, there is **no need** to attach additional documentation when submitting the project proposal. Eligible career breaks are:

- For maternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by 18 months for each child born before or after the PhD/MD award;
- For paternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by the actual amount of paternity leave taken for each child born before or after the PhD/MD award;
- For long-term illness (over 90 days), clinical qualification or national service the effective elapsed time since the award of the first PhD/MD will be considered reduced by the documented amount of leave taken for each event which occurred after the PhD/MD award.

Eligible events that take place within the extension of the eligibility window may lead to further extensions. The cumulative eligibility period should not in any case surpass 14 years and 6 months following the award of the first PhD/MD. No allowance will be made for principal investigators working part-time.

Please refer to the regional/national guidelines for details and eligibility criteria (also see Annex 2 in "Guidelines for Applicants").

Please note that in some countries MD may not be equivalent to a PhD but equivalent to Bachelor of Medicine or Bachelor of Surgery. Doctoral or equivalent level is designed primarily to lead to an **advanced research qualification**. For more details, please refer to UNESCO's International Standard Classification of Education (ISCED) (page 59).

<http://www.uis.unesco.org/Education/Documents/isced-2011-en.pdf>