

JOINT TRANSNATIONAL CALL FOR PROPOSALS (2022) FOR

“PREVENTION IN PERSONALISED MEDICINE”

 ERA PerMed

(ERA Net Grant 779282)

CALL TEXT

IMPORTANT DEADLINES

SUBMISSION OF PRE-PROPOSALS: 17 February 2022 at 17:00 (CET)
SUBMISSION OF INVITED FULL-PROPOSALS: 14 June 2022 at 17:00 (CEST)

Link to the electronic proposal submission tool:

<https://ptoutline.eu/app/erapermed2022>

ERA PERMED JOINT CALL SECRETARIAT

The JCS is hosted jointly by the French National Research Agency (ANR)

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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 the prevention, diagnosis and treatment of disease for each person, based on his or her unique biological characteristics. Accordingly, PM puts the patient at the very centre of healthcare, aiming for optimised management of a patient’s disease and/or predisposition to disease. Recent developments in many areas support and allow the shift towards PM implementation such as more specific diagnostic tests, medical imaging, biomarker monitoring to characterise patient phenotypes, omics technologies, data mining, investigation of molecular pathways, availability of exposome, lifestyle and environmental data, and information on the patient response to therapy, microbiome characterisation, real-time monitoring of parameters associated with disease-host interaction, adherence to medication and the integration of smart information technology.

The above-mentioned developments and identification of dedicated biomarkers offer considerable potential from the prevention perspective. Targeted preventive strategies could decrease the rate of incidence, prompt early detection to increase the efficacy of preventive therapies and prevent disease recurrence and improve patient care and quality of life, by avoiding overmedication and non-essential interventions at the same time.

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 2018–2020 Advice 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.”

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

The healthcare systems of the European Union represent the core of the European social protection system. In view of the existing health inequalities across countries and regions, as well as across socio-economic groups, European healthcare systems contribute to social cohesion and social justice. 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, while its implementation depends on the different regions and countries, and the respective structures and needs.

Current advances in the field of genomics and other omics approaches, together with technological progress, hold the key to finally bringing PM into practice and applying preventive and predictive care models. However, adapted frameworks are still needed for the large-scale implementation of PM approaches. Common and shared quality criteria for public databases, for example, should be developed, as the application of preventive and predictive care models relies on sound data. A European joint ethical framework is needed to implement PM and to process, use and exchange personal data.

Apart from potentially extending patient lifespan and increasing the quality of clinical practice through more targeted diagnostics and therapies, long-term PM improvements may also lead to a more efficient use of costs and resources for healthcare systems through early detection, prevention, accurate risk assessment and effective delivery of care.

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.

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

To be successfully implemented, these approaches need to include strategies on how to better involve patients and citizens in all stages of the process, in shared decision-making processes, and in training the various key contributors and stakeholders needed to implement PM approaches.

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 and to foster cooperation between the various contributors in PM. In this way, it seeks to promote excellence, improve the competitiveness of European contributors to PM and enhance European collaboration with non-EU countries.

³ For more information, please visit the ERA PerMed website: <https://erapermed.isciii.es/>

ERA PerMed is closely linked to the International Consortium for Personalised Medicine (**ICPerMed**⁴), established in November 2016. The **ICPerMed Action Plan**⁵ builds on the Strategic Research and Innovation Agenda (SRIA) “Shaping Europe's Vision for Personalised Medicine”⁶ developed by PerMed in 2015. **ERA PerMed** fosters 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 fifth **ERA PerMed JTC2022** 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 organisations in their respective regions/countries:

- **Austrian Science Fund, (FWF), Austria**
- **Fund for Scientific Research – FNRS, (F.R.S.-FNRS), Wallonia-Brussels Federation (Belgium)**
- **Brazilian National Council of State Funding Agencies, (CONFAP), Brazil**
- **Quebec Health Research Funds, (FRQS), Quebec (Canada)**
- **Agencia Nacional de Investigación y Desarrollo, (ANID), Chile**
- **Ministry of Science and Education of the Republic of Croatia, (MSE), Croatia**
- **Innovation Fund Denmark, (InnoFond), Denmark**
- **Estonian Research Council, (ETAg), Estonia**
- **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) / German Aerospace Center e.V. – Project Management Agency, (DLR), Germany**
- **Saxon State Ministry for Science, Culture and Tourism, (SMWK), Saxony (Germany)**
- **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)**
- **Latvian Council of Science, (LZP), Latvia**
- **Research Council of Lithuania, (LMT), Lithuania**
- **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**
- **Ministry of Education, Science and Sport, (MIZS), Slovenia**

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: https://www.icpermed.eu/media/content/PerMed_SRIA.pdf

- South African Medical Research Council, (SAMRC), South Africa
- 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)
- Sweden’s Innovation Agency, (VINNOVA), Sweden
- Ministry of Science and Technology, (MOST), Taiwan
- The Scientific and Technological Research Council of Turkey, (TUBITAK), Turkey

2. TIMELINE OF THE CALL

01 December, 2021	Publication of the call
01 December, 2021	Opening of the pre-proposals submission system
17 February, 2022 (17:00, CET)	Deadline for pre-proposal submission
Expected around 11 May, 2022	Communication of the results of the pre-proposal assessment and invitation to the full-proposal stage
14 June, 2022 (17:00, CEST)	Deadline for full-proposal submission
Mid/end of August 2022	Rebuttal stage
September 2022	Peer Review Panel (PRP) meeting and Call Steering Committee (CSC) meeting for funding recommendation to national funding agencies
Expected for October 2022	Communication of the funding decisions to the applicants
End of 2022, beginning of 2023	Expected project start (according to regional/national funding regulations)

