2018

EAPM

MILAN

# 2nd European Alliance for Personalised Medicine Congress

## Forward as One: Integrating Innovation into Europe's Healthcare Systems

26–28 NOVEMBER 2018 // MILAN // ITALY

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# CONTENTS

# WELCOME TO MILAN

**All of us at the European Alliance for Personalised Medicine are delighted to see you in here Milan for this, our second annual Congress. This year's event comes under the banner**
**Forward as one: Integrating Innovation into Europe's Healthcare Systems.**

EAPM's second annual Congress has, like the first edition and several Presidency conferences, pulled together leading experts in the fast-moving healthcare arena. This year we are also delighted to be working in partnership with the Lombardy Region. As well as being world-renowned for its hospitality, the region's capital Milan is a world-class driver of scientific innovation (especially in the area of cancer).

Lombardy as a whole represents **16,4%** of Italy's population, produces **21%** of national GDP, is host to **814,000 companies** (99% of which are SMEs) and is responsible for exports of 108 billion euro.
It is also home to **13** public and private universities, 18 Institutes for treatment and research, **12** national research council institutes plus **29** public hospitals and assistance centres.
Innovation is all around us, and there are certainly plenty of innovators at this Congress.

Hundreds of Life Sciences thought leaders are here for the coming days as we bring together key audiences who contribute to the vast programme content and vital knowledge exchange.

Large numbers of industry professionals, government regulators, patients, researchers, academia, healthcare professionals, journalists and exhibitors are here to drive insights into action and, more than ever this year, a focus will be on the upcoming European Parliament elections and the instal-lation of a new College of Commissioners. These institutions will be tasked with devising and implementing regulatory frameworks in all areas, including health of course.

As we all know, personalised medicine is in the news more-and-more often these days, with its goal of giving the right treatment to the right patient at the right time. Breakthroughs in genetics, calls for more and better screening, developments in imaging techniques and the emergence of what we now call **Big Data** have already changed the world of healthcare for ever.

One of the key goals of Congress is to engage politicians and lawmakers in this fast-growing field, and deliver political asks through our consensus-based process. Europe needs to grasp the fact that health equals wealth and that investment in research and in-novation, alongside laws and rules that are fit-for-purpose and reflect the swiftly changing world of medicine, are vital.

There needs to be encouragement and incentives for those looking to invest and innovate in Europe. We have the skills and facilities within the bloc but currently lack an ideal environment that will ensure better access to treatment for patients.
Innovation and the incentives for it are vital to health and wealth in the current EU-28 (and will be even more important after the UK leaves next year). It also encourages investment from outside of the EU, clearly good for business and jobs.

Topics covered at this event will include a two-day track on the **MEGA** initiative that is gaining considerable traction. **MEGA** stands for **Million European Genomes Alliance** and the joint declaration by a coalition of willing Member States in April was the result of continued engagement over several months. More countries have now signed up to the initiative, as has the Commission.

The declaration indicated political support for linking existing and future genomic databanks, on a voluntary basis, in order to reach a cohort of one million sequenced genomes accessible in the EU by 2022.

Also up for discussion at the Congress will be a multitude of disease areas, the ongoing and hugely important debate on HTA, men's health and a plethora of other relevant topics - all under the umbrella of facilitating innovation.

We are confident that the Congress will allow you all to air yours views prior to delivering key aspects to decision makers at European, national and regional levels. This will effectively allow for a bridge to representatives in various policy areas. We intend to make sure that your voices are heard exactly where they should be.

Going forward, much has already been achieved through stakeholder interaction, and **EAPM's** previous events have seen involvement from policymakers and regulators, MEPs, national healthcare officials, patient groups, HTA bodies, academics, researchers, healthcare professionals, industry representatives and more.

Still, the Alliance believes that the time has come to find on-the-ground ways to turn the dream of personalised medicine into reality. This essentially means the practical integration of innovation-based personalised medicine into Member State healthcare systems as quickly and efficiently as possible.

Again, welcome to this Congress, and the Alliance hopes that your time here in Italy's beautiful Lombardy Region will be enjoyable, rewarding and hugely constructive.

**Over to you!**

David Byrne, co-chair
Gordon McVie, co-chair
Denis Horgan, executive director

# BRINGING NEW HOPE TO PEOPLE WITH RARE DISEASES

**PETER MEEUS,**
HEAD OF REGION EUROPE, SHIRE

## CHAMPIONING PEOPLE WITH RARE DISEASES

At Shire, our ambition is to **help people with rare diseases to live better lives.** Rare diseases are among the toughest and most complicated of diseases. They are often severe, debilitating and can lead to early death. Most are genetic and start at birth or in childhood and, sadly, an estimated one in three children born with a rare disease does not reach their fifth birthday.

Worldwide, an estimated **350 million people live with one of over 7,000 recognised rare diseases.** The complexity, the disproportionate numbers of children affected and the small numbers associated with each disease make developing new medicines and more effective care extremely challenging. It's why **95% of rare diseases have no treatment.**

Today, **Shire has over 40 medicines available across many specialty and rare disease areas.** We are driving breakthrough science in poorly understood diseases so people can benefit from advances in personalised and individualised medicine and technology. For example in haematology we use prophylaxis to propel patients towards optimal personalised care and help them remain on the right therapy in order to achieve the best possible long term outcomes. Shire also develops technologies to personalize care to allow for optimal dosing tailored to individual needs. **Currently Shire is conducting over 40 research programs globally;** 20% of patients involved are children and 70% are rare disease specific.

However, to make a real difference in rare diseases **Shire is going beyond developing medicines to improving diagnosis, accelerating access to treatments** and supporting people with rare diseases, their families and caregivers throughout their journey.

## ENDING THE DIAGNOSTIC ODYSSEY

For a child with a rare disease, it can take over five years on average to get an accurate diagnosis. And up to 40% of rare disease patients are misdiagnosed more than once. This is why **Shire, Microsoft, and EURORDIS formed a strategic alliance to address the diagnostic odyssey for rare disease patients.**

**The Global Commission is a multi-disciplinary group of experts** who will launch a roadmap in February 2019 to help shorten the diagnostic journey by addressing the barriers to timely diagnosis:

- Improving physicians' ability to identify and diagnose patients with a rare disease.
- Developing standardised protocols to increase collaboration, efficiency and productivity within healthcare practices.
- Empowering patients and their families to have a more active role in their healthcare.
- Providing high-level policy guidance to help achieve better health outcomes for rare disease patients.

The Global Commission is optimistic that **its work will transform the lives of children with a rare disease.**

## CHAMPIONING INNOVATIVE PATIENT ACCESS SOLUTIONS

Since 2000, the **EU Orphan Regulation has helped create the right incentives to promote innovation and attract investment in developing treatments for rare diseases, leading to significant new research, clinical trials and new medicines.** For example, 174 medicines are now approved in Europe – up from 8 in 2000. We have also seen a significant increase in new clinical trials of 84% from 2006 to 2016 for medicines treating rare diseases.

**For people with rare diseases, speed matters, as delays to treatment can lead to serious consequences**. For example, for people with haemophilia, every bleed matters because as few as two or three bleeds in a joint, can cause irreversible structural changes to a joint.

However, **today's national pricing and reimbursement assessment processes for rare disease medicines can lead to substantial delays or failure to gain access**. For example, the average time to get funding is 2 years in England versus 7 months in Germany. And only 68 orphan medicines have been reimbursed in England, compared to 116 in France and 133 in Germany.

These **assessment processes often do not take into consideration that standard Health Technology Assessment (HTA) criteria are not designed for rare diseases.** This is why **Shire is advocating for new approaches in the evaluation of rare disease treatments and evidence generation.** The new approaches will also allow all stakeholders to better understand the challenges and opportunities for integrating future personalized treatments within the healthcare system. Our proposal focuses on enabling access for patients at the time of regulatory approval via a process of 'Immediate Access with Conditional Reimbursement', which has already been successfully implemented in France, Germany and Scotland.

We are also working with our partners to **improve patient access to rare disease medicines by designing innovative approaches that will accelerate access using Real-World Evidence (RWE).** For example, Shire is a partner in the multi-stakeholder 'Tool for Reducing Uncertainties in evidence generation for Specialised Treatments for Rare Diseases'' (TRUST4RD) project led by the Belgian payer RIZIV-INAMI. **TRUST4RD aims to build trust and facilitate early dialogue in adaptive payer models** between HTA bodies and ministries, regulators, patient representatives, clinicians, clinical research bodies and industry.

Now is the time to accelerate change and bring new hope, help and progress every step of the way for people with rare diseases.

# PATIENT POWER IN THE PERSONALISED MEDICINE REVOLUTION

The patient is at the heart of personalised medicine, or certainly should be. However, despite all the incredible technological advances in recent years, there remain issues surrounding access to the best healthcare possible and also around education as well as doctor/patient communication.

Here, EAPM executive director **Denis Horgan** talks to **Stephen McMahon** from the **Irish Patient Association.**

**Stephen McMahon**
Director,
*Irish Patients Association*

**Denis Horgan,**
Executive Director,
*EAPM*

**DH: Modern technology, Big Data and huge leaps in genetics have created potential new ways to put patients at the centre of their own healthcare. But are patients as empowered as they could be?**

**SM:** As you said, Denis, genetics and indeed other technology has opened new doors for patients in the form of personalised medicine and could potentially change the patient journey for the better. From a communication point of view, there is certainly more joint decision-making as lifestyle, work and personal preferences are now all increasingly coming into play. But we need our front-line healthcare professionals to be up-to-speed with the latest developments, and we need them to understand and tell patients where suitable clinical trials are taking place.

Today's patients are pushing to play a bigger role and carrying the message "Involve me!"

Of course, healthcare professionals are still vital and always will be but, by the same token, patients need to play an even bigger role than they already now are.

With the Big Data you mentioned, and citizens who deserve the best treatment having contributed to healthcare budgets throughout their working lives, the patient has, and deserves to have, a right to the best care possible.

**DH: Does everyone 'get' this concept?**

**SM:** Unfortunately not. Arguably, many old-school physicians as well as the medical schools that produce modern healthcare professionals haven't all grasped this. Which is one reason for EAPM's summer and winter schools, of course, for our new generation of specialists.
The underlying fact is that patients want to take control as much as possible of their treatment. Not as professionals, obviously, but as humans with a role to play. Some doctors need to put the old one-size-fits-all methods and I-know-best feelings aside and accept that a patient's will for empowerment is not a power grab, but simply a will and need to be involved on a meaningful level.

**DH: So, are things changing as they should be?**

**SM:** To a degree. There is clearly a reformation going on in healthcare systems. But we need new and clear thinking about the way that healthcare is delivered and there are excellent opportunities for positive change.

For example, the social fabric of how healthcare can be delivered must be allowed to grow and the role of all stakeholders should be recognised. Fortunately your own Alliance has meaningful input from patients but it needs to be even-more widespread. We desperately need bottom-up and top-down governing frameworks which will allow innovation to be integrated in a healthcare-friendly fashion that includes patient empowerment.

Things are actually moving forward in many ways, but the quality of an EU patient's treatment still varies from country-to-country, depending on resources and the incidence of a particular disease, screening programmes, and the awareness, or not, of potential over-treatment.

It is certainly a problem, but one that we must solve.

**DH: So, how expert is the patient? What is his or her role?**

**SM:** Most patients are certainly not experts on medical matters, whatever the internet may attempt to bring. But they are the 100 percent experts regarding their own lifestyles. As mentioned, some doctors still don't seem to fully understand that, and it needs too change.

Patient empowerment is a central point of personalised medicine as we know, but empowerment differs depending on the disease. Is someone with a rare cancer, with no clinical trial group within a thousand miles, able to be as empowered as someone with a breast tumour caught early and treatable?

What if the EU Member State where he or she lives is not the best at treating the condition, but suitable reimbursement is not available due to different costs in different countries with better resources in the particular case?

Yes, we now have cross-border treatment rights, but anyone working in this area would have to say, honestly, that it is far from living up to its potential, however well intended.

Meanwhile, drugs for rare diseases are, obviously, more expensive given the smaller market and the cost of development, trials, safety checks and the time taken to get approval to go on the market.

We're living longer, and many of us are nowadays suffering from co-morbidities. To say that resources are stretched would be an understatement. On the plus side, patients are generally better-informed than they have even been.
So as mentioned before, unsurprisingly, there is a debate about how much power'a non-expert patient should actually have, and there is clearly a communication gap between the healthcare professional and the patient in many cases. Patients don't always ask the right questions, and many doctors are unforthcoming unless asked specifically.

