RESEARCH PROJECTS ON PERSONALISED MEDICINE – MULTIDISCIPLINARY RESEARCH PROJECTS ON PERSONALISED MEDICINE – PRE-/CLINICAL RESEARCH, BIG DATA AND ICT, IMPLEMENTATION AND USER'S PERSPECTIVE"

ERA PerMed

NATIONAL GUIDELINES FOR APPLICANTS FOR THE IMPLEMENTATION OF ERA-NET ACTION ON PERSONALISED MEDICINE (PM)

JOINT CALL 2020

The Ministry of Science and Education of the Republic of Croatia (here after, MSE) is the national funding and coordination body responsible for the implementation of the ERA PerMed programme in the Republic of Croatia.

As such, the MSE hereby prescribes the National guidelines for applicants for the implementation of ERA PerMed in the Republic of Croatia (2017 – 2022) which provides information regarding national participation criteria, including scientific criteria, funding, consortium and other requirements.

FUNDING BODY DETAILS

National funding body	Acronym	Address	Telephone	Fax
Ministry of Science and Education of Republic of Croatia	MSE	Donje Svetice 38 10 000 Zagreb Republic of Croatia	+385 1 4569 000	+385 1 4594 301

NATIONAL CONTACT POINT DETAILS

NCP name and surname	E-mail	Telephone Number
Mateo Ante Bosnić	MateoAnte.Bosnic@mzo.hr	+38514594166

TOTAL BUDGET

Republic of Croatia has financially committed to contribute to *ERA PerMed programme* with a contribution of EUR 301.250,00. Hence, the Croatian applicants will have a budget for the Joint Call 2020 in the amount of EUR 120.000,00.

In particular, in 2020 Ministry of Science and Education is open to project proposals within all research areas (see "Scientific criteria"). The highest ranked project proposals evaluated on merit based criteria will be approved for funding, subject to available budget.

NATIONAL CRITERIA

Participation criteria: Terms and conditions of eligible entities

MSE funding is limited to a Croatian project partners only. Croatian project partner could be consortium (consisting of at least three national legal entities) or single legal entity.

Eligibility criteria for Croatian project partners are as follows:

- research organizations registered in the Register of Research Organizations at the Ministry of Science and Education of Republic of Croatia[1]:
    - public research institutes
    - public higher education institutions
    - other legal entities performing research activity

- other legal entities performing research activities
    - non-governmental and non-profit organizations (NGO's) or institutions whose main object is research activity or research and development activity registered by the Ministry of public administration
    - small and medium enterprises (SME's) registered by the Ministry of economy, entrepreneurship and craft.

- 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. All three legal entities must be independent of each other.

  At least two partners of the consortium must be from two different EU Member States or Associated Countries.

- The project coordinator must be eligible to be funded by his/her regional/national participating funding organisation.

- The maximum number of partners per project at the pre-proposal stage is six. At the full-proposal stage, the consortium may be expanded to up to seven partners in total only by inclusion of a partner from an underrepresented country. A list of underrepresented countries will be provided to the coordinators invited to submit full-proposals.

- Within one consortium, no more than two partners from the same country participating in the call will be accepted, including those partners with their own funding. For some funding agencies, the maximum number of eligible partners that can be funded in one project is limited to one (see also "Guidelines for Applicants" for individual funding rules)

[1] According to Article 22 of the Scientific Research and Higher Education Act (Official Gazette 123/03, 198/03, 105/04, 174/04, 02/07, 46/07, 45/09, 63/11, 94/13, 139/13, 101/14, 60/15, 131/17

- Partners not eligible for funding by one of the organisations participating in this JTC (e.g. from non-funding countries or not fundable according to the regional/national regulations of the participating funding organisations) may participate in projects provided that they demonstrate, with the full-proposal submission, that their economic and human resources have already been secured and will be available at the start of the project. No more than one partner with its own funding is allowed in consortia with at least three partners eligible for funding.

