ICPerMed
INTERNATIONAL CONSORTIUM

State of the Art Report 2020

Imprint

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Executive Summary

In November 2020, ICPerMed entered its fifth year and will share with this State of the Art Report 2020 an overview of its activities over the past four years, the progress made and future steps to be taken to fulfil its vision:

- Establish ICPerMed members as global leaders in personalised medicine research,
- Support the personalised medicine science base through a coordinated approach to research,
- Support research to investigate the benefits of personalised medicine to citizens and healthcare systems,
- Pave the way for personalised medicine approaches for citizens.

A retrospective analysis includes statements of ICPerMed's former vice-chair Wolfgang Ballensiefen and of the five ICPerMed Action Item Groups that paved the way for five new working groups with distinct topics related to personalised medicine: clinical studies, healthcare, patient involvement, education and curricula and health economic values. Ejner Moltzen (ICPerMed chair since summer 2020) provides a vision of ICPerMed's future activities, also in the view of the new European Commission Framework Programme "Horizon Europe".

We are pleased furthermore, to share a statement by **Irene Norstedt**, Director of the People Directorate within the DG for Research and Innovation of the European Commission, on personalised medicine and the role and position ICPerMed is taking in this field.

For its ambitious work, ICPerMed received direct support from the European Commission in the form of a "second edition" of the ICPerMed Secretariat (2021-2023) and additional support in the form of eight coordination and support actions (CSA) funded around the international consortium, strengthening with their dedicated PM focus ICPerMed's progress and contributing substantially to its success. These CSAs are presented in this report together with ICPerMed's longstanding partner programme: the ERA-Net, ERA PerMed.

Besides the ICPerMed Action Plan (2017), ICPerMed published in 2019 a second strategic document: The ICPerMed "Vision Paper on Personalised Medicine Research and Implementation by 2030", providing the framework for the ICPerMed virtual conference 2021: "Personalised Medicine – From Vision to Practice" held in February 2021.

We report how ICPerMed reflected in 2020 on building a sustainable PM framework to foster strategic reflections and funding opportunities in personalised medicine in the view of Horizon Europe: A Joint Sustainability Workshop organised together with ERA PerMed and a draft concept paper developed that is outlining ICPerMed's and ERA PerMed's view on the need for and potential of a future European Partnership for Personalised Medicine.

ICPerMed's achievements would not have been possible without the active and passionate contribution of the ICPerMed consortium that is 100% in-kind. The State of the Art report 2020 goes beyond a feedback of ICPerMed activities between November 2018 and October 2020, but presents the entire potential of the ICPerMed umbrella structure to enable personalised medicine to become a reality for all citizens.

State of the Art Report 2020

1. International Consortium for Personalised Medicine

ICPerMed has successfully served, since 2016, as a strategic platform bringing together high-level policy makers such as research and innovation ministries, health ministries, and regional authorities as well as regional and national funding organisations to foster a common understanding of PM and the defragmentation of the personalised medicine (PM) environment by aligning strategies in research funding and at the policy level. ICPerMed initiates and drives strategic reflections and the development of strategic documents in form of the ICPerMed Action Plan in 2017 and the Vision Paper in 2019. The entire consortium, currently comprising 47 organisations from 30 different countries, adopted these strategic documents.

That PM is a highly sensitive topic, not only in Europe but also worldwide, is underlined by the increasing number of organisations from 22 European member states, 27 European countries, 7 European regions and two countries associated to Horizon 2020[1], along with international partners from Canada (2016[2]), Brazil (2018[2], 2020[2]) and Iran (2019[2]), that have already joined ICPerMed.

In 2019, ICPerMed welcomed three new members: the Tuscany Region (Italy), the Iran Ministry of Health and Medical Education, and the Ministry of Social Affairs and Integration from Baden-Wuerttemberg (Germany, region). In 2020, the Department of Economy, Science and Innovation of the Flemish government (EWI Department, Belgium, region) joined the consortium as a new member and the Brazilian Federal Research Funding Agency CNPq joined as an observer. These are important steps for ICPerMed towards full coverage of the European landscape, including regions that are often pioneering for example in PM implementation, and for the alignment of PM strategies at the global level.

Besides organisations joining as members and observers, many others are following ICPerMed's activities via the ICPerMed website (more than 1000 visits per month from 167 different countries and 6 continents Asia, Africa, North America, South America, Europe and Australia) and the newsletter[3] (1038 subscribers) as well as via Twitter (219 followers since its launch in 2020). The ICPerMed mapping database[4] with information about funding opportunities in PM has already welcomed 284 users, while the ICPerMed Partnering Tool[5] is already connecting more than 982 universities, research and patient organisations, private partners, industry and other stakeholders with an interest in PM.

Stimulating cooperation and transfer of knowledge: ICPerMed events, ICPerMed Recognition and Best Practice Examples

One major goal of ICPerMed is to stimulate cooperation and transfer of knowledge. For this purpose, ICPerMed uses different means to raise awareness of PM and promote the establishment of international standards through regular ICPerMed events, the ICPerMed Recognition and the promotion of examples of best practices in research, implementation and funding.

ICPerMed engages with relevant stakeholders and discusses needs and barriers to be tackled. **Dedicated events** aim to strengthen cooperation and information exchange, allowing vision alignment and the harmonisation of PM implementation towards a less fragmented European and international ecosystem and thus ensuring fair access to PM for citizens, irrespective of their country of residence. Until 2021, ICPerMed organised annual events[6], i.e. two workshops and two conferences. The workshops each brought together up to 200 participants on invitation to discuss topics such as "Innovative Concepts on Data Generation and Use for Personalised Medicine Research" (26-27 June 2017, Milan, Italy) and "Personalised Medicine for all Citizens and Patients within Sustainable Implementation" (5-6 November 2019, Madrid, Spain).

The two ICPerMed conferences were open for participation, free of charge. The first conference "Personalised Medicine

1 https://ec.europa.eu/programmes/horizon2020/
2 Indicating the year for joining ICPerMed
3 https://www.icpermed.eu/en/services-newsletter.php
4 https://www.icpermed.eu/app/login
5 https://partnering.pt-dlr.de/ICPerMed
6 https://www.icpermed.eu/en/activities-events.php

in Action" (20-21 November 2018, Berlin, Germany) presented examples of best practices in policy, and research and innovation for successful implementation of PM approaches. The event brought together more than 300 participants from more than 30 different countries and 500 online followers via the livestream.

The second ICPerMed conference in 2021 "Personalised Medicine – From Vision to Practice" (25-26 February 2021, virtual event) discussed and promoted solutions and strategies for sustainably implementing PM approaches in five dedicated sessions around the five ICPerMed Vision Paper perspectives. During the conference, and together with over 500 registered attendees from all over the world, ICPerMed demonstrated the importance and the need to address PM challenges through the prism of the four critical pillars: Data and technologies, inter-sectoral synergies, healthcare system reforms and education and literacy, and promoted developments in PM by participation of world-leading researchers, ELSI (Ethical, Legal and Social Aspects) experts, health economists, payers, patients and industry representatives, regulatory authorities and HTA (Health and Technology Assessment) experts. A sixth session was dedicated to lessons learned from the COVID-19 pandemic and the contribution of PM to the fight against infectious diseases.

The workshop reports[7] [8], outlining the outcomes of the discussions, and the presentations held during the events are available on the ICPerMed website.

