State of the Art Report 2018
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Executive Summary

With its second State of the Art (StoA) Report, ICPerMed seeks to share information on the consortium's activities and achievements during the November 2017 to October 2018 period. Besides general information about ICPerMed's activities (meetings, consortium composition, reports/statements developed, etc.), the 2018 StoA report concentrates on the mapping database\(^1\) and the analysis of the data collected/presented.

Since its creation in 2016, the ICPerMed consortium has been constantly growing. Two new members joined ICPerMed in 2017, including one partner from Brazil. The ICPerMed consortium thus made an important step toward the inclusion of more international, non-European partners in the coming years.

In April 2018, Astrid Vicente of the National Health Institute Doutor Ricardo Jorge (INSA) in Portugal was elected as ICPerMed’s new vice-chair, replacing Ain Aaviksoo. A new ICPerMed chair will be elected in November 2018 and another new vice chair in the spring of 2019. We are grateful for the support of Mairéad O’Driscoll (HRB, Ireland) and Wolfgang Ballensiefen (DLR-PT, Germany), in their roles as current chair and vice-chair, respectively.

Making progress in Personalised Medicine (PM) also means understanding the PM landscape. Therefore, ICPerMed started intensive mapping activities on different levels including the collection of PM initiatives, platforms, infrastructures, programmes, etc. The outcome of the survey on funding activities in PM, launched within the consortium, is presented in the ICPerMed mapping database. The database is a major product of ICPerMed’s activities after the publication of the ICPerMed Action Plan in March 2017. The different mapping activities provide constant follow up on the implementation of the Action Plan. ICPerMed created five working groups to facilitate these mapping activities: The five Action Item Groups.

\(^1\) https://www.icpermed.eu/app/login
1. Development of ICPerMed and steps taken towards internationalisation

ICPerMed is an initiative led by EU Member States and supported with a grant for the ICPerMed Secretariat (2016-2020), a coordination and support action (CSA). Most members are therefore currently from Europe, but ICPerMed seeks to include more international partners in the coming years. Needs and progress made in PM differ between countries and their individual health care systems. The internationalisation of ICPerMed enables the consortium to create a platform to exchange on best practices in PM, with view for future implementation.

In October 2018, ICPerMed had 37 full members and 5 observers from 28 different countries and 4 regions, including representatives from most European countries along with several non-European members from Canada and Israel. Recently, two new members joined the ICPerMed consortium: Fondazione Telethon from Italy and the Oswaldo Cruz Foundation (Fundação Oswaldo Cruz) from Brazil. ICPerMed thus took an important step toward a more international composition of the consortium.

Wider internationalisation of ICPerMed will be underpinned by maintaining and expanding exchanges with its stakeholder group, and notably by collaborating with four new CSAs in PM launched in 2018: two CSAs on regional aspects, one CSA seeking to improve exchanges with the Community of Latin American and Caribbean (CELAC) countries, and one CSA concentrating on healthcare and pharma-economic models for PM. More information will be available on the ICPerMed website.

Stakeholder engagement and exchanges

ICPerMed also has ongoing exchanges with other stakeholders and initiatives. Representatives of ICPerMed have participated in more than 14 conferences, workshops and meetings organised by PM-related initiatives, presenting the consortium, its achievements and its goals.

The following external speakers were invited to the ICPerMed Executive Committee meeting in Vienna in April 2018:

Prof. Dr Julia Stingl from the Federal Institute for Drugs and Medical Devices in Germany (European “HARMONY” project) and Prof Andre Dekker from Maastricht University in the Netherlands (health research infrastructures for PM).

In reaction to the publication of the One Million Genomes Declarations, ICPerMed published a statement available on the ICPerMed website. ICPerMed is following further developments in the “One Million Genome Initiative” with interest.

2. ICPerMed’s mapping activities

Numerous activities in PM are already ongoing on the regional and national as well as the European and international levels. These baseline activities and their outcomes should be collected and communicated as the experiences and knowledge obtained could help to develop larger approaches on a European or even international scale.