The eligibility criteria of the applicant will be verified based on the Excerpt from the Register of Scientific Organizations, which will be provided by the Ministry of Science and Education.

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

Research groups, SMEs and industry partners (non-SMEs) not eligible for funding by one of the organisations participating in this Joint Transnational Call (e.g. from non-funding countries or not fundable according to regional/national regulations of the participating funding organisations) may participate 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 partners and have to be integrated in the pre- and full-proposal templates as such. **Please be aware that maximum one partner with own funding** is allowed in consortia with at least 3 partners that are 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 in the full-proposal step summarising the commitment of this partner to the project and demonstrating the source of funding. The budget of a non-funded partner shall not exceed 30% of total transnational project budget requested.

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

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

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

Each project partner has to be represented by **one principal investigator**. Within a joint proposal, each project partner's principal investigator will be the contact person for the JCS and the relevant regional/national funding organisation. Each consortium must nominate one project coordinator from among the project's principal investigators. The nomination of a co-coordinator is not allowed. The coordinator must be eligible to be funded by his/her regional/national participating funding organisation. The project coordinator will represent the consortium externally and in its dealings with the JCS and the **Call Steering Committee**[2] **(CSC)**, and will be responsible for its internal scientific management such as project monitoring, reporting, intellectual property rights (IPR) management and contact with the JCS.

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

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 regional/national regulations, and contact your regional/national funding organisation (see also Annex I).

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

For regional/national eligibility reasons, applicants must indicate in the pre-proposal form if the study submitted is subject to other evaluation processes, such as other joint transnational calls and regional/national calls. Applicants shall avoid applying to different calls for same research activities. Double funding is not allowed.

Patient involvement

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

Accordingly, consortia submitting proposals to this call are asked to describe the level of public involvement in the research throughout the various stages of research design, conduct, analysis and dissemination. The extent of citizen/patient involvement may vary according to the context of the study proposed and regional/national regulations of participating funding organisations. "Patient involvement" represents one evaluation subcriterion in "2. Impact", "c. Involvement of pertinent patient organisations, patient representatives (if available/applicable)".

[2] Call Steering Committee: composed of a single representative from each country/region funding organisation.

REPORTING REQUIREMENTS

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

Additionally, Croatian project partner receiving the funding under this call will be monitored by MSE. Croatian project partners have the obligation to submit annual and final financial and narrative reports on the project progress, describing in clearly manner whether or not they achieved the set of key performing indicators. MSE will proscribe the form for the annual and final reports. Furthermore, Croatian project partners also have the obligation to submit the final financial and narrative reports.

The eligibility criteria for the applicant will be verified based on the Excerpt from the Register of Scientific Organizations, which will be provided by the Ministry of Science and Education. Legal entities receiving basic funding from the MSE can only be granted for funds covering extra expenditure, i.e. as an addition to their basic financing.

Maximum limit requested per partner / per country / per proposal

Only costs directly related to the proposed research activities are eligible for financing under this call. Activities supported by other sources are not eligible for financing. Applicant must ensure that there is no double financing during the whole project implementation.

Total available budget for Joint Call 2020 for **Croatian project** partners is 120.000,00 Euro.

