



SINO-EU
PerMed

Cooperation between China and Europe
in Personalised Medicine



Policy Brief

**Fostering the collaboration between
Europe and China on Personalised Medicine**

*Challenges, policy implications and
key recommendations*

Imprint



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Summary

On February 17th, 2022 the Sino-EU PerMed project organised the 1st stakeholder workshop with the aim to present the Personalised Medicine landscape in Europe and China, highlight the main challenges to scientific and technological collaboration and initiate a debate on how to strengthen research and innovation between the two Regions.

The overall discussion was based on the outcome of the Science & Technological mapping performed within the Sino-EU PerMed project.

As a result, the Sino-EU PerMed Consortium, together with the Science & Technology Expert Task Force, have elaborated a set of recommendations for policymakers which are presented in this policy brief.

The document addresses three topics: 1. PM landscape in EU and China, 2. Traditional Chinese Medicine in PM and 3. Data sharing. For each topic the barriers and needs are identified and corresponding recommendations are provided.

Introduction

In 2014, the Horizon 2020 Advisory Group defined Personalised Medicine (PM) as a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging and lifestyle data) to: tailor the right therapeutic strategy to the right person at the right time, determine their predisposition to disease and deliver timely and targeted prevention. This definition was adopted by the European Council Conclusion on Personalized Medicine for patients, which specified that 'Personalized Medicine relates to the broader concept of patient-centered care and takes into account that, in general, healthcare systems need to better respond to patient needs' (2015/C 421/03).

PM is creating a new configuration of the healthcare system: similarly to what occurred with medicine, we can expect a healthcare system that includes personalized, predictive, preventive, participatory and person-centered care approaches¹.

The International Consortium of Personalised Medicine (ICPerMed), an EU member state-driven initiative, aims at aligning efforts in all areas of PM by fostering international coordination of research and innovation funding and policies. To support these efforts "Widening Sino-EU policy and research cooperation in Personalised Medicine" (Sino-EU PerMed) aims at connecting ICPerMed strategies and activities with relevant Chinese stakeholders. To achieve this goal the Sino-EU PerMed analysed the PM landscape in China via a scientific and technological mapping. On this basis a stakeholder workshop was organised to discuss barriers and needs in the PM collaborations between China and Europe, identify policy implications and suggest recommendations for policy makers.

1 P. De Koning and J. Keirns, "Clinical pharmacology, biomarkers and personalized medicine: Education please," *Biomark. Med.*, vol. 3, no. 6, pp. 685-700, 2009, doi: 10.2217/bmm.09.53.

The opportunities and challenges

Personalised Medicine Landscape in Europe and China

Chinese activities on Personalised Medicine:

With the 13th Five-Year Plan (2016 – 2020), China has confirmed its prioritisation of Personalised Medicine as a strategy to enable better healthcare outcomes. With the Chinese Personal Medicine Initiative (PMI), which is expected to be funded with \$9.2 billion by 2030², China has set up the most expensive plan in the world³. China's PMI has made it possible to gather and access data for millions of people in order to enable better healthcare provisions, particularly for oncology.

Targets and priorities of China's Precision Medicine program are:

1. Build a world-class research platform and support system for which China maintains ownership of the core technology.
2. Develop novel drugs, vaccines, devices, and equipment with China-owned intellectual property rights.
3. Establish a set of internationally recognized guidelines and standards for clinical interventions to prevent, diagnose, and treat diseases.
4. Improve prevention and treatment for major illnesses and stimulate growth in related industries, such as biopharmaceuticals, medical devices as well as health-services.
5. Contribute to reforming the health care system, revising the current model for medical practice, and successfully delivering the Healthy China 2030 initiative⁴.

As a result of PMI in 2020 and 2021, a total of 18 personalized drugs were approved, involving four disease fields, including tumor (11), infection (hepatitis C infection (3), HIV infection (2), haemophilia (1) and rare disease type II mucopolysaccharide storage disease (1), mainly in the field of tumor, of which the number of drugs for non-small cell lung cancer is the largest (4)⁵.

