



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

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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 :**

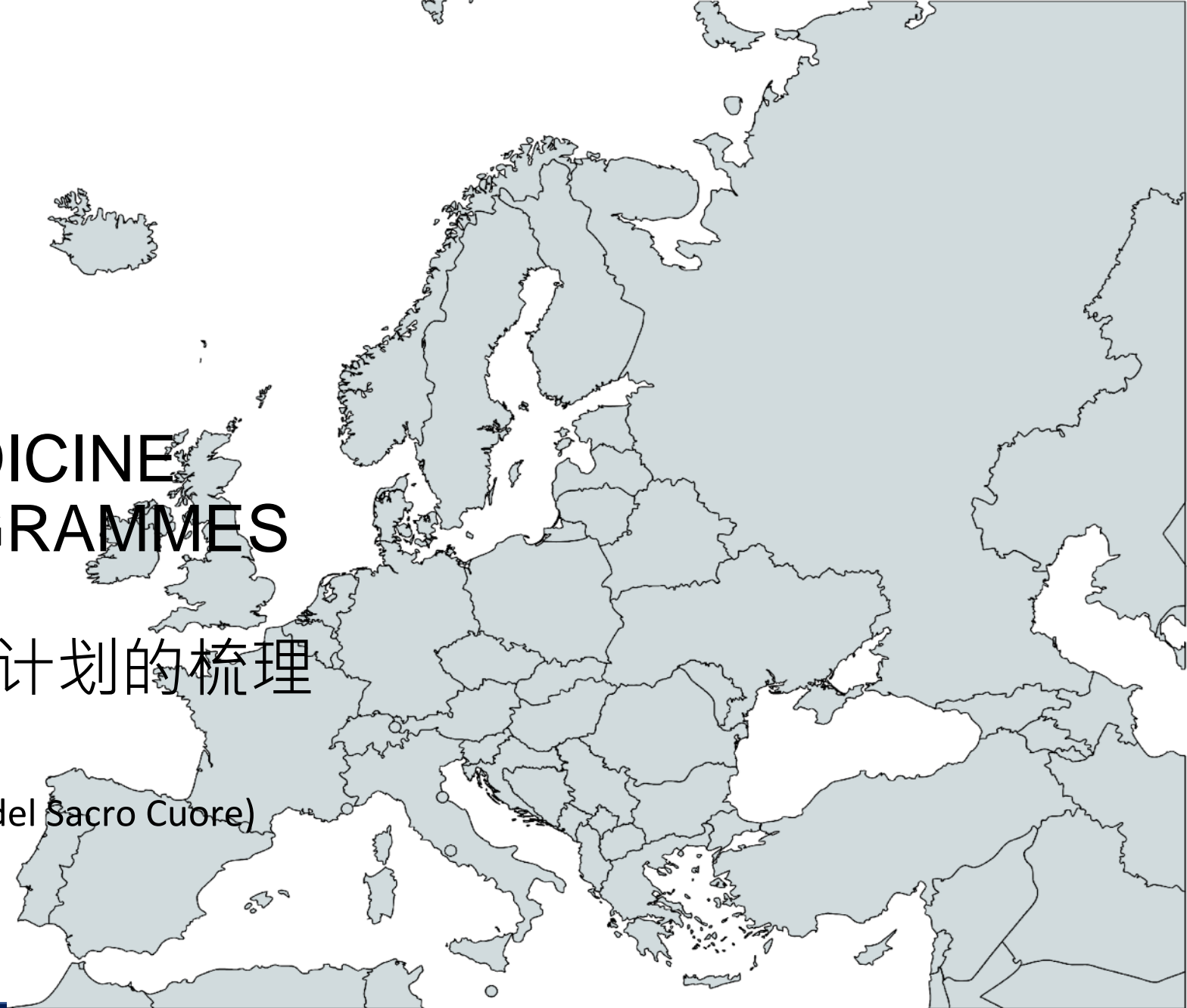
- D1.1. Scoping paper: Review on health research and innovation priorities in Europe and China
- D1.1. 范围确定文件：审查欧洲和中国的医疗研究和创新重点
- D1.2. Map of major funding agencies and stakeholders in Europe and China
- D1.2. 梳理欧洲和中国的主要出资机构和利益相关者
- D1.3. Mapping paper: Towards closer EU-China collaboration in PM
- D1.3. 梳理文件：加强中欧在个性化医疗领域的合作



