



Towards an International Consortium for Personalised Medicine (IC PerMed)

Personalised medicine: the time to work together is now

Personalised medicine¹ is an interdisciplinary field that will drive the health research and innovation agenda for years to come. Research and innovation in this vast area is moving rapidly but it is a fragmented field. Even in areas such as cancer, the implementation of personalised medicine in healthcare is slow. One reason is the lack of evidence that is needed to demonstrate the benefit of this approach to citizens and healthcare systems.

To address the challenges, several public health research funders and policy-making organisations, together with the European Commission, will work together on a new initiative called the International Consortium for Personalised Medicine, or "IC PerMed". Discussion and planning in the setting up of IC PerMed is ongoing; the aim is to officially launch by the end of 2016.

Vision statement: research as driver of personalised medicine

Together, the member organisations of IC PerMed will work to:

- **Establish Europe as a global leader in personalised medicine research**
- **Support the personalised medicine science base through a coordinated approach to research**
- **Provide evidence to demonstrate the benefit of personalised medicine to citizens and healthcare systems**
- **Pave the way for personalised medicine approaches for citizens**

IC PerMed will focus on fostering and coordinating research and innovation actions to deliver on its mission statement. A large part of this work will be to build the evidence base needed to progress in the area of personalised medicine, and in doing so, avoiding the duplication of ongoing policy discussions at an EU-level or intruding in areas of competence of the EU Member States.

¹ For a definition of personalised medicine, see the *Frequently Asked Questions* section.

Creating a flexible framework for cooperation

IC PerMed aims to provide a flexible framework for cooperation between member organisations. For that purpose, a so-called International Consortium model will be used. According to this model, the member organisations use their own funding rules and policy processes to contribute to the overall goals and objectives of the consortium. Current examples of initiatives in the health research field that use versions of this model include the International Rare Diseases Research Consortium (IRDiRC) and the International Human Epigenome Consortium (IHEC)².

Setting priorities for future research and implementing them together

The IC PerMed members will develop a roadmap based on the document "*Shaping Europe's Vision for Personalised Medicine*³". This is the Strategic Research and Innovation Agenda (SRIA) written up by the EU-funded project called PerMed. PerMed was funded from 2013–2015 and brought together many organisations active in the area.

The PerMed SRIA lists 35 recommendations for actions at national as well as EU-level. These recommendations are grouped into five overarching challenges: *Developing Awareness and Empowerment, Integrating Big Data and ICT Solutions, Translating Basic to Clinical Research and Beyond, Bringing Innovation to the Market, and Shaping Sustainable Healthcare*.

The IC PerMed roadmap will be structured as a list of research actions according to these five challenges. The first version of the roadmap, which is a living document to be updated at regular intervals, will be published in the end of 2016. IC PerMed members will work together to implement the actions identified in this document.

For more information and contact

For more information, see the *Frequently Asked Questions*.

IC PerMed's interim secretariat can be contacted by e-mail: RTD-IC-PERMED@ec.europa.eu

² For more information about IRDiRC and IHEC, please see <http://www.irdirc.org> and <http://ihec-epigenomes.org>

³ The PerMed SRIA is available on: http://www.permed2020.eu/media/PerMed_SRIA.pdf



International Consortium for Personalised Medicine (IC PerMed) Frequently Asked Questions

What is the definition of personalised medicine?

There is no universally accepted definition of personalised medicine. The IC PerMed initiative is based on a definition of personalised medicine which is used in the Horizon 2020 Work Programme for *Societal Challenge 1: Health, demographic change and well-being*⁴ and in the European Council Conclusions on personalised medicine for patients (2015/C 421/03)⁵.

According to this definition personalised medicine " [...] refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".

What are the aims of IC PerMed?

The aims of IC PerMed are outlined in its vision statement. The vision of IC PerMed is to:

- Establish Europe as a global leader in personalised medicine research
- Support the personalised medicine science base through a coordinated approach to research
- Provide evidence to demonstrate the benefit of personalised medicine to citizens and healthcare systems
- Pave the way for personalised medicine approaches for citizens

⁴ For Horizon 2020 Societal Challenge 1 Work Programme 2016-2017 see: http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-health_en.pdf

⁵ The Council Conclusions can be consulted at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.421.01.0002.01.ENG&toc=OJ:C:2015:421:FULL

How will the members of IC PerMed deliver on the aims of the initiative?

IC PerMed will focus on fostering and coordinating research and innovation actions to deliver on its mission statement. A large part of this work will be to build the evidence base needed to progress in the area of personalised medicine, and in doing so, avoiding the duplication of ongoing policy discussions at an EU-level or intruding in areas of competence of the EU Member States.

The organisations that have shown an interest in IC PerMed are currently drafting a roadmap with actionable research activities that need to be undertaken to progress in the area of personalised medicine. The roadmap will identify these research actions as well as their expected impact and the means and timelines for their implementation.

The first version of the roadmap will be published in the end of 2016. The member organisations of IC PerMed will coordinate the implementation of the roadmap actions. As the field evolves, the roadmap will be updated at regular intervals.

