



# **D1.3**

## **Towards closer EU-China collaboration in Personalised Medicine**



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### Abstract

This document aims to extend the mapping of Personalised Medicine in Europe and China by providing a review of Personalised Medicine-related treatment approaches, standards, and existing bilateral collaborations. It answers the fundamental questions: What are commonalities and differences in current personalised treatment approaches, data and biobanking standards as well as co-developments to Personalised Medicine? What are areas of mutual interest in the field of Personalised Medicine? What are lessons learnt from ongoing collaborations and implications therefrom for future Sino-European research and innovation interactions related to Personalised Medicine? The document thereby aims to derive initial recommendations on how to improve reciprocity and increase areas of interest for future Sino-European collaborations in the field of Personalised Medicine. The mapping has been conducted through extensive desk research, the consultation of country representatives and researchers as well as the contribution of experts within the IC2PerMed consortium.



### Keywords

Personalised Medicine, Precision Medicine, PM, ICPerMed, EU, China, Approaches, Treatment guidelines, Biobanking, Data sharing, Data protection, Standards, ISO, Detection, Sino-European, Collaboration, Projects, Initiatives, Research, R&I

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## Abbreviations and Acronyms

Abbreviation, Acronym	Description
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
BGI	BGI Group (formerly Beijing Genomics Institute)
CEN	European Committee for Standardization
CSA	Coordination and support action
CSCO	Chinese Society of Clinical Oncology
DNA	Deoxyribonucleic acid
DoA	Description of Actions
EC	European Commission
EN	European Standards
ERIC	European Research Infrastructure Consortium
ESMO	European Society of Medical Oncology
EU	European Union
FTELE	Fondazione Telethon
G.A.C.	G.A.C. Group (formerly INNO)
GB	Chinese Guobiao Standard by the SAC
IARC	International Agency for Research on Cancer
ICPerMed	International Consortium for Personalised Medicine
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KPI	Key Performance Indicator
MoST	Ministry of Science and Technology People's Republic of China
MT	Medical Technologies
NCC	National Cancer Centre of China
NCCN	National Comprehensive Cancer Network
OECD	Organization for Economic Co-operation and Development
OITB	Open Innovation Test Bed
PM	Personalised Medicine
RNA	Ribonucleic acid
S2i	Steinbeis 2i GmbH
SAC	Standardization Administration of the People's Republic of China
Sino-EU-PerMed	Widening Sino-EU policy and research cooperation in Personalised Medicine
SME	Small and medium-sized enterprises
THU	Tsinghua University
ToR	Terms of Reference
UCSC	Università Cattolica del Sacro Cuore (Catholic University of the Sacred Heart)
WFPHA	World Federation of Public Health Associations
WG	Working Groups
WHO	World Health Organization
WP	Work Package



## Executive Summary

This document has been developed under the International Consortium for Personalised Medicine (IC2PerMed) project, funded by the European Union's Horizon 2020 research and innovation programme under grant agreement No 874694. It represents the *Deliverable 1.3 - Scoping paper: Towards closer EU-China collaboration in Personalised Medicine*.

The project aims to provide key solutions for enabling the convergence under ICPerMed consortium of European and Chinese stakeholders towards a common approach of Personalised Medicine (PM) research, innovation, development, and implementation.

This document focuses on the detailed mapping of PM approaches and standards and current Sino-European collaborations related to health, aiming to extract implications for future bilateral interactions.

The mapping details four key areas of the PM ecosystem both in Europe and in China:

- Treatment approaches;
- Data and biobanking standards;
- Detection techniques, evaluation methods and data sharing mechanisms as co-developments in PM; and
- Current collaboration projects, initiatives, and joint research centres related to health.

The IC2PerMed consortium addresses the fundamental questions of:

- What are commonalities and differences in current personalised treatment approaches, data and biobanking standards as well as co-developments to PM?
- What are lessons learnt from ongoing cooperation?
- What are success factors for future collaboration?
- What are areas of mutual interest?

The mapping of PM-related treatment approaches and data/biobanking standards established in the EU and in China reveals that the ongoing “scaffolding” for a joint Sino-European bridge on a common clinical practice is already in preparation. However, a common and internationally standardised view on PM is yet to be elaborated through the joint effort from the EU and China in order to improve clinical practice.

The mapping of current Sino-European collaborations further reveals that the participation of European and Chinese researchers in joint Research and Innovation (R&I) activities related to PM has so far largely been facilitated by top-down initiatives and will continue to be coordinated through the bilateral joint roadmap currently under discussion between the European Commission and the Ministry of Science and Technology of the People's Republic of China. The research conducted here underlines the ongoing need for further framework programmes supporting bilateral exchanges and more specifically outgoing mobility to China. As the field of PM comprises an enormously wide range of possible application fields, Sino-European collaboration activities should ideally be focused on areas of mutual interest, such as sustainable healthcare, value for society, and interoperability in R&I, as identified in the present mapping.

The outline provides the basis for further discussions on elaborating recommendations to improve reciprocity and increase areas of interest for future PM-related collaboration between China and Europe.





# 1 Introduction

The field of Personalised Medicine (PM) is highly interdisciplinary in nature and requires the smooth interplay of many factors. In “D1.1 Scoping Paper: Review on health research and innovation priorities in Europe of China” we highlighted the importance of policies and measures regarding PM approaches in both regions and mapped their major focus of interest, working out common ground and strategic differences between Europe and China. In “D1.2 Map of major funding agencies and stakeholders in Europe and China” we gave a detailed picture of the important stakeholders and institutions involved in PM and listed the major PM-dedicated funding schemes in both regions.

In the present document, “D1.3 Towards closer EU-China collaboration in Personalised Medicine”, we complement our mapping activities focusing on detailed PM approaches and standards and assessing current Sino-European collaborations related to health and their implications for future bilateral interactions.

Considering the enormous range of possible application fields for PM, we have selected the field of cancer as an example for personalised treatment approaches in Europe and China. Cancer treatment guidelines are a prime example for the application of PM principles and act as a blueprint for rare and chronic diseases. Breast cancer, being a major global health concern and the cancer of highest incidence globally, serves as a case study for a detailed overview of existing approaches. Common data and biobanking standards pave the way for reproducible basic research in PM and make sure findings are generally applicable and independent of the research institution and the country of origin. Biobanking standards are developed and applied globally, acting as an example of collaborative international standardisation efforts and a future area for Sino-European collaborations. Detection techniques, evaluation methods and data sharing mechanisms represent further potential areas for collaboration with a focus on accompanying co-developments in PM.

With the objective to develop recommendations towards closer collaboration between Europe and China in the field of PM, we map the current EU- and non-EU-funded Sino-European projects, initiatives and bilateral joint research centres related to health, analyse lessons learnt from ongoing cooperation, and derive success factors for future collaboration. This mapping is primarily based on desk research and surveys of experts in PM, country representatives and EU and Chinese researchers working in the respective partner countries.

A synthesis of the information gathered from all the mapping activities provides a first outline for a deepened Sino-European collaboration in the field of PM. The outline contains best practices from the ICPerMed, areas of mutual interest as well as facilitators and enablers of future collaborations in PM. This synthesis serves as the basis for further discussion to elaborate recommendations on how to improve reciprocity and increase areas of interest for future collaboration between China and Europe.



## 2 Methodology

A four-step methodological process (see Figure 1) was applied to (a) map activities focusing on detailed PM approaches and standards, and (b) assess current Sino-European collaborations related to health:

- Step 1: Desk research  
(November 2020 – March 2021)
- Step 2: IC2PerMed Survey on China-European Union (EU) cooperation over PM developments  
(February 2021)
- Step 3: Survey on Sino-European collaboration addressing country representatives in China and Europe  
(January – March 2021)
- Step 4: Survey on Sino-European collaboration addressing European researchers in China and Chinese researchers in Europe  
(January – March 2021).

### **I) Desk research**

The goal of the desk research was to retrieve publicly available information on PM approaches and standards, treatment guidelines in cancer, data and biobanking storage, standardisation, detection techniques, data protection, and collaborations between China and Europe in PM. The desk research included information collection from institutional online repositories such as:

- European level:
  - European Society of Medical Oncology (ESMO)
  - The Community Research and Development Information Service (CORDIS)
- Chinese level:
  - Chinese Society of Oncology (CSCO)
  - Chinese Health Commission
- International level with focus on Europe and China:
  - International Organization for Standardization (ISO)
  - US-based National Comprehensive Cancer Network (NCCN)

as well as grey literature search using Google®, Google® Scholar and Microsoft® Academic search engines in combination with a broad set of search terms.

The information stemming from the desk research was reported in tables standardised for both EU and China and in a descriptive synthesis for each topic.

### **II) Survey on China-EU cooperation on PM developments**

A survey was elaborated within the IC2PerMed Consortium to explore the current landscape of implementation, priorities, and challenges of PM in China and Europe, with a focus on Sino-European collaborations in this field. The survey was made available from January 29<sup>th</sup> to February 28<sup>th</sup>, 2021 on the IC2PerMed website:

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

The survey (Appendix 1) consisted of four sections, of which section 3 addressed facilitators and barriers for collaborations between Europe and China in PM. This section comprised six questions related to:



- Awareness on collaborations in the field of PM between Europe and China
- Relevant facilitators or enabling factors for EU-China collaborations in PM
- Relevant barriers for EU-China collaborations related to PM
- Relevant contextual aspects (social, cultural, economic, ethical, etc.) to be taken into consideration in EU-China collaborations in PM
- Actions to be implemented by Chinese and European policy makers for intensifying EU-China collaboration in the field of PM
- Main priority and challenge areas to be considered towards EU-China collaborations in PM

### **III) Survey on Sino-European collaboration addressing country representatives in China and Europe**

This survey was designed to examine Sino-European collaboration aspects in the field of PM and closely related ones, and support EU-China collaboration over the developments of PM research, innovations, and policies through the ICPerMed initiative, providing people with access to personalised healthcare solutions in the near future.

Targeted survey respondents included representatives of the governmental sector (R&I, Health etc.), funding agencies, important PM research institutions, and international organisations.

The survey questions are available in Appendix 2.

The survey of EU Country representatives is accessible via <https://forms.gle/7GpW9UuDfUhm4vD66>  
For the survey of Chinese representatives, the questions were translated in Chinese language and are accessible via <https://survey.inno-projects.net/index.php/511687?lang=en>

### **IV) Survey on Sino-European collaboration addressing European researchers in China and Chinese researchers in Europe**

This survey was designed to better understand the situation of Chinese researchers in Europe and of European researchers in China and help to develop strategies for strengthening Sino-European collaboration in the long-term.

Targeted survey respondents included European researchers active in China and Chinese researchers active in Europe.

The survey questions are available in Appendix 3.

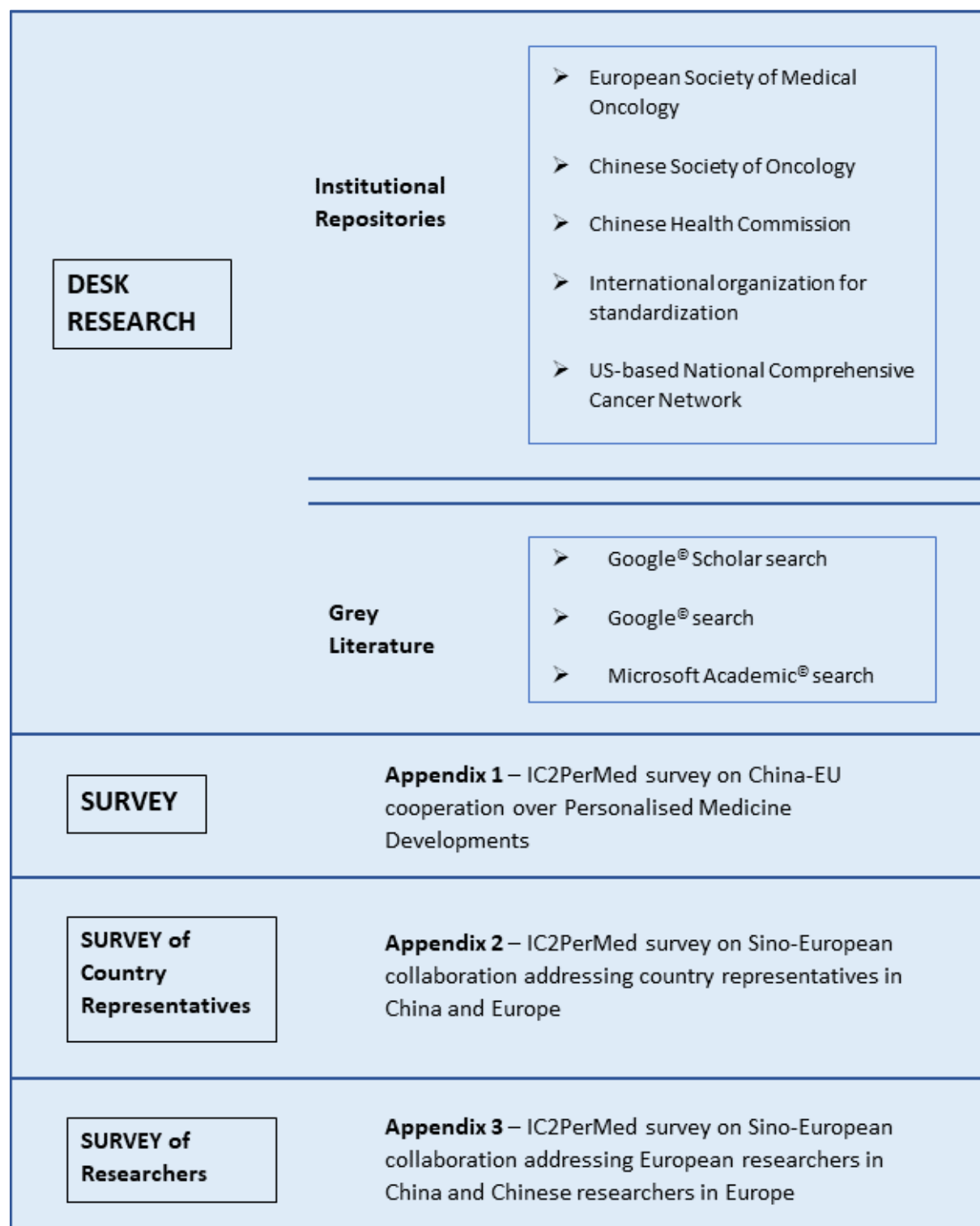
The survey of Chinese researchers in Europe is accessible via <https://forms.gle/5W5cd2KxsR9e8UR27>  
The survey of European researchers in China is accessible via <https://forms.gle/atq3tRuissEL7HQs5>

### **Synopsis of Desk Research and Surveys**

The results of the desk research represent the basis for the mapping on PM-related approaches and standards in EU and China (chapter 3), and the status quo in Sino-European collaboration related to PM (subchapter 4.1). The surveys' feedback was included in subchapter 4.2 "Lessons learnt from ongoing Sino-European cooperation" and subchapter 4.1 "Outline for a deepened Sino-European collaboration".



Figure 1: Overview of applied methodology



## 3 Mapping PM-related approaches and standards in EU and China

In this chapter, we focus on cancer treatment guidelines as a major priority area of PM and an example for established PM-related approaches in clinical practice. We then extend our view on data and biobanking standards, a topic that offers great potential for Sino-European collaboration in Research & Innovation (R&I). The final section on important co-developments in PM provides an overview on current trends in the omics field and associated detection techniques. It also addresses the quickly developing and controversial topic of data protection and data sharing mechanism, on which the EU and Ministry of Science and Technology of the People's Republic of China (MoST) have divergent views, and future strategic alignment may promise strong impulses for the further development of PM.

### 3.1 Treatment guidelines in PM

PM is a medical approach covering the areas of prevention and treatment<sup>1</sup>, both aiming at providing the most optimal tailor-made care for the individual patient. Thus, PM reaches beyond current healthcare approaches – understood as stratified medicine while treating patient groups based on comparable clinical and/or molecular phenotype.

#### Personalised preventive measures

Many diseases, e.g., neurodegenerative diseases, cardiovascular disorders, diabetes, and cancer, are diagnosed at rather late stages. In the case of neurologic disorders such as Alzheimer's and Parkinson's disease for example, the onset of the diseases is often asymptomatic or only associated with mild symptoms. It can take many years for patients to develop the characteristic symptoms and pathologies, which can cause a delayed diagnosis and often a patients' odyssey until the correct diagnosis is made. Thus, precious time might be lost before specific treatment can be administered to prevent disease progression, potentially translating into a more severe disease outcome and loss of life expectancy and quality. Hence, personalised prevention aims at identifying individuals at (genetic) risk to develop a certain disease and intends to prevent the development of such disease based on e.g., chemoprevention or change of lifestyle habits.

#### Personalised treatment strategies

Once a patient is correctly diagnosed with a certain disease, the medical approach should focus on the most effective and best-tolerable treatment strategy. For some patients, certain medications are associated with severe side effects or treatment failure and/or resistance. This has not only socio-economic drawbacks overall, but severely impacts on the life quality and expectancy of the individual patient. This is particularly true for cancer patients.

Thus, oncology has become one of the most visible and driving fields for the application of PM principles. In the context of this task, relevant treatment guidelines with a focus on cancer will be highlighted. The two subchapters 3.1.1 and 3.1.2 list European and Chinese treatment guidelines with an emphasis on specific cancer types including breast, lung, endocrine and neuroendocrine,

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<sup>1</sup> European Commission. Personalised medicine. [https://ec.europa.eu/health/human-use/personalised-medicine\\_en](https://ec.europa.eu/health/human-use/personalised-medicine_en)



gastrointestinal, and gynaecological cancers. Breast cancer is used as an example to identify disparities between Europe and China. The main differences and challenges are summarised in subchapter 3.1.3.

### 3.1.1 Relevant cancer treatment guidelines in Europe

Based on the determined priority area for EU the clinical practice guidelines for cancer were selected from the European Society of Medical Oncology (ESMO). ESMO is the leading professional organisation for medical oncology. With more than 25,000 members representing oncology professionals from over 160 countries worldwide, ESMO is the society of reference for oncology education and information. ESMO's core mission is to improve the quality of cancer care, from prevention and diagnosis all the way to palliative care and patient follow-up. It is to educate doctors, cancer patients and the public on the best practices and latest advances in oncology. The ESMO Clinical Practice Guidelines, prepared and reviewed by leading experts and based on the findings of evidence-based medicine, provide a set of recommendations to help patients with the best care options<sup>2</sup>.

Table 1 describes the content of the ESMO guidelines<sup>3</sup> in relation to cancer.