Part I: 第一部分：

MAPPING OF PERSONALIZED MEDICINE POLICIES AND PROGRAMMES IN EUROPE 欧洲个性化医疗政策和计划的梳理

by Dr. Ilda Hoxhaj (Università Cattolica del Sacro Cuore)



MAPPING METHODOLOGY

梳理方法

☐ Desk Research案头研究:

Websites网站:

European Commission, ICPerMed; National Health Ministries & Institutions, etc..
欧盟委员会 · ICPerMed ; 国家卫生部门和机构等

☐ Definitions定义:

- A **policy measure** embodies an institution's political vision and direction using a set of rules and guidelines that specify how a particular objective is being met long-term.
- **政策措施**通过一系列规定如何长期实现特定目标的规则和指南，体现机构的政治愿景和方向。
- A **programme** is an explicit outline of activities and events following a precise timeframe with rigid budget constraints.
- **计划**是在严格的预算约束下，在精确的时间范围内对活动和事件的明确概述。
- An **action plan** is a detailed proposal defining key priorities and objectives with the goal to improve regulations, finding schemes and knowledge about a certain topic.
- **行动计划**是详细的提案，定义了关键的优先事项和目标，目的是改进法规，查找有关特定主题的方案和知识。

Historical Developments of PM in Europe

个性化医疗在欧洲的发展历史

- **2008:** European Commission (EC) set a renewed vision for the pharmaceutical sector under the heading “**Towards more personalised medicines**”
2008 : 欧盟委员会 (EC) 以“迈向更加个性化的医疗”为题，为制药行业树立了新的愿景
- **2010:** PM strategy took shape at the EU level with a series of workshops on different research areas developing a new medicine model
2010 : 通过举办一系列针对不同研究领域的研讨会，开发新的医疗模式，形成了欧盟一级的个性化医疗战略
- **2013:** The report “Use of ‘-omics’ technologies in the development of PM” published by EC as a first European policy document in the field.
2013 : 欧盟委员会发布了“在个性化医疗开发中使用‘组学’技术”的报告作为该领域的首份欧洲政策文件
- **2015:** EU Health Ministers **defined PM** in the Council conclusions on personalised medicine for patients
2015 : 欧盟卫生部长在欧洲理事会关于患者个性化医疗的结论中**定义了个性化医疗**
- **2015:** EU funded project **PerMed** defines PM 5 challenges in its report “**Shaping Europe’s vision for Personalised Medicine**”
2015 : 欧盟出资的项目**PerMed**在其报告“**塑造欧洲的个性化医疗愿景**”中定义了个性化医疗的5项挑战
- **2016:** ICPerMed was launched to promote PM and support the science base, establish Europe as a global leader in PM
2016 : 启动了ICPerMed以促进个性化医疗并支持科学基地，使欧洲成为个性化医疗的全球领导者

PM Policy at EU level 欧盟一级的个性化医疗政策 (1)



- ❑ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic **medical devices**
- ❑ 欧洲议会和欧洲理事会于1998年10月27日发布的关于体外诊断**医疗器械**的指令98/79/EC
- ❑ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan **medicinal products**
- ❑ 欧洲议会和欧洲理事会于1999年12月16日发布的关于**孤儿药**的 (EC) 第141/2000号条例
- ❑ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on **medicinal products** for human use
- ❑ 欧洲议会和欧洲理事会于2001年4月4日发布的指令2001/20/EC, 该指令近似于成员国的法律、法规和管理规定, 涉及在**人类用药**的临床试验中实施良好的临床实践
- ❑ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to **medicinal products** for human use
- ❑ 欧洲议会和欧洲理事会于2001年11月6日发布的指令2001/83/EC, 关于与**人类用药**有关的欧洲共同体法规
- ❑ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 for the authorisation and supervision of **medicinal products** for human and veterinary use
- ❑ 欧洲议会和欧洲理事会于2004年3月31日发布的 (EC) 第726/2004号条例, 关于对人用和兽用**药品**的授权和监督
- ❑ Article 168 of the Treaty on the Functioning of the European Union (2008)
- ❑ 《欧洲联盟运行条约》(2008) 第168条
- ❑ Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy **medicinal products**
- ❑ 欧洲议会和欧洲理事会于2007年11月13日发布的关于先进疗法**药物**的 (EC) 第1394/2007号条例
- ❑ Commission Recommendation of 2 July 2008 on cross-border interoperability of **electronic health record systems** (notified under document number C (2008) 3282)
- ❑ 2008年7月2日欧盟委员会关于**电子病历系统**跨界互操作性的建议 (通知文件编号C (2008) 3282)



