

JOINT TRANSNATIONAL CALL FOR PROPOSALS (2020) FOR
“**MULTIDISCIPLINARY RESEARCH PROJECTS ON
PERSONALISED MEDICINE – PRE-/CLINICAL RESEARCH, BIG
DATA AND ICT, IMPLEMENTATION AND USER’S
PERSPECTIVE**”



(ERA Net Grant 779282)

CALL TEXT

IMPORTANT DEADLINES

SUBMISSION OF PRE-PROPOSALS: 5 March 2020 at 17:00 (CET)
SUBMISSION OF INVITED FULL-PROPOSALS: 15 June 2020 at 17:00 (CEST)

Link to electronic proposal submission:


<https://ptoutline.eu/app/erapermed2020>

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 person, based on his or her unique characteristics. Accordingly, PM puts the patient at the very centre of health care, aiming for an optimised management of a patient’s disease and/or predisposition to disease. Recent developments in areas such as diagnostic tests, medical imaging, biomarker monitoring to characterise patient phenotypes, omics technologies, interrogation of molecular pathways, lifestyle data, real-time monitoring of parameters associated with disease and compliance in taking medication and integration with smart information technology support this development.

Definition of Personalised Medicine:

ERA PerMed adheres to 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 this 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. They contribute to social cohesion, social justice, as well as to the systems 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,

¹ European Commission. Advice for 2016/2017 of the Horizon 2020 Advisory Group for Social Challenge 1, “Health, Demographic Change and Wellbeing”, July 2014: <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=15073&no=1>

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

while its implementation depends on the different countries and the respective structures and needs.

Current advances in the field of genomics and other omic disciplines, together with technological progress (such as high-performance computing), hold the promise of finally bringing PM into practice and applying preventive and predictive care models.

Besides the possibility of enhancing the lifespan of patients and increasing 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 and resources for healthcare 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. It requires truly multidisciplinary, cross-sectoral and transnational collaborations. To be successfully implemented, these approaches need to include strategies on how to better involve patients and citizens in all stages of the process, and on training the different key players and stakeholders needed for the implementation of PM approaches.

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, biostatistics, 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 co-funded by the European Commission. It aims to align regional and 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 (**ICPerMed**⁴), established in November 2016. The [Action Plan](#)⁵ 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 third **ERA PerMed** Joint Transnational Call (JTC2020) in order to fund international high-quality research projects in PM. The **Joint Call Secretariat (JCS)** will centrally coordinate this call for proposals.

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

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

- **Fund for Scientific Research – FNRS, (F.R.S.-FNRS), Belgium**
- **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**
- **Federal Ministry of Education and Research, (BMBF) / German Aerospace Center e.V. – Project Management Agency, (DLR), Germany**
- **Federal Ministry of Health, (BMG) / VDI/VDE Innovation + Technik GmbH, Programme Management Agency, (VDI/VDE-IT), 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**
- **Fondazione Regionale per la Ricerca Biomedica, (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 Secretariat for Science, Technology and Innovation of Panama (SENACYT), Panama**
- **National Centre for Research and Development, (NCBR), Poland**
- **Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI), Romania**
- **Ministry of Education, Science and Sport (MIZS), Slovenia**
- **Centro para el Desarrollo Tecnológico Industrial, E.P.E. (CDTI), Spain**
- **National Institute of Health Carlos III, (ISCIII), Spain**
- **The Scientific Foundation of the Spanish Association Against Cancer, (FCAECC), 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

16 December 2019	Publication of the call
16 December 2019	Opening of the submission system for pre-proposals
5 March 2020 (17:00, CET)	Deadline for pre-proposal submission
expected around 13 May 2020	Communication of the results of the pre-proposal assessment and invitation for full-proposal stage
15 June 2020 (17:00, CEST)	Deadline for full-proposal submission
Mid/end of August 2020	Rebuttal stage
September 2020	Peer Review Panel meeting and CSC meeting for funding recommendation to national funding agencies
Expected for October 2020	Communication of the funding decisions to the applicants
End of 2020, beginning of 2021	Expected project start (also subject to regional/national procedures)

3. AIM OF THE CALL

With its third 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, 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.