ICPerMed performs extensive mapping exercises and is collecting information on the different levels of activities in PM, e.g. funding activities, initiatives, platforms, examples of best practices, etc. This inventory on regional, national, European and international activities in the field of PM aims to increase the knowledge base for funders and stakeholders, to avoid the duplication of efforts and to use already existing infrastructures or platforms more efficiently.

The mapping exercise is furthermore used to monitor progress within the ICPerMed member states toward the Action Plan’s objectives and may serve, for example, to identify crucial research funding topics that can be addressed on the national and/or transnational levels.


3 https://www.icpermed.eu/media/content/ICPerMed%20statement%201%20Million%20Genomes%20Declaration.pdf
Internal reporting within ICPerMed and external input such as the results of workshops and conferences, not to mention exchanges with different stakeholders, all provide input for mapping. Outcomes of these mapping activities are communicated by various means. PM funding activities on the programme level are presented in the ICPerMed mapping database.

Mapping database on funding activities in Personalised Medicine

In March 2017, ICPerMed launched its first internal survey to collect information on funding activities in PM, national/regional funding schemes and general funding information from the participating organisations. Assembled information are presented in the ICPerMed mapping database that has been online since 19 June 2018. The database is linked to the ICPerMed website and open to the public after simple registration.

Currently, data from 30 different organisations from 22 countries and two regions are presented. The database is updated regularly and full coverage of information provided from all ICPerMed partner countries is expected within the next year.

The major part of the database concerns information on funding programmes. Additionally, general information about the funding organisations involved is available. In October 2018, 96 programmes had been identified, i.e. 20% more compared to the survey results in the previous year. ICPerMed has already successfully collected data from 77% of its members’ countries and plans to complete the mapping by launching the 2019 edition of the survey (Fig. 1).

As ICPerMed members and observers provide data, programmes presented are mainly supported by Ministries and funding agencies (Fig. 2A). The large number of programmes declared shows the active involvement of ICPerMed partners in PM funding programmes. There is frequently a common contribution by a Ministry and its respective National Funding Agency. In two cases, two distinct ministries (Ministry of Health and Ministry of Research) in Austria and Germany are directly involved in the consortium.

In total, out of the 96 distinct programmes being presented: Fifty-two ongoing programmes, or 56%, are dedicated to funding research projects in PM (Fig. 2B). Fourteen programmes are international in character, including 3 European Research Networks (ERACoSysMed, E-RARE and ERA PerMed). The “Personalized Health Initiative” of Canada (third-party country in terms of H2020), for example, demonstrates the global importance of personalised healthcare, as does the presence of Canada and Israel (as associated country) in several funding programmes. Overall, 27% of the programmes dedicated to PM are international. The main core activity of the participating organisations lays on regional and/or national funding instruments.

Forty-one programmes, or 44%, are not specifically dedicated to PM but allow funding of research projects in this field; this includes 11 international programmes and 7 programmes co-funded by the European Union’s Horizon 2020 research and innovation programme (NEURON Cofund, ERA HDHL, JPND, ERA CVD, EuroNanoMed III, EJP Rare Disease European Joint Programme Cofund, HDHL-4

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4 https://www.icpermed.eu/app/login
5 https://www.eracosysmed.eu/
6 http://www.erare.eu/
7 http://www.erapermed.eu/
8 http://www.chr.irsc.gc.ca/e/50117.html
Similarly, among those programmes dedicated to PM, 27% are international.

Finally, four programmes dedicated to funding PM research were under preparation in 2018.

The different programmes presented in the ICPerMed database tend to focus on early stages of the value chain and on funding for basic, translational and applied research (Fig. 2C). Clinical research is already well represented. This observation could be explained by the fact that the main contributions to the database were provided by Ministries and/or Regional/National Funding Agencies that essentially support public research. However, few industrial funding opportunities have been identified in the ICPerMed database. Among the "other" category, Austria and Germany are developing biobanking research infrastructures\(^\text{16,17}\); Germany is setting up a training/qualification programme called “Interdisciplinary Summer Schools in Systems Medicine”\(^\text{18}\), and Austria created a “National Coordination Platform on Personalized Medicine”\(^\text{19}\), to name just few.