3. AIM OF THE CALL

Through its fifth transnational call (non-cofunded by the EC), **ERA PerMed** aims to foster research on prevention in personalised medicine. Personalised prevention or targeted/tailored prevention considers both individual susceptibility to the risk of disease (e.g. depending on the genomic, environmental background or lifestyle) and its perceived value and benefit (cultural and social factors). Important components of prevention in personalised medicine also include the 1) integration of the patients and citizen’s needs, connected to autonomous decision-making, as a factor in the future up-take of preventive interventions by society, and 2) education and reimbursement strategies to allow equal access.

Taking this into account, proposals submitted to the JTC2022 must go beyond generic health promotion research applicable to society as a whole. Research proposals must include

individual risk assessment and strategies to develop tailored interventions in prevention for healthy individuals, individuals at-risk, individual patient groups or sub/populations.

The overarching goal of this call is the development of tailor-made strategies for the prevention of disease and disease progression, at three different levels: i) preventive measures to decrease the rate of incidence (primary prevention), ii) early detection to increase the efficacy of a preventive therapy, even before symptoms develop (secondary prevention), and iii) interventions to prevent disease recurrence or to improve patient care and quality of life (tertiary prevention). Research on prevention from over-treatment or overmedicalisation in primary, secondary and tertiary personalised preventive approaches is optional and could be part of research proposals, if applicable. For more detailed information about the type of studies expected to be submitted to the JTC2022, please see pages 14-15.

As personalised medicine is non-disease-specific, but rather an overall approach that can be adopted and adapted to a multiplicity of medical conditions, research projects in every disease entity are encouraged.

The clinical relevance of the proposed PM approach needs to be convincingly demonstrated. Moreover, proposals must combine pre-clinical or clinical research with research on data and information and communication technology (ICT) as well as research on ethical, legal and social aspects (ELSA) or health economics/implementation support. **ERA PerMed** fosters research and innovation activities that build close linkages between the afore-mentioned research areas. This implies a wide range of multidisciplinary activities brought together by different stakeholders from academia, clinical/public health research and private partners such as small and medium-sized enterprises (SMEs), policy makers, regulatory/health technology assessment (HTA) agencies and patients/patient organisations. The involvement of partners with the respective expertise in the consortium is required.

The early involvement of regulatory authorities and close interaction with the different key contributors along the value chain should be included right from the project development phase to bridge the gap between first discoveries or inventions and their implementation.

The overall objectives of the call are to:

- Support **translational and transnational research projects** in the field of PM;
- Encourage and enable **interdisciplinary collaborations towards the implementation of PM**, combining pre-clinical or clinical research with bio-informatics components as well as ELSA research or implementation research, including health economics;
- Encourage **collaboration between academia** (research teams from universities, higher education institutions, public research institutions, research centres), **clinical/public health research** (research teams from hospital/ public health, healthcare settings and other healthcare 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 JTC2022 is constructed around the following three research areas in order to ensure the development of specific PM approaches considering the major aspects needed for their successful implementation in the health systems: (1) **“Translating Basic to Clinical Research and Beyond”**, (2) **“Data and Information and Communication Technology (ICT)”** and (3) **“Responsible and Effective Implementation in Healthcare”**. Each proposal **MUST address at least one module out of each research area:**

Research area 1 “Translating Basic to Clinical Research and Beyond”	Research area 2 “Data and ICT”	Research area 3 “Responsible and Effective Implementation in Healthcare”
Module 1A: Pre-clinical Research	Module 2A: Enabling Technology	Module 3A: Health Economics and Implementation Support
Module 1B: Clinical Research	Module 2B: Towards Application in Healthcare	Module 3B: Ethical, Legal and Social Aspects

ICT: Information and Communications Technology (or Technologies)

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”.*

Improving bi-directional exchange between basic and clinical research to facilitate the transition from bench to bedside. This could be achieved not only by translating basic science research to clinical applications with appropriate models and strategies but also by using existing population and clinical databases and repositories to generate new hypotheses and paradigms, by sharing experiences obtained in conventional and innovative populations and clinical studies. Appropriate validation strategies should be described depending on the translational gap to be bridged.

Research area 1 includes research on the application and validation of newly discovered or known biomarkers for risk assessment or early detection, targeted therapies in clinical practice, and diagnostic and clinical decision support tools. Examples of research on therapeutic targets (e.g. data obtained by omics approaches, dynamic simulations, imaging, biomarker monitoring, etc.) include risk stratification to predict patient response prior to therapy or to adapt ongoing preventive therapy.

Applications submitted to this call should include a description of how investigators will ensure the robustness and reproducibility of results. Research proposals should outline how implementation of the tailor-made preventive approach and research findings will be transformed into clinical practice and address regulatory questions regarding implementation. To foster the integration of patients’ needs, studies could include approaches for the validation of research results by experiences provided by patient representatives.

It is highly recommended, whenever applicable, to build on existing repositories of biological and bio-molecular resources and related samples exchanges in order to increase the feasibility

of completing the study within the three-year project funding period. Sample collection during the course of the project is permissible, e.g. to add value to existing biobanks, to collect samples through studies with a short time frame or to measure new/novel biomarkers.

