3rd EAPM Annual Conference
2-3 June 2015
University Foundation
Brussels

European Alliance for Personalised Medicine

SMART

Smaller Member States And Regions Together

'STEPs in the Right Direction to a Brave New, Healthier & SMART Europe'

Latvian Presidency of the Council of the European Union

EU2015.LV


SIEPs
Specialised
Treatment
for Europe's
Patients

Welcome Message from the EAPM Co-Chairs and Executive Director to attend the EAPM Conference

We at the European Alliance for Personalised Medicine are delighted to welcome you to our third annual conference, here at the University Foundation, Rue d'Egmontstraat, Brussels.

EAPM is very pleased to have secured the use of this magnificent building; close to the European Parliament, as the venue for our top-level, two-day gathering.

Many of you attended our inaugural conference, held in 2013 in Dublin under the auspices of the Irish Presidency of the EU, as well as last year's forum at Bibliotheque Solvay, under the Italian Presidency. This year, with two smaller nations – Latvia and Luxembourg - holding the rotating EU Presidency, the Alliance will focus on the fact that health policies need to recognise and tackle the inherent health system vulnerabilities faced, specifically, by smaller countries and in the regions of the larger ones.

We call this a SMART approach – Smaller Member States And Regions Together; and this will be further developed here at the conference.

Among the speakers are high-level government health representatives from Latvia, Luxembourg and Malta, and several Members of the European Parliament. These will be joined by you - the most influential stakeholder representatives driving personalised medicine during six plenary sessions.

The plenary topics will be representative of EAPM's membership (patients, medical professionals, healthcare planners, industry, scientists and researchers), and reflect the solid work programmes developed since the Alliance's formation and, from these discussions, a set of recommendations will emerge which EAPM hopes will support and strengthen Luxembourg's Council Conclusions on Personalised Medicine due later in the year.

Uniquely in the sphere of PM in Europe, the Alliance has achieved one of its goals of bringing all stakeholders together under one roof. If EAPM and its members are to realise the ultimate goal of creating a healthier Europe for 500 million citizens across 28 countries, we must do so together. This conference will take us a few steps along the road to much-needed multi-stakeholder collaboration.

Indeed, our STEPs campaign - which stands for Specialised Treatment for Europe's Patients – highlights that the Alliance is working tirelessly to help deliver 'the right treatment for the right patient at the right time'.

Our goal is to ensure that personalised medicine forms a major part of the EU's health strategy, now and long into the future.

Once again, we are delighted to have you all here and sincerely hope you enjoy, and benefit from, the conference.

David Byrne and Helmut Brand, EAPM Co-Chairs.
Denis Horgan – Executive Director EAPM

European Alliance for Personalised Medicine

3rd EAPM Annual Conference
2-3 June 2015
Brussels

About EAPM

The European Alliance for Personalised Medicine (EAPM) brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics, through consensus.

EAPM was launched in March 2012, as the European discussion on personalised medicine gathers pace. It is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders. It works on case studies, education, training and communication to deliver practical policy recommendations designed to exploit the potential of personalised medicine to the full.

The mix of EAPM members provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry. Relevant departments of the European Commission have observer status, as does the European Medicines Agency. By bringing together all stakeholders, EAPM's aim is to help to forge constructive links between the EU institutions and society.

The EAPM Forum brings all members together every 2-3 months to review activity and to direct political strategy. Working groups develop positions on key topics and make proposals and recommendations to the Forum. The secretariat manages day-to-day operations, prepares Forum meetings, and co-ordinates the working groups. EAPM is funded by its members.

Contact:
Denis Horgan
EAPM Executive Director
Avenue de l'Armee/Legerlaan 10
1040 Brussels, Belgium
Ph: + 32 4725 35 104
Website: www.euapm.eu

SMART
Smaller Member States And Regions Together

*The European Commission's **Martin Seychell**, Deputy Director General, DG SANTE, and **Rudolf Strohmeier**, Deputy Director General, DG Research and Innovation, speaking at EAPM's 2014 Conference 'Integrating Personalised Medicine into the EU Strategy'*

2015 Annual Conference rationale: Smaller Member States And Regions Together (SMART)

This year, the rotating presidency of the European Union is being held by two of the EU's smaller states - Latvia and Luxembourg.

Since the EU enlargements of 1995 and 2004, there are now seven member states with a population of between six and 10 million and eight countries with five million or less. Prior to the 2004 'big bang', when ten new states joined the EU, smaller countries had to accept an Acquis communautaire which often failed to take into account their individual aspects and characteristics.

A significant turning point was reached, however, during the pre-2004 accession negotiations when part of the formulation of the pharmaceuticals package included a provision for abridged registration – Article 126a, also known as the 'Cyprus clause'.

Following this landmark event, smaller states have been active in shaping health policy at European level and can now act as vital policy entrepreneurs pursuing normative policy agendas.

This has been demonstrated by, for example, Slovenia and its leading role in promoting cancer policy development at EU level through the European Partnership for Action Against Cancer.

Meanwhile, co-operation in areas such as health technology assessments are likely to receive more support from these countries, which often rely heavily on networking and capacity building.

The European Alliance for Personalised Medicine (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.

In the EU health arena there is clearly a need for more collaboration and, in the smaller states, the pooling of resources, which will certainly need to occur more often. And it may well be the case that European health policy will be driven by the needs and aspirations of these small- and medium-sized member states as well as regions in the larger ones.

This scenario would certainly present an opportunity for an innovative dimension in health policy to be developed at European level in which the added value of joint working is easily realised through the visible benefits attained for smaller administrations.

The perception of what constitutes added value will differ between Member States and it is possible that smaller states will become active proponents of the further Europeanisation of health policy. **The conference will discuss the different threads in collaborative ways, develop consensus positions and propose 'SMART Approach' recommendations to relevant EU institutions.**

European Alliance for Personalised Medicine

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Day 1 - Tuesday, 2 June 2015

12.45 - 13.45 Registration

13.45 - 14.00 Welcome
David Byrne, *EAPM Co-Chair*
Cristian-Silviu Busoi, *MEP, Committee of Health, European Parliament*

14.00 – 16.00 Plenary Session I
'State of Play' of ensuring better treatments for patients: Learning from Smaller Member States and Regions
Chair: Gordon McVie, *European Institute of Oncology*

What opportunities does the session offer?

• Bringing together high-level stakeholders to discuss how we can take advantage of the opportunities that personalised medicine offers
• Engaging with Health Ministers from the Member States that hold the EU Presidency this year, the EU Commissioner for Health and Safety, as well as multi-stakeholders of EAPM including patients, medical professionals, healthcare planners, industry, scientists an researchers
(Read more about this session on Page 10)

Key Notes:
• **Lydia Mutsch**, *Minister for Health, Minister for Equal Oppurtunities, Luxembourg*
• **Solvita Zvidriņa**, *Secretary of State for Health, Latvia*
• **Christopher Fearne**, *Parliamentary Secretary for Health, Malta*

Followed by Questions & Answers

Multi-stakeholders representatives:

• **Elisabetta Gardini**, *MEP, Health Committee, European Parliament*
• **Anni Morsing**, *European Association of Nuclear Medicine*
• **Gunta Anca**, *Sustento (Latvia), European Patient Forum member organisation*
• **Paul De Raeve**, *Secretary General, European Federation of Nurses Association*
• **Richard Bergstrom**, *Director General, EFPIA*
• **Bonnie Wolff-Boenisch**, *Head of Research Affairs Unit, Science Europe*
• **Didier Jacqmin**, *European Association of Urology*
• **Françoise Meunier**, *Director Special Projects, European Organisation for the Research and Treatment of Cancer*

Followed by Questions & Answers

(Rapporteur: Helmut Brand, EAPM Co-Chair)

16.00 – 16.30 Coffee

Day 1 - Tuesday, 2 June 2015

16.30 – 18.00 Plenary Session II
Medical Adaptive Pathways to Patients (MAPPS) – Taking Steps Forward
Chair: Alastair Kent, *Genetic Alliance UK*

What opportunities does the session offer?

• Insight into the impact of MAPPs on the regulatory environment at Member State level, plus understanding how payers and patients will need to collaborate in the future for assessing risk/benefit and quantifying value
• Understanding of the ability of MAPPs to better respond to the rapidly evolving science of personalised medicines, and the wishes of patients dealing with unmet medical needs
• Knowledge of the current IT gaps that exist across the EU to implement MAPPs, and the next steps required to develop systems for medical data support and evaluation of real world data
(Read more about this session on Page 10)

High-level Panel Discussion
• **Philippe De Backer**, *MEP, ENVI Committee, European Parliament*
• **Magda Chlebus**, *Science Director, EFPIA*
• **Irene Norstedt**, *Acting Executive Director, IMI*
• **Yann Le Cam**, *Secretary General of EURORDIS*
• **Ulrich Jäger,** *European Hematalogy Association*
• **Sabine Juelicher**, *Head of Unit Medicinal Products authorisation, European Commission*

(Rapporteur: Helmut Brand, EAPM Co-Chair)

Day 2 –Wednesday, 3 June 2015

09.00 - 10.30 Plenary Session III
Activating National Cancer Plans in the era of Personalised Medicine and strengthening their patient-orientation
Chair: Louis Denis, *Europa Uomo*

What opportunities does the session offer?

• It will provide an overview of the approach that is being taken at the national and EU level to tackle cancer in the era of personalised medicine
(Read more about this session on Page 11)

Dialogue with the High-level Panel/European Parliament:
• **Sirpa Pietikainen**, *Member of the European Parliament*
• **Antoni Montserrat Moliner**, *Policy Officer for Cancer and Rare Diseases, Directorate of Public Health (DG SANTE)*
• **Josep Maria Borras**, *University of Barcelona, Ministry of Health and Social Policy, Spain*
• **Tit Albreht**, *National Institute of Public Health of Slovenia*
• **Ingrid Kossler**, *Rapporteur for EPAAC, ESSC, Former President of Europa Donna, Former Board Member, European Cancer Patient Coalition*

Followed by Questions & Answers

(Rapporteur: Helmut Brand, EAPM Co-Chair)

10.45 – 11.15 Coffee

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Day 2 - Wednesday, 3 June 2015

11.15 – 12.45 Plenary Session IV:
Overcoming Barriers to Access and Understanding Value: Patient Access to Innovative therapies
Chair and Welcome address: Stanimir Hasurdjiev, *MD, European Patient Forum, Board Member*
Introductory remarks: Ansgar Hebborn, *EAPM WG on Access Co-Chair, Head Global Market Access Policy at Roche Pharmaceuticals*

What opportunities does the session offer?

• Understanding that it is necessary for policymakers and payers to realise that investing now in advanced therapies and technologies - as well as in adequate regulatory and payer decision making frameworks - will be key in terms of improved patient outcomes and more efficient health care system
(Read more about this session on Page 11)

Setting the Stage for Patient Access:
• **George Kalamitsis**, *President, Hellenic Liver Patient Association "Prometheus"*
• **Breda Flood**, *President, European Federation of Allergy and Airways Diseases Patients*

Followed by Questions & Answers

Health Inequalities within the EU – The Situation in Smaller Member States
• **Andrey Kovatchev**, *MEP, Committee on the Environment, Public Health and Food Safety, European Parliament*
• **Zoltán Kaló**, *Professor of Health Economics, Eötvös Loránd University*
• **Aleksandra Baranowska**, *Urzuli Jaworskie Foundation*
• **Luís Mendão,** *Chair of the Board of European Aids Treatment Group (EATG)*

Followed by Questions & Answers

(Rapporteur: Helmut Brand, EAPM Co-Chair)

12.45 – 13.45 Lunch

13.45 - 15.15 Plenary Session V
Personalised medicine and a European Big Data-driven economy – The Lighthouse Effect
Chair: Alastair Kent, *Genetic Alliance UK*
Introductory remarks: Lester Russell, *Senior Director, Health & Life Sciences Innovation EMEA, Intel Corporation*
Angela Brand, *Founding Director and Full Professor of the Institute for Public Health Genomics, Maastricht University*

What opportunities does the session offer?

• Hear how getting a 'Data Strategy for Personalised Medicine' right would not only accelerate development of more effective treatments and potentially help with the management of healthcare resources, it would also act as a foundation for private sector investment and EU jobs in R&D
(Read more about this session on Page 11)

Dialogue with High-level Panel:
• **Kay Swinburne**, *MEP, Committee on Economic and Monetary Affairs, European Parliament*
• **Lester Russell**, *Senior Director, Health & Life Sciences Innovation EMEA, Intel Corporation*
• **Jillian Odenkirk**, *Senior Analyst, Organisation for Economic Cooperation and Development (OECD)*
• **Ernst Hafen**, *ETH Zurich*
• **Nicola Bedlington**, *European Patient Forum*
• **Lester Russell**, *Senior Director, Health & Life Sciences Innovation EMEA, Intel Corporation*
• **Angela Brand,** *Founding Director and Full Professor of the Institute for Public Health Genomics, Maastricht University*

Followed by Questions & Answers

(Rapporteur: Helmut Brand, EAPM Co-Chair)

15.15 – 15.45 Coffee

15.45 – 16.45 Plenary Session VI
Unlocking the value of research to provide evidence, and education of healthcare professions to realise the benefits for today and tomorrow's discoveries
Chair and introductory remarks: Mark Lawler, *EAPM Research Group Chair, Chair in Translational Cancer Genomics, Queen's University Belfast*

What opportunities does the session offer?

