



Integrating China in the
International Consortium for Personalised Medicine
将中国纳入国际个性化医疗联盟

Ilda Hoxhaj (UCSC), Sylvia Zhou (THU), Timo Strohäker (S2i)

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Part III:

第三部分：

Comparative analysis of PM efforts in
Europe and China

中欧个性化医疗工作的比较分析



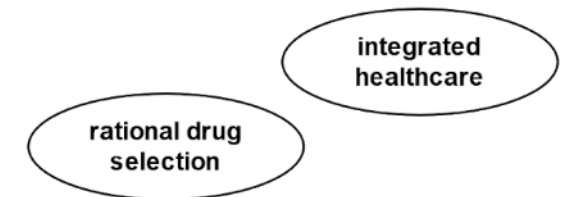
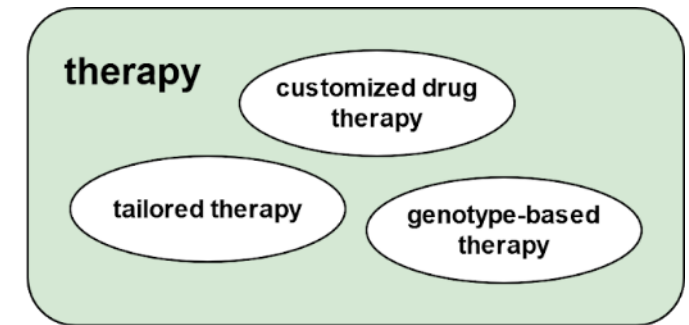
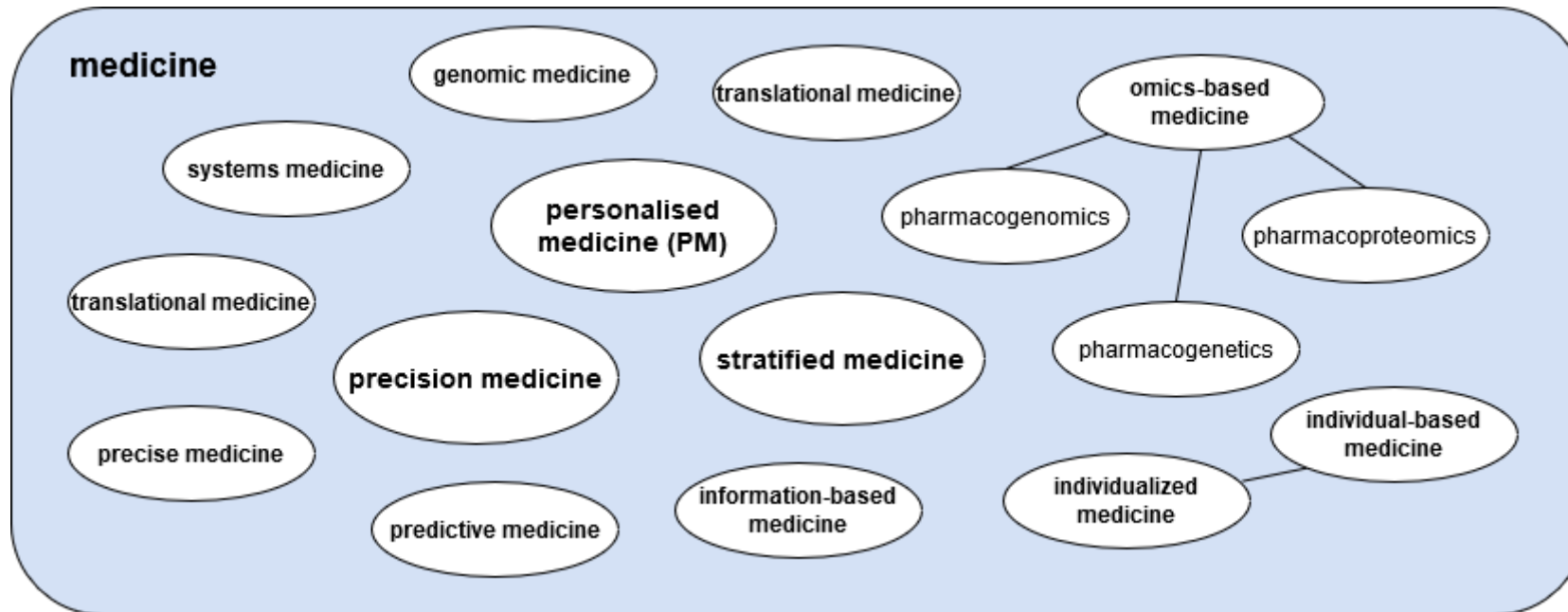
by Dr. Timo Strohäker



What are the definitions of
Personalised Medicine in Europe and
the People's Republic of China?
个性化医疗在中国和欧洲的定义是什么