Module 1A: Pre-clinical Research

Scope

- Characterisation of the role of biomarkers in predictive medicine for tailor-made prevention strategies, risk assessment and management of diseases in pre-clinical models (in terms of reproducibility, safety and efficiency) and the validation of biomarkers (in respect to validity and reliability).
- Development and implementation of high-throughput pre-clinical predictive models for (A) validation of data and hypotheses from human population, clinical, molecular and genomics studies or (B) prediction of clinical outcome (including rare or late clinical events) or (C) tailored prevention strategies and risk assessment or (D) selection of appropriate drugs/drug combinations and drug doses/dosage regimens. This may include *in silico* models, cell culture/co-culture, organoids and animal models, etc. or a combination thereof.
- Classification of diseases (molecular level, imaging, etc.), which can be instrumental for supporting successful clinical implementation of PM, including pre-clinical studies for the validation of biomarkers that can be used in early and accurate diagnosis, prognosis and prediction of a disease risk.

Module 1B: Clinical Research

Scope

- Improvement, validation and combination of analytical tools and methods (e.g. imaging, physiological monitoring, omics or other biomarkers) for diagnostics/screening (specific risk factors) and treatment (predictive outcome, including pharmacogenomics/pharmacogenetics). Use of integrated analytical methods, allowing the discovery and validation of molecular and environmental factors (including co-morbidities, ethnic and sex-related differences) for tailored risk assessment, early detection and targeted therapies. Risk assessment could include different levels, e.g. risk of developing a disease or risk of disabilities.
- Risk stratification for personalised screening to improve the benefit/prognosis especially for individuals at high-risk and reduce potential screening-related injury.
- Pilot pharmacokinetics or pharmacodynamic studies in preparation for clinical trials.
- Development and evaluation of concepts for innovative clinical trial methodologies, suitable for PM approaches in prevention, given that more flexible and innovative trial design is needed, considering both health benefits and health economics (see also

research area 3). Development of novel strategies to accelerate the transition from clinical observation to diagnostic development.

- Research on complex interventions or methods for evaluating complex interventions.
- Development of new concepts and stratification strategies in exploratory clinical studies (for further information, see also the blue box on page 14).
- Research on tailored prevention for patients with co/multimorbidity.

Research Area 2: *“Big Data and ICT⁸”.*

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. The PM approaches to be developed should support the easy flow, robust analysis and interpretation of information about an individual. Examples include clinical data (i.e. performed as part of an individual’s medical care strategy) such as imaging, comorbidities, laboratory values, patient reported outcomes such as quality of life surveys, and pathology and genetic results as well as non-clinical data (i.e. collected for research purposes or outside the healthcare system). Examples of non-clinical data include omics or other data on biological samples, and participant-generated health data including survey results or physiologic monitoring output from wearables, such as activity trackers. It will be important to describe the state of the data (structured vs. unstructured) as well as the location and type of data to be used. Developed approaches should have the potential to be translated to large cohorts (different genetic/omic background, including ethnic minorities, for instance).

The re-use and sharing of data through public databases are highly encouraged and the re-use or combination of existing tools is also welcome. Data collection during the course of the project is permissible, e.g. to add value to existing databases, to collect data through studies with a short time frame or to evaluate developed applications/tools.

Applicants must clearly describe all tools, technologies, and digital supports to be used in the project, as well as the methodological approach. This includes ICT-related activities supporting eHealth (such as telehealth) and mHealth. In addition, descriptions should be included of how data from different sources (such as different institutions) will be combined, how different data streams will be merged and how the primary outcomes will be meaningful across different institutions.

Data security is paramount in these types of studies. Applicants need to clearly describe the databases and the type of data, how data will be accessed, transferred, and stored to enable timely and safe data access and analysis. Data security, protection and privacy are of the utmost importance with health-related data and relevant steps being fully addressed whilst ensuring interoperability, completeness, and comparability of data.

It will also be important to outline how the ICT solutions/decision support tools developed/used in the study will be maintained after the project has ended and how data,

⁸ Information and communications technology (or technologies)

tools, code and algorithms generated and used in the study will be stored and made available or communicated to the wider research community during and after the project.

Module 2A: Enabling Technology

Scope

- Research on data harmonisation strategies and the development of ICT solutions to address research questions, e.g. ICT solutions enabling the use and combination of clinical and lifestyle data in research.
- Strategies for the development of common quality standards, semantics and minimal indicators, metrics for data and metadata, and demonstration of the utility of the strategy proposed in the research proposal.
- Development of computational (ICT) tools respecting interoperability of biomedical databases and clinical IT systems, the FAIR⁹ 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 to provide the basis for prevention, including personalised risk assessment, early detection and targeted and effective therapies as well as assessment of specific treatment response. The bioinformatic models/methods should allow, for example, the (automated or manually curated) integration and processing of data from unstructured sources and the combination of multiple data sources, e.g. of clinical, omics, environmental and lifestyle data but also of family history.
- Development of new devices/tools for data collection (e.g. mHealth, wearable devices for continuous online physiological monitoring, haptic devices, etc.) and measurement of individual risk factors or patient adherence with preventive measures or therapy to improve tailored prevention, diagnosis, treatment, monitoring and management of health-related issues and lifestyle-habits that impact health. This also includes procedures/algorithms for handling/integrating this data in an interoperable way.
- Development and application of clinical decision support tools using statistical and systems biology approaches (e.g. artificial intelligence and machine learning technologies).
- Development of platforms that will enable clinical scientists to speed up the transition from clinical observation to diagnostic development.

