Regions4PerMed

Interregional Coordination for a fast and deep uptake of Personalised Health

Regions4PerMed

Key Area 5: Tackling ethical, economical, legal and social aspects of Personalised Medicine

Report

HORIZON 2020

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DESCRIPTION

This report summarizes the content elaborated within the Interregional Conference and Workshop which took place online and in person in Siena in June 2022 and in Firenze in January 2023 respectively.

AUTHOR

Dr. Letizia Pontoriero (TLS)

CONTRIBUTORS

Claudia Mariut (TLS)
Gianni D'Errico (TLS)

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Abbreviations

CVD	Cardio Vascular Disease
EC	European Commission
EDI	Ethical, Diversity and Inclusion
EHDS	European Health Data Space
eHR	Electronic Health Record
GDPR	General Data Protection Regulation
GEP	Gender Equality plan
GWAS	Genome-Wide Association Study
HDAB	Health Data Access Body
HTA	Health Technology Assessment
KA	Key thematic Area

1. The project

The project Regions4PerMed, granted under the European Union Horizon 2020 Research and Innovation framework programme, aims to ease the implementation of Personalised Medicine (PM) in the European healthcare system supporting the shift from a reactive to preventive, personalised and predictive health system by leveraging the important role that regions play in Europe. The objectives of the project are in line with the European strategy launched in 2011 with the European Council Conclusions: "Towards modern, responsive and sustainable health systems" (2011/C 202/04).

Through PM, a shift is possible from the 'one size fits all' approach to the treatment and care of patients, focusing on the reaction to a condition, to one based on personalisation and prevention, using emergent technologies such as diagnostic tests, functional genomic technologies, and molecular pathway profiling to better manage patients' health and employ target therapies.

The current challenge for national and regional authorities is to implement this shift from a reactive healthcare system based on episodic and acute care models to a Personalised Health (PH) system that uses preventive and predictive measures, where risk is predicted using cutting-edge technologies before symptoms appear.

On the one hand, PH is paving the way toward better and more efficient patient care. On the other, however, there is a lack of cooperation at regional, interregional, intergovernmental level to coordinate and organise a response to the needs of PH and PM in terms of legislation and investments.

2. Rationale of the Key Thematic Area 5: "Tackling ethical, economical, legal and social aspects of Personalised Medicine"

According to the definition adopted in 2014 by the Horizon 2020 Advisory Group, the term Personalised Medicine (PM) refers to "a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".

The definition has also been adopted by the European Council Conclusion in 2015 on PM for patients, which specified that "Personalised medicine relates to the broader concept of patient-centered care, which takes into account that, in general, healthcare systems need to better respond to patient needs" (2015/C 421/03).

Nowadays this approach is increasingly a reality in medical practice thanks to the constant evolution of novel technologies and devices, even more sophisticated, which made possible to zoom into more accurate medical details and to tailor specific approaches with a real "person-centric" vision.

There is no doubt about the importance of implementing PM in clinical practice to create a healthcare ecosystem that is truly able to focus on the individual. The benefits for the individual are indeed reflected in society as prevention or patient-friendly strategies reduce costs both in terms of money and time.

However, while different countries are introducing whole genome sequencing and personalised medicine approaches into clinical care (i.e. the United Kingdom's National Health Service plan to sequence 5 million genomes in 5 years and France and Canada which, at various stages, are kicking off publicly funded genomic healthcare services), the awareness

about the ethical, economic, legal and social implication of PM are becoming central in the public discourse.

The KA5 was then conceived to tackle the socio-economic and ethical aspects linked to the development and implementation of PM in the healthcare system, with a focus on the regional level. In particular, the thematic Area addressed Ethics, Public trust, the Economic value of PM, Diversity and inclusion in PM and the issue of Sex and gender in PM.

3. Rationale of the KA5 Conference

***Figure 1**: KA 5 CONFERENCE BANNER*

3.1 Objective of the KA5 Conference

The aim of the conference was to enable a structured exchange among European regional Experts and Key Opinion Leaders on the main challenges related to ethical and socio-economic aspects also providing guidance for future policy developments. The outcome was to have a detailed overview of the Socio-economic barriers that hinder the implementation of PM in Europe and beyond. The outcomes of the conference lays also the groundwork for the thematic workshop.

***Figure 2**: FONDAZIONE TOSCANA LIFE SCIENCES AUDITORIUM*

The KA5 Conference took place on **June 27th - 28th 2022** in the Auditorium of Fondazione Toscana Life Sciences (TLS), the KA5 Leader

CONFERENCE

https://www.youtube.com/watch?v=rAuTtu0fi-Y&list=PLzJdPX0cqYa3n38DIYR6zd50_1zHfnn0i&index=2&ab_channel=ToscanaLifeSciences

IN-SITU VISITS

https://www.youtube.com/watch?v=BXyeDI4OD1M&list=PLzJdPX0cqYa3n38DIYR6zd50_1zHfnn0i&index=3&ab_channel=ToscanaLifeSciences

3.2 Sessions

3.2.1 Ethical Aspects

In recent years, legal and ethical challenges for PM have been linked to data collection, access, and sharing, well described by the motto "as open as possible and as closed as necessary". The Covid-19 pandemic has shown even more how difficult it is to transfer data (from member states to regions and even among regions within the same country) due to the fact that ethical and legal frameworks are currently non-harmonised, creating fragmentation.

The integration of basic research and clinical practice that underpins PM, which have historically been kept distinct, raising questions about which ethical principles should govern this practice: those of clinical care or those of research?

PM entails collection of data at research and clinical level, nevertheless the data collected from clinical settings and research settings are governed by two different ethical frameworks. While the doctor-patient relation is based on privacy and confidentiality, researchers need to share data as much as possible and as fast as possible to validate and disseminate their findings within the research community.

The current ethic challenges identified can be summarised as follows:

- Enabling data sharing while protecting patients' interest (de-identification, right not to know)
- Based on genetic information it is possible to re-identify patients with a combination of a surname and other types of metadata, such as age and state
- Return of genomic results/raw data
- Informed consent model & patients' self determination
- Educating and empowering patients, doctors and public about precision medicine.

Given this context, an approach to follow is based on three key aspects to respect the current ethic principles:

- Address the risk of de-identification in the patient consent form
- Set up a comprehensive data protection concept for genomic data (as very well described in the position paper titled: *"Cornerstone for an ethically and legally informed of whole genome sequencing"* (by Winkler et al., 2016)
- Raising awareness through the organisational codes of conduct.

Research results should be returned if there is a net benefit for the patient and/or study participants, as pointed out in the *"position statement on the release of raw genomic data to patients and study participants"* (by Winkler at. Al, 2019):

In this context, open challenges to tackle at national and regional level are:

- The implementation of appropriate risk communication for de-identification at regional, national and European level
- The development and application of a code of conduct for releasing results to study participants and make sure that appropriate genomic counselling strategies are in place
- The patient consent for sharing genomic data need to be developed and other legal bases for doing so need to be explored (i.e. data donation etc.)
- The patients' and citizens' participation remains crucial as research partners and release policies for raw data need to be in place and IC language need to be adopted.

At policy level, the European Parliament and the European Commission are tackling the challenge through the forthcoming European Health Data Space (EHDS). The new regulation will provide rules, common standards and practices, infrastructures and governance framework for the data use for healthcare, research innovation and policy. The EHDS is based on the concept of empowering the individual (patient and citizen) to access and control their personal health data.

The EHDS regulation is flanked by other policy actions such as the European Health Union, the Data Governance Act, the EU Cybersecurity Framework (Network and Information Security,

NIS directive), the Artificial Intelligence Act and Medical Device Regulation, whose full impact remains to be assessed.

Regions need to look forward and ahead in order to adapt and thrive in research and care.

3.2.2. Public trust

While public engagement and lay communication about PM is essential for broadening the debate and engaging citizens, several issues with this remain, such as the oversimplification of new scientific discoveries and their implications on human health, the difficulty of addressing the broad public rather than specific subgroups, and the risk of adopting a one-way communication model when experts educate the lay public (Marie Gaille, Ruth Horn & The UK-FR GENE Consortia 2021). Effective communication of the PM approach is of paramount importance to avoid resistances in implementing it within clinical routine. Together with its benefits, new risks, obligations for participants and even new conceptions of the role of the patient are emerging and need to be properly addressed.

PM moves beyond treating onset illnesses towards a "multilayer characterisation of individuals" (Eyal et al. 2019). To date, the main challenges arising from the introduction of PM to the clinic are already evident: the predictive aspect of genetic testing can create "patients-in-waiting" (Timmermans and Buchbinder 2010) and generate inequalities and discriminations. Furthermore, PM may change the traditional role of the general physicians as entrance door of healthcare and health information, and new players are being introduced to manage the 'datafication' of healthcare (Prainsack 2017).

PM can also create "new patterns of exclusion" in groups which cannot, or will not, participate in the datafication wave (see below) (Prainsack 2017).

As PM entails a shift in expertise and knowledge in medicines away from tools that helps doctors to do their job, towards tools that carry more informative ways on how medicine and treatments take place in practice, PM requires their trust in contributing data interactively.

PM also entails a close collaboration between public and private sectors, carrying out discussions on who controls, owns and gains from patients' data or patients' bodies.

The key points to work to ease the implementation of PM are:

- Public trust is complex and requires long term, bottom-up work at regional, national and international levels: studies are needed to document and analyse contextual factors in public trust and public acceptance of certain activities adapting it to the national and local dimension. There are issues that are intersectional and also questions that are related to the history of certain citizen groups.
- Two-way involvement of and engagement with the public is crucial in finding mutually beneficial solutions. Patients and the public should co-create PM solutions, including co-producing the definition of what benefits of PM means.
- Public trust in PM should be considered in conjunction with general questions of public trust in science, medicine and wider institutions like Governments; public trust in PM does not develop in isolation.
- It is useful to think in terms of trustworthy practices - what does it mean to act in a way that could be trusted, for example, transparency.

