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

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Abstract
This document presents a review on health research and innovation priorities in Europe and China with focus on Personalised Medicine. It maps Personalised Medicine policies, action plans and programmes in both regions and puts them in context of developments at the global level. The mapping aims to provide a comprehensive and representative view as to the state of play in the field of PM and provides important ramifications for further Sino-European collaboration on a broad level. This mapping acts as an initial input for the upcoming working group activities planned within the IC2PerMed project. The mapping has been done through extensive desk research, literature, and document analysis as well as the contribution of experts within the IC2PerMed consortium.

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Abbreviations and Acronyms

Abbreviation, Acronym	Description
CAGR	Compound Annual Growth Rate
CASyM	Coordinating Action Systems Medicine
CELAC	Community of Latin American and Caribbean States
CSA	Coordination and Support Action
DIFs	Domain-Specific Interoperability
EC	European Commission
EIF	European Interoperability Framework
EJP RD	European Joint Programme on Rare Diseases
EMA	European Medicines Agency (London)
ENISA	European Union Agency for Cybersecurity
ERA	European Research Area
ERA-Nets	European Research Area Networks
EU	European Union
FP	Framework programme
FYP	Five-Year Plan
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GMS	Genomic Medicine Sweden
ICPerMed	The International Consortium for Personalised Medicine
ICT	Information and Communication Technology
IMI	Innovative Medicines Initiative
INCa	French National Cancer Institute
ISA	Interoperability Solutions for European Public Administrations
IVDs	In vitro Diagnostic Medical Devices
JPIs	Joint Programming Initiatives
MOST	Ministry of Science and Technology
MS	Member States
PaM	Policies and measures
PM	Personalised Medicine, Precision Medicine
SRIA	Strategic Research and Innovation Agenda
WHO	World Health Organization
WP	Work Package

Executive Summary

This document has been developed under the IC2PerMed project, funded by the European Union's Horizon 2020 research and innovation programme under grant agreement No 874694. It represents the *Deliverable 1.1 - Scoping paper: Review on health research and innovation priorities in Europe and China*.

Recent scientific and technological progress as well as the combination of expertise and data from different disciplines and sectors have led to the emergence of the cross-cutting field of personalised medicine (PM). The term[1] describes a medical model based on the extensive study of an individuals' phenotypes and genotypes through techniques such as e.g. molecular profiling, medical imaging, biomarker detection and the collection of lifestyle data. The model then allows to identify the best therapeutic approach for each individual patient and in addition delivers insights in disease prevention by the identification of individual risk factors.

PM has shown its high potential to improve healthcare and sparked the attention of policy makers worldwide in their search for more efficient and sustainable health systems. PM is therefore a main priority of the European Commission's research agenda, with funding devoted to projects along the entire value chain. In the People's Republic of China, abbreviated to China in the following, PM is as well attracting massive interest, with the government capitalising on its expertise in biotechnology, computing hardware and the ability to put in place the infrastructures for supporting large bioinformatics projects.

Turning PM into an opportunity for all citizens and patients requires the engagement of stakeholders, in order to define common research and development approaches, standards, and priorities, and to scale up the collaboration at the international level. The European Union (EU) supports actions developed within the International Consortium for Personalised Medicine (ICPerMed) in order to respond to these challenges.

IC2PerMed stands for "Integrating China in the International Consortium for Personalised Medicine" and aims to provide key solutions for enabling the convergence towards a common approach of PM research, innovation, development and implementation between the EU and China.

The project is developed under the roof of the International Consortium for Personalised Medicine (ICPerMed) by Chinese and European stakeholders involving policy makers and healthcare beneficiaries. IC2PerMed wants to identify opportunities for Sino-European research collaborations mapping PM policies, programmes, standards and initiative in both areas.

The scope of the document is to map and deliver a comprehensive view on the wide spectrum of policies and programmes in the field of PM in both regions, determining the state of play and setting the basis for collaboration between Europe and China on a broad level. The mapping functions as an initial input for WP2 and WP3. The mapping has been done through desk research, literature and document analysis as well as the contribution of expertise from the IC2PerMed consortium partners.

The analysis of the mapping underlines that Personalised Medicine is already on the highest political agenda both in the European Union as well as in the People's Republic of China with a strong increase in policy measures on PM in recent years. A special focus lies on the harmonization and standardization of PM-related cross-border data sharing and transfers processes and the expansion of eHealth/telemedicine capabilities. Both economic zones are exploring and expanding the application of Big Data in public health and heavily invest in the necessary infrastructure and the development of

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[1] European Council Conclusion on personalised medicine for patients (2015/C 421/03) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217(01)

scientific expertise and technology. We have identified complementary approaches regarding data security among China and Europe, with the European Union tackling the issue from the individual citizen's end and the People's Republic of China being heavily invested in safeguarding data autonomy within its national boundaries.

There is an urgent need for international cooperation in the development and promotion of Personalised Medicine in our globalized world. Further Sino-European collaboration will improve the learning from each other and bring forward bilateral approaches to standardization, the expansion of technical and scientific capabilities and eventually concerted actions regarding important policy measures and detailed regulations in PM. IC2PerMed and its sister project Sino-EU PerMed are therefore important steps into the right direction and mirror the importance of sound and sustainable EU-China relations for both geographic areas.

1 Preface

This report has been developed within Work Package 1 (WP1) – Mapping of PM policy measures and programmes in Europe and China of the IC2PerMed project.

WP1 involves, with respect to deliverable 1.1, a detailed and extensive mapping of PM activities and initiatives in Europe and China organized along the categories of (1) policy measures, (2) programmes and (3) action plans building upon and extending the work performed by ICPerMed. Regarding Europe the mapping distinguishes between activities and initiatives under the roof of the EU and those promoted by its member states.

Besides the identification and listing of the mapping results, the key objective of D1.1 is to extract common priorities in PM and deliver a comparative analysis of the current policy frameworks in place between China and Europe, putting the results in a global context.

2 Methodology

To conduct the mapping, a four-step methodological desk research has been performed from March to December 2020:

Step 1: Scientific literature search

Step 2: Grey literature search

Step 3: Consultation of Horizon 2020 National Contact Points

Step 4: IC2PerMed survey of experts in PM

The scope of the desk research was the retrieval on information about Policy Measures, Programmes and Action Plans related to PM.

Scientific literature search

PubMed search of the MEDLINE electronic database was used to retrieve any available article, review or document on policies and strategies related to Personalised Medicine published in English language.

Grey literature search

Using Google Scholar, Google and Microsoft Academic search engines in combination with a broad set of search terms, the mapping was further extended identifying relevant publicly available documents at the European and EU Member State level including information on the People's Republic of China.

Desk research on institutional online repositories

Here's a list of the main repositories explored:

- European level:
  - European Union, European Commission
- EU Member state level:
  - Health ministries
  - Additional institutions related to public health
- China:
  - Ministry of Science and Technology of the People's Republic of China (MOST) and additional institutions related to public health
- ICPerMed webpage

Consultation of National Contact Points regarding health

The Horizon 2020 National Contact Points of the EU Member States were contacted and asked to provide relevant information along the scope of the desk research.

IC2PerMed survey of experts in PM

A survey was elaborated within the IC2PerMed consortium, aiming to explore the current landscape of implementation, priorities, and challenges related to Personalised Medicine in China and Europe, with a focus on Sino-European collaboration in this field (see Appendix 1). The survey was made available at the IC2PerMed website:

> https://www.ic2permed.eu/ic2permed-survey-on-china-eu-cooperation-over-personalised-medicine-developments/

> Duration: From January 29th until February 28th, 2021

The survey aimed in addition at retrieving novel information, validating the identified PM mapping results. It consisted of four sections, three of them addressing the D1.1 Scoping Paper.

1) Awareness on policies related to PM;
2) Priority areas to be considered in policy planning in the field of PM; and
3) Obstacles to the planning, development, and implementation of policies in the field of PM.

The data retrieved from the combined methodology of mapping was reported in tables, standardized for both EU and China, and the comparative analysis was structured and written based on the results.
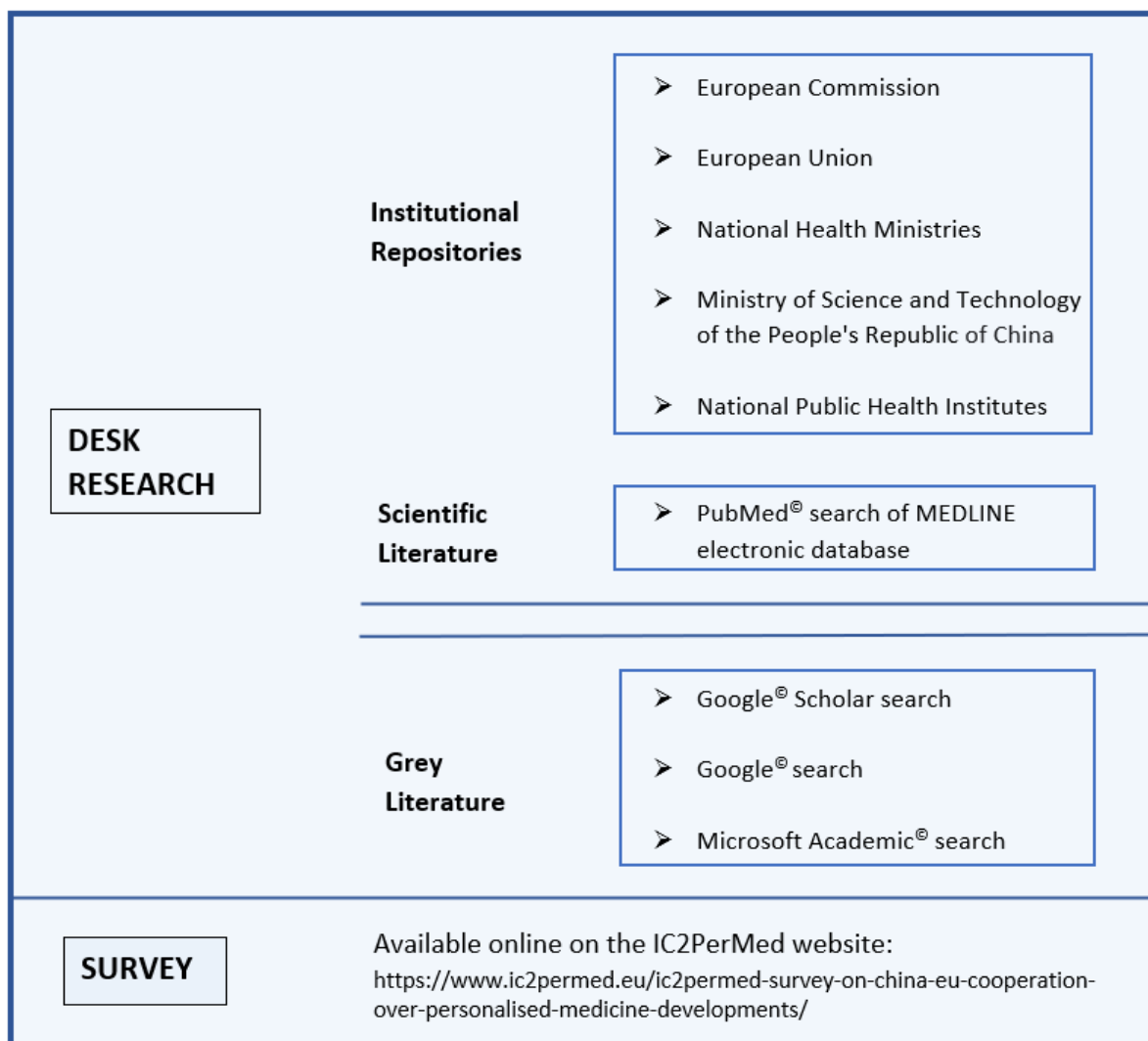
Figure 1 – Overview on the applied methodology.

3 Introduction to Personalised Medicine

In the light of the burden of ever-increasing healthcare costs associated with the constant new introduction of costly advanced therapies on one hand and an ageing society with a larger proportional share of chronically ill patients on the other, our healthcare systems are in direct need of a reform.

Personalised therapeutic approaches with tailored treatment strategies for individual patients or patient subgroups in combination with disease prevention strategies enabled by assessing both the genetic background of patients and their respective lifestyles, show high potential in reducing inefficiencies by overtreatment and the application of non-effective therapies in healthcare.

"Personalised Medicine" acts as an umbrella term for this new vision in medicine and healthcare. In such a wide and active field of research and debate among experts, a universally accepted definition of PM does not exist, and nuanced differences can still be observed from one country to another.

The Council of the European Union came up with a definition of PM in Europe in its 2015 conclusions on Personalised Medicine for patients[2]:

> *"It is widely understood that Personalised Medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs."*

Other terms frequently in use by the global community are precision medicine, stratified medicine, individualized medicine, genomic medicine, pharmacogenomics as well as tailored therapy and integrated healthcare among others[3].

In the People's Republic of China, academia and policy makers generally prefer the term "Precision Medicine" over "Personalised Medicine". Many of the modern concepts related to PM were introduced in 2006 in the context of precision surgery of liver resections[4], emphasising that patients differ markedly in their biological and social characteristics. This eventually led to the definition of Precision Medicine by the Chinese Academy of Sciences (CAS)[5]:

> *"Precision medicine is a medical model for high-efficiency, low-cost prevention and treatment of diseases tailored to individual patients based on their genetic content."*

Thanks to the significant overlap in definition and the context of their use, the terms Precision Medicine and Personalised Medicine are interchangeable, both are abbreviated to PM in this deliverable. Table 1 and 2 provide a short overview of the chronological development of PM in the European Union and China.

Pharmaceutical development has thankfully led to the availability of thousands of distinct approved medicines worldwide, often with several alternative drugs treating the same disease. This is particularly important because patients diagnosed to suffer from the same illness often react differently to drug therapy. Many medicines are not as effective as expected in all patients, and some patients even suffer from severe adverse reactions. Thanks to extensive research in this area, we have started to understand some of the underlying principles. One of the important reasons is that therapies traditionally have been developed and prescribed using an "average patient approach" that does not take into account the molecular background, environmental factors and lifestyle conditions of an individual that determine its susceptibility to disease, the course of illness and the response to treatment.[6]

Public expenditure on health and long-term care has been increasing over the last decades in all EU member states and is expected to rise even further. In 2017[7], it accounted for 9.9% of the GDP in the

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[2] Council conclusions on personalised medicine for patients (2015/C 421/03)

[3] Nimmesgern et al. (2017), Personalized Medicine in Europe. In *Clinical and Translational Science*, 10: 61–63

[4] Dong, J. et al. (2013), Precision in liver surgery. In *Seminars in liver disease* (Vol. 33, No. 03, pp. 189–203)

[5] China kicks off Precision Medicine Research - Chinese Academy of Science
http://english.cas.cn/newsroom/archive/news_archive/nu2016/201601/t20160111_158607.shtml

[6] Commission Staff Working Document: Use of "-omics" technologies in the development of personalised medicine. SWD (2013) 436 final

[7] The World Bank DataBank – Current health expenditure (% of GDP) in 2017
https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS

EU and 5.2% in China. The global Personalised Medicine Market[8] is expected to grow at a CAGR of 11.42% over the period from 2020 to 2025, with China exceeding the global average.

The rapidly developing science-driven approach of PM to healthcare has potentially great benefits for patients, clinicians and healthcare systems alike. Some potential advantages offered by this approach include:

- the ability to make more informed medical decisions,
- the higher probability of desired outcomes thanks to better targeted therapies,
- the reduced probability of adverse reactions to medicines,
- the focus on prevention and prediction of disease rather than reaction to it,
- earlier disease intervention than has been possible in the past and,
- improved health care cost containment.

While current health care models are organ-, system- or disease-oriented, it is expected that PM brings a change of paradigm by integrating large-scale genotype data with phenotype data, creating a holistic model of patients. This could lead on the longer run to new molecular definitions of disease and adding to or replacing the current clinical ones. A better understanding of the molecular basis of diseases, especially if combined with knowledge of the interplay between the environmental factors to which individuals are exposed and their genetic background, will allow a better characterisation of pathologies and selection of more suitable treatment strategies.

The combination of data-driven prevention strategies and tailored therapies have the potential to profoundly transform our health systems towards higher sustainability by creation of a healthier population and the more efficient allocation of resources, reducing the overall costs in health care.

To reach that long-term goal, all policy makers and stakeholders in PM must come together and get involved to make this thriving ecosystem in Personalised Medicine a reality.

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[8] https://www.datamintelligence.com/research-report/personalized-medicine-market

Table 1 – Chronological development of PM in Europe

In December **2008** in a Communication of the Commission on a renewed vision for the pharmaceutical sector under the heading "Towards more personalised medicines" the EC announced a report on the use of "-omics" technologies in pharmaceutical research and development.

In **2010** reflections on PM commenced at the EU level with a series of workshops on different research areas that contribute to the new model of practicing medicine, presented in the conference "Perspectives in Personalised Medicine" organized by the European Commission in **2011**.[9] The conference highlighted the role of molecular diagnostics in helping healthcare professionals identify which patients were most likely to respond to specific interventions. New diagnostic technology was making it possible to match patients with the most appropriate treatments.

In **2015** PM challenges were developed and discussed in the report Shaping Europe's Vision for Personalised Medicine[10] of the EU funded project PerMed[11]. Also, in **2015** in their Council Conclusions on Personalised Medicine for Patients[2], the EU Health Ministers adopted the definition of PM by the Horizon 2020 Advisory Group.

On June **2016**, the EC held a second conference on PM, this time to discuss a broader policy perspective.[12]

Since November **2016** the ICPerMed has been supported by a secretariat which is funded within the EU's Horizon 2020 research and innovation programme. The central aim of ICPerMed is to align and encourage joint efforts in PM research and implementation.

The first ICPerMed workshop took place on June **2017** in Milan, Italy.

The Personalised Medicine in Action conference in Berlin in November **2018** provided a number of best practice examples, strategies, and other ongoing activities in Europe and beyond.

The 2nd ICPerMed Workshop "Citizens, patients and implementation" took place in November **2019** in Madrid.

The ICPerMed Conference **2020** 'Personalised Medicine – From Vision to Practice' which was planned for October 2020 in Paris, will take place on February **2021** due to the coronavirus situation (COVID-19). The conference aims to demonstrate how PM will lead to the next generation of healthcare by **2030.**[13]

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[9] https://ec.europa.eu/research/health/pdf/personalised-medicine-conference-report_en.pdf
[10]https://www.researchgate.net/publication/301694017_Shaping_Europe's_Vision_for_Personalised_Medicine_Strategic_Research_and_Innovation_Agenda_SRIA
[11] https://www.icpermed.eu/
[12] https://ec.europa.eu/info/sites/info/files/conferences/permed2016/permed-2016_report.pdf
[13] https://www.icpermed.eu/media/content/Vision_Paper_2019.pdf

Table 2 – Chronological development of PM in China

In **2006**, the concept of "precision surgery" was first proposed in China.

In March **2015**, the first national precision medical strategy expert meeting was held and a development plan for precision medicine was formulated.

In **2016**, precision medicine was included in the 13th Five-Year Plan, which is the highest-level guidance document for the Chinese government's future development plan.

In the same year, China launched the national key research and development programme on "Precision Medicine", including a total of 56 approved projects in the first batch.

In **2017**, China launched the "Hundred Thousand People Genome Project", which is led by Harbin Institute of Technology, and aims to draw a Chinese fine genome map and to study the relationship between disease health and genetic inheritance.

In **2018**, China's key research and development programme on Precision Medicine launched a number of new projects. With a total investment of 1040.8 million yuan, the programme mainly focused on the new generation of research and development on Clinical Biomics Technology, the integration, storage, utilization and sharing platform of big data for precision medicine, and the accurate research of disease prevention and treatment plan.

In recent years, China has invested heavily in medical big data, advanced medical equipment, cell therapy and genetic testing industry clusters, and gene therapy. In terms of scientific research results, Chinese scholars decoded the 6mA methylation modification in human genomic DNA for the first time in **2018**, which is a breakthrough in the field of human epigenetics[14]. Currently, the scale of China's precision medicine market is rocketing with a growth of 20% per year, which has exceeded the global average, and many innovative technology companies have joined the field of Precision Medicine.

4 ICPerMed

Established in 2016, ICPerMed[15] builds on previous initiatives that enabled the identification of major challenges in PM. The overall aim of ICPerMed is to pave the way for the next generation of medicine.

Operating on the definition of Horizon 2020 and the European Council Conclusions on PM for patients[2] and covering the entire healthcare value chain, ICPerMed developed an Action Plan[16] of actionable research and support activities.

The Action Plan is intended to be the blueprint for establishing research activities within the entire range of PM at all levels; the national, the European as well as the international. It feeds into national and European strategic discussion of research funders shaping their future programmes including both single actions and joint efforts.

The development of actions to advance PM of ICPerMed members together with nominated experts is complemented by international conferences on PM organised in conjunction with the European Commission (EC).

