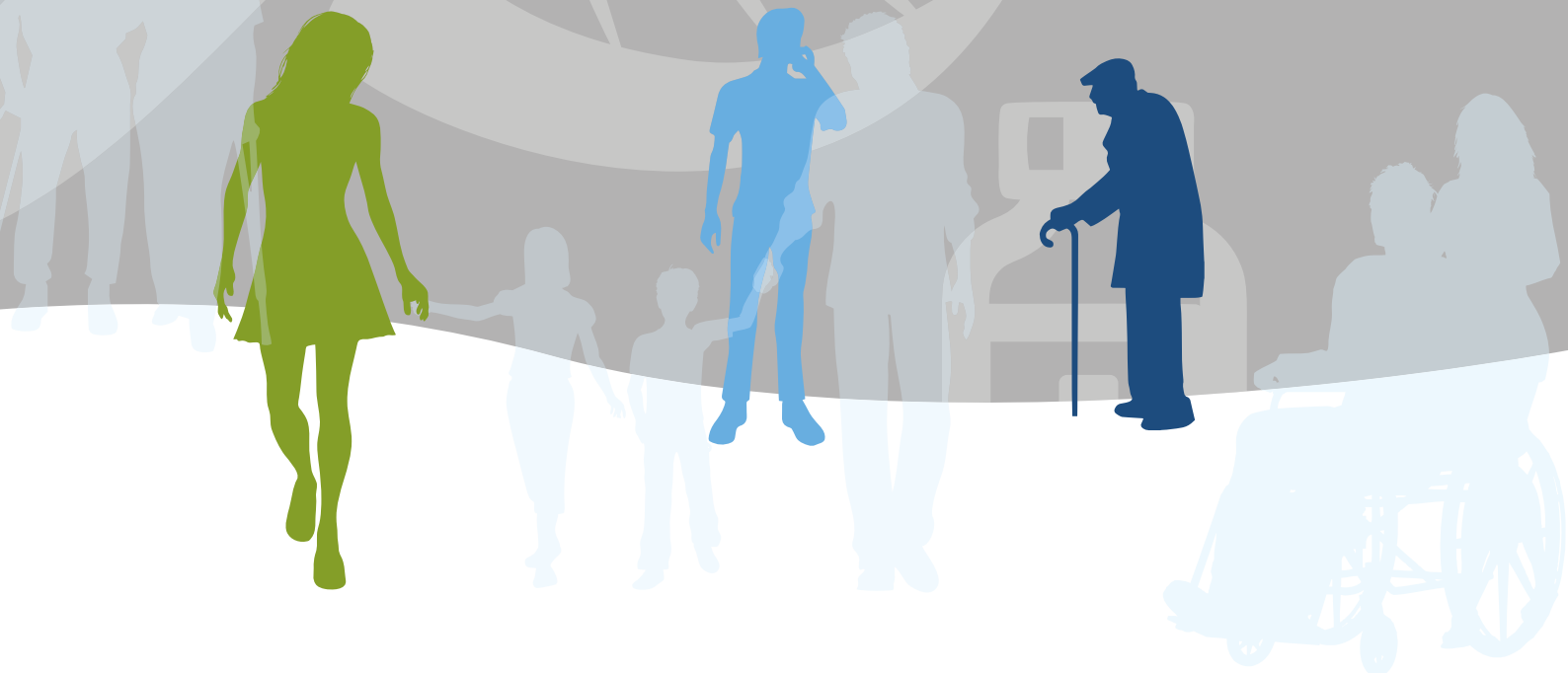
ICPerMed
INTERNATIONAL CONSORTIUM

Report

ICPerMed Family Meeting



ICPerMed Family Meeting – "Joining Forces"

9-10th November, 2021
Online

ICPerMed Family Meeting – Joining Forces

November 9 and 10, 2021

Meeting Report

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1. Executive Summary

The “ICPerMed Family Meeting – Joining Forces” took place virtually on 9-10 November 2021. Up to 75 invited participants followed the meeting actively. The aim of this first “ICPerMed Family” meeting was to foster collaboration between members of ICPerMed, ERA PerMed and the ICPerMed-related Coordination and Support Actions (CSAs) funded by the European Commission and to collect input on future research and implementation approaches. Five sessions around the following topics were organised by the ICPerMed working groups in cooperation with the related CSAs and ERA PerMed:

1. Clinical PM Research & Technology – Achievements, Challenges and Outlook
2. Health systems and PM implementation – Identification of research and implementation supporting requirements
3. The relevance of regions for implementing personalised medicine
4. Education and Literary – Identification of future activities to empower health care providers, patients and citizens
5. Internationalisation of ICPerMed activities – Facilitators and hurdles

The interactive session format with impulse talks followed by discussions in smaller breakout-rooms and panel discussions opened a forum for exchange on the above-mentioned topics. Besides the ICPerMed Executive Committee members, partners of ERA PerMed and of the ICPerMed related CSAs as well as members of the newly established ICPerMed Advisory Board, ICPerMed Working Group experts and specifically invited representatives of related initiatives brought in their diverse expertise in the field of personalised medicine (PM) leading to interesting discussions and conclusions. While several CSAs end in 2022, the upcoming European Partnership for Personalised Medicine (EP PerMed) provides the opportunity to consider the results and achievements of theses consortia and to be a platform for further collaboration in order to foster PM implementation in Europe and beyond.