Building public trust in PM also needs to acknowledge and fairly address psychological and psychosocial aspect of patients specificaly: most of the time the failure of a therapy does not depend on the quality of a treatment but on the patient's behaviour (i.e., non-adherence and non-compliance). Patient and citizen behaviour is therefore the rate-limiting step between healthcare innovation and optimal health gains.

While work to develop trust in PM and wider institutions can happen at a general level, understanding the attitudes and behaviours of specific, relevant patients is also crucial to the success of PM. The attention to the determinants of people behaviour is, however, still sub-optimal (i.e. motivations, trust, etc.). This is leading many scientists to consider the inclusion psychosocial aspects (or person omics) in the PM pathway: every patient has different illness perceptions, resilience, resources and believes about medicine. These aspects reverberate on families, society and healthcare systems.

The behavioural dimension is also extremely important for many diseases (like cardiovascular diseases) where psychological factors are strong determinants of the health status.

The following actions could be undertaken to ease the implementation of PM:

- Promoting a virtuous network of stakeholders to achieve a deeper PM approach from both a clinical and a psychosocial perspective.
- Collecting aggregated data to contribute to a broader understanding of patients' needs and values and, consequently, to a constantly evolving healthcare policy at a macro-population health level.
- Integrating psychosocial and societal issues in the preclinical curriculum to teach students that these contents are as important for patient care as the basic sciences. This approach would not only improves patient satisfaction or contributes to the positive perception of medical practice, but it also contributes to identifying the correct diagnosis and optimal treatment for the individual patient.

3.2.3. The economic value of Personalised Medicine

The last quarter of the past century was dominated by the economic reasoning and scientific management, and this can be certainly considered a mistake, considering that the optimisation of one dimension generates other imbalances as we live is multidimensional and interconnected environment, especially when it comes health which is even more multidimensional than any other human needs.

Economics has been established as a concept for allocation of limited resources. But the economy has another objective: getting more answers with the same resources: the positive aspects of good management and good economic behaviour are raising opportunities for humankind.

The positive of good management, on the other hand, means increasing opportunity for humankind.

As PM is developed and implemented in clinical practice, there is an increasing need to assess its value for citizens and healthcare. There is debate and uncertainty on whether PM provides economic value and how to balance the need for new technologies with affordability and overall sustainability of healthcare systems. If, on one side, genomics has the potential to reduce costs by ensuring that the most effective treatment is used for the most appropriate patients, decision makers and stakeholders need information on which approach provides relatively higher value in order to make appropriate investment decisions.

In many countries, economic evaluation is being used as a practical tool for making decisions about the introduction and implementation of health technologies. Therefore, Economic evaluation requires data on health outcomes and resource utilization associated with a technology to be combined in an analytical model to calculate the typical cost per life year or quality-adjusted life year (QALY) gained.

In a more technology-fcused analysis, recent studies on health economics are proving the value of PM. For example, the only HEcoPerMed project[1], reviewed 4774 studies, selected 128 studies and provided cost-effectiveness data for 279 PM interventions.

When PM is discussed, usually early diagnosis, genomics, therapies, post-acute rehabilitation is meant. However, PM is a wider concept that focusses on care that includes chronicity, disability, fragility conditions. It has a positive impact on the patients and their family or care giver.

When it comes to the role of regions in PM, they are capable of:

- Designing flexible delivery organisations that extend beyond conventional hospital service
- Promoting interdisciplinary teams that are needed to integrate specialized knowledge and competences
- Adopting a new reimbursement system based on "payment for performance (outcome)"
- Introducing new accounting systems for treatments that in general have high unit cost and reduction of cost for future years.
- Lifelong learning programs to change the patients' approach by professionals.

[1] *https://hecopermed.eu/*

3.2.4. Diversity, Inclusion and Personalised Medicine

How can we optimise a future where everyone can equally and equitably benefit the society?

Currently the ZIP code impacts health outcomes than the genetic code: This is largely due to the nature of the communities people reside in, such as whether they are wealthy, whether or not there is strong community investment, and whether hospitals and health centers are present, among others. Social and built environment determines your individual health and community health, above personal behavior and clinical care.

Thinking about moving towards in PM, social determinants of health need to be better understood and addressed in both healthcare systems and research & clinical research systems.

In fact, while PM marks new opportunities for healthcare, the participation of individuals of non-European ancestry remains low in many of the European and North American initiatives. Increasing the participation of under-represented populations in genomic studies is challenging and requires a long-term effort. Diversity should be kept at the forefront in designing and implementing studies from the beginning to the end, through a more inclusive approach. The participation of minority groups is of utmost importance as it has significant scientific implications and is essential to guarantee equal access to healthcare services for all. In consideration of the great number of PM initiatives carried out at the regional level in Europe, these stakeholders need to be aware and engaged in order to co-create and implement new policies and standards.

Reference research databases suffer from long standing biases because of the under representation of genomes across ancestral backgrounds. The vast majority of genetic information that is currently used to interpret diseases comes from people with a European ancestry (86% in 2021).

The biases persist in the access to healthcare, which is much lower in minorities, underserved and racialised individuals. Medical textbooks usually present phenotypic information using pictures of European descendant people. There is research confirming that health providers are much less likely to suspect a genetic condition in a family that is non-European, so that these might have less access to personalised

treatment, leading to higher mortality rates.

Citizens that are recruited for research come from clinics, but they are not representative specimens of society, reverberating biases in the whole treatment value chain.

There is a need to invest in diversity, inclusivity and equity. It is necessary to increase competence in cultural norms and to give priority to all the communities that need to be included in studies. How can this be done?

Implement Ethical, Diversity and Inclusion [EDI] by design is strongly advised: increase the participation of the whole society in data, precision care and governance. The core principles are transparency, inclusivity, cultural competency and partnerships.

One potential way to operationalise these changes are digital tools which have been proven to expand access to diverse and underserved communities, enhancing health literacy and promoting equitable participation and participation in the decision-making governance.

Genetics, science, technology, and society as a whole need to improve diversity.

The number of participants in genomic studies has massively increased. The goal of diverse data initiative at Genomics England is to reduce health inequalities in genomic medicine, by:

- Building and sustaining trust.
- Driving more and better research.
- Improving clinical care (diagnosis, prognosis and treatment).

Inequalities may arise from the way we phrase questions, the data we use, the study designs, the analytics we use, the way we monitor the impact, the broader context.

At the individual level, genetic biases can be misleading. For instance, benign genomic variation may be overinterpreted as disease-causing. Variations whose significance remains uncertain are likely to be detected; with genomics taking priority over real health needs.

At the group level, the reliance on large datasets to drive the decisions is increasing. If these datasets are dominated by

information from people with European ancestry, it means that entire ecosystems are based on these misrepresented datasets (i.e. skin cancer database) and thus become skewed.

In addition, recent ethic research has pointed out that ethic systems very often prioritize the individual autonomy over community benefits and harms.

When exploring the fields of identity, ethnicity race and ancestry in PM, genetic makeup needs to be coupled up with social aspects. One of those big questions is the relation between race, ethnicity and ancestry. These terms are NOT interchangeable. Race and ethnicity can have a more critical impact than simply influencing which box a person tick on a form. They also become the basis for what Ruth Wilson Gilmore refers to as **"group-differentiated vulnerability to premature death".** *(Golden gulag: Prisons, surplus, crisis, and opposition in globalizing California, 2007)*

Words convey a meaning and a perception of reality, and therefore lots of efforts even in genomic medicine are channeled into language toolkits for genomic data diversity (like the one developed by Genomics England).

Other efforts to reduce/eliminate biases in genomics and PM are devoted to:

- The creation/adoption of contextual (privacy-preserving) data models that respect/reflect diversity.
- The adoption of a culture of transparency, reflection and learning (*cultural humility*), through constant dissemination of information and participation/ speeches at public events.
- The building of relationships with other projects/ groups in order to incorporate data ethics practices into everyday operations.
- The monitoring of relevant equality, diversity and inclusion statistics.

3.2.5. Sex, Gender and Personalised Medicine

While sex refers to biological differences (biological characteristics in terms of reproductive organs and functions based on chromosomal complement and physiology), gender is related to social and cultural factors - it refers to cultural values and social attitudes that together shape and sanction "feminine" and "masculine" behaviors and also affects products, technologies, environments, and knowledge. Gender is a factor causing inequality in life duration since birth, and this inequality increases during life and influences different risk factors, lifestyle and life conditions. Sex and gender are an unmodified risk factor of numerous non-communicable diseases, Cardio Vascular Diseases (CVD), and cancer above all. Additional risk factors connected with lifestyle are increasingly being taken into account in combination with gender impact on the latter.

The role that sex and gender play in personalised medical care needs to be further assessed. As pointed out in multiple studies (Ewelina Biskup et al, Sex, Gender and Precision Medicine, 2020; Bartz et al., Clinical Advances in Sex- and Gender-Informed Medicine to Improve the Health of All. A Review, 2020), there are critical barriers to put sex and gender at the center of PM.

Sex- and gender-informed approaches to care are founded on community standards appropriately representing biological sex and the complex sociocultural construct of gender.

Over the last decades and especially in the last few years, gender medicine (or gender-specific medicine) has become a major driver in medical research, but although more research is available, significant shortcomings remain.

Gender norms, attitudes about what behaviors, preferences, products, professions or knowledge are appropriate for women, men and gender-diverse individuals:

- are (re)produced through social institutions (i.e. families, schools, workplaces, laboratories, universities, boardrooms, etc.) and wider cultural products (i.e. textbooks, literature, films, video games, etc.).
- may influence the development of products and technologies.
- draw upon and reinforce gender stereotypes, which are widely held, idealized beliefs about women, men and gender-diverse individuals, femininities and masculinities.
- are constantly in flux.

