ICPerMed
INTERNATIONAL CONSORTIUM

State of the Art Report 2021

Imprint

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Authors
The ICPerMed Secretariat, represented by The French National Research Agency (ANR), Dr Monika Frenzel and Dr Michael Joulie, on behalf of the International Consortium for Personalised Medicine, ICPerMed, with valuable contribution of the ICPerMed Advisory Board and the ICPerMed Working Groups.

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Contact
The French National Funding Agency (ANR)
Dr. Monika Frenzel
E-mail: monika.frenzel@agencerecherche.fr

ICPerMed Secretariat
E-mail: ICPerMed@dlr.de
ICPerMed webpage: http://www.icpermed.eu

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Executive Summary

The International Consortium for Personalised Medicine (ICPerMed) publishes a state-of-the-art report on an annual basis and seeks to facilitate the follow-up of the development of personalised medicine research and its implementation throughout Europe and beyond.

In this 2021 report, ICPerMed presents its activities (events, ICPerMed promotion videos, working group activities) of the past year 2021 and gives the stage to the ICPerMed Advisory Board to share their view on personalised medicine, the benefit personalised medicine can bring to healthcare, healthcare systems and for patients and citizens, as well as hurdles and important steps still to be taken to make personalised medicine a reality for all.

ICPerMed is looking forward to the upcoming European Partnership for Personalised Medicine, EP PerMed. In February 2021, ICPerMed published a concept paper for the future partnership, developed jointly together with representatives of ERA PerMed and with support of the European Commission. The concept paper was discussed in an open, virtual Information Event "European Partnership for Personalised Medicine (EP PerMed) calling for national and regional involvement" organised by ICPerMed and ERA PerMed on May 31, 2021. In this report, we outline how the drafting group took over the mandate to further develop the partnership, the advances made so far and the next steps until the (expected) launch end of 2023.

ICPerMed is continuously mapping activities in the field of personalised medicine in order to promote achievements and successes in research and implementation as well as to honour activities of ICPerMed member organisations. A set of currently running personalised medicine related initiatives is presented in this 2021 report.

State of the Art Report 2021

1. International Consortium for Personalised Medicine

ICPerMed serves 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 personalised medicine (PM) and the defragmentation of the 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, i.e. the ICPerMed Action Plan in 2017 and the Vision Paper in 2019.

The International Consortium for Personalised Medicine (ICPerMed) currently brings together 46 public and private 'not-for-profit' health research funding and policy organisations from 30 countries, seven European regions and four continents. The EC participates in ICPerMed as observer.

Furthermore, through the **"ICPerMed Family"**[1] even more countries and organisations are joining PM strategic reflections, fostering the implementation of the ICPerMed Action Plan and feeding input into ICPerMeds strategic reflections and recommendations. The ICPerMed Family consists of programmes and projects receiving (co-)funding by the EC, including the European Research Area Network for Personalised Medicine (ERA PerMed) as funding programme and nine Coordination and Support Actions (CSAs) with different thematic focus. A new CSA on Prevention in Personalised Medicine joins the ICPerMed Family in 2022.

To foster collaboration between members of ICPerMed, ERA PerMed and the ICPerMed-related CSAs, ICPerMed organised the **"ICPerMed Family Meeting – Joining Forces"** (virtually) on 9-10 November 2021. ICPerMed "family members" and invited experts discussed about current topics in PM research and implementation and exchanged ideas about future research priorities in five dedicated sessions:

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

Most ICPerMed related initiatives were initiated during the Horizon 2020 Framework Programme and will run until 2022 or 2023. Thus, a second ICPerMed Family meeting is planned for 2023 to exchange results and to discuss possible further collaborations, e.g. in the frame of the future partnership for PM. Thus, the motto of the first ICPerMed Family Meeting – Joining Forces – will be maintained for future collaboration and events showing the success of the initiatives and the ICPerMed family. The meeting report summarising the results of the interactive sessions is available on the ICPerMed website[2].