**DH: So the patient is a vital part of any dialogue?**

**SM:** Absolutely. As we keep saying, personalised medicine aims to put the patient right at the centre of his or her own healthcare, and that means taking decisions in concert with doctors, nurses and surgeons.

Patient groups also advocate the better training for healthcare professionals that we touched on before, and smarter use of resources, as well as cross-border sharing of health data, better coordination and collaboration in research, and the continuous exchange of knowledge and best practices.

But it is not only this aspect that should see more patient involvement. Patients should be involved in discussion about concepts of value, and be there in the early and subsequent stages of emerging new drugs.

On top of this, patients have to be involved in health technology assessment processes, which are currently being reviewed, of course.

To end with that, we are particularly disappointed that the European Parliament didn't see fit to make this provision when it voted on the Commission's proposals on HTA and the ENVI committee's amendments and compromises.

That in many people's view amounts to a lost opportunity as far as patients are concerned. It is certainly the view of patient organisations.

# DAY 1: 26TH NOVEMBER 2018

| 9:00–10:15 | Parallel Sessions |
|---|---|
| Pirelli Room | **Regional Track**<br>Session 1: Role of EU Funding Mechanisms to support Regional & National Level coordination |
| Room Arancio 34 | **Men's Health Track**<br>Session 1: Lowering the Risk and Mortality Rate of the Most Frequent Cancer in Men |
| Biagi Room | **Education Winter School Track**<br>Opening Session: Objectives of the Winter Summer School. Diagnosis & Decision Making Frameworks for Family Physicians & General Practitioners |
| Soresin Room | **Diagnostic/Medical Devices Track**<br>Session 1: Regulatory Framework for Companion Diagnostics |
| Testori Room | **Genomic Track**<br>Opening Session: Perspectives on Genomics |
| Room 31 | **Access & Early Diagnosis Track**<br>Session 1: Are Current Frameworks Useful to Capture the Value of P.M. Technologies? Are Other Frameworks/Methodologies Required? |
| **10:45–12:00** | **Networking and Break** |
| **10:45–12:00** | Parallel Sessions |
| Pirelli Room | **Regional Track**<br>Session 2: Structural Funds to Support Infrastructures for the Personalised Healthcare Era |
| Room Arancio 34 | **Men's Health Track**<br>Session 2: Setting the Framework for Political Action & Tools to realise this |
| Biagi Room | **Education Track**<br>Session 2: Shared Diagnosis and Decision – Making: Patient/Physician Communication |
| Soresin Room | **Diagnostic/Medical Devices Track**<br>Session 2: Reimbursement and financial framework for Diagnostics |
| Testori Room | **Genomic Track**<br>Session 2: Genomics – Time to Deliver |
| Room 31 | **Access & Early Diagnosis Track**<br>Session 2: Value from the Economic Perspective |

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 1: 26TH NOVEMBER 2018

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|---|---|
| **12:15–13:15** | **Opening Plenary Presidential Session**<br>Forward as one – Europe as a Global Player |
| **13:15–14:15** | **Lunch and Networking Break** |
| **14:15–15:30** | **Presidential Session**<br>Advancing Europe's Healthcare – Patients & Economy |
| **15:30–16:00** | **Networking and Break** |
| **16:00–17:15** | Parallel Sessions |
| Pirelli Room | **Regional Track**<br>Session 3: Private Investment to Drive Forward Healthcare |
| Room Arancio 34 | **Men's Health Track**<br>Session 3: Multidisciplinary Approach of Early Diagnosis: The Way Forward |
| Biagi Room | **Education Track**<br>Session 3: Emerging Screening & Diagnostic Tools to Facilitate Early Diagnosis of Disease |
| Soresin Room | **Diagnostic/Medical Devices Track**<br>Session 3: Value of diagnostic Information (VODI) from Concept to Reality |
| Testori Room | **Genomic Track**<br>Session 3: Implementation of Genomics into Healthcare Systems |
| Room 31 | **Access & Early Diagnosis Track**<br>Session 3: Value from Organizational Perspective Context Matters |

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 2: 27TH NOVEMBER 2018

| | |
|---|---|
| **8:00–8:30** | **Networking and Break** |
| **8:30–9:45** | **Parallel Sessions** |
| Pirelli Room | **Regional Track**<br>Regional Innovation in Nordic Countries |
| Gaber Room | **Hospital Track**<br>Recommendations for the implementation of personalised medicine in the clinical setting |
| Biagi Room | **Education Winter School Track**<br>Session III: Individualizing Clinical Decisions for Elderly Patients with Multiple Chronic Conditions |
| Soresin Room | **Lung Cancer Screening Track**<br>Screening Strategies, Epidemiology and Public Health |
| Testori Room | **Genomic / MEGA Track**<br>Million European Genomic Alliance (MEGA) – Bringing Innovation into Healthcare Systems |
| Room 4 | **Diabetes Track**<br>T1D prevention and personalization strategies in Europe |
| **10:00–11:15** | **Parallel Sessions** |
| Pirelli Room | **Regional Track**<br>Regional Innovation in Central European Countries |
| Gaber Room | **Hospital Track**<br>The Role of Data Sharing Within and Among Hospitals |
| Biagi Room | **Education Winter School Track**<br>Session IV: Pathways for Diagnosing Rare Cancer |
| Soresin Room | **Lung Cancer Screening Track**<br>Standardisation of LDCT reading parameters within nodules detection and surgical treatment |
| Testori Room | **Genomic / MEGA Track**<br>Why Should the EU Take a Lead?" |
| Room 4 | **Diabetes Track**<br>T1D complications – Blindness and Kidney disease in Europe |
| **11:30–12:45** | **Presidential Session**<br>Facilitating Access for Today's Diseases |

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 2: 27TH NOVEMBER 2018

| | |
|---|---|
| **12:45–14:00** | **Lunch & Networking Break** |
| **14:00–15:30** | **Presidential Session - Dialogue with CEOs:** From Here to 2025: Personalised Medicine and Healthcare for an Immediate Future |
| **15:45–17:00** | Parallel Sessions |
| Pirelli Room | **Regional Track**<br>Regional Innovation in East European Countries |
| Gaber Room | **Hospital Track**<br>Value-based indicators to measure the impact of research into clinical practice |
| Biagi Room | **Education Winter School Track**<br>Session V: Digital Tools to Connect with Patients |
| Soresin Room | **Lung Cancer Screening Track**<br>Smoking cessation activity and Lifestyle within the screening |
| Testori Room | **Genomic / MEGA Track**<br>Pillars to Realize MEGA |
| Room 4 | **Diabetes Track**<br>New technologies and personalization |
| **17:15–19:00** | Parallel Sessions |
| Pirelli Room | **Regional Track**<br>Regional Innovation in Mediterranean Countries |
| Gaber Room | **Hospital Track**<br>New Opportunities for Healthcare Communication |
| Biagi Room | **Education Winter School Track**<br>Session VI: Polypharmacy: Prioritizing Medical Treatments |
| Soresin Room | **Lung Cancer Screening Track**<br>Round Table and Final Conclusions |
| Testori Room | **Genomic / MEGA Track**<br>Next steps for MEGA |
| Room 4 | **Diabetes Track**<br>Value based health care and personalization |
| **20:30 – 22:30** | **Presidency Networking Dinner (by invitation only)** |

# DAY 3: 28TH NOVEMBER 2018

| | |
|---|---|
| **8:00–8:30** | **Networking and Break** |
| **8:30–9:45** | **Parallel Sessions** |
| Pirelli Room | **Regional Track**<br>Best Practice in sharing Data in regional Perspective |
| Gaber Room | **Hospital Track**<br>Biomarkers Health Literacy |
| Biagi Room | **Education Winter School Track**<br>Session VII: Redefining the Role of Family Physicians Through the use of EHRs and Artificial Intelligence |
| Room Arancio 34 | **Forward together with innovation with the regions at the centre: Regions4PerMed**<br>Setting the Scene |
| Soresin Room | **Rare Disease Track**<br>Why Should Europe Take a Lead? |
| Testori Room | **Translational Research Track**<br>Understanding the Diseases |
| **10:00 – 11:15** | **Parallel Sessions** |
| Pirelli Room | **Regional Track**<br>Better and Common Guidelines on Various Diseases |
| Gaber Room | **Hospital Track**<br>Ensuring that Patient Preferences are Valued when Assessing New Treatments |
| Biagi Room | **Education Winter School Track**<br>Session VIII: Tools to Individualize Clinical Decisions for HCPs in the Era of Co-mordities & Survivorship |
| Room Arancio 34 | **Forward together with innovation with the regions at the centre: Regions4PerMed**<br>**Session 1: 10:00–11:15**<br>Coordinating regional policies and innovation programmes in personalised medicine<br>**Session 2: 11:30–12:45**<br>Coordinating regional strategic investments |
| Soresin Room | **Rare Disease Track**<br>The promise of precision: improving communication and ethos in Precision Medicine |
| Testori Room | **Translational Research Track**<br>Delivery of Results |

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 3: 28TH NOVEMBER 2018

| | |
|---|---|
| **11:30–12:45** | **Presidential Session**<br>Interfacing with Public Policy Makers |
| **12:45–14:00** | **Lunch & Networking Break** |
| **14:00–15:15** | Parallel Sessions |
| Biagi Room | **Education Winter School Track**<br>Session IX: Recent Advances in Personalised Medicine |
| Room Arancio 34 | **Forward together with innovation with the regions at the centre: Regions4PerMed**<br>Technological challenges for system integration and data interoperability |
| Soresin Room | **Rare Disease Track**<br>Translating the Research & Diagnosis Landscape for the benefit of patients with pancreatic cancer |
| Testori Room | **Translational Research Track**<br>Therapeutics – Matching Conditions with Treatments |
| **15:30–16:45** | **Closing Presidential Session:**<br>Who is to do What? |

# Introducing

## Precision to Personalised Treatment Decision Making in Early Stage Breast Cancer

**Torsten Hoof,**
Senior Vice President International,
*Genomic Health*

For decades, no predictive factors were available that could precisely identify patients with early stage hormone receptor-positive, HER2-negative breast cancer more likely to benefit from chemotherapy. Treatment recommendations historically had to be made based on prognosis alone. Consequently, over-and under-treatment with chemotherapy was a major issue in breast cancer care.

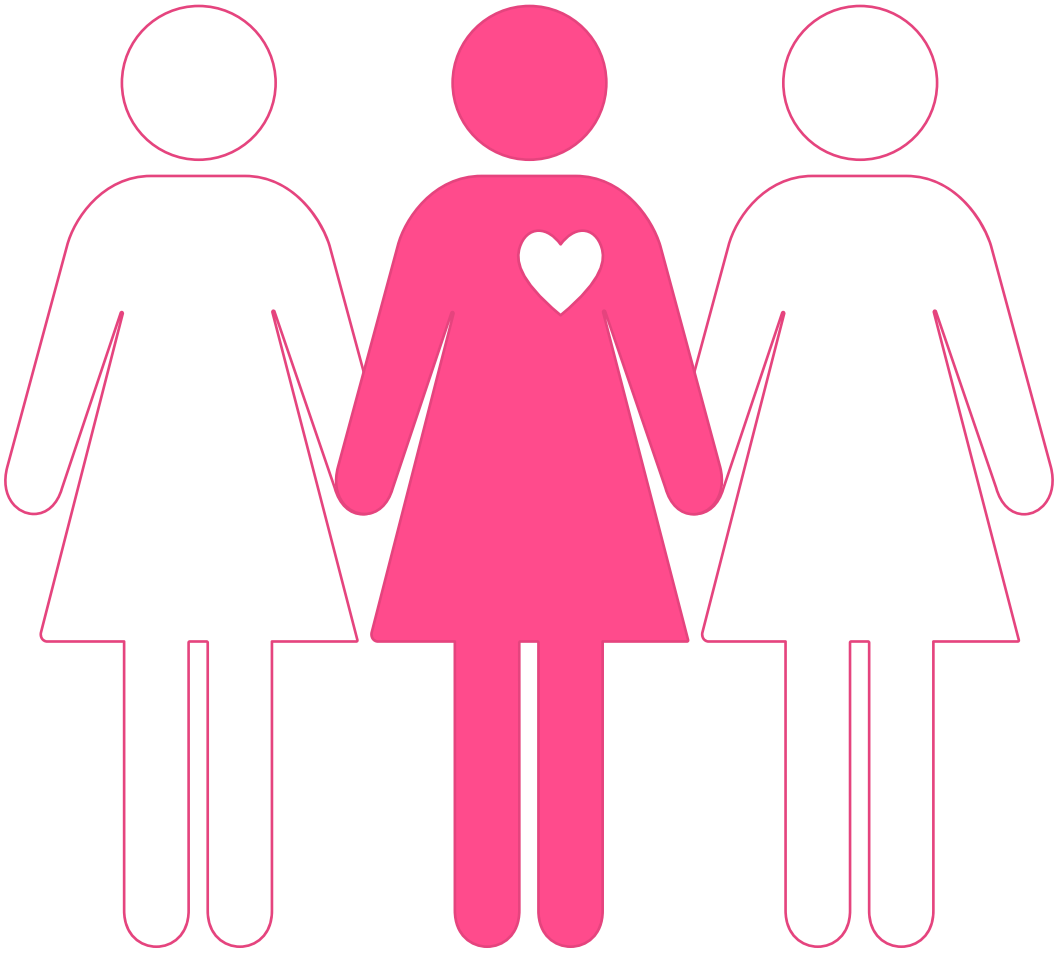
Over the last 20 years breast cancer mortality has been substantially reduced by applying radiation and systemic treatments such as endocrine therapy and chemotherapy. However, it has been known that for patients with hormone receptor-positive, HER2-negative, node-negative early breast cancer the benefit of chemotherapy overall is small and the vast majority of women remain free from distant recurrence when treated with endocrine therapy alone.

