This document was jointly developed and approved by the ICPerMed and ERA PerMed consortia as input and supporting document for the Member States consultation on the future European Partnership in Personalised Medicine organised by the EC. The document received valuable EC input but does not represent an official document developed and approved by the EC. The document is not the official partnership proposal.

1 General information

1.1 Draft title of the European Partnership

European Partnership for Personalised Medicine (**EP PerMed**)

1.2 Summary

Personalised Medicine (PM) is as a major opportunity for society to provide benefits to patients and citizens and health systems. Key questions that PM tackles are:

- **Why does a treatment for a certain disease work very well for one patient, but poorly or not at all for another patient?**
- **What is the benefit of individual molecular, clinical or lifestyle data for the development of personalised prevention, diagnostics, and treatment?**
- **How can the knowledge of an individual genetic profile or personal setting help to avoid health risks and support a healthy life?**
- **Can the use of PM be cost effective?**

There is a common understanding among researchers, healthcare providers and other stakeholders that PM, due to its great potential for disease prevention, diagnostic and treatment, is a principal driver towards optimised healthcare. But is Europe, with its heterogeneous regional and national healthcare systems, prepared for this improvement?

Major progress has already been achieved via many international, pan-European, national as well as regional initiatives. To further develop and promote implementation of PM approaches, and to address the challenge “to not leave anyone behind”, joint efforts are needed among all key European stakeholders.

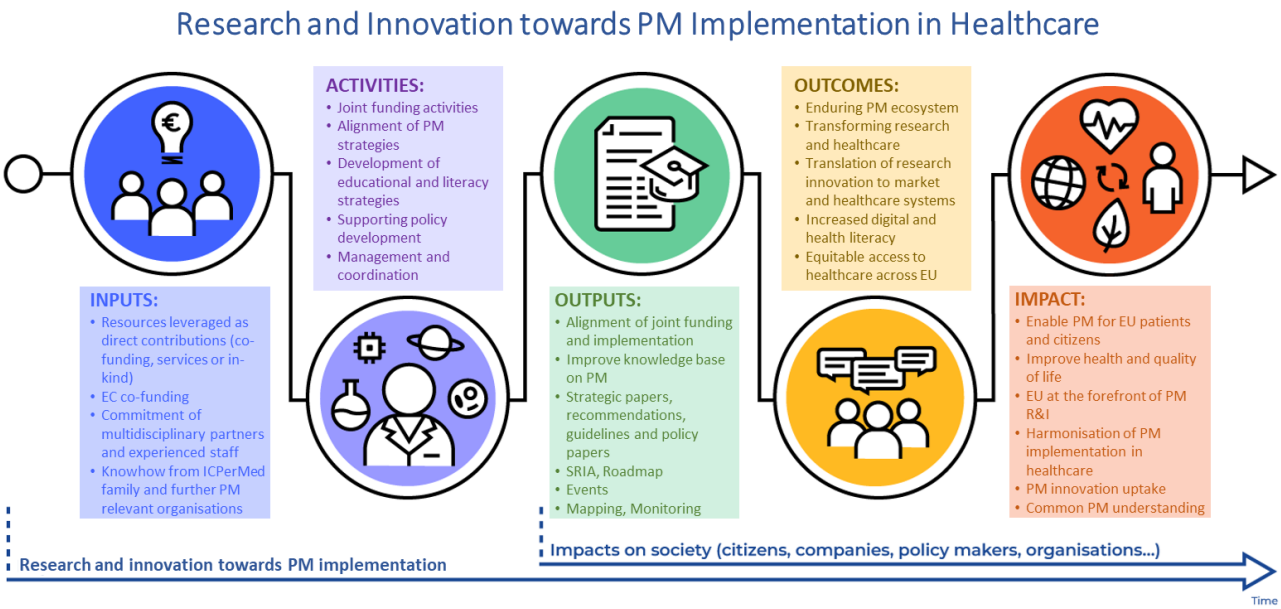
This can be achieved through a co-funded European Partnership for Personalised Medicine (EP PerMed) bringing together commitments of EU member states and participating organisations. The inputs will be sharing of information, evidence, know-how and the willingness to cooperate as well as contribution of resources in form of personnel, cash, in-kind and additional co-funding support by the European Commission.

With these inputs, EP PerMed will be a prime driver for developing and implementing PM by establishing priorities for **research funding**, **aligning PM strategies**, **developing educational and literacy strategies**, and **supporting policy development**. These activities are based on current initiatives like ICPerMed and ERA PerMed whose efforts will be further developed within EP PerMed to:

- Develop, promote, and support innovative PM solutions and implementation strategies.
- Promote, align, and encourage joint funding efforts within PM research and implementation.

- Promote the advances of PM as well as the state-of-the-art understanding by facilitating exchange of information, experiences, and ideas.
- Accelerate the discussion and decision-making by providing a platform for all key players and institutions involved in the PM research and implementation, including patient and citizen representatives.
- Support the communication and collaboration amongst European countries and regions at multiple levels.
- Strengthen the communication and collaboration between European authorities and international partners, as well as complementary initiatives and relevant stakeholders.

With seven years of funding and a steadily advancing PM environment, the EP PerMed platform, with its structure around the described four main activities and joint coordination and management, will act in a flexible and dynamic way to allow continuous adaption of the focus.



Comment: For more detailed information please see also Annex 7.1.

EP PerMed will support cooperation and investment across Europe and thus pave the way towards the efficient use of existing healthcare systems for the citizens, support translation of innovation to the market, foster a highly connected PM ecosystem, also on the national levels, and support increased literacy of citizens and health professionals. Hence, EP PerMed will influence the transformation of research and health care.

EP PerMed will create innovation and value by dedicated PM research funding activities, by developing new implementation tools, scientific concepts, knowledge bases, health economic models, etc. for implementation of PM in health care. This includes also social innovation to meet social needs for example around education and literacy and the development of a PM community along the whole value chain with active participation of patients and citizens.

The work of EP PerMed will lead to a harmonised PM research and implementation in health systems across Europe, facilitate the uptake of PM innovation by health systems and establish a common language and understanding on PM for citizens, patients and health professionals. EP PerMed will have a major impact on enabling PM implementation for citizens ensuring that Europe is at the forefront of PM research and innovation.

2 Context and necessity for joint collaborations in personalised medicine

2.1 Context and background information

During the last years, especially due to an improved understanding of diseases, development of advanced technologies (e.g. in diagnostics) and the emergence of the first clinical success stories, it has become evident that more personalised approaches in medicine and healthcare are needed for treatment, prevention as well as predictive and participatory medicine and health care. The efficiency of health inventions needs to be improved as it becomes clear that the "one size fits all" model is not sufficiently effective due to the specific characteristics of patients, e.g. age, gender, biological fingerprint and lifestyle choices. Personalised Medicine (PM) represents this paradigm change to more targeted and "personalised" interventions.

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

PM advancements so far concentrate on diagnostics, patient stratification and personalised treatment, but future progress in these fields will ultimately pave the way towards disease prediction and prevention. By definition of the European Commission (EC), PM refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, health and lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. This definition clearly shows the overall aim of the European Commission "to leave no one behind" with a focus on citizens and the benefit for the society.

The Health Directorate of the European Commission's Directorate-General for Research and Innovation stated already in 2012 that PM is one of the most innovative areas in the future of health research with a high potential for patients, citizens and the economy.

Within the last years, many countries increased their efforts in the PM field and allocated budgets for PM research and implementation on the regional and national level but also in collaborations across countries. Aiming at establishing Europe as a global leader in the field, the EC has been supporting joint efforts and activities related to PM. For instance, the EC was instrumental in the establishment of the International Consortium of Personalised Medicine (ICPerMed), a platform that today connects more than 40 countries with a common goal of aligning and supporting efforts on PM research and implementation. Furthermore, since the seventh Framework Programme (FP7) and during Horizon 2020, the EC provided a budget of more than 3 billion euros to fund research projects in PM as well as to PerMed (2013-2015), the ICPerMed Secretariat (2016-2021, and a new CSA Secretariat until 2023), ERA PerMed (2017-2022), and also various Coordination and Support Actions (CSA) that are part of the ICPerMed family (fig. 1, see also chapter 3.2).

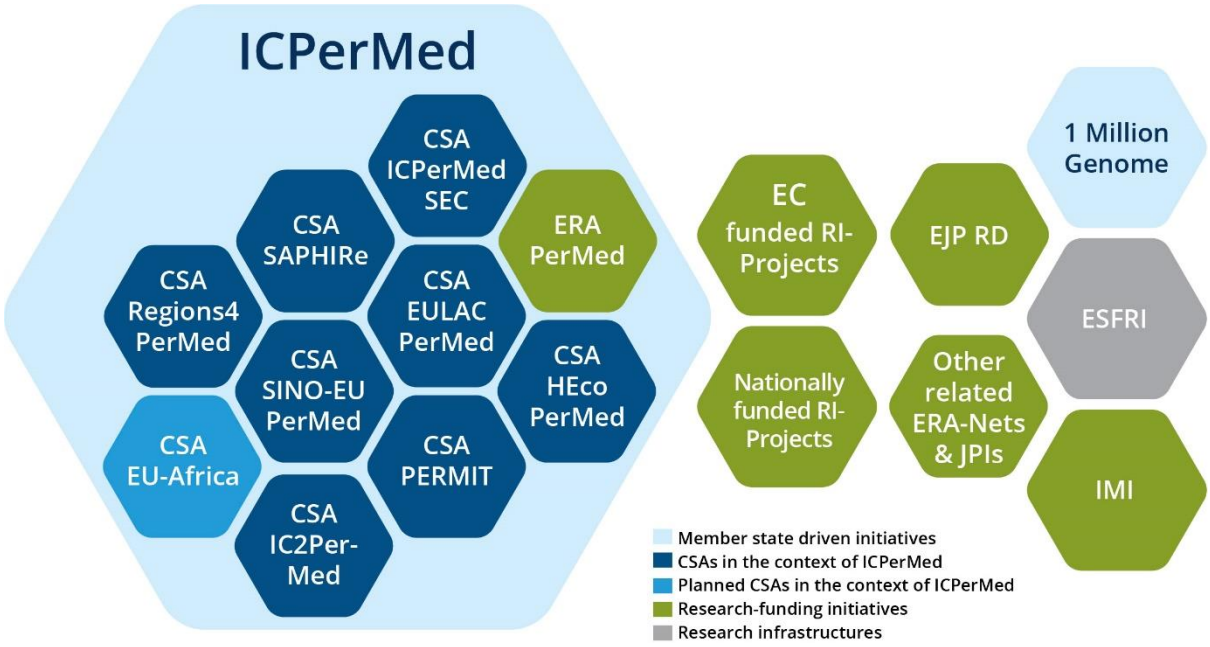


Figure 1: There is a close collaboration between ICPerMed with the European Research Area Network for Personalised Medicine (ERA PerMed), several Coordination and Support Actions (CSAs) funded by the European Commission, as well as with an increasing number of associated and related initiatives, research infrastructures and capacities. This so called ICPerMed 'Family' plays an important role in supporting the research and implementation of personalised medicine in Europe and beyond. ©ICPerMed (https://www.icpermed.eu/en/related-initiatives.php)

Within country borders, many EU regions are also investing in PM in order to push the research and innovation boundaries and maintain the health sector competitive and efficient (see fig. 2).

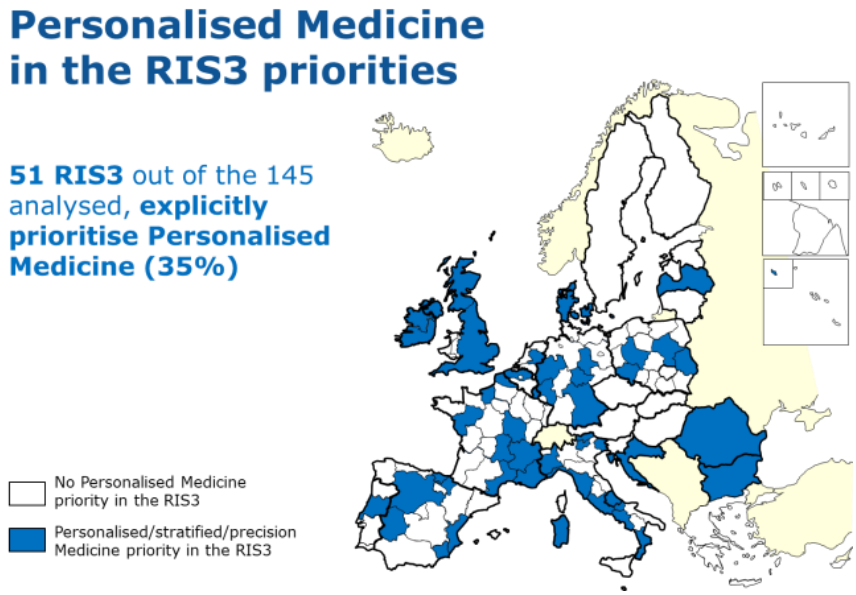


Figure 2: European Commission, Regions4PerMed kick-off Conference, November 2018. RIS3 (Research and Innovation Smart Specialisation Strategy) refers to regional strategic plans for development of region.

Together, these different actions allow research funding, strategic reflections and alignment of strategies in PM on the regional, national, European and international level, but also specific analyses of clinical interventions and health economics (https://www.icpermed.eu/en/related-initiatives.php).

That PM represents an area that concerns everyone is underlined by new European and international (e.g. of North and South America, Africa and the Asian continent) organisations joining the ICPerMed consortium and participating in the ERA PerMed calls.

