Research, Innovation and Technology Call (2026) for

Test and Demonstration of Multimodal Data Approaches for Personalised Medicine (“MultiPMData2026”)

(EP PerMed Grant 101137129)

Full proposal application form

**Please note:**

* Proposals that do not meet the regional/national eligibility criteria and requirements will be declined without further review. See “Guidelines for Applicants” for more details.
* All fields must be completed using “Segoe UI, size 10” characters, single-spaced. The page margins and page limitations of this form shall be respected.
* Incomplete proposals (proposals missing any sections), proposals using a different format
or exceeding length limitations of any sections will be rejected without further review.
* Sections in “italics” are instructions and should be deleted.
* Joint proposals consist of two parts: 1) This full proposal form to present mainly the description of the planned work, and 2) the electronic submission tool to provide particularly individual partner information and financial plans. **Both parts should be completed jointly by all applying consortium partners and need to be started in due time.**
* **In case of inconsistency between the information registered in the submission tool (**[PT-Outline](https://ptoutline.eu/app/EPPERMEDRITC2026)**) and the information included in the full proposal form, the information registered in the submission tool (**[PT-Outline](https://ptoutline.eu/app/EPPERMEDRITC2026)**) shall prevail.**
* Refer to the Call Text and the “Guidelines for Applicants” for information about the proposal submission requirements and process.
* Once completed, the full proposal must be converted to a single PDF document before being uploaded to the submission tool **(**[PT-Outline](https://ptoutline.eu/app/EPPERMEDRITC2026)**)**.

# General information

**Project title**

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**Project acronym (max. 15 characters)**

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**Project duration (months)**

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**Total project costs (€)\***

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| --- |
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**Total requested budget (€)\***

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*\*Please make sure that the same figures are entered in the sections that need to be completed online (*[*PT-Outline submission tool*](https://ptoutline.eu/app/EPPERMEDRITC2026)*) and in the financial overview in section 12 of this form. Thousand separators and whole numbers should be used only (e.g. 200.000, no decimal places).*

## Keywords (from 5 up to 7)

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## Proposal abstract (max. 2,000 characters, including spaces)

Please give a comprehensive summary of the project. Include **the medical need** being addressed using a Personalised Medicine approach and **the aims of the project**. Also, briefly describe **the test environment** being used, **the** **solution/s** being tested and **expected results**. Please note that if the project is selected for funding this abstract will be used for EP PerMed and involved funders’ public communication activities.

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## Focus of the proposal in relation to the call scope

1. **Please indicate the intervention aspect/s applying to this proposal:**

The proposed project will address the following intervention aspect/s (more than one aspect can be selected and they need to be described in section 3):

|  |  |
| --- | --- |
| Detection or characterisation of co-morbidities in chronically ill patients | [ ]  |
| Diagnosis, follow-up or monitoring of disease progression, including remissions and relapses | [ ]  |
| Promoting a shift from in-patient to out-patient care through remote monitoring or reporting using wearables or other technical solutions | [ ]  |
| Decision support for disease intervention strategies (e.g., medication type and dosage) | [ ]  |
| Tracking and managing multiple treatments (including drug combinations) to improve effectiveness or reduce adverse effects and potential harmful drug interactions | [ ]  |
| Adherence to long-term treatment regimens | [ ]  |

Please specify which chronic diseases will be addressed in the project. The project must involve a combination of **at least** **two** conditions, as outlined in the Call Text. (max. 1/3 page)

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1. **Which of the following test environment/s is/are included in this application?**

Please indicate the controlled real- world environment/s in which the proposed personalised medicine solutions will be tested (please tick the appropriate boxes):

|  |  |
| --- | --- |
| Hospital-based test environment | [ ]  |
| Out-patient care environment | [ ]  |
| Simulated clinical environment | [ ]  |
| Virtual test environment | [ ]  |
| Other | [ ]  |

The use of an appropriate suitable test environment will be part of the proposal evaluation. Please further describe the controlled real-world environment/s involved, and explain how they are suited for testing the proposed solutions (max. ½ page).

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1. **Has the primary solution proposed for testing in the project achieved a minimum of technology readiness level (TRL) 3?**

*Please note: It is required that TRL3 has been reached* *already at the start of the project, see the Call Text including the TRL guide in its Annex III.*

|  |  |
| --- | --- |
| Yes | [ ]  |
| No | [ ]  |

1. **Strategy for handling the multimodal health data**

*Please note: Proposals must include a robust and well-integrated strategy for all three stages of multimodal health data handling – collection, processing, and use. This strategy will be evaluated as part of the proposal review and should be tailored to the proposed activities and expected outcomes.*

*Importantly, the strategy should demonstrate how the data will be used to support improved health outcomes for patients. This includes ensuring that data is not only technically well-managed but also meaningfully applied to enhance diagnosis, treatment, monitoring, or patient engagement.*

*This requirement is distinct from the Data Management Plan described in Section 12 of the Call Text and section 9.5 of this application form.*

Please describe the strategy considered (max. ½ page).

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1. **Integration of the enabling elements in the proposal**

*Please note: The adequate inclusion of the six enabling elements in proposals submitted to this call is part of the evaluation and should be appropriate to the proposed research and innovation and the expected results.* The six elements are listed below, s*ee the Call Text and “Guidelines for Applicants” for further information.*

*1. Knowledge integration*

*2. Technologies, products, methods and processes*

*3. Infrastructures utilisation*

*4. Business/value model*

*5. Policies and regulations*

*6. Organisation, behaviour and values*

Please describe how each enabling element is considered and integrated in the proposal (max. 1 page).