What does Personalised Medicine refer to? 个性化医疗指的是什么？

The many faces of Personalised Medicine 个性化医疗的众多面孔





Definition of Personalised Medicine in Europe

个性化医疗在欧洲的定义

Personalised medicine 个性化医疗

- refers to a **medical model** using characterization of **individuals' phenotypes** and **genotypes** (e.g. molecular profiling, medical imaging, lifestyle data)
- 指的是使用**个体的表型和基因型**（例如分子表达谱、医学影像、生活方式数据）表征的**医疗模式**
- aim is to **tailor the right therapeutic strategy** for the **right person** at the **right time**
- 目的是在**合适的时间**为**合适的人**量身定制**合适的治疗策略**
- identification of **risk factors**, predisposition to disease, timely and targeted **prevention**
- 识别**风险因素**、**疾病易感性**，及时采取有针对性的**预防措施**
- relates to the concept of **patient-centred care**, healthcare systems need to better respond to **patient needs**
- 与**以患者为中心的护理概念**有关，医疗体系需要更好地响应**患者需求**





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

精准医疗在中国的定义

Precision Medicine 精准医疗

- refers to a **medical model** 指的是一种**医疗模式**
- of **high-efficiency, low-cost prevention and treatment of diseases** **效率高, 疾病预防和治疗成本低**
- **tailored to individual patients** 针对患者个体量身定制
- based on their **genetic content and lifestyle** 根据各自的遗传**信息和生活方式**



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

因此, **精准医疗**和**个性化医疗**这两个词是可互换的。



Concept of Precision Surgery (2006)

精准外科的概念（2006）

- **Precision surgery** originated in the context of precision liver resection **精准外科源于精准肝切除术**
- Concept puts emphasis on **individualization** **概念强调个体化** :
 - Patients differ markedly in **biological and social characteristics** mandating surgical care that is **precisely tailored** to the **individual patient** **患者在生物学和社会特征方面存在明显差异，因此必须针对患者个体精准定制外科护理**
 - Integration of evidence-based **rules**, surgeons' experience, as well as patients' **individual requirements** **整合基于实证规则、外科医生的经验以及患者的个人需求**
 - Precision surgery also highlights **individualization** and **flexibility** in the **application of rules** **精准外科还强调规则应用的个体化和灵活性**
- Link to **Traditional Chinese medicine** **与中医的关联** :
 - treating different diseases with the same method, the **same disease** with **different treatments** **用相同的方法治疗不同的疾病，用不同的治疗方法治疗相同的疾病**



European strategy in PM

欧洲在个性化医疗领域的战略



Key challenges and objectives 主要挑战和目标：

- **better understand disease mechanisms** 更好地了解疾病
- **harmonised methods for the handling and storage of tissue and data** 处理和存储组织与数据的统一方法
 - **biomarker development** 生物标志物开发
- **regulatory clarity** regarding the **qualification and validation of biomarkers** as well as the **approval of diagnostic tests** 关于生物标志物的鉴定和确认以及诊断测试的批准的清晰监管
- **faster uptake of validated 'omics' technologies in clinical practice** 更快地在临床实践中采用经过验证的“组学”技术
- **better training of healthcare professionals in the application of personalised medicines** 更好地就个性化医疗的应用培训医疗专业人员

Fields of interest 关注领域：

Data and technology / Inter-sectoral synergies / Healthcare and systems reform / Education and literacy 数据和技术/部门间协同/医疗和体系改革/教育与扫盲



Chinese strategy in PM

中国在个性化医疗领域的战略

Key challenges and objectives 主要挑战和目标：

- creation of PM sector through **China Precision Medicine Initiative (PMI)** - 15-year project to establish China as a world leader in the field 通过**中国精准医疗计划 (PMI)** 这一为期15年的项目创造个性化医疗行业，使中国成为该领域的世界领导者
- fostering **scientific research** to understand **genetics** and **biological make-up** of people 促进**科学研究**以了解人类的**遗传学**和**生物组成**
- development of **cutting-edge data collection and analysis tools** 发展**前沿的数据收集和分析工具**
- building of powerful **high-performance computing clusters** 构建强大的**高性能计算集群**

Fields of interest 关注领域：

New clinical life sciences technologies / Large scale cohort studies /

Big Data platforms and infrastructure / Sustainable healthcare system

新的临床生命科学技术/大规模队列研究/ 大数据平台和基础架构/可持续的医疗体系



Example 示例：

Comparative analysis of mapped policy measures
regarding data in PM

关于个性化医疗数据的已梳理政策措施的比较分析

Data Acquisition and Sharing in Personalised Medicine
个性化医疗中的数据采集与共享



Important European policies regarding medical data

欧洲有关医疗数据的重要政策

Specific policies 具体政策 :

Digital Health 数字医疗

[2008](#)

Commission recommendation on cross-border interoperability of electronic health record systems 欧盟委员会关于电子病历系统跨界互操作性的建议