⁹ Findable, accessible, interoperable and reusable (FAIR):
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

Module 2B: Towards Application in Healthcare

Scope

- Analysing large, multimodal datasets (“big data”) with artificial intelligence, machine learning and statistical approaches to enable a new understanding of disease mechanisms and to predict individual disease risk, adverse events, or specific outcomes. These risk stratification analyses could also support efforts to develop early diagnostics, biomarker validation or therapeutic interventions for specific subgroups. Additionally, research on health data integration and interpretation to support combining different kinds of datasets from various sources is encouraged. These datasets can originate from large, multimodal and multi-centre public data repositories or clinical records from different sources, for example. They can comprise data from multiple biological organisation levels or scales, for instance, behavioural, physiologic, molecular, or imaging data. 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 new, or validation and improvement of existing, innovative, simple, and dynamic prevention-focused clinical decision support tools tailored to the needs of healthcare professionals. Such tools should provide reliable and accurate algorithmic interpretation of complex multifactorial and multimodal data (e.g. clinically validated data and information on current diagnosis and treatment options). The tools should allow the integration of new research outcomes (e.g. genomics information) as well as changes to the individual’s environment and lifestyle risk factors (including family disease history) in real time.
- Development of good practices for sample and data management and analyses in compliance with FAIR principles and General Data Protection Regulation (GDPR) as well as local jurisdiction. Development of core standards and joint working practices or application of pre-existing standards for storage, accessibility, interoperability and reusability for samples and data. Development or use of approaches that allow sample analysis within local jurisdictions and cross-border data analysis through the application of coordinated iteration.
- Development of approaches for innovative use and combination of validated eHealth and mHealth technologies. For example, new physiological sensors or combining patient monitoring devices with mHealth devices for real-time personalised feedback.
- Research on the development of innovative telemedicine applications in different healthcare systems to complement direct contact between healthcare personnel, citizens and patients. This can be beneficial, for example, if there is a high risk of infection or for patients with limited mobility living in rural areas. Telemedicine approaches could also be used to facilitate exchange between physicians in highly specialised centres and those in a more general healthcare setting.

Research Area 3: “Responsible and Effective Implementation in Healthcare”.

Research on ethical, legal and social aspects (ELSA) of PM, for example in the context of fair access to new or often expensive diagnostic tools for prevention and therapies or availability of decision support tools for healthcare providers. This could include research aiming to avoid bias due to automated decision support tools, research on suitable regulatory approaches for diagnostics and development of tailored prevention strategies as well as fundamental societal challenges and the integration of the patient’s and citizen’s needs, connected to autonomous decision-making.

Research on aspects of health economics, e.g. on health economic modelling for assessing cost-effectiveness or socioeconomic aspects of tailor-made preventive approaches. New methods, models and tools to enable accurate health economic assessment of PM approaches can also be developed.

The studies conducted in research area 3 and the corresponding work package should relate directly to the research question(s) addressed in research areas 1 and 2.

Module 3A: Health Economic and Implementation Support**Scope**

- Health economic modelling of tailor-made prevention, e.g. demonstrating the cost-effectiveness of PM approaches for risk stratification, diagnosis or preventive therapies, prophylactic medications or interventions. This should consider patient outcomes, quality of life, patient preferences and socioeconomic contexts as well as healthcare settings.
- Research investigating whether a patient-centred PM approach in prevention requires refinement of – or even new – health economic and pharma-economic models, including the development of concepts for/conceptualisation of such models.
- Research on the economic impact (for the individual or the healthcare system) of improved health information available to citizens and patients as a result of a PM approach.
- Development of resource tools that enable healthcare commissioners to assess the benefits of incorporating a new PM approach, for instance through improved efficiencies or cost savings.
- Implementation support to demonstrate how the PM approach can be incorporated into clinical practice. This could, for example, include resources needed for service reconfiguration, health counselling or upskilling of practitioners.

Module 3B: Ethical, Legal and Social Aspects**Scope**

- Research on the use of tailored prevention approaches and stratification of the healthy society/population, fair and equal access to these interventions for all citizens and patients regardless of economic, educational or geographic status, including research on the impact on social inequalities and reflections on interventions for individuals at low and high risk.
- Research on the acceptance of the public, health professionals and policy makers for access to preventive screening, e.g. for individuals at high or low risk, based on tailored risk stratification (e.g. based on genetic profiling).
- Right to know/not to know and sharing of research findings: balance between citizens' and patients' rights and research needs.
- Research on therapeutic education of citizens and patients, e.g. individual levels of risk awareness and follow-up of health recommendations in relation to the free choice of lifestyle and informed decision making.
- Research on the role of genetic testing in clinical practice, the clinical interpretation of test results and on the potential clinical, ethical as well as legal consequences in the context of PM and particularly tailored prevention (including security and use of data).
- Research on advantages and disadvantages of genetic engineering (gene transfer technology).
- Research on how to overcome potentially biased datasets lacking (sample) heterogeneity of information (e.g. gender, mixed and diverse populations, different cultural perspectives, social inequalities, etc.). This can also include reflections on defining norms within stratification and decision support tools (definition on what is meant by a "normal/healthy" status).
- Research on how to enable stakeholder exchange and collaboration (including all different key contributors – academic researchers from different disciplines, healthcare providers, industry/pharma and regulatory authorities as well as citizens, patient representatives and communities, regardless of their social, environmental and economic conditions) in the development of tailored prevention approaches from study onset.
- Development of strategies for regulatory approval of clinical decision systems for prevention, based on statistical learning, machine learning and artificial intelligence technologies.
- Research on ethical, legal and social aspects, when using automated support tools: 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, privacy and personal data issues, obligation of information towards patients.

