

European Partnership for Personalised Medicine (EP PerMed)



EP PerMed

PHASING-OUT STRATEGY

Background, Considerations and Scenarios for EP PerMed beyond its current runtime

*This will be a “living document” during the lifetime of the **European Partnership for Personalised Medicine**, EP PerMed (11/2023 – 10/2033) and is provisional to the decisions made by the Partnership’s General Assembly (GeA). Furthermore, the presented options and perspectives will also be discussed on the member state level and with the European Commission (EC).*

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1) Preamble

The success, impact and long-term sustainability of the Partnership are central interests of EP PerMed, the EC and the Member states as well as all countries involved. This process will be in close consultation with all current and future partners and relevant stakeholders. The support of the partners *in-cash, in-kind* and beyond is vital to continue, especially without the perspective of an EU support (Scenario 1). Thus, it will also be dependent on the decisions and strategic advice of the governmental and advisory boards on European, national and regional level. Furthermore, the analysis and evaluation of the foreseen or running EP PerMed actions concerning their **income potential** and **perspective** as well as other achievements and developments in the years to come is another central aspect. Nevertheless, all steps and measures described in this document are subject to further development, discussion and decision within the EP PerMed governance and with the responsible units of the EC as well as dependent on future settings such as the officially published EU Framework Programme (FP)¹⁰ and beyond.

“The vision of the European Partnership for Personalised Medicine is to improve health outcomes within sustainable healthcare systems through research, development, innovation and implementation of personalised medicine approaches for the benefit of patients, citizens, and society.”

The EP PerMed vision is in line with several overarching regional, national, European, UN and WHO goals and priorities. Therefore, the Partnership aims to optimise the diagnosis, treatment and preventive options and strategies with the concept of Personalised Medicine (PM) on the basis of research achievements and their rapid and safe adaption, utilisation and implementation in the healthcare. This effort is supported by existing and emerging enabling technologies, such as artificial intelligence (AI), supercomputing, imaging, data technology to support collection, harmonisation and use, 3D-printing of tissues or PM-related devices for example for live treatment monitoring or digital twins. Here is the achievements and expertise of other European Partnerships will be significant and respective collaborations are already started or foreseen by EP PerMed.

The Partnership will increase and accelerate the development and implementation of the PM concept in the coming years for benefit of society through improved healthcare and prevention as well as contributing to economic growth and the employment market. Although, the focus is on Europe, the initiative continues to welcomes further organizations from around the world. Additionally, the European Partnership joined forces with the International Consortium for Personalised Medicine (ICPerMed established 2016) since the proposal phase. EP PerMed, ICPerMed and related projects developed an enormous impact and an “European Spirit” for Personalised Medicine, regionally, nationally as well as for Europe and beyond. It is significant that PM and EP PerMed is dependent on health research and the national healthcare system settings. In this line and for good reasons, it is generally not possible and allowed to have a direct market access for PM-related products, approaches or solutions. Before Personalised Medicine solutions and approaches create benefit for patients and people and bring profit to the private sector, several and often limiting or even blocking steps have to be passed. For example, clinical validation to assess safety, efficacy and cost effectiveness, regulatory approval or health assessment (HTA) as well as health economic modelling for investment and PM reimbursement and pricing. Additionally, it needs to be investigated whether a sufficient number of European healthcare payers are actually willing and able to implement innovations.

2) EP PerMed Future Scenarios

The objective of this Phase-out strategy is to develop and describe realistic and credible strategies and pathways to ensure the continuation of EP PerMed funding and other activities also beyond EU support and EC participation. These strategies are developed in dependence and the light of the current achievements of the Partnership as well as European framework and settings for co-funded Partnerships in general. Accordingly, the two below outlined scenarios serve to initiate and guide continuous internal and external discussions and developments. Revision and adaption of the presented scenarios in the future will consider accomplishments and impact of the Partnership along with other advances and adaptations in healthcare across Europe and beyond related to and influencing PM. Thus, EP PerMed and its partners will early and iteratively analyse and adapt, reduce uncertainties, and ensure that the Phasing out-strategy is feasible and realistic. Nevertheless, this will also be dependent on the latest developments in the European and national frameworks.