2. The ICPerMed Family

The International Consortium for Personalised Medicine (ICPerMed) provides a platform to initiate and support communication and exchange on personalised medicine (PM) research, funding and implementation. ICPerMed works in close collaboration with the European Research Area Network for Personalised Medicine (ERA PerMed) as well as several Coordination and Support Actions (CSAs) funded by the European Commission (Fig. 1). This so called ICPerMed 'Family' has an important role in supporting the research and implementation of PM in Europe, in the member states and regions and beyond. Table 1 provides an overview about these initiatives. In order to increase exchange and collaboration within the ICPerMed Family, ICPerMed organised with support of the ICPerMed Secretariat the first ICPerMed Family Meeting.

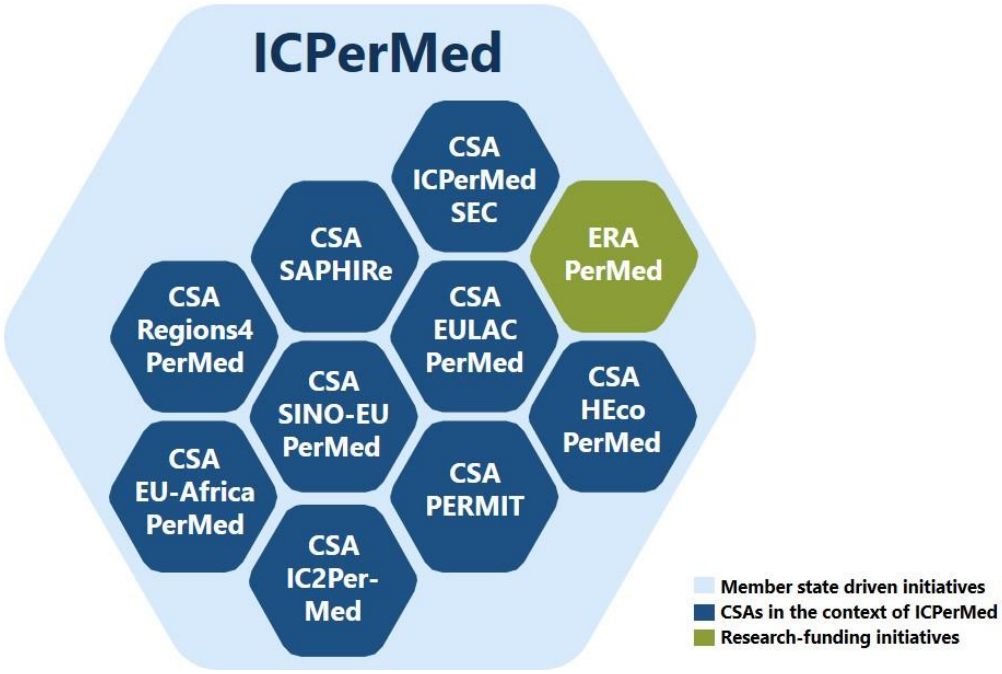

Fig. 1: The closely related ICPerMed Family comprises ICPerMed, ERA PerMed and the ICPerMed-related CSAs.

Table 1: Overview on the ICPerMed-related initiatives

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

	>> Further information on the ERA PerMed
ICPerMed INTERNATIONAL CONSORTIUM	ICPerMed provides a platform to initiate and support communication and exchange on PM research, funding and implementation. The high level of participation from all over Europe and beyond enables ICPerMed to efficiently map the scientific and political landscape. This allows an alignment of research and funding activities on European and international level. Based on the solid knowledge of ongoing efforts, ICPerMed members develop and agree on future research and research-supporting actions. In addition, ICPerMed aims to identify the requirements for a suitable framework in terms of infrastructures, resources and regulatory procedures to foster the development and implementation of PM. Thus, ICPerMed contributes to the reasonable and fair implementation of PM approaches into the health systems for the benefit of patients, citizens and society as a whole. >> Further information on the ICPerMed
ICPerMed-related Coordination and Support Actions	
ICPerMed SECRETARIAT	ICPerMed Secretariat is a Coordination and Support Action financed by Horizon 2020. It started in November 2016 with a budget of around € 2 million for four years and was prolonged in 2021 for another three years with a budget of another € 2 million. Its main objective is to contribute to ICPerMed's success. This will be achieved by supporting ICPerMed, its Working Groups and its chairs in all aspects of their work. These are mainly: • organisational support, e.g. coordination of consortium activities and events • first contact for all interested stakeholders and initiatives • support in communication and dissemination activities • monitoring ongoing research funding activities in Europe and beyond, the secretariat provides the basis for evidence-informed allocation of research funding • support in developing research policies, guidelines and where possible standards • assisting in developing a sustainability concept >> Further information on the ICPerMed Secretariat
HEcoPerMed Health Economics for Personalised Medicine	HEcoPerMed aims to identify the best health economic modelling and payment strategies for PM to differentiate between the

