

Joint Transnational Call for Proposals (2024) for

# Identification or Validation of Targets for Personalised Medicine Approaches (PMTargets)

*(EP PerMed Grant 101137129)*

## Call Text

### Important Deadlines

Submission of pre-proposals: 05 March 2024 at 17:00 (CET)

Submission of invited full-proposals: 20 June 2024 at 17:00 (CEST)

**Link to the electronic proposal submission tool:**

<https://ptoutline.eu/app/eppermed2024>

For further information, please visit our website: [www.eppermed.eu](http://www.eppermed.eu)

**or contact the EP PerMed Joint Call Secretariat (JCS)**

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**EP PerMed**

European Partnership  
for **Personalised Medicine**

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## 1. Introduction and aims of EP PerMed

**Personalised Medicine (PM)** represents a paradigm shift from a “one size fits all” approach to an optimised strategy for the prevention, diagnosis and treatment of disease for each individual, based on their unique characteristics, including biological features (e.g. phenotype, endotype, genotype), as well as lifestyle and environmental factors. Accordingly, PM puts the patient at the very centre of healthcare, aiming for optimised health promotion, treatments and management of disease or predisposition to disease. Today, the field of PM has been advancing rapidly and the range of technologies, methodologies and information utilised is much broader, supporting improved healthcare, diagnostics and tailor-made treatments, including rehabilitation, and prevention strategies.

### Definition of Personalised Medicine:

**EP PerMed** adheres to the definition stated in the PerMed SRIA: ‘Shaping Europe’s Vision for Personalised Medicine’ (2015)<sup>1</sup>, adopted from the Horizon2020 Advisory Group<sup>2</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 2018–2020 Advice of the Horizon 2020 Advisory Group for Societal Challenge 1, “Health, Demographic Change and Well-being”:

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

The **European Partnership for Personalised Medicine, EP PerMed**, is a platform for joint programming of national and European regional research and innovation (R&I) programmes putting into action “The Strategic Research & Innovation Agenda (SRIA) for Personalised Medicine (2023)”<sup>3</sup>, **SRIA for PM (2023)**, through dedicated research, development and innovation funding. The funding of transnational collaborative research is a joint activity to further enhance the cooperation between stakeholders across Europe and beyond to maximise the benefits of PM approaches and thus pooling resources and achieving investments of scale in this field. Furthermore, to ensure efficient utilisation and accessibility of new and improved PM approaches, project consortia are required to be multidisciplinary and intersectoral in EP PerMed calls for proposals, by including academia (universities, research performing organisations both public and private not for profit), clinical settings and public health organisations, and industry (spin-offs, start-ups, SMEs, the European biotechnology and health/pharma industries), but also considering the importance of the end-users perspective, such as patients, citizens, clinicians and healthcare providers.

<sup>1</sup> <https://www.eppermed.eu/wp-content/uploads/2023/09/EPPERMed-SRIA.pdf>

<sup>2</sup> European Commission. Advice for 2016/2017 of the Horizon 2020 Advisory Group for Social Challenge 1, “Health, Demographic Change and Wellbeing”, July 2014: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AC%3A2015%3A421%3AFULL>

<sup>3</sup> <https://www.eppermed.eu/action-areas/sria/>

## 2. Participating European regions, countries and funding organisations

The funding organisations listed below are jointly launching the EP PerMed Joint Transnational Call 2024 (JTC2024), co-funded by the European Union (EU). The JTC2024 is coordinated by the EP PerMed Joint Call Secretariat (JCS).

The call is opened and simultaneously supported by the following (38) funding organisations in their respective European regions (later only referred to as “region”) or countries:

| Country/Region                                | Funding Organisation  | Acronym     |
|---|---|-------------|
| <b>Austria</b>                                | Austrian Science Fund   | FWF         |
| <b>Belgium (Flanders)</b>                     | Vlaams Gewest - VLAIO Flanders Innovation & Entrepreneurship – Flemish Government                             | FIO (VLAIO) |
| <b>Belgium (Flanders)</b>                     | The Research Foundation – Flanders  | FWO         |
| <b>Belgium (Walloon region)</b>               | Service Public De Wallonie  | SPW EER     |
| <b>Belgium (Wallonia-Brussels Federation)</b> | Fund for Scientific Research – FNRS   | F.R.S.-FNRS |
| <b>Denmark</b>                                | Innovation Fund Denmark   | IFD         |
| <b>Estonia</b>                                | Estonian Research Council   | ETAG        |
| <b>Finland</b>                                | Business Finland  | BFRK        |
| <b>Finland</b>                                | Research Council of Finland   | AKA         |
| <b>France</b>                                 | The French National Research Agency   | ANR         |
| <b>Germany</b>                                | Federal Ministry of Education and Research, (BMBF) / German Aerospace Center e.V. – Project Management Agency | BMBF/DLR    |
| <b>Germany</b>                                | Federal Ministry of Health, (BMG) / German Aerospace Center e.V. – Project Management Agency                  | BMG/DLR     |
| <b>Germany (Saxony)</b>                       | Saxon State Ministry for Science, Culture and Tourism   | SMWK        |
| <b>Hungary</b>                                | National Research, Development and Innovation Office  | NKFIH       |
| <b>Iceland</b>                                | The Icelandic Centre for Research   | RANNIS      |
| <b>Ireland</b>                                | Health Research Board   | HRB         |
| <b>Ireland</b>                                | Science Foundation Ireland  | SFI         |
| <b>Israel</b>                                 | Ministry of Health, The Chief Scientist Office  | CSO-MOH     |
| <b>Italy</b>                                  | Italian Ministry of Health  | IT-MoH      |
| <b>Italy</b>                                  | Italian Ministry of Universities and Research   | MUR         |
| <b>Italy (Lombardy)</b>                       | Fondazione Regionale per la Ricerca Biomedica   | FRRB        |
| <b>Italy (Tuscany)</b>                        | Tuscany Region  | RT          |
| <b>Latvia</b>                                 | Latvian Council of Science  | LZP         |
| <b>Lithuania</b>                              | Research Council of Lithuania   | LMT         |
| <b>Luxembourg</b>                             | National Research Fund  | FNR         |
| <b>Norway</b>                                 | Research Council of Norway  | RCN         |
| <b>Poland</b>                                 | National Centre for Research and Development  | NCBR        |
| <b>Portugal</b>                               | Fundação para a Ciência e a Tecnologia  | FCT         |
| <b>Portugal (Azores)</b>                      | Vice-Presidency of Azores Regional Government   | VP-GRA      |
| <b>Portugal (Centro Region)</b>               | Comissão de Coordenação e Desenvolvimento Regional do Centro  | CCDRC       |
| <b>Romania</b>                                | Executive Agency for Higher Education, Research, Development and Innovation Funding                           | UEFISCDI    |
| <b>Spain</b>                                  | National Institute of Health Carlos III   | ISCIII      |
| <b>Spain (Catalonia)</b>                      | Health Department – Generalitat de Catalunya  | DS-CAT      |

|                        |  |         |
|------------------------|--|---------|
| <b>Spain (Navarre)</b> | Government of Navarre  | CFN     |
| <b>Sweden*</b>         | Swedish Research Council   | SRC     |
| <b>Sweden</b>          | Sweden’s Innovation Agency                                       | VINNOVA |
| <b>The Netherlands</b> | The Netherlands Organisation for Health Research and Development | ZonMw   |
| <b>Turkiye</b>         | The Scientific and Technological Research Council of Turkiye     | TUBITAK |

