Guide to a European Partnership for Personalised Medicine, EP PerMed

This guidance document aims to provide information about the European Partnerships developed in the 9th framework programme of the European Commission and in particular for the European Partnership for Personalised Medicine (EP PerMed, download the draft concept paper on the ICPerMed[1] and ERA PerMed[2] websites). It is intended to provide support for representatives of national and regional authorities, ministries, funders and policy makers and the Personalised Medicine (PM) stakeholder community. The path towards the EP PerMed is work in process. Thus, this guideline is a dynamic document that will be updated when new information or developments become available. In addition, topic-specific information sheets are available (and will be developed as the need arises, see also Annex 2) for relevant topics.

This document was jointly developed and approved by the ICPerMed and ERA PerMed consortia as guide for decision-makers and stakeholders in the preparation of the candidate European Partnership in Personalised Medicine, EP PerMed. The document received valuable input of the European Commission (EC) but does not represent an official document developed and approved by the EC.

Overall objectives of the document

With this document, ICPerMed and ERA PerMed (to learn more about both initiatives, please see annex 1) aim to promote the EP PerMed within countries and regions. We offer information on the EP PerMed preparations (e.g. the Member states consultations) and recommendations for regional/national organisations in preparation of the European Partnership (e.g. membership consultations, organisation of national PM hubs/stakeholder groups), to foster participation of interested organisations in the EP PerMed and help organising the baselines for preparations on the regional and national level. These steps are important aspects for mobilising the national budget commitments and receiving stakeholder input for the creation of the partnership.

1. Promoting EP PerMed within countries and regions

For the European Partnerships both the regional and national participations are important. The preparation of the partnership involves multiple steps. From EC side, Member States consultations will result in final framing and description of the partnership. From national/regional side the budget commitments and description of the input of a country into the Partnership must be defined and

[1] https://www.icpermed.eu/en/draft-concept-paper-european-partnership-for-personalised-medicine-777.php

[2] https://erapermed.isciii.es/draft-concept-paper-european-partnership-for-personalised-medicine-ep-permed/

decided. Since the national/regional commitments are absolutely vital to make the Partnership come alive, it is highly recommended and crucial to foster constructive interactions between the regional and national key players as soon as possible.
It is important to emphasise that EP PerMed is open to regional as well as national participation. Many regions have local programmes supporting health initiatives and such programmes, including EC-funded regional programmes, can in many cases be counted as commitments supporting EP PerMed. These programmes can include research and innovation, but also e.g. infrastructures, digitalisation processes, regional investments in e.g. hospitals etc. Such regional opportunities are detailed in the information sheet 4.
It shall also be mentioned that the new Horizon Europe Partnership framework is covering all aspects of society and not only health. Thus, it is essential that all good arguments in support of EP PerMed are brought forward in order to ensure a proper prioritisation of EP PerMed, not only in EC context, but also very importantly in the national and regional European Partnership portfolios (arguing for health vs. climate, green energy and others and within health arguing for personalised medicine).

Member States consultation

The European Partnerships are developed in a co-creation process[3] organised by the EC together with the Member States. Already in early stages, the EC requested a coordination at nation level: "*Please make sure to involve as appropriate sectorial ministries and relevant stakeholders in preparing the feedback per partnership. It is important to get the position of the national governments, not the views of individual research ministries.*" Furthermore, for each potential European Partnership candidate, the European Commission is consulting the Member States. This step is important, as the Member States will define their contribution (e.g. budgetary long-term commitment).

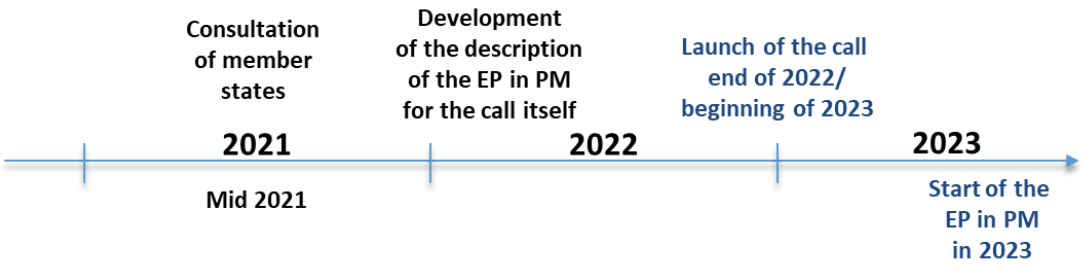

Figure 1: Tentative timeline for the expected steps to be taken for the EP PerMed until the potential launch in 2023.