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1. **Which of the following actor types are represented in your consortium?**

*Please note: Projects funded under this call are required to be intersectoral and interdisciplinary and clearly demonstrate how these aspects contribute to improved disease management using personalised medicine approach.*

Please tick the appropriate boxes:

|  |  |
| --- | --- |
| **\* Enterprise (for-profit) of all sizes,** e.g. SME(small and medium-sized enterprises) and industry | [ ]  |
| **\* Clinical partner,** public or private health sectorrepresented by research teams or clinicians (e.g. medical doctors, nurses or pharmacists) working in hospitals/public health or other healthcare settings and health organisations). | [ ]  |
| **Academia,** research teams working in universities, other higher education institutions or public or private research institutes. | [ ]  |
| **Private non-profit partners**, e.g. foundations, associations or non-governmental organisations. | [ ]  |

*\* It is* ***mandatory*** *to include at least one enterprise and one clinical partner*

Describe the intersectoral and interdisciplinary aspects, and the added value of the transnational, collaboration including the sharing of resources (registries, diagnosis, biobanks, models, databases, diagnostic and informatics tools, etc.), platforms/infrastructures, harmonisation of data and sharing of specific know-how. If European infrastructures, e.g. BBMRI, ECRIN, EATRIS or ELIXIR (see also Guidelines for Applicants), are involved in the proposal please outline (max. ½ page).

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# Project consortium

***For the project coordinator (indicated as “partner 0” in this form and as “coordinator” in the online submission forms) and each scientific partner (other than the coordinator, including partners participating on own funds),*** *please fill in the following table. For patient organisations participating in the consortium as partners, lines can be added, if needed.*

*Reminder of the widening possibility: Consortia are allowed to include in the full proposal* ***one*** *additional project partner eligible to receive funding from an underrepresented funding organisation 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).* ***The general call rules regarding the consortium composition have to be respected and the new partner must be eligible for funding from one of the following funding organisations: (list of funders to be updated after the first stage).***

***Attention: Detailed partner information must be provided in the online submission system (***[*PT-Outline*](https://ptoutline.eu/app/EPPERMEDRITC2026)***).***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name and Surname of the Principal investigator | Institution, Department, full Affiliations | City, Country | Type of entity: Enterprise, University, Hospital, Research Institute, Associations, other |
| Coordinator (= Partner 0) |  |  |  |  |
| Partner 1 |  |  |  |  |
| Partner 2 |  |  |  |  |
| Partner 3 |  |  |  |  |
| Partner 4 |  |  |  |  |
| Partner 5 |  |  |  |  |
| *Partner 6* |  |  |  |  |
| *Partner 7\** |  |  |  |  |

*\*Maximum number of consortium members allowed is 8 (including the coordinator) after inclusion of a new partner through the widening option. Exception: patient/citizen representing organisations are not included in the count, see Call Text for detailed information. Please add more lines, if needed (e.g. if patient/citizen representing organisations are included as partners).*

# Project description

## Changes between the pre- and full proposal stage (max. 1 page)

*Outline any modifications of the project plan and/or the consortium compared to the pre-proposal. Please include information for the reviewers or comments on the reviewers’ feedback from the pre-proposal evaluation.*

• Delete these bullet points and the explanation above in italics when entering your text.

• Do not change the text format (font type, font size, page margins)!

• Do not exceed the page limit of 1 page for this section!

## Proposed work (max. 3 pages)

*The following three subsections MUST be completed in these three pages:*

1. ***Introduction and Background:*** *Include the identified unmet medical and patient/societal needs, and the knowledge gap addressed by the project. Provide an overview of the current state of the art, including existing solutions relevant to the proposed work. Describe the innovation/solutions tested in the project, and explain how your solution adds new value in relation to existing solutions. Describe the technical or implementation challenge that is addressed by the proposed work and the potential health impact that the results of your proposed work will have.*
2. ***Call scope adherence****: Explain how the proposal fits in with the scope of the call to advance* *the management of chronic diseases and patients with multimorbidity. Explain the Personalised Medicine dimension of the proposed work, including an outline on the use of different types of data. Describe how the solutions to be tested are personalising the intervention, empowering patient involvement and improving health outcomes. Highlight the novelty, originality and feasibility of the project.*
3. ***Outcomes and Impact****: Briefly describe the expected outcomes and both short and long-term benefits of the project. Elaborate on the potential impact your work will have on the management of chronic diseases and multimorbid conditions, and the likeliness of the innovation to reach broader implementation.*

## Preliminary results and current status (max. 2 pages)

*Please describe prior work by the consortium members directly related to the proposal including preliminary results and the current developmental status of the solutions to be tested in the project.*

## Work plan (max. 8 pages)

*Please divide this section in Work Packages. For each Work Package, include: aim, methodology, strategies used, how the work package leverages on the multimodal health data how the work package integrates the enabling elements, the timeline, and milestones. Elaborate on the height of innovation and the added value of the proposed personalised medicine approach/es to address a medical need compared to existing ones. Clearly define roles and responsibilities and workloads (expressed in person months) of each participating partner. Comment on how the interdisciplinary approach is promoted through collaboration and how the management of the proposal will be achieved.*

