



Integrating China in the International Consortium for Personalised Medicine

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Part III:

Comparative analysis of PM efforts in Europe and China

by Dr. Timo Strohäker

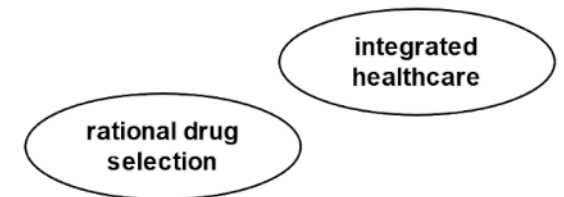
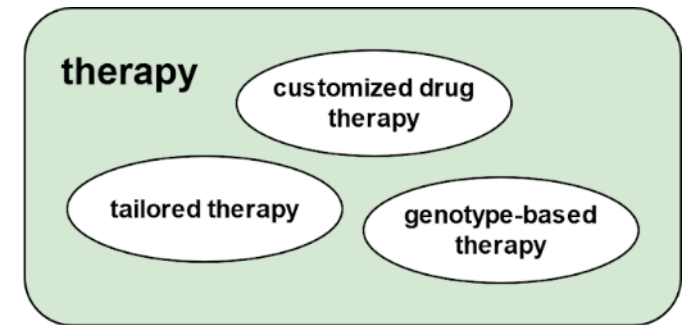
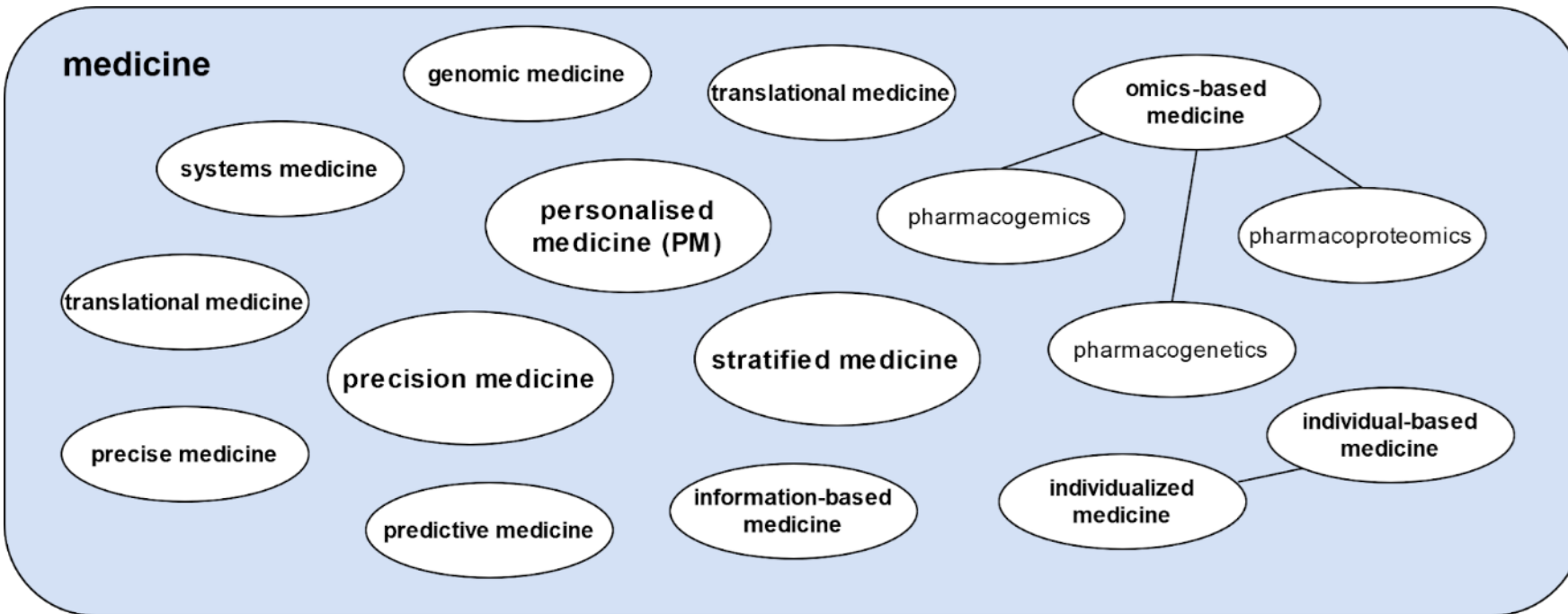




What are the definitions of Personalised Medicine in Europe and the People's Republic of China?