Regarding industrial research funding, 5 out of 18 programmes are funded by the Swedish funding agency Vinnova\(^\text{20}\), which also funds research projects in the upper range of the value chain and embraces innovation and entrepreneurship in new innovative approaches. Vinnova has decided to develop new strategies that are more suited to addressing new challenges and opportunities. “Challenge-driven innovation”\(^\text{21}\) is one example of their new funding programme that aims to solve societal challenges through innovation and broad
collaboration between industry, academic research, public sector activity and civil society. Vinnova has established an innovative, creative, sustainable funding instrument with increasing funding budgets over three stages. In the first stage, the “initiation phase”, collaborations are funded in order to develop new project ideas. In the second stage, a project can apply for further funding aimed at deepening the collaboration between the different actors and to begin developing and testing potential solutions. The third and last step is intended to support the implementation of a business model and to upscale the proposed solutions into the real world. This funding instrument is a good example of how to support projects aiming to implement actions starting from the bench site up to the market.

Implementation of the ICPerMed Action Plan:
The main aim of ICPerMed’s mapping activities is to follow-up on the implementation of the ICPerMed Action Plan. For each programme presented, its relation to the 30 actionable Research and Research-Supporting activities is indicated in the database. The Action Items are activities identified by ICPerMed as being essential to achieving full implementation of PM in future. For each subcategory, the number of programmes including at least one Action Item of the respective sections are shown to facilitate data interpretation (Fig. 3A and B). A more detailed analysis for the individual Action Items (AI) is presented in Annex 1. The same programmes may be presented in more than one subcategory.

Figure 3A shows that programmes dedicated to PM (indicated in dark blue) tend to focus more on “cross-cutting” actions and actions around “data” than programmes that are only susceptible to fund PM (indicated in light blue). This highlights the importance of these topics for PM development and implementation.

Overall, all programmes essentially focus their actions on data issues and new technologies, methods and/or processes in PM. Specifically, funding was used to increase the quality, completeness, validity and analysis of datasets and the harmonisation of data (AIs A1, 2, 3, 4, 12; Annex 1). The optimisation of data security, privacy and ownership in PM receives less emphasis, however, despite being crucial to enabling citizens to become actively involved in their healthcare course. Additionally, there is a need to develop common principles and legal frameworks enabling patient-level data to be shared for research.

Moreover, the programmes’ scopes mainly concern the implementation of actions supporting the translation of basic research into clinical research (AIs A9, 10, 13). Actions aimed at funding clinical trials (AI A14), where implementation can be
expected only in the longer-term and not without incremental progress on the ICPerMed Action Plan, are less addressed.

Among all the objectives defined by the Action Plan, funding programmes supporting research in post-marketing surveillance methodologies, aiming at assessing patient outcomes (AI A17), are the least represented, followed globally by programmes promoting PM approaches in a healthy, economically sustainable way (AI A11, 16, 18).

It is encouraging that programmes dedicated to PM are better placed to respond to ICPerMed’s objectives than programmes susceptible to finance PM (data not shown), as this suggests that ICPerMed has developed a well-defined set of goals aimed at specifically supporting the implementation of PM approaches by identifying the relevant needs in this area.

For the Research-Supporting activities, figure 3B shows that programmes presented in the database are having overall increased funding activities in promoting the development of new structures, resources and frameworks for implementing PM, such as the development and maintenance of biobanks and population/disease cohorts. Programmes dedicated to PM are notably focused on promoting the development of high-quality sustainable databases for PM-relevant data. Similarly, the following activities are recurrent in programmes dedicated to PM:

- Establish a new collaborative funding organisation model with healthcare providers to develop common strategies in research to support comparative and effective research, and sustainable technology transfer capacities (AI B3);
- Support research to analyse, compare and optimise national and regional health systems in the light of PM implementation (AI B6).

Patient-centred activities are less represented, however, meaning that an effort is needed to develop long-term strategic approaches on how to meet the challenges associated with access to PM from a public health perspective. Nevertheless, compared to all other actions, these objectives are more covered on the regional/national level than on the international level (Annex 1), probably due to the fact that every country (region) has different healthcare systems and thus, this is an intrinsically regional/national issue.