\*final decision on participation still pending

### 3. Timeline of the call



|                                       |   |
|---------------------------------------|---|
| <b>02 January, 2024</b>               | <b>Publication of the call</b>  |
| <b>12 January, 2024</b>               | <b>Opening of the pre-proposals submission system</b>   |
| <b>05 March, 2024 (17:00, CET)</b>    | <b>Deadline for pre-proposal submission</b>   |
| <b>Expected around 20 May, 2024</b>   | Communication of the results of the pre-proposal assessment and invitation to the full-proposal stage |
| <b>20 June, 2024 (17:00, CEST)</b>    | <b>Deadline for full-proposal submission</b>  |
| <b>Mid/end of August 2024</b>         | <b>Rebuttal stage</b>   |
| <b>Expected for October 2024</b>      | Communication of the funding decisions to the applicants  |
| <b>End of 2024, beginning of 2025</b> | <b>Expected project start</b> (according to regional/national funding regulations)                    |

## 4. Rational of the call

Personalised treatments are not yet widely accessible across a diverse range of diseases. This is primarily due to knowledge gaps of disease pathogenesis, which often lead to heterogeneity in clinical manifestation and, in turn, to a different response to treatment. These lacks of understanding mean that important target structures, such as proteins, nucleic acids or other molecules whose activity or function is altered by one (or more) drug(s), are not utilised and treatments or drugs are insufficiently effective or not available at all. Efforts are needed to increase the understanding of the complexity of relevant disease pathogeneses and to support the identification of the most significant potential treatment targets. Furthermore, the drugability of potential targets needs to be confirmed. In personalised approaches, patients are stratified, e.g. through companion biomarkers that support the target choice, i.e. individualising the treatment approach and selecting and monitoring the most effective therapy.

Research in the field should lead to more available specific therapeutic targets for defined sub-groups of patients, e.g. identification of new or validation of single or combination of already existing targets, aimed at the development of precise mechanism-based treatments or drugs.

The terms “target” and “biomarker” are defined as:

-  **Target:** Targeted (mechanism-based) treatments or prevention strategies require the identification and validation of disease-relevant biological targets. A target could be e.g., a protein, a nucleic acid, or other molecules whose activity/function is modified by a (set of) drug(s), hence often referred to as a drug target, resulting in the desired positive clinical outcome, while minimising unwanted adverse responses/effects.
-  **Biomarker** (biological biomarkers and those connected to lifestyle and environmental factors): A biomarker may be a single characteristic or a panel of multiple characteristics (multimodal biomarker). Biomarkers may support targeted treatments and prevention strategies as they can be used to stratify patients into groups, increase the definition of pathogenetic processes, predict disease progression, follow-up the efficacy of a treatment, guide adaptations of treatment strategies, or assess the treatment outcome. So-called companion diagnostics are based on companion biomarkers, that help in the identification of the mechanism to be specifically targeted, support the prediction of positive or negative response to a specific treatment, i.e., identify patients before or during treatment, who will most likely benefit from the drug (medicinal product) or patients with an increased risk of adverse reactions to the treatment/drug. (Multi-component/multimodal) Diagnostic, predictive or prognostic biomarkers can support early diagnosis, disease prevention, drug target identification, treatment selection, drug dosing, overall treatment safety, etc.

As indicated above, companion biomarker(s) (sets) stratify patients into groups for targeted treatments, monitor treatment efficacy and outcomes, guide clinical studies, predict and timely monitor disease progression or remission. For instance, the presence of a (“negative” or “exclusion”) biomarker (set) could reveal the futility of a given standard treatment and contribute to the personalisation of treatments at an individual level. Companion biomarker(s) (sets) could support an efficient resource utilisation and drug administration. Furthermore, a shift from a single-biomarker approach to inclusive models of marker profiles or marker signatures/patterns may be advantageous in multi-factorial diseases. Such models have high potential to support the monitoring and assessment of several relevant biological pathways in complex pathological processes.

## 5. Aim of the call

The EP PerMed JTC2024 is co-funded by the EU and **the overall objectives of the JTC2024 are to:**

- Support research projects in human health aiming at identifying or validating targets for personalised medicine approaches in combination with development of companion biomarkers or other markers to allow for monitoring of treatment outcomes and patient stratification;
- Encourage and enable interdisciplinary collaborations by combining pre-clinical and clinical research in translational projects, and multi-actor research by engaging a range of other relevant disciplines such as bioinformatics/health informatics/data research, ELSA research, implementation research or health economics research connected to the proposed research topic, including end-user perspective analysis to empower the implementation of PM;
- Encourage cross-sectorial collaborations, by including the private sector (e.g. SMEs, small and medium-sized enterprises), industry, as well as regulatory/HTA agencies and patient organisations.

Depending on the development phase of the research, projects can focus on the following stages (specific funding regulations might apply, see Annex 2 and “Guidelines for Applicants”):

- Stage 1: Identification of novel targets for the development of a concrete and feasible PM approach, based on a clearly circumscribed biological/clinical hypothesis, in combination with companion biomarker research. Applicants are advised to use existing clinical data as a basis for target identification.
- Stage 2: Development or validation of already known but not yet established targets for a PM approach, in combination with accompanying biomarker research. This includes target validation in vitro and in animal models (proof-of-principle studies), early pharmacological and toxicity tests and, if feasible, exploratory clinical studies (see information box below) to demonstrate clinical applicability (proof-of-concept studies).

**Research projects in all disease areas are encouraged.** Consortia are required to start from a relevant clinical (unmet) need and to include activities that support a comprehensive and efficient uptake of the developed PM approach in clinical practice, with the aim that “Today’s research is tomorrow’s healthcare”.

### Companion biomarker research

Companion biomarker research is mandatorily to be connected to the target that is the major subject of the proposed project. It can be focused on diagnostic, predictive or prognostic biomarkers (biomarker panels).

#### This includes:

- Further development and validation of biomarkers (or biomarker sets already identified by biological/medical findings) as new therapy-determining or accompanying diagnostics for PM approaches.
- Initiate the steps for clinical validation of pre-existing biomarkers in compliance with quality standards for clinical use, e.g. design and validation of processes devoted to include those biomarkers in clinical practice (diagnose/monitoring/toxicity) under quality assessment.
- Research for extending known biomarkers to other diseases.

- 🎯 Research on improvements of detection methods for known biomarkers (e.g. on blood samples vs. tissue).

Applicants have to demonstrate preliminary work that shows the stratification potential of the biomarker and its potential benefit for patients. Preliminary work must be presented in the application or justified and documented by corresponding publications or applications for intellectual property rights. Furthermore, if the research on a target cannot be connected to a companion biomarker (set) but to another type of marker, this needs to be explained and justified in detail in the proposal, and it is mandatory to outline the proposed alternative strategy for the personalised approach.

**Exclusion: Research focussing only on new biomarker discovery**

Projects submitted to the JTC2024 focussing on the identification of new biomarkers as the sole purpose of the research are out of the scope.

**The core of each application must be the identification or validation of a target for PM in combination with companion biomarker research. In addition, the consortia can address accompanying research if this is necessary for the identification or validation of the target and if appropriate to the development status of the project. Projects might include:**

- 🎯 Utilisation of existing clinical and healthcare data (real-world data), in addition to pre-clinical research for validating the target.
- 🎯 Research that investigates the function of relevant targets for PM in disease pathologies or pursues options for modifying their functionality.
- 🎯 Research for repositioning of known targets/drugs for a new PM indication.
- 🎯 Research on pharmacogenomics, dose optimisation, pharmacovigilance of PM drugs and optimisation of multi-medication settings. This could for example include (pre-)clinical pharmacogenetic research to study of the interactions between genes and drugs.
- 🎯 Research fostering the harmonisation of quality standards for sample collection, processing and analysis.