ICPerMed event concept 2021-2024

Over the next three years, ICPerMed is planning biannual events in different formats: five smaller events, including most probably three thematically focused workshops and one conference, and as new feature training events and summer schools.

The **presentation of best practice examples** is an important step to engage with and sustain interest of policy makers (e.g. the European Commission, national deputies, parliamentarians) by making research accessible to them and by strengthening cooperation between research and policymaking. In particular, to convince policymakers to consider new approaches, we often have to count on the work of courageous pioneers. Those pioneers are presented by ICPerMed in the form of examples of best practices in policy and research & implementation **in a dedicated section on the ICPerMed website**[9] to show that successful approaches for PM are becoming a reality. The examples presented are suggested by ICPerMed members and approved by the consortium. The examples cover different aspects of the value chain. In particular, two different types of best practices are featured:

1. Successful translation of PM research into an added value for the patient.

2. Policymaking and impact analysis for PM research.

Already, seven examples are presented are more are coming soon.

Furthermore, ICPerMed features and honours **best practices in PM research through the ICPerMed Recognition**[10], aiming to recognise, encourage, promote and disseminate outstanding examples. The Recognition calls have been launched annually since 2018 and are **open to candidates worldwide** since 2019. Awardees were invited to the ICPerMed events to present their results during plenary sessions, already resulting in 11 encouraging talks and 9 poster presentations in total. Additionally, the successful candidates received a non-cash award of 500 € to support the further dissemination of the awarded examples of best practice.

7 https://www.icpermed.eu/media/content/ICPerMed_Workshop-Report_Milan-June2017.pdf
8 https://www.icpermed.eu/media/content/ICPerMed_WorkshopReport_Madrid_2019.pdf

9 https://www.icpermed.eu/en/best_practice_examples.php
10 https://www.icpermed.eu/en/icpermed-academy.php

The ICPerMed Vision Paper on Personalised Medicine Research and Implementation by 2030

With the Vision Paper[11] published in September 2019, ICPerMed is sharing with the community its second strategic document following the ICPerMed Action Plan (2017). The Action Plan described a set of actionable research and supporting actions essential for the development of PM and its implementation and identified as being "ready for action". The Action Plan formed the basis of the work programme of ICPerMed members and other interested funders for two years.

With the Vision Paper, ICPerMed went a step further and developed a vision of how the use of PM approaches will promote "next-generation" medicine in 2030. The document describes a framework around five perspectives addressing (1) the role of the individual, (2) the role of health professionals, (2) the implementation of PM in health systems, (4) the use of personal health-related information, and (5) the economic value of PM approaches (fig. 1). The perspectives are sustained by four critical pillars representing transversal aspects that are crucial for the implementation of PM: Data and technologies, inter-sectoral synergies, healthcare system reforms and education and literacy.

ICPerMed is confident that its members, as well as the European Commission (EC), will take the perspectives of the Vision Paper into consideration when planning upcoming and future programmes and activities. During the 2021 conference "Personalised Medicine – From Vision to Practice" (25-26 February 2021), ICPerMed discussed and promoted, in five dedicated sessions around the five Vision Paper perspectives, solutions and strategies on how to successfully implement PM approaches.

ICPerMed has defined the vision and its perspectives in consultation with European and international experts, covering the entire range of relevant sectors and professional backgrounds. The method of the expert consultation is also further outlined in the article "International consortium for personalized medicine: an international survey about the future of personalized medicine" *(Venne et al., Personalized Medicine, 2020[12])*.

11 https://www.icpermed.eu/en/activities-vision-paper.php?pk_campaign=partnership&pk_kwd=2020-07-02&pk_source=newsletter
12 https://www.futuremedicine.com/doi/10.2217/pme-2019-0093

Furthermore, a commentary *(Vincente et al., Journal of Translational Medicine, 2020[13])* presenting the vision of ICPerMed on how PM will lead to the next generation of healthcare by 2030 was published in the Journal of Translational Medicine in April 2020.

CSA ICPerMed Secretariat: Secretariat for the International Consortium for Personalised Medicine

To effectively achieve its ambitious objectives, ICPerMed receives coordinating support from the EC in the form of the Coordination and Support Action (CSA), the ICPerMed secretariat. The Secretariat consists of four partner organisations:

- Deutsches Zentrum für Luft- und Raumfahrt e. V. (Germany, ICPerMed secretariat coordinator)
- Agence Nationale de la Recherche (France)
- Ministero della Salute (Italy)
- Instituto de Salud Carlos III (Spain)

13 https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-020-02316-w

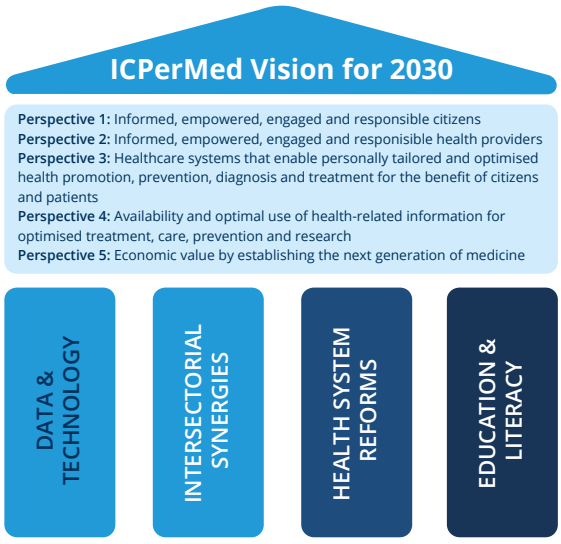

Figure 1: The ICPerMed vision for 2030, a framework of five perspectives, sustained by four critical pillars representing transversal crucial topics for the implementation of PM.

The ICPerMed secretariat substantially contributes to the success of ICPerMed by efficiently coordinating all consortium activities, by implementing an effective dissemination plan and by assisting in the development of the sustainability strategy of ICPerMed. By monitoring ongoing research funding activities in Europe and beyond, the Secretariat provides ICPerMed with the basis for evidence-informed allocation of research funding. For this purpose, the Secretariat has developed and maintains the mapping database on research funding activities that is open to all interested users.

The Secretariat provides ICPerMed with professional support in organising the ICPerMed events (i.e. workshops and conferences) and the meetings of ICPerMed bodies. In addition, the Secretariat guides the dialogue with relevant stakeholders and initiatives and facilitates the integration of new organisations from different countries in the ICPerMed consortium. Organisations interested in ICPerMed can contact the consortium via the functional ICPerMed(at)dlr.de email address that is hosted by the Secretariat coordinator.

To foster synergies and the exchange of ICPerMed with the PM community, besides the ICPerMed events, the ICPerMed secretariat prepares the newsletters and annual State of the Art reports and hosts the Twitter account. The Partnering Tool was developed and is maintained by the ICPerMed Secretariat and is of particular importance for ERA PerMed calls for proposals as this tool accelerates the partner search for newly formed research consortia.