ICPerMed is presenting itself, the ICPerMed family as well as the past and the future of PM through six promotion videos published in 2021 – have a look and visit our ICPerMed YouTube channel![3]:

1 https://www.icpermed.eu/en/related-initiatives.php

2 https://www.icpermed.eu/en/905.php

3 https://www.icpermed.eu/en/icpermed-and-icpermed-family-videos-853.php

- The International Consortium for Personalised Medicine in a Nutshell
- ICPerMed - The Personalised Medicine Journey
- ICPerMed Family - The Funding of Personalised Medicine Research
- ICPerMed Family - The Regional Perspective
- ICPerMed Family - The International Perspective
- ICPerMed Family - Health Economics and Clinical Perspective

All videos are available on the ICPerMed website and the ICPerMed YouTube channel with 5 subtitles (English, French, German, Italian and Spanish).

2. Statements of the ICPerMed Advisory Board

The ICPerMed Advisory Board[4] comprises international experts from multiple PM disciplines essential in research and for implementation, thus covering the full healthcare value chain. The scope of the Advisory Board is to counsel ICPerMed from an independent point of view to ensure the right focus and direction of its activities and its alignment with state-of-the-art and future developments in PM research and implementation approaches.

ICPerMed invited the panel to provide short statements to this year's ICPerMed state of the art report 2021 to share their view on PM, the benefit PM can bring to healthcare, healthcare systems and for patients and citizens, as well as hurdles and important steps still to be taken to make PM a reality for all:

Katherine Payne, The University of Manchester, United Kingdom

"The ICPerMed Advisory Board is the ideal environment to discuss the evidence needed to support the introduction of PM into clinical practice with like-minded colleagues. As a health economist, I think the key challenge to tackle is how to develop methods of cost-effectiveness analysis to take account of the bottlenecks (capacity constraints) in health-care systems hindering the implementation of PM and inform cost-effective strategies to enable the uptake of PM for the benefit of patients."

Liisa-Maria Voipio-Pulkki, Ministry of Social Affairs and Health, Finland

"Medical practice is always personalised in the sense that the patient´s best interest is our guide. To me, PM is simply a reflection and application of scientific progress in good clinical practice. At the same time the way, how we collect evidence and put together clinical guidelines has been challenged by the inherent nature of PM. This paradigm shift calls for innovative trial designs as well as transparent, evidence-informed and value-based decision making at all levels of the health system."

Henrique Martins, FCS-UBI, ISCTE-IUL, Portugal

"There are data challenges to make PM a deeper reality. The national level of personalised public health will require a mentality shift, the materialisation of national/European Health Data Spaces and the legal-ethical clarification of the status of our digital twins and how we can use them. At the healthcare provider level, the full integration of intra- and extramural data, including all health-relevant individual data about behaviours and ambience exposure, remains a sensing technology and interoperability quest."

Angela Brand, Maastricht University, The Netherlands

"PM is a fast moving social & technological innovation towards personal health and care implying a jump from stratification to individualisation, timely use of enabling technologies and analytical tools such as artificial intelligence, radical transparency, trusted data ecosystems such as health data cooperatives, highly dynamic models such as evolutionary behavioural economics. Just dishonest are buzzwords like precision public health or precision training, personalised prevention, business as usual, calling for new legal and ethical frameworks!"

4 https://www.icpermed.eu/en/icpermed-governance.php

Ulrike Köhl, Fraunhofer Institute of Cell Therapy and Immunology IZI, Germany

„The success of cell-based therapies is attracting growing interest for personalised treatment of various diseases, especially cancer. With further applications and increasing numbers of patients, the reproducible manufacture and up-scaling of autologous or allogeneic cells is becoming an ever-greater challenge. New automated, artificial intelligence-controlled processing techniques and quality control are required to meet both medical needs and regulatory restrictions."

Gerhard Schillinger, AOK-Bundesverband, Germany

"Personalised Medicine can open up new treatment options in conditions with unmet medical need. However, Personalised Medicine also requires high standards in the quality of diagnostics, test interpretation and therapy decisions based on current evidence. Existing care structures can no longer cope with this complexity, knowledge transfer is too slow. New networked treatment and a close interlinking of research and patient care is needed, if all affected patients shall benefit."

Barbara Prainsack, University of Vienna, Austria

"Personalised Medicine seeks to match prevention, diagnosis, and treatment better to the characteristics and needs of patients. As such, it can help to reduce side effects of treatments, improve their outcome, and ideally also give patients more meaningful control over what they want and do not want. One of the key challenges at present is to ensure that personalised medicine does not increase inequities, both within and across societies."