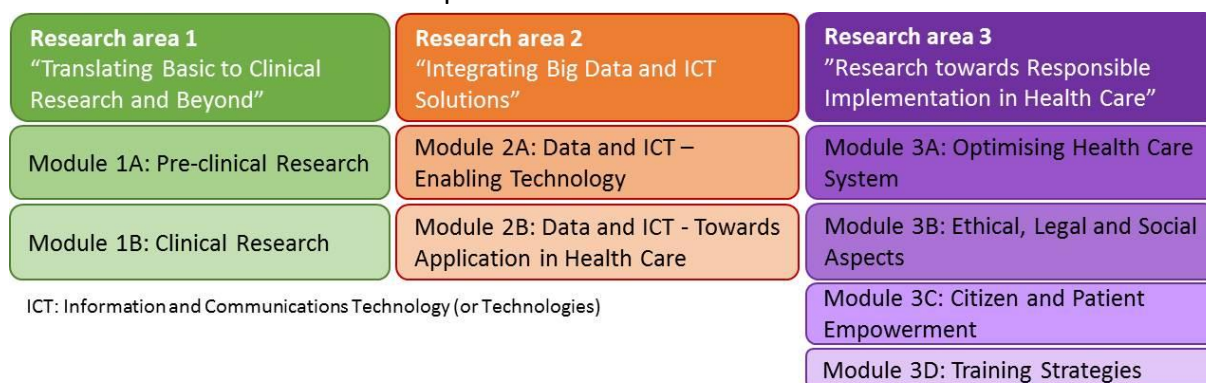
The overarching goal is to improve disease prevention and disease management, based on broader and more efficiently characterised and defined patient stratification, diagnostics and tailored treatment protocols. Early involvement of regulatory authorities and close interaction with the different key players along the value chain should be included right from the project development phase 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 proposed PM approach needs to be convincingly demonstrated. Moreover, proposals are expected to include research on ethical, legal and socio-economic implications, including health

economics and regulation, and/or research on the optimisation of health care systems. They may also consider patient and citizen empowerment and training strategies for the different stakeholders in PM.

The overall objectives of the call are to:

- Support **translational research projects** in the field of Personalised Medicine;
- Encourage and enable **interdisciplinary collaborations towards the implementation of PM**, combining pre-clinical and/or clinical research with bioinformatics components and research on relevant ethical, legal and social aspects and/or research on the optimisation of health care systems;
- 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.

The JTC2020 of **ERA PerMed** comprises three Research Areas:



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 proposals	Research Area 1 Module 1A or/and 1B	Research Area 2 Module 2A or/and 2B	Research Area 3 Module 3A or/and 3B or/and 3C or/and 3D
Eligible	X		X
Eligible		X	X
Eligible*	X	X	X
Not eligible	X	X	

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

Assessment of 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/other predictive tools to clinical application) but also vice versa by using, for example, existing clinical 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 and therapeutic targets (including omics and other data obtained, for example, by imaging, biomarker monitoring etc.) as well as diagnostic re-classification. This in turn will help to predict in advance how a patient will respond to a specific therapy.

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 robustness and reproducibility of results is strongly 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 *in silico* models, cell culture/co-culture, organoids and animal models, etc.
- Classification of diseases at the molecular level, which can be instrumental for successful implementation of PM, including pre-clinical studies for the 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 tools (e.g. imaging, physiological monitoring and omics) for diagnostics and integrated analytical methods, allowing the discovery of molecular characteristics involved in disease etiopathogenesis (including co-morbidities and sex-related differences), development and progression, and patient treatment including pharmacokinetics or pharmacodynamics.

- Development and evaluation of concepts for innovative clinical trial methodologies, suitable for PM approaches, taking into account the fact that more flexible and innovative trial design is needed, considering both health benefits and health economics (see also Module 3A). Development of novel strategies that will enable clinical scientists to speed up the transition from clinical observation to diagnostic development.
- Development of new concepts and stratification strategies in exploratory clinical studies (for further indications, see also the blue box on page 13/14).
- Clinical and omics data integration, use of machine learning technology to provide the basis for a more personalised treatment for patients.

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

Systematic integration of different bioinformatics resources (databases, algorithms, etc.), big data and ICT solutions should be an essential part of the research proposals submitted under this call wherever appropriate. The PM approaches to be developed 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 samples, as well as patient outcomes among different institutions while ensuring data security and data protection.