The organisational and logistical support of the Secretariat maximises the unique and long-term impact of ICPerMed by strengthening Europe's leading role in the successful implementation of PM in the global context. The success and importance of ICPerMed is underlined by the fact that the CSA ICPerMed secretariat is entering a second funding period. After a first CSA funded from 2016-2021 (including a six-month extension, budget: 2 M€), the ICPerMed secretariat is starting its second edition after approval of a new proposal successfully submitted in 2020 by the same highly qualified consortium. The Secretariat, which received 2 M€ in funding for an additional three years (2021-2024), continues its support for ICPerMed and even increases its activities with biannually launched newsletters, biannual ICPerMed events (workshops and conferences), training activities (summer schools), additional social media activities and even more dedicated communication and dissemination means. The Secretariat will of course continue the already established ICPerMed actions and tools and provide dedicated support to the newly formed ICPerMed working groups. Furthermore, the Secretariat will provide support in the development of and bridge the transition towards a European Partnership in Personalised Medicine.

2. ICPerMed and the growing "ICPerMed family"

The "ICPerMed Family" (fig. 2) allows further countries and organisations to join the PM strategic reflections of ICPerMed and to foster the implementation of the ICPerMed Action Plan. The ICPerMed Family consists of programmes and projects receiving funding by the EC, including the European Research Area Network for Personalised Medicine (ERA PerMed) as funding programme and eight Coordination and Support Actions (CSAs) with different thematic focus.

Research funding in the field of personalised medicine via ERA PerMed:

As first ICPerMed Family member, ERA PerMed, the European Research Area Network (ERA-Net Cofund) for Personalised Medicine, was launched in 2017:

ERA PerMed is the largest ERA-Net Cofund in the health sector, supported by 32 partners, national and regional funding organisations, from 23 countries and 5 regions. Most ICPerMed partner organisations also joined the ERA PerMed consortium. Additional organisations, countries and regions joined ERA PerMed for the annually launched calls including one region, one charity and five new countries (four non-European: Brazil, Chile, Panama and Egypt). The different regional and national funding organisations mutually agreed to launch joint transnational calls (JTC) for collaborative innovative research projects in the field of PM and to demonstrate the importance of PM, not only in Europe, but also at international level.

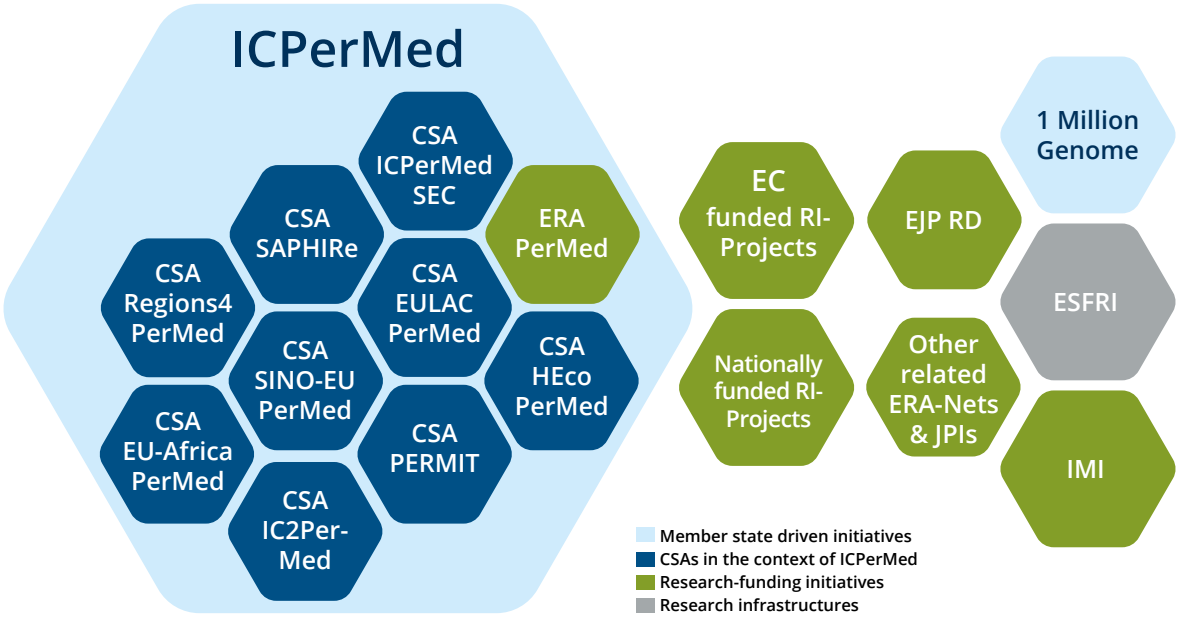

Figure 2: The ICPerMed family is closely connected to maximise efforts and impact, including dissemination activities as well as exchange of information, e.g. on mapping activities and examples of best practices. Detailed information about each initiative can be found on their respective websites. ICPerMed also reports on the progress of the entire ICPerMed family via the ICPerMed newsletters.

ERA PerMed is an outstanding programme aligning national research strategies, promoting excellence, reinforcing the competitiveness of European players in PM, and enhancing European collaboration with non-EU (European Union) countries. ERA PerMed efficiently implements the ICPerMed Action Plan, in particular by integrating the actionable research items, but also where applicable the research supporting items identified by ICPerMed, in the call scopes. With these calls, ERA PerMed fosters international collaboration and multidisciplinary research via three distinct research areas: (1) pre-/clinical research, (2) data and information and communication technology and (3) the social sciences perspective. The integration of different competences through multidisciplinary teams is the essential prerequisite for the efficient translation of PM research towards implementation in clinical practices and healthcare systems.

ERA PerMed launched its fourth joint transnational call on December 14, 2020, together with 30 funding organisations and a budget of 24 M€. Initially, ERA PerMed planned three calls with a potential fourth one and a first call in 2018 co-funded by the EC. Taking into account the success of the first three calls, ERA PerMed decided to not only implement the optional fourth call but also to prepare a fifth call in 2022.

The research projects are diverse in topics and reach out, besides the PM pioneer "cancer research", to projects in neurosciences, immunology, infectious diseases and other PM aspects such as rehabilitation. All ERA PerMed funded projects and the outcome of the calls are described in detail in the ERA PerMed newsletters[14].

14 https://erapermed.isciii.es/category/newsletter/

ERA PerMed in numbers (2018, 2019 and 2020 calls):

536	65	345	76.2 M€	>450
eligible research proposals received	**research projects** funded	**research teams** funded	invested in **PM research** (including 6.6 M€ EC contribution for the 2018 call)	**external experts** involved in the call management (preparation and evaluation)

ERA PerMed demonstrates the strength of the ICPerMed Family umbrella:

- Alignment of strategies in PM research funding by implementing the ICPerMed Action Plan supported and promoted by the ICPerMed Family,
- Efficient use of resources in fostering cross-border collaborations, also supported by the international and regional ICPerMed Family CSAs attracting new funding bodies for ERA PerMed calls,
- Promotion of the multidisciplinary spirit by requesting the combination and involvement of more than one discipline or field of study in research teams, to bridge the gap between first discoveries or inventions and further applications,
- The possibility to fund research projects with different technology readiness levels, including public and private partners, thanks to the diverse types of funding organisations engaged in the programme.

With its calls for proposals and the research projects funded, ERA PerMed aims to improve disease prevention and disease management, based on broader and more efficiently characterised and defined patient stratification, diagnostics and tailored treatment or prevention protocols for both patients and individuals at risk of disease.

