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Personalised Medicine Implementation into Healthcare as a Multistakeholder Approach

Reflections from the European Partnership for Personalised Medicine

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Abstract

Personalised medicine — often also referred to as precision medicine — is a patient-centred healthcare concept that tailors diagnostic and therapeutic measures to a patient's individual genetic, molecular and lifestyle characteristics. The European Partnership for Personalised Medicine (EP PerMed) is a platform to support research, innovation and implementation of personalised medicine (PM) approaches by fostering strategic and funding alignment and dialogue. Following a multistakeholder approach, EP PerMed has identified five pillars of action to support PM implementation: engagement and support of healthcare professionals; patient engagement; public awareness and health literacy of citizens; engagement with medical societies; and engagement with healthcare providers. This article formulates recommendations — reflecting EP PerMed's planned next steps — to support the translation of personalised medicine approaches into healthcare, building on the practical experience of partners and collaborators involved in the partnership.

Keywords: personalised medicine; precision medicine; EP PerMed; multistakeholder; healthcare implementation; medical education; patient engagement; health literacy.

Background

Over the last two decades, multiple remarkable scientific achievements and technology developments accelerated the concept of Personalised (or Precision) Medicine (PM) to become an increasing and successful reality in healthcare. It started in the areas of cancer treatment and rare diseases, but today more and more areas are seeing and implementing such personalised approaches and solutions. The progress in PM was further enabled by innovative technologies such as different types of fast-sequencing techniques, advanced imaging options, data collection, storage and analysis with cutting-edge bioinformatic and statistical methods and last but not least by increased digitisation of daily life and artificial intelligence approaches.

The European Partnership for Personalised Medicine (EP PerMed) [1] is at present the leading initiative to support PM for the benefit of patients, healthcare, societies and economies in Europe. The

Partnership is supported by national and regional partners from Europe and beyond and is substantially co-funded by the European Union. The overall vision of EP PerMed is, by application of PM approaches, to improve health outcomes within sustainable healthcare systems for the benefit of patients, citizens and society. The Partnership was officially launched in November 2023 and connects over 60 partners, mainly ministries and funding organisations, to join forces to advance transnational PM research, innovation and implementation in national health systems, creating an international PM community. As a blueprint for the Partnership's activities, a Strategic Research and Innovation Agenda for Personalised Medicine [2] was developed together with European predecessor PM-related initiatives such as the International Consortium for Personalised Medicine (ICPerMed) [3] and the ERA PerMed Consortium [4].

As indicated, EP PerMed builds on previous European PM initiatives, for example the ERA PerMed consortium (2017–2023), which already funded 111 transnational PM projects consisting of almost 600 research groups and comprising a budget of around 133 million Euro [4]. The current Partnership has already achieved two transnational calls resulting in 49 projects with 295 research groups and a total budget of 96.4 million Euro. EP PerMed also strives to analyse the research results stemming from the projects, including those of ERA PerMed, and to support the follow-up along the innovation chain.

Apart from research and innovation funding, the partnership is also eager to facilitate the implementation of PM approaches into healthcare systems since this is recognised as a major challenge that needs specific emphasis. This article describes the challenges of PM implementation, EP PerMed's potential to conduct a multistakeholder approach to overcome these challenges in the long term, and gives recommendations for concrete actions in the short term.

Multistakeholder Approach for the Enhancement of PM Implementation

PM implementation into healthcare is challenging because personalised prevention, diagnosis and treatment require innovative and collaborative healthcare settings, adequate infrastructure and resources, and an understanding and open-mindedness of society that have not yet been achieved to their full extent. In particular, the challenging factors for PM implementation are the requirement of collaboration across sectors, disciplines and professions, the need for robust (data) infrastructures, diagnostics and analytics, the high demand on knowledge and skills as well as on legal and ethical expertise. It requires the respective resource allocation by healthcare providers and health insurances with the challenge to ensure equal access to PM approaches within society. These requirements were clearly summarised by a working group of ICPerMed in its roadmap towards PM [5]. Also, the ICPerMed Vision for 2030 stipulates that PM implementation into healthcare requires an interplay of conditions such as informed, empowered and engaged citizens, PM-skilled health providers, enabling healthcare systems, accessible and interoperable health data infrastructures, and PM solutions that provide economic value for societies [6,7].

By this it becomes evident that to ensure PM implementation the collaboration of multiple stakeholders is necessary, such as researchers, clinicians, the private sector, various regulators, healthcare professionals, payers and last but not least patients and citizens. The partnership with its broad network of health and research policy partners all over Europe and beyond displays an excellent resource to conduct such a multistakeholder approach.