Chemotherapy treatment negatively impacts the quality of life of many patients due to drug toxicities and treatment related morbidities. Therefore, the consensus among the oncology community has long been to seek to identify those patients who can be safely managed with endocrine therapy alone and to target chemotherapy only to those patients who will derive a substantial benefit.

For decades though, no predictive factors were available that could guide chemotherapy treatment decisions. None of the sub-group analyses of data from 123 randomised trials of chemotherapy reported in the Oxford Overview identified any groups of patients, based on clinical pathological factors, who derived substantially greater benefit from chemotherapy.
At the turn of the century, the first multi-gene assays (MGAs) were developed which aimed to leverage underlying tumour biology to help guide treatment decisions. Most of these tests however, lacked any evidence of being able to narrow the field for chemotherapy.

In 2006, for the first time, the NSABP B-20 trial found that a group of patients could be identified – those with a high Oncotype DX Breast Recurrence Score® result – who derive substantial benefit from chemotherapy and that the vast majority of patients with a very low Recurrence Score® result remained free from distant recurrence when managed with endocrine therapy alone. However, a relatively small number of patients in the trial had mid-range Recurrence Score results, and more definitive information about the effect of chemotherapy for these patients was desirable.

This definitive information came in June 2018 when the highly anticipated TAILORx results were



presented at the annual ASCO meeting Plenary Session and published in the New England Journal of Medicine. With more than 10,000 patients enrolled, TAILORx is the largest ever prospective randomised adjuvant breast cancer treatment trial and was designed specifically to provide greater precision regarding the benefit, if any, of chemotherapy for most patients, who have a mid-range Recurrence Score result.
The study met its primary endpoint. TAILORx definitively identified a vast majority of women (~80%) who receive no benefit from chemotherapy, as well as the important minority for whom chemotherapy can be life-saving, and demonstrated that it is possible to identify these patients with the Oncotype DX® test.

The practice-changing precision made possible by the TAILORx trial and the Oncotype DX test can lead to improved quality of care and breast cancer survival, as well as reduced waste of healthcare resources by directing chemotherapy only to patients who have a high likelihood of deriving substantial benefit.

Truly landmark evidence from large, multi-country, prospective randomised clinical trials designed to answer a critical clinical question such as this comes around very infrequently. Clinical practice guideline bodies, health technology assessment groups and healthcare authorities can lead the way in advancing clinical practice, based on this latest and best evidence, allowing new levels of precision in the treatment of early breast cancer patients.
Based on TAILORx, Germany's health technology assessment body - the Institute for Quality and Efficiency in Health Care (IQWiG) - recommended the Oncotype DX test in September 2018 as the only multi-gene assay to add benefit for decision making. ,  In addition, in October 2018 the National Comprehensive Cancer Network (NCCN) updated its guidelines for invasive breast cancer chemotherapy treatment and classified Oncotype DX as the "preferred" multi-gene assay and the only one to be predictive of chemotherapy benefit.

**To learn more about TAILORx and the Oncotype DX Breast Recurrence Score test, please visit www.tailorx.co.uk**

# DAY 1: 26TH NOVEMBER 2018

| 09:00–10:15 | Parallel Sessions |
|---|---|

Pirelli Room

## Regional Track

Role of EU Funding Mechanisms to support Regional & National Level coordination

### CHAIR

**Ana Carriazo,**
*MD PhD, Senior Advisor, Regional Ministry of Health of Andalusia*

### PANEL

**Rafael de Andres Medina**
*Head of the EU & internationalizartion Dept – Instituto de Salud Carlos III (ISCIII)*

**Daniel Schneider**
*Diagnostics Strategy Leader, Genentech*

**Gianni D'Errico**
*International Project Officer & European Affairs, Toscana Life Sciences Foundation – Tuscany Region*

**Paola Larghi**
*Scientific Officer, Fondazione Regionale per la Ricerca Biomedica*

Room Arancio 34

## Men's Health Track

Lowering the Risk and Mortality Rate of the Most Frequent Cancer in Men

### OPENING

**James N'Dow**
*Chairman, Guidelines Office Board, EAU*

### PANEL

**Ken Mastris**
*President, EuropaUomo*

**Alex Asiimwe**
*Bayer, Lead for IMI Big Data for Better outcomes*

**Alberto Briganti**
*Associate Professor of Urology;*
*Deputy Director of Urological Research Institute, Scientific Institute San Raffaele*

Biagi Room

## Education Winter School Track

Opening Session: Objectives of the Winter Summer School. Diagnosis & Decision Making Frameworks for Family Physicians & General Practitioners

### OPENING

**Gabriella Pravettoni**
*Director of IRIDe, Interdisciplinary Research Center on Decision Making Processes, Università degli Studi di Milano*
**Christine Chomienne**
*Director of Research & Innovation, INCa, France*

### PANEL

**Barbara Moss**
*Patient Ambassador, EuropaColon and Bowel Cancer UK*

**Filippo de Braud**
*Chief, Medical Oncology Department, Fondazione IRCCS Istituto Nazionale del Tumori – Milan*

**Beata Jagielska**
*Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology; Department of Oncological Diagnostic, Cardio-Oncology and Palliative Care, Warsaw, Poland*

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 1: 26TH NOVEMBER 2018

Soresin Room

### Diagnostic/Medical Devices Track

Regulatory Framework for Companion Diagnostics

**CHAIR**

**Petra Zoellner**

*Senior Manager Regulations and Industrial Policy, MedTech Europe*

**PANEL**

**Armin Ritzhaupt**

*Regulatory Affairs Office, Scientific and Regulatory Management Department, European Medicines Agency (EMA)*

**Dr. Dieter Schönwald**

*Senior Manager International Affairs (IVD), Global Technical Officer IVD, TÜV SÜD PRODUCT SERVICE GMBH*

**Robert Johnstone**

*Board Member, European Patient Forum*

Testori Room

### Genomic Track

Perspectives on Genomics

**CHAIR**

**Tonu Esko**

*Deputy Director of Research, Estonian Biobank, Estonian Genome Center, University of Tartu, Estonia*

**PANEL**

**Denis Horgan**

*Executive Director, European Alliance for Personalised Medicine*

**Anna Middleton**

*Head of Society and Ethics Research Wellcome Genome Campus, Cambridge, UK*

**Draga Toncheva**

*President of the Bulgarian Society for Genetics and Human Genomics*

**Sergio Abrignani**

*Scientific Director of the National Institute of Molecular Genetics (INGM – IstitutoNazionale di GeneticaMolecolare) of Milan*

Room 31

### Access & Early Diagnosis Track

Are Current Frameworks Useful to Capture the Value of P.M. Technologies? Are Other Frameworks/Methodologies Required?

**CHAIR**

**Iñaki Gutiérrez-Ibarluzea**

*Basque Office for HTA. Basque Country*

**PANEL**

**Dario SaCchini**

*Università Cattolica del Sacro Cuore of Rome – The Institute of Bioethics*

**Jasmina Koeva-Balabanova**

*Chair of the Board BAPPM*

**Marco Marchetti**

*Istituto Superiore di Sanità, Rome, Italy*

**Stefan Gijssels**

*Executive Director of Digestive Cancers Europe and EuropaColon*

| | |
|---|---|
| **10:15 – 10:45** | **Networking and Break** |

# DAY 1: 26TH NOVEMBER 2018

| 10:45–12:00 | Parallel Sessions |
|---|---|

Pirelli Room

## Regional Track

Session 2: Structural Funds to Support Infrastructures for the Personalised Healthcare Era

### CHAIR

**Giovanni Codacci Pisanelli**
*Professor, University of Rome, "La Sapienza"*

### PANEL

**Dr Birute Tumiene, MD, PhD**
*Clinical geneticist, Coordinator for Competence Centers, Vilnius University Hospital Santaros Clinics*

**Mihai Ioana**
*University of Medicine and Pharmacy of Craiova; SCJU Craiova, Romania*

**Cristina De Capitani**
*Cluster Manager, Lombardy Cluster Technologies for Living Environments (TECHforLIFE – CTL TAV ), Senior Technologist, Institute of Polymers, Composites and Biomaterials (IPCB) , National Research Council of Italy*

Room Arancio 34

## Men's Health Track

Session 2: Setting the Framework for Political Action & Tools to realise this

### OPENING

**Bogi Eliasen,**
*Head of Denmark Unit – International Network*

### PANEL

**Anders Bjartell,**
*Professor in Urology, Dept. of Translational Medicine, Dept of Urology, Skane University Hospital*

**Bogi Eliasen**
*Head of Denmark Unit – International Network*

**Ken Mastris**
*Board Member, European Cancer Patient Coalition, UK*

**Arnulf Stenzl**
*EAU Scientific Officer Chairman*

Biagi Room

## Education Winter School Track

Session 2: Shared Diagnosis and Decision – Making: Patient/Physician Communication

### CHAIR

**Gabriella Pravettoni**
*Director of IRIDe, Interdisciplinary Research Center on Decision Making Processes, Università degli Studi di Milano*

### PANEL

**Nicla La Verde**
*Medical Doctor, Oncologist. Department of Oncology, ASST Fatebenefratelli Sacco, PO Fatebenefratelli Hospital, Milan, Italy*

**Maria Martinez Fresno**
*MSc, MBA EMEA Market Development Manager, Clinical Genomics Illumina*

**Lydia Makaroff**
*Director, ECPC, Belgium*

**Sari Neijenhuis**
*Medical Director, Europe for Agenda*

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 1: 26TH NOVEMBER 2018

Soresin Room

### Diagnostic/Medical Devices Track

Session 2: Reimbursement and financial framework for Diagnostics

**CHAIR**

**Hans Martens**
*Senior Advisor – European Policy Centre; Danish think tank Europa*

**PANEL**

**Francesca Boggio Mesnil**
*Principal, Executive Insight*

**Carlos Sisternas**
*Director, FENIN*

**Michael Paul Messenger**
*Principal Healthcare Scientist, Leeds Institute of Cancer & Pathology, Leeds*

Testori Room

### Genomic Track

Session 2: Genomics – Time to Deliver

**CHAIR**

**Peter Riegman**
*Head Tissue Bank, Erasmus MC*

**PANEL**

**Andres Metspalu**
*Estonian Genome Center/University of Tartu, Estonia*

**Gianpiero Cavalleri**
*RCSI Molecular & Cellular Therapeutics (MCT) Royal College of Surgeons in Ireland*

**Mark Caulfeld**
*William Harvey Research Institute, Queen Mary University of London, UK*

**Peter Riegman**
*Head Tissue Bank, Erasmus MC*

Room 31

### Access & Early Diagnosis Track

Session 2: Value from the Economic Perspective

**CHAIR**

**Hans Peter Dauben**
*Rheinische Fachhochschule Köln*

**PANEL**

**Americo Cicchetti**
*Professor of Management at the Catholic University, Faculty of Economics, Rome. President SIHTA. Italy*

**Jerome Foucaud**
*Directeur du département recherche en SHS, INCa*

**Filipe Costa**
*Deputy director of Operations at Hospital da Luz, Lisbon. Portugal*

**Emanuele Lettieri**
*Full Professor, Politecnico di Milano, Department of Management, Economics and Industrial Engineering and & Lombardy Cluster Technologies for Living Environments (TECHforLIFE)*

# DAY 1: 26TH NOVEMBER 2018

| 12:15–13:15 | Opening Plenary Presidential Session<br>**Forward as one – Europe as a Global Player** |
|---|---|