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.

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 terms of the relevant respects, including assessment of primary outcome.
- **Feasibility studies that are not pilot studies**, such as those in which the investigators attempt to answer a question as to 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 the form for “Exploratory Clinical Studies”, duly completed and appended (template available on the [ERA PerMed website](#)). Investigators must demonstrate that the required number of patients/individuals can be enrolled in the set period for the clinical exploratory study.

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.**

Please note:

Funded Technology Readiness Levels (TRL)¹⁰ 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”).

¹⁰ 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

Therefore, applicants are strongly advised to contact their relevant funding organisation (see also Annex 1) and to carefully read the regional/national eligibility rules (“Guidelines for Applicants”, Annex 2) prior to submission.

Aspects to be considered during the construction of proposals

Research proposals must include individual measurements, individual risk assessment and strategies to design tailored, preventive interventions for healthy individuals, individuals at-risk, individual patient groups or sub/populations. Studies have to go beyond generic health promotion research and the improvement of public health practices applicable for society as a whole. **The following types of studies are outside the scope of the JTC2022:**

- Studies on cohorts of citizens/patients exclusively based on health behaviour data.
- Long-term behavioural studies (extending beyond 3 years).
- Studies aiming to improve public health practices and contributing to generalisable knowledge, including studies on maintaining/enhancing health in healthy groups based solely on lifestyle information.
- Studies that are not performed by a truly multidisciplinary consortium with expertise in all three research areas and the respective modules chosen.

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 broad range of relevant scientific disciplines and research areas, and have the necessary expertise to achieve the proposed objectives. The individual project partners of the joint applications should complement each other. The proposed work should contain novel, innovative, ambitious ideas and promote innovative PM solutions moving from scientific value to patient benefits (including analyses of applicability to medical care in terms of money, time, resources and technical feasibility, etc.).

Consultation prior to proposal submission with stakeholders relevant for a successful implementation into healthcare (e.g. regulatory authorities or health insurance providers) is recommended. The outcome of these discussions and their impact on the overall project 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 plan with a topic fitting to the module. In addition, the partner responsible for the respective

work package needs to have the appropriate expertise. The fulfilment of these two requirements coupled with 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 25: “3. Quality and efficiency of the implementation”).

It is mandatory to integrate as principal investigator at least one early-career researcher (ECR) in a consortium. For ERA PerMed’s definition of ECR, please consult Annex III. Individual regional/national funding regulations might apply (see also Annex II and “Guidelines for Applicants”).

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, healthcare providers, health and social care service users 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 depending on the context of the study proposed and the regional/national regulations of participating funding organisations.

Patient organisations can be included in consortia as partners (on own funding or funded, if eligible according to regional/national funding regulations).

The involvement of patient organisations in research proposals submitted to this call is part of the evaluation: “2. Impact: c. *Involvement of pertinent patient organisations (if available/applicable)*” and “3. Quality and efficiency of the implementation: e. *Coherent integration of all kind of project partners (e.g. academia, clinical/public health sector, industry partners/SME, patient organisation) needed to successfully accomplish the proposed work*”.

Involving members of the public in research projects from the onset 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 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/recruitment of potential participants in research by making the research more comprehensive and therefore acceptable;

- Helping to improve patient adherence to a therapy by evaluating barriers to and strategies for medication adherence and predictors of adherence.

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

Inclusion of sex, gender analysis¹¹ or underrepresented populations

Applicants are strongly encouraged to integrate sex and gender considerations as well as underrepresented populations (e.g. ethnic minorities), 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 *per-se***. 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 or when its findings may affect individuals or groups.

The inclusion of gender or sex or underrepresented populations 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 25).

Scientific Data Open Access Policy

Proposals should explain how the data, tools, code or algorithms 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 principles¹²**, the **General Data Protection Regulation (GDPR)¹³** and in accordance with **Ethical principles¹⁴ for data management**]. The DMP represents an essential document for the implementation of the research, as it helps to define the responsibilities of research data management ahead of the start of the project. The 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.

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>. Please consider also the work of the European Commission on gender equality in research: <https://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=gender>.

¹² findable, accessible, interoperable and reusable (FAIR):

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

¹³ <https://gdpr-info.eu/>

¹⁴ 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

Compliance with the DMP must be reported in each annual scientific project progress report. Publication of the 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.

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 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** out of a minimum of three eligible project partners in 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 including one partner from an underrepresented country.** A list of underrepresented countries will be provided to coordinators invited to submit full-proposals.¹⁵
- **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 who 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 own funding is allowed** in the consortia with at least three partners eligible for funding.
- It is mandatory to **integrate at least one early-career researcher (ECR) as principal investigator in a consortium**. For the ERA PerMeds definition of ECR, please consult

¹⁵ **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.

Annex III. Individual regional/national funding regulations might apply (see also Annex II and “Guidelines for Applicants”).

