European Alliance for Personalised Medicine

Innovation, Public Trust and Evidence: Generating Alignment to facilitate personalized Innovation in Health Care Systems

Slovenia Presidency of the EU
Brussels, 1 July, 2021

Background

The theme of EAPM's 2nd Bridging Presidency conference, during the auspices of the Slovenia Presidency of the EU, will be "*Innovation, Public Trust and Evidence: Generating Alignment to facilitate personalized Innovation in Health Care.*" High-level speakers and attendees will come from a wide range of stakeholder groups including patients, healthcare professionals, academics, industry representatives, politicians and legislators, the media and more.

Issues to be addressed:

The potential of personalised healthcare has been increasingly recognised over the last decade. The scope is almost unlimited for exploiting new understanding of epidemiology, precision medicine and pharmacogenomics, focusing on technologies such as genomics, single cell sequencing, microbiome analysis and transcriptomics, as well as bioinformatics and digital innovations. But for all these possibilities, personal healthcare has not yet delivered the benefits it could. Among the many factors influencing this evolution, one of the most critical is the readiness of healthcare systems to respond to the opportunities offered. Personalised care is a disruptive concept that challenges – and often runs into resistance from - many rigid and traditional patterns of thinking about health. In consequence, an approach to healthcare that is fit for the 21st century is remaining only partially exploited because of practices, presumptions and even prejudices that date from before the millennium. Now, at the start of the 2020s and the times of COVID 19, with complex changes underway in European society and governance, the time is right to review how change can be leveraged to develop a policy framework that will permit maximisation of the potential of personalised healthcare.

The new era that is opening in Europe, with a growing conviction among Europe's policymakers that people must be at the centre of any successful and sustainable strategy, provides a conducive context. The political guidelines[1] issued by Ursula von der Leyen when she was named as the candidate to become the new President of the European Commission made clear her ambition for a Europe that 'must lead the transition to a healthy planet and a new digital world'. The same degree of ambition is evident in the message from the EU Health Commissioner-designate Stella Kyriakides in her confirmatory hearing before the European Parliament: "European citizens expect the peace of mind that comes with access to health care… and protection against epidemics and diseases." She added: "We have some of the world's…most affordable, accessible and high-quality health systems to deliver on these expectations."

[1] https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

Expectations have been heightened by the emphasis placed by Europe's strategists on three linked elements that are seen as essential for effecting the sort of courageous changes needed to transform Europe in this new decade: incentives, innovation and investment. These elements also reflect the pre-conditions for boosting healthcare into higher levels of efficiency, where the value of personalised medicine can be fully appreciated and make its full contribution to Europe's citizens.

The conference is divided into five sessions which cover the follows areas:

- Session 1: *Generating alignment in the regulation of Personalized Medicine: RWE and Citizen Trust*
- Session 2: Beating Prostate Cancer and Lung Cancer - The Role of the EU Beating Cancer: Updating EU Council Conclusions on Screening
- Session 3: *Health Literacy - Understanding Ownership and Privacy of Genetic Data*
- Session 4: *Securing patient Access to Advanced Molecular Diagnostics*
- Session 5: *Global Alignment in Personalised Healthcare*

Expected outcomes

It is necessary to formulate a patient centered strategy involving EU decision makers and regulators in the arena of public health, to enable EU and Member States to contribute to integrating Personalised Medicine into clinical practice while enabling much-greater access for patients.
In order to provide a clear focus and to devote sufficient space to analysis, discussions during the conference will concentrate on how:

- to assess and address obstacles to the integration of Personalised Medicine into Europe's healthcare systems
- to identify best practices and their added value globally and locally
- to outline the potential benefits of Personalised Medicine on public health and its impact on policymaking in the EU

Participants
Attendees will be drawn from key stakeholders whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum. These participants will include public health decision makers, representatives from the Commission, Members of the European Parliament, patient organisations, and European umbrella organizations representing interest groups and associations actively engaged in the field of Personalised Medicine. Each session will comprise panel discussions as well as Q&A sessions to allow best possible involvement of all participants.