**Table 1: ESMO clinical practice guidelines on cancer**

Cancer type	Guidelines (Target/Detection Gene)	Publication year	Description of content
<b>Breast Cancer</b>	BRCA Mutation Carriers and Other Breast/Ovarian Hereditary Cancer Syndromes	2016	Comprehensive guidelines for early and advanced breast cancer management plus prevention and screening for BRCA mutation carriers
	Breast cancer in the COVID-19 era	*	
	Consensus Recommendations – Advanced Breast Cancer (ABC5)	2020	
	Consensus Recommendations – Breast Cancer in Young Women (BCY4)	2020	
	Early Breast Cancer	2019	
<b>Cancers of Unknown Primary Site</b>	Cancers of Unknown Primary Site	2015	Definition, incidence, and biology, staging and treatment of this heterogeneous group of metastatic tumours
<b>Endocrine and Neuroendocrine Cancers</b>	Adrenocortical Carcinomas	2020	Including guidelines on thyroid and adrenal cancers, along with gastroenteropancreatic and bronchial and thymic neuroendocrine tumors
	Gastroenteropancreatic Neuroendocrine Neoplasms	2020	
	Lung and Thymic Carcinoids	2021	
	Thyroid cancer	2019	
	Anal Cancer	2014	

<sup>2</sup> ESMO, About ESMO. <https://www.esmo.org/about-esmo>

<sup>3</sup> ESMO, ESMO Guidelines. <https://www.esmo.org/guidelines>

\* These recommendations aim to develop guidance to mitigate the negative effects of the COVID-19 pandemic on the diagnosis and treatment of breast cancer patients. The situation is evolving, and pragmatic actions may be required to deal with the challenges of treating patients, while ensuring their rights, safety, and well-being. The points mentioned below are intended to provide guidance for all physicians involved in cancer care during this time. Due to the urgency and the rapidly evolving situation, further updates to this guidance are possible and likely. In addition, we recognise that there might be specific national legislation and guidance in place, which can be considered to complement this guidance, or, with respect to particular matters, may take priority over these recommendations. This document is however seeking to include most of the current guidance with the aim to serve as a set of recommendations.



Cancer type	Guidelines (Target/Detection Gene)	Publication year	Description of content
<b>Gastrointestinal Cancers</b>	Biliary Cancer	2016	Covering the breadth of gastrointestinal cancers, including biliary, gastric, oesophageal, pancreatic, anal, rectal, hepatocellular and colorectal cancer
	Gastric Cancer	2016	
	Gastrointestinal cancers: Colorectal cancer -in the COVID-19 era	2020	
	Gastrointestinal cancers: Gastro-oesophageal tumours in the COVID-19 era	2020	
	Gastrointestinal cancers: Pancreatic cancer in the COVID-19 era	2020	
	Hepatocellular Carcinoma	2018	
	Hereditary Gastrointestinal Cancers	2019	
	Localised Colon Cancer	2020	
	Metastatic Colorectal Cancer	2014	
	Oesophageal Cancer	2016	
	Pancreatic Cancer	2015	
Rectal Cancer	2017		
<b>Genitourinary Cancers</b>	Bladder Cancer	2014	Topics include prostate, urothelial bladder, testicular, penile, and renal cell cancers
	Penile Carcinoma	2013	
	Prostate Cancer	2020	
	Renal Cell Carcinoma	2019	
	Testicular Cancer	2013	
<b>Gynaecological Cancers</b>	Cervical Cancer	2017	Comprehensive guidance on cervical, endometrial, and ovarian cancers. Also including gestational trophoblastic disease guidelines
	Endometrial Cancer	2013	
	Gestational Trophoblastic Disease	2013	
	Gynaecological malignancies: Cervical cancer in the COVID-19 era	2020	
	Gynaecological malignancies: Endometrial cancer in the COVID-19 era	2020	
	Gynaecological malignancies: Epithelial ovarian cancer in the COVID-19 era	2020	
	Newly Diagnosed and Relapsed Epithelial Ovarian Carcinoma	2013	
Non-Epithelial Ovarian Cancer	2018		
<b>Haematological Malignancies</b>	Acute Lymphoblastic Leukaemia	2016	Providing guidelines on more than 15 topics in lymphoma, leukaemia, and myeloma
	Acute Myeloid Leukaemia	2020	
	Chronic Lymphocytic Leukaemia	2020	
	Chronic Myeloid Leukaemia	2017	
	Diffuse Large B-Cell Lymphoma	2015	
	Elderly Patient with Malignant Lymphoma	2017	
	Extranodal Diffuse Large B-Cell Lymphoma and Primary Mediastinal B-Cell Lymphoma	2016	
	Follicular Lymphoma	2020	
	Hairy Cell Leukaemia	2015	
	Hodgkin Lymphoma	2018	
	Management of ultra-high-risk Patients	2018	
	Mantle Cell Lymphoma	2017	
	Marginal Zone Lymphomas	2020	
	Multiple Myeloma	2021	
	Myelodysplastic Syndromes	2020	
	Peripheral T-Cell Lymphomas	2015	
Philadelphia Chromosome-Negative Chronic Myeloproliferative Neoplasms	2015		





Cancer type	Guidelines (Target/Detection Gene)	Publication year	Description of content
	Primary Cutaneous Lymphoma	2018	
	Prognostic Tools in Mature B-cell Lymphomas and Chronic Lymphocytic Leukaemia	2016	
	Waldenstrom's Macroglobulinaemia	2018	
<b>Head and Neck Cancers</b>	Nasopharyngeal Carcinoma	2020	Nasopharyngeal cancer and Head and Neck Squamous Cell Carcinoma guidelines are included covering diagnosis through to follow-up
	Squamous Cell Carcinoma of the Head and Neck	2020	
<b>Hereditary Syndromes</b>	BRCA Mutation Carriers and Other Breast/Ovarian Hereditary Cancer Syndromes	2016	Prevention and screening in BRCA mutation and other breast/ovarian cancer syndromes, along with diagnosis and treatment of hereditary gastrointestinal cancers
	Hereditary Gastrointestinal Cancers	2019	
<b>Lung and chest tumours</b>	Lung cancer in the COVID-19 era	2020	Comprehensive guidelines on early, locally advanced, and metastatic non-small-cell lung cancer, small-cell lung cancer, malignant pleural mesothelioma and thymic epithelial tumours
	Clinical Practice Living Guidelines – Metastatic Non-Small-Cell Lung Cancer	2020	
	Early-Stage and Locally Advanced (non-metastatic) Non-Small-Cell Lung Cancer	2017	
	Thymic Epithelial Tumours	2015	
	Malignant Pleural Mesothelioma	2015	
	Small-Cell Lung Cancer	2013	
<b>Melanoma</b>	Cutaneous Melanoma	2019	Incidence, diagnosis, staging and risk assessment, treatment, response evaluation and follow-up of cutaneous melanoma
<b>Neuro-Oncology</b>	Leptomeningeal Metastasis	2017	High-grade glioma and leptomeningeal metastasis guidelines are currently provided
	High-Grade Malignant Glioma	2014	
	Neurological and Vascular Complications of Primary and Secondary Brain Tumours	2020	
<b>Sarcoma and Gastrointestinal stromal tumours</b>	Bone Sarcomas	2018	Guidelines on soft tissues and visceral sarcomas, bone sarcomas and gastrointestinal stromal tumours developed in collaboration with the European Reference Networks
	Soft Tissue and Visceral Sarcomas	2018	
	Gastrointestinal Stromal Tumours	2018	
<b>Supportive and Palliative Care</b>	Palliative Care in the COVID-19 era	2020	Supportive and palliative care are areas of high importance in oncology and ESMO published Clinical Practice Guidelines on the management of a variety of issues
	Advanced Care Planning	2014	
	Anaemia and Iron Deficiency in Patients with Cancer	2018	
	Bone Health in Cancer Patients	2020	
	Cancer Pain	2018	
	Cancer-related Fatigue	2020	
	Cancer, Pregnancy and Fertility	2013	
	Central Venous Access in Oncology	2015	
	Chemotherapy Extravasation	2012	
	Constipation in Advanced Cancer	2018	
Delirium in Adult Cancer Patients	2018		





Cancer type	Guidelines (Target/Detection Gene)	Publication year	Description of content
	Diarrhoea in Adult Cancer Patients	2018	
	Febrile Neutropenia	2016	
	Fertility Preservation and Post-treatment Pregnancies in Post-pubertal Cancer Patients	2020	
	Infusion Reactions to Systemic Anticancer Therapy	2017	
	Management of Breathlessness in Patients with Cancer	2020	
	Management of Cardiac Disease	2020	
	Management of Orphan Symptoms	2020	
	Neurotoxicity	2020	
	Oral and Gastrointestinal Mucosal Injury	2015	
	Prevention and Management of Dermatological Toxicities Related to Anticancer Agents	2020	
	Prevention of Chemotherapy and Radiotherapy-Induced Nausea and Vomiting	2016	
	Refractory Symptoms at the End of Life and the Use of Palliative Sedation	2014	
	Toxicities from Immunotherapy	2017	
	Venous Thromboembolism in Cancer Patients	2011	

In addition to guidelines, standards deliver an essential basis for research in PM approaches (elaborated in detail in chapter 3.2). Regarding cancer research, BBMRI-ERIC's observer IARC published a Technical Standard specifically for biobanks dedicated to cancer research<sup>4</sup>. The International Agency for Research on Cancer (IARC) is the specialised cancer agency of the World Health Organization (WHO). The objective of the IARC is to promote international collaboration in cancer research. With the Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research it has been strongly emphasised that biological specimens collected, processed, and stored under optimal conditions increasingly provide a necessary foundation for cancer research. Information obtained from such samples opens opportunities to learn more about causes, prevention, and treatment of the disease. International comparisons made possible by the study of sample collections from different parts of the world are also invaluable in the pursuit of evidence-based cancer control.

### 3.1.2 Relevant cancer treatment guidelines in China

China applies both international cancer treatment guidelines of the US-based National Comprehensive Cancer Network (NCCN) and national guidelines issued by the Chinese Society of Oncology (CSCO) and the Chinese Health Commission. Relatively speaking, the CSCO guidelines are updated in a timelier manner, once every year, and have a higher industry recognition in China. The CSCO is one of the most well-known and authoritative medical science and technology academic groups in China and has a

<sup>4</sup> Mendy, et al. (2017) Common Minimum Technical Standards and Protocols for Biobanks dedicated to cancer research. IARC Technical Publication No. 44, Geneva: WHO press.



profound impact on the international clinical oncology community. Table 2 lists all relevant CSCO cancer treatment guidelines related to Precision Medicine<sup>5</sup>.

**Table 2: Relevant cancer treatment guidelines in China**

Cancer type	Guidelines (Target/Detection Gene)	Year	Description of content
<b>Breast cancer</b>	Breast Cancer Diagnosis and Treatment Guidelines, Shanghai International Breast Cancer Forum (HER-2)	2020	Experts generally agree that in the adjuvant treatment stage, all patients who meet single-targeted therapy can consider dual-targeted therapy. The immune targeted therapy strategies for different types of breast cancer have been adjusted.
<b>Colorectal cancer</b>	Colorectal Cancer Diagnosis and Treatment Guidelines (RAS, BRAF)	2020	All two-drug chemotherapy in the potentially resectable metastasis group was changed from Grade I recommendation to Grade II recommendation, and the recommended dose of 5-FU in FOLFOXIRI was revised to 2400-3200 mg/m <sup>2</sup> . The second-line treatment plan for BRAF V600E mutation patients recommends Dabrafenib + Trametinib + Cetuximab; For the third-line treatment after standard treatment fails, the recommendation of the new drug Trifluridine tepipyrimidine (TAS-102) has been added; Anti-HER2 targeted therapy is recommend for RAS/BRAF wild-type patients with HER2 amplification.
<b>Esophageal cancer</b>	Esophageal Cancer Diagnosis and Treatment Guidelines (EGFR, ERBB2, MET)	2020	Immunotherapy becomes the second-line standard treatment Esophageal squamous cell carcinoma: For patients with "PS=0-2", the level I expert recommends the addition of Carelizumab; Pembrolizumab (squamous cell carcinoma, PD-L1 CPS ≥10, Type 1A evidence) is adjusted to the level I expert recommendation; Nivolumab was adjusted to be recommended by level II experts.
<b>Gastro-intestinal stromal tumours</b>	Guidelines for Diagnosis and Treatment of Gastro-intestinal Stromal Tumour (KIT, PDGFRA, SDHA, SDHB, SDHC, SDHD, BRAF, NF1, KRAS, PIK3CA, FGFR1, NTRK3)	2020	Genotype-based drug therapy The application of new drugs represented by Avatinib and Repetinib has greatly promoted the transformation of the GIST drug treatment pattern, and there has been a trend of shifting from the traditional recommendation based on the number of treatment lines to the recommendation based on genotyping. It is still in the clinical trial stage in China and has not been listed, but the C-G guidelines have made corresponding recommendations for these two drugs in keeping with the times. The success of tyrosine kinase receptor inhibitors in GIST is a milestone in molecular targeted drug therapy in the era of precision medicine. Both CSCO and NCCN guidelines standardize GIST

<sup>5</sup> Personalised cancer treatment guidelines of the Chinese Health Commission (CN).



Cancer type	Guidelines (Target/Detection Gene)	Year	Description of content
			diagnosis and treatment practices based on the latest evidence-based medical evidence, and emphasize the concept of precise diagnosis and treatment.
<b>Head and neck cancers</b>	Guidelines for Diagnosis and Treatment of Head and Neck Tumour and Guidelines for Diagnosis and Treatment of Nasopharyngeal Carcinoma and Liver Cancer (EGFR)	2020	<p>Recurrent and metastatic head and neck squamous cell carcinoma: Platinum combined with 5-FU combined with cetuximab approved for treatment</p> <p>First-line treatment for patients with distant metastatic nasopharyngeal carcinoma: Class I experts recommend cisplatin + gemcitabine (class 1A evidence), cisplatin + docetaxel (class 2A evidence), carboplatin + paclitaxel (class 2A evidence);</p> <p>Level II experts recommend cisplatin/carboplatin+5-FU (Class 2A evidence), cisplatin+capecitabine (Class 2A evidence); second-line treatment or rescue treatment: Level II experts recommend gemcitabine (Class 2A), Docetaxel (type 2A evidence), capecitabine (type 2A evidence);</p> <p>Level III experts recommend the treatment of other indications such as Pembrolizumab, Nivolumab, Carrelizumab, and Teriprizumab (all of which are Type 2B evidence).</p>
<b>Kidney Cancer</b>	Kidney Cancer Diagnosis and Treatment Guide (VHL, VEGF)	2020	<p>Recommendations for the treatment of advanced renal cell carcinoma, continue the 2019 version to make stratified recommendations based on risk stratification: cytokines are no longer recommended as the treatment of advanced renal cell carcinoma;</p> <p>As the second-line treatment recommendation for advanced renal cancer, Lenvatinib combined with Pembrolizumab can be used as a third-level recommendation for the follow-up treatment of advanced renal cancer.</p> <p>In the treatment recommendation for advanced non-clear cell renal cell carcinoma, Bevacizumab combined with Erlotinib can be used as a grade III recommendation for papillary renal cell carcinoma.</p>
<b>Lymphoma</b>	Lymphoma Diagnosis and Treatment Guidelines (BCR pathway, NF-κB pathway, PI3K/AKT/mTOR pathway, JAK/STAT pathway, apoptosis signaling pathway and PD-1/PD-Ls pathway)	2020	<p>Treatment of relapsed/refractory Hodgkin's lymphoma: Tislelizumab, Carelizumab, and Sepalizumab were added to the level II expert recommendation; Carelizumab was added to the level III expert recommendation Combination of monoclonal antibody + Decitabine.</p> <p>Chronic lymphocytic leukemia: improve the recommended level of Zebutinib (del17(p)/p53 gene mutation-initial treatment or refractory), etc.</p>
<b>Melanoma</b>	Melanoma Diagnosis and Treatment Guidelines (BRAF, CKIT, NRAS)	2020	<p>As the first and currently only targeted program with dual indications for advanced and adjuvant treatment of BRAF V600 mutant melanoma in China, Dabrafenib combined with Trametinib (D+T) has authoritative guideline level I recommendation and 5-year follow-up The latest release of the data</p>



Cancer type	Guidelines (Target/Detection Gene)	Year	Description of content
			fills the gaps in the country and opens up a new era of dual-target treatment for melanoma in China.
<b>Non-small cell lung cancer</b>	Non-small cell lung cancer diagnosis and treatment guidelines (EGFR, ALK, ROS1, BRAF V600E, NTRK, KRAS, ERBB, (HER2), RET, MET)	2020	Treatment of EGFR mutation-positive advanced NSCLC: first-line treatment: Dacomitinib grade I recommendation (Class 1A evidence), and Osimertinib first-line treatment recommendation to grade I recommendation (Class 1A evidence); Treatment of advanced NSCLC with positive ALK fusion: first-line treatment: Brigatinib Grade III recommendation (Class 1A evidence), post-line treatment: Brigatinib as Grade III recommendation and limited to "first-generation TKI treatment failure" (Class 3 evidence) and Lorlatinib as Grade III It is recommended and limited to "the second-generation ALK-TKI first-line treatment or the first/second-generation ALK-TKI treatment fails" (3 types of evidence); ROS1 fusion-positive advanced NSCLC treatment: first-line treatment: Entrectinib first-line treatment grade III recommendation (3 types of evidence); BRAF V600E mutation/NTRK fusion treatment of non-small cell lung cancer: First-line treatment: Dabrafenib+Trametinib/Dabrafenib (Dabrafenib+Trametinib/Dabrafenib) for the treatment of BRAF V600E mutation patients with Grade III recommendation (3 types of evidence), Larotrectinib (Larotininib) or Entrectinib (Entrectinib) in the treatment of NTRK fusion patients with grade III recommendation (3 types of evidence). "
<b>Pancreatic cancer</b>	Guidelines for Diagnosis and Treatment of Pancreatic Cancer (ALK, NGR1, NTRK, ROS1, BRAF, BRCA1/2, HER2, KRAS, PALB2)	2020	The new POLO study is the first successful phase III study based on biomarker guidance in the field of pancreatic cancer. This study puts forward the concept of targeted maintenance therapy guided by biomarkers in pancreatic cancer for the first time. This created a precedent for the precise treatment of pancreatic cancer based on biomarkers: Class I recommend platinum-containing chemotherapy and Olaparib targeted maintenance therapy for BRCA-positive patients.
<b>Primary liver cancer</b>	Guidelines for Diagnosis and Treatment of Primary Liver Cancer (EGFR, VEGFR, MET, PI3K/Akt/mTOR, Multiple targets, TGFβ)	2020	The first-line systemic treatment of advanced liver cancer immuno-targeted therapy: Donafinib and Atelizumab combined with Bevacizumab "T+A" regimen (Class 1A evidence), Lenvatinib combined with pembrolizumab Anti- or Nivoliuzumab (class 2B evidence), Apatinib combined with Carelizumab (class 2B evidence), Oxaliplatin-based systemic chemotherapy combined with Carelizumab (class 2B evidence) ; Second line: Level I experts recommend as "PD-1 monoclonal antibodies (Nivoluzumab, Pembrolizumab, Carelizumab, etc.) (2A evidence)" and "Apatinib" (1A category evidence). Level II expert recommendation is "Cabotinib (Type



Cancer type	Guidelines (Target/Detection Gene)	Year	Description of content
			1A evidence)"; add "Past use of Sorafenib may consider Carelizumab combined with FOLFOX4" (Type 2A evidence) and "Previous use of Osha Libaplatin-based regimens may consider Carelizumab combined with Apatinib" (Class 2B evidence). Level III experts recommend adding "Nivolumab combined with Ipilimumab (Class 2A evidence).
<b>Prostate cancer</b>	Prostate Diagnosis and Treatment Guide (BRCA2, BRCA1, ATM, PALB2, FANCL, RAD51B, RAD51C, RAD51D, BRIP1, BRAD1, CHEK1, CHEK2, CDK12, RAD54L)	2020	The first-line treatment of mCRPC is still based on the recommendations of chemotherapy and endocrine therapy. In the second-line and third-line treatment options, the PARP inhibitor Olaparib appears in the first-line recommendation.
<b>Small Cell Lung Cancer</b>	Small Cell Lung Cancer Diagnosis and Treatment Guidelines	2020	/
<b>Soft tissue sarcoma</b>	Guidelines for Diagnosis and Treatment of Soft Tissue Sarcoma (EWSR1, ALK, NTRK)	2019	On June 24, 2019, NMPA officially approved China's self-developed innovative drug Anlotinib Hydrochloride Capsules (Focavi®) for soft tissue sarcoma. This is currently the first approved soft tissue sarcoma targeted drug in China; The product single drug is suitable for the treatment of acinar soft tissue sarcoma, clear cell sarcoma, and other advanced soft tissue sarcoma patients who have progressed or recurred after at least previously treated with anthracycline-containing chemotherapy regimens.
<b>Stomach cancer</b>	Guidelines for Diagnosis and Treatment of Gastric Cancer (TP53, EGFR, HER2, VEGF, VEGFR, MET, FGFR2, mTOR, Claudin 18.2)	2020	HER2+: The first-line chemotherapy regimen of Trastuzumab combined with CAPEOX and SP has been increased to "Oxaliplatin + 5-FU, Oxaliplatin + Capecitabine, Oxaliplatin + S-1, S-1+cisplatin", (Class 1A evidence), level II recommendation; HER2-: The level of evidence for Oxaliplatin + fluorouracil was changed from (2B to 1A), level I recommendation, and placed before the PF plan; PD-L1 monoclonal antibody third-line therapy: Nivolumab monotherapy, (1A evidence), level I recommendation; Pembrolizumab monotherapy is suitable for patients with PD-L1 positive combination score (CPS) ≥ 1, ( Class IB evidence), Class II recommendation.
<b>Thyroid cancer</b>	Guidelines for Diagnosis and Treatment of Thyroid Cancer (BRAF, RAS, RET/PTC)	2019	RAIR-DTC with current symptoms or progression: Sorafenib is recommended for grade I (type 1A evidence), Lenvatinib is recommended for grade II (type 1B evidence), and clinical trials are recommended for grade III (type 2B evidence).



