# IC2PerMed Working Groups

Working Group 1

Shaping sustainable healthcare

This WG's activities focus on awareness and empowerment of citizens and patients, education and curricula of healthcare professionals, and healthcare sustainability. For PM to be routinely implemented in clinical and public health practice, both patients and health professionals should be aware of the possibilities offered and how to make the most of them.

Given the need for informed, empowered, engaged and responsible citizens, there is a need to deepen digital literacy, knowledge of health data, public trust in institutions and easily accessible, reliable and understandable sources of medical information. Informed, accountable and empowered health service providers are also essential. The safe, responsible and optimal use of health information and research results required for PM should be routine in clinical settings. Clinical decisions should go through multidisciplinary teams, integrating new health professions. Clinicians and researchers, and all relevant stakeholders, should work closely together to support the rapid development and implementation of PM solutions.

The considerable global burden of non-communicable diseases and limited healthcare resources put the spotlight on the need for health systems to be sustainable. The careful use of resources, with prioritised allocation and equity, to ensure the translation of innovation and value, enables personalised and optimised health promotion and disease prevention, diagnosis and treatment for the benefit of patients.

To foster the adoption of new policies, following the public health policy cycle could be extremely helpful.
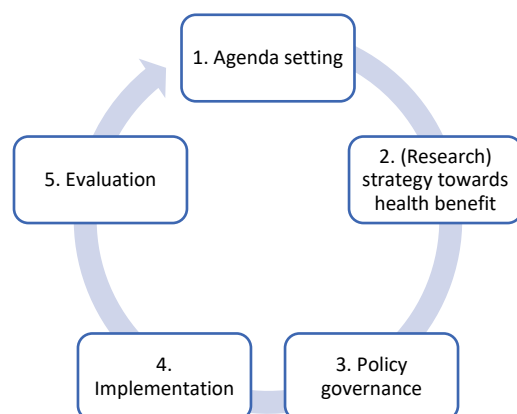

The Public Health policy cyle (adapted)

Working Group 2

Innovation and market

This WG's activities focused on Big Data and ICT solutions and on bringing innovation to market.

Big Data refers to datasets that are unprecedented in size and complexity, made possible by recent advances in automated collection of large-scale molecular and clinical data and the creation of new,increasingly powerful, computational approaches requiring novel ICT solutions. Big Data raises several issues for public policy makers, including personal data ownership and protection, skill gaps in labour markets and an emerging new digital divide. Hence, policies in this field are fundamental for the regulation of these aspects. Besides this prime example of disruptive innovation in the context of Big Data, the innovation ecosystem is similarly important to translating basic research and innovation progress into PM solutions in the hands of end users and eventually patients and citizens. The working group highlighted the importance of targeted innovation incentives tightly linked to questions of research and innovation funding. Besides prioritizing and supporting financially crucial PM. Technologies and infrastructures with adequate budget, the long-term perspective on market adoption and uptake of new approaches is central to bringing innovation to market.
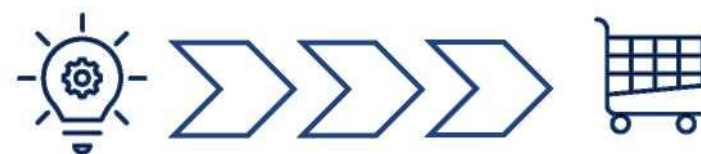

A citizen- and patient-centred approach is required to provide guidance to researchers and developers. Health budget constraints must be considered early on, and novel reimbursement measures are potentially necessary where cost- effectiveness is an issue. Innovations on personalized prevention measures in particular demand a holistic view on budget and should not be limited to healthcare.