Strategic reflections in Personalised Medicine via the different ICPerMed Family CSAs:

- **Health economics:**

HEcoPerMed
Health Economics for Personalised Medicine

CSA HEcoPerMed[15]: Health Economic modelling and payment strategies for Personalised Medicine

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. HEcoPerMed 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. The expected outcomes of HEcoPerMed are:

- Methodological guidance on how to conduct economic evaluations of PM
- Cost effectiveness and budgetary implication by using three PM technologies across three EU countries (UK, Netherlands and Hungary)

15 https://hecopermed.eu/personalised-medicine/

- Recommendation on design and refinement of finance and payment models for PM technologies
- Future scenarios on the benefits and challenges of PM for the health systems
- Dissemination of results among stakeholders (policymakers, scientists, industry, insurers, funders, etc.)

- **Clinical trial design:**

CSA PERMIT[16]: PERsonalised MedicIne Trials

Launched in January 2020 (two-year project running duration), PERMIT will develop recommendations for robust and reproducible PM research. PERMIT organises a series of workshops where 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.

- **International cooperation with Latin American and Caribbean countries, China and African countries:**

Collaboration with Latin American and Caribbean (LAC) countries, CSA EULAC PerMed[17]: Widening EU-LAC policy and research cooperation in Personalised Medicine

The EULAC-PerMed project was launched in January 2019, with the ambition of engaging Latin America and the Caribbean (LAC) countries in ICPerMed. A bi-regional consortium of 11 organisations from nine countries and a European Clinical Research Infrastructure Network are in charge of the project until December 2021 (three-year project running duration). EULAC PerMed aims to engage LAC countries towards the implementation of the ICPerMed Action Plan. EULAC PerMed is:

- Mapping existing programmes, capacities and expertise and gaps in CELAC 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 with PM focus.
- 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.

A set of recommendations will be developed, as result of diverse workshops launched in the course of the project, and published in form of workshop and SWOT (**S**trengths, **W**eaknesses, **O**pportunities, and **T**hreats) analysis reports on the EULAC-PerMed website.

Collaboration with China, CSA IC2PerMed[18]: Integrating China in the International Consortium for Personalised Medicine

IC2PerMed is a four-year project aiming at providing key solutions for enabling the convergence, under ICPerMed, of European and Chinese stakeholders, with an orientation towards a public health perspective. The project's European and Chinese partners will dedicate efforts towards:

- Mapping policies, programmes, standards and initiatives related to PM in Europe and China to identify opportunities for research collaborations
- Structuring developments of an ecosystem of European and Chinese experts, collaborating in working groups

16 https://permit-eu.org
17 https://www.eulac-permed.eu/
18 https://www.ic2permed.eu/

centred on ICPerMed Action Plan priorities
- Exemplifying research collaboration frameworks between China and Europe for PM by connecting Biobanking
- Building bridges with key official organisms involved in the definition and implementation of PM and healthcare systems in both economic areas in international contexts, through ICPerMed as well as relevant initiatives and networks.

Collaboration with China, CSA SINO-EU PerMed[19]: Cooperation between China and Europe in Personalised Medicine

The Sino-EU PerMed project was initiated in January 2020 with a four-year duration. The bi-regional consortium (Europe and China) of six partners from governmental, funding and research organisations supported by leading stakeholders as associated partners, aims to promote PM cooperation between Europe and China. One of the objectives is to foster collaboration between Chinese health organisations and ICPerMed, and to identify areas of mutual interest. Sino-EU PerMed builds on four pillars:

- The project's backbone: Coordination and management
- The project's senses: Mapping of landscape and stakeholders
- The project's heart: Science and policy dialogue between Europe and China / ICPerMed: establish a common understanding and work on common activities and goals
- The project's brain: Paving the science and technology way to Europe – China collaboration in PM: drafting concepts of the future

19 www.sino-eu-permed.eu

Collaboration with Africa, CSA EU-Africa PerMed[20]: Building links between Europe and Africa in Personalised Medicine

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 will be implemented by a consortium of 13 partners, six from Europe and seven from Africa and is organised around five main work packages:

- Mapping the health research and innovation, and policy landscape in Africa to identify key stakeholders, initiatives and expertise relevant to PM
- Cross-border collaboration and identification of future actions in PM between Africa and Europe
- Translating science to policy - Enhancing the dialogue between African countries and Europe in collaboration with ICPerMed and ERA PerMed
- Capacity building in personalised medicine
- Communication and dissemination

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 and policy makers, private practitioners, industries and health professionals and civil society. EU-Africa PerMed will work towards fostering a stronger global collaboration in PM through the umbrella of ICPerMed, and by this, will attempt to better tackle global health challenges such as infectious diseases and future pandemics as well as the prevention of non-communicable diseases.

20 The website is still under preparation

- **Regional perspective:**

CSA SAPHIRe[21]: Securing the adoption of personalised health in regions

The consortium for Securing the Adoption of Personalised Health In Regions (SAPHIRe), aims to structure the application of PM at the regional level, which will drive the transition towards sustainability of healthcare systems and PM. With the SAPHIRe observatory[22], the consortium provides a dynamic online tool for regional policymakers, funders and other key stakeholders to share relevant information concerning their policies, projects and innovation activities related to PM. The database allows users to search for a region and provides an overview of regional activities in PM. During the project, SAPHIRe will host a series of themed workshops in the area of personalised health and precision medicine. All information concerning the progress made by the SAPHIRe consortium can be found in the SAPHIRe newsletter[23], the website and the Twitter[24] account.

CSA Regions4PerMed[25]: Interregional coordination for a fast and deep uptake of personalised health

The mission of Regions4PerMed is to contribute 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 four years of the project's duration, Regions4PerMed aims to strengthen the collaboration of European Regions on personalised health through coordination and alignment of regional stakeholders (public institutions, governments, industry, civil society, patient organisations) in personalised health action across Europe and beyond in order to:

- Create a participatory approach,
- Build trust,
- Enable a multi-stakeholder process,
- Channel investments towards Personalised Health.

21 https://www.saphire-eu.eu/
22 https://www.saphire-eu.eu/saphireobservatory
23 https://www.saphire-eu.eu/services
24 https://twitter.com/projectSAPHIRe
25 https://www.regions4permed.eu/

3. International Consortium on Personalised Medicine: A Retrospective Analysis and Outlook

Four years since the launch... four years of intensive support of ICPerMed for PM, for the development and alignment of strategies, consolidation of solid collaborations of ICPerMed partner organisations and the PM community with support of the EC via two CSAs, the ICPerMed Secretariat (with two editions: 2016-2021 and 2021-2024, 2 M€ funding each).

We are pleased to share, in this State of the Art report, statements on the past and the future of ICPerMed by **Irene Norstedt**, Director of the People Directorate within the DG for Research and Innovation of the European Commission, **Ejner Moltzen** (Innovation Fund Denmark), current ICPerMed elected chair, and **Wolfgang Ballensiefen** (BMBF/DLR-PT), ICPerMed vice-chair 2016-2020.

Irene Norstedt

"I am happy to see the progress made of ICPerMed over the past few years and look forward to further developments in this promising area, which some see as the future of medicine."

