



EP PerMed
European Partnership
for **Personalised Medicine**

ICPerMed
INTERNATIONAL CONSORTIUM

ICPerMed & EP PerMed Conference on Personalised Medicine Research
Day 2, 27 November 2025

SESSION 3

Integrating Personalised Medicine approaches into Clinical Practice:
10 years of strategy and policy development

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SESSION 3

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Foreword to Session 3 and update on
ICPerMed Policy and Strategy Strategic Working Group



Foreword to Session 3 and the ICPerMed Policy & Strategy WG

An Experts Reflection on the Progress and Future of PM on the 10th Anniversary of the European Council Conclusions

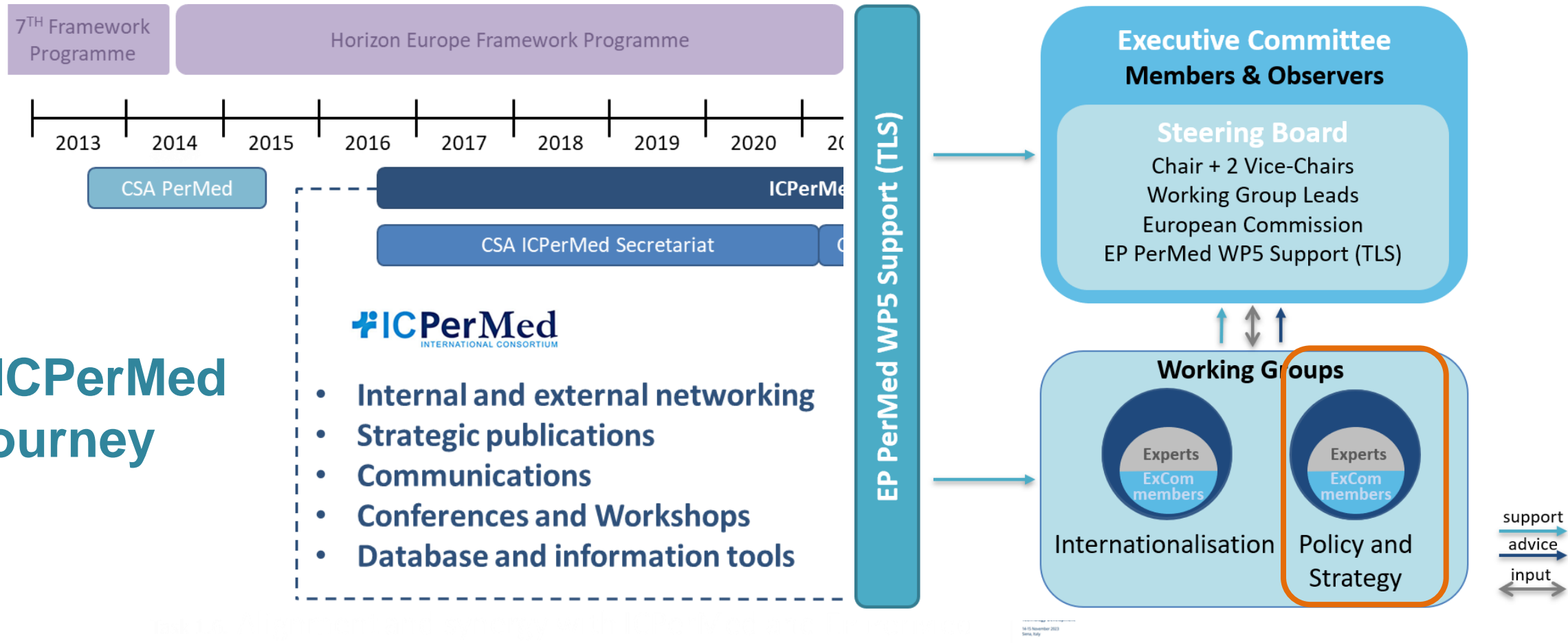
Astrid Vicente – Instituto Nacional de Saúde Doutor Ricardo Jorge, Portugal

27 November 2025



ICPerMed – Policy and Strategy development

The ICPerMed Journey

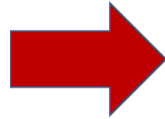


ICPerMed Policy and Strategy Working Group

STRATEGY ARM

Goal: contribute to improve strategic planning in a rapidly evolving field

- Identify evolving strategic goals for PM
- Define priorities
- Promote efficient use of resources



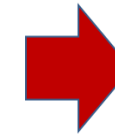
Specific objectives:

- Progress assessment
- Gap analysis
- Identify novel opportunities
- Identify priorities
- Identify actions for efficient use of resources
- Develop strategic recommendations

POLICY ARM

Goal: contribute to implementation policies for healthcare

- Identify key policies for translation of PM research to healthcare
- Improve awareness of key stakeholders



Specific objectives:

- Promote the involvement of policy makers and regulators
- Identify regulatory bottlenecks
- Identify novel opportunities
- Promote sharing of best practices
- Develop recommendations

European Council Recommendations on PM for patients – a reflection on the 10th anniversary

TOPICS



Informed,
empowered
citizens



Educated and
engaged health
professionals



Optimised
healthcare
systems



Accessible
health
information



Economic value



Biobanking &
Research

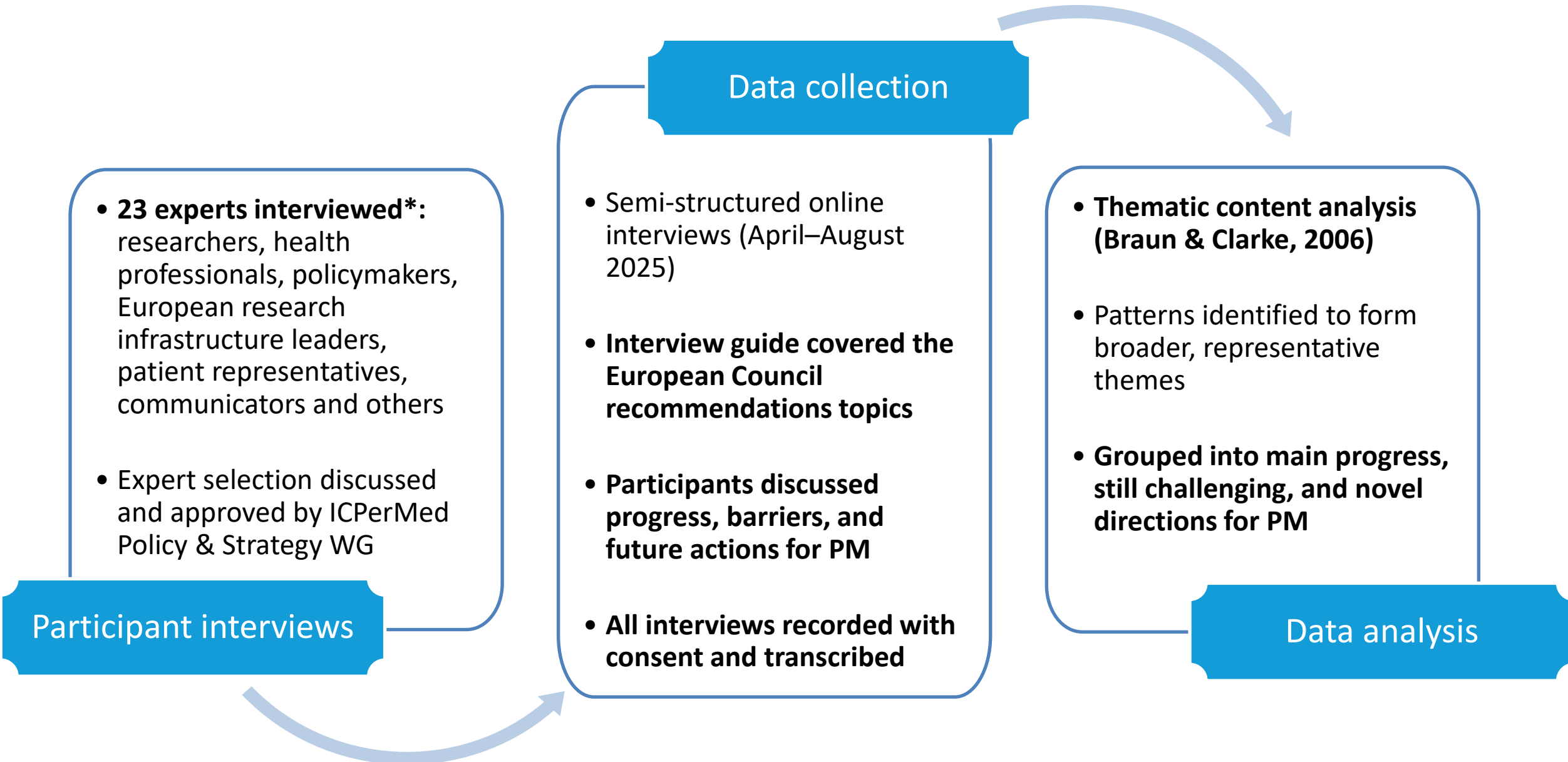


Ethical, Legal & Social
Implications (ELSI)

Main objective

Reflect on the past 10 years: the progresses, the barriers and the novel and pressing challenges in getting Personalised Medicine to benefit citizens

Prepare for the future



What has progressed significantly over 10 years?