	promises of PM and reality, and to stimulate the adoption of promising PM approaches across the EU. The project responds to the demand for economic models that evaluate treatments made possible through innovations in PM. HEcoPerMed also seeks to identify funding and reimbursement mechanisms that provide financial incentives for the rapid development and uptake of such innovations. It goes beyond current assessment and payment models in order to serve the need of PM for more comprehensive cost-effectiveness estimates – incorporating patient and societal perspectives – and for sustainable affordability of cutting-edge health innovations. >> Further information on HEcoPerMed
PERMIT PERsonalised MedicIne Trials	PERMIT is based on a series of workshops where the project participants and partners invite selected experts to address the various aspects of methodology, design, data management, analysis and interpretation in PM research programmes. The objective is to reach consensus and publish recommendations on methodological standards to ensure the scientific excellence, validity, robustness and reproducibility of results, and the acceptability of the results generated by PM programmes. >> Further information on PERMIT
EU Africa PerMed	The 4-year EU-Africa PerMed project started on 1st February 2021 with the overall aim of integrating African countries into ICPerMed activities, thus contributing to a successful implementation of PM in the global context. It will foster joint PM projects and programmes between Europe and Africa, as well as strengthening bilateral EU-AU science, technology and innovation relations in the area of health. The project is implemented by a consortium of 13 partners, 6 from Europe and 7 from Africa. As the COVID-19 pandemic is showing, addressing global health challenges is only possible by building and strengthening international, inter-continental and national scientific cooperation between scientists, decision/policy makers, private practitioners, industries and health professional and civil society. EU-Africa PerMed works towards fostering a stronger global collaboration in PM through the umbrella of ICPerMed, and by this, to better tackle global health challenges such as infectious diseases and future pandemics as well as the prevention of non-communicable diseases. >> Further Information on EU-Africa PerMed

EULAC PerMed	In order to strengthen the global efforts on personalised medicine and the cooperation of Europe (EU) with Latin American and Caribbean (LAC) countries, the EULAC PerMed project, funded by the Horizon 2020 Programme of the European Commission, has been launched in January 2019. EULAC PerMed has the ambition to engage LAC countries in ICPerMed and in ERA PerMed with the aim at advancing in the implementation of the Action Plan of ICPerMed. EULAC PerMed is the vehicle for: • Mapping existing programmes, capacities and expertise and gaps in LAC countries. • Facilitating the incorporation of LAC countries in ICPerMed and in the ERA PerMed. • Fostering the participation of LAC countries in research mobility and transnational projects on PM, and a platform for EU-LAC collaboration on clinical trials PM focused. • Cross-border learning from research and innovation and the ethical, legal and social aspects for implementing innovations between research capacities based in EU and LAC. >> Further information on EULAC-PerMed
IC2PerMed	IC2PerMed is a four-year project funded under the Horizon 2020 scheme as a CSA. It is coordinated by Prof. Walter Ricciardi from UCSC, current President of the World Federation of Public Health Associations and Italian Representative at the WHO. The IC2PerMed project aims at providing key solutions for enabling the convergence under ICPerMed of European and Chinese stakeholders, with an orientation towards a Public Health perspective. >> Further information on IC2PerMed
精准医疗 SINO-EU PerMed Cooperation between China and Europe in Personalised Medicine	The Sino-EU PerMed project started in January 2020. The project received a € 2 million grant from the European Framework Programme Horizon 2020. The four-years project aims to foster the cooperation between Europe and China in PM. The project is composed of six excellent research and research management entities in Europe and China, namely the German Aerospace Center - Project Management Agency (coordinator), Fondazione Toscana Life Sciences, Innovation Fund Denmark, Health Research Board Ireland, Jiangsu International Technology Transfer Center and Guangzhou Institutes of Biomedicine and Health.

	The European partners are actively involved in ICPerMed as well as related initiatives and activities. Therefore, one of the objectives of this project is to foster collaboration between Chinese health organisations and ICPerMed, and to identify areas of mutual interest. >> Further information on SINO-EU PerMed
Regions4PerMed	The project Regions4PerMed contributes to the achievement of the objectives of the European strategy launched in 2011 with the European Council Conclusion: Towards modern, responsive and sustainable health systems (2011/C 202/04) on and modernisation of the European Healthcare system. In the 2011/C 202/04, particular stress is put on the role of strategic investments in healthcare and the importance of an integrated and interoperable health data sharing system. >> Further Information on Regions4PerMed
SAPHIRe	SAPHIRe will actively engage with European regions, including sparsely populated and remote regions and regions with different innovation levels. SAPHIRe will host a series of interactive events to understand the barriers and obstacles that exist around the implementation of personalised medicine. SAPHIRe will engage with regional stakeholders (including policy makers, industrial, healthcare and academic sectors) in a two-way discussion, with a view to supporting collaborative efforts and networking activities between regions in the area of PM. >> Further information on SAPHIRe

3. Aim and Scope of the Meeting

The virtual "1. ICPerMed Family Meeting – Joining Forces" took place on November 9 and 10, 2021. The participation in this event was on invitation only. Invited participants were ICPerMed Executive Committee members, representatives of the European Commission, ERA PerMed partners, partners of all ICPerMed related CSAs, ICPerMed Advisory Board members, ICPerMed Working Group experts and specifically invited speakers or representatives of related initiatives for impulse talks (e.g. Beyond 1+M Genomes). A list of participants is attached to this meeting report.

The aim of the meeting was to further support the collaboration between ICPerMed, members of the ICPerMed-related CSAs, funded by the European Commission under topic H2020-SC1-HCO-01-2018-2020 and ERA PerMed, and to collect input on different aspect of PM such as future research and implementation approaches or the need for and benefit of regional, national and international collaboration. The meeting programme was compiled by the ICPerMed Working Groups, ERA PerMed and the CSAs with support of the ICPerMed Secretariat. In five sessions, the topics "Clinical PM Research & Technology", "Health Systems and PM Implementation", "Relevance of regions for PM

implementation", "Education and Literacy" and "Internationalisation of ICPerMed activities" have been highlighted by impulse talks followed by discussion rounds. Detailed information about the individual sessions, speakers, discussed key questions as well as list of relevant publications can be found in the attachment of this document.

