Azienda Ospedaliero Universitaria Careggi

European Alliance for Personalised Medicine

High-level Conference

Tackling the implementation gap for the uptake of NGS and advanced molecular diagnostics into healthcare systems: The Role of Pathology and Medical Laboratories

Careggi University Hospital, Florence, Italy
Aula Magna NIC 3
September 6th, 2024
08.30 – 16.30 CET

Purpose: Radical new possibilities of improved treatment of cancer are on offer from an advanced medical technology already demonstrating its significance – Next-Generation Sequencing (NGS). This refined testing provides unprecedentedly precise diagnosis and permits the use of focused and highly personalised treatment. But across regions in the EU, many cancer patients will continue to be denied the benefits of advanced molecular diagnostics, NGS and liquid biopsy as long as some of the yawning gaps in its implementation remain unattended, in particular in the area of pathology. Achieving the transformation of care for patients with this novel approach requires that conditions for increased deployment are met – and that depends on many stakeholders, ranging widely across policymakers, the medical and scientific community and patient organisations, and at national and international level.

Within different regions in the EU, getting those conditions right can be helped by linking efforts made at EU level – where patients have needs and where care is delivered – and at a EU as well at a global level, where major policy initiatives in the health field are underway or in preparation, many of them offering direct or indirect pathways for building those conditions. The challenges for countries and at EU level are linked because putting the solutions into effect is highly dependent on cooperation between national cooperation and EU levels – and could be hindered by shortfalls in interpretation or understanding.

Focus:

- Plenary Session I: Public & Private Sector Collaboration
- Plenary Session II: Reimbursement, Funding for labs & testing
- Plenary Session III: A policy framework to empower digital pathology in the EU

Outcome: The conference provides a chance to re-align priorities to evaluate the needs of patients, healthcare professionals and health systems to facilitate improved and safer access to diagnostics with the support of the pathology community.

Attendees: 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.

Attendees will receive a certificate of attendance. As such, registration is required.

Friday, Sept 6th, 2024

Moderator: D. Horgan, EAPM Executive Director

08:00- 08.30: Registration, coffee, networking

08.30 – 09.30 Setting the Scene

Welcome:

Andrea Galli, *Director of the Biochemical, Experimental and Clinical Sciences Dept., University of Florence*

Daniela Massi, *Professor of Pathology, Health Sciences Dept., University of Florence and Director of the Histopathology and Molecular Diagnostics, Careggi Teaching Hospital*

Setting the Scene:

- Role of Pathology**:** **Gabriella Nesi,** *Professor of Pathology and Director of the Residency Program in Pathology, University of Florence*
- Role of Labs: **Mario Pazzagli**, *Professor of Clinical Biochemistry, University of Florence, Florence*
- The needs of the Patients: **Fabrizia Galli***, Vice-President, aBRCAdaBRA*
- Equity of access*:* **Tilman Krueger,** *Director, MSD*
- Setting the Scene for the Day: **Denis Horgan,** *Executive Director, European Alliance for Personalised Medicine*

09:30-11:00 Plenary Session I: Public & Private Sector Collaboration

Effective cancer diagnosis, treatment and control depend on interactions among numerous distinct factors, from technology to data to skills to sociology. But a crucial influence is the extent to which the health system takes account of the distinct perspectives of the many different groups of interdependent stakeholders concerned with cancer, including patients, practitioners, industry and planners. This session will elucidate on how far and how efficiently these interactions currently take place in Europe. It will propose some tentative suggestions as to how conscious public private collaboration could improve cancer outcomes.

- Role of the European Health and Digital Executive Agency - European Union: **Stephane Hogan**, *Head of Unit for Health Research at HaDEA*
- AURORA (Aiming to understand the molecular aberrations in metastatic breast cancer): **Matteo Benelli, PhD,** *University. of Florence*
- PIONEER (Prostate Cancer DIagnOsis and TreatmeNt Enhancement through the Power of Big Data in EuRope**: Rossella Nicoletti, MD,** *Urology Resident, Careggi Teaching Hospital, Florence*

- CAN.HEAL (Building the EU cancer and public health genomics platform): **Marc Van Den Bulcke**, *Project Coordinator, CAN.HEAL*
- Instand-NGS4P: **Peter Riegman,** *Professor of the Erasmus Universitair Medisch Centrum Rotterdam, Netherlands*

