

JOINT TRANSNATIONAL CALL FOR PROPOSALS (2018) FOR  
“RESEARCH PROJECTS ON PERSONALISED MEDICINE – SMART  
COMBINATION OF PRE-CLINICAL AND CLINICAL RESEARCH  
WITH DATA AND ICT SOLUTIONS”



Co-funded by the European Commission (Grant 779282)

**CALL TEXT**

**IMPORTANT DEADLINES**

**SUBMISSION OF PRE-PROPOSALS: April 10<sup>th</sup>, 2018 at 17:00 (CET)**

**SUBMISSION OF INVITED FULL-PROPOSALS: July 26<sup>th</sup>, 2018 at 17:00 (CET)**

Link to electronic proposal submission:

<https://secure.pt-dlr.de/ptoutline/app/erapermed2018>

**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 the treatment and care of patients with a particular condition. To better support patients’ health and to target emerging therapies, new strategies will be developed using approaches in areas such as diagnostic tests, functional genomic technologies, molecular pathways, data analytics and real time monitoring of conditions. This is a step towards optimised outcome in the management of a patient’s disease or/and the predisposition to diseases.

### Definition of Personalised Medicine:

ERA PerMed follows the definition stated in the Strategic Research and Innovation Agenda (SRIA) of PerMed, adopted from the Horizon2020 advisory group<sup>1</sup>:

*“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”<sup>2</sup>:

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

The still very fragmented field of PM lacks European/international cooperation and coordination at the cross-sectional as well as at the transnational level. A reorganisation is needed in order to avoid a severe drawback to its development.

**ERA PerMed**<sup>3</sup> is an ERA-Net Cofund, supported by 31 partners of 22 countries and cofunded by the European Commission. It aims to align national research strategies and funding activities, promote excellence, reinforce the competitiveness of European players in PM, and enhance the European collaboration with non-EU countries.

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

<sup>2</sup> [https://ec.europa.eu/research/health/pdf/ag\\_advice\\_report\\_2018-2020.pdf](https://ec.europa.eu/research/health/pdf/ag_advice_report_2018-2020.pdf)

<sup>3</sup> For more information, please visit the ERA PerMed website: [www.erapermed.eu](http://www.erapermed.eu)

ERA PerMed is closely linked to the International Consortium for Personalised Medicine (ICPerMed<sup>4</sup>), established in November 2016. The [Action Plan](#)<sup>5</sup> of ICPerMed builds on the Strategic Research and Innovation Agenda (SRIA) "Shaping Europe's Vision for Personalised Medicine"<sup>6</sup> 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 first ERA PerMed Joint Transnational Call (JTC2018) in order to fund international high quality research projects in PM. The **Joint Call Secretariat (JCS)** will centrally coordinate the present call for proposals.

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

- National Institute of Health Carlos III, (ISCIII), Spain
- Fund for Scientific Research – FNRS, (F.R.S.-FNRS), Belgium\*\*<sup>7</sup>
- Austrian Science Fund, (FWF), Austria
- The Canadian Institutes of Health Research, (CIHR), Canada
- Quebec Health Research Funds (FRQS), Quebec (Canada)
- Ministry of Science and Education of the Republic of Croatia, (MSE), Croatia
- Innovation Fund Denmark, (InnoFond), Denmark
- Estonian Research Council, (ETAg), Estonia
- Estonian Ministry of Social Affairs, (MSA), Estonia
- Academy of Finland, (AKA), Finland
- The French National Research Agency, (ANR), France
- Federal Ministry of Education and Research, (BMBF) / German Aerospace Centre e.V. – Programme Management Agency, (DLR), Germany
- Saxon State Ministry for Higher Education, Research and the Arts, (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
- Regional Foundation for Biomedical Research, (FRRB), Lombardy (Italy)
- State Education Development Agency, (VIAA), Latvia
- National Research Fund, (FNR), Luxembourg
- Research Council of Norway, (RCN), Norway
- National Centre for Research and Development, (NCBR), Poland

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

<sup>5</sup> The ICPerMed Action Plan is published on: [http://www.icpermed.eu/media/content/ICPerMed\\_Actionplan\\_2017\\_web.pdf](http://www.icpermed.eu/media/content/ICPerMed_Actionplan_2017_web.pdf)

<sup>6</sup> The CSA PerMed SRIA is published on <http://www.permed2020.eu>; [http://www.permed2020.eu/media/PerMed\\_SRIA.pdf](http://www.permed2020.eu/media/PerMed_SRIA.pdf)

<sup>7</sup>\*\*The inclusion of F.R.S.-FNRS as full partner of ERA PerMed is pending on the approval of an amendment of the Grant Agreement of ERA PerMed by the EC.

- 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, (CDTI), Spain
- Health Department – Generalitat de Catalunya, (DS-CAT), Catalonia (Spain)
- Government of Navarre, (GN), Navarre (Spain)
- Swedish Research Council, (SRC), Sweden
- The Netherlands Organisation for Health Research and Development, (ZonMw), The Netherlands
- The Scientific and Technological Research Council of Turkey, (TUBITAK), Turkey

## 2. TIMELINE OF THE CALL

<b>February 9<sup>th</sup>, 2018</b>	<b>Publication of the call</b>
<b>February 14<sup>th</sup>, 2018</b>	<b>Opening of the submission system for pre-proposals</b>
<b>April 10<sup>th</sup>, 2018 (17:00, CET)</b>	<b>Deadline for pre-proposal submission</b>
<b>(expected around) June 26<sup>th</sup>, 2018</b>	Communication of the results of the pre-proposal assessment and invitation for full-proposal stage
<b>July 26<sup>th</sup>, 2018 (17:00, CET)</b>	<b>Deadline for full-proposal submission</b>
<b>Beginning of September 2018</b>	<b>Rebuttal stage</b>
<b>September 2018</b>	Peer Review Panel Meeting and CSC meeting for funding recommendation to national funding agencies
<b>October 2018</b>	Communication of the funding decisions to the applicants
<b>End of 2018, latest on 1<sup>st</sup> of July 2019</b>	<b>Expected project start</b> (also subject to national procedures)