Further members of the ICPerMed Advisory Board are: Fabrice André, Gustave Roussy (France); Jan Geissler, Patvocates GmbH (Germany); Deborah Marshall, University of Calgary (Canada) and Maria Teresa Moreno-Casbas, Carlos III Health Institute (Spain). ICPerMed thanks the entire Advisory Board for the valuable input and exchanges in the past and is looking forward to the different inspiring discussions still to come in the future.

3. ICPerMed Working Groups

The ICPerMed Working Groups (WG) were newly installed in 2021 and focus their work on topics prioritised by ICPerMed. The working groups consist of ICPerMed members and external experts (e.g. representatives of ICPerMed family projects and others). The common main objectives of the Working Groups are:

- contributing to the development of ICPerMed recommendations/strategic publications/reports and to ICPerMed dissemination activities (e.g. roadmap/ Scientific Research and Innovation Agenda);
- providing content-driven input for ICPerMed events;
- exchanging with stakeholders and representing ICPerMed in thematically focused events to improve the visibility and impact of ICPerMed in the respective community;
- identifying and validating Best Practise examples in personalised medicine.

There are currently five Working Groups addressing five dedicated topics[5]:

1. Clinical Studies in Personalised Medicine
2. Personalised Medicine in healthcare
3. Patients' empowerment
4. Education & Curricula in Personalised Medicine
5. Health economic value of Personalised Medicine

5 https://www.icpermed.eu/en/icpermed-governance.php

Four Working Groups have provided input for this year's state of the art report:

Working Group: Clinical Studies in Personalised Medicine

This Working Group started its work together with the other four ICPerMed working groups in 2021. In total, 13 members of the ICPerMed Executive Committee (ExCom) joined this group in person or via nominated representatives. Wolfgang Ballensiefen and Angel Alonso Sanchez have been elected as lead and co-lead of this group and regular conference calls have been performed. As external expert, Paula Grazia was invited to join the group to support the discussion with her expertise and representing the CSA PERMIT "Enhancing personalised medicine research" and ECRIN an European infrastructure to generate scientific evidence to optimise medical practice.

The first tasks were the organisation of a session within the ICPerMed Family meeting on November 9-10, 2021 and the preparation of an information sheet for the aims of this working group.

ICPerMed Family Meeting Session 1: This session on clinical PM Research & Technology started after a general welcome with an introductory talk by the ICPerMed Advisory Board member Fabrice André (Gustave Roussy, France) providing insights into state-of-the-art and future PM research approaches. While innovative research approaches have great potential for PM, they also open up a lot of new challenges in terms of scaling up and in terms of production/construction of individualised treatments such as antibodies, gene therapy or CAR-cells. Upcoming, promising PM research approaches, which are worth to be funded, comprise the assessment of protein activation; ex-vivo modelling via organoids, targeting rather mechanism than mutations, and the construction of personalised drugs (e.g. antibody-drug conjugates). Thereby, PM research can address several goals, such as:

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

Furthermore, a set of related PM best practise examples were identified to be finally published on the ICPerMed webpage.

Working Group: Personalised Medicine in Healthcare

The science basis for PM has been evolving and drives progress in discoveries demonstrating the benefit PM approaches are bringing to effective diagnosis, treatment and even prevention, health promotion, and disease management. Hence, implementation of PM in healthcare systems for the benefit of citizens is still at an early stage and involving a multitude of considerations beyond biomedical ones. There is still the need for a common understanding and valorisation of PM, including the shift from public health concepts traditionally developed for populations to a focus on the individual. Reforms in healthcare systems are necessary to accommodate this paradigm change.

This Working Group launched a survey on "Personalised Medicine Applications (PMA)" to collect implemented PM practices in care or those being under experimentation as well as approaches contributing to establish an adequate environment to allow PM implementation into practice.

This survey will enable ICPerMed to demonstrate the large panel of PM applications at local (healthcare facility), regional/national or supra-national/international level, in different medical intervention fields (prevention, diagnostic, treatment, etc.), and to better understand the environment favouring the implementation of PM approaches (e.g. infrastructure, standards, regulatory frameworks, etc.).

The PMAs will be further analysed to identify priorities and frameworks required for the implementation of PM by healthcare professionals, organisations (healthcare facilities, infrastructures as biobanks, etc.) or by health authorities and regulators. The analysis, by outlining hurdles and facilitators for PM implementation, can provide guidance to healthcare systems' roadmaps and support the successful uptake of PM practices in care.