The past years demonstrated the willingness to and the importance of exchange of knowledge and innovative PM practices between European member states and international partners, and to jointly fund research in this area. More than 80 million Euros are expected to be invested in PM research via ERA PerMed alone until 2021. A European and international PM research community is thus identified and further investment in this area is needed to broaden the structure and interlinks in this community, through research and network forming calls and also through specific support actions e.g. for policy development for PM implementation. This will achieve the multidisciplinary and cross-national collaborations that are essential elements to develop successful PM approaches. Therefore, funding is a very central element in the future **European Partnership in Personalised Medicine** (**EP PerMed**).

The involvement of different regional and national funders from Europe and beyond in EP PerMed will allow the integration of a large range of PM actors in innovative multidisciplinary research projects. ERA PerMed, currently running its third Joint Transnational Call (JTC), already demonstrated with excellence the successful alignment on a common strategic and innovation agenda, providing guidance for transnational calls, in combination with flexible call structures, both needed for funding research in PM especially when including a large number of participating funding organisations.

There is furthermore the need for innovative collaboration at the strategic and policy level, considering the varying levels of advancements of countries and regions towards the implementation of PM. Healthcare systems are heterogeneous, differing from one country to another and are often coordinated at the regional level.

Additionally, healthcare systems are closely interlinked with the local cultural and social background. The fragmentation of healthcare systems might delay the integration of recommendations at regional and national level, making the development of commonly applicable strategic decisions in PM a challenging exercise. Differences in healthcare systems and the accessibility of diagnosis and care increase the risk of migration of patients and citizens outside their healthcare system in other regions or countries affecting the efficiency of healthcare and especially the follow-up needed for the development of prevention strategies.

To help overcome this hurdle, the EP PerMed will promote innovative and successful solutions for PM implementation in the form of a “Best Practice catalogue” presenting and describing different PM approaches that can be tailored to different kinds of healthcare systems. This repertoire allows regions and countries interested in PM implementation to find potential models for their individual healthcare system and PM question to be tackled. It therefore contributes to addressing the challenge “to not leave anyone behind”. Joint efforts are needed to achieve alignment of strategies and common priority setting, to develop and launch innovative education strategies, and foster policy development and communication.

The EP PerMed will continue the work of ICPerMed by bringing together ministries, regional authorities and funding agencies with a common vision of PM. EP PerMed will serve as a platform to create the synergies needed for integration of essential expertise in PM, and to seek further input

from different stakeholders such as industry, clinics, research and patient organisations and health insurances and other payers[1].

Despite the heterogeneous healthcare systems of participating regions and countries, ICPerMed has already demonstrated complementarity of approaches allowing building common strategies in order to develop new standards. Through this approach, it will be possible to achieve convergence and harmonisation of approaches and systems at the European and international level.

The EP PerMed aims to foster advancements in PM by joint research funding efforts, creating a dialogue platform for all relevant stakeholders and providing a forum for promoting novel evidence to decision makers regarding current challenges and possible solutions in the implementation of PM. The EP PerMed will add value by bridge the gap between PM research and its implementation in healthcare systems, by bringing together all the stakeholders involved in this field in the partnership. This holistic approach has the potential to establish solid interconnections and alignments between the elements of the healthcare value chain including industry as well as civil society organisations, foundations, non-governmental organisations and relevant infrastructures (e.g. ESFRI) that are key players in the translation and implementation of the developed solutions.

2.2 Necessity for a European Partnership

Over the years, the science base for PM has been evolving from demonstrating the effectiveness of personalised diagnosis and treatment of some rare diseases and cancers to the possibility of using biomarkers to predict any individuals' disease risk and thus prevent onset of common complex diseases. It is nowadays clear that the potential of PM goes beyond treatment into prevention, health promotion, and disease management. The increased understanding of biological, lifestyle and environmental factors that regulate disease onset and disease progression, together with the prolific technological advancements for biomarkers discovery and detection in the last two decades are the driving force for discoveries supporting PM.

However, implementation of PM in healthcare systems for the benefit of the citizen is still lagging, involving a multitude of other considerations beyond biomedical ones. Conceptually, PM may be seen as a natural evolution of medicine. However, in practical terms it may well represent a major disruption for healthcare systems, implying a shift from public health concepts traditionally developed for populations to a main focus on the individual. Major reforms in healthcare systems are necessary. These include not only solid biomedical knowledge, but also evidence for cost-effectiveness, policy makers and healthcare administrators that understand the potential of PM, investment in novel technologies, tools and procedures at the healthcare scale, multidisciplinary teams with complementary competences, clear communication with patients, and solutions for access, reimbursement, insurance, equity, regulation and other issues.

For the citizens to effectively have access to PM, there is still a path to be followed towards development of crucial areas that might be clustered into four main axes: "Basic and Translational science", "Policy development", "Regulation and market access" and "Education and literacy" (fig. 3). R&I conducive of development in these axes is inherently multidisciplinary, including clinical, biomedical and data analytics, health systems and public health policies, economic modelling, ELSI solutions, innovation in digital and other technologies, pharma, regulation and market access strategies as well as parallel advances in education and literacy (indicated in yellow frames in fig. 3).

[1] "Payer" = health maintenance organisation, insurance companies, management services organisation, health ministries etc.

In many areas a lot has already been achieved, while progress in other crucial areas is still very slow (see also section 3.1).

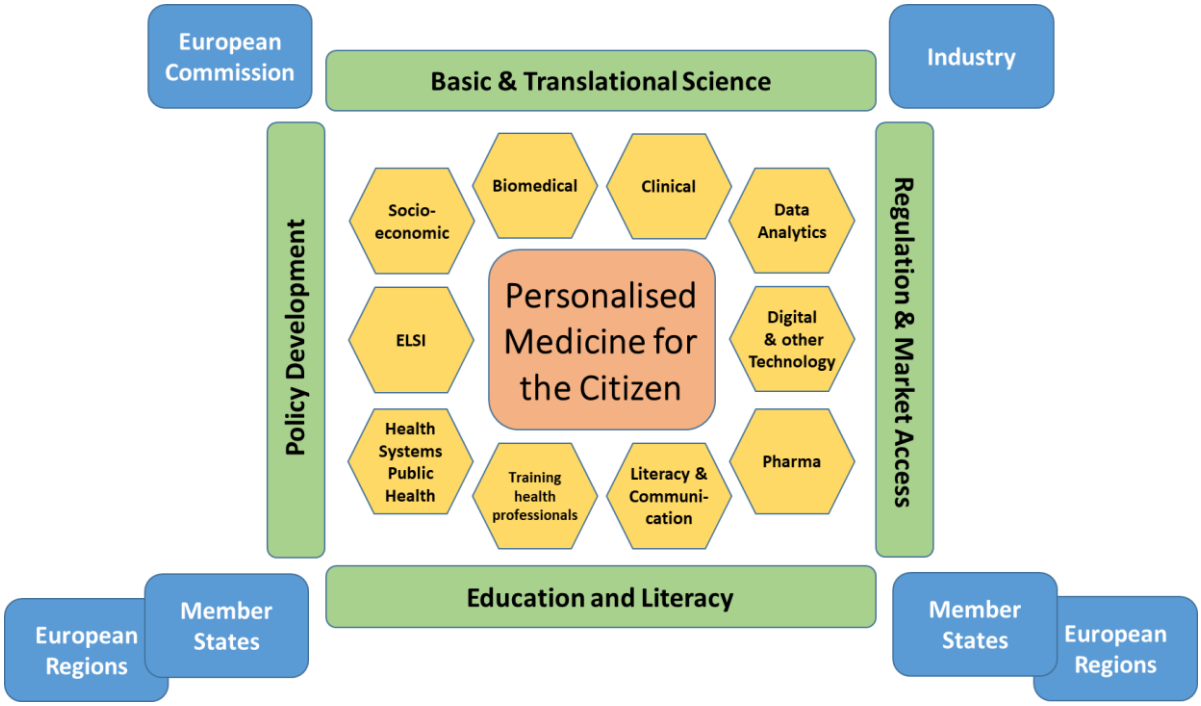


Figure 3: European Partnership on Personalised Medicine Concept

Cooperation and investment across Europe will strongly benefit the progress on PM implementation, allowing enhanced sharing, harmonisation and dissemination of knowledge, policies, and strategies, and ensuring that drivers of development really support equity across European countries and regions. R&I activities along each of the crucial axis of development will strongly impact how Europe will be placed at the forefront of:

- personalised diagnosis, treatment and prevention;
- the harmonisation of PM policies for healthcare systems across MS and regions, following the principle of "no one left behind" by fair access;
- the strategies for uptake of PM innovation by health systems;
- and, importantly, how citizens, patients and health professionals achieve a common language and understanding about PM approaches (see also table 1).

A final important point concerns sustainability, from two perspectives:

1) The multitude of PM-related activities under Horizon 2020 has created a wealth of results, cooperation and information.
2) The novel information that will have been created by the end of the Horizon Europe.

EP PerMed will be a key mediator in both, ensuring that the H2020 outputs will be available as a basis for further work and that value created under Horizon Europe will be sustained in future activities.

Overall, by fostering cooperation among the relevant stakeholders and investment in R&I, and transversal activities that promote development along the four crucial axes of development, EP PerMed will enable the different participating regions and countries to implement PM approaches for the benefit of citizens and patients.

2.3 Why to participate in EP PerMed?

By joining EP PerMed, funding organisations will have the possibility to participate in different joint funding activities, centrally organised by funding consortia with expertise in transnational, multidisciplinary research and network funding in the field of PM. Thanks to a flexible call structure, already successfully implemented in ERA PerMed, different kinds of organisations providing funding along the entire value chain can participate in supporting excellent projects and consortia.

The EP PerMed allows funders, via the joint funding activities, to align on a common strategic and innovation agenda, providing guidance for transnational calls, which could also be implemented in regional or national calls.

The participation of funders and researchers from third countries represents an added value to achieve multidisciplinary and increases available resources (including human resources as well as infrastructures), considering that PM is a global topic with excellent experts located also outside of the EU.

On the policy level, EP PerMed will provide a platform for ministries and regional authorities to exchange on policies, guidelines and recommendations to develop and align new strategies, to learn from each other and to present their specific advancements in the field of PM.

EP PerMed is the solution to go one step forward towards the harmonisation of healthcare systems. The currently existing fragmentation makes it difficult to rapidly integrate recommendations at national or regional level, and hampers the development of commonly applicable strategic decisions in PM. A solution to that issue will be a commonly developed regulatory framework, with recommendations for transnational care including for example cost-effectiveness solutions (cost mutualisation), patient's equity of access, new economics incentives, diagnostics and treatments.

The proposed joint funding activities as well as strategy reflections (see also section 4 and 6) enable the participation and are beneficial for all regions and countries, independent of their current PM implementation level. The "PM Best Practice catalogue" to be developed by EP PerMed will suggest solutions needed "to not leave anyone behind" in providing the best implementation approach for each individual healthcare system.

EP PerMed will serve as platform creating the needed synergies to integrate all essential expertise in PM development.

EP PerMed will in addition seek input from all key stakeholders such as industry, clinics, research and patient organisations and payers.

EP PerMed will be a prime driver in efforts to achieve alignment of strategies and common priority setting, to develop and launch education campaigns, and foster policy development and communication.

Through international collaboration, EP PerMed will contribute to defragmentation and consolidation of research beyond the EU.

3 General overview of the personalised medicine environment

The PM environment is strongly influenced by a diverse number of processes, actors and decision makers around the entire value chain (fig. 4):

Research and innovation (R&I) are the key elements in the very centre that are influencing and driving the development of PM approaches. Areas of R&I, essential as support and basis for the successful development and implementation of PM approaches, are represented in figure 4 in the inner circle. In the outer (grey) circle, the major stakeholders for the PM environment are shown, that are developing and monitoring and supporting R&I leading to PM implementation for patients and citizens. The decision makers (blue frames) are in the position to set important impulses in terms of funding, frameworks, infrastructures, and regulations.

