



*German Presidency Conference*  
*“Ensuring Access to Innovation and data-rich biomarker space to speed better quality of care for  
Citizens”*

*Brussels*  
*12 October 2020*

**Overview:**

This event will be the third Presidency conference that EAPM will be holding during 2020 - during the **Croatia Presidency**, a **bridging conference** between the Croatia and Germany presidencies, and this final event while **Germany** is at the helm. All three events reflect the nature of the relative presidency policies in the healthcare arena, but also act as major events during what will be the first full year of the two new legislative bodies - the European Parliament and the European Commission.

And, of course, since the start of the year we have been dealing with impact and fall out of the Covid-19 crisis. We need to look ahead to try and understand what a post-Covid world will mean for healthcare readiness and sustainability, health data gathering and sharing, cancer treatments and personalised medicine. The latter three topics are already being addressed, at least in part, by the European Commission *et al*, while the first issue cannot be dealt with in any way properly without Europe quickly bringing innovation into its healthcare systems.

Then there is the question of adequate resources being available and, of course, successful implementation. The optimal use of relevant data is clearly a huge issue as we attempt to optimise healthcare down the line, and there is clearly a need for better access to information, in order that resources can be more rationally allocated.

Other issues that have arisen during the current crisis are those surrounding the need for increased cross-border coordination and cooperation among Member States, and adequate capacity - given an ageing population and the fact that the novel coronavirus will not be our last pandemic. Essentially, Europe needs more agility in its healthcare systems, while it is clear that the use of the digital can support the much-needed innovation.

Specifically in the area of cancer, looking ahead to the next two decades, there will be a massive increase in cases Europe. Regulators, industry and healthcare professionals really need to step up to this new reality, and this also applies to citizens, who have a certain degree of responsibility for their own healthcare. Lifestyle changes will be paramount, and could amount in many cases to the best form of prevention.

This conference will showcase different objectives which both the public and private sector can support, with a view to allowing the EU to present a common objective.

As always, this EAPM event will be in a focused format to allow concrete issues to be tackled and to bring about a dialogue with our policymakers. In what will eventually (we hope!) be a post-covid world, and the sooner the better, this the perfect time for a lively, informative and productive gathering, involving large numbers of industry professionals, government regulators, patients, academia, and exhibitors all striving to drive insights to action.



09.00 – 09.10 **Welcome**

**Denis Horgan**, *Executive Director, EAPM*  
**Irena Joveva**, *Member of the European Parliament*  
**Pascal Canfin**, *Member of the European Parliament*  
**Mary Baker**, *Past President, European Brain Council*

09.10 – 10.30 **Opening Session: The Pharmaceutical Strategy of the EU: Developing a Framework to ensure capacity and equitability across the EU**

Massive gaps have been shown up in individual Member State healthcare system capacities in the current situation. The inconsistency and lack of coherence in testing for the virus as the situation has developed and spiralled has been striking for all the wrong reasons.

Meanwhile, shortages of ventilators, the ongoing shortages of ICU beds, a lack of sufficient PPE for frontline HCPs, a lack of coordination between Member States when it comes to dealing with the issues on an EU-wide basis...the list goes on.

And these issues will not disappear once the crisis is over, as not only will there be a similar one eventually, but with an ageing population and systems already stretched, these problems were there prior to Covid-19 and will continue to exist afterwards.

Clearly, our healthcare systems need more support as well as better frameworks to facilitate the better adoption of much-needed innovation and smarter use of scarce resources. Testing when needed simply has to be better organised, quicker, and more effective.

**Ceri Thompson**, *Deputy Head of Unit, eHealth, Well-being, and Ageing, DG Connect, European Commission*  
**Hon Christopher Fearne**, *Minster for Health, Deputy Prime Minister of Malta*  
**Christine Chomienne**, *Vice-Chair, Members of the Mission Board for Cancer, Professor of Cellular Biology at the Université Paris Diderot, Paris*  
**Marcus Guardian**, *EUnetHTA Chief Operating Officer*  
**Iskra Reic**, *Executive Vice President, Europe and Canada, AstraZeneca*

10.30 – 11.45 **Session I: Multi-stakeholder approach – Rational Allocation of Resources to support innovation and healthcare system efficiencies – Who to test, when to test and how to test?**

During the current pandemic it has become clear that advice given from governments and experts in such a situation needs to be correct, understandable and consistent. As does how figures are gathered.

During the current crisis this has not been the case. Take, for example, the conflicting advice over the use and usefulness of face-masks and other protective equipment. Areas such as this are key to prevention, as are developing serological testing for this particular virus and developing treatment pathways for Covid-19, alongside treatment for existing diseases.