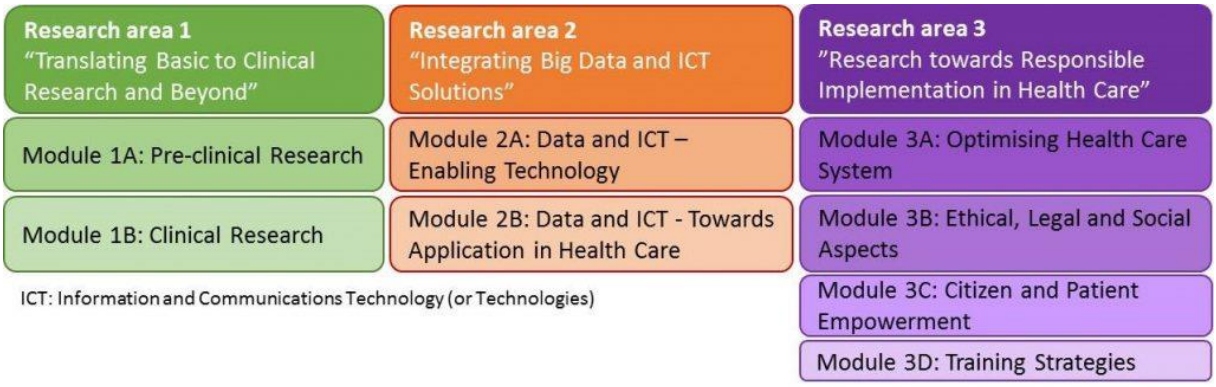
Project duration

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).

SCIENTIFIC CRITERIA

Thematic areas and topics to be funded

The JTC2020 of ERA PerMed comprises three Research Areas:



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

Research Areas/Modules combined in proposal	**Research Area 1 Module 1A and/or 1B**	**Research Area 2 Module 2A and/or 2B**	**Research Area 3 Module 3A and/or 3B and/or 3C and/or 3D (mandatory)**
Eligible	X		X
Eligible		X	X
Eligible	X	X	X
Not eligible	X	X	

Assessment of the coherent integration and combination of the different research areas and modules in the proposals is part of the evaluation process.

Research Area 1: *"Translating Basic to Clinical Research and Beyond".*

Research proposals should aim to improve the exchange between basic and clinical research. This is needed to allow the transition from bench to bedside (e.g. by translational science, transferring pre-clinical technologies/other predictive tools to clinical application) but also vice versa by using, for example, existing clinical databases, repositories and cohorts, and by sharing experiences obtained in classical and innovative clinical studies/trials. The aim is to achieve a better identification and validation of known biomarkers and therapeutic targets (including omics and other data obtained, for example, by imaging, biomarker monitoring etc.) as well as diagnostic re-classification. This in turn will help to predict in advance how a patient will respond to a specific therapy.

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

Research projects on diseases other than cancer are also encouraged.

Module 1A: Pre-clinical Research

Scope

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

Module 1B: Clinical Research

Scope

- Improvement, validation and combination of tools (e.g. imaging, physiological monitoring and omics) for diagnostics and integrated analytical methods, allowing the discovery of molecular characteristics involved in disease etiopathogenesis (including co-morbidities and sex-related differences), development and progression, and patient treatment including pharmacokinetics or pharmacodynamics.
- Development and evaluation of concepts for innovative clinical trial methodologies, suitable for PM approaches, taking into account the fact that more flexible and innovative trial design is needed, considering both health benefits and health economics (see also Module 3A). Development of novel strategies that will enable clinical scientists to speed up the transition from clinical observation to diagnostic development.
- Development of new concepts and stratification strategies in exploratory clinical studies (for further indications, see also the blue box on page 13/14).
- Clinical and omics data integration, use of machine learning technology to provide a personalised treatment for patients.

Research Area 2: *"Integrating Big Data and ICT[3] Solutions".*

Systematic integration of different bioinformatics resources (databases, algorithms, etc.), big data and ICT solutions should be an essential part of the research proposals submitted under this call wherever appropriate. The PM approaches to be developed should support the easy flow, robust analysis and interpretation of information such as clinical data (including imaging data and physiological monitoring data), omics data, data on biological samples, as well as patient outcomes among different institutions while ensuring data security and data protection.

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

3 Information and Communications Technology (or Technologies)

and ensuring interoperability, completeness, sufficient documentation and comparability of data on the other.

