Deliverable 2.3:

Workshop Report

Sino-Eu PerMed Stakeholder Workshop February 17th, 2022

Contents

List of Abbreviations

Abbreviation	Explanation
CM	Complementary Medicine
CAM	Complementary and Alternative Medicine
EPO	European Patent Office
EP PerMed	European Partnership on Personalised Medicine
IC PerMed	International Consortium on Personalised Medicine
IM	Integrative Medicine
IPC	International Patent Classification
MeSH	Medical Subject Headings
NKPs	Chinese National Key R&D Programmes
PM	Personalised Medicine
PPT	PowerPoint presentation
PubMed	Free search engine accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics
R&I	Research and Innovation
Sino-EU PerMed	Acronym of the EU funded project "Widening Sino-EU policy and research cooperation in Personalised Medicine"
TCM	Traditional Chinese Medicine
WP	Work Package

1. The SINO-EU PerMed Project

Personalised Medicine (PM) approaches bring along immense potentials to improve diagnosis and treatment of diseases and prevention strategies by taking into account individuals' geno- and phenotypes, biomedical, lifestyle or environmental data. The International Consortium for Personalised Medicine (ICPerMed) is a member state-driven initiative of over 40 international ministries and funding agencies. The European Commission (EC) is an active observer and supports by funding several related projects. ICPerMed aims at aligning efforts in all areas of PerMed by fostering international coordination of research and innovation funding.

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 will disseminate and coordinate the following activities. Inventory and analysis of the PerMed landscape in China through a mapping. In addition, the Sino-EU-PerMed consortium will exchange expertise and experts through workshops and delegation trips to China and in Europe. Thereby we will gain a better mutual understanding of PerMed activities and related cultural aspects as well as health economics issues. By establishing technical taskforces and running a series of targeted workshops, Sino-EU-PerMed will promote international standards and pave the way for future communication, collaboration, and undertakings. Therefore, the implementation of a dissemination plan is an essential part of the project.

Our consortium and activities aim at maximizing the unique and long-term impact PM approaches have on cooperation and are aligned with ICPerMed. The cooperation with China in the forms described within the Sino-Eu PerMed will allow the International Consortium for Personalised Medicine to further strengthen Europe's leading role in this area and contribute to a successful implementation of PerMed in the global context and foster joint PerMed projects between Europe and China.

2. Main objectives of the stakeholder workshop

The main objective of this workshop, which took place in Florence (Italy) on February 17th in a hybrid mode, were to:

- present the Personalised Medicine Landscape in China and Europe
- present the main barriers to the collaboration between China and Europe
- discuss each identified barrier and devise strategies to overcome the latter
- develop recommendations for policy makers' use.

Within the Stakeholder Workshop, the consortium has also shared the main outcomes of the scientific and technological mapping performed in 2020.

The outcome of the workshop will be gathered in a policy brief containing recommendations to enhance the current level of cooperation and foster the participation of Chinese stakeholders in the IC-PerMed consortium.

3. Stakeholders' profile

The Stakeholder Workshop laid on the main findings of the first 18 months of the project activities and the outcome from the discussion with and within the expert group. It has had primarily addressed:

- Personalised Medicine scientific and industry representatives
- Public and private non-for-profit funding agencies
- National and regional policy makers
- Other relevant decision-makers

4. Main topics of the Workshops

4.1. Overview of the European and Chinese Personalised Medicine Landscape

The workshop started with a brief introduction on the Personalised Medicine Landscape in China and Europe. The main aim of this session was to provide an overview to all participants with an overview of the current level of maturity of this approach as well as the main barriers to the implementation and collaboration on PM between the two Regions
The session has seen presentations from Dr. Ejner Moltzen, Chair of IC PerMed, Prof. Yang Ye, Shanghai Institute of Materia Medica, CAS and Mr. Gianni D'Errico, International Project Officer at Fondazione Toscana Life Sciences, partner of the project.

4.2. Data Protection Law

A fundamental topic that currently hampers the collaboration between the two regions has been identified with the applicable data protection laws. The definition of who owns the data is different in China and Europe. In China health-related data are treated differently (personal information, national security) according to the type of data while and in Europe health-related data belong to the single person who need to express a clear consent to its treatment by third parties. This has been an essential point that was discussed during the workshop.
Paramount insights on the topic have been provided by Dr. Thomas Pattloch from Taylor Wessing and Dr. Annie Xue from GEN Law Firm.

4.3. Traditional Chinese Medicine

Complementary Medicine (CM), Complementary and Alternative Medicine (CAM), and most recently Integrative Medicine (IM) are terms used interchangeably at international level to define a therapeutic approach to the disease based on person; this approach encompasses a vast variety of treatments and solutions that help to prevent, cure, and manage different conditions in combination with official medicine therapies.

To date, in China we witness plenty of research that, although published within the umbrella of Traditional Chinese Medicine (TCM), refers to Personalised Medicine whose approach is similar to TCM. This could therefore be an area in which collaboration between the two regions on Personalised Medicine could be increased.