Thursday 1 July

Welcome: **D. Horgan**, *Executive Director, European Alliance for Personalised Medicine*

09.00– 10.30 Session 1: **Generating alignment in the regulation of Personalized Medicine: RWE and Citizen Trust**

Personalized medicine is individual and citizen-centric. However, trust in personalized medicine is far from being limited to trust from individuals and patients. Each actor or process in the system should be trustworthy for what it aims to deliver. Although it is

difficult to define indicators and criteria of trust or trustworthiness for each, this is a necessary exercise for the successful development of personalised medicine. It is equally difficult to assess whether each actor or process is trusted in a given context or country, because of the complex network of institutions collaborating with each other in a multi-faceted process. Collaboration between actors, communication and transparency is thus an important cross-cutting theme, with the aim to reframe and redesign the trust system to accommodate precision medicine's goals to improve the practice of medicine in general. The concept of trust is central to each of the three stages or components of the precision medicine process (value chain): the collection of data, the analysis of data and the provision of health and medical care. This session will examine the different threads of this issue.

Chair: **Alastair Kent,** *Former Director, Genetic Alliance UK*

Regulatory Perspective: **Ralf Herold,** *Senior scientific officer, Task Force Regulatory Science and Innovation, Research and Innovation (Confirmed)*

Public Health Perspective: **Daria Julkowska,** *Assistant Director, Thematic Institute of Genetics, Genomics & Bioinformatics, INSERM, France, EJP RD Coordinator and IRDiRC Scientific Secretriat Coordinator (Confirmed)*

Country Representative Perspective: **Jan Korbel**, *Head of Data Science, European Molecular Biology Laboratory, Heidelberg, Germany (Confirmed)*

Public Private Cooperation**: Martina von Meyenn***, Global Group Medical Lead, Real World Evidence, Roche*

Genomics Perspective: **Mark Caulfield***, Chief Scientist, Genomics England (Confirmed)*

Patient*:* **Birgit Bauer,** *Digital Health & Social Media Expert, Patient Expert, MS Blogger. (Confirmed)*

Discussion

Q&A

10.30 – 12.15 **Session 2: Beating Prostate Cancer and Lung Cancer - The Role of the *EU Beating Cancer: Updating EU Council Conclusions on Screening***

Prostate and lung cancer screening implementation in Europe has been debated in the scientific community and with politicians at the national and European level for a long time. Different members of the European Parliament and most experts in the field have agreed that Europe's health systems need to adapt quickly to allow patients and citizens benefit early diagnosis of lung cancer and thus reducing mortality for this lethal disease. Besides the assessment of potential economic impact to start implementation, established guidelines to assure effective and safe implementation of lung cancer screening in Europe, are required. The following panel of experts from the country level will provide their expertise of why the revised EU Council Conclusion on Screening should include lung cancer screening.

Questions to be addressed:

- Which should be the target population? How often must we screen individuals? How will the target population be reached? Which are the best recruitment strategies? Are there molecular or radiological risk factors to help selection?
- Which are the economic impacts for the European public health care system?
- What are the best programs of education and training of screening team members and the impact?
- How to foreseen and adapt the impact of screening in different european countries

Chair: **D. Horgan**, *Executive Director, European Alliance for Personalised Medicine*

Lung Cancer
Italy: G. Scagliotti, *Professor of Oncology at the University of Torino, Italy (Confirmed)*
Netherlands/EU: H. De Koning, *Professor of Public Health & Screening Evaluation, Erasmus Medical School (Confirmed)*
Poland: W. Rzyman, Department of Thoracic Surgery, Medical University of Gdansk, Poland. *(Confirmed)*
UK: Richard Booton, *Clinical Senior Lecturer and Honorary Consultant Respiratory Physician at The University of Manchester and North West Lung Centre, Wythenshawe Hospital (Confirmed)*

Prostate Cancer
Setting the Scene**: Hendrik Van Poppel**, *Adjunct Secretary General of the European Association of Urology (Confirmed)*
Quality of life for Prostate Cancer Patients: **John Dowling**, *Board Member, Europa Uomo*
PROBASE trial**: Peter Albers,** *Chairman of the Department of Urology of Düsseldorf University Hospital (DE). (Confirmed)*

Discussion

Q&A

12.15 – 13.15 Session 3: **Availability, Accessibility, and Affordability: Understanding Ownership and Privacy of Genetic Data**

The power of digitalized health data and the growing public engagement with personal choices has created new appetites for information about individuals' data and how they can benefit from its exploitation. For this to provide a universal benefit, all stakeholders need the digital literacy and capacity to value, contribute, use and benefit from health data responsibly, ethically and sustainably. At the same time, effective information provision to the public – about the pandemic and about the uses their data can be put to - can also benefit frontline health professionals and policy makers, reduce public panic and help in promptly communicating crucial findings to the international scientific community.