### **Aspects to be considered during the construction of proposals**

Proposals **must be interdisciplinary and clearly demonstrate the potential impact on disease outcome and prevention through personalised medicine**, as well as **the added value of the transnational collaboration**; sharing of resources (e.g. registries, diagnoses, biobanks, models, databases, electronic health records, diagnostic and bioinformatics tools), platforms/infrastructures, interoperability of data harmonisation strategies and sharing of specific knowledge important for the project and the PM field. In order to achieve these goals, the necessary expertise and resources should be brought together from academia, clinical/public health sector (e.g. primary and specialised healthcare professionals), patients’ communities and private partners. The research teams within a consortium should include investigators from a broad range of relevant scientific disciplines and research fields, and bring together the necessary expertise to achieve the proposed objectives, i.e. besides pre-clinical and clinical research, it is recommended to include scientific project members with expertise in bioinformatics, ELSA research, implementation research or health economics research (see also section 2 of the “Guidelines for Applicants”). The individual project partners within a joint



application should complement each other. The proposed work should contain novel and ambitious ideas and promote innovative PM solutions moving from scientific value to patient benefits (including analyses of applicability to medical care in terms of money, time, resources and technical feasibility, etc.) and ensure an adequate analysis of the emerging ethical and the legal aspects related to the research, e.g. data sharing and protection of privacy.

Consultation with stakeholders relevant for a successful implementation into primary or specialised healthcare (e.g. regulatory authorities or health insurance providers) during the course of the project running time is recommended. How these discussions could be approached and could impact the overall project execution should be described in the proposal.

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

**EP PerMed can support exploratory clinical studies**, including e.g. those with a smaller number of patients/volunteers that aim to demonstrate the therapeutic influenceability of the target molecule under investigation or the clinical applicability of the target. This should be combined with a stratification of the respective patients/individuals using companion diagnostics. Exploratory clinical studies submitted to this call should be designed to allow future scalability, although large-scale studies cannot be funded under this call.

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

EP PerMed supports exploratory clinical studies that assess the viability of a future study (e.g. clinical trial):

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

Proposals including an exploratory clinical study must, at the full-proposal stage, include the form for “Exploratory Clinical Studies”, duly completed and appended (annex 2 of the full-proposal form). Investigators must demonstrate that the required number of patients/individuals can be enrolled in the period set for the clinical exploratory study.

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

**Please note:**

Funded Technology Readiness Levels (TRL)<sup>4</sup> differ between participating funding organisations. Please check the regional/national regulations (“Guidelines for Applicants”).

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

## End-user involvement

**EP PerMed strongly encourages the active involvement of end-users in the proposed research projects.** This includes patients, citizens, healthcare providers, health and social care service users as well as patient organisations. The goal is to raise awareness, share knowledge and improve dialogue between researchers, healthcare providers, policy-makers, industry, citizens and experts in ethics and legal field.

Accordingly, consortia submitting proposals to this call are asked to describe the level of end-user involvement in the research throughout the various stages of the research design, planning, conduct/implementation, analysis and dissemination and utilisation of the results. The extent of citizen/patient involvement may vary depending on the context of the study proposed and the regional/national regulations of participating funding organisations. The development of a patient involvement plan is recommended to describe the activities and methodologies for the patient’s involvement.

Patient organisations can be included in consortia as partners (on own funding or funded, if eligible according to regional/national funding regulations). Regardless of the funding sources, indications concerning the commitment of the partner participating in the project with own funding should be provided.

The involvement of patient organisations in research proposals submitted to this call is part of the evaluation: “2. Excellence: e. Quality of open science practices including sharing and management of research outputs and engagement of citizens, patients or patient representatives, civil society and other end users where appropriate; and 3. Quality and efficiency of the implementation: c. Interdisciplinary and intersectoral collaboration: coherent integration of suitable project partners (e.g. academia, clinical/public health sector, industry partner/SME, patient organisations) to successfully accomplish the proposed work, i.e. to identify, develop or implement personalised medicine approaches.”

## Inclusion of sex, gender analysis<sup>5</sup> or underrepresented populations

Applicants are strongly encouraged to integrate sex and gender considerations, as well as underrepresented populations (e.g. ethnic minorities), or underrepresented patient sub-groups (e.g.

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<sup>4</sup> Horizon 2020 scale for TRL: [https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016\\_2017/annexes/h2020-wp1617-annex-g-trl\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf)

<sup>5</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.cihr-irsc.gc.ca/e/49347.html>. Please consider also the work of the European Commission on gender equality in research: <https://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=gender>

children or elderly) as well as social components (e.g. different economic, educational backgrounds) in proposals submitted to the **EP PerMed** call. This includes not only the **sex distribution of research teams and the distribution of roles in a consortium** (gender balance), but also the **inclusion of sex or gender analysis in the research *per-se*** (gender dimension). This applies especially when patients are involved in the proposal. A project is considered sex- and gender-relevant when it concerns individuals or groups of people or when its findings may affect individuals or groups.

The inclusion of gender or sex or underrepresented populations analysis is assessed in the evaluation of proposals and represents one evaluation sub-criterion in “1. Excellence, c. *Appropriate consideration of the gender dimension, underrepresented populations, or specific sub-groups in research and innovation content; d. Consideration of sex aspects and underrepresented populations in research teams, if applicable.*”

## Scientific Data Open Access Policy

Applicants must clearly describe all tools, technologies, and digital supports to be used in the project, as well as the methodological approach. In addition, descriptions should be included of how data from different sources (such as different institutions) will be combined, how different data streams will be merged and how the primary outcomes will be meaningful across different institutions. Proposals should explain how the data, tools, code or algorithms gathered, developed or used through the project will be maintained after the project end and would be available (findable, accessible, interoperable and re-usable) or communicated to the wider research community, during and after the end of the project period.

In addition, **EP PerMed** expects proposals to develop data management plans (DMPs) according to international state-of-the-art standards for data security [following the **FAIR principles**<sup>6</sup>, the **General Data Protection Regulation (GDPR)**<sup>7</sup> and in accordance with **Ethical principles**<sup>8</sup> for data management]. The DMP represents an essential document for the implementation of the research, as it helps to define the responsibilities of research data management ahead of the start of the project. The consortia of projects selected for funding must submit a detailed DMP (template to be available: [www.eppermed.eu](http://www.eppermed.eu)). The project coordinator is responsible for sending the complete DMP to the JCS, no later than three months after the official start of the project and an updated DMP at the end of the project together with the final scientific report. Compliance with or updates of the DMP, must be reported in each annual scientific project progress report.

## Responsible Research and Innovation (RRI) and ethical compliance

Proposals should follow the principles of Responsible Research and Innovation (RRI). Consortia submitting a proposal to this call should demonstrate a commitment for investigating and addressing social, ethical, political, environmental or cultural dimensions of the proposed research.

Furthermore, proposed research must respect fundamental ethical principles. Applicants have to describe any potential ethical aspects of the work to be carried out, and how the project will fulfil

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<sup>6</sup> findable, accessible, interoperable and reusable (FAIR):

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

<sup>7</sup> <https://gdpr-info.eu/>

<sup>8</sup> [http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/ethics/h2020\\_hi\\_ethics-self-assess\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf),

[http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/ethics/h2020\\_hi\\_ethics-data-protection\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf)

applicable requirements in institutional, regional/national and European Union legislation (including the ethical standards and guidelines of Horizon 2020/Horizon Europe<sup>9</sup>).

Further information is available in the “Guidelines for Applicants” document, and consortia are requested to elaborate on both aspects, RRI and ethical dimensions, in the proposal application forms.

## 6. Expected Outcomes and Impacts

Research conducted in this call will specifically result in the identification or validation of targets for PM approaches for prevention, diagnosis, prognosis, and treatment of disease, and will lead to new evidence regarding their clinical impact.

Concretely, expected outcomes of funded research are:

- new or validated clinically addressable targets for the treatment of patient subgroups are available,
- the research results are shared through scientific publications and create knowledge,
- transnational and multidisciplinary collaboration or networks across sectors and in teams are achieved.