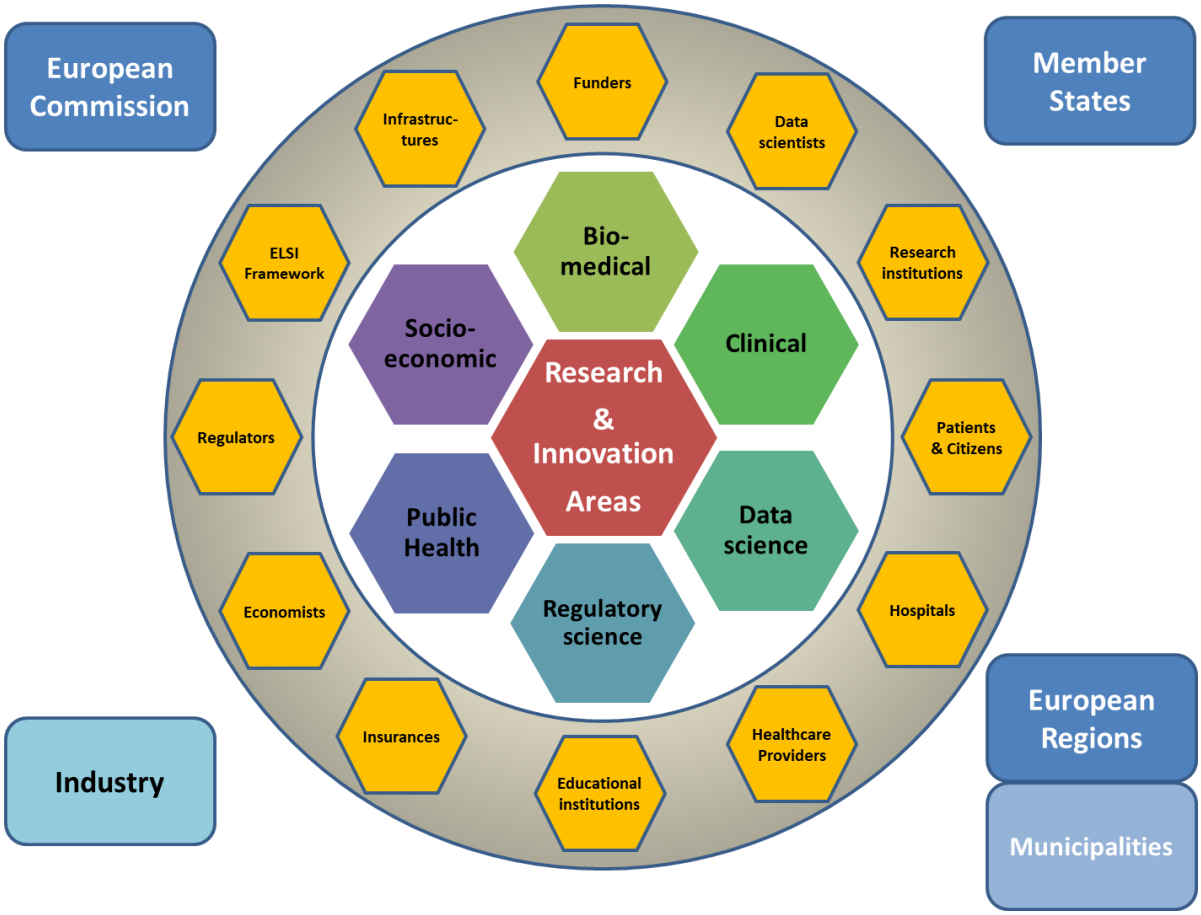


Figure 4: General overview of the three different circles strongly influencing the PM environment with the main decision makers in the four corners.

In figure 5, the major decision makers for the PM environment are presented in relation to examples of important trends and drivers to support the development and implementation of PM approaches. Such trends and drivers influence directly or indirectly the input for research and other activities to set up innovative PM approaches. Different kinds of output are outlined that are connected with implemented PM approaches.

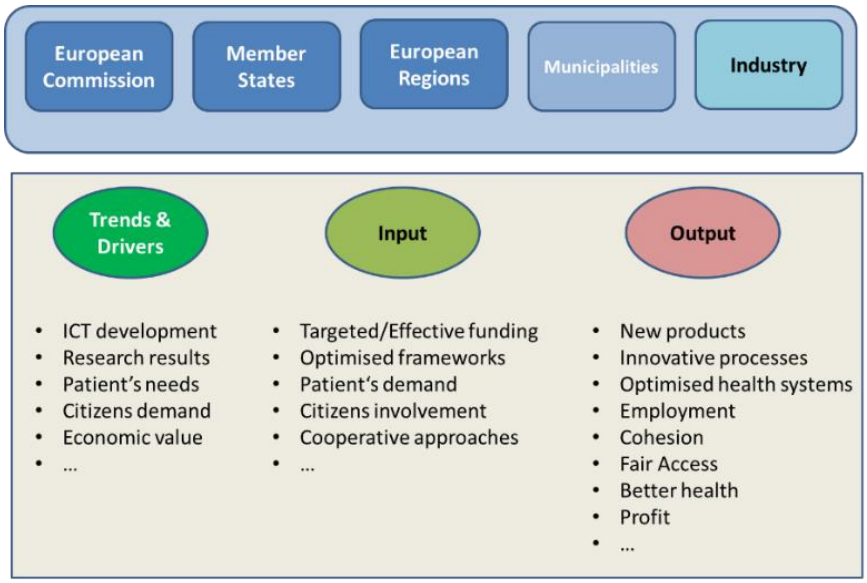


Figure 5: General Personalised Medicine Framework.

3.1 What challenges or strategic opportunities need to be tackled in the field of PM?

The growing realisation that PM in the future will constitute a central core of health care, both in terms of treatment as well as prevention, has fortunately resulted in highly increased focus on PM over the last decade as outlined above, both at policy level and at funding level, regionally, nationally as well as internationally. This increased focus has resulted in major progress in development of PM in many of the aspects outlined in the ICPerMed Action Plan.

However, it is also clear that the progress within PM is not evenly distributed over the value chain for several reasons. Some of the more important aspects are outlined below:

- **Genomic profiling**: Early discoveries, particularly in rare diseases and cancer, that specific genomic defects can be linked to specific diseases has triggered an enormous interest in exploring genomic profiling. Today, many countries (e.g. UK, France, Denmark and Estonia) have implemented plans for collecting genomic data, often on a very broad scale, to be used both for research purposes and for improving the treatment of the individual patient. Today, there is a strong drive from policy makers, funders and from researchers to promote the genomic profiling area, which has a strong potential to contribute for prevention and treatment of many common complex disorders in the next decade.
- **Diagnostics and prognostic biomarkers** are key elements of PM. Without precise ways to determine the exact illness of a specific patient, it is not possible to determine the precise treatment that will help the patient. Development of novel diagnostic tests and disease biomarkers, to a high degree based on genomics; has seen over the last years significant progress in cancer and rare diseases. However, there is still a strong need for reliable biomarkers for many diseases, for instance for psychiatric disorders (e.g. major depression is still treated on a "one size fits all" principle since no effective tools exist to stratify the patients) and neurodegenerative diseases (e.g. Alzheimer's disease where neither early biomarker nor effective treatments exist today). Beyond genomics, the potential of proteomics, transcriptomics, imaging and other biomarkers, as well as integration of these using systems medicine approaches is still insufficiently explored.

- **Translation of biologic information into effective treatments** is an area with many challenges. Only relatively few diseases (certain cancers and rare diseases) can be linked to monogenetic defects. The development of many common non-communicable diseases with high morbidity and mortality (e.g. cardiovascular, psychiatric, pulmonary, neurodegenerative, oncological) involve multiple genetic and proteomic variants combined with environmental factors. Thus, large research efforts are needed to understand the disease biology in order to identify the relevant targets for treatment within the particular disease biology. Many research projects are ongoing in this field (see e.g. the ERA PerMed project catalogue), but considering the complexity of the diseases progress is very slow and much more research is needed to turn treatment of these common diseases into personalised treatment or prevention. A further challenge in this context is the availability of drugs. Repurposing of the known pool of drugs is a frequently used strategy, but this pool of drugs is very limited and will not be able to deliver the best possible treatment for every patient. Thus, development of new, more specific drugs is needed once the right treatment targets have been identified. This is a very lengthy and costly process.
- **Infectious diseases** have traditionally not been considered in the context of PM since the main focus has been on combating the intruding pathogens in large groups of patients and not so much how the individual patients respond to the infection. However, the current Covid-19 crisis might very well change that perspective, showing that the host susceptibility to infection and response to treatment is very variable. There is growing evidence that pathogens affect the human body in complex ways and the fact that various co-morbidities have a large effect on the outcome of the disease points to the relevance of a PM based approach in treating patients.
- **Development of clinical trials for PM** is an area where there has been significant progress in recent years. It is clear that the traditional clinical trials with large pivotal Phase III trials is not a feasible strategy with the increased stratification of patients into smaller and smaller groups. Thus, new ways to run clinical trials are currently being explored for development of PM (see e.g. the ERA PerMed project catalogue, CSA PERMIT). This area will become more and more important as the main focus expands from cancer and rare diseases (where somewhat special conditions can be applied) to the common non-communicable diseases mentioned above.
- **Data sharing** is an area where there currently is a major focus, but where there also are major challenges. Health data (genomic, proteomic, clinical, phenotypical, real life) is overall needed for two purposes, namely for optimal treatment of the individual patient and for research. A key aspect of data sharing concerns the legal and ethical issues related to use of health data. To truly promote PM research and implementation across Europe and globally there is a strong need to share health data across borders. This raises issues related to the citizen's personal data safety and privacy. That national data legislations can be very different across countries also imposes restrictions. Data sharing also raises challenges related to infrastructure and to the global implementation of the concept of FAIR data (Findable, Accessible, Interoperable and Reusable). Major initiatives, e.g. the 1+ Million Genomes Initiative and others, are working to overcome these challenges.
- **eHealth, Digital Health and Artificial Intelligence (AI)** are areas of rapidly growing importance for health and PM. In relation to collection of real-life data, digital tools have become indispensable and there are now many examples how treatments, for example in psychiatric diseases, become truly personal due to real-time collection of clinical data through wearables. Thereby a much more efficient treatment becomes possible. Digital solutions are thus spreading rapidly within healthcare and it is essential that these new opportunities are being grasped and used for the benefit of patients. Importantly, strategies for effective integration

of the enormous amounts of data collected are being provided by AI tools and methods, and will eventually lead to much more comprehensive PM approaches.

- **Regulatory strategies** will need to be updated/revised as PM develops. Current regulation is very much based on the traditional clinical development model, but new clinical strategies as described above will require adaptation of regulatory guidelines. Otherwise, the new PM based treatments will not reach the patients. The EMA and FDA are fully aware of this aspect, but changing regulatory guidelines is a long and time-consuming process since the safety of the patient has to be in high focus all the time. Thus, there is a high need to have a close interplay between clinicians and regulators in order to develop new and improved regulatory strategies.
- **Market access and health economy** are key factors in getting the PM treatments out to the patients. Developing new treatments is very costly, for both healthcare providers and industry. As the stratified patient groups that respond to personalised treatments are smaller and smaller, the business potential of a specific treatment is being reduced significantly. Currently, the classical reimbursement models are used in most countries and the only way to get around the problem in this system is to price the specific treatment exorbitantly high. This is becoming a growing problem in many countries and frequently the result is that the patient cannot get access to the treatment because the Health Technology Assessments (HTA) consider the cost-benefit unfavourable. There is thus a high need to develop new market access/health economy models, which are sustainable, both for the producers and for the healthcare system and which ensure that the patients can get the best treatment (see e.g. CSA HEcoPerMed).
- **Implementation in healthcare systems** and full citizen and **patient benefit of PM** are two of the major end goals of PM. Implementation of PM in healthcare systems will need to have a broad societal perspective, including economic sustainability, societal benefits and equity of access for all. Citizen and patient literacy will have to be fully incorporated, so that shared decisions can be made. Significant investments are still needed for infrastructure in clinical settings, particularly regarding biomarker technologies and health data accessibility and interpretation by healthcare professionals. Training and life-long education of health professionals and the organisation of multidisciplinary clinical teams will be fundamental for PM implementation in healthcare systems. Several countries are well on the way towards this goal e.g. Germany (see cancer example presented in Berlin[1]), France and Spain (see Best Practice examples on the ICPerMed webpage[2]), but many countries are still in their infancy regarding these goals.
- **Regional and national differences** in development stage of PM in Europe are a challenge. The EP PerMed should develop a basis and toolbox that will support countries and regions in finding their specific solutions for PM implementation.

The picture that emerges of the overall progress of PM is not straightforward. Some areas are rather advanced whereas other areas have not progressed so much, and there are many regional asymmetries in Europe and globally.

Whereas it is important to progress all areas within PM, it is absolutely critical that EP PerMed focuses on the key bottlenecks to provide solutions. It is also critical that EP PerMed acts in a dynamic way and adjusts its focus areas over the time span of EP PerMed, since the key challenges will change over time. The developments over the last decade within PM provides a very good basis to build on.

[1] https://www.icpermed.eu/en/526.php
[2] https://www.icpermed.eu/en/best_practice_examples.php

None of the current and future challenges for PM can be solved by any one player alone. All key players in the field need to work together across borders in order to solve the problems and progress in delivering PM to the citizen. The EP PerMed will be in a unique position to make this happen.

3.2 Description of current PM initiatives: ICPerMed family

The EP PerMed builds on the successes of ERA PerMed and ICPerMed (fig. 6). The funding programme ERA PerMed was established in 2017 in the context of the International Consortium for Personalised Medicine (ICPerMed).

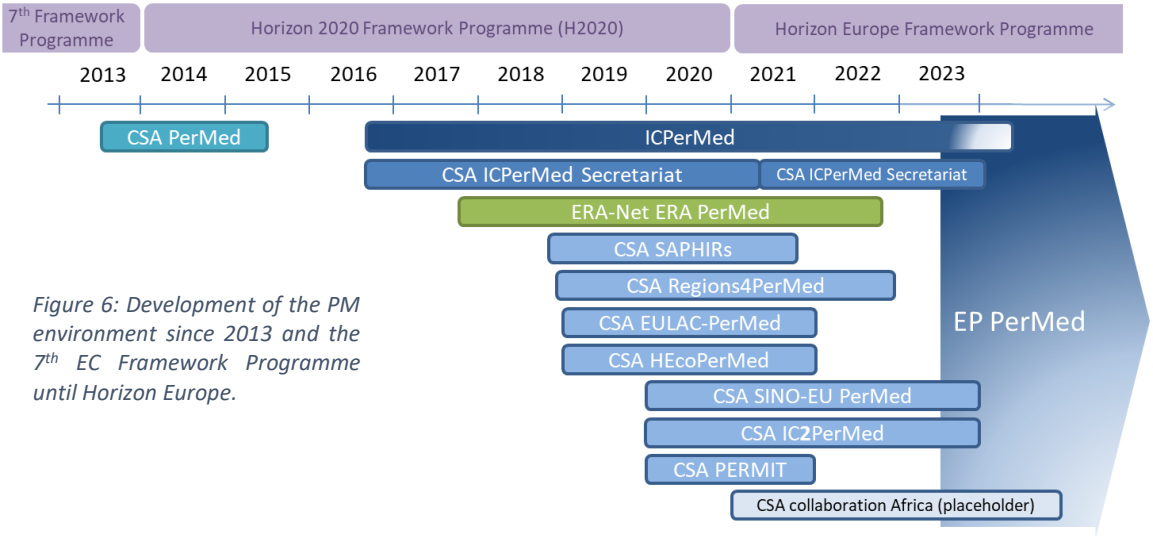


Figure 6: Development of the PM environment since 2013 and the 7th EC Framework Programme until Horizon Europe.