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[14] Xiao, C.-L. et. (2018). N6-Methyladenine DNA Modification in the Human Genome. Molecular Cell, 71(2), 306–318.e7. https://doi.org/10.1016/j.molcel.2018.06.015

[15] ICPerMed International Consortium https://www.icpermed.eu/

[16] https://www.icpermed.eu/media/content/ICPerMed_Actionplan_2017_web.pdf

Over time and with the support of the EC, ICPerMed has grown into a family of consortia, programmes, and actions. The "ICPerMed family" (Fig. 2), together with associated and related initiatives, plays an important role in supporting the research and implementation of PM on an international level.
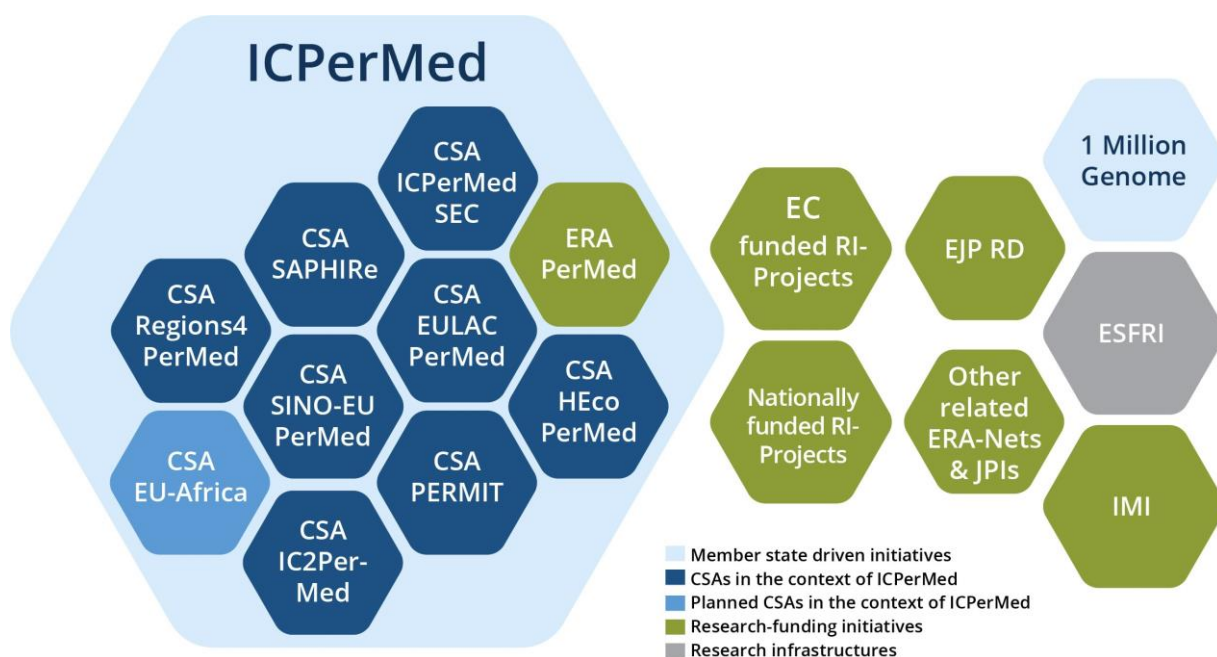

Figure 2 – Projects and initiatives forming part of ICPerMed. Taken from the ICPerMed Vision paper[17] (2019)

Under the ICPerMed leadership a set of coordination and support actions (CSAs) are bundled, such as the CSA for the ICPerMed secretariat, two regional intra-European CSAs on the adoption of PM: Regions4PerMed and SAPHIRe, the EULAC PerMed covering Latin American and Caribbean countries as well as the HEcoPerMed performing research on health economics including funding and reimbursement mechanisms.

ERA PerMed[18] is a COFUND of the European Commission that promotes excellence research and reinforces competitiveness of European players in PM. Further CSA calls, which have been published but not yet evaluated and funded, will soon be integrated into the ICPerMed platform.

In addition, there are research and innovation projects related to the aims of ICPerMed, either exclusively funded by the European Commission (EC) or regional entities as well as by joint efforts. Examples are the European Joint Programme on Rare Diseases (EJP RD), the European Research Area networks (ERA-Nets) and Joint Programming Initiatives (JPIs). Other programmes aligned with the aims and goals of ICPerMed include the "1+ Million Genome"[19] initiative, the European Strategy Forum on Research Infrastructures activities (ESFRI) and projects funded via the Innovative Medicines Initiative (IMI).

ICPerMed has developed a vision of how the use of PM approaches will promote "next-generation" medicine in 2030[20] building upon the general increased understanding of individual influencing factors

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that play an important role in disease outbreak and progression, eventually having the goal to align and encourage joint efforts in research and implementation of PM.

5 Policy Measures, Programmes and Action Plans related to PM in the EU and China

The following section is mapping major policy measures, programmes and action plans related to PM within the European Union and the People's Republic of China, providing summarized information on the respective activities.

In order to structure the mapping, the following criteria and definitions were applied:

- A *policy measure*[21] embodies an institution's political vision and direction using a set of rules and guidelines that specify how an 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*[22] is a detailed proposal defining key priorities and objectives with the goal to improve regulations, funding schemes and knowledge about a certain topic.

5.1 European Policy Measures, Programmes and Action Plans related to PM

The field of Personalised Medicine quickly progresses in an evolutionary manner through substantial advances in research and science as well as through the introduction of advanced technologies that are constantly improved by iterative development schemes. This requires policy makers to constantly monitor ongoing developments and adjust their strategies without falling behind. At the same time policy makers act as powerful players in the ecosystem itself by coordinating and funding of research efforts, providing guidance in the long-term vision of PM and acting as representatives of the citizens' general interest.

Policy measures, programmes and action plans are powerful tools for regulatory authorities to be engaged in the complex landscape of PM. In a vital discourse with research and industry stakeholders, PM legislation addressing the current limitations of healthcare and promoting the transformation to more sustainable health systems must be put forward.

In the political landscape of the European Union, we distinguish between the European level and the level of the member states (MS). European legislation falls under the authority of three main institutions[23]:

- the European Parliament,
- the Council of the European Union,
- and the European Commission.

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[21] https://op.europa.eu/s/oolW – Quality of Public Administration (2017)
[22] https://ec.europa.eu/futurium/en/action-plans/what-action-plan
[23] Institutions and bodies https://europa.eu/european-union/about-eu/institutions-bodies_en

How EU bodies work together

European Council
Heads of State or government
from each EU country
(e.g. Prime Ministers or their equivalent)

Sets the EU's policy agenda

European Commission
Commissioners
one from each EU country

Scrutinises

Proposes legislation and Budget

European Parliament
MEPS elected
directly by citizens

EU Council
Ministers from each
EU country

Input, feedback
and lobbying
on legislation
from, e.g.,
- public consultations
- citizens, civil society
- experts, interest groups
- political negotiations
- parliamentary hearings

Jointly decide legislation and Budget

Figure 3 – Scheme on the different EU bodies and their working. Taken from TASC[24]

In a complex interplay, these three bodies develop and apply the policies and laws in force throughout the political union. The national interests of the EU member states however are constantly involved in the legislative process either directly through the intergovernmental Council of the European Union formed by the member states' executive bodies or the elected members of the European Parliament (MEP) to name two examples.

In 2015, this concept of joint governance on PM in Europe has been elegantly described by the "Council Conclusion on Personalised Medicine for Patients"[25]:

> *"Under Article 168 of the Treaty on the Functioning of the European Union a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, and that Union action, which is to complement national policies shall be directed towards improving public health. The Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action. Union action shall fully respect the responsibilities of the*

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[24] CC BY-NC-SA 4.0: number of Commissioners removed – https://www.tasc.ie/opengovtoolkit/public-decision-making/european-union/

[25] http://data.consilium.europa.eu/doc/document/ST-15054-2015-INIT/en/pdf

> *Member States for the organisation and delivery of health services and medical care,*
> *including allocation of the resources assigned to them."*

This system shows high flexibility and allows individual member states to exceed the status quo on legislation and application of PM measures, making them a perfect testing field for future pan-European rules and guidelines if proven to be successful.

5.1.1 Policy Measures at EU level

The European Union has developed a diverse and finely nuanced set of policy measures[26], often also referred to as policies and measures (PaM), to express its political vision on a specific topic and implement concrete rules enforceable by law.

On one hand there are legally non-binding EU policy measures such as opinions and recommendations by the European Commission as well as conclusions and resolutions[27] by the Council of the European Union. Those instruments convey important strategic positions and promote broad discussions on the respective topics and issues.

On the other hand, there are legally binding policy measures such as directives, setting compulsory goals for the member states to be implemented in national law, and regulations, legislative acts applied in its entirety across the European Union. At the highest level stand the constitutional treaties of the European Union, such as the Treaty on the Functioning of the European Union, formerly known as Treaty of Rome, whose Article 168 in its current iteration of 2008 puts important ramifications on human health and health systems.

With respect to human health in the European Union, two regulatory systems are essential: a) the regulation on medicinal products for human use[28] including pharmaceuticals and b) the directive on in vitro diagnostic medical devices[29]. Both frameworks aim to ensure a high level of public health protection and promote the functioning of the internal market. They explicitly encourage innovation in medicine and have been extended by PM concepts over the last decade. Of similar importance are patient data, including acquisition, analysis and storage thereof. PM therefore also touches legislation in digital health and compliance with data protection rules. Figure 4 provides an overview about the manifold topics that European policy measures cover.

The EC's report "Use of '-omics' technologies in the development of PM" [30] was published in 2013 as a first European policy document in the field. The report highlights the high potential and important issues in the development of PM and concludes that the development of PM using "-omics" technologies offer new opportunities for the treatment of patients in the European Union. It underlines PM's strength in supporting healthcare providers to offer better-targeted treatments, avoid medical errors and reduce adverse reactions to medicinal products. It also identifies several challenges to the implementation and uptake of PM in health systems.

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[26] https://europa.eu/european-union/law/legal-acts_en

[27] https://www.consilium.europa.eu/en/council-eu/conclusions-resolutions/

[28] https://ec.europa.eu/health/human-use/legal-framework_en

[29] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0079-20120111

[30] https://ec.europa.eu/research/health/pdf/2013-10_personalised_medicine_en.pdf
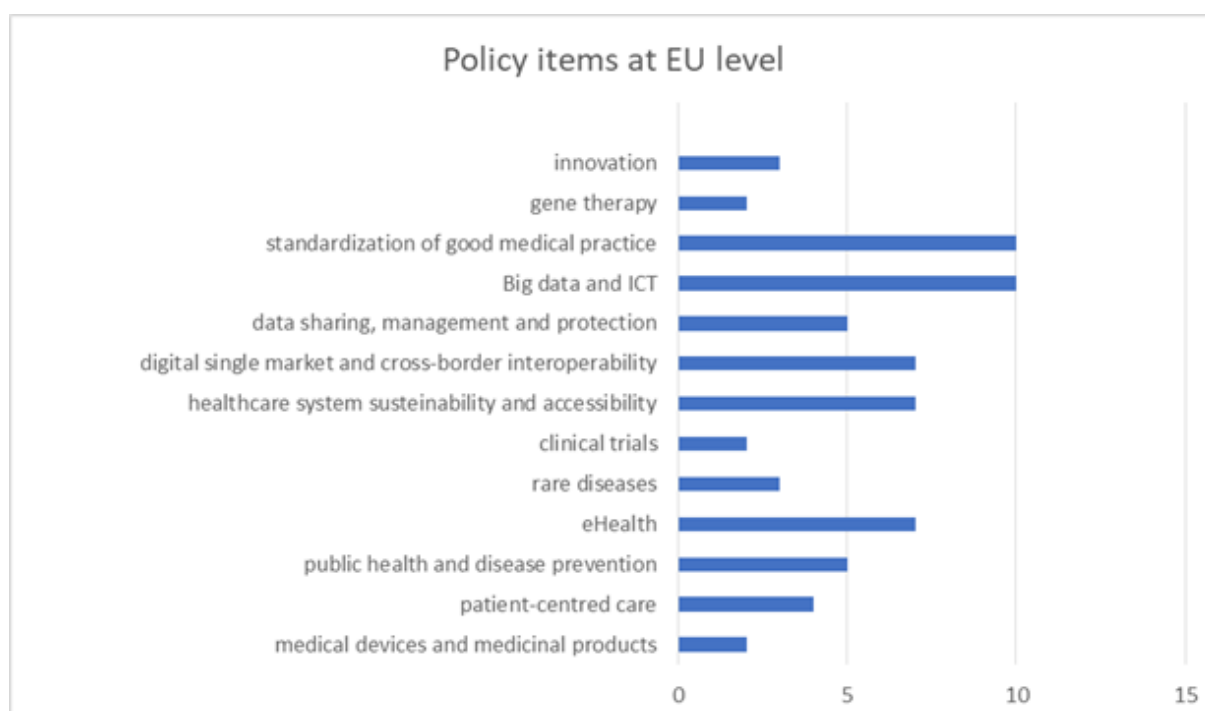
Figure 4 – Mapping of policy items at EU level

Table 3 summarises the mapping results of European policy measures in Personalised Medicine as well as PM related ones.

Table 3 – Policy Measures at EU level

PM related Policy	**Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices**
Description of the Policy	
In vitro diagnostic medical devices (IVDs) are products used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body. Such devices must comply with the essential requirements set out in Directive 98/79/EC (IVD Directive) to ensure a high standard of safety and performance when they are placed on the market.	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0079-20120111
PM related Policy	**Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products**
Description of the Policy	
The regulation encourages research, development and marketing of medicinal products for rare diseases affecting only up to five in 10,000 persons in the Community. It offers incentives such as fee waivers for the regulatory procedures and the possibility of an EU marketing authorisation with a 10-year market exclusivity period. There's a strong connection between PM-approaches and rare diseases, over 80 % of the rare – also often called "orphan" – diseases have a strong genetic background and require tailor-made therapeutic solutions and the development of orphan medicinal products.	

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000R0141-20190726
PM related Policy	**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**

Description of the Policy
The EU Clinical Trials Directive aims to ensure that clinical trials are conducted in compliance with good clinical practice (GCP), a set of internationally recognised ethical and scientific quality requirements that must be observed for designing, conducting, recording and reporting clinical trials involving the participation of human subjects. Compliance with GCP provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02001L0020-20090807
PM related Policy	**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**

Description of the Policy
The Directive states that no medicinal product may be placed on the market in the EU without a marketing authorisation. Medicinal products must comply with the requirements of EU pharmaceutical legislation. The legislation includes detailed rules on the requirements and procedures for obtaining marketing authorisation, coupled with a system of continuous monitoring of already authorised products on the market through pharmacovigilance.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02001L0083-20190726
PM related Policy	**Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 on procedures for the authorisation and supervision of medicinal products for human and veterinary use**

Description of the Policy
The purpose of this regulation is to lay down community procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use, and to establish a European Medicines Agency (EMA).

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02004R0726-20190330
PM related Policy	**Council conclusions on common values and principles in European Union Health Systems 2006/C 146/01**

Description of the Policy
The aim is to define a set of operating principles shared across the European Union, especially regarding patient involvement and quality and safety of care. The conclusion emphasises that all European Union health systems aim to be patient-centred.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52006XG0622(01)
PM related Policy	**Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products**

Description of the Policy
The scope of this Regulation is to regulate advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, in accordance with the general scope of the Community pharmaceutical legislation.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32007R1394
PM related Policy	**Commission White Paper of 23 October 2007 'Together for Health: A Strategic Approach for the EU 2008-2013' COM (2007) 630 final [no longer in force]**

Description of the Policy
The strategy relates to health in all sectors. It must also, in a single strategic framework, confront the growing challenges for the health of the population, such as demographic changes, pandemics, bioterrorism and illnesses related to unhealthy lifestyles. The white paper proposes four principles for the coming years: 1) a strategy based on shared health values; 2) health is the greatest wealth; 3) health in all policies; and 4) strengthening the EU's voice in global health. The objectives of the strategy are: 1) fostering good health in an ageing Europe; 2) protecting citizens from health threats; and 3) supporting dynamic health systems and new technologies.

Source	https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:52007DC0630
PM related Policy	**Article 168 of the Treaty on the Functioning of the European Union 2008**

Description of the Policy
A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, and Union action, which is to complement national policies, shall be directed towards improving public health. The Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action. Union action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care, including allocation of the resources assigned to them.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12008E168
PM related Policy	**Commission recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems 2008/594/EC**

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/TXT/?uri=CELEX:32008H0594

PM related Policy	**Council recommendation of 8 June 2009 on an action in the field of rare diseases 2009/C 151/02**

Description of the Policy

The council urges the EU member states 1) to develop plans and strategies in the field of rare diseases; 2) to standardize the definition, codification and inventorying of rare diseases; 3) to promote research on rare diseases; 4) to identify centres of expertise and build European reference networks for rare diseases; 5) to gather expertise on rare diseases at the European level; 6) to empower patient organizations by consulting them on the policies in the field of rare diseases; and 7) to guarantee the long-term sustainability of infrastructures related to rare diseases.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009H0703(02)

PM related Policy	**Directive 2011/24/EU on the application of patients' rights in cross-border healthcare**

Description of the Policy

The directive provides the regulatory framework to assure high-quality cross-border healthcare based on the principles of universality, access to good quality care, equity and solidarity within the European Union. In terms of Personalised Medicine, it focuses on patients' rights in cross-border care and identifies specific areas where Member State cooperation in eHealth can bring significant added value to national health systems, such as in the cross-border exchange of patient summaries and use of e-Prescriptions. The formation of European Reference Networks, in particular in the area of rare diseases, is highly encouraged and shall help to realise the potential of European cooperation and knowledge exchange.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011L0024

PM related Policy	**Council conclusions on innovation in the medical device sector 2011/C 202/03**

Description of the Policy

The Council conclusions on innovation in the medical device sector recognise that innovative medical devices could improve health and quality of life for patients and could contribute to addressing the sustainability of healthcare systems, and that innovation should be increasingly patient-centred. It proposes a holistic approach considering the whole healthcare process and all patients' needs (physical, social, psychological, etc.).

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011XG0708(03)

PM related Policy	**Council conclusions: towards modern, responsive and sustainable health systems 2011/C 202/04**

Description of the Policy
The conclusions emphasise inter alia the importance to create modern, responsive, efficient, effective and financially sustainable health systems that provide equitable access to health services for all. The closing of serious health gaps existing between and within Member States is of uttermost importance. It also reiterates the indispensable role of adequately trained health professionals in each Member State for the functioning of the healthcare systems.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011XG0708(04)

PM related Policy	**Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use [not yet in application]**

Description of the Policy
The Clinical Trials Regulation is planned to eventually replace the Clinical Trials Directive (Directive 2001/20/EC). The Regulation ensures a greater level of harmonisation of the rules for conducting clinical trials throughout the EU. It introduces an authorisation procedure based on a single submission via a single EU portal, an assessment procedure leading to a single decision, rules on the protection of subjects and informed consent, and transparency requirements. It also makes it easier for pharmaceutical companies to conduct multinational clinical trials, which intends to increase the number of studies conducted within the EU.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0536

PM related Policy	**Council conclusions on innovation for the benefit of patients 2014/C 438/06**

Description of the Policy
The Council conclusions on innovation for the benefit of patients are stressing the need to fully respect areas of Member States competence, advocate the need for cooperation on strategies to effectively manage expenditure on pharmaceuticals and medical devices, while ensuring equitable access to effective medicines within sustainable national healthcare systems. The important role of the European health technology assessment (HTA) networks is stressed in bringing innovation to the healthcare systems.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014XG1206(03)

PM related Policy	**Communication from the Commission on effective, accessible and resilient health systems COM/2014/0215 final**

Description of the Policy
The Communication concluded that Member States' future ability to provide high quality care to all will depend on making health systems more resilient, more capable of coping with the challenges that lie ahead. And they must achieve this while remaining cost-effective and fiscally sustainable.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52014DC0215

PM related Policy	**Council conclusions on personalised medicine for patients 2015/C 421/03**

Description of the Policy
The conclusion suggests broadly accepted – however not commonly agreed upon - definition of Personalised Medicine. It invites the Member States 1) to support access to clinically effective and financially sustainable Personalised Medicine; 2) to use genomic information; 3) to develop or strengthen public health communication strategies; 4) to put in place information and awareness strategies to improve health literacy; 5) to provide education and training to health professionals; 6) to foster cooperation in data standardisation; 6) to promote cross-disciplinary interaction to better understand available data; 7) to develop or adjust procedures aiming to evaluate the impact of Personalised Medicine; 8) to recognise the potential of population-based biobanks; 9) to consider the exchange of information as well as developing long-term, patient-centred, strategic approaches; and 9) exchange best practices in the field of Personalised Medicine.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015XG1217(01)

PM related Policy	**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)**

Description of the Policy
The Regulation prohibits the processing of special categories of personal data such as data concerning health (Article 8). This prohibition is only lifted in certain clearly defined circumstances. That will be the case inter alia when processing of data concerning health is necessary for health purposes and subject to the specific conditions and safeguards laid down elsewhere in the proposed Regulation (Article 81) or when processing is necessary for historical, statistical and scientific research purposes subject to conditions and safeguards set out in a separate provision (Article 83).

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0679-20160504

PM related Policy	**Council conclusions on the EPC-Commission Joint Report on health care and long-term care in the EU 2016**

Description of the Policy
The Council conclusions identify several reform measures to address policy challenges in health and long-term care systems, including strengthening health promotion and disease prevention; moving healthcare out of the hospital sector towards more cost-effective primary and ambulatory care services; and promoting integrated care.

