

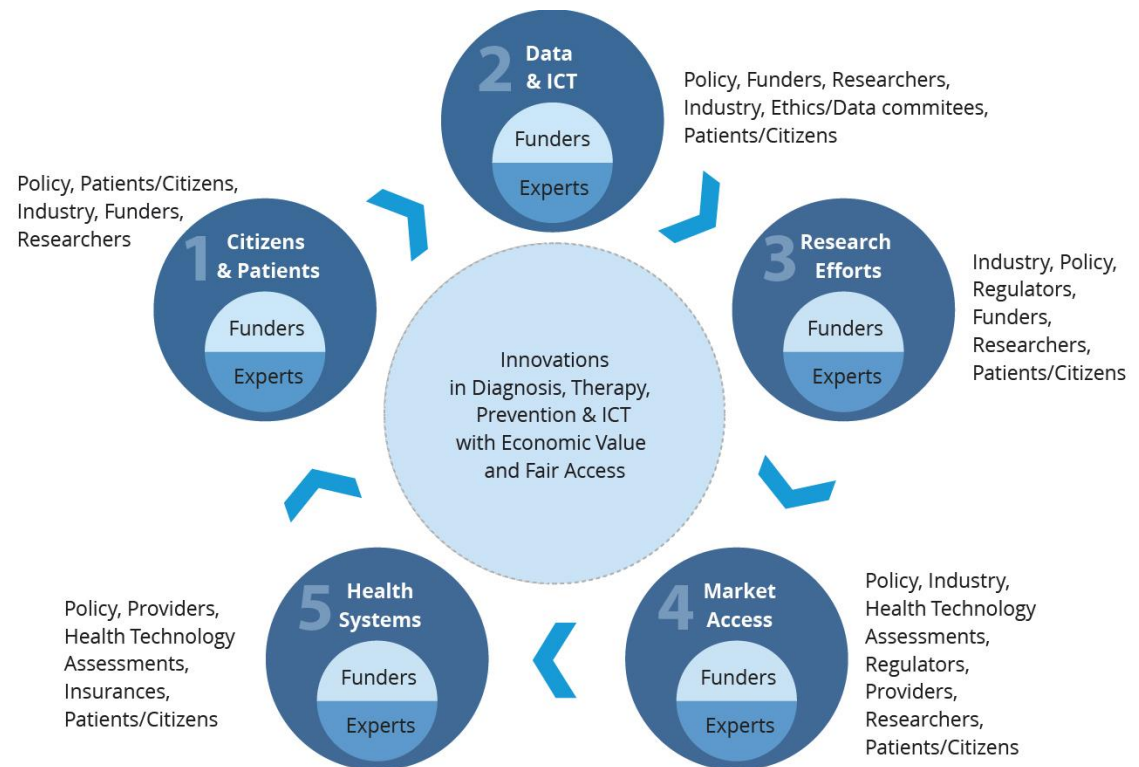
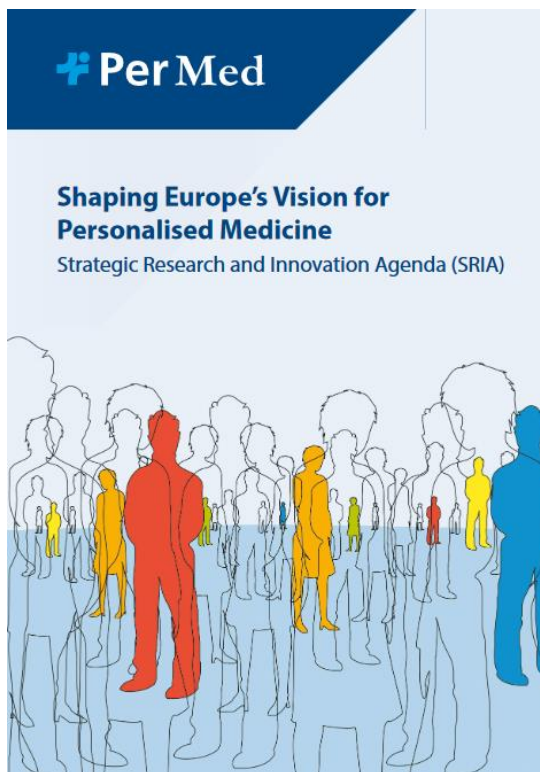
List of interests for international collaboration in Personalised Medicine from the European perspective