4. Meeting Results

4.1 Clinical PM Research & Technology – Achievements, Challenges and Outlook

The session on clinical PM Research & Technology started after a general welcome with an introductory talk by the ICPerMed Advisory Board member Fabrice André (Gustave Roussy, France) providing insights into state-of-the-art and future PM research approaches. While innovative research approaches have great potential for PM, they also open up a lot of new challenges in terms of scaling up and in terms of production/construction of individualised treatments such as antibodies, gene therapy or CAR-cells. Upcoming, promising PM research approaches, which are worth to fund, comprise the assessment of protein activation; ex-vivo modelling via organoids, targeting rather mechanism than mutations and the construction of personalised drugs (e.g. antibody-drug conjugates). Thereby, PM research can address several goals, such as:

- Improve treatment outcome
- Predict treatment outcome
- Support early detection of lethal cancers
- Decrease toxicity and identify substitute therapies to improve quality of life

This introductory talk was followed by a talk from Jacques Demotes (ECRIN) presenting the CSA Permit and by a talk from Christophe Le Tourneau presenting the results of one ERA PerMed project funded in the first call 2018. Christophe Le Tourneau (Institut Curie, France) underlined the added value of international cooperation and that the involvement of industry and patients is very valuable for research projects to increase expertise.

In the interactive break-out sessions three leading questions have been discussed:

- Question 1: How can patients, industry and payers be involved in the co-design of PM related clinical research programs and trials, if possible already at the early stages?

Patients, industry and payers should be systematically involved e.g. in the co-design of PM projects. Currently, clinical protocols are discussed with patient organisations, but it is recommended to involve them even in the stage of project planning. Thereby, one has to distinguish between patient involvement as active participants in the research projects and patient participation in studies. Patient engagement should be enabled through education. However, one should trust the patient's opinion and also consider that there are patients, which are also experts.
The involvement of industry is seen as highly important to get the PM approach to the patients. Thus, the interaction of industry and academy should be further encouraged (e.g. via workshops) to explain the respective needs (e.g. pragmatic models, safety protocols).

The involvement of healthcare providers is most challenging, as they are often included in the innovation process very late.
One has to understand which information payers need to be convinced to reimburse a PM approach e.g. by demonstrating patient needs and benefit as well as healthcare benefit. For this, the implementation of regional pilots with the aim of a later on national roll outs might be a way forward.

- Questions 2 and 3: How can we better overcome the challenges and maximise the opportunities of PM research programmes that are not only transnational, but also multidisciplinary? Which activities or adaptations could enhance the chances and speed of successfully implementing PM research into the health systems considering e.g. patient benefit, regulatory needs, cost-effectiveness, added value to current standard of care?

The discussants agreed that one of the most important facilitators for PM research is the access to electronic health data (e.g. data in primary and secondary care). For this GDPR alignment is a prerequisite. A project to start the collection of lifestyle data would also make sense, but sharing data and open access to data for researchers would be also a prerequisite here. These data would also help to evaluate not only the health but also the economic value. As further challenge, the transfer of academic results and tools to industry and the clinic was identified. Both aspects, data access and the need of technology transfer to translate PM approaches to the market and into clinics were also addressed in the previously published ICPerMed "Action Plan" (2017) and "Vision Paper" (2019), and will be also a priority for ICPerMed in the next years.

4.2 Health systems and PM implementation – Identification of research and implementation supporting requirements

The session on health systems and PM implementation started with three impulse talks by Sophia Schade (BMG), Katherine Payne (University of Manchester) and Matthijs Versteegh (Erasmus University Rotterdam). Sophia Schade presented the developments of the German Genomic Medicine project including the need of a specific legal framework and the construction and maintaining of respective research structures as concrete implementation example. She outlined the need of multi-stakeholder involvement (including patients) and education and training for successful implementation of PM approaches. Katherine Payne emphasized the need for economic evidence of PM approaches, while Matthijs Versteegh reported on studies[1] done within HEcoPerMed. Additional costs caused by PM have to be covered by "opportunity costs" like an earlier, effective treatment, improved responses and the minimisation of adverse drug reactions leading to an effective use of healthcare resources. Thus, the connection of healthcare and social care as well as considering patient preferences are important to measure the true value of PM. Furthermore, most medical approaches might be considered as very expensive, but the benefit for the patients will be

[1] e.g. Guidance for the Harmonisation and Improvement of Economic Evaluations of Personalised Medicine | SpringerLink

considered as being of high value. In summary, society should not base its decision only on economic analysis.

After the impulse talks the audience continued its discussion in three break-out rooms discussing diverse key questions leading to different conclusions and recommendations:

Break-Out-Room 1:

Break-Out Room 1 proposed to work on new "smart" models of payment to cope with innovations in PM. In these models, the following points should be considered:

- The economic analysis of PM interventions should include the testing phase which, in case of wide screening, may have a clear impact of cost-efficacy of the intervention. Thereby, two factors might be considered:
    - Exome or genome-based screening could screen for multiple treatment and thus diluting the testing costs
    - Wide genomic screenings could be covered by research and not by healthcare budget.
- Evidence of long-term benefit of innovative treatments such as gene therapy are difficult to estimate
- Consideration of social benefits, which is difficult to estimate

Further, the discussants of Break-Out-Room 1 proposed to identify incentives on prevention and diagnosis to better allocate existing treatments through patient stratification rather than developing new treatments to save costs.