The re-use and sharing of data through public databases are encouraged and the re-use or combination of existing tools is also welcome. Applicants are asked to describe both new and existing tools, methodologies, technologies and digital support to be used in the project. This includes ICT solutions (e.g. eHealth and mHealth solutions, and telehealth) for the timely and safe collection and transfer of health information and to facilitate the use of already collected data, including electronic medical records (structured and unstructured sources), by respecting data security, protection and privacy on one hand, and ensuring interoperability, completeness, sufficient documentation and comparability of data on the other.

Outlining how ICT solutions developed/used in the project will be maintained after the end of the project is also encouraged.

Module 2A: Data and ICT – Enabling Technology

Scope

- Research on data harmonisation strategies and the development of ICT solutions to address research questions raised in the consortium, e.g. ICT solutions enabling the use of clinical data in research.

⁸ Information and communications technology (or technologies)

- Strategies for the development of common quality standards, semantics and minimal indicators, and metrics for data and metadata, and demonstration of utility of the strategy proposed in the research proposal.
- Development of computational (ICT) tools respecting interoperability of biomedical databases, the FAIR data principles as well as relevant regulations on data protection and security.
- Development of bioinformatics models/methods to integrate information into databases, and to analyse and extract this information, allowing, for example, the (automated or manually curated) integration and processing of data from unstructured sources and the combination of multiple data sources.
- Development of new devices/tools for data collection (e.g. mHealth, wearable devices for continuous online physiological monitoring, haptic devices, etc.) and measurement of patient compliance with therapy. This also includes procedures/algorithms for handling/integrating this data in an interoperable way.
- Development of platforms that will enable clinical scientists to speed up the transition from clinical observation to diagnostic development.

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

Scope

- Research on data integration and interpretation of diseases aimed at advancing PM. Demonstration of the potential clinical benefit of using and combining different kinds of datasets from various sources. These datasets can originate for example from large, multimodal and multi-centre public data repositories or clinical records from different sources. They can comprise data from multiple biological organisation levels or scales, e.g. behavioural, physiologic and molecular data. In addition, different forms of mathematical, statistical and modelling frameworks can be used for exploring and validating data quality and information content. This might include, for example, the development of standardised strategies for cross-validating biomarkers across existing databases.
- Development of innovative and easy-to-handle clinical decision support tools tailored to the needs of healthcare professionals. Such tools should provide reliable and accurate 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 innovative use and combination of already validated and novel eHealth and mHealth solutions, such as e.g. new 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 implementations in healthcare systems and practice are yet to be realized. Research is needed on 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 the 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 (including GDPR) and social aspects (ELSA) to consider, e.g. research on regulations in diagnostics, and drug development as well as on fundamental societal challenges and patient involvement.

Moreover, research is needed on all different steps of citizen and patient empowerment for PM approaches, from education up to engagement, and on training strategies for the various players involved in PM (e.g. patients and citizens, researchers, general practitioners and health care professionals, health care providers, pharmaceutical industry, etc.). While training in the form of a pilot study may be part of research proposals, the pilot has to be accompanied scientifically and must be evaluated during the project period in terms of its benefit.

These different cross-cutting topics should be addressed as early as possible during the development of PM strategies.

For proposals submitted to this call, it is mandatory to address at least one module of Research Area 3. The research conducted in Research Area 3 and the corresponding work package 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 or newly developed best practice and lessons learned in the light of sustainable solutions. Investigation of the social conditions, such as availability of insurance, employment, affordability of medical innovation (and other aspects such as demographic details, ethnic group, gender, quality of life, etc.), should also form part of this research.
- Research on the development, application, and adoption of new models and approaches for health care and their application/adaptation to healthcare systems in different regions/countries. This should lead to support models and tools (such as

pharmaco-economic assessment, clinical risk assessment and management, among others) that enable better diagnosis and care for the benefit of citizens and patients, based on available data and current clinical status.