• Hear that, despite the significant advances that have been made, there is an urgent need to develop and adequately resource a patient-centred European Translational Research Platform that maximises the impact of new and existing activities at European and national levels.
(Read more about this session on Page 11)

- **Christine Chomienne**, *President, European Hematology Association*
- **Maria da Graça Carvalho**, *Senior Advisor in the Cabinet of Carlos Moedas, Commissioner for Research, Science and Innovation*
- **Miriam Gargesi**, *EuropaBio Healthcare Director*
- **Mark Lawler**, *EAPM Research Group Chair, Chair in Translational Cancer Genomics, QUB*
- **Wolfgang Ballensiefen,** *Coordinator German Aerospace Center, Project Management Agency*
- **Núria Malats**, *Centro Nacional de Investigaciones Oncológicas (CNIO), EU Pancreas - BM1204 COST Action*
- **Daniel Schneider**, *Genomic Health*

Followed by Questions & Answers

(Rapporteur: Helmut Brand, EAPM Co-Chair)

16.45-17.00 Concluding Remarks
Helmut Brand, *EAPM Co-Chair*

3rd EAPM Annual Conference
2-3 June 2015
Brussels

More about the Plenary Sessions

***Flaminia Macchia**, Director for European Public Affairs, EURORDIS, speaking at EAPM's 2014 Conference 'Integrating Personalised Medicine into the EU Strategy'*

Plenary Session I

'State of Play' of ensuring better treatments for patients: Learning from Smaller Member States and Regions

More than ever, health is a key policy instrument for sustaining the EU's economic growth. Health has been a key driver of the recovery of the European economy since the crisis, with health a sizeable proportion of EU GDP.

Personalised medicine could transform healthcare, by tailoring solutions to individuals, delivering 'the right treatment to the right patient at the right time' – and helping to get more value from healthcare spending.

It will make use of new scientific understanding and new technologies to adapt prevention, diagnosis and treatment of disease to an individual's specific profile.

Personalised medicine is a tool to generate prosperity, stability and long-term quality of life for patients. However, regulation needs adapting, research needs encouragement, new approaches are needed in assessing the value of personalised medicines, and training of healthcare professionals and awareness among patients and the public need to be boosted. European health care systems will need to take a more sophisticated view of health care that goes beyond merely responding to acute episodes associated with single illnesses.

There is an urgent need for engagement of a wide range of stakeholders. The success of personalised medicine will depend on a shift in thinking across wide areas of healthcare, and a new form of multi-disciplinary engagement.

Plenary Session II

Medical Adaptive Pathways – Taking Steps Forward

With the current adaption of the EMA pilot project in Medicine's Adaptive Pathways to Patients (MAPPs) now live, and the IMI2 research plan under Horizon 2020 agreed with the Commission and EFPIA officially launched, MAPPs and its associated areas of applied research funding will be a major area of focus across the EU for the next five years.

While many of the tenets and philosophies of MAPPs are well known by industry, regulators, and patient groups who have been involved with the EMA and IMI2 discussions, there is still a broad lack of awareness of the implications and barriers to the implementation of MAPPs, particularly at Member State level.

The core barriers to be addressed are:

• Key Member State stakeholders must be aligned at the design phase of a 'MAPP' and agree on the evidence package for early approval and re-assessment

• There is a need for a better understanding of patients' and payers' willingness to operate with greater uncertainty driven by the release of needed therapies with less evidence at the initial launch

• IT infrastructure and processes to provide the necessary evidence base using real-world data do not exist in most of Europe

• Insight into the impact of MAPPs on the regulatory environment at Member State level, as well as deeper understanding of how payers and patients will need to collaborate in the future for assessing risk/benefit and quantifying value

• Understanding of the ability of MAPPs to better respond to the rapidly evolving science of personalised medicines, and the wishes of patients dealing with unmet medical needs

• Knowledge of the current IT gaps that exist across the EU to

implement MAPPs, and the next steps required to develop systems for medical data support and evaluation of real-world data.

Plenary Session III
Activating National Cancer Plans in the era of Personalised Medicine and strengthening their patient-orientation

Following the 2009 Commission Communication on *Action Against Cancer: European Partnership*, the majority of EU Member States have developed and published National Cancer Plans (NCPs) with the goal to collectively advance cancer control in Europe.

One approach is the improvement of patient information with regards to accessibility, reliability and quality, in order to further strengthen patient-orientation in cancer care and to achieve more personalised care. Yet, NCPs in Europe are characterised by stark differences in content and implementation status with only few Member States even starting to evaluate their first cancer plans.

Thus, the questions remain: What role does patient information play in NCPs? Have we unlocked the NCPs' full potential to drive forward stronger patient-orientation and more personalised medicine in Europe? What can we learn from each other?

Plenary Session IV
Overcoming Barriers to Access and Understanding Value: Patient Access to Innovative therapies

Personalised medicine promises to revolutionise healthcare and has the potential to substantially improve patient care and outcomes, while supporting efforts aiming at more efficient healthcare systems. However, patient access to innovative technology varies dramatically between EU Member States. Changes will be necessary in the way medicines are developed, regulated, assessed (HTA) and paid for.

It is necessary to make policymakers and payers realise that investing now in these advanced therapies and technologies as well as in adequate regulatory and payer decision making frameworks will be a key pre-requisite in terms of improved patient outcomes and more efficient health care systems.

Plenary Session V
Personalised medicine and a European Big Data-Driven economy – The Lighthouse Effect

Nobody likes getting sick. But when we do fall ill, it is vital that our doctors have access to the best information and diagnostic techniques available. Thankfully, emerging technologies, such as analytics tools for 'Big Data' can help health care professionals improve diagnoses and reshape the way medicine is practiced.

Using these data to first understand the cause of disease, the medical profession can then develop new drugs and therapies to find cures or treatments as well as other health interventions targeting the individual.

The personalised, individual approach requires advanced technologies and processes to collect, manage and analyse the information and, even more importantly, to contextualise it, integrate it, interpret it and provide rapid and precise decision support in a clinical and public health context.

Getting a 'Data Strategy for Personalised Medicine' right in Europe would yield multiple benefits. It would not only accelerate the development of more effective treatments and potentially help with the management of healthcare resources, it would also act as a foundation for private sector investment and EU jobs in R&D.

Plenary Session VI
Unlocking the value of Research to provide evidence and Education of Healthcare Professions to realize the benefits for today and tomorrow's discoveries

European researchers have been at the forefront of major scientific healthcare discoveries in areas such as cancer, cardiovascular disease, genetic disorders, and infectious disease. The undeniable challenge is how best to translate this knowledge and expertise into medical advances that improve outcomes and enhance wellbeing for European patients?

EAPM recognises that translational research is a key enabler of the European Union research effort and represents the conduit through which European discovery science can be converted into new diagnostics, treatments, products and approaches that benefit European citizens and society.

However, despite the significant advances that have been made, PM's undoubted potential can only be realised by a harmonised European research agenda that enables efficient and effective translation of scientific innovation, underpinning a practice-changing clinical advances Research Platform that maximises the impact of new and existing activities at European and national levels, thus ensuring the efficient translation of research promise into innovative PM care for European patients.

3rd EAPM Annual Conference
2-3 June 2015
Brussels

A selection of EAPM articles published in the media

By European Alliance for Personalised Medicine
Executive Director Denis Horgan

Personalised medicine: An unstoppable force for good

Patients are overwhelmingly in favour of the use of cutting-edge companion diagnostics that can tell them what diseases they have and may get in the future, and the best way to treat them, while payers and lawmakers are much more cautious when weighing cost against 'value'.

Companion diagnostics are complex but critical for the appropriate prescription of personalised therapies and help doctors and patients to select a treatment or even exclude a treatment and assist with the decision between several therapeutic strategies.

To understand 'value' one must first understand a product and consider what it can provide, weighed against cost and other considerations.

These in vitro diagnostic tests give vital information to a medical professional regarding the likelihood of a patient responding to, or benefiting from, a specific treatment.

There is a reason why the phrase "prevention is better than cure" is so well known – and personalised medicine goes a long way towards addressing this. EAPM believes that earlier diagnostics and earlier treatment has many benefits, among them fiscal, because while cost is a major issue – and there are key questions about the cost-effectiveness of new and even existing treatments – better diagnostics will ease the burden on healthcare systems and lead to a healthier and, thus, wealthier, Europe.

EAPM has continuously worked with its membership to examine various approaches to value assessment. It believes that the case for prevention as treatment – as well as treatment as prevention – is overwhelming in a Europe struggling to deal with the demands that an ageing population of 500 million is putting on health-care systems.

That's 500 million potential patients spread out across 28 Member States and personalised medicine - the innovative,

ground-breaking method of treating individuals is expanding quickly, impossible to halt and promises longer and better lives.

Properly implemented in healthcare systems it will also save money while encouraging investment on a pan-European scale. Among others, the pharmaceutical industry is a key partner. It sets out to produce medicines that do the job for which they were created while at the same time minimising side effects – often a tricky balance.

And while a one-size-fits-all model works in many instances – most of us get the desired results from over-the-counter painkillers, for example – there are other scenarios in which it does not and cannot. Pharma has to react to this, as well as the fact that rare diseases are being discovered regularly and future clinical trials will have to be carried out on much smaller, geographically spread groups.

When it comes to font-line treatment and prescribing drugs, phamacogenetics today can give a clinician additional information about the probability that individuals, with shared genetic characteristics will have a therapeutic response or develop side effects.

It offers the benefits of more effective and timely treatment. And it leads to better- targeted use of medicines, given that

only those patients most likely to benefit will be prescribed the medicine or treatment.

But personalised medicine is not only about giving the right treatment to the right patient at the right time; it's also about communication and empowering the patient. This allows the patient to be closely involved in any decisions about his or her health, whether it comes down to the right medicine with respect to their respective lifestyles or awareness regarding the possible, or definite, side-effects.

Essentially it covers much more than diagnosing and treating patients – however individually and effectively. The modern-day patient wants to be informed in a transparent, unpatronising and clear way about his or her options.

The European Alliance for Personalised Medicine believes that one of the best ways to achieve this is through investment in better education. This would give clinicians the proper tools to treat and inform their patients and give professionals a better understanding of their patients' needs.

But it is also about collaboration and the uses of so-called Big Data – in the lab and beyond. In the past ten years, cutting-edge gene sequencing alongside information and communications technology has changed the way biologists and geneticists go about their science. The data produced requires sophisticated computational skills to be analysed. And, while bioinformatics is now a well-developed discipline, a new set of skills is required to navigate the masses of data generated.

It is clear that more collaboration between the ICT and life science industries is required to create solutions that biologists and scientists can use. It is vital, also, that front-line clinicians give feedback to researchers and others working in the pharma sector and this needs to be at a much greater level than is currently the case.

In this Big Data era, it is a fact that personalised medicine will deliver its benefits through greater involvement of patients in treatment decision-making and health management. Clearly, healthcare professionals and those in all other sectors – including manufacturers – cannot be expected to adapt to new ways of approaching patients and cutting-edge technologies without working together.

Meanwhile, for the patients, it's all about access. Access to treatment and medicines, access to clinical trials, access to more (and clearer) information, access to decision-makers and legislators for the chance to get their voices heard and their needs understood.

The modern-day patient wants to be involved in co-decision, to own – and have unreserved access to – their own medical data. And they are more than capable of being able to ask questions, even challenge and be actively involved in decisions about their condition, taking into account their own circumstances and lifestyle.

Meanwhile, doctors are expected to make decisions based on the best available evidence regarding the relative costs and benefits of the various treatments – assuming they actually know about them and understand them.

3rd EAPM Annual Conference 2-3 June 2015 Brussels

But it is vital that they take the patient's views into account. In a world in which patients' decision making is increasingly being influenced by information available online it remains the case that a doctor is a trusted source of knowledge and advice, and the latter must take into account the person who knows more about his or her own lifestyle than anyone else – the patient.

Communication between all stakeholders in the arena of health helps to empower our doctors and nurses who will then have a greater ability to empower their patients, in order to help them to make more effective choices.

For example, a clear understanding of patients' sensitivity to benefit versus risk information and building a meaningful interaction from it is hugely important.

In the main, conventional medicines need to rely on a patient being appropriately informed if they are to be used safely and effectively. Patients need to know how to take their medicines, when and how often, as well as being able to recognise any side effects. This is also the case when it comes to personalised medicines, but the need to understand the special nature of them gives it an added importance.

Patients need to fully comprehend the likelihood of benefit or harm, while effective and understandable information about medicines is a pre-requisite in what should be a partnership in medicine taking – which sees the patient and professional coming to an agreement about their medicines.