Regarding testing in general, this is such a central aspect of personalised medicine. we now live in a world of biomarkers and molecular diagnostics, aiding prevention and early diagnosis, and theoretically of particular benefit in the context of Covid-19.



Biomarkers certainly have a job to do, too, in modern personalised medicine. We need more of these that are relevant to treatment.

Unfortunately, the barriers in respect of data sharing mean that risks related to data security and privacy can have a paralysing effect on progress.

Back to testing, *per se*. There are obvious issues concerning who to test, when to test, and how to test, what resources are needed, who will conduct the tests, and what systems are needed for analysing and for providing feedback loops to decision makers.

One thing is clear, there is an overwhelming need for quality in testing, and the development of minimal and optimal testing requirements should be considered. But we need to consider how do we reach a target of agreement between all partners and all Member States.

Also, while the current public highest-of-high regard for healthcare professionals (HCPs) is to be welcomed, there needs the right methodology to tackle gaps in healthcare systems - not least the need for testing.

We need a serious look at the need for up-skilling of HCPs, as well as coordination in terms of guidelines across all areas of diagnosis, treatment and quality of life later.

**Chair: Alastair Kent**, *Formerly Director of Genetic Alliance UK*

**Sean Kelly**, *Member of the European Parliament*

**Joern-Peter Halle**, *Head of Research, Global R&D Healthcare, Merck KGaA*

**Benedikt Westphalen**, *University Hospital Munich, Department of Internal Medicine III & Comprehensive Cancer Center Munich, Germany*

**Inaki Gutierrez Ibarluzea**, *Director of Organisational and Managerial Innovation of the Basque Foundation for Health Innovation and Research*

**Marco Greco**, *President, European Patient Forum*

**Dipak Kalra**, *President, The European Institute for Innovation through Health Data (i~HD)*

Q&A

11.45 – 13.00 Session II: **Cancer: Case Study for EU Coordinated Action on Prostate, Lung, Breast and Cervical Cancer**

We will talk a great deal about collaboration and cooperation at this conference. But there needs to be a framework in which it can happen to its highest potential. Not least in policymaking.

And on a pan-European level, where member States have competence for their own healthcare, there needs to be trust. A certain degree of that could be seen building during the Covid-19 crisis, but there is still not enough.

The optimal framework for health is an EU Framework of cooperation. And that means it is all about the teamwork. And that cannot be achieved without trust. From the public. And between governments and the Commission, for example.

We hear teamwork praised again and again when bosses praise their staff, when football managers are happy after a good result, when someone picks up an Oscar for Best Director.



But is there really enough teamwork and collaboration happening?

The fact is, certainly in a healthcare sense, there is certainly too little cooperation to tackle the problems that beset our ageing society, which include under-resourced health services, an age spent getting new drugs to market, an increase in chronic diseases, *et al.*

In the case of healthcare, there are solid arguments that what we need is more, not less, Europe - and for practical purposes that means less silo thinking and more cooperation, across borders and across disciplines.

If Covid-19 has shown us nothing else, it has certainly demonstrated that. And we must identify then learn the lessons as we move ahead.

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

**Key note**

**Ciaran Nicholl**, *Head of Unit, F1“Health in Society”, JRC, European Commission*

**Bartosz Arłukowicz**, *Member of the European Parliament*

**Ljudmila Novak**, *Member of the European Parliament*

**Ouzna Morsli**, *Executive Medical Director Oncology, MSD*

**Prostate Cancer**

**Hein Van Poppel**, *EAU Adjunct Secretary General - Education*

**Lung Cancer Screening**

**Sofia Ravara**, *Medical Doctor of Universidade da Beira Interior, Covilhã (UBI)*

**Breast Cancer**

**Joe Duffy**, *Professor, Clinical Research Centre, St Vincent's University Hospital*

**Cervical Cancer**

**Marc Van Den Bulcke**, *Head of the Cancer Centre (Sciensano)*

Q&A

13.00 – 14.00 Lunch

14.00 – 15.15 Session III: **Biomarker testing: Piercing the fog of Alzheimer's and related dementia**

Alzheimer's disease (AD) is one of the growing threats to the sustainability of health and care systems in developed countries, and efforts to find therapies have had scant success. Biomarkers are making a major contribution to research, helping elucidate the disease and the search for treatments. They are also playing an increasing role in early detection and timely diagnosis, which are considered the principal hopes of effective management in the absence of an effective drug. The current arsenal of biomarkers could already, if more widely deployed, provide an effective minimum service to patients and health systems. A concerted action by policy makers and stakeholders could drive progress in access to AD biomarker testing to provide an optimum service in the medium term.