Similarly, also patent applications with scientific and technical innovations related to Precision Medicine refer to TCM.
In Europe, Complementary Integrative Medicine (CIM) is being more and more embedded within the healthcare systems. CIM is a term generally used to encompass a diverse range of therapies and health products that aim to prevent, treat or manage illness. The term CIM is often used interchangeably with traditional, holistic, natural or alternative medicine and other variations. CIM is often indicated to reinforce person-centered healthcare approaches
This suggested us that a dedicated session on TCM within the Stakeholder Workshop was of paramount importance.
For this topic, we have identified Prof. Gary Deng, from the Memorial Sloan Kettering Cancer Center (USA) and Prof. Gianni Amunni – Director of Institute for the Study and Prevention of Cancer (Italy) to make a presentation on the links between TCM and Precision Medicine and be a key point for the discussion on this aspect.

5. Logistics of the Workshop

The workshop took place in a hybrid modality, with project partners, speakers and relevant stakeholders meeting either in presence, or joining remotely.

The hybrid mode was a desirable solution during that phase of the pandemic (where most EU citizen have been fully vaccinated and certifications such as the EU Digital COVID Certificate are issued by

many EU health authorities) and combined the pros of virtual conferences (easy access, increased attendance) and face to face conferences (above all the personal contact).

The initial plan was therefore to have most project partners joining in person in Florence, but a last-minute increase of the number of COVID cases due to the new virus variation has made this option less favorable.

5.1 Location

Considering that we expected around 20 people to join the workshop in person, we searched for a venue big enough to ensure social distancing and follow the safety protocol of the hosting country. The certificates of full vaccination of proven negativity to COVID were mandatory for all the stakeholders joining in presence.

We contacted many location providers and asked for quotations in order to establish a best value for money approach in choosing the location. We visited three of them and eventually Congress Centre "Auditorium al Duomo", in Florence city center, was the most suitable and appropriate for this event. It was located 5' walk from the central train station, so easily accessible for everyone.

The location also provided technical service for the online connection set-up and internal catering, which we hired for breakfast and lunch.

The technical service took care of the online connection, WebEx platform management, as well as the audio/video settings of the room. The event has also been recorded, both via WebEx and a physical camera that was in the room.

The workshop last around 5 hours, where a fruitful discussion between partners, speakers and stakeholders took place.

Speakers who joined the event in person were also invited to a business dinner the night before the event. This reinforced the personal relations and put the basis to a fruitful discussion to be hold during the event.

Figure 1. Florence, location of the Workshop

It was unfortunately not possible for any of the Chinese speakers/participants to join the event in person, as travel restriction were applying in China.

The event did not have parallel sessions and was held in the same room.

5.2 Agenda

The agenda had been finalized weeks before the event and all speakers had been debriefed prior to the meeting, in order to make sure they would touch the points that were most important for the type of discussion and outcome we were aiming at.

17 February 2022 | Florence, Italy, Congress Centre "Auditorium al Duomo" & online

08:00 - 14:30 Central European Time

15:00 - 21:30 Beijing Time

In total, **we had 81 stakeholders** who registered to the event (both in presence and online). The group of registrants was heterogenous and coming from Europe, China and the United States.

WELCOME AND INTRODUCTION			
08.00 – 08.10	Institutional Welcome	**Dr. Paolo Morello Marchese**	CEO of Health Autority of Central Tuscany
08.10 – 08.20	Introduction to the project and to the workshop	**Dr. Sabine Puch**	DLR Project Management Agency
08.20 – 08.30	Horizon Europe and International aspects	**Dr. Jean Luc Sanne**	Policy Officer – Health Innovations, European Commission
SESSION 1			
08.30 – 08.50	Personalised Medicine landscape in EU	**Dr. Ejner Moltzen**	IC-PerMed Chair, Innovation Fund Denmark
08.50 – 09.10	Personalised Medicine landscape in China	**Prof. Yang Ye**	Materia Medica Center Shanghai
09.10 – 09.30	Technological and scientific mapping	**Mr. Gianni D'Errico**	International Project Officer & European Affairs, Fondazione Toscana Life Sciences
09.30 – 10.00	Break Out Session on Personalised Medicine Barriers and Needs		
10.00 – 10.10	Sum up Group discussions		
10.10 – 10.20	Coffee Break		
SESSION 2			
10.20 – 10.40	Traditional Chinese Medicine and Personalised Medicine	**Prof. Gary Deng**	Memorial Sloan Kettering Cancer Center
10.40 – 11.00	Traditional Chinese Medicine and Personalised Medicine	**Dr. Elio Rossi**	Presentation of "Centro Fior di Prugna – Outpatient clinic for traditional Chinese medicine, acupuncture and homeopathy"
11.00 – 11.25	Break Out Session on TCM and PM		
11.25 – 11.35	Coffee Break		
SESSION 3			
11.35 – 11.55	Privacy and data ownership	**Dr. Thomas Pattloch**	Taylor Wessing
11.55 – 12.15	Privacy and data ownership	**Dr. Annie Xue**	Gen Law Firm
12.15 – 12.40	Break Out Session on Privacy and data ownership		
12.40 – 12.50	Sum up group discussions Session 2-3 discussions		

12.50 – 13.00	Wrap up and closure

6. Main discussions of the Workshop

6.1 Welcome and Introduction

The main aim of this session was to provide attendees with a brief introduction on the project and how it is aligned with the EU mission and policy.