- Research on health economic aspects of newly developed PM approaches, e.g. on the cost-effectiveness of these approaches for treatments, taking into account patient outcomes, quality of life and socioeconomic contexts. Research investigating whether a patient-centred, new PM approach requires refinement of – or even new – health economic and pharma-economic models, not only for the 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 identifying the different economic stakeholders (market players) and their economic strategies.
- Research on the provision of equal 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 the development of a new clinical trial design methodology for PM. Research on the refinement of existing guidelines and, where appropriate, the 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-centre clinical trials with study centres in several countries, including, for example, 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 – academic researchers from different disciplines, health care providers, industry/pharma and regulatory authorities, as well as citizens, patients and communities, regardless of their social, environmental and economic conditions).

- Research on responsibility and liability as well as challenges concerning our view on the nature of humans, humankind and 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 when artificial intelligence techniques are used: availability and suitability of data for training (machine learning algorithms), requirements on transparent and explainable 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, including all steps of the process, identification of research questions, study design, recruitment processes, data collection and analysis of results.
- Research on 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).
- Development of strategies for regulatory approval of clinical decision systems based on statistical learning, machine learning and artificial intelligence technologies.

Module 3C: Citizen and Patient Empowerment

- Research on effective tools to develop awareness of PM among citizens and patients. The aim is to empower citizens and patients with sufficient knowledge to enable their active involvement in PM-related issues and their personal care (including prevention, diagnosis, treatment and medication).
- Research and development of instruments to enable public engagement initiatives in PM, and the evaluation of their effectiveness, contribution and impact. This includes the development of adequate applications/interphases for data sharing and collection (mHealth, eHealth, data sharing, patient-reported outcome measures – PROMs, etc.).
- Research on post-marketing surveillance methodologies to assess patients' outcomes by integrating direct patient contribution and reporting (e.g. PROM) in this process.

Module 3D: Training Strategies

- Research on and assessment of training strategies and/or data sharing platforms to allow an adequate level of awareness and education of all different stakeholders in PM: citizens and patients, researchers, healthcare providers, industry, health insurers as well as regulatory authorities and future stakeholders (e.g. medical students). Reflections should take into account the needs/background of the different stakeholders.

- Research on the development and assessment of knowledge network tools and procedures (e.g. web-based and/or social media, network of patient academies, etc.) for enhancing health and digital literacy, in order to increase the ability and capacity of individuals and communities to obtain, comprehend and act upon basic health care information.
- Research on education and training strategies for citizens, patients and patient advocates, and on the involvement of patients and patient organisations across the entire research and development lifecycle of PM.
- Research on – and assessment of – training strategies needed for health care professionals/providers (HP) to increase their knowledge base and skills related to PM with regard to its future implementation. This includes different aspects, such as (A) training of HP in new diagnostic and treatment options, (B) how to deliver health-related information to the general public, (C) reporting on treatment experiences and outcomes to research and to the industry, etc.

Small-scale 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 patients for existing drugs, for example. 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 aims of the call.

ERA PerMed supports exploratory clinical studies that assess 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 the relevant 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, no part of the future study is being conducted on a smaller scale. Feasibility studies that are not pilot studies serve to estimate important parameters that are needed to design the main study.

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

required number of patients/individuals can be recruited in the defined period for the clinical exploratory study.

Please note:

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

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

Aspects to be considered during the construction of proposals

Proposals **must be interdisciplinary and clearly demonstrate the potential impact on PM** as well as **the added value of the transnational collaboration**: sharing of resources (registries, diagnoses, biobanks, models, databases, electronic health records, diagnostic and bioinformatics 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 a board range of relevant scientific disciplines and research areas, and have the 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 money, time, resources, technical feasibility, etc.).

Consultation prior to proposal submission with stakeholders relevant for a successful implementation into health care (e.g. regulatory authorities or health insurance providers) is recommended. The outcome of these discussions and their impact on the project's concept should 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. To address a module/research area adequately, there has to be a dedicated work package in the work

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

plan with a topic fitting to the module. In addition, the partner responsible for the respective work package needs to have the appropriate expertise. This is especially important for the mandatory research area 3. The fulfilment of these two points as well as 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 24: *“3. Quality and efficiency of the implementation”*). The integration of all three research areas (inclusion of at least one module from each research area) 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 or equivalent doctoral degree at least 2 and up to 10 years prior to the proposal submission deadline.

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, health care providers, 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 citizens.