This Working Group aims to understand how successful PMAs integrated reflections on the benefit of the approach for patients, the citizens and the society, and considered socio-economic value, cost-effectiveness and health economics

or the engagement of patients and citizens during the development and implementation processes. With the PMA collection and the analysis of collected approaches, this Working Group intends to provide a better understanding on how to build-up successful PM approaches by identifying potential obstacles but most importantly levers, prerequisites (e.g. governance, infrastructure, funding/investment, regulatory, legislation) and instances to interact with.

Working Group: Patient Empowerment in Personalised Medicine

Introducing patient empowerment (PE) is a key element for personalised medicine (PM) implementation. This working group aims at fostering patient involvement and engagement in PM research and policymaking, through:

- the understanding of patients' expectations and how to better support patient involvement in PM, promoting the integration of patient perspectives in PM research to strengthen permanent participation and increase the societal impact;
- the promotion of existing patient engagement policies and the analysis of new initiatives;
- the exchange of best practices for patients' involvement in PM;
- the collaboration with experts, including patient representatives, to co-create solutions for patient engagement challenges;
- the development of a policy paper regarding the integration of patient perspectives into PM approaches;
- the collaboration with all WGs to ensure that patients' perspectives are included in all PM aspects;
- the building of awareness and engagement of different stakeholders, especially policymakers and patient advocacy organisations.

Through an internal consultation, this Working Group prioritised group activities aiming to improve patients' empowerment. The results of this survey showed that the main priorities are the collection of clinical practices related to patients' engagement and the improvement of health literacy for patients and citizens.

In order to give space to these two priorities, a database has been created, collecting a bibliography and videography related to patient empowerment, a list of Patients' organisations operating in the countries participating in the project, a list of experts in this field and a list of critical aspects and next actions to be implemented.

Working Group: Health Economic Value of Personalised Medicine

Health economics has been used to guide the evidence-based introduction of new drugs and therapeutic approaches in the healthcare system for many years. It is now increasingly recognised that for PM approaches, a broader approach to value assessment that includes societal aspects, real-life setting and patients' preferences will be required to evaluate the full potential of those innovative approach, beyond the limited healthcare system perspective. That can't be done without the rigorous health economic methods, but it appears that those are showing the limitation brought by the number of individuals to be screened to identify those that could benefit from the personalised approaches. However, with the increasing implementation of genomic medicine and associated accessibility of genomes linked to electronic health records, a paradigm shift in the value of PM value assessment is on the horizon. Such a shift will also need to support a life-cycle approach to health economic evaluation.

Today, the main challenge is to identify and document the value by identifying and detailing real-life health economic exemplars. There are certainly many of those emerging, examples that have in common an inclusive approach, considering many aspects of the implementation; from conducting rigorous health economics modelling, including ethical, legal and social aspects, considering system readiness, and integrating patients' preference as a central aspect.

Documentation of the value of PM related approaches goes closely together with access to real world data in a broad context. These data are needed to prepare the right health economics models and valuations, taking all aspects into account. The field is moving regarding access to real world data, but it is still an immature field which will need much more focus going forward.

4. European Partnership for Personalised Medicine – EP PerMed

Within the European Union's 9th Framework Programme for Research and Innovation, Horizon Europe, the set-up of a co-funded European Partnership for Personalised Medicine (EP PerMed) is proposed. This future partnership should promote regional and national priority setting and support the alignment and funding for research and implementation projects in the area of PM between the EU Member States, European regions and Associated Countries to Horizon Europe as well as international partner countries.

ICPerMed highly supports the upcoming partnership and published a concept paper[6] in February 2021. The concept paper was jointly developed by the Preparatory Group consisting of representatives of ICPerMed and ERA PerMed, and supported by the EC, to foster the reflections towards and to provide content-driven input for the partnership.

On May 31, 2021, ICPerMed and ERA PerMed, supported by the Preparatory Group, organised a virtual information event: **"EP PerMed Information Day: European Partnership for Personalised Medicine calling for national and regional involvement"[7].** All interested stakeholders, in particular national and regional authorities as ministries, funders, etc., were invited to participate. During the event, ICPerMed and ERA PerMed informed about the concept paper and proposal for the EP PerMed, its objectives, activities and expected impacts, and the overall framework for engagement in this partnership. The overall aim of the information day was furthermore, to engage with regional and national authorities, funders and other stakeholders interested in promoting and implementing PM approaches in their regions and countries to foster personalised diagnostics, therapies and prevention for the benefit of patients and citizens. The event was a great success with over 200 participants from 22 different countries that came together to discuss the opportunities and perspectives of the EP PerMed.