2 <https://www.biospectrumasia.com/opinion/30/18319/is-the-stage-set-for-precision-medicine-to-take-off-in-asia.html>

3 <https://innovator.news/china-leaps-ahead-in-precision-medicine-72cfc469df3d>

4 Zhan and Qian (2016) Opportunities and advantages for the development of precision medicine in China

5 Yang Ye, Shanghai Institute of Materia Medica (2022) Presentation on Sino-EU PerMed Stakeholder Workshop; title: "Personalised Medicine landscape in China"

In 2021 the 14th Five-Year Plan (2021 – 2025) was announced, “considerations for establishing legal frameworks for drones, online healthcare, financial technology, smart delivery, etc.”. However, Personalised Medicine no longer explicitly appears in the plan as it did in the 13th Five-Year Plan, and its approach inspire other disciplines such as 1. high-tech and new technology for better production and supply, 2. new technology for diagnostics, therapy and prevention, 3 Developing specific drugs for cancer and cardiovascular disease treatment, 4. Genetic technology, 5. Improve electronic health records and accelerate data sharing among medical and healthcare institutions and 6. telemedicine and remote diagnosis⁶.

Looking at China in terms of medicine, Traditional Chinese Medicine cannot be avoided. In the Sino-EU Permed S&T mapping China witnesses plenty of research that, although published within the umbrella of TCM, refers to Personalised Medicine⁷. The basic principle of TCM is to use individualized treatments adapted to the respective patient. However, these treatments are complex in their composition and effect. The use of findings from TCM in modern PM would have to be further researched, for example in the analysis of ingredients for new drugs or preventive measures.

China remains an important partner in many Scientific, Technological and Innovation (STI) related challenges, including healthcare research and PM. Formidable capacity in genomic sequencing, access to data from millions of patients and the promise of solid governmental support are the assets that China is bringing to the field of PM⁸.

China has taken important steps to favour international S&T collaborations, and it became part of the International Council of Harmonisation in pursuit of global harmonization of drug development standards and is heavily investing in health data infrastructure as well as on electronic health records format (EHR). China’s impressive rise as an innovation powerhouse requires a strategic vision of how Europe can grasp the opportunities arising from STI engagement with the world’s second-largest economy⁹. Enhanced cooperation between China and Europe will have a high impact on the way research is performed, innovation is promoted and healthcare services are delivered. Therefore, it could be of great benefit for citizen.

6 <https://cset.georgetown.edu/publication/china-14th-five-year-plan/>

7 I. Romagnuolo et al., “Sino-European science and technology collaboration on personalized medicine: Overview, trends and future perspectives,” *Per. Med.*, vol. 18, no. 5, pp. 455–470, 2021, doi: 10.2217/pme-2021-0030.

8 David Cyranoski, “China embraces precision therapy,” *Nature*, vol. 529, no. 7584, pp. 9–10, 2016.

9 M. Workshop and I. Paper, “Sharpening Europe ’ s approach to engagement with China on science, technology and innovation,” no. December, pp. 1–23, 2021.

European activities on Personalised Medicine:

Globally, nearly 40 countries have their own approach towards a Precision Medicine initiative¹⁰, while more than 30 states have joined the European initiative ICPeMed, including EU member states as well as Canada, Israel, Brazil and Iran¹¹.

ICPeMed was initiated during several workshops organised by the European Commission throughout 2016. The basis for this was the previous project, PerMed, funded from 2013 to 2015 by the European Union's 7th Framework Programme. PerMed already made clear that real progress in Personalised Medicine could only be achieved when research and implementation efforts are covering the entire value chain. This was documented in a Strategic Research and Innovation Agenda describing challenges and giving recommendations for advancing this field. The first action of the ICPeMed members was to refine the recommendations of PerMed and define "actionable research items" that can more or less directly be converted to research funding programmes on national, regional, European or even international level. This result was published as the ICPeMed Action Plan¹².

The European Commission's new EU Framework Programme for Research and Innovation: Horizon Europe (2021 – 2027) opens a new chapter of collaborations. From 2023-2033, the European Partnership for Personalised Medicine (EP PerMed) will provide the further framework for cross-member state cooperation in Europe. The vision of the European Partnership is to improve health outcomes within sustainable healthcare systems through research and the development and implementation of PM approaches for the benefit of patients, citizens, and society¹³.

Based on initiatives like ICPeMed the European PM funding landscape looks overall promising – although it has to be assured that funding will be still available over a longer time period since Europe is still at the beginning of the PM implementation. Even though PM in Europe has been able to raise substantial funding for science and innovation over the last years and with significant participation from industry, the main focus is still on cancer and rare diseases. There is a continued need for large investments in PM-related research in major diseases such as cardiovascular, metabolic, pulmonary, arthritis, infectious.