Accordingly, 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 citizen/patient involvement may vary according to the context of the study proposed and regional/national regulations of participating funding organisations. *“Patient involvement”* represents one evaluation sub-criterion in *“2. Impact”, “c. Involvement of pertinent patient organisations, patient representatives (if available/applicable)”*.

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

- Providing a different perspective – consortia can benefit from the experiences of those who are using the service or living with a health condition;
- Encouraging the use of a 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 suitable 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, involving members of the public ensures that research considers broader principles of citizenship, accountability and transparency.

Inclusion of sex, gender analysis¹⁰ and/or underrepresented populations

Applicants are strongly encouraged to integrate sex and gender considerations as well as underrepresented populations, or underrepresented patient sub-groups (e.g. children or elderly) in proposals submitted to the **ERA PerMed** call. This includes not only the **sex distribution of research teams**, but also the **inclusion of sex and/or gender analysis in the research** itself. This applies especially when 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 23).

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) according to international state-of-the-art standards for data security (following the **FAIR principles¹¹**, the **General Data Protection Regulation¹²** and in accordance with **Ethical principles¹³ for data management**). 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 a corresponding budget should be allocated for this in the proposal's budget plan.

¹⁰ 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>

¹¹ http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

¹² <https://gdpr-info.eu/>

¹³ http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf,
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_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.
- At least **two partners** of the consortium must be **from two different EU Member States or Associated Countries**.
- 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.¹⁴
- **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 provided that they demonstrate, with the full-proposal submission, that their economic and human resources have already been secured and will be available at the start of the project. **No more than one partner with its own funding is allowed** in consortia with at least three partners eligible for funding.

¹⁴ **Widening concept:** Consortia are allowed to include in the full-proposal phase a new project partner that is eligible to receive funding from a funding organisation that is underrepresented in the first stage of the call and that agrees to participate in the widening option.

Joint research proposals may be submitted by applicants belonging to the following categories (subject to regional/national funding regulations; 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. SMEs¹⁵** (small and medium-sized enterprises).

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

¹⁵ https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

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 project partner has to be represented by **one principal investigator**. 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. Each consortium must nominate one **project coordinator** from among the project's principal investigators. The nomination 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 Committee¹⁶ (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.

Although proposals will be submitted jointly by research groups from several regions/countries, research groups will be funded by the respective funding organisation of the region/country from which they have applied. Applicants are therefore subject to the eligibility criteria of the respective funding organisations (see also Annex II and "Guidelines for Applicants"). They should therefore carefully read the funding rules and eligibility criteria of their 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.**

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 can apply for a redress procedure. 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.

¹⁶ Call Steering Committee: composed of a single representative from each country's/region's funding organisation.

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 and regional/national calls. Applicants shall avoid applying to different calls for same research activities. Double funding is not allowed.

B. FINANCIAL AND LEGAL ASPECTS

The maximum duration of the projects is three years in accordance with **ERA PerMed** funding organisation regulations. The studies performed 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 the 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. The document must be submitted to the JCS by the project coordinator by uploading it on the electronic submission system (<https://ptoutline.eu/app/erapermed2020>). 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).

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

Pre-proposals must be received by the JCS in electronic format no later than **5 March 2020 at 17:00 CET**.

The decision on which applicants are selected to submit a full-proposal will solely be communicated by the JCS to applicants as soon as possible around 13 May 2020. The JCS will send a full-proposal application template to the coordinators of those research proposals that are recommended for the full-proposal stage.

Full-proposals must be received by the JCS in electronic format no later than **15 June 2020 at 17:00 CEST**. Please note that **joint full-proposals will be accepted only from those applicants explicitly invited to submit by the JCS**. Full-proposals that do not use the respective template are ineligible.

In general, fundamental changes between the pre- and full-proposals concerning the composition of the consortia, objectives of the project or requested budget will not be accepted. The CSC may, however, allow such changes 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 funding organisation if they have any questions.

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

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 (permed@dlr.de). 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 with their regional/national rules.

Please note that if a proposal includes an ineligible partner, the whole proposal may be rejected without further review (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).

After passing the eligibility check (performed by the JCS and the participating funding agencies), pre-proposals will be sent to at least three reviewers for the 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 the evaluation criteria.

In addition, the reviewers will assess whether the projects described in the pre-proposal documents fit the scope of the call.