Within the research community, sex and gender are a dynamic concept which puts researchers at the forefront of questioning gender norms and stereotypes and addresses the evolving needs and social roles of women, men and gender diverse.

The lack of consideration of sex and gender characteristics in health science has often led to misdiagnosis and lower health outcomes for patients and citizens. In CVD, for example, sex differences are recognized, but sexual dimorphism is neglected in clinical trial design, pointing to an urgent need **to analyse data by sex rather than adjusted for sex.**

Most research is done in males. Although this is slightly changing thanks to research funding organisations which are supporting the inclusion of the gender dimension in research, a 2020 study shows how only 18% of all the Covid-19 related clinical trials presented sex disaggregated data.

In order to reduce, and eventually eliminate, sex and gender biases we need to overcome three main barriers:

1. Lack of sex and gender disaggregated data
2. Doubling the sample size or changing the design of clinical trials.
3. Included a reporting methodology on sex and gender within all the phases of research.

3.3 Main outcomes

During the KA5 conference the experts highlighted important areas of development that scientific community and policy makers need to address in order to fully implement the paradigm of PM without generating inequity and biases for patients and citizens.

For the ethical part, policies need to further develop in order to properly balance fundamental aspects in research and clinical practice (access to data to refine research and produce more knowledge on one side, while guaranteeing safety and privacy of the subjects and study participants which provide the data on the other side). The current European regulation on data privacy [GDPR] seems no longer adequate and the forthcoming EHDS (currently under discussion at the EU Parliament), need to be further assessed.

Public Trust towards PM and health research in general need to be reinforced with specific studies and initiatives. Transparency of the process needs to be established by design and in a cross-sectorial way, acknowledging local, national and regional contexts, as it represents a prerequisite for public trust to be built around PM.

More health economic research should be produced to validate new PM approach (therapies and diagnostics) while regional and national authorities should adopt a new reimbursement system based on «payment for performance (outcome)» and introduce new accounting system for treatments that in general have high unit cost and reduction of cost in future years.

The data we use, might be biased as very different levels, and we do not tackle these biases inequality happen in access to care.

4. Rationale of the KA5 Workshop

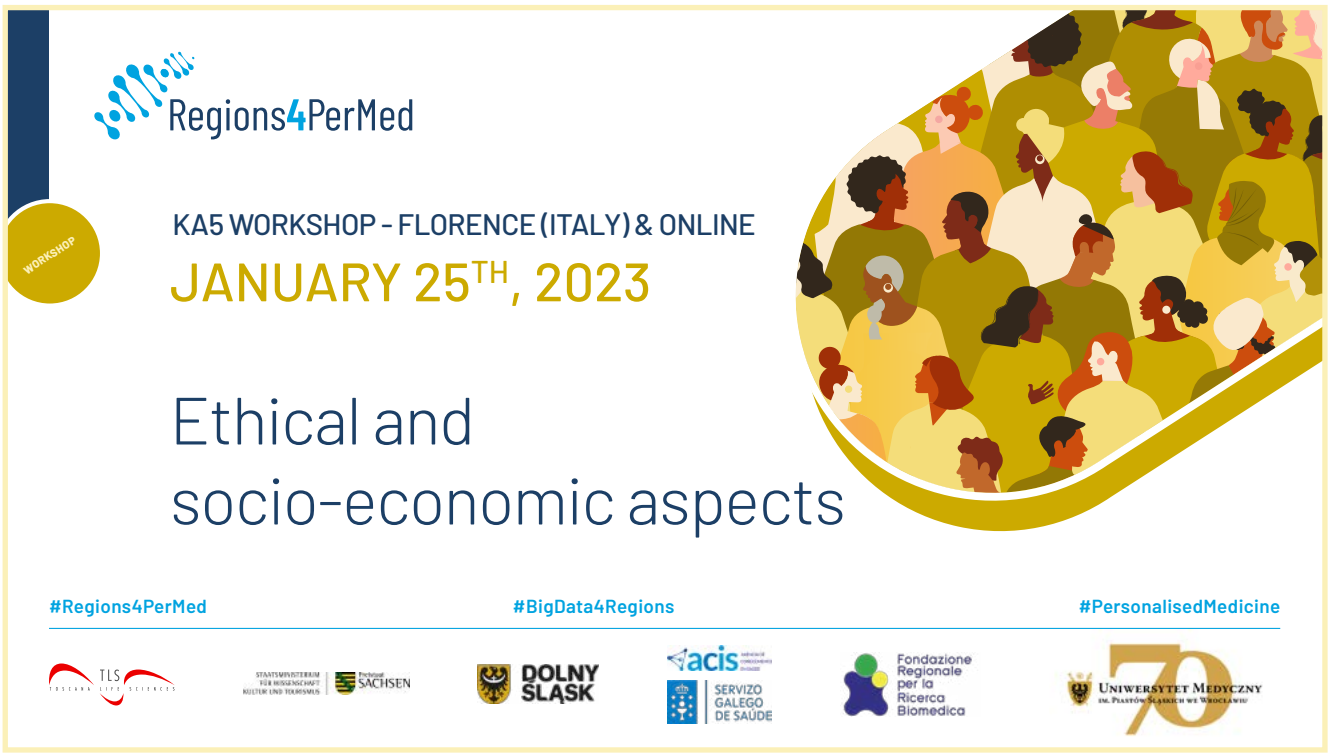

Figure 3: *KA 5 WORKSHOP BANNER*

4.1 Objective of the KA5 Workshop

The aim of the workshop was to exploit the main outcomes of the conference to investigate on the ethical, social ed economics implications of the implementation of PM at regional level and what can hamper this process. The goal is to provide concrete solutions in the form of good practice and key policy initiatives to drawn-up recommendations thanks to the involvement of session chairs and an Expert panel.

The introduction of the expert panel in the workshop represents a novelty in the structure of the Regions4PerMed and has been included to help leading the discussion and formulating better recommendations.

Taking into account the broader spectrum of topics related to the KA5 Thematic, we recruited professionals from different fields (genomics, regional policy makers, social scientists, clinicians etc etc) to create an ad-hoc group of experts with specific background to better address the aspect we were targeting.

The expert panel was involved in all the 5 sessions where the members were invited to discuss on the aspects emerged from the presentation of the topics conducted by the chairs and based on the outcomes from the previous Conference.

The chairs, selected according to the same criteria, were invited to particularly focus on feeding and stimulate the discussion.

Each presentation was prepared before the workshop and lasted no longer than 15/20 minutes and the remaining time (about 40 minutes) was dedicated to the debates. The aim was to prioritize hands-on interaction between the experts and participant stakeholders, rather than a lecture-style approach in a way to co-create key recommendations to collect and spread as outcome of the KA5 Workshop. To facilitate this, the event was designed with a unique roundtable setup. The goal was to create an effective environment for small break-out sessions that would enable the shaping of recommendations and best practices, as the consortium aimed to gather them for the Final report that will be presented to the EC.

To allow all stakeholders to prepare for the event, the recordings of some parts of the KA5 conference on "Tackling social, economic and ethical aspects of Personalised Medicine" were published online on YouTube channel and the corresponding links were distributed via social media as part of the event dissemination.

Additionally, we also thought to improve the interaction between online and in-presence participants using the online platform, Mentimeter. Mentimeter allows the creation of interactive presentations, which include polls and opened answers. Audience members can then participate, whether in the room or online, by using their laptop or smartphone and a dedicate link or a personalized QR code. This interactive tool provided immediacy in interactions, especially for online audience members who would otherwise only have the streaming platform's chat space to interact.

The chairs were invited to include Mentimeter slides within their presentations and present through Mentimeter. A special conference plan was obtained from Mentimeter to manage all the presentations from within the online platform.

The sessions were chaired by:

- **Dr Luca Marelli**, Department of Medical Biotechnologies and Translational Medicine, Università degli studi di Milano (Italy)
- **Dr David Wyatt**, King's College London, London (United Kingdom)
- **Dr Rositsa Koleva-Kolarova**, Health Economics Research Centre, HECO PerMed Project, Oxford (United Kingdom)
- **Diksha Srivastava**, Genomics England, London (United Kingdom)
- **Prof Susanna Chiocca**, European Institute of Oncology IRCCS (IEO), Milano (Italy)

***Figure 4**: Workshop venue*

The Experts Panel was composed by:

- **Dr Anna Lundgren**, Senior Research Fellow, Nordregio (Sweden)
- **Dr Marc Pattinson**, Thematic Expert Research and innovation, Interreg Europe Policy Learning Platform
- **Prof Martin Henriksson**, Associate professor, Department of Health, Medicine and Caring Sciences (HMV), Division of Society and Health (Sweden)
- **Dr Matthias Wienroth**, VC Senior Fellow, Northumbria University, (United Kingdom)
- **Dr Gabrielle Samuel**, Senior Research Fellow in the CELS-Oxford research group, and research fellow for the Ethics Advisory Committee of UK Biobank, (United Kingdom)
- **Paola Bello**, European Funding Officer, Gender Equality Coordinator, Fondazione Regionale per la Ricerca Biomedica, (Italy)
- **Prof Donata Kurpas**, Wroclaw Medical University, (Poland)
- **Dorota Stefanicka-Wojtas**, Clinical Research Coordinator, Wroclaw Medical University, (Poland)
- **Marta Duda-Sikula**, MBA, Director of the University Clinical Research Support Center, Wroclaw Medical University, (Poland)
- **Dr Eva Maria Stageman**, Policy Officer, SMWK - Sächsisches Staatsministerium für Wissenschaft, Kultur und Tourismus, (Germany)

4.2 Sessions

4.2.1 Ethical Aspects

The session was chaired by **Dr Luca Marelli**. He oriented the debate to a critical overview on the EHDS, currently under discussion at the European Parliament, as it could represent a game changer from the regulatory point of view in advancing PM implementation. He analysed most of the critical challenges of the current proposal pointing out on the likely outcomes. Once implemented, the EHDS will really became the technical overarching and regulatory instrument, shaping data access across and possibly beyond Europe.