6.2 Dr. Sabine Puch – Introduction to the project and to the workshop

Dr. Puch, Project Manager at DLR, the lead project partner gave the overview of the current strategic initiatives that the European Commission is supporting, International Consortium for Personalised Medicine (IC-PerMed), relation between Sino-EU permed and all the other Coordination and Support Actions which compose the so called IC-PerMed Family.

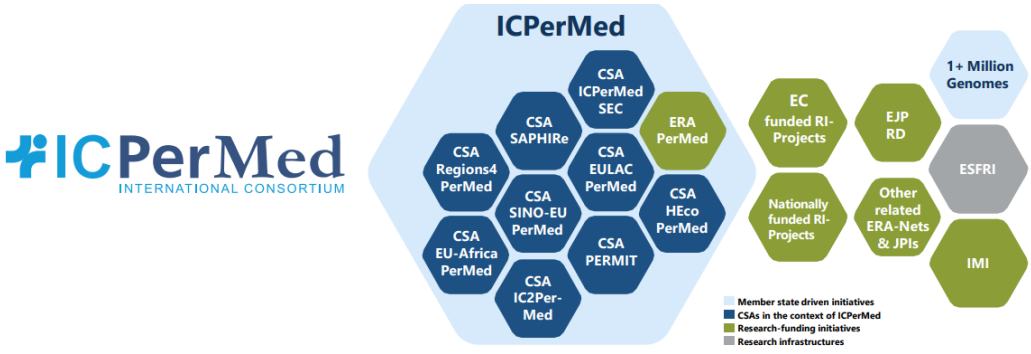

Figure 2. The ICPerMed Family

She then presented the main aspects of the Sino-EU PerMed, its objectives, methodology and structure.

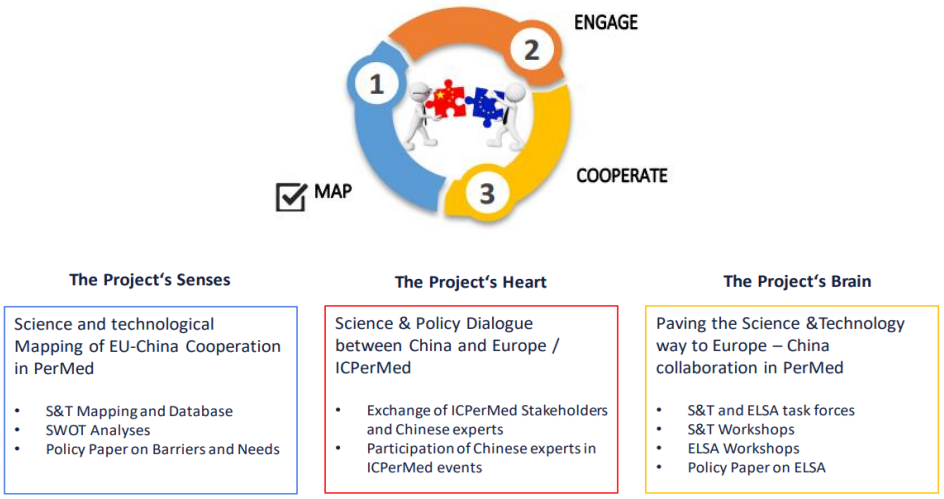

Figure 3. Major activities and objectives of Sino-EU PerMed

The main goals of the project:

- Map and analyse the PerMed landscape in China,
- Exchange expertise, engage stakeholders and create mutual understanding,
- Establish technical taskforces and running targeted workshops,
- Foster participation in IC PerMed and its Action Plan
- Promote international standards.
- Disseminate outcomes and communicate on opportunities.

She lastly presented the agenda of the workshop and the expected outcomes of the event.

6.3 Dr. Jean-Luc Sanne - Horizon Europe and international aspects

Dr. Sanne, Project Officer within the DG Research and Innovation at the European Commission started the presentation by introducing the ICPerMed Consortium and stating the importance of Personalised Medicine at the global level, by also mentioning ERA PerMed, which has achieved a relevant international dimension in its calls.

Dr. Sanne has also present the forthcoming European Partnership on Personalised Medicine (EP PerMed), which will be strategically important to allow enhance cross border collaboration to tackle the current bottleneck of PM and deliver better care to patients and citizens. The EP PerMed is thought to:

- Bridge the gap between PM research and its implementation in the healthcare system
- Bring together all the stakeholders involved in this field in the partnership.

Dr. Sanne, presented has presented European Commission's global approach to Research & Innovation (R&I) whose principles will have to guide the future collaborations between EU and Third Countries.