Furthermore, ICPerMed and ERA PerMed developed and published jointly an **EP PerMed guidance document and seven information sheets[8]**. The guide is intended to provide support for representatives of regional and national authorities, ministries, funders and policy makers and the PM stakeholder community towards the EP PerMed. In addition, topic-specific information sheets were developed and published for areas of action listed in the guideline paper:

- EP PerMed InfoSheet 1 – Summary of Draft Concept Paper
- EP PerMed InfoSheet 2 – Stakeholder Community
- EP PerMed InfoSheet 3 – National Hubs for Personalised Medicine
- EP PerMed InfoSheet 4 – Regional Opportunities
- EP PerMed InfoSheet 5 – Joint Funding Activities
- EP PerMed InfoSheet 6 – Industry Involvement
- EP PerMed InfoSheet 7 – International Perspective

The information sheets and the guide aim to promote the partnership, to foster participation of interested organisations and to help organise the baselines for preparations on the regional and national level, in order to mobilise national budget commitments and receive stakeholder input for the creation of the partnership.

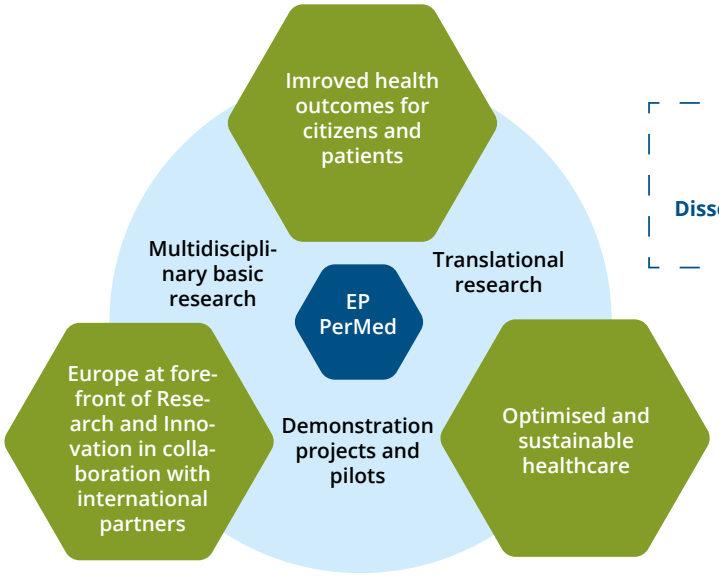
In September 2021, the EC organised the first (virtual) meeting with the Members States and Associated Countries to start concrete preparations towards the EP PerMed. An EP PerMed Drafting Group was established, consisting of Member States delegates and representatives of the EC. As first outcome, an **EP PerMed draft proposal[9]** was developed and published on February 07, 2022, describing the context, the objectives and expected impacts as well as the planned implementation of the upcoming partnership.

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

7 Video recording and presentations available here: https://www.icpermed.eu/en/830.php

8 https://www.icpermed.eu/en/ep-permed.php#Guidance%20Document

9 https://ec.europa.eu/info/files/european-partnership-personalised-medicine_en



Supported by
PM SRIA and priority setting
Suitable policy and regulatory frameworks
Dissemination, knowledge exchange, communication
and **Participation of all keyplayers**

The European Partnership for Personalised Medicine Vision is:

"**Improve health outcomes** within **sustainable healthcare systems** through **research**, and the development and **implementation of personalised medicine approaches** for the benefit of patients, citizens and society."

To realise its vision, the partnership will integrate all the elements needed in a collaborative effort to achieve the full potential of PM:

- Generate research and results through funding activities, for example via transnational and cross-sectorial research consortia, networks, pilots and collaborations.
- The partnership will be the most significant platform and initiative to connect key stakeholders in the PM field to share evidence, demonstrate solutions and to drive supportive activities in policy, regulatory science and health economics.

Therewith, the EP PerMed will align and promote regional/national priority setting and funding for research and implementation projects in the area of PM between the EU Member States (MS), European regions and associated countries to Horizon Europe as well as countries from all over the world.