***Irene Norstedt** works at the European Commission where she is the Director responsible for the People Directorate within the DG for Research and Innovation. Irene has been at the European Commission since 1996, and was instrumental in the creation of the Innovative Medicines Initiative (IMI) in 2008. From 16 December 2014 to 15 September 2015, Irene served as Acting Executive Director of the Innovative Medicines Initiative. Prior to joining the European Commission, she worked for the Swedish life science company Biacore AB and at the Swedish embassy in London. Irene studied biotechnology and polymer science, and holds a Master of Science (MsC) in Chemical Engineering.*

European Commission - Irene Norstedt

Personalised medicine has long been one of the focus areas for health research in the Framework Programmes for research and innovation of the European Commission. It has developed from the area of genomics and other omics, including pharmacogenomics, that were strongly supported at the end of last century and beginning of the current one. Many of the omics technologies that were developed with Commission funding are now included in the toolkit of life sciences research and also increasingly in medical practice, not least in cancer. Now personalised medicine is a much wider concept, with larger sets of data involved, including a plethora of information gathered around the individuals, their environment and medical history. All united and processed with the help of data technology. The COVID-19 pandemic has also underlined that individual response is not limited to chronic diseases but very much is also an issue for infectious diseases as well.

The Commission organised the first conference on personalised medicine already in 2011. One of the outcomes of that conference was the setting up of a network between the Member States discussing priority setting in personalised medicine. This resulted in the establishment of ICPerMed a few years later, following the second EC conference in 2016. **The Commission maintains a seat as observer on the board of ICPerMed and has been instrumental in funding several coordination and support actions to investigate and develop further aspects such as international and regional cooperation; health economy; clinical trials models and standards.** This in addition to the research and innovation projects, which over the past decade the Commission has supported with grants amounting to at least 3 billion Euros. ICPerMed organised its conference in Berlin in 2018 and now online from Paris and so has taken up the baton from the Commission in that regard. I am also pleased to see the progress with for example the publication of the Action Plan[26] and the 2030 vision[27].

Looking to the future, I am excited to see the preparations for the European Partnership for Personalised Medicine that we envisage for 2023. The work achieved in ICPerMed and

26 https://www.icpermed.eu/en/activities-action-plan.php
27 https://www.icpermed.eu/en/activities-vision-paper.php

the associated ERA-Net ERA PerMed will be crucial in ensuring that this partnership will be set up successfully and able to deliver in a timely manner. This coordinated approach, between the EU Member States and its partner countries around the world is bound to lead to a fruitful exchange of information, faster translation of research results and implementation of best practice and harmonisation and standardisation of approaches between the different actors. It will contribute to developing the European Research Area for health.

One aspect of personalised medicine, which is close to my heart, is its utilisation for individualised prevention; the identification of persons prone to develop a certain disease, before any noticeable symptoms appear. We have already several examples of the potential to do that, not least from the work done for rare diseases research. The speedy development of information technologies, including artificial intelligence, along with further life sciences and medical research, will surely open up several interesting avenues for profiling and early diagnosis that will support this work in the coming years. We need to be ready to embrace this and translate into health practice as soon as it becomes feasible and make sure this is widely used and accessible as part of affordable care for all citizens. ICPerMed, the associated initiatives and the future partnership can play a crucial role in guiding this process and the necessary education that goes along with it.

Wolfgang Ballensiefen

"I am certain that personalised approaches have and will improve the research strategies and even more importantly healthcare."

Former ICPerMed Vice-Chair (2016-2020) – Wolfgang Ballensiefen

The **PerMed** project has been a Coordination and Support Action (CSA) of 27 partners representing key decision-makers in research policy, research, healthcare, patient organisations and industry. The consortium's overall aim was to develop a **Strategic Research and Innovation Agenda**[28] (SRIA) with recommendations to foster the further implementation of Personalised Medicine (PM) in Europe and beyond. This document was published in June 2015. Since then numerous regional, national and European activities and initiatives were successfully started and some are still ongoing.

The most important achievements on the basis of PerMed, however, were the establishment of the International Consortium for Personalised Medicine (ICPerMed[29]) and the ERA PerMed[30], along with a growing "ICPerMed family" of **CSAs** supporting or related to ICPerMed. And it has been and will be crucial that all these initiatives are strongly supported by the European Commission and the participating member states and regions.

Throughout 2016, members of ICPerMed developed a common "Road Map" with actionable research and support activities in all areas related to PM taking the SRIA as a blueprint. The resulting Action Plan (2017) provides a distinct set of activities forming the basis of the work programme for the more than 40 funders from 29 countries, which are ICPerMed and other interested funding bodies. ICPerMed also published a "Vision Paper" (2019) forecasting the chances, developments, perspectives and challenges of PM. Furthermore, there are plans for a European Partnership (EP PerMed, planned for 2023) within the upcoming Horizon Europe programme.

I am pleased and proud to have been able to contribute to and support these important and impressive developments in some ways. First as coordinator of the CSA PerMed, then as facilitator of one of the five ICPerMed challenge groups and in the last four years as elected vice chair of the executive committee. I am dedicated to supporting ICPerMed and some of the "family" members in the years to come. Furthermore, I will support the transparent and successful development of EP PerMed. The acronyms of many "family" initiatives indicate that they are inspired, related and influenced by the CSA PerMed and ICPerMed. I am certain that personalised approaches have and will improve the research strategies and even more importantly healthcare. We need to continue, so

28 https://www.icpermed.eu/media/content/PerMed_SRIA.pdf
29 https://www.icpermed.eu/
30 http://www.erapermed.eu/

that one day everybody benefits from personalised diagnoses, treatment and prevention strategies. The current drivers for PM, among others, will be high-quality research, patient involvement and benefit, optimised and safe data gathering and utilisation, information technology support in healthcare, objective assessments of the value and economic impact of innovative PM approaches and, last but not least, fair access for citizens, so that maybe, one day, it will be "unethical" not to treat a patient with a personalised approach.

Ejner Moltzen

"I look very much forward to taking the next steps with ICPerMed in the new direction defined by the Executive Committee over the coming years."

ICPerMed Chair (since 2020) – Ejner Moltzen

ICPerMed currently stands at an important crossroads. Over the last 4 years, ICPerMed has established itself as a key player in the development and implementation of personalised medicine (PM). The Action Plan and the Vision Paper have become broadly used reference documents. The various workshops, conferences and meetings held have enabled networking among members and stakeholders of ICPerMed, thereby facilitating the development of PM at many levels. Through the establishment of the "ICPerMed Family" (nine Coordination and Support Actions (CSAs) and one ERA-Net Cofund Action) a further outreach, both internationally and to less PM developed parts of Europe, has become possible, with a CSA EU-Africa PerMed as the latest addition to the family.

The field of PM has fortunately progressed over recent years. In many areas, research results have been transformed into clinical reality for the benefit of patients. At the policy level, implementation of PM concepts has been realised by decision-makers as the best way forward to ensure optimal prevention and treatment of disease for the benefit of society. There are still many hurdles to overcome, however, before the full potential of PM is reached. Implementation issues relating to societal, ethical, legal, and economical aspects have turned out to be difficult to solve, both nationally and across borders.

To increase the focus on these aspects, ICPerMed has been restructured. Five new working groups have been formed, replacing the former Action Item and Challenge Groups. These groups will address topics from clinical studies in PM over PM in healthcare, patient empowerment, education and curricula in PM, to the health economic value of PM. To ensure a high level of competency in the groups, external experts will be heavily involved. It is our hope that the new groups, building on the ICPerMed network, can help overcome key bottlenecks to further progress PM for the benefit of citizens and society. Furthermore, an international advisory board will be established supporting ICPerMed to keep the right focus over the coming years.