The global approach will hopefully reinforce the international cooperation in Horizon Europe by while safeguarding the European values:

Figure 4. Global approach of the European Commission to Research & Innovation: Europe's strategy for international cooperation in a changing world

1. General openness to international participation: now more entities from all over the world can take part in Horizon Europe collaborative projects, researchers and innovators of any nationality can apply for grants and entities from most low-middle income countries are automatically eligible for funding
2. Targeted international cooperation actions specifically relevant for international cooperation and targeted with key partners on strategic thematic areas.

One of the underlying principle of the EU approach is Open Science which remain essential to generate new knowledge and its translation into new innovations: publications need to be freely available, in order to improve quality and efficiency of R&I and an active engagement of the society.

Data sharing, in this sense, needs to be "as open as possible, as closed as necessary".

This last topic was the main focus of one of the workshop sessions.

7. SESSION I

7.1 Dr. Ejner Moltzen - Personalised Medicine Landscape in EU

Dr. Ejner Moltzen, Chair of IC PerMed, gave his speech on the PM Landscape in the European Union.

Dr. Moltzen presented more in detail the work that IC PerMed is doing in facilitating the uptake of Personalised Medicine, engaging reginal, national and international stakeholders, favoring the development of new policies, promoting and coordinating investments in Research & Innovation along the full value chain to of personalized medicine solutions. He also presented ERA PerMed, a consortium of 32 international funding agencies from 32 countries which fund Research in PM through Joint Transnational Calls for proposal.

Dr. Moltzen presented the main documents the IC PerMed has published in preparation of the European Partnership on Personalised Medicine which describe its goals and overall vision as well as the potential impact of such undertaking.

The EP PerMed, specifically, will aim at improving health outcomes for citizens and patients and at an optimized and sustainable healthcare, with Europe being at the forefront of Research & Innovation, in collaboration with international partners.

The European PM funding landscape looks overall promising, although there is still room for improvement for:

- PM approaches outside cancer and rare diseases;
- Access to and use of biomedical and healthcare data across borders, which in Europe is still lagging behind;
- Patient engagement;
- The uptake of PM solutions in healthcare, in particular:
    - Healthcare reforms
    - Reduce the health inequalities that, also due to Regional/national differences in organization of health systems, might be generated
    - Explore and adopt new cost/reimbursement models
    - Invest more in Personalized prevention

PM remains a global challenge, and international collaborations are important to accelerate these transformations:

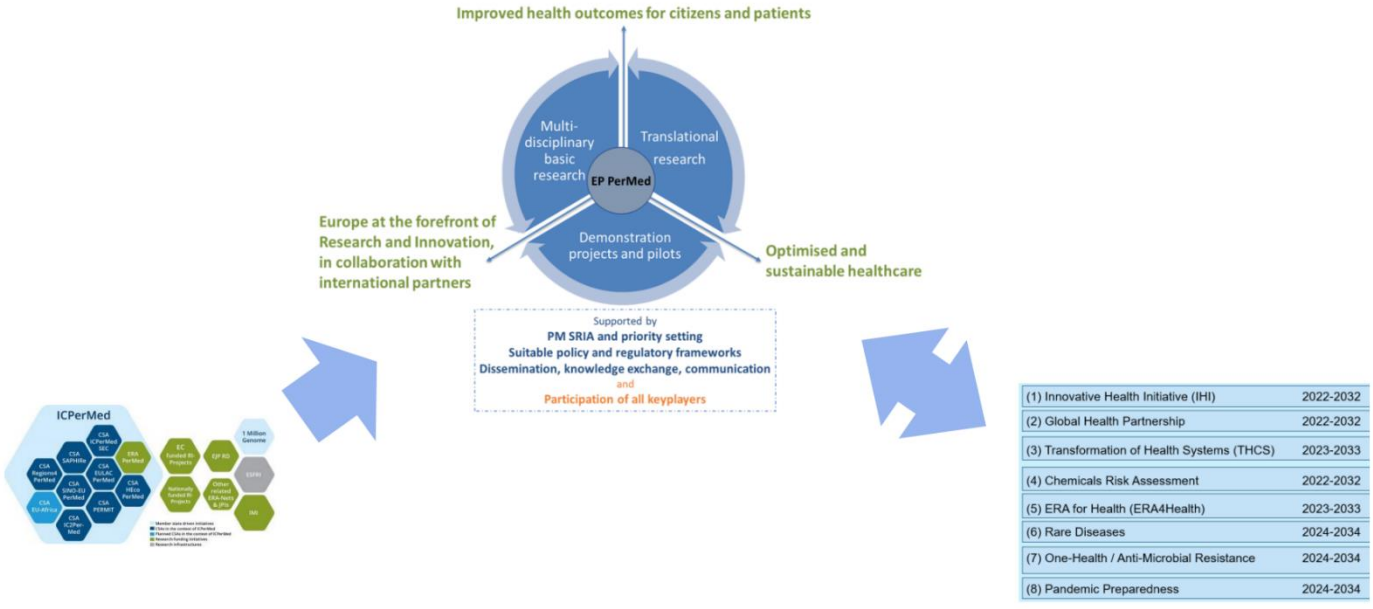

Figure 5. Investment in the future: European Partnership for Personalised Medicine 2023-33

7.2 Prof. Yang Ye - Personalised Medicine Landscape in China

Prof. Yang Ye from Shanghai Institute of Materia Medica, CAS and Dr. Yong Xu from The Guangzhou Institutes of Biomedicine and Health (GIBH) gave to the audience the overview of the Personalised Medicine landscape in China.