Break-Out-Room 2:

Break-Out Room identified the following aspects to succeed in PM implementation:

- Understand the perspective of different stakeholders in PM development and their interests. The ultimate driver should be better health outcome, which has different meanings for patients (e.g. improvement of diagnostics, quality of life and recovery from diseases) and healthcare providers (e.g. accuracy of prevention, diagnostics and treatment). Researchers should consider the clinical relevance. For accurate communication, the definition of PM needs to be carefully explained to avoid misunderstanding and false expectations.
- Pushing technology development and sustainable healthcare improvement needs to be balanced to fulfil the requirements of both sides.
- Develop new tools to evaluate the health and economic benefits considering the multidisciplinary perspectives including all gained value in the innovation chain to understand the real impact.
- Start to implement on regional and disease specific level before scaling up nationally. Create cross border platforms to learn from each other and to join forces to reduce initial implementation costs.

Break-Out-Room 3:

Break-Out-Room 3 focussed on international aspects of PM implementation as well as on the question how the value of PM could be increased:

- There is a need to consider equity in PM, and think globally by taking into consideration the disparities in the low- and middle-income countries, especially in Africa. For example, in South Africa the system is geared towards therapies for infectious diseases, but not as advanced in oncology. Here will be a very long process to get access to PM testing, and it will be at the charge of the patients; this demonstrates that universal healthcare coverage is important.
- When thinking about PM, there is a need not only to consider therapies but also consider the typology of behaviour, especially to improve the outcome of prevention measures. There is a potential impact of personalisation of areas like health psychology.
- The paradigm in PM could change from a focus on those that should get a medicine or screening to the identification of those that should not receive one. That approach could increase the value of PM.
- Currently, PM approaches still seem to be costly due to the lack of health data, e.g. genomic information. To identify today few individuals at risk, large screening campaigns have to be launched. Structured data collection and regionally/nationally organised screening mechanisms will set the baseline for less expensive and more effective PM approaches. This could be the case when every baby gets its genome sequenced at birth; however, this would need a structure to allow health data to be linked with electronic health records, and followed through lifetime.
- The notion of silos of budgets should be revisited. Currently, PM costs are linked only with healthcare budget, but there could also be links with social care budget.

4.3 The relevance of regions for implementing personalised medicine

The regional ICPerMed related CSAs (SAPHIRe and Regions4PerMed) organised an interactive discussion with the audience as well as external, regional projects presenting speakers. Regional cooperation on PM was seen very positively with the potential to lead to a high added value. Following points were identified to underline the relevance of regions for implementing PM:

- Regions are innovation power houses
- Regions are often close to the healthcare systems e.g. by being responsible for the organisation, making it easier to drive PM pilots.

The dissemination of regional Best Practice Examples is seen as important to raise awareness and facilitate the roll out of regional pilot projects for implementing PM and further scale up to national level.

Funding opportunities for regions are available e.g. structural funds or “Digital Europe”, which can be used for the roll out of successful pilot projects.

There is very broad consensus that regions should be full partners in the EP PerMed to further pioneer and implement innovative PM approaches. The EP PerMed could facilitate interregional knowledge/best practice exchange and collaboration across national borders and thus allows a very different type of knowledge transfer than the exchange on solely national level. This will bring a high benefit for PM development, innovation and implementation in Europe.

4.4 Education and Literary – Identification of future activities to empower healthcare providers, patients and citizens

The session on Education and Literacy started with a presentation by Stefan Constantinescu (Federation of European Academies of Medicine) giving examples how platforms and federations could interact with policy levels on national as well as European levels. In order to approach educational and literacy aspects for PM it is recommended to make more use of the impact of existing societies and platforms.

The talk by Marius Geanta (Working Group 4 lead, Center for Innovation in Medicine) provided insights in the medical literacy level in Romania, showing a high need of communication about the advantages of modern cancer therapies and other PM approaches in this country. It might be an interesting question, how the literacy level in other countries are developed, what the reasons for different literacy levels are and how to approach gaps in knowledge successfully. One should be aware of inequalities of PM knowledge in Europe but also international wise. Thereby, it is clear, that a target group specific communication is necessary to interact and educate on various levels.

In two interactive break-out sessions it was discussed how to effectively approach different PM stakeholders to improve PM awareness and thereby implementation.

One important communicator and enabler are universities that improved their communication work in the last years to approach not only students (e.g. via Master Programmes and summer schools) but also the interested public.

Regarding the communication to patients and citizens the role of the general practitioners (family doctors) as opinion leader and translators to the lay public is emphasized. Thus, they need special training to be able to communicate about available PM approaches properly. Another important way to approach the lay public is to weave the PM topic into school.

Other ways of interacting with the general public were discussed (social media, advertisement campaigns (e.g. in public transport systems), collaborations with digital tools to link PM knowledge to medical websites). An important aspect is to reserve a dedicated budget for these activities.

To target the training of healthcare employees and clinicians it is recommended to integrate PM courses in the curricula and education licences system for medical doctors. Here, doctoral chambers may play an important role. However, a transnational collaboration is needed to standardise curricula and to consider European and international inequalities in healthcare education.

The discussions showed a high need of tailored approaches and different communication strategies for different stakeholders (e.g. health professionals, interested public and lay public). Thus, a high

education and communication effort (e.g. in form of different courses) is needed to increase awareness of PM. As an equal awareness of PM advantages is prerequisite for equal access, it is an important aspect to harmonise curricular to ensure a common level of understanding of health professionals and to increase communication as much as possible. Therefore, the meeting audience developed the idea of establishing a CSA on education and training issues in PM. The challenges and hurdles of PM communication and education need to be addressed. The work of the ICPerMed Working Groups 3 and 4 is a good starting point. However, a strategic concept needs to be developed on how this topic will be approached by PM-related initiatives in future (e.g. via EP PerMed or other initiatives).