ICPerMed (launched in 2016)

ICPerMed is a Member States-led consortium with over 40 partners from close to 30 countries, which debates and agrees on priority areas for research and innovation investment in the field of PM. It includes several health and research/innovation ministries, funding organisations, foundations as well as regional authorities. Only public funders or policymaking institutions are admitted as regular members. The consortium includes international partners, from e.g. Canada, Iran and Brazil.

The main purpose of ICPerMed is to boost PM by an enhanced coordination and alignment of research activities and an investigation of its benefits to citizens and healthcare systems. With the **Action Plan (2017)**[1], ICPerMed has designed a blueprint for a coordinated approach for PM research and the reasonable implementation of innovative and promising approaches in the health systems. ICPerMed members implement elements of this blueprint within their national or regional funding activities. With this ICPerMed Action Plan for the first time public and private 'not-for-profit' health research funding and policy organisations defined funding actions ready for implementation. This Action Plan facilitated consensus-building and decision-making processes in participating organisations and thereby enabled more concerted actions in this field. The Action Plan was instrumental for the coordination of new transnational funding activities such as ERA PerMed.

ICPerMed furthermore developed a vision of how the use of PM approaches will promote "next-generation" medicine in 2030, more firmly centred on the individual's personal characteristics, leading to increased effectiveness, economic value, and equitable access for all citizens to the best possible

[1] https://www.icpermed.eu/en/activities-action-plan.php

healthcare. This vision and its five perspectives are outlined in the **ICPerMed Vision Paper**[1] (2019). According to the Vision Paper, by 2030, the PM vision will drive the organisation of health systems to support data management, interoperability and access, and data sharing between citizens, health professionals and researchers. Technological advances are creating the need for new skills, training programs involving health professionals, patients, and multidisciplinary teams.

The Vision Paper aims to achieve alignment amongst different countries, especially the European Member states, as well as the European Commission, and uptake of the perspectives presented in the paper in upcoming and future programs and activities.

ICPerMed acts therewith as a communication platform for existing and future initiatives and organisations related to PM and the perspectives presented.

ERA PerMed (2017-2022)

In close collaboration with ICPerMed, the European Research Area Network (ERA-Net), ERA PerMed, aims to implement the ICPerMed Action Plan. The ERA PerMed consortium comprises 32 partners from 23 countries (Member States, Associated Countries to Horizon 2020 and two partners from Canada) and 5 regions. More international partners from Panama and Egypt successfully joined ERA PerMed calls.

ERA PerMed works on aligning regional and national research strategies and funding activities, promoting excellence, reinforcing the competitiveness of European players in PM and enhancing the European collaboration with countries outside the EU.

ERA PerMed partners committed themselves to implement one call co-funded by the EU (with approx. 9.5 M€ EU contribution and approx. 23 M€ partners' contribution), followed by several calls exclusively on their own resources. Through these very successful calls, with an overall budget spent in PM research and innovation of approx. 80 M€ in 2021, ERA PerMed is supporting cross-border and multidisciplinary collaborations. The consortium is supporting an impressive amount of 25 projects in the JTC2018 (co-funded) and 22 projects in the JTC2019 (non-cofunded). The overall budget committed to the non-cofunded JTC2019 was even higher than in 2018 (co-funded call with EU top-up). The number of pre-proposals increased from 160 in 2018 to close to 200 in 2019 and 2020.

ERA PerMed was able to demonstrate that the combination of various type of funders in one programme is the key to integrate a large range of different kind of PM actors in multidisciplinary research projects. Only few funding organisations can cover the entire value chain due to their specific funding regulations and regional/national priorities, including different types of applicant[2] and research[3] eligible to be funded. With its joint research calls, ERA PerMed is able to provide funding to the whole spectrum, from basic and industrial research to implementation in health systems, over the whole value chain and all TRL[4] levels. ERA PerMed demonstrates that PM funding requires a strong flexibility of calls and sustainable collaboration between the involved funding organisations.

For ERA PerMed, the participation of funders and consequently researchers from third countries represents an added value to achieve multidisciplinary and increase of resources (including human resources as well as infrastructures), considering that PM is a global topic with excellent experts located also outside of the EU. International collaboration is also considered important for the defragmentation and consolidation of research beyond the EU.

[1] https://www.icpermed.eu/media/content/Vision_Paper_2019.pdf
[2] For example academic, clinic, foundation/association, private non-for profit, private for profit or industry.
[3] Basic, applied, translational, clinical, developmental and industrial research.
[4] https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf

PerMed (2013-2015)

The basis for both currently successful running initiatives ERA PerMed and ICPerMed was the previous project, CSA PerMed, funded by the European Union's 7th Framework Programme. The project brought together organisations from research, industry as well as ministries and funding organisations. PerMed already made clear that real progress in PM can only be achieved when research and implementation efforts are covering the entire value chain. This was documented in a **Strategic Research and Innovation Agenda**[1] (SRIA) describing challenges and giving recommendations for advancing this field.

ICPerMed family[2]

Since 2019, the European Union has funded several so-called Coordination and Support Actions (CSAs) in support of ICPerMed through its framework programme Horizon 2020. Seven CSAs are currently running:

- Health economic modelling and payment strategies: **CSA HEcoPerMed** ("Health economic modelling and payment strategies for personalised medicine"),
- Clinical trial design: **CSA PERMIT** ("Personalised Medicine Trials"),
- International cooperation: **CSA IC2PerMed** ("Integrating China in the International Consortium for Personalised Medicine") and **CSA SINO-EU PerMed** ("Cooperation between China and Europe in Personalised Medicine") for collaboration with China, and **CSA EULAC PerMed** ("Widening EU-LAC policy and research cooperation in Personalised Medicine") for collaboration with Latin American and Caribbean (LAC) countries,
- Regional perspective: **CSA SAPHIRE** ("Securing Adoption of Personalised Health in Regions") and **CSA Regions4PerMed** ("Interregional coordination for a fast and deep uptake of personalised health").

One more CSA is expected to be launched in the section "international cooperation" for collaboration with Africa.

4 EP PerMed: Common vision, objectives, expected impacts and synergies

PM represents a paradigm shift from a "one size fits all" approach to the treatment and care of patients with a particular condition, to one that uses emergent approaches for earlier diagnosis, to select personalised therapies that achieve the best outcomes or to predict predisposition to disease. Additionally, key objectives of PM are to develop personalised prevention strategies and to make health systems sustainable in a fully developed PM setting.

The vision of EP PerMed is full implementation of PM in healthcare to the benefit of patients, citizens and the society. In order to help make this vision come true, EP PerMed will build on a structure consisting of five key elements as shown in figure 7. These five elements together build a pyramid where the individual elements will interact in order to develop models and guidance regarding health policies and healthcare systems, which will support progress towards the vision of PM.

[1] https://www.icpermed.eu/media/content/PerMed_SRIA.pdf
[2] https://www.icpermed.eu/en/related-initiatives.php

Each element entails different types of activities (see also section 4 and Annex 7.1). The members of EP PerMed will drive these activities, host different roles and mandates for them, thereby ensuring that there is progress towards the PM vision coming alive.

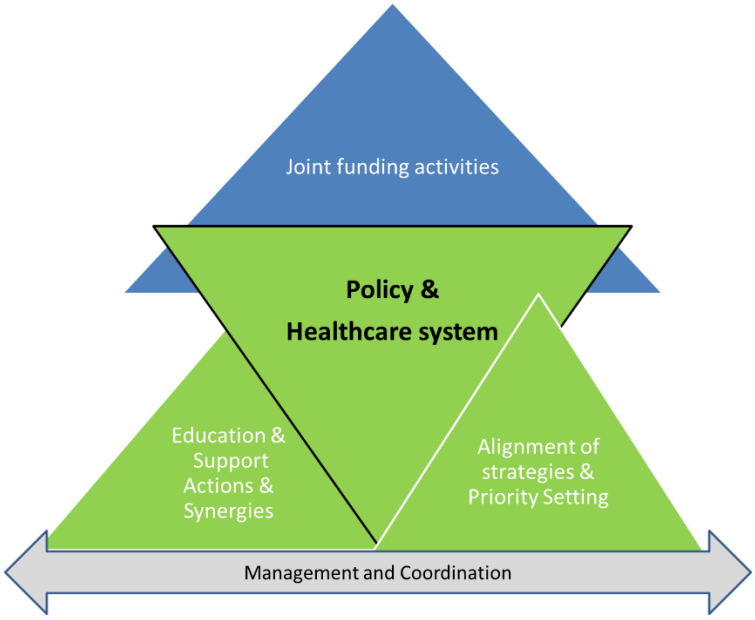


Figure 7: Key elements of the EP PerMed structure.

At the centre is "policy and healthcare system development" as the core activity. Setting the right policy priorities, developing sustainable health systems and finding solutions to the societal health economic and health related social problems are at the very centre of PM implementation. A policy coordination is needed for the identification of PM topics that are relevant from the national, European and international perspective. Countries and regions will take PM into account when developing their national/operational programmes and bring all players having an active role in PM, including regional and thematic funders, to the same table. This coordination is also needed to develop and implement a number of important aspects such as general rules related to data collection, harmonisation, quality control, reporting, sharing, and processing, taking into account ethical, legal and social implications (ELSI).

Joint funding activities are at the top of EP PerMed as research at all levels throughout the value chain is the starting point to develop needed PM solutions. These efforts are indispensable in order to achieve the set objectives and expected impacts. The EP PerMed will organise the necessary range of activities including calls for R&I proposals, network calls, and other funding and joint activities.

The two base units "Alignment of strategies & Priority setting" and "Education & Support actions & Synergies" will provide important input to achieve the core outcomes related to policy and healthcare systems. The prioritisation process will be developed by the governance bodies, once constituted, to develop the common strategy for the partnership. This process will be further refined during the life cycle of EP PerMed. Education and training needs of health professionals as well as literacy for citizens and patients, and also decision makers in funding and health policy organisations, will be more systematically identified. This knowledge will be disseminated for translation into training activities by academia, as well as into literacy-promoting campaigns for the common citizen, fostering updated knowledge on new approaches and tools for PM and improved involvement of the different stakeholders in PM implementation.

EP PerMed will benefit from the results, networks and experiences from ICPerMed and ERA PerMed partners. In addition, numerous important activities are ongoing in the field of PM with information

gaps between stakeholders and insufficient coordination at partnership, regional, national, and European level. In order to develop PM national and regional priorities and to achieve more impact, EP PerMed will work towards a better convergence of these activities. The EP PerMed therefore has an important role in planning and programming synergies and in interacting with interested stakeholders.

The coordination and management of these key activities is standing at the basis as 5th component in support of the pyramid structure and will be provided by the EP PerMed. This will guarantee appropriate governance, programme management and facilitate the information flow and cooperation within the partnership and with other initiatives.

4.1 Overall objectives

The partnership will coordinate research and innovation efforts of the participating organisations from Member States and third countries in the field of PM, create synergies between EU, Member States and regional programmes, and implement a common action plan for delivering progress in PM to the citizen and to patients.

Overall research and innovation objectives of EP PerMed are (fig. 8):

- Increase PM-related multidisciplinary research and innovation throughout the entire value chain.
- Promote translation of basic PM research results into clinical practice.
- Promote uptake of PM innovation by the market and ensure patient benefit.
- Track and communicate on successful implementation of PM in healthcare systems and provide socio-economic evidence that PM has created value for society.