## 3. AIM OF THE CALL

The overall aim of the call is to fund projects showing clinical feasibility of PM in complex/multifactorial diseases as well as other diseases (such as monogenic, rare diseases and cancer). Feasibility is intended to mean the demonstration of significant and clinically relevant improvement of current diagnostics and/or therapeutics, based on improved understanding of underlying molecular mechanisms. Furthermore, applicants are expected to combine pre-clinical and/or clinical research with bio-informatics components to enable data quality on one side and the potential applicability for health care providers on the other side. This should be based on methods that are possible to use in and/or be further developed for clinical, general practice and public health settings. This may involve validation of known biomarkers, interoperable data solutions and software for decision support for healthcare providers. Integration of other sources of clinically relevant data in the clinical decision

support, such as imaging or routine data, could also be considered to improve the diagnostic predictions. The projects could include exploratory clinical studies that demonstrate the feasibility of early diagnosis and/or stratification of patients for existing drugs. Larger clinical trials, for example for the identification of novel drugs, are beyond the scope of the call. Because understanding of molecular mechanisms in complex/multifactorial diseases but also other diseases (such as monogenic, rare diseases and cancer) involves multiple genes, gene products or regulators, it is likely that omics methods are required, as are *in vitro* or *in vivo* validation studies.

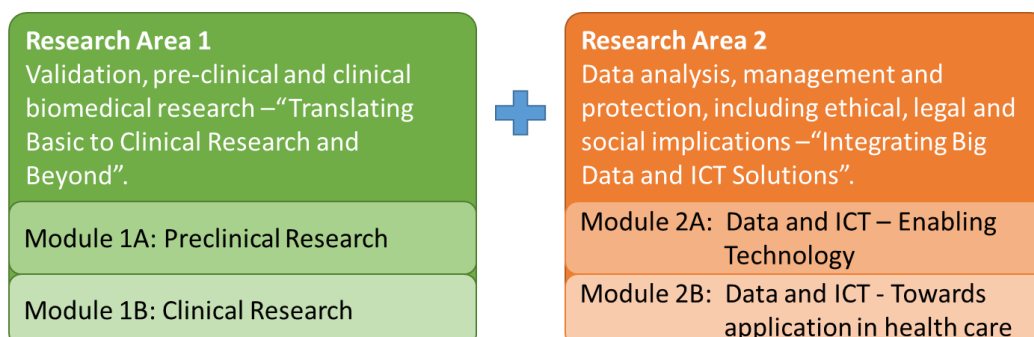
The overall objectives of the call are:

- To support **translational research projects** in the field of Personalised Medicine;
- To encourage and enable **interdisciplinarity**, in combining pre-clinical and/or clinical research with bio-informatics components;
- To encourage **collaboration between academia** (research teams from universities, higher education institutions, public research institutions), **clinical/public health research** (research teams from hospital/ public health, healthcare settings and other healthcare organisations) and private partners e.g. **SMEs**<sup>8</sup> (Small and Medium-size Enterprises).

Each project proposal needs to tackle both major research areas: The **Research Area 1: “Validation, pre-clinical and clinical biomedical research – Translating Basic to Clinical Research and Beyond”** and the **Research Area 2: “Data analysis, management and protection – Integrating Big Data and ICT<sup>9</sup> Solutions”** by addressing at least one module out of each research area:

- **Module 1A: Pre-clinical Research** and/or **Module 1B: Clinical Research** from Research Area 1.
- **Module 2A: Data and ICT – Enabling Technology** and/or **Module 2B: Data and ICT – Towards application in health care** from Research Area 2.

**Both research areas and the four modules are equal in relevance for this call:**



<sup>8</sup> [https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition\\_en](https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en)

<sup>9</sup> Information and Communications Technology (or Technologies)

**Research Area 1:** *Validation, pre-clinical and clinical biomedical research –“Translating Basic to Clinical Research and Beyond”.*

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

**Scope**

- Development and implementation of high-throughput pre-clinical models including e.g. animal and/or cell culture models, etc. to validate hypotheses generated from population, clinical and molecular studies.
- Classification of diseases at the molecular level for a successful implementation of PM, including animal and pre-clinical studies for biomarker validation (diagnosis, prognosis, molecular classification and therapeutic response). Studies on diseases other than cancer and neurodegenerative diseases are also encouraged.

**Expected impact**

The study findings should lead to functional test models and tools to understand the phenotypical and functional effects of omics-variations (e.g. genomic, epigenomic, proteomic, metabolomics, etc.) more rapidly and efficiently.

Research projects are expected to characterise pathogenic mechanisms at the molecular level and to validate them at pre-clinical level, allowing translation to the disease level. The identification of pathogenic mechanisms and biomarkers should allow further study on modulation effects and lead to recognition of possible new drug targets.

**Module 1B: Clinical Research**

**Scope**

- Improvement and validation of analytical methods and omic tools allowing the discovery of allelic variants of genes involved in disease mechanisms, drug metabolism, pharmacokinetics or pharmacodynamics.
- Development of concepts for new clinical trial methodologies and of new stratification strategies, e.g. based on the validation of known biomarkers (molecular, genetic, epigenetic, etc.) for diagnosis, prognosis, molecular classification and therapeutic response. This includes testing of new concepts in exploratory clinical studies.