Timeline for the next steps to refine and implement the Phasing-Out Strategy

Date	Activity	Responsibility
April 2026	Discussion and adoption of the latest version of the Phasing-Out Strategy and its foreseen measures at the next on-site meeting of the GeA (General Assembly of all partners) on April 21 st /22 nd in Brussels.	All partners (General Assembly, GeA), EC, HaDEA
2027 - 2029	Development of a concept of potential fees for EP PerMed partners and future members as well as further potential budget optimisation and income generating activities which will be included in the Phasing-Out Strategy (e.g. institutionalised partnership, non-FP EU funding, schools, trainings, other Personalised Medicine related services, events, tools and instruments etc.). In spring 2027, the EP PerMed/ICPerMed 2 nd Joint Conference and SRIA2027 finalisation will be a crucial activity which is suitable to advertise Partnership's sustainability strategies and gather further partners and members, recommendations and approaches to support the sustainability of the Partnership.	Coordination, Coordination Unit (CU, Coordinator, WP Leads, co-leads and EC) and GeA
2029	A survey among all partners, interested entities and stakeholders is foreseen to analyse the possibility and willingness to support EP PerMed not only with <i>in-cash</i> for Joint Transnational Calls (JTCs & RITCs), but also with an annual payment or contribute <i>in-kind</i> (amongst others) as well as with additional sources. Investigation of the opportunities of further EC sources and calls within FP10/11 and other EU programmes to support the EP PerMed goals, work and activities. More detailed budget considerations for both scenarios are developed, discussed and presented.	Coordination, GeA and EC
2030	Adoption of the EP PerMed Phasing-Out Strategy and an agreement of the amount of funding (in-cash), in-kind contribution and partner, membership fees by all committed entities and if possible, donations earliest by October 2030.	Coordination, GeA and EC

	<p>Adoption of a business and financial sustainability plan according to the the actual setting and frameworks in place at that time. If needed adaption according to the expected budget and of the governance structure as well as the legal entity of EP PerMed.</p> <p>2030 Conference and SRIA2030 update, which are activities suitable to further communicate and advertise EP PerMed sustainability strategies and gather further ideas and approaches to support this goal.</p>	
2032	<p>Refinement survey among partners and stakeholders with regard to the final adjustments according to current political agendas and frameworks. Analysis of relevant indicators, e. g. at least 20 partners and members provide signed letters of intent. Persons and/or institutions are identified and contacted for potential and support of PM and EP PerMed. In parallel income generating options and strategies on the basis of EP PerMed activities, expertise, funding, services and data are developed and prepared as a further source of support for the possible non EU funding period after 2033.</p> <p>Formal finalisation of the developed and adapted Phase-out strategy, followed by the start of the transition phase for the Partnership.</p>	Coordination, GeA and EC
2033	<p>Last year of EP PerMed’s funding period and start of the Phase-out scenario along the approved final strategy, depending on the actual setting and frameworks in place at that time on European and national level.</p>	Coordination, GeA and EC

The overall aim would be to continue EP PerMed at least **another 10 years** and if possible, establish a sustainable support of the Partnership beyond a defined deadline.

Scenario 1: EP PerMed is financed by “Partners”, “Members” and income generated budget

For this scenario “**Partners**” are active EP PerMed funders, such as **ministries, funding agencies, foundations or charities**, who join transnational calls with *in-cash*, conduct and/or organise activities *in-kind*, such as events or meetings (Status Quo). For this Phase-out scenario they have also to support the Partnership by a defined and agreed annual fee. Additionally, new “**Members**”, such as **research institutes, infrastructures, Medical Societies, Patient Organisations**, as well as **institutions or initiatives** from the **private sector** like **industry, SMEs or Start-ups** are welcome to join EP PerMed. There will also be the option of members participating from the **healthcare sector**, such as **hospitals or payers**. They will be able to support the Partnership’s activities by *in-cash, in-kind and a defined annual fee*. If no EU-funding is available, this scenario will maintain legacy and impact of the EP PerMed results, and the continuation of established valuable structures, networks and processes as independent as possible and at least on a basic level.