Working Group 3

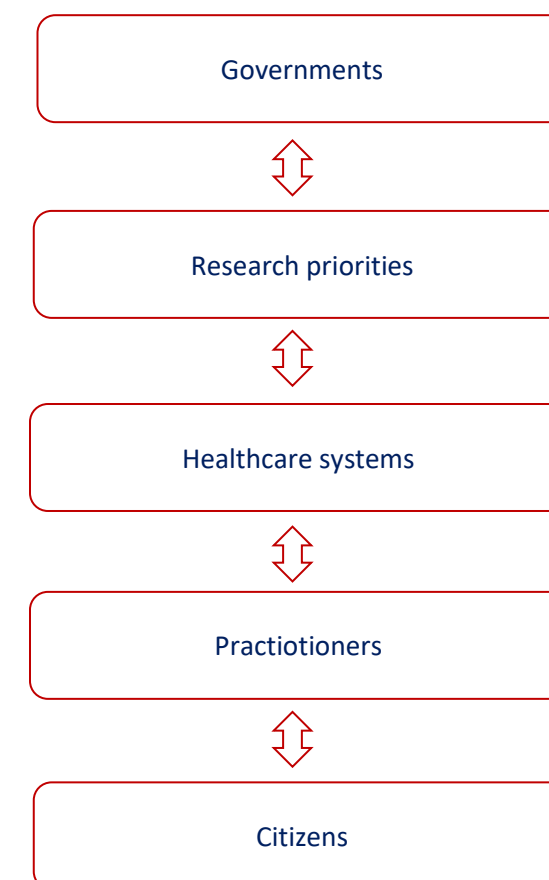### Research and clinical studies in PM

This WG's activities focus on translating basic clinical research and beyond, and on research funding.

In order for PM to reach its anticipated impact on human health and wellbeing, translation of discoveries and communication across the continuum of research is required. This starts with the integration of all '-omics' data to generate and implement meaningful interventions. Such processes should be supported by reclassifying diseases at the molecular level and by developing preclinical models to validate hypotheses resulting from molecular analyses. A Europe-wide process to evaluate and validate biomarkers, together with longitudinal and in- depth studies to further characterise diseases and their progression would support ongoing efforts towards this integration and re- classification. The development of new clinical trial designs that are adapted to these new approaches and the integration of preclinical testing with innovative clinical trials may further improve the effectiveness of interventions.
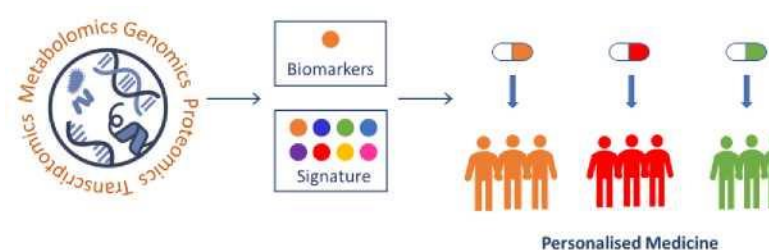
Collaborative pre-competitive and trans-disciplinary research and cross-sector collaborations need to be promoted and supported by suitable funding mechanisms, in order to truly bridge all steps of the PM research continuum.

PM requires integrated approach

Governments ⇕ Research priorities ⇕ Healthcare systems ⇕ Practiotioners ⇕ Citizens

Integrating China in the International Consortium for Personalised Medicine

IC2PerMed Roadmap

IC2PerMed actions

Based on the activities of WP1 and WP2, the IC2PerMed consortium developed a Roadmap which presents the main topics and priorities that emerged during the discussions held within the project. This document aims to propose, through the *actions* listed below, the items to deepen and promote alignment and creation of a common ground for European and Chinese collaborations on PM.

IMPROVING
EMPOWERED AND RESPONSIBLE CITIZENS

HEALTH LITERACY

Promoting health literacy is a prerequisite for better citizens' and patients' engagement and empowerment. Considering the emergence of digital technologies and the role of digital tools in supporting the engagement process, digital literacy should be improved. Given the advancement of genomics and the widespread use of preditive genetic/genomic testing, informing citizens and patients could provide them with greater awareness about their health trajectories. The impact of healthcare professionals' literacy should be considered, as they are a proxy for public engagement in self-management of

RESEARCH

Fostering needs-assessment research and communication activities in the field of citizens' and patients' education related to Personalised Medicine could lead to more effective empowerment.

PUBLIC TRUST

Scientific research, public organization and private institutions are key innovation actors in PM. Sustaining public trust and collaborations between different institutions, on a national and international scale, is the drive for healthcare transformation and public health promotion. In addition, public trust should be fostered and strengthened, in order to protect patients' rights, through clear data governance in accordance with the Helsinki Declaration and GDPR, implementing technical solutions to safeguard cyber security, citizens and health practitioner engagement, and developing comprehensive consent procedures where needed.

ETHICAL CHALLENGES

A strong set of values and ethical principles should be set, with a focus on the economic challenges and the inequality burden.