Discussion

11:00 -11.30 Coffee Break

11:30 -13:30: Plenary Session II: Reimbursement, Funding for labs & testing

Molecular diagnostics can offer important benefits to patients and are a key enabler of the integration of personalised medicine into health care systems. However, despite their promise, few molecular diagnostics are embedded into clinical practice (especially in Europe) and access to these technologies remains unequal across countries and sometimes even within individual countries. If research translation and the regulatory environments have proven to be more challenging than expected, reimbursement and value assessment remain the main barriers to providing patients with equal access to molecular diagnostics. Unclear or non-existent reimbursement pathways, together with the lack of clear evidence requirements, have led to significant delays in the assessment of molecular diagnostics technologies in certain countries. Additionally, the lack of dedicated diagnostics budgets and the siloed nature of resource allocation within certain health care systems have significantly delayed diagnostics commissioning. This session will consider the perspectives of different stakeholders (patients, health care payers, health care professionals, and manufacturers) on the provision of a research-enabled, patient-focused molecular diagnostics platform that supports optimal patient care. Through the discussion of specific case studies, and building on the experience from countries that have successfully integrated molecular diagnostics into clinical practice, this session will discuss the necessary evolutions in policy and health technology assessment to ensure that patients can have equal access to appropriate molecular diagnostics.

Setting the Scene:

- Use Case: Liquid Biopsy: **Pamela Pinzani,** *Professor of Clinical Biochemistry, University of Florence*
- Use Case: NGS in Clinical Microbiology: are we ready for that?: **Gian Maria Rossolini,** *Professor of Clinical Microbiology*

Panel:

- Role of Notified Bodies: **Marta Carnielli**, *IVD Technical Officer at TÜV SÜD Product Service GmbH*
- Brining Innovation into healthcare systems: **Dirk Kemming**, *Medical Director Diagnostics Europe Daiichi Sankyo*
- Health Technology Assessment in Spain: **Iñaki Gutiérrez-Ibarluzea,** Director, OSTEBA

- Use Case Example: Italy**: Ettore D. Capoluongo,** *Prof. of Clinical Biochemistry and Clinical Molecular Biology, Director of Clinical Pathology Department, Emergency Hospital "Cannizzaro" - Catania (Italy)*

- Health Technology Assessment in Germany**: Hans-Peter Dauben**, *Secretary General, EuroScan international network e.V.*

- Bringing Diagnostics into healthcare Systems: **Maciej Gajewski**, *International Affairs, Exact Science*

Discussion

13:30- 14.30 Lunch

14:30 – 16.15 Plenary Session III: A policy framework to empower digital pathology in the EU

In the field of contemporary medicine, where ongoing technological advancements consistently reshape healthcare practices, the advent of digital pathology represents a significant and transformative accomplishment. The paradigm shift can fundamentally transformed the traditional approach to medical diagnostics. It has introduced a combination of state-of-the-art technology, data analysis, and clinical expertise that can significantly transform how patient care is delivered. In this narrative review, we comprehensively examine the significant implications of digital pathology in modern medical diagnosis. During this session, we will explore various essential aspects that have played a significant role in the transformative journey of digital pathology and the policy framework that will best enable this.

Setting the Scene:

- **Manuel Salto-Tellez**, Clinical Professor, School of Medicine, Dentistry and Biomedical Sciences, Patrick G Johnston Centre for Cancer Research, Belfast, Northern Ireland

Panel:

- Germany*:* **Falko Fend**, *Institute of Pathology, Tuebingen University Hospital*

- Belgium: **Pieter Demetter**, *Belgium Society President, Belgium Department of Pathology Institut Jules Bordet Brussels, Belgium*

- Equity of Access: **Luiza Moore**, *Senior Director, Clinical Diagnostics, Global Oncology Diagnostics, OBU, AstraZeneca*

- Italy**: Raffaella Santi,** *Assistant Professor of Pathology, University of Florence, Italy*

- Greece**: Vassiliki Tzelepi,** *Associate Professor at the Dept. of Pathology, University of Patras*

Discussion

16:15 – 16.30 Concluding Session: Role of the EU and Member States

- **Denis Horgan,** *Executive Director, European Alliance for Personalised Medicine*