From a personal perspective, it has been a great pleasure and satisfaction to follow the development of ICPerMed from its start in 2016, initially as Executive Committee member representing Innovation Fund Denmark, then as lead of Action Item Group 4, and latest as Chair. For me it has of course been important to see the tangible results of ICPerMed's work (documents, events etc.), but it has been even more important to see the motivation and enthusiasm for PM live and grow within the constantly increasing circle of ICPerMed members over the years. It is this enthusiasm that ensures that ICPerMed makes a true difference in the implementation of PM, both now and in the future.

An important event in the future will be the start of the new European Partnership for Personalised Medicine under the Horizon Europe umbrella in 2023. The concept paper developed jointly by ICPerMed and ERA PerMed will hopefully provide a solid basis for this new EC-driven PM endeavour.

4. ICPerMed Action Item Groups and their contribution for the implementation of the ICPerMed Action Plan

The Action Item Groups (AIG, 2017-2020) were installed as internal ICPerMed working groups to follow-up and work towards the implementation of the ICPerMed Action Plan, e.g. by mapping and reporting on ongoing activities of ICPerMed members but also other organisations and initiatives engaged in the field of PM. In addition, the AIGs collected examples of best practices for the major topics of the Action Plan and developed strategies for putting the "actionable items" of the Action Plan into practice.

The five ICPerMed Action Item Groups (AIG)

- AIG1: Data and ICT – Enabling Technology
- AIG2: Data and ICT – Improving Health Care
- AIG3: Translational Research
- AIG4: Health Economics, Regulation, Market Access
- AIG5: People and Society

The AIGs consisted of representatives and nominated experts of ICPerMed member organisations with one elected lead each. Participation was in-kind. The AIGs provided valuable input for:

- ICPerMed mapping activities and analysis of collected data,
- Collection and presentation of examples of best practice in PM,
- Preparation and organisational support for ICPerMed events,
- Development of lessons learnt and participation in ICPerMed strategic document preparations,
- Representing ICPerMed externally.

The AIGs are now closed and ICPerMed started five new working groups at the beginning of 2021. The AIGs are reporting within this section on their work. Thanks a lot to all organisations for their valuable in-kind contribution to AIG activities (more details on the AIG participants are available in the annex).

AIG1: Data and Information and Communication Technology (ICT): Enabling Technology

Enabling technologies in data and ICT are essential aspects to be tackled as basis for PM implementation. They comprise topics as data collection, harmonisation, interoperability, mining, sharing as well as data security, privacy and ownership. In this context, Action Item Group 1 followed-up the further research (A) and research-supporting (B) activities:

A.1 Research projects to ensure the quality, completeness, validity and analysis of datasets

A.2 Support research on data harmonisation in the context of personalised medicine needs

A.4 Support research on enabling the extraction of structured data from unstructured sources

A.6 Research projects to optimise data security, privacy and ownership within PM approaches

B.1 Promote the development of high-quality sustainable databases for PM-relevant data

According to ICPerMed and the Action Plan, the starting point for the implementation of these actions was short-term or at least medium-term and suitable for the regional/national, European and International levels. Many successful examples of tackling these challenges are already available, though often at the local/regional level. For the development of national or European actions in these thematic areas in the future, common standards and frameworks are needed, for example to overcome fragmentations concerning legal regulations, but also on the regulatory and technical side in data interoperability and quality.

Just to mention some aspects still to be tackled in this context:

The basis for health research is databases and infrastructures. To efficiently use already existing and to develop new sustainable databases and infrastructures, funding and appropriate regulations are needed. To achieve this goal, the early involvement of regulatory authorities is essential. As an example, the Swiss Personalized Health Network[31], a national initiative of Switzerland, demonstrates the development, implementation and validation of coordinated data infrastructures in order to make health-relevant data interoperable and shareable for research.

For cross-border approaches at the European or global level, an overall applicable and accepted governance and ethics oversight could pave the way to organising and enabling access to health data (including secondary use of data). One potential solution could be the establishment of data governance boards that provide support and consultancy to individual organisations and a whole network regarding the implementation of policies and best practices.

The collection and use of data require consent, while providing of the consent itself is building on trust, e.g. for the protection of the data and data owners. A broad consent for defined research areas could enable tailored research and define preferences for communication of incidental findings. Dedicated training courses and adequate communication could foster improved understanding of patients and citizens, but also healthcare providers on different aspects such as data storage and protection, the use of and research performed on the data as well as the need to share and collect data.

Since the development of and inspired by the Action Plan, the above-mentioned topics have received support in different initiatives, e.g. via joint transnational calls for research proposals launched by ERA PerMed and a pan-Scandinavian (NordicPermed[32]) PM call.

The topics related to AIG1 are still of high importance and have just started to be addressed!

31 https://sphn.ch/

32 https://en.rannis.is/news/nordic-call-on-personalised-medicine-nordicpermed-1

AIG2: Data and Information and Communication Technology (ICT): Improving Health Care

The following AIG2 items have been selected from the priorities identified during the elaboration of the ICPerMed Action Plan and have also been highlighted on the Vision Paper:

A.3 Studies on data integration and interpretation of multifactorial diseases

A.5 Pilot projects to assess the impact of sharing data for researchers and other parties

A.7 Research projects to develop innovative decision support tools for healthcare providers

A.8 Support research to develop telehealth and telemedicine applications to support the implementation of personalised medicine

A.12 Classification of diseases at the molecular level

B.7 Introduce curricula reforms to create new models of healthcare for patients and citizens and broaden the focus on basic and clinical sciences to include health systems sciences in the education of all healthcare professionals

The AIG2-related discussions, at telephone conferences and during various ICPerMed events, focused on and revised all six items. The different time points for the implementation of these actions were short-term or at least medium-term and suitable for regional/national, European, and International levels. Currently, the five (A) item-mentioned topics are being supported via the joint transnational calls for research proposals launched by ERA PerMed.

The research-supporting (B) activities explored concerned curricular reforms. The education on pharmacogenetics for all healthcare professionals has been identified as priority. PM and pharmacogenetics both bring new developments to healthcare. Some examples of new training courses in this field were identified, mainly in bioinformatics applied to PM, health technology assessment and ethical, legal and social aspects of PM research. Some countries, such as Spain, are including a Precision Medicine Training Plan in the Strategic Plan for PM.

Internally, items A2 and A12 were discussed under the same perspective: nearly all conditions and diseases have a genetic component. Some disorders are caused by mutations in a single gene. Other disorders, however, are much more complex. Common medical problems such as heart disease, type 2 diabetes, and obesity do not have a single genetic cause – they are likely associated with the effects of multiple genes (polygenic) in combination with lifestyle and environmental factors. Conditions caused by many contributing factors are called multifactorial disorders. Researchers should look for major contributing genes for multifactorial diseases and for models of data integration. Since aetiology (causation of a disease) comprises the multilateral evaluation of how a disease can be classified, defined, and discovered, current classification of genetic diseases requires an update. A clinical project aiming to determine personalised risk scores for cardiovascular diseases was launched in 2018 in Estonia; restricted to people who have been genotyped: approx. 15% of Estonia's population have signed up to share their genetic info with the National Gene Bank.