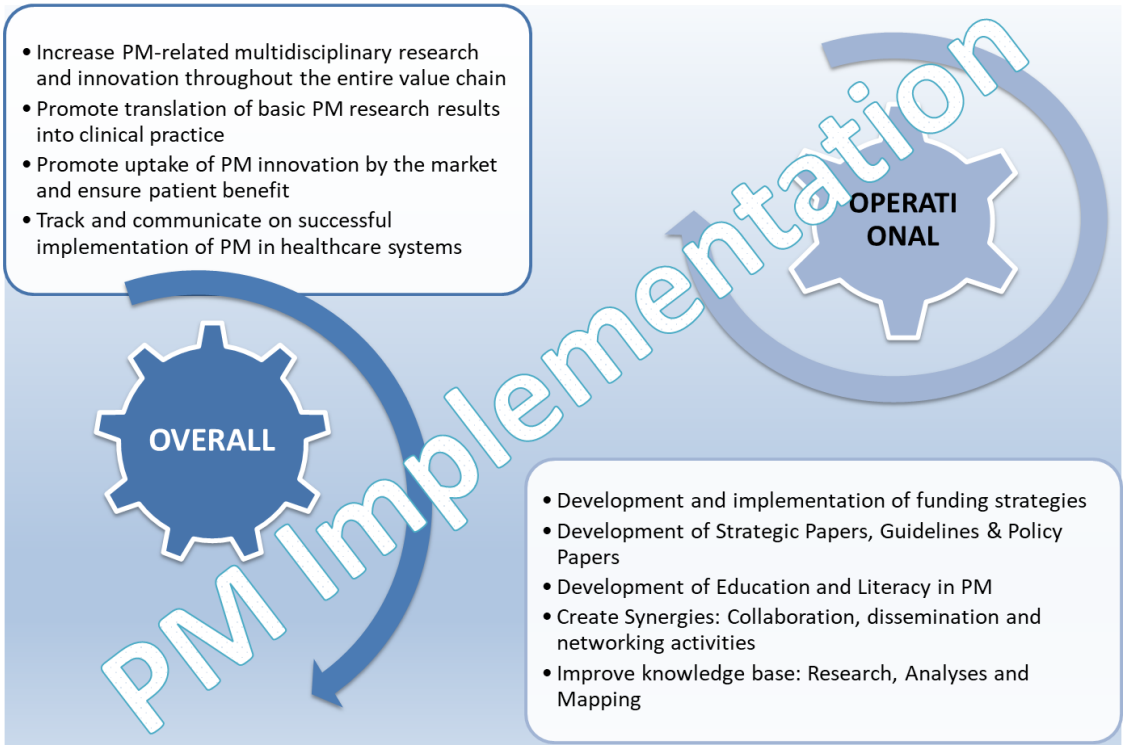


Figure 8: Overall and Operational objectives: These five operational objectives will assists EP PerMed to develop the overall objectives. Operational objectives will be evaluated using impact measures that help to determine whether it is on track or off course. The five overall objectives together with the operational objectives will help drive the field towards PM implementation

In order to have a natural structuring effect and maximise its impact, the partnership will be flexible to include new developments and open to additional regional and national organisations.

4.2 Operational objectives

The operational objectives will assist the EP PerMed in achieving its overall objectives.

Operational objectives will be evaluated using proper impact measures (see also Annex 7.1).

1. Development and implementation of funding strategies

This objective will focus on setting up appropriate incentives for research and innovation, working on aligning research priorities with the needs of the different health systems, while involving regulators, academia, healthcare professionals, industry and health insurances/payers to:

- Focus on supporting the PM science base through development of a coordinated approach to research and innovation.
- Support European innovation and research capacity to investigate the potential benefits of PM approaches to citizens and healthcare systems.
- Direct funding of PM research and innovation over the full value chain. The funding will be structured in calls with specific focus to cover all key areas of PM development.
- Motivate national and regional funding agencies to launch local investments in PM.

2. Development of Strategic Papers, Guidelines and Policy Papers

The policy decisions about introduction and use of new PM-based options for prevention, diagnosis, monitoring and treatment, based on research and innovation, are a major driver behind improvements in outcomes and cost-effectiveness:

- Support the healthcare systems to implement PM throughout the value chain by developing relevant strategic papers, guidelines and policy papers.
- Help ensuring equal access to personalised medicines and PM technologies.
- Support inclusion of PM in prevention health policies and to provide incentives for pharmaceutical and health industry innovation.
- Provide models and guidelines for developing PM sustainable health systems.
- Promote best practices and standards for PM implementation, PM approaches and application, harmonised procedures and new tools in PM.
- Support development of patient-centric healthcare models through patient awareness and empowerment by direct involvement of patients/patient organisations in the partnership.

3. Development of Education and Literacy in PM

- Support the development of education and life-long training strategies for all PM stakeholders, essential to achieve integration of PM research results into healthcare practice. Facilitate the development of common approaches across partners (countries or institutions), ensuring shared knowledge and exchange of good practice for the benefit of citizens and patients.
- Commit to educate the citizen, health professionals, policy makers and other relevant stakeholders on ELSI related to PM, through dissemination and promotion of best practices and codes of conduct.

- Stimulate the development of education and literacy to foster citizen and patient empowerment and engagement, e.g. by reflecting on different communication pathways between patients and their families with healthcare providers, researchers and other professionals, to support shared decision-making and the implementation of new PM approaches with appropriate levels of information. Patient associations will be involved in EP PerMed.
- Improve the knowledge base for health professionals, for the update of new tools and technologies, e.g. to facilitate the bench-to-bed-side translation of PM technologies. Improved communication of successful PM approaches aims to establish multidisciplinary decision taking teams, to allow the integration of PM at multiple levels of the healthcare system.

4. Create Synergies: Collaboration, dissemination and networking activities

To achieve the objectives of EP PerMed, synergies, collaborations, disseminations and awareness raising activities are required involving all stakeholders. Thus, the activities run in ICPerMed will be continued and expanded. There will be an increased focus on:

- Development of a catalogue of best practice examples, e.g. via the best practice presentation on the EP PerMed website: Preparation for publication of best practise examples for wider dissemination of PM implementation approaches, policies and other relevant successful PM topics.
- Follow uptake of PM in the different healthcare systems, also on the international level, based on the work of the different international ICPerMed family CSAs (LAC, China and Africa), but also regional CSAs and collaborations with other European Partnerships in the health systems and digital area.
- Stimulate collaborations and interactions with industry and innovation stakeholders to facilitate the knowledge transfer and the market access of developed solutions.
- Networking to seek synergies on clinical research capacities and research infrastructures, and to create more appropriate contexts for effective health services.
- Increase cooperation in PM research, innovation and on new preventive strategies, as well as on treatments, medicines, medical devices and sharing the outcoming results between European regions.
- Bringing together and seeking input from the different key stakeholder of the PM ecosystem e.g. via dedicated events as workshops, conferences and other form of meetings as well as for example surveys to discuss relevant PM topics, interlink the PM community and foster the wider dissemination of PM. Outcomes of these exchanges will feed into strategic documents.
- Connect with PM-relevant projects, partnerships and undertakings outside the EP PerMed umbrella in order to create synergies, learn from each other and avoiding overlaps.

5. Improve knowledge base: Research, Analyses and Mapping

The outcomes of the research, analyses and mapping exercises performed within ICPerMed are the basis for some of the most important achievements of ICPerMed. Thus, these activities will be continued in EP PerMed. They are essential to follow up on the advancements of PM in general and in particular on the implementation of strategic documents of EP PerMed.

4.3 Expected impacts

EP PerMed will move forward the overall impact "enabling PM for the citizen" by different means (see also Annex 7.1) and in particular by supporting reflections around the crucial development axis (see also section 2.2), with main impact on (fig. 9):

- Europe staying at the forefront of R&I and implementation towards personalised diagnosis, treatment and prevention,
- Harmonisation of PM implementation in healthcare systems across European Member States and regions, following the principle of "no one left behind",
- Facilitated uptake of PM innovation by health systems,
- Achieving a common language and understanding about PM for citizens, patients and health professionals.

The EP PerMed will foster R&I activities in multiple areas along crucial axes of development, with specific expected impacts outlined in table 1. Overall, development of each of the axis will strongly impact (see table 1 for more detailed impact indications):

- The knowledge base for better personalised diagnostics, treatment and prevention,
- The access to harmonised PM approaches in healthcare systems across Europe,
- The development of adequate strategies for PM innovation uptake,
- A common understanding of PM by citizens, patients and healthcare professionals towards a more empowered citizen.

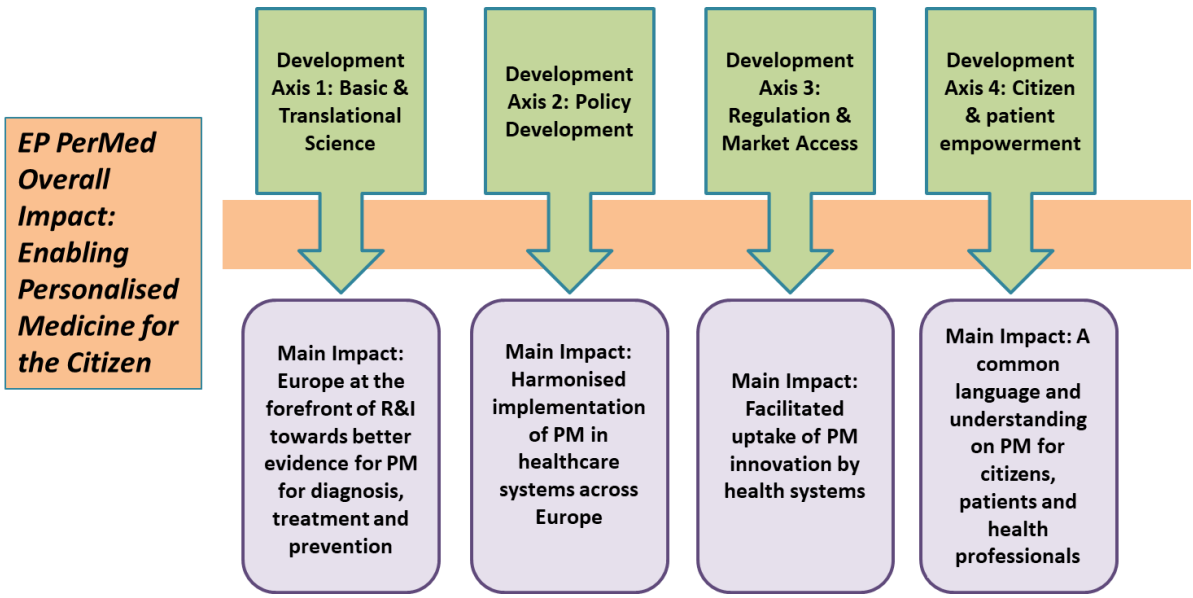


Figure 9: EP PerMed overall impact.

EP PerMed will serve as a platform to provide the different participating organisations with the tools for PM implementation in their respective region/country for the benefit of citizens and patients.

Table 1: Description of the four main axes of development of PM as well as of the expected and main impacts.

Axes of development	Area of R&I	Expected Impacts	Main Impact
1. Basic & Translational Science	Clinical and Biomedical Research	Better evidence for PM in diagnosis and treatment for RD and cancer Increased European clinical trials for PM Improved synergies between research, health, industry & SMEs and other sectors facilitates research and uptake of PM approaches Enhanced European cooperation for development towards prevention methods for common complex disorders	**Europe at the forefront of R&I towards better evidence for PM on diagnosis, monitoring, treatment and prevention**
	Data analytics	Improved big data analytics tools Enhanced data sharing among European countries Focus on data interoperability and harmonisation across Europe Widespread acceptance of FAIR (Findable, Accessible, Interoparable and reusable) principles for data assets Enhanced European cooperation for Systems Medicine methods	
2. Policy Development	Socio-economics	Harmonised methodologies for economic models in Europe Better evidence for cost-efficacy with a societal perspective across Europe	**No one left behind - Harmonised implementation of PM in an efficient Healthcare System**
	Health systems and public health	European healthcare systems aligned with respect to maturity indicators for PM Equity in access to PM among citizens from diverse European countries and regions Evidence-based strategies for PM-related investments Evidence-based public health decision making	
	Ethical, Legal and Social Issues	Enhanced European cooperation regarding health data sharing Patient centred approach Harmonized policies and code of conduct for health data sharing	
3. Regulation & Market Access	Digital & other technology	Market access models for PM benefit all European countries and regions Improved Health Technology Assessment for PM Adequate regulation policies facilitate implementation of PM across Europe	**Facilitated uptake of PM innovation by health systems. Increase development and growth of health industry and related jobs.**
	Industry & SMEs	Regulatory frameworks and responsibilities at country/ EU level Ethical framework on handling of personal data. Streamline investments	
4. Citizen & Patient empowerment	Literacy and communication for patients	Improved literacy and empowerment of European citizens on PM approaches for health and care Awareness on modalities of participation in genomic research and on ethical protection to stimulate data sharing PM concept is widely disseminated and understood in Europe	**A common language and understanding on PM for citizens, patients and health professionals** **Implementation of PM research** **Integration of PM at all levels of the healthcare system**
	Pathways for patient-HCP communications	Enhanced involvement of patients in PM decisions (including HTA approach and ELSI decisions) to support shared decision-making based on appropriate levels of information	
	Patient empowerment		
	Education & Literacy of health professionals	Widespread education for health professionals of variable specialisation on PM approaches, technologies and tools Multidisciplinary teams for PM in healthcare Quick bench-to bed side translation of PM technologies	

4.4 Development of impactful synergies

To advance successfully with PM implementation and complement the work proposed with other features of the European research landscape, EP PerMed will create synergies, in particular with the potentially co-funded European Partnerships on “Transforming Health and Care Systems”, “Health Innovation”, “One Health/AMR” and “Pandemic Preparedness and Societal Resilience”, and other Health Programmes and initiatives as the “Global Alliance for Genomics and Health (GA4GH)”.

5 EP PerMed composition and target group

The EP PerMed builds on previous projects, including ICPerMed, ERA PerMed, the ICPerMed-related initiatives (ICPerMed family), but also PerMed. These different actions already made clear that real progress in PM can only be achieved when research and implementation efforts are covering the entire value chain. This was documented in the PerMed Strategic Research and Innovation Agenda, describing challenges and giving recommendations for advancing the PM field, the ICPerMed Action Plan, defining "actionable research items" directly to be converted to research funding, and the ICPerMed Vision Paper outlining how the use of PM approaches will promote "next-generation" medicine in 2030.