Source	https://data.consilium.europa.eu/doc/document/ST-14182-2016-INIT/en/

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 the implementation of the Digital Single Market Strategy A Connected Digital Single Market for All COM/2017/0228 final**

Description of the Policy	
The communication suggested to increase coordination efforts on the digital transformation of health and care in Europe, focusing on three priorities: (i) Citizens´ secure access to electronic health records and the possibility to share it across borders and the use of ePrescriptions, (ii) Supporting data infrastructure, to advance research, disease prevention and personalised health and care in key areas including rare, infectious and complex diseases, (iii) Facilitating feedback and interaction between patients and healthcare providers, to support prevention and citizen empowerment as well as quality and patient-centred care, focussing on chronic diseases and on a better understanding of the outcomes of healthcare systems.	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2017:228:FIN
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 European Interoperability Framework – Implementation Strategy COM/2017/0134 final**

Description of the Policy	
The European Interoperability Framework (EIF) was adopted in the context of the implementation of the Interoperability Solutions for European Public Administrations (ISA) programme (2016–2020). It is meant to be a generic interoperability framework that could be used for the alignment of existing, or the creation of new, domain-specific interoperability frameworks (DIFs) such as those that could be developed in the field of electronic health records and other digital health applications.	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017DC0134
PM related Policy	**Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health 2017/C 440/05**

Description of the Policy	
The Council of the European Union invites the Member States to: 1) continue to implement policies that support digital innovation in the health sector, invest in and make active use of data-driven tools and methodologies which enable the provision of safe and high-quality healthcare services and support sustainable health systems, 2) set up sound and robust health data governance frameworks, as outlined in the OECD Recommendations on Health Data Governance, to ensure privacy and integrity of health data, 3) work together to facilitate the necessary convergence in regulatory and governance approaches to the use of health data for research and innovation purposes, by identifying and promoting best practices in the use of appropriate data protection safeguards and in health data governance within the Union, and, if appropriate, engaging with the bodies responsible for data protection for example in the framework of the European Data Protection Board provided for in the General Data Protection Regulation.	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XG1221(01)
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 COM/2018/233 final (2018)**

Description of the Policy	

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.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:233:FIN
PM related Policy	**Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (Text with EEA relevance)**

Description of the Policy

This recommendation assures the ability of citizens and healthcare providers to securely access and share electronic health records ('EHR's). It enables the secure access and sharing of health records across borders in the Union. It stresses the importance of digital solutions linked to health apps, or wearable devices, combined with a system that allows a citizen secure access to their own health data, should enable patients with chronic conditions, such as diabetes, or cancer, to monitor their own symptoms at home and share them quickly with their clinical teams.

Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019H0243
PM related Policy	**Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA and on information and communications technology cybersecurity certification**

Description of the Policy

This Regulation aims to achieve a high level of cybersecurity, cyber resilience and trust in the European Union by setting: a) objectives, tasks and organisational matters for a strengthened and renamed European Union Agency for Cybersecurity (ENISA), with a new permanent mandate; b) a framework for voluntary European cybersecurity certification schemes for Information and communications technology (ICT) products, services and processes. The regulation establishes a European cybersecurity certification framework to: 1) improve the functioning of the internal market by increasing the level of cybersecurity in the EU and enabling a harmonized approach at EU level to European cybersecurity certification schemes with a view to creating a digital single market for ICT products, services and processes; 2) set up a mechanism to establish certification schemes that confirm ICT products, services and processes that have been evaluated in accordance with such schemes comply with specified security requirements to protect the availability, authenticity, integrity or confidentiality of stored, transmitted or processed data or functions or services offered by, or accessible via, those products, services and processes throughout their life cycle.

Source	https://eur-lex.europa.eu/eli/reg/2019/881/oj
PM related Policy	**Council conclusions on shaping Europe's digital future 2020/C 202 I/01**

Description of the Policy	
The Council of the European Union recognizes that the COVID-19 crisis demonstrates the importance of the digital transformation of health and care and its value in strengthening the resilience of health systems and their response to the pandemic. It underlines that the development of a European Health Data Space by the Commission together with the Member States' health authorities holds potential to facilitate the development of effective prevention, diagnosis, treatments, and care. It may also ensure more cost-effectiveness and workflow optimisations in health care, thus leading to improved health outcomes for patients, better epidemiological surveillance systems, and longer-term sustainability of health systems.	
Source	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XG0616(01)

5.1.2 Programmes at EU level

The European Union provides funding to projects in a wide area of topics [31] through specific programmes. Of high importance are the seven-year long framework programmes (FP) to foster research and align the ongoing efforts of institutions across the European Union, forming a common European Research Area (ERA). The FPs help in coordinating national research policies and pool research funding to avoid duplications. These actions span from supporting basic research and development over product-centric innovations to the coordination and communication in important areas of interest.

The FPs provide provisions and are embedded in complementary forms of research funding and innovation programmes bringing together the EU and its Member States. Of special importance are e.g. the jointly funded (public-to-public) research partnerships [32]:

- European Research Area networks (ERA-NET) Cofunds
- Joint Programming Initiatives (JPIs)
- Research initiatives based on Article 185

Those instruments are described in greater detail in the mapping included in D1.2 - Map of Major Funding Agencies and Stakeholders in Europe and China.

Thanks to the importance given by the European Union to Personalised Medicine, there are important PM-related projects driven forward by each of its framework programmes. Only within the last two, FP7 and Horizon 2020 in the period from 2007 to 2020, the EU invested over 2.6 billion EUR in PM-associated research and innovation [33].

Table 4 provides a detailed overview on the structure and content of the 8th and upcoming 9th European framework programmes, Horizon 2020 and Horizon Europe respectively. It lists the biannual work programmes of the FPs' health section giving an overview on their programmatic content and includes furthermore other highly relevant FP initiatives related to PM.

<p style="text-align:center;">Table 4 – Programmes at EU level</p>

PM Programme	Section 8 on "Health, demographic change and wellbeing", HORIZON 2020 – Work Programme (2014 – 2015),

Description of the Programme

The Work Programme is divided into seven areas which reflect the need for a translational and integrated approach to the challenge of personalizing health and care: 1) Understanding health, ageing and disease; 2) Effective health promotion and disease prevention; 3) Improving diagnosis; 4) Innovative treatments and technologies; 5) Advancing active and healthy ageing; 6) Integrated sustainable citizen-centred care and; 7) Improving health information and data exploitation.

The programme aims to improve the understanding of the causes and mechanisms underlying health, healthy ageing and disease; improve the ability to monitor health and to prevent, detect, treat and manage disease; support older persons to remain active and healthy; and test and demonstrate new models and tools for health and care delivery.

Source	https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/main/h2020-wp1415-health_en.pdf
PM Programme	**Section 8 on "Health, demographic change and well-being", HORIZON 2020 – Work Programme (2016 – 2017)**

Description of the Programme

The Work Programme is divided into six areas implementing several research priorities: personalised medicine, rare diseases, human bio-monitoring, mental health, comparative effectiveness research, advanced technologies, e/m-health, robotics, patient empowerment, active and healthy ageing, data security, big data, valorisation, anti-microbial resistance, infectious diseases including vaccines, maternal and child health and the silver economy. The challenges associated with PM are: 1) Understanding health, well-being and disease; 2) Preventing disease; 3) Treating and managing disease; 4) Active ageing and self-management of health; 5) Methods and data and; 6) Health care provision and integrated care.

The programme aims to improve the quality of life of EU citizens, to position the EU as a central player in the global context and to stimulate the high quality of European research and innovation (R&I) and industrial competitiveness by mobilising relevant European R&I performers, both public and private. It will therefore contribute to the Commission priorities on: 'A new boost for jobs, growth and investment', 'A stronger global player' and 'A connected digital single market'.

Source	https://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-health_en.pdf
PM Programme	**Section 8 on "Health, demographic change and wellbeing", HORIZON 2020 – Work Programme (2018 – 2020)**

Description of the Programme

The Work Programme is divided into three major calls: I) Better Health and care, economic growth and sustainable health systems; II) Digital Transformation in Health and Care and; III) Trusted digital solutions and Cybersecurity in Health and Care. Call I itself focuses on 1) Personalised medicine; 2) Innovative health and care industry; 3) Infectious diseases and improving global health; 4) Innovative health and care systems; 5) Decoding the role of environment, incl. climate change, for health and wellbeing and; 6) Supporting the digital transformation in health and care.

With respect to PM, the key objectives of the programme are to make progress moving towards the effective integration of PM approaches into healthcare services and systems to the benefit of patients and citizens; to fight infectious diseases and antimicrobial resistance; to address the needs of most vulnerable groups; and exploring the digital potential for health innovations and healthcare.

Source	https://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf
PM Programme	**Third Health Programme (2014–2020)**

Description of the Programme

The EU Health Programme outlines the strategy for ensuring good health and healthcare. It feeds into the overall Europe 2020 strategy which aims to make the EU a smart, sustainable and inclusive economy promoting growth for all – one prerequisite for which is good health. The Programme is focusing on major Commission priorities.

Regulation (EU) 282/2014 is the legal basis for the 3rd Health Programme. With a budget of € 449.4 million and throughout 23 priority areas, the Health Programme serves four specific objectives to: 1) promote health, prevent disease and foster healthy lifestyles through 'health in all policies', 2) protect EU citizens from serious cross-border health threats, 3) contribute to innovative, efficient and sustainable health systems, 4) facilitate access to high quality, safe healthcare for EU citizens.

Source	https://ec.europa.eu/health/funding/programme_en
PM Programme	**Cluster 1 on "Health", HORIZON EUROPE, Annex 1 to the "Orientations towards the first Strategic Plan for Horizon Europe"**

Description of the Programme

Horizon Europe Cluster 1 "Health" is divided into six major destinations: 1) Staying healthy in a rapidly changing society; 2) Living and working in a health-promoting environment; 3) Tackling disease and reducing disease burden; 4) Ensuring access to innovative, sustainable and high-quality health care; 5) Unlocking the full potential of new tools, technologies and digital solutions for a healthy society and; 6) Maintaining an innovative, sustainable and globally competitive health related industry. The programme tries to address following PM- and health-related challenges by advancing knowledge and capabilities, improving the understanding of health and diseases, developing innovative methodological and technological solutions to better manage health and diseases, and designing sustainable approaches for the digital transformation and delivery of integrated, person-centred and equitable health and care services with improved accessibility and health outcomes supported by needs-driven innovation and reliable supply chains in Europe.

Source	https://ec.europa.eu/research/pdf/horizon-europe/annex-1.pdf
PM Programme	**Mission Cancer [Proposed Mission], "Conquering cancer: mission possible", Report of the Mission Board for Cancer**

Description of the Programme

Through the Horizon Europe Missions, the EU is committed to solve major societal challenges like e.g. fighting cancer, adapting to climate change, protecting our oceans, living in greener cities and ensuring soil health and food. "Mission Cancer" will be of particular interest with regard to Personalised Medicine and complements Cluster 1 on "Health" of the FP. By 2030: 1) more than 3 million lives shall be saved; 2) citizens shall live longer and better; 3) we shall achieve a thorough understanding of cancer; 4) prevent what is preventable; 5) optimise diagnosis and treatment; 6) support the quality of life of all people exposed to cancer; and 7) ensure equitable access to the above across Europe.

Source	https://op.europa.eu/en/publication-detail/-/publication/b389aad3-fd56-11ea-b44f-01aa75ed71a1

EU4Health Programme (2021–2027) [DRAFT]

Description of the Programme
The EU4Health programme aims to strengthen the EU's post-COVID-19 recovery by bringing innovation to the health sector. The aim is to strengthen the resilience of health systems and generally making the EU population healthier. The objectives are 1) protecting people in the EU from cross-border health threats; 2) making medicines, medical devices and crisis relevant products available and affordable; 3) investing in public health by strengthening health systems and health care workforce. The European Commission proposes to invest a total of 9.4 billion EUR over the period of the programme. In contrast to Horizon Europe, EU4Health is dedicated to facilitating the uptake, scale-up and deployment of health innovation in healthcare systems and clinical practice.
https://ec.europa.eu/commission/presscorner/api/files/document/print/en/qanda_20_956/QANDA_20_956_EN.pdf

5.1.3 Action Plans at EU level

Action Plans at the European level are tools to engage stakeholders in strategic discussions and harmonize European efforts towards reaching a common goal. In Table 5 we summarize essential Action Plans for the implementation of PM in the European Union.

Table 5 – Action Plans at EU level

PM Action Plan	**Commission Communication on "eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area" COM (2004) 356 final.**
Description of the Action Plan	
The Action Plan defined in 2004 the interoperability of electronic health records as one of the priorities for Member States. The Recommendation was intended to support the premise that connecting people, systems and services is vital for the provision of good healthcare in Europe insofar as it is necessary to enable the free flow of patients as well as digital health products and services, and hence may contribute significantly to the establishment and functioning of the internal market.	
Source	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF
PM Action Plan	**Strategic Research and Innovation Agenda for Personalised Medicine (SRIA)**
Description of the Action Plan	
Published in 2015, Shaping Europe's Vision for Personalised Medicine set out a comprehensive set of recommendations aimed at furthering the implementation of PM approaches. The SRIA was organised around five interrelated challenges, namely: • Developing awareness and empowerment • Integrating big data and ICT solutions	

- Translating basic to clinical research and beyond
- Bringing innovation to market
- Shaping sustainable healthcare

It also made nine prioritised recommendations with the potential for the greatest impact and outcome in facilitating the introduction of PM for the benefit of patients, citizens, and society.

Source	https://www.icpermed.eu/media/content/PerMed_SRIA.pdf

PM Action Plan	ICPerMed Action Plan

Description of the Action Plan	

Operating on the definition of Horizon 2020 and the European Council Conclusions on PM for patients and covering the entire healthcare value chain, ICPerMed developed an Action Plan of actionable research and support activities that was released in March 2017. The ICPerMed Action Plan is expected to guide strategic discussions of research and health funders around Europe and globally, as well as joint efforts of its members and the EC towards the implementation of PM.

Source	https://www.icpermed.eu/media/content/ICPerMed_Actionplan_2017_web.pdf

PM Action Plan	Europe's Beating Cancer Plan

Description of the Action Plan	

The Cancer Plan is structured around four key action areas with 10 flagship initiatives and multiple supporting actions. It will be implemented using the whole range of Commission funding instruments, with a total of €4 billion being earmarked for actions addressing cancer, including from the EU4Health programme, Horizon Europe and the Digital Europe programme. Its key areas of interest are: 1) prevention, 2) early detection, 3) diagnosis and treatment, and 4) the improvement of life quality.

Source	https://ec.europa.eu/commission/presscorner/detail/en/ip_21_342

5.1.4 Personalised Medicine in EU member states

The EU is a political and economic union of 27 Member States (MS). Article 4 of the Treaty on the European Union[34] highlights their important role stating that "competences not conferred upon the Union in the Treaties remain with the Member States".

In the preceding sections, we have shown EU's manifold means to interfere directly with legislation in order to set standards and best practices in public health related to PM. We have also seen the EU's important role in giving financial support to research and innovation stakeholders and the promotion of common actions in healthcare. However, regarding public health and health systems, the EU member states hold the primary responsibility for organizing and delivering health services and medical care.

The Council's conclusions on PM for patients in 2015 is a good example to demonstrate how the European Union helps in coordinating member state efforts by providing guidance and leadership in

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[34] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:12012M/TXT

steering the national governments towards specific goals. Here a short subset of examples how the EU invites member states to:

- support the access to clinically effective and financially sustainable PM. Member states shall, according to their national provisions, develop patient-centred policies, including patient empowerment. It mentions the importance of patient perspectives in the regulatory processes that are best assured involving patient organizations and other stakeholders.
- use genomics information in the light of recent advances in human genomics and integrating them into public health research as well as national policies and programmes, all in compliance with existing national provision concerning personal data and genomics.
- develop new or strengthen existing public health communication strategies using non-promotional data to increase public awareness of the benefits and risks of Personalised Medicine as well as the citizen's role and rights.
- foster cooperation in the collection, sharing, management and appropriate standardisation of data. This should benefit effective research and development of Personalised Medicine in compliance with data protection legislation, helping in the application of PM approaches.
- recognize the potential of biobanks, clinical as well as population-based, for speeding up the discovery and development of new medicinal products.

Though the ground-breaking and ambitious goals for PM have already been expressed and communicated to the member states in 2015, the member states are still in a transition phase translating the recommendations into their national legislation and strategies. The degree to which PM approaches have yet been implemented and applied to public health are differing substantially from one state to another.

During the PM Conference 2016 in Brussels[35] several of the aforementioned recommended aspects were addressed at a member state level. Examples for MS actions were given for the integration of big data and information and communication technology (ICT) solutions. Scotland for example uses information technology to predict and manage disease at a population level within the Scottish National Health Service and Estonia has organised its entire health system around electronic registries, the so-called electronic health records (EHS). A challenge for policymakers is to ensure that the system for obtaining patient consent is robust and the purpose for which it will be used is transparent. New electronic data sources not only have to be generated but they also require efficient management.[36] Member states' existing and future legislation, regarding the processing of data that concerns health, affects access to data across borders and the advancement of research and PM.

The Commission recommendations on cross-border interoperability of electronic health record systems and subsequent work carried out in the development of the European Interoperability Framework for eHealth[37] have so far been insufficient to deliver cross-border access to electronic health records by healthcare professionals or to ensure that citizens have the technical means to access and manage their personal health data.

Despite the significant investments made in this area by the EU, member states and regional authorities, the uptake of digital innovation for health and care remains slow and varies greatly amongst MS. Lack of coordination amongst MS in the development of their national laws in the area

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[35] https://ec.europa.eu/info/events/personalised-medicine-conference-2016-2016-jun-01_en

[36] https://ec.europa.eu/info/sites/info/files/conferences/permed2016/permed-2016_report.pdf

[37] https://www.uems.eu/__data/assets/pdf_file/0010/1504/eHealth_European_Interoperability_Framework_-_Study_report_-_July_2013.pdf

of health and research could result in the establishment of widely varying safeguards, conditions and applicable derogations and could negatively impact the establishment of the European Research Area. At the same time, European member states have embraced Personalised Medicine and are very active in the development and application of national policies, as summarized in the following section.

It is important to mention, that within many EU Member States, regions are important drivers of the adoption and application of PM principles. The ICPerMed has two dedicated coordination and support actions (CSA) to the mapping of such subnational PM initiatives and the promotion of the faster uptake of personal health: SAPHIRe, Securing Adoption of Personalised Health in Regions, and Regions4PerMed. For this reason, IC2PerMed does not provide information on subnational PaMs to avoid redundancies among the projects.

5.1.4.1 Policy Measures at EU MS level

Our mapping showed that starting from 2013, at the national level few countries have developed national policies and strategies in PM. Countries with available policies related to PM are shown in Figure 5.

Figure 5 – Map of countries with policies related to Personalised Medicine in place

These policies, although differing in the implementation process according to the national health systems, have a common focus, see Figure 6. In short, the policies are aiming at:

- providing patient-tailored treatment and targeted prevention;
- increasing the public understanding of PM and the education of healthcare workers on PM;
- growing patients' involvement in all phases of research and development;
- supporting healthcare delivery and enforce big data harmonisation fostered by ICT infrastructures; and
- attracting investments in PM by the healthcare industry.

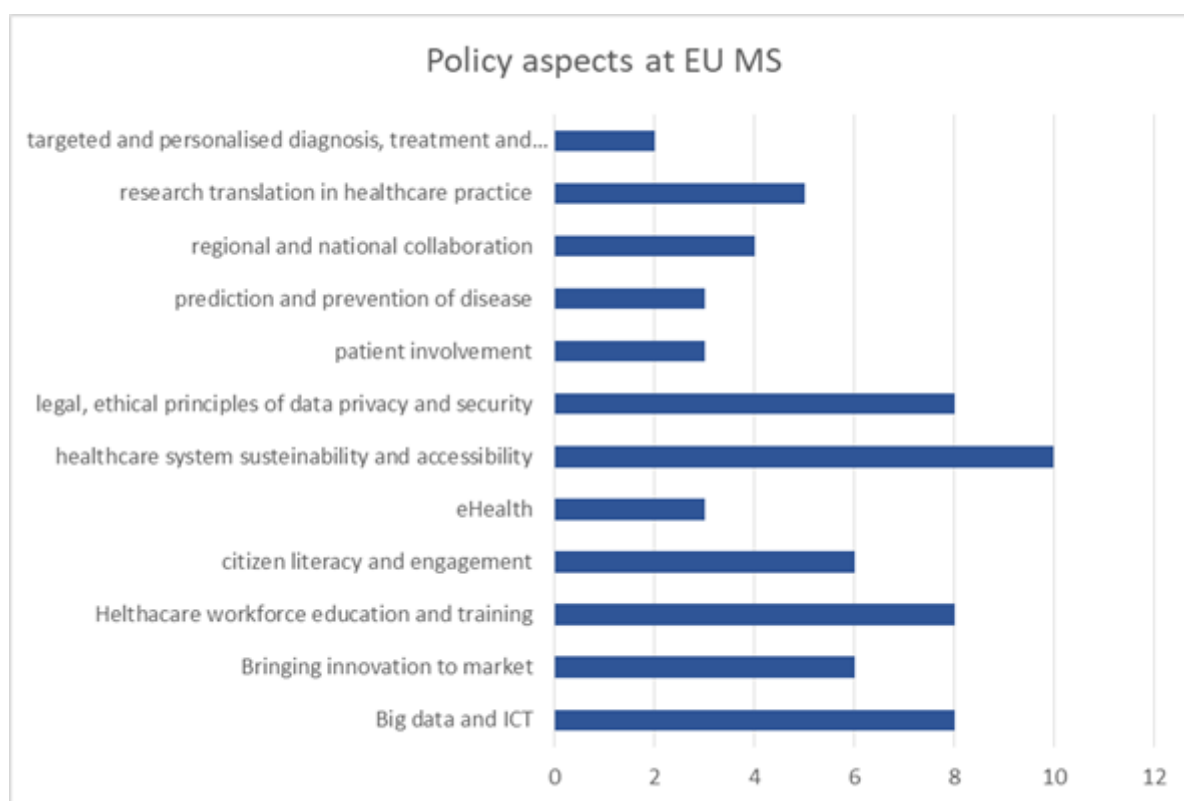[38] CC BY-SA 4.0 - Map created using mapchart.net

Figure 6 – Policy aspects in EU Member States

Table 6 gives a representative overview of key policy measures in the field of Personalised Medicine on the level of EU member states and the UK including a short description of their content and focus.