### 3.1.3 Breast cancer: A case study for differences between EU and China

Female breast cancer poses a major global health concern and has overtaken lung cancer as the leading cause of global cancer incidence in 2020, with an estimated 2.3 million new cases, representing 11.7% of all cancer cases including both women and men.<sup>6</sup> It is the fifth leading cause of cancer mortality worldwide, with 685,000 yearly deaths. Among women, breast cancer accounts for 25% of all cancer cases and for 17% of all cancer deaths, ranking first for incidence and mortality in many countries<sup>7</sup> (incidence: 159 and mortality: 110 of 185 countries). There is a strong positive correlation between breast cancer incidence and the general economic development of a country, while the mortality rate negatively correlates with the economic status and is therefore much higher in poorer countries.

According to the data of the European Cancer Information System, breast cancer is estimated to be the most diagnosed tumour among all cancer types and the first cause of cancer death among women in 2020. When comparing EU countries which are classified as developed economies, it was found that a higher incidence of breast cancer was indeed observed in the more affluent countries, usually those with a longer established western lifestyle<sup>8</sup> and its associated risk factors (see Figure 2) in line with the perceived worldwide patterns.

Figure 2: Breast cancer risk factors



China is following the global trend with an increasing health burden associated with cancers with more than 1.6 million people being diagnosed and 1.2 million people dying of the disease each year. Breast cancer is the most common cancer in Chinese women.

<sup>6</sup> Sung et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin.* 2020. <https://doi.org/10.3322/caac.21660>

<sup>7</sup> Sung et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin.* 2020. <https://doi.org/10.3322/caac.21660>

<sup>8</sup> Dafni et al. Breast Cancer Statistics in the European Union: Incidence and Survival across European Countries. *Breast Care* 2019; 14:344-353. doi: 10.1159/000503219

In comparison to Western high-income countries, the age at onset of breast cancer is lower in China, attributed partially to a lower abundance of post-menopausal oestrogen receptor-positive subtypes. The overall frequency of breast cancer is still less compared to Europe.<sup>9</sup>

It is reasonable to assume that major drivers of growing incidences observed between higher and lower income countries,<sup>10</sup> such as the women's lifestyle, age at first pregnancy, obesity and probably the extent of exposure to exogenous oestrogens, will more strongly affect China with a larger increase of breast cancer incidence over the next years compared to Europe. This might be due to changes regarding the socioeconomic status and "westernisation" of lifestyle habits associated with unprecedented economic growth. Ethnic differences on the population level based on genetic variations might play only a minor role. Advances in provisions and the uptake of modern screening procedures for breast cancers, early disease diagnosis and more advanced patient-tailored treatments will however directly help in decreasing the mortality rates in both geographic areas as partially observed in Europe over the last decades. Other key factors are the promotion of the population's general awareness about breast cancer risks and the access to high-quality care.

Regarding the cancer treatment guidelines of chapter 3.1.1 and 3.1.2, both China and Europe try to stratify patients according to their individual genetic risk factors (e.g., BRCA mutations<sup>11</sup>) as well as the precise diagnosis of certain molecular subtypes (e.g., HER2 positive breast cancers).

Mutations in the BRCA gene family negatively affect DNA repair mechanisms and the cells are therefore less effective in DNA repair, which in turn would prevent the development of breast cancer. Carriers of BRCA gene mutations are more likely to develop breast cancer and develop cancer at a younger age. It is estimated that 55 – 65% of women with a BRCA1 mutation will develop breast cancer before age 70. Approximately 45% of women with a BRCA2 mutation will develop breast cancer by age 70. Carriers of BRCA mutations diagnosed with breast cancer are more likely to develop special forms of breast cancers; these findings therefore have important consequences for treatment strategies.

HER2 is a growth-promoting protein on the outside of all breast cells. Breast cancer cells with increased levels of HER2 are called HER2-positive. These tumours tend to grow at an accelerated speed and are more likely to spread faster than other types of breast cancers; at the same time, they are also more prone to respond to the treatment with monoclonal antibodies targeting the HER2 protein<sup>12</sup>.

The challenge is to apply the guidelines in a way that ensures that all patients have informed choice and equitable access to these PM approaches including all treatment levels including surgery, radiation, hormone therapy, chemotherapy, and targeted antibody therapy. Many of these treatment strategies have serious cost implications, which are differently supported by the European and Chinese health systems. Differences in the political systems, cultural and ethical aspects might have a large influence on the application of available treatment guidelines.

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<sup>9</sup> Leong, S. P., Shen, Z. Z., Liu, T. J., Agarwal, G., Tajima, T., Paik, N. S., Sandelin, K., Derossis, A., Cody, H., & Foulkes, W. D. (2010). Is breast cancer the same disease in Asian and Western countries? *World journal of surgery*, 34(10), 2308–2324. <https://doi.org/10.1007/s00268-010-0683-1>

<sup>10</sup> Carioli et al. (2017). Trends and predictions to 2020 in breast cancer mortality in Europe. *The Breast*, 36, 89–95. <https://doi.org/10.1016/j.breast.2017.06.003>

<sup>11</sup> National Breast Cancer Foundation (2020). BRCA: The Breast Cancer Gene. <https://www.nationalbreastcancer.org/what-is-brca>

<sup>12</sup> American Cancer Society (2021). Targeted Drug Therapy for Breast Cancer. <https://www.cancer.org/cancer/breast-cancer/treatment/targeted-therapy-for-breast-cancer.html>

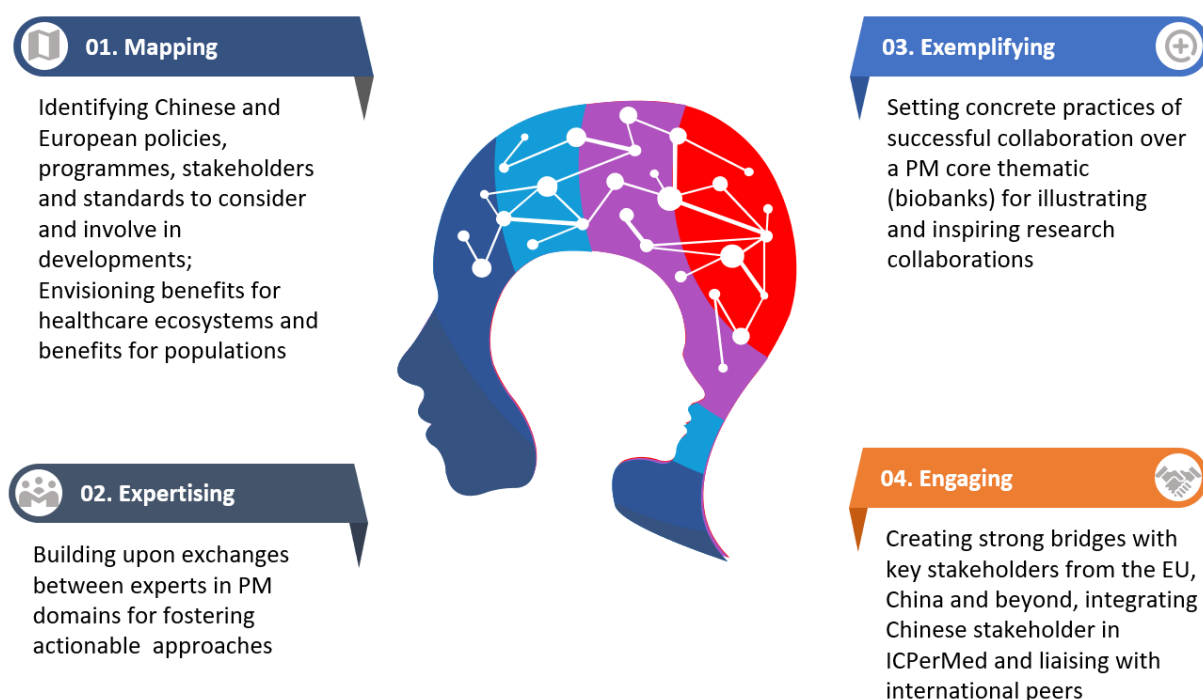




## 3.2 Data and biobanking standards in PM

The application of standards is highly relevant for biomedical research and PM approaches. If standards are observed, biological samples can be collected, processed, and stored under optimal conditions. Only controlled and well-treated samples provide valid data and are thus the necessary basis for research. The information obtained from such samples and their associated data guarantees to learn more about the individual causes, individual prevention, and individual treatment of the disease, which is what PM aims to do. The field of biobanking with its data and biobanking standards has been identified by the IC2PerMed consortium as a prime example for the translation of PM approaches into practices and is a key area for future collaboration between China and Europe, see Figure 3 on IC2PerMed’s vision.

Figure 3: IC2PerMed’s vision<sup>13</sup>



Consequently, biobanks need to ensure that human biospecimens, both the samples and their associated data, meet uniform standards. Especially when it comes to producing robust research data, the quality of bio samples and their associated data is of enormous importance. Therefore, harmonised standards need to be introduced and followed. In addition, the European Commission (EC) identified standardisation in its Horizon 2020 research framework programme as one of the main innovation-support measures bridging the gap between research and the market on one hand, as well as helping the fast and easy transfer of research results to the European and international market on the other hand.

Correspondingly, when things do not work as they should, it often means that standards are absent. Therefore, all parties involved in biobanking should commit themselves to follow data and biobanking standards and to implement quality management/assurance procedures. It is recommended that these procedures are compliant not only with the national but with applicable international standards.

<sup>13</sup> IC2PerMed Grant Agreement (GA). Annex 1 – Description of Action (Part B), pp. 7, 2019.



With this, the desired IC2PerMed bridge with key stakeholders from the EU, China and beyond, can be constructed.

### 3.2.1 Stakeholders in standardisation processes

Before dealing with international standards, it is necessary to clarify which standards organisations in Europe and China are the main stakeholders in standardisation processes:

- Europe is represented by the European Committee for Standardization (CEN), and
- China by the Standardization Administration of the People's Republic of China (SAC).

The CEN brings together national standardisation bodies of 34 European countries defining European Standards (EN). All CEN members must implement these ENs as national standards.

The SAC oversees national Chinese standards (GB Standards) and requirements<sup>14</sup> consistent across the entire country.

The International Organization for Standardization (ISO), an independent, non-governmental international organization including 165 national standards bodies as members, is the central bridge builder across the EU and China. Each member provides experts to ISO sharing the necessary knowledge to develop voluntary, consensus-based, market relevant international standards that support innovation and provide solutions to global challenges.

To ensure the global relevance and acceptance of standards, the ISO standards are developed according to good standardisation practices. This means that the development of standards itself, requires standardised systems and processes – the ISO rules – within the national standards bodies that are open, transparent, inclusive, impartial, effective, relevant, and coherent. Since ISO is a global network of national standards bodies, members are the main stakeholders and national standardisation authorities in their respective countries, and only one ISO member per country exists and represents ISO nationally. Individuals or companies can therefore not obtain ISO membership.

CEN directly cooperates with ISO and transposes a large part of the ISO standards into the European standards system. It is noteworthy that the transfer of ISO standards into the respective national standardisation structure is voluntary, while EN must be implemented as national standards by all CEN members.

Many Chinese GB Standards are themselves adoptions from international standards developers such as the ISO and the International Electrotechnical Commission (IEC). As of 2006, nearly half of all Chinese GB Standards were adoptions of international standards and China has explicitly expressed the goal to significantly increase the number of standards that are adoptions of international “advanced foreign standards”, engaging strongly in international standardisation processes.

This clearly shows that the “scaffolding” for a joint EU-China bridge is already in preparation, opening the way to a common and internationally standardised view on PM.

### 3.2.2 Biobanking standards applied in Europe and China

As highlighted in the previous chapters, standards are proven best practices produced by independent bodies, such as CEN, SAC, ISO, to help organisations, research infrastructures and health institutions implement effective quality management and assurance procedures and build upon them with the

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<sup>14</sup> CEN, European Committee for Standardization. Who we are? <https://www.cen.eu/ABOUT/Pages/default.aspx>



goal to increase reproducibility in research and eventually improve personalised treatment and prevention approaches.

Data and biobanking standards (ISO, EN, GB) cover a wide range of topics such as:

- Biotechnology and biobanking,
- Data quality,
- Quality management systems,
- Molecular in vitro diagnostic examinations (specifications for pre-examination processes),
- Information and communication technology,
- Databases,
- Digital specimen data, and
- Forensic DNA database.

They are crucial when trying to build the bridge between the EU and China and developing a common view on PM. In addition, data and biobanking standards ensure consistent quality of treatment as well as the secure storage and protection of confidential individual data and the exchange thereof. This builds reliable trust in the stakeholders involved from basic research to clinical practice and minimises all sources of error.

A prime example for Sino-European collaboration in standardisation processes is the ISO Standard 20387:2018 on biobanking<sup>15</sup>. Both the EU and China acknowledged the need for international harmonisation of biobanking standards and implemented the ISO standard in national legislation, see EN ISO 20387:2018 and GB/T 37864-2019, respectively in Table 3.

Most of the standards on data and biobanking however, except for the 8000 series, are either applied only in China or Europe. In case of a missing “x” in either column, neither Europe nor China have implemented this ISO standard (Table 3). Important stakeholders in public research and industry might still follow these ISO standards on a voluntary basis but are not obliged to do so by national legislation and prefer to establish their own individual standard procedures for the specific topic in place. This clearly shows that there is room for improvement in cooperation and collaboration between the EU and China, which is a central objective of the IC2PerMed project. The data for EU has been retrieved from the ISO and EN repositories.<sup>16,17</sup>

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<sup>15</sup> Wang et al. (2021). The Chinese National Stem Cell Resource Center. *Stem Cell Res.*, Vol 50: 101985. <https://www.sciencedirect.com/science/article/pii/S1873506120302865?via%3Dihub>

<sup>16</sup> International Organization for Standardization. Standards. <https://www.iso.org/standards.html>

<sup>17</sup> European Committee for Standardization. Search Standards. <https://standards.cen.eu/dyn/www/f?p=CENWEB:105::RESET::::>



Table 3: Data and biobanking standards in EU or China

Name Number	Preview	EU	China
<b>General Requirements for Biobanking</b>			
<b>Biotechnology - Biobanking - General requirements for biobanking</b> ISO 20387:2018 EN ISO 20387:2018 GB/T 37864-2019	<ul style="list-style-type: none"> <li>Specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.</li> <li>Is applicable to all organisations performing biobanking, including biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms for research and development.</li> </ul>	x	x
<b>Ethical requirement of human biobanking<sup>18</sup></b> GB/T 38736-2020	<ul style="list-style-type: none"> <li>Establishes:               <ul style="list-style-type: none"> <li>standard of human biological samples (hereinafter referred to as "samples"), including organs and groups containing human genome, genes and other genetic materials.</li> <li>ethical standards of collection, collection, preservation, distribution and use of tissues and cells,</li> <li>as well as the ethical requirements of data related to these samples.</li> </ul> </li> <li>Covers:               <ul style="list-style-type: none"> <li>clinical trials, clinical drug development trials and international and domestic scientific research cooperation using human biological samples.</li> </ul> </li> <li>Does not cover:               <ul style="list-style-type: none"> <li>sample related activities for the purpose of clinical diagnosis and treatment, organ transplantation, crime investigation, forensic identification, blood collection and supply service, doping detection and funeral.</li> </ul> </li> </ul>		x
<b>Conformity assessment— Application guide for evaluation and expression of uncertainty in biological sample measurement<sup>19</sup></b> GB/T 27420-2018	<ul style="list-style-type: none"> <li>Establishes:               <ul style="list-style-type: none"> <li>standard for the evaluation and expression of uncertainty of quantitative measurement results of biological samples in the field of conformity assessment.</li> </ul> </li> <li>Is applicable for the evaluation of uncertainty of test results related to the measurement process</li> <li>Does not include:               <ul style="list-style-type: none"> <li>influence of biological variation, pre-measurement and post-measurement process on the measurement results.</li> </ul> </li> </ul>		x

<sup>18</sup> <http://std.samr.gov.cn/gb/search/gbDetailed?id=A47A713B765014ABE05397BE0A0ABB25>