The CSC members will meet to decide which pre-proposals will be invited for full-proposal submission based on the reviewers' scores and 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 the proposal, and to reply to reviewers' questions. However, issues that are not related to 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 to 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, each as a whole, 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. Relevance of the concept for the advancement of PM;
- g. 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 in respect to the development of a personalised medicine;
- f. Consideration of sex aspects and underrepresented populations in research teams. Inclusion of sex and/or gender analysis, underrepresented populations, or specific sub-groups 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. Allocation of dedicated work packages in the work plan for each module/research area to be addressed. Appropriate expertise of the partner responsible for the respective work package;
- d. Balanced participation of project partners and integration of workload in the different work packages, quality and efficiency of the coordination and scientific management;
- e. Coherent integration of all kind of project partners (e.g. academia, clinical/public health sector, industry partner/SME) needed to successfully accomplish the proposed work;
- f. Scientific justification and adequateness of the requested budget (rational distribution of resources in relation to the project's activities, partner responsibilities and time frame);
- g. Risk assessment, regulatory and ethics issues properly addressed (when necessary);
- h. 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 that there is no conflict of interest concerning 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. After receiving the proposals, reviewers are bound to indicate

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; no complaints will be accepted or processed by the **ERA PerMed** consortium.

The project coordinator will be informed by the JCS of the 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 scientific project start date, which will be the reference date for the annual progress reports and final reporting. The scientific project start date must be stated in the Project Consortium Agreement (CA).

Project coordinators will be responsible for drafting the mandatory CA 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. The CA 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 scientific 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 the 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.

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>
Fund for Scientific Research – FNRS, (F.R.S.-FNRS)	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
Fonds de recherche du Québec - Santé, (FRQS)	CANADA QUEBEC	Maxime Beaudoin Tel: (+1) 514-873-2114 ext.1369 Maxime.beaudoin@frq.gouv.qc.ca
Ministry of Science and Education of the Republic of Croatia, (MSE)	CROATIA	Mateo A. Bosnić Tel: (+385) (1) 4594-166 MateoAnte.Bosnic@mzo.hr
Innovation Fund Denmark, (InnoFond)	DENMARK	Ejner Moltzen Tel: (+45) 31330306 Ejner.moltzen@innofond.dk Jens Peter Vittrup Tel: (+45) 61905023 Jens.peter.vittrup@innofond.dk
Academy of Scientific Research and Technology, (ASRT)	EGYPT	Dr. Amr Radwan Tel: (+20) 227920126 amm@sti.sci.eg ; innov@sti.sci.eg Salma Essawi Tel: (+20) 227920126 Sme@sti.sci.eg
Academy of Finland, (AKA)	FINLAND	Heikki Vilen Tel: (+358) (0)29 533 5135 heikki.vilen@aka.fi
Agence Nationale de la Recherche, (ANR)	FRANCE	Monika Frenzel Tel: (+33) (0) 1 73 54 83 32 Jeanne Guihot Tel: (+33) (0) 1 73 54 82 95 ERAPerMed@agencerecherche.fr
Federal Ministry of Education and Research, (BMBF) German Aerospace Center e.V. – Project Management Agency, (DLR)	GERMANY	Dr. Katja Kuhlmann Dr. Alexandra Becker Tel: (+49) 228 3821 2211 permed@dlr.de
Federal Ministry of Health, (BMG) VDI/VDE Innovation + Technik GmbH, Programme Management Agency	GERMANY	Dr. Sebastian Delbrück Tel: (+49) 30 310078 5765 Sebastian.Delbrueck@vdivde-it.de Dr. Anne Dwertmann Tel: (+49) 30 310078 427 Anne.Dwertmann@vdivde-it.de
Saxon State Ministry for Higher Education, Research and the Arts, (SMWK)	GERMANY (SACHSEN)	Dr. Eva Maria Stegemann Tel: (+49) 351 564 64270 Gabriele Süptitz