For the additional efforts and actions, like in the current status, resources will need to be acquired as described above. A supplementary option could be **crowd-funding** activities and **donations**, dedicated to Personalised Medicine and the Partnerships achievements as well as its aims and goals. Another source will be **fees** for EP PerMed **conferences and events**.

At the moment EP PerMed needs around 6 Mio. Euro per year for personnel and other costs to establish and run its activities and various types of calls or tools. This is about **15%** of the total EP PerMed budget of 375 Mio. Euro (*minimum 275 in-cash by partners and maximum EU-contribution of 100,5 Mio. Euro. Additional budget for 3rd parties is generated by groups which join the JTC consortia with own funds which is in average around ~8 Mio. Euro per JTC*). Roughly **85%** of the total budget is and will be utilised for funding and supporting 3rd parties via the co-funded calls (**7** annual JTCs and **3** RITCs) and other calls and measures funded via the EC-share of EP PerMed, like the Fast-Track, Twinning, Network support, Education Calls and the Tender for Surveys.

To ensure a **basic continuation**, EP PerMed needs a minimum of 1,2 Mio. Euros per year to manage at least the annual JTCs, maintain the webpage and organise PM-related events. If the Partnership agrees on an annual membership fee of for example 10.000 Euro per partner/member this would generate about 600.000 Euro per year, if 60 entities (*status quo*) are willing and able to participate and contribute. Additionally, the Partnership would need to generate at least of 600.000 Euro income to guarantee the basic continuation of EP PerMed by the options mentioned above. In such a setting, the main focus will remain on joint transnational funding for PM by the national funders, but then without EC top-up or purely by EC-share funded calls. Therefore, the Partnership will most likely not be able to continue and established measures to support personalised medicine innovations and their implementation into healthcare systems or the support Patient Organisations on the level established since the 2nd co-funded call, JTC2025 where already around 14 Patient Organisations will be funded with around 0,7 Mio. Euro.

The following steps and approaches can support this scenario with potential savings and generating extra budget:

- **Centralised processes** for the implementation of the different EP PerMed **call formats** could be established and streamlined towards the end of partnership (2033), utilising appropriate tools, such as the chance of assistance by AI, to facilitate suitable procedural steps. This process might also include EU tools, for example for the submission of proposal, monitoring, reporting or dissemination. Additionally, the management of co-funded calls in health is streamlined, simplified, automatised within EP PerMed, but maybe also across Health Partnerships and thereby reduce efforts and costs.
- To continue **all call management needs**, each participating country/region may support *in-cash* or with experienced staff the Joint Call Secretariats (JCSs). This could be backed by a type of **participation fee per JTC**, also by associated and external partners joining a call and fairly described in a call specific Memorandum of Understanding (**MoU**).
- Some **mitigation measures** will be prepared and agreed on, such as reducing the number of joint calls or developing less complex call formats and topics. This could reduce management efforts and budget by e.g. a one-step evaluation, a limitation of proposals, no rebuttal-step, no on-site evaluation panel meetings, reduced meetings in general, resign of the ethical clearance and/or data transfer, simplified monitoring, reduced communication and supporting efforts of the Partnership.
- Based on the experiences and achievement, the Partnership could further develop the **Venture Creation** and **Mentoring Programmes**, if feasible also jointly with interested companies, business schools or other stakeholders of the Personalised Medicine innovation systems. These activities can be offered commercially and connected with certificates or prizes. EP PerMed did already start first steps in these directions by a close cooperation with the University College London (UCL) and other interested European business schools.