Important: ONLY the Members States representatives are contacted and assembled by the EC. Each interested country should join in advance all relevant stakeholders in the country (including e.g. the regional representatives) to be in the position to provide comprehensive information about the potential commitment to the EP PerMed (primarily national and regional budget commitments, including regional funds – e.g. European Regional Development Fund (ERDF), but also other types of key contributions such as in-kind contributions, infrastructures, research facilities etc.).

[3] https://www.era-learn.eu/documents/guidelinesmsconsultation

The EC will decide, based on the outcome of the Member States consultation and the budget commitments proposed by the countries, if the European Partnership for Personalised Medicine can receive co-funding by the EC and thus be integrated in the Horizon Europe work programme.

National PM Hubs – establishment of national stakeholder groups

As a way to align regional and national stakeholders, the establishment of national PM Hubs can be suggested. Such Hubs or national stakeholder groups would enable countries to unite regions and stakeholders from the different PM aspects into national working groups. As a result, the combined contribution from a country (budgets, infrastructures, in-kind, direct or indirect costs) can be determined and be ready for the preparation of the EP PerMed and its work starting from 2023.

Such national groups would help to strengthen the PM community within the country and to connect them with those of other countries. The EP PerMed would act, as soon as being established, as platform to connect and coordinate in a sustainable way the different relevant stakeholders to develop further the PM ecosystem, allowing the alignment of strategies, exchange of knowledge and development of common dissemination and communication activities, towards PM implementation.

The constitution of the national PM Hubs is in the responsibilities of each country, but it is recommended that it reflects the different aspects/structure of the EP PerMed and thereby allows the country and autonomous region to provide a consolidated feedback on operational EP PerMed aspects.

Depending on the organisation of the country, it might be recommended to develop additional regional Hubs. They should in this case be represented by at least one person in the national Hubs.

Identifying relevant authorities and decision processes and how to approach them

Pull Approach (within and organised by the countries): The process to develop national Hubs will be different from country to country, depending on their internal structures and decision processes. However, it is strongly recommended that in particular the decision-making bodies for each country ensure that all relevant key players (e.g. regional and national authorities, funders, research institutions and infrastructures, universities and clinical organisation, industry etc.) are consulted, e.g. by forming relevant working groups. This process should be started as soon as possible in order to be able to provide input to the preparation phase of the European Partnership, i.e. the Member States consultation phase (expected in Q2/Q3 2021) organised by the European Commission and the preparation of the Partnership Proposal by the writing group (expected to be established in second half of 2021).

Push Approach (external input for each country): Regional and national authorities should be engaged and motivated to invest in PM within the framework of the coming EP PerMed.

ICPerMed and ERA PerMed are launching dedicated communications for regional and national authorities promoting the EP PerMed, i.e. via the draft concept EP PerMed document, the EP PerMed guidelines and dedicated events, e.g. workshops and information events.

Regions will be additionally motivated through dedicated communications of CSAs that are focusing on the regional dimension (SAPHIRe and Regions4PerMed), and through dedicated events and actions organised by these projects.