Multi-omics-based studies provide an interpretation of the complex relationships and an alternative classification for various metabolic diseases where compensatory mechanisms between the immune and metabolism systems are fundamental.

Important research is being done on developing e-health tools, based on machine learning, the use of big data and predictive mathematical models that can be implemented as clinical decision support systems. For example, COVID-19-related projects aim to characterise population groups that are at a risk of severe COVID-19 prognosis. In Estonia, existing genome patient data are analysed and compared, including patients who had COVID-19 with different levels of severity, to predict genetic predisposition factors for infection or more severe COVID-19 disease progression.

Various barriers have been identified in the implementation of telehealth and telemedicine, such as the acceptance of these methodologies by patients, lack of work protocols and health worker training in these aspects, the economic viability and lack of information and communication technologies infrastructures and the insurance of health data security and a specific regulatory framework. Different countries, however, have already developed National Strategic Telehealth Plans, such as for example Portugal (National Strategic Telehealth Plan[33]) and Italy (National Telehealth Plan[34]). The Spanish Quality Plan for the National Health System[35] includes the use of information technologies in the national health system to improve the care for citizens.

The last area of AIG2 activity has been to identify the published clinical trials involving APPs – smartphones for health care support, during the last five years in different countries, including a brief identification of APPs related to COVID-19 infection.

The challenges of data sharing were explored, together with the AIG1 considering the key words of security and privacy. Following the different items discussed, sharing of patients' health data across borders was identified as a common key point and PM goal, e.g. for the best interpretation of multifactorial diseases, to new classification of diseases, to identify the most appropriated support tools.

AIG3: Translational Research

The overall aim of AIG3 has been to exchange on and to enhance the implementation of actions that support the translation of basic into clinical research in the area of PM. In this respect, AIG3 covered the following action items of the ICPerMed Action Plan:

A. 9 Development and implementation of high-throughput preclinical models

A. 10 Implement translational programmes with shared access to, for example, genetically defined patient populations

A. 11 Integrate actions aimed at supporting and developing research for clinical validation of pharmacogenomics. Global impact evaluations of these actions on health systems.

33 https://www.isfteh.org/files/media/PENTS_English_Version.pdf
34 http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf
35 https://www.mscbs.gob.es/organizacion/sns/planCalidadSNS/docs/InformePlanCalidad_ENG.pdf

A. 13 Support research for clinical trials – a three-level process

A. 14 Longitudinal cohort studies of disease outcomes

A. 15 Research in adequate regulatory structures and pathways in personalised medicine

B. 2 Development and maintenance of biobanks and population/disease cohorts

B. 3 Establish a new collaborative funding organisation model with healthcare providers to facilitate investment in disease prevention research and therapy research

B. 4 Develop common strategies in research to support comparative and effective research and sustainable technology transfer capacities

General activities over the past two years were contributions to the mapping activities on PM initiatives as well as the identification and promotion of best practice examples in the above-mentioned areas.

In 2019, interactions with relevant experts and stakeholders were made in written consultation in order to collect input for the preparation of the ICPerMed workshop in Madrid, in particular for its workshop working group III on "Transfer of research results into the market: How to regulate and optimise a safe, fast and economic process to implement personalised medicine approaches?".

Also in this context, the AIG3 has given specific focus to action item A.13, to collect and enhance experiences of clinical studies within PM – what is the potential of clinical studies in PM and what are the challenges? Two experts - Dr Catharina Scholl, Federal Institute of Drugs and Medical Devices, BfArM, Germany, and Prof Gerald Prager, Medical University Vienna, Austria - were invited for presentation and discussion at the AIG3 meeting, taking place as satellite meeting to the Madrid workshop. Central messages of their talks and discussion were summarised in the meeting report. AIG3 has also initiated a mapping of pilot clinical studies in PM. A follow-up workshop, organised by the Paul Ehrlich Institute for Vaccines and Biomedicines, Germany, is under discussion.

AIG4: Health Economics, Regulation, Market Access

AIG4 has focused on actions from the ICPerMed Action Plan that promote PM approaches to become available to the patient in a health economically sustainable way. These include:

A.16 Support research in and development of health economics models and pharmacoeconomics models for personalised medicine

Research is needed to investigate whether a patient-centred, PM approach requires refinement of or even new health economics and pharmaco economics models, including prevention.

A.17 Support research in post-marketing surveillance methodologies aimed at accessing patient outcomes

PM development requires post-marketing surveillance methodologies. This raises legal, social, and ethical challenges as well as need for new ways to handle big data. Research in this area can outline what need to be done to facilitate the use of data across nations and cultures.

A.18 Support health economics research and assessments of available as well as newly developed personalised medicine approaches

Such research will provide important evidence to support effective and sustainable healthcare systems, now and in the future.

B.5 Support strategies to identify financial and risk-sharing instruments to develop personalised medicine approaches

Based on risk evaluations for PM approaches and products from all relevant perspectives, different scenarios could be built and analysed, thereby supporting improvement of regulatory and economic frameworks.

B.6 Support research to analyse, compare and optimise national and regional health systems in the light of personalised medicine implementation

Research projects to be conducted to analyse and compare selected health systems with focus on PM aspects, thus developing suggestions to optimise health systems.

As new PM-based therapies are developed, health economical and market access issues will become major bottlenecks preventing patient access to PM treatments. Solutions to these bottlenecks must be found.

Consequently, a major focus of AIG4 has been to collect and discuss examples of best practices covering the area of AIG4 in order to highlight and promote new ways of thinking within these areas. The identified best practices examples have shown, for example, how the personalised treatment of small, rare disease indications can be developed and implemented, even across borders, despite high costs, and how health technology assessment agencies have embraced the concept of PM in their assessment of whether treatments provide value for money.

Another area of activity has been to promote the development and implementation of new health economic models through workshops. Since resources to run such activities were not available within AIG4, discussions with the CSA HEcoPerMed were initiated for AIG4 to support the workshop activities within health economics, which are planned by HEcoPerMed to run in 2021.

A central activity has been the ongoing discussions of AIG4-related issues, both during telephone conferences as well as at various ICPerMed events. These discussions were fruitful and kept the focus on these issues alive. This would not have been possible without the engagement of representatives from a number of ICPerMed member organisations. Thanks to all for the commitment and interest.

AIG5: People and Society

AIG5 developed its activities based on the ICPerMed Action Plan. In particular, AIG5 placed its focus on a series of actions, including:

A.19 Research and develop the tools and modus operandi of a knowledge network for enhancing health and digital literacy

A.20 Develop and share best practices of patient engagement approaches for the need of a variety of European citizens

A.21 Research and develop the instruments for the evaluation of the effectiveness and impact of public engagement initiatives in PM

A.22 Support interdisciplinary research in challenges and drivers that influence bringing PM innovation to the market, from ethical, legal and societal perspectives

B.8 Build sustainable resources for educating and training citizens, patients and patient advocates on involvement of patients and patient organisations across the entire research and development lifecycle of personalised medicine

As PM emerges as a global approach to medicine, entailing the centrality of the patient as unique subject, AIG5 discussed how patients can play a fundamental role in the identification of research questions, as well as in the development of study design, data collection, and analysis of findings.

The discussions concerned the need for greater involvement of patients while, at the same time, dealing with the issue of available funding to cover their participation in the research projects. This is an issue that requires a paradigm shift in the consideration of patients, from “final beneficiaries” of care to integral part of the development of a treatment.