**Testori Room**

## Opening Plenary Presidential Session
Forward as one – Europe as a Global Player

### CHAIR
**Denis Horgan**
*Executive Director, European Alliance for Personalised Medicine*

### PANEL
**Minister Marcin Czech**
*Undersecretary of State/Vice Minister at Ministry of Health Poland*

**Walter Ricciardi**
*President, Italian National Institute of Health (Istituto Superiore di Sanità)*

**Christine Chomienne**
*Director of Research & Innovation, INCa, France*

**Michael Zaiac**
*Head of Medical Affairs, Oncology Region Europe, Novartis*

| 13:15–14:15 | Lunch and Networking Break |
|---|---|

| 14:15–15:30 | Presidential Session<br>**Advancing Europe's Healthcare – Patients & Economy** |
|---|---|

**Testori Room**

## Presidential Session
Advancing Europe's Healthcare – Patients & Economy

### CHAIR
**Alistair Kent**
*Formerly Director of Genetic Alliance UK*

### PANEL
**Ernst Hafen**
*Head of BSc Biology / Head of MSc Biology, ETH Zurich, Inst. f. Molekulare Systembiologie*

**Robert Johnstone**
*Board Member, European Patient Forum*

**Ciaran Nicholl**
*Research Centre Ispra, European Commission*

**Fabio Pamolli**
*CADS Coordinator of IIT/HT; Full Professor, Economics and Management, Politecnico di Milano*

**Simona Paratore**
*Head of Medical Cell & Gene Therapy, Oncology Region Europe, Novartis*

| 15:30–16:00 | Networking and Break |
|---|---|

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 1: 26TH NOVEMBER 2018

| 16:00–17:15 | Parallel Sessions |
|---|---|

Pirelli Room

### Regional Track

Session 3: Private Investment to Drive Forward Healthcare

**CHAIR**

**Paul Jones**

*Director, Population Genomics, Illumina*

**PANEL**

**Justina Januševičienė**

*Head of Health Care Innovation Center, Lithuanian university of Health Sciences/Kaunas clinic*

**Lars Bullinger**

*Professor in Personalized Medicine, Charite, Berlin, Partner of the HARMONY Alliance, public-private partnership for bigdata in hematology*

Room Arancio 34

### Men's Health Track

Session 3: Multidisciplinary Approach of Early Diagnosis: The Way Forward

**OPENING**

**Professor James N'dow**

*Chairman, Guidelines Office Board, EAU*

**PANEL**

**Tit Albreht**

*Coordinator of the EU Joint Action Cancer Control*

**Hendrik Van Poppel**

*EAU Adjunct Secretary General – Education, EAU*

**Jumana Mensah,**

*Certification Department, German Cancer Society, Deutsche Krebsgesellschaft (DKG)*

**Laetitia Gambotti**

*Director, Departement Recherche Clinique, INCa*

Biagi Room

### Education Winter School Track

Session 3: Emerging Screening & Diagnostic Tools to Facilitate Early Diagnosis of Disease

**CHAIR**

**Giulia Veronesi**

*Chief of the Robotic Thoracic Surgery Unit among the Division of Thoracic and General Surgery in Humanitas Research Hospital*

**PANEL**

**Nuria Malats**

*Grupo de Epidemiología Genética y Molecular, Programa de Genética del Cáncer Humano, Centro Nacional de Investigaciones Oncológicas (CNIO)*

**Andrea Raballo**

*MD, PhD, Childhood and Development Research Group, Department of Psychology, Norwegian University of Science and Technology*

**Gennaro Ciliberto**

*Scientific Director, IRCCS, Instituto Nazionale Tumori "Regina Elena, Rome, Italy*

**Stefania Boccia**

*Università Cattolica del Sacro Cuore, PRECeDI Coordinator*

# DAY 1: 26TH NOVEMBER 2018

Soresin Room

## Diagnostic/Medical Devices Track

Session 3: Value of diagnostic Information (VODI) from Concept to Reality

### CHAIR

**Hans Martens**
*Senior Advisor – European Policy Centre; Danish think tank Europa*

### PANEL

**Cor Oosterwijk**
*Secretary general, EGAN*

**Bernarda Zamora**
*Economist, The Office of Health Economics*

**Markus Ott**
*Head of Global Market Access & Health Policy, Roche Diagnostics International Ltd*

Testori Room

## Genomic Track

Session 3: Implementation of Genomics into Healthcare Systems

### CHAIR

**Ivo Gut**
*Director, Centre nacional d'analisi Genomica (CNAG)*

### PANEL

**Robert Johnstone**
*Board Member, European Patient Forum*

**Sarah Wordsworth**
*University of Oxford, UK – The Health Economic Evidence for Whole Genome Sequencing*

**Beata Jagielska**
*Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology; Department of Oncological Diagnostic, Cardio-Oncology and Palliative Care, Warsaw, Poland*

**Christian Bauer,**
*Sr Director International Marketing, Genomic Health*

**Steffan Ho**
*Vice President, Head of Translational Oncology, Pfizer*

Room 31

## Access & Early Diagnosis Track

Session 3: Value from Organizational Perspective Context Matters

### CHAIR

**Marco Marchetti**
*Istituto Superiore di Sanità, Rome ISS*

### PANEL

**Michele Tringali**
*Direzione Generale Welfare, U.O Programmazione Polo Ospedaliero, Struttura Farmaco, Dispositivi e HTA - Health Technology Assessment, Regione Lombardia*

**Iñaki Gutiérrez-Ibarluzea**
*Basque Office for HTA. Basque Country*

**Ansgar Hebborn**
*Head of Global HTA & Payment Policy at Roche*

**Fabien Calvo**
*Chief Scientific Officer, Cancer Core Europe*

# 4th EAPM SUMMER SCHOOL

**2019 will see the European Alliance for Personalised Medicine (EAPM) host its fourth, week-long summer school for young healthcare professionals, or HCPs, after successful annual events in Cascais, Bucharest and Warsaw.**

**For more information, please contact the EAPM Office:**
**Denis Horgan,**
**EAPM Executive Director**
**Email: denishorgan@euapm.eu**

Training and Education for Advanced Clinicians and HCPs

The title of the fourth edition will be **Mirroring Erasmus in Personalised Medicine** and is the latest step in an ongoing initiative that aims to educate young doctors in the latest developments of personalised medicine. The location for the next summer school is **Levuven 19-22 June** and, as ever, a key focus will be on positioning medical education as a political priority, keeping the 'person' in personalised healthcare, and tacking the vital issue of doctor-patient communication.

The nature of the Summer Schools is in the same vein as the famous Erasmus programme for students across Europe (EuROpean Community Action Scheme for the Mobility of University Students).
The student exchange programme was established in 1987 and is designed to allow students to travel and learn. EAPM aims to mirror these principles in the arena of personalised medicine. On top of this, as last year, each of the participants will receive a number of educational point as part of the continuing medical education, or CME, process.
The choice of Leuven as the school's location dovetails with EAPM's SMART Outreach project. The Alliance's June 2015 conference introduced the 'SMART' concept, which stands for Smaller Member states And Regions Together, and EAPM has been expanding this by taking its message directly to EU countries.
Also connected is the fact that the cross-discipline attendees will converge from multiple regions of the EU, as well as from a large number of Member States.

As ever, the faculty will be drawn from medical academic, clinical and research specialties, patient organisations and communication experts.
Once again the school will come under the Alliance's 'TEACH' banner, which stands for Training and Education for Advanced Clinicians and HCPs, and the goal is to bring young, front-line professionals up-to-speed with fast-moving developments in the field.

## With two key Congresses having passed, the first specifically oncology-focused and the second on the broader topic of personalised medicine, now seems like the right time to talk to a Member of the European Parliament who has been active in the arena of healthcare.

**DH: Cristian, these two keynote congresses will happen at a time when the hot topic of health technology assessment is filling everyone's minds. What are your thoughts on the Commission's proposal for EU-wide joint action and how does it impact access?**

**CB:** As you know, my colleague in Parliament Soledad Cabezón Ruiz was rapporteur for the ENVI committee on this topic and, as she said, we aim to improve access to health technology in the EU, especially in terms of quality but also in choosing research projects according to medical needs, as well as added value for patients and public health systems.

I fully agree with Soledad.

What Europe needs is a regulation on HTA to allow Member States to make the most reasonable choices for patients and for the public budget, and the regulation will help overcome disparities, reduce barriers to accessing innovative treatment, recognise the true value of new therapies, and improve the sustainability of national healthcare systems.

Strengthening cooperation across countries will also provide better estimates of the medical and social value of new therapies and medicines.

**DH: You mention barriers. What are the key barriers to access in your view?**

**CB:** Let's take personalised medicine...there is no doubt that it has the potential to improve outcomes for Europe's patients, but its promise must be balanced against a number of highly relevant challenges that may limit its positive impact.

We have issues such as increasing costs, and the need for a relevant ethical, regulatory and reimbursement environment.

These are among the barriers to implementing such innovative treatment at European and national levels.

Thinking now of oncology and the annual ESMO event, personalised medicine approaches have already been particularly effective in certain cancers, and have brought practice-changing clinical benefits to patients.

However, the spiralling costs associated with personalised or precision cancer medicine, even for new standard medicines, highlight the need to address the cost-value dilemma.

**DH: Ah, 'value'...**

**CB:** Indeed. There is a pretty solid argument that says that value should be decided by the consumer, in this case the patient. But of course we have payers and pharmaceutical companies, for example, with their own angles.

We certainly need to move beyond a simplistic 'what the market can bear' approach to a more nuanced value-based pricing philosophy. Employing this approach and embedding this philosophy into cancer-care pathways, for example, can help reward innovation that has truly transformative potential and allow the benefits of a value-centred strategy to accrue for patients and society in general.

But whether we can support innovation – and afford it – will depend on how smart health systems are at allocating resources in in the right way.

**DH: Do you have an example?**

CB: Research has shown that patient-centred care models are cost-effective and lead to better outcomes and patient satisfaction. We have learned that patient empowerment can be a vital element of high-quality, sustainable, equitable and cost-effective health systems.
There is a need to secure access to, and affordability of, healthcare, so technological and social innovations are needed to empower the health system, the citizen and patient.

A major issue, though, is whether society can afford, in the fiscal sense, personalised medicine. Judging by the seemingly never-ending debate about pharmaceutical pricing, it seems that ensuring a sustainable economic model that allows these medicines to be produced, profitably, but in an affordable way for health systems will be a challenge.

But it is one that we must rise to meet.

The latter's own event in Milan comes just a few weeks later from 26-28 November, and Denis Horgan, EAPM Executive Director grabbed the opportunity to ask MEP Cristian Busoi for his thoughts on healthcare in general and access for patients to personalised medicine in particular.

**Denis Horgan,**
Executive Director,
*EAPM*

**Christian Busoi**
*MEP*

**DH: You mentioned rare diseases earlier.**

**CB:** Yes, and I'd like to see the EU promote a European register of rare diseases and reference centres.

Existing systems were designed and developed to support innovation and access for patients to innovative medicines and treatment, but these systems are falling short in many instances and need to be reassessed.

One major shortfall, is that Europe has been slow in taking account of new technologies and that there is a clear need for new social contracts and relationships to be developed to facilitate collaboration and knock a big hole in 'silo' thinking.

New medicines have a positive contribution within society, providing effective treatments in the age of personalised medicine. IVDs and other diagnostics are also vital in this sphere.

Currently, there is a big gap between what drugs are out there and what medicines are authorised. Labyrinthine regulations need to be simplified to ensure a swifter take up; while obviously bearing in mind safety and efficacy in all cases.

Although, for example, genome sequencing is starting to be introduced to clinical care, improving diagnosis and care of patients with rare genetic diseases and starting to impact on cancer diagnosis and stratification of therapies, there remain a number of key challenges to ensure genomics and related technologies are applied.

The goal is that over the next few years we can fully realise the potential of personalised medicine.

**DH: Should there be 'more Europe' in healthcare?**

**CB:** Many people would argue that, instead of health being a 'local' competence, it should ideally be supra-national - ie at EU level. While this is impossible given the treaties that enshrine healthcare as a Member State competence, 'more EU' would surely help to ensure a level playing field.

Healthcare undoubtedly needs modernising and, while top-down legislation on clinical trials, IVDs and data protection and sharing has helped in recent times, arguably the EU should be doing more from a centralised point, at the very least in encouraging Member States to share more information on health from data banks, cooperate more fully, get out of their specialist silos, work to avoid research duplication and so on, for the benefit of the citizenry.