In summary, the high number of programmes dedicated to PM and those that are non-dedicated but include topics from the Action Plan demonstrates the importance of PM in our societies and the challenges of putting PM in place to the benefit of patients and citizens. The first steps have already been taken, but many challenges still lie ahead as PM is in its early stages, essentially with a need to develop basic knowledge before it can be applied. Efforts are needed in support of research further up the value chain, including strategies on efficient and active citizen and patient involvement/empowerment.

There are many PM approaches on the regional/national level despite the international nature of the topic. Indeed, PM implies a more accurate stratification of patients, and will therefore require larger sample sizes, which can be solved by pooling and sharing knowledge and data across borders. More international initiatives bringing together all the different actors, public and private, are therefore desirable.

The mapping database so far only contains information on funding opportunities mainly supported by ICPerMed members and observers. Although different organisations provided input for some countries, the information collected does not reflect the complete picture of funding opportunities in the field of PM. ICPerMed will continue to collect data on funding programmes and will integrate as well those maintained by organisations and countries that do not belong to ICPerMed.
3. ICPerMed Action Item Groups – follow-up on the Action Plan

At the Executive Committee meeting in October 2017 (Lisbon), the five ICPerMed Action Item Groups (AIG) were formed. These active working groups composed of ICPerMed representatives and external experts, aim to follow up on and to work toward the implementation of the ICPerMed Action Plan.

The 30 actionable Research and Research-supporting activities are allocated to the five AIGs with different thematic focuses (concerned Action Items are indicated):

- AIG1: Data and ICT – Enabling Technology (A1, A2, A4, A6, B1)
- AIG2: Data and ICT – Improving Health Care (A3, A5, A7, A8, A12, B7)
- AIG3: Translational Research (A9, A10, A13, A14, A15, B2, B3, B4)
- AIG4: Health Economics, Regulation, Market Access (A11, A16, A17, A18, B5, B6)
- AIG5: People and Society (A19, A20, A21, A22, B8)

The AIGs report biannually on their activities. In the spring of 2018, all five groups concentrated their work on the analysis of funding programmes/activities presented in the ICPerMed mapping database. Furthermore, the AIGs started extensive mapping activities assembling information on PM-related initiatives, platforms, infrastructures, coordination activities, examples of best practices, policy papers/support, etc. So far, over 70 different initiatives have been identified, including CSAs and infrastructures/biobanks, as well as activities on policymaking and dissemination/empowerment, running on regional, national and European levels.

A more detailed analysis of the 70 different initiatives will be performed within the next year. In this State of the Art Report, we would like to mention just three of them:

The Mayo Clinic’s initiative promoting shared decision-making through the development, implementation and assessment of patient decision aids and shared decision-making techniques through their “Shared Decision-Making National Resource Center”. The goal of this programme, in alignment with the ICPerMed’s objective to empower citizens, is to identify and evaluate ways to help patients to make well-informed decisions with their clinician via a decision-aid tools by reflecting and respecting the patient’s values and goals. A key partner for this activity is the Patient Advisory Group, a group of volunteer patients who meet with researchers to review and discuss research activities since 2004, learning about research, sharing their questions and priorities, and providing feedback on research projects.

The Italian INNOLABS initiative accompanying SMEs and start-ups to the market. The initiative notably targets innovative technologies regarding mHealth, with medical device development for self-diagnosis such as wearables.

Several initiatives have been identified for one of the main challenges facing PM implementation: data management. Indeed, data integration and interpretation requires harmonisation to be embedded in healthcare and research systems. Several initiatives have been launched to solve these issues. Among them, EHR4CR, now closed, aimed to provide adaptable, reusable and scalable solutions (tools and services) for reusing data from Electronic Health Record systems for Clinical Research. The EHR4CR platform was an open platform that unlocked the information stored in Electronic Health Records for improving clinical research.

