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 II:
第二部分：

Mapping of PM policies and programmes in China
中国个性化医疗政策和计划的梳理

by Sylvia ZHOU (Tsinghua University)
Sylvia ZHOU（清华大学）

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Meaning and Goals of IC2PerMed
IC2PerMed的含义和目标

01. Mapping

Identifying Chinese and EU appropriate policies, programmes, stakeholders and standards to consider and involve in developments; Envisioning benefits for healthcare ecosystems and benefits for populations

02. Expertising

Building upon exchanges between experts in PM domains for fostering actionable approaches

03. Exemplifying

Setting concrete practices of successful collaboration over a PM core thematic (biobanks) for illustrating and inspiring research collaborations

04. Engaging

Creating strong bridges with key stakeholders from the EU, China and beyond, integrating Chinese stakeholder in ICPerMed and liaising with international peers

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INTERNATIONAL CONSORTIUM

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WP1
MAPPING OF PERSONALIZED MEDICINE POLICIES AND PROGRAMMES IN EUROPE AND CHINA 欧洲和中国个性化医疗政策和计划的梳理

- **Task 1.1** Mapping PM policies and programmes

- **任务1.1** 梳理个性化医疗政策和计划

- **Task 1.2** Mapping health research and innovation initiatives and stakeholders

- **任务1.2** 确定医疗研究和创新计划以及利益相关者

- **Task 1.3** Mapping PM approaches and standards

- **任务1.3** 梳理个性化医疗方法和标准

- **Task 1.4** Assessment of current health research and innovation collaborations

- **任务1.4** 评估当前的医疗研究和创新合作

❑ **Output of WP1 WP1的成果：**

-D1.1. Scoping paper: Review on health research and innovation priorities in Europe and China

-D1.1. 范围确定文件：审查欧洲和中国的医疗研究和创新重点

-D1.2. Map of major funding agencies and stakeholders in Europe and China

-D1.2. 梳理欧洲和中国的主要出资机构和利益相关者

-D1.3. Mapping paper: Towards closer EU-China collaboration in PM

-D1.3. 梳理文件：加强中欧在个性化医疗领域的合作

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Mapping methods and results in WP1
WP1中的梳理方法和结果

Desk Research
案头研究

Field-trip
实地考察

Interview
访谈

D1.1 Results
D1.1结果

Policy 政策 – 11	
Program 计划 - 16	
Action Plan 行动计划 - 12	

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Timeline of PM development in China
中国个性化医疗的发展时间表

1970S
- The concept of "personalized medicine"
- "个性化医疗"的概念出现

2002
- Human/Disease Genome Project
- 人类/疾病基因组项目

2011
- Toward "Precision Medicine"
- 走向"精准医疗"

2015
- "Precision Medicine"
- "精准医疗"

2016
- White Paper on "Precision Medicine" in China
- 中国"精准医疗"白皮书

2030
- Healthy China 2030 Plan Outline
- 健康中国2030计划纲要

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Definition of PM in Chinese scenario
中国情景中个性化医疗的定义

- Precision medicine is defined by the leading Chinese experts at the summit as a new medical model that combines modern technological tools and traditional medical techniques to improve the understanding of human mechanisms and diseases to achieve optimal outcomes for the health of individuals and the general public through care provided in a more efficient, safe and affordable manner.

- **在峰会上，中国**领先的专家们将精准医疗定义为一种新的医疗模型，该模型结合了现代的技术工具和传统的医学技术，**以增**进对人体机制和疾病的了解，**从而通**过以更有效、**更安全和更廉价的方式提供**护理，实现个人和**公众健康的最佳**结果。

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Policies related to PM
与个性化医疗相关的政策

- *2020-Biosecurity Law of the People's Republic of China 2020-中华人民共和国生物安全法*

  - The law clarifies the importance and principles of biosafety and stipulates that biosafety is an important part of national security.
  - 该法阐明了生物安全的重要性和原则，规定生物安全是国家安全的重要组成部分。
  - It shall come into force on April 15, 2021
  - 它将于2021年4月15日生效