## Diagram which compiles the work plan and timeline (max. 1 page)

*The diagram must demonstrate the work plan, timeline, sequencing of work packages, deliverables and milestones as well as the contribution of the partners to each work package and their interactions (i.e. time plan, Gantt and/or PERT or similar).*

## Justification of requested budget and total project costs (max. 1 page)

*Please justify the resources to be committed. Where applicable, also specify co-funding from other sources necessary for the project.*

# Potential impact, exploitation and dissemination of expected project results (max. 1 page)

*Please indicate how the proposed study could influence or change the way that healthcare is delivered and the effect of the expected results for the patient/citizen, the future clinical, public health or other socio-economic health-relevant applications (also for commercial exploitation, product development), if available. Describe the measures proposed to exploit, implement, disseminate and communicate the project results in a tailored manner to different audiences (policy makers, industry, patients, etc.). Please describe the scale and significance of the project’s contribution to the expected outcomes and impacts (“scale” refers to how widespread the outcomes and impacts are likely to be, e.g. in terms of the size of the target group or the proportion of that group, that should benefit over time; “significance” refers to the importance or value of those benefits, e.g. number of additional healthy life years, level of adverse effects, etc.). Please describe potential barriers to the expected outcomes and impacts (e.g. regulatory environment, targeted markets, user behaviour) and mitigation measures proposed, if any.*

# Handling of Intellectual Property Rights (IPR) (max. ½ page)

*Outline arrangements of intellectual property rights (e.g. any barriers to sharing materials or results), both within and outside the project consortium (see the Guidelines for Applicants for supporting information and references on IPR).*

# Description of on-going projects, pending patents and patents (max. 1 page per group)

*Outline on-going projects, pending patents and patents, where applicable, of each participating group related to the present topic indicating funding sources and possible overlaps with proposal.*

# Inclusion of gender and/or sex analysis / research (max. ½ page)

*Please provide information about the relevance of consideration of sex aspects in research teams and the inclusion of sex and/or gender research.*

# Project management structures and procedures including risk assessment and innovation management (max. 1 page)

*Describe your management structures for the project. Provide a risk assessment for the proposed work procedures, including critical risks to the project implementation and proposed mitigation and contingency measures.*

# Responsible Research and Innovation (RRI), science and technology (page limits as indicated below)

Responsible research and innovation (RRI) is an approach to “orientate research and innovation towards societal needs, and to achieve ethical acceptability” [REF: EC report 2013 on RRI “Options for strengthening responsible research and innovation”]. The aim of implementing RRI is to foster the design of **inclusive and sustainable research and innovation to ensure a true societal impact**.

## General RRI aspects (max. 1 page)

In line with the definition of RRI, please explain how the project will demonstrate a commitment to considering and addressing the social, ethical, environmental or cultural dimensions of the proposed research.

For support, see the RRI site of the European Commission: <https://rri-tools.eu/> and The Societal Readiness Thinking Tool – Guide for the steps of including RRI in a project: <https://thinkingtool.eu/>**;** as well as the RRI site from ERA4Health**: https://era4health.eu/publications/rri.php**

*Include the following points:*

1. *Reflect on who will benefit from the outcome of the project;*
2. *Anticipate future risks associated with the solution in the proposal;*
3. *Reflect on the underlying assumptions and values driving a scientific research project; and*
4. *Describe how the three points above are considered by incorporating their outcomes into the design of projects and funding programmes.*

## Stakeholder involvement (max. 1 page)

To better align research and innovation development and outcomes with the values, needs and expectations of society, RRI implies close collaboration and interaction between a broad range of societal actors including enterprises, clinical/healthcare actors, researchers, patients and citizens, opinion leaders and policy makers.

While the specific roles of project partners are outlined in the work plan (section 3.5), this section expands on how various stakeholders – both partners and non-partners – are concerned and engaged throughout the project, or following its completion, particularly in relation to the uptake of potential solutions.

* ***Please outline the role and contribution of operational stakeholders*** *concerned by the proposal and potential outcomes of the project. These can include patient organisations, citizens or citizen representatives, local communities, schools, municipalities, local/regional/national NGOs, consumer organisations.*
* *Describe the level of involvement for each stage of the project.*
* *Explain reasoning behind involving/not involving certain stakeholders.*

**Please note:** To support the involvement of citizen/patient organisations, these organisations can act as full consortium partners and apply for funding directly from EP PerMed (see Call Text and guidelines for applicants).

## Market Potential in the Short to Medium Term (max. ½ page)

In line with the mentioned principles of RRI, and to achieve meaningful and efficient resource utilisation, it is essential to assess how project results can be translated into practical use – through both dissemination of outcomes and product development.

Describe the anticipated timeframe for bringing the proposed solutions to market and making it accessible to patients, whether through clinical or public health applications, pharmaceutical or medical device pathways, or other industrial uses.

Include an overview of the target market and end-user landscape, and outline the strategy for dissemination and exploitation of results. Emphasise how the project will support market readiness and facilitate the translation of innovation into practical use.