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
		Tel: (+49) 351 564 64210 permed@smwk.sachsen.de
General Secretariat for Research and Technology, (GSRT) Ministry of Development and Investments	GREECE	Georgia Kostopoulou Tel: (+30) 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 Louise Drudy Tel: (+353) 1234 5162 ldrudy@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. Monica Paganelli Directorate General for Health Research and Innovation Tel: (+39) 065994.2408 m.paganelli@sanita.it Dr. Maria Josè Ruiz Alvarez Tel: (+39) 065994.3214 mj.ruizalvarez-esterno@sanita.it
Fondazione Regionale per la Ricerca Biomedica, (FRRB)	ITALY (LOMBARDY)	Carmen De Francesco Tel: (+39) 02 6765 0170 Paola Bello Tel: (+39) 02 6765 0174 bandi@frrb.it
Tuscany Region, (TuscReg)	ITALY (TUSCANY)	Donatella Tanini Tel: (+39) (0) 55 43 83 256 Teresa Vieri Tel: (+39) (0)55 4383289 erapermed@regione.toscana.it
State Education Development Agency (VIAA)	LATVIA	Maija Bundule Tel: (+371) 67785423 Maija.Bundule@viaa.gov.lv Uldis Berkis Tel: (+371) 29472349 Uldis.Berkis@viaa.gov.lv
National Research Fund, (FNR)	LUXEMBOURG	Marie-Claude Marx Tel: (+352) 261925 – 21 marie-claude.marx@fnr.lu
The Research Council of Norway, (RCN)	NORWAY	Karianne Solaas Tel: (+47) 945 35 380 kso@rcn.no

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
<i>The National Secretariat for Science, Technology and Innovation of Panama (SENACYT)</i>	PANAMA	Carlos Aguirre (507) 517 0064 caguirre@senacyt.gob.pa
<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: (+40) (0) 21 302 38 84 cristina.cotet@uefiscdi.ro
<i>Ministry of Education, Science and Sport (MIZS)</i>	SLOVENIA	Dr. Eva Batista Eva.Batista@gov.si
<i>National Institute of Health Carlos III, (ISCIII)</i>	SPAIN	Mauricio Garcia-Franco Tel: (+34) 91 822 2885 Candi Sánchez Barco Tel: (+34) 91 822 2063 Cristina Nieto García eranetpm@isciii.es
<i>Centro para el Desarrollo Tecnológico Industrial, (CDTI)</i>	SPAIN	Héctor González Tel: (+34) 915810599 hector.gonzalez@cdti.es
<i>The Scientific Foundation of the Spanish Association Against Cancer, (FCAECC)</i>	SPAIN	Esther Aguilar Fadó Tel: (+34) 911111422 esther.aguilar@aecc.es 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 (NAVARRRE)	Sara Torres Tel: +34848427873 storresl@navarra.es
<i>Swedish Research Council, (SRC)</i>	SWEDEN	Johan Nilsson Tel: +46 (0)8 546 44 202 Johan.Nilsson@vr.se
<i>The Scientific and Technological Research Council of Turkey, (TUBITAK)</i>	TURKEY	Emine Derebay Yildiz Tel: +90 312 298 1195 emine.derebay@tubitak.gov.tr

ANNEX II. INDICATIVE FUNDING COMMITMENTS OF THE PARTICIPATING ORGANISATIONS OF THE ERA PERMED JTC 2020 (THIS TABLE IS MEANT FOR A FIRST OVERVIEW ONLY. PLEASE REFER TO THE REGIONAL/NATIONAL GUIDELINES FOR DETAILS.)

Participant organisation	Country / Region	Funding academic or clinical partner*	Funding private partners*	Funding of call topic research area								Tentative budget (M€ for 3 years)	Envisaged number fundable teams
				area 1		area 2		area 3					
				1A	1B	2A	2B	3A	3B	3C	3D		
F.R.S.-FNRS	BELGIUM	✓	✗	✓	✗	✓	✗	✓	✓	✗	✗	0.2	1
FRQS	CANADA (QUEBEC)	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	0.36	1
MSE	CROATIA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.12	1
InnoFond	DENMARK	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1.0	3-4
ASRT	EGYPT	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	0.3	3-5
AKA	FINLAND	✓	✗	✓	✓	✓	✓	✓	✓	✗	✗	1.5	3-5
ANR	FRANCE	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	2.5	~10
BMBF DLR	GERMANY	✓	✓	✓	✗	✓	✓	✗	✓	✗	✗	3 [modules 1A, 2A; 2B] 1.5 [module 3B]	10 [modules 1A, 2A; 2B] 5 [module 3B]
BMG VDI/VDE-IT	GERMANY	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	1.5	~5
SMWK	GERMANY (SAXONY)	✓[Academia]	✓ [possible with restrictions, please contact SMWK for consultation]	✓	✓	✓	✓	✓	✓	✓	✓	2.0	3-5
GSRT**	GREECE	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	1,5	6-7