The broad technical and legal framework of EHDS is linked to some critical entangled challenges that could be grouped in:

- legal misalignment and fragmentation,
- lack of robust governance and political legitimacy,
- barriers to implementation,
- issues on secondary use of data.

The coordination in legislation is lacking both from European and national point of view so it is clear how the action also from a regional level could speed up the necessary processes to overcome fragmentation. Further, this inhomogeneity often results in confusion and is reflected in diminished protection afforded to data subjects' rights on varied levels.

An example of legal disalignment is the Waiver to provision of individual-level information that is in contrast with the logical of article 14 of GDPR which, instead, mandates its.

There are, then, tensions with research ethics standards because EHDS is possibly hindering the withdrawal of consent and the opting out of research will no longer be possible. Last but not least, there's an increasing balancing between citizen's control of data and the aspirations of the data space which impact also public trust.

Some of the major concerns are linked to the lack of robust governance mechanisms which should be necessary to assure the legitimacy accountability of the processes imposed by the EHDS proposal. In order to overcome the problem, the Health Data Access Bodies (HDABs) were introduced and should be introduced by all the member states of EU. These entities are conceived to act as ethical committees and manage the secondary use of data, nevertheless their precise role is still not cleared and it is obscure how an ethical use of such data can be ensured. The ethics bodies' role, further, is not specified their eventual part and if they must deal with HDABs. It should not be forgotten also that many definitions are too broad or in contrast with well defined notions, generating

confusion without sufficient effort to correctly safeguard the use of data, particularly in the context of their secondary use. The kind of implementation difficulties that would come for institution like Italy makes to much uncertain on the local role of these boards, particularly in the regional context as, if it goes forward, it will generate lot of responsibilities for regional actors to really put in place a proper infrastructure.

Different actions were proposed but this seems insufficient to ensure that research and innovation are geared to the public good. In particular, they address how this public value is going to be generated within the contribution of EHDS. The purpose to facilitate access to data put the light on an additional issue as the large access EHDS ensures for the reuse of data make it largely accessible also to Big Tech. Albeit corporation are compliant with different criteria, in the long run, it is going to potentially create a gradual detrimental effect on public European health system for the ever-increasing dependence on privately owned research infrastructures. It is worth noting this might jeopardise the fundament of public healthcare and, as a consequence, the more immediate question to address is "how value generation from the EHDS will flow back to the public sector?"

Before EHDS proposal, during the first year of the project, it emerged that one of the role of Regions should be to centralise standardized and homogenised Health Record databases to be able to strengthen governance on this area and then open the doors of collaboration with big companies, acquiring a major control to the access of those data. This is mainly a lack of Italian governance as other EU country as Sweden, Norway have national infrastructure in place while we miss this "central bodies" which could facilitate use and reuse of data.

There is still the invitation to Italy to invest on this missing infrastructure. Action in this direction is now more urgent than ever. Especially in Countries with a decentralized healthcare system, Regions have to put themselves in the position to negotiate with private actors.

The heathcare system is differently organised in the European countries (as shown *here*) and this has a strong implication in the way Regions can concretely act.

Thus it is pivotal to allign the organisations who are responsible of the ethical and socio-economic aspects of PM, allowing them to communicate and act jointly, irrespective of who they are and at what levels they are operating (national, regional, local).

There are different models that can be explored: a fee-system based on economic capacities and the outcomes of their use of data, or "no-money" payments such sharing of outcomes of

their private research are two among plenty. This should lead regional system to adopt, for instance, free of charge medical devices which have been developed thorugh access to regional data platforms.

It also appears necessary to reflect on how to also ensure the culture of data for people who, for different reasons such as age or social class, can't have benefiting from EHDS because they miss the tools to access and consult it, leading to the paradox to make inaccessible the envisaged benefits of the EHDS to the people who could really benefit from it, with no equitable return.

It is worth noting the importance of the economic value of data, especially for the reassessment of PM, so it is necessary to define the necessity to involve the public in the process to make them more aware on the benefits but also different stakeholder communities, ethics researchers, ultimately will lead on the building of public trust.

Concerning the implementation, interoperability and lack of standards persist as the major problems together with standardization issues for the feeds of data from medical doctors, whose role would be central for steering medical information to the EHDS, the dealing with "digital dissident" and the necessity to implement infrastructures with an important time-consuming consequence. All the raised issues are strongly constrained by the inhomogeneity of policies at national level leading to the necessity of centralization of competence in health domain. Configuring the problem from an Italian perspective, the misalignment of health care at the national level immediately emerges, as this is managed locally by the Regions while in France is the opposite. This misalignment specifically emerges in Europe while, in parallel, it is not a matter of fact for competitors such as China and US. This is probably due by cultural differences, for instance the approach of US to data protection is less centralized, and there are currently no federal data protection laws that regulate the collection and processing of personal data. It is more oriented to share personal data for commercial reasons, overshadowing the importance of privacy. The process of alignment between the respective regulations is not immediate and would raise additional issues especially in the context where "European" data are treated by non-EU stakeholders. There is a danger of a clash between the two different system ideologies.

It is thus relevant to identify the correct way to avoid Big Tech draw out data, without assuring the holder on the purpose of their use.

Last but not least, Public-private partnerships (PPPs) can

be ineffective or inefficient for healthcare development for several reasons. PPPs can be complex to manage, with bureaucratic hurdles that reduce the efficiency. Issues of accountability and transparency can arise, and, in addition, there may be a misalignment of goals between public and private entities, with the former focusing on equitable access to healthcare and the latter being primarily motivated by profits.

Position papers have been published to highlight most of the discussed points, and they are surely starting points to shape counterproposals by research community to fill the gaps derived by EHDS.

A key message is that the various actors involved in the proposal have now a role to play by fostering trajectory to face the issues raised by the proposal. Time is right to addressing the bottleneck of the proposal.

Public-private partnerships (PPPs) can be ineffective or inefficient for healthcare development for several reasons. Firstly, there may be a misalignment of goals between public and private entities, with the former focusing on equitable access to healthcare and the latter being primarily motivated by profits. Secondly, PPPs can be complex to manage, with communication breakdowns, delays, and bureaucratic hurdles reducing efficiency. Thirdly, issues of accountability and transparency can arise, as private entities may be less accountable to the public and less transparent in their operations. Finally, PPPs can be vulnerable to the financial stability of private entities, and discontinuities in healthcare provision may result. However, effective PPPs can be established through clear role definition, open communication and collaboration, and ensuring accountability and transparency.

Recommendations

- Promote communication and alignment programmes of local, regional and national level organisation
- Invest in centralized, qualitative, interoperable health data infrastructures
- Promote benefit-sharing policies between public and private entities
- Endorse federated data mechanisms
- Strong data governance should be in place to avoid misuses and data leaks.
- For what concerns the EHDS, Strict/Precise/Articulated definitions on the role of ethical committee and Health Data Access bodies should be developed
- Established clear role definition, open communication and collaboration, and Ensuring accountability and transparency to make PPPs more effective

4.2.2 Public Trust

The session was chaired by **Dr David Wyatt** and started defining the concept of public trust in PM together with a recap on the key point gathered from the KA5 Conference.

Talking on public trust in PM refers to a whole health ecosystem. It is not only related to the development and implementation of PH solutions and clinical practice per se. It is asking patients to buy into a particular vision of future medicine, accept the promise of PM and its implementation into clinical pathways. In this sense, the public are being asked to trust numerous different research, clinical and governmental organizations, as well as individual clinicians and members of multidisciplinary teams when PM solutions are offered to a patient in the clinic. On the macro level, public trust cannot be separated from public trust in medicine and science, but on a meso and micro level, key factors that can influence public trust include level of transparency, open communication with patients and the general public about the use of secure and ethical data sharing practices, implementation of rigorous standards for safety and efficacy around the protection of patient data and clear acknowledgment of the benefits and limitations of PM, both in the short and long term. Gaining public trust is an ongoing process that must be continuously developed and maintained, Education is important in this. This means not only giving patients the knowledge and tools to assess PM for themselves, but providing clinicians with the knowledge and training to articulate what PM is, how it works in the patients specific case, the benefits of PM and any limitations. It would be useful to gather information on patients' needs, attitudes to PM and values, from institutions across Europe, which can then be analyzed to identify regional, and national differences.

A key question when thinking about public trust is *who* are we asking the public to trust (institutions, clinicians, scientific knowledge). Similarly, when thinking about trust, it is useful to think in terms of trustworthiness - how trustworthy are PM processes (as a starting point for public trust), and what actions does being trustworthy involve? In addition, it is crucial to consider that although 'public' is often referred to as a singular entity, it is very heterogeneous so it should be more appropriate to refer to "publics". In this frame, it is not easy to deal with heterogeneity as an one-fit model doesn't work, thus it is important to understand how to identify and articulate the mutual benefits of PM and address the varying concerns of diverse groups.

To trigger a common refection and giving a taste of this variety of issues at play, Dr Wyatt starts the first interactive session asking to the audience what words spring to mind when thinking about public trust in PM.