- **Exception: To facilitate the integration of patient organisations in consortia, they can be added to a consortium as additional partners at the pre-proposal stage or the full-proposal stage. The consortia must follow all of the above-mentioned rules regarding the consortia composition without counting the patient organisations. The latter can be added as additional partners either on own funds or by applying for funding, if eligible, from the respective funding organisations. Please note that not more than two consortium partners per country can request funding, including patient organisations. An exception is possible in countries with more than one funding organisation: in these countries, three partners from the same country may apply for funding, if one of them is a patient organisation and at least one of them is requesting funding to a regional funding organisation. All other rules continue to apply.**

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 healthcare settings and health organisations). Participation of clinicians (e.g. medical doctors, nurses) in the research teams is encouraged;
- C. Private for-profit (industry) partners, e.g. SME¹⁶** (small and medium-sized enterprises) **and private non-profit partners, e.g. foundations, associations or non-governmental organisations.**

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 nature 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) or not-for-profit organisations 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

¹⁶ https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

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 note that **no more than one partner with own funding** is allowed in consortia comprising at least 3 partners eligible for funding (i.e. proposals with 4-6 partners in total, including the partner with 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 at the full-proposal stage summarising the commitment of the partner participating in the project with own funding 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 patient 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 of 3 partners eligible for funding from three different countries participating in the call. Patient organisations are not included in this calculation.

** patient organisations are not included in this calculation and can be added as partners participating with own funding at the pre- and full-proposal stage.

*** patient organisations are not included in this calculation and can be added as additional partners in the pre-proposal or full-proposal stage. They can participate either on own funds or apply for funding, if eligible, from the regional/national funding organisation. Please note: **Not more than two consortium partners per country can request funding, including patient organisations.** For some funding agencies, the maximum number of eligible partners who can be funded in one project is one. In countries with more than one funding organisation, three partners from the same country may apply for funding, if one of them is a patient organisation and at least one of them is requesting funding to a regional funding organisation.

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 dealings with the JCS and the **Call Steering Committee**¹⁷

¹⁷ Call Steering Committee: comprises a single representative from each country's/region's funding organisation.

(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 read the funding rules and eligibility criteria of their funding organisations carefully. **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 within ERA PerMed 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 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** has been established for joint applications: 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 via the electronic submission system (<https://ptoutline.eu/app/erapermed2022>). The proposals must be written in English, must

follow the template form in terms of overall size and section page and character limits, and must strictly adhere to the “Guidelines for Applicants”. The pre-proposal form can be downloaded from the **ERA PerMed** website (<https://erapermed.isciii.es/joint-calls/>).

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 **17 February, 2022 at 17:00 CET**.

The decision on which applicants are selected to submit a full-proposal will be communicated to applicants solely by the JCS as soon as possible around 11 May 2022. 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 **14 June, 2022 at 17:00 CEST**. Please note that **joint full-proposals will be accepted only from those applicants explicitly invited by the JCS to submit**. 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, projects objectives or requested budget will not be accepted. The CSC may, however, allow such changes in exceptional cases, if duly justified to the JCS.

Further information on electronic submission of pre- and full-proposals is available on the **ERA PerMed** website (<https://erapermed.isciii.es/joint-calls/>) 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** 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 prior to 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 (<https://erapermed.isciii.es/joint-calls/>).

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 regulations.

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, project objectives or requested budget must be communicated to the JCS and to the regional/national funding organisations. In exceptional cases, these changes may be accepted if detailed justification is provided and if they are accepted by the CSC.

Each full-proposal will be allocated to at least three reviewers with the qualifying expertise fitting the topic of the submitted 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. 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 separately 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 achieved 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 relevance 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, potential for translation of project outcomes into practice or applicability on large cohorts, if applicable);

- f. Relevance of the concept for the advancement of personalised medicine;
- 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 (if available/applicable);
- d. Involvement of private partners (SME and/or industry, if available/applicable);
- e. Innovative potential with respect to the development of personalised medicine;
- f. Consideration of sex aspects and underrepresented populations in research teams, if applicable. 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. Adequacy 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 coordination and scientific management;
- e. Interdisciplinary collaboration: Coherent integration of all kinds of project partners (e.g. academia, clinical/public health sector, industry partner/SME, patient organisations) needed to successfully accomplish the proposed work;
- f. Scientific justification and adequacy 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 removed from 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 obliged 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 specific 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. The Data Management Plan must be submitted to the Joint Call Secretariat **no later than three months after the scientific project start date** (template available on the ERA PerMed call website).

8. REPORTING REQUIREMENTS

On behalf of all participating project partners, each project coordinator shall submit an annual and final scientific progress report in the first and second years, and a final report of the transnational project in English to the JCS. 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 executed. The project partners' principal investigators may also be required for 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 may be invited to attend at least one midterm seminar and one final symposium¹⁸. Travel expenses to attend these mandatory meetings should therefore be included in the proposal budget plans.

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

Upon notification, project coordinators are required to deliver a project abstract 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 proper acknowledgement of the **ERA PerMed** ERA-NET and **the respective funding partner organisations**. Publication with Open Access is mandatory.

¹⁸ If ERA PerMed funds are available.