**Expected impact**

Study findings should pave the way towards first steps in clinical validation of pharmacogenomics to facilitate a more rational treatment choice and the stratification of patients into non-responders and responders.

**Research Area 2:** *Data analysis, management and protection –“Integrating Big Data and ICT Solutions”.***Module 2A: Data and ICT – Enabling Technology****Scope**

- Research on data harmonisation strategies and development of specific ICT using either existing or newly established supporting infrastructures, including the development and definition of minimal datasets for clinical as well as general population databases.
- Development of strategies for common quality standards/indicators to guarantee a sufficient quality of data and metadata to obtain meaningful and reliable results from diverse sources of data.
- Development of bio-informatics, ICT and mathematics tools and models to integrate, analyse and extract value from databases (e.g. omics, health records, clinical data, imaging data, data from mobile devices and wearable sensors, behavioural data, environmental data). Specific attention should be given on the interoperability of the respective databases and the (automatic) integration of data from unstructured sources (e.g. text documents, documents in different languages or specific cultural areas, non-standardised clinical records etc.). Data privacy regulations must be respected and adhered to.
- Research on optimised data security, privacy and ownership within personalised medicine approaches ensuring the security and privacy of all citizens' and patients' data.

**Expected impact**

Ensuring the quality, completeness, validity and availability of harmonisation strategies of data across country borders, including already existing information. Development of manageable interoperability solutions and approaches of data curation, security, privacy and ownership in conjunction with a “big data” setting.

**Module 2B: Data and ICT – Towards application in health care****Scope**

- Studies on data integration and interpretation of complex/multifactorial diseases but also other diseases (such as monogenic, rare diseases and cancer) in PM using various datasets and different forms of mathematical frameworks. These datasets can consist of public data as well as clinical records from different sources: e.g. primary care, specialist medical doctors or hospital records on emergency and elective in-patients. The study should demonstrate the potential clinical benefit.

- Development of innovative decision support tools for healthcare providers (including clinical-grade data and information on current diagnosis and treatment options) to provide suitable and easy-to-handle support tools for collecting and presenting the latest PM improvements. Models addressing best practice diagnostic processes (sharable between institutions) and well-defined outcomes should be proactively developed. The question of data protection needs to be addressed and analysed within the project.
- Development of telehealth and telemedicine applications to support the implementation of PM, e.g. by using already existing and novel e-health and m-health options (including lifestyle assessment and monitoring, as e.g. nutrition, physical activity, sleep duration and –quality as well as drug compliance monitoring interfaces with remote monitoring, as e.g. heart rate and blood glucose).

### **Expected impact**

Providing successful examples of feasible approaches in potential diagnostics or therapeutic candidates for PM approaches, reaching the level for further pre-clinical validation (animal, cell culture, etc.) as the basis for future proof of concept studies.

Support tools (such as pharmaco-economy, clinical risk assessment and management, and others) to present data and information on current diagnosis have to be developed not only for the benefit of citizens and patients, but also in regards to economic aspects (for example personalised treatment versus multi-medication).

The research studies should lead to a better understanding of patient outcome measures, to a development of guidelines for new and reasonable ways to handle “big data” and to the adequate use of data. This includes the identification of data sharing resources, including internet-based patient involvement, spontaneous reporting via different channels and analysis of electronic health records as patient repositories across national borders. Studies should analyse the feasibility of the use of data resources (including the identification of possible barriers and/or an analysis/identification of affordable alternative opportunities).

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

**ERA PerMed can support exploratory clinical studies**, including those with a smaller number of patients/ volunteers that aim to demonstrate the feasibility of early diagnosis and/or stratification of, for example, patients for existing drugs. Exploratory clinical studies submitted to this call should have a design that allows 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 of novel drugs, **are beyond the scope of the call**.



Proposals have adhere to the requested budget and time frame of the planned studies. Studies need to be finalised within the 3-year funding period of the call and at the latest in June 2022 **before the end of ERA PerMed (with no possibility of extension)**. ERA PerMed will only fund those parts of the proposed study that are responding to the aim of the call.

**ERA PerMed is supporting exploratory clinical studies** assessing the viability of a future study (e.g. clinical trial). This might include:

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

**Please note:**

Consortia including partners applying for funding to NCBR (Poland), FRRB (Lombardy, Italy), TUBITAK (Turkey) and ZonMw (The Netherlands) need to send their proposals for national/regional eligibility check to their respective funding organizations **before final submission**.

Please note that the Technology Readiness Levels (TRL)<sup>10</sup> funded, differ between the funding organizations. Please check the national/regional regulations (Guidelines for Applicants).

Proposals should explain how the data gathered through their project would be available to the wider research community. In addition, the ERA PerMed expect proposals to apply data management following the **FAIR principles**<sup>11</sup>.

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

## Recommendations

Proposals **must be interdisciplinary and clearly demonstrate the potential impact on PM** as well as **the added value of transnational collaboration**: sharing of resources (registries, diagnosis, biobanks, models, databases, diagnostic and bio-informatics tools, etc.),

<sup>10</sup> Horizon 2020 scale for TRL: [http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016\\_2017/annexes/h2020-wp1617-annex-g-trl\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf)

<sup>11</sup> [http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/oa\\_pilot/h2020-hi-oa-data-mgt\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf)

platforms/infrastructures, interoperability of data harmonisation strategies and sharing of specific know-how. In order to achieve these goals, the necessary expertise and resources should be brought together from academia, clinical/public health sector and private partners. The research teams within a consortium should include investigators from all scientific disciplines, research areas and expertise necessary to achieve the proposed objectives. The individual project partners of the joint applications should be complementary. The proposed work should contain novel, innovative, ambitious ideas and promote innovative PM solutions to move from scientific value to benefit for the patients (including analyses of applicability to medical care in terms of e.g. money, time, resources, technical feasibility, etc.).