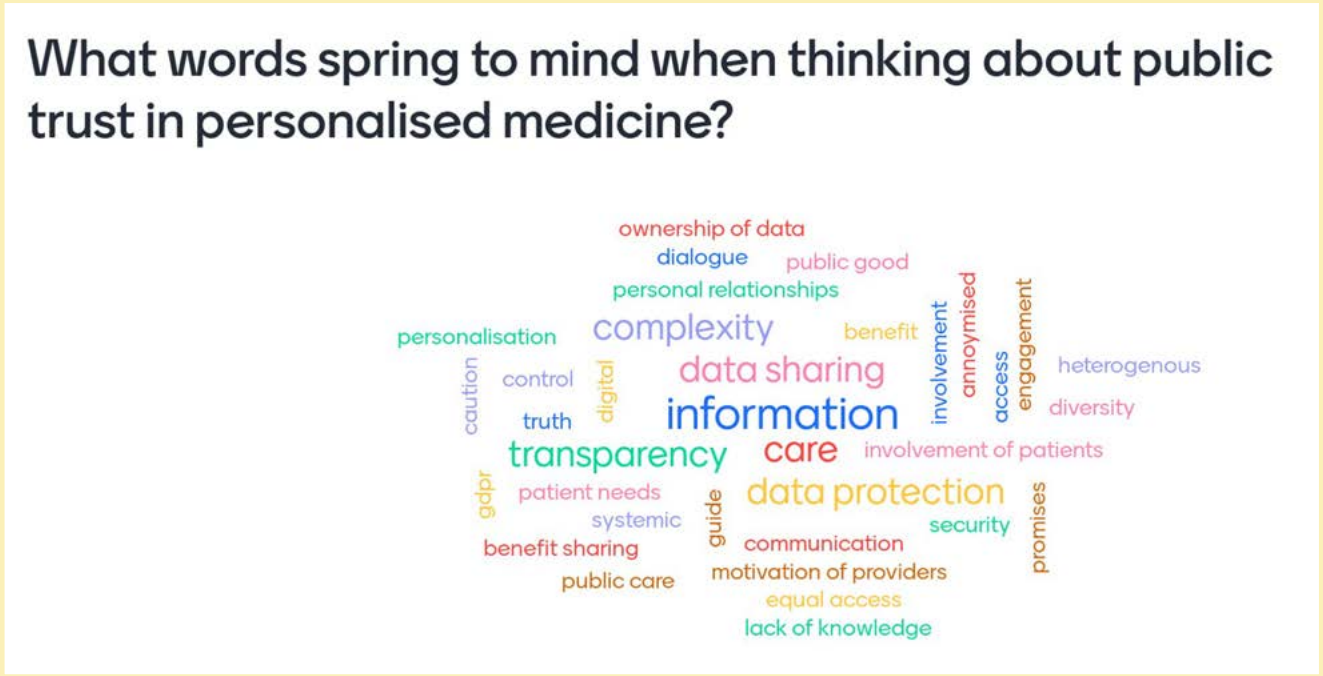

***Figure 5**: Words cloud of ethical aspects*

The resultant words cloud is showed in Figure 5 and it calls attention to the dynamic and varied responses received which overlap with those encountered in the "Ethical aspects" debates. It is interesting to note the prevalence of Care and care related concepts, which can indicate how PM is conceived as to give more caring approach to patients, even in terms of personal relationships. It is also noteworthy that issues around transparency, sharing (both data and benefits of PM), data protection and communication were raised. The importance of developing personal relationships between patient and clinician (but also the wider multidisciplinary team) was identified as pivotal.. While much interest on PM is focused on advanced technologies, is important not to ignore these core relationships and the patient-centric vision and aim from discussions of and practices in PM.

A clear example of the mismatch between research aims and that of the patient is how we measure outcomes. Research approaches PM from a quantitative perspective, focusing on measurable outcomes. In contrast, patients are seeking personalized solutions that enhance their quality of life, which is a more of a qualitative issue and cannot be easily evaluated using numerical methods (even with extant validated quality of life questionnaires.

Sticking to research there is also a paternalistic approach from ethic committees where patients and patients' representatives are missing. While the inclusion of patients and the public in these committees is common in some regions, this is not

consistently achieved and is necessary. Patients and the public are best placed to discuss their needs and concerns about research, and trust in certain practices and processes. Patient and public contributors will not provide a single uniform voice, but obtaining varied perspectives is important and ongoing dialogue can help coproduce solutions to, for example, identified barriers to public trust. Broad patient forums are necessary and ideal to engage patients in dialogue, and dissemination initiatives through different communities promoted by local and national authorities.

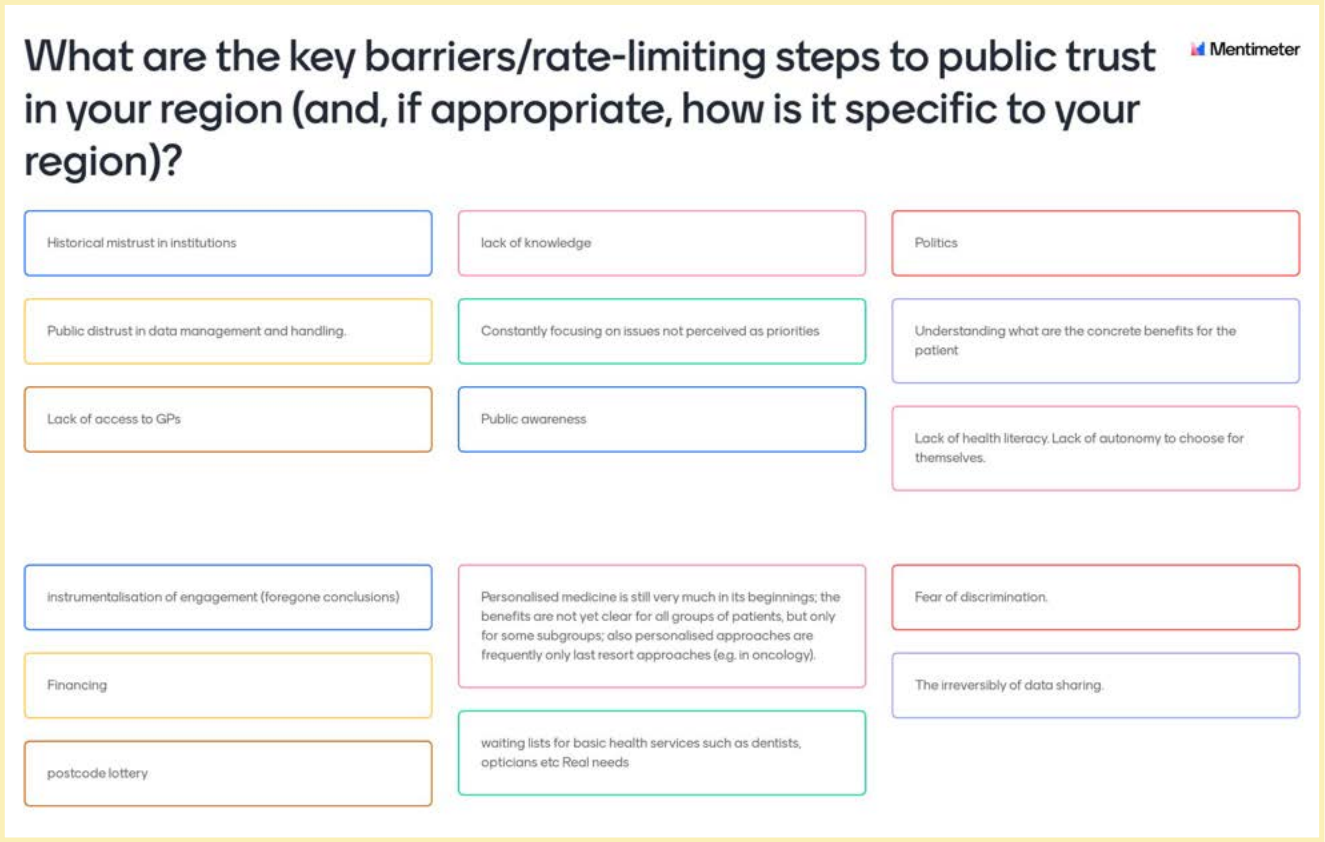

***Figure 6**: Participants answers to barriers to public trust towards PM*

***Figure 7A**: answers providing advice on how to support public trust in PM*

***Figure 7B**: Answers providing advice on how to support public trust in PM*

- Patients and citizen representatives should be included in ethic boards
- Training and education programs for clinician-to-person dialogue
- Language: More lay communication should be developed to explain the diverse benefits of PM
- Establish continuous patient engagement and empowerment programs which can be monitored, reviewed and updated
- Built Public trust exploiting precise dissemination and communication programmes dedicated to multifaceted audience, stressing on information before education
- Trustworthy practices (such as transparency) should be built all aspects of research and clinical delivery, acknowledging research is becoming more and more complex

4.2.3 The Economic Value of Personalised Medicine

The session was chaired by **Dr Rositsa Koleva-Kolarova** which kick-offed the session showcasing some HEcoPerMed project cases of study. The first session already showed that the concept of 'value' can take on several facets but here it is considered the assessment of economic value in the framework of Personalised approaches.