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Shaping Europe's Vision for Personalised Medicine - Strategic Research and Innovation Agenda (SRIA) – June 2015



https://www.icpermed.eu/media/content/PerMed_SRIA.pdf

Shaping Europe's Vision for Personalised Medicine - Strategic Research and Innovation Agenda (SRIA) – June 2015

- Challenge 1 – Developing Awareness and Empowerment
- Challenge 2 – Integrating Big Data and ICT Solution
- Challenge 3 – Translating Basic to Clinical Research and Beyond
- Challenge 4 – Bringing Innovation to the Market
- Challenge 5 – Shaping Sustainable Healthcare

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Challenge 1 – Developing Awareness and Empowerment

1. Provide further evidence for the benefit delivered by PM to health systems.
2. Develop and promote models for individual responsibility, ownership and sharing of personal health data.
3. Develop mobile health applications to maximise engagement of patients with their treatment pathways and track the safety and effectiveness of these interventions.
4. Understand how the changes related to PM will impact public health and ensure they translate directly to benefits for individual citizens and society.
5. Improve communication and education strategies to increase patient health literacy.
6. Incorporate patient participation in the healthcare system and increase the patient's role in all phases of research and development.
7. Develop common principles and legal frameworks that enable sharing of patient-level data for research in a way that is ethical and acceptable to patients and the public.

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Challenge 2 – Integrating Big Data and ICT Solutions

8. Promote strategies to make sense of 'big data'.
9. Develop and encourage the fast uptake of technologies for data capture, storage, management and processing.
10. Promote the development of high quality sustainable databases including clinical, health and well-being information.
11. Support translational research infrastructures and enforce data harmonisation fostered by specific ICT infrastructures designed to the health data.
12. Support analytical methods and modelling approaches to develop new disease models, e.g. 'Computerised Twins' or a 'Virtual Patient'.
13. Develop new decision support tools and methodologies of ICT to analyse and interpret data in order to support physicians in their decision-making process.
14. Create a European 'big data' framework and adapt legislation.

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Challenge 3 – Translating Basic to Clinical Research and Beyond

15. Develop methods to better integrate and evaluate the information provided by genomic, epigenetic, transcriptomic, proteomic, metabolomic and microbiome analyses.
16. Support research in preclinical models to validate hypotheses resulting from molecular analyses of patient samples and treatment outcomes.
17. Promote collaborative pre-competitive and trans-disciplinary research in all disease areas to gain trustworthy and objective information.
18. Instigate a European-wide biomarker evaluation and validation process.
19. Promote longitudinal studies in the areas of PM.
20. Support development of new clinical trial designs and promote integration with concomitant preclinical testing.
21. Re-classify diseases at the molecular level.
22. Develop suitable funding models to enable cross-sector working in PM research.

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Challenge 4 – Bringing Innovation to the Market

23. Formalise a risk-based approach for the evaluation of PM.
24. Optimise individual drug therapies and poly-pharmacy especially in the case of multi-morbidity.
25. Support research on an adequate regulatory and legal framework for PM.
26. Encourage a systematic early dialogue between innovators, patients and decision-makers throughout all regulatory steps to provide guidance and clarity.
27. Facilitate partnerships and innovation networks to encourage cross-disciplinary and cross-border collaboration in research and development using an 'Open Innovation' approach.
28. Provide support and guidance for companies to enter the market for PM with sustainable business cases.

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Challenge 5 – Shaping Sustainable Healthcare

29. Support health economics research of PM to support decision makers.
30. Develop prospective surveillance systems for personal health data that facilitate accurate and on-going assessment of highly dynamic health information across the life course.
31. Develop training programmes on PM for health professionals.
32. Encourage a citizen-driven framework for the adoption of electronic health records.
33. Promote engagement and close collaboration between patients, stakeholders and healthcare actors across sciences, sectors and borders.
34. Develop a framework for pricing and reimbursement for PM that ensures equitable access for all patients – regardless of economic or geographic status – and is sustainable for health systems.
35. Develop an optimised overall healthcare financing strategy.

