IC2PerMed

ROADMAP

Integrating China in the International Consortium for Personalised Medicine

Why Personalised Medicine?

The context

Personalised Medicine (PM) represents a comprehensive approach that tailors disease prevention, diagnosis, and treatment to individuals, by taking advantage of the new biomedical and digital technologies.

Turning PM into an opportunity for citizens and patients requires the engagement of stakeholders internationally to define common research and development approaches, standards, and priorities. In order to respond to these challenges, the EU supports actions developed within the International Consortium for Personalised Medicine (**ICPerMed**).

The perspectives on PM were defined within the document «**The ICPerMed Vision for 2030**», published in 2019, and the recently published Strategic Research & Innovation Agenda of the European Partnership on Personalised Medicine (EPPerMed) (**The Strategic Research & Innovation Agenda (SRIA) for Personalised Medicine (PM) (icpermed.eu)**).

The IC2PerMed Project

Under the ICPerMed initiative and inspired by its Vision, **IC2PerMed** is a Coordination and Support Action (CSA) project which aims to provide key solutions for enabling the convergence towards a common approach of PM research, innovation, development and implementation between European and Chinese stakeholders, from policy makers to healthcare beneficiaries but also seek to insert these developments into international contexts.

IC2PerMed **vision** is to become an efficient lever for supporting EU-China collaboration for the development of PM and enabling populations to access personalised, smart, and inclusive healthcare solutions by 2030. In this context, IC2PerMed, which lasts 4 years (2020-2024) and involves 7 EU and 3 Chinese partners, **aims** to support collaboration between Europe and China to identify common approaches in advancing research in PM at global level.

MAPPING

Identifying Chinese and EU appropriate policies, programmes, stakeholders and standards to consider and involve in developments; Envisioning benefits for healthcare ecosystems and benefits for populations

EXEMPLIFYING

Setting concrete practices of successful collaboration over a PM core thematic (biobanks) for illustrating and inspiring research collaborations

EXPERTISING

Building upon exchanges between experts in PM domains for fostering actionable approaches

ENGAGING

Creating strong bridges with key stakeholder from the EU, China and beyond, integrating Chinese stakeholder in ICPerMed and liaising with international peers

ICPerMed INTERNATIONAL CONSORTIUM

Project Partners

Università Cattolica del Sacro Cuore · Tsinghua University · BGI华大 · 中国医学科学院肿瘤医院 Cancer Hospital Chinese Academy Of Medical Sciences · Gemelli · Steinbeis Europa Zentrum · G.A.C. GROUP · BBMRI-ERIC · WFPHA · Fondazione Telethon

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874694

IC2PerMed scientific developments

WORK PACKAGE 1

Mapping of PM policies and programmes in EU and China

WP1 aims to provide a complete and actionable background mapping of current strategies, areas of interest, priorities, and initiatives between the EU and China in PM. The project conducted extensive desk research, literature review, and comparative analysis to identify future policy priorities, action plans, and relevant programmes in PM. Results are available at: **Publications & public deliverables – IC2PerMed**

WORK PACKAGE 2

Knowledge synthesis on the identification, transferability and scaling up of international standards in PM

Co-designing the appropriate framework and strategies fostering Chinese integration in ICPerMed consortium is the core objective of WP2. EU and Chinese high-level experts engaged within this WP participated in a survey and set the path for qualifying standards, approaches, and priorities for collaboration on PM (**A survey of experts on personalized medicine landscape in European Union and China | BMC Health Services Research | Full Text (biomedcentral.com)**).
Three collaborating WGs were established (see figure) and provided insights on the current status of implementation of PM approaches in the EU and China. The results of the three WGs activities are reported in form of position papers (**Publications & public deliverables – IC2PerMed**).

Mapping of Personalised Medecine's policies and programmes in Europe and China

WORKING GROUPS

Community of EU and Chinese PM stakeholders analysing and **designing a roadmap for developments upon PM R&I schemes for facilitating the integration of Chinese stakeholders in ICPerMed activities** by the relevant agencies.