The next important steps in the preparation of the partnership are:

- April 2022: Indicative budget request of the MS for their contribution to this partnership.
- During the course of 2022: The development of a Personalised Medicine Strategic Research and Innovation Agenda (PM SRIA).
- End of 2022: The publication of the call for the co-funded European Partnership for Personalised Medicine.

The EP PerMed proposal submission will be completed in spring 2023 and the partnership is supposed to be launched by the end of 2023.

Contact details to reaching out to the EP PerMed drafting group for any question around the EP PerMed: eppermed@dlr.de.

ICPerMed is looking forward to the upcoming partnership and contributes to the development at every stage in order to support the process and establish a continuous collaboration with the Drafting Group. ICPerMed plans to invite representatives of the EP PerMed drafting group to present the SRIA in the next ICPerMed Family Meeting planned at the end of 2023 in order to join forces for the future of PM.

5. Snapshot: Initiatives in the field of personalised medicine

ICPerMed is continuously mapping activities and advancements in the field of PM in order to promote achievements and successes in the field as well as to honour activities of ICPerMed member organisations. A set of significant PM related initiatives is presented in this section:

- Two initiatives related to data: **TEHDAS** and the **SPHN Federated Query System**
- Two innovative approaches strengthening the importance of regions in research and innovation: **Vanguard Initiative** and **inDemand**
- Two national plans working on the implementation of personalised medicine: **IMPaCT** and **Mosaic**

Data Aspects

Joint Action for the European Health Data Space

The creation of a European Data Space is one of the priorities of the European Commission (2019-2025) as well as the EU Member States. A common European Health Data Space will promote better exchange and access to different types of health data (electronic health records, genomics data, data from patient registries, etc.), not only to support healthcare delivery (so-called primary use of data) but also for health research and health policy making purposes (so-called secondary use of data).

TEHDAS Towards European Health Data Space

The Member States and the Commission launched in February 2021 a joint action **Towards the European Health Data Space (TEHDAS)** to advance the cross-border secondary use of health data in Europe. With the participation of 25 EU Members States, TEHDAS seeks to develop and promote legal, technical and infrastructure concepts for the sharing of health data with the goal to improve health research and innovation in Europe.

The initiative is coordinated by the Finnish Innovation Fund Sitra and is focusing on five pillars:

- Engage other European projects and policymakers in a dialogue;
- Ensure sustainability of the secondary use of data;
- Develop a governance model for cross-border cooperation;
- Promote the reliability and access to health data;
- Clarify the role of individuals in use of health data.

TEHDAS engages dialogue with national health authorities of the participating countries and international stakeholders and incorporates their views into the project. The initiative's results will be considered in drafting future EU health legislation, in particular the regulation on the European Health Data Space.

The initiative develops options for governance models for the exchange and secondary use of health data between European countries, based on transparency, trust, citizen empowerment and a common good. TEHDAS results will help European countries on planning national legislation to enable cross-border exchange and secondary use of health data.

They provide recommendations for the trustworthy secondary use of health and healthcare data with a view to promoting the digital transformation of European health systems. TEHDAS develops guidance on ensuring data quality such as anonymisation of data and handling of data disparity.

TEHDAS promotes technical solutions for the interoperability of the secondary use of health data in the European Health Data Space and encourages the participation of future users of data, such as researchers and policymakers, and of technical implementers, such as companies and institutions, in co-designing the services.

Finally, they seek to obtain a better understanding of citizens' attitudes towards sharing of personal health data and to identify ways to inform people about the use of their health data and raise awareness for the benefits that the secondary use of data offers.

For more information about TEHDAS.

The SPHN Federated Query System for clinical studies

The Swiss Personalised Health Network (SPHN) Federated Query System (FQS) is an information retrieval system enabling researchers to query for specific clinical information of patients. This new system allows to search for fully anonymised clinical information across five Swiss university hospitals, while allowing each hospital to retain the entire control over its data.

It enables researchers to verify the feasibility of their study and to assess whether and where patients or patient data, potentially suitable for a specific clinical question, are available at Swiss university hospitals. The tool allows designing and optimising the study protocol by providing information on how many hospitals are to be included, how long researchers need to run the study to get enough patients enrolled and to have the statistical power for the analysis.

The system is based on a central query system where research criteria, as demographic data (age and gender), the diagnosis results, procedures performed in the hospitals, the treatment received and laboratory tests performed and results obtained, can be assessed.