The call aims at supporting research projects that contribute to the EP PerMed (operational, specific and global) objectives and therewith contribute to the following expected impacts:

- The transnational, multidisciplinary, intersectoral and public-private collaborations established in this call will support the ‘Personalised Medicine System of Health’<sup>1</sup> in that the research, innovation and implementation fields and the involved actors are interconnected. This will contribute to a comprehensive and faster uptake of PM approaches from pre-clinical to clinical research, innovation and implementation in a circular and bidirectional manner and support the development of innovative tools, technologies and digital solutions for health and care.
- With this funding measure, EP PerMed aims to enhance the understanding of diseases and translate research achievements (diagnostic tools, biomarkers, clinical strategies, advanced therapies, prevention strategies and digital solutions, big data, health economics, ELSI) within PM and towards personalised care.
- Overall, PM research funded in this call is expected to support Europe’s strategy to stay in forefront of research and innovation and foster, simultaneously, synergies between regions and countries. Outcomes of the research projects are meant to impact the European biotechnology and health/pharma industry. PM approaches will lead to reduced adverse effects, more efficient diagnostics and (follow-up of) treatments as well as new drug and technology production, faster adoption of innovation and increase the market competitiveness.

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<sup>9</sup> [https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm)

## 7. Application

### A. Eligibility criteria

- Only transnational projects will be funded.
- **Each consortium must involve at least three partners from three different EU Member States or Associated Countries<sup>10</sup> whose funding organisations participate in the call** (see list above)<sup>11</sup>. **Each of these partners must be eligible and request funding from the respective funding organisation.** All three legal entities must be independent of each other.
- The **project coordinator must be eligible to be funded** by his/her regional/national participating funding organisation.

#### Consortium composition:

- **Max. 2 project partners per consortium can request funding from the same funding organisation.** For some funding organisations, the maximum number of eligible partners who can be funded in one project is limited to one (see also “Guidelines for Applicants” for individual funding rules).
- **Pre-proposal stage:**
  - Maximum number of partners is 6 (no more than 2 partners from the same country),
  - Maximum number of partners can be 7 if the consortium includes a 3<sup>rd</sup> partner of the same country (**condition:** funding requested from at least 2 different funders of the respective country; applies to only one country per consortium).
- **Widening concept<sup>12</sup>:** Consortia are allowed to include in the **full-proposal phase** an additional project partner that is eligible to receive funding from a funding organisation that is underrepresented in the second stage of the call and that agrees to participate in the widening option (a list of underrepresented regions/countries will be provided to coordinators invited to submit full-proposals).
- **No more than one partner with their own funding is allowed** in the consortia with at least three partners eligible for funding (more indications in “B. Funding recipients” of this section 7).
- **Exception:** To facilitate the integration of patient organisations in consortia, they can be added to a consortium as additional partners at the pre-proposal stage or full-proposal stage. Patient organisations can be added as additional partner(s) either on own funds or by applying for funding, if eligible, from the respective funding organisations. The consortia must follow all of the above-mentioned rules regarding the consortia composition without counting the patient organisations, except for the following rule: **within one consortium, no more than 2 partners can request funding from the same funding organisation, including patient organisations.** For some funding organisations, the maximum number of eligible partners who can be funded in one project is one.

<sup>10</sup> Indications for Associated Countries and Third Countries to Horizon Europe: [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation\\_horizon-euratom\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf)

<sup>11</sup> If ERDF funds are used, the following applies: “(...) must involve at least three Member States, or alternatively two Member States and at least one associated country whose (...)” Please consult the Guidelines for Applicants document.

<sup>12</sup> **Widening concept:** Consortia are allowed to include in the full-proposal phase a new project partner that is eligible to receive funding from a funding organisation that is underrepresented in the first stage of the call and that agrees to participate in the widening option.

## B. Funding recipients

Joint research proposals may be submitted by applicants belonging to an entity according to the following categories (subject to regional/national funding regulations; see “Guidelines for Applicants”):

- A. Academia** (research teams working in universities, other higher education institutions) **or research institutes;**
- B. Clinical/public health sector** (research teams working in hospitals/public health and/or other healthcare settings and health organisations). Participation of clinicians (e.g. medical doctors, nurses) in the research teams is encouraged;
- C. Private for-profit (industry) partners, e.g. SME<sup>13</sup>** (small and medium-sized enterprises) **and private non-profit partners, e.g. foundations, associations or non-governmental organisations.**

**Consortia submitting applications to this call are strongly encouraged to include partners from different categories (A, B and C) in line with the crosscutting/multidisciplinary nature of the call, where the aim is to include partners at different levels in the value chain.** The number of participants, the category of partner organisations and their research contribution should be appropriate for the aims of the call (section 5), the aims of the research project and should be reasonably balanced in terms of international participation (the different points are reflected in the three evaluation criteria). Each collaborative project should represent the critical mass necessary to achieve the ambitious scientific goals and should clearly demonstrate the added value for the cooperation.

Research groups, SMEs and industrial partners (non-SMEs) or not-for-profit organisations not eligible for funding by one of the organisations participating in this joint transnational call (e.g. from non-funding countries or not fundable according to regional/national regulations of the participating funding organisations) may participate if they are able to secure their own funding. They are treated as full partners and must be included in the pre- and full-proposal templates as such. Please note that **no more than one partner with own funding** is allowed in consortia comprising at least 3 partners eligible for funding (i.e. a consortium of min. 4 project partners). A letter of commitment must be included as an annex to the proposal, at the full-proposal stage, summarising the commitment of the partner participating in the project with own funding and demonstrating the source of funding. The budget of a non-funded partner shall not exceed 30% of the total project budget requested.

To collect the necessary patient data or samples for the proposed study, a consortium may need to collaborate with other centres. If the only role of those centres is to provide patient data 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.

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** among the project’s principal investigators. The nomination of a project co-coordinator is not allowed. The coordinator must be eligible to be funded by his/her regional/national participating funding organisation. The project coordinator will represent the consortium externally and in dealings with the JCS and the **Call Steering Committee<sup>14</sup> (CSC)**, and will be responsible for its internal scientific

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<sup>13</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>14</sup> Call Steering Committee: comprises a single representative from each country’s/region’s funding organisation.

management, such as project monitoring, reporting, intellectual property rights (IPR) management and contact with the JCS.

| Number of partners in the proposal*           | Pre-proposal |   |   |   |   | Full-proposal<br>(only by inclusion of one underrepresented region/country) |
|---|--------------|---|---|---|---|---|
|   | 3            | 4 | 5 | 6 | 7 | +1  |
| Maximum number of partners with own funding** | 0            | 1 | 1 | 1 | 1 | 1   |
| Maximum number of partners per country***     | 1            | 2 | 2 | 2 | 3 | 3 (for consortia with 8 partners)   |

\* minimum of three partners eligible for funding from three different EU Member States countries, or two EU Member States and at least one Associated Country whose funders participate. Patient organisations are not included in this calculation.

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

\*\*\* patient organisations are not included in this calculation and can be added as additional partners in the pre-proposal or full-proposal stage. They can participate either on own funds or apply for funding, if eligible, from the regional/national funding organisation. Please note: **within one consortium, not more than 2 partners can request funding from the same funding organisation, including patient organisations.** For some funding agencies, the maximum number of eligible partners who can be funded in one project is one.

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

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

A consortium can apply for a redress procedure in the case a proposal has been rejected (see also section 10).

For regional/national eligibility reasons, applicants must indicate during pre-proposal submission 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.

### C. Financial and legal aspects

The maximum duration of projects is three years in accordance with **EP 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).

#### **D. Submission of joint proposals**

A **two-step submission and evaluation procedure** has been established for joint applications: pre-proposals and full-proposals. In both phases, one joint proposal document shall be prepared by the partners of a joint transnational project. The document must be submitted to the JCS by the project coordinator by uploading it via the electronic submission system (<https://ptoutline.eu/app/eppermed2024>). The proposals must be written in English, must follow the template form in terms of overall size and section page and character limits, and must strictly adhere to the “Guidelines for Applicants”. The pre-proposal form can be downloaded from the **EP PerMed** website ([www.eppermed.eu](http://www.eppermed.eu)). Pre-proposals that do not use the respective template will be declared ineligible. **Pre-proposals** must be received by the JCS in electronic format no later than **05 March, 2024 at 17:00 CET**.