## Open Science, data management and data sharing (max. 1 page)

*Develop a plan for data handling according to the FAIR principles – making it findable, accessible, interoperable, and reusable. Describe the handling of research data during and after the end of the project; proposed frequency and scope of data collection; what data will be collected, processed or generated or reused; which methodology and standards will be applied; whether data will be shared/made open access; how data will be curated and preserved. Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate.*

*In this section, the Data Management Plan (DMP) must be outlined in brief. Consortia of projects selected for funding must submit a detailed DMP (a template will be provided to the respective consortia). Include Open Science practices and intellectual property management.*

# In addition, two more pages can be added to the full proposal (page limits per optional section as indicated below)

*Please note: A page with diagrams, figures, etc. to support the work plan description* ***is NOT eligible in section 11****.*

## List of references (max. 1 page)

*Please list you references in bullet points as the following example:*

*[1] loren ipsum 1*

*[2] loren ipsum 2*

*[3] loren ipsum 3*

*[4] loren ipsum 4*

…

* Delete these bullet points and the dummy reference list above when entering your text.
* **Do not change the text format** (font type, font size, page margins)!
* Do not exceed the page limit of **1 page** for this section!
* This section is optional – delete if not needed.

## List of abbreviations (max. 1 page)

ANOVA Analysis of Variance

CI Confidence Interval

CSV Comma Separated Value

RMC Root Mean Square

* Delete these bullet points and the dummy list of abbreviations above when entering your text.
* Do not change the text format (font type, font size, page margins)!
* Do not exceed the page limit of 1 page for this section!
* This section is optional – delete if not needed.

# Financial plan of project budget (in €1): Please make sure that the same figures are entered in this section and the online form ([PT-Outline submission tool](https://ptoutline.eu/app/EPPERMEDRITC2026))

*Please note that not all types of expenditure are fundable by all funding organisations (see the “Guidelines for Applicants” for details on the eligibility criteria and contact the relevant EP PerMed regional/national funding organisation). Thousand separators and whole numbers should be used only (e.g. 200.000, no decimal places).*

*Please adapt the table and add columns in this section, in the case the consortium integrates more than seven scientific partners (including the coordinator, e.g. through the widening option) or if patient organisations are included as partners (for more details, please read the Call Text).*

***Please ensure that all fields in the table are completed. Submissions with incomplete tables may be rejected.***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Coordinator(Partner 0) | Partner 1 | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 |
| PI (group lead) |  |  |  |  |  |  |  |
| Institution |  |  |  |  |  |  |  |
| Country |  |  |  |  |  |  |  |
| Funding organisation |  |  |  |  |  |  |  |
| PROJECT COSTS (€)1 | Total *=**requested + in-kind* | Requested | Total *=**requested + in-kind* | Requested | Total *=**requested + in-kind* | Requested | Total *=**requested + in-kind* | Requested | Total *=**requested + in-kind* | Requested | Total *=**requested + in-kind* | Requested | Total *=**requested + in-kind* | Requested |
| Person Months  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Personnel € |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Consumables € |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Equipment € |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Travel €2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other direct costs €3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Overheads €4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Subcontracting3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **TOTAL** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

1 Those countries whose currency is different than € shall include their national currency in brackets.

2 Travel expenses should include the participation of the coordinator and regional/national partner leads for at least two status seminars to present the project results.

3 e.g. subcontracting, provisions, licensing fees; may not be eligible costs in all countries (will be handled according legal framework and funding body regulations).

4 Overhead costs: funding according to regional/national legal framework and funding body regulations. Check the respective funding organisation Annex III “Guidelines for Applicants”.

# Brief CVs of each Principal Investigator (max. 1 page per PI)

*Please provide a brief CV of the Project Coordinator (to be indicated as partner 0) and each Project Partner’s Principal Investigator (PI). Please complete the table below and replicate the table as required.* ***Please be reminded that partners participating on own funds and patient organisations/representatives participating as consortium partners should be also presented.***

***Subcontractors or collaboration partners that are not part of the consortium must not be listed.***

*Each partner should be represented by a single Principal Investigator (co-PI’s are not accepted). Proposals with extra-CVs or with CVs not following the page limit per partner will be rejected (****max. 1 page per PI****, Segoe UI 10, single-spaced, the margins of the page are not allowed to be adapted).*

|  |  |
| --- | --- |
| Partner | Please indicate what applies: coordinator (partner 0), partner 1, partner 2, etc. |
| Personal information | First name, last name, academic title (if applicable)Institution and department (complete name) |
| Expertise | Max: 200 words |
| Role within the consortium | Please indicate the work package the PI will be working in. |
| Publications | Please list around five of your most relevant publications of the last ten years |
| Additional information | Patents, entrepreneurial achievements, honours, awards, memberships or references; up to 5 relevant third-party funded projects conducted in the area in the past 5 years |

# Signature

***The following Data Privacy Notice applies:***

*By applying to the call, applicants consent to the use, processing and retention of their data, in line with the above notice and for the purposes of:*

* *processing and evaluating the application where processing shall be lawful - only if and to the extent that - processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;*
* *administering any subsequent funding award;*
* *managing the funding organisation’s relationship with them;*
* *analysing and evaluating the call;*
* *reporting to the European Commission/ European Health and Digital Executive Agency (HaDEA) on the call;*
* *providing aggregate data to regional/national and European surveys and analyses;*
* *complying with audits that may be initiated by the funding organisations.*

*The members of the EP PerMed consortium may share an applicant’s data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).*

*The members of the EP PerMed consortium may link the data that applicants provide in the application with regional/national, bibliographic or external research funding data which is available through public subscription-based databases (e.g. Scopus, Web of Science, etc.) or other regional, national or open datasets. The members of the EP PerMed consortium may also link the data that applicants provide in their application with future data that applicants provide as part of the ongoing management and reporting.*

*Data on funding organisations including contact details of Call Steering Committee[[1]](#footnote-2) (CSC) members are kept for the purpose of the call communication. The information will be published with prior consent of the respective management bodies.*

***In addition, the applicants declare their willingness to cooperate with the project consortium and they did not receive other public funds to accomplish any tasks described in the project proposal.***

*Digital signatures or scanned signatures are accepted. These signatures should be from the principal investigators (PI) listed in section 2. Please add signature lines, if needed.*

**Signature Coordinator (Partner 0) (place, date, signature of PI):**

A stamp of the Coordinator’s institution (e.g. the relevant university institution or company) should be added.