The HTA proposal is a step in the right direct in this regard, I believe.

**DH: Finally, regarding real-world data and date sharing, one of the many important topics set to be discussed by ESMO in Munich, and at EPM's Congress in Milan, will be the use of such data to complement the traditional evidence from randomised clinical trials. How do you see real-world data and its potential?**

**CB:** Real-world data promises to substantially increase the effectiveness and efficiency of all processes in the development and utilisation of medicines, from research and development, to regulatory decision-making, pricing and reimbursement decisions to use in medical practice.

However, to realise the full potential of real-world data requires a 'learning healthcare system', based on electronic health records and other collected healthcare data.

This would allow real-world data to be continuously fed into the system, and would complement the traditional evidence from randomised clinical trials.

However, healthcare systems must be ready in terms of technology to collect data, using a methodology that analyses information taking into account aspects such as protection of personal data, consent, ethics and data access.

The digital market in the healthcare sector needs to be ready and able to take up the challenge.

# DAY 2: 27TH NOVEMBER 2018

| | |
|---|---|
| **08:00–08:30** | **Networking and Break** |
| **08:30–09:45** | **Parallel Sessions** |

Pirelli Room

## Regional Track

Regional Innovation in Nordic Countries

### CHAIR

**Laurenz Baltzer**
*Publication Manager, Karger*

### PANEL

**Bogi Eliasen**
*Senior Researcher, Copenhagen Institute For Futures Studies*

**Johanna Arola MD. PhD.**
*Professor of Molecular Pathology, Head of Department, Helsinki University Hospital*

**Birute Tumiene**
*Coordinator of Competence centers, Vilnius University Hospital Santaros Clinics*

Gaber Room

## Hospital Track

Recommendations for the implementation of personalised medicine in the clinical setting

### CHAIR

**Prof. Carlo Tacchetti**
*Director of Experimental Imaging Center, OSR*

### PANEL

**Prof. Gerald Prager**
*Division of Oncology, Department of Medicine I, Comprehensive Cancer Center, Medical University Vienna*

**Elena Garralda MD**
*Director of Early Drug Development program*

**Dr Josep Quer**
*Vall d´Hebron University Hospital, Barcelona*

**Prof Dr Ron van Schaik**
*Professor in Pharmacogenetics Erasmus MC Rotterdam*

Biagi Room

## Education Winter School Track

Individualizing Clinical Decisions for Elderly Patients with Multiple Chronic Conditions

### CHAIR

**Giovanni Codacci Pisanelli**
*Professor, University of Rome, "La Sapienza"*

### PANEL

**Michael Liebman**
*Managing Director, IPQ Analytics, LLC and Professor, Drexel College of Medicine*

**Prof Patrice Boyer**
*EBC Vice President*

**Sebastien Moine**
*European Association of Palliative Care (EAPC)*

**Giovanni Codacci Pisanelli**
*Professor, University of Rome, "La Sapienza"*

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 2: 27TH NOVEMBER 2018

Soresin Room

### Lung Cancer Screening Track

Screening Strategies, Epidemiology and Public Health

**MODERATORS**

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

**Giulia Veronesi**
*Chief of the Robotic Thoracic Surgery Unit, Division of Thoracic and General Surgery, Humanitas Research Hospital, Milan*

**PANEL**

**Harry de Koning**
*Department of Public Health, Erasmus MC, Rotterdam, Netherlands*

**John Field**
*Professor of Molecular Oncology, University of Liverpool, UK*

**Sergio Iavicoli**
*ICOH Secretariat General, Italian Workers' Compensation Authority – INAIL, Department of Occupational and Environmental Medicine, Epidemiology and Hygiene*

**Nir Peled**
*Head of the Thoracic Cancer Unit at Davidoff Cancer Center, Rabin Medical Center*

Testori Room

### Genomic Track

Million European Genomic Alliance (MEGA) – Bringing Innovation into Healthcare Systems

**CHAIR**

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

**PANEL**

**Jan Korbel**
*Group Leader, Genome Biology Unit, European Molecular Biology Laboratory (EMBL), Heidelberg, Germany*

**Jean-Francois Deleuze**
*Director, Centre National de Recherche en Genomique Humaine*

**Mario Romao**
*International Lead for Public Policy, INTEL*

Room 4

### Diabetes Track

T1D prevention and personalization strategies in Europe

**CHAIR**

**Olivier Arnaud**
*Senior Director, European Research JDRF*

**PANEL**

**Francesca D'Addio**
*Assistant Professor in Endocrinology, Pediatric Clinical Research Center Romeo ed Enrica Invernizzi, University of Milan, Milan Italy*

**Heather Ascani**
*Director, Business Operations – Applied Systems Biology Core University of Michigan Health System*

**Marco Marsella**
*Head of Unit eHealth, Wellbeing & Ageing – European Commission*

| | |
|---|---|
| **9:45–10:00** | **Networking and Break** |

# DAY 2: 27TH NOVEMBER 2018

| 10:00–11:15 | Parallel Sessions |
|---|---|

Pirelli Room

## Regional Track
Regional Innovation in Central European Countries

### CHAIR
**Prof Patrice Boyer**
*EBC Vice President*

### PANEL
**Patrick Boiessau**
*Coordinator ESTHER Task Force, CEA/ESTHER*

**Paul Galvin**
*Head of ICT for Health Strategic Programme, Tyndall University*

**Fabien Calvo**
*Chief Scientific Officer, Cancer Core Europe*

**Anne Wurz**
*Ministry of Social Affairs and Integration Baden-Württemberg, Unit 51 (Policy, Prevention, Public Health Service)*

Gaber Room

## Hospital Track
The Role of Data Sharing Within and Among Hospitals

### CHAIR
**Lisa Hollins**
*Executive Director of Transformation and ICT, Kings College Hospital, KPH*

### PANEL
**Dr Alex Sánchez**
*Vall d´Hebron University Hospital, Barcelona*

**Dr Jack Barker**
*Chief Clinical Information Officer for Kings College Hospital and South East London Strategic Partnership, KHP*

**Prof Frank Rademakers**
*Director of medical technology and innovation, UZ Leuven*

**Dr. Giovanni Tonon**
*Director of Translational Genomics and Bioinformatics Centre, Ospedale San Rafaele*

**Prof Jan Hazelzet**
*Erasmus MC, Department of Public Health*

Biagi Room

## Education Winter School Track
Pathways for Diagnosing Rare Cancer

### CHAIR
**Alastair Kent**
*Formerly Director of Genetic Alliance UK*

### PANEL
**Lydia Makaroff**
*Maria Martinez Fresno*

**Barbara Moss**
*Patient Ambassador, EuropaColon and Bowel Cancer UK*

**Paolo Casali**
*Director, SC Oncologia medica 2, Fondazione IRCCS Istituto Nazionale Tumori; Associate Professor, Medical Oncology, Università degli Studi Milano*

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 2: 27TH NOVEMBER 2018

Soresin Room

### Lung Cancer Screening Track

Standardisation of LDCT reading parameters within nodules detection and surgical treatment

**MODERATORS**

**David Baldwin**
*Honorary Professor of Medicine and Consultant Physician, University of Nottingham*

**Luca Bertolaccini**
*Department of Thoracic Surgery, AUSL Bologna, Maggiore Teaching Hospital, Bologna, Italy*

**PANEL**

**Matthijs Oudkerk**
*Scientific Director Centre for Medical Imaging, North East, Netherlands*

**Claudia I. Henschke**
*Clinical Professor Radiology, Icahn School of Medicine at Mount Sinai, New York, US*

**Gaetano Rocco**
*Division Chief of Thoracic Surgery, and Department Head, Thoracic Surgery and Oncology, at the National Cancer Institute, Pascale Foundation, Naples, Italy*

Testori Room

### Genomic Track

Why Should the EU Take a Lead?

**CHAIR**

**Gordon McVie**
*Co-Chair, EAPM*

**PANEL**

**Antonio Andreu**
*Scientific Director, EATRIS*

**Gary Saunders**
*ELIXIR*

**Mariya Gabriel**
*Commissioner, Digital Economic and Society, European Commission*

Room 4

### Diabetes Track

T1D complications – Blindness and Kidney Disease in Europe

**CHAIR**

**Jeannette Soderberg**
*European project manager jDRF*

**PANEL**

**David Nathan**
*Director, Diabetes Center and Clinical Research Center, Massachusetts General Hospital, Boston, US*

**Colin Palmer**
*Chair of Pharmacogenomics, University of Dundee, Dundee, UK*

**Matthias Kretzler**
*Professor of Internal Medicine/Nephrology and Computational Medicine and Bioinformatics, Medical School, University of Michigan, Ann Arbor, US*

| 11:15–11:30 | Networking and Break |
|---|---|

# DAY 2: 27TH NOVEMBER 2018

## 11:30–12:45 Presidential Session
## Facilitating Access for Today's Diseases

**Testori Room**

**Presidential Session**
Facilitating Access for Today's Diseases

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

**PANEL**
**Peter Meeus**
*Head of Region Europe, Shire, London, UK*

**Marco Marsella**
*Head of Unit eHealth, Wellbeing & Ageing – European Commission*

**Alberto Mantovani**
*Scientific Director of Istituto Clinico Humanitas*

**Stanimir Hasurdjiev**
*Secretary General of PACT*

**Jennifer Mills**
*Vice President, Patient and Professional Partnerships, Foundation Medicine, Inc.*

## 12:45–14:00 Lunch and Networking Break

## 14:00–15:30 Presidential Session
## Dialogue with CEOs: From Here to 2025: Personalised Medicine and Healthcare for an Immediate Future

**Testori Room**

**Presidential Session**
Dialogue with CEOs: From Here to 2025: Personalised Medicine and Healthcare for an Immediate Future

**CHAIR**
**Gordon McVie**
*Co-chair, EAPM*

**PANEL**
**Michele Perrino**
*President Italy and Regional VP, Medtronic*

**Elena Bottineli**
*CEO of San Raffaele Hospital*

**Torsten Hoof**
*SVP, International, Genomic Health*

**Nicoletta Luppi**
*Managing Director, MSD Italy*

**Maurizio de Cicco**
*President, Managing Director & General Manager, Roche, Italy*

## 15:30–15:45 Networking and Break

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 2: 27TH NOVEMBER 2018

| 15:45–17:00 | Parallel Sessions |
|---|---|

Pirelli Room

### Regional Track

Regional Innovation in East European Countries

**CHAIR**

**Prof Joanna Chorostowska-Wynimko**
*National Institute of Tuberculosis and Lung Diseases*

**PANEL**

**Maria Sąsiadek**
*Medical University in Wroclaw, Department of Genetics*
**Joanna Chorostowska – Wynimko**
*National Institute of Tuberculosis and Lung Diseases*
**Prof Andrzej Marszałek**

**PANEL DISCUSSION**

**Beata Jagielska**, *Polish Coalition of Personalized Medicine Association*, **Beata Ambroziewicz**, *Polish Coalition of Patients*, **Janusz Homa**, *MD, Phd, CEO of Ardigen*, **Bartosz Wazag**, *Medical University of Gdansk*, **Łukasz Kozera**, *Federation of Polish Hospitals*

Gaber Room

### Hospital Track

Value-based indicators to measure the impact of research into clinical practice

**CHAIR**

**Dr. Fatima Nuñez**
*Deputy Director Vall d´Hebron Research Institute*

**PANEL**

**Dr. Maisa Omara**
*BDS,MSc, Researcher in Health Science, Institute for Outcomes Research, Center for Medical Statistics, Informatics and Intelligent System, Medical University of Vienna*

**Prof John Moxham**
*King´s Health Partners*

**Prof. Thorsten Schlomm**
*Director Clinic for Urology, Charité*

**Dr. Maria Karsten**
*Senior Physician Clinic for Gynecology, Charité*

**Prof Johan Van Eldere**
*Ex Medical Director, UZ Leuven*

**Miquel Casas**
*Senior Consultant at the Vall d'Hebron Psychiatry Department and head of the Research Group in Psychiatry of the Vall d'Hebron Research Institute (VHIR)*