Based on the experiences of ERA PerMed and ICPerMed, the **EP PerMed members (beneficiaries)** should be composed of European and international stakeholders such as Health and R&I ministries, regional authorities, regional and national research funding agencies (R&I and technology funding agencies) and foundations. Further public and private ‘not-for-profit’ health research funding, policy organisations, payers and healthcare institutions can join the partnership as partners.

Members of the EP PerMed are requested to sign the Grant Agreement (GA) and to work actively towards achieving the overall aims of the EP. They commit to the EP PerMed activities (e.g. financial support provided to joint funding) with a dedicated budget and are eligible to receive reimbursements, e.g. in form of travel/accommodation for joining meetings or of personnel costs.

For **EP PerMed partners**, there is no monetary commitment required to join the EP PerMed. In return, no financial support is provided for their participation. Partners commit by signing a letter of intent to work actively towards achieving the overall aims of the EP PerMed consortium. They will be expected to report annually on their activities and to actively participate in the running of the initiative.

Joining of new members and partners in the course of the EP PerMed is possible while the overall envelop of the EP PerMed will remain unchanged. The EP PerMed will seek participation of all European countries and international organisations from different continents.

While the member and partner status within the EP PerMed is restricted to ministries, public and private ‘not-for-profit’ health research funding, policy organisations and healthcare institutions, other stakeholders with strong interest in PM are welcome to participate via **dedicated stakeholder groups**. This could include e.g. payers, research institutions, universities, patient initiatives/organisations, platforms and infrastructures, related projects or industry organisations, bodies with a public service remit at local, regional, national or international level or civil society organisations including foundations and non-governmental organisations (NGO). Through these stakeholder groups, the EP PerMed is in close and steady contact with all these interested parties. The stakeholders are informed about the work of the partnership, invited to workshops and conferences and solicited by the different pillars to be part of the work and to contribute to the goal/achievements of the EP PerMed. Experts

and stakeholders are also invited to Executive Committee meetings for information and discussion on certain topics.

EP PerMed can also involve external experts in form of advisory boards. Different expert groups might need to be formed depending on the task to be tackled related to the EP PerMed work programme. Experts participating in such advisory boards will have an **observer status** within the partnership. They do not need to sign the GA, nor to provide a letter of intent. They do not represent a certain organisation but are solicited for their specific expert view. Observers are not involved in decision making processes within the partnership.

The proposed member and partner composition allow to cover ERA-Net-like funding activities, based on a common research agenda, and at the same time supports strategic discussions and other support actions for that ERA PerMed and ICPerMed as well as the ICPerMed family already prepared the ground work by involving regional, national and international stakeholders. Therewith, the future partnership links the setting of ICPerMed for the development of policy recommendations and those of ERA PerMed for the management of joint funding. An even closer involvement of industry, the civil society and patient organisations can be achieved via the stakeholder groups (see also section 6.4).

With its dedicated member and partner organisations, the EP PerMed will provide a platform to initiate and support PM research, to communicate and exchange on funding and PM implementation, to align strategies, education activities as well as policy development and dissemination. EP PerMed aims to involve organisations from all European countries and international organisations. This allows an alignment of research and funding activities on the European and international level.

Based on the solid knowledge of ongoing efforts that will be collected, analysed and communicated via the strategic pillars, the EP PerMed will define and agree on joint funding actions. In addition, the EP PerMed will identify the requirements for a suitable PM framework in terms of infrastructures, resources and regulatory procedures to foster the development and implementation in an efficient and multinational coordinated approach aiming to avoid duplications and allowing the inclusion of all different countries in the process, independent on their progress and achievements in this field. This allows in the first line Europe to fulfil its aim to “leave no one behind” and to provide the needed support for the PM end-users in form of healthcare including patients and citizens, independent on their origin and social status, but also to generalists and other prescribers to understand and apply PM approaches. Thus, EP PerMed will contribute to the reasonable and fair implementation of PM into the health systems for the benefit of patients, citizens and society as a whole.

The involvement of organisations as members, partner or stakeholder, allows a flexible framework for cooperation and efficient execution of the proposed work programme on the operational level.

The high-level participation, in form of ministries and funding organisations, allows multinational funding activities with high and sustainable funding commitments (see also 6.2). Furthermore, the alignment of strategies (political priorities) amongst these high-level organisations is the key element to translate these efforts into practice for healthcare innovation and implementation in healthcare processes and systems in a coordinated way, even collaborative cross border where applicable, to allow the best diagnosis and treatment to patients and to move towards prevention for a healthy society in sharing knowledge and joining forces. EP PerMed connects national activities and programmes and incorporates actively regions. Strategic documents developed in EP PerMed will facilitate consensus-building and decision-making processes in participating organisations and countries, especially EU member states, and thereby enable more concerted actions in the PM field.

Considering that PM is a global topic with excellent experts and initiatives located also outside of the EU, the participation of organisations from third countries in the Horizon Europe framework programme should be considered to achieve transnational collaborations in research funding but also alignments on the strategic level as well as increase of resources (e.g. human resources as well as infrastructures). International collaboration is also important for the defragmentation and consolidation of research beyond the EU.

6 Planned Implementation

A co-funded European Partnership with an annual programming provides the flexibility to fund a broad range of activities, enabling a pipeline approach that supports translation of research results into clinical application and uptake by healthcare systems (see also Annex 7.1). Open calls for proposals address the large multidisciplinary PM community. Communication of demonstration activities, pilots and examples of best practice ensure that experiences are shared amongst different countries and stakeholders, to deploy and scale-up validated approaches in the clinical practice, and to develop alignment of strategies and policy. Promotion of education and literacy activities empower citizens and patients, support the uptake of PM approaches by health professionals and help the spread of knowledge and understanding of PM-related challenges and solutions to larger stakeholder groups. The governance model proposed builds on successful experiences from the current ERA PerMed and ICPerMed.

6.1 Activities

The overall aim of the EP PerMed is to support PM implementation. For the years to come and to advance PM further into national or regional healthcare systems **four main pillars** are proposed (fig. 10):

- Joint funding activities.
- Alignment of strategies/priority setting. This pillar links all relevant stakeholders and will develop an updated SRIA and roadmap.
- Education and literacy: improve the knowledge base, support the development of education programmes and literacy campaigns, create synergies, communication, E&T activities.
- Policy: improve the knowledge base, support the development of strategic recommendations and policies for PM implementation in healthcare systems.

The pillars are interconnected and coordinated by an overall management structure that will guarantee appropriate governance, programme management and facilitate the information flow and cooperation between the different activities and across the pillars. The management unit contains the EP PerMed Secretariat.

The pillars reflect the key activity axes of EP PerMed as described in section 4.3. Activities in the pillars will be further elaborated in line with the ICPerMed Action Plan and the ICPerMed Vision for 2030 Paper.

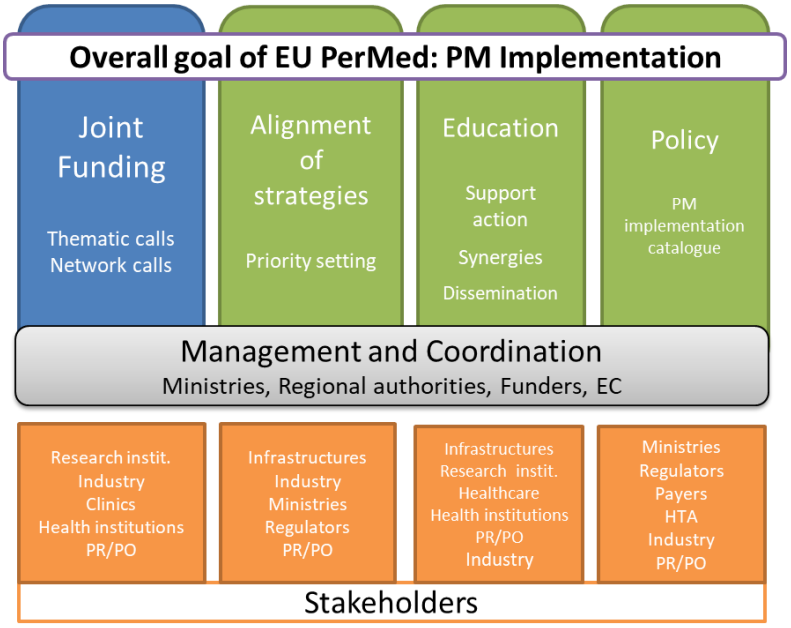


Figure 10: Potential structure of the EP PerMed under the general objective/goal: "PM Implementation". The dark blue and the three green columns could be seen as pillars. Joint funding is one important aspect of the EP PerMed and could include different kind of funding activities, e.g. research project funding and network calls. The green pillars are placed in specific order: 1) Alignment of strategies, 2) education, and 3) policy development. The management of the EP PerMed is overarching and includes the members and partners of the EP PerMed while stakeholders involved in the different activities are indicated below (in the orange frames). The list of stakeholders is not exhaustive, might be adapted in the course of the partnership and further stakeholders might play a role in and could be solicited by the EP PerMed for the respective activities. PR = Patient representatives, PO= Patient organisations

6.1.1 Joint Funding

With the different joint funding activities, EP PerMed coordinates regional and national public investments, funds transnational research and activities and fosters innovation by implementation of the common PM Strategic Research and Innovation Agenda (SRIA).

EP PerMed will coordinate different kinds of joint funding actions, comprising e.g.:

- Transnational, multidisciplinary research funding – ERA Net like calls;
- Networking calls;
- Research Innovation and Technology Calls (RITC) – towards start-ups and market access.

While for the development of the different calls for proposals this pillar builds on and is consulting the framework of the priorities developed in the strategic pillars, the decision on call topics is in the responsibility of the participating funding organisations.

Agreement on a common strategic and innovation agenda is the baseline to align European, regional and national strategic agendas in the field of PM. It provides guidance for joint funding activities by keeping the calls flexible in giving the participating funding organisations the responsibility for the scope development for example by consulting a scientific committee, if such need should arise.

The main actors of this pillar are public and private funders. Besides members and partners of the EP PerMed, the different calls are open to be joined by other regional and national funders in the field of PM, also coming from third countries. Organisations can join one or several calls.

I. Transnational, multidisciplinary research funding calls

EP PerMed can build on ERA PerMed experiences and groundwork for launching joint transnational calls (JTC) to:

- Support multidisciplinary research projects in the field of PM.
- Promote research dedicated to PM and foster innovative research.
- Promote scientific excellence in peer-reviewed transnational calls.
- Allow access to infrastructures, databases, platforms, knowledge, data and cohorts.
- Develop new and maintain existing transnational collaborations.
- Foster regional/national coordination efforts in transnational research projects.
- Establish transnational collaborations also with non-European countries.

Based on ERA PerMed experiences, the JTCs could have the following features:

- Implementation of a **virtual "common pot"**, where each organisation is funding research teams of their own region/country according to their individual regional/national specific funding regulations. A "common pot", where the participating funding organisations sharing the budget of one common pot, is not supported by the majority of funding organisations.
- Implementation of A) **co-funded calls**, with participation of the EC, e.g. via gap filling (EC top-up); and B) **non-co-funded calls**, organised only amongst funding organisations without additional budget from the EC for research project funding.
- **Annual calls (two-stage and peer-reviewed)** to allow efficient management and continuous funding commitment.
- The funding organisations participating in the call are responsible for the development of the call scope.
- A scientific committee can be consulted for the refinement of the call scopes. As the PM field is broad, it is recommended to install an **ad hoc Call Advisory Boards (CAB)** for each individual call with experts having the respective expertise to the proposed scope.

With a potential duration of 7 years, the EP PerMed could commit to implement up to three JTCs co-funded by the EC with top-up funding (3-years project funding duration), increasing therewith the expected impact of the funding activity.

Additionally, it could be optional to organise smaller scaled multilateral calls, e.g. bilateral calls, with a subset of interested funders and 1-2 years funding periods.

II. Networking calls

Network calls aim to enhance resource alignment and maximise existing and future efforts in the field of PM for example to:

- Foster the development of white papers, prospective views, guidelines, recommendations and best practice frameworks in order to identify key questions to be addressed or outlining potential solutions to overcome barriers connected to PM questions and implementation.
- Create synergies in form of new collaborations for PM knowledge sharing amongst healthcare professionals, researchers, informatics experts, industry/private sector and patients, to enable or increase multidisciplinary network structures to design and implement potential solutions for supporting PM research.
- Bridge the gap from research to market-access ➔ development of innovative collaborations.

- Enable or increase the participation of usually underrepresented countries in new and existing PM research networks – fostering the participation of EU13 countries in research networks and therewith in future consortia funded in JTCs.

Via networking calls, EP PerMed will:

- Connect PM key players with different geographic and research origin.
- Facilitate sharing of knowledge and infrastructures.
- Build synergies and capacities for a growing and stable PM community.
- Increase PM awareness and visibility.

Networks may build upon new or existing global collaborations/partnerships and could receive funding for one or two years, to connect PM experts and to establish expertise clusters in the PM community. There are different possible funding schemes (e.g. funding provided to one Network coordinator or several ones in multi-coordinator Networks).

Network calls do not fund research projects.

III. Research Innovation and Technology Calls (RITC)

The Research Innovation and Technology Calls (RITC) are distinct from the transnational, multidisciplinary research funding calls and aim to push PM approaches and research outcomes further towards to the translation to the market, by connecting actively experts of the different PM fields including the private sector, research, clinics and education to develop the most promising solutions into commercially viable products or services.

RITCs follow a multistep process:

1. In dedicated events, RITCs are bringing together experts from different fields of PM to develop innovative ideas for novel PM approaches aiming to transform healthcare following specific PM questions developed by the participating funders and based on the EP PerMed SRIA.
2. Selected projects/topics are invited to further develop and present their approaches in a peer-reviewed process.
3. The outcome of RITCs are innovation projects ready to pass into application in form of start-up funding.