PM Policy at EU level 欧盟一级的个性化医疗政策 (2)

- ❑ Council recommendation of 8 June 2009 on an action in the field of [rare diseases](#) 2009/C 151/02
- ❑ 欧洲理事会2009年6月8日关于在罕见病领域采取行动的[建议](#)2009/C 151/02
- ❑ Council conclusions on innovation in the [medical device](#) sector 2011/C 202/03
- ❑ 欧洲理事会关于[医疗器械](#)行业创新的[结论](#)2011/C 202/03
- ❑ Directive 2011/24/EU on the application of [patients' rights in cross-border healthcare](#)
- ❑ 关于患者权利在跨境医疗中应用的指令2011/24/EU
- ❑ [Clinical trials](#) - Regulation EU No 536/2014
- ❑ 临床试验 - 欧盟第536/2014号条例
- ❑ Council conclusions on [innovation](#) for the benefit of patients (2014/C 438/06)
- ❑ 欧洲理事会关于患者益处创新的[结论](#) (2014/C 438/06)
- ❑ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of [personal data](#) and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- ❑ 欧洲议会和欧洲理事会于2016年4月27日发布的 (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, 并废除指令95/46/EC (通用数据保护条例)
- ❑ Council Conclusions on the EPC- Commission Joint Report on [health care](#) and long-term care in the EU, 2016
- ❑ 2016年欧洲理事会关于EPC-欧盟委员会有关欧盟[医疗](#)和长期护理的联合报告的[结论](#)
- ❑ Council conclusions on shaping Europe's [digital](#) future 2020/C 202 I/01
- ❑ 欧洲理事会关于塑造欧洲[数字](#)未来的[结论](#)2020/C 202 I/01
- ❑ Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European [Electronic Health Record](#) exchange format
- ❑ 欧盟委员会于2019年2月6日发布的有关欧洲[电子健康记录](#)交换格式的建议 (EU) 2019/243

PM National Policy and Programs at EU MS level 欧盟成员国一级的个性化医疗国家政策和计划

- 2013 Italian National Plan for Public Health Genomics 2013年意大利国家公共卫生基因组计划
- 2013 German Personalised Medicine – Action Plan 2013年德国个性化医疗-行动计划
- 2014 - 2020 Malta National Health Systems Strategy 2014-2020年马耳他国家医疗体系战略
- 2015 NHS England Personalised Medicine Strategy 2015年NHS英格兰个性化医疗战略
- 2015 Finland's Genome Strategy 2015年芬兰基因组战略
- 2015 - 2020 Research, Development and Innovation Strategy for the Estonian Health System 2015-2020年爱沙尼亚医疗体系研究、开发和创新战略
- 2016 Roadbook for the implementation of next-generation sequencing in clinical practice in oncology and hemato-oncology in Belgium 2016年在比利时的肿瘤和血液肿瘤临床实践中实施下一代测序的路线图
- 2016 Scotlands' National Clinical Strategy 2016年苏格兰国家临床战略
- 2016 - 2018 Finland: Health Sector Growth Strategy for R&I Activities Roadmap 2016-2018年芬兰：研究与创新活动路线图的医疗行业增长战略
- 2017 Italian National Plan for Innovation of the Health System based on -omics sciences 2017年基于组学技术的意大利国家医疗体系创新计划
- 2017 - 2020 Denmark National Strategy for Personalised Medicine 2017-2020年丹麦个性化医疗国家战略
- French National Health Strategy 2018-2022 2018-2022年法国国家医疗战略
- 2019 Sweden's National Life Science Strategy 2019年瑞典国家生命科学战略
- 2020 GENOME UK national genomic healthcare strategy 2020年GENOME英国国家基因组医疗战略
- 2020 Estonian eHealth Strategic Development Plan 2020年爱沙尼亚电子医疗战略发展计划
- National Research Priorities for Luxembourg in 2020 and beyond 2020年及以后的卢森堡国家研究重点
- 2020 The Finnish National eHealth and eSocial Strategy 2020年芬兰国家电子医疗和电子社会战略
- 2020 Spanish Strategy for Personalised Medicine 2020年西班牙个性化医疗战略