ANNEX I. REGIONAL/NATIONAL CONTACT DETAILS

<i>Name of participating organisation</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
<i>Austrian Science Fund, (FWF)</i>	AUSTRIA	Milojka Gindl Tel: (+43) 1 505 67 40 8209 milojka.gindl@fwf.ac.at Ena Linnau Tel: (+43) (0) 1 505 67 40-8205 Ena.Linnau@fwf.ac.at
<i>Fund for Scientific Research – FNRS, (F.R.S.-FNRS)</i>	BELGIUM (WALLONIA-BRUSSELS FEDERATION)	Joël Groeneveld Tel: (+32) (0) 2 504 92 70 Florence Quist Tel: (+32) (0) 2 504 93 51 international@frs-fnrs.be
<i>Brazilian National Council of State Funding Agency, (CONFAP)</i>	BRAZIL	Elisa Natola Tel: (+ 55) 61.996138850 elisa.confap@gmail.com
<i>Quebec Health Research Funds, (FRQS)</i>	CANADA (QUEBEC)	Maxime Beaudoin Tel: (+1) 514-873-2114 ext.4369 Maxime.beaudoin@frq.gouv.qc.ca
<i>National Agency for Research and Development, (ANID)</i>	CHILE	Andrea Cibotti Ortiz acibotti@anid.cl
<i>Ministry of Science and Education of the Republic of Croatia, (MSE)</i>	CROATIA	Mateo A. Bosnić Tel: (+385) (1) 4594-166 MateoAnte.Bosnic@mzo.hr
<i>Innovation Fund Denmark, (InnoFond)</i>	DENMARK	Ejner Moltzen Tel: (+45) 31330306 ejner.moltzen@innofond.dk Martin Kyvsgaard Tel: (+45) 61905081 martin.kyvsgaard@innofond.dk
<i>Estonian Research Council, (ETAg)</i>	ESTONIA	Margit Suuroja Tel : (+372) 731 7360 Margit.Suuroja@etagee
<i>Agence Nationale de la Recherche, (ANR)</i>	FRANCE	Monika Frenzel Tel: (+33) (0) 1 73 54 83 32 Michael Joulie Tel: (+33) (0) 1 80 48 83 57 ERAPerMed@agencerecherche.fr
<i>Federal Ministry of Education and Research, (BMBF) German Aerospace Center e.V. – Project Management Agency, (DLR)</i>	GERMANY	Katja Kuhlmann Alexandra Becker Tel: (+49) 228 3821 2211 permed@dlr.de
<i>Federal Ministry of Health, (BMG) German Aerospace Center e.V. – Project Management Agency, (DLR)</i>	GERMANY	Katja Kuhlmann Alexandra Becker Tel: (+49) 228 3821 2211 permed@dlr.de

<i>Name of participating organisation</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
<i>Saxon State Ministry for Science, Culture and Tourism, (SMWK)</i>	GERMANY (SAXONY)	Eva-Maria Stegemann Tel: (+49) 351 564 64270 Gabriele Süptitz Tel: (+49) 351 564 64210 permed@smwk.sachsen.de
<i>National Research, Development and Innovation Office, (NKFIH)</i>	HUNGARY	Klára Horváth Tel: (+36) 1 896 37 48 klara.horvath@nkfi.gov.hu
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<i>Name of participating organisation</i>	<i>Country / Region</i>	<i>Regional/National contact</i>
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<i>Ministry of Education, Science and Sport Slovenia, (MIZS)</i>	SLOVENIA	Eva Batista eva.batista@gov.si
<i>South African Medical Research Council, (SAMRC)</i>	SOUTH AFRICA	Rizwana Mia Rizwana.Mia@mrc.ac.za
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ANNEX II. INDICATIVE FUNDING COMMITMENTS OF THE PARTICIPATING ORGANISATIONS OF THE ERA PERMED JTC 2022 (THIS TABLE IS PROVIDED FOR INITIAL OVERVIEW ONLY. PLEASE REFER TO THE REGIONAL/NATIONAL GUIDELINES FOR DETAILS.)

Name of participating organisation	Country / Region	Funding academic or clinical/ academic partner*	Funding private partners*	Funding of Early Career Researchers (ECR)	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	✓	✓	✓	✓	✓	✓	✓	✓	✓	1.5	5
Fund for Scientific Research – FNRS, (F.R.S.-FNRS)	BELGIUM/ WALLONIA-BRUSSELS FEDERATION	✓	✗	✓ (if eligible to F.R.S.-FNRS funding regulations)	✓	✗	✓	✗	✓	✓	0.2	1
Brazilian National Council of State Funding Agency, (CONFAP)	BRAZIL	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.1	1
Quebec Health Research Funds, (FRQS)	CANADA (QUEBEC)	✓	✗	✓	✓	✓	✓	✓	✓	✓	~0.32	1
National Agency for Research and Development, (ANID)	CHILE	✓	✓ if it is Non Profit Research Organisation ✗ if it is For Profit	✓	✓	✓	✓	✓	✓	✓	0.23	3

Name of participating organisation	Country / Region	Funding academic or clinical/ academic partner*	Funding private partners*	Funding of Early Career Researchers (ECR)	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		
Ministry of Science and Education of the Republic of Croatia, (MSE)	CROATIA	✓	✓	✗	✓	✓	✓	✓	✓	✓	0.12	1
Innovation Fund Denmark, (InnoFond)	DENMARK	✓	✓	✓	✓	✓	✓	✓	✓	✓	1.0	2-3
Estonian Research Council, (ETAg)	ESTONIA	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.1	1
Agence Nationale de la Recherche, (ANR)	FRANCE	✓	✓	✓	✓	✓	✓	✓	✓	✓	2.5	~10
Federal Ministry of Education and Research, (BMBF) German Aerospace Center e.V. – Project Management Agency, (DLR)	GERMANY	✓	✓	✓	✓	✓	✗	✗	✗	✓	3 (RA 1) 1 (module 3B)	10 (RA 1) 3-4 (module 3B)
Federal Ministry of Health, (BMG) German Aerospace Center e.V. – Project Management Agency, (DLR)	GERMANY	✓	✓	✓	✗	✗	✓	✓	✓	✓	1.8	6-7