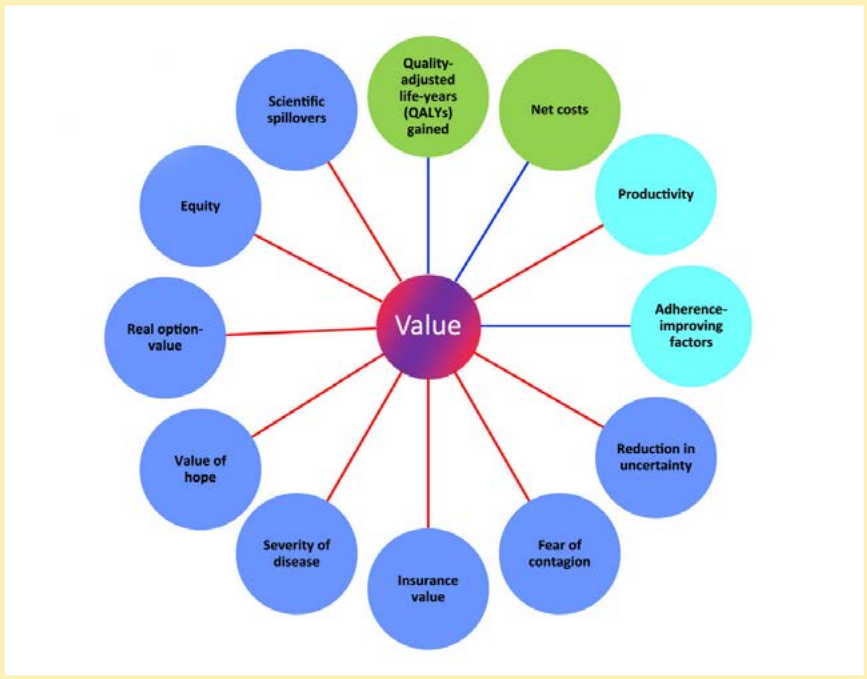

Figure 8: *Graph of the value of pm (from Lakdawalla, Value in Health, 2018)*

There is the necessity to discriminate between Economic Evaluation, as the comparative analysis in terms of costs and benefits, and Value of PM in terms of cost effectiveness and net monetary benefit, even if there are many additional elements which contributes to determine its entity, as depicted in figure 8. The trouble of this kind of broad definition can be connected to how to measure values, risk of double counting, sole focus on positive value elements, threshold should be adjusted. It is also necessary to take in mind that usually the concept is addressed only from its positive effect while it's equally important to evaluate the negative effects. All these issues led to use net cost and QALYs are considered an index to evaluate value assessment in some jurisdictions. The HEcoPerMed consortium published a systematic literature review on the potential to provide net benefit of PM, in terms of both clinical outcomes and cost-effectiveness. The file is consultable at the *following link*.

Some relevant cases of study about investing strategies were proposed. The cost-effectiveness of PM varies by disease

and intervention, with some cases demonstrating potential cost savings, while in other cases it may be more expensive than standard care. While there is evidence supporting the short-term benefits and cost-effectiveness of personalized medicine, limited evidence is available on the long-term benefits and costs. Implementation challenges, including the need for improved data collection and sharing, development of new infrastructure and technology, and addressing regulatory and ethical issues, need to be addressed to maximize the benefits of PM.

The analysis is based on costs of diagnostic over the costs of standard procedures or cost saving from regional/ national healthcare system. The economic analysis is heavily influenced by local guidelines, as they are intrinsically tied to the policies and regulations under which they are implemented. An example of this is that the Netherlands includes caregiving costs in health technology assessments (HTAs), whereas in the UK, such costs are generally not incorporated into economic assessment analyses. Questioning the public on Mentimeter about the definition of value of PM, two points can be picked up: Inclusive can means different layers of personalization, but HTA are based on robust results, so they are limited by availability of data.

Scarisity of data is one of the limiting steps together with the difficulty to assess the value of emerging technologies as their role in standard clinical practice is not really know early on.

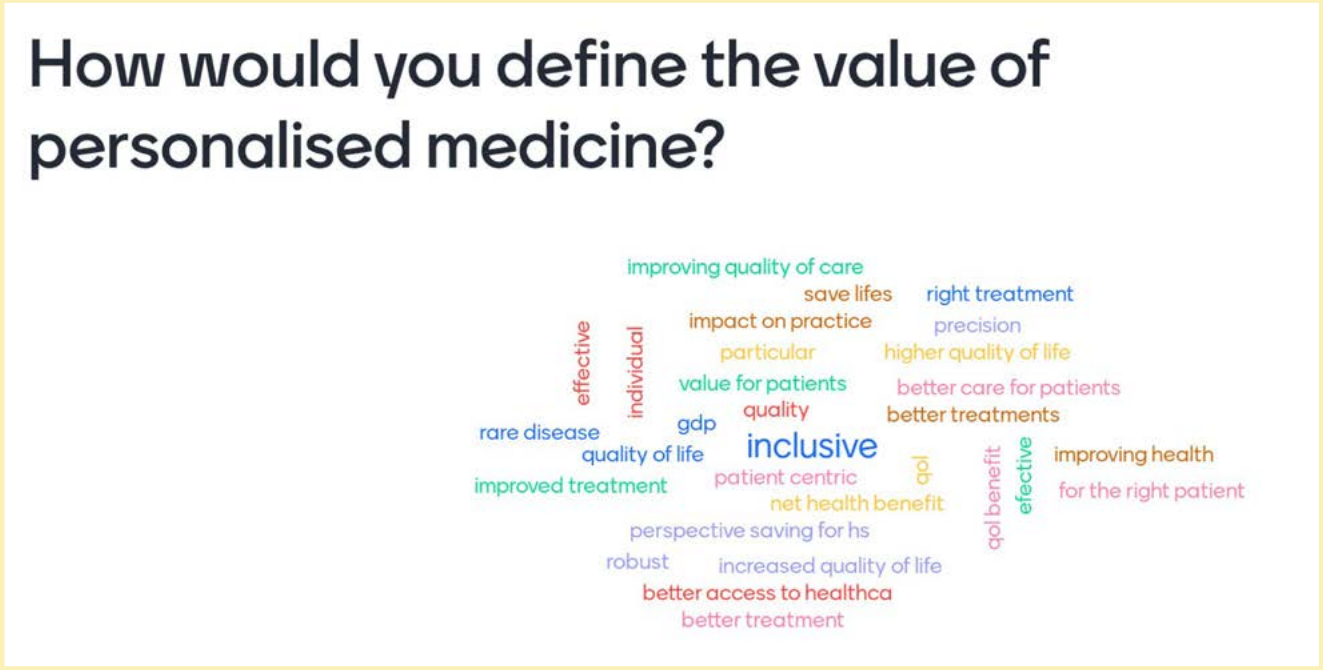

***Figure 9**: Cloud of keywords wround the definition of Value of OPM*

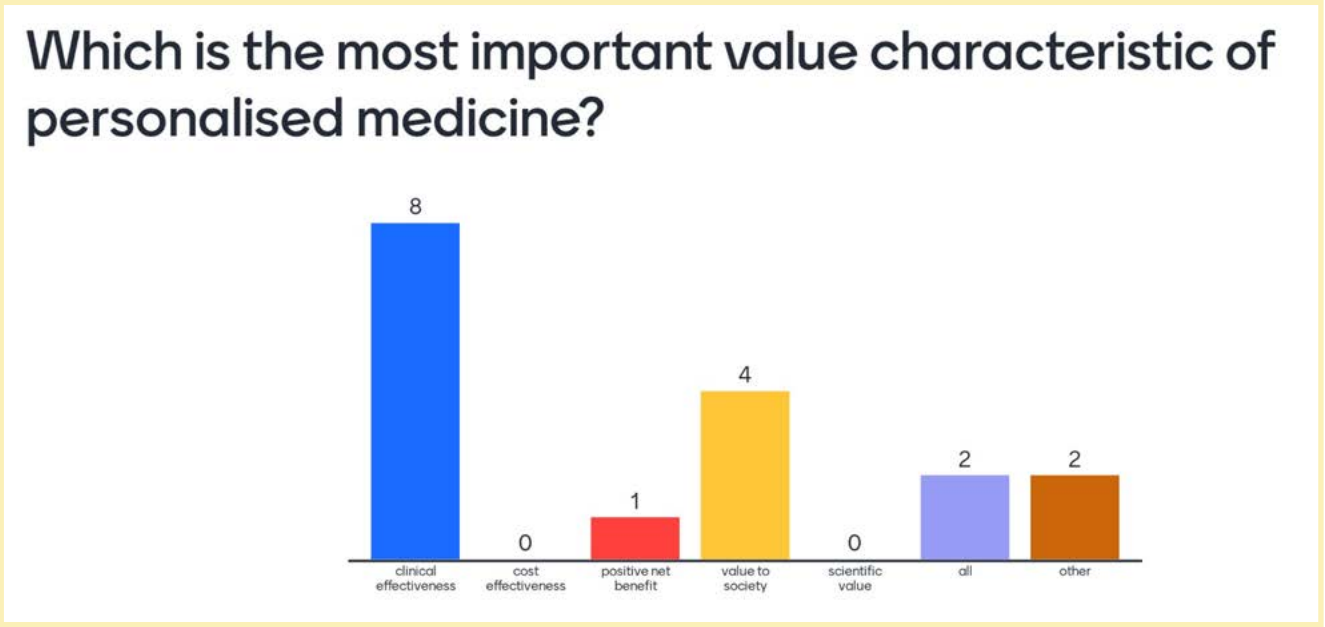

***Figure 10**: Istogramm of the importance of charatcteristics of value in PM*

Assessing the economic value of PM is, indeed, challenging, especially when considering factors such as clinical effectiveness and budget availability. The funding of innovative medicines can be a complex issue, as some treatments may not be cost-effective but may still provide significant benefits to patients. Innovative Medicine funds are sometimes used to provide financial support for these treatments. Furthermore, compliance with clinical guidelines in the healthcare setting can impact how we assess value and carry out health economic analysis. Guidelines are designed to ensure that patients receive appropriate and effective treatments, and adherence to these guidelines can help to optimize the use of healthcare resources.

From a regulatory perspective, many countries do not currently reimburse for PM tests, which can make it also difficult to assess the economic value of these interventions. However, as PM continues to evolve and gain acceptance, it is likely that this situation will change.