RITC invites especially those funders to participate that are interested in start-up funding and that can provide funding to higher TRL levels. These calls would highly benefit and in addition to public funders seek the participation of industry as funding partners.

6.1.2 Joint efforts on strategic reflections

The joint strategic reflection pillars (fig. 10 indicated in green colour) are highly interlinked: Implementation of Personalised Medicine. The pillars concentrate on the objectives and development axes described in section 4.

Alignment of strategies and Priority setting

EP PerMed develops within the first year a common strategic and innovation agenda to align European, national and regional strategic agendas in the field of PM. The EP PerMed SRIA is outreaching internationally by involving organisations from third countries in the partnership.

This SRIA will be transformed into annual work plans in the form of a roadmap or action plan outlining the implementation plan until the end of the partnership, serving as reference for policy development, resource allocation and alignment of research funding strategies.

This pillar joins all relevant stakeholders needed for the SRIA development and will build on previous work including the PerMed SRIA (2015), the ICPerMed Action Plan (2017), the ICPerMed Vision for 2030 Paper (2019) and other strategic documents developed until the start of the EP PerMed.

Dedicated mapping activities including the collection, monitoring and analysis of information about relevant developments in PM allow EP PerMed to follow-up on the implementation of the SRIA and annual work plans. Outcome analysis would feed into the Education and Policy pillars.

Input for future strategic document developments within EP PerMed could be obtained by different means, e.g. via events, workshops, surveys, consultation and input provided by EP PerMed members, partners and stakeholders.

Education and literacy

This pillar works towards a common language and understanding of PM for citizens, patients and health professionals.

A main focus is on providing a platform promoting informed and empowered citizens and patients regarding PM approaches to their healthcare. EP PerMed will support the development of literacy programmes, including ethical, regulatory and data-control issues, so that patients and citizens are better able to participate in decisions related to the best options for their personal health care. EP PerMed will also support the development of improved interfaces and tools that provide rigorous and updated information, while preserving the patient-clinician interaction. EP PerMed will further work to guarantee that the vision of patients and citizens is taken into account in policy development and in research strategies (including research projects and research funding evaluation and selection procedures).

EP PerMed will further promote capacity building and education of health professionals to facilitate the adoption of PM approaches in clinical practice. This will involve collecting better evidence on the gaps of knowledge and needs for training diverse health professionals (e.g. medical doctors, nurses, pharmacists, therapists, data analysts and others), with a strong emphasis on digital literacy and interpretation of biomarker information. This will also require addressing the training of professionals with non-clinical backgrounds towards a better understanding of healthcare and clinical issues, facilitating interactions among clinical teams that integrate different professional backgrounds. Based on such evidence, EP PerMed can promote discussions among relevant stakeholders around the changes needed in medical and other health professional *curricula* and life-long education, as well as raise the awareness regarding the value of multidisciplinary teams for adoption of PM approaches in clinical practice.

Capacity building activities on the benefits of PM for citizens and healthcare systems will equally target healthcare managers and policy makers, promoting informed decisions when addressing effectiveness, efficiency, equity, and ethical issues underlying the development and implementation of PM approaches.

Additional activities may be developed to foster education and literacy, as already identified by ICPerMed:

- The collection and presentation of examples of best practices (e.g. on research, policy and implementation level).
- Best practice recognition awards.
- Education and training courses around dedicated PM topics to facilitate implementation of PM into practice.
- Dedicated workshops and conferences to establish information exchange, dialogue and cooperation with relevant stakeholders, key initiatives and research consortia internationally.
- Development of dedicated and adapted communication and dissemination means to share the EP PerMed vision as well as PM outcomes by reaching out to the multi-stakeholder PM community including citizens and patients, the PM-research community, healthcare institutions, the private and industrial sector and also higher authorities.

This pillar is of high importance to strengthen the leading role of EP PerMed and the involved organisations in the successful implementation of PM in a global context.

Policy development for PM implementation

EP PerMed will support the development of policies, guidelines and standards. A key role for EP PerMed in policy development is to collect evidence through extensive mapping activities, and foster sharing of information and PM best practices. For instance, EP PerMed can provide evidence regarding best practices or standards for data sharing, clinical approaches, etc., which can support better policy decisions and share information about existing infrastructures, platforms, databases and cohorts, to avoid duplication of efforts in policy development. Common evidence and shared information are crucial for aligned policies across Europe. For instance, the EP PerMed Best practice catalogue is likely to provide major contributions for policy development aligned across Europe along the entire chain of value, potentially offering tested solutions for instance for data management, clinical interpretation tools, healthcare system organisation, reimbursement models, and all other aspects relevant for PM adoption in healthcare.

Another essential contribution of EP PerMed for policy development is the international network and promotion of synergies among stakeholders, which will allow the integration of multidisciplinary perspectives for complex policy decisions for PM implementation. Finally, the strategic documents produced by EP PerMed can further stimulate policy decisions that are aligned between regions, countries and globally.

The close contact of EP PerMed with the PM community in Europe and also beyond allows the partnership to support the development of evidence-based recommendations and concepts for the long-term sustainability of PM. Documents will be shared with the different stakeholders by dedicated means and could find implementation in the EP PerMed itself, e.g. within the joint funding activities.

The development of an agreement on common strategic documents is essential for an alignment on a common PM vision and future objectives, e.g. towards a European Institute for Personalised Medicine or other transnational collaboration in healthcare for the benefit of patients and citizens and the society as a whole. One step towards these ambitious goals could be a PM “Best Practice catalogue” developed by EP PerMed that would allow the different countries to share their advancements and to build together on the gathered experiences, with solutions that are adapted to the different healthcare systems already existing.

6.2 Resources

EP PerMed will only be successful if all members and partners are and remain committed. Binding commitments to their contributions will be necessary to achieve the objectives.

Members (beneficiaries) of the EP PerMed are requested to sign the Grant Agreement (GA) and to work actively towards achieving the overall aims of EP PerMed. They commit to the EP PerMed activities (e.g. financial support provided to joint funding activities) with a dedicated budget and are eligible to receive reimbursements, e.g. in form of travel/accommodation for joining meetings or of personnel costs.

For **EP PerMed partners**, there is no monetary commitment required to join the partnership. In return, no financial support is provided for their participation. Partners commit by signing a letter of intent to working actively towards achieving the overall aims of the EP PerMed consortium. As EP PerMed partners they are part of the Executive Committee, together with EP PerMed members, and will be expected to report annually on their activities and to actively participate in the running of the initiative.

It is not expected that all members and partners of the partnership will participate in all pillars, but combination of different types of activities is possible.

Joining of new members and partners in the course of the EP PerMed is possible while the overall envelop of the EP PerMed will remain unchanged. The EP PerMed will seek **participation of all European countries** and **international organisations from different continents**.

Based on the ERA PerMed and ICPerMed experiences, underlined through internal surveys (launched in 2019/2020), for the majority of organisations it is important to receive financial support for their participation in the partnership, e.g. reimbursement for management costs in form of personnel costs for human resources, and for travel costs incurring connected to internal meetings. The role and commitment (budget and time invested) of each members/beneficiary in the EP PerMed should be clearly defined at the beginning of the partnership. Organisations of EU member states and associated countries could receive EC contribution for research funding in form of top-up when participating in a co-funded call.

Clear budget commitments are expected from the funding organisations participating in the joint funding activities especially for the co-funded calls. According to a survey launched by ERA PerMed within the ERA PerMed consortium and the ICPerMed family, the majority of participating funding organisations expect increased funding commitments or at least stable investments in PM research funding in future.

The reimbursement conditions might vary between the different pillars of the EP PerMed.

Members and partners agree at the beginning of the partnership on a common strategic and innovation agenda helping to align European, regional and national strategic agendas in the field of PM. The expected impact of joint funding activities for the regional/national research communities is high and includes the establishment or maintenance of transnational collaboration also with non-European countries, the promotion of research dedicated to PM and support of innovative research.

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.

6.3 Governance

The EP PerMed is organised around an Executive Committee consisting of members and partners (fig. 11). The Executive Committee is supported by a coordination unit comprising the elected chair and two vice-chairs, the pillar/work package leads, the EP PerMed Secretariat and the European Commission. The coordination unit is a sub-group taking care of the consortium's everyday work.

The Executive Committee elects the chair and the two vice-chairs for two years each. Their responsibility is to chair Executive Committee meetings and to lead the coordination unit. The chair and the two vice-chairs can be re-elected once.

The EP PerMed Secretariat consists of 3-4 organisations supporting the coordination unit and the Executive Committee in logistics (financial and administrative) and organisational aspects. One of the involved organisations acts as Secretariat coordinator.

Each pillar is led by one organisation being member/beneficiary of the EP PerMed. The pillars might be further structured in work packages. The pillars are interconnected but shall work independently and autonomously if the work requires for example a certain level of confidentiality, as it is the case in certain joint funding activities.

As main decision taking body, the Executive Committee is at the very centre of the EP PerMed structure. EP PerMed members, partners and observers nominate representatives to be part of the Executive Committee. Members and partners can be ministries, public and private 'non-profit' health research funding and policy organisations as well as healthcare institutions (see also section 5). Several organisations from one country can join the Executive Committee while each country in the case of decisions to be taken is having only one vote. This includes both, EP PerMed members and partners. Each country is requested to identify the entity that is acting as spoke person.

The status of EP PerMed members is restricted to ministries, public and private 'not-for-profit' health research funding and policy organisations participating in funding activities and one or several strategic pillars. Members of the EP PerMed participate in one or several of the operational pillars. As member organisation of the EP PerMed, they are requested to sign the Grant Agreement (GA) and to work actively towards achieving the overall goals of the EP PerMed, the developed strategic documents and annual work plans. They can receive financial support for their work in the form of personal cost and travel reimbursements.

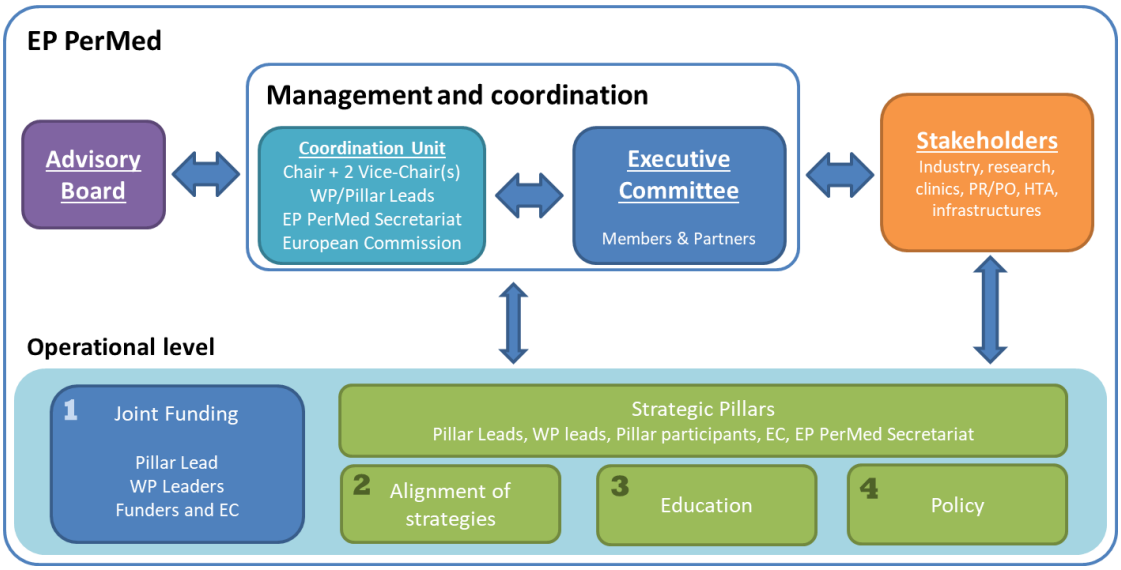


Figure 11: The EP PerMed governance structure

Partners belong to the same type of organisation as members. They commit by signing a letter of intent to working actively towards achieving the overall aims of the EP PerMed consortium. They are expected to report on their activities and to actively participate in the running of the initiative.

Organisations and initiatives with a strong interest in PM, but not being eligible to participate as a member or partner in the partnership, can be part of the stakeholder group. This concern e.g. research institutions, patient initiatives, related projects or industry organisations. Through its stakeholder group, the EP PerMed is in close contact with all these interested parties. As part of the stakeholder group, they are informed about the work and are invited to workshops and conferences to be part of the partnership. Experts and stakeholders are also invited to Executive Committee meetings for information and discussion on certain topics. Therewith, the EP PerMed creates the vital synergies between all key actors in the field of PM. This represents the solution for a successful PM implementation.

The different pillars are constituted by EP PerMed members and partners and are led by EP PerMed members. This aspect is essential to ensure the feasibility of the proposed work and the commitment of members taking over the respective task. Partners are invited to participate in the different pillars and work packages without receiving financial support.

A permanent Advisory Board consisting of maximum 10 senior experts of the PM field with overarching expertise along the whole value chain and overall PM knowledge could be envisaged e.g. to provide support for keeping the overall coherence of the partnership.