Name of participating organisation	Country / Region	Funding academic or clinical/ academic partner*	Funding private partners*	Funding of Early Career Researchers (ECR)	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		
Saxon State Ministry for Science, Culture and Tourism, (SMWK)	GERMANY (SAXONY)	✓	✗	✓	✓	✓	✓	✓	✓	✓	2	3-5
National Research, Development and Innovation Office, (NKFIH)	HUNGARY	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.5	2-3
Health Research Board, (HRB)	IRELAND	✓	✗	✓	✓	✓	✗	✓	✓	✓	0.37	1-2
Chief Scientist Office, Ministry of Health, (CSO-MOH)	ISRAEL	✓	✗	✓	✓	✓	✓	✓	✓	✓	0.3	~2
Italian Ministry of Health, (IT-MoH)	ITALY	✓ [Scientific Institutes for Research, Hospitalisation and Healthcare (Istituti di Ricovero e Cura a Carattere Scientifico pubblici e privati, IRCCS)]	✗	✓	✓	✓	✓	✓	✓	✓	1.5	6-7
Fondazione Regionale per la Ricerca Biomedica, (FRRB)	ITALY (LOMBARDY)	✓	✗	✓	✓	✓	✓	✓	✓	✓	2.0	4

Name of participating organisation	Country / Region	Funding academic or clinical/ academic partner*	Funding private partners*	Funding of Early Career Researchers (ECR)	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)	✓	✗	✓	✓	✓	✓	✓	✓	✓	0.3	1-2
Latvian Council of Science, (LZP)	LATVIA	✓ [Clinical as enterprises, academic as scientific institutions]	✓ [Only enterprises – see eligibility rules]	✓	✓	✓	✓	✓	✓**	✓**	0.6	1-2
Research Council of Lithuania, (LMT)	LITHUANIA	✓	✓*	✓	✓	✓	✓	✓	✓	✓	0.2	1
National Research Fund, (FNR)	LUXEMBOURG	✓ [under the conditions specified in the FNR eligibility rules]	✗	✓ [under the conditions specified in the FNR requirements for PIs and supervisors]	✓	✓	✓	✓	✓	✓	0.3	1-2
The Research Council of Norway, (RCN)	NORWAY	✓	✗	✓	✓	✓	✓	✓	✓	✓	1	3-4
National Centre for Research and Development, (NCBR)	POLAND	✓	✓	✓ if employed in eligible	✓	✓	✓	✓	✗	✗	0.6	1-3

Name of participating organisation	Country / Region	Funding academic or clinical/ academic partner*	Funding private partners*	Funding of Early Career Researchers (ECR)	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		
				entity (please refer to national guidelines)								
Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI)	ROMANIA	✓	✓	✓	✓	✓	✓	✓	✓	✓	0.5	1-2
Ministry of Education, Science and Sport Slovenia, (MIZS)	SLOVENIA	✓	✓	✓	[if research organisations registered in SICRIS, performing non-economic activity]						0.42	1-2 funded proposals
South African Medical Research Council, (SAMRC)	SOUTH AFRICA	✓	✓	✓	✓	✓	✓	✓	✓	✗	0.69	3-4
National Institute of Health Carlos III, (ISCIII)	SPAIN	✓	✓ If it is Non Profit. ✗ If it is For Profit.	✓	✓	✓	✓	✓	✓	✓	1.75	8-12
The Scientific Foundation of the Spanish Association Against Cancer, (FCAECC)	SPAIN	✓	✓ If it is Non Profit ✗ If it is For Profit	✓	✓	✓	✓	✓	✓	✓	0.45	~2-3

Name of participating organisation	Country / Region	Funding academic or clinical/ academic partner*	Funding private partners*	Funding of Early Career Researchers (ECR)	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 Department – Generalitat de Catalunya, (DS-CAT)	SPAIN (CATALONIA)	✓	✓ if it is Non Profit Research Organisation. ✗ if it is For Profit	✓	✓	✓	✓	✗	✗	0.5	2-3	
Government of Navarre, (GN)	SPAIN (NAVARRRE)	✓	✓	✓	✓	✓	✓	✓	✓	1.0	3-4	
Sweden’s Innovation Agency, (VINNOVA)	SWEDEN	✓	✓	✓	✓	✓	✓	✓	✓	1.5	~4	
Ministry of Science and Technology, (MOST)	TAIWAN	✓	✗	✓	✓	✓	✓	✓	✓	0.81	3	
The Scientific and Technological Research Council of Turkey, (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 additional information from each individual funding agency in the “Guidelines for Applicants”.

** LZP: Modules 3A and 3B research concerning implementation support cannot be funded.

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 7 years' prior to the proposal submission deadline of the ERA PerMed JTC2022 (after 1st January 2014). Extensions to this period may be allowed in the event of eligible career breaks, which must be properly documented and could be subject of verification by the respective regional/national funding organisation. 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 ninety 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. However, the cumulative eligibility period should not, under any circumstances, exceed 11 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 further details, see the UNESCO International Standard Classification of Education (ISCED) (page 59)

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