From *Priorities* to *Actions*

Based on the activities of WP1 and WP2, the IC2PerMed consortium developed a Roadmap which presents the main topics and priorities that emerged during the discussions held within the project and during the Roadmap Validation Workshop, which took place in Rome in June 2022.
This document aims to propose, through the actions listed below, the items to deepen and promote alignment and creation of a common ground for European and Chinese collaborations on PM.

Delegation visits

Creating a solid framework for collaboration formalising engagement of relevant Chinese stakeholders within the ICPerMed initiative

This project has received funding from the Chinese MOST Intergovernmental Project of National Key R&D programme under grant N#2021YFE0192400

The IC2PerMed Roadmap: the actions

IMPROVING
empowered and responsible citizens

HEALTH LITERACY

Promoting health literacy is a prerequisite for better citizens' and patients' engagement and empowerment. Considering the emergence of digital technologies and the role of digital tools in supporting the engagement process, digital literacy should be improved. Given the advancement of genomics and the widespread use of preditive genetic/genomic testing, informing citizens and patients could provide them with greater awareness about their health trajectories. The impact of healthcare professionals' literacy should be considered, as they are a proxy for public engagement in self-management of health and disease.

RESEARCH

Fostering needs-assessment research and communication activities in the field of citizens' and patients' education related to Personalised Medicine could lead to more effective empowerment.

PUBLIC TRUST

Scientific research, public organization and private institutions are key innovation actors in PM. Sustaining public trust and collaborations between different institutions, on a national and international scale, is the drive for healthcare transformation and public health promotion. In addition, public trust should be fostered and strengthened, in order to protect patients' rights, through clear data governance in accordance with the Helsinki Declaration and GDPR, implementing technical solutions to safeguard cyber security, citizens and health practitioner engagement, and developing comprehensive consent procedures where needed.

ETHICAL CHALLENGES

A strong set of values and ethical principles should be set, with a focus on the economic challenges and the inequality burden.

PROMOTING
trained and up-to-date healthcare workforce

EDUCATION & ETHICS

Improving healthcare professionals' literacy and expertise, valuing integrity and ethics, could help foster PM. Research aimed at identifying methods that are more effective should be promoted.

COLLABORATIONS

The future of healthcare professionals training relies on multidisciplinary collaborations. Fostering collaborations between professionals from different specialties and between professionals and stakeholders, while establishing more partnerships among countries, to facilitate sharing of best practice.

POLICIES

Healthcare professionals' literacy in Personalised Medicine is an emerging priority in national governmental strategies, policies and plans.

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FOSTERING
healthcare systems' sustainability

RESOURCES

A better allocation of resources on PM can foster the sustainability of health systems. In particular, the identification of a large investment stream for the long-term storage of data is a fundamental prerequisite for implementing PM strategies.

Investment priorities for product and process innovation should be defined, considering the relationship between results and costs, also by identifying new payment models for public reimbursement.

- Governance
- Financing
- Workforce and Competence
- Health Technologies innovation and management
- Delivery systems

EVALUATION

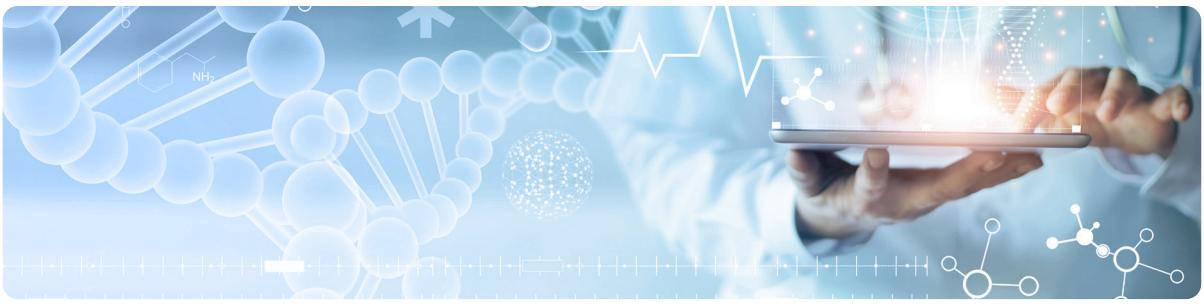
Health technologies are evolving rapidly and the translation of new discoveries underpins innovation and quality of care. Therefore, a system of continuous assessment of technologies and processes already in use and a change of perspective in Health Technology Assessment (HTA) is needed to integrate end-user perceptions into the whole innovation process. This would ensure greater effectiveness and usability.