The decision on which applicants are selected to submit a full-proposal will be communicated to applicants solely by the JCS around 20 May, 2024. The JCS will send a full-proposal application template to the coordinators of those research proposals invited to the full-proposal stage.

**Full-proposals** must be received by the JCS in electronic format no later than **20 June, 2024 at 17:00 CEST**. Please note that **joint full-proposals will be accepted only from those applicants explicitly invited by the JCS to submit**. Full-proposals that do not use the respective template are ineligible.

Any fundamental changes between the pre- and full-proposal concerning the composition of the consortium, project objectives or requested budget must be communicated to the JCS and to the regional/national funding organisations. In exceptional cases, these changes may be accepted if detailed justification is provided and if they are accepted by the CSC.

Further information on electronic submission of pre- and full-proposals is available on the **EP PerMed** website ([www.eppermed.eu](http://www.eppermed.eu)) and in the “Guidelines for Applicants”. Applicants should take note of individual regional/national rules, and should contact their regional/national funding organisation if they have any questions.

Applicants from some regions/countries may be required to submit the additional regional/national proposal or other information (in some cases before the deadline of this call) directly to their relevant regional/national funding organisations. Applicants are therefore **strongly advised** to check their funding organisation’s specific regulations. See “Guidelines for Applicants” for more details.

**Ethical and legal issues** must be addressed in each application, according to the relevant region’s/country’s regulations.

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

#### **E. Further information**

Applicants should contact their corresponding regional/national representative to enquire about eligibility with their respective funding organisations prior to submitting an application (see regional/national contact details, Annex I). For additional information, please contact the JCS



([EPPerMed@agencerecherche.fr](mailto:EPPerMed@agencerecherche.fr)). Adherence to the regional/national funding regulations in the “Guidelines for Applicants” document is mandatory ([www.eppermed.eu](http://www.eppermed.eu)).

## 8. Formal check and evaluation of proposals

### A. Formal check and evaluation of pre-proposals

The JCS will check all proposals to ensure that they meet the call’s formal criteria (see also “7. Applications, A. Eligibility Criteria”). In parallel, the JCS will forward the proposals to the regional/national funding organisations, which will perform a check for compliance with their regional/national regulations.

Please note that if a proposal includes an ineligible partner, the whole proposal may be rejected, without further review (for the definition of eligible partners see “Guidelines for Applicants” and regional/national funding regulations and contact your regional/national contact person listed in Annex I).

After passing the eligibility check (performed by the JCS and the participating funding agencies), pre-proposals will be sent to at least three reviewers for the first evaluation (see evaluation criteria below, “8. Formal check and evaluation of proposals, C. Evaluation criteria”). The reviewers will assess the pre-proposal and complete a written evaluation form with scores and comments for the evaluation criteria.

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

The CSC members will meet to decide which pre-proposals will be invited for full-proposal submission based on the reviewers’ scores and recommendations, and to ensure a reasonable balance of requested and available regional/national budgets.

### B. Formal check and evaluation of full-proposals. Rebuttal stage

The JCS will review the full-proposals to ensure that they meet the call’s formal criteria and have not changed substantially from the respective pre-proposals prior to sending them to the reviewers.

Each full-proposal will be allocated to at least three reviewers. The reviewers will assess the full-proposal and complete a written evaluation form with scores and comments for each criterion (see evaluation criteria below).

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

The reviewers will meet in a Peer Review Panel (PRP) to discuss all proposals (and the rebuttal letters), to produce a joint assessment report for each full-proposal, to be sent by the JCS to the project coordinators, and a ranking list of proposals recommended for funding. The composition of the PRP may be communicated through the EP PerMed website at the end of the entire review process.

## C. Evaluation criteria

Pre-proposals and full-proposals will be assessed according to specific evaluation criteria using a common evaluation form. A scoring system from 0 to 5 will be used to evaluate the proposal's performance with respect to the different evaluation criteria.

### Scoring system:

**0: Failure.** The proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.

**1: Poor.** The criterion is inadequately addressed, or there are serious inherent weaknesses.

**2: Fair.** The proposal broadly addresses the criterion, but there are significant weaknesses.

**3: Good.** The proposal addresses the criterion well, but a number of shortcomings are present.

**4: Very Good.** The proposal addresses the criterion very well, but a small number of shortcomings are present.

**5: Excellent.** The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.

Evaluation scores will be awarded for the three main criteria, each as a whole, and not separately for the different aspects listed below the criteria. The three criteria are weighted equally and the maximum total score for the three evaluation criteria that can be achieved in the remote evaluation is 15 points. The threshold for every individual criterion based on the evaluation of the three reviewers will be 3 (overall threshold of 9 for proposals in both steps of the evaluation process).

### Evaluation criteria:

#### 1. Excellence:

- a. Clarity and pertinence of the project's objectives (and them fitting to the scope of the call, including the demonstration of the stratification potential of the companion biomarker/s), and the extent to which the proposed work is ambitious, and goes beyond the state-of-the-art (including innovative potential);
- b. Soundness of the proposed methodology, including the underlying concepts, models, assumptions, multidisciplinary and intersectoral approaches;
- c. Appropriate consideration of the gender dimension, underrepresented populations, or specific sub-groups in research and innovation content;
- d. Consideration of sex aspects and underrepresented populations in research teams, if applicable;
- e. Quality of open science practices including sharing and management of research outputs and engagement of citizens, patients or patient representatives, civil society and other end users where appropriate.

#### 2. Impact:

- a. Credibility of the pathways to achieve the expected outcomes and impacts specified in the call text, and the likely scale and significance of the contributions due to the project;

- b. Potential impact with respect to the development of personalised medicine (e.g. clinical and other health-related applications, translatability of the proposed research to practice in healthcare);
- c. Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities;
- d. 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.

Sub-criterion 2c will be evaluated at the full-proposal evaluation stage.

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

- a. Quality and effectiveness of the work plan (including adequacy of the time schedule) and appropriateness of the effort assigned to work packages, and the resources overall;
- b. Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise. This includes: appropriate expertise of partners responsible for proposed work packages (including international competitiveness of participants in the field(s) and previous work supporting the proposed study with preliminary data);
- c. Interdisciplinary and intersectoral collaboration: coherent integration of suitable project partners (e.g. academia, clinical/public health sector, industry partner/SME, patient organisations) to successfully accomplish the proposed work, i.e. to identify, develop or implement personalised medicine approaches;
- d. Appropriateness of the management structures and procedures to address risk assessment, innovation management and RRI, including ethical considerations;
- e. Sustainability of the research capacities initiated by the project (e.g. FAIR data management, Open Science practices). Quality of the Intellectual Property management.

Sub-criteria 3d and 3e will be evaluated at the full-proposal evaluation stage.

## **D. Conflicts of interest (Evaluation panel)**

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

A first review for conflicts of interest will be performed by the JCS when analysing the reviewers' publications. After receiving the proposals, reviewers are requested to indicate whether there is a conflict of interest with any of the researchers or research groups in the proposals for review. Reviewers will be asked to declare 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.

## E. Ethical clearance - Ethics and RRI evaluation

It is mandatory for applicants to complete and “Ethical self-assessment” (Annex 1 of the full-proposal application form). After the PRP meeting, an Ethics and RRI evaluation will take place for the full-proposals which are recommended for funding by the PRP and selected for funding by the CSC, to verify alignment with ethical norms and regulations. If further clarifications are necessary, the consortium will be contacted to take some actions or submit additional documents. The ethics experts may put forward additional conditions that need to be fulfilled by the applicants. Only those proposals approved by both the scientific evaluation and ethical assessment, complying with the central Horizon Europe and regional/national ethical requirements, will be funded.