Verbal information tends to be patients' prefered method but written information is without question an important back-up. Ideally, the two methods should be complementary and act in tandem.

Adherence, of course, has always been and remains a problem. But it is a two-way problem and not just the fault of the patient. Yes, these days there are wearables and 'smart' pill-boxes to remind the patient in the home about sticking to his or her medicines regime but this is often not enough – patients also need to be supported through effective knowledge transfer.

Things are changing fast. The cost of full genetic sequencing has plummeted in recent times and is now less than 1,000 euro. The option of using genetics to stratify medicines is becoming better known by the day. The cat is out of the bag and will not be put back in.

Therefore, it is incumbent upon all stakeholders – whether they be clinicians, researchers, academics, regulators, patients themselves, payers and, of course, industry – to realise that much more cross-disciplinary dialogue and collaboration is vital.

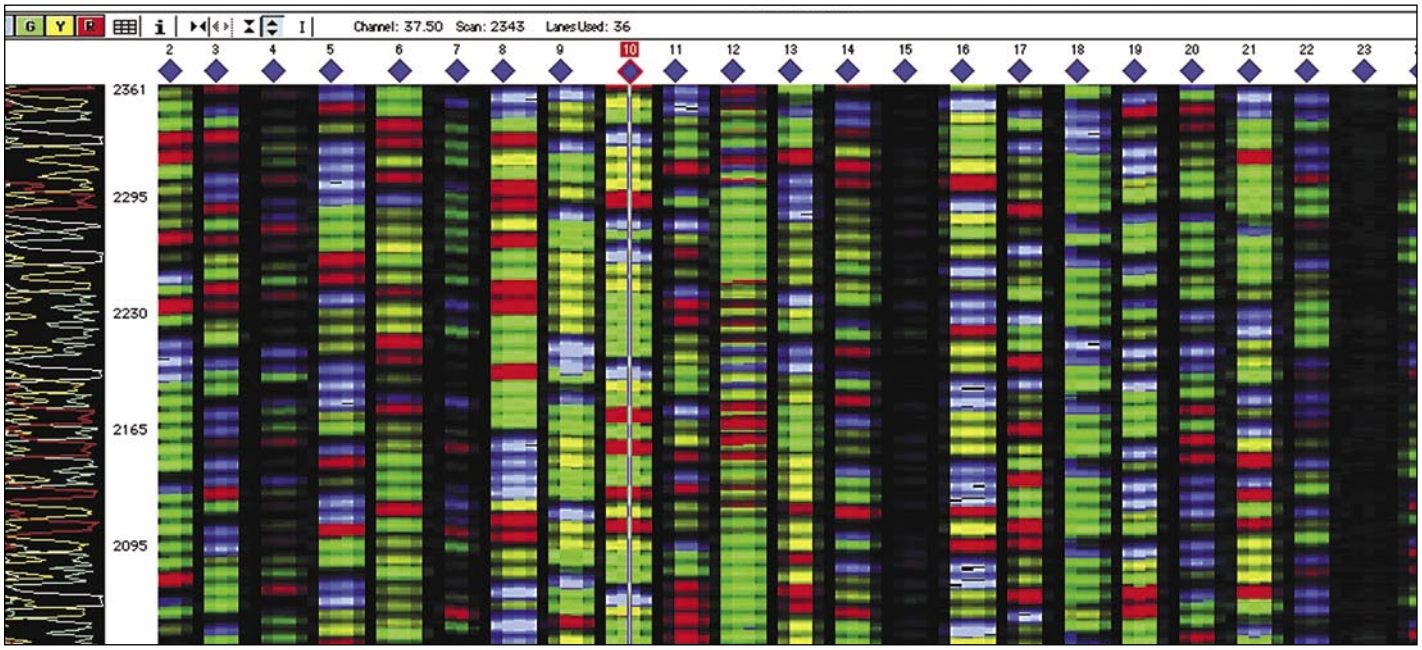
This will result in a better understanding of each other's discipline and allow more effective, modern-day synergies to be developed – for the benefit of Europe's patients not only in this generation, but for many more to come.

Why the EU's health programme needs a reboot

Recent weeks have seen the European Commission's health strategy come in for considerable criticism in sections of the Brussels-based media, from stakeholders in the health arena, and even from the Commission's own staff.

Some have argued that, actually, there's no real strategy at all and, even if there is, that its implementation currently leaves a great deal to be desired.

For example, some officials in the Commission's health unit have reportedly said that legislation is being held up by slow



decision-making from the EU Executive's Vice President in charge of Better Regulation, Frans Timmermans. The result has been a delay in publication of numerous reports related to health and consumer issues, they say.

Other officials deny that this is the case but the grumbles continue to rumble. There are, of course, many challenges in terms of health today. These include issues posed by demography and Europe's ageing population, patients' lifestyles, inequalities, the question of how to properly apply exciting new genetics-based science, plus the need for investment in R&D and to bring regulatory systems up to date.

While the Commission, Parliament and Council have combined in recent years to move legislation along while taking on board the views of various stakeholders – most notably patients – many big issues remain, not least within the Commission's own infrastructure at the present time.

The European Medicines Agency currently has no boss, due to a recruitment error, while the same applies to the European Centre for Disease Control. Meanwhile, the Commission has had no director-general for health for more than six months, and the Innovative Medicines Initiative (IMI) has an interim head (speaking at this conference, in fact). This is hardly a perfect environment in which this relatively new Commission can pursue an agenda.

On the upside, progress has been made in recent times in the vital areas of the Clinical Trials Directive, Data Protection Regulation, Big Data issues, Horizon 2020, IMI I and II and the legislation on In Vitro Diagnostics. Elsewhere, the Commission's new Semester process could potentially aid healthcare systems if used wisely and in a forward-thinking manner.

Against this backdrop, EAPM believes that the true potential of personalised medicine needs to be fully realised and, among other things, cooperation among Member States in areas such as Big Data, research, sharing of best-practice, education for healthcare professionals, tackling pricing issues when it comes to medicines, and more, needs to be stepped up dramatically for this to occur.

One problem, of course, is that individual countries' health budgets are not an EU competence and member states closely guard their right to self-administration in this regard.

This may help them, but EAPM maintains that this very often does not help the most important people – the patients. Millions of them.

However, in a recent move regarding expensive orphan drugs that treat rare diseases, the Belgium and Netherlands health ministries joined forces to negotiate prices with pharma companies, to try to exploit economies of scale. There is also a chance of a third smaller nation joining the scheme.

Most price deals for new medicines are struck between a company and a single Member State, and it will be interesting to see how successful this new partnership is in negotiating terms that save money and, in the end, benefit patients.

3rd EAPM Annual Conference 2-3 June 2015 Brussels

As it happens, the Netherlands will take over the rotating presidency of the European Union on 1 January next year, and plans to focus on European cooperation on drug prices. Another key element of the presidency, the Dutch have said, will be a drive to bring innovative medicines to the market faster - a shot in the arm for advocates of personalised medicine across its broad stakeholder base.

EAPM believes that initiatives such as that of the Netherlands and Belgium offer a good example of the type of co-operation necessary to improve the lives of our citizens and that, crucially, the Commission must do all in its power to facilitate and encourage the breaking down of silo mentalities in the health arena – within stakeholder groups and within Member States.

One way to start would be by setting out a clear, long-term health agenda and quickly appointing the right people to carry it through.

Time to 'STAMP' out lack of access to new treatments

More and more patients' groups and individual citizens are becoming aware of the potential of personalised medicine, with its ability to give them the right treatment at the right time.

They want empowerment, they want to have their illnesses and the treatment options explained in a transparent, understandable manner (from a clinician with up-to-date knowledge) to allow them to become involved in co-decision, and, crucially, they want greater access to treatments that could improve their lives and, in some cases, save them.

In this 500 million citizen-strong EU with a population that will inevitably become ill at some stage, giving patients access to the best possible treatment available in Europe is a massive issue. Indeed, the importance of access to medicines and innovative treatments is undergoing particular scrutiny at the moment and is currently a big issue in the European institutions.

Representing the Latvian Presidency of the EU at a recent Parliamentary plenary session, Zanda Kalniņa-Lukaševica, President-in-Office of the Council, stated that "access for patients to medicines that efficiently treat illness is an important issue that must be addressed both at national and EU level".

"It involves several aspects", she added, "namely: availability – meaning that new medicines are developed or existing products are adapted; also accessibility – bringing the products to patients who need them. It is also about affordability – ensuring that patients, healthcare providers and governments can afford the products; and lastly, ensuring quality so that the medicinal products work as intended and are efficient and safe."

At the same plenary, MEP Cristian-Silviu Buşoi (who will speak at this conference) explained that despite the existence of innovative new drugs, new technologies and developments in medical science, many citizens are not able to access them, often due to high costs.

Other issues include overly bureaucratic reimbursement procedures and a lack of implementation of the Cross-Border Health Care directive.

Buşoi believes that EU policymakers should ensure that regulatory decisions on the value of innovative therapies are based on what matters most to patients, and ensure that they get access to innovative treatments following a centralised cost-benefit analysis by the European Medicines Agency.

Minister Kalniņa-Lukaševica highlighted the creation of the Expert Group on Safe and Timely Access to Medicines for

Patients, otherwise known as STAMP, which began its work in January with a second meeting taking place in May.

According to the Commission, the STAMP expert group has been set up to provide advice and expertise to Commission services in relation to the implementation of European Union pharmaceutical legislation, as well as programmes and policies in the field.

STAMP is intended to "exchange views and information about the experience of member states, examine national initiatives and identify ways to use more effectively the existing EU regulatory tools with the aim to further improve safe and timely access and availability of medicines for patients".

A further goal is to explore ways to increase information sharing and cooperation among Member States. The reality is that to introduce new medicines requires considerable investment and time. There is clearly a need for more modern and realistic approaches to reimbursement and agreement over the use of so-called Big Data for vital research purposes, bearing in mind that it is incumbent on European lawmakers to protect citizens from unwanted and unnecessary exploitation in this regard.

There is also an obvious need for all medicines, as well as in vitro diagnostic devices, to be proven to be safe and cost-effective if much-needed innovative and personalised medicines are to come onto the market.

The creation of a robust evidence base is vital for good decision making to ensure that resources are used for the maximum benefit of patients and this must take into account the views of different stakeholders as well as decision making in any given member state health system.

Payers clearly need to trust that any evidence base is solid before decisions are made.

There are many issues surrounding early, and timely, access and, during the first meeting of STAMP, several Member States gave presentations, including Belgium, France and Spain, offering their perspectives on how to improve it, especially in certain cases. The Belgian presentation highlighted the need to find a balance between addressing unmet medical need while providing complete information on benefits, risks and relative effectiveness.

There was also a focus put on new national legislation regarding early temporary authorisation (known as ETA) with a possible link towards early temporary reimbursement. In Belgium, there is leeway for the provision of medicinal products that are not yet authorised, to patients with a chronically or seriously debilitating disease or whose disease is considered to be life threatening, and who cannot be treated satisfactorily by an authorised medicinal product. This is enabled by 'Compassionate Use Programmes'.

Meanwhile, products authorised in Belgium (but not yet licensed for critical indication), or licensed but not commercially available yet, can be given to patients via Medical Need programmes.

3rd EAPM Annual Conference 2-3 June 2015 Brussels

Spain's presentation also covered Compassionate Use and its possible implementation in cases where patients would benefit from accessing the medicine and when any delay would mean a lost opportunity. Also, where no alternative is available, or where alternatives have been previously tried but failed.

Spain highlighted the use of Compassionate Use programmes in severe clinical situations, in a hospital setting only while not hindering medical research – as far as possible, a clinical trial should be considered.

France, meanwhile, highlighted the TAU scheme – Temporary Authorisation for Use – in the case of a drug fitting an unmet medical need, where there is no option for patient enrollment in clinical trials and where the drug is intended for treatment, prevention or diagnosis of a rare or serious disease with no satisfactory alternative available. So far, 240 drugs have been used for individual TAUs, with 20,000 patients currently under TAU programmes.

Of course, in all of the above circumstances the pricing is an issue and is being handled in differing ways. And it is plain to see that, currently, there is a huge difference in how healthcare systems handle funding across the EU. It's a massive issue and is being closely watched by advocates of, and stakeholders in, personalised medicine.

