EP PerMed
European Partnership
for Personalised Medicine

EUROPEAN PARTNERSHIP

Joint Transnational Call for Proposals (2027) for

**Cell and Gene Therapy for Personalised Medicine (CGT4PM2027)**

(EP PerMed Grant 101137129)

# Pre-proposal application form

**Please note:**

- ***Proposals that do not meet the regional/national eligibility criteria and requirements will be declined without further review.***
- *All fields must be completed using "Segoe UI, size 10" characters, single-spaced. The page margins 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 pre-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 must be submitted in due time.***
- *In case of inconsistency between the information registered in the online submission tool (**PT-Outline**) and the information included in the pre-proposal form, the information registered in the submission tool (**PT-Outline**) shall prevail.*
- *Refer to the "Guidelines for Applicants" for information about the proposal structure.*
- *Once completed, this pre-proposal form must be converted in a single PDF document before being uploaded to the submission website.*
- *Applicants are invited to add figures or graphics where needed provided the respective section page limits are respected.*

Co-funded by
the European Union

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101137129.

# 1 General Information

**Project title**

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| |

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

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| |

**Project duration (months)**

| |
|---|
| |

**Total project costs (€)***

| |
|---|
| |

**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**) and in the financial overview in section 7 of this form. Thousand separators and whole numbers should be used only (e.g. 200.000, no decimal places).*

## 1.1 Keywords (from 5 up to 7)

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

Please give a comprehensive and readable summary of the most important aims and methods of the project. Please note that if the project is selected for funding this abstract will be published in the newsletter and on the funding organisations' websites.

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## 1.3 Focus of the proposal/research proposed related to the call scope

**a) Please indicate the aspect/s applying to this application:**

This proposal will address the following aspect/s (more than one aspect can be selected):

| | |
|---|---|
| Somatic cell therapeutics (e.g., in the form of stem cells, organoids, or cells of the immune system). | ☐ |
| Gene therapeutics in the form of gene substitution, addition or suppression therapies using viral and non-viral vectors or genome editing. | ☐ |
| Combined cell and gene therapeutics in the form of genetically modified cells. | ☐ |

| | |
|---|---|
| Novel biological products such as mRNA, other nucleic acid-based methods, and extra-cellular vesicles as vehicle for gene-based therapeutic procedure. | ☐ |

For the selected aspect/s above, please specify 1) which disease/s will be addressed in the project, 2) the innovative personalised therapeutic approach, and 3) how does the cell and gene therapy (CGT) offer significant advantages compared to the standard of care (max. ½ page).

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| |

**b) Which of the following accompanying aspects are considered in this application?**

Please tick the appropriate box/es:

| | |
|---|---|
| Diagnostic approaches linked to personalised CGT to enable patient stratification or predict response, efficacy, dosage optimisation, adverse effects or toxicity. | ☐ |
| Development of novel manufacturing or delivery methods that incorporate a personal-ised CGT backbone. | ☐ |
| Preclinical *in vitro/in vivo* characterisation assays for novel and personalised CGT, to as-sess key aspects such as batch-to-batch consistency, biodistribution, potency, stability, safety and tolerability. | ☐ |
| Not applicable: the proposal does not include any of these accompanying aspects. | ☐ |

**c) Preclinical development and Chemistry, Manufacturing and Controls**

*Please note: Projects funded under this call are required to include a dedicated work package addressing preclinical development and early Chemistry, Manufacturing and Controls (CMC) for the proposed CGT. Activities under this work package should aim to anticipate and support the preparation of the quality and nonclinical sections of an Investigational Medicinal Product Dossier in accordance with the require-ments of the European Medicines Agency (see also Call Text, section 5).*

Please indicate the number of the work package focussing on preclinical development and CMC:

| |
|---|
| |

Please indicate which partner is the respective work package lead:

| |
|---|
| |

Outline shortly the work proposed (max. ½ page):

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|---|
| |

## 2 Project consortium

***For the project coordinator (also indicated as "partner 0" in this form and as "coordinator" in the online submission forms) and each scientific partner (others than the coordinator, including also partners participating on own funds and patient organisations participating as full partner not collaboration partner),*** *please fill in the following table. For patient organisations participating in the consortium as partners, lines can be added, if needed.*

*Reminder (eligibility criteria and consortium composition in the pre-proposal stage): 1) Maximum number of scientific partners is 6, including the coordinator (no more than 2 partners from the same country); 2) Maximum number of scientific partners can be 7 if the consortium includes a 3rd partner of the same country*. Patient organisations are not included in this calculation (for more details, please read the Call Text).*