## 9. Final decision on funding

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

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




## 10. Redress procedure

Applicants can appeal against the evaluation outcome if they suspect a breach in the application of the evaluation and selection procedures. This redress procedure only covers the procedural aspects of the call. The redress will not call into question the scientific or technical judgement of appropriately qualified experts/evaluators.

Applicants shall submit their appeal to the JCS via email ([EPPerMed@agencerecherche.fr](mailto:EPPerMed@agencerecherche.fr)) up to seven (7) calendar days following the dispatch of the evaluation outcome email by the JCS at the end of each stage (first or second step). The proposal outcome email containing the results of the evaluation will give information on the appeals procedure, which is described below.

### Admissibility of appeals

For an appeal to be admissible the following conditions must be met:

-  The appeal must be submitted by the coordinator of the proposal to which the appeal relates;
-  Only one appeal per proposal will be considered;
-  The appeal must be submitted via email within a seven (7) calendar days deadline. The appeal must contain the following minimum information:
  - The name of the call for proposals;
  - The proposal acronym;
  - The title of the proposal;
  - A description of the alleged shortcomings of the evaluation procedure.

The appeal must demonstrate a procedural irregularity, factual error, manifest error of assessment, misuse of powers, or a conflict of interests. Appeals that do not meet the above conditions, or do not deal with the evaluation of a specific proposal or express mere disagreement with the result or the reasoning of the evaluation might be judged as not suitable for redress.

## Procedure

Upon receipt of an appeal, an acknowledgement of receipt will be sent by the JCS within seven (7) calendar days. The acknowledgement shall report the redress process and the anticipated date by which a decision on the appeal will be communicated to the appellant.

All appeals received by the seven (7) calendar days deadline will be processed together, and the decision of the CSC2024 will be communicated to the appellant by the JCS within seven (7) calendar days from the deadline for submitting the appeals.

## 11. Project Start, Consortium Agreement and Data Management Plan

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

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

## 12. Reporting requirements and Open Access to publications

On behalf of all participating project partners, each project coordinator shall submit annual scientific progress reports, in English to the JCS, in the first and second year, and a final scientific report of the transnational project at the end of the project duration. A report template will be provided by the JCS stating the scientific progress, the goals that have been met and corrective measures in the event that the annual project plan has not been executed. The project partners' principal investigators may also be required to submit individual reports to their respective funding agency/body in accordance with the respective regional/national regulations. In addition, project coordinators may be asked to present the project results at EP PerMed meetings and may be invited to attend at least two status seminars. Travel expenses to attend these mandatory meetings should be included in the proposal budget plans. In case of events being organised online, all partners of the consortia will be encouraged to participate.

Funded project consortia shall participate in follow-up surveys up to two years after the project has officially be ended.

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

Upon notification, project coordinators are required to deliver a project abstract suitable for communication and dissemination purposes.

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

Publication of the scientific outcomes of the project is mandatorily subject to open access, and a corresponding budget should be allocated for this in the proposal's budget plan. Research projects funded through EP PerMed are eligible to publish on Open Research Europe (ORE)<sup>15</sup>, an open access publishing platform of the EC.

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational EP PerMed-funded projects include proper acknowledgement of the EP PerMed and the respective funding partner organisations:

*“This project received funding from [name of funding organisations, or an acknowledgment as requested by your regional/national funding organisation] under the frame of the European Partnership for Personalised Medicine, EP PerMed, (GA N° 101137129 of the EU Horizon Europe Research and Innovation Programme)”.*

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<sup>15</sup> <https://open-research-europe.ec.europa.eu/>

### 13. Annex I. Regional/National Contact Details

| <i>Name of participating organisation</i>  | <i>Country/Region</i>                  | <i>Regional/National contact</i>  |
|--|--|---|
| <b><i>Austrian Science Fund, (FWF)</i></b>   | Austria                                | Hannes Zwickl<br>hannes.zwickl@fwf.ac.at<br>Tel.: +43 676 83487 8219  |
| <b><i>Vlaams Gewest - VLAIO Flanders Innovation &amp; Entrepreneurship – Flemish Government, (FIO (VLAIO))</i></b>                   | Belgium (Flanders)                     | Patricia Menten<br>patricia.menten@vlaio.be<br>Tel.: +32 2 432 43 29  |
| <b><i>The Research Foundation – Flanders, (FWO)</i></b>  | Belgium (Flanders)                     | Toon Monbaliu (FO)<br>Kristien Peeters (SBO)<br>europe@fwo.be<br>Tel.: +32 (0)2 550 15 70<br>Tel.: +32 (0)2 550 15 95         |
| <b><i>Service Public De Wallonie, (SPW EER)</i></b>  | Belgium (Walloon region)               | Thierry Lemoine<br>Thierry.lemoine@spw.wallonie.be<br>Tel.: +(0)32 81 33 45 26  |
| <b><i>Fund for Scientific Research – FNRS, (F.R.S.-FNRS)</i></b>   | Belgium (Wallonia-Brussels Federation) | Agnès Roba<br>Joël Groeneveld<br>international@frs-fnrs.be<br>Tel.: +32 2504 9236<br>Tel.: +32 2504 9270                      |
| <b><i>Innovation Fund Denmark, (IFD)</i></b>   | Denmark                                | Katrine Boeriis<br>katrine.boeriis@innofond.dk<br>internationale@innofond.dk<br>Tel.: +45 61 90 50 06                         |
| <b><i>Estonian Research Council, (ETAG)</i></b>  | Estonia                                | Margit Suuroja<br>Margit.Suuroja@etag.ee<br>Tel.: +372 731 7360<br>Argo Soon<br>Argo.Soon@etag.ee<br>Tel.: +372 515 3424      |
| <b><i>Business Finland, (BFRK)</i></b>   | Finland                                | Matti Hiltunen<br>matti.hiltunen@businessfinland.fi<br>Norma Jäppinen<br>norma.jappinen@businessfinland.fi                    |
| <b><i>Research Council of Finland, (AKA)</i></b>   | Finland                                | Rita Rinnankoski-Tuikka<br>rita.rinnankoski@aka.fi<br>Marko Uutela<br>marko.uutela@aka.fi                                     |
| <b><i>Agence Nationale de la Recherche, (ANR)</i></b>  | France                                 | Monika Frenzel<br>Tel: (+33) (0) 1 73 54 83 32<br>and (+33) 1 78 09 80 36<br>Mathias Vetillard<br>EPPerMed@agencerecherche.fr |
| <b><i>Federal Ministry of Education and Research, (BMBF)<br/>German Aerospace Center e.V. – Project Management Agency, (DLR)</i></b> | Germany                                | Alexandra Becker<br>permed@dlr.de<br>Tel.: +49 228 3821-2211  |