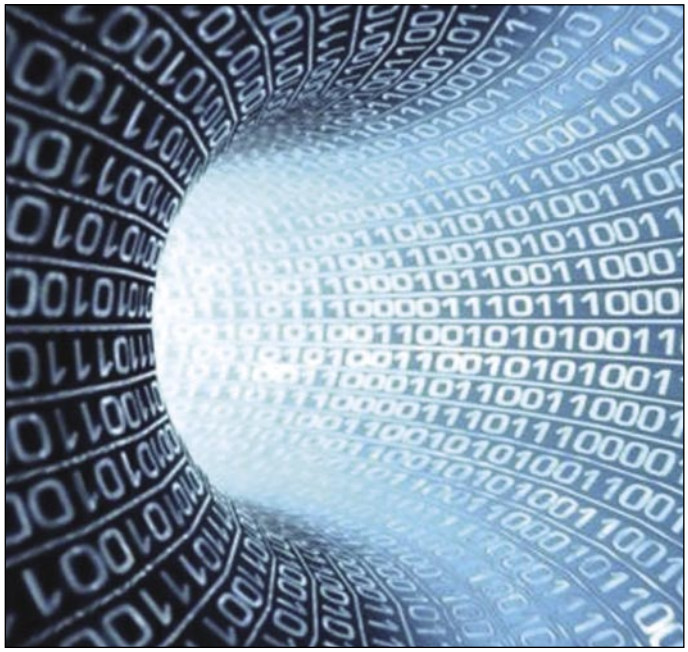
EAPM is a key player, and regularly meets with Members of the European Parliament and the Commission to discuss many of the goals of, and barriers to, personalised medicine.

As well as its Working Group on Early Access and Better Decision Making, it also hosts an MEPs' Interest Group. The Alliance has been in continuous dialogue with Members since its formation, on access and many other topics.

EAPM notes that among the basic tenets of the EU are equality and access to the best healthcare for all, regardless of who or where they are.

Yet it is clear that there are large organisational, fiscal, clinical, and practical barriers to the full introduction of personalised medicine into Europe's many and varied individual healthcare systems, and many more when it comes to implementing it on a pan-European scale.

The Alliance believes that what the European Commission needs to do, in tandem with the Parliament, is to create a



regulatory environment which allows early patient access to novel medicines and treatments – and to do this as soon as possible. A close scrutiny of, and changes to, the current system for incentives and reimbursement, right across Europe, may represent a very solid start.

Meanwhile, in an ideal world, the Commission's new initiative will leave its 'STAMP' for the benefit of all Europe's patients.

Data co-operatives: Giving BIG choices to the patient

'Big Data' is a huge area, especially in healthcare. We are sharing more personal data than ever before and this stored information will keep expanding and is certainly not going to go away.

Big Data can be used to drive innovation in translational research and health outcomes tailored to the individual – offering the potential to revolutionise the effectiveness of health interventions in what are increasingly cash-strapped public health-care systems.

Personal health data comes from a multitude of sources including individual patient records, clinical research

recruitment, biobanking and patient-generated information: all of these data are valuable in their own way.

Scientists need to be able to work with and test on large datasets. Of course, then there are questions about how best to link these results to clinically meaningful and actionable information, and how to create tailored responses to them. These factors represent further challenges.

Meanwhile, right now, these data are stored in 'silos' which may not just mean one hospital but even in different departments of the same hospital so that, while the data is useful on an individual level, its broader value is being under-utilised.

Another massive issue is the debate over a patient's right to own his or her data, and to be able to get to it whenever he or she wishes, as well as the moral and ethical concerns regarding Big Data's usage, sharing, storage and more. It's a practical, moral and ethical minefield.

However, one idea that is gaining popular support is the use of data co-operatives in which every patient and data donor controls when, where and how his or her data can be used.

When the medical benefits to themselves and for society in general are clearly explained, most patients are willing to share their data in a 'controlled' way that gives them the choices. One reason may well be the fact that nearly everyone knows, or will know, a friend or relative who has – for example – had a heart attack or has suffered from cancer., diabetes, blindness, obesity or mental illness.

There is no doubt that citizens need to be informed about the use made of their data, when they wish to be informed. However, when it comes to regulation, the legal obligation needs to be proportionate and advances in communication technology should be considered to bring together needs and realities of health research and privacy. Accountability should go hand-in-hand with flexibility for re-use of data.

The exciting new field of personalised medicine requires, in most instances, personalised data, and thus it is important to navigate the complex regulatory landscape of data protection and, in many instances, clarify the boundaries of what is and is not possible.

However, by ensuring the right regulatory frameworks that cover these issues, researchers would potentially be able to access millions of genetic markers. In turn this would accelerate science towards better understating of diseases in specific patients.

EAPM believes that is vital that any regulations should strike a balance between protection of the patient while not blocking vital research.

It should also create a framework in which these new data co-operatives are feasible and can operate properly, thus empowering the patient and giving him or her the choice of where sensitive data can be used and where any subsequent monies should go.

Health research is already conducted within a robust ethical

framework with strong safeguards supported by internationally recognised guidelines.

In most European countries, it is the mission of Ethical Committees to ensure that patient rights and privacy are respected. This ensures that an individual's data are only used in research when this is proportionate to the potential benefits for society as a whole.

Ethical Committees focus in particular on the nature and relevance of patient consent, broad or specific, explicit or "opt-out" or any eventual exemption from these as applicable to the precise project they review.

Also, it is a fact that modern healthcare is based on evidence and this evidence comes from data. The processing of personal data is vital for clinical trials and observational research performed in industry and academia.

It is fair to say that the EU has been at the forefront of innovative research that has improved understanding of the causes of disease and led to the discovery and development of new treatments and diagnostics.

EAPM believes that this must continue – and data co-operatives may well be one fundamental way to help this happen.

Juncker's subsidiarity goals must take health into account

The European Commission, led by Jean-Claude Juncker, stated very early on that the principle of subsidiarity will be a cornerstone of this administration.

Subsidiarity – meaning, in this case, that the EU will only perform those tasks which cannot be performed at a more local level – is nothing new, of course, and has been a tenet of the European Union for some years, being widely welcomed.

In a statement to the European Parliament, Juncker said: "My agenda will focus on ten policy areas. My emphasis will be on concrete results in these ten areas. Beyond that, I will leave other policy areas to the Member States where they are more legitimate and better equipped to give effective policy responses at national, regional or local level."

"I want a European Union that is bigger and more ambitious on big things, and smaller and more modest on small things," the Commission president added.

He went on to say that: "Not every problem that exists in Europe is a problem for the European Union. We must take care of the big issues."

EAPM would argue that health is among the biggest issues facing the EU today and into the forseeable future – and that subsidiarity, by itself, has failed to address many health issues arising down the years.

These have included, and still include, inequalities in access to a high standard of treatment for patients in different countries and regions, as well as similar issues affecting citizens' abilty to take part in clinical trials.

It is absolutely clear that individual countries cannot tackle the enormous health problems thrown up by an ageing population individually. There are too many differences in resources per Member State (and variations even within regions), differing population sizes, access issues and often huge differences in the standards of health care available.

On a positive note, these wide variations in terms of cost and outcomes in health offer hope for substantial efficiency gains.

It is interesting to note that, despite the subsidiarity principles, Europe's courts have intervened in areas such as determining the right to cross-border healthcare for all citizens. Such rulings have had the effect of side-stepping a lack of legal competence over health that the EU enjoys elsewhere. In short, there has been a growing influence over the years from the ECJ and other European courts.

Meanwhile, there has been a large amount of change and influence brought about by the impact of guidelines and recommendations in various arenas. With regard to health, these have led to a great deal of self regulation by medical societies and other organisations.

In health research, for example, we have seen many instances of self governance in areas covering such issues as the sharing of data and the ongoing exchange of best practice.

The above does not break the subsidiarity rule, nor do pan-EU regulations such as those affecting in vitro diagnostics (IVDs), public health and the internal market. These regulations have undoubtedly made Europe a safer and better place for its citizens and could be taken as an argument for more EU, rather than less.

Regarding IVDs, the current Medical Devices Directives were adopted under Treaty laws covering the establishment and functioning of the internal market. These have been complemented by laws that set high standards for the quality and safety of devices for medical use.

Rules such as these, protecting public health across all Member States, can only be employed at European Union level. This stops individual states from adopting different product regulations which would fragment the internal market and the knock-on health benefits to EU citizens are clear.

Such rules also allow manufacturers to reduce costs related to national regulatory differences, while ensuring a high and equal level of safety throughout Member States. Subsidiarity alone, in these instances, would not do this.

Generally speaking, the EU has always had a patchwork of healthcare systems but, as a result of the financial crisis, a shift has been occuring that affects – in a surprisingly direct manner – these systems and other issues.

To ensure that EU countries reach their Europe 2020 targets, the Commission has set up a yearly cycle of economic policy coordination called the European Semester. Every year, now, the Commission gives recommendations on member states' programmes of economic and structural reforms for the following year.

European countries' large healthcare expenditures mean that individual health care systems are more than likely targets for such reforms. So the EU's influence is clearly growing when it comes to the costs and sustainability of its Member States' health systems.

On top of this, as part of the financial crisis bailouts involving Ireland, Greece and Portugal, these countries had to agree economic adjustment programmes, including detailed changes to their health systems.

Bailouts aside, all EU countries are under great pressure to ensure cost effectiveness of their health systems. The times they are a-changing...

The EU cannot regulate everything, nor should it. But EAPM believes that for subsidiarity to work in an arena as diverse, complex and important as health, it is vital that there is much more cooperation between Member States, cross-border alliances, interaction between disciplines and more.

This is a prerequisite if we are to create a broad and effective 'virtual EU health system' that satisfies the needs of all citizens across Europe.

In the end, much as it is to be welcomed, subsidiarity does

not come without its issues – especially in a 28-Member State union, and especially in huge areas such as health. Finding the right balance is key, and inter-state cooperation at national level, where EU law does not and perhaps will not exist, is vital.

Investment in health: A proven driver of growth

Very early in his mandate, European Commission President Jean-Claude Juncker unveiled his 'Investment Plan for Europe', telling MEPs: "Europe needs a kick-start."

Describing the plan as "ambitious, yet realistic", Juncker revealed that the new European Fund for Strategic Investments is set to launch in mid-2015 and run for three years.

Much of Juncker's touted figure of €315 billion will, according to the president, be made up of private investment (a wished-for €252bn) with the rest "guaranteed with public money from the EU budget and the European Investment Bank."

Some economists criticised the plan, saying that the sum – while sounding impressive – is insufficient to revive an EU economy whose eurozone growth rate sits below 1%, whose unemployment level is more than 11% and whose entire economy is teetering close to deflation.

Juncker himself conceded during his speech to MEPs that investment levels are down to €370 billion below "pre-crisis norms", a situation he blamed on investors lacking confidence and trust in the 28-country bloc's economy.

The Commission chief added that the EU's "debt levels have increased from 60% of GDP to 90% in the space of just a few years". Clearly, then, Europe does need that kick-start – and quickly too.

Whether €315bn, even if generated, is enough remains to be seen. But regardless of the amount, where should the new investment be targeted to get the best value, not only for the economy in general, but also for the EU's citizens?

Juncker told the parliament that he has: "a vision of a hospital in Florence saving lives with state-of-the-art medical equipment". Of course, he didn't only mean Florence, but hospitals all over Europe, and there he hits the nail on the head.

EAPM believes that the healthcare sector, and in particular the innovative research, treatments, data streams, new education and unprecedented collaborations that come with personalised medicine, can be a prime driver of the EU's economy and help to unlock much-needed investment that is currently lacking.

But why health and personalised medicine? Well, we all know that Europe has an ageing population and, at any one time, millions are ill to some degree or another. One of the EU's basic tenets, that of equality, has not been achieved when it comes to patients gaining access to existing best treatments, or even advice, equally across the Union.

Scientific advances continue, leading to better treatments and medicines being developed all the time. Add to this the advances in genomic science, a major factor in personalised medicine and individually targeted treatments, and it is clear that the possibilities for a healthier Europe exist.

The sector is ripe for new investment.

If the Commission needs convincing, it should make no mistake about the correlation between wealth and health. Studies – at least one conducted on behalf of the EU executive itself – have repeatedly shown that the benefits of improved

public health extend beyond simply reducing healthcare costs.

Thetruth is that better health – in both richer and poorer countries, as it turns out – makes a positive contribution to the productivity of citizens.

Add to this the facts that less hospital beds are used up, people tend to work longer before retiring when they are healthier, citizens are more productive when healthy and often work longer hours, there are less sick days taken, and we already have clear and concrete reasons why better health can contribute substantially to economic growth.

On top of this, consistent evidence from richer countries has shown that healthier people have higher earnings and, even, that they are more likely to be employed, with less healthy citizens often overlooked in the jobs market

Also, when viewed historically, there is no doubting the importance of investment in better health as a way to promote economic growth.

Of course, the difference in poorer countries is more substantial – due to sudden availability of previously unaffordable basic drugs, and so on – but, still, it is a fact that the economic wealth of even the richer member states owes a great deal to improvements in health down the decades.

In the UK, for example, from 1790 to 1980 some 30% of economic growth is thought to be directly related to better health and diet. Elsewhere, a study in 10 industrialised countries over the hundred years up to the mid-1990s found that better health increased the rate of economic growth by almost one third.

One third. Imagine. How Mr Juncker and all of us could do with that today.

EAPM and its broad range of stakeholders has always maintained, and continues to do so, that solid and sustained investment in health and the new technologies inherent in the provision of personalised medicine will help to create an environment in which healthy countries attract new money, promote growth and, vitally important, get the right treatment to the right patient at the right time, to keep medical costs down, productivity up and the standard of health care as good as it can be for all.