Biagi Room

### Education Winter School Track

Digital Tools to Connect with Patients

**CHAIR**

**Stephen McMahon**
*Chairman and co-founder of the Irish Patients' Association (IPA)*

**PANEL**

**Dr Tõnu Esko**
*PhD Vice Director, Estonian Genome Center, Institute of Genomics, University of Tartu*

**Mihai Ioana**
*University of Medicine and Pharmacy of Craiova; SCJU Craiova, Romania*

**Francois Cadiou**
*Healint*

**Jesús Rueda Rodríguez**
*Director, International Affairs, MedTech Europe*

# DAY 2: 27TH NOVEMBER 2018

Soresin Room

## Lung Cancer Screening Track

Smoking cessation activity and Lifestyle within the screening

### CHAIR

**Claudia I. Henschke**
*Clinical Professor Radiology, Icahn School of Medicine at Mount Sinai, New York, US*

### PANEL

**Joseph Shemesh**
*Director of the Shibat Medical Screening, Sheba Medical Center, Israel*

**Dr Rachael Murray**
*Associate Professor in Health Policy, Faculty of Medicine & Health Sciences*

**Ugo Pastorino**
*Thoracic Surgery, National Cancer Institute*

**David Baldwin**
*Honorary Professor of Medicine and Consultant Physician, University of Nottingham*

**Simone Ghislandi**
*CERGAS and Department of Social and Political Sciences Bocconi University, Milan, Italy*

Testori Room

## Genomic Track

Pillars to Realize MEGA

### CHAIR

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

### PANEL

**Paolo Gasparini**
*Professor of Medical Genetics at the Faculty of Medicine at the University of Trieste (Italy)*

**Ivo Gut**
*Director, Centro Nacional de Análisis Genómico*

**Jasmina Koeva-Balabanova**
*Chair of the Board BAPPM*

**Paul Jones**
*Director, Population Genomics, Illumina*

Room 4

## Diabetes Track

New technologies and personalization

### CHAIR

**Olivier Arnaud**
*Senior Director, European Research JDRF*

### PANEL

**Yves Verboven**
*Director, Market Access and Economic Policies, MedTech Europe, Brussels, Belgium*

**Pau Herrero-Vinas**
*Faculty of Engineering, Department of Electrical and Electronic Engineering*

**Bastian Hauck**
*Diabetes Advocate, Patient Entrepreneur & Healthcare Consultant*

| 17:00–17:15 | Networking and Break |
|---|---|

## 2ND EAPM CONGRESS, MILAN AGENDA

# DAY 2: 27TH NOVEMBER 2018

| 17:15–18:30 | Parallel Sessions |
|---|---|

Pirelli Room

### Regional Track
Regional Innovation in Mediterranean Countries

**CHAIR**
**Mario Pazzagli**
*Professor of Clinical Biochemistry, Department of Clinical and Experimental Biochemical Science, University of Florence, Italy*

**PANEL**
**Antonio Barone**
*Head of Unit, LISPA (Lombardy Informatics)*

**Sara Pasalodos Sánchez**
*Navarrabiomed*

**Andrea Paolini**
*General Director Tuscany Life Sciences*

**Andrea Belardinelli**
*Director, DG Innovation in Welfare, Tuscany Regional Government*

Gaber Room

### Hospital Track
New Opportunities for Healthcare Communication

**CHAIR**
**Dr César Velasco**
*Director of Health Care Innovation and Integral Management, Vall d´Hebron University Hospital, Barcelona (TBC)*

**PANEL**
**Ms Lisa Hollins**
*Executive Director of Transformation and ICT, Kings College Hospital, KPH*

**Eng. Alberto Sanna**
*Health and Well-Being in socio-Technological ecosystem: Medicine in the era of Internet of Things and Wearable Sensors, Cloud Computing and 5G networks, service robotics and artificial intelligence*

**Mireille Spapens**
*Director of Communications, Erasmus MC*

Biagi Room

### Education Winter School Track
Polypharmacy: Prioritizing Medical Treatments

**CHAIR**
**Ketti Mazzocco**
*Researcher and lecturer in General Psychology at the University of Milan and psychotherapist in the Division of Psycho-oncology of the European Institute of Oncology (IEO)*

**PANEL**
**Giovanni Martinelli**
*Associate Professor, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna*

**Vangelis Manolopoulos**
*Professor of Pharmacology, President, Greek Society of Basic and Clinical Pharmacology*

**Prof. Norman Delanty**
*Consultant Neurologist, Professor, Clinical Neurological Sciences, Beaumont Hospital*

# DAY 2: 27TH NOVEMBER 2018

Soresin Room

## Lung Cancer Screening Track
Round Table and Final Conclusions

### CHAIR
**Giulia Veronesi**
*Chief of the Robotic Thoracic Surgery Unit, Division of Thoracic and General Surgery, Humanitas Research Hospital, Milan*

### PANEL
**Prof. Jan Van Meerbeeck**
*Head of Thoracic Oncology Assembly, ERS*

**Professor Lorenzo Bonomo**
*Former ESR President*

**Dario Consonni**
*Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinco, Milano*

**John Field**
*Professor of Molecular Oncology, University of Liverpool, UK*

### CLOSING REMARKS
**Giulia Veronesi**
*Chief of the Robotic Thoracic Surgery Unit, Division of Thoracic and General Surgery, Humanitas Research Hospital, Milan*

Testori Room

## Genomic Track
Next steps for MEGA

### CHAIR
**Dennis Horgan**
*Executive Director, European Alliance for Personalised Medicine*

### PANEL
**Regional Political Representatives**

**Etienne Richer**
*CIHR Institute of Genetics Associate Director*

**Rafael Solana**
*General Secretary for Research, Development and Innovation, Regional Ministry of Health of Andalusia, Seville, Spain*

**Gianni D'Errico**
*International Project Officer & European Affairs, Toscana Life Sciences Foundation – Tuscany Region*

Room 4

## Diabetes Track
Value based health care and personalization

### CHAIR
**Jeannette Soderberg**
*European project manager jDRF*

### PANEL
**Frédéric De Reydet**
*Director, Global Market Access NSO, Novartis, Basel, Switzerland*

**Henk Veeze, MD, PhD**
*Pediatrician, Senior international Medical Director, General Manager Diabeter*

**Mona Khalid**
*Vice President, Outcomes Research and Development*

**Fabrizio Carinci**
*Vice President of the School of Economy, Management and Statistic, Bologna*

**20:30–22:30 | Presidency Networking Dinner (by invitation only)**


The Alliance's June 2015 conference introduced the 'SMART' concept, which stands for Smaller Member states And Regions Together, and EAPM has been expanding this by taking its message directly to EU countries.

EAPM is convinced that the perspective of these countries, as well as regions in larger states, is extremely important when it comes to determining whether there is a case for EU-level action on health.

Smaller states have been active in shaping health policy at European level and can now act as vital policy entrepreneurs pursuing normative policy agenda.

It is clear that the EU's smaller Member States and the regions within larger ones, find collaboration a necessity and will very likely show Europe the way when it comes to achieving this.

The rotating EU presidencies of 2018 and early 2019 all feature smaller Member States at the helm (Bulgaria, Austria, and Romania), and the Alliance will have a presence in each.

The clear focus is bringing innovation into healthcare systems and the contribution of smaller countries and the regions of larger ones can never be underestimated..

## EAPM's SMART Outreach project will continue to be rolled out in 2018 and beyond.

SMART
Smaller Member States And Regions Together

For more information, please contact the EAPM Office:
Denis Horgan,
EAPM Executive Director
Email: denishorgan@euapm.eu

# NEVER THE TWAIN SHALL MEET?

## WELL, ACTUALLY...

**Sirpa Pietikäinen,** MEP

**The next European Parliament elections are due in May 2019 - and that's not so far away.**

The European Alliance for Personalised Medicine (EAPM), **Denis Horgan** spoke to current Member of the European Parliament **Sirpa Pietikäinen** allied to the EPP Group, to get an insight into cross-party cooperation in a field where they can all hopefully agree, *at least in principle*, regardless of political bias.

**DH: In the arena of healthcare, which as we know encompasses all of us at some time or another, is it important to work with colleagues from other parties?**

**SP:** Yes, of course! OK, most people may think that politicians spend a lot of their time disagreeing and having a go at each other but, say, on a committee such as ENVI, for example, we work hard to find consensus and beyond that we all care about our citizens and those outside our domestic borders.

Having been elected by people who chose to place their trust in us, we obviously have a responsibility to our constituents. But many issues cross borders and are not quite so 'local', and it's incumbent upon those of us in the hemicycle to do the best for everyone.

**DH: OK. So that obviously means compromises from time to time...**

**SP:** Indeed. Pretty much all of the time, in fact! Take the latest movements on health technology assessment, or HTA.

ENVI, under the rapporteur Soledad Cabezón-Ruiz, had to take the European Commission's initial proposal, look at tabled amendments, then reach acceptable compromises before putting the issue to the full parliament. This was a long but ultimately successful procedure, given that the Strasbourg plenary accepted what was eventually put in front of them.
This was an excellent example of parties working together to come up with a workable plan, which has now been put to the Council.
But we can only do so much, of course! Over to you, Member States...

**DH: That's a very good recent example. Do you have any others?**

**SP:** Plenty, but I'll highlight just a few.

Although one could argue with some justification that cross-border healthcare is currently failing to live up to its promise, Parliament worked very hard across the colourful political spectrum to pave the way for what should be a massive boon to Europe's citizens.
Electronic health records working properly should certainly help, too, and the Commission is looking at the issues surrounding EHRs. But the fact is that MEPs from left, right and centre were very keen to facilitate the rights of patients to be treated in other Member States.

On top of this, members had a huge role to play in helping to formulate the General Data Protection Regulation, or GDPR. There were more amendments than you would believe and the debates went on and on.

Every MEP from whichever party had to listen to arguments from various stakeholders, EAPM included, and try to find the right balance between protecting privacy while not slamming the door in the face of those who push science forward through the sharing of data.

Lest we forget, most patients are happy to share their data if it helps themselves and others, but they also want to do so secure in the knowledge that their data will not be misused.

It's a tough balance to strike but, to me - to most of us in the chamber - it's not a party political issue.

**DH: Any other examples?**

**SP:** Of course. There are many, many examples. But let's stick to health and healthcare... We've had, in very recent times, consensus in areas such as clinical trials. And right now we're putting our thoughts across in respect of the Horizon Europe budget, of which healthcare is a big part.

This is ongoing and we're trying to reach a point where we can agree and, meanwhile, are putting pressure on the Commission to up the budget in real terms for the benefit of research into issues that affect the health of Europeans.

OK, sometimes we MEPs disagree - of course we do - but its not just one great political bunfight. We have work to do and we all want to walk out of the hemicycle happy that we have the best result possible under whatever circumstances we have had to deal with.

**DH: Many stakeholders in, for example, personalised medicine will say that there is a lack of incentives for research and development, while the issue of the pricing of medicines is always under the microscope and other matters on top. What can Parliament do?**

**SP:** Well, as you know, our role is limited. Having said that, it has grown of late but we are still not in a position to literally propose regulations. That is not to say that MEPs do not have considerable influence, because we do.

And in a democratic Europe I would argue that this is as it should be.

People talk about a democratic deficit and that can only be addressed by greater Parliamentary involvement in legislation.

As I said before, there is a responsibility that every elected representative carries on his or her shoulders. We need to have weight behind us and we try to push and push with the weight that we have.

The research agenda and its budget are vitally important in many areas, not least healthcare, and we need to make sure that projects such as IMI, for example, are not all just a great idea but are adequately supported.

The incentivisation has to be there or everybody may as well just pack up and go home.

That cannot be allowed to happen, of course, because Europe needs the investment from outside that our talented scientists and innovators deserve.

At the end of the day it's our job as MEPs to do the very best we can to make sure that the doors are as open as possible to those providing incentives. And that is absolutely NOT a one-party issue.

**DH: So you're saying that there's often what we could call 'a joined-up' approach?**

**SP:** Oh, for sure. Although we could always do with more of it! But whatever the media may wish to portray on occasion we, the elected representatives of all the hundreds of millions of citizens, are aware that we have to find the right road to travel.

Science, especially in healthcare, is moving at a rocket-fast pace. Think molecular biology, think innovative clinical research, think biomarkers and more.

It's blindingly obvious to at least most of us that the best way to optimise all of these great rocket launches is to deal with them jointly in a spirit of cooperation.

You know that they say two heads are better than one? So, arguably, 27 'heads' will be better than just two when it comes to EU cross-fertilisation of ideas and policies that are designed to help all citizens.

**DH: So what next?**

**SP:** Ha ha. Well, it's always busy, but two current important areas immediately come to mind with their attendant challenges. MEPs cannot do it alone - we are just one EU institution - but beeping away on the radar are the facts that orphan drugs need to be reasonably priced, which they often are not, and there is demonstrably a need for the EU to harmonise and integrate its legal framework in respect of health research.

As I've said, MEPs can only do so much. But we are democratically elected and thus have influence and, if we are asking Europe in all its great and grand diversity to work together, then surely it's reasonable for citizens to expect their representatives in the hemicycle to do the same.