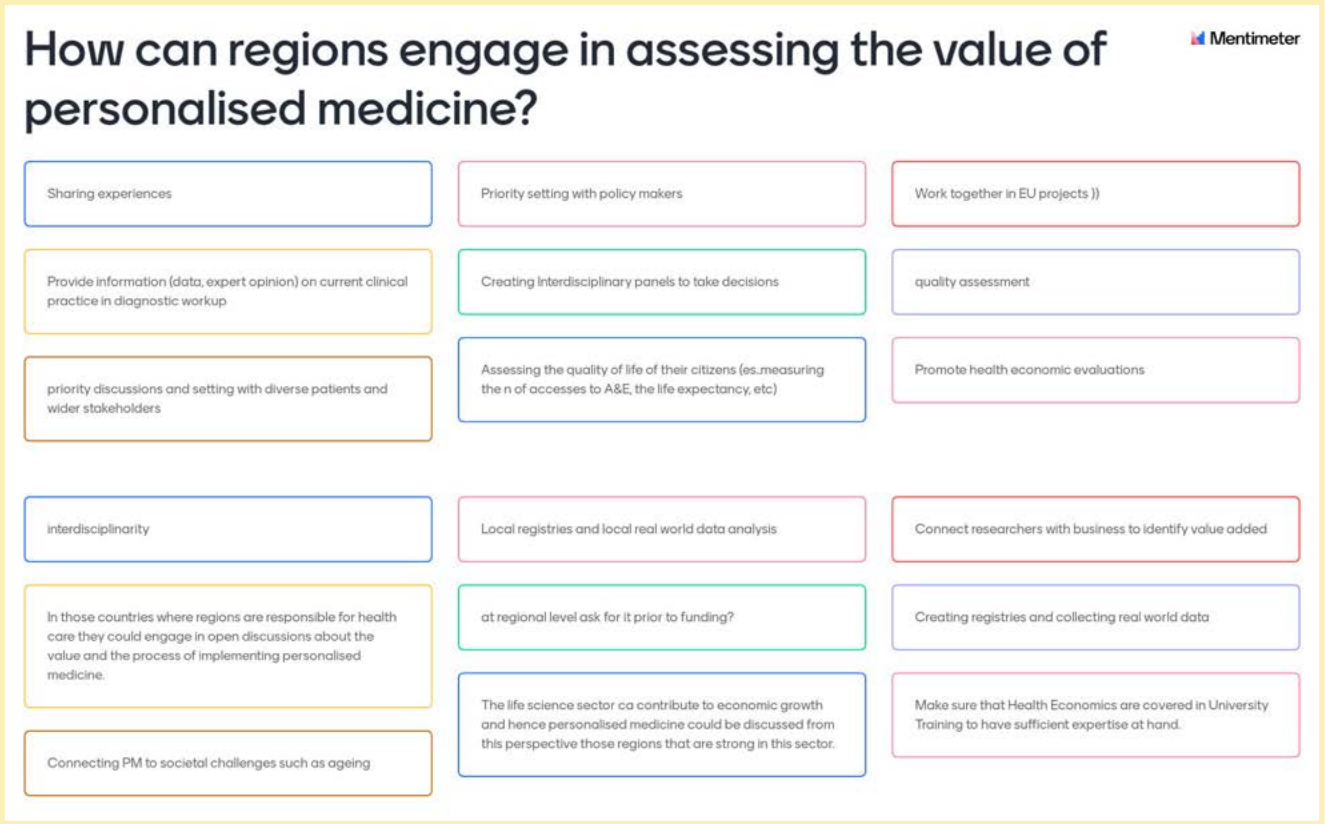

***Figure 11**: Answers provided by experts and particvipant on how the regional authorities can be engage in assessing the value of PM intervention*

Through the discussions held during the debate, it was possible to create an insightful diagram that clearly depicts (and summarise) the close correlation between the discussed issues and their disentanglement.

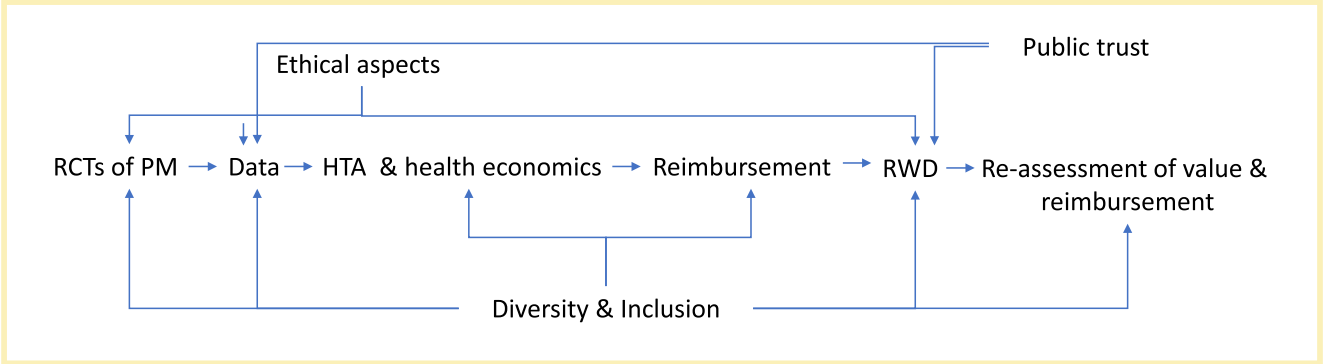

***Figure 12**: Represenatation of the close correlation between the challenges of PM and their disentanglement*

Recommendations

- More research on health economics of PM, that also factor in costs of tests should be supported by at regulatory
- Provide access to clinical trial and Real World Data (RWD) would ensure more qualitative Health Economic Evaluations
- Sharing best practices and examples among regions and Countries
- Establish re-assessment of value and reimbursement based on RWD
- Having a dynamic evaluation approach of evidence synthesis that can re-evaluate the cost-effectiveness of a technology when more evidence is available and when the technology may have evolved and its intended use in clinical practice altered.
- Considering indirect costs that are supported by the patients and their families, for example transportations, accommodation and other expenses.
- Higher compliance by patients.
- Design flexible organisation.
- Promote interdisciplinary teams needed to integrate specialized knowledge and competences.
- Develop and adopt a new reimbursement system based on «payment for performance (outcome)».
- Explore ways to deal with uncertainty using P4P schemes in reimbursement.
- Introduce new accounting system for treatments that in general have high unit cost and reduction of cost for future years.

4.2.4 Diversity, Inclusion and Personalised Medicine

The session was chaired by **Diksha Srivastava**. *Genomics* is one of the most recurrent terms of the day and this is because Genomic analysis holds great promise for improving patient outcomes and reducing healthcare costs in the future. The use of genomics in PM involves analyzing an individual's genetic makeup to develop treatments that are specific to their unique genetic profile. This can lead to more effective and targeted treatments for diseases, particularly in cancer treatment, and can also be used to predict a patient's response to certain medications. The genetic traits of an individual are largely determined by factors such as their geographical region, ethnic group, and population, terms that can be considered synonymous, as they all reflect the individual characteristics that are dependent on a person's genetic origins. These aspects introduce us the concept of Diversity and inclusion in PM. In principle, PM should ensure accessibility and effectiveness for all patients, regardless of their background. To achieve this goal, clinical trials and research studies must include diverse patient populations from various ethnic and racial backgrounds, as well as different socioeconomic statuses and levels of education.

Different countries and regions interpret the concept of "Diversity" differently, so it is intriguing to investigate on this starting from the workshop audience

***Figure 13**: How the participants and the experts define diversity in PM*

In the context of genomics, scientists use a genome-wide association study (GWAS) to detect genetic variations that are passed down from ancestors and linked to a higher chance of developing a disease or exhibiting a specific characteristic. Massive gap in data, particularly for GWAs. Despite the great progress attempted to fill this gap, many populations such as African, Latino-American, Hispanics, pacific Islander are incredibly underrepresented, and this implicates limits in the use of genomic databases. The poor diversity in genomic data derived by this underrepresentation produce ambiguities and it is biased if applied to non-European ancestry descendants. Equitable genomic-enables medicine must be world representative so it is pivotal to support initiatives oriented to inclusivity but there is a complete lack of Governance Structure for diversity and inclusivity in Europe besides few examples such as Genomics England.

The latter is a company founded and participated by the UK government to lead the *100,000 Genomes Project*, which aimed to sequence the genomes of 100,000 people in the UK with rare diseases and cancer to advance understanding of these conditions and develop new treatments.

With their "The Diverse Data Initiative" programme, Genomic England aims to reduce health inequalities and improve patients' outcomes in genomics for diverse populations. The programme workstream is articulated in four blocks where the investigation in Data gap is supported also with the involvement of patients, clinicians, researchers and data communities for the implementation of equity-enhancing strategies.

Although the advantages of PM, disparities still exist there needs to be a unified clinical, research, policy and outreach approach to mitigate against the widening disparities.

Despite the promises and premises of improving population health, Precision medicine, also poses a risk of further widening health disparities, especially among racial and ethnic minority groups. There are various obstacles that hinder the delivery of precision care, including but not limited to structural racism, unconscious bias, patient-provider mistrust, and a history of exploitation, abuse, and marginalization of minority communities. Discrimination in healthcare and inadequate medical treatment are commonly experienced by minority communities worldwide. The lower participation of minority groups in health research cannot be solely attributed to distrust or unwillingness, as it is influenced by deeper-rooted factors. Diversity is not just diversifying data but much more, it is about all elements of the PM processes as the problems configures itself in a more systemic way.

Figure 14: *Experts and participant advice on how regional authoriteas can shape more inclusive policies*

Asking the audience to define their professional provenience, it emerged the very diverse backgrounds of participants, a feature often ignored but, instead, which should be always considered when talking on PM implementation.

If regions want to overcome disparities, one of the first point would be disseminating biases and their impact. To increase "diversified information", however, health knowledge and health system should be equally accessible to all part of the population.

Even if can bring some diversity in data, the "quantity of these data" is also an important feature to be considered.