Support provided by the ICPerMed/ERA PerMed preparatory group

For questions around the EP PerMed guiding document or the draft concept paper for the European Partnership for Personalised Medicine, EP PerMed, please contact the Preparatory Group: ICPerMed@dlr.de and ERAPerMed@agencerecherche.fr

2. Financial aspects of co-funded European Partnerships

This section provides interested organisations with overall information around budget questions around European Partnerships (eligible costs, in-kind, cash, etc.) as well as links and guidelines for budget calculations (e.g. based on lessons-learned from 1st wave EP candidates). It must be strongly emphasised that the financial rules for the European Partnerships are not fixed yet. First information about current discussions are available on the ERA Learn website: https://www.era-learn.eu/support-for-partnerships/governance-administration-legal-base/financial-issues

Regarding the general financial framework within a co-funded European Partnership amongst partners and the EC (see also ERA Learn):

- The financial rules for EC funding are governed in a Grant Agreement between the Commission and the consortium of beneficiaries. Activities are described in the description of activities and further detailed per year in the Annual Action Plan.
- The overall budget of the co-fund action and the EC contribution are defined in the Grant Agreement for the full duration of the partnership.
- Beneficiaries to the Grant Agreement carry out activities and report their costs. The EC reimburses parts of these costs. The reimbursement rate (usually 30%, in exceptional cases 50%) is defined in the Grant Agreement and applies to all activities and partners.

Commitments and Contributions – Eligible costs (in-kind, cash, reimbursable costs, regional funds)

The Member States group design, in liaison with the relevant regional authorities, a common programme for the Partnerships to be implemented under their responsibility. This programme pools national and regional funding/resources with co-funding from the European Union. The European Union contribution is based on the eligible costs reported based on the Grant Agreement. The non-reimbursed eligible costs are the contributions from the participating states.

For research and innovation (R&I) activities addressed by open calls for proposals, as proposed in the EP PerMed concept document, financial contributions arise from transnational (or national/regional) calls for proposals organised within the Partnership. Thus, the funding allocated to applicants by the Partnership members (beneficiaries) at national and regional level counts as financial contributions to the Partnership. **Financial contributions in form of Cohesion Policy funds[4] can be considered as national contribution of the participating Member State.** This includes (as most pertinent for EP PerMed) **European Regional Development Fund (ERDF)**[5] and the **European Social Fund (ESF)** [6].

[4] https://ec.europa.eu/regional_policy/en/funding/cohesion-fund/ or https://www.cocir.org/regulations/cohesion-policy.html
[5] https://ec.europa.eu/regional_policy/en/funding/erdf/
[6] http://ec.europa.eu/esf/home.jsp

Partnership members (beneficiaries) participating with these funds in EC co-funded calls are eligible to receive EC top-up funding.
It shall also be mentioned that other types of PM related R&I actions besides EC co-funded calls might be relevant under the EP PerMed umbrella. This includes e.g. regional activities such as interregional pilot actions and other types of actions if they are directly related to the Partnership aims, objectives and activities.

The "eligible costs" are defined by the Grant Agreement. In general, eligible costs incurred by the beneficiary must be related to the action, must be reasonable and justified and must comply with the principle of sound financial management.
Examples of eligible costs are:

- direct costs:
  - direct personnel costs (e.g. unit costs, actually costs),
  - direct costs for subcontracting (actual costs),
  - direct costs of providing financial support to third parties (e.g. cash contribution),
  - other direct costs (actual costs, e.g. travel, etc.)
- indirect costs (flat rate, to be calculated on eligible costs)

Examples of activities related to eligible costs are:

- Funding provided to research projects, e.g. selected in transnational calls for proposals,
- Coordination and management of the partnership, including the management and implementation costs of Joint Transnational Calls (JTC) (unit costs or actual costs),
- Costs of any other activity foreseen in the Partnership (including e.g. monitoring and impact assessment),
- Other costs, e.g. for certificates on financial statements.

More information are available on the ERA Learn website:

- **Draft Factsheet on In-Kind Contribution** for European Partnerships: Supporting document on the calculation of in-kind contribution for the commitments in European Partnership Initiatives.
  https://www.era-learn.eu/documents/era-learn_inkindcontributioneuropeanpartnerships_2020.pdf
- **Draft Factsheet Financial Management** for co-funded European Partnerships: Supporting document on the financial management with concrete examples for the calculation:
  https://www.era-learn.eu/documents/era-learn_draft_financialmanagement.pdf

Financial Management in co-funded European Partnerships

The consortium manages the EC contribution/co-funding and decides (in their consortium agreement) on the allocation to activities and partners. Thus, the consortium decides internally on the allocation of EC funding - this is not defined by the Commission.