10 <https://innovator.news/china-leaps-ahead-in-precision-medicine-72cfc469df3d>

11 <https://www.icpermed.eu/en/icpermed-members.php>

12 <https://www.icpermed.eu/en/icpermed-about.php>

13 https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_he-personalised-medicine.pdf

In Europe, the health-related data belong to the person and its use is strictly regulated. Access to and use of health-related data within and across borders in Europe still lags behind and it represents a bottleneck for scientific and health care advances: adequate legislative frameworks and digital infrastructures need to be fostered. Patient engagement and involvement plays a key role particularly in consideration of the potential benefit real world data represent.

On the other side, the uptake of PM-solutions in healthcare is slowly progressing across Europe: Major healthcare reforms will be needed down the road. Regional/national differences in the organization of health systems need to be addressed to avoid access inequalities to PM-based healthcare; this comes even more into effect when thinking on a global PM approach. This has shed lights on the sustainability considerations and new cost/reimbursement models are being developed in Europe, taking the whole societal picture into account¹⁴.

Overall PM is a nowadays global opportunity thus European/International collaborations are of key importance.

14 Ejner Moltzen, Innovation Fund Denmark (2022) Presentation on Sino-EU PerMed Stakeholder Workshop; title: Personalised Medicine Landscape in EU

Common opportunities in the Sino-EU PM cooperation:

China remains an indispensable partner in many societal challenges, including health research and Personalised Medicine¹⁵.

Personalised Medicine is fuelling cross-sectorial and trans-national collaborations worldwide both at a scientific and technological level. China and Europe are at the forefront of the PM rush, with increasing level of STI collaborations in the past years¹⁶.

Great opportunities arising from collaborations in PM between Europe and China are:

- Access to millions of patients and thus a larger group of individuals with rare diseases for whom PM approaches can be developed.
- Cardiovascular diseases, since this type of disease is highlighted twice in 14th Five-Year Plan (Building National Medical Centers for cardiovascular, pulmonary, cancer, trauma, and child health; Developing specific drugs for cancer and cardiovascular disease treatment
- Valorisation of the Chinese largest genomic sequencing capacity in the world.
- The ongoing digitalization process in the implementation of PM is a great opportunity in sharing experience.
- Pre-clinical data research seems most promising in the moment for joint scientific collaboration.
- MOST funding and EU funding for PM projects. In China's provinces budget for research projects is available.

15 David Cyranoski, "China embraces precision therapy," *Nature*, vol. 529, no. 7584, pp. 9–10, 2016.

16 I. Romagnuolo et al., "Sino-European science and technology collaboration on personalized medicine: Overview, trends and future perspectives," *Per. Med.*, vol. 18, no. 5, pp. 455–470, 2021, doi: 10.2217/pme-2021-0030.

Common challenges in the Sino-EU PM cooperation:

The Europe–China relationship in health research and innovation is of high importance to advance PM-related Science, Technology and Innovation (STI) activities. China and Europe share the same strategic goals and interests. Both regions have challenges that are primarily related to and driven by their regional environment. In addition, there are the challenges that arise when two regions start from different bases to achieve the same goal in a different legal and social environment and looking for global interaction. The following are the *challenges* that are currently influencing cooperation in PM between Europe and China.

- Due to the different culture, values and language, establishment of deep and trustful cooperation needs time.
- Focus on different research topics. The western medicine is looking for a patient-centered modern medicine PM approach. In China, Traditional Chinese Medicine is practiced alongside modern medicine.
- The Corona pandemic and legal obstacles make it difficult to obtain and exchange scientific data especially human samples. Established collaborations are hampered by the lack of mobility and slowly come to a standstill, new collaborations can hardly be established.
- Research collaborations fails due to legal uncertainty, especially in the area of data laws. Data sharing between players in the private sector also takes place only to a very limited extent.
- PM can only be successful if a global approach is taken. Strategic initiatives in Europe and China, exist to establish and implement PM. Currently, there is only limited exchange.
- The healthcare systems in China and Europe are different and various obstacles that arise in the implementation of PM in the regions are China and Europe specific. Is this limiting to collaborations in science? A deeper understanding of the Healthcare System of both regions is needed.
- Current research funding in China and the EU is not aligned. The Third Country participation of China in the EU research framework programs with its own budget is possible and a co-fund exists, but this is not oriented to the EU calls.
- The advent of the new Chinese data laws combined with the by now fully implemented GDPR laws in the EU has made it difficult to collaborate between China and the EU if data/sample sharing is involved. This issue needs to be more elaborated by a deeper look into the topic. (see excursus Data Protection Laws).