- *2019-Cyber Security Law of the People's Republic of China 2019-中华人民共和国网络安全法*

- *2019-Regulations of the People's Republic of China on the Management of Human Genetic Resources 2019-中华人民共和国人类遗传资源管理条例*

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Policies related to PM
与个性化医疗相关的政策

- *N/A-Law of the People's Republic of China on the Protection of Personal Information (2017 Draft)*

- *N/A-中华人民共和国个人信息保护法（2017年草案）*

- *2018-Management Measures on National Health and Medical Big Data Standards, Security and Service (Trial)*

- *2018-国家健康医疗大数据标准、安全和服务管理办法（试行）*

- *2014-Management Measures on Population Health Information (Trial)*

- *2014-人口健康信息管理办法（试行）*

- *N/A-Data Security Management Measures (Consultation Draft)*

- *N/A-数据安全管理办法（征求意见稿）*

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Policies related to PM
与个性化医疗相关的政策

- Outline 纲要

  - *2016-Outline of Healthy China 2030 Plan*

  - *2016-健康中国2030规划纲要*

  - *2016-Outline of National Innovation-driven Development Strategy*

  - *2016-国家创新驱动发展战略纲要*

- Guidance 指导

  - *2015-Tumour personalized treatment testing technology guide (trial)*

  - *2015-肿瘤个体化治疗检测技术指南（试行）*

  - *2017-Infectious Disease-Related Personalized Medical Molecular Detection Technology Guide*

  - *2017-感染性疾病相关个体化医学分子检测技术指南*

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PM Programs
个性化医疗计划

- The 13th Five-Year Plan for National Economic and Social Development of the People's Republic of China – MOST, 2015

- 中华人民共和国国民经济和社会发展第十三个五年计划–MOST, 2015
  - By 2030, 60 Billion RMB investment 到2030年，投资额将达到600亿人民币
  - Research platform 研究平台
  - Core key technology 核心关键技术
  - Drugs, vaccines, devices and equipment 药品、疫苗、仪器和设备
  - Guidelines, clinical pathways and interventions 指南、临床路径和干预措施
  - Health system reform 医疗体系改革

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PM Programs
个性化医疗计划

- The 13th Five-Year Plan for National Economic and Social Development of the People's Republic of China – Special Plan