PM National Policy and Programs at EU MS level

...Common Focus:

欧盟成员国一级的个性化医疗国家政策和计划

...共同的关注点：

- Patient-tailored treatment 患者定制治疗
- Targeted prevention 有针对性的预防措施
- Public understanding of PM 公众对个性化医疗的了解
- Education and training of healthcare workforce on PM
对于个性化医疗劳动力的教育和培训
- Patient empowerment 患者授权
- Big-Data and ICT-Solutions 大数据和ICT解决方案
- Healthcare delivery infrastructure and data management systems
医疗服务基础架构和数据管理系统
- Increased investments in PM by healthcare industry
医疗行业增加对个性化医疗的投资



A brief mapping of PM Projects and Initiatives

个性化医疗项目和计划的简要梳理

- ❑ **1+MillionGenomes Initiative**
1+MillionGenomes计划
- ❑ **Trans4mMED - Transformative Patient Centred Personalised Medicine Initiative**
Trans4mMED-以患者为中心的转化式个性化医疗计划
- ❑ **Perso-Med**
- ❑ **The Genomic Medicine Sweden Initiative**
瑞典基因组医疗计划
- ❑ **The Genome Denmark Platform**
丹麦基因组平台
- ❑ **FinnGen (Finland)**
FinnGen (芬兰)
- ❑ **The French Platform for Personalised Medicine**
法国个性化医疗平台
- ❑ **pMedGR (Greece)**
pMedGR (希腊)
- ❑ **Austria National Coordination Platform on Personalized Medicine**
奥地利个性化医疗国家协调平台

The Greek Research Infrastructure for Personalised Medicine

Towards more accurate and cost-effective health management for the Greek citizen

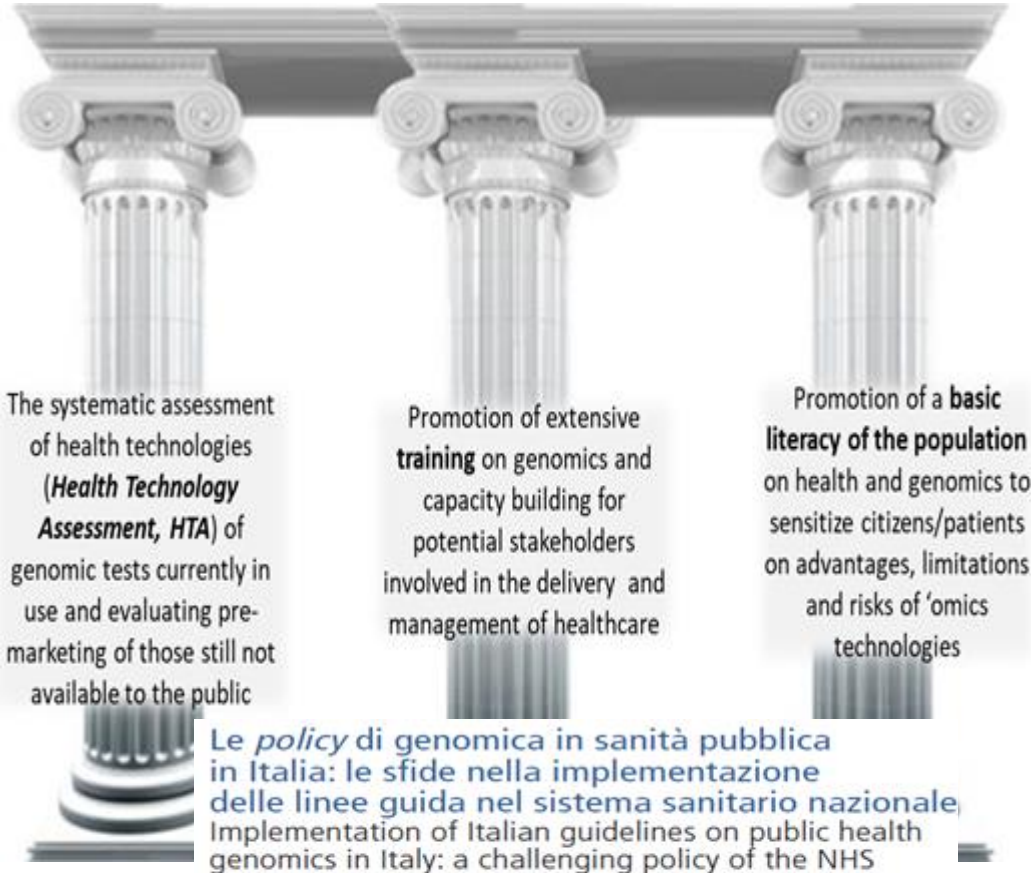
Our Goals

- Strengthen basic research
- Harness the “big data” revolution
- Revise clinical trial designs
- Move regulatory science forward
- Foster collaboration
- Enhance patient access to innovative medicines