When it comes to the crunch, we work together. Which is not a bad plan, really, from whatever end of the political spectrum you look at it.

# IMPROVING PATIENT CARE: THE INTELLIGENT ENTERPRISE FOR HEALTHCARE

Martin Kopp, Global General Manager Healthcare at SAP

Today's healthcare is plagued by cognitive dissonance where the twin requirements of superior patient care at reasonable costs trigger constant discomfort. While every healthcare provider strives to deliver high quality care, the business of healthcare can get in the way of treating patients and their families.

Workflows, processes, and paperwork put healthcare practitioners behind computer screens when they would rather be engaging directly with their patients. While mobile devices, laptops, and apps aren't leaving healthcare, a new wave of advanced technologies is rolling in to replace current technology that separates patients from their nurses, doctors, and clinicians.

Hospitals are launching digital initiatives that are moving them toward a new operations model - the intelligent enterprise—that allows them to deliver value-based healthcare and a seamless patient experience.

At the center of this model is intelligent technology, which is taking a lead role in patient care.

> **"We are on the journey towards creating an intelligent enterprise. Healthcare providers are thinking about integrated, automated solutions that can communicate with each other and with other departments"**
>
> Martin Kopp, Global General Manager Healthcare at SAP.

He notes that these technology platforms are increasingly creating information parity between a providers IT systems to allow healthcare providers to reimagine operations and care delivery. By applying intelligent technologies such as the Internet of Things (IoT), Artificial Intelligence (AI), Machine Learning (ML), and advanced analytics, healthcare practitioners can change where and how they spend their limited time.

> **"With the right technology, providers can begin to automate repetitive tasks. This enables them to focus on higher-value tasks and focus on individual patient care"**
>
> Martin Kopp, Global General Manager Healthcare at SAP.

## Some of the advanced technologies he sees on the horizon include:

- More data collected from mobile devices, sensors and patient wearables will enable clinicians to continuously monitor patients, find new digital biomarkers and predict medical events before they happen;
- Machine-learning based clinical decision-support platforms will provide guidance for healthcare professionals and predict multiple medical events, such as length of stay, readmissions and mortality;
- Billing and invoicing systems that are a lot more accurate will enable claims processing that is as much as two times faster and able to identify potential fraudulent activities.
- Data, Data, Everywhere
- In addition to advanced technology, at the foundation of the intelligent enterprise for healthcare is patient data. While the digitization of healthcare has progressed slower than other industries, the amount of usable patient data has increased drastically.
- “The variety of data types, all in different formats, contained within the medical ecosystem is overwhelming,” says Kopp. This includes patient demographics, interactions, diagnosis, pathology, laboratory results, medications, radiology, procedures, post-therapy care, clinical documents, operational, financial and insurance information etc. “Healthcare providers are in need of automated ways to mine, share, and analyze these enormous data pools,” says Kopp.
- Patient data available in EMR systems is only partly structured and allows mining to a lesser extent. Since most of the data used to treat a patient is unstructured—entered as notes and free text from doctors-providers need to turn to natural language processing tools. “Digitizing doctor’s notes and making them available for structured data analysis is a vital piece to improving patient care within the healthcare enterprise,” he adds.
- The Intelligent Enterprise for Healthcare
- As providers launch successful digital transformation initiatives, the future model of value-based patient care starts to emerge. SAP along with healthcare experts have outlined a framework of key components that are needed to enable an intelligence enterprise for healthcare:
- Health data platform: A fully digital platform with optimized health data management and security, and operational in the cloud
- Intelligent technologies: A portfolio of advanced technologies that includes AI, machine learning, IoT, and real-time, in-memory analytics embedded within business applications and processes.
- Intelligent healthcare application suite: A set of business process optimization and innovation applications that can enable better patient outcomes at lower costs. This includes apps that reimagine core hospital processes, ensure operational efficiency, better patient experience and better empowerment of the workforce.

> **“Healthcare providers need a 360-degree view of their operations. They need to see business processes and technology solutions holistically, with patient needs at the core of their innovation strategy”**

When that happens, intelligent technologies will help providers accelerate the delivery of value-based care, in which providers are paid based on patient health outcomes vs. the quantity of healthcare services delivered.

*Reference: https://www.techemergence.com/where-healthcares-big-data-actually-comes-from/

# DAY 3: 28TH NOVEMBER 2018

| | |
|---|---|
| **08:00–08:30** | **Networking and Break** |
| **08:30–09:45** | Parallel Sessions |

Pirelli Room

## Regional Track
Best Practice in sharing Data in regional Perspective

### CHAIR
**Angelo Paradiso**
*Vice Scientific Director, Istituto Tumori Bari, National Cancer Research Center*

### PANEL
**Mario Romao**
*EMEA Global Public Policy Team, Intel*

**Peter Riegman**
*Pathologist, Erasmus MC*

**Brendan Barnes**
*Director IP & Data Protection, EFPIA*

Gaber Room

## Patient Track
Biomarkers Health Literacy

### CHAIR
**Nuria Malats**
*Group Leader, Genetic and Molecular Epidemiology Group, Spanish National Cancer Research Centre, Madrid, Spain*

### PANEL
**Prof Nicola Normanno**
*Istituto Nazionale Tumori, Napoli*

**Lydia Makaroff**
*Director, ECPC, Belgium, Civil society: Personalised Medicine Awareness Month*

**Tonu Esko**
*Deputy Director of Research, Estonian Biobank, Estonian Genome Center, University of Tartu, Estonia*

**Ilona Schelle**
*Inspire2Live*

Biagi Room

## Education Winter School Track
Redefining the Role of Family Physicians Through the Use of EHRs and Artificial Intelligence

### CHAIR
**Lars Rohwer**
*Senior Director, Government Affair & Policy, Siemens*

### PANEL
**Luke Slawomirski**
*Senior Economist/Policy Analyst, OECD Paris, France*

**Valere Dussaux**
*Director, Health and Life Sciences Industry Sales Specialist, INTEL*

**Marco Sacco**
*Head of CNR-STIIMA subsidiary – Institute of Intelligent Industrial Technologies and Systems for Advanced Manufacturing*

# DAY 3: 28TH NOVEMBER 2018

Room Arancio 34

## Forward together with innovation with the regions at the centre: Regions4PerMed

Setting the Scene

### INSTITUTIONAL WELCOME

**Maurizio Bersani**
*DG Welfare, Lombardy Region*

### INTRODUCTION:

**Gianni D'Errico**
*Project Coordinator, Regions4permed*

### CHAIR

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

### PANEL

**Gaetano Gugliemi**
*Director, DG research and health innovation, Italian Ministry of Health*

**Paola Castagnoli**
*Scientific Director, Toscana Life Sciences*

**Andrea Paolini**
*General Director, Tuscany Life Sciences*

**Gianpietro Van De Goor**
*European Commission, Unit Personalised Medicine, DG Research & Innovation*

**Jurgi Camblong**
*CEO Sophia Genetics*

Soresin Room

## Rare Disease Track

Why Should Europe Take a Lead?

### CHAIR

**Robert Johnstone**
*Board Member, International Foundation for Integrated Care (IFIC) and European Forum for Good Clinical Practice (EFGCP)*

### PANEL

**Antonio Montserrat**
*Former Senior Expert on Cancer and Rare Diseases, DG Public Health, European Commission, Brussels, Belgium*

**Mariangela Pellegrini**
*ERN Manager on behalf of ERN-EuroBloodNet Coordination Team*

**Luana Banu**
*International Public Affairs Head, Shire International GmbH*

Testori Room

## Translational Research Track

Understanding the Diseases

### CHAIR

**Etienne Richer**
*CIHR Institute of Genetics Associate Director*

### PANEL

**Phil Hieter**
*Professor, Department of Medical Genetics Department of Biochemistry and Molecular Biology*

**Jacques Simard**
*Canada Research Chair in Oncogenetics, Vice-Dean of Research and Graduate Studies, Full Professor, Faculty of Medicine, Université Laval*

**Giovanni Apolone**
*Scientific Director, Fondazione IRCCS Istituto Nazionale dei Tumori (INT) Milano*

| | |
|---|---|
| **9:45–10:00** | **Networking and Break** |

# DAY 3: 28TH NOVEMBER 2018

| 10:00–11:15 | Parallel Sessions |
|---|---|

Pirelli Room

## Regional Track

Better and Common Guidelines on Various Diseases

### CHAIR

**Ken Mastris**
*President, EuropaUomo*

### PANEL

**Jasmina Koeva-Balabanova**
*Chair of the Board BAPPM*

**John Field**
*Professor of Molecular Oncology, University of Liverpool, UK*

**Sebastian Schmidt**
*Head of Strategy and Medical A airs Computed Tomography, Siemens Healthineers*

Gaber Room

## Patient Track

Ensuring that Patient Preferences are Valued when Assessing New Treatments

### CHAIR

**Peter Kapitein**
*Inspire2Live*

### PANEL

**Isabelle Huys**
*KU Leuven, Belgium*

**Ivana Cattaneo**
*Novartis, Italy*

**Francesco de Lorenzo**
*ECPC President, Italy*

**Hans Peter Dauben**
*Rheinische Fachhochschule Köln*

Biagi Room

## Education Winter School Track

Tools to Individualize Clinical Decisions for HCPs in the Era of Co-morbidities & Survivorship

### CHAIR

**Alessandra Gorini**
*University of Milan*

### PANEL

**Alessandra Gorini**
*University of Milan*

**Claire Champeix**
*European Association working for carers (EuroCarers)*

**Fedro Peccatori**
*MD PhD, is Director of the Fertility and Procreation Unit within the Division of Gynecologic Oncology in the Department of Gynecology at the European Institute of Oncology, Milan*

**Fabrizio Tagliavini**
*Scientific Director, Fondazione IRCCS Istituto Neurologico "Carlo Besta" (FINCB), Milano*

# DAY 3: 28TH NOVEMBER 2018

Room Arancio 34

## Forward together with innovation with the regions at the centre: Regions4PerMed

### Session 1: 10:00–11:15
Coordinating regional policies and innovation programmes in personalised medicine

**CHAIR**
**Gianni D'Errico**
*Project Coordinator, Regions4permed*

**PANEL**
**Maurizio Bersani**
*DG Welfare, Lombardy Region*

**Rafael Solana**
*General Secretary for Research, Development and Innovation, Regional Ministry of Health of Andalusia, Seville, Spain*

**Andrea Belardinelli**
*Digital Health and Innovation – Tuscany Region*

**Richard Barker**
*Founding Director, New Medicines Partners*

### Session 2: 11:30–12:45
Coordinating regional strategic investments

**CHAIR**
**Richard Barker**
*Founding Director, New Medicines Partners*

**PANEL**
**Fabio Pammolli**
*EFSI Investment Committee Member, EIB*

**Paola Pozzi**
*Venture Consultant – Sofinnova Partners*

**Felicitas Riedl**
*Head of Life Sciences Division, EIB*

**Fabrizio Landi**
*President, Toscana Life Sciences*

**Mikel Irujo Amezaga**
*Vanguard Initiative Board*

Soresin Room

## Rare Disease Track
The promise of precision: improving communication and ethos in Precision Medicine

**CHAIR**
**Alastair Kent**
*Formerly Director of Genetic Alliance UK*

**PANEL**
**Prof Tim Maughan**
*University of Oxford*

**Prof Joshua Hordern**
*University of Oxford Healthcare Values Partnership*

**Prof Stuart Elborn**
*Imperial College London*

**Dr Janet Allen**
*Dr Janet Allen, Cystic Fibrosis Trust*

Testori Room

## Translational Research Track
Delivery of Results

**CHAIR**
**Jeanne Egar**
*Assistant Director, Management & Operations for CIHR Institute of Genetics*

**PANEL**
**Gillian Bartlett**
*iChange project, Oncology, Canada*

**Alison Elliott**
*Investigator, BC Children's Hospital*

**Eduard Hergenreider,**
*Senior Subject Matter Expert, SAP*

| 11:15–11:30 | Networking and Break |
|---|---|

# DAY 3: 28TH NOVEMBER 2018

| 11:30–12:45 | Presidential Session<br>**Interfacing with Public Policy Makers** |
|---|---|

**Testori Room**

## Presidential Session
Interfacing with Public Policy Makers

### CHAIR
**Antonio Montserrat**
*Former Senior Expert on Cancer and Rare Diseases, DG Public Health, European Commission, Brussels, Belgium*