Another area explored concerned the researchers’ ability to involve patients: a few examples of training for researchers and medical staff to involve patients were presented.

The work on people and society needs to be further explored, and it will be key to future discussions on PM.

5. Horizon Europe and the European Partnership for Personalised Medicine

The new framework programme **"Horizon Europe"** of the EC was launched during a dedicated event on 2 February 2021. Horizon Europe represents the most ambitious Research and Innovation (R&I) programme of the EU and the largest transnational programme of this kind worldwide, with a budget of 95.4 billion Euros. This innovative programme provides new instruments, such as the European Innovation Council, Research Missions and European Partnerships to support the EU R&I landscape.

Three forms of European Partnerships in particular aim to bring the EC and private or public partners together to address some of Europe's most pressing challenges through concerted R&I initiatives. They represent a key implementation tool in Horizon Europe, and will contribute significantly to achieving the EU's political priorities.

Personalised Medicine is selected as topic for a co-funded European Partnership after consultation of the Members States and will be further discussed in 2021 with a publication expected in 2023.

To foster reflections and to provide content-driven input, ICPerMed and ERA PerMed jointly published a draft concept paper for the candidate **European Partnership for Personalised Medicine - EP PerMed[36].**

In this draft concept paper, ICPerMed and ERA PerMed underline the need to establish a European Partnership for Personalised Medicine and propose their vision for EP PerMed, its objectives, activities and expected impacts (fig. 3). It also outlines the composition of the partnership consortium and its interaction with the PM ecosystem, at the European and international levels.

The EP PerMed draft concept paper was prepared between June and August 2020 by the ICPerMed and ERA PerMed

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

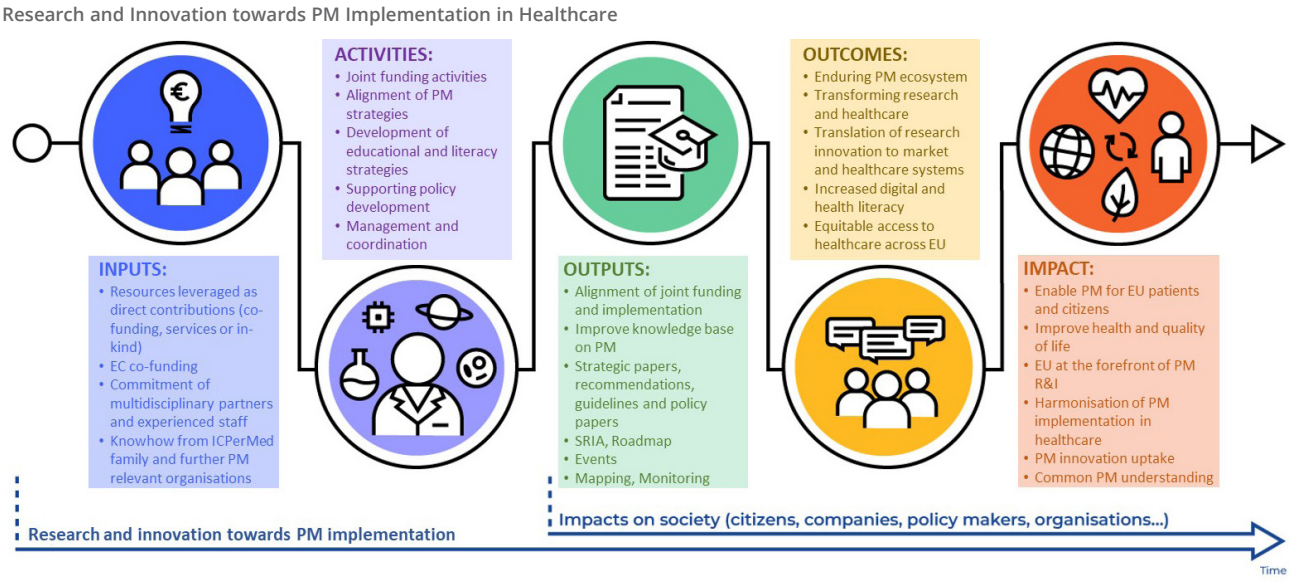

Figure 3: The EP PerMed framework as proposed in the EP PerMed draft concept paper.

"Preparatory Group", consisting of four representatives of each initiative. The group received valuable input from the EC. The draft concept paper was presented and discussed during a Joint Sustainability Workshop of ERA PerMed and ICPerMed at the beginning of September 2020. It is a living document and will be further developed and updated after input from other stakeholders. Its current version was provided to the EC after being approved, in October 2020, by the over 50 organisations of more than 30 countries (24 European countries) involved in both initiatives.

The 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. 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 hand in hand with international partners to allow the defragmentation of the PM field on global level.

Outlook

ICPerMed is looking back on four years' extensive work and important outcomes achieved, but especially forward to exciting years ahead of us with **biannual events, training courses and summer schools** fostering exchanges with and the active involvement of the PM community; the further preparation of the **European Partnership in Personalised Medicine (EP PerMed)**; the promotion of **examples of best practices** on the ICPerMed website and via the **ICPerMed Recognition** and the work of the **five new working groups (WG)** around the topics:

- WG1: Clinical Studies in Personalised Medicine
- WG2: Personalised Medicine in Healthcare
- WG3: Patient Empowerment
- WG4: Education & Curricula in Personalised Medicine
- WG5: Health Economic Value of Personalised Medicine

Stay tuned to ICPerMed's activities via our newsletters, soon to be published biannually, the ICPerMed website and Twitter.

 https://twitter.com/ICPerMed

Annex

ICPerMed would like to thank all organisations and experts who supported the five Action Item Groups by their commitment, the valuable input provided and their contribution:

Action Item Group 1
The Ministry of Science and Education of the Republic Croatia; the Estonian Ministry of Social Affairs; the French Ministry of Higher Education and Research; the French National Funding Agency (group-lead); the German Federal Ministry of Education and Research; the Hungarian Ministry of Human Capacities; the Italian Mistry of Health; the Italian National Research Council; the Luxembourg National Research Fund; the National Institute of Health Carlos III from Spain; the Swiss Academy of Medical Sciences and the Turkish Ministry of Health.

Action Item Group 2
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Action Item Group 3
Ministry of Education, Science and Research, Austria (group-lead); Academy of Finland; Ministry of Health, Germany (group-lead); VDI/VDE Innovation & Technik GmbH, Germany; Federal Institute for Drugs and Medical Devices-BfArM, Germany; Paul Ehrlich Institute for Vaccines and Biomedicines-PEI, Germany; DLR-Project Management Agency, Germany; Hungarian Society of Personalized Medicine; Health Research Board, Ireland; Tehran University of Medical Sciences, Iran; Ministry of Health, Israel; Ministry of Health, Italy; National Research Council of Italy; State University of Medicine and Pharmacy Nicolae Testamitsanu, Moldavia; Ministry of Science and Higher Education, Poland; Agency for Science and Technology, Portugal; National Institute of Health – INSA, Portugal; Gobierno de Navarra, Spain; Swedish Research Council; Vinnova – Swedish Innovation Agency; The Netherlands Organisation for Health Research and Development – ZonMw; Health Institutes of Turkey.

Action Item Group 4
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Action Item Group 5
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