From the industrial point of view, China has witnessed an incredible growth of the companion diagnostics.

Personalized therapies as well are one of the important trends in the medical and health industry in the future. Presently, they are increasing all over the world, but its R&D still faces big challenges, such as insufficient understanding of the molecular mechanism of disease, which requires new research tools or methods to search for relevant biomarkers and the slow clinical application of new technologies.

On the other hand, with the vigorous development of personalised medicine within the last 13th Five-Year Plan (2016-2020), new PM therapies and companion diagnostics and a modernization of the regulatory framework have been generated.

The presentation of Prof. Ye was concluded with an example of a pilot project in the Chinese Academy of Sciences, "Personalised medicine – drug research and development based on the molecular mechanisms of disease", which has the following objectives:

- To discover biomarkers to enable the personalized treatment of clinically used drugs or drug candidates under the development
- To develop new personalized drugs
- To integrate resource, technology and information platforms for personalized medicine research
- To establish an innovative system for the research and development of personalized drugs

7.3 Mr. Gianni D'Errico - Technological and Scientific Mapping

The technological and scientific mapping on Personalised Medicine was carried out, during the first phase of the project, by Fondazione Toscana Life Sciences (TLS).

Mr. Gianni D'Errico, Project Officer at TLS, presented the overall outcomes of the mapping, starting with a brief introduction on the methodology underlying the mapping.

The work aimed to outline the status of EU–China collaborations in the field of PM through the mapping of patents and publications and providing an overview of the main funding programs in PM. The results of the analysis helped identifying strategic areas of interest for collaboration to further strengthen Europe–China cooperation and meet the global health challenges of the future. The results were also used as background for the organization of the Stakeholder Workshop.

Considering the importance Traditional Chinese Medicine (TCM) has in China and that many of the activities there also fall within the Personalised Medicine umbrella, it has been decided to also map patents and publicaitons in this area as it was observed that a lot of work that is carried out under

the umbrella of TCM matches also PM criteria, suggesting that TCM presents some common ground with PM approaches to treat medical disorders.

The mapping highlighted a high level of papers on Personalised Medicine published both in China and in Europe (research groups affiliated to China or to European Institutions) which suggests us that PM is seen as a priority in the two Regions (Figure 2).

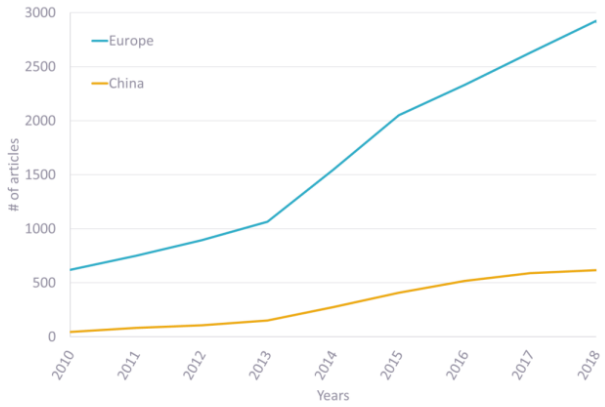

Figure 6. Trends in the publication of articles related to PM in EU and China

This trend is confirmed also in terms of collaboration (which are to be intended as joint publications) between China and Europe. In particular, there are 448 SINO-EU joint papers, participated by 1171 Chinese research groups and 6543 European research groups.

The collaborations identified by the patent mapping (26 EU-CN co-assigned and 140 EU-CN collaboration patents) are few and have been reduced in recent years.

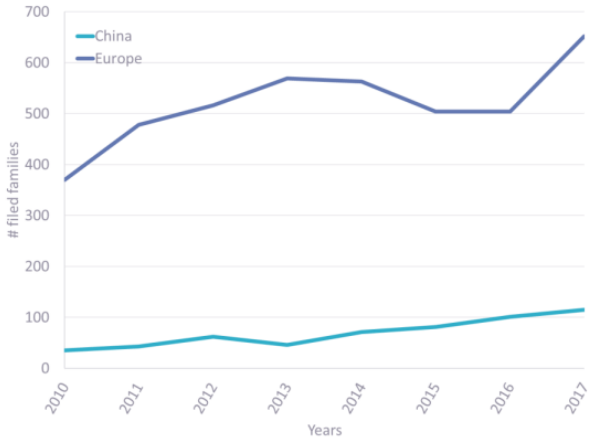

Figure 7. Trends in the filing of patents related to PM in EU and China

In most cases they are collaborations between EU and CN subsidiaries of the same firm. Only two collaborations between EU and CN have been carried out by public institutions, in particular INSERM (France) and Shanghai Jiao Tong University and University of Singapore.