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22 https://www.icpermed.eu/media/content/ICPermed_Action_Item_Group_1.pdf
23 https://www.icpermed.eu/media/content/ICPermed_Action_Item_Group_2.pdf
24 https://www.icpermed.eu/media/content/ICPermed_Action_Item_Group_3.pdf
25 https://www.icpermed.eu/media/content/ICPermed_Action_Item_Group_4.pdf
26 https://www.icpermed.eu/media/content/ICPermed_Action_Item_Group_5.pdf
while fully respecting patient privacy and ensuring a high level of security. The project is now continuing within the environment of the “European Institute for Innovation through Health Data” (i-HD)
. The i-HD was formed as one of the sustainable entities emanating from the EHR4CR project. Other ongoing initiatives were also born of this project, notably an early adopter Champion Programme launched as the first step in building a pan-European network of hospital sites connected to EHR4CR implementation: the “InSite” platform
. The Champion Programme serves to prove the value of Real World Data for clinical research and EHR4CR/InSite technology on a wide scale.

Finally, the European Commission has launched the European Open Science Cloud (EOSC) aimed at providing free, open services for data storage, management, analysis and re-use across disciplines.

4. Towards the identification of Examples of Best Practices

The first step towards the implementation of PM lies in exchanging experiences to share knowledge of successful and/or ongoing activities. ICPerMed is fostering these exchanges through different means:

Annual conferences and workshops
. The ICPerMed Academy
 focuses on the implementation of and training in PM and aims to recognise, encourage, promote and disseminate outstanding examples of BPs in PM. The winners for 2018 will present their work at the ICPerMed conference and will receive support for the dissemination of the examples of BPs by the ICPerMed Secretariat.

Furthermore, examples of BPs will be presented on the ICPerMed website. The “story telling” of good practice will be organised by the AIGs as an outcome of the mapping activities.

All these different approaches to presenting examples of BPs seek to demonstrate the shift in PM from theory to practice. The collection of diverse PM approaches and the sharing of experiences are crucial, especially taking into account the diversity of health care systems and the enormous variations between different countries regarding the understanding of PM and the steps to be taken toward its implementation.

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The ICPerMed conference “Personalised Medicine in Action”, held in November 2018 in Berlin, Germany, will focus on examples of BPs in PM in “research and implementation” as well as “policy”. The presentations in “research and implementation” will consider all the different perspectives of patients, research, clinics, industry and health care professionals.

27 https://www.i-hd.eu/
28 https://www.insiteplatform.com/
5. Position of ICPerMed in the PM environment

As ICPerMed’s mapping exercise demonstrates, many activities in the field of PM are already ongoing. Some of them are specifically dedicated to PM; others are more general in character, including some aspects related to PM. There are structural initiatives for creating platforms and/or infrastructures, for example data collection and sharing, biobanking, etc. Others mainly focus on individual aspects such as regulatory, economic and social questions.

Compared to other initiatives, ICPerMed has multifaceted capacities:

- The composition of ICPerMed partners allows exchanges on PM questions on a high regulatory level, since the consortium includes public and private “not-for-profit” health research funding and policy organisations, and thus mainly funding organisations, and notably different types of Ministries.
- High-level participation within ICPerMed enables the consortium to gather information on PM and the political landscape on the regional and national levels, as well as to transmit recommendations to the authorities in the respective countries, such as actions to be taken for the implementation of PM described in the ICPerMed Action Plan.
- Even if funding for the consortium is provided by the European Commission via the ICPerMed Secretariat, ICPerMed has become an international initiative. The global character of ICPerMed enables the consortium to share experiences and knowledge not only across borders within Europe but also to foster exchanges on the international level. Each country contributes to the reflections on PM with its specific experiences and individual health care system.
- ICPerMed’s close connection to PM experts enables the consortium to develop strategic documents such as the ICPerMed Action Plan, including the different perspectives of the various key players involved in PM (citizens and patients, researchers, health care providers and professionals, industry, funding organisations and the various regulatory authorities).
- With its annual events (two workshops and two conferences in all), ICPerMed creates synergies and brings together the various actors of the entire value chain (see previous bullet point) to foster exchanges on PM and, most importantly, to demonstrate the shift from simple theory to practice. Outcomes of these events are summarised and published in collaboration with PM experts and shared with the community.
- ICPerMed promotes a common understanding of Personalised Medicine to concentrate and focus all efforts in the same direction. This represents a challenge, taking into account the different type of actors involved in PM (e.g. the general public, professionals, but also regulatory authorities) as well as the different needs, structures and advances of the healthcare systems in the various countries.
- ICPerMed is a platform where research-supporting organisations such as funding agencies and ministries can meet to develop new funding strategies and programmes to foster research in PM. For ICPerMed, support for research is the first step toward the future implementation of PM. For example, the ERA-Net ERA PerMed, closely connected to ICPerMed, is launching annual calls. The different actions in the ICPerMed Action Plan are considered within the scope of calls for proposals. Thus, ERA PerMed is aligning research and funding activities not only on the European level but also internationally.