<sup>19</sup> <https://max.book118.com/html/2020/1115/6003005014003022.shtm>



Name Number	Preview	EU	China
<b>Data Quality</b>			
<b>Part 1: Overview</b> ISO/TS 8000-1:2011	<ul style="list-style-type: none"> <li>• Contains an introduction to ISO 8000, its scope, principles of data quality, the high-level data architecture of ISO 8000.</li> <li>• Provides a description of the structure of ISO 8000.</li> <li>• Summarises the content of the other parts of the general data quality series of parts of ISO 8000.</li> <li>• Describes the relationship between ISO 8000 and other standards.</li> </ul>		
<b>Part 2: Vocabulary</b> ISO 8000-2:2017	<ul style="list-style-type: none"> <li>• Defines terms related to data quality used in ISO 8000.</li> </ul>		
<b>Part 100: Master data: Exchange of characteristic data: Overview</b> ISO 8000-100:2016	<ul style="list-style-type: none"> <li>• Provides an overview of the master data quality series of parts of ISO 8000 addressing: <ul style="list-style-type: none"> <li>- master data-specific aspects of quality management systems</li> <li>- master data quality metrics.</li> </ul> </li> <li>• Describes fundamentals of master data quality and specifies requirements on both data and organisations to enable master data quality addressing: <ul style="list-style-type: none"> <li>- specification of the scope of the master data quality series of parts of ISO 8000;</li> <li>- introduction to master data;</li> <li>- description of the data architecture;</li> <li>- overview of the content of the other parts of the series.</li> </ul> </li> <li>• Does not cover: <ul style="list-style-type: none"> <li>- aspects of data quality that apply to all data regardless of whether they are master data;</li> <li>- aspects of data quality that apply to data that are not master data.</li> </ul> </li> </ul>		
<b>Master data: Exchange of characteristic data: Syntax, semantic encoding, and conformance to data specification</b> ISO 8000-110:2009	<ul style="list-style-type: none"> <li>• Specifies requirements that can be checked by computer for the exchange, between organisations and systems, of master data that consists of characteristic data.</li> <li>• Focuses on requirements that can be checked by computers.</li> </ul>		
<b>Part 120: Master data: Exchange of characteristic data: Provenance</b> ISO 8000-120:2016-10	<ul style="list-style-type: none"> <li>• Specifies requirements for the representation and exchange of information about the provenance of master data that consists of characteristic data.</li> <li>• Supplements the requirements of ISO 8000 110.</li> <li>• Does not specify a complete model for characteristic data, nor does it specify an exchange format for characteristic data with provenance information.</li> <li>• Focuses on: <ul style="list-style-type: none"> <li>- scenarios for data provenance;</li> <li>- requirements for capture and exchange of data provenance information;</li> <li>- data model for data provenance information.</li> </ul> </li> </ul>		



Name Number	Preview	EU	China
	<ul style="list-style-type: none"> <li>• Does not cover:                             <ul style="list-style-type: none"> <li>- exchange format for data provenance information;</li> <li>- scheme for registering and resolving organisation identifiers and person identifiers;</li> <li>- provenance of data that are not characteristic data represented as property values;</li> <li>- configuration management;</li> <li>- change control;</li> <li>- syntax of identifiers;</li> <li>- resolution of identifiers.</li> </ul> </li> </ul> <p>NOTE: Some of the requirements in ISO 8000-120:2016 can apply to exchange of data that is not master data, which consists of characteristic data represented as property values.</p>		
<p><b>Part 130: Master data: Exchange of characteristic data: Accuracy</b> ISO 8000-130:2016</p>	<ul style="list-style-type: none"> <li>• Is an optional addition to ISO 8000 120.</li> <li>• Specifies requirements for representation and exchange of information about accuracy of master data that consists of characteristic data.</li> <li>• Does not specify a complete model for characteristic data, nor does it specify an exchange format for characteristic data with data accuracy information.</li> <li>• Focuses on:                             <ul style="list-style-type: none"> <li>- requirements for capture and exchange of data accuracy information in the form of statements and assertions of data accuracy;</li> <li>- conceptual data model for data accuracy information in the form of statements and assertions of data accuracy.</li> </ul> </li> <li>• Does not cover:                             <ul style="list-style-type: none"> <li>- requirements for data accuracy;</li> <li>- exchange format for data accuracy information;</li> <li>- scheme for registering and resolving organisation identifiers and person identifiers;</li> <li>- accuracy of data that are not characteristic data represented as property values;</li> <li>- syntax of identifiers;</li> <li>- resolution of identifiers.</li> </ul> </li> </ul> <p>NOTE: Some of the requirements in ISO 8000-130:2016 can apply to exchange of data that is not master data which consists of characteristic data represented as property values.</p>		
<p><b>Part 140: Master data: Exchange of characteristic data: Completeness</b> ISO 8000-140:2016</p>	<ul style="list-style-type: none"> <li>• Is an optional addition to ISO 8000 120 and specifies requirements for representation and exchange of information about completeness of master data that consists of characteristic data.</li> </ul> <p>NOTE: ISO 8000 110 specifies that such data be represented as property values. ISO 8000 120 provides additional requirements for property values when data provenance information needs to be captured.</p> <ul style="list-style-type: none"> <li>• Does not specify a complete model for characteristic data, nor does it specify an exchange format for characteristic data with data completeness information.</li> </ul> <p>NOTE: This is done in other standards that reference this part of ISO 8000, e.g., ISO/TS 22745 40.</p> <ul style="list-style-type: none"> <li>• Focuses on:</li> </ul>		



Name Number	Preview	EU	China
	<ul style="list-style-type: none"> <li>- requirements for capture and exchange of data completeness information in the form of statements and assertions of data completeness;</li> <li>- conceptual data model for data completeness information in the form of statements and assertions of data completeness.</li> </ul> <ul style="list-style-type: none"> <li>• Does not cover:               <ul style="list-style-type: none"> <li>- requirements for data completeness;</li> </ul> </li> </ul> <p>NOTE: The requirements for data completeness depend on many factors, e.g. the kind of data, how the data are being used, industry, and needs of the partners exchanging the data. It is not possible to state general requirements for data completeness.</p> <ul style="list-style-type: none"> <li>- exchange format for data completeness information;</li> <li>- scheme for registering and resolving organization identifiers and person identifiers;</li> <li>- completeness of data that are not characteristic data represented as property values;</li> <li>- syntax of identifiers;</li> <li>- resolution of identifiers.</li> </ul> <p>NOTE: Some of the requirements in ISO 8000-140:2016 can apply to exchange of data that is not master data, which consists of characteristic data represented as property values.</p>		
<b>Part 150: Master data: Quality management framework</b> ISO/TS 8000-150:2011	<ul style="list-style-type: none"> <li>• Specifies fundamental principles of master data quality management, and requirements for implementation, data exchange and provenance.</li> <li>• Contains an informative framework that identifies processes for data quality management. This framework can be used in conjunction with, or independently of, quality management systems standards (e.g., ISO 9001).</li> </ul>		
<b>Part 8: Information and data quality: Concepts and measuring</b> ISO 8000-8:2015	<ul style="list-style-type: none"> <li>• Describes fundamental concepts of information and data quality, and how these concepts apply to quality management processes and quality management systems.</li> <li>• Specifies prerequisites for measuring information and data quality when executed within quality management processes and quality management systems.</li> </ul>		
<b>Part 61: Data quality management: Process reference model</b> ISO 8000-61:2016	<ul style="list-style-type: none"> <li>• Specifies the processes required for data quality management. The processes are used as a reference to enhance data quality and assess process capability or organisational maturity for data quality management.</li> </ul>		
<b>Interactive electronic technical manuals - Part 3: Common source database requirement<sup>20</sup></b> GB/T 24463.3-2009			x

<sup>20</sup> <https://max.book118.com/html/2019/0205/5321340122002010.shtml>



Name Number	Preview	EU	China
<b>Format specifications of nucleotide sequence database<sup>21</sup></b> GB/T 34798-2017			x
<b>Specification for exchanging biological digital specimen data<sup>22</sup></b> GB/T 33919-2017	<ul style="list-style-type: none"> <li>Establishes: <ul style="list-style-type: none"> <li>item, format, and exchange mode of the data of biological digital specimen used for exchange in the computer system.</li> </ul> </li> <li>Is suitable for data exchange of biological digital specimen.</li> </ul>		x
<b>Criterion for forensic DNA database<sup>23</sup></b> GB/T 21679-2008	<ul style="list-style-type: none"> <li>Establishes: <ul style="list-style-type: none"> <li>function, structure, and responsibility of forensic DNA database,</li> <li>sample collection, requirements, procedures, and loci of the database</li> </ul> </li> <li>Is applicable to all laboratories undertaking the construction of forensic DNA database.</li> </ul>		x
<b>Information security technology—Personal information security specification<sup>24</sup></b> GB/T 35273-2020	<ul style="list-style-type: none"> <li>Establishes: <ul style="list-style-type: none"> <li>principles and security requirements for personal information processing activities such as collection, storage, use, sharing, public disclosure and deletion.</li> </ul> </li> <li>Covers: <ul style="list-style-type: none"> <li>standardizing the personal information processing activities of various organizations,</li> <li>supervising, managing and evaluating the personal information processing activities of competent regulatory departments, third-party evaluation institutions and other organizations.</li> </ul> </li> </ul>		x
<b>Information security technology—Security technical requirements for database management system<sup>25</sup></b> GB/T 20273-2019	<ul style="list-style-type: none"> <li>Establishes according to the 5-level security protection level: <ul style="list-style-type: none"> <li>role of database management system in information system.</li> </ul> </li> <li>Specifies security technical requirements for each security level of database management system.</li> <li>Is suitable for the design and implementation of the security database management system according to the hierarchical requirements</li> <li>Can be used as reference for the security testing and management department of the database management system according to the hierarchical requirements.</li> </ul>		x

<sup>21</sup> <https://max.book118.com/html/2019/0619/8104005014002031.shtm>

<sup>22</sup> <https://max.book118.com/html/2018/0816/6043004104001212.shtm>

<sup>23</sup> <https://www.doc88.com/p-893104747788.html>

<sup>24</sup> <http://c.gb688.cn/bzgk/gb/showGb?type=online&hcno=4568F276E0F8346E80FBA097AA0CE05E>

<sup>25</sup> <https://max.book118.com/html/2019/0112/5041243114002001.shtm>



Name Number	Preview	EU	China
<b>Quality management systems</b>			
<b>Requirements</b> ISO 9001:2015 EN ISO 9001:2015	<ul style="list-style-type: none"> <li>Specifies requirements for a quality management system when an organisation:               <ul style="list-style-type: none"> <li>- needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and</li> <li>- aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.</li> </ul> </li> </ul> <p>NOTE: All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.</p>	x	
<b>Molecular in vitro diagnostic examinations</b>			
<b>Specifications for pre-examination processes for frozen tissue</b>			
<b>Part 1: Isolated RNA</b> ISO 20184-1:2018 EN ISO 20184-1:2018	<ul style="list-style-type: none"> <li>Gives guidelines on the handling, documentation, storage, and processing of frozen tissue specimens intended for RNA examination during the pre-examination phase before a molecular assay is performed.</li> <li>Is applicable to any molecular in vitro diagnostic examination performed by medical laboratories and molecular pathology laboratories that evaluate RNA extracted from frozen tissue. It is also intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions, and commercial organizations performing biomedical research, and regulatory authorities.</li> <li>Does not cover:               <ul style="list-style-type: none"> <li>- Tissues that have undergone chemical stabilisation pre-treatment before freezing are not covered in this document.</li> </ul> </li> </ul> <p>NOTE: International, national or regional regulations or requirements can also apply to specific topics covered in this document.</p>	x	
<b>Part 2: Isolated proteins</b> ISO 20184-2:2018 EN ISO 20184-2:2018	<ul style="list-style-type: none"> <li>Gives guidelines on the handling, documentation, storage and processing of frozen tissue specimens intended for the examination of isolated proteins during the pre-examination phase before a molecular assay is performed.</li> <li>Is applicable to any molecular in vitro diagnostic examination performed by medical laboratories and molecular pathology laboratories that evaluate proteins isolated from frozen tissue.</li> <li>Intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.</li> </ul>	x	





Name Number	Preview	EU	China
	NOTE: International, national or regional regulations or requirements can also apply to specific topics covered in this document.		
<b>Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue</b>			
<b>Part 1: Isolated RNA</b> ISO 20166-1:2018 EN ISO 20166-1:2018	<ul style="list-style-type: none"> <li>• Gives guidelines on the handling, documentation, storage and processing of formalin-fixed and paraffin-embedded (FFPE) tissue specimens intended for RNA examination during the pre-examination phase before a molecular assay is performed.</li> <li>• Is applicable to molecular in vitro diagnostic examinations including laboratory developed tests performed by medical laboratories and molecular pathology laboratories.</li> <li>• Is intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.</li> </ul> <p>NOTE: International, national or regional regulations or requirements can also apply to specific topics covered in this document.</p>	x	
<b>Part 2: Isolated proteins</b> ISO 20166-2:2018 EN ISO 20166-2:2018	<ul style="list-style-type: none"> <li>• Gives guidelines on the handling, documentation, storage and processing of formalin-fixed and paraffin-embedded (FFPE) tissue specimens intended for the examination of isolated proteins during the pre-examination phase before a molecular assay is performed.</li> <li>• Is applicable to molecular in vitro diagnostic examinations including laboratory developed tests performed by medical laboratories and molecular pathology laboratories.</li> <li>• Is intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions, and commercial organizations performing biomedical research, and regulatory authorities.</li> <li>• Is not applicable for protein examination by immunohistochemistry.</li> </ul> <p>NOTE: International, national or regional regulations or requirements can also apply to specific topics covered in this document.</p>	x	
<b>Part 3: Isolated DNA</b> ISO 20166-3:2018 EN ISO 20166-3:2018	<ul style="list-style-type: none"> <li>• Gives guidelines on the handling, documentation, storage, and processing of formalin-fixed and paraffin-embedded (FFPE) tissue specimens intended for DNA examination during the pre-examination phase before a molecular assay is performed.</li> <li>• Is applicable to molecular in vitro diagnostic examinations including laboratory developed tests performed by medical laboratories and molecular pathology laboratories.</li> <li>• Is intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions, and commercial organizations performing biomedical research, and regulatory authorities.</li> </ul>	x	



Name Number	Preview	EU	China
	NOTE: International, national or regional regulations or requirements can also apply to specific topics covered in this document.		
<b>Methods to prepare samples for high-throughput gene sequencing—Part 1: Preparing samples of animal tissues<sup>26</sup></b> GB/T 33681.1-2017	<ul style="list-style-type: none"> <li>• Establishes:               <ul style="list-style-type: none"> <li>- technical requirements for pre-treatment of animal tissue samples to be examined in high-throughput gene sequencing.</li> </ul> </li> <li>• Is suitable for the pre-treatment of animal tissue samples to be detected in the process of high-throughput sequencing:               <ul style="list-style-type: none"> <li>- blood, skin swab samples, fresh animal tissue samples (muscle, organ, hair, bone), formaldehyde-fixed animal tissue samples, paraffin embedded animal tissue samples.</li> </ul> </li> </ul>		x
<b>Specifications for pre-examination processes for venous whole blood</b>			
<b>Part 1: Isolated cellular RNA</b> ISO 20186-1:2019 EN ISO 20186-1:2019	<ul style="list-style-type: none"> <li>• Gives guidelines on the handling, storage, processing, and documentation of venous whole blood specimens intended for cellular RNA examination during the pre-examination phase before a molecular examination is performed.</li> <li>• Covers specimens collected in venous whole blood collection tubes.</li> <li>• Is applicable to any molecular in vitro diagnostic examination performed by medical laboratories.</li> <li>• Is intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions, and commercial organizations performing biomedical research, and regulatory authorities.</li> <li>• Does not cover:               <ul style="list-style-type: none"> <li>- Different dedicated measures are taken for stabilising blood cell free circulating RNA and RNA in exosomes circulating in blood.</li> <li>- Different dedicated measures are taken for collecting, stabilising, transporting, and storing capillary blood as well as for collecting and storing blood by paper-based technologies or other technologies generating dried blood.</li> <li>- Isolation of specific blood cells and subsequent isolation of cellular RNA therefrom.</li> </ul> </li> </ul>	x	
<b>Part 2: Isolated genomic DNA</b> ISO 20186-2:2019 EN ISO 20186-2:2019	<ul style="list-style-type: none"> <li>• Gives guidelines on the handling, storage, processing and documentation of venous whole blood specimens intended for genomic DNA examination during the pre-examination phase before a molecular examination is performed.</li> </ul>	x	

<sup>26</sup> <http://std.samr.gov.cn/gb/search/gbDetailed?id=71F772D81EECD3A7E05397BE0A0AB82A>



Name Number	Preview	EU	China
	<ul style="list-style-type: none"> <li>• Covers specimens collected in venous whole blood collection tubes.</li> <li>• Is applicable to any molecular in vitro diagnostic examination performed by medical laboratories.</li> <li>• Is intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.</li> <li>• Does not cover:               <ul style="list-style-type: none"> <li>- Different dedicated measures are taken for stabilizing blood cell free circulating DNA, which are not described in this document.</li> </ul> </li> </ul> <p>NOTE: Circulating cell free DNA in blood is covered in ISO 20186-3.</p> <ul style="list-style-type: none"> <li>- Different dedicated measures are taken for collecting, stabilizing, transporting, and storing capillary blood as well as for collecting and storing blood by paper-based technologies or other technologies generating dried blood.</li> <li>- Isolation of specific blood cells and subsequent isolation of genomic DNA therefrom.</li> <li>- DNA in pathogens present in blood.</li> </ul>		
<p><b>Part 3: Isolated circulating cell free DNA from plasma</b></p> <p>ISO 20186-3:2019</p> <p>EN ISO 20186-3:2019</p>	<ul style="list-style-type: none"> <li>• Provides recommendations and requirements on the handling, storage, processing, and documentation of venous whole blood specimens intended for circulating cell free DNA (ccfDNA) examination during the pre-examination phase before an analytical test is performed.</li> <li>• Covers specimens collected in venous whole blood collection tubes.</li> <li>• Is applicable to any molecular in vitro diagnostic examination performed by medical laboratories.</li> <li>• Is intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions, and commercial organisations performing biomedical research, and regulatory authorities.</li> <li>• Does not cover:               <ul style="list-style-type: none"> <li>- Different dedicated measures for stabilizing blood genomic DNA</li> </ul> </li> </ul> <p>NOTE: Blood genomic DNA is covered in ISO 20186-2.</p> <ul style="list-style-type: none"> <li>- Different dedicated measures are taken for preserving DNA in circulating exosomes, which are not described in this document.</li> </ul> <p>NOTE: ccfDNA obtained from blood by the procedures cited in this document can contain DNA originally present in exosomes.</p> <ul style="list-style-type: none"> <li>- DNA in pathogens present in blood is not covered by this document.</li> </ul>	x	



Name Number	Preview	EU	China
<b>Collection and processing of human blood biomaterial<sup>27</sup></b> GB/T 38576-2020	<ul style="list-style-type: none"> <li>Establishes:               <ul style="list-style-type: none"> <li>basic requirements for the preparation, collection and treatment of human blood samples before collection</li> </ul> </li> <li>Is applicable for the collection and processing of biological sample bank related to human diseases and blood samples for clinical and basic medical research.</li> <li>Does not cover:               <ul style="list-style-type: none"> <li>collection and processing of blood samples for clinical diagnosis and treatment.</li> </ul> </li> </ul>		x
<b>Specifications for pre-examination processes for human urine biomaterial</b>			
<b>Collection and processing of human urine biomaterial<sup>28</sup></b> GB/T 38735-2020	<ul style="list-style-type: none"> <li>Establishes:               <ul style="list-style-type: none"> <li>general principles of human urine sample collection and processing, preparation before collection, sample information recording, urine collection and urine processing.</li> </ul> </li> <li>Is suitable for the collection and processing of human urine samples in the fields of clinical research, basic research and biological sample library construction.</li> </ul>		x
<b>Information technology</b>			
<b>Biometric sample</b>			
<b>Part 1: Framework</b> ISO/IEC 29794-1:2016 GB/T 33767.1-2017 <sup>29</sup>	<ul style="list-style-type: none"> <li>Establishes for any or all biometric sample types as necessary the following:               <ul style="list-style-type: none"> <li>terms and definitions that are useful in the specification and use of quality metrics;</li> <li>purpose and interpretation of biometric quality scores;</li> <li>encoding of quality data fields in biometric data interchange formats;</li> <li>methods for developing biometric sample datasets for the purpose of quality score normalisation;</li> <li>format for exchange of quality algorithm results;</li> <li>methods for aggregation of quality scores.</li> </ul> </li> <li>Does not cover:               <ul style="list-style-type: none"> <li>specification of minimum requirements for sample, module, or system quality scores;</li> <li>performance assessment of quality algorithms;</li> <li>standardisation of quality algorithms.</li> </ul> </li> </ul>		x
<b>Part 4: Finger image data</b> ISO/IEC TR 29794-4:2017	<ul style="list-style-type: none"> <li>Establishes:               <ul style="list-style-type: none"> <li>terms and definitions for quantifying finger image quality,</li> </ul> </li> </ul>		x

<sup>27</sup> <http://std.samr.gov.cn/gb/search/gbDetailed?id=A24AF19F41245C2EE05397BE0A0A5E0D>

<sup>28</sup> <http://std.samr.gov.cn/gb/search/gbDetailed?id=A47A713B762814ABE05397BE0A0ABB25>

<sup>29</sup> <http://www.gb688.cn/bzgk/gb/newGbInfo?hcno=9925B6F84E004F66C4258D6034A73471>



Name Number	Preview	EU	China
GB/T 33767.4-2018 <sup>30</sup>	<ul style="list-style-type: none"> <li>- methods used to quantify the quality of finger images, and</li> <li>- standardized encoding of finger image quality, for finger images at 196,85 px/cm spatial sampling rate scanned or captured using optical sensors with capture dimension (width, height) of at least 1,27 cm × 1,651 cm.</li> </ul>		
<b>Information technology</b>			
<b>Vocabulary</b>			
<b>Vocabulary</b> ISO/IEC 2382:2015 GB/T 5271.17-2010 <sup>31</sup>	Vocabulary		x

### 3.2.3 Liaisons to international standardisation organisations

The International Organization for Standardization builds a platform for the PM community to cooperate and facilitates a dialogue among the key players globally through membership of the national standardisation bodies, not exclusively restricted to the EU and China. A second mean to get involved in standardization processes are liaisons to Technical Committees of key standardisation organisations (e.g., ISO, CEN and SAC) involved in data and biobanking standards relevant for PM.