Active participation of early career researchers/scientists in project proposals is encouraged. An early career researcher/scientist 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<sup>12</sup> (see further details in Annex III).

#### Patient involvement

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

Patients/patient organisations might, for example, be involved in the choice of the research topic of the proposal, in the design and advising on the research project or/and in carrying out the research.

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

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

- Providing a different perspective – to profit from experiences obtained in research and experiences of those who are using the service or living with a health condition;
- Using 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 adapted and sensitive to the situations of potential research participants;

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<sup>12</sup> PhD equivalence and eligible extensions to this period in case of career breaks are detailed in Annex III.

- Helping to ensure that the research performed 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 thereby acceptable.

In addition to improving relevance and quality of research, the involvement of members of the public ensures that research is taking into consideration broader principles of citizenship, accountability and transparency.

#### Inclusion of gender and/or sex analysis<sup>13</sup>

Applicants are highly encouraged to integrate sex and gender consideration in submitted proposals to the ERA PerMed call, as well as underrepresented populations in the contender research. This includes not only the **sex distribution in research teams**, but also the **inclusion of sex and/or gender analysis in the research** itself. This applies especially in the case where patients are involved in the proposal. A project is considered sex and gender relevant when it concerns individuals or groups of people and/or when its findings may affect individuals or groups.

## 4. APPLICATION

### A. FUNDING RECIPIENTS

Eligibility Criteria:

- Only transnational projects shall 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 from each other.
- The **project coordinator must be eligible to be funded** by his/her national/regional participating funding organisations.
- **The maximum number of partners per project at the pre-proposal stage is six. At the full-proposal stage, the consortium can be increased up to seven partners in total only by inclusion of a partner coming from an underrepresented country.** A list of underrepresented countries will be provided to coordinators invited for full-proposal submission.
- **Within one consortium, not more than two partners from the same country participating in the call will be accepted.** For some funding agencies the maximum

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<sup>13</sup> 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.cih-irsc.gc.ca/e/49347.html>

number of eligible partners that can be funded in one project is limited to one partner (see also "Guidelines for applicants" regarding 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 national/regional regulations of the participating funding organisations) may participate in projects if they are able to secure their own funding (for more information see below).

Joint research proposals may be submitted by applicants belonging to one of the following categories (according to national/regional regulations of the funding organizations, please see "Guidelines for applicants"):

- A. Academia** (research teams working in universities, other higher education institutions) **or research institutes;**
- B. Clinical/public health sector** (research teams working in hospitals/public health and/or other health care settings and health organisations). Participation of medical doctors in the research teams is encouraged;
- C. (Industry) Private partners, e.g. SMEs<sup>14</sup>** (small and medium-size enterprises).

**We strongly encourage that the consortia submitting applications to this call include partners coming from different categories to follow the crosscutting/multidisciplinary character of the call, allowing the integration of partners from different levels of the value chain.** The number of participants, the category of partner organisation and their research contribution should be appropriate for the aims of the transnational research project and be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from the cooperation.

Research groups, SMEs and industry partners (non-SMEs) not eligible for funding by one of the organisations participating in this Joint Transnational Call (e.g. from non-funding countries or not fundable according to national/regional regulations of the participating funding organisations) may participate in transnational projects if they are able to secure their own funding. Such partners must state in advance their source of funding for the project. They are considered as full project partners. 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.

However, no more than one research group with its own funding can be included in a consortium and the coordinator must be eligible to be funded by his/her national/regional

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<sup>14</sup> [https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition\\_en](https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en)

participating funding organisation (see Annex II). The budget of a non-funded partner shall not exceed 30% of 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 unique role of those centres is only to provide patient' data and/or samples for the study, they will not be considered as partners of the consortium but can be included otherwise, e.g. via cooperation agreements or subcontracting.

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

\*minimum 3 partners eligible for funding from three different countries participating to the call

Each consortium must nominate only one **project coordinator** among the project's principal investigators. The coordinator must be an eligible project partner for the national/regional funding organisation participating in the call. The project coordinator will represent the consortium externally and towards the JCS and **Call Steering Committee<sup>15</sup> (CSC)**, and will be responsible for its internal scientific management such as project monitoring, reporting, intellectual property rights (IPR) management and the contact with the JCS.

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

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

<sup>15</sup> Call Steering Committee: composed of a single representative from each country/region funding organisation.

Please note that if a **partner** is found to be non-eligible 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 national/regional regulations, and contact your national/regional contact person (see also Annex I).

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

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

## **B. FINANCIAL AND LEGAL ASPECTS**

The maximum duration of the projects must be three years in accordance with ERA PerMed funding organisation regulations. The performed studies must be finalised within the 3-year of funding period and at the latest in summer 2022 **before the end of ERA PerMed** (funded projects implementation cannot be extended). **Eligible costs and funding provisions may vary according to the respective funding organisation's regulations.** Project partners must refer and adhere to their own specific national regulations and scientific remits as detailed in the relevant National/Regional Announcements (see Annex I).

## **C. SUBMISSION OF JOINT PROPOSALS**

A **two-step submission and evaluation procedure** for joint applications has been established: pre-proposals and full-proposals. In both phases, one joint proposal document shall be prepared by the partners of a joint transnational project proposal, and must be submitted to the JCS by uploading it on the electronic submission system (<https://secure.pt-dlr.de/ptoutline/app/erapermed2018>) by the project coordinator. The proposals must be written in English and respect the template form (in terms of overall size, limit of pages and characters in the different sections). Submission of a pre-proposal not using the respective template will be declared non-eligible.