On that note, EAPM urges President Juncker and his team to work tirelessly towards creating an environment in which potential investors feel confident in, among other things, regulatory frameworks, the quality of research, talented innovators and tomorrow's growing EU economy.

We need these investors to put their much-valued time, expertise and, yes, cash into building a healthy and wealthy continent, now and into the future. Put simply, better health for all means more productivity and an increase in growth, quite aside from the Union's custodians' moral and ethical obligations to care for the EU's population in the best way possible.

Throughout 2015, with its ongoing STEPs campaign and many other initiatives, EAPM will continue its drive to help deliver the best standards of health care to all citizens of the EU, now and for generations to come.

STEPs

European Alliance for Personalised Medicine


Alliance for
ed Medicine


an Alliance for
lised Medicine


SIEPs
Specialised Treatment for Europe's Patients
Why Personalised Medicine adds Value to EU Healthcare
SIEPs
Specialised Treatment for Europe's Patients


SIEPs
Specialised
Treatment
for Europe's
TOSHIBA


SIEPs
Specialised
Treatment

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Speaker biographies

Solvita Zvidriņa
Republic of Latvia Secretary of State for Health

Solvita Zvidriņa is the Republic of Latvia's State Secretary at the Ministry of Health, a position she has held since late 2014.

Solvita attended the Riga Technical University Faculty of Engineering Business Management from 1993-1995, as well as its Faculty of Engineering Construction Economics and Management prior to that.

In 1996, she also spent time at the University of Halifax in Canada.

Workwise, she has spent time at both Latvia's Ministry of Culture and the Ministry of Finance. At the latter, she was at one time Deputy State Secretary with responsibility for budget issues. As well as her native Latvian,

Solvita speaks English, Russian and is learning French.

Lydia Mutsch
Luxembourg Minister for Health

Lydia Mutsch was born in 1961 in Dudelange and, after attending secondary school at the Lycée Hubert Clément in Esch-sur-Alzette, she studied political and social sciences at the University of Göttingen, Germany, graduating in 1985.

Following the legislative elections of 2013, Lydia joined the government as Minister of Health and Minister for Equal Opportunities. Other political posts saw her as a municipal councillor in Esch-sur-Alzette in 1988 and, in 2000, she was appointed mayor, an office she held until her appointment to the government. Lydia was elected to Parliament for the first time in 1989 at the age of 27 and was re-elected in 1994, 1999, 2004, 2009 and 2013, assuming the role of vice-president of Parliament.

During her time in Parliament she has, among other roles, been chairwoman of the Committee for Health and Social Security.

Christopher Fearne
Parliamentary Secretary of Health, Malta

The Hon. Christopher Fearne was born in Attard, Malta in 1963. Prior to his appointment as Parliamentary Secretary for Health in April 2014 he worked as a Consultant Paediatric Surgeon and Clinical Chairman at Mater Dei Hospital. He is a Member of Parliament for the ruling Labour Party and was Chairman of the Foreign and European Affairs Committee at the Maltese House of Representatives.

Christopher has worked as a doctor and surgeon for the last 27 years. He received his formal education at St. Aloysius College and at the University of Malta graduating in Medicine and Surgery in 1987, becoming a Fellow of The Royal College of Surgeons of Edinburgh. Fearne is a founding director of the Malta Institute for Medical Education and the chairperson of the Celebrities for Kids, voluntary NGO promoting children's rights. He has served as Secretary General of the Maltese Federation of Youth Organisations, officer within the University Students' Council, KSU, and in the Malta Medical Students' Association, MMSA.

Andrey Kovatchev
Member of the European Parliament

As a Member of the European Parliament, Andrey serves on the Committee on the Environment, Public Health and Food Safety. He was born in 1967 in Sofia and gained a PhD from the University of Saarland, Germany. He has been Deputy Chairman Foreign Policy and European Affairs Commission, Regional Director for Central and Eastern Europe, Elsevier BV, Amsterdam, Territory Manager for Ukraine, Kazakhstan, Byelorussia, Russia for John Deere International GmbH and Sales Director for Bulgaria at the Tetra Laval Group in Hamburg. Andrey has been an MEP since 2009.

Nessa Childers
Member of the European Parliament

In 1987 Nessa graduated from Trinity College Dublin with an Arts and Psychology degree, and two years later received a postgraduate diploma in Psychotherapy from University College Dublin.

During her time in Trinity she was Registrar of the University Philosophical Society. She established a private practice as a psychoanalyst in 1986 and worked as a self-employed person for more than twenty years. In 1993, along with colleagues, she established the MSc course in Psychoanalytic Psychotherapy at Trinity College, and between 2001 and 2006 was course director. Nessa also served on the board of the Office of Tobacco Control from 2006- 2008 and was elected to the European Parliament in 2009.

Vicky Ford
Member of the European Parliament

Vicky Ford was elected a Member of the European Parliament in 2009. She is the Chairman of the Internal Market and Consumer Protection Committee.

She was previously the Conservative Spokesman for Industry and Research on the Parliament's ITRE committee and sat on the Economic and Monetary Affairs Committee where she was also Conservative Spokesman from 2009-2011.

Vicky was born and grew up in Northern Ireland. Her parents were both English doctors. She read Maths and Economics at Trinity College, Cambridge, where she met her husband Hugo, who is a cancer consultant at Addenbrookes Hospital.

Before becoming an MEP Vicky was a local councillor. Prior to that, she was a managing director of a major international bank. Most of her 14-year career in banking from 1989 to 2003 was with JP Morgan. She worked with many of Europe's largest companies as well as advising national governments and central banks.

Marian Harkin
Member of the European Parliament

Marian is a member of the Committee on Employment and Social Affairs and Delegation for relations with the United States. She is a substitute for the Committee on Economic and Monetary Affairs, Committee on Petitions and Delegation for relations with Australia and New Zealand.

Marian is Chair and founding member of the Carers Interest Group and the Volunteering Interest Group, and is also Vice Chair of the Cervical Cancer Group, Mental Health Group, Epilepsy Support Group, Human Dignity Working Group and Complementary and Alternative Medicine Group. Marian is also a member of the MEP Heart Group, LGBT Intergroup and MEPs against Cancer Group.

In 2011, in the MEP of the Year Awards, Marian won the 'Outstanding Achievement Award' in recognition of her work in promoting the interests of volunteers and volunteering in the European Union. A year later, she won the MEP of the Year award for her work in the area of Employment and Social Affairs.

Speaker biographies

in promoting the interests of volunteers and volunteering in the European Union. A year later, she won the MEP of the Year award for her work in the area of Employment and Social Affairs.

Philippe De Backer
Member of the European Parliament

Philippe holds a PhD in biotechnology from Ghent University and an MBA from Solvay Business School. Before joining the European Parliament, he worked as Technology Transfer Officer at CRP-Santé and as an analyst at Vesalius Biocapital, a Luxembourg based venture capital firm specialising in the life-sciences. He has expertise in the valorisation of IP developed by public research institutes and setting up early ventures in the life-sciences.

In the European Parliament, Philippe is a member of the Industry, Research and Energy Committee and Delegation for relations with the People's Republic of China. He is also a substitute for the Commitee on Economic and Monetary Affairs and Delegation for relations with the countries of Southeast Asia and the Association of Southeast Asian Nations.

Sirpa Pietikainen
Member of the European Parliament

Sirpa Pietikainen is a member of the Committee on Economic and Monetary Affairs and Delegation for relations with the People's Republic of China. She is a substitute for the Committee on the Environment, Public Health and Food Safety, Committee on Women's Rights and Gender Equality and Delegation to the ACP-EU Joint Parliamentary Assembly.

Born in 1959, in Hämeenlinna, she has a Master of Science in Economics and Business Administration, from Helsinki School of Economics and has been an instructor and lecturer of negotiation theories at the same institution, and the University of Joensuu. Sirpa sat on Hämeenlinna town council (1981-1992), was a Member of the Executive, Regional Council of Häme (1991-1992), a Member of the Finnish Parliament from 1983-2003 and an Elector for the Finnish President in 1988.

Since then, she has held the posts of Minister of Environment (1991-1995), Vice-Chairman of Kokoomus (1989-1995), Chairman of the programme committee, Kokoomus (1989-1995), Chairman of the Working Party on an Ecologically and Socially Sound Market Economy, EDU (1989-1992) and Chairman of the Finnish UN Association (1996-2007).

From 2000-2005, Sirpa was Chairman of the World Federation of United Nations Associations, and is curerently a Member of the boards of the IDEA International Institute for Democracy and Kone Oy (2006-). She has been an MEP since 2008.

Kay Swinburne
Member of the European Parliament

Kay was born and raised in Wales. She studied Biochemistry and Microbiology at King's College London, and gained a Ph.D. in medical research and an MBA from the University of Surrey.

Kay was elected as the Conservative MEP for Wales in June 2009. A successful career in investment banking has equipped her with in-depth knowledge of the global financial markets. This, combined with her experience advising businesses in Europe and the US, has led to her appointment on the Economics and Monetary Affairs Committee in the European Parliament.

Kay is a member of the Committee on Economic and Monetary Affairs and Delegation for relations with Switzerland and Norway as well as the EU-Iceland Joint Parliamentary Committee and the European Economic Area (EEA) Joint Parliamentary Committee. She is a substitute for the Committee on the Environment, Public Health and Food Safety.

Elisabetta Gardini
Member of the European Parliament

Elisabetta is a member of the Committee on the Environment, Public Health and Food Safety, the Delegation for relations with Mercosur and the Delegation to the Euro-Latin Amercian Parliamentary Assembly. She is a substitute for the Committee on the Internal Market and Consumer Protection, Committee on Petitions and Delegation for relations with the United States.

Born in 1956, she has been a theatre and TV actress and RAI TV presenter in her native Italy as well as a theatre producer. From 2004-2008, she was National spokesman for Forza Italia and has also been its deputy group leader. Elisabetta was elected to the European Parliament in 2008.

Cristian-Silviu Busoi
Member of the European Parliament

Cristian-Silviu Busoi was born in Drobeta Turnu Severin, a city in the south-western part of Romania, and has been a member of the European Parliament since 2007.

He is currently a member of the Committee on the Environment, Public Health and Food Safety, Delegation to the EU-Ukraine Parliamentary Coorperation Committee and Delegation to the Euronest Parliamentary Assembly.

Prior to this, he was a member of the Romanian Parliament from 2004 to 2007, where he was part of the Health and Family Committee. He was a member of the National Liberal Party for more than 15 years.

Cristian-Silviu graduated from the Carol Davila University of Medicine and Pharmacy in Bucharest, Carol I National Defence College, and the Law School of Titu Maiorescu University. In 2010 he obtained a Ph.D in Public Health and Health Management from the University of Medicine and Pharmacy Victor Babes Timisoara.
Government to the Board of the Karolinska Institute.

Antoni Montserrat Moliner
Policy Officer for Cancer and Rare Diseases, Directorate of Public Health (DG SANTE)

Antoni Montserrat Moliner (born in Barcelona) works at the Directorate of Public Health in the European Commission.

He is policy officer for rare diseases, neurological and neurodevelopmental disorders, health surveys and management of the European Health Information System.

Antoni has been working at the European Commission since 1986 after studying Economy and Statistics at the University of Barcelona where he specialised in health information systems.

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Speaker biographies

David Byrne
EAPM Co-Chair

David Byrne began his career as a barrister in Ireland in 1970, became Attorney General of Ireland in 1997, and was appointed the first European Commissioner for Health and Consumer Protection in 1999.

As Commissioner, David's responsibilities included policy development and bringing forward legislation to the European Parliament and the Council of Ministers. He maintained a particular interest in tobacco control and was responsible for the drafting and enactment of legislation in Europe banning cross border advertising and sponsorship of tobacco products.

His other responsibilities included the pan-European response to health threats and the food crises arising from BSE and Foot and Mouth disease; development and implementation of a new EU Health Strategy and Programme; development of the strategy on bio-terrorism; the formation of agreements with the trading partners of the European Union; regulation of GMOs in the EU; and promotion of consumer confidence in e-commerce and cross-border trade.

Helmut Brand
EAPM Co-Chair

Helmut is Jean Monnet Professor of European Public Health and head of the Department of International Health at Maastricht University, The Netherlands. He studied Medicine in Düsseldorf and Zürich and earned a Master in Community Medicine from the London School of Hygiene and Tropical Medicine and London School of Economics. He specialises in Public Health Medicine with European Integration in Health as his main topic of work.

Helmut is president of the European Health Forum Gastein and past-president of the Association of Schools of Public Health in the European region. As a policy advisor he serves on the European Advisory Committee on Health Research of WHO Europe and on the Expert Panel on 'Investing in Health' for the European Commission.

Maria da Graça Carvalho
Senior Advisor in the Cabinet of the Commissioner for Research, Science and Innovation

A former MEP, Maria was elected to the European Parliament in 2009 and has served as a member of the ITRE-Industry, Research and Energy Committee, substitute member of the Budgets Committee and member of the ACP-UE Joint Parliamentary Assembly.