The crisis represents an opportunity to stimulate societal participation through citizens' involvement and broad stakeholder engagement by engaging society in a co-management strategy where citizens plays a proactive role. This effort will also contribute to building a scientifically literate patient community and support their

involvement in science and technological development so supporting the availability, accessibility, and affordability of healthcare innovation.

Chair: D. Horgan, *Executive Director, European Alliance for Personalised Medicine*

Breast Cancer: **Tanja Spanic,** *President, Europa Donna (Confirmed)*

Role of Health Literacy**: Kristine Sorensen** *Global Health Literacy Academy (Confirmed)*

Lymphoma: **Natacha Bolaños,** *Global Alliances Manager, Lymphoma Coalition (Confirmed)*

Bring innovaton into HC Systems**: Emanuele Ostuni,** *Head of Cell and Gene Therapy, Novartis Oncology Region Europe*

Colorectal Cancer*:* **Stefan Gijssels**, Chair, Belgian Patient Expert Center (Confirmed)

Discussion

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Q&A

13.15-14.00 Lunch

14.00 – 16.00 Session 4: **Securing patient Access to Advanced Molecular Diagnostics**

Increased molecular understanding is transforming the prospects for health care, and molecular diagnostics are opening the pathway to a shift in healthcare strategy. Molecular testing has informed some major preventative public health strategies – such as the significant reduction in cancer mortality. This is the threshold of a new future in which emphasis will shift away from treating illness and move toward maintaining the health of the individual. Early diagnosis and personalised healthcare will have a central part to play, particularly in the cancer arena. The objective for all stakeholders should be to see discovery 'hits' translated into robust but affordable clinical 'wins' for patients.

As the EU is itself in constant evolution, both organically, as its competences are progressively refined, and in response to changes in the world it inhabits. In healthcare, its evolution is marked not only by the emergency of the Covid-19 pandemic, which has largely monopolised the attention of all the major EU institutions throughout most of the early months of the year, but also by the constant increase in morbidity, that now affects more than its ageing population.

2021 was already designated as the year for action against cancer, with two parallel initiatives, and for the initiation of a European Health Data Space and a new Pharmaceutical Strategy. It is an appropriate moment also for it to review its approach to testing as an intrinsic element in an integrated health strategy. In these straitened circumstances, a reappraisal of the significance and potential of biomarkers can provide the EU and its citizens with a much-needed immediate up-tick in quality and accuracy of care, and a change in policy that holds out the prospect of a radical transformation of care in coming years as the full benefits of an optimum approach to the use of biomarkers begin to be felt.

Chair: **Antoni Montserrat,** *Former Senior Expert on Cancer and rare Disease, DG Public Health, European Commission*

Setting the Scene:

Role of Guideline and the State of Play in France: **Fabrice André**, *Research Director at Gustave Roussy, Paris, France*
Q&A

Multistakeholder Approach to bring NGS into healthcare systems

HARMONY and State of Play in Germany***: Lars Bullinger MD,*** *Professor of Hematology and Oncology, Medical Director of the Department of Hematology, Oncology and Tumorimmunology, Charité University Medicine Berlin. (Confirmed)*

Central Eastern Europe**: Piotr Rutkowski***, Professor of Surgical Oncology at the Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology in Warsaw, Poland. (Confirmed)*

Patient access to multigene NGS: **John Longshore,** *Head of Scientific Affairs, AstraZeneca (Confirmed)*

Discussion

Best Practice outside the EU:

Étienne Richer, PhD, *Associate Scientific Director, CIHR Institute of Genetics. (Confirmed)*

Gilad W. Vainer, *MD PhD, Onco-proteomics lab, Head Department of Pathology, Hadassah Hebrew-University Medical Center, Jerusalem, Israel. . (Confirmed)*

Discussion:

Q&A

16.00 **Conference End….**