PROMOTING
TRAINED AND UP-TO-DATE HEALTHCARE WORKFORCE

EDUCATION & ETHICS

Improving healthcare professionals' literacy and expertise, valuing integrity and ethics, could help foster PM. Research aimed at identifying methods that are more effective should be promoted.

COLLABORATIONS

The future of healthcare professionals training relies on multidisciplinary collaborations. Fostering collaborations between professionals from different specialties and between professionals and stakeholders, while establishing more partnerships among countries, to facilitate sharing of best practice.

POLICIES

Healthcare professionals' literacy in Personalised Medicine is an emerging priority in national governmental strategies, policies and plans.
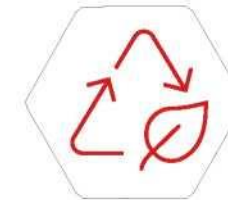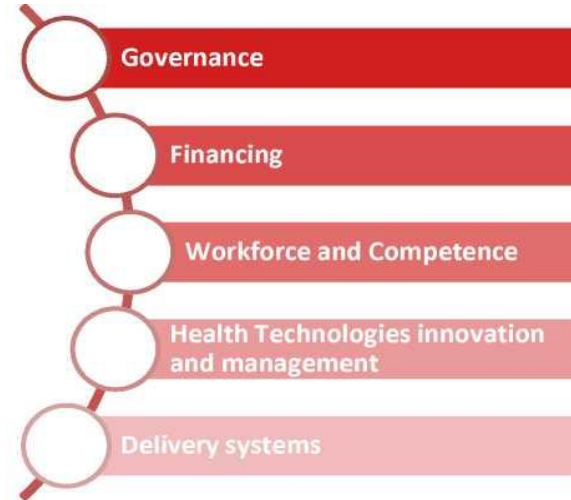
FOSTERING
HEALTHCARE SYSTEMS' SUSTAINABILITY

RESOURCES

A better allocation of resources on PM can foster the sustainability of health systems. In particular, the identification of a large investment stream for the long-term storage of data is a fundamental prerequisite for implementing PM strategies.
Investment priorities for product and process innovation should be defined, considering the relationship between results and costs, also by identifying new payment models for public reimbursement.

- Governance
- Financing
- Workforce and Competence
- Health Technologies innovation and management
- Delivery systems

ELSI & COSTS

Ethical, Legal and Social Implications (ELSI) aspects and related costs should always be considered in the process of Personalised Medicine policymaking, evaluation, and management of technological innovation.

EVALUATION

Health technologies are evolving rapidly and the translation of new discoveries underpins innovation and quality of care. Therefore, a system of continuous assessment of technologies and processes already in use and a change of perspective in Health Technology Assessment (HTA) is needed to integrate end-user perceptions into the whole innovation process. This would ensure greater effectiveness and usability.

Sustainable healthcare system
- Long-term strategic perspective & innovativeness
- Disease prevention & health promotion
- Quality
- Institutionalisation of environmental concerns
- Institutional accountability & personal responsibility

NETWORKS

Multidisciplinary and cross-sectoral collaborations for PM can promote the sustainability of health systems. Public-private partnerships and international networks should be valued for sharing experience, and for promoting and evaluating best practice and progress in PM.

Integrating China in the International Consortium for Personalised Medicine

IC2PerMed Roadmap

BRINGING
INNOVATION TO MARKET

COST EFFECTIVENESS

The application of personalised diagnostics and therapeutics should be geared towards lowering economic costs and barriers to market uptake. With regard to diagnostics, promoting research in PM aimed at a more appropriate use of diagnostic tools (avoiding overuse, overdiagnosis and overtreatment) could lead to an optimal use of resources in the field of prevention and consequently an increase in the value of healthcare. Health insurance providers should extend their coverage to innovative and high value PM solutions and reimbursement of services should be promoted or attempts should be made to reduce barriers to reimbursement. In implementation processes, economic, cost-effectiveness and relative value analyses should take into account both social and health budgets as well as non-optimal resource use in the system.

NEEDS ASSESSMENT

New solutions on the market must put the emphasis on maximising health outcomes for patients. An early, intensive, coordinated and continuous dialogue between all PM stakeholders involved is needed.

PRINCIPLES & GUIDELINES

The various PM actors should follow a set of shared principles and universal guidelines on data sharing and exchange. Innovations that aim for higher therapeutic value should be rewarded. Social value assessment should be systematically applied.