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature Partner 1 (place, date, signature of PI):**

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

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**Signature Partner 2 (place, date, signature of PI):**

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

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**Signature Partner 3 (place, date, signature of PI):**

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature Partner 4 (place, date, signature of PI):**

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

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**Signature Partner 5 (place, date, signature of PI):**

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

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**Signature Partner 6 (place, date, signature of PI):**

☐ I declare my willingness to cooperate with the project consortium

☐ I declare to not receive other public funds to perform the described tasks in this application

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# Annexes (templates provided in this full proposal application form)

* Annex 1 – Ethical self-assessment (**mandatory**)
* Annex 2 – Description of the clinical research/study (if any)
* Annex 3 – Description of Animal Research Projects (if any)
* Annex 6 – The patient/citizen involvement plan, describing the activities and methodologies for the involvement and providing information about the organisation requesting funding from EP PerMed (mandatory if funding is requested from EP PerMed to clarify the eligibility of funds).

Please submit the annexes as separate documents via the online submission tool.

# Annex 1: Ethical self-assessment

*Please note that all participants in a proposal must follow regional/national ethical regulations for their part of the proposed work. All proposals appoint an ethics contact point for the consortium in the ethics self-assessment. Ideally this person also oversees that the proposal holds cross-border high ethical standards.*

***Scientific and Ethics Contact Point for the Consortium:***

*In order to complete this section, please ensure you provide all information requested. Please remove all red guiding text.*

|  |  |
| --- | --- |
| Contact information of the scientific coordination contact for the consortium | Please indicate here the person in charge of the consortium (e.g. PI, coordinator). This person is responsible that the highest standards of rigour and integrity in all aspects of research are met, including all relevant legal and ethical requirements.  |
| Name and surname |  |
| Email address |  |
| Phone |  |
| Contact information for ethics contact point for the consortium | Please indicate here the person in charge of monitoring the ethical issues raised in your project. This person will also be in charge of maintaining the project ethics file (e.g., project manager, ethics manager).  |
| Name and surname |  |
| Email address |  |
| Phone |  |

***Short description of ethics and legal aspects in your proposal:***

*For this open call in the context of the European Partnership for Personalised Medicine, EP PerMed, we employ the same standard as operated by Horizon Europe, the EU's research and innovation programme for 2021-2027. Hence, it is mandatory for every applicant to fill in the Ethics Issues Table. In order to complete the ethics self-assessment, please go through the table below.* ***Please add a description of information at the end of each relevant section, if applicable.*** *Please also provide an overview on related* ***tasks, responsible partners and documents to be provided for each question.***

*For more information please see:* [*https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment\_en.pdf*](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf)

*This ethical clearance process does not replace the ethical vote by a competent Research Ethics Committee (REC). All ethical and legal requirements necessary must be met before the research can begin. To ensure this, is the responsibility of the applicant and cannot be substituted by the EP PerMed ethical clearance process.*

***[ ]  I certify as the coordinator of this proposal that the consortium has all relevant ethical and legal requirements in place for conducting this study.***

*Please attach any supporting documents that are already available and, for the documents that are not yet available, indicate when you expect that they will be available. All relevant documents listed in the table and that are not yet available have to be ready to be submit-ted upon request.*

|  |  |  |
| --- | --- | --- |
| Section 1: Human embryonic stem cells and human embryos  | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this research involve Human Embryonic Stem Cells (hESCs)?  |  |  |
| If YES:  | Will they be directly derived from embryos within this project?  |  |  |
| Are they previously established cells lines?  |  |  |
| Are the cell lines registered in the European registry for human embryonic stem cell lines?  |  |  |
| Does this research involve the use of human embryos?  |  |  |
| If YES:  | Will the research lead to their destruction?  |  |  |
| Does this research involve the use of other human embryonic or foetal tissues / cells?  |  |  |
| Description (mandatory if this section is relevant to your project; indicate here the country where the research is carried out): |