- 中华人民共和国国民经济和社会发展第十三个五年计划-**特**别计划
  - Health and Health Technology Innovation　医疗与医疗技术创新
  - Biotechnology Innovation　生物技术创新
  - Biological Industry Development　生物产业发展
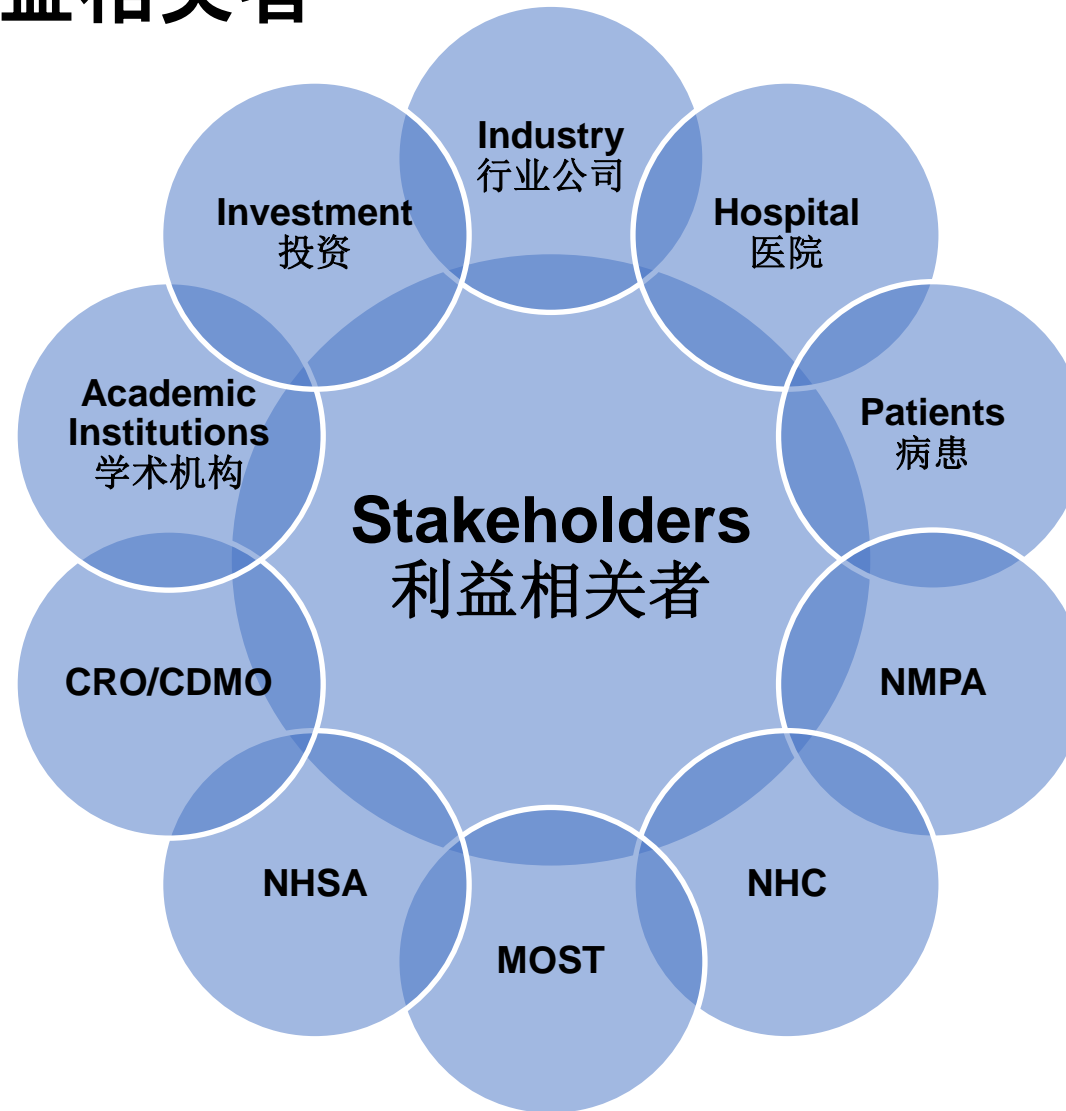 - Health and healthcare　健康与医疗
  - Informatization　信息化

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PM Action Plans
个性化医疗行动计划

- *2014-Notice on Strengthening the Management of Clinical Use of Gene Sequencing Related Products and Technology*

- *2014-关于加强临床使用基因测序相关产品和技术管理的通知*

- *2015-Notice of the National Development and Reform Commission on the implementation of major engineering packages for emerging industries*

- *2015-国家发展改革委关于实施新兴产业重大工程包的通知*

  - Build 30 gene detection technology application demonstration centers within 3 years to rapidly promote the clinical application of gene detection.

  - 三年内建立30个基因检测技术应用示范中心，快速推广基因检测的临床应用。

- *2017-Technical Specifications of Microarray Gene Chips for Personalized Medical Testing*

- *2017-个体化医学检测微阵列基因芯片技术规范*

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Identification of Stakeholders in China
确定中国的利益相关者

NMPA-National Medical Products Administration
NMPA-国家药品监督管理局
MOST-Ministry of Science and Technology
MOST-科学技术部
NHC-National Health Commission
NHC-国家卫生健康委员会
NHSA-Nation Healthcare Security Administration
NHSA-国家医疗保障局

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Conclusion 结论

- The development of PM needs to focus on communities and hospitals
- 个性化医疗的发展需要关注社区和医院
- The development PM needs the support of big data
- 个性化医疗的发展需要大数据的支持
- The development PM requires the joint efforts of politics, industry and academia
- 个性化医疗的发展需要政治、工业和学术界的共同努力
- The development of PM needs to develop simultaneously with regulatory science
- 个性化医疗需要与监管科学同时发展
- The development of PM requires international cooperation
- 个性化医疗的发展需要国际合作

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China Team
中国合作单位