Joint **pre-proposals** must be received by the JCS in an electronic version no later than **10<sup>th</sup> of April 2018 at 17:00 CET**. The pre-proposals should strictly follow the "Guidelines for applicants". The pre-proposals form can be downloaded on the ERA PerMed website ([www.erapermed.eu](http://www.erapermed.eu)).

The decision regarding the selection of applications for the invitation to submit a full-proposal will be communicated to applicants as soon as possible around 26<sup>th</sup> of June 2018. At the same time, the JCS will send the coordinator an application template of the full-proposal.

**Full-proposals** (in English) must be received by the JCS in an electronic version no later than **26<sup>th</sup> of July 2018 at 17:00 CET**. Please note that **joint full-proposals will be accepted only from those applicants explicitly invited to submission by the JCS**. Submission of a full-proposal not using the respective template will be declared non-eligible.

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

For applicants from some countries/regions it might be mandatory to submit the additional national/regional proposal and/or other information, in some cases before the deadline of this call, directly to the national/regional funding organisations. Therefore, applicants are **strongly advised** to check their funding organisations specific regulations. See "Guidelines for applicants" for more details.

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

The consortium will take all lawful steps to ensure confidentiality of the information and documents obtained during the evaluation and selection procedure of the joint call.

#### **D. FURTHER INFORMATION**

Applicants must contact their corresponding national/regional representative and confirm eligibility with their respective funding organisations in advance of submitting an application (see national/regional contact details, Annex I). For additional information, please contact the JCS [eranetpm@isciii.es](mailto:eranetpm@isciii.es). The adherence to the national/regional funding regulations in the "Guidelines for applicants" document is mandatory ([www.erapermed.eu](http://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 (date of submission; number and categories of participating countries; inclusion of all necessary information in English; appropriate limits on length; etc. See also "4. Applications, A. Funding recipients"). In parallel, the JCS will forward the proposals to the national/regional funding organisations, who will perform a check for compliance according to their national/regional rules.

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

Each pre-proposal passing the eligibility check (performed by the JCS and the participating funding agencies) will be provided to at least three reviewers for a first evaluation (see evaluation criteria below, "*4. Applications, C. Evaluation criteria*"). The reviewers will perform the assessment of the pre-proposal and complete a written evaluation form with scores and comments for each criterion. The CSC members will meet to decide which proposals will be invited for the full-proposal submission based on the reviewers' recommendations and to ensure a reasonable balance of requested and available national/regional 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 national/regional funding organisations. In exceptional cases, these changes may be admitted if detailed justification is provided and if they are accepted by CSC.

Each full-proposal will be allocated to three reviewers who provide expertise within the profile of the application. The reviewers will perform the assessment of 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 list of proposals recommended to be considered for funding in a ranking list. The composition of the PRP will be communicated through the ERA PerMed website at the end of the entire reviewing 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 (remaining anonymous). This stage allows applicants to comment on factual errors or misunderstandings that may have been committed by the reviewers while assessing their proposal and to reply to reviewers' questions. However, issues which are not related with reviewers' comments or questions cannot be addressed and the work plan cannot be modified at this stage. Answers sent after the notified deadline, or not related with reviewers' comments or questions will be disregarded.



### C. EVALUATION CRITERIA

Pre-proposals and full-proposals will be assessed according to specific evaluation criteria by using a common evaluation form (proposals not fitting with the scope of the call will not be further evaluated). 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 3 main criteria, and not singularly for the different aspects listed below the criteria. The three criteria are weighted equally and the maximum score that can be reached together is 15 points. The threshold for individual criteria will be 3.

#### Evaluation criteria:

##### 1. Excellence:

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

##### 2. Impact:

- a. Added value of the transnational collaboration; sharing of resources (registries, diagnosis, biobanks, models, databases, diagnostic and informatics tools, etc.),

platforms/infrastructures, harmonisation of data and sharing of specific know-how.;

- b. Potential impact of the expected results on clinical and other health related applications;
- c. Involvement of pertinent patient organisations, patient representatives (if available/applicable);
- d. Involvement of private partners (SME and/or industry, if available/applicable);
- e. Innovative potential;
- f. Consideration of sex aspects and underrepresented populations in research teams. Inclusion of sex and/or gender analysis and underrepresented populations in the research, if applicable.

### **3. Quality and efficiency of the implementation:**

- a. Quality of the project plan;
- b. Adequateness of the work package structure and work plan (tasks, matching events, time schedule);
- c. Balanced participation of project partners and integration of workload in the different work packages, quality and efficiency of the coordination and scientific management;
- d. Scientific justification and adequateness of the requested budget (rational distribution of resources in relation to the project's activities, partner responsibilities and time frame);
- e. Risk assessment, regulatory and ethics issues properly addressed (when necessary).

### **D. CONFLICT OF INTEREST (EVALUATION PANEL)**

All necessary steps will be taken by the JCS and the CSC to ensure no conflict of interest by PRP members for those proposals which have been assigned to them for review. The PRP members will be required to formally declare that no conflict of interest exists at any time of their evaluation duty and will sign a confidentiality agreement concerning all documents and the entire process. In case of breaching the rule of no conflict of interest, the PRP member will be discharged from participation in the PR panel. Projects that were assigned to the respective reviewer will be assigned to another reviewer.