Due to the complexity and broad frame of the PM field the EP PerMed will further constitute ad hoc formed scientific boards for specific tasks of the partnership work plan. Those boards consist of experts covering the scope/area of PM topic(s) needed for the respective exercise/work to be performed. The role of the experts depends on the pillar and the task where input is required, e.g.:

- Call Advisory Board (CAB): The CABs consists of experts covering the scope of PM topic(s) to be covered in a joint transnational call. Their role is to offer technical support in defining the joint call topic(s) in joint funding activities;
- Input for strategic document: e.g. by participating in surveys and writing groups;
- Scientific Committee: e.g. for the preparation of events.

Each pillar is managed by one EP PerMed partner. Every pillar can be subdivided in different work packages with dedicated leads.

To ensure coherence and synergies within the EU research and innovation landscape, to advance successfully within PM implementation, following the SRIA developed, and complement the work proposed with other health topics, EP PerMed will create close synergies with related initiatives. This concerns in particular the potentially co-funded European Partnerships on “Transforming Health and Care Systems”, “Health Innovation”, “One Health/AMR” and “Pandemic Preparedness and Societal Resilience”, and other Health Programmes as the “Global Alliance for Genomics and Health (GA4GH)”.

6.4 Interaction with stakeholders

The uptake of multidisciplinary research and innovation results into general health practice will be an important challenge for the integration of PM approaches in healthcare systems for benefiting citizens and patients. In order to achieve the overall objectives of EP PerMed, interactions with a number of important stakeholders outside EP PerMed are needed.

Depending on the nature of the particular stakeholder, these interactions can occur in various ways, e.g. via direct discussions and dedicated exchange, involvement in EP PerMed events (workshops and conferences), involvement in preparation of publications and guidelines, participation of EP PerMed representatives in externally organised conferences.

Contact to industry will primarily go through industrial organisations, e.g. EFPIA or PhRMA. The contact to patients will be achieved via collaboration and exchange with patient organisations. These organisations can participate in EP PerMed in different ways, e.g. as consortium partners of funded research projects, as funder in joint funding activities but also as experts in the different strategic reflections planned within the partnership. As one asset to the innovative potential of EP PerMed, this would allow an improved transfer of research to the market and facilitate the uptake of PM approaches by citizens and patients.

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

6.5 Openness and transparency

EP PerMed will maximise its impacts by involving all relevant organisation in its structure as members, partners and stakeholders aiming to go beyond a narrow composition of core partners. Furthermore, EP PerMed is open for new collaborations and the integration of new organisations during its lifetime and the different activities.

EP PerMed will foster openness and transparency on three different levels:

1. Creating synergies, dedicated communication and dissemination of the EP PerMed;
2. Open science in funded research project (joint funding activities);
3. Recommendations around this aspect development by EP PerMed.

EP PerMed will develop different means of communication and dissemination strategies adapted to the different PM key players. Sharing of strategic documents and outcomes of the partnership are key success factors to successfully achieve the goals of the partnership, PM implementation and acceptance of PM approaches not only for translating research into clinical practice but also for improved education and literacy of citizens, patients and healthcare providers, e.g. for a better understanding of diagnostic and treatment options and towards future prevention. Furthermore, dedicated communication is needed with higher authorities to allow and enable a future uptake of PM in regional and national healthcare systems. With the inclusion of all European countries and international partners as well as the high-level participation of ministries, the EP PerMed might pave the way towards cross-border collaborations to allow citizens and patients independent on their home region/country to benefit from the most suitable diagnostic and treatment option available. A high level of openness and transparency regarding common vision can be achieved by EP PerMed thanks to the involvement of international organisations and stakeholders from different sectors. Other possibilities to inform and engage stakeholders will be explored in view of timely feasibility.

Creating synergies is one essential objective of EP PerMed including consultations of the PM community around the entire value chain, allowing new organisations to enter, participate in and benefit from its activities, and add value to the partnership. As there are different levels of participation, involvement of external stakeholders is possible anytime, actively seek and highly welcome without compromising the ownership and commitment of EP PerMed partners.

EP PerMed seeks the involvement of all EU members states and regions and of international partners, independent of their advancements in PM, as well as of PM related initiatives and others via the stakeholder group to search input for the objectives set but also to include all relevant key players that could benefit from the partnership's outcomes from the very beginning in the process. The main activities of the partnership will be led by partner organisations for feasibility reasons.

EP PerMed will implement and maintain an information channel through a dedicated partnership website and social media, allowing the partnership to share information about the work plans, protocols, data, results, strategic developments and other outcomes.

EP PerMed might develop an open access publication strategy for the partnership itself and for the results obtained during the joint funding activities that will have to follow the FAIR[1] principles, as well as develop recommendations around this aspect for the PM community.

With seven years funding duration and a steadily advancing PM environment, EP PerMed has to act, in a dynamic way and adjust its focus areas over the time span of the partnership. By following well-defined annual work plans but by keeping simultaneously the required flexibility, EP PerMed can adapt the focus on the key bottlenecks that might change over time.

[1] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

7 Annexes

7.1 Annex 1: EP PerMed Performance Framework

The performance framework (figure 12) outlines the implementation of the vision and strategy of EP PerMed to achieve and support expected outcomes and expected impact on global health and PM implementation. The framework can be assessed by a systematic review process following solid, measurable and reproducible indicators for the input, activities and output to evaluate the partnerships' performance. Dedicated and regularly performed evaluations will provide information about the benefits and changes (outcomes) towards PM implementation and the impact on the society.

Controlled and managed by EP PerMed are the **input** provided to the partnership, the performed **activities** and the **output**. They concern planned objectives and measurable work performed by the participating organisations:

Input: What is invested in EP PerMed and what resources are used?
The input describes the resources and added value that are brought to the partnership in order to carry out the proposed activities: Resources (budget, human and others), people, skills, knowledge.

Activities: What will be done by EP PerMed?
The activities are the concrete actions of EP PerMed. They outline what the EP PerMed consortium will do with its resources (input) to produce specific outputs and meet EP PerMed objectives (see also 4.1). For a better visibility, the figure only contains the overarching pillar titles, but diverse activities are needed as outlined in 2 examples:

1. Education: Amongst other activities, EP PerMed will create synergies by animation of the PM ecosystem, e.g. via events, and will create dedicated dissemination channels.
2. Policy activities will include besides the development of policies, guidelines and standards, the collection and dissemination of effective implementation models.

Output: Represents the work accomplished by EP PerMed and resulting from the activities performed. The output is under the control of the EP PerMed consortium. The indicated outputs can be further detailed, for example "*Regional and national strategic alignment of collaborative research and implementation*" concerns several sub-categories for the level of alignment as:

- Geographical: Collaboration across borders, in Europe and beyond,
- Budget: Investments and budget lines by joint funding activities (research projects and networks)
- Towards innovation: Funding along the value chain,
- Joint responsibility: Along policy-making layers (Ministry of Health, Ministry of Science, Ministry of Technology and Innovation),
- Improved and aligned knowledge base of PM in Europe and internationally along all sectors and disciplines,
- Integrating different payers (insurances, social security providers, community support, and private consumers).

In contrast to the upper sections, the **outcome** and **impact** cannot be controlled by EP PerMed but could be influenced by the consortium. For monitoring if intended results are achieved, the partnership can perform dedicated evaluations on specific PM related objectives.

Outcome: Changes initiated and pushed by EP PerMed outputs.
Represents the likely or achieved effects and benefits of EP PerMed outputs and their use by the targeted population, e.g. via induced behaviour changes as strategies adopted by governments. The outcomes could be short and long-term and are not fully under the control of EP PerMed but are influenced by the work and output of the partnership.

Impact: Changes on the society level promoted by EP PerMed.
The impact is different from the outcome/output and falls normally outside of the time range of the duration of a project. It is therewith describing the long-term aim of the partnership as (besides the impact already outlined in 4.3 and the below figure) e.g. *increased sustainability of healthcare systems by tailored and effective investments in health and care systems at national and regional level. More specifically for PM*, e.g. *increased translation of PM research into healthcare systems leading to improved health and quality of life for EU patients and citizens, by:*

- *Increased uptake of effective personalised diagnostic and therapeutic strategies,*
- *Increased uptake of effective preventive strategies in PM on a population level,*
- *Reduction of non-effective treatments.*

With its objectives, dedicated outputs, outcomes and expected impact, EP PerMed supports the six targeted impacts ("destinations") of the **Horizon Europe cluster 1 – Health**.

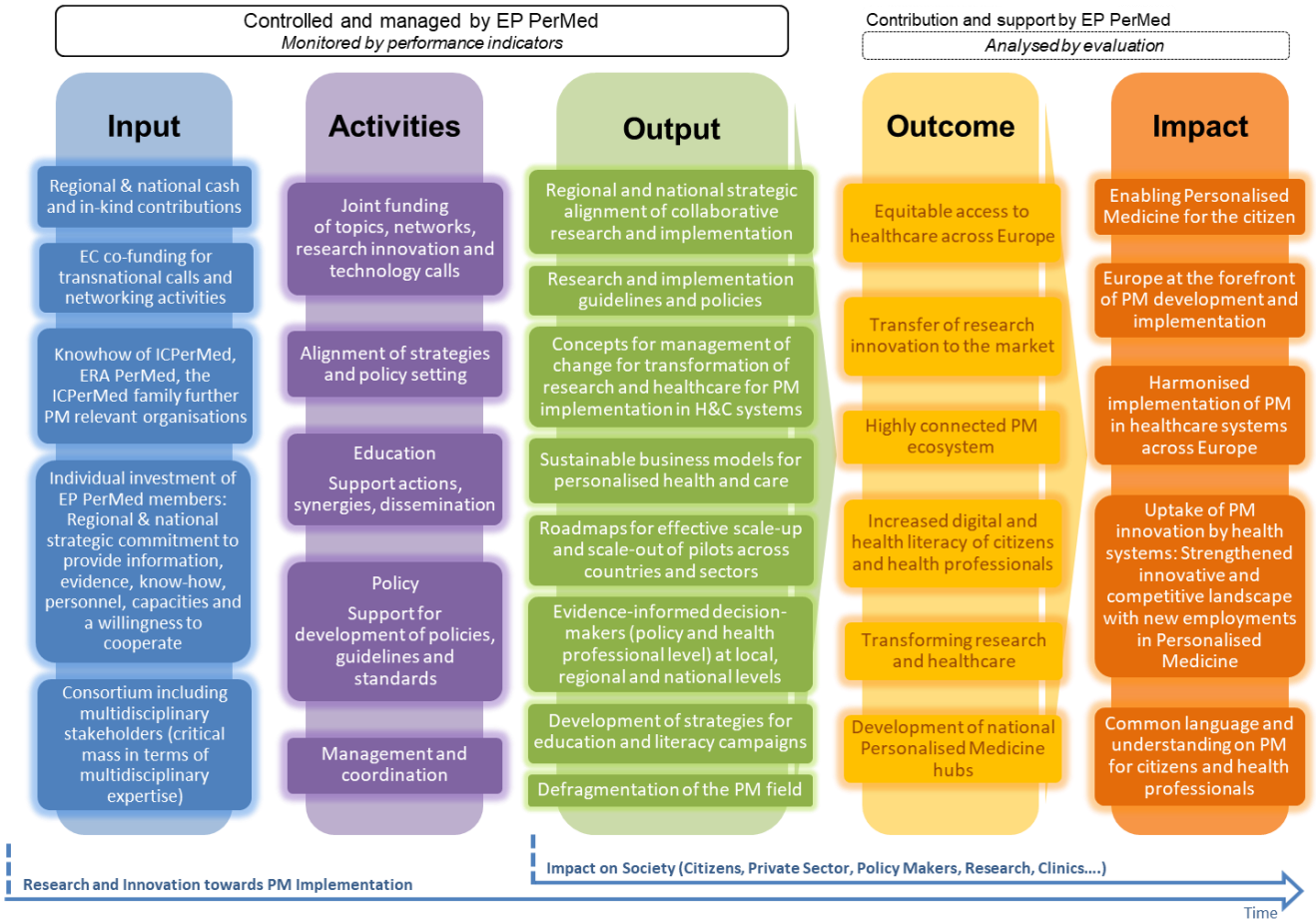


Figure 12: EP PerMed Performance Framework

7.2 Annex 2: Abbreviations

Table 2: List of abbreviations and their individual explanations.

AI	Artificial Intelligence
CAB	Call Advisory Board
CSA	Coordination and Support Action
E&T	Education and Training
EC	European Commission
ELSI	Ethical, legal and societal implications
EP PerMed	European Partnership in Personalised Medicine
ERA-Net	European Research Area Network
ERA PerMed	European Research Area Network for Personalised Medicine
EU	European Union
FAIR	Findable, accessible, interoperable and reusable
FP	Framework Programme
HCP	Healthcare Provider
HTA	Health Technology Assessment
ICPerMed	International Consortium for Personalised Medicine
ICT	Information and communication technologies
JTC	Joint transnational call
LAC	Latin American Countries
PM	Personalised medicine
PO	Patient organisation
PR	Patient representative
R&I	Research and Innovation
RITC	Research innovation and technology call
SRIA	Strategic and innovation agenda
WP	Work package

7.3 Annex 3: List of key documents and initiatives

The further list shows the current PM key documents and initiatives:

- CSA PerMed (2013-2015) together with its SRIA (2015)
- ICPerMed (launched in 2016) together with the Action Plan (2017) and the Vision Paper (2019)
- ERA PerMed (implementation of the ICPerMed Action Plan in funding research projects and creation of synergies by fostering the development of multidisciplinary consortia)
- The ICPerMed family CSAs, with focus on
    - International collaborations (4)
    - Regionals aspects (2)
    - Clinical standard (1)
    - Health economics (1)