As reported in a recent Nature Biotechnology editorial, 81% of researchers are constrained by the inadequate quantity and quality of biospecimens and 80% of companies find accessing materials difficult'.<sup>32</sup> This shows the need to align standardisation organisations with partners in academia and industry to jointly improve areas such as sample collection, storage and sharing. Liaisons offer a direct route to interact and engage in standardisation processes.

For the biobanking community, BBMRI-ERIC takes over this role. BBMRI-ERIC as an international organisation under EU law facilitates access to over 600 biobanks and holds over 100 million samples across Europe offering these services on a not-for-profit base. It is the largest network of biobanks in Europe, bringing together and bridging the entire European biobanking community. Through its international liaisons it can shape and influence important developments in the field of biotechnology processes, clinical laboratory testing, in vitro diagnostic test systems, health informatics and in vitro diagnostic medical devices, all areas of high relevance to PM.

An overview of BBMRI-ERIC's international liaisons that pave the way for IC2PerMed to engage in standardisation processes is reported in Table 4. On the Chinese side, the BGI group, through its

<sup>30</sup> <https://www.chinesestandard.net/PDF/English.aspx/GBT33767.4-2018>

<sup>31</sup> <https://www.chinesestandard.net/PDF/English.aspx/GBT5271.17-2010>

<sup>32</sup> Nature Biotechnology (2020): Thank you for sharing, URL: <https://doi.org/10.1038/s41587-020-0678-x>.



affiliation to the China National GeneBanks and additional stakeholders in biobanking, acts as a similar mediator<sup>33</sup>

**Table 4: Liaisons of the EU and China to international standardisation organisations**

Technical Committee	Scope Delegates	EU	CN
<b>Biotechnology processes</b>			
<b>ISO/TC 276 <a href="#">Biotechnology</a></b>	<p>Standardisation in the field of biotechnology processes that includes the following topics:</p> <ul style="list-style-type: none"> <li>• Terms and definitions;</li> <li>• biobanks and bioresources;</li> <li>• analytical methods;</li> <li>• bioprocessing;</li> <li>• data processing including annotation, analysis, validation, comparability and integration;</li> <li>• metrology.</li> </ul> <p>BBMRI-ERIC Delegates: Andrea Wutte and Petr Holub</p>	x	
<b>Clinical laboratory testing and in vitro diagnostic test systems</b>			
<b>ISO/TC 212 <a href="#">Clinical laboratory testing and in vitro diagnostic test systems</a></b>	<p>Standardisation and guidance in the field of laboratory medicine and in vitro diagnostic test systems:</p> <ul style="list-style-type: none"> <li>• Quality management,</li> <li>• pre- and post-analytical procedures,</li> <li>• analytical performance,</li> <li>• laboratory safety,</li> <li>• reference systems and</li> <li>• quality assurance.</li> </ul> <p>BBMRI-ERIC Delegates: Andrea Wutte</p>	x	
<b>SAC/TC 136 <a href="#">Medical clinical laboratory and in vitro diagnostic system</a></b>	<p>Standardisation of national clinical laboratory quality management, reference systems, in vitro diagnostic products and other professional fields.</p> <p>BGI Delegates: Xun Xu</p>		x
<b>Health information technology</b>			
<b>ISO/TC 215 <a href="#">Health Informatics</a></b>	<p>Standardisation in the field of health informatics, to facilitate:</p> <ul style="list-style-type: none"> <li>• Capture, interchange and use of health-related data, information, and</li> <li>• knowledge to support and enable all aspects of the health system.</li> </ul> <p>BBMRI-ERIC Delegates: Andrea Wutte</p>	x	

<sup>33</sup> Liaison of BGI Group to China National GeneBank <https://en.genomics.cn/en-gene.html>



Technical Committee	Scope Delegates	EU	CN
	Since 2016, BBMRI-ERIC has established and actively maintains a liaison to the European Standardisation Organization (CEN/TC)		
<b>SAC/TC 28 <a href="#">Information technology</a></b>	Standardisation, design and development of systems and tools for national information collection, presentation, processing, transmission, exchange, presentation, management, organization, storage and retrieval, etc.		x
<b>In vitro diagnostic medical devices</b>			
<b>CEN/TC 140 <a href="#">In vitro diagnostic medical devices</a></b>	<p>Standardisation in the field of in vitro diagnostic medical devices which are reagents, reagent product, calibrators, control materials, kits, instruments, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:</p> <ul style="list-style-type: none"> <li>• concerning a physiological or pathological state or;</li> <li>• concerning a congenital abnormality or;</li> <li>• to determine the safety and compatibility with potential recipients, or;</li> <li>• to monitor therapeutic measures.</li> </ul> <p>‘Specimen receptacles’ are in vitro diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.</p> <p>Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.</p> <p>BBMRI-ERIC Delegates: Andrea Wutte</p>	x	
<b>SAC/TC 136 <a href="#">Medical clinical laboratory and in vitro diagnostic system</a></b>	<p>Standardisation of national clinical laboratory quality management, reference systems, in vitro diagnostic products, and other professional fields.</p> <p>BGI Delegates: Xun Xu</p>		x

### 3.2.4 From theory to practice: Application of relevant PM standards

BBMRI-ERIC’s quality management section (BBMRI.QM) offers in-house and online trainings as well as short courses and workshops to explain the theoretical principles of ISO standards from an end-user perspective. Renowned experts give comprehensive presentations with detailed examples on the



practical application of these standards. Noteworthy is the BBMRI.QM Training & Education Programme providing an online trainings series on PM standards covering:

- Molecular in vitro diagnostic examination standards – specifications for pre-examination processes: 16 recordings available to listen in and delve into the presentation at any time; and
- Biobanking standard ISO 20387:2018: 22 recordings available to listen in and delve into the presentation at any time

Well-known specialists give detailed presentations on the usage of these standards in and outside of the lab or at a biobank, Questions&Answers and discussions included. End users are provided with a closer look at each individual chapter of the standard’s documentation and learn about the precise meaning and the practical implications of each ISO standard.

Both training series provide in-depth training on the ISO standards 20184 | 20166 | 20186 | 20387 relevant for PM in biomedical research and biobanking.

### 3.3 Important Co-developments in PM

This chapter focuses on two areas of important co-developments in the field of PM, namely detection techniques and evaluation methods, as well as data protection and sharing mechanisms.

#### 3.3.1 Detection techniques and evaluation methods relevant for PM

The term “omics sciences” describes various disciplines dedicated to the study of different categories of biological molecules such as:

- DNA in **genomics** (sequential information) and **epigenomics** (DNA methylation);
- mRNA in **transcriptomics**;
- protein in **proteomics** and **epigenomics** (post-translational modifications of histones);
- small molecules/metabolites in **metabolomics**; and
- amphiphilic lipids (e.g. phosphatides, acylglycerols and sterols) in **lipidomics**.

In addition, new disciplines have entered the field in recent times with the example of microbiomics, which is dedicated to the study human-associated microorganisms. This was only possible due to disruptive advances in technology allowing the direct quantification and elucidation of those molecules from sample tissues<sup>34</sup> in a high-throughput manner.

#### Genomics

Derived from the sequencing of the human genome, genomics focuses on the entirety of the structure and function our genome, and the interactions of genes with each other and with environmental factors. Genomics differs from genetics, which is the science of inheritance and addresses the functioning, structure, and effects of a single gene. Moving from genetics to genomics has given new

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<sup>34</sup> K. J. Karczewski and M. P. Snyder, “Integrative omics for health and disease,” *Nature Reviews Genetics*, vol. 19, no. 5. Nature Publishing Group, pp. 299–310, May 01, 2018, doi: 10.1038/nrg.2018.4.





insights in understanding the genotype changes that can cause disease and in developing new approaches to prevention, treatment, and diagnostic methods highly relevant for PM approaches.<sup>35</sup>

### **Transcriptomics**

Transcriptomics studies the complete set of RNA transcripts of a cell, tissue or organism. The transcriptome includes ribosomal RNA, messenger RNA, transfer RNA, microRNA, and other non-coding RNA. Two main technologies used for high-throughput characterisation are: Microarrays and RNA sequencing. Microarrays quantify a set of predetermined sequences, whereas RNA sequencing uses next generation sequencing to study the transcriptome.

### **Proteomics**

Proteomics is dedicated to the study of the entire proteome - all proteins expressed within a cell, tissue or organism. Proteomics studies the incredibly diverse structural and functional properties of polypeptide chains. In addition, proteomics is dedicated to the elucidation of the complex interaction networks with other proteins and biomolecules. Proteomics involves an additional layer of complexity by looking at side-chain modifications of the primary amino acid sequence, the so-called post-translational modifications that themselves influence the structure and function of a protein. Protein microarrays and mass spectrometry are among the main techniques used for the assessment of the proteome, with mass spectrometry being the tool of choice. Technological advances in protein detection and characterisation methods have allowed the discovery of several biomarkers, thereby improving the diagnosis of a wide range of diseases, including cancers<sup>36</sup> with is highly relevant in the field of PM.

### **Epigenomics**

Epigenomics is tightly associated with the field of proteomics and genomics. Post-translational modifications of DNA histones regulate the transcription of genetic information as well as chemical alterations of the nucleotides themselves in the case of DNA methylation. Environmental factors and lifestyle behaviour can interfere with the genome by up- or downregulation of certain genes and play an important role in many diseases. The regulation of genetic expression is what eventually also guides cell function and determines the different cell types.

### **Metabolomics**

Metabolomics is the large-scale identification of metabolic intermediates and end products, often small molecules present in cells, biofluids, tissues or organisms and their interaction networks in vivo. Metabolites are often low molecular-weight molecules including amino acids, nucleic acids, carbohydrates, lipids, hormones, exogenous substances such as drugs and food ingredients. The metabolome is dynamic and several factors such as stress, physical activity, changes in diet and disease

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<sup>35</sup> C. Manzoni et al., "Genome, transcriptome and proteome: The rise of omics data and their integration in biomedical sciences," *Brief. Bioinform.*, vol. 19, no. 2, pp. 286–302, Mar. 2018, doi: 10.1093/BIB/BBW114

<sup>36</sup> K. Chandramouli and P.-Y. Qian, "Proteomics: Challenges, Techniques and Possibilities to Overcome Biological Sample Complexity," *Hum. Genomics Proteomics*, vol. 1, no. 1, Jan. 2009, doi: 10.4061/2009/239204



may change the metabolite profile. Metabolites can be detected and quantified with high-throughput mass spectrometry and nuclear magnetic resonance spectroscopy<sup>37</sup>.

The association of omics-based molecular measurements, with several clinical outcomes, such as cancer survival time or cancer therapy, have contributed to develop more accurate predictive or prognostic models for a particular disease. Continued progress of analytical tools has accelerated the application of omics technologies in science research to understand disease biology and to facilitate new therapeutic discoveries.<sup>38</sup> The potential use of omics technologies has a wide range of application, which should ensure quality, safety, and efficacy to satisfy the quality standard requirements. This remains a concern, therefore, to tackle these issues, the following steps: data quality control; computational model development and cross-validation; confirmation of the computational model on an independent dataset; and release of data and computational procedures to the scientific community.

### 3.3.2 Data protection and sharing mechanisms in PM

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.

When aiming for a comparison of data protection regimes between the EU and China, the conceptual differences between the understanding of privacy needs to be remembered. In the EU, the right to data protection is derived from the right to privacy (Universal Declaration of Human Rights, article 12) and incorporated as a separate fundamental right (article 8) in the EU Charter of Fundamental Rights. In contrast, the PRC does not consider data protection a fundamental right. Rather, in China, the focus lies on national security and stability. The right to privacy is only indirectly mentioned in the PRC’s constitution.<sup>39</sup>

The EU’s General Data Protection Regulation (GDPR), which entered into force on 24 May 2016 and applies since 25 May 2018 is considered one of the most comprehensive data protection regimes and seeks to reconcile the often-competing values of privacy (protection of personal data) and innovation (free flow of data). Its influence exerts beyond EU borders and similar rules have been established in Brazil, India or the state of California, USA.<sup>40</sup>

The GDPR strives to align the data protection laws of the EU Member States but leaves some options in relation to research at the discretion of the national legislatures of which more than a dozen countries opted for specific legislation recognising the importance of PM is of growing importance in

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<sup>37</sup> J. H. Wang, J. Byun, and S. Pennathur, “Analytical approaches to metabolomics and applications to systems biology,” *Semin. Nephrol.*, vol. 30, no. 5, pp. 500–511, Sep. 2010, doi: 10.1016/j.semnephrol.2010.07.007.

<sup>38</sup> I. Glurich et al., “Progress in oral personalized medicine: Contribution of ‘omics,’” *J. Oral Microbiol.*, vol. 7, no. 1, 2015, doi: 10.3402/jom.v7.

<sup>39</sup> van Deursen, S., Kummeling, H. The New Silk Road: a bumpy ride for Sino-European collaborative research under the GDPR?. *High Educ* 78, 911–930 (2019). <https://doi.org/10.1007/s10734-019-00377-5>

<sup>40</sup> European Commission. EUR-Lex. <https://eur-lex.europa.eu/eli/reg/2016/679/oj>



Europe. A survey concluded that specific legislation is in place for the processing of genetic information in 20 EU Member States and which was deemed adequate to allow for the use of genetic data to provide PM services.<sup>41</sup>

China's data protection laws, which until recently contained relevant data protection provisions in numerous regulations, is currently undergoing a period of change aiming for a comprehensive data protection regime. At the same time, it draws inspiration from the GDPR.<sup>42</sup> On 21 October 2020, China published a draft of the Personal Information Protection Law (Draft PIPL)<sup>43</sup> for consultation.<sup>44</sup> The Draft PIPL, together with who fundamental laws on cybersecurity and data protection, the Chinese Cybersecurity Law (CSL)<sup>45</sup> that entered into force on 1 June 2017 and the 2021 draft of the Data Security Law (DSL) are considered the three corner stones of a comprehensive data protection regime currently in development. This change needs to be observed and could lead to an 'adequacy decision' as the EC concluded with countries such as Japan<sup>46</sup> or Canada (partial recognition for commercial organisations)<sup>47</sup>. This is critical as the GDPR has extraterritorial applicability, whereas the Chinese legislation largely concentrates on domestic application. To reach an adequacy decision, equal protection needs to be demonstrated. The GDPR requires for instance each Member State to have independent public authorities responsible for monitoring and facilitating a consistent application of the GDPR throughout the EU (e.g., the French Data Protection Authority, NIL<sup>48</sup>). An equivalent authority, however, does not exist in China, which could render negotiations challenging.

Hence, having comprehensive data protection regimes is not enough. In practice, the legal frameworks need to be complemented with, ethical oversight, appropriate technical and ethical safeguards

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<sup>41</sup> European Commission (2019) Assessment of the EU Member States' rules on health data in the light of GDPR. p.30. [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ms\\_rules\\_health-data\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ms_rules_health-data_en.pdf)

<sup>42</sup> Geller A, How Comprehensive Is Chinese Data Protection Law? A Systematisation of Chinese Data Protection Law from a European Perspective. GRUR International, Volume 69, Issue 12, December 2020, Pages 1191–1203, <https://doi.org/10.1093/grurint/ikaa136>

<sup>43</sup> No official, certified translation available. The Draft PIPL, CSL and DSL are available at the [www.npc.gov.cn](http://www.npc.gov.cn)

<sup>44</sup> Overview of Draft Personal Information Protection Law in China. KPMG Advisory (China) Limited, Shanghai SF Lawyers. 2020. <https://assets.kpmg/content/dam/kpmg/cn/pdf/en/2020/11/overview-of-draft-personal-information-protection-law-in-china.pdf>

<sup>45</sup> Creemers, Triolo, Webster. Translation: Cybersecurity Law of the People's Republic of China. 2018. <https://www.newamerica.org/cybersecurity-initiative/digichina/blog/translation-cybersecurity-law-peoples-republic-china>. This translation is revised and corrected based on an earlier version by Rogier Creemers and Paul Triolo. Any future revisions or annotations will be logged at the foot of the live online version of this document at DigiChina. This is version 2018.06.29. – DigiChina (accessed 28 April 2021)

<sup>46</sup> Jourová. EU Japan Adequacy Decision. European Commission. 2020. [https://ec.europa.eu/info/sites/default/files/research\\_and\\_innovation/law\\_and\\_regulations/documents/adequacy-japan-factsheet\\_en\\_2019\\_1.pdf](https://ec.europa.eu/info/sites/default/files/research_and_innovation/law_and_regulations/documents/adequacy-japan-factsheet_en_2019_1.pdf)

<sup>47</sup> Adequacy decisions. European Commission. [https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en)

<sup>48</sup> CNIL. Commission Nationale de l'Informatique et des Libertés. <https://www.cnil.fr/en/home>



including communication and engagement with the various publics and citizens<sup>49, 50</sup> on top of technical solutions for data exchange (e.g., federated, centralised, and with trusted partners as proposed by the policy framing organisation Global Alliance for Genomics & Health, in short GA4GH<sup>51</sup> or developed by BBMRI-ERIC, the Pan-European Research Infrastructure for Biobanks and Biomolecular Resources.<sup>52</sup>

## 4 Towards a closer collaboration between Europe and China in PM

This chapter provides an analysis of the status-quo of current Sino-European collaborations in health research related to PM with the aim to derive initial recommendations on how to improve reciprocity and increase areas of interest for future Sino-European collaboration in the field of PM. To do so, we first provide a non-exhaustive mapping of Sino-European projects, initiatives, and joint research centres to provide an overview of existing collaborations and derive lessons learnt therefrom. We then extend our view by elaborating on concrete push and pull factors affecting collaboration, on the role of R&I support schemes, and on the influence of social and culture aspects. The final section provides an outline for a deepened Sino-European collaboration by listing potential areas of mutual interest and enablers to be considered.