4.5 Internationalisation of ICPerMed activities – Facilitators and hurdles

The international ICPerMed related CSAs (EULAC-PerMed, Sino-EU PerMed, IC2PerMed and EU-Africa PerMed) as well as the CSA "Beyond One Million Genomes" exchanged their experiences. The discussion has been supported by a talk from Rizwana Mia (SAMRC) of South-Africa as a mid-to-low income country and new ERA PerMed participating organisation/country.

Especially, for the international CSAs is the impact of the COVID-19 crisis very high, as international cooperation is strongly building on trust, which need to be developed by personal meetings and exchange. Although company contacts and innovation aspects might be good entry points (e.g. in China), the establishment of international cooperation in a particular field and continent takes time. Challenges are the heterogeneity, e.g. different cultural and legislative frameworks, leading to a different view on ELSI aspects of PM, the political will for wider cooperation and infrastructure readiness. Thus, the international engagement and communication with policy makers is a very important pillar to establish successful collaborations.

Based on the session discussions, it is recommended that ICPerMed continues its engagement to global funding bodies and policy makers to ensure equity of access to PM approaches. A special challenge is to ensure that international funding partners from mid- and lower-income countries joining ERA PerMed feel positively about their participation in this initiative, e.g. via gaining successful projects in the international joint calls.

Formulated expectations from a ERA PerMed participation are the exchange of (funding) strategies and pipelines and the successful co-funding. These aspects should be considered in ERA PerMed and, if applicable, later in EP PerMed calls.

Mobilisation of specific funding for countries with very limited research and monetary resources could be a way forward. Furthermore, visibility of PM and also ICPerMed is very important to reach the expected international collaboration and global impact for PM. International collaborations between Europe, China, LAC-countries and Africa need to be further fostered and supported, to develop PM approaches that are broadly applicable and to allow equity of access to healthcare towards the overall goal "to no one left behind".

The following opportunities for internationalisation have been identified:

- Increase visibility and raise awareness on political level by
  - Identification and communication of Best Practice Examples on equity
  - Building common methodologies (e.g. PM approaches, mapping strategies, communication means) and carrying out joint activities (e.g. newsletter, events)
  - Development of specific funding concepts to foster equity
- Development of common guidelines/standards in ELSI
- EP PerMed to continue and foster international cooperation and increase PM visibility. Of note, the EP PerMed Drafting Group and the EC are currently clarifying the question, how third countries can be involved in EP PerMed.

5. Outlook

Most ICPerMed related initiatives have been initiated during the Horizon 2020 Framework Programme and will run until 2022 or 2023 (see Fig. 2). Thus, the second ICPerMed Family meeting is planned for 2023 to exchange the partially final results of the ICPerMed related CSAs and to discuss possible further collaborations. In this regard, the start of EP PerMed is planned for the end of 2023 providing an excellent opportunity to continue and ensure collaboration to foster PM implementation for the benefit of patients and citizens. The preparations for the partnership have just gathered momentum and the report of the ICPerMed Family meeting will be sent to the newly established EP PerMed drafting group, in order to support the process and establish a continuous collaboration between ICPerMed and the Drafting Group.

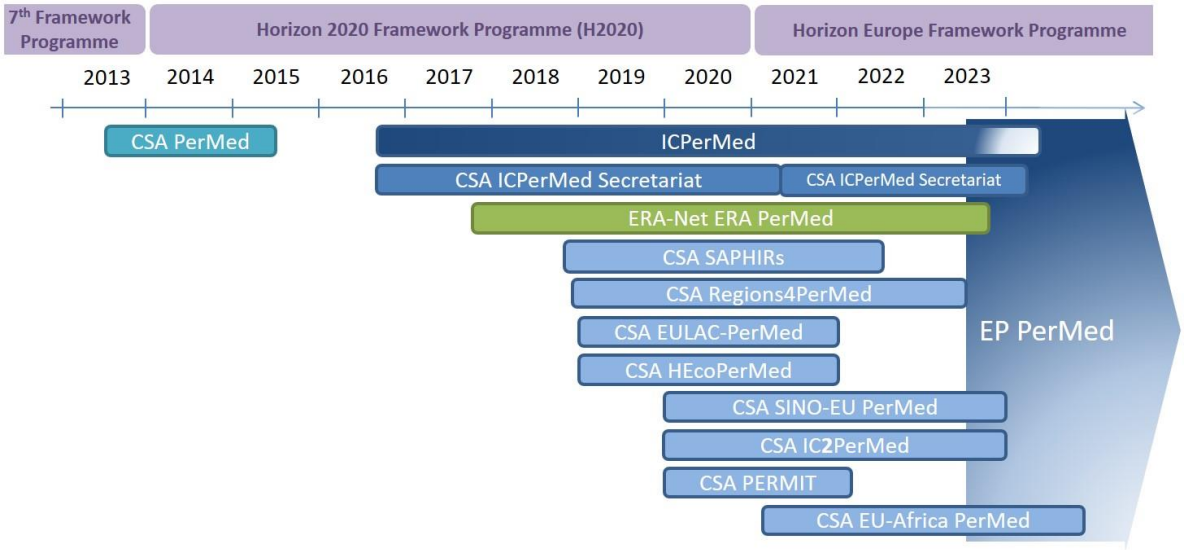

Fig. 2 Runtime of ICPerMed Family members.