Accessible
health
information

FOSTER cooperation in the collection, sharing, management and appropriate standardisation of data necessary for effective research into, and development and application of personalised medicine, in compliance with data protection legislation;

Pan-European initiatives and national programmes for data governance

European regulation for data access - gradual adaptation to GDPR and EHDS regulation

FAIR data principles mainstreamed

"(...) the 1+Million Genome Initiative (...) was a good way to put all the MS in the same table to discuss, because European countries are so heterogenous." (...) these Pan European initiatives mean that local governments also have to align with this vision that is coming from EU."

"I believe there has been some progress in thinking about how regulation, legislation, and competences at the European level are structured."

"(...) FAIR data has been integrated, (...). Now, we need to put more effort into data quality, particularly through education and training."

"(...) Medical Informatics Initiative (MII) served as a cornerstone for the country's digital health transformation (...) the initiative enabled the development of essential infrastructures for data management, standardization, and ethical governance"

"Access to data remains a challenge at the national level, although many barriers have been lifted. Time is needed for this access to be fully deployed. It will also take time for the clinical research community to shift its practices - from "bringing the data" to researchers, to "bringing researchers to the data platforms."

What has progressed significantly over 10 years?



Ethical, Legal & Social Implications (ELSI)

DEVELOP common principles on data collection based on standards and a sound legal framework and enabling the processing of patient data and the availability of comparable data at European Union level, allowing secondary use and analysis of data on a larger scale in compliance with data protection legislation, while fully respecting Member States' competences;

Improvement of ethics committees awareness in genomics - Transition to informed dialogue

Improved awareness of the sensitive nature of genomic data

"(...) about the health data space, which is a brilliant idea for research but has a number of aspects related to legal and ethical issues, and I find positive the way all these delicate issues are taken into accounts (...) It shows that the conscience on how sensitive are those data and specific care that they need for being managed."

Reinforcing the social contract and ethical boundaries in data governance

"(...) I see the EHDS as a valuable complement to the GDPR. Of course, it will not make data freely or easily available, but it will ensure that data can be accessed for legitimate purposes."

"(...) think of this social solidarity, the sense that I will put my data into a into this big system, this European Health Data Space or 1Million genomes, I benefit from the previous research as well as my family and future people. (...) exploring what we called the social contract model, the idea of understanding what people want and what they expect in return. This brings us back to the ethical and legal boundaries that must remain absolute 'red lines'. These principles really need to be rigorously reinforced, especially concerning issues such as commercial access, or access for criminal justice, immigration, or national security purposes."

What has progressed significantly over 10 years?



Optimised
healthcare
systems

CONSIDER developing long-term, patient-centred, strategic approaches on how to meet, with a public health perspective, the challenges associated with access to personalised medicine, while ensuring the sustainability of National health systems and fully respecting Member States' competences;

USE genomics information with a view to **integrating advances in human genomics into public health research, policy and programmes**, in compliance with existing national provisions concerning personal data and genomics

Push to integrate genomics in healthcare with
national Personalised Medicine programs

Increased use of genomic technologies in healthcare

Awareness of need for equity in genomic knowledge

Cross-country genomic initiatives foster EU-Level cooperation: 1 Million Genomes Initiative

There has been very good progress in terms of the ability to make genomics fairly routine in healthcare."

"(...) the key initiative that really created a clear understanding among policymakers at the ministerial level, about what genomics is and why it matters, was the 1+ Million Genomes Initiative."

"(...) we saw that there is increasingly use of genomics technologies in a much broader way (...) We see increasingly the establishment of national genomics programmes in a number of countries, in particular upper middle income countries. (...) There's also a big push to increase the equity of the knowledge that stems from genomics information

"(...) recognise the importance of communication and when we talk about strengthening Public Health Communication strategies

What has progressed significantly over 10 years?