### 4.1 The status quo in Sino-European collaborations related to PM

The current Sino-European collaboration in Science, Technology and Innovation is mostly assessed through the participation of Chinese stakeholders in the successive European funding programmes (FP7, Horizon 2020, etc.).

In the framework of Horizon 2020 such collaboration was defined by the agreement between the EU and Chinese authorities i.e., MoST and the Ministry of Industry and the National Science Foundation of China, of the ‘Flagship initiative’ and the setup of the ‘Co-funding mechanism’ for the 2014-2020 programming period. The ‘Flagship initiative’ focuses on Sino-European collaboration on five major topics, one of them being “Biotechnologies for Environment and Human Health”.

While new funding programme i.e., Horizon Europe for the 2021-2027 programming period, is currently under discussion, the EU and MoST already agreed that Sino-European collaboration in the future will be based on a bilateral joint roadmap, currently under preparation, that will aim to rebalance the actual cooperation. This joint roadmap will be constituted of two pillars:

- The future thematic priority areas for collaboration (with climate change, biodiversity and health being very high on the agenda); and

<sup>49</sup> Dive, L., Critchley, C., Otlowski, M. et al. Public trust and global biobank networks. *BMC Med Ethics* 21, 73 (2020). <https://doi.org/10.1186/s12910-020-00515-0>

<sup>50</sup> Slokenberga S, Tzortzatou O, Reichel J, editors. *GDPR and Biobanking - Individual Rights, Public Interest and Research Regulation across Europe*: Springer International Publishing; 2021. <https://link.springer.com/book/10.1007%2F978-3-030-49388-2>

<sup>51</sup> Global Alliance for Genomics and Health. <https://www.ga4gh.org>

<sup>52</sup> BBMRI-ERIC. Services and Support. <https://www.bbmri-eric.eu/services-support>



- A list of 13 framework conditions (including IPR, access to public markets, mobility of researchers, reciprocal access to research programmes, ethics, standardisation etc.).

The bilateral joint roadmap is expected to have a high impact on Sino-European collaboration, facilitating the participation of European stakeholders in Chinese funded projects/Chinese stakeholders in European funded projects, but also facilitating all bottom-up initiatives not directly funded by the EU/China or the EU Member States, but also contributing to increasing collaboration.

Chapter 4.1 presents an overview of the different kinds of Sino-European collaborations developed with both a top-down (4.1.1: Sino-European projects, funded by the EC, Chinese or Member States' funding agencies and other initiatives) and a bottom-up approach (4.1.2: success stories of other kinds of collaboration directly developed by various health organisations on the ground, notably the creation of joint centres and the development of researchers' exchanges).

### 4.1.1 Sino-European projects and initiatives related to health

Historically, health was not prioritised among the common interests of the EU and China. However, as mentioned, previous EU funding programmes have offered the EU and China a framework for a more active and balanced approach for cooperation focusing on mutual interests and common benefits. Health is an area which significantly benefited from the openness of the Horizon2020 funding programme, as highlighted by the participation of 600 Chinese entities in 270 Horizon2020 projects, of which 21 Chinese entities applied to Health-related calls<sup>53</sup>. The projects listed below intend to showcase a selection (non-exhaustive) of EU-funded projects, primarily under the Horizon2020 umbrella, as well as few non-EU-funded projects and initiatives between the EU and China related to health.

#### 4.1.1.1 EU-funded projects and initiatives

<b>BAMOS</b> Biomaterials and Additive Manufacturing: Osteochondral Scaffold innovation applied to osteoarthritis	
<b>Programme:</b> MSCA-RISE-2016 - Research and Innovation Staff Exchange	
<b>Budget</b> Overall budget: € 774 000 EU contribution: € 639 000	<b>Timeline</b> Start date: 1 January 2017 End date: 31 December 2020
<b>Objective:</b> Osteoarthritis (OA) is a degenerative joint disease, typified by a loss of quality of cartilage and changes in bone at the interface of a joint, resulting in pain, stiffness, and reduced mobility. BAMOS project particularly addresses the challenges in OA treatment by providing novel cost-effective osteochondral scaffold technology for early intervention of OA to delay or avoid the joint replacement operations. This project has the potential to relieve pain in patients with OA improving their quality of life by keeping people active. It fits with the scope of EU Societal Challenges to encourage the provision of improved clinical care for patients in the field of healthcare, especially for elderly patients.	
While developing this new treatment for mid- to late-stage OA, BAMOS aims to establish and embed a new collaboration between six internationally leading research organizations (four universities, one healthcare provider and one manufacturer with expertise in additive manufacturing). The partners propose an integrated programme of research activities and the development of a collaborative graduate training scheme. The dissemination of research will result in at least 15 high profile joint research publications, and the consortium will organise two international scientific conferences (one in the EU, one in China) and 3 workshops.	

<sup>53</sup> Replay of the SENET Policy Meeting, March 2021, available at: [https://www.youtube.com/watch?v=6I5gvWhY0OU&ab\\_channel=SENETHub](https://www.youtube.com/watch?v=6I5gvWhY0OU&ab_channel=SENETHub)



BAMOS will develop new materials and manufacturing technologies for the fabrication of custom-tailored osteochondral scaffolds. Novel biopolymeric composites, processed by additive manufacturing, will be characterised, and tested, as well as coatings on titanium scaffolds. In addition, thermal welding technique will be used to join the cartilage component with the bone component to form an osteochondral unit.

The new technologies will undergo full pre-clinical evaluation in order that the scaffolds are able to enter clinical trial after the project.

**Link:** <http://risebamos.eu>

#### ERICENA

##### European Research and Innovation Centre of Excellence in China

**Programme:** ENG-GLOBALLY-09-2016 - Centres/Networks of European research and innovation

#### Budget

Overall budget: € 3 589 000  
EU contribution: € 2 997 600

#### Timeline

Start date: 1 January 2017  
End date: 31 December 2020

**Objective:** Europe actively engages internationally to strengthen its leadership in the field of Science, Technology and Innovation (STI) in the global scene and improve synergies between Member States. Europe aims to foster international cooperation and strengthen its STI presence in China due to its growing importance and STI opportunities for European actors.

ERICENA (European Research Innovation Centre of Excellence in China), a 48-month initiative implemented by 8 European and 5 Chinese partners, proposes to set up a Centre and its networks in China to promote European STI interests in China, creating synergies with existing STI structures. ERICENA will connect and support European researchers, entrepreneurs and other STI stakeholders, while providing and facilitating provision of STI services (e.g., networking, advice and support, training, among others) to private and public clients.

ERICENA will effectively contribute to improve cooperation between European STI organizations and researchers and their Chinese counterparts, strengthen the presence of European STI excellence in the Chinese market, maximize the impact of European STI actors in China, improve the framework conditions for EU-China cooperation, and expand the impact of results from existing European STI projects and initiatives in China. This vision will be closely supported and empowered through the wide involvement of stakeholders, including the consortium and more than 100 STI stakeholders in the EU and China involved as Associated Partners.

**Link:** <https://china.enrichcentres.eu>

#### MNR4SCell

##### Micro/Nano Robotics for Single Cancer Cells

**Programme:** H2020-EU.1.3.3.

#### Budget:

Overall budget: € 1 755 000  
EU contribution: € 1 215 000

#### Timeline:

Start date: 1 January 2017  
End date: 31 December 2021

**Objective:** The project wants to establish long-term research collaboration between Europe and China in the challenging field of micro/nano robotics for the characterisation, diagnosis, and targeted therapy of single cancer cells. The synergistic approach and knowledge established by MNR4SCell will serve as the building blocks of the micro/nano robotics and biomedical applications, and thus keep the consortium's leading position in the world for potential major scientific and technological breakthroughs in nanotechnology and cancer therapy.

**Link:** <https://warwick.ac.uk/fac/sci/eng/research/grouplist/measurement/mnr4scell>





Blood Biomarker-based Diagnostic Tools for Early Stage Alzheimer's Disease	
<b>Programme:</b> H2020-EU.1.3.1.	
<b>Budget:</b> Overall budget: € 3 434 981,39 EU contribution: € 3 434 981,39	<b>Timeline:</b> Start date: 1 January 2017 End date: 31 December 2021
<b>Objective:</b> The project underlines the need for innovative training of a new generation of researchers related to Alzheimer's disease. The project unites leading academic and industrial experts from five major consortia in Europe to build a triple-i research & training platform with the required multidisciplinary expertise and cutting-edge technologies.	
<b>Link:</b> <a href="https://cordis.europa.eu/project/id/721281">https://cordis.europa.eu/project/id/721281</a>	

SENET Strengthening international R&I cooperation between China and the EU	
<b>Programme:</b> SC1-HCO-11-2018 - Strategic collaboration in health research and innovation between EU and China	
<b>Budget</b> Overall budget: € 1 240 150 EU contribution: € 917 337,50	<b>Timeline</b> Start date: 1 January 2019 End date: 31 December 2021
<b>Objective:</b> EU and China have made significant progress in terms of their collaboration on the development of enabling biotechnology for human health – an important subject for ageing populations. In fact, China was the third most important international partner country in the EU's FP7 funding programme (2007-2013). Even though a continuous and sustainable health-based research and innovation dialogue between the EU and China remains important, Chinese participation is currently limited due to changing research priorities. The EU-funded SENET project will promote bilateral and multilateral cooperation between the EU and China in the fields of health research and innovation. It will aim to increase Chinese participation in future EU and Chinese joint health research programmes. The project will establish a sustainable health networking and knowledge hub.	
<b>Link:</b> <a href="http://www.senet-hub.eu">www.senet-hub.eu</a>	

SAFE-N-MEDTECH Safety testing in the life cycle of nanotechnology-enabled medical technologies for health -	
<b>Programme:</b> H2020-EU.2.1.3.; H2020-EU.2.1.2.	
<b>Budget:</b> Overall budget: € 18 466 649,10 EU contribution: € 14 534 365,88	<b>Timeline:</b> Start date: 1 April 2019 End date: 31 March 2023
<b>Objective:</b> The SAFE-N-MEDTECH consortium aims to bring a strong and competitive cooperation to compete in the market for a coordinated Open Innovation Test Bed (OITB) for nano-enabled Medical Technologies (MTs). SAFE-N-MEDTECH will build an innovative open access platform to offer to companies and reference laboratories, the capabilities, knowhow, networks, and services required for the development, testing, assessment, upscaling, and market exploitation of nanotechnology-based Medical and Diagnosis Devices. This across the whole Life Cycle. This OITB will offer a multidisciplinary and market-oriented innovation approach to SME's, Healthcare providers and Industries for the translation to the market of MTs, based on a deep understanding and knowledge of the material-nanoproperties, their advance use and applications in MTs and other aspects involved in MTs safety (electric compatibility, electromagnetic properties, etc).	
<b>Link:</b> <a href="https://cordis.europa.eu/project/id/814607">https://cordis.europa.eu/project/id/814607</a>	



<b>CORONADX</b> Three Rapid Diagnostic tests (Point-of-Care) for COVID-19 CoronaThree Rapid Diagnostic tests (Point-of-Care) for Coronavirus, improving epidemic preparedness, public health, and socio-economic benefits	
<b>Programme:</b> SC1-PHE-CORONAVIRUS-2020 - Advancing knowledge for the clinical and public health response to the 2019-nCoV epidemic	
<b>Budget</b> Overall budget / EU contribution: € 2 970 208,76	<b>Timeline</b> Start date: 1 April 2020 End date: 31 March 2023
<b>Objective:</b> The control of disease outbreaks requires rapid and accurate diagnostic tests. So far, testing for COVID-19 has relied on methods suited only for well-equipped centralised laboratories. The scope of the EU-funded CORONADX project is to develop tests that can be performed by minimally or briefly trained personnel at primary healthcare units, mobile laboratories or even at home. These include point-of-care tests for first-line diagnosis and second-line diagnostics that require portable equipment. Their development will be supported by clinical and molecular epidemiological studies. The project's deliverables will facilitate the fast detection and surveillance of the COVID-19 pandemic, contributing to the clinical management of infected patients. (With the participation of the Chinese National Institute for Viral Disease Control and Prevention, Chines Center for Disease Control and Prevention)	
<b>Link:</b> <a href="https://coronadx-project.eu/">https://coronadx-project.eu/</a>	

<b>EVA-GLOB</b> European Virus Archive GLOBAL	
<b>Programme:</b> H2020-EU.1.4.1.2.	
<b>Budget:</b> Overall budget: € 11 602 748,75 EU contribution: € 11 602 748,75	<b>Timeline:</b> Start date: 1 January 2021 End date: 31 December 2023
<b>Objective:</b> The project gathers 43 laboratories associated with key Non-Governmental Organizations including WHO and OIE. It is reinforced by 12 Associate Partners and 5 Associate international networks and aims at becoming the most responsive network to improve the control of emerging or re-emerging virus outbreaks at the global level.	
<b>Link:</b> <a href="https://cordis.europa.eu/project/id/871029">https://cordis.europa.eu/project/id/871029</a>	

#### 4.1.1.2 Non-EU funded projects and initiatives

<b>Healthy Silk Road</b>	
<b>Programme:</b> Belt and Road Initiatives (BRI)	
<b>Budget:</b> Not available	<b>Timeline:</b> Start date: 2013 End date: 2030
<b>Objective:</b> The Belt and Road or New Silk Road project is a Chinese initiative, which aims to improve connectivity and cooperation among multiple countries in Asia, Africa, and Europe. As an important part of the construction of the Belt and Road, the main objective of the Healthy Silk Road is to improve the overall health and hygiene standards with the countries, which have taken part in the Belt and Road initiative.	
<b>Link:</b> <a href="https://www.yidaiyilu.gov.cn/ghsl/gnzjgd/125638.htm">https://www.yidaiyilu.gov.cn/ghsl/gnzjgd/125638.htm</a>	

<b>The Ministry of Science and Technology of China (MoST) and the National Research Council of Italy (CNR) Cooperation Programme</b>
<b>Programme:</b> MoST / CNR Cooperation Programme





<b>Budget:</b> € 100 000,00	<b>Timeline:</b> Start date: 1 January 2021 End date: 31 December 2022
<b>Objective:</b> October 1, 2019, the Ministry of Science and Technology of China (MOST) and the National Research Council of Italy (CNR) signed a Joint Bilateral Agreement. The main goal of this Agreement is to reinforce the cooperation between Italian and Chinese researchers and research centres. The research areas of common interests cover Marine Technologies, Modern and Precise Agriculture, ICT – Artificial Intelligence in Intelligent Manufacturing, and Personalised Medicine and Innovative Biomaterials for medical services. Following the joint call for Research Projects 2021-2022 in April 2020, four projects have been selected to receive EUR 25,000/ RMB 200,000 per project every year for a period of 2 years.	
<b>Link:</b> <a href="https://www.cnr.it/en/bilateral-agreements/agreement/79/most-ministry-of-science-and-technology-of-china">https://www.cnr.it/en/bilateral-agreements/agreement/79/most-ministry-of-science-and-technology-of-china</a>	

### EU-China Health Summit on Medical Innovation, Medical Informatics, Medical Imaging and Medical Technology Transfer

**Organisers:** European Federation for Medical Informatics / CMIA

**Objective:** The summit invites contributions in the form of talks, e-pitches, e-posters, and e-workshops to the summit, addressing specific topics in the MI3 areas, as follows: Medical Imaging physics and processing, Findable Accessible Interoperable Reusable (FAIR) Health Data Sets, Health technology standards and interoperability, Robotics of health and social care, Citizen engagement with digital health technology, Mobile health assessment and contact tracing apps, Digital health for nursing and rehabilitation, Health technology in Living environments and the Internet of Things, Medical Innovation, Intellectual Property, and Patent Management, Digital health technology for emergency care, AI in Health and Wellness Technology, AI in the hospital of the future, Privacy, ethics, and Cyber-security in the AI age.

**Link:** <https://efmi.org/2020/08/03/2nd-eu-china-health-summit-on-medical-innovation-medical-informatics-medical-imaging-and-medical-technology-transfer/>

### Ministry of Science and Technology of China (MOST) and the Coalition for Epidemic Preparedness Innovations signed Memorandum of Understanding (MoU) on Cooperation

**Programme:** Memorandum of Understanding on Cooperation

**Objective:** In March 2021, CEPI and MOST signed a MoU on cooperation. CEPI is the Coalition for Epidemic Preparedness Innovations and is a global partnership to develop vaccines to stop future epidemics. CEPI has secured financial support from different countries, initiatives and the European Commission<sup>54</sup>. The signing of the MoU is of great significance for promoting cooperation and exchanges between China and CEPI in the field of epidemic preparedness innovations. According to the memorandum, the two sides will strengthen cooperation in epidemic preparedness and response, including supporting scientific research projects in the field of public health, and conducting vaccine research and development and international cooperation and exchanges in science and technology. In the future, the two sides will tap into their respective strengths to proactively share experience and practices of research on COVID-19 and strengthen the sharing of scientific data and information; enhance cooperation among COVID-19 vaccine developers, select and support promising and mature projects that give full play to each other's advantages; boost communication and policy coordination with regulators; and create synergy with other governments, international organizations, and bilateral and multilateral cooperation mechanisms in the fields of science, technology and health.

**Link:** [http://www.most.gov.cn/eng/eng/pressroom/202101/t20210121\\_160937.htm](http://www.most.gov.cn/eng/eng/pressroom/202101/t20210121_160937.htm)

<sup>54</sup> CEPI. Investors & Partners. 19.04.2021. <https://cepi.net/about/whoweare/>



## 4.1.2 Success stories of current collaborations in health research

Understanding the major impact of coordinated health research and innovation, some European and Chinese organisations have developed strong collaborations often based on personal relations or on previous collaborations in the framework of a funded project. These long-term collaborations often take the form of a joint centre or an exchange programme. Such collaborations allow for a strong involvement of researchers, the development of trustful relationships at the organisation, researchers and students levels and a better knowledge of a different ecosystem, paving the way for disruptive thinking and more innovation.

### 4.1.2.1 Joint research centres

The participation in collaborative Sino-European projects may be complicated by some factors that cannot be changed by the participants (funding difficulties, restraints in the exchange of data and biological samples etc.).