Participant organisation	Country / Region	Funding academic or clinical partner*	Funding private partners*	Funding of call topic research area								Tentative budget (M€ for 3 years)	Envisaged number fundable teams
				area 1		area 2		area 3					
				1A	1B	2A	2B	3A	3B	3C	3D		
NKFIH	HUNGARY	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.3	2-3
HRB	IRELAND	✓	✗	✓	✓	✗	✓	✓	✓	✓	✓	0.37	1-2
CSO-MOH	ISRAEL	✓	✗	✓	✓	✗	✓	✓	✓	✗	✗	0.3	2
IT-MoH	ITALY	✓ [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)]	✗	✓	✓	✓	✓	✓	✓	✓	✓	1.5	7-8
FRRB	ITALY (LOMBARDY)	✓[Universities and research centers are eligible ONLY in partnership with IRCCS – public or private - and ASST]	✗	✓	✓	✓	✓	✗	✗	✗	✗	1	2-3
TuscReg	ITALY (TUSCANY)	✓ [Tuscany Healthcare Service-SST (Local Health Authorities, University Hospitals, Fondazione Toscana Gabriele Monasterio and ISPRO. Tuscany Universities and other	✓[[private non for profit research organisations]	✓	✓	✓	✓	✓	✓	✓	✓	0.5	2-4

Participant organisation	Country / Region	Funding academic or clinical partner*	Funding private partners*	Funding of call topic research area								Tentative budget (M€ for 3 years)	Envisaged number fundable teams
				area 1		area 2		area 3					
				1A	1B	2A	2B	3A	3B	3C	3D		
		research institutes are eligible ONLY in partnership with the former.]											
VIAA	LATVIA	✓ [Clinical as enterprises, academic as scientific institutions]	✓ [Only enterprises – see eligibility rules]	✓	✓	✓	✓	✓	✓	✗	✗	0,42	2
FNR	LUXEMBOURG	✓ [under the conditions specified in the FNR eligibility rules]	✗	✓	✓	✓	✓	✓	✓	✓	✓	0.3	1-2
RCN	NORWAY	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	0.8	2-3
SENACYT	PANAMA	✓	✗	✓	✓	✗	✓	✓	✗	✓	✓	0.3	1-2
NCBR	POLAND	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	0.6	1-3
UEFISCDI	ROMANIA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.5	1-2
MIZS	SLOVENIA	✓ [if research organisations registered in SICRIS, performing non-economic activity]	✓ [if research organisations registered in SICRIS, performing non-economic activity]	✓	✓	✓	✓	✓	✓	✓	✓	0.42	1-2 funded proposals
CDTI	SPAIN	✗	✓ [For Profit]	✓	✓	✓	✓	✗	✗	✗	✗	0.5	3-5
ISCIII	SPAIN	✓	✓ if it is Non Profit. ✗ if it is For Profit.	✓	✓	✓	✓	✓	✓	✓	✗	0.5	3-5
FCAECC	SPAIN	✓	✓ if it is Non Profit.	✓	✓	✓	✓	✓	✓	✗	✗	0.4	2-3

Participant organisation	Country / Region	Funding academic or clinical partner*	Funding private partners*	Funding of call topic research area								Tentative budget (M€ for 3 years)	Envisaged number fundable teams
				area 1		area 2		area 3					
				1A	1B	2A	2B	3A	3B	3C	3D		
			✗ if it is For Profit.										
DS-CAT	SPAIN (CATALONIA)	✓	✓ if it is Non Profit Research Organisations. ✗ if it is For Profit.	✓	✓	✓	✓	✗	✗	✗	✗	0.5	2
GN	SPAIN (NAVARRE)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.5	1-2
SRC	SWEDEN	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	1.4	3-5
TUBITAK	TURKEY	✓	✓	✓	✓	✗	✓	✗	✓	✗	✓	0.35	2-3

* 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”.

** For Greek partners the project duration is limited to 24 months (see “Guidelines for Applicants”).