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General comments

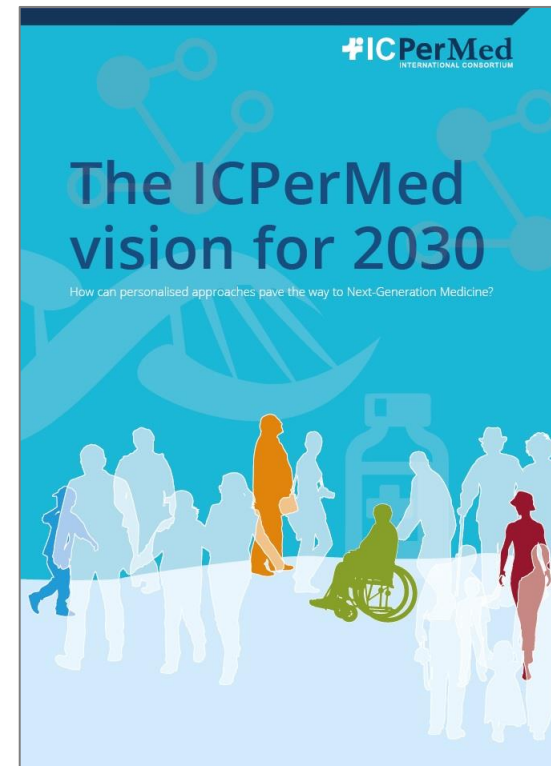
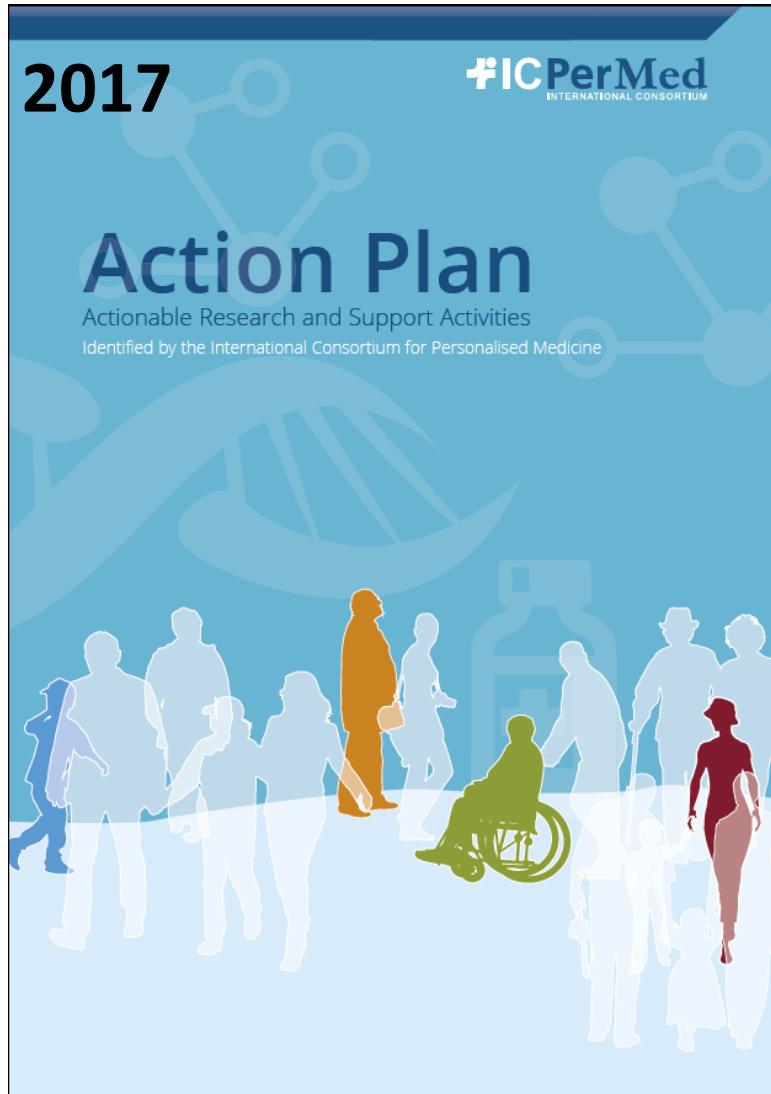
- **Independent international communication platforms** – especially for funders, policy makers and healthcare providers – are scarce.
- **New networking structures needed:** Stakeholders originate from highly diverse fields, lack tradition of collaboration
 - E.g. transnational European research consortia - including countries at the forefront of innovative and extensive research funding.
 - Crucial to also include developing countries facing a rapid increase in the incidence of chronic diseases, e.g. diabetes.
 - Giving access to new perspectives, approaches and research opportunities
 - Opening new business opportunities for these countries as well as for Europe