This session discusses how to improve the use of and access to biomarker testing in the detection and diagnosis of Alzheimer's disease and other diseases featuring dementia, and how EU healthcare systems could benefit. It outlines the challenges, lists the achievements to date, and highlights the actions needed to allow biomarker testing to deliver more fully on their potential in Alzheimer's disease.

**Chair: Denis Horgan**, *Executive Director, European Alliance for Personalised Medicine (EAPM)*

**Maria Da Graça Carvalho**, *Member of the European Parliament*

**Karim Berkouk**, *Deputy Head of Unit for Combatting Diseases, DG Research and Innovation, European Commission*

**Timo Grimmer**, *Professor, Department of Psychiatry and Psychotherapy, Klinikum rechts der Isar der Technischen Universität München*

**Charlotte Teunissen**, *professor of Neurochemistry at the Department of Clinical Chemistry, VUmc*

**Dr. Frances-Catherine Quevenco**, *International Medical Associate, CNS - Alzheimer's Disease (AD), Global Medical and Scientific Affairs, Roche Diagnostics International Lt*

Q&A

#### 15.15 – 16.30 Session IV: **Propelling Healthcare with Advanced Therapy Medicinal Products (ATMPs)**

Recent advances in biomedicine are opening the door to new approaches – particularly for diseases such as cancer and rare diseases, where limited or no alternative treatment options exist and unmet need remains high.

These products – which are known in the EU as advanced therapy medicinal products (ATMPs) - have the potential to provide life-changing benefits to patients and their families, and dramatically change people's lives. After a slow start, the field is at last advancing fast, as demonstrated by the number and variety of clinical trials and the new products now becoming available. ATMPs have already demonstrated outstanding results in treatment in patients with B-cell acute lymphoblastic leukaemia, melanoma, and rare inherited disorders such as treatment of children with spinal muscular atrophy or vision loss due to retinal dystrophy. They hold one of the keys to making a reality of genuinely personalised medicine.

The discussion will focus on the potential of these as well as the policy framework to facilitate this.

**Chair: Denis Horgan**, *Executive Director, EAPM*

**Tilly Metz**, *Member of the European Parliament*

**Falk Ehmann**, *chair of the Innovation Task Force, EMA*

**Oumeya Adjali**, *Directrice du laboratoire, Université de Nantes, Nantes, France*

**Thomas Szucs**, *University of Basel, European Center for Pharmaceutical Medicine*

**Declan Noone**, *Patient Advocates – Hemophilia*

**Dimitrios Athanasious**, *Board member, World Duchenne Organisation*

**Thomas Thum**, *Institut für Molekulare und Translationale Therapiestrategien*

**Marie-Christine Ouillade**, *Board French Muscular Dystrophy Association (AFM)*

Q&A



16.30 – 17.45 Closing Session: **Realising the potential of Data & Early Diagnosis through biomarker testing & Molecular Diagnostics**

As mentioned in previous sessions there has been much learned from this dreadful battle against Covid-19. But we need to implement the lesson because, despite the great leaps in science and progress made in, for example, personalised medicine, it is not enough even now and certainly will not be enough even in the near future.

We clearly cannot u-turn on innovation on personalised medicine processes, we cannot u-turn on genome sequencing, and we cannot u-turn on the mass of data now available. Our only real recourse is to accept that what was once the future is here, right now, today.

Data is everywhere among us and around us and, as part of this, Europe has the chance to create and harness a data-rich, decentralised, secure, and GDPR-compliant blockchain system.

But, as ever, nothing is that simple, as all healthcare data will need to be evidence-based data as the questions of what constitutes 'value' refuse to go away.

Real-world evidence is necessary to generate comparative effectiveness studies using data from patients with, for example, common cancers, who are treated in different environments. This in order to enable the evaluation of care outcomes provided when specific biomarkers are used to direct patient care with targeted management.

One key challenge for Europe is the need for a number of translational scientists to ensure that clinical data, cancer biomarkers, blockchain technology, ISO standards, and data science can come together in one, cohesive project.

Another is to bring together huge amounts of biomarker data using the decentralised nature of blockchain technologies, its security and privacy characteristics.

Times have moved swiftly. And our only real recourse is to accept that what was once the future is here, right now, today.

**Chair: Denis Horgan**, *Executive Director, EAPM*

**Andreas Glück**, *Member of the European Parliament*

**Marzia Zambon**, *External Affairs Director, EUROPA DONNA - The European Breast Cancer Coalition*

**Stefan Gijssels**, *Chief Executive Officer, Digestive Cancers Europe*

**Benjamin Gannon**, *Vice President International Access, Policy And Advocacy, Myriad Genetics*

**Sara Cerdars**, *Member of the European Parliament*