With the EP PerMed Strategic Research and Innovation Agenda (SRIA), which is forseen to be developed and published in 2022, the way for future PM research and necessary research-supporting requirements for its implementation will be paved. ICPerMed plans to invite representatives of the

EP PerMed drafting group to present the SRIA in the next ICPerMed Family Meeting in order to join forces for the future of PM. Thus, the motto of the first ICPerMed Family Meeting – Joining Forces – will be maintained for future collaboration and events showing the success of the initiatives and the ICPerMed family.

6. Attachments

- Meeting Agenda
- List of Key Questions
- List of Relevant Publications
- List of Participants

Agenda

1. ICPerMed Family Meeting – Joining Forces

Dial-in Information for November 9, 2021: Join Meeting here

Dial-in Information for November 10, 2021: Join Meeting here

9 November 2021

12:15 h **Dial-in and sound check**

12:30 h **Introduction and welcome by ICPerMed Chair**
Ejner Moltzen (ICPerMed Chair)

12:35 h **Current developments of EP PerMed preparation**
Ejner Moltzen & Wolfgang Ballensiefen (EP PerMed Drafting Group)

12:45 h **Lessons learnt by ERA PerMed**
Maria Cristina Nieto Garcia (ERA PerMed coordinator)

13:00 h **Clinical PM Research & Technology – Achievements, Challenges and Outlook**
Responsible for session: WG1 in collaboration with CSA Permit and ERA PerMed

- Welcome (Wolfgang Ballensiefen, WG1 Lead)
- Impulse talks
    - Fabrice André (ICPerMed Advisory Board) about Personalised Cancer Treatment
    - Jacques Demotes (CSA PERMIT & ECRIN) about PERMIT
    - Christophe Le Tourneau (Institute Curie) about ERA PerMed PEVOdata Consortium

13:50 h 3 Break-out session to discuss lead questions
- Break-out session 1: Moderation WG1 - Angel Alonso
- Break-out session 2: Moderation WG1 – Avi Israeli
- Break-out session 3: Moderation WG1 - Eric Solary

14:35 h Presentations of Session results and Wrap up

10 min Break

15:00h **Health systems and PM implementation – Identification of research and implementation supporting requirements**
Responsible for session: WG2 and 5 in collaboration HEcoPerMed

- Welcome (Monika Frenzel, WG2 Lead)
- Impulse Talks:
    - Sophia Schade (BMG) about Personalised Medicine implementation
    - Katherine Payne (University of Manchester) about Health systems and implementation of precision medicine: the need for economic evidence
    - Matthijs Versteegh (iMTA) about Health economic methodology for personalised medicine evaluation

15:30 h 3 Break-out session to discuss lead questions
- Break-out session 1: Moderation WG5 – Stefano Benvenuti
- Break-out session 2: Moderation WG2 – Monika Frenzel and Paolo Parini (Karolinska Institutet)
- Break-out session 3: Moderation WG5 – Etienne Richer

16:25 h Presentations of Session results and Wrap up

10 min Break

17:00 h **The relevance of regions for implementing personalised medicine**
Responsible for session: CSAs SAPHIRe and Regions4PerMed

- Welcome (Jolien Roovers, SAPHIRe)
- Joint introductory talk by the CSAs SAPHIRe & Regions4PerMed
- Impulse talks:
    - Olaf Müller (Healthy Saxony) about Regional Innovation on PM (Saxony Region)
    - Romano Danesi (Molecular Tumor Board – Tuscany Region) about reimbursement of personalised therapies for cancer patients
    - Dieter Therssen (Flemish spearhead cluster on health tech) about strategy & vision in Flanders with a focus on industry
    - Marc Pattinson (Smart Specialisation, Interreg) about RIS3 strategies and interregional cooperation

17:50 Panel Discussion to discuss lead questions with:
- Kathleen D'Hondt (SAPHIRe)
- Gianni D'Errico (Regions4PerMed)
- Olaf Müller (Healthy Saxony)
- Romano Danesi (Molecular Tumor Board – Tuscany Region)
- Dieter Therssen (Flemish spearhead cluster on health tech)
- Marc Pattinson (Smart Specialisation, Interreg)

- Wrap up

18:50 h **End of Day 1**

10 November 2021

12:15 h **Dial-in and sound check**

12:30 h **Education and Literary – Identification of future activities to empower health care providers, patients and citizens**
Responsible for session: WG3 and 4

- Welcome (Maria Grazia Mancini (WG3 lead) and Marius Geanta (WG4 lead))
- Impulse Talks:
  - Stefan Constantinescu (President of Federation of European Academies of Medicine) about Educational Curricula for Personalised Medicine at University Level
  - Marius Geanta (ICPerMed WG4 Lead) about awareness of Personalised Medicine and cancer innovation in Romanian population

13:20 h 3 Break-out session to discuss lead questions
  - Break-out session 1: Moderation WG3 - Maria Grazia Mancini
  - Break-out session 2: Moderation WG4 – Marius Geanta
  - Break-out session 3: Moderation WG4 – Manoel Barral-Netto

14:05 h Presentations of Session results and Wrap up

10 min Break

14:30 h **Internationalisation of ICPerMed activities – Facilitators and hurdles**
Responsible for session: EULAC PerMed, SINO-EU PerMed, IC2PerMed, Africa-EU CSA

- Welcome & Introduction to the topic (Esther Rodriguez (EULAC PerMed))
- ICPerMed view on international cooperation (Astrid Vincente, ICPerMed Vice Chair)
- Impulse talks:
  - Esther Rodriguez from EULAC PerMed
  - Carolin Lange from SINO-EU PerMed
  - Chiara Cadeddu from IC2PerMed
  - Joaquin Guinea from EU-AFRICA PerMed
- External Experts:
  - Serena Scollen about other international cooperation initiatives in Personalized Medicine: “1 Million Genome”:
  - Rizwana Mia (SAMRC, South Africa) about PM initiatives from other countries and expectations on ICPerMed