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General comments

- **New networking structures**
 - Transnational funding consortia → Joint research funding activities
 - International research consortia
- Recommendation: Networking structures developed should collaborate closely with existing (European) platforms and research structures such as the ESFRIs (European Strategy Forum for Research Infrastructures).
- “European initiatives could be a good starting point for further international activities which would generate enough impact to enable the implementation of Personalised Medicine routinely in the clinic and in health as a whole.”

International Consortium for Personalised Medicine



Alignment of strategies

ICPerMed Action Plan

Actionable Research and Support Activities

Collection of actions to advance personalised medicine in all relevant areas and at all levels

- 22 Research activities (A1–A22)
- 8 Research-supporting activities (B1–B8)

...deemed to be “ready for action”.

➔ Indication if suitable for implementation at a regional/national, European and/or **international level**

ICPerMed Action Plan – (14/22) Actionable Research Activities

DATA

- 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.5 Pilot projects to assess the impact of sharing data for researchers and other parties
- A.6 Research projects to optimise data security, privacy and ownership within personalised medicine approaches
- A.7 Research projects to develop innovative decision support tools for healthcare providers

TECHNOLOGIES, METHODS AND PROCESSES

- 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
- A.14 Longitudinal cohort studies of disease outcomes
- A.16 Support research in and development of health economics models and pharma-economic models for personalised medicine
- A.17 Support research in post-marketing surveillance methodologies aimed at assessing patient outcomes

PEOPLE

- 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 needs 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

CROSS-CUTTING

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

ICPerMed Action Plan - (6/8) Actionable Research-Supporting Activities

STRUCTURES

- | | |
|-----|---|
| B.1 | Promote the development of high-quality sustainable databases for personalised medicine-relevant data |
| B.2 | Development and maintenance of biobanks and population/disease cohorts |

METHODS & PROCESSES

- | | |
|-----|---|
| B.4 | Develop common strategies in research to support comparative and effective research, and sustainable technology transfer capacities |
| B.5 | Support strategies to identify financial and risk-sharing instruments to develop personalised medicine approaches |
| B.6 | Support research to analyse, compare and optimise national and regional health systems in the light of personalised medicine implementation |

PEOPLE

- | | |
|-----|---|
| 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 |
|-----|---|

International collaboration: Key to foster the uptake of personalised approaches in healthcare

- Excellent experts and initiatives located around the globe
- Reaching critical mass of data from various sources to develop and train algorithms and models used in PM approaches.
- ensuring that developed approaches are applicable as broadly as possible and not limited to a specific regional context → increase the value of developments for the common good.

https://www.icpermed.eu/media/content/EPPerMed_InfoSheet7%20-%20International_perspective.pdf

Why this collaboration in the field of Personalised Medicine is so important

- Facilitating access to new tools and technologies.
- Contribute to shorten existing health disparities between developing and developed countries.
- Full implementation is complex and we need to join forces
- “Ensuring healthy lives for all at all ages” and make healthcare more efficient and equitable

More information about ICPerMed

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