She was elected co-President of the Economic Development, Finance and Trade Committee of ACP-UE Joint Parliamentary Assembly and was Principal Adviser to former Commission President Barroso in the areas of Science, Higher Education, Innovation, Research Policy, Energy, Environment and Climate Change, from 2006 to 2009.

She is a Full Professor at theTechnical University of Lisbon and has 30 years of research experience in the areas of energy, environment and climate change. Maria has also been Minister of Science and Higher Education and Minister of Science, Innovation and Higher Education in her native Portugal.

She was decorated by the President of Portugal with the designation 'Great Official of the Order of Public Instruction' within the scope of International Women Day Programme (2002) and by the Chancellery of the International Order of Merit of the Discoverer of Brazil with the high honour of the Great Cross (2005).

Sabine Juelicher
Head of Unit Medicinal Products authorisation, European Commission

Sabine holds a veterinary degree from the Free University Berlin and has a postgraduate qualification in food hygiene. She initially worked in research and later moved to public administration, working both at national and international level. Sabine joined the European Commission in 1999, working in the area of food safety before taking

up management functions. She has been Head of Unit in the Health and Consumers Directorate-General since 2008 and is currently in charge of unit D5 - medicinal products, authorisations and EMA.

Fernand Sauer
Member of the French Academy of Pharmacy

Fernand Sauer, now a member of the French Academy of Pharmacy, retired from the European Commission in 2006 as an a Honorary Director General and continues to advise European Institutions and Agencies on health matters, pharmaceutical policy and research.

He advises the University of Maastricht on the European Public Health Masters' programme and is a member of the scientific committees of Sciences-Po Santé and of the Institute of Health Law (Paris V).

Fernand qualified in pharmacy at the University of Strasbourg. He subsequently received a masters in European and International Law from the University of Paris II and various post-graduate diplomas in public health, pharmaceutical legislation and European studies. From 1972 to 1979 he held various positions in France as a hospital pharmacist and pharmaceutical inspector at the Ministry of Health.

In 1979 Fernand joined the Commission in Brussels becoming Head of Pharmaceuticals in 1986. He was involved in the completion of the European internal market for pharmaceuticals, the accession of the Community to the European Pharmacopoeia Convention and the development of pricing transparency and industrial policy in the sector.

He played a key role in launching the trilateral harmonisation of regulatory requirements between Europe, the US and Japan and in fostering close co-operation between European regulatory authorities and the US Food and drug Administration.
He created the European Agency for Medicinal Products and became its first Executive Director in London from 1994-2000. He put in place a fast, effective and transparent scientific evaluation sytem for innovative medicines (human and veterinary use) and "orphan dugs" for rare diseases.

Fernand contributed to better patient information, stronger pharmacovigilance systems and sound scientific advice for pharmaceutical R&D in Europe. And, as director for public health in the European Commission, he was until responsible for the first European public health programme (2003-2007), for health measures relating to the quality and safety of blood, tissues and cells and for tobacco control.

He contributed to strengthening surveillance and response to threats from communicable diseases and bioterrorism and also participated in the creation of the new European Centre for Disease Prevention and Control in Stockholm in 2005, and in the revision of the WHO International Health Regulation.

Fernand launched the EU Health Forum composed of fifty non-governmental organisations to promote health in all relevant European policies. He has provided independent expertise for European research activities: impact assessment of the Innovative Medicines Initiative, two evaluation reports of the European and Developing Countries Clinical Trials Partnership Programme on AIDS, TB and Malaria, and on the Future of European Public Health Research.

Among his honours are the Chevalier de l'Ordre national du mérite, Chevalier de la Légion d'honneur and becoming an Honorary Fellow of the Royal Pharmaceutical Society of Great Britain.

Jillian Odenkirk
Senior Analyst, Organisation for Economic Cooperation and Development

Jillian Oderkirk is a Senior Economist and Policy Analyst at the Health Division of the Organisation for Economic Co-operation and Development (OECD) in Paris, France.

Speaker biographies

She leads a project on developing health information infrastructure including the development of electronic health record systems; the use of personal health data for health system performance monitoring and research; and the privacy and data protection challenges associated with the secondary use of data.

Jillian also leads efforts to model health systems within the OECD, including the development of decision-support platforms and health expenditure forecasting methods.

Prior to joining the OECD, she had a long career with Statistics Canada in Ottawa, and was the Director of the Health Analysis Division there from 2006 to 2011. Jillian Oderkirk has a Master's Degree in economics from McMaster University, Hamilton, Canada.

Gordon McVie
EAPM Board Member & European Institute of Oncology

Professor Gordon McVie is a leading international authority in the research and treatment of cancer. He qualified in the 1960s in science and medicine at Edinburgh University, was appointed Foundation Senior Lecturer at the Cancer Research Campaign oncology unit at the University of Glasgow in 1975, trained in the US and spent sabbaticals in Paris, Sydney and Amsterdam.

He is currently Senior Consultant to the European Institute of Oncology, Milan, and is founding editor of ecancer.org and ecancerpatient.org - online Open Access free websites. He is visiting professor at Glasgow University, the University of Milan and the University of Wales and was previously Chief Executive of the Cancer Research Campaign (CRC). He led CRC into a merger with Imperial Cancer Research Fund which formed Cancer Research UK, in 2002, and was joint CEO with Sir Paul Nurse.

Gordon was Clinical Research Director at the National Cancer Institute of the Netherlands where he co-founded the European Organisation for Treatment and Research into Cancer (EORTC) New Drug Development Office. As President of EORTC, he set up the present Drug Development Group in Brussels and, with NCI support, the European New Drug Development Network. He was Chair of the UICC Fellowships Programme for eight years.

Gordon was one of the architects of the Cancer Trials Networks in Scotland, Wales, and England, and a founding member of the National Cancer Research Institute. He has received numerous awards and has honorary doctorates in science from six universities. He has served on key committees of AACR and ASCO, and on the boards of the National Cancer Institutes of France, Italy, and Holland.

His commitment to drug discovery and delivery is evidenced by approximately 240 patents granted to CRC scientists under his leadership, several drugs registered including carboplatin, temozolomide and abiraterone and the foundation of 10 biotechnology companies based on some of the intellectual property.

He chairs a start-up company (ORIL) in Adelaide which is taking a saponin derived from a Chinese grass into the clinic, and is a partner with ecancer in three FP7 projects from the European Union.

Richard Bergström
Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Richard Bergström has been the Director General of EFPIA since April 2011. Previously he served for nine years as the Director-General of LIF, the Swedish Association of the Pharmaceutical Industry, following positions in Switzerland in regulatory affairs at the pharmaceutical companies Roche and Novartis. He was also appointed by the Swedish Government to the Board of the Karolinska Institute.

Richard is a pharmacist by training, receiving his MScPharm degree from the University of Uppsala, Sweden in 1988.

Didier Jacqmin
EAPM Treasurer and Chair of the SPO, European Association of Urology

Professor Didier Jacqmin is certified as an MD from Paris VI University. He trained in Strasbourg where he received certification in General Surgery, Urology and Oncology.

In 1989 he was nominated Professor of Urology in the "Urological Surgical" department of the University hospital of Strasbourg and teacher at Strasbourg University Medical School.

In 1992 he became the Chairman of the University hospital Surgical Urology Department and Director of the Education and Residency programme. The same year he became EAU Active member.

He has been coordinator of the Robotic Surgery programme of HUS since 2006 and was a board member of the EUSP Office in 1996 and, from 1998 to 2004, its chairman.

Didier was nominated Chairman of the Strategy and Planning Office of the EAU in 2012 and, since 1998, has been a member of the ESU faculty and participates in courses during EAU meetings, European Countries and national meetings, and also outside Europe.

His clinical practice is mainly Uro-Oncology and he is responsible of the Uro-Oncology teaching programme for the Universities of Amiens, Lille, Reims, Dijon, Besançon and Strasbourg.

Françoise Meurnier
Director General of the European Organisation for Research and Treatment of Cancer (EORTC)

Françoise Meunier is Director General of the European Organisation for Research and Treatment of Cancer, and received her medical degree from the Université Libre de Bruxelles (ULB), completing her research fellowship at the Memorial Sloan-Kettering Cancer Center in New York in 1977-1978 (Fulbright award).

She holds a Master's Degree from the ULB in Medical Oncology (1976) and Internal Medicine, and a PhD from the same university. She is certified as a Pharmaceutical Medicine specialist by the Faculty of Pharmaceutical Medicine in the UK and Belgium and has been a Fellow of the Royal College of Physicians of the UK since 1994.

Françoise has led the coordination and administration of all EORTC activities since 1991 and, before joining EORTC, she was Head of the Infectious Disease Department at the Institut Jules Bordet in Brussels.

She is a member of the Belgian Royal Academy of Medicine and, in 2007, she was conferred the honorary title of Baroness by His Royal Majesty King Albert II of Belgium. In 2009, Françoise received the Pezcoller Foundation-ECCO award as a recognition for her unique contribution to oncology and for the dedication of her professional life to the improvement of cancer treatment, care and research. Since 2011, she has been a Fellow of the European Academy of Cancer Sciences.

Josep Maria Borras
University of Barcelona, Ministry of Health and Social Policy, Spain

Josep Maria Borras is Professor of public health at the Department of Clinical Sciences of the University of Barcelona. He is also advisor to the cancer strategy of the Department of Health of the Region of Catalonia as well as to the Ministry of Health.

He holds an MD and PhD in public health and has worked for the Department of Health in cancer control and technology assessment in cancer as well as being director of the Catalan Institute of Oncology.

His research interests include the analysis of trends in cancer incidence and mortality and health services research in

Speaker biographies

determinants of utilisation of cancer prevention and care. Josep Maria has been Work Package leader (healthcare) in the European Partnership Action Against Cancer and is presently involved in the joint action on Cancer Control.

Tit Albreht
National Institute of Public Health of Slovenia

Dr. Tit Albreht holds a PhD in Health Services Research from the University of Amsterdam and is Head of the Centre for Analyses of Health Systems at the Institute of Public Health of the Republic of Slovenia.

Tit is also a Researcher in the field of health services research, health policy and health systems research, a member of the Scientific Committee of EUPHA, a member of the Academy Health, and a member of the Slovenian Preventive Medicine Society.
As well as these, he is a member of the Health Council of the Ministry of Health of Slovenia and an Associate Professor of Public Health at the Department of Public Health of the Medical Faculty in Ljubljana. He acts as a reviewer of several scientific journals and of projects submitted for financing to the European Commission.

Tit acted as work package leader on the European Partnership on Action Against Cancer, exploring the national cancer plans, and is the co-ordinator of the new Joint Action on Cancer.

Ingrid Kossler
Former President of Europa Donna, Former Board Member, European Cancer Patient Coalition

Ingrid Kössler holds a Bachelor of Arts degree and a Master of Business Administration from the University of Gothenburg, School of Economics and Commercial Law.

She has been involved in the Breast Cancer Organization since 1988, when she was diagnosed with breast cancer, and was president of the Swedish Breast Cancer Association from 2001-2010.

In 2004, Ingrid became a Board Member of Europa Donna and was its president from 2006-2008).

Due to family and her own experiences from other cancer diagnoses Ingrid has developed a broader interest and engagement in the combat of cancer. She served as a board member of the Swedish Cancer Society from 2005-2009 and was expert in the Official Inquiry on a National Cancer Control Strategy, Sweden. She is now involved in the implementation of the National Cancer Control Strategy in that country and a board member of European Cancer Patient Coalition.

Ingrid Kössler has been a Member of the European Economic and Social Committee in Brussels since 2006. And, in 2009, she was rapporteur on the European Partnership for Action Against Cancer.

George Kalamitsis
President of the Hellenic Liver Patient Association "Prometheus"

George Kalamitsis is a founding member and President of the Hellenic Liver Patient Association 'Prometheus'. He has studied psychology and worked in the rehabilitation center 'Epistrofi' from 2005 until 2011.

He is also a member of the scientific committee of the NGO 'Nifalioi', a citizens' movement concerning alcoholism and the environment.

Yann Le Cam
Chief Executive, EURORDIS

Yann Le Cam is a patient advocate who has dedicated 25 years of professional commitment to health and medical research non-governmental organisations in France, Europe and the United States in the fields of cancer, HIV/AIDS and rare diseases.

Yann is one of the founders of EURORDIS and has been its Chief Executive Officer since 2001. He has participated in the revision and adoption of European regulations having an impact on rare disease patients' life, including the EU Regulation on Orphan Drugs.

He was one of the first patient representatives appointed to the Committee for Orphan Medicinal Products at the European Drug Agency where he served for nine years and was its Vice-chairman for six. He served on the Management Board and Executive Committee of the French HTA agency for five years, and on the DIA Advisory Committee Europe for three. Yann was Vice-chairman of the EU Committee of Experts on Rare Diseases from 2011 to July 2013, and is nominated on the current Commission Experts Group on Rare Diseases.