Informed,
empowered
citizens

PUT in place information and awareness strategies for patients, based on available, objective, balanced and non-promotional data, in order to improve health literacy and access to reliable, relevant and understandable information on existing treatment options, including expected benefits and risks, thus enabling patients to actively cooperate with healthcare professionals in choosing the most appropriate treatment strategies;

Patient advocacy shaping genomic policy

Patient and citizen groups amplifying their voice in awareness, research and EU dialogues

*"One example of how much the patients voice is for this count is **the introduction of DPYD testing into the EMA guidelines** because it was actually the **families** of people who died because of this quite severe, as stupid as toxicities, that demanded that something needs to be done."*

(...) a seat at all of the conversations around what, where, who gets to look at the data that's been collected, what happens to it and they get to inform the ethical framework that shapes that."

"(...) more patient organisations, patient communities and citizen groups have formed, amplifying the voices of patients and citizens, not only in awareness campaigns, but also in research and EU-level dialogues."

Inclusion of patient perspectives in major initiatives design

*"I think that is a relatively well **agreed principle**. (...) **The idea that you should bring your patient community** with you is something which I think is nicely embedded in genomics as a discipline."*

What has progressed significantly over 10 years?



Biobanking &
Research

RECOGNISE the potential of **clinical and population-based biobanks** for accelerating the discovery and development of new medicinal products; support the standardisation and networking of biobanks to combine and share resources, in compliance with data protection legislation

Recognition of biobanks' significant
contribution to research

Integration of biobank data with genomic and
health datasets

"Biobanks have been 'absolutely very good' for research."

"The establishment of interdisciplinary structures (...) and integrated biobanks enabled direct translation of genomic findings into clinical decisions. These platforms helped bridge the gap between laboratory research and routine care."

Biobanks considered strategic resources for healthcare and
research

Strong network of biobanks across Europe

*"I think that is the **strong network of biobanks**. I've seen that **the way biobanks are built depends a lot on the specific needs of healthcare providers and healthcare institutions**. (...) But definitely, **it's an enormous resource that we have, and there has been a lot of progress over the last ten years**. And I'm happy with the way policymaking decisions around the biobanking ecosystem in Europe have been made."*

*"The work we've done on **connecting or translating biobank data into specific ontologies, such as the correct tagging of samples according to existing ontologies, was extremely important**."*

What are still main challenges?



Optimised
healthcare
systems

SUPPORT access, as appropriate, according to national provisions, to clinically effective and financially sustainable personalised medicine by developing patient-centred policies including, as appropriate, patient empowerment and the integration of patient perspectives in the development of regulation processes, in cooperation with patient organisations and other relevant stakeholders

Persistent inefficiency in using health and genomic data

Eurocentric approach to data sharing may not be
applicable to other contexts

Pathway from discover to implementation is too long

Disconnect between research and healthcare data governance

Significant initial investment

Insufficient infrastructure for data storage and sharing, laboratory capacity for testing

Lack of genomic data integration in electronic health records

*“**capacity of laboratories** as well to be able **to provide testing.** (...) the testing provided may be quite variable in quality. And the reports that you get as well, and that doesn't help. So **that reduces the confidence of the public in terms of trying to utilize this.**”*

*“(...) **how we integrate genomics into the electronic health records so that you get interruptive alerts,** (...) would suggest that you change the dose. So that requires **intelligent clinical decision support. Doctors, pharmacists, nurses don't need to be experts on pharmacogenomics or personalized medicine, they just need some help.**”*

*“So if you look at pharmacogenomics more broadly, **implementation lags well behind.** We discover, we write guidelines, but healthcare systems don't take it up, and do not implement it for population benefit. **And that is where we really do need to focus.**”*

*“(...) even though many of these drug-gene pairs have been shown to be cost effective and panel-based testing is also cost effective, **there is still an outlabel required at the beginning, in order to set up the genetic testing and then to make it available to the population, and that cost may be considerable to be able to do that at a national level and that clearly acts as a deterrent in many cases.**”*

What are still main challenges?