PERSPECTIVES

Stakeholders stimulating innovation should take a holistic and long-term perspective on the balance sheet. The interconnection and mutual dependence between diagnostic and therapeutic innovations and potential for inappropriate use/ overuse must be taken into account.

ADOPTING
### BIG DATA AND ICT SOLUTIONS

DATA EXCHANGE

To promote PM, Big Data needs to be analysable, comparable and interoperable across borders. The need emerges to carefully identify the type of information to be retained, increasingly favouring those related to health outcomes rather than information with no proven clinical or management value.. To facilitate data exchange procedures, greater cooperation between academia, healthcare systems (including providers and payers) and industry would be advisable.

PRIVACY, SECURITY & TRUST

Data security measures are a priority in the development of new ICT solutions, which are crucial at global level and not only focusing on high-income countries. Social and cultural differences between Europe and China should also be considered when it comes to public trust in government and state authorities, trying to reach a common understanding of shared challenges within PM. Public engagement can improve awareness and understanding of the benefits of data sharing, how data will be used beyond improving personal care, anonymisation procedures, privacy risks, data security, the involvement of private companies and protection options pertaining to personal data, and can help to develop frameworks that reflect broader societal consensus.
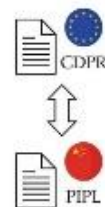
STANDARDS

In the field of PM, it is essential to study solutions aimed at effectively combining data from different sources (genetics, clinical data) and regions, focusing on their standardization for effective usage. Standards for data use should be adopted and implemented, also with a view to establishing common policies and global efforts for cross-border data sharing.

FOSTERING
RESEARCH FUNDING

PATIENT NEEDS
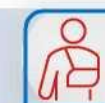
Funding agencies should tailor investments to the needs of patients. There is a need to promote the voice of patients (and caregivers) at all stages of PM research, from co-designing research projects to advisory roles and enhancing educational initiatives to improve the scientific literacy of patients and researchers. Defining unmet needs and potential incremental innovation could help in laying the groundwork for new international collaborations.
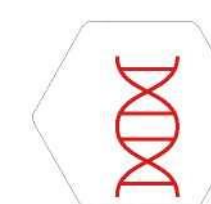
VALUE CHAIN

Investment plays an important role in the entire value chain and is needed from basic science to the implementation of PM in healthcare. Funders, both public and private, act as a first filter on the prioritisation of resource allocation, and this should be done responsibly. Furthermore, adequate investments are crucial in the research translation system.

SYNERGIES

Establishing synergies between funders and the research community is the first step in implementing PM as a community. Implementing the exchange of researchers through mobility funding programmes could promote collaboration and knowledge sharing between different countries and foster data sharing. Collaborations between funders should be established to align on research themes and to fund larger projects that are bold and cutting-edge, and enable risk sharing.

TRANSLATING
BASIC CLINICAL RESEARCH AND BEYOND

OMICS SCIENCE

Omics sciences are fundamental to the development of PM. Phenotyping patients, following defined standards, could identify similar patients. Besides genomics, applications of different omics sciences and technologies should be promoted and used for the identification of biomarkers suitable for PM. Innovative methods that have shown great promise in the field of PM, including the use of induced pluripotent stem cell and organ-on-chips models, should be evaluated and adopted, valuing international partnerships.

DATA & STANDARDS

Standardising approaches, including controlled access models for data sharing and clinical trials, may facilitate their implementation and help in patient stratification. Patient stratification in the field of non-genetic/complex diseases would benefit from research programmes on machine learning algorithms. Furthermore, using specific use cases from the fields of rare diseases and cancer could help in the development of common international standards and tools for research. Exchanges and dialogue between regulatory agencies should be promoted to overcome regulatory problems in PM, in particular on benefit-risk relationships.

COLLABORATIONS

To promote international collaborations, especially on oncological care and rare diseases, it is important to support non-profit foundations and funding agencies. Establishing incentives and frameworks for public-private collaboration can facilitate academic and industrial access to biological samples and data for research purposes. It is necessary to facilitate and strengthen the dialogue with regulatory and HTA agencies, companies and academic entities to gain a clear vision in terms of outcomes researched, and to identify the most appropriate research methods to investigate PM both ensuring patient safety and adapting to the characteristics of study populations.