- Alternative **resources** in the areas of PM will be identified and developed, like interfaces for data, tools and services, knowledge repositories, guidelines, ethical and legal frameworks, strategic and policy documents as well as PM impact examples. Some of these might be suitable and feasible to generate a certain income for the Partnership.
- Based on suitable EP PerMed activities, such as the **Education** and **Twinning Call**, these could be further developed, maybe together with interested companies, hospitals or other stakeholders from the PM innovation and healthcare systems and then been offered commercially.
- Furthermore, opportunities by **EU calls** and other support of the Partnership and its activities will be monitored as soon as FP10 is officially launched. Other EU programmes, like the European Competitiveness Fund or new measures will also be monitored.
- Additionally, support for these and further tasks by **non-for-profit, philanthropic bodies** or **foundations** could be assessed. In this way, the dependence on EU funding may be reduced directly or most likely gradually while enabling the process of diversified funding.
- For patient engagement and empowerment, the development of concepts and activities for the **structural support** by relevant European societies could be explored, e.g. to get **financial support** from philanthropic foundations or private persons or even **crowd-funding** or **citizen science grants**.
- Activities and instruments established by EP PerMed could be offered with fees and hence be another source of **income generation**. For instance, trainings, schools, event or education instruments, tools and services. These could partly be connected with an EP PerMed certification, conference, workshop or be supported via specific courses for early career researchers and healthcare professional, start-ups and others. This approach might be even more promising if organised together with medical or research societies, patient organisations or PM-relevant infrastructures as well as other Partnerships on national and European level.
- In connections with the above-mentioned PM innovation activities, the Partnership will investigate options of so-called “**payback approaches**”, similar to the ones established for European Institute of Innovation and Technology for Health, EITH. The concept would be, that when EP PerMed’s support of 3rd parties was successful e.g. for a Spin-off, Start-up or any other business concepts, the respective contracts with the Partnership could include a clause defining a time-frame, e.g. 3 years, after which a defined amount is paid to EP PerMed as a kind of payback agreement. However, this might be a complex, legally challenging and time-consuming activity.
- So-called regional or national **PM Hubs** for Personalised Medicine are encouraged by the Partnership as decentralised entities to foster alignment and implementation within national agendas for research and healthcare. These groups could maintain or even enforce their activities to ensure exchange and sustained alignment of scientific and policy strategies and integration in national as well as regional programmes. This could also be the case for the International Consortium for Personalised Medicine (**ICPerMed**) on a global level.

Policy reflections of a non-EU-funded EP PerMed, scenario 1

- **Reduced participation** and active involvement of funders, patient and public organisations and initiatives as their and EP PerMed budget is limited. The Partnership will for example not be able to

continue the established Round-Tables, schools and training and needs to reduce other PM related event and meetings Transnational Consortia.

- **Reduced impact**, as fees will be limited for most national and regional partners raising a significant budget for management is unlikely. Furthermore, several funders are in diverse Partnerships, so the fees sum-up and especially for regions and smaller countries, e.g. E13 countries, this might be a challenging situation. There is the danger that partners do have to select Partnerships they can and want to join with the result of reducing the available fee-generated budget by fewer partners and members. Also, this might lead to a competition within a cluster or even across clusters.
- The influence of EP PerMed from the **private sector** could modify the objectives of the Partnership funding and its activities along their interests. And this might not align with the goals of several non-for-profit partners, the existing societal challenges, the burden of disease or the technological opportunities for Personalised Medicine.
- **Fewer participation of E13 countries** as the budget will be limited and the chance of being successful in the joint transnational calls, also because they do not offer anymore the gap-filling/top-up funding.
- In the absence of a **coordinated European mechanism**, countries with strong and well supported national research communities and systems may increasingly rely on national or bilateral funding schemes, which would lead to fragmentation of the European personalised medicine research, innovation and healthcare landscape.
- The loss of the **Partnership's infrastructure** which has been developed over the decades is likely. This would for example include the transnational communities of ministries and funders as well as the call management structures and procedures, evaluation networks, monitoring systems or the data, collaboration networks and the continuity of the developed strategic goals and roadmap, especially outlined in the EP PerMed SRIA and its updates.
- In parallel the **funded communities** and **institutions** in all areas of Personalised Medicine will reduce their transnational collaboration and communication, which will reduce their chances to develop promising high-quality consortia to apply for EC calls related to PM.
- Furthermore, it is undecided which legal status EP PerMed will have without EU support and how the income and fee generated budget could be managed, distributed and controlled.
- EP PerMed is no longer able to support **ICPerMed** on an organisational, cooperation and secretariat level due to the reduced budget available for the Partnership.