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

Module 2A: Data and ICT – Enabling Technology

Scope

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

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

Scope

- Research on data integration and interpretation of diseases aimed at advancing PM. Demonstration of the potential clinical benefit of using and combining different kinds of datasets from various sources. These datasets can originate for example from large, multimodal and multi-centre public data repositories or clinical records from different sources. They can comprise data from multiple biological organisation levels or scales, e.g. behavioural, physiologic and molecular data. In addition, different forms of mathematical, statistical and modelling frameworks can be used for exploring and validating data quality and information content. This might include, for example, the development of standardised strategies for cross-validating biomarkers across existing databases.
- Development of innovative and easy-to-handle clinical decision support tools tailored to the needs of healthcare professionals. Such tools should provide reliable and accurate interpretation

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

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

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

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

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

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

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

For proposals submitted to this call, it is mandatory to address at least one module of Research Area 3. The research conducted in Research Area 3 and the corresponding work package should relate directly to the research question(s) addressed in Research Area(s) 1 and/or 2.

Module 3A: Optimising Health Care System

Scope

- Research on the analysis, comparison, and optimisation of national and regional health care systems in the context of PM. Suggestions for the optimisation of health care systems can be elaborated in order to support the reasonable implementation of existing or newly developed best practice and lessons learned in the light of sustainable solutions. Investigation of the social conditions, such as availability of insurance, employment, affordability of medical innovation (and other aspects such as demographic details, ethnic group, gender, quality of life, etc.), should also form part of this research.
- Research on the development, application, and adoption of new models and approaches for health care and their application/adaptation to healthcare systems in different regions/countries. This should lead to support models and tools (such as pharmaco-economic assessment, clinical

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

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

Module 3B: Ethical, Legal and Social Aspects

Scope

- Research on optimised data security, protection, confidentiality, privacy and ownership within PM approaches; responsible ways to enable the use of personal and patient data for research purposes.
- Research on adequate regulatory structures and pathways in PM; e.g. in the context of the development of a new clinical trial design methodology for PM. Research on the refinement of existing guidelines and, where appropriate, the development of new guidelines and reflection papers for researchers to facilitate the approval process with regulatory authorities and their communication with reimbursement authorities.
- Research on how to overcome the challenges posed by different regional or national regulatory frameworks, for example in multi-centre clinical trials with study centres in several countries, including, for example, the impact of different cultural codes (affecting the collection of informed consent), educational attainment and/or social/economic status.
- Research on fundamental societal challenges raised by PM, e.g. questions of solidarity, fairness or rationality of allocation of resources and research foci.
- Development of new forms and interplay of stakeholder exchange (including all different key players – academic researchers from different disciplines, health care providers, industry/pharma and regulatory authorities, as well as citizens, patients and communities, regardless of their social, environmental and economic conditions).
- Research on responsibility and liability as well as challenges concerning our view on the nature of humans, humankind and human dignity, heritability and generational responsibility or the interface – and tension – between the state of health and illness.
- Research on ethical, legal and social aspects in the context of decision support systems, especially when artificial intelligence techniques are used: availability and suitability of data for training (machine learning algorithms), requirements on transparent and explainable decision-making, questions of responsibility and liability, potential changes in the role and self-image of physicians.
- Research on appropriate ways and methods for participatory health research/patient involvement in research projects for PM, including all steps of the process, identification of research questions, study design, recruitment processes, data collection and analysis of results.

- Research on different users' perspectives (expectations vs. capacity and willingness to provide requested input) among the various key players (e.g. researchers, health care providers, etc.) and professional dynamics connected to PM approaches. This research might also include reflections on organisational innovation (changes in the organisation of the health service).
- Development of strategies for regulatory approval of clinical decision systems based on statistical learning, machine learning and artificial intelligence technologies.