### PANEL
**Francesco De Lorenzo**
*President, European Cancer Patient Coalition*

**Elena Fattori**
*Italian Senator*

**Eva Weinreich-Jensen**
*President, Hope*

**Mary Harney**
*Chancellor University of Limerick*

**Francesco Scopesi**
*General Manager, Italy, Shire*

**Gaetano Guglielmi**
*Head Office Health and Biomedical Research IRCCS, Italian Ministry of Health*

| 12:45–14:00 | **Lunch & Networking Break** |
|---|---|

| 14:00–15:15 | Parallel Sessions |
|---|---|

**Biagi Room**

## Education Winter School Track
Recent Advances in Personalized Medicine

### CHAIR
**Mario Pazzagli**
*Professor of Clinical Biochemistry, Department of Clinical and Experimental Biochemical Science, University of Florence, Italy*

### PANEL
**Olivier Arnaud**
*Senior Director, European Research, JDRF*

**Giuseppe Curigliano**
*European Institute of Oncology (IEO), Italy*

**Gianvito Martino**
*Scientific director, IRCCS Ospedale San Raffaele*

**Mario Pazzagli**
*Professor of Clinical Biochemistry, Department of Clinical and Experimental Biochemical Science, University of Florence, Italy*

**Antonella Isacchi**
*Director, Biotechnology Kinase Platform Coordinator - Nerviano Medical Sciences*

**Room Arancio 34**

## Forward together with innovation with the regions at the centre: Regions4PerMed
Technological challenges for system integration and data interoperability

### CHAIR
**Jackie Hempel**
*Armstrong Craven*

### PANEL
**Francois Cadiou**
*Co-founder, Healint*

**Jan Verheyden**
*VP Traumatic Brain Injury, IcoMetrix*

**Paolo Gazzaniga**
*Director of Studies Center, Assobiomedica*

**Fabrizio Landi**
*President, Toscana Life Sciences*

# DAY 3: 28TH NOVEMBER 2018

**Soresin Room**

## Rare Disease Track

Translating the Research & Diagnosis Landscape for the benefit of patients with pancreatic cancer

### CHAIR

**Giovanni Codacci Pisanelli**
*Professor, University of Rome, "La Sapienza"*

### PANEL

**Jesús Rueda Rodríguez**
*Director, International Affairs, MedTech Europe*

**Gabriele Capurso MD, PhD**
*Chief of Clinical Research, PancreatoBiliary Endoscopy and EUS Division, Pancreas Translational and Clinical Research Center, San Raffaele Scientific Institute*

**Nuria Malats**
*Group Leader, Genetic and Molecular Epidemiology Group, Spanish National Cancer Research Centre, Madrid, Spain*

**Testori Room**

## Translational Research Track

Therapeutics – Matching Conditions with Treatments

### CHAIR

**Steve Robbins**
*Scientific Director of CIHR Institute of Cancer Research*

### PANEL

**Nada Jabado**
*iChange Project Oncology, Canada*

**Jeannette Soderberg**
*European project manager, JDRF*

**Elena Tremoli**
*Scientific Director, Centro Cardiologico Monzino*

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|---|---|
| **15:15–15:30** | **Networking and Break** |
| **15:30–16:45** | Closing Presidential Session<br>**Who is to do What?** |

**Testori Room**

## Closing Presidential Session

Who is to do What?

### CHAIR

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

### PANEL

**Fabrizio Landi,**
*President of Foundation Toscana Life Sciences, Italy*

**Tom Lillie, VP,**
*Head of European Clinical Development, Merck*

**Anna Sobczak,**
*Policy Officer, DG Grow, European Commission*

**Paola Testori Coggi,**
*President of the Pricing and Reimbursement Committee, of AIFA, Italy*

**Gianpietro Van De Goor**
*European Commission, Unit Personalised Medicine, DG Research & Innovation*

**On the back of its MEGA initiative (Million European Genomes Alliance),adopted by 16 countries in a joint declaration in April 2018, EAPM is zooming in on the key goal of engaging EU and national policy makers now, in order that they understand and shape the landscape for the successful implementation of genomics and related technologies throughout healthcare.**

The joint declaration constituted a major commitment on behalf of a coalition of willing Member States, alongside the Commission, to join genomic databanks at an EU level for medical research. The signatories agreed to work together *towards building a research cohort of at least one million genomes accessible in the EU by 2022.*

**Denis Horgan**, EAPM Executive Director asked long-time proponent of personalised medicine and Member of the European Parliament **Marian Harkin** her thoughts on genomic research and its implications.

### DH: Marian, how important is is that we share genomic data across Europe?

MH: Very. It's vital. And now is the time to step it up to an EU-wide level. A coordinated, pan-European project would garner crucial genetic information that could have an immeasurable benefit when it comes to the health of current and future citizens.

Data, of course, has to be protected and consent has to be given, but most patients are happy to share their data to help current patients and those that will follow.

Lest we forget, genomics is the foundation that enables the vast potential of personalised medicine to be realised, much of it preventative.

We have an ageing population, and with rising healthcare costs and individual health systems being increasingly challenged, genomics has the potential to have a huge impact on the health of all of us.

It will provide diagnostic, economic and efficiency benefits, ensuring that patients receive the right information and the right treatment at the right time - the basic tenet of personalised medicine.

This will ease the burden on healthcare systems and lead to a healthier and, thus, wealthier, Europe.

But although genomics and genome sequencing are starting to be introduced to clinical care, improving diagnosis and care of patients with rare genetic diseases and starting to impact on cancer diagnosis and stratification of therapies, there remain a number of key challenges to ensure genomics and related technologies are applied such that over the next few years we can fully realise the potential of personalised medicine.

### DH: Could you elaborate?

MH: Fundamental is the need to understand the present, and develop agreed EU-wide standards.

We need to achieve stronger cross-border research partnerships, the Introduction of research results into clinical environment and practice, and vitally needed EU-wide research collaboration on personalised medicine. And we must build on existing national and regional personalised medicine initiatives, strengthening cooperation among Member States and regions of the EU.

Genomics is starting to be implemented across a number of clinical areas in different geographies. Europe must ensure that models of best practice for clinical implementation and application are shared across these.

And from an education point of view, the majority of current clinicians have not trained in the genomic era and have little experience of using such information in healthcare.

Put simply, for patients to be correctly identified for the most relevant test, and the appropriate information from results to be conveyed back to them, this educational deficit among healthcare professionals must be addressed quickly.

But that is not all - current regulatory mechanisms can make implementing effective innovative diagnostics rapidly to patients challenging, particularly as genomic tests tend to evolve quickly. Regulation has to keep up with the science.

Meantime, test results must be delivered quickly, and data must be presented so as to to allow relatively simple decision making by physicians.
And, of course, adapting sequencing to potentially

life-saving clinical work needs much higher levels of sensitivity and specificity than is currently required for research.

There are many other issues to be dealt with in the coming years and decades. These are just a few.

## DH: Do you have suggestions as to the way forward?

MH: I think, for a start, we should focus on six key areas in Europe which should help to promote the use of genomics while allaying fears among the public at large.

These involve agreeing standards for data generation and analysis, plus genomic sequencing and analysis, and agreeing guidelines around the sharing of genomic and associated clinical data.

Europe also needs to promote the uptake and alignment of existing agreed standards and define principles for interoperability of health informatics systems. And it must coordinate national activity to ensure shared best practice, clinical implementation and application.

As I mentioned earlier we need to structure a training programme in genomics, informatics and personalised medicine for clinical staff, and we must also promote broad discussion with European regulators on the appropriate mechanisms for clinical genomic testing.

I feel, as do many others, that once these guidelines and safeguards are in place, the scene will be set to allow genomics to become an even bigger actor on the healthcare stage than it is already.

## DH: You've said earlier that most patients are happy to share their data, within an ethics-based system with solid safeguards, but are there any fears?

MH: Yes, there are understandable societal fears, in this era of Big Data, about personal information-mining against the will of the individual, not least regarding possible discrimination.

Research Ethics Committees came about as a result of the post-war Nuremberg Code established after the trials in the same city.

The holocaust was, of course, a huge event but genetic discrimination can occur if people are treated unfairly because of differences in their DNA that increase their chances of getting a certain disease.

For example, a health insurer might refuse to give coverage to a woman who has a DNA difference that raises her odds of getting breast cancer.

We need robust systems in place to ensure that such examples cannot happen, in order to allay any fears that the public may have.
Patients should always be put at the centre of healthcare, not least when it comes to genomic sequencing, and they need above all to be confident in the processes.

They know that more information, more knowledge, is a good thing. Especially when it comes to health, which citizens value highly. But they also want frameworks in place that protect them and, indeed, their families.

## DH: What about the so-called right to be forgotten?

MH: I've noted, as I'm sure you have, that under a new legislative proposal, people in Belgium applying for insurance policies wouldn't have to say whether or not they've recovered from a major illness or have a chronic condition that's under control. They have similar legislation in France
covering conditions such as cancer or diabetes.

There are pros and cons to this, of course, and the insurance companies don't like it. They say it will lead to higher risk and thus higher premiums.

But to take your question more literally, as I said earlier, most patients are willing to share their health data for the benefits of science and, in that regard, do not want to be forgotten if they can help fellow patients.

That's even if they would very much like insurance companies to forget about their previous diseases!

**Denis Horgan,**
Executive Director,
*EAPM*

**Mary Harkin**
*MEP*

European Alliance for Personalised Medicine

# EAPM

## 7th Annual Conference

# BRUSSELS

The European Alliance for Personalised Medicine's seventh annual Presidency Conference will once again take place in the historic Bibliothèque Solvay in Brussels, this time over the days 8-9 April 2019.

To be held under the auspices of the Romanian Presidency of the EU, which will run from 1 January to 30 June, the title of the 7th edition will be: **Forward as one: Healthcare innovation and the need for policymaker engagement.**

As ever, the event will pull together leading experts in personalised medicine drawn from patient groups, payers, healthcare professionals plus industry, science, academic and research representatives

Also attending will be the aforementioned Members of the European Parliament, plus representatives from the Commission and Council, as well as from Member State governments.

As well as the huge current debate about HTA, on the innovation front, breakthroughs in genomics will also be on the agenda, not least given the emergence of 'Big Data' and EAPM's Million European Genomes Alliance (MEGA) initiative having produced a landmark declaration earlier this year.

An opening session will set the scene for where personalised medicine is today, while a final wrap-up slot will focus on conclusions and where we can hope to go moving forward. The whole day will be highly interactive, so there will be a great deal of input, not just from the speakers, but also from the floor.

It is planned that this latest Presidency Conference will end with an endorsement from MEPs to support the conclusions in time for their re-election campaigns.

We would be delighted to have you join us in Brussels.

For more information, please contact the EAPM Office:
**Denis Horgan,**
**EAPM Executive Director**
**Email: denishorgan@euapm.eu**

European Alliance for Personalised Medicine

# EAPM

## 3rd Annual Congress

# BRUSSELS

The European Alliance for Personalised Medicine (EAPM) has scheduled its third annual Congress from Monday-Wednesday, 18-20 November, in Brussels.

**The Belgian capital has been chosen to host the event as the new Parliament will be in place after the summer elections - it is political group week in the Brussels seat - while a new European Commission will be in the process of being formed, ready to formally move into the Berlaymont just over a month later.**

The event will be held under the auspices of the Finnish Presidency of the EU, which will run from July to December, 2019. As well as acting as a one-stop shop for all aspects of the growing field of personalised medicine, attendees and partners will be able to meet and interact with policy makers in the shape of MEPs old and new, Commission o cials and Member State government representatives.

The opportunity will be firmly grasped to engage relevant Directorates-General in order to pass on needs and aims while prioritising work plans going forward, especially on the complex topics surrounding fully integrating innovation into Europe's healthcare systems.

To aid the ongoing process, regulators, payers, investors and, of course, medical experts, patients and healthcare journalists will also be present.

Added value at the Congress will be the opportunity for attendees to: ¾ Meet the expert ¾ Meet the influencer ¾ Meet the scientist ¾ Meet the researcher, and more.

Of course, a key aspect is that the event will be held at the perfect time to engage incoming Members of the European Parliament, who will at the time have only recently been designated their dossiers for the five-year term. Not only that, but the timing at the end of the year means that many conferences and Congresses will already have taken place across the year, allowing EAPM and its attendees to review the latest developments and communicate with policy makers.

Essentially, the 3rd annual Congress will provide the ideal space to allow for a meeting of minds and expertise and represent a vital opportunity for top-level discussion and the formulation of real action plans, for example in the area of translational research.

It is expected that up to 1000 Life Sciences thought leaders will convene at the event, which will bring together key audiences who contribute to the vast programme content, themed tracks, and vital knowledge exchange.

For more information, please contact the EAPM Office:

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