To date, we observed that around 3,7% of EU-owned patents are filed in China and around 9,8% of Chinese-owned patents are filed in an EU country, suggesting that cultural barriers and different standards and regulation may represent a weakness for technological collaboration.

The mapping has also been published in the international journal Future Medicine and can be accessed here: https://www.futuremedicine.com/doi/10.2217/pme-2021-0030

8. SESSION II

8.1 Dr. Gary Deng - Traditional Chinese Medicine and Personalised Medicine

The second session has started with a presentation given by Prof. Gary Deng from Memorial Sloan Kettering Cancer Center.

Dr. Deng has provided an introduction to Traditional Chinese Medicine (TCM) and its key tenents:

- **Health** is based on the balance between Yin (relaxed, calm, damp, quiet, passive) and Yang (excited, heat, dry, moving, active), the harmonic interactions between organic systems and the proper flow of qi (energy), blood and humor along meridians
- **Illnesses** depend on the interaction between internal elements of the host and external elements
- **Diseases** are described in syndrome patterns, rather than specific pathology
- **Diagnosis** is achieved by "望闻问切": looking, listening, asking, taking the pulse
- **Treatment** is usually multi-modal, including behavioural changes, dietary changes, herbal formulations, acupuncture, manual manipulation, etc.
- **Prevention:** "The Tao (Way/Art) of Nurturing Life 养生之道". Strengthening the body with proper diet, movements, management of emotions, and circadian rhythms
- Each individual has a base **body constitution**, which influence susceptibility to and presentation of diseases. E. g. a "Phlegm-Dampness Constitution" is more prone to metabolic syndrome, diabetes, and obesity.

Dr. Deng then presented SymMap, an integrative database of Traditional Chinese Medicine enhanced by **Sym**ptom **Map**ping. They manually curated 1717 TCM symptoms and related them to 499 herbs and 961 symptoms used in modern medicine based on a committee of 17 leading experts practicing TCM. Next, we collected 5235 diseases associated with these symptoms, 19 595 herbal constituents (ingredients) and 4302 target genes, and built a large heterogeneous network containing all of these components. SymMap integrates TCM with modern medicine in common aspects at both the phenotypic and molecular levels. Furthermore, we inferred all pairwise relationships among SymMap components using statistical tests to give pharmaceutical scientists the ability to rank and filter promising results to guide drug discovery

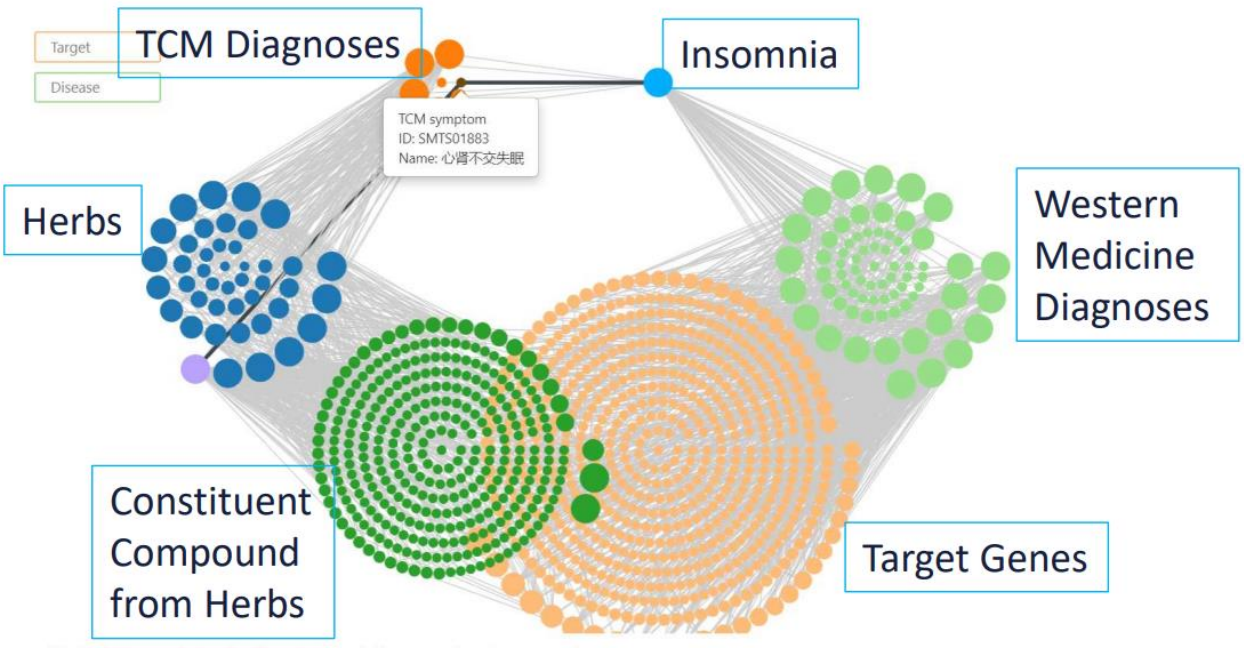

Figure 8. SymMap: an integrative database of Traditional Chinese Medicine enhanced by symptom mapping

TCM symptom–herb relationships provide tremendously valuable guidance for drug discovery programs. Prof. Deng presented SymMap as a comprehensive database integrating TCM with Modern Medicine via external symptom mapping and internal molecular mechanisms

He concluded drawing the potential connections between PM and TCM: Western medicine can offer a rigorous scientific research methodology (e.g., omic technology, bioinformatics, clinical trial design), while TCM can offer a different perspective in looking at the problems, as well as a holistic clinical view (rather than a single pathology) and access to a tremendous amount of data which can be further exploited globally.