Digital Health 数字医疗

[2011](#)

Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare 欧洲议会和欧洲理事会关于患者权利在跨境医疗中应用的指令2011/24/EU

PM & Digital Health 个性化医疗和数字医疗

[2018](#)

Commission communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society 就在数字单一市场中实现医疗和护理数字化转型的欧盟委员会信函；赋予公民权力并建设更健康的社会

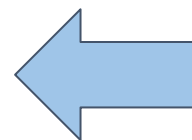
Complementary policies on data procedures 有关数据程序的补充政策

[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) 欧洲议会和欧洲理事会的 (EU) 第2016/679号条例，关于在个人数据处理和此类数据的自由流通方面保护自然人

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. 主要关注个性化医疗和个性化护理，为公民赋权数字工具的远景研发提供更好的数据，创造适用于所有成员国的个性化医疗数据标准。

Gain of importance of PM principles





Important Chinese policies regarding medical data

中国有关医疗数据的重要政策

Specific policies: 具体政策 :

Electronic Health Records 电子健康记录

2014

Management measures on **population health information** (Trial) - National Health Commission of the PRC **人口健康信息管理办法（试行）** - 中华人民共和国国家卫生健康委员会

Big data & governance 大数据与治理

2015

Outline of action to **promote the development of big data** - State Council of the PRC **促进大数据发展行动纲要** - 中华人民共和国国务院

Guidelines for Big Data in Health 健康大数据指南

2018

National health and medical big data standards, safety and service management measures (Trial) - National Health Commission of the PRC **国家健康医疗大数据标准、安全和服务管理办法（试行）** - 中华人民共和国国家卫生健康委员会

Complementary policies on data procedures

有关数据程序的补充政策

2019

Cyber Security Law of the People's Republic of China - Cyberspace Administration of China **中华人民共和国网络安全法** - 中国互联网信息办公室

2020

Data Security Management Measures (Consultation Draft) - Cyberspace Administration of China **数据安全管理办法（征求意见稿）** - 中国互联网信息办公室

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

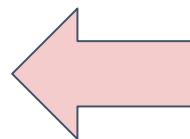
Healthcare-related Big Data must be stored in China.

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.

定义有关大数据的生成、收集、存储、使用、传输、共享、交换和销毁的义务。

与医疗相关的大数据必须存储在中国。

如果出于商业原因必须将此类数据传输到国外，则必须根据相关法律法规进行安全评估。





Identified common objectives between EU & China through policy mapping 通过政策梳理确定了中欧的共同目标

- **Upscaling of health systems** by reducing ineffectiveness and overtreatment (PM approach) 通过减少无效和过度治疗（个性化医疗方法）来扩大医疗体系
- **Overcoming fractionation** in domestic market (multi-tier health systems, national states/provinces) 克服国内市场的分级（多级医疗体系，国家/省）
- **Standardization of data** (omics-research and electronic health records) 数据标准化（组学研究和电子健康记录）
 - interoperability between different stakeholders and across borders 不同利益相关者之间以及跨国界的互操作性
- **Development of solutions** in storage and filing of **large datasets** and **efficient analytics** (AI, algorithms) 开发大数据集存储和归档以及高效分析的解决方案（人工智能，算法）
- **Data protection** (GDPR, Cyber Security Law) 数据保护（GDPR，网络安全法）
 - protection of internal value chains, securing patients' rights 保护内部价值链，保障患者权利
- **Data sharing** to develop new services and applications 数据共享以开发新的服务和应用



Synergies and gains from a closer cooperation

紧密合作带来的协同增效

- **Health challenges** must be tackled **globally** in a **concerted manner** 健康挑战必须在全球范围内协调应对
- **Alignment of research efforts** leads to more **efficient research**, reduction of redundancies 研究工作协调可提高研究效率，减少重复
- Big **economic potential**, important stakeholders/global leaders (e.g. BGI in whole genome sequencing) extend their reach and value chains to new markets 巨大的经济潜力，重要的利益相关者/全球领导者（例如全基因组测序中的BGI）将其影响力和价值链扩展到新市场
- **Sino-European** collaboration on **standardization** in PM will benefit the whole field 中欧就个性化医疗标准化的合作将惠及整个领域
 - Drivers of innovation 创新驱动力
- Further **intensification** of common **research initiatives** in science and technology 进一步加强科学技术的共同研究计划
-

More to come, stay tuned! 更多内容，敬请期待！



Thank you for your attention!
感谢您的关注！

谢谢



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timo.strohaeker@steinbeis-europa.de

Appendix

附录



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

欧盟委员会关于电子病历系统跨界互操作性的建议 (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)

欧洲议会和欧洲理事会关于患者权利在跨境医疗中应用的指令2011/24/EU (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)
就在数字单一市场中实现医疗和护理数字化转型的欧盟委员会信函；赋予公民权力并建设更健康的社会（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