AUSTRIAN PLATFORM FOR PERSONALIZED MEDICINE:

“The Austrian Platform for Personalized Medicine constitutes a national networking platform aiming to connect all stakeholders and interested parties in the field. The platform is open to individuals and organizations that would like to contribute to the future of personalized medicine in Austria.”

2013 Italian Plan on Public Health Genomics 2013年意大利公共卫生基因组计划



2017 Italian National Plan for Innovation of the Health System based on Omics Sciences

2017年基于组学技术的意大利国家医疗体系创新计划

COMMENTARY

Epidemiology Biostatistics and Public Health - 2017, Volume 14, Number 4



Implementation of genomic policies in Italy: the new National Plan for innovation of the Health System based on omics sciences

Stefania Boccia ¹*, Antonio Federici ², Roberta Siliquini ², Giovanna Elisa Calabrò ¹, Walter Ricciardi ^{1,4,5} on behalf of the Expert Table of the Ministry of Health[^]

The main objectives of the national plan for innovation are:

1. to transfer genomic knowledge into the practice of health services, in a patient-centric approach;
2. to increase the effectiveness of prevention, diagnosis and treatment of diseases at a higher burden, taking into account individual differences in genetic heritage, lifestyles and the environment, and providing professionals with the resources needed to customize interventions;
3. to promote the cultural, scientific and technological innovation of the healthcare system.



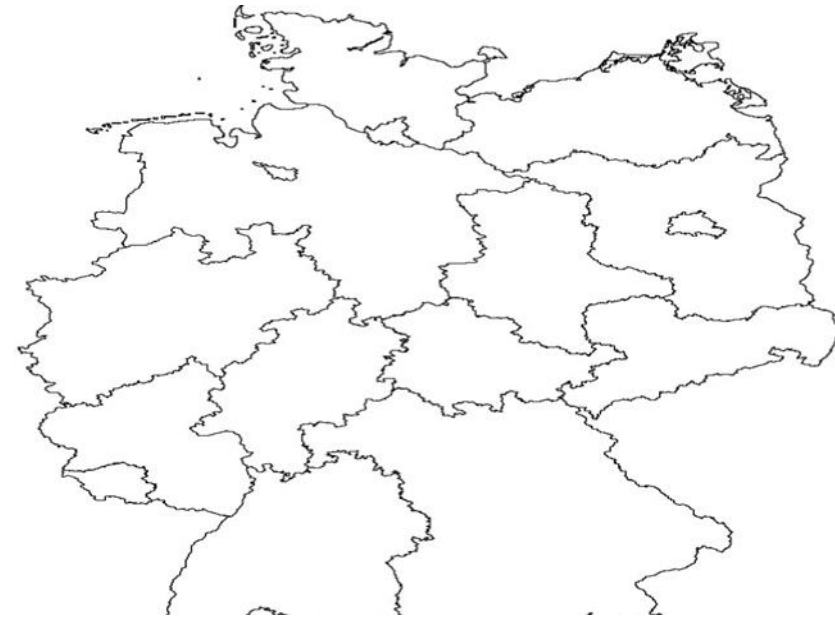


2013 German

2013年德国

Personalised Medicine – Action Plan

A New Approach in Research and Health Care



Short-term achievements (1-5 years)

- Faster and more precise diagnosis on the basis of validated biomarkers
- Improved treatments thanks to closer linking of diagnosis with therapy and the integration of data into research and medical practice
- Increased investment in personalised medicine by the health care industry
- Better public understanding of personalised medicine

Long-term achievements (6-10 years)

- Reduction of side effects thanks to targeted drugs
- Avoidance of ineffective treatments
- Accelerated market entry for personalised medicine products and services
- Establishment of more patient-tailored medicine



Thank you! / 谢谢！



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