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

## 6. FINAL DECISION ON FUNDING

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

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

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

## 7. PROJECT START AND CONSORTIUM AGREEMENT

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

It will be the responsibility of the project coordinators to develop a Project Consortium Agreement suitable to their own group in order to manage the delivery of the project activities, intellectual property rights (IPR), decision making and to avoid disputes, which might be detrimental to the completion of the project. The coordinator is responsible for sending the CA signed by all partners to the JCS. This consortium agreement must state that funding and administrative matters are not regulated by the CA and are issues addressed bilaterally between each project partner and its funder in the relevant Grant Agreement (GA). The CA will be made available to the concerned funding organisations. The project consortium is strongly encouraged to sign this CA before the official project start date and, in any case, the CA should be signed **no later than six months after the official project start date**. Projects have to start officially **no later than July 1<sup>st</sup> 2019**. Please note that national and regional 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 partners, shall submit to the JCS an annual and final scientific progress report (first year, second year and final report) of the transnational project (in English). A report template will be provided by JCS stating the scientific progress, the goals that have been met, and corrective measures set in case 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 national/regional regulations. In addition, project coordinators may be asked to present the project results during ERA PerMed meetings (invitation 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 composition, the coordinator must promptly inform the JCS. The JCS will inform the relevant funding organisations, who will decide upon the proper action to be taken.

Selected project coordinators, upon notification, are mandatorily expected 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-NET ERA PerMed and the respective funding partner organizations. Publication with Open Access is mandatory.

## ANNEX I. NATIONAL/REGIONAL CONTACT DETAILS

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>National/regional contact</i>
<b><i>Austrian Science Fund, (FWF)</i></b>	AUSTRIA	Stephanie Resch Tel: (+43) (0) 1 505 67 40-8201  Iris Fortmann Tel: (+43) (0) 1 505 67 40-8211
<b><i>Fund for Scientific Research – FNRS, (F.R.S.-FNRS)</i></b>	BELGIUM	Joël Groeneveld joel.groeneveld@frs-fnrs.be Tel: (+32)2 504 9270  Florence Quist florence.quist@frs-fnrs.be Tel: (+32)2 504 9351
<b><i>Canadian Institutes of Health Research, (CIHR)</i></b>	CANADA	Bryan Lemire Competition Lead, Competition Delivery / Priority Driven Research / Research, Knowledge Translation and Ethics Portfolio Canadian Institutes of Health Research / Government of Canada Tel: +1 613-952-5728 bryan.lemire@cihr-irsc.gc.ca
<b><i>Fonds de recherche du Québec - Santé, (FRQS)</i></b>	CANADA QUEBEC	Dr Anne-Cécile Desfaits Tel: 514-873-0463 Annececile.desfaits@frq.gouv.qc.ca
<b><i>Ministry of Science and Education of the Republic of Croatia, (MSE)</i></b>	CROATIA	Staša Skenžić Stasa.Skenzic@mzo.hr  Alen Hutinovic Alen.Hutinovic@mzo.hr
<b><i>Innovation Fund Denmark, (InnoFond)</i></b>	DENMARK	Ejner Moltzen Tel: (+45) 31330306 Ejner.moltzen@innofond.dk
<b><i>Estonian Research Council, (ETAg)</i></b>	ESTONIA	Aare Ignat Tel: +372 73 1 73 64 Aare.Ignat@etag.ee
<b><i>Estonian Ministry of Social Affairs, (MSA)</i></b>	ESTONIA	Angela Ivask Tel: +372 626 9735 angela.ivask@sm.ee
<b><i>Academy of Finland, (AKA)</i></b>	FINLAND	Nina Kaminen-Ahola Tel: +358 29 5335027 nina.kaminen-ahola@aka.fi

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>National/regional contact</i>
<b><i>Agence Nationale de la Recherche, (ANR)</i></b>	FRANCE	Monika Frenzel Tel: (+33) (0) 1 73 54 83 32 ERAPerMed@agencerecherche.fr
<b><i>Federal Ministry of Education and Research, (BMBF)</i></b>  <b><i>German Aerospace Centre e.V. – Programme Management Agency, (DLR)</i></b>	GERMANY	Katja Kuhlmann katja.kuhlmann@dlr.de Tel: (+49) 228 3821 2211 Wolfgang Ballensiefen wolfgang.ballensiefen@dlr.de
<b><i>Saxon State Ministry for Higher Education, Research and the Arts, (SMWK)</i></b>	GERMANY (SACHSEN)	Eva Damm Tel: (+49) 351 564 6425 permed@smwk.sachsen.de  Gabriele Süptitz Tel: (+49) 351 564 6422 permed@smwk.sachsen.de
<b><i>National Research, Development and Innovation Office, (NKFIH)</i></b>	HUNGARY	Dr. Klára Horváth National Research, Development and Innovation Office Budapest 1077, Kéthly Anna tér 1. +36 1 896 37 48 klara.horvath@nkfi.gov.hu
<b><i>Health Research Board, (HRB)</i></b>	IRELAND	Dr Caitriona Creely Tel: (+353) 1234 5204 ccreely@hrb.ie
<b><i>Chief Scientist Office, Ministry Of Health, (CSO-MOH)</i></b>	ISRAEL	Yahaloma Gat Tel: (+972) (0) 56 242 476 y.gat@moh.gov.il
<b><i>Italian Ministry of Health, (IT-MoH)</i></b>	ITALY	Dr. Gaetano Guglielmi Directorate General for Health Research and Innovation Tel: (+39) 065994.3528 g.guglielmi@sanita.it  Dr. Maria Josè Ruiz Alvarez Tel: (+39) 065994.3214 mj.ruizalvarez-esterno@sanita.it