Overall, the system includes currently more than 70 million data elements from over 450 000 patients.

For more information about SPHN Federated Query System
Please find here the link to the FQS video on Youtube: https://youtu.be/Jj-wLlFeWNo

Innovative Regional Ecosystems

Vanguard Initiative

The Vanguard Initiative is an alliance that gathers 39 regions in Europe, focusing on stimulating industrial innovation and building European value-chains based on complementarities across regions.

By connecting innovation ecosystems and sharing knowledge and facilities across its member regions, the Vanguard Initiative facilitates interregional collaboration, stimulates interregional innovation investments, strengthens open innovation, and speeds up the introduction and market-uptake of new products and innovations in Europe. To do so, the Vanguard Initiative brings regions, clusters and stakeholders together to discuss common objectives and find complementarities; map and better understand regions' industrial competencies and capabilities; develop joint strategic action plans (building critical mass and complementary specialisations); align strategic investments arising from these roadmaps; better support start-ups and SMEs in their innovation process; make the process of matchmaking between promising SMEs and start-ups more efficient and effective.

The Vanguard Initiative set in place several pilot projects in different domains with one project dedicated to PM called **Smart Health**. This pilot aims to bring the PM implementation agenda to the next level while transforming the connected European industrial value chains. The partner regions already established solid ecosystems combining biomedical, technological and data-driven expertise. By bringing these ecosystems together, a higher added value is sought to be reached together with a boost of PM implementation.

After an initial scoping, the network has been established as a learning- and co-creation community, which exchanges knowledge on a regular basis by organising tailor-made workshops and connecting the different regional stakeholders in events or digital seminars. This connection is based on involving stakeholders from research & innovation, businesses and field labs, regional and local governments, hospitals and healthcare centres as well as clients and citizens.

Potential projects are presented by partner regions and a GAP- and SWOT-analysis aims to highlight the knowledge that needs to be added to the project and identify the pilot partners best suited to take up the role in question. An implementation phase in the regions finally enables the commercialisation of new products and services by the private sector.

1. Personal Data Management Platform

The personal data management platform project brings together three regions and their health ecosystem to provide personal digital safe and control over it to each individual citizen. This data organised in a citizen-centric governance model provides currently non-existing possibilities for innovation and an ethically correct market place for personalised products and services.

2. P4 Medicine-Citizen Lab

In the aim of establishing a European wide living lab for PM measures in different (chronic) diseases a first consortium has been established on Diabetes Type II. A broad programme on prevention including learning communities and social innovation clusters will be developed based on mission programmes in the field of cardiovascular diseases, kidney diseases and arthrosis.

3. Mobile Health Evolution – Chronic Disease Control

The project aim is to generate value to users and society by offering elderly chronic disease patients continuous, personalised health professionals' support through mobile health management for better self-management of chronic diseases and quality of life. The project addresses social challenges (communication, inclusion of patients in the healthcare process, patient motivation) and biomedical aspects (pharmaceutical care). The empowerment of patients will be achieved with knowledge and motivation as well as ICT tools to take over disease management and ultimately improve quality of life.

For more information about the Vanguard Initiative.

inDemand

inDemand is an EU project funded by Horizon 2020 whose objective is to develop a new model in which healthcare organisations and companies co-create digital health solutions with the financial support of regional public funds.

The inDemand Community currently includes 3 main pilot regions and 12 others testing whether the model is sustainable and replicable.

inDemand execute a consultation in which healthcare professionals report challenges that could be solved with digital health solutions. Regional public funders then launch a call for companies to finance a maximum of 60% of the project development. Selected companies co-develop their solution with the healthcare professionals. They also get business support to optimise business model, access to funding and support commercialisation. The solution is finally tested and validated within the participants healthcare organisations.

The project aims to demonstrate that this implementation model increases the systematic identification and solving of unmet needs by health entities and create business opportunities for innovative private companies.

For more information about inDemand.

National Personalised Medicine Initiatives

IMPaCT – A Spanish Personalised Medicine Initiative

IMPaCT INFRAESTRUCTURA DE MEDICINA DE PRECISIÓN ASOCIADA A LA CIENCIA Y LA TECNOLOGÍA

IMPaCT, Infrastructure of Precision Medicine associated with Science and Technology, is a national initiative in Spain coordinated by the Health Institute Carlos III that aims to realise PM in our day-to-day life. The initiative is built around three strategic axes with values of ethics and scientific integrity and internationalisation:

- The first axis, predictive medicine, aims to address the design and the establishment of a representative population-based cohort. The cohort will be representative for the population residing in Spain, its ethnic variability, geographic and environmental diversity. With this programme they aim to design precision strategies and predictive models for prevention, diagnosis and treatment.