|  |  |  |
| --- | --- | --- |
| Section 2: Humans | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this research involve human participants? |  |  |
| If YES:  | Are they volunteers? |  |  |
| Are they healthy volunteers for medical studies? |  |  |
| Are they patients for medical studies?  |  |  |
| Are they potentially vulnerable individuals or groups? |  |  |
| Are they children/minors? |  |  |
| Are they persons unable to give informed consent?  |  |  |
| Does this research involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?  |  |  |
| If YES:  | Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)?  |  |  |
|  | Does it involve collection of biological samples?  |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 3: Humans cells / tissues | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this research involve human cells or tissues? (other than from Human Embryos/Foetuses, see section 1) |  |  |
| If YES: | Are they human embryonic or foetal cells or tissues? |  |  |
| Are they available commercially?  |  |  |
| Are they obtained within this project? |  |  |
| Are they obtained from another project, laboratory or institution?  |  |  |
| Are they obtained from a biobank (if yes, please provide the name of the biobank)? |  |  |
| Does this research involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?  |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 4: Personal data  | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this research involve processing of personal data? |  |  |
| If YES:  | Does it involve the processing of special categories of personal data (e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?  |  |  |
| Does it involve processing of genetic, biometric or health data?  |  |  |
| Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?  |  |  |
| Does this research involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)?  |  |  |
| Is it planned to export personal data (data transfer) from the EU to non-EU countries? |  |  |
| Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non- EU country to another non-EU country?  |  |  |
| Does this research involve the processing of personal data related to criminal convictions or offences?  |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 5: Animals | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this research involve animals? |  |  |
| If YES: | Are they vertebrates?  |  |  |
| Are they non-human primates (NHPs)?  |  |  |
| Are they genetically modified?  |  |  |
| Are they cloned farm animals?  |  |  |
| Are they endangered species?  |  |  |
| Please indicate the species involved:  |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 6: Non-EU countries | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? Specify the countries involved:  |  |   |
| Is it planned to use local resources (e.g. animal or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?  |  |  |
| Is it planned to import any material (other than data) from non-EU countries into the EU or from a non- EU country to another non-EU country? |  |  |
| If YES:  | Specify material and countries involved:  |  |  |
| Is it planned to export any material (other than data) from the EU to non-EU countries?  |  |  |
| Does your activity involve low or lower-middle income countries? |  |  |
| Could the situation in the country put the individuals taking part in the research at risk?  |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 7: Environment, Health and Safety | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this activity involve the use of substances or processes (or technologies) that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?  |  |   |
| Does this research deal with endangered fauna and/or flora/protected areas? |  |  |
| Does this activity involve the use of substances or processes (or technologies) that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, or the deployment of the technology as a possible impact)?  |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 8: Artificial Intelligence | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?  |  |   |
| Could the AI based system/technique potentially stigmatise or discriminate against people (e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)? |  |   |
| Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)? |  |  |
| Does the AI system/technique have the potential to lead to negative social (e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance) and/or environmental impacts either through intended applications or plausible alternative uses? |  |  |
| Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above (e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life- like humanoid robots, etc.)? |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 9: Other ethics issues | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Are there any other ethics issues that should be taken into consideration (e.g. process for the return of results)? |  |  |
| Description (mandatory if this section is relevant to your project): |

|  |  |  |
| --- | --- | --- |
| Section 10: Crosscutting issues – Potential misuse of results | YES/NO  | If yes, Add description in the appropriate section at the end of the table  |
| Does this research have the potential for misuse of research results? |  |   |
| Description (mandatory if this section is relevant to your project): |

# Annex 2: Clinical research (max. 7 pages for sections 1-7)

*The following section only has to be filled in by consortia that will perform clinical research/study. Please delete if not needed.*

*Please prepare your description in English, Segoe UI, font size 10, single-spaced, do not change the margins of the pages.*

# Study summary

|  |  |
| --- | --- |
| **APPLICANT/COORDINATING INVESTIGATOR** | Name, address, telephone, fax, e-mail*In case of multiple applicants, the principal investigator / coordinating investigator of the study who will assume responsibility for conducting the clinical study, should be listed first.* |
| **TITLE OF STUDY** | *Descriptive title identifying the study design, population, and interventions.*  |
| **CONDITION** | *The medical condition being studied (e.g. lymphoma, M. Parkinson)* |
| **OBJECTIVE(S)** | *Which principal research questions are to be addressed? Specify clearly the primary hypotheses that determine sample size calculation.*  |
| **INTERVENTION(S)** | *Brief description of the experimental and the control treatments or interventions, if applicable: dose and mode of application.* Experimental intervention:Control intervention:Duration of intervention per patient:Follow-up per patient: |
| **KEY INCLUSION AND EXCLUSION CRITERIA** | Key inclusion criteria:Key exclusion criteria:  |
| **OUTCOME(S)** | Primary efficacy endpoint:Key secondary endpoint(s):Assessment of safety: |
| **STUDY TYPE** | *e.g. randomised / non-randomised, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over* |
| **STATISTICAL ANALYSIS** | Efficacy: Description of the primary efficacy analysis and population:Safety: *Please describe the strategy for assessment of safety issues in the study. Which are relevant safety variables?*Secondary endpoints: |
| **SAMPLE SIZE** | To be assessed for eligibility (n = …)To be allocated to study (n = …)To be analysed (n = …) |
| **STUDY DURATION** | Time for preparation of the study (months):Recruitment period (months):First patient in to last patient out (months):Time for data clearance and analysis (months): Duration of the entire study (months): |
| **PARTICIPATING CENTERS** | To be involved (n): *if applicable; how many centres will be involved? Please also list the cities.* |

# Justification of design aspects

*Please provide justifications. It is not sufficient to list respective parameters only.*

## Control(s)/Comparator(s)

*Justify the choice of control(s) / comparison group(s).*

## Type, mode and scheme of intervention (if applicable)

*Describe the intervention scheme / study flow in depth and give a schematic diagram (flow chart) of design, procedures and stages. Justify the type, the mode and the scheme of the intervention. How does the intervention compare to other interventions for the same condition?*

## Additional treatments

*Please describe additional treatment(s) permitted and not permitted before and / or during the study, if applicable.*