Table 6 – Policy Measures at EU MS level

PM Policy	Denmark National Strategy for Personalised Medicine 2017–2020	
Description of the Policy		
The Strategy aims to ensure the coordination and direction for collective efforts the Danish Government and Danish Regions have developed a National Strategy for Personalised Medicine 2017–2020. The six principles of the strategy are: 1) The Danish efforts within Personalised Medicine are to focus on the patients. Genome sequencing is to be used for treatment purposes and in research projects. 2) Confidentiality, the individual's right to self-determination, protection of information and research ethics approval are paramount. 3) The use of Personalised Medicine as a standard offer in the healthcare system must be evidence-based and economically sustainable. 4) Genome sequencing and data processing must be based in the public sector. 5) The national infrastructure and adopted standards must be used, and data must be shared securely for the benefit of future research and treatment. 6) The distribution of research funds as part of the strategy must take place in competition – and research projects should in principle be nationwide. The strategy contains seven strategic action areas are: 1) transparent governance structure with nationwide involvement; 2) clear legal framework addressing ethical principles and data privacy and security; 3) patients and citizens must be involved; 4) a technological infrastructure with secure, efficient and equal access; 5) genomics research must be international and deeply integrated in the healthcare system; 6) tools and competencies to use genetic data; 7) Denmark must have an attractive development environment in relation to Personalised Medicine.		
Source	https://www.healthcaredenmark.dk/news/new-national-strategy-for-personalized-medicine.aspx	

PM Policy	NHS England Personalised Medicine Strategy	🇬🇧

Description of the Policy		

In this document developed for the NHS board, a strategy has been outlined that embraces four overarching principles of Personalised Medicine: 1) prediction and prevention of disease; 2) more precise diagnoses; 3) targeted and personalised interventions and 4) more participatory role for patients. It also mentions UK's important participation in the "100,000 Genomes Project" and sets out a re-procurement strategy for a new genomic laboratory infrastructure within the NHS England.

Source	https://www.england.nhs.uk/wp-content/uploads/2015/09/item5-board-29-09-15.pdf

PM Policy	GENOME UK: 2020 national genomic healthcare strategy	🇬🇧

Description of the Policy		

This strategy is focused on 3 key areas: 1) Diagnosis and Personalised Medicine: to incorporate the latest genomics advances into routine healthcare to improve the diagnosis, stratification and treatment of illness. 2) Prevention: Enabling predictive and preventative care to improve public health and wellness; Expanding screening in early life; Targeted screening: 3) Research: Supporting fundamental and translational research and ensuring a seamless interface between research and healthcare delivery, focusing on: Data to support innovation; Responsible use of data; Ensuring diversity and equity of access.

Alongside these 3 pillars, the strategy will focus on five cross-cutting themes: I. Engagement and dialogue with the public, patients and our healthcare workforce; II. Workforce development and engagement with genomics through training, education, and new standards of care; III. Supporting industrial growth in the UK, facilitating entrepreneurship and innovation for projects and companies of all sizes, through common standards, funding, procurement, and R&D structures; IV. Maintaining trust through strong ethical frameworks, data security, robust technical infrastructure, and appropriate regulation; V. Delivering nationally coordinated approaches to data and analytics.

Source	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/920378/Genome_UK_-_the_future_of_healthcare.pdf

PM Policy	Research, Development, and Innovation Strategy for the Estonian Health System 2015 – 2020	🇪🇪

Description of the Policy		

This strategy presents a common understanding of how research, development and innovation can more efficiently support the goals of the Estonian health system. The development of the strategy is based on four courses of action: 1) Increasing the research and innovation capacity of health care providers; 2) Organisation of research based on the needs of the health system and testing of innovative solutions; 3) Development of an exemplary health data infrastructure; 4) Efficient organisation of research and innovation in the health field

Source	https://bit.ly/3dIt2BN[39]

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[39] https://www.sm.ee/sites/default/files/content-editors/eesmargid_ja_tegevused/Tervis/strategy_research_and_innovation_for_health.pdf

PM Policy	**Estonian eHealth Strategic Development Plan 2020**	

Description of the Policy		

Government approved in 2015 the "Estonian e-Health Strategic Plan until 2020"developed by the Task Force set up at the Government Office. The strategy addresses 5 focus areas: 1) the quality and infrastructure of health data; 2) personalised e-services and personal medicine; 3) comprehensive case management and cooperation between organizations; 4) development of effectiveness of health services and capacity for analysis; and 5) development of remote services. The general aim of the Focus area on persons and personal medicine is to improve possibilities of people to participate in active management of their state of health; by person-based health and gene data analysis and digital decision support, in order to offer better targeted services to people. To achieve these goals, the following measures are applied: 1) Development of personalised and user focused e-services; 2) Development of decision-supporting solutions; 3) Creation of conditions for association / integrated handling of gene and health information; and 4) Empowerment of people by technology

Source	https://www.sm.ee/sites/default/files/content-editors/sisekomm/e-tervise_strateegia_2020_15_en1.pdf

PM Policy	**Estonia: Human Genes Research Act 2001**	

Description of the Policy		

The objectives of this Act are to regulate the establishment and maintenance of a Gene Bank, to organise the genetic research necessary therefore, to ensure the voluntary nature of gene donation and the confidentiality of the identity of gene donors, and to protect persons from misuse of genetic data and from discrimination based on interpretation of the structure of their DNA and the genetic risks arising therefrom.

Source	https://www.riigiteataja.ee/en/eli/531102013003/consolide

PM Policy	**Finland: Health Sector Growth Strategy for R&I Activities Roadmap for 2016–2018**	

Description of the Policy		

Published in 2016, this strategy contains 12 key action, four of which explicitly refer to Personalised Medicine/health care. Strong coordination at the national level and common actors are required to fully utilise the unique social welfare and health care data resources, sample resources of the biobanks and genome data.

Source	https://julkaisut.valtioneuvosto.fi/handle/10024/75145

PM Policy	**The Finnish National eHealth and eSocial Strategy 2020**	

Description of the Policy		

In 2015 the Ministry of Social Affairs and Health published a Finnish National eHealth and eSocial Strategy 2020 emphasising the importance of data management in developing research, innovation, health care and commercial activities. The objective of the strategy is to support the renewal of the social welfare and health care sector and the active role of citizens in maintaining their own well-being by improving information management and increasing the provision of online services.

Source	https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74459/URN_ISBN_978-952-00-3575-4.pdf
PM Policy	**Finland's National Genome Strategy**

Description of the Policy
Published in 2015, the strategy will establish the conditions that are required for the effective utilisation of genomic data in Finnish health care. The strategy comprises seven main goals with proposed measures: four enabling goals to create the possibility for full utilisation of genome information in health care, in research and business activities, and in people's own lives; and three utilisation goals to produce the actual benefit to the individual, Finnish health care, and society from the use of genome information. The respective goals are specified below: Enabling goals: – Ethical principles and legislation exist for the use of genome information. – Genome research is closely linked with activities of health care. – Health care personnel are well prepared for the use of genome information. Finland has data systems that allow for the effective use of genome information.

Source	https://media.sitra.fi/2017/02/28142539/Improving_health_trough_the_use_of_genomic_data.pdf
PM Policy	**Finland Act on secondary use of social and health data**

Description of the Policy
An act regulating the secondary use of health and social data is being drawn up in the Ministry for Social Affairs and Health. The aim is to ensure flexible and secure use of data by establishing a centralised electronic licence service and a licensing authority for the secondary use of health and social data. The act is closely related to the Biobank Act, but it concerns health data instead of biological samples. The new act would streamline the processing of data requests, allow faster access to data and improve data security.

Source	https://bit.ly/3bxLlqF[40]
PM Policy	**Finnish Gene Technology Act (2014)**

Description of the Policy
The aim of the Act is to promote the safe use and development of gene technology in accordance with the precautionary principle and in a way that is ethically acceptable; and to protect human and animal health and the environment when carrying out the contained use or deliberate release into the environment of genetically modified organisms.

Source	https://www.finlex.fi/en/laki/kaannokset/2014/en20140771_20140771.pdf
PM Policy	**French National Health Strategy 2018–2022**

Description of the Policy

The strategy outlines four priority areas: promoting health and prevention across all life stages; tackling social inequalities in health and access to care; ensuring the quality, safety, and relevance of care; and identifying innovative approaches to transform the health care system. These areas are further divided into 43 specific goals, and progress will be monitored on an annual basis.

Source	https://www.gouvernement.fr/sites/default/files/locale/piece-jointe/2018/10/france-national-health-strategy-2018-2022.pdf

PM Policy	**Italian National Plan for Public Health Genomics**

Description of the Policy

The first National Plan for Public Health Genomics was published in 2013, with the support of the Italian Network for Public Health Genetics (GENISAP Network). The aim of this plan was to provide general guidelines to facilitate the governance of genomics in public health in the NHS. The Italian guidelines were based on three strategic pillars: 1. Systematic health technology assessment (HTA) of genetic tests for complex diseases in use and a pre-marketing assessment of those not yet currently available. 2. Promotion of genomics education for physicians and capacity building for all potential stakeholders in health care provision and management. 3. Promotion of basic genomic health literacy in the general population, in order to raise awareness of potential benefits, limits and risks of genomic technologies.

See also: Simone B et al., for the GENISAP Network (2013). The policy of public health genomics in Italy. Health Policy, 110(2–3):214–219, doi: 10.1016/j.healthpol.2013.01.015

Source	https://bit.ly/2NYYfWI[41]

PM Policy	**Italian National Plan for Innovation of the Health System based on "-omics" sciences**

Description of the Policy

The Plan published in 2017 aims to support the Italian National Health System in order: (1) To increase awareness of all stakeholders on the innovation of "-omics" sciences and the effects on the health of individuals and populations, enhancing the capacity of society to cope with the cultural, ethical, psychological aspect of the 'genomic revolution'. (2) To put in place a strategy of 'government of innovation' of genomics and related fields. (3) To evaluate and implement the opportunities currently offered by genomics and the other -omics sciences for the health of the population.

Source	http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?menu=notizie&id=3270

PM Policy	**National Research Priorities for Luxembourg in 2020 and beyond**

Description of the Policy

The national research and innovation strategy defines four research priority areas, which have emerged to be of particular importance for the societal, ecological and economic development of the country: 1) Industrial and Service Transformation; 2) 21st Century Education; 3) Personalised

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Healthcare; 4) Sustainable and Responsible Development. Personalised Healthcare Priority addresses the aspects of: Complex biomedical systems – data and models; Understanding, preventing, and treating the health-disease transition; Precision medicine, including environmental, lifestyle and socio-economic factors and Data-driven healthcare.

Source	https://bit.ly/2NE7k7c[42]

PM Policy	**Malta National Health Systems Strategy 2014 – 2020**

Description of the Policy

The National Health Systems Strategy (NHSS) evolves around a set of four overall objectives: 1) Respond to increasing demand and challenges posed by the demographic changes and epidemiological trends focusing on the whole course of life, children, the elderly and vulnerable; 2) Increase equitable access, availability and timeliness of health and social services, medicines and health technologies; 3) Improve quality of care by ensuring consistency of care delivered by competent health workers supported by robust information systems; 4) Ensure the sustainability of the Maltese Health Systems.

Source	https://deputyprimeminister.gov.mt/en/Documents/National-Health-Strategies/NHSS-EN.pdf

PM Policy	**Spanish Strategy for Personalised Medicine 2020**

Description of the Policy

The objective of the Spanish Strategy for Personalised Medicine is to improve the capacities of the National Health System, and, therefore, the health situation of the population, as well as to contribute to advancing the country's economic competitiveness, using scientific knowledge as a vector and innovation. The strategy was launched in the second half of 2020 and until 2021 will include action plans on:1) Big-Data in Health; 2) Genomic Medicine; 3) Advanced and Personalised Therapies; 4) Predictive Medicine; 5) Training in Precision Medicine; and 6) Positioning of Spain in the European environment in the field of Personalised Medicine. The total financing of the Spanish Strategy for Personalised Medicine amounts to 77.3 million euros.

Source	https://www.ciencia.gob.es/portal/site/MICINN/menuitem.edc7f2029a2be27d7010721001432ea0/?vgnextoid=6e7cfcd89bd64710VgnVCM1000001d04140aRCRD

PM Policy	**Sweden's National Life Science Strategy**

Description of the Policy

This national strategy, released in 2019, aims to strengthen the long-term competitiveness of Sweden as a life sciences nation and is intended for stakeholders with a mandate and ability to change conditions for life sciences in Sweden. In the strategy, the Government outlines eight priority areas and 30 objectives, in which change is considered particularly important. Here are the four priority areas that heavily focus on PM principles:

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[42] http://www.mesr.public.lu/presse/communiques/2020/FEVRIER-2020/Presentation-de-la-strategie-nationale-de-la-recherche-et-de-l_innovation1/09711_MESR_SnRI_Broch_en_WEB-_002_.pdf

1) Structures for collaboration (Objectives: Strengthened national coordination in life sciences, Partnerships for regional and national mobilization, Nordic region – a world-leading life sciences hub).

2) Unlocking the potential of health data for use in research and innovation (Objectives: Effective and secure sharing of patient data, Increased use of health data in research and innovation, Effective, secure and ethical use of register data, Better use of biobanks, Follow-up using real-world data).

3) Responsible, secure and ethical policy development (Objectives: Efficient process for implementing new therapies, Accelerated, secure and ethical policy development, Implementing new medical device regulations, Greater focus on preventive interventions and self-management).

4) Integration of research and innovation into care delivery (Objectives: Incentives and good opportunities to combine clinical practice and research, more industry-initiated clinical studies in Swedish health care, High-quality clinical studies, Pioneering the introduction of Precision Medicine in care services).

Source	https://www.government.se/4abc0d/contentassets/a8cdfafc39444985973d729ecb95ed63/swedens-national-life-sciences-strategy.pdf
PM Policy	**Swedish Biobanks in Medical Care Act (SFS 2002:297)**

Description of the Policy

The purpose of the biobank act is to protect patient and/or donor's integrity and rights meanwhile allowing samples to be used in research and clinical trials. It also requires full traceability of all samples collected within healthcare and therefore must be registered in a biobank. This act regulates how human biological material is to be collected, stored and used for certain purposes with respect for the personal integrity of the individual.

Source	https://biobanksverige.se/wp-content/uploads/Biobanks-in-medical-care-act-2002-297.pdf
PM Policy	**A national clinical strategy for Scotland**

Description of the Programme

Scotland uses information technology to predict and manage disease on a population level within the Scottish National Health Service. The strategy highlights the significant changes in Scotland's population and in the needs and demands placed on health and social care services. It makes proposals for how clinical services need to change in order to provide sustainable health and social care services fit for the future.

Source	https://bit.ly/3qMkugS[43]

5.1.4.2 Programmes at EU MS level

In addition, often in concordance with the efforts on the level of the European Union, EU member states are individually addressing the development of Personalised Medicine with national programmes, Table 7 provides examples thereof including the UK.

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[43] https://www.gov.scot/binaries/content/documents/govscot/publications/strategy-plan/2016/02/national-clinical-strategy-scotland/documents/national-clinical-study-scotland/national-clinical-study-scotland/govscot%3Adocument/00494144.pdf

Table 7 – Programmes at EU MS level

PM Programme	The Genome Denmark Platform	

Description of the Programme		

Genome Denmark is a national platform for sequencing and bioinformatics, which includes universities, hospitals and private firms. The platform is established through two large demonstration projects and investments in technological equipment.

Source	http://www.genomedenmark.dk/english

PM Programme	UK Stratified Medicine Programme	

Description of the Programme		

In June 2010 Cancer Research UK created the Stratified Medicine Programme 1 to test the feasibility of running a genetic pre-screening programme within existing NHS infrastructure. Following a successful Stratified Medicine Programme 1, then the Stratified Medicine Programme 2 was launched. The Programme aims to ensure that the National Health Service is ready for the new era of Precision Medicine.

Source	https://www.cancerresearchuk.org/sites/default/files/smp1_booklet_1.2_-_no_marks.pdf

PM Programme	Business Finland programme on Personalised Health	

Description of the Programme		

In 2018 Business Finland launched a new programme in the area of personalised health. The aim is for Finland to become a global pioneer in the provision of personalised health by 2025. The programme will provide innovation funding amounting to EUR 80 million to start-ups, SMEs and large companies, universities and research organisations as well as hospital districts and other health care organisations.

Source	https://www.businessfinland.fi/en/for-finnish-customers/services/programs/personalized-health-finland/

PM Programme	Genomic Medicine France 2025	

Description of the Programme		

France aims through this programme to construct a medical and industrial system to introduce Precision Medicine into the care pathway and develop a national framework in this matter.

Source	https://aviesan.fr/en/aviesan/accueil/toute-l-actualite/plan-france-medecine-genomique-2025

PM Programme	The Swedish Genome Programme	

Description of the Programme		

The Genomic Medicine Sweden (GMS) initiative aims to contribute to PM and improved healthcare across Sweden. This will be accomplished through the implementation of large-scale sequencing

techniques within healthcare. As new technologies mature, the aim is also to include other "-omics" technologies to provide next-generation diagnostics in healthcare.

Source	https://ki.se/en/mmk/genomic-medicine-sweden-national-initiative-for-precision-medicine

5.1.4.3 Action Plans at EU MS level

Some of the EU member states have in addition developed action plans for PM-based research and innovation, extending their existing national strategies on PM and following EU's recommendations. Hereby a special focus lies on the development and implementation of PM in the healthcare services, see Table 8.

Table 8 – Action Plans at EU MS level

PM Action Plan	Roadbook for the implementation of next-generation sequencing in clinical practice in oncology and hemato-oncology in Belgium
Description of the Action Plan	
This roadbook entitled "Introduction of Next-Generation Sequencing in routine diagnostics in oncology and hemato-oncology in Belgium" was officially approved by the Ministry of Social Affairs and Health in 2016. The roadbook includes a description of the governance structure of the intervention; the major technical and logistic actions to be undertaken including an allocated budget; and a number of awareness raising initiatives for health professionals and patient/citizens, structured in the following 10 actions: 1) Establish a commission: Commission of Personalised Medicine; 2) Development of guidelines for NGS use in oncology and hemato-oncology; 3) Development of criteria for NGS use in oncology and hemato-oncology 4 & 5) Develop and organize a benchmarking trial and EQA program for NGS use in oncology and hemato-oncology; 6) Implement NGS registration, storage and data management; 7) Provide NGS education and training (For healthcare professionals); 8) Informed consent, legal and ethical implications of NGS use in oncology and hemato-oncology molecular diagnostics; 9) Pilot study 'NGS use in routine diagnostics' and 10) Build on hospital networks for NGS use in oncology and hemato-oncology.	
Source	https://archpublichealth.biomedcentral.com/articles/10.1186/s13690-018-0295-z
PM Action Plan	**Germany: Personalised Medicine – Action Plan**
Description of the Action Plan	
The Federal Ministry of Education and Research supports a wide range of projects on individualized medicine ranging from basic research to applied and clinical research. In its Action Plan for Individualized Medicine, the Ministry pools initiatives that open new perspectives both for the treatment of patients and for innovations in the health industry.	
Source	https://www.gesundheitsforschung-bmbf.de/files/Action_Plan_IndiMed_englisch.pdf

5.2 Chinese Policy Measures, Programmes and Action Plans related to PM

5.2.1 Policy Measures in China

Chinese Policy Measures are mainly included in laws, regulations, strategic outlines, guiding opinions and normative standards according to the different organizations issuing the documents. Different levels of policies have different applicable scopes and regions. China's legislative procedures include four stages: proposal, deliberation, voting and announcement.

In its "13th 5-Year Special Plan on Technological Innovation for Health and Healthcare" The Chinese government reviewed the past research achievements of the People's Republic of China in the international frontier science and technology fields that stretch across areas such as stem cell research, genome sequencing, vaccine design, structural biology and tumour immunotherapy among many others. The support and financing of frontier technologies has pushed forward the development of China's health-related research activities and related industries.

Since 2017, the Chinese government has advocated the establishment of a multi-level precision medical knowledge base system and a national biomedical big data sharing platform, with a focus on the core technologies of Precision Medicine such as next-generation gene sequencing, "-omics" research and big data fusion analysis.

The following Table 9 summarizes relevant policies by the Chinese ministries concerning PM and PM related topics.

<div align="center">Table 9 – Policy Measures in China</div>

PM related Policy	Management Measures on Population Health Information [Trial] – National Health Commission (May 2014)
Description of the Policy	
These measures apply to the collection, management, use, security and privacy protection of the health information of the population involved such as basic population information, information on medical and health services, and other information on population health generated by various institutions of medical and health family planning services at all levels, for various types of institutions of medical and health family planning services at all levels. Electronic information on the health of the population in accordance with the People's Republic of China's Electronic Signature Act and other relevant laws and regulations have the same legal effect as the paper text. The aim is to standardise the management of information on the health of the population, which must be planned as a whole with unified standards in land management, accountability and power consistent with ensuring safety, convenience and efficiency. Medical and health services and family planning institutions at all levels (including Chinese medical service institutions, the same below) are responsible for collecting, using, managing, security and protecting the privacy of the population's health information and are the units responsible for managing such information.	
Source	http://www.nhc.gov.cn/mohwsbwstjxxzx/s8553/201405/916e50f62c804ae68de6bd811edcaf38.shtml

PM related Policy	Guiding Opinions on Actively Promoting the "Internet+" Action – State Council (July 2015)

Description of the Policy

China has made positive progress in Internet technology, industry, applications, and cross-border integration. It has a solid foundation for accelerating the development of "Internet +", but there are also many problems, such as the lack of awareness and ability of traditional enterprises to use the internet, the understanding gap between the internet enterprises and traditional industries, the institutional and institutional obstacles for the development of new industrial formats, and a serious shortage of cross-border integration talents.