Monitoring of transition to a non-EU-funded future, scenario 1

Due to the complete withdrawal of EU financial support in this scenario, the Partnership is not anymore, an EU funded consortium and the respective regulations and rules are suspended. However, EC representatives are still welcome to join the governance as advisors and observers to support the alignment of the related activities and funding in the areas of PM. The information and communication activities can be continued on a voluntary basis, e.g. funded consortia, events, documents and input for EC data bases and documents such as the Biennial Monitoring Report ([BMR](#)) 2022 and 2024 on Partnerships in Horizon Europe launch.

Scenario 2: A sustainable or partially EU-supported EP PerMed

It is assumed that the EU and the Member States continue to recognise the importance of the Personalised Medicine concept for the present and the future particularly for the well-being of our societies and economies. Thus, the EU will continue to provide reasonable support for funding research, innovation and implementation of Personalised Medicine as well as the management and coordination via EP PerMed in a range similar to the contribution at present, which is 30% of the total budget. Furthermore, national ministries and funding agencies will be able and willing to support the calls and the activities of the Partnership as currently which is 70% of the total budget.

Accordingly, EP PerMed activities would be aligned, communicated and support the parallel efforts for Personalised Medicine by the EU and the member states. Moreover, the health and societal challenge addressed by Personalised Medicine in research and at the level of national and regional healthcare systems will be centrally supported. Moreover, research achievements and technology developments will generate new opportunities for Personalised Medicine, like AI, Apps, Wearables and supercomputing.

In the best of all options the EU funding continues on the current level, which is 30% of the total budget in addition to the contribution of the partners (70% in-cash and in-kind). This would allow the continuation and further optimisation of the established and foreseen calls and activities by EP PerMed. These are very successful not only in the area of transnational research funding, but also supporting innovations and their implementation into healthcare systems. Furthermore, the funding of Patient Organisations and, together with ICPeMed, offering an international platform for cooperation and exchange on Personalised Medicine. However, if the budget will be substantially reduced, it should at least allow the continuation of the joint transnational funding and some top-up budget for the individual co-funded calls. This could be achieved if at least 1,5 Mio. Euro per year are available and an EU contribution is provided, e.g. via a Support and Coordination Action, similarly to a Secretariat (as formerly in ICPeMed) or as done before in ERA-Net co-funds. In this case, there is a need for additional concerted and joint efforts including funding by member states, the EU and other crucial national and regional stakeholders.

All under scenario 1 mentioned further steps and approaches will be considered to support also in this scenario. The under scenario 1 mentioned risks, regarding e.g. reduced impact and participation, apply here too.

In this scenario, also **ICPeMed** could be further supported organisationally and thereby the structural and policy support on a global level will be sustained and could even be further extended.

The EP PerMed partners are looking forward to the coming years and are dedicated and convinced that the established and planned funding as well as the various additional activities to support Personalised Medicine will have a strong and positive impact on healthcare, society as well as on the economy by its achievements and opportunities in Europe and beyond. The Partnership will actively analyse and establish measures and strategies to ensure the EP PerMed activities for at least 10 further years even in case the EU contribution stops.