Economic value

DEVELOP OR ADJUST, where necessary, procedures aiming to **evaluate the impact of personalised medicine, in particular health technology assessment (HTA) procedures**, to the specific nature of personalised medicine, taking into account, inter alia, added value from the patients perspective as well as enhanced cooperation and exchange of best practices, while fully respecting Member States' competences

Complexity of Health Technology Assessment (HTA) and reimbursement processes

Lack of big projects that include comprehensive economic data

*"From a sustainability perspective, **this means we need to understand what is the best sustainable approach.** When you build a healthcare intervention, you need to **bring everyone to the table - patients, clinicians, policymakers, and payers** to assess and design what the specific economic model for that intervention will be. This is a crucial element in the research and innovation ecosystem for healthcare delivery. It's **essential to evaluate both the efficiency and the sustainability of what we aim to deliver through health technologies, products, and services.**"*

Economic dimension of personalised medicine remains underdeveloped - Limitations of traditional health economics in assessing the value of genomic medicine

*"**These HTA and reimbursement mechanisms are some of the most difficult areas to navigate.**"*

*"**(...) the economic models often don't fit well within the broader healthcare system. The challenge is that traditional health economics doesn't fully capture the wider benefits, for example, how genomic medicine can stimulate the life sciences industry or attract further investment.**"*

*"**(...) focus in terms of evidence for policy decisions and the reforms in the health system (...) start to collect data downstream from the diagnostic test to show the clinical utility and a learning health system model where you can start to use and track the data, both research and clinical data, so that you can answer these health system, health service, public health questions in real time**"*

What are still main challenges?



Educated and
engaged health
professionals

PROVIDE education, training and continuing professional development for health professionals in order to equip them with the necessary knowledge, skills and competences to make the most of the benefits that personalised medicine brings to patients and healthcare systems

Primary care physicians' need for simplified, ready-to-use
genomic information

Preference for concise expert recommendations over complex
technical explanations

Need to engage GPs in genomic literacy and patient education

Postgraduate genetics interdisciplinary programs

*"We need to have **education which suits different people**. For example, a general practitioner doesn't need to be an expert in pharmacogenetics, they just need basic education in that. But somebody who wants to specialize in PM needs to do a higher degree to get that deeper level of knowledge. (...) tailor it to your audience. (...) need information which is just in time, (...) a decision support system that tells you that you need to do this for your patient, that you can click to get more information and that naturally expands your knowledge and experience."*

"As primary points of contact for most patients, GPs hold a critical position in shaping patient understanding and attitudes toward new medical approaches. Comprehensive training at the GP level should therefore focus on equipping physicians with both the scientific knowledge and the communication skills needed to explain the benefits and limitations of genomic medicine."

"Pharmacogenomics, personalized medicine, precision medicine is not just the domain of doctors. It should be the domain of the healthcare team, which includes the doctors, but also nurses, pharmacists, genetic counselors. (...) the IT people, the pathologists, etc. It is very much a team approach rather than dependent on one person. Having those team approaches to move things forward."

Pressing themes

COMMUNICATION

*"One of the main priorities was the **need to share information in a more accessible way.**"*

Whatever you do, in whichever specific category, if you don't know how to communicate your findings, it's for nothing."

*"I think probably **we should have a common communication.** The communication should be very clear, should use **the same wording in all the countries with all the physicians explaining clearly which are the pros, which are the cons.** It's very difficult to make an homogeneous communication understand. It's also cultural stuff, the way in which physician communicate, the way in which citizens understand depends from a number of variables. But I'm not sure if we are doing well. (...) So if they have a sort of guidance, maybe it's easier. **I think guidelines of communication can help so that physicians use the right terminology.**"*

*"(...) we need to be **talking to the general public at large.** (...) **we need to be creating a social movement.** We're not thinking enough about it in terms of a social movement change, in other words, **where people demand it.**"*

*"We need to be outside the bubble. **We need to be talking to younger groups because we need to design health services that are fit for five and 10 years time.** When views may be completely different, and it will be completely normal to consult your genome."*

*"(...) we **should never undermine the soft influencers** that already exist within communities and are able to penetrate the community, **going down to the grassroot,** people who within those communities can effectively bring that message (...)."*

Pressing themes

EQUITY

I'm not sure that it's equitable [the progress over the last 10 years]. It's quite at this moment and I'm actually not sure that the coming years are going to improve that. And because there's so many things that governments could invest in, this isn't necessarily going to be one of the highest profile because as you see, the potential benefit is likely to be on a subset of the population rather than everybody.

"It will get worse in terms of accessing because of economic issues, but also equity across countries regarding maybe the aspect of capacity. Lots of people now they pay out of pocket and the insurance do not cover all those expenses. (...) in the past few years, we had a lot of people that do not even access basic care, think about whatever other expensive test. I think that equity issues will get worse. But luckily because in the field of cancer, the mission of cancer made a lot of grant efforts direct to European Member states from the East part probably they can accelerate, but (...) there still be a problem in equity."