8.2 Dr. Elio Rossi - Traditional Chinese Medicine and Personalised Medicine

Presentation of "Centro Fior di Prugna – Outpatient clinic for traditional Chinese medicine, acupuncture and homeopathy"

The presentation of the clinic was given by Dr. Elio Rossi from Centro Fior di Prugna, the Tuscan regional reference center for acupuncture and Traditional Chinese Medicine (TCM), which has been established in 1995 as the first public service of TCM in Italy.

The patients of the Centro Fior di Prugna are Italian and foreign people living in Tuscany, who can access the services of the facility without medical prescription, and for whose services their contribution to the public healthcare system is correlated to their personal income. Exceptions include patients with disabilities, oncological pathologies or unemployed patients for whom the service is covered by the regional healthcare.

Traditional TCM techniques include integrative medicine, a combination of therapeutic Chinese techniques, change in the lifestyle and self-care techniques to help treat a series of diseases that have been presented by Dr. Rossi, including cancer side effects.

The Center also organizes training programmes for healthcare professionals as well as research activities to evaluate TCM efficacy, also through a close and constant collaboration with Chinese experts. Some of the current collaborations involve The Memorial Sloan Kettering Cancer Center (MSKCC) of New York and The National Health System of the People's Republic of China.

Dr. Rossi has, highlighted the common objectives of Personalised Medicine and Traditional Chinese Medicine approaches: PM stratifies the population in relation to gender in order to identify who benefits most from a treatment, to reduce the number of patients treated unnecessarily and the related costs. In acupuncture, the population is stratified to target therapeutic treatment, also in relation to gender and to improve the "constitutional terrain".

The association between acupuncture and PM could clarify the relationship between the symptom onset, biological mechanisms that determine it and the function of the acupuncture point. For example, in precision oncology, patients with the same type of cancer, the same mutation, and who are similar to each other, may have different results in terms of effectiveness of anticancer treatment, side effects of therapy, quality of life.

Acupuncture could preventively detect the possible onset of side effects and reduce them also through the choice of specific points related to the "omics" profile of the person and his/her gender.

9. SESSION III

9.1 Dr. Thomas Pattloch - Privacy and data ownership in the EU

Dr. Thomas Pattloch presented the Personalized Medicine, Privacy and Data-related Issues by starting with an example of cross-border hospital cooperation on cancer-related research with patient studies.

A fundamental barrier that currently complicates the global PM collaboration is the different data protection regulations in place in EU and China.

In Europe exists the General Data Protection Regulation (GDPR). 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.

According to the regulations national laws are entitled to, and very often do, apply a more restrictive approach adding further requirements to the ones established by the GDPR.

When it comes to cross-border collaboration and data transfer from EU to Third Countries (such as China), the Art. 44 of the 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 for the transfer of personal data to third countries. According to these clauses Chinese standards have been regarded as comparable.

In China, on the other level, several laws and regulations came into force over the past years to regulate the data use: The Data Security Law (which focusses on national security, public and fundamental interests); the Cybersecurity Law (which focusses on security of information infrastructures and facilities), and in Aug. 20, 2021, the Standing Committee of China's National People's Congress promulgated China's Personal Information Protection Law (PIPL), which took effect on Nov. 1, 2021 and Served as China's first comprehensive law in the personal information.

Lastly, For the scientific activities, in 2018 the Chinese government adopted the "The Measures for Managing Scientific Data, which might be the most important regulations when it comes to scientific data.

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

9.2 Dr. Annie Xue - Privacy and data ownership in China

Dr. Annie Xue presented Personalized Medicine under China Privacy Rules: Opportunities and Challenges.

The topic was introduced by examining the critical differences of data regulation between EU and China.

The European Union has a dedicated data protection authority with sufficient expertise and independence, while China has multiple agencies with overlapped, blurred and sometimes broken boundaries of jurisdictions and enforcement may not be consistent across agencies and regions. The difference lays therefore in one encompassing data regulation that applies in EU [GDPR], with one pillar regulation supported by guidelines and local laws that are consistent with the former, and, on the Chinese side, on multi layered rules and different legal hierarchies monitored by multiple rules at each level. Between the two, there is also difference in the type of data concerned and on the legal consequences of non-compliance.