ICPerMed has successfully managed to provide a flexible framework for cooperation between its member organisations, and is a platform for initiating and supporting communication and exchanges on PM research, funding and implementation. ICPerMed’s extensive mapping activities enable the consortium to identify the requirements for a suitable framework in terms of infrastructures, resources and regulatory procedures to foster the development and implementation of PM.
6. ICPerMed events/activities in 2018

Between November 2017 and October 2018, the ICPerMed Executive Committee met once in Vienna on 19–20 April, 2018. The second Executive Committee Meeting for 2018 will take place in satellite to the ICPerMed conference in Berlin on 20–21 November in Berlin, Germany.

The first ICPerMed Academy was launched on 19 January 2018, and focused on the following areas:

1. Scientific papers focused on novel approaches for the implementation of PM;
2. Training programmes for health personnel, increasing the level of awareness on the potential of PM;
3. Examples for interdisciplinary or intersectoral groups of collaboration (governmental and non-governmental organizations, academic management, medical research and health care), for the implementation of PM, including Ethical, Legal and Social Issues (ELSI) activities.

In total, 18 proposals were submitted and evaluated by a group of scientific experts in the field. The three top-ranked proposals have been invited to the ICPerMed conference in Berlin and will have the opportunity to present their work during a plenary session. In addition, the successful candidates will receive a non-cash award of €500 to support the dissemination of their examples of BPs.

The following proposals were selected:

- **In vivo evidence for ribavirin-induced mutagenesis of the hepatitis E virus genome**, Daniel Todt, Twincore, Germany.

Furthermore, ICPerMed has invited four proposals in fourth position to present a poster of their work during the 2018 ICPerMed Conference. These are:

- **Reducing the risk of catheter-associated urinary tract infections via a smartphone application for patients**, Prof Robbert G. Bentvelsen, Leiden University Medical Center, The Netherlands.
- **A Harmonization Study for the Use of 22C3 PD-L1 Immunohistochemical Staining on Ventana’s Platform**, Dr Tzahi Neuman, Hebrew University Hadassah Medical Center, Jerusalem, Israel.
- **Nasal chondrocyte-based engineered autologous cartilage tissue for repair of articular cartilage defects**, Prof Andrea Barbero, Universitätsspital Basel, Switzerland.
- **Value of Information Analysis in Personalised Medicine**, Prof Enrico Capobianco, CNR (ISOF) Bologna, Italy and University of Miami, USA.
Outlook

The ICPerMed consortium, supported by the ICPerMed Secretariat, is successfully entering into its third year after its creation in 2016.

In 2019, the ICPerMed Action Groups will concentrate on the further collection of examples of Best Practices and their presentation on the ICPerMed website as “Story Telling”. Please feel free to contact the individual group leaders if you are interested in that working group’s topic.

We are looking forward to the first ICPerMed conference on „Personalised Medicine in Action“ on 20-21 November, 2018, in Berlin, Germany, to learn more about the different approaches to the implementation of PM to be presented.

Furthermore, in November 2019, ICPerMed will organise a workshop in Madrid and a second international conference beginning of October 2020 in Paris. We hope to welcome you at one of our ICPerMed events.
Annex

Annex 1A: Research Activities

Figure A: Inclusion of the individual Action Items of Research Activities in funding programmes dedicated to PM (dark blue) and those susceptible to finance PM (light blue).

Annex 1B: Research-supporting Activities

Figure B: Inclusion of the individual Action Items of Research-Supporting Activities in funding programmes dedicated to PM (dark blue) and those susceptible to finance PM (light blue).