ELSI & COSTS

Ethical, Legal and Social Implications (ELSI) aspects and related costs should always be considered in the process of Personalised Medicine policymaking, evaluation, and management of technological innovation.

NETWORKS

Multidisciplinary and cross-sectoral collaborations for PM can promote the sustainability of health systems. Public-private partnerships and international networks should be valued for sharing experience, and for promoting and evaluating best practice and progress in PM.



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BRINGING innovation to market

COST EFFECTIVENESS

The application of personalised diagnostics and therapeutics should be geared towards lowering economic costs and barriers to market uptake.

With regard to diagnostics, promoting research in PM aimed at a more appropriate use of diagnostic tools (avoiding overuse, overdiagnosis and overtreatment) could lead to an optimal use of resources in the field of prevention and consequently an increase in the value of healthcare. Health insurance providers should extend their coverage to innovative and high value PM solutions and reimbursement of services should be promoted or attempts should be made to reduce barriers to reimbursement. In implementation processes, economic, cost-effectiveness and relative value analyses should take into account both social and health budgets as well as non-optimal resource use in the system.

NEEDS ASSESSMENT

New solutions on the market must put the emphasis on maximising health outcomes for patients. An early, intensive, coordinated and continuous dialogue between all PM stakeholders involved is needed.

PRINCIPLES & GUIDELINES

The various PM actors should follow a set of shared principles and universal guidelines on data sharing and exchange. Innovations that aim for higher therapeutic value should be rewarded. Social value assessment should be systematically applied.

PERSPECTIVES

Stakeholders stimulating innovation should take a holistic and long-term perspective on the balance sheet. The interconnection and mutual dependence between diagnostic and therapeutic innovations and potential for inappropriate use/ overuse must be taken into account.

ADOPTING Big Data and ICT solutions

DATA EXCHANGE

To promote PM, Big Data needs to be analysable, comparable and interoperable across borders. The need emerges to carefully identify the type of information to be retained, increasingly favouring those related to health outcomes rather than information with no proven clinical or management value.. To facilitate data exchange procedures, greater cooperation between academia, healthcare systems (including providers and payers) and industry would be advisable.

PRIVACY, SECURITY & TRUST

Data security measures are a priority in the development of new ICT solutions, which are crucial at global level and not only focusing on high-income countries. Social and cultural differences between Europe and China should also be considered when it comes to public trust in government and state authorities, trying to reach a common understanding of shared challenges within PM.

Public engagement can improve awareness and understanding of the benefits of data sharing, how data will be used beyond improving personal care, anonymisation procedures, privacy risks, data security, the involvement of private companies and protection options pertaining to personal data, and can help to develop frameworks that reflect broader societal consensus.

STANDARDS

In the field of PM, it is essential to study solutions aimed at effectively combining data from different sources (genetics, clinical data) and regions, focusing on their standardization for effective usage. Standards for data use should be adopted and implemented, also with a view to establishing common policies and global efforts for cross-border data sharing.

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FOSTERING research funding

PATIENT NEEDS

Funding agencies should tailor investments to the needs of patients. There is a need to promote the voice of patients (and caregivers) at all stages of PM research, from co-designing research projects to advisory roles and enhancing educational initiatives to improve the scientific literacy of patients and researchers. Defining unmet needs and potential incremental innovation could help in laying the groundwork for new international collaborations.