| <b>Name of participating organisation</b>  | <b>Country/Region</b> | <b>Regional/National contact</b>   |
|--|-----------------------|--|
| <b>Federal Ministry of Health, (BMG)<br/>German Aerospace Center e.V. –<br/>Project Management Agency, (DLR)</b> | Germany               | Fabian Gondorf<br>permed@dlr.de<br>Tel.: +49 228 3821-2211   |
| <b>Saxon State Ministry for Science,<br/>Culture and Tourism, (SMWK)</b>   | Germany (Saxony)      | Gabriele Süptitz<br>gabriele.sueptitz@smwk.sachsen.de<br>EuProNet@smwk.sachsen.de<br>Tel.: +49 351 564-64210   |
| <b>National Research, Development and<br/>Innovation Office, (NKFIH)</b>   | Hungary               | Klára Horváth<br>klara.horvath@nkfi.gov.hu<br>Tel.: +36 1 896 37 48  |
| <b>The Icelandic Centre for Research,<br/>(RANNIS)</b>   | Iceland               | Helga Snævarr Kristjánsdóttir<br>Helga.s.kristjansdottir@rannis.is   |
| <b>Health Research Board, (HRB)</b>  | Ireland               | Siobhan Hackett<br>eujointprogrammes@hrb.ie<br>Tel.: +353 1 234 5000   |
| <b>Science Foundation Ireland, (SFI)</b>   | Ireland               | Maria Nash<br>maria.nash@sfi.ie<br>eu-Cofund@sfi.ie  |
| <b>Chief Scientist Office, Ministry of<br/>Health, (CSO-MOH)</b>   | Israel                | Liron Even-Faitelson<br>Liron.ef@moh.gov.il<br>Tel.: +972-2-5082168  |
| <b>Italian Ministry of Health, (IT-MoH)</b>  | Italy                 | Maria José Ruiz Alvarez<br>mj.ruizalvarez-esterno@sanita.it<br>Tel.: (+39) 06 5994.3214<br>and (+39) 06 4990 6836<br>Chiara Ciccarelli<br>c.ciccarelli@sanita.it<br>Tel.: (+39) 06-5994 3919 |
| <b>Italian Ministry of Universities and<br/>Research, (MUR)</b>  | Italy                 | Aldo Covello<br>aldo.covello@mur.gov.it<br>Tel.: +39 375 510 2431  |
| <b>Fondazione Regionale per la Ricerca<br/>Biomedica, (FRRB)</b>   | Italy (Lombardy)      | Erica Torti<br>Carmen De Francesco<br>bandi@frrb.it<br>Tel.: (+39) 02 6765.0166<br>Tel.: (+39) 02 6765.0170  |
| <b>Tuscany Region, (RT)</b>  | Italy (Tuscany)       | Donatella Tanini<br>Teresa Vieri<br>eppermed@regione.toscana.it<br>Tel.: +39 055 4383256<br>Tel.: +39 055 4383289  |
| <b>Latvian Council of Science, (LZP)</b>   | Latvia                | Uldis Berkis<br>Uldis.Berkis@lzp.gov.lv<br>Tel.: +37129472349  |
| <b>Research Council of Lithuania, (LMT)</b>  | Lithuania             | Živilė Ruželė<br>zivile.ruzele@lmt.lt<br>Tel.: (+370) 676 14383  |



| <i>Name of participating organisation</i>  | <i>Country/Region</i>    | <i>Regional/National contact</i>   |
|--|--------------------------|--|
| <b>National Research Fund, (FNR)</b>   | Luxembourg               | Gideon Gießelmann<br>gideon.giesselmann@fnr.lu<br>Tel.: +352 691 362 805   |
| <b>The Research Council of Norway, (RCN)</b>   | Norway                   | Karianne Solaas<br>kso@rcn.no<br>Tel.: +47 945 35 380<br>Katrine Rolid<br>karo@rcn.no<br>Tel.: +47 415 48 328  |
| <b>National Centre for Research and Development, (NCBR)</b>  | Poland                   | Anna Stępień<br>anna.stepien@ncbr.gov.pl<br>Tel.: +48 22 39 07 210   |
| <b>Fundação para a Ciência e a Tecnologia, (FCT)</b>   | Portugal                 | Rita Cavaleiro<br>Pedro Ferreira<br>EPPerMed@fct.pt<br>Tel.: +351 213 911 541 /<br>+351 213 924 445  |
| <b>Vice-Presidency of Azores Regional Government, (VP-GRA)</b>   | Portugal (Azores)        | Maria Vale<br>Tel.: 00351 296 308 922<br>Maria.LA.Vale@azores.gov.pt   |
| <b>Comissão de Coordenação e Desenvolvimento Regional do Centro, (CCDRC)</b>                           | Portugal (Centro Region) | Sophie Patrício<br>Dora Cabete<br>ccdrc.projects@ccdrc.pt<br>Tel.: +351 239 400 100  |
| <b>Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI)</b> | Romania                  | Mihaela Manole<br>mihaela.manole@uefiscdi.ro<br>Tel.: +4021.302.38.63  |
| <b>National Institute of Health Carlos III, (ISCIII)</b>   | Spain                    | María Callejo Arranz<br>mcallejo@isciii.es<br>Tel.: +34918222503   |
| <b>Health Department – Generalitat de Catalunya, (DS-CAT)</b>  | Spain (Catalonia)        | Montserrat Llavayol<br>peris@gencat.cat<br>Tel.: +34 935566103   |
| <b>Government of Navarre, (CFN)</b>  | Spain (Navarre)          | Javier Rodrigo<br>Javier.rodrigo.aznarez@navarra.es<br>Tel.: +34 848 42 76 69  |
| <b>Swedish Research Council, (SRC)</b>   | Sweden                   | Karin Sikström<br>karin.sikstrom@vr.se<br>Maria Nilsson<br>maria.nilsson@vr.se   |
| <b>Sweden’s Innovation Agency, (VINNOVA)</b>   | Sweden                   | Anna-Carin Christoffersson<br>anna-<br>carin.christoffersson@vinnova.se<br>Tel.: +46 730 51 98 41<br>Malin Eklund<br>Malin.eklund@Vinnova.se<br>Tel.: +46 730 20 39 53 |

| <i>Name of participating organisation</i>   | <i>Country/Region</i> | <i>Regional/National contact</i>   |
|---|-----------------------|--|
| <b><i>The Netherlands Organisation for Health Research and Development, (ZonMw)</i></b> | The Netherlands       | Rob Diemel<br>Kirsten IJsebaert<br>EP-PerMed@zonmw.nl<br>Tel.: +31 70 349 5252 |
| <b><i>The Scientific and Technological Research Council of Turkey, (TUBITAK)</i></b>    | Turkiye               | N. Selcan TÜRKER<br>selcan.turker@tubitak.gov.tr<br>Tel.: +90 312 298 1760     |

## 14. Annex II. Indicative funding commitments of the participating organisations of the EP PerMed JTC2024

(This table is provided for initial overview only. Please refer to the regional/national guidelines for details.)

| Name of participating organisation  | Country / Region                       | Funding academic or clinical/ academic partner* | Funding private partners*        | Funding of research stage (see section 5) |   | Tentative initial funding commitment (M€ for 3 years) | Envisaged number of teams potentially funded with the tentative initial funding commitment |
|---|--|---|----------------------------------|---|---|---|--|
|   |  |   |                                  | 1   | 2 |   |  |
| <b>Austrian Science Fund, (FWF)</b>   | Austria                                | ✓   | ✓                                | ✓   | ✓ | 1.8   | 3-4  |
| <b>Vlaams Gewest - VLAIO Flanders Innovation &amp; Entrepreneurship – Flemish Government, (FIO (VLAIO))</b> | Belgium (Flanders)                     | ✗ academic partner<br>✓ clinical partner        | ✓                                | ✓   | ✓ | 1.0   | 2-3  |
| <b>The Research Foundation – Flanders, (FWO)</b>  | Belgium (Flanders)                     | ✓   | ✗                                | ✓   | ✓ | 0.7   | 2-3  |
| <b>Service Public De Wallonie, (SPW EER)</b>  | Belgium (Walloon region)               | ✓ academic partner<br>✗ clinical partner        | ✓ For-profit<br>✗ Not for-profit | ✗   | ✓ | 1.0   | 3  |
| <b>Fund for Scientific Research – FNRS, (F.R.S.-FNRS)</b>   | Belgium (Wallonia-Brussels Federation) | ✓ academic partner<br>✗ clinical partner        | ✓ Not for-profit<br>✗ for-profit | ✓   | ✗ | 0.3   | 1  |
| <b>Innovation Fund Denmark, (IFD)</b>   | Denmark                                | ✓   | ✓                                | ✓   | ✓ | 1.0   | 2-5  |
| <b>Estonian Research Council, (ETAG)</b>  | Estonia                                | ✓   | ✓                                | ✓   | ✓ | 0.3   | 1  |

