



Integrating China in the International Consortium for Personalised Medicine

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WP1

MAPPING OF PERSONALIZED MEDICINE POLICIES AND PROGRAMMES IN EUROPE AND CHINA

- **Task 1.1** Mapping PM policies and programmes
- **Task 1.2** Mapping health research and innovation initiatives and stakeholders
- **Task 1.3** Mapping PM approaches and standards
- **Task 1.4** Assessment of current health research and innovation collaborations

☐ **Output of WP1:**

- D1.1. Scoping paper: Review on health research and innovation priorities in Europe and China
- D1.2. Map of major funding agencies and stakeholders in Europe and China
- D1.3. Mapping paper: Towards closer EU-China collaboration in PM



Part I:

MAPPING OF PERSONALIZED MEDICINE POLICIES AND PROGRAMMES IN EUROPE

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



MAPPING METHODOLOGY

☐ Desk Research:

Websites:

European Commission, ICPeMed; National Health Ministries & Institutions, etc..

☐ Definitions:

- 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.
- A **programme** is an explicit outline of activities and events following a precise timeframe with rigid budget constraints.
- An **action plan** is a detailed proposal defining key priorities and objectives with the goal to improve regulations, funding schemes and knowledge about a certain topic.

Historical Developments of PM in Europe

- **2008:** European Commission (EC) set a renewed vision for the pharmaceutical sector under the heading “**Towards more personalised medicines**”
- **2010:** PM strategy took shape at the EU level with a series of workshops on different research areas developing a new medicine model
- **2013:** The report “Use of ‘-omics’ technologies in the development of PM” published by EC as a first European policy document in the field.
- **2015:** EU Health Ministers **defined PM** in the Council conclusions on personalised medicine for patients
- **2015:** EU funded project **PerMed** defines PM 5 challenges in its report “**Shaping Europe’s vision for Personalised Medicine**”
- **2016:** ICPeMed was launched to promote PM and support the science base, establish Europe as a global leader in PM

PM Policy at EU level



- ❑ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic [medical devices](#)
- ❑ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan [medicinal products](#)
- ❑ 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
- ❑ 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
- ❑ 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
- ❑ Article 168 of the Treaty on the Functioning of the European Union (2008)
- ❑ Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy [medicinal products](#)
- ❑ Commission Recommendation of 2 July 2008 on cross-border interoperability of [electronic health record systems](#) (notified under document number C (2008) 3282)
- ❑ Council recommendation of 8 June 2009 on an action in the field of [rare diseases](#) 2009/C 151/02
- ❑ Council conclusions on innovation in the [medical device](#) sector 2011/C 202/03
- ❑ Directive 2011/24/EU on the application of [patients' rights in cross-border healthcare](#)
- ❑ [Clinical trials](#) - Regulation EU No 536/2014
- ❑ Council conclusions on [innovation](#) for the benefit of patients (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)
- ❑ Council Conclusions on the EPC- Commission Joint Report on [health care](#) and long-term care in the EU, 2016
- ❑ Council conclusions on shaping Europe's [digital](#) future 2020/C 202 I/01
- ❑ Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European [Electronic Health Record](#) exchange format

PM National Policy and Programs at EU MS level

- 2013 Italian National Plan for Public Health Genomics
- Personalised medicine programme of Estonia 2016-2020
- Denmark National Strategy for Personalised Medicine 2017-2020
- Finland's Genome Strategy 2015
- Finnish Gene Technology Act (377/1995)
- Finland Personalised Health Program 2018
- French National Health Strategy 2018-2022
- Genomic Medicine France 2025
- Norwegian Strategy for Personalised Medicine in Healthcare 2017-2020
- 2015 England Personalised Medicine Strategy
- 2016 Scotlands' National Clinical Strategy
- 2017 Italian National Plan for Innovation of the Health System based on -omics sciences
- 2017 Belgian next generation sequencing guidelines for haematological and solid tumours
- 2020 Spanish Personalised Precision Medicine National Strategy
- German Personalised Medicine – Action Plan 2013
- 2018 Swedish Life Science Action Plan



PM National Policy and Programs at EU MS level

...Common Focus:

- Patient-tailored treatment
- Targeted prevention
- Public understanding of PM
- Education and training of healthcare workforce on PM
- Patient empowerment
- Big-Data and ICT-Solutions
- Healthcare delivery infrastructure and data management systems
- Increased investments in PM by healthcare industry



A brief mapping of PM Projects and Initiatives

- ❑ 1+MillionGenomes Initiative
- ❑ Trans4mMED - Transformative Patient Centred Personalised Medicine Initiative
- ❑ Perso-Med
- ❑ The Genomic Medicine Sweden Initiative
- ❑ The Genome Denmark Platform
- ❑ FinnGen (Finland)
- ❑ The French Platform for Personalised Medicine
- ❑ pMedGR (Greece)
- ❑ Austria National Coordination Platform on Personalized Medicine

The Greek Research Infrastructure for Personalised Medicine

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

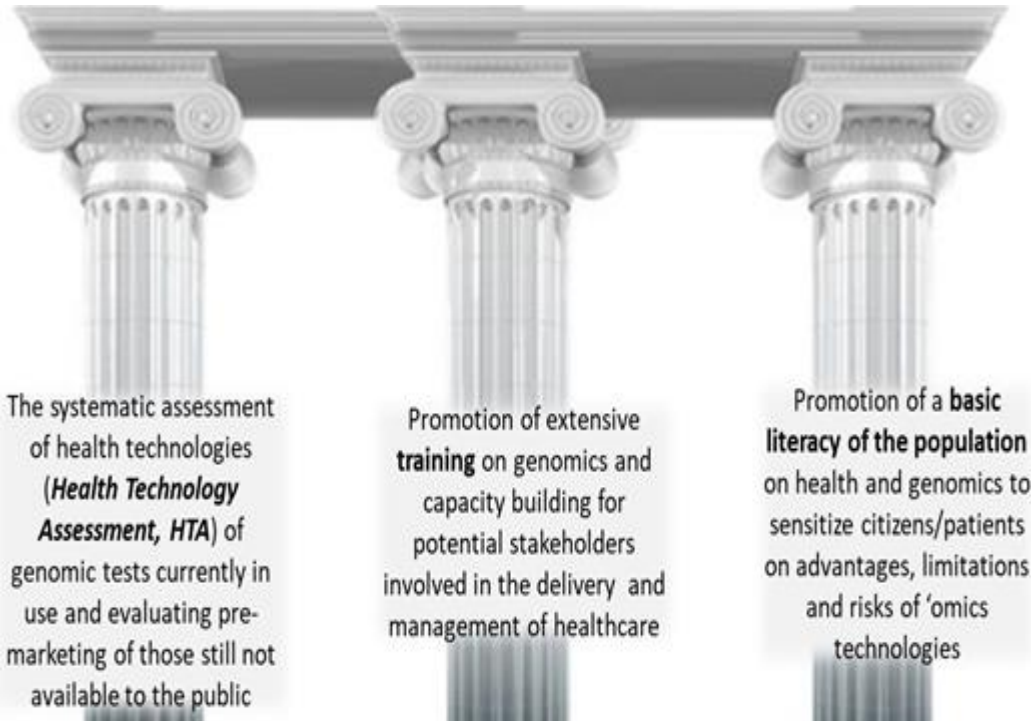
Our Goals

- 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



The systematic assessment of health technologies (**Health Technology Assessment, HTA**) of genomic tests currently in use and evaluating pre-marketing of those still not available to the public

Promotion of extensive **training** on genomics and capacity building for potential stakeholders involved in the delivery and management of healthcare

Promotion of a **basic literacy of the population** on health and genomics to sensitize citizens/patients on advantages, limitations and risks of 'omics technologies

Le policy di genomica in sanità pubblica in Italia: le sfide nella implementazione delle linee guida nel sistema sanitario nazionale
Implementation of Italian guidelines on public health genomics in Italy: a challenging policy of the NHS

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

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 Boccia¹*, Antonio Federici², Roberta Siliquini², Giovanna Elisa Calabrò¹, Walter Ricciardi^{1,4,5} on behalf of the Expert Table of the Ministry of Health⁶

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

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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