The Internet + program wants improve standards and regulate the use of the internet by increasing security awareness, strengthening the management and protection of security and ensuring that it is networked. The aim is to establish a method of supervision of the scientific and effective market which will promote the orderly development of the market, protect fair competition and prevent the formation of industrial monopolies.

Source	http://www.gov.cn/zhengce/content/2015-07/04/content_10002.htm

PM related Policy	Outline of Action to Promote the Development of Big Data – State Council (September 2015)

Description of the Policy

The convergence of information technology and economic society has triggered rapid data growth, and data has become a basic strategic resource for the country. At present, China has a certain foundation in the development and application of big data, but there are also problems such as insufficient government data opening and sharing, weak industrial foundation, and lagging laws and regulations.

The aim is to vigorously promote information and containment systems for public data, which are interconnected with government data to promote the development and application of big data in the next 5–10 years (2020–2025) and to gradually achieve different objectives. In particular, with regard to big data health services of medical and health services, China wants to build electronic medical records and databases of electronic health records and build a system of medical health services and management applications that covers public health, medical services, medical safety, drug delivery, family planning and comprehensive management. Explore services such as appointment registration, hierarchical diagnosis and treatment, telemedicine, sharing inspection and inspection results, combining prevention and treatment, combining medical and nursing care and health advice, and optimizing the formation of standardized, shared and mutually trusted diagnosis and treatment processes. In addition, encourage and standardize relevant businesses and institutions to research innovative medical and healthcare big data applications and create comprehensive applications for healthcare services.

Instead, with regard to the use of Big Data in social security services, China wants to build a unified platform of big data of social assistance that extends from cities to rural areas, strengthening the docking of data and sharing information with the competent departments and supporting big data in work and employment, in the supervision of social security funds, in the monitoring of medical insurance.

The intention is to use big data to innovate service models to provide public with more personalised and targeted services.

Source	http://www.gov.cn/zhengce/content/2015-09/05/content_10137.htm

Notice regarding the publication of the 2016 national project application guidelines for key special projects on precision medicine research in the National Key R&D Programme - Ministry of Science and Technology (March 2016)

Description of the Policy

Precision Medicine research was listed as one of the prioritized special projects launched in 2016. The notice document is about detailed guidelines on how to apply for funding from the National Key R&D Programme answering e.g. the questions who is entitled to participate, what are the application requirements and details of the submission process.

Source	http://www.most.gov.cn/tztg/201603/t20160308_124542.htm

PM related Policy	**Guiding Opinions on Promoting the Healthy Development of the Pharmaceutical Industry - State Council (March 2016)**

Description of the Policy

By 2020, the innovation capability of the pharmaceutical industry will be significantly improved, and the supply guarantee capability will be significantly enhanced. More than 90% of major patent expired drugs will be copied and listed, and the clinical shortage of drug supply will be effectively alleviated; the green development of the industry, safe and efficient, and the quality management level will be significantly improved.

China wants to persevere in pharmacological market leadership. It will strengthen the status of enterprises as major players in the market so that they play a decisive role in the allocation of resources. Relevant policies for medical reform will be proposed, which will adhere to open, innovation-based cooperation. China wants to accelerate the formation of a diversified and personalized medical service model to expand access to medical services. In addition, by implementing the "One Belt One Road strategy", China is going to think about the global allocation of resources through the adoption of a variety of forms of cooperation to promote mergers and acquisitions abroad, equity investments and venture capital from higher pharmaceutical companies, establishing research and development centres abroad, production bases, sales networks and service systems. It aims to acquire new products, key technologies, production licences and sales channels and accelerate international integration by working towards international cooperation in the field of public health and to continue to expand and consolidate the international market.

Source	http://www.gov.cn/zhengce/content/2016-03/11/content_5052267.htm

PM related Policy	**Outline of National Innovation-driven Development Strategy – State Council (May 2016)**

Description of the Policy

China issued the National Innovation-driven Development Strategy Outline, proposing a "three-step" strategic target: to become an innovative country by 2020, a forefront of innovation-oriented country by 2030, and world's top scientific and technological innovation powerhouse by 2050. The Outline proposed that, for the implementation of innovation-driven development strategy, China must take more measures on open and reform, environmental construction and the allocation of resources.

In detail, China proposed the implementation of an innovation-driven development strategy, emphasizing that technological innovation is an important strategic support for improving social productivity. The aim is to create the basis for the development of innovation. Due to the Chinese authorities, the development of science and technology is entering a period of qualitative growth in which scientific research is becoming more and more complete with a constantly growing talent team and the capabilities of independent scientific, technological, engineering and industry innovation are rapidly improving.

China wants to proceed in three steps: 1) Join the ranks of innovative countries by 2020 and establish a national innovation system with Chinese characteristics and strongly support the achievement of the goal of building a well-to-do wealthy society; 2) Become one of the leading innovative countries by 2030, to achieve a fundamental transformation and significantly increase the level of economic and social development and international competitiveness, laying solid foundations for building an economically powerful country and a common prosperous society and; 3) Build the world power plant of scientific and technological innovation by 2050 and become the main scientific centre to build a modern, prosperous, democratic, civilized and harmonious socialist country and realize the Chinese dream of the great rejuvenation of the Chinese nation.

Priorities are to develop advanced, effective, safe and affordable health technologies to address the main diseases and challenges of an ageing population. Promote the integration of technologies in life sciences, Chinese and Western medicine, bioengineering and other fields and improve technical support skills for the prevention and control of major diseases, public health and reproductive health. China wants to do research and development of innovative drugs, new vaccines, advanced medical equipment and biological treatment technologies and promote the modernization of traditional Chinese medicine, but also research on big data and health care.

In addition, it aims to develop Precision Medicine, develop genetic screening technologies for susceptibility to chronic and genetic diseases and improve the diagnosis and treatment of major diseases such as cardiovascular and cerebrovascular diseases, malignant tumours, chronic respiratory diseases and diabetes, and develop digital medical and telemedicine technologies, promote networking and personalization of social services such as prevention, medical care, rehabilitation, health care and care for the elderly and develop new models of integrated health services to significantly improve the health protection capacities of the population and strongly support the construction of a healthy China.

Source	http://www.gov.cn/xinwen/2016-05/19/content_5074812.htm
PM related Policy	**Guiding Opinions on Promoting and Regulating the Development of Health and Medical Big Data Applications – State Council (June 2016)**

Description of the Policy

Health and medical big data are an important basic strategic resource of China. The development of big data for the healthcare sector will bring profound changes in the health care model, which will help stimulate the reform of the medical and health system, improve the quality of health services, provide resources and continue to satisfy people by increasing their access to medical services, expand resources and continue to satisfy the sick.

The basic concept aims to incorporate the development of the application of big data for the health system into the strategic layout of national big data, promote joint collaborative innovation, strengthen basic research and basic technological research, highlight key areas and key links in the healthcare sector and use big data to expand service channels and increase the quality of medical services. It is therefore essential to establish and regulate laws and systems that regulate the protection of health and medical big data, strengthening the standards of security systems and the

development of security of appropriate applications and effectively protecting personal privacy and information security.

By the end of 2017, national and provincial population health information platforms and national drug offering and procurement platforms for business applications will be interconnected, basically forming an interdepartmental model of sharing health and medical data resources. By 2020, a hierarchical open application platform of national medical and health information will be built to achieve interdepartmental and interregional sharing of basic data resources such as population, legal entities and spatial geography.

Source	http://www.gov.cn/zhengce/content/2016-06-24/content_5085091.htm

PM related Policy	**Cyber Security Law of the People's Republic of China – Cyberspace Administration of China (June 2017)**

Description of the Policy

The state shall encourage the development of technologies for protecting and using network data, promote the availability of public data resources, and promote technological innovation and social and economic development.

In case a production security emergency or incident occurs due to a cybersecurity incident, it must be handled in accordance with the People's Republic of China Emergency Response Act, and the People's Republic of China Production Safety Act. Due to the need to maintain national security and social public order and to address major social security incidents, with the decision or approval of the Council of State, temporary measures may be taken as restrictions on network communications in specific areas. Anyone who violates the provisions indicated in the law will be severely sanctioned. This law shall enter into force on 1 June 2017.

Source	http://www.cac.gov.cn/2016-11/07/c_1119867116_3.htm

PM related Policy	**Opinions on Promoting the Development of "Internet + Medical Health" – State Council (April 2018)**

Description of the Policy

Key opinion on the implementation of the strategy for a healthier China. Need for the creation of innovative models of medical services and the requirement to reducing their costs in order to meet people's growing medical and health needs, in accordance with the "Healthy China 2030" planning scheme and the State Council's Guiding Views on the Active Promotion of "Internet+ Action" approved by the State Council in 2015.

The goal is to encourage medical institutions to use the internet and new technologies to expand the space and content of medical services and build a model of integrated medical service online and offline that covers prevention and treatment during and after diagnosis. It is also intended to allow the development of internet hospitals, which rely on medical institutions. Medical institutions can use, and hospitals are advised to use Internet technology to provide safe and appropriate medical services and allow online check-ups to be booked for certain common and chronic diseases. After the doctor becomes familiar with the patient's medical records, he is allowed to make prescriptions online. In addition, supporting medical and healthcare institutions and qualified third-party institutions to build internet information platforms to perform telemedicine, health consulting, and health management services which will promote effective communication between hospitals, medical staff, and patients.

In addition, the protection of information from medical and health institutions, medical and health service platforms on the internet, intelligent medical equipment, critical IT infrastructure and data enforcement services will be strengthened, and investigations into information security risks, monitoring and early warning will be regularly carried out. Sensitive data such as patient information must be stored in China. If it is really necessary to provide the data abroad, it is necessary to carry out a safety assessment in accordance with the relevant regulations.

Source	http://www.gov.cn/zhengce/content/2018-04/28/content_5286645.htm
PM related Policy	**National Health and Medical Big Data Standards, Safety and Service Management Measures [Trial] – Health Committee (September 2018)**

Description of the Policy

The document clearly stipulates the definition, connotation, and extension of health and medical big data, as well as the purpose, basis, scope of application, principles, and general ideas for formulating management methods.

The measure lists in detail the responsibilities of institutions and authorities in the planning, guidance, evaluation and general supervision of the management of national health standards and big data, safety management and service management.

They are responsible for establishing and improving the relevant security management systems, operational procedures and technical specifications. In particular, they must strengthen the security, management and use of big health and medical data that involve state secrets and that must be implemented in accordance with the relevant state secrets regulations, as well as ensure the privacy and security of citizens' data (Art. 21). The standard big data system is implemented in the province. Citizens, legal entities or other organisations may submit proposals for the formulation and review of health and medical standards for big data and submit corresponding standard project proposals. When the responsible unit changes, the institutions have to not lose or leak them. When the responsible unit discloses health and medical big data to the public, it complies with the relevant state regulations and does not disclose the content, violating its national and public interests (Articles 34 and 35).

Suppliers of products and services related to health and medical big data systems must comply with the relevant national cybersecurity review system and not interrupt or mask technical support and they are responsible for the interaction of health and medical big data between the different systems.

The Administrative Department of Health will conduct daily inspections on the safety management of big data health and doctors of all responsible units in the administrative area. Medical and health institutions of all types and levels must connect to the national health information platform in the corresponding area, transmit and save the data generated by medical and health services making it possible for the Administrative Department of Health to access and control. These measures must be implemented from the date of issue: 12/08/2018.

Source	https://bit.ly/3uDETHs[44]

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[44]http://www.nhc.gov.cn/xxgk/pages/viewdocument.jsp?dispatchDate=&staticUrl=/guihuaxxs/s10741/201809/758ec2f510c74683b9c4ab4ffbe46557.shtml&wenhao=%E5%9B%BD%E5%8D%AB%E8%A7%84%E5%88%92%E5%8F%91%E3%80%942018%E3%80%9523%E5%8F%B7&utitle=%E5%85%B3%E4%BA%8E%E5%8D%B0%E5%8F%91%E5%9B%BD%E5%AE%B6%E5%81%A5%E5%BA%B7%E5%8C%BB%E7%96%97%E5%A4%A7%E6%95%B0%E6%8D%AE%E6%A0%87%E5%87%86%E3%80%81%E5%AE%89%E5%85%A8%E5%92%8C%E6%9C%8D%E5%8A%

PM related Policy	**Data Security Measures [Management Consultation Draft] – Cyberspace Administration of China (2020)**

Description of the Policy

According to the network security law of the people's Republic of China and other laws and regulations, the laws clearly stipulate the activities of data collection, storage, transmission, processing and use within the territory of the People's Republic of China through the Internet.

In detail, the draft law aims to regulate internet use to carry out activities such as data collection, storage, transmission, processing and use in the territory of the People's Republic of China (called data activities), as well as the protection, supervision and management of data security, with the exception of purely family and personal matters.

The Central Commission for Cyber Security and Computerization Coordinates, guides and controls the security of personal information and important data and is responsible for supervising the cybersecurity and computerization departments of the various prefectures (cities) and superiors, which guide and control the security protection of personal information and important data in their respective administrative areas according to their tasks.

When network operators collect important data or sensitive personal information for commercial purposes, they must deposit it with the local network information department. The content of the storage includes the rules of collection and use, purpose, scale, method, scope, type, period, etc. of collection and use, excluding the content of the data itself. Before providing personal information to others, network operators assess possible security risks and obtain the consent of the data subject. Except in the following cases: (1) collected from legal and open channels and obviously does not violate the wishes of the data subject; (2) the subject matter of personal information shall be actively disclosed; (3) if there is anonymity; (4) special provisions for law enforcement agencies; and (5) special provisions for the national security, the public social interest and the security of life of personal information subjects.

If network operators release, share, exchange or provide important data abroad, they should assess possible security risks and report them to the relevant regulatory authority and request their approval.

Source	http://www.moj.gov.cn/news/content/2019-05/28/zlk_235861.html
PM related Policy	**Biosecurity Law of the People's Republic of China [Not Yet Effective] (October 2020)**

Description of the Policy

The Biosecurity Law of the People's Republic of China, as adopted at the 22nd session of the Standing Committee of the Thirteenth National People's Congress of the People's Republic of China on October 17, 2020, is hereby issued, and shall come into force on April 15, 2021. The law clarifies the importance and principles of biosafety and stipulates that biosafety is an important part of national security.

Source	http://www.lawinfochina.com/display.aspx?id=33962&lib=law&SearchKeyword=&SearchCKeyword=%c9%fa%ce%ef%b0%b2%c8%ab%b7%a8#

5.2.2 Programmes in China

We identified the Five-Year Plans as the major source of programmes in the People's Republic of China. China's long-term planning occurs via Five-Year Plans at the national level. In addition, they make up an integral part of the national economic plan of the outlined five-year period. These plans include strategies for many key development areas at the national level. They provide planning for major national construction projects, the distribution of economic productivity and serve as important guidelines for the national economy, setting goals and directions for the vision of national economic development.

The most recent 13th Five-Year Plan (2016–2020)[45] has formed several new biotechnology enterprises with strong international competitiveness and bio-economic clusters with the goal to promote the development of new medical treatments relying on concepts of Precision Medicine in healthcare.

At present, China's genomics and proteomics research is already at the forefront of the international scientific community, and technologies such as biomarkers, molecular targets and big data are developing rapidly within the country. Meanwhile, China is rich in clinical resources and thanks to its large and diverse population, the country provides a solid foundation to the study of a broad range of diseases, including rare diseases. This makes China an ideal playing field where to deliver Precision Medicine.

The National Health Commission (NHC) and the Ministry of Science and Technology (MOST) have each led two major PM-related projects at the national level.

The MOST allocated 130 million yuan, around 16.4 million euro, to support the national key special project of Precision Medicine research in the period of 2018–2020. The funds are used for six key research projects on three main tasks: I) research and development of next-generation clinical histology technology; II) resource integration, storage, utilization and sharing platform construction of precision medical big data; and III) precision research on disease prevention and treatment programmes.

Table 10 – Programmes in China

PM related Programme	Proposal of the Central Committee of the Communist Party of China on Formulating the 13th Five-Year Plan for National Economic and Social Development (October 2015)
Description of Programme	
Include "Healthy China" into the programmatic document and give great support to the health industry in the next 5 years.	
Source	http://www.gov.cn/xinwen/2015-11/03/content_5004093.htm

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[45] 13th FYP English version - https://cset.georgetown.edu/wp-content/uploads/Circular-of-the-State-Council-on-Issuing-the-National-13th-Five-Year-Plan-for-the-Development-of-Strategic-Emerging-Industries.pdf

PM related Programme	**Outline of the 13th Five-Year Plan for National Economic and Social Development of the People's Republic of China – Ministry of Science and Technology (March 2016)**
Description of Programme	
Vigorously promote innovation and industrialization in emerging frontier fields such as Precision Medicine and form several new growth points. Strengthen forward-looking layout on life sciences and other fields and cultivate a batch of strategic industries.	
Source	http://www.most.gov.cn/mostinfo/xinxifenlei/gjkjgh/201608/t20160810_127174.htm
PM related Programme	**State Council Executive Meeting – State Council (July 2016)**
Description of Programme	
Voted to pass the 13th Five-Year National Science and Technology Innovation Patent Program, to lead and support the upgrade of the construction of an innovative country, and to launch several new major scientific and technological projects in important fields such as Precision Medicine.	
Source	https://bit.ly/2ZMKSLO[46]
PM related Programme	**13th Five-Year National Strategic Emerging Industry Development Plan – State Council (October 2016)**
Description of Programme	
Grasp the deep development of life sciences and the trend of wide application of new biological technologies and take the rapid development of genetic technology as an opportunity to promote the development of medical care to Precision Medicine and Personalised Medicine.	
Source	http://www.nhc.gov.cn/bgt/gwywj2/201701/99bdf698d04448529052f4bf08c75787.shtml
PM related Programme	**13th Five-Year Biological Industry Development Plan – National Development and Reform Commission (November 2016)**
Description of Programme	
Understand the impacts the Precision Medicine makes on the revolution of drug research and development and accelerate the development of new drugs and improve the quality of drugs. Promote the application of emerging technologies such as genetic testing.	
Source	https://www.ndrc.gov.cn/xxgk/zcfb/tz/201701/t20170112_962867.html
PM related Programme	**13th Five-Year Special Plan for Biotechnology Innovation – Ministry of Science and Technology (April 2017)**
Description of Programme	

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[46] https://cset.georgetown.edu/wp-content/uploads/Circular-of-the-State-Council-on-Issuing-the-National-13th-Five-Year-Plan-for-the-Development-of-Strategic-Emerging-Industries.pdf

Breakthrough of several cutting-edge key technologies, including a new generation of genetic manipulation technology

Source	http://www.most.gov.cn/mostinfo/xinxifenlei/fgzc/gfxwj/gfxwj2017/201705/t20170517_132857.htm
PM related Programme	**13th Five-Year Special Plan for Health and Health Technology Innovation – Health and Family Planning Commission (June 2017)**

Description of Programme

Establish a multi-level precision medical knowledge base system and a national biomedical big data sharing platform, focusing on the core key technologies of Precision Medicine such as next-generation gene sequencing, "-omics" research and big data fusion analysis technology.

Source	http://www.nhc.gov.cn/qjjys/s3577/201706/1f3657c3dfc94d138ebbb2a4f791896c.shtml
PM related Programme	**13th Five-Year Plan on Health and Healthcare – State Council (January 2017)**

Description of Programme

China's current internal structural problems that restrict the reform and development of health and wellness undertakings still exist. First, the total amount of resources is insufficient, the layout is irrational and has not been fundamentally changed, and high-quality medical resources are particularly lacking. The second is that grassroots service capacity is still a prominent weak link. The technical level of grassroots medical personnel needs to be improved urgently, and service facilities and conditions need to be continuously improved. The third is to deepen the reform and further resolve the deep-seated contradictions of the system and mechanism. Fourth, the ideas and methods of family planning work need to be changed urgently.

Source	http://www.gov.cn/zhengce/content/2017-01/10/content_5158488.htm
PM related Programme	**13th Five-Year Plan on Informatization – State Council (December 2016)**

Description of Programme

Organize the implementation of the Health China Information Service Action, create efficient and convenient smart health care services that benefit the people, comprehensively promote the population health information service system for the whole population, promote and standardize the application of health care big data, and improve the global public health risk monitoring and early warning decision system. Establish an international travel health network to provide travel health and safety services for entry and exit personnel.

Source	http://www.gov.cn/zhengce/content/2016-12/27/content_5153411.htm
PM related Programme	**13th Five-Year Plan on Technological Innovation – State Council (August 2016)**

Description of Programme

Vigorously develop a new generation of information technology with ubiquitous integration, green broadband, security and intelligence, develop a new generation of Internet technology, ensure the

security of cyberspace, and promote the extensive penetration and deep integration of information technology into various industries such as medical treatment.

Source	http://www.gov.cn/zhengce/content/2016-08/08/content_5098072.htm
PM related Programme	**"Healthy China 2030" Planning Outline – Ministry of Science and Technology (October 2016)**

Description of Programme

Strengthen key technological breakthroughs such as chronic disease prevention and control, Precision Medicine, and smart medical treatment; by 2030, fully realize the standardized management and use of population health information to meet the needs of personalised services and Precision Medicine.

Source	http://www.gov.cn/xinwen/2016-10/25/content_5124174.htm
PM related Programme	**Notice regarding the publication of the 2016 national project application guidelines for key special projects on precision medicine research in the National Key R&D Program – Ministry of Science and Technology (March 2016)**

Description of Programme

The "Precision Medicine Research" was listed as one of the prioritized special projects launched in 2016. The first batch of special PM -related projects involved four key tasks, focusing on "life group research", "large cohort construction", "big data of precision medicine" and "precise prevention and treatment scheme of diseases".