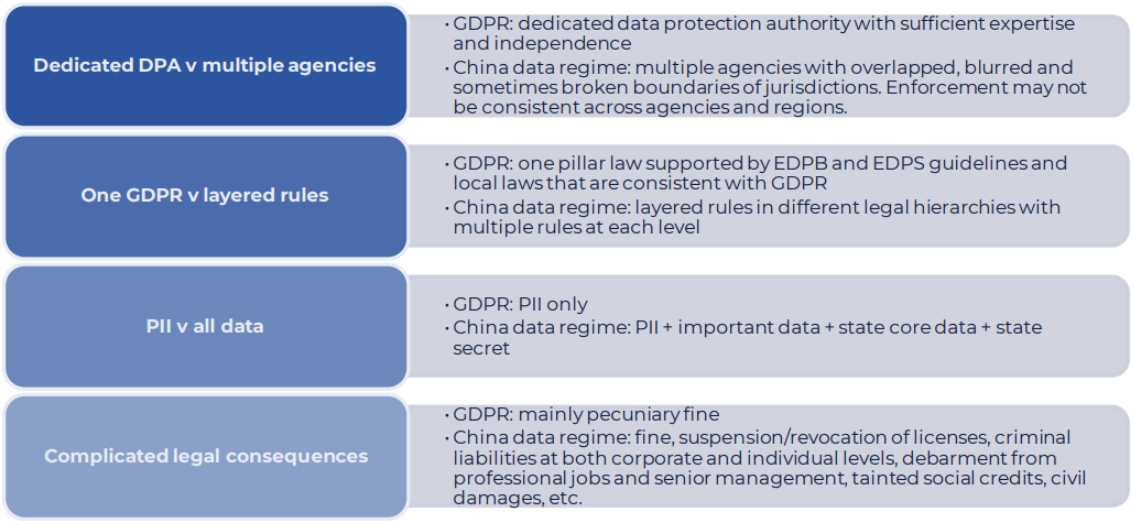

Figure 9. Critical differences of data regulation between the EU and China

Despite the encouragement that comes from the top, both for the industry policy and data regulation, there are still some challenges that PerMed stakeholders need to face that regard the stringent regulation throughout the data life cycle, that is privacy protection on:

- Informed & separate consent on collection
- Restriction on use of health data
- Limitation on redisclosure without the consent
- Cross-border data transfer

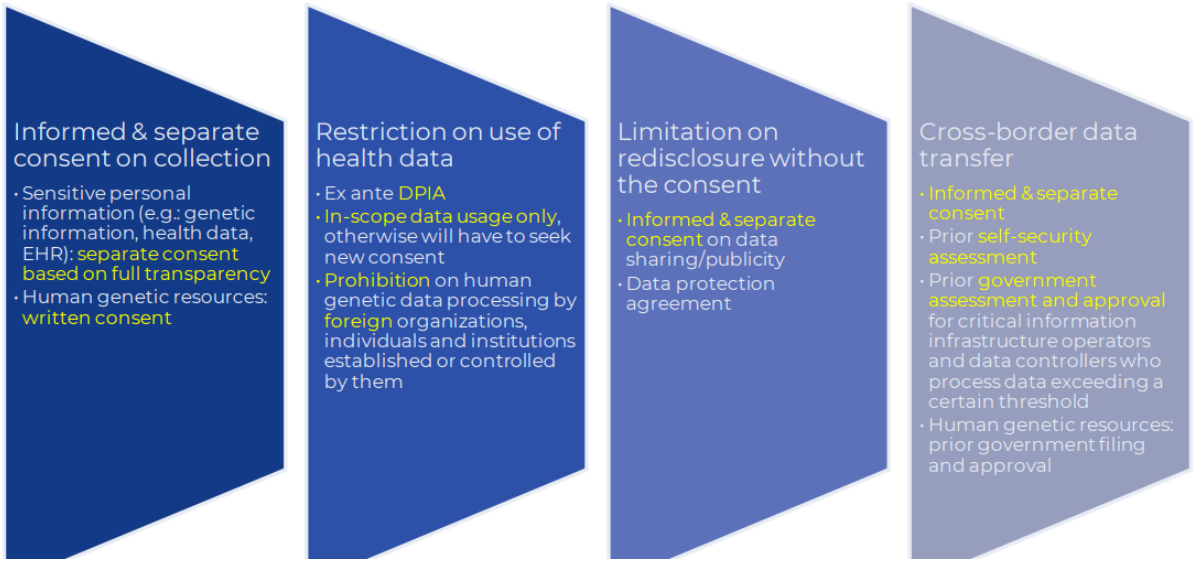

Figure 10. Stringent regulation throughout data life cycle: privacy protection angle

There are though brighter prospects for the future, like increasing endorsement in industry policy at various levels, an open attitude regarding data flows and rigid rules in practice on data collection, data transfer (including R&D) purposes and cross-border data flow.

Some recommendations provided by Dr. Xue include exchange programmes where Chinese stakeholders can learn from EU when it comes data transfer (such as the EU Data Act that is under approval process) for personalised medicine purposes and beyond; enhance Sino-EU policy conversation and create reciprocal treatment regarding the cross-border transfer sensitive (especially genetic) information and enhancing knowledge and experience about privacy computing technologies and data classification to promote layered data sharing mechanisms.