Recommendations

- Disseminate how biased the information we use are, to make decision and highlight its impact on people's health
- Promoting minorities representation in health research, through public trust data (through focus group ecc.)
- Promote Diversity and inclusivity within the organizational changes and their gender equality plans
- Use policy platforms like Interreg Europe and Vanguard to promote policy in this sense

4.2.5 Sex, Gender and Personalised Medicine

The session was chaired by Prof. Susanna Chiocca. When discussing sex, we are referring to biology; however, when discussing gender, we are delving into a complex socio-cultural process that encompasses various factors we have discussed today such as diversity, minority groups, and more. This is of great significance to scientists and individuals in the medical field as it has an impact on products, technology, environment, and knowledge. Therefore, it is imperative that we constantly examine this topic and think to specific norms. In particular, Gender norms are constantly evolving and dynamic, with variations existing within countries, regions, and even globally. The beliefs and expectations around gender that were prevalent a decade ago have also transformed with time. It is crucial to acknowledge that gender stereotypes continue to persist and are deeply ingrained in our subconscious. These stereotypes influence our views on femininity and masculinity, among other things, and are a part of our daily lives. Gender can contribute significantly to inequalities in lifespan, starting at birth. There are a number of non-communicable and non-renewable disorders, including cancer and cardiovascular diseases, that are related to gender. In addition, individuals may have specific lifestyle risk factors that must be taken into account when providing personalised care. Healthcare must be comprehensive and tailored to each person's specific needs, strengths and preferences, taking into account their unique characteristics, including gender. The analysis of gender, sex, or both is contingent on the area of study we are examining. For instance, in CVDs and heart diseases, it's evident how the disease varies significantly between men and women. However, the symptoms differ greatly between the two sexes, and this is where the gap lies, as some physicians are still unable to recognize the differences. For instance, in a *study published in Science*, the authors noted that sex differences in CVD are acknowledged, but sexual dimorphism is overlooked in clinical trial design. Therefore, there is a pressing need to examine data by sex rather than adjust it for sex. In parallel, even if sex is considered it is not clear how properly use and assess data. It is worth noting sex bias derives also from the used cells and animal models in research and this should not be neglected in studies. In addition, there is scientific research on animals in which it is observed, for example, that the sex of the scientist working on the animals can have an impact on how the animals, as mice, respond to pain. There is therefore data on this aspect, which is, however, gender-related, because it depends on the hormones that the researcher administers at that particular time. As for gender, there is still a lot of work to be done and genomic data could help us. However, while taking into account sex is easier if compared to gender because there's really no ways yet to "measure" it.

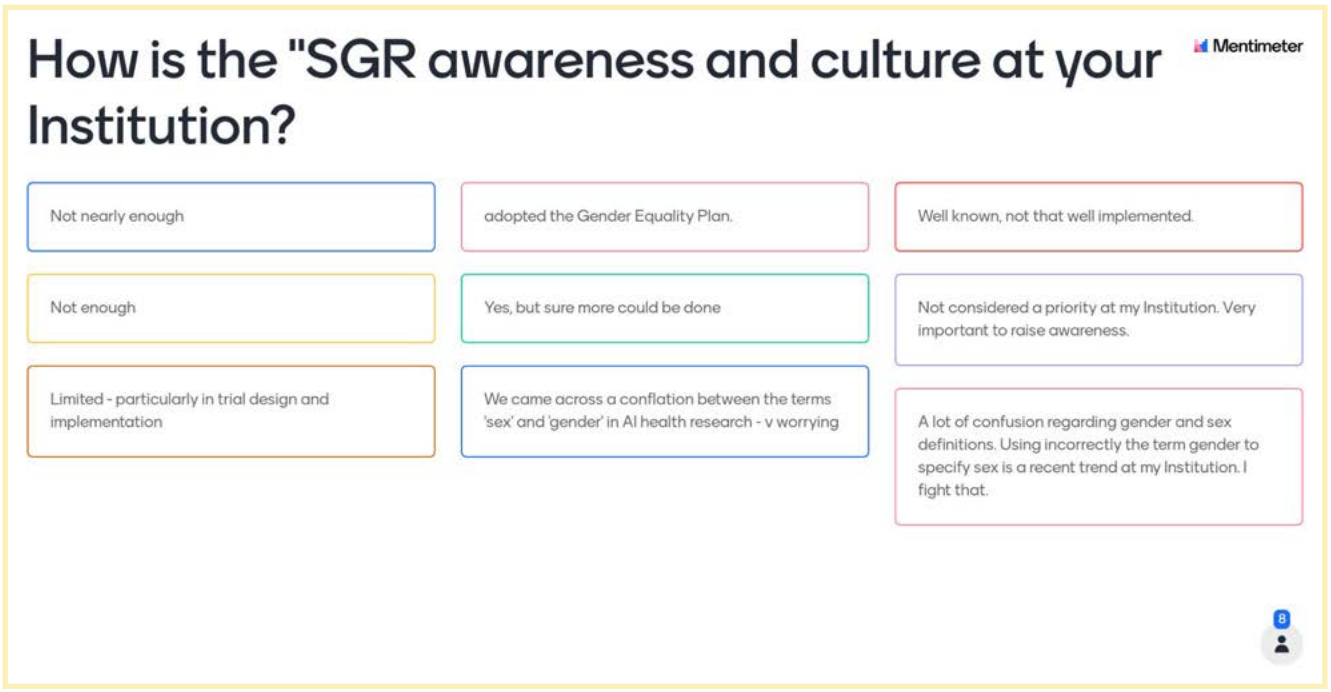

Figure 15: *Experts and participants response on how Sex and gender in biomedical research (SGR) relationship awareness is tackled at their institutional level*

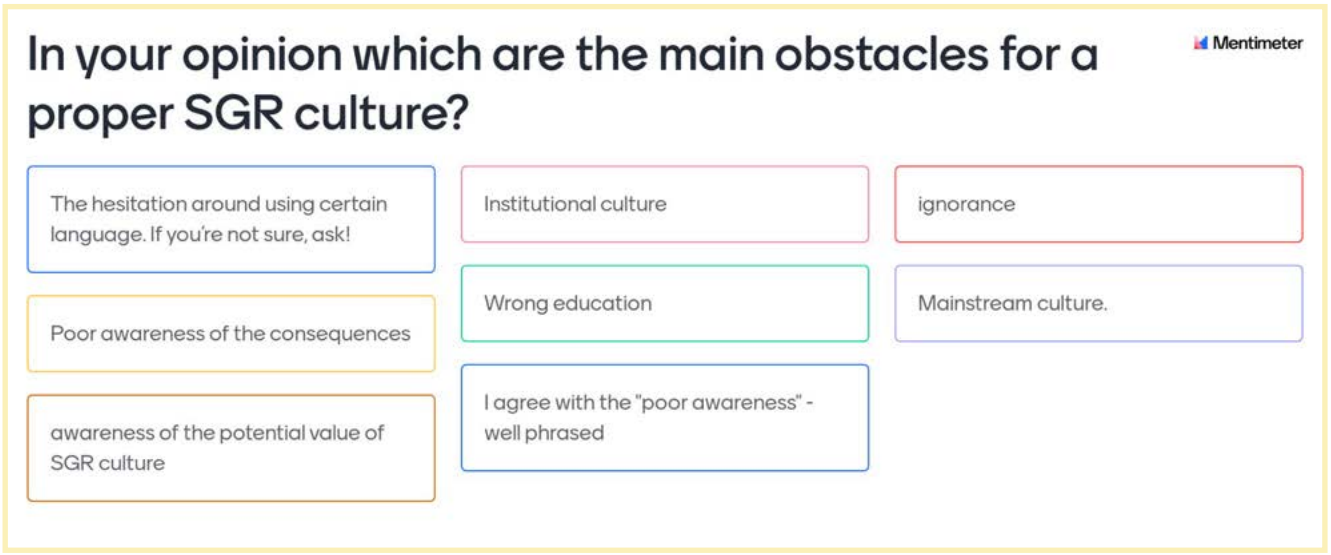

Figure 16: *Main barriers to the SGR culture according to experts and participants*

Recommendations:

- Include Sex and Gender in Clinical Trial Design
- Report Sex Gender in Scientific Papers and journals
- Randomized Clinical Trial need to include equity
- Raising awareness in Ethical Committee and Clinical trial office on how to assess clinical protocols including the Sex and gender perspective.
- Integrate quantitative analysis with qualitative analysis
- Fill the gap on the lack of sex and gender disaggregated data
- Doubling the sample size or changing the design of clinical trials
- Include a reporting methodology on sex and gender within all the phases of research.

Conclusions

The workshop brought together experts from various fields and, despite the diversity of the topics discussed, it was evident that they are all untangleable. The integration of PM into healthcare systems is a complex process involving many different stakeholder and several socio-economic factors, such as funding, access to healthcare, public trust and patient education.

They play a key role in ensuring that PM is available to all citizens, regardless of their socio-economic background and, particularly on all the related ethical aspect.

As Data demonstrated to be at the core of PM development/ implementation, the related issues of collecting, using and sharing data proved to be as fundamental as tricky and must be overcomed. While issues about ownership (public vs private) and benefits are contested, different legislative frameworks complicate the scenario together with the regulations and practices at different levels of government. Furthermore they are different between clinics and research.

In this complex situation, regional bodies and authorities have a significant role to play in the development and implementation of PM, leading the necessary actions to revolutionise the heathcare assept. Regions should act as promoters of initiatives that can help regulate and disseminate information on personalised medicine to the public. This will ensure that citizens are better informed and are encouraged to participate in the integration of PM in their healthcare systems. Regional bodies can also play a crucial role in promoting policy changes that prioritise PM and make it accessible to all citizens. Based on these considerations, it is pivotal to invest in promoting initiatives that can facilitate the development and integration of PM in regional health systems. The involvement of regional bodies in the decision-making process is also crucial to ensure a comprehensive and inclusive approach to personalised medicine in the EU. This will require collaboration between various stakeholders from different local or national level, including politicians, healthcare professionals, patients and experts, to create a sustainable and equitable approach to PM and PH.


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