| Name of participating organisation  | Country / Region | Funding academic or clinical/ academic partner* | Funding private partners*        | Funding of research stage (see section 5) |   | Tentative initial funding commitment (M€ for 3 years) | Envisaged number of teams potentially funded with the tentative initial funding commitment |
|---|------------------|---|----------------------------------|---|---|---|--|
|   |                  |   |                                  | 1   | 2 |   |  |
| <b>Business Finland, (BFRK)</b>   | Finland          | ✓ academic partner<br>✗ clinical partner        | ✓ For-profit<br>✗ Not for-profit | ✓   | ✓ | 3.0   | ~14  |
| <b>Research Council of Finland, (AKA)</b>   | Finland          | ✓   | ✓ For-profit                     | ✓   | ✓ | 0.85  | ~3   |
| <b>Agence Nationale de la Recherche, (ANR)</b>  | France           | ✓   | ✓                                | ✓   | ✓ | 3.5   | ~13  |
| <b>Federal Ministry of Education and Research, (BMBF) / German Aerospace Center e.V. – Project Management Agency, (DLR)</b> | Germany          | ✓   | ✓                                | ✓   | ✓ | 3.0   | 10   |
| <b>Federal Ministry of Health, (BMG) / German Aerospace Center e.V. – Project Management Agency, (DLR)</b>                  | Germany          | ✓   | ✓                                | ✓   | ✓ | 2.0   | 6-7  |
| <b>Saxon State Ministry for Science, Culture and Tourism, (SMWK)</b>  | Germany (Saxony) | ✓   | ✓                                | ✓   | ✓ | 1.4   | No limitation  |
| <b>National Research, Development and Innovation Office, (NKFIH)</b>  | Hungary          | ✓   | ✓                                | ✓   | ✓ | 0.5   | 2-3  |
| <b>The Icelandic Centre for Research, (RANNIS)</b>  | Iceland          | ✓   | ✗                                | ✓   | ✓ | 0.3   | 1  |
| <b>Health Research Board, (HRB)</b>   | Ireland          | ✓   | ✗ For-profit<br>✓ Not for-profit | ✓   | ✓ | 0.53  | 1-2  |

| Name of participating organisation                           | Country / Region | Funding academic or clinical/ academic partner*                          | Funding private partners*                                  | Funding of research stage (see section 5) |    | Tentative initial funding commitment (M€ for 3 years) | Envisaged number of teams potentially funded with the tentative initial funding commitment |
|--|------------------|--|--|---|----|---|--|
|  |                  |  |  | 1   | 2  |   |  |
| <b>Science Foundation Ireland, (SFI)</b>                     | Ireland          | ✓ academic partner   | ✗  | ✓   | ✓* | 1.5   | ~3-5   |
| <b>Chief Scientist Office, Ministry of Health, (CSO-MOH)</b> | Israel           | ✓  | ✗  | ✓   | ✓* | 0.32  | 2  |
| <b>Italian Ministry of Health, (IT-MoH)</b>                  | Italy            | ✗ academic partner<br>✓ clinical partner                                 | ✗  | ✓   | ✓  | 2.0   | 5  |
| <b>Italian Ministry of Universities and Research, (MUR)</b>  | Italy            | ✓  | ✓  | ✓   | ✓  | 1.0   | 4  |
| <b>Fondazione Regionale per la Ricerca Biomedica, (FRRB)</b> | Italy (Lombardy) | ✓  | ✗  | ✓   | ✓  | 1.5   | 3-4  |
| <b>Tuscany Region, (RT)</b>                                  | Italy (Tuscany)  | ✓  | ✗ For-profit<br>✓ Not for-profit<br>Research organisations | ✓   | ✓  | 0.3   | 2-3  |
| <b>Latvian Council of Science, (LZP)</b>                     | Latvia           | ✓ Universities and research institutes<br>✓ Clinical only as enterprises | ✓ Only as enterprise, subject to additional requirements   | ✓   | ✓  | 0.6   | 2  |
| <b>Research Council of Lithuania, (LMT)</b>                  | Lithuania        | ✓  | ✗  | ✓   | ✓  | 0.3   | 2  |
| <b>National Research Fund, (FNR)</b>                         | Luxembourg       | ✓  | ✗ For-profit<br>✓ Not for-profit                           | ✓   | ✓  | 0.3   | 1-2  |

| Name of participating organisation   | Country / Region         | Funding academic or clinical/ academic partner* | Funding private partners*        | Funding of research stage (see section 5) |   | Tentative initial funding commitment (M€ for 3 years) | Envisaged number of teams potentially funded with the tentative initial funding commitment |
|--|--------------------------|---|----------------------------------|---|---|---|--|
|  |                          |   |                                  | 1   | 2 |   |  |
| <b>The Research Council of Norway, (RCN)</b>   | Norway                   | ✓   | ✓                                | ✓   | ✓ | 1.5   | 4-5  |
| <b>National Centre for Research and Development, (NCBR)</b>  | Poland                   | ✓   | ✓ For-profit<br>✗ Not for-profit | ✓   | ✓ | 1.1   | 1-3  |
| <b>Fundação para a Ciência e a Tecnologia, (FCT)</b>   | Portugal                 | ✓   | ✓                                | ✓   | ✓ | 0.3   | 2-3 consortia  |
| <b>Vice-Presidency of Azores Regional Government, (VP-GRA)</b>   | Portugal (Azores)        | ✓   | ✗ For-profit<br>✓ Not for-profit | ✓   | ✓ | 0.1   | 1  |
| <b>Comissão de Coordenação e Desenvolvimento Regional do Centro, (CCDRC)</b>                           | Portugal (Centro Region) | ✓   | ✓                                | ✗   | ✓ | 0.3   | ~2-3   |
| <b>Executive Agency for Higher Education, Research, Development and Innovation Funding, (UEFISCDI)</b> | Romania                  | ✓   | ✓                                | ✓   | ✓ | 1.0   | ~4-5   |
| <b>National Institute of Health Carlos III, (ISCIII)</b>   | Spain                    | ✓   | ✗ For-profit<br>✓ Not for-profit | ✓   | ✓ | 3.0   | ~10  |
| <b>Health Department – Generalitat de Catalunya, (DS-CAT)</b>  | Spain (Catalonia)        | ✓   | ✗ For-profit<br>✓ Not for-profit | ✓   | ✓ | 0.7   | 3-4  |
| <b>Government of Navarre, (CFN)</b>  | Spain (Navarre)          | ✓   | ✓                                | ✓   | ✓ | 0.2   | 1-2  |
| <b>Swedish Research Council, (SRC)</b>   | Sweden                   | ✓   | ✗                                | ✓   | ✓ | 1.15  | 3-5  |
| <b>Sweden’s Innovation Agency, (VINNOVA)</b>   | Sweden                   | ✓   | ✓                                | ✓   | ✓ | 2.1   | 5-7  |

| Name of participating organisation   | Country / Region | Funding academic or clinical/ academic partner* | Funding private partners* | Funding of research stage (see section 5) |   | Tentative initial funding commitment (M€ for 3 years) | Envisaged number of teams potentially funded with the tentative initial funding commitment |
|--|------------------|---|---------------------------|---|---|---|--|
|  |                  |   |                           | 1   | 2 |   |  |
| <b>The Netherlands Organisation for Health Research and Development, (ZonMw)</b> | The Netherlands  | ✓   | ✗                         | ✓   | ✓ | 2.0   | 8  |
| <b>The Scientific and Technological Research Council of Turkey, (TUBITAK)</b>    | Turkiye          | ✓   | ✓                         | ✓   | ✓ | 0.4   | 2-3  |

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