Source	http://www.most.gov.cn/tztg/201603/t20160308_124542.htm
PM related Programme	**Notice regarding the publication of the 2017 national project application guidelines for key special projects on precision medicine research in the National Key R&D Program – Ministry of Science and Technology (December 2017)**

Description of the Programme

In 2017, continuously support forward-looking technology research and development urgently needed in platform projects, and continue to carry out the whole process research of Precision Medicine "from big data acquisition to clinical diagnosis and treatment" in some advantageous areas, so as to lay a solid foundation for the realization of the long-term goal of China's Precision Medicine plan.

Source	http://www.most.gov.cn/mostinfo/xinxifenlei/fgzc/gfxwj/gfxwj2016/201610/t20161012_128170.htm
PM related Programme	**Notice of the Ministry of science and technology on Issuing the application guidelines for key special projects in the national key R & D program in 2018, such as research on Causes and control technology of air pollution in 2018 – Ministry of Science and Technology (December 2018)**

Description of the Programme

Published in 2018, five key projects focus on three prioritized programs had been introduced and open for application: I) Research and development of new generation clinical life group technology; II) Construction of resource integration, storage, utilization and sharing platform of Precision Medicine big data; and III) precise research of disease prevention and treatment plan.

Source	http://www.most.gov.cn/mostinfo/xinxifenlei/fgzc/gfxwj/gfxwj2017/201712/t20171212_136764.htm
PM related Programme	**Notice of the National Health Commission on Pilot Working Plan for Multidisciplinary Diagnosis and Treatment of Cancer (2018–2020)**

Description of the Programme

From 2018 to 2020, a certain number of hospitals will be selected to carry out multi-disciplinary cancer diagnosis and treatment pilot (hereinafter referred to as pilot hospitals), in order to promote the coordinated development of various specialties, improve the comprehensive diagnosis and treatment level of diseases, improve the medical experience of patients, and further enhance the sense of gain of the people. The tertiary general hospitals and cancer hospitals with tumour diagnosis and treatment will be selected as the first maven pilot hospital. Pilot scope will focus on digestive system.

Source	https://bit.ly/3ssnBLx[47]
PM related Programme	**Notice of the general office of the National Health Commission on the establishment of a national cooperation network for diagnosis and treatment of rare diseases**

Description of the Programme

In early 2019, the NHC announced the establishment of a national rare disease diagnosis and treatment collaboration network to strengthen the management and treatment of rare diseases in China. The NHC has selected 324 hospitals with strong rare disease diagnosis and treatment capabilities and many relevant cases to form the collaboration network, including Beijing Union Medical College Hospital of the Chinese Academy of Medical Sciences as the national leading hospital, 32 provincial leading hospitals and 291 member hospitals.

Source	http://www.nhc.gov.cn/yzygj/s7659/201902/3a8228589bf94e6d9356008763387cc4.shtml
PM related Programme	**Proposal on Formulating the 14th Five-Year Plan for National Economic and Social Development and the Visionary Goals for 2035 - CPC Central Committee (October 29, 2020**)

Description of the Programme

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[47]http://www.nhc.gov.cn/xxgk/pages/viewdocument.jsp?dispatchDate=&staticUrl=/yzygj/s3594q/201808/0cfe48391dd14876951cf6262e28c062.shtml&wenhao=%E5%9B%BD%E5%8D%AB%E5%8A%9E%E5%8C%BB%E5%87%BD%E3%80%942018%E3%80%95713%E5%8F%B7&utitle=%E5%85%B3%E4%BA%8E%E5%BC%80%E5%B1%95%E8%82%BF%E7%98%A4%E5%A4%9A%E5%AD%A6%E7%A7%91%E8%AF%8A%E7%96%97%E8%AF%95%E7%82%B9%E5%B7%A5%E4%BD%9C%E7%9A%84%E9%80%9A%E7%9F%A5&topictype=&topic=&publishedOrg=%E5%8C%BB%E6%94%BF%E5%8C%BB%E7%AE%A1%E5%B1%80&indexNum=000013610/2018-00236&manuscriptId=0cfe48391dd14876951cf6262e28c062

Regarding the national health strategy in the plan, medical services should put the protection of people's health in a strategic position of priority development, adhere to the policy of prevention-oriented, weave a national public health protection network, and deepen the reform of the medical and health system.	
Promote telemedicine based on technological development. Telemedicine is a solution for the government to balance the layout of medical resources and a way for hospitals to serve patients. The state has promoted telemedicine services through policies such as health insurance payment and network capacity building. During the 14th Five-Year Plan period, we should combine "Internet + medical services" to improve telemedicine projects and innovate telemedicine models. As the 14th Five-Year Plan at the national level has just been released, other more detailed local and exclusive 14th Five-Year Plans in the medical field are still being developed.	
Source	http://english.www.gov.cn/policies/latestreleases/202011/03/content_WS5fa159 efc6d0f7257693edc1.html

5.2.3 Action Plans in China

In this section, we list some of the topics and studies that are subordinate to government departments, universities and academic institutions, which is different from strategic planning at the national level. In China, the government departments directly related to the field of Precision Medicine include the National Health Commission (NHC), the Ministry of Science and Technology (MOST), the National Medical Products Administration (NMPA) and their subordinate units. In addition to this, some local policies or guidelines can also be used as specific action plans.

The NMPA launched the China Drug Regulatory Science Action Plan in 2019. The first batch of action plan projects launched included a study on the technical evaluation and regulatory system of cell and gene therapy products, which is expected to formulate relevant guidelines including genetically modified immune cells, oncolytic virus products, etc.

<div align="center">Table 11 – Action Plans in China</div>

PM related Action Plan	Notice of CFDA on the definition of 3 product categories including genetic analysers – China Food and Drug Administration (January 2014)
Description of the Action Plan	
Gene analysis is managed as a Class III medical device, and a general-purpose sequencing reaction kit (sequencing method) is managed as a Class I medical device.	
Source	http://www.nmpa.gov.cn/WS04/CL2197/324796.html
PM related Action Plan	Notice on Strengthening the Management of Clinical Use of Gene Sequencing Related Products and Technology – Health and Family Planning Commission (February 2014)
Description of the Action Plan	
Products such as testing instruments, diagnostic reagents and related medical software need to be approved and registered by CFDA and approved by the Health and Family Planning Commission before they can be applied. The National Commission for Health and Family Planning is responsible for managing the clinical application of gene sequencing technology. All provinces, autonomous regions and municipalities directly under the Central Government Health and Family Planning Commission (Department of Health) should strengthen the management of	

gene sequencing technology. Before the enactment of the relevant access standards and management standards, any medical institution must first apply for authorization, if it has been operating so far it cannot continue its operation until official approval.

Source	http://www.nhc.gov.cn/yzygj/s3593/201402/c395a20d3815430d8b1a54313ce23b2b.shtml
PM related Action Plan	**Notice of standardising and orderly carrying out prenatal screening and diagnosis of free DNA of pregnant women's peripheral blood foetus – Health and Family Planning Commission (November 2016)**

Description of the Action Plan

Since the advent of prenatal screening and diagnosis of free foetal DNA in the maternal peripheral blood in 1997, the technology has progressed rapidly, gradually evolving from laboratory research to clinical use. To meet the needs of new molecular genetics services for prenatal screening and diagnosis, prenatal screening and diagnosis of free DNA from pregnant women's peripheral blood and foetus must be carried out orderly.

The aim is to ensure the safety and efficacy of gene sequencing diagnostic products used by the public and to strengthen the management of clinical applications of medical technology.

The notice refers to CFDA's "Notice on Strengthening the Management of Gene Sequencing Related Products and Technologies for Clinical Use" (Food and Drug Administration Office Equipment Management [2014] No. 25).

The objectives are to 1) rationally plan the layout and improve the service network; 2) standardize technical services and improve the quality of service and; 3) strengthen supervision and management to ensure orderly development.

Source	http://www.nhc.gov.cn/fys/s3582/201611/bcc3075de60441b8b6699dd12cb6338e.shtml
PM related Action Plan	**Decision on the cancellation of non-administrative approval items – State Council (May 2015)**

Description of the Action Plan

The State Council cancelled the approval of the clinical application of the third type of medical technology, including the clinical application of the third type of medical technology such as hematopoietic stem cell transplantation, gene chip diagnosis, and immune cell therapy.

Source	http://www.gov.cn/xinwen/2015-05/14/content_2861932.htm
PM related Action Plan	**Notice of the National Development and Reform Commission on the implementation of major engineering packages for emerging industries – Development and Reform Commission (July 2015)**

Description of the Action Plan

In section 2, the programme deals with "new health technology for the benefit of the people". The goal is on one hand to give full play to the role of new medical technologies such as genetic testing and modern Chinese medicine in the prevention and treatment of diseases and on the other hand to improve people's health protection capabilities.

The first is to support institutions with basic technologies, innovation capabilities and related qualifications to adopt a networked layout and take a leading role in building 30 demonstration centres for the application of genetic testing technology, focusing on genetic screening for genetic diseases and birth defects and promoting advanced health such as genetic testing. It's about

spreading technology for the benefit of people and guide the industrialization of important innovations.

The second is to make full use of advanced technologies and methods to build a standard high-quality product system for the entire Chinese medicine industry chain, formulating high-quality product standards that cover more than 50% of China's large varieties of patented medicines, and over 50% of the clinically most commonly used Chinese medicine decoction standards, and build Chinese medicine standards to support a system platform, implement a regular announcement mechanism for information on high-quality products of traditional Chinese medicine, build a long-term mechanism for high-quality Chinese traditional medicine product standards, promote high-quality, high-quality products, and promote overall improvement in the quality of traditional Chinese medicine products to better meet people's health needs.

Source	https://www.ndrc.gov.cn/xxgk/zcfb/tz/201507/t20150723_963393.html
PM related Action Plan	**Tumour personalised treatment testing technology guide [Trial] – Health and Family Planning Commission (July 2015)**

Description of the Action Plan

The goal is to distribute the "Tumour Individualized Therapeutic Technology Test Guide" with the objective to understand the clinical significance of the test results and the role of treatment. Provide timely and accurate inspection reports and provide them with report-related consulting services.

Standardization, laboratory access and quality assurance place specific requirements on hospitalization and medical laboratories to make sure that the most accurate test results are guaranteed.

Source	http://www.nhc.gov.cn/yzygj/s3593/201507/fca7d0216fed429cac797cdafa2ba466.shtml
PM related Action Plan	**Technical Guideline for Gene Detection Technology of Drug Metabolizing Enzymes and Drug Action Targets [Trial]**

Description of the Action Plan

Distribute the Technical Guideline for Gene Detection Technology of Drug Metabolizing Enzymes and Drug Action Targets.

Source	http://www.nhc.gov.cn/yzygj/s3593/201507/fca7d0216fed429cac797cdafa2ba466.shtml
PM related Action Plan	**Catalogue of key products and services for strategic emerging industries – National Development and Reform Commission (February 2017)**

Description of the Action Plan

Aiming at the genetic testing service for personalized health and Precision Medicine, establish an intelligent diagnosis and treatment ecosystem combining online and offline.

In fact, the programme will take care about personalized health care and Precision Medicine gene testing services, online and offline combination of intelligent diagnosis and treatment ecosystem, biotherapy services for major difficult diseases, based on the "internet of things" and other technologies for community and home remote health management services.

Source	https://www.ndrc.gov.cn/xxgk/zcfb/gg/201702/t20170204_961174.html

PM related Action Plan	**Infectious Disease-Related Personalised Medical Molecular Detection Technology Guide – Health and Family Planning Commission (December 2017)**
Description of the Action Plan	
Standardize clinical laboratory activities in medical institutions for individualized medical molecular testing.	
Source	http://www.nhc.gov.cn/yzygj/s7659/201712/604f9c561922467ba6d603d51e18132d.shtml
PM related Action Plan	**Technical Specifications of Microarray Gene Chips for Personalised Medical Testing – Health and Family Planning Commission (December 2017)**
Description of the Action Plan	
Regulate medical institutions to carry out personalized medical testing service activities of microarray gene chips. In particular, the program focuses on DNA microarrays also called gene or DNA chips. A DNA microarray can quickly detect multiple genes and sites at once. It can be used in clinical diagnosis to quickly identify pathogens, detect genetic mutations and gene expression, detect tumour gene markers earlier and more conveniently, and detect drug response and metabolism-related gene polymorphism. The Commission organised experts to formulate the "Gene Chips Microarray Technical Specifications for Individualized Medical Tests" to provide technical guidance on the use of gene chip microarrays to detect nucleic acid sequences and gene expression in personalised medical tests.	
Source	http://www.nhc.gov.cn/yzygj/s7659/201712/604f9c561922467ba6d603d51e18132d.shtml
PM related Action Plan	**Notice on further reform and improvement of the examination and approval work of medical institutions and physicians – National Health Commission, Administration of Traditional Chinese Medicine (June 2018)**
Description of the Action Plan	
Further reform and improve the medical institutions and physician approval work and once again emphasized that the institution can entrust an independent medical laboratory and/or pathological diagnosis centre to provide medical testing and pathological diagnosis and other services.	
Source	https://bit.ly/2ZLCpIF[48]
PM related Policy	**Guiding Principles for Clinical Application of New Antitumour Drugs, 2018 Edition – National Health Committee (September 2018)**

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[48]http://www.nhc.gov.cn/xxgk/pages/viewdocument.jsp?dispatchDate=&staticUrl=/yzygj/s3576/201806/bad4e33d8ef34e9ba67979b34aaff8ee.shtml&wenhao=%E5%9B%BD%E5%8D%AB%E5%8C%BB%E5%8F%91%E3%80%942018%E3%80%9519%E5%8F%B7&utitle=%E5%85%B3%E4%BA%8E%E8%BF%9B%E4%B8%80%E6%AD%A5%E6%94%B9%E9%9D%A9%E5%AE%8C%E5%96%84%E5%8C%BB%E7%96%97%E6%9C%BA%E6%9E%84%E3%80%81%E5%8C%BB%E5%B8%88%E5%AE%A1%E6%89%B9%E5%B7%A5%E4%BD%9C%E7%9A%84%E9%80%9A%E7%9F%A5&topictype=&topic=&publishedOrg=%E5%8C%BB%E6%94%BF%E5%8C%BB%E7%AE%A1%E5%B1%80&indexNum=000013610/2018-00187&manuscriptId=bad4e33d8ef34e9ba67979b34aaff8ee

Description of the Action Plan	
The guidelines are regularly revised and updated to guide the rational use of antitumour drugs in clinic.	
Source	http://www.nhc.gov.cn/yzygj/s7659/201809/0ea15475f58a4f36b675cfa4716fa1e4.shtml

6 The status quo of Personalised Medicine in Europe and China

The mapping results summarized in Table 3 to 11, show that both Europe and China have addressed PM and PM-related topics in a large number of policies and programmes. This section is therefore dedicated to outline the key priorities in Europe and China by extracting information from the table entries.

The aim is to derive a full picture of Personalised Medicine in Europe as well as Precision Medicine in the People's Republic of China. We later want to address similarities and differences in the local strategies by comparing the two approaches to each other. This is crucial to define a common basis for future cooperation and collaboration in PM. Both the European Union and the People's Republic of China shall bring in their respective strengths and foci of interest in order to create synergies in PM.

This is no trivial task, because China and Europe are both partners and economic competitors at the same time. The basis for a comprehensive strategic partnership has been recently laid out by the EU-China 2020 Strategic Agenda for Cooperation[49] stating explicitly on health in its "key initiative I: Science, technology and innovation" that:

> *Joint research and innovation initiatives will be further explored, in particular in the areas of food, agriculture and biotechnology, sustainable urbanisation, aviation, water, health and ICT, by developing joint funding programmes and promoting enhanced mutual participation of Chinese and EU researchers and innovators into respective programmes.*

The aspect of systemic rivalry and the importance of safeguarding a level playing field was summarized in 2019 in the joint communication "EU-China – A strategic outlook"[50], by the European Union. In parallel the People's Republic of China has also shifted and adjusted its diplomatic strategy in recent years culminating in a ground-breaking speech of the Chinese minister of foreign affairs on July 20, 2020, with the title "Deepening the study and earnest implementation of the Xi Jinping Thought on Diplomacy to break new ground for the major country diplomacy with Chinese characteristics"[51]. There, a new era of diplomacy guided by "Xi Jinping's thought" under global Chinese leadership has been introduced and the balance of international cooperation and Chinese dominance described.

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[49] https://eeas.europa.eu/archives/docs/china/docs/eu-china_2020_strategic_agenda_en.pdf
[50] https://ec.europa.eu/commission/sites/beta-political/files/communication-eu-china-a-strategic-outlook.pdf
[51] https://www.fmprc.gov.cn/mfa_eng/zxxx_662805/t1799305.shtml

On December 30th, 2020, EU and China concluded the negotiations for a Comprehensive Agreement on Investment (CAI)[52], an important landmark in providing European companies a better level playing field for their activities in China. China has shown good will in lifting some of the current restriction in the area of R&D related to biological resources. This is a very strong sign for Sino-European cooperation and lays the groundwork for a further intensification of bilateral activities, whereas ratification through the European Parliament and China's institutions is still pending.

6.1 PM in Europe and China: A comparative analysis

6.1.1 State of play in PM

State of play in Europe

In a recent communication from 2018 on *enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*[53], Europe identified three main priorities:

1. Citizens' secure access to their health data, also across borders,
2. PM through shared European data infrastructure in research and
3. Citizen empowerment with digital tools for user feedback and person-centred care.

In addition, the International Consortium for Personalised Medicine highlights complementary common future priorities in its Action Plan[54] as well as in its Vision Paper[55]. It stresses the importance of interdisciplinary research and inter-sectoral collaboration. Basic and translational research must follow the principle of best available evidence and follow stringent ethical values. By that the consortium guarantees sound and comprehensive information on the full potential of PM for citizens and patients, healthcare professionals and providers, payers and researchers.

Not only the integration of all stakeholders is of high importance but also the availability of comprehensive, validated, accessible and interoperable datasets, which include genomic, biomedical and clinical information, and ideally also incorporate lifestyle and other personal data. Therefore, the regulation of data protection, safety, security and ownership issues, is a fundamental requirement for further development of PM and existing and newly collected data requires harmonisation to be comparable for research and development.

ICPerMed suggests that the established disease classification might need to be scrutinized and a new classification taking into account the evolution of PM need further development. Finally, medical approaches following the principles of Personalised Medicine need to demonstrate not only their scientific evidence but also their cost-effectiveness in order to support the sustainability of the different health systems.

In its perspectives for PM in 2030 ICPerMed focuses on the relevance of:

- Informed, empowered, engaged, and responsible citizens
- Informed, empowered, engaged, and responsible health providers

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874694

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- Healthcare systems that enable personally tailored and optimised health promotion, prevention, diagnosis, and treatment for the benefit of citizens and patients
- Availability and optimal use of health-related information for optimised treatment, care, prevention, and research
- Economic value by establishing the next generation of medicine

This should represent the European orientation of the coming years in PM and will be discussed in the forthcoming ICPerMed conference in 2021.[56]

State of play in China

In 2016, Precision Medicine was incorporated into the State Council's 13th National Science and Technology Five-Year Innovation Plan. The overall goals of PM development in China were further elaborated and defined in a series of national plans related to the 13th FYP.

The main strategy with respect to PM is to:

- Provide more accurate and efficient medical and health services for the public;
- Establish an international Precision Medicine research platform to promote key technologies;
- Develop new prevention and treatment drugs, vaccines, devices and contribute internationally in the field of disease diagnosis, treatment guidelines, clinical pathways and intervention measures;
- Significantly improve the level of major disease prevention and control, promote the construction of a "healthy China".

The priorities of Precision Medicine in China have been implemented on a step-by-step basis to reach China's overall strategic goals. From 2016 to 2020 e.g., the Ministry of Science and Technology organized and implemented the "Precision Medicine National Key R&D Programme" focusing on:

1. New life science "-omics" technology development;
2. Large-scale cohort study;
3. Big data integration, storage, utilization and sharing platform;
4. Precise prevention and treatment of diseases and
5. Precision medicine healthcare system.

Dedicated projects about the precise prevention and treatment of malignant tumour, hypertension, diabetes, birth defects and rare diseases strengthen the field of innovation, others have attracted major funding and aim to improve the regulatory policy system and construction of a sustainable security system.

From 2021–2030, based on the established "China Precision Medicine research system", PM approaches are meant to expand to other important fields of disease and are tackled by the following set of principles:

1. Large population cohort studies, biobanking and big data research;
2. Research on precise prevention techniques and control technologies to prospectively protect high-risk population;
3. Discovery of molecular markers and their clinical use;
4. Accurate diagnosis of molecular imaging and pathology;

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[56] https://www.icpermed.eu/en/ICPerMed-Conference-2020.php

5. Clinical treatment; such as the comprehensive treatment of cancer by targeted, immune- and cell therapy, rational drug usage based on big data.

It is noteworthy that China and Europe share many priorities of PM in enhancing public health. Both regions e.g. prioritize:

- Person-centred care, supply a more accurate and efficient medical and health services for the public
- Prevention of diseases, accurate diagnosis and target treatment
- Data management and use of biobank information
- Harmonization in the collection of genetic information as key to achieve international collaboration and development of PM scientific advances.

In the light of the *Chapter 5 – Policy Measures, Programmes and Action Plans related to PM in the EU and China*, we would like to compare the two geographic areas in-depth along the lines of the following topics.