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>National/regional contact</i>
<b><i>Regional Foundation for Biomedical Research, (FRRB)</i></b>	ITALY (LOMBARDY)	Gianni D'Errico Tel: +39 02 6765 0174 gianni.derrico@frrb.it  Carmen De Francesco Tel: +39 02 6765 0170 carmen.defrancesco@frrb.it
<b><i>State Education Development Agency (VIAA)</i></b>	LATVIA	Maija Bundule Tel: +371- 67785423 Maija.Bundule@viaa.gov.lv  Uldis Berkis Tel: +371 29472349 Uldis.Berkis@viaa.gov.lv
<b><i>National Research Fund, (FNR)</i></b>	LUXEMBOURG	Marie-Claude Marx Tel: +352 261925 – 21 marie-claude.marx@fnr.lu
<b><i>The Research Council of Norway, (RCN)</i></b>	NORWAY	Karianne Solaas Tel: (+47) 945 35 380 kso@rcn.no
<b><i>National Centre for Research and Development, (NCBR)</i></b>	POLAND	Marcin Chmielewski Tel: +48 22 39 07 109 marcin.chmielewski@ncbr.gov.pl
<b><i>Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI)</i></b>	ROMANIA	Mihaela Manole Tel: +40 21 302 38 63 Mihaela.manole@uefiscdi.ro  Nicoleta Dumitrache Tel: +40 21 302 38 86 Nicoleta.dumitrache@uefiscdi.ro
<b><i>Ministry of Education, Science and Sport, (MIZS)</i></b>	SLOVENIA	Dr. Eva Batista Tel: +38614784754 eva.batista@gov.si
<b><i>National Institute of Health Carlos III (ISCIII)</i></b>	SPAIN	Dori Campo Tel: +34 9182 22461 eranetpm@isciii.es
<b><i>Centro Tecnológico Industrial, (CDTI)</i></b>	SPAIN	Juan Luis Romera Tel: +34 5815500 juanluis.romera@cdti.es

<i>Participant organisation name</i>	<i>Country / Region</i>	<i>National/regional contact</i>
		Sara Alfonso Tel: +34 915810716 sara.alfonso@cdti.es
<i>Health Department – Generalitat de Catalunya, (DS-CAT)</i>	SPAIN (CATALONIA)	Montserrat Llavayol Tel: +34935566172 peris@gencat.cat
<i>Government of Navarre, (GN)</i>	SPAIN (NAVARRA)	Sara Torres storresl@navarra.es
<i>Swedish Research Council, (SRC)</i>	SWEDEN	Malin Eklund Tel: +46 (0)76 526 72 56 Malin.Eklund@vr.se
<i>The Netherlands Organisation for Health Research and Development, (ZonMw)</i>	THE NETHERLANDS	Erica Hackenitz Tel: +31-70-3495159 Hackenitz@zonmw.nl
<i>The Scientific and Technological Research Council of Turkey, (TUBITAK)</i>	TURKEY	Banu Gokcay Tel: +90 312 298 1211 banu.buruk@tubitak.gov.tr



**ANNEX II. INDICATIVE FUNDING COMMITMENTS OF THE PARTICIPATING ORGANISATIONS OF THE ERA PERMED JTC 2018** (THIS TABLE IS MEANT FOR A FIRST OVERVIEW ONLY. PLEASE REFER TO THE NATIONAL/REGIONAL GUIDELINES FOR DETAILS.)

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding academic or clinical partners with private partners*	Funding private partners*	Funding of call topic research area		Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
			(please specify if is private for profit or non for profit)		area 1	area 2		
<b>Austrian Science Fund, (FWF)</b>	AUSTRIA	YES*	YES*	YES*	YES	YES	0.6	2
<b>Fund for Scientific Research – FNRS (F.R.S.-FNRS)</b>	BELGIUM	YES**	NO	NO	1A only	2A only	0.26	1-2
<b>Canadian Institutes of Health Research, (CIHR)</b>	CANADA	YES	NO	NO	1B only	YES	2.8****	9
<b>Fonds de recherche du Québec - Santé, (FRQS)</b>	CANADA (QUEBEC)	YES	YES (But funding given only for academic or clinical partners)	NO	1B only	YES	0.32	1-2
<b>Ministry of Science and Education of the Republic of Croatia, (MSE)</b>	CROATIA	YES	YES	NO	YES	YES	0.1	1
<b>Innovation Fund Denmark, (InnoFond)</b>	DENMARK	YES	YES	YES	YES (with main focus on area 1B)	YES (with main focus on area 2B)	1.0	2-4

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding academic or clinical partners with private partners*	Funding private partners*	Funding of call topic research area		Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
			(please specify if is private for profit or non for profit)		area 1	area 2		
<b>Estonian Research Council, (ETAg)</b>	ESTONIA	YES	YES	NO	YES (1A)	YES	0.1	1 project (If in 1 project are several Estonian partners, their total maximum funding is 100 000 €)
<b>Estonian Ministry of Social Affairs, (MSA)</b>	ESTONIA	YES	YES	YES	YES (1B)	YES	0.3	1-2 projects (total maximum allocation of funds is 100 000 € per year; project funding is disbursed annually)
<b>Academy of Finland, (AKA)</b>	FINLAND	YES	NO	NO	YES	YES	1.2	3-4
<b>Agence Nationale de la Recherche, (ANR)</b>	FRANCE	YES	YES	YES	YES	YES	2.5	10
<b>Federal Ministry of Education and Research, (BMBF) German Aerospace Centre e.V. – Programme Management Agency, (DLR)</b>	GERMANY	YES	YES*	YES*	YES	YES	3	10