VALUE CHAIN

Investment plays an important role in the entire value chain and is needed from basic science to the implementation of PM in healthcare. Funders, both public and private, act as a first filter on the prioritisation of resource allocation, and this should be done responsibly. Furthermore, adequate investments are crucial in the research translation system.

SYNERGIES

Establishing synergies between funders and the research community is the first step in implementing PM as a community. Implementing the exchange of researchers through mobility funding programmes could promote collaboration and knowledge sharing between different countries and foster data sharing. Collaborations between funders should be established to align on research themes and to fund larger projects that are bold and cutting-edge, and enable risk sharing.

TRANSLATING basic clinical research and beyond

OMICS SCIENCE

Omics sciences are fundamental to the development of PM. Phenotyping patients, following defined standards, could identify similar patients. Besides genomics, applications of different omics sciences and technologies should be promoted and used for the identification of biomarkers suitable for PM. Innovative methods that have shown great promise in the field of PM, including the use of induced pluripotent stem cell and organ-on-chips models, should be evaluated and adopted, valuing international partnerships.

DATA & STANDARDS

Standardising approaches, including controlled access models for data sharing and clinical trials, may facilitate their implementation and help in patient stratification. Patient stratification in the field of non-genetic/complex diseases would benefit from research programmes on machine learning algorithms. Furthermore, using specific use cases from the fields of rare diseases and cancer could help in the development of common international standards and tools for research. Exchanges and dialogue between regulatory agencies should be promoted to overcome regulatory problems in PM, in particular on benefit-risk relationships.

COLLABORATIONS

To promote international collaborations, especially on oncological care and rare diseases, it is important to support non-profit foundations and funding agencies. Establishing incentives and frameworks for public-private collaboration can facilitate academic and industrial access to biological samples and data for research purposes. It is necessary to facilitate and strengthen the dialogue with regulatory and HTA agencies, companies and academic entities to gain a clear vision in terms of outcomes researched, and to identify the most appropriate research methods to investigate PM both ensuring patient safety and adapting to the characteristics of study populations.

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What are the main areas of cooperation?

The EU and China are global leaders in the field of PM. The IC2PerMed project aims to identify facilitators and barriers to cooperation. Trying to overcome socio-cultural differences and language barriers, the international collaboration will promote the sharing of best practices and set a common ground for a broader implementation of PM.

Common objectives

- Upscaling of health systems by reducing ineffective treatments and overtreatment (PM approach)
- Overcoming fractionation in the domestic market (multi- tier health systems, national states/provinces)
- Standardization of data (omics-research and electronic health records)
- Interoperability between different stakeholders and across borders
- Development of solutions in storage and aggregation of large datasets and efficient analytics (AI, algorithms)
- Data protection (GDPR, Cyber Security Law)
- Protection of internal value chains, securing patients' rights
- Data sharing to develop new services and applications

Synergies and gains from closer cooperation

- Health challenges must be tackled globally in a concerted manner
- Alignment of research efforts leads to more efficient research, reduction of redundancies
- Large economic potential, important stakeholders/ global leaders (e.g., BGI in whole genome sequencing) extend their reach and value chains to new markets
- Sino-European collaboration on standardization in PM will benefit the whole field
- Further intensification of common research initiatives in science and technology

Facilitators

- ✓ Funding of bilateral activities
- ✓ Identification of common opportunities
- ✓ Shared research and funding platforms
- ✓ Frameworks for the exchange of knowledge, personnel and ideas

Barriers

- ✗ Communication barriers
- ✗ Different political systems
- ✗ Ethnic differences
- ✗ Public understanding and acceptance of the value of PM
- ✗ Lack of knowledge sharing platform and framework
- ✗ Lack of consensus in guidelines on interpretation and use of PM

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