What does Personalised Medicine refer to?

The many faces of Personalised Medicine





Definition of Personalised Medicine in Europe

Personalised medicine

- refers to a **medical model** using characterization of **individuals' phenotypes** and **genotypes** (e.g. molecular profiling, medical imaging, lifestyle data)
- aim is to **tailor** the **right therapeutic strategy** for the **right person** at the **right time**
- identification of **risk factors**, predisposition to disease, timely and targeted **prevention**
- relates to the concept of **patient-centred care**, healthcare systems need to better respond to **patient needs**





Definition of Precision Medicine in the People's Republic of China

Precision Medicine

- refers to a **medical model**
- of **high-efficiency, low-cost prevention and treatment of diseases**
- **tailored to individual patients**
- based on their **genetic content and lifestyle**

The terms *Precision Medicine* and *Personalised Medicine* (PM) are therefore interchangeable.





Concept of Precision Surgery (2006)

- **Precision surgery** originated in the context of precision liver resection
- Concept puts emphasis on **individualization**:
 - Patients differ markedly in **biological** and **social characteristics** mandating surgical care that is **precisely tailored** to the **individual patient**
 - Integration of evidence-based **rules**, surgeons' experience, as well as patients' **individual requirements**
 - Precision surgery also highlights **individualization** and **flexibility** in the **application of rules**
- Link to **Traditional Chinese medicine**:
 - treating different diseases with the same method, the **same disease** with **different treatments**



European strategy in PM



Key challenges and objectives:

- better **understand disease mechanisms**
- **harmonised methods** for the **handling and storage of tissue and data**
 - **biomarker development**
- **regulatory clarity** regarding the **qualification and validation of biomarkers** as well as the **approval of diagnostic tests**
- faster **uptake of validated 'omics' technologies** in clinical practice
- better **training of healthcare professionals** in the application of **personalised medicines**

Fields of interest:

Data and technology / Inter-sectoral synergies / Healthcare and systems reform / Education and literacy



Chinese strategy in PM

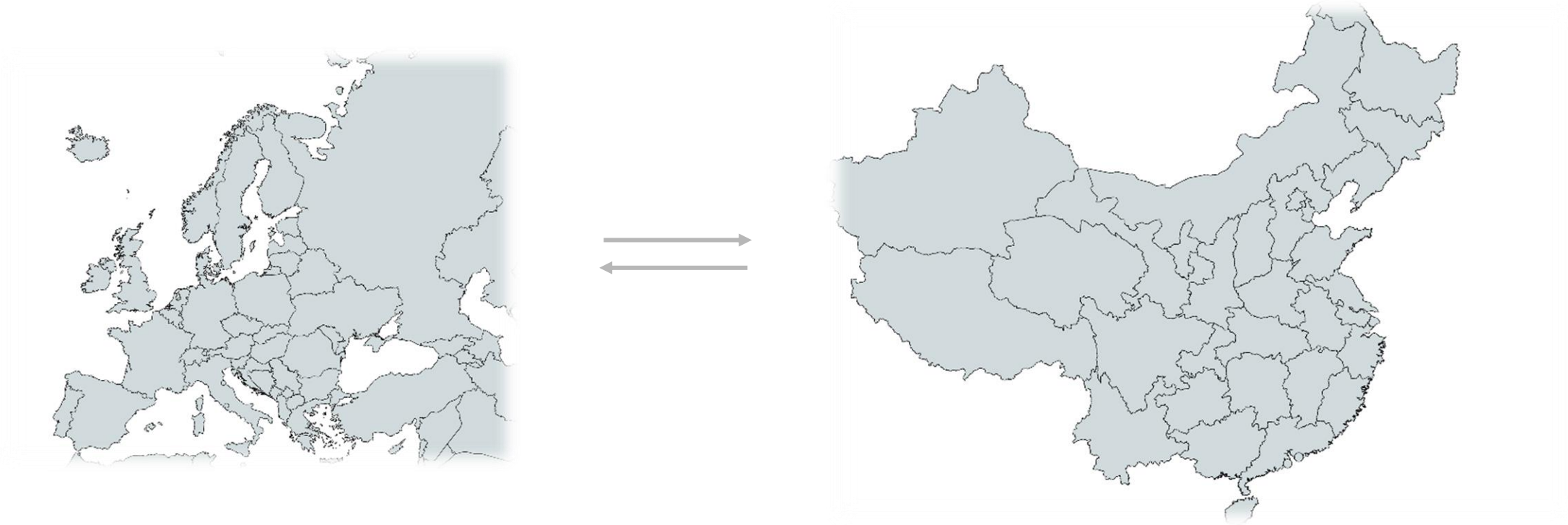
Key challenges and objectives:

- creation of PM sector through **China Precision Medicine Initiative (PMI)** - 15-year project to establish China as a world leader in the field
- fostering **scientific research** to understand **genetics** and **biological make-up** of people
- development of **cutting-edge data collection** and **analysis tools**
- building of powerful **high-performance computing clusters**

Fields of interest:

New clinical life sciences technologies / Large scale cohort studies /

Big Data platforms and infrastructure / Sustainable healthcare system



Example:
Comparative analysis of mapped policy
measures regarding data in PM

Data Acquisition and Sharing in Personalised Medicine



Important European policies regarding medical data

Specific policies:

Digital Health

[2008](#)

Commission recommendation on cross-border interoperability of electronic health record systems

Digital Health

[2011](#)

Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare

PM & Digital Health

[2018](#)

Commission communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society

Complementary policies on data procedures

[2016](#)

Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR)

Major focus on PM and personalised care, offering better data to advanced research and the development of digital tools for citizen empowerment, creation of PM data standards across all member states.

Gain of importance of PM principles



Important Chinese policies regarding medical data

Specific policies:

Electronic Health Records

2014

Management measures on **population health information** (Trial) - National Health Commission of the PRC

Big data & governance

2015

Outline of action to **promote the development of big data** - State Council of the PRC

Guidelines for Big Data in Health

2018

National health and medical big data standards, safety and service management measures (Trial) - National Health Commission of the PRC

Complementary policies on data procedures

2019

Cyber Security Law of the People's Republic of China - Cyberspace Administration of China

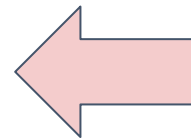
2020

Data Security Management Measures (Consultation Draft) - Cyberspace Administration of China

Defines obligations regarding the **generation, collection, storage, use, transmission, sharing, exchange and destruction of Big Data**.

Healthcare-related Big Data must be stored in China.

Where such data must be transferred abroad for business reasons, a security assessment must be carried out in accordance with the relevant laws and regulations.





Identified common objectives between EU & China through policy mapping

- **Upscaling of health systems** by reducing ineffectiveness and overtreatment (PM approach)
- **Overcoming fractionation** in 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 filing 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 a closer cooperation

- **Health challenges** must be tackled **globally** in a **concerted manner**
- **Alignment of research efforts** leads to more **efficient research**, reduction of redundancies
- Big 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
 - Drivers of innovation
- Further intensification of common research initiatives in science and technology
-

More to come, stay tuned!



Thank you for your attention!

谢谢



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Appendix



Commission recommendation on cross-border interoperability of electronic health record systems (2008)

PM related Policy	Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (notified under document number C (2008) 3282)
Description of the Policy	
The Recommendation supports the cross-border interoperability and access to health data among Member States and between national healthcare systems, while safeguarding fundamental rights of the individual. It commits to the development of any necessary additional standards, preferably open standards on a global scale, involving the relevant European and international standardisation bodies with respect to electronic health records.	
Source	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008H0594



Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (2011)

PM related Policy	Directive 2011/24/EU on the application of patients' rights in cross-border healthcare
Description of the Policy	
The Directive on patients' rights in cross-border care identifies specific areas where Member State co-operation in eHealth can bring significant added value to national health systems, such as in the cross-border exchange of patient summaries and use of ePrescriptions, and for clinical professionals through the European Reference Networks.	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011L0024



Commission communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2018)

PM related Policy	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2018)
Description of the Policy	
<p>The Commission's Communication on the Transformation of Digital Health and Care of April 2018 aims to enhance the digitisation of the health and care sectors. Health data may be available in various forms, but it is not managed in the same way in all EU MPs or within national health systems. It is often not even available to the patients themselves or to public authorities, medical professionals or researchers to help them develop and deliver better diagnosis, treatment or personalised care. Even where it exists, health data often depends on technologies that are not interoperable, thus hindering its wide use. The EU wants to take further action to enable citizens' secure access to and sharing of health data across borders; to offer better data to advance research, disease prevention and personalised health and care; and to develop digital tools for citizen empowerment and person-centred care.</p>	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:233:FIN