3. Envisaged target groups / stakeholder community (beyond the members of the Partnership)

To allow successful implementation of PM, key players along the whole value chain need to be involved in the EP PerMed. This includes citizens and patients, researchers, healthcare providers and professionals, policy makers, regulators, health economists, experts on ethical, legal and societal implications (ELSI), data/information and communication technology (ICT) experts and industry stakeholders.

Each country interested to participate in the EP PerMed should reflect on the potential regional/national key stakeholders. This information is crucial for the input, e.g. in terms of excellence that can be provided to the Partnership by each country.

Besides the public collaborators (beneficiaries and partners of the EP PerMed as well as other public stakeholders), it is important and expected by the Commission that Partnerships stimulate collaborations and interactions with industry and innovation stakeholders to facilitate the knowledge transfer and the implementation of developed PM solutions to the benefit of citizens, patients and society[7].

4. International collaboration

International collaborations allow EP PerMed to contribute to the defragmentation and consolidation of PM research beyond the EU. Countries and regions are expected to consider PM when developing their national/operational health programmes and bring all players having an active role in PM, including regional and thematic funders, to the same table. EP PerMed aims to involve organisations from all European countries and international organisations from different continents. This allows an alignment of research and funding activities on the European and international level. Making EP PerMed a global leader in the PM field by fostering transnational coordination efforts improves the international standing of EP PerMed members and partners. This development is already on the way, driven by the international CSAs within the ICPerMed family that are currently running. However, the value generated by these international CSAs must be sustained in the framework of the EP PerMed.

For international stakeholders, the interactions might occur directly with the individual organisations or through relevant initiatives.

[7] Draft Report Member States participation in European Partnerships with industry: https://www.era-learn.eu/documents/draft-report_member_states_participation_in_european_partnerships_with_i.pdf

5. Overview/Links

Contact details: ICPerMed/ERA PerMed preparatory group:
ICPerMed: ICPerMed@dlr.de
ERA PerMed: ERAPerMed@agencerecherche.fr

ERA Learn:
The ERA Learn programme provides a large amount of information on the European Partnerships that are updated on a regular basis: https://www.era-learn.eu/partnerships-in-a-nutshell/european-partnerships

Draft Report Member States participation in European Partnerships with industry https://www.era-learn.eu/documents/draft-report_member_states_participation_in_european_partnerships_with_i.pdf

Information about the writing group
To be updated: This information will be provided as soon as available.

- **Annex 1: Description of ICPerMed and ERA PerMed**

ICPerMed: https://www.icpermed.eu

ICPerMed provides a platform to initiate and support communication and exchange on personalised medicine research, funding and implementation. ICPerMed was initiated during several workshops organised by the European Commission throughout 2016. ICPerMed aims to provide a flexible framework for cooperation between its member organisations. Together, they work on fostering and coordinating research as driver of personalised medicine.

ERA PerMed: www.erapermed.eu/

ERA PerMed (2017-2023) is an ERA-Net Cofund Action on personalised medicine, supported by 32 partners from 23 countries and cofunded by the European Commission. It aims to align national and regional research strategies and funding activities, promoting excellence, reinforcing the competitiveness of European players in personalised medicine, and enhancing the collaboration with non-EU countries.

- **Annex 2: List of EP PerMed information sheets**

- **EP PerMed Information Sheet 1:** Definition of PM and the value for healthcare systems & Summary of the EP PerMed draft concept document
- **EP PerMed Information Sheet 2:** Stakeholder's Community for Personalised Medicine
- **EP PerMed Information Sheet 3:** National Hubs for Personalised Medicine
- **EP PerMed Information Sheet 4:** Opportunities for regions in relation to funding in EP PerMed
- **EP PerMed Information Sheet 5:** Joint Funding Activities for Personalised Medicine
- **EP PerMed Information Sheet 6:** Collaboration with industry in the EP PerMed
- **EP PerMed Information Sheet 7:** International collaboration in the EP PerMed