In general, in its strategic research and innovation agenda EP PerMed has developed a concept called the "PM value continuum", since the partnership believes that the translation of PM research results into innovation and implementation needs to take place in a bidirectional manner [2]. To establish a

multistakeholder networking approach, EP PerMed has identified the following five pillars of action to foster PM implementation:

1. Engagement and support of Healthcare Professionals
2. Patient and People Engagement
3. Public Awareness and Health Literacy of Citizens
4. Engagement with Medical Societies
5. Engagement with Healthcare Providers to adopt and transfer existing PM approaches and solutions

Each pillar requires the support and collaboration of PM stakeholders. In the following, we will provide some insights and views of opportunities and challenges for relevant stakeholders in the pillars. Of note, the listed recommendations are a selection of discussion results with PM experts and learnings from a multitude of EP PerMed and ICPerMed events.

Identified Pillars of Action

1. Engagement and Support of Healthcare Professionals

In order to offer PM-specific education measures for healthcare professionals, EP PerMed developed the so-called Education Calls [8]. The purpose of this call-format is to support the provision and development of educational content for healthcare professionals on specific or practical aspects of PM in a certain field. So far, the first call has paved the way for the development of the first six educational PM modules. Furthermore, EP PerMed continuously organises “Implementation Schools” [9] to foster networking and knowledge transfer of specific topics relevant for PM implementation. Additionally, the Partnership executes measures such as roundtables, interviews or surveys in order to exchange and learn from the healthcare professionals about their PM experiences. Still, increased offers of indication-specific PM education measures could provide a pull-effect for successful PM implementation.

> **Recommended next step:** *Integration of PM in curricula of healthcare professionals and medical education and the development of certified indication-specific PM online-courses.*

2. Patient Engagement

Since nowadays it is recognised that the involvement of patients in medical research is of benefit for its quality, it is increasingly demanded by research funding programmes [10]. However, financial support for the work of patient- or citizen-representing organisations in research projects is still often insufficient or even missing. EP PerMed has evolved as a forerunner for the integration of patient- or citizen-representing organisations in research projects by providing specific funding for that. EP PerMed perceives patient organisations as very valuable partners in research consortia in terms of development of research questions according to patient needs and in terms of dissemination. These measures also contribute to the capacity building of patients capable to support medical research projects. Still, more educational offers for patient organisations should be developed.

> **Recommended next step:** *Development of online courses for patient or citizen representing organisations on PM topics such as PM in general, PM in special indications, expectations on patient or citizen involvement in research projects and PM implementation.*

3. Public Awareness and Health Literacy of Citizens

A factor that should not be underestimated for the implementation of PM in daily life is the level of health literacy of citizens on PM. To increase PM-related health literacy, more public awareness on this topic needs to be created. EP PerMed has launched a European-wide citizen survey [11] in 16 languages to understand the status of citizen awareness in Europe. As a first campaign measure to address the public, EP PerMed produced the podcast series "The Science of You" [12], which received the "Life Science Excellence Award" as "Best Communication Project of the Year" [13] in Italy. Dissemination efforts will be needed to inform European citizens that for several indications and disease areas there is the possibility of personalised diagnosis and/or treatment. Implementation of PM would highly benefit from an increase in health literacy in terms of higher acceptance of citizens for sharing health data for research, accepting complex treatments and increasing patient compliance. Besides an informed society as a pull-factor, PM implementation may also be enhanced by policies and suitable frameworks such as the Romanian law ensuring access to a PM treatment by law [14].

> **Recommended next step:** *Implementation of public campaigns and inclusion of the concept of PM in school curricula to educate the future beneficiaries of PM-approaches and to foster public awareness.*

4. Engagement with Medical Societies

Medical societies play a key role in the enhancement of innovative PM approaches since they are involved in the dissemination of research results, in education and training of healthcare professionals, as well as in the development of recommendations and standard clinical care guidelines. In turn, EP PerMed comprises a huge network of European research and health policy makers and may assist in the advocacy for the implementation of PM-related approaches into healthcare. Building on the outcomes of surveys and interviews with medical societies (so far 7 surveys and 4 interviews completed), EP PerMed will initiate stakeholder workshops and other measures in order to follow up on issues of common interest.

> **Recommended next step:** *Foster dialogue with Medical Societies to support the establishment of PM working groups, where they are not already existing, and to enhance cooperation.*

5. Engagement with Healthcare Providers to Adopt and Transfer Existing PM Approaches and Solutions

An important measure of efficient PM implementation is a strong PM network to learn from successful implementation experiences. Thus, EP PerMed developed Twinning Calls [15] to accelerate the implementation of PM solutions from one country to another through peer-to-peer exchanges. Furthermore, EP PerMed is eager to disseminate international Best Practice Examples [16]. Seven best practice examples have been published already and more will follow. The International Consortium for Personalised Medicine (ICPerMed) [3], which is supported by EP PerMed, displays a platform to exchange on frameworks related to PM research and implementation even beyond Europe. As the successful example of the widely established molecular tumour boards has demonstrated, a (cross-border) cooperation between medical specialists and healthcare providers for knowledge transfer and exchange is key for a broad implementation of PM in Europe.