6.1.2 Cross-border data transfer

Advances in Personalised Medicine are linked to the collection of "big data", massive amounts of individual statistics such as data on risk factors, disease outcomes, lifestyle, genetics, environment, behaviour and treatment responses. Those large amounts of data often require cutting-edge computing infrastructure and the application of advanced algorithms to draw meaningful insights from them. In PM huge collections of health-related data are therefore continuously shared among commercial organizations, states and their respective public health bodies: universities, research centres and hospital laboratories.

The European Union has made substantial progress in the creation of a Single Digital Market with healthcare data still being one of the most sensitive type of data concerning intra-EU data transfers with many national restrictions and additional requirements in place[57]. The introduction of the General Data Protection Regulation (GDPR) on May 25, 2018 has further harmonized the system of data protection and reduced the obstacles for cross-border data transfers.

The legal framework of the GDPR defines personal data as *any information that can identify or help to identify a person* (Article 4 (1) GDPR) and defines health data, named data concerning health, as *personal data related to physical or mental health of a natural person including the provision of health care services* (Article 4 (15) GDPR).

When it comes to processing and the transfer of personal data within the EU, the GDPR does not impose any additional requirements with regard to the direct applicability of the GDPR's six principle (Article 6): (I) consent, (II) contract, (III) legal obligation, (IV) vital interests, (V) public task and (VI) legitimate interests. For special categories of personal data such as health data additional means for the purpose of processing are defined (see Article 9 GDPR).

Things however become much more complicated when cross-border data transfers to Non-EU "Third Countries" are involved. Those are prohibited by the general rule of the GDPR, only becoming legal

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[57] EC report: Facilitating cross border data flow in the Digital Single Market https://ec.europa.eu/digital-single-market/en/news/facilitating-cross-border-data-flow-digital-single-market

due to three exceptions to the rule: (I) an adequacy decision by the European Commission, (II) transfers being subject to appropriate safeguards and (III) derogations for specific situations[58].

When it comes to adequacy decisions, the European Commission currently recognises Andorra, Argentina, commercial organisations of Canada, Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Switzerland and Uruguay as secure Third Countries[59]. Norway, Liechtenstein and Iceland as members of the EEA fully comply to GDPR and are not considered Third Countries. It is not clear to what degree the Brexit affects cross-border data transfer, but an adequacy decision is expected by the EC within a four-month transition period starting from January 1st, 2021[60]. For the United States of America, the EU has ratified a special bilateral agreement, the so-called EU-US Privacy Shield[61], covering special safeguards for data exchange to the US by complying companies.

In the context of Personalised Medicine and the exchange of medical data for research purposes, none of the aforementioned exceptions are ideal and very often anonymization of data is the option of last resort to allow cross-border data transfer. The GDPR however does not provide legal clarity about when health patient datasets can be considered anonymized. Genomic sequences and biometric data are, by their very nature, unique to individuals and - at least in theory - it is possible to relate them back to their donors. It is not clear whether common deidentification techniques are enough to render such data truly anonymous or merely pseudonymized. Pseudonymized samples would still be covered by the legal framework of the GDPR[62].

In summary, the high standards of European data protection laws render cross-border data exchange very difficult and often pose limits to international research collaborations in PM.

The situation of cross-border health data exchange in the People's Republic of China is even more restrictive. China has put a complex system of regulatory requirements in place governing specific types of data with various supervisory authorities involved. It distinguishes between health care big data, human genomic resources, pharmaceutical data, medical device data, medical records and scientific data[63].

The draft of the upcoming Personal Information Protection Law is supposed to have important ramification for cross-border data transfer and further clarifies restrictions imposed by the Cyber Security Law (CSL) of 2017[64].

The CSL (Article 37) has so far imposed strict data localisation requirements, in short personal data and important data gathered and produced during operations are required to be stored only within the mainland of the People's Republic of China. For exporting data, special permits from Cyber Security Administration of China are required.

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[58] https://medium.com/golden-data/what-are-the-requirements-for-cross-border-data-transfers-under-eu-data-protection-law-e59bfce908f0

[59] https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en

[60] https://www.mondaq.com/privacy-protection/1024752/brexit-what39s-the-deal-with-data

[61] https://www.privacytrust.com/privacyshield/gdpr-vs-privacy-shield.html

[62] Bradford, L et. al, International transfers of health data between the EU and USA: a sector-specific approach for the USA to ensure an 'adequate' level of protection, *Journal of Law and the Biosciences*, https://doi.org/10.1093/jlb/lsaa055

[63] Health Care Data Compliance in China https://www.natlawreview.com/article/health-care-data-compliance-china-faq

[64] https://www.twobirds.com/en/news/articles/2020/china/china-data-protection-update-and-deep-dive-1

The bilateral cross-border data transfer between the EU and China could eventually be eased by a Sino-European agreement following the EU-US Privacy Shield's example.

6.1.3 Big data in PM

Big Data, the retrieval of information and meaning from very large datasets not accessible by classical data processing techniques, is radically disrupting biomedical research. Big Data refers to large and complex datasets that are difficult to process using traditional ICT applications and require complex multivariate statistical analysis often described as "Big Data Analysis/Analytics". Big Data's characteristics are best described by "The Four Vs": 1) 'volume' - being large in size; 2) 'variety' – being heterogeneous and obtained from different sources; 3) 'velocity' – being collected or analysed in near real-time; and 4) 'veracity' – being trustworthy.[65]

Big Data are radically changing biomedical research. The unprecedented advances in automated collection of large-scale molecular and clinical data pose major challenges to data analysis and interpretation, calling for the development of new computational approaches. The creation of powerful systems for the effective use of biomedical Big Data in Personalised Medicine will require significant scientific and technical developments, including infrastructure, engineering, project and financial management. Big data raises several issues for public policy makers, such as privacy and personal data protection, data ownership, barriers to the free flow of data, skills gaps in labour markets and an emerging new digital divide. The European Council described in 2013 Big Data as "an important enabling technology for productivity and better services" and called for the right framework to create a single market for Big Data, including a network of national digital coordinators from the Member States.[52]

The EU has a long-standing focus on the promotion of big data in PM. In 2013 a strategic initiative on value data chains was launched, followed by an EC communication on the Digital Single Market in 2015 emphasizing the potential of Big Data to maximise growth and stimulate competitiveness, through investment in ICT infrastructure and technologies. In 2015, the European Data Protection Supervisor highlighted the need for user control, transparency and accountability in Big Data usage. The 2016 regulation 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 prohibits the processing of special categories of personal data such as data concerning health.

During the period from 2016 to 2020, the EU has designated more than €500 million from the Horizon 2020 research FP for Big Data research. The European Commission's communication "Towards a common European data space" in 2018 and its accompanying staff working document proposed a package of measures as a key step towards the creation of a common data space in the EU. In November 2020, the Commission adopted a proposed regulation on data governance that will boost data sharing across sectors and Member States, increase trust in data sharing, strengthen mechanisms to increase data availability and overcome technical obstacles to the reuse of data.

The Council's conclusions on "Shaping Europe's digital future" in 2020 may ensure more cost-effectiveness and workflow optimisations in health care, create a European health data space to foster targeted research, diagnosis and treatment; leading to improved health outcomes for patients, better epidemiological surveillance systems, and longer-term sustainability of health systems. Among EU MS,

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[65] https://www.europarl.europa.eu/RegData/etudes/BRIE/2016/589801/EPRS_BRI(2016)589801_EN.pdf

Finland e.g. approved a policy on the secondary use of health and social data that aims to establish conditions for the effective and secure processing of, and access to personal health and social data.

In China, in the period from 2018 to 2020, the national key special project of Precision Medicine research supported by the MOST had a total funding budget of 130 million yuan, around 16.4 million euro. The funds are used on five main tasks:

1. Research and development of next-generation clinical histology technology,
2. Large-scale population cohort research,
3. Resource integration, storage, utilization and sharing platform construction of precision medical Big Data,
4. Precision research on disease prevention and treatment programmes, and
5. Construction of Precision Medicine integrated application demonstration system.

Large-scale population cohort research comprises natural population and disease cohort studies with the aim to create a network of genetic and clinical data. This type of research itself provides support for the development of Big Data in PM by stimulating resource and data integration, the extension of data storage capabilities and the utilization and construction of data sharing platforms.

Promoting the application of Big Data in the medical field has become a focus of development in China. In July 2016, the General Office of the State Council issued the "Guiding Opinions on Promoting and Regulating the Application and Development of Health and Medical Big Data" (hereinafter referred to as the "Opinions"). The opinions pointed out that Big Data on health care is an important basic strategic resource of the country. The development of health care Big Data application will bring profound changes in the health care model, which will help stimulate the motivation and vitality to deepen the reform of the medical and health system, improve the efficiency and quality of health care services, expand the supply of resources, and continue to meet the multi-level and diverse needs of the people The demand for health is conducive to cultivating new business formats and economic growth points.

With the continuous emergence of regional medical centres in Shanghai and Ningbo, the National Health Commission announced the launch of a national pilot project for the construction of health care Big Data centres and industrial parks. Fujian Province, Jiangsu Province, Fuzhou, Xiamen, Nanjing, and Changzhou are identified as the first batch of pilot provinces and cities.

After these Big Data centres are completed, the following data sources will be integrated:

- Regional medical data including national basic medical insurance data,
- Management data of the local health management department,
- Key chronic disease monitoring data and maternal and child health data collected and managed by the Centre for Disease Control and Prevention,
- Birth and death registration data, and
- Electronic medical record (EMR) data from first, second and third-level hospitals.

A "Precision Medicine integrated data platform" that will store all the data and biological samples of a series of large population cohorts has begun construction. This platform will include at least 700,000 research subjects, of which more than 400,000 will come from natural population cohort studies, and more than 300,000 will come from key chronic non-communicable disease patient cohort studies. Thanks to China's huge population and centralized management, large sample research will provide great value for the development of PM.

In addition to government-guided research projects, Chinese medical academic research teams and institutions have also begun to take action in the field of data sharing research. In October 2017, Peking

University School of Public Health released the China Cohort Consortium[66]. The first batch of China's cohort sharing platform has included nearly 20 cohorts and related research projects, such as the 500,000 Chinese adult cohort and twin cohort led by Professor Li Liming, covering many research fields such as chronic diseases, infectious diseases, maternal and child health, and occupational diseases. The platform will be able to use common data models to achieve data coordination; complete meta-analysis of individualized patient data; and even form new cohort projects. Platforms based on specific disease data sharing are also emerging, covering cardiovascular diseases, stroke, cancer, and kidney diseases. For example, the China Kidney Disease Network[67] launched in 2015 applies cutting-edge technology to analyse and integrate kidney disease data from multiple sources, which can provide evidence support for health and medical policies, and It can be used to accelerate the process of academic research and can effectively promote disease management in the field of kidney disease.

6.1.4 Disease prevention

Disease prevention is a central pillar of all PM approaches and as mentioned in *Chapter 3 – Introduction to Personalised Medicine* forms part of its European and Chinese definition, being a medical model:

- in Europe "[…] to determine the predisposition to disease and/or to deliver timely and targeted prevention", and
- in China "[…] for high-efficiency, low-cost prevention […]".

Different from traditional public health care, PM seeks to find the optimum outcome for individuals rather than focussing on the entire population or subgroups thereof. Prevention is achieved by the collection and analysis of an ever-increasing quantity of data from various sources. Employing powerful and adaptive computational assistance, PM will enable to predict the individual risk to develop disease and guide medical personnel and healthcare providers.

The ICPerMed predicts that by 2030, the focus of medicine will shift from actual treatment to risk definition, patient stratification, personalised health promotion and disease prevention strategies[68]. This is of special importance in ageing societies such as the EU Member States and the People's Republic of China. An increasing ageing population requires in addition to medical treatment a stronger focus on health promotion and prevention strategies.

Adding environmental and lifestyle factors to accuracy medicine is important, there is a wealth of randomized clinical trials indicating that a healthy lifestyle, characterized by daily physical activity, maintenance of normal body weight, good psychological health, a healthy and non-smoking diet, reduces the risk and/or prevents the development of several chronic diseases, such as diabetes and CVD[69].

China has expressed a deep interest in implementing Personalised Medicine prevention schemes within its FYP framework with the aim of developing genetic screening technologies for assessing the susceptibility of an individual to chronic and genetic diseases as well as improving the diagnosis and treatment of major diseases such as cardiovascular and cerebrovascular ones, malignant tumours, chronic respiratory diseases and diabetes. The Chinese government strongly supports the construction of a "Healthy China" that relies on the development and application of digital technologies,

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[66] China Cohort Consortium, Webpage: chinacohort.bjmu.edu.cn

[67] China Kidney Disease Network, Webpage: kidney.net.cn

[68] The ICPerMed vision for 2030 https://www.icpermed.eu/media/content/Vision_Paper_2019.pdf

[69] Ross Arena et al., "Applying Precision Medicine to Healthy Living for the Prevention and Treatment of Cardiovascular Disease", *Current Problems in Cardiology*, Volume 43, Issue 12, 2018, Pages 448–483,

telemedicine, integrative health services and the promotion of personalised social services, touching all aspects of health care, such as medical prevention, treatment and rehabilitation. Similar to Europe there is strong interest in geriatric medicine by the increasing number of elderly people due to demographic changes[70].

China also launched major PM projects related to chronic disease prevention and control. It established large-scale population cohort studies on its native population such as disease-specific cohorts:

- Common rheumatic immune diseases in China cohort study,
- Cardiovascular disease specific cohort study,
- Cerebrovascular diseases cohort study,
- Respiratory diseases cohort study,
- Nervous system diseases cohort study,
- Metabolic diseases cohort study,
- Cancer cohort studies: breast, oesophageal, prostate and colorectal,
- Rare disease cohort study

and special subgroups, e.g. twin cohorts, mothers and infants, the elderly and other special groups with national birth cohort, China health and retirement prospective cohort to name a few.

During the last three years, the following cohort studies have been granted based on their geographic regions: East, South, Northwest, Southwest and Northeast China natural population cohort research.

6.1.5 Telemedicine and Digital Healthcare

Similar to the European Union, the People's Republic of China has identified telemedicine and digital healthcare as one of its main areas of interest in PM, see also its manifold Policy Measures in Table 9. However, the digital penetration rate was rather low.

The COVID-19 pandemic starting in late 2019 in the city of Wuhan in China's Hubei province acted as a strong driver for the adoption of telemedicine and digital healthcare. During the pandemic, the National Health Commission (NHC) promoted the use of internet-based medical services to minimize population movements through strict lockdown measures and physical containment strategies with the goal of reducing the risk of infection. This successfully led to a strong increase[71] in the usage of China's online health platforms.

The shift to digital healthcare[72] affects both the delivery of healthcare services via telemedicine (e.g. remote patient monitoring and surveillance, online booking etc.) as well as digitally supported medical services (e.g. artificial intelligence, machine learning for diagnostics and treatment, augmented reality surgeon training and assistance etc.).

The pandemic however is not the only explanation for the online health services boom, the People's Republic of China has developed a multi-tier healthcare system that, in short, comprises hospitals of

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[70] How health research will support China's ageing population https://www.nature.com/articles/d41586-020-00279-y

[71] https://www.ft.com/content/22b22543-0fb5-4a8a-8ec0-e3fd067a5190

[72] https://www.china-briefing.com/news/china-investment-outlook-telemedicine-digital-healthcare-industry/

three distinct classes[73]. Class I healthcare institutions, also called primary healthcare, are responsible for first-contact care and mainly comprise smaller community health centres (CHCs), whereas class II and III institutions are bigger in size and offer higher-quality services through better equipment and highly trained medical specialists.

The bottleneck of China's healthcare system is the patient access to high-quality institutions of class II and III, often also due to limited insurance coverage. Telemedicine promises citizens affordable and fast access to medical services without relying on primary healthcare with its diverse challenges[74]. It is safe to say that the central government will further invest in this transformation process in the coming years.

Eventually there will internet hospitals[75] will become a complementary pillar of the Chinese healthcare system and allow access to medical services even in its sparsely populated and remote geographic areas.

The European Union and its member states also heavily invested in the promotion of eHealth services over the last decade and tried to set a common strategy for the entire political union. One of the main challenges is the fragmentation of healthcare systems along the member state borders. Therefore, most of the policy measures of the EU regard the setting for standards in public health, electronic health records and cross-border interoperability.

Having set the regulatory landscape, it is now up to the member states to apply common data standards and data exchange processes maintaining the high standards of data protection given by the General Data Protection Regulation (GDPR).

There's no lack of innovative start-ups and technical solutions. The bottleneck, rather, is still the slower adoption rate in comparison to China in digital health, though some of the member states have advanced a lot and should be taken as examples for the transformation of the European member states' healthcare systems.

6.1.6 Citizens and patients' empowerment

The implementation of PM in healthcare requires citizens and patients to understand and be aware of the potential benefits of PM on the population health. Citizens and patients need to trust that their health data are being used in a safe, appropriate and equitable way for the provision of the best possible care to them and the general population. For the participation of citizens and patients in PM initiatives, policies and regulatory frameworks are necessary to raise awareness on the opportunities and challenges posed by PM, empowering them as fundamental actors in shaping the future of their own health. Citizens might be actively engaged in all phases of research and development, in several ways, such as discussing the target-therapeutic approaches or preventive measures based on their genetic predisposition with their healthcare practitioners; sharing their health-related data for scientific research; participating in research projects, in public debates on the PM priorities, and health technology assessment process[76]. The patients, including their families and caretaker, are themselves

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[73] https://www.pacificbridgemedical.com/publication/chinas-hospital-market/

[74] Quality of primary health care in China: challenges and recommendation, Li et al., The Lancet, Volume 395, Issue 10239, 1802 - 1812

[75] http://www.iresearchchina.com/content/details7_64339.html

[76] Budin-Ljøsne and J. R. Harris, "Ask not what personalized medicine can do for you - Ask what you can do for personalized medicine," Public Health Genomics, vol. 18, no. 3, pp. 131–138, Apr. 2015, doi: 10.1159/000373919.

core stakeholders in the implementation of research in health[77] as well as the development and application of PM approaches. Patients' involvement facilitates design and reduces likelihood of wasted research; it enhances the effectiveness of research increasing the chance of achieving improved outcomes and of making the health care process more personalized, patient-driven and proactive.[78]

In Europe, one of the five challenges to advance PM, defined by the PerMed agenda, is developing awareness and empowerment. Health education of both, citizens and patients, enables them to be actively involved in decisions related to their own health. Personalised systems for monitoring and supporting citizens and patients, such as e-Health services, provide timely information tailored to individuals.

Health literacy of European citizens and patients, has been the focus of several EC recommendations, that aim to increase their empowerment and enhance the digitalisation of healthcare sectors, through the provision of secure access and data sharing procedures, in particular of electronic health records, and the development of digital tools for their engagement in health care[79]. The Horizon 2020 Work Programme (2014–2015) in Section "Health, demographic change and wellbeing" addressed the need for increased education level of individuals and patients with regards to ICT applications for personalised care and for their participation in the healthcare process. In the period from 2016–2017, the Horizon 2020 Work Programme considered citizens' digital health literacy as a key element for the successful e-health deployment that will empower citizens to have the adequate knowledge to make health decisions and play an active role in health management.

Public engagement strategies, educational needs and targeted interventions has not been addressed in the Chinese policies yet. PM requires citizens and patients' health literacy – comprising their ability to access, understand, appraise and apply health information – to be considered and improved. This allows the patients to make appropriate health decisions for themselves and become the centre of healthcare.

The national strategies for PM at the EU MS level addressed the importance of patients' and citizens' involvement to inform and shape national health systems approaches to PM. The elaboration of personalised and user-focus e-services and the active involvement of citizens and patients in the development and adoption process will increase the awareness about their health and create possibilities for active management, see e.g. the Estonian eHealth Strategic Development Plan (2020) and the Finish National eHealth and eSocial Strategy (2020).

Among EU MS, Italy[80] has been the first country to address health literacy in the national policies in 2013, followed later by other countries such as UK, Finland and Denmark[81]. To summarize, these countries promoted the basic genomic literacy in the general population through engagement programmes with different stakeholders, the development of secondary education curricula and the

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provision of up-to-date information to build citizens' capability in the application of PM information and to let them make informed decisions.

6.1.7 Healthcare professionals' education

The implementation of PM in healthcare practice requires appropriately trained healthcare professionals that can understand, interpret, and communicate the PM concepts and results to the patients. Workforce development and engagement with PM through education and training are the key elements to advance PM knowledge and empower healthcare professionals.

Coordinated efforts of EC have been made to improve the required knowledge for healthcare workforce according to their educational needs, and to facilitate the translation of research into practical application. In the "Council conclusions on Personalised medicine for patients" in 2015, EU MS are encouraged to provide and foster education, training and continuing professional development for health professionals, in order to equip them with the necessary knowledge, skills and competences to make the most of the benefits that Personalised Medicine brings to patients and healthcare systems.

The overall objective of EU strategies has been to build sustainable resources for educating and training, to improve access to training programmes, to assess the effectiveness of training strategies, with a particular focus on eHealth solutions[82]. Having access to comprehensive and secure electronic health records by providing health professionals with a better understanding of the patient's history and of previous interventions or treatments, facilitates the appropriate treatment of patients and improves the quality of care and patient safety. Healthcare systems require health professionals equipped with a sufficient level of IT skills to make the optimum use of eHealth information technology.[83]

Education and training of healthcare workforce is a recognized need and has been an important component of the national strategies related to PM in some of the EU MS. Considering the promotion of genomics education towards physicians and capacity building for stakeholders in the healthcare provision and management in the 2010–2012 National Prevention Plan, Italy is the pioneer of public health genomics policies in Europe. Within the Italian health policy for genomics, another important milestone was reached in 2017 with the approval of the "National Plan for innovation of the Health System based on omics sciences", which aimed to support the National Health System to increase the awareness of all stakeholders on the innovation of omics sciences and its effects on the health of individuals and populations enhancing the capacity building, professional education and definition of core competencies.