- The second axis is dedicated to data and its secondary use by establishing a data space integrating clinical, molecular and genomic data. Through this programme, models will be generated providing solutions for the challenges of the national healthcare system.
- The third axis focuses on genomics and aims to increase the sequencing capacity and is dedicated on the primary use of data for diagnosis. It will also serve the needs of the cohort programme and to contribute to the 1M Genome initiative.

For more information about IMPaCT (in Spanish only).

Mosaic (Psifas in Hebrew) Initiative: a Launchpad for Personalised Medicine

The 21st century presents numerous health challenges, such as population aging, increased prevalence of chronic diseases, as well as increasingly unhealthy lifestyles.

Most of the diagnostics and therapies in medicine today are one size fits all, which are ineffective for many of the patients. The personalised medicine approach for the prevention and treatment of diseases considers the biological, behavioural and environmental differences between individuals. By means of an elaborate analysis of big data, including clinical and genetic data, this approach may facilitate administering the most effective therapy to each patient, thus by dramatically improving the chances for successful remedies and for saving lives, while decreasing the administration of superfluous treatments.

The Israeli Ministry of Health, together with five other governmental organisations: the Israel Innovation Authority, the High Council of Education, Digital Israel Bureau, Ministry of Treasury and the Medical Corps, all agreed to establish and finance a new entity called Mosaic, an entity meant to serve the purposes of research and public health.

The goals of the initiative are:
1. Improve the health of all Israelis;
2. Generate an innovative national infrastructure for promoting basic translational genomic-clinic research in Israel's research institutes, health organisations and life science industry;
3. Develop an enabling ecosystem for personalised medicine in Israel by creating synergy between the biomed industry, health organisations and the academia.

For this initiative, the vision of sequencing-based medicine is not just another genome project, but rather the formation of a research and innovation platform that will enable scaling of new sequencing-based technologies in the real world. Mosaic is aiming at this vision, based upon the following foundations:

- Funding support by the government – 80M USD, but recently (2021) outsourced to a non-profit-company,
- Strategic alliance of the major Israeli hospitals, Health Maintenance Organisations (HMOs), academia and industry,
- Recruitment of hundreds of thousands of fully consented individuals,
- Deploying massive clinical data layers based on modern existing Electronic Health Record (EHR) systems,
- Israel Reference Genome Study (IRGS) is already on its way, developing comprehensive germline genomic maps for 63 unique Israeli sub-populations,
- Coupling sequencing of clinically defined participants with full "live" interface to their updating EHRs,
- Building a unique framework for launching collaborative academia and industry-driven R&D projects. Championing advanced molecular analysis of biosamples,
- Mosaic will employ advanced tools that were developed over the past 5 years through extensive work on complete data of 4.5M Israeli individuals. Many classical gaps and confounders affecting retrospective EHR analysis and patient stratification will be effectively solved in the system.

The Mosaic initiative represents a formal Israeli agenda and is a part of a bigger program - the government's resolution no. 3709 to promote digital health as a growth engine and a means to improve health.

For more information about Mosaic.

Outlook

ICPerMed is looking forward to 2022 with:

- **biannual ICPerMed events**: ICPerMed Workshop "Personalised Medicine: How to Ensure Value-based Implementation", on invitation only and taking place in Brussels on June 21-22, 2022 and the ICPerMed Conference on 5-6 October, 2022, in Paris (SAVE THE DATE!);
- **training courses and summer schools** fostering exchanges with and the active involvement of the PM community;
- new **examples of best practices** in personalised medicine presented and promoted on the ICPerMed website and through the **ICPerMed Recognition**;
- the preparations of the **European Partnership for Personalised Medicine (EP PerMed)** and particularly the **development of the EP PerMed Strategic Research and Innovation Agenda**.

Stay tuned for ICPerMed's activities via our newsletters[10] (published quarterly), the ICPerMed website and through the ICPerMed YouTube channel as well as Twitter and since 2021 the new LinkedIn account.

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New ICPerMed LinkedIn Account

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