16:00 Panel Discussion to discuss lead questions with:
  - Esther Rodriguez from EULAC PerMed
  - Carolin Lange from SINO-EU PerMed
  - Chiara Cadeddu from IC2PerMed
  - Joaquin Guinea from EU-AFRICA PerMed
  - Serena Scollen from 1 Million Genome
  - Rizwana Mia from SAMRC

- Wrap up

16:30 h	**Summary of the meeting results & Outlook**
17:00 h	**Virtual Get together**
18:00 h	**End of ICPerMed Family Meeting**

List of Key Questions

1. ICPerMed Family Meeting – Joining Forces

Overarching Question of the Meeting:

What are the most important issues that should be tackled by ICPerMed and the upcoming EU partnership on personalised medicine?

Session 1: Clinical PM Research & Technology – Achievements, Challenges and Outlook

- How can patients, industry and payers be involved in the co-design of PM related clinical research programs and trials, if possible already at the early stages?
- How can we better overcome the challenges and maximize the opportunities of PM research programmes that are not only transnational, but also multidisciplinary?
- Which activities or adaptations could enhance the chances and speed of successfully implementing PM research into the health systems considering e.g. patient benefit, regulatory needs, cost-effectiveness, added value to current standard of care?

Session 2: Health systems and PM implementation – Identification of research and implementation supporting requirements

- Identification of requirements for implementation and requirements to achieve perspective 3 and 5 of the Vision Paper
- future health services research or research supporting questions/research requirements/necessary pilot projects and studies for implementation or need for support provided to research in form of frameworks, infrastructures etc. by chairing person of session:
    - Use of real-world data to feed economic models of personalised medicine approaches?
    - What are the most important bottlenecks on the health economic side? Who is developing the health economic evaluation and who is using them for which purpose?
    - How can prevention programs become personalized and does it make sense?
        - How can the value of personalised prevention be evaluated (Health economic value of prevention based on personalized approaches)? Who is going to pay for such programs (individuals, insurances, healthcare system)?
    - Do you think that personalized medicine interventions should have a dedicated and different health economic assessment that could incentivize the adoption of such interventions?
    - What are the economic barriers to make personalised medicine more accessible and affordable? (short term and long-term perspective)
    - What could be the strategies to lower the costs of personalised medicine interventions?
    - What European/national/regional regulations may facilitate or prevent the implementation of PM?
    - What are the legislations necessary for the practice of PM?
    - What are the necessary policies and strategies to be developed by regions, countries?

- What lessons have been learned in a crisis situation to improve and accelerate the development and adoption of medical devices, treatment and medical practices?
- How to successfully implement PM approaches into practice or establish an environment suitable for the implementation of PM?
  - What are incentives or success factors for PM implementation?
  - What are the needs for HC professionals or for the director of the programme?
  - What are the requirements to be respected or set in place?
- What are the most important issues regarding implementation that should be tackled by ICPerMed and the upcoming EU partnership on personalized medicine?
- What should the role of patients, the public and clinicians be in the design and implementation of personalised medicine?

Session 3: The relevance of regions for implementing personalised medicine

- What are regions doing to ease the implementation of PM in their communities?
  - funding, policies, …
  - reimbursement approaches
  - Differences in organization/ authority levels between countries
- What roadblocks do regions face when implementing PM? What is needed to remove these roadblocks? What are the drivers/enablers for regions when implementing PM?
- Recommendations for actions? What can ICPerMed do to help regions? How can ICPerMed benefit from the successes in regions?
- How can ICPerMed build on the experiences regions have in communication and dissemination strategies towards the general population?
- What could be future collaboration synergies between regions and ICPerMed? What are the most important issues for ICPerMed to be tackled on the future of the partnership and EP PerMed?

Session 4: Preparing the citizens, patients, healthcare professionals (and society) for personalised medicine

- What are the enablers and main barriers for the implementation for education and curricula for personalised medicine?
- Which insights will feed the knowledge of science for targeted groups to act in reforms and improve an equitable point of care?
- How can ICPerMed or a future partnership contribute to improved awareness of Personalised Medicine in the general population? How can communication and dissemination strategies be set up to address this target group?

Session 5: Internationalization of ICPerMed activities – Facilitators and Hurdles

- In your experience, Is there any common methodologies for international cooperation we may apply together?
- Any activity/ies that could be jointly organized?
- How do you envision future collaboration of the region with the future EP PerMed?
- What do you think is needed to successfully engage with the region?
- What can be done from the EP PerMed perspective?

List of Relevant Publications

1. ICPerMed Family Meeting – Joining Forces

Publications by ICPerMed

1. ICPerMed Action Plan
2. ICPerMed Vision Paper

Publications by the ICPerMed related CSAs

1. Publications by CSA Permit
2. Guidance for the Harmonisation and Improvement of Economic Evaluations of Personalised Medicine and other publications by HEcoPerMed
3. The evolution of personalized healthcare and the pivotal role of European regions in its implementation and other publications by Regions4PerMed
4. Webinar and Meeting Reports by SAPHIRe

Publications regarding the preparation of the EP PerMed

1. Draft document EP PerMed (oct 2020)
2. Guide to a European Partnership for Personalised Medicine, EP PerMed
3. EP PerMed Information Sheet 7: International collaboration in the EP PerMed

List of Participants

1. ICPerMed Family Meeting – Joining Forces

Last name	First name	Organisation
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