Which organisations can become members?

The IC PerMed membership will be made up of public and private not-for-profit health research funding and policy-making organisations. In this context *health research funding organisation* refers to an organisation which manages a programme that funds health research. This organisation can be publicly or privately run, but should not have a commercial interest. *Policy-making organisations* refer to ministries or other public organisations involved in formulating policies for implementing personalised medicine. Currently, the organisations involved in setting up IC PerMed are health research funding agencies as well as national ministries of health and research. Although the current focus of the initiative is on Europe, organisations from other parts of the world can become members.

Organisations that do not qualify for membership could gain an observer status or participate by providing expert input into the discussions. The exact framework for this input is still to be defined.

How does membership work?

Organisations become members of IC PerMed by signing a Letter of Interest to join the initiative. The Letter of Interest is not a legally binding document and IC PerMed will not have legal personality. The letter shows the organisations intentions of working actively towards the overall aims of IC PerMed.

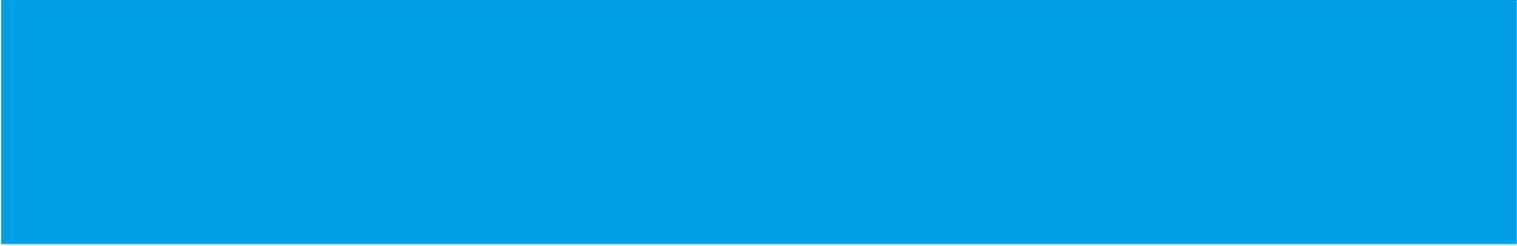
There is no monetary commitment to join the initiative; however members will commit to report yearly on their activities contributing to IC PerMed and to actively participate in the running of the initiative.

Who is involved in drafting the IC PerMed roadmap?

The IC PerMed roadmap is structured around five "Challenges". It builds on a strategic document developed by the EU-funded project called PerMed⁶. The Challenges denote overarching areas where research and innovation actions are needed to bring personalised medicine forward. The roadmap is drafted by five Challenge groups made up of members from organisations that have shown an interest in the initiative. Each group is led by a 'Challenge Facilitator' (see table below).

Challenge	Challenge Facilitators
Developing Awareness and Empowerment	Maria Judith Molnar, Health Ministry, Hungary
Integrating Big Data and ICT Solutions	Wolfgang Ballensiefen, Research and Education Ministry (DLR-PT), Germany
Translating Basic to Clinical Research and Beyond	Hemma Bauer, Science, Research and Economy Ministry, Austria Natalia Martin & Daria Julkowska, National Research Agency, France
Bringing Innovation to the Market	Peter Høngaard Andersen, Innovation Fund Denmark
Shaping Sustainable Healthcare	Gaetano Guglielmi, Health Ministry, Italy

⁶ The PerMed Strategic Research and Innovation Agenda is available on: http://www.permed2020.eu/_media/PerMed_SRIA.pdf



The Challenge groups can consult with external experts, including relevant EU-level networks and working groups, to make sure that the research actions they have identified are pertinent.

Will IC PerMed provide funding for research and how can one apply?

IC PerMed will not directly fund research or launch calls for proposals. The IC PerMed members will implement the roadmap by funding research through their own funding programmes.

What does the IC PerMed governance structure look like?

IC PerMed will be officially launched in the autumn of 2016. Until the official launch, it will be run *ad-interim*. During the interim phase, the governance structure is made up of an Executive Committee and five Challenge groups.

The Executive Committee is made up of one representative per organisation that has shown an interest in IC PerMed (nominated by that organisation). These organisations are potential members but after the official launch, only organisations that have signed a Letter of Interest will be able to nominate representatives to the Executive Committee. So far, organisations from some 25 different countries have shown an interest in IC PerMed and participated in the Interim Executive Committee meetings.

The Executive Committee is the decision-making body that oversees the work of the initiative. It will have a Chair and Vice-Chair elected among its members. During the interim phase, it is chaired by the European Commission.

The five challenge groups are made up of members from the organisations represented on the Executive Committee. They can consult with experts from various organisations that are not represented on the Executive Committee.

How can I get in touch with IC PerMed?

The IC PerMed secretariat is currently run by the Innovative and Personalised Medicine Unit of the European Commission's Directorate-General for Research and Innovation. The unit can be contacted by e-mail at the following address: RTD-IC-PERMED@ec.europa.eu