"Many European countries, we cannot collect information on ethnicity. (...) That is one of the things that needs to change. And we're now developing the Genome of Europe project, in which we're going to have every country contributing with a number of samples that is proportionate to the size of the overall population without looking at any ethnicity aspects. In many countries, there will be a big diversity already, which will be very, very interesting to analyse."

Pressing themes

ARTIFICIAL INTELLIGENCE

“AI tools are coming to healthcare and will change the way how primary care works. And I see that this will change tremendously.”

*“I must say that to me that the **future of personalised medicine is partly in the non genomic personalised medicine** and the stratification based on all the markers closer to the phenotype and **using artificial intelligence to stratify the patients.**”*

*“Artificial intelligence will be central to the future of precision medicine. Over the next decade, AI is expected to evolve from a research tool to an integral part of clinical decision-making and health system operations. However, for AI to reach its potential, **we must ensure access to high-quality, representative data, a ROBUST ETHICAL AND LEGAL FRAMEWORK, AND REGULATORY CLARITY for AI-based medical applications**”*

*“We use coders to be able to code healthcare. But this is a really difficult thing to do. And I'm sure some of that workload could be reduced, not taken away, but reduced by **incorporating AI in actually coding some of our healthcare data** and so on. (...) But we also need to start using unstructured data and developing natural language processing, etc, to allow us to be able to utilize that as well in a better way. And so **AI is going to be really important in terms of the advances that occur over the next 10 years.** However, we need to **make sure that the AI is being done in a fair and equitable manner** and does not introduce **unintended consequences because of the bias in the data** that we may have.”*

Pressing themes

PREVENTION

*“In terms of indications, genomic medicine is currently focused on diagnostics and therapeutic orientation. **The development of care pathways for early diagnosis across various indications could guide the use of genomic medicine toward precise biological profiling for preventive purposes.** For example, France has recently funded a preventive vaccine research project for patients at a precancerous stage of colon cancer.”*

*“Looking ahead, **one of the most promising areas for the application of precision medicine is aging and age-related diseases.** In the context of Europe’s rapidly aging population, **personalized approaches to prevention and care will be crucial to ensuring long-term sustainability of health systems.** Precision medicine offers the tools to better understand individual aging trajectories and to tailor preventive strategies accordingly. **This will allow for earlier interventions, improved quality of life, and reduced healthcare costs. Personalized prevention programs that account for genetic, environmental, and lifestyle factors influencing aging can enable healthy aging on a population level.**”*

*The models for polygenic risk (...) but really **that's what patients are going to want. They're going to want the preventative measures of the future. So there are companies I think around that of moving away from using genetics, for example, to define a new drug target, they're moving more towards how can we look at developing preventative measures through someone's genetic profile.***

*“I think **pharmacogenomics is going to be a massive thing here because (...) like 99.5% of us have something genetic which will indicate that we are more or less respect responsive to at least one drug out there.**”*

Pressing themes

INDUSTRY

*“A key priority for the advancement of personalized and genomic medicine in Europe is the enhancement of collaboration between academic research institutions and industry stakeholders. At present, significant delays exist in the translation of scientific discoveries into clinically applicable tools, diagnostics, and therapies. (...) To accelerate the translation of research findings into healthcare practice, **it is essential to establish structured frameworks that promote early and continuous dialogue between academia, biotechnology firms, pharmaceutical companies, and healthcare providers.**”*

*“Over the next 10 years, and **the tools are there, but they're not used because** there's all sorts of companies that develop this kind of tools but then **the healthcare system may not trust that, in terms of not want to integrate that in some way.** It's interesting because **in other areas, these tools like imaging, these tools are being used much more.**”*

*“And I think **what's been difficult is that industry hasn't engaged in the implementation of those GA4GH standards to the extent to which they're required to make them truly democratized globally. Industry adoption is the biggest [barrier to progress].**”*

Main messages

PROGRESS

Data governance and sharing – infrastructure and regulation

ELSI – people’s data for people’s benefit

Genomics in healthcare

Patient empowerment

Biobanks and research

CHALLENGES

Wide and **sustainable implementation** in healthcare, including primary care

Regulation and **data governance**

Health professionals engagement and tailored training

Citizens and patients trust and engagement

Evidence of **clinical utility** and **economic gains**

NEXT 10 YEARS

Equity from research to outcomes

Prevention - wider implementation of pharmacogenomics and genomic screening

Clear communication – patients, citizens, younger generations, policy makers

Artificial Intelligence – regulation is key

Industry – regulated partnerships



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THANK YOU!

