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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

- Personalised medicine (PM)
- Genomic medicine
- Translational medicine
- Omics-based medicine
- Pharmacogenomics
- Pharmacoproteomics
- Precision medicine
- Stratified medicine
- Pharmacogenetics
- Individual-based medicine
- Individualized medicine

Therapy
- Customized drug therapy
- Tailored therapy
- Genotype-based therapy
- Integrated healthcare
- Rational drug selection

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**


Precision medicine in China (Booklet), *Science*, 23 Dec 2016
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**
  - Commission recommendation on cross-border interoperability of electronic health record systems
  - **2008**

- **Digital Health**
  - **2011**

- **PM & Digital Health**
  - Commission communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society
  - **2018**

Complementary policies on data procedures

- 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)
  - **2016**

Gain of importance of PM principles

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.
Important Chinese policies regarding medical data

Specific policies:

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

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

**Guidelines for Big Data in Health**
National health and medical big data standards, safety and service management measures (Trial) - National Health Commission of the PRC

Complementary policies on data procedures

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

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

**Guidelines for Big Data in Health**

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!

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Appendix

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<td><strong>Description of the Policy</strong></td>
<td>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.</td>
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<td><strong>Source</strong></td>
<td><a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008H0594">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008H0594</a></td>
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<th>PM related Policy</th>
<th>Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare</th>
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<td>Description of the Policy</td>
<td>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.</td>
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Commission communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2018)

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<th>PM related Policy</th>
<th>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)</th>
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<td><strong>Description of the Policy</strong></td>
<td>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.</td>
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