To facilitate collaboration and benefit from the advantages of both being in the EU and in China, some European research centres have opened “joint centres” with their counterparts in China. A joint centre is a strong collaboration between different research institutes characterised by important exchanges, scientific cooperation and the co-creation of laboratories shared by the European and Chinese research teams.

Joint centres therefore facilitate collaborative research projects, the organisation of common events such as conferences and seminars and co-publications, benefiting from the knowledge accessible in both countries. Besides the team members from the joint research centre, researchers from both countries benefit from a privileged access to the co-created laboratories in the other country and from facilitated data exchanges.

The development of joint research centres can be facilitated thanks to a strong personal interest of researchers or after a successful collaborative project (as for the Institute Pasteur in Shanghai), encouraged, and supported by some European Embassies. For instance, the French Embassy largely encouraged the development of health-related joint centres in China, notably between 2005 and 2013 through a strong communication, the research of partners and the organisation of visits.

Several EU Member States have supported the development of joint research centres in China. Depending on the national strategies and support of the Embassies, joint research centres focus on health or on other thematic such as energy, climate change or space.

Table 5 reports a list of joint research centres in EU Member States focusing on health research, referenced by Euraxess<sup>55</sup> and IC2PerMed:

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<sup>55</sup> European Commission. Europe-China Joint Research Structures Directory. <https://euraxess.ec.europa.eu/worldwide/china/directory-europe-china-joint-research-structures>





Table 5: Joint Research Centres

Name of the joint centre	Location	Research areas	European Research partner	Chinese Research partner
<b>Austria</b> 				
Sino Austrian Collaborating Centre for Chinese Medical Sciences	Beijing	Traditional Chinese Medicine	University Graz	Chinese Academy of Medical Sciences
Sino-Austrian Diagnosis, Treatment and Research Centre of Cardiovascular Diseases	Nanjing	Cardiovascular diseases	Medical University of Vienna	Nanjing Medical University & First Hospital
Sino-Austrian Research Centre for High-Tech Acupuncture and Clinical & Experimental Integrative Medicine	Beijing	Acupuncture, Integrative Medicine, Traditional Chinese Medicine	University of Graz	Capital Medical University, Beijing
<b>Belgium</b> 				
Sino-Belgian Collaboration Laboratory for Single Cell Analysis Technologies	Shanghai	Single cells analysis technologies	Vlaams Instituut voor Biotechnologie, Flanders Institute of Biotechnology	Shanghai Institute of Materia Medica, Chinese Academy of Sciences
<b>France</b> 				
Sino-French Research Centre in life sciences and genomics	Paris/ Lyon/ Shanghai	Life sciences, genomics, cancer, blood diseases	INSERM	National Centre of Genomics Research, Shanghai Institute of Life Sciences
Pasteur Institute of Shanghai	Paris/ Shanghai	Microbiology, virology, immunology, cancer, epidemiology, vaccinology, immunotherapy	Pasteur Institute	Shanghai Institute of Life Sciences
Sino-French Centre for Urology	Paris/ Shanghai	Urology, cancer, prostate	Cochin Hospital	Pudong hospital, Shanghai
Christophe Merieux Laboratory	Beijing	Respiratory viral infections	Laboratory Merieux	Chinese Academy of Medical Sciences



Name of the joint centre	Location	Research areas	European Research partner	Chinese Research partner
Sino-French biomedical information research centre	Rennes/ Nankin	Imaging technologies	INSERM/ Rennes University	Southeast University, China
Sino-French laboratory of molecular pathology	Paris/ Shanghai	Targeted therapies, human lymphoma, biological markers	INSERM/ Paris Universities Sorbonne and Diderot	Ruijin's hospital, Shanghai and Jiaotong University, Shanghai
Medical engineering and theory in image and signal laboratory	Lyon/ Harbin	Image processing, cardiac and pulmonary applications	CREATIS	Harbin Medical University
Sino-French Laboratory of physiology and pathophysiology	Paris/ Shanghai	Physiology, pathology, cancer, pulmonary chronic diseases	Cochin hospital and University Paris Descartes	Tongji University, Shanghai and Shanghai East Hospital
Laboratory of cell and tissues engineering and applications in regenerative medicines	Nancy/ Wuhan	Pharmacology, stem cells, cell therapy	INSERM, CHU Nancy Brabois	Wuhan Medical University
China-France joint laboratory for healthcare theranostics	Paris/ Shanghai	Theranostic, cancer	CNRS, University Paris Descartes	Donghua University, Shanghai
<b>Germany</b> 				
Joint Laboratory for Biomaterials and Regenerative Medicine	Tianjin	Biomaterials, regenerative medicine	GKSS Research Center Geesthacht	Tianjin University
Shandong University-Helmholtz Joint Institute of Biotechnology	Qingdao	Biotechnologies, anti-infective therapy	Helmholtz Centre for Infection Research	Shandong University
SiGeNet Health: Sino-German research network on public health and bioethics	Shanghai	Public health, ethics	Charité University	BGI Shenzhen, Jiaotong University
Shanghai-Tübingen Twin Centre of Basic and Applied Life Sciences	Tübingen/ Shanghai	Medicine, bioinformatics, traditional chinese medicine, neurosciences	University Tübingen	Tongji University



Name of the joint centre	Location	Research areas	European Research partner	Chinese Research partner
<b>Netherlands</b> 				
Sino-Dutch Centre for Preventive and Personalised Medicine	Dalian	Personalised medicine, genomics	Leiden University, Netherlands Organisation for Applied Scientific Research, Netherlands Genomics Initiative	Dalian Institute of Chemical Physics
Sino-Dutch Biomedical and Information Engineering School	Shenyang	Medical equipment, health electronics, biomedical imaging	Eindhoven University of Technology	North-eastern University of China
<b>Poland</b> 				
LVRI-PIWet-PIB Joint Lab for Animal Disease Control	Lanzhou	Animal diseases	National Veterinary Research Institute	Lanzhou Veterinary Research Institute

#### 4.1.2.2 Bilateral exchange activities

Exchange activities are an important way to learn from each other, collaborate and support the development of future collaborative projects, reducing the needs for a dedicated flagship.

In this regard, framework programmes have been developed at a European (Marie Skłodowska-Curie and Erasmus +) and EU Member States' level to facilitate the exchange activities between European Member States and other countries. However, most of these programmes do not specifically target China and the exchanges with China therefore often remain only possible thanks to interpersonal connections and a strong will of some researchers. One important counterexample is the 2019's Sino-German Centre Call for Proposals on Mobility.<sup>56</sup>

Outgoing European mobility to China remains therefore limited, even though it is slowly increasing. One of the main reasons for it has to do with the difficulty to study and work in English in China – most of the European researchers going to China are former Chinese students who stayed abroad, or Europeans related to China – and the lack of recognition of the Chinese Health Research Institutes in Europe.

On the Chinese side, the main funding program for exchange activities are the “Thousand Talents Program” – 7000 European researchers have benefitted from it to go to China since 2008; the “Thousand Youth Talents Plan” – administered by the Chinese Communist Party Organization Bureau;

<sup>56</sup> Sino-German Center. 2019. Results of the Sino-German Center Call for Proposals 2019 in the Mobility and Workshop Programs. [http://www.sinogermanscience.org.cn/de/aktuelles/de\\_2019/201911/t20191112\\_489317.html](http://www.sinogermanscience.org.cn/de/aktuelles/de_2019/201911/t20191112_489317.html)



the “Recruitment Program of Foreign Experts” – run by the State Administration of Foreign Experts Affairs of China (SAFEA); and the “Changjiang Scholars Program” of the Ministry of Education.<sup>57</sup> These programs fund the recruitment of world-class researchers, professionals, and entrepreneurs who it is hoped will help to leapfrog China into a leading position in strategic fields.

In addition to the above-mentioned funding programmes, many foreign researchers work in China as part of smaller bilateral university cooperative projects (see also the joint research centres). These bilateral university cooperative projects and exchange activities allow research institutes/universities to get a direct counterpart for what they fund. Indeed, a European research institute or university will fund Chinese researchers to come to Europe or fund their own researchers to go to China, with the Chinese research institute/university proposing the same services to its researchers.

Following are three examples of established exchange activities between European and Chinese research institutes:

- The **Centre for Genomic Regulation (CRG)**<sup>58</sup> in Barcelona has developed a common PhD programme together with the Guangzhou Regenerative Medicine and Health Guangdong Laboratory in China. This programme is dedicated to European and Chinese students, offering them a work contract either in Europe (paid by CRG for a maximum of 4 years for the students in Europe and paid by the Guangdong Laboratory for a maximum of 4 years for the students going to China). The research institutes provide a full administrative support for their integration in the other country.
- At the **Idélinikken**<sup>59</sup> clinic in North Jutland Region in Denmark, an exchange of doctors and PhD students has been setup and has been running for 8 years. The manager that developed this collaboration was specifically attracted to China for personal reasons and found partners’ hospital in China interested to send and receive doctors. To support this collaboration and prepare Danish doctors to receive their Chinese counterparts and/or go to China themselves, a training has been provided allowing the doctors to better understand the Chinese culture and learn basic knowledge in Chinese. This training played a huge part in the success of each exchange.
- Finally, the **Nordic Centre**<sup>60</sup> is a good example of several Member States joining forces to collaborate with China, namely with the Fudan University. It gathers 29 organisations from Denmark, Finland, Iceland, Norway, and Sweden, and supports the setup of joint educational programmes/conferences for students and business organisations, as well as student exchanges both from Europe to China and China to Europe. The Centre covers many different topics, from literature to health with topics of common interest such as healthy ageing.

Such examples have proven to benefit both European and Chinese researchers and research institutes. However, the fact that it is based on some researchers’ initiatives drastically reduces their impact at the European/Chinese level. The new Sino-European joint roadmap and international networks such as ICPeMed are therefore necessary to encourage more local initiatives with a top-down perspective and incentive.

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<sup>57</sup> d’Hooghe, Montulet, de Wolff, Piek. Assessing Europe-China Collaboration in Higher Education and Research. 2018. LeidenAsiaCentre. <https://leidenasiacentre.nl/wp-content/uploads/2018/11/LeidenAsiaCentre-Report-Assessing-Europe-China-Collaboration-in-Higher-Education-and-Research.pdf>

<sup>58</sup> Centre for Genomic Regulation. CRG - GDL International PhD Programme. <https://www.crg.eu/en/content/training-phd-students/crg-gdl-international-phd-fellowship-programme>

<sup>59</sup> Idélinikken - Region Nordjylland. <https://ideklikken.rn.dk>

<sup>60</sup> Nordic Centre (Shanghai). <http://www.nordiccentre.net>



## 4.2 Lessons learnt from ongoing Sino-European cooperation

China and the EU have both become global hubs for higher education, research, and innovation. In 2018, it was reported that China has the second-largest budget for research and development worldwide, as well as the second-largest pool of researchers after the EU.<sup>61</sup> Growing international collaboration between China and the EU has also been mutually beneficial. In fact, co-publications are more frequently cited than those written without international partners.<sup>62</sup> With respect to higher education, China is supposed to be the world's largest source of international students. In 2017, 608,400 students left China to study abroad, representing an 11% increase from the year before. By the following year, 1.454.100 Chinese students were enrolled in international higher education institutions.<sup>63</sup> In many European countries, such as the UK, Germany, and France, Chinese students represent the largest group among students from abroad. However, as of 2018, 73,618 Europeans accounted for 14.96% of all international students studying in China, with the highest proportion of students coming from France.<sup>64</sup> Although migration patterns have not been consistently measured across Member States, the mobility of students and researchers from the EU to China is remarkably lower.

### 4.2.1 Reciprocity in collaborations

The EC's Directorate-General for Research and Innovation, Jean-Eric Paquet, commented on the nature of existing research collaborations between the EU and China, suggesting that the Chinese have more open access to opportunities in Europe, with reciprocity becoming more difficult.<sup>65</sup> Following Chinese policy reforms in the 1980s, many European governments began taking advantage of China's increased openness to initiate student and staff exchanges.<sup>61</sup> These opportunities encompassed increased recruitment of Chinese students, more collaborative education and research projects, and the establishment of joint institutions. While China has always supported higher education institutions in their effort to establish branches, labs, and additional sites in China, the government has become increasingly selective when importing foreign expertise. This exclusivity could be due, in part, to differing motivations between the Chinese government and other foreign partners.<sup>61</sup>

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<sup>61</sup> d'Hooghe I, Montulet A, de Wolff M, Pieke FN. Assessing Europe-China collaboration in higher education and research. Leiden Asia Centre. 2018;56.

<sup>62</sup> Kwiek M. What large-scale publication and citation data tell us about international research collaboration in Europe: changing national patterns in global contexts. *Studies in Higher Education*. 2020 Apr 10:1-21.

<sup>63</sup> 2017 sees increase in number of Chinese students studying abroad and returning after overseas studies [Internet]. Ministry of Education of the People's Republic of China. 2018. [http://en.moe.gov.cn/News/Top\\_News/201804/t20180404\\_332354.html](http://en.moe.gov.cn/News/Top_News/201804/t20180404_332354.html)

<sup>64</sup> Statistical report on international students in China for 2018 [Internet]. Ministry of Education of the People's Republic of China. 2019. [http://en.moe.gov.cn/news/press\\_releases/201904/t20190418\\_378586.html](http://en.moe.gov.cn/news/press_releases/201904/t20190418_378586.html)

<sup>65</sup> EU-China research relationship 'unbalanced', policy head warns [Internet]. *Times Higher Education (THE)*. 2020. <https://www.timeshighereducation.com/news/eu-china-research-relationship-unbalanced-policy-head-warns>





## 4.2.2 Push-and-Pull factors affecting collaboration

Nonetheless, the important connection between higher education and research development is emphasised in Chinese policies and strategies, including the Belt and Road Initiative. This strategy is designed to accelerate and enhance development and trade for China and partners throughout Asia, Africa, the Middle East, and Europe.<sup>61</sup> This initiative has been applied through the launch of the “Belt and Road Science and Technology People-to-People Exchange Initiative” and the “Joint Laboratory Initiative”, among others. This plan promises to offer young, foreign scientists 2,500 short-term research placements, with an additional 5,000 spots open for training foreign scientists, engineers, and managers.<sup>61</sup> As these programs expand in both China and the EU, migration patterns and the motivations of students and researchers are likely to evolve.

In the survey targeting Chinese researchers, the latter were asked to describe their motivation for pursuing PM research in the EU. In brief, the respondents cited their top three reasons, from highest to lowest frequency, as being education, excellence of research, and availability of cutting-edge technologies. Of nine participants surveyed, half hoped to continue their research in Europe and six expressed interest in partaking in future EU-Chinese collaborations. Drawing from the survey insights, several Chinese respondents indicated that push factors such as increased job opportunities, adoption of more student exchange programs, and better funding would encourage other Chinese academics to pursue PM research in Europe.

While the IC2PerMed survey did not fully capture the perspectives of European researchers coming to China, other articles and surveys detail some push factors of interest. In China, EU researchers cited both funding and personal support as compelling reasons to conduct their research abroad.<sup>8</sup> The Chinese Thousand Talents Program offers similar funding opportunities for European scientists coming to China, allowing for more opportunities for EU scientists to fast track their careers and establish independent labs. The Chinese government in 2008 established the program, with funding set aside for the recruitment of overseas high-level scientists and experts. Over a decade, this program has drawn more than 6,000 ‘talents’ to China for research, entrepreneurship, and innovation.<sup>66</sup> On top of their research funding, European scientists in China noted the generous support they received for travel and housing expenses as they relocated.<sup>67</sup>

Interestingly, European researchers coming to China commented on the willingness of “top-notch” Chinese scientists to offer support and foster local collaboration. Foreign scientists bring with them contacts from their home country and other parts of the world, and Chinese researchers are often eager to tap into these vast social networks.<sup>67</sup> Some suggested that these connections are considered prestigious, offering even more incentive for Chinese-EU research collaboration.

## 4.2.3 Role of R&I support schemes

In recent years, European programs like Horizon 2020 have been the main source of funding for Chinese researchers in the EU. Between 2016 and 2020, the EU and China committed €630 million through their co-funding mechanism for research projects, with €500 million funded by Horizon 2020

<sup>66</sup> Thousand Talents Plan [Internet]. China Innovation Funding. <http://chinainnovationfunding.eu/thousand-talents-plan/>

<sup>67</sup> Mervis J. When Europeans do science in China [Internet]. Science. 2019. <https://www.sciencemag.org/news/2019/09/when-europeans-do-science-china>





and the remainder coming from MoST.<sup>68</sup> The continuation and expansion of these programs in Europe should motivate Chinese researchers to continue collaborative research efforts in the EU, especially within the context of PM. In fact, the latest, joint transnational call for research proposals in PM has an available budget of €24 million, with immense potential to renew interest in joint EU-Chinese PM research initiatives.<sup>69</sup>

#### 4.2.4 Social and cultural aspects

In both China and the EU, researchers coming from abroad mentioned the importance of maintaining an enjoyable lifestyle and personal social connections. Efficient communication and language were also cited as important cultural considerations. In fostering research collaborations, funding must be prioritised alongside these aspects to ensure that scientists are motivated to live abroad and continue engaging in these projects over a longer period.

In the context of PM, there are no known publications, to our knowledge, that characterise the motivation of researchers participating in international research collaborations. As the IC2PerMed initiative evolves, there is a critical opportunity to explore the push factors that drive the migration of students and scientists between China and the EU. These insights will clarify policy changes and funding priorities to ensure that research collaboration in PM can be expanded and sustained as the field changes over time.

### 4.3 Outline for a deepened Sino-European collaboration

This chapter provides the first synthesis of the information gathered from the mapping activities detailed in previous chapters on PM approaches, schemes, and additional surveys. This information will serve as the basis of further discussions towards convergence and collaboration in PM approaches between China and Europe. A great deal can be learned from the existing collaborations between China and European countries or organisations in biomedical research. Opportunities lay in the International Consortium for PM and its related projects as an optimal forum to allow stakeholders to engage and discuss. Nevertheless, it is important to take into consideration of the potential cultural barriers and leverage on the push factors that stimulate exchange in identified areas of mutual interest.

#### 4.3.1 Best practices from ICPerMed

Within the Horizon2020 programme, Chinese researchers, enterprises, research institutions and universities can already team up with European partners to participate in projects and make use of Europe's research and innovation excellence.<sup>70</sup> International participation is open for all fields of research, including PM. However, not all international partners are eligible for funding. These partners usually need to bring their own funding to the project via their own regional/country funding agencies.

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<sup>68</sup> EU-China Co-Funding Mechanism [Internet]. China Innovation Funding. 2020. <http://chinainnovationfunding.eu/eu-china-co-funding/>

<sup>69</sup> Joint Transnational Call 2021 [Internet]. ERAPermed. 2020. <https://erapermed.isciii.es/joint-calls/joint-transnational-call-2021/>

<sup>70</sup> European Commission (2019). People's Republic of China - Country Page. [https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020\\_localsupp\\_china\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020_localsupp_china_en.pdf)



International Consortia funded by the EC, such as ICPerMed, support a flexible platform for global dialogue in a thematic area. The international consortium model, with an established and transparent governance offer an alternative way to engage with respect to standard Horizon2020 projects. ICPerMed welcomes funding agencies in PM as members from anywhere in the world and has also taken an inclusive approach to allow observer status if an agency has considerations on commitments or wishes to first learn more about the network. Funding members can be national funders, regional funders, public or private organisations. ICPerMed members engage in several working groups to tackle on specific or prioritised topics by the Consortium. ICPerMed does not work in isolation, but works in synergy with many related projects, all together called “ICPerMed Family”, to leverage on experts at large to drive the implementation of PM. This family of projects allows strategic development in technical thematics such as PM clinical trials and health economics, drive implementation of PM in regional contexts, and international outreach and alignment. The ICPerMed related international projects for Latin American countries, China and Africa are excellent mechanisms to foster collaborations from different parts of the world.