Finland, in the 2015 National Genome Strategy, addressed also the enhancement and update of genetics education in the curricula of healthcare professionals; development and implementation of a training programme for different groups of healthcare professionals; definition of new roles among health professionals and their provision with of a clinical decision-making support tool based on genomic data. Recently, workforce development and engagement with genomics through training, education and new standards of care has been integrated into the national strategies in UK and Spain, 2020 UK national genomic healthcare strategy and Spanish Strategy for Personalised Medicine 2020, respectively.

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[82] See 5.1.2 – Programmes at EU level: HORIZON 2020 – Work Programme (2016 – 2017) Section 8 on "Health, demographic change and well-being"

[83] See 5.1.1 – Policy Measures at EU level: 1) COM(2004) 356 final

In China, healthcare workforce capacity building has been considered at the 12th FYP for 2011–2015[84], which is calling for better hospital and clinical infrastructure, including management, public health and medical education, and greater use of information technologies in healthcare.

6.2 Health care funding mechanisms

The EU has developed policies to move towards PM, through sustained and significant investments made available in support of PM. The EC has been a driver for the implementation of PM developments in healthcare practice through the Europe-wide research framework programmes, which are among the largest integrated research funding programmes in the world. The research in different aspects of PM has been supported since the "Seventh Framework Programmes for Research and Technological Development" (FP7, 2007–2013). The funding research for PM has been expanded under the current programme Horizon 2020 (2014–2020). Under the FP7, a total of 209 funded projects addressed PM and the EU investment for these PM related projects is 1.334 billion euro. Horizon 2020 is still running and, from 2014 until 2016, 163 projects addressed PM, with an EU contribution in these projects of more than 870 million euro. The PM projects funded under FP7 and Horizon 2020 address a wide range of PM aspects, like "-omics" and related technologies, diagnostics, biomarkers, big data and clinical trial methodologies.[85]

However, research funding at the EU level represents only about 10% of total investment in the area of health research in Europe. An important aspect of the EU funding is to complement investments made by EU Member States. Several European countries are investing in innovation, research and development of PM technologies, to enhance the integration of PM in healthcare.[86] At the national level, governments have developed National Strategies or Action Plans for PM that provide funding for the support of a wide range of projects. A complete list of the EU countries' national funding mechanisms as well as a PM image of the current state in the PM field inside EU and China will be reported in detail in deliverable "D1.2 - Map of Major Funding Agencies and Stakeholders in Europe and China".

Health financing in China comes from both government and private sector sources.[87] The National Health Commission (NHC) and the Ministry of Science and Technology (MOST) have each led two major PM-related projects at the national level. In 2015, as part of China's Five-Year Plan, the China Precision Medicine Initiative was launched. This initiative is providing large investments to expand and develop PM that could amount to as much as 9 billion euro in spending over the next 15 years. State level agencies, including the Ministry of Science and Technology (MOST) and regional and local agencies, are responsible for investing in key infrastructure and initiatives with a focus on the development of PM and diagnostic services.[88]

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[84] China's 12th FYP – https://policy.asiapacificenergy.org/node/37

[85] Nimmesgern, E. et al. (2017). Enabling personalized medicine in Europe by the European Commission's funding activities. Personalized Medicine, 14(4), 355–365. https://doi.org/10.2217/pme-2017-0003

[86] Advancing Access to Personalized Medicine: A Comparative Assessment of European Reimbursement Systems – http://personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_europe_reimbursement.pdf

[87] Myint, C.-Y. et al. (2019). A systematic review of the health-financing mechanisms in the Association of Southeast Asian Nations countries and the People's Republic of China: Lessons for the move towards universal health coverage. PLOS ONE, 14(6), e0217278. https://doi.org/10.1371/journal.pone.0217278

[88] Innovate UK Global Expert Mission: Precision Medicine & Vaccines China (2018) https://admin.ktn-uk.co.uk/app/uploads/2019/09/06_KTN_China-Precision-Medicine_v2.pdf

In March 2015, the Ministry of Science and Technology held the first strategic meeting of experts of Precision Medicine in China, and proposed China's Precision Medicine Initiative. In the meeting, it was proposed that China would invest 60 billion yuan (7.6 billion euro) in the field of Precision Medicine by 2030, including 20 billion yuan (2.5 billion euro) from the central budget and 40 billion yuan (5.1 billion euro) from enterprises and local governments.

Current research and development priorities in biomedicine include issues of PM, reproductive health, birth defects, and medical devices. According to the 13th Five-Year Plan, China's Precision Medicine Initiative aims to develop a batch of new domestic drugs of prevention and treatment and medical devices, to form a series of domestically-customized and internationally-recognized guidelines of disease diagnosis and treatment, so as to significantly improve the level of prevention and treatment of major diseases.

China's Precision Medicine projects are highly systematic. They have focused on China's common and frequently-occurring major diseases and a number of rare diseases with relatively high prevalence as breakthrough points, established multi-layer knowledge base system of precise medicine and biomedical big data sharing platform, formed precise prevention, diagnosis and treatment schemes and clinical decision system with steps of major disease risk assessment, forecast and warning, early screening, classification, individualized treatment, efficacy and safety prediction, monitoring, etc. They have also constructed a demonstration, application and promotion system of precise clinical schemes for Chinese typical diseases. The Precision Medicine projects would also deploy five major tasks, such as to construct a platform of resource integration, storage, utilization and sharing in terms of a new generation of clinical "-omics" technology research and development, large-scale group study and precision medicine big data, to research precisely on disease prevention, diagnosis and treatment schemes, to build precision medicine integrated application demonstration system and so on. At an administrative level, the projects can be classified into national, provincial, municipal or university levels, etc., mainly belonging to major special projects of the Ministry of Science and Technology, provincial science and technology projects, municipal science and technology projects, university-level science and technology projects and various special projects of biomedical research.

National Key R&D Programme of China shall be funded in a diversified way, including central financial funds, local financial funds, self-raised funds and funds obtained from other sources. The central government will provide financial support in the form of both pre-subsidy and post-subsidy, which will be specified in the formulation of implementation plans for key special projects and guidelines for annual project application.

Taking the National Natural Science Foundation of China as an example, one can see how , together with the relevant local government and enterprises, it funded the " Regional Innovation and Development Joint Fund" and the " Enterprise Innovation and Development Joint Fund" to unify expenditure, release guidance, strengthen overall management, appraisal procedures and project management, and help establish a more effective joint funding system in the new era.

At the same time, funding also derives from non-governmental public welfare funds such as the Beijing Medical and Health Foundation (BMHF), which support with funding towards scientific research, academic exchanges, education and training and also oversee exchange and cooperation projects in the field of medical and health care in China.

With the continuous support of national policies, Precision Medicine is very favoured by the investment of capital. With more and more enterprises and money entering the field, PM has been promoted to make continuous breakthroughs in market and technology. In 2017, there were 101 cases

of investment in Precision Medicine in China with a total investment amount of 12.236 billion yuan (1.6 billion euro).

7 Global perspective

In the same way that globalisation processes influence national and international health policy issues, global health issues are linked to other policy areas such as development, security, trade and travel, the economy, human rights, nutrition, agriculture, research, employment, education, migration, the environment and climate protection, as well as humanitarian aid.

The most significant authority in global health policy is the World Health Organization (WHO). The organisation's goal is to achieve the best possible level of health for all by combating disease and promoting overall health of all people.[89]

In 2013 the Report "Priority Medicines for Europe and the World" was released, produced by the WHO and supported by the EC. The Report is an update to the original 2004 version and considers changes in global health and pharmaceutical innovation since 2004. It discusses the role and the current limitations of PM, called 'stratified medicine' in the context of the report, and recommends investments to further strengthen research in and knowledge of stratified medicine and pharmacogenomics.[90]

Special emphasis was placed on identifying relevant research needs on an international level. While progress has been made in the past years on a number of areas towards effective treatments, efforts are still required in areas already mentioned in the report. These include for instance Alzheimer disease, HIV/AIDS or antimicrobial resistance. Several health threats have also become more pressing over the last years, such as low back pain and pneumonia.

Twenty-four diseases and disease groups were prioritised. Those diseases are selected based on burden of disease and mortality ranking, projections, social solidarity and risk factors. The following diseases were selected, based on

- burden of disease and mortality ranking: ischaemic heart disease, diabetes, cancer, acute stroke, HIV/AIDS, tuberculosis, malaria, Alzheimer disease and other dementias, osteoarthritis, chronic obstructive pulmonary disease, alcohol use disorders and alcoholic liver disease, hearing loss, depression, diarrhoea, pneumonia, neonatal conditions and low back pain.
- projections: antimicrobial drug resistance, pandemic influenza.
- social solidarity: rare diseases, postpartum haemorrhage, neglected tropical diseases
- risk factors: tobacco use, obesity.

Research gaps need to be addressed in the coming years to achieve the expected advantages from PM focusing in subgroups of patients. The needs of children, the elderly and women are emphasised, as they are often under-represented in the pharmaceutical development process. Research should be funded to allow biomarker-based prescribing during pregnancy and childhood.

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[89] https://www.who.int/about/who-we-are/our-values
[90] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217(01)&from=EN

Approaches to promote innovation, such as public-private partnerships, regulatory structures, pricing and reimbursement models, real-life data and learning from practice, and the involvement of patients and citizens are included in the report.

The guidelines of the different regulatory agencies on the use of pharmacogenetic methodologies in assessing drug pharmacokinetics, are showing that PM mainly focuses on the development of new medicines, drug targets and diagnostics. In addition, pharmaceutical companies may be less interested in assessing PM post-approval, due to pricing inflexibility and possible loss of market share.

Several genomics initiatives are emerging in low-resource settings, but PM approaches are still rare and should be further encouraged. In countries where resources are limited, PM could be very successful in ensuring that limited health care resources are used as efficiently as possible.

7.1 Europe and China with respect to the WHO

In the field of Personalised Medicine, Europe with e.g. its EULAC PerMed project[91] aims to integrate countries from the Latin American and Caribbean (CELAC) region in ICPerMed and ERAPerMed, with the goal of increasing and encouraging a worldwide implementation of PM approaches across the whole healthcare value chain.

The project aims to introduce PM for the benefit of patients, citizens and society, with the goal of contributing to the "UN sustainable development goal No. 3", that is to "Ensure healthy lives and promote well-being for all at all ages". The project activities are open to organizations from both Latin American, the Caribbean and Europe.

Experts on various disciplines as well as different types of stakeholders work together towards a bi-regional common consensus in PM methodologies, data standards, and analysis of the potential uptake by the national/regional health systems. The focus lays on gaining knowledge and understanding of the scientific landscape of PM in CELAC countries and their scientific policy, as well as engaging with relevant PM stakeholders and to discuss the main needs and barriers for PM research and policy in the CELAC region.

Advantages of collaboration in PM between CELAC and EU countries is promoted with the idea to foster the participation of organizations with an interest in PM R&I and policy in ICPerMed. This will help to analyse and discuss with major stakeholders the way forward to integrate CELAC countries in the ICPerMed challenge groups, workshops, conferences and other events and initiatives.

Finally, awareness rising of PM to disseminate and communicate project activities and main results are emphasized to promote the establishment of international standards in cooperation with ICPerMed contribute to engage the CELAC countries in the ICPerMed Action Plan and the activities derived from it.

The People's Republic of China in the field of Precision Medicine is highly interested to expand its global reach along its massive "Belt and Road initiative" (BRI) via its "Internet +" programmes becoming a leader in the internet-powered healthcare sector.[92] The Chinese government often describes its efforts

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[91] https://www.eulac-permed.eu/
[92] https://www.globaltimes.cn/content/1164169.shtml

under the umbrella term "Digital Silk Road"[93]. The BRI is globally the most ambitious and expansive infrastructure programme outreaching to over 140 countries worldwide as of January 2021[94].

In addition to seeking a more prominent global position, China is constantly increasing its commitment to key institutions of the United Nations, such as the WHO in the field of health and healthcare. Via its BRI initiative China is a strong advocate of the UN's goal of universal health coverage by the year 2030[95].

8 Conclusions

This report extensively reviews the status quo of Personalised Medicine in China and Europe. It includes a state-of-the-art mapping of policy measures, programmes and action plans in the field of PM, providing detailed information on the content of the policy measures themselves and their relevance to PM. This allows the profound analysis of China's and Europe's PM strategy, working out common ground and strategic overlap as well as the discrepancy and gaps of the respective plans and actions. The report identifies both matching and divergent innovation priorities and reviews all relevant factors of health research in the context of Personalised Medicine.

In addition, it focuses on future priorities for cooperation in global health and provides a comparative analysis of China's and EU's healthcare financing mechanisms. The full picture of recent PM developments lays a solid foundation for a detailed discussion over the direction of future Sino-European collaboration in Personalised Medicine.

The mapping serves on one hand as initial input and policy compendium for IC2PerMed's WP2 expert panel working groups on the identification, transferability and scaling up of international standards in PM. On the other hand, it anticipates the upcoming agenda of WP3 that is about fostering research collaboration between the European Union and the People's Republic of China.

Personalised Medicine is one of the most promising concepts in the gradual evolution of medicine and even has the potential to disrupt the medical field bringing major improvements for the benefit of public health. PM affects both citizens and patients, their families and communities, as well as all levels of the entire healthcare system. The development of PM requires concise action across universities, industries and national governments and urges for synchronous development on a global scale.

At present, Personalised Medicine is developing rapidly at the technical level e.g. targeted drugs, biological therapy, "-omics" technology, Big Data, molecular diagnosis and molecular imaging. Main challenges, however, remain in the application of new technologies in areas such as pathogenesis, new drug development and registration policies, clinical pathways, regulatory guidelines, market access and pricing, and legal ethics. We believe that in face of public demand, government support and market expectations, the development of Personalised Medicine will see a bright future. The IC2PerMed consortium is looking forward to contributing to key aspects of Sino-European collaboration on PM and bringing forward the whole field.

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[93] https://www.cfr.org/blog/belt-and-router-china-aims-tighter-internet-controls-digital-silk-road

[94] https://green-bri.org/countries-of-the-belt-and-road-initiative-bri/

[95] Tang, K., Li, Z., Li, W., & Chen, L. (2017). China's Silk Road and global health. *Lancet (London, England)*, *390*(10112), 2595–2601. https://doi.org/10.1016/S0140-6736(17)32898-2

Appendix 1

IC2PerMed survey on China-EU cooperation over Personalised Medicine developments

Description of the Project and aim of the Survey

Integrating China in the International Consortium for Personalised Medicine (IC2PerMed) project aims to support EU-China collaboration over the developments of Personalised Medicine research, innovations, and policies through the ICPerMed initiative, providing people with access to personalised, smart and inclusive healthcare solutions in the near future [Grant Agreement N. 874694] (https://www.ic2permed.eu/).

According to the Council of the European Union, Personalised Medicine is defined as a "medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."

You are invited to participate in a survey, elaborated within the IC2PerMed project, which aims to explore the current landscape of implementation, priorities, and challenges of Personalised Medicine in China and Europe, with a focus on Sino-European collaboration in this field.

The results of this survey will complement the ongoing mapping activities within IC2PerMed project, of which the preliminary findings can be consulted here[96]. These results will be useful to have an overview of the past, current and future policy, research, and funding in Personalized Medicine in your country and will serve the basis for the Working Groups (WG) of the IC2PerMed project. The WGs' activities will take advantage of the results of this survey, to support the project in developing recommendations for implementing the ICPerMed's Action plan into China (https://www.ic2permed.eu/working-groups/).

The records from this questionnaire will be kept confidential and your data and responses will be anonymized and processed for the purpose of IC2PerMed project development only, in agreement with the project's privacy policy (available at: https://www.ic2permed.eu/gdpr). Your data will be treated in accordance with GDPR regulation. If you wish to not disclose your personal data, you can fill in the questionnaire anonymously.

For any further information, please contact: IC2PerMed@unicatt.it.

Thank you very much for your participation

Walter Ricciardi, on behalf of IC2PerMed the consortium

If you agree to participate in this survey according to GDPR regulation, please click **Next**.

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[96] https://www.ic2permed.eu/publications-public-deliverables/

SECTION 1: Personal details

(The questions with the symbol # are mandatory)

1. What is your nationality? (Open question) _____

2. Please indicate the country where you are currently working in # (Open question)

3. Please indicate your field(s) of expertise (Open question) _____

4. Which type of organisation or institution are you currently working for?
    a. Government - Research & Innovation
    b. Government - Health
    c. Funding Agency
    d. Innovation/Development Agency
    e. Cluster organisation
    f. Research institution
    g. Hospital
    h. Regulator
    i. Patient organization
    j. Private sector organization (e.g., biotechnology, information technology, pharma, health insurance company)
    k. Other, please specify _____

SECTION 2: Policies and agencies in the country you are working in

In this section, you will be asked about your knowledge on policies (including policy measures, programmes, strategies, and action plans), agencies and funders in the field of Personalised Medicine in your respective country.

1. Are you aware of any **policies** focused on or related to Personalised Medicine in the country you are working in?
    o   Yes*
    o   No
    o   I do not know

    *If yes, please specify:

    o   Name(s)/title(s) _____
    o   Source or website, if available _____
    o   Any additional information you consider useful _____

*If yes, according to you, in which of the following fields so far have these policies had an impact on Personalised Medicine in the country you are working in (select up to three)?

- o Citizens', patients' awareness and empowerment
- o Health Professionals' education and curricula
- o Practices and strategies for Personalised Medicine in sustainable health care
- o Big data and ICT Solutions
- o Bringing innovation to market
- o Translating basic to clinical research and Beyond
- o Research Funding
- o Privacy/Ethical regulations
- o Other (please specify) _____
- o I do not know

2. What are the priority areas to be considered in policy planning in the field of Personalised Medicine in the country you are working in?
   - o Citizens' awareness and empowerment
   - o Health Professionals' education and curricula
   - o Practices and strategies for Personalised Medicine in sustainable health care
   - o Big data and ICT Solutions
   - o Bringing innovation to market
   - o Translating basic to clinical research and Beyond
   - o Research Funding
   - o Privacy/Ethical regulations
   - o Other (please specify) _____

3. According to your opinion, what are main obstacles to the planning, development, and implementation of policies in the field of Personalised Medicine, in the country you are working in?
   _____ (Open question)

4. Please indicate the main policy agencies/institutions that monitor or are involved in overseeing implementation/fostering of Personalised Medicine in the country you are working in.
   _____ (Open question)

5. To your knowledge, which are the **research priorities** in the field of Personalised Medicine in the country you are working in?
   _____ (open question)

6. Please name important **funding sources** in the field of Personalised Medicine in the country you are working in.
   _____ (open question)

7. Please name additional **relevant initiatives** (e.g., relevant national or international projects or consortia) related to Personalised Medicine in the country you are working in.
   _____ (open question)

SECTION 3: Facilitators and barriers for collaborations between Europe and China in Personalised Medicine

1. Are you aware of any collaborations in the field of Personalised Medicine between Europe and China?
    a. Yes*
    b. No
    c. I do not know

    *If yes, please indicate:

    Name of the project/collaboration _____

    Source or website, if available _____

    Any additional information you consider useful _____

2. In your view, which are the most relevant **facilitators or enabling factors** for EU-China collaborations in   the field of Personalised Medicine?
    _____ (open question)

3. In your view, which are the most relevant **barriers** for EU-China collaborations related to Personalised Medicine?
    _____ (open question)

4. In your view, please indicate relevant **contextual aspects (social, cultural, economic, ethical, etc.)** to be taken into consideration in EU-China collaborations in the field of Personalised Medicine.
    _____ (open question)

5. In your opinion, which actions should Chinese and European policy makers implement for intensifying EU-China collaboration in the field of Personalised Medicine?
    _____ (open question))

6. In your opinion, which are the most important priorities and challenge areas towards EU-China collaborations in Personalised Medicine to be considered in the following areas?
    (Please select up to three areas and specify the respective priorities)
    a. Citizens', patients' awareness and empowerment
    b. Health Professionals' education and curricula
    c. Practices and strategies for Personalised Medicine in sustainable health care
    d. Big data and ICT Solutions
    e. Bringing innovation to market
    f. Translating basic to clinical research and Beyond
    g. Research Funding
    h. Privacy/Ethical regulations

SECTION 4: WORKING GROUPS

In this section, you will be asked questions regarding the activities of the three Working Groups (WGs)[97]. The WGs will focus on the following topics:

Working Group	Topics
WG1: "Shaping sustainable healthcare"	- Awareness and empowerment - Education and curricula - Personalised Medicine in sustainable healthcare
WG2: "Innovation & market"	- Big data and Information and Communication Technology (ICT) Solutions - Bringing innovation to market
WG3: "Research and clinical studies in Personalised Medicine"	- Translating basic to clinical research and Beyond - Research Funding

1. Are you already involved in the activities of any of the IC2PerMed Working Groups?
   a. Yes*
   b. No

2. a). If yes, in which Working Group are you or would you like to be involved?
   a. Working Group 1: Shaping sustainable healthcare
   b. Working Group 2: Innovation & market
   c. Working Group 3: Research and clinical studies in Personalised Medicine

2. b) If no, would you like to be involved in Working Groups?
   a. Yes, please specify
      I. Working Group 1: Shaping sustainable healthcare
      II. Working Group 2: Innovation & market
      III. Working Group 3: Research and clinical studies in Personalised Medicine
   b. No

Thank you very much for your participation! We would like to invite you to share the survey with your colleagues.

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[97] https://www.ic2permed.eu/working-groups/