Data Protection Laws

A fundamental barrier that currently complicates the global PM collaboration are the data protection regulations in place in EU and China. Not only in consideration of the ownership of the personal data but especially for how the regulations are set and administered. In China health-related data are treated as a national priority while in Europe the health-related data belong to the single person.

In Europe the General Data Protection Regulation (GDPR)¹⁷ regulates the use of data. The general principle of the GDPR is that health data may not be used except if there is a consent (Art. 4) or a legal exemption (Art. 9) such as processing for archiving and public health purposes and research purposes. When it comes to cross-border collaboration that might require a data transfer from EU to Third Countries (such as China) Art. 44 GDPR requires the same level of data protection in the country where the data is transferred. In this regard the European Commission adopted new standard contractual clauses 18 for the transfer of personal data to third countries. According to these clauses Chinese standards has been regarded as comparable. On top of this, national laws often add further requirements to GDPR regulation. Currently researchers need to precisely explain which data is being collected and how it is used to avoid a fine.

In China several laws and regulations came into force over the past years to regulate the data use and build a comprehensive framework.

The Data Security Law focusses on national security, public interest and fundamental data. The Cybersecurity Law focusses on security of information infrastructures and facilities. On 1 November 2021 the Personal Information Protection Law (PIPL) of the People's Republic of China came into force.¹⁹ From a broader cyber and data security governance perspective, the PIPL, the Cybersecurity Law, and the Data Security Law form an over-arching framework to govern data protection, cybersecurity and data security in China for years to come.

For what concerns scientific collaborations, The Measures for Managing Scientific Data, which came into force since 2018 remains the most important regulations when it comes to scientific data. The measures announce the transfer of scientific data to data centers. These should be operated by the respective administrative levels, which guarantee the confidentiality and security of the data and, if necessary, enable quality control by third parties. The measures relate to scientific data supported by government budget funds. Scientific data should not be made public if they concern state secrets, national security, the public interest, trade secrets or privacy (Art. 25 of the Measures).²⁰

All this considered, the data protection architecture in China is very complex. It is multi-layered with different levels of hierarchies and multiple rules at each level and administered by various agencies.

17 General Data Protection Regulation (GDPR) – Official Legal Text (gdpr-info.eu)

18 E. COMMISSION, "ANNEX to the COMMISSION IMPLEMENTING DECISION on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council." 2021.

19 Annie Xue, GEN Laws Firm (2022) (2022) Presentation on Sino-EU PerMed Stakeholder Workshop; title: Personalized Medicine under China Privacy Rules: Opportunities and Challenges

20 State Council (2018). Measures for Managing Scientific Data. 17. März. http://www.gov.cn/zhengce/content/2018-04/02/content_5279272.htm

Recommendations

1. Gain Knowledge

Creation of an active exchange platform for scientific experts in PM to push the PM agenda at scientific, innovation and policy level. The platform should facilitate dialogue, understand barriers and co-create potential solution enabling research collaborations.

2. Exchange of Knowledge

Establish a continuous dialogue between European and Chinese expert groups and other relevant bodies and set up regular interactions between them.

3. Implementation of PM

Learning how PM is being implemented in EU and China, taking into account the ongoing digitalisation process and the different approaches at regional level.

4. Funding opportunities for EU-China PM cooperation

Stronger exchange between MOST and European Commission and better coordination on calls to facilitate STI collaboration. Open collaboration with and among scientific and industrial partner should also be promoted. Lastly, exchange with regional funding bodies should be considered.

5. Data protection law

Compilation of information/guidelines for scientists on how well-known players in the field as e.g., international companies deal with data protection laws, data transfer and data savings. Adapting the approaches for scientists.

6. Data sharing

Promote workshops to reduce grey areas under data protection law and lack of clarity regarding the rights to use data in EU and China; Jointly co-develop a pilot project or a study case to disseminate the right model(s) for collaborations and data sharing



Innovation Fund Denmark