A core activity of ICPerMed is to highlight and raise awareness to successful examples of progress or implementation towards PM. The annual call for the Best Practices prize is open for application globally, and as such, can also serve as a channel for engagement between EU and China, to showcase successful PM projects and cases from either region.

### 4.3.2 Areas of mutual interest in PM and Sino-European synergies

The large number of clinical data, the efficiency, and productivity along with cutting-edge technology players such as BGI and strengths in artificial intelligence, are advantages that China has over Europe in research, innovation, and research and development in health, healthcare, and PM (Figure 4). On the other hand, Europe has competitive advantages in the best way of standardising clinical trials in addition to academic freedom, the existence of platforms and organisations, and open access to the latest information. Chinese and European policymakers should take actions to enhance synergies through openness, tolerance, understanding, and cooperation based on agreed regulation.

Through the policy and programs mapping activities (D1.1), several common objectives between EU and China have been identified. These **areas of mutual interest in PM** can allow developments and synergies between the two regions and support gains from a closer cooperation, including:

- Upscaling of health systems by reducing ineffectiveness and overtreatment (PM approach);
- Overcoming fractionation in domestic market (multi-tier health systems, national states/provinces);
- Achieving interoperability between different stakeholders and across borders;
- Standardisation of data (omics-research and electronic health records);
- Development of solutions in storage and filing of large datasets and efficient analytics (AI, algorithms);
- Data sharing to develop new services and applications;
- Data protection (GDPR, Cyber Security Law) and
- Protection of internal value chains, securing patients’ rights.

These mutual interests fall in **major categories under the themes of sustainable healthcare, value for society and interoperability in research innovation** (Figure 4). EU-China collaborations in these thematic areas can be tackled globally in a concerted manner to improve efficiency and reduce redundancies.



Alignment of research efforts can drive economic potentials both in terms of technological leadership as well as through improved value chains to new markets. With the outcome of the mapping analyses, IC2PerMed will create working groups for each of these common objects with experts from both regions to develop a roadmap towards collaborations.

### **Shaping Sustainable Healthcare**

Harmonising strategies and practices to ensure that the PM provides added value to the health systems by fostering their effectiveness, efficiency, and sustainability. It should consider the complementary topics of education and patients' engagement and empowerment trying to identify the key factors that can ensure a fast uptake of PM strategies at micro level (hospital, healthcare organization), meso level (integrated care, local level) and macro level (health system) to ensure their sustainability. Understanding the key contextual factors and barriers at different levels in translation of PM new approaches are fundamental to ensure sustainability of health systems.

### **Data innovation and Market**

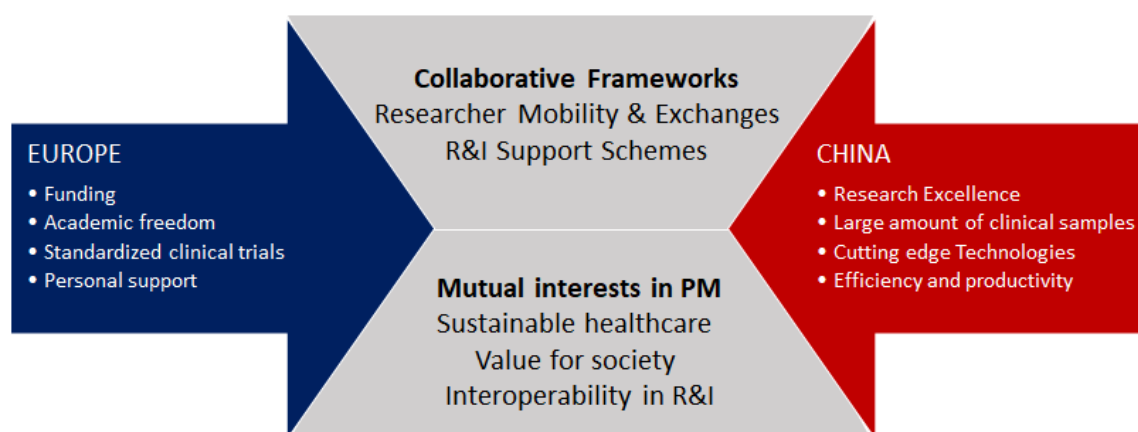
Medical, genetic, and environmental data schemes are the backbones of PM innovations. Diagnosis, treatment, prognosis, drugs developments derive from these inputs. Roadmap which encourages international alignment in standards, regulatory aspects to market barriers is of uttermost importance for collaboration and will be discussed.

In addition, how health economic models' parameters can be applied both in EU and China will be explored, taking into considerations the specificities of pricing, insurance and reimbursement models applied.

### **Research and Clinical studies in PM**

Aligning the research funding priorities and procedures in the field of PM across the relevant funding agencies in EU and China can subsequently drive the alignment of synergistic collaborations in PM. Areas of mutual interest in standardisation of approaches to translate basic to clinical research, especially related to data must be considered.

**Figure 4: Sino-European synergies and areas of mutual interest**



### 4.3.3 Facilitators and enablers of future collaboration

Bilateral EU-China programs are an important cooperation tool, and their number has been increasing rapidly in recent years. Following is what emerged from the IC2Permed survey on what needs to be implemented by European and Chinese policymakers to intensify and facilitate collaborations:

- Establishing a common understanding of PM
- Harmonising ethical and clinical trials rules
- Working on privacy and data openness
- Setting up working panels comprising experts from both nations to identify niches and future directions
- Releasing collaborative funding calls between EU and China in Personalised Medicine
- Setting up an official association and annual conference for EU-China Union for Personalised Medicine
- Strengthening communication and enhance communication activities
- Strengthening the process of managing quality control

The outcomes of the survey supported the evidence of facilitators and enablers for EU-China collaboration in PM. Increased bilateral exchanges of people, knowledge, and ideas, as well as the alignment of regulatory and ethical requirements, will be a useful factor in facilitating EU-China collaborations. In addition, common funding and collaborative projects between leading institutions will be essential and necessary to further enable these collaborations. This will be possible through the identification of common opportunities such as mutual knowledge transfer, good personal relationships, trust, and clear common goals. For example, the existence of a platform, accessible without Internet barriers, and by everyone, including the public, could facilitate the development of EU-China collaboration initiatives in PM.

Not to be forgotten that some relevant contextual aspects (social, cultural, economic, legal, ethical, etc.) will need to be taken into consideration. Ethical aspects with respect to rights of the individual, data privacy, and data ownership are also important, as well as differences in the legal protection. Furthermore, language, communication, and cultural differences are relevant factors to consider for enabling collaboration. Least but not last, social aspects such as social media differences, disparities in healthcare, etc. play an important role in facilitating these collaborations. Additional barriers to be considered include the lack of consensus in guidelines on the interpretation and use of PM, public understanding and acceptance of the value of PM, and political misalignment along with geographical differences.



## 5 Conclusion

Building upon previous IC2PerMed activities that reviewed health research and innovation priorities (D1.1) and major funding agencies and stakeholders in the field of PM (D1.2), the present report extensively reviews PM approaches and standards in place in Europe and in China. It further assesses current Sino-European collaborations related to health and their implications for future bilateral interactions.

The synthesis of the information gathered aims to provide a first outline for discussion to elaborate recommendations on how to improve reciprocity and increase areas of interest for future Sino-European collaboration in the field of PM. The report identifies both push and pull factors from existing collaboration in health research in the context of PM. In addition, it focuses on identifying success factors of current collaborations, areas of mutual interest and opportunities for future cooperation in the field of PM.

The mapping of PM-related treatment approaches and data/biobanking standards established in the EU and in China revealed the following **Lessons learnt from the clinical practice side**:

- **Lack of unified treatment guidelines application:** Treatment guidelines should be applied in a way that ensures all patients are able to make informed choices and have equitable access to these PM approaches including all treatment levels including surgery, radiation, hormone therapy, chemotherapy, and targeted antibody therapy. Many of these treatment strategies have serious cost implications, which are differently supported by the European and Chinese health systems. Differences in the political systems, cultural and ethical aspects might have a large influence on the application of available treatment guidelines.
- **Lack of cooperation in standardisation:** Most of the standards on data and biobanking, except for biobanking standard ISO20387:2018, are however either applied only in China or Europe, but not in both geographic areas. This clearly shows that there is room for improvement in cooperation and collaboration between the EU and China
- **Insufficient use of ISO as the international bridge builder for standards related to PM:** CEN directly cooperates with ISO and transposes a large part of the ISO standards into the European standards system and many Chinese GB standards in turn are adoptions from international standards developers such as the ISO. This clearly shows that the “scaffolding” for a joint EU-China bridge is already in preparation, opening the way to a common and internationally standardised view on PM.

The assessment of current Sino-European collaborations related to health and their implications for future bilateral interactions revealed the following **barriers, strengths, and opportunities for future bilateral interactions**.

- **Central strategy for cooperation in place:** Sino-EU collaborations related to PM have, to a large extent, been dominated and facilitated by top-down initiatives i.e., the participation in both EU and Chinese funding programmes.
- **Bilateral roadmap under preparation:** This will continue in the future and be reinforced notably through the bilateral Joint Roadmap in the context of Horizon Europe currently under discussion - health being a high thematic priority on the agenda.
- **Joint research centres as institutionalised facilitators of cooperation:** This Joint Roadmap also intends to mitigate the gap of bottom-up initiatives possibly by fostering and supporting the creation of new joint research centres and the development of researchers’ exchanges.



- **Research mobility programmes as drivers for outgoing mobility to China:** More bilateral exchange framework programmes targeting China are necessary to support outgoing mobility to China.
- **Multi-level solutions for remaining barriers:** However, some barriers remain (e.g., language barrier, lack of recognition of the Chinese Health Research Institutes in Europe), thus requiring actions to be taken on a different level. Further support to researchers and local initiatives is essential to overcome these barriers.

The extensive desk research and consultation of country representatives and researchers in the framework of this report revealed first **potential areas of mutual interest** for future Sino-European collaboration in the field of PM:

- **Biobanking:** The field of Biobanking with its data and biobanking standards represent a prime example for the translation of PM approaches into practices and is a key area for future collaboration between China and Europe. Collaboration could comprise:
  - **Joint elaboration of common standards** for data and biobanking purposes or applications (except for biobanking standard ISO20387:2018)
  - **Sharing of best practices** for treatment guidelines
  - **Training on data and biobanking standards** to ensure their correct application
- **Specific topics:** Considering the enormous range of different possible application fields for PM, **concrete Sino-European collaboration projects/initiatives should ideally be narrowed down to specific topics** of mutual interest to ensure maximum output. Potential areas of mutual interest identified here include:
  - **Sustainable healthcare system**
  - **Value for society**
  - **Interoperability in research and innovation**

The mapping will now serve as (a) 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 and (b) basis for WP3's mission to foster research collaboration between Europe and China.



# 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<sup>29</sup>. 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](mailto: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**.





## 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?
  - Yes\*
  - No
  - I do not know

\*If yes, please specify:

- Name(s)/title(s) \_\_\_\_\_
- Source or website, if available \_\_\_\_\_
- 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)?

- Citizens', patients' awareness and empowerment
- Health Professionals' education and curricula
- Practices and strategies for Personalised Medicine in sustainable healthcare
- Big data and ICT Solutions
- Bringing innovation to market
- Translating basic to clinical research and Beyond
- Research Funding
- Privacy/Ethical regulations
- Other (please specify) \_\_\_\_\_
- 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?

- Citizens' awareness and empowerment
- Health Professionals' education and curricula
- Practices and strategies for Personalised Medicine in sustainable healthcare
- Big data and ICT Solutions
- Bringing innovation to market
- Translating basic to clinical research and Beyond
- Research Funding
- Privacy/Ethical regulations
- 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?
- Yes\*
  - No
  - 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)

- Citizens', patients' awareness and empowerment
- Health Professionals' education and curricula



- c. Practices and strategies for Personalised Medicine in sustainable healthcare
- 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)<sup>30</sup>. The WGs will focus on the following topics:

Working Group	Topics
WG1: “Shaping sustainable healthcare”	<ul style="list-style-type: none"> <li>• Awareness and empowerment</li> <li>• Education and curricula</li> <li>• Personalised Medicine in sustainable healthcare</li> </ul>
WG2: “Innovation & market”	<ul style="list-style-type: none"> <li>• Big data and Information and Communication Technology (ICT) Solutions</li> <li>• Bringing innovation to market</li> </ul>
WG3: “Research and clinical studies in Personalised Medicine”	<ul style="list-style-type: none"> <li>• Translating basic to clinical research and Beyond</li> <li>• Research Funding</li> </ul>

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.



## Appendix 2

### **IC2PerMed survey on Sino-European collaboration addressing country representatives<sup>71</sup> in China and Europe**

Dear participant,

the International Consortium for Personalised Medicine (ICPerMed), umbrella initiative of IC2PerMed, aims at initiating and supporting communication and exchange on Personalised Medicine (PM) for aligning national agendas on research and funding activities. It brings together representatives of funding agencies and authorities from 29 countries and expands for increasing PM developments' synergies at international level.

The IC2PerMed project's core objective is to build upon collaborative developments of Chinese and European experts on PM for elaborating a common strategy, enabling Chinese institutions to join the ICPerMed consortium.

This survey is anonymous, we do not collect your email addresses. Your feedback is used only internally and will not be shared with 3rd parties.

We would like to better understand the situation of Chinese researchers in Europe and develop strategies to strengthen Sino-European collaboration long-term.

You can find our full privacy policy here: <https://www.ic2permed.eu/gdpr>

If you wish to participate in the survey and agree with our privacy policy, please indicate below.

x – Agree

#### **Personal background**

What is your nationality?

*Open Answer*

Please indicate the country where you are currently working in:

*Open Answer*

Please indicate your field(s) of expertise:

*Open Answer*

Which type of organisation or institution are you currently working for?

*Multiple choice:*

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<sup>71</sup> "Country representatives" has been defined as experts of international collaboration with respect to Sino-European cooperation



- Government – Research and Innovation
- Government – Health
- Funding Agency
- Innovation/Development Agency
- Cluster Organisation
- Research institution
- Hospital
- Regulator
- Patient organization
- Other: \_\_\_\_\_

### **Mapping of Sino-European collaborations**

Could you please name Sino-European collaborations in healthcare, Precision/Personalised Medicine or related fields? Indicating e.g. the project's name, organization, the stakeholders involved etc.?

*Open Answer*

If possible, please name a specific example of a successful recent collaboration between Europe and China.

*Open Answer*

If you have been personally involved in collaboration projects between China and Europe in the field of health or related to Personalised Medicine, please indicate the name of these projects

*Open Answer*

Which are the most relevant facilitators or enabling factors for EU-China collaborations in healthcare and in particular in Personalised Medicine?

*Open Answer*

Which are the most relevant barriers and obstacles for EU-China collaborations in healthcare and in particular in Personalised Medicine?

*Open Answer*

What are the relevant contextual aspects (social, economic, ethical, etc.) to be taken into consideration in EU-China collaborations in the field of Personalised Medicine?

*Open Answer*

What are the cultural aspects to be considered in EU-China collaborations?

*Open Answer*



In your opinion, in which areas does China have competitive advantages over Europe in research and innovation related to Personalised Medicine?

*Open Answer*

In your opinion, in which areas does Europe have competitive advantages over China in research and innovation related to Personalised Medicine?

*Open Answer*

What recommendations would you provide to Chinese and European policymakers in order to improve bilateral collaboration in the future?

*Open Answer*

**Thank you very much for your participation.**

## Appendix 3

### **IC2PerMed survey on Sino-European collaboration addressing European researchers in China and Chinese researchers in Europe<sup>72</sup>**

Dear participant,

the International Consortium for Personalised Medicine (ICPerMed), umbrella initiative of IC2PerMed, aims at initiating and supporting communication and exchange on Personalised Medicine (PM) for aligning national agendas on research and funding activities. It brings together representatives of funding agencies and authorities from 29 countries and expands for increasing PM developments' synergies at international level.

The IC2PerMed project's core objective is to build upon collaborative developments of Chinese and European experts on PM for elaborating a common strategy, enabling Chinese institutions to join the ICPerMed consortium.

This survey is anonymous, we do not collect your email addresses. Your feedback is used only internally and will not be shared with 3rd parties.

We would like to better understand the situation of Chinese researchers in Europe and develop strategies to strengthen Sino-European collaboration long-term.

You can find our full privacy policy here: <https://www.ic2permed.eu/gdpr>

If you wish to participate in the survey and agree with our privacy policy, please indicate below.

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<sup>72</sup> Chinese researchers in Europe and European researchers in China have been addressed separately



x – Agree

## Section 1 - Personal background

In which country and institution China/Europe do you currently perform your research activities?

*Open Answer*

What is your current research position?

*Open Answer*

How is your research linked to Personalised Medicine?

*Open Answer*

If applicable, in which institution and country in Europe/China have you conducted research before?

*Open Answer*

What are the driving reasons to perform research in China/Europe from a European/Chinese perspective?

Multiple choice:

- Education
- Research infrastructure
- Salary/Job opportunities
- Excellency of research
- Regulatory environment
- Availability of cutting-edge technologies
- Recommendation by European contacts
- Recommendation by Chinese contacts
- Sino-European exchange programmes
- Funding from EU or EU members States
- Add option: *add personal category*



What are the obstacles and barriers for coming to China/Europe as a European/Chinese researcher?

*Open Answer*

## **Section 2 - Mapping of Sino-European collaborations**

Could you please name Sino-European collaborations in healthcare, Precision/Personalised Medicine or related fields? Indicating e.g. the project's name, organization, the stakeholders involved etc.?

*Open Answer*

If possible, please name a specific example of a successful recent collaboration between Europe and China.

*Open Answer*

If you have been personally involved in collaboration projects between China and Europe in the field of health or related to Personalised Medicine, please indicate the name of these projects.

*Open Answer*

If you had the chance to be involved in future collaboration projects between China and Europe, would you like to participate and for what reasons?

*Open Answer*

What do you think are the facilitators and enablers towards collaborations between Europe and China in healthcare and in particular in Personalised Medicine?

*Open Answer*

What do you think are the obstacles and barriers towards collaborations between Europe and China in healthcare and in particular in Personalised Medicine?

*Open Answer*

What are the cultural aspects to be considered in EU-China collaborations?

*Open Answer*

In your opinion, in which areas does China have competitive advantages over Europe in research and innovation related to Personalised Medicine?

*Open Answer*





In your opinion, in which areas does Europe have competitive advantages over China in research and innovation related to Personalised Medicine?

*Open Answer*

What recommendations would you provide to Chinese and European policymakers in order to improve bilateral collaboration in the future?

*Open Answer*

**Thank you very much for your participation.**