In November 2013, Yann was elected Chair of the Therapies Scientific Committee of the International Rare Diseases Research Consortium.

Bonnie Wolff-Boenisch
Head of the Research Affairs Unit, Science Europe

Dr Bonnie Wolff-Boenisch leads the Research Affairs Unit of Science Europe, a Brussels-based organisation representing 52 Research Funding Organisations and Research Institutes across 28 countries and provides strategic leadership and guidance to six Scientific Committees.

Bonnie has worked as coordinator of a multinational research infrastructure initiative linked to climate change and has conducted scientific research in the fields of cosmo- and geo-chemistry and in the field of paleo-climate research.

Magda Chlebus
Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations

Magda is in charge of policy and legislative debates which shape the research environment in Europe. This includes public-private collaborations (including the Innovative Medicines Initiative) and enabling and sensitive technologies. She joined EFPIA in 1995. Her experience covers public and government affairs, including designing and implementing advocacy campaigns on EU legislation and policies, as well as implementation of pharmaceutical legislation in new Member States.

Her mantra is From science to patients: connecting research and healthcare agendas and people for a vibrant R&D ecosystem which delivers innovative prevention and therapies to society.

Louis Denis
Founding member of EORTC

Louis became Director of the Oncology Centre Antwerp, Belgium, in February 1998 after a long career as an academic urologist specialising in urological oncology.

After finishing his training at the Medical College of Virginia in 1964, he joined the urological department of the Antwerp City Hospitals to become coordinating chairman in 1973, and joined the Faculty of the Antwerp University in 1974 and the Faculty of the Vrije Universiteit Brussel as Professor in 1978.

Louis introduced transrectal ultrasonography to Europe in 1976 and became active in new drug development and

Speaker biographies

clinical research studies in urological oncology. He has served as President or Board Member of a number of national and international urological organisations, as well as serving as a Visiting Professor in Urology to a number of universities worldwide. He became an Honorary Member of six urological associations, including the American and Japanese Associations. Louis is also a board Member of a dozen urological and oncological journals and was the first managing director of the European Journal of Cancer.

He was a founding member of the Urological Group of the European Organisation for Research and Treatment of Cancer (EORTC) and was President from 1988-91. During his career Louis has also been Chair of the Education & Training Division, Chair of the Flemish Advisory Council for Cancer Prevention and held several positions in the European School of Oncology and the European Institute of Oncology. He also served as an officer of the European Society of Surgical Oncology and the Federation of European Cancer Societies.

He is currently treasurer of the Union Internationale contre le Cancer (UICC), treasurer of the International Consultation on Urological Diseases, and chairman of the International Prostate Health Council.

His recent work includes the co-coordination of the European Randomised Screening Study for Prostate Cancer, as well as being a founder and secretary of Europa Uomo.

Zoltán Kaló
Professor of Health Economics at the Department of Health Policy and Health Economics, Eötvös Loránd University, Budapest

Zoltán is the director of an international post-graduate masters programme in Health Policy, Planning and Financing and is the Founder and Chief Executive Officer of Syreon Research Institute, an international research corporation specialising in health policy, health economic modeling and technology assessment.

He graduated from the Budapest University of Economics (Bachelor of Economics), the Semmelweis Medical University (Medical Doctor) and the University of York (MSc in Health Economics) and has received scientific degrees from the Semmelweis University (Pharmaceutical Sciences) and Eötvös Loránd University (Sociology).

He has 20 years of international experience in academia and industry, specialising in health systems design, HTA implementation, outcomes research, economic modeling, patient access and value based pricing policies of new healthcare technologies. He serves as a policy advisor to public decision-makers and global health care corporations and is Chair of the ISPOR CEE Network Executive Committee.

Kaisa Immonen-Charalambous
Senior Policy Advisor, European Patients Forum

Kaisa is EPF's Senior Policy Adviser. A Finnish native, she holds an MA in International Relations and Conflict Resolution from the University of Kent at Canterbury, UK, and a BA in International Relations from the University of Tampere in Finland.

She has worked in the private (financial) and NGO (culture and health) sectors in the UK and Cyprus and, in her previous role, she was responsible for the coordination of European policy work and liaised with EU-level partner organisations and the Commission. She also has a background in external communications/marketing and relationship management.

Miriam Gargesi
Director for Healthcare Biotechnology, EuropaBio

Miriam Gargesi is currently Director for Healthcare Biotechnology at EuropaBio, the European Association for Bioindustries. In this role, she leads the advocacy and public affairs of EuropaBio's healthcare department, in close coordination with the association's Healthcare Council and Working Groups, and maintains a strong network of contacts with policymakers and other stakeholders.

Miriam has long-standing experience in the field of European healthcare policies, spanning across major pillars of the sector such as biotechnologies, pharmaceuticals and diagnostics .

Prior to joining EuropaBio, she served for several years as Director for Public Affairs and Communications at EDMA, the European Diagnostic Manufacturers Association, and worked for the healthcare practice of a front-runner international consultancy. She also gained extensive insights into the political institutions through her work at the House of Commons in London and the Italian Chamber of Deputies in Rome.

Miriam holds an MSc in European Political Economy from the London School of Economics and Political Science, as well as a BSc in International Relations from the University of Wales, Aberystwyth, and McGill University.

An Italian national, she is fluent in English and French, and has a working level of Spanish.

Núria Malats
Centro Nacional De Investigaciones Oncologicas

Núria was born in 1962 in Barcelona, Spain. She obtained her MD in 1986 and her PhD in 1995 from the Universitat Autònoma de Barcelona and was one of the first scientists working in genetic and molecular epidemiology in Spain.

From 1992-1995 she coordinated a national multicentre project on the molecular epidemiology of pancreatic cancer. In 1996 she was Visiting Scientist at the International Agency for Research on Cancer in Lyon, France, where she trained until 1998 in genetic epidemiology. She then returned to Spain and obtained a research contract from the Ministry of Health.

Prior to joining the CNIO in 2007 she was a scientist at the Centre de Recerca en Epidemiologia Ambiental, leading and participating in national and international competitively funded projects, and also coordinated the Spanish research network on bladder cancer.

She is PI of the European Study on Pancreatic Cancer Genetics and Epidemiology and co-PI of the Spanish Bladder Cancer/EPICURO Study, both being large case-control/cohort studies integrating scientific interests from different disciplines in cancer development and progression.

Núria is the Spanish delegate of the Public Health Genomics European Network and has participated in teaching programmes for under- and post-graduate courses at several universities. She is also a Member of the Scientific Board of the European Society of Urological Research and the European Association of Urology Research Foundation.

Luís Mendão
Chair of the Board of GAT – Treatment Activist Group

Luís Mendão studied biochemistry at the University Pierre et Marie Curie in Paris until 1983 and is currently Chair of the Board of GAT – Treatment Activist Group, an NGO founded in 2001 working in prevention, early diagnosis, treatment and care of HIV/AIDS, related diseases and most-at-risk groups.

Luís is also the founder of the AntiProhibitionist Association and represents Portugal in the Civil Society Forum on HIV/AIDS at the European Commission. He is a member and Vice-Chair of the European AIDS Treatment Group and also integrates the Steering Committee of the HIVPORTUGAL initiative. For the last ten years, he has been community consultant of the Regional Office of the World Health Organization Europe), EMCDDA and ECDC. Luís was diagnosed with HIV and HCV in 1996.

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Speaker biographies

Breda Flood
President of the European Federation of Allergy and Airways Diseases Patients Associations

Breda developed asthma in 1984 and joined the Asthma Society of Ireland in 1992 before being elected to its Board in 2000. In 2009, she was elected to the Board of the European Federation of Allergy and Airways Diseases Patients' Association (EFA), and was appointed treasurer in 2010 and elected President in 2011.

She is EFA Board lead in the IMI project U-BIOPRED and patient representative in the Commission's FP7 project AirPROM. Breda was appointed as a patient expert by EFA to the European Medicines Agency in 2009 and is also EFA's patient representative in the European Lung Foundation Council.

Breda has spoken about the patients' perspective on numerous occasions and is a member of the Scientific Committee for the European Commission initiative for smoking cessation, 'Ex-Smokers are Unstoppable'.

Nicola Bedlington
Executive Director, European Patients Forum

Nicola has been the European Patients Forum's Executive Director since the setting up of its secretariat in 2006. She has worked as an external expert for the European Commission on disability policy and NGO cooperation and was the first Director of the European Disability Forum during the 1990s.

More recently she led the ENSI Secretariat, an OECD initiated international governmental network on education and sustainable development.

Ulrich Jäger
Past President of the European Hematology Association (EHA)

Ulrich Jäger is Professor of Hematology and Head of the Division of Hematology and Hemostaseology at the Medical University of Vienna. He gained his medical degree in 1982 at the same university. He worked on molecular genetics of lymphoma, in particular the BCL2 proto-oncogene, during a three-year post-doctoral fellowship in the laboratory of Prof. Stanley Korsmeyer at Washington University, St. Louis, Missouri.

He is currently leading a hematology institute which focuses on translational research in leukemia and lymphoma at the Medical University of Vienna.

Uli's research interests are molecular hematology, molecular biology of leukemias and lymphomas, minimal residual disease, molecular mechanisms of chromosomal translocations and chronic lymphocytic leukemia.

He served as president of the European Hematology Association from 2011 to 2013 and is currently its past-president. He is also the chair of the association's European Affairs Committee.

Daniel Schneider
Senior Director at Genomic Health

Daniel is the Director of International Marketing at Genomic Health. He is responsible for marketing Oncotype DX assays in Europe.

The Onco type DX breast cancer assay personalises early-stage breast cancer treatment by identifying which patients are likely to benefit from chemotherapy and which patients can avoid the toxicities and costs associated with it. Daniel has played an active role in the launch and commercialisation of Oncotype DX tests since 2002 in both Europe and the US.

He has an MBA from Rotterdam School of Management, Erasmus University. Prior to his degree, Daniel served as Subspecialty Manager at the American Academy of Ophthalmology.

Stanimir Hasardzhiev
Board member of the EPF

Stanimir Hasardzhiev is a founder and current Chairperson of the Bulgarian National Patients' Organization (NPO). In 2011, he represented Bulgarian patients on the Supervisory Board of the National Health Insurance Fund. He is a board member of the European Patients' Forum, a member of the Steering Committee of the European Liver Patients' Association and several regional and international organisations and networks, such as the World Hepatitis Alliance, European Community Advisory Board, International Capacity Building Alliance and others.

Stanimir has many Bulgarian and international awards, such as the Best Media Award for the World Hepatitis Day campaign in 2008 "Am I number 12". In 2011 the National Patients' Organization was awarded a prize by Effie Worldwide Awards for its campaign "If the healthcare system doesn't hear you".

Ernst Hafen
Professor at ETH Zurich, Institute of Molecular Systems Biology (IMSB)

Ernst Hafen, PhD, is a Professor of Systems Genetics at ETH Zurich and former President of ETH. In addition to 26 years of academic research, he has founded and advised several biotechnology companies. He endeavors to assist scientific discovery and its efficient translation into products that help society and the economy.

As a trained geneticist, Ernst has a strong interest in human genetics and personalised medicine. He posits that an individual's control over his or her personal health data will be a key asset for better and more effective health care.

In 2012 he was a founding member of the Association Data and Health (DatenundGesundheit.ch) whose aim it is to discuss legal, ethical and societal issues about health data ownership and to find commercial models permitting owners, not third parties, to benefit from their personal data assets.

Gunta Anca
Sustento (Latvia), European Patient Forum member organisation

Gunta Anca has been a proactive disability rights activist throughout her career. Since 2002, she has been Chair of the Latvian Umbrella Body for Disability Organisations (Sustento) and, since 2005, a board member of the European Disability Forum (EDF).

Gunta is also very active in promoting gender equality in her capacity of member of the EDF Women's Persons with Disabilities and is a member of the European Economic and Social Committee and an Advisor to the Disability Rights Fund - a collaboration between donors and the disability community .

Gunta is also a member of the policy advisory board of the European Patient Forum.

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Speaker biographies

Alastair Kent
Genetic Alliance UK

Alastair Kent (OBE) is the Director of Genetic Alliance UK – the national charity of more than 150 patient organisations, supporting all those affected by genetic conditions.

Genetic Alliance UK's mission is to promote the development of the scientific understanding of genetics and the part that genetic factors play in health and disease, and to see the speedy transfer of this new knowledge into improved services and support for patients.

Alastair has worked in the field of genetic and rare disease healthcare for over 20 years. He represents the interests of patients on numerous platforms; he is the president of the European Genetic Alliances Network, Immediate Past Chair of the European Platform for Patient Organisations, Science and Industry and the EU Committee of Experts on Rare Diseases amongst others. He is a past member of the Orphan Medicinal Products Committee and Committee for Advanced Therapies at the European Medicines Agency as well as a member of the Human Genetics Commission.