> **Recommended next step:** *Promote a dialogue between international university clinics and tertiary care hospitals to support the development and adoption of new and existing PM approaches.*

Apart from these five specific pillars, EP PerMed organises conferences and workshops on a regular basis where the different stakeholder groups are invited and engaged. These formats provide fora where PM implementation challenges are discussed, best practice examples are showcased, and reports and working papers are developed.

Summary

In summary, the Personalised Medicine concept implementation in healthcare across Europe and beyond requires a multi-stakeholder cooperation. To initiate and support the engagement of all relevant PM stakeholders, EP PerMed developed different call and event formats. EP PerMed builds on the practical experience of its partners and collaborators to formulate the following recommendations as its planned next steps:

1. Integration of PM in curricula of healthcare professionals and medical education and the development of certified indication-specific PM online-courses.
2. Development of online courses for patient or citizen representing organisations on PM topics such as PM in general, PM in special indications, expectations on patient or citizen involvement in research projects and PM implementation.
3. Implementation of public campaigns and inclusion of the concept of PM in school curricula to educate the future beneficiaries of PM-approaches and to foster public awareness.
4. Foster dialogue with Medical Societies to support the establishment of PM working groups, where they are not already existing, and to enhance cooperation.
5. Promote a dialogue between international university clinics and tertiary care hospitals to support the development and adoption of new and existing PM approaches.

These recommendations aim to support the optimisation of healthcare by utilising Personalised Medicine approaches and solutions. Of note, further funding measures and efforts beyond EP PerMed and its runtime around 2033 are necessary to ensure the successful translation of research achievements and provision of real-world evidence. Independent from any funding, the engagement and cooperation of all stakeholders are key for further establishment of PM. This has been proven by best practice examples of PM implementation, for example by the national Paediatric Screening of Familial Hypercholesterolaemia in Luxembourg [17] or the Genetics-based Personalised Breast Cancer Prevention and Screening in Estonia [18].

> *One of the next opportunities of stakeholder engagement will be the establishment of an EP PerMed stakeholder forum (SHF) as well as the updated Strategic Research and Innovation Agenda for Personalised Medicine (SRIA) in 2027. Furthermore, everyone is invited to follow our website https://www.eppermed.eu/ to receive information for participation, being informed about latest developments of the Partnership and regarding PM and contribute for example by suggesting best practice examples for Personalised Medicine.*

Author Profiles

Dr. Christine Hasenauer: Christine Hasenauer holds a PhD in Biochemistry and has 14 years of experience in planning and coordination of research and development projects, market analyses and public research funding in the health field. In her current position as senior scientific officer at DLR Projektträger, she carries out national project funding in the field of personalised medicine and cell and gene therapy in Germany. She is part of the coordination team of the European Partnership of Personalised Medicine (EP PerMed) and promotes the strategic collaboration of international funders to fund research, innovation and implementation of personalised medicine.

Dr. Hemma Bauer: Hemma Bauer holds a doctorate in Molecular Biology and is head of the department of life sciences and animal procedures at the Austrian Ministry of Women, Science and Research (BMFWF). She has 20 years of experience in life sciences and health research policy on

national as well as European level and co-authored area-related strategy papers such as the Austrian Life Science Strategy 2016 or the EP PerMed-related Strategic Research and Innovation Agenda SRIA 2023. She is Austrian delegate to the programme committee of the cluster “Health” in Horizon Europe and coordinates the EP PerMed task dedicated to the engagement with medical societies.

Dr. Wolfgang Ballensiefen: Wolfgang Ballensiefen is project manager and policy adviser for health research topics and related funding measures on the European level and nationally primarily on behalf of the German Federal Ministry of Research, Technology and Space (BMFTR). He coordinates the European Partnership for Personalised Medicine (EP PerMed). He co-authored several strategic and policy-oriented publications in different areas of health research, such as the EP PerMed-related Strategic Research and Innovation Agenda SRIA 2023 [2], the STARS Common Strategy: Regulatory Support and Advice for Academia (2022) [19], the Strategic Research Agenda for Cardiovascular Diseases (SRA-CVD, 2019) [20] and the ICPerMed “Vision Paper”, 2019 [6].

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Declaration of Interest

The authors declare no conflict of interest. The authors confirm that this article is their own original work and that all listed authors have approved its submission. The authors confirm that the submission is not under consideration elsewhere.

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