Module 3C: Cituzen and Patient Empowerment

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

Module 3D: Training Strategies

- Research on and assessment of training strategies and/or data sharing platforms to allow an adequate level of awareness and education of all different stakeholders in PM: citizens and patients, researchers, healthcare providers, industry, health insurers as well as regulatory authorities and future stakeholders (e.g. medical students). Reflections should take into account the needs/background of the different stakeholders.
- Research on the development and assessment of knowledge network tools and procedures (e.g. web-based and/or social media, network of patient academies, etc.) for enhancing health and digital literacy, in order to increase the ability and capacity of individuals and communities to obtain, comprehend and act upon basic health care information.
- Research on education and training strategies for citizens, patients and patient advocates, and on the involvement of patients and patient organisations across the entire research and development lifecycle of PM.
- Research on – and assessment of – training strategies needed for health care professionals/providers (HP) to increase their knowledge base and skills related to PM with regard to its future implementation. This includes different aspects, such as (A) training of HP in new diagnostic and treatment options, (B) how to deliver health-related information to the general public, (C) reporting on treatment experiences and outcomes to research and to the industry, etc.

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. This is especially important for the mandatory research area 3.

Croatian Principal Investigator

Principal investigator for Croatian project partner must hold a Ph.D. degree and should have at least 5 years of research experience after having obtained Ph.D. Research leader must be employed under employment contract at Croatian institution participating in transnational consortium. Croatian project partner will commit that minimum 30% of research leader's workload will be dedicated to the ERA PerMed project. Croatian project partner research leader will repost on project progress to national coordinating and funding body – MSE.

If coordinator of transnational consortium, Croatian project partner will appoint one research leader (principal investigator) who will monitor the implementation of transnational project activities, and report on it to ERA PerMed secretariat.

The funds will be allocated to the Croatian project partner when evaluated positively by ERA PerMed Secretariat and validated by MSE.

Only one principal investigator represents 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.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 (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.

FUNDING CRITERIA FOR CROATIA'S PROJECT PARTNER IN ERA-NET ACTION ON PERSONALISED MEDICINE (PM)

Eligible costs categories

For Croatian applicants, eligible costs are as follows[4]:

PERSONNEL COSTS	DIRECT COSTS	SUBCONTRACTING	INDIRECT COSTS
- living allowance only for the new employees on the project - mobility allowance (accommodation and transport costs, per/diem allowances, meeting/seminar/conference organizational directly connected with the research)	-research costs - dissemination and visibility costs	-only in justified cases and subjected to the evaluation	- up to 25% of total approved project budget for the Croatian project partner - management cost overheads

All budget items must be justified and provided for eligibility. All costs must be made during the period of the project duration. Applicants are advised to contact the national contact point for the pre-eligibility check.

VAT eligibility

For Croatian applicants, the general H2020 rule applies regarding VAT eligibility within the ERA-Net Action on Personalised Medicine (PM) programme. VAT is an acceptable cost for all applicants that are non-profit legal entities if there is no right to tax deduction. VAT is in that case the ultimate expense for the applicant and as such is recorded in the accounting books. Regarding profit organizations (that are liable for paying and collecting VAT, and VAT for them is not the ultimate expense, the VAT expense is not eligible cost for the project cost within the ERA-Net Action on Personalised Medicine (PM).

Subcontracting rules

Subcontracting for the sake of performing and implementing certain tasks/activities that are part of the main project activities is allowed and considered eligible. For more information regarding subcontracting rules please consult http://www.obzor2020.hr/userfiles/Smjernice_O2020_projekti_final.pdf.

LINKS AND REFERENCES TO FIND SPECIFIC (NATIONAL) REQUIREMENTS

[4] For more information on the eligible and ineligible costs please consult: http://www.obzor2020.hr/userfiles/Smjernice_O2020_projekti_final.pdf.

http://www.obzor2020.hr/userfiles/Smjernice_O2020_projekti_final.pdf
Applicants are advised to contact the national contact point for the pre-eligibility check.

The full version of ERA PerMed national guidelines for applicants for the implementation of ERA-Net Action on Personalised Medicine (PM) in the Republic of Croatia (2017 – 2022) will be published on the MSE website.