## Inclusion/Exclusion criteria

*Justify the population to be studied, include reflections on generalisability and representativeness, specifically with regard to gender and age.*

## Outcome measures

*Justify the endpoints chosen. Discuss the relevance of the outcome measures for the target population/patient. Have the measures been validated? Justify appropriateness and limitations of composite endpoints, if applicable.*

### Determination of primary and secondary measures

*How will primary and secondary endpoints be derived from actual measurements, e.g. how is the figure used in the statistical test calculated from the variables initially measured in the subjects?*

## Methods against bias/ Assessment of confounding factors

*Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating participants to study groups? Will study site effects be considered in randomisation?*

*Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome). What are possible confounding factors and how will they be considered?*

## Proposed sample size / Power calculation

*What is the proposed sample size and what is the justification for the assumptions underlying the power calculations? Include a comprehensible, checkable description of the power calculations and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians, the software used for sample size calculation etc., as appropriate. Justify the size of difference that the study is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the study is powered to exclude. Give evidence / references for the estimated effect size. Sample size calculations need to take into account anticipated rates of non-compliance and losses to follow up.*

### Compliance / Rate of loss to follow up

*Provide details for assumptions on compliance issues. On what evidence are the compliance figures based?*

*What is the assumed rate of loss to follow up? On what evidence is the loss to follow up rate based? How will losses to follow up or non-compliance be handled in the statistical analysis?*

## Feasibility of recruitment

*What is the evidence that the intended recruitment rate is achievable?*

*a) Pilot study*

*Has any pilot study been carried out using this design?*

*b) Achievability of recruitment rate*

*Demonstrate conclusively the potential for recruiting the required number of suitable subjects (the best piece of evidence being pilot studies and preceding studies in a similar population / same institutions).*

## Stopping rules

*Please specify the “stopping rules” or “discontinuation criteria”*

*a) for the individual participant,*

*b) for the whole study.*

# Strategies for data handling

## Frequency and scope of data collection

*What is the proposed frequency and scope of data collection and, if applicable, the duration of post-trial follow-up?*

## Strategies for data management

*Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate.*

# Statistical analyses

*What is the proposed strategy of statistical analysis? If multiple hypotheses are foreseen for confirmatory testing what is the procedure to ensure Type I error control and what will be the primary data analysis set (e.g. ITT-population in case of superiority RCT). What is the strategy for analysing the primary outcome? If applicable, how will multiple primary end points be analysed statistically? If interim analyses are planned, please specify. Are there any subgroup analyses? How will missing data and subjects withdrawn from the trial be handled statistically?*

# Ethical considerations

*Give a description of ethical considerations relating to the study (assessment of risks and benefits, care and protection for research participants, protection of research participants’ confidentiality, informed consent process).*

# Quality assurance and safety

## Quality assurance/monitoring

*What are the proposed measures for quality assurance? Which institution will perform the monitoring? Which SOPs will be utilised? Describe and justify the monitoring strategy (percentage of source data verification, number of monitor visits per study site).*

## Safety

*Describe and justify briefly the proposed strategy for the assessment of participants’ safety in the study (monitoring of adverse events, documentation, reporting procedures, etc.).*

## Management structure and procedures

*Arrangements for the management of the studies will vary according to the nature of the study proposed. However, all should include an element of expert advice and monitoring, that is entirely independent of the principal / coordinating investigator and the medical institutions involved. This can take the form of an external scientific supervisor with human clinical study expertise.*

# References

# Study timeline flow

*Please provide a diagram reflecting preparation, recruitment, follow-up and data cleaning/analysis. An example of such a diagram is given below.*



# List of investigators involved in the study

|  |
| --- |
| **Sponsor / Institution** |
|  |
| **Management** |
| # | Name | Affiliation | Responsibility / Role | Signature |
|  |  |  |  |  |
|  |  |  |  |  |
| **Statistician** |
| # | Name | Affiliation | Signature |
| 1 |  |  |  |
| **Supporting Facilities** *(reference laboratories, food supplier etc.)* |
| # | Name | Affiliation | Responsibility / Role |
|  |  |  |  |
|  |  |  |  |

# Annex 3: Description of Animal Research Projects (max. 5 pages)

*The following section only has to be filled in by consortia in case animal research is included in the proposal and should focus on that part of the research.*

***Only one form is to be submitted per consortia, i.e. if animal studies are conducted at different sites, the information have to be adapted to the indicated page limitation.***

*Please prepare your description in English, using “Segoe UI, size 10” characters, single-spaced, do not change the margins of the pages.*

# Project summary

|  |  |
| --- | --- |
| Principal Investigator |  |
| Title of Project |  |
| Topic |  |
| Aim(s) |  |
| Keywords |  |

# Research design and work plan

## Rigorous experimental design

*Explain the experimental approach how the animal model being used can address the scientific objectives. Explain the study’s relevance to human biology.*

*Please use the subsections below to further describe the experimental approaches, study designs and techniques of your research project. Indicate and justify if any of the subsections does not apply.*

## Experimental procedures

*Describe the experiments, study design and techniques that will be used. Please justify, e.g. drug formulation and dose, anaesthetic and surgical procedures, equipment (how, when, where, why?). Justify the number of experimental and control groups. Which steps will be taken to minimise the effects of subjective bias? How is an experimental unit defined?*

## Experimental animals

*Please comment on the experimental animals: species, strain, sex, developmental stage, age, weight, source of the animals, genetic modification status, etc.*