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding academic or clinical partners with private partners*	Funding private partners*	Funding of call topic research area		Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
			(please specify if is private for profit or non for profit)		area 1	area 2		
<b>Saxon State Ministry for Higher Education, Research and the Arts, (SMWK)</b>	GERMANY SAXONY (SACHSEN)	YES (see regional regulations)	YES (see regional and BMBF regulations)	See regional and BMBF regulations	YES	YES	1.5	not defined
<b>National Research, Development and Innovation Office, (NKFIH)</b>	HUNGARY	YES	YES	YES	YES	YES	0.33	2-3
<b>Health Research Board, (HRB)</b>	IRELAND	YES	YES	NO	YES	YES	0.37	1-2
<b>Chief Scientist Office, Ministry Of Health, (CSO-MOH)</b>	ISRAEL	YES	NO	NO	YES	YES	0.3	2
<b>Italian Ministry of Health, (IT-MoH)</b>	ITALY	YES [Scientific Institutes for Research, Hospitalization and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico pubblici e privati, IRCCS) and ISS (Istituto Superiore di Sanità)]	NO	NO	YES	YES	1.75	6

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding academic or clinical partners with private partners*	Funding private partners*	Funding of call topic research area		Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
			(please specify if is private for profit or non for profit)		area 1	area 2		
<b>Regional Foundation for Biomedical Research, (FRRB)</b>	ITALY (LOMBARDY)	YES (Academies and research centers are eligible <b>ONLY</b> in partnership with <b>IRCCS</b> and <b>ASST</b> )	Industries are <b>NOT</b> eligible	Industries are <b>NOT</b> eligible	YES	YES	4	8-12
<b>State Education Development Agency, (VIAA)</b>	LATVIA	YES*	Private partners – scientific institutions or enterprises*	Private partners – scientific institutions or enterprises*	YES	YES	0.3	1-2
<b>National Research Fund, (FNR)</b>	LUXEMBOURG	Yes (under the conditions specified in the FNR eligibility rules)	Yes (but funding given only for academic or clinical partners)	NO	YES	YES	0.3	1-2
<b>The Research Council of Norway, (RCN)</b>	NORWAY	YES	NO	NO	YES	YES	0.8	3-4
<b>National Centre for Research and Development, (NCBR)</b>	POLAND	YES	YES	YES	YES	YES (R&D only, please refer to national regulations)	0.5	1-2
<b>Executive Agency for Higher Education, Research, Development and</b>	ROMANIA	YES*	YES*	YES*	YES	YES	0.5	1-2

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding academic or clinical partners with private partners*	Funding private partners*	Funding of call topic research area		Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
			(please specify if is private for profit or non for profit)		area 1	area 2		
<b>Innovation Funding, (UEFISCDI)</b>								
<b>Ministry of Education, Science and Sport, (MIZS)</b>	SLOVENIA	YES**	YES**	YES**	YES	YES	0.42	1-2 funded proposals, in case of top-up funding up to maximum 4
<b>National Institute of Health Carlos III, (ISCIII)</b>	SPAIN	YES	YES	NO	YES	YES	0.5	3-5
<b>Centro Tecnológico Industrial, (CDTI)</b>	SPAIN	NO	NO	YES( FOR PROFIT)	YES	YES	0.7	6-10
<b>Health Department – Generalitat de Catalunya, (DS-CAT)</b>	SPAIN (CATALONIA)	YES	Yes, only for non profit	NO	YES	YES	0.5	Not defined
<b>Government of Navarre, (GN)</b>	SPAIN (NAVARRE)	YES	YES	YES	YES	YES	0.5	Not defined
<b>Swedish Research Council, (SRC)</b>	SWEDEN	YES	YES (But funding given only for academic and clinical partners)	NO	YES	YES	2.0	3-5 (0.1-0.2 M euro/project/year)
<b>The Netherlands Organisation for Health Research and</b>	THE NETHERLANDS	YES	YES***	YES***	Area 1A***	NO	0.5	2-3

Participant organisation name	Country / Region	Funding academic or clinical/academic partner*	Funding academic or clinical partners with private partners*	Funding private partners*	Funding of call topic research area		Tentative initial funding commitment (M€ for 3 years)	Envisaged number of teams potentially funded with the tentative initial funding commitment
			(please specify if is private for profit or non for profit)		area 1	area 2		
<b>Development, (ZonMw)</b>								
<b>The Scientific and Technological Research Council of Turkey, (TUBITAK)</b>	TURKEY	YES	YES, but funding for non-profit organizations is not provided.	YES, but funding for non-profit organizations is not provided.	YES	YES	0.3	1-2

\* subject to National/Regional Eligibility Criteria (see Guidelines for Applicants).

\*\* if research organisations registered in SICRIS, performing non-economic activity.

\*\*\* ZonMw has strict rules for the topic within this call. Consult the attached National ZonMw conditions for this call before applying.

\*\*\*\* CIHR's funding commitment is the equivalent of \$4,087,500 CAD.

### ANNEX III. DEFINITION OF EARLY CAREER RESEARCHER/SCIENTIST

Early career researchers/scientists must have been awarded their first PhD/MD or equivalent doctoral degree, at least 2 and up to 10 years' prior the proposal submission deadline of the ERA PerMed JTC 2018. Extensions to this period may be allowed in case of eligible career breaks, which must be properly documented. However, there is **no need** to attach additional documentation when submitting the project proposal. Eligible career breaks are:

- For maternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by 18 months for each child born before or after the PhD/MD award;
- For paternity: the effective elapsed time since the award of the first PhD/MD will be considered reduced by the actual amount of paternity leave taken for each child born before or after the PhD/MD award;
- For long term illness (over 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. The cumulative eligibility period should not in any case surpass 14 years and 6 months following the award of the first PhD/MD. No allowance will be made for principal investigators working part-time.

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

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

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