Mark Lawler
Chair in Translational Cancer Genomics and Associate Director of Postgraduate Studies, Centre for Cancer Research and Cell Biology, Queen's University Belfast

Mark Lawler has published widely in high-impact international journals and has received national and international prizes for his research. He is a member of EAPM and is leading their development of a Research Roadmap for Personalised Medicine in Europe.

Mark was an active member of the Ireland-Northern Ireland-National Cancer Institute Consortium, serving on its Scientific Advisory Committee and acting as Chair of the Scholar Exchange Committee. He sits on a number of European Commission and European Research Council Committees in Brussels.

Mark was the Project Lead for the European Cancer Concord and a driving force behind its launch of the European Cancer Patient's Bill of Rights on World Cancer Day, 2014 in the European Parliament in Strasbourg. He recently published a widely quoted editorial in the British Medical Journal (BMJ) entitled 'Ageism in Cancer Care: We need to Change our Mindset!'

Ansgar Hebborn
Head Global Market Access Policy at Roche Pharmaceuticals

Dr. Ansgar Hebborn is Roche Pharma's Global Head of Economic Value Strategy. He leads a multidisciplinary team tasked with the development of global reimbursement strategies and accompanying clinical, health economic, and other outcomes research programs based in Basel, Switzerland and Nutley, New Jersey, USA.

He is an active contributor to a number of a pharmaceutical policy forums of national and international pharmaceutical industry associations.

Ansgar joined Roche in 1997 as a Pharmacoeconomic Research Scientist. He held positions of International Economic Strategy Leader, Director Outcomes Research & Strategic Pricing, and Group Head Economic Policy and Training in Basel, Switzerland and New Jersey. He has also been Roche's Global Head of Health Economics and Strategic Pricing.

Ansgar was managing director of the Institute of Social Security Law and Health Economics at the University of Bayreuth, and has written or co-written publications in the areas of health policy, health economics and pharmaceutical outcomes research as well as a popular monograph on the German health care market which now appears in an updated 3rd edition.

Angela Brand
Founding Director and Full Professor of the Institute for Public Health Genomics (IPHG)

Prof. Angela Brand, MD PhD MPH (USA) is Founding Director and Full Professor of the Institute for Public Health Genomics (IPHG) at the Faculty of Health, Medicine and Life Sciences at Maastricht University, the Netherlands, as well as Dr. T.M.Pai Endowed Chair on Public Health Genomics and Adjunct Professor at the Manipal Life Sciences Centre of Manipal University, India.

She is Paediatrician and Specialist in Public Health Medicine, holds a PhD in pathology (Münster University, Germany) and a Master of Public Health from Johns Hopkins University, USA.

Angela received her habilitation in Public Health Genomics focussing on Health Technology Assessment (Bremen University, Germany). She is Director of the European Centre for Public Health Genomics. She is Coordinator of the Public Health Genomics European Network, Full Partner of the EU Flagship Pilot Project IT Future of Medicine, President of the Section Public Health Genomics within the European Public Health Association, Edtor-in-Chief of the international journal Public Health Genomics, Excecutive Director of the Public Health Genomics international network, and an Associated Member of the international consortium Public Population Project in Genomics (P3G) on biobanking,.

She is also an Advisory Board Member of the EU Innovation Medicine Initiative (IMI) project OncoTrack, Steering Committee Member of the 'Forward Look on Personalized Medicine' of the European Science Foundation and EAPM, and Scientific Consultation Group Member of the European Centre for Disease Prevention and Control.

Angela serves as an Expert for the European Agency for Reconstruction, the OECD, WHO, the European Commission, the Netherlands Genomics Initiative (NGI), the German Robert Koch-Institut (RKI), Genome Canada and the European Science Foundation among others.

She has collaborated with industry partners including Roche, Pfizer, Novartis, MSD and Bayer HealthCare, producing HTA reports on health innovations. She is a Fellow of the Rockefeller Foundation, USA, and of the 21st Century Trust of the Wellcome Trust, UK.

Lester Russell
Senior Director, Health & Life Sciences Innovation EMEA, Intel Corporation

As Senior Director of Health & Life Sciences in EMEA, Lester draws on his combined skills and experience in clinical, commercial and health service roles.

He is responsible for strategy leadership, cross-group orchestration, ecosystem leadership, solution incubation and sales support. He engages with clinicians and stakeholders across the health and life sciences eco-system, represents Intel in international and national advisory and regulatory groups, and provides clinical input to business development activities.

Lester brings a wealth of experience of working in senior medical advisory roles and his practical experience as a frontline clinician with an enthusiasm for the adoption of ICT to improve healthcare.

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Speaker biographies

Paul De Raeve
Secretary General, European Federation of Nurses

Paul De Raeve graduated as a registered nurse in 1984. He obtained a Master's Degree in Nursing Science at the Free University of Brussels in 1989 and, in 1996, received a Master 's in Statistics from the city's Catholic University. He is a Doctoral Student at the Kings College University of London.

From 1984, Paul De Raeve worked full time as a Registered Nurse in a centre for children with muscular disease. He was a Head nurse Neonatology in the Al Hada Hospital in Saudi Arabia from 1990-1992 and was appointed as a staff manager at the Free University hospital of Brussels, part-time delegated to the Belgium Ministry of Health and Environment.

In 2002, Paul was appointed as General Secretary of the European Federation of Nurses Associations.

Wolfgang Ballensiefen
Coordinator, Coordination and Support Action on Personalised Medicine

Wolfgang Ballensiefen obtained his PhD in biology at the University of Göttingen in 1997, followed by a fellowship at the Medical Research Council, Laboratory for Molecular Cell Biology (MRC LMCB) in London.

In 2000 he joined the DLR Project Management Agency as scientific officer. Since then, he has been involved in the setting up and managing of several national funding programmes on behalf of the Federal Ministry of Education and Research or the Federal Ministry of Health. Since 2013, he has been the coordinator for the EU funded Coordination and Support Action on Personalised Medicine (CSA PerMed).

Anni Morsing
European Association of Nuclear Medicine

Anni Morsing is currently Department chairman, at the Department of Nuclear Medicine & PET Centre, Aarhus University Hospital and an assistant professor at the university. She has a special interest in molecular imaging in oncology.

Since 2003, Anni has been a national representative for Nuclear Medicine in the European group of experts and multicentre studies under the pediatric cancer group SIOP-Europe and, since 2008, has been the departmental managerial representative for the Department of Clinical Physiology and Nuclear Medicine, also at Aarhus Hospital, in work groups to implement cancer pathways for the Danish Board of Health.

Anni has been a member of the European Association of Nuclear Medicine since 2009.

Christine Chomienne
Institut Universitaire d'Hématologie (IUH), Hôpital St Louis, Paris, France

Christine Chomienne is Director of the Cell Biology Department, Hôpital Saint Louis, Paris and Professor of Cellular Biology and Hematology at Université Paris Diderot Paris.

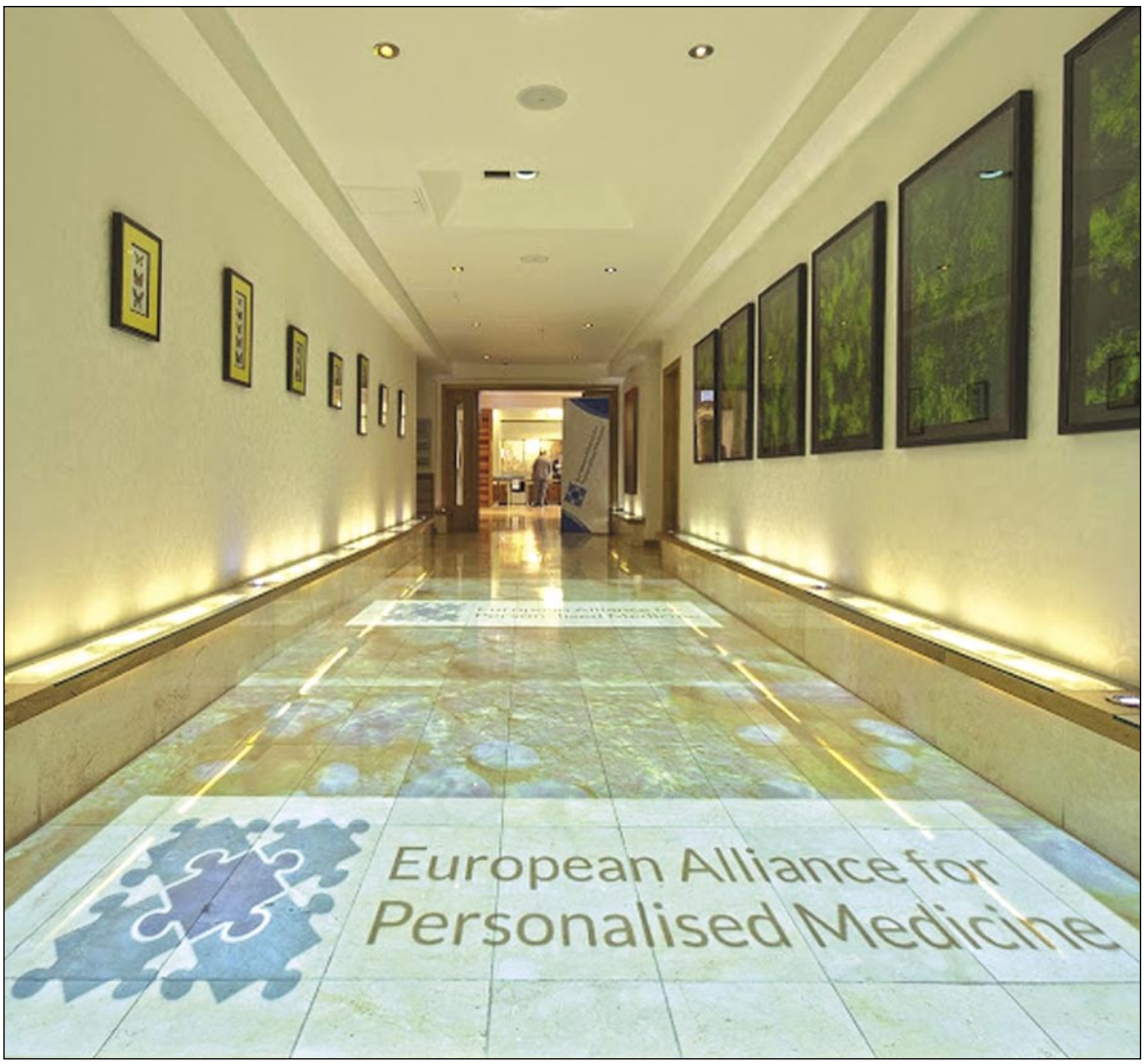
Since 1994, she has been the Director of the Research Unit at the University Hematology Institute in Paris. She is a consultant in the Hematology Department of Hôpital Saint Louis in myeloproliferative disorders and head of the Cellular Biology department at the same hospital where she monitors tumor markers.

Dr Chomienne received her medical training at the Université Paris and her specialty in Human Biology and Hematology at Université Paris. She is coordinator of Cellular Biology University Paris Medical School, coordinator of the French National Biotherapy Course, the Stem Cell Master1 and Master 2 and the Functional and Molecular Biology of Hematopoïetic Cells Master 2 at the University Paris.

Christine is an adjunct of the University of Sharjah, responsible for a Dual master and PhD program in translational medicine. She created the Institute of PhD Schools at University Paris Diderot.

Her research focuses on cross-talk in myeloid cell signaling pathways and the identification of therapeutic targets and strategies. She has translated into practice, the first targeted and differentiation therapy in France with all trans retinoic acid, and coordinated translational research on retinoids in cancer, and the identification of markers and targets for differentiation/transcriptional/epigenetic therapy. She has coordinated the Paris network on Cancer and Leukemic Stem Cells since 2007, is a member of several national and international groups and, since 2013, she has been President of EHA.

Christine has received several scientific awards.



3rd EAPM Annual Conference
2-3 June 2015
Brussels

EAPM's STEPs campaign
Specialised Treatment for Europe's Patients

EAPM's initiative calls on Europe's decision-makers to commit to the following STEPs for 2015-2019:

- **STEP 1: Ensuring a regulatory environment which allows early patient access to novel and efficacious personalised medicine (PM)**

- **STEP 2: Increasing R&D for PM, while also recognising its value**

- **STEP 3: Improving the education and training of healthcare professionals**

- **STEP 4: Supporting new approaches to reimbursement and HTA, required for patient access to PM**

- **STEP 5: Increasing awareness and understanding of PM**

EAPM believes that achieving these goals will improve the quality of life for patients in every country in Europe.

European Alliance for Personalised Medicine


SIEPs
Specialised
Treatment
for Europe's
Patients

European Alliance for Personalised Medicine

3rd EAPM Annual Conference
2-3 June 2015
Brussels

Sponsored by

Roche

EORTC
European Organisation for Research and Treatment of Cancer
50 years of Progress Against Cancer

EHA
EUROPEAN HEMATOLOGY ASSOCIATION

Genomic Health

SCIENCE EUROPE
Medical Sciences Committee

efpia

eau European Association of Urology

intel

Pfizer

Lilly