## Housing and husbandry

*Please comment on housing and husbandry: type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions, type of food, access to food and water, environmental enrichment etc.*

## Sample size

*Specify and justify the total number of animals used in the experiment (or each experiment), and the number of animals in each experimental group. Explain how the number of animals was arrived at. Provide details of any sample size calculation used (expected effect size, the software used for sample size calculation etc.). Give evidence/references for the estimated effect size. Indicate the number of independent replications of each experiment, if relevant.*

## Allocating procedures and methods against bias

*Describe how animals are allocated to the experimental groups. Is randomisation or matching feasible? Describe steps to minimise the effects of subjective bias.*

## Experimental outcomes

*Define and justify the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).*

## Gender aspects

*Indicate how gender specific aspects are addressed regarding the research questions, the analyses, and the relevance of the results. If you find that gender aspects do not apply to your research questions, please give a comprehensive justification.*

## Statistical analysis

*What is the proposed strategy of statistical analysis? Provide details of the statistical methods used for each analysis. Justify any methods used to assess whether the data meet the assumptions of the statistical approach. Specify the unit of analysis for each dataset (e.g. single animal, group of animals)? How will missing data and subjects withdrawn from the trial be handled statistically? Please include a biostatistician for data analysis in your financial planning.*

## Work packages

*Explain your work plan in detail. Define and describe work packages. Which tasks will be done? How will the aims be reached?*

## Milestone plan

*Indicate work packages (WP) into which the project is divided and schedule events that indicate the completion of major deliverables. Milestones are measurable / observable events and serve as progress markers.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No. of WP** | **Milestone (**▼**)** | **year 1** | **year 2** | **year 3** | **year 4** |
|   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |
|   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |
|   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |

# Team and expertise

## Main participants

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Name** | **Affiliation** | **Role** |
|  |  |  | *Principal investigator* |
|  |  |  | *Methodological expertise* |
|  |  |  | *Biostatistician (required for animal studies)* |
|  |  |  |  |

# Strategies for data handling

*Describe what measures will be implemented to ensure data management, maintenance and long-term accessibility for future reuse of your results (also by third parties). Please use existing standards and data repositories where appropriate.*

# References

# Annex 6 – The patient/citizen involvement plan

*The development of a patient/citizen involvement plan (to be uploaded electronically as annex 6 to the application form) is requested to describe the activities and methodologies for the involvement. Annex 6 is* ***mandatory*** *if funding is requested from EP PerMed (see also Annex II of the “Guidelines for Applicants document”).*

# Description of activities and methodologies for the patients’/citizens involvement (max. ½ page)

*Please describe the activity/ies and methodologies for patient/citizen involvement performed by the consortium. Explain the allocation of tasks to and the role/s of project partners. Especially contributions by the Patient or Citizen organisations applying for EP PerMed funding have to be described in detail.*

*If patient/citizen involvement is not deemed appropriate within a research project, this should be explained and justified.*

# Information concerning the organisation representing patients or citizens and requesting funding from EP PerMed in this call, if applicable.

*It is mandatory to provide information about the patient or citizen organisation and indicate if funding is requested from EP PerMed (DLR), see also Guidelines for Applicants, Annex II. If the consortium is containing more than one of such an organisation, this table can be duplicated.*

*Please note: Max. 50.000 € per project. If more than one organisation representing patients or citizens is participating in one consortium the amount should be shared. If no organisation representing patients or citizens is included, consortia are invited to only fill-in section 1.*

|  |  |
| --- | --- |
| **Name of the organisation representing patients or citizens** |  |
| **The organisation is requesting funding from DLR on behalf of EP PerMed as outlined in Annex II of the Guidelines for Applicants***Please select what applies* | Yes/No |
| **Name of the contact person** *Please provide name, surname, Email, address and phone number* |  |
| **Legitimacy***Please provide the following information: Proof that the organisation is formally established and registered as a not-for-profit organisation in one of the EU Member States or Associated Countries (registration number and website of the register).* |  |
| **Mission/objectives***Please outline shortly the mission/objectives of the organisation requesting funding of EP PerMed.* |  |
| **Structure***Please describe the governing structure and provide information about the designated representative legally authorised eligible to sign a contract with DLR on behalf of EP PerMed.* |  |
| **Accountability**1. *For the patient organisation or citizen organisation requesting funding from EP PerMed in this call, please describe activities, such as patient/patient family/citizens support and/or advocacy activities and/or health research.*
2. *Please describe the account system*
3. *Please confirm the ability to trace costs related to the project and archive these costs for a duration of 5 years after the end of EP PerMed).*
 | 1) Description2) Description3) Yes/No |
| **Transparency**1. *The organisation is financially independent, particularly from the private sector (max. 50% of funding from several companies in total).*
2. *The organisation agrees to disclose on request (e.g. for contract negotiations) to EP PerMed its sources of funding, both public and private, by providing the name of the bodies and their individual financial contribution, both in absolute terms and in terms of overall percentage of the organisation budget. Any relationship with corporate sponsorship will be made clear and transparent.*
3. *The organisation agrees to communicate to EP PerMed on a regular basis and/or to publish on its website the registered statutes, sources of funding, and information on their activities.*
 | 1) Yes/No (plus description if needed)2) Yes/No3) Yes/No |

1. Call Steering Committee: comprises a single representative from each country’s/region’s funding organisation [↑](#footnote-ref-2)