***Attention: Detailed partner information have to be provided in the online submission forms (PT-Outline).***

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

**Maximum number of scientific partners can only be 7 (including the coordinator) if the consortium includes a 3rd 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; including partners on own funds). Patient organisations are not included in this calculation.*

# 3 Project description

## 3.1 Proposed work (max. 5 pages)

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

1. ***Background:*** *Provide the rationale for the disease focus. Describe the unmet medical, patient and societal need that the project addresses. Provide an overview of the current state of the art, including existing solutions relevant to the proposed work. Identify knowledge gaps and bottlenecks that hinder the development and implementation of novel approaches in the targeted health area/s;*
2. ***Work plan:*** *Describe the overall objectives, the proposed strategy/ies, expected results, the rationale and the connected personalised medicine approach and methodology. Highlight the novelty, originality and feasibility of the project;*
3. ***Call scope adherence:*** *Explain how the proposal fits in the scope of the call (see section 1.3). Explain the personalised medicine dimension of the proposed work, including an outline on the use of different types of data, the multi-omics strategy/ies and/or cutting-edge technology/ies in the project.*
4. ***Added value:*** *Describe the 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. If European infrastructures, e.g. BBMRI, ECRIN, EATRIS or ELIXIR (see also Guidelines of Applicants), are involved in the proposal, please outline. Please describe the added value of the multidisciplinary and inter-sectorial collaboration.*
5. ***Impact****: Briefly describe the expected outcomes of the proposed work and the potential health impact (medium and long-term benefits) that the results of your proposed work will have for patients in your disease field.*

## 3.2 Preliminary results (max. 2 pages)

*Proposals are **required to show solid preliminary data** (e.g., defined vector or cell system, existing preclinical model) supporting the work plan description.*
*Please describe prior work by the consortium members related to the proposal including preliminary results and the current developmental status of the solution to be tested in the project.*

- **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 indicated in each section!**

## 3.3 Credible Pathway towards clinical application (max. ½ page)

*Proposals are **required to describe a credible pathway** towards clinical application. Please specify how the proposed CGT can reach clinical application (e.g., proof of principle, next translational steps for clinical trial readiness).*

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

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

# 5 Responsible Research and Innovation (RRI) and other cross cutting issues (page limits as indicated below)

## 5.1 General RRI aspects (max. ½ page)

***Responsible research and innovation (RRI)*** *is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation to ensure a true societal impact.*
*RRI implies that societal actors (researchers, healthcare systems, citizens, policy makers, industry, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.*
*RRI is closely related to other cross-cutting issues, and actions can be taken that address both RRI and other important values, such as public/end-user engagement, open science or ethical assessments.*

In line with the RRI approach, please **explain how the project will demonstrate a commitment to considering and addressing the social, ethical, environmental or cultural dimensions of the proposed research** (see also "Guidelines for Applicants" for support).

*Include the following points:*

a. *Reflect on and anticipate the future known and unknown risks associated with a science or technology;*
b. *Include a broad range of stakeholders in the development of science and technologies, hence working multidisciplinary and inter-sectoral;*
c. *Reflect on the underlying assumptions and values driving a scientific research project; and*
d. *Respond to these processes by incorporating their outcomes into the design of research projects and funding programmes.*

## 5.2 Stakeholder involvement (max. ½ page)

- *Describe the role and contribution of operational stakeholders (e.g. patient organisations, citizens or citizen representatives, local communities, schools, municipalities, local/regional/national NGOs, consumer organisations).*
  ***Please note:*** *The development of a patient/citizen involvement plan (to be uploaded electronically as* ***Annex 6*** *in both stages) is strongly recommended for all applicants and* ***mandatory*** *if funding is requested from EP PerMed (see also Annex II of the "Guidelines for Applicants document). If patient/citizen involvement is not deemed appropriate within a research project, this should be explained and justified.*
- *Describe the level of involvement for each stage of the research.*
- *Explain reasoning behind involving/not involving certain stakeholders.*

### 5.3 For projects with high potential of applicability at short/medium term (max. ½ page)

*Expected time for market and transfer to patients towards clinical and public health applications, pharmaceutical/health device applications, other industrial applications including market and end user's scenario, quality of dissemination, exploitation and business plan.*

### 5.4 Ethical considerations

*Please note: If research activities are undertaken in a non-European country, the applicants should verify that the research activities will follow the Ethical recommendations of the country where the research will be conducted as well as the EU Ethical recommendations. Full proposals will be checked by an independent ethical board. You can already check here the Ethical Issues potentially raised by your proposal. Please tick the respective box below: The proposal complies with ethical principles (including the highest standards of research integrity, as set out, for instance, in the European Code of Conduct for Research Integrity, and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).*

Yes ☐ No ☐

## 6 List of references (1 page)

*Please list you references in bullet points as in 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!

## 7 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)

*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 also enter the budget of partners on own funds and patient organisations. Please adapt the table and add new columns in this section if patient organisations are included as partners.* ***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 organi-sation | | | | | | | | | | | | | | |
| PROJECT COSTS (€)[1] | Total = *requested + in-kind* | Re-quested | Total = *requested + in-kind* | Re-quested | Total = *requested + in-kind* | Re-quested | Total = *requested + in-kind* | Re-quested | Total = *requested + in-kind* | Re-quested | Total = *requested + in-kind* | Re-quested | Total = *requested + in-kind* | Re-quested |
| Person Months | | | | | | | | | | | | | | |
| Personnel € | | | | | | | | | | | | | | |
| Consumables € | | | | | | | | | | | | | | |
| Equipment € | | | | | | | | | | | | | | |
| Travel €[2] | | | | | | | | | | | | | | |
| Other direct costs €[3] | | | | | | | | | | | | | | |
| Overheads €[4] | | | | | | | | | | | | | | |
| Subcontracting[3] | | | | | | | | | | | | | | |
| **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".

**Maximum number of scientific partners can only be 7 (including the coordinator) if the consortium includes a 3rd 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). Patient organisations are not included in this calculation (for more details, please read the Call Text).*

## 8 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<br>Institution and department (complete name) |
| Early Career Researcher (ECR) | Yes ☐ No ☐<br>Please indicate the year the ECR has been awarded the first PhD or equivalent medical degree:<br>*If the ECR has received the first PHD or equivalent MD before 1st January 2019, a justification must be submitted as Annex 2 explaining the career break/s.* |
| 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 | Honours, awards, memberships or references; up to 5 relevant third-party funded projects conducted in the area in the past 5 years |

# 9 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] (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 research 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. An official signature of the respective institutions is not necessary. Please add signature lines, if needed.*

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

☐ I declare my willingness to cooperate with the research 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 research consortium

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

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[1] Call Steering Committee: comprises a single representative from each country's/region's funding organisation

**Signature Partner 2 (place, date, signature of PI):**
☐ I declare my willingness to cooperate with the research 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 research 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 research consortium
☐ I declare to not receive other public funds to perform the described tasks in this application

_____

**Signature Partner 5 (place, date, signature of PI):**
☐ I declare my willingness to cooperate with the research 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 research consortium
☐ I declare to not receive other public funds to perform the described tasks in this application

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## Annex (template provided in this pre-proposal application form)

- 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 annex as separate documents via the online submission tool.

# Annex 6 – The patient/citizen involvement plan

*The development of a patient/citizen involvement plan (to be uploaded electronically as Annex 6) 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").*

## 1 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 to the work plan 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.*

## 2 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 consortium. If two organisations representing patients or citizens are participating in one consortium and asking funding from EP PerMed, they need to be indicated as separate partners. The amount of max. 50 000 € needs to be divided between both organisations in the application and Annex 6 needs to be filled for both organisations. If no organisation representing patients or citizens request funding from EP PerMed, consortia are invited to only fill-in section 1.*

| | |
|---|---|
| **Name of the organisation representing patients or citizens** | |
| **Participant Identification Code (PIC)**<br>*Please indicate the 9-digit Code.*<br>*PIC is the number under which the administrative details of an organisation are filed with the European Commission. It is important that each organisation only receives one PIC. You can check whether your organisation is already registered using the **PIC search** function in the Funding & Tenders Portal. If no PIC number is available, this can be requested via the following link: **https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register**.* | |
| **The organisation is requesting funding from DLR on behalf of EP PerMed as** | Yes/No |

| | |
|---|---|
| **outlined in Annex II of the Guidelines for Applicants**<br>*Please select what applies* | |
| **Name of the contact person**<br>*Please provide name, surname, Email, address and phone number* | |
| **Legitimacy**<br>*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**<br>*1) Please outline shortly the mission/objectives of the organisation requesting funding of EP PerMed.*<br>*2) Please describe activities, such as patient/patient family/citizens support and/or advocacy activities and/or health research.* | |
| **Structure**<br>*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 (name and affiliation).* | |
| **Accountability**<br>*1) Please describe the account system*<br>*2) 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) Description<br>2) Description<br>3) Yes/No |
| **Transparency**<br>*1) The organisation is financially independent, particularly from the private sector (max. 50% of funding from several companies in total, included are donations). The decisive factor is the* ***mean proportion of private sector funding in the annual balance sheets for 2023-2025****. If the organisation was founded recently, please use the existing balance sheets as a basis and comment accordingly.*<br>*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.*<br>*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 according to the balance sheets of 2023-2025 (plus description if needed)<br>2) Yes/No<br>3) Yes/No |